Articulating and Reloadable Fixation Devices for Hernia Repair

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ABSTRACT

There have been a variety of absorbable and permanent tacks, tack deployment systems, and fasteners developed for the fixation of mesh during laparoscopic ventral hernia repair. The manufacturer recommendation for all systems is for perpendicular deployment of these tacks into the tissue. Achieving this optimal angle with previously developed deployment systems is often challenging and can lead to tack failure, mesh migration, and recurrence, or may require the placement of additional ports. Additionally, current tack deployment systems lack the ability to reload, leading to increased cost when entire systems must be opened each time a reload is necessary. This article presents products designed to addresses both of these problems. These deployment instruments incorporate an articulating shaft or a hinge mechanism allowing for improved access to different parts of the abdominal cavity and delivering perpendicular placement of tacks with fewer port sites. Devices with the option of reloadable fixation decrease costs and reduce waste.

INTRODUCTION

Laparoscopic approaches to ventral hernia repair have become a standard alternative to open surgery with technical refinement and widespread adoption since its introduction in the early 1990s by LeBlanc.[1] High-level evidence has demonstrated at least equivalent rates of recurrence with decreased wound morbidity and shorter length of hospital stay.[2,3] Importantly, surgical site infections are reduced for all types of ventral hernias repaired laparoscopically.[4] In addition to advances in operative technique, the ability to perform a safe and effective repair has been facilitated by material advances in mesh and fixation devices. Numerous products have been developed to laparoscopically secure mesh to tissue. Tacks, tack deployment systems, and fasteners for mesh fixation are the most commonly used devices for this purpose, with several products available.[5,6] Tack fixation has been shown to be both easy and effective, with recurrence-free rates above 70%.[7]

Given the numerous products available, evidence is limited regarding the ideal fixation method. However, all manufacturers recommend, and studies have supported, that tacks should be deployed perpendicularly to the tissue to optimize their performance.[8] This recommended angle is often difficult to achieve and may require non-ergonomic fixation, excess traction placed on ports, or the placement of additional port sites. These factors may lead to increased pain, cost, and inefficiency. This technical limitation may also result in non-ideal tack placement in some circumstances, which is a mechanism for mesh shift, migration, inadequate mesh overlap, folding, and tack dislodgement.[9] This can directly affect the success of the operation and primary patient outcomes of pain and recurrence. Additionally, exposure of a partially deployed or displaced tack or fastener may rarely cause bowel obstruction, perforation, volvulus, or erosion into visceral (bowel and bladder) structures.[10-14] A non-commercial prototype fixation device with the ability to articulate was described in 2011, demonstrating that tacks could be deployed at the optimal angle more reliably, resulting in increased strength of mesh fixation.[15] However, articulating fixation devices were not widely commercially available until late 2014.

Another drawback to the previously available deployment systems was the inability to reload the deployment device with additional tacks. Instead, if more tacks than came with the device were required, an entirely new deployment system had to be opened, increasing operative time, waste, and cost. This potentially leads to inadequate fixation when a lesser number of tacks are used than needed or a higher expense if a new device is opened for a few additional tacks.

This article discusses currently available articulating and reloadable devices, their theoretical advantages, and available preclinical and clinical data.

ARTICULATING FIXATION DEVICES

Two articulating fixation devices for hernia repair are currently commercially available. Both achieve shaft articulation with between 60–65 degrees of angulation, allowing for greater access to the abdominal cavity and perpendicular mesh fixation.

iMeshTacker™ (EasyLap Ltd. Bonita Springs, FL) is a sterile, single-use tacker for fixation of prosthetic material to soft tissue. The device received FDA 510(k) market clearance in June of 2011 as a substantially equivalent device to existing tackers including the ProTack™ permanent metallic tacker (Medtronic (formerly Covidien LLC), North Haven, CT) and AbsorbaTack™ absorbable PGLA tacker (Medtronic, North Haven, CT).[16] This original version was not widely commercially available. A modified version of the iMeshTacker™, (THD, Natick, MA) received FDA 510(k) clearance in March of 2016 and is currently commercially available. The modified tacker is identical to the 2011 construct with the exception of a change in the color of the tacks to violet, minor internal changes, and revision of the packaging.[17]

The novel design features a proprietary articulating tip that allows the shaft to angulate up to 60 degrees, allowing for perpendicular tack fixation throughout the abdominal cavity (Figs. 1 and 2). The initial construct was designed for use in single-site laparoscopic surgery with the ability to fixate the prosthetic from a single trocar site.

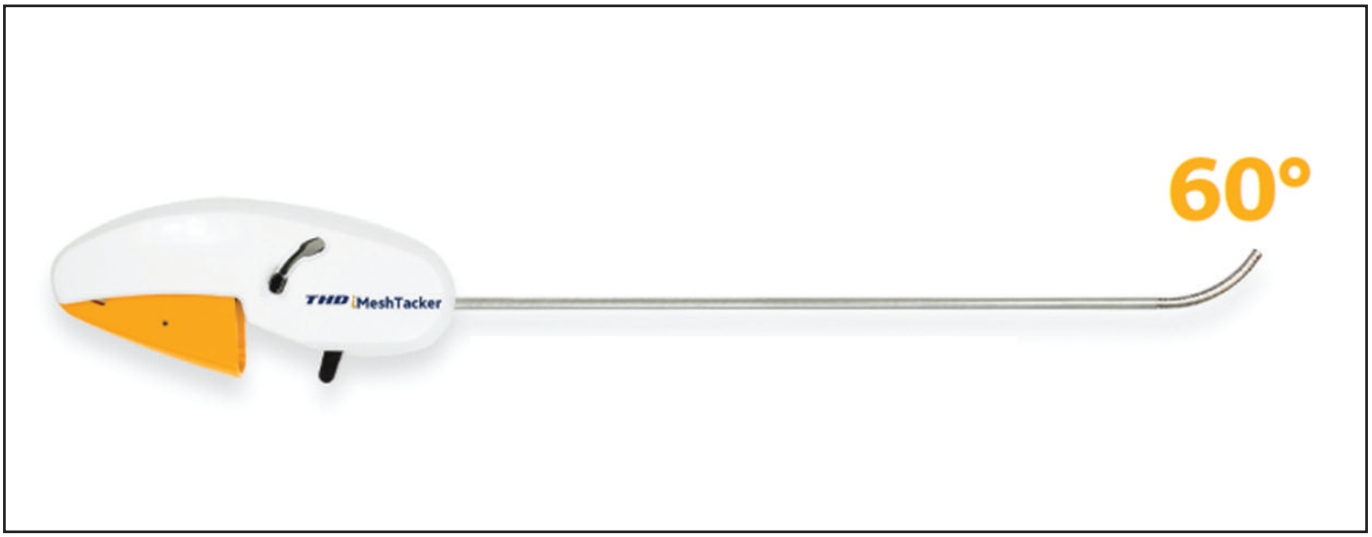

Figure 1. iMeshTacker™ fixation device (THD, Natick, MA).

The compact self-articulating tip increases accessibility within the working field, including on the ipsilateral side of the mesh and adjacent to working ports. Counter pressure is not required for deployment of the tacks.

The iMeshTacker™ deploys a helical absorbable open spiral tack measuring 6 mm in length with a greater depth of purchase (5.2 mm) than most available absorbable tackers. The absorbable tack is made of synthetic polyester derived from a lactic acid and glycolic acid copolymer (PLA/PGA) dyed violet for improved intraoperative visualization. This device is preloaded in six configurations with 10 to 38 tacks, providing inherent time savings from not having to reload cartridges contingent upon not requiring more than this number of tacks for the operation. These tacks have been tested for compatibility with most commercially available hernia mesh prostheses.

ReliaTack™ articulating reloadable fixation device (Medtronic, North Haven, CT) is a reloadable, sterile, single-use tacker for fixation of prosthetic material to soft tissue. The device received FDA 510(k) market clearance in March of 2014 as a substantially equivalent device to existing tackers including the ProTack™ permanent metallic tacker and AbsorbaTack™ absorbable PGLA tacker.[18] The key novel feature is a hinge mechanism that allows the shaft to angulate up to 65 degrees as well as the ability to articulate in the horizontal plane by rotating the handle of the device (Figs. 3 and 4). This articulation increases the ability to reach different parts of the abdominal wall and prosthetic and makes perpendicular fixation feasible from ipsilateral ports.

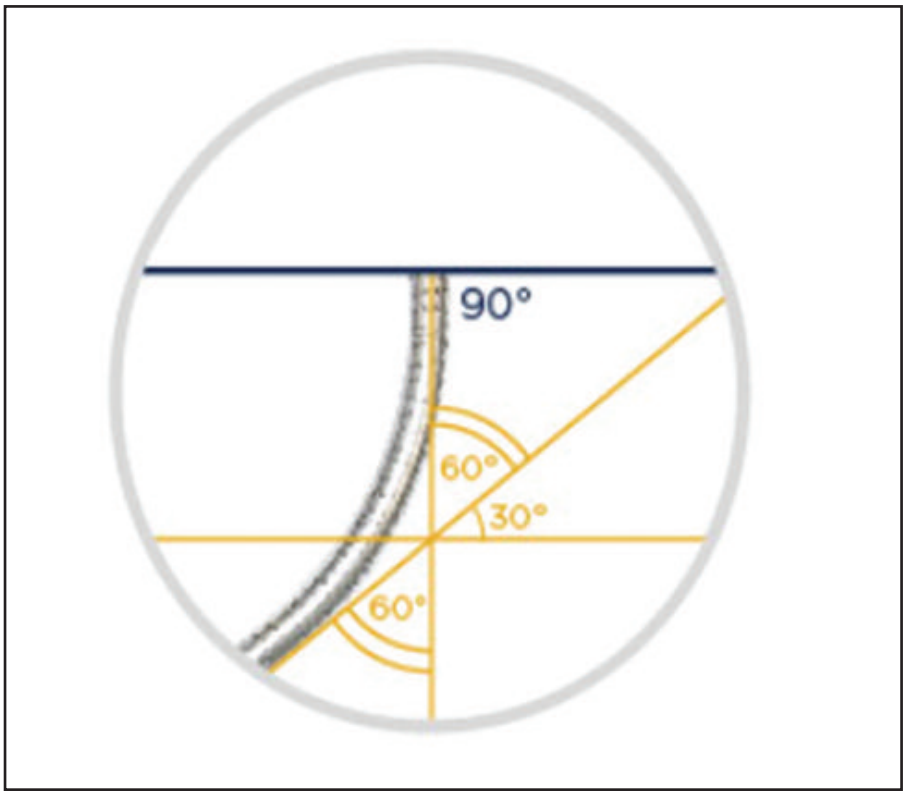

Figure 2. Achievement of perpendicular firing angle with 60 degrees of articulation.

The standard purchase ReliaTack™ is 5.1 mm with a screw-like configuration and is constructed from a violet-dyed absorbable synthetic polyester copolymer derived from lactic (PLA) and glycolic acid (PGA). This construct results in a tissue purchase of 4.1 mm subtracting out the 1 mm head of the screw, is deeper than prong-style tacks, and is identical to the non-articulating AbsorbaTack™. An additional option for deep purchase tacks (7 mm) received FDA 510(k) market clearance in July of 2015 as a substantially equivalent device to the existing ReliaTack™ device.[19] This construct allows for 6 mm penetration and provides more tissue depth of purchase for patients with thicker tissue, greater adiposity, or for use with thicker prosthetic materials.

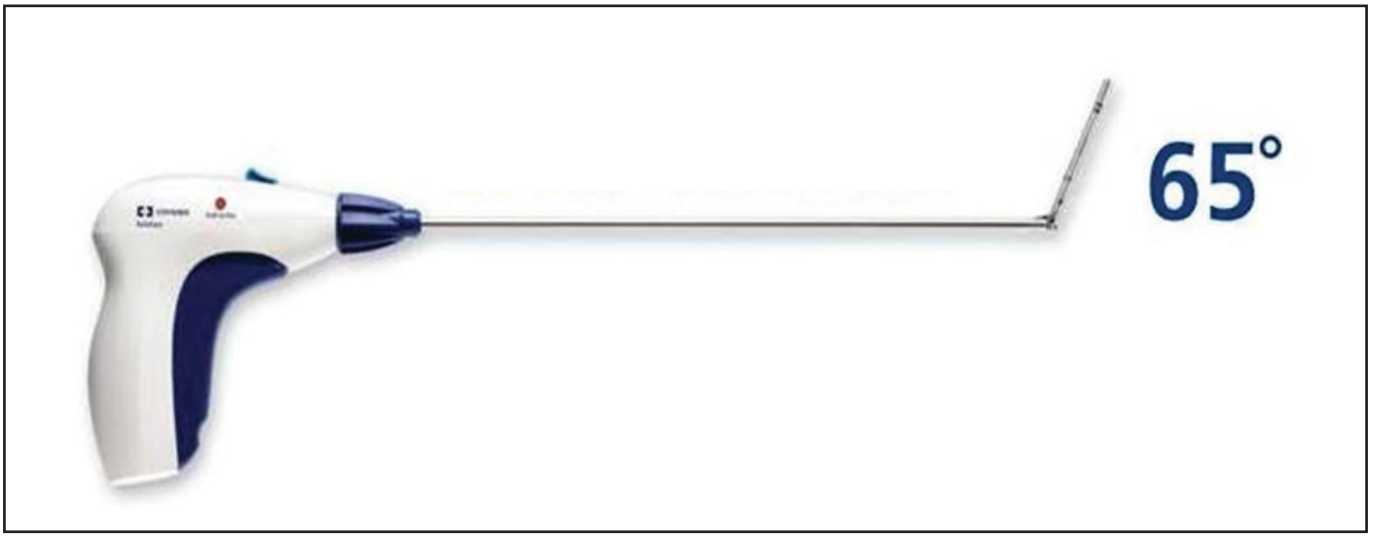

Figure 3. ReliaTack™ fixation device (Medtronic, North Haven, CT).

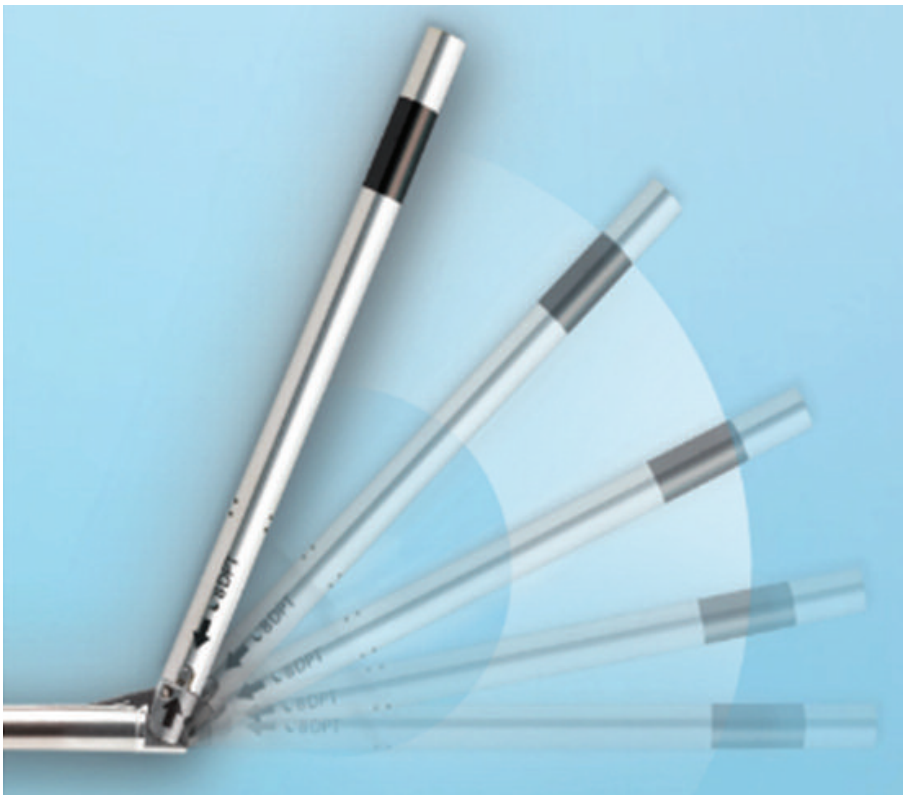

Figure 4. Adjustable angulation of the hinge mechanism with 65 degrees of articulation.

RELOADABLE FIXATION DEVICE

The ReliaTack™ deployment instrument incorporates a reloadable mechanism and each packaged deployment system contains multiple tack cartridges. Through interchangeable reloads, ReliaTack™ can be fired up to 60 times. Most commercially available tackers are preloaded with 25–30 tacks. The additive cost of two devices represents a significant expense as compared to the incremental expense of additional cartridges. As fixation devices in laparoscopic ventral hernia repair comprise one of the most expensive material costs of the procedure, efforts to minimize waste, maximize efficiency, and limit overuse are important on both a local and societal level.

The deep purchase tack fixation device is packaged with three 8-tack deep purchase reloads, one 5-tack deep purchase reloads, as well as the option to use additional 8-tack or 5-tack deep purchase reloads as needed (Fig. 5). The standard purchase tack fixation device comes with three 10-tack standard purchase reloads as well as the option to use additional 10-tack or 5-tack standard purchase reloads as needed (Fig. 6). Each device can accommodate up to 10 reloads.

AVAILABLE DATA

There are very limited data available studying the efficacy of articulating fixation devices limited to preclinical studies, internal industry benchmarks, and ex-vivo laboratory mechanical testing. There are no clinical studies available to date. Theoretical benefits of perpendicular fixation can be extrapolated from mechanical studies and known limitations of standard devices.

Preclinical data using a non-commercial prototype of the articulating iMeshTacker™ studied tack deployment and fixation strength in a porcine model as compared to a traditional non-articulating absorbable tacker (AbsorbaTack™). Strips of mesh were fixated to the abdominal wall and the detaching force was measured at 0, 14,

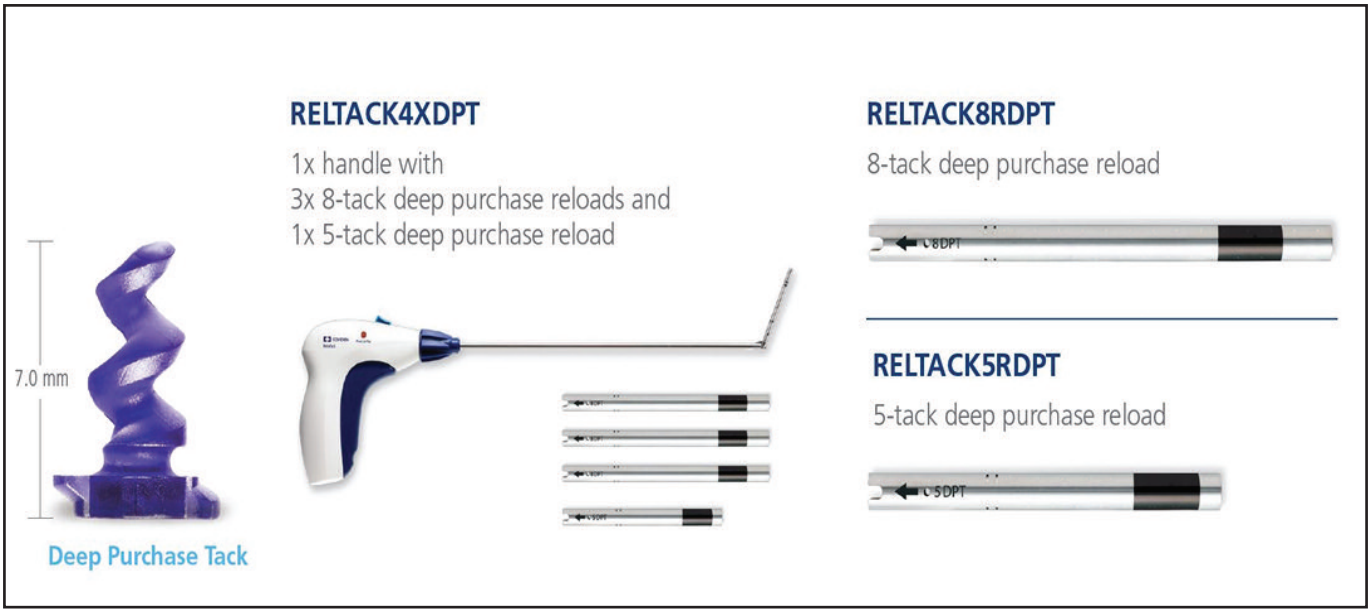

Figure 5. ReliaTack™ deep purchase tack with reloads (Medtronic, North Haven, CT).

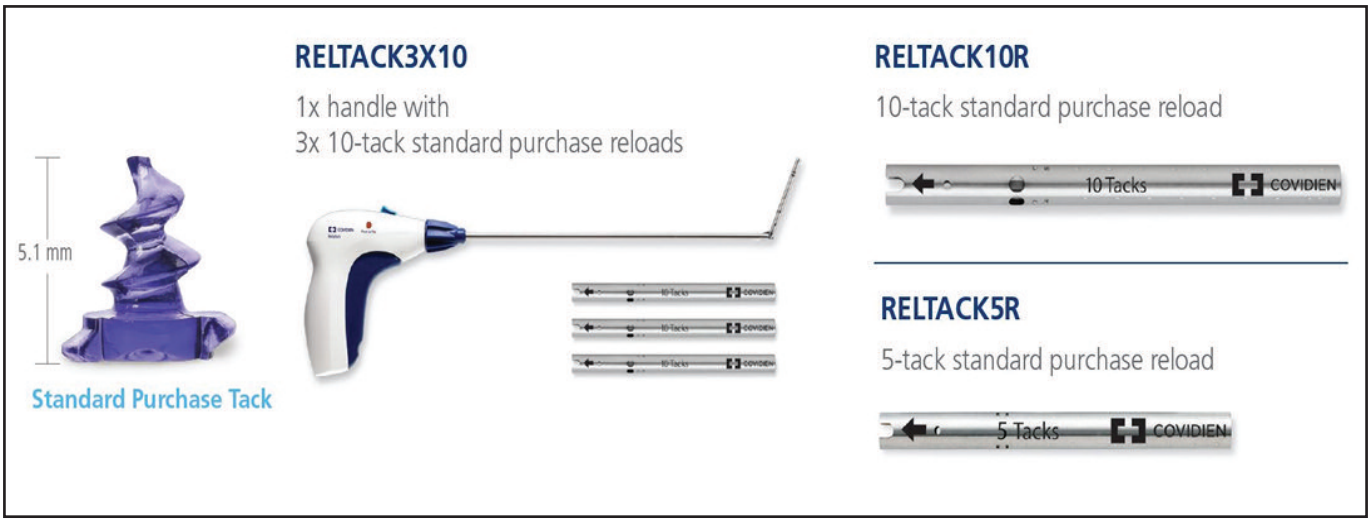

Figure 6. ReliaTack™ standard purchase tack with reloads (Medtronic, North Haven, CT).

and 28 days. There was no difference seen at the early time point while the average detaching force at the intermediate and late intervals were significantly increased ($p<0.05$) with articulating fixation.[15] This very limited evidence involved only three animals and the clinical relevance is difficult to extrapolate from this.

Preclinical manufacturing data used for FDA clearance of the ReliaTack™ device demonstrated superior performance with regard to consistent tack purchase, fixation strength, and mesh shear pull test force with the shaft angled at 30, 45, and 65 degrees as compared to other commercially available absorbable tackers and fasteners.[20] Theoretical benefits include better tack purchase leading to less tack displacement or loss, reliable fixation leading to less potential for mesh migration and recurrence, and fewer ports leading to improved efficiency, lower cost, and potentially decreased pain.

Within the FDA Manufacturer and User Facility Device Experience (MAUDE) database, there is only one report of a potentially adverse event from articulating tackers in over 18 months of clinical deployment. This was related to a cartridge disengaging the handpiece within the abdomen during an endoscopic case using ReliaTack™. This was retrieved without any adverse sequelae. Clinical benefits of improved ergonomics, ease of use, efficiency of fixation, decreased operative time, and surgeon satisfaction are available. However, results from clinical experience will elucidate if the theoretical and practical benefits of articulating devices translate into improved clinical outcomes.

DISCUSSION

Mesh shift resulting in off-centered mesh relative to the defect and asymmetric overlap is a known mechanism for recurrence after laparoscopic ventral hernia repair and is common after traditional unidirectional fixation. In a retrospective review of 201 patients, 48% demonstrated mesh shift with 17% resulting in grade IV major mesh shift with recurrence.[9] This migration effect increases with time. The shift is typically found on the proximal operative side, with most recurrences occurring in this location presumptively attributed to limitations of mesh fixation in this portion of the abdomen.[9] Recommendations to address these mechanistic problems include increasing mesh overlap (>6cm), closing the midline defect, placing transfascial sutures, securing the operative side of the mesh first, and placing contralateral ports.

Articulation of the deployment device reduces the potential for mesh to be pushed away from the surgeon during fixation, thus maintaining mesh position and overlap of the defect. Additionally, articulation allows for easier achievement of a tack deployment angle perpendicular to the tissue, with the main benefits being more secure mesh fixation, reduced incidence of tack complications, as well as the need for fewer port sites. Thus, articulating fixation devices may lead to a reduction in mesh migration, hernia recurrence, and postoperative pain.

The option of a reloadable instrument is practically appealing as fixation devices in laparoscopic ventral hernia repair comprise one of the most expensive material costs of the procedure. The introduction of fixation devices with available reloads will likely minimize waste, maximize efficiency, and help to reduce the overall expense of the operation as a whole.

CONCLUSION

New articulating and reloadable fixation devices on the market for laparoscopic ventral hernia repair have the potential to address two limitations of current tack deployment systems. Articulation of the device allows for the easier achievement of a deployment angle perpendicular to the tissue, with theoretical advantages including reduction in mesh migration, pain, and hernia recurrence. The ability to reload these devices have been projected to reduce cost and improve efficiency per case. These outcomes merit further study as articulating and reloadable devices are more widely used. STI

AUTHORS' DISCLOSURES

Dr. Chen is on the speaker's bureau for Medtronic. Dr. Moore has no conflicts of interest to disclose.

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