

Evaluation of absorbable and permanent mesh fixation devices: adhesion formation and mechanical strength

J. F. Byrd · N. Agee · R. Z. Swan · K. N. Lau · J. J. Heath ·
I. H. Mckillop · D. Sindram · J. B. Martinie ·
D. A. Iannitti

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Abstract

Purpose Laparoscopic ventral hernia repair is commonly performed with mesh prostheses; however, there is no standard for fixation devices used to secure mesh to the abdominal wall. This study is a functional comparison of novel, screw-type absorbable and permanent fixation devices with a traditional titanium fixation device.

Methods Fifteen pigs each underwent the laparoscopic placement of two 11 × 14-cm mesh prostheses and were randomized for mesh fixation with either titanium spiral tacks (TS), absorbable screw-type fasteners (SF), or permanent screw-type fasteners (PF) ($n = 10$ mesh prostheses for each fixation group). Adhesions were assessed laparoscopically at 4 weeks. The fixation devices were also embedded in porcine abdominal rectus muscle for ex vivo mechanical testing along with partial thickness polypropylene suture (PR) as a control group ($n = 40$ for each group). Maximum pull-off forces were measured. All statistical tests were two-tailed, and a P -value < 0.05 was considered to be significant.

Results The mean tenacity adhesion scores were 1.40 ± 0.52 (PF), 1.7 ± 0.82 (SF), and 2.6 ± 1.07 (TS). Adhesions in the PF group were significantly less tenacious compared with the TS group ($P = 0.01$). Quantitative adhesion scores were not significantly different among groups. The maximum pull-off forces, measured in Newtons, were $28.61 \text{ N} \pm 4.89 \text{ N}$ (TS), $22.71 \text{ N} \pm 7.86 \text{ N}$ (SF), $16.98 \text{ N} \pm 7.59 \text{ N}$ (PF), and $20.83 \text{ N} \pm 6.25 \text{ N}$ (PR). The pull-off force

in the TS group was higher than all of the other groups ($P < 0.001$). The SF group also had a higher pull-off force compared with the PF group ($P < 0.001$).

Conclusions The screw-type absorbable and permanent fixation devices provided adequate fixation and were associated with decreased adhesions in this porcine model.

Keywords Ventral hernia repair · Mesh fixation

Introduction

Ventral hernias are common complications following abdominal surgery. Up to 20% of patients develop ventral hernias following laparotomy [1–3]. If not repaired, these hernias enlarge over time and lead to significant morbidity, causing pain, bowel incarceration, and enterocutaneous fistulas. Surgical repair is the only option to permanently restore the abdominal wall integrity.

The development of mesh prostheses was a significant advancement in the surgical repair of ventral hernias. Initially, mesh was used during open ventral hernia repairs in which laparotomies were required for mesh placement and fixation. Laparoscopic ventral hernia repair with mesh has shown several advantages compared with the open approach. A meta-analysis by Pierce et al. pooled data from 45 published series including 5,340 patients to compare laparoscopic (LVHR) versus open (OVHR) ventral hernia repair [4]. LVHR was associated with lower recurrence rates compared to OVHR (4.3% vs. 12.1%, $P < 0.0001$). Other advantages of LVHR included fewer wound complications and decreased length of hospital stay. Other published meta-analyses found similar advantages for LVHR [5, 6]. Laparoscopic hernia repairs incorporating mesh prostheses have emerged as the superior hernia repair

J. F. Byrd · N. Agee · R. Z. Swan · K. N. Lau · J. J. Heath ·
I. H. Mckillop · D. Sindram · J. B. Martinie · D. A. Iannitti (✉)
Section of Hepatopancreatobiliary Surgery,
Department of General Surgery, Carolinas Medical Center,
Morehead Medical Plaza, Suite 300,
1000 Blythe Blvd., Charlotte, NC 28203, USA
e-mail: David.Iannitti@carolinashealthcare.org

operation. A major debate surrounding this type of repair is which mesh fixation device should be used.

Successful ventral hernia repair must combine an ideal mesh prosthesis with an ideal fixation device. There is no consensus regarding an optimal fixation method. Transabdominal sutures and titanium tacks or staples are the most traditional fixation methods. These permanent devices may lead to complications. Transabdominal sutures can cause chronic pain syndromes by entrapping sensory nerves [7, 8]. Titanium tacks and staples can cause excessive adhesions and may lead to the penetration and perforation of hollow viscera if they fall away from the abdominal wall [9, 10].

The ideal fixation device provides strong adherence of mesh to the abdominal wall while minimizing complications resulting from the fixation constructs themselves. Novel screw-type fasteners have been developed to provide adequate mesh fixation without the complications associated with other devices. Fixation constructs made from absorbable polymers may offer additional advantages by providing adequate mesh fixation early in the postoperative course while minimizing the long-term complications associated with permanent fixation devices. This screw-type design incorporated with permanent and absorbable fixation devices may represent a substantial advance in mesh fixation technology.

We hypothesized that novel screw-type fixation devices made of permanent and absorbable polymers will provide strong mesh fixation to the abdominal wall with minimal complications associated with other fixation methods. This study specifically evaluates the formation of intraabdominal adhesions in a porcine model of ventral hernia repair and *ex vivo* pull-off strength associated with screw-type fixation devices.

Methods

Animals

All animal protocols were approved by our medical center's Institutional Animal Care and Use Committee (IACUC) and conformed to Federal Care and Use of Laboratory Animals guidelines. Fifteen pigs (Yorkshire females, 35–45 kg) were randomized into three groups for mesh fixation with titanium spiral tacks (TS), absorbable screw-type fasteners (SF), or permanent screw-type fasteners (PF). Animals underwent the laparoscopic placement of a composite polypropylene/expanded polytetrafluoroethylene (ePTFE) mesh (11 × 14 cm). The mesh was placed bilaterally, and a single type of fixation device was used for each animal. This produced ten specimens for each fixation group. Throughout the study, animals were maintained in

standard conditions and given free access to food and water.

Fixation devices

Three commercially available fixation devices were used in this study: ProTack™, TS, a titanium spiral construct (Covidien, Inc., Mansfield, MA); SorbaFix™, SF, an absorbable poly (D, L) lactide fastener (Bard Davol, Inc., Warwick, RI); and PermaFix™, PF, a permanent acetal fastener (Bard Davol, Inc., Warwick, RI). SF and PF are mandrel-guided fasteners that enter soft tissues with a screw-type orientation. These fasteners also have a hollow core to facilitate tissue ingrowth through the fasteners themselves (Figs. 1 and 2).

Surgery

Animals were anesthetized, intubated, and placed supine on the operating table. The abdomen was prepped, draped, and all surgical procedures were performed using sterile techniques. Laparoscopic trocars were placed at the umbilicus and at the right and left subcostal positions. Composite polypropylene/ePTFE mesh was introduced through the 10-mm umbilical port. Prior to fixation, suture was placed in the center of each mesh to aid in the positioning. These sutures were removed following fixation with fasteners. A double-crown method was used to secure the mesh to the abdominal wall with two concentric rings of fasteners. For the inner ring, individual fasteners were placed at the 3, 6, 9, and 12 o'clock positions. Next, a series of three tacks was evenly positioned 1 cm apart between each anchor for a total of 16 tacks placed inside the ring channel. A second ring of tacks was positioned outside of the ring channel in a similar fashion, so that each mesh prosthesis was secured with 32 tacks. No tacks were placed in the center of the ring channel (Fig. 3).

The abdominal fascia at the trocar sites was closed with 0-polydioxanone (PDO) absorbable suture. Skin edges were re-approximated with staples, and a dry dressing was applied over silver sulfadiazine cream. Following surgery, animals were placed in a recovery area and given appropriate analgesia.

Adhesion testing

Four weeks following mesh implantation, the animals were assessed for adhesions and euthanized. Laparoscopic inspection was used to measure the intraabdominal adhesions. Adhesions were grossly evaluated with a 10-mm 30° laparoscope. Qualitative and quantitative measurements of adhesions were made using validated scales. The Modified Diamond Scale [11] was used to measure the quantity of adhesions (Table 1), and tenacity measurements were made using a scale validated by Garrard et al. [12] (Table 2).

Fig. 1 **a** Titanium spiral fixation device, ProTack™ (Covidien, Inc., Mansfield, MA). **b** Screw-type absorbable fixation fastener, SorbaFix™ (Bard Davol, Inc., Warwick, RI). **c** Screw-type permanent fixation fastener, PermaFix™ (Bard Davol, Inc., Warwick, RI)



Mechanical testing

Pull-off strength was measured *ex vivo* using porcine abdominal rectus muscle. The three fixation constructs were applied to the anterior rectus fascia and underlying muscle approximately 1 cm apart in an alternating fashion. Polypropylene sutures (3–0) were also sutured to the anterior rectus fascia and muscle at a partial-thickness depth for a control group ($n = 40$ for each group). A tensiometer was used to extract the fixation devices and suture at a constant rate of 20 mm/min. The maximum force required for the removal of embedded tacks and suture (pull-off force) was measured in Newtons.

Statistical analysis

Data are presented as mean values with standard deviations and proportions. Interval data were compared using analysis of variance (ANOVA), followed by Tukey's honestly significant differences (HSD) post hoc tests. Kruskal–Wallis tests were used to compare ordinal data. Statistical significance was defined as $P < 0.05$.

Results

Mortality

On postoperative day 5, 1 animal in the PF group was euthanized. Necropsy revealed a loop of infarcted bowel in close approximation and adherent to a portion of mesh and a PF fixation construct. The small bowel was proximally dilated and distally decompressed, consistent with a bowel obstruction as the most likely pathology. This death resulted from a technical error in the placement of the fixation device that allowed the fastener to fall away from the abdominal wall. This animal was replaced. All other animals survived for the study duration, and there were no other complications.

Laparoscopic inspection

All animals underwent laparoscopic inspection 4 weeks following implantation and immediately prior to euthanasia. All composite mesh grafts were firmly fixed to the

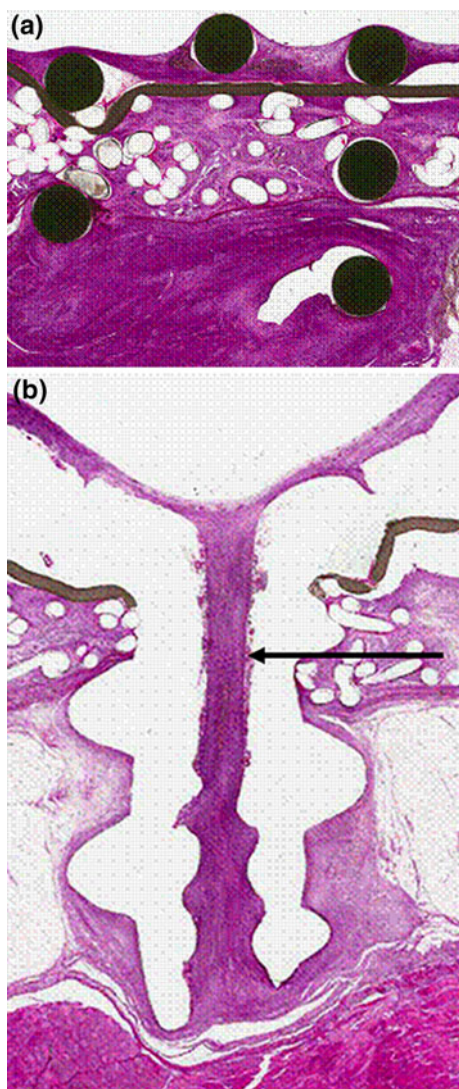


Fig. 2 Histological preparations showing (a) axial view of screw-type fasteners surrounded by host tissue and (b) coronal view of connective tissue in-growth through the hollow core (arrow)

abdominal wall musculature and exhibited a connective tissue covering indicative of early in-growth of host tissue into the mesh. All fixation devices were securely in place, and there was no graft migration. There were no indications of surgical site or mesh infections.

Adhesions

Adhesions were measured with quantitative (Modified Diamond) and qualitative scales. Modified Diamond scores were 0.9 ± 1.1 (SF), 0.5 ± 0.7 (PF), and 1.6 ± 1.2 (TS), and there was no statistical difference among groups, $P = 0.084$ (Table 3, Fig. 4). The mean tenacity adhesion score for the SF group was 1.7 ± 0.82 . The mean tenacity scores for the PF and TS groups were 1.40 ± 0.52 and 2.6 ± 1.07 , respectively. Adhesions in the PF group were



Fig. 3 Double-crown mesh fixation technique

Table 1 Modified Diamond Scale [11]

Score	Percent adhesion (%)
0	No adhesions
1	<25
2	25–50
3	>50

Table 2 Adhesion Tenacity Scale [12]

Score	Description
0	No adhesions
1	Filmy adhesions, easily broken manually
2	Dense adhesions requiring blunt dissection to separate viscera from mesh
3	Very dense adhesions with viscera matted to mesh surface and requiring sharp dissection to separate viscera from mesh

significantly less tenacious than adhesions in the TS group ($P = 0.01$). Adhesions in the SF group were generally less tenacious compared with the TS group, although this difference was not statistically significant, $P = 0.058$ (Table 4, Fig. 4).

Pull-off strength

The maximum pull-off force measured in Newtons was $28.61 \text{ N} \pm 4.89 \text{ N}$ for the TS group. The maximum pull-off forces for the other groups were $22.71 \text{ N} \pm 7.86 \text{ N}$ (SF), $16.98 \text{ N} \pm 7.59 \text{ N}$ (PF), and $20.83 \text{ N} \pm 6.25 \text{ N}$ (PR). The pull-off force for the TS group was greater than all of the other groups ($P < 0.001$ for all comparisons). The pull-off force was significantly greater in the SF group compared with the PF group ($P < 0.001$) (Fig. 5).

Table 3 Modified Diamond adhesion scores

Diamond score	PF (%)	TS (%)	SF (%)
None	60 (6/10)	20 (2/10)	50 (5/10)
<25	30 (3/10)	30 (3/10)	20 (2/10)
25–50	10 (1/10)	20 (2/10)	20 (2/10)
>50		30 (3/10)	10 (1/10)

PF PermaFix™, TS ProTack™, SF SorbaFix™

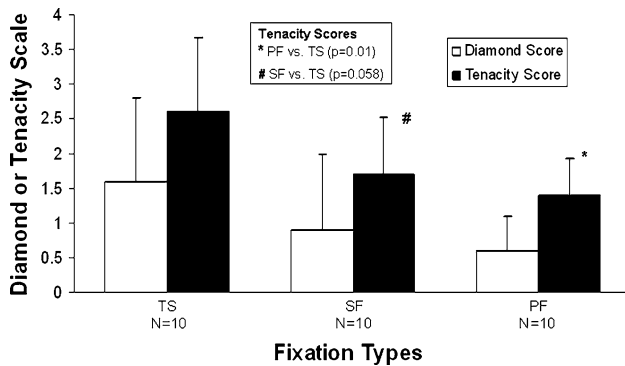


Fig. 4 Adhesion scores associated with fixation devices

Table 4 Tenacity adhesion scores

Tenacity score	PF (%)	TS (%)	SF (%)
None	60 (6/10)	20 (2/10)	50 (5/10)
Filmy	40 (4/10)	20 (2/10)	30 (3/10)
Dense		40 (4/10)	20 (2/10)
Very dense		20 (2/10)	

PF PermaFix™, TS ProTack™, SF SorbaFix™

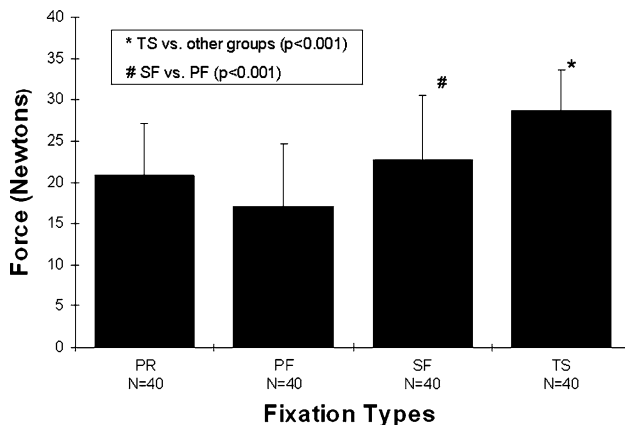


Fig. 5 Maximum pull-off forces associated with fixation devices

Discussion

Laparoscopic evaluation showed that mesh prostheses secured with the screw-type fasteners (SF and PF) were firmly fixed to the abdominal wall without mesh migration. These fasteners showed a trend toward fewer adhesions, and the PF group formed significantly less tenacious adhesions compared with the TS group. Ex vivo mechanical tests showed that titanium screws (TS) had the greatest pull-off strength. The pull-off strengths of the screw-type fasteners (SF and PF) were both comparable to the polypropylene suture control group.

The positioning of mesh fixation constructs is critical to successful ventral hernia repair. Significant morbidity resulting from abdominal viscus injury during mesh fixation has been reported. Great care must be taken to reflect the bowel caudally and posteriorly in order to prevent bowel injury while grafts are secured to the abdominal wall. One animal in the PF group was euthanized following complications from a bowel obstruction. The authors believe that this resulted from a loop of bowel interposed between the abdominal wall and the inferior edge of the graft during fixation. This was a technical error, and more scrupulous attention to ensure that the bowel was protected prior to graft fixation would have likely prevented this complication.

Fixation devices have been clinically associated with intraabdominal adhesions following mesh implantation. Our data corroborates findings from other animal studies [13–16] showing differences in adhesions when different fixation devices are used to secure mesh prostheses. Both the quantity and density of adhesions are clinically important because more tenacious adhesions will likely lead to increased morbidity. At least half of the animals implanted with the screw-type fasteners developed no adhesions (SF 50%, PF 60%). When present, adhesions in the SF and PF groups were generally filmy omental attachments that were easily lysed with blunt dissection. Only animals in the TS group developed “very dense” adhesions requiring sharp dissection.

The mechanical strength of mesh fixation devices is important for ventral hernia repair. There is currently no standardized method for the mechanical testing of fixation devices. Misawa et al. evaluated three fixation devices by counting the number sponges captured when each device was fired [17]. The present study uses a more physiologic method for mechanical testing by embedding fixation devices into porcine rectus muscle and measuring the maximum pull-off forces. A similar technique comparing fixation devices has been reported using porcine abdominal wall and polypropylene mesh for the ex vivo measurement of pull-off strength [18]. Again, the technique used in the present study is unique in measuring the pull-off strength of

fixation devices embedded directly into abdominal wall musculature without the presence of intervening mesh.

Given the structural composition of the titanium metal devices, it is not surprising that the TS group demonstrated strong pull-off strength. Even so, laparoscopic inspection revealed that mesh implanted with the screw-type fasteners (SF and PF) remained securely fixed to the abdominal wall without migration 4 weeks after implantation. Partial-thickness polypropylene sutures were used as a control group for mechanical strength testing. SF and PF fasteners performed as well as the control group in mechanical testing. This suggests that SF and PF fasteners provide adequate fixation to overcome physiologic stresses that can lead to the separation of mesh prostheses from the abdominal wall during the critical early postoperative period. The higher pull-off force measured in PF fasteners compared with the SF group may result from differences in the material composition of these fasteners.

The fixation capacity of the SF and PF fasteners is likely enhanced by the design and shape of these devices. The screw-type shape of these fasteners combined with the twisting orientation as they enter soft tissues allows for a 5.9-mm depth of purchase compared with 3.8 mm for the TS device [16]. The hollow cores of the SF and PF fasteners allow for tissue in-growth through the fasteners themselves, further improving fixation strength.

This study used a porcine model to evaluate intraabdominal adhesions associated with absorbable and permanent screw-type fasteners. Mechanical strength was also evaluated using *ex vivo* porcine abdominal rectus muscle. Although porcine models have been used extensively to evaluate adhesions and mechanical strength associated with mesh fixation constructs [13, 18], prospective clinical trials are needed to further examine the performance of screw-type fasteners and any functional advantages compared with other fixation devices. The data in this study show that novel screw-type fasteners with a hollow core may be an effective alternative to titanium fixation devices.

Conflicts of interest C. R. Bard, Inc. (Davol, Inc.) provided an unrestricted educational grant to fund this study. In addition, Dr. Iannitti is on the speaker's bureau for Davol, Inc. Drs. Byrd, Agee, Swan, Lau, McKillop, Sindram, Martinie, and Ms. Heath have no additional financial or personal relationships with persons or organizations that could inappropriately bias this work.

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