

EDITORIAL

The importance of 3D printing in vascular surgical simulation and training

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Abstract

Surgical simulation is now commonplace across many disciplines. However, limitations of existing surgical simulation modalities prevent it from being widely incorporated into training schemes. Three-dimensional (3D) printing technology, a subset of rapid prototyping, has the potential to fill the gaps in vascular surgical simulation. This Editorial discusses the current gaps in vascular surgical simulation and delineates the importance of 3D printing, particularly its applications, in vascular surgical simulation and training. Besides being a useful adjunct to existing simulation modalities in surgical training, the 3D printing technique has great utility in patient-specific pre-procedure rehearsal, particularly for pre-operative planning, enhancing patient outcomes, customizing implants, reducing risks and complications, and increasing operative efficiency. With further advancements in production costs, speed and face validity of 3D-printed models, as well as more robust regulations, 3D printing technology has the potential to benefit patients, surgeons and educators tremendously. Future studies with higher levels of evidence coupled with standardized reporting guidelines, larger sample sizes, and more robust outcome measurements are warranted.

Keywords: 3D printing; surgical simulation; vascular surgery; surgical training; patient-specific

Introduction

It could not be a more exciting time for vascular surgeons. The invention of three-dimensional (3D) printing by Chuck Hull in 1984¹ has fortuitously overlapped with the endovascular revolution with Juan Carlos Parodi implanting the first endovascular stent graft for an abdominal aortic aneurysm (AAA) in 1991.² Although endovascular surgery is now commonplace, the use of 3D printing in vascular and endovascular surgery is arguably yet to achieve its full potential. With costs no longer prohibitive,³ this will hopefully change as further rapid progress is made. This editorial discusses the current gaps in vascular surgical simulation and delineates the importance of 3D printing, particularly its applications, in vascular surgical simulation and training.

3D printing is a subset of rapid prototyping that allows the fabrication of 3D-printed anatomic structures using computer-aided design (CAD) data derived from two-dimensional (2D) imaging techniques, through an additive layering

process.⁸ The potential to fabricate accurate models of anatomy and pathology, coupled with the availability of multi-material 3D printers,³ contributes to the burgeoning role that 3D printing plays in vascular surgical training and patient-specific pre-procedure rehearsal for both open and endovascular procedures.

Current gaps in vascular surgical simulation

A vast literature substantiates the use of surgical simulation as an adjunct to surgical training³ for pre-procedural planning, skills acquisition, device training, and maintenance of skills across an array of learner groups⁵ in a safe learning environment. Although a variety of simulation modalities are available, two recent reviews^{4,6} highlighted some of the problems that have prevented them from being widely incorporated into the surgical training curriculum. These include regulatory and logistical issues, which limit the use of animal and cadaveric models. The utility of synthetic

models, on the other hand, is constrained by the lack of realism. By far, virtual reality simulation appears the most propitious because of the possibility of “patient-specific rehearsal, haptic feedback and 3D perception”,⁶ but high costs serve as a huge disincentive. Therefore, an ideal simulation model, as proposed by Nesbitt et al.,⁴ should exhibit face validity, which is the extent of how realistic the simulation is,⁷ aid in improving skills, and be cost-effective. Thus, 3D printing technology has been suggested to fill the gaps in surgical simulation.⁸

Importance of 3D printing in vascular surgical simulation

Open surgical procedural skills are essential prerequisites that a surgical trainee is expected to master before advancing to more technically demanding operations such as endoscopic surgeries.⁶ Although endovascular techniques lower morbidity and mortality compared with their equivalent open procedure options,⁴ greater cognitive skills in discernment, decision making and communication¹⁰ are required because of the challenge of hand–eye coordination and distorted haptics when operating in a 3D field from a 2D view.⁴ Hence, it is vital for surgical trainees to gain intensive simulated training in open and endovascular procedures through what we propose as the use of 3D-printed anatomic models.

Applications in simulation and training

The utility of 3D-printed models promotes safe surgical skills acquisition outside the operating theatre and provides opportunities for intensive training, especially useful in cases with complex anatomy or uncommon complications.¹¹ This addresses some constraints of Halsted’s classic apprenticeship model of training, in which trainee operative practice could potentially be compromised by the recent decline in operative exposure secondary to trainee work-hour restrictions (most notably in Europe) and the need to ensure operating room efficiency and patient safety.^{6,12,13} Besides promoting uniformity in skill acquisition among trainees,⁵ pre-operative simulation using 3D-printed models provides surgeons with the invaluable opportunity of establishing an ideal operating plan, thus increasing their operative confidence.¹⁴ These advantages allow 3D printing to be a valuable adjunct to current modalities of surgical simulation.

Open procedures

Visualizing challenging anatomy

Besides enhancing the 3D visualization of anatomy at the operative site, 3D-printed phantoms also improve

visualization of the surrounding structures. This was demonstrated in a case study led by Gillis and Morris¹⁵ where they fabricated a 3D-printed replica of the dominant internal mammary artery perforator (IMAP) and its regional anatomy using cadaveric computerized tomography (CT) data, which is relevant to identifying and dissecting the dominant perforator while raising the IMAP flap. The authors also suggest processing the 3D-printed models with wax after printing to increase their durability.

Endovascular procedures

Visualizing challenging anatomy

The visualization of 2D or 3D representations on a 2D monitor prevents the full appreciation of depth¹⁶ and can be inadequate for understanding complex anatomy. In particular, 3D visualization of AAAs may be especially challenging for novice trainees. The results of a pertinent comparative study conducted by Wilasrusmee et al.¹⁷ demonstrated that surgical trainees across all years of residency training lack adequate visual-spatial skills to accurately interpret 3D CT angiograms (CTA). When 3D-printed aneurysm models were used in conjunction with pre-operative radiological images, it was found that trainees’ abilities in the visualization of the diseased aorta were enhanced and this facilitated the planning process for endovascular aneurysm repair (EVAR).

A survey conducted by Tam et al.¹⁸ also revealed that most novice and expert endovascular surgeons found the 3D-printed aortic models to be useful in gaining a better 3D visualization of complex pathologies. Planning confidence was increased in 41% of cases. Following the provision of 3D-printed aortic models, there was a change in management plans for 20% of the decisions previously based on CTA data alone, mostly from an endovascular approach to an open surgery approach, and from off-label procedures to greater confidence in standard procedures. The changes from endovascular to open were most notable with angulated or tortuous necks, and less so with short or conical necks.

Realistic surgical simulation

3D-printed models provide realistic simulation of surgical procedures and allow surgeons to anticipate complications. Sulaiman et al.¹⁹ demonstrated the utility of a magnetic resonance imaging data-derived 3D-printed thoracic aortic aneurysm model in simulating endovascular stent implantation under in vivo conditions. The replica facilitated optimal stent positioning and the absence of violet coloration outside the graft after methylin blue injection indicated successful stent implantation.

In a similar study conducted by Berry *et al.*²⁰ the practicality of CT scan data-derived 3D-printed flexible silicone replicas representing a myriad of vascular geometry and tortuosity was demonstrated for training in endovascular AAA repair. The replicas were perfused at arterial pressure and connected to a bench-top training device. Endovascular devices were deployed under fluoroscopic control. The radiolucent models allowed visualization of post-stent deployment complications such as endoleaks.

Applications in patient-specific pre-procedure rehearsal

The option of using patient imaging data in 3D printing of anatomic models offers a valuable opportunity to build accurate patient-specific vascular phantoms to simulate realistic pre-procedure rehearsal. Accurate simulation is especially useful in pre-operative planning, improving patient outcomes, customizing implants, reducing risks and complications, and increasing operative efficiency. 3D printing applications in open and endovascular patient-specific pre-procedure rehearsal are discussed in this section.

Open procedures

Pre-operative planning: visualizing challenging anatomy

A pertinent case study led by Lin and Myers²¹ demonstrated the construction of a CT data-derived 3D-printed complex renal artery aneurysm model used for the visualization of complex vascular anatomy, pre-procedural rehearsal, and patient education. The patient's post-operative course following an open repair of the renal artery aneurysm was uneventful and a renal artery ultrasound scan indicated a patent bypass graft.

Endovascular procedures

Pre-operative planning: visualizing challenging anatomy

Patient-specific 3D-printed models are especially crucial in patients with complex anatomy. Schmauss *et al.*²² fabricated a 3D-printed replica of an extensive arteriosclerotic aortic aneurysm (as shown in Fig. 1A²²) in a 70-year-old man. The haptic perception and hands-on opportunity that the 3D-printed model offers facilitated pre-operative decisions regarding stent graft implantation. In addition, complications concerning the high-risk operation in individuals with complex aortic arch anatomy could be predicted. The frozen elephant trunk procedure and post-operative course were uneventful, and good outcomes were sustained even at the patient's 12-month follow-up.

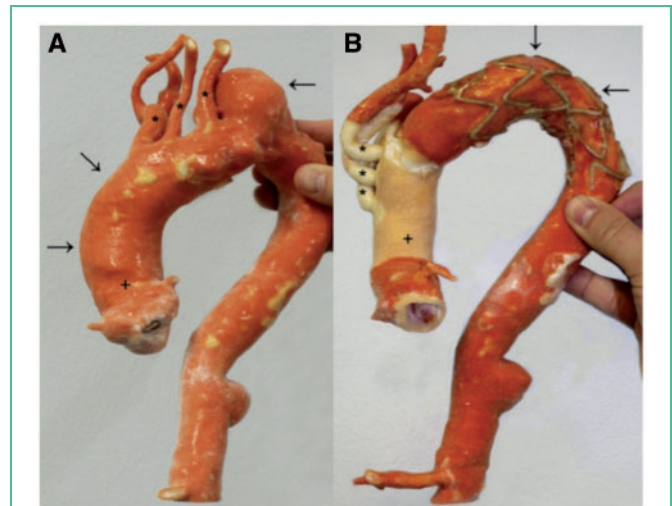


Figure 1. Pre- and post-operative 3D-printed models of a complex arteriosclerotic aneurysm.²² [A] 3D aortic aneurysm model. + represents the ascending aorta, * represents the supra-aortic vessels. The black arrow indicates the aneurysm extending from the ascending to the descending aorta. [B] Post-operative model shows the prosthesis replacing the ascending aorta (+) and the supra-aortic vessels (*). The black arrow indicates the stent. Images reprinted from Schmauss *et al.*²² with permission from Elsevier and The Society of Thoracic Surgeons.

Improve patient outcomes

Patient-specific 3D-printed replicas can also be used to rehearse stent implantations. Tam *et al.*²³ created hollow replicas of an AAA with a highly angulated aortic neck. Before EVAR, the hollow model was utilized for test deployment of a stent graft, which was checked and scanned before the procedure. Stent graft implantation was uneventful, and a 6-week follow-up CT scan confirmed adequate graft placement. As these 3D models aid case selection, particularly in off-label techniques (which are more prone to complications), model-assisted EVAR could potentially enhance patient outcomes.

Customize implants

Patient-specific 3D-printed phantoms can be used to create customized implants or devices. Leotta and Starnes²⁴ demonstrated this via on-site modification of endovascular grafts to preserve branch vessels in a patient with juxtarenal AAA. This was done by first creating a patient-specific CT data-derived 3D-printed rigid replica of the proximal neck of the aorta, including locations of branch vessel origins. In order to accommodate patient-specific branch vessels origin sites, fenestrations were subsequently added to standard commercial stent grafts. The greatest value of the template's transparent property is that it allows rapid and accurate placement of fenestrations, elimination of measurement errors and prevention of re-intervention.

Customize implants and lower risks and complications

Sodian and colleagues²⁵ also demonstrated the utility of a 3D-printed model in the customization and accurate positioning of a transcatheter-delivered occluder device in a patient with an aortic arch pseudoaneurysm after previous replacement of the ascending aorta and aortic arch. When the anatomic models were measured and compared with pre-operative CT scans, there was a high correlation ($98.76 \pm 4.1\%$), which suggests the accuracy of 3D-printed model dimensions. With the use of 3D printing, this otherwise complex surgical procedure with a high operative mortality (17.2%) and risk of false aneurysm rupture during re-sternotomy (>30%) produced positive clinical outcomes, as validated by the patient's 3-month post-intervention follow-up CT scan, which showed a completely thrombosed aneurysm.

Lower risks and complications and increase operative efficiency

Surgical experience and intra-operative trial and error are the main guidance for the optimal selection of catheter and wire combinations. This uncertainty can, however, be eliminated with the use of patient-specific 3D-printed vascular models. A study conducted by Itagaki²⁶ evaluated equipment performance via pre-operative testing of catheters and wires in an anatomically accurate multiple splenic artery aneurysm replica using CT data from a 62-year-old patient. Pre-procedure determination of optimal equipment combinations reduces intra-operative trial and error, shortens operative time, and increases the rate of operative success, as was illustrated in this study. One-year follow-up CT revealed persistent occlusion and stable treated aneurysms with blood flow to the spleen preserved. 3D-printed models, however, may not have the same haptics, wall fragility, and endovascular flow of a realistic arterial system, and these limitations should be considered during testing.

Limitations

Despite the substantial potential of 3D printing, several barriers, such as time, production costs and technological issues, remain to be overcome. The time required to plan and manufacture the 3D model, ranging from 10 hours to 2 weeks,²⁷ often delays surgical procedures. Thus, the use of 3D printing may be limited in emergency cases.²² A recent review conducted by Malik *et al.*²⁶ deduced that 3D printing software and hardware made up the highest expenditure, ranging from US\$13,000 to \$40,000, albeit still less expensive than virtual reality simulators.⁴ To reduce production costs, 3D printing can be carried out in-house using free open-source software.^{26,28} The costs of the technology can

also be shared between surgical teams.²⁸ In-house 3D printing labs are also more time efficient (manufactured within 12 hours²⁶) and are ideal for clinical collaboration and direct implementation.²⁹ Outsourcing, on the other hand, has a longer lead time and requires a small start-up cost, but offers a greater variety of 3D printing technologies and expertise.²⁹ Future advancements are likely to bring forth an improvement in the speed and cost of 3D printers as well as a greater variety of raw materials to fabricate more durable and realistic models.² Such advancements on top of the benefits of 3D-printed models will certainly widen the uptake and scope of 3D printing applications in vascular surgical simulation and training.

Intellectual property considerations and regulations

The increasing application of 3D printing technology in medicine warrants greater deliberation of its intellectual property implications and regulations. Patent, copyright, and trademark laws apply to 3D printing of medical devices;³⁰ patent laws protect against unauthorized 3D printing of patented medical devices;³¹ copyright protection extends to the CAD design files used for 3D printing;³¹ trademarks protect against counterfeiting of medical devices.³¹ The potential of 3D printing in revolutionizing health care has also come under the attention of regulatory organizations such as the United States Food and Drug Administration (FDA).²⁸ Following a public consultation regarding the safety and sustainability of 3D printing in October 2014,³² the FDA released draft guidance in May 2016 with recommendations for device design, manufacturing, and testing considerations when producing 3D-printed medical devices.³³

Future direction

In order to improve the quality of studies, a standardized reporting guideline is needed for the reporting of 3D printing experience in future studies. This includes specifying technical details such as the 3D printer model used, software, printing material and resolution type.³⁴ Our observation of case reports and case series as the most common study types also highlights the need for more studies with a higher level of evidence, such as cohort studies, case-control studies, randomized controlled trials and meta-analyses with larger sample sizes and more robust outcome measurements. These steps are paramount to further establishing the cost-effectiveness of 3D printing and its ability to improve patient outcomes.

Conclusion

3D printing is an exciting manufacturing technology, and its current and potential contributions to the field of vascular surgical simulation are unequivocal. 3D-printed models are useful adjuncts to existing simulation modalities in surgical training largely due to the following advantages: safe surgical skills acquisition and advancement, uniformity in surgical skills acquisition, and enhanced confidence. Pre-operative planning, improved patient outcomes, customized implants, reduced risks and complications, and increased operative efficiency promote the continual uptake and utility of 3D printing in vascular surgical practice for patient-specific pre-procedure rehearsal. With further advancements in production costs, speed and face validity of 3D-printed models, as well as more robust regulations, 3D printing has the potential to benefit patients, surgeons and educators tremendously. Future studies with higher levels of evidence coupled with a standardized reporting guideline, larger sample sizes, and more robust outcome measurements are warranted.

Conflict of interest

The authors report no conflicts of interest in this work.

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