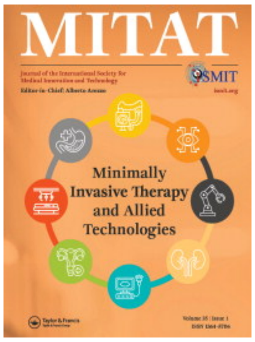

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The LeakChecker: quantitative air leakage assessment in laparoscopic intestinal anastomosis training

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ABSTRACT
Background: Performing an intestinal anastomosis is a challenging part of laparoscopic surgery, and ensuring adequate closure is essential to prevent anastomotic leakage. The aim of this study was to develop an objective method for quantitative assessment of laparoscopic intestinal anastomosis during simulation training.
Methods: A modular intraluminal air leakage device, the LeakChecker, was designed and validated by comparing laparoscopic intestinal anastomoses performed by laparoscopic novices and experts. The MaxForce, MeanNon-zero force, PathLength and DepthPerception parameters from the Lapron box-trainer vs MaxPressure and PressureArea from the LeakChecker were used for comparison.
Results: A functional prototype was built and the data of 10 laparoscopic novices and seven experts were included. Anastomoses made by the experts tolerated a higher MaxPressure (3,10(2,51-7,24)kPa vs 0,98(0,81-1,35)kPa; p=0.010) and showed a higher pressureArea (24,89(16,13-100,04)kPa*t vs 5,99(4,78-9,23)kPa*t; p=0.032). The Lapron box trainer data showed significant differences between the experts and novices for almost all including force and motion parameters.
Conclusion: The LeakChecker can quantify anastomotic leakage during training as it objectively distinguishes between novices and experts. Implementing this kind of smart training task in a training program with objective skill assessment would inform participants of both their instrument handing skills and the quality of their execution.

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Bowel-anastomosis; leakage; pressure; sensors; laparoscopy

Introduction

The rise of laparoscopic surgery has coincided with the expansion of surgical skills training, and the traditional 'see one, do one, teach one' approach is gradually being replaced by 'see one, simulate many, do one' [1,2]. Simulation training enables surgeons to enter clinical settings with an advanced skill set and greater confidence in their abilities [3–5].

A particularly challenging aspect of laparoscopic surgery is the creation of intestinal anastomosis after the resection of a diseased segment of the bowel. Although surgical staplers are frequently used to restore continuity, laparoscopic suturing remains indispensable [6]. If an intestinal anastomosis is not performed properly, an anastomotic leak may occur, potentially leading to septic complications, prolonged hospital stays, reoperation, and high mortality rates [7–9]. This emphasizes the importance of adequate education and training before performing an intestinal anastomosis in a clinical setting. During training, surgeons need to acquire a specific set of skills, including proficiency in laparoscopic suturing, knot tying, needle driving, and tissue manipulation [10–12]. Simulation training is recognized as an effective method for acquiring this advanced skill set [3,4].

Current training curricula include dry-lab training (box trainers or virtual reality), wet-lab training (animal tissue or human cadaver laboratories), clinical experience, and didactic lectures [2,13]. Compared to animal and cadaver models, simulation models are often more cost-effective, user-friendly, reusable, and pose less

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ethical concern [2]. Therefore, these simulators are ideal for novices to train and acquire the necessary skill set.

The Amsterdam University Medical Center and Amsterdam Skills Centre (ASC) utilize the Lapron box trainer for laparoscopic simulation training (Figure 1). The Lapron box trainer is equipped with an objective assessment system that provides trainees with force, motion and time feedback [11,14]. The trainees are expected to achieve a proficiency level set by experts. This helps evaluate trainee performance and progress, as well as predict the volume of training that is required [11,15]. Recently, the ASC developed a laparoscopic intestinal anastomosis training task, enabling simulation training on artificial tissue before attempting the anastomosis in cadaver labs or clinical settings [16] (Figure 1).

Although the training task is assessed based on objective force, motion, and time measurements, coupled with recorded videos (OSATS) [17], there is also a desire for a quantitative assessment of the suture itself. In literature, the burst pressure of the colon has been correlated with wall stresses and suture type, with mixed findings [18–20]. In these studies, the main interest appears to be the influence of healing on the anastomosis quality. In another study, a new objective assessment system was developed that used internal air-pressure measurements and image processing to evaluate suturing skills in an intestinal anastomosis model [21]. The findings demonstrate that gas or fluid pressure can be directly used to indicate relevant openings in an anastomosis model. This enables a training task to be developed that instantly quantifies intestinal connection leakage, independent of suturing technique used. Therefore, the aim of this study was to develop a simple, independent, objective quality assessment device for evaluating leakage in a laparoscopic intestinal anastomosis model. To investigate the potential influence of external factors on the quality of the anastomosis, the Lapron Boxtrainer was used to correlate instrument-task interaction forces, instrument motion and task time with anastomosis leakage.

Material and methods

Conceptualization

The laparoscopic intestinal anastomosis model consisted of an artificial intestinal bowel (Double Layer Bowel model; Limbs&Things, Bristol, UK) [22] with a 10×20 mm enterotomy, clamped to a custom-made task plate (Figure 1). To ensure objective measurements of anastomosis quality, the leak assessment device had to meet the requirements detailed in Table 1. Evaluation of concept solutions and the final product was based on the criteria listed in Table 2. At the start of the design process, all required functionalities for leakage testing were documented. Various sub-ideas were devised and listed for each functionality, and a morphological chart was created. From this chart, three viable combinations were selected and developed into different concept solutions. A Harris profile was used to evaluate the strengths and weaknesses of each concept solution [23]. Based on grading and evaluation against the seven established criteria, the air-leakage model was

Figure 1. Lapron box trainer with forceSense.NET interface (left) and standard intestinal anastomosis task being trained within the Amsterdam Skills Center (right).

Table 1. Product requirements.

Nr	Requirement
1	The device gives objective feedback on the quality of the suture based on leakage
2	The device measures one sutured defect at the time
3	The device allows cooperation with the Lapron box trainer
4	The device can be used at least 100 times without having to replace parts of the device
5	The device can be disassembled and components can be reused or replaced (modular design)
6	The device should not damage the artificial intestinal bowel when performing the test

Table 2. Product criteria.

Nr	Criterium
1	The test should be executed in the least amount of steps and effort for the user (Plug and Play)
2	The connection to the bowel should be as airtight as possible
3	The device should generate feedback to the trainee within the least amount of time
4	The costs of the setup are as low as possible
5	The artificial intestinal bowel should be reusable as many times as possible
6	The interpretation of data should be as efficient as possible for the manufacturer (taking into account time, storage, filtering, translating)
7	The test setup reflects the clinical situation well

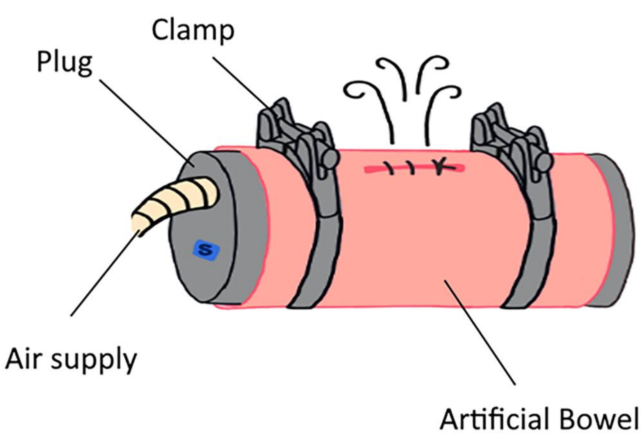

Figure 2. An artistic impression of the most suitable concept design: air-leakage model.

chosed as the concept with the most potential, progressing to prototype development (Figure 2).

LeakChecker prototype

To create the prototype for the air-leakage device the following aspects had to be considered. Two plugs were necessary to fully seal the intestinal anastomosis model. A pressure sensor (BMP280; Robert Bosch GmbH, Gerlingen, Germany) was mounted to one of the plugs to objectively measure the intraluminal air pressure, while also accommodating for air inflow. To secure the bowel model over the plugs, hose clamps had to be incorporated. The sensor data were transferred to an I/O interface connected to a computer, and data analysis software facilitated recording, storing, and analyzing the data through a wired connection. A plug-and-play system was established for user-friendliness and easy cleaning, featuring a resilient external case and an internal power supply. The prototype had a sustainable modular design, allowing for the straightforward replacement of parts, and the materials used were recyclable. System leakage was tested by inflating an intestinal bowel model without a defect. To test the device sensitivity, the minimum pressure difference was determined. Accuracy was determined by measuring deviation in the maximum pressure output when inflating the system to a specific pressure ten times. Finally, the maximum pressure and natural leak flow were determined over time.

Characterization

Intraluminal pressure data acquisition involved several steps. The threshold pressure was determined by measuring the current atmospheric pressure and adding 1 kPa, which was then programmed into the Arduino code. The value of the input pressure was based on observation of the dynamic model behavior during inflation. A pressure of 1 Kpa was enough to fully inflate the specimen into a balloon shape without overstressing the sutures or causing them to fail, cut, or shift. The anastomosis model was secured on the aluminum plugs using clamps, and when the device was switched on, the air pump increased intraluminal pressure. Once the threshold pressure was reached, the pump was shut down, and intraluminal pressure was measured for 20 s. If the threshold pressure could not be reached, the pump automatically shut down after 25 s. The intestinal anastomosis model could then be removed, and the cycle repeated. To test the repeatability of the device, two samples—one from an expert and one from a novice—were tested 15 times.

Initial validation protocol

Following initial device characterization and calibration tests, novices and experts were included from the Amsterdam UMC based on availability of participants and supervisors during a basic suture course. The laparoscopic intestinal anastomosis model was sutured in the Lapron box trainer using polysorb 2/0 V-20 1/2 taper (Medtronic, Minneapolis, MN, USA). The

Lapron box trainer was equipped with one curved Maryland grasping forceps (Aesculap, B. Braun, Melsungen, Germany) and a laparoscopic needle holder (Adtec needle holder; B. Braun, Melsungen, Germany). The task consisted of closing the intestinal anastomosis model starting from the top with a suture and a surgical knot, followed by four sutures, and completed with a final surgical knot. A rectangular hole measuring 20×10 mm was created using a mold to indicate the outline. Once the outline was drawn on the wall, participants used scissors to make the cut. No further instructions were provided. Pressure measurements were conducted by simultaneously recording and filtering pressure (Pa) and time (s) data, which were then exported to Microsoft Excel 365 (Microsoft, Redmond, WA, USA), IBM SPSS 28 (IBM, Armonk, NY, USA), and GraphPad Prism 9 (GraphPad Software, San Diego, CA, USA) for analysis. Based on earlier studies, a laparoscopic novice was defined as a student who had performed fewer than 10 laparoscopic procedures, including intestinal anastomoses, whereas an expert was defined as someone who had performed more than 50 such procedures [16]. Ethical approval was granted by the Medical Ethics Review Committee (METC) of the Amsterdam UMC under a standing institutional agreement for research conducted during training courses involving residents. As the study involved anonymized performance data collected during voluntary simulator-based training with no consequences for participants, the requirement for individual informed consent was waived by the committee. Instrumented data collection using the ForceSense system (ForceSense, Ghent, Belgium) was covered by this approval. Laparoscopic videos were recorded and stored in ForceSense.NET database, only accessible to authorized researchers. LeakChecker data were stored locally and were accessible only to the authors who processed the data for article preparation.

Performance metrics

From the data obtained, multiple objective performance parameters were derived to assess the anastomosis task performance. From the LeakChecker, two parameters were calculated. Max Pressure is defined as the highest intraluminal air pressure acquired inside the intestinal bowel model in the 20-s measurement. To represent the pressure slope profile, the 'Pressure Area' was calculated, describing the pressure loss over a defined period after the peak pressure was reached (Figure 3). From the Lapron box trainer, the most discriminating parameters—TaskTime, MaxForce, MeanNonzeroForce, PathLength (Left and Right), and DepthPerception (Left and Right)—which best represent performance in a 3D suturing task, were included [15,24,25].

Statistics

Within an initial step, the distribution of the data from each system was assessed using the Shapiro-Wilk test, which indicated non-parametric distribution for all parameters ($p < 0.5$). Therefore, the Mann-Whitney U test was used to indicate potential differences between the novice and expert groups for each parameter. A p-value < 0.05 was considered statistically significant.

Results

LeakChecker prototype

The developed air-leakage device was named the LeakChecker (Figure 4). Two aluminum plugs were fabricated to match the dimensions of the artificial bowel. Cavities were milled into one plug to accommodate the atmospheric pressure sensor and air supply. A 3D-printed PLA holder was designed to keep the sensor in place and prevent a short circuit between the aluminum cap and the sensor. Butterfly hose clamps secured the intestinal anastomosis model to the plugs, and the electronic hardware was housed in a sturdy case. The lid, slightly concave, facilitated stable placement of the intestinal anastomosis model (Figure 5). The prototype

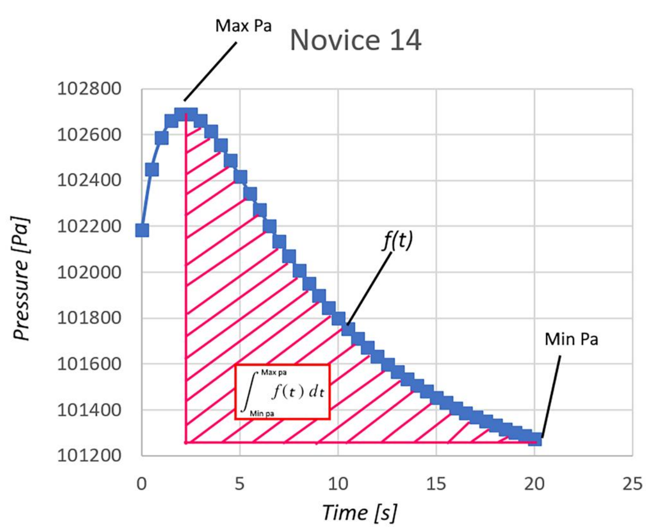

Figure 3. The Pressure Area is indicated by the red area spanned between the lowest and highest points of a pressure profile.

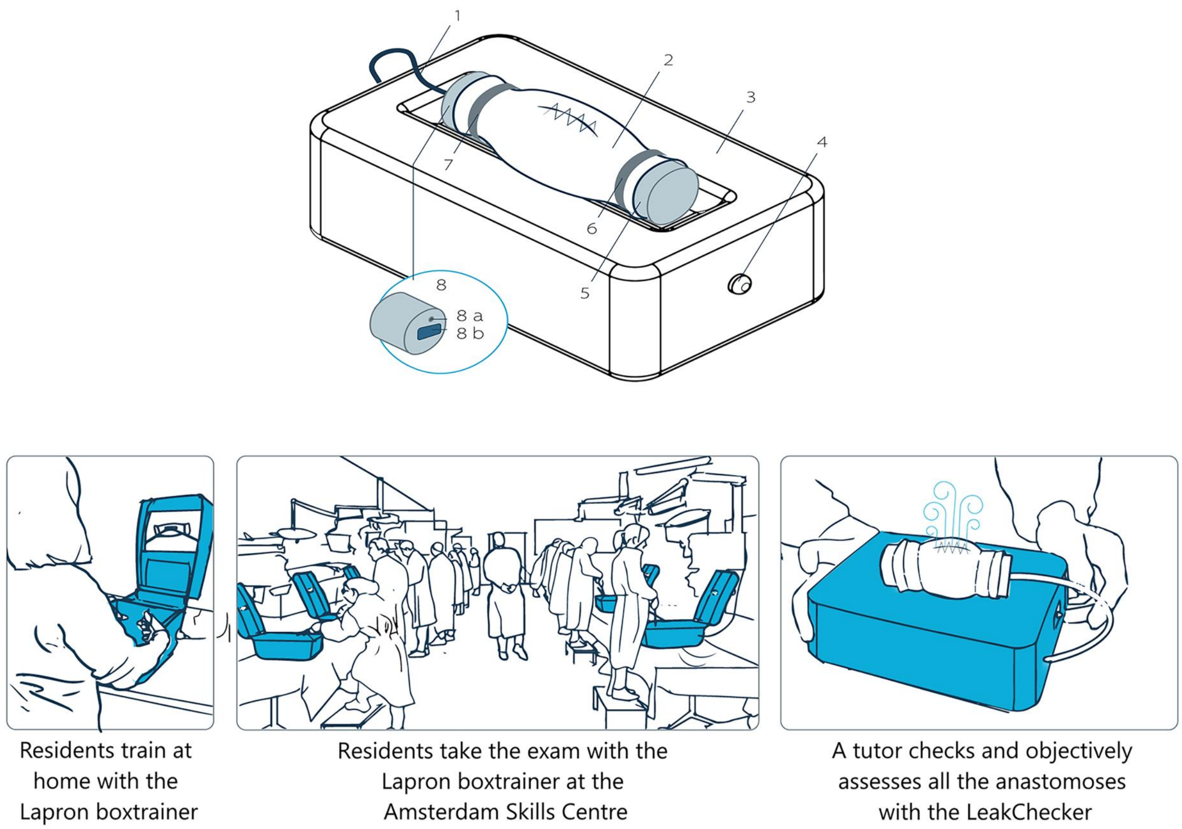

Figure 4. LeakChecker final design and user scenario.
(1) Canal for air and electricity; (2) Intestinal anastomosis model; (3) Case with hardware; (4) Momentary button; (5) Aluminum plug; (6,7) Butterfly hose clamps; (8) Aluminum plug with sensor and air tube; (8a) Air tube; (8b) BMP280 digital pressure sensor and 3D-printed PLA sensor holder.

was wired and programmed using an Arduino Uno (Arduino, Ivrea, Italy), with the code written in the Arduino IDE version 1.8.19. The closed-loop feedback system, activated by a momentary button, simultaneously initiated the pump and atmospheric pressure sensor. The sensor measured the rising intraluminal pressure as air was pumped into the sutured intestinal bowel model. Upon reaching the threshold pressure, the software stopped the pump and collected pressure data for 20 s. If the intraluminal pressure failed to reach the threshold within 25 s, the air pump ceased, and no further data were collected. The modular design of the LeakChecker allowed for individual component replacement, with eco-friendly materials carefully selected for construction, including a 3D-printed case from bioplastic and recycled metal for the aluminum plugs [26]. The LeakChecker successfully met the requirements outlined in Table 1. Although the LeakChecker's data were not directly integrated into the Lapron box digital environment, both sets of results could be manually combined for research purposes. Requirement 5, concerning electronics accessibility, was fulfilled by lifting the inner cover for easy access. The Arduino electronics platform facilitated the straightforward replacement of parts, meeting Requirement 6.

Characterization

The maximum pressure of the diaphragm pump was >60 Kpa with a maximum flow rate of 2 L/min. Component leakage testing of the components was performed by applying a maximum hand pressure of approximately 5 kg on a 10 ml syringe filled with water for 20 s, connected to the relevant part of the system. Both tests showed no fluid leakage from any of the components. As the pressure was monitored directly using a standard off-the-shelf digital pressure sensor (BMP280 Barometer Module; Bosch, Gerlingen, Germany), no further calibration of the system was required, given the nature of this study. Leak testing with a control anastomosis model (intestinal bowel model without a defect) confirmed the LeakChecker's airtightness. The control model showed a continuous pressure increase over the full 20 s until stabilization, whereas pressure loss occurred in both novice and expert suture models (Figure 6). As the device produced reproducible and accurate measurements, the initial construct validation followed.

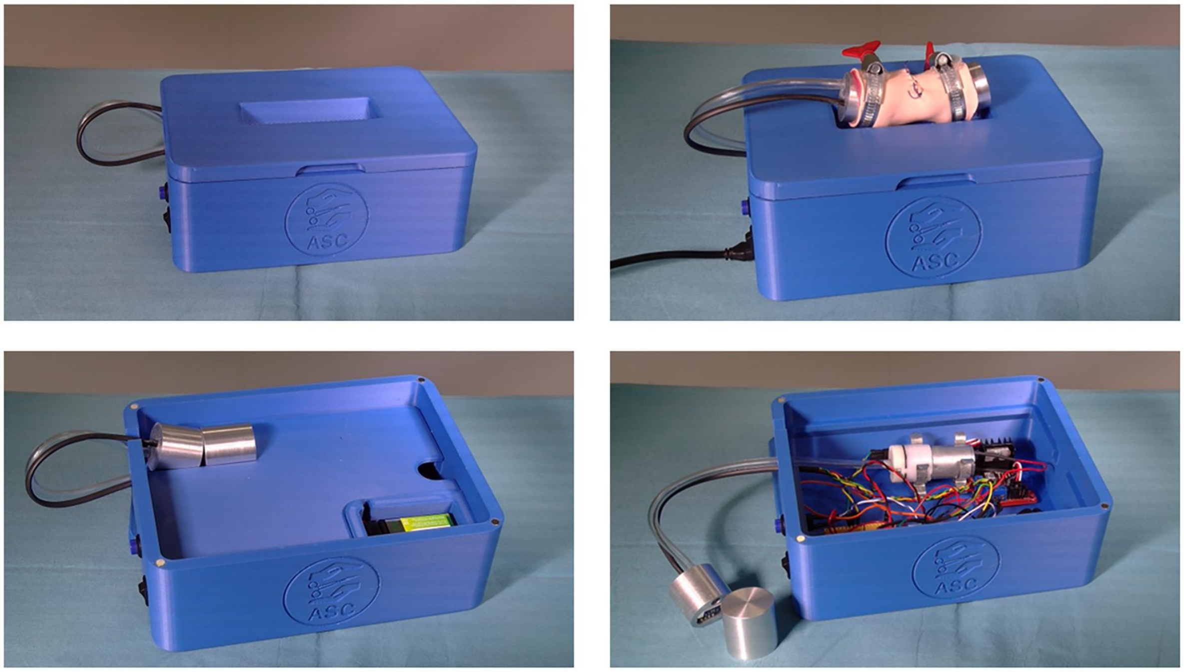

Figure 5. Final prototype of the LeakChecker.

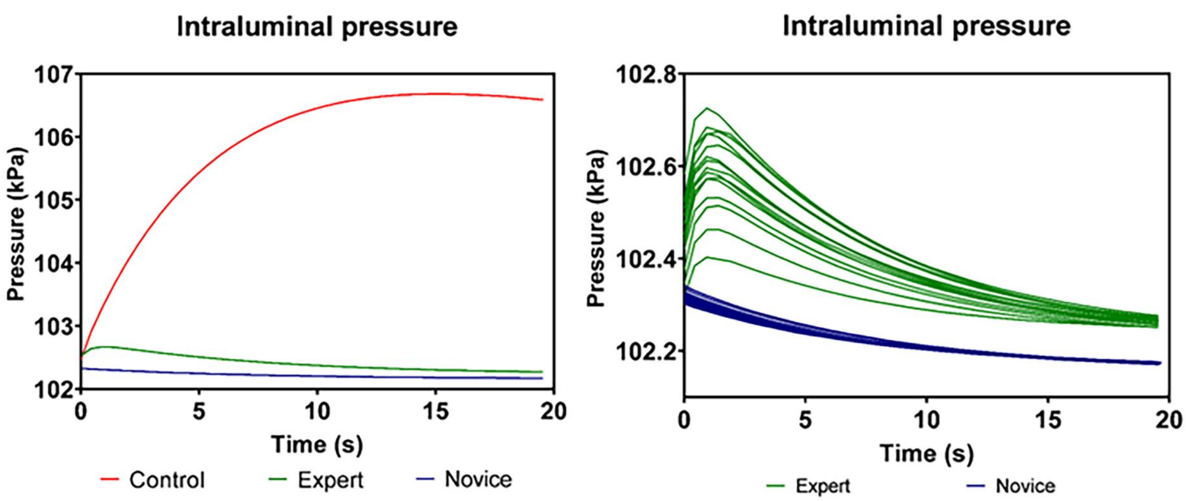

Figure 6. Feasibility results from the LeakChecker: control, novice, and expert anastomoses (left); 15 repetitions on a 'good' and 'bad' anastomosis (right).

Initial validation

Seven experts and 13 laparoscopic novices were included from seven Dutch teaching hospitals. All experts and 10 of the novices completed the task successfully, allowing inflation and Lapron data collection. The remaining three students were removed from the dataset. From this data set, it was observed that two experts exhibited a pressure profile in which the pressure difference did not become negative shortly after reaching the threshold, resulting in an alternative type of profile. The expert group also demonstrated higher Max Pressure (3.10 [2.51–7.24] kPa vs. 0.98 [0.81–1.35] kPa; $p = 0.010$) and greater Pressure Area (24.89 [16.13–100.04] kPa·s vs. 5.99 [4.78–9.23] kPa·s; $p = 0.032$) compared with the novice group. Table 3 and Figure 7 show the differences in performance parameters from both the LeakChecker and Lapron box trainer for the novices and experts.

Discussion

The LeakChecker provides an objective method for assessing the quality of intestinal anastomosis simulation training in the Lapron box trainer. Initial validation measurements demonstrated that the LeakChecker could

Table 3. Difference in intraluminal air pressure parameters and lapron parameters between the novices and experts.

Parameter	Novice median (IQR)	Expert median (IQR)	p-value
MaxForce	**3.27 (2.24–4.50)**	**1.97 (1.85–2.05)**	**0.004**
MeanNonZeroForce	**0.74 (0.63–0.93)**	**0.58 (0.50–0.61)**	**0.015**
MeanRPathlength	**12141 (11050–15332)**	**5703 (4185–7046)**	**0.003**
MeanLPathlength	**11292 (8999–16028)**	**5679 (4195–8730)**	**0.004**
MeanRDepthperception	20.6 (16.7–22.1)	17.7 (11.4–22.1)	0.071
MeanLDepthperception	**28.2 (18.2–31.9)**	**15.9 (14.2–20.5)**	**0.021**
Max Pressure	**0,98 (0,81-1,35)**	**3,10 (2,51-7,24)**	**0.010**
Pressure Area	**5,99 (4,78-9,23)**	**24,89 (16,13–100,04)**	**0.032**

* Green = Lapron Parameters, Purple = Leakchecker parameters. Bold indicates that significant differences were observed.

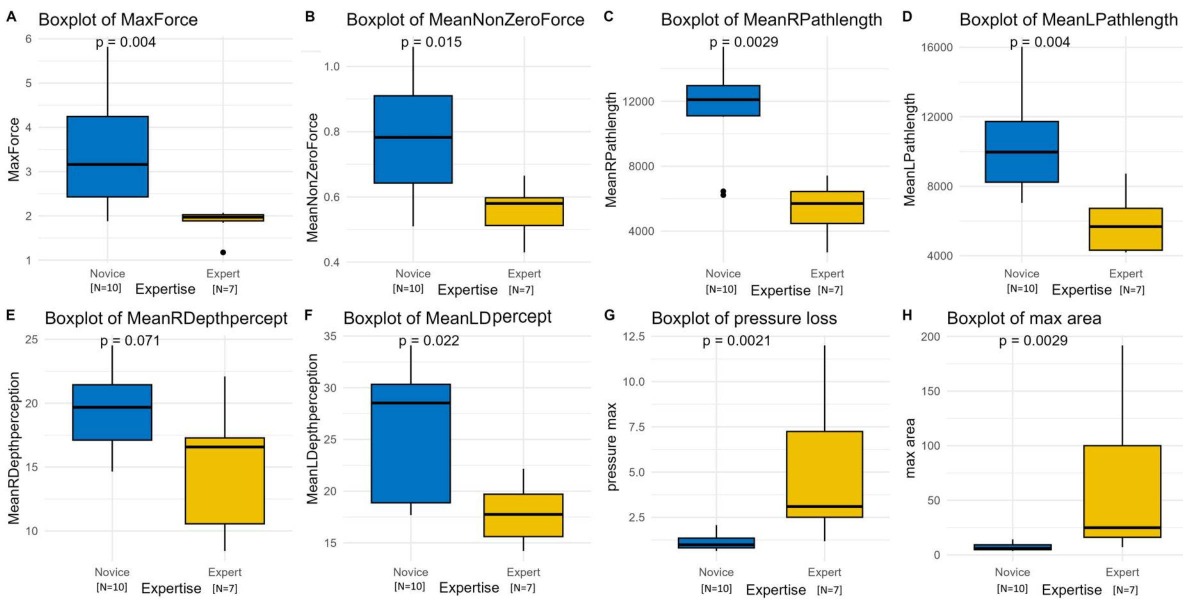

Figure 7. Initial validation boxplots of all parameters; Lapron and LeakChecker data combined.

effectively distinguish between intestinal anastomosis performed by novices and experts by objectively assessing differences in Pressure Area. The 15 repetition tests conducted on a 'good' and a 'bad' anastomosis showed that, despite the maximum force fluctuating, the pressure loss profile remained largely consistent. Fluctuations in the maximum pressure point for the 'good' sample may have been caused by variations in environmental air pressure. Interestingly, two experts from the group were able to create an airtight anastomosis suture, resulting in a deviant pressure drop profile. In fact, the data indicated that the pressure loss due to leakage was smaller than the residual pressure increase, closely resembling the data and profile of the intact control specimen. Combining this quantitative pressure data with the objective force, motion, and time data from the Lapron box trainer indicated that experts exerted less force on the specimen during suturing, resulting in higher-quality anastomoses that leaked less air. This indicates that leakage is influenced not only by the amount of tension in the thread but also by the position and orientation of the stitches. Combining these objective parameters could therefore provide more informative, automated feedback during training. Furthermore, the LeakChecker was designed as a sustainable, modular device made from recycled and eco-friendly materials, providing an affordable and accessible training model with potential global reach. It also serves as a preparation for, or alternative to, cadaveric or animal training.

The use of air leakage for clinical intestinal anastomoses assessment was not a new concept. Mechanical assessment techniques, such as the air leak test (ALT) or the dye leak test (DLT), are clinically used to investigate the air- or water-tightness in an anastomosis [27,28]. It has been shown that there is a significantly higher chance of anastomotic leakage in patients with a positive ALT compared to a negative ALT, which proves air leakage can be used clinically to predict anastomotic leakage risk [29]. This indicates that air leakage is a valid way to assess anastomoses in training settings as well. The purpose of LeakChecker is to train and improve technical skills in intestinal anastomosis before performing the procedure on patients. In the future, the LeakChecker will also be implemented in wet-lab training, using *ex vivo* porcine bowel models. When different sample materials are used in the LeakChecker concept, it is recommended to redefine the maximum pressure and monitoring time based on the observed behavior of the specimen and the plateau phase of the pressure curve. It should be noted that when real tissues with non-homogeneous wall properties are used, the overshoot behavior may be less predictable compared to synthetic samples. In this study, the Lapron system was used to test and validate the LeakChecker task; however, the task itself operates independently of the Lapron interface. Therefore, it can be used, without modification, with any trainer that provides sufficient internal space.

Uemura et al. also developed an air-pressure device to assess laparoscopic and robot-assisted suturing skills [21,30]. In addition to leakage measurements, the device used image-processing technologies to evaluate suturing performance: it could determine whether the participant placed the correct number of stitches ($n = 3$), estimate suture tension based on deformation of the suture area, and estimate the open area when the suture did not fully close the defect. The higher Max Pressure and Pressure Area observed in the expert group indicate that expert sutures on the anastomosis were more resistant to pressure than those of novices. Uemura's results for wound opening area also favored experts over novices. The wound opening area was ideally as small as possible, with an acceptable range being between 0 and 3.92 mm^2. Experts achieved an average of 1.76 $mm^{2,}$ whereas novices had an average wound opening area of 11.06 mm^2. These numbers match the results of our device, which also show that the expert anastomosis is more leak-resistant compared to the novice anastomosis.

The strengths of the LeakChecker include its simplicity, precision, and sustainability. Operation requires only a single button push, achieving a pressure difference sensitivity of 0.01 Pa, and eco-friendliness and reusability have been considered from the very start of production. Its greatest potential lies in combining the assessment capabilities of the LeakChecker with data from the Lapron box trainer. This combination ensures feedback is provided on performing the task as well as on the resulting anastomosis. Therefore, novices not only know whether their suture is of high enough quality, but also how they can improve their skills and what aspects of training to target.

Limitations

The LeakChecker has some limitations, providing opportunities for future innovations. These could include wireless functionality and direct feedback from the box, eliminating the need to connect to a laptop. Given the limited sample sizes in this initial validation study, we must recognize that findings may be underpowered. Although statistical differences were observed for most parameters, the group sizes were too small to analyze correlation between parameters. Future work should therefore include larger groups to investigate which instrument–tissue manipulation behaviors most influence anastomosis quality.

Future work

To further investigate the discriminative power of the new parameters, a Linear Discriminant Analysis (LDA) with Leave-One-Out-Cross-Validation (LOOCV) could provide additional insight into parameter performance during training. Moreover, learning curves (LCs) can be recorded over multiple repetitions (training trials) to identify proficiency levels in relation to training time [16,24]. To further strengthen both engineering and criterion validation when moving toward a final product, a short bench repeatability study—including test-retest of the same anastomosis with inter-day variability—would be necessary.

Conclusion

The LeakChecker, a modular measuring device, was developed and successfully used to assess intestinal anastomosis gas leakage based on objective pressure data. It effectively distinguished between novice and expert groups performing intestinal anastomosis. This quantitative, objective assessment of laparoscopic training tasks provides an invaluable tool for examining and advancing minimally invasive surgical skill development.

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Author contributions

CRediT: **A. Masie Rahimi**: Conceptualization, Investigation, Methodology, Project administration, Supervision, Visualization, Writing – original draft, Writing – review & editing; **Eline Cox**: Data curation, Investigation, Methodology, Software, Validation, Visualization, Writing – original draft; **Sem Hardon**: Data curation, Investigation, Methodology, Writing – review & editing; **H. Jaap Bonjer**: Project administration, Resources, Supervision, Writing – review & editing; **Freek Daams**: Resources, Supervision; **Tim Horeman**: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Resources, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

Disclosure statement

Dr. Masie Rahimi, Eline Cox, Dr. Sem Hardon, Prof. H. Jaap Bonjer, Dr. Freek Daams, and Dr. Tim Horeman have no conflicts of interest or financial ties to disclose.

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