NEXT-GEN SURGICAL NAVIGATION: DEMOCRATIZING SURGERY BY 2030?

WORKSHOP REPORT 2019

A workshop hosted by Cambridge Consultants

Cambridge Consultants recently hosted a workshop for senior leaders in the surgical navigation and robotics industry, focusing on how surgical navigation could democratize surgery in the future. The workshop's charter was to envision the surgical navigation ecosystem of 2030 and outline a path to achieve it. We asked delegates to explore how the role and capabilities of surgical navigation are likely to change over the coming years. Addressing the market and technology drivers, the group was asked to consider how these might impact on commercial and clinical aspects of the sector.

Workshop delegates represented a wide spectrum of backgrounds and expertise, including commercial, clinical, engineering and investors. With companies ranging from dynamic start-ups to global blue-chips, the delegates also covered a broad spectrum of clinical disciplines, including laparoscopy, cardiology, neurosurgery, dentistry and orthopedics. From this diversity came rich and valuable insights.

We are grateful to our delegates for their willingness to invest significant time and effort to attend and for their readiness to share insights and opinions so freely. This report summarizes the combined vision formulated during the event. It offers unique insight into the future of our industry and its therapies, as seen by the sectors' leading authorities.

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IN SEARCH OF ANSWERS

Our reliance on machines to safeguard lives has grown consistently since the industrial revolution. With the advent of navigation systems, autopilot has become a standard on most commercial flights. Space exploration is an even more extreme example of an industry that places significant trust in navigation systems.

However, despite the potential benefits of proven and potentially life-saving navigation technology, it has not managed to gain widespread adoption in the surgical space. Is this because today's technology is incapable of meeting the exacting demands of surgical procedures, or are there other barriers that we need to overcome? Could the navigation systems of the future enable general surgeons to do more specialized procedures, thereby providing access to high-level care to an ever-increasing patient population? Can it enable new procedures or treat new conditions? Will it give rise to new clinical disciplines? These questions are not being asked for the first time, but the answers remain elusive.

This report distils the key findings from our workshop on the future of surgical navigation, in order to answer some of these questions. The report outlines a vision of the future, the benefits that navigation brings to surgery and identifies the challenges involved in delivering this vision, as seen by our delegates. Also captured are our own experience and the thoughts of our delegates on how technology, innovation and business models have a role to play in delivering the outlined vision.

Surgical navigation technology is intended to safely and precisely localize specific anatomical and pathological structures and delineate a safe path to get to them.

A FUTURE WITH NAVIGATION

Our delegates agreed that by 2030, the surgical navigation industry will be facing a new landscape of opportunities and threats. The global patient population will be more tech and data savvy, leading to a consumerization of patient and healthcare systems. New technologies will enable new procedures, while software giants such as Apple and Amazon, alongside new tech entrants, will be players in MedTech. This will require new business strategies, shifts in organizational thinking and new approaches to innovation on the part of today's industry leaders.

New tools will change the way that navigation is used. Navigation combined with automation, sensing enabled tools and AI will help to improve the repeatability and predictability of outcomes. The reliance on traditional imaging alone for planning and navigation will decrease, as more low-cost and low-power sensing modalities will be integrated into surgical tools. These sensors can identify force, vibration, tissue stiffness, chemical makeup, optical signatures and other indicators of critical structures or areas of interest, which will take the place of image-guided navigation for certain procedures. Advanced manufacturing capabilities will allow for on-the-spot, 3D printed, low-cost sensors which can further benefit image-based navigation by bringing the cost of the procedure down. The use of conventional instruments will slowly decline and give rise to multipurpose tools.

Easy access to information has led to people becoming more conscious of their consumer decisions. Yelp, TripAdvisor and others, have enabled people to make more informed choices about discretionary spend. Our delegates considered that the same will be true for healthcare, adding that patients are demonstrating a strong buying preference for robot assisted procedures, largely due to increasing direct-to-patient marketing by device companies. More and more patients are self-diagnosing over the internet, using resources such as Web-MD. Patient choice is also ensuring that older patients receive support from their internet-savvy children and grandchildren. Already, doctors and surgeons are being rated by patients as well as payers. As a result, physicians and surgeons will need to competitively demonstrate their value to patients.

"Patients will be proactive consumers, seeking earlier intervention"

In the near future, payers will pay for earlier intervention and even prevention. Navigated procedures have the potential to enable more early interventions and more minimally invasive interventions. The Monarch system from Auris Health[1] shows how navigation coupled with robotics and micro instrumentation has the potential to improve outcomes and reduce cost, by allowing physicians to accurately access small and hard to reach lung nodules early. This has enabled a low-morbidity, early intervention lung cancer procedure where none existed previously.

"In the future we may see a tiered healthcare system"

By 2030, the consumerization of healthcare will be firmly established, and future care services will reflect this. Some of our delegates took the view that payers will drive for minimum viable outcomes, potentially leading to tiered offerings whereby patients are incentivized to maintain a certain basic level of health. The group defined minimum viable outcome as a standard of care that allows people to participate in society with a minimum quality of life, for example the ability to earn wages, complete daily chores, etc. More personalized medicine would be available only to those that could afford higher tier healthcare packages. These will enable a higher quality of life through a more active life style or cosmetic or wellness enhancements, on top of maintaining a basic health profile.

Today's technology giants, such as Apple, Amazon and Google, have capabilities well beyond data management and that could lead to a transformation in the medical market. The ability to extract insight from the data that they hold, given the large numbers of data scientists they employ, is one. Robotics is another, as Amazon has one of the world's largest dedicated robotics capabilities. Few capabilities are missing from these consumer technology companies should they intend to displace the current leaders in the medical market. Ultimately, partnership provides a symbiotic relationship. The medical device business will provide hard won access to a market segment while the consumer companies will provide leading edge software and services.

1 https://www.aurishealth.com/

NEXT-GEN SURGICAL NAVIGATION: DEMOCRATIZING SURGERY BY 2030? REPORT

"The CIOs of software and firmware companies will be the CEOs of the MedTech companies of the future"

Our delegates agreed that the coming decade will see the rise of more widespread, intra-operative live navigation. While the capabilities of portable and affordable MRI scanners will increase, intra-operative imaging will still not match the quality and availability of pre-operative imaging in the coming decade. Therefore, high-detail, pre-operative imaging will continue to be used to localize the target, in combination with lower resolution and potentially lower dose imaging in real-time, to register and reach the target. The group commented that by 2030, the amount of radiation dosage will certainly be reduced, both from increased use of ultrasound as the live imaging modality as well as better interpolation between C-arm images. Multimodal imaging, coupled with AI, will increase the opportunity to support real-time planning and surgeon decision making.

Technological advances, such as augmented reality, mixed reality and AI-powered surgical planning promise to further enhance the capabilities of surgeons, making average surgeons into great surgeons. The delegates agreed, however, that even with more automation, the surgeon will remain the key decision maker in the decade to come. Because the surgeon must make decisions in real time to direct the OR team, the group saw the "surgeon as player/coach", or "surgeon as quarterback" as a useful analogy. A future where the surgeon is acting solely as a coach from the side lines is further away.

UNLOCKING PROCEDURES

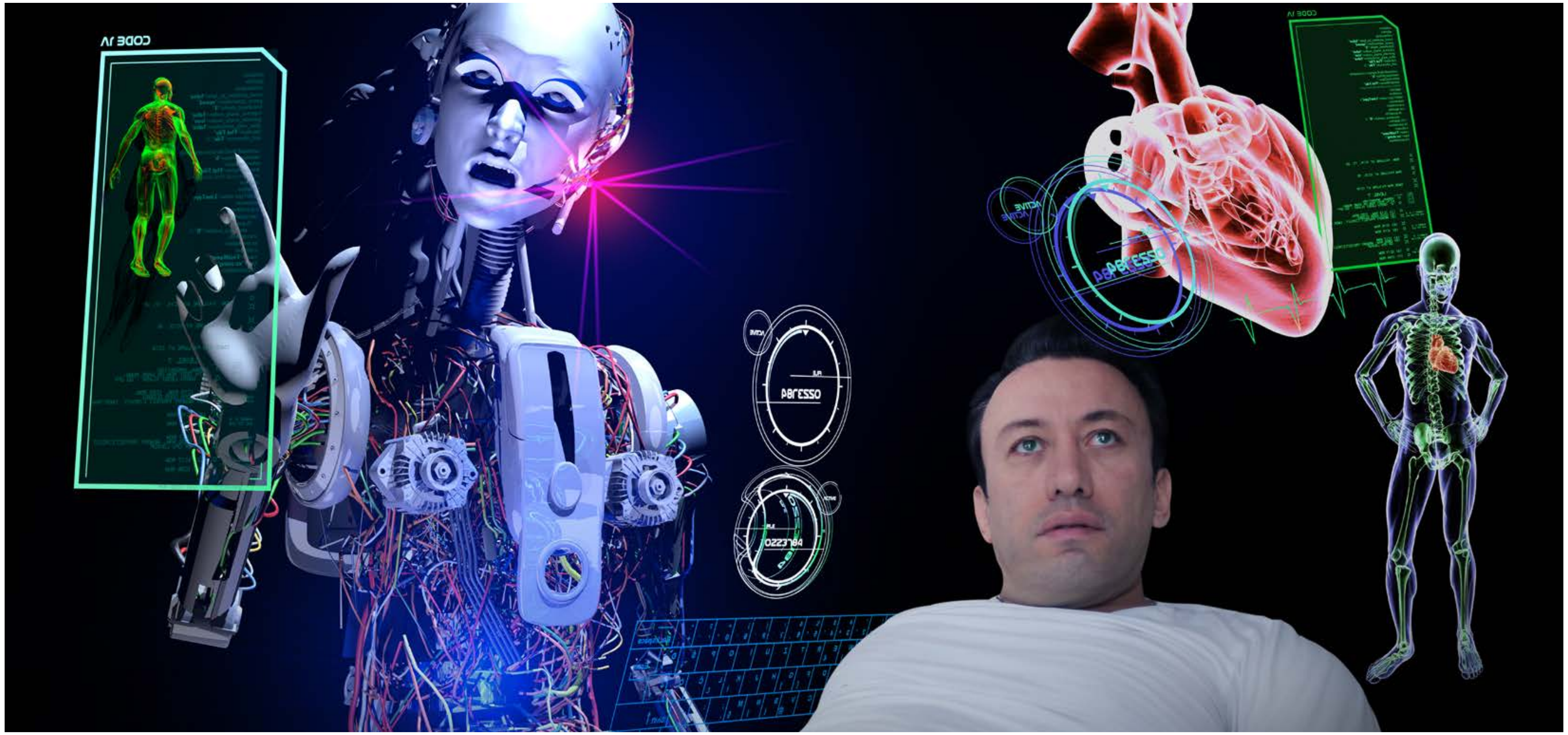
If navigation is to reach its potential by 2030 it must provide a strong value promise. Navigation has been well adopted in neurosurgery, where it has proven its value. In the majority of neurosurgical interventions, navigation technology helps visualize the location of a desired target (a tumor or anatomical location for an implant) in relation to the skull, resulting in shorter surgical operation times and smaller craniotomies. Smaller and better-centered craniotomies are associated with reduced blood loss, minimized trauma and brain retraction. This reduces the risk of postoperative swelling and/or hematomas, and that in turn results in shorter hospitalization of the patient and lower hospital costs. Other procedures, such as pedicle screw placement, have also benefited from navigation as navigated screw placements have resulted in shorter procedures and fewer revision surgeries. Procedure time, blood loss, etc. have served as proxies that tie navigation to outcomes.

Looking into the future, our delegates expressed the opinion that navigation has the potential to enable the execution of more complex minimally invasive surgeries that do not exist today. Pulmonology and structural heart interventions are prime candidates. For example, navigation technology can enable a beating-heart mitral valve repair without cardiopulmonary bypass. This involves the combination of next-generation imaging and robotic manipulation technology and demonstrates how understanding the anatomy in real-time can enable new interventions.

Evaluating the economic trade-offs inherent in navigation technology is key for the hospitals of the future. Current navigation systems involve heavy capital investment on the part of hospitals and a steep learning curve for the surgeons. However, navigation (particularly in combination with robotics) can convert high complexity procedures to high throughput, by driving consistency of outcomes with improved predictability. If outcomes remain the same, but navigation helps in improving efficiency, there is an economic benefit for hospitals.

For our delegates, navigation also has a role to play in elevating the minimum viable outcome and delivering more personalized treatment, thereby positioning itself as a core technology of the future. For example, navigated procedures such as deep brain stimulation for Parkinson's disease have enabled patients suffering with Parkinson's disease to gain independence and self-confidence. Similarly, navigated procedures have enabled relatively safe extraction of tumors from delicate organs such as the brain and spine.

There was consensus that in the next decade AI will enable navigation with guidance in a much wider range of procedures. For example, machine learned algorithms will be able to make recommendations on screw size and placement for spine surgery, offer alternative surgical approaches that minimize disruption to nerves and vasculature for brain surgery and provide accurate tumour margins for lung resection. AI-powered systems will provide the ability to tailor every procedure approach to the specific patient.



WHAT'S IN NAVIGATION'S WAY

As we've discussed, our delegates foresaw an increase in the consumerization of healthcare worldwide. Nevertheless, strong cultural influences in some parts of the world cause patients to treat surgeons and doctors with reverence, trusting their instructions without question. Our delegates agreed that cultural attitudes are unlikely to change, but future patients will become increasingly empowered in influencing their own healthcare. However, this also presents an interesting paradox. On the one hand, it is in a patient's best interest to do their research, but information overload can lead to 'analysis paralysis', preventing the patient from making the right choices. Empowerment is good, but misinformation is bad and can potentially lead to harmful delays in care.

Navigation must rise above the challenges presented by brain anatomy. The brain is an organ entirely composed of highly sensitive areas that directly correlate with a patient's mental and physical well-being. Due to the abundance of risk structures and eloquent cortical and subcortical areas, cranial neurosurgery has been on a quest for minimally invasive surgery. Navigated neurosurgery has enabled surgeons to minimally invasively treat tumors, vascular malformations and other intracranial lesions, as well as to implant electrodes. Navigation gained widespread adoption in both cranial and spinal neurosurgery because these procedures offer rigid anatomical landmarks, such as vertebrae, skull, etc. to register pre-operative images to the actual position of the patient on the operating table, thereby allowing precise access to the target anatomy. However, the adoption of navigation outside of neurosurgery remains very low. One delegate highlighted that 90% of spinal surgeries, despite also being performed by neurosurgeons, are still not navigated. Craniomaxillofacial (CMF) and Ear Nose & Throat (ENT) procedures have only now begun to realize the benefits of navigation. Additionally, soft tissue surgeries have yet to reap the benefits of navigation, as few technologies are able to translate pre-operative imaging into guidance information for soft tissue. Organ shift and tissue deformation present a huge challenge. Specifically, in aligning pre-operative 3D imaging frame of reference, containing the image of anatomy as well as the surgical plan, with the actual patient position in the operating room (OR).

Our delegates perceived that there remains a gap in translating the high-resolution pre-operative understanding of the anatomy into actions intraoperatively. For example, procedures such as deep brain stimulation and subdural Electroencephalography still require the surgeon to spend hours of un-reimbursed planning time in order to take advantage of the increased accuracy that navigation enables.

The sceptics in the workshop cautioned that technology will develop at a much faster pace than regulation, thereby creating a bottleneck that could slow progress. They suggested that the requirement for quality navigation systems could demand the creation of an international standard for navigation.

Today there are a variety of spine implant companies operating worldwide. The majority of these companies have relied on a "razor – razor blade model" where a platform technology is typically sold at a loss and is paired with consumables that generate the profits. This model is employed in order to commit a consumer to a platform or proprietary tool for a long period. In this case, implants are the "razor blades", generating profits and advancing the navigation and robotics technology, which is the "razor". Our delegates took the view that this is not sustainable in the long term and that there will be consolidation of hardware companies. Companies that make implants and imaging equipment will need to respond as IBM did in the 1990s, in response to the commoditization of computing hardware. IBM had to fully transform its product portfolio and culture to stay relevant in the marketplace. Less focus on hardware and more on software implementation will provide the key differentiation. Custom navigation software deployed on commoditized hardware platforms will be the way of the future.

This presents an interesting question: Will the medical device companies have the capability to roll out a software as a service model? This will require hospitals to allocate budgets differently. The pace of technological advancement is too fast to expect hospitals to pay for new hardware and software packages every few years. From a hospital's perspective, having access to planning software in the cloud, unlimited installs of the software and automatic updates, all for an annual subscription fee, could be advantageous. Medical device companies are used to placing their capital equipment in return for selling the implants. In this new paradigm, companies will have to find a way to use software modules as the "razor blade".

REALIZING NAVIGATION'S POTENTIAL

"For navigation to democratize surgery, the key will be to improve the throughput of complex procedures, so they can be done more routinely"

As technology matures, our delegates expect to see the automation of straightforward procedures and portions of procedures. For example, robots already aid the placement of pedicle screws during spinal interventions, whereas the decompression step remains in the hands of the surgeon. Trust between surgeon and robot will develop over time. In the very near future, navigation systems and robots will make initial recommendations that the surgeon will confirm. This trend will continue to mature in the coming decade, where we will see increasing automation of surgical steps, such as suturing, anastomosis, etc. where the group cited the STAR[2] robot as a step in that direction. Wider navigation and robot use enables another data capture channel, which can be associated with outcomes, thereby improving adoption.

Delegates agreed that "big data" will play a huge role in transforming medicine. Historically, the nature of medicine has been sharing knowledge and best practices through conferences, papers and publications. But the analogue nature of information sharing has become an impediment. As sensor technology becomes smaller and cheaper, the use of sensor systems will become more widespread, and more data will be generated on a per-patient basis. Technology that enables the processing, understanding and security of this data will be critical.

"The patient is always on"

As data collection becomes easier, an important challenge will be to identify what data to collect. The delegates agreed that we will need access to multiple data streams in order to have personalized approaches for each patient. The goal is to combine intra-operative data, such as tissue imaging data[3], overlaid with mechanical interaction data[4], with pre-operative patient information[5] to enable a richer dataset with which to guide decision making. UI/UX design will play a key role in creating composite views of the anatomy from this multitude of data, to aid the user without overwhelming them.

There was consensus that healthcare will be outcome based. However, it is not always easy to link a device or technology to outcomes. Outcomes are usually multifactorial and the link between outcomes and a device becomes even more challenging when the device is used only for a portion of the procedure. Navigation technology coupled with automation and sensorized tools promise to digitize surgery and this can be used to establish the precious link between outcomes and the device.

With evolving technology, the role of surgical teams will also evolve. More and more procedures will be carried out by technicians. The delegates cited an example from dentistry, where the patients spend most of the time with a hygienist and see the dentist only for a few minutes. Delegates also highlighted that in order to support the changing ecosystem, new training and education models for surgeons, nurses and support staff will be needed. Augmented and virtual reality (AR & VR) can be used for low-cost workflow training in different scenarios. Incorporation of training platforms in teaching hospitals will be the difference in how surgeons learn and adopt the new workflows.

Both AR and VR will have a place in the OR of 2030. AR will allow relevant information to be overlaid on a patient,

2 https://www.eedesignit.com/star-the-smart-tissue-autonomous-robot/

3 e.g. data from confocal microscopy or Raman spectroscopy

4 e.g. data from force sensors

5 e.g. data from genomic analyses and blood tests

as opposed to looking at a screen, making that information available to the entire surgical team. VR will be more useful as the scale of surgical manipulation changes. For example, when using robots to carry out micromanipulations (such as those enabled by miniature origami robots), VR will enable an interface where the surgeon can view the anatomy and robot at a much larger scale. Enabling and integrating with these training platforms will be a key challenge for device manufacturers of the future. While there is a trend towards keeping device sales representatives out of the operating room, that places more burden on the hospitals to train clinical staff.

The scarcity of trained medical professionals will be highlighted even more as emerging markets continue to grow. Telemedicine will play a significant role in addressing this problem. In-office consultants will be a thing of the past and most care will be delivered virtually. Surgical navigation and robotics are prime candidates for this transition, as telemedicine evolves from diagnosis to treatment to intervention. As computer processing becomes cheaper and more efficient, and as the data ecosystem evolves, more tasks can be carried out automatically and in the cloud, increasing the availability of benefits such as surgical planning.

The model of the medical device manufacturer providing access to a market can be extended beyond simple partnerships into a complex ecosystem. This may consist of software and physical architecture and in turn could extend the capabilities of single-purpose surgical navigation or robotics systems into multi-capability tools, essential to surgeon workflow. Both open and closed architectures have their advantages. Closed platforms extend control over the shaping of the ecosystem, allowing closer integration and bringing interfaces together. Open platforms require well defined interfaces and clear segregation of responsibility, but they can enable a more rapid pace of innovation.

WHERE DO WE GO FROM HERE?

The group believed that there is more power in collective experience. In the future, we will see crowdsourced planning models from which the surgical teams can learn and improve upon. Surgeons will thus spend more time on carrying out more surgeries, as opposed to spending time planning the surgical approach and anticipating possible issues. But to harness the power of collective experience the companies must first understand what data to collect in order to make their offering more powerful. They then must develop an entire ecosystem (both front and backend infrastructure) to store the vast amount of data and run analytics that can provide the necessary and timely guidance needed by the surgeon. The need to ensure appropriate security adds a further layer of complexity.

The medical device companies have the relationships with doctors and hospitals and understand the unmet needs of the market, but so far they have been reluctant to make investments in *data*. Consumer technology companies entering the medical market, such as Google, normally seek to remain in the data business rather than the surgical robotics business. As a result, partnerships present a logical route to innovation. We have already seen this happen with Verb Surgical, and more recently in the partnership between Zimmer Biomet and Apple. In the coming years there will be more such partnership deals. Many opportunities remain, for example, no consumer company has managed to tap into the electronic medical records (EMR) market. Yet, the EMR industry has huge potential for data that could be mined to link procedures to outcomes.

For navigation technology to cross over from neurosurgery to other disciplines we need to address the challenges involved with soft tissue navigation. A major challenge of soft tissue navigation is the registration of preoperative image data or surgical planning and intraoperative patient images, because shape and orientation of unconstrained organs may change, post intervention planning. Certain approaches, such as those that do not require registration, for example sensing-enabled intraoperative imaging devices such as US transducers and the endoscope, have been tried but suffer from poor accuracy.

The use of intraoperative imaging devices offers a solution to counter the effects of organ shift and tissue deformation. Many concepts for endoscopic navigation in thoracic and abdominal surgery employ intraoperative ultrasound, as ultrasound is inexpensive, easy to use, and non-invasive. However, these benefits are at the cost of image quality. Other imaging modalities such as intra-operative MRI have better image quality but are very expensive and not very portable.

The workshop and this report have identified a range of opportunities that together can usher the surgical navigation industry into a new era. Will you seize the opportunity?

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