Scaling the Autonomy of Surgical Robots *

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***Abstract*—Computer-Integrated Surgery (CIS) has been around for almost three decades, covering the entire field of interventional technologies, from medical image guidance and augmented reality applications to automated tissue ablation. Numerous CIS systems are already on the market, adding technology-supported quality to the standard of care. Furthermore, a real breakthrough in medical robotics is just around the corner, yet there is practically no safety regulatory framework developed for them. The first surgical robot standards are just now becoming effective after many years of development, setting the concept of autonomy, and the assessment of autonomous functions into the center system of evaluation. New, community-level consensus should be reached regarding the scaling of surgical robot autonomy to facilitate product qualification, regulatory procedures and future product development.**

I. Introduction

Automation and robotics have changed manufacturing, and now are transforming medicine. The first surgical robot applications appeared over 25 years ago, and since then, hundreds of different prototypes have been developed [1]. These all have used alternative clearance pathways, trying to be matched against existing technologies (especially in the US FDA 510(k) procedure). Now, the market is growing steadily, and there is a strong urge from the governments to better regulate this domain as well [2]. The importance of standardization had become paramount in the medical domain, since that is the only way to increase safety systematically—through standardized testing requirements and protocols. A first step towards this is the standardized assessment of robot capabilities, primarily focusing on their autonomous functions. The very first *International Organization for Standardization* (ISO) and the *International Electrotechnical Commission* (IEC) joint standardization document (*IEC/TR 60601-4-1*) addressing the problem of autonomy in medical robotics just appeared, and practical methods for robot categorization are also on the horizon.

II. Existing Medical Robot 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 tasks", and a service robot being a "robot that performs useful tasks for humans or equipment excluding industrial automation applications", by which da Vinci-type robots are inherently excluded, since they do not present autonomy, only teleoperated features. (Surgical robot manufacturers exploited this point to avoid compliance with any robotic standard). 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". Other CIS products are typically regulated by particular standards within the IEC 60601 standards family. In the case of robots, this includes all kinds of systems from psychological rehabilitation to natural orifice surgery. The diversity of functions and appearance make the regulation, standardization of the domain extremely difficult.

While classical mechanical and electrical hazards are well covered, there is a gap in the ISO/IEC standards regarding surgical robots, given the historically industrial manipulator-oriented context of the existing standards. 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.

III. New Standard for Autonomy in CIS

When the ISO/IEC TC working group thoroughly analyzed the current situation of surgical robot standardization, roughly eight years ago, the only major gap identified was the *Degree of Autonomy* (DoA): introduced in ISO 8373, yet not properly defined. Understanding the fact that the proper definition of autonomy and its conjugated forms "autonomous", "automation", or related definitions can be unambiguous, yet are key to standardize different surgical platforms, the ISO/IEC joint working group decided to extend the scope of their work to all CIS devices, i.e., 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 the brand 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*. This document defined DoA as "taxonomy based on the properties and capabilities of the MEE or MES related to AUTONOMY", and gave some examples, how to calculate it. A method for the classification of DOA can be formulated based on an industrial robotic template, first proposed by Kaber and Endsley in 2004 [3]. By parametrizing DoA along four cognition-related functions of a system, which are affecting capabilities of an MES to *Generate, Execute, Monitor* and *Select* an option related to a robot task. Each of these functions can be driven 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 full system. DoA can vary from low to high, with zero meaning "no autonomy", at least on the system level, excluding low level electronic and

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computational functions of the MEE (such as motor control, kinematics calculations).

IV. New Standard for Surgical Robots

The ISO/IEC TC 62/SC 62D joint committee worked to provide a practical degree of safety for surgical robots, resulting in a brand new standard to be published next year (*IEC/CD 80601-2-77: Medical electrical equipment -- Part 2-77: Particular requirements for the basic safety and essential performance of medical robots for surgery*). It defines the basic different types of surgical robots and tools, and identifies integrated components. The standard collects all relevant mechanical and thermal hazards, along with the fault conditions of the equipment and the required usability trials. This will help manufacturers in the future to classify and benchmark their systems. This is especially welcomed, since the numerous clinical procedures targeted with robots require completely different assessment approaches and test cases.

V. Level of Autonomy of Surgical Robots

Parallel to the mainstream standardization efforts, yet fitting to the commonly used terms, the Level of Autonomy (LoA) taxonomy was proposed recently [4]. While it employs terms and conditions much more aligned to the common language, it is believed that with a little modification, the scale can be made compatible with the IEC 80601-2-77 (Fig. 1). The interpretation of the levels is the following:

- **LoA 0 – No autonomy:** all the system-level functions (generating, selecting, executing and monitoring actions) are performed by the human operator;
- **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
- **LoA 3 – Supervised autonomy:** the system can complete large section of the surgical procedure autonomously, 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 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.

VI. Conclusion

Assessment of medical robot capabilities is of great importance. Once existing and new systems (independent from their platform) are scaled along their DoA and LoA, this will create a basis for objective comparison of functions and capabilities. As a next step, the standardization bodies are looking into developing complete test cases and scenarios for practical benchmarking. It is believed that the near future of medical robotics largely lies in cooperatively controlled systems, where robots and humans share the control, to exploit advantages of both. 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 evaluation and categorization of these systems.

References

[1] A. Takacs, D.A. Nagy, I.J. Rudas and T. Haidegger, Origins of Surgical Robotics: From Space to the Operating Room, Acta Polytechnica Hungarica vol. 13, no. 1, pp. 13–30, 2016.

[2] T. Haidegger and I. Rudas "From Concept to Market: Surgical Robot Development," ch. 10. in M. Habib, Handbook on Research in Robotics and Mechatronics, IGI Global, Hershey, PA. ISBN: 978-146-66-7387-8, pp. 242–283, 2015.

[3] D.B. Kaber and M.R. Endsley, The effects of level of automation and adaptive automation on human performance, situation awareness and workload in a dynamic control task; Theor. Issues in Ergon. Sci., vol. 5(2), pp. 113–153, 2004.

[4] G-Z. Yang et al. Medical robotics—Regulatory, ethical, and legal considerations for increasing levels of autonomy, in Science Robotics, (2017): eaam8638.

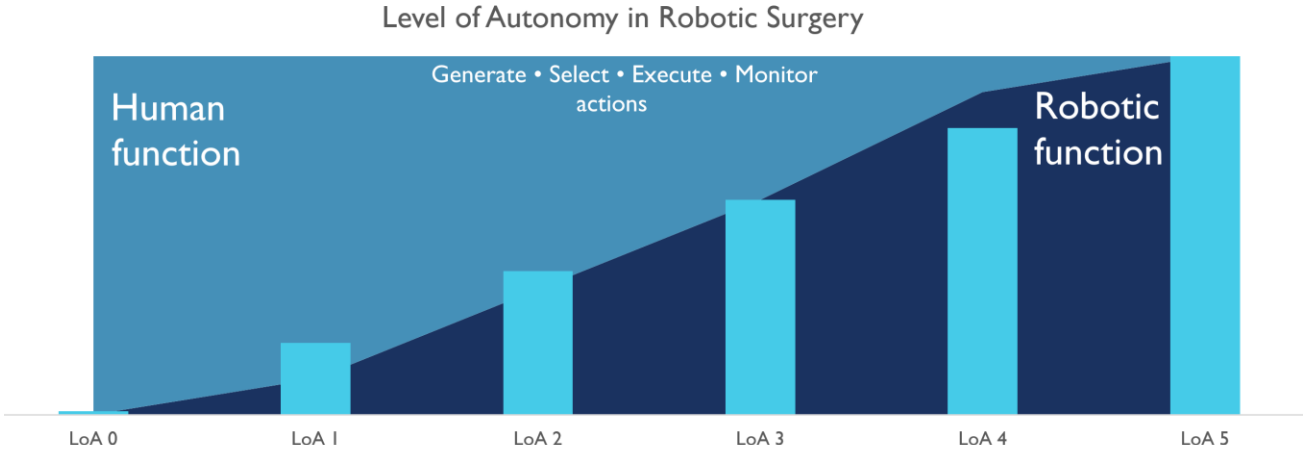

Figure 1 The 6 Levels of Autonomy aligned to the current ISO/IEC robot standard nomenclature. LoA 0 represents no function-level autonomy at all, LoA 5 means complete, unconditional autonomy under all conditions (similar to that of self-driving cars).