RESEARCH ARTICLE

Validity of a Soft and Flexible 3D-Printed Nissen Fundoplication Model in Surgical Training

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Abstract: Rapid development of three-dimensional (3D) printing technique has enabled the production of many new materials for medical applications but the dry laboratory surgical training model made of soft and flexible materials is still insufficient. We established a new 3D-printed Nissen fundoplication training model of which materials simulate the real mechanical properties. In this study, 16 participants were divided into two groups: Experimental group and control group. The validity of model was tested using Likert scale by the experts and the experimental group. To evaluate the efficacy, performances of the experimental group were scored at the first, fourth, and eighth training by OSATS system and the duration of procedure was compared through the use of recorded video. Meanwhile, an *ex vivo* model was used to compare the performance of the experiment group and control group after the training in the same way. Our results showed that the 3D-printed model can support the future surgical applications, help improve surgical skills, and shorten procedure time after training.

Keywords: 3D-printed model; Nissen fundoplication; Surgical training; Soft materials

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1. Introduction

Three-dimensional (3D) printing is a technique that could enable the production of anatomically matched or patient-specific device and allow high on-demand fabrication of products for medical application in highly cost-effective manner[1]. Highly accurate products derived from patient's radiological imaging data were reportedly used in pre-operative planning, counseling with patients, training of students and residents, surgical training, intraoperative navigation, and templates or guides for specific task[2]. 3D-printed models range from hard tissues such as bones to soft-tissue structures such as heart, liver, lung, and vasculature are used in surgical simulation for different surgical procedures training. Compared to studies about hard tissues, however, studies about 3D-printed soft tissue for surgical training are scarce. Unlike fabrication of hard tissue, simulations using soft tissues are limited by the simulation of mechanical properties, which vary between organs or individuals[3,4]. There are several types of methods in 3D printing available for soft-tissues fabrication, including material extrusion (fused deposition modeling and [FDM] and direct ink writing), vat photopolymerization (VP), material jetting, and powder jet fusion[4,5]. Different printing materials and techniques are chosen depending on their benefits and limitations, especially in 3D bioprinting area, considering that the unique living or bioactive materials (bioink) used and the type of methods used are usually determined by the desired materials[6]. Various requirements, including appearance similarities, mechanical properties similarities, and simulations of true organ environment, should be taken into consideration when researchers or companies select the appropriate printing strategies[7]. As one of the methods used in early phase, material jetting is low cost and has high printing speed, but this technique demands high criteria and standards for bioinks used, especially in viscosity and clotting issue. Material extrusion, a process driven by pressure, allows the use of viscous liquid, such as cell suspension at a high density, but has a relatively slow printing speed and low resolution. Powder jet fusion was also an economic choice for fast and stable printing of soft tissue, while may more effort in post-processing modification is needed due to residual powder that leads to low surface accuracy and deficient structure. VP, including stereolithography, digital light processing, and two-photon polymerization, allows a relatively quick and precise fabrications of sophisticated internal or external anatomical structures[8-11]. Polyurethane, silicone gel, and hydrogels are some of the most commonly used materials in soft-tissue printing. Polyurethane can be combined with other hydroxyl or amine polymers, offering a changeable designation of chemical backbone, which can achieve different mechanical performances, but these can be a concern of toxicity and flammability. Despite low solubility in other solvents, silicone gel is widely used in industry because of its excellent elasticity and resilience, chemical stability, thermal and electrical resistance, biocompatibility, and low permeability compared with other polymer systems. Hydrogel is an attractive material used in medications attributed to its capability of absorbing and desorbing solvents in response to its environment; however, this property of absorbing and desorbing solvents depends on restricted environmental conditions, such as low humidity. With the availability of advanced materials and printing technique, there has been a growing number of surgical simulation models of soft tissues that are generated from different systems. The surgical models, including anatomical model and disease model, of liver and kidney are well-established; however, the studies on fabricating a stomach model are still scarce although researchers had attempted to simulate mechanical properties in an anthropomorphic gastric model[7,12,13]. The structures and organs in human have specific physical properties (for dissection), which differ from one other. For example, the texture of liver is softer than stomach, although they are both made of soft tissue. This should be considered in the process of creating an organ or disease model. Tissue response to surgical insults also should be considered. For example, the materials used should respond well during dissection by harmonic scalper[14].

Laparoscopic Nissen fundoplication (LNF) is a surgical treatment option for gastroesophageal reflux disease (GERD). GERD is a common disease with typical symptoms of acid regurgitation and heartburn, and complications including esophagitis, peptic strictures, and Barrett esophagus. The application of LNF requires high levels of expertise and training[15]. Developed by Dr. Rudolf Nissen, the use of LNF started as early as 1955 and was well established in Western countries, whereas at the same time, its application was still at its initial stage in China[16]. Relatively low prevalence (1.9–7%) in China coupled with delayed developments of surgical treatment of GERD had limited training or practicing opportunities of laparoscopic anti-reflux surgery for residents or attendings[17]. Nissen fundoplication was not included in the national textbook for medical college student until 2018; therefore, most of the Chinese students are unfamiliar about this surgical technique. Watching recorded video or direct observation of surgery are how most surgeons are trained but in the absence of practices.

Cadaver model, animal model, and *ex vivo* organ model are common wet laboratory models used in laparoscopic surgery training[14,18]. However, due to the concerns of high cost, social stress, and biosafety issue, the need for more proper alternatives to the wet laboratory models is emerging[19,20]. At present, animals such as swine, rats, or mouse are still the most widely used models for anti-reflux surgery training[21-23]. Therefore, a lack of alternative models for anti-reflux surgery has driven us to generate a new dry laboratory model. A 3D-printed pancreaticojejunostomy model for use in robotic-assisted surgery training was generated in our previously work[24]. To extend the application of 3D-printed model in surgical training, we designed a new LNF model with a curriculum that incorporates the key steps in Nissen fundoplication to address the key issues related to failure during LNF, and conducted a trial to estimate the validity and efficacy of this model[25].

2. Methods

2.1. Model establishment

(1) Mold print

Anonymized Digital Imaging and Communication in Medicine files were obtained using Mimic 23.0 system from 3D computed tomography scans of disease-free human esophageal-gastric fundus and extracted/remodeling anatomy models of esophagus, stomach, diaphragm, spleen, and surrounding tissues. STL file abstracted was imported to Magic 24. The model was repaired to obtain a watertight structure. Then, OBJ files were exported from Magic 24 and imported to Zbush for further modification. Mold designations were completed by NX 1899 and either positive mold or negative mold was designed depending on the shape of organs. The STL files of designed mold were imported to Magic 24 for further designation of support structure and positioning. Next, FDM 3D printer was used to print the mold based on the sliced data, which would be given surface treatment and support structure removement after printing.

(2) Model formation

Resembled mold was treated with Vaseline on the build face to ensure smooth removal of the models from the mold. Silicone gel was poured into the mold from vacuum bin and cured under 25°C for 1 h. Finally, a model was obtained by removing the mold after solidification. Additional changes after initial palpation (by percentages) of silicon oil in silicone materials were implemented to manually adjust the texture until all experts agreed on the texture of the model.

(3) Model properties

The silicone material used for the stomach was pink, with modulus of elasticity of 0.15 MPa and a tensile strength of 0.95 MPa. The silicone material used for diaphragm was red, with modulus of elasticity of 0.18 MPa and a tensile strength of 0.82 MPa. The 3D-printed box simulates the abdomen, with 2 mm perforated silicone gel for the placement of laparoscopy and 5 mm silicone gel layer simulating the abdominal wall. The printed organs inside the box include: (i) Diaphragm, simulated by a silicone gel of 3 mm layer, which was made into a curved shape to simulate the shape of crus in real surgery, coupled with a hole with 5 cm diameter through which the esophageal part of the stomach can be pulled, simulating the hiatal hernia; (ii) stomach; (iii) liver; and (iv) mesentery, the surrounding connective part of esophagus and stomach, attaching both side of curvature of stomach and linking diaphragm with the angle of His. In compliance with the suturing requirements, we used a square-shaped mesh during the simulation surgery and removed a U-shaped piece from the mesh. In this study, we assume that the model needs mesh and manual suture although it is optional in real situation **(Figure 1)**.

2.2. Criteria for selecting participants

The present study was approved by Zhejiang Provincial People's Hospital to carry out experiments within its facilities. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. All volunteers were PYG-3 residents from the standardized training program of general surgery department from June 2020 to March 2021. All selected participants had individually performed more than 30 laparoscopic cholecystectomy cases but never participated or preformed any laparoscopic fundoplication. Participants' performance was evaluated by two experts. Sixteen residents were assigned into the experimental group (n = 8) and control group (n = 8) based on their basic conditions, such as age, gender, and number of laparoscopic surgeries they have attended **(Table 1)**.

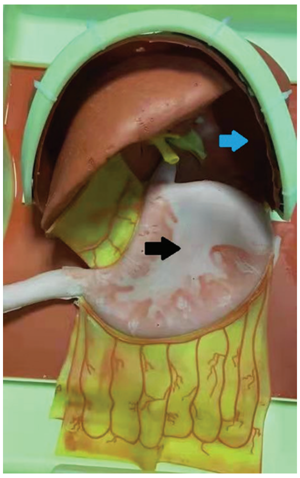

Figure 1. 3D-printed Nissen fundoplication training model. Blue arrow: Diaphragm; black arrow: Stomach.

2.3. Training curriculum

Operators were required to finish following steps: (i) Operators cut open silicone gel layer around the esophagus using ultrasonic scalpel to establish posterior esophagus tunnel **(Figure 2B)**; (ii) operators perform interrupted suture 2–3 times to close bilateral diaphragmatic crura with 2-0 non-absorbable Ethilon thread to close hiatal hernia **(Figure 2D-E)**; (iii) operators flatten the mesh and 6–8 suture on due spot for fixation of mesh on diaphragm **(Figure 2F-G)**; (iv) in Nissen fundoplication, operators

Table 1. General information of participants

	Experimental group	**Control group**	***P*-value**
Age	28.13	29	>0.9999
Gender	M (7/8), F (1/8)	M (7/8), F (1/8)	
Hand dominance	R (8/8), L (0/8)	R (8/8), L (0/8)	
PGY level	PGY-3 8/8	PGY-3 8/8	
Average no. of basic laparoscopic procedures	95.63	99.38	>0.9999
Average no. of intermediate laparoscopic procedures	0.25	0.375	0.5598
Average no. of advanced laparoscopic procedures	0	0	
Average no. of laparoscopic bariatric procedures	0	0	
Box training experience	Y (8/8) N (0/8)	Y (8/8) N (0/8)	
VR experience	Y (0/8) N (8/8)	Y (0/8) N (8/8)	
3D printing model experience	Y (0/8) N (8/8)	Y (0/8) N (8/8)	
Ex vitro animal experience	Y (0/8) N (8/8)	Y (0/8) N (8/8)	
Live animal experience	Y (0/8) N (8/8)	Y (0/8) N (8/8)	
Average no. of laparoscopic cholecystectomy (LC)	42.38	46.88	0.3113
Psychomotor skills (OSATS SCORE)	23.00	22.13	>0.9999
Average knowledge test score	8.125	8.625	>0.9999

M: Male; F: Female; Y: Yes; N: No; VR: Virtual reality.

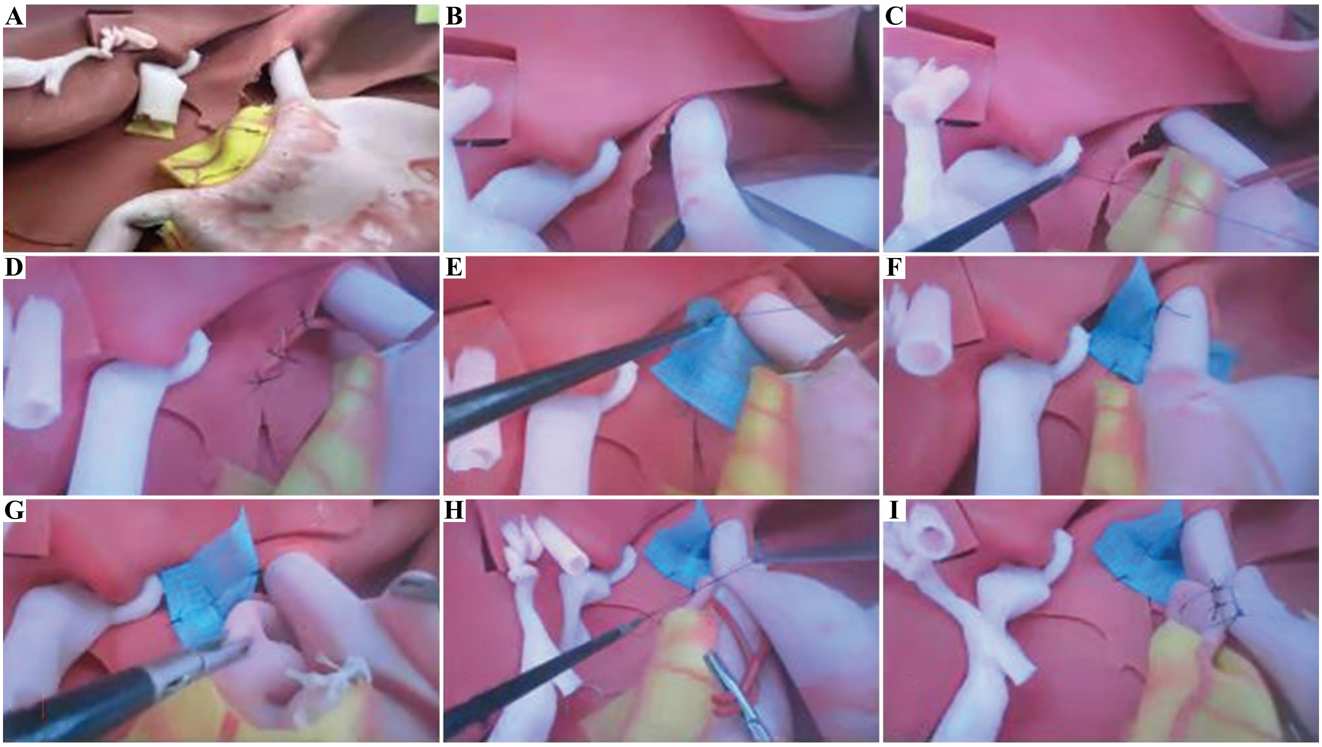

Figure 2. Model Nissen fundoplication procedure. (A) An overview of model under laparoscopy on simulation platform. (B) Established posterior esophagus tunnel. (C) Interrupted suture on hiatal hernia. (D) Enclosed hiatal hernia. (E) A step of placing mesh and fixation suture on diaphragm. (F) Fixed mesh. (G) Fundoplication through shoeshine maneuver. (H) Making a wrap using interrupted suture. (I) Forming a wrap.

incubate esophagus with 44F bougie tube and perform fundoplication through shoeshine maneuver of the fundus before making a ~3 cm wrap around the esophagus by 3–4 interrupted sutures **(Figure 2H-I)**.

2.4. Training method

Pathogenesis mechanism, symptoms, Nissen fundoplication, and surgical indications of GERD were introduced and explained to all participants at the beginning of the trial through recorded video. Questions from participants were answered by two experts. All participants were required to recap the surgical procedure and details after the introductory demonstration. No further training was given to control group in addition to their rotations. Participants in the experimental group were trained using the 3D-printed anti-reflux surgery model under a laparoscopic platform twice a week, and the training concluded after eight sessions. Videos were recorded for evaluation by two experts using OSATS score system.

2.5. Face validity and content validity

The validity of model was assessed using the 5-grade Likert scale by five experts and the experimental group (5: strongly agree; 4: agree; 3: neither agree nor disagree; 2: disagree; and 1, strongly disagree). This assessment involved nine parameters as follows: (i) The model is similar with real tissue or organ (experimental group skipped this parameter); (ii) the model is easy to use; (iii) using the model in surgical training is reasonable (experimental group skipped this parameter); (iv) training using the model can help reduce surgical risk to patient; (v) the model can help participants concentrate in learning; (vi) the model can help boost confidence in future surgery; (vii) the model can enhance tactile feedback; and (viii) the model is recommended for use in the training of anti-reflux surgery (experimental group skipped this parameter).

2.6. Construct validity

Performance of the experimental group was assessed by two experts who independently evaluated the recorded video using the global surgical and technical skills assessment tool (OSATS). Faces and voices of participants were not recorded in video. Seven aspects with five different levels each (35 points in total) were included in OSATS. The average of scores given by the two experts was the final score, and duration of the procedure was recorded at the same time.

2.7. Evaluation of efficacy of 3D model training

After 4 weeks of training, we compared the performances of laparoscopic anti-reflux surgery on *ex vivo* swine organs between two groups to assess the efficacy of model training **(Figure 3)**. Assessment method was the same as mentioned above.

2.8. Statistics analysis

In this study, *t*-test was used in parametric test. No non-parametric test was used in this study. SPSS 20.0.0 and GraphPad Prism 8.3.0 were used for statistical analysis and figure plotting. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Model assessment

The validity of the model used by the experimental group was assessed by experts **(Table 2)**. All experts confirmed that (i) the model organs or tissues are similar to the real ones, the model training for anti-reflux surgery is reasonable, and (iii) the model can be applicable to anti-reflux surgery. This model was considered easy to handle, able to reduce the risk to patient, and able to improve skill, boost confidence, and tactile feedback of participants.

3.2. OSATS score and procedure duration in different training sessions

All participants of the experimental group had successfully completed eight training sessions. OSATS score was increasing whereas the procedure duration was reducing as the training was progressing **(Figure 4)**. The OSATS score was improved and the procedure duration was shortened as the training progressed **(Table 3)**.

3.3. Model training validity and efficacy assessment

Participants of the experimental and control groups performed Nissen fundoplication on *ex vivo* swine organs after 8 weeks of training. All participants (eight out of eight) of the experimental groups successfully finished the surgery while six out of eight participants of the control group completed the surgery with the helps from experts. OSATS of the experimental group (26.25 ± 1.67) was higher than that of the control group (17.50 ± 2.07, $t = 9.31$). Procedure duration of the experimental group (76.25 ± 2.49) was lower compared to the control group (110.13 ± 3.36, $t = 22.92$) (**Table 4** and **Figure 5)**.

4. Discussion

In China, it is very common that surgeons learn how to perform laparoscopic anti-reflux surgery by watching video or observing during surgery. Furthermore, the lack of practice is attributed to very limited number of medical centers that are equipped to perform this type of surgery. Laparoscopic fundoplication is a expertise demanding procedure, and surgeons who perform laparoscopic fundoplication should be sufficiently trained given the

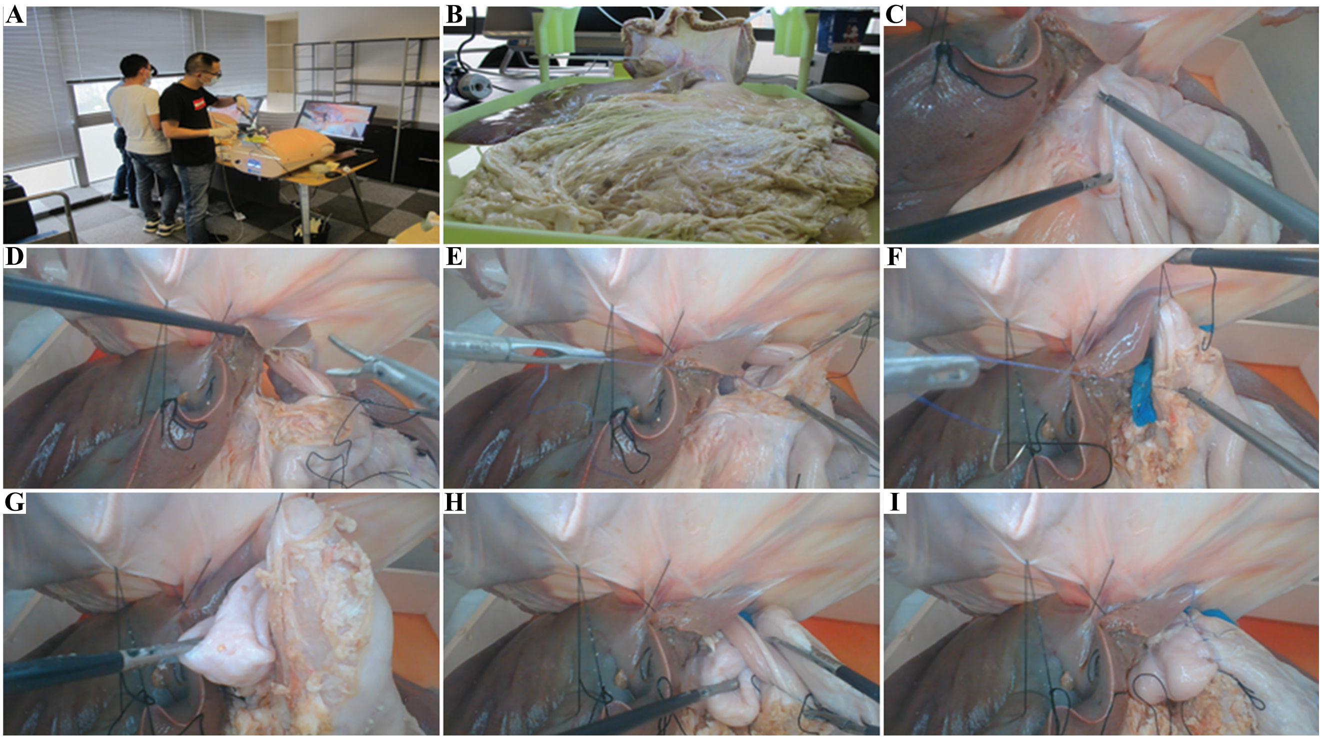

Figure 3. *Ex vivo* Nissen fundoplication procedure. (A) Participants were practicing on laparoscopic surgery platform. (B) *Ex vivo* swine organ. (C) Dissociation of lesser omental sac. (D) Establishment posterior esophagus channel. (E) Hiatal hernia closure. (F) Fixation mesh on diaphragm. (G) Fundoplication through esophagus. (H) Shoeshine maneuver. (I) Making a wrap using interrupted suture.

Table 2. Likert scale results of experts and experimental group

Parameters	Experts	Experimental group
The model is similar with real tissue or organ.	4.36±0.50	-
The model is easy to use.	4.52±0.50	4.24±0.12
Using model in surgical training is reasonable.	4.80±0.45	-
The model can help improve surgical skills.	4.28±0.08	4.76±0.16
Training using the model can help reduce surgical risk to patient.	4.36±0.23	4.66±0.11
The model can help participants concentrate in learning.	4.32±0.46	4.29±0.18
The model can help boost confidence in future surgery.	4.24±0.19	4.73±0.15
The model can enhance tactile feedback.	4.28±0.19	4.63±0.17
The model is recommended for use in the training of anti-reflux surgery.	4.80±0.45	-

Data are expressed as mean±standard variation.

anatomical complexities of esophagogastric junction, possibilities of disruption, herniation or slippage of wrap due to dynamical mechanical stress, and difficulty in reestablishment of anti-reflux barrier which prevents the wrap from being too tight or too loose[15]. Being unfamiliar with the key procedure during surgery can cause severe iatrogenic complications[26]. According to a study involving 2655 patients, 4.1% of patients developed complications within 30 days, including infection (1.1%), bleeding (0.9%), and iatrogenic esophageal perforation (0.9%). The recurrence rate of GERD was 17.7%[27]. Cadaver model or animal models are still the most commonly used training models for this procedure in China; however, these models are expensive and may raise ethical concerns, and thus, an alternative model for Nissen fundoplication training is now in a great demand in China[14,18].

3D printing is an appropriate alternative technique for fabricating models to be used in surgical training. 3D-printed products can be developed rapidly and become commonly used as biomaterials and applied in the fields of medicine and surgery[1,28]. Different types of surgical simulation models offer an economic-friendly way to multiple medical approaches[3]. However, despite significant progress, the mechanical simulation of soft tissue is not optimized yet, which greatly hampers its application in surgical training (for example, the mostly common techniques applied in surgery, such as suturing and dissecting). In our study, we attempted to generate a soft and flexible surgical training model for Nissen fundoplication procedure which considers

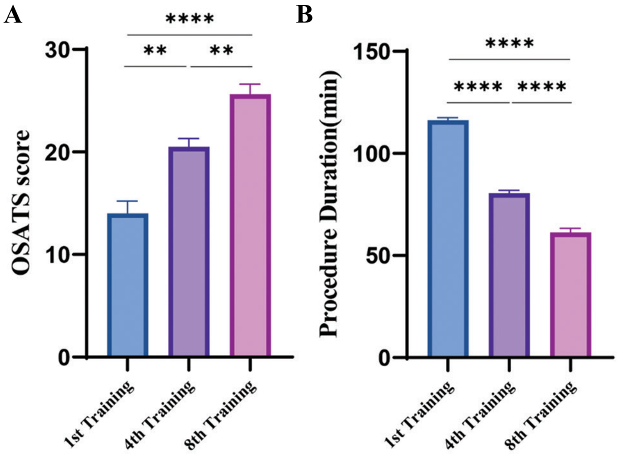

Figure 4. OSATS score and procedure duration of the experimental group in different training sessions. (A) OSATS score and (B) procedure duration (min) at the first training, fourth training, or eighth training. **$P < 0.005$, ****$P < 0.0001$.

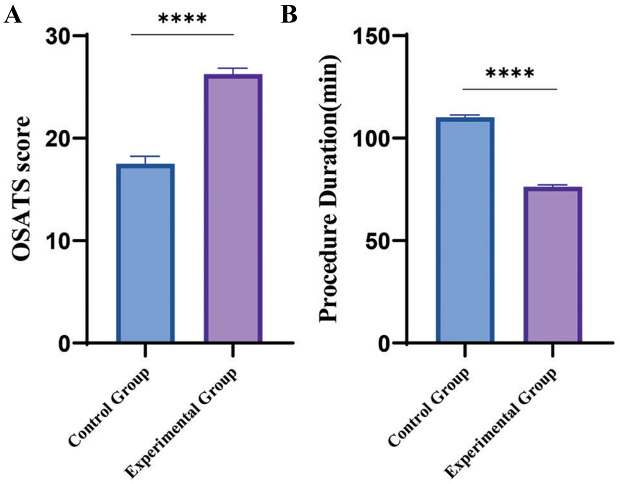

Figure 5. OSATS score and procedure duration of *ex vivo* Nissen fundoplication surgery. (A) OSATS score and (B) procedure duration (min) of the control group and experimental group. ****$P < 0.0001$.

Table 3. OSATS score and procedure duration in different training session

	First training	Fourth training	Eighth training
OSATS score	14.0±3.46	20.5±2.27[c]	25.63±2.77[a,b]
Procedure duration (min)	116.25±3.54	80.50±4.21[c]	61.25±5.95[a,b]

[a]$P<0.005$ compared to first training, [b]$P<0.0001$ compared to fourth training, [c]$P<0.005$ compared to first training. Data are expressed as mean±standard variation

not only the anatomical relations and resemblance to the original tissue or organ in appearance but also the mechanical properties. All organs used in our training curriculum are required to be soft and flexible, especially when fundoplication is performed. Thus, silicon gels were used to manufacture the model considering its excellent resilience and elasticity together with toxicity concern of polyurethane and strict ambient environment requirement for hydrogels[5]. Instead of performing a direct printing of the model, we chose to use an indirect printing method, which printed the mold by FDM in the first place that is relatively low cost and is able to manufacture the model in high throughput, considering that some of the molds could be reused for several times irrespective of the changes in materials and this method can be used in industrial productions in the future. Although several parameters related to the texture of the materials to simulate the organ tissue should be taken into consideration, it should be noted that the complex anatomical and histological aspects are not easy to be replaced in 3D printing, rendering the model imitation ineffective.

Table 4. OSATS score and procedure duration of *ex vivo* experiments

	Control group	Experimental group
OSATS score	17.50±2.07	26.25±1.67[a]
Procedure duration (min)	110.13±3.36	76.25±2.49[a]

[a]$P<0.0001$ compared to the control group.

3D-printed models are superior to the conventional animal models in simulation and offer more individual-specific anatomic details of organs and tissues before surgery. They can also help enhance our understanding to a disease, enhance familiarity to the surgical procedure, improve surgical skills, reduce procedure duration, or predict underlying risk and complications[20]. A growing line of evidence shows that with a low quantum of investment and running cost, 3D-printed model can help reduce surgery time and blood loss[29]. After the first version of the model was produced, several engineers and surgeons worked together to modify the texture and tactility of the model through adjusting the ratio of silicon gel and silicon oil used. We tested different conditions until all surgeons agreed that the texture and tactile feedback of the model were similar to those of real organs. Participants of the experimental group considered that using 3D model could effectively improve surgical skills, level of confidence, and tactile feedback.

Our model training modules contained four parts which included the principal and difficult procedure of the anti-reflux surgery[25]. Residents (the participants) could understand the whole procedure and connections between each step using the 3D-printed model. The efficacy of 3D-printed model in anti-reflux surgery training was evaluated through comparing OSATS score and procedure duration after training between the experimental group and control group[30]. In the control group, only two out of eight participants were able to complete whole procedure by themselves, and six out of eight participants needed extra help in using ultrasonic scalpel as well as establishing posterior esophagus tunnel and suture under laparoscope. However, all participants in the experimental group were able to finish the *ex vivo* organ procedure by themselves, and they scored higher in OSATS and completed the procedure in shorter duration. Interestingly, we found that the duration of the procedure on *ex vivo* organs was longer than that on 3D-printed model. We speculate that a large amount of adipose tissue accumulation within lessor omental bursa **(Figure 3C)**, which varies among patients, increased the difficulty of dividing lessor omental bursa by harmonic scalpel while the participants of the experimental group were performing the procedure on *ex vivo* organ. According to the results, the training efficacy using 3D-printed model was promising and the model we generated in this study attained a good face validity that all experts agreed that this model was vividly constructed with anatomic structures seen in a LNF surgery; therefore, this model is recommended for application in anti-reflux surgery in the future. 3D-printed models can be reusable for 20–30 times. Hence, the application of 3D-printed models incurs lower costs compared to the application of animal models.

However, our model does not take into consideration some important or unique anatomical details which might be encountered in surgery, such as greater omentum, endothoracic fascia, endoabdominal fascia, infracardiac bursa, mesoesophagus, and vagus nerve. Another limitation is that the objective assessment of the face and content validity of our model is lacking. We recommend that more participants with different levels of clinical practice experiences should be included in similar studies to validate the model. In addition, we will follow up with the participants of this study to learn more about their LNF performances in clinical practice.

6. Conclusion

Through this study, we manufactured a new 3D-printed model that mimics the anatomical details of patient and manifests similar mechanical properties. We also showed that the 3D-printed model for Nissen fundoplication surgery training could help accelerate the learning curves of surgical residents.

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Conflict of interest

The authors declare no known conflicts of interest.

Authors' contributions

Z.W. and M.Y. reviewed related articles and designed the study, Y.Z drafted the article and did the statistics, J.X. recruited the surgeons and organized the training, J.Z, J.M, H.C., H.L., X.X., J.P. and X.H. participated in the designing of the model and modified it into the final edition.

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