Case Report

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Branched Endovascular Thoracoabdominal Aneurysm Repair Under Electromagnetic Guidance in an in Vitro Model

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Abstract

Purpose: We report a new approach to perform endovascular treatment of thoracoabdominal aneurysms under electromagnetic navigation guidance using a modified system (IOPS; Centerline Biomedical, Inc., Cleveland, OH, USA) and a modified branched endograft (E-nside TAAA Multibranch Stent Graft System; Artivion Inc., Kennesaw, GA, USA). **Case Report:** We performed this case in an aortic in vitro model made from transparent polyurethane in our research hybrid room (Discovery IGS 730; GE HealthCare, Chicago, IL, USA). While the implantation of this device typically involves several challenging steps, including precise endograft implantation, snaring of preloaded guide wires, and cannulation of target visceral arteries, all were successfully performed using electromagnetic navigation guidance. **Conclusion:** Our preliminary experience suggests that endograft implantation under electromagnetic navigation guidance in an integrated hybrid operating room is an innovative option to address technical challenges and reduce patient and operator radiation exposure associated with complex endovascular surgery.

Clinical Impact

Most steps of a branched endografting procedure can be performed without X-Ray exposure when using electromagnetic navigation guidance and a modified branched endograft.

Keywords

multimodal imaging, electromagnetic navigation system, endovascular aortic repair, inner branch

Introduction

The aim of this experiment was to assess the feasibility of guiding a branched endovascular thoracoabdominal aortic aneurysm (TAAA) repair primarily under electromagnetic (EM) navigation guidance using a modified off-the-shelf, pre-cannulated, inner-branch-based endograft, to help address procedural technical challenges and reduce subject and operator radiation exposure.

Materials and Methods

The image guidance used in this experiment is an investigational extension of the intraoperative positioning system (IOPS) technology marketed by Centerline Biomedical Inc. (Cleveland, OH, USA). The IOPS generates a virtual 3-dimensional (3D) model of the anatomy and devices and provides interactive 3D image guidance without continuous fluoroscopic imaging by incorporating an EM tracking system (Aurora; Northern Digital Inc., Waterloo, Ontario, Canada), which includes an EM field generator and sensors embedded into interventional devices as well as miniaturized sensor coils. During the procedure, the Aurora tracking

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Figure 1. (A) Overview of the setup, with the guidance system integrated to a discovery IGS 730 hybrid room (GE HealthCare, Chicago, IL, USA). (B) A polymer box containing a thoracoabdominal aneurysm model was installed on the imaging table, under which was placed the EM field generator. (C) Because the procedure was almost exclusively performed under electromagnetic navigation, it was not necessary to wear lead for the majority of the experiment. The thoracoabdominal aneurysm model is made from transparent polyurethane.

system computes the position and orientation of these devices by processing the signals received by each of the sensors.

The commercial IOPS technology available in the United States includes sensor-equipped catheters and guidewires. A fiducial tracking pad holds EM and radioscopic markers to allow registration and merging of the information by the IOPS software. In this experiment, a prototype of a novel steerable sensor-equipped catheter was used to provide a bidirectionally steerable device capable of navigating sensor-equipped guidewires as well as off-the-shelf snares, with a real-time 3D non-radiation-based visualization of the catheter and wire within the anatomy.

In addition, in this experiment, Aurora sensors were fitted to a modified endograft delivery system. The E-nside device (Artivion, Inc., Kennesaw, GA, USA) is an off-the-shelf aortic endograft designed with inner branches for the renal and visceral arteries. Its delivery system features four 0.018″ luminal diameter micro catheters preloaded into the inner branches to secure rapid branch access. For the purpose of this experiment, these micro catheters were themselves preloaded with Aurora sensor coils. The position of each preloaded sensor was calibrated beforehand and programmed into the investigational IOPS software. These preloaded micro catheters were mobile, allowing their use as simulated guidewires. For this experiment, IOPS was thus augmented with functionality to monitor and simulate the graft based on this telemetry.

Case Summary

The procedure was organized in June 2022. A multidisciplinary team was involved, including vascular surgeons, R&D teams from the endograft manufacturer (Artivion), the hybrid operating room (GE HealthCare, Chicago, IL, USA), the EM tracking system manufacturer (Northern Digital Inc.), and the navigation system manufacturer (Centerline Biomedical, Inc.).

Case Preparation and Registration

Our research lab is equipped with a Discovery IGS 730 hybrid room (GE HealthCare). A batch containing a silicon-printed TAAA model was installed on the imaging table, under which was placed the EM field generator (Figure 1). The transparency of the 3D-printed TAAA model could have theoretically influenced our outcomes, but during the case the flat panel was above it and our vision focused on the large display monitor.

A cone-beam computed tomography (CBCT) was first performed. The generated 3D data set was used to generate a 3D model of the relevant vasculature, including the aorta, iliac, visceral, and renal arteries. These 3D models are rendered visually on the hybrid room's large display monitor.

Endograft Placement

The E-nside Endograft (Figure 2) still constrained into its delivery system modified with EM sensors was observed under fluoroscopy outside of the 3D model, as we would do in standard practice before inserting it, to check the position of the inner branches. On the IOPS display (Figure 3A and B), we could visualize the sensors and a simulation of the graft in its mathematically predicted layout when it would be deployed. This simulation was computed from a 3D geometric drawing generated from engineering data regarding the graft, combined with an a priori calibration of sensor positions relative to landmarks of the graft.

On a Lunderquist wire inserted from the groin, the endograft was positioned with the distal tip of the inner branches approximately 10 mm above the origin of the target vessels exclusively under EM navigation guidance. A single fluoroscopy image allowed to confirm the correct placement of the endograft, prior to the deployment of the endograft under EM navigation tracking.

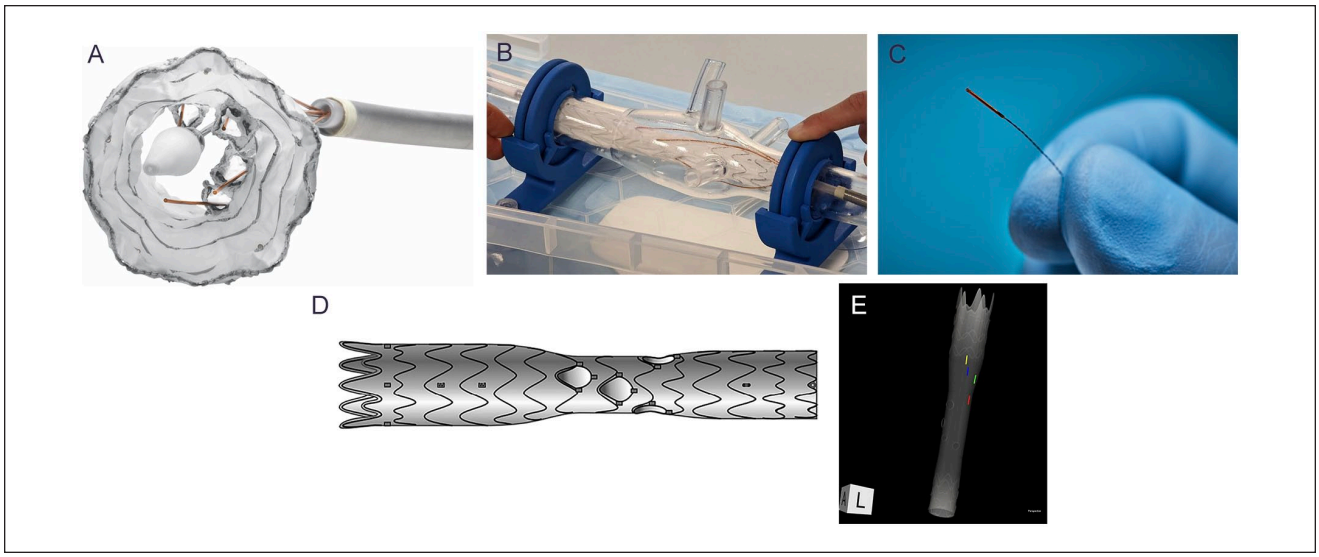

Figure 2. (A and B) The E-nside device (Artivion, Inc., Kennesaw, GA, USA) is an off-the-shelf aortic endograft with 4 inner branches for the renal and visceral arteries. Micro catheters of 0.018″ luminal diameter are preloaded into the inner branches. (C) Electromagnetic sensors (Aurora; Northern Digital Inc., Waterloo, Ontario, Canada) were integrated into these catheters for this experiment. (D) This geometric 3D drawing of the graft was used to compute its predicted layout when it would be deployed. (E) Visualization of the sensors (red, green, blue, and yellow markers) on a simulated deployed endograft based on the 3D geometric drawing of the graft and the sensor positions.

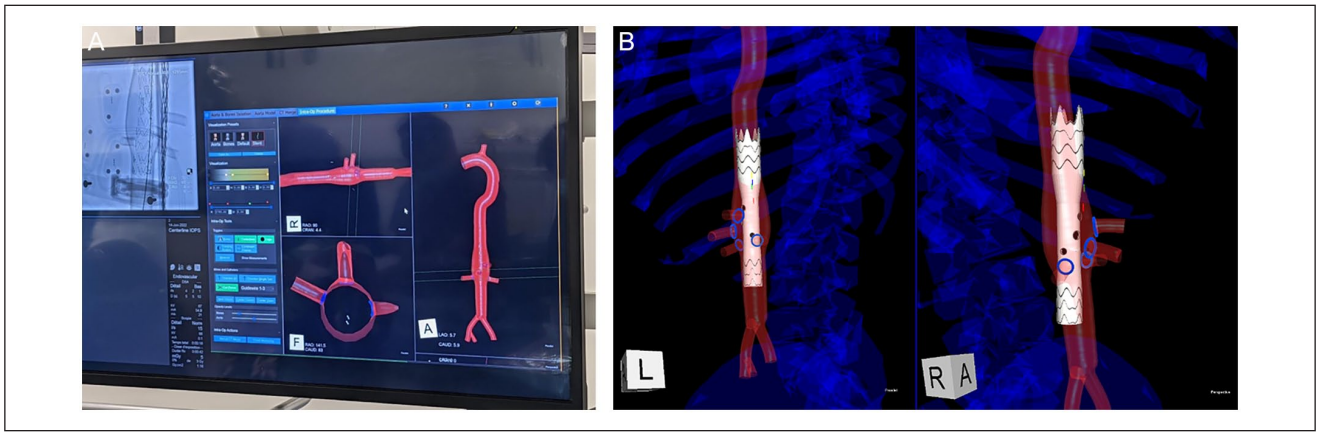

Figure 3. (A) Display of the intraoperative positioning system (IOPS) multiplex window on the hybrid operating room large display monitor. (B) Endograft placement is performed using electromagnetic guidance. The graft is not deployed on this figure, but we used the possibility to display a simulation of the endograft geometry once it will be deployed. Note the relative positions of the branch inlet on the virtual graft compared with the native ostia on the IOPS vessel map. There is a slight misalignment of the simulation at the proximal and distal extremes of the graft due to extrapolation error.

Inner-Branch and Target Vessel Catheterization

After deployment, another low-dose CBCT was acquired to perform a new registration and to accurately visualize the endograft in IOPS guidance (Figure 4).

The preloaded micro catheters functioning as sensor-equipped wires were successively advanced through their respective inner branches up to the descending thoracic aorta (DTA). From a sheath positioned through the left subclavian artery into the DTA, a snare inserted into a sensor-equipped 6 Fr steerable catheter was advanced to the level of the sensor tip. Under EM navigation guidance, snaring from above was achieved and the wire retrieved from the upper approach sheath. Over this wire, we advanced the sensor-equipped steerable catheter through the inner branch into the aneurysm sac.

Through this catheter, a 0.035″ sensor-equipped guidewire was advanced to catheterize the target vessel (Figure 5).

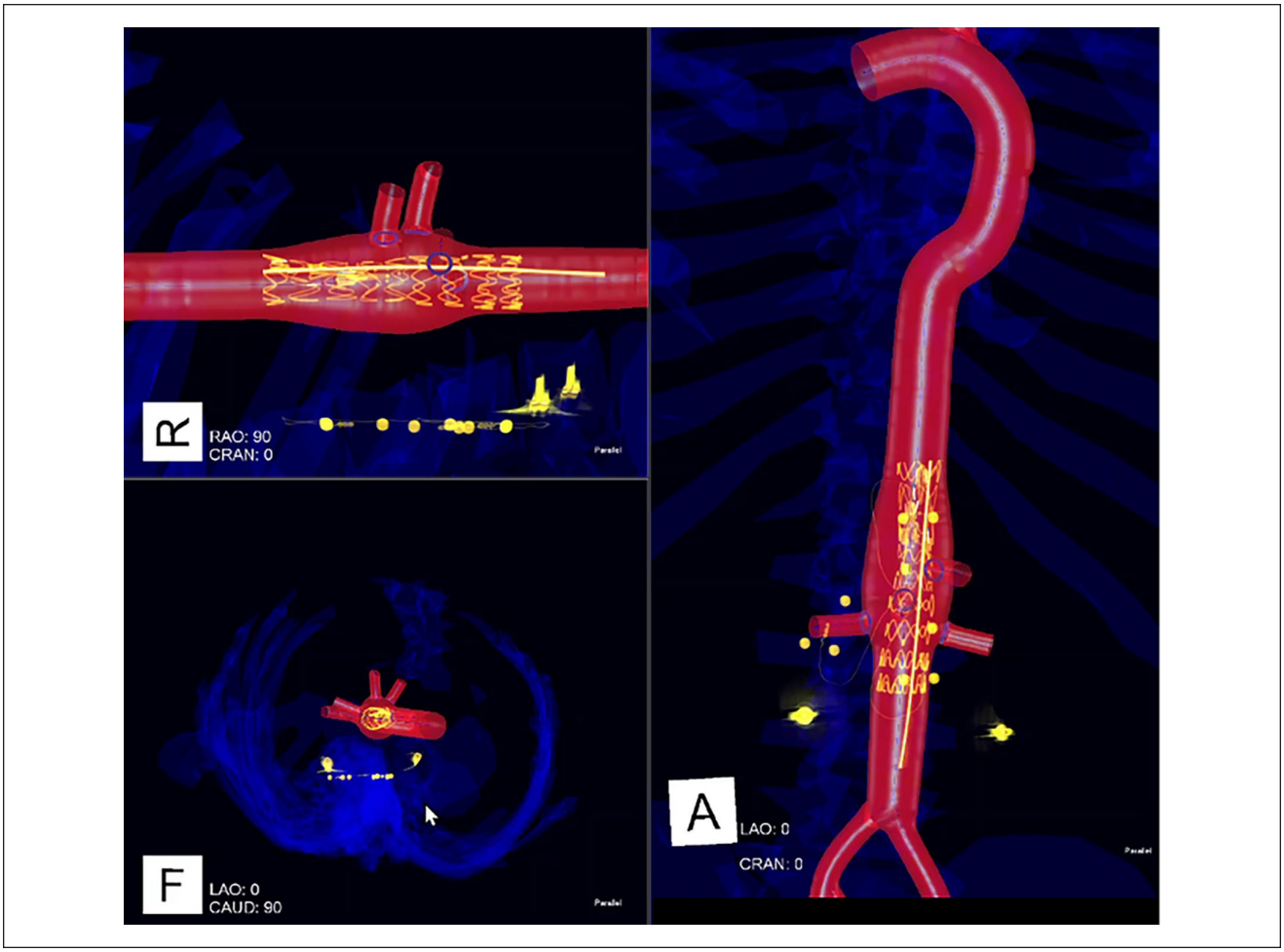

Figure 4. Intraoperative positioning system guidance after the second cone-beam computed tomography showing the deployed graft.

Stenting was performed using a BeGraft Peripheral bridging stent (Bentley, Hechingen, Germany). Only this last step required fluoroscopic guidance; all other tasks were performed under EM navigation alone.

Discussion

Despite numerous advances in imaging technology to perform complex aortic endovascular repairs, standard guidance still relies on 2-dimensional (2D) and 3D x-ray imaging. Patient and operator radiation exposure has decreased with latest generation hybrid operating rooms equipped with flat panel and with the routine use of fusion guidance, but still remains an issue in extended complex procedures. When guided by a single flat panel, only one projection can be imaged real time. Extreme angulations, especially craniocaudal, are physically restricted by the patient's body.

Ultrasound, fiber optic real shape (FORS), and EM navigation guidance have been described as alternative options to reduce x-ray imaging during endovascular procedures.[1] A recent publication by Muluk et al[2] reports successful IOPS guidance to perform superior mesenteric artery (SMA) stenting.

The case described in this article confirms that many steps of complex aortic endografting with branched endografts may be performed exclusively under EM navigation guidance with a simple modification of the endograft delivery system. The workflow was smooth, with the IOPS guidance system integrated into the Discovery IGS 730 hybrid operating system. Images from both systems were available on the large display monitor (Figures 3A, 3B,4, and 5). Unlike previously published reports,[3] we did not experience any interference between the hybrid operating room imaging system and the EM sensors. The EM field generator is easily attached underneath the hybrid operating room table with adjustable clamps and allows simultaneous or interleaved IOPS guidance with augmented fluoroscopy imaging.

EM navigation guidance requires modified guidewires, sheaths, and even endografts, which did not, however, alter their usability. The custom-made catheters showed perfect

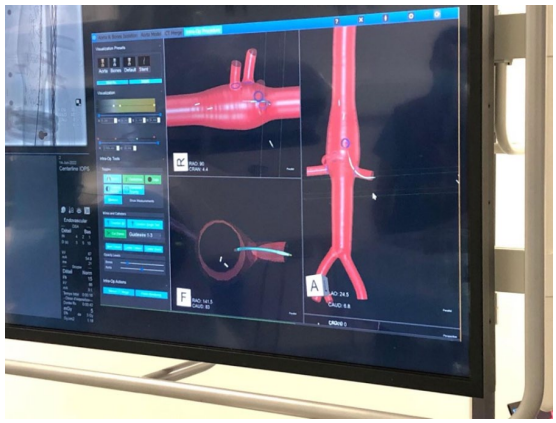

Figure 5. Catheterizing the left renal artery with sensor-equipped steerable sheath and 0.035″ guidewire. At this stage, we decided to remove the endograft representation from the intraoperative positioning system display to gain visibility.

compatibility with standard guidewires and an off-the-shelf snare. The need for various shape catheters is reduced by the use of a commercially available steerable sheath.

As a result, we could successfully deploy the endograft, snare the preloaded wire from above, and catheterize the target vessels under EM navigation guidance exclusively. No x-ray was required for these steps.

We performed 2 low-dose CBCTs to allow registration of the 3D vessel map to the 3D model aortic anatomy in the EM field initially and to enable visualization of the endograft in its actual geometry after its deployment, and one single image to check the positioning of the endograft before deploying it. The ability to visualize a 3D simulation and intraprocedural assessment of the deployed device when inserting the delivery system was also very innovative and provided valuable information to accurately position the endograft.

This case shows that multimodal imaging has the potential to decrease patient and operator radiation exposure when performing endovascular aortic repairs. One of the most time- and dose-consuming steps, target vessel cannulation, was achieved exclusively under EM navigation guidance. For the majority of this experiment, the hybrid room imaging system was not actively imaging (Figure 1) and could thus be backed away from the patient. Although, in clinical practice, 2D and 3D x-ray imaging (including fusion imaging) will still be needed, with both x-ray and EM guidance used alternatively or together along the case, EM navigation has the potential to significantly reduce patient and operator radiation exposure.

The image display provided by the IOPS system was very intuitive and facilitated endovascular navigation, although the physicians involved in this experiment had no experience with EM navigation guidance technology. The 3 different simultaneous virtual projections were of great help for the snaring, especially the z-axial cut that follows the guidewire tip, and provide an aortic luminal view (Figure 3A, "F" display).

We also used other functionalities such as magnification and rotation of the projections to better adapt to each step of the procedure. When catheterizing the renal artery, the ability to simultaneously visualize 2 projections of the steerable sheath allowed us to quickly and accurately position it in front of the artery.

The ability to combine a sensor-equipped steerable catheter with EM navigation guidance has already been successfully tested in vivo by Penzkofer et al,[4] who reported the use of this technique to perform in situ fenestrations on porcine models. Tystad Lund et al[5] suggest a learning curve with EM-guided catheterization of renal arteries, with a significant difference in median duration time between before and after 30 attempts. However, no difference was observed in comparison with fluoroscopy. Another study by Manstad-Hulaas et al,[6] however, showed that EM guidance resulted in fewer attempts to correctly insert a guidewire in the contralateral leg of an endovascular aortic aneurysm repair (EVAR) graft in humans. As stated above, we managed to perform a complex endovascular procedure under EM navigation primary guidance despite no prior experience and without experiencing any major challenges.

Conclusion

Obviously, further experiments, especially in vivo, are required before performing branched endovascular aneurysm repair (BEVAR) under EM navigation guidance in routine practice. There are opportunities to improve the navigation algorithms and sensor placement to minimize extrapolation errors. Further collaborative efforts between physicians, researchers, and partners in the endograft, imaging, navigation, and sensor fields are needed to further streamline workflows and develop clinically suitable devices based on the prototypes used in this experiment. But this initial experience suggests that branched endografts such as the E-nside endograft slightly modified with integrated sensor coils can be implanted with the use of IOPS's navigation as primary guidance in an integrated hybrid operating room, with promising patient and operator radiation exposure reduction.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: V.R.G. and S.K.S. are employed by and have a vested interest in Centerline Biomedical, Inc. A.R. is employed by GE HealthCare. S.v.H. is employed by and has a vested interest in Northern Digital Inc. F.M. and A.G. are employed by Artivion, Inc. S.H. has intellectual property and is a consultant for GE Healthcare. A.O. and D.F. have no conflict of interest to disclose.

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