A Revolution of EVAR Imaging Technologies

Approaching complex aortic repairs with nonionizing radiation.

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Endovascular aneurysm repair (EVAR) has dramatically evolved over the past 2 decades—from relatively simple tubular endografts to extraordinarily complex branched endografts that allow endovascular coverage from the sinotubular junction through the iliac bifurcation. With this increasing complexity of repairs, parallel improvements in imaging and navigation technologies have ensued. These complex procedures have required increased fluoroscopy times, resulting in higher radiation dose exposure to both patients and operators. It has also necessitated the development and use of an increased number of various-shaped catheters, sheaths, and wires to cannulate target vessels. In addition, it has led to an increase in the amount of contrast doses administered during the course of the procedures as compared with more simple, standard aortic endovascular procedures.

Although there has been some improvement in imaging systems during this time, we have still relied on two-dimensional (2D), grayscale, fluoroscopic images to drive these procedures. Image overlay technology has reduced contrast use, increased procedure speed, and reduced radiation doses.[1] In addition to these standard imaging technology and endovascular tools, there has been a growing interest in developing improved imaging capabilities, image visualization, and navigation through complex arterial trees, as well as more precise endograft placement—all using nonionizing radiation–based systems. These systems include intravascular ultrasound (IVUS), robotic-assisted placement of endovascular tools, and electromagnetic (EM) tracking of endovascular tools. The current evaluation of these modalities does not entirely negate the need for imaging modalities that rely on ionizing radiation, but the purpose of this article is to demonstrate clinical feasibility, improvements in operative imaging, and the potential to significantly improve the accuracy and safety of device placement and treatment of patients with aortic disease by using these new technologies.

INTRAVASCULAR ULTRASOUND

Complex aortic lesions require imaging for operative planning and execution of endovascular procedures. IVUS allows for real-time imaging during aortic interventions, which is beneficial in evaluating and treating aortic pathologies.[2,3] This modality provides accurate assessment of access vessels, proximal and distal fixation sites, location of and distance between branch vessels, endograft sizing based on vessel size, and the presence of associated lesions and other relevant pathologies during EVAR and thoracic endovascular aortic repair (TEVAR). IVUS reduces the need for contrast load and radiation doses, which may be of particular importance in patients with renal disease.

During fenestrated endovascular aneurysm repair (FEVAR), IVUS provides accurate imaging of the visceral segment of the aorta for locating target vessels, identifying thrombus or calcification, and aortic sizing. IVUS also allows fluoroscopic marking of visceral vessel origins. These saved images can be used as a reference, based on bony landmarks, for accurate deployment of the fenestrated endograft using the graft radiopaque markers in conjunction with the image. This allows for the operator to potentially avoid precannulation of the visceral vessels before endograft placement, which in turn decreases contrast dose, fluoroscopic time, and the possibility of vessel injury.[3,4] Knowles et al evaluated the use of IVUS for FEVAR, with IVUS predominantly used to locate target vessels and aid with alignment of the corresponding fenestrations.[5] The sensitivity for target vessel localization was 95% for the celiac artery, 96% for the superior mesenteric artery, and 90% for the renal arteries. Sensitivity was higher in juxtarenal aneurysms and diminished in more extensive aneurysms involving the portion of the aorta where the target vessels arose, thus making IVUS visualization more difficult.

In terms of complex aortic repair with chimney/snorkel technology, IVUS can be particularly useful in assessing endograft compression among the chimney grafts, graft expansion, apposition, and residual stenosis due to com-

pression.[6] If significant compression is evident, further ballooning or adjunct stenting using balloon-expandable or self-expanding stents may be necessary.

Overall, IVUS is an excellent adjunct tool in complex aortic repair because of its ability to assist with accurate deployment; precisely gauge the intraluminal diameter of the aorta, arch, and visceral vessels; and evaluate the intra-aortic morphology to select the deployment site. When used appropriately, IVUS may reduce fluoroscopy time and decrease the need for contrast volume.

ROBOTIC TRACKING

Endovascular robotic catheters are a more recent tool being evaluated for endovascular procedures. This technology combines minimally invasive remote catheter intervention with the ability to remotely operate catheters, thus removing the need to have an interventionalist at the bedside. Currently, new developments allow planning from three-dimensional (3D) reconstruction models followed by semiautonomous movement of the catheter to a target that is controlled robotically. This provides an opportunity to integrate 3D steering with precision and improved high-resolution 3D imaging.

However, improvement in 3D imaging is not unique to robotic-assisted catheters; it is a key feature of EM navigation systems as well.[7] Although not the direct focus of this article, improvements in 3D imaging compared with the 2D grayscale images associated with conventional fluoroscopy contribute to an operator's improvement in understanding the complex anatomy involved in fenestrated and branched endografting. Advancements in generating these images will likely lead to significant improvements in our ability to address complex lesions—comparable to the improvements endovascular tools have made in this area.

Endovascular robotic technology has evolved from its use in cardiac ablation procedures and is now being investigated more readily in coronary and peripheral vascular interventions. Use of these devices is limited in EVAR and TEVAR, and there is even less evidence of their clinical use during complex aortic procedures, such as branched/fenestrated aortic endografts. Two main systems have been evaluated for use in vascular intervention over the past several years: Magellan (Auris Health, Inc.) and CorPath (Corindus, a Siemens Healthineers company).[8] These systems have similar hardware. Both include a remote workstation from which the surgeon can operate the equipment and a bedside unit that allows deployment and manipulation of catheters and wires within the vascular tree. In some systems, specialized catheters and sheaths can be manipulated to rotate or articulate nearly 180°, and the catheter systems can be controlled with movements as small as 1 mm.

The Magellan system received FDA 510(k) approval in 2012, but production was halted in 2016.[8] The CorPath system received FDA 510(k) clearance in 2018 for peripheral vascular interventions. Its use in aortic interventions has not been documented, but its application in coronary interventions was studied in the PRECISE trial. The system met the expected technical and clinical performance standards and provided lower radiation exposure to the operators.[9] CorPath has demonstrated true remote intervention, one of the most sought-after benefits of robotic systems, with five patients undergoing coronary interventions with the operator 20 miles away.[10]

Despite limited clinical use and availability, robotic endovascular systems have promise in treating complex aortic disease.[8] Fenestrated and branched aortic endografting depends on the precise placement of the endograft to align the fenestrations with the target vessels. Once unsheathed, the operator must connect an endovascular "bridge" between the fenestration and branch and the target vessel. This process can be tedious and time-consuming depending on the complexity of the anatomy. In addition, when the systems cross large aneurysmal spaces, instability of the standard endovascular tools (catheters and wires) can contribute to procedural failure. This is a scenario in which robotic systems may thrive.

The first reported use of robotics in EVAR was in 2009 to cannulate the contralateral gate.[11] Since this success, there has been an interest in applying it to more complex fenestrated and branched technology. Riga et al initially used robot-assisted antegrade in situ fenestration and subsequent stent placement through the endograft into the renal artery in a porcine model.[12] Later, it was demonstrated that within a pulsatile fenestrated stent graft model, operators could cannulate all four target vessels in approximately 3 minutes using the Sensei system (Auris Health, Inc.), compared with approximately 17 minutes when using standard endovascular tools.[13] In these preclinical settings, robotic technology significantly reduced the learning curve associated with these complex aortic intervention skills.[14]

In the clinical setting, Cochennec et al reported the use of a robotic system to cannulate 37 renal and visceral target vessels in 15 patients undergoing FEVAR.[15] The success rate was 81%, with a mean vessel cannulation time of approximately 4 minutes. Despite this, there is still debate over the clinical utility and cost of these devices. Further attempts are needed to assess the improved outcomes and demonstrate fewer complications. Although robotic endovascular tools have shown a potential opportunity to reduce the forces applied on the aortic wall, as well as cerebroembolic events during TEVAR, these results have not translated to widespread use. With improvements in the technology and growing clinical experience—together with rising concerns over radiation exposure to operators and

personnel—the future application of robotic therapies in endovascular interventions appears robust but is currently limited by the availability of affordable, usable systems.

ELECTROMAGNETIC NAVIGATION SYSTEMS

The evaluation of EM tracking in complex aortic endograft repairs is in a state of infancy compared with other endovascular tools. An EM navigation system is a combination of EM tracking technology linked with preprocedurally obtained image data sets (typically from preoperative CT), providing real-time 3D representations of the anatomy, tracked images, and the position of those instruments within the anatomy. Similar imaging systems for the tracheobronchial tree are commercially available and in clinical use, such as the superDimension navigation system (Medtronic) and Spin thoracic navigation system (Veran Medical Technologies). Commercialized products for aortic and peripheral vascular applications have not achieved similar clinical success as of yet and are limited to the StealthStation Treon Plus (Medtronic) and the IOPS intraoperative positioning system (Centerline Biomedical, Inc.), which received 510(k) clearance in mid-2019.

These systems provide an interaction of imaging and tracking. One of the main components is a 3D image reconstructed from DICOM images performed on a pre-procedural CT scan. The need for these CT-based images is a limitation of the current systems because it does not allow the entire process to be free from ionizing radiation. These images are then rendered on a platform that is easily viewed by the operator, and they can be manipulated so that the anatomy can be observed from any viewpoint (Figure 1). This image is then linked or registered to the patient's anatomy in a similar fashion to the registration of overlay images currently used with many fluoroscopy units. However, the 3D image is not displayed on top of the fluoroscopy-generated image but independently on a separate workstation (Figure 2).

The next key to using these systems is to identify the location of the endovascular tools within the image, which should be an exact representation of where these tools reside within the patient. EM tracking is somewhat similar to a standard global positioning system, except rather than relying on satellites to relay localization information, a local magnetic field is generated around the patient. Endovascular tools have embedded sensors that can be detected within this field and are used to determine the position of the tool relative to the image and the patient. These sensors are miniature and capable of being embedded into sheaths, catheters, wires, and ultimately stent graft delivery systems. This information is then displayed on the monitor (Figure 3). Initial evaluations of this technology have occurred within phantom and animal models to verify utility and precision.
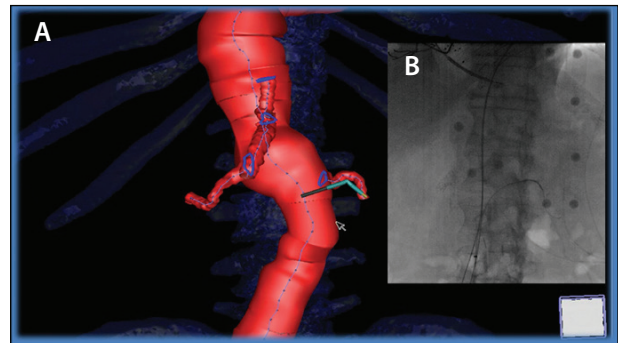

Figure 1. An early generation 3D image of a thoracoabdominal aortic aneurysm generated for guidance of an EM-sensored catheter into the left renal artery (A), compared to a 2D, grayscale image (B).

Tystad Lund et al evaluated the ability to cannulate renal arteries using an aortic phantom model guided by EM navigation.[16] Five operators performed a series of renal artery cannulations using either fluoroscopy or EM as the sole method of navigation or guidance, with a total of 120 cannulations performed. The time to cannulation was similar between the two groups, but EM tracking showed a trend toward faster cannulation times in the latter half of the experience.

The StealthStation Treon Plus system has been similarly tested in several aortic phantoms of the aortic arch and the visceral aorta.[17] The initial testing in the aortic arch evaluated the ability to successfully cannulate the great vessels using the navigation system. A second part of the study tested the system's ability to guide placement of a fenestrated endograft within a visceral segment of the aorta. In the aortic arch model, the time to vessel cannulation was longer for the EM navigation system but had reduced fluoroscopic times and wall hits. Within the

Figure 2. A workstation in a fluoroscopic hybrid operating room. The addition of the workstation is designed to be incorporated into the normal workflow of the endovascular suite, maintaining a relatively small footprint.
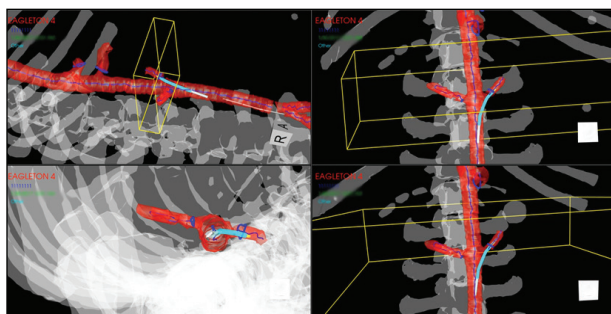
Figure 3. Three-dimensional imaging of an EM-sensored catheter placed in a porcine renal artery using an EM navigation system. The 3D image can be displayed in multiple views to give the operator the best understanding of the anatomy, which is important when performing endovascular procedures to treat complex aortic disease.
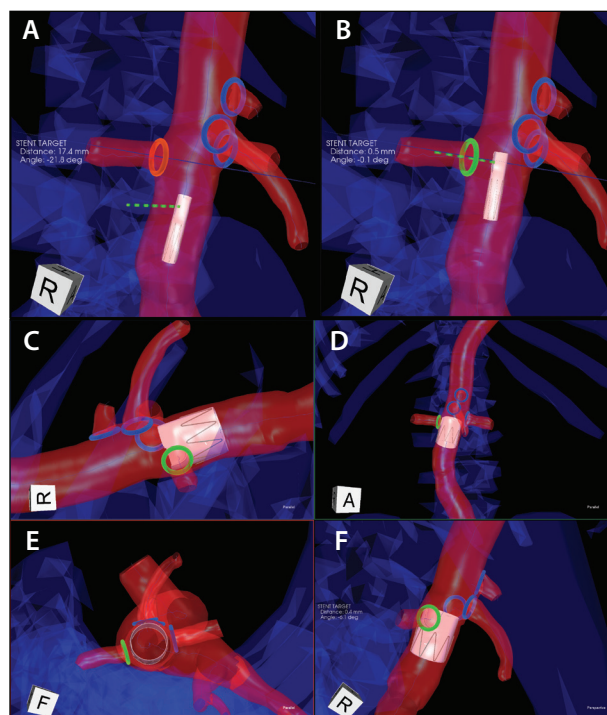

Figure 4. Real-time feedback during advancement and orientation of a fenestrated endograft into a porcine aorta. Given the location of the stent graft delivery system, the fenestration was approximately 17 mm caudal to the renal branch and nearly 22° off rotation (A). The device was then advanced and rotated to correct alignment before unsheathing (B). Prior to unsheathing, a simulated deployment can assess the location of the proximal and distal seal, and prior to full deployment, the alignment of the fenestration can also be assessed. This allows for fine-tuning of the deployment process, hopefully limiting the manipulation of a partially deployed stent graft within a diseased aorta (C–F).

visceral segment of the aorta, successful orientation and placement of a stent graft was deemed feasible solely with the EM navigation system. Subsequent studies of this system by other investigators have shown that it was accurate to < 1 mm and demonstrated equivalence to fluoroscopy with regard to success at vessel cannulation, time to cannulation, total procedure time, and total guidewire and catheter hits to the vessel wall.[18] Similar outcomes in phantom models using alternate systems have also been demonstrated.[19,20]

The combination of flexible robotic catheters with EM tracking has been shown to significantly reduce mean fluoroscopy time and the number of submovements required to cannulate vessels in a phantom model.[18-20] As the application is extended to in vivo use, we can begin to see the potential clinical benefit of the technology, particularly with its use in treating the paravisceral aorta. Real-time feedback to operators is not just visual. For example, the IOPS system can provide information feedback to the operator, such as the distance of a fenestration on the stent graft from the target artery or the degrees of rotation that must be obtained prior to unsheathing to specifically align the fenestration with the target vessel (Figure 4). Using an EM navigation system with an EM-guided catheter, steerable tip, and trackable wire allowed for placement of a stent graft in a porcine model with in situ fenestration of the graft at the renal ostia.[21] To date, application of this technology in humans is limited, but use of an EM navigation system has demonstrated early success in guiding cannulation of the contralateral limb during EVAR.[22]

The limitations of these systems, whether robotic- or EM-driven, are similar. Vessel deformation is a technical challenge for current overlay technology and remains a challenge for robotic- and EM-based systems.[23,24] One of the benefits of the improved 3D image constructions necessary for these newer navigation systems is that they serve as a platform for beginning to predict vessel deformation during endovascular procedures. Research is underway that will allow the projected image to more accurately mirror the true anatomy, even as a rigid device is advanced through a flexible, tortuous system, thus allowing correct prediction of device location. These improvements will revolutionize the technology.

In addition, improvements in visualization are currently under evaluation. The most recent additions are heads-up displays and holographic visualization (Figure 5). Heads-up displays are "goggles" worn by the operator that project an image in one or more of the lenses, as opposed to only visualizing it on a monitor. Three-dimensional holographic images of the patient's anatomy localize the endovascular tools within the images and are visualized in the goggles. In addition, the 3D holographic images can be

Figure 5. A heads-up display used during EM tracking of a catheter and wire system in a porcine model. This provides a 3D holographic image of the procedure that is taking place.
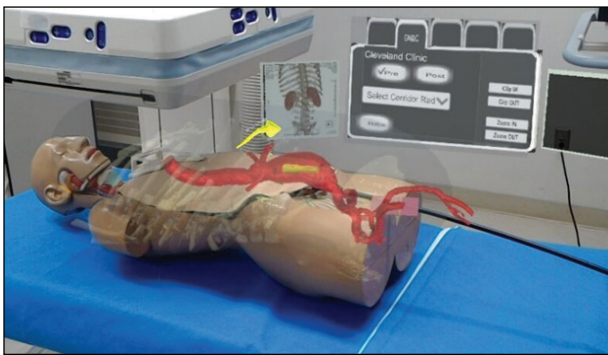

Figure 6. A representation of the holographic display seen in a heads-up unit. With virtual reality, the image is fused to the patient's location. In this instance, the 3D image of the aortic model is visualized by the operator in its correct anatomic location on the "patient."

directly linked to the patient, providing visualization of the anatomy exactly where it is in the patient (Figure 6). This technology has been used in both a phantom model and a porcine model using the IOPS system.

CONCLUSION

Endovascular therapy has revolutionized our approach to treating patients with aortic disease, and the evolution of this technology has allowed for increased complexity to be addressed in a less invasive fashion with outcomes competitive with, if not better than, conventional surgery. All of these procedures, both simple and complex, rely on imaging (preoperative, intraoperative, and postoperative) to perform them safely. Alternate imaging modalities and navigation systems are in their early years of develop-

ment, at least in comparison to the rapidity with which the other endovascular technologies have advanced. However, their continued evaluation and improvement will drive our procedures and make them safer for both patients and operators. ■

1. Dijkstra ML, Eagleton MJ, Greenberg RK, et al. Intraoperative C-arm cone-beam computed tomography in fenestrated/branched aortic endografting. J Vasc Surg. 2011;53:583-590.
2. Marty B, Tozzi P, Ruchat P, et al. Systematic and exclusive use of intravascular ultrasound for endovascular aneurysm—the Lausanne experience. Interact Cardiovasc Thorac Surg. 2005;4:275-279.
3. Hoshina K, Kato M, Miyahara T, et al. A retrospective study of intravascular ultrasound use in patients undergoing endovascular aneurysm repair: its usefulness and a description of the procedure. Eur J Vasc Endovasc Surg. 2010;40:559-563.
4. Bush RL, Lin PH, Bianco CC, et al. Endovascular aortic aneurysm repair in patients with renal dysfunction or severe contrast allergy: utility of imaging modalities without iodinated contrast. Ann Vasc Surg. 2002;16:537-544.
5. Knowles M, Stanley GA, Baig MS, et al. Accuracy and utility of intravascular ultrasound for fenestrated endovascular aortic aneurysm repair. J Vasc Surg. 2013;58:1157.
6. Scali ST, Feezor RJ, Chang CK, et al. Critical analysis of the results after chimney endovascular aortic aneurysm repair raises cause for concern. J Vasc Surg. 2014;60:865-873; discussion 873-875.
7. Goel VR, Greenberg RK, Greenberg DP. Mathematical analysis of DICOM CT datasets: can endograft sizing be automated for complex anatomy? J Vasc Surg. 2008;47:1306-1312.
8. Ghamraoui AK, Ricotta JJ. Current and future perspectives in robotic endovascular surgery. Curr Surg Rep. 2018;6:21.
9. Weisz G, Metzger C, Caputo RP, et al. Safety and feasibility of robotic percutaneous coronary intervention: PRECISE (percutaneous robotically-enhanced coronary intervention) Study. J Am Coll Cardiol. 2013;61:1596-1600.
10. Patel TM, Shah SC, Pancholy SB. Long distance tele-robotic-assisted percutaneous coronary intervention: a report of first-in-human experience. EClinicalMedicine. 2019;14:53-58.
11. Riga C, Bicknell C, Cheshire N, Hamady M. Initial clinical application of a robotically steerable catheter system in endovascular aneurysm repair. J Endovasc Ther. 2009;16:149-153.
12. Riga CV, Bicknell CD, Wallace D, et al. Robot-assisted antegrade in-situ fenestrated stent grafting. Cardiovasc Intervent Radiol. 2009;32:522-524.
13. Riga CV, Cheshire NJ, Hamady MS, Bicknell CD. The role of robotic endovascular catheters in fenestrated stent grafting. J Vasc Surg. 2010;51:810-819; discussion 819-820.
14. Riga CV, Bicknell CD, Sidhu R, et al. Advanced catheter technology: is this the answer to overcoming the long learning curve in complex endovascular procedures. Eur J Vasc Endovasc Surg. 2011;42:531-538.
15. Cochennec F, Kobeiter H, Gohel M, et al. Feasibility and safety of renal and visceral target vessel cannulation using robotically steerable catheters during complex endovascular aortic procedures. J Endovasc Ther. 2015;22:187-193.
16. Tystad Lund K, Tangen GA, Manstad-Hulaas F. Electromagnetic navigation versus fluoroscopy in aortic endovascular procedures: a phantom study. Int J Comput Assist Radiol Surg. 2017;12:51-57.
17. Cochennec F, Riga C, Hamady M, et al. Improved catheter navigation with 3D electromagnetic guidance. J Endovasc Ther. 2013;20:39-47.
18. Sidhu R, Weir-McCall J, Cochennec F, et al. Evaluation of an electromagnetic 3D navigation system to facilitate endovascular tasks: a feasibility study. Eur J Vasc Endovasc Surg. 2012;43:22-29.
19. Manstad-Hulaas F, Ommedal S, Tangen GA, et al. Side-branched AAA stent graft insertion using navigation technology: a phantom study. Eur Surg Res. 2007;39:364-371.
20. de Lambert A, Esneault S, Lucas A, et al. Electromagnetic tracking for registration and navigation in endovascular aneurysm repair: a phantom study. Eur J Vasc Endovasc Surg. 2012;43:684-689.
21. Penzkofer T, Na HS, Isfort P, et al. Electromagnetically navigated in situ fenestration of aortic stent grafts: pilot animal study of a novel fenestrated EVAR approach. Cardiovasc Intervent Radiol. 2018;41:170-176.
22. Manstad-Hulaas F, Tangen GA, Dahl T, et al. Three-dimensional electromagnetic navigation vs. fluoroscopy for endovascular aneurysm repair: a prospective feasibility study in patients. J Endovasc Ther. 2012;19:70-78.
23. Riga CV, Bicknell CD, Hamady M, Cheshire N. Tortuous iliac systems—a significant burden to conventional cannulation in the visceral segment: is there a role for robotic catheter technology? J Vasc Interv Radiol. 2012;23:1369-1375.
24. Maurel B, Hertault A, Gonzalez TM, et al. Evaluation of visceral artery displacement by endograft delivery system insertion. J Endovasc Ther. 2014;21:339-347.

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