AUTOMATED CLOSURE DEVICE OF THE ABDOMINAL WALL FASCIA AFTER LAPAROTOMY TO REDUCE THE INCIDENCE OF INCISIONAL HERNIAS

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Introduction

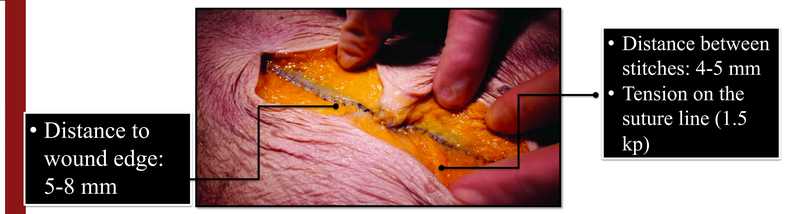
Incisional Hernia (IH) is a frequent complication after laparotomy. IH is associated with high morbidity, decreased quality of life, and high costs. It usually occurs due to suture cutting through the facia from poor technique and is often not due to suture knot breakdown.
I am proposing a handheld innovative automated abdominal fascial closure device technology to decrease the incidence of IH in high-risk patients in open procedures.

Background

Traditionally, after an open procedure, the abdominal fascia wall is closed using a manual suture and needle technique. The recommendation to reduce the incidence of Incisional Hernia is a SBT suture closure technique, which requires precise technical specs making it difficult to implement and reproduce. Thus, a better way to close the fascia with advanced physical and automated technology is needed in open laparotomy procedures.

Cost Burden and Potential Marketplace

The annual healthcare burden for IH is $4.5 billion. In addition to high cost, there is significant morbidity and mortality associated with hernia repair and mesh complications. The marketplace for is estimated to be $1 billion for fascial closure in high-risk patients.



Small Bite Technique

Device Description

- Our automated fascial closure device is intended for use during open surgical procedures to close surgical incisions, e.g., through abdominal fascia after a laparotomy.
- The devices, systems, and methods herein generally involve the use of pairs of closure elements, e.g., including double broad-based rectangular/square shaped bioabsorbable contact members, and piercing technology, which may better distribute the forces applied to tissue while closing the fascia. In addition, the distance between the contact members and/or the distance between the hole and the edge of the contact members may facilitate spacing and distance from the fascial edge of the fasteners directed through the tissue along an incision substantially uniformly, following the principles of SBT (Fig 1)
- In an exemplary embodiment, the closure elements and fasteners may be delivered via an automated process/stapler device (Fig 2)

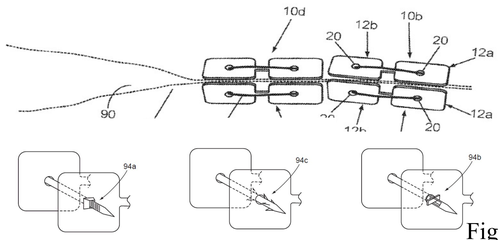


Fig 1

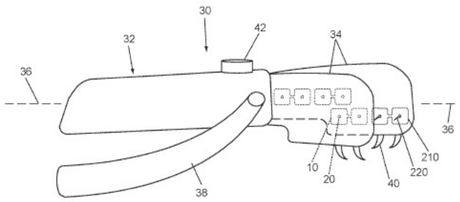


Fig 2

Product Claim

- Reduce incisional hernia incidence by < 10% in high-risk patients within 18 months
- Surgical Site Infection <10%
- Reduce operative abdominal closure time by 25%
- Cost less than $500
- Disposable
- One person operation (OPO)

Intellectual Property

PCT No. 2020/252430

Regulatory Pathway

FDA Class 2 medical device 510(k)

Future Directions

- Prototype created
- First phase of proof of concept on bench models
- Initial results shows our technology is superior to traditional closure techniques; less dehiscence and more equal distribution of forces with higher fascial tension

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