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Rise of the Robots: The robot-assisted orthopaedic surgical revolution

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Insights

- The incorporation of robotics into surgical settings is growing at a rapid rate and will soon become a common feature of surgical units.
- Surgical robots improve the visualization of surgical sites, increase surgical precision, and for various orthopaedic surgical applications, improve patient outcomes and recovery time.
- Machine learning will be used to improve surgical workflows by guiding surgical decision making, improving surgical site visualization, and providing surgical evaluation metrics and training.
- Fully autonomous surgical robots are unlikely to be commercially available in the near future, and instead, automation will be present in the form of a more limited set of automated procedures which support the surgeon during the procedure.
- Virtual and augmented reality will offer new opportunities for surgical training, and will integrate with surgical robots to provide surgeons with information in real-time.
- In the age of COVID-19, the rise of 5G cellular networks will synergize with surgical robots to provide bona fide telesurgery opportunities, especially for rural settings, and further support contactless surgeries.
- Robot-assisted surgeries remain expensive, and this may represent a barrier to their ubiquitous use.

> "Ongoing surgical challenges faced by orthopedic surgeons result from the use of manual instruments causing inconsistency in implant placement and bone removal, the introduction of human error, and less predictable outcomes because of the lack of reproducible accuracy. The surgeon's desire to achieve the best outcome for the patient fueled interest in alternative techniques to achieve this goal." (1)

Robots Rise

As popularized in science fiction stories such as, "I, Robot" (2), robotics has captured the public imagination as a tool that will launch the human race into a technological future. For medicine, the future is near, as robotics is already transforming clinical care. Over the last decade, robot-assisted surgery has seen a meteoric rise, and in the United States (US), and was estimated to have increased from 1.8% of total surgeries in 2012 to 15.1% of total surgeries in 2018 (3). Coinciding with this growth has been a surge in surgical robotics related research, which according to our time trend analysis of the Medline database, has quadrupled in yearly publications over the past decade (Exhibit. 1). Beyond serving as a new tool for enhancing surgical precision, robots provide a platform for surgeons to leverage the latest technological advancements in machine learning, virtual reality, and telecommunications. In this OE Insight we explore the latest innovations for robotics in medicine, and in doing so explore important questions on the role of robotics now and in the future.

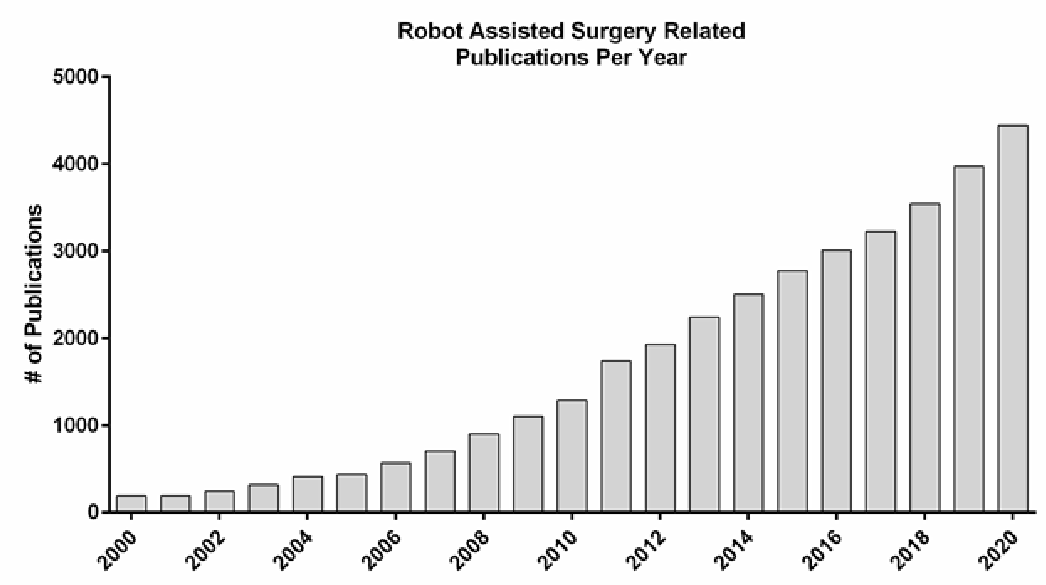

Exhibit. 1: The time-course frequency of publications, available through PubMed, on the subjects of "surgery" and "robot".

"It seems as if every orthopedic device company is getting involved in robot-assisted surgery — rolling out robots to assist surgeons operating on the knee, hip, shoulder or spine." (4)

The Orthopaedic Industry is Betting on Robotic-Assisted Surgery

Exhibit 2: Near market and commercially available surgery assisting robots.

Company	Robot	Application	Production Stage	Capital Investment	Ref.
Intuitive	Da Vinci	General Surgery	Commercially Avaialble	N/A	(1)
Stryker	Mako	Knee and hip surgery	Commercially Avaialble	Acquired Mako for $1.7 billion	(5)
Medtronic	Dmazor X Stealth	Spinal surgery	Commercially Avaialble	Acquired Mazor robotics for $1.7 billion	(6)
Zimmer Biomet	Rosa	Knee and spine surgery	Commercially Avaialble	Acquired Medtech for $132 million	(4)
Smith & Nephew	Navio	Total knee arthroplasty	Commercially Avaialble	Acquired Blue Belt technology for $275 million	(4)
Globus Medical	ExcelsiusGPS	Spinal surgery	Commercially Avaialble	N/A	(4)
Johnson & Johnson	Velys	Knee surgery	Received FDA clearance	Acquired Orthotaxy for an undisclosed amount	(7)
NuVasive	Pulse	Spinal surgery	In development	N/A	(4)

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Driven by the success of the Intuitive da Vinci robot, which by 2019 had reached a market of capitalization of $65 billion on the back of 5300 shipped units, the robot-assisted surgical market has become a growth industry (8). As such, large medical technology companies are taking notice and, as highlighted by Stryker's $1.7 billion acquisition of Mako in 2013, and Medtronic's $1.7 billion purchase of Mazor in 2018, are pushing to develop their own surgical robotics platforms (Exhibit 2). To date, there are atleast 8 major companies offering commercially available, or near market ready surgery assisting robots, and at least 20 start-ups aiming to break into the market (9). Burnishing this explosion of new competition, is a substantial and growing demand for surgical robots. By some pre-COVID-19 estimates, the surgical robotics market will nearly quadruple from 2018 levels to $6.8 billion by 2026. However, reductions to elected surgery due to COVID-19 will likely impact this forecast (8). Nevertheless, the medical technology industry is betting on robot-assisted surgery, and the ascent of surgical robotics is only just beginning.

> “The technological innovations in robotic assistance have allowed surgeons to improve pre-operative planning and its execution at operation, resulting in greater accuracy and precision”(10)

The 3 Categories of Robots

Orthopedic robotic devices can typically be divided into three broad categories: computer-assisted or passive surgical systems, haptic or Robot-Assisted Minimally Invasive Surgical (RAMIS) systems, and autonomous systems. Computer-assisted surgical systems primarily provide the surgeon with computer-guided navigational data that can help to visualize the surgical area peri-operatively. This in turn provides the surgeon with real-time data on the 3D structure of the surgical site, and therein provides significantly more information for guiding surgical decision making (10). RAMIS-type systems typically build off computer-assisted surgical systems by also providing precision-guided robotic instrumentation. In a sense, the robot becomes an extension of the surgeon’s hands. While RAMIS-type systems are ultimately under the control of the physician, they can enhance surgical precision and accuracy by constraining the surgeon’s actions to a predefined plan. This can prevent the surgeon from, for example, placing screws too far away from a target site, or cutting too deeply into bones or tissue (10). Finally, autonomous systems require the surgeon to setup a work-flow, but otherwise perform the surgery independently without aid. Amazingly, the very first surgical robot, the ROBODOC, was fully autonomous, and was first introduced in 1992 to perform femoral side hip arthroplasty. It, however, was not a commercial success (1). While there are examples of fully autonomous robots (11), currently autonomous robots are not widely used clinically, but instead are an intense focus for research.

The recent commercial success for surgical robots, and RAMIS-type surgical robots in particular, can in part be attributed to their capacity to improve surgical workflows and outcomes. For example, a meta-analysis conducted by Agarwal et al. found that for total knee arthroplasty, robot-assisted total knee arthroplasty improved Hospital for Special Surgery scores (HSS), and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores when compared with conventional surgical approaches (12). Robot-assistance in surgery has also been found to significantly increase precision, and reduce the incidence of mechanical misalignment (12,13). However, two meta-analyses of only randomized-control trials conducted by OrthoEvidence suggest that robot-assisted surgeries did not produce significantly different results than conventional surgeries for total hip replacement**(14)**, and total knee replacement **(15)**.
Thus, perhaps the real driver for its adoption is the preference for surgical-robots by surgeons and patients. As outlined by an editorial published in Nature Index, “Surgeons prefer to use the da Vinci robot because it offers improved visualization and hand and wrist flexibility, and they can be seated throughout the 2- to 4-hour procedure” (16). Moreover, robot-assisted surgeries improve patient recovery times and therefore, the overall patient experience – a goal for orthopaedic surgeons (17). Dr. Parsley further sees the rise in robots as a kind of rejection by surgeons of the inefficient procedures, and sometimes unreproducible accuracy introduced through human-error in conventional surgeries (1).

> “The first widespread uses of [artificial intelligence] are likely be in the form of computer-augmentation of human performance.” (18)

Robots that learn

Besides offering improved precision, surgical robots also provide a platform to leverage the burgeoning field of machine learning (ML), which promises to automate and improve surgical workflows. While ML and robotics may convey allusions of a dystopian future, vis-à-vis “The Terminator”, the truth is, such sophisticated examples of general artificial intelligence are unlikely to occur anytime soon. Current applications of ML are much narrower in scope and not so different from the statistical analyses used in routine clinical research.

As it applies to medicine, perhaps the most common application of machine learning is classification analysis - the machine learning equivalent to diagnosing a patient. While classification analysis is by no means the only application for machine learning, it can be used to solve a wide variety of problems. A typical classification problem might be to diagnose osteoporosis based on a set of clinical characteristics (Exhibit 3). More generally, classification analysis can be thought of as a method to predict an outcome from a rigid set of choices, and this can be broadly applied. Even self-driving cars can be thought of as a complex combination of many classification problems, i.e., given a curve in the road, should a car turn left, right, go straight or brake? As it pertains to orthopaedics, common applications of classification-type analysis include diagnosing a fracture from an x-ray, and segmenting pixels indicative of an organ from background noise. While the decision and data that go into such judgements are complex in nature, the machine learning process generally converges to a simple question, given a set of information how do you draw a line to separate data from different categories (Exhibit. 3)? Typically, this line, termed the decision function, is determined by learning patterns present in previously known examples, and once learned can be used to make future predictions. For more information on ML in medicine, see our recent **OE original** (Deep Neural Networks (machine learning) in Healthcare) and **insight** (The Promise of Big Data: Conquering COVID-19 with Data and Intelligence) on the topic.

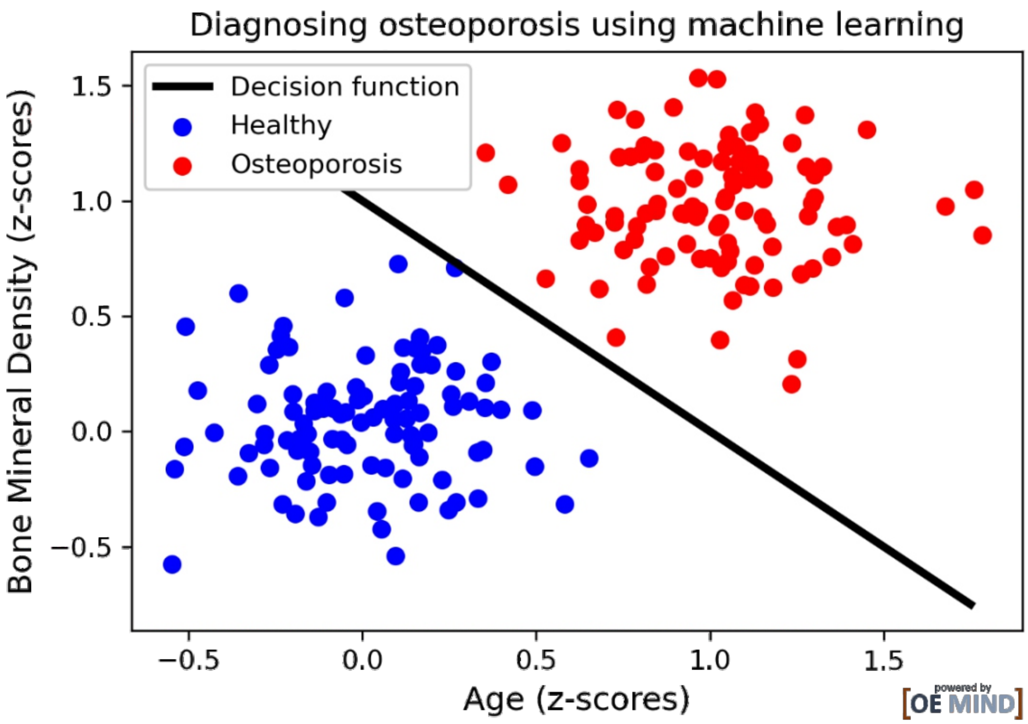

Exhibit. 3: Diagnosing osteoporosis: a generic machine learning classification problem. Given a set of information (i.e., age, and bone mineral density), can we learn the parameters of a function (i.e., the decision function) that can distinguish between two outcomes (i.e., healthy and osteoporosis). Note: this is simulated data.

Using methodologies like classification analysis, ML has been used to enhance the capacity of robot-assisted surgery at almost every level. At the heart of robot assisted surgery is the capacity to visualize the surgical site and therein provide guidance to the surgeon. Current research is focused on how ML can be used to improve the rendering of surgical sites in 3D, or to accurately account for perturbations in the tissue which are introduced throughout surgery. Pre- or intra-operatively, ML may aid surgeons with real-time diagnosis, predicting a patient's prognosis, and making recommendations on next surgical steps (19)(20). Post-operatively, machine learning can be used to track surgeon performance and derive lessons to improve training (21).

> "Despite unpredictable scene changes and soft tissue deformation, complex surgical tasks requiring human dexterity and cognition can be programmed and executed." (11)

Will robots replace surgeons?

Given the rapid rise of machine learning throughout medical research and clinical practice, the unaddressed elephant in the room is whether ML and robotics can and will replace physicians. A common view in the medical literature is that machine learning is not meant to be a replacement but instead, is meant to co-exist with physicians and serve as a new supportive tool. For the most part, there are reasons to believe this sentiment to be true as surgery, and the practice of medicine as a whole, is incredibly complex. Beyond performing a multi-step surgery, which can vary dramatically between patients, any fully autonomous surgical robot would also have to be able to respond to any and every unexpected complication. Besides these technical challenges, there are additional regulatory hurdles which are particularly cumbersome for fully autonomous robots (9). For these reasons, most commercial companies have focused on equipping RAMIC-type systems with simpler, targeted automation capabilities (9). Akin to how many cars are equipped with automatic parallel parking procedures, surgical robots may be equipped with a limited number of autonomous procedures to, for example, drill in pedicle screws once the surgical site is exposed. Under this paradigm, robotic assistance offers clear advantages for improving and expediting surgical workflows, and may even help to reduce surgeon work load, therein potentially improving surgeon quality of life (18). Indeed, many believe the integration of machine learning into surgery is critical for improving patient outcomes, and reducing costs, and is a future that should be actively supported through data scientist-surgeon collaborations (18).

However, if you ask data scientists, the technical challenges surrounding the application of machine learning towards medicine are not insurmountable, and there are no shortage of start-up companies wanting to prove that fact. Indeed, an editorial in the New England Journal of Medicine in 2016 predicted that machine learning will largely replace much of the work performed by radiologists and pathologists in the near future (22). This view is largely echoed by Dr. Geoffrey Hinton, one of the pioneers of neural networks and "godfathers" of ML, who in 2016 declared, "we should stop training radiologists now" (23)(24). While it is true that surgery is significantly more complex than radiographic evaluations, it should not be underestimated how good neural networks are at memorizing behaviours from data. Moreover, the integral ingredient for any machine learning project, data, is likely to soon be in abundant supply. Alongside incorporating machine learning and automation into their workflows, surgical robots are already generating and storing lots of surgical data (21). In fact, there is currently a larger debate occurring in the medical community on how confidentiality rules apply to robot-acquired data, and how, or whether, this data should be regulated (25)(26). Nevertheless, while it is difficult to prognosticate the future of surgery, it seems unlikely that the role of surgeons will be replaced entirely by robotics. However, it does seem likely that there is significant potential for day-to-day operations to change. Whether that future is one decade, two decades, or longer away, only time will tell.

> "In the future, AR may fully replace many items required to perform a successful surgery today, that is, navigation, displays, microscopes, and much more, all in a small wearable piece of equipment." (27)

Entering the Matrix: virtual and augmented reality for robot-assisted surgery

If ML and robotics alone did not stir feelings of living in a science fiction story, surgical robots are also leveraging advances in virtual reality (VR) and augmented reality (AR). In brief, VR uses a headset that immerses its users into a virtually constructed environment that is responsive to the user's actions (Exhibit 4a). VR is analogous to a very advanced Nintendo Wii or Xbox connect, and allows for users to control a fully immersive virtual environment through handheld controllers (Exhibit 4a). By comparison, AR is a less immersive version of VR, and instead of providing a fully virtualized world, layers virtual elements over reality (Exhibit 4b). In this way, AR creates an interface for providing virtual content to users as they navigate everyday life.

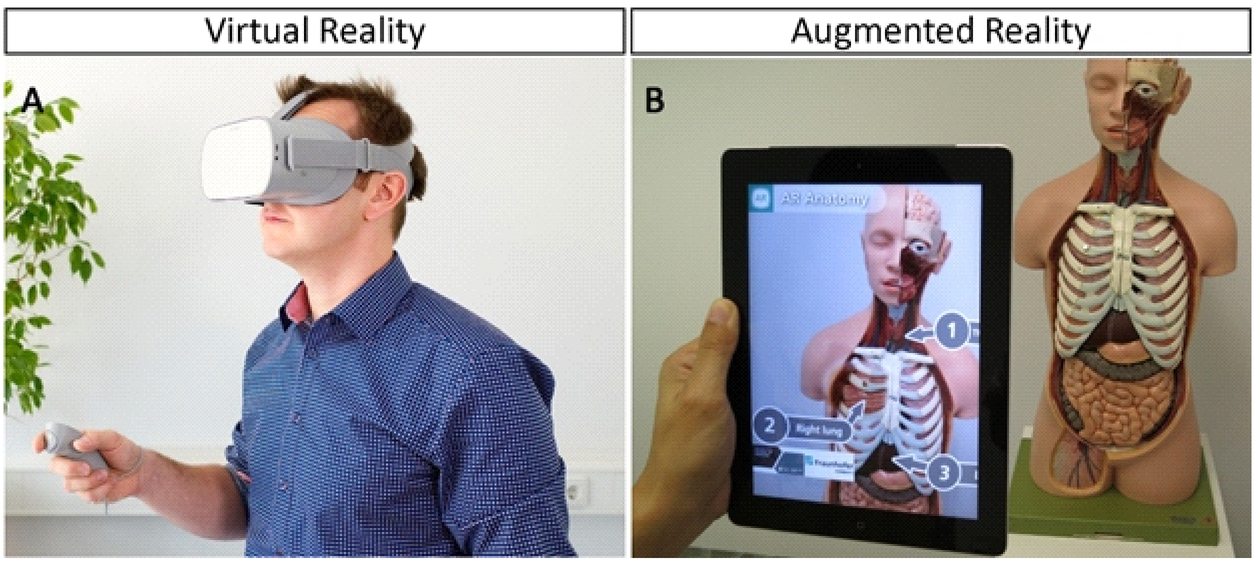

Exhibit. 3: Exhibit 4: Real-world examples of (A) virtual reality, where the user visualizes and controls a virtually constructed world, and (B) augmented reality, where virtual elements are overlaid on top of reality. Images by dlhoner and zedinteractive at Pixabay.com, available at: https://pixabay.com/photos/vr-virtual-reality-glasses-3411378/; and https://pixabay.com/photos/augmented-reality-medical-3d-1957411/.

Primarily, VR has served as an important educational tool both for training surgeons and for informing patients about the surgery. With the increasing complexity associated with surgery, there is concern that surgical residents are not sufficiently trained. A 2017 study found that in the US, an estimated 1 in 3 surgeons could not operate independently after completing their residency (28). To this end, VR provides an opportunity to simulate the surgical environment. This allows for surgeons to preplan and visualize their surgeries before the operation, but also serves as an important learning tool for surgeons in training. As a proof of principle, a recent small randomized controlled trial showed that VR improved training and knowledge retention among medical school students (29). Besides training, VR also provides surgeons with a virtual tool to engage with patients, and allow them to explore the surgery step-by-step. Such interactivity can be particularly advantageous for overcoming language barriers or explaining complex concepts to patients (30).

Whereas VR has primarily seen utility as a training tool, AR may have more wide-reaching applications within surgical robotic systems themselves. By allowing for the overlaying of information onto reality, AR could in real-time be used to virtually outline key surgical sites, provide informational tidbits to remind the surgeon in real-time of their surgical plan, or serve as the visual interface for ML driven surgical recommendations. Nevertheless, like VR, a current leading application for augmented reality is training and mentorship. AR provides the capacity for mentors to oversee and illustrate virtual graphics onto the students' field of view during surgeries. Such technology clearly represents an opportunity to provide more personalized and intuitive education to students, or to more effectively facilitate teamwork in real-time during complicated surgical cases.

> "The breakthrough in surgical robot technology and the 5G network system makes real the practice of telerobotic spinal surgery. It also pushes further the development of "one-to-many" remote clinical patterns." (31)

Telesurgery and the rise of 5G networks during the COVID-19 era.

A key application for robots is to serve as a vehicle for venturing into environments unsafe for human exposure. Likewise, in the age of COVID-19, surgical robots can also be used in this role, and offer several levers for reducing exposure to infectious agents. First, surgical robots themselves create a physical barrier which separates the surgeon from the patient. However, given that any surgery requires a large team of physicians, nurses, and technicians, this alone does not fulfill the requirements for contactless surgery. Besides the robotic automation of various hands-on surgical processes, such as intubation (32), robotics have shown significant promise in their capacity to facilitate remote operations. In combination with augmented and virtual reality, robot-assisted surgeries provide the computer-assisted guidance necessary for surgeries to be monitored in rooms separate from the actual operating room (33). This by itself should serve to reduce the number of personnel in the operating room. However, with the emergence of super fast 5G networks, remotely operated and monitored surgeries are now possible, and this has generated significant promise that telesurgery will soon become a reality.

But first, what is 5G, and why the hype? In brief 5G is a next generation cellular network that promises to increase cellular internet bandwidth by 10 to 100-fold, therein producing download speeds of 1 gigabyte per second or more. For perspective, whereas downloading a full HD movie could take minutes on a regular network, on a 5G network it could instead be accomplished in a few seconds. However, before you rush out and buy a new 5G network phone, it seems current offerings of 5G, at least in the US, may be less than advertised and only offer speeds which are at most 2x greater than current 4G offerings (34). Nevertheless, by promising an order of magnitude larger download speeds, 5G represents the internet infrastructure that will link the ever-growing number of smart devices into a network capable of running complex big-data driven algorithms. For example, imagine a world where we all drove internet connected self-driving cars, a 5G network capable of linking those cars could be used to organize and reduce traffic, or identify emergency situations in real-time.

However, as it pertains to medicine, the major advance afforded by such high download speeds is the capacity to reduce lag time between a controller and a surgical robot, which has been a major impediment towards a seamless remote robotic control. Using 5G networks, lag can be maintained to acceptably small levels (between 0.01s and 0.1s) (31). Moreover, whereas previously such fiber optic cable products could reach similar speeds, remote locations often do not have access to fiber optic infrastructure, and its use in the clinic required large teams of technicians (35). Thus, 5G cellular networks represent a major opportunity to realize the dream of telesurgery. As a general rule, rural settings tend to be underserved and have greater levels of disease burden. Besides a lack of medical infrastructure including operating rooms, there are also a lack of general practitioners and specialists (36). To this end, 5G networks have facilitated bona fide telesurgeries across large distances, to rural locations. Indeed, remotely controlled surgical robots have been used in trials for spinal surgery and have so far proved to be just as effective as control surgeries (31). While fully remote surgeries may be the ultimate goal, as an incremental step, in combination with robotic computer assisted guidance modules, 5G technology has also facilitated the remote supervision of surgeries (37). Thus, rather than flying patients to distant locations to receive highly specialized surgeries, it may instead be possible to perform those surgeries locally under the guidance of non-local experts. This in turn also serves as an important avenue for knowledge transfer, and ensuring the best techniques are available globally.

Despite all it’s challenges, the COVID-19 pandemic has generated important opportunities for revolutionizing the telemedicine infrastructure. To this end, robot-assisted surgical devices will play an important role for conducting surgery contactless and safely, both now, and for future pandemics (33). .

> “Institutions considering the implementation of robotic-assisted systems should anticipate other potential associated costs (e.g., capital investments, maintenance fees, disposable costs, and preoperative imaging requirements) specific to the different platforms.” … “Therefore, in order to remain economically feasible, these costs must be offset by high case volumes and improvements in outcomes.”(38)

Limitations of robot assisted surgery: who is going to pay for it?

As a new technology, robot-assisted surgeries come with a new set of adaptability challenges that surgical units should be aware of and actively address. For example, a recent systematic review found that robotic-assisted surgeries changed the team dynamics in the operating room, as supporting nurses, technicians, and physicians found it difficult to interact with and assist the surgeon (39). Moreover, while the magnitude of the learning curve for performing robot-assisted surgeries is presently unclear (40), it does exist, and it will require time for surgeons and operating rooms to adjust. However, such challenges should hardly preclude the use of surgical robots.

Perhaps the greatest impediment to the ubiquitous use of robot-assisted surgeries are their associated costs. Analyses of the da Vinci robot indicate that instrumentation costs alone average approximately $3500 (41–43), a number which is significantly greater than the hundreds of dollars in instrumentation required for conventional surgeries (43). Further costs are associated with increased operating room times resulting from robot-assisted surgeries (13,41,44). These expenses can be somewhat offset by the fact that patients treated by surgical robots recover quicker and on average spend less time in the hospital (45). However, realizing these savings are further complicated by hospital financial structures, such as silo budgets, where each unit's operating budgets exist independent of each other (46). Consequently, savings due to less hospitalization expenses may not translate to additional funds for the operating room.

But if robot-assisted surgeries purport to improve outcomes, and offer advantages for surgeons and patients alike, why should we care about the costs? Considering that many populations have insufficient access to healthcare, governments, especially in publicly funded healthcare settings, are sensitive to costs. Based on an estimate that robot-assisted radical prostatectomy surgeries were costing an additional $6000 per patient (47), the provincial government of Ontario, Canada, recommended retracting funding to reimburse hospitals and patients. Importantly, more recent analyses contrast this view and have found that after considering long-term patient outcomes, the costs associated with robot-assisted radical prostatectomies are in line with traditional surgical approaches (48). There is further speculation that instrumentation expenses for newer generation devices will be more comparable with conventional surgeries (43).

Nevertheless, there remains significant uncertainty surrounding the cost-effectiveness for robot-assisted surgeries, and this is due to a lack of research. There is particularly a dearth of high-quality randomized-controlled trials comparing the outcomes and cost-effectiveness between robot-assisted surgeries and conventional approaches. Thus, this cautionary tale raises an important point. As explained by Dr. Anthony Adili to the Hamilton Spectator when asked about his first goals after purchasing a new robot for St. Joseph's Hospital in Hamilton, Canada, "We will be trying to assess the economics. Is it cost-effective to use a robot rather than conventional surgery? We will develop a body of evidence."(49) Thus, in spite of all its advantages, robotics in surgery remains expensive, and it is therefore incumbent on the healthcare community to demonstrate its added value.

Final thoughts

Three decades after the first surgical robot was developed, we remain in the early days of the surgical robotics revolution. Currently, surgical robots offer significant improvements to surgical precision, and improve patient recovery. Adding to their capacity to incorporate advancements in machine learning, virtual reality, and 5G networks, surgical robots represent a potentially disruptive technology that will transform surgical practice as we know it. As with any emerging technology, current issues surrounding cost-effectiveness will hopefully resolve with continued technological advancements and economies of scale. Nevertheless, more research is needed on the costs and benefits associated with surgical robots. Altogether, the age of robotics is coming and surgical units should begin now to re-align training practices and establish expertise in order to welcome the incoming era.

Contributors

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