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Application of a novel suture anchor to abdominal wall closure

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ABSTRACT

Background: Mesh suture used in high-tension wound closures produces large knots susceptible to increased palpability, infection, and foreign body response; yet has superior tensile strength and increased resistance to cutting through tissue compared to standard suture. This study investigates mesh suture fixation in abdominal tissue with a knotless novel, low-profile anchor-clip.
Methods: Single and double end fixation of mesh suture in swine rectus abdominus fascia with an anchor-clip, a knot, and predicate device fixation underwent cyclic testing followed by pull-to-failure testing.
Results: Failure load of standard knot, single corkscrew and double anchor-clip were not statistically different, but were significantly greater than single anchor-clip and double corkscrew fixation ($p > 0.05$).
Conclusions: The anchor-clip is ~60% smaller than a standard knot while maintaining fixation strength when exposed to physiologic forces using double anchor-clip fixation in abdominal wall closure.

Introduction

Abdominal wall closure remains a major challenge in surgery. Currently 10–15% of patients develop open abdomens (i.e. the fascial edges of the abdomen are un-approximated), There is a 10–30% hernia occurrence rate following elective laparotomies, and ventral hernia cases cost an estimated total of 3–6 billion dollars annually.[1–6] Often, musculoskeletal, skin or trunk wounds are repaired by surgeons using mesh, scaffolds or textiles anchored with standard suture; however, these devices frequently fail and wounds persist because of excessive tension, which causes sutures to cut through tissue. To overcome this failure mode of suture cutting through tissue, mesh suture has been developed.[7]

Mesh suture has a larger surface area compared to standard braided and monofilament suture. This increased area distributes the load in tissue which reduces stress at the suture/tissue interface; thereby, preventing suture tearing through tissue. Mesh suture's increased resistance to pulling through tissue [2] along with their greater tensile strength compared to standard suture makes it a desirable alternative for use in high-tension tissue closures, such as in hernia repair of laparotomy closure.[8]

Initially investigated to overcome suture pull-through and address recurrence in hernia repair, mesh suture has demonstrated increased work to failure and enhanced early wound strength in comparison to standard of care suture in a swine laparotomy closure model.[8] Mesh suture has proven to provide reliable tissue closure under tension and is associated with low rates of dehiscence, delayed wound healing, and low hernia recurrence in human abdominal wall closure.[9]

Despite the many benefits of mesh suture, a major concern is the fixation of the terminal end of suture. A common surgeon's knot has been shown to have significantly greater failure load for securing mesh suture than other common fixation devices such as tacks,[1] staples,[2] corkscrews,[3] and straps[4]. Furthermore, tacks,

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[1] OptiFix™ Absorbable Fixation System (Davol, Inc., Warwick, RI).
[2] Endo Universal™ 65 Hernia Stapler (Medtronic, Inc., New Haven, CT).
[3] ProTack™ Fixation Device (Medtronic, Inc., New Haven, CT).
[4] ETHICON SECURESTRAP™ Absorbable Fixation Device (Ethicon, LLC., Guaynabo, PR).

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staples, corkscrews, and straps fail under fatigue loading while a surgeon's knot does not fail under the same fatigue loading.[10] However, mesh suture results in large, high-profile knots that are susceptible to increased palpability and foreign body response.[11] Additionally, larger knots have increased area for bacterial adherence and may increase the risk of infection.[12,13] Thus, we have developed an alternative low-profile mesh suture fixation device, called the anchor-clip, with superior mechanical performance to multiple suture anchoring devices including tacks, staples, corkscrews, and straps to replace the large knots. Our novel suture anchoring device also outperformed traditional knot fixation of mesh suture in pull-to-failure benchtop testing using silicone.[10] Added advantages to suture anchor devices are that they can be applied with greater ease in hard-to-reach places and may be more effective in areas of high tension where knots may unravel.

The goal of this study was to determine the ability of the anchor clip to fixate mesh suture in abdominal wall tissue for application to hernia repair and laparotomy closure under various closure configurations.

Material and methods

Anchor-clip design & application

The anchor-clip was iteratively developed using 3D design software (Fusion 360®) and produced via 3D printing (Carbon3D® Printer) using a urethane methylacrylate liquid polymer resin. The anchor design and material were selected based on prior mechanical testing in a silicone-based suture fixation mode.[10] The anchor-clip featured two interlocking male/female components. The male component included three lateral projections along the midline surface designed to penetrate through suture and join into the female component. The two lateral projections featured a locking element to enable secure fixation when attached to the female component. The female component consisted of corresponding holes to allow entry and internal recesses to enable locking of the male projections. The anchor-clip design and its application to mesh suture are demonstrated in Fig. 1.

Modifications were made to the anchor-clip used in this study to enable improved suture fixation. The size of the midline projections of the male component were increased to lessen their susceptibility to fracture. Specifically, the area of the lateral projections was increased from 1 mm^2 to 2.5 mm^2 and the diameter of the middle projection was increased from 1.5 mm^2 to 2.1 mm^2. These changes required an increase in the anchor height from 2 mm to 2.5 mm which was compensated by a decrease in the anchor width from 10 mm to 8 mm to maintain the same material volume.

Size comparison

The size of the anchor-clip was compared to a mesh suture knot (width: 9 mm, 4 throws) and a predicate corkscrew fixation. The length, width, and height of each fixation was measured and used to calculate their respective volumes.

Experimental model

A benchtop abdominal wall closure model was developed to assess the ability of the anchor-clip to approximate abdominal tissue under tension. The model consisted of approximating two sections of swine rectus abdominus muscle using mesh suture. Mesh suture was applied through the muscle fascia using either a single simple interrupted or simple running pattern (3 bites). For each pattern, the suture entered the fascia 1 cm from the wound edge and a 1 cm gap was placed between each tissue bite for the simple running pattern. Following completion of the suture pattern and approximation of tissue edges, the opposing ends of tissue were secured into an Instron® machine (Model 1321, Illinois Tool Works, Inc., Norwood, MA) using mechanical vice grips (Fig. 2).

Suture fixations

The suture patterns were secured with the anchor-clip, a standard of care knot, or using a predicate corkscrew fixation

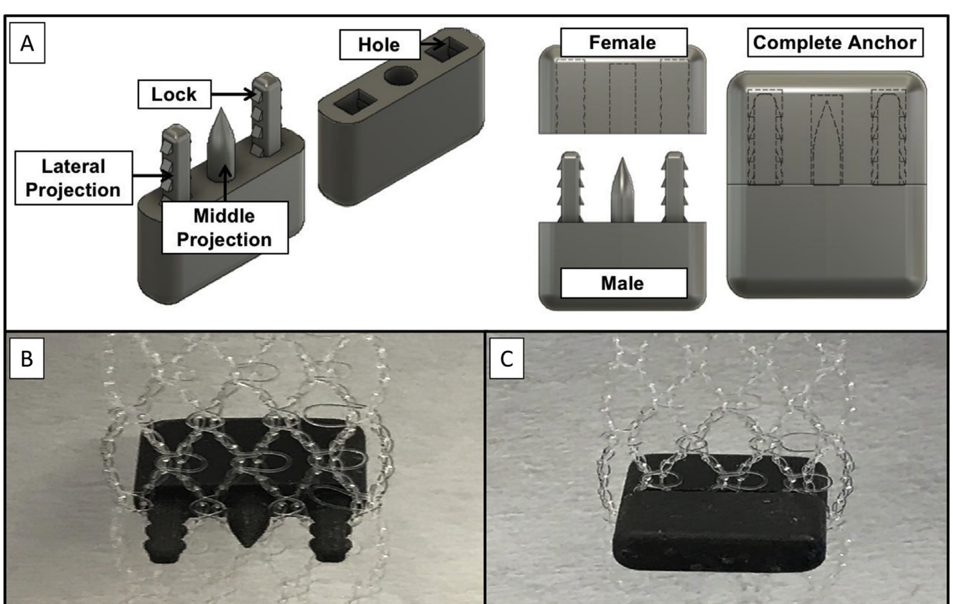

Fig. 1. Anchor clip design and application. (A) The anchor consists of two interlocking male/female components. The male component has three midline projection to provide suture fixation. The lateral projections have locking elements to secure attachment into the female component. The female component has corresponding holes with internal recesses to enable attachment and locking. (B) The projections of the male component penetrate through mesh suture pores (C) The male and female components are attached and stabilize suture position at the tissue surface under tension.

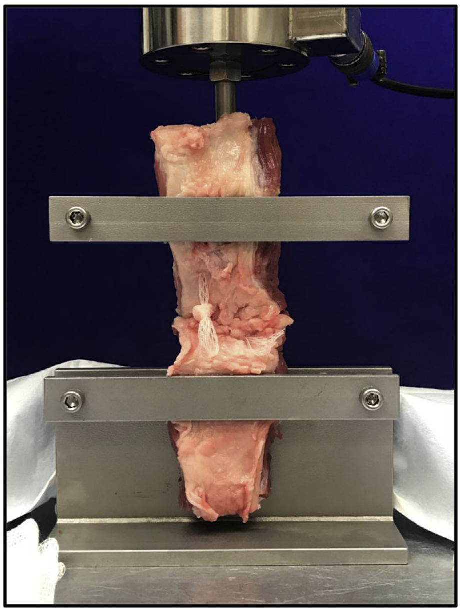

Fig. 2. Abdominal Wall Closure Model. A benchtop model which approximates two sections of porcine rectus abdominus muscle using mesh suture. The opposing ends of tissue are secured into an Instron® machine (Model 1321, Illinois Tool Works, Inc., Norwood, MA) using mechanical vice grips.

(ProTack™ Fixation Device, Medtronic, Inc., New Haven, CT). The anchor-clip was applied to suture using slip-joint pliers until the male/female components were fully approximated. The knot fixation consisted of an instrument tie in which the initial throw was a square, surgeon's knot followed by three alternating square knots, which is a standard surgical approach. The corkscrew fixation was applied in accordance with manufacturer recommendations. Anchor-clip and corkscrew suture fixations were tested in single and double fixation formats to represent potential clinical applications (Fig. 3). The single and double fixations were applied to the simple interrupted pattern. Only the double fixation format was applied to the simple running suture pattern due to the increased distance between the opposing suture ends limiting clinical application.

Mechanical testing

Cyclic fatigue testing was applied to the model at a force range of 10–20 N (maximum physiologic force on the abdomen is 16 N/cm)[14] at 2 Hz for 200 cycles, then pull to failure at a rate of 300 mm/min. Six samples were tested for each suture fixation. Completed cycles for each fixation, post-cyclic failure load, and failure mode were recorded.

Failure mode

Failure was defined as deapproximation of the tissues along the entire length of the attachment. The types of failure modes recorded were tissue failure, fixation failure, and suture failure. Tissue failure was deapproximation secondary to either suture cutting through tissue (suture pull-through), a tissue defect remote to the suture site (remote tissue failure), or the fixation pulling through the suture tract (fixation pull-through). Fixation failure occurred in the form of the knot unraveling, the anchor-clip disassembling, or detachment of the corkscrew from suture. Suture failure was a defect development (e.g. tearing or fraying) in the suture resulting in deapproximation.

Results

Size comparison

The size of the suture fixations, as determined by volume, were as follows: anchor-clip = 200 mm^3; knot = 630 mm^3; and corkscrew = 0 mm^3. The anchor clip was 68% smaller than a mesh suture knot. The corkscrew fixation completely penetrates beneath the tissue surface and therefore did not have a volume. A side-by-side comparison of the suture fixations are shown in Fig. 4.

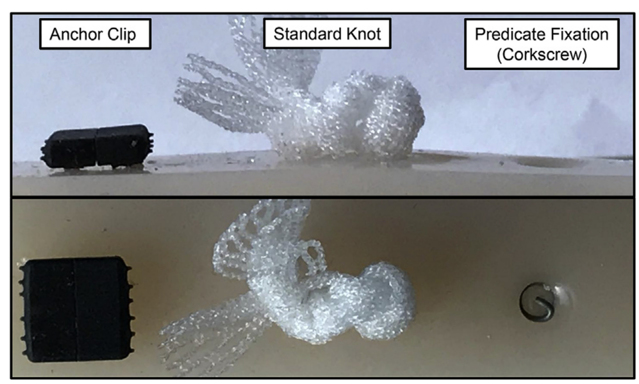

Fig. 4. Size comparison of suture fixations. The size of the suture fixations, as determined by volume, were as follows: anchor clip = 200 mm^3; knot = 630 mm^3; and corkscrew = 0 mm^3. The anchor clip was 68% smaller than a mesh suture knot The corkscrew fixation complete penetrates beneath the tissue surface and therefore did not have a volume.

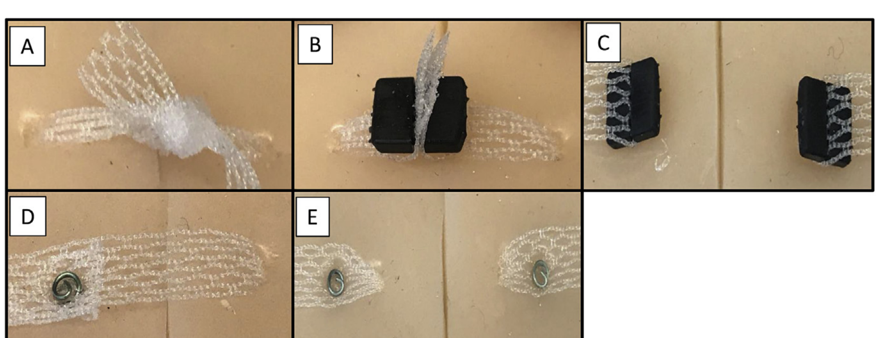

Fig. 3. Suture Fixations. (A) Standard of care mesh suture knot. (B) Single anchor clip. (C) Double anchor clip. (D) Single corkscrew. (E) Double corkscrew.

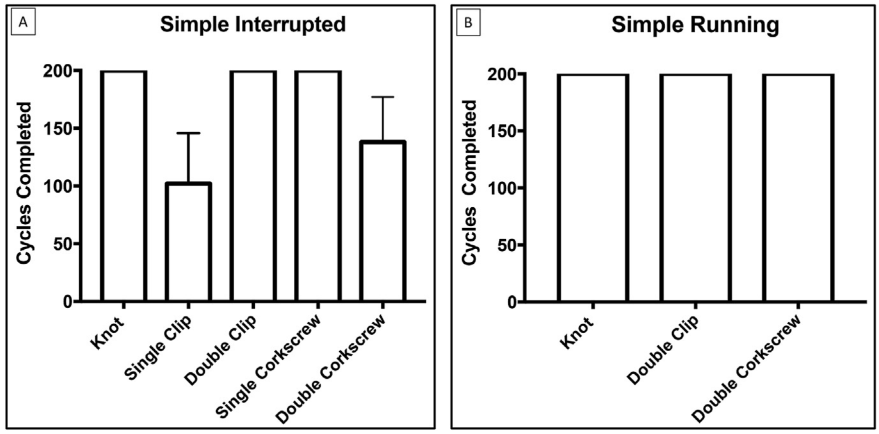

Fig. 5. Completed cycles. (A) For the simple interrupted pattern, knot, double clip, and single corkscrew fixations consistently completed cyclic testing (200 ± 0 cycles) while the single clip (102 ± 107 cycles) and double corkscrew (138 ± 96 cycles) experienced premature failure. (B) For the simple running pattern, the knot, double clip, and double corkscrew fixations consistently completed cyclic testing (200 ± 0 cycles) (n = 6).

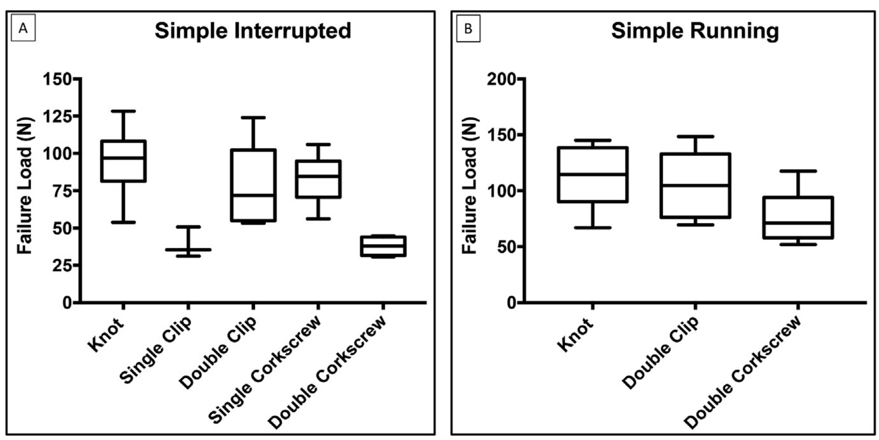

Fig. 6. Post-cyclic failure loads. (A) For the simple interrupted pattern, the post cyclic failure loads of the knot (95 ± 24 N), double clip (79 ± 27 N), and single corkscrew (83 ± 17 N) were significantly greater than the single clip (39 ± 10 N) and double corkscrew (38 ± 7 N) ($p < 0.05$). For the simple running pattern, the failure loads of the knot (113 ± 28 N), double clip (105 ± 30 N), and double corkscrew (76 ± 24 N) were statistically similar ($p > 0.05$) (n = 6).

Mechanical testing

When applied to the simple interrupted pattern, the knot, double anchor-clip, and single corkscrew fixations consistently completed cyclic testing (200 ± 0 cycles) while the single anchor-clip (102 ± 107 cycles) and double corkscrew (138 ± 96 cycles) experienced premature failure (Fig. 5-A). For the simple running pattern, the knot, double anchor-clip, and double corkscrew fixations consistently completed cyclic testing (200 ± 0 cycles) (n = 6) (Fig. 5-B).

For the simple interrupted pattern, the post-cyclic failure loads of the knot (95 ± 24 N), double anchor-clip (79 ± 27 N), and single corkscrew (83 ± 17 N) were significantly greater than the single anchor-clip (39 ± 10 N) and double corkscrew (38 ± 7 N) ($p < 0.05$) (Fig. 6-A). For the simple running pattern, the failure loads of the knot (113 ± 28 N), double anchor-clip (105 ± 30 N), and double corkscrew (76 ± 24 N) were statistically similar ($p > 0.05$) (n = 6) (Fig. 6-B).

Failure mode

When applied to the simple interrupted pattern, the knot consistently experienced tissue failure (100%). The single anchor-clip consistently failed by fixation failure (100%) through disassembly. The double anchor-clip failed by tissue failure (83%) or suture failure (17%). The single corkscrew failed by fixation failure (83%) and tissue failure (17%). The double corkscrew consistently experienced fixation failure (100%) (n = 6) (Fig. 7-A). For the simple running pattern, the knot (100%) and double anchor-clip (100%) consistently failed by tissue failure in the form of suture pull-through or remote tissue failure. The double corkscrew failed by fixation failure (60%) or tissue failure (40%) (n = 6) (Fig. 7-B).

Discussion

While mesh sutures have a larger surface area to resist tissue failure and possess greater tensile strength compared to standard sutures, they produce large knots which are susceptible to complications such as palpability in superficial closures, increased foreign body response, and increased risk of infection. Our anchor-clip, while considerably smaller than mesh suture knots, demonstrated comparable ability to fixate mesh suture and secure abdominal tissue closure in comparison to a standard knot and the predicate fixation device. By being smaller in size, this novel anchor-clip decreases the risk of palpation, discomfort, foreign body response, and infection in mesh suture in comparison to

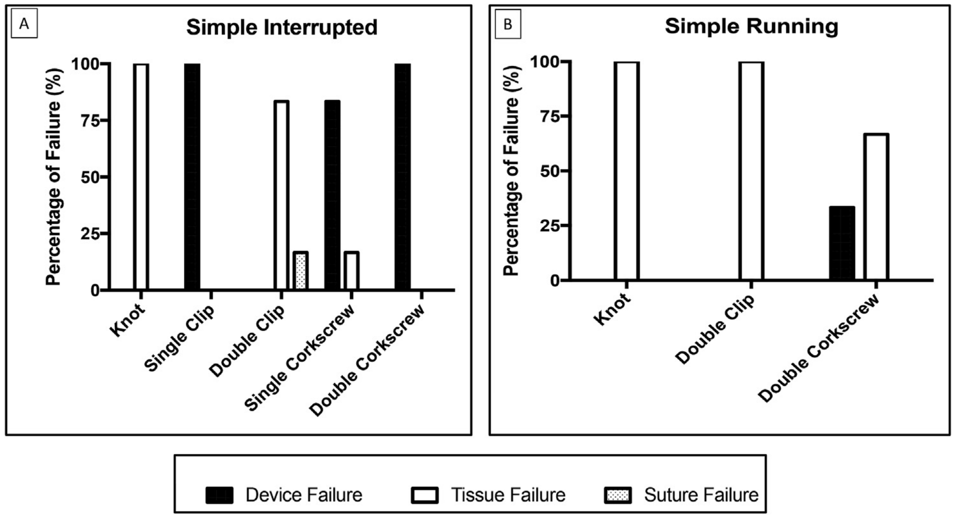

Fig. 7. Failure Mode. (A) For the simple interrupted pattern the knot failed by tissue failure (100%). The single anchor clip failed by fixation failure (100%). The double anchor clip failed by tissue failure (83%) or suture failure (17%). The single corkscrew failed by fixation failure (83%) and tissue failure (17%). The double corkscrew failed by fixation failure (100%). (B) For the simple running pattern, the knot (100%) and double anchor clip (100%) failed by tissue failure. The double corkscrew failed by fixation failure (60%) and tissue failure (40%) (n = 6).

standard knot fixation without sacrificing mechanical performance.

While numerous stitch patterns exist for approximating soft tissue; abdominal wound closure is most often accomplished through either a simple interrupted or simple running pattern. Therefore, a single interrupted stitch and a simple running pattern with three bites were selected as the fundamental suture patterns translatable to more complex suture patterns. The mesh suture ends were secured with either a standard knot, our anchor-clip, or a predicate device (a corkscrew-designed fixation that tacks mesh to tissue). The anchor-clip and corkscrew were applied in a single and double fixation format to represent potential clinical applications.

The anchor-clip consisted of two interlocking components, one of which features three midline projections. The projections integrated into the pores of mesh suture stabilizing its position at the tissue interface when tension was applied. When tension is applied perpendicular to the midline projections the anchor-clip functioned as designed by securing the suture's position until tissue or suture failure occurred. However, the anchor-clip disassembled when loaded parallel to the projections in the single anchor-clip configuration. The failure loads for all configurations of the anchor clip were supraphysiologic as they ranged between 50 and 150 N, much higher than the 16 N/cm reported in the literature.[14]

Unfortunately, the two components of a single anchor-clip securing two ends of mesh suture consistently disassembled under cyclic testing. The disassembly of the locking mechanism is understandable as it is designed to approximate the anchor components and not to secure suture patterns. Based on the results of this study a single anchor-clip is not advised to secure two ends of mesh suture together for a simple interrupted stitch; instead, each end of the mesh suture should be secured with an individual anchor clip.

When analyzing failure mode, suture patterns with knot and double anchor-clip fixations consistently failed secondary to tissue failure, meaning that the fixation and suture remained intact while a defect in the tissue caused de-approximation of the wound. The anchor-clip demonstrated itself as a superior fixation device when applied in a simple running stitch by completely resisting device failure, not causing tissue damage as its mechanism of securement and maintaining the same failure loads as the standard-of-care with a large size reduction.

However, limitations exist in this study including the use of swine fascia which has different mechanical properties than human fascia, specifically greater tensile strength and stiffness. Therefore, a future study will repeat testing in human cadaver tissue. Another limitation was that the material used for prototyping isn't an FDA-approved biocompatible material. Once cadaveric fascia testing is completed and indicates the use of anchor-clips in abdominal wall closure, we will develop an injection molded anchor-clip utilizing FDA-approved biocompatible materials such as Polyether ether ketone (PEEK) and Polylactic Acid (PLA) followed by repeat testing to ensure consistency in performance.

Conclusions

The anchor-clip secures mesh suture under physiologic force ranges in abdominal wall tissue. Anchor-clip fixation of a single end of mesh has similar mechanical performance to a standard knot and double-end corkscrew fixation. Other advantages to the anchor-clip include its reduced size relative to a knot and decreased tissue damage in comparison to a corkscrew which penetrates tissue. The inferior pull-to-failure performance of the single anchor-clip fixation of two ends of mesh suggests a need to improve the locking mechanism to prevent disassembly. This study provides a preliminary indication for the use of anchor-clips in abdominal wall closure, such as hernia repair and laparotomy closure.

Funding

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Conflicts of interest

Dr. Howard Levinson is founder of Deep Blue Medical Advances who has licensed this technology from Duke University. Dr. David Ruppert and Dr. Ken Gall also have equity in Deep Blue Medical Advances.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2019.04.016.

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