((Title))

The Future of Surgery:
A Siemens Healthineers Position Paper on Surgery 20 Years from Now

((Intro))

We are living in an age of impressive medical progress. Thanks largely to research in molecular biology, hundreds of new pharmaceutical treatments have hit the market. But despite all progress: Medical therapy continues to be, by and large, about treating, not about curing patients. Surgery is a discipline that is (mostly) about curing, and as such it is irreplaceable and will remain so. But it is subject to change, too. What molecular biology research is to internal medicine, technological progress is to surgery: Miniaturization, automation, precision imaging, and artificial intelligence all open new avenues towards a future in which surgery will be visibly different from today. So where, exactly, is surgery heading to?

((Copy)

An example to begin with: Colorectal cancer is the third most common cancer in the world, with nearly 1.4 million new patients diagnosed annually, many of them with liver metastases. (1) Today, only a fraction of patients with liver metastases can be cured surgically. 20 years from now, data acquired from multiple data sources will be used to create “digital twins” of individuals that help optimize prevention, diagnosis, treatment, and follow-up care. Even the smallest liver metastases can be detected and thus be treated at an early stage. Minimally-invasive, partially automated interventional procedures, deeply interweaved with multimodality intraoperative imaging and artificial-intelligence-powered guidance tools, will have sharply increased the likelihood of curative therapy. The individual therapeutic approach will be founded on both evidence-based guidelines and digital real-world patient registries, so that, for our exemplary patient with colorectal cancer, the ideal type of intervention with the lowest possible risk and the best possible outcome can be chosen. After the intervention, procedural and long-term follow-up data will be fed back into registries and into the patient’s digital twin. This will create a “knowledge loop” that continuously updates and refines the guidelines.

((Subheading))

Drivers of Change and Ways to Address Them

((Copy))

Medicine is transforming, and so is surgery. Demographic change, medical and technological progress, and economic constraints are putting pressure on healthcare systems. There is a generalized shortage of healthcare professionals. Hospitals are having difficulties to find qualified interventional radiology experts. (2) In regards to surgery, they are struggling to find general surgeons who are capable of a broad spectrum of acute (emergency) care procedures while having enough volume of complex procedures to retain high proficiency on them. (3) Furthermore, health insurers and HTA bodies are increasingly expecting solid outcome data and

transparency for surgical procedures and interventions. Value-based payment models are already being implemented in some healthcare systems. (4)
There is no simple way to cope with any of these challenges, but there is broad agreement among surgical experts about what is needed in principle:

- **Expanding precision medicine**
  The surgical or interventional approach chosen for every individual patient should depend on personalized diagnostic and therapeutic decision making, as well as highly-accurate imaging and laboratory data integration.
- **Transforming care delivery**
  Treatment pathways need to be optimized and standardized at both departmental and system level. A "despecialization" of invasive therapy has to take place, while at the same time workforce productivity needs to increase, and access to care has to improve.
- **Improving patient experience**
  Healthcare providers need to make sure to optimize patient experience from diagnosis through treatment and follow up, by reducing waiting times and hospital stays. More than ever, providers need to be able to prove that they are able to deliver outcomes that matter to patients, such as long-term therapy results accompanied by fewer side effects, fewer complication rates, and shorter recovery times.

((Subheading))
Enabling Technologies

((Copy))
It will take an effort in various areas to reach these goals. In terms of medical technology, which is the focus of this position paper, the future of surgery will essentially depend on whether surgery succeeds in escaping the hyperspecialization trap. Can the ever more imaging-dependent, ever more minimally-invasive practice of surgery be standardized in a way that surgical procedures and interventions are easily available and performable even in times of shrinking workforces and cost-constraints?
There is an interesting historic example: In the late 19th century, appendectomies were performed only by a few very skilled surgeons. Today they are among the most basic of all procedures – due to standardization and general anesthesia. When we talk about the future of surgery, we should keep this in mind: How can we get to a point where surgical "organ specialists" or "organ teams" can choose between different easy-to-learn, broadly available and cost-effective surgical or interventional approaches, instead of being "methodology specialists" who are restricted, by virtue of complexity, to a very limited set of tools?
There is a number of enabling technologies on the horizon that will help pave the way:

- **Advanced pre- and peri-procedural imaging**

Pre-procedural imaging allows to better plan surgical procedures and interventions, while peri-procedural imaging increases the precision of surgical interventions, reduces complications, makes structures available for surgery that otherwise would have been out of reach, and allows to evaluate treatment responses right away.

There are examples from the past that illustrate the benefits of bringing imaging and surgery closer together. The switch from whole-organ resection to selective resection in cancer surgery would have been unthinkable without a more comprehensive use of imaging technologies. And radiofrequency ablation (RFA) was limited to small, superficial lesions for decades. Only when ultrasound was introduced to monitor needle placement and to assess tissue response, RFA became a broader treatment option.

In order to link imaging and surgery more closely, it will be necessary to refine existing approaches and devise new ways of “seeing” diseases to decide on treatments, optimize and evaluate results, or detect recurrences or complications. There is also an economic dimension: Better diagnostics will ultimately lead to lower costs, since it is therapy that is driving healthcare expenditure. In Germany, 9,424 million euro were spent on diagnostic radiology in 2015 and 8,574 million on laboratory diagnostics, while 53,220 million euro were spent on medication, 67,461 million on nursing, and 74,907 million euro on physicians. (5)

- **Virtual and augmented reality**

Some surgical specialties became almost fully minimally-invasive in the past decade. A key challenge here is to compensate the loss of “tactile dimension” of traditional surgery. Augmented reality (AR) can help fill this gap. By fusing, for example, laparoscopic videos with 2D/3D radiological datasets, additional information can be provided to the surgeon.

- **Knowledge-based systems and artificial intelligence**

So far, decision support in medicine has been about knowledge-based systems. More recently, machine learning approaches, or artificial intelligence (AI), have generated considerable attention that don’t use predefined models but “learn” from real world data. Both can be used in surgery to predict the outcome of procedures and, in conjunction with imaging technologies, to guide and/or partially automate/steer surgical interventions. Compared to knowledge-based systems, machine learning approaches are better applicable to a wide range of problems and avoid complex modelling of underlying physics and biomechanics. (6)

- **The digital twin**

In the years to come, ever more encompassing and more precise health-related data will accumulate for each individual. Anatomical and functional imaging data will be supplemented by laboratory data, genetic information derived from next generation sequencing, and lifestyle information delivered by wearables – to name just a few. This data will be used to create “digital twins” of organs or persons that mirror anatomical, physiological, functional, or biochemical features of the real self. In conjunction with VR and AR applications and machine learning, these data sets can help personalize therapeutic decision making and assist during procedures and interventions. And in conjunction with cloud infrastructures, digital twins can be updated continuously and contribute to depersonalized data lakes to draw upon for decision support tools, for simulation training, or population health research.

- **Automation and miniaturization**

All enabling technologies mentioned above act on the background of further automation and miniaturization of surgical interventions and equipment. It is important to understand, though, that miniaturization and automation – i.e. conventional robotics – per se won't help. Only a successful integration of miniaturized and partially automated approaches with imaging, VR/AR, and AI will bring the desired progress. (6)

((Subheading))

Components of the Therapy Suites of the Future

((Copy))

Enabling technologies like advanced imaging, VR/AR, machine learning/predictive analytics and the digital twin will contribute on different levels to what could be called a "surgical therapy suite" of the future. Innovative surgeons, interventional radiologists, researchers, and industrial partners are currently carving out its components. Some are on their way into routine already, while others are in early stages of research and development. Together, the following and other components form what the digitally integrated, data-driven future of surgery will likely be about.

- **Simulation training**

Simulation training is among the lower-hanging fruits on the way towards the future of surgery. In disciplines such as laparoscopic surgeries, efforts are under way to create digital training environments for resident surgeons. Advanced simulation uses real-world imaging data to create virtual 3D models that are as close to reality as possible. Virtual environments will be created that feel increasingly real and allow increasingly more realistic training of common and less common procedures. For example, Gmeiner et al from Kepler University in Linz, Austria, recently reported the development of a virtual cerebral aneurysm clipping simulator for neurosurgical education. It is based on real patient anatomies and provides real-time haptic force feedback. 9 out of 10 neurosurgeons considered head positioning and craniotomy as realistic, and nearly all recommended integration into neurosurgical education. (7)

- **Personalized therapy planning**

Personalized therapy planning is closely related to simulation training. On an anatomical level, imaging will be used to create 3D models of the target organs. These models are then 3D-printed in order to plan or even test interventions before they take place. This is well under way already. Interventional neuroradiologists from German University Medical Center Hamburg-Eppendorf have reported that 3D rotational angiography datasets can be used to create

virtual 3D models of intracranial aneurysms which are, by way of 3D printing, converted into highly accurate 3D replications. This has made it into clinical routine. (8)
Rapid prototyping is also used at Great Ormond Street Hospital for Children in London. Based on 3D CT or MRI datasets of children's hearts, an accurate model is 3D-printed both for planning an intervention and to illustrate it to parents. (9)
Personalized therapy planning can also happen purely in-silico: At University of Minnesota Masonic Children's Hospital, two newborn sisters who were conjoined at the heart had to be separated. Based again on CT and MRI data, a virtual 3D model of the intertwined hearts was created. And by using VR goggles, the doctors navigated the organs to identify the best approach for surgery, resulting in an alteration of the surgical strategy. (10)
Further ahead in time, the virtual or 3D printed organ model will likely be replaced or supplemented by a fully digital twin of the complete patient, based on multiple data sources like imaging data, functional data, genetic data, and lab values. In addition to planning interventions, a "full-body twin" will help predict and avoid systemic complications of surgery like renal failure, systemic inflammatory responses, or neurological complications of general anesthesia.

- **Intraprocedural guidance**

Sophisticated intraprocedural guidance tools are a key feature of digitally integrated ORs. They have the potential to reduce surgical risk and intervention times. They will also help to standardize and partially automate surgical and interventional procedures and make them less dependent on the individual doctor's knowledge and abilities.
The number of reports on successful prototypes of intraprocedural guidance tools increases by the week. A recent German example is the Fraunhofer research project 3D-ARILE, an AR system based on infrared light and fluorescent dye that superimposes a virtual image of the exact position of a sentinel lymph node in melanoma surgery. (11) AR guidance tools are also prototyped in minimally invasive surgery, where they partly replace visual and tactile feedback mechanisms by augmented reality visual feedback. (12)
Next is intraoperative combination of imaging modalities with AI. Mori et al from Japan recently presented an interesting clinical study at the United European Gastroenterology (UEG 2017) conference in Barcelona. They equipped an endocytoscopy system with a machine learning algorithm that analyzed colorectal polyps based on live colonoscopic endocytoscopy data. After having been trained with more than 30,000 pictures, the performance of the AI algorithm was measured against the gold standard, i.e. histology. 94 out of 100 malign polyps were identified correctly – in real time. (13)

- **AI-powered surgical robots**

As Kassahun et al have recently pointed out, the few computerized assistants/robots that are already commercially available "possess no intelligence whatsoever and are merely advanced and expensive instruments". They automate or partially automate certain surgical procedures, but will only work in very stable environments, which "severely limits the range of procedures [and] also the performance that can be achieved". (6) Since there is a relevant interaction between surgeons and deformable tissue structures in the majority of surgical interventions, surgical robots of the future will have to be supplemented and integrated with state-of-the-art imaging, self-learning algorithms fed with datasets like the "digital twin", and innovative AR-based guidance tools.

Take robotic laparoscopy in the abdomen. Efforts to automatically steer laparoscopes in this setting date back to the 1990s. (14) The problem has always been the reliability of the tracking system. Short-term predictive analytics can help to come to terms with repetitive movements like breathing or heartbeat, but this will likely not be enough. A recent suggestion included a self-learning approach with a guidance system that collects information on the movement of instruments (and possibly on outcomes) from former interventions for more long-term predictive analytics that could help make tracking systems more reliable. (15)

- **Workflow optimization – the digital workflow twin**

The aim of workflow optimization technologies is to enable a surgeon to perform both standard and complex procedures more quickly, better, and if possible more safely. To get there, process steps at all stages of the surgical patient journey will increasingly be standardized. By adding sensor-based information and AI algorithms, it should be possible to create what could be called a "digital workflow twin" of individual surgical procedures.

Similar to the "digital patient twin", it could have self-learning capabilities by drawing on meticulously recorded former procedures. Using real-time surgical workflow analysis, such a system would "know" the stage of an ongoing surgical intervention and could provide context-sensitive assistance, be it by making certain instruments or tools ready and available, be it by superimposing relevant information or imaging data via an AR or VR system.

Workflow optimization systems with and without AR systems are under development in projects that Siemens Healthineers, together with clinical partners, is currently working on. Ultimately, standardized workflows that feature process intelligence will make surgery more cost-effective and more independent from individual persons and institutions. They will help broaden the scope of interventions an individual doctor feels comfortable to perform and thus contribute to a future of surgery in which specialization will be more along the lines of organs and/or disease entities and less along the lines of technologies.

((Subheading))

Challenges on the Road Ahead

The therapy suites of the future outlined above can provide answers to many of the challenges surgery is facing today. Various components of it are beginning to become visible or – in the case of hybrid ORs and multimodal surgery environments – are already hitting the market. Nevertheless, there are challenges that have to be overcome.

- **Technical and workflow interoperability**

If the worlds of imaging and of surgery are set to grow together, environments will be needed that help interweave the surgical and interventional processes with multimodality imaging capabilities. On a technical level, this means deep integration of data sources of all kind with interventional platforms in order to develop useful applications that transform data into action. This is not easy. In Germany, interoperability projects like OP 4.1 (16) or OR.NET (17) are trying to pave the way towards open-standards-based platforms.

- **Interdisciplinary work and sub-specialization**

Another challenge that will need to be addressed is the way interventional medicine, including surgery, is structured. The vision outlined above implies that surgical and interventional disciplines will begin to come closer or even merge at some point. This will not happen overnight. What we will likely see is an increase in interdisciplinary cooperation at the decision-making stage as well as at the stage of interventions. These processes are ongoing. Trans-catheter aortic valve replacement (TAVI) has made it necessary for heart surgeons and interventional cardiologists/radiologists not only to decide jointly but also to work together table-side in hybrid ORs. Something similar could happen in cancer care, where multidisciplinary tumor boards have been established in many places and big-data-based therapeutic decision making is gaining momentum by the month.

- **Making sense of “big” data**

Finally, using and processing the vast amounts of data that can be expected once every device used and every measure taken becomes a data source should not be underestimated. A key challenge is to structure today’s multi-scale information so that it is extractable and usable in complex models. An extremely precise registration of imaging and surgical devices, for example, is essential to make AR guidance tools really useful to the surgeon or interventional radiologist. And machine learning algorithms, as impressive as some of the recent results may be, have well-described limits when applied to situations they are not trained for.

((Subheading))
Conclusion

((Copy))
The future of surgery is digitally integrated and data-driven. Surgeons and interventional radiologists will not be replaced by technology. Much rather, machines and humans will form a partnership, with the strengths of both adding to each other. Data which is generated before, during, and after surgical interventions will be used to create a digital representation of the patient and her or his “journey” across the institution and beyond. This data-driven approach will change surgery on various levels.

First, it will allow for more informed therapeutic decision making and for better planning of interventions. It will thus personalize surgery and improve outcomes beyond what is possible today. Second, it will help surgeons or interventional radiologists to learn (by simulation) and perform (with the help of peri-operative imaging, guidance tools, and AI-powered robotics) predominantly minimally-invasive procedures of all kind in multi-modality, multi-specialty OR environments.

In the long run, multi-specialty environments, better integration of peri-operative imaging into OR-workflows, and "big"-data-driven improvement of interventions will result in more standardized and at the same time more personalized surgical care. The amount of technological expertise required will decrease. Disciplines will start to merge, and new surgico-interventional sub-specialties will evolve along the lines of organs and diseases rather than along the lines of technologies.

((References))

References

(1) World Cancer Research Fund International. http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/colorectal-cancer-statistics, accessed 23 January 2018

(2) Campbell D. Lack of specialist surgeons putting patients at risk. 31 December 2017. The Observer. Health Policy. https://www.theguardian.com/politics/2017/dec/31/lack-of-specialist-surgeons-putting-patients-at-risk, accessed 24 January 2018

(3) Kurihara H. Acute Care Surgery: A Necessity Across Europe. Are We Ready to Take the Lead? Chirurgia 2017; 112:630-31

(4) Lee TH, Kaiser LS. Turning Value-Based Health Care into a Real Business Model. NEJM Catalyst. 24 October 2016. https://catalyst.nejm.org/turning-value-based-health-care-into-a-real-business-model/, accessed 24 January 2018

(5) Statistisches Bundesamt Germany / DESTATIS, Gesundheitsausgaben nach Leistungsarten 2015, https://www.destatis.de/DE/ZahlenFakten/GesellschaftStaat/Gesundheit/Gesundheitsausgaben/Tabellen/Leistungsarten.html, accessed 22 January 2018

(6) Kassahun Y et al. Surgical Robotics Beyond Enhanced Dexterity Instrumentation. Int J Comput Assist Radiol Surg 2016; 11(4):553-68

(7) Gmeiner M et al. Virtual cerebral aneurysm clipping with real-time haptic force feedback in neurosurgical education. World Neurosurg 2018; doi 10.1016/j.wneu.2018.01.042

(8) Frölich AM et al. 3D Printing of Intracranial Aneurysms Using Fused Deposition Modelling Offers Highly Accurate Replications. Am J Neuroradiol 2016; 37(1):120-4

(9) Brookes L. SOMATOM Sessions. Reconstructing the Heart to Save Children's Lives. 36: 20-23

(10) Holley P. Washington Post. How doctors used virtual reality to save the lives of conjoined twin sisters. 23 July 2017; https://www.washingtonpost.com/news/innovations/wp/2017/07/21/how-doctors-used-virtual-reality-to-save-the-lives-of-conjoined-twin-sisters/?utm_term=.6d20df8b6ecc, accessed 23 January 2018

(11) Fraunhofer-Gesellschaft. AR glasses help surgeons when operating on tumors. 2 November 2017; https://www.fraunhofer.de/en/press/research-news/2017/november/ar-glasses-help-surgeons-when-operating-on-tumors.html, accessed 24 January 2018

(12) Dodd K, Brooks NP. The Development of Augmented Reality to Enhance Minimally Invasive Surgery. Surg Technol Int 2017; pii: sti31/883

(13) Mori Y et al. Diagnostikc yield of AI-assisted endocytoscopy for colorectal polyps: a prospective study. UEG 2017, Barcelona. https://www.ueg.eu/press/releases/ueg-press-release/article/ueg-week-artificial-intelligence-is-this-the-future-of-early-colorectal-cancer-detection/, accessed 24 January 2018
(14) Casals A et al. Automatic guidance of an assistant robot in laparoscopic surgery. Proceedings of the IEEE International Conference on Robotics and Automation (ICRA). 1996; 895-900
(15) Weede O et al. An intelligent and autonomous endoscopic guidance system for minimally invasive surgery. Proceedings of the IEEE International Conference on Robotics and Automation (ICRA). 2011; 5762-8
(16) www.OP41
(17) www.ornet.org, accessed 24 January 2018