

**SUPPORTING ENGINEERING DESIGN OF ADDITIVELY MANUFACTURED
MEDICAL DEVICES WITH KNOWLEDGE MANAGEMENT THROUGH
ONTOLOGIES**

A Dissertation Presented

By

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Knowledge Management Through Ontologies

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ABSTRACT

SUPPORTING SUPPORT ENGINEERING DESIGN OF ADDITIVELY MANUFACTURED MEDICAL DEVICES WITH KNOWLEDGE MANAGEMENT THROUGH ONTOLOGIES

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Medical environments pose a substantial challenge for engineering designers. They combine significant knowledge demands with large investment for new product development and severe consequences in the case of design failure. Engineering designers must contend with an often-chaotic environment to which they have limited access and familiarity, a user base that is difficult to engage and highly diverse in many attributes, and a market structure that often pits stakeholders against one another. As medical care in general moves towards personalized models and surgical tools towards less invasive options emerging manufacturing technologies in additive manufacturing offer significant potential for the design of highly innovative medical devices. At the same time however these same technologies also introduce yet more challenges to the design process.

This dissertation presents a knowledge-based approach to addressing the existing and emerging challenges of medical device design. The approach aims to address these challenges using knowledge captured in a suite of modular ontologies modeling knowledge domains that must be considered in medical device design. These include

ontologies for understanding clinical context, human factors, regulation, enterprise, and manufacturability. Together these ontologies support design ideation, knowledge capture, and design verification. These ontologies are subsequently used to formulate a comprehensive knowledge framework for medical device design, and to enable an innovative design process. Case studies analyzing the design of surgical tools in several medical specialties are used to assess the capabilities of this approach.

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$$V_{\text{designer}}(x) = \sum_{j=1}^n w_j x_j 225$$

$$w_1 + 0.5w_2 + w_4 \leq w_1 + w_2 + 0.5w_3 226$$

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$$V_{\text{surgeon}} = \sum_{j=1}^n w_j x_j 233$$

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$$\text{'bearer of' some ('realization affects' some } \left(\begin{array}{l} [\text{invasiveness or accuracy}] \\ \text{or quantity or duration} \end{array} \right) 246$$

'has function' some $\left(\begin{array}{l} \text{'aligning function' or 'positioning function'} \\ \text{or 'guiding function' or 'removing function'} \end{array} \right)$ 246

$$\text{Minimize } f(x) = \left(1 - \sum_{j=1}^n w_j \right)^2$$

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$$w_1 - .5w_2 - w_3 \leq 0 251$$

$$-.5w_1 + w_3 + .5w_4 \leq 0 251$$

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CHAPTER 1

MEDICAL DEVICE DESIGN

1.1. Motivation

Globally, the medical device industry accounts for nearly a half trillion dollars of economic activity, comprising an estimated 1.5 million types of devices in ten to twenty thousand unique categories. In the United States (US), healthcare is one of the largest sectors of the economy, and direct government investment in research and development (R&D) comprised nearly 37 billion dollars, with total national expenditures on health R&D exceeding 158 billion dollars in 2016 [1]. The sheer size of the healthcare market, its ample funding, and the direct impact of medical advances on health provide significant economic and social incentives for innovation [2]. Recent technological advances have enabled a range of promising new medical treatments and device types. Research in genetics is beginning to translate to impressive new diagnostic procedures, and personalized therapies [3]. Advances in data analytics and communications technology promise a new generation of smart devices with highly integrated data and greater ability to tailor treatment to individual patients [2]. Complementing these biological and information technologies are a range of manufacturing technologies that are seeing increased adoption in medical contexts. Additive manufacturing (AM) technologies for example are in the early stages of extending the concepts of personalized medicine from analytics and treatment to personalized surgical tools, operative aids, and implants [4].

Despite the incentives for innovation and the technological advances that underpin it in the medical device industry, realizing these innovations remains

challenging. Reviewing the medical device industry from a business development perspective, Herzlinger [5] points to several factors that hinder innovation in medicine. The market is highly fragmented: most healthcare delivery occurs in small practices, or small to medium sized hospitals. Various players within the industry have dramatically different incentives, and these incentives change rapidly. Funding structures are often ill equipped for the long term investments needed to bring health technology to market. Regulation is pervasive and places a large burden upon new technologies. Patients may have limited capacity to direct aspects of their own care and so accountability is often difficult to determine [5]. As a result the development of innovative medical devices is a considerable challenge even for veterans of the industry. Given the market oriented nature of these challenges it is unsurprising that past research into medical device innovation and success factors has largely focused on the question of how to manage product development. For example, past research has determined the most important factors in medical device new product development (NPD) are largely management related. These management factors include things such as having a business model for a new device up front and having executive participation in NPD [6].

These types of market and management factors are undoubtedly important for medical device design, but offer little guidance to a team attempting to design a medical device. This is important as the design aspect of NPD is critical to realizing products that are appropriate for a given design context, have innovative features that appeal to customers with decision making authority, and are compliant with market regulations. This dissertation will argue that significant challenges inhibit good design in medical devices generally and surgical tools specifically. It will moreover make the case that

these challenges may be exacerbated by the challenges of adopting new manufacturing technologies with significant promise in medicine. In response to the challenges laid out in the remainder of Chapter 1 and in Chapter 2 it will propose an overarching framework for medical device design, as well as methods and tools that aim to better utilize information to create innovative, effective designs.

1.2. New Product Development Considerations and Challenges in the Medical Sector

1.2.1. Clinical Knowledge in Medical Device Design

Clinical knowledge is critical to the development of effective medical products. Engineering design is a demanding process requiring both ingenuity and a methodical approach to collecting, interpreting, and using information. The specific field of medical device design, however, poses an additional number of challenges for engineering design. Medical environments involve a complex interaction between regulations, a highly diverse user base, a multitude of established, essential procedures, and a vast body of underlying science [7]. All of these considerations must be factored into any medical device design process. Adding to this challenge, engineering design teams are typically not composed of medical domain experts and therefore often lack detailed knowledge of potential users or use environments [8]. Clinical and biological contexts often drive both customer and design requirements and similarly can impose significant restrictions on the set of viable engineering solutions. A failure to fully account for this could negatively impact a design by limiting a team's ability to anticipate and adapt to challenges during the development process. As such, the close participation of clinical domain experts is regarded as essential to effective medical device design.

The usability and accessibility of clinical knowledge is a significant challenge for medical device design. The exact method of clinical expert and end-user inclusion in the design process varies widely in industry. As noted in areas of bio-inspired or design in contexts that are heavily dependent on biological knowledge [9], typical engineering designers are not medical domain experts [7]. This can lead to difficulties parsing highly technical medical terminology or concepts without additional aid. The opposite effect is seen in clinicians. Clinicians have training in clinical science and the practice of medicine, but are typically not well versed in the range of technologies available or how to implement them in a clinical context. As a result there is a mismatch in communication between clinicians and designers wherein neither group is well equipped to effectively exchange information with the other [10]. Even when knowledge can be rendered usable the complexity of the medical system often introduces additional design challenges. Sharples et al. [11] found via a literature review and four case studies of medical adverse events that the medical system's increasing complexity renders robust design far more difficult. The authors observed that devices must interact with a great variety of operators over time. Any device will also serve as only a small part of a much larger system that is often inconsistent between institutions. As a result, even seemingly robust evaluations of product designs might be insufficient [11].

The use of medical knowledge is made more difficult by severely limited access to medical environments. Access to end users may also be difficult in the case of patient operated devices. Several studies note that ethical and privacy constraints pose large barriers to user engagement in medical device design. In a review of human factors methods that can be applied to medical device design, Martin et al. [7] note that privacy

concerns often make highly effective engagement difficult. While potentially useful from a design perspective, forms of contextual inquiry and ethnographic research such as shadowing are difficult due the sensitive nature of medical interactions. When interviewing industry leaders in the medical device field, Money et al. [12] observed that several manufacturers were similarly unenthusiastic about patient engagement. The industry members interviewed noted that the need for and requisite time commitment of ethical reviews for this style of engagement made them undesirable. In a similar set of structured interviews with 6 stakeholders in companies that manufacture personalized medical devices (e.g. adapted to specific end user geometry or other traits) Mihoc et al. [13] noted a similar limitation. Respondents reported significant frustration obtaining ethical approval for testing. The time commitments involved in obtaining ethical approval and the potential for time sensitive testing protocols to miss their deadline were noted as particularly large barriers. The authors concluded that in many instances manufacturers simply regarded the cost in both time and money of robust user engagement to be simply too high to justify even for a custom device [13].

Even clinical knowledge that is easily understood and accessible via publication may be difficult to utilize effectively. The case of population anthropomorphic and human factors data is instructive. Based on a set of guided interviews of 32 engineers, Fidel and Green [14] found that attributes such as accessibility and familiarity were among the main drivers of information usage among designers. Given this influence of accessibility then, it is likely significant that McGinley and Dong [15] noted several limitations in the accessibility of current human factors data and especially in data relating to human anthropometrics. In an initial investigation of the accessibility of

human anthropometric data the authors first noted several issues. Data points of interest were often isolated from one another, widely distributed across many locations, and frequently rendered inaccessible by additional barriers such as pay-walls or poor cataloguing. A separate investigation by the same group exploring designer attitudes revealed a general skepticism of the relevance of available anthropometric data to user populations of interest. The participating designers thus questioned the usefulness of anthropometric data even when it was available. In a series of interviews with ten representatives of design consultancies, the interviewees expressed that they felt current anthropometric data sources are out of date, difficult to use, and for the most part not particularly relevant to their designs [16-18].

The difficulties of effective medical domain information utilization may be compounded by attitudes and practices within the device industry. Martin et al. [19] found significant issues with designers' inclusion of key domain knowledge during a series of assessments of user engagement strategies implemented alongside an ongoing medical device design process. The authors noted that the designers' means of device assessment were almost entirely technical and found that the design team overlooked key contextual aspects of the device's intended use environment. The research team reported a belief that these factors would not significantly impact the overall product design. This was not the case; users in fact would have preferred a product that was significantly different from the one under development. Beyond this, ineffective communication between users and designers, and a lack of explicit responsibility for user interface and usability design meant that these aspects of the design were largely overlooked. Underpinning these practices is a view that many human factors and contextual factors

are ultimately a secondary consideration, to be considered only after the technical design is complete [19]. Guliksen et al noted a similar attitude in a review of current usability design practice in industry. The authors observed that many designers viewed contextual and human factors considerations to be largely cosmetic concerns and so such considerations were simply layered on top of an already complete design [20].

1.2.2. Regulation of Medical Devices

Any description of the medical device product development process must consider the impact of regulation. Medical devices comprise a vast array of product categories. Some are fairly simple equipment used on an everyday basis in clinical settings, while others are highly complex implants that must directly sustain life. Given this range of products, regulatory regimes governing medical devices are similarly diverse. Though necessary, this diversity of regulation contributes a great deal of complexity to the medical market. In the United States (US), the Food and Drug Administration (FDA) identifies three broad classes of device based on their assessed risk. Class 1 devices are considered low risk and are subject only to a broad set of regulatory guidance that applies to all medical devices irrespective of application. Class 2 devices are treated as having somewhat greater risk and so various subsets of devices are subjected to additional guidance and standards beyond the general requirements of a Class 1 device. Class 1 and 2 devices can be brought to market so long as a mandated pre-market notification is provided. By contrast, Class 3 devices are seen as having high risk. These include such devices as those that directly sustain life or constitute a fundamentally new type of device, and as such typically require regulatory assessment and approval prior to sale [21][22].

New medical devices have several paths to market. In the case of a fundamentally new device, a class 3 designation is the default until reviewed and reclassified. In this pathway, manufacturers must provide data to demonstrate the safety and efficacy of the device in large, expensive clinical trials. They can moreover expect a lengthy approval process to delay entrance into the market. However, many new devices can alternatively be brought to market through the FDA's substantial equivalence regulations, commonly called the 510K pathway. In this path to market a manufacturer must make the case that the device is substantially equivalent to some existing device, and so avoid the need for a lengthy pre-market approval process. This for example allows for new generations of devices with some feature changes to come to market based on their similarity to prior generations. Alternatively, the Humane Device Exemption can be used to bring devices that affect small numbers of patients to market with smaller trials that demonstrate device efficacy, and that potential benefits likely outweigh risks [21].

1.2.3. Medical Device Users

The sheer diversity of users within the medical field poses a significant burden to designers that might make user engagement far more difficult than in other fields. In a 2008 review of 418 peer reviewed articles Shah and Robinson [23] noted that users themselves posed a particularly large challenge when considering design alternatives. Even within a single specialty they found that users vary dramatically. At one extreme were highly trained, skilled professional users such as doctors, surgeons, and other highly credentialed or experienced providers. These skilled users were also joined by less experienced or credentialed professional users, and lay people who might range from family caregivers to impaired or elderly individuals with potentially limited cognitive or

physical faculties. As the authors noted, any product might be exposed to a wide variety of users. These users may themselves pose large and potentially difficult barriers to inclusion due to physical or ethical constraints [23, 24].

1.2.4. User Engagement in Medical Device Design

Given the regulatory requirement for consideration of human factors in medical device design, it is not surprising that at least at first glance there is widespread support for user engagement in the design of medical programs and devices. Harrison et al [25] found overall strong support for the premise of including users in healthcare endeavors in a 1998 series of interviews with managerial personnel involved in such end user and patient engagement. Money et al. [12] found similar results when consulting 11 senior members of medical device manufacturing companies via structured interviews. Multiple respondents noted that user engagement was critical to the design process overall. The actual state of practice in industry however is far more complicated, reflecting broad institutional challenges impeding the deployment of best design practices. The same two studies found that this outward support for user engagement did not necessarily translate to actual engagement activities. Indeed, much of the reported enthusiasm for user engagement belied great skepticism about its true value. Harrison et al. [25] noted that respondents supported user engagement overall, but were highly skeptical about the representativeness of user panels. Instead, user engagement was used to justify decisions that in many cases had already been made or to simply confirm pre-existing views. In this sense, the authors conclude user and public engagement served more as a “technology of legitimization” rather than a robust assessment of market needs [25].

1.2.5. Medical Device Market Structure

The medical sector is somewhat unusual in its payment structure, and so medical device design must often balance the needs of a range of stakeholders with widely varying incentives. Sales of medical products and services are frequently paid for by third parties such as private insurers and national insurance schemes. At a hospital level many surgical tools are purchased through department or hospital wide administrators. As such device end-users exert diminished or near non-existent choice in the medical devices they use [12][26]. Indeed, for new medical technologies three key third party determinations can have major implications for its financial performance. First, the device must be approved by a regulator, then insurers in the private and national markets must make coverage decisions, and finally an actual reimbursement rate must be set based on Current Procedure Terminology (CPT) codes [27]. This introduces a high degree of complication and conflict for designers and businesses seeking to identify customer requirements and maximize product value because the needs and desires of multiple stakeholders must be served. Mihoc et al. [13] found that structural factors in the medical market impact the design process. Survey research among designers working in the medical realm has shown respondents were inconvenienced by the interventions of third parties throughout the market, which greatly limited access to the end user. Third party payment schemes meant that devices were typically released with sub-optimal performance when sold in national insurance markets, and high level functionality when sold to private individuals [13].

The separation between patients, payers, and decision makers is a recurring theme in the medical device usability literature. The medical device design process is expensive,

costing tens of millions of dollars and several years in many instances to bring a device to market [22]. As such, projects are under significant commercial pressure at their launch, with manufacturers adopting their development methods to help ensure this investment can be made back. In a set of interviews with device manufacturers Money et al. [12] noted that manufacturers perceived relatively little market incentive to serve the needs of typical users. Instead, respondents reported a preference for engaging influential opinion leaders who could serve as brand champions rather than representative users as their primary source of clinical viewpoints. Shluzas et al. [26, 28] reached a similar conclusion based on a series of four case studies of paired successful and unsuccessful medical devices. The authors evaluated the financial performance to each device and then, based on subjective assessment, assigned scores to each device across a range of metrics previously found to relate to device uptake. When compared across metrics of patient, physician, hospital, and payer benefit, the authors noted that the financially successful and market dominating devices performed far better on the physician and hospital benefit metrics, but were not different on patient ones [28]. In one case the authors noted that a device became more successful by sacrificing its competitive edge in patient outcomes in favor of financial benefits flowing mainly to providers and institutions [26]. Similarly Sharples et al. [11] noted via a review of the literature that in a staggering number of cases existing medical devices seem to lack any meaningful consideration of the user, let alone offer a user a centered design.

Organizational structures within the medical device industry appear to contribute to these trends. Van der Peijl et al. [29] noted based on a case study of a medical device manufacturer that design teams frequently had no personnel explicitly responsible for

usability or human factors considerations. Instead, these considerations were left as an afterthought since no company stakeholder was explicitly responsible for them [29]. A series of ten structured interviews with stakeholders in a device design firm conducted by Vincent et al. [30] found similar limitations. The interviewees noted recurring conflicts between various stakeholders within their organization, especially marketing and engineering. Attempts to use third party standards from ISO and other standards organizations were largely deemed unhelpful, as it required additional research time to identify the appropriate standards and usability design standards were typically too vague or unclear in their intention. Practices such as usability assessments were deemed only minimally useful due to internal structures that separated design engineers from device testing personnel and difficulty finding truly representative test participants [30]. A second series of interviews with 8 individuals further revealed that much of the design space was splintered. Different units were reported to gather disconnected parcels of information of questionable usefulness. The second set of respondents also noted that business interests were often seen as distinct from, or in some cases in opposition to, user need assessment. Instead, user considerations were largely deemed to be in the purview of marketing departments that primarily focused on device aesthetics [31].

1.3. The Medical Device Design Process

1.3.1. Key factors in Medical Device Design

The complex context of medical device design directly impacts the product development process. The medical device design process development has been well described for various medical sub-fields and device types. Similar to a typical engineering design process [32, 33], a simplified description of the medical device design

process is divided into six basic activities: market analysis, design specification, concept design, detailed design, manufacturing, and sales. While high level methods are no doubt important, a focus purely on the engineering design aspect of device design ignores a large subset of activities that are essential to medical product development. [34]. More detailed assessments are needed to understand the key contextual factors and activities that are essential to medical product development. A 2013 study by Medina et al. [35] provides a high level conceptual model of the medical device design process. The authors used document analysis of FDA regulations and guidance to iteratively develop a formal Universal Model Language description of the key aspects of medical device design. Documents were then iteratively added and concepts that were consistent between iterations were noted as being critical to the process. The resulting model focuses on a set of 5 major clusters. These include regulation via the FDA, standards endorsed by regulators, intellectual property considerations, and the product development process itself. For the actual design process the authors' note the importance of clinical need identification and customer analysis as essential to product definition. They moreover note that post-market activities such as clinical validation are essential to the process. A study by Santos et al. [36] using similar methods to analyze the European market yielded similar findings, suggesting these factors are relatively consistent in Western markets.

In the orthopedic surgical context, Aitchison et al. [34] described the development process, noting that direct design activities comprise a small part of the process. Instead, much of the development process is concerned with feasibility and marketability verification, followed by extensive design verification, validation, documentation, and market surveillance. Importantly, the authors note that detailed documentation of design

history is essential to the medical device development process for regulatory reasons. Their revised development process is thus composed of initial feasibility checking, device design, verification, manufacturing, a technology transfer process, and subsequent design changes, documentation, and post-market surveillance. Each step is completed sequentially, with review and documentation to preserve design rationale occurring at the conclusion of each step [34]

Though largely neglecting the design phase of device development Kaplan et al. [37] provide a thorough summary of the design verification and validation phases of device design. The authors note that the design phase typically consists of a prolonged process of iterative design, testing, and re-design often costing in the tens of millions of dollars. Similar to other reviews of the medical device development process [34, 38-40], close coordination with clinical advisors is viewed as essential to a successful design process. Moreover, the authors stress that medical devices typically require extensive pre-trial and clinical trial testing and are often developed in close coordination with national regulators [22].

1.3.2. New Product Development Methods in Medical Device Design

1.3.2.1. Project Management Approaches for Medical Device Design

Based on a literature survey and interviews with a cohort of medical device industry representatives in the UK, Eatock et al. [41] found project management techniques common to new product development (NPD) across industries to be common within the medical device industry as well. These include quality function deployment (QFD), use of stage-gate methods to guide decisions for project progress, design for manufacturing (DFM) methods, and both cross functional and dedicated team

configurations. However, the authors were unable to draw strong conclusions about the efficacy of each respective management technique [41].

In addition to adaptation of common engineering management methods, several specialized approaches to NPD for medicine have been proposed. In the areas of project management, Pietsch et al. [42] proposed a method based on specialized stage-gates organized around the key steps for product verification and regulatory approval. At each gate projects are to be either continued or discontinued based on a set of project-specific decision-making criteria. Das et al. [43] by comparison proposed a concurrent engineering approach for medical devices based off the experiences of medical device manufacturers. In the approach, the design team formulates a set of attribute driven specifications, aided by a set of standardized specifications. Attributes are then scored based on their performance level through the design process. The impact of regulators on time to market has also been considered. Medina et al. [40] proposed a Design for FDA methodology for medical devices based on an analysis of approval times for new medical devices submitted to the FDA. Using a Bayesian network analysis with a suite of device and submission characteristics and inputs the authors found that both extrinsic and intrinsic factors affected approval time. Based on their findings the authors recommended that designers minimize the number of materials included in new devices and utilize a process that involves close coordination with the FDA.

1.3.2.2. Methods to Balance Multiple Stakeholders Interests

Several studies have proposed approaches aimed at mitigating conflicting stakeholder viewpoints arising from the complexities of the medical market. De Ana et al. [44] proposed a method based on identifying stakeholders internal and external to a

device manufacturer, dubbing the respective contributions voices of business, customers, and technology. In the proposed approach business considerations begin the development process and then are supplemented by additional stakeholder voices represented through “experience maps.” These maps catalogue clinical processes from the perspective of target stakeholder groups, and are obtained through a variety of shadowing and interview techniques. Once constructed, the experience maps are then used to identify pain points that are then addressed by the design. However, the authors’ approach offers little insight into how one might balance competing stakeholders with conflicting priorities.

Other research has considered this question based on the relative contribution of stakeholders to a medical device’s success. Shluzas et al. [26] analyzed the financial performance of eight medical devices in the context of a retrospective comparison of dyads of successful and unsuccessful medical devices. Based off financial analysis, interviews, and research into the clinical performance and subsequent changes made to devices, the authors scored devices based on their benefits to hospitals, clinicians, patients, and insurers. The resulting analysis found that the main distinguishing factor between pairs was the relative benefit to clinicians [26]. These results however are based entirely on a very small sample. Nonetheless, the authors used this finding to propose an “Insight, Value, Perception” method for device design, which in part aims to maximize clinician benefit in cases where conflicts arise between stakeholders [28].

1.3.2.3. Institutional and Philosophical Frameworks for Medical Device Design

Alternative institutional structures and philosophies for medical device design have also been considered. Grotcott [45] investigated medical device design from an organizational standpoint. The author suggested the establishment of companies or

research centers devoted to intellectual property development and licensing to promote device design that better reflects use context. In this model a third-party company would be freer to develop user engagement specialties, incorporate direct relationships with hospitals and patients, and perhaps have more incentives to generate usable products. These would then be licensed to traditional manufacturers to generate revenue [45]. While an interesting way of structuring basic research, there has been relatively little subsequent investigation into the efficacy of this approach.

Aviles et al. [46] propose a similar approach. Noting that most clinical technologies die in a so called “Death Valley” between discovery in academic settings and commercialization, the authors propose the use of “Communities of Practice” which blend teams of varying skill sets. The central premise is that these communities have the effect of enabling more effective management of the collective knowledge required to bring a technology to market and moreover bring more commercially minded viewpoints closer to emerging technologies. In the proposed view, academic, clinical, administrative, and industry professionals collaborate throughout the design process. However, they offer little insight as to how exactly these teams should interact, or how knowledge and viewpoints should be managed.

Demers-Payette et al. [10] take a different approach, focusing on the social impacts of clinical technologies rather than market ones. The authors used focus groups to identify significant issues in the interaction between technological progress in medicine and its social implications. Based on participant responses and literature review, they explore methods to implement four previously identified aspects of socially responsible innovation (inclusiveness, reflexivity, responsiveness, and anticipation) for the medical

context. The result is a prescriptive list of best-practices for realizing socially responsible innovation in medicine.

1.3.2.4. Usability Design Methods in Medical Device Design

1.3.2.4.1. Requirements Capture

Design aspects such as usability and requirement elicitation have also been considered. Shefelblaine [47] proposed a usability design process aided in part by a guiding workbook that describes the basics of user requirement elicitation and identification of potential design risks. Ward [48] assessed the workbook with both junior and senior designers, finding that both groups agreed that their current design processes were plagued by missing or conflicting requirements because of miscommunication. Using the workbook, junior engineers were found to be able to generate higher quality requirements for a theoretical design exercise than they had been without the workbook. Based off of this feedback Ward et al. recommended a combination of functional analysis, alongside Shefelblaine's workbook, design checklists, and regulatory guidance [48].

1.3.2.4.2. Customer Engagement Strategies

Specific engagement methods have been described in detail. A 2010 review paper by Martin et al. [7] lays out the various tools available for customer engagement and usability assessment, and attempts to document their advantages and potential pitfalls in the context of medicine. These include methods that occur prior to design to engage users, such as surveys, focus groups, and contextual inquiry as well as methods to evaluate a fully designed system such as heuristic evaluations and user testing. While

perhaps useful for formulating a user engagement strategy, this information does not necessarily prescribe a best course of action or recommend how the resultant data can be used to impact a design. Garmer et al. [49] used a design case study to offer a more prescriptive approach, noting that focus groups were a valuable tool to establish contextual issues involved in the design process and stressing that usability tests were ultimately necessary to ensure design quality. Shah et al. [50] by comparison took a theoretical approach, describing a high-level design framework for user centered design that focuses on different types of user (professional versus nonprofessional). Based on this division, they then recommend a set of user engagement methods for each of four major design phases. Their approach provides guidance for different types of design exercises, such as a redesign or creation of an entirely new product [50]. This framework could be used as reference to guide a specific design process, but ultimately does not provide a basis to deal with unspoken human factors criteria or to link user attributes to meaningful design variables. However, the sheer number of prescribed engagement strategies for each phase is moreover likely to be problematic given the time and cost restrictions noted by industry members

1.3.2.4.3. Design Heuristics

An alternative approach is to forgo direct customer assessment in favor of heuristic rules for device development. Graham et al. [51] demonstrated the use of heuristic rules to discover usability issues in an infusion pump. Provided sufficient individuals familiar with the authors' heuristics inspected the pump, 93% of usability issues in the user interface could be detected with relatively little time input and no direct use engagement. Other authors however have reported less striking results, such as a

prior study of infusion pumps finding that single evaluators could only detect around 35% of issues with a computer based interface. Moreover, neither study detailed what kind of usability problems remained or their severity in a medical context. This approach also requires pre-existing domain specific heuristics, which poses a rather large limitation given the sheer number of user interface types and environments found in medicine.

There has only been limited work in the development of heuristics for usable medical devices. Zhang et al. used an analysis of adverse events to propose a taxonomy of medical errors based on cognitive factors, from which subsequent design rules might be extrapolated [52]. The authors fall short however of proposing a set of general rules for medical device design. Ginsburg proposed heuristics in the context of device acquisition for a healthcare provider [53]. Using a set of existing rules and principles developed for other domains, the author developed a set of 15 guidelines for medical devices that can be used to rate devices for acquisition or potentially to assess designs. These include factors such as visibility of system status and the use of recognition rather than recall to promote good system design. Alongside the guidelines, the authors developed a set of device specific evaluations and compared three infusion pumps. The results showed both wide disparities between models, as well as broad agreement between their proposed principles, existing standards, and device specific evaluations [53].

1.4. Summary and Conclusions

While a wealth of research has described various aspects of medical device design, major questions still exist as to how to design medical devices. Past research has shown major challenges in clinical knowledge utilization. Most reported strategies for

addressing these types of knowledge discovery and management challenges rely on institutional structure rather than any specific approach. These structures by all appearances are not the norm in industry. Usability challenges have also been shown to be a major consideration in medical device design, but again specific methods of addressing these in the context of a realistic design process are lacking. The question of how exactly to factor usability into the design has not been thoroughly addressed. This is even more problematic given that human factors approaches that have been proposed for obtaining information may not be in line with industry objectives. Moreover, relatively little work has analyzed innovation in this area from a design or business perspective. These shortfalls in past research point to a need for a greater focus on methods and frameworks that might assist in medical device design.

The remainder of this dissertation will seek to address these previously reported shortfalls. The underlying view taken in this work is that many of the issues of medical device design stem from the challenge of accessing and reasoning upon knowledge from multiple domains. Without an explicit link between domain knowledge and a design, it may be difficult or impossible to reach an overall understanding of its impact. From this perspective many of the challenges of medical device design are ones of knowledge management. The research comprising this dissertation uses linked ontologies to address this knowledge management problem. Using an ontological foundation, it will describe the development of a set of tools and methods for medical device design that take advantage of automated reasoning and enhanced knowledge querying abilities. It will then apply these tools to the problem of medical device design generally, and to the emerging area of additively manufactured medical devices.

Chapters 2 through 4 will summarize existing literature and provide a foundation for understanding the subsequent ontology development work. Chapter 2 will address the history, applications, and challenges of additive manufacturing. Chapter 3 will introduce the philosophical fundamentals of ontologies, their basic composition in modern applications, and ontology development practices. Chapter 4 will review ontology applications in engineering and biomedicine. Chapters 5-9 present the original work and unique contributions of this research. Four foundational works are described in chapters 5-8. The process of integrating these works into a coherent framework and validating the result via a case study is described in Chapter 9. Chapter 10 will then discuss some conclusions and potential avenues for future research.

To briefly summarize the specific research presented in each chapter, Chapter 5 introduces an ideation framework for medical devices based on the use of clinical knowledge and functional terminology. Chapter 6 describes the development of a framework for integrating usability information and assessment into a design. Chapter 7 considers an ontological framework for innovative design using additive manufacturing and a knowledge base of existing additively manufactured products. Chapter 8 extends the work of Chapter 7 to assist in detailed design and process planning. Finally, Chapter 9 integrates these works into a single, multi-domain medical device design framework.

CHAPTER 2

ADDITIVE MANUFACTURING

2.1. Additive Manufacturing

2.1.1. History of Additive Manufacturing

Additive manufacturing (AM) comprises a range of manufacturing technologies that construct parts by progressively adding material as opposed to removing it as in conventional machining. Compared to additive processes such as welding, AM typically implies that this process is being driven by a computer working to replicate the geometry specified in a digital model. The technology was originally conceived out of works in the domains of topology and visual arts. The primary mechanisms and considerations for additive manufacturing using stereolithography techniques were first proposed in a series of patents in the 1950s [54]. Since its inception, additive manufacturing has expanded to support an increasing set of methods. These include processes to fabricate parts from a variety of plastics, ceramics, metals, and even biological materials. The technology has moreover seen expanding use in areas as diverse as rapid prototyping, mass customized products, aerospace, and medical devices [55].

The first modern AM systems were patented in the early 1980s, with a photo-hardening approach introduced in 1981. This was followed by the first modern stereolithography systems and the stereolithography file format (STL) introduced in 1984. In these machines, ultraviolet light is used to selectively cure photopolymers layer-by-layer to generate a three-dimensional (3-D) object. Non stereolithography machines were first commercialized in the early 1990s. Fused Deposition modeling (FDM), in which polymer filaments are extruded to form individual layers, debuted in 1991. The

same year saw the introduction of the first laminated object manufacturing system, and solid ground curing systems, [55]. Laminated object manufacturing uses a laser to cut sheets of material. Solid ground curing uses UV light to cure photopolymer layers through a series of masks. Powder bed systems emerged in 1992 and 1993 based on research and patents from the late 1980s and early 1990s [56], as well as work showing applications in plastic, metals, and ceramics [57]. These include such processes as selective laser sintering (SLS), where a laser and scanning system fuse layers of powder together, and binder jetting, in which a binding agent is deposited in layers of powder material. Subsequent years saw the emergence of printers using modified inkjet print heads, as in wax printing technologies, as well as paper and resin lamination technologies. Throughout the 2000s the maturation of AM technologies, reductions in system cost, and the introduction of new printing systems and procedures that enabled higher quality production led to wider adoption of the technology. This period also saw the introduction of consumer and hobbyist focused systems [55]. AM however is still an emerging field, with new manufacturing methods and improvements to existing ones being reported rapidly.

2.2. Additive Manufacturing of Surgical Products

2.2.1. Overview

Medical applications constitute a major subset of AM use in industry. AM is increasingly used across the medical field, regardless of medical specialty. While medical applications are still in their infancy, AM is expected to revolutionize many aspects of medical treatment. It is thus integral to future medical device innovations [58]. Applications are correspondingly diverse, including custom prosthetics and orthotics,

drug delivery, and cutting edge applications combining AM with tissue engineering [59]. Surgical specialties have similarly seen widespread investigation of and experimentation with AM manufactured models, implants, and tools.

2.2.2. Additive Manufacturing of Anatomically Customized Surgical Products

AM's compatibility with economical mass customization is one of its most widely realized capabilities in surgical specialties. As a patient's individual anatomy and their exact medical needs in surgery are unique, AM offers significant potential benefits for customization of surgical implants and devices. Moreover, in many instances 3D scanning data such as computed tomography (CT) scans and magnetic resonance imaging (MRI) scans are already available from standard care. A typical workflow involves first acquiring scan data, resulting in "stack" of anatomical cross sections contained in a standard Digital Imaging and Communications in Medicine (DICOM) file. Specialized software is then used to visualize and "segment" the resulting scan data. In segmentation, the stack of 2D images is extrapolated to a 3D structure bounded by surfaces representing the interior and exterior anatomy of the scan region. This process typically requires both computationally intensive operations and lengthy manual adjustment of the resulting surface model [60]. The result is a 3D computer aided design (CAD) model which can then be manipulated for the creation of custom devices or directly fabricated creating a so-called biomodel.

Biomodels have seen a variety of reported uses in medicine. Two common and closely related applications are training and patient education. In the former case, realistic models which might incorporate both visual and material considerations in patient anatomy are used to train medical students and residents in surgical procedures. PolyJet

processes for example allow fabrication of highly accurate models of human anatomy with varying material qualities such as relative stiffness [61]. Such models have a variety of potentially useful applications. They include teaching and learning human anatomy absent or supplementing traditional cadaver models [62, 63], replication of pathological anatomy for training [61, 64], and pre-operative patient education [65]. AM has also been used for planning complex surgeries, providing a useful tactile interface for surgeons to simulate various surgical tasks or determine optimal approaches [66].

Customized surgical implants have also been studied extensively in the literature. One such application for cosmetic surgery described in the clinical literature is jaw replacement surgery [67-69]. In such operations, 3D medical imaging technologies are used to create geometric models, which are subsequently used to generate mirror images of existing anatomy prior to entering the operating room. This preparation can save time in the operating room and improve the aesthetic result. Cranial reconstruction is another area that has seen significant interest in AM applications. In such surgeries large skull defects can be repaired using biocompatible titanium implants designed based off a patient's skull geometry and 3D imaging of the defect itself. A near perfect fit titanium implant can then be fabricated and affixed directly to the defect [70]. Surgical guides have also been investigated in orthopedic operations, which often require a high degree of precision to obtain optimal clinical results. In such applications CT imaging is used to generate patient specific cutting and drilling guides, which can then be reversibly affixed to patient anatomy. AM has also been used to a lesser extent in soft tissues. Soft tissue applications include the fabrication of AM tracheal stents designed to better maintain position [71] and for pediatric respiratory applications for which off the shelf medical

devices are often ill suited [72]. However, these soft tissue applications are in their infancy, and have not yet been evaluated for safety, efficacy, and value.

2.2.3. Additive Manufacturing of Surgical Tools

A relatively small segment of the literature has investigated fabrication of surgical tools using additive manufacturing. An early study by Rankin et al. [73] investigated the feasibility and economics of fabricating common surgical equipment using AM. Based off the observation that a non-trivial percentage of the cost of common surgical equipment comes from distribution rather than manufacturing, the authors proposed an alternative market in which parts are manufactured on site in hospitals and surgical centers. Using a relatively simple retractor tool as a case study, the authors demonstrated that it was feasible to manufacture sterile surgical tools that meet common operating requirements using desktop FDM printers. They similarly argue that the cost of these devices is competitive with mass produced metal equivalents. The result is intriguing, not least of all because the authors made little effort to optimize their design, instead electing to simply copy the existing geometry of common tools [73].

This positive outcome however is not universal. While other authors have similarly seized upon the ability of AM to distribute manufacturing, results across studies have often been somewhat mixed when a larger set of surgical tools is considered. A study by Kondor et al. [74] considered fabrication of a simple surgical toolkit for conflict zones where one might not be able to ensure a steady supply of surgical equipment. The authors found that they could not reliably obtain cutting results using scissors manufactured by AM and given razors as blades. Another study, investigating the fabrication of a full set of surgical tools to theoretically be used in space missions found

that the material quality of plastic parts made by FDM was insufficient for common medical tasks. The authors instead were forced to re-design a large surgical toolkit, including various sizes of retractor, hemostat, and the like with significant adjustments to part thickness. While a viable toolkit was eventually manufactured, this adjustment of tool size may be undesirable for economic, ergonomic, and clinical reasons [75]. Material problems have similarly been reported in research attempting to manufacture common surgical clips using additive manufacturing. Using PolyJetting, the authors attempted to manufacture designs based on clips commonly used in a range of surgeries. However, the authors found that they could not replicate the performance of commercial clips, even with subsequent redesign to help avoid device fracture. [76]

More complex surgical devices have also been developed based on AM's ability to create complex geometries. Jelineck et al. [77] for example made extensive use of AM's ability to fabricate otherwise difficult or impossible to manufacture geometry. Noting that minimally invasive graspers had significant tradeoffs between reliability due to cable fatigue and overall range of motion, the authors designed a modified device to be fabricated by AM. The resulting design demonstrated an increased number of actuated degrees of freedom, a significant reduction on cable wear, and moreover realized greater range of motion than could be achieved with standard devices [77]. The same group applied similar AM design principles to manufacture a steerable, cable driven biopsy tool [78]. Micro-scale AM technologies such as electrochemical fabrication have also been proposed for fabrication of minimally invasive surgical tools at previously unrealizable size scales. One such application used the technology to fabricate hydraulically actuated

forceps, approximation devices, and clips that could be used in very tight surgical spaces, allowing potentially greater scope for minimally invasive operations [79].

Other studies have proposed the use of AM to facilitate new types of device that take advantage of the material properties of a subset of materials used in AM processes. Printed shape memory materials have been noted as having a wide range of uses in AM. In plastic AM, Zhou et al. [80] noted several potential applications for AM using polylactic acid (PLA), a bioresorbable shape memory polymer. Investigating a wide range of applications, the authors demonstrated two potential use cases for PLA, though more likely exist. In the first, FDM was used to manufacture a set of shape memory staples that would pull tissues together at body temperature, allowing them to heal together and eventually be resorbed by the body. In another, the same basic principles were used to manufacture an implant that could be deformed such that it could be delivered via a catheter, and then reconfigure itself into a device to reversibly block a blood vessel. This combination of geometric complexity and shape memory has also been used in metal powder bed fusion. Anderson et al. [81] for example developed a spine implant with shape memory hinges using direct metal laser sintering (DMLS). After first developing a printing parameter set appropriate for nitinol medical devices, the authors then demonstrated the design and fabrication of an implant that could be deformed sufficiently to deliver through a cannula. Once placed it could then fold into the shape of a spinal fusion cage. If used in surgery the implant would dramatically reduce the invasiveness of a subset of spinal operations.

Despite its significant promise in medicine, several factors continue to impede the advancement of AM in the field. In a systematic review of AM applications in

surgery, Martelli et al. [82] note several technical and systemic barriers to wider use of AM. On the technical end, they note that over 20 percent of studies included in their sample reported unsatisfactory dimensional accuracy, stemming from a combination of measurement error in medical imaging and subsequent creation of a 3D model. Imaging issues were also reported to limit applications of biomodels to tissues that are thin, and to provide a great challenge for soft tissue model creation. The time required for preparation and potentially added to surgical operations, cost, mechanical properties of AM parts, potential complications, and a dearth of high quality patient outcome data also represent major barriers to wider use of AM. The authors also noted that a subset of papers also reported systemic barriers to AM. AM products have few surgical indications, many institutions lack sufficient equipment or expertise to produce AM parts, there is only limited ability to reuse or reproduce AM applications, and any utilization requires users to coordinate many stakeholders across disciplines [82]. On top of these concerns, regulatory hurdles are likely to be a major barrier to more complex AM devices going forward. Using a case study in pediatric respiratory devices, Morrison et al. [83] for example note that even creation of a simple device requires extensive consideration of virtually every aspect of the design, manufacture, and post processing of each device. Based on their experience designing an implant, the authors conclude that current guidance is insufficient to guarantee safe, effective devices. Wider uptake of AM in many specialties may thus be hampered until this regulatory guidance is better defined.

Others have questioned the value of AM for many surgical subfields. Analyzing AM applications in orthopedic trauma, Gibbs et al. [84] concluded that many widely touted applications for AM are not yet ready for widespread use. Biologically useful

feature sizes of less than 100 microns for example remain outside the capabilities of most machines. Moreover, they note that widespread mistrust of AM machine suppliers, a lack of information regarding biological properties, and poor reproducibility also impede use of AM outside of a research context. Economic issues may also be of concern. While some authors have reported positive results using AM in various contexts [73, 75], few studies have evaluated the cost effectiveness of introducing AM into existing surgical practice. One study that did conduct this type of analysis looked at the cost effectiveness of using custom patient cutting guides in knee replacement surgery. Based on a review of past reported efforts and their own analysis the authors concluded that the guides have very high barriers to cost effectiveness that are not met in the current market [85]. Other studies have echoed this finding [86, 87] In the case of planning models, Martelli et al.'s review found that several studies concluded that the benefits of AM were largely dependent on the individual surgeon's skill level, throwing many of the supposed benefits into question. [82].

The applications and shortfalls of AM in surgery are similar to those experienced across many industries. The next section will address the advantages and disadvantages of AM, as well as the challenges of using it from an engineering perspective.

2.3. Advantages and Disadvantages of Additive Manufacturing

2.3.1. Advantages of Additive Manufacturing

The advantages of additive manufacturing are typically described in terms of the ability to economically produce products with various types of complexity. Gibson et al. [88] for example note that AM can manufacture structures that exhibit shape, functional, and hierarchical complexity. Shape complexity refers to the intricate geometries that are

possible with AM. Functional complexity is the ability of some product to do many things and to consolidate assembly functions into a single part. Hierarchical complexity describes the inclusion of both macro-and meso scale features [88]. In a review of design for AM (DFAM) methods, Rosen et al. stress the ability to manufacture parts exhibiting material complexity, or variations in material or material properties throughout a part. The authors also emphasize the importance and uses of forms such as cellular structures [89]. These technical advantages have significant potential to both disrupt current market supply chains and business practices [90] and offer exciting new opportunities for innovation in products and services [91]. Notably AM has little to no tooling cost, and so small batch production and highly diverse product lines might be more economic with AM than in the case of conventional manufacturing [92, 93].

2.3.2. Disadvantages of Additive Manufacturing

While often advantageous, AM does have several notable drawbacks. Reviewing the use of AM for surgical uses, Martelli et al. noted that material accuracy, mechanical properties, cost, and workflow issues were often reported as problems by authors applying 3D printing in the medical domain [82]. These concerns have been echoed across domains. While tooling costs are low, per-part costs enjoy little scope for economies of scale. Coupled with slow process speeds, this limits the usefulness of AM for mass production. Material costs are also high relative to bulk material for conventional processes and machines often involve a significant capital investment [93]. Material choices, though expanding, are much more limited than with conventional manufacturing [54, 94]. Moreover the material performance of parts produced by many processes has been reported to be somewhat inconsistent. They also may be difficult to

predict as they are dependent on a vast array of process parameters that are difficult to control [94, 95]. As a result, deployment of AM technologies requires careful consideration of both the needs and economics of the design itself. On top of these issues the field is rapidly changing, imposing additional challenges for knowledge management and design assessment.

2.4. Design for Additive Manufacturing

The dramatic expansion of fabrication capabilities and the desire to use them effectively has led to a growing recognition of a need for methods and tools to fully exploit the design freedom offered by AM processes. Past research into design for additive manufacturing (DFAM) methods has focused on four overlapping areas: embodiment design for AM products through optimization and part consolidation techniques, decision making methods for process selection, process parameters, and broad design guidelines.

2.4.1. Design Guidelines for DFAM

2.4.1.1. Additive Manufacturing Best Practices

A straightforward approach to DFAM is to simply create broad descriptions of best practices that might help a designer realize better part design for AM. Gibson et al. provide a high-level description of the key advantages that might be exploited by parts produced by AM processes (complexity of shape, hierarchy, and function), but do not go so far as to suggest how these might best be used [88]. Other authors have used reviews of AM in industry and in academia as a basis to somewhat more specific guidelines for DFAM. Yang et al. [96] developed one such set of design guidelines based on a review of other DFAM methods. They conclude that designers should consider biologically

inspired structures, disregard conventional design guidelines, and create multifunctional parts where convenient among other suggestions. Perez et al. [97] based a list of 23 design principles on a review of designs contained in an online AM design repository. These included recommendations that designers should use cellular structures to reduce material and weight, align parts for building so as to leave small features unsupported to avoid damage, and by designing for the resolution limitations of the specific printer in question. While guidelines are certainly useful for one unaccustomed to the freedom of AM, they may not offer more than non-specific advice to solve non-specific problems.

2.4.2. Innovation Using AM

Beyond broad recommendations of best practice, a subset of DFAM methods have focused on creative processes that help designers consider new possibilities made feasible by AM. From this viewpoint the most effective use of AM is not to re-design of existing components or assemblies for a new manufacturing process, but instead to develop fundamentally new products that would be infeasible without AM. A subset of studies considers methods or frameworks for innovative design in additive manufacturing. Laverne et al. [98] focus on introducing AM early into the design process. While not proposing an explicit methodology, the authors compared multidisciplinary design groups with no AM design expertise, with no expertise but access to documents about AM, and with experts in AM design. The authors found that while non-AM experts generated more ideas, groups with AM knowledge generated more original ideas. While suggestive however, the results do not offer clear guidance on how to best use AM knowledge. Rodrigue et al. describe a high level process for how to design for additive manufacturing using a combination of traditional design methods, optimization, and

broad guidelines [92]. However, these recommendations might not be sufficient to significantly alter designs from what might be obtained with traditional design methods. Yang et al. [96] propose using a functional consolidation method early in the design process to facilitate more appropriate or innovative designs for additive manufacturing. In their re-design method, existing CAD models are used to generate a function graph of an existing part. A function consolidation process is then used to re-define a new set of functional features, which can then be realized for part re-design. The authors do not however specify how these later steps of consolidation and realization might be accomplished. Boyard et al. [99] proposed a DFAM technique based on functional similarity for the design of products without internal movements. The authors' approach is based on 3-dimensional functional graphs, wherein each function's location corresponds roughly to where that function is needed in the part. The authors propose that these could then be compared to similar graphs and used to infer design solutions. However, neither study provides details of how such knowledge bases might be implemented.

In addition to broad approaches to innovation using DFAM, a major area of focus is methods for re-use of existing AM knowledge in subsequent projects to improve AM design overall. Several approaches have been proposed. Bin Maidin et al [100] for example propose the use of an AM feature database, detailing four broad types of customer requirement and mapping these to a set of features that can be manufactured using AM. However, as implemented the database might only be able to provide broad, non-specific information about how various features were used in the past, and not what problem context led to their use. Rias et al. [101] coupled a feature database inspired by

the one proposed by Maidin et al. with a design process based on synthesizing ideas from domains into design concepts using a dossier depicting features, images, to help inspire creativity [102]. Another study took a similar approach implemented in software, using search function to feed users a series of images and information depicting various ways of using the capability in question [103]. Kumke et al.[104] proposed using association aids and design catalogues in early design, coupled with subsequent economic evaluation and the modular use of design optimization and functional consolidation methods. The approach was later incorporated into software developed by the authors, which used a “semantic network” to link a set of AM properties relating to various types of complexity (which the authors call levers) to various generic design values. These relations were then used to annotate a set of existing products [105]. While a promising approach, it’s not clear the extent to which these approaches can be easily extended to describe more complex utilization of AM capabilities, or that the network can be enhanced with knowledge from additional domains.

2.4.3. Design Rules for Additive Manufacturing

An important and non-trivial consideration in designing for AM is simply whether a part is manufacturable as specified. Even within one process this is a challenging endeavor, requiring knowledge of both machine and process limitations. The sheer variety of processes available and variance in performance fabricating various feature types across processes or even machines has led to an interest in formulating formal design rules for individual processes. These can provide simple rules of thumb for verifying manufacturability depending on the process, and thus aid in process selection and planning.

Process specific rules are often difficult to locate, and relatively little research has focused on this area. Thomas et al. report a comprehensive set of design guidelines for the selective laser melting (SLM) process [106]. Based on a set of experiments and subsequent evaluation of part success and variance of feature geometry, the authors propose both size and tolerance limitations for common features such as holes in various orientations, a variety of overhanging features, and point out good design practices to obtain features with desirable density or surface finish. Work in often similar plastic powder bed processes defined similar limitations for overhanging features among others. Seepersad et al. [107] reported similar findings based on a series of experiments using custom benchmark parts for plastic SLS. Aiming to provide a rough guide for how to dimension and tolerance parts made by SLS, the authors fabricated test parts and developed rating scales for a range of features, including thin gaps, circular holes, overhangs, and text. Based on fabrication in multiple dimensions they established orientation specific printing rules. A notable finding of this study was that minimum feature sizes to successfully build features such as thin walls and narrow gaps were highly dependent on both the orientation of the print and secondary dimensions. This suggests rules for AM have a high degree of complexity [107]. A similar approach was taken by Meisel et al. [108] with the PolyJet manufacturing process. The authors found different limitations depending on printer mode, material, and orientation.

Others have investigated multiple processes for comparison. Baufield et al. [109] compared electron beam melting, laser beam deposition, and shaped metal deposition to compare both internal process limitations (speed, feed rate, etc.), and to determine maximum feature sizes that could be built by each process. Adam et al. [110, 111]

evaluated best practices for selective laser sintering, selective laser melting, and fused deposition modeling alongside one another by printing a series of test specimens of varying size and geometry. From their results, the authors propose a catalogue of design rules for the processes, consisting of both recommendations and hard cut offs for features that experience failures with certain dimensions. Additional work evaluated the same processes to establish norms for their respective tolerances, and to compare these to each other and to traditional manufacturing processes. This evaluation found that the processes performed similarly to casting, but that these results were highly susceptible to spatial and geometric variations [112].

Beyond identifying allowable feature sizes in various processes there have been a number of efforts aimed at investigating the achievable tolerance of various AM processes. Hanumiah et al. [113] looked at flatness and circularity tolerances in SLM and DMLS, finding what they deemed to be poor quality in the former, but much better accuracy in the latter. However, the authors used only a limited set of samples. Most work instead focuses on the complex relations between various process parameters and resulting tolerances. Layered printing makes many tolerances highly susceptible to part orientation. Past research using a test specimen with flatness tolerances coupled to a mathematical model found that only limited ranges of orientations could achieve the tolerance due to layer based construction, a feature of all AM processes [114]. Other authors [115]) reported similar results for cylindricity tolerances. Moreover, off the shelf parameters may not achieve the best result for some geometries. Past work has found that process modifications such as alterations to the printer tool path can lead to improved

tolerances, though these types of modifications may be beyond the ability of typical operators [71].

2.4.4. Design Aids for Additive Manufacturing

Past research reporting complex relations between printing conditions and part quality have motivated a subset of studies that look at methods to either predict or improve the quality of printed parts based on process models. Three approaches are generally taken: analytical models, numerical models, or empirical models [116]. One such case is a model for SLA accuracy using response surfaces to relate part surface tolerances to process variables [117]. Another used a model based on deposition and layer thickness to account for thermal shrinking [118]. Other approaches have forgone process models to instead use statistical modeling to predict aspects of part quality, such as relative density, as a function of parameter data [119]. While useful for characterizing process capabilities however, these approaches also point to a large knowledge challenge for those looking to design parts for additive manufacturing. One must, from the outset of a design process have a means to know and predict the effect of both design and manufacturing parameters on resulting part quality.

The sheer wealth of past work and the complexity of various recommendations points to a need for design aids to help assess specified designs. Past work has looked into the use of design tools for DFAM and process selection based on known process rules and limitations. Ranjan et al. combined a feature recognition algorithm with a set of guidelines for DMLS to identify and flag problematic features [120]. A later effort then used the same basic approach to support an iterative design process using topology optimization [121]. However, the authors do not report a method of dealing with a case

with multiple material or process options. Another approach uses a printability map based on the expected deviations of a part from its specified design due to orientation effects and process limitations. The method uses information about a printer's resolution and minimum feature sizes to simulate each individual layer of the printing process individually. Each layer is then characterized by a set of unique geometric features, and deviations between these and a specified geometry are graphically represented [122-124]. Ponche et al. [125] propose another method for DFAM in the additive laser manufacturing process. The authors propose a linked system in which manufacturing process characteristics and constraints are used to first help determine a best part orientation, which is subsequently followed by optimization of both the part itself and the manufacturing tool path to ensure performance [125]. However, the approach is only applicable to a single process. Similar tool path optimization processes have been proposed for the FDM process [126], but are again limited to considering a single process.

2.4.5. AM Process Selection

The sheer number of possible AM processes and their respective strengths and weaknesses make process selection important. Before identifying a specific process, there is also a question of whether a part or assembly should be made with AM at all. Eddy et al. [127] address these issues somewhat, considering the case of a decision between AM and traditional manufacturing techniques at the conceptual design phase for a new part or assembly. User preferences for estimated performance metrics and between cost and quality are used to determine a preferred option across a range of production volumes. However the results choose AM as a single option, rather than a potentially large set of

options with differing capabilities. A second approach proposed by Lindemann et al. [128] instead focused on screening an existing set of parts. The process unfolds in three phases, with the first focusing on understanding AM and the second on identifying parts that might be made by AM based on functional and economic requirements. These assessments culminate in the creation of a trade-off matrix. A final decision phase then focuses on identifying which parts specifically to make or redesign with AM based on the broader goals of the organization. This study however treats AM as a homogenous technology, and thus may not identify the possibilities offered by a specific process versus AM generally.

Another suite of approaches is based off of the observation that AM offers low tooling costs, but often does not scale well to large volumes. Several authors have approached AM from an economic standpoint. Ruffo et al. [93] used cost modeling methods to weigh the choice between fabricating parts via AM versus buying them. The approach however offers little insight as to what design changes might facilitate in-house manufacturing. Further work looked at the economics of part re-design to determine volumes at which using a metal AM process makes economic sense. The authors used cost models for competing processes, which were then used to compare a traditional and redesigned part to determine economical production volumes using AM [129]. Though straightforward, this process does however require a time consuming re-design process, and does not consider issues of part quality, which may be positively or negatively affected by an AM process.

Selection between processes has also been studied. Several studies have employed models to aid in the decision-making process. In one such study a generic test part was

used to construct models of four AM processes, with subsequent measurement used to fit models of part attributes such as surface roughness and process ones such as building time [130]. In another, the authors [131] used a combination of cost and build time models to decide between fused deposition modeling and selective laser sintering processes. Their approach relies upon prediction of these factors based on part and broad process parameters to predict a part's build time. In both cases a finished design is needed, and it is more or less assumed that a process can actually fabricate the part to within some specification. An alternative approach is to use a formal decision analysis. One study for example used the Analytic Hierarchy Process to first identify key machine factors, and then to rank a set of candidate processes and machines. This resulted in a formal decision method for finding an appropriate AM system given some design [132]. While this yields a formal way of choosing a process, it does point to a significant information challenge for the choice of an AM process, and like other methods cannot necessarily give insight on how a part should be designed.

2.5. Summary and Conclusions

While past research in AM suggests the potential of the technology in medical applications, manufacturing and materials research in the area suggests major barriers to its wider adoption. Some of these are clearly technological, such as limitations in the achievable feature sizes or manufacturability of certain parts. Others clearly have to do with the availability of AM expertise, which is limited by the relative youth of the technology. However, as with the medical device design, a significant subset of the challenges of DFAM stem from the availability of knowledge and the ability of a

designer to access, share, and capture it. The next two chapters thus focus on a powerful approach for achieving just these goals: ontologies.

CHAPTER 3

FUNDAMENTALS OF ONTOLOGY

3.1. The Semantic Web

The semantic web was first described by Tim Berners Lee in 2001 [133]. In Lee's vision, information represented on the World Wide Web (WWW) would be extended and enhanced by a formal knowledge structure. This would have the effect of providing machine readable meaning to the web's human readable content. As proposed, this implementation would promote standards to tag data with formal, logically coherent human knowledge implemented using standardized web protocols and syntax. Several approaches have subsequently been developed for semantic web markup. These include query languages [134] , basic methods for describing information [135-137], and rule languages [138]. One method that has been used to implement the proposed semantic web is ontologies.

3.2. Knowledge Representation with Ontologies

3.2.1. Ontologies in Computer and Information Science

In a philosophical context ontology refers to a metaphysical study of the nature of reality dealing with the definition of types of entity that can be said to exist, and exploring how they relate to one another. Though the study of ontology dates back thousands of years, the underlying goals of categorizing types of knowledge became highly relevant to the field of computer science. Researchers recognized the potential of such approaches for the development of automated reasoning and artificial intelligence. Though the modern use of ontology in computer science predates the definition, Gruber [139] formulated the modern definition of ontology in information science in the early

90s. In Gruber's view ontologies for knowledge management consist of a taxonomy of classes of thing, relations between those classes, and formal definitions and axioms that define and restrict the meanings of each term. In this approach the aim is to develop semantically expressive taxonomies representing and formally defining the types of entity in some domain, coupled with formal semantics to represent relations between entities and axioms that restrict their definition.

3.2.2. Advantages of Ontologies

Ontologies have a range of other properties that distinguish them from other information models. Most notably, ontologies are meant to be open, existing as the underpinning semantic web and so by extension interacting with many other ontologies. This open nature is responsible for the theoretical advantages of ontologies compared to models such as data schemas, expert systems, and the like. Ontologies are openly available to all potential users, their knowledge model can be extended by subsequent users and developers, and in theory ontologies can interoperate with one another [140]. Since the ontology is meant to reflect knowledge generally, its terms, definitions, and axioms should be true across applications and application domains. These advantages however can only be realized in the case that an ontology has been developed and maintained properly, and so in many instances may be more theoretical than realizable.

3.2.3. Ontology Languages

3.2.3.1. Semantic Web Knowledge Representation

The formally defined knowledge underlying the semantic web of which ontologies are a part may be specified using a variety of development languages. A common approach is to develop ontologies using markup languages that annotate

documents using standardized syntax. Extensible Markup Language (XML) [141] is commonly used as a basis for markup. Semantic web domain languages in particular have seen widespread usage as a result of the adoption of ontologies as a framework for implementing semantic web technologies. As such the World Wide Web Consortium (W3C) has worked to develop a number of language standards for knowledge modeling and the development of ontologies. The Resource Description Framework (RDF) for example was first adopted by the W3C in 1999. RDF characterizes entities using statements known as triples, which consist of a subject, predicate, and object, with the predicate expressing some relation between the subject and object. RDF forms the basis for RDF schema (RDFS) [141], which define the basic types of RDF classes that are used for knowledge representation using RDF. These include types such as classes, properties, data types and literals which form the basis of RDFS based standards for expressing ontologies.

3.2.3.2. The Web Ontology Language

3.2.3.2.1. Web Ontology Language Overview

RDFS provides the basis for the Web Ontology Language (OWL) [136], which has seen widespread usage since its publication as a language for ontology development. OWL was developed specifically for ontology development in 2004, and was subsequently updated with OWL 2.0 in 2009 [142]. Rather than existing as a monolithic language, OWL is a family of closely related languages with subtle, but important differences. OWL Lite is a simplified version of OWL for straightforward models that has slightly diminished expressivity. OWL DL by contrast aims to deliver the most expressive possible language while preserving completeness and decidability. OWL Full

aims to be compatible with RDFS, and can be seen as a way to enhance existing RDFS or OWL constructs. OWL 2 preserves these variants on OWL while generally expanding the expressivity of OWL with additional relation types, annotations, restrictions, and the like. It moreover introduced a new syntax [143].

3.2.3.3. Components of OWL Ontologies

3.2.3.3.1. Underlying Logical Framework

The underlying basis of OWL is description logic (DL), a subset of first order logic distinguished by the fact that it supports relations between up to two distinct atoms. This approach that preserves decidability while allowing expressiveness, both of which are important for the development of knowledge models [144]. In formal logic, decidability refers to ability to determine membership within sets defined in the logic system. In an ontology, this might for example be a determination as to whether some object with a set of defined properties is a specific type of object defined within the ontology. While highly versatile, DL must sacrifice some constructs that can be expressed through more complete logical languages such as first order logic in order to preserve its decidability. OWL ontologies are thus restricted to evaluation of a subset of first order logic that can be expressed in DL [145]. It should be noted that many of the constructs discussed in the following section in the context of OWL ontologies stem from OWL's basis in DL.

OWL's underlying logic notably uses an open world assumption (OWA) in its creation of knowledge models. In the open world assumption, unknown knowledge is not assumed to be false, as in closed world models. In practice, this means that knowledge not explicitly asserted in an OWL ontology through a class hierarchy or logical axioms

cannot be assumed to be non-existent. From a development and logical reasoning standpoint, this means that an axiom is only assumed to be invalid if some explicitly stated axiom contradicts it. Thus, the possible relations between entities in an OWL ontology are defined through restrictions to the set of possibilities [136]. From a practical perspective, this also means that certain types of logic, such as reasoning on the basis of the absence of some relation, are not possible in most cases.

3.2.3.3.2. Entities

Entities correspond to the types of thing represented by an ontology. Depending on the scope of the ontology, this might comprise all things that could possibly exist, or alternatively a set of things that are relevant to the domain or application. Entities can be subdivided into two main types: particulars and universals, or as often denoted in ontology engineering Abox (assertion components) and Tbox (terminological components). Particulars (Abox) are individual things, such as a specific person. Universals (Tbox) are broad classes of thing sharing some set of traits. The particular person might be a member of the universal human. Axioms restricting particulars or universals are thus inherently different. If a particular person is asserted to have some weight, that assertion can only be considered necessarily true for that individual. However if an axiom asserts that humans have some weight or range of weights then this is taken to be true for all humans [146].

Universals, or classes, are defined in OWL using axioms that define the particulars of class membership in machine-readable syntax. Good ontology development practice will supplement this with additional plain text definitions that help form a human readable, formal definition. Primitive classes are described solely in terms of the

necessary conditions for class membership. These conditions specify that all members of some class of thing must have some set of properties, such as saying all members of a class “atom” have mass. While true for all atoms, there exist things that are not atoms that also have mass. This means that the condition of having mass is not sufficient to define something as an atom. Defined classes by contrast may be described by some necessary conditions, but must also include a set of conditions that are sufficient to determine membership. If some entity meets the sufficient conditions, then it is a member of that class [145]. From an automated reasoning standpoint this is quite significant. Reasoning software can determine membership in defined classes, but can only determine membership in primitive classes if it is explicitly asserted in the ontology’s structure. However, care must also be taken when defining sufficient conditions: if not thorough enough the ontology will no longer accurately reflect reality, and so will classify non-member entities as members [145], 131].

3.2.3.3.3. Properties

Properties define the relations between different entities. The most basic type of property relation, the Is-a relation, is inherent to all taxonomies. Is-A relations are represented in the class-subclass relations that define the tree structure of a taxonomy having more than one level. Beyond this basic relation the extent and types of relation defined with an ontology will otherwise be largely a function of its scope. Since OWL is based in DL, its relations are always binary (e.g. they have only two members) and unidirectional (they operate in one direction).

Property relations are defined in part by axioms that specify the types of entity that can bear a relation and those that are borne via the relation, or in other words the

domain and range of the relation. Two types of relation are expressed in machine readable syntax, and thus can be reasoned on by the ontology. A third relation type is expressed in human readable form. The first, object property relations, defines a relation between two entities defined within the ontology. In other words, object properties have a domain and range that consists of classes defined within the ontology hierarchy, or particulars instances of them. The second type of relation is a data property relation. Data property relations link entities to data types commonly defined in programming languages such as strings, integers, doubles, and Booleans. These relations introduce actual data into the ontology as opposed to the purely relational knowledge of object properties. The final relation type, annotation properties, is used to add definitions, comments, and curation information to the ontology for use in ontology engineering and dissemination of the ontology [146].

3.2.3.3.4. Restrictions

Restrictions are the primary means through which semantic expressions formalize knowledge within OWL ontologies. The most common restriction in an OWL ontology is the subsumption (Is-a, subclass) relation. A subsumption relation is one wherein an entity is described as a member of some parent class having some additional set of property relations. Drawing an example from a commonly used teaching ontology about pizza [147], one might create a restriction such that a pepperoni pizza is a pizza that has a topping that is a member of the class pepperoni. Throughout this manuscript **boldfaced** text will represent classes, while ***bolded and italicized*** text will be used to highlight properties. Given this format and using the Manchester OWL syntax [148], one would write this restriction as

pepperoni pizza' SubClassOf Pizza and 'has topping' some pepperoni (1)

where the keyword “and” implies an intersection relationship between pizza and the pepperoni via the relation **'has topping'** and “some” implies that there exists at least one member of the class **pepperoni** that is a topping for any member of the class **'pepperoni pizza'** [149].

Three types of restrictions are used in OWL ontologies. The previous example used an existential restriction, which, as in the case of the pizza topping, simply implies that there is some member of the class in the range of the restriction that is tied to the domain via the **'has topping'** relation. Alternatively, these existential restrictions can be used to specify not only that some member from a class is linked, but instead some specific member. Universal restrictions by contrast impose a far more expansive restriction, wherein the only things linked to the entity by the property in question are those expressed in the restriction. Were the above example to be expressed by with a universal restriction (swapping the keyword “some” with “only”) the corresponding interpretation would be that pepperoni is the only topping that can be on a pepperoni pizza. The scope of Cardinality restrictions is somewhat between existential and universal restrictions, and can be added on in addition to either. Rather than specify that a property links an entity to members of some or only some other class, the cardinality restriction states that it links a specific number or range of entities. Taking the example of an assembly, one might say that an assembly has at least two sub-parts. In the case of an assembly class consisting only of those having fewer than five parts (inclusively) a cardinality restriction might set a maximum of 5 ‘has part’ relations for the class [150].

3.2.3.4. Enhancements to Ontologies since OWL 1

Since the introduction of OWL the subsequent release of OWL 2.0 and related research have resulted in a number of additional components that enhance the base expressivity of ontologies [150].

3.2.3.4.1. Expanded Property Types and Uses

With the release of OWL 2.0, OWL ontologies feature expanded property types. Functional properties can only be asserted in a single axiom for a given entity, and were the only specialized property in OWL 1.0. Anti-functional properties mean that the range of the property can only be used in one assertion using the property. Transitive properties imply relations wherein if A has some transitive relation to B, and B has the same relation with C, then A also has that relation with C. A common example of this in engineering ontologies is between parts in an assembly. Parts belonging to some sub-assembly must necessarily be part of the parent assembly. Reflexive relations are those in which the domain and range are the same entity. Anti-reflexive are those wherein the range is all entities other than the entity that constitutes the range of the property. Symmetric properties express relations wherein the assertion of a predicate between the subject and object implies the same relation is true with the roles of the subject and object reversed. An example of this is the relation between two individuals of being siblings; if a person is another's sibling then the reverse is necessarily true. Antisymmetric properties are those in which this subject predicate reversal cannot be true, such as in the case of paternal relations between people [150].

In addition to new types of property, other syntactical changes allowed for more expressive use of properties. Notably, OWL 2.0 introduced property chains into OWL

ontologies. Property chains allow the conditional expression of a property relation given other properties form a “chain” composed of overlapping domains and ranges of properties. In an engineering ontology for example, one might wish to note that problems affecting some part in an assembly are problems of the assembly overall. If one expresses that a part has a problem using a property called ‘**has problem**’ and denote that an object is part of an assembly via a relation called ‘**has part**’, then a property chain might be constructed using these two properties to express the desired logic. If an **assembly** ‘**has part**’ some **object**, and that **object** ‘**has problem**’, some **problem**, then the assembly ‘**has problem**’ that same **problem**, a simple logical sequence that is captured with a property chain.

Though not as critical to the range of logical axioms that can be expressed in OWL ontologies, it should be noted that OWL 2.0 also introduced an expanded set of literals for the expression of data properties.

3.2.3.4.2. Semantic Reasoning Software

The formal semantics underpinning OWL ontologies allows them to be evaluated using semantic reasoning software. Semantic reasoning software automatically evaluate the logical consequences of a set of axioms. Given that they require logical consistency among those axioms, they also by extension can be used to evaluate whether an ontology is internally consistent. The power of automated reasoning enabled by Reasoners is apparent when used to evaluate ontologies. In addition to affirming consistency, Reasoners can infer class hierarchy and membership information, note relations between entities that are not explicitly asserted in the ontology but implied through its axioms,

evaluate logical rules not directly expressible in OWL, and in some cases even perform mathematical operations on the data contained in literals in the ontology.

A range of reasoning software is freely available and distributed via ontology development software. Native DL compatible Reasoners include FACT++ [151], HermiT [152], and Pellet [153]. Others such as the Jena Framework [154] or Drools [155] have native rule-engine capabilities or have semantic extensions that allow rule-based reasoning.

3.2.3.4.3. Ontology Rules

Coupled with reasoning software rules greatly expand the expressivity of ontologies. While DL has limitations aimed at preserving the decidability of an ontology, the addition of rules helps remove many of these limitations for the ABox entities in an ontology.

3.2.3.4.3.1. Rules

Rules in OWL are implementations of Horn logic, a subset of logic that is otherwise unavailable in DL. Horn logic deals with Horn clauses, a subset of formal logic clauses that are distinguished by the inclusion of at most one positive literal. In rules expressed as Horn formulas (Horn Rules) the first clause forms an antecedent, which establishes a condition under which the second clause is true [156]. In a simple example:

$$A \wedge B \rightarrow C \quad (2)$$

Where the equation is read “If A and B, then C”, and A and B are a set of conditions. The advantage in the context of ontologies is that DL is limited to two variable logic, whereas Horn Rules are not [157]. This however comes at the cost of decidability, meaning that

the full range of Horn logic is typically restrained within an ontology by protections implemented within reasoning software. As implemented, these protections limit evaluation of Horn Rules to ABox, which significantly restricts their use.

3.2.3.4.3.2. SWRL

The Semantic Web Rule Language (SWRL) [138] uses OWL and the Rule Markup Language to formulate conditional statements composed of two parts: the antecedent and consequent. The antecedent specifies a set of conditions that is met by some ABox entity, leading to the assertion of the conditions listed in the consequent. SWRL was introduced by the W3C in 2004 as the standard rule language for semantic web technologies [138].

3.3. Types of Ontology

Given the sheer scope of human knowledge that might be represented using ontologies, and the range of potential applications, it is perhaps unsurprising that there are several common types of ontologies.

3.3.1. Upper Level Ontologies

3.3.1.1. Purpose and Scope

Top or upper level ontologies aim to provide a unifying information model that describes the basic classification scheme that will be used to define types of entity from specific knowledge and application domains. In this sense, they are essentially meta-descriptions of the larger information model consisting of the upper level ontology and less abstract domain level ontologies. While often highly abstract, the use of upper level ontologies is nonetheless essential to realize the ontology properties of interoperability

and extensibility [158]. In cases where ontologies have not been developed to conform to the same knowledge model or simply lack an upper level knowledge model altogether interoperability is more theoretical than practical.

Beyond this broad goal however, there is little agreement as to the scope or structure that should be used to define an upper level ontology. Indeed, even the basic constituents of an upper level ontology are not universally agreed upon. For example, while it has been suggested that upper level ontologies should only deal with universals, this is not universally accepted. Similarly while it has been argued that an upper level ontology should be as minimalistic as possible, this limitation of scope is not universally adhered to [159, 160]. The underlying perspective of upper level ontology and modeling approach have been similarly debated, resulting in significant philosophical differences between proposed ontologies.

3.3.1.2. Distinctions between Upper Level Ontologies

Several key distinctions divide upper level ontologies. At a philosophical level, top level ontologies must specify whether things that do not exist in space-time can exist (descriptive versus revisionary ontologies), whether different entities can co-locate in space-time (a multiplicative versus reductionist viewpoint), how to deal with hypothetical entities, and whether to use a 3D (endurantism) or 4D (perdurantism) modeling approach [161]. These distinctions have major implications for both the scope and manner of knowledge representation. For example, a 4D perspective will account for time varying aspects of entities while a 3D perspective necessarily lacks temporal parts. Beyond these distinctions, a major question in both philosophical study of Ontology and its practical implementation is how an ontology should be developed. One approach that has gained

traction and is used in many upper level ontologies is that of formal ontology. Dating back to the philosopher Edmund Husserl, formal ontology is based on a conceptualization of ontology as similar to formal logic [162, 163]. In this view, the ontology should be universally true, rather than dependent on specific context. It moreover should remain consistent even as expanded with additional content, and accommodate different levels of granularity [162, 164]. Formal Ontology notably draws from mereology for its representation of relations between entities, focusing on a characterization of knowledge as a set of part-whole and boundary relations between entities. This is distinct from many other ontological approaches which utilize set theory as a basis for describing these types of relations.

3.3.1.3. Examples of Upper Level Ontologies

Several efforts have proposed upper level ontologies. The Suggested Upper Merged Ontology (SUMO) [165] was developed by merging a set of previous high level ontologies. SUMO's upper level model splits the world between physical and abstract entities, with things like quantities belonging to the latter and objects and processes to the former. SUMO has been used previously to classify the terminology included in WordNet [166], a large thesaurus used for natural language processing among other things. As a result, some SUMO classes may be beyond the scope of an upper level ontology [167]. Another approach, the Descriptive Ontology for Linguistic and Cognitive Engineering (DOLCE) [168] instead splits all entities into four broad categories. These include endurants (such as objects), perdurants (such as events), qualities for things that can be measured (such as location) and a catch all abstract class, for things like relations, facts, and sets that lack spatial or temporal qualities. The GALEN project [169] also

introduced an upper level ontology specifically for tagging biomedical information. In GALEN a distinction is made between continuants and occurrents (endurants and perdurants), as well as several other distinctions, such as things that are biological versus non biological. While introducing a number of useful distinctions for a biomedical ontology, this approach does have drawbacks: the class structure in GALEN's upper level ontology makes a considerably larger commitment than is desirable, and so its breadth of applications may be limited [170].

A notable upper level ontology is the Basic Formal Ontology (BFO) [160, 171], which implements that basic knowledge structure advocated in Formal Ontology. BFO splits all entities into continuants and occurrents. Continuants are further subdivided into those that are independent, dependent on some specific independent continuant to exist, or dependent on some entity that may change over time (generically dependent). BFO has been applied widely in biomedical knowledge management, and serves as a basis for integrating disparate medical ontologies [172]. Subsequent work using BFO as a foundation has also promoted standards for developing interoperable ontologies in biology and medicine [159].

3.3.2. Domain Ontologies

While upper level ontologies aim to create a knowledge model for all entities, domain ontologies focus on representation of a specific knowledge domain. As such, they focus less on large divisions between major concepts than on the formalization of terminology for domain concepts, and the determination of relations between these various classes of thing. Two main approaches are used to define ontologies within a specific domain. In a thesaurus-based approach a pre-existing collection of domain

terminology, such as a literal thesaurus or a database of domain specific documents, is used as a starting point to define a more formal knowledge structure for the domain [173]. Since it is based on terminology that is used already within in a domain, this approach has the potential advantages of leading to ontologies that more closely resemble natural language. Alternatively, an ontology engineering approach relies upon expert consensus within a domain, and is based on a top down approach. In ontology engineering one first defines a scope, which can then be fleshed out by identifying key information capture objectives that define what types of question will be answered by knowledge in the ontology [174]. This approach is advantageous as it can be used to identify existing ontologies that might be reused in the development of a new ontology, promoting interoperability across domains.

CHAPTER 4

ONTOLOGIES IN ENGINEERING AND MEDICINE

4.1. Overview

Ontologies and ontology-like information models have been applied in both the engineering and medical domains. In engineering this is motivated by a perceived information overload reflected in the sheer volume of information generated during a typical engineering project. Past work has thus focused on frameworks that allow this information to be captured and reasoned upon to create and query engineering knowledge. In biology and medicine, domain complexity, billing procedures, and the public health goals of national insurers have all contributed to the development of various types of medical model [175]. Information models and ontologies have been previously proposed for knowledge capture and reuse in both engineering and medicine. These include formal ontologies as well as a number of large terminologies that support tagging of domain information.

Despite a common interest across domains these efforts have seen significantly different outcomes. In the engineering domain, few ontologies have seen widespread use and adoption of ontologies in engineering projects has been inconsistent at best. Only a small fraction of engineering ontologies are readily available, few are curated, and there is relatively little effort to promote interoperability through the creation of orthogonal ontologies using agreed upon upper level models. Nonetheless there are a significant number of engineering ontologies proposed in the literature that might serve as a basis for future integration. In the life sciences a number of large terminologies have been advanced and are curated by large national and international consortiums. Several

ontologies have seen widespread adoption, and are readily available through centralized repositories. Collaborations to create domain models exist at both a national and international level, and some progress has been made towards creating modeling standards for domain ontologies.

4.2. Medical and Biological Ontologies

4.2.1. Lexicons for Tagging Biomedical Research

The life sciences have seen enthusiastic adoption of ontologies of varying levels of formality to manage domain information. A significant subset of work has been on the creation of standardized terminologies for medical and biological concepts, as well as the creation of semantic relations to define relations between sub-domains. A highly successful case has been the Gene Ontology (GO) [176], a standardized terminology for biological research that is used in part to enhance the National Library of Medicine (NLM) and National Institutes of Health (NIH)'s PubMed search engine. Motivated by the wealth of interrelated genetic sequence information and recognition that much of this information is common throughout biology, the gene ontology seeks to unify the biology domain by introducing a standardized model to describe chemical and biological processes. Subsequent work such as the TermFinder software has allowed enrichment of the GO through enhanced searching capability [177]. Similar efforts include such tagging systems as the Medical Subject Headings (MeSH) [178] and the National Center for Biomedical Information (NCBI) [179] terminology, which have similarly been incorporated into article repositories. MeSH is a controlled lexicon used to tag academic publications in the biomedical domain, and is used in article repositories and search

engines such as MEDLINE, PubMed, and NLM to catalog their contents. The NCBI terminology similarly introduces a set of commonly used biomedical terms.

4.2.2. Medical Coding Systems

The field of medical ontology has seen similar development of large domain terminologies, as well as buy in and leadership from national and international organizations. Medical information models are commonly implemented as coding systems which implicitly introduce limited classification and terminology to the domains of medical billing and public health research. These efforts have been driven in part by a government insurers and medical trade organizations across national borders. The International Classification of Diseases (ICD) [180] coding system is used in several countries including the United States to encode information medical procedures and diagnoses. ICD 10 (the current iterations) implements a coding standard for generating alphanumeric codes, ICD 10 (the current iteration) breaks the medical domain into broad domains, which are then subsequently represented via a series of codes that represent various body systems, medical operations, contextual information and qualifiers relating to a medical case. Within the US the Current Procedural Terminology (CPT) [181] code, a coding approach maintained by the American Medical Association, takes a similar approach for the classification of medical procedures, and is commonly used in medical billing.

4.2.3. Medical Ontologies

Beyond more limited code based approaches, several efforts have proposed explicit models to accompany a standardized medical lexicon. The Foundational Model of Anatomy (FMA) for example implements an ontology of the anatomical domain. The

FMA is a large (more than 75000 terms) ontology that captures anatomical information at the cell, tissue, organ, system, and organism level, as well as important anatomical information such as planes, directions, and clinically important points. Other work has yielded terminologies for the entire medical domain. One such effort is the Systemized Nomenclature of Medicine Clinical Terminology (SNOMED CT) [182] maintained by the International Health Terminology Standards Development Organization (IHTSDO). SNOMED CT aims to create a standard set of clinical terminology for international use. SNOMED CT primarily is used for accurate storage and sharing of health information, and is incorporated into health records. It uses an informal ontological approach to support a large thesaurus of medical terminology mapped to numerical terms and linked by relationships. The terminology and a set of related codes are arranged as a class structure, with relations used to form triplets compliant with DL logic. A similar approach was taken in the Open GALEN project, though with more emphasis on creating a formal upper level ontological model to support medical and biological ontology. GALEN uses an upper level ontology that provides unifying structure to a smaller set of biological ontologies, which can then be used to render medical records searchable [169, 170].

4.2.4. Coordination of Medical Domain Information Models

Motivated by the advancement of a number of large medical terminologies, a subset of efforts have focused on the development of methods and tools to or at least identify similar or shared terms. One such effort is the National Center for Biomedical Ontology's (NCBO) Bioportal service [183], which acts as both a repository of biomedical ontologies and a search engine which will return all ontologies that contain a

search term. As of 2017 Bioportal contains 20 ontologies maintained by 10 separate groups. A separate effort by the US NLM is the Unified Medical Language System (UMLS) [184]. The UMLS links a wide array of biomedical terminologies, including those of the GO, MeSH, and NCBI, using a “Metathesaurus” to identify equivalent terms. Terms within the UMLS are supported by a semantic network portion, essentially an ontology that defines relations between biomedical domain concepts [185]. The semantic network defines a limited class structure that defines broad types described by the various UMLS terminologies. These are then linked by a series of relations that describe high level interactions between types, such as saying that a body function is a process of the human body. While useful for coordinating disparate terminologies, this approach is significantly limited in its ability to provide a fully coherent, consistent model of biomedical concepts.

4.2.5. The Open Biomedical Ontology Foundry

An alternative approach to unifying ontologies is the coordinated development of a set of orthogonal ontologies using pre-agreed upon modeling principles. The Open Biomedical Ontology (OBO) Foundry coordinates the development of non-overlapping ontologies that have strictly defined scope and fully defined, logically constructed terminologies that use the BFO as an upper level ontology. Submitted ontologies are reviewed to assess their adherence to a set of overarching development principles, which govern formatting, naming conventions, open licensing, ontology scope, and also assess the quality of the ontologies. As of 2017, ten ontologies had been fully vetted and accepted by the OBO, though many more are hosted and are in a review and revision

process. As a result of this curation, OBO ontologies are highly reusable and interoperable.

4.3. Ontologies in Engineering

Engineering ontologies have been developed largely for the broader purpose of knowledge management (KM) in engineering projects. The related processes of engineering analysis and engineering design are both regarded as knowledge intensive activities, resulting in considerable interest in technologies and practices that can allow knowledge to be reused [186]. In this capacity, engineering ontologies allow creation of shareable domain knowledge, explicitly represent knowledge related to a specific modeling domain, and allow that knowledge to be reused and reasoned upon [187].

4.3.1. Ontologies of Manufacturing

Several ontologies have been proposed to model parts of the manufacturing domain. Lemaignan et al. proposed a Manufacturing Semantics Ontology (MASON). In MASON's knowledge model, manufacturing entities consist of technological and cost entities. Technological entities include things like raw materials, geometries, and assemblies, and are modeled as interacting with resources such as machine tools to carry out manufacturing operations, which in turn induce costs. Various operations are restricted to be suitable for creation of a subset of geometric entities. This model is then combined with a class hierarchy for various manufacturing operations and technological entities [188]. Borgo et al. [189] used DOLCE as upper level for a manufacturing domain ontology. The result attempts to map the concepts included in the Adaptive Holonic Control Architecture (ADACOR), and identifies a set of resources which are used to fulfill work orders, that result in the production of a product according to some governing

process plan. Properties then express various skills, manufacturing outcomes and the like. However, more detailed information about ADACOR was not reported

More detailed domain ontologies have also been created for the manufacturing domain. The Manufacturing Service Description Language (MSDL) [190] for example uses a large class hierarchy of manufacturing processes and services, and moreover includes types to define such disparate domains as material properties, various industries, and broad types of product. MSDL primarily seeks to capture information about the manufacturing capabilities of manufacturing enterprises, and so focuses on both a detailed hierarchy of processes and various links between processes in the delivery of a service. A similar approach by Eddy et al. [191] used MSDL as the basis to create an ontology of AM processes, with the goal of aiding in process planning. The result, the Semantic Additive Manufacturing Process (SAMPro) ontology combined a hierarchy of AM procedures with a set of properties allowing processes to be tagged with information relating to the types of material used in the process, their states, and various process limitations. Though large in scope however, both these and other manufacturing ontologies are hindered by a lack of an upper level domain model, and as such may not be expressive enough to capture detailed manufacturing information relating to machines or various methods of operation.

4.3.2. Ontologies for Engineering Design

Engineering design is a major focus of past ontology engineering work for the engineering domain. High level product information for example has been modeled using multiple ontologies. Tudorache [187] proposed a series of four, small, linked ontologies that describe many fundamental engineering domain concepts. The four ontologies deal

with components, connections between components, requirements of systems, and constraints. The ontologies define various types of component, focusing on car engines as a demonstrative example, and propose a series of *part of / has part* relations between various components. The connections ontology then defines topological relations between various components using specifically created slots to link two components with types representing connectors and directional information. The proposed requirements ontology differentiates between customer requirements and detailed requirements stemming from engineering analysis, and introduces simple relations between system components and requirements, such as a “fulfills” relation that indicates some system fulfills a requirement. The constraints ontology then indicates various constraints using slots for instances that contain mathematical expressions related to constraints on a system. While basic, the model makes very little ontological commitment, and is designed to act as a high-level model for subsequent application ontologies.[187]

Other high-level design ontologies have been proposed for the engineering domain. The Engineering Design Integrated Taxonomies (EDIT) for example seeks to be a high level model of product design, breaking the design domain into design processes, issues, functions, and products. These sub-types were then expanded based on analysis of engineering documents and past research to create subclasses by both the authors and related research [192, 193]. For example, Sim and Duffy [194] proposed an ontology in which design activities are modeled as having input and output knowledge, undertaken with some goal. They then classified a hierarchy of design activities based on past design process research, creating a set of activities that include design definition activities, evaluation activities, and management activities. An alternative model is the Design

Ontology (DO), which aims to provide a formal model for engineering design. Unlike many ontologies, DO is an upper level ontology with formal philosophical roots that are well suited to design. DO distinguishes between physical things like objects and processes, and abstract ones like attributes, propositions, quantities, and relations [195]. While formal, the class hierarchy and axioms provide little information relating to engineering design, or engineering products.

The National Institute of Standards and Technology (NIST) Core Product Model (CPM) [196] and Core Product Model 2 (CPM2) proposed by Fenves et al. models product level engineering knowledge [196, 197]. In the core product model engineered objects, called artifacts are linked into more sophisticated, assembly artifacts via part of / has part relations. Artifacts are subject to requirements, constraints, and are additionally described via specifications. However, CPM also deals with sub-component level information, with classes that represent features of components and the actual form of each component. This model thus proposes a hierarchical description of an engineering artifact. A form consists of some material with some geometry. Features are made of forms and additionally have intended or designed functions. Artifacts are composed of features, and have designed behavior. Additional slots are used to track information relating to design pedigree, and relations capture the rationale behind requirements and the like. Each term notably is provided a detailed definition, which helps to reduce ambiguity associated with an isolated class structure.

Various subparts of the design domain have also been modeled with ontologies. A subset of the literature focuses on the definition of requirements for engineering design. One such model was developed based on competency questions regarding requirement

refinement, traceability, and satisfaction, resulting in an ontology that combined a simplified product model with slots for expressing weighted requirements relating to product attributes. These were then modeled such that they were traceable to internal and external sources depending on whether the ontology was driven by a customer interaction [198]. A second design requirements ontology sought instead to identify the types of information that relate to requirements. The Engineering Design Requirement Ontology uses a terminology based on various influences, stakeholders, and contextual information like capture methods. This was then linked to a larger set of technical ontologies, such as one for machining and surface finish, to create a framework that allowed less ambiguous tracing of requirements [199]. A formal model of various types of requirement has also been proposed. The ontology identifies various types of stakeholder statement that express some form of a requirement, and then uses this classification to distinguish between types such as goals, preferences and the like [200].

In the general area of engineering design, the Center for e-Design research team has created several ontological representations of the design process, especially in the areas of engineering analysis, optimization and decision making [201-206]. The combined ontologies, alongside additional application level ones for things like common components, form the e-Design framework, a modular set of ontologies for capturing design information [207].

4.3.3. Ontologies of Engineering Models

Ontologies have also been proposed to describe various types of engineering model. Functional decomposition and modeling have been an area of interest for both controlled lexicons and formal ontologies. The Functional Behavior Representation

Language (FBRL)⁵ [208] for example is a limited terminology used to describe objects, their behavior, and a set of high level functions. “Port” features on objects allow for flows to move between objects, establishing relations between them. Using a trees structure based on different observed behaviors of objects, FBRL defines an ontological hierarchy of functions, which can then be mapped to each of the linked objects.

The Functional Basis [209] represents a separate effort to create a functional modeling language. The Functional Basis uses a set of well-defined functions and flows as a controlled terminology for functional decomposition and functional modeling, with the goal of removing ambiguity in such models that limit their reusability. In the Functional Basis, a model of an object is created based on a set of functional operations, which are connected by a set of flows of material, energy, or signal. The approach has shown promise in several areas, including extension with biological terminology and for use in biomimetic design ideation [210, 211]. Later work organized the Functional Basis into the Functional Basis Ontology (FBO), which organized Functional Basis terms into a hierarchy, and expressed formalized relations between entities defined with FB models. The FBO allows FB models to be fully expressed in an OWL ontology, which in turn enables these models to be reasoned upon using automated reasoning software [212]. This is potentially useful in the context of a broader design model, but little work has explicitly linked functional modeling ontologies to a larger knowledge base, or to other technical ontologies.

The Engineering Analysis Model (EAM) [213] ontology focuses on unambiguously capturing information relating to analysis models so that it may be reused. The ontology splits analysis models into physics based and non-physics based

models, with subsequent classes defined by the various aspects of model operation, such as the use of analytical or numerical techniques in modeling some problem. Model descriptions are then enhanced with information relating to objectives, assumptions, idealizations, and metadata about the actual model creation. Additional classes are used to express the resolution, accuracy, and causality of the models, as well as the inputs and outputs used to define the model.

Engineering ontologies have also been proposed for decision models and decision methods. The Decision Support Ontology (DSO) [214] proposed by Rockwell et al. for example uses an information model that links various types of evaluation information to classes for criteria, issues, alternatives, and decisions. In DSO's knowledge model criteria are influenced by a set of constraints that are introduced by requirements. As envisioned, evaluation information is provided by various types of model, which in turn leads to decisions. This is then enhanced by a set of decision method ontologies. An alternative model, the Decision Model Ontology (DMO) [215], was proposed by Kornyshova et al. In DMO problems contain decision making situations, which in turn contain a criterion set and alternative set stemming from various goals of some stakeholder or the decision maker, or alternatively from the consequences of some perceived alternative. Generic model elements such as preferences, rules, weights, and the like are similarly captured, with the resulting ontology distinguishing between intuition and methods driven decisions. More recent work by Ming et al. [216] has proposed yet another ontology, largely using similar terms, but not interoperating with either previous ontology.

4.4. Conclusions

Past work in engineering and medical ontologies show two strikingly different outcomes. Medical ontologies have seen a great deal of coordination among various proposed terminologies, and so interoperability is preserved, though with a good deal of work. More methodical approaches such as that taken by OBO may further integrate medical information, and realize the principles of extensibility, interoperability and openness that underpin the semantic web. Engineering ontologies by contrast have shown isolated applications were they might have value to industry.

CHAPTER 5

A CONCEPT IDEATION FRAMEWORK FOR MEDICAL DEVICE DESIGN

5.1. Background and Motivation

This chapter presents work first published in the manuscript “A Concept Ideation Framework for Medical Device Design,” published in the Journal of Biomedical Informatics in 2014 [217]. This work considers an approach to overcoming the challenges of using medical domain knowledge in design when a typical designer lacks the requisite training (and likely access) to fully understand medical procedures and surgical environments. As noted in [10], many of the challenges associated with medical device design stem from a mismatch between the training and even the language of engineering design teams and the healthcare providers they are often designing for. This work aims to address this issue by linking a large medical knowledge base with an engineering terminology in an ontology, and then use a set of shared properties to tag clinical knowledge with engineering descriptors. Thus, the work represents an ontological framework for managing medical knowledge and incorporating it into the early phases of engineering design.

The framework was developed to accomplish three distinct but interrelated tasks aimed at improving the design and innovation process. First, it aims to unify a high-level understanding of medical concepts, practices, and resources with detailed engineering descriptions of their functional characteristics, as well as a repository of similarly annotated design solutions. Second, it seeks to facilitate automated reasoning both within each domain, as well as across domains, enabling high level inferences not immediately

available in any individual field. Finally, this work intends to create a basis for identifying analogous solutions to an engineering problem in a domain agnostic way, so that a designer can incorporate methods and innovations made in other medical specialties or entirely different fields into a medical device design.

The work was undertaken with a set of hypotheses relating to the types of inferences that might be made using such an approach, as well as their use for design. First, it was hypothesized that such an approach might allow the automated creation of linked surgical models using a knowledge base of sub-procedures and reasoning software. If accomplished, this might justify an initial investment to tag surgical procedures as knowledge could be re-used at least at the sub-step level. Second, it was hypothesized that parallel tagging of surgical processes and existing designs might allow for query-based identification of candidate designs for new surgical tools.

The result of this work is the Concept Ideation Framework for Medical Device Design (CIFMeDD), a unified framework incorporating large medical reference ontologies in combination with functional basis models, and a suite of ontologies of patent information. Rather than create new knowledge models of existing domains, the ontology principles of extensibility and interoperability are used to re-use existing medical, engineering, and intellectual property ontologies to develop a novel concept ideation framework for the early phases of engineering design. The following sections detail the steps to construct a framework for integrating information relating to medical science and practice into the early phases of design, focusing on the enhancement of existing functional basis tools with medical information and a repository of design

solutions. The usefulness of the resulting framework is assessed using medical design case studies.

5.2. Materials and Methods

Ontologies modeling engineering, medical, and patent knowledge individually exist at least in part, and they serve as the backbone for this integrated semantic medical device framework. These ontologies are modified from their original state and integrated together to allow seamless transfer of information between the different domains and to facilitate identification of new insights and automated inter-domain reasoning.

5.2.1. Obtaining Ontologies from Online Repositories

The selected ontologies were obtained via reputable online repositories and imported into Protégé version 4.3 using the software's built in import functions and plugins. OWL was chosen for CIFMeDD due to its rich vocabulary for constructing relations between classes, complex object properties, and ability to construct links between properties, all of which were deemed necessary to meet CIFMeDD's reasoning requirements. SNOMED CT was obtained from The National Library of Medicine's Unified Medical Language System website¹, which contains download links for SNOMED CT with a registration. SNOMED CT contains over 400,000 classes relating to all aspects of the medical lexicon. As this ontology contains several hierarchies that are outside the scope of this work, only the relevant sections of SNOMED CT was used as the basis in the development of CIFMeDD. Utilization of a non-complete version of SNOMED CT also dramatically reduces the requirements needed to classify SNOMED with the built in Reasoner. Selected classes and their properties were extracted using Protégé 4.3's built in Refactor tab, which allows a user to extract parts of an ontology

¹ http://www.nlm.nih.gov/research/umls/Snomed/us_edition.html

based on referenced classes and properties. For this work, the class hierarchies relating to Procedures, Physical Objects, Pharmaceutical and Biological Products, Body Structures, Observable Entities, and Environments and Geographic Locations were retained. Qualifier Value class hierarchy was also kept intact, as this is used throughout SNOMED CT to provide definitions and more detailed knowledge and context to other classes. In addition, the original SNOMED CT Object properties were preserved, including the ***Procedure Device, Direct Substance, Route of Administration, Associated Morphology*** and ***Method*** properties among others. For this work the SNOMED_CT top level classes and the bulk of their child classes were saved into a local OWL ontology and imported into CIFMeDD.

The functional basis ontology was chosen to represent engineering knowledge in CIFMeDD. It was chosen due to its versatility for use in multiple domains and strictly limited vocabulary, both of which lend them to a cross domain application such as CIFMeDD. Specifically, the ability to use a limited and identical terminology regardless of the application or knowledge domain lends is a powerful tool for linking different domains, making cross-domain inferences, and formulating meaningful queries. The functional basis ontology (FBO) was acquired via the UMass Center for e-Design website² and was imported directly into Protégé from its online source. Patents and patent metadata were subsequently included using the Patent Upper Level Ontology (PULO), Patent Structure Ontology (PSO) and Patent Metadata Ontology (PMO) [218]. The PULO, PMO, and PSO were obtained from Multimedia Knowledge and Social Media Analytics Laboratory website³. This suite of ontologies includes classes and

² <http://edesign.ecs.umass.edu/ontologies/Framework2.0/FunctionalModel2.0.owl>

³ <http://mklab.itи.gr/>

properties to categorize and relate patent data, metadata, and document elements, as well as an upper level ontology to link the patent data and metadata domains to one another.

5.2.2. Modification of Ontologies

5.2.2.1. Modification of SNOMED CT

While the preexisting object properties in SNOMED CT relate **Procedures**, **Substances**, **Body Structures**, and a number of related qualifiers in the medical domain, additional properties were added to SNOMED CT to enable a more detailed understanding of each procedure from an engineering perspective. The goal was to provide a means to input more detailed information about the design environment of interest, and the entities that interact with it. The class structure acquired from SNOMED CT was modified with additional properties to allow a more meaningful description of medical environments and to model knowledge in a way that is useful for engineering design (Table 1). This was done to enable SNOMED CT concepts to be related to one another so as to accomplish two distinct goals: first, to model information relating to medical environments and personnel; and then to decompose complex medical concepts into simpler ones that can be used as building blocks to construct a detailed functional understanding. A series of properties were also defined to serve as the inverses of SNOMED CT's preexisting properties to expand the possible class expressions in the new framework.

Table 1. Object properties added to SNOMED CT

Property	Type	Inverse	Description
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<i>hasSubProcedure</i>	Transitive	<i>SubProcedureOf</i>	A property that indicates that a Procedure has a sub step that is some other procedure
<i>usedInProcedure</i>			Used to connect a Physical_Object used to complete some procedure to said procedure
<i>hasSubcomponent</i>	Transitive	<i>subComponentOf</i>	Used to assign subcomponents to a larger physical structure. For example, a part of some larger machine
<i>hasEnvironment</i>		<i>isEnvironmentOf</i>	Indicates the location in which some procedure is performed
<i>hasUser</i>		<i>userOf</i>	Assigns a specific user or class of user to an object or tool
<i>performedOn</i>			Indicates the recipient of some procedure, such as a patient
<i>performedBy</i>		<i>performs</i>	Indicates the individual(s) that performs some procedure
<i>hasEquipment</i>			Denotes the presence of some physical object in an Environment.
<i>hasPersonnel</i>		<i>personnelOfEnvironment</i>	Indicates that a person is present in some environment
<i>containsSubstance</i>			Indicates that an environment contains a substance

Properties were added to more accurately model knowledge in the **Procedure** class, which can be anything from a surgical operation to some administrative task that relates to a medical environment. The **Procedure** members were first linked to an individual or group of individuals carries out the procedure via a newly defined ***performedBy*** property. Using the concepts organized under SNOMED CT's **Person** class and subclass found under the **Social Context** hierarchy, this property can be used to

define a potential product's user base, or individuals with whom it will interact. Where a **Procedure** involves interaction with a recipient of the procedure, an additional link or links was introduced using a newly defined *performedOn* procedure. Beyond linking with specific personnel, properties were also used to define the Procedure in terms of simpler sub-steps using the *hasSubProcedure* property. For example, a more complicated operation might begin with administration of anesthesia, or something as simple as an incision. Additional medical information is represented using the newly defined *hasEnvironment* property. The *hasEnvironment* property can be used to indicate an operational environment. For example, a procedure might take place in a hospital environment versus a home environment, or in one that is sterile versus non-sterile. Environment specific factors are further mapped out using additional property relations to describe environmental factors relevant to a design. People and objects available in the environment are added via newly defined *hasPersonnel* and *hasEquipment* properties, so as to document available resources in any given area. **Qualifier Value** subclasses are also used in tandem with other classes to better define an environment. For example the *hasSterility* property uses subclasses of the **Qualifier Value** class tree can be used to indicate whether an environment or object is sterile, as indicated by the declaration “*hasSterility* some ‘Sterile (qualifier value)’”. This property was used to define three new classes: **Sterile_Object**, a subclass of the **Physical_Object** class, **Sterile_Procedure** a subclass of **Procedure**, and ‘**Sterile Environment**’, an existing class within SNOMED CT. These were each defined as equivalent to their parent class and having the *hasSterility* property asserted as some member of the **True** class, with further assertions placed on the **Sterile_Procedure** class to stipulate a sterile operating

environment and tools. Additional properties could also be added to further define environmental factors, or to indicate uncertainty about some operating environment.

A series of property chains were added to the framework to further integrate the new object properties, and allow inferences of useful information not directly asserted in CIF-MeDD (Table 2). The Hermit Reasoner in Protégé [152] was used to evaluate first order logic based on the newly created properties and property chains to make automated inference on the framework. Hermit is an open source OWL 2 compatible Reasoner, capable of determining whether an ontology is consistent. It was selected for this application, as it has built in support for rules and property chains and has been used to successfully classify SNOMED CT previously [219].

Table 2. Property chains for automated reasoning on modified SNOMED CT. The terms in parenthesis denote the domains and ranges of each property in the chain

	Property Chain			Explanation
1	usedInProcedure	o	isSubprocedureOf	\rightarrow If a sub-step of some procedure uses an object, (Physical_object, Procedure) o (Procedure, Procedure) \rightarrow (Physical Object, Procedure)
2	isEnvironmentOf	o	performedBy	\rightarrow hasPersonnel (Environment, Procedure) o (Procedure, Person) \rightarrow (Environment, Person)
3	isEnvironmentOf	o	Procedure	Device \rightarrow An object used in a procedure must be present in the (Environment, Procedure) o (Procedure, Physical object) \rightarrow (Environment, Physical object)

- 4 isEnvironmentOf o ‘Using substance (attribute)’ Substances used in a
→ containsSubstance procedure are present in that
(Environment, Procedure) o (Procedure, procedure’s environment
Substance) → (Environment, Substance)

The property chains shown in Table 2 ensure that environments and procedures are populated with a more complete set of relevant design data by inferring the presence of people and objects. Property chain 1 ensures that devices used in sub-procedures are recognized as being used in their parent procedure, such as a scalpel being used in a procedure involving an incision. Chain 2 by comparison can help to conclude that the surgeon performing the procedure is also in the operating room. Chain 3 allows the Reasoner to conclude that environments where procedures take place must contain the procedure equipment, meaning that the scalpel in the previous example must be in the place where the procedure is performed. Chain 4 employs similar logic to place substances in the relevant environment.

5.2.2.2. Modification of Patent Ontologies

The patent ontologies were only slightly modified from their original release. First, the ***hasSection*** property was redefined to be transitive, so that a hierarchy of sections can be used to break down an entire patent document. For example, a claims section might be broken down into a series of sections for each level of claims and sub-claims. Because the property is transitive, each of the sub claims would be inferred to be subsections of the parent claim, even if nested in multiple levels. This means that the entire hierarchy can be accessed via a query relatively easily via a defined claims section of a patent. The ***SubCategory*** property was also defined as transitive for similar reasons.

A new top-level class **Invention** was added to accommodate the design concepts disclosed in patents. This is done so as to draw a distinction between the existing objects found in the ‘**Physical Object**’ classes in SNOMED CT and object concepts described in the patent documents.

5.2.2.3. Linking of Medical Ontologies with Functional Basis Ontology

Cross domain object properties and basic logical rules were used to link SNOMED CT to the FBO. This allows medical concepts to be closely related to an engineering functional model, and to specifically associate operations, functions, and flows with the specific concepts that they represent in existing procedures or products. The initial link between a medical concept and a corresponding functional model was created based on the object property *hasFunctionalModel* and its inverse *isFunctionalModelOf*, as well as with the *submodel* property and its newly defined inverse *isSubmodelOf*. With the two ontologies merged in a single framework, other properties added during modification are also used to more intimately associate the two domains. Towards this end, the domains and ranges of several properties were modified to include concepts from both knowledge domains. First, the *Input_source* domain was extended to include the **Physical_Object** and **Body_Structure** classes so as to allow flows entering a model from sources outside the model system to have their origin explicitly stated. Subsequently, a new object property *representedByFlow* and its inverse (*flowRepresenting*) were also defined to allow various physical things, such as objects, body parts, and substances to be tied to a specific flow in a functional model. For example, the SNOMED CT **Substance** class was redefined as a being a subclass of a **Thing** and *representedByFlow* some **Material_Flow** and the Physical object class was

redefined as SubClassOf Thing and *representedByFlow* some **Object_Flow** using this property. A specific **Substance** might in be tied to a more specific material, such as a **Liquid_flow**. Similar subclass axioms were used to further define the **Body Structure** and **Observable entity** classes as well. For example, a **Signal_flow** might be tied to a specific physiological signal, such as a heartbeat, found in the **Observable entity**. Similarly, additional property chains were subsequently added to allow meaningful automated reasoning using SNOMED CT and the FBO classes and class axioms (Table 3).

Table 3. Property chains used for inferences across SNOMED CT and FBO

	Property Chain*	Explanation
5	isFunctionalModelOf o hasSubcomponent o hasFunctionalModel → submodel (Functional_model, Physical_object) o (Physical object, Physical object) o (Physical object, Functional_model or Operation) → (Functional_model, Functional_model or Operation)	The model of an object has, as its submodels, the models of its subcomponents.
6	isFunctionalModelOf o hasSubProcedure o hasFunctionalModel → submodel (Functional_model, Procedure) o (Procedure, Functional_model or Operation) → (Functional_model, Functional_model or Operation)	If a procedure has a subprocedure that has a functional model, then the base procedure's functional model has the subprocedure's model as a submodel.
7	isFunctionalModelOf o ‘Using object (attribute)’ o hasFunctionalModel → submodel (Functional_model, Procedure) o (Procedure, A, and (Functional_model, Procedure) o (Procedure, uses an object with some	If a procedure has a functional model, A, and uses an object with some

	Physical object) o (Physical object, second functional model, B, Functional_model or Operation) → then model B is a sub model (Functional_model, Functional_model or of model A. Operation)	
8	isFunctionalModelOf o ‘Using Substance (attribute)’ o hasFunctionalModel → submodel (Functional model, Procedure) o (Procedure o Substance) o (Substance, Functional model or Operation) → (Functional model, Functional model or Operation)	When a substance with some known function is used in a procedure, that substance’s function is a sub model of the procedure’s functional model .
9	isFunctionalModelOf o ‘Method (attribute)’ o hasFunctionalModel → submodel (Functional model, Procedure) o (Procedure, Qualifier value) o (Method, Functional_model or Operation) → (Functional_model, Functional_model or Operation)	A functional model of a medical method is a submodel of the model of any procedure using that method
10	isFunctionalModelOf o ‘Route of administration (attribute)’ o hasFunctionalModel → submodel (Functional model, Procedure) o (Procedure, Qualifier value) o (Qualifier value, Functional model or Operation) → (Functional model, Functional model or Operation)	A functional model of a medical treatment approach is a submodel of the model of any procedure using that method

*To be technically correct SNOMED CT property restrictions must use Role Groups [220]. Since these chains do not require the use of multiple, grouped SNOMED CT restrictions we have omitted mention of role groups for the sake of clarity.

Property chain 5 links models of an object’s subcomponents to one another. For example, a scalpel has a handle and blade, each of which has functions of their own. Based on this breakdown, chain 5 infers that the individual function of the handle and blade are both sub-functions of the model of the entire scalpel. Chain 6 uses similar logic

to associate a model of a procedure with its sub-steps. This linking of models is extended by property chains 7, 8, 9 and 10 which associates object functions, substance functions, methods, and treatment routes of administration with procedures that use them. For example a procedure might use a scalpel to access some tissue, at which point some known surgical method is used to perform an operation via a route of administration. If these are all associated with functional models, the Reasoner will directly link to those models via the ***submodel*** property.

5.2.2.4. Linking with Patent Ontologies

The patent ontologies were linked to the functional and medical ontologies with new classes and properties, with the goal of linking each patent to a functional description of the invention disclosed in the patent and patent elements to aspects of that invention. A new property ***discloses*** and its inverse ***disclosedBy*** were added to link members of the newly defined **Invention** class to the patent documents that describe them. Inventions were then linked to the medical realm with the property ***hasEmbodiment*** and its inverse ***isEmbodimentOf***, and they were used to indicate instances where an invention disclosed in a patent document is in part or in whole embodied by some existing entity.

The patent ontologies were further linked to the FBO via the ***hasFunctionalModel*** property and its inverse ***isFunctionalModelOf***, which were extended to members of the **Invention** class and patent classifications. The first connection allows a high level functional model to be assigned to a design concept disclosed in an invention, while the second allows simple functional behaviors to be ascribed to entire classes of patent, such as assigning a model with a **Constrain_function**

to a class of fasteners. The newly defined *implies_function* property allows a functional model's operations and sub operations to be attributed to specific patent sections mapped with PSO and PULO. Thus, if a claim or section describes some operation mode for the disclosed invention, the model of that invention's functions can be linked to the relevant document elements. With the aid of this new property, along with the PULO and PSOs existing properties *hasSection*, a patent document structure can be mapped to a functional model of the invention it discloses

The newly defined properties linking the modified SNOMED CT and FBO framework to the patent ontologies were then incorporated into a series of property chain relations designed to allow automatic inferences using knowledge from across domains (Table 4).

Table 4. Property chains used for inferences utilizing the patent ontologies, SNOMED CT, and FBO

	Property Chain	Explanation
11	<pre> disclosedBy o isPatentOf → hasEmbodiment (Invention, Patent) o (Patent, Physical object) → (Invention, Physical object) </pre>	An object (or its subcomponent) that has a patent is an embodiment of the invention disclosed in that patent
12	<pre> isFunctionalModelOf o hasEmbodiment → isFunctionalModelOf (Functional model, Invention) o (Invention, Physical object) → (Functional model, Physical object) </pre>	An embodiment of an invention with some functional model will also have that functional model

	isFunctionalModelOf	o	
	classifiedPatent	o discloses	→ The invention disclosed in a patent of a class with some functional characteristics expressed in a functional model has those functional characteristics
13	isFunctionalModelOf (Functional model, Patent class)	o (Patent class, Patent)	→ (Patent, Invention) → (Functional model, characteristics Invention)
	isFunctionalModelOf	o	
	subCategory	→	Subcategories of patent categories with defined functional models have the same functional top level model as their parent category
14	isFunctionalModelOf (Functional model, Patent class)	o (Patent class, Patent class)	→ (Functional model, Patent class)
	impliedBy	o sectionOf	o discloses
	o	hasFunctionalModel	→
	submodel		
15	(Functional Model, Section)	o (Section, Patent)	o (Patent, Functional model or Operation) → (Functional model, Functional model or Operation)
	impliedBy	o hasSubsection	o
	impliesFunction	→ submodel	Functional models implied by document subsections are submodels of the model that is described in their parent section.
16	(Functional model, Section)	o (Section, Section)	o (Section, Functional model or Operation) → (Functional model, Functional model or Operation)

Property chain 11 links **Physical_Object** members to the **Invention** concept they embody using patent documents. For example, if a tool used in a procedure were covered

by some patent, then the invention disclosed by that patent would be linked via chain 11 to the object used in the procedure. Chain 12 would then allow the Hermit Reasoner to infer that the object will behave in the manner described in the patent and represented via a functional model of the **Invention**. Property chain 13 allows a general model associated with a patent class to be linked to all inventions disclosed in patents of that class. For example, a patent classification might contain inventions that separate sediment from a liquid. Property chain 13 allows the framework to recognize that all of the inventions disclosed in patents classified that way will have that basic functionality. Property chain 14 simply allows this same inference to be made about its subclasses. Chains 15 and 16 allow aspects of an **Invention**'s functional model to be attributed to specific document elements, such as claims or descriptions. This links the functional understanding to specific document elements. For example, if a patent claim notes a linear actuator, a functional model of that actuator can be attributed to the invention and vice versa.

5.2.3. Case Studies

The ontologies successfully classified without issue using the Hermit Reasoner [152] in Protégé 4.3 indicating that the CIFMeDD is internally consistent. CIFMeDD's usability and usefulness in medical knowledge capture from an engineering design perspective was then explored with the aid of two case studies. A subset of SNOMED CT classes was further defined with additional information using the functional basis and the newly defined object properties. In addition, a number of specific patent classes and patents were defined using similar methods. These included patents relating to each

specific medical field considered in the case studies, several patent classes, and links to relevant physical objects and medical concepts.

The first case study focuses on medical knowledge capture, the application of automated reasoning to make useful inferences on this information, and CIFMeDD's ability to render knowledge useful for medical device design applications. The focus of the case study is fat grafting, a cosmetic surgical procedure that uses human fat as a volume filler. The second focuses on the ability to identify functionally similar designs for use in design ideation and exploration of a design space. For this application, the more mature field of bariatric surgeries was used to demonstrate potential uses in an engineering design context.

5.3. Results

5.3.1. Case Study 1: Fat Grafting Surgery

5.3.1.1. Summary of Results

Fat grafting is a cosmetic surgical procedure used to achieve desirable aesthetic effects by adding volume to surface features, resulting in changes to contours. The procedure offers favorable biocompatibility properties achieved using autologous tissue and is appealing to patients in part due to the necessity of liposuction to obtain tissue [221]. The procedure is performed in a sterile operating room and has three primary steps: a tissue harvest performed using liposuction, a processing step in which desirable cells (adipocytes, stem cells) are separated from blood, cellular debris, and other waste, and a tissue grafting step in which isolated tissue is injected into a selected site [222]. The tissue harvest, which is the focus of this case study, is essentially liposuction. The patient is anesthetized and a small incision is made at the harvest site. A mixture of saline and

local anesthetic is used to swell the harvest site, constrict blood vessels, and partially break down connective tissue structures that enclose the desired cells. A sharp cannula is then connected to a vacuum source and used to shear the weakened tissue, detaching lobules which are then evacuated to a collection vessel via a negative vacuum pressure [223]. In this case study we focus on CIFMeDD's ability to capture medical knowledge, link it to functional models, and make cross domain inferences that enrich a designer's understanding of the procedure. The operation is performed by a plastic surgeon, and typical patients include both healthy individuals and breast cancer survivors seeking a breast reconstruction via fat grafting [222]. As this procedure was not represented in any significant detail in SNOMED CT, a breakdown of the procedure with a focus on the tissue a harvesting was created using subclass axioms in Protégé (Figure 1).

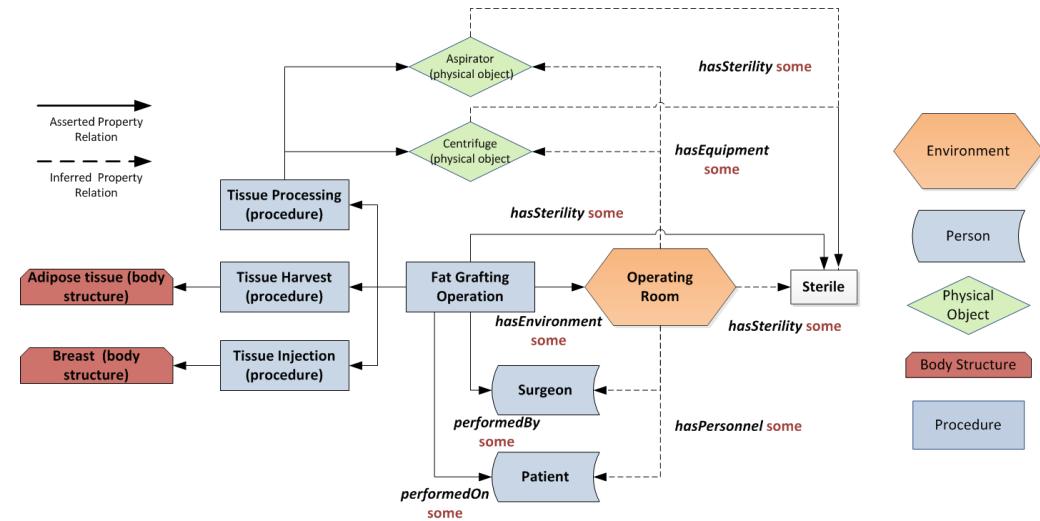
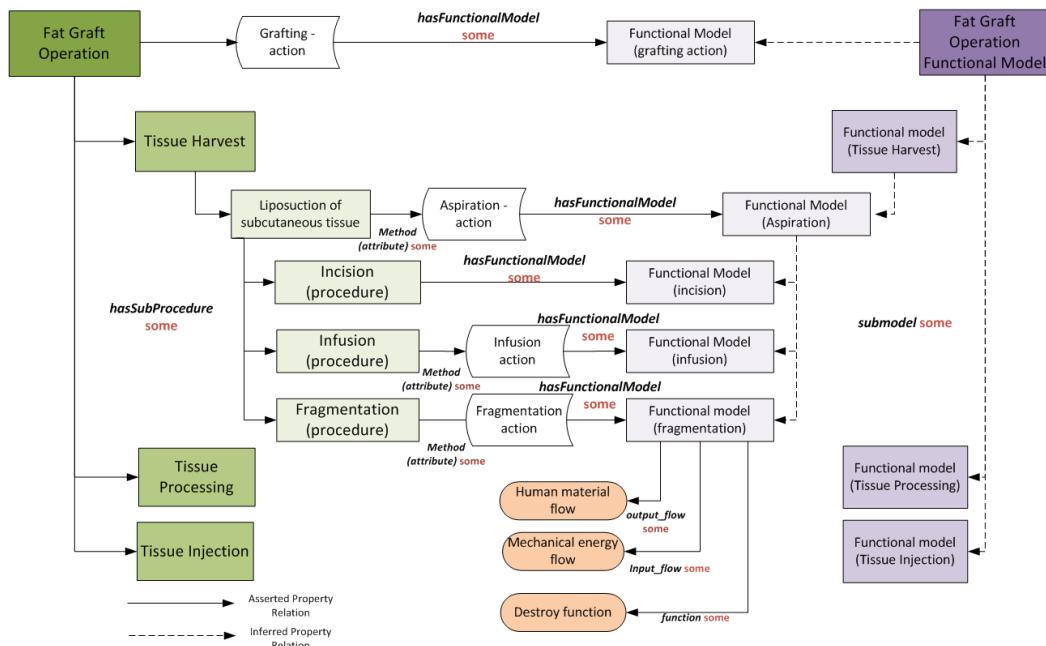


Figure 1. Breakdown of a fat tissue harvest as entered in the ontology

In addition to the asserted properties, the property chains and class definitions mentioned in the section 2 above mean the Reasoner is able to make a number of inferences. First, as noted in Figure 1, procedure must be performed using a sterile

technique, as indicated by the ***hasSterility*** property. A design engineer, however, would likely be more interested in having this information directly related to a procedure being considered. Using the definitions of a sterile procedure and its asserted subclass axioms ('***Using device (attribute)***' only **Sterile_Object** and ***hasEnvironment*** only '**Sterile environment (environment)**'), the Reasoner concludes that the operating environment and surgical devices must also be sterile. This is effectively a constraint placed on any device that interacts with the procedure, which is something a design engineer would need to be aware of early in the design process. Similarly, as declared in the framework, the functional models linked to each aspect of the procedure are not themselves connected with the asserted class axioms. Instead, they are constructed separately and linked to procedures and methods used throughout SNOMED CT. However, the property chain relations 5, 6 and 7 allow automatic inference of the relations between procedures and sub procedures and models and sub models (Figure 2).



2. Fat grafting procedures (left) and their respective functional models (right). The

Figure

relations between functional models are inferred by the Reasoner based on the relation between procedures using chain 9.

In this case, the intricacies of the tissue harvest are directly linked to the detailed information connected to its liposuction sub-step. The liposuction procedure is more complex, with multiple sub-operations, each defined with their own functional model in their subclass axioms. The same is true of the other sub-steps. This capability opens up considerable potential for easy and effective knowledge re-use. If various classes of basic medical procedure are defined in terms of a set of simple functional models, one can easily construct the skeleton of a model for a more complicated procedure by simply breaking it down into its most basic series of steps and their associated methods. This means that any knowledge defined in the framework can very easily be reused to define medical procedures or concepts that share attributes.

The functional effects of drug substances are also accounted for using a combination of the properties listed in Table 2. As noted at the beginning of this case study, a tumescent containing a local anesthetic is infused into the harvest site during the surgery, swelling tissue and causing blood vessels to constrict as a result of the anesthetic [222]. This constricting effect is important from a procedural perspective and from the perspective of a designer in this space. Constricted vessels limit blood loss, leading to a less contaminated aspirate being removed by liposuction and preventing serious trauma for larger grafts. The functional model of the introduction of the tumescent into the body is shown in Figure 3.

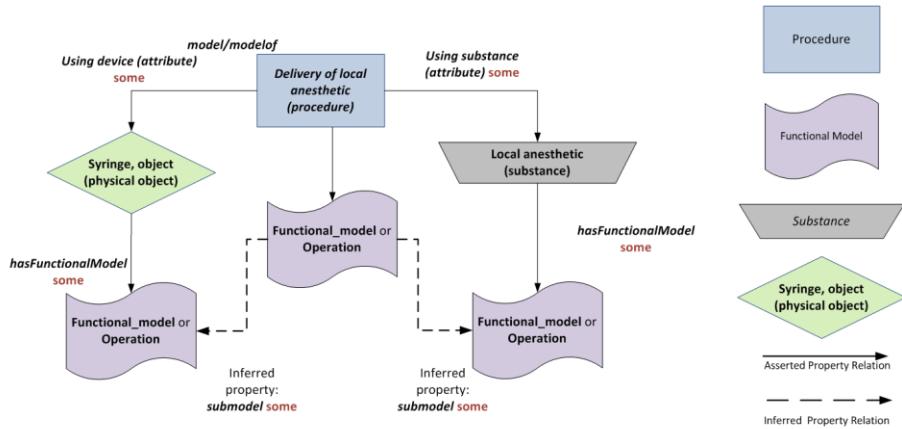


Figure 3. Administration of tumescent using a syringe as represented in the framework.
Based on the functional model of the syringe in this procedure and the substance delivered, the framework infers the effects of the tumescent are part of the model

As can be seen in Figure 3, the delivery of the tumescent is modeled as a **Delivery of anesthetic** procedure, which is in turn defined as **Using substance (attribute)** some member of the **Local anesthetic** class. The **Local Anesthetic** class is itself defined as a subclass of its parent class and as having some functional model corresponding to its chemical effects. This model can in turn be linked to various body structures such as blood vessels to further model the specific details of the procedure. This knowledge, the necessary elements are present to infer via property chain 9 that the functional model of the local anesthetic contained in the tumescent is inferred to be part of the procedure model created in this case study.

With a detailed model of the procedure created and enriched automated inferences, the groundwork is laid to make additional inferences about the fat grafting procedure considered in this case study. For example, the model can be used to study if it might be useful to know of other procedures or devices that perform functions that are similar to those achieved via a procedure or device used in the fat grafting operation. In the case of liposuction, a simplistic model might note that a negative pressure is supplied

to a tool that is used to cut tissue, and that this pressure aids in the removal of the tissue from the body cavity (Figure 4).

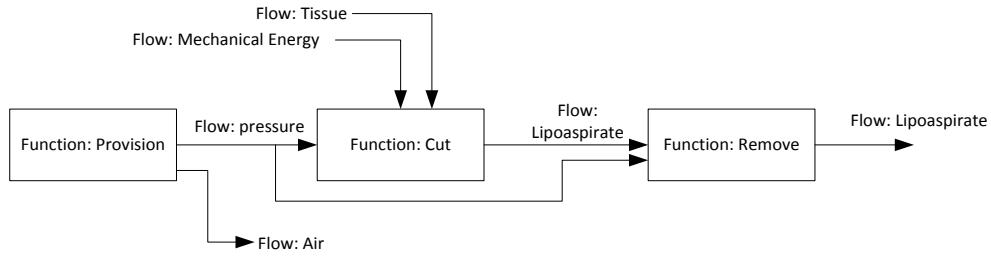


Figure 4. A simplified functional model of a liposuction procedure

Here, one aspect of the procedure that might be of interest to a designer is an alternative method of removing tissue from the body. Liposuction requires the use of a large and often very expensive aspirator to supply the negative pressure (i.e. vacuum) that is used to remove tissues from the body. A potential area of interest for a designer would be to learn about alternative methods of generating a negative pressure that are already used in other medical applications. They could either be a different procedure or device. Without an integrated medical device design tool such as CIFMeDD, even relatively straightforward information such as this could be difficult to obtain. However, with the aid of our CIFMeDD, designers can systematically find, study, analyze and compare similar designs. In this case, the key functionality can be recognized as the supply of pressure, as represented in the liposuction model with the **Provision_function**, and the **output_flow** of a **Pneumatic_flow** (pressure). Because tools in the framework can be associated with 1 functional models of their operation, concepts with similar functional models can be identified using a DL query in Protégé 4's DL Query tab. As can be seen in the reasoning presented in Figure 5 below, the linked domains allow a simple query to

conclude that **Physical Objects** of the class **Syringe, device (physical object)** are also able to supply pressure.

The screenshot shows a DL Query interface with the following text:

Explanation 1 Display Iaconic explanation

Explanation for: 'Syringe, device (physical object)' SubClassOf hasFunctionalModel some ((Functional_model or Operation) and (((function some Provision_function) and (output_flow some Pneumatic_flow)) or (submodel some ((Functional_model or Operation) and (((Functional_model or Operation) and (function some Channel_function) and (input_flow some Pneumatic_flow) and (output_flow some Material_flow) and (output_flow some Pneumatic_flow))) and (submodel some ((Functional_model or Operation) and (function some Provide_function) and (output_flow some Material_flow))) and (submodel some ((Functional_model or Operation) and (function some Provision_function) and (output_flow some Pneumatic_flow))) and (submodel some ((Functional_model or Operation) and (function some Store_function) and (input_flow some Material_flow)))))))

Figure 5. DL Query and results showing procedures in which tissue is removed in the framework

Thus, the framework facilitates identification of functionally equivalent sets of objects. Similarly, by removing these class restrictions, one could also search the entire database without regard for field of use, thus providing a potential for finding even non-obvious uses of existing technology.

5.3.1.2. Discussion of Results

From the Fat Grafting Case study, it can be seen that CIFMeDD captures information related to an existing medical procedure, enriches that information with a set of simple automated inferences, and then that information can be used as the basis to identify an alternate class of tools. By combining SNOMED CT and the FBO, CIFMeDD enables a user to make queries of the information entered to find functionally similar procedures, and potentially objects, substances, or any other thing whose behavior can be functionally modeled. This is a potentially powerful tool to work within some established procedure and identify alternative methods of achieving the same end. The addition of patent data allows this same method to be extended to open-ended inventions, enabling a field of agnostic means to search for functional behaviors that might be of use in related contexts.

5.3.2. Case Study 2 – Bariatric Surgery

Case Study 1 (section 3.1) focused primarily on effective capture of medical knowledge and basic reasoning across domains. This second case study touches upon the ways one might use this information and the automated inferences that can subsequently be made based upon that knowledge. The goals of Case Study 2 are twofold: first, to show how a very basic, initial understanding of medical goal can be used to determine current treatment and device operations in a medical field, and second to determine alternative design options based on these current treatments and existing intellectual property. In this case study the application domain is bariatric surgery, a fairly mature medical field where a diverse range of treatment options are available. We will look at the ability of CIFMeDD to identify relevant medical knowledge based on a concept idea for an obesity treatment. Similar to the fat grafting case study patent data, **procedures**, and medical device individuals relating to the bariatric field of medicine were entered into the framework using the class structures and new properties added into the modified ontologies. In addition, the individuals from the fat grafting and patent case studies were left intact and unaltered for use as necessary throughout the study.

Surgical operations are used in some cases to treat obesity by limiting a person's caloric intake, leading to weight loss over time [224]. A common method is to shrink or constrict the stomach, which can have the effect of helping to create a mechanical barrier to overconsumption among other potential pathways. When this happens, the interior volume and cross section of the patient's stomach is reduced, inhibiting the passage and food and meaning that a smaller bolus causes the stomach wall to stretch [225]. As a result, the patient feels satiated and is thus less likely to eat in excess. In practice, this is

accomplished through a number of means including surgeries to remove part of the stomach or by deforming the stomach with a surgical band to achieve a similar result. Based on this general idea, a simple functional description of the concept pathway focusing on stomach altering treatments can be generated as shown in Figure 6 .

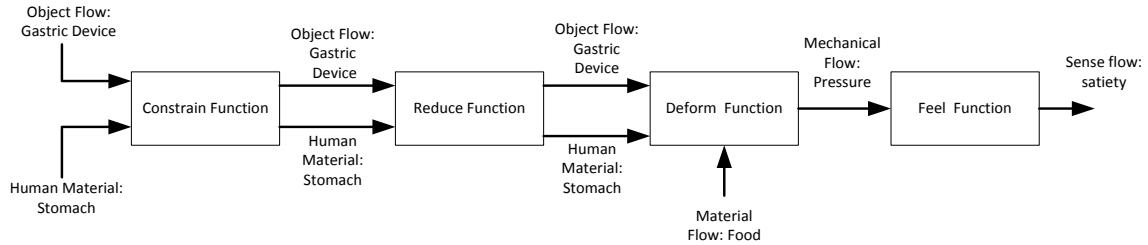


Figure 6. A simplified functional representation of a generic bariatric treatment method made with the Functional Basis. A medical device is used to constrain the stomach, reducing its volume and causing it to be quickly deformed by incoming food. This results in a feeling of satiety

Given an objective based on the weight loss pathway described above, it would be helpful for a designer to know if there is already some existing procedure or medical device used to accomplish this goal. Using Protégé's built in DL Query tab, the ontologies can be queried based on this functional model created using the FBO. Based on the functional model, one might want to know the existing medical techniques for constricting an object, as well as patents describing methods to do so. Since this a very general query, additional medical data can be used to limit the search results to individuals that act upon the stomach. Thus, one might look for classes and individuals with a designated anatomical site (*hasAnatomicalSite*) referring to the stomach, and whose functional model contains some operation with a **Constrain_function**. When this query is run, the Reasoner is able to recognize a number of classes that meet these criteria, including an existing gastric band in SNOMED CT and a remotely adjustable gastric band disclosed in one the patents entered into the framework (Figure 7).

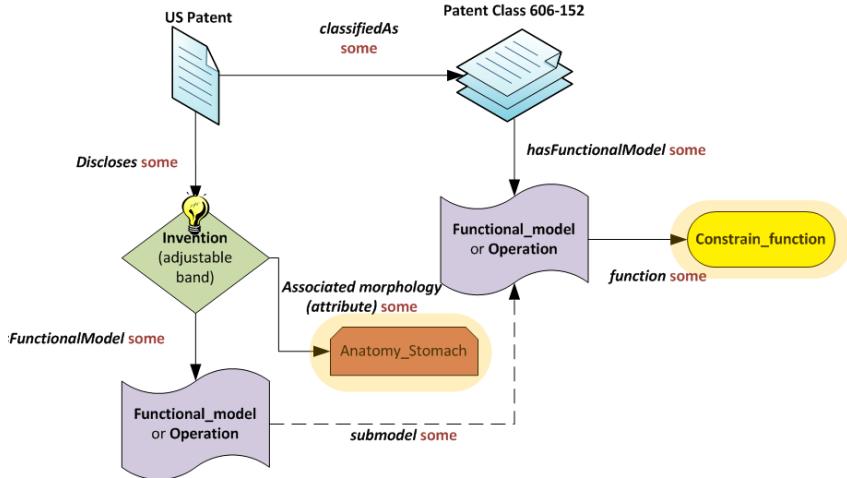


Figure 7. Example of reasoning used to determine that an object constrains the stomach

This result provides a useful background for understanding the procedure that would be otherwise difficult to obtain quickly. Already, based on a very general idea to constrain the stomach, a number of potential pathways are described. From this result, a designer can easily determine that encircling the stomach is one way to achieve the objective. What is notable in this query is that the linkage of the patent domain with the FBO allows the Reasoner to infer based purely on patent class and an associated anatomical site from SNOMED CT that the band is a device that constrains the stomach. While a powerful demonstration, this particular example is somewhat limited. Due to the simplicity of the query, many tangentially related objects such as a laparoscopic stapler (commonly used in bariatric surgery) and various medical fasteners were included in the results. Since this is only tangentially related to the topic of interest (weight loss), a more refined query is needed.

Other aspects of the initial functional model might yield different and potentially more useful results for a designer investigating potential pathways to target, or mechanisms to achieve specific goals. The **Constrain_function** specified in the initial

search is largely a means to the desirable end of shrinking the stomach. As in the functional model above, this goal can be represented using the FBO as one that has a **Reduce_function** linked to an observable measurement, such as a volume associated with the stomach via the *Associated Morphology* property in SNOMED CT. This combination very specifically points to models in which stomach volume is reduced. Combined with the linkages created using properties and chains, this means that relevant **Inventions** can be selected with greater specificity (Figure 8).

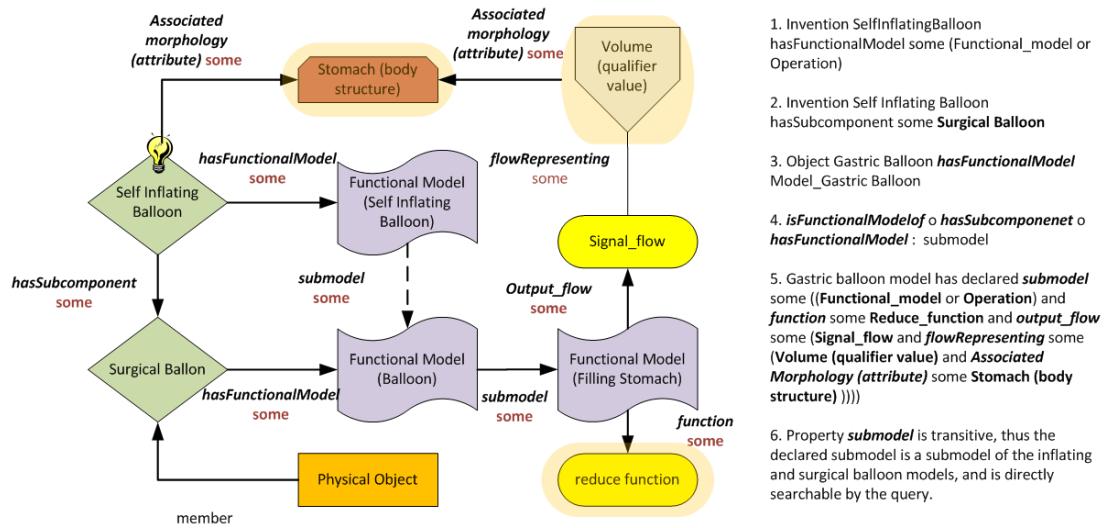


Figure 8. Reasoning used to identify an invention in the framework that reduces the volume of the stomach

Compared to the stomach restriction case, this search is someone broader, incorporating **Physical Object** members such as gastric balloons, and device concepts for a gastric balloon and other devices that have been disclosed and modeled in patents. Just as in the stomach constricting example, a potentially broader search could again be useful. All of the procedures and medical devices considered thus far ultimately operate by causing the patient to feel a sense of satiety, leading to a decrease in overall food consumption. This can again be represented by a fairly simple operation using the FBO

and SNOMED CT classes to provide specificity to a query of the framework. In this case, a query can search for instances or classes operating on the stomach, and including a model with a **Sense_function** and an output flow linked to the **Observable Entity** representing satiety (Figure 9).

The screenshot shows a 'DL query' interface with the following details:

- Query (class expression):**

```
'Associated morphology (attribute)' some 'Stomach structure (body structure)' and
hasFunctionalModel some ((Functional_model or Operation) and (output_flow some (Sense_function
and hasObservable some 'Satiety, function (observable entity)') or submodel some ((Functional_model
```
- Buttons:** Execute, Add to ontology.
- Query results:**
 - Sub classes (0)
 - Results: Adjustable_Gastric_Band, Gastric_Balloon, Gastric_Band, Gastric_Implant, Gastric_Pacemaker
- Legend:**
 - Direct super classes
 - Super classes
 - Equivalent classes
 - Direct sub classes
 - Sub classes
 - Instances

Figure 9. Results of searching for objects that cause a person to feel satiety

This final query shows a broader view of the potential pathways towards treating obesity, most of which are actually invention concepts disclosed in various patents that were entered into CIFMeDD. The results include devices similar to those returned by previous searches, as well as an electrode device described in a patent. By doing so this formulation returned a potential approach to weight loss not even considered in previous queries and demonstrates the potential power of using these linked domains to uncover novel inferences from existing knowledge.

As can be seen by the widely varying query results for this case study, use the functional basis in tandem with SNOMED CT and a patent ontology provides a potentially powerful tool to better utilize and understand existing medical data. Considering different aspects of a simple weight loss concept allows a user to identify a variety of different existing mechanisms of approaching a new device and to explore

ideas well outside the original queries. As the mechanism searched for with the query became broader, a greater variety of functional approaches were revealed. This requires knowledge from all three original ontologies, as well as the inferences made using the rules entered to yield a meaningful result. In this case study, SNOMED CT acts as a repository of various procedures and tools, while also serving as the basis to restrict a search such that it is meaningful to the domain under consideration, or to introduce specific desirable concepts. The patent ontologies provide a potentially large repository of device concepts, many of which can be automatically assigned functional behaviors based on their classification using the Reasoner. Finally the FBO provides the backbone of the search, by acting as a unifying terminology between the medical domain and the broader set of inventions in the patent database.

5.4. Discussion

At present, there are very few tools to integrate knowledge of medical science and practice into the engineering design process for medical devices, and even fewer to use and reuse this knowledge to better understand a design environment and alternatives. While a number of methods exist to collect information, retrospectively assess designs, and guide device development stages, current research does not adequately address the challenge of effectively using medical knowledge to guide designers who lack domain specific expertise. Here, we present a knowledge-based framework to assist in the early stages of medical device design by linking knowledge from the clinical domain directly to the engineering design domain and provide a basis to reason across the two. By including an additional link to the patent database with the functional basis as a common terminology, CIFMeDD allows direct comparison of existing objects and methods to a

potentially vast design repository containing candidate design solutions from many disciplines. Furthermore, the system enhances existing knowledge to inform the design process with automated reasoning to identify similarities between knowledge contained in class axioms in SNOMED CT in various medical fields. The resulting medical device framework enables one to record and contextualize medical knowledge as it relates engineering design process, use this knowledge to gain further insights about medical science practice, and to use these insights to identify potential design concepts or pathways. CIFMeDD provides a basis for automated reasoning between the different domains by representing medical and engineering knowledge and interlinking these domains with meaningful and useful relations.

The usefulness of CIFMeDD is demonstrated with the aid of two medical device design case studies. The results show that by unifying domains, patent metadata can be used to gain a basic functional understanding of design concept disclosed in an intellectual property disclosure. The same unification allows complex medical concepts to be described in relatively simple terms via functional models and their sub models. The new property relations combined with automated reasoning moreover allowed useful inferences to be made explicitly throughout the framework, enriching knowledge already contained in the framework. Because this information is unified in a single framework, it can be used to better understand a medical knowledge area as in the first case study and using that understanding to identify useful design concepts as in Case Study 2. These powerful inferences can in turn be used to better understand a design's requirements based functional models, and to use those inferences to identify design concepts or opportunity areas based on the patent database.

Many additional benefits arise when functional and engineering information are merged and used to enhance one another as in this framework. First and foremost, this process allows engineering reasoning that was used to define a design problem, as well as the medical science and practice information on which the design was based to be preserved in unambiguous terms for future reference. Beyond this immediate level, medical ontologies are retooled in this application to allow for a description of procedures and concepts. Complex operations are thus broken down into approachable sub-operations, and they can act as a reference for a design engineer considering modifications to the process, or who is attempting to innovate in some similar process. While medical ontologies such as SNOMED CT do associate different medical concepts in this way, the functional design goals of this project have led to modifications that support a finer level of simplification. Because a common language is used to describe medical treatments and concepts, as well as design concepts from the patent database, these can be queried interchangeably, as in the case studies. As a result a designer can quickly and easily assess existing tools for gaps, and identify novel design concepts by querying existing patents and inventions.

Under this framework a medical concept is described in terms of existing practice, deconstructed, and provided basic functional descriptions using the FBO. Because the terminology used is theoretically a near universal representation of the medical field (as opposed to domain specific as is often the case in medicine), it can easily be reapplied to consider additional medical concepts. For example, the low level surgical procedures such as incisions and simple tools shown in Case Study 1, could just as easily be applied to the understanding of a bariatric surgery found in the queries shown in Case Study 2.

As a result, useful clinical knowledge is represented and saved for later use in the design process, and such information is readily available for use in future design work, as well as when investigating novel concepts during the innovation process. By interlinking these knowledge domains, the framework presented in this chapter enables automatic reasoning to reach conclusions from the interaction of different medical and engineering concepts. These inferences can thus form the basis to better represent a design problem and to ultimately find potential solutions.

The approach used by CIFMeDD differs fundamentally from existing medical device design frameworks, as well as techniques for engineering design. Most medical device methods have focused on the process of development, be it the necessary decision making steps [42, 53, 226], information gathering techniques [7], or the necessary components for a medical device design. Instead, CIFMeDD approaches the issue from a different perspective, focusing on the use of domain specific knowledge relating to medical processes to construct models that aid in concept development and innovation in the medical realm. This allows rapid creation of detailed functional models based on a pre-defined understanding of how a procedure is carried out. It also facilitates the creation of new medical concepts from existing classes that have been fully defined using functional models. As a result, the existing knowledge capture benefits realized in the Functional Basis are extended for highly efficient knowledge reuse. This approach also offers the benefit of linking these concepts of one medical process to any other functionally similar process in the medical domain, as well as to the broader repository of design knowledge found in the patent database. Thus, it assists in a morphological design by providing a means to easily locate potential solutions for design sub-components by

searching across many technical areas for functionally similar behaviors. This combination of rendering medical knowledge more usable to a design engineer and utilizing it to facilitate multiple approaches to engineering design represents a significant change from the methods discussed previously for medical device design.

This work does have several limitations. The design alternatives presented in the case studies represent only a small subset of the possible candidate solutions in each domain. In a fully implemented version of CIFMeDD with detailed breakdowns of procedures and more extensive functional modeling of the medical and patent domain, this limitation would be greatly mitigated. Thus, this limitation is largely a function of the large breadth of medical knowledge that would need to be modeled using this method, rather than a inherit flaw in the method itself. It is also notable that there is significant room for knowledge reuse even with the limited scope of the current examples. For example, the functional model associated with the procedure Incision in the first case study can easily be incorporated in any procedure involving an incision as a sub-step. Another limitation is due to the use of a subset of SNOMED CT rather than the whole distribution. While this was done to reduce complexity, and limit the computational requirements of classifying SNOMED CT, this will have an impact on the ability to express and model certain medical concepts within the resulting framework. Integration with a complete version of SNOMED CT with additional modifications along the lines described in this paper would provide the added capability to describe features such as patient specific information that might correspond to more complex medical devices. While it is beyond the scope of this concept ideation framework, future work should investigate ways to incorporate these details into the medical device design concept

ideation. That said, there is still significant benefit for concept ideation even when these details are explicitly contained in the framework. Furthermore, devices that are simpler and more focused in their application, or that simply rely on the judgment of a clinician rather than a designer may not require such additional information at the conceptual design phase.

In summary, CIFMeDD offers significant benefits to a medical device designer. The close relationship between a product's functional model and the existing practice is potentially valuable, as existing practices have specific, clinical reasoning and underpinnings that can be extended to the product itself. With the additional benefits gained by interlinking this information in a semantic framework, the integrated CIFMeDD framework helps to overcome the difficulty of effectively using medical knowledge in engineering design, while ensuring that the generated and captured knowledge is readily available in the future. Its implementation in a semantic web platform makes it readily extended to additional knowledge domains. The use of ontologies further ensures that the problems are better defined, inferences are easily made, and the basis for the definitions and inferences are clearly preserved.

CHAPTER 6

DEVELOPMENT OF AN INFORMATION MODEL TO SUPPORT USER CENTERED DESIGN OF MEDICAL DEVICES

6.1. Background and Motivation

This chapter presents work first published in the manuscript, “An Information Model to Support User-Centered Design of Medical Devices,” published in the Journal of Biomedical Informatics in 2015 [227]. The manuscript details the creation of an information model that unifies a detailed model of engineering design with concepts of usability, ergonomics, and use environments. As detailed throughout chapter 1, industry practice medical device design often lacks sufficient consideration of human factors. This work aims to facilitate user-centered design by linking user data more closely with the design realm and serving as a basis for automated design inferences

In a typical design process, a designer must consider the complex interactions between a product, its various subsystems, its environment, and its user. As this challenging process proceeds, the designer must also balance the often-conflicting needs of end users with commercial considerations such as the constraints of time, money, and available expertise that influence the entire design process. In any environment, this poses a significant challenge. However, in the case of the design of surgical tools and other medical device designs, this problem is further complicated by limited access and unfamiliarity with the environment [7]. As a result, detailed investigation of user needs and end use environments remain difficult in medical device development. Industry practice norms, such as a focus on decision makers over true end users and a general

skepticism towards economic value and inclusion of human factors in engineering process reflect this difficulty [12, 31]. Even in scenarios where such data might be relatively accessible, it is often unclear how they can be best used to improve the design process and the designed product's overall utility. Similarly, it is unclear how improvements in any of these domains might impact the usability of the end product itself or the exact nature of how end users might view such a product or be affected by it. Without the necessary information or the inferences that must be made from them, there is limited ability to find an ideal balance between the needs of a design, and those of the regulatory commission, medical device manufacturer, and end user. These challenges point to a need for a more robust knowledge management in medical device design.

The ontological approach taken in this work was hypothesized to have two major advantages, which would be reflected in the reasoning capabilities of the ontology. First, it was hypothesized that the approach could allow human factors considerations to be evaluated via a design checker implemented using a semantic reasoning software, and that this evaluation could be carried out concurrently with more traditional checking of adherence to requirements. The second hypothesis was that the ontology would be able to flag these types of issues, or otherwise provide information about users automatically, resulting in a framework that is generalizable to virtually any potential user group, incorporating sufficient information to characterize a wide variety of both clinical and non-clinical devices (Figure 10).

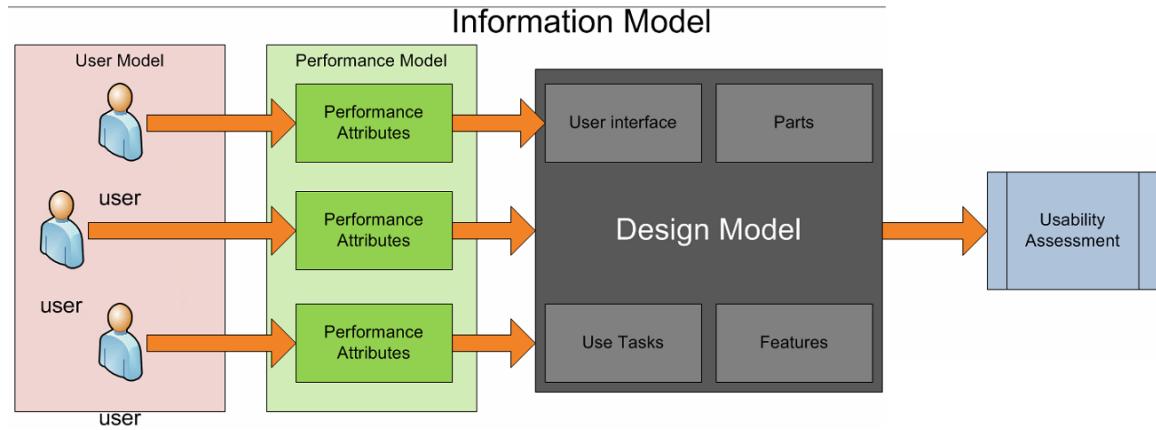


Figure 10. Envisioned structure of the proposed ergonomics ontology

The described model was fully implemented in a semantic framework for testing and evaluation. The expressiveness of the model, and subsequently, its usefulness are proportional to the sheer volume of data that is expressed through it. While this work will seek to demonstrate the potential applications of the implemented model, the data input into the model is not meant to be exhaustive and is intended for demonstrative purposes. Instead, this chapter discusses the design of the information model and discusses its usefulness with the aid of two case studies relating to an ongoing medical device design project.

6.2. Objectives and Scope

In this chapter, we present an information model that unifies a detailed model of engineering design with concepts of usability, ergonomics, and use environments. This was developed with the aim of creating an approach that facilitates user-centered design by linking user data more closely with the design realm and serving as a basis for automated design inferences. The model seeks to be generalizable to virtually any potential user group, and to incorporate sufficient information to characterize a wide

variety of both clinical and non-clinical devices. The described model was fully implemented in a semantic framework for testing and evaluation.

6.3. Materials and Methods

6.3.1. Information Model

An information model was used to model both the design domain and the user domain. The goal of this approach was provide useful links between a model of user performance and a model of the design itself, with a focus on the interactions between a user and the design. This section describes the basic underpinnings of a unified model of design and user domains, while subsequent sections describe the implementation of the model in a semantic framework and detail its potential usefulness with the aid of multiple case studies.

6.3.1.1. Systems Model

The proposed information model relies upon a characterization of products and various stakeholders in a product as interacting **systems**. Systems are viewed as being either **physical_systems** or **abstract_systems** that are denoted as having various subsystems using a transitive **hasSubSystem** relation. In this view a medical product is primarily a means by which the user affects changes within the patient **system** with some **objective** in mind. Each system has pre-defined set of possible **states**, assigned with a **hasState** property and potentially has multiple subsystems, such as the individual parts and assemblies that form a tool. Each system state is assigned using a **hasState** property. **States** are simply discrete configurations that systems might be in at some point in time and correspond to the systems' degrees of freedom. **Inputs** into each system cause state changes and result in **outputs** from the system denoted with **hasInput** and **hasOutput**.

properties, respectively. These may involve simple user **Tasks** or otherwise reflect **flows** of information, energy or material into the system which in turn cause changes. Each subsystem is similarly characterized in terms of available **states**, a set of **tasks** that the **system** can complete, and **performances** on each of those tasks. Each task is modeled as a series of simpler sub-tasks using a transitive **hasTask** property. Each task is also noted as **performedOn** some system, **performedBy** another system, and potentially **performedWith** a third. For example an incision **task** might be **performedBy** a physician, **performedOn** a patient, **performedWith** a scalpel, and have **hasTask** some sub-task like applying iodine to the cut site. Similarly subtasks have chronology, indicated by the properties **hasConcurrentTask**, **hasProceedingTask**, and **hasPreceedingTask**.

The process of using the device is modeled as a series of actions that cause changes in the system state, with a **task** that initiates some state (**initiatesState**), and a related **initiatesStateFrom** property. Since some states might only be available from a subset of other states, permissible state changes are indicated using a **transitionsTo** property and its inverse. In the case of an electric light, a task involving flipping a switch might initiate a “light on” state from the “light off” state. Within the information model each task is specifically denoted as being performed by some system and systems can optionally be indicated as having some user. For example, a tool might directly interface with some patient system as an intermediary, such as in the case of using a surgical tool on a patient, but a human user can ultimately be noted as operating the tool. While each different type of system is unified by the same basic information model, some might then be characterized by an ability to perform certain specific types of task, or having distinct types of state.

Systems are modeled as capable of performing **tasks**, though the possible tasks might differ based on the system's current **state**. For example, a software platform might accept user inputs in one **state**, but not in another, as expressed by **hasTask** relations associated with each state. **Performances** are used to indicate how well a system can complete a task via a **hasPerformance** property relation. For example, a **system** might generate torque as a **task**, but might only be able to generate torque within some pre-specified range. That range would be thus be expressed as a **performance** on a torque generating **task**. Each individual performance might be linked to a specific **task** instance, or alternatively to an entire class of related **tasks**. Specifics of system performance are expressed using data properties, which ascribe specific values (**hasValue**) or be used to represent an entire distribution of possible behaviors (**hasMean**, **hasStandardDeviation**, etc) in a distinct subpopulation. For example, a population might be assigned a range of physical strengths when performing some motion so as to represent differences between individuals. The scope of some performances can also be restricted using additional references to **abstract_systems** to denote **axes**, **coordinate_systems**, **references** for some **performance**, as well as units. Performances are also used to express **performance_requirements** using a **hasRequiredPerformance** property, which links a **task** to a **performance** describing its minimum needs. (Figure 11).

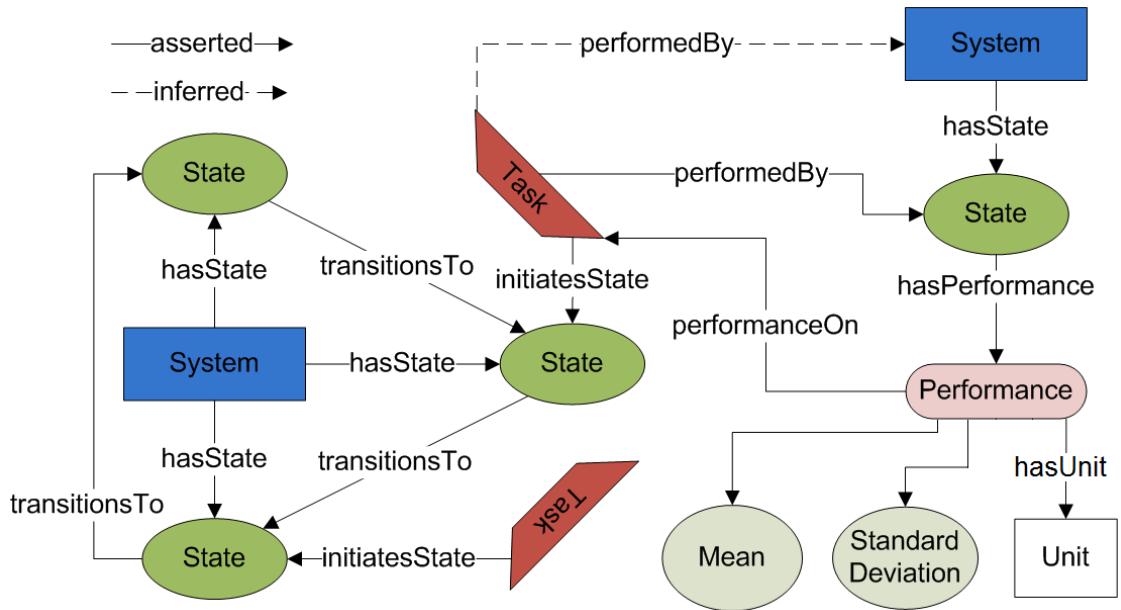


Figure 11. Partial representation of products and other entities as systems with a finite set of states

Should a described **system** reflect a user or at the very least something that performs a task of interest, these sets of **performances** and **performance_requirements** can serve as the basis for device assessment. For example, a design component might need to maintain some performance to avoid failure, or a user might need to have some level of dexterity to manipulate a product properly. By using the system view to model users as **systems** comprised of a (potentially large) series of **sub-systems** with distinct **states**, it is possible to describe a large range of performance characteristics across many different classes of **task**.

6.3.1.2. Product Design Model

The engineering design portion of the information model is structured as a subset of the larger systems model. The implementation is based on the NIST's Core Product Model [196], reformulated to fit within the broader hierarchy of systems, system

properties, and system states. As defined in the information model, the product and its design are simply subclasses of the larger **system** class, and various aspects important to the design, such as parts, features, etc. are modeled as a set of **system properties** and **subsystems**. In this implementation the **product** is differentiated from the **design**, acting as the physical embodiment of the more abstract product design that is created during the engineering design process. The detailed **design** itself is composed of a set of **design_features** and **design_artifacts**, which are defined similarly to the Core Product Model. To summarize, features are aspects of the design having both a **design_form** and **function**, while artifacts have a **design_form**, **function**, and **design_behavior**. These are linked to the design uses two sub-properties of the **hasSubSystem** property, **hasPart** and **hasFeature** so as to distinguish from the two in reasoning and queries. While no formal representation of behavior or form as been added to the information model, an information model implementation of the Functional Basis described by Hirtz et al [201] was included to allow construction functional models of various **design_artifacts** to represent product functions unambiguously. These are linked to specific **design_artifacts** and other systems via a **hasFunctionalModel** property. Within the model, each **design_artifact** is considered to be its own system (which may in turn be a subsystem of some larger collection of **parts**, an **assembly**) while **design_features** must be defined as a subsystem of some larger one. Each of these is described in greater detail via a set of relations to **design_properties**, which are simply a subclass of the broader set of **system_properties**. The **design_properties** class includes the basic constituents of defining features and artifacts: form, function, and behavior. It also includes subclasses to represent **design_variables**, which can be controlled in the case of some design

component or may be uncontrolled in the case of some use environment property. The design process is driven by **design_motivations**, such as **objectives**, **opportunities**, **problems** in the current design iteration, internal design **requirements**, and **stakeholder requirements**. Potential **problems** are noted using a **hasIssue** property. Resolutions to problems are modeled with a **hasSolution** property which links the issues to some action or feature that resolves the issue. For example, a preliminary medical device design might be noted as having a difficult to use interface based on a performance assessment of the target user population. This would constitute a **problem** to be fixed. In response to this flagged problem, a designer might re-design the user interface, completing a **task** that resolves the problem.

Stakeholders are solicited by way of **tasks** that yield **data** and identify **requirements (identifiedBy)**. A **hasStakeholder** property is used to specify specific individuals participating in various user engagement **tasks**. A number of classes of stakeholder are included such as **customers**, **users**, and **payers** to denote various types of relation with the product. Each **requirement** is described in terms of a **metrics** via a **hasRelatedMetric** property, with data values used to represent design specifications and the importance of the **requirement**. Metrics themselves relate to one another via the **hasRelatedMetric** and to **design_variables** via the **hasRelatedVariable** property. Each **relation** can also be expounded upon by linking the entities to an intermediate entity using an **isInRelation** property, allowing the relation between two entities to be described in greater detail with **equations** or other material.

The design process itself is represented as a series of **tasks** that yield **data**. These data are stored in **documents**, which divided into content and sections using a

hasContent and **hasSection** property. In many instances in a design, documents might be prescriptive. For example, it might contain data relating to a customer's feedback, or perhaps be a regulation or standard that applies to the design. These types of situations are captured by the property **imposesRequirement**, which links **requirements** to any **document** from which they might originate. These links to **documents** are made explicit using an additional property, **hasRelatedDocument** and its sub-property, **affectedByGuidance**, which link **guidance_documents** to a **system**. For example, a medical device will be affected by the FDA's general device requirements, which are described in a specific regulatory document. The **affectedByGuidance** property would link this document, as well as related ones, to the medical device. While not explicitly included in the information model, annotations or linked data values could include file paths, URLs, a DOI or similar to trace the instance back to a real world document. In order to trace **requirements** back to the specific individuals responsible for them, the property **hasStakeholder** is used to connect individuals to a **document**, while a second property **isMaintainedBy** links a document to the person or organization that maintains it, such as a standards making organization (Figure 12).

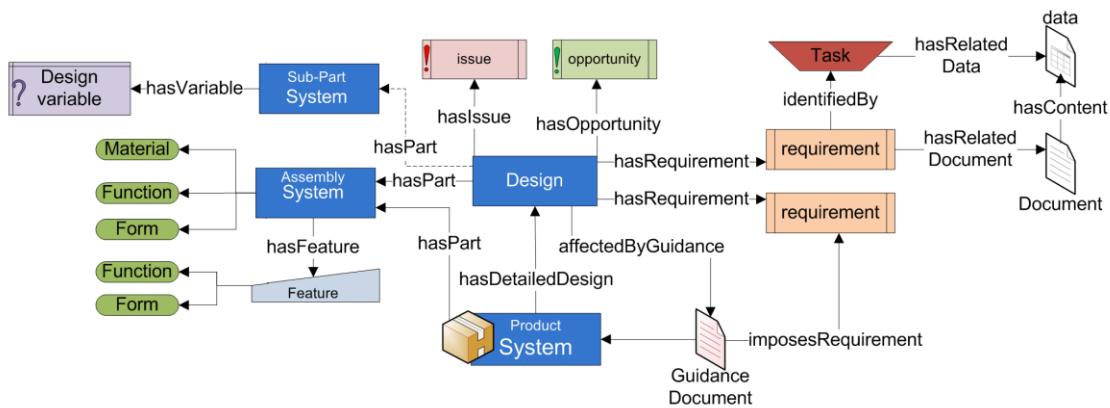


Figure 12. A partial representation of the design and design process model used in the information model

6.3.2. Implementation in a Semantic Framework

The information model and method described in the section 2.1 was implemented in the OWL 2 knowledge representation language using the Protégé 4.3, an ontology editor. Ontologies are formal representations of a knowledge domain, characterized by both a defined hierarchy and descriptive axioms that are used to distinguish various types of concept from one another. This hierarchical representation and classification mirrors the hierarchies of concepts used to distinguish various systems and tasks from one another in the information model. An ontology was used for implementation of the information model due the formal semantic underpinning of ontologies and the intrinsic ontology properties of interoperability, extensibility, and compatibility with the Semantic Web. The former allows the execution of first-order logical rules based on both the model's structure and the statements asserted by a user, while the latter means that this multidisciplinary framework can incorporate or extend existing knowledge bases.

6.3.3. Creation of Ontology Representation

Three class hierarchies (Figure 13) and corresponding sets of class properties and relations between classes were individually defined. The first pertained to design guidance and maps documents into a set of structure and content elements which can impose a set of requirements onto the design domain. The second class hierarchy follows the basic structure of NIST's Core product model [196], expanded with additional subclasses [138], and defined class relations to function within the broader system view used throughout the model. Aspects of the model were also expanded based on past research into good practice in medical device design [53, 228]. The third one deals

specifically with ergonomics and introduces the user interface and performance concepts discussed in section 2.1. A variety of ergonomic concepts were also included based on past research classifying various types of stakeholder requirement [229], errors [52], and engagement techniques [7] that were used to create various classes of task. The three sub-ontologies were then imported into a single environment, and unified using additional relations, equivalent classes and properties, linked property chains, and semantic rules to implement simple logical expressions.

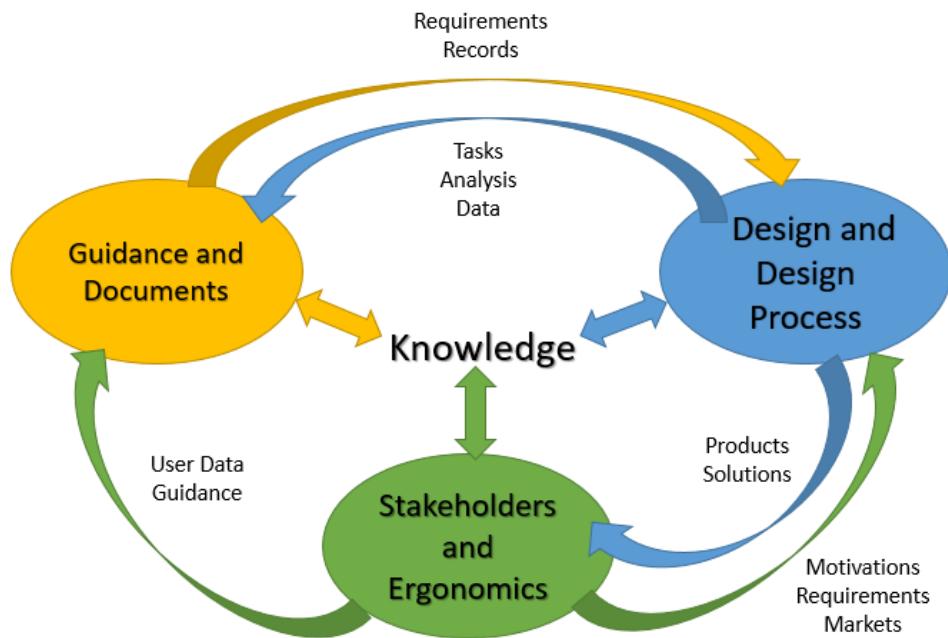


Figure 13. The three hierarchies created in the OWL 2 implementation of the model

Two additional ontologies were added to incorporate concepts relating to functions and to allow accounting for units in the ontology. The former was deemed necessary to express the functional behaviors of various aspects of a product or system.

The latter was deemed particularly important for expressing user performances unambiguously and allows for meaningful comparisons between user performance measurements and required performances associated with specific tasks. Functional behavior was modeled using the Functional Basis Ontology [201, 230], which is a semantic implementation of the functional basis modeling lexicon. This terminology describes the functional behaviors of a system using a restricted vocabulary of functions that are performed on flows of matter, energy, and information. Units were added to the ontology by importing the NASA Units Ontology [231].

6.3.3.1. Automated Reasoning Support

Automated reasoning capabilities were added to the implemented information model to enrich the knowledge entered into the model and to help demonstrate how the framework might be utilized in a user-centered product design. The core attributes of this reasoning layer are described in this section, while non-essential components are omitted for brevity. The majority of the desired functions of the information model's reasoning layer demand relatively simple logical expressions that can be expressed using class and property axioms (defined classes, complex property types, property chains etc.) to reason on the structure of the information model (TBox). For the purposes of demonstrating how the information model might be used in practice, two rules were created using the Semantic Web Rule Language (SWRL), which work exclusively on instantiated knowledge (ABox). While this significantly increases the computational demands of automated reasoning software and demands more robust data entry to consistently reach meaningful inferences, inclusion of SWRL rules allows for far more complex inferences and simple mathematical computations and comparisons that are critical to the

information model. These rules will be discussed in the context of a case study in section 3.1.

An initial set of property chain axioms (which imply that if object A is linked to object B by a property, and B to C by a second property then A is linked to C by some specified property) were used to more closely connect the system view described in section 2.1, and this was done throughout the information model (Table 5). The goal of these chains is to automatically create links between concepts, fully expressing the relations between various systems and their interactions.

Table 5. Property chains used to link model of system, states, tasks, and performances.

Each “o” indicates that the range of the preceding term is the domain of the proceeding one. The property to the right of the arrow is inferred to have the domain of the first property, and the range of the last property expressed to the left of the arrow.

Num	Property Chain	Explanation
1	<i>hasSubSystem o hasInput → hasInput</i>	Inputs to a subsystem are inputs to the parent system
2	<i>initiatesState o isStateOf → hasInput</i>	Tasks that induce changes in a system's state are inputs of that system
3	<i>hasState o hasPerformance → hasPerformance</i>	The performance of some state of the system is a performance of that system
4	<i>performsTask o performedWith → isUserOf</i>	A system that performs a task that is completed with some other system is a

			user of that system
5	<i>performsTask</i>	o <i>hasTask</i>	→ A system that performs a task with subtasks performs those subtasks
6	<i>hasSubSystem</i>	o <i>performsTask</i>	→ Parent systems perform the tasks performed by its subsystems
7	<i>performsTask</i>	o <i>hasRequiredPerformance</i>	The performance required of a system's tasks is a performance requirement of that system
8	<i>isUserOf</i>	o <i>hasPerformance</i>	A system that uses an intermediate to complete a task is modeled as having the performance capabilities of the intermediate
9	<i>isUserOf</i>	o <i>hasInput</i>	A user system is required to meet the performance requirements of the target system
10	<i>hasSubSystem</i>	o <i>hasRequirement</i>	→ The requirements of a subsystem are requirements of the system itself

Chains 1 and 2 simply relate attributes of system states to the top level system, while chain 3 specifies that inputs that cause state changes in a system are system inputs. In the case of chain 2, it is worth noting that performances are considered to be past “up” to higher level systems, but the reverse is not true. For example, if a person’s hand can perform some task in a specific grip, clearly that performance capability is an attribute of

the person. By contrast, the person's cognitive performance is not considered an attribute of the hand. Chains 4 through 6 relate tasks and systems to one another and specify which systems constitute "users" for the purpose of performance and design assessment. This is explored in more detail in case study 1 in section 3 below. Chains 7 through 9 deal with the performance requirements that arise from task completion. They help to clarify how the use of tools can potentially affect the user system's performance model. For example, in the case of a provider who must move a patient of certain weight, chain 7 simply stipulates that the provider must be capable of moving that weight in the manner prescribed by the task model. However, Chain 8 notes that if the provider uses certain relevant tool, such as a patient lift, their performance is effectively enhanced; allowing them to move a patient whom might exceed their unassisted muscle power. This comes with the caveat, expressed via chain 9, that the provider must at least meet the performance requirements of the tool.

The same approach was used in the requirements domain to enhance the traceability of requirements back to various stakeholders and design activities. The primary focus is relating regulatory documents, which often involve multiple references to other forms of guidance and have complex document structures. In order to facilitate more accurate reasoning, two sub-properties of the ***hasSection*** property were included: ***hasHorizontalSection*** and ***hasVerticalSection***. These refer to the common arrangement of regulatory codes in which the sections of document might apply to all devices within a broad class (horizontal) or some subset (vertical). The chains are shown in

Table 6 below.

Table 6. Stakeholder and document property chains

Num	Property Chain	Explanation
		Guidance documents that affect
11	<i>hasClassification</i> o <i>affectedByGuidance</i> → <i>affectedByGuidance</i>	specific classes of product apply to products of that are classified as such
12	<i>hasRelatedGuidance</i> <i>affectedByGuidance</i>	If a system is affected by some <i>affectedByGuidance</i> o guidance document, and that → document cites another guidance document, the design is affected by the second document as well
13	<i>affectedByGuidance</i> <i>hasHorizontalSection</i> <i>affectedByGuidance</i>	o Horizontal sections of a section of a → document that affects a system also affect that system
14	<i>identifiedBy</i> o <i>hasStakeholder</i> <i>hasStakeholder</i>	Stakeholders linked with activities → and documents that identified some relevant knowledge are stakeholders in that knowledge as well
15	<i>affectedByGuidance</i> <i>imposesRequirement</i> <i>hasRequirement</i>	o The requirement imposed by various → guidance documents are requirements of affected products

Chain 11 simply states that when regulatory or other classifications are applied to a system have related guidance documents, that system is ultimately subject to their contents. Chain 12 operates in a similar manner, and is mainly included for cases when regulators cite standards and other documents as part of their guidance. Property chain 14 serves purely to make requirements more explicitly traceable and simply states that, for example, if a survey leads to the conclusion that a product must have some requirement, then the people who answered the survey have some stake in that requirement. Chain 15 makes regulatory requirements explicit by assigning them to affected products.

6.3.4. Case Studies

The information model was tested using two case studies. The case studies not only help to clarify the information model, but they also illustrate associated reasoning capabilities and reveal a potential way the model might be used to gain further information about the design process from the unified domains and knowledge model structure.

6.3.4.1. Case Study 1 - Information Model – Reasoning Ability

An initial case study of surgical staplers was used to investigate the information model's expressive and reasoning capability. A thorough market study was conducted, including reviews of the current projects, the scientific literature, and discussion with a surgeon familiar with the field aimed at generating a set of requirements for a new surgical stapling device. In addition, two surgical stapling products (Figure 14) were obtained and evaluated for usability by two raters in order to better understand the current market. The findings of this review were rendered as a series of project specific instances and property assertions in the implemented information model. Regulatory information

was also researched, and the FDA classification database partially rendered as set of classes and class axioms in the information model.



Figure 14. Staplers evaluated for the case study

From the review exercises it was determined that ideally the stapler would be completely operated one-handed, leaving surgeon's opposite hand free to manipulate other tools. The task model instantiated in the information model was formulated accordingly, with all interactions between the user systems and the stapler systems based around an idealized one handed motion. Since the tasks considered in the case study were primarily hand manipulations with the hand in a power grip configuration represented by a distinct state, hand performance data were researched for the case study. These performances were ascribed to two instances that were created to represent an average male and female user from the general population for the purpose of demonstration, though in practice virtually any group or individual could be represented in this way. Data values for the performance data for each representative instance were entered based on studies of human anthropometrics [232-234] in male and female populations, as was grip strength data for both sexes [235].

Individual evaluation of the two staplers by the engineers found that neither stapler was particularly difficult to fire, both in terms of the accessibility of the trigger and the required force. However, neither engineer could access the articulation and rotation functions on stapler 3 without using a second hand nor could one evaluator close stapler 2 due to an issue reaching the fully extended lever required to do so. All other functions and user interface points were accessed with relative ease using a single hand during the firing phase of use. No difficulties were found during the two-handed device preparation and reloading phases of use. These assessments were recorded and used as the basis for comparison with the information model.

Required user performances were defined based on direct measurements of the devices. A simple 2D coordinate system was defined such that the x axis points from the base of the palm to the fingers and the y axis points towards the extended thumb. All tasks were modeled as being performed with the hand in a power grip configuration, represented by a system and state. Measurements based off the one-handed use requirement were gathered and input into the model. Stapler A required a 90 degree rotation of the thumb and extension thumb at least 50 mm to successfully close the device and an extended index finger to reach 60 mm from the base of the thumb to access rotation features. Stapler B required the user to grip a trigger 60-65 mm from the base of the thumb to operate basic functions and also required an extended index finger to reach 130 mm from the base of the thumb to access rotation functions. These measurements were recorded, instantiated in the model, and used as a basis for evaluation using the Reasoner.

Once all data were instantiated in the implemented information model, Protégé's built in Pellet Reasoner [153] was used to check the information model for consistency, evaluate the class based reasoning, and also apply a number of rules that were added to expand functionality. This was chosen due to its ability to evaluate mathematical expressions in semantic rules, which was deemed to be important for comparisons of performance data values.

6.3.4.2. Case Study of Complexity Metrics

The second case study considers how the structure of the information model might be used to formulate new design metrics. A number of authors have proposed that complexity is an important aspect of a product's success in both the design marketing phase. Visual complexity has also been proposed as a measure of usability [236]. Based on this underlying assumption that complexity is an important product attribute in both the product design and usability domain, a number of authors have proposed metrics to quantify various types of complexity. It was hypothesized that the model might be used to formulate hybrid metrics that represent aspects of both design and task complexity. A number of existing metrics (Table 7) were selected for evaluation in the case study based on past use evaluating medical devices [237] and availability of a formal definition [238]. These were included to serve as a basis of comparison for the information model based metrics.

Table 7. Existing complexity metrics evaluated for the case study

Equation	Variables	Ref
$DC = \sum^n k.F$	K_i Weight for level i in a	42

		functional
		decomposition
F_i		Number of functions in the i th level
$DC = M^2 + I^2$	(4)	M Number of modules or components
		47
		Number of interactions I between components
$TC_1 = \sum_{j=0}^{j=p} \sum_{i=1}^{i=n} W_{ij}$	(5)	W_i Number of information cues involved in the i th j act of the j th subtask
		50
		p Number of subtasks
		n Number of acts in each subtask
$TC_2 = \sum_{i=1}^{i=n} r_i$	(6)	the number of precedence relations r_i between the i th subtask and all other tasks
		50

The first measure derived from the information model is based on the idea that from a design perspective a system with a more highly connected set of states (e.g. from each state one can enter a greater number of states) is more challenging to design. Similarly, from a user perspective this high level of interconnection means a greater number of decisions must be made. The measure C used is the total number of possible

one way transfers between states, maximum theoretically possible number of transfers based on the number of states, shown below.

$$C = \frac{T}{S(S-1)} \quad (7)$$

C is the complexity as measured by the metric. T refers to the number of transfers between states, while S refers to the total number of states defined for the device. The quantity S(S-1) is based on the theoretical maximum number of connections between nodes for a network of S nodes. The total is multiplied by 2 so as to account for the potentially unidirectional nature of each connection specified in the information model. For example a product might have one state that's accessible from another, but the reverse may not necessarily be true. The forward and reverse case are considered as distinct from one another, doubling the mathematically possible number of connections.

The second metric uses the task breakdown used to characterize user interfaces in the information model. In this formulation of complexity, a design which must accommodate a greater number of user interactions is considered more complicated, as the designer must account for and control each of these interactions. To calculate this metric, a task is decomposed into a hierarchy of subtasks that involve direct input from users. The number of entries into the hierarchy is then tallied to obtain a complexity value for the task.

$$TC = \sum_{i=1}^n k_i T_i \quad (8)$$

In equation 8 T_i refers to the subtask required to accomplish some larger goal task, such as utilizing a designed system, and k_i is the weight given to level i of the task.

A set of currently available medical products (Figure 15) was chosen based on similar high-level functionality (though the surgical indications vary) and further researched using information from manufacturer websites and third-party data sources such as medical product vendors' websites. To be included, products needed to have sufficient available information to compute the metrics described below and to have a high-level function consisting of joining tissues at a minimum (some products also performed additional functions such as simultaneously cutting).

From the research of the nine selected devices, each metric was computed and the relations between explored by calculating Pearson correlation coefficients.



Figure 15. The devices evaluated in the case study

6.4. Results

6.4.1. Classification of Information Model

The ontology was classified using Protégé 4.3's built in Pellet Reasoner without any errors. During the data entry phase, the semantic model described in section 2 of the

paper was sufficient to capture the full set of information required to compute the desired metrics of task and design complexity, as well as the two-hybrid metrics. Automated reasoning from semantic rules and chains of properties were able to link the largely disparate user and design domains to one another provided only human input during the data entry phase.

6.4.2. Case Study 1

The model was found to be sufficient to express all information relating to the design, requirements, users, and other stakeholders of the device upon instantiating the necessary information. A review of reasoning assertions similarly found no erroneous or nonsensical inferences had been made upon classification with the Reasoning software. Instead, information entered into the model was used to make a number of potentially useful inferences about instantiated products.

Looking first into the process of requirement elicitation and understanding of contextual information, the first case study was used primarily to explore the handling of regulatory data. Based on background research into classification of stapling products, the instances representing the two individual stapling products were determined to be classified as implantable staples by the FDA, a classification that would be sought for any subsequent products. Because the model incorporates support for requirements, regulation, and documentation, a variety of class axioms were able to be asserted a priori for both the specific device class and regulated devices in general. While the specific class of device had few special requirements, it does have a Class 2 regulatory classification, expressed via a subclass axiom and the *hasClassification* property. The devices are also medical products regulated by the FDA, meaning that they are subject to

a set of general requirements; a relation expressed using the *affectedByGuidance* property.

Using only these class axioms, which are applied to any information subsequently entered into the model, the Reasoner is able to make a number of conclusions about the devices under consideration in the case study. Most general requirements of a medical device are expressed using references to consensus standards maintained by third party organizations. Without sufficient information links, this knowledge might otherwise be lost, and more detailed guidance ignored to the detriment of the designer. Within the information model however property chain 12 allows the Reasoner to conclude that these third-party standards are in fact guidance documents that are of importance to any classified medical device. Combined with chain 15, these requirements are then assigned to the regulated product (Figure 16)

```
FDA_medical_device SubClassOf affectedByGuidance value FDA_General_Medical_Device_Requirements
FDA_General_Medical_Device_Requirements hasRelatedGuidance standard_62366_Edition_11_2014_01
standard_62366_Edition_11_2014_01 imposesRequirement req_usability_engineering
affectedByGuidance o hasRelatedDocument SubPropertyOf affectedByGuidance
affectedByGuidance o imposesRequirement SubPropertyOf hasRequirement
```

Figure 16 . Simplified Reasoning steps used to assign regulatory requirements to a classified device

The same basic process can be used to express stakeholder requirements and link them to useful design metrics that might later be used to assess the device.

Because performance evaluations require numerical comparisons and conclusions that require multiple conditions to make concrete inferences, property chains like those described in section 2 cannot be used. Instead, a SWRL rule can be defined to evaluate performance on a specific task. There are several ways this might be approached. For

example, when considering usability in one or several populations, it might be useful to quantify the proportion of the population for which the task might difficult or impossible. One way to do this would be to compute a Z score to measure the distance of a required performance from a population's mean. Such a rule might utilize a *performanceOn* property or its inverse that links each performance of a particular class of tasks and thus be written as:

$$\begin{aligned}
 & \text{hasRequiredPerformance}(\text{?task}, \text{?required}), \text{hasValue}(\text{?required}, \text{?Val}), \\
 & \text{hasUnit}(\text{?required}, \text{?Unit}), \text{performanceOn}(\text{?task}, \text{?performance}), \\
 & \text{hasUnit}(\text{?performance}, \text{?Unit}), \text{hasMean}(\text{?performance}, \text{?mean}), \\
 & \text{hasStandardDeviation}(\text{?Performance}, \text{?StdDev}), \text{subtract}(\text{?sub}, \text{?Value}, \text{?mean}), \\
 & \text{divide}(\text{?Zscore}, \text{?sub}, \text{?StdDev}) \longrightarrow \text{hasZScore}(\text{?performance}, \text{?zsore})
 \end{aligned} \tag{9}$$

Rule (9) simply checks that the units expressed in a performance and a required performance, before computing the relative distance of the requirement from the mean (Figure 17). The score is assigned to the user's performance, but this is arbitrary and could be assigned to virtually any instance in the model. When this rule was implemented, it computed a score larger than 2 on Stapler A's opening and closing tasks when compared to the performance data entered for female users, indicating a significant proportion of female users would be unable to complete the task. Similar results were automatically detected in both male and female users for the case of using Stapler B's articulation and rotation functions. If one defines a threshold Z score, one can also automatically flag such findings as **design_problems** thus making the interpretation of such data more straightforward.

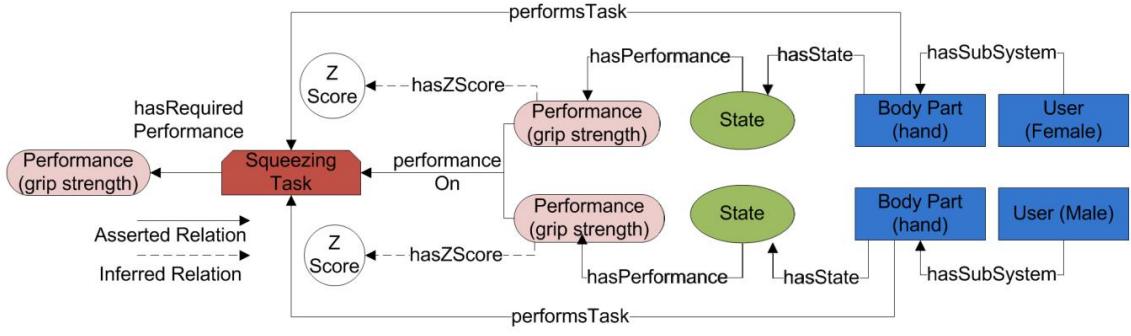


Figure 17. Simplified set of information used to compute a z score for a trigger gripping task. Additional information such as units and orientation are used in the complete rule comparison. Both comparison are made simultaneously

While rule (9) demonstrates one way that a performance evaluation might be conducted using the information model, it requires that each individual user population's performance be tied to a specific task associated with a specific task, limiting usability as each connection must be asserted manually. Moreover, only definite required performances are allowed as opposed to a range, which is likely more realistic. However, the information model contains additional information that might was used to formulate an alternative rule that can be evaluated automatically on all user populations with sufficiently defined performance attributes. One such implementation of the use is:

```

hasInput(?product,?task), hasRequiredPerformance(?task, ?required)

hasPerformance(?system, ?performance), hasAxis(?performance, ?axis)

hasAxis(?req, ?axis), hasUnit(?performance, ?unit)

hasUnit(?required, ?unit), lowerBound(?required, ?low) (10)

upperBound(?performance, ?high), greaterThan(?low, ?high) --->

hasProblem(?task, ?req)

```

The same basic reasoning aimed at comparing units of a performance and required performance is used as a prerequisite to flagging a problem, but in rule (10) an additional matching requirement is added. In order to flag a problem, the motion tasks must be performed about an abstract axis (Figure 18), which in this case simply describes an anatomical axis that could be included in a detailed human anatomy model. In non-movement cases, other abstract descriptors could be defined in similar rules. An inequality is used to assess whether the lower bound of acceptable user performance (such as a reach) is within the acceptable upper bound of user capability, with both values potentially calculated with an additional rule based descriptive statistics and user input. Using this same approach, the stapler 2 was deemed to have no usability issues for male users; the required thumb size to effectively open and close the stapler was found to be well above the predefined cutoff for female users. Stapler 3 had usability issues for both sexes, as the required hand size to rotate the stapling apparatus one handed was well beyond the mean anthropometric size of average male and female users. The same rule could be extended to provide information about the proportion of users who might be affected by a problem, as in rule 1.

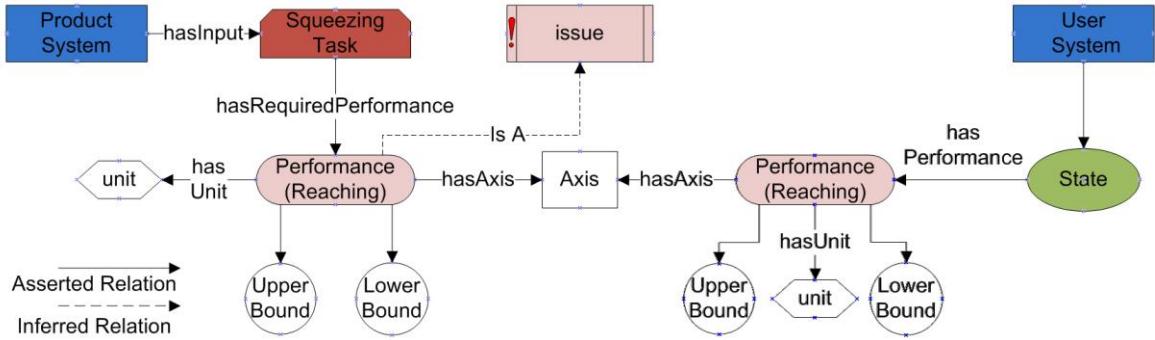


Figure 18. Information used by Rule 2 to automatically detect a design problem based on a specific user group's pre-specified performance. No directly asserted link is required between the required performance and user performance

In an implementation of the information model using Rule 2 and assuming a well-defined set of user performance parameters, a designer of a new device will be guided by the information on the user interaction with the new product and the performance requirements during that interaction. Thus, if designing a simple trigger mechanism, the designer would only need to specify the reach required to effectively grasp the trigger and the grip or finger strength needed to actuate it. Once this information is defined in the model, Rule 2 will initiate an automated assessment of whether the proposed parameters would constitute a design violation? issue. Since performance requirements are modeled identically in both user-product interactions and part-part interactions, similarly defined instances will enable identification of other design violations.

6.4.3. Case Study 2

The initial evaluation by the authors led to a ranking of each of the 9 included products. Computation of the design complexity metrics found that the subjective rankings and the design complexity metrics proposed Bashir and Thompson and Keating

et al. mostly agreed in their overall ranking of the products' respective complexities, with limited exceptions (Table 8).

Table 8. Computed complexity measure values for the four existing complexity metrics and two proposed metrics

Subjective	$DC = M^2 + I^2$	$DC = \sum_{i=1}^n k_i F_i$	$TC_1 = \sum_{j=0}^{i-1} \sum_{i=1}^{i+j} W_j$	$TC_2 = \sum_{i=1}^{i+n} r_i$	$C = \frac{T}{S(S-1)}$	$TC = \sum_{i=1}^n k_i T_i$
Stapler 1	1	277	32	6	4	0.84
Stapler 2	2	269	40	8	6	0.82
Stapler 3	3	369	45	6	6	0.9
Stapler 4	4	832	52	5	5	0.916
Stapler 5	5	861	60	9	5	0.91
Stapler 6	6	1170	61	6	5	0.92
Stapler 7	7	881	61	8	5	0.85
Stapler 8	8	1618	64	10	7	0.925
Stapler 9	9	2165	70	9	5	0.925

The pre-existing task complexity metrics by comparison did not align particularly strongly with the subjective evaluation of the included product's perceived complexity. The two new metrics based on the information model structure performed similarly to the two existing metrics of design complexity, and overall agreed with the subjective rankings more than the metrics of task complexity (Table 6). Correlation measurements between metrics showed overall strong correlation between the two design complexity metrics and slightly weaker correlation between the two task complexity metrics (Table 7). The design complexity metrics however were had much stronger correlation with the subjective ratings. The two new metrics analyzing complexity from the perspective of design states and user interactions (tasks) with the products had strong correlation to one another. Overall there was only moderate correlation between the design complexity and task complexity metrics previously proposed in the literature, with minimum correlation coefficients of 0.427 and a maximum of 0.762. By comparison however the two proposed

metrics showed overall moderate to strong correlation with both the design and task complexity metrics. These correlation coefficients were as high 0.912 between the “subtasks” measurement and the complexity metric proposed by Bashir and Thompson, and as low as 0.624 between the measure of complexity based on states and Wood et al.’s proposed metric of coordinative complexity. Overall, the new metrics correlation to both metrics of task and design complexity was stronger than those of the two to one another.

Table 9. Correlation coefficients between design, task, and hybrid complexity measures for the 10 included medical device products

Subjective	$DC = M^2 + I^2$	$DC = \sum_{i=1}^n k_i F_i$	$TC_1 = \sum_{j=0}^{i-1} \sum_{i=1}^{i+j} W_j$	$TC_2 = \sum_{i=1}^{i+n} r_i$	$C = \frac{T}{S(S-1)}$	$TC = \sum_{i=1}^n k_i T_i$	
Subjective	1.000						
$DC = M^2 + I^2$	0.928	1.000					
$DC = \sum_{i=1}^n k_i F_i$	0.966	0.884	1.000				
$TC_1 = \sum_{j=0}^{i-1} \sum_{i=1}^{i+j} W_j$	0.603	0.544	0.478	1.000			
$TC_2 = \sum_{i=1}^{i+n} r_i$	0.264	0.177	-0.252	0.366	1.000		
$C = \frac{T}{S(S-1)}$	0.621	0.696	0.604	0.055	0.295	1.000	
$TC = \sum_{i=1}^n k_i T_i$	0.846	0.820	0.641	0.778	0.423	0.372	1.000

6.5. Discussion

Engineering design requires a product development team to manage a detailed and potentially complicated design, preserve design rationale, and ultimately balance the needs and limitations of various stakeholders with those of the designing institution. In the case of medical device design, this challenge is made more difficult by the presence of a large number of stakeholders, and particularly complex use environments. Given the sheer volume of information that must be managed at any given time, it is unsurprising that knowledge management approaches have been suggested as possible aids to the

design process. Despite the number of knowledge models that have been proposed in the literature to manage design information, few if any have attempted to link this information with a more detailed view of the stakeholders involved in the design process. In this chapter, we present an information model broad enough to encompass design and design process information, detailed information regarding stakeholder needs, and a model of the stakeholders themselves. The two case studies demonstrate its reasoning capabilities for design support and design knowledge management, and its potential usefulness as the basis for new design assessment metrics.

The resulting information model is differentiated from past information modeling approaches in two significant ways. First, it considers a detailed view of users and other stakeholders alongside information about both the design itself and the process that led to the creation of the design. There are several benefits to this approach. First, it facilitates desirable design practices, such as maintaining traceability of requirements, retaining and contextualizing knowledge, facilitating reuse of design expertise, and ultimately taking a user centered approach to the design of medical and other devices. Second, when coupled with automated reasoning capabilities, the approach allows direct assessment of the impact of a design choice on the performance of various users without a significant expansion of designer's effort, potentially allowing faster and better informed ergonomic decision making. This is a particularly pressing issue in medical contexts where access to stakeholders is limited and stakeholder capabilities may vary widely. The second area of differentiation between the proposed model and past efforts is that it employs a consistent viewpoint across the design and user domains. This approach is beneficial as it allows a large number of concepts to be intricately linked requiring large numbers of classes that

make usability problematic. Instead, a great number of concepts reside alongside one another and utilize a common set of properties affected by a relatively small set of critical class and property axioms. For example, the task and performance model described in this chapter largely in the context of user-product interactions could just as easily be used to model interactions between the product and its subsystems

The two case studies are instructive in how the fully implemented model might be used to improve upon medical device design. In the first case study, requirements and regulatory documents were attached to designs based solely on a link to a particular regulatory stakeholder. What is more important, however, is the implication of how similar links might be used. For example, various stakeholder requirements, regulatory or otherwise, can easily be linked to specific aspects of a design, either at the detailed design or concept level. This is noteworthy as it means that mere association with some set of stakeholders can be used to partially define design requirements. The approach also facilitates requirements traceability by linking each requirement back to specific market research activities with specific stakeholders. With each of the findings well catalogued with a structured dataset, the process preserves design rationale. That traceability and design rationale preservation also offers the ability to tailor a design towards the needs of specific subsets of stakeholders in a more methodical way during the initial design process and in subsequent re-designs. When coupled with the individual tracking of stakeholders, their performance characteristics, the modeling approach described provides potential for rapid and potentially automated evaluation of design changes.

As seen in case study 1, simply setting a parameter allowed a simple rule to investigate the usability based on population performance values for male and female

population subsets. A second approach was also demonstrated, showing how more detailed modeling can be used to reduce the need for direct intervention by the designer while still allowing automated assessments. While this is a simple example, it is significant as the same approach could be used to assess the effects of some design change on a variety of different types of users, or on some other system that must interact with the system in question. For example, the same modeling approach might be used to compare a series of competing designs or off the shelf parts when considering some subsystem of a larger design. Though the case study focuses on a review of existing designs, this process can be equally useful during the development of a new product. Once a design concept and form factor are defined in the information model, the designer will be able to progress to a more detailed design by using the model to evaluate the user implications of various design points within the feasible design space. The approach can be used to iteratively improve and add more fidelity to the product from a usability standpoint as a more detailed design is developed. More importantly, it can be used to address both usability and non-usability requirements simultaneously, thus serving as a basis for an informed design decision based on multiple criteria. However, accessibility alone is not sufficient to characterize a product; its overall effectiveness remains a critical aspect of the design [239]. Since both usability and non-usability requirements can be expressed using identical semantics and evaluated with the same set of rules, each potential design point evaluation can serve as the basis for an informed design decision based on multiple criteria. The information modeling approach proposed in this paper can thus be used to aid in the design of products that are more usable in the sense of accessibility, but also potentially aids in the creation of more effective overall designs.

Though obviously these applications would require a large amount of performance data to be entered into the model, doing so might pay high dividends as data would be usable in all subsequent design queries. As a result, medical devices could potentially be adapted for different user populations rapidly or alternatively developed as more universal products from the start. In the short term, the benefit of this approach is that it supports design checking across domains. While initial information gathering might be added work, there is a significant payoff in the form of integrated design checking that can be used throughout the design process. Thus, initial effort can help aid in both user-friendly design and identifying potential technical issues with design choices. This initial burden might also be circumvented in part by simply integrating existing knowledge bases into the information model, such as incorporating a well instantiated model of human anatomy in place of independently defining anatomical planes, dimensions, and landmarks. In the longer term, the approach is amendable to detailed information retention across projects, and offers the benefit of a constantly evolving repository of design knowledge that nevertheless remains an accessible and query-able record of past design rationales.

The second case study also showed potential usefulness in design assessment. While metrics of design and task complexity have existed for some time, the introduction of the information model provides a repository of a significant amount of data that can be used to formulate new metrics. In case study two, metrics were developed by simply applying the basic logic of other complexity metrics to the knowledge model proposed in this chapter. The correlation data with existing metrics of task and design complexity showed the new metrics, which utilize both design and user data, were able to correlate

reasonably well with both, though they did tend to skew closer to the design metrics. While less correlated with the subjective rankings, the overall order did generally agree in both cases. Based on correlations between the subjective rankings and the design complexity metrics, it would appear that they were largely influenced by the complexity of the design rather than use process. This particular finding may betray the raters' technical rather than clinical background. Notably, while task and design complexity metrics were only very weakly correlated with one another, the new metrics were moderately correlated with both. Though only a simple demonstration, this hints at the possibility of other useful formulations of data that can be extracted from the unified model.

Though promising, the work described in this chapter has some limitations. As with any system designed to make automated inferences on structured data, the model proposed in this chapter ultimately relies on the quantity and quality of data entered into it. Especially in the area of characterizing human performances, moving beyond simple comparisons of the type seen in case study 1 could prove labor intensive and require larger and far more complex rule set. Similarly, the usefulness of the approach only emerges when sufficient performance data has been correctly instantiated into the model, as the data entry process is fairly labor intensive. It likely does not make sense for a designer to render information in the model specifically for one design, as the process would require collection and parsing of all data necessary to simply evaluate the design manually. While we have made the argument that such detailed modeling may well pay significant dividends across multiple projects, this represents a significant impediment to further usage. Similarly, while the model might be sufficient to contain information

relating to various aspects of design metrics such as the complexity measures discussed in case study 2, it was ultimately labor intensive to extract the necessary information to compute the measures. Though this is more of an issue of user interface, it nonetheless represents a shortcoming of the current implementation.

Despite these limitations, the approach taken in this chapter does have several strengths. Once entered, data relating to the design or stakeholder domains are easily reused in subsequent design efforts. The model itself is extensive and highly expressive, capable of containing information as varied as the composition of various assembly structures for each device, regulatory documentation, and human performance data. This unified platform for all of this data facilitates reasoning and analysis beyond the scope of this chapter. Future work could investigate how best such unified data might be used to improve medical device designs and design decision making.

CHAPTER 7

AN INNOVATION FRAMEWORK FOR ADDITIVE MANUFACTURING

SUPPORTED BY LINKED ONTOLOGIES

Given the likely importance of AM in future medical innovations, the question of how designers might utilize AM effectively is of the upmost importance to any broad medical device design method or framework. The work presented in this chapter deals with the ideation and innovation aspect of DFAM, using an opportunistic DFAM approach to support the early design phase. Like a subset of past research into innovative use of AM, this work is based upon a view that the design process must begin to consider AM as early in the design process as possible so as to realize radical innovation rather than incremental improvement to designs. The method and realization presented in this chapter is based on the insight that the innovative potential of AM stems from a set of expanded manufacturing capabilities, which in turn enable value to be delivered to a product's market. These values are in many instances difficult, economically non-viable, or simply impossible using traditional manufacturing methods. These capabilities are then realized in the form of features in AM products. This work is based on the observation that the specific problems and contextual factors that made use of AM desirable in past product designs or business ventures are likely not entirely unique. While a given project might have specific design requirements, use environments, and the like, many designs might address similar issues in different contexts. If information relating to capabilities and how they have been leveraged previously to generate value in

past contexts were easily accessible, it could then help to provide the insights needed to innovate in another context.

From this viewpoint innovation can be treated in part as a knowledge management problem to which a well structured information model and knowledge base can offer a solution. An ontology was used so that the underlying model takes advantage of the properties of interoperability and extensibility, and can moreover be used in future DFAM technologies. In this chapter we present the development of an ontology that enables knowledge capture from past uses of AM that have been reported in the academic literature or have been released in the commercial market. The same linked, well defined knowledge model that captures this information then provides a basis to semantically query this knowledge to identify solutions to specific product or market needs.

7.1. Development of the Innovative Capabilities of Additive Manufacturing (ICAM)

Ontology

The ICAM ontology was developed as a suite of modular ontologies developed in OWL [142]. In addition to aligning domain ontologies, the development process also led to the creation of two ontologies representing information relating to business models and manufacturing capabilities. The former was included out of recognition that innovation comprises both design and enterprise. Similarly, the use AM capabilities to disrupt existing markets and supply chains was considered an important aspect of ICAM. In this work we envision (Figure 19) ICAM and related ontologies providing a linkage layer between disparate design, manufacturing, and enterprise considerations so that information from these domains might be re-used to foster creativity

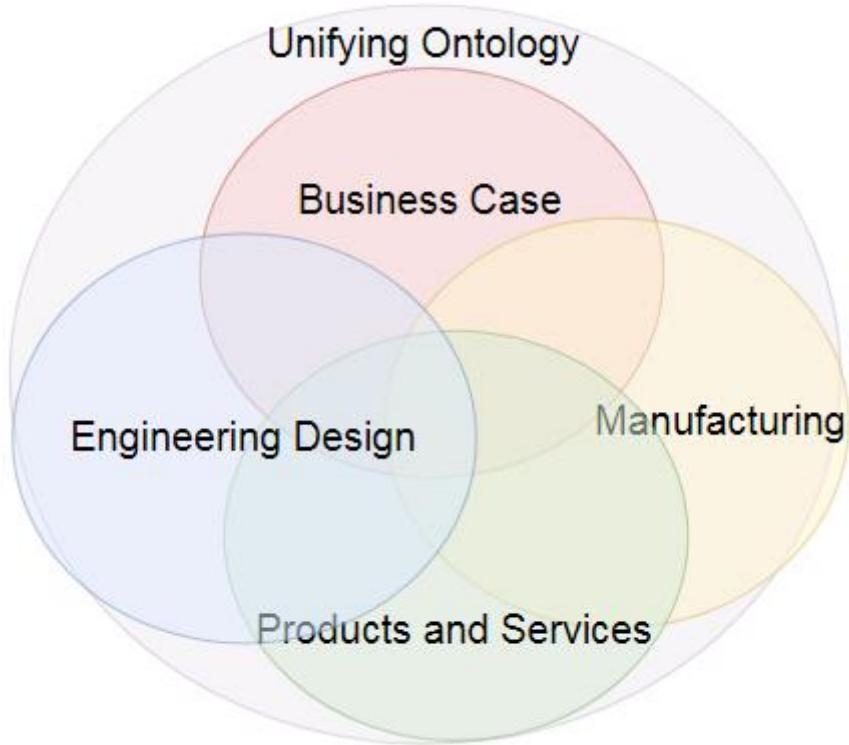


Figure 19. Envisioned unification of knowledge domains pertinent to DFAM

7.1.1. Identification of a Top-Level Ontology

Upper-level ontologies provide a formal definition of a set of entities to which all other (non-represented) entities can be considered sub-types, and so offer an abstract model of information models that utilize their classification structure. An upper-level ontology was deemed necessary to facilitate the extensibility and reusability of ICAM for future projects, as well as to impose a well-documented, formal information model on the various knowledge domains that are unified in ICAM. The Basic Formal Ontology (BFO) [171] was chosen for this project due to its small class structure, extensive use in other scientific domains, readily available guidelines and training material, and considerable success it has enjoyed in the biomedical field. BFO breaks all entities into two types, **continuants**, or entities without temporal parts, and **occurrents**, which comprise things

like processes and events which have temporal parts that unfold in time (Figure 20). Continuants are further divided into those that are independent and cannot inhere in others, those that must inhere in a single independent continuant such as intrinsic qualities or realizable dispositions (specifically dependent), and those that must inhere in some independent continuant that can change over time (generically dependent), such as information [162].

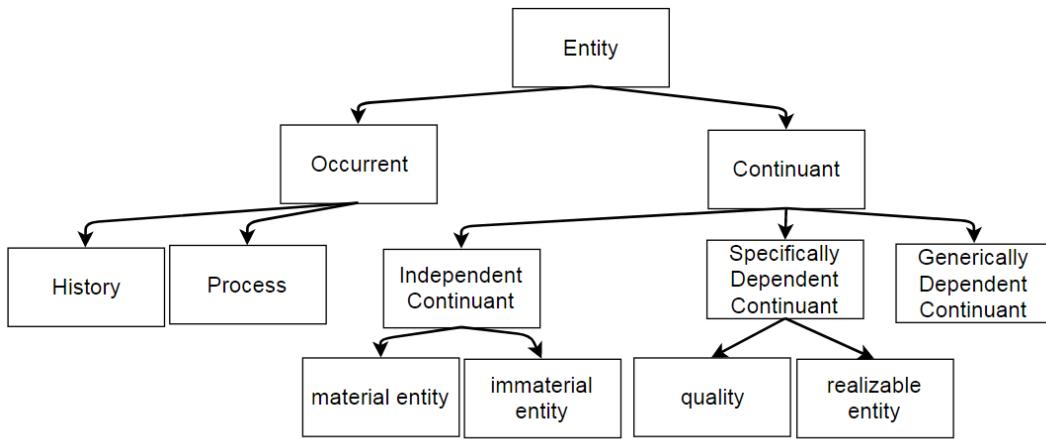


Figure 20. Partial representation of BFO class structure. Arrows represent a subclass relation between boxes

7.1.2. Use of Existing Ontologies

A number of existing ontologies were used to expedite the creation of ICAM. To that end two additional BFO conformal ontologies were used to provide the higher level information model that serves as the backbone of ICAM. The first, the Relations Ontology (RO) [240], provides a core set of property relations between entities within BFO while defining no additional classes of entity. Though more specific properties and sub-properties can be added as appropriate for domain specific relations these can be thought of as a core set of properties through which most relations between entities will be expressed. In the context of ICAM this is convenient, as it greatly eases querying the

ontology. The second, the Information Artifacts Ontology (IAO) [241], provides a formal treatment of **information content entities** (ICEs) which comprise everything from text and figures to models and directive expressions. As ICAM deals extensively with models that describe the basic operational structure of an enterprise as well as models of product function, these ICEs are critical to its knowledge capture abilities.

Past research in the engineering field has resulted in the development a number of ontologies describing subsets of the engineering domain. Though ontologies are theoretically interoperable, achieving this requires use of common upper level models and a high degree of orthogonality (limited overlap) between domains. Though few engineering ontologies meet these criteria, for this work interoperability was achieved by redefining existing ontologies through a process of realignment with a common upper level, elimination of incompatible terms, and consolidation of properties under the RO. Ontologies were selected for inclusion based on several inclusion criteria: publication in a peer reviewed source, definition using OWL or a compatible language, and availability through free online ontology repositories. Where multiple alternatives exist, decisions were made based on consistency with BFO and scope relative to that of ICAM.

An OWL implementation of the NIST Core Product Model (CPM) [196] was included provide an information model of basic product attributes. The CPM models a product as being composed of forms consisting of materials and geometry, features composed of forms and having designed functions, which in turn ultimately build to individual artifacts and assemblies. The Manufacturing Service Description Language (MSDL) [190] was included to provide knowledge relating to manufacturing processes and services, as well as a subset of axioms relating to material performance. The MSDL

consists of a hierarchy of (mostly reductive) manufacturing processes and manufacturing services, with additional information about process parameters. The Semantic Additive Manufacturing Process ontology (SAMPro) [191], an ontology of additive manufacturing processes that nests within the original MSDL, was also included to provide an explicit model of additive manufacturing processes. Finally, the Functional Basis ontology (FBO) [201], developed based off the functional modeling terminology of the same name [209], was included to provide a set of formally defined functions for describing various parts and features. The Functional Basis is used to compose functional models with a limited, defined terminology.

7.1.3. Implementation of Modular Ontologies

ICAM was created to support innovative design in additive manufacturing by capturing information relating to various fabrication capabilities of additive manufacturing in general as well for specific machines, by representing the functional purpose of these capabilities, and by facilitating a searchable knowledge base of past innovative solutions using additive manufacturing. To this end, it comprises a suite of linked ontologies covering three domains: product realization, manufacturing, and business, which in turn are linked by a unifying application ontology (ICAM) that connects a series of otherwise disparate knowledge bases (Figure 21).

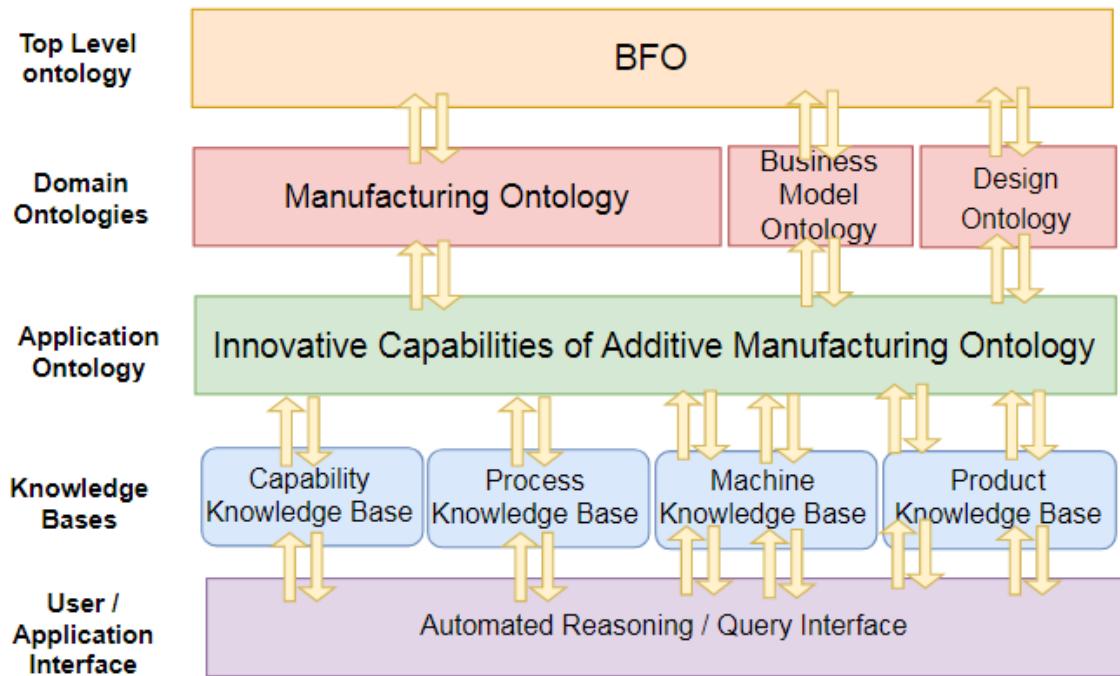


Figure 21. High level schematic of the implementation of the ICAM ontology

Since few engineering domain ontologies have been extensively vetted it is possible that future research will yield more comprehensive or better defined ontologies of domains included in ICAM. A modular structure, based on the spoke and wheel approach advocated in BFO style guidelines, was adopted to guard against this possibility (Figure 22). The highest-level ontology is BFO, which provides a top level view of all entities. Just below this level of abstraction is IAO, and by extension RO, which were deemed necessary to accurately and appropriately model all subsequent domains. From this point, the ontology splits into domain specific models, with CPM providing the main model of the design domain, MSDL and SAMPro the manufacturing domain, and custom-made business model ontology capturing enterprise considerations. All of these are supported by a set of un-pluggable ontologies that define shared concepts, such as

dimensions, various engineering material qualities, and the FBO, meaning that each domain can reference the class structure independently.

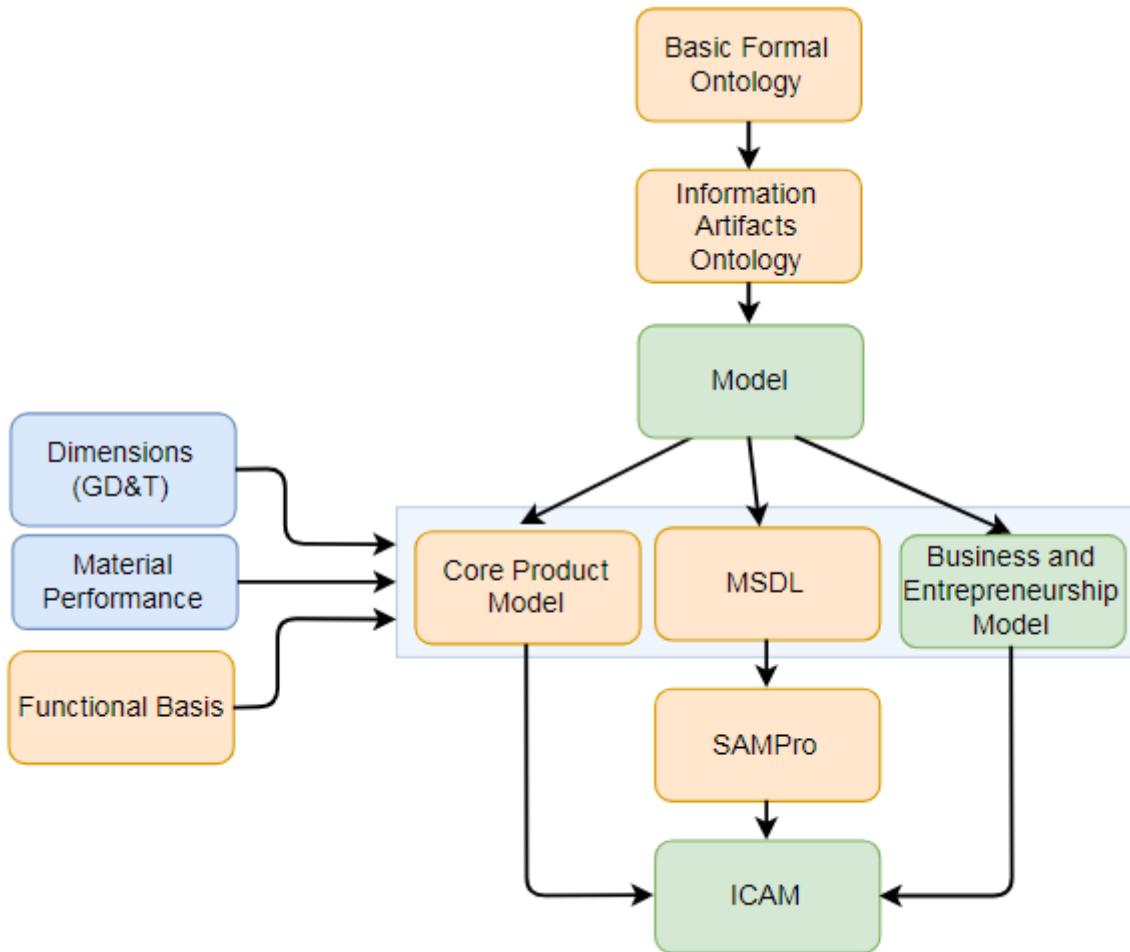


Figure 22. Dependency relations among modular ontologies. Green boxes are ontologies developed for this work, beige boxes represent existing ontologies included, and blue boxes represent custom class trees shared among ontologies

7.1.3.1. Creation of an Ontology of Business Models

An ontological representation of business models was incorporated into ICAM to capture information relating to the market aspects of product innovation using AM. This allows ICAM to represent information on how AM facilitated the delivery of value to a customer, even in cases where value to a market that is entirely divorced from the

physical embodiment of the product. Without a formal ontology to capture these details, such value propositions would be difficult to express as they rely largely on how some enterprise carries out its operations.

The new ontology, the Business and Entrepreneurship model (BEM) was developed based on existing business model development methodologies. To summarize, business models are defined as **descriptive models** that represent the constituent parts of a hypothetical business venture, documenting the resources, revenues streams, and value offered by a business to some customer or group of customers. Because they are **information content entities**, the model itself largely describes objectives, which relate various entities. Like any other model, this representation is developed with a known **rationale, assumptions, and idealizations**. Key to it is a set of **hypotheses** as to how value is delivered to some group of **agents** that constitute a **market** for the product (Figure 4). The information model thus captures the ways in which resources are exploited, and various streams of cost and revenue are realized.

Within the broader context of ICAM, AM machines treated as a type of resource available to a business, which in turn have a set of capabilities. Ownership or access to a machine bestows these capabilities to the business, and their realization enables the creation of products or services that have value to a target market. That value might be any number of things and so the ontology is designed such that it can express many types of value to consumers.

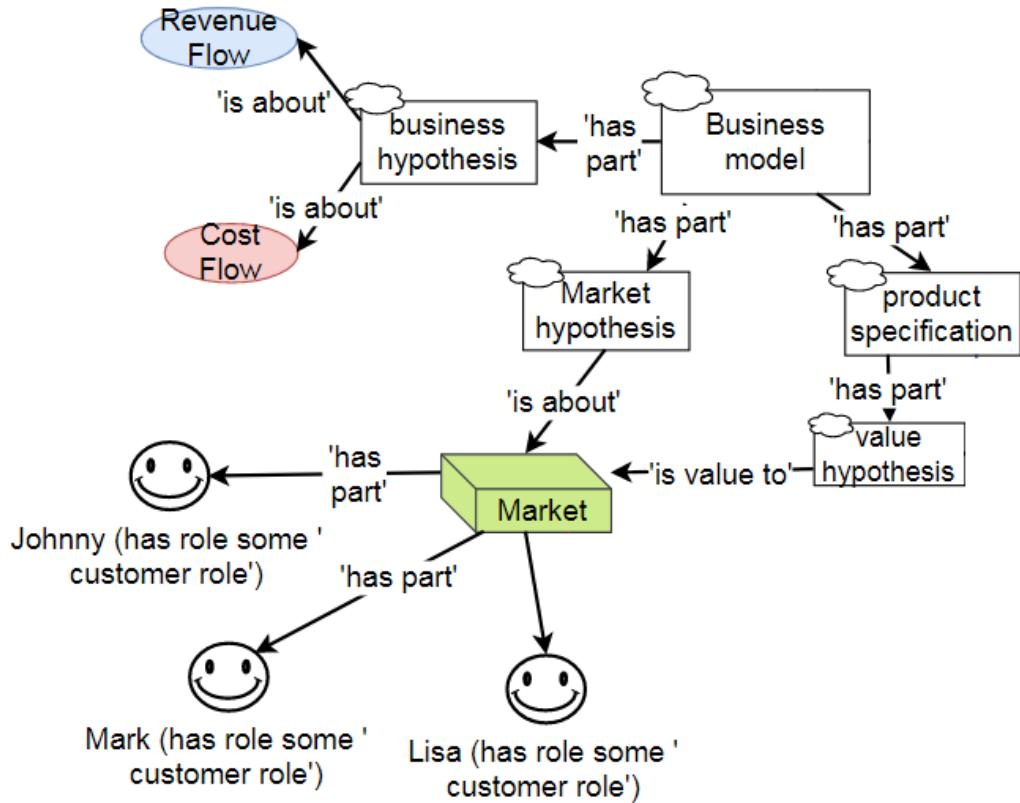


Figure 23. Partial representation of the information model implemented in the proposed BEM ontology

In the case of a physical product, it might for example have **dispositions** or **qualities** that are advantageous to customer, such as a pleasing aesthetics, or some set of functionalities that the consumer deems desirable. Alternatively, the product may itself enable its owner to participate in a process that has value, perhaps by altering or eliminating some task that potential customers might already undergo, such as in the case of a product that automates certain customer tasks. Third, the AM system may instead enable the business to instead sell a service in which they perform some process that a customer either cannot or is disinclined to complete on their own (Figure 5).

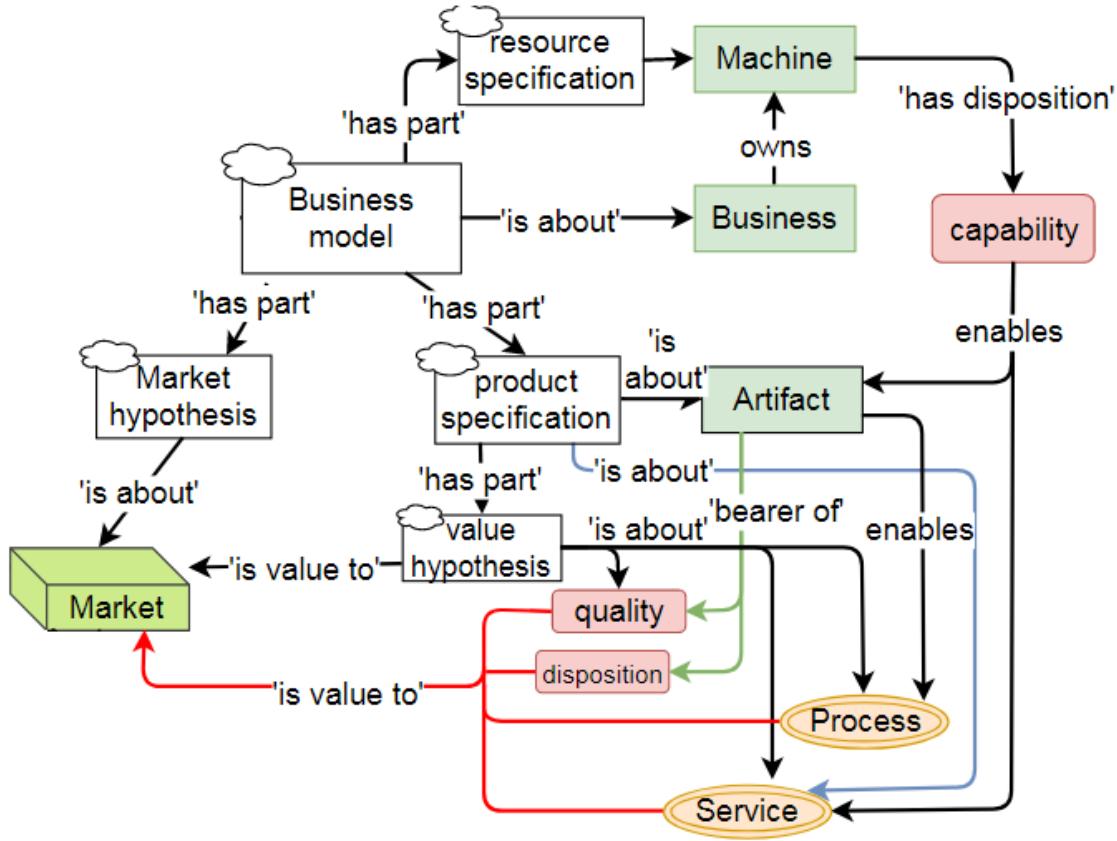


Figure 24. AM Machinery role in value delivery model in the BEM ontology

7.1.3.2. Identification of AM Capabilities

A necessary step in the creation of ICAM was to review the current market for additive manufacturing machines and to identify process or machine capabilities that have been previously reported. This served two purposes. First, it helped to directly identify and record instances that could serve as a basis for a knowledge base of AM products. Second, it facilitated the creation of a comprehensive list of capabilities, and machines having those capabilities based on both manufacturer specification and previously reported information.

A capability in ICAM is defined as a disposition of some object to be able to participate in a process at a level of quality specified in some process plan to the benefit

of it or some other agent. Put simply, a capability implies completion of a process of value to some agent at some minimal level of quality. A review of manufacturers and machines was conducted to identify both AM machines and the capabilities that they possess. It should be noted this review was not meant to populate a comprehensive machine knowledge base, but rather to identify the range of capabilities on offer from current AM machines. This review was then supplemented with a review of AM based upon published studies describing existing or proposed devices or fabricated by AM, specifically focusing on the medical device domain where use of AM is common. These capabilities were assigned specific processes or machines as appropriate.

Based on this review, a class tree (Figure 25) was created to characterize capabilities of AM systems. To keep the model consistent in the case of expansion into other manufacturing domains, we characterize these as broad manufacturability capabilities, rather than capabilities that inhere only in AM systems. We characterize three broad types of capability found in AM: fabrication capabilities, contextual fabrication capabilities, and manufacturing process output capabilities. Fabrication capabilities include the commonly cited ability to create objects that have a high degree of shape, hierarchical and functional complexity. Contextual capabilities describe the ability to complete processes under some set of conditions and include things like desktop printing and distributed manufacturing. Process output capabilities describe the capabilities of entities created with a manufacturing process, such as shape memory or bi-stability.

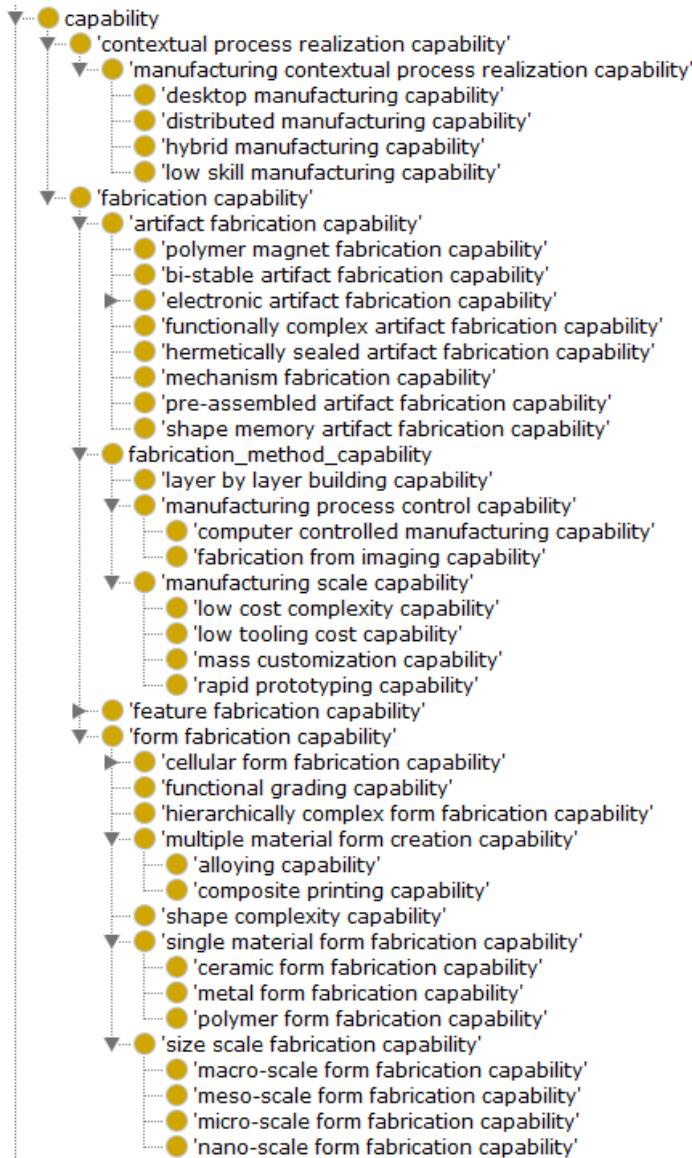


Figure 25. Partial class hierarchy depicting AM capabilities identified during the literature review

Enabling relations between capabilities were also incorporated to first show how various capabilities might be combined to realize new ones, and second to allow more efficient querying of machines and processes. For example, a **functionally graded form fabrication** capability is might be '*enabled by*' an ability to fabricate multi-material forms, a combination of shape and hierarchical complexity fabrication capabilities, or

both. By tracking these enabling relations, it is possible to automatically identify machines that have ways to create various capabilities using reasoning software and semantic queries.

7.1.4. ICAM Information Model

ICAM implements a set of relations between the disparate domain ontologies, by linking similar classes and by connecting multiple domain ontologies to knowledge bases. Details of the product are captured in a design domain, consisting of various types of information content entity. These include specifications for various aspects of the product, such as dimensions or an intended function or behavior, as well as models, metrics, and other information that motivate various aspects of the design. This design process is ultimately driven by a set of **requirements**, a class shared with BEM. **Requirements** are themselves derived from a set of customer needs or problems imposed by some existing product or customer activity. A business that is modeled by some business model uses a set of resources to realize products and services to address these needs and resolve those problems, the act of doing which is hypothesized to be of value to some consumer. These resources may in fact be manufacturing systems that complete the plan associated with the design and realize a physical product.

7.1.5. Use Process for ICAM

We propose a straightforward method for concept ideation and feasibility assessment using both the machine and use-case knowledge bases captured by the ontology (Figure 26). The process begins with a problem or need identification stage, wherein the designer solicits customer feedback to identify potential market opportunities for new product or re-design. The AM use case knowledge base is queried to identify

products or product features that targeted similar problems, product attributes, or market opportunities based on broad product ideas or customer needs. The previous cases found by queried are intended to help inspire a product concept, and to catalogue the exact set of capabilities, materials, and specific features required to realize that concept.

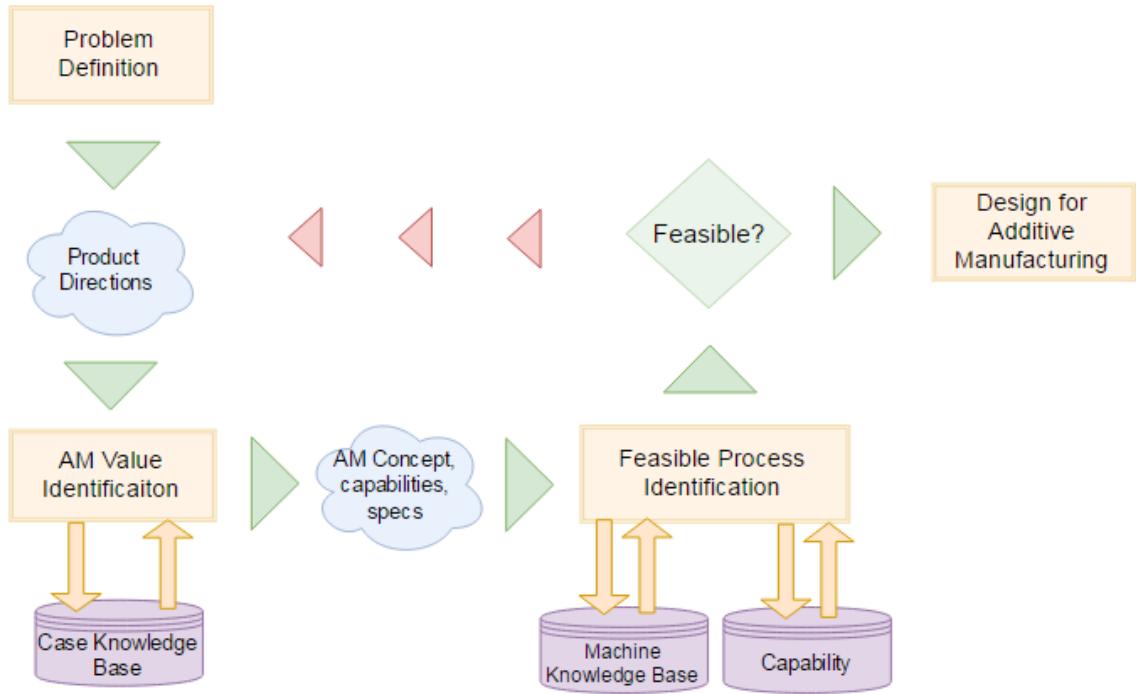


Figure 26. Proposed process for design ideation using ICAM

A second query then searches for machines that are capable of manufacturing such a product based on these requirements. For example, the designer might want to create a product that uses a self-supporting lattice and must also be made of some high-performance metal. A query then might return a set of machines that perform direct metal laser sintering or directed energy deposition processes, but not return printers that struggle with self-supporting lattices or perform processes that do not use that metal. In this case, the designer can move to select what they believe to be the best concept, and move onto a restrictive DFAM process based on the set of machines and processes

returned by the query. Alternatively, they may find that there is no system that suits their needs, and so be forced to search for more product ideas.

7.1.6. Instantiation of Product Knowledge Base

Information uncovered during capability identification process was used as a starting point to instantiate a knowledge base of machines, capabilities, and previous use cases of AM. For each use case, a hypothetical business model was created, though in many instances the products discussed are academic in nature, and thus may be incomplete in this regard. Care was taken to note the type of AM used in each product or process, and the types of capabilities used. The value of each entry was then mapped to various customers and shared concepts, such as functions, modifications of existing processes, and adjustment of qualities relevant to some customer. These were then implemented as a set of instances in the ontology as a separate knowledge base which can be opened or closed as necessary.

7.1.7. Case Studies

Two case studies were used to better understand the knowledge capture, design support, and innovation capabilities of ICAM. The first considers a design case previously described in the literature, with the aim of evaluating knowledge capture and the ability to query ICAM to solve a simple design problem arising from the author's solution. In the second, we consider an in-house design case for a surgical instrument.

7.1.7.1. Case study 1

The first case study focuses on knowledge capture. Many of the proposed functions of ICAM rely on the ability to capture information about various products enabled by or manufactured with AM. In this case we consider relatively simple surgical

products described previously in the literature. In the both studies considered, a set of simple surgical products are fabricated via AM with minimal re-design, with the authors of the reports suggesting hypothetical value in the form either cost savings [73] or the elimination of a logistical delivery problem [75]. However, both reports noted issues with the use of AM for these products, such as mechanical failure under loading that could realistically be encountered during an operation. In this case study ICAM is used capture information relating to the proposed AM surgical tools, including design and manufacturing information, capability usage, and the underlying business cases. Once complete, ICAM's product and machine knowledge bases are then queried to identify potential solutions to the authors' reported difficulties.

7.1.7.2. Case study 2

In the second case study, we consider an in-house design of a novel minimally invasive surgical instrument. Minimally invasive operations are performed through small ports with internal diameters of that are often a centimeter or less in diameter. This necessitates the creation of “tool on a stick” style devices, consisting of a handle, an elongated shaft, and a tool head remotely operated from the handle. Operations are then performed through the port, visualized with a similarly designed camera. While offering significant benefits to patients, the operational context requires a great deal of skill, and in many instances makes finesse driven tasks such as suturing quite difficult due to loss of dexterity, tactile feedback and visibility. Thus, in many operations stapling devices called endocutters are frequently used to partition and seal tissues. However, their size and shape often makes them poorly suited to range of operations due to small operating fields, inconveniently shaped anatomy, and significant limitations on the actual device

geometry due to the port structure. The focus of this case study is thus a design where the objective is to deliver a smaller, potentially more flexible tool through a port.

7.2. Results

7.2.1. Construction and Classification of ICAM

ICAM was successfully constructed in Protégé 5.2 [242]. The ontology was subsequently instantiated with existing knowledge relating to machine specific capabilities and past products using the Cellfie plug-in [243] to read in spreadsheets of related data. A fully implemented version of ICAM with instantiated knowledge bases was classified with the Pellet Reasoner [153] without any inconsistencies. Manual inspection of the inferred and asserted class hierarchy showed that they were identical.

7.2.2. Case Study 1: Knowledge Capture for Additive Manufacturing of a Simple Surgical Tool

7.2.2.1. Case Study 1 Results

ICAM was used to capture information relating to the case studies. In both cases, the devices in question provided a value to their customers by eliminating the need for a customer to participate in a series of processes. As represented ICAM then, both cases focus on two processes – the only required without AM and the one required with AM. For both the retractor and field surgical kit case, an agent participates in some process of inventory management, which has sub-processes consisting of maintain a stock of relevant parts, tracking that stock, and then ordering and receiving parts. As ICAM does not have an inventory management model, these are simply represented as instances of a **planned process** that realize various receiving, storing, and transferring functions, with readable language comments describing details of what the instances represent.

The surgical kit for space missions is fairly demonstrative of the knowledge capture abilities of ICAM's linked ontologies. In this instance, the problem the customer has is a process that is typical of terrestrial operations (the shipping and delivery of surgical tools) that is impossible, or at least very inconvenient in the case of a space mission. Thus, the process itself is a problem, rather than a disposition it realizes. The solution is simply to use AM to replicate existing surgical tools. A simple property chain axiom infers that because the service (AM printing) eliminates a process (shipping and receiving), then clearly it is a value to the customer. Going further, it can be seen that several capabilities of the printer used (its ability to realize certain material qualities, be run by low skill users and desktop printing ability) enable the very process that solves the problem. Thus, the use of AM in this case offers advantages in the form of the manufacturing context, rather than the specific product being created. In the study, the authors did additionally note that the AM material strength was not reliable at the given thickness, and so they increased thickness. This is reflected in the instantiated case as a problem with one output (a thin surgical tool), having to do with its **ultimate tensile strength** (indicated by membership of the problem instance in said class), which is solved by a manufacturing plan that which realizes an increasing function that affects thickness. This is connected to the problem disposition via the **has solution** property, indicating that the thickness change fixed the strength problem.

In the case of the retractor, each of these sub-processes realizes costs, with the receiving portion being an output of a process that includes shipping, which itself realizes yet another cost. These costs are seen as a problem to customer. The described service, in which the retractor is instead printed on site from a 3D CAD eliminates the shipping and

receiving process, and in doing so eliminates the cost. As in the previous case, a property chain infers then that the AM printing service is of value to the customer (in this case a hospital). The information model moreover captures that the key AM contributions were the realization of several capabilities: distributed manufacturing, low skill manufacturing, and desktop manufacturing, all of which combined enable the service in the first place.

As noted by the original authors however, there is still a problem introduced by the new service. The retractors break at too low of a load. Thus, the output of the printing service (an AM retractor) is noted to have a problem with a '**has problem**' relation, which is an instance of the class **failure process**, which realizes some **ultimate tensile strength**. This provides the basis for a search of ICAM's broader AM use case knowledge base to identify a suitable design change and or process substitute that will improve strength of the part (assuming bounding geometry changes are infeasible or undesirable) while still enabling the delivery of the printing service. To do so, a simple query is used to search the ontology for an analogous case:

(‘**bearer of**’ some (‘**is solution** to’ some ‘**ultimate tensile strength**’) and ‘**is specified output of**’ some (‘**performed by**’ some (‘**has capability**’ some ‘**desktop manufacturing capability**’ and ‘**has capability**’ some ‘**low skill manufacturing capability**’ and ‘**has capability**’ some ‘**distributed manufacturing capability**’)))

The first statement looks for entities that have a disposition (presumably strength) that solves a problem stemming from an ultimate tensile strength. These would presumably be cases where a new material was used, or some reinforcement was added. The second narrows the search to cases where the part is manufactured by a system with the same capabilities that enabled the retractor service in the first place. Running the query returns a case where an existing part was specifically reinforced with carbon fiber using a desktop fiber printer, resulting in a part that was stronger. Applied to this case,

the fiber printer could be used in place of the authors' system and used to create a part with mechanical properties that are more appropriate for the use case in question. Provided geometric changes are also permissible, the query also returns the surgical toolkit case, where printed devices were thickened

7.2.3. Discussion Case Study 1

The results of the first case study show two key findings about the use of ICAM to capture knowledge and then reason upon it. In both cases, the model was sufficient to capture information relating to each case relatively unambiguously. Because of the information driven approach used to express relations in ICAM using primarily the RO, the knowledge from the first case was made reusable. It is difficult to see otherwise how an issue relating to mechanical failure as a result of relatively poor mechanical strength would otherwise have been identified. ICAM's proposed use case also appears to have been shown to be reasonable. In addition to the first case where simple geometric changes resolved a device failure, the second case used a query that consolidated the ideation and feasibility checking aspects of ICAM. A past solution used a printer with the necessary capabilities, and thus the query returned a result. However, this also implies that there exists a printer within the knowledge base that has the full set of required capabilities in addition to those needed to implement the reinforcement solution concept. The second major takeaway however is that ICAM is limited largely by the scope of its knowledge model. It is at the moment impossible to look for cases where a "shipping process" was disrupted. This suggests that further extension with domain specific knowledge might be of value.

7.2.4. Case Study 2: Minimally invasive surgical tool

7.2.4.1. Case Study 2 Results

Unlike the first case study, no instantiation of ICAM was required as it is being used to investigate a device concept. In this case, the key concern is ideation to find ways to reduce the cross section of the proposed surgical tool. To do so, a query must be formulated so as to identify relevant cases from the case study knowledge base. Several methods approaches might be feasible, and so can be combined into a single query using multiple “And” statements. First, it should be noted that the endocutter tool is modeled in ICAM as a design specification, having some dimension specification that exceeds the corresponding specification in its requirements. From the problem, the designer can infer that they are looking for solutions that either solves problems have to do with other members of the class **area**, or alternatively realize a reducing function that affects area, expressed using the function hierarchy from the FBO. To identify potential design directions from the AM case knowledge base, a query such as the following is used:

‘is solution to’ some **area** or (**realizes** some ‘**reducing function**’ and **affects** some **area**) (11)
or **‘has function’** some (‘**reducing function**’ and ‘**realization affects**’ some **area**)

As with the past case, the first statement in the query identifies cases where some aspect of the case was a solution to a problem with an area. The second part looks for AM use cases where a product or service realizes a function that has the effect of reducing area. The third looks at cases where the product itself is designed to have the function of reducing some area.

A query to search the case knowledge base instantiated in ICAM yields two results representing different ways of reducing area. In the first case (Figure 27), and FDM process is used to make a bi-stable structure with surrogate hinges that is folded in

one configuration during introduction through a port, and then unfolded to achieve its desired grasping functionality. The fold pattern then, has some function which reduces area. In both cases however, some information is lost as ICAM does not have a medicine specific information model to draw upon, so the results are not searchable by field.

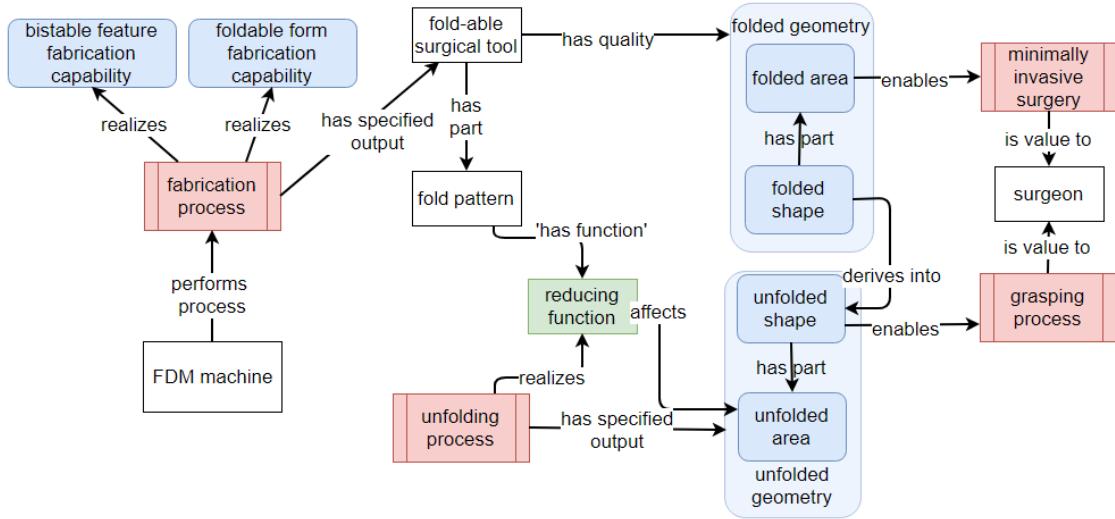


Figure 27. Representation of folding surgical tool model in ICAM. The tool is inserted in a folded configuration, then unfolds in vivo. Model based on device reported in [244]

The second case (Figure 28) is quite similar. Rather than use a designed folding structure, it instead relies upon a shape memory material and a geometry that can be stretched like a cable. In this case the shape memory allows a deformation process that substantially changes the overall shape of the part, reducing the area such that it can be introduced via an endoscopic port (Figure 28). Once introduced, the shape memory of the material causes it to unwind, blocking off a vessel.

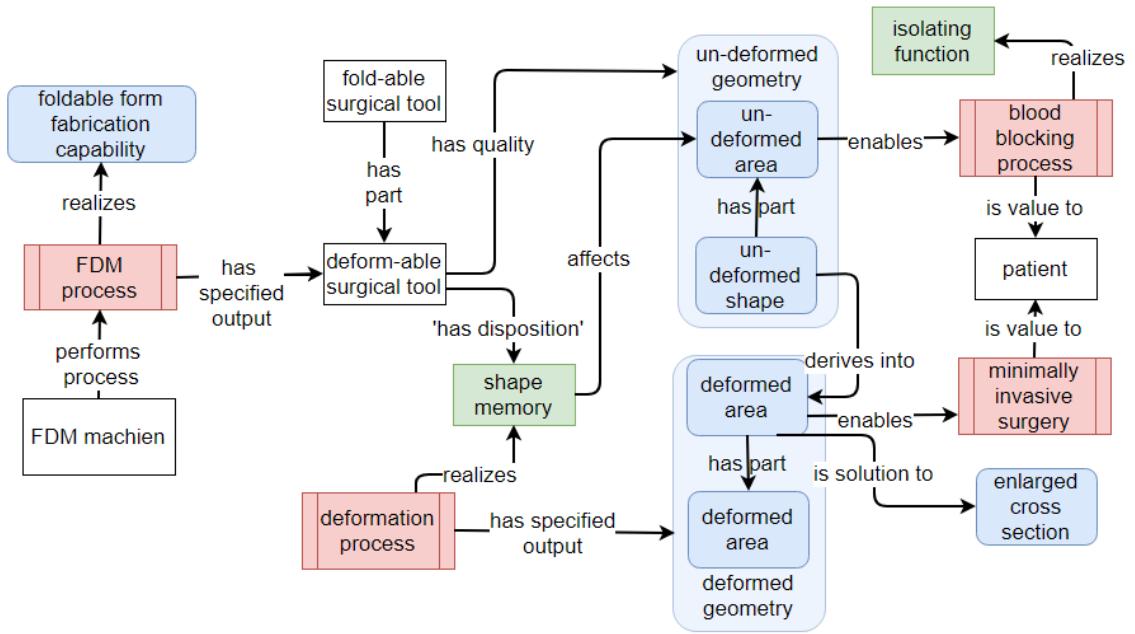


Figure 28. Representation of case in ICAM. The tool undergoes significant deformation during introduction. However, it is made of a shape memory material, which changes shape in-vivo to block a vessel. From [80]

Having seen these two options in ICAM, it was quickly determined that the necessary rigid structures of endocutter prohibit large scale deformation as in the case of the shape memory approach. However, foldable structure was deemed to be a viable approach. From this, a concept for an endocutter which has a hinge structure in its distal and proximal sides was developed. The hinge is bent during introduction, leading to an elongated longitudinal dimension, but a reduced transverse width, reducing the overall size of the stapler (Figure 29).

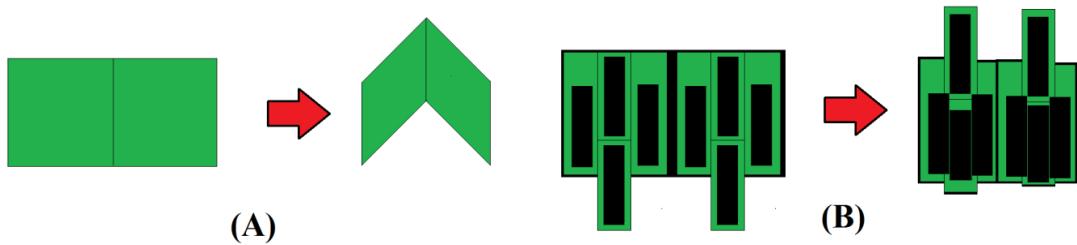


Figure 29. Concept generated from queries of ICAM. (A) Folding box structure that uses a hinge to fold. (B) Base unit of endocutter stapling surface. Black rectangles represent wells containing staples. The individual segments fold over on another as the box itself folds, advancing the center rows.

This slight fold, coupled with a modified internal structure to allow transverse movement would a slight, but significant reduction in area, and coupled with further design cases could also introduce novel functionality into the device.

7.2.4.2. Case Study 2 Discussion

Case study 2 demonstrates the use of ICAM for a less simplistic device. Even for this more complex device, the querying needed to identify the device was nonetheless relatively straightforward. Because ICAM contains a sub-ontology dealing with various design dimensions and material properties it can be queried using these in combination with functional information. So long as the problem can be defined in terms of various dimensions, something which could be supported using rules to operate on various specifications. In doing so, it found two directly related devices that employed potential solutions from a related field. While ICAM has a limited knowledge base of AM use cases at present, this could be expanded further, potentially opening the door to solution from outside contexts. This points to both a potential advantage and a potential problem. In the latter case, ICAM lacks domain specific models to capture full context, meaning that as the number of cases increases the percent that are ill suited might increase in turn.

However, this concern might be mitigated by simply importing domain models into ICAM to support various domain-specific case sets. The advantage however is that this same property might allow a great degree of cross domain reasoning, whether domain knowledge is included or not.

7.3. Discussion

Many approaches have been proposed for the use of creativity in DFAM, many of which utilize past AM successes to inspire new design directions. On its own this approach is potent, but somewhat limited. Without a robust way of selecting past successes that are directly relevant to a specific design a designer is left to sift through a large mass of disparate data that may or may not be relevant. This relevance may moreover not be immediately obvious from pictures and may be labor intensive to associate with a design based on plain text descriptions. With the introduction of ICAM we propose an extension of past methods. Rather than use information about past successful deployment of AM, we instead propose to capture the knowledge from those past experiences and model it in such a way that it can be easily, very specifically retrieved, and analyzed by a designer to aid in ideation. Though at this phase ICAM is only implemented as a less easily usable information model, we believe that this model could serve as a basis for highly effective design ideation tools.

As seen in both case studies, ICAM has potential for innovative design ideation. In the first, a simple problem is presented in the case of a retractor that is not necessarily strong enough, and the knowledge base is queried to find a correspondingly simple set of solutions. Realistically, an intelligent designer might have come up with these by themselves based on first principles. Less likely would be that the designer would know

that a reinforcement option might be swapped directly into the original model of distributed manufacturing envisioned in both cases. While a person highly familiar with the AM domain might know of printers that had the necessary combination of capabilities, they would be forced to rely on recall. A person without this expertise might be utterly unable to make such an association. Thus, the capture of knowledge in this case has potentially significant value in even a simple design case.

By comparison, although the second case study solutions might be simple once the retrieved designs are fully understood, that understanding might not be particularly easy to reach. Certainly, text based descriptions could capture the information, but lacking a way to mine that text to identify a subset of potentially useful cases that approach has severe limitation on how many alternatives a designer might reasonably consider. A database lacking a knowledge model might capture the use of foldable or shape memory structure in AM, but its application to the specific problem would again be difficult to surmise without significant mental effort. Picture-based systems might be sufficient to indicate shape memory to reduce area, but the dynamics of folding would be difficult to represent to say the least, and yet again difficult to associate with a specific design challenge. In this case then, ICAM appears to offer a significant benefit to the designer. Rather than browse through random and or semi-complete use cases, they can instead limit their reuse of past knowledge to cases that have some desired similarity to the problem at hand. If expanded to include many cases from many domains, this might make ICAM a very powerful tool for design ideation.

Though we focus primarily on the usefulness of ICAM for ideation, it should be noted that ICAM has its roots in a highly formal knowledge model, designed to support

interoperability and reusability of information. The usefulness of this knowledge intensive approach is seen in both case studies. Because ICAM supports a knowledge driven approach, ICAM can be used to identify highly specific information, such as specific functionality or alteration of specific attributes of some entity. This means that every instance added to its knowledge base makes ICAM more powerful overall, able to search a wider array of products and along more and more value generation pathways. Case study one shows how two related instances might be used to gain knowledge about each other, and how an only tangentially related case might be used to solve a problem common to both AM applications. As ICAM is expanded, these tangential solutions might become more numerous, and ICAM as a whole more utile. This is not necessarily the case in solutions that lack a formal knowledge layer. More design instances might mean there are more cumulative design directions available to the designer in the entire framework, but their chances of finding them might become increasingly slim as a database expands.

The demonstrative case studies however did unveil some limitations in this approach. First, the quality and number of relevant products returned from a given query is very much dependent on the contents of ICAM's knowledge bases. While case study one identified a useful case via a highly restricted query, it may not have done so were the knowledge base less robust in this area. In a simpler case, an incomplete machine database might erroneously lead a designer to conclude that no available system has the set of capabilities they require to realize some product concept. On top of this, instantiation of knowledge is fairly involved. One must map out several aspects of a product. In this study we accomplished this via an ontology software plug-in, but this

approach requires extensive knowledge of both the plug-in and the underlying ontology, something that makes mass use deployment difficult. More work may thus need to focus on tools built upon the ontology to render it more usable and less labor intensive to operate.

A second, minor limitation points to a potential direction for future research with ICAM. In both cases, lack of a specific domain model led to a loss of information that might have been useful in future querying. In projects where the products discussed in case study one are relevant, it may be useful to search for solutions that simply eliminate certain types of process. Similarly, in case study two both solutions were from the same domain (minimally invasive surgery) as the proposed product under investigation. Being able to look at devices in the knowledge base used in minimally invasive surgery could be useful for both design ideation (as it would quickly yield a laundry list of small mechanisms used in these surgeries) and for analyzing the current market to identify innovative new business models. This suggests that domain specific expansions of ICAM might support highly detailed reasoning based on non-engineering domain knowledge.

The potential for expansion points to one of several strengths in this approach. The multi-domain model in ICAM is clearly engineering focused but supports expansion into other domains using a similar process to the one used to re-align engineering ontologies. This might be used to further define existing knowledge within the knowledge bases and expand upon it for use elsewhere. Absent a formal information model, this would be difficult to do in a replicable way. Moreover, the development approach used in this work means that the ontology should interoperate easily with other BFO conformal ontologies. The use of enterprise information is also a major strength.

Though case study one focused largely on a knowledge capture and reuse exercise, it is notable that the retractor design points to a highly unorthodox business model for the medical space. Distributed production of various medical products is uncommon, but application of this principle elsewhere could yield interesting new innovations. Without an approach analyzing both manufacturing and economic factors, this data would likely be lost.

CHAPTER 8

SUPPORTING DESIGN FOR ADDITIVE MANUFACTURING USING A MODULAR FRAMEWORK OF ADDITIVE MANUFACTURING DOMAIN ONTOLGIES

This chapter focuses on the development of a Design for Additive Manufacturing Processes Ontology (DAMPrO) and a method to use the knowledge captured in the ontology to aid detailed design of AM products and AM process planning. While the work presented in CHAPTER 7 focuses mainly on the issues of innovative use for AM, effective DFAM also presents major challenges. Many DFAM processes instead focus on the limitations of some process, and then design around those. However, this approach typically involves first selecting a manufacturing method, and then using some DFAM method to complete the design process.

The view taken in this work is that a designer must have the ability to reason upon a diverse set of AM knowledge throughout the detailed design process. This would allow the designer to gauge the effect of various design decisions on manufacturability across a range of possible manufacturing and potentially design options. In doing so, the designer is able to benefit from a more open design space, which they only restrict once a process is deemed non-viable. The work presented in this chapter seeks to address the challenges inherent to many DFAM methods by using a suite of ontologies to support the capture and representation of knowledge about additive manufacturing processes and specific machine models. This knowledge can then be applied to engineering design problems. It is envisioned insights gained from queries and automated reasoning on this knowledge

will allow a designer to design for AM broadly, rather than for a specific AM process.

The result is the Design for Additive Manufacturing Processes Ontology (DAMPrO).

8.1. Methods

8.1.1. Structure of the Proposed Ontology Framework

DAMPrO is structured as a series of linked modules, each which captures information about a specific subset of information needed for DFAM. These are then used to link a domain ontology (the core of DAMPrO) to knowledge bases containing specific AM process and machine knowledge. This domain ontology and knowledge base is then linked to an ontology capturing design knowledge.

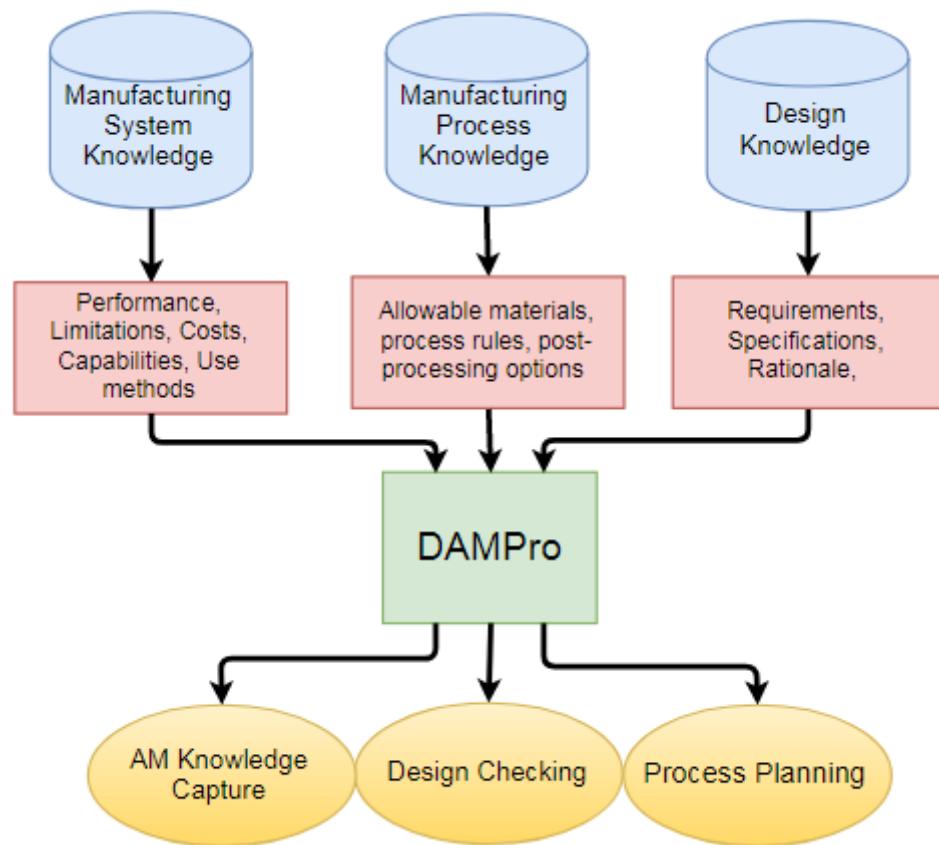


Figure 30. Information types and intended capabilities of DAMPrO

DAMPrO was implemented using a set of modified legacy ontologies and several small, custom ontologies. These custom ontologies aim to capture aspects of the engineering domain that have not been modeled with an upper level ontology. The design is intentionally modular, with each domain of interest kept largely independent of domains at similar levels of abstraction. Because of this structure, computations can be completed using only a subset of the framework.

8.1.2. Construction of DAMPro

8.1.2.1. Selection of a Top-Level Ontology

A upper-level ontology model was used to ensure DAMPrO's formality and reusability by future researchers. The Basic Formal Ontology (BFO) [171] was selected for this work due its past success in the biomedical domain, as well as ongoing efforts to extend it into the engineering domain. In BFO, all entities are considered to either be **continuants** or **occurrents**, with the latter representing discrete events that unfold in time, and the former comprising entities that exist maintain identity throughout time. Continuants are split into **independent continuants** (things made of matter, spatial regions, and the like), **specifically dependent continuants** (traits such as inherent qualities of and dispositions that may be realized by those objects and thus cannot exist without some independent bearer), and **generically dependent continuants**, which include entities like information which may continue to exist even if a specific bearer ceases to.

8.1.2.2. Inclusion of Existing BFO Conformal Ontologies

The Information Artifacts Ontology (IAO) [241] was included to provide additional classes and relations for dealing with information. This is important for dealing

with information intensive design activities and specifications. The IAO consists of a hierarchy of various types of **information content entities**, which are essentially anything that can be used to bear information. These were extended to the design domain by adding classes for **technical models**, design rationale, and directives that define product requirements, specifications, and manufacturing plans. Inclusion of IAO by extension also imported the Relations Ontology (RO), which defines a minimal set of relations between the high level classes of the basic formal ontology. Most notably, this includes relations that are used to express that objects bear various qualities and dispositions, that these in turn might concretize various information content entities such as measurements or specifications, and dispositions are realized in processes in which their bearer is a participant. Taken together, these three ontologies define the high-level ontology used throughout DAMPrO.

8.1.2.3. Engineering Domain Ontologies

In addition to the BFO, RO, and IAO, a set of engineering domain ontologies were also included in DAMPRO based on their relatedness to DAMPRO's DFAM application area. The NIST Core Product Model (CPM) [196] was selected as a starting point for defining a subset of design domain concepts in DAMPRO. CPM is an ontology of engineering products. Designed objects are modeled as forms having material and geometry, features composed of forms and having specified functions, and artifacts composed of features and having some designed behavior. The Manufacturing Service Description Language (MSDL) [190] developed by Ameri et al., was included for its detailed hierarchy of manufacturing processes, and axioms dealing with a range of material properties. MSDL is extensive, with a comprehensive class hierarchy defining

various types of manufacturing process, as well as classes that deal with manufacturing as a service and capability of some manufacturer. The Semantic Additive Manufacturing Process (SAMPro) [191] ontology, which extends MSDL with AM information, was also included to provide classes to support AM process knowledge capture.

8.1.3. Re-Alignment of Engineering Domain Ontologies

8.1.3.1. Redefinition of Ontologies

The engineering domain ontologies had to be extensively edited to conform to BFO's knowledge model and style guidelines. Protégé [242] version 5.2 ontology editing software was used, along the Pellet automated reasoning software [153]. An iterative process was used to re-define each ontology. An initial pass was used to nest the various classes within a BFO parent, and to classify the relations as sub-relations of RO properties. Next, the semantic reasoning software was used to identify inconsistencies resulting from this re-classification, which were then resolved through subsequent modifications. This process was repeated until no inconsistencies were noted, indicating that the realigned ontologies were internally consistent. Subsequent editing then modified the domains and ranges of object properties so as to express more information rich content. For example, a ***hasMaterialProperty*** relation might have its domain modified to be (**object** and '**bearer of**' some **material property**), and its range modified to be (**material property** and ***concretizes some measurement datum***). This redefinition process allows assertions of the original property in a domain ontology to be queried and reasoned upon more easily in the unified framework. In the context of knowledge rich ontologies like MSDL, this has the effect of making the knowledge more searchable and easier to reason upon.

A final set of modifications split ambiguous terms within the ontology to better defined separate ones and update all usage accordingly. For example, a ***has process*** relation in MSDL might refer to many different types of object relations, such as a machine performing some process, an artifact resulting from some process, or a service including some process. By splitting these types of relation, the ontology is made both more formal and more expressive. This allows coherent domain and range restrictions to be placed on each property without introducing inconsistencies or erroneous inferences. Because of this final modification process, the use of a property it implies a very specific relation between types, reducing ambiguity.

Once each ontology was made conformal to BFO, the full set of included ontologies had to be integrated into one another. While ontologies are theoretically extensible and interoperable, this typically depends on shared development principles. In the case of the engineering domain ontologies, many terms in the ontologies overlapped one another. This makes integration difficult as terms might be subtly different in each context, and because entities with unique IRIs are interpreted as separate terms. To solve this the engineering ontologies were refactored to create a hierarchy of non-overlapping, interdependent ontologies. One of two actions were used to address this issue on a case by case basis. For shared terms deemed vital to this work, terms from various ontologies were split from their respective models and re-engineered as separate unplug-able ontologies. These separate sub-ontologies were then imported into the overlapping ontologies, and the ontology assertions edited to refer to the IRIs of the new sub-ontology. Terms were deprecated and moved to an **Obsolete Class** super-class outside of BFO's hierarchy if they were deemed non-essential or outside the reasonable scope of a

parsimonious ontology of some domain. For example, MSDL information relating to materials and material properties was split so that it might be referenced by CPM, which has a slot for materials. Other terms, such as a classification of various types of product were deemed non-essential and deprecated.

8.1.3.2. Development of Engineering Design Module

Engineering design is a major sub domain of DAMPrO. CPM provides many core classes for describing engineered products. However, it does not distinguish between material and immaterial aspects of a product, such as physical features and holes. It also lacks an upper level model for how to deal with specifications for the dimensions or performance requirements of the product. It was thus deemed necessary for DAMPro to support an expanded model of engineering design (Figure 31). This led to the creation of a design framework including CPM, IAO, and set of sub-ontologies aimed at capturing fundamental engineering domain knowledge. To this end, simple, BFO conformal class hierarchies were created and given definitions to represent information about geometry, engineering materials, material properties. These extend CPM alongside a set of information entity classes that capture information about how the designer has specified the intended design, as well as occurrents reflecting the steps of the design process. The design process itself was modeled as a set of **planned processes** that *realize plans*, which in turn are described in instances of the newly defined **design specifications**. So, a customer engagement process might be the subject of a plan which specifies what customers to engage, how they should be engaged, what the objective of this engagement is, and so on.

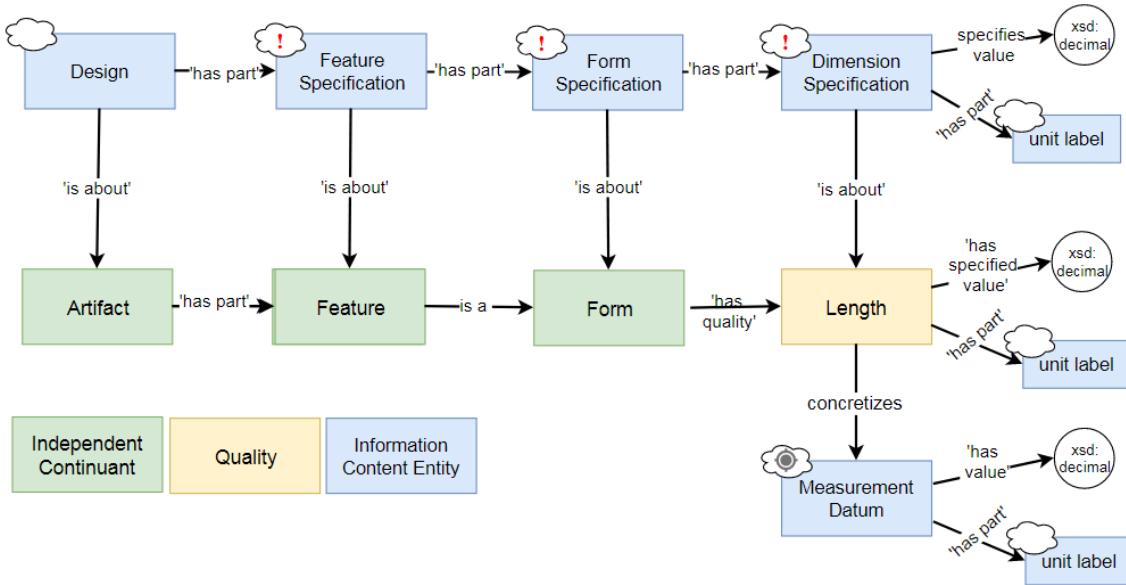


Figure 31. Treatment of design information in DAMPro. The basic structure used by CPM is supplemented by information artifacts.

The resulting design module also contains several classes to reflect knowledge contained in and gained from engineering models, as well as various types of specification that are specific to engineering design. Cumulatively, this and information gained from other activities forms a design rationale, which underpins the design itself. While generally applicable to designs, the relevant parts of the design for DFAM are its capture of a product's specified geometry and information relating to manufacturing plans. In the former case, the design's intended shape and structure is expressed via a set of specifications relating to the various forms, features, and intended functions of the final. These are supplemented by the engineering terms and a set of classes of dimension defined based on geometric dimensioning and tolerance symbols and callouts. In the latter case, the manufacturing plan is another information content entity composed of a set of sequentially ordered manufacturing processes, or process candidates which can then be assessed at a process or system level.

8.1.4. Development of AM Modules to Support Process Planning

The framework described in sections 8.1.2 and 8.1.3 provides the core information model for capturing information relating to additive manufacturing knowledge. However, additional modeling work is required to implement process planning and design checking functionality in DAMPro. These extensions of the core terminology combine knowledge bases with reasoning capabilities. For this reason, they are discussed hereafter as applications or modules within DAMPro. While these applications could be created as a single coherent addition to the ontology, a modular approach was used for this work. This offers several advantages. Smaller, less memory intensive modules can be classified relatively quickly with Reasoning software. It also means that in certain applications one can define classes that are overly specific and/or impractical in other cases. By isolating these to applications where they are useful, other modules can be defined at a more appropriate level of granularity. The following sections detail the creation of applications to support automated and query-based identification of appropriate processes, process plans, and machines to support DFAM.

8.1.4.1. Development of a Model to Classify AM Forms and Features

A limited classification of AM forms was developed to support the instantiation of manufacturing process design rules. Design rules and guidelines rely typically specify limitations on the set of forms that may be manufactured using some process, the dimensions of these forms, or tolerances on those dimensions. Corresponding terminology is thus needed to express these rules in a way that enables automated reasoning. For example, instantiation of a rule for a self-supporting hole might rely upon terminology to describe a circular hole.

The resulting terminology differs from traditional manufacturing features such as slots, pockets, etc. While commonly used to describe geometric features, they are often ambiguous and defined based on specific process limitations. In the context of AM, many of these limitations do not exist, creating a challenge for an ontology that seeks to be universally true in its definitions and assertions. For example, it is difficult to define a distinguishing line between a hole and a slot without appealing to some tooling and tool path. These are often not universal, and indeed are may not exist or are simply not important in the case of AM. These issues point to a need for a more general model of features within the context of AM. To avoid this, we characterize product geometry in terms of forms and voids. The former, as with CPM, has a combination of material composition and geometry while the latter bears only geometry and position type information. Geometries that are commonly important to AM are simply forms or voids having specific qualities or are compositions of both such as the case of overhangs. This characterization has the advantage of being coherent irrespective of manufacturing process, and indeed could be applied to biological or other naturalistic structures. More specific descriptors such as terms indicating various types of shape or size can then be used to construct more granular descriptions of the forms that compose some design.

8.1.4.2. Model for AM Process Parameters

As noted in Chapter 2, the quality of AM parts is highly dependent on the process specific parameters utilized when building an AM part and the post-processing performed on the part. Material properties can vary dramatically as a result of any number of factors depending in the process, and many manufacturers provide process information based on specific parameter sets (sometimes called “recipes” or “plans”). As a result, different

processes can be manipulated to affect the outcome of a product. The ontology was extended to capture this input output relation, meaning that for any given process or machines a potential user might query this information to identify process plans suitable to their needs.

A given process plan is captured in the ontology as a **manufacturing plan specification**, which describes a realizable entity (a **plan**) that is *realized as* a manufacturing process. The specification is used to link information relating process parameters to various machines that might realize the specified plan. Subsequent measurements of part traits are then captured as **information content entities** that are “about” the traits that are born by parts resulting from realization of the process plan. Extrinsic factors such as measurements of process conditions are captured in a similar manner and used to further contextualize data. These entities can then be queried to identify plans that have or are expected realize desired material qualities.

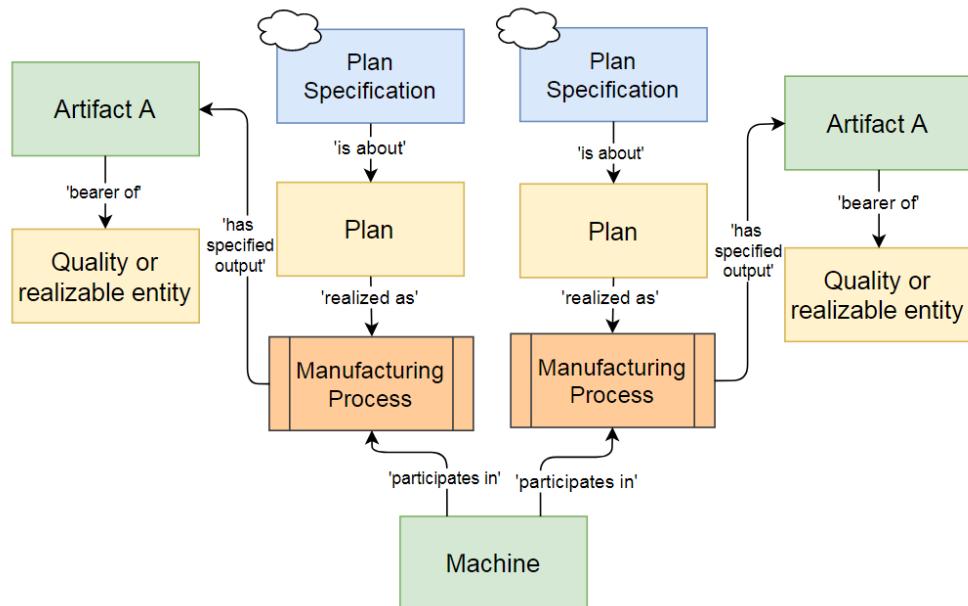


Figure 32. Information model to express process plans implemented by AM machines

These manufacturing plans can be assigned to specific machines. Along with linked measurement data reflecting part properties that some given machine might be able to realize. They constitute assertions of machine **capabilities**. These might be used to discriminate between possible candidate machines or between candidate parameter sets. In cases where raw data are available, these material property and capability measurements can be further summarized using **technical models** such as statistical models which can serve as the basis for estimates be of expected material property values.

8.1.4.3. Model for Additive Manufacturing Process Rules

A set of process rule modules were developed to capture information about known problem features identified in the literature. Within the context of an ontology, these rules can be used to enable semantic reasoning about the manufacturability of an object based on a set of geometric specifications. DAMPrO uses a multi-step process within the class structure to assert and reason upon rules. First defined classes are used to define the conditions where the rule applies. Defined classes in OWL are distinguished by axioms specifying both the necessary conditions for class membership and those that are sufficient to determine class membership. This means that an entity's membership or non-membership can be automatically determined with reasoning software. Thus, if a class is defined according to a threshold beyond which a rule is violated, design specifications that violate the rule can be aggregated automatically.

The second step is formulation of the rules themselves. Each rule is an instance within the ontology. This instance is linked to a unique class as described above that has been defined according to the conditions under which some specification *is subject to* the

rule. The rule instance itself is linked to a consequence. This consequence might be any number of things. For example, a **warning** might indicate the likely effects of attempting to manufacture a form having problematic geometry. Alternatively, a **recommendation** might describe some course of action that can be used to avoid a potential problems. In case of a steep overhang for example, a warning might point to a **requirement specification** that details the need for a sacrificial support structure or note that surface roughness might be expected to fall within some increased range. Combined with a simple binary logic chain, automated reasoning software can automatically append these consequences to problematic design specifications allowing them to be easily queried once the ontology is classified (Figure 33).

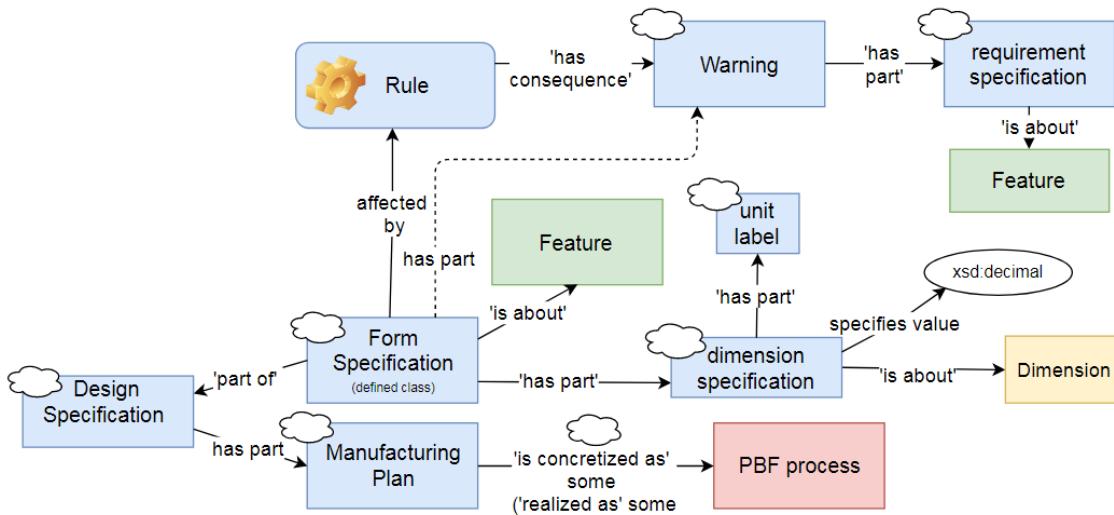


Figure 33. Information model used to express and assess process-specific design rules

Sets of rules for a given process were implemented as a module in a unique ontology file that can then be imported into an application ontology that contains instances of interest to the designer. By importing multiple process rule files and running

semantic reasoning software to classify the case instances, the user can obtain design feedback about multiple processes simultaneously.

8.1.4.4. Model for Additive Manufacturing Machine Parameters

While broad process rules might restrict possible designs, many issues are likely stem from a specific machine or machine model. For example, different machines using the safe process might have different minimum layer thicknesses or accuracies. Alternatively they might operate at different speeds, or realize different costs. These types of constraints and properties are asserted in an AM machine module. The module uses the design and manufacturing ontologies to annotate a knowledge base of different machine models. Machines are captured in the ontology as a set of classes having subclass axioms defining aspects of machine performance. So, for example, all members of one specific machine model might be asserted to have some minimum feature size, represented as a capability described in some specification. Additional subclass axioms form restrictions on the type of process that the machine can complete, permissible materials, and any other capabilities or limitations shared by all machines of the same model. The Reasoner evaluates these specifications automatically using a rule created in the Semantic Web Rule Language (SWRL) [138]:

```
'design specification'(?design), 'manufacturing specification'(?plan), 'length specification'(?spec1), 'length specification'(?spec2), is about'(?plan, ?machine), 'has part'(?design, ?plan), 'has disposition'(?machine, ?cap), 'is about'(?spec2, ?cap), 'specifies minimum value'(?spec2, ?val2), 'has part'(?design, ?spec1), 'specifies value'(?spec1, ?val1), swrlb:lessThanOrEqual(?val2, ?val1) ---> 'incompatible with'(?plan, ?machine)
```

(12)

The rule compares the specified feature size to a dimension specification on a given machine. The first set of conditions ensures restricts the rule to individuals of the specific types, preventing erroneous inferences. The second half checks for instances where the conditions shown in Figure 34 are met. If a design specifies a dimension are below a machine's minimum feature size, the machine and specification are flagged. Similar rules can be used to indicate issues with other types of specification, such as tolerances.

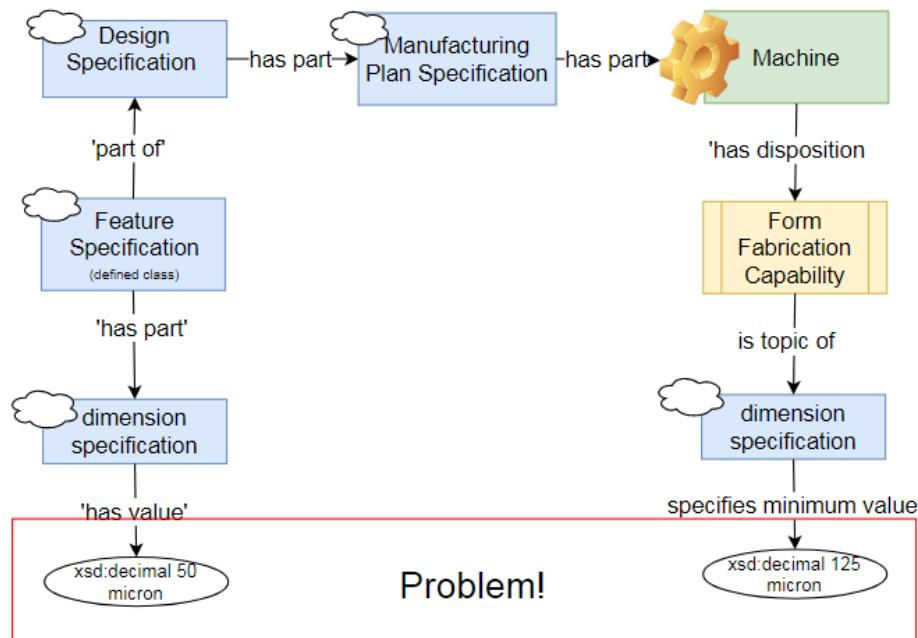


Figure 34. Information model used to detect specifications below a printer's minimum feature size

8.1.5. Instantiation of Additive Manufacturing Knowledge Bases

The modules described in section 8.1.4 rely upon instantiated knowledge in the ontology. As part of an effort to assess how the ontology might be used for a real design, this a knowledge base was created using a combination of existing literature on things like design rules, manufacturers' specifications of machine capabilities and resulting

material properties, and in-house knowledge about various AM technologies derived from the operation of a additive manufacturing laboratory. This is not meant to be an exhaustive representation of AM domain knowledge. Instead it reflects the type of partial domain knowledge that an institution might reasonably be expected to have. Rules were manually input due to a need to create complex defined classes to activate each rule. Machine level information was collected in a spreadsheet of machine parameters. This spreadsheet was then read into the DAMPrO machine knowledge base module as a series of instances and subclass type information using Protégé’s Cellfie plug-in [243].

8.1.6. Use Method for DAMPro

The information model and knowledge bases captured in DAMPrO provide automated reasoning and querying that could be used to support the use of AM knowledge throughout the detailed design process. Four main phases of deployment are envisioned, to be used iteratively. As early decisions, such as its identification of broad classes of material and the like are made, DAMPro can first serve as a knowledge base to identify candidate processes. For example, selection of a plastic versus a metal already dramatically reduces the number of viable processes. Similar estimation of part qualities such as minimum feature sizes can reduce it further.

As the design is specified, relevant features are instantiated in the ontology as a set of specifications, classified by a human operator or alternatively by software that can recognize the small set of features relevant to AM. This would likely be easier than in a reductive manufacturing case as there are far fewer forms that might cause an issue for AM. Once instantiated, the design geometry is then evaluated using the process rules for the candidate processes. These generate warnings about manufacturing the design in its

current form as appropriate. Should any of the consequences of these warnings prove unacceptable, process candidates are removed, or the designer might consider a partial part re-design. For example, an internal support structure or enclosed powder might be undesirable in a hollow structure. A potentially smaller set of candidate processes or more diverse set of design alternatives is then considered in subsequent evaluation.

Once viable processes are identified, a two-phase, machine specific assessment can begin. These can utilize the machine knowledge base implemented in DAMPro, or alternatively the knowledge base might be limited to a small subset of systems available to some organization. The design is then evaluated against any machine that completes a candidate process to determine if a specific machine can fabricate the it as specified. Machines whose capabilities are not sufficient to manufacture the specified geometry are eliminated.

Provided there are still candidates available, material considerations are used to identify truly viable systems and plan specifications. Once the specific material requirements in the part are known from additional engineering analysis, the machines are then queried to determine which ones can produce parts up to this specification. This remaining subset thus forms a set of candidate systems to manufacture the design, with the designer left to decide between them based on preferences on build time, cost, or other factors. Alternatively, the information contained in each module could be mined to support geometry forming processes such as topology optimization, or to set geometric requirements based off of a known manufacturing method (Figure 35).

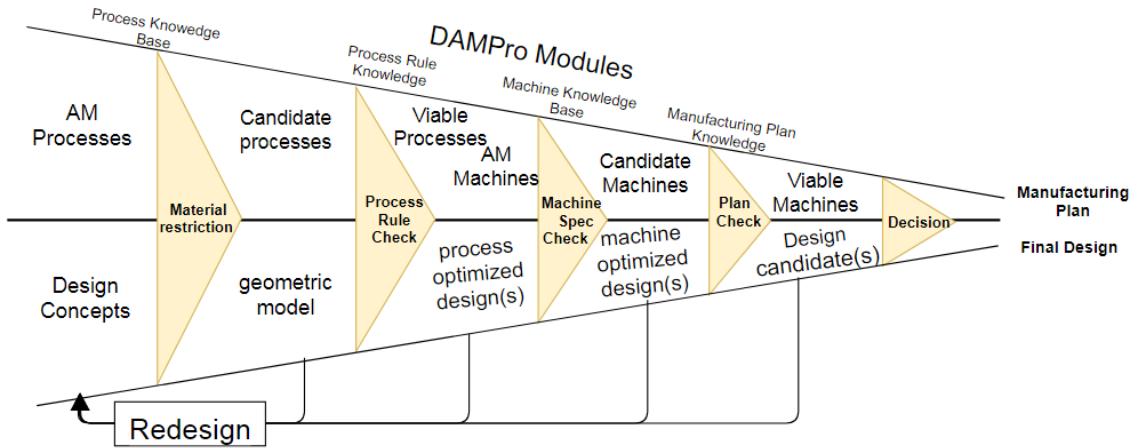


Figure 35. Proposed DFAM process using DAMPro

8.1.7. Case Studies

The DAMPro modules and proposed use method were assessed using two case studies. The first focuses on a manufacturability evaluation of a test part. The test part (Figure 36) was intentionally designed to have an assortment of features that are difficult or impossible to manufacture with AM. These include various degrees and type of overhang, holes of varying size and orientation, as well as cylindrical and rectangular features having a wide range of dimensions. The part's manufacturability was then assessed using the process rule and machine knowledge base sub-modules of DAMPrO

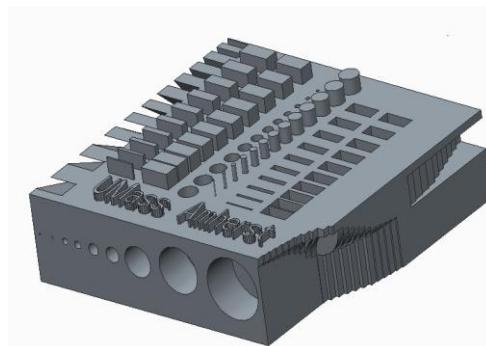


Figure 36. Non-manufacturable AM test part used in DAMPrO case study 1.

The second case study focuses on DAMPrO as a design aid an ongoing design and prototyping of a novel variant on a minimally invasive surgical tool called an endocutter. Endocutters are used to cut and seal tissue using biocompatible staples, deployed from reloadable cartridges. Though usually mass produced, this case study focuses on the creation of a printable, functioning prototype. The end effector of an endocutter has two main portions, a jaw and anvil assembly and a staple cartridge. This case study will focus on the design of the anvil. The surgical context of the device limits materials to a subset that can withstand some sterilization process. Minimally invasive operations require assemblies to be made small enough to fit through ports that may be a centimeter or less in diameter, requiring small features in many instances. The functional aim of stapling requires that an opposing anvil bend a set of titanium staples into a “B” shape repeatedly throughout use.

In both case studies a subset of AM processes was considered based on the availability of literature describing quantitative design rules. These include selective laser melting (SLM), selective laser sintering (SLS), fused deposition modeling (FDM), and PolyJetting. Machine level information was based on manufacturers' specifications, and so reflects a partial knowledge of the full capabilities and limitations of each system. Instances representing the part's geometric model and dimensional specifications were created and classified manually. Instances were first entered as a spreadsheet, and then read into Protégé version 5.2 using the built in Cellfie plug-in.

8.2. Results

8.2.1. Implementation of DAMPro

DAMPro and its sub-modules were successfully created in Stanford’s Protégé 5.2 ontology editor [242], and classified by the Pellet Semantic Reasoner [153] without any inconsistencies. Inspection of the inferred class structure and instances showed no sign of erroneous inferences.

8.2.2. Case Studies

8.2.2.1. Case Study 1 Results

Instances representing the test part were successfully created from the spreadsheet to represent part geometry using the Cellfie plug-in. Since the part has no real functional requirements, it was decided that a model made from any material would be acceptable for manufacturing. Since almost every additive process meets this description, the first step of DAMPrO’s proposed use process may not be necessary in this case. As such, the corresponding rule ontologies were thus imported into the case study alongside the geometric model instances.

Classification with the Reasoner resulted in automatic classification of the features of the part. A query was used to identify those features that ran afoul of at least one of the process rules. The Reasoner found issues for all four processes. Further inspection moreover, found that in many cases the part might have dimensional accuracy issues. These results thus indicate that part re-design would be necessary to manufacture the part with AM (Figure 37).

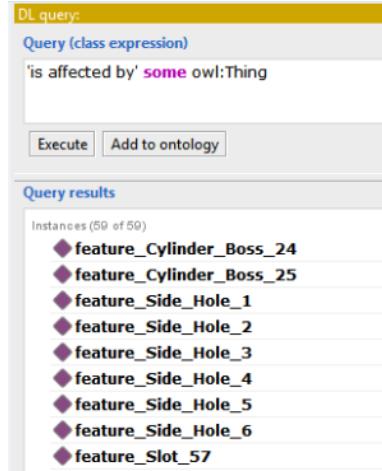


Figure 37. Partial depiction of features noted as problematic by the Reasoner

Prior to re-design however, one might be interested in evaluating the part against various machines to know the full set of features which might need to be revised. To obtain this information, the part design was given ‘manufacturing plan specification’, listing a set of candidate machines. This allows individual features to be evaluated by the Rule in Equation (12). As with the process rules, machine specific reasoning revealed several manufacturability issues. None of the machines for example could manufacture thin walls at the lower end of those specified, nor could they manufacture overhangs as specified without the addition of support. Thus, like the process analysis, several features would have to be removed to fabricate the part without issue.

8.2.2.2. Case Study 2 Results

DAMPrO and the proposed design method were used to facilitate the design of the endocutter jaw and anvil mechanism. To begin an initial set of queries were used to identify printers that could print in at least one sterilizable material, based off standard sterilization methods. Since the ability to be sterilized, the additive manufacturing processes were instead queried based on their use of common sterilizable materials in

medical devices such as nylon and stainless steel. Since there is no medical or biological terminology to reflect the property of sterilizability, the queries must instead search for specific materials that the user happens to know meet this requirement. These would be identified by querying:

'additive manufacturing process' and **'has specified output'** some (**'is made of'** some
(**'portion of <material>'**))

In this case of the four processes considered in the case study, each can fabricate parts in at least one sterilizable material, and so all processes were considered candidates. An initial design phase developed a geometric model (Figure 38) of representative subunits of the jaw and anvil assembly. To evaluate the design in DAMPrO, a sub-ontology with instances representing the design was created and the rule modules were imported into it (Appendix H). The ontology was then classified with the HermiT Reasoner [152].

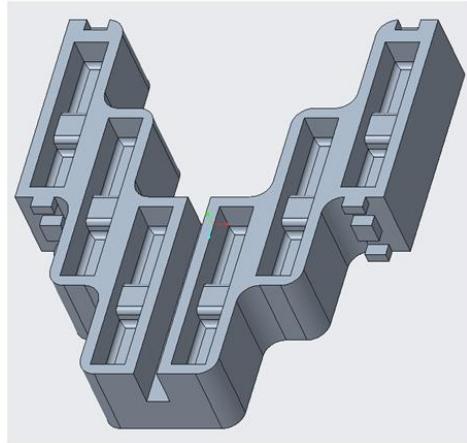


Figure 38. Initial design of a representative anvil subunit

A query for instances that fall within the scope of one of the rules returned all rule violations. Based off the initial geometry, the Reasoner noted multiple possible issues depending on the manufacturing process (Figure 39). For every process the part has

overhangs in critical features. Adjustment of orientation only changes the critical features in question. A closer look at the warnings given by the ontology reveals potential accuracy and surface finish issues in the part linking features or staple forming wells with SLM depending on the orientation. If printed with the wells facing up, the peg features used to link segments are overhangs which will require support. If printed upright, the wells will likely have surface finish and accuracy issues due to rounded overhangs, which tend not to print well with SLM.

The screenshot shows two panels from a DL query interface. The left panel, titled 'DL query: Query (class expression)', contains the query: 'form specification' and is_affected_by some rule. It has 'Execute' and 'Add to ontology' buttons. The right panel, titled 'Property assertions: feature_spec_blade_gap', lists object property assertions for four instances: 'feature_spec_blade_gap', 'feature_spec_lock_peg_1', 'feature_spec_lock_peg_3', and 'feature_spec_pock_peg_2'. The assertions include: 'has part' dim_spec_blade_gap_1, 'has part' dim_spec_blade_gap_2, 'part of' design_spec_extendable_endocutter_anvil, 'is subject to' 'rule: SLM slot width', 'is subject to' 'requirement: SLM slot', and 'is subject to' warningslmslotwidth.

Property assertions: feature_spec_blade_gap	
Object property assertions +	
'has part'	dim_spec_blade_gap_1
'has part'	dim_spec_blade_gap_2
'part of'	design_spec_extendable_endocutter_anvil
'is subject to'	'rule: SLM slot width'
'is subject to'	'requirement: SLM slot'
'is subject to'	warningslmslotwidth

Figure 39. Stapler anvil features affected by ontology rules for SLM when run with the part instantiated with the wells facing up

Since the affected features are critical features and in require good geometric accuracy this was deemed unacceptable, and so redesign would be needed for SLM. All processes were noted as needing supports except SLS, which would only benefit from them. Further inspection shows that support removal would require costly machining for SLM, but easier removal for FDM and PolyJet. Based on the process rule phase then, SLM was judged infeasible for the original design, but likely could be accommodated in a redesign. As the design requirements permitted some flexibility around the problematic features, a modified version eliminating problematic overhangs and re-sizing key features

was thus developed for these processes. FDM and PolyJet machines were thus considered for manufacturing with the original design.

Machine level analyses were completed using the same machines evaluated in case study 1. The machine knowledge base was imported into the case study ontology, and Pellet Reasoner was used to evaluate manufacturability at a machine level. No issues were noted for the re-designed SLS and SLM design part, nor were there any issues for the original part if produced by the FDM machine. However, several other manufacturability issues were noted for the PolyJet version of the part. A thin wall on the part was flagged as too thin to be manufactured by the PolyJet machine. Analysis of the part geometry and size requirements showed that the thin wall could be widened without violating any other specifications. As a result, a revised design with thicker walls was created for PolyJetting and the original design used for FDM (Figure 40).

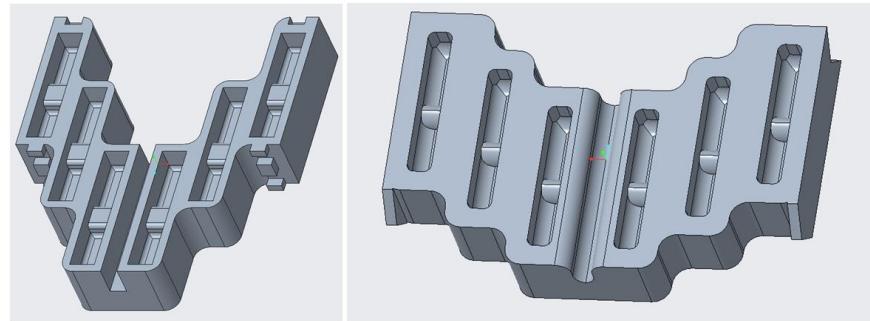


Figure 40. Original and re-designed part for PolyJetting. Thickening the wall features eliminates the thin wall issues

The final step in creating a process plan for either design was to identify a suitable process plan. The hardness of the printed materials was deemed to be the most critical process outcome based analysis of the part geometries, performance of available materials on the two printers under standard parameters. To function, the anvil must deform a titanium staple, rather than being penetrated. Querying the hardness obtained in

different manufacturing plans however returned no result for the FDM, SLS or PolyJet machines, indicating that there are no plans within the knowledge base to obtain sufficient hardness of the material. However, SLM was easily able to meet this requirement.

Another version of the part was designed to accommodate the SLM process parameters. The original part was problematic largely due to sizing reasons. It had a gap of a width too small for the process, and so simply widening this feature slightly would eliminate the problem. Second, the original pegs used to mate were overhanging features are stepped overhangs, and so will not print properly and would require support. Since the SLM rule for overhangs notes that no support is needed for overhangs less than 30 degrees this means that an angled feature below 30 can be used without issues. On this basis, the SLM process optimized part (Figure 41) was selected for manufacturing.

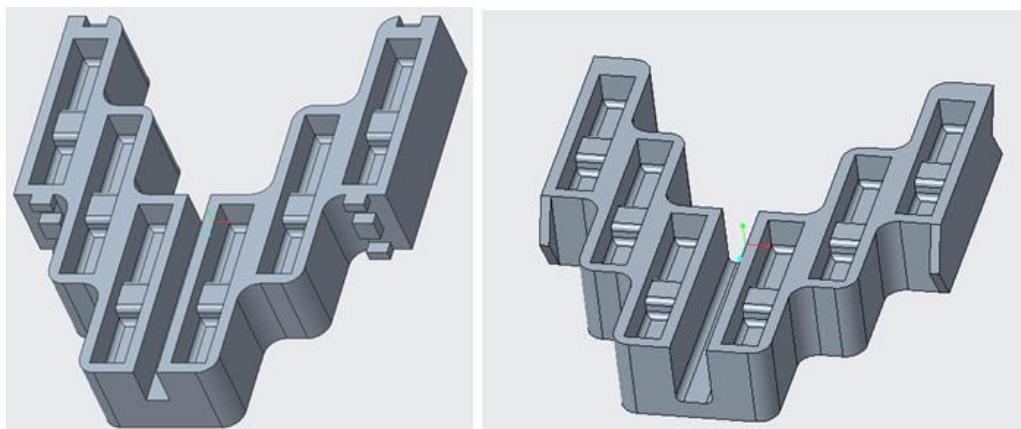


Figure 41. Original and design revised design

8.3. Discussion

Though AM offers increasingly attractive manufacturing options for a variety of products, significant challenges impede its effective use. The purpose of this study was to overcome some of these challenges by using an ontology and an ontology enabled design

method to facilitate design and process planning. This is achieved by capturing process, machine, and parameter knowledge within a set of linked ontologies. The resulting ontology framework, DAMPrO, was subsequently evaluated with two case studies. The results indicate that DAMPrO might be of use for DFAM and AM process selection, and to potentially allow for a design paradigm aimed more at utilizing the full potential of AM technologies rather than simply designing for an individual process.

The two case studies demonstrate the potential usefulness of ontologies for AM design and process planning. As seen in the first case, it is possible for a relatively complex part to be easily assessed for manufacturability based on knowledge of several processes. Though requiring a labor-intensive classification and instantiation process, evaluation of the part against each process simply required classifying the ontologies with reasoning software. The same result can just as easily be obtained with several processes simultaneously, or several processes and several machines. While DAMPrO was implemented with only a subset of process rules fully instantiated and this case only looked at minimum feature sizes at a machine level, the modular nature of this work means that it can be extended as needed without affecting existing knowledge.

The second case study suggests that DAMPrO might be useful for part design and redesign. Most approaches to DFAM require either an early choice of process, or simply treat AM as uniform across processes. By contrast this approach considers many options simultaneously, including multiple processes and potentially many machines. By doing so, DAMPrO and the method tested in this case study allows the designer to consider any resources available and tailor multiple design variants to each resource. They can then decide between these resulting part designs and determine the best option. As a result a

potential multitude of designs might be generated to optimize around various process options. Automated warnings of violations similarly allow the designer to alter designs or eliminate processes based on competing requirements and design priorities.

Though promising, DAMPrO and ontology based approaches do have limitations, which may limit their wider adoption and application to designs utilizing AM. Most notably, individual forms on a part must be classified manually for evaluation of process rules. In the case of many features, automated feature recognition would be ideal, but might prove difficult. This work seeks to address this somewhat by providing simplified feature definitions more relevant to additive processes, but future work is needed to investigate their feasibility. A second limitation is that the quality of design process supported by DAMPrO is directly related to the quality of the information in its knowledge base. As implemented, DAMPrO reflects only a subset of all known AM processes. These can however be expanded as needed. Additionally, complex relations between multiple dimensions may moreover stretch the expressive or computational abilities of ontologies and semantic reasoning software respectively. While some relations of this nature were investigated, more research is needed. Especially where ratios of variables are used, ontologies and automated reasoning likely need to be enhanced with semantic web technologies that are better suited for mathematical manipulation.

Despite these limitations DAMPrO and a modular, knowledge based approach to DFAM offer significant advantages. The highly formal ontological structure used in this work means that it can be extended with relative ease to reflect as much domain specific knowledge as needed. This capability offers the potential to use DAMPrO in tandem with

additional AM modules, other types of AM knowledge useful for design and innovation, and to link it to outside engineering or domain knowledge. These combinations might yield potent knowledge management and design support tools. On top of this, it means DAMPrO can be extended and refined without the need for subsequent redefinition of the ontology as more, higher quality data becomes available. As seen in the case studies, this knowledge based approach also enables novel design processes that are better suited to designing with AM's promising geometric and complexity capabilities. As most methods, currently in use require designing for a more limited, specific process, this offers a potentially large benefit.

CHAPTER 9

A METHOD OF MEDICAL DEVICE DESIGN ENABLED BY LINKED, INTEROPERABLE ONTOLOGIES

9.1. Motivation

The prior work described in Chapters 5 to 8 addresses in part the challenges presented in Chapters 1 and 2 in a piecemeal fashion. The ideation framework addressed in Chapter 5 (CIFMeDD) and the ergonomics ontology aim to address the knowledge challenges of medical device design. To create a relevant and effective surgical tool a typical designer must reason upon domain knowledge that is well outside their training. They must often make decisions that are dependent on scientific knowledge and domain concepts that are often inaccessible to those outside medicine. In CIFMeDD functional tagging and automated reasoning are used to help the designer overcome this challenge. To create usable surgical tools the designer must also consider human factors relating to users whom are diverse across many traits directly relevant to a design. In many instances relevant user data are scattered across multiple datasets, and are in no way linked to the designer's specifications for a device. Moreover, user engagement is expensive, usability assessment difficult, and regulation expansive in the medical domain. The ergonomics framework presented in Chapter 6 seeks to instead link these datasets directly to a design, and to provide reasoning that supports traceable requirements and designs rationale.

The medical domain is also somewhat unusual. Users vary widely and may have significantly diminished choice when selecting products. Thus, methods that favor users but neglect other stakeholders may not lead to the best design solution. The needs of

many competing stakeholders may need to be satisfied, and different values delivered to different stakeholders. The business model ontology along with the ICAM ideation method seeks to directly link a medical concept to a specific value proposition and provides a knowledge model that can express how different stakeholders are served by the model.

As the medical domain moves towards personalized healthcare, these challenges must be met in the context of the underlying challenges of AM. AM adds considerably to this already challenging design domain. Like medicine, data sources are dispersed, incomplete, and critical information may be beyond the knowledge of a typical designer. These considerations are moreover changing rapidly as new processes and process refinements are made available. DAMPrO seeks to mitigate this issue by assisting with design verification, and by allowing designers to progress forwards without artificially limiting the design freedom afforded by AM. This same freedom has the potential to provide significant value in the medical domain. To do so, however, it must be exploited through designs based on meaningful and well-reasoned value propositions. ICAM facilitates this process by enabling a designer to query knowledge of past AM projects so that they can potentially reuse this knowledge to address similar problems.

While these solutions address many of the issues of medical device design separately, they also reflect overlapping knowledge that needs to be considered concurrently to create innovative medical devices. Manufacturability concerns need be addressed, but one needs do so in a manner that also keeps regulatory and usability considerations in mind. Reusing manufacturing knowledge is certainly useful but might be made more relevant if that knowledge was tied to clinical knowledge. The work

presented in Chapters 5 to 8 of this dissertation seeks to overcome specific challenges in the development of surgical tools but has thus far ignored the potential to consider these diverse knowledge domains alongside one another. Given this gap in the work presented thus far, this chapter describes a framework and method for surgical tool design. At its core is an ontological model that links previously disparate domain knowledge in a manner that facilitates easy interpretation, querying, and reasoning.

9.2. Method

9.2.1. Knowledge Management Approach

9.2.1.1. Framework for Knowledge Management

As noted in the literature review in Chapters 1-2, knowledge from any one of these domains can be difficult to relate to a given product development process. These individual links are thus of value in and of themselves, and in many instances likely have applications outside of medical device design. Given a common platform (Figure 42), one might make any design decision, or support any inference based on a much more complete view of the design domain. The common platform allows a designer to access cross domain information through a combination of queries and automated reasoning to make powerful associations and enable new insights based on all domains simultaneously.

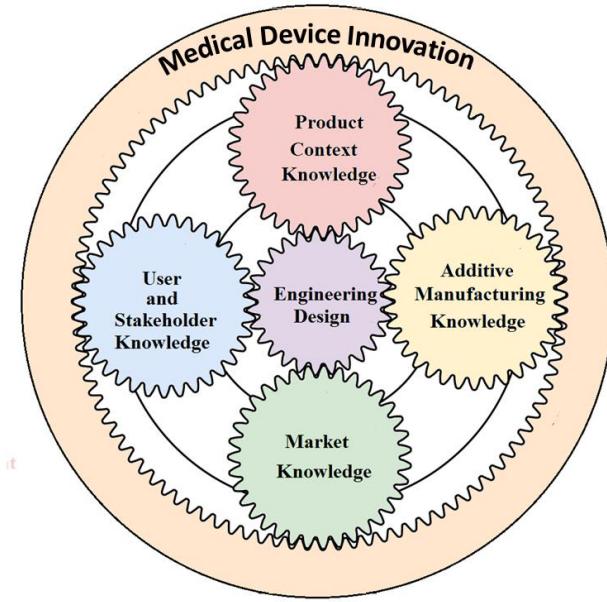


Figure 42. A knowledge management framework to facilitate the design of surgical tools by linking knowledge across domains

As represented in Figure 42, engineering design is the driving force behind this framework and is thus represented by the sun gear. While medical innovation (the ring gear) is the ultimate goal, it is ultimately realized through a design process that is able to consider the knowledge domains that are critical to innovation in medical device design. The planet gears represent the knowledge domains deemed critical to medical device design outlined in section 9.1.

The hypothesis of this work is that the reasoning enabled by enhanced accessibility and inference capabilities upon each knowledge domain will yield insights as to how one might address design problems encountered during product development in medical device design. This holds for both individual links between the engineering design sun gear and knowledge sub-domain planet gears, as well as for the combination of all the knowledge domains represented by the four planet gears. It is moreover hypothesized that this cumulative framework will enable rich information capture and

reuse. For example, one might capture information identifying how past medical products impact certain surgeries, and then use this as a basis for future ideation. This works thus implements an Integrated Framework for Additive Manufactured Medical Device Design (IFAMMeDD). This integrated framework is in turn hypothesized to enable a design process wherein the designer to query a knowledge base consisting of clinical tools as a basis for ideation, resulting in innovative and ensuring a manufacturable design.

The framework is implemented as a series of ontology modules linking various knowledge domains to engineering design knowledge and exploring how individual links might be utilized. Ontologies have the properties of being extensible and interoperable if developed properly. These two properties are ideal given the multi-domain and modular approach used to implement IFAMMeDD. Once constructed in such a way that these various linked domain models might coexist and be further tied to one another, they can then be evaluated with further exploration of reasoning capabilities.

9.2.2. Implementation of IFAMMeDD

Specific details for the implementation and scope of the individual sub-modules are described in Chapters 5-8. The remainder of this chapter will discuss the construction of IFAMMeDD from these otherwise isolated works, a methodology to use the framework, and a case study to validate it.

9.3. Development of Ontology

The Integrated Framework for Additive Manufactured Medical Devices was implemented as a BFO conformal suite of ontologies, making extensive use of past work published in the literature, as well as the ontologies presented in Chapters 5-8. An upper ontology was once more used to help proscribe a basic view of the world within the

ontology that allows easier rationalization of the included knowledge domains. Since ontologies sharing a common upper level can be linked seamlessly with one another use of BFO allowed the multi-domain ontologies to coexist and interoperate more easily. This also allowed re-use of published reference ontologies to provide a middle level of abstraction to the framework.

The Tbox components of ICAM and DAMPrO, and by extension the existing ontologies used to construct them were both included without modification to their information model or class definitions. This was deemed sufficient to create the additive manufacturing knowledge portion depicted in Figure 42. However, the product knowledge base used to implement ICAM was extended with additional instances to facilitate more useful querying across a more diverse set of AM products.

9.3.1. Introduction of Medical Terminology

9.3.1.1. Selection of a Clinical Information Model

SNOMED CT, though the basis for CIFMeDD, is not a BFO conformal ontology. Moreover, its size and informal implementation means that it cannot be easily re-aligned. Given this challenge a review of the NCBO's Bioportal [183] ontology repository, as well as the OBO Foundry [159] ontologies was conducted to identify possible candidates to replace SNOMED CT. In order for a replacement to be considered, it needed to be BFO conformal, judged easily modifiable to become BFO conformal, or offer significant knowledge benefits over SNOMED CT that would justify its replacement. Based on this review however, no other clinical information model having sufficient scope for this application conforms to BFO. Thus, no other information model offered any comparative advantage for implementation of a clinical module.

An evaluation of SNOMED CT, however, noted that its specialization and informal knowledge model would make realignment with BFO difficult for a non-medical domain expert. Instead, medical knowledge was included by refactoring a subset of SNOMED CT, keeping its terminology but losing much of its larger information model. The drawbacks of this approach are significant. Most of the clinical knowledge in the SNOMED CT class hierarchy relies upon this information model and is thus lost to IFAMMeDD. However, the terminology itself allows IFAMMeDD to capture a great deal of contextual information. It is moreover sufficient with a small expansion of the properties in RO to re-implement and extend the capabilities discussed in Chapter 5 with little to no loss of functionality.

9.3.1.2. Refactoring SNOMED CT

Four subsets (Figure 43) were created from SNOMED CT's class structure using the Refactor tool in Protégé 5.2 [242]. The refactoring tool allows a user to selectively copy subsets of an ontology or move subsets into another ontology. As opposed to simple replication of terms, this preserves the Internationalized Resource Identifier (IRI) linked to each term. This uniquely identifies the term across all ontologies. In cases where multiple ontologies are integrated into one another, matching IRIs allows ontology development packages and reasoning software to recognize two entities as being the same without the need for equivalency axioms. The four terminological subsets were extracted from SNOMED CT to deal with surgical tools, procedures (specifically surgical actions, which are classified as qualifier values in SNOMED CT), a limited anatomical terminology, and terms relating to clinical roles and environments.

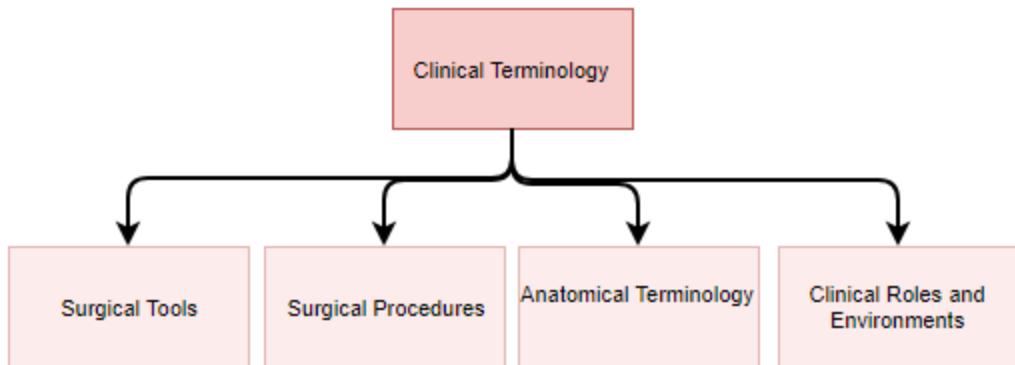


Figure 43. Clinical terminology subsets used to define the clinical ontology

The tool and procedure subsets perform similar functions in the proposed ontological framework. They allow the capture of contextual information about how clinical procedures are carried out currently. When integrated into the larger framework this helps describe a detailed process for how some new product might be used relative to an existing process. The roles and environments subset details clinically significant aspects of context, such as the types of features an environment might have, or the individuals who might be responsible for various tasks. Capturing this type of information might allow for better and more specific capture of stakeholder information and to characterize requirements that emerge implicitly from use context. The anatomical terminology is included to help capture of the anatomical context of some surgery and also offers an ability to express some aspects of user capability in greater detail via interactions with the ergonomic subset of the framework.

The refactored ontologies use a spoke and wheel structure, wherein a central hub for the clinical subset implements an information model and associated class relations at a very high level, while subsequent spokes simply introduce a problem specific set of classes for describing medical knowledge. This has two advantages. First, it means that

while this work proposes to use four subsets of SNOMED CT to support the development of surgical tools, other medical types of devices might use different subsets. A drug eluding device for example might require a far more sophisticated model of local physiology than a surgical tool. The second advantage is that it allows the same information model to support information from non-medical problem contexts. Thus, the mostly medicine-specific aspect of this work might as easily be swapped out for another product domain.

SNOMED CT's terminology relating to surgical tools presents problems from an ontology engineering perspective. This is a large terminology which details various types of surgical tools. However, these classifications notably may be somewhat arbitrary in some places, and many classes have multiple parents. Neither of these factors is desirable, given that BFO style guidelines specifically advise against multiple inheritances. Instead, SNOMED CT terms were treated as **designative information artifacts** that classify real world objects or designs. This approach is advantageous as it makes a substantially smaller ontological commitment. Rather than propose an ontology of surgical tools for example, one instead posits that there exists a classification system. A given object might bear several classifications belonging to one or multiple such systems. These might include regulatory classifications from different agencies or nations. This is especially useful in the case of surgical tools which might be more usefully grouped with similar, non-clinical tools, such as in the case of scissors, saws, drills and the like. The other subsets shown in Figure 43 were deemed considerably less problematic, both because fewer instances of multiple inheritance were found and

because many of the terms were more explicitly unique to medical fields. Thus, for these subsets the terms were imported “as is” and nested within BFO’s class hierarchy.

9.3.1.3. Integrating Clinical Terminology

The clinical terminology was enhanced with additional axioms to provide useful contextual information. First, existing ‘**has part**’ and ‘part of’ relations are used to construct more complex surgical procedures from the more basic ‘**surgical action (qualifier value)**’ classes refactored from SNOMED CT. This provides a greater degree of granularity than is typically encountered in SNOMED CT process classes. Other RO relations were used to define what tools are used when, the roles of various process participants (surgeons, technicians, patients, etc.), and to capture the environmental context of the surgery.

The second integration approach is based on the approach taken in CIFMeDD in Chapter 5. This involves linking surgical terms from SNOMED CT with a more detailed breakdown of sub-steps and tools. These more detailed surgical process descriptions were further enriched with functional information using the functional basis ontology. This was accomplished by first replicating the functional model linking property chains described in Chapter 5, with slight modification so as to avoid use of SNOMED CT properties that were not preserved. Since BFO characterizes functions as dispositions that are realized in processes, much of this information was linked directly to surgical procedure classes without an explicit functional model. Instead, the process subclass axioms were expanded with assertions describing the types of **function** that it *realizes* (Figure 44). Information about **flows** was added the same way.

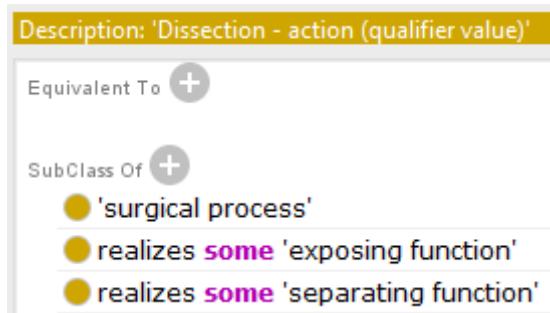


Figure 44. Example of a SNOMED CT class definition expanded with functional information

A similar approach was used to assert axioms about the medical device classes refactored from SNOMED CT. Since the medical device classes are treated as classifications of objects in the framework, they are instead used to classify devices that have some function, again indicated using the functional basis. Thus, a **scalpel** class from SNOMED CT might be asserted to be the '*classification of* an **object** that '*has function*' some '**severing function**'. This same logic can be used to indicate virtually any property of a medical device that is permitted to be borne by an object in BFO. Subsequent integration of the medical environments, roles, and anatomical terminologies were then used to support the development of a BFO conformal ontology for human factors design.

9.3.2. Development of a Human Factors Ontology

The human factors ontology was developed to replicate and extend the ergonomics ontology described in Chapter 6. The scope and the contents of the ontology is similar to that of the previous work but re-engineered to conform to BFO and interoperate with the other ontologies in IFAMMeDD. The human factors ontology was made from four sub-ontologies defining terms relating to various stakeholders. While users are the primary focus, regulators, and by extension regulations and standards were

also included as they are important to the medical domain. In addition to an ontological treatment of regulations and standards, the human factors ontology includes terminology to describe users, their requirements, and their capabilities (Figure 45).

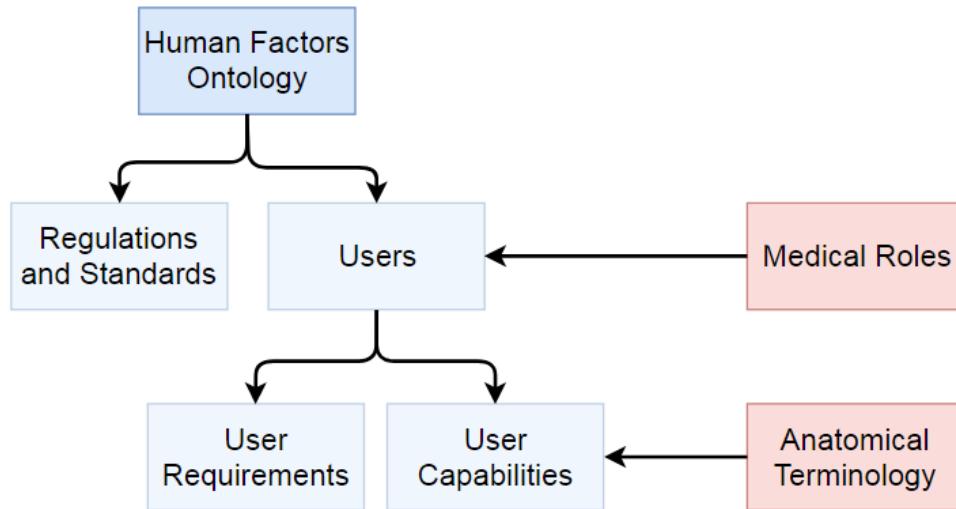


Figure 45. Structure of the human factors ontology

9.3.2.1. Regulatory Terms

The regulatory ontology creates classes to capture regulatory information. Regulations are treated similar to the SNOMED CT medical device terminology. While classified as **directive information entities**, they also have two components: scope and consequences. The information model is similar to the design rules in Chapter 8. Scope relates the regulation to various other entities via a '*is within scope of*' object property. This property points from specific regulations to regulatory classifications, which in turn are used to classify entities. As with the medical terminology, this means that the ontology does not have to accept the regulatory classification as ontologically correct, but simply acknowledge that such a classification exists.

The regulation secondly has consequences. Should an entity fall within the scope of the regulation, it must bear certain consequences. These are typically in the form of additional requirement specifications that are attached to some entity, or the specification that describes its intended form (Figure 46). For example, an instance representing a design of a medical device falling within the scope of a US medical device regulation would be automatically linked via ‘has part’ relations to a set of instances representing FDA General Requirements. These in turn are about various processes, methods, and the like which must be included in a design process.

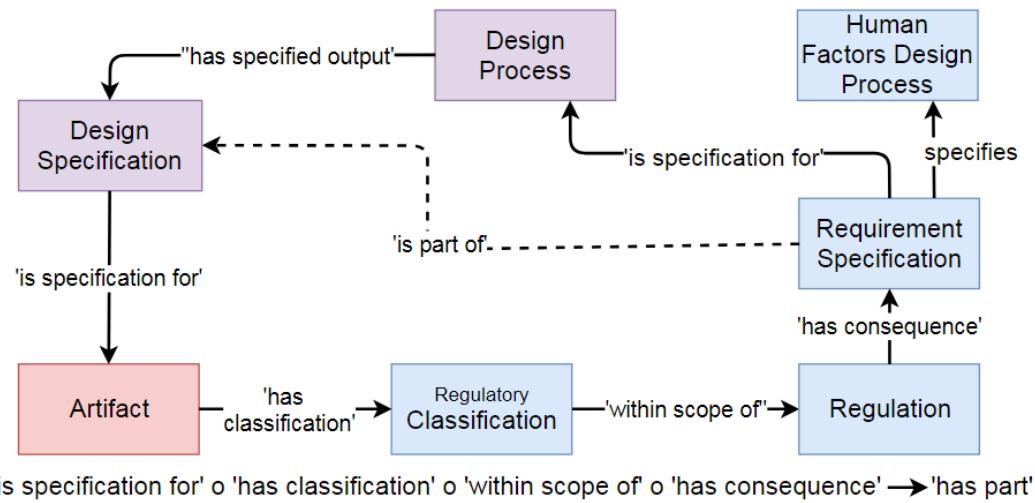


Figure 46. Information model and axioms linking regulatory requirements to a design

Specific regulatory classes and instances were added to describe FDA regulation of medical devices. On top of this, the medical device terminology was enriched with additional information about risk and regulatory classes. Because any object can have an arbitrary number of classifications assigned to it, FDA risk classes and SNOMED CT device type classifications are able to coexist within the model without issues.

9.3.2.2. User Ontologies

The user requirements ontology captures information relating to the needs of users or any other stakeholder and the processes by which these needs are elicited. The capabilities ontology deals with the mental and physical capabilities of a user, as well as those demanded by some process. These are then combined to form an overall user ontology, which additionally captures the types of process where a user realizes various capabilities. A user is specified via an information entity that identifies the users of some product described in a design. This specification indicates that a person (or more likely a group of people) is being directly considered in the design process. Other users may exist. Their existence might be inferred when the realization of a design in the form of a product is then used in some process that the user performs, an inference supported by the ontology (Figure 47).

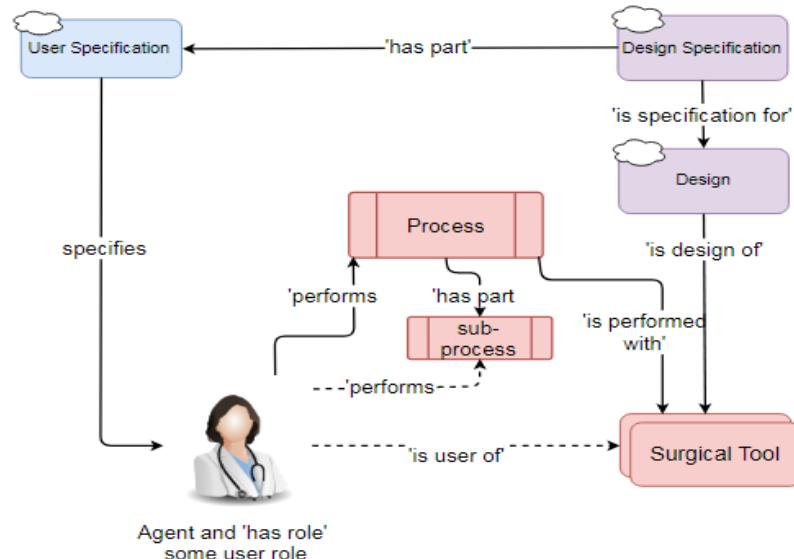


Figure 47. Information model depicting user processes, and their relation to a design

Capabilities are treated as dispositions that are borne by continuants. For the purposes of the ontology, a capability is simply defined as a beneficial disposition of some continuant to successfully be able to participate in a process in some pre-specified way. This implies not just participation, but some quality of participation. Thus, capabilities *enable* various processes. This is identical to the capability definitions used in Chapter 7, and the framework makes no real distinction between, for example, machine capabilities and the capabilities of a person or some software.

The human factors ontology extends characterization of capabilities to those relevant to the usability of a design. Within the context of a proposed design, user demographics have some set of tasks (processes that they must participate in) that are required for them to successfully use the design in the manner a designer intends (Figure 48).

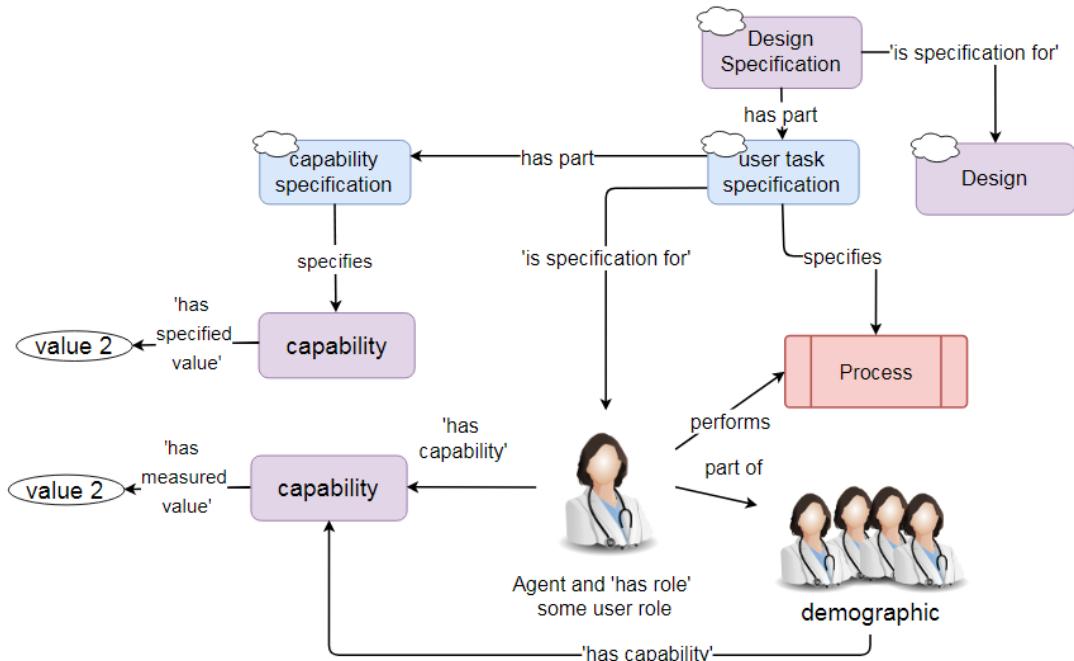


Figure 48. Information model describing user capabilities enabled by the ontology

Capturing this information and the user's related capabilities allows for potential comparisons between the user capability and the specified capability requirements. The same type of machine level capability rules from Chapter 8 is used to infer potential usability issue. For example:

*Rule: swrlb:lessThan(?uv, ?sv), specifies(?creq, ?cap), '**has disposition**'(?entity, ?cap), '**has value**'(?cap, ?uv), '**has specified requirement**'(?entity, ?creq), 'specifies value'(?creq, ?sv) ---> '**has problem**'(?entity, ?creq)* (13)

The above rule simply compares a specified value of required performance and the actual performance within the scope of that specification, and flags a mismatch as a problem.

Use of more specialized data properties can be used to formulate various types of usability issues, such as ranges of acceptable capabilities. Thus, as with the non BFO conformal ontology presented in Chapter 6, the revised ontology enables semantic usability assessments if provided instantiated knowledge of various demographic capabilities. Since capabilities are defined identically across ontologies, the Reasoner can check virtually any capability of any type against requirement specifications related to the design using a very limited rule set. In the case of the additive manufacturing ontologies this allows assessment of machine level feature fabrication capabilities. In the newly defined human factors ontology, it allows the Reasoner to assess usability. While depicted in rule (13) above as a binary decision, one could also implement population style assessments as was shown in Chapter 6.

A similar re-use of information models deals with the instantiation of usability rules. A set of 15 rules previously developed for medical device design [53] was instantiated in the top level human factors ontology to support usable medical device design. While they cannot be assessed automatically, heuristic rules can be assessed by a

designer, and violations populated within the ontology. Once populated, usability rules use the same information model as manufacturing rules and regulations.

9.3.3. Integrating the Ontologies.

The use of an upper ontology and replication of IRIs where terms were shared between ontologies means that integration process was largely a matter of simply importing the ontologies into one another. The order of imports is not particularly important because ontology development software can automatically manage dependences between ontologies. The highly integrated nature of the ontologies ultimately yields the expressive capabilities required by IFAMMeDD (Figure 49).

Where desired, cross domain reasoning is enabled by either importing terms or whole ontologies from the domains of interest. However, to enable quick reasoning, the knowledge bases, rules, and application specialized classes were separated from completed IFAMMeDD framework. During use, these can be selectively imported along with the TBox elements of the completed framework. This selective approach allows classification and automated inferences about the ontology without the burden of considering potentially unrelated terms, or portions of the framework that are not of interest for an application.

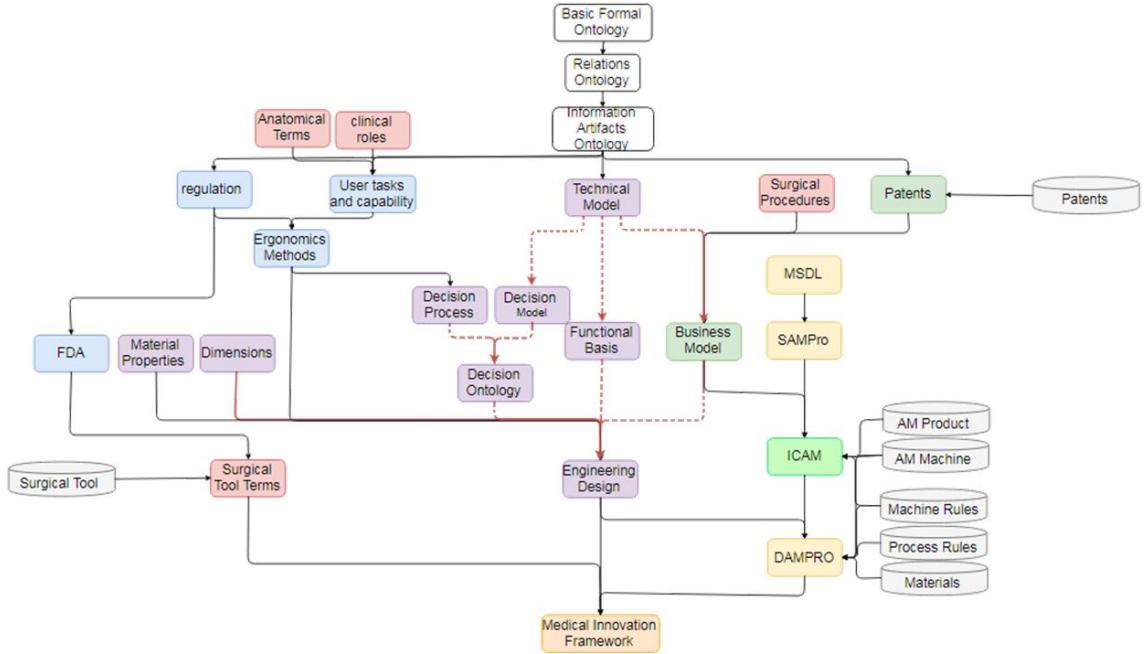


Figure 49. Sub-ontologies used to construct IFAMMeDD framework, and the dependency framework. Red dotted arrows connect ontologies that form a domain agnostic engineering design terminology. Cylinders represent knowledge bases.

9.4. Design with Additive Manufacturing

9.4.1. Motivation

On its own IFAMMeDD may offer some benefit to a conventional design process. However, the breadth of knowledge captured within it, as well as the methods enabled by DAMPrO and ICAM, point to the potential for a specialized design methodology. In practice, this would leverage the cross-domain inference capabilities that the framework is hypothesized to deliver to support all phases of the design process. As noted, IFAMMeDD is implemented such that it can be modified relatively easily to apply to other industries. Thus, the method developed to use IFAMMeDD is not necessarily specific to medicine. The knowledge used in this implementation, however, and the choices of modules reflect the challenges of MDD highlighted in Chapter 1.

The method advanced in this work is Design With Additive Manufacturing (DWAM). As noted in Chapter 2, DFAM methods typically require either early commitment to a specific process or conversely cannot distinguish between how a specific process might require substantial design changes. Since DWAM relies on IFAMMeDD's AM knowledge bases to support design, it makes no such commitment. These types of evaluations typically happen in an environment that is devoid of problem specific knowledge. DWAM aims to alleviate these difficulties through close integration of AM knowledge into the larger context of a design. In doing so, it is envisioned that decisions made regarding AM processes might be informed both by process knowledge, as in ICAM and DAMPrO, and by the broader design context. This integration of knowledge is achieved using the knowledge capture, reuse, and reasoning capabilities hypothesized to be enabled by IFAMMeDD.

9.4.2. Design With Additive Manufacturing Process

The DWAM method is composed of a set of engineering design steps that closely follows traditional engineering design (Figure 50) but is enhanced with the knowledge captured by IFAMMeDD.

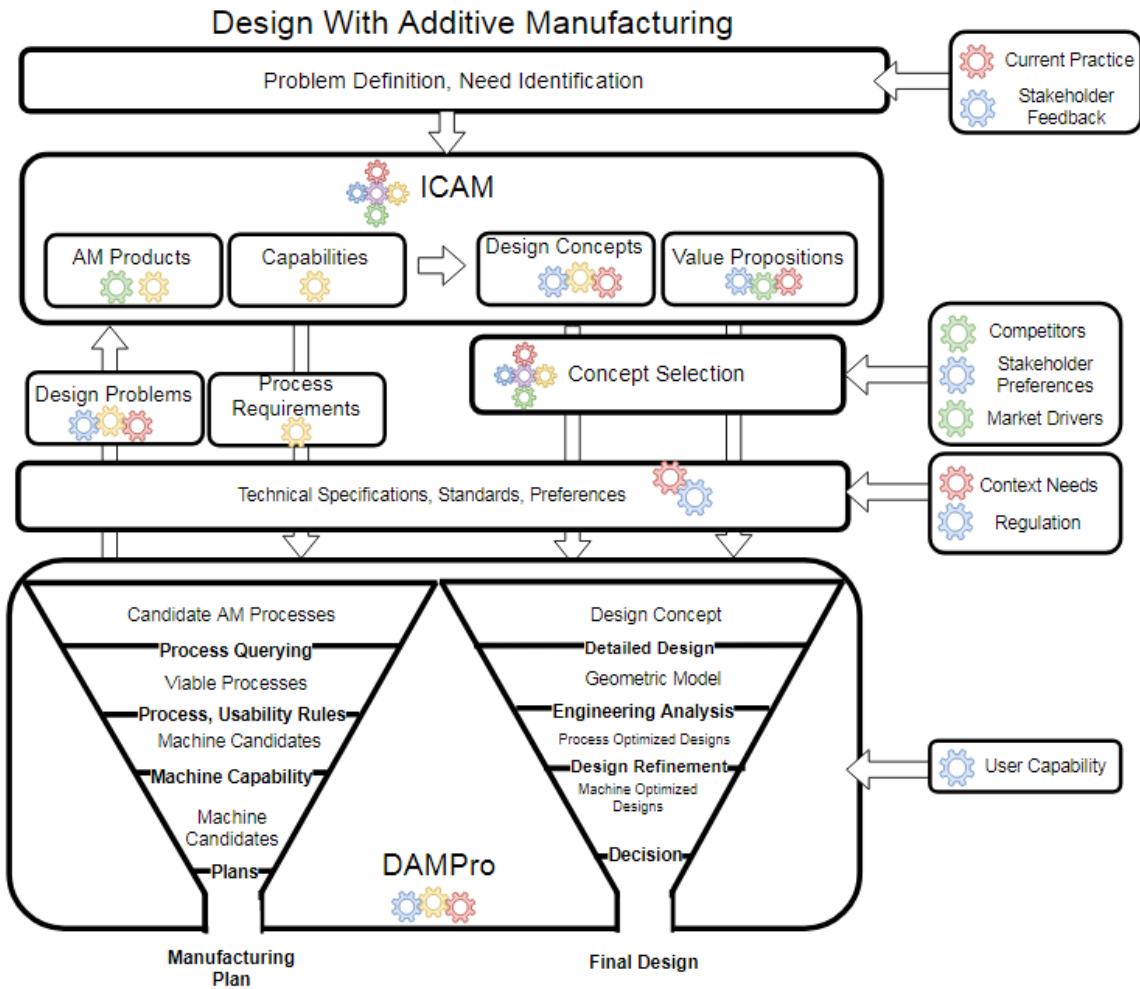


Figure 50. The DWAM process. Gear colors correspond to the knowledge domains in Figure 42

9.4.2.1. Identifying Customer Needs

The initial step is common to virtually any new product development process: to identify customer problems and needs which could be addressed by some new product. This process is completed through any number of contextual analysis methods and can be traced with IFAMMeDD using its ergonomic methods terminologies. The inclusion of domain terminology allows these requirements to be represented unambiguously using

ontology terms and relations. The business module is simultaneously used to capture information about the market, such as value propositions offered by competing products.

9.4.3. Concept Ideation

Once a basic set of requirements is identified, the next step is to use ICAM for ideation, following the same basic procedure shown in Figure 26. This allows the designer to use past products to inspire creative uses of manufacturing capabilities, and to ensure that some known machine can deliver these capabilities. Integrated with greater clinical knowledge, these queries can be more specific to certain medical contexts, or reuse ideas from existing devices and procedures. Based on queries to IFAMMeDD's knowledge base and the augmented clinical terminology, the designer then formulates a set of possible design concepts. IFAMMeDD assists in capturing the full rationale of the concepts by allowing them to be mapped to existing clinical procedures. BEM's properties are used to express the types of modifications that are made to the procedure with the introduction of the proposed device. Similarly, it can capture information about the business case for each device: to whom it will be sold to, how it will be distributed, and what specific value it offers its customers. These data can then be compared to both a standard clinical procedure and those that are realized when a competing device is used to better understand the relative value of each concept. In the case that a concept does indeed use a unique capability of AM, the framework captures any costs or difficulties that might arise aided by the clinical terminology.

9.4.4. Design Concept Selection

9.4.4.1. Decision Making Approach

The presence of multiple, potentially conflicting stakeholders means that in the medical context the DWAM method must include some approach to distinguish between them. Much of the information captured in IFAMMeDD might help to accept design concepts for consideration or reject them without further analysis. Fatal usability flaws inherent to some concept, conflicts with regulations, or a simple lack of meaningful differentiation from existing products might all be valid reasons to reject a concept. However, the designer must ultimately make some choice between potentially viable ideas.

While any variety of decision methods might be used, DWAM operates under the assumption that a designer or some entity involved in the design has final say over what concept is pursued. Given some estimated level of concept value for all stakeholders that are deemed relevant, the question is simply one of how much the decision maker values benefits to each stakeholder group. The decision is thus addressed using a multi-level preference model. At the bottom level is some representation of the preferences of each stakeholder, such as a value model linked to aspects of product performance. These then feed into an upper model that specifically characterizes the decision maker's preference between each stakeholder group. In this approach, we assume the decision maker is indifferent about performance on specific design criteria but instead cares about the net effect on the stakeholder. Thus, given a preference model for all relevant stakeholders, the decision maker formulates a decision based on a weighted sum of these models.

Considering a decision made disregarding uncertainty, the designer's preference model takes the form:

$$V_{\text{designer}}(x) = \sum_{j=1}^n w_j x_j \quad (14)$$

where V_{designer} is the designer's value for the alternative, w_j is the preference weight of the j th stakeholder considered and obtained from the optimization problem above, and x_j is the j th stakeholder value. Multiattribute utility theory might also be used in the top-level model of the designer's preferences to adjust concepts based on the perceived risks of each concept and the designer's risk appetite. Irrespective of approach, the designer can select the highest-ranking concept for further exploration in the DWAM method.

9.4.4.2. Elicitation of Preferences

The top level designer value model is constructed using the method of hypothetical equivalents and inequivalents, which has been applied previously in conceptual design [245, 246]. In this method, a stakeholder is presented a set of hypothetical alternatives in pairs. They are then asked to indicate whether they prefer one alternative to the other or are indifferent between the two. These stakeholder preference measurements are then used to formulate an optimization problem and solve for the weights in Equation (14).

For the case of a medical device, four stakeholder groups are considered in DWAM, based on previous assessments of stakeholder groups in medicine [26]. These are the clinicians, the hospital, the insurers or payers, and the patients. Using a three-level fractional factorial design, it is possible to construct a set of 9 hypothetical alternatives using an L9 orthogonal array (Table 10). In this approach, the four variables of the array

correspond to level of a preference model for each stakeholder normalized between 0 and 1.

Table 10. Hypothetical alternatives used to construct a model representing the student designer's preferences towards medical stakeholders

Alternative	Doctor Value	Patient Value	Hospital Value	Insurer Value	Decision Maker Value
1	0	0	0	0	$0w_1 + 0w_2 + 0w_3 + 0w_4$ (15)
2	0	0.5	0.5	0.5	$0.5w_2 + 0.5w_3 + 0.5w_4$ (16)
3	0	1	1	1	$w_2 + w_3 + w_4$ (17)
4	0.5	0	0.5	1	$0.5w_1 + 0.5w_3 + w_4$ (18)
5	0.5	0.5	1	0	$0.5w_1 + 0.5w_2 + w_3$ (19)
6	0.5	1	0	0.5	$0.5w_1 + w_2 + 0.5w_4$ (20)
7	1	0	1	0.5	$w_1 + w_3 + 0.5w_4$ (21)
8	1	0.5	0	1	$w_1 + 0.5w_2 + w_4$ (22)
9	1	1	0.5	0	$w_1 + w_2 + 0.5w_3$ (23)

For each alternative a 0 indicates no value to the stakeholder. A 1 indicates that the alternative has reached the maximum achievable value to that stakeholder. Using the alternatives in Table 10, a decision maker might indicate a preference towards alternative 9 over alternative 8. Expressing this preference as a relation between the values in Table 10, this would be written as:

$$w_1 + 0.5w_2 + w_4 \leq w_1 + w_2 + 0.5w_3 \quad (24)$$

Rearranging to more closely resemble a constraint in an optimization problem yields:

$$-0.5w_2 - 0.5w_3 + w_4 \leq 0 \quad (25)$$

Such preferences can be elicited and expressed as inequalities (or equalities in the case of indifference) so as to establish a rank ordering of alternatives. Taking a set of non-redundant expressions, the decision maker can then solve for the values of the weights using an optimization problem:

$$\begin{aligned} \text{Minimize } f(x) &= \left(1 - \sum_{j=1}^n w_j\right)^2 \\ \text{Subject to } h(x) &= 0 \\ g(x) &\leq 0 \end{aligned} \tag{26}$$

where w_j is the vector of attribute weights in a value function, x represents the stakeholder value levels for each alternative, $h(x)$ represents choices where the designer indicated they were indifferent, and $g(x)$ represents choices where the decision maker voiced a choice. Using the weights, the decision maker then ranks the concepts, and selects the highest ranking one.

9.4.5. Detailed Design

The detailed design is developed iteratively, with the design space progressively winnowed down using the knowledge bases and rule engine implemented in DAMPrO. The manufacturability assessment process is augmented by the more general ergonomic design rules implemented in the ergonomics module. This might include both usability analyses and SWRL-based assessments like those discussed in Chapter 6. This augmentation means that the design can be simultaneously evaluated for both manufacturability, conformation to requirements, and usability depending on the level of detail instantiated in the design. As new problems are discovered, the reasoning software is used to append the design specification with the appropriate warnings and recommendations. The designer can then investigate these warnings and

recommendations to determine a best course of action, be it resolving, mitigating, or ignoring them.

DWAM has a built-in mechanism for dealing with design problems as they arise. Just as ICAM can be used to query existing designs for solutions to various customer problems, the full knowledge base implemented in IFAMMeDD can be queried to find solutions to manufacturability and usability problems encountered throughout the design process. These might look for designs that encountered or resolved similar problems; or alternatively look for certain functionality that might be used to overcome some issue. This yields a set of candidate design changes, which are then evaluated using the stakeholder preferences. The modified design is then once more assessed with the regulation and user capability expanded implementation of DAMPrO's assessment model, until a final design or set of designs can be derived.

9.5. Case Study

9.5.1. Method

The ontological framework and the DWAM method were evaluated using a senior undergraduate mechanical engineering student design project investigating custom knee replacement cutting templates. The student was tasked with researching the surgery and the knee replacement market, developing design concepts to address unmet needs they uncovered, and then creating a 3-D model of the concept they chose to pursue. During this entire period the student had contact with the author as a project mentor, but only generic guidance regarding good design practice and ideation methods were provided. Parallel to this effort, IFAMMeDD and DWAM were used to first capture and reason upon the information gathered by the student, and then aid the student in ideation after an

initial period of unaided ideation. Once the student selected a design, she created a 3-D model of their concept, which was then evaluated by the author and subsequently refined based on results uncovered with the DWAM method. As part of this effort, a preference model as described in 9.4.4 was created to reflect the student's views and create final decisions.

9.5.2. Summary of Student Design Project

9.5.2.1. Overview

The student's initial research into total knee replacement surgeries was used as a basis to construct a House of Quality [247]. This was used to represent information about the product and to better understand the relation between customer requirements and various metrics. The student developed and distributed a survey to orthopedic surgeons to assess their preferences for new technologies. These responses were used to compute importance weights for each requirement. This information, along with subsequent ideation, detailed design, and manufacturing process planning were captured in the framework. The capture process resulted in the creation of a series of instances representing the total knee replacement surgery, various competing devices, and the requirements, metrics, specifications, and the like captured in the student's House of Quality. These were then augmented with regulatory, intellectual property, and procedural information that were instantiated in the ontology independent of the student's findings.

9.5.2.2. Background

Total knee replacements are used to treat osteoarthritis of the knee that cannot be addressed with conservative treatment. Osteoarthritis is characterized by a breakdown of

cartilage between joints, causing non-lubricated contact between the femur, tibia, and patella. This results in pain and decreased quality of life. In a typical tri-compartmental surgery, diseased bone that has been damaged by bone on bone contact is removed using a series of saw cuts, and all three bones are resurfaced to conform to the mating surface of an artificial joint prosthesis. The process removes the entire joint surface, and typically removes the cruciate ligaments to accommodate a joint prosthesis. The prosthesis replaces the removed bone, providing metallic joint surfaces buffered by a polymer pad simulating joint cartilage [248].

Aside from general orthopedic equipment such as bone saws, rods, alignment jigs, and the like, the student found that many manufacturers sell custom knee cutting guides to aid in total knee replacement surgeries. The guides aim to replace a process in which proper knee alignment is achieved by a process of manual measurement and placement of cutting jigs. Instead, a custom guide designed to mate directly onto the patient's individual anatomy is used to position a standard set of knee cuts and resurface the femoral head and tibial plateau. The guide(s) are fabricated based on models created from 3-D medical imaging. Once fabricated, they are shipped to the surgeon.

9.5.2.3. Customer Survey

Two surgeons responded to the student survey. The customer survey revealed that the surgeon respondents were very sensitive to matters of cost and independence from third parties, as indicated by strong negative responses to questions gauging the impact of additional imaging, direct device costs, and outside collaboration. By contrast the surgeons responded positively to reduction of operative time and surgical steps and were largely indifferent to the number of tools used. These responses were used to generate a

set of customer weights (Table 11), which were used to represent the value of competing products and subsequent concepts created by the student. These also form the basis for a additive value function that models of the surgeon's preferences.

Table 11. Customer requirements and weights based on survey of orthopedic surgeon

Customer Attributes, Needs, Requirements, or Demanded Quality	
Less Invasive	4
Short Operating Time	5
Reduced Number of Tools Used	4
Cognitive Burden	3
Short Recovery Time	4.5
Reduced Number of Steps	4.5
Physical Labor	4
Imaging in Excess of Standard Care	5
Up-Front Costs	4
Operating Costs	4.5
Preoperative Planning Time	3
Training	4.5
Collaboration with Outside Entity	5
Accurate Coronal Alignment	4.75

9.5.2.4. House of Quality

Based on their House of Quality (Appendix A) the student concluded that many of the devices on the market offer fairly similar benefits, while falling into the same basic traps. Cutting guides on the market were found to be fast, but additional medical imaging is by all appearances unavoidable with newer technologies requiring 3-D models of the bone to operate. Though an issue based on customer feedback, the student felt there was no way to avoid this pitfall. The student concluded that there were opportunities for operating room time savings, reduction of invasiveness, and elimination of many procedural steps as opportunities that had either been poorly addressed by past products or addressed relatively inconsistently [249]. This feedback was then used to create a

series of queries to the knowledge bases instantiated within the framework. Additional queries searched for function specific devices that might be of use to the student for ideation.

9.5.2.5. Conceptual Design

During this initial ideation phase, the student was asked to generate concepts for new devices for total knee replacement surgeries, focusing on the femoral guide. The resulting concepts were then ranked using estimates of their performance along each of the requirements noted in the surgeon survey. The student then undertook a second ideation phase using information retrieved from the ontology. Since ontologies are highly specialized, its knowledge base was instead queried and the results compiled in a document summarizing the proposed value, basic function, and any drawbacks of products retrieved by the query. A digital copy of the finished dossier was provided to the student to provide potential inspiration for new designs. The student was then instructed to engage in a second ideation phase.

9.5.3. Modeling of Stakeholder Preferences

Preference models were created to support use of the DWAM method independent of the student's work. These are used in both the initial concept selection and the subsequent design iterations in DWAM to distinguish between potential solutions to problems, and selection of a best design.

The surgeon point of view was captured via the student survey (Appendix B. The surgeon was asked to rate each requirement in terms of how important it would be in a decision to use or not use a new orthopedic device of an unspecified nature. These were

used to construct a simple value function to represent the surgeon preferences of the form:

$$V_{surgeon} = \sum_{j=1}^n w_j x_j \quad (27)$$

where w_j is the weight of the j th surgeon requirement obtained from the survey and normalized so that the sum of all weights is equal to one, and x_j is the estimated performance of the alternative of the j th requirement in the House of Quality normalized between 0 and 1.

Other stakeholders were assumed to be indifferent to intraoperative factors that do not directly affect them. For example, insurers would not necessarily care about issues relating to the number of tools used during the operation. Instead these groups were modeled as interested in solely minimizing incurred costs. More nuanced preference information might be better, such information would also be difficult to come by even in an industrial setting due to major legal and ethical barriers [19]. Moreover, for commercial stakeholder groups this is somewhat similar to characterization in past literature [26].

Requirements were mapped to each stakeholder, and cost rate information identified via subsequent research. These rates then acted as weights for each requirement. The student was then asked to estimate the performance of each design on a scale from 1 to 5, with 1 the worst possible outcome (equal to or exceeding that of the unassisted surgery) and 5 the best (large scale improvement on the criteria).

9.5.3.1. Creation of Stakeholder Value Models

Four requirements were considered to have an effect on the costs incurred by the non-surgeon stakeholders. These included the recovery time, considered in this case as

the expected length of hospital stay, reduction in the number of tools, reduction of operating room time, and the cost of sterilization. Weights for each requirement derived based on the total incurred cost of the surgery (Table 12).

Table 12. Cost rates used to construct value functions for the non-surgeon stakeholders

Item	Cost Rate	Base Surgery	Reference
Operating Room Time	\$62.00 / minute	120 minutes	[250, 251]
Tool Sterilization Cost	\$0.43 / instrument	150 instruments	[252]
In Hospital Days of Recovery	\$2271.00 / day	3 days recovery	[253]
Additional Imaging	\$1000.00	No imaging	[254]

It should be noted that these factors are not intended to be models of the entire cost incurred by any of these groups. Instead, they aim to characterize which of the student's metrics would meaningfully impact stakeholders and estimate the extent of that impact. The stakeholder value models were constructed relative to the costs incurred during the typical total knee replacement surgery, with any cost exceeding those costs assigned zero value. Value then increases linearly towards one as cost decreases towards zero for all stakeholders. For the patient the value model is directly related to the days of recovery in the hospital, which will directly impact any contribution they make to the cost of their care:

$$V_{patient} = w_r E_r \quad (28)$$

where V_{patient} is the estimated value to the patient, E_r is the estimated performance on the recovery time, and w_r is a constant restricting the range of the value between 0 and 1. Since only one factor is included, m_r is 0.25. For insurers, the model is nearly identical, but a second term is added for additional imaging requirements. The value function for the insurer group is:

$$V_{\text{insurer}} = w_r E_r + w_{\text{img}} E_{\text{img}} \quad (29)$$

where V_{insurer} is the estimated value to the insurer, w_r and E_r are the same as above, E_{img} is the estimated performance on the imaging requirement, and w_{img} is weight. The two weights are normalized such that they scale 0 to 100% elimination of their cost between 0 and 0.5 and sum to 1. E_r and E_{img} are similarly normalized.. In practice, the E_{img} will almost always be 0 or 5, as the function would require the elimination of imaging entirely to “beat” a traditional knee replacement surgery.

By comparison the hospital’s value function is dependent on equipment and timing factors that represent a combination of direct costs and opportunity costs. These include the cost of sterilizing equipment and the amount of operating room time required to complete the surgery. Preparation and cleanup times in the operating room are assumed to be the same regardless of surgery.

$$V_{\text{hospital}} = w_{\text{tool}} E_{\text{tool}} + w_{\text{OR}} E_{\text{OR}} \quad (30)$$

where V_{hospital} is the estimated value to the hospital from a given device, E_{tool} is the estimated performance on the tool reduction requirement and E_{or} is the performance on OR time saving. The constants w_{tool} and w_{or} are computed as in the insurer value function. E_{or} and w_{or} are a performance ranking and scaling constant for operating room time. The constant w_{tool} is based off an estimated 7 trays of tools used in a typical knee

replacement, and w_{OR} is based off an estimated 2 hours of operating room time for the surgery.

The value functions allow consideration of multiple classes of stakeholder during the execution of the DWAM method. Given a more expansive set of device requirements based on more extended solicitation, more granular measures of each stakeholder or new classes of stakeholder would also be possible.

9.5.4. Measurement of Student Preferences

The student participant's preferences towards stakeholders were measured as described in 9.4.4.2. The student was presented with a series of choices between alternatives (Table 13). This process was continued until a unambiguous rank ordering of hypothetical alternatives could be constructed.

Table 13. Alternative pairings presented to the student for ranking. Contents represent the minimum set needed to create a preference ranking based on student responses

Alternative 1				Alternative 2			
Doctor Value	Patient Value	Hospital Value	Insurer Value	Doctor Value	Patient Value	Hospital Value	Insurer Value
1	0	1	0.5	0.5	0	0.5	1
0	0.5	0.5	0.5	1	0	1	0.5
0.5	0.5	1	0.5	0	0.5	0.5	0.5
0.5	0.5	1	0.5	1	0.5	0	1
1	0.5	0	1	0	1	1	1
0.5	1	0	0.5	0	1	1	1
1	1	0.5	0	0.5	1	0	0.5

9.5.5. Concept Selection and Detailed Design

The student selected a design concept based on scoring of the assisted and unassisted design concepts and created an initial CAD model of the device. The CAD

model was then used for subsequent completion of the proposed DWAM method. Four AM processes were considered: FDM, DMLS, PolyJetting, and SLS. The model was used to manually instantiate key features of the design into the ontology. These specifications were then assessed using the AM process, machine, and plan knowledge bases to identify a best manufacturing process for the design as is, and to identify potential problems with the design. The device usability was also assessed. This information was used for a secondary design refinement phase wherein the knowledge base was used to reconsider problematic features. Subsequent design phases also aimed to improve the initial design for specific processes. The final designs were then compared against the student's preferences, and a final design and manufacturing process selected.

9.5.6. Evaluation of DWAM

9.5.6.1. Concept Creativity Assessment

The concepts created with and without the aid of IFAMMeDD were both rated by two graduate student judges to characterize the perceived creativity and quality of the design. The student was also asked to self-assess their work, and their project mentor also provided a rating. While many product creativity metrics have been proposed, this work required a metric suitable for products at the sketch phase of design. Since the student was encouraged to flesh out high quality design ideas, group-based methods that consider the quantity of ideas were also deemed inappropriate. Based on these constraints, two evaluation methods were used. First, the judges were asked to rate their perception of the creativity of the design on a scale of 1 to 10, with 1 being not at all creative and 10 being the most creative. Since this approach only captures broad perceptions of creativity, for a more granular evaluation, the judges also completed the Multi-Point Creativity

Assessment (MPCA) [255]. This assessment uses Likert scale ratings between antonym adjective to rate the design along scales such as the extent to which it is surprising, logical, well formulated, etc.

9.5.6.2. Testimonial Data

The student participant was interviewed and asked to complete a survey to assess the usefulness of the information provided in the ideation dossier (Appendix F). This assessment was constructed to focus on the creative aspects of DWAM, and IFAMMeDD's role in enabling them. A second set of testimonial data was obtained after part redesign. A 3D model of the redesigned part was sent to an additive manufacturing expert with experience in all four processes considered. Their feedback and recommendations were then compared to those obtained via IFAMMeDD's reasoning.

9.6. Results

9.6.1. Ontology Development Results

IFAMMeDD was successfully constructed from the ontologies shown in Figure 49. Disregarding the knowledge bases, the core framework consists of 2535 classes, 266 properties, and 3915 logical axioms. The AM knowledge bases contained 26 products and 15 generic features. Rule sets for five manufacturing processes and 15 heuristic usability rules were included [53]. Over 150 terms from SNOMED CT including over 60 biomedical devices were enriched with functional information. The core ontological framework, sub-modules created to support the case study, and knowledge bases were classified using the Pellet Reasoner [153] with no inconsistencies.

9.6.2. Case Study Results – Student Work

9.6.2.1. Capture of Background Information in Ontology

9.6.2.1.1. Capture of Total Knee Surgery

Initial evaluation of IFAMMeDD focused on capturing a model of the total knee surgery as practiced both with and without various competitors. A similar instantiation process was also used for device concepts based on descriptions and drawings provided by the student.

SNOMED CT includes a term for total knee replacement surgery, which was specifically refactored to support the instantiation of the surgical details in the ontology. Surgical sub-steps were incorporated using the surgical procedure terminology component, and linked together using '*has part*' and '*part of*' relations to create a hierarchical representation of the surgical steps. These are then inferred to be part of the knee replacement operation. The tools used during each step are similarly linked to the main surgical instance (Figure 51).

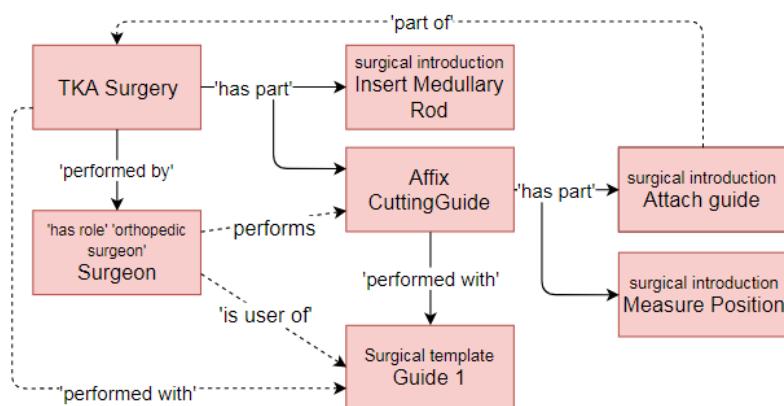


Figure 51. Partial representation of total knee replacement surgery instantiation. Dotted lines indicate inferred relations

Both instance level type axioms, a subset of Tbox that can be used to classify instances using classes not explicitly included in the ontology terminology, were used to represent additional surgical information (

Figure 52). This was mainly done to demonstrate multiple ways the ontology might be used. Instance level representations can be useful for keeping track of specific tools, while type axioms might be more practical to indicate things like the functions realized in a specific sub-set.

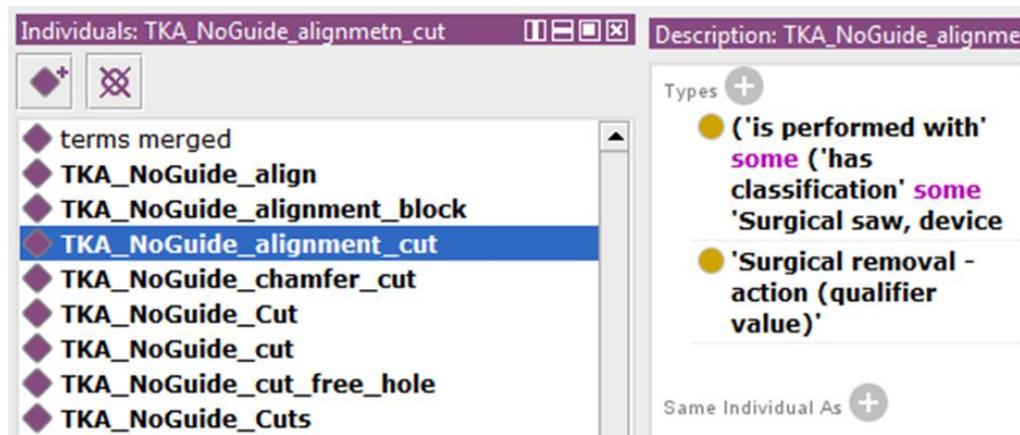


Figure 52. Instances in the ontology enriched with additional Tbox axioms

Individual sub-steps were classified using refactored clinical terminology for surgical actions wherever possible. This means that instances can be identified later using both queries for specific types of surgical action. It also means that assertions made about these terms are inherited by specific instances in the surgery. For example, in

Figure 52 above, the highlighted instance represents a single cut made during the surgery. Its type is a ‘Surgical removal – action (qualifier value)’, a type of surgical process named using SNOMED CT’s naming conventions. However, this class of procedure is noted as realizing a ‘removing function’, a functional basis term. So, the instance also realizes a removing function. A second axiom, however, notes that the

procedure ‘is performed with some entity having the classification of a ‘Surgical saw, device (physical object)’ in SNOMED CT. The surgical saw classification is similarly enriched with additional axioms, such as noting that the entity it classifies has a ‘severing function,’ and that it is the subject of a specification indicating hospital use environment. Similar to the procedure axioms, these are inherited by the single instance of the cut. As a result, it can be returned in future queries searching for processes that realize specific functions, or processes performed with devices intended for use in specific environments (Figure 53).

The screenshot shows a user interface for a DL query. At the top, there is a yellow header bar labeled "DL query:" followed by a sub-header "Query (class expression)". Below this is a text input field containing the query: "'occurs in' **some** ('has classification' **some** 'Operating theatre (environment)')." Underneath the input field are two buttons: "Execute" and "Add to ontology".

Below the query area is a section titled "Query results" with a sub-header "Instances (23 of 23)". This section lists 23 entities, each preceded by a purple diamond icon:

- TKA_NoGuide_alignment_block
- TKA_NoGuide_cut
- TKA_NoGuide_cut_free_hole
- TKA_NoGuide_drill
- TKA_NoGuide_drill
- TKA_NoGuide_finish_surgery
- TKA_NoGuide_get_reading
- TKA_NoGuide_insert_block
- TKA_NoGuide_meniscus**

For the entity "TKA_NoGuide_meniscus", there is an "Explanation for TKA_NoGuide_alignment_block Type 'occurs in' some ('has classification'" section. It contains five numbered steps:

- 1) 'has part' **SubPropertyOf: inverse** ('part of')
- 2) TKA_No_Guide 'has part' TKA_NoGuide_alignment_block
- 3) TKA_No_Guide **Type** 'Arthroplasty of knee (procedure)'
- 4) 'part of' **o** 'occurs in' **SubPropertyOf: occurs in'**
- 5) 'Arthroplasty of knee (procedure)' **SubClassOf** 'occurs in' **some** ('has classification' **some** 'Operating theatre (environment)')

Figure 53. Query, partial results, and logic used to identify surgical steps in the knee replacement surgery that occur in an operating room.

Business and human factors modules were used to represent the surgery from a designer perspective. The student found that there were several areas where existing products at least attempted to provide value to a customer. These included improving or ensuring the coronal alignment of the knee, reducing the amount of work required, shortening the surgery, and reducing tool use, which in turn reduces the need for tool sterilization. Some of these routes are human factors related, such as various roles played, the accuracy achievable by some surgeon, and the duration and complexity of task. Combined with the business terminology, these were instantiated as opportunities for new products. For example, the surgery realizes some invasiveness that negatively affects someone having the role of the patient in during the surgery. Modifying this invasiveness would provide value to this individual. Similarly, the duration and physical work involved in the surgery might pose a problem to a surgeon, or even a hospital administrator. A design aiming to affect these traits of the surgery might also be valuable (

Figure 54).

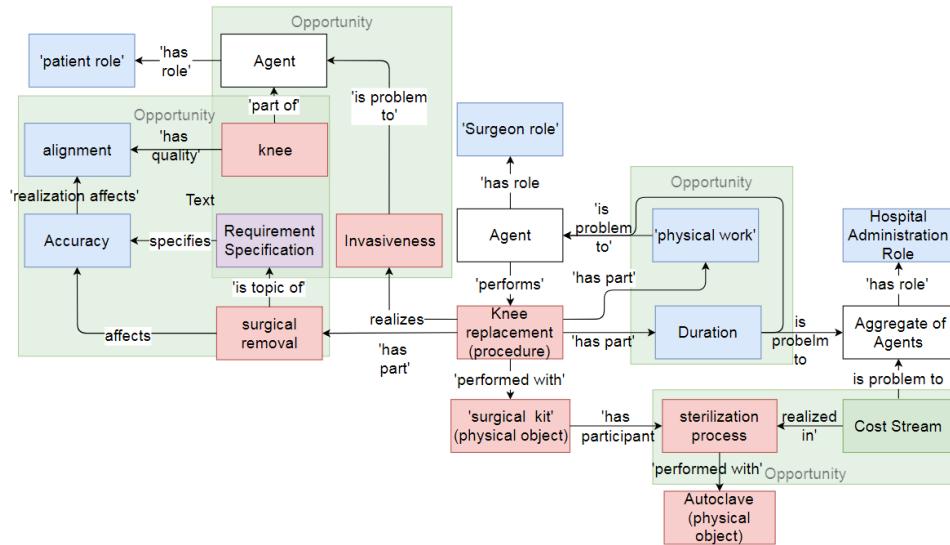


Figure 54. Information model depicting ontology representation of the opportunities for new products targeting total knee replacements

These observations were later used to formulate queries to identify possible design routes for the new product. They are similarly used to annotate competitor devices. In both cases opportunities were noted as being values of competitor devices or subsequent product designs created during the concept and detailed design process. That design process was also captured in the ontology and linked to these initial characterizations of the total knee replacement surgery.

9.6.2.1.2. Capture of the House of Quality

The student's house of quality was captured in IFAMMeDD using a combination of its design terminology and its medical terminology. The design terminology was used to create specifications or requirements, metrics, and the numerical data included in the ontology. These exist as information entities within BFO, which in turn characterize or “are about” other entities. The inclusion of regulatory information captures information beyond the student's House of Quality. In capturing the design specification for the

student's work, it was asserted to be a specification for some object that was classified as an Orthopedic cutting template in the FDA classification database. The object was also noted as having a classification as a 'Surgical template (physical object)' in SNOMED CT. The regulatory classification information links the related requirements and standards to the design and design specification. These are represented by a '*is subject to*' property (Figure 55).

A

Description: design_spec_TKA_Product

Types +

- 'design specification' **and** 'is specification for' **only**
- ('has classification' **value** 'FDA template for clinical use classification') **and** 'is specification for' **only**
- ('has classification' **some** 'Surgical template (physical object)')

B

Query (class expression)

'has function' **some** 'guiding function'

Execute Add to ontology

Query results

Instances (1 of 1)

device_new_orthopedic_cutting_guide

C

Property assertions: device_new_orthopedic_cutting_guide

Object property assertions +

- 'has classification' 'FDA risk class 1' ? @ classification
- 'has classification' 'FDA template for clinical use classification' ? @
- 'is topic of' design_spec_TKA_Product ? @
- 'is topic of' 'FDA risk class 1' classification ? @
- 'is topic of' classification_FDA_classification_syst ? @
- 'is topic of' 'FDA template for clinical use classification' ? @
- 'is topic of' regulation_888.4800 ? @
- 'is subject to' section_11-199 ASTM_F565-04 ? @
- 'is subject to' requirement_stainless_steel_material ? @
- 'is subject to' section_8-344 ISO_7153-1 ? @

Figure 55. (A) Tbox statements assigning classifications to the design specification (B) Query showing functional information inferred about product from SNOMED CT classification (C) Requirements information inferred from regulatory information

The initial classification used regulatory terminology to link the design to a specific regulatory document, which in turn references subsequent standards. The reasoner made two inferences. First, it inferred that the product (and specification for it) is within the scope of a regulation because they bear a classification within that scope.

Next, the standard and the requirements it specifies were linked to the product because they are referenced by the regulatory document using a specialized '*references guidance property*'. Like the surgery capture, the SNOMED CT classification leads the reasoner to infer functional information. In this case, the reasoner infers that the student's design for a custom cutting guide was being designed for a guiding function.

9.6.2.1.3. Representation of Competitors

Inclusion of competitors was based on information from all domains. A combination of the business model and human factors ontologies is used to map relations between a "typical" surgery and modifications of that procedure that are enabled by a competing device (Figure 56). Each competitor enables a surgical process that is viewed as a modified version of the base process. From this the modified process can be inferred to have the same basic steps and tools as the base surgery with subsequent axioms expressing modifications to this base user process.

Assembly and functional information were used to express the composition, the intended functions of the competitor, and implications of those functions. These and other device traits were then annotated as values to various stakeholders. Additional clinical information represents an effect on invasiveness. Taken together these traits, and perhaps the elimination of surgical processes should it be desirable, were mapped to a value proposition or set of value propositions. In cases where additive manufacturing is used to create the competitor, as in the case of the printed cutting guides, the product can moreover be mapped to a set of enabling manufacturing capabilities. An identical approach was used to capture the design concepts, though the concepts are not noted as having a competitor role.

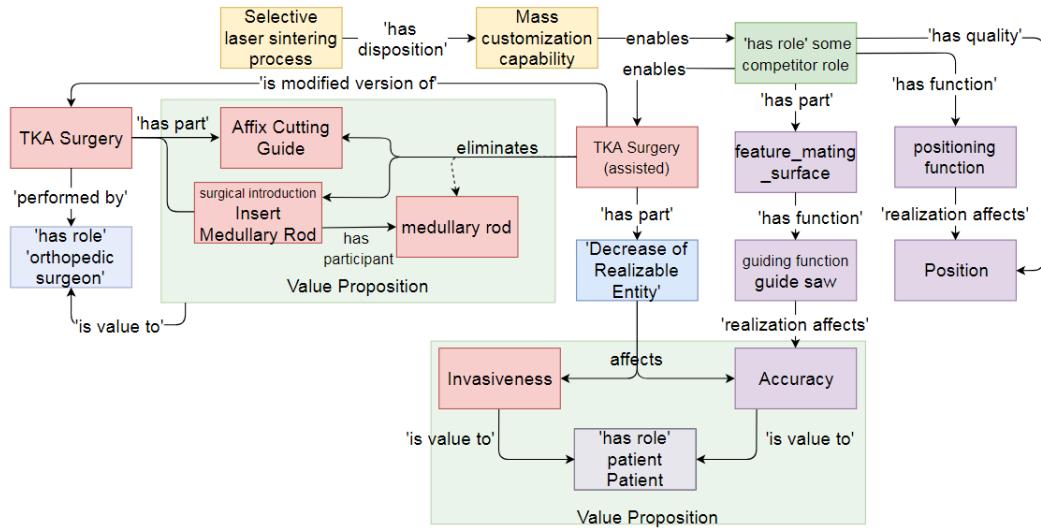


Figure 56. Capture of a representative additively manufactured cutting guide competitor used in orthopedic surgery

9.6.2.2. Querying Ontology Knowledge Bases

9.6.2.2.1. Formulation of Queries

A series of ontology queries were created based on the knowledge obtained from the student's background research and subsequently captured in the ontology. From the captured knowledge, the opportunities of interest included an increase of accuracy realized during a surgical process. Another patient focused opportunity is to reduce the invasiveness realized during a surgical process. Reduction of the quantity of non-disposable surgical tools used during the process, the number of steps of required, or the number of tools were noted to be of interest during the surgery and competitor capture processes. Based on competing products, existing products that guide, align, or position (or in the ontology participate in a process that realizes corresponding functions) may also be of interest. Devices having some variation of a '**removing function**' were also determined to be of potential interest as they might be repurposed. While it might make

sense to limit this specifically to a bone removing tool, neglecting this restriction gives opportunities for non-orthopedic results to be useful. Based on these findings, the following DL queries were used to discover instances of products in any of the knowledge bases that might match these descriptions:

$$[\text{enables or 'participates in'}] \text{ some } \left(\begin{array}{l} [\text{affects or 'has value'}] \text{ some } \\ \left(\begin{array}{l} [\text{invasiveness or accuracy}] \\ \text{or quantity or duration} \end{array} \right) \end{array} \right) \quad (31)$$

$$\text{'bearer of' some ('realization affects' some } \left(\begin{array}{l} [\text{invasiveness or accuracy}] \\ \text{or quantity or duration} \end{array} \right) \quad (32)$$

$$\text{'has function' some } \left(\begin{array}{l} \text{'aligning function' or 'positioning function'} \\ \text{or 'guiding function' or 'removing function'} \end{array} \right) \quad (33)$$

In each of the queries above, the bracketed expressions refer to terms that may be used in separate query clauses, as DL queries do not support queries of this type. The query in Equation 31 locates processes affecting the invasiveness or accuracy of the procedure, or alternatively a quantity of some entity or the duration of the operation. Equation 32 shows a query does the same for objects, and Equation 33 search for objects having some function. Outside of the keyword “some” all terms are classes or properties from the ontology.

9.6.2.2.2. Query Results

Invasiveness queries returned 12 unique devices and features across domains. These included both additively manufactured devices from ICAM’s knowledge base, the competitors captured from the House of Quality and subsequent representation in the ontology, and design features used by a subset of the devices. Accuracy queries largely returned the same information, with the addition of the ‘Surgical template (physical

object)' class from SNOMED CT and several devices classified as such including additively manufactured ones and competitor guides. A custom made neurological tool was also included in the results. Duration queries returned many of the same devices, as well as an additively manufactured surgical training model. Quantity queries returned no unique results. Functional queries also largely replicated the existing knowledge, with the addition of a set of SNOMED CT classes representing various types of surgical saw, knifes, scissors, reamer, and other tools used in tissue removal.

The screenshot shows a user interface for querying an ontology. At the top, there is a 'Query (class expression)' input field containing the following text:

```
('bearer of' some ('realization affects' some accuracy)) or ('has value' some accuracy) or (enables some (affects some accuracy)) or ('participates in' some (affects some accuracy))
```

Below the input field are two buttons: 'Execute' and 'Add to ontology'. The main area is titled 'Query results' and displays a list of 14 instances. The list includes:

- Competitor_Signature
- Competitor_TruMatch
- Competitor_Visionaire
- competitor MAKO_reamer
- competitor_SAN
- competitor_conformis
- competitor_conformis_femoral_cut_jig1
- competitor_navigo
- comptetitor_MAKO
- device_maxillofacial_cutting_guide
- device_neurological_guide
- device_orthopedic_cutting_guide
- feature_cutting_slot
- part_biopsy_holder

Each item in the list has a question mark icon to its right. To the right of the list is a sidebar with 'Query for' and 'Result filters' sections. In the 'Query for' section, 'Instances' is checked. In the 'Result filters' section, there is a 'Name contains' input field and a checkbox for 'Display owl:Thing (in superclass results)', which is unchecked.

Figure 57. Example query and results for devices affecting accuracy

In total, 7 broad types of additively manufactured device were returned, along with 8 competing devices, and 16 SNOMED CT biomedical device classes. These results were then compiled into a summary document with descriptions and pictures of each device. Since many devices were variations of the same type of device, these were aggregated combined summaries rather than unique devices in the ideation document.

9.6.2.3. Design Ideation Results

9.6.2.3.1. Initial Design Concepts

The student's first concepts were based largely on trying to eliminate tooling or steps required to align, secure, or swap cutting guides during the surgery. However, they introduced no fundamental changes to the basic surgical process. The student developed three concepts (Figure 58) during the design phase. The first is largely focused on reducing the size of the guide. The envisioned device would sit between the anterior epicondyles of the femur, with pins securing on both the anterior and distal faces of the knee. A bone saw is then used to remove the epicondyles and flatten the surface. The guide is then removed, and a standardized cutting block placed on the newly flattened surface. The process largely replicates the fixation process used by many of the cutting guides, and the novelty of the device is less clear. The second concept wraps around the knee and incorporates a plastic version of the standard cutting block used in most operations. Thus, this design consolidates the first concept with the other aspects of standard practice. In practice though, this may be difficult to achieve due to interference between the bone saw and hardware used to secure the guide. Thus, pins have to be driven and removed in a piecewise fashion to avoid interference. The third concept aims to avoid this as well by offsetting the cutting block portion off of the surface of the bone. Elongated pins are inserted at an angle so as to avoid the saw tool path. As a result the entire cutting process can occur without having to place or remove pins or use additional guides as in the other concepts and the competing devices.

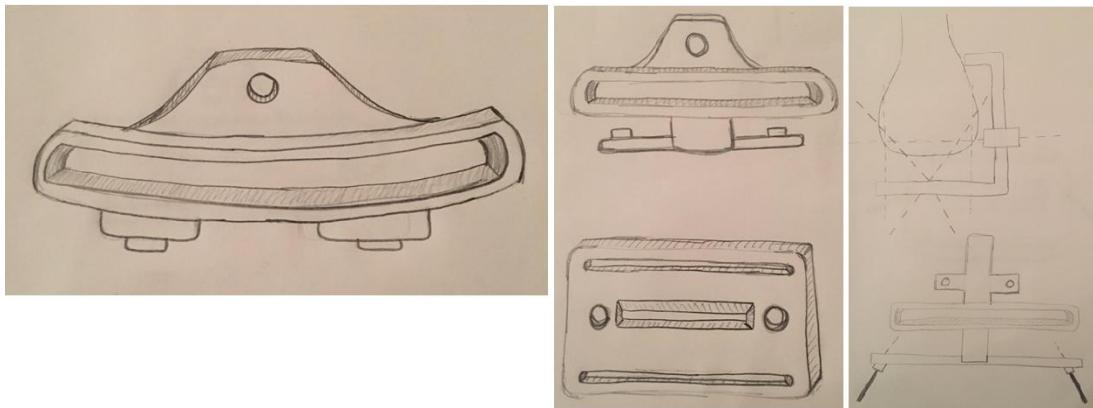


Figure 58. The first, second, and third concepts (left to right) created during the initial design ideation process

9.6.2.4. Concepts Created with Ideation Dossier

The student's second set of concepts were developed with access to the ideation dossier consisted of two closely related ideas. The student considered used a surgical reaming tool to instead remove tissue, with an externally placed guide serving to orient and limit the tool path of the reaming tool. The guide (Figure 59) is placed using a surface that conforms to the medial and lateral sides of the distal femur, and side oriented pins. The guide could optionally contain a slot which would then be used to secure the reamer and orient it close to the bone. The approach would have the effect of significantly simplifying the surgery, and the surgeon would simply trace the contour of the guide to completely resurface the bone.

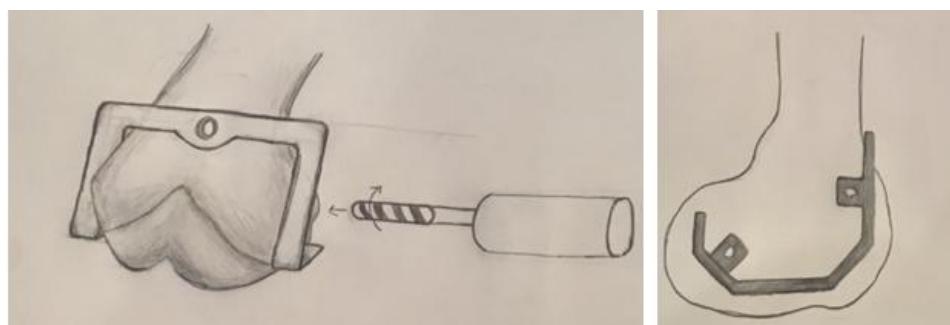


Figure 59. First student reaming concept created using the ideation dossier (Concept 4)

The second concept (Figure 60) uses a guide to implement a surgical process similar to that which is used in the surgical robots used for knee replacement surgeries. The reaming tool is reoriented normal to the bone, and the bit changed appropriately to resemble an end mill. A guard on the tool interfaces with the edges of a locally placed guide that limits the depth of material removal. This approach theoretically avoids issues with tool-guide interaction in the previous concept, and would also be appropriate for less invasive partial knee replacement operations.

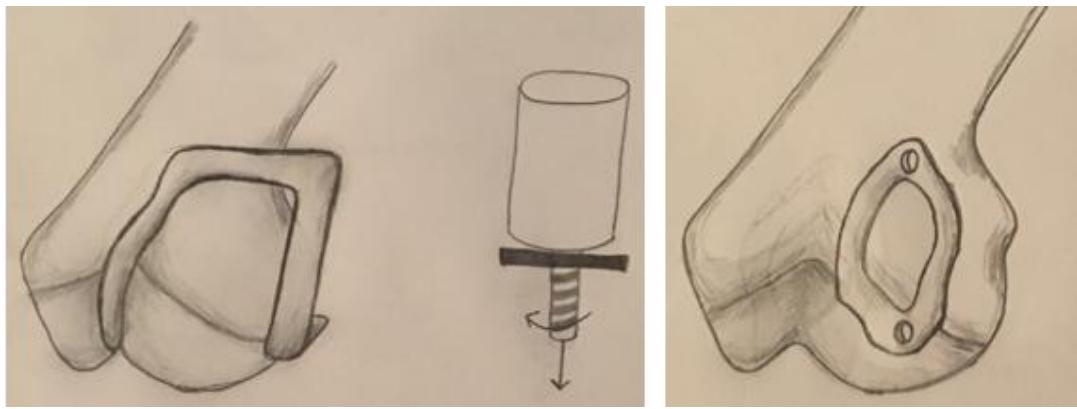


Figure 60. Second ideation concept created using the ideation dossier (Concept 5)

9.6.2.5. Student Preference Model Results

The student responses to paired hypothetical alternatives were used to establish rankings between the concepts. The results indicate:

$$1 \prec 4 \prec 7 \prec 2 \prec 5 \prec 8 \prec 3 \prec 6 \prec 9 \quad (34)$$

where each number represents the corresponding alternative in Table 10 on page 226 and the operator \prec indicates the right hand side of the expression is preferred to the alternative on the left hand side. This preference ordering, was used to formulate an optimization problem in form of equation (26) on page 228.

$$\text{Minimize } f(x) = \left(1 - \sum_{j=1}^n w_j\right)^2$$

Subject to:

$$\begin{aligned}
 -.5w_1 - .5w_3 + .5w_4 &\leq 0 \\
 w_1 - .5w_2 + .5w_3 &\leq 0 \\
 -w_1 + .5w_3 - .5w_4 &\leq 0 \\
 -.5w_1 + w_3 - .5w_4 &\leq 0 \\
 w_1 - .5w_2 - w_3 &\leq 0 \\
 -.5w_1 + w_3 + .5w_4 &\leq 0 \\
 -0.5w_1 - 0.5w_3 + .5w_4 &\leq 0 \\
 0 \leq w_i &\leq 1 \text{ (Slack constraints)}
 \end{aligned} \tag{35}$$

The optimization problem shown in equation (35) was solved by sequential linear programming. The solution was obtained using MATLAB's linprog function, which implements a primal dual interior point algorithm [256] with a fixed starting point. Subsequent verification using the same function with a simplex algorithm [257] found the exact value of the weights to be somewhat susceptible to the choice of starting point. An evaluation of robustness of the model [258] by using weights obtained via a grid sample of feasible start points. This analysis found the rank ordering of the student concepts did not change with the starting point. For the concept evaluations the initial (default) solution was used resulting in $f(x) = 7.08 \times 10^{-30}$, $w_1 = 0.133$, $w_2 = 0.780$, $w_3 = 0.035$, and $w_4 = 0.0518$.

9.6.2.6. Evaluation of Concepts

9.6.2.6.1. Un-weighted Evaluation

Concepts were ranked based on the student's estimates of device performance on the customer requirements. A 1 was given to designs that were deemed to have the worst result of either no improvement to the surgery or worsening of performance on the

requirement. A 5 was awarded when a concept was felt to have the best possible result. The student's rankings (Table 14) suggest overall mixed performance among alternatives.

Table 14. Student rankings of the five concepts generated during the design ideation processes

Customer Attributes, Needs, Requirements, or Demanded Quality	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5
Less Invasive	3	3	4	4	4
Short Operating Time	3	4	4	4	5
Reduced Number of Tools Used	3	3	4	4	5
Cognitive Burden	3	3	3	4	4
Short Recovery Time	3	3	3	3	4
Reduced Number of Steps	3	4	4	4	5
Physical Labor	3	3	3	4	4
Imaging in Excess of Standard Care	1	1	1	1	1
Up-Front Costs	3	3	3	3	3
Operating Costs	3	4	4	4	4
Preoperative Planning Time	3	3	3	3	3
Training	1	1	1	1	1
Collaboration with Outside Entity	1	1	1	1	1
Accurate Coronal Alignment	4	4	4	4	4

Like the competitors, all concepts had poor performance on the imaging, training, and collaboration requirements. The student felt these were inherent to the cutting guide devices, and so there was limited scope to alter these aspects of the devices. Otherwise, the student generally estimated similar levels of performance between the first three (unassisted) concepts, and slightly higher performance in the final two (assisted) concepts.

9.6.2.6.2. Competitor and Concept Value to Stakeholders

The value models and student preference model were used to rank both the concepts and the competing devices in terms of value to each stakeholder group. The

competitor calculations (Table 15) indicate that the competitors were overall weak for the hospital and insurer, but comparable (Table 16) to the newly devised concepts in value for the patient and insurer.

Table 15. Ranking of competitor values based on student performance rankings and stakeholder value models

	Competitor 1	Competitor 2	Competitor 3	Competitor 4	Competitor 5	Competitor 6
Surgeon:	0.55	0.47	0.47	0.49	0.55	0.52
Patient:	0.60	0.60	0.60	0.60	0.60	0.60
Insurer:	0.44	0.44	0.44	0.44	0.44	0.44
Hospital	0.50	0.50	0.50	0.25	0.50	0.50

The rankings show relatively stronger performance for the assisted concepts, and overall the student's estimated value for their own concepts meets or exceeds that of the competitors.

Table 16. Value estimate of the five student concepts for the medical stakeholders and the designer

	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5
Surgeon:	0.52	0.57	0.59	0.62	0.68
Patient:	0.60	0.60	0.60	0.60	0.80
Insurer:	0.44	0.44	0.44	0.44	0.65
Hospital:	0.50	0.75	0.75	0.75	1.00
Designer:	0.58	0.60	0.61	0.61	0.80

The rankings of the concepts show that across all stakeholders the overall concept selection decision is dominated by Concept 5 under the condition of certainty for all performance estimates. Indeed, even neglecting this option closer inspection of the results reveals that in any pairing of the five concepts one alternative is dominated.

9.6.2.7. Detailed Design Model

The student created a CAD model based off Concept 5. This was used to complete the DWAM method. Since the student did not complete detailed engineering analysis of their design, these aspects of DWAM were neglected.

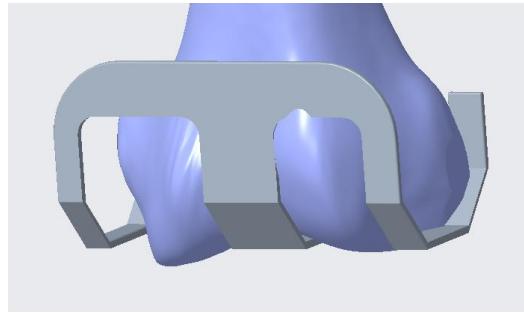


Figure 61. Student design of selected cutting guide concept

9.6.3. Case Study Results: Implementation of DWAM Methods

The student designer's design ideation phase completed the initial phase of DWAM utilizing the basic infrastructure provided by ICAM and enriched with additional medical and human factors terminology. The resulting design model was evaluated and modified using the full DWAM method.

9.6.3.1. DWAM Assessment

9.6.3.1.1. Instantiation of Student Design

The student's CAD model was used classify features and dimensions for manufacturability analysis. These were captured in a spreadsheet and read into the ontology using Protégé's Cellfie plugin. The instantiation was completed for two orientations: one in which build platform area was minimized by printing the joint surface overhanging and one which minimized the amount of overhanging material. Additional manufacturing requirements were determined based on the student's design

requirements. Notably, as the device must be able to accurately guide the motion of a reaming tool, the contact surfaces with the bone must be of high enough quality to ensure a good fit.

9.6.3.1.2. Human Factors Assessment

Three usability issues were noted. First, the device securing process has a possible error during attachment, which is common to most guides. Since the device is in no way anchored while being affixed with pins, manual application of pressure is the only way to secure the guide. As noted in the student's review of the market, this is an area that can negatively impact the overall accuracy of the device. Second, the template as designed by the student does little to control the reamer position outside of the depth of reaming. Tool rotation could however cause unwanted bone damage or removal, and potentially damage the guide itself. Both constitute high priority usability issues as they directly affect the clinical outcome and are thus of high importance to most of the stakeholders. The third issue relates to the accessibility of all planes, which may be limited by joint anatomy the position of the knee during the operation.

9.6.3.1.3. Manufacturability Assessment

Four processes were considered based on the availability of process rules, machine information, and likelihood of applicability to the design. These were Polyjetting, selective laser sintering, fused deposition modeling, and direct metal laser sintering. The first step in assessment of each process was to identify whether a feasible material might be found. Since the device is to be used in a surgical case, the material must be appropriate for medical usage. The medical terminology has no terms relating

suitability for medicine, and so this check had to be done manually by researching the availability of medical grade materials for printers in each process. Outside of this restriction and later material performance concerns, no other material requirements restrict what can be used for this device. All four processes support printing for medical applications, with Polyjetting using a proprietary medical grade polymer, SLS and FDM having medical grade nylon materials, and DMLS uses medical grade stainless steel, cobalt chrome, or titanium. Thus all four processes pass an initial check.

The second DAMPrO phase checked the instantiated design specification against process rules for each of the four processes. The platform area reducing option was rejected for all processes except Polyjetting. In this print orientation, the contact surface orientation generates warnings for all printers indicating an issue due to its orientation as a concave overhanging structure. In the case of DMLS this leads the framework to generate a warning that indicates that this form will cause issues with accuracy. Moreover, in the case where the overhang is unsupported another rule notes potential surface roughness issues. For SLS similar a similar rule leads to similar warnings. Need for support, the sensitivity of affected regions to accuracy defects, and the potential for sagging, and other build issues with FDM also led to worries for this process. Since the contact surface in question is critical to the function of the guide and directly impacts the quality of the surgery, this orientation had to be rejected considering these warnings

The overhang reducing orientation was less problematic. Process rules noted the same features in all cases, though the severity of the resulting warning varied given the template requirements (Figure 64). For DMLS, several features require overhangs that require support. Almost all the overhangs were noted by the framework warnings

potential surface quality issues without support. The support requirements might be highly problematic for DLMS given the need for expensive post processing. No severe issues were noted for SLS. Though accuracy and roughness might suffer somewhat in the stepped overhang regions of the guide, these areas are less critical to the function of the device. They were thus deemed to not have any major impact on the results. No critical issues were noted for PolyJetting, though all overhanging features required support. Since the PolyJet support structures are easily removed with chemical baths or washing, this was deemed less problematic than in the case of DMLS. The warnings attached to the FDM assessment were similar to DMLS. As printed the high angularity overhangs require support, but since this support can be removed easily it was not deemed to be as critical an issue.

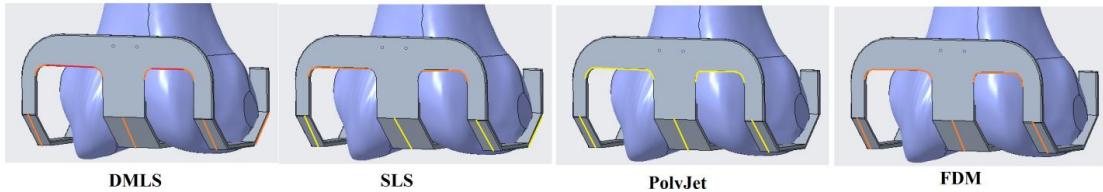


Figure 62. Representation of problem features on the student design flagged in the manufacturability check with process rules. Red indicates a problem judged to be severe in the context of the design requirements, orange a moderate problem, and yellow a mild one.

Assessments of the design against the specified performances of the machines in the AM machine knowledge base yielded no issues. Since the student has did not analyze their model for structural strength, no performance related issues were noted.

9.6.3.2. Re-Design of Cutting Guide

9.6.3.2.1. First Re-design

Based on the human factors and manufacturability assessments the student's design had two major issues. Since these likely require non-trivial geometric modification they were considered first and the geometry rechecked after modification. The first issue is comparatively minor: the guide has no way to be secured during fixation. The AM knowledge base was queried to identify instances where some AM feature or product was used to fix objects. The medical knowledge base was excluded for this query since the selected solution would likely need to be included as features of the device barring substantial design changes.

The query returned five instances from the knowledge base (Figure 63). One of these was a surgical clip created using Polyjetting. The clip had two designs: one with a soft material hinge to allow it to flex, and one in which the device was printed with a living hinge feature formed from a hollowed section near the union of its two arms. In both cases, the hinge allowed the device to deform into position. Combined with shrinking on the posterior fixation arm of the guide, this might allow the device to snap fit over the bone. A second feature that could be used is a snap fitting hook. With AM this could be printed directly into guide and used to along with a living hinge feature or flexure to physically tighten the guide around knee.

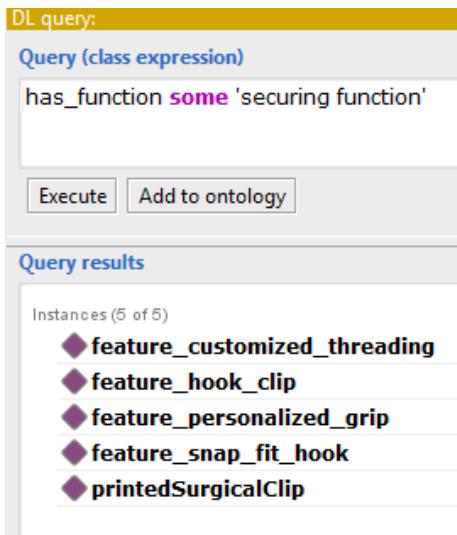


Figure 63. Query results for usability problem fix ideation.

The second issue was control of the tool path. In this case the knowledge base was searched to identify AM products and features that had been used to control a motion. This returned three instances, but two were deemed irrelevant as they dealt with guiding the motion of cable elements. The third was a track and ball feature, which Bin Maidin et al. [100] noted can be printed fully encapsulated with AM. The encapsulation was deemed not useful, but the creation of tracks was considered useful.

The third issue was the accessibility of the rear of the device using a reaming tool. While this could be addressed by gaining posterior access to the knee, this would be substantially more invasive. An alternative approach, such as another tool or guide configuration, was judged to possibly be appropriate. Thus, the knowledge base was queried to find instances of AM products that guide the path of a tool with the hope of finding a more advantageous approach. This notably returned the competitor products, which resurface the rear of the knee using a cutting guide and saw. While not ideal this was deemed compatible with the device overall

The different options were evaluated and in two decisions using the preference model derived in section 9.6.2.5 (Table 17). The track option taken since no other alternatives were identified. The options using an incorporated saw guide similar to competing products to posterior bone and the snap fit option were selected based on the student's preference model.

Table 17. Value to stakeholders and designer of usability fixes

	Decision 1		Decision 2	
	Rear-Access	Saw-Guide	Snap-fit	Hook-Clip
Value Surgeon:	0.58	0.65	0.68	0.66
Value Patient:	0.60	0.80	0.80	0.80
Value Hospital	1.00	0.75	1.00	1.00
Value Insurer:	0.50	0.72	0.94	0.94
Value Designer:	0.61	0.77	0.80	0.80

The guide was redesigned based on these decisions. The rear portion of the guide was removed, and the rear end of the guide converted to a flexure that deforms to accommodate the bone, securing the guide in place. This flexure also contains pinning hole that replaces the rear guide hole. Horizontal tracks were added to the cutting surface of the device. As designed the reamer bit must be large enough to remove the material underneath the tracks, with a neck of sufficiently small diameter to allow the bit to pass between the tracks. The resulting design (Figure 64) incorporates horizontal tracks that form fit to the bone, and which can guide a reamer to remove a volume of bone determined by the 3-D outer surface of the arms.

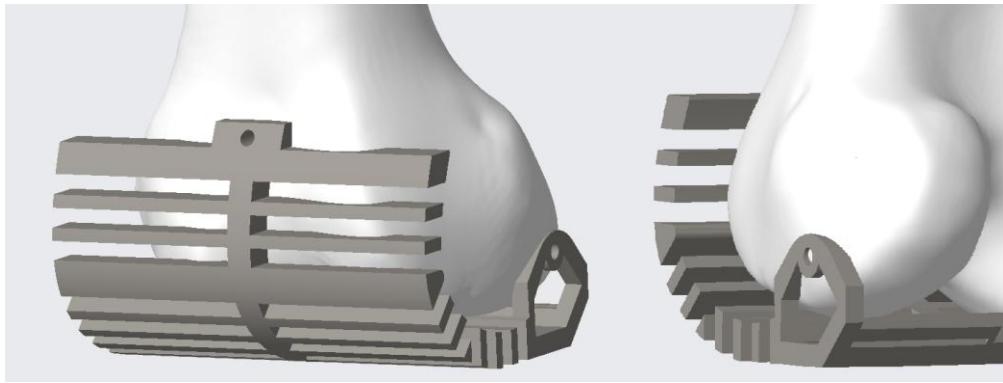


Figure 64. Left: front view of the revised cutting guide design. Right: rear view showing pinning flexure and posterior straight cut saw guiding slot

The new design was instantiated and assessed using the same method as in the original student design. The rule violations were essentially the same to those of the original design. The added features on the clipping portion and rails were noted as possible issues for DMLS and FDM and requiring support and possibly having poor surface finish or dimensional accuracy for SLS and Polyjetting. In these latter cases however, the areas where these issues occur will not cause major issues for the final functionality of the design and were regarded as acceptable. As with the original design, no machine level issues were noted.

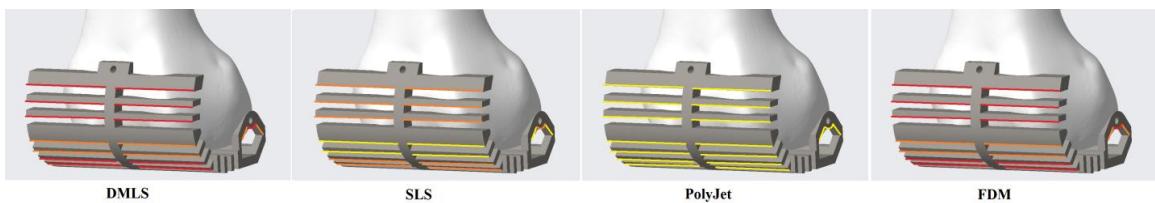


Figure 65. Representation of problem features on the revised design flagged in the manufacturability check with process rules. Red indicates a problem judged to be severe in the context of the design requirements, orange a moderate problem, and yellow a mild one.

9.6.3.3. Second Re-design

The manufacturability assessment points to major issues for both DMLS and FDM. The SLS and PolyJet issues noted were deemed to be acceptable as neither is expected to have a significant effect on the overall accuracy of bone removal. A second re-design process aimed to limit the amount of support required and the number of inaccurate features. Instead of querying the knowledge base, the DMLS and FDM process rules were queried to identify allowable overhangs. This revealed that both processes could fabricate overhangs between 30 and 45 degrees without issue. This rule of thumb was used to re-design a version of the part for DMLS and FDM (Figure 66). The design revised design changes the orientation of the tracks and uses sloping features to eliminate most overhanging portions of the guide.

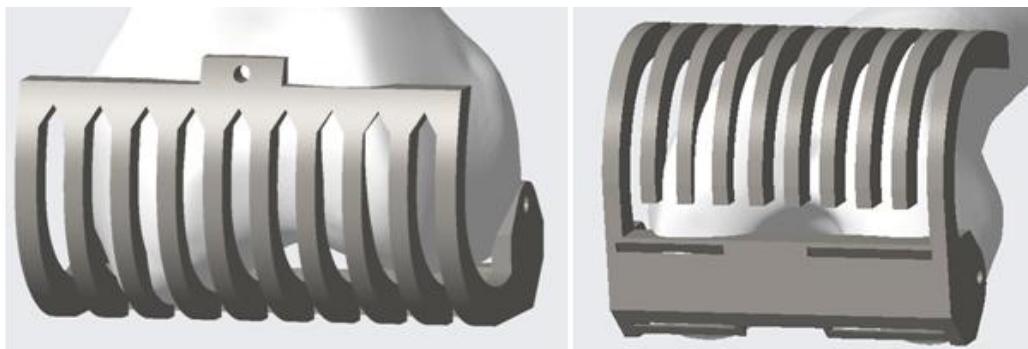


Figure 66. Front and bottom view of the revised design for FDM and DMLS

A final evaluation using the rule and machine assessment modules showed that the resulting model still required support for both processes, but this was considerably more limited than seen in the previous design (Figure 67). Nonetheless, for DMLS this represents a major issue, and so process was rejected as an option for all designs. For FDM the support remains a problem, but not necessarily a fatal one, and so the second design was accepted for FDM. This second design could also be constructed by PolyJet

and SLS without issues. Subsequent machine level analysis showed that the second design could be manufactured for FDM.

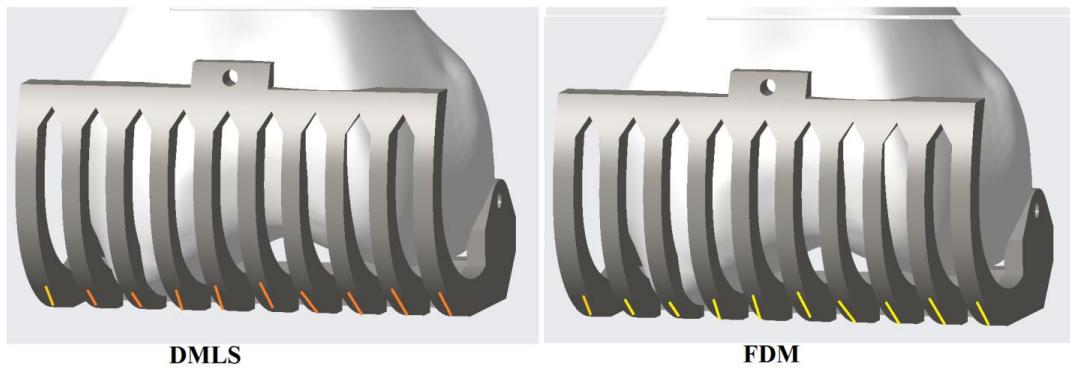


Figure 67. Representation of problem features on the revised design flagged in the manufacturability check with process rules. Orange indicates a moderate problem, and yellow a mild one

9.6.3.4. Selection of Final Design and Manufacturing Method

The decision on the design variant and manufacturing method were chosen using the model of the stakeholders' and student's preferences. Six total options emerged: the first design made with either PolyJet or SLS or the second made with any of the four candidate processes. The differences in manufacturing method and the final design were judged to only affect the accuracy of the surgery and the final cost, and so only these attributes were considered (Table 18). Since only the surgeon value model considers these attributes, only surgeon value is presented.

Table 18. Ranking of the cost and accuracy of each design

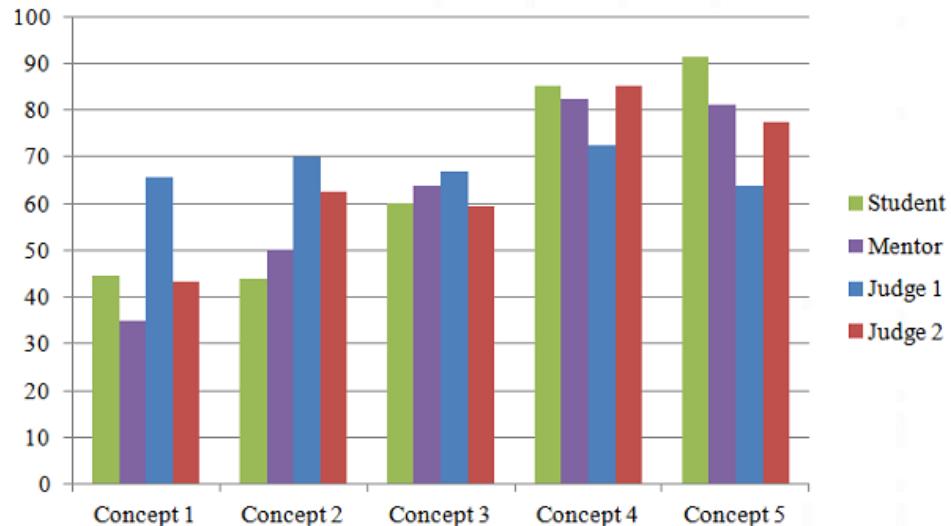
	Design 1			Design 2		
	SLS	Polyjet	DMLS	SLS	Polyjet	FDM
Cost:	4	2	1	3	2	4
Accuracy:	4	4	4	3	3	2
Surgeon Value:	0.65	0.55	0.52	0.57	0.54	0.58

Based on the scoring of the designs and the preference assessment, SLS with the first of the two designs was selected as the final design.

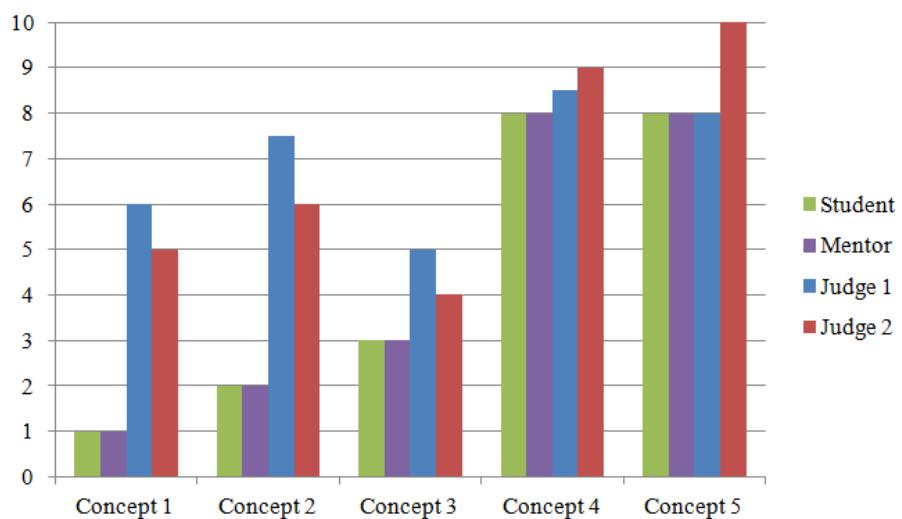
9.6.4. Evaluation of DWAM Method

9.6.4.1. Innovativeness Ranking

The student, mentor, and two judges completed the innovativeness assessment using both the MCPA scale and a simple creativity ranking (Figure 68). The student and mentor assessments generally follow the same trend, with overall higher rankings for the concepts developed with the aid of the ideation materials. The judge's responses were more mixed, with one judge indicating higher values for the assisted concepts, and the other indicating no consistent difference between the two sets. These findings are replicated in the simple creativity assessment.



(A)



(B)

Figure 68. Responses from the student, mentor, and judges on the MCPA creativity assessment (A) and the 1-10 scale assessment of the student concepts

Looking more closely at the individual sub-scales of the MCPA gives more insight into how the different judges ranked the concepts. The student innovativeness self-assessment (Table 19) showed overall higher rankings for the two concepts developed with assistance from ontology linked knowledge bases. In general, the student scored the

assisted designs more strongly on attributes having to do with creativity, such as the originality of the design and the extent to which the design was astonishing or unique. The responses for other concept attributes also tended to be higher, but the difference was less pronounced.

Table 19. Results of student self-assessment using MCRA scoring sheep and 1-10 creativity ranking

Attribute	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5
Original	10	45	55	90	100
Well-Made	70	20	55	80	80
Surprising	5	40	50	90	100
Ordered	90	40	60	80	80
Astonishing	5	45	70	90	100
Functional	70	40	55	80	80
Unique	5	45	60	90	100
Logical	100	75	75	80	90
Average	44.375	43.75	60	85	91.25
1-10 Ranking	1	3	5	8	9

The mentor's average assessment (Table 20) followed the same basic trend as the student assessment, with the exception that concepts 4 and 5 were rated essentially equal. However, this conceals relative indifference between many of the concepts when rated on the functional, ordered, and logical scales.

Table 20. Results of mentor assessment using MCRA scoring sheep and 1-10 creativity ranking

Attribute	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5
Original	10	30	50	90	85
Well-Made	70	70	80	80	80
Surprising	5	25	40	85	80
Ordered	70	75	85	80	80
Astonishing	5	20	40	85	80
Functional	50	60	85	75	80

Unique	5	45	50	90	85
Logical	65	75	80	75	80
Average	35	50	63.75	82.5	81.25
1-10 Ranking	1	2	3	8	8

The two independent judges similarly nuanced when comparing the assisted and unassisted concepts (Table 21). Again, the judges on average rated the assisted concepts higher attributes dealing with creativity, such as originality and uniqueness, but were often very skeptical of their functionality relative to the unassisted designs. As a result, there is only a small improvement in the average MCPA score for the assisted concepts when the judges are averaged together, and no consistent trend when looked at individually.

Table 21. Average MCPA responses for the two independent judges

Attribute	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5
Original	60	70	72.5	95	92.5
Well-Made	55	67.5	27.5	67.5	32.5
Surprising	22.5	47.5	67.5	87.5	85
Ordered	75	85	70	60	47.5
Astonishing	40	50	67.5	85	90
Functional	70	75	67.5	60	57.5
Unique	52.5	50	52.5	95	95
Logical	60	85	80	80	65
Average	54.4	66.3	63.1	78.8	70.6
1-10 Ranking	6	7.5	5	8.5	8

However, follow up remarks from the judges confound these findings somewhat. Notably, the judges were confused as to the student's design intent in several cases. Their responses in these instances may thus represent ambiguity in the student's sketches or

intended device functionality rather than an assessment of the overall creativity of the design.

9.6.4.2. Student Survey and Testimonial Data

The student survey and written testimonial indicated a consistently positive response. She indicated that the ideation dossier helped expose the student to medical devices they were not familiar with and would have had to spend additional time searching for otherwise. They also noted that the information helped with the development of ideas that they would have been unlikely to come up with otherwise.

Survey data indicated a similarly positive response. Based on their experiences using the dossier of devices drawn from IFAMMeDD, the student reported that the information was very useful for ideation. The student reported that the information was particularly useful for thinking of alternative ways of removing bone. In this specific case, awareness of the use of reaming tools in surgical robots helped the student realize that there might be tissue removal options. The student reported that other designs returned by the queries were also useful, such as contoured surfaces for aligning surgical hardware and the use of 3-D printed hardware to control the 3-D position of a surgical tool. This would appear to indicate that both medical domain knowledge and additive manufacturing examples were useful in the creation of the designs.

9.6.4.3. Manufacturability Validation

Consultation with an additive manufacturing expert verified the manufacturability findings obtained from the framework. As noted by the rule checks, the overhanging features on both versions of the part required overhangs for FDM, PolyJetting and SLM. The expert noted no other issues relating specifically to machines. Based on this

assessment and information regarding the requirements of the device, the expert concluded that SLS would be the best option for either design.

9.7. Discussion

This dissertation has argued that the challenges posed by medical device design are largely ones relating to the application of knowledge. The ontology-based methods presented throughout and culminating in the creation of IFAMMeDD fundamentally seek to facilitate better design through automated reasoning, semantic querying, and knowledge management. While individually considering knowledge domains relevant to medicine, as in Chapters 5-8, the combination of these domains into a coherent framework and method offers a powerful approach to aid in the creation of medical devices.

The underlying hypotheses driving the development of IFAMMeDD and DWAM are all related to the value of linked information. It was hypothesized that the multi-domain approach, for example, would allow detailed knowledge capture and reasoning across domains. As seen in the surgical capture, this in fact allowed for a rich view of the surgical process, and from that view the ontology was able capture possible value avenues for new devices. Similar to this, each competitor and design concept could be mapped to a base surgical process, and so the impact of each design on various stakeholders could be captured fully. DWAM was hypothesized to facilitate creative design ideation and problem solving. The ability to obtain relatively useful information via queries throughout this chapter can be seen as verification that this is the case. The student case study offers some validation to these hypotheses as well.

The student case study points to the practical uses of an ontological approach to support design. On the ideation side, the use of a knowledge base linked to functional, clinical, and value driven terms provided a fairly diverse set of devices that might inspire new design solutions. From both the student testimonial and judge assessments, this seems at the very least to help with creativity. The overall quality and functionality of the devices had more mixed results. This suggests that the ideation aid implemented using IFAMMeDD might help generate more creative ideas, but that these ideas ultimately need to be subjected to robust, context dependent engineering assessment. While the student did not have access to this information, much of this was already represented in IFAMMeDD. Future work with a more accessible version of the framework might be useful to see the extent to which designs can be made both more creative and functional.

The multi-domain knowledge in IFAMMeDD also seems to be of note. Much of the student's later designs focus not just on a change to the form of the device, but also to the tooling used. The ideation dossier included substantially different tools than are used in many of the competing devices. The student noted that this type of information was among the most useful. Greater knowledge of the resources already available proved to be critical to the final design.

Beyond the student work, the fully implemented DWAM method appears to be of considerable value. Notably, the conclusions reached using the framework were largely identical to those reached by the AM expert when presented with the re-designed parts. This is valuable, as it may allow designers with comparatively little AM expertise to nonetheless develop designs that are suitable to AM processes. As seen in the case study, the combined use of manufacturability assessment and ideation aid meant that it was

possible to both identify problems and then identify solutions to them within the framework. Inclusion of human factors assessment in this process meant that the design was substantially altered, possibly preventing costly investment in a problematic design. Machine level information proved less useful in this case study due to the overall size of the device and limited capability requirements. However, in other designs these types of consideration may well dominate the design, and so their inclusion in DWAM seems merited.

Despite these promising findings, the student case study does leave some avenues less explored. While value functions were created for multiple stakeholders, both the student preferences and assessments of the devices ultimately rendered these value functions redundant for most of the design process. The student was largely indifferent to most stakeholders, and so there was relatively little scope to explore tradeoffs between different designs. The individual student concepts also dominated one another, meaning that there was no real need to apply a preference model to determine a best course. Future work should explore cases where this decision analytic component is more informative.

IFAMMeDD and DWAM do have notable limitations. As with any knowledge based approach, the quality of knowledge that one can retrieve from the framework depends on what knowledge has already been captured. Formulation of these knowledge bases is difficult and time consuming. Accessing that knowledge requires a fairly specialized skill set, along with extensive knowledge as to the structure of the ontology itself. Future work should investigate integration of the ontological portions of this work into existing engineering tools and workflows so that they might be made more usable.

Despite these limitations, IFAMMeDD and DWAM have several notable strengths. One aspect that was only touched upon in the case study is the reusability of information from one's own past designs. Notably, the information captured in the ontology for this work might be used as the basis for future design processes. This means that future designs can reuse the insights from the redesign of the student cutting guide. Another strength of this approach is traceability enabled by their approach. Instance relations and other ontology constructs capture much of the rationale used to formulate the design, thus problems and solutions to problems can be traced throughout the design. The effect of specific regulations or stakeholders is similarly transparent thanks to their inclusion in both IFAMMeDD and DWAM. Overall, the results suggest the approach used in IFAMMeDD and DWAM have significant potential to aid in medical device design.

CHAPTER 10

CONCLUSIONS AND FUTURE WORK

10.1. Conclusions

The research presented in this dissertation advances an approach to medical device design based on automated reasoning and detailed semantic querying that are enabled by linked domain ontologies. It addresses in part the challenges of medical device design relating to usability and accessibility of diverse, multi-domain knowledge. The broad approach consists of capturing this knowledge in ontologically tagged knowledge bases, and then linking it to a central framework for engineering design. By doing so, it allows this knowledge to be used more effectively during the design process and facilitates design innovation, verification, and traceability irrespective of domain. As seen in the case study in Chapter 9, the capabilities enabled by the ontological approach taken throughout this work can be used to enable powerful design methods that aid in the development of more innovative products.

Cumulatively, the research presented in this dissertation offers several unique contributions to the literature on medical device design and engineering design more broadly. Though addressed as a management problem, little prior research focused on the practical challenges of understanding medical problems and ideating to solve them. To our knowledge the framework presented in Chapter 5 and extended in Chapter 9 is the first and only attempt to extend existing medical information frameworks for use in engineering design. Similarly, Chapter 6 introduces a basic approach for representing human factors data in a way that is directly relatable to design specifications and analyses. While many authors have addressed data collection and human factors design

methods, few have considered how these data might be integrated into a broader understanding of the design domain. Combined these works offer both a methodology and set of tools for overcoming many of the fundamental challenges of medical device design. Medical context can be represented *a priori*, and knowledge used across clinical and outside knowledge domains. Regardless of application area, user information, requirements, and other stakeholder considerations can be directly linked to a set of design specifications. These links can moreover be exploited to allow automated design checking. This application need not be limited to the medical domain, and so represents a contribution to engineering design research more broadly.

In addition to addressing problems unique to medical device design, the additive manufacturing frameworks described in this dissertation are a major contribution to existing literature on DFAM. The query based ontological design ideation approach described in Chapter 7 potentially allows existing opportunistic DFAM methods to be carried out with far greater specificity on much larger databases of past design solutions. This potential for re-use, and additional linking to knowledge of the underlying business case for using AM might help with more creative use of emerging technologies. The process and machine knowledge base developed in Chapter 8 moreover represent one of if not the only attempt to approach restrictive DFAM without first specifying a process. This may allow far greater scope to optimize designs across multiple processes and moreover might be extended to consider additive, reductive, and hybrid manufacturing approaches. Even absent the human factors and clinical portions of the integrated framework presented in Chapter 9, this work contributes the methodology, knowledge bases, and tools required to seamlessly link the previously disparate areas of

opportunistic and restrictive AM into one another. The research presented in this dissertation thus makes a major contribution to the broader design literature for AM.

When combined, these two major subsets of research enable a novel approach to medical device design. It first offers a novel method and computational basis for capturing and applying domain or institutional knowledge to new design problems. This in turn allows more innovative designs based on identifying new uses for existing solutions. It also may provide the basis for large scale integration of manufacturing or other types of reliability data into the design process. To our knowledge this work is the first exploring the use of linked domain ontologies to support ideation and design verification based on many otherwise disparate knowledge domains. As seen in Chapter 9, it offers a potentially powerful tool for ideation and design refinement. These capabilities and the knowledge capture abilities that enable them may have significant value in both medical device design and in other engineering fields.

Finally, it should be noted the ontology approach used in Chapters 7, 8, and 9 itself represents a significant contribution to the broader area of engineering ontologies. The ontological frameworks developed as part of this research medical device design are among the first engineering domain ontologies to be developed as orthogonal, interoperable ontologies that are conformal to a single upper level ontology and its style guidelines. These ontologies and the demonstration of the power of this approach embodied by the design methods and tools validated as part of this research represent a significant contribution to the broader area of applying ontologies to the engineering domain. While past work has been held back by the challenge of interoperation, the ontological framework developed as part of this work overcomes these challenges, and

moreover offers significant evidence of the usefulness and power of this approach. Subsequent extension of this framework and others like it in future works may offer significant benefits in the form of powerful, knowledge-based design tools that enable better designed and more innovative products.

10.2. Future Work

There remain several avenues for future research stemming from the work presented in this dissertation. Broadly, these include creation and evaluation of ontology augmented engineering design software, combination of cross domain design ontologies with data intensive applications, and more exhaustive and formal ontological modeling of the domains considered in this dissertation.

Much of the work presented in this work implements the theoretical basis for software to support the design of additively manufactured medical devices. Within any of the given applications, however, more future research should explore the practicality and usefulness of software supported by an ontological knowledge model. The case studies presented in this work show how these knowledge models might aid in design, but not whether they will be of use to a typical designer in a typical design. Within the context of this work, future research should focus on the implementation of the semantic web and software architecture to realize practical tools based upon linked ontological models. These might include standalone tools or alternatively retroactively introduce knowledge into existing engineering design tools. Building upon this implementation aspect should also be further investigation of the usefulness of ontologically augmented software, and indeed the ways these types of tools might be used in practice.

The use of both vast amounts of data and knowledge in engineering design is another potential avenue of future research. This work focuses largely on the use of knowledge, and cross domain linking of that knowledge to better reason upon a design. However, the same terminology used to support this work ultimately was created to contextualize and link entire healthcare systems worth of data that is unused in this work. While currently untapped, these data might support the design of products that are more responsive to the latent needs of patients and healthcare systems if used in the context of an engineering design. Similarly, the use of AM in this work largely ignores a broader understanding of processes. The data collection, modeling, and simulation that underscore process characterization could potentially be integrated into this work to enhance design, decision making, and process planning. The ability to reason upon these data in the context of design might yield desirable capabilities, such as an AM data enhanced version of DWAM that can account for process variation seamlessly with other design considerations. Alternatively, it might support better traceability of data and subsequent ability to construct large datasets, realizing in part the vision of the semantic web. Thus, future work should investigate the intersection between the use of ontologies for engineering design and data integration, machine learning and other data intensive analytics.

On the purely ontological side, there remain significant subsets of the engineering field and medical domain that have not been modeled in an ontologically rigorous way. The ability to construct cross domain ontologies and applications built upon them ultimately relies upon the existence of these types of model. This work addressed this larger shortcoming of the field in largely piecemeal way. Subsets of domains were

created to support the specific aims of this work, but in reality, larger, more robust modeling of these domains would be far more preferable in terms of flexibility, future interoperability, and the potential for supporting the design of complex systems. The creation of a core of engineering domain ontologies should certainly be a priority. On top of this engineering subfields and areas of scientific discovery in addition to biology should be further modeled with ontologies to support the design of useful domain applications.

APPENDIX A
STUDENT HOUSE OF QUALITY

Customer Attributes, Needs, Requirements, or Demanded Quality	Relative Importance of Engineering Metrics of Requirements															
	Volume	Incision Size	Attachment Locations	Number of Steps	Number of Tools	Size	Manufacturing Method	Accuracy of Coronal Alignment	Operation Time	Weight	Training Time	Imaging Machinery	Durability	Number of Cuts	Preoperative Planning Time	
Less Invasive	4	9	9	3		9				3				3		
Short Operating Time	5			3	9	3			9					9	3	
Reduced Number of Tools Used	4			9	3	9			3							
Cognitive Burden	4		3	9	9				3					9		
Short Recovery Time	4		3					9								
Reduced Number of Steps	5			9	9	3			3					9		
Physical Labor	4		3	3	9	3			3					9		
Imaging in Excess of Standard Care	1							9			9			9		
Up-Front Costs	3			3		9	9		9		9	9	3		9	
Operating Costs	3				3	9			9		3		3	3		
Preoperative Planning Time	1						9	3		9	9	3		9		
Training	2			3	3					9				9		
Collaboration with Outside Entity	1									9	9	3		9		
Accurate Coronal Alignment	4	9	9				3	9			9	9	9	9		
Direction of Improvement																
Measurement Units (SI)		cm^3	cm	#	#	trays	cm	type	%	hr	g	days	type	Pa	#	wks

Figure 69. Left and center rooms of student House of Quality

Table 22. Combined information from the left and right rooms of the student's House of Quality

	Competitor 1	Competitor 2	Competitor 3	Competitor 4	Competitor 5	Competitor 6
Less Invasive	2	3	3	4	3	3
Short Operating Time	3	3	3	2	3	3
Reduced Number of Tools Used	4	2	2	3	3	3
Cognitive Burden	3	2	2	2	3	3
Short Recovery Time	3	3	3	3	3	3
Reduced Number of Steps	4	2	2	3	4	3
Physical Labor	3	2	2	3	3	3
Imaging in Excess of Standard Care	1	1	1	1	1	1
Up-Front Costs	3	3	3	3	3	3
Operating Costs	3	2	2	2	3	3
Preoperative Planning Time	2	2	2	2	2	2
Training	3	3	3	3	3	3
Collaboration with Outside Entity	1	1	1	1	1	1
Accurate Coronal Alignment	4	4	4	3	4	3

APPENDIX B

ORTHOPEDIC SURGEON PREFERENCE SURVEY

Total Knee Replacement Surgical Device Requirements Survey

Please rate on a scale of 1-5, 1 being not likely and 5 being very likely, what the likelihood is that each of the following traits of a new surgical device for total knee replacement surgery would encourage you to use this device.

1. The device is **less invasive** than the technique you currently use.

1 2 3 4 5

2. The device **decreases operating time**.

1 2 3 4 5

3. The device **decreases the number of tools** needed for the surgery.

1 2 3 4 5

4. The device **decreases the amount of cognitive burden** required during the surgery.

1 2 3 4 5

5. The device **decreases recovery time** for the patient.

1 2 3 4 5

6. The device **decreases the number of steps** needed to complete the surgery.

1 2 3 4 5

7. The device **decreases the amount of physical labor** required to perform the surgery.

1 2 3 4 5

8. The device produces **more accurate coronal alignment** than the technique you currently use.

1 2 3 4 5

Please rate on a scale of 1-5, 1 being not likely and 5 being very likely, what the likelihood is that each of the following traits of a new surgical device for total knee replacement surgery would discourage you from using this device.

1. The use of the device requires **imaging in excess of standard care**.

1 2 3 4 5

2. Overall **cost per surgery is higher** when using this device.

1 2 3 4 5

3. The device **increases lead time** in planning the surgery.

1 2 3 4 5

4. The device requires **extensive additional training** for surgeons.

1 2 3 4 5

5. Use of the device requires **collaboration with an outside entity**.

1 2 3 4 5

6. The device produces **less accurate coronal alignment** than the technique you currently use.

1 2 3 4 5

Please list any other important traits that would encourage/discourage you from using this new device that are not listed above, as well as their respective rankings. Feel free to leave any other additional comments that you feel are necessary.

APPENDIX C

STUDENT SURVEY RESPONSES AND WRITTEN TESTIMONIAL.

Please rate on a scale from 1 to 5 with 1 being not at all and 5 being a great deal the extent to which you felt the ideation materials were useful in the following aspects of design ideation

1. Gaining new perspective on your design challenge

1	2	3	4	X5
---	---	---	---	----

2. Overcoming technical challenges in your design

1	2	3	X4	5
---	---	---	----	---

3. Inspiring new product directions you had not previously considered

1	2	3	4	X5
---	---	---	---	----

4. Taking Advantage of new technology

1	2	3	4	X5
---	---	---	---	----

5. Taking Advantage of the capabilities of new technology

1	2	3	4	X5
---	---	---	---	----

6. Taking Advantage of existing medical technology

1	2	3	4	X5
---	---	---	---	----

On a scale of 1 to 5 please rate the extent to which you felt the ideation materials helped make your design concepts...

7. More responsive to customer needs

1	2	3	X4	5
---	---	---	----	---

8. Higher quality

1	2	3	X4	5
---	---	---	----	---

9. More innovative

1	2	3	4	X5
---	---	---	---	----

The ideation materials were useful for identifying medical devices, that I did not previously know existed, that could be applied to my design idea. These materials save the designer time that they otherwise would have had to spend searching for relevant medical devices, and provides them with devices and design ideas they probably would not have found/thought of on their own without extensive research.

APPENDIX D

CREATIVITY ASSESSMENT FORM

Creativity Rating Score Sheet

The figure consists of eight horizontal scales, each with 15 tick marks and a vertical line at the 8th tick mark. The scales are arranged vertically, with 'Original' at the top and 'Logical' at the bottom.

- Original** (Top): From **Original** on the left to **Unoriginal** on the right.
- Well-Made**: From **Well-Made** on the left to **Crude** on the right.
- Surprising**: From **Surprising** on the left to **Expected** on the right.
- Ordered**: From **Ordered** on the left to **Disordered** on the right.
- Astonishing**: From **Astonishing** on the left to **Common** on the right.
- Functional**: From **Functional** on the left to **Non-Functional** on the right.
- Unique**: From **Unique** on the left to **Ordinary** on the right.
- Logical** (Bottom): From **Logical** on the left to **Illogical** on the right.

APPENDIX E

WEIGHT COMPUTATION MATLAB SCRIPT

```
%Solve for the weights for student value function
```

```
%Inequality constraint LHS
```

```
G = [-.5 0 -.5 .5; ...
       1 -.5 .5 0; ...
      -1 0 .5 -.5; ...
     -.5 0 1 -.5; ...
       1 -.5 -1 0; ...
     -.5 0 1 .5; ...
       -.5 0 -.5 .5];
```

```
%Inequality constraint RHS
```

```
B = zeros(7,1);
```

```
%bound weights
```

```
ub = [1 1 1 1];
lb = [0 0 0 0];
```

```
%objective function
```

```
%linprog only takes vector input
f = [-1 -1 -1 -1];
```

```
%Combine with equality constraint to get soln
```

```
%equality constraint
```

```
%w1 + w2 +w3 +w4 = 1
```

```
H = [1 1 1 1];
```

```
Heq = 1;
```

```
% options = optimoptions('linprog','interior point');
```

```
opts=optimset('LargeScale','off');
```

```
c=1;
```

```
for i = 1:50
```

```
    for j = 1:50
```

```
        for k = 1:50
```

```
            for n=1:50
```

```
                guess = [i/50 j/50 k/50 n/50];
```

```
                guessave{i,j,k,n}=guess;
```

```
                c=c+1;
```

```
                guess = rand(1,4);
```

```
                guess = guess/sum(guess);
```

```
                W(:,c) = linprog(f,G,B,H,Heq,lb,ub,guess,opts);
```

```
                y(c)=(1-[1 1 1]*W(:,i))^2;
```

```
            end
```

```

    end
end
end

% check for robustness of concept ranking
[m n] = size(W);
Iold = [1; 2; 3; 4; 5];
for i = 1:n
    score = concepts'*W(:,i);
    [temp I] = sort(score);
    if sum(Iold-I)~=0
        disp('rank reversal!')
        disp(i)
    end
    Iold = I;
end

```

APPENDIX F

IDEATION DOSSIER PROVIDED TO STUDENT

Ideation Dossier for TKA Surgery:

Overview:

This document summarizes a series of cases retrieved from a knowledge base of additive manufacturing use cases, surgical tools, surgical procedures etc. These have been further annotated with information about the underlying value proposition of various devices, the clinical personnel involved, and functional information about what the device has.

The contents of this document reflect plaintext descriptions and images reflecting the content individuals in the ontology returned by queries, as well as explanatory text summarizing the knowledge contained in OWL axioms attached to each instance.

All items are instantiated in the ontology and searchable using the DL query interface the fully classified knowledge base.

Procedure: Partial Knee Replacement Surgery



<http://totalknee.org/patient-education/partial-knee-replacement/>

Functional Description:

Partial knee replacement surgeries REDUCE INVASIVENESS and RECOVERY DURATION by reducing the amount of bone and soft tissue removal required in a knee replacement surgery. The knee replacement uses a minimally invasive incision to access the knee compartment in question (in the unicompartmental case) with a SURGICAL ROBOTIC SYSTEM.

Value Description:

Partial knee replacement surgeries REPLACE total knee operations in a subset of patients, and REDUCE INVASIVENESS, which leads to a shorter DURATION for recovery

Drawbacks:

Typical operations utilize robotic guidance which INCREASES COST. The partial knee replacement is

Device: NAVIO Surgical System: Smith and Nephew



<http://www.smith-nephew.com/professional/microsites/navio/>

Functional Description:

The NAVIO surgical system uses an infrared camera and motion tracker balls to capture the position of a bone REMOVING surgical tool and the knee joint of the patient. The bone removing surgical tool incorporates an ORTHOPEDIC REAMER. The computer uses a 3-D model of the patient's bone created through imaging and inter-

operative landmark palpation, planning parameters chosen by the surgeon, and joint prosthesis geometric data to SELECT bone to be removed.

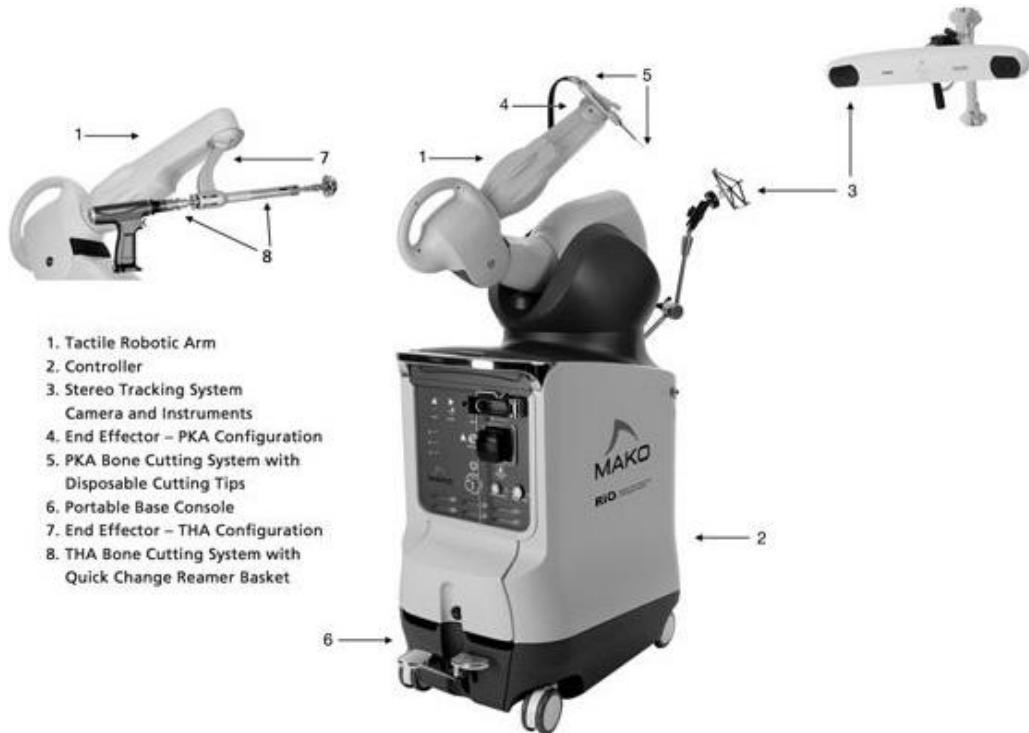
Value Description:

The NAVIO boasts INCREASED ACCURACY relative to other surgical devices. It REPLACES the cutting procedure used to prepare the joint for the implant. It ENABLES a less INVASIVENESS PARTIAL KNEE ARTHROPLASTY surgery by realizing a GUIDING FUNCTION with the robotic end effector, preserving bone, muscle, and ligament relative to total knee replacement. It incorporates MEASUREMENT DATA from the mechanical motions of the knee to PREPARE a surgical plan

Drawbacks:

The surgery has a longer DURATION compared to unassisted procedures. It adds multiple procedural steps to align. It may require a dedicated person having the role of a TECHNICIAN . It requires clinicians to participate in a TRAINING PROCESS. It requires 3-DIMENSIONAL MEDICAL IMAGING pre-operatively

Device: MAKO Surgical System



<https://www.wealthdaily.com/articles>this-robot-will-perform-your-next-surgery/6102>

Functional Description:

The MAKO surgical system uses an infrared camera and motion tracker balls to capture the position of a bone REMOVING surgical tool and the knee joint of the patient. The bone removing surgical tool incorporates an ORTHOPEDIC REAMER.

Value Description:

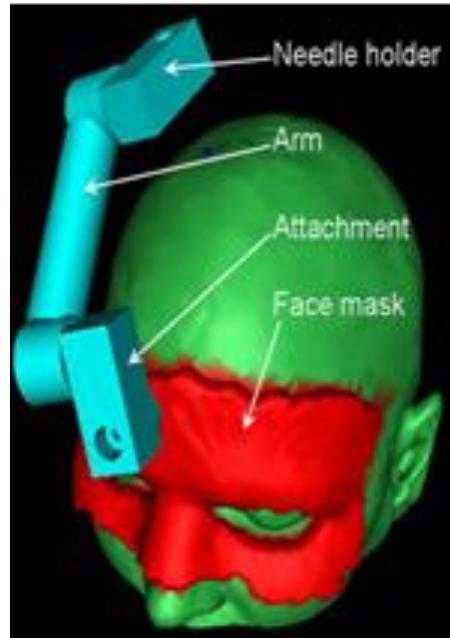
The MAKO boasts INCREASED ACCURACY relative to other surgical devices. It REPLACES the cutting procedure used to prepare the joint for the implant. It ENABLES a less INVASIVENESS PARTIAL KNEE ARTHROPLASTY surgery by realizing a GUIDING FUNCTION with the robotic end effector, preserving bone, muscle, and ligament relative to total knee replacement. It incorporates

MEASUREMENT DATA from the mechanical motions of the knee to PREPARE a surgical plan.

Drawbacks:

The surgery has a longer DURATION compared to unassisted procedures. It adds multiple procedural steps to align. It may require a dedicated person having the role of a TECHNICIAN . It requires clinicians to participate in a TRAINING PROCESS. It requires 3-DIMENSIONAL MEDICAL IMAGING pre-operatively

NEUROLOGICAL BIOPSY GUIDE



Rajon, D.A., Bova, F.J., Chi, Y.Y. and Friedman, W.A., 2009. Rapid fabrication of custom patient biopsy guides. *Journal of Applied Clinical Medical Physics*, 10(4), pp.260-272.

Functional Description:

The biopsy guide is used to perform a GUIDING FUNCTION using a biopsy needle guiding arm obtain the POSITION and then to LIMIT the DEPTH of a biopsy tool that performs a REMOVING FUNCTION and RETRIEVING FUNCTION. A custom mask affixes to the patient anatomy, an used to SUPPORT and POSITION a BIOPSY NEEDLE to within a few mm.

Value Description:

The biopsy guide uses a MASS CUSTOMIZATION capability and a PRINT FROM IMAGING capability, and a RAPID FABRICATION capability to realize an INCREASE in ACCURACY, providing a benefit to PATIENTS by avoiding morbidity and to CLINICIANS by REPLACING EXPENSIVE robotic surgical tools.

Drawbacks:

The printing DURATION is exceeded the authors' desired 2 hour time frame.

ORTHOPEDIC SURGICAL REAMER



alibaba.com

Functional Description:

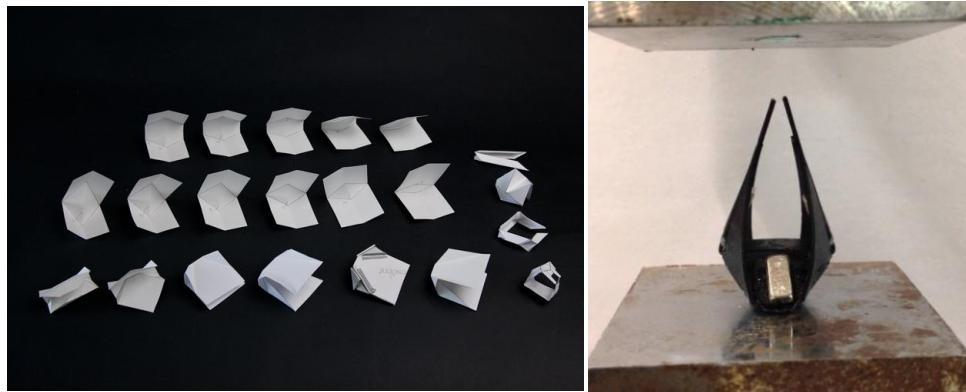
An Orthopedic reamer REMOVES BONE TISSUE by using a rotating bit that removes bone oriented NORMAL to its bit. It is similar to a router in woodworking, or amilling machine. Bits can be

Value Description:

The biopsy guide uses a MASS CUSTOMIZATION capability and a PRINT FROM IMAGING capability, and a RAPID FABRICATION capability to realize an INCREASE in ACCURACY, providing a benefit to PATIENTS by avoiding morbidity and to CLINICIANS by REPLACING EXPENSIVE robotic surgical tools.

Drawbacks:

FOLDING SURGICAL TOOL



Functional Description:

The folding surgical tool uses a FOLDABLE ARTIFACT FABRICATION CAPABILITY combined with a BISTABLE ARTIFACT FABRICATION CAPABILITY to create a folding surgical FORCEP for use with a ROBOTIC SURGICAL SYSTEM. The tool is introduced in a low profile configuration, and then folds itself into a tool for GRASPING and SECURING FUNCTIONS. This folding and unfolding process changes the AREA of the device, allowing introduction through a small TROCHAR

surgical tool

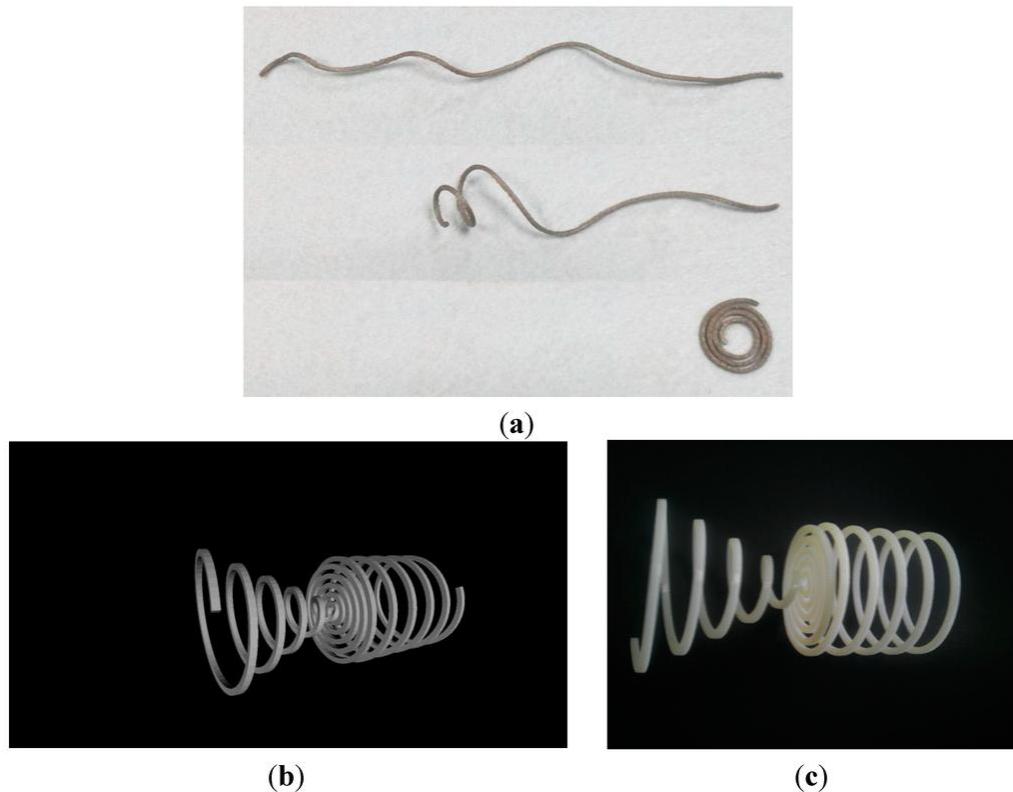
Value Description:

The tool REPLACES a larger surgical forcep. It's DECREASING FUNCTION affecting AREA has the effect of decreasing INVASIVENESS as well, as the tool may be introduced via a smaller TROCHAR compared to similar devices.

Drawbacks:

At present the tool geometry has only been applied to surgical robots

SHAPE MEMORY OCCLUSION TOOL



Yang, W.G., Lu, H., Huang, W.M., Qi, H.J., Wu, X.L. and Sun, K.Y., 2014.

Advanced shape memory technology to reshape product design, manufacturing and recycling. *Polymers*, 6(8), pp.2287-2308.

Functional Description:

The shape memoery occlusion tool uses a PLA wire with the disposition of SHAPE MEMORY behavior. The tool is subjected to a large DEFORMING FUNCTION. Now a straight wire, it is undergoes an INTRODUCING FUNCTION via a CATHETERIZATION PROCEDURE. This r

Value Description:

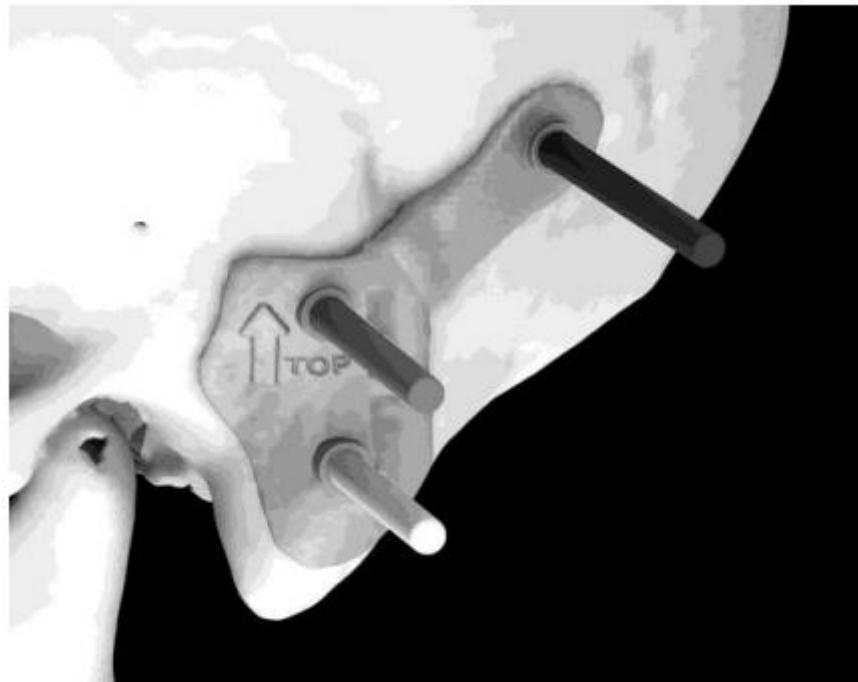
The tool REPLACES an OPEN SURGICAL PROCEDURE with a CATHETERIZATION PROCEDURE, dramatically reducing INVASIVENESS and the

DURATION of recovery. It REPLACES an OPEN SURGICAL PROCEDURE. It uses a SHAPE MEMORY ARTIFACT FABRICATION CAPABILITY to print PLA (polylactic acid) into a BLOOD VESSEL implant that realizes a ‘CLOSING FUNCTION’

Drawbacks:

The design is untested

SURGICAL DRILLING GUIDE



Functional Description:

The surgical drilling guide (and guides like it) is a SURGICAL TEMPLATE that GUIDES a SURGICAL DRILL to improve ACCURACY and aid in obtaining a desirable POSITION for some implant

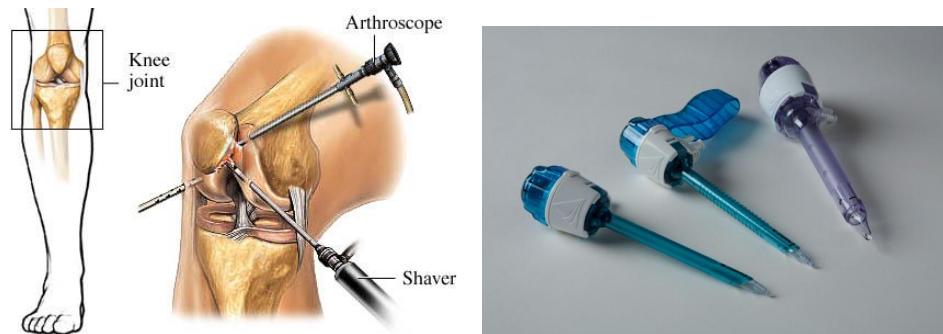
Value Description:

The drilling guide uses a MASS CUSTOMIZATION CAPABILITY to print a metal SURGICAL TEMPLATE that can realize an INCREASING function that affects ACCURACY of placement of FASTENING TOOLS

Drawbacks:

The templates require an additional REDUCTIVE MACHINING PROCESS after they are fabrication.

MINIMALLY INVASIVE SURGERY



WebMD

Functional Description

MINIMALLY INVASIVE SURGICAL PROCEDURES use small incisions, coupled with elongated instruments and camera systems (ARTHOSCOPE, LAPAROSCOPE). The camera is used to visualize PATIENT ANATOMY, while subsequent tools are introduced through ports called TROCHARS. MINIMALLY INVASIVE SURGICAL TOOLS are designed such that their CROSS SECTIONAL AREA does not exceed that of the TROCHAR.

Note from related surgical tools:

MINIMALLY INVASIVE SURGICAL TOOLS frequent use flexures or cables to ACTUATE a distal TOOL from an external HANDLE. To do this they use various joints and mechanisms to PROVIDE and CONTROL DEGREES OF FREEDOM. These remote actuators allow the tools REDUCE the AREA of the tool.

Value Description

MINIMALLY INVASIVE SURGERIES greatly REDUCE INVASIVENESS, with the added benefit of REDUCING the DURATION of patient recovery

Drawbacks

Poor VISIBILITY can limit the ability to locate ANATOMICAL LANDMARKS, and perform surgical tasks. This can reduce the clinical effectiveness of minimally invasive surgeries.

CUSTOM ORTHOPEDIC CUTTING TEMPLATES



Krishnan et al. A review of rapid prototyped surgical guides for patient specific total knee replacement, Society of Bone and Joint Surgery, **94B**, 2012.

Functional Description

CUSTOM ORTHOPEDIC CUTTING TEMPLATES use 3-DIMENSIONAL IMAGING combined with ADDITIVE MANUFACTURING to fabricate templates that conform to PATIENT ANATOMY. The templates have slots through which a SURGICAL SAW is passed to resurface the bone to accept a JOINT PROSTHESIS. Pins are placed to FIX the guide, and ALIGN subsequent guides.

Value Description

The cutting guides claim to REDUCE the DURATION of TOTAL KNEE REPLACEMENT SURGERY. The templates ENABLE a modified procedure that ELIMINATES surgical subtasks. The templates also claim INCREASE the ACCURACY of SURGICAL SAW placement, and subsequent prosthesis ORIENTATION.

Drawbacks

Value of eliminated procedures may be overblown. Required imaging is non-standard.

Additional Tools Returned:

Surgical saw, sub-classes of saw



healmeds.en.alibaba.com

[Http://www.alibaba.com](http://www.alibaba.com)

Scalpel, subclasses of scalpel



<https://en.wikipedia.org/wiki/Scalpel>

APPENDIX G

CASE STUDY TUTORIAL

Overview:

This tutorial aims to introduce the basic use process for the ontological framework described in Chapter 9 by providing a step by step walkthrough of the case study. It represents the basic steps for evaluating and refining the design once the design and knowledge bases have been populated in the ontology modules. It assumes basic familiarity with ontologies, BFO, and Protégé version 5.X. All instructions are written for Protégé 5.X. This approach can be used to replicate the case study in CHAPTER 9, and extend it with additional designs.

Most of the ontology pieces are contained in separate files, allowing the reasoner to classify smaller, more manageable ontologies. This may be necessary to limit the memory requirements of some of the reasoning and querying operations.

Opening the Case Study

1. Open the main ontology:
 - a. Navigate to the file: *IFAMMeDD.owl*. This can be done using either a local or hosted ontology, with the appropriate opening tools in Protégé.
 - b. This will load the ontologies that constitute the core engineering terminology, clinical terms, and AM process and machine terminology.
2. Load the case study:
 - a. The case study is split into a number of separate files, which can be imported into a common ontology. They are:
 - i. *TKA procedure.owl* – captures the steps of the surgery itself

- ii. *TKA case study* – captures the requirements, metrics, and specifications, and shows how concepts and competitors might be scored
 - iii. *TKA competitor.owl* – Contains competing devices, effects of devices on surgery
 - iv. *TKA DAMPrO.owl* – Contains the specifications for the student's initial design and subsequent redesigns
 - b. Use the ontology opening tools in Protégé to open these ontologies. They are co-dependent, so if working locally all will need to be downloaded.
3. Using the Pellet Reasoner, classify the case study ontologies.
- a. Select Reasoner > Pellet Reasoner
 - b. Select Reasoner > Start Reasoner
 - c. Allow the Reasoner to run. Depending on the system specifications this might take a while.
 - d. Once classified the ontology can be browsed in the instances or entities tabs to see some of the inferences that are made.
4. To flag opportunities or problems, navigate to the entity of interest, and use the object property box to enter in 'has problem' and the name of the instance in question, or 'has opportunity' and the name of the instance that represents an opportunity.

Instantiating the Design:

This section will cover how to instantiate design modifications to the original student design in the file TKA DAMPrO

The design consists of a BFO continuant and specifically dependent continuants, as well as specifications for these things. A design specification can be added in two ways. The first is to use axioms to link specifications to classes of dimensions, such as saying a specification *specifies* some **Width** or **Length** or **Angularity**. The second way is more appropriate. In this approach, one creates instances to represent a part (as it would exist if fabricated) and specifications which are tied to these instances. Using this latter method, to create a design:

1. Create the design instance
 - a. Create an instance of the class ‘design specification’, which represents the design
 - b. Create an instance of the class artifact, which represents the embodiment of that design
 - c. In the instances tab of Protégé 5.2, add an object property such that the ‘**design specification**’ ‘*is specification for*’ the artifact
2. Add a feature to the design
 - a. Create an instance of a ‘**flat object part**’ or feature representing the embodiment of the feature. If appropriate, instantiate as a **feature** or **form**
 - b. Create instances representing its dimensions, such as instances of **Length**, **Width**, **Thickness**, **Angularity**, etc.
 - c. Link these to the **artifact** using the object property ‘**bearer of**’ or the appropriate sub-property
 - d. Link the feature to the design by adding a ‘has part’ / ‘part of’ relation between the feature instance and the design instance

3. Create specifications for the design feature
 - a. Create an instance of a ‘**form specification**’ representing the feature
 - b. Link this specification to the feature using the *specifies* property with the specification as its domain, and the feature instance as the range
 - c. Add dimensional information by creating instances of the class ‘**dimension specification**’ or the appropriate subclass.
 - d. Link these dimension specifications to the dimensions of the feature using the *specifies* property, which points from the specification to the feature dimension
 - e. Link the dimensions to the feature specification, and the ‘**form specification**’ to the design using the ‘*has part*’ / ‘*part of*’ object properties
4. Repeat this process until the design is fully represented.

Assessing Manufacturability:

The manufacturability assessment considered DMLS, SLS, PolyJet, and FDM. To perform the manufacturability assessment:

1. Open a new ontology. This will contain the individuals for the case study design assessments
2. Import the design and assessment files
 - a. *DMLS rules.owl*
 - b. *PolyJet rules.owl*
 - c. *FDM rules.owl*
 - d. *SLS rules.owl*

e. *TKA DAMPrO.owl*

Though it is not interesting for this case study, the file *am machines.owl* also contains machine level feature size information. Cumulatively, these will look for violations of the rules noted in Appendix ____.

3. Rule the reasoner to perform the process (and if imported machine) level assessments of the design
4. Rule violations or manufacturability issues can be identified using the query: “‘is subject to’ some rule,” which will return any rule violations in the design as specified. Be sure to have the instances checkbox activated.
5. Using the individuals tab, navigate to the flagged instances to view appended warnings, etc.

Querying to Find Usability Issues

The additive manufacturing product knowledge base can be used to identify solutions to the issues stemming from the usability assessment.

1. Open the file *am case know base.owl*
2. Go to the Reasoner tab in Protégé and select the Reasoner of your choice
3. Run the Reasoner to classify the case knowledge base
4. Go to the DL Query tab, and click the Query for Instances checkbox
5. Run Queries:
 - a. To search for a way to secure the guide, run the query: ‘**has function**’ some ‘**securing function**’
 - b. To search for a way to control tool path, run the query: “ ‘**has function**’ some (‘**function**’ and ‘**realized in**’ some **motion**)

6. The results will be displayed. Using the entities tab one can navigate through these for more information.

APPENDIX H

ADDITIVE MANUFACTURING RULES

Table 23. SLM Rules in rule module

Condition	Consequence
Concave fillet > 3 mm	Warning: Requires Support
Convex fillet > 2 mm	Warning: Requires support
Parallel Hole Diameter > 7 mm	Warning: Requires support
Parallel Hole Diameter < 1 mm	Warning: Minimum parallel hole diameter is 1 mm
Perpendicular Hole Diameter < 0.7 mm	Warning: Minimum perpendicular hole diameter is 0.7 mm
Gap Width < 0.3 mm	Warning: Minimum gap width is 0.3 mm
Material Form Width < 0.4 mm	Warning: Minimum width is 0.4 mm
Material Form Thickness < 0.15 mm	Warning: Minimum thickness is 0.15 mm
Overhang < 30 degrees	Warning: Requires Support
Overhang < 45 degrees and > 30 degrees	Warning: Surface Roughness

Table 24. DMLS Rules in rule module

Condition	Consequence
Parallel Hole Diameter > 6 mm	Recommendation: Add arched or angled top surface to hole
Parallel Hole Diameter > 6 mm	Warning: Requires Support
Overhang > 20 degrees	Warning: May Require support
Overhang > 20 degrees	Warning: Surface roughness issues
Radius < 0.5 mm	Warning: Form cannot be manufactured
Wall < 1 mm	Warning: Feature accuracy
FDM Rules	

Table 25. FDM Rules in rule module

Condition	Consequence
Gap width < 0.4 mm	Warning: Minimum gap width is 0.4 mm
Overhang angle > 45 degrees	Warning: Requires support
Overhang angle > 30 degrees	Warning: Surface roughness issues
Stepped Overhang > 1.8 mm length	Warning: Requires Support
Perpendicular hole diameter < 0.7 mm	Warning: Minimum hole diameter is 0.7 mm

Table 26. SLS Rules in rule module

Condition	Consequence
Parallel hole diameter < 1.3 and < 1 mm thick	Warning: Minimum hole thickness is 1 mm
Parallel hole diameter < 0.6 mm	Warning: minimum hole diameter is 0.6 mm
Overhang < 30 degrees	Warning: Requires Support
Overhang < 45 degrees and > 30 degrees	Warning: Surface Roughness

Table 27. PolyJet rules in rule module

Condition	Consequence
Overhang > 20 degrees	Warning: Requires Support in X orientation
Overhang > 15 degrees	Warning: Requires Support in Y orientation
Cylindrical Form Diameter < 15 degrees	Warning: Not Manufacturable
Form Length < 0.3 mm	Warning: Minimum feature length is 0.3 mm
Perpendicular Hole Diameter < 0.1 mm	Warning: Minimum hole diameter is 0.1 mm
Rectangular Form	Warning: Tolerance Limitations
Channel Area < 50 square micron	Warning: Minimum Channel area is 50 square micron

REFERENCES

- [1] Anonymous 2016, "U.S. Investments in Medical and Health Research and Development 2013-2015," Research America, Arlington, Virginia.
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