Title: Validation of an Inanimate Low Cost Model for Training Minimal Invasive Surgery (MIS) Esophageal Atresia with Tracheoesophageal Fistula (AE/TEF) Repair

Keywords: neonatal minimal invasive surgery; thoracoscopy; Esophageal atresia repair; training model; low cost; validated

Abstract: Summary/Abstract: We present the results of the validation of an inanimate model created for training thoracoscopic treatment of esophageal atresia with lower tracheoesophageal fistula (EA/TEF).

Material and Methods: We used different domestic materials such as a piece of wood (support), corrugated plastic tubes (PVC) of different sizes to simulate ribs, intercostal spaces, trachea and spine and tubular latex balloons to simulate the esophagus and lungs to make the basic model. This device was inserted into the thoracic cavity of a rubber dummy simulating a 3kg newborn with a work area volume of 50ml. The model was designed taking into account the experience of doing this procedure in neonates. The cost of the materials used was 50 US$.

Thirty-nine international faculty or pediatric surgeons attending hands on courses with different levels of training in minimal invasive surgery (MIS) repair of EA/TEF performed the procedure in the model. We compared the performance of the practitioners with their experience in thoracoscopic repair of EA. A Likert-type scale was used to evaluate results. Previous experience in MIS, anatomical appearance of the model, surgical anatomy compared to a real patient, and utility as a training method were analyzed. We also used a checklist to assess performance. We evaluated: number of errors and types of injuries, quality of the anastomosis, and duration of procedure. To analyze the results we used a T-test, Chi-Square test and Excel® database to match up some results.

Results: Thirty-nine questionnaires were completed. Seven surgeons were experts (≥30 TEF/EA repairs as surgeon), 10 had intermediate level of experience (5 to 29 repair as surgeon) and 22 were beginners (less than 5 repairs). To simplify the analysis we divided the respondents into low experience LE (<5 real procedures - beginners) n=22; and high experience HE (intermediate,10; and experts,7) n=17.

In relation to the anatomical characteristics of the model, 94,48% (n=37) respondents considered that the model has a high degree of similarity or
good similarity; in relation to surgical anatomy 88.2% (n=34) respondents considered that the model has a high degree of similarity or good similarity; and 87.17% (n=34) respondents considered that the model can generate a good amount of skills and/or can generate great majority of skills to EA/TEF repair; and 12.82% (n=5) respondents consider that it can generate some skills or a few skills, only in relation to trocar placement, one of the surveyed items.

The number of errors was 29±7SD (20 to 51) for the low experience group (LE) and 9±6SD (1 to 20) for the high experience group (HE). P value < 0.0001. Time in minutes was significantly lower in the HE group 40±9SD (49 to 118min), in relation with LE 81±19SD (26 to 58min) P < 0.0001. T-test. Deficient or incomplete anastomosis also showed differences 7 (32%) in the LE group; 1 (6%) in the HE group. P 0.04. Chi-Square test.

Conclusions: We saw a correlation between the previous experience of the surgeon and their performance in the model considering operating time, quality of anastomosis and peripheral tissue damage. According to the suggestions registered in the questionnaires, we have now improved the model. We have also started using it in an scenario to simulate the whole neonatal MIS operative room setting and team work.
We present the results of the validation of an inanimate model created for training thoracoscopic repair of esophageal atresia with lower tracheoesophageal fistula (EA/TEF). This paper seeks to highlight the strategies and resources used for making a model of endosurgical training. Likewise, we present the model and features.
Dear reviewers:

First of all thanks for the comments and for encouraging me to go ahead with this educational project.
Attentive to your suggestions:
1. I have corrected the grammar with professional assistance,
2. I have also removed the images that you suggested me,
3. I have summarized the discussion
4. I have changed liker by likert.
5. And I have also changed the order of the words on the title careful not modify its content.

Thanks again for your contribution.
Yours Sincerely

Maximiliano A. Maricic, MD.
Pediatric Surgeon
Validation of an Inanimate Low Cost Model for Training Minimal Invasive Surgery (MIS) Esophageal Atresia with Tracheoesophageal Fistula (AE/TEF) Repair.

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Regular video endoscopic equipment and 3 mm instruments were used.
Thirty-nine international faculty or pediatric surgeons attending hands on courses with different levels of training in minimal invasive surgery (MIS) repair of EA/TEF performed the procedure in the model. We compared the performance of the practitioners with their experience in thorascoscopic repair of EA.

A Likert-type scale was used to evaluate results. Previous experience in MIS, anatomical appearance of the model, surgical anatomy compared to a real patient, and utility as a training method were analyzed. We also used a checklist to assess performance. We evaluated: number of errors and types of injuries, quality of the anastomosis, and duration of procedure. To analyze the results we used a T-test, Chi-Square test and Excel® database to match up some results.

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According to the suggestions registered in the questionnaires, we have now improved the model. We have also started using it in an scenario to simulate the whole neonatal MIS operative room setting and team work.

KEYWORDS: neonatal minimal invasive surgery, thoracoscopy, Esophageal atresia repair, training model.
Introduction:

Esophageal atresia (EA) is a congenital uncommon disease with an incidence varying from 1/3000-1/4500 live births, depending on the analyzed series. Thoracoscopic correction of EA with tracheoesophageal fistula (TEF/EA) requires a high level of training in neonatal minimally invasive surgery (MIS). Surgery training is classically done in the operating room under the supervision of the senior surgeon, and MIS training is usually done with conventional training devices with general programs focused on endosuturing and precision tasks. The difficult learning curve (not clear), combined with the few cases per year and the selection of cases that will be repaired by thoracoscopy, make the number of cases of MIS TEF/EA very low; even in reference centers worldwide.

Training in experimental animal models is under debate nowadays. Excellent models that combine inanimate materials using 3D printing technology and biological material for specific training have been published\textsuperscript{12}. We have worked on developing a completely inanimate, portable, reproducible model and at a very low cost, which aims to meet the training needs in MIS TEF/EA reparative surgery for surgeons in training, as intermediate or senior surgeons who want to perfect or improve their technique.

Our plan is to develop a model that not only can be used in simulation scenarios but also that brings experience and training as much as possible to reality, in a safe teaching environment.

Materials and Methods

Simulation model design and manufacture

A piece of wood of 7 x 4 x 1cms with a groove(5mm depth) along the entire length of the upper surface was employed to hold the structures. Three corrugated PVC plastic tubes of different diameters (50mm, 25mm, and 15mm) were used to simulate the rib cage, spine and trachea, respectively. All structures were glued and painted orange these structures represent the view of the right hemithorax.

Two latex tubular balloons with a diameter of 5mm and 3 mm, and of different colors respectively, were disposed within each other, to simulate the muscle layer and mucosa of the esophagus.

The distal pouch was next inserted into a hole previously created in the corrugated tube, simulating the trachea and TEF.

A thin sheet of rubber or dental floss, arranged along the esophagus represented the vagus nerve. A small tubular balloon was placed over the TEF to simulate the acygos vein. A thin adhesive transparent film fixed and covered all structures, as the parietal and mediastinal pleura. An additional
latex balloon was used to simulate the lung; this can be connected to a sphygmomanometer bulb or resuscitation bag to simulate the functionality of the lungs. It can also be connected to the anesthesia machine.

The simulation model was at last placed, into the chest of a common rubber dummy, simulating a 3kg baby. It is positioned to take the prone position, which is the most commonly recommended by most authors to MIS TEF/EA reparative surgery.

The work area average volume is less than 50ml. Fig 1 and 2.

We used 3mm regular instruments and conventional equipment. The trocars position is: One 4mm in third intercostal space, posterior axillar line for 3mm short 30 degree scope; the second 3mm trocar is the axillar, in the second intercostal space; and the third trocar is a 3mm in the fourth intercostal space near the spine.

**Inclusion Criteria**

Surgeons with previous experience in the MIS EA repair as surgeon or assistant, with high level of endosuturing skills, were included. The participants were classified into beginner, intermediate and senior according to the total number of thoracoscopy TEF/EA, but in order to analyze and simplify the results we divided the respondents into low experience LE (<5 TEF/EA repairs); and high experience HE (≥ 5 TEF/EA repairs).

**Validation**

The validation consisted of a likert-type survey completed by 39 international experts and pediatric surgeons attending training courses. In that survey we asked about previous experience in MIS, number of TEF/EA repairs as surgeon and assistant, difficulties to perform this kind of procedures, anatomical appearance of the model, surgical anatomy in comparison with a real patient, and utility of the model to specific training. This allowed us to have a rating of the opinion of the respondents in relation to external and internal anatomy, surgical anatomy, dimensions and useful as a training method to TEF/EA repair.

All of them completed the simulation model using 3 mm instruments and a 4 or 5 mm scope. And were evaluated by a checklist (form of performance) with the steps proposed of the surgery previously shown in a video and template. The same two instructors completed that sheet. The checklist evaluated the performance of the participants during the practice in the model; the number of errors and types of injuries, quality of anastomosis, and time of practice, was evaluated with that sheet. Also we took a picture of the model used for further evaluation of peripheral tissue injuries (lung, nerve, parietal pleura, ribs, trachea or esophagus).
Once surgeons had completed their practice, they gave us feedback (comments and suggestions) about the simulation model. To evaluate the model as a training method we used the database to match up and analyze the results using T-test, and chi-square test. And we compared the performance of the practitioners with their previous experience in thoracoscopic repair of TEF/EA, errors and injuries.

**Method and characteristics of assessment tools:**

Surgeons were shown a video or instructional sheet before using the simulation model. These show the steps to TEF/EA repair:

1. Position and fixation of trocars and instruments.
2. Dissection of the pleura, performed with 3mm microsurgical scissors.
3. Tying of the azygos vein with 4-0 or 5-0 multifilament suture.
4. Suturing of the TEF with intra- or extracorporeal 4-0 or 5-0 monofilament knots. We encourage the use of both knots. A clip applier can also be used, but in this case a 5mm axillar trocar is needed. That is why we don’t recommend it.
5. Section of the fistula with scissors.
6. Dissection of the upper esophageal pouch taking special care with the trachea.
7. Cut on the blind end of the upper pouch with a microsurgical scissor.
8. Performing the esophageal anastomosis with 5-0,C1 (preferably) needle mono or multi filament suture by using different techniques: square, sliding, intra- or extracorporeal knots. We recommend the use of intra corporeal knots.
10. Completion of the esophageal anastomosis
11. Control the esophageal anastomosis

In the likert-type scale survey the questions were designed to evaluate the anatomical features, ergonomics and functionality of the simulation model. It included questions about the following variables:

**Anatomical characteristics of the model**

External appearance and dimensions of the model; position of the instruments for working; internal dimensions and appearance of the working area; endoscopic appearance of vision (visual environment); anatomical appearance (pleura, ribs, trachea, Azygos vein, nerve, lung); esophageal anatomy; esophageal dimensions.
Surgical anatomy in comparison with the real surgery.

Dissection of the esophagus and acygos vein; ligation and section of the TEF; dissection of the upper esophageal pouch; double-layered esophageal anastomosis; trans anastomotic probe passage.

Usefulness of the model as a tool for specific training.

Placement and positioning of the trocars; camera handling (scope handling); use of 3mm instruments; dissection in general; suture/anastomosis; tissue handling.

The pre-established likert-scale answers for all questions were:

1. No degree of similarity / cannot be used to generate skills
2. Small degree of similarity / can generate a few skills
3. Medium degree of similarity / can generate some skills
4. Good degree of similarity / can generate good amount of skills
5. High degree of similarity / can generate the great majority of the skills

The checklist used during the practice in the trainer was developed to evaluate the performance of participants in each of the landmarks of the surgery mentioned above. Assessors / instructors were always the same two, who are also authors of this paper. What is therefore settled in this form is: the participant’s data for comparison with the survey; practice time, if it meets the landmarks of surgery or not, or if difficulties were found in performing certain maneuvers; if they make the knots correctly, its overall performance; and a space for additional comments.

Results:

Based on the surgical experience of the experts consulted, who participated in this work, we divided the participants into 3 groups: (n = 39)

Beginners (n=22): less than 5 thoracoscopic EA repairs. Or Have not performed an EA/TEF repair as surgeon, but participated as assistants in more then 5 procedures, and well endosuturing level referral.

Intermediate (n=10): Have performed between 5 to 29 endoscopic repairs of EA/TEF as surgeons.

Experts (n=7): Have performed 30 repairs of EA/TEF or more as surgeons.
To simplify the posterior analysis of this issue, we divided the respondents in two groups, low experience LE, and high experience HE. See below (functional validation)

**Anatomical validation:**

In relation to the *Anatomical characteristics of the model*, 37 respondents (94.48%) considered that the model has high degree of similarity or good similarity in: External appearance and dimensions, positioning of the instruments, internal dimensions and appearance of the work area, visual environment, esophageal anatomy and esophageal dimensions.

Table 1 and Figure 3 show the distribution of the choices of the respondents in percentage, and in absolute number (n) of choices to each issue and also a general graphical distribution. In Red/Bold the most common option for each category is marked.

Thirty-four (88.2%) respondents considered that the model has a high degree of similarity or good similarity in relation to *surgical anatomy* in comparison with the real surgery for the following characteristics: Dissection of the esophagus and acygos vein; ligation and section of the TEF; dissection of the upper esophageal pouch; double-layered esophageal anastomosis; trans anastomotic probe placement.

Table 2. Red/bold shows the most common option for each category. Green/Bold; no differences for ligation and section of FTE. Figure 4 percentages.

Thirty-three (87.17%) participants considered that the model can generate good amount of skills / can generate great majority of skills to EA/TEF repair training; and 5 participants (12.82%) considered that it can generate some skills or a few skills, only in relation to one of the surveyed items, trocar placement. This is related to the position of the trocars we suggested in the model, it was not the best choice for respondents, based on their own surgical preference. Table 3: Red/bold is marked as the most common option for each category and Figure 5 shows percentage of choices for this issue.

The suggestions and comments from questionnaires were that what was most liked about the model was the good dimensions, proper anatomical and visual similitude to a real chest, the low cost and reproducibility of the model in addition to the possibility of performing a double-layer anastomosis. What Trainees mostly disliked about the model was that structures were a little bit rigid compared to the real ones.
As additional information, trainees also explained the reasons for their limitations in obtaining thoracoscopic repair of EA experience (some respondents consigned more than one option):

- Lack of training: 91%
- Few cases per year: 27.5%
- Inadequate technology (instruments and equipment): 27.5%
- Teamwork inexperience: 18%
- Education: 18%
- Patient-related conditions: 9%

**Functional Validation (validation as a training model)**

To simplify the analysis of this issue, we divided the respondents in two groups: Low Experience, LE (<5 real procedures - beginners) n=22; and High Experience, HE (≥ 5 real procedures – intermediate,(10); and experts,(7)) n=17.

The number of errors or injuries was 29±7SD (20 to 51) for LE group; and 9±6SD (1 to 20) for HE. *P value < 0.0001. T test*.

Time in minutes was significantly lower in HE group 40min±9SD (49 to 118min); in relation with LE 81min±19SD (26 to 58min) *P < 0.0001. T test*. Deficient or incomplete anastomosis also showed differences 7 (32%) in LE group; 1 (6%) in HE group. *P 0.04. Chi-Square test**. Table 4.

In Figure 6, Comparison of the number of errors and time represented in graphics where column 1 are low experience (LE); and column 2 high experience (HE) participants.

Additional information for tissue damage is, in LE group two of them damaged lung and nerve, while in group HE only 2 participants generated lung injury, and they were the least experienced of the group, with 5 and 7 respective repairs. Curiously these participants took relatively little time doing practice (46 min and 56 min), and in both cases the anastomosis failed.

if we analyze the injury in three original groups, beginners; intermediate; and experts, we obtain:

**Beginners** n=22 average damage 29.7 injuries, range (20 to 51). Severe injury; lung + nerve (2). Average time 81.25 min, range (49 to 118min). Poor or incomplete anastomosis: 7/22

**Intermediate** n=10 average damage 13.9 injuries, range. (5 to 20) Severe injury; lung (2). Average time 46.42min range (36 to 58min). Poor or incomplete anastomosis: 2/10
Experts n=7 average damage 3.5 injuries, range (1 to 5). No severe injury. Average time 33.57min range (26 to 40min). Poor or incomplete anastomosis: 0/7

Figure 7 distribution of number of errors / injuries in the model, in relation to the operator's experience.

**Discussion**

The results show that the model has wide acceptance among participants in relation to the anatomical and functional characteristics. As well as the usefulness of specific advanced training method.

The analysis performed allowed us to observe the sensitivity of the model as a valid training method, in relation to the previous experience of the participants. In other words, more experienced participants (HE) took less time and had few errors and better results in the anastomosis than those with less experience (LE); with statistically significant values.

Training with simulation models has many advantages such as: safety for patients and students; faster and easier learning curve that can be achieved outside the operating room; Operative time and costs can be reduced significantly; it can be repeated as often as required; if the models are validated these may be included in the curriculum of medical training, even for doctors with better training; reducing costs in health.

This kind of trainers can be used to testing procedures and tricks according to global trends, it can even be used to test new technologies.

Necessarily, this and other training models should be included in a training program that allows the integral formation, and this is mainly tutored by qualified staff.

The model presented is of very low cost, reproducible and completely inanimate, making it very versatile. This trainer was developed as an additional tool to facilitate the learning curve in MIS TEF/EA repair. We designed it focusing on the dimensions, anatomic projections and technical details of a newborn undergoing a thoracoscopic repair of EA with a lower TEF (i.e. a Type C or III AE) but our model can also be used for other types of
EA, with a few modifications. As part of the improvements we have made to the model, it is the possibility of being connected, through a conventional tracheal tube, to the anesthesia machine; and thus realistically simulate breathing movements. If we add a better working environment (such as an operating room, the presence of a scrub nurse, a neonatologist, specialized equipment to simulate different signs as bradicardia or others) to simulate diverse clinical situations for a high-fidelity result, Figure 8.

Encourage endosurgery enthusiastic to do their own models according to the learning needs of each center and further validate them. Our validation process is still ongoing, and needs improvements in order to make the model as real as possible using new technologies.

The validation process as a method of training is a delicate long-term process which should not be undertaken without proper anatomic and functional validation as the one presented in this work.

We are planning to compare the results obtained with these young surgeons vs. retrospective ones obtained from those who did not use the simulating model. Moreover, we are working on comparing the results of surgeons before and after using it. However this strategy is quite laborious due to the small number of cases and of surgeons who are able to perform MIS EA and MIS EA/TEF.

Thoracoscopic repair of EA/TEF is a technically challenging surgical procedure. Since this congenital anomaly is rare, training opportunities for surgeons are limited. There are few validated simulation tools available to help train pediatric surgery trainees. The simulator authors developed is a low-cost, reusable complete inanimate model. It simulates a term neonate chest and contains low cost materials to replicate the anatomy of EA/TEF.
References:

Figure 1: Base model ready to be used. With anatomical replaceable silicone structures positioned.
Figure 2: The model into the training dummy. The lung has been removed for a better view of the area.
Figure 3: Anatomical characteristics of the model. Percentage distribution of each answer.
Figure 4: Surgical anatomy of the model. Percentage distribution of each answer.
Figure 5: Utility of the model as a training method in the opinion of the respondents.
Figure 6: Comparison between Low Experience (LE) column 1 and High Experience (HE) column 2 (both graphs); in relation to the number of errors (left graphic) and Time (right graphic) see text for more details.
Figure 7: Distribution of number of injuries to the model in relation to the surgical experience. For a better analysis of results, we have grouped the beginners and intermediate participants as LE (Low Experience) and experts HE (High Experience). Beginners who have not performed the procedure as surgeons are to the left of the vertical blue line.
Figure 8: High fidelity simulation stage
<table>
<thead>
<tr>
<th>Anatomical Characteristics of the Model</th>
<th>No similarity</th>
<th>Very Little Resemblance</th>
<th>Some similarity</th>
<th>Good Likeness</th>
<th>High Degree of Similarity</th>
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<tbody>
<tr>
<td>External Appearance and Dimensions</td>
<td></td>
<td>56.4% (22)</td>
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<td>43.6% (17)</td>
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<tr>
<td>Positioning instruments</td>
<td>7.7% (3)</td>
<td>35.9% (14)</td>
<td>56.4% (22)</td>
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<tr>
<td>Internal dimensions and appearance of the Area of work</td>
<td>7.7% (3)</td>
<td>56.4% (22)</td>
<td>35.9% (14)</td>
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<tr>
<td>Endoscopic Appearance of vision (visual environment)</td>
<td></td>
<td>35.9% (14)</td>
<td>64.1% (25)</td>
<td></td>
<td></td>
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<tr>
<td>Anatomical appearance (pleura, ribs, trachea, Azygos vein, nerve, lung)</td>
<td>15.4% (6)</td>
<td>56.4% (22)</td>
<td>28.2% (11)</td>
<td></td>
<td></td>
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<tr>
<td>Esophageal Anatomy</td>
<td>74.3% (28)</td>
<td></td>
<td></td>
<td>25.7% (10)</td>
<td></td>
</tr>
<tr>
<td>Esophageal Dimensions</td>
<td>7.7% (3)</td>
<td>64.1% (25)</td>
<td></td>
<td>28.2% (11)</td>
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</table>

Table 1: Anatomical characteristics of the model. percentage distribution of each answer.
Table 2: Surgical Anatomy of the model. Distribution of each

<table>
<thead>
<tr>
<th>Surgical Anatomy in Comparison with the Real Surgery</th>
<th>No similarity</th>
<th>Very Little Resemblance</th>
<th>Some similarity</th>
<th>Good Likeness</th>
<th>High Degree of Similarity</th>
</tr>
</thead>
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<tr>
<td>Dissection of the esophagus and azygos vein</td>
<td>28.2% (11)</td>
<td>43.6% (17)</td>
<td>28.2% (11)</td>
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<tr>
<td>Ligation and section of FTE</td>
<td>7.7% (3)</td>
<td>46.15% (18)</td>
<td>46.15% (18)</td>
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<td>Upper pouch esophageal Section</td>
<td>7.7% (3)</td>
<td>35.9% (14)</td>
<td>56.4% (22)</td>
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<td></td>
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<tr>
<td>Esophageal Anastomosis in Double Layer</td>
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<tr>
<td>Trans Anastomotic catheterisation</td>
<td>15.4% (6)</td>
<td>38.4% (15)</td>
<td>46.4% (18)</td>
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Table 3

<table>
<thead>
<tr>
<th>Usefulness of the Model as a Tool to Specific Training</th>
<th>No contribute to acquisition of Skills</th>
<th>Can Generate Very Few Skills</th>
<th>Can Generate Some Skills</th>
<th>Can Generate Good Amount Skills</th>
<th>Can Generate Great Majority Skills</th>
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<td>7.7% (3)</td>
<td>7.7% (3)</td>
<td>46.15% (18)</td>
<td>38.4% (15)</td>
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<tr>
<td>Handling the Camera</td>
<td>7.7% (3)</td>
<td>18.00% (7)</td>
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<td>74.3% (29)</td>
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<td>Using 3mm Instrumental</td>
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<td>25.7% (10)</td>
<td></td>
<td>74.3% (29)</td>
<td></td>
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<td>Dissection</td>
<td>18% (7)</td>
<td>46.15% (18)</td>
<td></td>
<td>35.9% (14)</td>
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<tr>
<td>Suture / Anastomosis</td>
<td>18% (7)</td>
<td>28.2% (11)</td>
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<td>53.8% (21)</td>
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<td>Tissue handling</td>
<td>18% (7)</td>
<td>35.9% (14)</td>
<td></td>
<td>46.15% (18)</td>
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Table 3: Useful as a training method in the opinion of respondents. Percentage distribution of each answer.
Table 4: Chi Square test results.

<table>
<thead>
<tr>
<th></th>
<th>LOW EXPERIENCE</th>
<th>HIGH EXPERIENCE</th>
<th>P VALUE</th>
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<tbody>
<tr>
<td></td>
<td>N 22</td>
<td>N 17</td>
<td></td>
</tr>
<tr>
<td>NUMBER OF ERRORS (X SD)</td>
<td>29 ± 7</td>
<td>9 ± 6</td>
<td>&lt; 0.0001 *</td>
</tr>
<tr>
<td>TIME IN MINUTES (X SD)</td>
<td>81 ± 19</td>
<td>40 ± 9</td>
<td>&lt; 0.0001 *</td>
</tr>
<tr>
<td>INCOMPLETE OR DEFICIENT ANASTOMOSIS</td>
<td>7 (32%)</td>
<td>1 (6%)</td>
<td>0.04 **</td>
</tr>
</tbody>
</table>

Table 4
Authors Disclosure:

1. Maricic Maximiliano Alejo, MD
2. Bailez María Marcela, MD
3. Susana Rodríguez, MD

Nothing to disclose.