ForceClip: a novel force sensing platform for laparoscopic clip application training

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Clip appliers are important instruments in laparoscopic surgery, as they are used to close tubular structures such as vessels. Incorrect application of ligation clips can lead to tissue damage or sub-optimal closure of the vessel. However, clip application quality is currently only evaluated by eye in surgical training. In this paper, a novel force sensing system, ForceClip, is developed and integrated in a box trainer task for clip application training. The proposed solution measures light through a silicone phantom as an indication of the clipping force. It is capable of detecting both insufficient and excessive forces, doesn't interfere with the clip application task and is independent of the surgical instrument. A functional prototype is used to evaluate the system with different test set-ups. The final result represents the first design iteration for the development of a fully working device. It consists in an affordable training task which costs less than 20 euros, measures clipping forces with a mean sensitivity of 0.0843 V/N, and provides visual feedback. A current limitation is the repeatability, which can be improved in future work.

1 Introduction

Laparoscopic clip appliers are instruments used in minimally invasive surgery to close small tubular structures such as blood vessels or the cystic duct [1]. To guarantee the safety and success of the surgery, correct use of such instruments is crucial. In particular, the force exerted by the surgeon to close the ligation clip can influence the surgical outcome, leading to severe tissue trauma or ineffective closure of the vessel. The latter can result in clip migration, perioperative leaks, and infections [2, 1]. It is therefore important to develop a method to investigate the correct use of these devices and employ this knowledge to train surgeons.

Different methods to assess the forces applied by laparoscopic instruments (e.g., graspers or clamps) on tissues are found in literature [3, 4]. These methods can be used to evaluate the instruments and enhance haptic feedback during surgery [5], or they can be implemented in boxtrainers and virtual reality for training of surgeons [6, 7]. In boxtrainers, in particular, studies have shown that visual or tactile feedback can shorten the learning curve while providing an objective assessment of performance [3, 8]. Force sensors can be integrated in the instrument to measure direct forces, as done for example by Yokota et al. [9] and Olivas et al. [10], or placed in the environment, as in the Force Platform developed by Horeman et al. [11]. In this case, they are used to assess interaction forces without interfering with the task or modifying the surgical instrument [3, 7].

To our knowledge, there are currently no tools designed specifically to train and evaluate clip applying tasks. The present research aims to develop and validate ForceClip, a sensing system that measures the interaction forces between laparoscopic clip appliers and a tissue phantom during training. The platform will be implemented in a dedicated box trainer task to provide real-time feedback during training.

First, the specific requirements for this design are explained. Then, the sensing system and the final design of ForceClip are presented. Finally, a preliminary evaluation of a functional prototype is performed and the results are discussed in relation to possible limitations and future work.

2 Requirements

There are several challenges associated with developing a force sensing system for clip application training. To make ForceClip resemble application during laparoscopic surgery as much as possible, a set of requirements is specified.

First of all, the system must be able to measure the force applied by a ligation clip (typically 8-10 mm long, 1 mm wide) on a tubular phantom and alert the trainee if it is too little, correct, or too high. Special interest is set on detecting excessive forces to avoid tissue damage. Secondly, the system should not interfere with clip application and should be independent of the clip applier. The task should fit inside the visual range of a box trainer (approx. 30x20x10 cm in the 3-Dmed T5 box trainer). It is also important that the training task allows for the application of several clips, which should be easily removed after each application. Moreover, the trainee should be able to place the clip freely within a

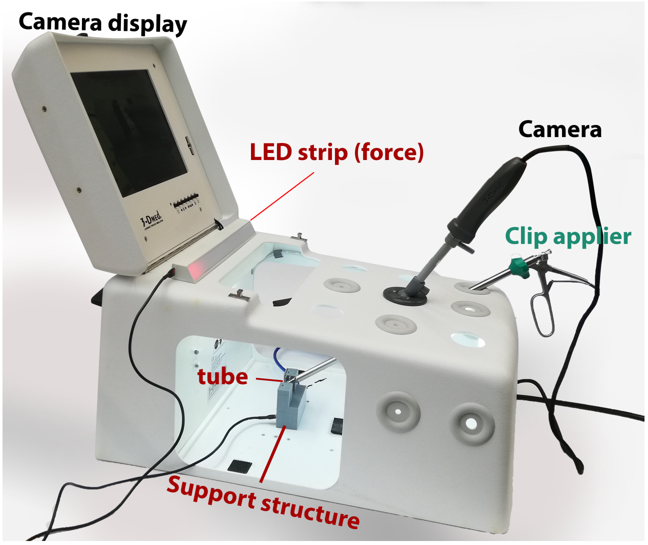

Fig. 1. Example of use of the developed sensing platform. Its main parts are: silicone tube mimicking a vessel, structure for support and electronics casing and LED strip for visual feedback. The platform is placed in a box trainer and used for laparoscopic clip application training.

specified range.

The phantom must be tubular and have a diameter (d), wall thickness (w) and Young's modulus (E) comparable to anatomical structures such as veins ($\overline{d}$ = 5 mm, $\overline{w}$ = 0.5 mm, $E \approx 0.03$ MPa) and arteries ($\overline{d}$ = 4 mm, $\overline{w}$ = 1 mm, $E \approx 0.2$ - 0.6 MPa) [12, 13, 14]. Also, it should be easy to replace.

Finally, the platform should provide real-time feedback on the applied force without distracting the trainee from the task, and record the data for future use.

3 Design

ForceClip is developed to meet the goal of providing feedback on the optimal force for clip application in a box trainer (see Fig.1). As the trainee uses a clip applier to place a ligation clip on a silicone tube, the force exerted on the tube is measured, and shown as visual feedback on a LED strip.

The main challenges are to not interfere with the task and be independent of the clip applier. These exclude the use of commonly used sensors, which are either too big to fit the task or would influence the clipping force.

Therefore, a novel sensing system is developed. This is based on measuring the IR light that travels through the walls of a silicone tube. A description of the sensing system and design components follows.

3.1 Sensing

The measuring system used has to our knowledge never been attempted before. Previously, light has been used to detect forces via optical fiber and transparent material bending [15], but not by measuring the compression of a soft transparent material.

In the setup presented in Fig. 2, the LED sends IR light

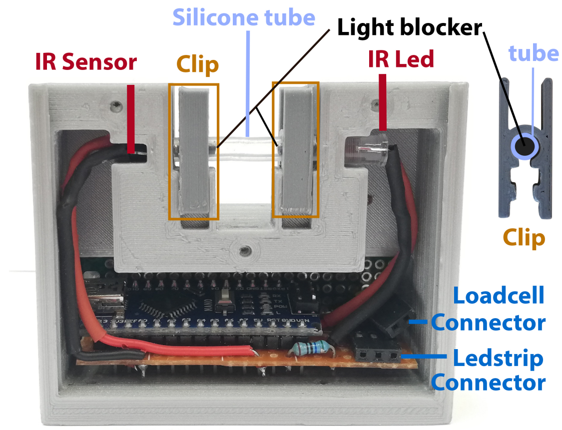

Fig. 2. Internal components of the force sensing system. The clipping force is measured by sensing the decline in IR light when the tube is clipped. Two 3D printed clips hold the silicone tube into place.

to the sensor on the other side of the tube. Two 2 mm metallic rods coated in black marker are placed at both ends of the silicone tube, so that light is forced to travel through the tube's walls. Together with a limited length of 2.4 mm, this eliminates the effect of bending on the sensor output. The IR light emitter KY039 and the phototransistor contained in the product TCRT5000 are used. From the sensors available, this pair gave the best sensitivity results. They both work at $\lambda = 950$ nm, resulting in no visible light interference. The force measurement is based on the compression of the silicone walls upon clipping. Because the light travels through the tube walls, the reduction of light sensed by the receiver will be related to the amount of clipping force exerted.

An Arduino nano (ATmega328) is employed to measure the clipping force and give feedback via the LED strip. It is also used in combination with a loadcell to perform calibration.

The electrical circuit and components used in the ClipForce are shown in Fig. 3. The red and blue region electronics can be plugged in via the connectors in Fig. 2.

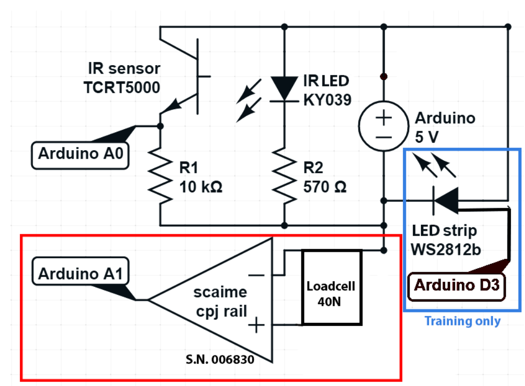

Fig. 3. Schematics of the circuit used to measure, calibrate and display the force applied on the silicone tube via detection of light.

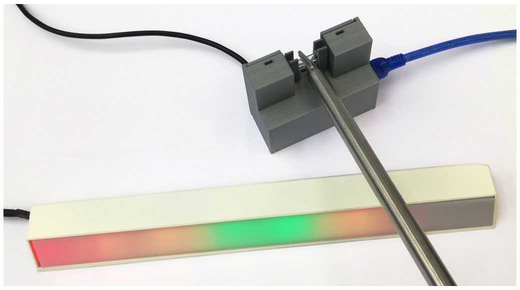

Fig. 4. Visual feedback is implemented using an LED strip. With more clipping force, the LEDs turn on from left to right. The green area is when an optimal force is applied. The left region refers to too little force, the right region to too much force.

3.2 Support, clips and tube

A silicone tube (24 mm long, 2 mm inner diameter, 4mm outer diameter [16]) is chosen as a phantom. The shape, size and stiffness resemble human vascular tissue, although other mechanical properties are not realistic. A 3D printed support structure holds the tube and electronics into place (see Fig. 2). The tube is kept in place by two 3D printed clips, which also allow for easy replacement after a clip application. The clips are currently optimised for the tube diameter, and should be reprinted in case of using differently sized tubes. They were printed on an Ender 3 V2 in Polyterra PLA, but in the future PETG should be used for increased durability. The support structure was printed on the Ultimaker S5 Pro in PLA with dissoluble support.

3.3 Visual Feedback

To give feedback on the applied force to the trainees, LEDs turn on with increasing force, as shown in Fig. 4. A color scale is achieved using 6 LEDs: red, orange, green, green, orange and red. The lights turn on at certain IR sensor thresholds, which can be related to force values via calibration. The green area is optimal, while the red and orange represent insufficient or excessive force application.

4 Validation Methods

For the development of the sensing platform presented here, two experiments were carried out: one for calibration and one to determine the force required for optimal tube closure.

4.1 Calibration

To relate the measured light intensity with the applied force, the system was calibrated with the setup shown in Fig. 5. The jaws of an ETHICON Ligaclip 12 clip applier were glued to a 3D printed support to resemble the original instrument closure, see Fig. 5. A clip of this applier was also cut in two parts, and glued to the jaws, to match the jaws' surface during use. The 3D printed support was attached to a S-beam FUTEK loadcell measuring up to 40 N with a resolution of 0.0412 N.

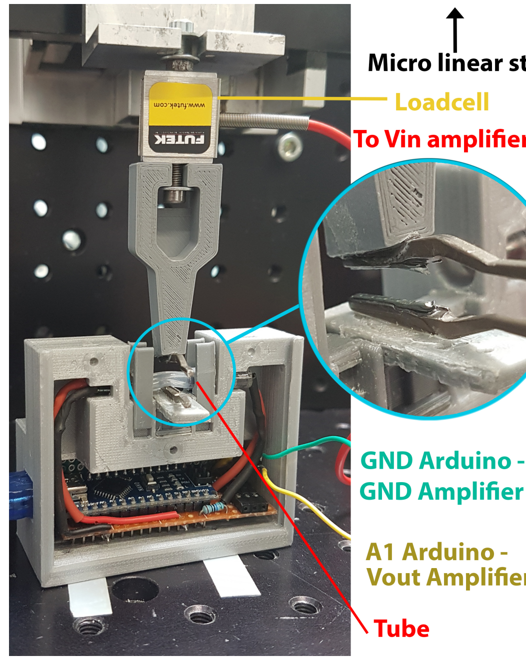

Fig. 5. Calibration setup consisting of a loadcell and two cut up clip applier tips with a clip, glued to a 3D printed support which is attached to a linear micro-stage. Downwards movement of the support results in tube compression, resembling clip application.

By operating a 6 mm linear micro-stage by hand, the support can be moved downwards, making the upper jaw and clip close the tube. This was repeated 21 times, attempting to obtain data on three ranges of speed to analyse its effect. From this, the milliseconds timestamps, force from the load cell and light sensor output were obtained with a sampling speed of 18 ms per sample. The light sensor readout between 0 and 1023 can be converted to volts by multiplying by the Arduino's resolution of 5 V / 1024 units. Lower light values indicate more force being exerted during clipping, which is expected to result in a more tightly closed tube.

4.2 Force required for tube closure

A second experiment was carried out to determine the optimal clipping force for tube closure. First, clip application was performed 14 times with varying forces, which resulted in varying IR sensor outputs. Then, the effectiveness of tube closure was tested with pressurised water. For that, a 10 ml syringe (piston diameter = 14.25 mm) was filled with water and attached to one free end of the tubular structure. Next, the syringe piston was pushed against a weighing scale and the grams at which the ligation clip failed to close the tube (water started flowing through) were noted down. A laparoscopic reusable clip applier by Dufner Instrumente GmbH containing medium-large titanium clips by LocaMed Ltd. was used.

From this, two measurements are obtained. First, the minimum light intensity detected by the IR sensor during clip application. The minimum light value relates to the maximum clipping force exerted on the tube. The second mea-

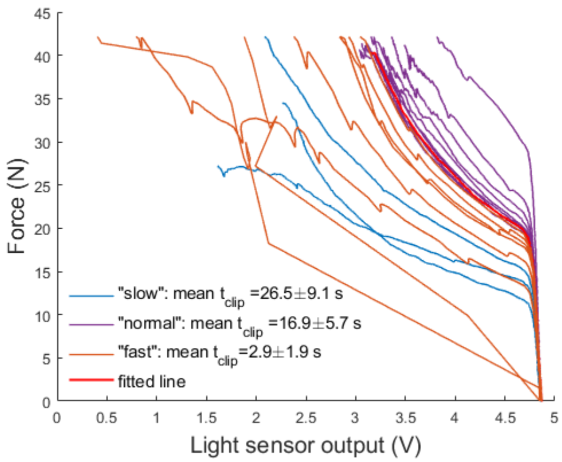

Fig. 6. Data-sets obtained with the calibration setup by moving the linear micro-stage at different speeds. The lines are divided in three groups referring to ”slow”, ”normal” and ”fast” speed. To exemplify how the data can be fitted for calibration of the system, the highlighted red line is used. Mean t_{clip} refers to mean clipping time.

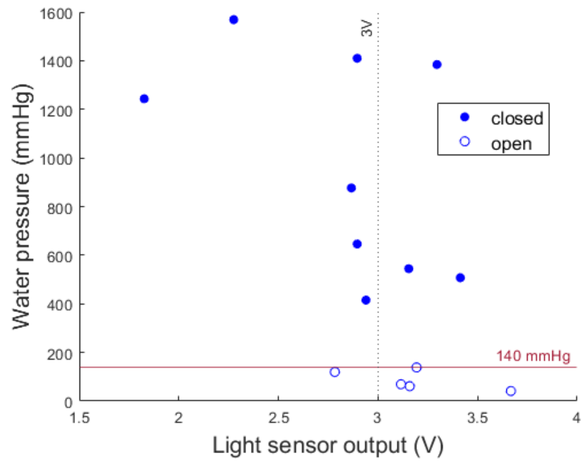

Fig. 7. Water pressure (mmHg) when tube closure fails versus minimum light (V) recorded during clipping. Lower light values indicate higher clipping force. The red line (140 mmHg) indicates the maximum blood pressure in humans. The dashed line defines the light threshold below which 85.75 % of the tubes are effectively closed.

surement is the weight exerted on the syringe piston right before the ligation clip fails and lets water flow through. For the following analysis, the grams measured are converted into pressure values by taking into account the area of the syringe piston.

5 Results

5.1 Calibration

The data from the calibration experiment was processed to consider only the compression of the tube, as release of the tube is not relevant to the clip application task. The resulting curves all show a similar behavior: at force = 0 N, the maximum amount of light travels through the tube, reading 4.87 V. In the first part of the curves, a steep increase in force corresponds to a small decrease in light intensity. Then, all the curves bend, and the IR sensor output decreases at a higher rate. All bending points fall approximately at 4.74 V but the curves vary within the three experimental groups. The two fastest measurements don't show the same behavior, as too few data-points were acquired.

The average duration of each group of measurements is computed based on the timestamps and reported in the graph. From these results, the sensitivity of the sensing system is computed separately for the two parts of the curve, resulting in an average slope of 0.0887 V/N before the bending and 0.0801 V/N afterwards. The overall (mean) sensitivity is 0.0843 V/N.

This data can be fitted to find an expression to convert the IR sensor output into force values in the Arduino code. For example, the two parts of the curve highlighted in Fig. 6 can be fitted separately using the ”polyfit” function in MATLAB. For getting the best fit, it is recommended to fit with two different polynomials left and right of the bending point near 4.8V. Due to the variability of the data, further analysis is required to optimise fitting, as discussed in section 6. However, once this becomes more reliable, the polynomials can be used to display the corresponding force to the light value.

5.2 Force required for tube closure

The recorded data from the second experiment is visualized in Fig. 7. This shows water pressure (mmHg) against recorded light (V). A pressure value of 140 mmHg is taken as a threshold. This value is considered as the highest blood pressure inside human vessels. Therefore, clips withstanding a water pressure above it are considered closed (filled circles in Fig. 7).

From Fig. 7, we extract that a value of 3 V or lower achieves effective tube closure in 85.71% of cases. This will be used as a threshold to indicate sufficient clipping force via the visual feedback. Below 3 V, only one tube was not effectively closed. This measurement took twice as long as the rest (53.3 s vs. 25.89 s average time), indicating that the clipping time was significantly slower.

6 Discussion

6.1 Results analysis

The presented system is capable of sensing the forces exerted by a clip applier onto a silicone phantom by measuring light intensity through the phantom's walls, with a high sensitivity (0.0843 V/N) and resolution (which depends on the IR sensor and sampling rate). This method can sense the compression of the walls past the closing point, which is particularly suitable to measure excessive force as an indicator of tissue damage.

Regarding the first experiment, the shape of the force-light curve (see Fig. 6) can be explained as follows: initially, the tube's walls are not compressed, so the amount of light passing through changes only slightly. From the bending point onward, the sensor's output decreases significantly as the walls' thickness decreases. The bending point indicates contact between the walls, but the clip should be able to withstand blood pressure, so a higher force is required to consider the tube fully closed. This was investigated in the second test and is discussed later.

As previously stated, there is significant variability across the datasets. There is a difference between the three measurements groups, especially between the "normal" and "fast" ones, but no direct correlation is found. The possible influence of clipping speed on the sensed light should be analyzed by repeating the experiment with a motorized linear stage, so that speed can be directly controlled. Other possible factors are the slipping of the calibration tip, the clip's position on the tube, and the mechanical behavior of the silicone under compression.

From the results of the second experiment (see Fig. 7) we set a light sensor value of 3V as the minimum threshold for effective tube closure, which will be indicated with a green color by the visual feedback . However, one tube was found ineffectively ligated at 2.78 V. The difference in clipping time between this specimen and the rest could account for this result. That could be due to dependency of the force-light relation on clipping time.

This exemplifies that depending on the application, which will define a certain clipping time, tube's size, clip applier and ligation clip among others, a representative curve from the calibration experiment should be fitted. That will result in a model relating the force to the light sensor output under specific conditions. Combining that with the results from the second experiment, one will be able to assess the exact clipping force that guarantees an effective tube closure.

From Fig. 7, the effectively closed clips underwent a mean clipping time of 24.8 s, which falls into the "slow" group in Fig. 5. From that plot it can be extracted that a force of approximately 23 N is required to achieve 3 V of light intensity under such conditions. This is in disagreement with other papers, which report that a maximum force of 5-10 N is usually applied with other laparoscopic instruments [3, 4]. This difference could be due to considering the force applied by the surgeon on the handle, rather than the one directly on the tissue. Nevertheless, lower clipping times are expected during training, so new measurements at faster speeds are required.

6.2 Limitations and future work

The main limitation of this research is the high variability of the data, which results in a low reliability and precision of the sensing system. Only preliminary tests were conducted to evaluate the performance of the platform, which limits our understanding of the system's behavior and of other possible factors that influence it. Furthermore, while the lower threshold for force was determined experimentally, excessive force evaluation was not conducted. Since the silicone phantom differs in mechanical properties to real tissue, it is not possible to assess damage directly. Consultancy with multiple expert surgeons could provide a rough estimation of the threshold, but ultimately a protocol should be defined to correctly determine it. Other future developments should include: user testing, to determine the efficacy of the visual feedback; improvement of the phantom to better resemble real tissue and modification of the calibration setup to closely simulate the clipping task.

Although this research represents only the first step in the development of a functioning device, the final product can be integrated with a dedicated interface to record learning curves, and with other sensing devices and possibly other forms of feedback, such as haptics, to improve the user experience. The same system can also be used to evaluate the performance of current clip appliers, and possibly adapted to other surgical instruments.

7 Conclusion

A novel force sensing platform for laparoscopic clip application training, ForceClip, was developed. The final product is equipped with a 3D printed support that ensures easy use in box trainers, along with a visual real-time feedback system and a data recording function.

The novelty of the platform refers to the use of light to measure the clipping force. This confers the main strength of the system, which is the ability to detect not only the tube's closure but also excessive force. This cannot be achieved with more traditional force sensing methods used in literature. The developed system is compact and affordable under 20 euros, with a mean sensitivity of 0.0843 V/N and a resolution of 0.0412 N. However, the experiments carried out reveal poor precision and repeatability of the measurements. Results seems to indicate that the clipping speed has an effect on the force-light relation. Therefore, it is crucial to calibrate the current system with data representative of the task to be studied. Although the speed is not the only factor influencing the outcome, the other factors are not clearly understood yet.

Upon further research, ForceClip could be implemented in practice and provide a new tool to improve laparoscopic surgery training.

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