

Advanced Technologies and the Future of Medicine and Surgery

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Technology has become a major driver of the future direction of healthcare and surgery. Likewise, the speed of change has accelerated beyond comprehension, with a number of revolutions occurring during a surgeon's career. Being an agent of change or rapidly adapting to change has become the hallmark of the gifted surgeon. The fundamental challenges to a future surgeon are addressed from a technological viewpoint, with emphasis on the impact upon healthcare.

Key Words: Robotics, simulation, virtual reality, advanced technologies, biointelligence

INTRODUCTION

Everything occurs in cycles: revolution, change, adaptation to change, acceptance of the new standard, codifying the new establishment, resistance to further change, revolution ... and the cycle begins again. In healthcare and surgery, this cycle had been occurring about every 100 years, but recently there has been a perceptible acceleration of this cycle. The first revolution for surgery came during the Industrial Age in the mid 1800's with the simultaneous introduction of anesthesia, asepsis, pathology, new instrumentation, and so on. Nearly a hundred years later, in the mid 20th Century as the Information Age was about to begin, surgery was advancing with antibiotics, intravenous fluid and hyperalimentation, radical surgery resections and chemotherapy to name but a few. By the 1990s, laparoscopic (or minimally invasive) surgery emerged and became the standard for many procedures. Information Age technologies, such as video cameras and monitors,

continued the evolution. But technology is accelerating faster than ever, and we are on the threshold of yet another revolution. This is referred to as the BioIntelligence Age,¹ an age of multidisciplinary medicine, which can achieve much more than a single researcher or clinician. The complexities of nature are yielding to inter-disciplinary teams performing multi-disciplinary research - genomics as a combination of biology and information sciences or robotics as a combination for physical (engineering) and information sciences. Much as previous revolutions, this current transformation is occurring because many different technologies are converging to fundamentally change surgery. There is a veritable explosion of new discoveries, such as genomics, micro-electromechanical systems (MEMS), robotics, intelligent systems, molecular biology, etc. The entire healthcare environment and culture are changing at an unprecedented rate of innovation that challenges the practicing physician every day. The change is occurring because of "disruptive technologies", which seemingly completely reverse the fundamental approaches overnight that have been standard for decades. In addition to technology, the surgical environment includes clinical practice, reimbursement, regulatory, education and training, certification, research and clinical trials. Since it is not possible to do justice to all those competing forces, the focus shall be upon the impact of technology, while fully admitting that at any one time, any of the factors plays a dominant role in the life of a physician.

Received August 6, 2008

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CLINICAL PRACTICE

Most practicing physicians have already seen at

least 1 significant revolution during their careers, the radical changes brought by the many discoveries of the Information Age. One of the most dramatic has been the shift to minimal access surgery (laparoscopic, endoscopic, etc). The surgeon of the near future will be trying to decide whether it will be necessary to train and practice with robotic surgical systems. Surgeons already have multiple options-open surgery, laparoscopic, endoluminal, endovascular, percutaneous and so on. The answer to robotic surgery is an unequivocal yes.

Current view of robotic surgery is that the robot is used to enhance the performance of the surgeon -either through more precise motions or providing access to very restricted places. While this is true, the real value of robotics is that it brings surgery completely into the Information Age. Open surgery is Industrial Age, with directly looking and feeling the organs and directly moving the tips of the instruments. Laparoscopic surgery is a transition: half in the Industrial Age - still directly moving instrument tips - and half in the Information Age - looking at the monitor with the electronic image (information) of the organs, not looking at the organs themselves. Robotics make the transition to the Information Age complete by looking at information (the monitor) and manipulating information (hand motions send electronic signals which control the tip of the instruments). It is no longer blood and guts, but it is bits and bytes.

This is a profound revolution because it is now possible to integrate the entire surgical care of a patient with information science right at the surgical console of a robotic surgery system. From the console, the surgeon can perform open surgery or laparoscopic surgery; can remotely operate with telesurgery; can rehearse a specific surgical procedure on a patient-specific 3-dimensional image derived from the patient's CT scan; can integrate the image during surgery with image-guided surgery to give the surgeon "x-ray vision"; and can practice and train on the console using virtual reality surgical simulation. Thus, from pre-operative planning to specific surgical procedure rehearsal, to open or laparoscopic or interventional procedure, to training (for new procedures) - all components become a single, seamless con-

tinuity for patient care. Although not yet implemented, the surgeon's hand motions can be recorded and archived as proof of proficiency on a continual basis (instead of periodic recertification).

Next generation robotic systems will also incorporate automatic tool changers (instead of scrub nurse to change the instruments) and automatic supply dispensers (instead of the circulating nurse) for suture, gauze, etc. Soon the surgeon will become a solo-surgeon in the truest sense of the word, controlling the entire operation from the console. Because there will be no people assisting the robot (the robotic systems together are called a "robotic cell"), the surgeon can sit at the console just outside of the OR (looking through a glass window) and there will be no people in the OR. Every time a tool is changed or a supply is dispensed, three actions immediately occur. The patient is billed, the tool or supply is restocked, and an order is sent to inventory control to order a new tool or supply - all within 50 msec with 99.99% accuracy (which is the current industry standard). The result is clearly a dramatic improvement in performance and efficiency, as well as cost saving.

Another change in robotic systems is that they are incorporating new types of tools. By using MEMS technology, tiny sensors can be inserted into instruments to measure pressure, forces, etc. to provide surgeons with the sense of touch,² not only mimicking what the surgeon would actually feel, but also providing delicate touch beyond what is possible with the human fingertip.

There will also be an entirely new tool-set for surgeons of the future. Although the scalpel will still be required, many other modalities will be used. The trend is from mechanical instruments (of the Industrial Age) to energy directed instruments (of the Information Age). Surgeons have begun using lasers, and next generation systems will employ high intensity focused ultrasound (HIFU), thermal directed systems (brachytherapy and cryo therapy), microwave instruments and femtosecond lasers. These systems will require a complete rethinking of what it means to be a surgeon. HIFU concentrates two beams of ultrasound at a distance, in this case inside the body. Early clinical trials are being conducted in breast,

prostate and liver tumors to completely coagulate or vaporize them from external HIFU system. In addition, animal trials have been successful in stopping bleeding from the liver and spleen transcutaneously.³ Thus, surgeons will have to begin thinking about performing surgical procedures without entering the body or using a scalpel. There is also significant progress with femtosecond lasers. These new lasers are totally different from those used today - they release their energy in 10 - 15 seconds ultra-short pulses. The result is that it is possible to create a hole in the cell membrane without injury to the cell. This allows optical tweezers (another form of laser) to enter the cell and manipulate individual organelles, such as Golgi bodies or mitochondria. Additional progress is being made on entering the nucleus and directly manipulating the DNA. The significance is that surgeons of the future may not be removing organs or tissues, but rather using a microscope and laser to rearrange the DNA inside the cell to change the fundamental biology - this is referred to as biosurgery.⁴

EMERGING TECHNOLOGIES

The craft of surgery has revolved around correcting the structural and anatomic consequences of diseases. Malignant growths require the removal of entire organs or tissues, and even radical resection of adjacent areas. However, there is always the conflict of goals between removing enough tissue and conserving enough organ function. Transplantation has been a growing discipline because of the opportunity to remove entire organs and then replace their function with a donated organ. However, the supply is limited and rejection is a constant problem. Tissue engineering artificial organs has progressed to a level where a small number of organs are being synthetically grown. Atala et al. now have a 5 year follow up of synthetically grown urinary bladders from the patient's own stem cells that have been implanted and are functioning normally.⁵ These and other approaches by different researchers point to a time in the near future when it will be possible to grow a new organ from a patient's own stem cells. If this becomes the case, then it is theoretically possible that for nearly every

disease, the surgeon will simply remove the patient's diseased organ and replace it with a new one (grown from the patient's own stem cells), without the fear of rejection. Therefore, it may be that the future surgeon will perform only one operation for each organ system, no matter what the disease - remove the old one and replace it with a new one. This will dramatically impact the way the surgeon will practice, either by having a single operation for all patients in a practice (in the case of specialists) or a return of preeminence of general surgery, where every surgeon practice will consist of a few operations to take care of all the major organs systems.

The replacement of human organs or functions has also been addressed by the use of prostheses, however, with the exception of the cardiac pacemaker, all prostheses have been inert and "dumb"; that is, they do not respond to the changing conditions in the body. Once implanted, artificial hips keep their position, and over time either wear out or cause problems such as loosening or damage to surrounding structures. Now, prostheses are becoming "smart", with MEMS sensors to detect changes and actuators to adjust prostheses. This same feedback is being programmed into implantable devices, such as an insulin pump for diabetes.⁶ Ophthalmologists are implanting the first generation of artificial retinas into patients.⁷ This implies a future where surgeons will be asked to implant more artificial "parts", to either replace or enhance human function.

EDUCATION AND TRAINING

Until the beginning of the 20th century, nearly all training of physicians was done by passing down conventional knowledge from previous physicians - this was not based upon any scientific principles, but rather by ritual and tradition. In 1908, Nicholas Senn was the first surgeon to criticize this practice,⁸ and bring forward the scientific principles of using observation and experience for education and training. Although this mentoring process continued, it was strict scientific principles, gained through experimentation and evidence, which formed the basis for surgical education and training. The Halstedian method of apprenticeship

has become the model for surgical training, based upon these rigorously applied scientific principles. However, this model is somewhat capricious, with the determination of competency of the resident being at the discretion of the supervising faculty and department chairman. With the exception of the written examination of the resident's knowledge, there are no objective measures of performance.

There is a new paradigm emerging in the field of surgical education. Objective measures are the new basis for training and assessing residents. Some of this change is being driven by new training methods, such as the Objective Structured Clinical Exam (OSCE) and the Objective Structured Assessment of Technical Skills (OSATS).⁹ Other pressure is coming from the need for objective demonstration of competency. One technology that is fueling this change is the use of simulators, which can accurately measure hand motions and quantitatively report psychomotor skills. This ability to measure is driving the most fundamental change of all - that of training for a given period of time to the new paradigm of setting of criteria which the resident must achieve before progressing to the next level: the so called criterion- or proficiency-based training. In 2002, Seymour et al. demonstrated unequivocally that residents that train on a simulator perform better in the operating room, taking less time and making less errors.¹⁰ Thus, the time is near when every resident will have to train on a simulator to reach a certain level; those who have better skills will achieve it faster, and those who are slower will take longer. However, no resident will operate on a patient until they have passed the simulator by achieving a high level of technical proficiency. No longer will residents be permitted to "practice" on patients. This will eventually spread to all physicians, especially in learning new procedures such as laparoscopy or robotics. A week-end course may or may not be long enough-for the gifted surgeon may be able to demonstrate proficiency in that short period of time, while others may need further training. For the long term maintenance of surgical privileges, it will be required to be recertified, including technical skills, on a simulator. Eventually, each surgical procedure will be objectively assessed, as a

method to continuously assure maintenance of surgical skills. This is not unlike the requirement for airline pilots today. Thus, surgical simulation and continuous assessment of performance to an objective level of proficiency will become the new standard for training, assessment, credentialing and practice.

RESEARCH FOR CLINICAL TRIALS

Many practicing clinical physicians engage in clinical research, whether for a new medication, a new surgical procedure or other innovation. The simple reporting of a series of cases to the literature has yielded to randomized double-blind clinical trial, adding a new level of scientific rigor to the research and reporting of new therapies. This requirement for "evidence-based medicine" is significantly increasing the quality of research and improving overall patient care; however, the time and cost involved in conducting such rigorous trials are enormous, and has delayed many new therapeutic options. In addition, it is not possible to know the final outcomes in many instances, such as cancer, where it takes 20 years or more until the long term results (including possible complications) are known. However, other industries have been using modeling and simulation to predict outcomes into the future. Theoretically, the day will come when a virtual clinical trial will use predictive simulation of a therapy on a million (virtual) patients over fifty years - on one week of supercomputer time. Accuracy of such predictions will be determined by how accurate the models of humans can become, from the genetic and cellular all the way to the organ and whole body level. Today, drug companies are using "rational drug design" by computer programs, then doing virtual testing and evaluation of products based upon the pharmacologic properties. This is the first step toward doing "predictive simulation" for clinical trials. The advantage for surgeons is that it will be possible to provide much more accurate information on the efficacy of drugs or surgical procedures than is available today as well as to customize the therapy for each patient.

MORAL AND ETHICAL CHALLENGES

A number of these new technologies will be raising moral and ethical questions that have never been considered before. Success with nanotechnology will be forthcoming rather soon, with a significant amount of speculation on the role of "nano-machines" - tiny systems that are injected into the blood stream or other areas of the body, for diagnostic or therapeutic purposes. The long term effect of such systems will not be known for decades to come, however, there will be pressure to begin inserting them. Should surgeons comply with their patients' requests, even in the face of unconvincing evidence of efficacy- or if efficacy is shown but long term results are not known? Robotics is moving forward deliberately, but a new dimension will likely be soon available - femtosecond lasers to operate within the cell and even upon the nucleus and DNA. Although it seems reasonable to remove a gene that leads to a congenital defect, should surgeons be tinkering with genes directly, and leading to the purposeful genetic design of children for characteristics such as eye or hair color? Or perhaps provide genetic material, such as the sequence which allows the pit viper snake to use infra-red vision to see in the dark, to have characteristics that humans do not naturally have? With smart prostheses and artificial organs, it may be possible to extend life beyond the average life span for humans - to 150 or 200 years. What would the consequences to society be of such a prolonged lifespan, and will a person retire at age 65 with 90 to 100 years of "retirement". The results of the research in today's laboratories are providing potential to not only change an individual or even society, but what it means to be human. If 90% of our body parts are replaced with artificial organs or prostheses, will we still be human - is it the flesh and blood which we were born with to determine whether we are "human"? While these ethical questions have previously been mere speculations of fantasy, the scientific underpinnings are being created in the laboratory today, and the students we are training today will have to answer the above questions- and more. How can we prepare for such a future challenge?

CONCLUSION

This is a time in the history of medicine when truly revolutionary change is occurring, and at a rate that has never been seen before. While it is a historic fact that each generation of physicians greatly surpasses the accomplishments of the preceding generation, the order of magnitude of change that is occurring now is unprecedented. The surgeon of the future will need to adapt and be able to learn a wider range of the new technologies quicker than ever before. The amount of information that needs to be learned will increase. The paradigm of training is changing from simple mentorship to proficiency-based, quantifiable assessment, and surgeons will be held to even higher standards than today. Yet, the extra amount of work required to achieve these new standards is essential in order to be worthy of the enormous responsibilities that the changes of the coming generation will bring - the surgeons of the future will not only hold the lives of their individual patients in their hands, but may be responsible for the future of what it means to be human.

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