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Validation of low-cost models for minimal invasive surgery training of congenital diaphragmatic hernia and esophageal atresia☆

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ABSTRACT

Background: Minimal invasive surgery (MIS) is increasingly used for the correction of congenital diaphragmatic hernia (CDH) and esophageal atresia (EA). It is important to master these complex procedures, preferably preclinically, to avoid complications. The aim of this study was to validate recently developed models to train these MIS procedures preclinically.
Methods: Two low cost, reproducible models (one for CDH and one for EA) were validated during several pediatric surgical conferences and training sessions (January 2017–December 2018), used in either the LaparoscopyBoxx or EoSim simulator. Participants used one or both models and completed a questionnaire regarding their opinion on realism (face validity) and didactic value (content validity), rated on a five-point-Likert scale.
Results: Of all 60 participants enrolled, 44 evaluated the EA model. All items were evaluated as significantly better than neutral, with means ranging from 3.7 to 4.1 ($p < 0.001$). The CDH model was evaluated by 48 participants. All items scored significantly better than neutral (means 3.5–3.9, $p < 0.001$), with exception of the haptics of the simulated diaphragm (mean 3.3, $p = 0.054$). Both models were considered a potent training tool (means 3.9).
Conclusion: These readily available and low budget models are considered a valid and potent training tool by both experts and target group participants.
Type of study: Prospective study.
Level of evidence: Level II.

Congenital diaphragmatic hernia (CDH) and esophageal atresia (EA) are both rare congenital anomalies [1–4]. Both require surgical correction, which can be performed by either open or minimally invasive surgery (MIS). A higher complication and recurrence rate is reported for correction via MIS compared to open surgery [5–10]. It is assumed that this is because of the rarity of these neonatal minimally invasive surgery procedures and the corresponding steeper learning curve of junior pediatric surgeons and residents [5,11]. As a result, it is challenging to acquire and maintain these specific MIS skills.

Regular practice can reduce the learning curve and aids in acquisition and retainment of skills. Owing to the rarity of these conditions, frequent practice cannot be achieved in clinical practice alone. Therefore, simulation models may be used for training. The importance of simulation-based training for obtaining, retaining and transferring surgical skills to the clinical setting has previously been proven [12–14]. Simulation based training is shown to be effective in improving the performance in the operating room, decreasing operating time and reducing the rate of intraoperative errors [15]. Concurrently, simulation-based training could be a valuable asset to improve the quality of the surgical treatment of neonates needing a complex procedure, such as CDH or EA repair [16]. Especially for rare and complex MIS procedures, training models could be a great advantage in the training of pediatric surgeons and residents. Although MIS training models for both CDH [1,17] and EA [2,18,19] repair exist, the costs are often high, and the models are not readily available or not easily reproduced. This causes the urge for validated low cost MIS training models for both CDH and EA repair procedures, which can easily be acquired, used and replicated by surgeons and surgical residents, for training either at the hospital or

☆ Declaration of interest: Dr Guus Bökkerink and Dr Sanne Botden are co-owners of PediatrickBoxx, which is a small not-for-profit cooperation that has developed the CDH and AE model used in this study. This cooperation is founded to develop and sell the pediatric training models for low budget prices, to make sure all pediatric surgeons over the world can have access to the models. The minimal profit on selling the models is used in the development and production of new models. Dr Maja Joosten, Dr Erik Leijte, Dr Maud Lindeboom and Dr Prof Ivo de Blaauw declare no conflicts of interest.

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at home. The aim of this study was to develop and validate two low cost, readily available models for the practice of esophageal atresia (EA) anastomoses and congenital diaphragmatic hernia (CDH) closure.

1. Materials and methods

1.1. Development of models

Because the aim was to develop models that can be reproduced and used by anyone, common materials that could be found in a hospital or bought at a dime store were used for the development of these models. It is important that the models can be used in any inanimate MIS simulator to create an independent model that is usable for everyone.

1.1.1. Esophageal atresia (EA) model

For the EA model, two water balloons were used (±€0.10 each). They were prepared by cutting the small end side off from one balloon (±5 mm from the edge) and the wide end side off from the other (also ±5 mm from the edge). Both balloons were attached to the suturing pads of the simulators used in this study, resembling both ends of the interrupted esophagus (Fig. 1). A gap of 2–3 mm was used between the balloon ends to make sure the balloons would not tear during the suturing; however, a larger gap could be larger to create suturing under even more tension.

1.1.2. Congenital diaphragmatic hernia (CDH) model

The CDH model was made of a round clear plastic cup (Ø 7 cm, ±€0.50) and one nonlatex surgical glove (size 8, ±€1.00). The cup was prepared by removing the bottom and the glove was prepared by cutting off the fingers at ±7 cm from the opening. Afterward, this glove was placed over the prepared cup as shown in Fig. 2, with the cut end over the removed bottom of the plastic cup, simulating the diaphragm defect. The cup with glove was attached to an exercise board with an elastic band (±15 cm, ±€0.15), as shown in Fig. 2.

1.2. Simulators

The simulators used in this study were the LaparoscopyBoxx (Fig. 3) and the EoSim (Fig. 4) laparoscopic simulators. The instruments used were the 3 mm needle holder, dissector and scissors.

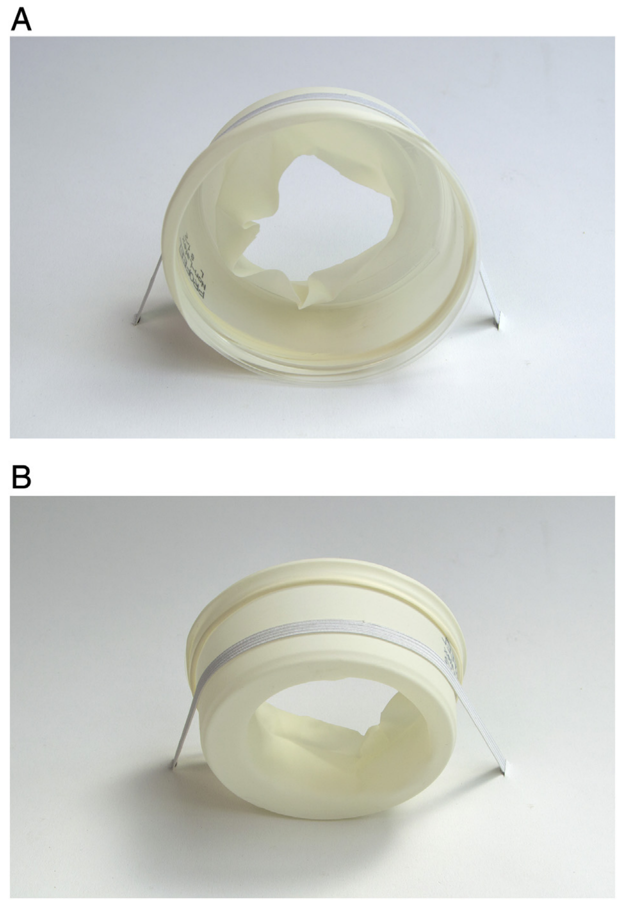

Fig. 2. (a) CDH model (front) consisting of a clear plastic cup with a surgical glove. An online video of the construction of the CDH model can be found using the following link: https://youtu.be/1Pn75M625w4. (b) CDH model (back) consisting of a clear plastic cup with a surgical glove. An online video of the construction of the CDH model can be found using the following link: https://youtu.be/1Pn75M625w4.

1.2.1. LaparoscopyBoxx

The LaparoscopyBoxx is a wooden training box, by PediatrickBoxx, the Netherlands, consisting of multiple self-assemble wooden parts

Fig. 1. EA model consisting of a suturing pad with two small water balloons. An online video of the construction of the EA model can be found using the following link: https://youtu.be/r-yAMFdlHVk.

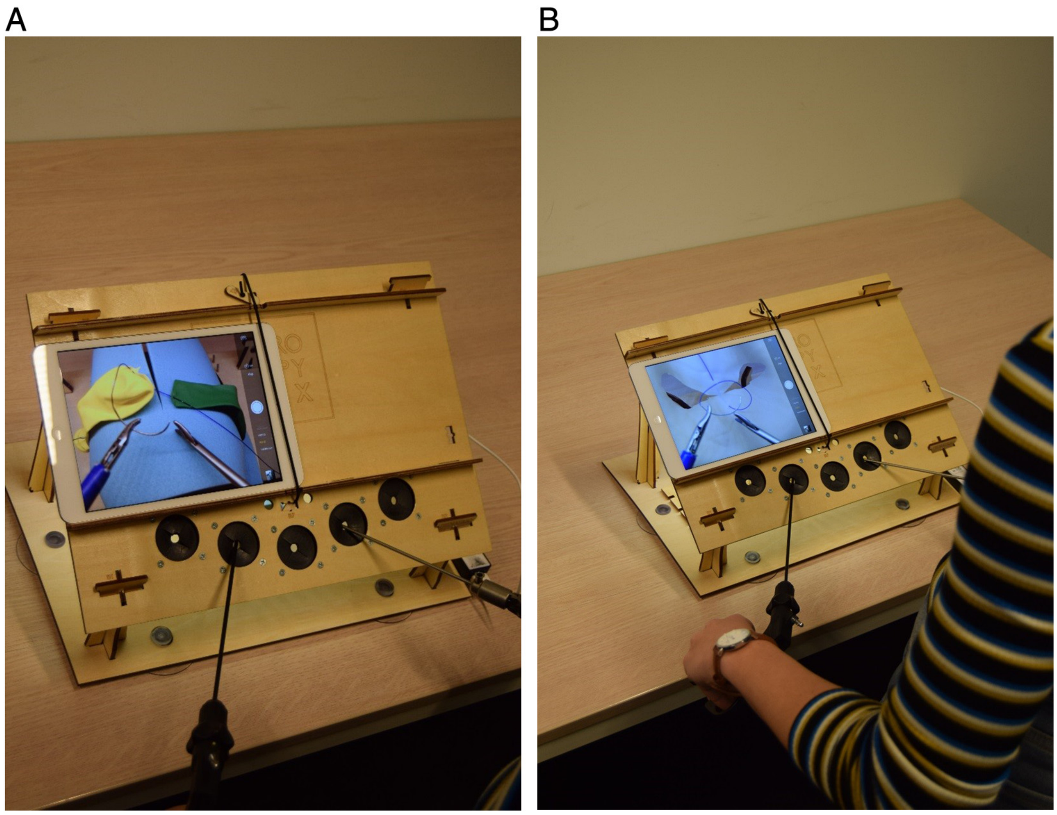

Fig. 3. (a) The LaparoscopyBoxx simulator with EA model. (b) The LaparoscopyBoxx simulator with CDH model.

[20]. The Special LaparoscopyBoxx has five instrument ports and is therefore suitable for neonatal, pediatric and adult surgery. The box is delivered with a suturing pad and two exercise boards, on which the suturing pad can be placed in accordance with the LaparoscopyBoxx manual. For this study, a 9.7-in. tablet (iPad, Apple) was used as a displaying screen and high-resolution camera. Both the EA model and the CDH model were attached to the exercise board with an elastic band.

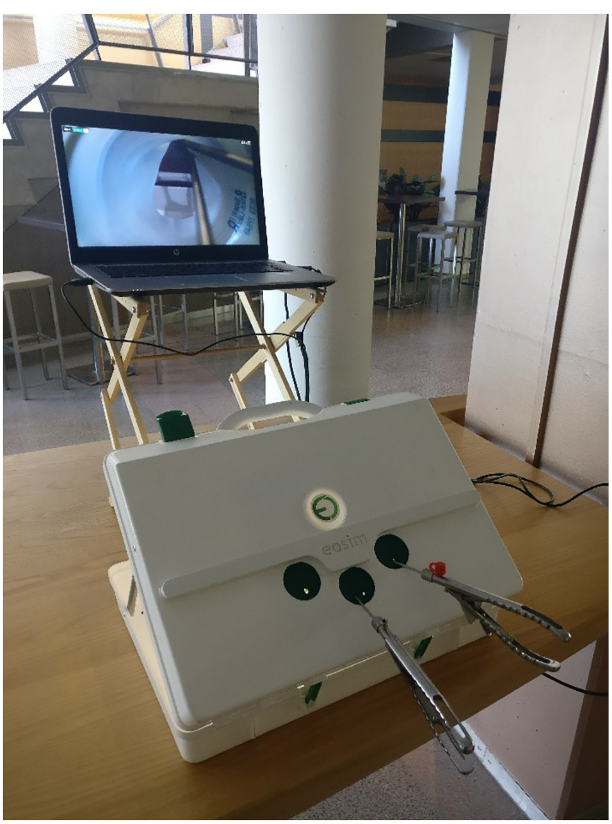

Fig. 4. The EoSim simulator.

1.2.2. EoSim

The EoSim is an augmented reality laparoscopic simulator by Eosurgical ltd., Edinburgh, Scotland, United Kingdom [21]. For this study, the standard setup was used with an internal high definition camera, suturing pad, several connecting parts, exercise equipment and the EoSim software. A 15-in. laptop with required specifications and software was used as displaying screen. The EA model was attached to the suturing pad. The CDH model was placed on one of the exercise boards, attached with an elastic band. For the EA model, the model was placed at a distance of approximately 10 cm from the camera. The CDH model was placed on a curved exercise board at a distance of 5 cm from the camera. As long as there was a clear contrast between the glove and the suture, the color of the glove did not affect the working of the camera in the simulator box.

1.3. Protocol

This validation study uses the personal experience of the participants, extracted from an evaluation form, to determine the usefulness of these low-cost models for MIS training. The participants were asked to perform an EA and a CDH repair procedure on one of the simulators. During this procedure, the participants were able to ask questions and change instruments if needed. The participants were randomly assigned to one of the simulators. There was no fixed order of operation for both procedures and participants were not obligated to perform both procedures or practice on both simulators. After (partly) completing the procedure, all participants completed a questionnaire on their opinion regarding the realism and didactic value for training of component

Table 1
Demographics of participants are presented as mean with standard deviation (SD) or number.

	Novice $n = 13$	Intermediate $n = 29$	Experienced $n = 18$	Total $n = 60$
Mean age (SD)	22 (2.6)	35 (5.1)	45 (10.4)	34 (10.7)
Sex				
Male	3	13	8	24
Female	10	16	10	36
Profession				
Pediatric surgeon	0	6	17	23
Pediatric urologist	0	0	1	1
General surgeon	0	2	0	2
Fellow pediatric surgery	0	7	0	7
Surgical resident	0	14	0	14
Medical intern	13	0	0	13

tasks of the specific pediatric procedural skills on the models. The performance of the participants during the procedure was not scored or evaluated.

1.4. Participants

The participants recruited for this study were pediatric surgeons, pediatric surgery fellows, surgical residents, and medical interns or students. The aim was to include 'experienced participants' (with experience of >20 basic pediatric MIS procedures and >10 advanced pediatric MIS procedures), 'an intermediate group' (at least some general MIS experience, but ≤20 basic pediatric MIS procedures and ≤10 advanced pediatric MIS procedures) and 'novices' (no surgical experience, but with a knowledge of the medical background, consisting of medical students and interns). Because the novices had no surgical training, their opinion was considered the reference neutral opinion. The opinion of the intermediate group and experienced group was used for the validation of the models.

The participants were asked to participate during several national pediatric surgical courses in the Netherlands from January 2017 until October 2018, at the Pediatric Minimally Invasive Symposium, September 2018, Utrecht, the Netherlands and at the 11th European Pediatric Colorectal congress, December 6–8th 2018, Nijmegen the Netherlands.

1.5. Questionnaire

The questionnaire used in this study was based on previously used and validated questionnaires, used in multiple validation studies [22–25]. It was adapted to suit the properties of these models and assessed by experts to reach consensus. The questionnaire consisted of two parts. The first part of the questionnaire entailed the clinical experience of the participants. The laparoscopic experience was defined as number of basic MIS procedures (cholecystectomy, appendicectomy), basic pediatric MIS procedures (pyloromyotomy, appendectomy) and advanced pediatric MIS procedures (including incorporeal suturing). The second part of the questionnaire consisted of items regarding EA anastomosis suturing and CDH repair suturing; the participants were asked to score the separate items on a 5-point Likert scale (1 = very unrealistic, 2 = unrealistic, 3 = neutral, 4 = quite realistic, 5 = very realistic). At the end of the questionnaire a comments option was included for participants to leave remarks about each model.

1.6. Statistics

Statistical analysis was performed using IBM SPSS Statistics 25. All values were represented as mean with the standard deviation. Either an independent samples t-test or a one-way ANOVA was used to determine significant differences between groups. If equal variances were not assumed according to Levene's test for equality of variances, the p-value was defined with a Welch's test. Post-hoc analysis was performed using a Hochberg's GT2 or a Games–Howell if equal variances were not assumed. P-values of <0.05 were considered to be statistically significant. A mean of >3.5 was considered a significantly better opinion than neutral, although a mean of >4.0 was considered as a potent training tool for that component step. These differences were calculated with a one-sample t-test.

2. Results

2.1. Demographics

A total of 60 participants were included to evaluate the models, which came from all over the world, although the majority was European. The participants were divided into three groups: novices (13 participants), intermediates (29 participants) and experienced participants (18 participants), as shown in Table 1. The experienced group consisted of seventeen pediatric surgeons and one pediatric urologist. The intermediate group consisted of six pediatric surgeons, two general surgeons, seven fellows pediatric surgery and fourteen surgical residents. The novice group consisted of thirteen medical interns. The number of participants varied between the two models because not all participants assessed both models. The EA model was evaluated by 44 participants (thirteen novices, nineteen intermediates and twelve experienced participants), whereas the CDH model was evaluated by 48 participants (thirteen novices, twenty intermediates and fifteen experienced participants).

Table 2
Mean grading outcomes with standard deviation based on a 5-point Likert scale (1 = very bad, 3 = neutral, 5 = very good) of the EA model.

Esophageal atresia model	Novice $n = 13$	Intermediate $n = 19$	Experienced $n = 12$	Total $n = 44$	P-value
Visual aspects	3.2 (0.60)	4.1 (0.87)	4.0 (0.74)	3.8 (0.83)	*0.005*
Haptics of the simulated esophagus and fistula	3.3 (0.48)	3.7 (0.87)	3.5 (1.00)	3.6 (0.82)	0.149
Grabbing of the tissue	3.1 (0.64)	3.7 (0.95)	3.8 (0.94)	3.6 (0.90)	0.054
Opening of the pouch	3.0 (0.58)	3.8 (0.88)	3.8 (0.84)	3.6 (0.85)	*0.010*
Placing sutures for the anastomoses	3.5 (0.52)	3.9 (0.80)	3.9 (0.90)	3.8 (0.76)	0.257
Tension on the sutures (and option to adjust)	3.3 (0.48)	4.1 (0.81)	4.1 (1.17)	3.9 (0.91)	*0.026*
Training tool for the EA anastomosis	3.5 (0.52)	4.0 (0.75)	3.8 (1.06)	3.8 (0.80)	0.172

Significant differences between groups ($p < 0.05$) were calculated with the one-way ANOVA and Hochberg's GT2 (equal variances assumed with Levene's test for equality of variances).

Table 3
Mean grading outcomes with standard deviation based on a 5-point Likert scale (1 = very bad, 3 = neutral, 5 = very good) of the CDH model.

Congenital diaphragmatic hernia model	Novice $n = 13$	Intermediate $n = 20$	Experienced $n = 15$	Total $n = 48$	P-value
Visual aspects	3.7 (0.48)	3.6 (0.76)	3.9 (0.59)	3.7 (0.65)	0.419
Haptics of the simulated diaphragm	3.2 (0.60)	3.3 (1.02)	3.3 (0.82)	3.3 (0.84)	0.926
Grabbing of the tissue	[a]	3.6 (0.68)	3.3 (0.88)	3.5 (0.78)	0.392
Defect size of the hernia (and option to adjust)	3.2 (0.56)	3.8 (0.83)	4.0 (0.54)	3.7 (0.75)	*0.001*
Placing sutures to close the diaphragm defect	3.4 (0.51)	3.9 (0.59)	3.7 (0.88)	3.7 (0.69)	0.192
Tension on the sutures	3.1 (0.64)	4.0 (0.65)	3.5 (0.83)	3.6 (0.79)	*0.010*
Training tool for the closure of a diaphragmatic hernia	3.2 (0.60)	3.9 (0.72)	3.8 (0.56)	3.7 (0.69)	*0.012*

Significant differences between groups ($p < 0.05$) were calculated with the one-way ANOVA and Hochberg's GT2 (equal variances assumed with Levene's test for equality of variances) or Welch's test and Games–Howell.
[a] Missing.

2.2. Esophageal atresia model

Comparing all three groups together, the EA model scored significantly better than the neutral 3.0 score on all items, with means ranging from 3.6 to 3.8 ($p < 0.05$, Table 2). Mean scores were highest for 'tension on the sutures' (3.9), followed by 'visual aspects' (3.8), 'placing sutures for the anastomosis' (3.8) and 'overall suitability as training tool for EA repair' (3.8). 'Haptics of the simulated esophagus and fistula' and 'grabbing of the tissue and opening of the pouch' were scored the lowest with an overall mean score of 3.6.

The novices, however, rated the model worse than the intermediate and experienced group (Table 2). Because the novices had no reference to the clinical setting, the novices were excluded for the face and content validity and only served as a reference group, as explained in the methods.

The target group (consisting of the intermediate and experienced group) gave a significantly higher score than the novice group to visual aspects (4.0 vs 3.2, $p = 0.002$), for grabbing of the tissue (3.8 vs 3.1, $p = 0.020$), for opening of the pouch (3.8 vs 3.0, $p = 0.003$) and for tension on the sutures (4.1 vs 3.3, $p = 0.006$). The target group scored all items significantly better than neutral, with means ranging from 3.7 to 4.1 ($p < 0.001$), as shown in Table 4.

2.3. Congenital diaphragmatic hernia model

The mean scores for all aspects of the CDH model were better than the neutral 3.0 score, with means ranging from 3.3 to 3.7, when evaluating the total group.

'Visual aspects', 'defect size of the hernia' and 'placing of the sutures' and 'overall suitability as training tool for CDH repair' were scored the highest (3.7), followed by tension on the sutures (3.6) and grabbing of the tissue (3.5). Haptics of the simulated diaphragm were scored the lowest (3.3).

As for the EA model, the novices rated the CDH model worse than the intermediate and experienced group (Table 3).

The target group scored significantly higher than the novice group for 'defect size of the hernia' (3.9 vs 3.2, $p = 0.001$), 'tension on the sutures' (3.8 vs 3.1, $p = 0.003$) and 'potent training tool' (3.9 vs 3.2, $p = 0.003$). All items scored significantly better than neutral (means 3.5–3.9, $p < 0.001$), with the exception of the haptics of the simulated diaphragm (mean 3.3, $p = 0.054$), as shown in Table 4.

3. Discussion

The models used in this study are regarded as good training tools for the practice of advanced pediatric MIS skills for both the esophageal atresia (EA) anastomosis and congenital diaphragmatic hernia (CDH) closure. They can be used in any inanimate MIS simulator, which is suitable for pediatric and neonatal surgery. For the vast majority of the aspects of the EA as well as the CDH training model, face and content validity was established. For the intermediate and experienced group, the scores were significantly higher compared to neutral scores and higher compared to the reference group on all aspects, except for the haptics of the simulated diaphragm. Additionally, there were no significant differences between the opinion of the intermediate and experienced group on both models, indicating that a general consensus has been reached.

A relatively large difference in scores was found between the reference group (the novice group) and the target group (the intermediate and the experienced group). This difference could perhaps be explained by the difference in expectations and the lack of experience in the novice group. Owing to biased expectations of the real EA or CDH repair procedure, the novice group may be of the opinion that low budget models are less comparable with the real procedure. However, the more neutral opinion of the novice group could also indicate that they did not know what to answer, because they had not reference value. Therefore they scored it a neutral (3 on the five-point Likert scale). This would actually be the expected value for nonexperienced participants. Additionally

Table 4
Mean grading outcomes with standard deviation, based on a 5-point Likert scale (1 = very bad, 3 = neutral, 5 = very good) for the target group (consisting of the intermediate and experienced group) for both the MIS models.

MIS models	EA model Target group $n = 31$	CDH model Target group $n = 35$
Visual aspects	4.0 (0.80)	3.7 (0.70)
Haptics of the simulated esophagus and fistula	3.7 (0.90)	3.3 (0.92)
Grabbing of the tissue	3.8 (0.92)	3.5 (0.77)
Defect size of hernia		3.9 (0.71)
Opening of the pouch	3.8 (0.83)	
Placing sutures to close diaphragm defect		3.8 (0.71)
Placing sutures for the anastomoses	3.9 (0.81)	
Tension on the sutures (and option to adjust)	4.1 (0.93)	3.8 (0.75)
Potent training tool	3.9 (0.86)	3.9 (0.64)

the intermediate and experienced group could perhaps more easily consider a low budget model to be a suitable alternative to live practicing on patients.

This study shows that especially the intermediate group qualifies both the EA and CDH training models as a potent training tool. Previous studies also showed positive scores compared to neutral for different aspects of other simulation models [4,26]. Some studies report even higher scores than our study. This might be because of several reasons. Firstly, owing to different scales or scoring systems used, these studies are not generally comparable. Some studies have used a 4-point Likert scale and others have a defined number allocated to 'I do not know' (1 or 3) [1,2]. Secondly, the total cost of the models (EA ± €0.20 and CDH ± €1.65) is much lower and the possibility to gain one is easier in this study compared to models used in other studies. Most other models are not low-budget, with prices ranging from €50 to €200 for EA [2,27] and from €14 to €150 for CDH [4,17,28,29], and are not readily available [2,4,18]. The models used in this study are both low-budget and easily available. All models can be constructed with low-budget materials or bought online via www.pediatrickboxx.com (€10,- for a model that is adapted for the LaparoscopyBoxx simulator).

Lastly, previous studies mainly focused on groups with less experience [4] or had a lower sample size (seven to nineteen participants). This study used a larger sample size to increase the reliability, thus meeting the requirements to validate the models. Furthermore, this study focuses on the less-experienced professionals, the target group for this specific pediatric surgical training. The intermediate group is therefore the largest group, which improves the relevance of the findings for the end-users of the models.

3.1. Limitations

There are some limitations of this study. First of all, the realism of the visual aspects of the models is limited, which is based on the low budget feature of the model. The focus, therefore, mainly lay on the suturing tasks of the procedure and not the dissection needed for the procedure. This would be very difficult to simulate properly, making the model very expensive and not easily reusable or accessible. Secondly, no data were included on the performance of participants working with the model. Therefore, no conclusions can be drawn on the suitability of these models for improving technical skills, such as time of procedure and quality of the performance. Further studies could also evaluate the way of learning with these models to improve the efficiency of the training methods. Studies focusing on the learning curve of these trainings could help provide useful information to develop more efficient training methods.

4. Conclusion

The two low-cost, readily available models evaluated in this study are considered valid for training and suitable for residents, fellows, starting and more experienced pediatric surgeons. The minimally invasive anastomoses of an esophageal atresia and closure of congenital diaphragmatic hernia can be practiced using these newly developed models. These models can contribute to improve simulation-based training in pediatric surgery.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jpedsurg.2020.05.045.

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