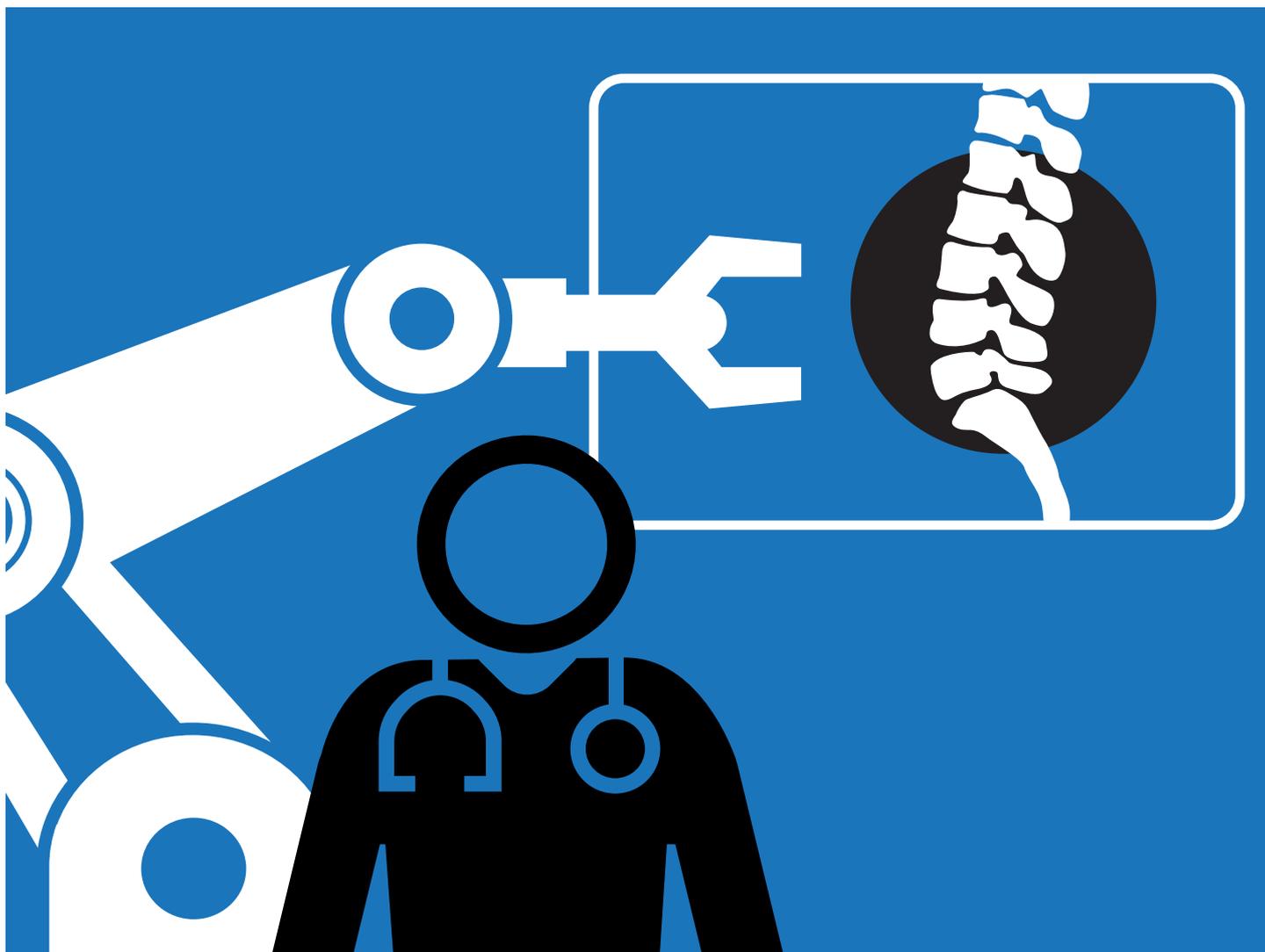
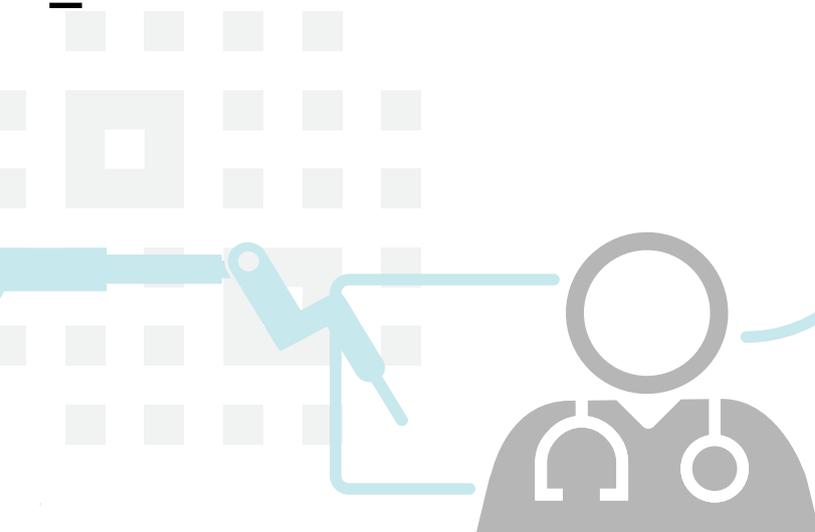

Robot-assisted surgery has the potential to advance health outcomes for patients worldwide. But getting the technology into the hands of surgeons has been a journey.

Robotic surgery gives doctors new savvy





Jeffrey Gum remembers his early-career surgeries with wonder. “We dissected a lot of muscle off the bone,” says Gum, an adult and pediatric spine surgeon at the Norton Leatherman Spine Center in Louisville, Kentucky. That resulted in “more blood loss than we’d prefer and big reconstructive surgeries.” With a traditional, open surgery, a patient could take six months to a year to recover.

At that time, in the early 2010s, Gum was skeptical about the value of robot-assisted surgery (RAS), which promised to widen access to the benefits of minimally invasive procedures – less bleeding and scarring and less recovery time in the hospital. “I felt the technology wasn’t advanced enough to be applied in spine surgery – the nerve roots, the spinal cord right there.”

But in 2017, Gum started to look at RAS, also known as robotic surgery, from a process point of view. He recognized how much in spine surgery is consistent and reproducible; RAS could help streamline his procedures while reducing waste. “This technology is really going to change the shape of our operating room,” he said. “I wanted to be a part of that.”

Using RAS, Gum says his procedures are less traumatic to the body, more precise, and more predictable, and his patients are up and walking much sooner after surgery, compared with traditional, open spine surgery.

Like Gum, surgeons around the world have come to realize that RAS offers many health-care advantages for the future – even though there hasn’t been widespread adoption. That may be changing though, as advancements in technology and design are addressing effectiveness and raising the bar on system intelligence. And several

Key takeaways

- 1 Robot-assisted surgery (RAS), which expands access to benefits of minimally invasive surgery such as less scarring and shorter recovery times, is on the verge of greater adoption worldwide, owing to technological and design advancements.
- 2 RAS augments the expertise of surgical teams and can be used in a number of procedures, from spine surgeries to kidney removal to hip replacement.
- 3 Future applications of RAS include remote surgery, enabling surgeons to operate on patients potentially thousands of miles away, and even autonomous surgery, with no human directing it.

“This technology is really going to change the shape of our operating room. I wanted to be a part of that.”

Jeffrey Gum, Spine Surgeon, Norton Leatherman Spine Center

studies have shown that frequent use of RAS for an expanding number of surgeries could boost its long-term value.^{1,2,3} Looking ahead, remote RAS – with a surgeon operating on a patient potentially thousands of miles away – could lead to wider access to high-quality surgery around the globe.

A revolution decades in the making

RAS is far from new. The first procedure was in 1985 – a neurosurgical biopsy using a PUMA 560 robotic surgical arm. But the US Food and Drug Administration didn't clear an RAS system for use until 2000. Two decades later, the market for RAS still hasn't grown beyond the early adopter phase. Of the more than 50 million soft-tissue surgeries performed in 2018 globally,

less than 2% were robot-assisted, according to Medtronic, a medical technology company. The United States has a higher adoption rate than elsewhere, but RAS still accounted for only 10% of all surgeries in 2018.⁴

RAS has been held back because of the high costs (starting at about \$1 million a unit) and a shortage of trained professionals. But with developments in converging technologies and methodologies, RAS is poised to mature, encouraging wider adoption. Stimuli include advances in assistive navigation, 3D imaging, artificial intelligence, big data, and of course robotics, which is becoming more sophisticated and less expensive.^{5,6} What's more, as with all maturing technologies, the cost of RAS will likely come down as new, more efficient designs are developed, bringing it more in line with the typical cost of non-robotic minimally invasive surgery.

One thing that isn't holding RAS back is patient interest. Perceptions of robotic surgery have been bolstered by movies and TV shows that represent the tools as more advanced than they are. That has fueled patients' positive expectations. Matt Beane, assistant professor in the University of California Santa Barbara's Technology Management Program, studied RAS implementation and training from 2014 to 2018. When interviewing patients, he noted frequent assumptions of "how capable these systems are, and how willing they are to be operated on by a machine."

Some of the most important forces driving adoption are the proven benefits of RAS techniques. Though some RAS can be used for traditional open surgeries, it is generally associated with minimally invasive procedures. That means it involves smaller incisions than traditional open surgery, which results in less blood loss and pain, fewer complications such as infections, reduced procedure time, shorter hospital stays, and quicker recovery.⁷

RAS benefits extend to the hospitals and surgeons. Using robotic systems in procedures such as orthopedic or endovascular surgeries reduces the number of radioscopic images required during an operation and can lead to less radiation exposure for the patient and the operating team. RAS standardizes surgical workflows, "democratizing excellence in these procedures and allowing more and more surgeons to do them," explains David Simon, Medtronic's vice president of research and development for cranial and spine technology.



Data mining RAS

RAS is a treasure trove of data. While the 3D cameras and their captured video exist to guide the surgeon, the data inherent in the images represent an important and powerful byproduct. Digital Surgery is developing algorithms to mine that data. Jean Nehme, who co-founded the technology company with Andre Chow, describes his vision as "combining technologies—robotics, artificial intelligence, and data analytics—to make surgery predictable, repeatable, and remove risk to the patient in real time."

The equivalent of an aircraft's flight recorder will be built into future RAS systems. Over time, as more and more data is captured and cataloged, the accumulated analytics will uncover correlations and patterns for improving surgeons' performance. More than that, it will bank the vast amount of experience embodied in highly skilled surgeons performing thousands of operations. Now, when a surgeon retires, all that experience is lost. Nehme sees using that data to pass on that kind of knowledge to the next generation of surgeons, both human and robotic.

Using RAS in some procedures reduces the number of radioscopic images required during an operation, and that leads to less radiation exposure for the patient and the operating team.

RAS augments surgeons' expertise

Relatively few surgeons are currently trained to use RAS.⁸ But that's not for lack of interest. Robotic surgery is recognized among professionals as an important component of a surgeon's skill set, and one that will enable medical teams to deliver more effective care.

The biggest difference between performing traditional and robot-assisted surgery is the need to master complex computer and robotics skills. For example, when Gum prepares for spine surgery, using a Medtronic RAS system, he creates a computerized patient-specific pre-operative plan, using a computed-tomography (CT) scan of the patient's spine and 3D software. Before entering the operating room, he knows exactly where to make the incisions, as well as the final positions and the precise sizes and types of screws, rods, and other devices to be implanted in the spine. In the future, surgical data collected over time will help determine the effect of planned implants on the functionality and health of the spine before a single incision is made.

In the operating room, a robotic arm is mounted to the bed. Gum's team x-rays the patient on the operating table, and "the software looks at those views, and it aligns the anatomy of the patient asleep to that CT scan," he explains. The RAS stereotactic guidance system – the surgical equivalent of a car's global positioning system – places the arm at the surgical site on the patient, or where the incision will be made. Gum then fits his instruments into a sheath in the arm to guide him as he makes a small incision and inserts the implants.

Benefits of RAS

Robotic surgery extends minimally invasive surgery,⁹ meaning the incisions made in the body are very small. That can have a number of advantages for the patient, including:



By extending minimally invasive surgery, RAS can have benefits for the surgeon as well, allowing:

- 1 **Greater range of motion and dexterity** 
- 2 **Magnified, high-res image of the operating path and site** 
- 3 **Better access to the area being operated on** 

Throughout the operation, Gum can check a screen next to the operating table, so his every move is guided by the navigation software. A 3D camera directs him to the target to enable the placement of implants and devices during the procedure.

Soft-tissue RAS: Alone together

For other robot-assisted operations, such as soft-tissue procedures on organs, surgeons don't do the same kind of

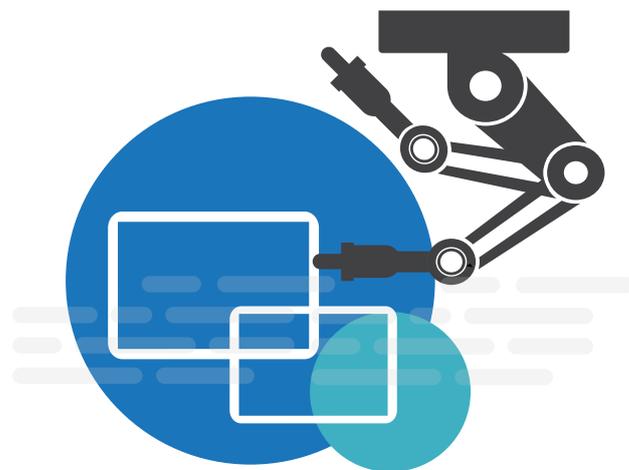
pre-operative visualization and planning as a spine surgeon does, and the operation-room setup is different. The surgeon sits at a console pod, which may be 15 feet away from the patient, while controlling the console's handles and pedals to manipulate the robotic arm and watching the process inside the patient in 3D on the console screen.

Though microphones and speakers provide immediate communication between the surgeon's console pod and the medical team around the operating table, the surgeon is physically isolated – even though the assistants and the patient are often just a few feet away. A screen placed around the console to help curtail reflections and glare spots on the console's monitor can further block the surgeon's view.

Timothy McAleese, a surgical resident in trauma and orthopedics at the Royal College of Surgeons in Ireland, has assisted in soft-tissue RAS procedures. He was usually at the operating table, obeying the disembodied voice of the surgeon at the console and watching the whole procedure on two screens. His role was essentially to assist the RAS system performing the surgery. "You can hear the person in the pod say, 'Can you retract that tissue,' or 'Can you dissect that?'" While McAleese says this kind of isolation didn't affect his concentration or his ability to do his work, it could hamper the traditional dynamics and strengths of surgical teamwork.

Now several companies are building new systems that intend to make the process easier for surgical teams. For instance, Medtronic's mobile soft-tissue RAS platform, now in development, uses an open design that takes the console out of the static pod and puts it on wheels, allowing the surgeon to move freely around the operating table and patient and interact with the medical team – while keeping full control via the screen, handles, and pedals. Since the other components of the system are also mobile, the entire RAS system can be moved to different operating rooms. The system will also be modular, with interchangeable arms so the system can be used for a variety of procedures, such as urological, gynecological, thoracic, colorectal, and general surgery. This flexibility and mobility will increase the value proposition of RAS, because the unit can potentially be used more often.

Over the next few years, similar innovations will alter the look and effectiveness of operating rooms, making it easier for hospitals to acquire, manage, and more fully use RAS.



Technological and design innovations will alter the look and effectiveness of operating rooms, while making it easier for hospitals to acquire, manage, and more fully use RAS.

Remote surgery advances

In 2001, Jacques Marescaux, the founder of the European Institute of Telesurgery at the University of Strasbourg, removed a patient's gallbladder. What set the procedure apart was that the surgeon was in New York, while the patient was thousands of miles away, in France. Marescaux performed the operation by controlling the Zeus RAS system in Strasbourg via a high-speed fiber-optic network.

Remote surgery is a natural evolution of the RAS setup that separates the patient on the operating table from the surgeon sitting at a console. Yet many patients are uncomfortable with the idea of not having their surgeon in the operating room with them. That may be about to change, driven in part by the 2020 coronavirus pandemic. Physical-distancing policies and practices are resulting in wider acceptance of telemedicine, in which doctors and patients confer using teleconferencing software. This familiarity and comfort with the practice, combined with

Training for robotic surgery



Introducing robotics in surgery requires new teaching methodologies. At present, the medical field has no standardized teaching protocols for robot-assisted surgery, and as with any training of residents, each hospital establishes its own requirements for surgeons to be credentialed for RAS. Generally speaking, RAS training involves workshops, hours of working on simulators, sometimes practicing on cadavers, then assisting with live surgeries. Further, digital learning technologies, such as a new mobile app from Digital Surgery, offer supplementary training opportunities alongside hands-on training, and RAS training on the app is currently in development.

In 2018, Matt Beane, of the University of California Santa Barbara, published a study that found RAS training was uneven, and that “the radically different practice of robotic surgery greatly limited trainees’ role in the work, making approved methods ineffective.”¹⁰ Beane found that watching videos of someone performing RAS was a significant component of residents’ studies. But, as Beane says, “You don’t become an actor by watching movies.”

Not all teaching hospitals have access to RAS systems. And even when they do, residents find that getting time for simulation training on an RAS console can be highly competitive. Senior

residents often vie for the privilege, and juniors are usually edged out.

When Timothy McAleese managed to get a slot, he did dexterity and hand-eye coordination drills such as “pick up a grape and put it in a pot, or thread a needle or tie a suture.” The surgical resident at the Royal College of Surgeons in Ireland has assisted in several RAS procedures but hasn’t occupied the surgeon’s console during an operation, because that privilege is reserved for more senior residents.

Other surgical residents, especially at major hospitals, benefit from more robust, structured training in RAS. Also, manufacturers have workshops for established surgeons to learn how to use their systems. Medtronic, for example, has trained approximately 1,200 surgeons on spinal RAS systems.

As with any surgical skill, the more one trains with an RAS system, and the more hours spent doing robot-assisted procedures, the more adept one becomes. McAleese says learning how to technically manage a robot isn’t as important as knowing the patient, understanding human tissue, and having the proven ability to perform the surgery. So until he has a chance at another RAS system, he will keep refining his skills as a surgeon.

“In my grandchildren’s children’s time, we could see robots doing surgery without a doctor driving it in some cases.”

Tracy Accardi, Vice President, Surgical Robotics Research and Development, Medtronic

faster broadband networks, will likely boost acceptance of remote surgery as well.

The vast majority of highly skilled surgeons are in big-city hospitals. To a large extent, that’s because cities’ greater population density affords surgeons more opportunities to refine their skills by practicing a high volume of complex operations in their specialty areas. For patients in small towns and rural areas, these specialist skills are less available, and the travel time to the nearest metropolis can result in lives lost.

Remote surgery makes it possible to bring the surgeon to the patient. It doesn’t matter where the patient is – a rural region of Montana, a community in Africa, or a village in the Andes. When RAS is inexpensive enough for units to be placed in all corners of the world, local physicians and nurses will be trained to use it for simple, routine procedures, and assist remote specialist surgeons on more delicate and complex operations. For emergency situations, it would even be possible to eventually fit RAS-equipped ambulances staffed by paramedics who could work with a remote surgeon.

Is autonomous robotic surgery ahead?

In his 2014-2018 study, Beane found that when patients came in for their surgical consultation, as many as half of them asked, “When will the robot take over?” The answer is not for many years.

“It’s a big leap to get there, and then it’s going to be an even bigger leap to get a robot that can do more than one type of surgery in more than one type of patient,” says Andre Chow, co-founder of Medtronic-acquired software company Digital Surgery and a former surgeon.

Medtronic’s Tracy Accardi agrees. “In my grandchildren’s children’s time, we could see robots doing surgery without a doctor driving it in some cases.” Accardi, vice president

of surgical robotics research and development, believes the first fully autonomous surgical robot might do knee replacements or other common orthopedic procedures. Unlike organs or other soft tissue, bones don’t breathe and pulse; they stay in nearly the same position once a patient is immobilized. While knees vary from patient to patient, as do other parts of the body, pre-op imaging can establish the exact shape, size, and position of the knee. Then a 3D printer could create a precise duplicate, edited to fit the patient’s needs. While a human would likely supervise the operation, a surgical robot equipped with artificial intelligence capabilities would, one day, perform the entire procedure.

Eventually, there will be a hierarchy of surgical care. Robots will be used for simple, repetitive surgeries. RAS medics will handle the common operations, in which inherent variability requires human judgment. And remote surgeon specialists will be called in for the more difficult, creative procedures.

Innovators around the world are working to change the robotic-surgery landscape. For instance, Xuanhe Zhao, of MIT’s Zhao Lab, is developing a filament-sized, magnet-guided robot that will thread through the brain’s blood vessels to clear the clot of an ischemic stroke. And Digital Surgery is generating data and analytics that can be used to improve the performance of human surgeons and robotic platforms.

From his office at the Norton Leatherman Spine Center, Gum sees a drastically changed operating room in the next five to 10 years. “If you’ve ever watched *Minority Report* or these futuristic movies, that’s where we’re headed.” RAS will become even more streamlined, precise, and pervasive. But, to use one of Gum’s favorite phrases, the most important change will be “improved patient recovery kinetics.” In other words, the goal of RAS is to create better patient outcomes, which is a win for all.

Robotic surgery at work

Robot-assisted surgery (RAS) can be used to perform a range of procedures. Here are the two main types.

SPINAL RAS

In robotic surgery involving bones, such as spine surgery, surgical teams have three main tasks:



1 Visualizing

In some surgeries, the surgeon takes a computed tomography, or CT, scan of the area of the patient that will be operated on and then uses the RAS software to generate a 3D image of the surgical site.



2 Planning

The surgeon uses 3D software to detail surgical trajectories and, in the case of spine surgery, the positions of screws, rods, and other implements. The software lets the surgeon review the impact of the planned implants on the spine.

3

Operating

In the operating room, a robotic arm is mounted to the bed, and the surgical team takes an x-ray of the patient. The RAS software aligns the x-rays with the CT scan. Then, it coordinates the surgical plan with the position of the patient.

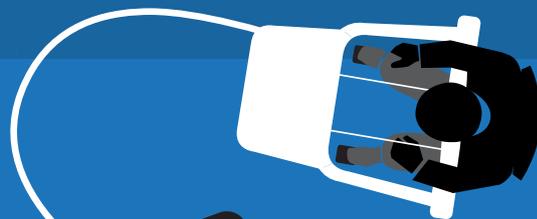


The surgeon uses a sheath in the surgical arm as a guide to make an incision, use a drill, and insert an implant, and watches the software's 3D visualization on a screen as a guide throughout the surgery.

Images courtesy of Medtronic

SOFT-TISSUE RAS

For procedures on organs such as the heart, kidneys, or other soft tissue, the surgeon is separated from the patient and the rest of the surgical team.

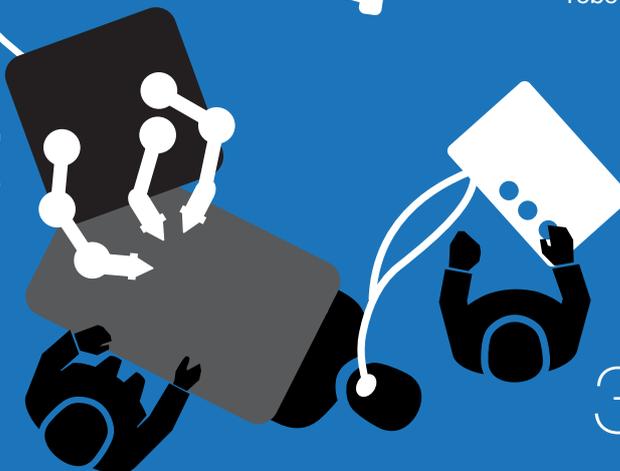


1

The surgeon sits at a special operative console throughout the surgery, using hand and foot controls to manipulate robotic arms and direct the surgery.

Robotic arms perform surgery on the patient while nurses and resident surgeons assist in the operation.

2



3

Via a small, 3D camera placed inside the patient through tiny incisions, the surgeon can see the operation unfold on a high-definition screen.



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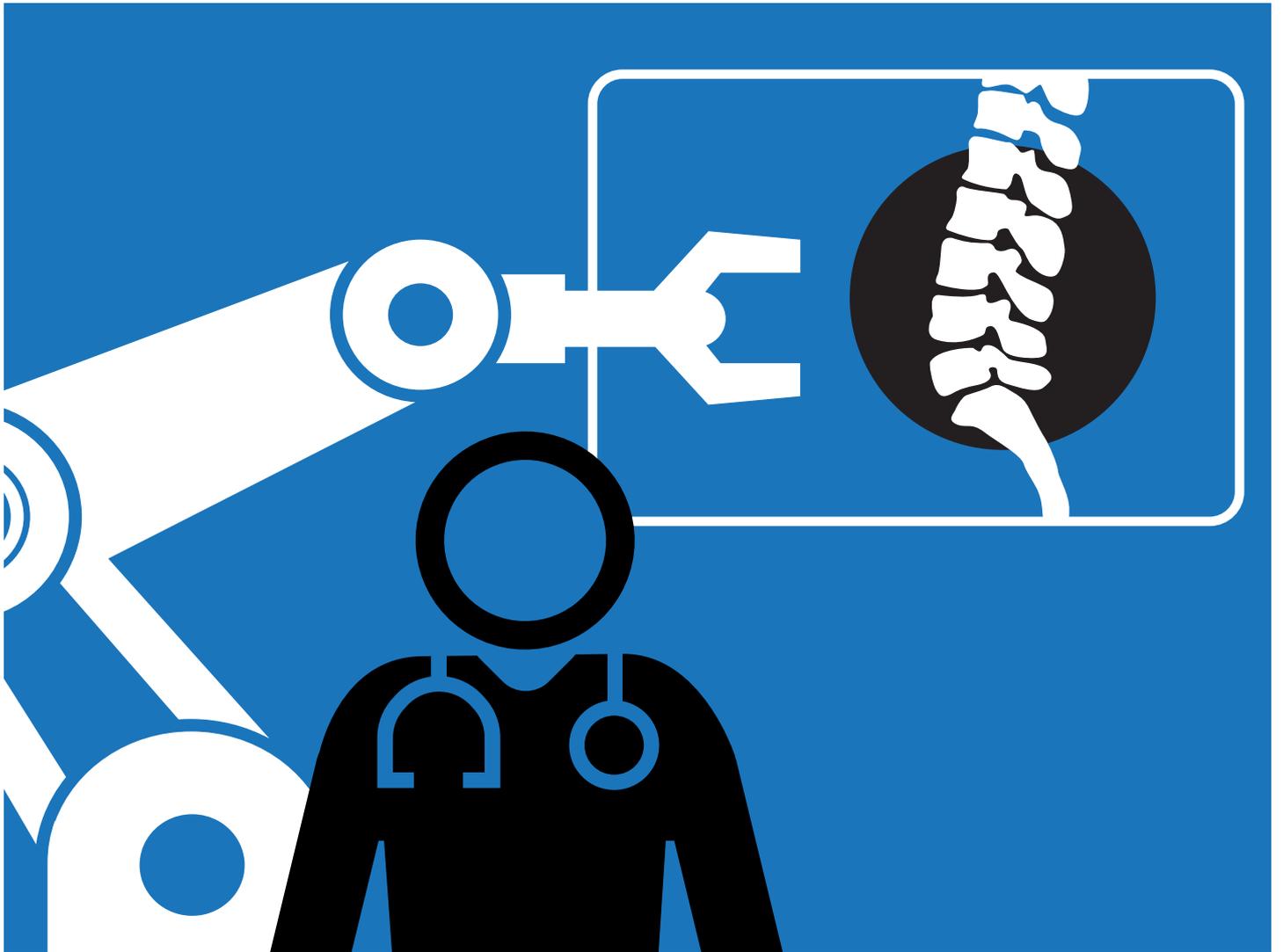
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Illustrations

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