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ORIGINAL ARTICLE

Suturable mesh better resists early laparotomy failure in a cyclic ball-burst model

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Abstract

Purpose The small bites surgical technique supported by the STITCH trial has been touted as a strategy for preventing early laparotomy dehiscence through greater force distribution at the suture–tissue interface. However, this hernia prevention strategy requires an alteration in the standard closure technique that has not been widely adopted in the USA. This study seeks to determine whether incorporating a mid-weight polypropylene mesh material into a hollow-bore surgical suture material will effectively increase the force distribution at the suture–tissue interface and potentially help prevent early laparotomy dehiscence in an ex vivo model.

Methods A cyclic stress ball-burst model was used to compare suturable mesh (0 DuraMesh™) to conventional suture. After midline laparotomy, 28 porcine abdominal wall specimens were closed with either 0 DuraMesh™ or #1 polydioxanone double-loop suture. A custom 3D-printed ball-burst test apparatus was used to fatigue the repair on a MTS Bionix Load Frame. The tissue was repetitively stressed at a physiological force of 15–120 N cycled at a rate of 0.25 Hz for a total of 1000 repetitions, followed by a load to failure, and the maximal force was recorded.

Results The mean maximal force at suture pull-through was significantly higher ($p < 0.0095$) in the 0 DuraMesh suture group (mean: 850.1 N) compared to the 1 PDS group (mean: 714.7 N).

Conclusion This ex vivo study suggests that using rational suture design to improve force distribution at the suture–tissue interface may be a viable strategy for preventing the suture pull-through that drives incisional hernia.

Keywords Wound closure techniques · Suture · Incisional hernia · Laparotomy · Trauma · Mesh

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Introduction

When one considers the number of patients affected, the rate of failure, and the cost and morbidity of repair, laparotomy failure and subsequent incisional hernia formation may represent the single greatest failure of modern surgical practice. Currently, incisional hernia continues to affect as many as 1 in 5 patients following midline laparotomy [1–3]. The high incidence, significant morbidity, and costly care of incisional hernia after laparotomy make it crucial to understand the limitations of existing laparotomy closure techniques and to investigate alternative strategies for closure [1, 4]. In the USA, the most widely used laparotomy closure technique employs a running technique, whereby a permanent or long-lasting monofilament suture is placed at 1-cm intervals and aims to incorporate 1 cm of fascia on each side of the midline laparotomy. This closure technique

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is largely based on surgical dogma, loosely derived from clinical outcome studies [5, 6].

Several recent clinical trials have argued that a small bites laparotomy closure technique yields a lower rate of hernia formation than the established large bites technique [7, 8]. Despite the benefits attributed to the small bites surgical technique, many surgeons in the USA have resisted adopting it as standard practice [6]. The elective nature of the laparotomies and the low mean body mass index of the studied populations are frequently cited as barriers to generalization of these study results to patient populations in the USA. While this caution may be justified, the failure of these robust clinical outcome studies to drive practice change underscores surgeon resistance to new techniques and exemplifies the known translational lag between dissemination of evidence and alteration in clinical practice [9]. The need to improve outcomes in the face of these obstacles necessitates investigation into hernia prevention strategies that optimize, rather than alter, the established surgical technique.

At its core, incisional hernia is the result of suture pull-through, which results in early fascial dehiscence and failed healing of the abdominal wall tissues [10, 11]. The clinical trials supporting the use of a small bites surgical technique grew from biomechanical studies demonstrating increased resistance to suture pull-through. The benefit of more frequent suture placement was hypothesized to be the result of greater force distribution across a larger combined suture–tissue interface [7, 8]. By incorporating multiple small filaments into a novel, hollow-bore suture design, DuraMesh™ aims to achieve greater force distribution at the suture–tissue interface without the need to alter the established surgical technique (Fig. 1). The efficacy of this "suturable mesh" design has been previously established in a small animal hernia model, as well as multiple linear testing models [12, 13]. Here we aimed to compare the ability of DuraMesh™ and conventional suture to resist suture pull-through using a ball-burst apparatus that better approximates the cyclic and multidimensional nature of forces experienced by the abdominal wall than conventional linear testing [14, 15].

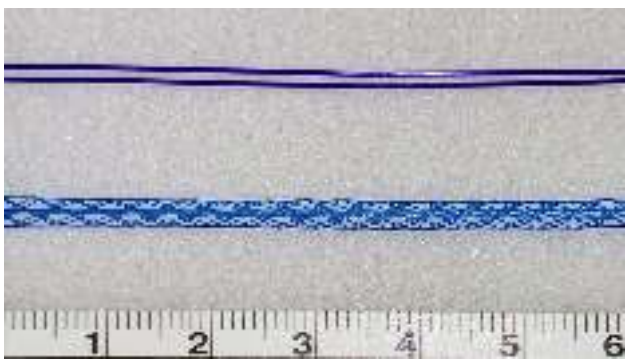

Fig. 1 Image of 0 DuraMesh (bottom) and 1 PDS double loop (top)

Methods

Porcine tissue acquisition and sample preparation

The porcine abdominal wall was selected as a model for this study due to its biological and mechanical similitude with human tissue and readily available supply [16]. Abdominal wall specimens were obtained from a local abattoir (Wagner's Meats, LLC; Mount Airy, MD) under the direction of our research staff. These abdominal wall sections were immediately wrapped in 0.9% NaCl-soaked surgical blue towels and transported on ice to our facility within 45–60 min [17]. They were then dissected to remove all skin, adipose tissue and excess soft tissue. The final specimen included the anterior and posterior rectus sheath, linea alba and rectus muscle. Muscle was removed from the periphery of each sample in order to optimize clamp hold on the tissue during testing.

To account for the natural variation between porcine specimens, a random number generator was used to assign a unique number to each of the specimens. They were subsequently divided into supraumbilical and infraumbilical sections (A and B, respectively) in an effort to maximize specimen use.

Methylene blue dye was used to mark the midline of each specimen and determine suture and clamp placement. An incision was made along the marked midline of each sample, and a 7-cm-long section of the incision was then repaired using the assigned suture type. Sutures were placed using a standardized surgical technique, whereby sutures were placed at 0.5–1-cm intervals and incorporated 0.5–1 cm of fascia on each side of the midline depending on the study group. The suture was knotted at each end, with each closure construct consisting of seven spanning segments of an otherwise continuous suture.

In order to avoid desiccation and prevent tissue breakdown, samples were always stored wrapped in blue surgical towels kept damp with 0.9% NaCl and in a refrigerator set at 4 °C. In order to standardize the temperature at testing, samples were removed 1 h prior to testing in order to allow for acclimatization to room temperature. All samples were tested within 48 h of procurement.

Control group determination

In anticipation of this ball-burst study, our group aimed to determine an appropriate control group in comparison with the DuraMesh™ closure group, as well as to determine an

effect size needed for power analysis. Using a linear traction methodology derived from the study by Harlaar et al. [8], we utilized a MTS Bionix Load Frame and a set of 3D-printed clamps specially designed by the 3D Medical Applications Center at our facility. Twenty-eight porcine abdominal wall sections were randomized into four different groups—1 PDS with 0.5-cm intervals, 1 PDS double loop with 1-cm intervals, 2-0 PDS with 0.5-cm intervals and DuraMesh group at 1-cm intervals. These groups were chosen, as they are representative of previously conducted studies, to include the suture type and spacing advocated by the STITCH trial [7, 8]. The maximal force at failure was recorded. The mean maximal force for the DuraMesh group was found to be significantly higher than the other groups at 473.3 N (1PDS at 0.5 cm was 386.6 N, 2-0 PDS at 0.5 cm was 355.4 N, and 1PDS at 1 cm was 325.5 N). Notably, this study did not demonstrate a statistically significant difference between the 2-0 PDS group at 0.5-cm intervals when compared to the 1 PDS at 1-cm intervals. Given the lack of significant difference between 2-0 PDS with small bites and 1.0 PDS at large bites, the absence of comparable preclinical data to support biomechanical superiority of the 2-0 PDS small bites technique, and our goal to directly compare DuraMesh closure to existing practice, we chose 1.0 PDS at 1-cm intervals as the control group for our ball-burst testing.

Ball-burst testing

The ball-burst model was chosen in an effort to better mimic the multi-axial force experienced by the abdominal wall. For this reason, it has previously been utilized for testing various hernia mesh characteristics (Fig. 2), but has yet to be applied to a laparotomy closure model [15, 18]. The ball-burst test is comprised of a spherical head attached to a piston and is used to apply a perpendicular force to a loaded sample for the purposes of materials testing. A ball-burst apparatus was developed at the WRNMMC 3D Medical Applications Center by utilizing 3D printing of titanium and plastic materials. This apparatus was then affixed to the commonly used MTS Bionix Load Frame. A protocol was developed for the MTS in order to exert a cyclic fatiguing stress followed by a load to failure. The cyclic stress portion was adapted from a physiologic model presented by Sahoo et al. to test hernia mesh [15, 19]. When adjusted to the surface area represented by our model, it yielded a series of 1000 force-controlled cycles oscillating between 15 and 120 N at a physiologic rate of 0.25 Hz.

Fig. 2 Ball-burst Apparatus—Right—3D printed titanium with plastic head colored green. Upper portion includes spherical head attached to piston in order to apply force to the sample being held in the ring below. Left: computer-aided design (CAD) image of ball-burst apparatus. Ring diameter of ball-burst apparatus is 7 cm (color figure online)

Another 28 porcine specimens were collected and dissected in the same fashion as stated above. The supraumbilical and infraumbilical sections (A and B) were alternated between the DuraMesh group and 1 PDS both placed at 1-cm intervals. This allowed for both suture groups to be used in each porcine sample with an even distribution between the A and B sections.

Once the fatiguing stress was completed, the tissue was subjected to a load to failure at a rate of 100 mm/min and ultimate force was recorded. Video-assisted observation of the tissue verified that maximum force occurred in conjunction with suture pull-through. Suture pull-through was defined as the moment at which one throw of the continuous pattern had completely separated from the tissue through which it passed (Fig. 3). The initial moment of failure was identifiable as a deflection in the force curve, and this was defined as the maximal force in which the repair could withstand, regardless of whether additional force was needed to compromise the rest of the closure.

Statistical analysis

Independent tests were run on 14 samples per group. Ultimate force data are presented as the mean ± SEM with statistically significant differences defined as $p < 0.05$ using Student's T tests.

Results

The mean maximal force observed prior to suture pull-through was higher in the 0 DuraMesh™ group (mean ± SEM = 850.1 N ± 40.73) when compared to the control 1 PDS (polydioxanone) double-loop group (mean ± SEM = 714.7 ± 24.79 N) ($p = 0.0095$) (Table 1 and Fig. 4).

Fig. 3 Screen captures of 0 DuraMesh (left) and 1 PDS double-loop (right) laparotomy closure failure via ball-burst apparatus. The tissue sample is circumscribed by the black ring, and the ball-burst piston is colored in green, pushing through the sutured section of the sample. Top row shows samples prior to pull-through, and bottom row illustrates examples of pull-through

Table 1 Maximum force resisted at the time of suture pull-through

2 mm DuraMesh [Force in Newtons (N)]	1-0 looped PDS [Force in Newtons (N)]
1100	815
1040	669
828	513
892	702
933	718
553	790
810	845
788	647
747	742
904	719
799	707
809	709
Mean: 850.1 N	Mean: 714.7 N

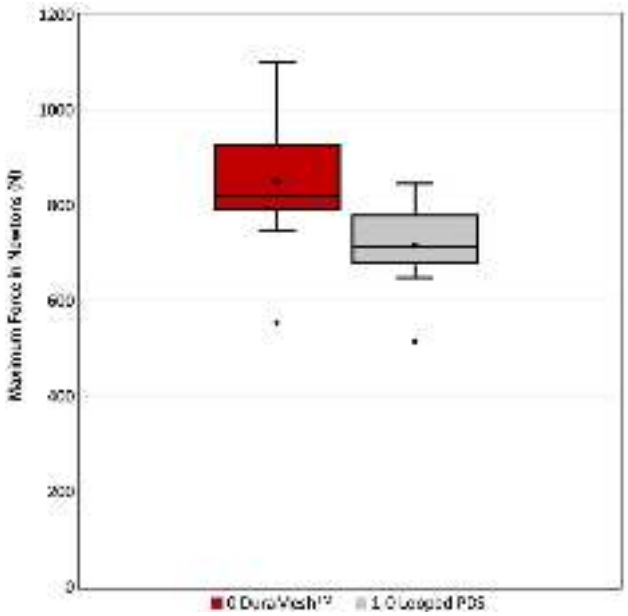

Fig. 4 Box and Whisker plot of maximum force (in Newtons [N]) at failure, by suture type. Failure is defined as suture pull-through

The superior (A) and inferior (B) control groups were also compared and not found to differ (p value = 0.1882). Therefore, it can be assumed that the sections were approximately equal in their tensile strength.

During the study, two of the samples exhibited tearing at the grip interface: one from the control and one from the experimental group. Therefore, both samples (A and B) from these two pigs were excluded from further analysis. All other samples exhibited pull-through at the suture line.

Discussion

Suture pull-through results from a known limitation of conventional surgical suture design—suture under tension cuts through tissue. While this design flaw affects all fields of surgery, nowhere is suture pull-through more problematic than in the abdominal wall, where an estimated 400,000 to 500,000 new incisional hernias are produced annually as a result of failed laparotomy closures [7]. Over the past 100 years, various techniques and materials have aimed to prevent the phenomenon of suture pull-through, but none has proven universally effective [20]. Most recently, a small bites surgical technique has been proposed to decrease the incidence of incisional hernia formation through greater force distribution at the suture–tissue interface [21]. While small bites laparotomy closure has been supported by level 1 clinical evidence, the modified surgical technique has failed to gain traction among surgeons in the USA [5, 6, 9].

Recognizing the limitations of suture-based strategies, prophylactic mesh augmentation (PMA) of laparotomy closure has emerged as an alternative approach to address this significant and persistent problem. Although a growing body of literature has demonstrated the efficacy of PMA for hernia prevention, increased surgical-site complications and added technical complexity have prevented widespread adoption of the technique. Likewise, concern for infection of the planar mesh used in PMA precludes its use in a contaminated or emergent setting [22, 23].

To address the gap between suture and mesh-based strategies for hernia prevention, a novel suturable mesh, DuraMesh™, has been purposely designed to provide the durability of a planar mesh repair, while dramatically limiting the amount of foreign material and surgical complexity required for implantation. DuraMesh™ achieves this by incorporating multiple small filament polypropylene sutures into a hollow-bore suturable mesh that can be used to close a laparotomy in the same fashion as with conventional suture. These small filaments provide a suture–tissue interface that is five times as large as that offered by conventional suture, with only double the amount of implanted material. The power of the technology is in its simplicity—it optimizes the use of existing materials into a construct that is easier to use and better able to distribute forces across the suture–tissue interface.

The benefit of this greater force distribution is well illustrated by the ball-burst model outlined in this study. Our results show a clear improvement in the force distribution properties of DuraMesh™ over conventional suture by markedly increasing the force at which suture pull-through occurs. The DuraMesh™ group experienced suture pull-through at a force that was 135.4 N higher than the control group. While DuraMesh demonstrated a significantly greater resistance to failure, it is worth noting that the failure mechanisms also differed between groups. Video observation of the ball-burst testing identified a consistent pattern in which conventional suture tended to cut through the tissue without much impediment. Conversely, DuraMesh frequently resisted pull-through along the midline closure; instead, the failure was through dehiscence lateral to the DuraMesh™ closure.

The intrinsic resistance to suture pull-through demonstrated that this ex vivo study may be further augmented in vivo, as the macroporous design provides the opportunity for tissue ingrowth [12]. This tissue reinforcement may yield even greater closure strength post-implantation [24, 25]. Compared to a closure with planar mesh, DuraMesh™ closure is limited to the midline, and the small filament structure may improve biocompatibility and decrease scar response.

While this study illustrates the potential benefit of DuraMesh™ laparotomy closure, there are several limitations that must be acknowledged. First, there are limitations to all ex vivo methods for simulating abdominal wall forces. The scale of the ball-burst model did not allow for testing of a full-size laparotomy closure construct. In addition, the use of force to failure as a primary outcome measure yielded forces that are far beyond the physiologic range of forces experienced by the abdominal wall. This outcome measure was chosen because it could be clearly identified on the MTS-generated force curve and readily correlated with video observation of the failure mechanism. Clinically, hernia formation is more commonly the result of subtotal failure from repetitive forces that create gaps in the closure. An attempt was made to simulate this subtotal failure mechanism through cyclic application of physiologic forces, but complete failure was ultimately required to generate the data demonstrating relative resistance to suture pull-through.

Finally, the ex vivo laparotomy closures tested in this study did not assess repair strength after tissue integration has taken place. Based on prior studies, we hypothesize that the strength of the DuraMesh™ laparotomy repair will be enhanced by tissue integration [26]; however, additional testing is needed to further explore this concept.

Conclusion

The findings of this study support the contention that greater force distribution can be achieved at the suture–tissue interface through the use of a suturable mesh construct. Given that enhanced force distribution serves as the basis for use of the small bites laparotomy closure technique, and this

technique has yet to be embraced for hernia prevention in the USA, DuraMesh™ laparotomy closure may represent a viable alternative strategy for preventing initial suture pull-through and wound dehiscence which may lead to incisional hernia formation. The findings of this study could be further enhanced with the utilization of live animal study or clinical series.

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Compliance and ethical standards

Conflict of interest The authors received the DuraMesh samples used in this study at no cost from the manufacturer, Mesh Suture Inc. Mesh Suture Inc. did not otherwise influence the study design, study execution, data collection, analysis of the study data, or decision to disseminate the study data. The authors declare that they have no conflict of interest.

Ethical approval All applicable international, national, and/or institutional guidelines for the care and use of animals were followed. All experiments conducted in this study are in the compliance with the current laws of the USA.

Human and animal rights This article does not contain any studies with human participants performed by any of the authors. All procedures involving animal tissue were performed in accordance with the ethical standards of our institution and the Institutional Animal Care and Use Committee at the Uniformed Services University of the Health Sciences, Bethesda, MD

Informed consent This article does not contain studies with human participants performed by any of the authors. Therefore there is no identifiable data that requiresd informed consent.

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