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ORIGINAL ARTICLE

Face and content validity of novel three-dimensional hydrogel models for vascular anastomosis simulation

Rachel Falconer,[a,]* Catriona M. Semple,[b] Weixing Wang,[c,d] Wenmiao Shu,[c,d] Jennifer Cleland[e] and Angus J.M. Watson[a,f]

[a]*Centre for Health Science, Old Perth Road, Inverness, IV2 3JH, UK;* [b]*Victoria Hospital, Hayfield Road, Kirkcaldy, KY2 5AH, UK;* [c]*Organlike Ltd, Solasta House, 8 Inverness Campus, Inverness, IV2 5NA, UK;* [d]*Department of Biomedical Engineering, Wolfson Building, University of Strathclyde, 106 Rottenrow, Glasgow, G4 0NW, UK;* [e]*Medical Education Research & Scholarship Unit (MERSU), Lee Kong Chian School of Medicine, Nanyang Technological University, Novena Campus, 11 Mandalay Road, Singapore 308232;* [f]*Department of General Surgery, Raigmore Hospital, Old Perth Road, Inverness, IV2 3UJ, UK*

Corresponding author at: Centre for Health Science, Old Perth Road, Inverness, IV2 3JH, UK. Email: rachel.falconer4@nhs.scot

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Abstract

Background: Simulation is widely recognized as a valuable adjunct to operative experience in modern surgical training. The aim of this study is to determine the face and content validity of novel 3D hydrogel vascular models for use in anastomosis simulation training. **Methods:** Vascular consultants and specialty trainees in tertiary units in the United Kingdom used the models to perform simulated end-to-side anastomoses and provided feedback via an anonymous written questionnaire. **Results:** Nineteen vascular consultants and 14 vascular specialty trainees provided feedback (N=33). Overall, most rated both the double-layer artery model and the vein model as good or very good and believed the models were as good, if not better than, those currently used. Ninety-four percent of participants rated the models as suitable for vascular anastomosis training. **Conclusions:** The first generation of OrganLike (Ltd) hydrogel models have appropriate face and content validity for use in vascular anastomosis simulation training for junior surgical trainees. This technology offers an exciting opportunity to develop a range of inexpensive, biodegradable models with standardized pathology to address a wider range of learning needs throughout vascular training.

Keywords: *vascular surgical procedures; hydrogels; simulation training; anastomosis; surgical*

Introduction

There are many challenges in delivering comprehensive training for vascular surgery trainees within the current health care system, including work-hour restrictions, complexity of cases and increasing prevalence of endovascular over open approaches.[1,2] This has prompted many to re-evaluate the suitability of the traditional learning by doing apprenticeship model.[3] Although operative experience will remain important, it is imperative to consider other ways to facilitate surgical skill acquisition that are standardized, evidence-based and do not risk harm to patients.

Surgical simulation can provide a risk-free environment in which trainees can undertake repeated practice, make mistakes and receive feedback.[4] Simulation has been shown to significantly improve both global and task-specific skills, technical outcome and trainee confidence in performing a range of vascular procedures.[5–9] Junior trainees, in particular, benefit from this type of learning.[10,11]

A national needs assessment using expert consensus to inform priorities for open vascular simulation ranked vascular anastomosis as the number one procedure.[12] Duran et al.[13] also showed that junior trainees place most value on anastomotic models, demonstrating concordance between faculty and trainee assessment of current simulation training needs. Vascular anastomotic techniques have previously been taught using a range of models, from bench-top jigs with single-use synthetic tubing to cadavers and live, anaesthetized animals.[8,11,14–16] However, advances in three-dimensional (3D) printing and bio-fabrication technology now provide an opportunity to create new simulation models without the attendant financial, ethical and ecological restrictions of those currently in use.[17]

Results from this study were previously reported at the in the ASME Annual Scholarship Meeting 2020 – Disrupting medical education: validation of novel 3-D hydrogel models for vascular anastomosis simulation. https://doi.org/10.1111/tct.13238

Validation provides an assessment of the appropriateness of a model for teaching a specific task. Ideally, the model should provide visual and tactile likeness (face validity) and be deemed suitable as a teaching aid (content validity).[18,19] However, there are no guidelines and little consensus on how this validity should be established.[20] In published studies, subjective validation (such as face and content validation) of simulation relies on the use of questionnaires to elicit expert opinion on the realism and educational benefit of new models.

The purpose of this study was to undertake an assessment of the face and content validity of novel 3D bio-fabricated hydrogel models for vascular anastomosis simulation.

Materials and methods

Models

The models were primarily made from hydrogel-based materials, comprising cross-linked polysaccharide polymers that provide elastic mimicking properties (OrganLike Ltd, Inverness). A pioneering bio-fabrication technique was used to create the single-layer artery and vein models.[17] The single-layer arterial model had a wall thickness of 2 mm with a 12 mm internal diameter. Red food dye was used as a colourant. The double-layer artery model was fabricated by hand from two separate 1-mm-thick single-artery models with an internal diameter of 12 mm. The two layers were adhered to each other but could be separated by surgical tools. The wall thickness was 1 mm for the vein model, with a 4 mm internal diameter and a white dye was used to create the opacity. Examples of the models are shown in Fig. 1a and b, and a video demonstrating these being used for simulation of vascular anastomosis is available online at https://youtu.be/9uT9OjdE65U.

Subjects and protocol

Vascular trainees (ST3–8) and consultants were voluntarily recruited from seven vascular units in the United Kingdom. An introductory email was sent to the consultants in each unit explaining the aim of the project, along with detailed information for participants. In five units, a short presentation was subsequently given by the lead author (RF) during a departmental audit or education session, and all those attending were given the opportunity to participate. Following this, kit boxes and information sheets were left with a designated trainee in each unit for 1 month to allow those who had been unable to attend the teaching session to participate if they wished to. In two units, the models, kit boxes and instruction sheets were sent out to a designated consultant within the unit who then recruited participants locally.

After giving written consent, participants used the models to perform a simulated end-to-side anastomosis. Each participant was provided with a standard set of instruments including a Castroveijo needle holder, deBakey forceps, scalpel, scissors and a rubber-shod clip (Fig. 2a). All participants were asked to wear gloves and used 5/0 double-ended polypropylene sutures (Prolene; Ethicon, Raritan, NJ, USA) to complete the anastomoses. During the task, the arterial model was secured in the modified sponge jig using two small pins (Fig. 2b).

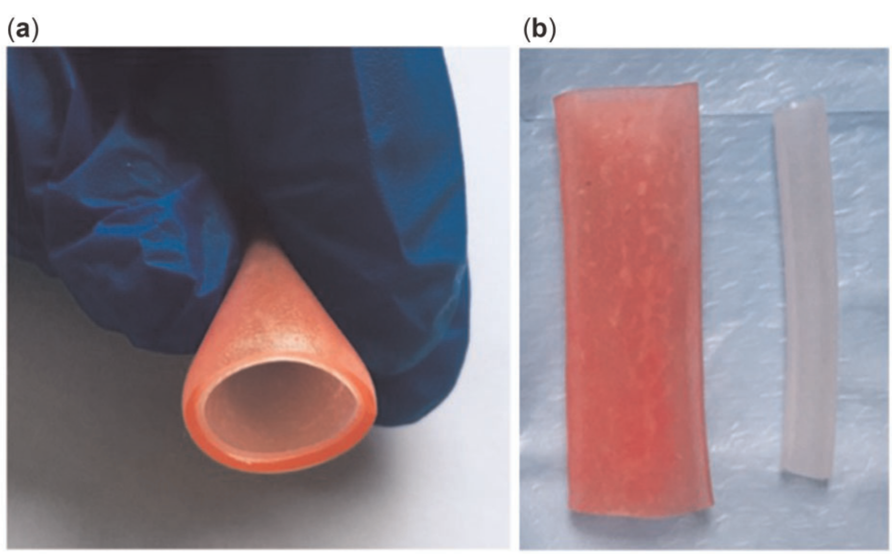

Figure 1. OrganLike (Ltd) 3D hydrogel models: (a) double-layer artery and (b) single-layer artery and vein models.

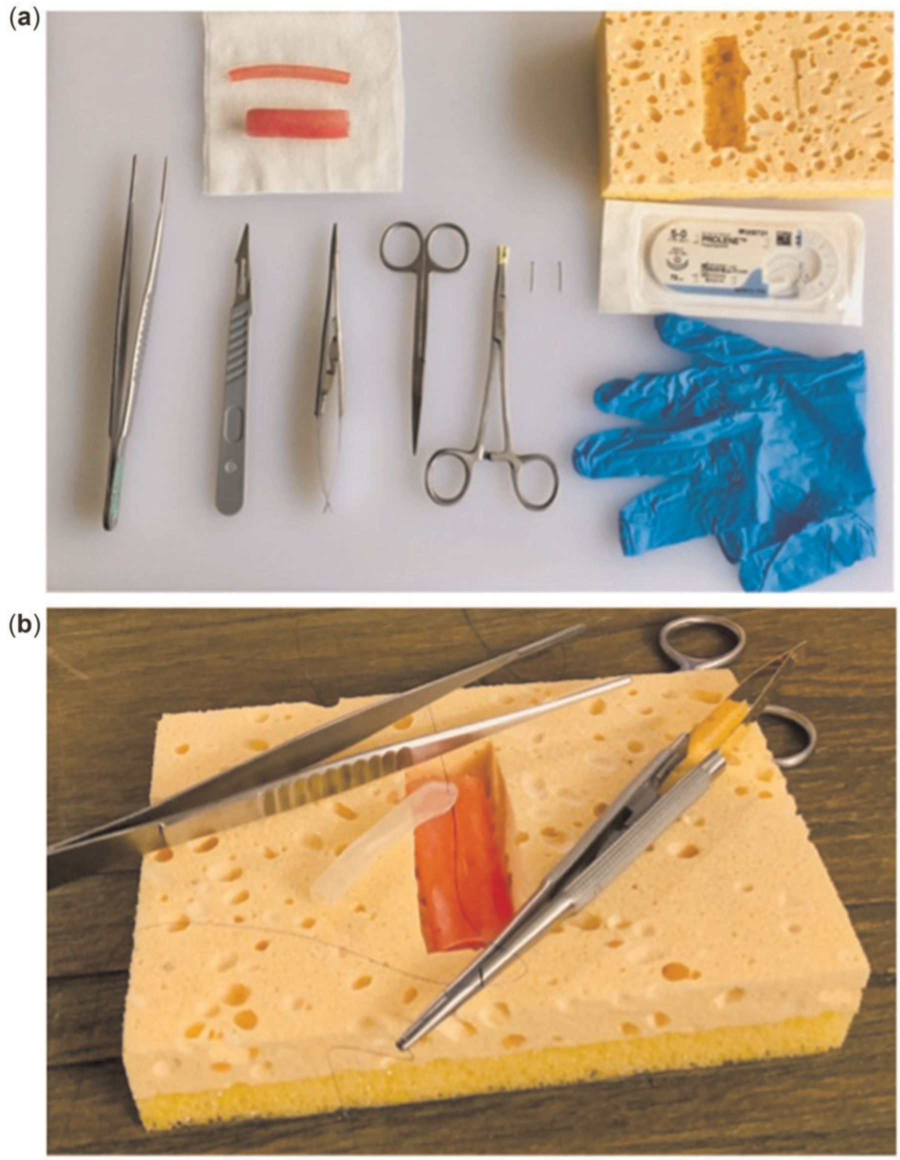

Figure 2. Instruments (a) and jig (b) for vascular anastomosis.

Participants then completed an anonymous, written questionnaire in which they were asked to provide feedback on the double-layer arterial model and the vein model across multiple domains (Supplementary material). The questionnaire was piloted in a single unit and following this, two additional questions were included (suitability of single- versus double-layer artery for anastomosis training in junior surgical trainees and overall impression of the vein model). As a result, not all participants were asked all ten single-best answer questions outlined.

Biomechanical properties (elasticity, rigidity, thickness, resistance to needle insertion and resistance to pulling the suture through) were scored on a 10-point Likert scale, anchored with 5 (about right), from 1 (not elastic/rigid/thick enough/not enough resistance) to 10 (too elastic/rigid/thick/too much resistance). Behavioural properties of the models during the task (tactile feel, handling with instruments, response to making an arteriotomy, ability to hold a suture and ability to hold tension of a knot) were scored using a 10-point Likert scale from 1 (not realistic) to 10 (very realistic). Participants were asked to rate their overall impression of the double-layer artery and vein models (very poor/poor/equivocal/good/very good/excellent) and if used, whether they believed the single-layer artery model was more acceptable/as acceptable/not as acceptable compared with the double-layer artery model in simulation training for junior surgical trainees. Participants were also asked to rate the suitability of the models for the task and compare them with other models previously used for vascular anastomosis simulation (very poor/poor/equivocal/good/very good/excellent); free text comments were also possible.

Results

Participants

Thirty-three participants (19 vascular surgery consultants and 14 vascular surgery trainees) took part. All 19 consultants and 10 of the trainees rated themselves as confident to complete an open end-to-side anastomosis without assistance or supervision. All ten single-best answer questions were completed by 25 of 28 (89%) participants. Five participants answered all 8 (100%) questions in the initial pilot questionnaire. Two participants did not rate the single-layer artery for simulation training, one of whom also did not score two domains (ability to hold a suture and ability to hold tension of a knot) for the double-layer artery model.

Face validity

For the double-layer artery model, the median score was 6 for elasticity and 4 for rigidity but 5 (about right) for thickness, resistance to needle insertion and pulling a suture through (Fig. 3). For the vein model, the median score was scored as 5 (about right) for elasticity, rigidity and thickness. The median score for resistance to needle insertion and resistance to pulling a suture through was also 5 (Fig. 3). The median scores for the behavioural properties of the double-layer artery were 5 for tactile feel, response to making an arteriotomy and ability to hold a suture, 6 for handling with instruments and 7 for ability to hold the tension of a knot (Fig. 4). The median scores for the vein model were 5 for tactile feel and handling with instruments and 6 for ability to hold a suture and tension on a knot (Fig. 4).

Content validity

Most participants scored both the double-layer artery and vein models as good or very good (Fig. 5) and all participants rated the arterial model as good as or better than models currently used for vascular anastomosis simulation training. Eighteen of 25 (72%) participants who compared the single-layer and double-layer arteries believed the single-layer artery model was as acceptable or more acceptable for training junior surgical trainees. Overall, 19 (100%) consultants believed that the models were suitable for vascular anastomosis training. Twelve (86%) trainees also rated the models as suitable for anastomosis simulation. Two trainees (14%) believed they were not suitable, with free text comments that the models were "more elastic than usual", "need to be more rigid" and that "needle pulls through".

Discussion

Although there are guidelines for validation of virtual reality simulators, no specific standards have been published for validation of models for open vascular simulation.[21] In this study, multi-centre consensus of opinion from vascular trainees and consultants found that these 3D hydrogel models have appropriate face and content validity for anastomosis simulation.

The double-layer artery model was thought to be an appropriate thickness but was a little too elastic and not quite rigid enough. However, all biomechanical properties of the vein model were judged to be about right. Interestingly, the realism of the behavioural characteristics of both models elicited a wider range of scores, which may partly reflect the relative importance placed on each by individual participants, their operative experience and familiarity with using other simulation models. Nevertheless, such detailed feedback is not commonly elicited in validation studies and is likely to be valuable in helping to refine and improve future models.

There is still some debate regarding the impact of model fidelity on skill acquisition in junior surgical trainees. A systematic review by Fonseca et al.[1] found that most studies on open surgical simulation successfully used low-fidelity bench-top models to train junior residents to perform basic surgical skills. In contrast, Sidhu et al.[9] found that junior trainees who practiced on a high-fidelity model (cadaveric brachial artery) were significantly better at performing a vascular anastomosis than those who learned on a low-fidelity model (plastic tube). This suggests that learning on a model that cannot demonstrate the consequences of poor technique (e.g. rough vessel handling) may prevent accurate discrimination between those who do and do not subsequently perform well on a real artery. Currently, the single-layer artery models are quicker and cheaper to manufacture than the double-layer models and interestingly, most participants though that these were as acceptable for training junior trainees. Therefore, further research is needed to clearly delineate which properties of an anastomotic model contribute most to effective simulation training and whether different models are appropriate for different stages of training.

A recurring criticism of validation studies is that many are undertaken at surgical conferences and involve a small

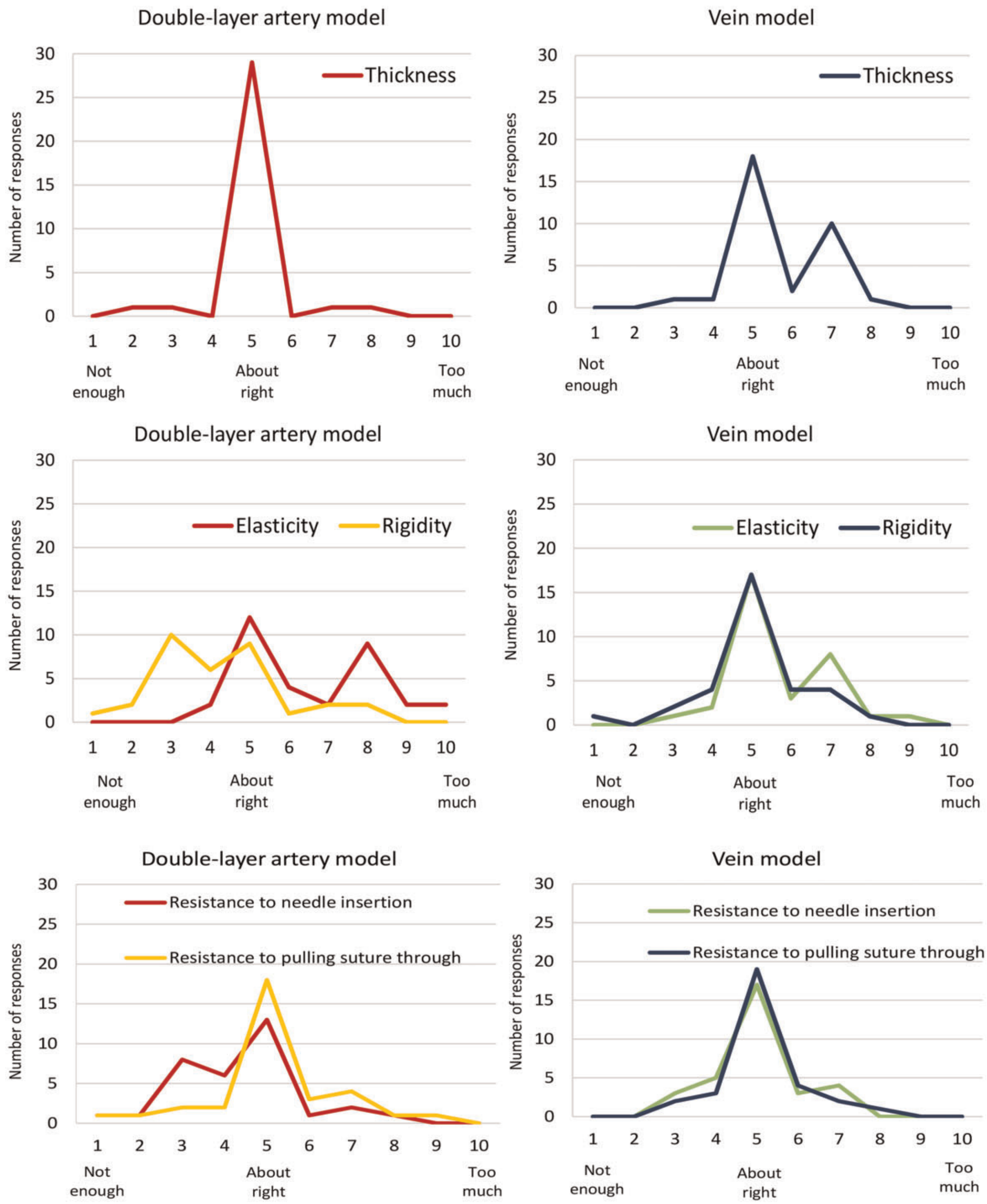

Figure 3. Biomechanical property scores for the double-layer artery model and the vein model.

number of self-selecting participants.[18,20] This study aimed to provide a more representative cohort by inviting vascular trainees and consultants in multiple vascular units across the UK to participate. However, it is acknowledged that because participation was voluntary, there may still be inherent selection bias, because those who chose to take part may have a greater interest in simulation or education.

Future work

Although the double-layer artery may not offer a significant advantage over the single-layer model in acquisition of basic anastomosis skills, it does provide a foundation for the development of pathological models (e.g. with intrinsic, removable plaque) in the future. Currently, no vascular models provide standardized pathology or unusual anatomy

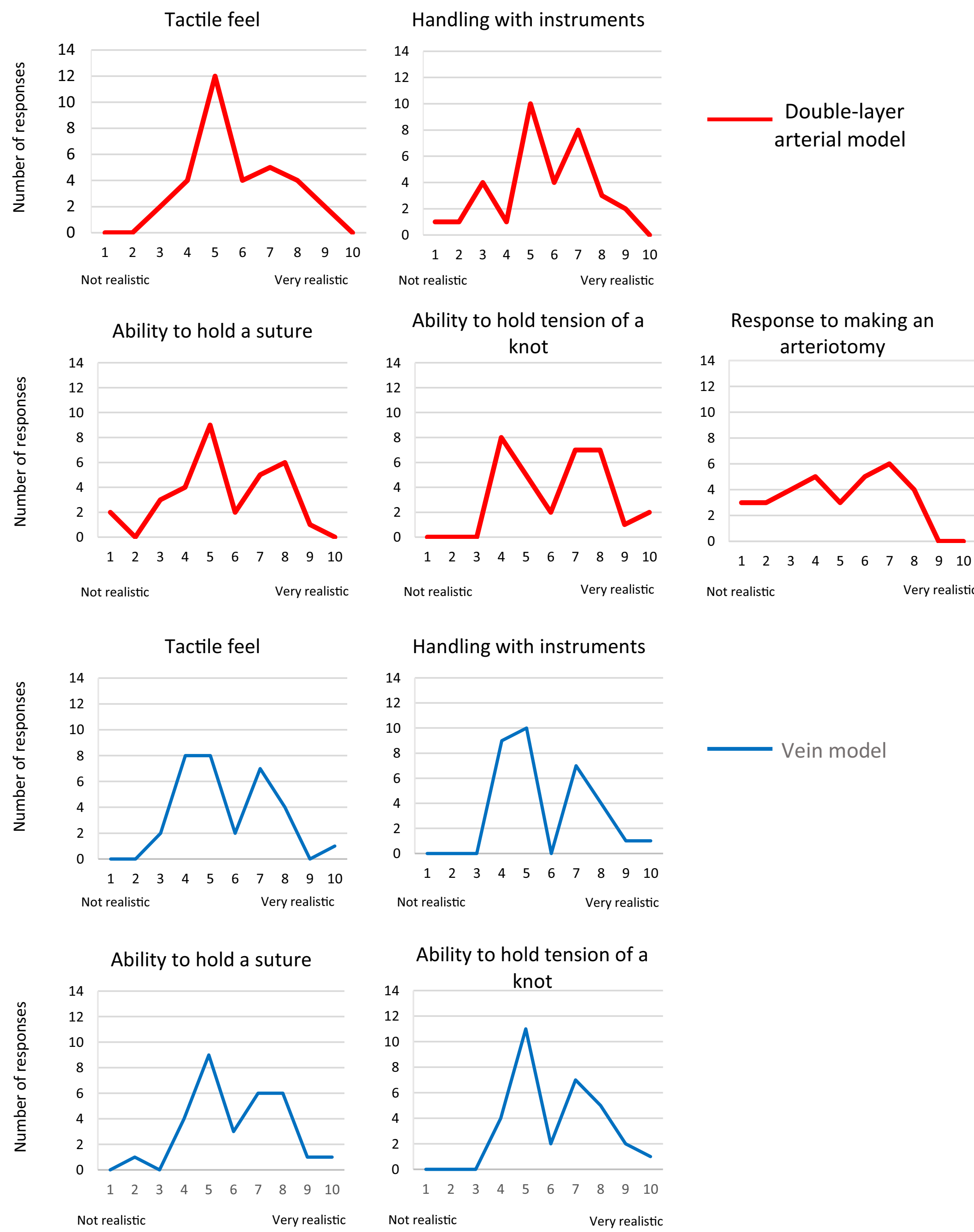

Figure 4. Realism of behavioural properties for the double-layer artery and vein models while performing a simulated end-to-side anastomosis.

at a cost that would facilitate deliberate, repeated practice. Looking to the future, it is imperative that new models are developed to support skill acquisition in more senior trainees, providing access to regular, low-cost open vascular simulation throughout training. Our data suggest that the models are appropriate. However, at this point, these models are prototypes and as such, accurate costs are dependent on the production scale and hence are not yet established. In addition, further studies are needed to establish the biodegradability and disposability of these models, as well as the optimal storage conditions and shelf-life to fully justify the benefits of replacing alternative materials such as rubber, animal tissue and even cadavers.

Conclusion

Vascular surgery is a dynamic and innovative speciality and simulation is likely to play an increasingly prominent role in

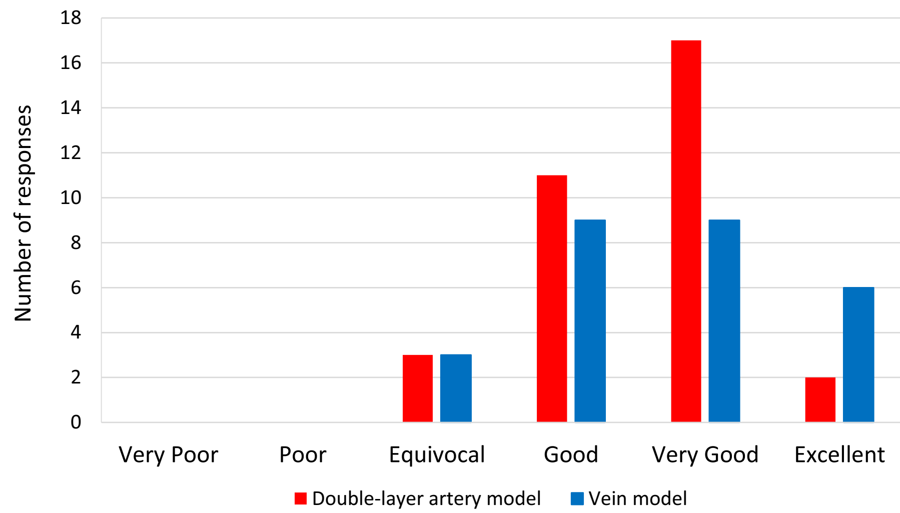

Figure 5. Overall impression of the models for simulation training.

modern vascular surgery training. There is increasing evidence from other surgical specialities that simulation can improve performance in the theatre, reduce risk of patient harm during training operations, and ultimately improve patient outcomes.[22–24] It is therefore imperative to look at how existing technologies can be used to improve training for future generations of vascular surgeons.

This study represents the first step in validating a range of affordable, realistic and clinically relevant vascular models that could help to provide equitable access to regular open vascular simulation throughout training. Further work is needed to provide a standard for validation of vascular simulation models, as well as to define the optimal model characteristics for effective skill acquisition in different learner groups.

Conflict of interest

R.F. received the models for the study free of charge but received no other financial incentive from OrganLike Ltd. W.W. is an employee of OrganLike Ltd and W.S. is the founder of OrganLike Ltd. J.C., C.S. and A.W. have no conflicts of interest to declare.

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Supplementary material

Participant questionnaire. Available online at: https://doi.org/10.5281/zenodo.6533248

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