Chapter 21
Industrial Drivers for AM Adoption

Abstract Additive Manufacturing is in its fourth decade of commercial technological development. Over that time, we have experienced a number of significant changes that have led to improvements in accuracy, better mechanical properties, a broader range of applications, and reductions in costs of machines and the parts made by them. In this chapter, we explore the evolution of the field and how these developments have impacted a variety of applications over time. We note also that different applications benefit from different aspects of AM, highlighting the versatility of this technology.

21.1 Introduction

Additive Manufacturing is in its fourth decade. AM has significantly evolved over this time, leading to improvements in accuracy, better mechanical properties, a broader range of applications, and reductions in costs of machines and the parts made by them. AM has found applications in design and development within almost every consumer product sector, and the advent of low-cost AM machines has brought these technologies into peoples' homes. As AM becomes more popular and as technology costs inevitably decrease, this can only serve to generate more momentum and further broaden the range of applications.

Even though AM is applicable to every major industry in one way or another, many of the improvements to AM have been driven by the needs of specific industries. Three industries which adopted AM early, and continue to drive AM developments, are the automotive, aerospace, and medical industries. Another consistent driver for AM has been the use of AM to produce prototypes. This chapter discusses the use of AM for these industries and for prototyping. In aerospace and automotive industries, AM is valued mainly because of the complex geometric capabilities and the time that can be saved in development of products. With medicine, the benefit is primarily in the ability to include patient-specific data from medical sources so that customized solutions to medical problems can be found. Although many of these techniques and applications were covered in a previous chapter, the point here is to

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put this activity in a historical context and realize how early in the AM field's development these applications were investigated. We begin with a brief survey of historical developments in Rapid Prototyping (RP), rapid tooling, and other advances, with a focus mostly on aerospace and automotive industries.

21.2 Historical Developments

In the late 1980s, 3D Systems started selling their first stereolithography (SL) machines. The first five customers of the SLA-1 beta program were AMP Incorporated, General Motors, Baxter Health Care, Eastman Kodak, and Pratt & Whitney [1]. These companies represent the four largest industrial sectors, in terms of historical AM usage, including automotive (GM and AMP, their automotive and consumer business group was the customer), health care (Baxter), consumer products (Eastman Kodak), and aerospace (Pratt & Whitney). Texas Instruments, specifically their Defense Systems and Electronics Group, was also an early adopter which applied AM to the aerospace field. Similarly, one of the first customers of DTM was BF Goodrich, which is a supplier to the aerospace and automotive industries.

Focusing on the aerospace industry, many success stories were realized by design and manufacturing engineers who used AM for Rapid Prototyping purposes. In many cases, thousands of dollars and months of product development time were saved through the use of RP, since prototype parts did not have to be fabricated using conventional manufacturing processes. Additionally, many new applications for AM parts were discovered.

21.2.1 Value of Physical Models

Early adopters discovered that AM, through the Rapid Prototyping function, provided several benefits including enhanced visualization, the ability to detect design flaws, reduced prototyping time, and significant cost reductions associated with the ability to develop correct designs quickly. Of course, there were also significant costs associated with being an early adopter. AM machines were more expensive than conventional machine tools, and people had to be hired and trained to run the AM machines. New post-processing equipment had to be installed and hazardous solvents used to clean SL parts. But, for those companies willing to take the risk, the significant investments in AM had a large return on investment when AM was integrated into their product development processes.

For example, in 1992, Texas Instruments reported several case studies demonstrating thousands of dollars and months of prototyping time saved through the use of stereolithography [1]. Furthermore, they were one of the first companies to explore the use of SL parts as patterns for investment casting.

Chrysler purchased two SLA-250 machines in early 1990 and reported that they fabricated over 1500 parts in the first 2 years of usage, with the machines running virtually 24 hours per day and 7 days per week [1]. They also reported significant time and cost savings particularly for form/fit and packaging assessments. Many other companies soon realized that they could greatly increase their chances of winning contracts to supply parts if they included RP parts with their quotes. By including physical prototypes, they can demonstrate that they understand the design requirements, and both customer and supplier can identify potential problems early on.

In the medical industry, DePuy, Inc. was another early adopter of SL. They reported on a project that began in 1990 to develop a new line of shoulder implants with dozens of models for various component sizes [1]. They used SL models, fabricated on their in-house SLA-250 machines, of the implant components during several iterations of early project reviews, saved several months of development time, and avoided costly changes before production. Furthermore, they used SL masters for urethane tooling to make wax patterns for investment casting for the first 500 pieces of each size. As they noted, this allowed them to proceed with product launch as part of their development process.

21.2.2 Functional Testing

Engineers at aerospace, automotive, and medical device companies soon discovered that AM parts could be used for a variety of functional testing applications. Specifically, flow testing was investigated by these companies, even with the early SL resins that were brittle and absorbed water easily. As one example, Chrysler tested airflow through several cylinder head designs in early 1992. They built a model of the cylinder head geometry in SL, installed steel valves and springs, and then ran the model on their flow bench. They achieved a 38% improvement in airflow.

Other companies reported similar experiences. Engineers at Pratt & Whitney pioneered several new types of flow apparatus and experiments with SL in the early years with both air and water. A report from Porsche in 1994 described water flow testing in a series of engine models to study coolant flow characteristics [2]. By using SL and an early epoxy resin, they could successfully design, fabricate, and test engine models within about 1 week per iteration.

Also in 1994, AlliedSignal reported on a study where SL models of turbine blades were used to determine their frequency spectra [2]. To study the use of SL models, they built SL models at full scale and at 3:1 scale, tested all three blades experimentally, and compared the results to finite element analysis. Theoretically, the full-scale SL models should have natural frequencies that are 35.7 percent of those of the steel blades; experimentally, they determined that the SL blades exhibited frequencies of 35 percent. Similarly, the 3:1 scale SL blades had natural frequencies that were 12 percent of the steel blade frequencies, compared to a theoretical prediction of 11.9 percent. In comparison, FEA predictions ranged from 3.6 percent lower to 19.4 percent higher than experimental results. As a consequence, AlliedSignal had much more confidence in their use of SL models than FEA, since the SL models enabled much more accurate determinations of natural frequencies.

Concurrently, aerospace companies started using AM parts to perform wind tunnel testing. Wind tunnel models are typically instrumented with arrays of pressure sensors. Standard metal models required considerable machining in order to fabricate channels for all of the wiring to the sensors. With AM, the channels and sensor mounts could be designed into the model. Automotive companies also adopted this practice. For high-speed testing, or large aerospace models, rapid tooling methods were commonly used in order to fabricate stiffer metal wind tunnel models. With proper designs, engineers could design the channels and sensor mounts into the AM patterns that were subsequently used to produce the tooling.

21.2.3 Rapid Tooling

Prior to 1992, Chrysler experimented with a variety of rapid tooling processes with stereolithography master patterns. This included vacuum forming, resin transfer molding, sand casting, squeeze molding, and silicone molding.

An area of significant effort in both the aerospace and automotive industries was the use of SL parts as investment casting patterns. Early experiments used thin-walled SL patterns or hollow parts. Because SL resins expand more than investment casting wax, when used as patterns, the SL part tended to expand and crack the ceramic shell. This led to the development of the QuickCast™ pattern style in 1992, which is a type of lattice structure that was added automatically to hollow part STL files by SL machine pre-processing software. The QuickCast style was designed to support thin walls but not to be too strong. Upon heating and thermal expansion, the QuickCast lattice struts were designed to flex, collapse inward, break, but not transfer high loads to the part skins which could crack the shell.

The QuickCast 1.0 style worked, but not as well as desired. This led to the development of QuickCast 1.1 by 3D Systems in 1995 and then QuickCast 2.0 by Phill Dickens and Richard Hague at the University of Nottingham in the late 1990s. This was quickly adopted by many manufacturers and service bureaus and, arguably, revolutionized the investment casting industry.

Another interesting development in the early 2000s was the large-frame Binder Jetting (BJT) technology by ExOne, where a sand material was developed that was suitable for use as sand casting dies. As mentioned in Chap. 8, ExOne marketed the S15 BJT machine for several years (the technology was purchased from a German company Generis GmbH in 2003). As one example, two of these sand machines were operating at the Ford Dunton Technical Center in England in the mid-2000s to support their design and development activities. Much of the Ford of Europe operations are housed here, including small car design, powertrain design and development, and some commercial vehicles. As of the end of 2005, ExOne had reportedly sold 19 S15 machines, each of which cost over $1 M.

More recently, Boeing, Northrop Grumman, and other aerospace companies have used Material Extrusion (MEX) technology to fabricate tooling. They developed tooling designs for composite part layup that were suitable for MEX fabrication. Other reported tooling applications included drill guides and various assembly tools.

21.3 The Use of AM to Support Medical Applications

AM models have been used for medical applications almost from the very start. AM could not have existed before 3D CAD since the technology is digitally driven. Computerized tomography (CT) was also a technology that developed alongside 3D representation techniques. Figure 21.1a–c shows a CT machine, a model directly generated from this machine (shown as cross-sectional slices), and a model with all segments combined into a 3D image. CT is an X-ray-based technique that moves the sensors in 3D space relative to the X-ray source so that a correlation can be made between the position and the absorption profile. By combining multiple images in this way, a 3D image can be built up. The level of absorption of the X-rays is dependent on the density of the subject matter, with bone showing up very well because it is much denser than the surrounding soft tissue. What some people don't realize is that soft tissue images can also be created using CT technology if the tissues of interest have enough contrast with surrounding tissues. Clinicians use CT technology to create 3D images for viewing the subject from any angle, so as to better understand any associated medical condition. Note that this is one of a number of medical scanning technologies working in the 3D domain, including 3D MRI, 3D ultrasound, and 3D laser scanning (for external imaging). With this increasing use of 3D medical imaging technology, the need to share and order this data across

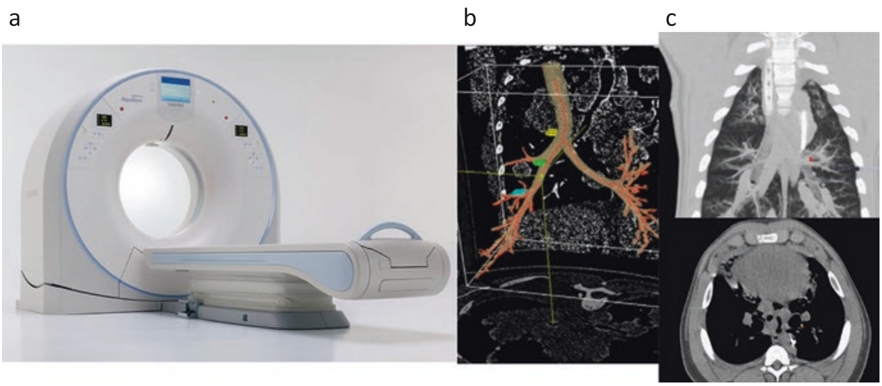

Fig. 21.1 (**a**) Toshiba Aquilion One CT scanner with sliced images. (Photo courtesy of Canon), (**b–c**) a 3D image and cross-sectional views created using this technology (Elsevier license agreement number 4650650233936) [4]

platforms has led to information exchange standards like DICOM [3], from the National Electrical Manufacturers Association in the USA, which allows users to view patient data with a variety of different software and sourced from a variety of different imaging platforms.

While originally used just for imaging and diagnostic purposes, 3D medical imaging data quickly found its way into CAD/CAM systems, with AM technology being the most effective means of realizing these models due to the complex, organic nature of the input forms. Medical data generated from patients is essentially unique to an individual. The automated form of production that AM provides makes it an obvious route for generating products from patient data.

AM-based fabrication contributes to many areas in medical diagnostics and treatment. Orthopedics was described in previous chapters. In this chapter, we will highlight the following categories of medical applications:

- Surgical and diagnostic aids
- Prosthetics and implants
- Tissue engineering
- Software tools and surgical guides

21.3.1 Surgical and Diagnostic Aids

The use of AM for diagnostic purpose was probably the first medical application of AM. Surgeons are often considered to be as much artists as they are technically proficient. Since many of their tasks involve working inside human bodies, much of their operating procedure is carried out using the sense of touch almost as much as by vision. As such, models that they can both see from any angle and feel with their hands are very useful to them.

Surgeons work in teams with support from doctors and nurses during operations and from medical technicians prior to those operations. They use models in order to understand the complex surgical procedures for themselves as well as to communicate with others in the team. Complex surgical procedures also require patient understanding and compliance, and so the surgeon can use these models to assist in this process too. AM models have been known to help reduce time in surgery for complex cases, both by allowing the surgeons to better plan ahead of time and for them to understand the situation better during the procedure (by having a physical model on hand to refer to within the operating theater). Machine vendors have, therefore, developed a range of materials that can allow sterilization of parts so that models can be brought inside the operating theater without contamination.

Most models for bony tissue result from CT data. MRI data is more commonly used for soft tissue imaging, including cases with complex vascular models [5]. Bone models are easy to produce and interpret, because many of the materials used in AM machines actually resemble bone in some way and can even respond to cutting operations in a similar manner. AM models of soft tissue are commonly used for visualizations, and multi-material AM processes as well as molded parts from

AM patterns enable practicing surgery on physical models if their compliance can be made to match the tissue of interest.

Many models may benefit from having different colors to highlight important features. Such models can display tumors, cavities, vascular tracks, etc. MEX, MJT, and BJT technologies can be used to represent this kind of part. Sometimes, these features may be buried inside bone or other tissue, and so having an opaque material encased in a transparent material can also be helpful in these situations. For this, the Stereocol resin for SLA machines [6] or Connex materials from Stratasys [7] can be used to see inside the part. The Stereocol material no longer appears to be commercially available, however. Some examples of different parts that illustrate this capability can be seen in Fig. 21.2.

Some of the most noteworthy applications of AM as medical models were from well-publicized surgeries to separate conjoined twins. Surgeons reported that having multicolored, complex models of the head or abdomen areas were invaluable in planning the surgeries, which can take 12–24 hours and involve large teams of surgeons and support staff [8].

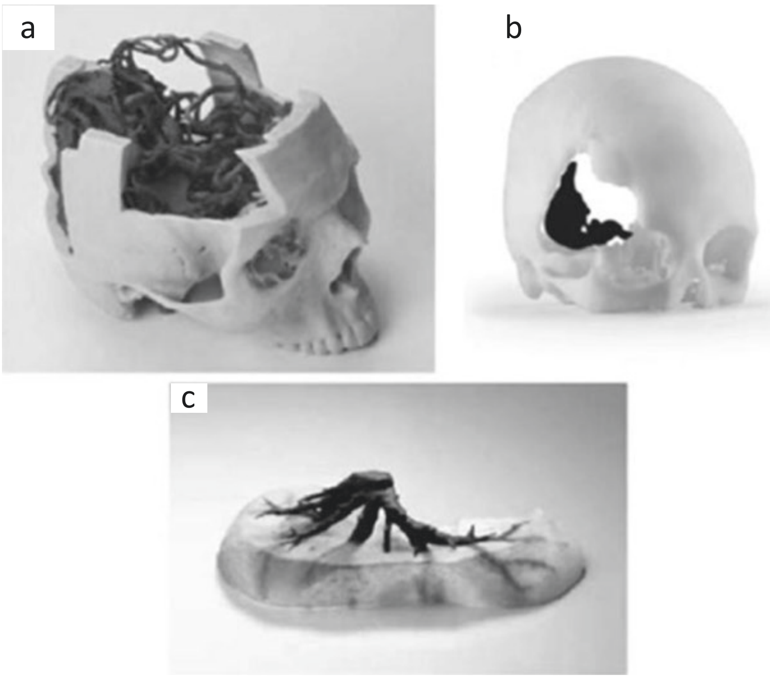

Fig. 21.2 Images of medical parts made using different colored AM systems. (**a**) 3DP used to make a skull with vascular tracks in a darker color. (**b**) A bone tumor highlighted using ABS. (c) Stratasys Connex process showing vascularity inside a human organ

21.3.2 Prosthetics and Implants

The low resolution of CT-generated 3D data combined with the low resolution of earlier AM technology led to models that may have looked anatomically correct but were perhaps not very accurate when compared with the actual patient. As technologies improved over the past few decades, models have become more precise, and it is now possible to use scanning plus AM to create close-fitting prosthetic devices. Wang [9] states that CT-based measurement can be as close as 0.2 mm from the actual value. While this is subjective, it is clear that resulting models, when built properly, can be sufficiently precise to suit many applications.

Support from CAD software can add to the process of model development by including fixtures for orientation, for tooling guidance, and for screwing into bones. For example, it is quite common for surgeons to use flexible titanium mesh as a bone replacement in cancer cases or as a method for joining pieces of broken bone together, prior to osteointegration. While described as flexible, this material still requires tools in order to bend the material. Models can be used as templates for these meshes, allowing the surgeon's technical staff to precisely bend the mesh to shape so that minimal rework is required during surgery. Figure 21.3 shows a customized biomodel implant for craniofacial reconstruction surgery that has been used for this purpose [10].

Many prosthetics are comprised of components that have a range of sizes to fit a standard population distribution. This means that precise fitting is often not possible, and so the patient may still experience some postoperative difficulties. These difficulties can further result in additional requirements for rehabilitation or even corrective surgery, thus adding to the cost of the entire treatment. Greater comfort and performance can be achieved where some of the components are customized, based on actual patient data. An example would be the socket fixation for a total hip joint replacement. While a standardized process will often return joint functionality to the patient, incorrect fixation of the socket commonly results in variable motion that

Fig. 21.3 Titanium mesh formed around a maxillofacial model

may be a discomfort and painful and require extensive physiotherapy to overcome. Customized fixtures can be made directly in titanium or cobalt–chromium (both of which are widely used for implants) using Powder Bed Fusion (PBF) technology. Such custom devices reduce the previously mentioned problems by making it possible to more precisely match the original or preferred geometry and kinematics. The use of metal systems provides considerable benefit here. While metal AM systems are not capable of producing the smooth surface finish required for effective joint articulation, the characteristic slight roughness can actually benefit osteointegration when placed inside the bone. Smooth joint articulation can be achieved through extensive polishing and use of coatings. Most metal systems may provide custom-shaped implants, but the use of highly focused energy beams will mean that the microstructure will be different and the parts may be more brittle than their equivalent cast or forged components, making brittle fracture from excessive impact loading a distinct possibility. An excellent example of a customized implant can be found in the case shown in Fig. 21.4, where Prof. J. Poukens led a multidisciplinary team to implant a complete titanium mandibular joint into an 83-year-old woman [11].

There are now examples where customized prosthetics have found their way into mainstream product manufacture. The two examples from Chap. 2 are among the most well-known in the industry: in-the-ear hearing aids and the Invisalign range of orthodontic aligners [12]. Both of these applications involve taking precise data from an individual and applying this to the basic generic design of a product. The patient data are generated by a medical specialist who is familiar with the procedure and who is able to determine whether the treatment will be beneficial. Specialized software is used that allows the patient data to be manipulated and incorporated into the medical device.

One key to success for customized prosthetics is the ability to perform the design process quickly and easily. The production process often involves AM plus numerous other conventional manufacturing tasks, and in some cases, the parts may even be more expensive to produce; but the product will perform more effectively and can sell at a premium price since it has components which suit a specific user. This

Fig. 21.4 Titanium jaw implant being located during surgery

added value can make the prosthetic less intrusive and more comfortable for the user. Additionally, the use of direct digital manufacturing makes it easier for manufacturers and practitioners.

21.3.3 Tissue Engineering and Organ Printing

The ultimate in fabrication of medical implants would be the direct fabrication of replacement body parts. This can feasibly be done using AM technology, where the materials being deposited are living cells, proteins, and other materials that assist in the generation of integrated tissue structures. There has been a great deal of active research in this area, and commercial applications are now emerging. Most of these activities use jetting and extrusion-based technology to form parts. This is because droplet-based printing technology has the ability to precisely locate very small amounts of liquid material and extrusion-based techniques are well-suited to build soft tissue scaffolding. However, ensuring that these materials are deposited under environmental conditions conducive to cell growth, differentiation, and proliferation is not a trivial task. This methodology is leading to the fabrication of complex, multicellular soft tissue structures like livers, kidneys, and even hearts. There are several 3D cell printers commercially available that can create simple layer-wise formations of cells.

An indirect approach that is appropriate to the regeneration of bony tissue is to create a scaffold from a biocompatible material that represents the shape of the final tissue construct and then add living cells at a later time. Scaffold geometry normally requires a porous structure with pores of a few hundred microns. This size permits good introduction and ingrowth of cells. Microporosity is often desirable to permit the cells to insert fibrils in order to attach firmly to the scaffold walls. Different materials and methods are used, including bioreactors to incubate the cells prior to implantation. Figure 21.5 shows a scaffold created for producing a mixture of bone

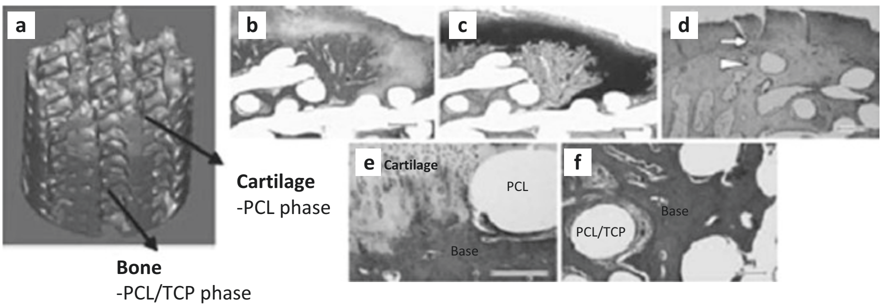

Fig. 21.5 Hybrid scaffolds composed of two phases: (**a**) Polycaprolactone (PCL) layer for cartilage tissue and bottom PCL/TCP (tricalcium phosphate) layer for bone. (**b–f**) Implantation in a rabbit for 6 months revealed formation of subchondral bone in the PCL/TCP phase and cartilage-like tissue in PCL phase. Bar is 500 μm in (**b–d**) and 200 μm in (**e**) and (**f**)

and cartilage and then implanted into a rabbit [13]. The scaffold was a mixture of polycaprolactone (PCL) which acts as a matrix material, which is also biodegradable. Mixing tricalcium phosphate (TCP) enhances the biocompatibility with bone to encourage bone regeneration and also enhances the compressive modulus of the scaffold. Even with this approach, it is still a challenge to maintain the integrity of the scaffold for sufficient lengths of time for healthy and strong bone to form. While using this approach for mass customization of soft tissue structures or load-bearing bone for everyday medical issues is some way from reality, non-load-bearing bone constructs have already been commercially proven [14], and many other commercial applications are in various stages of medical trials and adoption.

21.4 Software Tools and Surgical Guides for Medical Applications

There are a number of software tools available to assist users in preparing medical data for AM applications. Initially, such software concentrated on the translation from medical scanner systems and the creation of the standard STL files. Models made were generally replicas of the medical data. With the advent of the DICOM scanner standard, the translation tools became unnecessary, and it became necessary for such systems to add value to the data in some way. The software systems therefore evolved to include features where models could be manipulated and measured and where surgical procedures like jawbone resections could be simulated in order to determine locations for surgical implants. These have further evolved to include software tools for inclusion of CAD data in order to design prosthetic devices or support for specific surgical procedures.

Consider the application illustrated in Fig. 21.6a–c [15]. In this application, a prosthetic denture set is fixed by drilling precisely into the jawbone so that posts can be placed for anchoring the dentures. A drill guide was developed using AM,

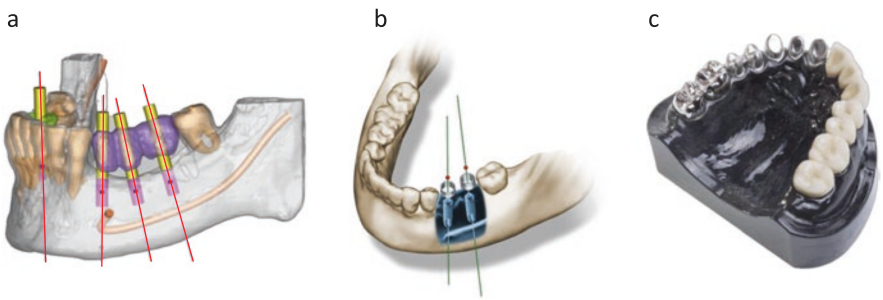

Fig. 21.6 (**a**, **b**) Drill guides developed using AM-related software and machines from FLEMING and DC Imaging. (**c**) Anchored printed tooth (From SLM Solutions Group, Lübeck, Germany) [16–18]

positioning the drill holes precisely so that the orthodontist could drill in the correct location and at the correct angle. The software system allows the design of the drill guide to be created, based on the patient data taken from medical scans. AM models can also be used in the development of the prosthetic itself.

Most CAD/CAM/CAE tools are used by engineers and other professionals who generally have good computer skills and an understanding of the basic principles of how such tools are constructed. Clinicians have very different backgrounds, and their basic understanding is of biological and chemical sciences with a deep knowledge of human anatomy and biological construction. Computer tools must therefore focus on being able to manipulate the anatomical data without requiring too much knowledge of CAD, graphics, or engineering construction. Software support tools for medical AM applications should therefore provide a systematic solution where different aspects of the solution can be dealt with at various stages so that the digital data are maintained and used most effectively, like the application in Fig. 21.6 where software and AM models were used at various stages to evaluate the case and to assist in the surgical procedure.

Tissue engineering software tools are likely to be very different from conventional CAD/CAM tools. This is because the data are constructed in a different form. Medical data are almost by definition freeform. If it is to be accurately reproduced, then these models require large data files. In addition, the scaffolds to be created will be highly porous, with the pores in specific locations. STL files are likely to be somewhat useless in these applications, plus if the STL files included the pore architecture, they would be inordinately large. Figure 21.5a, for example, would normally be made using an extrusion process similar to MEX, where each cross-member of the scaffold would normally correspond to an extrusion road. It would be somewhat pointless for every cross-member to be described using STL, since the slices correspond to the thickness and location of these cross-member features. Most scaffold fabrication systems, like the 3D-Bioplotter from EnvisionTEC [19], shown in Fig. 21.7, include an operating system that includes a library of scaffold fill geometries that include pore size, layer thickness, etc. rather than STL slicing systems.

21.5 Limitations of AM for Medical Applications

Although there is no doubt that medical models are useful aids to solving complex surgical problems, there are numerous deficiencies in existing AM technologies related to their use to generate medical models. Part of the reason for this is because AM equipment was originally designed to solve problems in the more widespread area of manufactured product development and not specifically to solve medical problems. Development of the technology has therefore focused on improvements to solve the problems of manufacturers rather than those of doctors and surgeons. However, recent and future improvements in AM technology may open the doors to

Fig. 21.7 The EnvisionTEC Bioplotter. (Photo courtesy of EnvisionTEC) [20]

a much wider range of applications in the medical industry. Key issues that may change these deficiencies in favor of using AM include:

- Speed
- Cost
- Accuracy
- Materials
- Ease of use

By analyzing these issues, we can determine which technologies may be most suitable for medical applications as well as how these technologies may develop in the future to better suit these applications.

21.5.1 Speed

AM models can often take a day or even longer to fabricate. Since medical data needs to be segmented and processed according to anatomical features, the data preparation can in fact take much longer than the AM building time. Furthermore, this process of segmentation requires considerable skill and understanding of anatomy. This means that medical models can effectively only be included in surgical procedures that involve long-term planning and cannot be used, for example, as aids for rapid diagnosis and treatment in emergency operations.

Many AM machines now have excellent throughput rate, both in terms of build speed and post-processing requirements. A few more iterations toward increasing this throughput could lead to these machines being used in critical care clinics, at least for more effective diagnosis. However, it must be understood that this use must be in conjunction with improvements in supporting software for 3D model generation that reduces the skill requirements and increases the level of data processing automation. For tissue engineering applications, the time frames are a lot longer since we must wait for cells to proliferate and combine in the bioreactors. However, the sooner we can get to the stage of seeding scaffolds with cells, the better.

21.5.2 Cost

Using AM models to solve manufacturing problems can help save millions of dollars for high-volume production, even if only a few cents are saved per unit. For the medical product (mass customization) manufacturing applications mentioned earlier, machine cost is not as important as perhaps some other factors. In comparison, the purpose of medical models for diagnosis, surgical planning, and prosthetic development is to optimize the surgeon's planning time and to improve quality, effectiveness, and efficiency. These issues are more difficult to quantify in terms of cost, but it is clear that only the more complex cases can easily justify the expense of the models. The lower the machine, materials, and operating costs, the more suitable it will be for more medical models. Some machines are very competitively priced due to the use of low-cost, high-volume technologies, like inkjet printing. Some other processes have lower-cost materials, but this relates to consumable costs, which can also be reduced with increase of volume output.

21.5.3 Accuracy

Many AM processes are being improved to create more accurate components. However, many medical applications currently do not require higher accuracy because the data from the 3D imaging systems are considerably less accurate than the AM machines they feed into. However, this does not mean that users in the medical field should be complacent. As CT and MRI technologies become more accurate and sophisticated, so the requirements for AM will become more challenging. Indeed, some CT machines appear to have very good accuracy when used properly. Also, this generally relates to medical models for communication and planning, but where devices are being manufactured, the requirements for accuracy will be more stringent. Applications which require precise fitting of implants are now becoming commonplace.

21.5.4 Materials

Only a few AM polymer materials are classified as safe for transport into the operating theater, and fewer still are capable of being placed inside the body. Those machines that provide the most suitable material properties are generally the most expensive machines. Powder-based systems are also somewhat difficult to implement due to potential contamination issues due to powder coming loose in the body or fluids entering the porous parts. This limits the range of applications for medical models.

Metal systems, on the other hand, are being used regularly to produce implants using a range of technologies, as reported by Wohlers [21]. Of these, it appears that titanium is the preferred material, but cobalt–chromium and stainless steel are both available candidates that have the necessary biocompatibility for certain applications.

21.5.5 Ease of Use

AM machines generally require a degree of technical expertise in order to achieve good quality models. This is particularly true of the larger, more complex, and more versatile machines. However, these larger machines are not particularly well-suited to medical laboratory environments. Coupled with the software skills required for data preparation, this implies a significant training investment for any medical establishment wishing to use AM. While software is a problem that all AM technologies face, it doesn't help that the machines themselves often have complex setup options, materials handling, and general maintenance requirements.

21.6 Further Development of Medical AM Applications

It is difficult to say whether a particular AM technology is more or less suited to medical applications. This is because there are numerous ways in which these machines may be applied. One can envisage that different technologies may find their way into different medical departments due the specific benefits they provide. However, the most common commercial machines certainly seem to be well-suited to being used as communication aids between surgeons, technical staff, and patients. Models can also be suitable for diagnostic aids and can assist in planning, in the development of surgical procedures, and for creating surgical tools and even the prosthetics themselves. Direct fabrication of implants and prosthetics is mostly limited to the direct metal AM technologies that can produce parts using FDA (the US Food and Drug Administration)-certified materials plus the small number of technologies that are capable of non-load-bearing polymer scaffolds.

For more of these technologies to be properly accepted in the medical arena, a number of factors must be addressed by the industry:

- Approvals
- Insurance
- Engineering training
- Location of the technology

21.6.1 Approvals

While a number of materials are now accepted by the FDA for use in medical applications, there are still questions regarding the best procedures for generating models. Little is known about the materials and processes outside of the mainstream AM industry. Approval and certification of materials and processes through ASTM and ISO will certainly help to pave the way toward FDA approval, but this can be a very long and laborious process.

Those surgeons who are aware of the processes seem to achieve excellent results and are able to present numerous successful case studies. However, the medical industry is understandably conservative about the introduction of these new technologies. Surgeons who wish to use AM generally have to resort to creative approaches based on trusting patients who sign waivers, the use of commercial AM service companies, and word of mouth promotion. Hospitals and health authorities are only just beginning to implement procedures for purchase of AM technology in the same way they might purchase a CT machine or standard medical tool.

21.6.2 Insurance

Many hospitals around the world treat patients according to their level of insurance coverage. Similar to the aforementioned issue of approvals, insurance companies need protocols for coverage using AM as a stage in the treatment process. It may be possible for some schemes to justify AM parts based on the recommendations of a surgeon, but some companies may question the purpose of the models, requiring additional paperwork that may deter some surgeons from adopting that route.

This issue will become less prominent as AM is legitimized in the medical industry. As AM has shifted from producing prototypes in the early phases of product development to mainstream manufacturing, the medical industry and consumers have taken note. Certification processes have become more common, and insurance companies are more likely to accept these technologies as part of the treatment process as more effective quality control mechanisms are now in place. Also, the increasing number of successful applications in the literature that improve patient outcomes while reducing costs makes the general use of AM more acceptable in the medical community. As such, we believe that insurance company acceptance of AM costs will continue to accelerate over the next few years.

21.6.3 Engineering Training

Creating AM models requires skills that many surgeons and technicians will not possess. While many of the newer, low-cost machines do not require significant skill to operate, preparation of the files and some post-processing requirements may require more ability. The most likely skills required for the software-based processing can be found in radiology departments since the operations for preparation of a software model are similar to manipulation and interpretation of CT and MRI models. However, technicians in this area are not used to building and manipulating physical models. These skills can however be found in prosthetics and orthotics departments. It is generally quite unusual to find radiology very closely linked with orthotics and prosthetics. The required skills are, therefore, distributed throughout a typical hospital.

21.6.4 Location of the Technology

AM machines could be located in numerous medical departments. The most likely would be to place them either in a laboratory where prosthetics are produced or in a specialist medical imaging center. If placed in the laboratories, the manual skills will be present but the accessibility will be low. If placed in imaging centers, the accessibility will be high, but the applications will probably be confined to visualization rather than fabrication of medical devices. Fortunately, most hospitals are now well equipped with high-speed intranets where patient data can be accessed quickly and easily. A separate facility that links closely to the patient data network and one that has skilled software and modeling technicians for image processing and for model post-processing (and associated downstream activities) may be a preference.

21.6.5 Service Bureaus

It can be seen that most of the hurdles for AM adoption in the medical industry are essentially procedural in nature rather than technical. A concerted effort to convince the medical industry of the value of AM models for general treatment purposes is, therefore, a key advancement that will provide a way forward.

There are a small but increasing number of companies developing excellent reputations by specializing in producing models for the medical industry. Companies like Medical Modeling LLC [8] and Anatomics [22] have demonstrated that AM companies can successfully focus on medical applications for creating models for surgeons and assisting in the development of new medical products. These service bureaus fill the skill gap between the medics and the manufacturers. AM technology is becoming better suited to a wider range of medical applications, and hospitals and clinics are beginning to have their own machines with the in-built skills to use them properly. Furthermore, the large medical product manufacturers are adopting the benefits of DDM. As AM technology becomes cheaper, easier to use, and better suited to medical application, such support companies may no longer be necessary. However, the benefits of outsourcing, as shown in many industries, still give AM services bureaus an effective role today in medical AM and likely for many years into the future.

21.7 Aerospace Applications

The aerospace industry was an early adopter of AM and continues to drive AM development today. The primary advantage for production applications in aerospace is the ability to generate complex engineered geometries with a limited number of processing steps. Aerospace companies have access to budgets significantly larger than many industries, and increased complexity in general fits well with the high-performance needs of the products being produced.

21.7.1 Characteristics Favoring AM

Significant advantages are realized when aerospace components are improved with respect to one or more of these characteristics:

Lightweight: Anything that flies requires energy to get it off the ground. The lighter the component, the less energy is required. This can be achieved by use of lightweight materials, with high strength to weight ratio. Titanium and aluminum have traditionally been materials of choice because of this. More recently, carbon fiber-reinforced composites have gained popularity. However, it is also possible to address this issue by creating lightweight structures with hollow or honeycomb internal cores. This kind of topology and lattice optimization is quite easy to achieve using AM.

High temperature: Both aircraft and spacecraft are subject to high-temperature variations, with extremes in both high and low temperatures. Engine components are subject to very high temperatures where temperature-resistant materials and innovative cooling solutions are often employed. Even components within an aircraft cabin are required to be made from flame-retardant materials. This means that AM generally requires its materials to be specially tailored to suit aerospace applications.

Complex geometry: Aerospace applications can often require components to have more than one function. For example, a structural component may also act as a conduit, or an engine turbine blade may also have an internal structure for passing coolant through it. Furthermore, geometric specifications for parts may be determined by complex mathematical formulas based on fluid flow, etc.

Economics: AM enables economical low production volumes, which are common in aerospace. Hard tooling is good for applications where the cost of the tool is amortized over a very large number of components. In the case of AM, hard tooling is not needed, and so AM is more economical than tooling-based approaches for low-volume production. In addition, designers and manufacturing engineers need not spend time designing and fabricating molds, dies, or fixtures or spend time on complex process planning (e.g., for machining) that conventional manufacturing processes require.

Digital spare parts: Many aircraft have very long useful lives (20 to 50 years or longer) which places a burden on the manufacturer to provide spare parts. Instead of warehousing spares or maintaining manufacturing tooling over the aircraft's long life, the usage of AM enables companies to maintain digital models of parts. This can be much easier and less expensive than warehousing physical parts or tools.

21.7.2 Production Manufacture

All of the major aerospace companies in the USA and Europe have pursued production applications of AM for many years. Boeing, for example, has installed tens of thousands of AM parts on their military and commercial aircraft. By 2014, over 200 different parts were flying on at least 16 models of aircraft [23]. Those numbers have dramatically increased since then. Until recently, all of these were non-structural polymer parts for military or space applications, such as the ducts in Fig. 21.8 (c). For commercial aircraft, polymer parts need to satisfy flammability requirements, so their adoption needed to wait until flame-retardant polymer PBF materials were developed. For metals, material qualification and part certification took many years to achieve. In addition to parts manufacturing, aerospace companies are also developing new higher-performance materials in both metals and polymers, as well as processing methods.

Some of the first large-scale, metal part production manufacturing applications are emerging in the aerospace industry. GE purchased Morris Technologies in 2012 as part of a major investment in metal AM for the production of gas turbine engine components. The part that has received the most attention is a new fuel nozzle design for the CFM LEAP (Leading Edge Aviation Propulsion) turbofan engine, as shown in Fig. 21.8a [24]. The new fuel nozzle took the part consolidation concept to new levels by reportedly combining 18–20 parts into one integrated design and avoiding many brazed joints and assembly operations. This new design is projected to have a useful life five times that of the original design, a 25 percent weight

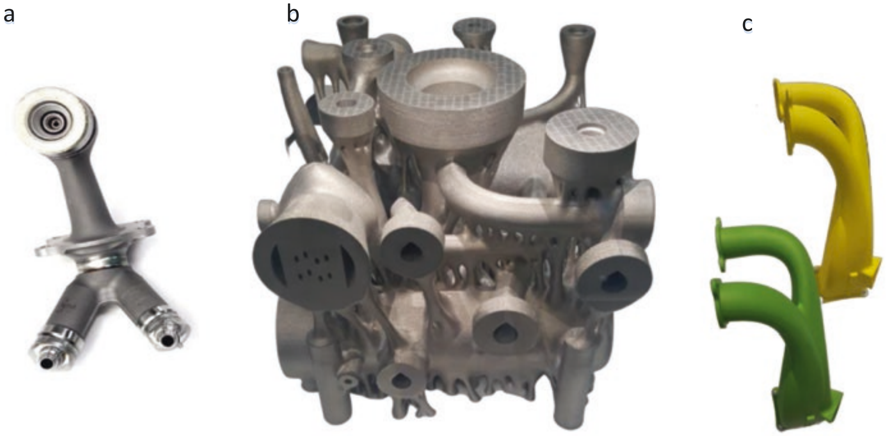

Fig. 21.8 (**a**) GE Aviation fuel nozzle [25], (**b**) manifold from Spartacus3D, (**c**) ducting made by SLS from Jabil

reduction, and additional cost savings realized through optimizing the design and production process. Additionally, the fuel nozzle was engineered to reduce carbon buildup, making the nozzle more efficient.

Each LEAP engine contains 19 fuel nozzles, and more than 16,300 engines had been ordered by 2018 (see [26]), so total production volume should exceed 1,000,000 total parts over the lifetime of the engine program. This single part is claimed to save 1000 lb of weight out of each engine. The nozzles are fabricated using the cobalt–chrome material fabricated in EOS metal PBF machines. Parts are stress relieved while still attached to the build plate, followed by hot isostatic pressing (HIP) to ensure that the parts are fully dense. Every part is CT scanned to ensure it is free of large porosity.

Figure 21.8b and c show a PBF metal manifold from Spartacus3D and ducting made from polymer PBF by Jabil. These both illustrate good uses of metal and polymer AM for aerospace.

Titanium alloy materials are readily available for use on almost every metal PBF platform. Ti has excellent biocompatibility and is of great interest in the medical industry. Its lightweight, high strength, and high toughness properties mean that it is a good candidate for aerospace applications as well. A recent ASTM standard addresses specifications for metal PBF parts fabricated from this alloy. Ti alloy compositions are commonly tweaked in consideration of the unique processing challenges inherent in AM. For instance, a variant of titanium called Ti–6Al–4V ELI, which denotes a titanium alloy with about 6 percent aluminum, 4 percent vanadium, and extra low interstitials (ELI), meaning the alloy has lower specified limits on iron and interstitial elements carbon and oxygen, is increasingly popular for aerospace applications. The ELI variant has better corrosion resistance, fatigue properties, and mechanical properties at cryogenic temperatures than standard

Ti–6Al–4V. Since titanium alloys are particularly susceptible to oxidation during melting, metal PBF of Ti alloys always result in as-built parts that have a higher % oxygen than the incoming powder. Using the ELI version of Ti, the as-built part still oxidizes, but since it starts out with a particularly low oxygen amount, the end result is a part that can be within specification for standard Ti64 alloys.

Airbus developed an aluminum–magnesium–scandium alloy, called Scalmalloy, for metal PBF processes. The material reportedly has mechanical properties that are twice as good as commercially available aluminum alloys, with high corrosion resistance and good fatigue properties [23].

An in-process inspection technology was developed by Sigma Labs for use in the metal PBF machines and which is utilized by several aerospace manufacturers. Called PrintRite3D, the technology is used to monitor surface characteristics during the build to help verify the build quality of metal parts while they are being fabricated. It consists of software for monitoring and data analysis to determine if parts are within specification.

Early efforts toward production manufacturing with polymer PBF systems were performed at Boeing. In 2002, a Boeing spin-off company, On Demand Manufacturing, was formed, which was subsequently purchased by RMB Products in 2005. Their first application was to manufacture environmental control system ducts to deliver cooling air to electronics instruments on F-18 military jets, as previously discussed. To ensure reliable and repeatable manufacturing, they rebuilt several SLS Sinterstation machines to meet their needs. Many aerospace companies followed their lead and made their own modifications to AM machines. In the early years of AM, machine-to-machine variations were quite large, and so each machine had to be calibrated and certified individually. As AM has moved from prototyping to DDM, machine manufacturers have had to rethink their machine designs to reduce machine-to-machine variation. While much has been accomplished in this regard, machine-to-machine variation is still too common of a problem in the AM industry today.

Airbus has investigated topology optimization applications in order to develop part designs that are significantly lighter than those from conventional manufacturing. Shown in Fig. 21.9 is an A320 nacelle hinge bracket that was originally designed as a cast steel part but was redesigned to be fabricated in a titanium alloy using PBF [27]. Reportedly, they trimmed 10 kg off the mass of the bracket, saving approximately 40 percent in weight. This study was performed as part of a larger effort to compare life-cycle environmental impacts of part design.

Aerospace remains a major driver for AM innovation. Many more production applications are expected in the near future as materials improve and production methods become standardized, repeatable, and certified. New design concepts can be expected, such as the A320 hinge bracket, for not only piece parts but entire assemblies. AM vendors are developing larger frame machines so that larger parts can be fabricated, opening up new opportunities for structural metal components and functional polymer parts.

Fig. 21.9 A320 hinge bracket redesigned for AM. (Photo courtesy of EOS GmbH)

21.8 Automotive Applications

As an early adopter of AM, the automotive industry has had an outsized influence on the history of AM technology development. Automotive companies pioneered many of the AM applications in use today, and automotive-related AM expenditures remain one of the largest segments for machine and material sales in the AM industry.

Since production volumes in the automotive industry are often high (hundreds of thousands or millions of parts per year), AM has typically been evaluated as too expensive for production manufacturing, in contrast to the aerospace industry. To date, most manufacturers have not committed to AM parts on their mass-produced car models. However, AM is widely used in the automotive industry for prototype development as well as for jigs, fixtures, tooling, and many niche DDM applications.

As mentioned in the Historical Developments section, a variety of Rapid Prototyping applications were developed by automotive companies and their suppliers. In addition to RP and rapid tooling, suppliers to this industry used AM parts to debug their assembly lines. That is, they used AM parts to test assembly operations and tooling to identify potential problems before production assembly commenced. Since model line changeover involves huge investments, being able to avoid problems in production yielded very large savings.

In the metal PBF area, Concept Laser, a German company now owned by GE, developed their X line 1000R machine with a build chamber large enough to accommodate a V6 automotive engine block. This machine was developed in collaboration with Daimler AG. Although it doesn’t appear that any automotive manufacturers fabricate production engine blocks in this machine, the machine was developed with production manufacture in mind. According to Concept Laser, the 1000R is capable of building at a rate of 65 cm^3 per hour. Additionally, the machine was designed with two build boxes (powder chambers) on a single turntable so that one build box could be used for part fabrication, while the other could be undergoing cool-down, part removal, preheating, or other non-part-building activities.

For specialty cars or low-volume production, AM can be economical for many more types of parts. Applications include custom parts on luxury cars or replacement parts on antique cars. Examples from Bentley Motors and Bugatti were given in Chap. 19. At Bentley, for instance, polymer PBF is used to fabricate custom interior components that are subsequently covered in leather and other materials. Typically, Bentley has production volumes of less than 10,000 cars for a given model, so this qualifies as low production volume.

Among the racing organizations, Formula 1 has been a leader in adopting AM. Originally, using AM for Rapid Prototyping, most teams started putting AM parts on their race cars in the early to mid-2000s, and today all Formula 1 teams regularly use AM for production components. Initially, these were non-structural polymer PBF parts, but they have since adopted most AM technologies as appropriate and commonly use metal PBF for structural components. Similar to the aerospace industry, Formula 1 teams utilize AM models for wind tunnel testing of scale models, as well as for full-size car models. Teams from other racing organizations, including Indy and NASCAR, have also made AM an integral aspect of their car development process.

21.9 Questions

1. How does computerized tomography actually generate 3D images? Draw a sketch to illustrate how it works, based on conventional knowledge of X-ray imaging.
2. What are the benefits of using color in production of medical models? Give several examples where color can be beneficial.
3. Why might MEX technology be particularly useful for bone tissue engineering?
4. What AM materials are already approved for medical applications and for what types of application are they suitable?
5. Consider the manufacture of metal implants using AM technology. Aside from the AM process, what other processing is likely to be needed in order to make a final part that can be implanted inside the body?
6. Why would AM be particularly useful for military applications?
7. How can the use of AM assist in the development of a new, mass-produced automobile?
8. Find some examples of parts made using AM in F1 and similar motorsports.
9. Find an example not covered in this book of both direct and indirect fabrications of biocompatible scaffolds using AM technology. Describe these examples and discuss the current commercialization status of this approach.
10. In what ways has Additive Manufacturing affected the orthodontic industry?

Table Q21.1 Question 16

AM machine utilization	2000 h/year
Depreciation time	4 years
Investment costs	500,000$
Costs for maintenance	20,000$/year
Scanning speed	1m/s
Recoat time	15 s/layer
Part volume	1 × 1 × 1 cm
Hatch space	100 μm
Layer thickness	30 μm

11. Why might it be better for a patient to use customized fixtures rather than the mass-produced standard prosthetics?
12. What are the reasons AM applications in the medical field are growing?
13. How is Additive Manufacturing involved with surgical planning? What are the advantages of this?
14. Find an article no more than 1 year old describing a recent example of tissue engineering. How close is this example to being adopted as a common medical practice, and why?
15. Describe an example of a successfully implanted prosthetic within the past 5 years. List the material, AM process, and other characteristics of the example and why this prosthetic used AM rather than a traditional manufacturing technique.
16. A company does research on AM production cost on the basis of a sample part. A simple stainless steel part has to be evaluated. In their cost model, the following information and conditions are given. The cost of machine takes up 70 percent of the total cost.

    (a) If we want to build five pieces per build, what is the cost per piece?
    (b) If we want to build ten pieces per build, what is the cost per piece?
    (c) Please draw a graph of piece versus cost per piece and give a recommendation for number of parts manufactured in one build.

17. Explain why AM is used to produce jigs and fixtures for automotive production.
18. Why is AM popular within the motorcycle industry?

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