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Educational Impact of a Pulsatile Human Cadaver Circulation Model for Endovascular Training

Craig I. Nesbitt [a,*], **Samual J. Tingle** [b], **Robin Williams** [c], **James E. McCaslin** [d], **Roger Searle** [e], **Sebastian Mafeld** [c], **Gerard P. Stansby** [d]

[a] Department of Vascular Surgery, Northern Vascular Centre, Freeman Hospital, UK
[b] Faculty of Medical Sciences, Newcastle Medical School, Newcastle Upon Tyne, UK
[c] Department of Interventional Radiology, Northern Vascular Centre, Freeman Hospital, Newcastle Upon Tyne, UK
[d] Department of Vascular Surgery, Northern Vascular Centre, Freeman Hospital, Newcastle Upon Tyne, UK
[e] Anatomy and Clinical Skills, Newcastle University, Newcastle Upon Tyne, UK

WHAT THIS PAPER ADDS

Previous endovascular literature has focused on virtual reality based simulation for training endovascular skills. The face and construct validity of a novel pulsatile human cadaver model was recently demonstrated for endovascular training. The present study builds on this literature by proving the educational impact of the human cadaver model, and by demonstrating various potential benefits over virtual reality simulation. This work could lead to improvements in the way that future endovascular practitioners are trained. As endovascular procedures become increasingly common across multiple specialties, improving endovascular training will have clinical benefits for a large population of patients.

Objectives: The face and construct validity of a novel pulsatile human cadaver model (PHCM) was recently demonstrated for endovascular training. This study aimed to assess the model's educational impact.

Methods: Twenty-four endovascular novices were recruited and split into two equal training groups: PHCM and virtual reality simulator (VRS). Each candidate performed eight consecutive training attempts of endovascular renal artery catheterisation on their designated model, and a final crossover attempt on the alternate model. Performances were video recorded and scored using a validated scoring tool by two independent endovascular experts, blinded to the candidate's identity and attempt number. Each participant was given a task specific checklist score (TSC), global rating score (GRS), and overall procedure score (OPS).

Results: In the PHCM group average OPS improved gradually from 19.42 (TSC 8.58, GRS 10.83) to 39.50 (TSC 15.00, GRS 24.5) over eight attempts ($p < .0005$). In the VRS group OPS improved from 20.54 (TSC 10.29, GRS 10.25) to 36.04 (TSC 14.21, GRS 21.88) between the first and eighth attempts ($p < .0005$), with limited improvement after the second attempt. PHCM training significantly improved OPS on their VRS crossover attempt ($p \leq .0001$), achieving a similar OPS to candidates who had completed VRS training ($p = .398$). VRS training significantly improved OPS on PHCM ($p < 0.05$); however, OPS was significantly worse than candidates who had completed PHCM training ($p \leq .001$).

Conclusions: PHCM training has a longer learning curve, with gradual improvement, reflecting the enhanced difficulty of a more realistic model. These results support the use of PHCM preceded by VRS training, prior to performing endovascular surgery on patients.

Keywords: Endovascular training, Human cadaver, Pulsatile model, Simulation
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INTRODUCTION

The introduction of endovascular intervention has transformed the specialty of vascular surgery. The key attraction of endovascular surgery is the minimally invasive nature of the techniques, which offers reduced morbidity and mortality when compared with their equivalent open procedure

* Corresponding author. Department of Vascular Surgery, Northern Vascular Centre, Freeman Hospital, UK.
E-mail address: craigiainnesbitt@gmail.com (Craig I. Nesbitt).
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options.[1] For these reasons there has been a rapid increase in the number of endovascular procedures being performed.[2] Modern endovascular surgeons must equip themselves with a full repertoire of vascular interventional competencies including aneurysmal and occlusive disease.

As the number of endovascular procedures being completed continues to increase, robust training methods must be developed. One attempt to fulfil this training need is the use of endovascular virtual reality simulators (VRS).[3] Although virtual reality is now becoming integrated into endovascular training across Europe and America, it is not without its limitations. Simulators lack the tactile feedback found in real patient vessels, are unable to simulate arterial puncture, and units cost in excess of £100,000.

The last decade has also seen an increasing number of human cadaver based workshops in higher surgical training.[4] The suitability of the human cadaver for training open vascular surgical procedures is recognised.[5] Garret et al. described a technique for creating isolated pulsatile segments in a human cadaver model,[6] and the use of cadavers for stent graft development has also been reported.[7–9] However, there is a lack of literature investigating the use of human cadavers for endovascular training, despite the increased use of cadavers for training in other fields.

Whereas the purchase cost of VRS is very high, patients donate their bodies to training facilities free of charge. It is, however, difficult to estimate the overall cost of human cadaveric training as facilities' overheads (staffing, rental, cadaver storage and disposal) can vary, although, as its popularity has grown, access to cadavers has become increasingly straightforward.

The present study group previously produced a technical note detailing a method for establishing a pulsatile fresh frozen human cadaver model (PHCM), which has the potential to be used for endovascular training.[10] After that, the study group published a paper demonstrating that this model exhibits face validity;[11] a simple form of validity where participants judge the degree of resemblance between a model and a real life situation.[12] More recently, the group published a study demonstrating the construct validity of the model;[13] its ability to differentiate between participants of varying expertise.[12] Although the feasibility and validity of this PHCM has been demonstrated, further work is required to assess the educational impact of the model.

The aim of this study was to establish the educational impact of the PHCM as a training model for teaching endovascular skills, and to compare the educational impact of the PHCM with that of a VRS.

METHODS

Medical students and foundation trainees with no prior endovascular experience or training were invited to take part. None of the included participants had taken part in the previous studies of face and construct validity.[11,13]

All participants completed a pre-study questionnaire to determine the candidate demographics listed in Table 1. A single index procedure was selected to compare the performances of the participants: cannulation of the left renal artery and confirmatory angiogram from access in the right femoral artery. Details and images of this procedure have been published previously.[11,13] All candidates attended an identical introductory lecture, comprising explanation of the basics of endovascular intervention, details of the PHCM and VRS, a step by step explanation of the index procedure, and video footage of an expert performing the index procedure on both the PHCM and VRS. Candidates were given access to identical basic endovascular tools (albeit in a virtual manner on VRS) to complete the procedures (standard 0.035 J-tip wire, angled glide/hydrophilic wire, 4Fr non-calibrated pigtail catheter, 4Fr cobra catheter). Common femoral artery (CFA) puncture was excluded as this was not possible on VRS.

After this uniform basic training, candidates were split into a PHCM group and a VRS group. Each candidate performed the index procedure for eight consecutive attempts with a break of 60 min between procedures. Then, they attempted the index procedure a final time using the alternative training method (a crossover attempt). To avoid

Table 1. Baseline characteristics of 24 study participants

	Pulsatile human cadaver model (n = 12)	Virtual reality simulator (n = 12)	p value (Fisher's exact test)
Seniority			.59
Foundation trainee	3	1	
Medical student	9	11	
Wears glasses	1	3	.59
Left handed	0	1	1.0
Plays a musical instrument	6	9	.40
Able to type	12	12	1.0
Plays video games regularly	7	6	1.0
Previous virtual reality endovascular training	0	0	1.0
Previous cadaver endovascular training	0	0	1.0
Previous cadaver training (any)	12 (undergraduate prosection)	12 (undergraduate prosection)	1.0

The absolute numbers of participants are given, and comparisons were performed using the Fisher's exact test.

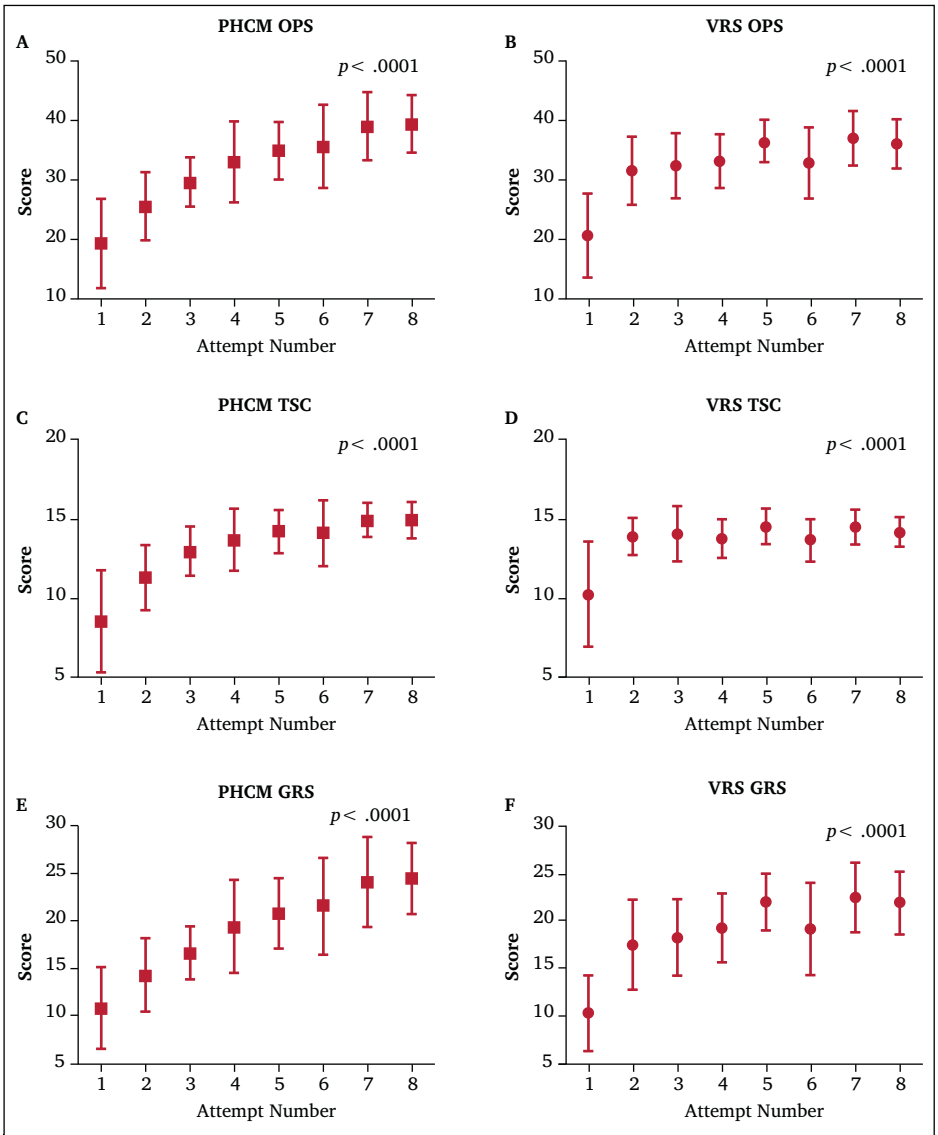

Figure 1. Learning curve of participants over eight consecutive attempts at the index procedure. Two independent endovascular experts marked anonymised video recordings to produce a TSC and GRS, which were summed to produce the OPS. (A), (C), and (E) show the learning curve using PHCM and represent OPS, TSC, and GRS, respectively. (B), (D), and (F) show the learning curve using VRS and represent OPS, TSC, and GRS, respectively. ANOVA was used for statistical analysis. Error bars display standard deviation. $n = 12$ for each panel. GRS = global rating score; OPS = overall performance score; PHCM = pulsatile human cadaver model; TSC = task specific checklist score; VRS = virtual reality simulator; ANOVA = analysis of variance.

any introduction of bias, no feedback was given during or in between attempts.

Each individual attempt at the index procedure was video recorded under exam conditions. Recordings included only the participant's hands and the fluoroscopy screen, thus fully anonymising candidates for subsequent analysis.

The videos were assessed separately by two independent endovascular experts. These examiners gave a task specific checklist score (TSC) and a global rating score (GRS). Checklists for generating these scores were identical to those described in a previous study of construct validity,[13] and are available as supplementary files to the present study. Averaging the scores from each examiner gave a final TSC and GRS for each attempt, which was then added to give an overall procedure score (OPS). Finally, examiners were asked to "pass" or "fail" each participant depending on whether they would be happy to supervise them performing the procedure on a real patient; a "satisfactory performance." To avoid bias, the videos were edited to remove any identifying candidate features and their order was randomised, thus the examiners were blind to the participant's identity and attempt number. In addition to examiner scores, quantitative data were collected on total procedure time, total fluoroscopy time, and volume of contrast used.

The endovascular experts were initially shown a compilation of clips from 10 videos of edited performances of the

index procedure being performed on the PHCM. They openly discussed these video recordings to establish joint standards of scoring, prior to scoring videoed performances in isolation and without collaboration.

Details of the PHCM model evaluated in this study have been published previously as a technical note.[10] Briefly, this model uses a pulsatile blood pump (1405 Harvard Apparatus, MA, USA) to perfuse a fresh frozen cadaver, with inflow through the right common carotid artery and outflow through the left common femoral and right superficial femoral arteries. The VRS used in this study was the Simbionix Angiomentor.

Formal ethical approval was not required as it was deemed that the proposed study represented "technical development and training." Participants were consented for involvement in the study, including video recording.

Statistical analysis

Statistical analysis was undertaken using the Statistical Package for the Social Sciences version 19 (SPSS, Chicago) and graphs were generated using GraphPad Prism 6.01.

One way ANOVA plus post hoc tests with Bonferroni correction were used to assess differences in expert scores between attempts. Cronbach's α was used as a measure of inter-rater variability. Categorical variables were analysed using Fisher's Exact Test. Quantitative parameters where analysed using paired *t* tests.

A value of $p < .05$ was considered statistically significant. Graphs display mean values with error bars representing SD.

RESULTS

Twenty-four participants were recruited to the study; 12 would train using PHCM and 12 would use the VRS. Relevant demographic information can be found in Table 1. There were no differences between groups in terms of their baseline demographics.

Learning curve

The learning curve for each training method is shown in Fig. 1, which displays how performance scores evolved over eight consecutive attempts at the index procedure. Inter-rater variability score (Cronbach's α) was 0.907 for the PHCM group and 0.877 for the VRS group, indicating good agreement between the two blinded assessors who generated the performance scores.

Both VRS and PHCM led to significant improvements in TSC, GRS, and OPS with increasing training (Fig. 1). In the PHCM group, the average OPS for the initial attempt was 19.42 (TSC 8.58, GRS 10.83) compared with 39.50 (TSC 15.00, GRS 24.5) on their last attempt ($p < .0005$). In the VRS group, average OPS improved from 20.54 (TSC 10.29, GRS 10.25) to 36.04 (TSC 14.21, GRS 21.88) between the first and final attempts ($p < .0005$). Candidates' final scores reflect those of experts reported in an earlier publication.[13]

As described above, assessors were also asked to pass or fail each performance of the index procedure. Where they disagreed, a grade of borderline was given. On the initial PHCM attempt, one candidate received a pass, six received a borderline, and five received a fail. By the final PHCM attempt, 11 candidates received a pass and one received a borderline. This improvement is statistically significant ($p < .0005$). On the initial VRS attempt, three candidates received a pass, three received a borderline, and six received a fail. All 12 candidates received a pass on their final VRS attempt ($p < .0005$).

In addition to scoring by blinded experts, quantitative parameters were also analysed. Using either training method, candidates significantly improved in the following domains between their initial and final attempts: total procedure time, total fluoroscopy time and volume of contrast used (Table 2).

Crossover performances

After eight consecutive attempts on their allocated training model, candidates were invited back for a single "crossover" attempt on the alternate model. The initial attempt of the original groups was considered to be a reasonable marker of novice baseline performance and was therefore used as a control. One of the VRS trained candidates could not attend their PHCM crossover training attempt. The remaining 23 candidates completed their crossover attempt.

Fig. 2 displays the mean OPS of the crossover performances, along with the first and eighth attempts of the group, which were originally allocated to the relevant method. Candidates who had completed eight training procedures on the VRS after the introductory lectures performed significantly better than the control group (attempt 1 of the PHCM group) on the PHCM (Fig. 2A,

Table 2. Differences in quantitative parameters between candidates' initial and final training attempts.

	Pulsatile human cadaver model group			Virtual reality simulator group		
	Attempt 1	Attempt 8	*p*	Attempt 1	Attempt 8	*p*
Total procedure time - s	596 ± 10	293 ± 175	< .001	523 ± 99	149 ± 35	< .001
Fluoroscopy time - s	285 ± 100	172 ± 102	.026	338 ± 138 ss	100 ± 11	< .001
Volume of contrast - mL	23 ± 8	13 ± 4	.008	26 ± 8	11 ± 1	< .001

Values represent the mean ± standard deviation of the 12 candidates in each group. *p* values are the result of paired *t* tests.

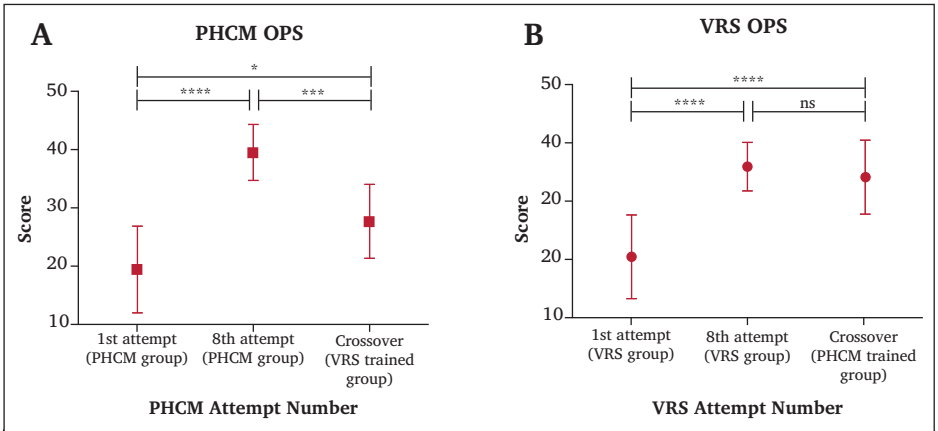

Figure 2. Analysis of mean OPS for crossover performances. Columns labelled 1st and 8th attempt refer to performances by the original PHCM group and VRS group in (A) and (B), respectively. The crossover data in (A) show the mean OPS for the VRS trained candidates' single attempt on the PHCM. Crossover data in (B) represent the PHCM trained candidates' single attempt on the VRS. ANOVA was used for statistical analysis and the results of post hoc tests with Bonferroni correction are shown (NS = not significant, *$p \leq .05$, ***$p \leq .001$, ****$p \leq .0001$). Error bars display standard deviation. $n = 12$ for all except the crossover attempt in (A) ($n = 11$). OPS = overall performance score; PHCM = pulsatile human cadaver model; VRS = virtual reality simulator; ANOVA = analysis of variance.

OPS = 27.7 vs. 19.4; $p < .05$). This improvement was not seen when scores were compared with candidates who had completed eight repetitions on PHCM (Fig. 2A, OPS = 27.7 vs. 39.5; $p \leq .001$. In contrast, PHCM trained candidates performed similarly on their single VRS attempt to those candidates who had completed training on the VRS system (Fig. 2B, OPS = 34.2 vs. 36.0; $p = .398$). PHCM trained candidates attempting VRS outperformed the control (attempt 1 of the VRS group; Fig. 2B, OPS = 34.2 vs. 20.5; $p \leq .0001$).

Fig. 3 displays whether examiners passed or failed each candidate's performance of the index procedure. Significant improvements were seen between candidates' initial and final performances on VRS and PHCM. When VRS trained candidates attempted their crossover performance on the PHCM they recorded more "passes" compared with the controls (5 vs. 2), although this did not reach statistical significance. PHCM trained candidates attempting their crossover performance on VRS recorded significantly more "passes" than the controls ($p = .012$).

DISCUSSION

The present study compared the educational impact of a PHCM and a VRS in teaching basic endovascular surgical skills. Twenty-four candidates were recruited and split into a PHCM training group and a VRS training group. Under controlled conditions, candidates training on the PHCM achieved continual improvement over their eight training

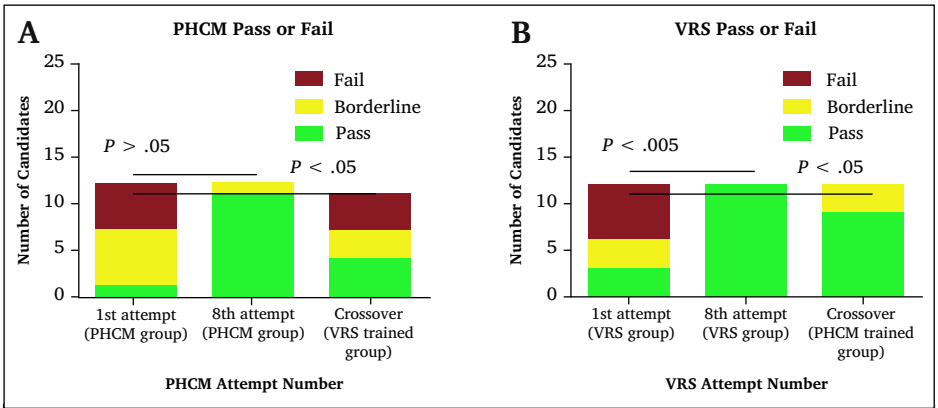

Figure 3. Analysis of examiners rating of "satisfactory performance" for crossover performances. Columns labelled 1st and 8th attempt refer to performances by the original PHCM group and VRS group in A) and B) respectively. The crossover data in panel A) shows the "satisfactory performance" score for the VRS trained candidates' single attempt on the PHCM. Crossover data in panel B) represents the PHCM trained candidates' single attempt on the VRS. Fisher's exact test was used for statistical analysis when comparing candidates 1st versus 8th attempt and 1st versus cross-over attempt. N=12 for all except the crossover attempt in panel A (N=11). PHCM: pulsatile human cadaver model, VRS: virtual reality simulator.

attempts, whereas candidates using the VRS saw a rapid improvement between the first and second attempts, after which their performance scores plateaued (Fig. 1). Candidates using the VRS could perform the index procedure quicker ($p = .014$), and with less fluoroscopy time ($p = .044$), compared with candidates using the PHCM, adding further evidence that VRS is an easier model to master.

Training on the VRS led to a superior performance on the PHCM in terms of TSC (12.32 vs. 8.58), OPS (27.68 vs. 19.42), and "satisfactory performances" (5 vs. 2) compared with the novice control group (Figs. 2B and 3B). PHCM trained candidates also significantly outperformed the controls in all measurable parameters (Figs. 2B and 3B). Previous work has demonstrated the superior fidelity of PHCM,[11] and the current results support its increased complexity compared with VRS, suggesting that performing on the PHCM is more similar to performance on a real patient. If indeed the PHCM is considered a pseudo-patient, this study supports the use of VRS training prior to real patient contact. The observation that training on the PHCM leads to superior performance on VRS training is perhaps less clinically relevant, but this study was not designed to prove the efficacy of VRS or PHCM training prior to real patient contact and it is acknowledged that further research is required to answer this pertinent question. It is believed, however, given the universally improved performance scores seen in these results, that this supports a period of simulation training (VRS, PHCM, or a combination of both) prior to performing procedures on real patients in an operating theatre.

The combination of TSC scores and global rating scores as a reliable way to assess surgical skill was first reported two decades ago.[14] Since then it has become the gold standard in reliably assessing technical skills in the endovascular literature.[15,16] The reliability of these scoring systems was further supported by the high level of inter-rater reliability reported in this study (Cronbach's α 0.907 and 0.877 for the PHCM and VRS group, respectively). Previous research looking at surgical training in novices has found that learning curves plateau at between two and seven repetitions of a technical skill.[17–19] It was for this reason that eight was selected as the number of initial training attempts.

The initial attempts of the original groups were considered to be a fair marker of novice ability and were therefore used as a control for the crossover attempts. This was considered a valid control, as the only difference between the crossover attempts and the initial attempts was that candidates performing a crossover attempt had trained using the alternative model. Both groups had received an identical introduction to the topic, and none of the candidates had any experience of the relevant model prior to their initial or crossover attempt.

Several limitations were encountered during this study. Although stenting and angioplasty are possible on the PHCM, it is not possible to recreate these procedures in a standardised and repeatable fashion, and hence the study is based on a simple angiographic task. The authors acknowledge that this task does not represent the full range of skills required by the modern endovascular surgeon. More complex procedures may be more discriminatory of a candidate's level of skill, and work is required to investigate the efficacy of the PHCM for training both angioplasty and stent deployment. Another potential limitation was the prohibition of feedback between subsequent attempts. This differs from how training would realistically be delivered; however, it was felt that feedback could not be standardised and it was desirable to remove this potential source of bias so that any observed improvement could be attributed more reliably to the training model. Candidates partaking in the study did so for a minimum of 8 h (as there were 60 min breaks between attempts); it is possible that fatigue may have played a role in the plateau effect observed in the VRS group. However, no such plateau effect was seen in the PHCM group, who would be expected to be at least equally affected by fatigue. Candidates who trained on VRS did not wear protective lead gowns or gloves; this could have affected their subsequent crossover performance on the PHCM. Candidates were not questioned about their desired careers; it would have been interesting to observe whether those interested in surgery demonstrated enhanced ability.

The PHCM is prone to tissue degeneration; one cadaver was able to train six candidates (total of 48 procedures) before it needed to be replaced. The use of VRS training prior to PHCM could lower the number of PHCM training attempts, and therefore make more efficient use of each cadaver. This study did not examine the most efficacious way of delivering simulation training, and it is not clear whether combining PHCM and VRS training would be advantageous or if, indeed, a lower fidelity model such as the three dimensionally printed ArterioSim[20] could be just as effective. Further work is required to answer these pertinent questions.

CONCLUSION

Repeated endovascular training on both VRS and PHCM led to significant improvements in both quantitative parameters and technical performance scores while performing a simple endovascular procedure. Improvements on the VRS plateaued after the second attempt, PHCM training has a longer learning curve, with more gradual improvement, reflecting the enhanced difficulty of a more realistic model.

VRS training enhanced performance on the PHCM when compared with performance by novice controls, supporting the assertion that endovascular VRS training improves novice performance on patients in real clinical situations.

The PHCM represents an efficacious training model, challenging, lifelike, and susceptible to the frailties of the real human vasculature. Although this study was not designed to answer the question of transferability of PHCM training into real "live" patients, one could postulate that the vastly enhanced realism will train candidates in a more sustainable, and clinically relevant, manner. Further research into the role of the PHCM is needed to evaluate its true efficacy in training endovascular skills.

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CONFLICTS OF INTEREST

None.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2019.03.026.

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