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ROBOTIC AORTIC SURGERY

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Abstract

Surgical robotics was first utilized to facilitate neurosurgical biopsies in 1985, and it has since found application in orthopedics, urology, gynecology, and cardiothoracic, general, and vascular surgery.[1] Surgical assistance systems provide intelligent, versatile tools that augment the physician's ability to treat patients by eliminating hand tremor and enabling dexterous operation inside the patient's body. Surgical robotics systems have enabled surgeons to treat otherwise untreatable conditions while also reducing morbidity and error rates, shortening operative times, reducing radiation exposure, and improving overall workflow.[2] These capabilities have begun to be realized in two important realms of aortic vascular surgery, namely, flexible robotics for exclusion of complex aortic aneurysms using branched endografts, and robot-assisted laparoscopic aortic surgery for occlusive and aneurysmal disease.

Flexible Robotics

Diagnostic and interventional catheters are currently limited by the ability to simply rotate around one axis. One depends on a variety of preformed catheters to fit non-uniform vascular anatomy. Therefore, catheters are often inadequate when performing complex interventions, and surgeons are forced to use a multitude of catheters to get to the site of the intended intervention. Having a catheter with which movement could be controlled in multiple planes would allow for greater precision, confidence, and safety as the surgeon proceeds through the often complex arterial system. Robot-assisted surgery provides such a catheter, enabling fine, predictable, and consistent movements that ultimately increase procedural speed and reliability.

In 2007, Hansen Medical, Inc., the lead developer of robotic technology for endovascular interventions, received FDA approval of their Sensei® Robotic Catheter System for use in cardiac ablation procedures. Vascular surgeons began investigating the value of using the robot to assist in placing endovascular grafts in the aorta with the goals of improving performance, reducing operative time, and overcoming prohibitive obstacles when managing thoracoabdominal aneurysms. The most extensive non-clinical experience in endovascular robotics comes out of work from St. Mary's/Imperial College in London, which demonstrated clear benefits in cannulation times, tool movements, accuracy in cannulation, and performance scores over conventional methods when performing complex endovascular procedures in silicone aortic models.[3, 4] They have also shown clear advantages in terms of minimizing radiation exposure for the operator, with cannulation times reduced from over 17 minutes for conventional methods to less than 3 minutes using the robotic system; this data mirrors studies of ablation for atrial fibrillation, which showed clear reduction in procedure times as well.[5] Valderrabano has also shown decreased radiation times for ablation cases, down to only 5 minutes of fluoroscopy time.[6] In unpublished data, we have recently demonstrated the technical feasibility of robot-assisted antegrade in-situ fenestration of a stent grafting using the Artisan™ catheter (Figure 1), Hansen's first-generation endovascular catheter system, in pigs, which has also previously been shown.[7] Although this technique is far from perfected, it can potentially provide an "off-the-shelf" solution to complex aortic aneurysms. Furthermore, it can provide a solution for troubleshooting when a visceral/renal branch has inadvertently been covered.

Figure 1. The Sensei Robotic Catheter System and Artisan™ Control Catheter from Hansen Medical.

However, the Artisan catheter has notable limitations in practical utility. The 14-French (Fr) sheath is too large for use in a variety of vascular beds, including the infrainguinal, renal, and visceral arteries. The reduced range of motion (1-way fixed bend on sheath, 4-way variable on leader) limits movement of the catheter to a single plane. As such, Hansen has developed a vascular prototype catheter. This new vascular catheter is 9 Fr (outer diameter), while a 6-Fr inner diameter for the sheath accommodates 6-Fr third-party devices. It has steerable inner and outer guidable catheters enabling 6 degrees of freedom and further enhances tactile and visual depiction of tissue deformation. Early work once again shows improvement in the learning curve, and improved cannulation times should further reduce radiation exposure to the patient and operator.

An experienced vascular surgeon and interventional radiologist have compared cannulation times of contralateral iliac, renal, and superior mesenteric arteries, demonstrating improved cannulation times (data submitted for publication). Looking at the incidence of vessel injury in animal models, we have shown superiority of the robotic cannulations with less damage to vessel walls (only 1 event) and intimal thrombus formation (no events) as compared to the manual arm.[8] We anticipate that as these systems continue to advance, the flexible catheters will further enable operators to

Figure 2. The Intuitive Surgical da Vinci® System.

navigate difficult angles from femoral access points, improve off-wall navigation, and enable successful in-situ fenestration of stent grafts in humans.

Robotic-Assisted Laparoscopic Surgery

Throughout surgical disciplines, the advantages of minimally invasive surgery have been demonstrated and have, in many cases, become the standard (Tables 1, 2). However, the particular difficulty of performing vascular anastomoses has heretofore proved prohibitive for accomplishing timely and safe minimally invasive operations for patients requiring aortic repair. In 1995, Intuitive Surgical, Inc. created the computer-enhanced robotic system known today as the da Vinci Surgical System (Figure 2). The goal of this device was to create familiar hand movements from open surgery while performing operations via a minimally invasive approach. The advent of robotics in cardiovascular surgery made a minimally invasive approach to aortic surgery, a technically challenging procedure, more practicable. Key to the success of the robotic approach was EndoWrist® (Intuitive Surgical, Inc., Sunnyvale, CA). EndoWrist® attachments for da Vinci are modeled after the human wrist, which allows full range of motion, facilitates hand-eye coordination similar to the human brain, and provides dual-channel (3-dimensional) vision necessary for the more dexterous maneuvers required in creating vascular anastomoses.[9]

Animal studies confirmed the benefits of the da Vinci Surgical System by showing that the time required to perform an anastomosis, clamp time, and total operative times were reduced.[5, 9, 10] Wisselink and colleagues pioneered robotic-assisted surgical repair of aortic occlusive disease, publishing reports of the first two cases performed in humans and demonstrating feasibility of the operation.[11] They went on to publish promising results with respect to the steep learning curve of the operation in the initial series of 17 patients, demonstrating a 50% reduction in clamp times for the later 9 patients as compared with the initial 8 patients.[12]

Stadler and colleagues, the group having the largest experience with robot-assisted laparoscopic aortoiliac procedures, recently published results from a series of 150 patients. They reported a 97.3% rate of successful completion, a 2.7% complication rate, and shortened anastomosis and clamp times (27 and 39 minutes, respectively) as compared to a purely laparoscopic approach.[13] Several groups in Europe have now demonstrated not only the feasibility of robot-assisted aortic reconstruction but also safety and shortened anastomosis times.[11-14] Our group has initiated an Investigational Device Exemption (IDE) trial, which we hope will pave the way for introducing robotic vascular surgery in the United States. We have developed and participated in a training program that begins with work on inanimate models, thereafter advancing to pig models and ultimately cadavers. We have shown the effectiveness of this training insofar as having a great degree of preparedness for the cadaver labs, where we were able to perform aortobifemoral bypasses within 2 hours. Inanimate and team training are probably the two elements that played the greatest role in our training paradigm. With the direct involvement and supervision of Dr. Petr Stadler, we plan to perform the first robot-assisted repair of aortic disease in humans in the United States later this year.

Table 1. Advantages and disadvantages of conventional laparoscopic surgery and robot-assisted surgery using a master/slave device (adapted from Lanfranco et al.).[14]

	Advantages	Disadvantages
Conventional laparoscopic surgery	• well-developed technology • affordable and ubiquitous • proven efficacy	• loss of touch sensation • loss of 3D visualization • compromised dexterity • limited degrees of motion • fulcrum effect • amplification of physiologic tremors
Robot-assisted surgery	• 3D visualization • improved dexterity • seven degrees of freedom • elimination of fulcrum effect • elimination of physiologic tremors • ability to scale motions • micro-anastomoses possible • telesurgery possible • ergonomic position	• absence of touch sensation • expensive • high start-up cost • may require extra staff to operate • new technology • unproven benefit • requires square footage (large)

Table 2. Advantages and disadvantages of robotic-assisted and conventional vascular catheterization.

Human strengths	Human limitations
• strong hand-eye coordination • dexterous • flexible and adaptable • can integrate extensive and diverse information • rudimentary haptic abilities • able to use qualitative information • good judgment • easy to instruct and debrief	• limited dexterity outside natural scale • prone to tremor and fatigue • limited geometric accuracy • limited ability to use quantitative information • limited sterility • susceptible to radiation and infection
Robot strengths	**Robot limitations**
• good geometric accuracy • stable and untiring • scale motion • can use diverse sensors in control • may be sterilized • resistant to radiation and infection	• no judgment • unable to use qualitative information • absence of haptic sensation • expensive • technology in flux • more studies needed

Conclusion

Robotic technology is set to revolutionize the manner with which cardiovascular surgery is performed. It has the potential to expand on current surgical treatment modalities in both endovascular and "open" vascular interventions. Some issues such as lack of haptics, tactile feedback, and interface in human-robotic interactions remain a significant safety concern and will add another level of safety when resolved. It remains to be seen whether or not the benefit of its usage overcomes its cost. Although feasibility has largely been shown, more prospective randomized trials evaluating efficacy and safety must be undertaken, and further research must evaluate cost effectiveness or a true benefit over conventional therapy for robotic surgery of the aorta to take full root.

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