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Research Paper

A novel latex patch model enables cost-effective hands-on teaching in vascular surgery

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HIGHLIGHTS

- We developed a low-cost, low-threshold training model for vascular suturing skills.
- We validated our model in a single-blinded, RCT with fifty 5th year medical students.
- We used a vascular surgery-specific modification of the OSATS score.
- We demonstrated an increase in technical skills and confidence.
- Our data suggests comparable results to the conventional model.

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ABSTRACT

Objectives: We developed a new simulator for hands-on teaching of vascular surgical skills, the Leipzig Latex Patch Model (LPM). This study aimed to quantify the effectiveness and acceptance of the LPM evaluated by students, as well as evaluation of the results by experienced vascular surgeons.
Methods: A prospective, single-center, single-blinded, randomized study was conducted. Fifty 5th-year medical students were randomized into two groups, first performing a patch suture on the LPM (study group) or established synthetic tissue model (control), then on porcine aorta. The second suture was videotaped and scored by two surgeons using a modified Objective Structured Assessment of Technical Skill (OSATS) score. We measured the time required for suturing; the participants completed questionnaires.
Results: Participants required significantly less time for the second suture than the first (median: LPM 30 min vs. control 28.5 min, $p = 0.0026$). There was no significant difference in suture time between the groups (median: 28 min vs. 30 min, $p = 0.2958$). There was an increase in confidence from 28 % of participants before to 58 % after the course ($p < 0.0001$). The cost of materials per participant was 1.05€ (LPM) vs. 8.68€ (control). The OSATS-scores of the LPM group did not differ significantly from those of the control (median: 20.5 points vs. 23.0 points, $p = 0.2041$).
Conclusions: This pilot study demonstrated an increase in technical skills and confidence through simulator-based teaching. Our data suggests comparable results of the LPM compared to the conventional model, as assessed by the OSATS-score. This low-cost, low-threshold training model for vascular suturing skills should make hands-on training more accessible to students and surgical residents.
Key message: We developed and validated a low-cost, low-threshold training model for vascular suturing skills. This should make hands-on training more accessible to medical students and surgical residents in the future.

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Introduction

Surgical experience and the practice of manual skills are integral components of surgical disciplines, supplementing clinical expertise in the determination of indications and perioperative management. Typically, the initial steps of training for students and residents aspiring to specialize in surgery involve active participation in operations during clinical traineeships. Although these somewhat passive assistantships can undoubtedly teach important lessons, a comprehensive learning style analysis conducted over a 14-year period on 130 surgical residents revealed, that individuals adopting an active "hands-on" approach operated on significantly more cases by the end of training. Notably, those who transitioned to non-surgical specialties or non-physician activities were more likely to exhibit passive learning tendencies [1]. A parallel study conducted at Vanderbilt University demonstrated the feasibility of successful training during the university phase. In this study, fourth-year medical students lacking prior surgical experience underwent intensive practical training in coronary anastomoses on pig hearts for four months. Remarkably, their outcomes in terms of quality and operative time were comparable to those of advanced general surgery residents with over three years of work experience, including rotations in transplant, vascular and pediatric surgery, along with exposure to microsurgical techniques [2]. These findings underscore the significance of practical training achieved through active and independent execution of surgical steps. Addressing a challenge in training the next generation of vascular surgeons without compromising patients' outcomes, the use of simulators has emerged as viable solution. Numerous studies have affirmed the learning and transfer effectiveness of simulator-based trainings [3–7]. However, existing studies pronominally utilize material such as pig hearts [2], pig carotids [8], rat aortas [5], pig aortas and iliac vessels [9], bovine hearts [6], human body donors [4,10,11] or synthetic simulators (microfixation anastomosis training kit, Biomet [12]; silicon vein grafts, Chamberlain group, MASS [7]; silastic tubes [5]; vascular procedure simulators, Limbs and Things, UK [13]). These materials accurately mimic the haptics of human vessels but are associated with complexities in procurement and disposal (in the case of animal materials), limited accessibility (body donors) and are sometimes prohibitive costs (simulators). Notably, the curriculum for German medical students lacks simulators specifically designed for vascular surgery training, particularly in the form of suture models. Although artificial intestine models are employed, they do not faithfully reproduce the surface structure of the blood vessels. Recognizing the substantial skills involved in suturing patch grafts on blood vessels, the Department of Vascular Surgery of the University Hospital Leipzig developed in April 2020 the Leipzig Latex Patch Model (LPM). The LPM represents a novel approach to vascular patch preparation, serving as a valuable addition to the vascular surgery curriculum for medical students in their final year of medical school. The aim of this study is to quantify the effectiveness and acceptance of the LPM in practical surgical teaching.

Materials and methods

Trial design and participants

We developed LPM as a training model for suturing vascular patch grafts. To validate the LPM, a prospective, single-center, single-blinded, randomized study was designed and approved by the Ethics Committee of the Medical Faculty of the University of Leipzig under the number AZ 471/20 – EK from 17th of November 2020.

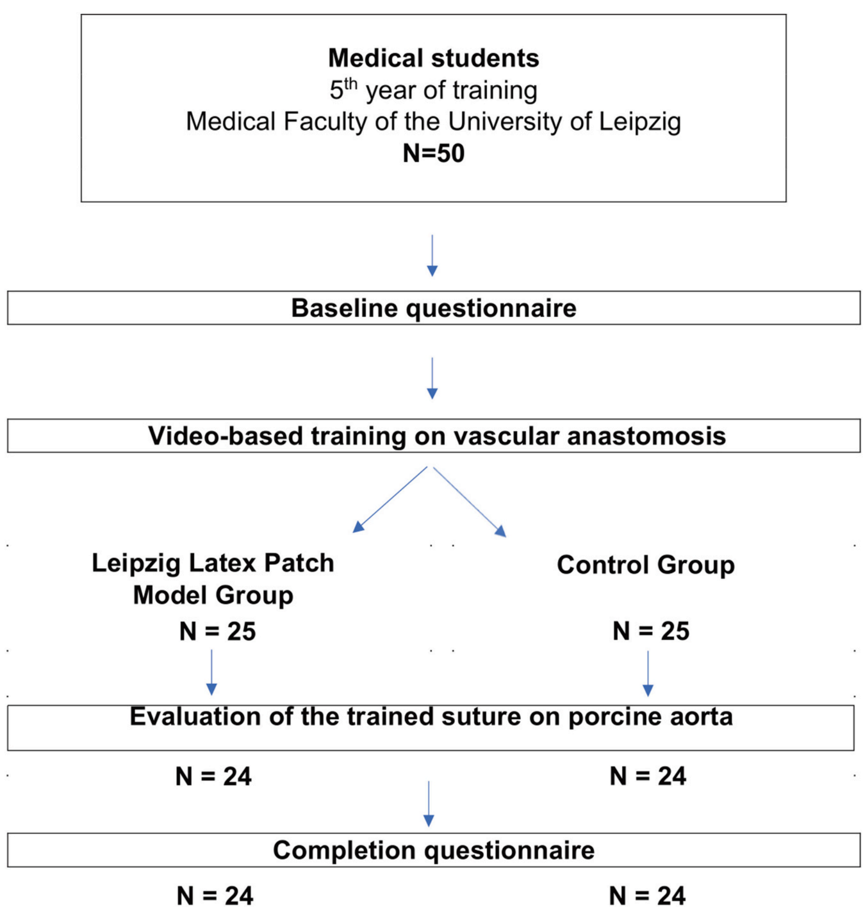

Fig. 1. Study design flow chart.

We included medical students enrolled in their 5th year of training at the Medical University of Leipzig (Fig. 1). The exclusion criteria were completion of professional training in a health profession related to surgery and medical research in a surgical subject with practical experience in suturing. This was done to eliminate students with advanced surgical skills and reduce statistical bias.

Study group

The study group was trained to perform patch graft reconstruction on the LPM (Fig. 2A–C). For the LPM, we used a commercially available latex cleaning glove with a thickness of 0.8 mm, and attached it to a cork board by pins (Fig. 3A).

Control group

The control group performed the same procedure using a synthetic tube designed for general surgical training ("Task insert-2-layer intestine 20 mm," Limbs&Things, UK) and routinely used in suture courses for medical students at our institution (Fig. 3B).

Hands-on training session

Participants were asked to complete the baseline questionnaire (Appendix 1). They were then shown a videotaped demonstration of a bench model vascular patch graft reconstruction performed using the parachute technique on an LPM by an experienced vascular surgeon (DB). The introductory video also explained the key points of vascular sutures [14] and the criteria, by which the quality of patch reconstruction should be evaluated [7]. Furthermore, an intraoperative example of patch graft reconstruction performed at our institution was presented. These training sessions were conducted in groups of eight students. After the training, the students were assigned to the LPM and control group 1:1 ratio using the online tool 'Research Randomizer'. The participants were allocated pseudonyms and divided into pairs of one student each from the LPM and the control groups.

Two students formed a team acting as surgeon and an assistant, and then they switched roles. Each team was provided with anatomical forceps, a scalpel with a blade size 11, Pott's scissors and material scissors, needle drivers, and a double-armed Prolene 4-0 suture (Ethicon Inc., NJ, USA) Fig. 3C.

According to their randomization, the students were assigned to the LPM or control models. A 4 cm longitudinal incision was made. The patches used for all sutures consisted of the cut-off and trimmed underside of a commercially available cleaning sponge cut into pieces of $70 \times 15 \times 1$ mm. The students were instructed to perform the sutures, as demonstrated in the introductory videos.

For each participant, we measured the time required to complete the

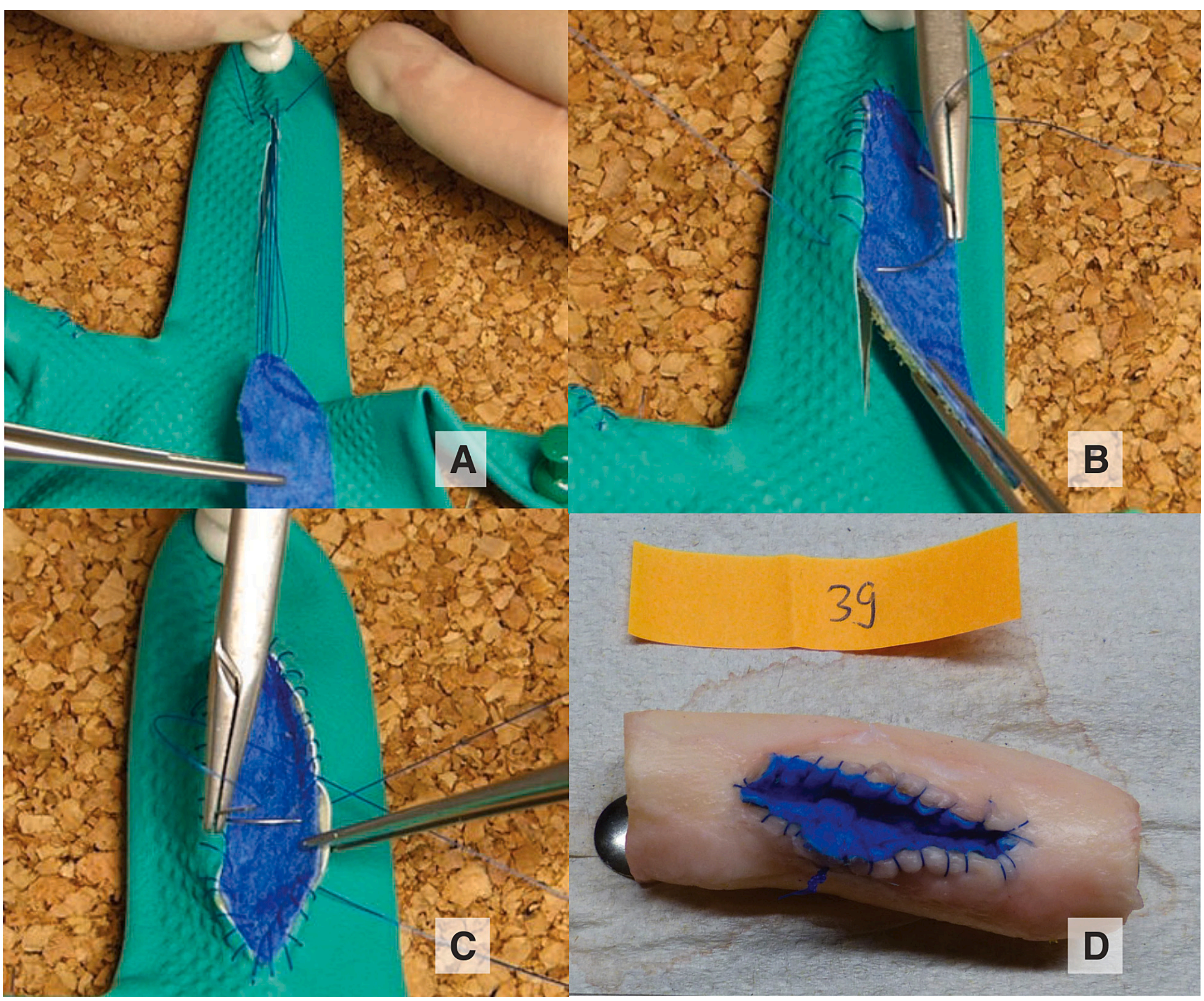

Fig. 2. Training of a vascular patch graft suture on the Latex Patch Model. A) First stiches in parachute technique; B) and C) continuous suture and trimming of the patch graft; D) patch graft on porcine aorta.

Fig. 3. Setup for the training session. A) Leipzig Latex Patch Model consisting of a Latex cleaning glove pinned on a cork board; B) conventional synthetic tissue simulator (Limbs&Things, UK); C) Instruments and materials provided for each pair of participants.

task and documented the results.

Evaluation session

The second part of the course consisted of the evaluation of the trained suture on porcine aorta seven days after the training session. For this purpose, previously harvested and frozen porcine vessels were unfrozen in a warm water bath for 30 min, pinned to cork pads, and labeled with the participants' pseudonyms (Fig. 2D).

The students were again instructed by a prerecorded video to perform patch graft reconstruction. A longitudinal incision of 4 cm was made, and suturing was performed on the porcine aortas. During this task, the instructor filmed the students' hands and simultaneously documented the suture times. This was followed by additional photo documentation of the sewn patches both from the outside and after cutting open the vessel from the inside.

The evaluation of the participants' performance was done by two investigators independently (MG, AS), who were blinded to the participants' identities and randomization. We used a vascular surgery-specific modification [7] of the validated Objective Structured Assessment of Technical Skill (OSATS) score [15] (Table 1). The mean OSATS-score for each participant was calculated from the scores assigned by both surgeons.

Finally, participants were asked to complete a completion questionnaire (Appendix 2).

Endpoints

We hypothesize, that the participants trained on the LPM will achieve comparable results as those trained on the conventional model.

Table 1
Items of the Objective structured assessment of technical Skill (OSATS)-Score, modified after Fann et al. [7].

Modified OSATS-Score	
1	**Orientation of the patch graft** Correct orientation, appropriate start and end point of the suture
2	**Appropriate placement of the stitches** Insertion and exit points, number of punctures
3	**Appropriate distance between the stitches** Equal distance to the last stitch and to the tissue margin
4	**Handling the needle driver** Finger position, rotation of the instrument, placement of the needle, pronation, supination, movement of the hand and fingers, lack of movement in the wrist
5	**Handling the forceps** Finger position, hand movements, assisting with needle placement, appropriate traction on the tissue
6	**Needle angles** Angle between tissue and needle holder, anticipate the following angles
7	**Needle transfer** Placement and transfer of the needle from stitch to stitch, use of hand and instrument to load the needle
8	**Suture management/tensioning** Tension of the suture, using tension to facilitate exposure, avoid entanglement
9	**Surgical knot** Tension, skill, finger and hand control when pushing down the knots
Evaluation of the items	
1	Excellent, goal is met, no hesitation, excellent progress and flow
2	Good, goal is consciously fulfilled, minimal hesitation, good progress and flow
3	Average, goal is fulfilled with hesitation, interrupted progress and flow
4	Below average, goal is only partially met with hesitation
5	Poor, goal is not met, pronounced hesitation

The primary endpoint of the study was the quality of the sutured patch on the porcine aorta, measured by the modified OSATS-Score. Secondary endpoints of the study were suture time for the patch on porcine aorta and self-assessment of surgical skills using questionnaires with Likert-type items (Appendices A, B).

Statistical analysis

As this was a pilot study, we did not perform a formal sample size calculation. Fifty students were aimed to be included, as this would support study inclusion and completion within one year. The results were analyzed using the GraphPad software (San Diego, CA, USA). The null hypothesis states that there is no difference between the OSATS scores of the LPM and the control groups. The alternative hypothesis states that there is a difference between the OSATS scores of the LPM and the control groups. We used the Mann-Whitney *U* test and a significance level of $p < 0.05$.

The data from the questionnaires were analyzed in GraphPad (San Diego, CA, USA) using the Mann-Whitney *U* test for comparisons between the LPM and control groups, and the Wilcoxon test for paired samples for comparisons between the training and evaluation sessions. Again, a *p*-value < 0.05 was considered statistically significant.

Results

Participants' characteristics

Fifty participants were recruited. We had one dropout from the LPM group and one from the control group due to the absence of participants in the evaluation session.

The majority of participants were right-handed ($n = 49$, 98 %), thirty-one participants were female (62 %), and the median age was 23 years (range 21–30). A substantial number of the participants played musical instruments ($n = 28$, 56 %). Students in both groups had a median of 1 month (range 0–12 months) of surgical experience through internships and had already completed the compulsory suture course, and most participants had already seen the performance of a skin suture on a patient ($n = 46$, 92 %). A total of 58 % ($n = 29$) of the participants had already performed a skin suture under supervision. Six participants (12 %) had seen a vascular suture before, and one had already performed one.

Twenty-one (42 %) participants aspired for surgical residency (trauma, general, vascular surgery, gynecology, and otorhinolaryngology) Table 2.

OSATS-Score for patch graft reconstruction on porcine aorta

The modified OSATS-score includes nine items. The detailed distribution of our participants' results is shown in Table 3. The median total OSATS-Score was 20.5 points in the LPM group (range 13.50–26) and 23 points in the control group (range 14.5–30 points, $p = 0.2041$; Fig. 4). A lower score indicated a better result.

Table 2
Basic characteristics of participants, LPM: Latex Patch model.

Variable	LPM group (n = 25)	Control group (*n* = 25)
Female	15 (60 %)	16 (64 %)
Age in years, median (range)	23 (22–27)	23 (21–30)
Right-handed	24 (96 %)	25 (100 %)
Plays musical instrument	15 (60 %)	13 (52 %)
Years of playing musical instrument, median (range)	11,3 (5–18)	12,8 (5–22)
Practical surgical experience in months, median (range)	1 (0–12)	1 (0–12)
Participated in basic suture course	25 (100 %)	25 (100 %)
Seen skin sutures	24 (96 %)	22 (88 %)
Performed skin sutures	13 (52 %)	16 (64 %)
Seen vascular sutures	1 (4 %)	5 (20 %)
Performed vascular sutures	0 (0 %)	1 (4 %)

Suture time

The first suture was performed at an average of 30.6 ± 3.3 min. The second suture was performed within 29.2 ± 5.3 min, which represents a significant improvement ($p = 0.0026$; Fig. 5). However, there was no significant difference between the LPM and control groups in the porcine vessel suture ($p = 0.2958$).

Cost of materials

The cost for training materials for one participant in the LPM group was €1.05 (Latex glove €0,87, two patches €0,18) and therewith only 12.1 % of the €8.68 cost for one participant in the control group (synthetic tube €8,50, patches €0,18).

Baseline and conclusion questionnaire

Overall, 94 % of the students 'agreed' or 'strongly agreed' that there should be more practical training in the curriculum. This increased to 95.8 % after the completion of the course ($p = 0.3750$). No difference was found when comparing the LPM and control groups for this question ($p = 0.1696$). Only 28 % of the participants 'agreed' or 'strongly agreed' to the statement 'I feel confident in using the suturing instruments.' before the course, the percentage increased to 58.3 % after the course ($p < 0.0001$). However, no significant difference was observed between the groups ($p = 0.7253$).

The statement 'I was able to transfer what I learned on the simulator well to the biological material' was agreed upon by 100 % of the LPM group and 96 % of the control group ($p = 0.1202$). Of the participants, 89.6 % found the instructional video to be helpful. In the final self-assessment on a scale of 1 (unsatisfactory) to 10 (perfect), the students rated themselves with a median of 7 points (range 2–8, $p = 0.564$).

Discussion

The practice of manual skills is imperative for the training of the next generation of medical professionals. However, a large proportion of medical students feel that they would need more practical training than offered in traditional curricula, in our study this was stated by an overwhelming 95,8 % of participants. The initial practice in the protected environment of a skills course enables medical students to improve their technique effectively and gain self-confidence [16]. Because simulation materials developed for medical use are expensive and difficult to procure, we aimed to develop a low-cost model for the training of vascular surgical skills, which would lower the overall costs of practical courses and be available for extracurricular at-home practice. By using a latex cleaning glove and a simple, homemade set-up, we could reduce the costs of single-use materials to 1.05€ per participant, and therefore only 12 % of the initial costs. Discarded surgical instruments and expired sutures are widely available in teaching hospitals and can still be used for training purposes at minimal cost. A low price is essential if one wants to expand the use of simulators in student teaching, since it must be accommodated in the teaching budgets available for this purpose.

Musicality may be a marker for basic surgical skill development useful in identifying suitable candidates for surgical training. Thus, we have included musical training as a potential cofounding factor into our entry questionnaire [17].

There are many methods for testing specific operative skills in surgical trainees, including the OSATS Score. Numerous specific adaptations and validations of the OSATS Score [15] have been described since its first publication in 1997. The one, that appeared most useful to our

Table 3
Objective Structured Assessment of Technical Skills (OSATS)-Scores for the Latex Patch Model (LPM) group vs. the control group. Mann-Whitney *U* test was performed to compare the two groups.

OSATS-Item	Group	OSATS-Score					p-Value LPM vs. Control group
		1, "excellent"	2, "good"	3, "average"	4, "below average"	5, "poor"	
Orientation of graft	LPM	3	18	2	1	0	0,0857
	Control	3	12	8	1	0	
Placement of stitches	LPM	4	13	7	0	0	0,1669
	Control	2	14	2	6	0	
Distance between stitches	LPM	5	15	3	1	0	0,1157
	Control	3	12	5	4	0	
Handling the needle driver	LPM	5	14	4	1	0	0,1338
	Control	0	14	9	1	0	
Handling the forceps	LPM	11	12	1	0	0	**0,0041**
	Control	4	15	3	2	0	
Needle angles	LPM	7	15	2	0	0	0,1693
	Control	4	15	5	0	0	
Needle transfer	LPM	6	10	7	1	0	0,6109
	Control	4	13	5	2	0	
Suture management/tension	LPM	2	12	6	4	0	0,3548
	Control	2	8	7	7	0	
Surgical knot	LPM	2	12	2	7	1	0,0864
	Control	7	10	1	5	1	

The bold p value indicates the only statistically significant difference between the two groups ($p < 0{,}05$).

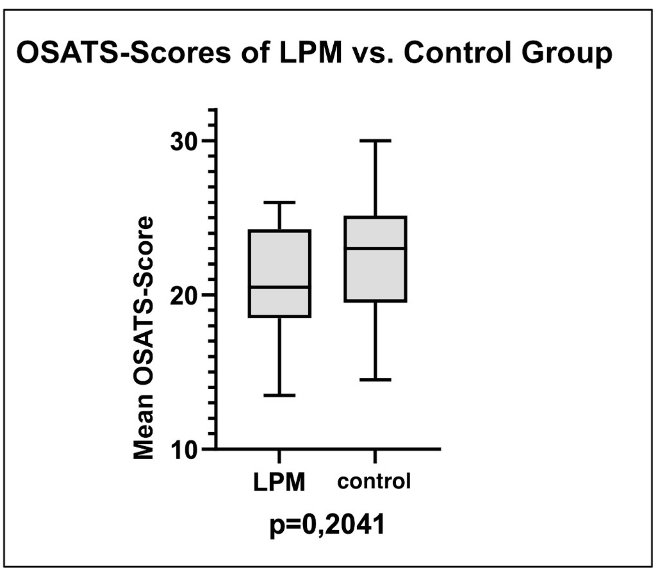

Fig. 4. Boxplot of mean Objective Structured Assessment of Technical Skills (OSATS)-Score, as calculated from the ratings of two independent observers. Mann-Whitney-*U* test showed no significant difference between the two groups ($p < 0.05$). A lower score indicates a better result.
LPM: Latex Patch Model.

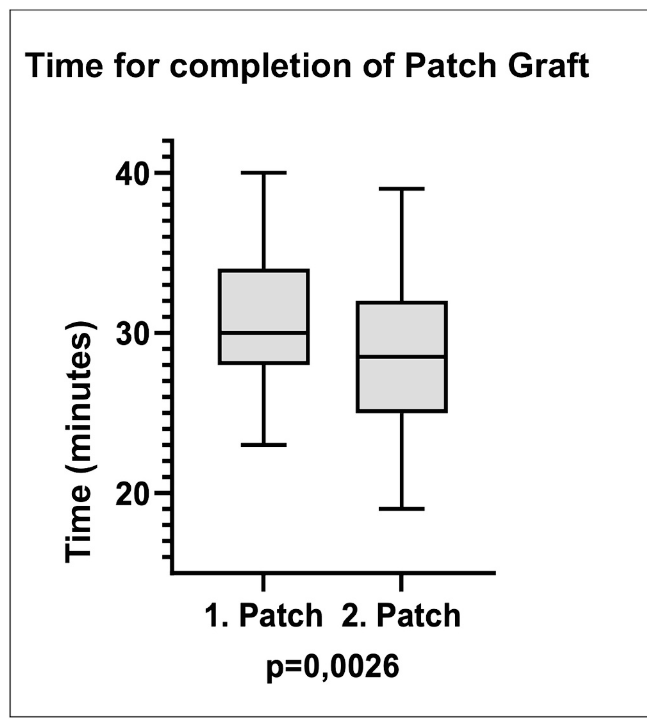

Fig. 5. Boxplot of time in minutes, in which the participants completed the suture of the 1st patch (on simulator) vs. the 2nd patch (on porcine aorta). Wilcoxon test for paired samples showed a significant decrease in time ($p < 0.05$).

participants evaluation is the cardiovascular modification by Fann et al. [7] Using a five-point-scale such as this, surgeons provided reliable ratings without extensive training in the validation study. The inter-rater reliabilities in the initial validations study indicated, that the use of one examiner is adequate, which makes the OSATS a feasible tool in daily teaching practice and Objective Structured Clinical Examinations (OSCE) [15]. We found the OSATS Score to be a useful and intuitive tool for rating surgical skill, and now use it in our teaching and examination routine.

The overwhelming positive feedback from the participants indicates the need for more hands-on training. The highly significant increase in confidence in using suture instruments from 28 % of the participants before the courses to 58 % after only two 90 minute-courses can be considered a great success.

Participants required significantly less time for the second patch suture (on the animal model) than for the first suture (on the artificial model), with a median reduction of more than 2 min. This pattern is also evident in many other practical skill training studies [5,7].

There was no significant difference between the two groups regarding the primary endpoint, representing the quality of a patch graft suture on porcine aorta as measured by the OSATS-Score. Our data suggests comparable results of our low-cost model compared to the established synthetic tissue simulator.

The item 'use of forceps' was even rated significantly better in the LPM group. This might be owed to the fact, that the Latex somehow simulates the elasticity of vessel tissue better than the established model, initially developed for intestinal anastomoses.

The suture time as a sole surrogate parameter to measure progress in learning a motor skill is controversial, as it says nothing about the quality of the suture performed [18].

In future, simulator-based training of surgical skills will gain importance, as we see a decrease in working hours due to stricter employment laws and the desire for a better work-life balance among employees [19]. Rigid hospital hierarchies, economic pressure, and a lack of standardization in surgical training represent challenges in training tomorrow's surgeons [20]. These developments are in sharp contrast to progressive specialization and striving for improved patient outcomes, which, especially in surgery, are strongly linked to the operator's skill and experience [21]. The integration of simulators into medical training ensures hands-on experience without compromising patient safety [22]. However, an analysis of the use of simulators in German surgical departments in 2019 showed that simulators were available in only 35 % of teaching hospitals, and 81.8 % of the surveyed physicians said that simulator training was not a component of their training. However, a large majority (94.5 %) wished for this to be the case in the future [23].

Limitations of the study: As is common in pilot simulation studies, our project has a small sample size. Although the groups were randomized by the level of surgical experience, it is certainly possible that some students had more experience than others. In addition, the quality of the vascular suture was not assessed, since we did not have access to the pressurized vascular models during the testing phase of the study.

In conclusion, learning and teaching in medical schools and residency programs will change over the next few years. We developed and validated a low-cost, low-threshold training model for vascular suturing skills. This should make hands-on training more accessible to medical students and surgical residents in the future.

CRediT authorship contribution statement

Maximilian Gaenzle: Writing – review & editing, Investigation, Conceptualization. **Antonia Geisler:** Writing – review & editing, Conceptualization. **Hannes Hering:** Writing – original draft, Visualization, Investigation. **Arsen Sabanov:** Methodology, Investigation, Formal analysis. **Sabine Steiner:** Validation, Methodology, Formal analysis. **Daniela Branzan:** Supervision, Formal analysis, Conceptualization.

Declaration of competing interest

Daniela Branzan: grants: Artivion, Bentley Innomed, COOK Medical, Endologix, Getinge, Medtronic; Sabine Steiner: Consulting/speakers' honorarium: Cook Medical, Boston scientific, iThera Medical; The remaining authors have nothing to disclose.

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Ethics approval

This study was approved by the Ethics Committee of the Medical Faculty of the University of Leipzig under the number AZ 471/20 – EK from 17th of November 2020.

Appendix A. Baseline questionnaire

Baseline questionnaire	
Age	__ years
Gender	☐ female ☐ male ☐ divers
Semester	
Aspired specialty	
Practical experience in a surgical specialty (e.g. internship, previous employment)	__ months
Do you play a musical instrument?	☐ yes, for __ years ☐ no
Dominant hand	☐ right ☐ left
How often have you….?	

	never	1–5×	5–10×	>10×
Participated in suture courses	☐	☐	☐	☐
Seen/assisted cutaneous sutures	☐	☐	☐	☐
Performed a cutaneous suture yourself	☐	☐	☐	☐

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(*continued*)

Baseline questionnaire					
Assisted vascular surgical procedures	☐	☐	☐	☐	
Performed a vascular suture yourself	☐	☐	☐	☐	
How much do you agree with the following statements?	Very much – partly – not at all				
I feel confident handling suture instruments.	☐	☐	☐	☐	☐
Practical skills courses should play a bigger role in the medical curriculum.	☐	☐	☐	☐	☐

Appendix B. Conclusion questionnaire

Conclusion questionnaire					
How much do you agree with the following statements?	Very much – partly – not at all				
I am satisfied with my result.	☐	☐	☐	☐	☐
I felt confident suturing the patch graft.	☐	☐	☐	☐	☐
I felt confident handling the suture instruments.	☐	☐	☐	☐	☐
The instructional video was helpful in learning the process and particularities of a vascular suture.	☐	☐	☐	☐	☐
I would recommend this course to other students.	☐	☐	☐	☐	☐
Practical skills courses should play a bigger role in the medical curriculum.	☐	☐	☐	☐	☐
The simulator training was helpful.	☐	☐	☐	☐	☐
I was able to transfer the skills I learned on the simulator to the biological tissue.	☐	☐	☐	☐	☐
I would grade my patch as follows: (10 – perfect | 1 – insufficient)	10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1				

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