From T to I-Fastener: A Novel Method of Tissue Apposition for Minimally Invasive Procedures

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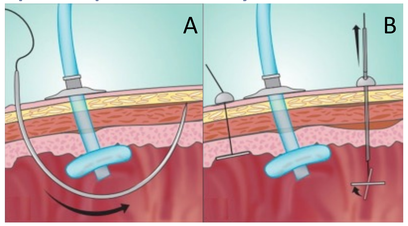
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Background and Objective

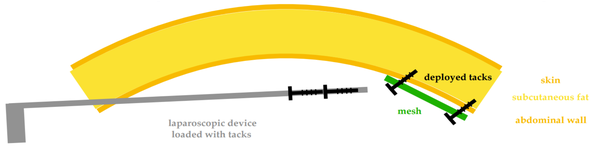
Currently employed methods for gastropexy during gastrostomy insertion include transabdominal sutures or T-fasteners, and for ventral hernia repairs include laparoscopic tacking device or transfascial sutures, all of which pose challenges to users and patients.

FIGURE 1: I – Current Methods of Gastropexy in Laparoscopic Gastrostomy Tube Placement



- Transabdominal suture (Figure 1A) – is cumbersome and difficult with thick abdominal walls
- T-Fastener (Figure 1B) – requires external fixation and is prone to erosion, infection, and pain

FIGURE 2: I – Laparoscopic Tacking Device for Hernia Repair

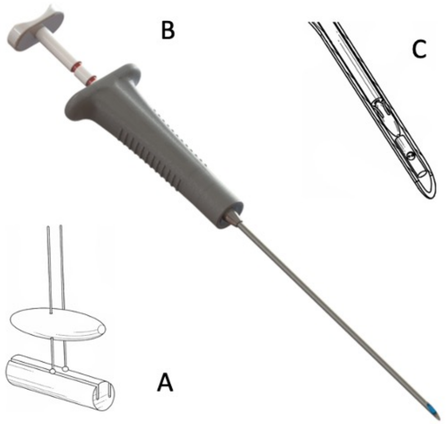


- Laparoscopic tacking device (Figure 2) is often difficult to maneuver, requires external assistance, and is potentially dangerous with blind deployment.
- Transfascial sutures may also be used in hernia repairs but pose similar challenges to transabdominal sutures.

Objective: To describe **a novel device that addresses the clinical need for a safe and easy minimally invasive method of tissue apposition.**

Device Description and Method of Use

FIGURE 3: I – Fastener Device Model



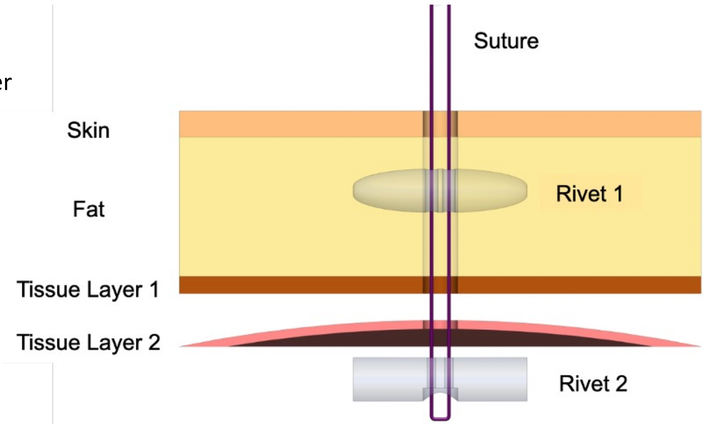
- The I-Fastener is a two-part deployment device with two rectangular-shaped rivets, as shown in Figure 3.
  A) The bioabsorbable rivets after deployment in position.
  B) 3D Model of the complete I-Fastener device
  C) The rivets before deployment held within the needle shaft

- The device is composed of:
  - A reusable handle containing an internal plunger that aligns with the needle shaft sequentially deploying the rivets with a clicking mechanism.
  - A detachable, disposable needle housing both rivets

Steps for Use (in Gastropexy):

1. The needle punctures through all layers of the abdominal wall and stomach into the gastric lumen
2. Through the needle lumen, a rivet is deployed as the inner fastening element to be retained inside the stomach wall
3. The device is then pulled back to the level of subcutaneous tissue or fat and another rivet is deployed as the outer fastening element
4. Both rivets are connected through a bioabsorbable suture, which -- when tied with a secure knot -- will appose the two rivets as well as any interpositioned tissue.
5. Thus, apposition of the stomach to the abdominal wall is accomplished efficiently. The needle is then discarded safely, and the handle is reloaded with another needle.

FIGURE 4: I – Fastener Deployment



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Conclusion

- We believe the I-Fastener provides several key advantages to tissue apposition in minimally invasive settings, especially in contrast to current market standards for gastropexy in laparoscopic gastrostomy tube placements and mesh securement in laparoscopic ventral hernia repairs.
- Our solution:
  - single needle hole entry
  - no external fixation
  - bio-absorbable
  - reloadable for multiple deployments within a single case

Feedback and Future Direction

- We are looking for feedback on this device, please let us know your thoughts:
- We hope to incorporate this feedback into further market analysis and potential prototype development and testing.