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A simulated training model for laparoscopic pyloromyotomy: Is 3D printing the way of the future?☆

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ABSTRACT

Background: Hypertrophic pyloric stenosis (HPS) is a common neonatal condition treated with open or laparoscopic pyloromyotomy. 3D-printed organs offer realistic simulations to practice surgical techniques. The purpose of this study was to validate a 3D HPS stomach model and assess model reliability and surgical realism.
Methods: Medical students, general surgery residents, and adult and pediatric general surgeons were recruited from a single center. Participants were videotaped three times performing a laparoscopic pyloromyotomy using box trainers and 3D-printed stomachs. Attempts were graded independently by three reviewers using GOALS and Task Specific Assessments (TSA). Participants were surveyed using the Index of Agreement of Assertions on Model Accuracy (IAAMA).
Results: Participants reported their experience levels as novice (22%), inexperienced (26%), intermediate (19%), and experienced (33%). Interrater reliability was similar for overall average GOALS and TSA scores. There was a significant improvement in GOALS ($p < 0.0001$) and TSA scores ($p = 0.03$) between attempts and overall. Participants felt the model accurately simulated a laparoscopic pyloromyotomy (82%) and would be a useful tool for beginners (100%).
Conclusion: A 3D-printed stomach model for simulated laparoscopic pyloromyotomy is a useful training tool for learners to improve laparoscopic skills. The GOALS and TSA provide reliable technical skills assessments.
Level of Evidence: II.

Infantile hypertrophic pyloric stenosis (IHPS) is the most common cause of neonatal emergent surgery, affecting between 1 and 4 in 1000 live births [1–4]. IHPS affects males more than females (4:1) and is often diagnosed within the first 2 to 8 weeks of life, after the baby presents with increasing nonbilious vomiting, a palpable pyloric tumor, and visible peristaltic waves [4–7]. Symptoms arise because of hypertrophy of the pyloric muscle causing narrowing of the pyloric channel, resulting in gastric outlet obstruction [4]. The etiology, while associated with some genetic, environmental and mechanical factors, is not fully understood [4,8].

Ramstedt performed the first extramucosal pyloromyotomy in 1912 while the first laparoscopic pyloromyotomy was described in 1991 [4,9,10]. Both open and laparoscopic procedures are used to treat IHPS. A prospective randomized trial by St. Peters et al. [11] showed no difference in operating or recovery time, but fewer complications and better cosmetic results for laparoscopic pyloromyotomy. Furthermore, Alain et al. [10] found laparoscopic pyloromyotomy to lower abdominal-wall complications when compared to open surgery in low-weight and extremely ill infants. However, there is a learning curve associated with laparoscopic pyloromyotomy [7,12,13]. Oomen et al. [13] reported a drop in complication rate from 21.1% to 3.5%, and a drop in major complications from 10.4% to 1.7% in laparoscopic pyloromyotomy after a learning curve was achieved. Plymale et al. [14] experimented with a middle fidelity model of pyloric stenosis and found it to significantly improve technical skills related to laparoscopic pyloromyotomy. Simulation is increasingly required to develop competence in advanced laparoscopic skills owing to limited OR time, financial constraints, and ethical considerations.

Conflicts of Interest: Dr. Quantz is the founder of Simply Simulators, who provided the 3D printed neonatal stomachs.

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The purpose of this study was to evaluate the use of a 3D infant hypertrophic pyloric stenosis model as an educational tool for surgical residents. 3D printing is a relatively new technique allowing for customizable models to be made from either scanned data or software built schematics. We hypothesized that participant's laparoscopic skills would improve with repeated pyloromyotomies.

1. Materials and methods

1.1. Materials & tissue synthesis

The initial design was developed using CAD software. Prototypes of rigid polylactic acid were generated using a Lulzbot TAZ4 3D printer (Aleph Objects Inc., Colorado, USA). After finalizing the design, serial molds were generated using the CAD software for both the mucosa and body of the stomach followed by 3D printing. The mucosa was formed with tin cure silicone rubber (Smooth-On Inc., Pennsylvania, USA) using the first mold. The mucosa was then transferred to a second mold where an additional polymer, closely mimicking gastric tissue, was added to create the two layered model. The use of CAD software for model development combined with 3D printing of the molds provided a custom, realistic, reproducible and inexpensive model (approximate cost $30/stomach).

1.2. Model testing

After IRB approval (#106945), medical students, general surgery residents, and adult and pediatric general surgeons were recruited from a single center. Medical students were included since they are true novice learners. Consent was obtained from each participant who was then assigned an anonymous number. Each individual then viewed a short video outlining the key aspects of laparoscopic pyloromyotomy (LP) (https://www.youtube.com/watch?v=RkCLEaMCM8c - 4:00 to 6:33) [15]. The participant then performed a videotaped, laparoscopic pyloromyotomy 3 times using standard pediatric 3 mm laparoscopic instruments (Storz) and a box trainer containing a 3D printed pyloric stenosis model (Fig. 1). A voluntary survey was then completed by each study subject using the Index of Agreement of Assertions on Model Accuracy (IAAMA).

1.3. Procedure evaluations

After all participants involved in the study had carried out their three attempts, three independent reviewers, blinded to the participant's name and experience level, graded each participant's LP techniques using the previously validated Global Operative Assessment of Laparoscopic Skills (GOALS) and Task Specific Assessments (TSA) [16]. Scores for GOALS had a maximum value of 25, while the TSA had a maximum value of 3 (Figs. 2 & 3).

1.4. Analysis

The time-based data and the data collected from the GOALS and TSA assessments did not meet the normality assumption and required the use of the Kruskal Wallis ranked sums test as a substitute to the repeated measures ANOVA. All categorical variables (e.g., IAAMA) were analyzed using chi-square tests. The two-tailed alpha level for these tests was set at 0.05 to determine significant differences. All statistical analyses were performed using SAS Software (version 9.4).

2. Results

A total of 27 participants completed the study: 4 medical students, 18 general surgery residents, 3 adult general surgeons, and 2 pediatric surgeons. Of these participants, 6 self-reported as novice with no minimally invasive surgery (MIS) experience, 8 reported being inexperienced (<10 MIS cases), 4 as intermediate (20–50 MIS cases), and 9 as experts (>50 MIS cases). The three consecutive attempts by each participant on the 3D model were evaluated by three reviewers for the GOALS assessment and two reviewers for the TSA assessment. GOALS scores did not significantly differ overall ($p = 0.5643$) or between the three trials for all 3 raters (Table 1). The average TSA scores were also similar

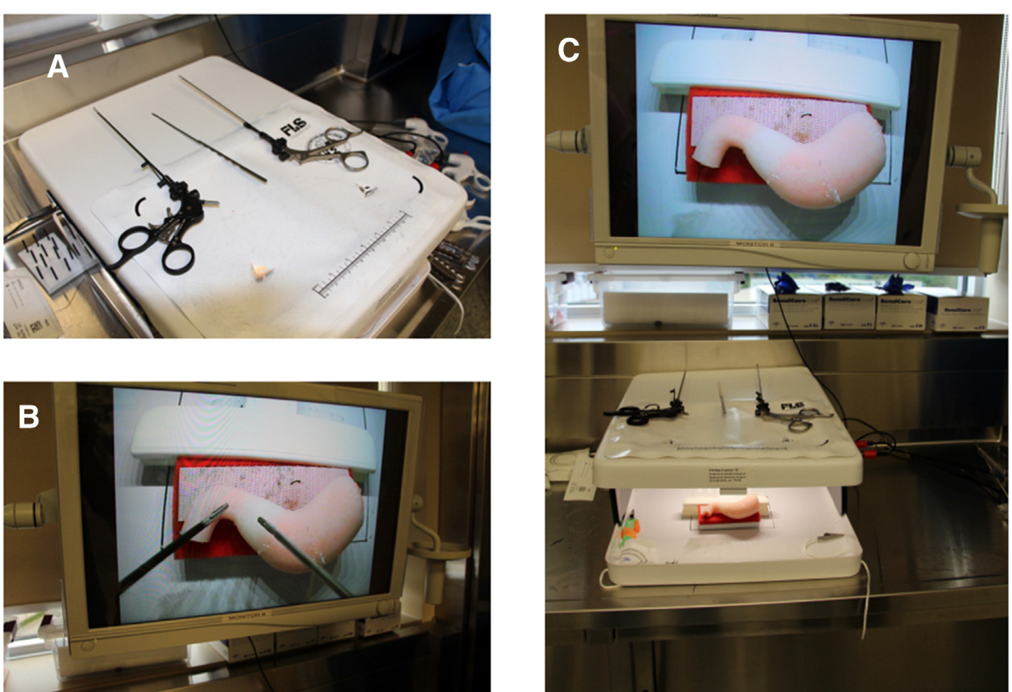

Fig. 1. 3D printed stomach model box trainer. A. Pediatric laparoscopic 3mm instruments (atraumatic grasper, pyloric spreader [both Storz] and pyloric knife), shown on top of adult laparoscopic box trainer. B. Screen view of 3D printed neonatal pyloric stenosis model with instruments in use (overlying pylorus muscle). 3D printed stomach is held in place by silk suture to backing. C. Complete model, as used by participants.