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**ORIGINAL ARTICLE**

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# 3D printed mitral valve models: affordable simulation for robotic mitral valve repair

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ADULT CARDIAC

## Abstract

**OBJECTIVES:** 3D printed mitral valve (MV) models that capture the suture response of real tissue may be utilized as surgical training tools. Leveraging clinical imaging modalities, 3D computerized modelling and 3D printing technology to produce affordable models complements currently available virtual simulators and paves the way for patient- and pathology-specific preoperative rehearsal.

**METHODS:** We used polyvinyl alcohol, a dissolvable thermoplastic, to 3D print moulds that were casted with liquid platinum-cure silicone yielding flexible, low-cost MV models capable of simulating valvular tissue. Silicone-moulded MV models were fabricated for 2 morphologies: the normal MV and the P2 flail. The moulded valves were plication and suture tested in a laparoscopic trainer box with a da Vinci Si robotic surgical system. One cardiothoracic surgery fellow and 1 attending surgeon qualitatively evaluated the ability of the valves to recapitulate tissue feel through surveys utilizing the 5-point Likert-type scale to grade impressions of the valves.

**RESULTS:** Valves produced with the moulding and casting method maintained anatomical dimensions within 3% of directly 3D printed acrylonitrile butadiene styrene controls for both morphologies. Likert-type scale mean scores corresponded with a realistic material response to sutures (5.0/5), tensile strength that is similar to real MV tissue (5.0/5) and anatomical appearance resembling real MVs (5.0/5), indicating that evaluators 'agreed' that these aspects of the model were appropriate for training. Evaluators 'somewhat agreed' that the overall model durability was appropriate for training (4.0/5) due to the mounting design. Qualitative differences in repair quality were notable between fellow and attending surgeon.

**CONCLUSIONS:** 3D computer-aided design, 3D printing and fabrication techniques can be applied to fabricate affordable, high-quality educational models for technical training that are capable of differentiating proficiency levels among users.

**Keywords:** 3D printing • Polyvinyl alcohol moulding • Mitral valve modelling • Preoperative rehearsal • Robotic surgery

## INTRODUCTION

The 3D printing of anatomical models is being increasingly utilized in presurgical planning and the education of patients and clinicians [1]. Advanced image segmentation software capable of directly importing patient data from clinical imaging systems has made it possible to create 3D printed models from X-rays, computed tomography scans, magnetic resonance imagings and ultrasound images. The feasibility of using 3D transoesophageal echocardiogram (3D-TOE) data to generate patient-specific anatomical models of disease for presurgical planning has already been well established due to its convenience, with applications including mitral valve (MV) pathologies, ventricular septal defects and other congenital defects. The 3D image sourcing with 3D-TOE has been explored for its ability to rapidly generate 3D images with no radiation exposure, although magnetic resonance imaging and computed tomography data are more readily available [1, 2]. Opportunities to apply these anatomical models to educational and surgical applications are numerous.

Robotic, minimally invasive MV repair has been shown to improve long-term clinical outcomes over complete replacement with bioprosthetic or mechanical valves [3, 4], although repair procedures have been underutilized due to lack of confidence in the surgical techniques [5, 6]. Realistic surgical simulation of MV repair utilizing models that provide life-like tissue feel and capture patient-specific pathology could provide opportunities for personalized *ex vivo* rehearsal and increase surgeon preference to perform robotic repair techniques over complete replacement. The utility of low-fidelity approaches to simulating MV repair has been demonstrated, but these methods are limited in their ability to provide tissue-like realism or model pathological valve morphologies [7]. Furthermore, traditionally 3D printed acrylonitrile butadiene styrene (ABS) models are limited in their utility as surgical training models by their solid plastic composition [8, 9].

Previous studies have shown utility in similarly fabricated models using 3D printed moulds and liquid platinum-cure silicone for laparoscopic pyeloplasty that qualitatively exhibited a high level of realism and usability [10]. Although direct 3D printing of silicon models of MVs and other applications has also been accomplished, this process requires specialized, expensive 3D printers capable of directly extruding proprietary silicones and other liquid materials that can limit access to the technology [2, 11–13]. Polyvinyl alcohol (PVA) can be used as a moulding material with inexpensive home desktop printers.

The eventual goal is to develop life-like models that accurately mimic patient-specific pathology and can be used for *ex vivo* surgical rehearsal utilizing a fabrication technique that is rapid, affordable and maintains realistic tissue response. Studies have already shown that simulation with accurate suture feel is a valuable asset for surgical applications in urology [14]. For the technology to become widely adopted, it must also be affordable, accessible and integrate with currently available imaging modalities. This study aims to apply a low-cost fabrication method utilizing 3D-TOE, computer-aided design (CAD) software, PVA and platinum-cure silicone to develop MV models with realistic suture feel and to preliminarily assess the utility and value of these models to cardiothoracic surgeons as training tools.

## METHODS

### Image segmentation and 3D model rendering

Anonymized 3D-TOE images in Digital Imaging and Communications in Medicine (DICOM) format were collected from a patient who consented to full participation in a biorepository. The 3D-TOE DICOM images were collected using a Philips EPIQ7 3D-TOE system. Philips QLAB 10 was used to adjust the gain to a value of 48 to limit artefacts resulting from blood speckling.

Images were imported into medical image segmentation software (Materialise Mimics 11.0, Leuven, Belgium) and frames in mid systole were selected. The image would eventually serve as a 3D volume from which a cleaner MV can be drawn. The images were then manually segmented using pixel intensity threshold settings. Pixel intensity was set at 170 units to reduce the appearance of blood speckling and artefacts while maintaining integrity of soft tissue structures.

After segmentation, 3D volume rendering was performed automatically with native software functions. The 3D volume rendering was exported to 3D CAD software (Materialise 3-matic, Leuven, Belgium) and then smoothed by creating a hollow mesh wrap of the volume and applying integrated smoothing tools that mathematically normalize model surface geometries.

Trimming and drawing tools within the CAD software were used to manually manipulate the 3D volume into the shape of an artificial MV with anterior leaflets, posterior leaflets and commissures. Boolean subtraction methods were used to render a negative mould of the 3D MV model. Trim tools in the CAD software were used to create slits in the mould to allow filling of the final 3D printed mould with liquid platinum-cure silicone. The 3D CAD models of the positive MV model and the mould were exported in stereolithography format (.stl) for 3D printing. This process was repeated twice to generate an MV model with normal morphology and an MV model with P2 flail morphology.

### 3D printing and fabrication of mitral valve models

PVA, a dissolvable 3D printing filament (SainSmart.com, Lenexa, KS, USA) of 1.75 mm diameter, was stored in vacuum-sealed bags (Ziplock Space Bag, S.C. Johnson & Son, Racine, WI, USA) with silica gel packets to prevent deformation of the material due to environmental moisture exposure. Moulds ($n = 15$) were 3D printed using PVA on a Flashforge Creator Pro desktop 3D printer (Zhejiang Flashforge 3D Technology Co., Ltd, Jinhua, China) in single extruder mode with an extrusion temperature of 200°C, platform temperature of 65°C, a feed rate of 40 mm/s and travel feed rate of 55 mm/s. The products of the 3D prints were solid moulds of PVA, containing no ABS or polylactic acid (PLA) components.

The 3D-printed moulds were then filled with platinum-cure silicone with Shore hardness 10A certified to ISO-10993-10, evaluation for medical devices, part 10 (Smooth-on Dragon Skin Very Fast 10, Smooth-On, Inc., Macungie, PA, USA) mixed 2:1 with a platinum-cure silicone thinner (Silicone Thinner, Smooth-On, Inc.). The filled mould was allowed to sit at room temperature for 1 h before dissolving in water at 90°F with constant stirring at 300 rpm. The silicone MV model was removed from the mould as soon as enough of the mould was dissolved, allowing recovery of the final product. Time to dissolution of the mould and recovery of the MV models was recorded. Figure 1 provides an overview of the fabrication process.

The positive model .stl file of the same MV was 3D printed using ABS with an external raft support as controls ($n = 15$) for both the normal and P2 flail morphologies.

### Suture testing and qualitative assessment of silicone mitral valve models

A collapsible Train Anywhere Skill Kit (TASKit) (Ethicon Endo-Surgery, Cincinnati, OH, USA) was used as a thoracic model. P2 flail silicone MV models were adhered to a custom 3D printed mount that was designed to be directly compatible with the TASKit kit mounting pegs. A da Vinci Si system equipped with Mega Suturecut Needle Driver and Prograsp Forceps was used for testing. One cardiothoracic surgery fellow and 1 attending physician performed a P2 leaflet foldoplasty with annuloplasty. A stitch was placed in the leading edge of the prolapsed P2 leaflet and folded back underneath the leaflet towards the annulus then tied in place with CV-2 Gortex suture on a TH-26 needle. Annuloplasty was performed using a Cosgrove–Edwards ring and 2-0 Ethibond suture on an SH-2 needle. A survey was administered to collect preliminary qualitative assessment of tissue feel under suture, tensile strength, durability and overall realism using a 5-point Likert-type scale.

## RESULTS

### Silicone mitral valve model fabrication and validation

The 3D-TOE images were successfully imported in mid systole, segmented and rendered into 3D volume models. A manually drawn 3D MV model was successfully created by manipulating the preliminary mid systole 3D volume (Fig. 2B). Drawing a 3D MV model from a previously rendered volume from 3D-TOE images bypassed some of the challenges of drawing an irregular

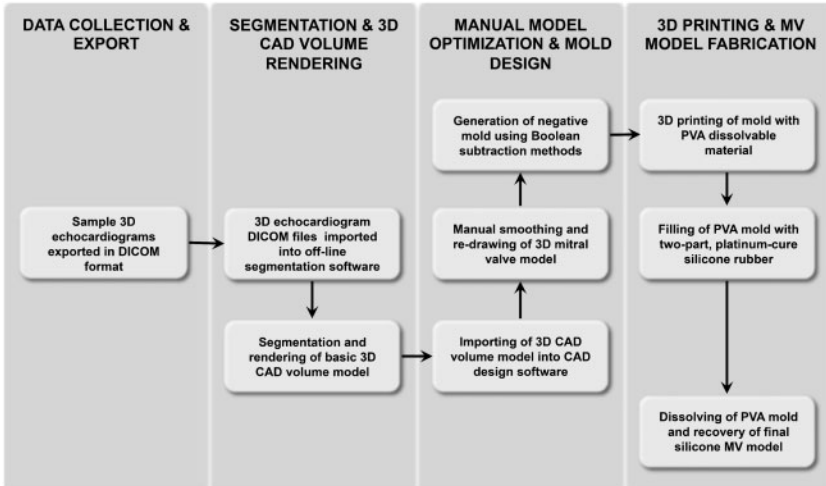


**Figure 1:** Overview of MV modelling workflow from 3D echocardiogram exporting to silicone model fabrication. CAD: computer-aided design; DICOM: Digital Imaging and Communications in Medicine; MV: mitral valve; PVA: polyvinyl alcohol.



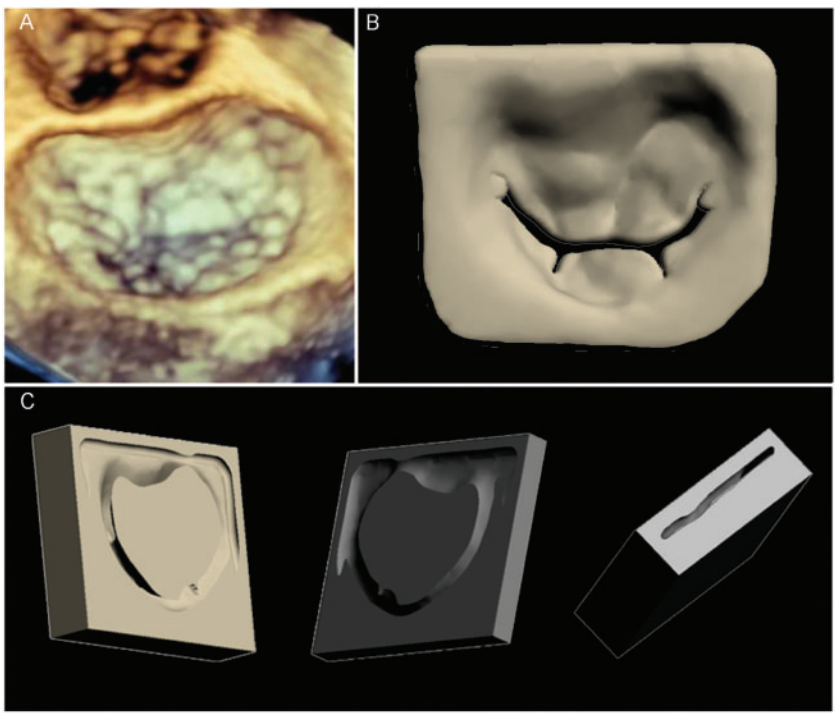


**Figure 2:** (**A**) 3D transoesophageal echocardiogram of mitral valve in mid systole used to generate preliminary 3D volume. (**B**) Manually drawn mitral valve model generated from 3D volume with computer-aided design software. (**C**) Computer-aided design rendering of fillable one-piece mould and internal structure. These moulds were created for both morphologies.

and complex 3D shape in traditional CAD software. Boolean subtraction was successfully applied to create negative moulds that could be filled with platinum-cure silicone. Figure 2B shows the manually drawn 3D MV CAD model, whereas Fig. 2C shows the result of Boolean subtraction and the interior mould contours of the resulting moulds. The anterior leaflets, posterior leaflets and commissures are distinguishable in the CAD model of the drawn MV as seen in Fig. 3, which also illustrates the commissure-to-commissure distance and P2 leaflet width that were measured in comparison of silicone moulding with direct ABS 3D printing.

Fifteen hollow moulds were successfully printed with pure PVA, not requiring any ABS or PLA material. The PVA material maintained its structural integrity and preserved fine details of the mould throughout the duration of the print (Fig. 4). The time required to print each mould was about 1 h and 10 min for MV models with a diameter of 28 mm, including the annulus, equivalent to the size of a human MV. All 15 moulds were used to produce silicone MV models and were successfully dissolved with recovery of the final product. The time required to dissolve the PVA moulds in warm water to recover the final MV model was 6 h. The total time from

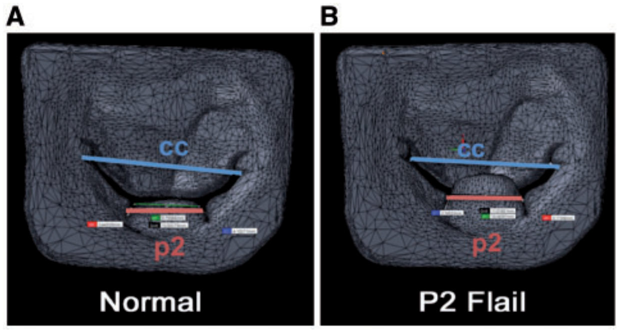


**Figure 3:** 3D computer-aided drawing with commisure-to-commisure (cc) distance and P2 leaflet (p2) width illustrated for normal mitral valve morphology (**A**) and (**B**) P2 flail morphology. Line segments included for illustration purposes only and have no scale.

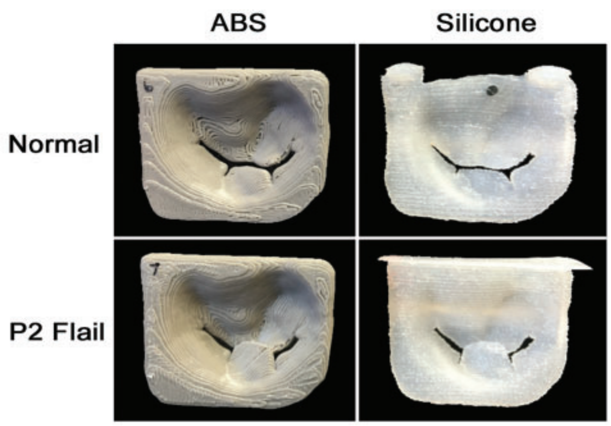


**Figure 4:** Fabricated ABS control models and silicone mitral valve models for both normal mitral valve morphology and P2 flail morphology. ABS: acrylonitrile butadiene styrene.

beginning the 3D print of the mould to dissolving the PVA mould was approximately 8.5 h with <30 min of hands-on labour time. The cost of each MV was approximately US$2.00 or less for disposables (PVA and platinum-cure silicone), excluding the one-time cost of the FlashForge desktop 3D printer (approximately US$1200.00).

Commissure-to-commissure distance and P2 leaflet width were measured for the 15 moulded silicone MVs and 15 ABS controls for both the normal and the P2 flail morphologies and were found to be within 3%.

## Suture testing and qualitative assessment results

The evaluators 'agreed' that the suture feel, tensile strength and anatomic realism of the models resembled real MVs and were appropriate for training applications. Overall score out of 5 for tissue feel under suture was 5.0, sufficient tensile strength compared with real tissue was 5.0 and anatomic realism was 5.0. Evaluators 'somewhat agreed' that the overall durability was sufficient for training applications, which was rated at 4.0 out of 5. During the foldoplasty, the P2 leaflets could be folded and sutured towards the annulus without abnormal tearing or deformation. The P2 leaflet height was effectively reduced in the final result (Fig. 5A and B). The annuloplasty ring was sutured without tearing of the silicone valve, and the model is able to recapitulate the proper anatomical orientation of the ring as seen in Fig. 5C and D. Occasionally, the valves detached at the annulus from their custom-fabricated mount during suturing, which affected the overall durability score. Overall, the perception of the MV models was highly positive, as they were able to capture the qualitative manifestations of varying robotic surgical proficiency between the attending surgeon and the fellow.

## DISCUSSION

The silicone MV models exhibited sufficient mechanical realism to perform P2 leaflet foldoplasty and annuloplasty without issues. The suture feel, tensile strength and anatomical recapitulation were good, although overall realism likely suffered due to idealization of the valve appearance and morphology to obtain functional, separate leaflets and for simplification of model design and fabrication with mould 3D printing. This study demonstrates proof of concept and the ability of silicone-moulded MV models to serve as an *ex vivo* surgical rehearsal tool prior to performing posterior leaflet repair. Furthermore, it validates the PVA moulding and casting technique as a realistic, inexpensive method for fabricating these models when taken together with the dimensional agreement within 3% compared with ABS controls. As the valves were approximated to cost several dollars a piece and we utilized a desktop 3D printer costing about the same as an average laptop, the affordability offered with this moulding and casting approach is an important aspect of allowing simulation education to become widespread. Although model testing was performed with a da Vinci robotic surgical system, it is likely that laparoscopic training would also benefit from such models.

Compared with virtual reality trainers commonly used in surgical training, actual operable models provide a dimension of realism that is unmatched. Although suturable models have been commercially available for some time, they are limited in the variety of scenarios or morphologies that can be reproduced, whereas 3D printing custom-fabricated models allow users to optimize their designs to suit their training needs. In terms of tactile response, the moulded models provide similar suture feel and durability compared with a commercially available P2 flail model but at a significantly reduced cost. The ratio of thinner to platinum-cure silicone can be adjusted to optimize tissue feel. A visual comparison confirmed that the 3D printed mould fabrication method is capable of reproducing a degree of anatomical realism that is comparable to commercial solutions (Fig. 6). Furthermore, these models may provide a unique opportunity when combined with virtual reality simulation resulting in novel augmented reality applications. Augmented reality simulation consists of overlaying virtual imagery over real operable models, but many augmented reality simulations are expensive and limited in the patient-specific pathology [15]. The work in this study may contribute to reducing the cost of augmented reality or other simulation modalities.

Because the MV models fabricated in this study were able to capture the gap in proficiency with foldoplasty between attending surgeons and fellows, the models may serve as a useful tool for measuring progress with trainees in augmented reality and simulation applications. Future studies can assess the rate of progress with practice while allowing teaching of critical technique based on qualitative appearance of the repair as performed by a trainee.

A particular strength of this study illustrates that an alternative fabrication method applying 3D printing and moulding can be used to fabricate realistic surgical training models that may be optimized through CAD at a low cost and that are capable of

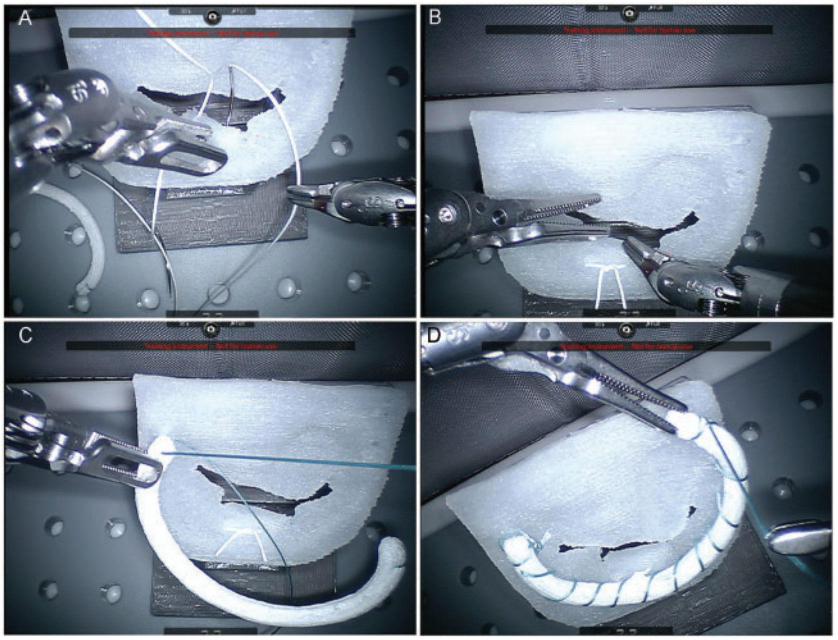


**Figure 5:** Laparoscopic view of valve (**A**) during robotic P2 foldoplasty and (**B**) after P2 foldoplasty. Laparoscopic view (**C**) prior to annuloplasty with Cosgrove–Edwards style ring and (**D**) after annuloplasty. All testing was performed with a da Vinci Si system utilizing Prograsp Forceps and Mega Suturecut Needle Driver.

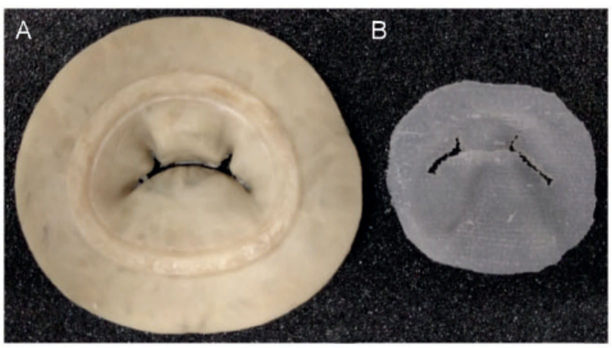


**Figure 6:** Photographic comparison of (**A**) commercially available mitral valve P2 flail model and (**B**) polyvinyl alcohol-moulded mitral valve P2 flail model with P2 leaflet tucked to illustrate comparable anatomic dimensions and detail of the commissures and leaflets. The proprietary mounting mechanism of the commercial solution requires additional material encircling the valve annulus.

serving as disposable training models. Although this study demonstrates proof of concept of an affordable 3D printed moulding technique, the weakness of the study lies in the limited number of designs tested with the fabrication process. Although both the normal and P2 flail morphologies were fabricated without issue, further work is required in the modelling and fabrication process to translate the method to a wide range of patient pathologies. Additionally, the designs of the models were optimized for the fabrication process, which detracts from their anatomic realism. The benefits of omitting some anatomical structures, such as the chordae tendineae, towards the ease of fabrication and affordability were acceptable, as our testing surgeons felt that including them was less valuable compared with recapitulating the anatomical deformities of the leaflets for simulating MV repair.

The realism of customized models should be assessed in the context of surgical rehearsal and the ability to elucidate differences in proficiency between users. Furthermore, the impact of such models on the objective proficiency and confidence levels of surgeons in training should be assessed in larger studies with access to large numbers of trainees. This was found to be a limitation at our institution due to the limited number of cardiothoracic fellows and attending physicians who are proficient in performing robotic-assisted MV repair.

The workflow for fabricating these MV models would benefit greatly from more software automation and increased imaging resolution. Attempts to apply automated segmentation algorithms to raw 3D-TOE DICOM files resulted in structurally non-functional valve designs that would be anatomically inaccurate precluding their use for suture testing without manual redesign. The design process is curtailed by limited imaging resolution and a subjective segmentation process that does not reliably discriminate between soft tissue structures that are physically in contact but anatomically separate. As a result, image segmentation and 3D model rendering from imaging data in the DICOM format are not entirely able to capture the necessary solid tissue detail with sufficient accuracy to generate 3D printed models without significant manual redesign in the CAD suite. As improved segmentation methods are being readily explored, advances in automated image segmentation and 3D volume rendering may eventually resolve this issue [16–18]. As imaging resolution and automated segmentation methods improve, the ability to produce affordable, life-like tissues that accurately replicate patient-specific pathology could have profound impacts on surgical outcomes. Concomitantly, outcome-oriented studies should be continued with improved MV models to elucidate their true potential in improving technical proficiency.

## CONCLUSION

The 3D printing and 3D-TOE technology can be leveraged to create patient-specific surgical training models that will enable surgical simulation with realistic tissue response and appropriate anatomical detail, but further development of various aspects of the technology could extend its utility and ease of use. Affordable MV models fabricated from a customizable 3D printing process are suitable as basic surgical training tools that may offer advantages over simulation alone as evidenced by the ability of these models to capture qualitative differences in surgical skill. It is our hope that this work will inspire similar technologies that could have a positive impact on surgical outcomes and ultimately reduce complications by enhancing the quality of planning and rehearsal.

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