Robotics and Computational Surgery.

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The process of surgery is exquisitely personal. One human being, the patient, with a body in need of an intervention – a repair of an injured or failing part, removal of an infected or invasive element, or at times a replacement of a failed organ - seeks the help of another, a skilled and knowledgeable stranger, a surgeon. That surgeon uses his or her hands and tools, coupled to skills, knowledge, wisdom and experience, to affect the remedy, the invasive operation with inherent risks and benefits. That patient sleeps silently on a metal table in a room filled with other capable strangers - nurses, technicians, anesthetists - all gathered as a team to perform the operation. The human trust in this experience is remarkable, both for the surgeon who inherently causes harm with the intervention and relies on the patient's body to heal, and for the patient. This would seem to be the most uniquely of human expressions of trust.

The experience of surgery for the surgeon has long included a sense of tactile contact with the patient, the warmth of human tissue, a sure sign of life. Surgeon experience based on a decade of initial training, knowledge of anatomy, physiology and disease states, guides the hands of the surgeon. Increasingly, however, mechanical devices span the space between surgeon hand and the patient's body, leaving only visual clues to guide a procedure at the cost of tactile guidance and connection. In fact, the very human process of surgery over the last two decades is now typically augmented by new technologies including computer aided surgery, imaging technology to allow augmented visualization, and devices to enable precision of the surgical movements at remote sites. This interfacing technology is utilized at the cost of the surgeon's tactile contact with the patient's body. The impact on this technology interface on the fundamental human connection between patient and surgeon is not yet known. Will surgeons still feel the bond of human connection with their patients when a machine is placed between them?

Further, this bridging technology introduces the possibility of mechanical or computational failure necessitating that surgeons not only be facile with the modern interface technology, but also a master in conventional methods, perhaps an overly ambitious expectation of surgeon competency. We must also address the simple fact that each new technology and procedure inherently brings a period of disruption: a need to acquire a new skill or incorporate a new technology safely without patient harm, for a surgeon to advance through the learning curve of adoption into fluent competent practice. Where do surgeons train in new technologies are how do we achieve this fluency of skill in the actual practice environment of surgery? How do our patients knowingly participate in that process of safe adoption?

In this monograph we will consider the current state of robotic technologies and computational methods in surgery from the ethical perspective. First, we will define current robotic technologies in surgery and the risks and benefits they present to patients and their impact on the patient: surgeon relationship. We will examine the current gaps in the process of robotic surgery training necessitated by adoption of this or any disruptive innovative technology. We will then consider the challenges to autonomous robotic platforms in the setting of highly variable human anatomy and physiology, and the limitations of present technologies to reregister during procedural interventions. How do these factors inform the development of robotic surgery platforms capable of autonomous performance? In what settings would autonomous function – absent realtime surgeon engagement – be justifiable?

Last, we will consider the evolving body of research known as computational surgery. This field uses computational methods, coupled to our understanding of human biology and evolving technologies in computer enabled hard sciences: imaging, robotics, modeling, to enhance the process of surgery. The field may enable predictive modeling of surgical decease and outcomes to inform surgeon and patient decision making and may be fundamental to development of new technologies that will deliver greater precision and predictability to the very human process of surgery.

What is robotic in surgery? Present and future considerations.

The public perception of robotics presumes autonomous function: a fully programmed device that is capable of independently navigating a task based on accumulated data sets and precise and adaptable programming. As a surgeon, I am pleased to dispel this notion in the current practice of surgery. So, called robotic surgery, in current form, is not performed by an autonomous robotic system, but rather is a computer enabled system which provides an intervening set of technologies to manipulate surgical tools under the direct control of a surgeon. The so called robotic surgery systems in current practice are remote control facilitating systems. The “robotic” surgery systems are in wide use in many surgical disciplines in high income nations around the globe, including chest, abdominal, pelvic, oncologic, orthopedic, neurological and ophthalmologic surgery. In every application, the robotic system facilitates the principles of precision surgery: minimal access sites, augmented visualization including magnification, precision of motion and procedural manipulation in areas not accessible to human hands armed with conventional instruments, and in some cases image guidance to sites of disease not visible to surface visualization. While the surgeon may be seated at a console adjacent to the patient and may touch the patient only by these remotely manipulated devices, the surgeon is fundamentally the decision maker and the performer of the procedure. Patient’s confusion over this modality is routinely noted by surgeons who have embraced robotic technologies in their practices, who report that their patients often inquire as to whether the robot or the surgeon herself is preforming the procedure!

The ethical challenges inherent in current platform robotic surgery are not, however, insignificant. At the most fundamental level, surgery is a human to human agreement of an exceptional sort. A surgeon commits to deliver their skills to a patient with the exclusive goal of improving health. Unlike many other forms of health care agreements between physicians and patients, surgery intrinsically comes with patient harm – wounds that must heal, inherent risk of unpreventable complications, and even pain. When placing a technology between surgeon hand and patient body, one relinquishes a certain degree of control to technology. Both parties must agree that the benefits of this technology, and reliability of the technology, is a positive factor in the risk associated with any procedure. IN skilled and experienced hands and in well-resourced environments, reliability of robotic surgery systems and surgeon performance justifies this insertion of an enabling technology for certain procedures. However, an enabling technology inherently separates the surgeon from the tactile connection with the patient. This separation, despite professional commitments, has the potential to bring as emotional separation from responsibly for the patient’s outcome. Devices may, although rarely, fail. Surgeons trained in the recent past have benefited from extensive periods of training encompassing a broad scope of patient contact: their hand know the warmth and softness of the human body and, I believe, embrace their very personal responsibility for the patient's welfare. One can envision, however, that with ever expanding development of remote control technologies, coupled to imaging-based diagnostics which diminish the requirement for physical examination and human discussion, that surgeons may be challenged to affirm that personal bond and responsibly that a surgeon must feel for the surgeries they perform. It will be an ethical challenge to ensure that going forward as technology separates a surgeon from his or her patients, preservation of the responsibility that surgeons feel for their patients, that human bond, is preserved as a highest value.

Another confounding element of current robotic surgery is the challenge of safe adoption and dissemination of the technology. Remote control, computer enabled surgery is a certain component of the future of surgery. Such platforms will be increasingly available to surgeons and healthcare systems as the manufacturers develop next generation, less costly systems. Each innovative technology however, comes with potential disruption in surgeon performance. Every new procedure, every technology must be acquired with training pathways that recognize the imperative of protecting patients from the harm of surgeon learning curves. Use of simulation non-human based training, training to proficiency prior to use in patients, proctoring of surgeons during early adoption periods, and a commitment to track outcomes of procedures in the patients who have been treated with robotic technologies is essential. Such infrastructure, throughout the developed world, remains underdeveloped as evidenced by the historical and ongoing patterns of patient harm associated with premature adoption of novel technologies over the last two decades. The extraordinary pace of technology advancement has on occasion fueled patient harm in the rush to adopt in all disciplines of surgery. We have not yet developed the requisite educational infrastructure and processes for oversight to ensure consistent patient safety associated with disruptive technology dissemination.

Interestingly, premature adoption is often stimulated by a misconceived perception of the public that novel surgical technologies are intrinsically "better"; driving patients to fact seek out providers who are early adopters, a process that in the past has led to premature adoption of novel technologies before surgeon training and clinical infrastructure was sufficient for patient safety. We as members of the surgical community, bear an ethical imperative to ensure that surgeons and systems who embrace new technologies, including robotic systems, have developed processes and infrastructure to support surgeon retooling and safe adoption practices to minimize the risk of patient harm and to optimize the opportunity for patient benefit, regardless of financial drivers.

In the United States, until recently, the responsibility for training surgeons in practice in new technologies has often been borne by the technology industry that manufactures the new robotic technology system platforms. While the effort by industry to fully and adequately train the adopters of new commercial technology have been thoughtful, the conflict of pressure for early adoption to ensure business success, has not uniformly resulted in adequate training prior to utilization of robotic platforms in human surgery. However, in actuality, it is the responsibility of surgeons to ensure that they are skilled and proficient prior to using robotic platforms in their surgical practices, not the role of industry to ensure that capability. Further, it is the responsibility of the healthcare system - the surgeons, the hospitals where we work, the purchasers of health care, and industry - to ensure that adequate retooling infrastructure is available to ensure safe dissemination of robotic technologies when such innovations are ready for dissemination.

We have developed a prototype facility, the Houston Methodist Institute for Technology, Innovation and Education (MITIE) in Houston Texas which has incorporated sophisticated simulation-based training platforms to deliver non-patient based simulation training in advanced surgical technologies of precision surgery, including robotic surgery, laparoscopic and thoracoscopic surgery and other disciplines. To date we have hosted over 13,000 surgeons in retooling technologies at our institute, with the goal of ensuring that procedural training is sufficient prior to using these technologies in our operating rooms for patient procedures. Ensuring safe adoption of any new technology that bridges the connection between human surgeon and patient is a fundamental ethical priority.

Autonomous Robotic Systems for Surgery

Autonomous robotic surgical systems are not yet utilized in patient care, although the technology to do so, is strikingly near. Advances in imaging, image analysis, data acquisition and sorting, all facilitate the application of machine learning to inform procedural performance in some situations. Machine learning from complex data sets, in the setting of surgical interventions data sets drawn from surface or body imaging, can lead to formation of knowledge sets that can lead to decision making pathways for autonomous robotic systems. From the procedural perspective, predictable patterns of disease expression – irregularities of surface landmarks as in cutaneous malignancies or luminal findings in the gastrointestinal or pulmonary systems, can, in theory, be assembled to design and execute an autonomous procedural intervention. Such innervations on small scale, immobile, and surface-based lesions is conceivable and approaching deliverability by certain technology industries currently. The risk of the innervations is "limited" in these simpler surface interventions and the boundaries of variability are low in these simpler examples of surgery.

However, expansion of autonomous robotic systems to areas of greater procedural complexity remains a daunting technological challenge, and further ethical challenge. Human anatomy and physiology is remarkably and wonderfully consistent, yet highly variable in when expressed in each human form. Disease states further deform the predictability of human structures. This deformity is also highly mutable during the actual performance of a procedure itself, as elements of tissue are mobilized, removed, or restructured, making machine learning algorithms, in current context, far too complex for autonomous robotic systems. While machine learning may foster uniform and predictable surgical interventions, a human-in-the loop, to reinterpret and interpret the inherent complexity related to variability and contemporaneous change in the patient's condition, remains essential for complex procedures in surgery.

Conditions where autonomous robotic systems could be justifiable from the ethical perspective include those settings in which harm to the surgeon and health care team is intrinsically potentially life-threatening or logicalltially impossible. Examples include care of battle zone injured soldiers, remote inaccessible environments including space exploration, or in disease conditions where risk of contamination to the health care team is deemed exceptionally high risk. Regrettably the life-threatening conditions in these zones are often complex conditions, and current robotic surgery systems, even those with human remote-control interfaces, remain in early development stages.

What is computational surgery?

Computational surgery is a recently articulated discipline that brings the tools of the computational sciences, mathematics and computer science, to the process of surgery. The scope of investigation of this discipline, in part, includes a) modeling and simulation of biological processes and procedural interventions to predict surgical outcomes; b) real-time augmented visualization to enhance surgical procedures to foster precision surgery; c) multi-scale modeling of surgical disease with integration of patient –specific data in procedural planning, and d) design of interventional and tracking devices to inform real-time assessment of surgeon performance. Computational surgery as a discipline is central to the development of precision surgery.

Precision surgery is the modern embodiment of the practice of the interventional procedures which we collectively refer to as surgery. Precision surgery thematically advances the process of surgery based on four characteristics: minimal access approaches (keyhole incisions or natural orifices) are utilized to approach the targeted areas of the body in need of the procedure; image guidance is utilized to foster a more focused and direct approach to the diseased site; augmented visualization is utilized to enhance visibility using magnification, remote camera approaches or other technologies; and computer-enabled as in the use of "robotic" technologies which enable a surgeon to perform a a procedure with remotely controlled tools coupled to augmented visualization of the operative field. The technological capabilities of data capture, image processing, and ultimately machine learning coupled to technical execution of procedural skills are fundamental to the development of autonomous robotic surgery.

In current form, precision surgery is evidenced as surgery encompassing the fields of laparoscopic surgery, endoluminal and endoscopic surgery, thoracoscopic surgery, arthroscopic and minimal access orthopedic surgery and image guided neurosurgery. The computer enabled platform of the commercially available so called robotic surgery systems are the most recent addition to the armamentarium of precision surgery technologies.

In bringing the tools of computational science to the process of surgery, several areas of research that may ultimately fuel autonomous robotic systems are operative. These include augmented visualization and digital image capture for virtual reality procedural guidance, incorporation of preprocedural imaging into the operating room for real time guidance for resection, ablation or placement of devices, and mathematical modeling and real time calculation of the "invisible" such as energy delivery or sheer stress to guide operative interventions in vascular or ablative procedures. Further, mathematical modeling of tissue forces, spatial derangements associated with surgery, and the impact of the healing process may inform surgeon and patient decision making in procedures such as breast cancer surgery, vascular reconstruction for atherosclerotic or cardiac disease, and other aspects of soft tissue modeling to repair defects.

Digital data in medical imaging has revolutionized the ability to both craft patient specific interventions and to predict the outcomes of interventions. Prediction of outcome is both a blessing and a curse. A prediction of success, at times engenders false hope; alternatively, even the predictably anticipated poor outcome of a high risk patient, on certain occasion fails to deliver that adverse fate in real life. As all predictions are based on models from accumulated data sets, prediction is inherently limited by the reliability and strength of that primary data set.   Given the complexity and variability of the human body, prediction of the results of procedural interventions are often not as accurate as one would wish for a specific induvial patient.

Nonetheless, as with pharmacological therapies for malignancy, we have learned that greater incorporation of accurate patient specific data can inform therapeutic choices and offer superior methods for prediction of outcome of therapeutic choices. We have learned that precision medicine, the use of molecularly targeted agents for treatment of disease, has found its greatest success when coupled to patient specific markers rather than disease specific markers: e.g. only breast cancer patients with overexpression of the EGF receptor can respond to Her2 targeted therapy. Once we can measure patient specific markers, we can offer a validated precision approach to therapy.

The benefits of precision modeling in surgery is substantially different from the clearly beneficial role of offering precise therapy for a known molecular mapped malignancy. In computational surgery modeling, the objective is to provide guiding predication of outcome to inform the patient of possible outcomes – what type of success can one anticipate from a planned surgical procedrue? However, given the complexity of factors that contribute to the structural outcomes of surgery, the mathematical modeling is complex, and our data sets to date are limited.

An example of the application of computational modeling to a surgical condition is provided in the disease of breast cancer. Women diagnosed with breast cancer face the need to make many choices during the care. Many of these choices are informed by data; the molecular features of their tumor, stage of disease, underlying medical conditions, family history and genetic risk. However, one primary choice to be made is whether to pursue breast conserving therapy (BCT) with the procedure of breast lumpectomy coupled to radiation treatment of the breast or to undergo surgical removal of the entire breast – a total mastectomy. Many factors, particularly the choice of woman, in this most common solid malignancy of women, influence this decision, but one element that remains a challenge is predicting the outcome of the procedure of breast lumpectomy and radiation on the physical outcome of these therapies. While it is well established that for patients with early stage breast cancer that breast conserving therapy is equivalent to total mastectomy to cure the woman's breast cancer, we do not have reliable models to predict the impact of BCT on the cosmesis of the breast. The goal of breast conserving therapy is to both spare the woman the deforming consequences of mastectomy and a major surgery, but also to preserve a breast with satisfactory cosmetic result to the patient to feel satisfied and whole after her treatment.

Using breast imaging data, coupled to virtual breast lumpectomy for tumor removal, and mathematical multiscale modeling of the healing process, one can build preliminary predictive models to describe the surface contour of the breast after completing the process of breast conserving therapy. While 70% of women will have an excellent cosmetic result with excellent arm mobility and comfort, up to 30 percent of women may have less satisfactory results. The goal of predictive modeling is to inform the patient of anticipated results to aide the patient with decision making relative to her surgical choice for treatment of her breast cancer. Multiscale modeling of mechanical and tissue factors, stress, and gravity are operative in this complex model as demonstrated in this series of figures. In a preliminary cohort of patients, we have shown that this modeling can be a reliable predictive tool. One can envision that the routine application of data capture and machine learning could amplify the validity of these models in the wide spectrum of patients with breast conserving therapy, and lead to development of autonomous decision making for procedural planning to optimize results. Coupled to devices, human guided or autonomous robotic technologies, a predictable lumpectomy based on patient specific imaging, virtual lumpectomy surgery with modeled healing, the procedure of breast conserving therapy may ultimately be completed with predictable and satisfactory results. Such information would allow a patient to make a choice on accurate prediction rather that the current status in which choices are based on opinion, fear, or false optimism. Patient specific prediction based on complex biologic processes, however challenging, is a potentially achievable and laudable goal.

Conclusion: Fundamentally, surgery is an exquisitely human exchange – one highly trained and experienced surgeon using their skill and knowledge to benefit the health of another by performing a procedure on the body of another, the patient. Both patient and surgeon take on risk; the patient who consents to the service of the surgeon, and the surgeon who commits to using their hands, however enabled by technology, to aid the patient. Current advances in surgical technology increasingly place technologies between the surgeon and the patient, and development of autonomous robotic technologies to supplant the human factor are likely in our future.

We must recognize that technology failures are inevitable, and such failures harm not only the patient but also cause emotional harm to the surgeon. Technology interfaces that enter the space between this human bond must be crafted and deployed in a manner that places the highest priority on patient safety and the moral principle and practice of serving as a physician. Advances in computational methods, including creation of predictive models of surgical diseases and outcomes of procedures, may offer opportunities to inform and improve the process of surgery in the years ahead.

The introduction of autonomous robotic technologies must be fully informed by the goal of ensuring patient health, and yet, recognize the variably of the human body. Given this complexity, one cannot justify removing the human factor from surgical procedures on human patients, except in exceptional circumstances. Future developments will surely overcome current limitations of machine learning and technology enabled autonomous robotic surgical platforms. However, even then we must ensure that the contract between surgeons as healers and their patients are based on compassion, service, and personal responsibility for their wellbeing and the outcomes of their care.