Multifunctional Laparoscopic Trocar With Built-in Fascial Closure and Stabilization

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1 Background

Laparoscopy is a minimally invasive technique that uses small incisions (~5 to 15 mm) to replace surgeries traditionally performed through large abdominal incisions. Insufficient closure of these incisions can lead to post-operative complications. Current methods for closure are technically challenging, time-intensive, and require ancillary devices. To streamline laparoscopic procedures, we introduce a multifunctional device that serves both as a trocar—a channel through which laparoscopic procedures can be performed, and as a fascial closure device. The device features rotation-actuated wedges at the distal end that allow better retraction of the abdominal wall both during surgery and for controlled fascial closure. The device has the potential to simplify incision closure, while simultaneously enhancing overall safety.

There are challenges and risks unique to laparoscopy. For example, incisions greater than 5 to 8 mm need to be closed to reduce the risk of complications such as hernias, bowel strangulations, and infections (Lajer et al., 1997). Current closure methods require removal of the trocar and insertion of another device to ensure a suture is placed at the inner most abdominal layer, entailing multiple steps within a very small incision. In the process, the large force required for needle insertion during suture placement, together with the elasticity of the abdominal wall may bring the needle dangerously close to underlying structures. Also, during instrument exchange, trocars may slide against the abdominal wall, resulting in limited instrument mobility or the need to reinsert the trocar.

There have been considerable attempts to find simple and safe solutions to improve fascial closure (Elashry et al., 1996) and trocar stability. Current designs for trocar stability include grooves along the trocar body to increase friction, suturing the trocar to the abdominal wall, or rubber annuli and inflatable balloons to secure the trocar in place. For fascial closure, needle guiding devices such as the Carter-Thomason CloseSure System® or automatic suturing devices like NeatStitch™ have been developed. While these devices are functional, they limit the suture location, provide little protection against over-penetration, are vulnerable to perforation, require reinsertion after trocar removal, and increase costs by requiring ancillary devices. Frustrated surgeons often improvise by inserting other instruments such as the handle of a probe or their own fingers through the incision to elevate the abdominal wall in order to prevent over-penetration, thereby imposing the risk of needle injury to the surgeons themselves.

The design in this paper integrates traditional trocar function, a stability mechanism, and fascial closure capability that aims to reduce technical difficulty, increase operating room efficiency, improve surgeon/patient safety, and reduce cost by integrating multiple functions into a single device.

2 Device Design

The device, as seen in Figure 1, has wedges (1) at the bottom of the trocar that are actuated by rotating two concentric tubes (2a & 2b). The stabilization mechanism is provided by opened wedges and a torus-shaped rubber stop (3) that slides down to the outer surface of the abdomen. Vertical slits (4) on the sides of the trocar

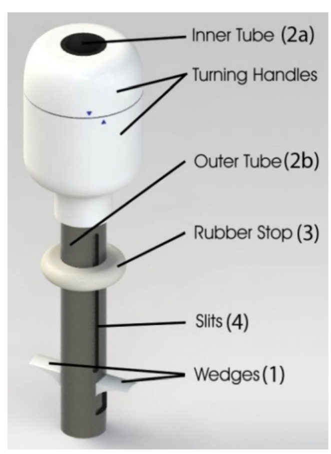

Fig. 1 Trocar components

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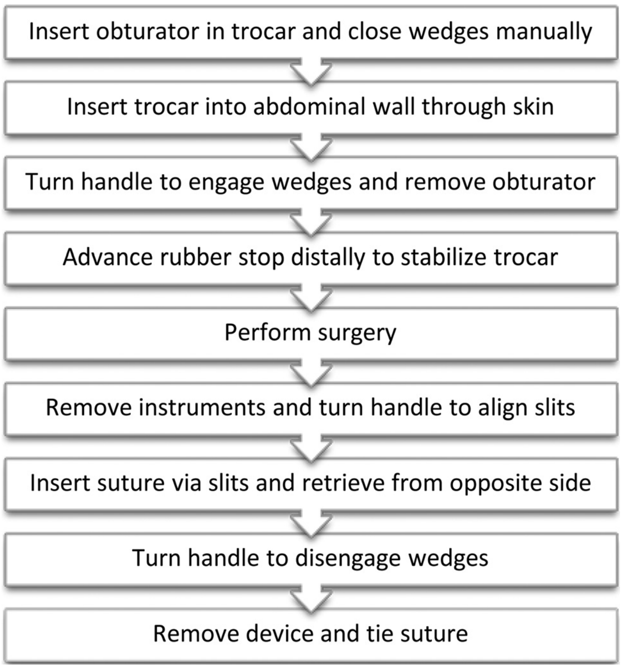

Fig. 2 Procedural workflow

tube wall enable needle entrance for suture placement during fascial closure.

The wedges are deployed from inside of the tube intra abdominally. The device can be used for in-surgery stabilization and elevation of the abdominal wall during needle insertion for incision closure. The wedge design is capable of supporting at least 40 N of normal force, estimated to be the force necessary to elevate the abdominal wall of an average patient (Hur, 2012). The wedges are connected to the outer tube by plastic flexures, or "living hinges". They are actuated and supported by the inner tube, which pushes the wedges open as it moves down (see Figure 2). The wedges are then locked in place by virtue that they are pressed up against the wall of the inner tube. When the inner tube returns to the up position, the wedges can retract back inside the outer tube as the device being pulled out from the body.

The outer and inner tubes are connected to the lower and upper handles respectively, and inner tube is lowered by rotating the

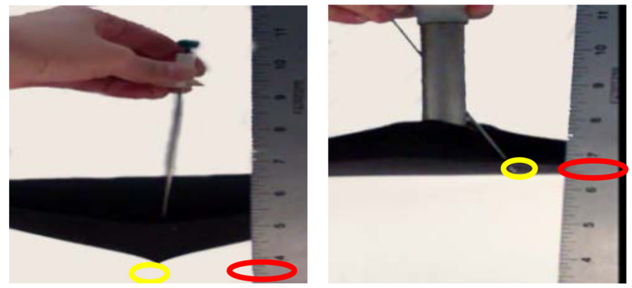

Fig. 4 Simulation: suturing on elastic cloth with (right) and without (left) the presented device

upper handle, which deploys the wedges. For ease of use, less than one full turn is needed to bring the inner tube down completely.

Two vertical slits were cut through walls of both tubes directly opposite of each other. The slits are wide enough to accommodate standard needles, and long enough to give surgeons the flexibility to adjust the angle of penetration so that suture placement can be tailored to individual patient. The slits are designed to be misaligned between the inner and outer tubes during surgery so that the trocar can remain airtight to maintain insufflation. During fascial closure, the slits can be aligned by rotating handles. A locking mechanism will be added to future designs to secure each rotational position. Additionally, leak-proof rubber seals will be added to the outer-tube slits so the trocar will remain airtight even during needle insertion.

3 Results

The overall work flow using our device during a laparoscopic procedure is outlined in Figure 3.

The design was intended to be made entirely by injection-molding. However, for the proof of concept, the main functions were implemented on a prototype with metal parts, and polyester-film was used to simulate the living hinges. Experiments demonstrated that the simulated hinges were able to withstand more than 250 N of normal force before failure, which is over six times the load-bearing capacity for a surgery on a normal patient [3]. While the load-bearing capacity of the prototype does not translate directly to the capacity of injection-molded living hinges, the experiment demonstrated that the design based on concentric tubes with attached wedges can support a significant load.

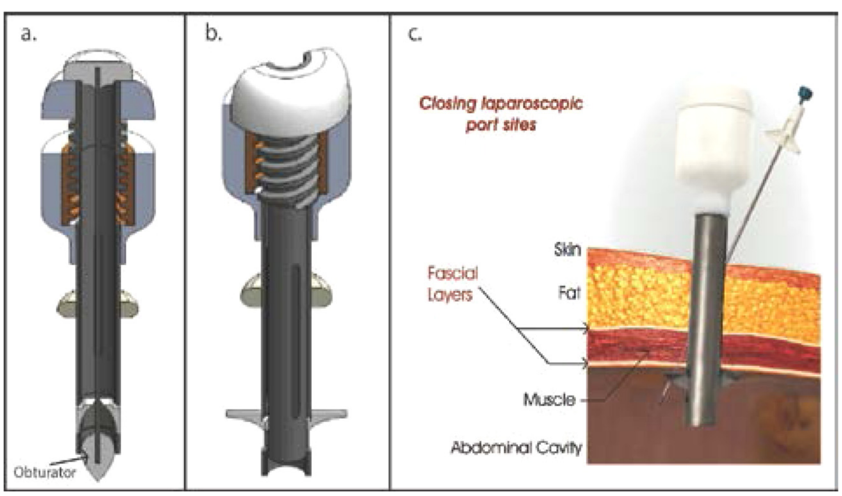

Fig. 3 Cross-sectional view of trocar at (*a*) Pre-insertion with wedges closed and obturator — a device used to penetrate the abdominal wall during the initial introduction of the trocar — in place, (*b*) Surgery with inner tube down, wedges open, slits closed, and (*c*) Closure with needle passing through opened slits.

The usability of our prototype was tested by a surgeon in a simulated surgical environment. An elastic cloth was used to simulating the elasticity and resistance of the abdominal fascia. The surgeon placed sutures with and without our device. The device allowed the abdominal wall to be elevated during needle penetration, as seen in Figure 4; the more controlled needle entry greatly reduced over-penetration.

For the future, thermal, stress, and fatigue tests will need to be performed on the injection-molded prototype to determine the safe load range and number of reuses recommended for the living hinge design given the chosen material.

4 Conclusions

With over 4.4 million laparoscopic surgeries being performed annually in the US (Barnaby, 2006), the need for safe, efficient, and economical surgical tools is significant. The multifunctional trocar design with integrated fascial closure and stabilization mechanisms presented here can streamline laparoscopic procedures and enhance safety. In the future, it is envisioned that the trocar will be mass-produced using injection molding with autoclavable materials. The enhanced safety and agility of this multifunctional surgical tool, as well as the potential for mass-production and reusability provide the potential for commercialization and widespread adoption of this device for laparoscopic surgery.

References

[1] Lajer, H., Widecrantz, S., Heisterberg, L., 1997, "Hernias in Trocar Ports Following Abdominal Surgery," ACTA Obstreticia et Gynecologica Scandinavia, **76**(5), pp. 389–393.

[2] Elashry, O., Nakada, S., Wolf, J., Frigenshau, R., McDougall, E., Clayman, R., 1996, "Comparative Clinical Study of Port-Closure Techniques Following Laparoscopic Surgery," Journal of the American College of Surgeons, **183**(4), pp. 335–344.

[3] Hur, Hye-Chun, M. D. Personal Interview. Beth Israel Deaconess Medical Center, March, 2012

[4] Barnaby J. Feder. "Surgical Device Poses a Rare but Serious Peril," *New York* Times 03/2017/2006