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LABORATORY INVESTIGATION

Simulation of Endovascular Aortic Repair Using 3D Printed Abdominal Aortic Aneurysm Model and Fluid Pump

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Abstract

Background Abdominal aortic aneurysm (AAA) models can be manufactured with 3D printing technology. This study describes detailed methodology and validation of endovascular aortic repair (EVAR) simulation using 3D printed AAA model connected to hemodynamic pump.

Method The AAA model was printed with Objet500 Connex3 (Stratasys, Eden Prairie, MN) and connected to BDC PD-0500 fluid pump (BDC Laboratories, Wheat Ridge, CO). EVAR procedure metrics were benchmarked in two expert implanters and compared to 20 vascular surgical trainees with different levels of EVAR experience (< 20 or ≥ 20 cases). All simulations were performed using commercially available stent grafts, guidewires, catheters, fluoroscopic guidance and digital subtraction angiography. Studied outcomes included ability to complete the procedure independently, time to deploy aortic component, ability to cannulate contralateral gate and complete the repair, and total fluoroscopy and procedure times.

Results A total of 22 EVAR simulation procedures were performed with mean procedure time of 37 ± 12 min. Experienced trainees had significantly lower total procedural time (32 ± 9 vs. 44 ± 6 min, $P = 0.003$) and fluoroscopic time (13 ± 5 vs. 23 ± 8 min, $P = 0.005$). All experienced trainees completed the procedure independently in < 45 min, compared to six (46%) of those with less EVAR experience ($P = 0.016$). Among less experienced trainees, only two (15%) completed the entire procedure independently ($P < 0.001$). Benchmark implanters performed significantly better than both trainee groups in nearly all EVAR metrics.

Conclusion EVAR simulation was feasible and simulated all procedural steps with high fidelity. This model may be applicable for assessment of technical competencies and standard endovascular skill acquisition within vascular surgery training curricula.

Keywords Endovascular aortic repair · EVAR · Simulation · 3D printing · Abdominal aortic aneurysm

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Introduction

A simulation-based approach has proved to be effective in training surgical residents to perform catheter-based interventions [1]. Computer-based simulation of endovascular aortic repair (EVAR) may shorten fluoroscopy times,

decrease amounts of contrast agent used and improve delineation of the aortic neck sealing zones for both novice and experienced operators [2–4]. However, endovascular simulators are expensive and computer-based approach does not allow training with the actual implants and catheters that are used in real-life situation [5].

Fabrication of abdominal aortic aneurysm (AAA) phantoms, based on computed tomography angiography (CTA) data, is possible using rapidly spreading three-dimensional (3D) printing technology. 3D printed templates have been applied for prototype testing of manufactured fenestrated aortic endografts [6], decision making and device selection in complex EVAR [7, 8], and creating fenestrations for physician-modified endografts [9–11]. Furthermore, patient-specific AAA models have been used for training before implantation of custom-made endografts [12]. In addition, 3D printed models can be used to teach routine EVAR effectively in a realistic operation room setting [13].

The purpose of this study was to describe methodology of EVAR simulation using a 3D printed AAA model and a fluid pump and to test its feasibility in training vascular surgical residents in a prospective pilot study.

Methods

Study Design and Statistical Analysis

This study was approved by the institutional review board; it did not involve patient subjects. A total of 22 EVAR simulations were performed in a single institution using 3D printed AAA model, fluid pump and commercially available bifurcated modular stent grafts. The simulations were performed in four sessions over a 3-week period. All trainees rotating in vascular surgery and those available at the time of the study participated, including general surgery, vascular fellows and residents. Twenty trainees and two experienced operators implanted endografts using fluoroscopic guidance. The trainees were divided into two groups based on their previous EVAR experience: group A ($n = 13$) consisted of trainees with previous experience in less than 20 EVARs, whereas trainees in group B ($n = 7$) had experience in 20 or more cases. EVAR procedure metrics were benchmarked in two expert implanters (control group). Each operator's performance was analyzed using both quantitative and qualitative measures (Supplement 1; Simulation Report Form). Correlation of the level of training with the measured metrics was assessed. Fisher's exact test or Pearson Chi-squared test was used to compare nominal data. The 2-sample t test, the Mann–Whitney U test and the Kolmogorov–Smirnov test were used to compare mean values between the groups. P values < 0.05 were considered significant. All statistical analyses were performed using SAS version 9.4 software (SAS institute Inc, Cary, NC, USA).

Creation of a Virtual 3D AAA Model

A virtual aortic 3D model was created using CTA images of an actual patient with an AAA. DICOM (Digital Imaging and Communications in Medicine) data were imported into Mimics (Materialise, Leuven, Belgium) software for conversion of the DICOM data to a stereolithography (STL) file, a commonly used 3D printing file type. The aortic lumen was isolated from the DICOM data using Mimics. Thresholding, region growing and multiple slice edit were the common tools used to segment the aortic lumen from the rest of the tissue in the imaging. Once segmented, the subset of pixels representing the aortic lumen were converted into a 3D object (Fig. 1A) which was exported as an STL. The lumen STL file was then imported into computer-aided design (CAD) software 3-matic (Materialise, Leuven, Belgium) where it was smoothed, trimmed and marginally dilated to optimize internal flow through the simulation model. The lumen was hollowed, a wall thickness was added, and appropriately sized pre-designed pump connectors were added and connected to the hollow model (Fig. 1B, Supplement 2; Aortic Model Connector Dimensions). To ensure stability, an inner core of rigid material was designed within the walls of the model. The final 3D model has a three-layer design with approximately 3-mm-thick rigid inner layer and a flexible outer layer consisting of approximately 3-mm layer on the outside and 1-mm layer on the inside (luminal side) covering the entire rigid core. A sphere of the flexible material was added around the visceral vessel side branches for reinforcement and stability of the model. The parts were optimized, and the final STLs that represent the virtual model were exported for 3D printing of the final model (Fig. 1C). An interactive 3D PDF file representing the final virtual model with the multiple layers is included as a downloadable online supplement with this article (Supplement 3) and is accessible with Adobe Acrobat Reader.

Manufacturing of the 3D AAA Model

The virtual 3D model was uploaded to an Objet500 Connex3 printer (Stratasys, Eden Prairie, MN). The AAA model was printed using material jetting technology and photopolymers cured with ultraviolet (UV) light (Fig. 2A). Two photopolymers were used to create the AAA model: VeroClear, a transparent rigid material, and Agilus, a rubber-like flexible material. The rigid inner core of the model was printed in pure VeroClear with a hardness shore value of 90. The surrounding shell was printed in a mixture

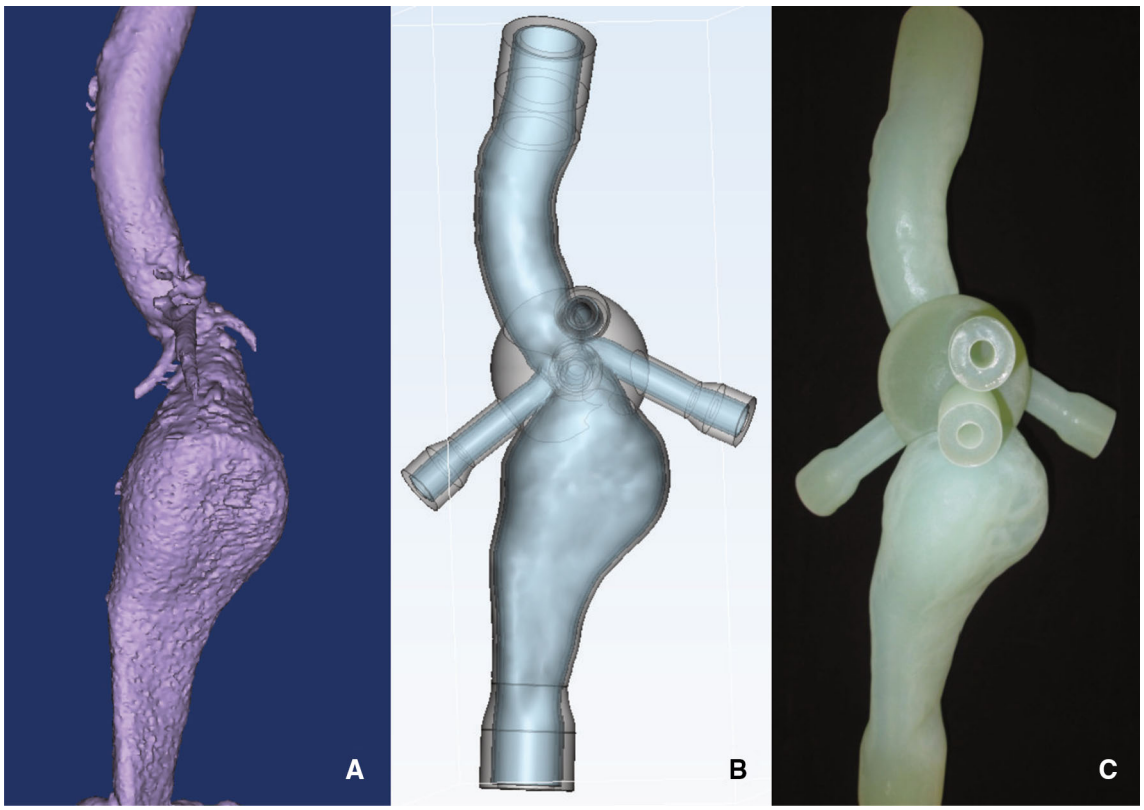

Fig. 1 **A** 3D reconstruction of the aortic lumen using patients CTA data. **B** Virtual 3D model of the AAA with three-layer design (3D PDF version of the model available online, Supplement 3). **C** Final 3D printed AAA model

of Agilus and VeroClear with a hardness shore value of 40. The support material used was SUP705, another photopolymer that is removed after the printing process by cycles of pressurized water and a sodium hydroxide bath (Fig. 2B). Size-matching plastic tubes were connected to both ends of the aorta and to the side branches of the model, and attached with Loctite sealant and heat shrink tubes (Fig. 2C).

EVAR Simulation Setup Using the 3D Printed Aortic Model and Fluid Pump

The 3D printed AAA model was placed on a free-floating angiography table, which was covered with sheets to prevent damage from possible leakage of water. The outflow from the pump (BDC Laboratories Model PD-0500, Wheat Bridge, CO, USA) was connected to the proximal part (representing descending thoracic aorta) of the 3D model (Fig. 3A). The flow was drawn out of the model along the visceral vessel side branches and "iliac arteries" created with Y-connectors and additional tubes. Two Gore Dryseal sheaths were shortened and connected to the tubes representing "iliac arteries" (Fig. 3B). The flow rate of the pump was set to 5L/min with mean arterial pressure of 80 mmHg, and the water temperature was adjusted to 36 °C and pulse rate to 60 BPM. EVAR simulation was performed under fluoroscopy using either Siemens Cios Alpha mobile C-arm or Siemens Artis zeego hybrid angiography system (Siemens Healthineers, Erlangen, Germany). Digital subtraction angiographies were performed using power injector or manual injection (Fig. 4A, B).

Results

Prior to the simulation, the trainees' experience with EVAR was less < 5 cases in seven trainees and 6–19 cases in six trainees in group A. In group B, the previous experience of the trainees ranged from 20 to 100 cases. The two benchmark operators had vast experience in hundreds of cases as the main operator. The mean procedure time for all 22 simulations was 37 ± 12 min. Experienced trainees had significantly ($P < 0.003$) lower total procedural time (44 ± 6 min in group A vs. 32 ± 9 min in group B) and fluoroscopic time (23 ± 8 vs. 13 ± 5 min, respectively). The time lag between procedural steps was 7 ± 2 in group A and 5 ± 2 min in group B. All experienced trainees (group B) completed the procedure independently in less than 45 min. Among less experienced trainees (group A),

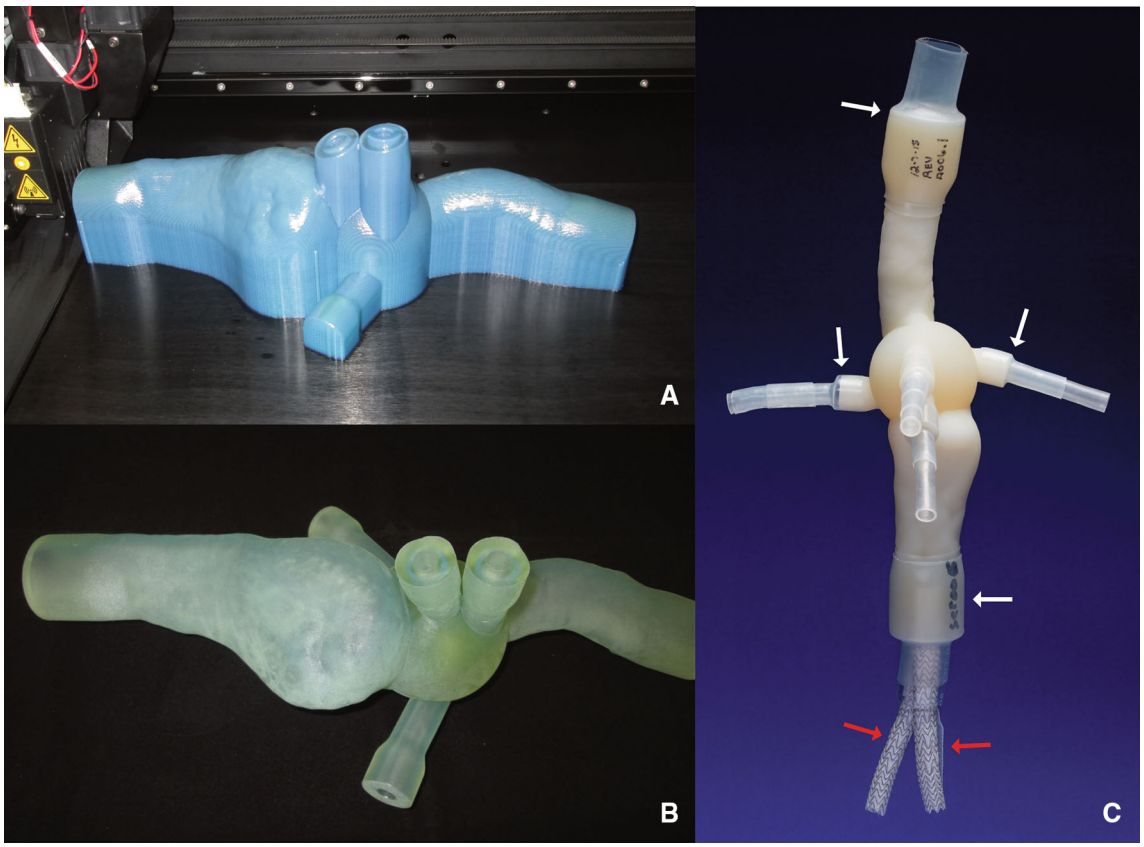

Fig. 2 **A** 3D printed AAA model on the printer with supporting material. **B** 3D printed AAA model after the supporting material has been washed out. **C** 3D model with clear heat shrink tubes added to reinforce the attachment of the plastic/silicone connector tubes of the proximal and distal part of the aorta and the visceral vessels (white arrows). A modular bifurcated endograft has been implanted with the two legs coming out of the lower end of this model (red arrows)

only two (15%) completed the entire procedure independently and six (46%) completed in < 45 min ($P < 0.05$). The expert implanters performed significantly better than both trainee groups in nearly all EVAR metrics (Table 1). The mean contrast volume for all cases was 32 ± 11 ml. There were no significant differences in contrast agent usage between the three groups ($P = 0.73$). The median number of digital subtraction angiography runs was four; there were no differences between the groups. All operators except one trainee in group A were able to cannulate the contralateral gate; three trainees lost the guidewire access to the contralateral gate during the procedure.

Discussion

The main purpose of this publication was to describe how to create a 3D printed aortic model that is durable and feasible to use together with a fluid pump for high-fidelity EVAR simulation. We described the methodology in such detail that other teaching institutions could emulate and adapt this technique as a standard. Furthermore, we performed a prospective pilot study to validate our methodology, and it clearly demonstrated a correlation between overall performance and the operator's previous experience.

Only two of the 13 inexperienced trainees were able to do all the procedural steps independently, whereas all the trainees with more experience accomplished to complete independently. The endovascular training involves a lot of learning how to use the instrumentation and getting to understand their behavior inside vessels. In comparison to training with computer-based endovascular simulators, our setup makes use of the actual guidewires, sheets, catheters, implants and the interventional radiology devices that are used in real-life scenario. Moreover, the effect of blood pressure to the behavior of guidewires and catheters and to the implant deployment can be emulated. It is crucial to learn to use the free-floating table, contrast injector, fluoroscopy and digital subtraction angiography fluently before performing complex endovascular procedures such as EVAR on a real patient. Based on our experience, high-fidelity training with 3D printed model is an effective way to prepare surgical and interventional radiology trainees for

Fig. 3 **A** Schematics of the silicone tubing and connections of the AAA model to the fluid pump (red arrows indicate direction of flow). **B** Live setup of the EVAR simulation and benchmark operator at work. By permission of Mayo foundation for Medical education and research. All rights reserved

live EVAR procedures. The metrics used in this pilot study (Supplement 1) may be used to evaluate the operator's performance and progress during the course of his/her training.

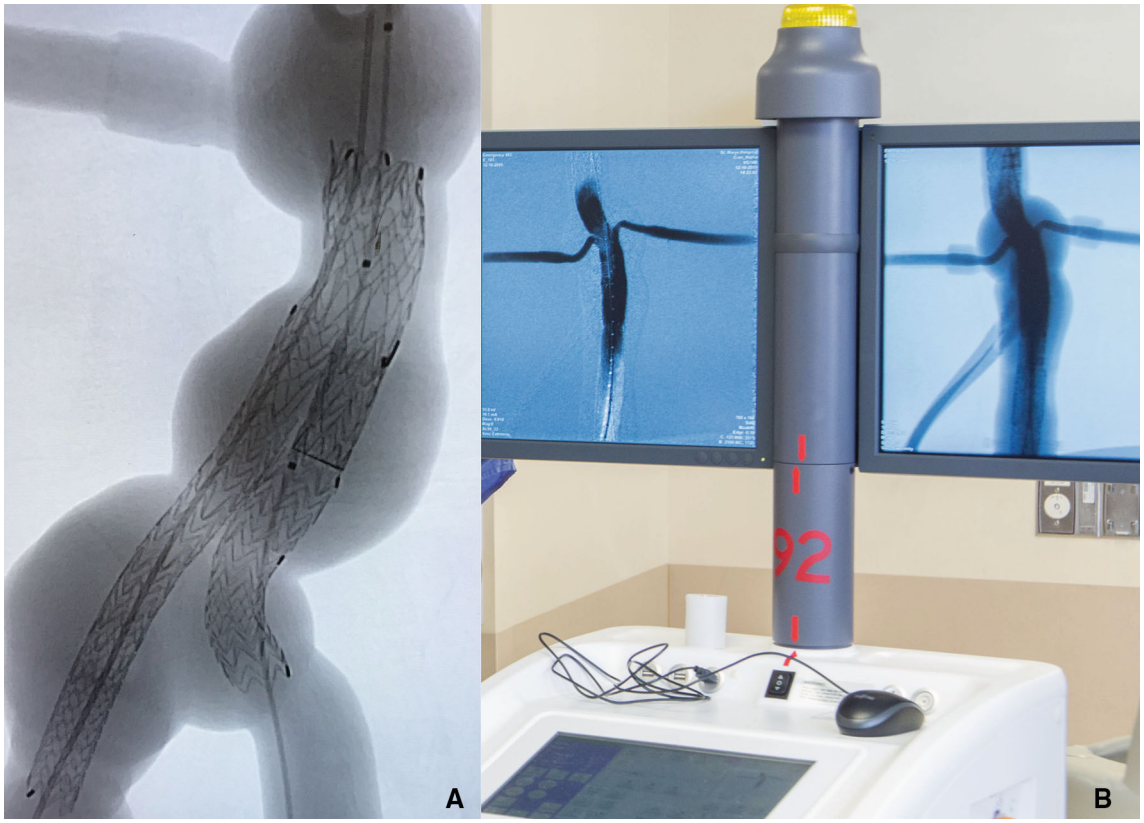

Fig. 4 **A** A fluoroscopy image of a bifurcated modular endograft inside the 3D printed AAA and right iliac aneurysm model. **B** A C-arm display showing digital subtraction angiography of the final result after EVAR simulation

Table 1 Analyzed variables according to each group. Group A—less experienced trainees (with less than 20 EVAR cases of experience); group B—more experienced trainees (with more than 20 EVAR cases of experience); control group—benchmarks/experienced EVAR implanters

Variable	Group A (n = 13)	Group B (n = 7)	Control (n = 2)	P value	A versus B P value
Complete main body deployment (min ± SD)	33 ± 6	25 ± 8	5 ± 2	< 0.001	0.02
Contralateral gate cannulation (min ± SD)	9 ± 7	7 ± 5	0 ± 0	0.2	0.6
Contralateral limb deployment (min ± SD)	34 ± 6	26 ± 10	7 ± 1	< 0.001	0.07
Total time (min ± SD)	44 ± 6	32 ± 9	9 ± 0	< 0.001	0.003
Fluoroscopy time (min ± SD)	23 ± 8	13 ± 5	5 ± 0.1	0.001	0.005
Completed independently [n (%)]*	2 (15)	7 (100)	2 (100)	< 0.001	< 0.001
Finished under 45 min [n (%)]	6 (46)	7 (100)	2 (100)	0.03	0.02

*Did not require assistance during the steps (such as contralateral gate cannulation) and finished within 45 min

The operator's radiation exposure during the simulation is minimal since there is no human body that would produce scatter and the x-rays need to penetrate only the thin 3D printed aortic model. However, proper radiation protection is required during the simulation for all participants and radiation hygiene is an important part of the training.

The manufacturing process of the 3D printed model was not without problems in the early phase. The first models were made of only soft materials, and they were not durable. The models fractured and started leaking during the simulation process due to the forces caused by pressurized water flow inside the lumen. These issues caused a design evolution toward the more rigid three-layer design of the AAA model currently in use. The visceral side branches still need to be reinforced, for example with a sphere added around the visceral aortic segment.

The downsides of computer-based endovascular simulation are typically the costs. The price of a virtual simulator ranges from $100,000 to $200,000 depending on software and modules, and with that comes additional annual service contract ranging from $10,000 to $16,000 [14]. In comparison, the cost of a single 3D-printed aortic

model is roughly around $300 to $400, and it can be reused multiple times. The fluid pump is worth approximately $16,000, and 3D printer of this style ranges from $150,000 to $400,000. Currently, many institutions are using high-end 3D printers for various other applications, such as faciomaxillary surgery, and the same machine may be used to create aortic models whenever the printer is not in clinical use. Optionally, growing number of commercial 3D printing services could be utilized to produce vascular 3D models [15]. The use of sheets, catheters, guidewires and implants adds to the costs, although most of the endovascular instruments can be washed and reused.

The creation of one 3D printed model is broken down into four processes: image segmentation, model design, 3D printing and post-processing of the model. Image segmentation can take 2–4 h depending on image quality. Model design can take 3–6 h depending on requirements of the flow model, such as number of access points and variety of pump connectors needed. The printing of the 3D model usually takes between 24 and 36 h, and post-processing can take 6–8 h including removal of internal support material, NaOH soak, final rinsing and drying.

Besides EVAR training, 3D printed aortic models connected to a fluid pump can be used in training of complex fenestrated and branched EVAR procedures for thoracoabdominal and aortic arch aneurysms. 3D printed modeling is especially useful when planning the use of a complex new implant for the first time. In addition, we have created iliac aneurysm models to simulate cases for the use of iliac branch endografts. 3D printed models can also be created using improvised sketches, for example to create AAA models with angulated necks to simulate the use of conformable aortic endografts.

Study Limitations

This pilot study was only to test feasibility of our high-fidelity EVAR simulation methodology in training vascular surgeons. We demonstrated that the trainees previous experience correlates in simulation performance; however, the study does not prove that repeated training with this method actually increases performance in real-life situation. This should be addressed in future prospective studies.

Conclusions

EVAR simulation is feasible using a 3D print AAA model and fluid pump. Procedural steps were reproduced with high fidelity and subject's performance metrics correlated with level of training and experience of the operator. This model may be used to identify areas of proficiency or deficiency during vascular training. Endovascular simulation using 3D printed models has become and integrated part of our clinical practice and training. The methodology described in this article could be adopted in other institutions worldwide.

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Compliance with the Ethical Standards

Conflict of interest Dr. Kärkkäinen has received personal research grants from following nonprofit organizations: Paulo Foundation (Finland), The Finnish Medical Foundation, Orion Research Foundation sr (Finland), Finnish Surgical Society and Finnish Society for Vascular Surgery. Dr. Oderich has received consulting fees and grants from Cook Medical, W. L. Gore and GE Healthcare (all paid to Mayo Clinic with no personal income). The other authors declare no conflict of interest.

Ethical Approval This study did not involve any patient subjects; all simulations involving human participants were in accordance with the ethical standards of the institutional review board and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed Consent This study has obtained IRB approval from Mayo Clinic and the need for informed consent was waived.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

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