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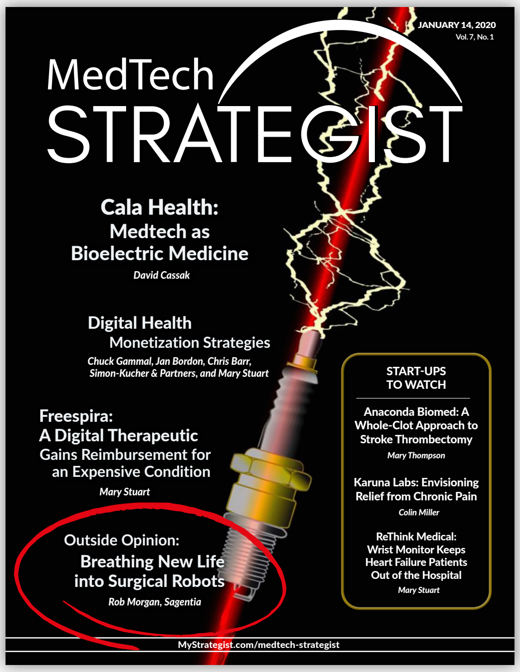
# Breathing New Life into Surgical Robots

*by Rob Morgan, VP Medical, Sagentia*

How can surgical robotics manufacturers deliver targeted innovations that dramatically improve patient outcomes and cost-efficiency in healthcare? It's about developing procedural solutions that clearly surpass what humans can achieve. Clinical and financial benefits need to be tangible and measurable, so end-users can build a robust business case for investment.




Today's healthcare providers are faced with complex, often conflicting, demands surrounding the need for efficiency and effectiveness. Patient volumes, demands and requirements are growing faster than budgets. So, there's increasing pressure to improve clinical outcomes and patient-reported outcome measures (PROMs) while reducing the overall cost of the care cycle.

From a surgical perspective, robotics could represent part of the solution to this challenge.

Since achieving FDA clearance in 2000, **Intuitive Surgical Inc.**'s *da Vinci* Surgical System has been adopted by hospitals around the world. Initially used in prostate and gynecological procedures, it is now widely used in more general surgery.

With an installed base in excess of 5,400, more than five million procedures have been performed using the system. **Stryker Corp.**'s *Mako* for knee replacement and **Medtronic plc**'s *Mazor* for spine surgery have also enjoyed some commercial success.

These first-generation surgical robots have largely been developed with surgeon performance improvements in mind. They tend to focus on factors such as accuracy, dexterity, and tremor removal.

Another approach has been to identify specific procedures with lower long-term success rates than others within a given field, then aim to improve them with robotics. This is evident in arthroplasty. Multiple studies suggest that around 10-20% of patients report some level of dissatisfaction following total knee arthroplasty.

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However, hip arthroplasty tends to be more successful, with better PROMs and overall clinical outcomes. It's no coincidence that procedures related to the knee are gaining more attention from a robotics perspective than those related to the hip. If use of robot-assisted surgery significantly improves long-term patient outcomes and cost-efficiency of knee surgery, learnings may later be applied to robotic solutions for hip surgery.

## The Need for Clinical Data

Uptake of surgical robots has increased steadily over the past two decades and anecdotal evidence of the associated benefits is readily available. However, clinical evidence of improved patient outcomes is harder to come by. Unless this dichotomy is resolved, adoption of first-generation systems is likely to plateau.

Surgical robotic technology is expensive. It's not easy for small hospitals, or those with limited budgets, to make a business case for such a significant capital investment. It's harder still when there is a lack of tangible, robust evidence surrounding benefits for patients and overall healthcare efficiency.

So, what is the best way forward for surgical robotic innovation? The next generation needs to provide better clarity on clinical benefits and return on investment. Procedural specialization could offer a route to achieve this.

## Procedural Specialization

To deliver meaningful improvements in surgical procedures, patient outcomes, and healthcare efficiency, robot-assisted capability needs to extend far beyond that of humans alone. It's about pushing boundaries to achieve things that would simply not be possible with the human hand and eye in isolation. Framing surgical robotics in this way provides a strong rationale for focusing innovation on specialist rather than generalist applications.

For instance, recent developments such as **Auris Health Inc.**'s *Monarch* robot and Intuitive Surgical's *Ion* revolutionize the way lung biopsies are performed. The *Monarch* combines surgical and endoscopic robotic technology with micro-instrumentation, enabling high-accuracy biopsy of small peripheral lung nodules via the body's natural openings. The *Ion* has been designed to fit into a bronchoscopy suite and integrate with existing technologies. Both developments look set to unlock new possibilities in the diagnosis and treatment of peripheral lung nodules.

Similarly, **Medrobotics Corp.**'s *Flex* Robotic System offers a steerable, pliable robotic scope, allowing surgeons to access hard-to-reach anatomy to enable less invasive or natural orifice procedures, such as transanal colorectal surgery. Many research groups are developing robotic systems for use in flexible endoscopy and endovascular applications, introducing robotics to interventional medicine.

Another interesting development is the **Preceyes BV** surgical robot allowing eye surgeons to perform more complex retinal surgery. Any ophthalmic surgery demands the utmost precision, so providing surgeons with a precision better than 20μm to position and hold instruments empowers them in entirely new ways. This robotic assistant enables surgeons to conduct procedures and techniques that might previously have been considered too risky, such as subretinal injections, delivering groundbreaking outcomes.

An important consideration for such specialized robots is whether procedural volumes justify their expense. Clearly, in some situations or specialist subsets of the medical world like lung cancer and ophthalmic treatment they do. In more general healthcare scenarios, there may be a case for initially introducing a specialist robot for a targeted procedure such as laparoscopic biopsy or a specific microsurgical application. Over time, once there is a larger installed base and end-users' skills develop, it could become economically viable for manufacturers and hospitals to invest in an extension of those capabilities to deliver additional procedures. The most exciting benefits may arise from surgeons themselves developing new procedures, enabled by specialized robotics, which would be impractical with conventional surgical instrumentation.

## Affordability

For viability and uptake to scale, surgical robots need to improve patient outcomes and the financial cost of achieving them. With many healthcare systems facing a perfect storm of growing and aging populations, purposeful steps must be taken to deliver the best possible outcomes in the most cost-efficient ways. The core robotic unit of the da Vinci Surgical System costs up to $2.5 million, with additional ongoing costs related to instruments ($700-$3,500 per procedure) and servicing ($80-$190,000 per year). Together, these contribute to a relatively high per-procedure cost additional to the initial capital investment. Furthermore, while the benefits of a minimally invasive approach versus open surgery are clear, there are still questions surrounding how well the *da Vinci* performs compared to laparoscopic surgery.

For some surgical applications, it's been claimed that the robot increases cost per procedure by thousands of dollars without delivering a tangible improvement in clinical outcomes. Findings published by Colombia University Medical Center in 2014 concluded that "for benign gynecological conditions, robot-assisted surgery involves more complications during surgery and may be significantly more expensive than conventional laparoscopic surgery." In this study, the median total cost for robot-assisted oophorectomy was $7,426 compared to $4,922 for conventional laparoscopicoophorectomy.

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It's vital that new developments in surgical robotics consider not just how hospitals will fund the technology but how the investment will translate into savings elsewhere. When a large capex investment is required upfront, a commercial decision must be made and a transparent return on investment framework is essential.

To maximize chances of success, manufacturers should give thought to the pricing model at an early stage in the design process. Failure to do so could prove a significant barrier to uptake, even if FDA clearance is secured. Just because the technology works, it doesn't necessarily followthat hospitals will invest in it.

Novel funding models, such as loaning or leasing equipment, deserve serious consideration. Intuitive Surgical has been operating a direct leasing model since 2013 and Medtronic has suggested that its recently unveiled *Hugo* RAS could be sold via operating leases.

The *Hugo* system offers further efficiencies for hospitals, particularly existing Medtronic customers, because it uses the same end-effectors as Medtronic's existing portfolio, making inventory management easier. The system's tower and scope can be used in both conventional laparoscopy and robot assisted surgery, meaning the operating room doesn't have to be dedicated to robotic procedures alone. Similarly, Switzerland-based **DistalMotion SA** has unveiled its *Dexter* robot, designed for integration into existing laparoscopic setups and workflows, for use in longer, more complex surgical tasks like suturing and dissection. This open system allows hospitals to use their preferred and existing laparoscopic imaging systems, bringing potential efficiencies in equipment use.

Naturally, financial considerations extend beyond the initial investment and cost per procedure to encompass longer term factors related to patient health. A proven reduction in adverse incidents related to surgery—such as sepsis or pulmonary embolism—will have a positive impact on total healthcare cost. And if robots perpetuate a "done once, done well" culture, reduced readmission rates could bring significant financial benefits.

Measuring these factors requires new ways of thinking, and the results may not be immediately apparent. But it is important to make strides here and set benchmarks for the future.

**CMR Surgical Ltd**. claims its recently launched *Versius* robot incorporates the world's first clinical registry for a surgical robotics system. This will underpin post-market surveillance, monitoring patient outcomes of all procedures, such as operative time, length of stay, return to hospital within 30 days and return to operating room within 24 hours. Developments in this vein will help demonstrate the efficacy and effectiveness of robot-assisted surgery at the macro and micro level.

## The Digital Future of Surgical Robotics

Technology is evolving at a rapid pace in the digital age. Advancements in specialist fields such as connectivity, AI, data analytics, voice recognition, haptics, and enhanced visualization hold much promise for surgical robotics. They unlock new ways to conduct procedures that would not have been considered possible when the *da Vinci* Surgical System launched 20 years ago.

Some of these developments could advance global healthcare, enabling people in remote or deprived areas to access world-class treatment in an affordable way. The rise of 5G wireless networking makes widespread adoption of telemedicine combined with remote, robot-assisted surgery a realistic proposition, allowing robotics the opportunity to deliver on the original telemedicine premise of developments started in the late 1980s. Corindus Vascular Robotics, acquired earlier this year by **Siemens Healthineers**, recently announced a trial of transcontinental simulated telerobotic procedures, performed over three network types (5G, fibre and public internet) in the US to evaluate key performance factors such as latency. It has also supported the world's first in-human telerobotic coronary intervention, performed in India during 2018.

Further innovation may come in the form of automation, returning robotics to the autonomy introduced by ISS with the ROBODOC system in the 1990s. New developments in this space are likely to focus on allowing surgeons to automate specific tasks within a procedure. **Activ Surgical Inc**.'s founding vision was to provide surgeon-supervised automation of tasks such as suturing in order to outperform expert surgeons operating manually or with robotic assisted surgery.

The roles of AI, machine learning, and data analytics in surgical and digital robotics are at risk of being over-hyped. Nevertheless, there is clear potential for AI in autonomous robotic tasks since a system can train algorithms and refine performance based on data from earlier cases. Likewise, AI holds promise in advanced visualization, using automated feature recognition algorithms to highlight critical structures to the surgeon, with the goal of reducing the rate of adverse events.

We are likely to see a shift in how such robotics innovations are brought to market and how investors can achieve an exit. Medical device talent expert Joe Mullings says "software is the new manufacturing" in surgical robotics, pointing to an age where open platforms will use aggregate software solutions from multiple providers. Perhaps developments in this vein will enable surgical robotics to take a leap forward and realize its full potential.

Researching and commercializing a surgical robotic system is an enormous and complex undertaking. Start-ups that aren't capitalised to the tune of several $100 million lack the cash to get through the work required. Bigger players who might have the funds often lack the agility and appetite for risk. A more nuanced, open, and collaborative approach to innovation and development might be the answer. Interestingly, it was recently confirmed that GE Healthcare participated in CMR Surgical's Series C funding round for Versius. This indicates its intention to join other medtech majors in the field of surgical robotics, and shows how the strength of established players can be married with the vitality of newer market entrants.

## Solving the "More for Less" Conundrum

Ultimately, it will take more than minimally invasive procedures and digital technologies to tackle the extreme challenges facing contemporary healthcare. The next generation of surgical robots needs to break new ground in the improvement of patient experiences and outcomes while lowering the total cost of care.

Harnessing meaningful insights about the holistic surgical process, and using them to inform innovation efforts, will be a critical success factor. Robot-assisted surgery must demonstrably improve factors that drive up costs and indicate subpar performance, from time in the operating room and length of hospital stay to readmission rates.

The pay for performance (P4P) movement in healthcare could be an influencing factor driving evolution and uptake of surgical robotics. As healthcare providers and professionals become more accountable for certain performance measures, such as reducing adverse events and increasing throughput, robot-assisted procedures could unlock new ways of working, overhauling established processes to deliver better outcomes and efficiencies.

Can next-generation surgical robots use technology in transformative ways, rather than incrementing on what has always been done? The 2020s will be a pivotal decade. To quote Bill Gates, "We always overestimate the change that will occur in the next two years and underestimate the change that will occur in the next 10."


## Final Thoughts

It would be easy to get swept along by exciting new technologies, integrating them to create super-surgical robots. But obtaining and harnessing clinical data proving that robotic surgery is better for patients needs to be central to product development. Manufacturers must act responsibly, methodically, and prudently. That means embracing learnings from first-generation surgical robotics and putting clearly defined healthcare needs at the heart of the equation. It means focusing on the 10 years, not just the two years, to identify innovation hotspots and breathe new life into surgical robots.

Achieving more for less in healthcare is an acute challenge of our age. The pressure is on to improve clinical outcomes for individuals and wider healthcare systems with focused innovation that earns its keep.

## About Sagentia

Sagentia is a global science, product and technology development company. Our mission is to help companies maximize the value of their investments in R&D. We partner with clients in the medical, consumer, industrial and food & beverage sectors to help them understand the technology and market landscape, decide their future strategy, solve the complex science and technology challenges and deliver commercially successful products.

Sagentia employs over 150 scientists, engineers and market experts and is a Science Group company. Science Group provides independent advisory and leading-edge product development services focused on science and technology initiatives. It has ten offices globally, two UK-based dedicated R&D innovation centers and more than 350 employees. Other Science Group companies include OTM Consulting, Oakland Innovation, Leatherhead Food Research, TSG Consulting and Frontier Smart Technologies.

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