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Microvascular anastomotic coupler application learning curve: A curriculum supporting further deliberate practice in ex-vivo simulation models

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Abstract *Introduction:* Microvascular anastomosis with coupler devices has revolutionized microsurgery practice. Couplers are considered easier to apply and offer improved operating time while maintaining success rates. This study aims to map the learning curve, skill acquisition, and decay of novice microsurgeons in performing coupler anastomosis.
Methods: Novice microsurgeons performed consecutive coupler applications on a three-layer silastic vessel in two phases. Overall time, total movements, and total path-length were objectively measured and the overall surgical performance was calculated using hand motion analyzer (Dextrous MD, Inition, London, UK).
Results: Sixty coupler anastomoses were performed using the synthetic, three-layered silicone vessel by 5 novices, 40 for *phase 1*, 12 for *phase 2* and 8 for *phase 3*. During the *phase 1* and *phase 2* learning curves deliberate practice, the novices required an average of 8 (6-9) and 4 (2-6) consecutive repetitions, respectively, before reaching the experts' performance. There was an average improvement of 69% ($p < 0.001$) from their baseline performance during phase I and 37% ($p < 0.001$) during phase II. End-product assessment revealed that 4 out of 40 coupler applications during *phase* 1 (10%), 3 out of 20 during phase 2 (15%), and 1 out of 8 during exit performance-phase 3 (12.5%). During phase 3 end-product assessment with *f-cMP*, 7 out of 8 arterial and venous coupler anastomoses demonstrated an adequate range of flow measures.

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Conclusion: This study demonstrated objectively learning curves and skill decay following a suggested coupler application curriculum and quantified objective thresholds for ethical animal model training and safe supervised clinical sessions in the OR.

Introduction

Microvascular anastomoses are required for a wide range of plastic surgical reconstructive procedures.[6,7] The coupler device has revolutionized microsurgical venous anastomosis, reducing the average anastomotic time four-fold, with no increase in complications.[5,9] From its description in 1962,[11] through its widespread introduction to microsurgery in 1986,[13] it has evolved to be routinely employed for end-to-end and for some, end-to-side, venous anastomoses all over the body.[5,15,8,9,16-18] Less commonly, arterial coupling has also been successfully reported,[6,8-10] as has lymphovenous coupler anastomosis.[19]

Though highly successful, couplers must be prepared and applied correctly to achieve the complete intima-to-intima contact on which they rely for their good clinical outcomes; like any new skill, there is a learning curve.[20] Simulation is increasingly bridging the gap between theoretical knowledge and clinical performance in surgical skills training, and familiarization with couplers should form a part of any microsurgical training curriculum. We know that the learning curve for venous hand-sewn anastomosis requires at least 25 repetitions to achieve proficiency.[21] Neither the learning curve nor the simulation curriculum has been established.

This study aimed to map the learning curve and skill acquisition and decay of novice microsurgeons in performing coupler anastomoses, in a simulation environment, using three-layered silastic vessels, and *ex vivo* chicken thigh vessels, and to propose a competency-based training curriculum in nonliving models.

Method

Participants and study design

Novice surgeons without any microsurgical experience, and expert microsurgeons, were recruited – the latter defined by performing at least one microvascular anastomosis per week.[1] Novices attempted a baseline coupler anastomosis without any instructional video, supervision or trainers' input, and the number of anastomotic attempts, total procedure time, total number of hand movements, total path length and patency were measured. Two experts performed consecutive coupler anastomoses using the same measurements, until they reached a plateau in hand motion analysis parameters. Those hand motion analysis parameters defined a skill-based "competency threshold". The novices were then shown how to perform a coupler anastomosis by one of the experts using the mnemonic "COUPLER" hierarchical task analysis (HTA) tool (Table 1). The novices performed consecutive anastomoses using the coupler device on the synthetic vessels until they reached the experts' hand motion analysis performance in three phases. *Phase 1*: comprised a baseline and consecutive attempts to reach the experts' performance in a single attendance, *phase 2*: assessed the skill decay and the interval training attempts required to reach the experts' "competency threshold" a month after phase 1. *Phase 3*: occurred immediately after phase 2 and represented the "exit performance test" (an arterial and venous coupler anastomosis using the chicken thigh ischiatic vessels). For each phase, the number of anastomotic attempts, time to complete, total number of hand movements, total path length, and patency were recorded for each coupler anastomosis.

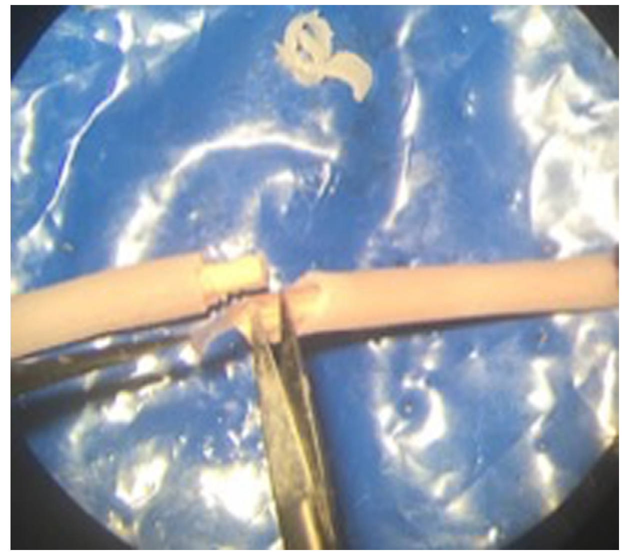


Figure 1 Three-layered silicone vessel preparation – dissection of adventitial layers.

Simulation set-up and equipment

Three-layer silicone-based synthetic vessels were provided by Limbs & Things (Bristol, UK). *Ex vivo* chicken thigh arteries and veins were prepared and cryopreserved. The synthetic vessel required preparation with microsurgical scissors and jewelers' forceps, by dissection of the outer layer, to enable coupler application while using the pusher (Figures1–3). The 1.5 mm coupler was used for the 1 mm silicone synthetic vessel, and the 2 mm coupler (Microvascular anastomotic COUPLER device and system, Synovis, Micro Companies Alliance, Inc., GEM) was used for the chicken thigh artery and vein in a standardized protocol. The same coupler device and coupler rings were re-used for each candidate by careful extraction from the vessel and

Table 1 'COUPLER' HTA tool.

C	***Clean, Cut, and Create*** smooth vessel ends to allow accurate sizing and intimal exposure
O	***Overlap*** the vessel through the coupler ring and across each pin to visualize intimal surface
U	***Use*** the pusher device to secure the tissue onto each coupler pin
P	***Push*** the vessel walls through the pin while avoiding crushing injury
L	***Line up*** all pins with a uniform tension along the vessel diameter
E	***Equalize*** all inter-pin distances to avoid cheese-tear injury to vessel wall
R	***Rotate*** the coupler devise to enable safe coupler device rings interposition

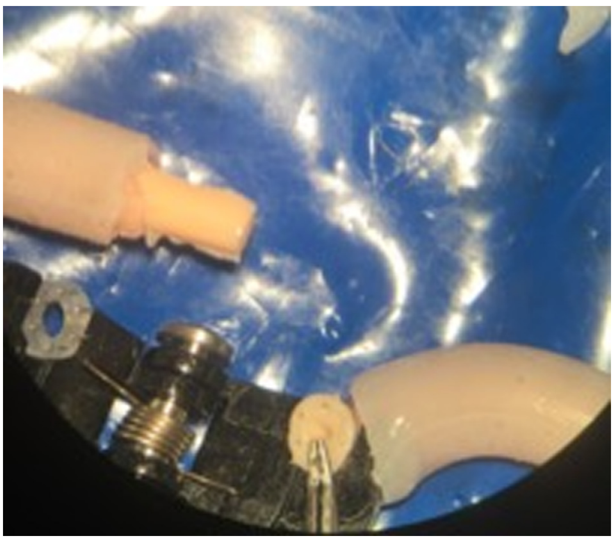


Figure 2 Right side overlap and line-up of vessel intimal surface – the pusher instrument is used to press the vessel wall onto the pin of the polyethylene ring while everting.

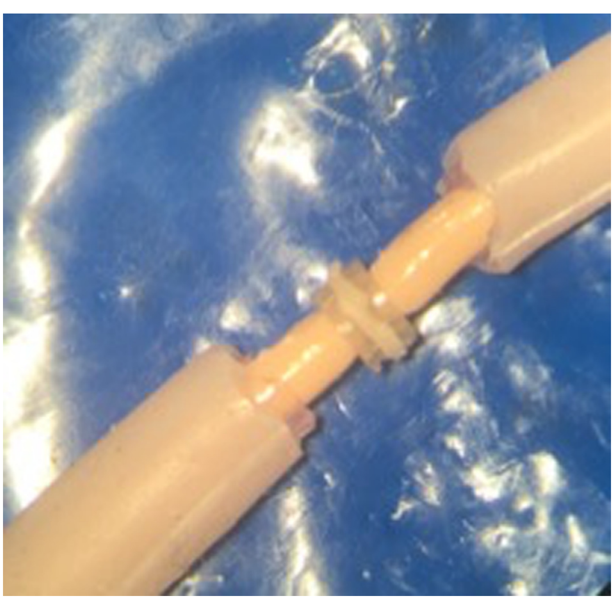


Figure 3 The interlocking pins from the two rings allowed intimal-to-intimal opposition to allow eversion in the complete coupler anastomosis.

repositioning of each ring to the initial format on the device, under microscopic magnification (x6-10), (M651/M655, Leica Microsystems - Schweiz).

Hand motion analysis was performed with four sensors: one on the dorsum of each hand across the second metacarpophalangeal joint, and one on the dorsum of each index finger middle phalanx. An electromagnetic field of 72 cm in diameter was generated and the Dextrous MD software (Inition, London, UK) processed each sensor x, y, zs' Cartesian coordinates during each coupler repetition (excluding vessel preparation, and from the start of the coupler application to completion of the coupler anastomosis with detachment of the anastamosis from the device). The number of anastomotic attempts, operative time, total number of movements, and total path length were recorded for each candidate as objective measures of skill. The quality of the coupled anastomosis was assessed by an independent expert observer for: device security, vessel torsion, vessel end eversion, and evidence of trauma to the coupler rings and/or vessels. Once the coupler showed signs of wear, e.g., bent spikes or a distorted plastic ring, it was replaced.

Competency thresholds using the flow-capable "Micropump" (f-cMP) and pilot microvascular flowmetry

For each candidate consistently achieving the "expert" operating surgical performance (OSP) competency on synthetic vessels, an "exit performance test" confirmed their competency by demonstrating patency of the arterial and venous coupler end-product on chicken thigh ischiatic vessels. This was performed by flow-capable patency testing – passing artificial blood through the recently described *f-cMP*.[22] Transit time volume flowmetry (Transonic Aureflow) was used to measure the flow (ml/min) while the anastomosed vessels are connected to the *f-cMP*. Flow measurements, leakages, and jet streams established the end-product assessment and recorded (Figure 4).

Statistical analysis

A performance indicator was generated to reflect the overall surgical performance: OSP = Total Time (TT) (seconds) + Total Movements (TM) (number of movements) + Total Path length (TP) (meters). Data were modified to allow numerical comparison; ($OSP = TT + TM/10 + TP/100$).

Statistical analysis was conducted using GraphPad Prism version 7.0. Data are expressed as mean ± standard error of

Figure 4 *Micropump' (f-cMP)* apparatus demonstrating the artificial blood patency success of the coupler application.

mean (SEM). An independent-sample t-test was performed for each individual parameter and collectively for overall surgical performance. A p-value < 0.05 was considered statistically significant (Figures 5-9).

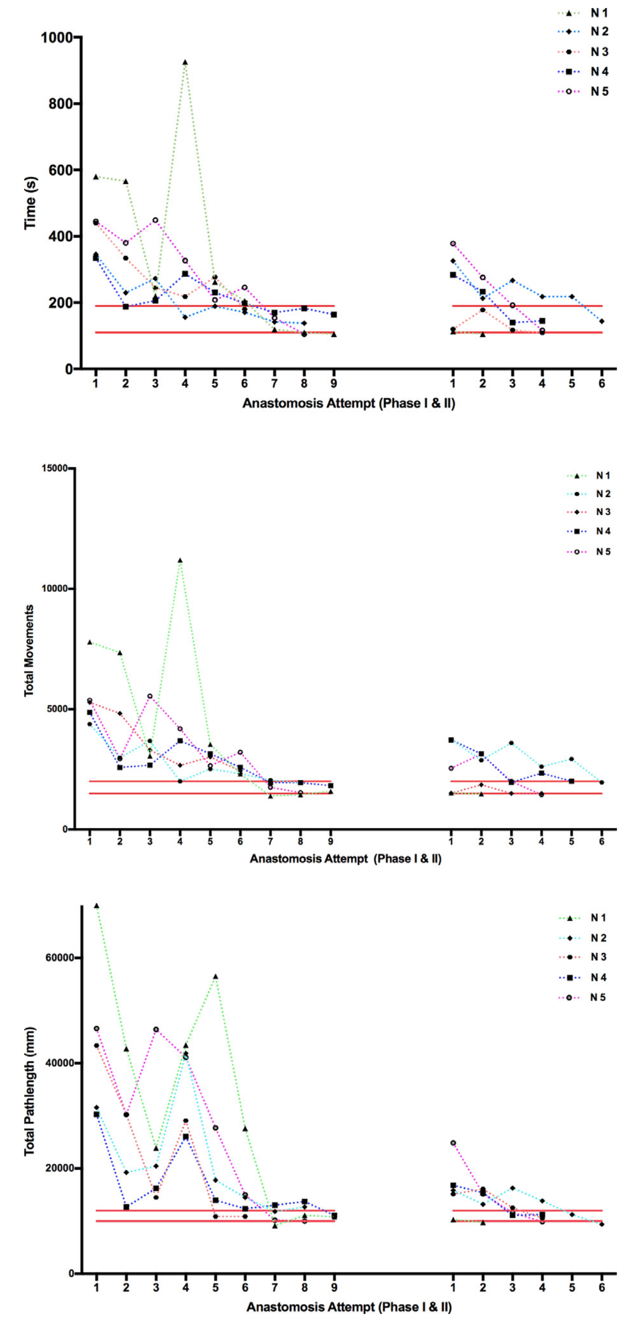
Results

Two experts established competency thresholds for synthetic coupler anastomosis in a synthetic vessel. These were set as follows: total time of 110–190 s, total path length 9000–12,500 mm, total movements 1300–1600, operative surgical performance of 440–475 and successful end-product assessment. A total of 60 coupler anastomoses were performed using the synthetic, three-layered silicone vessel by 5 novices, 40 for *phase 1*, 12 for *phase 2* and 8 for *phase 3*.

During the *phase 1* and *phase 2* learning curves deliberate practice, the novices required an average of 8 (6-9) and 4 (2-6) consecutive repetitions, respectively, before reaching the experts' performance. There was an average improvement of 69% ($p < 0.001$) from their baseline performance during phase I and 37% ($p < 0.001$) during phase II. Skill loss was evident, between phase I and phase II, after an average time of 27 (15–38) days with 20% increase in OSP from their initial average baseline.

End-product assessment revealed that 4 out of 40 coupler applications during *phase* 1 (10%), 3 out of 20 during phase 2 (15%) and 1 out of 8 during exit performance-phase 3 (12.5%), failed due to inadequate pin-ring interposition, resulting in the dislodgement of each ring when minor tension was applied.

During phase 3 end-product assessment with *f-cMP*, 7 out of 8 arterial and venous coupler anastomoses demonstrated an adequate range of flow measures (1-50 ml/min) without any leakages of jet streams from inaccurate ring interposition; however, one arterial coupler ejected due to pulsatile flow (> 27 ml/min) before reaching the maximum flow.



Figures 5-7 A histogram for each novice trainee learning curves during phases I and II demonstrating the time, total movements, and total path length. The numbers of anastomotic attempts are demonstrated along x-axis.

Discussion

Microvascular anastomosis is a core part of the contemporary microsurgeons' free tissue transfer skillset, and the reported rates of flap survival are now impressive.[23]

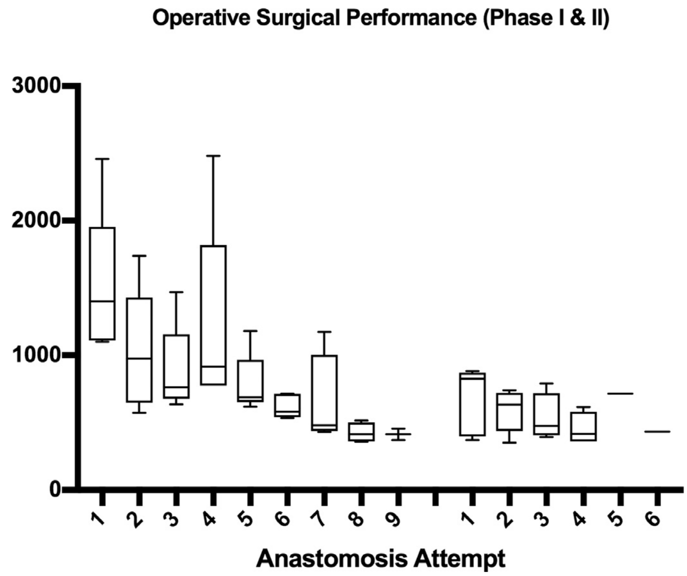


Figure 8 Operative Surgical Performance (OSP) learning curves during Phases I and II and competency thresholds.

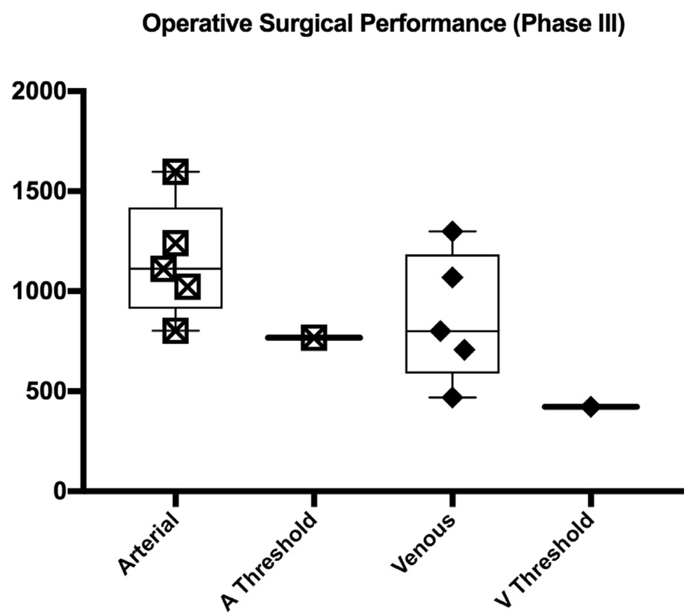


Figure 9 Exit test (Phase III) operative surgical performance with arterial and venous coupler anastomosis on chicken thigh ischiatic vessels.

Technical challenges and a lack of training exposure affect clinical training in microvascular anastomosis; nevertheless, simulation training is increasingly recognized as a way to attain an acceptable technical competency to precede safely supervised practice in the operating room (OR).[23] Alternative methods of anastomosis, such as sutureless anastomosis devices, coupler devices, and stents, have been trialed to enable efficiency, efficacy, and reinforce safety in microvascular anastomosis. The coupler device performs better than traditional technique in the majority of cases in operating efficiency and efficacy from expert surgeons not routinely performing venous hand-sewn anastomosis,[5,13] and therefore that explains the routine use of venous coupler device. Consequently, coupler learning curves and routine training of coupler application deserves routine place in microsurgical training curricula in safe simulation environment.[5,6,15]

The learning curve to reach early competency in hand-sewn venous anastomosis has been established at 25 repetitions.[21] Though flap failures are rare, when they occur, they can be devastating for the patient, and venous thrombosis is often responsible.[7,16] Sutured venous anastomoses potentially introduce thrombogenic nidi: foreign suture material in the lumen, sub-endothelial collagen exposure from imperfect intima-to-intima contact, and luminal stenosis from unrecognized "back-walling".[17,10,24] In a coupled venous anastomosis, any handled vessel is everted between the rings, thereby "extra luminal", and the anastomosis is stented open with a smooth intima-to-intima junction,

Table 2 A suggested microvascular coupler training curriculum (60 + 10 min training session-anastomosis).

Theory: *(30 min)*
■ General training principles: Deliberate practice and competency-based feedback[1-4]
■ Principles of microsurgery: setting up the microscope and preconditions
■ Coupler theory: How the coupler is designed, sizing procedure, "COUPLER" HTA
■ Procedure theory: Positioning; how to instruct using an assistant
■ The sequence: Mounting the flap vessel first, due to its increased freedom compared to the recipient[5]
Technical components: *(30 min per candidate and 10 min per anastomosis repetition)*
■ The ability to mount and dismount the coupler
■ Gentle vessel manipulation and performance of 8 end-to end anastomoses
■ The gentle application of forceps pressure to reinforce the join[5]
■ Carefully taking apart the coupler and remounting (we have found that each coupler could withstand 10 uses)
Advanced components:
■ Performance of an arterial coupler anastomosis[8-10]
■ Using a smaller caliber coupler (< 1.5 mm)
■ Using couplers with attached flow devices[12,7]
■ Vessel mismatch training[14]
Introduction of OR simulation: distractions, using the coupler at depth, using breathing or beating heart simulators, etc.

rendering the thrombogenic profile close to that of a pristine vessel.[5,6,13] Only 0.6% of 1000 consecutive coupled anastomoses thrombosed in one series, significantly lower than the 2.8% of standard sutured anastomoses from the same group,[5,25] a finding consistent with the literature.[20,9] Whether coupler device application technical competency can be taught in the simulation lab and how many repetitions are required to reach experts level of technical competency have not been previously shown. Furthermore, the skill decay in microvascular coupler application from non-expert operators has not been previously explored to allow safe OR exposure in the form of clinical supervised sessions.

There is inevitably a learning curve to coupler use,[27] with experienced consultants having an anastomosis failure rate of 0.57%, considerably lower than more junior surgeons (fellows or registrars) at 4.5% ($n = 319$).[20,9,5] Our study attempts to quantify and qualify this learning curve and demonstrate objectively that skill decay occurs, following a considerably adequate to experts' threshold skill acquisition. It took an average of 8 (6–9) and 4 (2–6) consecutive repetitions from the novices group during *phase I* and *phase II*, respectively, to reach the experts' performance in the protocol simulation environment. This is significantly fewer than the 25 required to master a hand-sewn anastomosis,[21] reflecting the relative simplicity of the task. It is likely that with the added challenges of the OR including vessel mismatch, working at depth, or in a ventilated patient, the competency thresholds will differ. These cognitive and decision making skills, along with the surgical hierarchical execution, will be addressed in future studies with experts and trainees to develop a clinically orientated and validated advanced curriculum.[26] *Ex vivo* simulation training lends itself to the early part of this learning curve with skill acquisition in a safe and ethical environment.

The objective measures of skill were as follows: total time to complete anastomosis, total hand movements, total path length and patency. Flow was measured for the last two "exit" anastomoses, using the f-cMP.[22] All measures improved with repetition as were observed by Hui et al. regarding the learning curve for hand-sewn anastomoses on rat femoral veins. [21] Here, an initial patency of 48%, rose to 88% with repetition.[21] Using a coupler, end-product assessment revealed that 10% of coupler applications during *phase I*, 15% of coupler applications during phase II and 12.5% during exit performance-phase III, failed due to inadequate pin-ring interposition resulting in the dislodgement of each ring when minor tension was applied. For venous hand-sewn anastomoses, time to completion reduced by 63%, from 45 to 20 min.[21] In our study, the average time to completion reduced by 70%, from 425 s to 126 s. Hui et al. did not use hand motion analysis, but such outputs are likely to have improved in step with speed. The use of a global surgical performance parameter (OSP) competency-based feedback in deliberate practice appears to be an efficient and effective way to quantify and objectify simulation training outcomes during learning curve progression. However, it was observed that even when trainees reached competency in OSP during phase II, there was a non-statistically significant difference in performance during phase II – exit test, which can be justified to the lack of experience in biological tissue interaction from the novice trainees. It was also interesting to observe a significant skill loss after a month from initial training phase which suggest deliberate practice may be subject in consideration for revalidation in various levels of competencies.

Based on our results, we would recommend the incorporation of coupler training into microsurgical curricula, and we believe that this can be performed on nonliving materials. The syllabus can be divided into theoretical and technical sections, and may be performed as a workshop lasting for approximately 2 h (see Table 2). Coupler training should not be taught in isolation, because the basic principles of microsurgery apply, and any clinician using a coupler must be able to hand-sew an anastomosis. There are situations where a coupler is not ideal for venous anastomosis, and in < 1% of cases, the surgeon need to convert to a hand-sewn technique[9]: in vessel discrepancies > 1.5:1, for example, or where the coupler fails. Even once the arterial coupler is in mainstream practice, hand-sewn arterial anastomosis will still be required, when the wall is nonpliable, e.g., with atherosclerosis or irradiation.[9,8] Interestingly, the multi-layered synthetic vessel used in this study, required stripping of the adventitia and media layers, for intimal eversion to be possible with a coupler. This suggests the use of venous couplers clinically to anastomose the arterial intima alone, with no or limited product development. It is often the case that simulation environments point the direction for training and product development.

This study was limited by the numbers of participants. However, it provides an insight into the type of learning curve that we might expect in the use of a venous coupler. We have set a standard "expert" proficiency to inform deliberate practice in the simulated environment with an end-to-end anastomosis of equivalent lumen size. Further studies will be required to set the proficiency threshold for more complex situations.

There was no significant difference in performance on synthetic vessels compared to that on *ex vivo* chicken arteries and veins ($p > 0.05$), suggesting that synthetic vessels are adequate for coupler training. The significance of this rests in considering the ethical drive to refine, replace, and reduce the use of animals in simulation training, mandated by the Animals (Scientific Procedures) Act of 1986, and a further directive in 2012.[28-30] There is an economic argument for nonliving models; when M. Singh et al.[32] were able to replace animal material with synthetic for some tasks, they noticed a 50% reduction in the cost of their 3-day microsurgical course.[31] Nonliving models are easier and cheaper for autonomous practice than living animals.[32]

The use of venous couplers is mainstream, and can be effectively taught to an "expert" level in a non-biological and non-living simulation models. It would appear that arterial coupling will soon prove to be, similarly, less challenging, cost-effective, and widespread clinically. This study demonstrated objectively the learning curves and skill decay following a suggested coupler application curriculum and quantified objective thresholds for ethical animal model training and safe supervised clinical sessions in the OR.

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