CONSTRUCTION OF ULTRASOUND PHANTOMS WITH

2	WALL-LESS VESSELS USING 3D PRINTING
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Summary.

Ultrasound phantoms are invaluable as training tools for vascular access procedures. We developed ultrasound phantoms with wall-less vessels using 3D printed chambers. Agar was used as a soft-tissue mimicking material, and the wall-less vessels were created with rods that were retracted after the agar was set. The chambers had integrated luer connectors to allow for fluid injections with clinical syringes. Several variations on this design are presented, which include branched and stenotic vessels. The results show that 3D printing can be well suited to the construction of wall-less ultrasound phantoms, with designs that can be readily customised and shared electronically.

Key words: ultrasound phantom, vascular access; 3D printing; wall-less vessels; tissue-mimicking material.

Ultrasound guidance is increasingly used to guide vascular access procedures, which include peripheral venous, central venous, and arterial cannulation. Its usefulness depends significantly on the skill of the operator, however. Proficiency with ultrasound-guided vascular access involves extensive practice, as image interpretation and visualisation of the needle tip can be challenging. Ultrasound phantoms are important for acquiring clinical skills before practising on live patients¹; it was recently shown that clinicians who undertake simulation training on ultrasound guided vascular access achieve higher success rates.^{2,3}

A wide range of commercial ultrasound phantoms have been developed for vascular access. They tend to be expensive, with lifetimes limited by the tracks created by needle insertions. As such, they are used sparingly in all but the most affluent clinical departments. Many custom phantoms have been proposed as inexpensive alternatives to commercial phantoms. Lo et al., Kendall et al., Chatnler et al., Domenico et al., Terilinck et al.] [Daniil, I don't think your current ref. 8 is relevant to this set of references] An aqueous gel such as agar can be advantageous as a tissue-mimicking material (TMM) as it can readily be remade or melted to remove needle tracks. [Hocking et al.] [Replace authors with numbers]

Many methods for creating vessels with flow in ultrasound phantoms have been proposed, with or without vessel walls. Vessel walls can be mimicked with tubes positioned within the TMM [refs], which can include simple cylindrical geometries [refs] and more realistic geometries created using 3D printing moulds [refs]. They can be also created using tissue *ex vivo*¹⁰⁻¹² [also Bale-Glickman et al. 2003; KEber et al. 1992; Motomiya et al. 1984 – see references in Meagher 2007] at the expense of experimental flexibility and repeatibily. In wall-less phantoms, vessel walls are absent; a blood-mimicking material (BMM) flows through a space created in the TMM. These types of phantoms can be well suited to vascular access, as the vessel lumens can readily be accessed with needles and the vessel boundaries can have realistic ultrasonic apperances. ^{21,22} A simple construction method for wall-less vessels involves retracting rods positioned into a TMM. ²⁰ Wall-less vessels with more realistic geometries can be created a lost-core method, which involves creating a solid, lumen-less vessel, embedding it in a TMM, and subsequently melting away the solid vessel to create a space for the BMM ²³⁻²⁸ Despite their advantages, wall-less phantoms are not widespread in clinical practice.

Their limited adoption at present may be due in large part to the inconvenience and the mechanical workshop resources required to create chambers with ports with which wall-vessels can be created.

In this study, ultrasound phantoms with 3D printed chambers and different wall-less vessel geometries were developed for vascular access. Variations in the surface quality of the chambers, which can arise from different chamber geometries and the use of different printers, were explored.

Materials and Methods

Each ultrasound phantom comprised a 3D printed rectangular chamber in which agar was poured as a soft-tissue mimicking material (Figure 1).³⁰ The dimensions of this chamber (100 × 100 mm; 60 mm height) were compatible with typical ultrasound imaging probes and they allowed for in-plane and out-of-plane needle insertions. Wall-less vessels were created by placing rods in the chamber before the agar was poured, and removing them after the agar was set (Figure 2a-e). Within the chamber, the rods were fixed in angle with small support tubes printed in the sides of the box (star on Figure 1). Since the diameters of the wall-less vessels were significantly larger than those of the lumens of the luer connectors, the support tubes extended out of the chamber but not within the luer connectors. On one side of the chamber, the ends of the support tubes had luer connectors that allowed for fluid to be injected through the vessels after the rods were removed (Figure 2f). Support tubes on the other side of the box could be connected to tubing (inner diameter: 8.5 mm) to receive fluid from the vessels. The support tubes protruded slightly inside the chamber to accommodate shrinkage of the agar after setting. A small tray accommodated fluid outflow when tubes on the side of the box opposite the luer connectors were not connected to tubing. Printed caps for the luer connectors were used to prevent the agar from flowing out of the chamber before it was set.

Three ultrasound phantoms with wall-less vessels were created. The first phantom comprised two parallel wall-less vessels with different diameters (12 mm and 6 mm) that were made using solid rods. These diameters were chosen to correspond to a large artery/vein pair. In one variation of this phantom, the vessels were horizontal; in another, they were vertically angled at 20 degrees. With both variations, polytetrafluoroethylene (PTFE rods, DirectPlastics, Sheffield, UK) was chosen as the material for the rods to minimise adhesion with the agar. The second phantom comprised a branched

vessel, which was created with two rods. Each of these rods was 3D printed, as a combination of two hemispherical parts (Figure 3a). The first rod was positioned horizontally in the chamber; the second was partially inserted into a groove in the first and vertically angled at 20 degrees (Figure 3b). The two-part rod design stemmed from the need for smooth surfaces to minimise adhesion to the agar and thereby to create smooth vessels when retracted, and from the observation that 3D printed surfaces that were in contact with support material during the printing process tended to be significantly less smooth than those that are not. Each hemispherical part was printed with its curved surface upward, so that it was not in contact with support material. The third phantom comprised a stenotic vessel that was created with two rods, similar to one that was previously demonstrated by Qian et al. [31]. These rods were 3D printed in the same manner as they were for the second phantom, except that one rod had a small cavity in which the other could be positioned (Figure 3c). The diameter of these rods was 4 mm along a distance of 20 mm (centred at the point of apposition) and 6.2 mm elsewhere; the narrowing mimicked a stenosis when the rods were retracted.

The chamber was designed using two freely available software programs: Blender (Stichting Blender Foundation, Amsterdam, the Netherlands), and FreeCAD (Juergen Riegel, Werner Mayer, Yorik van Havre, OpenSource, freecad.com). The 3D printing files (STL format) are included as supplemental materials. Two different printers were used; each required approximately 240 g of build material and 80 g of support material. The first printer, which will be denoted Printer 1, was an additive polymer resin printer (Objet30 Pro, Stratasys, Eden Prairie, Minnesota) using a rigid opaque white or blue material with a gloss finish (VeroWhitePlus RGD835 or VeroBlue, accuracy <0.1mm). The second (Printer 2) was a an extruded thermoplastic polymer printer (Ultimaker2, Ultimaker, Chorley Lancashire, UK) using a filament material (PolyMax, Polymakr, Changshu, China, accuracy >0.1mm). The printing costs varied significantly with the printer: £44 GBPper phantom for Printer 1 and £3 GBP per phantom for Printer 2. By comparison, the costs of commercial vascular access phantoms are typically in excess of £1000.

The agar (A7002; Sigma-Aldrich, St. Louis, Missouri) was dissolved in hot water (> 90°C) outside the chamber to bring it above its melting point (85 °C), with a concentration of 5.5% by weight. This concentration is similar to those previously used.^{6,32}. A hot plate was found to be useful

to maintain the high temperature during dissolution; without it, rapid mixing is required and consequently there is a risk of introducing bubbles. It was found that the use of a degassing chamber for 5 minutes was useful to remove residual bubbles.³⁴ After mixing, the melted agar solution was cooled to a temperature in the range of 50 to 55 °C, which was below the range in which the 3D printing material distorts and above the gel point of agar. The solution was poured into the 3D printed chamber and the phantom was placed in a refrigerator (~4 °C) for 24 hours prior to removing the rods.

The phantom was imaged with a linear array transducer probe (L14-5/38; SonixMDP, Analogic Ultrasound, Richmond, BC, Canada). Prior to imaging, the vessels were filled with water using two 10 mL syringes connected directly to the chamber. In-plane and out-of-plane needle insertions were performed using ultrasound imaging guidance with an injection needle (18 G, Terumo).

Results

The surface quality and the mechanical robustness of the 3D printed chambers depended significantly on the printing process that was used (Figure 1). Both chambers were waterproof and could withstand accidental needle pricks. Printer 1 produced a chamber with a much smoother surface and its output had superior resolution and mechanical integrity. A prominent difference between the printer outputs was found between the luer connectors: those obtained with Printer 2 readily broke with regular usage and the grooves were incompletely delineated (Figure 3 insets). Manual removal of the printing support material, which is required before the chamber can be used, could be achieved more easily when Printer 1 was used.

As seen with ultrasound imaging, wall-less vessels in all three phantoms had circular cross-sections throughout their length (Figure 4). Needles could readily be inserted into the agar and into the vessels. The resistance to insertion was less than that typically encountered in vascular access procedures, however, and resistance was not encountered during transitions from agar to the vessel lumens. Needles were readily visualised on ultrasound, with out-of-plane (Figure 4a) and in-plane (Figure 4b) insertions. Residual needle tracks were apparent, but these could be removed by remaking the phantom.

The agar surrounding these vessels had a homogeneous speckled appearance on ultrasound, similar to that of tissue. At the surface of the phantoms, the agar was sufficiently rigid to resist deformation by the ultrasound imaging probe with light pressure consistent with clinical practice, but care was needed to ensure integrity of the surface. The vessels maintained their shape during injections of water, without fluid leaks. In the branched vessel phantom, the thin agar at the bifurcation point (Figure 4c) was prone to damage during injections. With the stenotic phantom, the variation in vessel diameter was clearly apparent (Figure 4d), and the stenotic region presented as uniform along its length with smooth walls that tapered on either side to wider regions.

Discussion

In this study, the use of 3D printing for the manufacturing of agar wall-less vascular phantoms was explored with three different vessel geometries. The use of 3D printing has two main advantages that make it compelling for use in clinical environments. First, it makes the creation of chamber geometries with multiple inset tubular structures and fabrication of luer connectors straightforward, even in the absence of mechanical workshop resources. Second, the design files can readily be shared electronically and modified to accommodate different types of training.

The phantom chamber design lends itself to several variations that could provide different functionalities. For instance, a pump that provides pulsatile flow and blood mimicking fluid could be used for practising with Doppler ultrasound imaging, as considered in a previous study.^{31, 34} Wall-less vessel phantoms have been found to be inferior to those with vessel-mimicking material¹⁵, and so testing would be required before this method of fabrication could be recommended.

A homogenous agar region surrounding the wall-less vessels is attractive from the standpoint of simplicity, but the use of different materials could allow for inhomogeneities that increase realism. As a variation on the phantom in this study, different layers of aqueous gels could be formed by pouring melted gel on top of a set gel layer; the resulting layers could have additions with different concentrations to control their ultrasonic properties. For instance, gelatine, as an acquous gel, could include a combination of graphite particles for control of ultrasound attenuation and alcohol for control of the speed of sound. 30,35. Ultimately, 3D printing could be used to deposit soft-tissue

mimicking materials directly with 3D printing, which could lead to printing complex structures such as the brachial plexus and even to creating patient-specific phantoms based on segmented preprocedural images. An analogous approach was explored for creating optical phantoms ³⁶.

This study demonstrated that 3D printing is well suited to the creation of wall-less vascular ultrasound phantoms that include branched and stenotic vessels. The approach taken in this paper is particularly well suited to efficient, low-cost vascular phantoms for clinical training.

Acknowledgements

The authors gratefully acknowledge funding from European Starting Grant 310970 MOPHIM and from an Engineering and Physical Research Council (EPSRC) Vacation Bursary for A. Barburas, and helpful discussions with Dr. Wenfeng Xia.

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278	Figure Captions
279	Figure 1. Chamber for phantom with two parallel vessels: (a) software rendering; (b) printed with
280	Printer 2; (c) printed with Printer 1. The insets provide a close-up of one of the luer connectors
281	(arrow). * denotes support tubes.
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283	Figure 2. Phantom fabrication using the 3D printed chamber.
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285	Figure 3. Design of the vessel rods for the development of (a) the wall-less phantom; (b) the
286	branching phantom; (c) the stenotic phantom (outer diameters: $D1 = 4$ mm; $D2 = 6.2$ mm).
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288	Figure 4. Wall-less vessel phantoms imaged with a linear array transducer probe. During imaging, the
289	vessels were filled with water using two 10 mL syringes connected to the chamber. Needle insertions
290	into the parallel vessel phantom were performed (a) out-of-plane and (b) in-plane; the needle tip was
91	visible in both views (dashed circles). The branching phantom (c) and the stenotic phantom (d) are

imaged in cross-section; in the latter, the boundaries of the narrow diameter region are shown with arrows.







