The importance of simulation training in pediatric surgery

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Ph.D. Thesis

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LIST OF FULL PAPERS RELATING TO THE SUBJECT OF THE THESIS

I. Barroso C, **Etlinger P**, Alves AL, Osório A, Carvalho JL, Lamas-Pinheiro R, Correia-Pinto J. Learing curves for laparoscopic repair of inguinal hernia and communicating hydrocele in children. Front Pediatr. 2017; 5:207. (**IF 2017: 2.335**)

II. **Etlinger P,** Barroso C, Miranda A, Moreira Pinto J, Lamas-Pinheiro R, Ferreira H, Leão P, Kovács T, Juhász L, Sasi Szabó L, Farkas A, Péter V, Kálmán A, Géczi T, Simonka Zs, Cserni T, Nógrády M, Fodor G, Szabó A, Correia-Pinto J. Characterization of technical skill progress in a standardized rabbit model for training in laparoscopic duodenal atresia repair. Surg Endosc. 2021 May 17. doi: 10.1007/s00464-021-08530-x. (**IF 2020: 4,584**)

III. **Etlinger P**, Miskolczi N, Hajnal D, Szabó A, Kovács T. Our initial results with 3-port laparoscopic inguinal hernia repair in childhood – Experience of a pediatric unit of a university center. Gyermekgyógyászat, 2021; 72(3):153-7. (In Hungarian)

ABSTRACTS RELATING TO THE SUBJECT OF THE THESIS

I. **Etlinger P**, Osório A, Carvalho N, Correia-Pinto J. A modified laparoscopic PIRS technique for repair inguinal hernia and hydrocele in children. IPEG Annual Meeting, Fukuoka, Japan, 2016.

II. **Etlinger P,** Kovács T, Correia-Pinto J. In vivo animal models for training neonatal and infantile endoscopic surgery: a systematic review. ESPES Annual Meeting Brussels, Belgium, 2018.

III. **Etlinger P,** Barroso C, Miranda A, Szabó A, Correia-Pinto J. When are trainees ready transfer skills from the lab to the OR? IPEG Annual Meeting, Santiago de Chile, Chile, 2019. J Laparoendosc Adv Surg Tech A. 2019; 29(6):A1-A72. doi: 10.1089/lap.2019.29028.abstracts, QS 102.

IV. **Etlinger P**, Szabó A, Correia-Pinto J, Kovács T. Educational experience of advanced pediatric laparoscopic surgical techniques in a skill laboratory setting. Magy Seb. 2019; 72(4):pp183. (In Hungarian)

LIST OF ABBREVIATIONS

GOALS	Global Operative Assessment of Laparoscopic Skills
LS-CAT	Laparoscopic Suturing Competency Assessment Tool
MISTELS	McGill Inanimate System for Training and Evaluation of Laparoscopic Skills
OSATS	Objective Structured Assessment of Technical Skills
OSATS-GRS	Objective Structured Assessment of Technical Skills - Global Rating Scale
PIRS	Percutaneous Internal Ring Suturing
VAS	Visual Analogue Scale

CONTENTS

SUMMARY

Duodenal atresia surgery is a highly demanding task in pediatric practice. Our aim was to create a clinically relevant *in vivo* laparoscopic training option which would allow for improved laparoscopic anastomosis suturing skills in preclinical settings. We also investigated how a standardized dry lab laparoscopic training course influences future skill development by using this new model as a test operation. We also wanted to define criteria that would allow trainees to perform the same laparoscopic procedure in a clinical setting. To this end, we analysed objective and semi-quantitative indicators of skill improvement using a rabbit model of duodenal atresia with diamond-shaped anastomosis. The results show that the minimum number of required repetitions can be determined, as the quality of anastomosis (an indicator of the success of this type of surgery) reaches its optimal value, and the Global Operative Assessment of Laparoscopic Skills (GOALS) score does not show significant further improvement after the fifth surgery. Among the different domains of the GOALS score system, depth perception, tissue handling and efficiency score values reach a major degree of improvement during this laparoscopic suturing approach. Another important achievement was that the performance of participants undergoing standardized and structured basic laparoscopic skill training reached the levels of experienced, but non-uniformly trained residents. This manifested in similar anastomosis quality as well as similar values of GOALS score and surgery time.

Since knowledge of the minimum number of operations enabling pediatric surgeons to perform successful interventions is crucial in clinical settings, we aimed to assess the characteristics of the learning process of two inguinal hernia operations (the percutaneous internal ring suturing (PIRS) and 3-port inguinal hernia techniques) during their introduction in pediatric surgery units. Here, surgeons' learning curves were assessed focusing on perioperative surgery time, intra- and postoperative complication and conversion rates, ipsilateral recurrence and incidence of metachronous hernia. Surgery time did not show any significant improvement during the time frames under examination (35 and 17 operations with PIRS and 3-port techniques, respectively) in the presence of remarkably low intraoperative and early postoperative complication rates. Our data suggest the superior relevance/importance of complication rate over surgery time to detect achievement if clinical hernia operations are introduced at pediatric surgery units.

The present results emphasize the importance of standardized preclinical laparoscopic training protocols and the benefits of detailed analysis of learning curves to determine the minimum number of procedures to safely perform laparoscopic techniques in pediatric surgical practice.

1. INTRODUCTION

1.1. Special challenges of pediatric laparoscopic interventions

The number of advanced endoscopic surgical interventions is continuously increasing worldwide. Nonetheless, pediatric surgery (surgery on newborns and infants) faces special challenges, including the use of special surgical instruments and limited interventions due to a smaller workspace, while the safety of surgical interventions plays a particularly large role with children [Trudeau MO 2018]. Accordingly, development of pediatric minimally invasive techniques has been somewhat slower than with adult approaches. Another feature of pediatric surgery is that it is not typically divided into subspecialities; therefore, every pediatric surgeon is expected to be familiar with numerous types of surgical interventions. A decreasing number of live births and an increasing tendency of artificial abortions also have a huge impact on the frequency of congenital pathologies, especially in developed countries. These demographic aspects also influence the number of surgical interventions and hence the possibilities for surgical skill acquisition.

The most frequent and technically least demanding pediatric surgical interventions that can be performed with the minimally invasive approach include appendectomy, inguinal hernia closure, abdominal testis surgeries and varicocele ligation. There are other surgical procedures which (owing to their more challenging technical features) can also optionally be conducted via laparoscopy, e.g. pyeloplasty, pyloromyotomy, fundoplication and nephrectomy. These latter surgeries definitely require profound experience with endoscopic surgery. The most demanding surgeries (oesophageal atresia, congenital airway malformation and duodenal atresia) are nearly impossible to carry out in a minimally invasive way without proper prior and continuous skill development. Particularly in these cases of advanced laparoscopic procedures, the benefit/risk ratio and the safety of the actual surgical intervention should be considered carefully and be assessed individually for the particular pediatric surgeon.

Before conducting any demanding/advanced task, pediatric residents and junior pediatric surgeons need to gain experience with simpler laparoscopic techniques. One should bear in mind, however, that there is a tremendous leap in technical difficulty between these types of surgery. All these facts underline the importance of laboratory trainings designed to master advanced techniques before carrying them out on pediatric patients. The aim of the studies summarized in this thesis was to share our experience gained during different steps of a learning process, including a structured, standardized dry lab laparoscopic training, implementation of a complex, clinically relevant animal model, and pediatric interventions which already incorporate non-technical skills.

Examples of pediatric laparoscopic interventions I: Inguinal hernia surgery (basic level of difficulty)

Inguinal hernia is one of the most common congenital pathologies in pediatric surgery [Clarke S 2010]. Unlike in adults, inguinal hernias are mostly indirect in nature in the pediatric population; therefore, the use of meshes – which are usually preferred in adult general surgery – is not appropriate here. Various laparoscopic herniorrhaphy techniques arose from the late 1990s [Ponsky T 2014]. Probably the most important viewpoint is their comparability with the open approach focusing on surgery time as well as complication and recurrence rates. Based on individual preferences, some surgeons follow the “cut and run” approach, while others prefer the “burnia” approach (by burning the patent vaginal process) [Novotny NM 2017]. Other techniques rely on the 3-port purse-string or the percutaneous internal ring suturing (PIRS) methods, the latter of which has many variations and has gained remarkable popularity [Patkowski D 2006]. These techniques are safe, and, importantly, surgery time and recurrence rate (below 1%) show similar values to those of the open approach (if performed by an experienced surgeon). As opposed to open surgery, the main advantage of laparoscopic hernia repair is that it results in revelation (or discovery) of asymptomatic contralateral (metachronous) hernias [Wenk K 2015]. Metachronous hernias are present in approximately 6% of the cases and often require later operation at a second spot [Kokorowski PJ 2014].

As noted before, surgical solutions used for pediatric hernia repair greatly depend on the preferences of the surgical team and the surgeon performing the operation. For institutes in Portugal and most centres in Hungary, PIRS is the primary choice. The essence of this operation is a laparoscopy-controlled percutaneous extraperitoneal hernia sac ligation creating two half-circles around the internal inguinal ring (Figure 1). Since patient safety is a key issue when a new surgical procedure is introduced at a clinical unit, we wanted to define a minimum number of surgeries after which the complication rate is reduced to a minimum. Therefore, we conducted a retrospective analysis of learning curves among pediatric surgeons using semiquantitative methods to provide a benchmark for this type of surgery at a Portuguese pediatric centre, where this procedure is conducted in relatively high numbers.

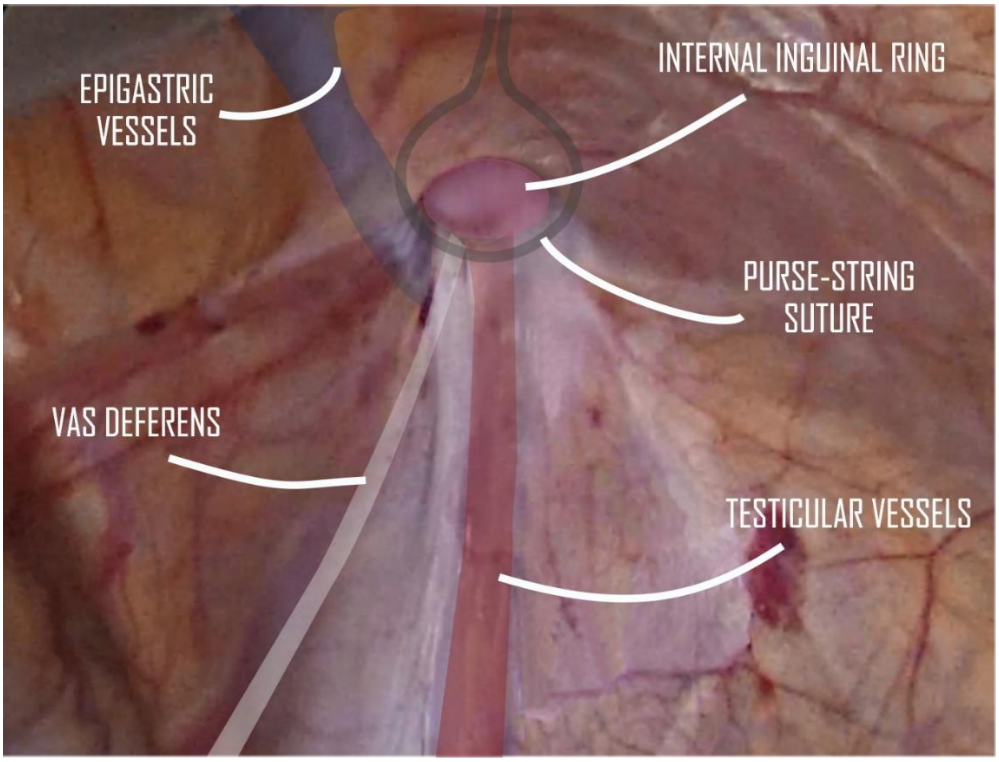

Figure 1. Inguinal anatomy and schematic image of the PIRS technique

At our parent institution in Szeged, however, the 3-port technique is preferred. This includes an intracorporeally tied purse-string suture after complete dissection of the internal inguinal ring (see later). This technique requires prior acquisition of complex laparoscopic skills.

In the present studies, we assessed the characteristics of the learning process of the PIRS in a clinical setting. Furthermore, we aimed to describe our experience with the clinical introduction of the 3-port inguinal hernia technique at our clinical pediatric surgery unit.

Examples of pediatric laparoscopic interventions II: Duodenal atresia surgery (higher level of difficulty)

Duodenal atresia is a relatively rare pathology in children with an overall incidence of 1:5000–10000 [Escobar AM 2004]. The aetiology of this condition has not yet been clarified, but unsuccessful recanalization, retinoic acid defect and fibroblast growth factor 2IIIb receptor mutations are among the potential mechanisms [Orr-Urtreger A 1993; Reeder AL 2012; Tandler J 1900]. It can also be caused by external compression (e.g. pancreas anulare). The classification is based on severity, ranging from stenosis to complete atresia. A detailed description of the surgical management of the different anatomical localizations of duodenal atresia was first provided by Ladd in 1931 [Ladd WE 1931]. Restoration of the continuity of the passage is based on anastomoses between the duodenal stumps or the duodenum and jejunum (depending on the localization of the defect) and special care must be taken so as to prevent biliary complications (i.e. lesions of the papilla of Vater) [Ladd WE 1931]. The most frequent postoperative complications include stenosis or insufficiency of the anastomosis and pouchitis (in the case of duodenojejunostomy). To overcome these difficulties and also those originating from the disproportionate calibres of the atretic duodenal stumps, Kimura described the diamond-shaped technique (Figure 2) [Kimura K 1990]. Diamond-shaped anastomosis gained popularity worldwide due to its lower postoperative complication rate. The laparoscopic version of duodeno-duodenal anastomosis was first described in 2001 by Bax et al. [Bax NM 2001] with an approach based on the same principles as those of the open version of diamond-shaped anastomosis (described by Kimura), but side-to-side anastomoses were also conducted later laparoscopically. The technique is one of the most challenging laparoscopic tasks performed on neonates. Furthermore, a low incidence rate may also contribute to difficulties in mastering surgical skills. From a technical point of view, tissue fragility, limited working space, distally located atresia and the need for knot tying and for proper identification of the stumps require a higher level of expertise.

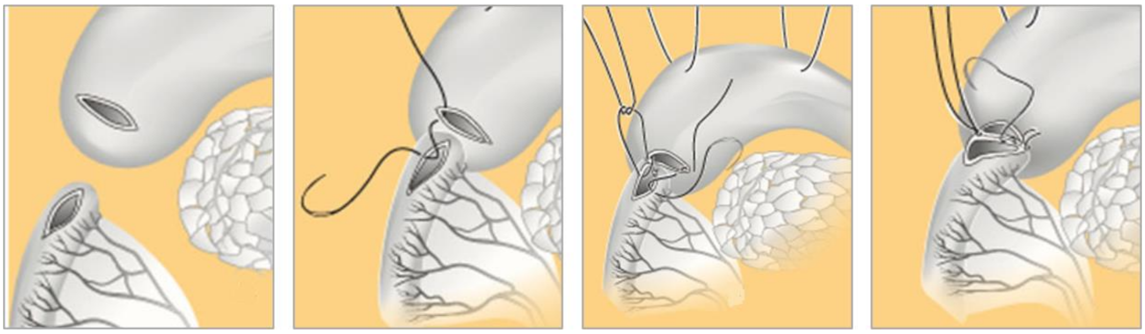

Figure 2. Scheme for the diamond-shaped anastomosis (see Van der Zee DC 2011)

Clearly, the duration of the minimally-invasive technique for duodenal atresia is longer, especially in the first phase of the learning curve, as described in a recent meta-analysis [Mentessidou A 2017]. Complication rates and hospitalization times are comparable with those of the open approach. As shown by a single-centre study, however, remarkable advancement in the surgical outcomes of this procedure can be achieved when comparing the first and second five-year period [Van der Zee DC 2011].

The authors aimed to establish a reproducible laparoscopic duodenal atresia model to practise the most complex and surgically most demanding steps of the operation and thus enabling participants to improve their performance and surgery time. Such a model could greatly contribute to successful and safe implementation of the acquired skills in clinical practice.

1.2. Personal experience and motivation in conducting the present studies

The author of this thesis has some personal experience regarding both preclinical and clinical laparoscopic skill development related to pediatric surgery. As for Hungary, a free-of-charge, compulsory preclinical surgical skill training programme is integrated into the first year of the curriculum in which laparoscopy has a dedicated role. The remaining laparoscopic skill acquisition greatly depends on personal attitude and diligence. The author has also had a chance to access the previous preclinical training centre (Institute of Surgical Research, University of Szeged, Hungary), where he always found an open door for individual training sessions. Later, an international congress of the European Pediatric Surgeons' Association was organized by his pediatric surgery division in Szeged, where he met Professor Correia-Pinto (one of his later supervisors). This was followed by a one-year clinical training/research fellowship in Braga (Life and Health Research Institute - ICVS Laboratory, University of Minho), Portugal, where he participated in a high-tech laparoscopic laboratory dry lab training and *in vivo* trainings. After successfully completing basic dry lab training programmes, he had the opportunity to contribute to the development and execution of an advanced laparoscopic training model, diamond-shaped anastomosis in a rabbit model. Validation steps in this model for clinical relevance and feasibility based on standard methods of assessment will be discussed in detail later in the thesis. Later, he became a supervisor of laparoscopic training programmes at the unit, where he witnessed steep development in pediatric surgery fellows (from their early steps to their successful completion of the highly complicated task noted above a few weeks later). This thesis will also describe how these residents were involved in the validation process of the novel diamond-shaped anastomosis model.

1.3. The importance of various types of training approaches in laparoscopy: Models of laparoscopic training

Dry lab and virtual reality models

The aim of dry lab trainings during the course of laparoscopic skill development is to help overcome depth perception problems (adaptation to 2D-vision) and to improve hand-eye coordination and bimanual dexterity, as well as to attain sufficient ergonomics and instrument handling. Typically, two- or three-day courses with increasing difficulty of task are organized involving peg transfer, simple dissection exercises, needle transfer and knot tying. Technical tricks can also be practised on remarkably simple portable box trainers, webcam-equipped devices or mobile phone-based simulators, and cheap basic laparoscopic instruments are also widely available.

Inanimate models and virtual reality simulators have also gained considerable popularity. Virtual reality simulators, e.g. Integrated Cognitive Simulator® and LapSim®, include real-time perception and structured teaching scenarios with the advantage that movement coordination analysis is automatically provided based on a computer algorithm. These allow for numeric feedback during simulated surgical scenarios. More recent versions also include haptic feedback [Loveday BPT 2010; Najmaldin A 2007; Patel AE 2019]. Advanced models can rely on 3D printing of the operated tissues by which reality of shape and tissue perception also greatly improve. The models range from cheap handcrafted models to expensive sophisticated dummies that are available to simulate even advanced surgical tasks, e.g. oesophageal atresia, duodenal atresia, pyeloplasty and congenital diaphragmatic hernia [Barsness KA 2015; Maricic MA 2016; Reino-Pires P 2018]. These approaches, however, lack the real surgical circumstances (real anatomy, respiratory movements, bleeding, perioperative injuries, stress factor etc.) that are present during *in vivo* surgeries. Therefore, skills acquisition should be continued using animal tissue first *ex vivo* and then *in vivo*.

"Wet lab" and "vet lab" training models

Training sessions involving the use of animal organs *ex vivo* ("wet lab") or surgical procedures on anaesthetized animals ("vet lab") provide more realistic circumstances and simulate human surgical procedures remarkably better. Although numerous authors have described the superiority of *in vivo* animal models over dry or wet lab approaches, animal surgeries are greatly limited in many countries out of ethical considerations. Among the animals used for surgical training, lapine and porcine models appear to be the most popular, although rat, dog and sheep models have also been described among potential solutions (Table 1). For simulation of pediatric surgical procedures, the rabbit probably seems to be the best model animal due to similarity to newborns in anatomy and size, financial considerations and veterinary viewpoints, although the mortality rate is significantly higher than those of porcine models (see References in Table 1). Results of a systematic search on PubMed with keywords “pediatric minimally invasive surgery training” are summarized in Table 1.

Table 1. Summary of pediatric surgery animal models of minimally invasive surgery (laparoscopy/thoracoscopy/cystoscopy)

Species	References	Animal numbers	Type of surgery (number of animals used)			Mortality	Similar anatomy	Advantages	Disadvantages
			Abdominal surgery	Thoracic surgery	Urology				
Rabbit	Luks FI 1995 Till H 2001 Kirlum H-J 2005 Kirlum H-J 2005 Heinrich M 2006 Usón-C J 2014 Valdivieso J 2003 Marecos M 2006 Simforoosh N 2011 Jones V 2008 Esposito C 2016 Glenn I 2016	115	Fundoplication (N=11, N=11, N=5), splenectomy (N=8, N=11), pyloromyotomy (N=5), gastrostomy (N=5), gut biopsy (N=5, N=6), cholecystectomy (N=11), inguinal hernia (N=11, N=5), appendectomy (N=11)	Tracheoesophageal fistula (N=7, N=7), diaphragmatic hernia (N=25), decortication (N=20), lung biopsy (N=5)	Nephrectomy (N=8, N=11, N=11, N=18, N=5), spermatic vessel ligation (N=11, N=5), nephropexy (N=18), orchidopexy (N=11)	12	10	Cheap, reproducible	Disturbances related to pneumoperitoneum
Pig	Lima M 1997 Krauss A 2009 Bidarkar S 2012 Naryanan S 2014 Jones V 2008 Esposito C 2016 Bin F 2007	107	Fundoplication (N=10, N=12, N=31, N=5), pyloromyotomy (N=31), adrenalectomy (N=31, N=36), cholecystoduodenostomy (N=36), laparoscopic pull-through (N=36), distal pancreatectomy (N=36), inguinal hernia (N=5)	Oesophageal atresia (N=31, N=3, N=1), diaphragmatic hernia (N=31, N=36), lung biopsy (N=31, N=36), lobectomy (N=36)	Pyeloplasty (N=31, N=16), ureter reimplantation (N=36), spermatic vessel ligation (N=5), nephrectomy (N=5)	1	3	Larger intercostal space, suitable for subureteric Teflon injection procedure	Higher cost, stomach too big
Dog	Simforoosh N 2011	54			Nephrectomy (N=54), nephropexy (N=54)	0	1	n/a	n/a
Rat	Kellnar S 1997 Fenandez-P I 2007	15	Splenectomy (N=8)	Tracheoesophageal fistula (N=15)	Nephrectomy (N=8)	1	1	n/a	n/a
Sheep	González-L M 2017	8		Cardiac anomalies (N=8)		0		n/a	n/a

1.4. Measures of efficacy for different training methods

Measures of efficacy for dry lab trainings

Defining milestones or threshold criteria during basic laparoscopic training sessions is particularly important because repetition of basic tasks is indispensable, but real skill development can only be achieved by continuously increasing the difficulty level of tasks within a well-tailored curriculum. Quantification methods (e.g. the well-known McGill Inanimate System for Training and Evaluation of Laparoscopic Skills, or MISTELS, score) is also based on assessment of skill development with increasing difficulty. The original approach comprises completion of five tasks (peg transfer, pattern cutting, endoloop, and extra- and intracorporeal knots). This assessment is based on (1) successful completion of the task within a given time frame and (2) rewarding faster accomplishment with proportionately higher scores (as assessed by two trained observers). Other possible assessment tools for basic introductory laparoscopic exercises include the Organized Structured Assessment of Technical - Global Rating Scale (OSATS-GRS) [Martin JA 1997) applied to specific tasks as well as three modifications of OSATS-GRS which are also available, such as the "Laparoscopy Checklist by Moorthy" [Bilgic E 2018] and the "Van Sickle Laparoscopy Error Rating" [Bilgic E 2018]. All of these assessment methods define a threshold (typically % of scores) by which the trainee can move forward to a more advanced task. Virtual reality trainers (such as the Laparoscopic Suturing Competency Assessment Tool (LS-CAT®) or LapSim®) provide sophisticated analysis of bimanual coordination (based on computed algorithms of instrument positions). These latter approaches provide objective measures of performance, whereas the previous approaches have the advantage of the evaluation being performed by senior surgeons examining the performance in a more holistic way. After reaching a previously defined threshold, further improvement can be achieved using animal tissues *ex vivo* (wet lab training) or on anaesthetized animals (vet lab training).

Measures of efficacy for "wet lab" and "vet lab" trainings

More complex tasks related to "wet lab" and "vet lab" training typically necessitate scoring approaches based on simultaneous consideration of numerous parameters. The efficacy of the training sessions can be judged on the basis of both quantitative and semiquantitative measures. These can focus on (a) duration of the intervention, (b) success of the surgery, (c–d) occurrence of a number of intraoperative complications and their management or (e) technical skills and bimanual dexterity of the surgeon. (f) Another important aspect is the self-evaluation of the participants' own performance using standardized criteria. Various assessment tools have been tested for this purpose of being all based on an expert observer's opinion, such as the Global Operative Assessment of Laparoscopic Skills (GOALS) score [Vassiliou M 2005] or checklists [Bilgic E 2018] and the Visual Analogue Scale (VAS) [Bilgic E 2018]. Movement analysis may also be a feasible method to evaluate intraoperative performance which can be implemented during live surgeries as well (e.g. the KINOVEA software which was originally used for motion analysis in sport education; https://www.kinovea.org/ and the Robotics Video & Motion Assessment Software; ROVIMAS which can also be used during human surgeries performed with the da Vinci system) [Dosis A 2005].

It is well-recognized that acquisition of proper technical skill should be based on a sequence of repetitive exercises, but it has also been demonstrated that a surgeon's performance cannot be improved significantly after reaching this benchmark by further repeating the same tasks, even with complex laparoscopic interventions. This means (at the discussed level of laparoscopic skill development) that after achieving this threshold, further advancement is possible by conducting the same surgeries under human circumstances. In the case of laparoscopic pyeloplasty, Fu et al. clearly described this benchmark after performing this type of surgery five times on a porcine model [Fu B 2006].

Based on these considerations, we aim to define criteria for a novel standardized rabbit model of duodenal atresia (diamond-shaped anastomosis as described by Kimura) which could enable training participants to perform the same surgical pediatric intervention in clinical practice. According to our hypothesis, the model is appropriate and sufficiently complex to evaluate advancement and compare development of the technical skills of the trainee groups with different levels of expertise using learning curve-based assessment methods. Furthermore, we hypothesized that a minimal repetition number of diamond-shaped anastomosis surgeries can be defined in this animal model by which threshold values for clinical transferability to complex operations can be recommended.

Measures of efficacy for laparoscopic interventions in clinical settings

The success of the laparoscopic surgical intervention and low peri- and postoperative complication rate(s) are the most evident and clinically most relevant measures of success when human (and in particular pediatric) surgeries are concerned. Here, similarly to vet lab trainings, the most frequently used assessment tools for laparoscopic performance include VAS, global rating scales and task-specific checklists. A recent review summarizing the applicability of the available clinical assessment methods [Bilgic E 2018] shows that (among the generally used tools) the GOALS score and its specific modifications (e.g. the GOALS groin hernia score) have been proven the most feasible methods in both simulation settings and human operating theatres [Bilgic E 2018]. If a new method is established at surgical institutes, efficacy and safety are the most important factors to be considered. For this reason, in the present clinical studies (where the PIRS and the 3-port hernia surgery methods were introduced at pediatric units), changes in surgery time as well as success and complication rates over relatively short initiation periods were assessed.

2. MAIN GOALS OF THE STUDIES

- Since treating duodenal atresia is a highly demanding task in pediatric practice, we aimed to establish a clinically relevant *in vivo* rabbit model of duodenal atresia (involving diamond-shaped anastomosis) by which the technical skill of laparoscopic anastomosis suturing can be acquired in preclinical settings. The feasibility of this model was tested by means of sophisticated quantification methods.
- Since repetitive training is a crucial step during the learning process of any laparoscopic intervention, we tested how a standardized dry lab training session influences future skill development using the rabbit ("vet lab") model of duodenal atresia noted above as a test operation.
- Using this experience with learning curves of vet lab laparoscopic duodenal atresia surgery, we also wished to define criteria enabling trainees to perform the same laparoscopic intervention in clinical settings. To this end, we analysed objective and semiquantitative indices of improvement in skill development related to this rather demanding laparoscopic diamond-shaped anastomosis model.
- Since knowledge of the minimum number of operations enabling pediatric surgeons to perform successful interventions is crucial in clinical settings, we aimed to assess the characteristics of the learning process of two inguinal hernia operations (the PIRS and 3-port inguinal hernia techniques) during their introduction in clinical pediatric surgery units.

3. MATERIALS AND METHODS

The present thesis includes an analysis of the learning process in a "vet lab" laparoscopic training programme involving a duodenal atresia model in rabbits (Study 1) and two clinical studies on inguinal hernia (PIRS, Study 2, and the 3-port technique, Study 3).

3.1. Methods for the rabbit model of duodenal atresia (Study 1)

3.1.1. Participants of the preclinical (vet lab) training model of duodenal atresia

The present study was conducted between September 2016 and September 2017 at the Endoscopic Research and Training Laboratory of the Surgical Sciences of the Life and Health Sciences Research Institute in Braga, Portugal. A total of 15 laparoscopic trainees were recruited and allotted into one or the other of two groups. (1) A beginner group (n=8) consisted of medical doctors soon after graduation without any previous laparoscopic experience. This group underwent at least twelve hours of laparoscopic training with the same supervisor based on a modified, previously validated inanimate assessment method known as the McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) [Vassiliou M 2006]. An advanced group (n=7) comprised pediatric surgery fellows with previous laparoscopic experience of at least 25 human cases (e.g. appendectomy, varicocelectomy or herniorrhaphy). These participants had not received any standardized, structured, minimally invasive laparoscopy surgery training at this institute.

3.1.2. Set-up of the test operation

Participants in both groups were invited to perform eight laparoscopic, diamond-shaped bowel anastomosis surgeries using the same surgical technique and steps on anaesthetized rabbits (see below). The scheduling of the operations was not pre-determined (it was dependent on participant preferences) with a maximum of two operations per day. The interval between the first and last operations ranged between four and 150 days. All test operations were supervised by two instructors, who had already performed at least 15 surgeries using the same model. Continuous guidance was provided based on drawn schemes and video tutorials of the procedure (Figures 3–4).

3.1.3. Equipment

Karl Storz laparoscopic equipment was used during all of the surgeries. Insufflation was performed with CO_2 using 6 mmHg pressure and 1.5 L/min gas flow. Surgical instruments included 5-mm telescope 30º and 3-mm instruments (Maryland dissector, bowel grasper, needle holder, anatomical forceps and scissors). 2/0 Prolene thread (Ethicon, Inc., Somerville, NJ, USA) was used for bowel suspension, and 5/0 Prolene (Ethicon, Inc., Somerville, NJ, USA) was used for continuous suture of the anastomoses. Port placement followed the standard method.

Figure 3. Laparoscopic set-up for training

3.1.4. Animal model

Ethical approval for this study was obtained from the Portuguese General Directorate for Food and Veterinary Affairs (Direção Geral de Alimentação e Veterinária-DGAV 0421/000/000/2017) and the University of Minho Ethics Committee (SECVS 004/2016). *Oryctolagus cuniculus* rabbits weighing 2000–2500g were used. Anaesthesia was achieved using ketamine (35 mg/kg; Ketamidor, Richter Pharma AG, Austria*)*, medetomidine (0.5 mg/kg; Sededorm, VetPharma Animal Health, Spain) and buprenorphine (0.03 mg/kg; Bupaq, Richter Pharma AG, Austria) administered through the ear vein. Every animal underwent a tracheostomy and was ventilated. Animals were sacrificed using pentobarbital (200 mg/kg; Euthasol, Le Vet Beheer B.V., Netherlands) after surgery. In compliance with the 3R principle, more than one surgical intervention (with a maximum of three) was performed per animal.

3.1.5. Method of test operation

An optic port was inserted through the umbilical region of the rabbit followed by symmetrical placement of two working ports bilaterally. A jejunal segment was selected and suspended to the abdominal wall (Figure 4B). A proximal transverse enterotomy and a distal longitudinal one were made in the selected bowel segment to simulate the atretic stumps. This method was established based on preliminary studies with less ideal results involving anastomoses between the stomach and small bowel, between the small bowel and the vermiform appendix, and between the gallbladder and the small intestine. Two fixation corner stitches were then placed to unite the proximal and distal stumps according to the method developed by Kimura et al. (Figure 4A) [Kimura K 1977; Van der Zee D 2011]. After suturing the posterior wall with continuous sutures, the anterior site was approximated in the same manner, followed by tying the stitches at the corners (Figures 4B–D).

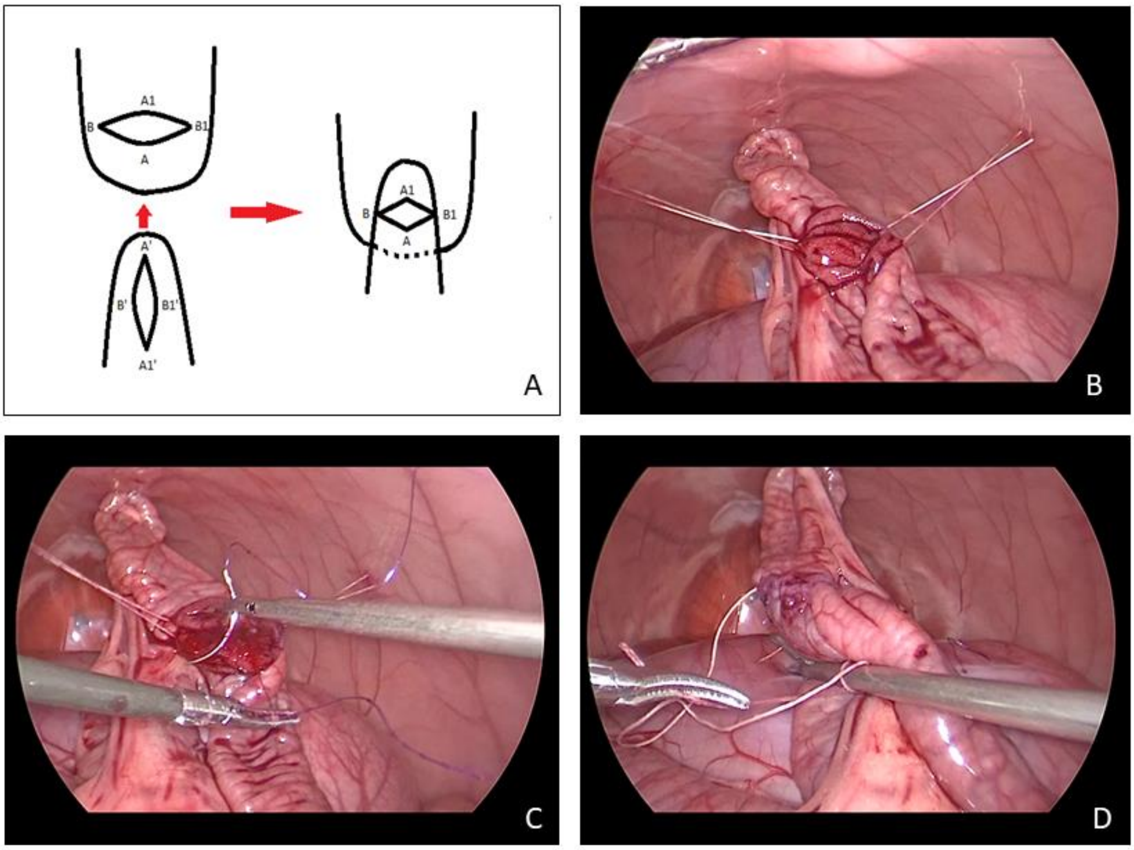

Figure 4. Scheme for diamond-shaped anastomosis (the order of stitches follows reference points A-A’, B-B’, A1-A1’ and B1-B1’, with continuous sutures on the posterior and anterior walls); intraoperative photos: B: after suspending the bowel; C: suturing the posterior wall; D: placing the last stitch after suturing the anterior wall.

3.1.6. Video recording and segmentation

Each video segment of the net anastomosis procedure was saved separately, encoded with randomly generated numbers, shared using secure cloud storage and used for analysis. The duration of the segments was recorded. Each of the eight surgeries per participant was encoded separately. Each segment was assessed by four experts in a randomized, blinded fashion (see later).

3.1.7. Assessments and parameters examined

Four parameters were used after each surgery:

- Surgical time: the time interval between the proximal opening of the bowel segment and the last surgical knot.

- Quality of the anastomosis: luminal passage and macroscopic leakage of the anastomosis were assessed after the animals were sacrificed by pressing the luminal content through the anastomosis.
- Expert evaluation was performed using the modified GOALS score [Carlsen CG 2014]: video recordings were assessed in a blinded fashion by fellow surgeon experts in laparoscopy using the GOALS score developed by Vassiliou et al. [Vassiliou M 2005] based on certain criteria (see Table 2).
- Participants' feedback: a 1–5-scale questionnaire was used for the following parameters: (1) working space, (2) workflow, (3) level of self-confidence and (4) level of self-achievement.

Table 2. Parameters and values of GOALS score used in Study 1

Parameters	**Score**		
	1	**3**	**5**
Depth perception	Constantly overshoots target, wide swings, slow to correct	Some overshooting or missing of target, but quick to correct	Accurately directs instruments in the correct plane to target
Bimanual dexterity	Uses only one hand, ignores non-dominant hand, poor coordination between hands	Uses both hands, but does not optimize interaction between hands	Expertly uses both hands in a complimentary manner to provide optimal exposure
Efficiency	Uncertain, inefficient efforts; many tentative movements; constantly changing focus or persisting without progress	Slow, but planned movements are reasonably organized	Confident, efficient and safe conduct, maintains focus on task until it is better performed by way of an alternative approach
Tissue handling	Rough movements, tears tissue, injures adjacent structures, poor grasper control, grasper frequently slips	Handles tissues reasonably well, minor trauma to adjacent tissue (i.e. occasional unnecessary bleeding or slipping of the grasper)	Handles tissues well, applies appropriate traction, negligible injury to adjacent structures
Overall competency (Autonomy)	Unable to complete entire task, inefficient effort	Able to complete task safety even if the task is slightly challenging	Able to complete task in spite of challenging case, and can resolve complications (bleeding, leakage)

3.2. Methods for the clinical study on PIRS (Study 2)

3.2.1. Participants (groups) and patient selection in the clinical study on PIRS (Study 2)

This retrospective study was approved by the local scientific ethics committee of the University of Minho (reference number: SECVS 133/2014). All staff members involved in the programme were consultants with basic training as pediatric surgeons with different skill levels in laparoscopic surgery. All children referred for surgical repair of indirect inguinal hernia (at any age) or communicating hydrocele (over two years old) were included between June 2011 and November 2016 at the Department of Pediatric Surgery, Braga Hospital. Patients with hernias other than indirect inguinal hernia were excluded. Demographic data and clinical details were gathered, including gender, age, diagnosis (hernia vs. communicating hydrocele), pre- vs. perioperative laterality match, identification of silent patent processus vaginalis, conversion to open repair, ipsilateral recurrence and metachronous contralateral hernia, perioperative complications reported by the surgical team, such as puncture of femoral vessels (Figure 5A), and postoperative complications that caused early return to the hospital, such as haematoma, wound infection or foreign body reactions (Figure 5B).

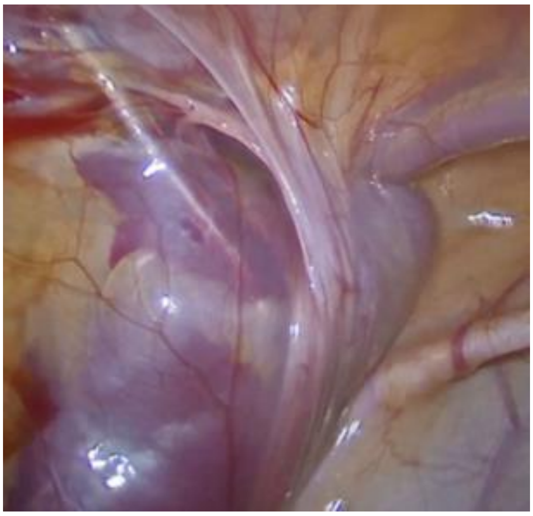

Figure 5A. A perioperative complication: puncture of the femoral vein. The procedure was interrupted and the bleeding controlled with external compression.

Figure 5B. Inguinal foreign body reaction, a postoperative complication emerging four weeks after surgery.

3.2.2. Operative technique for PIRS

Karl Storz laparoscopic equipment was used during all of the surgeries. Insufflation was performed with CO_2 using 6 mmHg pressure and 1.5 L/min gas flow. Surgical instruments included 5-mm telescope 30º and a 3-mm Maryland dissector.

PIRS was performed by ligating the processus vaginalis as described by Patkowsky et al. [Patkowski D 2006] under general anaesthesia (laryngeal mask) with the patient lying in a supine position. The surgeon stood at the right side of the patient regardless of the affected side, and the monitor was placed at the bottom of the table. First, a single transumbilical incision was made for a 5-mm trocar (30° optics). In males, a 3-mm dissection grasper was introduced (above the trocar for the optics) through a stab incision through the linea alba to aid in mobilizing the peritoneum. Insufflation pressure was between 6 and 10 mmHg depending on the age of the patient. The peritoneal cavity was inspected to confirm the diagnosis. If there was a contralateral patent processus vaginalis or a different type of hernia, it was repaired during the same intervention. Either a 16G Abbocath needle or an 18G hypodermic needle (depending on surgeon preference), armed with a loop of Prolene® 2-0 thread (Ethicon, Inc., Somerville, NJ, USA), was introduced through the skin at the level of the deep inguinal ring. Under laparoscopic guided vision, the needle was passed extraperitoneally between the peritoneum and the vas deferens and testicular vessels, leaving no peritoneal gaps, along half of the internal inguinal ring. Then the needle punched the peritoneum and entered the peritoneal cavity to push the thread through the barrel of the needle into the peritoneal cavity, forming an intraperitoneal loop. The needle was pulled out of the abdominal cavity leaving the Prolene® (Ethicon, Inc., Somerville, NJ, USA) loop inside. The needle was introduced again, through the previous skin puncture point, this time armed with an Ethibond® 2-0 thread (Ethicon, Inc., Somerville, NJ, USA), which dissected the peritoneum of the other half of the ring, and passed through the peritoneal opening created before. The Ethibond® (Ethicon, Inc., Somerville, NJ, USA) was pushed inside the Prolene® loop (Ethicon, Inc., Somerville, NJ, USA), and the needle was taken off. From the outside, the Prolene® loop was pulled out of the patient's body taking the Ethibond® (Ethicon, Inc., Somerville, NJ, USA) end with it. Both Ethibond® (Ethicon, Inc., Somerville, NJ, USA) ends exited the skin through the same puncture point, and a perfect Ethibond® (Ethicon, Inc., Somerville, NJ, USA) cerclage was created around the internal inguinal ring, leaving no peritoneal gaps. During the entire procedure, extreme care was taken so as not to damage the vas deferens, testicular, epigastric or femoral vessels. In girls, the round ligament was included in the cerclage. The knot was tied extracorporeally and buried under the skin. Steri-strip® (3M, St. Paul, MN, USA) were used over the skin puncture point at a cartoon fashion. The umbilical access was closed with an absorbable suture and covered with a waterproof dressing. All the patients were discharged on the day of surgery unless there was a clinical contraindication.

3.2.3. Assessments of learning curves for PIRS

Five staff surgeons who adopted PIRS as the technique of choice with a minimum operation number of 35 were selected. During repair of inguinal hernia and communicating hydrocele with the PIRS method, each intervention was considered as a single procedure, independently of being unilateral or bilateral repair. During the analysis, individual operation times were measured and the following rates calculated: (1) perioperative complications (2.3%), (2) postoperative complications (2.6%), (3) ipsilateral recurrence (1.5%) and (4) conversion to open repair (0.9%).

3.3. Methods for the clinical study on the “3-port approach to inguinal hernia” (Study 3)

3.3.1. Participants and patient selection in the clinical study on the “3-port approach to inguinal hernia” (Study 3)

In our retrospective study, we included patients operated on with the laparoscopic 3-port technique at the Pediatric Surgery Unit, Department of Pediatrics, University of Szeged, between November 2015 and July 2020 (ethical licence number: 87/2017-SZTE). Only children undergoing indirect inguinal hernia or communicating hydrocele operations were included in the analysis. A total of 112 patients were operated on by eight surgeons at our unit, but since only three of them had performed a large number of interventions, the results for surgery time for these three colleagues were included in the analysis. Since the minimum number of operations was 17 among them, learning curves for these surgeons were analysed during this preliminary period. During the study period, both open and laparoscopic techniques for inguinal hernia surgeries were available at our department; the decision on the type of surgery was made by the parents based on detailed information provided by the surgeon.

3.3.2. Operative technique for the “3-port approach to inguinal hernia”

Laparoscopic equipment: Karl Storz laparoscopic equipment was used during all of the surgeries. Insufflation was performed with CO_2 using 6 mmHg pressure and 1.5 L/min gas flow. Surgical instruments included a 5-mm 30º telescope and 3-mm instruments (Maryland dissector, needle holder and scissors).

The surgeries were performed under general anaesthesia, in the form of a laryngeal mask or intubation anaesthesia with the patient lying in a supine position. The anaesthesiologist used additional epidural or regional anaesthesia with parental consent. At the beginning of the surgery, a 5-millimeter-diameter camera port was inserted periumbilically using the open (Hasson) technique to avoid injury to the abdominal organs. Two additional 3-millimeter-diameter working ports were inserted on both sides between the umbilicus and the inguinal regions. During the examination of the abdominal cavity, the contralateral inner inguinal ring was brought into view, and bilateral intervention was performed on the patent processus vaginalis. As a first step, the peritoneum was incised around the inguinal ring with Metzenbaum scissors (separated from the vas and the vessels in boys and from the ligamentum rotundum in girls) (Figure 6), and then a 3/0 calibre polypropylene thread was introduced into the abdominal cavity. This was followed by a row of stitches circularly enclosing a slit peritoneum in purse string fashion. Patients under the age of one year were hospitalized overnight, whereas others were discharged on the day of surgery unless there was a clinical contraindication.

3.3.3. Assessments of learning curves for the "3-port approach to inguinal hernia"

In the case of the 3-port technique, three staff surgeons with a minimum operation number of 17 were selected. All laparoscopic inguinal hernia and communicating hydrocele procedures were included, with each intervention being considered as a single procedure independently of being unilateral or bilateral repair. During analysis, individual operation times were measured and the following rates calculated: (1) perioperative complications (0%), (2) postoperative complications (0%), (3) ipsilateral recurrence (0.9%%) and (4) conversion to open repair (1.8%).

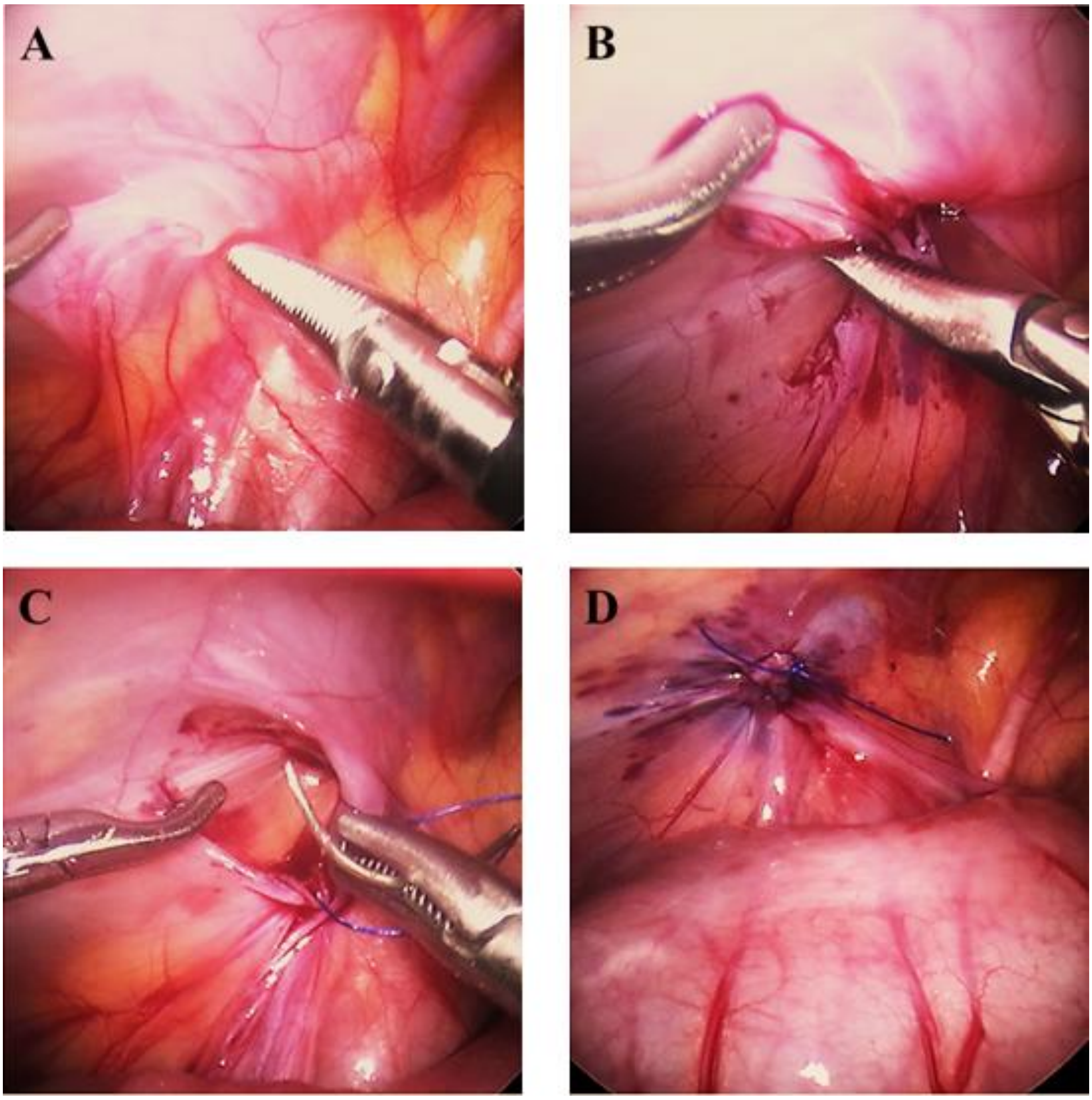

Figure 6. The steps in the 3-port technique

3.4. Statistical analyses

Statistical analyses were performed with Sigmaplot 13.0 (Systat Software, Inc., San José, CA, USA, 2014) software. In Study 1, the two-way ANOVA test was used to assess intra- and intergroup differences followed by the Holm–Sidak test. In Studies 2 and 3, RM-ANOVA was used followed by the Holm–Sidak test to assess operation time-related changes. Data are presented as means ± SEM, $P<0.05$ if not indicated otherwise (see later).

4. RESULTS

4.1. Results of the vet lab (duodenal atresia) study

All of the participants succeeded in completing all eight of the test operations without any major complications; therefore, all of the overall 120 surgical interventions were included in the analysis.

4.1.1. Surgical time

The duration of the first two operations was significantly lower in the advanced than in the beginner group. In the beginner group, the operative time fell from 170.9±11.6 to 107.1±11.4 min (37.4%) versus a drop from 124.9±15.6 to 61.8±5.1 min (a 50.5% decrease) in the advanced group. Nevertheless, a significant difference persisted even during the sixth and eighth operations (Figure 7A). This parameter showed a continuous decrease in both groups, and, as a result of their steep reduction in operation time, the beginner group reaching the values of the advanced group in the middle of the study. In the sixth and eighth operations, the advanced group again performed the task faster.

4.1.2. Anastomosis quality

As evidenced by a relatively rapid reduction in the occurrence of leakage, the overall surgical performance showed a dramatic improvement in both groups (Figure 7B). Specifically, 5/8 of anastomoses showed leakage in the beginner group, and this decreased to zero after the fifth intervention. In the advanced group, the anastomosis leakage rate was smaller (leakage occurred only at 1/7 cases) than in the beginner group as early as from the first to the third surgery; the difference achieved significance at the first two time points of the studies only.

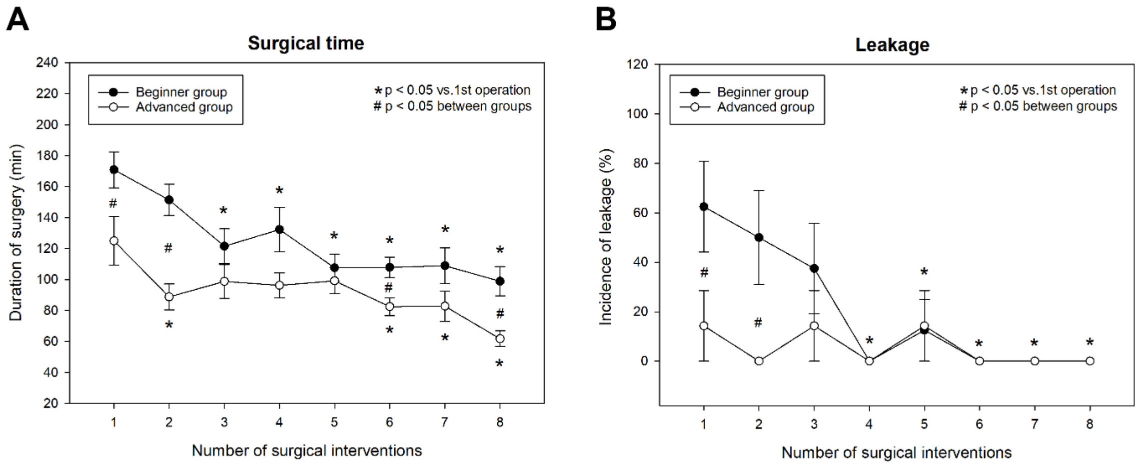

Figure 7. Time course of change in the time of operation (A) and in anastomosis quality (incidence of leakage) (B) in the beginner and advanced groups in Study 1. The two-way ANOVA test was used to assess intra- and intergroup differences followed by the Holm–Sidak test. Data are presented as means ± SEM, *P*<0.05. **P*<0.05 vs. baseline, #*P*<0.05 between groups.

4.1.3. Expert opinion (GOALS)

The GOALS score (which is a generally accepted assessment tool for laparoscopic surgical performance) showed similar initial values in both groups. Values for this score displayed a similar trend of improvement during the course of the learning process, with the values only being significantly different at a few time points (i.e. at the second, seventh and eighth time points) of the study. This score showed significant improvement in the advanced group at each time point. In the beginner group, however, this progress started later (being confined to the second part of the study) (Figure 8A). Since the GOALS score comprises five evaluation criteria, the relative contribution of these elements can also be included in the analysis when the key determinants of the inter-group differences are in focus. Among the components of the GOALS score, dexterity and overall performance showed similar values during the entire study period in both groups. In parallel with the early difference in GOALS score between the study groups (seen at operation 2), marked inter-group differences in depth perception, tissue handling and efficiency score were observed (Figures 8B, D, E). The advanced group also showed better performance (i.e. better GOALS scores) at the last stage of the observations, with a simultaneous difference in depth perception values (Figure 8B).

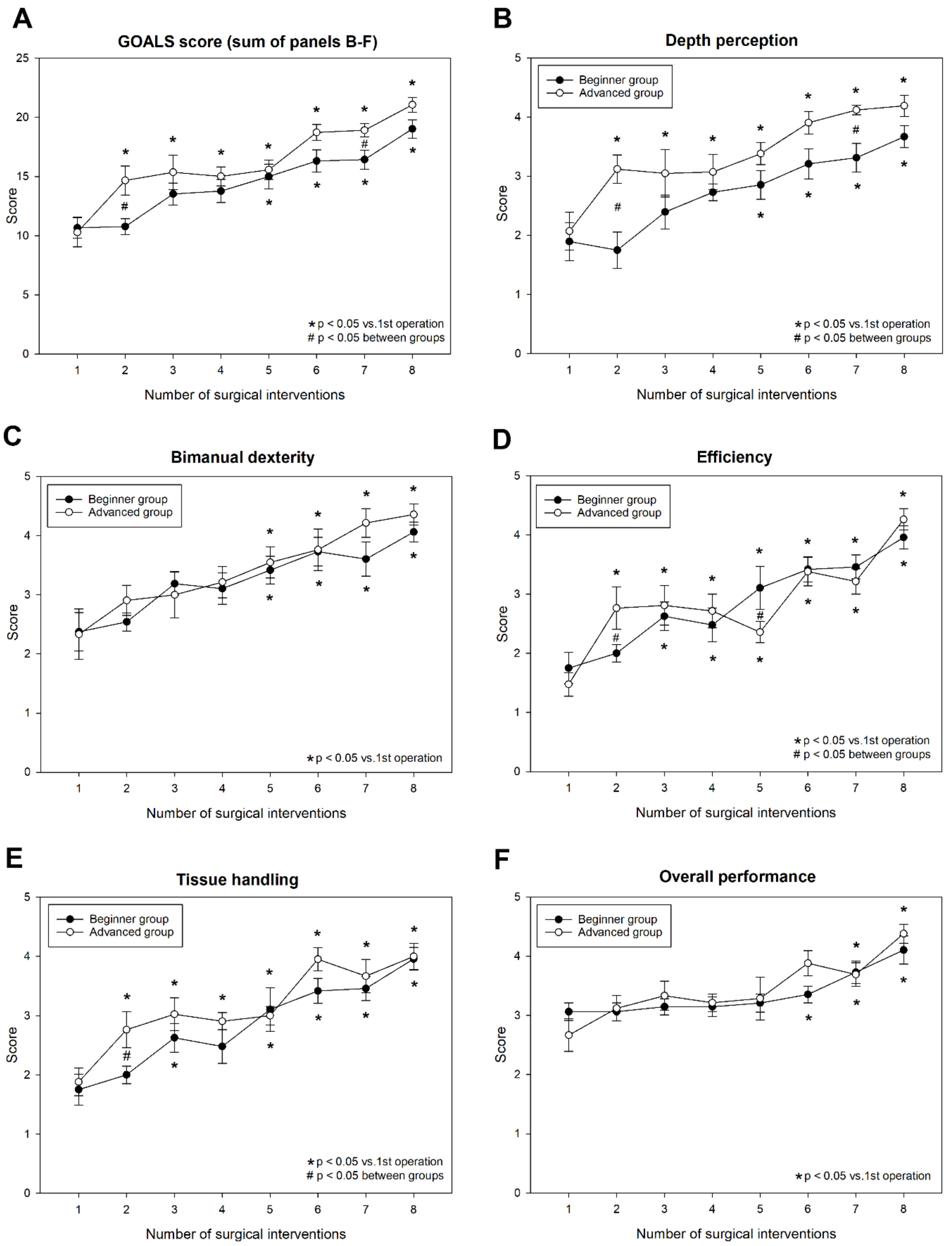

Figure 8. Average GOALS score (A), depth perception score (B), bimanual dexterity score (C), efficiency score (D), tissue handling score (E) and overall performance score in the beginner and advanced groups in Study 1. The two-way ANOVA test was used to assess intra- and intergroup differences followed by the Holm–Sidak test. Data are presented as means ± SEM, **P*<0.05 vs. baseline, #*P*<0.05 between groups.

4.1.4. Participant feedback

Participant feedback forms focused on three self-reflective parameters and a further one based on the available surgical workspace (Figures 9A–D). All of the self-reflective parameters improved over time, and no significant differences were in evidence between the groups. As compared to the baseline, the advanced group expressed earlier satisfaction with its own performance (workflow) (after the third operation), whereas this occurred later in the beginner group (Figure 9B). As for other self-reflective parameters, both self-achievement and self-confidence showed gradual improvements (albeit reaching a similar extent in both groups). Values for satisfaction with the size of the available workspace were only slightly below the maximal score during the entire study period and, similarly, showed no differences between the groups (Figure 9A). The tendency observed in the results of the self-evaluation questionnaire was similar to that of the GOALS assessment, although the linear regression did not show any strong correlation between the two scoring systems (R=0.469, data not shown).

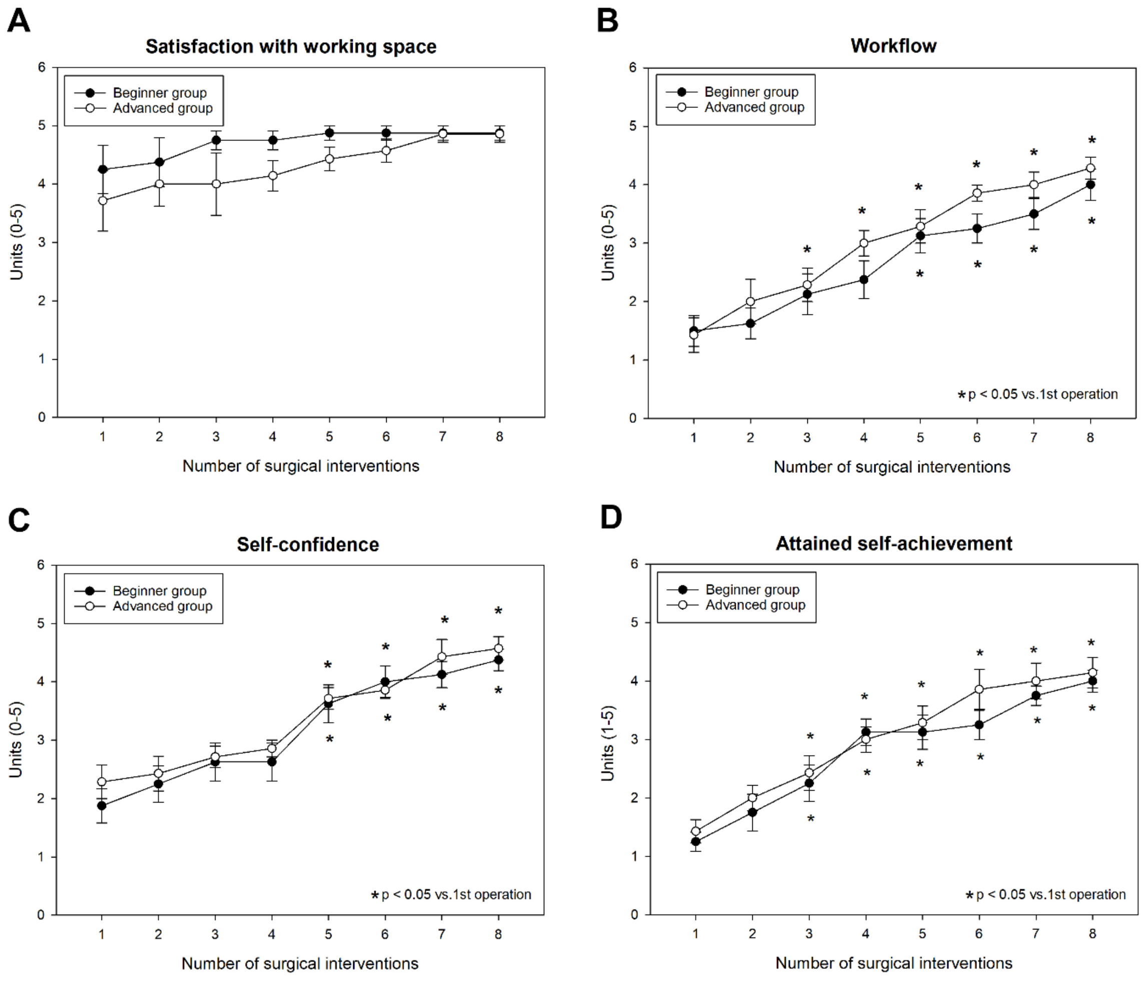

Figure 9. Participants' feedback based on working space (A), workflow (B), self-confidence (C) and self-achievement (D) in Study 1. The two-way ANOVA test was used

to assess intra- and intergroup differences followed by the Holm–Sidak test. Data are presented as means ± SEM, *P<0.05 vs. baseline.

4.2. Demographic characteristics and clinical outcomes in studies involving the PIRS and 3-port techniques

In the PIRS study in Braga, 341 children were operated on, whereas 112 children underwent surgery with the 3-port technique in Szeged (Table 3). Demographic characteristics were similar in both operated populations with respect to age, gender and preoperative diagnosis. The occurrence rate of silent patent processus vaginalis was also similar in both studies. The rate of perioperative complications (e.g. incidence of vessel injury) and unfavourable postoperative events (haematoma, wound infection and foreign body reactions), however, appeared to be higher with the PIRS technique. Nevertheless, ipsilateral recurrence was similarly low with both techniques.

Table 3. Demographic characteristics and clinical outcomes for the PIRS and 3-port techniques (for the entire patient population operated on during the period under examination)

	PIRS (N=341 patients)	**3-port technique (N=112 patients)**
PREOPERATIVE CHARACTERISTICS		
Male gender, No (%)	218 (63%)	58 (52%)
Age in years, mean (min-max)	4.2 (0.27–15.11)	4.7 (0.3–18.0)
Diagnosis, No (%)		
Hernia	311 (91%)	109 (97.3%)
Hydrocele	30 (9%)	3 (2.7%)
Right side	204 (59.8%)	62 (55.3%)
Bilateral	27 (7.9%)	8 (7.1%)
PERIOPERATIVE RESULTS		
Silent patent processus vaginalis, No (%)	58 (17%)	23 (20.5%)
Conversion, No (%)	3 (0.9%)	2 (1.8%)
Perioperative complications, No (%)	8 (2.3%)	0
POSTOPERATIVE OUTCOMES		
Postoperative complications, No (%)	9 (2.6%)	0
Ipsilateral recurrence, No (%)	5 (1.5%)	1 (0.9%)
Metachronous recurrence, No (%)	1 (0.1%)	0

No=number of patients

4.3. Learning curves during clinical introduction of the PIRS techniques (Study 2)

When analysing the first 35 PIRS surgeries in the introductory phase, operation times of uni- and bilateral as well as complicated (eventually converted) cases of inguinal hernia were taken into consideration (Figure 10A–E). Therefore, we attempted to simultaneously depict the values of surgery durations and the frequency of bilateral and complicated cases (marked with hatched bars and in red, respectively) on the same individual learning curves (Figure 10A–E).

Surgery times showed surprisingly high individual variability over time, with bilateral cases usually associated with long durations of surgery. Since we could not detect a statistically significant improvement in individual operation times during the time frame under examination (35 operations), the mean values of individual operation durations were also calculated. As regards the entire study period, mean surgical time (including only unilateral cases) was 38.5 minutes (ranging from 10 to 90 minutes) and did not differ significantly between the five surgeons recruited in this study (Figure 10F).

Rate and time-wise occurrence of intraoperative complications (i.e. bleeding, which required conversion to open surgery) are also important features of PIRS operations; they occurred only in three of the cases and no later than the tenth surgery (see Table 3 and Figure 10B–C).

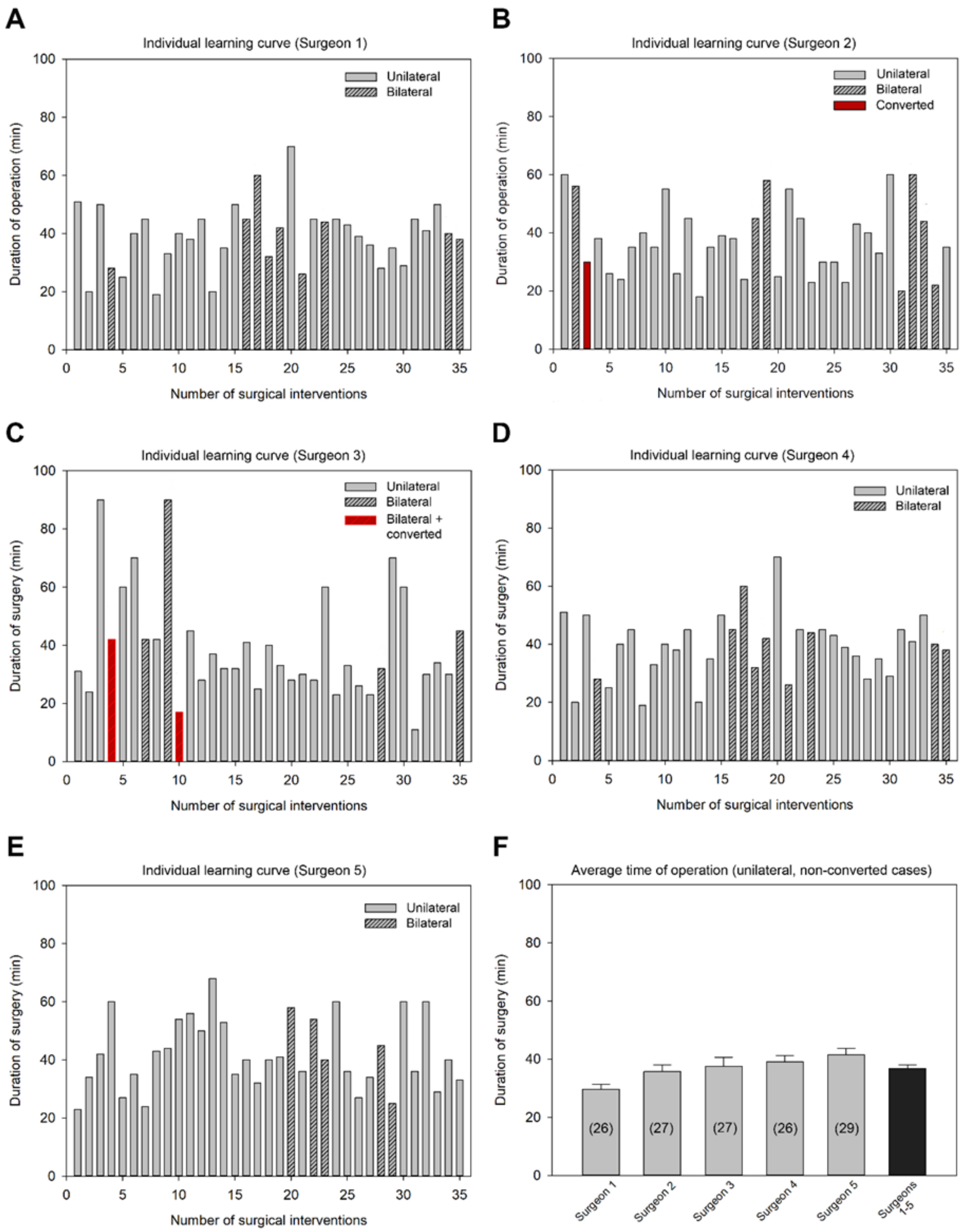

Figure 10. Individual (A–E) and average (F) durations of operation in the first 35 cases of PIRS. Individual data are presented in panels A–E. Cases of bilateral hernia operations are marked with hatched bars; conversion to open surgery is indicated in red. Average operation durations (± SEM) are shown in panel F, including unilateral, non-converted cases only (the number of cases is shown in brackets). Here, the one-way ANOVA test was used followed by the Holm–Sidak test.

4.4. Results of the clinical study on the "3-port approach to inguinal hernia" (Study 3)

Characteristics of the learning curve are presented on the graphs similarly to those of Study 2. Individual operation time did not show significant improvement in this study either and was greatly influenced by the uni-/bilateral nature of the surgical intervention (e.g. bilateral cases usually required longer surgical interventions) (Figure 11A–C). However, we found significantly shorter surgical durations in the case of Surgeon 2 as compared with his colleagues. As regards the entire study period, the average surgical time was 41.3 minutes (ranging from 15 to 115 minutes) with this technique. Conversion to open surgery was associated with longer operation durations (marked in red).

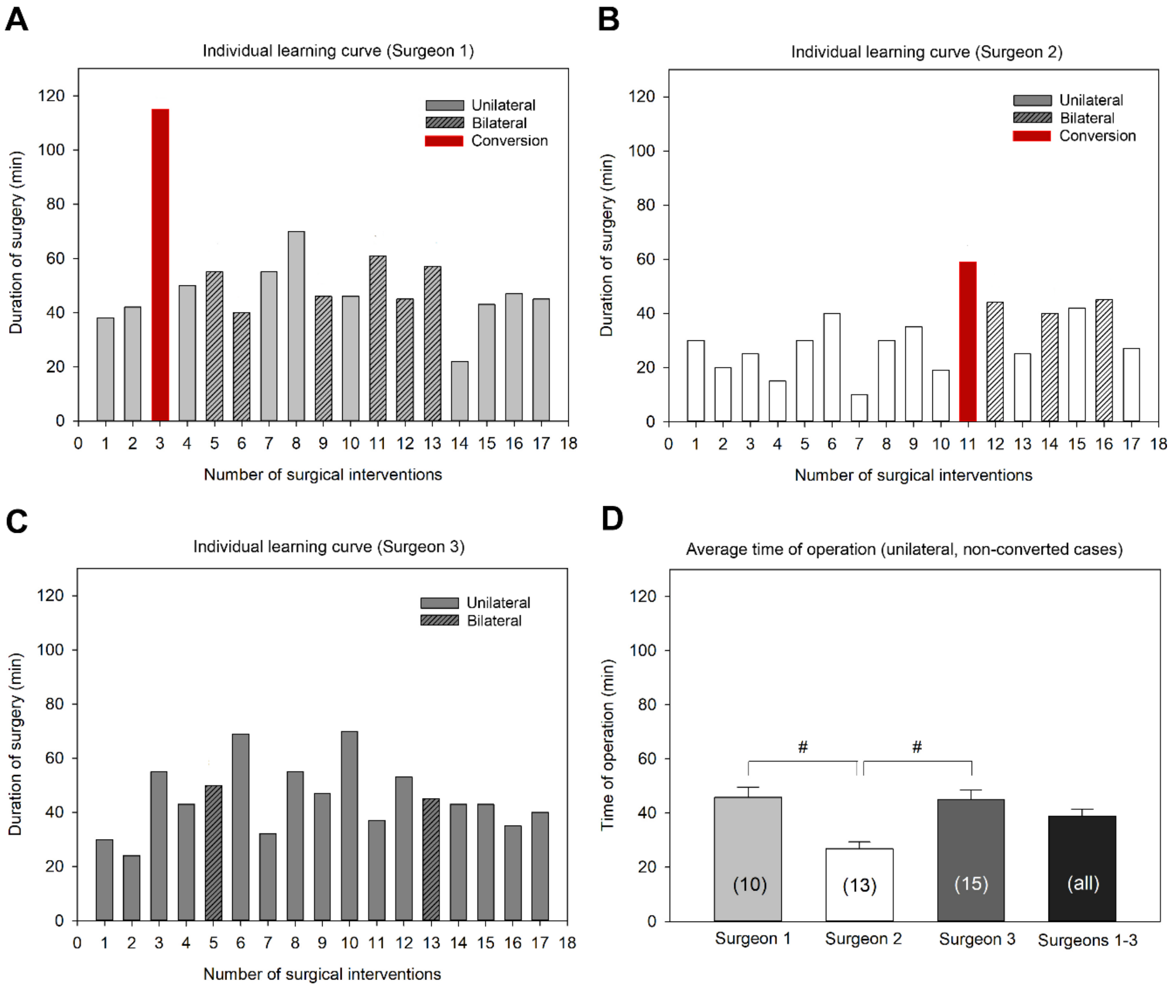

Figure 11. Individual (A–C) and average (D) durations of operation in the first 17 cases of the 3-port hernia approach. Individual data are presented in panels A–C. Cases of bilateral hernia operations are marked as hatched bars; conversion to open surgery is indicated in red. Average operation durations (± SEM) are shown in panel D, including unilateral, non-converted cases only (the number of cases is shown in brackets). Here, the one-way ANOVA test was used followed by the Holm–Sidak test; #*P*<0.05 between groups.

We experienced no intraoperative complication. The laparoscopic technique had to be converted to an open surgical approach twice (due to technical difficulties; marked in red in Figure 11). The mean follow-up was 13.2 months. Hernia recurrence was only observed in one case.

5. DISCUSSION

5.1. Assessment of laparoscopic performance in an animal model of duodenal atresia using multiple modalities

Laparoscopic duodenal atresia repair is still one of the most challenging tasks in pediatric surgery. As a standard surgical solution, diamond-shaped anastomosis was first described by Kimura in 1977 [Kimura K 1990]. A laparoscopic approach was also established by Bax et al. and Rothenberg S [Bax N 2001; Rothenberg S 2002], but it requires advanced laparoscopic abilities, including meticulous dissection and laparoscopic intracorporeal knotting skills [Correia-Pinto J 2014; Mentessidou A 2017; Rothenberg S 2002]. Nowadays, clinical outcome and complication rate are found to be the same for open and minimally invasive approaches, although the latter type is somewhat lengthier [Mentessidou A 2017]. The performance of this relatively demanding surgery, however, greatly improves over a period of nearly a decade at a given surgical unit [van der Zee D 2011]. This observation underlines the importance of repetitive performance of highly challenging interventions, which was also highlighted in guidelines issued by members of the European Society of Pediatric Endoscopic Surgeons, which recommend at least 10–20 hours of dry lab training and a minimum of ten hours of animal model-based training to gain expertise before performing human surgeries [Esposito C 2015]. The superiority of *in vivo* models over *ex vivo* ones was concluded by Kirlum et al. in a rabbit model of an intestinal biopsy showing a slower learning process, but a markedly better final performance in the *in vivo* group [Kirlum HJ 2005]. Repetition of interventions is also indispensable toward improved performance as confirmed by various preclinical and clinical studies (e.g. duodenal atresia and bowel biopsy) [Kirlum 2005; van der Zee DC 2011].

A special dimension of laparoscopic interventions represents another important aspect of pediatric surgery. As shown by Trudeau et al., suturing tasks in pediatric-sized box trainers were more difficult to perform than those in adult-sized trainers (even for experienced colleagues attending a Society of American Gastrointestinal Endoscopic Surgery/International Pediatric Endosurgery Group course) [Trudeau MO 2018]. Therefore, we chose a model relevant in size, space and technical challenges involved in suturing. As regards complex approaches to laparoscopic duodenal atresia repair, only one previous *in vivo* study on rabbits was reported with feasibility tested on the basis of a single surgical intervention [Ordorica-Flores R 2019]. Here, the characteristics of the model were assessed based on an analysis of individual learning curves and a comparison of performance of two trainee groups with the aim of showing a threshold expertise, thus making the same procedure possible in clinical practice. Apart from providing a novel training model, probably another novelty of our present study is that the analysis was based on simultaneous consideration of multiple perspectives. Moreover, as duodenal atresia often occurs in premature infants, the model we use is well-suited to simulate this age group.

Surgery time is one of the most objective and easily accessible indices of performance [Bansal VK 2012; Cserni T 2020; Heinrich M 2006; La Torre M 2012; Ordorica-Flores R 2019], which was found to be similar to those in clinical practice for laparoscopic diamond-shaped anastomosis [Mentessidou A 2017]. Owing to a standardized, structured MISTELS-based training in our study, the beginner group only completed the tasks more slowly than the clinically experienced advanced group in the first few test operations. However, probably the most important and clinically most relevant measure of technical achievement is the success of the intervention [Kimura K 1977; Mentessidou A 2017] (here, anastomosis quality refers to the passage and water tightness of an anastomosis). This is a binary parameter specific to the actual model. The fact that this desired outcome was reached relatively early in both groups shows (1) the efficacy of the dry lab laparoscopic training of the beginner group and (2) the feasibility of the present *in vivo* rabbit model.

In addition to the parameters noted above, we also used other methods, thus enjoying the advantage of including several aspects of surgical performance when challenging laparoscopic tasks are evaluated. Validated tools were used for the open surgical interventions (e.g. the OSATS) [Bilgic E 2018]; however, this is usually less applicable in minimally invasive interventions. For dry lab laparoscopic trainings, MISTELS and Laparoscopic Suturing Competency Assessment Tool scores are probably more adequate tools [Ijgosse WM 2020; Vassiliou MC 2006], while the GOALS score appears to be an appropriate approach for both basic and complex interventions [Wolf R 2018]. It enables assessors not only to classify surgeons based on their technical performance (detailed in the Methods section) [Bansal V 2012; Bilgic E 2018; Dawe SR 2014; Wolf R 2017], but also to compare advancement in different training groups [Bansal V 2014; La Torre M 2013]. We observed significant improvement in both groups as regards the GOALS score, but a statistically significant difference between the study groups was only observed at a few time points in the learning curve (and appeared only in terms of a few domains of the

GOALS score, e.g. depth perception, tissue handling and efficiency). This underlines the efficacy of standardized laboratory (e.g. MISTELS) training, enabling beginners to show similar results to those of more experienced colleagues during the test operation. Bansal et al. also used operation time and anastomosis quality to compare the performance of beginner and trained residents after a laparoscopic training using five test operations in an *ex vivo* model of gastrojejunostomy. In their model, gradual improvements were found in all parameters, with a minor and gradually vanishing initial difference between the two groups over time [Bansal V 2012].

When the transferability of lab training findings to clinical situations is considered, the GOALS score may also represent a good tool to assess the efficacy of laparoscopy trainings [Bansal V 2014; Dawe S 2014; Wolf R 2018]. In another study by Bansal et al., a five-day (wet lab) laparoscopic training programme for cholecystectomy resulted in marked differences in clinical performance of the same operation [Bansal V 2014]. During their human "test operation" on a single occasion, the GOALS score (and each domain of the GOALS score) appeared to be significantly higher (together with other indices of improvement examined, i.e. surgery time and complication rate) in the trained group. In our study, international participants were recruited; therefore, a clinical "test operation" could not be conducted to assess the transferability of our findings, but this could be a highly important aspect of future studies.

Interestingly, certain trials found no significant improvement in participant performance at a certain stage after repeatedly conducting the same type of laparoscopic procedure. The same was demonstrated by Fu B et al. with an *in vivo* pyeloplasty in a porcine model [Fu B 2007], where a stationary phase was reached in the learning process after the fifth operation. However, surgery duration showed further improvement in our study, while leakage rate and GOALS score values indicated a lower degree of improvement between the fifth and eight surgeries. This suggests that a minimum number of laboratory surgeries is definitely needed (which also happen to be five) in the present diamond-shaped anastomosis model, but any further skill development should most probably be monitored under clinical conditions. Our findings are also supported by results from participant feedback forms which are regarded as important tools to gain insights into personal or self-assessment [Gause CD 2016; La Torre M 2012; Ordorica-Flores R 2019]. The feedback questionnaire used in our study showed that both groups found the task similarly challenging at different stages of the study, with the values gradually increasing in parallel with the improvement in technical skills (as indicated by the GOALS score). Self-reflective parameters (particularly workflow and self-confidence) also showed significant improvement as of the fifth surgery (as compared to the baseline).

Our study has certain limitations, however. First of all, this model only focuses on the technical aspects of laparoscopic duodenal atresia surgery, and dissection of the atresia sites, for instance, was not included in the protocol. This issue could be important because misconducted distal pouch (e.g. in the case of type C atresia) could represent a source of severe complications. Another limitation is the lack of long-term follow-up and monitoring of surgical outcomes; this could have been overcome by establishing a surviving model. Furthermore, study participants in the advanced group were not selected and tested by standard criteria, whereas initial (dry lab) performance was only assessed in the beginner group.

In summary, our observations suggest that standardizing repetitive preclinical laparoscopic training tasks and using an *in vivo* model specifically designed for pediatric surgical challenges represent useful learning tools for pediatric residents. In our first study, the performance of participants undergoing standardized laparoscopic skill training reached the levels of experienced, but non-uniformly trained residents during repetitive *in vivo* practice. We conclude that the diamond-shaped anastomosis model used on rabbits is particularly suited to simulating similar surgical interventions on humans. The same model or similarly complex methods may also be used for examination purposes before pediatric laparoscopic interventions. In our present study, sufficient anastomosis quality was achieved after the fifth surgery in this model with no further substantial improvements in objective skill assessments. Based on the minor further improvements after the fifth diamond-shaped anastomosis surgery in this animal setting, we assume that this number of interventions of this relatively difficult operation is sufficient for laboratory trainings, presumably enabling residents to participate even in complex surgeries (such as duodenal atresia) in clinical practice. Translation of the present results and further improvements in performance should probably be tested under clinical conditions where the importance of further skills (non-technical skills, e.g. decision-making expertise, stress-related factors and teamwork) can also be taken into consideration.

5.2. Assessment of performance during laparoscopic hernia operations in children

In our clinical studies of minimally invasive inguinal hernia repair, surgery time and intraoperative complication (including conversion) rate were chosen to assess among the clinically most relevant parameters. Similarly to other types of laparoscopic interventions, these parameters of hernia surgeries are not expected to be significantly different from those of the open approach and based on the literature data, superiority of neither the open nor the laparoscopic approach can be stated (if all of the clinical aspects are considered). Therefore, benefits of laparoscopic and open hernia surgeries should be considered simultaneously, and decisions should be made on an individual basis (including adequate indication and appropriate patient selection), also taking the surgeon's concerns into account [Dreuning K 2019].

In both of our laparoscopic hernia repair studies, surgery time approximated the values of open procedures [Dreuning K 2019], but the continuous improvement in surgical times shown by others in parallel with the increase in the number of surgical interventions [Montupet P 1999] was not observed with either of the procedures here (irrespectively of the number of repetitions). Probably a longer follow-up period would be required to identify such a phenomenon. It appears that open inguinal surgeries associated with various aspects of surgical challenges (patient age and possible obesity, as well as hernia hose quality and scarring to surrounding formulas) can cause great variance in surgical time, while laparoscopic interventions involve the use of similar technical steps and show more uniform anatomical conditions. It is also noteworthy that the inevitably more time-consuming bilateral analysis interventions have also been included in the analysis.

The intraoperative complication rate is also definitely related to the technical skill level of the surgeon during the learning process. In the case of PIRS, injury to the epigastric artery or femoral vein is the most common surgical complication. According to a large study [Patkowski D 2006], the vascular injury rate with PIRS varies between 2.3 and 3.6%, while it is very low (typically zero) with the 3-port technique [Becmeur F 2004]. The present PIRS approach is a slight modification of the original one as it is performed completely extraperitoneally, and, since it leaves no gap above the funiculus, the recurrence rate is also expected to be low. In line with this reasoning, the surgical team agreed to perform this somewhat more challenging modified technique so as to lower the potential recurrence rate when PIRS surgeries were initiated. In our study, the number of complications during PIRS surgeries showed a decreasing trend during the learning process, as no surgical conversion or surgical injury occurred after the 35th surgery. As for the 3-port technique, the reason for more efficient prevention of vascular and ductal injuries is probably the lifting of the peritoneum, which is routinely done with this approach. It should be mentioned that PIRS surgeries also have advantages, which lie in their lower degree of invasiveness and better cosmesis as well as usually requiring shorter mean surgical time. Certainly, a direct comparison of these procedures is difficult because the length of surgery is influenced decisively by the child's gender and age and whether the hernia is bilateral. In addition, further future improvement in surgery time after the introduction phase can be expected with both approaches according to other studies [Montupet P 1999]. This assumption may also be supported by a previous paper involving the 3-port technique, whereas the surgical times were reported to be similar to ours (the average surgical time for boys was 28 minutes for unilateral hernia and 23 minutes for girls, and the average was 40 minutes for boys and 30 minutes for girls for bilateral surgeries) [Becmeur F 2004]. As mentioned above, somewhat lower surgery durations (the mean surgical time was 19.36 minutes for unilateral cases and 24 minutes for bilateral cases) were found elsewhere with the PIRS technique [Patkowski D 2006].

It appears that adequate indication and appropriate patient selection greatly influence both surgery time and the intraoperative complication rate, particularly at the beginning of the learning process. As regards surgical indication, we intended to conduct an appropriate patient selection in both studies, simultaneously also taking parental needs into account. It should be noted, however, that older children and primarily girls were recruited at the beginning of the learning process in both studies. In the case of the PIRS study, the proportion of operated boys reached the expected gender ratio (which is known from open surgery data) in the last third of the study period. With the 3-port technique, one of the surgical conversions at the beginning of the learning curve was most probably also attributable to the young age of the operated infant and therefore represented a mismatch between the actual surgical skill of the surgeon and the challenge of the anatomical size. With the same type of operation, later operations were successfully conducted without any major intraoperative complications irrespectively of the young age of the infants.

Intraoperative diagnosis of silent contralateral hernias is an important non-technical skill during laparoscopic hernia operations, and one of the most prominent advantages of the laparoscopic surgeries also lies in the potential to detect contralateral patent processus vaginalis intraoperatively. According to the literature on open surgeries, asymptomatic contralateral hernias are mostly explored in infant girls, and the overall incidence of asymptomatic hernias was found to be 6–7.3% [Kokorowski PJ 2014; Wenk K 2015]. During laparoscopy, a routine search is always performed to detect open contralateral inguinal ring, and its incidence is reported to be approximately 30% [Kokorowski P 2014]; however, this was somewhat lower in our studies (~17% with PIRS and ~23% with the 3-port study). Asymptomatic hernias were automatically resolved in both of our studies, although approximately 4% of cases were shown to develop symptoms according to the international literature (and therefore their closure is not necessarily recommended routinely at the same spot) [Chong A 2019; Davies D 2020; Dutta S 2009]. Furthermore, the 0% postoperative recurrence rate of operated silent hernias observed in our studies seems to confirm this decision. Since this is technically easier to perform than the originally operated (manifest hernia) site, we believe that closure of the contralateral open inguinal rings may also provide an optimal opportunity for less trained pediatric surgeons to master the steps in the surgery during PIRS operations (by becoming a performing surgeon temporarily). This may be a reasonable decision, since due to a lesser level of difficulty, the complication rate is lower in the latter case. With the 3-port technique, however, operation of both sides represents a similar challenge.

Cosmesis is also an important benefit of laparoscopic hernia surgery. In this respect, open surgery leaves no visible scar either, and minimally invasive techniques also cause only very small scar formation. In the case of PIRS, only a tiny, mostly completely invisible umbilical wound is expected, whereas the 3-port technique leaves only two 3-mm scars along the umbilicus. While the 3-port technique is associated with standard laparoscopic wounding, the technical skill of the pediatric surgeon performing PIRS may influence final cosmesis because the need for additional instruments may require additional incisions.

Postoperative recurrence at the operated site is also a crucial issue due to surgical inexperience, use of absorbable suture materials and peritoneal defects not being closed sufficiently [Grimsby GA 2015; Xiang B 2015]. The incidence was found to be 0–4.2% for laparoscopic surgeries [Chong A 2019] and 0.68–4% for open hernia surgeries [Askarpoura S 2013]. Postoperative recurrences (within <2 years) in the PIRS group were also observed in girls where the gap below the ligamentum rotundum was most probably not resolved. For this reason, great emphasis was placed on the dissection of the peritoneum above the ligament and its complete closure. The procedure was similar among boys, where the entire peritoneum was dissected, thus avoiding a recurrence gap at the edge of the inguinal ring.

This reduced the recurrence rate seen with the original PIRS technique; however, longer surgical time was required, which was accompanied by a greater risk of injury to surrounding arteries. Nevertheless, even in the case of large defects in infants, the gapless technique appeared to be effective as no recurrence was found in the PIRS group when operating on this kind of defect. One child had recurrent ipsilateral hernia after the 3-port technique (0.7%), which falls within the lower value range of both laparoscopic and open postoperative recurrence rates.

5.3. Conclusions to be drawn from the studies

Although surgical time is of great importance in clinical practice, achievement during a learning process should most probably be related to the reduction of complications related to surgery (both in the short and long run). As for surgery time, preclinical and clinical studies provided somewhat different findings in our studies. During the learning process in the vet lab study, a significant improvement was observed in the surgical times after the fifth operation, whereas this significant improvement could not be detected during human studies (involving 17 and 35 operations). One of the possible explanations is that the animal model was based on repetitions of the same surgical tasks, whereas clinical situations are inevitably more diverse and complicated. Furthermore, non-uniform factors (stress, and different anatomy and size) and non-technical skills (e.g. effectiveness of teamwork) may also critically influence surgery time, but, according to our present findings, these factors do not seem to reduce the ultimate success of surgical performance.

In our vet lab study, development of laparoscopic skills was assessed using the GOALS score, and this approach seems to be applicable to establishing a benchmark that allows pediatric trainees to further develop their skills in a clinical setting. The potential use of GOALS and other scores is most probably greatly limited when performance of surgeons should be compared in clinical settings during a learning process. This is partially due to lack of time and resources, but, on the other hand, clinical surgeons already have a certain degree of prior laparoscopic skills and their performance improvement may not be quantified by the same means. It is reasonable to assume that the learning process for a newly introduced procedure is typically not based on development of merely new technical skills, but more likely on knowledge and understanding of the steps in the new procedures to be adopted. Analysis of video recordings and online video-based telemedicine/telesurgery approaches may, however, have great potential in skill development. Scoring systems can also be used to provide objective criteria to define further necessary steps of improvement during telesurgery approaches (a visiting professorship with potential real-time scoring) and certainly also for retrospective self-assessment.

Although the time of surgery is important for patient safety (e.g. from an anaesthetic point of view), it is not in itself a suitable way to characterise the learning process, as the process of successful surgery consists of optimizing technical skills (also described by GOALS score). Their success can be characterised by firstly achieving the planned surgical outcome and avoiding intra- and late operative complications, as it will eventually manifest in improvement in surgical time.

6. SUMMARY OF NEW FINDINGS

1. We successfully developed and validated a new laparoscopic duodenal atresia training approach (diamond-shaped anastomosis) in rabbits. As shown by quantitative means of assessment during the learning process, the model represents a sufficiently high-degree and clinically relevant *in vivo* laparoscopic suturing challenge. Using this approach, the most important basic characteristics of laparoscopic surgery-related learning processes (time, success/outcome and technical improvement) can be assessed.
2. The GOALS score represents an excellent assessment tool to detect technical improvements in this “vet lab” training model. Among the domains of the GOALS score system, depth perception, tissue handling and efficiency score values reach the major degree of improvement during this laparoscopic suturing approach.
3. A minimum number of necessary repetitions can also be defined in this model, since anastomosis quality (the indicator of success of this surgery type) reaches its optimal value and GOALS shows no considerable further improvement after the fifth surgery.
4. Performance of participants undergoing standardized and structured basic laparoscopic skill training reached the levels of experienced, but non-uniformly trained residents, using diamond-shaped anastomosis surgery as a technically challenging test operation. This manifests in similarly ideal anastomosis quality as well as approximated values of GOALS score and surgery time.
5. In our pediatric laparoscopic hernia studies involving the PIRS and the 3-port hernia techniques, surgery time did not show significant improvement during the time frames under examination (35 and 17 operations, respectively), but remarkably low intraoperative and early postoperative complication rates were achieved. Our data suggest the superior relevance/importance of complication rate over surgery time to ascertain achievement (reflecting improved technical performance) if novel hernia operation techniques are introduced at pediatric surgery units.

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9. ANNEX

PAPER I.

frontiers in Pediatrics

ORIGINAL RESEARCH
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Learning Curves for Laparoscopic Repair of Inguinal Hernia and Communicating Hydrocele in Children

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Introduction: We analyzed the department and surgeon learning curves during implementation of the percutaneous internal ring suturing (PIRS) technique in our department.

Methods: Children proposed for inguinal hernia or communicating hydrocele repair were included (n = 607). After mentorship, all surgeons were free to propose open or PIRS repair. From gathered data, we assessed department and surgeon learning curves through cumulative experience focusing in perioperative complications, conversion, ipsilateral recurrence, postoperative complications, and metachronous hernia, with benchmarks defined by open repair.

Results: Department-centered analysis revealed that perioperative complications, conversion, and ipsilateral recurrence rates were higher in the beginning, reaching the benchmarks when each surgeon performed, at least, 35 laparoscopic repairs. Postoperative complications and metachronous hernia rates were independent from learning curves, with the metachronous hernia rate being significantly lower in PIRS patients. During the program, the percentage of males in those operated by PIRS progressively increased reaching the percentage of males, in our sample, when department operated over 230 cases.

Conclusion: Thirty-five laparoscopic cases per surgeon are required for perioperative complications, conversion, and ipsilateral recurrence reach the benchmark. The gap between the percentage of males, in those operated by PIRS and in those proposed for surgery, monitors the confidence of the team in the program.

Keywords: inguinal hernia, communicating hydrocele, children, laparoscopy, percutaneous internal ring suturing, learning curve

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INTRODUCTION

For years and years, infants and children with surgical indication for repairing inguinal hernia or communicating hydrocele were treated with high ligation and division of the sac by an open inguinal approach. Around the 1990s, after the first report of a laparoscopic inguinal hernia repair (1), several techniques have been described that can be clustered in two major groups: intracorporeal techniques that generally comprise dissection, ligation, and division of the sac similarly to the classic inguinal approach (true herniotomy) (2–5) and extracorporeal percutaneous techniques that just ligate the patent *processus vaginalis* without division (6–15). Even though no consensus exists favoring any of the techniques, there are enough evidence-based data supporting minimally invasive repair as a safe and effective method, if proper training and mentorship are assured (16).

A few years ago, our department decided to implement a minimally invasive program to repair inguinal hernia and communicating hydrocele embroiling all staff members. After a systematic review and mentorship, the percutaneous internal ring suturing (PIRS) technique (11) leaving no peritoneal gaps was selected and implemented. It favored our choice, the satisfactory cosmesis and the possibility to identify the patency of the contralateral *processus vaginalis* (17); among potential disadvantages, we had some reports mentioning higher rates of complications and recurrence (18, 19).

Herein, we evaluate our department- and surgeon-centered learning curves trying to extract some lessons we can share with other centers implementing a similar program.

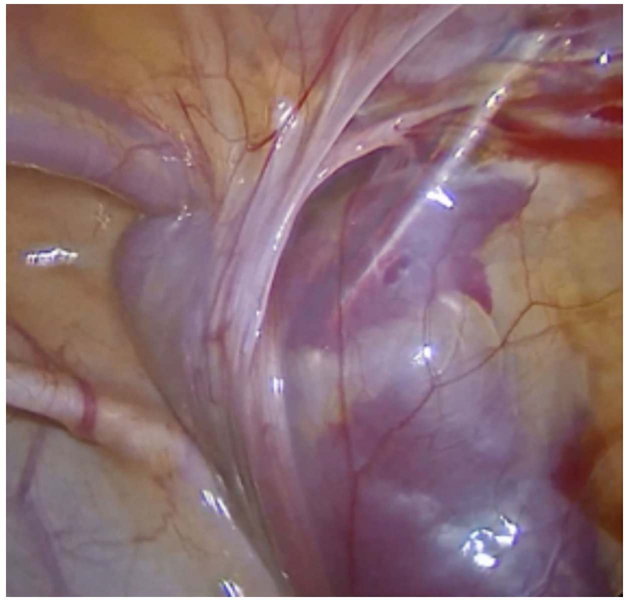

FIGURE 1 | Femoral vein puncture, a perioperative complication. The procedure was interrupted, and the bleeding was controlled with external compression.

FIGURE 2 | Inguinal foreign-body reaction, a postoperative complication emerging 4 weeks after surgery.

MATERIALS AND METHODS

Population and Data Collection

This study was approved by the scientific ethic committee from our institution with the reference: SECVS 133/2014. All staff members involved in the program were consultants with basic training as pediatric surgeons and different skill levels in laparoscopic surgery. We included all children submitted to surgical repair of indirect inguinal hernia (at any age) or communicating hydrocele (older than 2 years old) since June 2011 until November 2016 in our department. The patients were either operated by open approach (OA group) or by percutaneous internal ring suturing (PIRS group). The decision of proposing the minimally invasive approach was surgeon-dependent, and determined by each surgeon's experience, beliefs, and confidence on the technique. Patients with hernias other than indirect inguinal hernia were excluded.

Demographic data and clinical details were gathered, including gender, age, diagnosis (hernia vs. communicating hydrocele), pre- vs. perioperative laterality match, identification of silent patent *processus vaginalis*, conversion to open repair, ipsilateral recurrence and metachronous contralateral hernia, perioperative complications reported by the surgical team such as puncture of femoral vessels (**Figure 1**), and postoperative complications that caused early return to the hospital, such as hematoma, wound infection, or foreign-body reactions (**Figure 2**).

Operative Techniques

Both techniques were performed under general anesthesia (laryngeal mask) with the patient lying in a supine position.

OA Group

For open repair, we used a classic technique that divides the sac and closes the peritoneum at the level of the internal inguinal ring after opening the skin, Scarpa's fascia, and the aponeurosis of the external oblique muscle.

PIRS Group

The procedures were performed under general anesthesia (laryngeal mask) with the patient lying in a supine position. The surgeon stood at the right side of the patient regardless of the affected side, and the monitor was placed at the bottom of the table. Our minimally invasive approach included the ligation of the *processus vaginalis* based on PIRS technique as described by Patkowsky et al. (11) (see Video S1 in Supplementary Material). Briefly, it included a single transumbilical incision for a 5-mm trocar (30° optics). In males, we introduced a 3-mm dissection grasper above the trocar for the optics through a stab incision across the *linea alba* to help in mobilization of the peritoneum. Insufflation pressure was between 6 and 10 mmHg depending on the age of the patient. The peritoneal cavity was inspected to confirm the diagnosis. If there was a contralateral patent *processus vaginalis* or a different type of hernia, it was repaired in the same intervention. Either a 16G Abbocath or a 18-G hypodermic needle (depending on surgeon preference), armed with a loop of Prolene® 2-0 thread, was introduced through the skin at the level of the deep inguinal ring. Under laparoscopic guided vision, the needle was passed extraperitoneally between the peritoneum and the *vas deferens* and testicular vessels, leaving no peritoneal gaps, along half of the internal inguinal ring. Then the needle punched the peritoneum and entered the peritoneal cavity to push the thread through the barrel of the needle into the peritoneal cavity, forming an intraperitoneal loop. The needle was pulled out of the abdominal cavity leaving the Prolene® loop inside. The needle was introduced again, through the previous skin puncture point, this time armed with an Ethibond® 2-0 thread, which dissected the peritoneum of the other half of the ring, and passed through the peritoneal opening created before. The Ethibond® was pushed inside the Prolene® loop and the needle was taken off. From outside, the Prolene® loop was pulled out of the patient's body taking the Ethibond® end with it. Both Ethibond® ends were exiting the skin through the same puncture point and a perfect Ethibond® cerclage was created around the internal inguinal ring leaving no peritoneal gaps. During the whole procedure, extreme care was taken not to damage the *vas deferens*, testicular, epigastric, or femoral vessels. In girls, the round ligament was included into the cerclage. The knot was tied extracorporeally and buried under the skin. Steri-strip® were used over the skin puncture point at a cartoon fashion. The umbilical access was closed with absorbable suture and covered with a waterproof dressing. All patients were discharged home at the same day of surgery unless they had clinical contraindication.

Appraisal of the Minimally Invasive Program Implementation (Learning Curves)

Global data regarding both OA and PIRS groups were analyzed and compared when appropriate. To assess the success of implementation of the minimally invasive program for repairing inguinal hernia and communicating hydrocele, the learning curves were studied in two different ways: through a department- and a surgeon-centered analysis. The intervention on each patient was always considered a single procedure independently of being unilateral and bilateral repairs.

In the department-centered analysis, the OA group was used to set the benchmarks of the department. PIRS group was divided in chronological sequential tertiles (PIRS 1st–114th; PIRS 115th–228th; PIRS 229th–341st). The following rates were calculated for each tertile: i. perioperative complications (%); ii. postoperative complications (%); iii. ipsilateral recurrence (%); iv. conversion to open repair (%); and v. males benefiting from PIRS (%). The first three rates aimed to assess either the efficacy of the technique and the expertise of the surgical team. The other two rates mainly assessed the belief of the surgical team on the benefits of the procedure and their own self-confidence in performing the technique. The tertiles were compared with each others and with the benchmark (when appropriate).

In the surgeon-centered analysis, the staff surgeons who adopted PIRS as the technique of choice were selected, in order to achieve individual sequential case series. For each surgery serial number, we calculated the rate of perioperative complications, ipsilateral recurrence, and conversion to open surgery. The results were displayed in a surgeon's cumulative experience chart. A visual analysis was performed based on the events decline to determine the serial number of cases required to complete the learning curve.

Data Analysis

Data analysis was performed using SPSS software version 24.0 (SPSS, Chicago, IL, USA). Chi-square test was used to compare the distribution of categorical variables between groups. Statistical significance was defined as a two-sided p-value < 0.05.

RESULTS

Six hundred seven cases matched the inclusion criteria and were included in this study (**Table 1**). Even though the mean ages had been similar in both groups, the rate of male gender was lower in PIRS group, whereas a higher percentage of hydrocele cases fell in OA group. This clearly suggest a case-selection bias introduced by the surgical team during their learning curve based on beliefs and confidence in the PIRS technique. In cases of unilateral hernia (or hydrocele) treated by PIRS, we could identify a contralateral silent patent *processus vaginalis* (patent *processus vaginalis* without previous diagnosis) in around one-fifth of the cases. Moreover, we identified a mismatch with preoperative laterality (when laterality was not confirmed or no patency was identified preoperatively) in 4.4% of children. Three cases of PIRS group were converted to open surgery due to technical difficulty. Reported perioperative complications (puncture of femoral vessels) were not statistically different between OA ($n = 1$; 0.4%) and PIRS groups ($n = 8$; 2.3%), yet we identified a slight tendency for higher rate in PIRS group, but regarding postoperative complications (hematoma, wound infection, and foreign-body reactions) the rates were clearly similar in both groups ($n = 6$; 2.3% and $n = 9$; 2.6%). Metachronous contralateral recurrence was significantly lower in the PIRS group ($n = 1$; 0.3% vs. $n = 14$; 5.3%), whereas PIRS ipsilateral recurrences were not different from the OA group ($n = 5$; 1.5% and $n = 1$; 0.4%).

Department Learning Curve

In the department-centered analysis, perioperative complications rate was significantly greater than the benchmark in the first and third tertiles (**Figure 3A**), whereas the rate of postoperative complications was consistently identical between each tertile and the benchmark (around 2.5%) (**Figure 3B**). Ipsilateral recurrence

TABLE 1 | Demographic characteristics and clinical outcomes of the open approach (OA) and percutaneous internal ring suturing (PIRS) groups.

	Open group (n = 266 pts)	PIRS group (n = 341 pts)	p-Value
Preoperative characteristics			
Male gender, no. (%)	228 (86%)	216 (63%)	
Age, mean (SD), years	3.8 ± 3.5	4.2 ± 3.4	
Diagnosis, no. (%)			
Hernia	164 (62%)	311 (91%)	
Hydrocele	102 (38%)	30 (9%)	
Perioperative results			
Silent patent *processus vaginalis*, no. (%)	–	58 (17%)	
Mismatch with preoperative laterality, no. (%)	–	15 (4.4%)	
Conversion, no. (%)	–	3 (0.9%)	
Reported perioperative complications, no. (%)	1 (0.4%)	8 (2.3%)	0.085
Postoperative outcomes			
Postoperative complications, no. (%)	6 (2.3%)	9 (2.6%)	0.799
Ipsilateral recurrence, no. (%)	1 (0.4%)	5 (1.5%)	0.238
Metachronous recurrence, no. (%)	14 (5.3%)	1 (0.3%)	<0.001

Pts, patients; no, number.

rate was higher in the first two tertiles and decreased in the last tertile (**Figure 3C**). Conversion rate was 2.6% in the first tertile and sank to 0% from the second tertile onward (**Figure 4A**). Overall, the percentage of males in patients proposed for inguinal hernia and/or communicating hydrocele was 73%. Interestingly, rate of males submitted to PIRS was 56% on the first tertile and boosted along further tertiles reaching the rate of our sample at the third tertile (**Figure 4B**).

Individual Learning Curve

Out of six surgeons beginning the program only five adopted PIRS as the technique of choice. Each of these performed a minimum of 50 surgeries. The results chart (**Figure 5**) reflected the cumulative experience of the five selected surgeons along their first 50 PIRS procedures. A decline of the events was observed along the accumulated individual experience: perioperative complications reached its nadir at 35th surgery (**Figure 5A**). No recurrence occurred after each surgeon's 33rd case (**Figure 5B**) and there were no conversions after the 12th case of each surgeon (**Figure 5C**).

DISCUSSION

This study assessed the evolution of the department and surgeon's learning curves during a minimally invasive program to repair inguinal hernia and communicating hydrocele in children. The program was presented 5 years ago to our staff surgeons (all with different experience in minimally invasive procedures) and the proposed benchmarks were leastwise the results we had in the classical open repair. The selected minimally invasive technique was the PIRS (11) leaving no peritoneal gaps in the sac ligation at the level of the internal inguinal ring. As potential benefits, we found a better cosmesis with minimal dissection of the *vas deferens* and spermatic vessels, and the possibility to examine and fix the eventual patency of the contralateral internal inguinal ring. Meanwhile, we were aware of the increased risk of peri- and

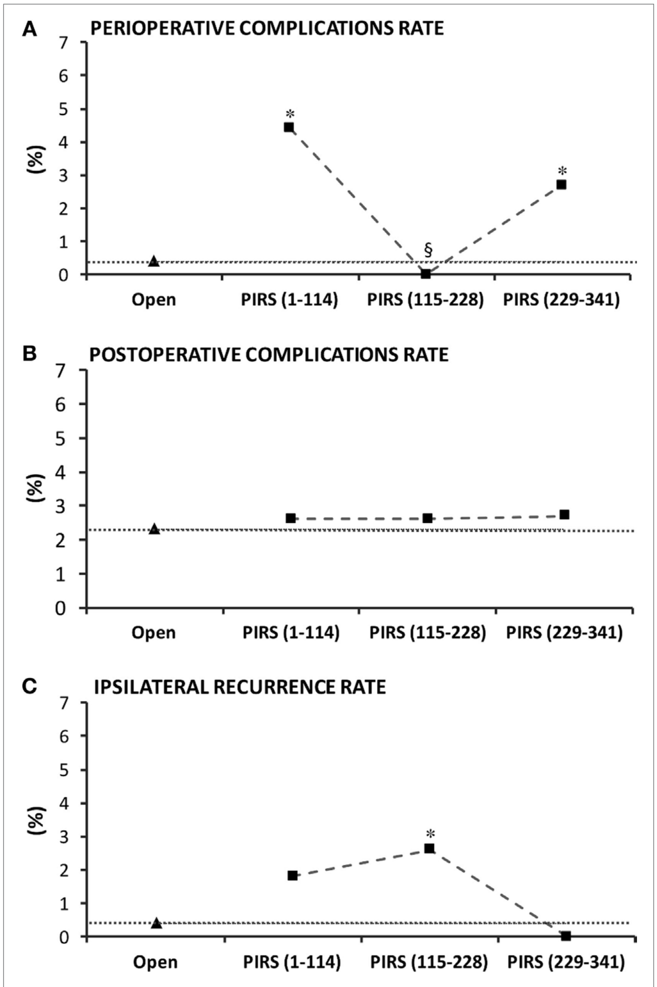

FIGURE 3 | Department-centered analysis of the learning curve of percutaneous internal ring suturing (PIRS) technique considering **(A)** perioperative and **(B)** postoperative complications rates and **(C)** ipsilateral recurrence rate. $p < 0.05$ indicated significance: * vs. open; § vs. lap (0–114).

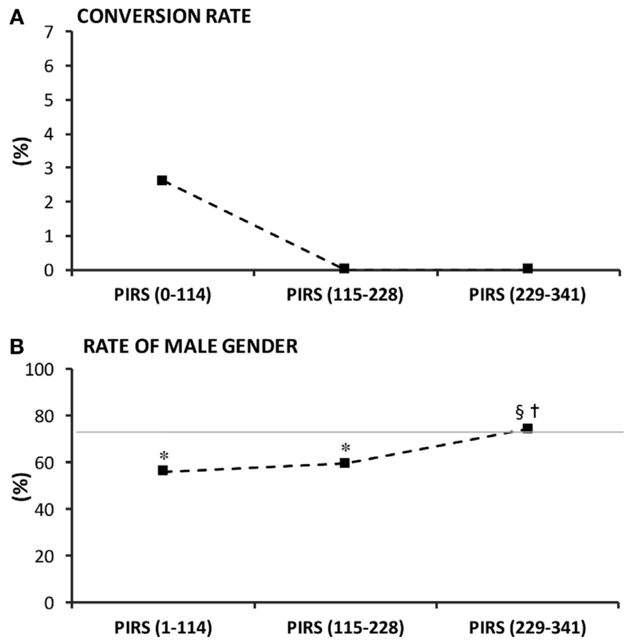

FIGURE 4 | Confidence of the surgical team on the technique reflected by **(A)** conversion to open surgery rate, and **(B)** rate of male gender proposed for percutaneous internal ring suturing (PIRS). In **(B)**, the full horizontal line represents the overall rate of males among our population. $p < 0.05$ indicated significance: * vs. overall prevalence; § vs. lap (0–114); †vs. lap (114–228).

postoperative complications as well as of higher ipsilateral recurrence rate (17, 18). The drawback in operative time, inherent to every learning curves, tends to decrease along cumulative experience and was not the focus of this study.

In the department-centered learning curve analysis, five of the six staff members adhered to the program. However, there was a disparity on the implementation cadence by each of them. Therefore, we also performed a surgeon-centered learning curve analysis.

The cosmesis was excellent with our strategy to insert the optics and dissecting 3-mm instrument through the umbilicus. In fact, there were no visible scars at the end of the procedure. In the department analysis, perioperative complications and ipsilateral recurrence rates showed some undulant pattern, despite the downward trend along the tertiles. The underlying explanation might be the surgeons' cadence disparity when starting their learning process, as each surgeon's accumulated experience contributing to each tertile was not the same. When analyzing the surgeon-centered learning curves, we perceived a more consistent decline in perioperative complications and ipsilateral recurrence with experience. In contrast to perioperative complications, ipsilateral recurrence, and conversion rates, the postoperative complications rate was consistently similar along all tertiles (PIRS group) and the benchmark (OA group). We concluded that postoperative complications are not dependent on the learning curve, but on the technique *per se*, and most likely occur due to the type of thread, knots not deeply buried under the skin, dressing gown care, or aseptic measures. The most common postoperative complications were incisional infections and foreign-body reactions. Interestingly, most inguinal foreign-body reactions in PIRS group occurred around 2 months after the procedure and the only measure that could resolve it was the removal of the stitch, which did not determine recurrence in the majority of cases. Likely the associated inflammation promoted effective and definitive closure of the defect.

In the literature, PIRS technique had been associated with higher rates of ipsilateral recurrence and residual hydroceles (9, 17, 18) This had been attributed to several factors such as the inexperience of the surgeons, the use of absorbable suture for ligation of the patent *processus vaginalis*, the use of a single-suture, larger defects and the presence of other factors (i.e., chronic cough, constipation) (19–21). More recent publications report lower recurrence and complications rate (22, 23). Before starting the program, we discussed this issue and advanced the possibility that the ligation of the peritoneum leaving some gaps over the *vas deferens* and spermatic vessels could contribute to ipsilateral recurrence and residual hydrocele, also hypothesized by others (17). Thus, we implemented our program with recommendation to ligate the peritoneum at the level of the internal inguinal ring without leaving any gaps. For the dissection of the peritoneum over the *vas deferens* and spermatic vessels, we used the cutting tip of an Abocath 16G. This was likely the trickiest step of the procedure. Indeed, at the beginning, a complete cerclage with no gaps was not always possible to achieve, which perhaps justified the higher ipsilateral recurrence rate observed during the first tertile. Moreover, the surgical maneuvers to perform this type of ligation, in some cases, led to puncture/pierce of the femoral vessels. This was the most common perioperative complication and the main cause for conversion in the first tertile, consistently with other studies in the literature (17). In fact, this was the outcome that mostly demanded experience, once at least 35 procedures by surgeon were necessary to minimize it. To avoid this disturbing complication, some staff members used a blunt needle (hypodermic needle) which carries less risk of laceration, although it has the risk to drag or/and entrap the *vas deferens*. Meanwhile, we emphasize that ligation of the peritoneum at the level of the internal inguinal ring with no peritoneal gaps might be a determinant factor for the low ipsilateral recurrence rate and absence of residual hydrocele observed in the last tertile of patients. Incidentally, we had a successful experience fixing communicating hydroceles with this technique. It was interesting to testify that large defects in small infants, where we just ligated the peritoneum without reducing the internal ring muscular defect, evolved very well with no recurrence. This raises the necessity to ascertain unknown mechanisms led by the peritoneum in the process of anatomic–physiologic closure of the patent *processus vaginalis*.

The laparoscopic approach allows the identification of contralateral patency of the *processus vaginalis* and its repair within the same surgical intervention. This strategy is likely the leading cause for the almost disappearance of metachronous contralateral hernia as we observed a significant reduction from 5.3% (OA group) to 0.3% (PIRS group) in our series ($p < 0.001$). This outcome is intrinsic to the technique, not dependent of learning

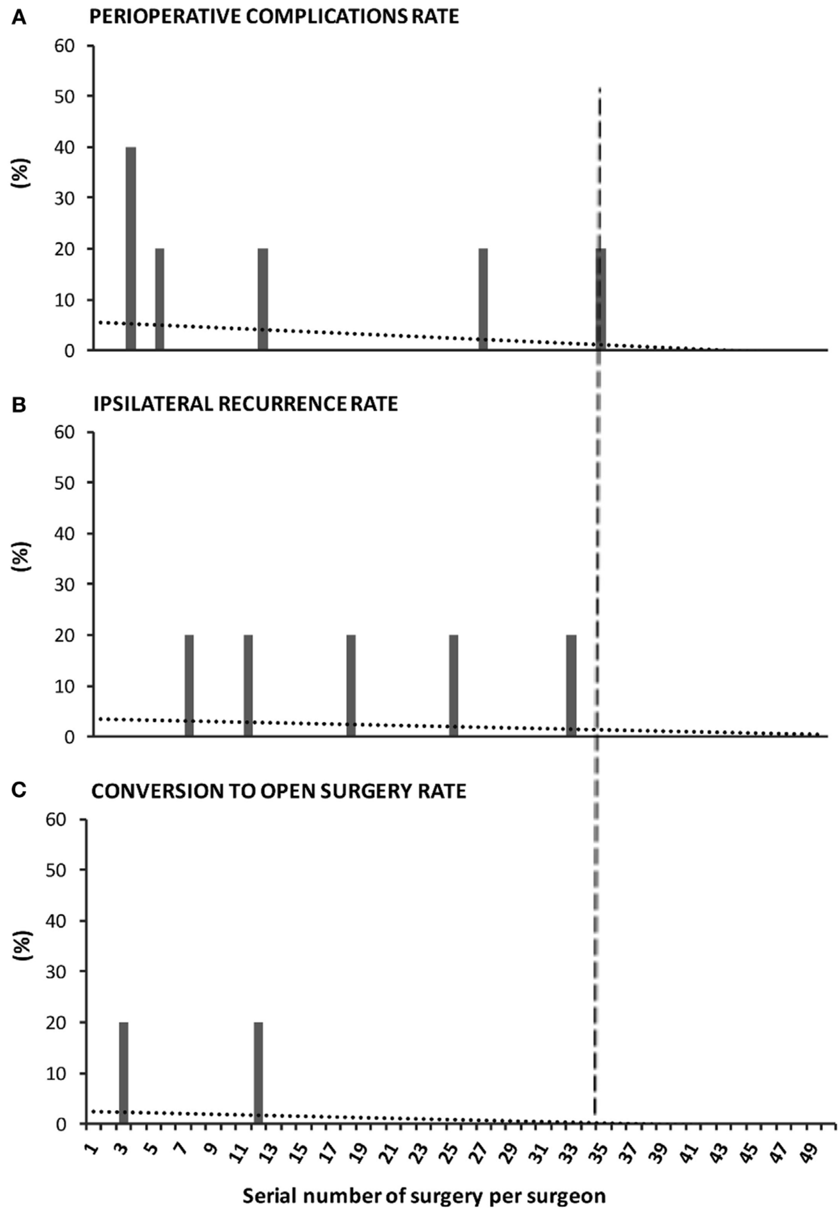

FIGURE 5 | Surgeon-centered analysis of the learning curve of percutaneous internal ring suturing (PIRS) technique. The graph reflects the cumulative experience of five staff surgeons throughout their first 50 surgeries by PIRS. The performance was evaluated by the **(A)** rate of perioperative complications, **(B)** rate of ipsilateral recurrence, and **(C)** rate of conversion to open surgery. The dotted lines represent the tendency lines. The dashed vertical line crossing the *x*-axis at point 35 marks the end of the learning curve, as no events occur after the 35th case of each surgeon.

curve, as it was observed since the first cases of laparoscopic repair. It is well known that patency of the *processus vaginalis* not always manifests as a hernia or a hydrocele, and because of that, there is no consensus whether it should or not be closed (16, 24). The principal argument to leave a patent *processus vaginalis* untouched is to avoid complications (25). Interestingly, in our series, we had no complications related with the closure of the contralateral patent *processus vaginalis*. In fact, the closure of an asymptomatic patent *processus vaginalis* was technically less demanding as the patency tends to be smaller. In PIRS group, we identified a prevalence of 17% asymptomatic patent *processus vaginalis* that were fixed within the same surgical intervention, while in the OA group, metachronous hernia occurred in 5.3% of the patients, during follow-up. We speculate that almost a third of the metachronous hernias are avoidable, if a laparoscopic approach with identification and closure of an asymptomatic patent *processus vaginalis* is adopted.

Finally, a deep analysis of our data suggested that the main reasons generating some distress among surgeons for proposing a minimally invasive approach in the beginning of the program were the male gender and the youngest ages of infants. In fact, we could verify that the percentage of males with inguinal hernia or communicating hydroceles proposed for minimally invasive repair increased along the tertiles and reached the benchmark (percentage of males with inguinal hernia or communicating hydroceles in our population) only at third tertile. At the beginning of the program, surgeons selected female patients to start with as their anatomy appears more favorable (2). However, we emphasize that most recurrences, in procedures performed by less experienced surgeons, occurred in females, because in many of them there is a fold of peritoneum under the round ligament that might easily be missed during cerclage that intends to leave no peritoneal gaps. Also interesting, we realized we could use the gap between the percentage of males in our population and the percentage of males in those proposed for laparoscopic repair as an index to monitor the confidence of the surgical teams that decide to adopt a minimally invasive repair program.

In conclusion, our study demonstrates that independently of previous surgical experience in minimally invasive surgery, pediatric surgeons easily adhere to the implementation of a minimally invasive program to repair inguinal hernia and communicating hydrocele. In contrast to postoperative complications, which were technique and experience independent, there was a learning curve for perioperative complications, ipsilateral recurrence, and conversion rates that reached the nadir after each surgeon performed at least 35 cases. After this, the laparoscopic repair is a safe and effective approach, whereas the cosmesis and the virtual extinction of metachronous contralateral hernia were the major advantages. The gap between the percentage of males in those proposed for surgical repair and the percentage of males in patients operated by PIRS can be used as an index to monitor the confidence of the surgical teams that decide to adopt a similar program to repair inguinal hernia and communicating hydrocele by minimally invasive surgery.

ETHICS STATEMENT

This study was carried out in accordance with the recommendations of the Declaration of Helsinki with written informed consent from all subjects. The protocol was approved by the scientific ethic committee from our institution.

AUTHOR CONTRIBUTIONS

The study conception was performed by CB, RL-P, and JC-P, data acquisition by CB, PE, AA, and JC. For interpretation of data and analysis, CB, AO, RL-P, and JC-P were involved. The manuscript was written by CB and JC-P and revised by JC, RL-P, and JC-P.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at http://journal.frontiersin.org/article/10.3389/fped.2017.00207/full#supplementary-material.

VIDEO S1 | Percutaneous internal ring suturing leaving no peritoneal gaps.

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Conflict of Interest Statement: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

PAPER II.

Surgical Endoscopy
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Characterization of technical skill progress in a standardized rabbit model for training in laparoscopic duodenal atresia repair

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Abstract

Background Laboratory skills training is an essential step before conducting minimally invasive surgery in clinical practice. Our main aim was to develop an animal model for training in clinically highly challenging laparoscopic duodenal atresia repair that could be useful in establishing a minimum number of repetitions to indicate safe performance of similar interventions on humans.

Materials and methods A rabbit model of laparoscopic duodenum atresia surgery involving a diamond-shaped duodeno-duodenostomy was designed. This approach was tested in two groups of surgeons: in a beginner group without any previous clinical laparoscopic experience (but having undergone previous standardized dry-lab training, $n=8$) and in an advanced group comprising pediatric surgery fellows with previous clinical experience of laparoscopy ($n=7$). Each participant performed eight interventions. Surgical time, expert assessment using the Global Operative Assessment of Laparoscopic Skills (GOALS) score, anastomosis quality (leakage) and results from participant feedback questionnaires were analyzed.

Results Participants in both groups successfully completed all eight surgeries. The surgical time gradually improved in both groups, but it was typically shorter in the advanced group than in the beginner group. The leakage rate was significantly lower in the advanced group in the first two interventions, and it reached its optimal level after five operations in both groups. The GOALS and participant feedback scores showed gradual increases, evident even after the fifth surgery.

Conclusions Our data confirm the feasibility of this advanced pediatric laparoscopic model. Surgical time, anastomosis quality, GOALS score and self-assessment parameters adequately quantify technical improvement among the participants. Anastomosis quality reaches its optimal value after the fifth operation even in novice, but uniformly trained surgeons. A minimum number of wet-lab operations can be determined before surgery can be safely conducted in a clinical setting, where the development of further non-technical skills is also required.

Keywords Pediatric surgery · Laparoscopy · Diamond-shaped anastomosis · GOALS score

Abbreviations

GOALS	Global Operative Assessment of Laparoscopic Skills
MISTELS	McGill Inanimate System for Training and Evaluation of Laparoscopic Skills

The number of advanced endoscopic surgical interventions is continuously increasing worldwide. Nonetheless, pediatric surgery faces special challenges, including the use of special surgical instruments and limited interventions due to a smaller workspace, with the safety of surgical interventions playing a particularly important role with children [1]. Furthermore, pediatric surgery is not typically divided into subspecialties; every pediatric surgeon is therefore expected to be familiar with numerous types of surgical interventions. Duodenual atresia is one of the technically most challenging neonatal laparoscopic interventions. All these facts underline the importance of laboratory training designed to master advanced techniques before carrying them out on pediatric patients [2].

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As for training alternatives, high-fidelity models are required to adequately simulate pediatric surgical conditions. Although many simulation-based training methods have been established [2–4] and numerous inanimate solutions have appeared recently [4, 5], the superiority of live anesthetized animal models over *ex vivo*, virtual reality and plastic models has been suggested [6–13]. A key issue here is transferability of laboratory skills to real clinical scenarios. Quantitative assessment can focus on multiple factors, such as (a) duration of the intervention, (b) success of the surgery, (c–d) occurrence of a number of intraoperative complications and their management, or (e) the surgeon's technical skills and bimanual dexterity. (f) Another important aspect is self-evaluation of the participants' own performance using standardized criteria [2, 12, 13].

The aim was to define criteria for a novel standardized rabbit model of duodenal atresia (diamond-shaped anastomosis) which could enable training participants to perform the same surgical pediatric intervention in clinical practice. According to our hypothesis, the model is appropriate and sufficiently complex to evaluate advancement and compare development of the technical skills of the trainee groups with different levels of expertise using learning curve-based assessment methods. Furthermore, we hypothesized that a minimal repetition number of diamond-shaped anastomosis surgeries can be defined in this animal model by which threshold values for clinical transferability to complex operations can be recommended.

Materials and methods

Participants

The present study was conducted between September 2016 and September 2017 at the Endoscopic Research and Training Laboratory of the Surgical Sciences of the Life and Health Sciences Research Institute in Braga, Portugal. A total of 15 laparoscopic trainees were recruited and allotted into one or the other of two groups. (1) A *beginner group* ($n = 8$) consisted of medical doctors soon after graduation without any previous laparoscopic experience. This group underwent at least twelve hours of laparoscopic training with the same supervisor based on a modified, previously validated inanimate assessment method known as the McGill Inanimate System for Training and Evaluation of Laparoscopic Skills (MISTELS) [14]. An *advanced group* ($n = 7$) comprised pediatric surgery fellows with previous laparoscopic experience of at least 25 human cases (e.g. appendectomy, varicocelectomy or herniorrhaphy). These fellows had not received any standardized and structured, minimally invasive laparoscopy surgery training at this institute.

Surgical procedure

Setup of the test operation

Participants in both groups were invited to perform eight laparoscopic, diamond-shaped bowel anastomosis surgeries using the same surgical technique and steps on anesthetized rabbits (see below). Scheduling of the operations was not pre-determined (it was dependent on participant preferences) with a maximum of two operations per day. The interval between the first and last operations ranged between four and 150 days. All test operations were supervised by two instructors, who had already performed at least 15 surgeries using the same model. Continuous guidance was provided based on drawn schemes and video tutorials of the procedure (Fig. 1).

Equipment

Karl Storz laparoscopic equipment and recording devices were used during all of the surgeries. Insufflation was performed with CO_2 using 6 mmHg pressure and 1.5 L/min gas flow. Surgical instruments included 5-mm telescope 30º and 3-mm instruments (Maryland dissector, bowel grasper, needle holder, anatomical forceps and scissors). 2/0 Prolene thread (Ethicon, Inc., Somerville, NJ, USA) was used for bowel suspension, and 5/0 Prolene (Ethicon, Inc., Somerville, NJ, USA) was used for continuous suture of the anastomoses. Port placement followed the standard method.

Fig. 1 Laparoscopic setup for training

Animal model

Ethical approval for this study was obtained from the Portuguese General Directorate for Food and Veterinary Affairs (Direção Geral de Alimentação e Veterinária-DGAV 0421/000/000/2017) and the University of Minho Ethics Committee (SECVS 004/2016). *Oryctolagus cuniculus* rabbits weighing 2000–2500 g were used. Anesthesia was achieved using ketamine (35 mg/kg; Ketamidor, Richter Pharma AG, Austria), medetomidine (0.5 mg/kg; Sededorm, VetPharma Animal Health, Spain) and buprenorphine (0.03 mg/kg; Bupaq, Richter Pharma AG, Austria) administered through the ear vein. Every animal underwent a tracheostomy and was ventilated. Animals were sacrificed using pentobarbital (200 mg/kg; Euthasol, Le Vet Beheer B.V., Netherlands) after surgery. In compliance with the 3R principle, more than one surgical intervention (with a maximum of three) was performed per animal.

Method of test operation

An optical port was inserted through the umbilical region of the rabbit followed by symmetrical placement of two working ports bilaterally. A jejunal segment was selected and suspended to the abdominal wall (Fig. 2). A proximal transverse enterotomy and a distal longitudinal one were made in the selected bowel segment to simulate the atretic stumps. This method was established based on preliminary studies with less ideal results involving anastomoses between the stomach and small bowel, between the small bowel and the vermiform appendix and between the gallbladder and the small intestine. Two fixation corner stitches were then placed to unite the proximal and distal stumps according to the method developed by Kimura et al. (Fig. 2A) [15, 16]. After suturing the posterior wall with continuous sutures, the anterior site was approximated in the same manner, followed by tying the stitches at the corners (Fig. 2B–D).

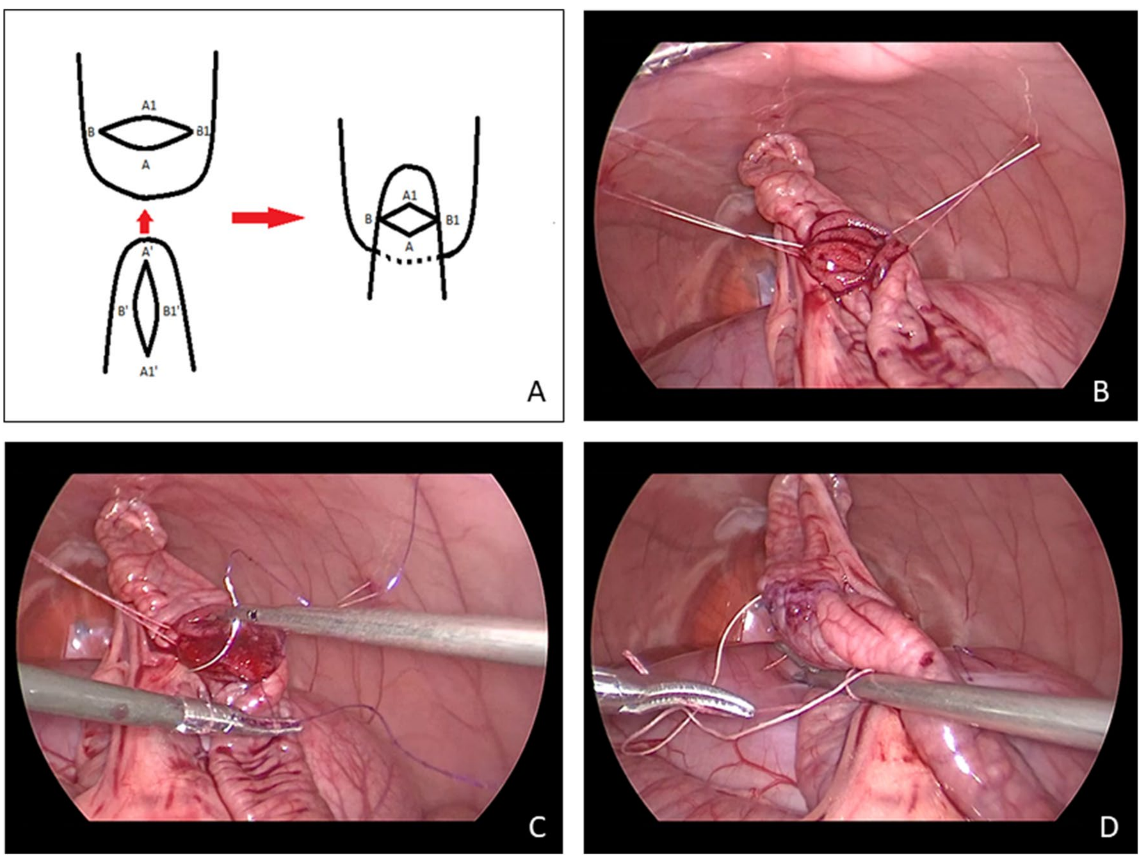

Fig. 2 **A** Scheme for diamond-shaped anastomosis (the order of stitches follows reference points A-A′, B-B′, A1-A1′ and B1-B1′, with continuous sutures on the posterior and anterior walls); intraoperative photos: **B** after suspending the bowel; **C** suturing the posterior wall; and **D** placing the last stitch after suturing the anterior wall

Video processing and segmentation

Each video segment of the net anastomosis procedure was saved separately, encoded with randomly generated numbers, shared using secure cloud storage and used for analysis. The duration of the segments was recorded. Each of the eight surgeries per participant was encoded separately. Each segment was assessed by four experts in a randomized, blinded fashion using individual information sheets (containing assessment criteria and video codes, but no information about the identity of the participant or the stage of the learning process).

Assessments and parameters examined

Four parameters were used after each surgery:

- Surgical time: The time interval between proximal opening of the bowel segment and the last surgical knot.
- Quality of the anastomosis: luminal passage and macroscopic leakage of the anastomosis were assessed after the animals were sacrificed by pressing the luminal content through the anastomosis.
- Expert evaluation was performed using the modified Global Operative Assessment of Laparoscopic Skills (GOALS) score [17]: video recordings were assessed in a blinded fashion by fellow surgeon experts in laparoscopy using the GOALS score developed by Vassiliou et al. [18] based on certain criteria (see Table 1).
- Participants' feedback: a 1–5-scale questionnaire was used for the following parameters: (1) working space, (2) workflow, (3) level of self-confidence and (4) level of self-achievement.

Statistical analysis

Statistical analysis was performed with Sigmaplot 13.0 software (Systat Software, Inc., San José, CA, USA, 2014). The two-way ANOVA test was used to assess intra- and inter-group differences followed by the Holm–Sidak test. Data are presented as means ± SEM, $P < 0.05$.

Results

All of the participants succeeded in completing all eight test operations; 120 surgical interventions were, therefore, included in the analysis. The duration of the operations was uniformly longer in the beginner group than in the advanced group (Fig. 3A). This parameter showed a continuous decrease in both groups. In the beginner group, the

Table 1 Parameters and GOALS score values used in the study

Parameters	Score		
	1	3	5
Depth perception	Constantly overshoots target, wide swings, slow to correct	Some overshooting or missing of target, but quick to correct	Accurately directs instruments to target in correct plane
Bimanual dexterity	Uses only one hand, ignores nondominant hand, poor coordination between hands	Uses both hands, but does not optimize interaction between hands	Expertly uses both hands in a complementary manner to provide optimal exposure
Efficiency	Uncertain, inefficient efforts; many tentative movements; constantly changing focus or persisting without progress	Slow, but planned movements are reasonably organized	Confident, efficient and safe conduct, maintains focus on task until performance is improved via an alternative approach
Tissue handling	Rough movements, tears tissue, injures adjacent structures, poor grasper control, grasper frequently slips	Handles tissues reasonably well, minor trauma to adjacent tissue (i.e. occasional unnecessary bleeding or slipping of the grasper)	Handles tissues well, applies appropriate traction, negligible injury to adjacent structures
Overall competency (Autonomy)	Unable to complete entire task, inefficient effort	Able to complete task safely even if task is slightly challenging	Able to complete task in spite of challenging case and can resolve complications (bleeding, leakage)

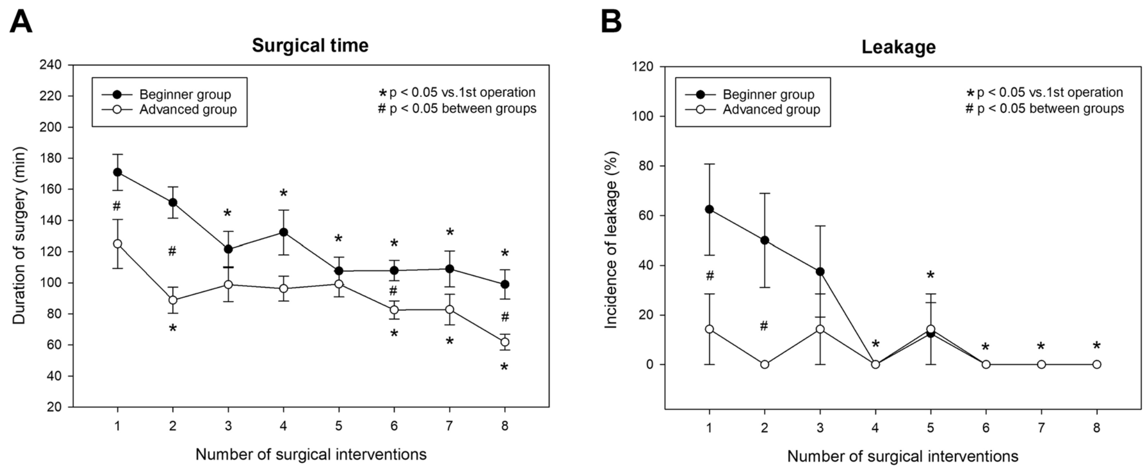

Fig. 3 Time course of change in operation time, **A** and in anastomosis quality (incidence of leakage), **B** in the beginner and advanced groups

operative time fell from 170.9 ± 11.6 to 107.1 ± 11.4 min (37.4%) versus a drop from 124.9 ± 15.6 to 61.8 ± 5.1 min (a 50.5% decrease) in the advanced group. Nevertheless, a significant difference persisted even during the sixth and eighth operations.

The leakage incidence was significantly higher in the beginner group in the first two interventions, but both groups showed similar results thereafter (Fig. 3B).

Even though the expert evaluation (GOALS) score showed higher values for the advanced group (Fig. 4), it displayed a similar trend of improvement during the learning process for both groups. The difference only reached statistical significance at a few time points (i.e. at the second and seventh time points) of the study. In the beginner group, this positive progress with training started later than in the advanced group (being more evident in the second part of the study) (Fig. 4A). The early difference (seen at operation #2) between the study groups in the GOALS score was associated with intergroup differences in depth perception, tissue handling and efficiency scores (Fig. 4B, D and E), while the later difference in the GOALS score (seen at the seventh time point) resulted from a difference in depth perception (Fig. 4B). Bimanual dexterity and overall performance showed similar values during the entire study period in both groups.

Participant feedback forms reflect a nearly maximum satisfaction score with the size of the available workspace during the entire study period, whereas self-reflective parameters (workflow, self-confidence and self-achievement) showed gradual improvements with no significant differences between the groups (Fig. 5A–D).

Discussion

Laparoscopic duodenal atresia repair is still one of the most challenging tasks in pediatric surgery [19, 20] requiring advanced laparoscopic abilities, including meticulous dissection and laparoscopic intracorporal knotting skills [20–22]. Performance, however, greatly improves over time due to the increased number of repetitions in clinical settings [16]. In general, at least 10–20 h of dry-lab training and a minimum of ten hours of animal model-based training have been recommended by the European Society of Pediatric Endoscopic Surgeons guidelines to gain expertise before performing basic laparoscopic human surgeries [23]. Repetition of interventions is also indispensable toward improved performance as proven by various preclinical and clinical studies (e.g. duodenal atresia and inguinal hernia) [16, 24], and it is particularly important in infants due to the small dimensions of the operative field. The size of the animals used in our model corresponds to the size of premature neonates who are often subjects of this rather challenging laparoscopic duodenal atresia operation. The feasibility of another rabbit model of laparoscopic duodenal atresia repair (gastro-duodenostomy) was also tested elsewhere, but it was only based on a single surgical intervention [13]. Here, characterization of the model was based on an analysis of individual learning curves during eight operations. Furthermore, the performance of the two trainee groups was compared with the aim of showing threshold expertise for the same procedure in clinical practice. Apart from providing a novel training model, probably

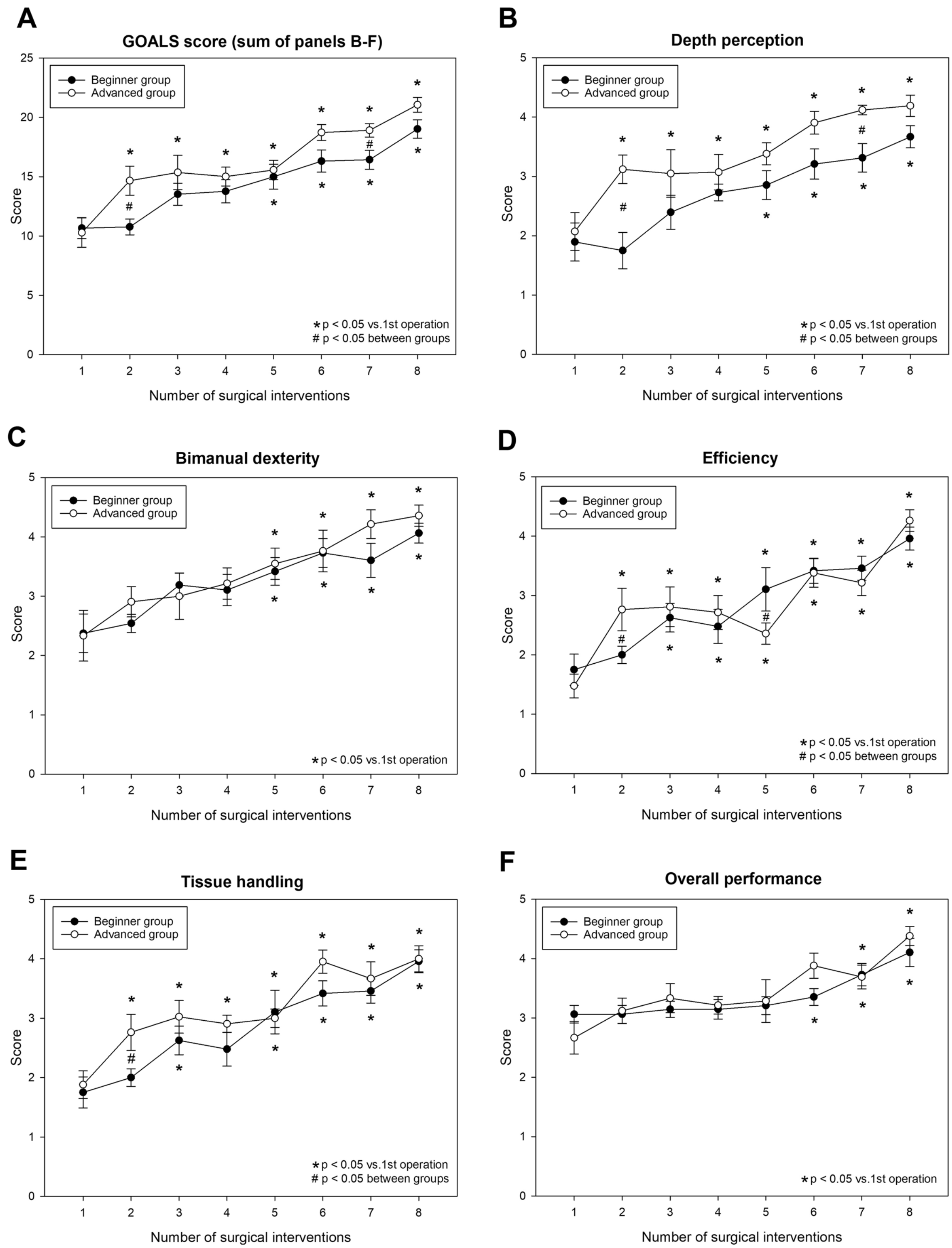

Fig. 4 Average GOALS score (**A**), depth perception score (**B**), bimanual dexterity score (**C**), efficiency score (**D**), tissue handling score (**E**) and overall performance score in the beginner and advanced groups

another novelty of our present study is that the analysis was based on simultaneous consideration of multiple perspectives.

Surgery time is one of the most objective and easily accessible indices of performance [6, 12, 13, 25, 26], which was found to be similar to those in clinical practice

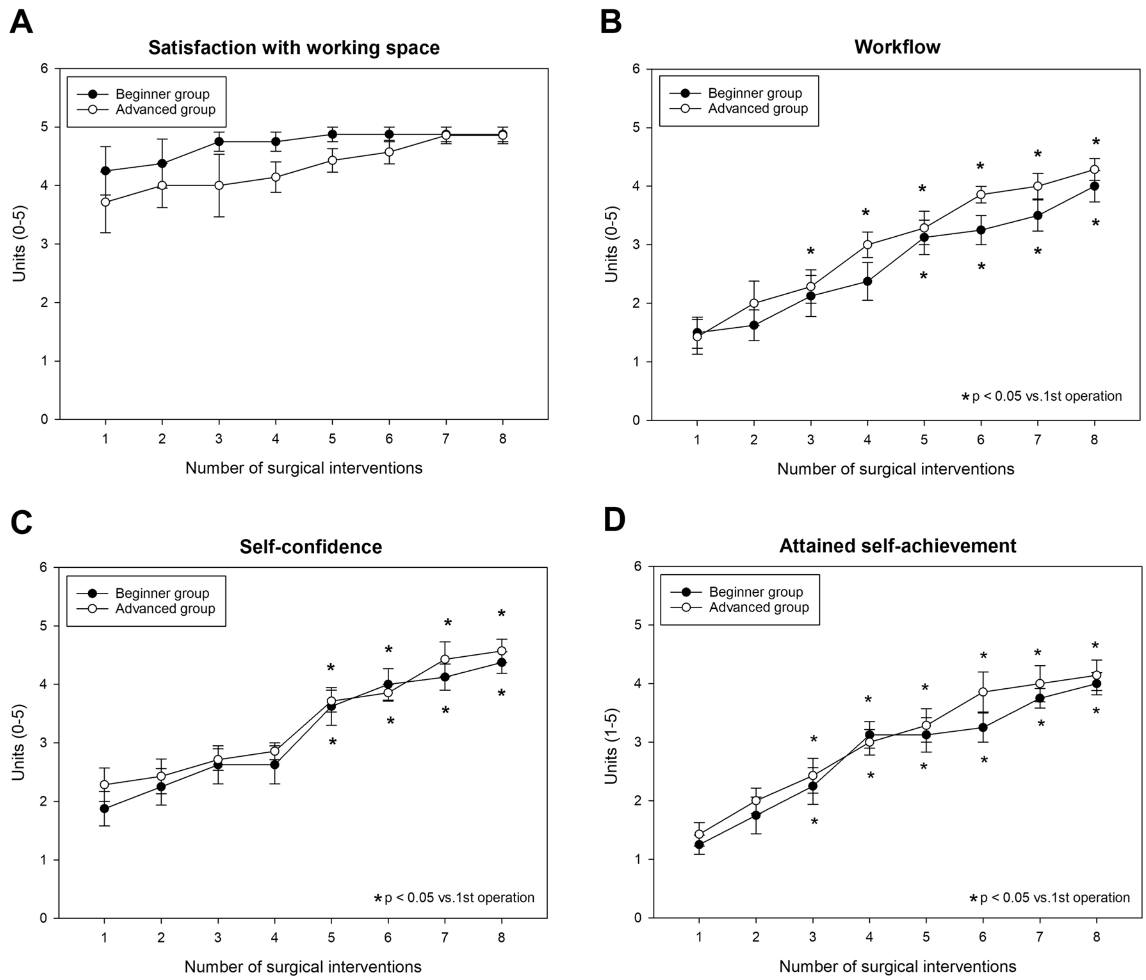

Fig. 5 Participant feedback. Working space (**A**), workflow (**B**), self-confidence (**C**) and self-achievement (**D**)

for laparoscopic diamond-shaped anastomosis [22]. Owing to a standardized, structured MISTELS-based training in our study, the beginner group completed the tasks more slowly than the clinically experienced advanced group only at certain stages of the study. However, probably the most important and clinically most relevant measure of technical performance is the success of the intervention [13, 22] (here, anastomosis quality refers to the passage and water tightness of an anastomosis). This binary parameter is specific to the actual model. The fact that this desired outcome was reached relatively early in both groups shows (1) the efficacy of the dry-lab laparoscopic training of the beginner group and (2) the feasibility of the present in vivo rabbit model.

We also used other methods enjoying the advantage of including several aspects of surgical performance when challenging laparoscopic tasks are evaluated. Validated tools were used for the open surgical interventions (e.g. the Objective Structured Assessment of Technical Skills-OSATS) [27]; however, this is usually less applicable in minimally invasive interventions. For dry-lab laparoscopic training sessions, MISTELS and Laparoscopic Suturing Competency Assessment Tool scores are probably more adequate tools [15, 28], while the GOALS score appears to be an appropriate approach for both basic and complex interventions [29]. It enables assessors not only to classify surgeons based on their technical performance (detailed in the Methods section) [17, 25], but also to compare advancement in different training groups [12, 30]. We observed significant improvement in both groups as regards the GOALS score, but a statistically significant difference between study groups was only observed at a few stages of the learning process (and appeared only in terms of a few domains of the GOALS score, e.g. depth perception, tissue handling and efficiency). This underlines the efficacy of standardized laboratory (e.g. MISTELS) training enabling beginners to show similar results to those of more experienced colleagues during the test operation. Bansal et al. also used operation time and anastomosis quality to compare the performance of beginner and trained residents after laparoscopic training using five test operations in an *ex vivo* model of gastrojejunostomy. In their model, gradual improvements were found in all parameters, with minor and gradually vanishing initial differences between the two groups over time [25].

When the transferability of lab training findings to clinical situations is considered, the GOALS score may also represent a good tool to assess the efficacy of laparoscopy training [29–31]. In another study by Bansal et al., a five-day (wet-lab) laparoscopic training program for cholecystectomy resulted in marked differences in clinical performance of the same operation [30]. During their human "test operation" on a single occasion, the GOALS score (and each domain of the GOALS score) appeared to be significantly higher (together with other indices of improvement examined, i.e. surgery time and complication rate) in the trained group. In our study, international participants were recruited; therefore, a clinical "test operation" could not be conducted to assess the transferability of our findings, but this could be a highly important aspect of future studies.

Interestingly, certain trials found no significant improvement in participant performance at a certain stage after repeatedly conducting the same type of laparoscopic procedure. The same was demonstrated by Fu B et al. with an in vivo pyeloplasty in a porcine model [11], where a stationary phase was reached in the learning process after the fifth operation. Surgery duration showed further improvement in our study, while leakage rate and GOALS score values indicated a lower degree of improvement between the fifth and eight surgeries. This suggests that a minimum number of five laboratory surgeries is definitely needed in the present diamond-shaped anastomosis model, but any further skill development should most probably be monitored under clinical conditions. Our findings are also supported by results from participant feedback forms which are regarded as important tools to gain insights into personal or self-assessment [2, 12, 13]. The feedback questionnaire used in our study showed that both groups found the task similarly challenging at different stages of the study and the values gradually increased in parallel with the improvement in technical skills (as indicated by the GOALS score). Self-reflective parameters (particularly workflow and self-confidence) also showed significant improvement as of the fifth surgery (as compared to the baseline).

Our study has certain limitations, however. First, this model only focuses on the technical aspects (i.e. suturing skills) of laparoscopic duodenal atresia surgery, and dissection of the atresia sites, for instance, was not included in the protocol. This issue could be important because a misconducted distal pouch (e.g. in the case of type C atresia) could represent a source of severe complications. Another limitation is the lack of long-term follow-up and monitoring of surgical outcomes; this could have been overcome by establishing a surviving model. Furthermore, study participants in the advanced group were not selected and tested by standard criteria, whereas initial (dry-lab) performance was only assessed in the beginner group.

Conclusions

In summary, our observations suggest that standardizing repetitive preclinical laparoscopic training tasks and using an in vivo model specifically designed for pediatric surgical challenges represent useful learning tools for pediatric residents. In our study, the performance of participants undergoing standardized laparoscopic skill training reached the levels of experienced, but non-uniformly trained residents during repetitive in vivo practice. We conclude that the diamond-shaped anastomosis model used on rabbits is particularly suited to simulating similar surgical interventions on humans. The same model or similarly complex methods may also be used for examination purposes before pediatric laparoscopic interventions. In our present study, sufficient anastomosis quality was achieved after the fifth surgery in this model with no further substantial improvements in objective skill assessments. Based on the minor further improvements after the fifth diamond-shaped anastomosis surgery in this animal setting, we assume that this number of interventions of this advanced operation is sufficient for laboratory training, presumably enabling residents to participate even in complex surgeries in clinical practice. Translation of the present results and further improvements in performance should probably be tested under clinical conditions where the importance of further skills (non-technical skills, e.g. decision-making expertise, stress-related factors and teamwork) can also be taken into consideration.

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Declarations

Disclosures Drs. Etlinger, Barroso, Miranda, Moreira Pinto, Lamas-Pinheiro, Ferreira, Leão, Kovács, Juhász, Sasi Szabó, Farkas, Vajda, Kálmán, Géczi, Simonka, Cserni, Nógrády, Fodor, Szabó and Correia-Pinto have no conflicts of interest or financial ties to disclose.

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PAPER III.

Gyermekkorban végzett 3 portos laparoszkópos lágyéksérv műtéttel elért kezdeti eredményeink – egy egyetemi centrum tapasztalatai

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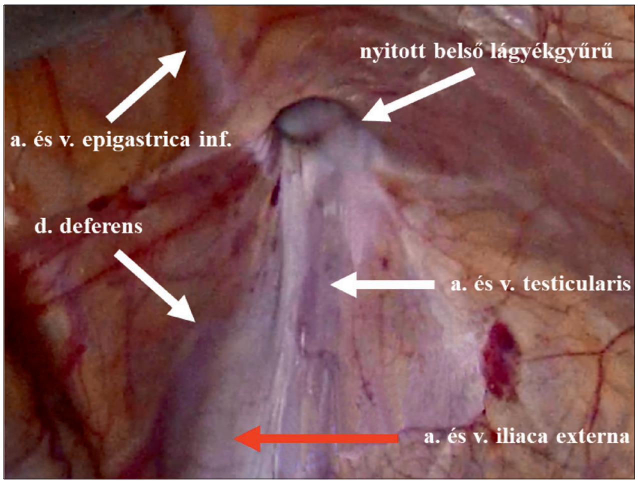
ÖSSZEFOGLALÁS *Célkitűzések. Az osztályunkon bevezetett 3 portos laparoszkópos sérvműtét első eredményeinek vizsgálata a műtéti idő, a szövődmények és a kiújulás vonatkozásában.*
Betegek és módszerek. A 2015–2020 közötti időszakban 112 gyermeket operáltunk. A műtéti időt a három legtöbb műtétet végző sebész első 17–17 műtétje vonatkozásában elemeztük.
Eredmények. 112 operációból 104 esetben egyoldali, 8 esetben kétoldali volt a műtéti indikáció, 23 esetben a műtét során észleltünk ellenoldali lágyékgyűrűt. Két konverzió és 1 kiújulás történt (a 13,2 hónapos utánkövetési periódusban). A standard egyoldali esetekben a műtéti idő 15 és 70 perc között mozgott a 3 sebész vonatkozásában.
Következtetések. Kedvező rövid és hosszú távú eredményeink alapján ez a lágyéksérv műtéttípus jó alternatívája lehet mind a nyitott, mind az egyéb laparoszkópos beavatkozásoknak.

KULCSSZAVAK *laparoszkópia, lágyéksérv, műtét, tanulási folyamat*

Bevezetés

A gyermekkori (indirekt) lágyéksérv az időre született gyermekpopuláció 3,5–5%- át érinti (1). A nyitott műtéti megoldásokat hosszú évtizedek óta alkalmazzák, melyek egy tapasztalt sebész kezében rutinnak mondható beavatkozások. Az igény – mint a legtöbb műtét esetében – a műtéti rövid és hosszú távú szövődmények elkerülése, a kiújulás megelőzése és a lehető legjobb kozmetikai eredmény. A laparoszkópos érában a lágyéksérv esetében is több műtéti technikát dolgoztak ki, a korábban leírt elvárások ezek esetében is kulcsfontosságúak (2). A laparoszkópos lágyéksérvműtétek célja (a nyitott műtéthez közelítő műtéti idő mellett) a kevesebb sebzéssel és ezáltal kisebb megterheléssel és gyorsabb felépüléssel járó eredmény elérése. Ezeknek a beavatkozásoknak további előnye a műtét idejében jelen lévő, de tünetet nem adó ellenoldali nyitott lágyékgyűrű felismerésének és ellátásának lehetősége. Ezek előfordulását a szakirodalom mintegy 6–30%-ra teszi (3, 4). A korábban nyitottan operált, de kiújult lágyéksérvek esetében a laparoszkópos megközelítés különösen előnyös lehet (5). A gyermeksebészetben jelenleg is alkalmazott laparoszkópos eljárások közül a leginkább elterjedtek a nyitott belső sérvkapu zárása Z-öltéssel (6), az extraperitonealis technikák (7, 8), mint például a belső inguinalis gyűrű percutan zárása (percutaneous internal ring suturing, PIRS) (9), a lágyékgyűrű beégetése lányoknál („Burnia") (10), illetve a jelen közleményben leírt 3 portos eljárás is (11, 12). A PIRS esetében legfeljebb 1 laparoszkópos eszköz bevezetése szükséges, a beavatkozás döntő többségében egy, a lágyéktájon bevezetett hajlított injekciós tű segítségével zajlik, melynek során a sérvtömlő a a peritoneum folytonosságának megszakítása nélkül két irányból körbejárható és lezárható. A 3 portos technikát (leírását lásd később) jelenleg Magyarországon csak Szegeden alkalmazzák, míg a többi gyermeksebészeti osztályon a PIRS technika terjedt el.

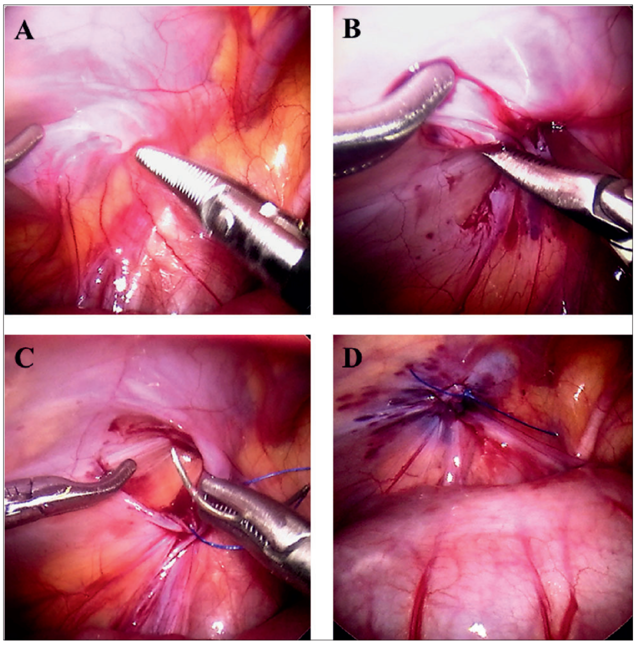
A kezdeti eredmények birtokában célunk a műtét biztonságosságának és kivitelezhetőségének vizsgálata a tanulási folyamat elemzésével, valamint az eredmények összevetése a nyitott technika és egyéb laparoszkópos technikák eredményeivel. Összehasonlítási szempontként a műtét során fellépő szövődmények és a posztoperatív kiújulás gyakoriságát, valamint a műtéti időt használtuk.



1. ábra: A jobb oldali lágyéktáj intraabdominalis anatómiája, nyitott belső lágyékgyűrű

Betegek és módszerek

Retrospektív vizsgálatunkba a 2015. novembere és 2020. júliusa között, az SZTE Gyermekgyógyászati Klinika Gyermeksebészeti Osztályán laparoszkópos 3 portos technikával operált betegeinket vontuk be (etikai engedélyszám: 87/2017-SZTE). Az érintett gyermekek mindegyikénél indirekt lágyéksérv vagy kommunikáló vízsérv miatt került sor a beavatkozásra. A műtéteket összesen 8 orvos végezte, de mivel közülük 3 fő hajtott végre nagyobb számú beavatkozást a 3 portos technikával (a minimális műtéti szám 17, a maximális 68 volt), a műtéti idő elemzésébe az ő első 17–17 műtétjük eredményét vontuk be. A vizsgált időszakban osztályunkon lágyéksérvműtétekre nyílt eljárással és laparoszkópos technikával volt lehetőség; a műtét típusát a sebész preferenciája és a szülő részletes tájékoztatást követő döntése határozta meg.



2. ábra: A műtét folyamata: a nyitott lágyékgyűrű előemelése (A), körkörös bemetszés a lágyékgyűrű körül (B), zárás dohányzacskó-öltéssel (C), zárt lágyékgyűrű (D).

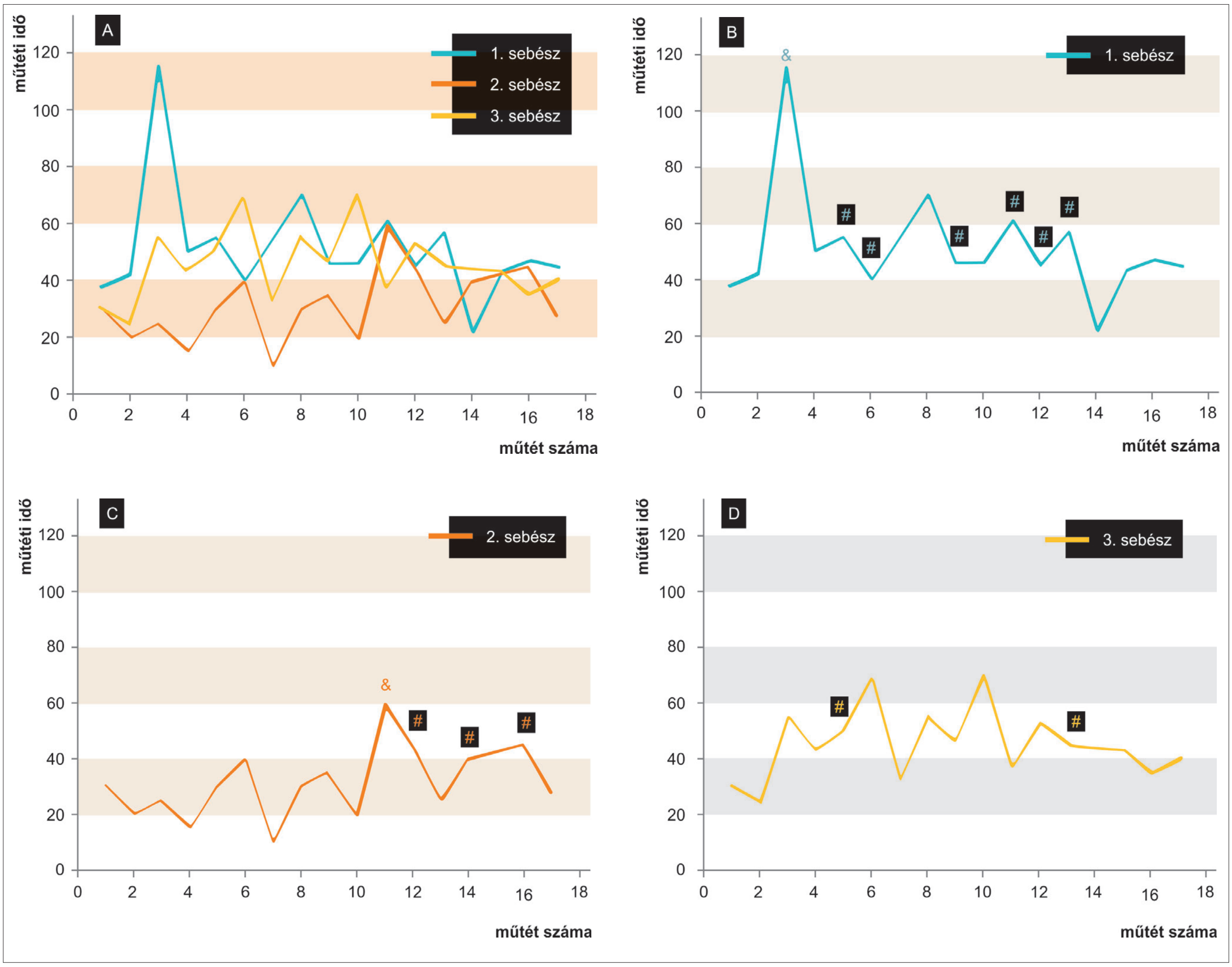
A műtétek általános anesztéziában, laryngealis maszk vagy intubációs narkózis alkalmazásával történtek. Az aneszteziológus szülői beleegyezés esetén kiegészítő epiduralis vagy regionális anesztéziát alkalmazott. A műtét kezdetén a kamera befogadására alkalmas 5 milliméter átmérőjű portot a köldök alatt vagy mellett vezettük be nyitott (Hasson-) technikával a hasűri szervek sérülésének elkerülése céljából. Két további 3 milliméter átmérőjű munkaportot vezettünk be a köldök és a lágyéktáj (1. ábra) között kétoldalt. A hasüreg áttekintése során látótérbe hozható az ellenoldali belső lágyékgyűrű, melynek nyitottsága esetén kétoldali beavatkozást végeztünk. Első lépésként a lágyékgyűrű körül Metzenbaum-ollóval a peritoneumot bemetszettük (fiúknál az ondózsinór képleteiről, lányoknál a ligamentum rotundumról lepreparáljuk) *(2. ábra)*, majd laparoszkópos tűfogóval sítalp-formára hajlított tűvel 3/0-as polipropilén fonalat (nem felszívódó) vezettünk a hasüregbe. A behasított peritoneumot dohányzacskó-öltéssel zártuk.

Eredmények

A vizsgált időszakban összesen 1082 sérvműtétet végeztünk osztályunkon, melyekből 112 beteget operáltunk a 3 portos laparoszkópos technikával [58 fiú, 54 lány, átlagos életkor 4,7 év (112 nap–18 év)].

Az elemzésbe bevont három sebész műtéti idejének változását a műtéti szám függvényében (az első 17 műtétjük vonatkozásában) a *3. ábrán* szemléltetjük, ahol a grafikonokon a nyilvánvalóan hosszabb időigényű, az eredeti műtéti indikációban szereplő, vagy a műtét során felismert szükségességű kétoldali beavatkozásokat is megjelenítettük (11 esetben, „#" jelzéssel). A grafikonon látható, hogy a vizsgált három sebész műtéti ideje nem ér el plató fázist és nem javul jelentősen a vizsgált periódusban. Az átlagos műtéti idő 41,3 perc volt, a legrövidebb 15, a leghosszabb 115 percig tartott (mely utóbbi konverzióval is zárult, lásd alább). A nagyobb időbeli eltérések a technikailag nehezebb műtéti helyzetekhez társulnak, ahogy azt a két konverzió is jelzi. A laparoszkópos technikát két ízben kényszerültünk nyílt műtétre váltani (egy alkalommal a hasűri kitapadások okozta szűk mozgási viszonyok, egyszer a kezdeti tapasztalatlanság miatt); ezt a *3. ábrán* „&" jellel ábrázoltuk.

A 112 operált beteg vonatkozásában 62 esetben jobb oldali, 42 esetben bal oldali lágyéksérv miatt végeztünk műtétet, ebből 1 alkalommal varicokele



3. ábra: A 3 portos technikával kivitelezett lágyéksérv beavatkozások műtéti idejének változásai az elemzésbe bevont 3 sebész (A) és az egyes sebészek esetében (B-D) a szokásostól eltérő, műtét során bekövetkező események megjelölésével (& konverzió, # kétoldali sérv)

műtét kapcsán diagnosztizáltunk korábban fel nem ismert baloldali nyitott lágyékgyűrűt (0,89%). Habár a műtéti indikációban 8 kétoldali műtét szerepelt, további 23 esetben találtunk klinikailag csendes ellenoldali sérvet (20,5%) a műtét során, melyet minden esetben korrigáltunk. A lágyéksérvhez egyéb rendellenességek is társultak, melyek jellemzően köldök- és epigastrialis sérvek (14,2%), phimosis (1,7%) és varicokele (0,89%) voltak. Intraoperatív szövődményünk nem volt. Az átlagos követési idő 13,2 hónap volt. Betegeinket személyes kontrollra a műtétet követő 1 hónapon belül hívtuk vissza, a hosszútávú utánkövetést telefonon végeztük, ahol a szülőt részletesen kikérdeztük a kiújulás tüneteiről. A sérv kiújulását 1 esetben észleltük (0,7%).

Megbeszélés

A laparoszkópia térhódításával számos műtéttípus minimálisan invazív megfelelőjét dolgozták ki. A gyermekkorban igen gyakori lágyéksérvműtét esetében kritérium, hogy hossza és szövődményei ne térjenek el jelentősen a bevált nyílt technikáknál megfigyeltektől. A laparoszkópos lágyéksérv-beavatkozás szövődményei (magától értetődő módon) különböznek a nyitott műtétnél tapasztaltaktól. Bár a szövődmények tekintetében statisztikailag szignifikáns eltérést nem talált egy, a nyitott és laparoszkópos lágyéksérvműtéteket összehasonlító metaanalízis, a 8 randomizált kontrollált vizsgálatot magába foglaló tanulmány a műtét közben bekövetkező szövődményeket a laparoszkópos sérvműtétek csoportjában találta jellemzőbbnek (13). A hosszú távon jelentkező szövődményeket (vízsérv, here magasabb pozíciója vagy sorvadása) a nyitott műtéttel kezelt esetekben bizonyult gyakoribbnak (13). Meg kell jegyezni továbbá, hogy a lágyéksérv műtétek esetében a nyitott és laparoszkópos megközelítés egyike sem tekinthető minden szempontból előnyösebbnek a másiknál. A tanulmány szerzői szerint a laparoszkópos, illetve nyílt sérvműtét előnyeit betegenként érdemes mérlegelni, figyelembe véve a sebész szempontjait is (13).

A műtéti indikációknál osztályunkon mi is törekedtünk a megfelelő betegszelekcióra, figyelembe véve a szülői igényeket is. Mivel jelen tanulmányunkban az új technika tanulási folyamatának első fázisát elemezzük, fontos kiemelni, hogy kezdetben idősebb gyerekeket és elsősorban lányokat válogattunk be a könnyebb kivitelezhetőség miatt. Az egyik műtéti konverzió is egy kiscsecsemő műtétének technikai nehézségével magyarázható, a későbbiekben azonban (a műtéti tapasztalat növekedésével) a legkisebb korosztály műtéteit is sikeresen végeztük ezzel a laparoszkópos módszerrel. A laparoszkópos műtétek esetében az is elvárható, hogy a műtéti idő megközelítse az adott nyitott beavatkozásokét. A fent említett nemzetközi tanulmány szerint a laparoszkópos műtéti idő féloldali esetben 7,6–35 perc között változott centrumonként, míg a nyitott műtét esetén a műtéti idő 12,8–53,2 perc között adódott. A nyílt lágyéktáji műtétek esetében a változatos műtéti kihívások (a beteg életkora, esetleges túlsúlya, valamint a sérvtömlő minősége, környező képletekhez való hegesedése) okozhatnak nagy szórást a műtéti időben, míg a laparoszkópos beavatkozások hasonló technikai lépései és az egységesebb anatómiai viszonyok következtében rendszerint kisebb időbeli eltérést mutatnak. Esetünkben elmondható, hogy a vizsgált időszakban az átlagos műtéti időtartam hosszabb, mint a szakirodalomból ismert adatok, de mindhárom sebész esetében találkozunk az ezeknek megfelelő 45 perc alatti értékekkel is (11). Természetesen szükséges a tendencia további követése, hiszen az esetszám növekedésével folyamatosan javuló műtéti időkre számíthatunk a nemzetközi tapasztalatok alapján (11).

A laparoszkópos módszer egyik leghangsúlyosabb előnye a műtét előtt nem jelentkező ellenoldali sérvek műtét közbeni felismerésének lehetősége. Irodalmi adatok szerint a nyílt műtétek során főleg korábban végeztek tünetmentes ellenoldalt érintő feltárást lány csecsemőknél. Az így észlelt tünetmentes sérv előfordulási gyakorisága 6–7,3% (3, 4). A laparoszkópia során rendszerint rutinszerűen keresett nyitott ellenoldali lágyékgyűrű átlagos előfordulása 30%-os (4). A tünetmentes sérvek műtét alatti megoldása rutinszerűen javasolt, habár tünetek kialakulására csak az esetek mintegy 3,8%-ában kell számítani (14). A mi betegcsoportunkban az ellenoldali nyitott lágyékgyűrű előfordulása (23%) nagyságrendileg követi a nemzetközi adatokat, ezekben az esetekben a műtétet mindkét oldalon elvégeztük.

A műtét utáni kiújulás szintén központi kérdés, ennek előfordulási gyakorisága irodalmi adatok alapján a laparoszkópos technika esetében 0–4,2%-nak (14), a nyitott sérvműtét után pedig 0,68–4%-nak adódik (15). Az intézetünkben kezelt gyermekek közül 1 esetben alakult ki újra sérv az operált oldalon (0,7%), ami így mind a laparoszkópos, mind a nyitott műtét utáni kiújulás alsó értéktartományába esik. Hasonló kiújulási arányokat találtak az extraperitonealis műtéttípusoknál is (lásd PIRS műtét) (9).

A PIRS esetén az érsérülés (az arteria epigastrica vagy vena femoralis sérülése) a leggyakoribb műtéti szövődmény, aminek előfordulása több nagyobb tanulmány alapján 2,3–3,6% között változik (9, 16), míg a 3 portos technika esetén ez jellemzően nagyon alacsonynak (akár nullának) adódik (12). A 3 portos technikánál rutinszerűen alkalmazott peritoneum elemelésével jobban megelőzhetőek az ér- és ductussérülések. A PIRS műtét előnye a 3 portos technikához képest az alacsonyabb invazivitáson és a jobb kozmetikai eredményen túl a rövidebb átlagos műtéti idő lehet, ám az utóbbi tekintetében az adatok direkt összehasonlítását nehezíti, hogy a műtét hosszát döntően befolyásolja a gyermek neme és kora, valamint a sérv kétoldali volta. Mivel a jelen tanulmány a műtéti beavatkozás bevezetési/begyakorlási fázisának megfigyelésein alapul, a műtéti idő vonatkozásában további javulás várható (11). Ezt a feltevést egy, a 3 portos technikáról született korábbi közlemény is alátámasztja, hiszen a fiúk átlagos műtéti ideje egyoldali sérv esetén 28, míg a lányoké 23 perc volt, kétoldali műtétnél a fiúk 40, a lányok 30 perces átlagos műtéti időt igényeltek (12). A PIRS technikát leíró tanulmányban 19,36 perces átlagidőt regisztráltak, egyoldali, és 24 perces műtéti átlagidőt kétoldali esetben (9).

Következtetések

A 3 portos technika előnyét abban látjuk, hogy a kétkezes laparoszkópos eszközhasználat következtében a PIRS technikánál kontrolláltabban végezhető, miáltal vélhetően hatékonyabban előzhetők meg a társsérülések (pl. érsérülések). Tapasztalataink alapján az egyéni tanulási folyamat elején a betegválasztás kiemelt fontosságú, mivel a műtét technikai lépései nagyobb gyermek hasüregében könnyebben elsajátíthatók, majd alkalmazhatók a fiatalabb populációban is. A 3 portos technika sok európai centrumban is preferált műtéti eljárás, ezek tapasztalatával egybehangzóan állítjuk, hogy jó eredménnyel, kevés társsérüléssel, javuló műtéti teljesítménnyel és kis kiújulási aránnyal alkalmazható bármely életkorban.

Summary

Preliminary results with the 3-port laparoscopic inguinal hernia surgery in children – experience of a university center

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Objectives. To summarize our preliminary results with the 3-port laparoscopic hernia technique in terms of operation time, complication- and recurrence rates.
Patients and methods. We operated 112 children between 2015 and 2020. Operation time of 3 colleagues with the highest number of operations (17-17) was analyzed.
Results. Within the 112 cases, 8 bilateral operations were initiated, but we also discovered 23 contralateral cases intraoperatively. Two conversions and 1 recurrence occurred (within 13.2 months). In standard one-sided cases, the surgical time ranged from 15 to 70 minutes for the 3 surgeons.
Conclusions. Our short- and long-term results show that this 3-port laparoscopic hernia approach can represent a good alternative to both open and other laparoscopic procedures.

KEYWORDS laparoscopy, inguinal hernia, surgery, learning curve

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Útravaló tudnivaló

- A 3 portos technika egy intraperitoneális laparoszkópos beavatkozás, mely hagyományos eszközös csomózással zárja a nyitott belső lágyékgyűrűt
- A gyermekkori lágyéksérvek sikerét a műtét során bekövetkező és hosszú távú szövődmény (here atrófia, kiújulás) alacsony előfordulási gyakorisága jelzi
- A jelen technika alacsonyabb szövődményrátája miatt különösen előnyös a gyermekpopulációban.

Tesztkérdések

1. Melyik a laparoszkópos sérvműtét bizonyított előnye?

a) rövidebb műtéti idő
b) kisebb műtét utáni fájdalom
c) az ellenoldali nyitott lágyékgyűrű diagnózisa
d) szignifikánsan kisebb kiújulási ráta
e) kevesebb műtéti szövődmény

2. Melyik az ismertetett 3 portos technika műtéti lépése?

a) Z-öltés a belső lágyékgyűrű magasságában
b) hidrodisszekció
c) lasszóképzés a peritoneumon kívül
d) dohányzacskó öltés
e) a sérvkapu beégetése

Az egyszerű választásos tesztekre a megoldást a társaság honlapján kérjük megjelölni: www.gyermekorvostarsasag.hu.
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