ORIGINAL ARTICLE

SuSiPed 2.0: the next step towards a future practical examination for pediatric minimally invasive surgery

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Abstract

Introduction: Simulation-based training of minimally invasive surgery (MIS) has been shown to serve as an important tool in improving safety in surgical care, especially in pediatric surgery. Nevertheless, there are no internationally standardized practical examination programs in pediatric surgery so far. It is also unknown how basic pediatric MIS training impacts on the performance of more advanced courses. **Methods:** After establishing a basic 3D-printable pediatric MIS curriculum (SuSiPed1.0), we developed an advanced curriculum (SuSiPed2.0) consisting of six training modules. All participants repeated the curriculum three times and evaluated the curriculum regarding closeness to reality and relevance (Likert Scales 0/worst–6/best). The study population consisted of group 'S1', which had already completed the SuSiPed1.0 curriculum, group 'BC' (board-certified pediatric surgical experts) and group 'S0', which was naive to any previous training. We compared the time needed for completing the single exercises and the whole curriculum at the third appointment. Statistical analysis was conducted with Welch's *t*-test. **Results:** A total of 77 participants were recruited. Overall, groups S1 ($n = 11$) and BC ($n = 5$) completed the tasks faster and with fewer mistakes than group S0 ($n = 61$). The analysis of the participants' subjective evaluation showed an overall positive assessment of the curriculum of 5 or above in all categories. **Conclusion:** This study shows that prior basic training significantly increases the performance in a more advanced pediatric MIS simulator. We therefore believe that both basic and advanced SuSiPed modules can be combined into a comprehensive pediatric MIS training program. It may also be a means of evaluating trainees at different stages of their training.

Keywords: *simulation; minimally invasive; pediatric surgery; skills assessment; 3D printing*

Introduction

Simulation-based training of minimally invasive surgery (MIS) has become an important part of surgical education.[1–3] Because of the small dimensions, delicate tissues, and complexity of the standard index procedures, it is particularly relevant to pediatric surgery.[3,4] On average, studies have shown that it takes between 20 and 30 procedures for a pediatric surgeon to reach the best performance in the operating room (OR) for a particular operation.[5,6] The literature shows that simulation-based training leads to shortened operating times and lower error rates, especially at an early stage in a surgeon's learning curve.[4,7–9]

In adult general MIS, there are basically two standardized and validated training programs available, the Fundamentals of Laparoscopic Surgery (FLS) and the so-called Lübecker Toolbox (LTB). However, both systems are commercially available only at a substantial price of over 1000 US dollars/ 1000 Euros.[7,10] This kind of price poses a substantial barrier to routine implementation, particularly in low-resource countries. The so-called LapPass is a more cost-effective alternative. It was developed through a consensus process by the executive council of the Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI). It consists of comparable exercises to the FLS curriculum and is a nationally recognized certificate for MIS.[11]

Interestingly, there are only a few validated pediatric MIS training programs.[3,4,9,12] An example of a validated training program is the pediatric MIS curriculum for residents established in Buenos Aires, which is based on locally created training modules.[13,14] The so-called Pediatric Laparoscopic Surgery Simulator (PLS) was developed in Toronto and is equivalent to the FLS Trainer in a training environment adapted to pediatric dimensions but has never been made

commercially available.[15] A curriculum based on this device and the FLS trainer was established in France. To date, it is the only simulator in pediatric surgery that also serves as a standardized national examination program.[16,17]

Over the last few years, we have introduced a basic, validated pediatric simulator and examination platform that we termed SuSiPed1.0 (Surgical Simulation in Pediatrics). The program consists of six MIS training modules: camera guidance, shell transfer, figure cutting, cyst resection, single interrupted suturing, and slipknot suturing. Participants had to complete all exercises on three different days.[18] The modules are 3D printable from downloadable open-source files so that anyone can use them at a very low production cost. Furthermore, the curriculum along with instructions is also available online, free of charge.

After the success of SuSiPed1.0, we went on to design a more advanced training curriculum called SuSiPed2.0, which is based on the typical skills required to complete pediatric surgical minimally invasive index cases.

The goal of this study was to validate SuSiPed2.0 and to evaluate whether basic training in pediatric MIS using SuSiPed1.0 had any impact on the performance of the more advanced modules. The study was performed in accordance with the STROBE statement.[19]

Methods

Ethics and study design
The study was approved by the ethics committee of our university, project number 21-1131.

It was designed as a prospective comparative cohort study.

The study population consisted of three groups: participants were either defined as 'inexperienced' (group S0: medical students who had never undergone MIS training before) or 'experienced', which were categorized as medical students or junior pediatric surgical trainees who graduated from SuSiPed1.0 (group S1), and board-certified pediatric surgical experts (group BC).

All groups completed the curriculum three times to account for a learning curve.

Conditions were identical for all participants and instructions were given by video tutorials.

The director of our training lab (AL) was the supervisor during each training session. He was responsible for camera guidance, the measurement of time to completion (in seconds) and number of errors (for definition of errors see description of the respective exercise).

All participants completed an evaluation form before and after the training. The exercises were subjectively evaluated by the participants in terms of closeness to reality, relevance and user-friendliness using Likert Scales ranging from 0 to 6. In addition, the subjective assessment of the participants' own technical skills as well as the progress throughout the training was surveyed.

Validation study

Face validity was determined by evaluation of participants' feedback on the realism of the modules in terms of handling. Content validity was determined by the feedback on visual appearance.

Participants were either defined as 'inexperienced' (group S0: no training completed so far) or 'experienced' (group S1: SuSiPed1.0 training completed, group BC: board-certified pediatric surgical experts). To assess construct validity, we compared the mistakes made and time needed for completing the individual exercises and the entire curriculum as a whole at the third appointment between the inexperienced group (S0) with both experienced groups (S1 and BC). For those modules that demonstrated a significant difference comparing group S1 and S0, subgroup analysis was performed to test for any potential bias, as group S1 consisted of junior pediatric surgical trainees and medical students, and group S0 consisted of medical students only.

Statistical analysis was conducted with Welch's *t*-test. A pre-hoc power analysis was performed based on the total time of the participants of the S0 group to calculate the needed sample size with an estimated time reduction of 33%. The outcome variables for the validation study were time to completion of the task and occurrence of previously defined mistakes. The mean results of the last round of exercises were compared statistically. A value of $P < 0.05$ was considered significant, a value of $P < 0.10$ was considered a trend.

Description of the training modules

The SuSiPed2.0 simulation training consists of six training modules: (A) angulated stitching; (B) continuous stitching; (C) 3D-knot tying; (D) general knot tying; (E) fundoplication; and (F) esophageal anastomosis (Fig. 1 A–F). The models were adapted to a more advanced level of difficulty compared to the basic exercises in SuSiPed1.0 including simulation of complex surgical steps and working at unusual angles. The necessary hardware was designed using computer assistance and either 3D printed directly or cast with silicone in 3D-printed molds.

The SuSiPed2.0 box simulator consisted of a nylon-mesh covered box with three trocar sites. We used a standard laparoscopic tower with a 10 mm diameter 30 degree camera
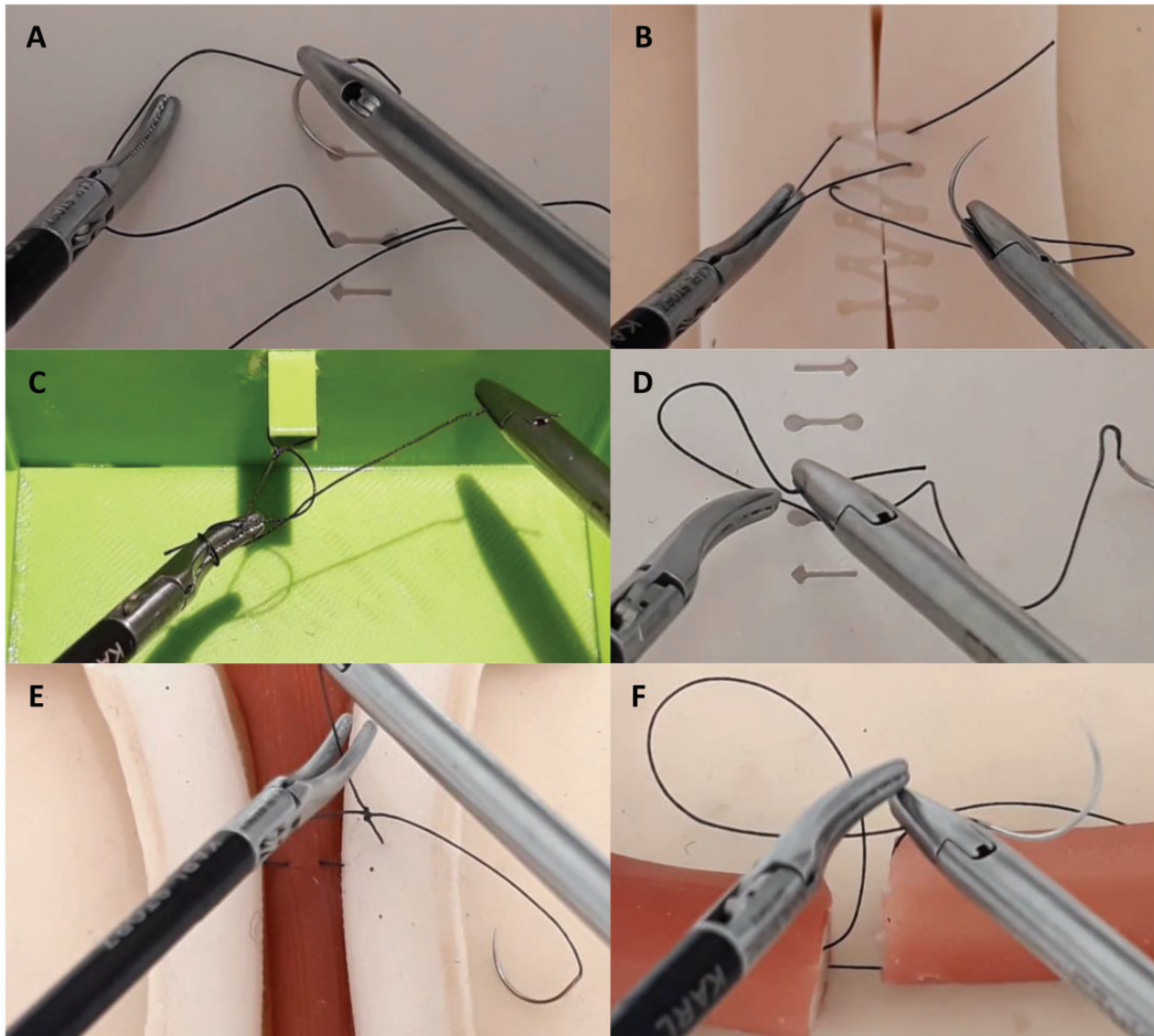
Figure 1. A-F. Modules of the SuSiPed2.0 curriculum. (A) Angulated stitching; (B) continuous stitching; (C) 3D-knot tying; (D) general knot tying; (E) fundoplication; (F) esophageal anastomosis.

optic. Further instruments used were 5 mm diameter scissors, two 5 mm dissectors, and a 5 mm needle holder. For suturing, a fine 14 cm long braided suture (e.g. Vicryl 4-0) was used.

The first module 'angulated stitching' (Fig. 1A) consisted of a rectangular silicone surface. The areas through which the participant was to insert and exit the needle were marked on the silicone by 2 mm inset fields. The stitching direction was marked by arrows. The task began by inserting and exiting the needle through the marked spots. This was used to practice precise insertion and removal of the needle into the tissue at different angles and with the correct circular motion. The time was measured from grasping the needle with the second instrument until the needle exited from the last mark. Errors

were defined as stitching outside the markings and damaging the silicone (tearing through the simulated tissue).

The second module 'continuous stitching' (Fig. 1B) consisted of a rectangular silicone surface, which simulated two tissue parts to be sutured together separated by a longitudinal gap. The continuous suture sequence was marked on the silicone by inset fields. The task began by inserting and exiting the needle through the marked spots. The goal was to practice precise insertion and removal of the needle into the tissue while creating a continuous suture under a small amount of tension. Again, the time was measured from grasping the needle with the second instrument until exiting the needle through the final mark. Errors were defined as stitching outside the markings and damaging the silicone.

The third module '3D-knot tying' (Fig. 1C) consisted of a 3D-printed plastic cube, which opened to the top and front. On the back wall through an opening in the plastic, a suture was fixed. The task involved placing knots (double knot in one direction, single knot in opposite directions) in this challenging position.

The time was measured from the moment the participant touched the thread with an instrument until a tight knot was completed. Errors were defined as performing an air knot or tearing the suture.

The fourth module 'general knot tying' (Fig. 1D) consisted of a rectangular silicone surface. The participant was instructed to insert and exit the needle through the marked insert fields on the silicone. The stitching direction was marked by arrows. The task began with inserting and exiting the needle through the marked spots. A surgical knot was to be created by forming a double loop, then alternating hands for a total of two additional simple knots. The time was measured from grasping the needle with the second instrument until the knot was finished. Errors were defined as stitching outside the markings and damaging the silicone, as well as the creation of an air knot and cutting the thread too short (<3 mm).

The fifth module 'fundoplication' (Fig. 1E) consisted of three tubular structures sewn onto a silicone pad. The middle structure simulated the esophagus, the outer ones the right and left gastric cuff, which had already been placed behind the esophagus as a simulated Nissen fundoplication. The task was to bring the two cuffs together in front of the esophagus by means of a slipknot. The participants were instructed to take a bite of the left simulated cuff, a superficial bite through the esophagus, and a bite of the right sided simulated gastric cuff with the needle. The two cuffs were supposed to be brought together using a slipknot. The time was measured from grasping the needle until the knot was finished. Errors were defined as an air knot, as well as damaging the silicone or tearing out the thread as well as cutting the thread too short (<3 mm).

The sixth module 'esophageal anastomosis' (Fig. 1F) consisted of two tubular structures fixed longitudinally on a plastic holder. In contrast to the fundoplication model, the tubular structures had two layers and thus simulated two opened esophageal ends with the tunica muscularis and mucosa, which were to be approximated and anastomosed. The task was to bring the tubular structures together with a slipknot. The needle was brought into and out of the back wall of one end of the esophagus, as well as the corresponding other end. A slipknot was to be created and the ends were brought together. The time was measured from grasping the needle with the second instrument until the knot was finished. Errors were defined as an air knot as well as tearing out the thread and cutting the thread too short (<3 mm).

Results

A total of 77 participants were recruited. The power analysis determined a minimum number of nine participants in the S1 and BC groups. The experienced group S1 ($n = 11$) consisted of four junior pediatric surgery residents and seven medical students. The experienced group BC ($n = 5$) consisted of board-certified pediatric surgical experts. The inexperienced group S0 ($n = 61$) consisted of medical students without experience in the field of MIS.

The analysis of the subjective evaluation survey showed an overall positive assessment of the training curriculum and the modules of 5 or above, with 0 being the worst and 6 the best score possible (Table 1).

A comparison of the inexperienced group (S0) with the two experienced groups (S1 and BC) showed that the experienced groups completed the exercises both faster and with fewer errors, although this effect was only partially significant (Tables 2–6). Overall, the S1 group completed all tasks (total time) significantly faster than S0, as shown in Table 2. Group S1 completed the angulated stitching (A) and esophageal anastomosis (F) modules significantly faster than group S0. Regarding general knot tying (D), there was a trend towards faster performance of participants in group S1 versus S0, as demonstrated in Table 2. Subgroup analysis for these three modules by level of training is shown in Table 3.

Group S1 showed significantly fewer errors completing the tasks continuous stitching (B), general knot tying (D) and esophageal anastomosis (F), as displayed in Table 4. Group BC made significantly fewer mistakes than group S0 except for the exercises angulated stitching and 3D-knot tying (Table 6) and was faster (although this was not statistically significant) than group S0 for all exercises except for general knot tying. For continuous stitching, group BC was significantly faster than group S0 (Table 5).

Table 1. Evaluation by participants

	Mean (Likert Scale: 0/worst–6/best)
Closeness to reality (visual appearance)	5
Closeness to reality (handling)	5.2
Relevance	5.7

Table 2. Time to task completion Group S1 vs. Group S0

Task / module	Time		P value
	Group S1 (n = 11)	Group S0 (n = 61)	
A. Angulated stitching	212 s ± 97	307 s ± 215	**< 0.03**
B. Continuous stitching	240 s ± 106	266 s ± 142	> 0.48
C. 3D-knot tying	109 s ± 100	142 s ± 121	> 0.3
D. General knot tying	222 s ± 138	306 s ± 130	**< 0.09**
E. Fundoplication	327 s ± 130	383 s ± 131	> 0.2
F. Esophageal anastomosis	229 s ± 53	352 s ± 149	**< 0.001**
Total	1340 s ± 489	1757 s ± 629	**< 0.03**

P-values in bold denote statistical significance.

Table 5. Time to task completion Group BC vs. Group S0

Task / module	Time		P value
	Group BC (n = 5)	Group S0 (n = 61)	
A. Angulated stitching	255 s ± 145	307 s ± 215	> 0.5
B. Continuous stitching	173 s ± 34	266 s ± 142	**< 0.001**
C. 3D-knot tying	120 s ± 105	142 s ± 121	> 0.7
D. General knot tying	358 s ± 212	306 s ± 130	> 0.6
E. Fundoplication	359 s ± 174	383 s ± 131	> 0.8
F. Esophageal anastomosis	249 s ± 121	352 s ± 149	> 0.1
Total	1513 s ± 252	1757 s ± 629	> 0.1

P-values in bold denote statistical significance.

Table 3. Subgroup analysis of modules showing significance or a trend time to task completion

Task / module	Time		P value
	Group S1 / medical students (n = 7)	Group S0 (n = 61)	
A. Angulated stitching	229 s ± 89	307 s ± 215	**< 0.09**
D. General knot tying	202 s ± 57	306 s ± 130	**< 0.002**
F. Esophageal anastomosis	233 s ± 57	352 s ± 149	**< 0.001**
Total	1346 s ± 294	1757 s ± 629	**< 0.01**

P-values in bold denote statistical significance.

Table 6. Errors during task completion Group BC vs. Group S0

Task / module	Time		P value
	Group BC (n = 5)	Group S0 (n = 61)	
A. Angulated stitching	0 ± 0	0.09 ± 0.4	> 0.6
B. Continuous stitching	0 ± 0	0.05 ± 0.2	**< 0.04**
C. 3D-knot tying	0 ± 0	0.02 ± 0.13	> 0.2
D. General knot tying	0 ± 0	0.15 ± 0.34	**< 0.001**
E. Fundoplication	0 ± 0	0.05 ± 0.22	**< 0.04**
F. Esophageal anastomosis	0 ± 0	0.07 ± 0.3	**< 0.04**
Total	0 ± 0	0.4 ± 0.7	**< 0.001**

P-values in bold denote statistical significance.

Table 4. Errors during task completion Group S1 vs. Group S0

Task / module	Errors		P value
	Group S1 (n = 11)	Group S0 (n = 61)	
A. Angulated stitching	0 ± 0	0.09 ± 0.4	> 0.6
B. Continuous stitching	0 ± 0	0.05 ± 0.2	**< 0.04**
C. 3D-knot tying	0 ± 0	0.02 ± 0.13	> 0.2
D. General knot tying	0 ± 0	0.15 ± 0.34	**< 0.001**
E. Fundoplication	0.2 ± 0.4	0.05 ± 0.22	> 0.31
F. Esophageal anastomosis	0 ± 0	0.07 ± 0.3	**< 0.04**
Total	0.18 ± 0.4	0.4 ± 0.7	> 0.2

P-values in bold denote statistical significance.

Discussion

This study demonstrates the face, content and construct validity of our low-cost, 3D printable pediatric MIS curriculum SuSiPed2.0. It also shows that participants who underwent the basic SuSiPed1.0 curriculum beforehand performed most tasks significantly faster and better than those who had no prior basic training.

Preventable iatrogenic complications in surgery are common.[1,20,21] Furthermore, Singh et al. conclude that 'lack of technical competence' (58%) was the most prevalent contributing factor regarding errors involving surgical trainees.[22] Thus, simulation-based training and standardized assessment of technical skills are recognized as important tools in improving safety in surgical practice,[4,7,8,23,24] most importantly in pediatric surgery.[25,26] Ziv et al. therefore referred to simulation-based training as an 'ethical imperative'.[2] According to most authorities in the field, simulation-based training should be considered a complement to hands-on supervision and mentoring by surgical educators inside the OR.[16,22]

While many pediatric MIS simulators exist, only very few are validated and may therefore serve for structured training and skills assessment.[3,4,9,12] Our SuSiPed1.0 and 2.0 programs offer both basic and more advanced MIS training for pediatric surgeons.

The modules are available as open-source files, so that cost is not an impediment for the implementation of a standardized institutional curriculum, even in low-resource settings.

The tasks of SuSiPed2.0 were designed with pediatric surgical index cases in mind. The required skills are markedly different from those of adult general surgery; therefore, there is

need for a specialized pediatric simulation program. For example, suturing up at an angle is an important skill in thoracoscopic diaphragmatic hernia repair. In the SuSiPed2.0 curriculum, this skill is simulated by the angulated stitching and 3D-knot tying module. Intracorporeal slipknot suturing is another specific task important for pediatric MIS. It is particularly useful when structures need to be brought together under a certain amount of tension, while avoiding tissue tearing. Slipknot tying is particularly important for minimally invasive esophageal atresia repair and fundoplication. In the SuSiPed2.0 curriculum, this skill is simulated by the fundoplication and esophageal anastomosis modules.

All reconstructive procedures in pediatric surgery heavily rely on a tight, secure intracorporeal knot. Depending on the technique and position of the instruments during the procedure, this can be achieved by alternately using the opposite ends of the thread for the C-loop. This technique is simulated by the general knot tying module. Continuous intracorporeal suturing is particularly important in pediatric MIS for indications such as the Anderson–Hynes renal pyeloplasty or intestinal suturing. In the SuSiPed2.0 curriculum, this skill is simulated by the continuous stitching module.

Overall, the experienced groups S1 and BC completed the tasks faster and made fewer mistakes than the inexperienced group S0. Our study furthermore demonstrates the highest level of construct validity for the esophageal anastomosis model, since it most highly distinguished the different skill levels of the participants, based on both the measured time and the errors. Construct validity was also demonstrated for the angulated stitching and general knot tying task, since they distinguished the different skill levels based on the measured time as well.

Our study is not without limitations. For one, we have so far not demonstrated predictive validity regarding performance in the clinical setting. However, the literature shows that proficiency measurement by construct validity correlates with predictive validity.[7,10] Also, although the sample size in the S1 group fulfilled our power analysis, the number of participants was limited simply by the fact that it was difficult to recruit subjects from the previous study on the validity of SuSiPed1.0 due to graduation and relocation of our prior participants. The inclusion of residents and medical students in S1 is another potential source of bias. Nevertheless, when comparing only medical students between groups S1 and S0 (subgroup analysis), the results were similar. Group BC did not fulfill the power analysis. The comparison with this group can therefore only be interpreted as a trend.

Based on our data, we propose the following benchmarks for task completion of the SuSiPed2.0 curriculum: we

Table 7. Authors' recommendation for benchmarks

Training module	Cut-off	
	Time to completion	Errors
A. Angulated stitching	6 min	1
B. Continuous stitching	5 min	1
C. 3D-knot tying	3 min	1
D. General knot tying	6 min	1
E. Fundoplication	8 min	1
F. Esophageal anastomosis	7 min	1

recommend three runs of the curriculum on three different days; time to completion and errors should be measured during the third run; we suggest using a cut-off for time to completion and errors so that 75% of the novice participants (Group S0) would have passed the exam (see Table 7). Furthermore, an international study among specialists is planned to determine more specific benchmark values regarding specialty training examination.

To our knowledge, this is the first study to describe the development of an advanced training program aimed at teaching and assessing pediatric MIS skills based on 3D-printable simulation models that are explicitly developed for training pediatric surgical skills at different skill levels. Therefore, SuSiPed2.0 is the logical next step to our already published SuSiPed1.0 basic training program. Both are easily available at a low cost using 3D-printing equipment.

Our goal is to allow all pediatric surgeons to use the SuSiPed2.0 modules for preparing their trainees to become proficient at the manual skills required to perform advanced pediatric surgical index cases successfully and safely. The improvement and further development of these models, as well as the development of an evidence-based, international assessment of pediatric MIS skills based on these models, will be addressed in subsequent studies.

Data availability

The data supporting the findings of this article are available from the corresponding author on request. The files necessary to print the simulation modules are available open access at https://www.lmu-klinikum.de/hauner/kinderchirurgische-klinik-und-poliklinik/lehre/simulationstraining/building-instructions/a84c59d1968399f8.

Conflict of interest

All authors declare that they have no conflicts of interest.

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