Autonomy for Surgical Robots: Concepts and Paradigms

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(Invited Paper)

***Abstract*—Robot-assisted and computer-integrated surgery provides innovative, minimally invasive solutions to heal complex injuries and diseases. The dominant portion of these surgical interventions has been performed with master–slave teleoperation systems, which are not capable of autonomous task execution or cognitive decision making. Much of the most advanced technologies foundered on the drawing boards or at the research labs for a long time, partially due to the fact that the surgical domain is resistant to the introduction of new hazards via the increased complexity of novel solutions. It has been seen with similar heavily regulated areas that internationally accepted standards can facilitate the adoption of new technologies in a safe manner. This paper reviews the existing autonomous capabilities of surgical robots, and investigates the major barriers of development presented by the lack of autonomy benchmarks and standards. The emerging safety standard environment is presented, as a key enabling factor to the commercialization of autonomous surgical robots. A practical scale is introduced to assess the level of autonomy of current and future surgical robots. Regarding the forthcoming robotic platforms, it is crucial to improve the transparency of the regulatory environment, streamline the standardization framework, and increase the social acceptance.**

***Index Terms*—Computer-integrated surgery, robot standardization, level of autonomy, degree of autonomy, robot-assisted minimally invasive surgery.**

I. Introduction

THE development of robotics in the past three decades resulted in the rise of entirely new paradigms across various industries and domains, including surgical care. Robotic devices are directly integrated in the execution of treatment plans in the operating rooms, and over 6 million successful procedures have been accomplished worldwide. Traditionally, autonomy is considered as a fundamental component of robots, yet it is one of the hardest terms to define, assess and regulate [1]. It presents a great challenge within the medical field to quantify system autonomy and related safety and performance issues. The aim of this article is to offer some cornerstones in autonomous capability assessment of surgical robots from the safety standardization point of view.

The importance of standardization has become paramount in the medical domain since that is the primary way to increase safety systematically—through standardized testing requirements and protocols. A first step towards this is benchmarking, the standardized assessment of robot capabilities, primarily focusing on their autonomous functions. In general, standards represent consensus built with the joint effort of academic, industrial and government experts, addressing the key developer/manufacturer/user issues of a distinct application domain [2]. While standards are voluntary, regulatory bodies often embrace and adopt them for their own clearance processes. This is particularly true in medicine and medical robotics within, where a notable ongoing international efforts are present to advance the state of standardization. The two global leading Standard Development Organizations (SDOs) *International Organization for Standardization* (ISO) and the *International Electrotechnical Commission* (IEC) created the very first joint standardization document (IEC/TR 60601-4-1) addressing the problem of autonomy in medical robotics, and practical methods for robot categorization and manufacturer's guides are also on the horizon.

The rest of the article is structured as follows: Sections I–III describe the general context of surgical robotics, provide basic definitions, introduce control concepts. Section II offers the problem statement with respect to the automation of surgical tasks. Section III gives an overview of the current surgical robot standardization landscape, as a first approach to manage automation within the domain. Section IV introduces the new concept of system classification based on their Level of Autonomy, and then Section V provides current examples for those. Discussions and Conclusions summarizes the findings in Sections VI and VII, respectively.

A. The Rise of Surgical Robots

Computer-Integrated Surgery (CIS) is the most commonly used term to cover the entire field of interventional medical technologies, from medical image guidance and augmented reality applications to automated tissue ablation [3]. One of the most exciting areas of CIS is robotic surgery, where the first applications appeared over 30 years ago [4], starting with image-guided (stereotactic) needle placement and tool positioning, ranging to autonomous radio therapy. Since then,

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hundreds of different prototypes have been developed [5]. The SAGES–MIRA Robotic Consensus Group (*Society of American Gastrointestinal and Endoscopic Surgeons and Minimally Invasive Robotic Association*) defined it as *"a surgical procedure or technology that adds a computer-technology-enhanced device to the interaction between the surgeon and the patient during a surgical operation, and assumes some degree of freedom of control heretofore completely reserved for the surgeon. This definition encompasses micro-manipulators, remotely controlled endoscopes and console-manipulator devices. The key elements are enhancement of the surgeon's abilities—by the vision, tissue manipulation or tissue sensing—and alteration of the traditional direct local contact between surgeon and patient"* [6].

According to our records, there are over 45 commercially available surgical robots, and another 40 systems are under development for commercial purposes. Importantly, many of these systems fall outside of the standard definition of a robot, as in *ISO 7383:2015 - Robots and robotic devices – Vocabulary* Typical outliers are robotic microscope holders, hand-held devices and teleoperation systems The most common type of surgical robots are the master–slave telesurgery devices, which are commonly addressed as *Robot-Assisted Minimally Invasive Surgery* (RAMIS).

Interestingly, all currently available surgical robots on the U.S. market went through the *Food and Drug Administration*'s (FDA) *510(k)* clearance pathway, where the substantial equivalence to an approved device has to be demonstrated. This means, manufacturers were reluctant to implement new (e.g., autonomous) features in their systems. They rather not claim them "robots", fearing that the FDA might divert them to the more stringent *Premarket Approval* (PMA) regulatory process. The difference might be significant; on average, to get 510(k) clearance costs $31 m and 10 months , while the PMA takes $94 m and 54 months on average [7]. The procedures both in Europe and in the U.S. are focusing on the safety and transparency of systems, as FDA also shares the view that medical robots are only different from other robots in terms of "intended use" [8].

To avoid regulatory hurdles, even the most successful surgical robot, the da Vinci Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA) was decided to get cleared not as a robot, but as a *teleoperated endoscope holder (510(k) NAY FDA)*, where the motion of the tools are always fully under the direct control of the human surgeon. This control paradigm has proved to be so successful that the company has shipped over 5300 units worldwide, and their market capitalization reached $65 bn recently. There are at least 20 start-up companies aiming to repeat their success with RAMIS, following the same control principle with their systems, sometimes with completely different architectures, and the biggest medtech companies started to invest heavily into the domain (Johnson & Johnson, Medtronic, Stryker, Zimmer Biomet each spent hundreds of millions of dollars on surgical robot technology acquisitions recently).

B. Control Concepts for Surgical Robots

From the technical point of view, robot autonomy is directly a derivation of the robot control algorithm, and it means autonomous task execution. Robots can be involved in surgical procedures with different levels of autonomous functions, and each type requires different approach during the control system development, verification and testing [9], [10]. Some of them serve as a stable tool holder, once directed to the desired position (as a passive tool). Others actively support the procedure: systems that are able to perform well delimited, fully automated procedures—such as Computed Tomography (CT) based biopsy or cutting—are called autonomous (in the industrial robotic sense) or supervisory controlled devices since they are able to execute a surgical plan, once it has been approved by a human, and the robot is registered to the patient's coordinate system [11].

On the other hand, if the robot is entirely teleoperated (RAMIS type), the surgeon is absolutely in charge of its motion. Safety here inherently comes from the human-in-the-loop control. Based on the gathered visual (and optional haptic) information, the surgeon guides the arm by moving the controller, and closely watching its effect (typically through the image of an endoscopic camera). In most of the cases, the slave system and the camera are acting as the remote hands and eyes of the surgeon, and therefore they are parts of the operation.

Modifying the teleoperation control paradigm, cooperative control was introduced (also called shared control or hands-on surgery). Here, the surgeon directly gives control signals to the machine with their hands, e.g., via a force sensor [11]. It is possible to read and process these signals in real-time to achieve smooth motion control for the robot. The human is always in physical contact with the robot, as the master and the slave devices are identical. In this case, the robot is the extension of the doctor's hand, equipped with special features and effectors. This approach keeps the human in the loop, and thus allows the surgeons to use all of their senses. It is often employed in the case of micro-manipulation operations, such as micro-vascular, urologic or brain procedures [5]. It may be combined with other features, such as a small robot being hand-held [12]. Cooperative control has seen a wider application in commercial systems as well, such examples include the MAKO (Stryker Co., Kalamazoo, MI) for knee arthroplasty and the Mynutia (Mynutia Co, Leuven, Belgium) for retina surgery. Cooperative control is a promising way to provide highly integrated robotic support for procedures, while introducing safety measures through autonomous functions.

C. Process-Level Approach to Surgical Automation

Beyond autonomous physical operation, cognitive capabilities should also be addressed for surgical robots. The domain of cognitive robotics typically refers to active decision making, reasoning or human decision support. It is already present in many forms, providing a solid background to the medical robotics domain to nurture on [13], yet the principles of this field mostly on methods developed for manual surgery. Most medico-surgical processes follow specific guidelines, such as generic diagnostic and treatment plans, relying on domain knowledge and medical practice [14]. Automation is already present on this high (task-oriented) level, e.g., with pre-defined treatment plans for the common diseases, however this is

not the focus of this article. With the rapid development of CIS, automation is penetrating into the task execution layers of surgical practice, addressing the issues of *Human–Robot Interaction* (HRI) from the robot–patient perspective [15].

One of the cornerstones of recent advancement in HRI is the evolution of knowledge transfer, which may happen in the form of descriptive logics, community vocabulary, formal languages and ontologies [16]. Ontologies, defined as *the formal description of the concepts and relationships for an agent or a community of agents*, are essential for HRI, especially for representing and sharing knowledge among humans and robots. A general framework of knowledge representation for robotic reasoning was defined first in the scope of the *1872-2015 – IEEE Standard Ontologies for Robotics and Automation* standard, which appeared as a consensus of over 50 experts from 20 different countries, from industry, academia and government organizations.

For the past 15 years, *Surgical Process* (SP), which is defined as "*a set of one or more linked procedures or activities that collectively realize a surgical objective within the context of an organizational structure*", along with the term *Surgical Process Model* (SPM) as "*a simplified pattern of an SP that reflects a predefined subset of interest of the SP in a formal or semi-formal representation*" represent a leading area of research for modelling and automating surgery [17]. The development of SPMs required the accurate description of agents in surgery, and therefore resulted in the creation of complex data/knowledge representation systems. These are ontologies able to accurately represent surgical procedures so that they can be automatically analyzed. The general aim is to become able to objectively assess, benchmark the domains of surgery. Besides skill assessment, ontologies have a wide spectrum of use, including:

- evaluation of tools/surgical approach/systems;
- surgical education and assessment;
- optimization of OR management;
- context-aware systems;
- robotic assistance.

SPMs can describe surgery at many levels of granularity, starting from the complete task level to the finest level, meaning the surgeon's motion primitives [18]. On one end, critical and time consuming steps of the surgery can be analyzed, and on the other hand, finer level of details can be used to link the surgeon's actions to robotic execution primitives.

II. Technical and Non-Technical Challenges in Automating Surgery

Safety is of paramount concern with respect to robotics, therefore starting from the early days, robotic capabilities were developed with advanced safety functions, primarily focusing on the mechanical and electrical safety [19]–[21]. Despite the emerging safety concepts [22], none of the currently accepted methods focus directly on the autonomous capabilities of the robot, as a primary source of hazard.

As indicated above, there still exist a number of technological gaps. While some surgical procedures are routine and predictable (therefore less complex and cheaper to perform), most are highly variable, with possible complications unique to the patient [23]. Developing an *Artificial Intelligence* (AI) that can follow a surgical plan, and able to identify when a complication has emerged requires expertise and structured knowledge, which is not yet available in a robot-compatible format anywhere. Recently developed Deep Learning type AIs have contributed to solve many issues in medicine, mostly in the domain of surgical imaging, task planning [24] and surgical skill assessment [25]. This leaves current robotic task execution algorithms to rely more on deterministic methods, while unsupervised learning is rapidly developing in this domain as well [26].

With the increase of the adoption, a more pressing issue becomes the guarantee of fallback options. If there are no more human personnels capable or qualified to safely operate by hand, it creates a significant hazard. This leads to a similar ethical and societal happening right now around self-driving technologies. There, a safety approach was recommended for low level autonomous system, which might be adaptable to medicine as well. It aims to optimize the handover process given the concept of stability region based predictive horizon of the human operator [27]. Physical and IT security of the autonomous systems are crucial, especially for RAMIS. Inherent communication errors and latencies can make almost impossible to detect a critical system override in time [28].

The medical device industry is very conservative, therefore it takes a lot of effort to bring changes to the field. Human medicine has changed a lot recently due to CIS, yet fundamental ethical principles still hold, with much bias against robotic systems. Elevating it to the regulatory level, the EU is working on a robot ethics doctrine [29], and also the IEEE is drafting relevant standards (*IEEE P7000 - Model Process for Addressing Ethical Concerns During System Design*, *IEEE P7001 - Transparency of Autonomous Systems* and *IEEE P7007 - Ontological Standard for Ethically Driven Robotics and Automation Systems*).

The primary tool to achieve a unified regulatory environmen is through implementing international standards. Safety and performance benchmarks should get adapted to the current state-of-the-art of the technology, especially in the medical domain, where standards are typically emerging as compulsory directives [30]. Without proper standardization and testing frameworks, autonomous functions mean higher associated risk, something industrial companies are usually willing to avoid [31]. They are to streamline the regulatory processes, since authorities are currently struggling to implement clearance methods for autonomous robots, classified as high-risk devices.

III. Surgical Robot Standardization

There is an obvious gap in the ISO/IEC standards regarding surgical robots, given the historically industrial manipulator-oriented context of the existing standards.

An industrial robot is currently defined in ISO 8373:2015 as a "*programmed actuated mechanism with a degree of autonomy, moving within its environment, to perform intended*

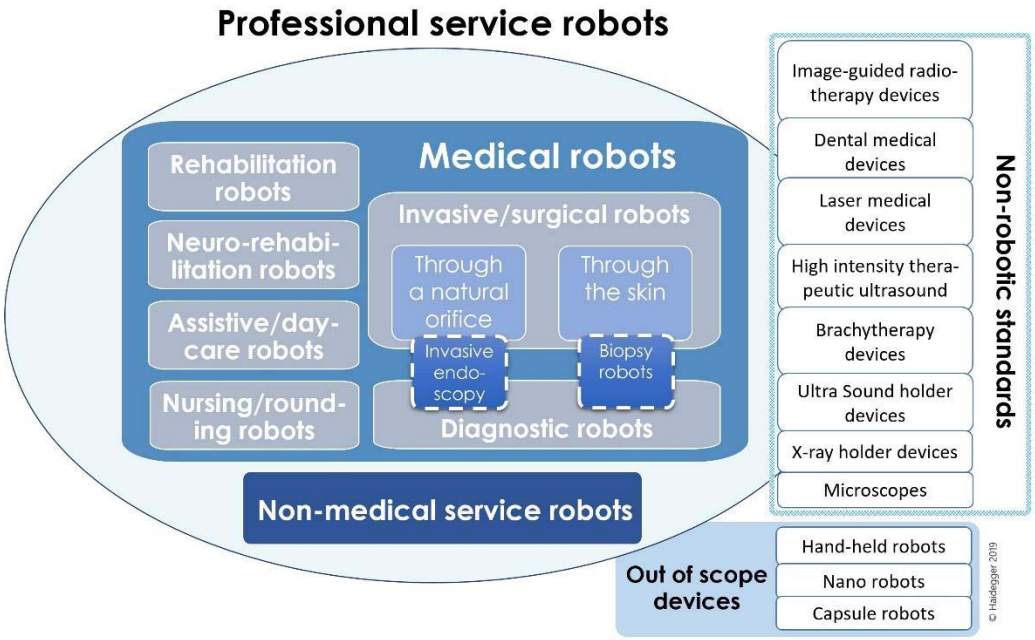

Fig. 1. The different domains of medical robotics, and surgical robots within apt for standardization, following the convention of the ISO 8373 Vocabulary standard.

tasks", and a service robot being a "*robot that performs useful tasks for humans or equipment excluding industrial automation applications*", thus a system's internal moving mechanisms do not count as a robotic system. Da Vinci-type robots are also excluded, since they do not present decision making capabilities, only teleoperated features. (Surgical robot manufacturers exploited this point to avoid compliance with any robotic standard). On the hand, essentially all radiation beam therapy systems are also medical robots that move a source around the patient to deliver beams of radiation from different angles, showing a high level of autonomy.

Nevertheless, the *IEC 60601-1 – Medical electrical equipment* standard and the *93/42/EEC Medical Devices Directive* are applicable to all systems with a "medical intended use". In the case of robots, this includes all kinds of systems from psychological rehabilitation to natural orifice surgery. The diversity of functions and appearance makes the regulation, standardization of the domain extremely difficult.

ISO/IEC started to work a decade ago on the integration of the new robotic application domains, and within the *ISO/TC 299 Robotics technical committee*, numerous working groups are active. As a result, the very first collaborative robotic standard was published *ISO/TS 15066:2016 Robots and robotic devices – Collaborative robots*, together with the *ISO 13482:2014 Robots and robotic devices – Safety requirements for personal care robots*, which regulated service robots, apart from medical devices. It has to be noted that until the publication of the ISO 15066, it was impossible to have a surgical "robot" (robot in the ISO sense) certified in a standardized environment, since the *previous ISO 10218-1:2011 - Robots and robotic devices – Safety requirements for Industrial Robots* forbade any human presence in their workspace [32].

In the meantime, industry continues to put new systems on the market: teleoperated and autonomous patient visiting robots (e.g., RP-Vita from iRobot and InTouch Health, Boston, MA, USA) have been cleared as medical devices for hospital use in the USA, and various minimally invasive and percutaneous systems have been released in Europe [33].

Consequently, the first critical issue for the standardization of surgical robots was the delimitation of the domain, to make it clear for manufacturers, regulatory bodies and users as well, what types of devices fall under these standards. Starting from the ISO 8373, a draft classification of the domain can be performed, while the boundaries are still not sharp [34]. Fig. 1 presents the identified medical robot sub-domains targeted by the ISO/IEC standardization activities. It was made clear that until there are more commercial products available, certain brand new types of robotic devices cannot be assessed by the standard. There shall be new particular standards developed under the IEC 80601 family addressing the needs of, e.g., capsule robots.

In 2018, the *IEEE Engineering in Medicine and Biology* (EMB) (co-sponsored by the *IEEE Robotics and Automation Society* (RAS)) started a new working group: *IEEE P2730 Standard for Classification, Terminologies, and Definitions of Medical Robots*, with the scope to "*specify the category, naming, and definition of medical robots*". The early working drafts did not get past the ISO terms for robot and medical robot, nevertheless, the working group shall only deliver new results within its three-year-long approved term.

A. Degree of Autonomy of Surgical Equipment

Roughly eight years ago, when the ISO/IEC TC group thoroughly analyzed the current situation of surgical robot standardization, the only major gap identified was the *Degree*

of Autonomy (DoA): introduced in ISO 8373, had not properly defined. Understanding the fact that the proper definition of autonomy and its conjugated forms "autonomous", "automation", or related definitions can be unambiguous, the ISO/IEC joint working group decided to extend the scope of their work to all *Medical Electrical Equipment* (MEE) or *Medical Electrical System* (MES) with a DoA (other than zero). The outcome of a decade-long discussion was concluded in a new Technical Report (TR) *IEC/TR 60601-4-1: Medical electrical equipment – Part 4-1: Guidance and interpretation – Medical electrical equipment and medical electrical systems employing a degree of autonomy*. The TR recommends to omit the use of the words "automation" or "automatic" within the frames of this robotic standard, to avoid further confusion. DoA is defined as "*taxonomy based on the properties and capabilities of the MEE or MES related to autonomy*".

Relying on some earlier work in the field of industrial automation [35] and service robotics [36], the TR recommends the parameterization of DoA along four cognition-related functions of a system, which are affecting *options* of an MES:

- *Generate* an option: to formulate possible options, based on the result of the monitoring task for achieving predefined goals;
- *Execute* an option: to carry out the selected option. Robots can typically be active or passive supporters of a surgical task execution;
- *Monitor* an option: to collect necessary information to perceive the status of MEE or MES, patient, operator or environment. Therefore signals beyond the internal (proprioceptive) control signals of the robot;
- *Select* an option: to decide on a particular option from the pool of generated.

$$\mathrm{DoA} = \mathcal{F}\{G|E|M|S\},$$

where the overall DoA metric is normed sum of the four function of the system assessed on a linear scale, 0 meaning fully manual and 1 fully autonomous.

Each of the four functions can be performed by a human or by a computer (maybe mixed under some conditions), which would then lead to the objective assessment of the DoA of the system. DoA can vary from low to high, with $\mathrm{DoA} = 0$ meaning "no autonomy", and the other end of the scale meaning "full autonomy" for the system. Having no autonomy is meant for the capabilities on the system level, excluding low-level electronic and computational functions of the MEE or MES (such as motor control, kinematics calculations, communication). DoA can be classified at different granularity levels, depending on where and how the above functions are implemented.

Generating options through AI methods is fairly common in medicine already (especially in medical imaging), however, decision making during a surgical procedure is a new domain for robots. *Execution* is already happening in an autonomous manner in numerous systems (primarily in Image-Guided Surgery). *Selecting*, i.e., decision making is still a key distinguishing factor, and dominantly done by skilled human professionals. On the other hand, *monitoring* capabilities of computer systems are typically more effective than humans, since most of the critical processes happen at a much faster time scale than humans can notice, assess and control. This safety concept is called *Situation Awareness* (SA), and a separate standard deals with it (Section III-B).

While the TR does not require one particular way of DoA assessment, it offers various alternatives. One of the most applicable is derived from industrial automation, where 10 DoA levels were identified according to Table I. In practice, when performing the risk management of a surgical robot (typically according to *ISO 14971 – Application of risk management to medical devices*), the DoA should be taken into consideration. While the DoA does not necessarily has a direct correlation with the level of risk, it can largely impact the risk management. If an operator is required to assert control over surgical system when there is an error or malfunction, a human may not be able to adequately control the situation (loss of SA), and thus the DoA will determine the handling of the hazardous situation. At lower DoA levels, there can be a shared responsibility between the operator and the robot, while the failure of function at higher DoA is a critical hazard.

The implementation of the concept of autonomy has been perceived through particular safety standards, which are also released under the ISO/IEC umbrella.

B. Basic Safety and Essential Performance of Surgical Robots

From the user's (and the manufacturer's) point of view, avoiding and managing any kind of failure (software, hardware, communication, system-level) is critical. Industrial robots caused over 33 documented casualties in the USA in the past 30 years, which is still a relatively low number, constituting 0.0005% of all working-related deaths [29]. This number does not include any surgical robotic case as for those (especially for RAMIS), the human surgeon is 100% liable for the outcome (as ruled in all juridical cases up to now).

When systems move toward higher autonomy, risk mitigation and management becomes very important. Several groups have published risk-based methodologies to support the safety of design and development of robotic devices, such as the generic *Hazard Identification and Safety Insurance Control* (HISIC) policy that has been applied to multiple robotic systems so far [37].

The ISO/IEC TC 62/SC 62D joint committee started to work on the minimum requirements for a practical degree of safety for surgical robots in 2015. The result of the work, the *IEC 80601-2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment* is to be published in 2019. It defines the basic different types of surgical robots (Section I-B), and identifies their relevant components. For RAMIS the standard focuses on:

- robotic surgical instruments;
- the patient-side part of the robot;
- the operator-side part of the robot;
- the endoscope holder (if any).

TABLE I
DESCRIPTIVE CLASSIFICATION OF DEGREE OF AUTONOMY ADAPTED FROM KABER AND ENDSLEY [35] BASED ON IEC/TR 60601-4-1. H: THE HUMAN OPERATOR PERFORMS THE GIVEN FUNCTION. C: THE COMPUTER-DRIVEN SYSTEM PERFORMS THE GIVEN FUNCTION

DoA	Description	Monitor	Generate	Select	Execute
0	**Full Manual (FM):** No autonomy involved. The operator performs all tasks including monitoring the state of the system, generating performance options, selecting the option to perform (decision making) and executing the decision made, i.e, physically implementing it.	H	H	H	H
1	**Teleoperation (TO):** The equipment assists the operator with the execution of the selected action, although continuous operator control is required. The operator performs all tasks, including monitoring the state of the equipment, generating options, selecting the desired option and execution of it. (Master–Slave teleoperation.) Note: traditional robotics standards consider teleoperation as zero DoA.	H/C	H	H	H/C
2	**Pre-programmed execution (PE):** The operator generates and selects the options to be performed without any analysis or selection by the equipment. Note: traditional robotic standards considered this as "autonomous" or "automatic" operation.	H/C	H	H	C
3	**Shared decision (SD):** Both the operator and the equipment generate possible decision options. The operator retains full control over the selection of which option to execute. Both the operator and the equipment participate in the execution.	H/C	H/C	H	H/C
4	**Decision support (DS):** Me equipment generates a list of decision options, which the operator can select from, or the operator may generate alternative options. Once the human has selected an option, it is turned over to the equipment to execute it.	H/C	H/C	H	C
5	**Blended decision (BD):** The equipment generates a list of decision options, which it selects from and executes if the operator consents. The operator may also generate and select an alternative option; the equipment will then execute the selected action. BD represents a high-level decision support system that is capable of selecting among alternatives as well as executing the selected option.	H/C	H/C	H/C	C
6	**Guided decision (GD):** The equipment presents a set of actions to the operator. The operator's role is to select from this set, he/she cannot generate any other additional options. The equipment will fully executes the selected action.	H/C	C	H	C
7	**Autonomous decision (AD):** The equipment selects the best option and executes it, based upon a list of alternatives it generates (this list can be augmented by alternatives suggested by the operator).	H/C	H/C	C	C
8	**Operator Monitoring (OM):** The equipment generates options, selects the option to implement and executes it. The operator monitors the equipment and intervenes if necessary. Intervention places the human in the role of making a different option selection. During the procedure there may be decision making points that will be decided by the equipment.	H/C	C	C	C
9	**Full Autonomy (FA):** The equipment carries out all actions. The operator does not intervene except to e-stop the equipment (which is a general requirement).	C	C	C	C

For image-guided system the surgical robotic tool, the *robot* and the *tracking device* are considered. The standard collects all relevant mechanical and thermal hazards, along with the fault conditions of the equipment and the required usability trials. Another particular standard (*IEC/CD 80601-2-78: Particular requirements for the basic safety and essential performance of medical robots for rehabilitation, compensation or alleviation of disease, injury or disability*) coming from the same committee addresses the hazards associated with the loss of SA. SA is defined as the "*the operator's perception, comprehension and prediction of a robot's behavior in its environment.*" The loss of SA may be critical when a human operator is needed to supervise a task, or interact with a robot to reduce risk. According to the new standard the manufacturers will have to include the necessary information about SA for their upcoming medical robotic systems. It is important to mention that the HRI of the system has a crucial role in the quality of SA: if the critical data is presented in an adequate, human-sensitive way (such as sound alerts), SA can be efficiently supported. The system should also provide advanced decision support to resolve complex situations [38].

The community strongly believes that future standards should focus more on patient safety and treatment improvement rather than pure technical metrics, and will continue to work towards that goal.

IV. LEVEL OF AUTONOMY FOR SURGICAL ROBOTS

While the above mentioned standards are indispensable to rigorously assess surgical robotic system capabilities, they are not definite enough to offer taxonomy to generally assess the development phases of the domain, or to perform benchmarking. There is a need to classify surgical robotic systems based on their advancement, relative in the field. For this purpose, a gradual mapping was proposed recently by a group of senior authors to categorize the autonomous capabilities of surgical robots [39]. Employing similar concepts from the domain of self-driving cars, a scale of 6 was introduced from no autonomy to full autonomy [40]. It is argued that at higher levels of autonomy, the robot is not only a medical device but it practices medicine, which then falls under a completely different regulatory case. For example, the FDA regulates medical devices, but not the practice of medicine, which is left to the applicable law and the medical professional societies, composed of 100% humans, as of today. Some earlier work put the HRI into the center of the classification setting a 0–7 scale [41].

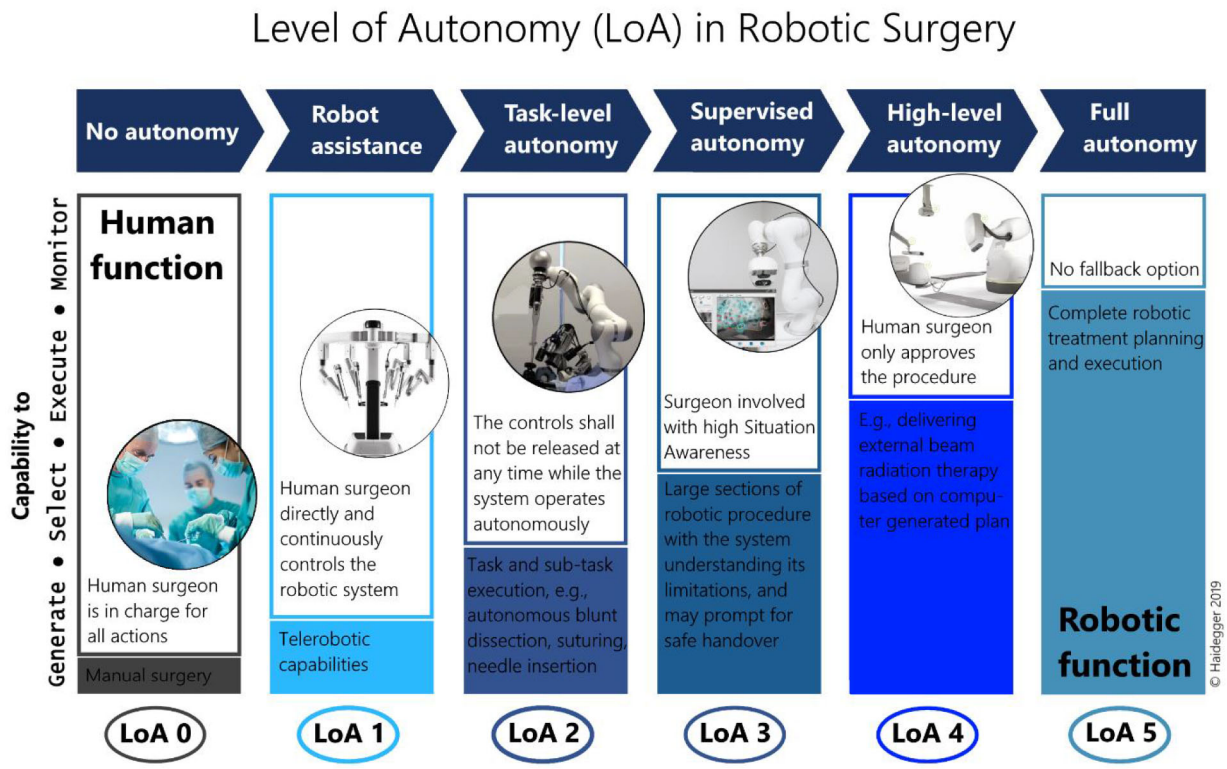

Fig. 2. The proposed 6-stage classification for assessing the autonomous capabilities of surgical robots. The concept of Level of Autonomy follows the ISO/IEC standardization framework, determining LoA based on the human versus robotic functions of the system.

The fundamental problem with the LoA scale of [39] is that in the middle ranges LoA 2–4 (where most current autonomous capabilities would fall) it does not offer a metric along which to distinguish the required level of human supervision. The SA may have a crucial role in determining the cognitive level up to which the human may be able and shall be allowed to intervene. This approach was described earlier as the human-on-the-loop control [42].

Employing the rational presented in Section IV, it is evident that there is a graduality in any autonomy-related scale, depending on the human supervision. Given the limited human sensory and processing bandwidth capabilities—especially when we discuss emergency reactions—the loss of SA would mean that the conditional enabling of a robot functionality, or a supervising its actions require SA, and only the cognitive time horizon is different, in which the human is capable of reacting.

Coherent to the mainstream standardization efforts, yet fitting to the commonly used terms, the following *Level of Autonomy* (LoA) scale is proposed (Fig. 2):

- *LoA 0 – No autonomy:* all system-level functions (*generating, selecting, executing* and *monitoring* actions) are performed by the human operator. Technically it means that during the surgery no active robotic equipment is used, thus it may be considered identical to a non-robotic case.
- *LoA 1 – Robot assistance:* the surgical robot performs specific, low level functions only, e.g., teleoperated systems, tremor filtering, minor safety features.
- *LoA 2 – Task-level autonomy:* the system is trusted to complete certain tasks or sub-tasks in an autonomous manner, e.g., image-guided bone drilling, wound closure. It may only happen for a short instance.
- *LoA 3 – Supervised autonomy:* the system can autonomously complete large section of a surgical procedure, while making low-level cognitive decisions. All actions are performed under human supervision, assuming the operator's situation awareness.
- *LoA 4 – High-level autonomy:* the robotic system executes complete procedures based on human-approved surgical plans, while the human only has the capability to emergency stop (e-stop) the procedure. The robot shall be able to complete the task even if the human fails to respond appropriately to a request to intervene.
- *LoA 5 – Full autonomy:* a full-time performance of the robotic system, handling all environmental and adverse conditions. The system succeeds in scenarios where even the best human operator would fail, therefore there will be no need for a human fallback option.

As opposed to DoA, this LoA definition is empirical, focusing on the key enabling robot capabilities of a system. Full autonomy in the medical domain still belongs to science fiction, nevertheless, numerous AI and machine learning techniques are currently being developed targeting advanced surgical robot systems in various surgical domains [43]. Most probably—just as it is expected in the case of self-driving cars—the market will suddenly tip toward autonomy

Fig. 3. The da Vinci Xi teleoperated system with a self-adjusting operating table. *Image credit: Intuitive Surgical.*

Fig. 4. Think Surgical's TSolution One system (formerly called ROBODOC) offering image-guided (autonomous) knee arthroplasty. *Image credit: Think Surgical.*

once reliable LoA 3 (Supervised Autonomy) devices hit the mainstream.

V. Currently Available Autonomous Functions

This section aims to briefly overview the key existing and upcoming autonomous functions in surgical robotics. Given the spread of the applications and large number of systems only a few typical commercial examples are cited along with some much-promising research concepts and porotypes.

A. Commercially Available Robot Functions

The market dominating RAMIS system is definitely the da Vinci from Intuitive Surgical Inc. The first three generations of the da Vinci only had low-level robotic functions (such as redundancy resolution, gravity compensation or master and slave synchronization) extended with the capability of motion scaling (1:5 between the master and the slave) and hand tremor filtering (above 25 Hz). It has been a principle of development to ensure that the human operator is always in charge of the motion of the robot. The da Vinci Xi generation (2014) was the first to feature automated docking, instrument positioning and camera adjustments. Minor ergonomic functions that can be performed autonomously by the robot, still belong to LoA 1. Trumpf Medical (Ditzingen, Germany) introduced an integrated operating room table (TruSystem 7000dV OR Table) for the da Vinci Xi that is able to automatically follow the adjustments made with the robot base, to maintain the position of the patient relative to the robot (Fig. 3).

More autonomy has been implemented into supervisory controlled robots, where one of the earliest examples, the ROBODOC (currently called TSolution One Surgical System from THINK Surgical, Fremont, CA, USA) already featured autonomous image-to-robot registration, force-driven cutting feed and virtual fixture-based safety features [44], [45]. The robot is capable of autonomous bone drilling based on the surgical plan, derived from pre-operative CT images (Fig. 4). Based on the above definition, these capabilities fall under LoA 3.

Veebot (Veebot LLC, Mountain View, CA, USA) is a recently developed autonomous blood sampling robot that can find a vein based on IR camera images, and then use ultrasound to place a needle into a vein. The robot was shown to work fine on an average arm (finding the best vein to target autonomously 83% of the time), although, it has not been shown how it succeeds with hidden vessels [46]. Since the entire workflow can be automated (given a simple procedure), Veebot may be considered to be at LoA 4.

Real-time image guidance is also realized with the ARTAS hair restoration robot (Restoration Robotics Inc., San Jose, CA, USA), which identifies and cuts folliculi from the head in a fully autonomous manner, much more accurately than humans can typically do [47]. The latest ARTAS iX version was built on a KUKA LBR Med collaborative robot for improved safety, completing an LoA 3 system, since implantation is still performed mostly manually.

Probably the most advanced autonomous capabilities are integrated in the CyberKnife stereotactic radiosurgery system (Accuray Inc., Sunnyvale, CA, USA). It combines image guidance with robotic positioning: a linear accelerator is mounted on a KUKA KR 240 industrial manipulator (Fig. 5). the primary mobilization of the effective part is resolved with a standard industrial manipulator. CyberKnife's main deployment is the irradiation of brain and spine tumors. X-ray cameras are used to track the spatial displacement of the patient and compensate for any motion caused by, e.g., breathing. To improve the accuracy, radioopaque fiducial markers can be implanted in/near the tumor region several days before CT scanning for treatment planning to be tracked by the X-ray cameras. An additional custom developed software tool builds a correlation model between the positions of periodically detected fiducials and the real-time locations of optically tracked markers placed on the chest to track tumor location. It uses 4D CT (CT through time) to measure respiratory tissue motion/deformation and to account for the effect of displacement through the irradiation [48]. CyberKnife realizes highly autonomous operations as real-time image-guided radiotherapy, where once the treatment plan (designed by the system)

Fig. 5. The CyberKnife M6 radiosurgery robot with automated patient motion tracking and safety features. *Image credit: Accuray.*

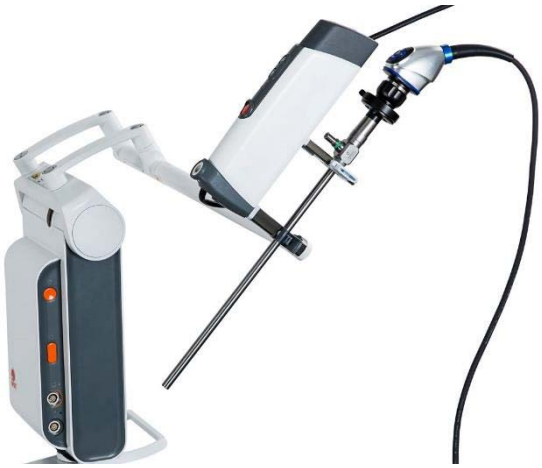

Fig. 6. The AutoLap image-guided endoscope holder robot with advanced tracking and visual servoing capabilities. *Image credit: MST Medical Surgery Technologies.*

is approved by the human, there is only an e-stop function for human use (LoA 4). If it were amended with an additional computer-supervision module and automated patient management environment, it could be categorized as LoA 5.

A similar concept has been employed for diagnosis and interventional radiology support by the Artis Zeego Pheno (SIEMENS AG, Munich, Germany), aimed for actuated X-ray imaging, where a C-arm is manipulated by an industrial robot. Since treatment is not performed here, it is rather an LoA 3.

As long as the robotic functions are not involved in the invasive part of the procedure, there is a lower risk of any damage during malfunction; therefore more advanced capabilities can be programmed, such as typical assistance functions.

A good example for robotic tool holding is the AutoLap camera-handling robot (developed by MST Medical Surgery Technologies Ltd., acquired by TransEnterix for $33 m), which offers feature-tracking with visual servoing and image guidance during laparoscopic procedures (Fig. 6), representing LoA 2.

Another LoA 2 system is the KIEVO 900 robotic microscope holder for neurosurgery with automated optimal positioning (Carl Zeiss Meditec AG, Jena, Germany).

Cooperative controlled systems, such as the hand-held Micron [49] offers active compensation for hand tremor and

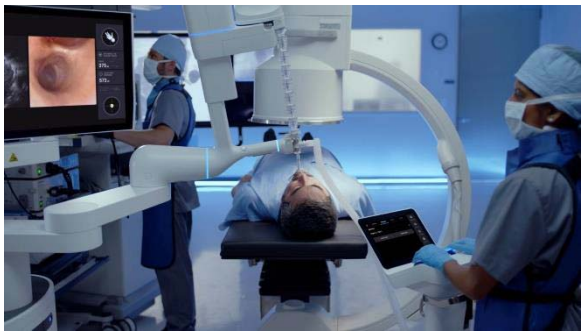

Fig. 7. The new Ion system from Intuitive features a 3.5 mm maneuverable catheter that allows navigation into the peripheral lung for biopsy, with real-time shape sensing. *Image credit: Intuitive Surgical.*

image-guided targeting during, e.g., a needle based procedure making it a LoA 1 device.

A new type of robot, flexible catheter robot appeared recently, offering single port or natural orifice transluminal surgery. Auris Health (San Carlos, CA, USA) developed the Monarch system, employing Hansen Medical's catheter drive, and offering simplified remote control under fluoroscopy. This represented new engineering challenges, since the control of the complex mechatronics cannot be easily solved by traditional user interfaces. Intuitive Surgical made it further with its flexible catheter system, the Ion (Fig. 7), that is claimed to be able to perform automated tumor biopsy supporting peripheral lung cancer treatment based on pre-operative images and real-time optical fiber-based shape sensing (a technology licensed from Luna Inc., Roanoke, VA, USA). The system received FDA clearance in early 2019 for various clinical applications [50]. If used in an autonomous approach mode (instead of teleoperation), this would constitute LoA 3.

B. Prototypes and Future Concepts

Increasing the LoA of a clinical system is not easy. Considering either a less complex biopsy tool, ultrasound guided procedure or a teleoperated, MR compatible robot, safety may come from adding in vivo imaging at a cost of system complexity and computational requirement [51]–[53]. Execution can be done robotically in the case it is simple and well defined task with a clear medical target. Needle placing and targeting robots have been developed successfully for primarily prostate brachytherapy [54]. Robotic needle steering is a particularly well examined area from this aspect, where the advanced control of bending needles can reach targets with high accuracy and even behind obstacles [55], [56]. However, with the current systems, surgical planning and path planning are typically done and manually validated by humans before the execution.

Non-commercial, research prototypes of the da Vinci have gone much further than the commercial versions: a complete user group exists employing the robot's hardware capabilities through the open source *Da Vinci Research Kit* (DVRK), an open controller platform that was created by the Johns Hopkins University, Worchester Polytechnic Institute (WPI) and partners [57]. With the DVRK, various LoA 2 types'

demonstrations have been performed: automated suturing, anastomosis, injection, needle insertion and numerous laparoscopic training tasks [58]. Other groups have demonstrated autonomous trajectory planning, ex-vivo anastomosis and blunt dissection as well [59]–[63]. The collaborative control concept has also been extended to the RAMIS type devices with the use of the DVRK [64], and semi-autonomous laparoscopic electro-surgery was also demonstrated [65].

As for LoA 2–3 capabilities, more complex tasks have been automated by the Hopkins CISST and the UC Berkeley CalMR groups [66]–[68].

Smaller scale robots, such as capsules, natural orifice and nano-size robots are representing a rising domain, however, these will fundamentally change the clinical workflow, therefore cannot be handled together with the current surgical robots regarding standardization [69]. Already the locomotion capabilities of an active capsule robot require significant autonomous functions from the system, as such are now being tested by many companies, and human clinical trials are underway [70].

In the meanwhile, capturing the essence of human surgery remains a significant challenge for computer systems. Ontologies and SPM are believed to serve efficiently the current automation needs for certain more simple sub-tasks at LoA 3 and presumably LoA 4 [25], [71]. Most of the publicly disclosed projects are in the stage of *Technology Readiness Level* (TRL) 4–6, in the research and development phase.

C. Surgery 4.0

The trend lines in automating medicine have already outlined a rather revolutionary jump. similar to Industry 4.0 and Robotics 4.0 [72], the term Surgery 4.0 emerged with the aim to identify the new capabilities that CIS technologies can offer at LoA 3+ [73]. Surgery 2.0 was considered to be MIS, the introduction of laparoscopy, 3.0 represents the current RAMIS and Surgery 4.0 denotes the seamless integration of medical decision support systems, imaging and automated execution. Verb Surgical (Mountain View, CA, USA), a venture created by Google and Johnson & Johnson was the first to claim developing a Surgery 4.0 robot system, where advanced visualization, robotic instrumentation, data analytics and machine learning are combined [74]–[76]. Their first prototype was created in 2016, and the company aims to enter the market in 2019.

VI. Discussion

Surgical robots have been around for three decades, and they are finally close to a breakthrough in surgery, partially due to their mounting autonomous capabilities. This is first happening at sub-function or sub-task level at LoA 1–3. The novel systems promise more in terms of clinical and commercial success, and are different in two ways: either being specialized on particular procedures (such as the iSYS robot from iSYS Medizintechnik GmbH, Kitzbüchel, Austria), or remained generalistic, like the da Vinci, but integrated the technical advancements of the past 20 years, such as Versius (CMR Surgical Ltd., Cambridge, U.K.). Being application-oriented (ideally driven by a strong clinical need) means that the system's entire architecture may be defined by the targeted treatment, allowing space for reliable AI and machine learning solutions [77]. The advantage of versatility comes at a price with the emergence of issues with control, adverse event handling and emergency protocols. This requires the fine assessment of surgical robots for safety and performance. It is a historical fact that some of the early ventures acquired clearance for their products at times when no clear guidance and practice were in place from the regulatory bodies. Clearance shall be a fair process, where all existing and future products adhere to the same requirements.

The widening adoption of service robots in the surgical domain also increases the incidence of malfunctions, potential injuries and damage. As a consequence, litigation fears are escalating for companies developing new types of robots Parallel, urgency is growing to have international safety standards published to allow new robots to get certified in a transparent way to operate in complex, real-world scenarios.

The market has well understood the need for rigorous development methods and stringent testing. Representing this, the funding of the surgical robotics projects has risen significantly (to the extremes of Auris Health, which collected $733 million venture capital money for development and early sales).

It is remarkable that over 1 m RAMIS interventions were performed in 2018, yet this is still a fraction of the global annual 300 m surgeries. The rise of robotic MD training is obviously leading to the wider spread of robotic procedures, and will eventually resolve currently existing resistance among surgeons [78]. Given the popularity of open source initiatives (such as ROS-Industrial)[1] software development pathways have become streamlined, successful FDA clearances have been backed by toolkits such as 3D Slicer[2] and PLUS [79].

Transparency of the domain would help the acceleration of technology transfer, the rise of new, alternative surgical robots and the moderation of costs. The proposed categorization of LoA would enable to clearly distinguish the surgical robotic system based on their autonomous capabilities—and the inherent hazard that presents. With the anticipated revision of the FDA 510(k) procedure and the new Medical Device Regulation (MDR) in Europe from 2020, regulatory bodies are willing to establish some standards for the new, complex systems entering the medical device market. Information sharing and post-market surveillance will be cornerstones of the MDR, bringing more transparency through access to information.

Nevertheless, technology readiness is still only a fraction of the complete domain automation challenge, since surgical training, skill assessment and benchmarking need to develop a lot to match the level of technical advancement [80].

VII. Conclusion

Despite the tremendous development in medical imaging, image guidance, advanced robot control and human–machine

[1]https://rosindustrial.org/
[2]https://www.slicer.org/

interfacing, the global research community has not reached to the point to significantly alter the traditional manual way surgery is done today at most parts of the world. Main reasons for that can be found in economics (high capital and operation expenses), societal challenges (limited acceptance from the patients and the surgeons) and regulatory issues (complexity of clearance procedures). Directly or indirectly, international standards can foster the adoption of CIS technologies through offering transparent processes, increasing acceptance and accountability. This is especially true in the rising domain of autonomous surgical robots, which need benchmarks and safety protocols along their pathway to wider adaption.

This article presented some key features regarding autonomous functions of surgical robots, introducing the latest trends in development. Also, an insider's view was provided to the emerging surgical robot standards, hoping to assist the upcoming systems' developers. A key aspect of system assessment is the classification of the autonomous capabilities, for which the concept of Degree of Autonomy and Level of Autonomy were introduced in a practical way, disambiguating the prior alternatives.

Humans will be able to benefit from the advantages of autonomous medical systems in the long term. The upcoming standards and test protocols should put emphasis on the unambiguous evaluation and categorization of these systems.

DISCLOSURE

T. Haidegger has no conflicts of interest or financial ties to disclose.

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