The Utility of 3D Printed Abdominal Aortic Aneurysm Phantoms - A Systematic Review

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Abstract

**Purpose of Study:** 3D printed (3DP) Abdominal Aortic Aneurysm (AAA) phantoms are emerging in the literature as an adjunct for the visualization of complex anatomy, particularly for presurgical device selection and simulation. This is the first systematic review to provide a comprehensive overview of 3DP for endovascular aneurysm repair (EVAR) planning and intervention, evaluating the readiness of current levels of technology for mainstream implementation.

**Methods:** A systematic literature search of PubMed and MEDLINE was performed as per PRISMA guidelines using the terms “3D Printing,” “Abdominal Aortic Aneurysm” OR “EVAR” and related index terms, and further relevant articles were appraised via a snowballing approach. Our last search was conducted on 14 November 2020.

**Results:** 25 articles were identified for critical analysis, with 14 case or technical reports. Nineteen publications utilised 3DP AAA phantoms to aid presurgical decision making, device selection and design. Four publications explored the utility of 3DP phantoms as EVAR trainers, and one publication examined the technology as a tool for patient education. Flexible, transparent phantoms were deemed most useful, however the cost and availability of higher end machines limited accessibility.

**Conclusion:** 3DP phantoms have been used in EVAR to facilitate visualization of complex patient anatomy, appropriate device selection, in predicting navigational difficulties and the shape and position of endograft after deployment. These phantoms show promise in reducing known complications such as endoleak, stent graft occlusion and migration, however larger scale prospective studies are required to validate its impacts on patient outcomes and cost savings to the healthcare system.
Introduction
3D printing (3DP) is rapidly advancing technology that has seen growing use in surgery. Belonging to the field of additive manufacturing, this technology involves building structures by depositing material in layers, in contrast to traditional manufacturing techniques which are either subtractive or involve moulding materials. This allows for the conversion of digital 3D models into physical ones with unprecedented ease and lends itself to producing geometry and anatomy that was previously challenging to create 1.

3DP anatomical models have demonstrated utility in patient and trainee education, presurgical planning and intraoperative visualisation. Due to the expiry of patents leading improved access to 3DP technologies, desktop 3D printers are now in the price range of office paper printers and within reach of surgical departments seeking to produce patient-specific 3DP anatomical models in-house.

Endovascular interventions have likewise enjoyed remarkable growth and innovation. Endovascular Aneurysm Repair (EVAR) has become increasingly common for treatment of Abdominal Aortic Aneurysm (AAA) in patients with suitable anatomy 2. Although technology has progressed to enable endovascular treatment of juxtarenal and thoracoabdominal aortic aneurysms, more complex anatomy requires further refinement of devices and techniques to minimise complications such as endoleak, stent graft occlusion, migration or infection 3.

As such, adequate visualisation of each patient’s unique anatomy, appropriate device selection, the ability to predict intraoperative difficulties and the shape and position of the graft after deployment are paramount to the iterative improvement of this evolving technique 4. The use of 3DP AAA phantoms is growing in the literature, with studies suggesting they serve as a valuable adjunct in planning complex EVAR3, 5, 6. Figures 1 and 2 are examples of 3D printed AAA phantoms for complex FEVAR.

This is the first systematic review to provide a comprehensive overview of the current landscape of 3D printing for the purposes of EVAR planning and intervention, and to evaluate the readiness of current levels of technology for implementation into the mainstream.

Methods
A literature search of PubMed and MEDLINE was performed as per PRISMA guidelines using the terms “3D Printing,” “Abdominal Aortic Aneurysm” OR “EVAR” and related index terms. Publications that were peer reviewed, available in English and involved the 3D printing of AAAs were included. Publications relating to other vascular territories, that were non-clinical in nature, and conference abstracts were excluded. In addition, available references were appraised to identify further relevant articles via a snowballing approach. Our last search was conducted in 14/11/20. Our PubMed and MEDLINE search strategies are described in Figure 3, Appendices 1 and 2 respectively.

Results
Our literature search returned 21 articles. Snowballing revealed a further 4 articles, resulting in a total of 25 articles for critical appraisal. 19 publications utilised 3DP AAA phantoms to aid presurgical decision making and device selection, constituting the majority of publications 3-21. Of these, nine publications specifically explored the utility of 3D printing the visceral aortic segment to facilitate Physician Modified Stent Grafts (PMSGs) 8-10, 13-15, 17, 18, 20, with one publication detailing the incorporation of phantoms into the commercial fenestrated device manufacturing workflow 22. Four publications explored the utility of phantoms as EVAR trainers 23-26, and one publication examined the technology as a tool for patient education 27.
Discussion

The utility of 3DP phantoms for presurgical planning and device selection, FEVAR stent graft customization, trainee education and patient education was studied in the literature. A summary of the applications of 3DP phantoms in appraised publications can be viewed in Tables 1-4.

3D Printing Workflow

3DP phantoms in the literature ranged in cost from $3.50 to $726, requiring from 2 hours to one week to manufacture. Plastic models created using Fused Deposition Modelling (FDM) technologies were the most affordable, with resin models created using Inkjet technologies the most expensive.

The majority reported transparent or translucent materials to create phantoms, and were in agreement that a flexible, transparent model would be of greatest utility, with current levels of technology posing a limitation with regards to accessibility and cost. Some achieved a flexible, transparent model by silicone casting via a 3D printed negative cast of the AAA model, a time-consuming process. A frequently cited limitation surrounding rigid materials was their lack of conformation when inserting wires, delivery systems and endografts. Rigid phantoms fail to account for straightening of the native aorta that occurs during deployment, which has been postulated by publications to limit the utility of these phantoms in accurately predicting endoleaks when sizing and selecting devices.

CT aortograms were the imaging modality of choice to create patient-specific phantoms. However, only 8 studies disclosed imaging slice thickness, a key aspect of the workflow which has implications on the resolution and dimensional accuracy of the final model. Chung et al specified the highest resolution imaging at 0.5mm, while Mees et al reported the thickest slices at 2.5mm. Mimics (Materialise, Leuven, Belgium) was the most commonly used commercial software to generate 3D models, although 2 publications opted for open source alternatives such as 3D Slicer (Harvard, Boston, MA, USA) and the Vascular Modelling Toolkit (VMTK, Mario Negri Institute, Toronto, Canada).

Presurgical Planning

The first publication exploring the utility of 3DP phantoms for EVAR was by Winder et al in 2002 with a hollow and transparent aneurysm neck 3D printed using stereolithography technology. It was used to assess the suitability of a Cook Zenith endograft (Cook Medical, Bloomington, IN, USA) in a patient-specific phantom with a short neck.

Since Winder et al, device selection has remained a key application for these phantoms, with a wide variety of stent grafts appraised in the literature, including the Zenith Flex, Bolton Treo and Bolton Relay (Bolton Medical, Sunrise, FLA, USA), Endurant (Medtronic, Minneapolis, MN, USA), Anaconda (Terumo, Inchinnan, UK), and Aorfix (Lombard Medical, Didcot, UK) devices. For example, a 3DP AAA led to a Medtronic Endurant being selected over an Aorfix device in a case report by Tam et al. This was due to a 90° angulation of the aortic neck when regarding the physical model, which was less apparent with centerline analysis which suggested an angulation of >75°.

Although most earlier work featured solid AAA models for enhanced visualisation of anatomy, it was quickly established that hollow models were of greater benefit, allowing the phantoms to be used for navigational rehearsal. 3DP is most applicable in complex EVAR cases such as fenestrated and branched grafts, or hybrid thoracoabdominal debranching procedures. However, most work to date has been case reports demonstrating how phantoms have aided presurgical planning and device selection, with larger scale prospective studies yet to be performed. There are currently
no clinical trials investigating if 3DP models improve patient outcomes in endovascular intervention.

The initial literature studied the utility of 3DP phantoms in addressing the anatomical complexities of the visceral segment of AAAs. As the technique has become more widely used, more recent work has highlighted its utility in navigating tortuous iliac anatomy and in selecting iliac branched devices. Complex iliac anatomy is equally important to address during EVAR, as it is predictive of stent graft rotation and associated with poorer patient outcomes.

Crawford et al evaluated the impact of insertion technique and iliac artery torsion on fenestrated stent graft rotation. The study assessed the degree of rotation associated with the three most common insertion techniques. The simulated device rotation matched intraoperative values, with an absolute error <5°. The study resulted in a change in practice as the authors’ previous technique was found to be associated with the highest degree of rotation.

In addition, the study found that torsion more significantly impacted rotation when vessels were stiff, an analogue for calcification. No significant rotation was observed in iliac phantoms representing healthy iliac arteries or in the phantoms with no torsion, validating the utility of the patient-specific phantoms in planning iliac navigation. Anatomical models allow the opportunity to perform multiple reinsertions on a particular iliac anatomy to fine tune one’s approach, providing an opportunity for even experienced operators to iteratively self-evaluate and reflect on nuances in their technique.

**Physician Modified Stent Graft Templates**

A key aspect of fenestrated EVAR (FEVAR) planning focuses on adequate visualisation of the visceral segment of AAAs, with 3DP leveraged to produce stent graft templates for PMSGs.

Huang et al performed the first reported case of a 3DP template used to modify an endograft which was successfully deployed into a live patient, with the concept first described by Leotta and Starnes in 2015. Once the 3DP templates are produced, they are sterilized prior to introduction onto the backtable and the splanchnic branch ostia are marked through the template. The stent graft fabric is cut and soft radiopaque wires are sutured around the circumference of the fenestrations, providing reinforcement and facilitating visibility under fluoroscopy in lieu of gold markers. As with 3DP EVAR phantoms, transparent models were favoured. As only the visceral segment of the AAA is 3D printed, these templates are faster and cheaper to produce, taking 3-12 hours and costing $20-500. PMSGs offer an affordable alternative to commercial custom FEVAR grafts which are only offered by Cook and Terumo, costing upwards of AUD$20,000. Modifying an off-the-shelf stent graft would halve this cost, resulting in significant cost savings as stent grafts are the largest contributors to the overall cost of FEVAR and EVAR. In addition, this would allow FEVAR to be performed in emergency situations, while commercial custom fenestrated grafts require a minimum of a month to be produced.

Starnes et al’s prospective trial involved 30 patients with juxtarenal AAAs treated with 3DP template-assisted PMSGs. The outcomes of this cohort were compared to another arm of the trial where PMSGs were planned via traditional centerline analysis, with equivalent 30-day results. No Type II or III endoleaks, ruptures or conversions to open repair resulted. The 30-day mortality rate was 6.7%, with 16.7% of patients experiencing a major adverse event.

Tong et al 3D printed fenestration templates for 34 patients, of which 15 presented with thoracoabdominal aneurysms and the remaining 19 had thoracoabdominal aortic dissections. Although they did not report the outcomes separately for each patient group, over the mean follow-up time of 8.5 months, the mortality rate was 3% due to one fatal retrograde dissection rupture one week
after surgery. Adverse events included five endoleaks (three of which were due to distal dissection rupture requiring iliac branch devices) and one minor cerebral infarction postoperatively, with no renal insufficiency or paraplegia.

**Trainee Education**

There is a substantial learning curve associated with EVAR training, due to its technical nature. Simulation seeks to improve trainee confidence by allowing the key steps of EVAR to be performed in a risk-free environment, improving psychomotor skills and procedural understanding.

3DP AAA phantoms allow basic catheter and guidewire skills to be learned prior to performing the procedure, which may benefit patient safety. In addition, they allow for the skill-specific repetition of a key step on realistic anatomy, either under the supervision of a surgical educator, or in the hands of an experienced operator seeking to experiment.

For the purposes of trainee education, 4 of the studies reviewed created standard infrarenal AAA phantoms. Mafield et al created a low cost, low maintenance EVAR simulator to replicate real life haptics when using hydrophilic wires, allowing trainees to experience the practical concepts of pushability, torquability and trackability. Trainees found the 3DP model to be a useful tool for improving basic guidewire skills, and that the simulation exercise was valuable and worth repeating.

Similarly, Torres et al reported that patient-specific phantoms improved the performance of trainees during the actual procedure, with significant improvements in fluoroscopy time, total procedure time, and volume of contrast required, resulting in a reduction in radiation exposure for both patients and operators. A measure of the 3DP simulator’s success was that the five residents surveyed found the phantoms useful in improving their understanding of the case’s anatomy, improved their guidewire and catheter skills, and aided their selection of devices. Importantly, the simulation was rated to be realistic compared to real life conditions and improved trainee confidence.

The study found 3DP AAA phantoms a cost-effective option for patient-specific simulation when compared to VR and cadaveric training, with the 25 phantoms produced ranging from $150-563. Despite the promise that VR has shown in medical education, current levels of technology offer limited haptic discrimination between endovascular devices used during simulation.

As a result of the study’s simulation exercises, the diameter of one stent graft was increased for the actual procedure to avoid a Type Ia endoleak. Despite the intended use of the phantom for training, the process resulted in a change in device selection. This emphasizes that 3DP phantoms can serve multiple applications once implemented and can be reused after planning a complex case for inexpensive, high fidelity simulation for trainees.

Kaswich et al produced an EVAR training model for end-to-end procedural simulation in an angiography suite, starting with a surface imitating human skin, and bony landmarks to allow for anatomical orientation. The phantom was connected to a fluid pump and the circuit was designed to be modular, allowing phantoms to be exchanged as required depending on the lesson plan.

In addition to its utility as a trainer, the simulator was designed to aid the development of new endovascular techniques and devices. 3DP AAA phantoms have also been incorporated into the current endograft manufacturing process by Taher et al to plan commercial FEVAR grafts. The use of high-fidelity phantoms to prototype, test and design new devices could in future be analogous to high throughput screening in pharmacotherapeutic research, allowing for an agile approach to endovascular device innovation as new technologies continue to accelerate.
Patient Education

Khural et al produced an infrarenal AAA model, printed in flexible plastic using FDM technology. The model was cost effective at $146 for the first prototype, with subsequent models costing $24. As part of a quality improvement project ten physicians (Interventional Radiologists, Vascular Surgeons, General Surgeons and Orthopaedic Surgeons) were surveyed to provide feedback on the utility of the model for patient education. However, personalized 3DP AAA models are still of unproven benefit in patient education as the study did not recruit patients to provide feedback on the models. Despite this, they may be of benefit to aid informed consent, such as counselling patients as to why an approach is recommended, particularly if a phantom has been created prior for complex interventional planning.

Anatomical Accuracy

Slice thickness of the CT imaging used to create the AAA models impacts the dimensional accuracy of the final product. The most common method used to validate the dimensional accuracy of 3DP AAAs was to re-image the resultant phantoms for comparison. Winder et al CT scanned the phantom and performed comparative measurements to the pre-interventional patient imaging. Prior to 3D printing, Mafeld et al visually overlaid their digital model on the original CT to confirm anatomical accuracy, however did not compare the final product to the original patient imaging to validate the phantom’s utility in predicting interaction with endografts.

Kaswich et al performed the most extensive validation of the anatomical accuracy of 3DP phantoms to date. The phantom’s fluoroscopic 3D roadmap was overlaid on the original patient CT data and found to be an exact match. In addition, comparison of the centerlines of the 3DP model and the 3D reconstruction revealed a median absolute deviation of 0.91mm, a minimum deviation of 0.43mm, and maximum of 3.61mm at the level of the aneurysm. In addition, the same Medtronic Endurant stent graft was deployed into the simulator as used for the patient and CT scanned the phantom, displaying the image next to the patient’s post-intervention imaging for comparison. An interesting next step would have been to overlay these two CT images to compare the degree of shape change in the patient’s anatomy post-intervention with the phantom post-simulation.

Hemodynamics and Fluoroscopy

To optimize the simulation environment, several studies simulated EVAR in the angiography suite, filling the phantoms with water to facilitate the passing of hydrophilic wires and connecting them to a fluid pump set to physiological parameters. Despite the fact that appraised studies utilised a wide variety of 3D printers and materials, all phantoms were satisfactorily visible under fluoroscopy. Connecting fluoroscopic phantoms to a fluid pump adds a dimension of complexity and realism during simulation, allowing pulsatility to affect device trajectory.

Material Properties

As described, the rigidity of current aortic phantoms has been postulated in studies to limit endoleak production. Due to the constraints of current levels of technology, few studies have developed a suitably flexible model to replicate aortic conformation during stent graft insertion. Mees et al based the material properties of their phantom on the mechanical properties of intraluminal thrombus within AAAs as reported by Wang et al, using a readily available Inkjet resin. Crawford et al approximated the Young’s Modulus of severely atherosclerotic arteries when designing the mechanical properties of their phantoms, based on values reported by Kamenskiy et al; however, the study’s cadaveric samples only included one AAA specimen, with rupture as the cause of death. Furthermore, this sole cadaveric abdominal aorta with known aneurysmal pathology was not included for biaxial mechanical testing, although values for the thoracic region of the specimen were tested and reported. More recently, Meekel et al have reported specifically on the Young’s Moduli of live AAA tissue sections.
Mainstream Implementation

We have summarized the advantages of 3DP phantoms for EVAR planning and education in the literature. In a promising development, the American Medical Association (AMA) approved reimbursement codes for patient-specific 3DP anatomical models and surgical guides in 2019 \(^{40}\).

3DP phantoms have resulted in reduced procedural time and radiation exposure for both operator and patient \(^{26}\). However, for the technology to transition from novelty into contemporary practice, the 3D printing workflow must be integrated into the broader hospital system to ensure an efficient and financially sustainable service. Several barriers exist, such as the lack of standardised guidelines, the lack of knowledge in implementing the technology and the initial investment in purchasing 3D printers and software. Ideally, anatomical models created within a healthcare environment could be used within hours.

Due to the nascency of 3D printing in hospitals, many studies relied on third party companies to design and print their anatomical models. While outsourcing these steps to a commercial provider removes the labour to create the 3DP models and maintain equipment, the time advantage of being able to manufacture these models on demand is lost. In addition, the current COVID-19 pandemic has highlighted the advantages of maintaining self-sufficiency within a hospital system.

Another consideration is the time and labour invested in creating phantoms, and the time and resources involved in presurgical simulation. For example, Mees et al reported a simulation time of 3.5 hours using the model under fluoroscopy \(^{16}\), requiring clinician time, support staff time, and the usage of an angiography suite to be factored into the cost-benefit analysis.

There has been complementary advancement of the fidelity of EVAR simulators with increasing complexity of the endovascular procedures being simulated. When Winder et al first reported in 2002 their infrarenal phantom, EVAR was considered a new procedure, and regarded with the same complexity as current fenestrated and branched procedures \(^{6}\). As EVAR has increased in complexity, 3D printing has evolved to plan fenestrated and branched grafts. The value of 3DP in visualizing the visceral segment now established, with the next emerging focus on assessing and navigating iliac anatomy.

Study Limitations

The nascency of 3DP EVAR phantoms contributed to the major limitation of this systematic review, with most publications comprising low-level evidence. Despite a broad search strategy amalgamated with a snowballing approach, only 25 articles were identified, of which 14 comprised case or technical reports. A further systematic review may be of value when higher level evidence becomes available.

Conclusion

3DP phantoms are a potential new tool to aid the advancement of EVAR, meriting further investigation. To assess the benefits and longer-term utility of this technology, further studies outside case reports are warranted, including follow up on longer term outcomes post-procedure. The investment in purchasing 3D printers, the hiring and training of staff, and the time required by members of the endovascular team to perform pre-surgical rehearsal must be compared against projected cost savings and improved patient outcomes to assess the potential positive impacts of this emerging technology.

Conflict of interests: The authors have no conflict of interests to declare.

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References

Figure Legends

Figure 1. Hollow 3D printed AAA phantoms. The left is translucent and flexible, 3D printed using Inkjet technology. The right is translucent and rigid, 3D printed using stereolithography.

Figure 2. Translucent 3D printed templates of the visceral aortic segment for planning Physician Modified Stent Grafts. The left was 3D printed using rigid autoclavable resin. The right 3D printed using a flexible Inkjet resin.

Figure 3. Search strategy following PRISMA guidelines.
Figure 1. Hollow 3D printed AAA phantoms. The left is translucent and flexible, 3D printed using Inkjet technology. The right is translucent and rigid, 3D printed using stereolithography.
Figure 2. Translucent 3D printed templates of the visceral aortic segment for planning Physician Modified Stent Grafts. The left was 3D printed using rigid autoclavable resin. The right 3D printed using a flexible Inkjet resin.
<table>
<thead>
<tr>
<th>Source</th>
<th>Study Design</th>
<th>Segmentation Software</th>
<th>Slice Thickness (mm)</th>
<th>3D Printer</th>
<th>Material</th>
<th>Phantom Cost (USD$)</th>
<th>Manufacturing Time</th>
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*Table 1. A summary of publications utilising 3D printed AAA phantoms for presurgical planning.*
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Table 2. A summary of publications utilising 3D printed AAA templates for Physician Modified Stent Grafts (PMSGs) and commercial stent graft customisation.
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<tr>
<td>Torres et al</td>
<td>Prospective controlled</td>
<td>iNtuition</td>
<td>Not disclosed</td>
<td>Form 1+ (Formlabs Inc, Somerville, MA), Makerbot, Connex350 (Stratasys, Eden Prairie, MN, USA)</td>
<td>Flexible Resin (Formlabs Inc, Somerville, MA), PLA and reproduction in silicone, Polyjet Material Rubber, Standard Plastic, TangoPlus/VeroClear blend (Stratasys, Eden Prairie, MN, USA)</td>
<td>150-563</td>
<td>1 week</td>
<td>Endurant, Anaconda (Terumo, Tokyo, Japan), Excluder (Gore, Newark, DE, USA)</td>
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<tr>
<td>(2017)</td>
<td>single center study</td>
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<td></td>
<td>Infrarenal</td>
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<tr>
<td>Kärkkäinen et</td>
<td>Prospective pilot study</td>
<td>Mimics</td>
<td>Not disclosed</td>
<td>Objet500 Connex (Stratasys, Eden Prairie, MN, USA)</td>
<td>Rigid VeroClear and flexible Agilus (Stratasys, Eden Prairie, MN)</td>
<td>300-400</td>
<td>35-54 hours</td>
<td>Not disclosed</td>
<td>Infrarenal</td>
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<td>al (2019)</td>
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<tr>
<td>Kaswich et al</td>
<td>Technical report</td>
<td>Not disclosed</td>
<td>1</td>
<td>Felix 3 (FELIXprinters, Utrecht, Netherlands)</td>
<td>PVA negative cast silicone (Shore A37)</td>
<td>Not disclosed</td>
<td>Not disclosed</td>
<td>Endurant</td>
<td>Infrarenal</td>
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<td>(2020)</td>
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</table>

Table 3. A summary of publications utilising 3D printed AAA phantoms for trainee education.
<table>
<thead>
<tr>
<th>Source</th>
<th>Study Design</th>
<th>Segmentation Software</th>
<th>Slice Thickness (mm)</th>
<th>3D Printer</th>
<th>Material</th>
<th>Phantom Cost (USD$)</th>
<th>Manufacturing Time</th>
<th>Endografts Used</th>
<th>Endografts Used</th>
<th>Endografts Used</th>
<th>Anatomy</th>
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</thead>
<tbody>
<tr>
<td>Khural et al (2020)</td>
<td>Qualitative survey</td>
<td>Model shared by another group</td>
<td>Not disclosed</td>
<td>Ultimaker S3</td>
<td>Ninjaflex Cheetah</td>
<td>24</td>
<td>Not disclosed</td>
<td>N/A</td>
<td>Infrarenal</td>
<td>Infrarenal</td>
<td>Infrarenal</td>
</tr>
</tbody>
</table>

Table 4. A summary of publications utilising 3D printed AAA phantoms for patient education.
Minerva Access is the Institutional Repository of The University of Melbourne

Author/s:
Coles-Black, J; Bolton, D; Robinson, D; Chuen, J

Title:
Utility of 3D printed abdominal aortic aneurysm phantoms: a systematic review

Date:
2021-04-06

Citation:

Persistent Link:
http://hdl.handle.net/11343/274942