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A new innovative laparoscopic fundoplication training simulator with a surgical skill validation system

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Abstract
Purpose We developed and validated a specific laparoscopic fundoplication simulator for use with the objective endoscopic surgical skills evaluation system. The aim of this study was to verify the quality of skills of surgeons.
Materials and methods We developed a 1-year-old infant body model based on computed tomography data and reproduced pneumoperitoneum model based on the clinical situation. The examinees were divided into three groups: fifteen pediatric surgery experts (PSE), twenty-four pediatric surgery trainees (PSN), and ten general surgeons (GS). They each had to perform three sutures ligatures for construction of Nissen wrap. Evaluate points are time for task, the symmetry of the placement of the sutures, and the uniformity of the interval of suture ligatures in making wrap. And the total path length and velocity of forceps were measured to assess bi-hand coordination.
Results PSE were significantly superior to PSN regarding total time spent ($p < 0.01$) and total path length ($p < 0.01$). GS used both forceps faster than the other groups, and PSN used the right forceps faster than the left forceps ($p < 0.05$). PSE were shorter with regard to the total path length than GS ($p < 0.01$). PSE showed most excellent results in the symmetry of the wrap among three groups.
Conclusion Our new model was used useful to validate the characteristics between GS and pediatric surgeon. Both PSE and GS have excellent bi-hand coordination and can manipulate both forceps equally and had superior skills compared to PSN. In addition, PSE performed most compact and accurate skills in the conflicted operative space.

Keywords Endoscopic surgery · Objective skill assessment · Pediatric surgeon · Fundoplication

Endoscopic surgery has many merits; it leaves a smaller operative scar, allows for an earlier recovery, and has cosmetic advantages for both adult patients and pediatric patients. In pediatric surgery, endoscopic procedures began in the early 1990s with comparatively simple procedures, such as laparoscopic pyloromyotomy and laparoscopic cholecystectomy in the early 1990s [1, 2]. Many kinds of endoscopic surgical procedures were applied for specific pediatric diseases, such as esophageal atresia and choledochal cysts [3, 4]. In pediatric endosurgery, the working space for forceps is very small and the ports are near each other and easy to conflict, especially in the cases neonate and infant. Therefore, pediatric surgeons require both basic and highly advanced endoscopic surgical skills applied for many kinds of both operative procedures and the body size of child, which varies according to the age of the child.

In general, number of experienced surgery is thought to be the index of the expert. So, surgeons who have performed many operations are considered "expert surgeons." On the other hand, pediatric surgeons have lower opportunities to

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perform endoscopic surgery compared to general surgeons due to the rarity of pediatric surgical diseases. So, pediatric surgeons have to acquire not only basic and universal clinical endoscopic skills as described above [5], but also disease-specific skills. In recent years, disease-specific simulators mimicking neonate and infant became important and demonstrated those usefulness in pediatric surgery [6, 7].

Our group investigated and reported the effectiveness of basic endoscopic surgical skill training for pediatric surgeons and compared the findings to those in general surgeons that were reported previously [5]. We then developed and validated a pediatric surgery-specific disease model with an objective evaluation system for pediatric surgeons [8, 9]. In this paper, we developed and validated an innovative laparoscopic fundoplication simulator for use with the objective endoscopic surgical skills evaluation system. The reason that we choose laparoscopic fundoplication is an endoscopic surgical skill qualification (ESSQ) system developed by the Japanese Society of Pediatric Endoscopic Surgeons. In the ESSQ system of pediatric surgery, the task operation is laparoscopic fundoplication. Some simulators specifically mimicking fundoplication have been reported [10], but they were just used for training. Our simulator has skill validation system including forceps motion analysis as objective evaluation tool. We have already reported that the hand motions of expert surgeons and pediatric surgeons differ significantly from those of novice surgeons and pediatric surgeons [11].

The aim of this study was to verify the quality of skills of surgeons, using the new innovative laparoscopic fundoplication model with an objective evaluation system.

Materials and methods

A new innovative laparoscopic fundoplication model with a surgical skill validation system

We developed this evaluation model in collaboration with Kyoto Kagaku Co., Ltd. We developed a 1-year-old infant body model (body weight: 10 kg) based on computed tomography (CT) data and reproduced a pneumoperitoneum body model based on the clinical situation (Fig. 1A). The esophageal crura unit was made as a detachable sheet (5 cm $\times$ 5 cm rubber sheet) and consisted of two layers that had a 3.0 $\times$ 1.5 cm spindle-shaped hole (Fig. 1B). Stomach, liver, and spleen were made of styrene materials ($C_6H_5CH{=}CH_2$), and physical proportions of the organs were derived from three-dimensional imaging of CT scan of the human data. These artificial organs were placed in the pneumoperitoneum model and covered with synthetic skin (Fig. 1C).

Two trocars were placed on the right and left side of the umbilicus. The abdominal esophagus of the stomach model was constructed through the hole of the thoracic side and fixed. The left lobe of the liver was retracted with V-shaped suturing, so the operative field was reproduced based on the clinical situations. The scope was 5 mm in diameter and fixed at 30° by an arm.

The AURORA® was used as the three-dimensional position measuring instrument (Northern Digital Inc., Ontario, Canada) and was placed at the thoracic side of the model to record the tracing of the tips of the forceps (Fig. 1D). The right and left forceps had sensors mounted on the tips, and their paths were traced on a computer with an electromagnetic tracking system that has been reported previously (Fig. 1E) [5]. This system consists of sensor coils, a field generator, a system control unit, and a sensor interface unit that uses an electromagnetic measuring technology designed for applications requiring precise, real-time, and spatial measurements.

The image of Nissen's wrap was captured by a USB camera that was connected to a personal computer and analyses of the symmetry of the placement of the sutures using the suture evaluation software. This model can only assess the suture ligature of wrap making in procedures of laparoscopic fundoplication (Fig. 1F).

Study participants

The examinees were divided into three groups, which included pediatric surgery experts (PSE), pediatric surgery trainees (PSN), and general surgeons (GS). The expert pediatric surgeon group included 15 pediatric endoscopic surgeons that were either certified by the ESSQ system or corresponded to the same skill level. The trainee group included 24 trainees who were specializing in pediatric surgery but had not experienced <50 cases of endoscopic surgery in a year. The ten general surgeons were participants of the 27th Annual Congress of Japanese Society of Endoscopic Surgery 2014. Only one expert pediatric surgeon was left-handed, and the other surgeons were right-handed.

Tasks for participants

The participants had to perform Nissen fundoplication using three suture ligatures for intracorporeal knot tying (Fig. 2). Based on study participants, especially general surgeons, and past report [12], we set a 5-mm needle driver as the right forceps and a 5-mm Maryland-type forceps as the left forceps (Karl Storz, Tuttlingen, Germany). The suture material used was the SH-1 curved needle with 15 cm black silk (Ethicon Endosurgery, Cincinnati, USA) for each suture ligature. We set after completion of task, and each of the participant's skills was evaluated using objective assessment points.

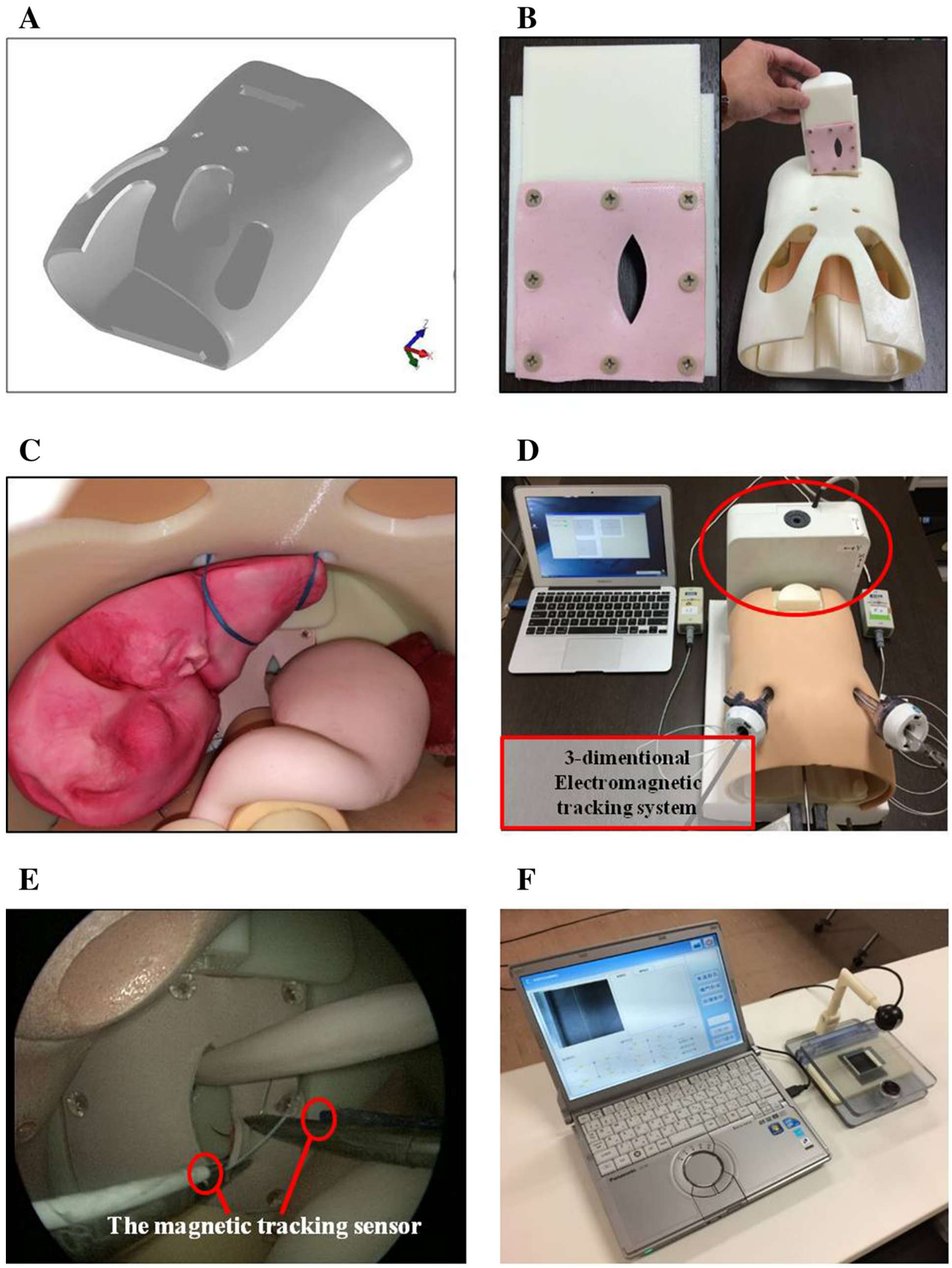

Fig. 1 Laparoscopic fundoplication simulator with endosurgical skill validation system. **A** 3-dimensional image of the pediatric pneumoperitoneum body model, **B** the pneumoperitoneum body model and the detachable crura sheet with a 3.0 × 1.5 cm spindle-shaped hole, **C** laparoscopic view: stomach, spleen, and retracted liver were placed in pneumoperitoneum model, **D** the overview of the 3-dimensional position measurement instrument of the electromagnetic tracking system, **E** the tracking sensor which was mounted on the tips of forceps, and **F** the overview of the image analysis system using a USB camera connected to a computer

The assessment points

The assessment points were as follows, improving upon the methods previously reported by Uemura et al. [11]:

1. Time required to complete the task
   The required time, which was defined as the performance time from the start to completion of task, was measured in seconds.
2. Suturing balance of the right and left side in making 3 ligatures
   The suturing balance was measured by an image analysis software using a USB camera connected to a computer (Fig. 1F) in task. The sum of the bilateral gap in each suture ligature ($|a - a'| + |b - b'| + |c - c'|$, Fig. 3) was calculated and evaluated as the symmetry of the placement of the sutures. The result of this assessment point determined that a smaller gap was superior.
3. Suturing interval between 3 ligatures in wrap construction
   The suturing interval of first and second and those of second and third were measured by an image analysis software using a USB camera connected to a computer (Fig. 1F). The gap of the suturing interval was

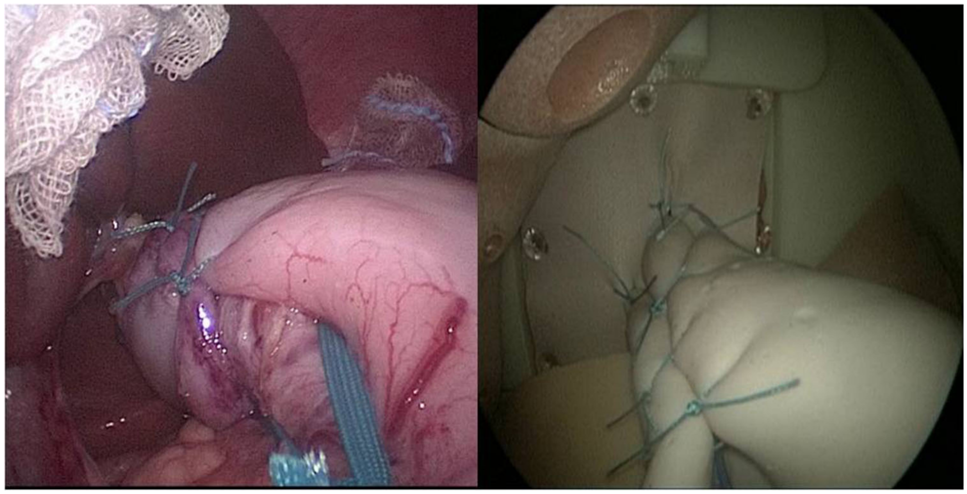

Fig. 2 Comparison of the clinical image and our laparoscopic simulator view. Task: construction of the Nissen fundoplication

measured (|d − d′|, Fig. 3). The result of this assessment point determined that a smaller gap was superior to the pitch of wrap suturing, which was measured in task. This value was monitored by the image analysis system connected to a PC.

4. Sum of the total path length of the forceps
   The total path length of the forceps was considered to be the total spatial movement measured in millimeters (mm) in task.
5. Average velocities of both forceps tips
   The average velocities of each tip of the forceps were measured using the AURORA system and defined as the velocities for each 0.05 s in task.

Statistical analysis

All data were expressed as the mean ± standard deviation. Two-tailed paired and unpaired Student's *t* tests were conducted to compare results from the experts and the novices using the JMP® 11.0 statistical software program (SAS Institute Inc., Cary, NC, USA). All data were defined as statistically significant at p values < 0.05.

Results

The assessment points

All forty-nine participates completed the task, and the results of the skill evaluation were shown as follows:

1. Comparison of the time required to complete the task.
   The time required to complete task in PSE, PSN, and GS were 515 ± 120, 888 ± 307, and 562 ± 156 s, respectively (Fig. 4A). The time for PSE and GS was significantly shorter than PSN ($p < 0.01$, $p < 0.01$).
2. Comparison of the suturing balance in task.
   The right and left side suturing balance of wrap was measured and calculated the sum of the gap in each suture ligatures in task (Fig. 4B). The sum of the gaps of the right and left side balance in PSE, PSN, and GS was 3.23 ± 1.37, 5.08 ± 3.22, and 5.52 ± 1.69 mm, respectively. PSE group's result was superior to those of the PSN ($p < 0.05$) and GS ($p < 0.01$).
3. Comparison of the suturing interval between three ligatures in wrap construction.
   The interval of three wrap sutures was measured in task (Fig. 4C). The sum of the gap of the suturing interval of PSE, PSN, and GS groups was 1.27 ± 0.73, 1.34 ± 1.24, and 1.32 ± 0.97 mm, respectively. There is no significantly difference between the groups.
4. Comparison of the sum of the total path length of both forceps and comparison between the right and the left hand.
   The sum of the total path lengths of both forceps in task was 21,110 ± 4137, 33,029 ± 10,305, and 27,943 ± 5673 mm in PSE, PSN, and GS, respectively. The PSE group required significantly shorter path lengths than the PSN ($p < 0.01$) and GS ($p < 0.01$) in Fig. 5A.
   The total path length of the right and left forceps was 9850 ± 2079 and 11,259 ± 2512 mm in PSE, 15,396 ± 5461 and 17,633 ± 5187 mm in PSN, and 12,899 ± 2452 and 15,045 ± 3728 mm in GS, respectively (Fig. 5A). There was no significant difference related to the dominant hand in each groups.
5. Comparison of the average velocities of right and left forceps
   The average velocities of the right and left forceps were 30.0 ± 6.22 and 26.3 ± 5.43 mm/s in PSE, 28.1 ± 5.89 and 24.0 ± 4.84 mm/s in PSN, and 37.3 ± 5.19 and 32.8 ± 8.69 mm/s in GS,

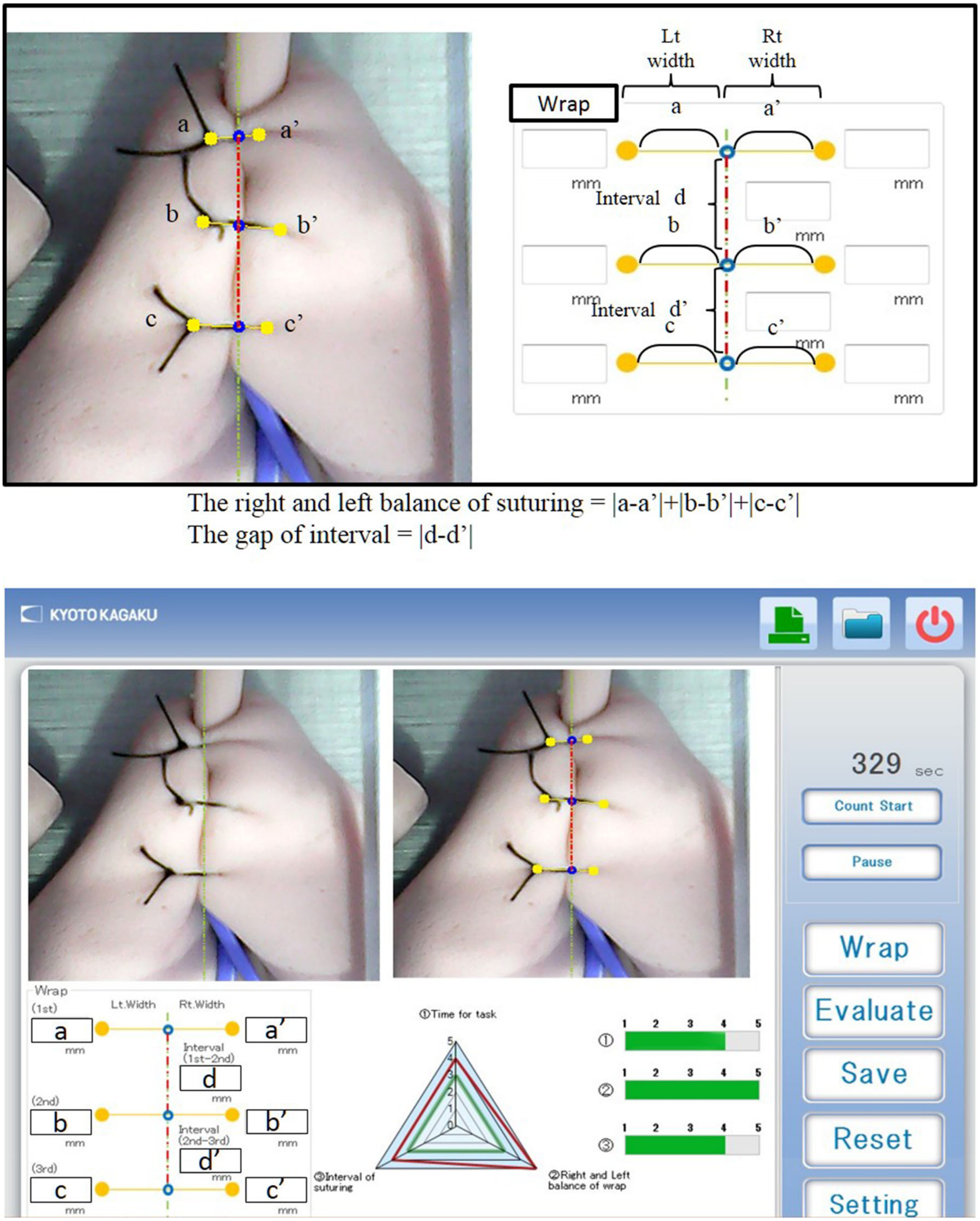

Fig. 3 The sum of the gap of the *right* and *left* widths of suturing and the gap of the suturing interval was calculated (**A**). The monitor view of the suturing balance analysis (**B**)

respectively(Fig. 5B). The average velocities of both forceps in GS were significantly faster than both those of PSE ($p < 0.01$) and PSN ($p < 0.01$). In PSN, the average velocities of the tips of the right forceps (dominant hand) were significantly faster than those of the left forceps in task ($p < 0.05$).

Discussion

The purpose of this study was to validate and analyze our new objective evaluation system for endoscopic surgical skills for surgeons that included expert pediatric surgeons, pediatric surgeon trainees, and general surgeons, by using a

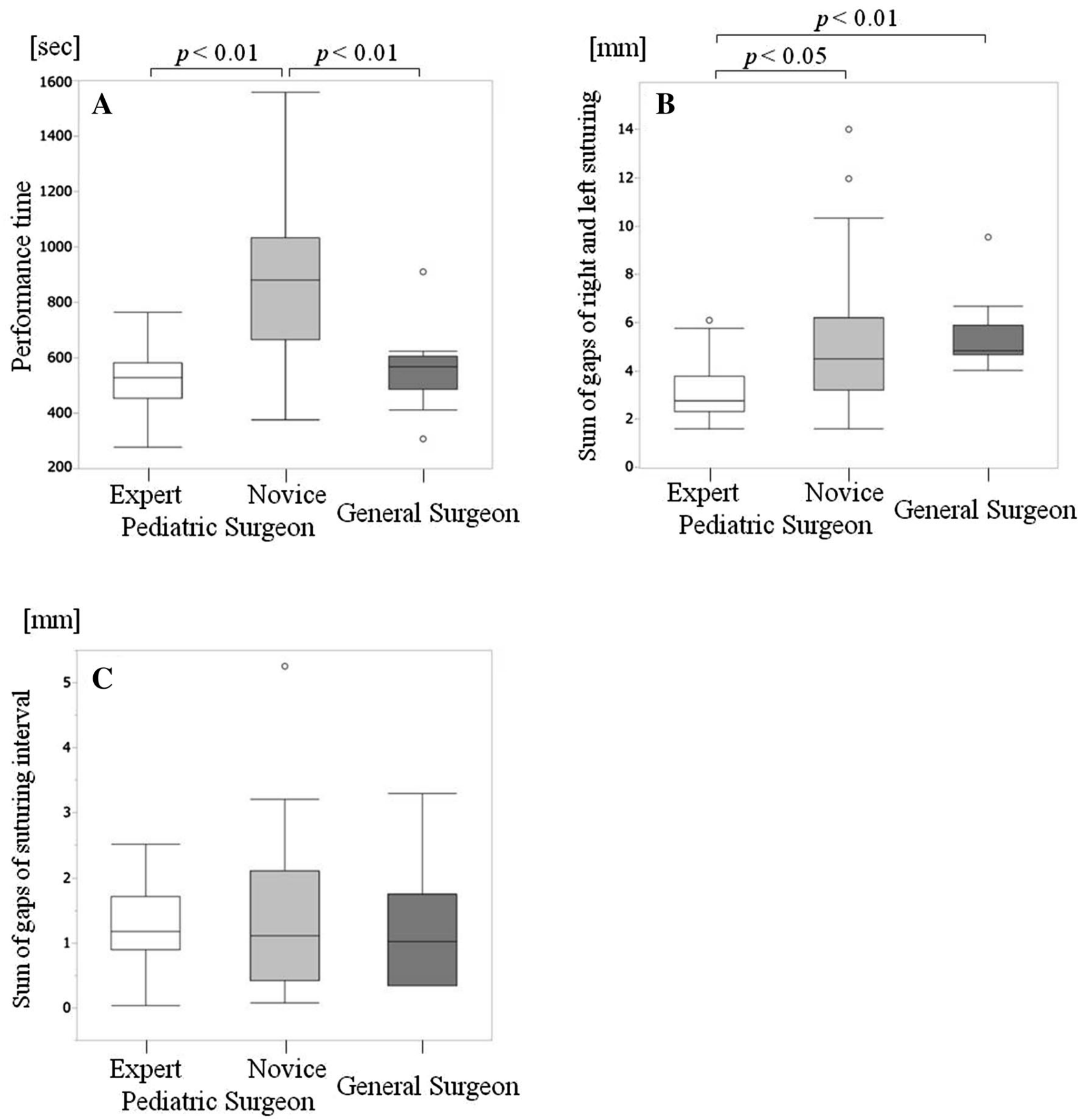

Fig. 4 Comparison of the performance among the pediatric surgery expert, the pediatric surgery novices, and the general surgeons. **A** Performance time required to complete the task. The time required to complete task in PSE, PSN, and GS was 515 ± 120, 888 ± 307, and 562 ± 156 s, respectively. The time for PSE and GS was significantly shorter than PSN. **B** The sum of gaps of right and left suturing widths. The right and left side suturing balance of wrap was measured and calculated the sum of the gap in each suture ligatures in task. The sum of the gaps of the right and left side balance in PSE, PSN, and GS was 3.23 ± 1.37, 5.08 ± 3.22, and 5.52 ± 1.69 mm, respectively. PSE group's result was superior to those of the PSN and GS. **C** The sum of gaps of suturing interval between 3 ligatures in wrap construction. The pitch of 3 wrap suture was measured in task. The sum of the gap of the suturing interval of PSE, PSN, and GS groups was 1.27 ± 0.73, 1.34 ± 1.24, and 1.32 ± 0.97 mm, respectively. There is no significantly difference between the groups

new laparoscopic fundoplication model. We used five assessment points to evaluate the endoscopic surgical skills of the participants by improving our previous report [11]. The major findings of the present study are as follows:

1. We developed a fundoplication simulator with the pneumoperitoneum model, which was used for objective assessment of endoscopic surgical skills. No relevant papers were found in the literature search, and this is the first report to validate the endoscopic surgical skill of both pediatric surgeons and general surgeons.
2. Based on the data from our study participants, PSE was superior to PSN in almost all assessment points, except for the sum of the gap of suturing interval in task.
3. The time for task was not significantly different between PSE and GS, but the total path length of

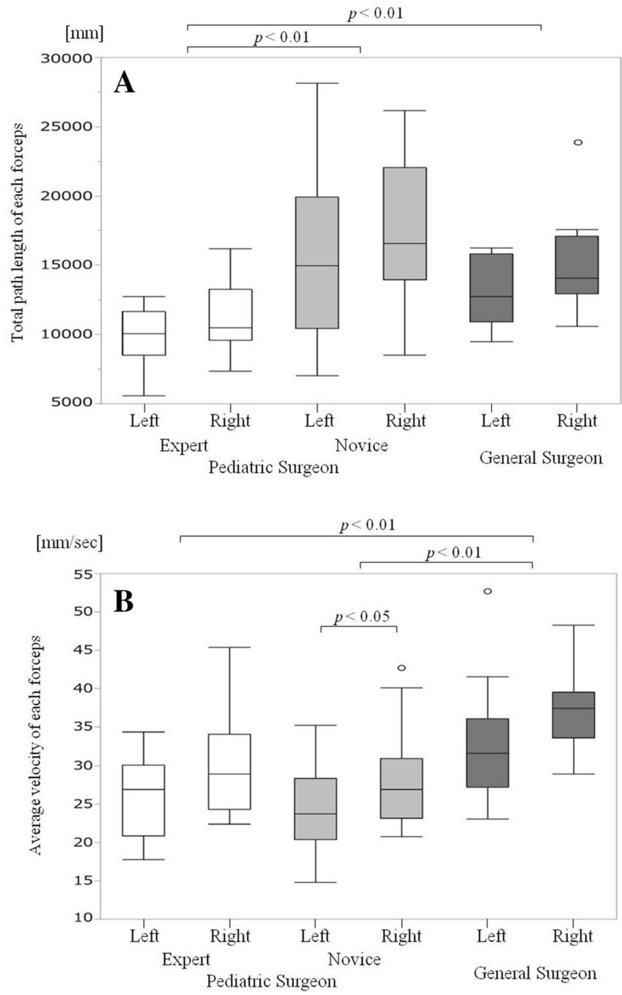

Fig. 5 Comparison of the total path length and the average velocity for task. **A** The sum of the total path length of each forceps. The total path lengths of sum of both the forceps in task 2 were 21,110 ± 4137, 33,029 ± 10,305, and 27,943 ± 5673 mm in PSE, PSN, and GS, respectively. The PSE group required significantly shorter path lengths than the PSN and GS. Each path length of the right and left forceps was 9850 ± 2079 and 11,259 ± 2512 mm in PSE, 15,396 ± 5461 and 17,633 ± 5187 mm in PSN, and 12,899 ± 2452 and 15,045 ± 3728 mm in GS. **B** The average velocities of right and left forceps. The average velocities of the each tip of the right and left forceps were 30.0 ± 6.22 and 26.3 ± 5.43 mm/s in PSE, 28.1 ± 5.89 and 24.0 ± 4.84 mm/s in PSN, and 37.3 ± 5.19 and 32.8 ± 8.69 mm/s in GS. In PSN, the average velocities of the tips of the right forceps (dominant hand) were significantly faster than those of the left forceps in task. The average velocities of both forceps of the GS were significantly faster than both those of PSE and PSN

PSE in task was significantly shorter than that of the GS group.

4. In PSN, the average velocities of the right forceps, which were the dominant hand, in task were significantly faster than those of the left forceps, which were the non-dominant hand.
5. Instead of the average velocity of GS was most fast, GS required the similar time as PSE group and required a longer total path length for tasks.
6. PSE was superior to other groups with regard to the symmetry of the suturing points of Nissen construction in task.

Both PSE and GS manipulate right and left forceps equally. The PSE required the shortest time and path length in task, and they performed superior balance of suturing in Nissen construction in task. On the other hand, the GS groups manipulated both forceps the fastest, but they need the longer path length compared with PSE. This result suggested that the PSE can manipulate forceps compactly and efficiently in the small working space of our pediatric laparoscopic models. Conversely, GS could not adapt to the narrow operative field and performed the large and rapid motion of both forceps in the constrained operative field for the first touch of our models. The PSN group had significantly worse results with regard to time for tasks, total path length, and the suturing balance. But PSN was not significantly different with regard to the average velocity of forceps compared to the PSE group. The PSE group required the shortest total path length, but they did not need the rapid motion of both forceps and time for tasks. These data mean that the PSE group performed more accurate and economical motions of the forceps regardless of the velocity of forceps, as was reported in our previous study [8]. The PSN group tended to use the dominant (right) hand because the tasks required the operators to use sutures and the PSN group was not familiar with suturing. A possible explanation is that junior residents who are not usually as efficient at coordinating efforts between their 2 hands may be neglecting their nondominant hand, thus giving a falsely improved time and suturing balance. In fact, the expert group could not only perform a faster and more precise operation, but also had excellent coordination for both hands. We have already reported the results of which compared the findings between the expert pediatric surgeons and the novice pediatric surgeons, using an objective endoscopic surgical skill assessment system [8]. But our research results also compared the findings between pediatric surgeons and general surgeons.

Surgical training using a simulator has spread widely this last decade. The acquisition of this new technique and facilities equipped with new instruments and technological devices is crucial for performing a safe and effective operation. Many studies have assessed simulation for basic laparoscopic skills, such as inguinal hernia repair and cholecystectomy [13], and basic surgical training has proven its positive impact on basic skills during real laparoscopic procedures in patients [5]. The next step of laparoscopic training is to train complex procedures along with a clinical situation, which are required for the advanced endoscopic skills and include a feedback system.

Training models may be inanimate, such as video trainers, virtual reality, and augmented reality simulators, as well as live animals or cadavers [14, 15]. Currently, animal tissue models, especially porcine, are used regularly in skills centers to train for laparoscopic procedures, such as the Nissen fundoplication, outside the clinical setting. The animal organs are prepared and preserved until they are used for practice. However, the animals providing the organs usually are specially bred for these purposes and are therefore expensive. Consequently, these models are associated with some limitations, including their expensive cost, limited quantity for training, and reasons pertaining to animal protection. Furthermore, live tissue models and tissue organ models cannot be used repeatedly. Therefore, these animals are not used frequently. In addition, porcine models cannot be used for training due to religious reasons. So we developed the innovative artificial fundoplication model with objective evaluation system, which was regarded as a repeatable training tool for the laparoscopic Nissen fundoplication procedure. To the best of our knowledge, our simulator with an objective endoscopic skills evaluation system was the first such system to be reported according to the systematic review reported by Beyer-Berjot et al. [14]. The aim of the developed simulator is to train repeatedly, help trainees and acquire the endoscopic skills, by trainees and to decrease the learning curve, and to provide teach safe implementation during real live operations in the OR.

In the USA, the fundamentals of laparoscopic surgery (FLS) program was introduced in 2004 by the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) as an endoscopic surgical training program unique to laparoscopic surgery. Since then, this program has been available through the SAGES and the American College of Surgeons (ACS) and has become the most well-known training program for laparoscopic surgery in the USA [16, 17]. The FLS program is very simple and can adequately evaluate the surgeon's skills, but does not have a feedback system [18]. The importance of objective feedback about the training has received limited attention in the current literature [19]. Young trainees have limited endoscopic surgery training time, and there are only a few systematic curriculums for endoscopic surgery. We apply new tools for the training and acquisition of endosurgical basic and advanced skills. Therefore, to evaluate an individual's endoscopic surgical skills, an objective evaluation system that has appropriate feedback for the surgeons would be ideal [13, 20]. The main aspects of evaluation should concentrate on how the task is completed and how the training is more effective rather than how fast the task is completed. This form of training suggests an effective acquisition of both basic and new endoscopic skills.

We herein established a disease-specific skill evaluation system and used it for feedback for trainees to acquire new endoscopic surgical skills. This laparoscopic fundoplication model of gastroesophageal reflux would be suitable for basic and advanced skill evaluations, including the bi-hand coordination and suture ligature of Nissen construction. In the clinical cases, early learning experiences may be associated with a higher rate of intraoperative and postoperative complications. Various factors may influence the length of a learning curve and its consequences to patients. In the case of Nissen fundoplication, experienced supervision should be sought by surgeons beginning laparoscopic fundoplication during their first 20 procedures. When individual experiences are examined, it is apparent that problems are most likely to occur during the first five procedures performed by individual surgeons [21]. Our model is useful for specific training of individual surgeons and providing effective feedback to the trainee; these training approaches may reduce the learning time and increase the possibility of safety.

In conclusion, this study revealed that PSE possessed economical and accurate skills using our Nissen fundoplication model. The PSE had not so rapid motion of the forceps, but excellent bi-hand coordination. GS had the excellent bi-hand coordination and most rapid skills, but their skills may be inefficient and risky movement of forceps in the small working space such as neonate and infant. Our model validated the quality of the endoscopic surgical skills and showed that there were heterogeneous differences among PSE, PSN, and GS. Our next step is to investigate the effectiveness of this Nissen fundoplication model as a training model for pediatric surgeons and clarify whether this model is effective as a feedback system.

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Compliance with ethical standards

Disclosures Takahiro Jimbo, Satoshi Ieiri, Satoshi Obata, Munenori Uemura, Ryota Souzaki, Noriyuki Matsuoka, Tamotsu Katayama, Kouji Masumoto, Makoto Hashizume, and Tomoaki Taguchi declare that they have no conflict of interest or financial ties to disclose.

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