

Robot-Assisted Minimally Invasive Surgery—Surgical Robotics in the Data Age

This article summarizes the state of the art in robot-assisted minimally invasive surgery and provides an overview of key emerging technologies associated with next-generation systems.

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ABSTRACT | Telesurgical robotics, as a technical solution for robot-assisted minimally invasive surgery (RAMIS), has become the first domain within medicosurgical robotics that achieved a true global clinical adoption. Its relative success (still at a low single-digit percentile total market penetration) roots in the particular human-in-the-loop control, in which the trained surgeon is always kept responsible for the clinical outcome achieved by the robot-actuated invasive tools. Nowadays, this paradigm is challenged by the need for improved surgical performance, traceability, and safety reaching beyond the human capabilities. Partially due to the technical complexity and the financial burden, the adoption of telesurgical robotics has not reached its full potential, by far. Apart from the absolutely market-dominating da Vinci surgical

system, there are already 60+ emerging RAMIS robot types, out of which 15 have already achieved some form of regulatory clearance. This article aims to connect the technological advancement with the principles of commercialization, particularly looking at engineering components that are under development and have the potential to bring significant advantages to the clinical practice. Current RAMIS robots often do not exceed the functionalities deriving from their mechatronics, due to the lack of data-driven assistance and smart human-machine collaboration. Computer assistance is gradually gaining more significance within emerging RAMIS systems. Enhanced manipulation capabilities, refined sensors, advanced vision, task-level automation, smart safety features, and data integration mark together the inception of a new era in telesurgical robotics, infiltrated by machine learning (ML) and artificial intelligence (AI) solutions. Observing other domains, it is definite that a key requirement of a robust AI is the good quality data, derived from proper data acquisition and sharing to allow building solutions in real time based on ML. Emerging RAMIS technologies are reviewed both in a historical and a future perspective.

KEYWORDS | Remote-controlled teleoperation; robot-assisted minimally invasive surgery (RAMIS); telesurgical robotics.

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NOMENCLATURE

AI	Artificial intelligence.
CAD	Computer-aided design.
CAM	Computer-aided manufacturing.
CE	Conformite Européenne.
CT	Computed tomography.
DVRK	da Vinci Research Kit.
DoF	Degrees of freedom.
FDA	U.S. Food and Drug Administration.
IEC	International Electrotechnical Commission.

ISO	International Organization for Standardization.
MEE/MES	Medical electrical equipment/system.
MIS	Minimally invasive surgery.
ML	Machine learning.
MRI	Magnetic resonance imaging.
OR	Operating room.
RAMIS	Robot-assisted minimally invasive surgery.
TRL	Technology readiness level.
US	Ultrasound.

I. INTRODUCTION

Robotic surgery in the common language has become associated with the telerobotic execution of MIS, where the surgeon is physically separated from the patient—typically just a few steps away—and the surgical instruments are under the direct guidance and remote control of a human operator. This clinical approach is named RAMIS, also called robotically assisted or simply robotic MIS. The ergonomic arrangement for such systems is well suited to the modern and increasingly popular paradigm of MIS, performed through keyhole ports, which has replaced many traditionally open surgery procedures, due to the reduced tissue trauma, resulting in direct patient benefits, and offering better ergonomics for the surgeons while introducing numerous technological components for use in the OR [1]. This article focuses on linking the technical capabilities of systems to their clinical applicability, considering the regulatory environment in which they need to perform. Understanding the state of the art shall begin with looking into the current market landscape, where a single product has dominated the last two decades.

RAMIS relies on real-time imaging, using an endoscopic camera, which provides a wide-angle, high-resolution, white-light, video stream as the main sensory feedback from the surgical site. The robotically articulated instruments are maneuvered by the surgeon, through a surgical console, i.e., human-machine interface (HMI), which relies on the video stream. This synergy of the minimally invasive paradigms has been a catalyst for the use of robotic assistance and has grown rapidly over the last decade, as reflected by the annual 1.5 million procedures (with a 15% annual growth) performed using the “da Vinci surgical system” alone (from Intuitive Surgical Inc., Sunnyvale, CA, USA), making it by far the most popular RAMIS system to date [2]. The main factors that contributed to the outstanding success of da Vinci and its telerobotic concept include the followings [3], [4]:

- 1) advanced technology features, including better vision and instrumentation;
- 2) ergonomics and safety (EndoWrist for suturing, tremor filtering, and improved situation awareness);
- 3) strong evidence for improved patient outcome collected over the years;
- 4) targeting procedures, where the quality of life can be improved significantly (prostatectomy, benign hysterectomy, and so on);
- 5) strong training program developed over the years (including simulators);

- 6) no high-level autonomy introduced, therefore the legal responsibility remained with the surgeon;
- 7) massive marketing and promotion;
- 8) solution selling (consumable and service-based business model).

On the healthcare providers’ side, patient benefit has been a driving factor of robotic programs, and over the years, significant clinical evidence emerged supporting various (but not all) application domains, starting with prostatectomy and benign gynecological procedures. Since 1998, over 29 000 peer-reviewed studies have been published on da Vinci surgery alone. Yet, recent studies still leave some key questions open regarding the long-term benefits of MIS versus open surgery in, e.g., in the case of radical hysterectomy [5]. It has to be noted that since separate approval is required for each intended clinical domain of a RAMIS system, the approach and timeline chosen by the manufacturer will fundamentally determine the pathway the system may take [6]. Arguably, there is a strong correlation between costs and the adoption of robotic surgery; in the United States, where healthcare expenditures account to 18% of the gross domestic product (GDP), approximately 5% of all surgeries are performed robotically, while in the European Union (EU), which spends on average 10% of its GDP on healthcare, robotic surgery adoption is only around 2% [7], and adoption remains below 1% in most of the rest of the world. Medtronic assumes that altogether, only 3% of the total addressable market of RAMIS is achieved yet. In parallel, the total market value of surgical robotics was estimated by Frost and Sullivan at \$8.3 billion in 2020, expected to reach \$33.6 billion by 2026 [8].

RAMIS in practice is predominantly represented by remote-controlled leader-follower (formerly called master-slave) robots, used exclusively in the telemanipulation mode, where the surgeon is decoupled from the direct handling of the surgical tools. In the meanwhile, several other classes of surgical or interventional robots are also in clinical use with different architectures [9]. A popular domain of application (excluded from the scope of this article) is where the robotic execution of a predefined surgical plan relies on medical imaging, thus called image-guided interventional robotics (discussed in [10]), while collaborative control is also a popular choice; especially in neuro and orthopedic applications, it is not discussed further in this article. Microsurgical systems and endoluminal robots are also excluded from this analysis, despite the fact that they share a lot with RAMIS in terms of mechatronics, control architecture, and future perspectives (sometimes even the physical platform is shared, as in the case of the da Vinci SP)—these are covered in the article by Dupont *et al.* [11].

Technically, almost all surgical robot systems have a common feature, and they employ a robotic mechanism (robot in the widest sense [12]) to provide accurate guidance, assistance, or direct delivery of instruments or energy. Such systems can focus energy, as in radiotherapy



Fig. 1. Most advanced RAMIS systems, featuring only commercially available, and ready-to-launch platforms, already cleared for at least a limited set of surgical indications (presented in the order of time of appearance). (a) da Vinci Xi. (b) Senhance Surgical Robotic System. (c) Revo-i. (d) Versius. (e) Avatera. (f) Hinotori. (g) Dexter. (h) Symani Surgical System. (i) Toumai Endoscopic Robot. (j) Mantra. (k) Hugo RAS System. (l) Bitrack. Table 1 at the end provides details regarding these robots' basic engineering and clinical capabilities. (Image credit: the manufacturers.)

or high-intensity focused ultrasound (HIFU) treatment for example, or steer needles or other tools. These rely on precise preoperative planning, performed on patient imaging information usually using 3-D modalities such as CT or MRI. We only include in our RAMIS classification full-scale, teleoperational surgical systems, where the end-effector typically does not require continuum robot-like complex (6++) DoFs articulation.

II. HISTORY AND EARLY CHRONICLE

While an exact inventor behind the idea of telerobotic surgery cannot be identified, some early pioneers at the U.S. National Aeronautics and Space Administration (NASA) and the U.S. Department of Defense, Defense Advanced Research Projects Agency (DARPA) laid the foundations of the domain already in the late 1960s, inspired by the remote manipulators employed in nuclear facilities and developed for space [13]–[15]. Given the outstanding commercial success of the first FDA cleared RAMIS system, Intuitive's da Vinci in 2000, it was evident that many other research projects and companies aimed to create their own systems, with little or no deviation

from the da Vinci [16]–[19]. Intuitive overtook its former rival, Computer Motion (Goleta, CA, USA) in 2003, and discontinued their Zeus Robotics Surgical System product line immediately, therefore they remained alone on the U.S. market for 15 years. The lack of direct competitors can partially be explained with Intuitive's outstanding patent portfolio, effectively defending their technology, and also with the fact that many in-house surgical robot developments at the competitors, could not conclude in a product (due to cost, regulatory, and complexity issues) and therefore remained unreported. Only recently, we are seeing a massive wave of novel entrants, looking forward to introduce radical technological changes compared to the past decades' evolutionary development.

III. STATE OF THE ART IN RAMIS

A scoping literature review identified over 65 documented research projects aimed at developing new, complete RAMIS systems, yet only 15 managed to acquire some national clearance and only five achieved sales in more than one country (Fig. 1) [20], [21]. Table 1 includes a list of known, recognized RAMIS systems at the TRL 9+.

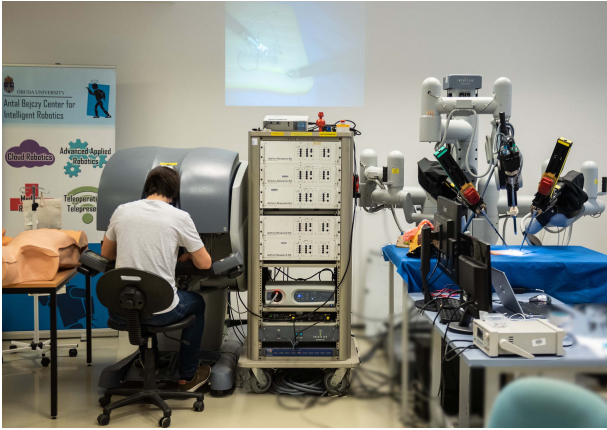


Fig. 2. DVRK at Óbuda University, one of the 40 sites that employs the DVRK as an advanced research platform.

A recent review by Moglia *et al.* [22] covered the types and variations of these systems. Another recent systematic review by Dupont *et al.* [23] pointed out initial efforts on the development of surgical automation and the integration of force sensing into laparoscopic tools as probably the most important upgrade of the past decade, along with the novel robot architectures aiming to reduce procedural invasiveness.

On the research platform side, the most notable recent achievement is arguably the DVRK, an open hardware and software platform created by the Laboratory for Computational Sensing and Robotics (LCSR) at Johns Hopkins, Worcester Polytechnic Institute (WPI) and partners, supported by Intuitive Foundation (<https://www.intuitive-foundation.org/dvrk/>) [24], [25]. More than 40 university groups and research centers are in the program, using retired classic da Vinci surgical systems as repurposed, reassembled research platforms, capable of exploring innovative new concepts in RAMIS (Fig. 2). A recent review by D’Ettorre *et al.* [26] collected the most relevant projects with the platform (Fig. 2).

Current research efforts on the DVRK can be considered as good proxies for RAMIS development directions and can be categorized as follows (Fig. 3):

- 1) hardware implementation and integration;
- 2) system simulation and modeling;
- 3) imaging and vision;
- 4) feature automation;
- 5) training, skill assessment, and gesture recognition.

In most of the identified research topics, access to data with the DVRK is seen as a key enabling factor. Both kinematic and system data derived from the robot, or clinical data acquired through the vision system, are paving the way for the application of data-driven ML methods.

IV. RAMIS IN THE DATA AGE—NEW CAPABILITIES

RAMIS systems inherently provide a great platform for surgical innovation, given the fact that there is a digital data link between the surgeon console and the patient-side

manipulators. While there has been a constant engineering development in all of the core components of RAMIS, i.e., the HMI, the patient-side applied surgical part, and the vision and control systems [27], radically new paradigms are emerging primarily due to the recent capability to use ML and more generic AI methods. AI has the potential to bridge the gap between the current limited application of autonomy and software capabilities already demonstrated in other industries (for example, starting with NLP and real-time annotation of scenes to anomaly detection), by combining robotics and surgical data science (SDS), and thereby, AI methods can improve therapy and patient outcome [28]–[32].

A. Autonomy Classification Framework for RAMIS

Autonomy is probably the most important feature related to the applicability of a robotic system. Medical robotics also started to employ the level of autonomy (LoA) concept (originally proposed for the automotive industry), which helps to identify and compare system functions and capabilities [33]. It builds on the classical model of analyzing tasks and decisions along the generate–model–plan–execute cycle, an overarching autonomy concept from industrial robotics [34] to image-guided interventional systems [35]. The classical surgical CAD/CAM control flowchart is technically applicable even to RAMIS systems—assuming a very high control loop frequency. This means that the fundamental concept that digital information enables accountable, measurable system engineering, and quality management concepts in CIS through medical imaging, image processing, and robotic execution is completely valid in the case of RAMIS as well.

Fig. 4 presents the most recent classification of LoA of surgical robots [36], where current RAMIS systems reside at LoA 1 and LoA 2 at the most. While the standardization experts still argue what degree of autonomy to be considered as a minimum requirement regarding “robots” in general [12], undoubtedly, the direction of development is toward achieving higher LoAs through improved autonomy, driven by a technology push and an economic pull.

Current successful approaches focus on subtask and task-level automation in RAMIS, allowing surgeons to better focus on the critical parts of their procedures [37], [38].

Meanwhile, novel RAMIS research concepts are emerging on the system side, in the form of miniaturization, and complete systems are being downsized for microsurgery, while there are other robot-ensemble and robot swarm prototypes being considered [39].

B. Advanced Communication Strategies’ Influence on Telesurgery

One of the key applications of 5G communication network was thought to be telesurgery (first demonstrated in China in 2019, with the KangDuo-Surgical Robot-01), where the inherent capabilities of the network (high bandwidth, low delay, and high throughput) would enable real-time telesurgery [40], [41]. While telesurgery—up

Table 1 List of Most Advanced RAMIS Systems. Only TRL9+ Robots Are Shown, Which Have Already Achieved Regulatory Clearance in At Least One Country

No	RAMIS System Name	Old name / Legacy	Year	Producer/Manufacturer/Developer	HQ	Website	Capital invested in the dev. phase (public data)	Estimated # units sold
1	da Vinci Surgical System Xi, X	da Vinci S, Si	FDA 2014 (FDA 2000)	Intuitive Surgical Inc.	Sunnyvale, USA	http://www.intuitive.com	\$250 m (1995-2004)	>7000
2	Zeus (defunct 2003)		FDA 2001	Computer Motion Inc.	Gallena, CA	http://www.computer-motion.com	n/a	<50
3	Senhance Surgical Robotic System	ALF-X	FDA 2017 (CE 2011)	Asensus Surgical Inc. (before: TransEnix Surgical Inc., Sofar S.p.A.)	Morrisville, NC	http://www.asensus.com	\$263 m (2013-)	<100
4	X-Surgical	Surgenius	(CE 2012)	X-Surgical (prior: Surgical Robotics S.p.A)	Cambridge, MA (prior: Verona, IT)	http://www.x-surgical.com	n/a	0
5	Revo-i,	Eterne	Korean MFDS 2017	Meere Robot	Seoul, KR	http://www.meerorobot.com	\$38.8 m (2011-)	<20
6	Verius		CE 2019	CMR Surgical (before: Cambridge Medical Robotics)	Cambridge, UK	http://www.cambridgemedical.com	\$ 947.7 m (2016-)	>100
7	avatera		CE 2019	avateramedical	Jena, DE	http://www.avateramedical.com	\$ 203 m (2011-)	<10
8	hinotori		CE 2020 (JP 2019)	Medicardi, Kawasaki Heavy	Kobe, JP	http://www.medicardi.com	n/a	<20
9	Dexter		CE 2020	DistalMotion SA	Loussane, CH	http://www.distalmotion.com	\$ 17m (2011-)	<5
10	Symni Surgical System		CE 2020	MMI microsurgery platform	Calci, IT	http://www.mmirobotics.com	\$ 20m (2015-)	<5
11	Toumai Endoscopic Robot		CFDA (NMPA) 2021	MicroPort Medbot	Shanghai, CN	http://www.microport.com	\$ 512 m (2014-)	0
12	Mantra		India temporary, 2021	SS Innovations (China: Robosurg Pte. Ltd., Singapore: SSI Group Company)	Cambridge, MA, Hangzhou	http://www.ssiinnovations.com	n/a	<10
13	Hugo RAS System	Einstein	CE 2021	Medtronic plc	Dublin, IE	http://www.medtronic.com	n/a	0
14	Bitrack		CE 2022*	Rob Surgical System	Barcelona, ES	http://www.rob-surgical.com	\$ 10 m (2012-)	0
15	Micro Hand S	Micro Hand A	In progress	Nankai Uni. and Tianjin Medical Uni. & General Hospital	Tianjin, CN	http://www.nankai.edu.cn	n/a	0

to the extremes of intercontinental RAMIS had been demonstrated already 20 years ago [42]—5G, 5G+, and 6G may really be needed in terms of bandwidth, data load, and robustness to perform remote surgery when high fidelity, extreme resolution, multimodal information is streamed continuously [43], [44]. Even Intuitive Surgical plans to release a wireless version of the da Vinci by 2023. Edge, fog, and cloud computing technologies will allow to keep the AI-related, computationally intensive processes virtualized, therefore keeping the patient-side system component relatively simple, while there can still be a huge

added value on the quality of data processing provided through the cloud. Nevertheless, the infrastructure to make remote telesurgery a commodity is missing on a global scale, and cybersecurity issues are still unsolved [45], [46]. It can be considered our luck that we have not experienced a massive cyberattack on our healthcare infrastructure, as Western hospitals are becoming massively connected and always online. Unfortunately, there is a significant rise in the recent number of incidences [47], and current RAMIS systems can claim for little or no protection [48].

Level of Autonomy (LoA) in Robotic Surgery

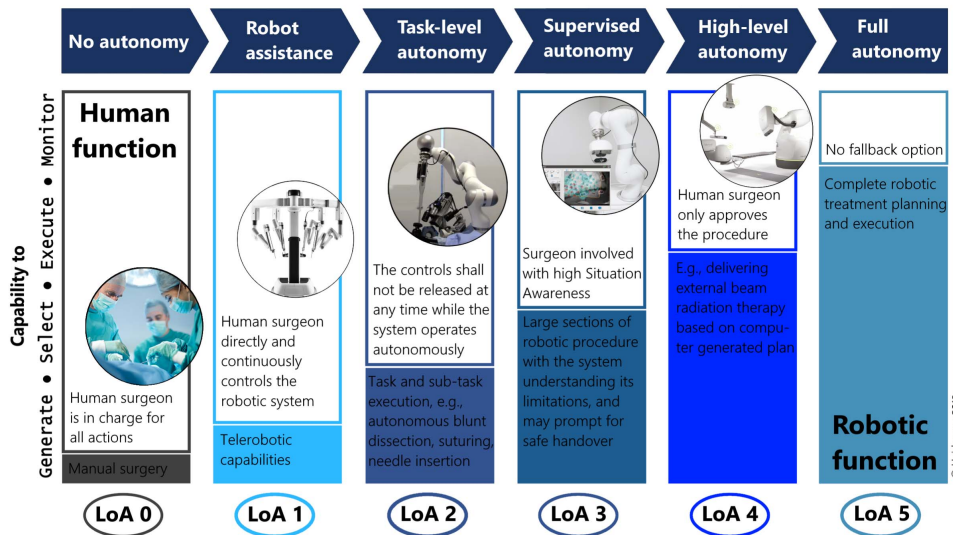


Fig. 4. Concept of LoA classification in RAMIS, where current teleoperational systems reach only LoA 1 typically, providing assistance with basic safety support under remote control [36].

structured light or time-of-flight endoscopic camera, and RAMEN spectroscopy [67]–[71].

Surgeons' vision may also be enhanced via semantic information, and therefore, active research is underway in the community on surgical tool identification and tracking, which may be an efficient tool not only for compensating robot inaccuracies or performing surgical skill assessment but also a necessary safety feature during autonomous task execution, replicating the surgeon's visual feedback loop [72], [73]. Computer vision-based methods are known for identifying the anatomy and providing situation awareness in the environment [74] or to provide accurate surgical phase and workflow reconstruction [75], [76].

Another feature currently not implemented profoundly in clinical RAMIS systems is the ability to sense interaction forces between instruments and tissue and enable a sense of touch through haptic feedback [77]–[79]. This could be an important development allowing fine-tuned surgical actions for instrument manipulation to adapt to various important vibrations, pressure, or texture that have clinical meaning while operating [80]. The technology to upgrade to haptic sensations on the surgeon's console needs both the appropriate sensing in the instrumentation to obtain the relevant signals and the means to relay the senses back to the surgeon, whereas significant complexity, safety, and cost challenges are present today [81].

E. Simulation and Training in RAMIS

It had been recognized that simulation and training are essential to bring surgeons up to standard when using RAMIS systems, and various physical and virtual simulators have been developed to support skill training [82], [83]. The large datasets generated through training sessions have already been fed back

to improve usability and to better understand human capabilities [84]. Skill assessment has seen a tremendous research interest recently, applying classical and ML-based methods to improve outcome prediction [85]. In addition, technologies that could benefit new generations of surgical consoles may enable more sensing and interactive modalities. For example, eye-tracking system could allow an adaptive console to perform functions tailored to specific zones of the surgeons' focus [86].

Nontechnical skill assessment has been recognized as an important contributing factor to patient outcome, yet greatly understudied [87]. At a basic level, simple stress measurements can be introduced via skin dryness sensing, pupillometry, or eye tracking [88], [89], while more complex brain activation sensing systems, such as functional near-infrared spectroscopy (fNIRS), may be able to provide similar adaptation to cognitive processes or to allow the console to detect stress and risk and may monitor surgical skill development [90].

V. TRANSLATIONAL RESEARCH FROM PROTOTYPE TO PRODUCT

In the past 20 years, the success of the da Vinci robot inspired numerous groups and companies to invest into creating their own RAMIS systems. What typically was underestimated is the complexity of a commercial medical device versus a functional laboratory prototype [91]. When system design, safety, and robustness are tested against regulatory requirements, standard laboratory good research practices fall short [92]. Strict regulations apply to Class II and Class III category medical devices, which got much more rigorous in Europe, due to the recent EU Medical Device Regulation (MDR) (EU 2017/745) [93]. The two main standardization bodies, the ISO and the IEC,

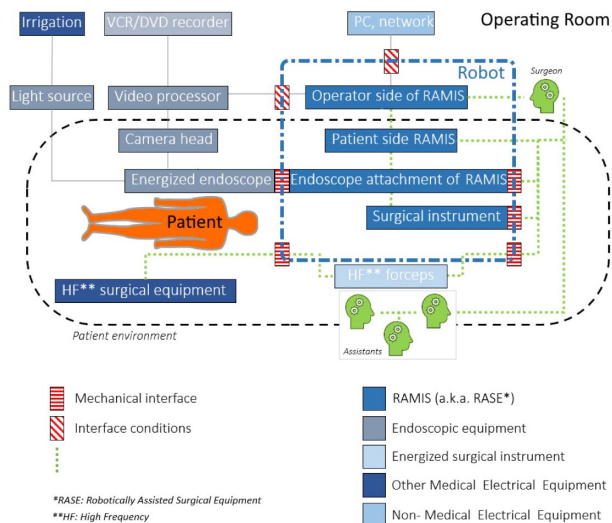


Fig. 5. ISO/IEC standard concept of RAMIS components and interfaces linking the robotic parts to the other medical devices (MEE/MES) in the OR. (Modified from [94].)

have been working on these issues for over a decade. Apart from ISO 13485:2016—Quality management systems and the IEC 60601-1—Medical electrical equipment, general standards of the domain, more specific recommendations appeared recently, in the form of the 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 and the IEC 80601-2-77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment [94]. These new standards bridge the gap between the traditional approach of treating medical devices (i.e., MEE and MES in the standard’s taxonomy) separate from robots (falling under the machinery directives). It has been clearly defined that an MEE/MES can be a robot, while still being regulated as a medical device, with a certain degree of autonomy. This ends the confusion around RAMIS, which are clearly robotic systems, despite the fact that all of the known devices got cleared by FDA in the 510(k) process, providing that they are “substantially equivalent” to something already cleared and existent, such as the da Vinci being an endoscope holder, a “surgical system, computer-controlled instrument.” The standards establish the necessary mappings and correlations between the robotic components and the traditional medical device nomenclature (Fig. 5).

The development and application of ML methods in robot-assisted surgeries require well-defined criteria for validation [95]. In addition, methods that can deal with data heterogeneity as well as sparsity and real-time capability are needed [28]. This requires real-time control and novel communication networks, with a low latency and a high resilience in the OR [96]. Especially in surgical applications, explainability and transparency are important aspects [97], research areas within AI that have just recently gained attention. According to the data-driven research framework for a trustworthy AI (DaRe4TAI) group

[98], [99], a system shall have the properties of the following:

- 1) beneficence;
- 2) non-maleficence;
- 3) autonomy;
- 4) being just;
- 5) explicability.

Dealing with all of the above, the subject of AI governance is actively debated these days, not only the EU and U.S. government bodies are looking for formalized solutions but also a set of emerging standards from ISO and IEC target this domain (including healthcare and robotics among their target application areas), such as follows:

- 1) ISO/IEC CD 23894.2 ISO JTC 1/SC 42/WG 3 Information Technology—Artificial Intelligence—Risk Management;
- 2) ISO/IEC NP TS 8200 Information Technology—Artificial Intelligence—Controllability of Automated Artificial Intelligence Systems;
- 3) ISO/IEC TS 4213: 2021 Information Technology—Artificial Intelligence—Assessment of Machine Learning Classification Performance;
- 4) IEEE 7000-2021—IEEE Model Process for Addressing Ethical Concerns During System Design. Ethically Aligned Design project (<https://ethicsinaction.ieee.org>);
- 5) IEEE 7007-2021—IEEE Ontological Standard for Ethically Driven Robotics and Automation Systems [99].

Most recently, sustainability of robotics has also become a major topic, bringing together experts at the UN level to create recommendations and preferred research practices [100].

Fulfilling the regulatory requirements does cost a significant amount of time and money to the manufacturers. Table 1 presents some publicly disclosed dollar amounts invested into technology development by companies that eventually succeeded. In the current economic environment, new entrants still in the research and development phase should not be underestimated, given their rich resources. Notable funding rounds from the past years include MicroPort MedBot Company (Shanghai, China) with \$512 million venture capital investment, Memic Ltd. (Or Yehuda, Israel) \$127.8 million; Edge Medical Robotics Company (Shanghai, China) \$309.7 million, and Activ Surgical (Boston, MA, USA) with \$84.5 million capital.

Nevertheless, a significant fraction of the development efforts never achieved clinical practice level. Even Verb Surgical had difficulties, and while the mechatronics-wise complete prototype was presented at closed meeting already in 2017 [Fig. 6(a)], their envisioned Surgery 4.0 capabilities were never demonstrated, and the company was sold to J&J at around \$300 million in 2019. Verb later fused their achievements to the development activities of the J&J Ottava robot. Ottava is still two years away from entering the market. Allegedly, it builds on the extended version of Auris’ (now a J&J company)

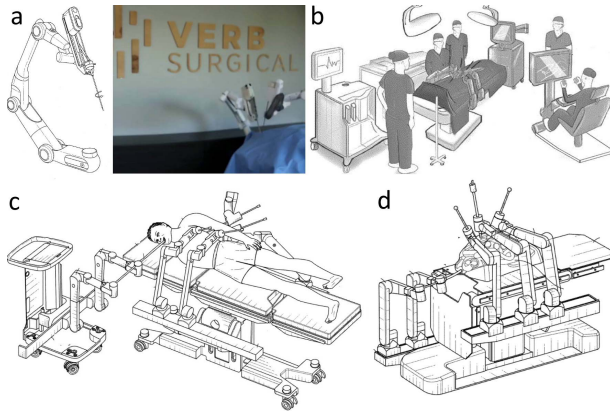


Fig. 6. (a) Engineering design and only visual recording on Verb Surgical's cognitive surgical robot prototype from 2017. (b) J&J Ottawa RAMIS robot concept, sketched in their patent US20180078034A1. (c) and (d) Application schemes of J&J's RAMIS robot concept, built on Auris' Monarch platform, from their patent US20180078440A1.

Monarch system [Fig. 6(b)–(d)]. In the meanwhile, other companies took up the baton, aiming to redefine MIS, such as Vicarious Surgical (Waltham, MA, USA), introducing AI algorithms and extended reality capabilities straight into the surgical workflow [64], [101].

If funds were less available, companies tried to develop more simple approaches, such as a single-arm camera-holding unit [102]. Some of these simplified surgical robotic systems, such as Brainlab's Medineering (Munich, Germany), could also be transferred more easily to a complete RAMIS system, as reported development work is underway (currently CE marked for endoscope holding).

VI. DISCUSSION AND FUTURE PROSPECTS

The development of RAMIS robots requires a significant investment, especially with the rising regulatory requirements all over the world. Clinical and financial success of any new system would likely build on the advanced technological components reviewed in this article. One of the key research questions of the community is how to ensure that AI-driven new features and inherently growing complexity lead to added patient benefit and not compromising system safety. These questions can only be assessed within the overarching frames of the regulatory environment, starting with guidelines, standards, and directives.

The fact that there are over 7000 da Vinci (and few hundred other RAMIS) systems now in daily clinical use shows that this form of surgical robotics is popular among the public, helping in general the rise of new systems via new investments [103].

The volume of RAMIS procedures (over 1.5 million per year) reached a level, where the data collected during surgery have become an asset itself, paving the road for some further technological advancements. Based on large datasets, SDS techniques can be applied to many particular problems and thus improve system capabilities. Recent advances in AI hold promise and perils regarding

robot-assisted surgery [104]. The use of surgical robots is still marginal, current systems are more focused on mechanical enhancements and do step up to the role of a data-driven assistant to the surgeon [101].

Autonomous quality control and safety assurance methods can largely increase the reliability of the systems, primarily through continuous supervision measures in robotics [35], [105]. Therefore, standardization organizations and clearance bodies have been looking into the classification of autonomy from a quality assurance and risk management point of view. The more recent ISO and IEEE standards put system-level safety a priority in surgical robotics as well, aiming to bring in more transparency, accountability, and trustworthiness.

Improving and rethinking the ways energy can be delivered to the tissues will fundamentally change the whole RAMIS concept. Current days RAMIS archetype, the da Vinci is then being a transition system between MIS and non-invasive surgery, providing a suitable hardware and software platform for both. It is already foreseeable that current data-driven ML and AI methods are well applicable to this domain, given the high yield of visual, spatial, tactile, and kinematic data derived from surgeries.

While traditionally, paradigm changes only occurred in a complex domain such as RAMIS over decades, the past two years of the global pandemic situation brought a tremendous gain in robot acceptance, and the rise of public robotic services, along with medical robotics also advanced significantly [106]. As RAMIS is considered to enable contact-less surgery, in the near future, it is a key technology that promises to maintain the volume of elective surgeries, even during a pandemic, while this still would require additional development to replace and automate the scrub nurse [107].

VII. CONCLUSION

RAMIS is the dominant form of surgical robotics as of today, affecting the life of millions of patients. The economic cost/benefit of RAMIS has already been demonstrated for a set of procedures, and some systems are well accepted by the general public. In its present architecture, RAMIS fundamentally builds on a safe human teleoperation control, allowing only minor technical enhancements, such as motion scaling or tremor filtering.

Current research and development trends are largely focusing on the mechatronics and surgical tools, leading to incremental, evolutionary progress. In parallel, the available sensory information is used as a growing dataset for general ML and AI solutions, aimed at improving the cognitive support to the surgeons. On the controller side, the console is a key for better HMI, and it can make the whole robot an information system, eventually changing the human to a computer. Human factors will play an increasing role in improving patient outcome through better understanding, quantifying, and training of technical and nontechnical surgical skills. Besides improving situation awareness and supporting decision-making, AI will

also play a major role in quality assurance, in the evaluation and assessment of procedures, proving systematic data on human and robot-made errors. We are already seeing the rise of alternative concepts of RAMIS robots, yet the regulatory and the safety requirements toward invasive medical devices have been raised significantly recently, making additional research necessary, primarily

on the software side of the systems. The present and future impact of RAMIS cannot be underestimated, yet we need to constrain it along ethical and sustainability considerations.

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