In-house Design and Construction of the Toronto Lap-Nissen Simulator

Gad Acosta[1], Maciej Bauer[1,3], Hideki Ujiie[2]

[1] Department of Medical Engineering, Toronto General Hospital, University Health Network, Toronto Ontario; [2]Division of Thoracic Surgery, Toronto General Hospital, University Health Network, University of Toronto, Toronto, Ontario, Canada;

[3]maciej.bauer@uhn.ca

Abstract. Simulators for surgical trainees are utilized to improve laparoscopic technical skills. Following the request and directions from Dr. Hideki Ujiie and Dr. Kazuhiro Yasufuku's team, Maciej Bauer and Gad Acosta from the Surgical Support Group, Medical Engineering Department at the UHN, designed and constructed the Toronto Lap-Nissen Simulator. As an in-house team, close collaboration and fluent communication was established with the clinical team, which enabled an efficient progression from the prototypes to the model used during actual training. The desired outcome was to produce an inexpensive and relevant training model. The objective of this presentation is to illustrate the design process, methods and materials used for the construction of the Toronto Lap-Nissen Simulator. The technical aspects for this device will be discussed.

Keywords: surgical simulators, device design, laparoscopic forces.

1 Introduction

Surgical simulators for laparoscopic procedures offer an opportunity for trainees to safely develop their skills in a controlled environment, however the price of these devices can be a constraint in their acquisition as it can be up to U.S. $ 5000 [3]. This cost can be reduced by recruiting in-house Technologists who are proficient in fabrication techniques and testing of devices. This study examines the technical project aimed at constructing the Toronto Lap-Nissen Simulator, which would allow for training on laparoscopic myotomy and fundoplication [5]. The rationale concerning the selection and evaluation of materials is described in section 2. The experiments concerning the analysis of capacities for fastening mechanisms was performed in section 3. The findings are summarized in section 4.

2 Methods

During the selection of materials for the development of an ex-vivo surgical simulator, the two following requirements were highlighted by clinical researchers: the prototype must be durable, anatomically relevant, and cost efficient. The components selected were able to withstand harsh environments, due to the cleaning agents used in between simulations. For the base, transparent acrylic was chosen since it would allow for printed material to be utilized to simulate thoracic cavity if desired. A medium fidelity plastic shell was selected over high fidelity to cover the model due to similar results [2], and the laparoscopic access points were indicated by the clinical researchers. 316 stainless steel perforated sheet was selected due to its resistance against corrosion [1] and formability properties. The staggered hole pattern allowed for multiple testing of the tissue fixing mechanism.

3 Fastening Mechanism Selection Experiment

The maximum holding capacity of the selected options for the mechanism that would secure the diaphragm was not rated by the supplier, and there were two main alternatives: alligator clips or spring clamps. This was a crucial part of the model, as this was the area of interest for this specific application. In order to determine an optimal solution, it was determined that each mechanism should be able to withstand double the amount of force experienced during laparoscopy. According to reports, forces during endoscopic gestures range from 0.1–12 N [6].

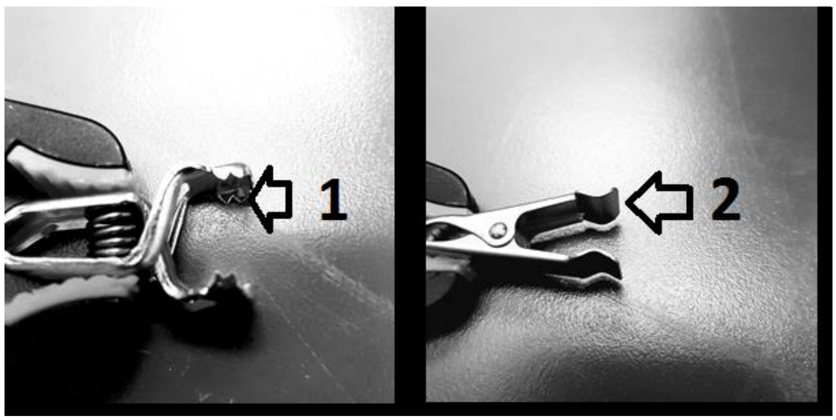

Fig. 1. The alligator clip (5) has a toothed jaws, and the spring clamp (2) has two curved surfaces for jaws. Both of these fastening mechanisms are shown in an open position. Pictures were edited in greyscale to show further detail regarding the styles of the jaws.

<u>3.1 Experimental Design</u>

There were three factors that were considered for this experiment. The jaw style was either alligator clip or spring clamp, the position was perpendicular or parallel with respect to the operating surface. For support there was fastening at a single point, or having a support underneath the fastening mechanism.

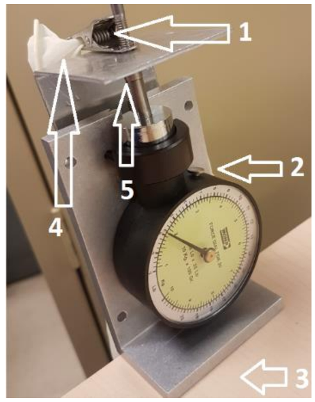

Fig. 2. The experimental setup. The spring clamp (1) attached parallel to the operating surface to the force gauge (2) which is clamped to the operating surface (3). The tissue equivalent (4) is pulled downwards by a participant, and this figure shows a support being added to stabilize the spring clamp (5). The force gauge would hold the value prior to the breaking point, which would be recorded as the maximum fastening achieved by a combination of three factors.

3.2 Experiment Results

The combination of the jaw style and position had the greatest magnitude among the interactions, as observed in the Fig. 3. The alligator clip jaw would lacerate the equivalent diaphragm tissue, whose rated breaking point was measured at 40N. The damage caused by the toothed jaws of the alligator clip resulted in a lower holding capacity. Positioning the fastening mechanism parallel to the operating surface produced higher securing force before damaged occurred. The forces needed to deform the alligator clip or the spring clamp were not measured since the maximum points were reached prior to structural issues with the fastening mechanism options.

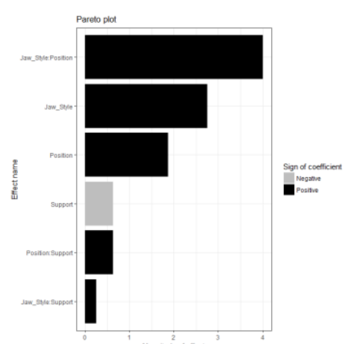

Fig. 3. The interaction of the three factors resulted in eight experiments which were performed by two participants. By using R software, a Pareto plot was generated for observing the magnitude of the effect and the interactions of different combinations.

As for the support, it was the factor with the lowest magnitude of effect. This was useful for determining that the selected securing mechanism could be placed parallel to the operating surface, while attaching by one fastener. As observed in Figure 4, this allowed for the spring clamps to be installed in the inner part of the arch, allowing for the shell to be positioned flushed to the arch, and increasing the diameter of the arch. This could result in the ability to utilize larger diaphragms if necessary. Adequate tension similar to the one encountered in the anatomical cavity was achieved [5]. The alligator clips were useful for holding the esophagus, as they were available, and there are no significant forces applied to this area of the simulator. These were attached to an L-shaped acrylic piece, which had an orifice for holding an endotracheal tube.

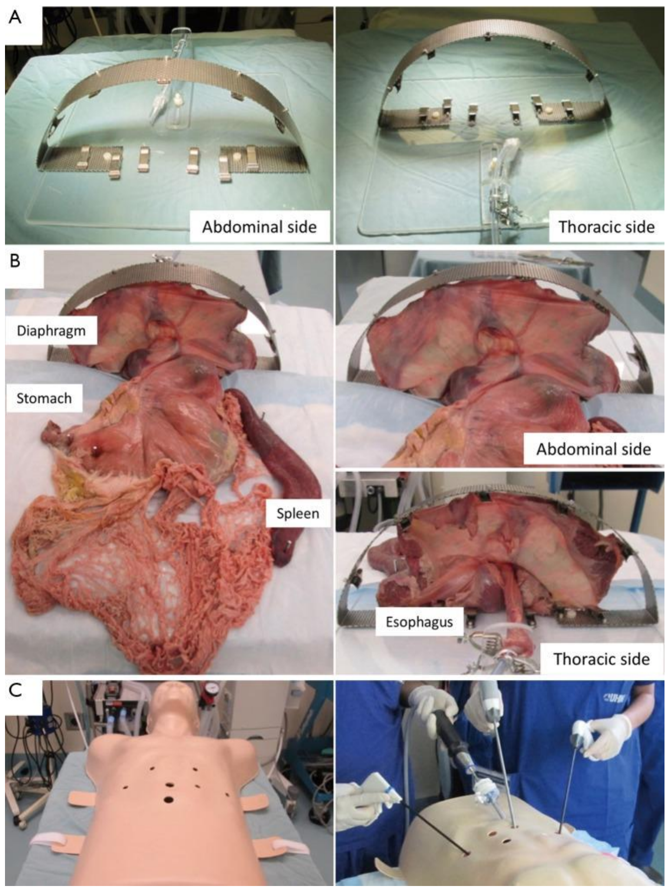

Fig. 4. Demonstration of Toronto Lap-Nissen Simulator. (A) Laparoscopic arch system with 5 spring clips installed on the arch, and 6 on the flat surface; (B) *ex vivo* porcine organ configuration. The simulator includes intact porcine esophagus, stomach, diaphragm and spleen; (C) torso set up. The diaphragm is suspended by an arch inside of the torso fitted with trocar ports for insertion of instruments. Reprinted from H.Ujiie, 2017, Retrieved from URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5506143/# Copyright 2017 Journal of Thoracic Disease. Reprinted with permission.

4 Discussion and Conclusions

The highest force measured was 30N per spring clamp, positioned in parallel to the operating surface. For this reason they were selected as the best option to hold the area of surgical interest. At a price of $300 CAD for materials, and $70 CAD for an intact porcine organ block, the simulator is cost-effective. During utilization, the Toronto Lap-Nissen simulator secured the diaphragm in place, and allowed for simulation of the procedures to be performed. From the clinical perspective, it was reported that it increased trainees' comfort level when performing and/or assisting with myotomy and fundoplication [5]. For future directions, other materials could be investigated for the construction of the arch, such as titanium or Aluminum 6061, and further research can be performed on the tensile strength of porcine diaphragms.

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