Dr. Robot, Prepare for Surgery
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DR. ROBOT, PREPARE FOR SURGERY
How hospitals and doctors should prepare for the growth of surgical robots.

By Andrew Williams

The use of surgical robots has surged in recent years as a growing number of hospitals and care providers wake up to the vast potential they offer in the delivery of services to patients. Since the initial tentative steps in the late 1980s, the number and variety of devices used in clinical settings has continued to expand - and robots are now deployed for a wide range of surgical applications around the human body.

Estimates vary on the growth and size of the surgical robotics market, but most agree that growth will continue. A July 2019 report by Fortune Business Insights predicts a $1.4 billion market in 2018, expected to reach $6.87 billion by 2026, with a compound annual growth rate of 21.4%. A September 2019 report by Arizton suggests a 17% CAGR between 2018 and 2024 in the “Robotic Surgery Devices Market.” Driving the growth is the growing use of robotic platform in orthopedic surgeries, the development of new investigational robotic surgical devices, and new product approvals and launches, the firm says.

This report takes a closer look at the range of issues associated with deploying a surgical robot in hospitals and other clinical settings, and profiles some of the leading companies and devices in the field. It also shines a light on some of the approaches organizations might adopt when
training surgeons and their support teams in the use of equipment, and outlines some interesting case study examples of how surgical robotics technology is being used. In addition, it considers how key innovations and trends like robots-as-a-service (RaaS) and artificial intelligence (AI) might influence the way in which surgical robots are designed, purchased and used in the coming years.

SURGICAL ROBOTS
HISTORY AND KEY FUNCTIONS
According to *A Short History of Robotic Surgery* - a concise 2018 review of the history of surgical robotics - although observers sometimes differ in their views of what constitutes the first surgical robotic procedure, the majority point to a team of surgeons at the Memorial Medical Center in Long Beach, Calif., which used the Unimation PUMA 560 robotic system to carry out more accurate neurosurgical biopsies in the late 1980s. Following this early breakthrough, two rival systems, the three-armed voice-activated ZEUS platform (the successor of the AESOP system produced by Computer Motion) and the three-to-four-armed da Vinci system (the first FDA-approved robotic surgery system used in general laparoscopic surgery), went on to dominate the field of robotic surgery for at least 10 years - helping to “push back the frontiers of minimally invasive surgery.”

Following the early success of these two devices, dozens of companies emerged in the surgical robotics market – resulting in the creation of a vast array of innovative devices focused on this growing segment of the healthcare sector. These robots are capable of carrying out a wide range of functions, ranging from assisting surgeons in identifying the correct location of incision points, to performing mundane tasks or deploying computer vision to spot important occurrences during surgery. Surgical robots are also proving to be very flexible – and the technology is finding its way into tools that address all parts of the body, from the abdomen, brain, heart, knees and hips, to the spine, eyes, teeth and even hair transplantation.

Broadly speaking, surgical robots can be divided into three key types: active, semi-active and master–slave systems. Although ultimately controlled by surgeons, **Active Systems** are essentially autonomous and capable of carrying out a range of pre-programmed functions.
Semi-active systems are also pre-programmed, but enable surgeons to assume a more hands-on approach to complement the robotic device. Master–slave systems are completely dependent on surgeons, and do not possess any pre-programmed or autonomous functions. Such devices include laparoscopic surgical instruments, which closely reproduce surgeon hand movements while positioned inside the body.

DEPLOYMENT
Deploying surgical robots to provide services to patients represents a significant strategic decision and investment – one that is rarely achieved successfully by simply buying one or two machines and training a couple of surgeons. Installations generally involve a significant upfront investment in equipment to cover the purchase of robots, instrumentation and supplies, as well as the configuration of the operating room and surgical department to optimize the use of devices.

Another key factor to consider is the acquisition and training of a core set of surgeons and surgical teams to deliver the service. Crucially, such specialized staff will require sufficient caseloads to allow them to develop, maintain, and grow their expertise over a period of years - the successful delivery of which will rely on getting the message out to the community and local physicians that such services are available.
One organization at the forefront of surgical robot deployment is the AdventHealth Nicholson Center - the largest training facility in the U.S. not associated with an educational institution, which trains physicians on foundational surgical techniques, including robotic surgery and laparoscopic surgery, using tools like robotic simulators, as well as wet and dry labs. As the center’s CTO, Dr. Roger Smith, explains, Nicholson has hosted, organized or taught robotic surgery programs for Intuitive Surgical, CMR Surgical, TransEnterix, Titan Medical, Medtronic Mazor, Stryker Mako, Corindus, Medrobotics and others - meaning that “no other facility has such broad experience with and exposure to robotic surgical systems.”

“Surgery is not a solved problem,” Smith says, but rather an evolving practice in which humans, technology, and business systems “all work together to deliver a service that does the best that it can to help people with their physical conditions.”

“These services are constantly changing and improving as new technologies are created, new knowledge is acquired, and new business models evolve,” he continued. “The 21st century healthcare system cannot be satisfied to deliver the exact same services that were acceptable in the 20th century. That would be a disservice to the patients who rely on the system for help. Robots are just one part of this evolving ecosystem.”

TRAINING
Following installation, other key deployment steps include efforts to ensure physician and staff acceptance, as well as appropriate training in the use of the surgical robots in a team environment so that each person fully understands the benefits that are yielded from delivering the technology.

The processes involved in training surgeons and staff members in the use of surgical robots are likely to vary depending on a number of factors, including: the clinical setting, the robotic system used and the regulations laid down by organizations like the U.S. Food and Drug Administration (FDA), as well as the established practices and business standards of the
particular area. Even so, Smith reveals that, in general, a four-step model has evolved over the years.

The first step involves introducing the surgeon and team to knowledge about the device, its application, and regulations. This typically begins with web-based courseware that includes reading material, video instruction, animation, photos, and exams. The second step is attending a face-to-face, hands-on course. In addition to including additional knowledge delivery and reinforcement, these courses also focus on providing students with sufficient time to develop the necessary psychomotor skills to use the device. This step entails learning how to operate the robotic system with time on simulators, as well as on the robot itself, and guides students from simple to more complex skills as they demonstrate competency and their proficiency is measured.

“Our lab team travelled to an existing program and were able to observe the system in real-time. This allowed us to understand the implications for a successful program,” says Dr. Ron McKechnie, managing director at the Chesapeake Regional Medical Center, which hosts the first fully robotic vascular hospital in the world.

During the third step, students return to their home hospital and work under an experienced mentor who can observe their skills in real procedures and gradually move them into the most complex portions of a procedure.

“After a given number of cases, this mentor will typically vouch for their competence level and the hospital will allow the new surgeon to use the robot on patients independently. In a final step, the newly practicing surgeon will often seek out an advanced course taught by a leader in their own speciality. At these events they are introduced to techniques as developed and mastered by the leaders in the field,” says Smith.

**MANAGING COSTS**

When it comes to costs, it is difficult to deny that the process of deploying surgical robots can sometimes be an expensive undertaking – with areas such as capital investment, maintenance and training.
One innovative method of managing the capital costs associated with surgical robots is through systems designed to facilitate the more efficient use of existing systems. An interesting example of this approach is the Monarch Platform (see Case Study 1, below), a first-of-its-kind robotic technology cleared by the FDA for diagnostic and therapeutic bronchoscopic procedures.

“As hospitals move to value-based models, it’s important to avoid non-diagnostic procedures and also consolidate procedures, for example diagnosis and staging, where necessary,” says Eric Davidson, Vice President of Sales and Marketing at Auris Health.

Another very interesting way to manage costs is via the use of ‘robots-as-a-service’ (RaaS) systems, an emerging business model in which hospitals lease a device or pay for it on a ‘per-use’ basis, rather than buying it outright, as more commonly been the case in the past. According to Smith, such innovative approaches have the advantage of removing what he describes as the “extremely large up-front investment of capital” and instead accessing the system through annual operating funds that are “directly matched against the revenue generated by volume of procedures.”

“This would make these services more accessible to smaller healthcare systems in the USA and to nationalized systems like those in Europe,” he adds.

Some Leading Surgical Robotics Companies

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<td>Versius laparoscopic robot - capable of performing gynaecology, urology, colorectal and general surgery</td>
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<td>Corindus Vascular Robotics**</td>
<td><a href="https://www.corindus.com">https://www.corindus.com</a></td>
<td>U.S.</td>
<td>CorPath System - described as the ‘first remote telerobotic interventional platform’</td>
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CASE STUDY 1 - FIRST IN-HUMAN STUDY OF MONARCH PLATFORM

During May 2019, Redwood City, Calif.-based outfit Auris Health (part of Johnson & Johnson Medical Devices Companies) announced the interim results of the BENEFIT project, the first in-human study using the Monarch system, an innovative robotic endoscopic platform that aims to enhance physicians’ capabilities and dramatically improve clinical outcomes for patients by accessing and treating disease through the body’s natural openings.

The BENEFIT study is a multi-center, prospective, single-arm pilot and feasibility study to evaluate the safety and feasibility of performing robotic-assisted bronchoscopy in consecutive patients with lung nodules referred for...
bronchoscopic biopsy. Following a total of 82 procedures using the Monarch Platform between June and October 2018 at the University of Chicago Medicine, University of Pittsburgh Medical Center (UPMC) Hamot, and Fox Chase Cancer Center, the system has been shown to successfully overcome the reach limitations of conventional bronchoscopic systems - and achieve the “successful localization” of lung nodules in 92% of cases.

In basic terms, the Monarch Platform works by integrating endoscopes, instruments, navigation and robotics into one easy-to-use platform, allowing physicians to possess a full suite of capabilities when carrying out endoscopic intervention. As Eric Davidson, vice president of sales and marketing at Auris, explains, the platform is designed to increase what he describes as “diagnostic yield” by virtue of its ability to reach and access lesions that are located far out in the periphery, and by more accurate targeting during the biopsy.

“It is also easy to use, especially when compared to other medical robotic systems,” says Davidson. “However, like any new technology, the platform requires training, for which Auris has designed a robust physician and staff training curriculum. Our first training center is located at our headquarters in Redwood City, California. We are also exploring expanding to other training center locations this year.”

Davidson added that Auris is now “moving rapidly from limited launch into full commercialization” of the Monarch Platform, which is already in use in several centers across the U.S. with more installs slated for the remainder of 2019.

CASE STUDY 2 - WORLD’S FIRST ROBOTIC VASCULAR HOSPITAL

Another organization at the forefront of surgical robot deployment is the Chesapeake Regional Medical Center, which during May 2019, announced the successful deployment of Corindus CorPath GRX Vascular Robotic Systems in both of its catheterization labs - in the process becoming the
first ever hospital to equip all its vascular intervention treatment rooms with vascular robotic systems. As Dr. Ron McKechnie, managing director at the center, explains, the installation was prompted by the administration’s desire to couple its interests with its physicians’ desire to provide optimum patient outcomes, while reducing intraprocedural risks to the physician.

“We felt that offering this technology in all of our cardiovascular catheterization labs was of utmost importance, as opposed to just providing it in a single room where access would have otherwise been limited,” McKechnie says.

According to McKechnie, the robotic technology offers precision while focusing on the best patient results, and allows the physician to distance themselves from the radiation source and physical burden of wearing lead aprons. Each of the center’s resident cardiologists underwent simulation-training with the robotic product, as well as an educational session to understand the technology.

“The simulator offered endless hours of practice until the physician was comfortable with its use,” says McKechnie. “The skills necessary to use the robot are translatable from their prior interventional experience. The catheterization lab staff had similar access to the equipment and simulator, and were able to practice with the device. The key step is to develop a team approach to implementation of the robot - with simultaneous interactions of your physicians and cath lab staff.”
McKechnie says the initial costs included those incurred for the robotic arms, as well as the individual costs of the robotic cassette for each case – with success measured through “reduction of exposure to radiation, successful patient outcomes and similar procedural times compared to historic interventional times.”

“We expect that we will continue to use the robot with a higher percentage of cases, even in the setting of acute interventional cases. Our goal is to continue to push physician radiation safety while holding the line for patient outcomes,” says McKechnie.

“Extending the robotic technology into rural areas may also offer the ability to deliver care to patients who otherwise may not have timely access to reperfusion therapy. Physician interaction will always serve as the decision-making aspect in clinical care, but it will extend their ability to deliver their knowledge in a worldwide fashion,” he adds.

CASE STUDY 3 - SURGERY ON THE MOVE

Following the success of two different generations of surgical robots Cambridge, Mass.-based company XSurgical is now devoting its attention to the development of a third generation, known as the Gamma. As well as being capable of operating in typical hospital environments, Gianluca De Novi, CEO at XSurgical, reveals that the new generation includes a number of novel features and is also designed to be deployed in what he refers to as “critical environments, such as war zones, areas affected by disasters and third world countries.”

A key feature of the Gamma is that it can be easily transported and installed and operate in small containers, truck trailers and camp hospitals. According to De Novi, it can also work with virtually any different type of power source and “employs AI to make the communication more reliable and efficient.”

“In our case, the steps involved in the deployment of a surgical robot, depend on the particular environment, as well as on whatever undertakings are necessary to make the system reliable in that environment,” he says. “We
are not talking about mobile environments, but environments that might lack reliable power sources or have a high level of moisture or temperature and so on.”

For De Novi, the key benefit of working with the Gamma system is the fact that it can be used to provide a “very effective technology where no one else wants to go, but ironically where certain types of patients really need them.” This is particularly important because the system can “improve the outcome of many types of conditions especially when used within the first hour from the occurrence of an injury.”

In contrast to many existing robotic systems, De Novi explains that the Gamma can also perform minimal invasive surgery and open surgery in critical environments, helping to improve options and outcomes for casualties. To illustrate this point, he points out that this could equip governments and armed forces coordinators with the ability to provide the “best possible care on the battlefield, which would result in a dramatic reduction of costs for the follow up care for veterans.”

“Our mission is to deliver a fully autonomous surgical robot in the future. Today we are still far from that goal but we are on that path and gradually we will be embedding more and more AI into our systems,” he adds.

WHAT DOES THE FUTURE HOLD?
Looking ahead, De Novi says he believes the future is looking “pretty bright” for surgical robotics, especially as the technologies and robots continue to
integrate AI capabilities and become “smarter and more autonomous”. He predicts it is likely that other technologies, such as augmented reality and data fusion from imaging datasets, will also be integrated.

“The more the market is populated by competitors the more the new technologies will penetrate in the attempt to differentiate and enhance the different products. From our end, the integration of AI is a mission so we will be investing a lot of effort in it,” he says. “Especially if we want to get on Mars, we need a fully autonomous platform. If no one else will go there then we will be the pioneers and lead the way,” he adds.

As the robust level of technology continues to push the limits of robotic units, McKechnie also stresses that software updates, as well as periodically mandated system updates, will always be necessary to ensure that clinical teams deliver the most relevant options to patients. He and his team also suspect that artificial intelligence will “someday permit delivering an interventional device down a coronary artery through input of point A to point B along the architecture of a stenotic lesion.”

Ultimately, in much the same way that the number of specialized laparoscopic instruments grew from their initial introduction in the 1980s to the present, Smith predicts that the same expansion and specialization will happen with robotic devices. Today, most people imagine a surgical robot as a very large, very expensive piece of equipment, but several companies are also already working on robotically assisted tools that are hand-held or miniaturized, or even incorporate AR and virtual reality (VR).

Against a background of growing media speculation about the role of AI in next-generation surgical robotics systems, Smith also stresses that intelligent assistance and a greater understanding of the surgical procedure by the robot is ‘definitely coming to this field.’

Interesting examples include orthopedic robots like those created by Medtronic Mazor and Stryker (via its Mako system), which use imagery of the patient to assist in guiding the actions of the surgeons. Although, strictly speaking, such systems are not ‘fully’ AI, Smith believes they still point to the advantages that can accrue when the robot ‘knows something about what the human surgeon is doing.’ Smith also expects to see more systems featuring built-in navigation, enabling robots to know where they are with respect to patients and their anatomy.

“When coupled with intelligent computer vision, this knowledge is the beginning of enabling the robot to highlight specific anatomy in the body,
provide recommendations on which tools to use, insert warnings around areas that should not be touched, and perhaps suggest the most effective path that has been used by previous surgeons,” says Smith.

“In science fiction we have envisioned robots that perform surgery on their own. That may be a long time coming, but teaching the machine more details about what it is doing is a necessary first step for this kind of AI to come into play,” he adds.

ROBOTS NOT ALWAYS THE ANSWER FOR ALL PROCEDURES, DOCTOR SAYS

The rush towards surgical robots to perform every procedure could make healthcare costs rise compared with alternatives in certain specialties, doctor tells Robotics Business Review.

By Keith Shaw

As more surgical robotics systems get developed to treat different procedures around the human body, at least one doctor is suggesting that robotics is not a cure-all approach when it comes to some of those procedures.

Robotics Business Review chatted with Dr. Paul MacKoul, co-founder of the Center for Innovative GYN Care (CIGC), about the rise of robotics in surgeries, and whether patients are being pressured into choosing robotic surgery when other options are available.

Dr. MacKoul and Dr. Natalya Danilyants, another co-founder of CIGC, recently presented an analysis that showed laparoscopic-assisted myomectomy (LAM) was just as effective as open surgery or robotic procedures.

“It is CIGC’s mission as an innovative gynecological surgical practice to provide access to these types of treatments for as many women in

Dr. Paul MacKoul
need as possible and equip patients with the knowledge to help them make the best gynecological decisions for themselves,” said Dr. Louise van der DOES, director of research and public policy at CIGC. “Many women continue to undergo open surgery or costly robotic procedures despite clear evidence showing that minimally invasive procedures ... provide better outcomes and quality of life after surgery.

Q: Are you seeing more and more companies trying to get doctors to use robotic systems for other procedures?

MacKoul: The way that [robotics companies] market their products, they usually go for those physicians, first of all, who aren’t all that well-versed in surgery. Then they move towards other positions in different surgical specialties and see if they can penetrate those specialties with a robotic approach. They actually may, in some cases, save time, complications, and money.

Where I’m coming from as a GYN – GYN is an entirely different specialty because a gynecologist is an obstetrician and gynecologist, so most gynecologists do primarily obstetrics, and surgery becomes a secondary issue in their practice. So they targeted a group of physicians that don’t do a lot of surgery, and was not adopting laparoscopic surgery to any great extent.

I’ll use hysterectomies as an example. If someone had a hysterectomy 10 to 15 years ago, it was mostly open, and then some people were picking up laparoscopy. Now here comes the robot. The robot now provides this option for the OB-GYN to do a procedure using that robot that they otherwise would hve to do open. Now you say to yourself, ‘Gee, that makes a lot of sense. We’re stopping open surgeries and going to robotic surgeries.’

But the problem is that the robotics have a very high cost overrun and the individual who is using it is mostly an obstetrician. In that particular specialty, it’s not 100% surgery at all, it’s only about 20% to 25% surgery.
Q: Are there some additional complications as well?
MacKoul: There have been several articles, including our own, that says the cost of doing robotics is much higher than laparascopy. The problem now is that residents coming out of these OB-GYN programs are learning robotics. You’ve got to realize these residents and OB-GYNs are not surgeons – they do surgery, but then mostly obstetricians. People teaching these techniques are also OB-GYN.

Inherently because of the way medicine is nowadays, if you’ve got a bunch of OB-GYNs doing robotic surgeries and getting hysterectomies done and billing for them and getting paid, it’s going to be difficult for an OB-GYN to drop a robot and send the patient to a laparoscopic fellowship-trained doctor and give up the income and the patient.

Q: Within your specialty, what are the differences between laparoscopic surgery and robotic approaches?
MacKoul: The standard laparoscopic surgery for hysterectomies uses three to four ports or incisions, and are five millimeters in size and generally its belly button and two or three incisions down low. Now a robot is inherently very different, because now you’re placing incisions in the upper abdomen, and you can use anywhere from
three to five or six incisions. The time of the procedure is longer – it takes a lot longer for a robotic surgeon to complete a robotic hysterectomy in general than that same skilled surgeon doing a laparoscopic case.

So there’s a time factor, which is significant for costs. There is the cost of the purchase of the equipment and robots at $1.5 million to $2 million investment, with a couple hundred thousand for maintenance, as well as the disposables that the robot requires. It’s the time and disposables that are increasing the cost of doing those surgeries, which is increasing the cost of medicine in general.

Q: With hysterectomies, for example, are the large majority of them laparoscopic now versus open, or do you still see open surgery?

MacKoul: It’s still 50% open and 50% laparoscopic. About 10 to 15% of the laparoscopic cases, up to 20% may be robotic, but of course robotic is gathering steam, and people are being trained on how to do robotics. So you’re actually changing the dynamic on the cost savings and GYN surgery in a negative way with the robot. Rather than going back to getting into laparoscopy where you’re saving money, you’re inherently including this very expensive device that takes longer to perform surgeries with higher complication rates and you’re increasing the cost and the time to do the procedure. This is not what’s supposed to be happening in a system that is promoting value-based care.

Q: Do you get a sense that patients are finding out more about robotic procedures, and they might be lured into telling their doctor, ‘I want a robot to do this procedure.’?

MacKoul: The OB-GYN still has a great influence on what patients do and where they go. If the OB is going to use a robot for a hysterectomy and the patient has been in their practice for many years, that patient is going to get a robotic surgery. It really depends on the doctor’s ability to say, ‘Well, you know, I’m going to use a robot because I’m comfortable with it, even though it
costs more, and the associated complication rates are higher, I'm still going to use it.' That isn’t fair to the patients, the patient is not getting the best option available.

Would that doctor ever say, 'I'm going to send you to Dr. MacKoul because Dr. MacKoul does it with two ports, and I need five, and Dr. MacKoul's time of the surgery is 40 minutes and mine is two hours, and Dr. MacKoul's complication rates are lower than mine, and I'm going to cost more doing this and you're going to end up paying more on your deductible and co-insurance. But Dr. MacKoul sounds like a better option. I'm going to send that patient to you.' They don’t.

Q: When would there be a good case for robotics within your specialty?

MacKoul: If I had a patient that was out in any part of the country that could get a robot over an open surgery, I think that’s better. But if the doctor has the ability to send the patient to someone else who can do a better job than the robot, that’s even better. But that referral pattern is not happening.

Further, the robots are now being used for some really ridiculous procedures – ovarian cystectomies, a robot for an ovarian cyst; a robot for endometriosis that’s not advanced. There’s no indication to use this very expensive device in all of these procedures, but yet it is.

A gynecologic oncologist that needs to do more intricate node dissections, yes, a robot may be beneficial. We don’t typically need it, but that doesn’t mean other doctors shoulden if there’s a more complex and difficult surgery that may benefit from a robot. I’m not saying it shouldn’t be used in the specialty at all, what I’m saying is that it’s being overused, even to the point of being abused, with an abandonment of the cost issues and time involved.
Q: Do you think this is happening with other specialties beyond the OB-GYN space?

MacKoul: Why do you need a robot to do an appendectomy? Do we need a robot to do a gallbladder and general surgery? Of course you don’t. But there’s a lot of marketing and doctors want patients, and doctors like being coddled, and they like the attention. So you’ll see robotic gallbladders. I just have no rational reason why a robot should be used for a gallbladder, appendix, or hernia repair. There really isn’t the need to place this huge device on a patient with more incisions to get these cases done.

Q: Could it be that there’s not enough awareness about alternatives?

MacKoul: I think patients need to be made more aware, because if the patient gets the right information, they may realize that maybe there is a better alternative than robotics.

For example, one patient comes to me and says, ‘I want that robot to operate on me.’ The patient actually thought the robot would be programmed like they’ve seen on TV to do this surgery, and the doctor doesn’t do anything. The doctor is actually over there at a console sitting down doing the procedure, telling the robot what to do. If the doctor doesn’t know how to do the surgery very well, the robot’s going to follow that command. If the doctor is a great surgeon, the robot will follow that command, so you’re going to get a good result. The result depends on the doctor’s skill, not the robot’s ability to do the surgery.