

Training for laparoscopic Nissen fundoplication with a newly designed model: a replacement for animal tissue models?

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Abstract

Background To bridge the early learning curve for laparoscopic Nissen fundoplication from the clinical setting to a safe environment, training models can be used. This study aimed to develop a reusable, low-cost model to be used for training in laparoscopic Nissen fundoplication procedure as an alternative to the use of animal tissue models.

Methods From artificial organs and tissue, an anatomic model of the human upper abdomen was developed for training in performing laparoscopic Nissen fundoplication. The 20 participants and tutors in the European Association for Endoscopic Surgery (EAES) upper gastrointestinal surgery course completed four complementary tasks of laparoscopic Nissen fundoplication with the artificial model, then compared the realism, haptic feedback, and training properties of the model with those of animal tissue models.

Results The main difference between the two training models was seen in the properties of the stomach. The wrapping of the stomach in the artificial model was rated

significantly lower than that in the animal tissue model (mean, 3.6 vs. 4.2; $p = 0.010$). The main criticism of the stomach of the artificial model was that it was too rigid for making a proper wrap. The suturing of the stomach wall, however, was regarded as fairly realistic (mean, 3.6). The crura on the artificial model were rated better (mean, 4.3) than those on the animal tissue (mean, 4.0), although the difference was not significant. The participants regarded the model as a good to excellent (mean, 4.3) training tool. **Conclusion** The newly developed model is regarded as a good tool for training in laparoscopic Nissen fundoplication procedure. It is cheaper, more durable, and more readily available for training and can therefore be used in every training center. The stomach of this model, however, still needs improvement because it is too rigid for making the wrap.

Keywords Animal tissue model · Artificial model · Laparoscopic training · Procedural training

Laparoscopic Nissen fundoplication requires the ability to perform an operation in multiple planes in a three-dimensional environment with two-dimensional visual feedback. The acquisition of these skills and the need to acquire facility using new instruments, suturing techniques, and new technological devices are challenges in performing a safe and effective operation [1, 2].

Studies have shown laparoscopic Nissen fundoplication to be safe and as effective as open fundoplication [1, 3–7], and it has become the preferred surgical option [1, 3]. However, reports have described higher risks for complications with the laparoscopic approach such as esophageal perforation, acute paraesophageal herniation, and stenosis of the esophageal hiatus and pneumothorax [2, 7, 8]. Also,

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studies have shown a higher reoperation rate at the early stages of the laparoscopic approach, which decreased with increasing experience [2, 6, 9].

A learning curve of 20 procedures per surgeon individually was established previously for laparoscopic fundoplication [1, 2, 10], although it is recognized that individuals may progress at different rates. Various factors may influence the length of a learning curve and its consequences for patients [2]. Important indicators denoting the learning curve for laparoscopic surgery are the conversion rate and operative complications. When individual experiences are examined, it is apparent that problems are most likely to occur during the first five procedures performed by individual surgeons [2], with a complication rate of 24% to 55% at the beginning of the learning curve [1, 2, 5, 9]. The rate of complications (including reoperations and conversion) declines to approximately 10% during the next 15–25 procedures, with little further improvement beyond this point [2].

Most conversions during the first 20 cases were performed for technical reasons such as adequate dissection of the posterior “window” behind the oesophagus, division of the short gastric vessels and fundal mobilization, closure of the diaphragmatic crura, and suture of the fundoplication [1]. Once these steps were learned, conversion rates remained low (2–10%) [1, 2, 6, 9, 10].

Currently, animal tissue models are used regularly in skills centers to train for laparoscopic procedures such as the Nissen fundoplication outside the clinical setting [11, 12]. 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 therefore expensive. In a few selected centers, surgeons still practice their procedural skills on live animals, but because of ethical objections and high costs, these are not used frequently.

To have an alternative for the animal tissue models, an anatomic model of the upper abdomen was developed to train for laparoscopic Nissen fundoplication. This model can be combined with an instruction video and step-by-step demonstration videos to bridge the early learning curve in the clinical setting to a safe environment. This study aimed to develop a reusable, low-cost model that can be used as a tool to be used in training for laparoscopic Nissen fundoplication.

Materials and methods

Artificial model

The artificial model was developed by independent researchers from the Technical University of Delft and the Catharina Hospital Eindhoven in The Netherlands. Before

development of the organs, the mechanical characteristics of the tissue were examined, and material that most closely resembled these characteristics was used to produce the separate organs. The physical proportions of the organs were derived from three-dimensional imaging of a computed tomography (CT) scan of the human anatomy to resemble the clinical setting closely. The model included the parts important in both the visual and tactile aspects of the training for laparoscopic Nissen fundoplication. Thus, all anatomic structures that could be either seen or touched during execution of the procedure were integrated into the model. If an organ could not be recreated realistically or did not have a significant influence on the training for the procedure, it was excluded from the model.

The model (Figs. 1, 2) included the stomach with the omentum minor and major and the short gastric vessels (vasa brevia) attached to it as well as the esophagus attached to the stomach, which entered the mediastinum through the opening between the crura. The crura were covered with a peritoneal layer, which had to be dissected to free the esophagus. The liver had to be held up by a liver retractor for visualization of the operating field. The model also included the spleen, to which the short gastric vessels were connected.

The connections between the different organs were by velcro, pins, or buttons to make it easy and fast to replace the disposable parts (peritoneal layer over crura and omentum with short gastric vessels). The stomach and crura could be used 15–20 times, but the peritoneal layer and omentum had to be replaced after every practice.



Fig. 1 Artificial model for Nissen fundoplication in which the liver is held up to show the operating field

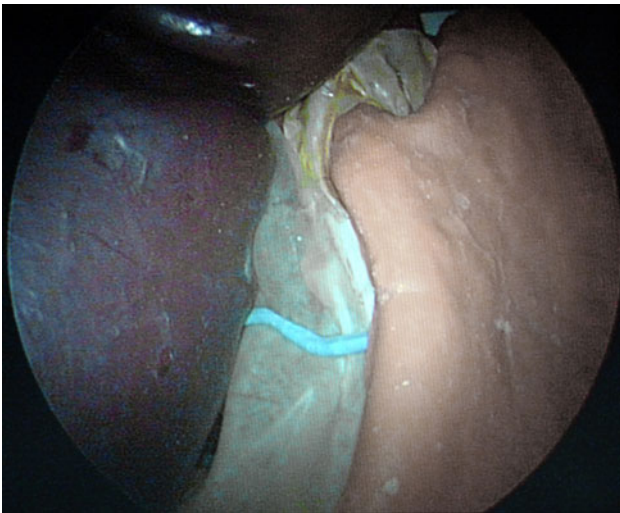


Fig. 2 Vision of the artificial model shown on the screen during the performance of Nissen fundoplication. The liver is being held up by a liver retractor

Training module

The laparoscopic Nissen fundoplication procedure [1, 6, 13, 14] was divided into multiple steps, and the importance of each step to be trained preclinically was determined. The ability to perform these steps of the procedure on the model and the importance of each step, together with the limitations of the model itself, concluded in four component tasks.

Figure 3 shows the four complementary tasks that could be practiced on the model by the participants. In the first task, the lesser omentum had to be opened, after which the phrenoesophageal ligament had to be divided to free both the left and right crura. The esophagus had to be totally free, and the participant had to be able to pull it into the abdomen. In the second task, the short gastric vessels (*vasa brevia*) had to be dissected to ensure that the fundus would be mobile enough to make the wrap. Therefore, the gastrophrenic attachment also had to be dissected. In the third task, the crura had to be sutured with two thumb knots. Then the wrap could be made. It had to be closed with three sutures to make a proper wrap around the esophagus. The end points of the procedure were proper closure of the crura with two sutures and the wrap, not too tight, closed with three sutures over a length of 1.5 to 2 cm.

Protocol

After the model was developed and the procedure divided into the component tasks, the participants were asked to complete the selected tasks on the model placed in a box trainer. Before the start of the training, the participants were shown an introduction video, and before each task,

they viewed a step-by-step demonstration video showing the corresponding part of the procedure to be performed.

After performing the procedure on the model, the participants filled out a questionnaire to evaluate the realism and haptic sensations of the artificial organs and the anatomic model as a training environment for laparoscopic Nissen fundoplication. The target group also practiced laparoscopic Nissen fundoplication on a validated animal tissue model [15] as part of an upper gastrointestinal surgery course at the Cuschieri skills center, Dundee, Scotland (Fig. 4). The experienced surgeons all had previous experience with training on animal tissue models. Next, the participants gave their preference for the training of this procedure using either the described model or the still often-used animal tissue models.

Subjects

Both the participants and tutors ($n = 20$) of the European Association of Endoscopic Surgery (EAES) upper gastrointestinal surgery course at the Cuschieri skills center, Dundee, Scotland, from 23 to 26 September 2008 completed this study. All the participants in this study were unbiased in relation to the model because it was developed at an independent research center. To have a reference point, the participants in the course first received their initial training on animal tissue models, then practiced on the artificial model. The tutors all were experienced with laparoscopic suturing, the Nissen fundoplication procedure, and the use of animal tissue models.

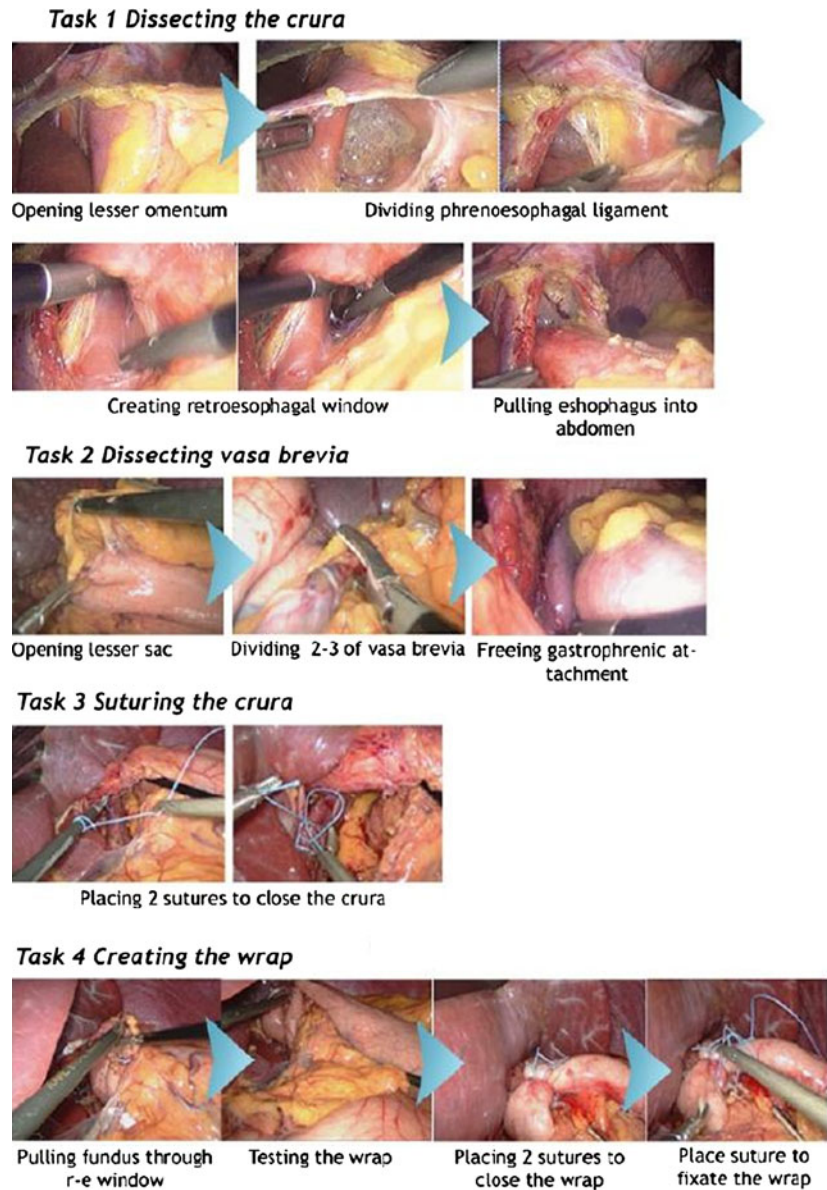
Questionnaire

The questionnaire used to evaluate the model was divided in four parts. The first part dealt with demographics and laparoscopic experience. The second part contained questions about the realism and haptic feedback with both the artificial model and animal tissue models, with ratings on a 5-point Likert scale. The third part focused on the training properties of the model and whether it would serve as proper training for Nissen fundoplication. The fourth part asked for an opinion on the separate organs with regard to visual aspects and haptic feedback. The questionnaire concluded with an open-ended question for remarks and improvements on the model and tasks.

Statistical analysis

All data were processed and analyzed using the Statistical Package for the Social Sciences (SPSS) 13.0. A statistically significant difference in opinion ($\alpha = 0.05$) between the artificial model and the animal tissue model was determined to be at least 0.7 points in the rating on the 5-point Likert

Fig. 3 The four complementary tasks of Nissen fundoplication that could be performed with the artificial model



scale, with a maximum standard deviation of 0.90 and a power of 80%. This calculated to a sample size of 20 subjects.

The results for the properties of the artificial model were compared with the null hypothesis of a neutral opinion on the model (mean 3.0) rather than with the animal tissue model. A *p* value less than 0.05 showed a significantly better or worse opinion than a neutral opinion on the artificial model.

Results

All the participants had experience with laparoscopic procedures, and 17 participants also had experience with general upper gastrointestinal procedures. All had previous

experience with laparoscopic suturing, either in the clinical setting or with box trainers. Of the 20 participants, 12 had previous experience with laparoscopic Nissen fundoplication and 8 did not. However, no significant differences in the ratings of the model between these two groups were found.

Table 1 shows the participants' difference of opinion between the artificial model and animal tissue model. The main difference in opinion between the two training models is seen in the properties of the stomach. The stomach of the artificial model was rated significantly lower than that of the animal tissue model. The main criticism concerning the stomach of the artificial model was that it was too rigid and that the fundus was not

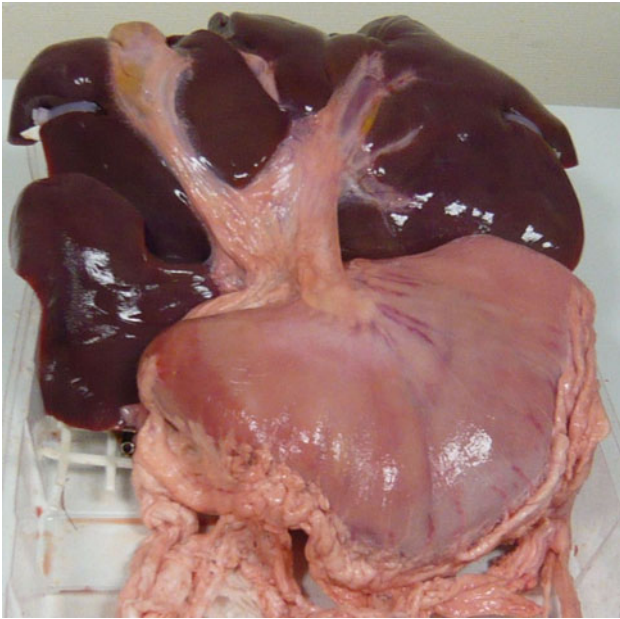


Fig. 4 Animal tissue model used in the upper gastrointestinal surgery course [15]

sufficiently flexible to make a proper wrap. The suturing of the stomach wall, however, was regarded as fairly realistic (mean, 3.6; Table 2).

The creation of the retrosophageal window also was regarded as significantly less realistic with the artificial model than with the animal tissue model (Table 1). The crura on the artificial model were rated better than those on the animal tissue model, but the difference was not

Table 2 Properties of organs in the artificial model

	Rating mean	<i>p</i> Value
Stomach		
Shape	3.8 ± 0.61	<0.001
Size	3.8 ± 0.70	<0.001
Flexibility of the stomach wall	2.3 ± 0.87	0.002
Haptic feedback of the stomach wall in the grasper	2.7 ± 0.98	0.186
Haptic feedback during suturing	3.6 ± 0.83	0.008
Crura		
Shape	3.9 ± 0.64	<0.001
Size	4.0 ± 0.46	<0.001
Haptic feedback during suturing	3.8 ± 0.72	<0.001

Rating for the several properties of the organs of the artificial model given by the 20 participants. They were rated on a 5-point Likert scale on which 1 is really unrealistic, 3 is neutral, and 5 is very realistic. The *p* values were calculated with the one-sample *t*-test comparing the rating with the neutral opinion of 3.0. A *p* value less than 0.05 was considered to indicate a statistically significant difference

statistically significant (Table 1). The properties of the crura were rated as realistic (mean, 3.8–4.0), which is a significantly better result than a neutral opinion.

The other organs in the model also were rated by the participants. The omentum was rated at 2.6 in visual appearances and flexibility (*p* = 0.042 and 0.025, respectively) and at 2.5 in haptic feedback (*p* = 0.014). The main remark was that it did not look realistic and should be more transparent but that it was not essential for the model and served its purpose. The liver was rated at a mean of 3.25

Table 1 Ratings for the complementary tasks of Nissen fundoplication

	Artificial model Mean	Animal tissue models	<i>p</i> Value
Task 1			
Dissecting the lesser omentum	3.3 ± 0.79	3.2 ± 1.04	0.649
Dissecting the phrenoesophageal ligament	3.4 ± 0.75	3.5 ± 1.00	0.606
Creating the retrosophageal window	3.2 ± 0.83	3.7 ± 0.92	0.014
Task 2			
Dissecting the vasa brevia	3.2 ± 0.82	3.4 ± 1.09	0.834
Freeing the gastrophrenic ligament	3.3 ± 0.81	3.3 ± 0.95	0.806
Task 3			
Suturing the crura	4.3 ± 0.55	4.0 ± 0.86	0.234
Bringing the crura together	4.3 ± 0.57	4.1 ± 0.64	0.104
Task 4			
Pulling the fundus through retrosophageal window	3.2 ± 1.23	4.1 ± 0.61	0.004
Creating the wrap	3.6 ± 0.89	4.2 ± 0.75	0.010

Ratings of the artificial model and the animal tissue model for laparoscopic Nissen fundoplication given by the 20 participants. They were rated on a 5-point Likert scale on which 1 is really unrealistic, 3 is neutral, and 5 is very realistic. The *p* value was calculated with the paired *t*-test, and a *p* value less than 0.05 was considered to indicate a statistically significant difference

Table 3 Training properties of the artificial model

	Rating mean	<i>p</i> Value
Training tool for surgical residents	4.3 ± 0.57	<0.001
Training tool for surgeons	3.6 ± 1.00	0.014
Replacing the porcine model	3.5 ± 0.76	0.016
Replacing pigs under anesthesia	2.9 ± 1.15	0.695

Rating for the training properties of the artificial model for laparoscopic Nissen fundoplication given by the 20 participants. They were rated on the 5-point Likert scale. The *p* values were calculated with the one-sample *t*-test comparing the rating with the neutral opinion of 3.0. A *p* value less than 0.05 was considered to indicate a statistically significant difference

(*p* = 0.287), the spleen at 3.5 (*p* = 0.009), and the esophagus at 3.6 (*p* = 0.012) (Table 2).

The general remarks given at the end of the questionnaire were “(very) good” (*n* = 10), “effective model” (*n* = 2), “excellent for training” (*n* = 1), “very nice” (*n* = 1), and “anatomy is superior to animal tissue models” (*n* = 1).

In answer to the question about the potential of the artificial model as a training tool for surgical residents learning to perform Nissen fundoplication, the model was rated good to excellent (mean, 4.3). As a replacement for the animal tissue model, it was rated at a mean of 3.5 (Table 3). In answer to the question whether this model was a proper trainer for laparoscopic Nissen fundoplication, 15 participants said it was a proper training instrument.

Discussion

A Nissen fundoplication prevents transient lower esophageal sphincter relaxation [6, 14]. It even increases the pressure of the distal esophageal sphincter to three times the preoperative levels. This new 360° high-pressure zone restores the competence of the esophagogastric junction, thus eliminating both acid and nonacid gastroesophageal reflux [14]. With regard to reflux control, no difference exists between the laparoscopic and open procedures. However, the complication of persistent severe dysphagia is reported to be greater with the laparoscopic procedure than with the open procedure [3, 7, 14]. Both the length and tightness of the fundoplication [3, 7, 16] play a part in this complication. However, the role of the division of the short gastric vessels has not been proved in this matter [4]. The artificial model allows training and objective assessment of the essential technical skills for crural closure and creation of a wrap around the esophagus to minimize these types of complications in the clinical setting.

Animal tissue models and live animals are used quite regularly to train procedures before they are performed on patients [11, 12]. However, as articulated in the statements of the American College of Surgeons, only as many animals as necessary should be used. Any pain or distress that animals may experience should be minimized or alleviated, and wherever feasible, alternatives to the use of live animals should be developed and used [17].

Other drawbacks of animal tissue models are the costs, the short preservation period, and the fact that they can be used only once. Besides this, the haptic feedback of dead tissue is different from that of living tissue [18]. Another important aspect of animal models is the infection rate. Therefore, they cannot be used in hospital settings, but only in specialized animal labs. An artificial model with reusable organs and replaceable tissue that can be used over and over again is more cost effective.

With the artificial model, only the peritoneal layer over the crura and the omentum with the short gastric vessels must be replaced after each practice. The stomach and crura can last for approximately 15–20 procedures. A modular model, as presented in this study, allows the exchange of organs or tissue on demand, which is not the case with animal tissue models. Thus, the costs per training can remain low, making such training accessible for all training centers and hospitals. This model also is easier to preserve, has a better scent than animal tissue models, is portable, and can be used in any skills center that has at least one box trainer.

Study limitations

The most important aspect in the development of this model was the material used for the production. To realize a product that can compete with the use of animal tissue, it is of great importance that the material be perceived as realistic. Realism is perceived when the properties of the material closely approach the properties of real human tissue. However, human and animal tissue is very complicated material consisting of several layers. Its properties therefore depend on the number of layers, the layer thickness, the orientation of the muscular layers, the moisture level, the temperature, and the like. Information about the mechanical characteristics of human abdominal tissue is limited, which made it challenging to develop the organs for the artificial model that resemble realistic characteristics.

The participants in this study regarded the artificial stomach as less realistic for making a proper wrap than the stomach in the animal tissue model because the artificial stomach was too rigid and the stomach wall was slightly too thick. This aspect should be improved to make the model more suitable for laparoscopic Nissen fundoplication training. Also the color could be more realistic. The

artificial stomach appeared to be a bit too orange, which made it less realistic. On the screen, however, it looked less bright (Figs. 1, 2).

The haptic feedback during the suturing was regarded as realistic, and this property of the stomach should therefore not be changed. The crura were regarded as realistic, and most participants preferred to train for this task on this Nissen model rather than on an animal tissue model. The human anatomy is quite different from the porcine anatomy, which means that the surgical resident trains for a different type of procedure when using the animal tissue model. For practicing the dissection of tissue (e.g., tissue connected to the esophagus), an animal tissue model is regarded as superior because it was not possible to simulate such dissection realistically with the artificial model. The step of dissecting is implemented in the tasks (Fig. 3), but in a simplistic form, so that the trainee learns the sequence of the procedure. This step is important for the prevention of esophageal perforations and pneumothorax, but it cannot be trained using the artificial model in its current form.

In Middle Eastern countries, animal tissue models cannot be used for training for ethical reasons. Therefore, a model with the proper anatomy could be a good way to train these types of advanced procedures.

Conclusion

The newly developed artificial model was regarded as a good training tool for the laparoscopic Nissen fundoplication procedure by the participants in this study. It is cheaper, more durable, and readily available for training and can therefore be used in every training center. Further improvements on the stomach are necessary because in the current form, the artificial stomach is too rigid for making a proper wrap around the esophagus. We recommend the development of such models for more laparoscopic procedures to replace the animal models (e.g., porcine cadaver models and pigs under anesthesia) that are still used in skills centers.

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Disclosures Sanne M. B. I. Botden, Lorna Christie, Richard Goossens, and Jack J. Jakimowicz have no conflicts of interest or financial ties to disclose.

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