ABSTRACT

Objectives: We sought to measure the strength of tissue attachment to mesh after laparoscopic ventral hernia repair in a porcine model.

Methods: Twelve swine had two 10-cm x 16-cm sheets of ePTFE and polypropylene/ePTFE composite mesh fixated to the abdominal wall laparoscopically. Animals were euthanized at 2, 4, 6, and 12 weeks. The strength of tissue ingrowth was measured using a lap-shear method. Data are reported as mean force in pounds.

Results: Average surface area of adhesions to percentage of surface area was not statistically significant between the composite and ePTFE materials. For the composite material, there was a 98.7% posterior probability that the force required at 2 weeks was less than that required at 12 weeks. There was no difference in graft-abdominal wall interface strength between week 2 and week 12 for ePTFE material. Both prosthetics achieved the majority of their strength from tissue ingrowth by 2 weeks, but the composite prosthesis continued to gain strength while the ePTFE plateaued. Composite mesh demonstrated a statistically significant increase in strength between the lap-shear force, whereas no statistically significant difference occurred in the ePTFE graft. For the composite material, there was complete cellular infiltration through the entire thickness of polypropylene (approximately 500 μm) to the ePTFE layer at 2 weeks. At 2 weeks for ePTFE, the cells did not penetrate into the graft on the visceral side. On the abdominal wall side, the grooves filled with tissue, but no cellular penetration into the ePTFE occurred. No histological difference existed in cellularity.

Conclusion: This study demonstrates that the strength of tissue ingrowth is significantly higher (P<0.05) for the composite grafts relative to the ePTFE grafts at each time point. Approximately 74% of tissue ingrowth and strength occurs by 2 weeks postoperatively for the composite prosthesis. The ePTFE graft tissue strength peaked and plateaued by 2 weeks. This may have clinical implications for human ventral hernia repair by partly addressing the issue of graft fixation to the abdominal wall during laparoscopic ventral hernia repair.

Key Words: Ventral hernia, Tissue ingrowth, Composite, ePTFE.

INTRODUCTION

Incisional hernias occur at a rate of 3% to 20% after uncomplicated laparotomy. In patients who are obese, immunosuppressed, develop a wound infection, or have had previous abdominal surgery, the rate of hernia formation may be as high as 40%. Over 2 million laparotomies are performed in the United States each year, resulting in about 100 000 incisional hernia repairs annually. Primary incisional hernia repairs are often ineffective, with reported recurrence rates from 25% to 52%. The use of prosthetic materials has decreased recurrence rates to less than 10%. Unfortunately, placement of a prosthetic mesh with the traditional open technique requires extensive soft tissue dissection, which can result in significantly increased wound complication rates.

Laparoscopic incisional hernia repair was first described in 1992. Since its introduction, the minimally invasive approach is now commonplace in hernia repair. Multiple authors have reported that laparoscopic incisional hernia repair is a safe, effective procedure, resulting in reduced hospital stay, less pain, fewer recurrences, and fewer complications compared with the traditional open surgical technique.

Although the technique for laparoscopic repair varies...
somewhat among surgeons, it generally involves intraperitoneal placement of a prosthetic material. Prosthetics today include pure expanded polytetrafluoroethylene (ePTFE), a polypropylene/ePTFE composite grafts, and other polypropylene- and polyester-based meshes. Questions have arisen regarding the timing of tissue ingrowth and tissue strength with the use of these materials. We have previously reported on strength of tissue ingrowth of polypropylene-based composite mesh using a similar animal model. We have demonstrated that rapid tissue incorporation and adhesive strength of polypropylene occurs in the first 2 weeks postoperatively. This study compares the strength of tissue attachment and ingrowth between ePTFE grafts and a composite prosthetic.

To prevent hernia recurrence, the mesh must be affixed to the abdominal wall and must be able to withstand the pressures generated by coughing, straining, and normal postoperative activity until adequate tissue ingrowth occurs. A common method currently used to secure the mesh is the transfascial suture technique, whereby sutures are placed through all layers of the abdominal wall and the mesh using a suture passer, and then tied. Various stapling or tacking devices are often used to first affix the graft to the abdominal wall, closing the gaps between the sutures. This technique has been shown to yield acceptable healing and a low recurrence rate, ranging from 4% to 6% at a follow-up period of 8 months to 36 months. One problem with transfascial sutures can be significant pain at the suture sites, which may last months beyond the postoperative period and may eventually require reoperation to remove the sutures.

Controversy is ongoing regarding the fixation method with the use of pure ePTFE and polypropylene/ePTFE composite or polypropylene based meshes. Most proponents of ventral hernia repair who use pure ePTFE grafts believe that all grafts need to be transfascially sutured to maintain a strong attachment between the implanted prosthetic graft and the abdominal wall because minimal tissue ingrowth occurs. Those who use polypropylene/ePTFE composite or other polypropylene-based meshes believe that transfascial sutures may not be necessary, and the mesh can be secured by tacks only because the longevity and strength of the repair is based on strong tissue ingrowth into the polypropylene.

This study utilizes a porcine model of laparoscopic incisional hernia repair with a polypropylene/ePTFE composite mesh (EX) (Composix E/X, Davol, Cranston, RI) and a pure ePTFE mesh (DM) (WL Gore, Flagstaff, AZ) to evaluate these opinions. The composite is composed of polypropylene mesh on one side for tissue ingrowth and a sub-micronic ePTFE graft on the visceral side to minimize adhesions to the prosthesis and to form a long-term barrier between the hollow viscous structures and the polypropylene. The pure ePTFE mesh has a rough surface on one side to encourage tissue adherence to the graft, and a smooth surface on the other side that is placed adjacent to the viscera to minimize adhesions. Our objective was to assess the timing of tissue ingrowth and strength of tissue attachment to a polypropylene/ePTFE composite mesh and a pure ePTFE prosthesis at various time points after the grafts were affixed with a tacking device only.

**METHODS**

All animals were used and cared for in accordance with the Guide for the Care and Use of Laboratory Animals (NIH publication No. 86–23) and the Brown University policy for the care and use of animals. Twelve female swine (26 kg to 41 kg) were laparoscopically implanted with two 10-cm x 16-cm sheets of polypropylene/ePTFE composite prosthesis and ePTFE graft to the abdominal wall on either side of the midline. The same surgeon (DAI) performed all procedures.

For the implantation, the swine were anesthetized and placed in a supine position. All animals received one gram of intravenous cefazolin before induction of anesthesia. A small infraumbilical incision was made in the midline, and a 12-mm laparoscopic port was placed using the Hassan trocar technique. The abdomen was insufflated to 15 mm Hg using carbon dioxide, and under direct vision, two 5-mm ports were placed in the midline. The prostheses were fixated to the abdominal wall by using a 5-mm helical tacking instrument (Protack Helical Tacker, Autosuture, United States Surgical Corporation, Norwalk, CT). No transfascial sutures were used to secure the grafts. Care was taken to ensure that the prostheses were placed flush against the abdominal wall with minimal ridges or folds. After implantation, the port sites were closed with interrupted nonabsorbable sutures, and the skin was closed with interrupted, absorbable subcuticular sutures.

Postoperatively, each animal was returned to its pen and received analgesia with 0.01 mg/kg buprenorphine if necessary. All animals were given free access to a normal diet and water immediately after surgery. At 2, 4, 6, or 12 weeks after surgery, 3 animals were sacrificed with a bolus of intravenous potassium chloride. Approximately 6 patches from each time group were available for evalua-
tion. The patches were explanted by excising a full thickness specimen of the abdominal wall.

The specimens were grossly examined and the extent of adhesions (percentage of implant covered by adhesions) noted. The strength of the abdominal wall attachment to the prosthesis was determined by using a lap-shear method. All the muscle and adipose tissue was removed from the graft, leaving a readily demonstrable fibrotic lamina on the abdominal wall side of the material. The fixation tacks were also removed from all specimens. Each patch was divided in half in the short axis then cut into six 2-cm x 7-cm strips along the long axis of the graft. A flap was started at the center edge of each strip by sharply dissecting the fibrotic lamina from the prosthetic material. The dissected lamina was then placed in one grip of an Instron servohydraulic tensile testing frame (Instron Corporation, Canton, MA) with the graft placed in the other grip (Figure 1). By using a crosshead speed of 20 mm/min and a 50-pound load cell (Omega), the fibrotic lamina was “peeled” from the prosthesis with lap-shear forces in pounds recorded at a frequency of 10 Hz (Figure 2). The technician operating the frame was blinded with regard to the test groups and material.

The Student $t$ test was used to compare continuous variables. A P-value of 0.05 was considered significant. A Bayesian hierarchical model was used to estimate the force required to remove the mesh strips from the abdominal wall in each time period. Random effects were assumed for each animal, side, and measurement (observation) error. Results are reported for each parameter as the estimated mean and standard deviations of the Bayesian posterior distribution.

Portions of the specimens were fixed in formalin and sectioned perpendicular to the plane of the graft for histologic evaluation. Hematoxylin and Eosin (H&E) staining was performed.

**RESULTS**

No intraoperative complications occurred. All prosthetic implantations were successfully attached laparoscopically. All animals survived the length of the study without major complications. One of the 6-week animals developed some minor respiratory difficulties in the first several days after the operation. This animal was treated with 3 doses of methylprednisolone, and the symptoms were resolved.

No difference existed between groups in the mean starting weight, operative time, or number of tacks used to secure each patch. When adhesions to the undersurface of the grafts were evaluated, the average surface area of adhesions to percentage of surface area was not statistically significant between the composite and ePTFE materials. The overwhelming majority of adhesions was omental and easily lysed. Two specimens had liver or spleen ad-
hesions to the grafts. There was no bowel adherence directly to the prosthetic in either group.

The mean “peel” (lap-shear) force in pounds for test materials at each time period is reported in Table 1. By week 2, the composite prothesis-abdominal wall interface had achieved 73.6% of the strength it had at 12 weeks, while the ePTFE had attained 98.4% of its ultimate strength at 2 weeks postoperatively. When differences in means for week 2 versus week 12 were compared for the composite material, there was a 98.7% posterior probability that the force required at 2 weeks was less than that required at 12 weeks. In contrast, there was no difference in graft-abdominal wall interface strength between week 2 and week 12 for ePTFE material. While both prosthetics achieved the majority of their strength from tissue ingrowth by 2 weeks, the composite prosthesis continued to gain strength while the strength of the ePTFE plateaued.

The composite mesh demonstrated a statistically significant increase in strength between the lap-shear force at each time point (2, 4, 6, and 12 weeks), whereas no statistically significant difference occurred in the ePTFE graft during the same time period. Lap-shear strength for the composite mesh was greater at 2 weeks (0.83 lbs vs 0.50 lbs, P<0.05), 4 weeks (1.06 lbs vs 0.53 lbs, P<0.05), 6 weeks (0.88 lbs vs 0.47 lbs, P<0.05), and 12 weeks (1.12 lbs vs 0.51 lbs, P<0.05) compared with the ePTFE prosthesis. Although the mean lap-shear force was actually greater at 4 weeks than at 6 for both materials (1.062 vs 0.875 for composite and 0.529 vs 0.469 for ePTFE), this difference did not reach statistical significance (Figure 3).

Histologic examination of the specimens was carried out at all time points. For the composite material, there was complete cellular infiltration through the entire thickness of polypropylene (approximately 500 μm) to the ePTFE layer at 2 weeks. Fibroblasts were distributed evenly throughout the polypropylene layer, and inflammatory cells (PMNs and giant cells) were aggregated around the filaments of the mesh (Figure 4A). At 2 weeks for ePTFE, the cells did not penetrate into the graft on the visceral side. On the abdominal wall side, the grooves filled with tissue, but no cellular penetration into the ePTFE occurred. The cells near the ePTFE were relatively benign appearing with minimal aggregation of inflammatory cells (Figure 4B).

Collagen deposition was seen by H&E stain as well as polarized light throughout the thickness of the polypropylene aspect of the composite material, while no cellular penetration or collagen deposition into the PTFE portions of either graft material occurred. No histological difference existed in cellularity at all 4 time points for either material.

### Table 1.

| Week | ePTFE | Composite |
|------|-------|-----------|
|      | N     | Mean | SD | Max | SD | N     | Mean | SD | Max | SD |
| 2    | 36    | 0.502 | 0.062 | 1.025 | 0.122 | 36    | 0.825* | 0.062 | 1.408* | 0.120 |
| 4    | 33    | 0.529 | 0.066 | 1.187 | 0.124 | 39    | 1.062 | 0.067 | 1.714 | 0.118 |
| 6    | 23    | 0.469 | 0.079 | 0.912 | 0.153 | 26    | 0.875 | 0.083 | 1.539 | 0.147 |
| 12   | 27    | 0.510 | 0.072 | 1.305 | 0.132 | 32    | 1.121* | 0.068 | 1.918* | 0.130 |

*P < 0.05.
DISCUSSION

The type of material and the technique used to implant mesh during ventral hernia repair is clearly important. A properly placed mesh must withstand the forces of normal postoperative coughing, straining, and everyday movement until adequate tissue ingrowth occurs. Until recently, these pressures that are generated inside the abdomen and that the mesh must withstand have been largely unknown. Cobb et al.19 reported intraabdominal pressures for healthy nonobese adults giving us a surrogate for the strength of mesh needed in hernia repairs. They reported average intraabdominal pressures of 16.7 mm Hg while sitting and 20.0 mm Hg while standing with the highest pressures occurring while coughing and jumping, 107 mm Hg and 171 mm Hg, respectively.19

Previous authors20 have shown that significant inflammatory reaction and tissue ingrowth occurs within 7 days of implantation. Despite this, it is not known exactly how much time it takes to achieve a prosthetic material-abdominal wall interface with sufficient strength to prevent recurrence. We presumed that at 12 weeks postoperatively, barring infectious complications, a hernia repair graft should be incorporated into the patient’s abdominal wall and complete wound healing should have occurred.

In 2002, van’t Riet et al.21 compared the tensile strengths of mesh fixation with transfascial sutures versus helical tackers. Their group explanted abdominal wall specimens from pig cadavers and affixed polypropylene mesh to each. They then used a dynamometer to record the force required to disrupt the mesh from the abdominal wall. They found that transfascial sutures were stronger than tacks and that increased numbers of fixation points provided more strength. They concluded that to prevent recurrences, transfascial sutures should be used in laparoscopic incisional hernia repair. These results are difficult to translate to clinical ventral hernia surgery because the study was done on cadavers. We postulate that the overall strength of any hernia repair comes from the type of mesh implanted as well as the fixation method in the early postoperative period; however, over time, the long-term strength is derived from tissue ingrowth, collagen deposition, and the body’s ability to incorporate the prosthetic material.

LeBlanc and others22 studied the tissue attachment strength of polypropylene versus ePTFE mesh in a rabbit model. Although they implanted meshes in living animals, they retrieved the grafts only 3 days postoperatively. They then used a hand-held tensiometer to measure “tissue attachment strength,” or the peak force required to separate the entire piece of mesh from the soft tissue. They also performed histologic analysis of the specimens, to evaluate for inflammatory response and cellular ingrowth. They found that ePTFE had a stronger attachment to tissue than polypropylene. Further, ePTFE had significant cellular ingrowth at just 3 days, whereas polypropylene had almost none. Again it is difficult to translate these findings into clinical surgery because the end point was only 3 days postoperatively.

In this study, we measured the strength of tissue attachment of ePTFE grafts and composite mesh at various time points during a 12-week period. A servohydraulic testing frame was used to measure the strength of the mesh-abdominal wall interface. The benefit of using the servohydraulic testing frame was for the precise measurement of the lap-shear force, the mean pulling force required to
separate the graft and the scar. In comparison, shear force measures the sliding force of 2 materials relative to each other; tensile strength measures the strength of the graft itself as it is pulled apart. We believe lap-shear force accurately represents the strength of the adhesion between the graft and the scar plate.

During analysis, the scar was placed in one grip and the graft in the other on the computer controlled servohydraulic testing frame system. The grips were hydraulically regulated to maintain the tension constant, as the tissue was being pulled apart at 2 cm per minute. We measured the lap-shear force at 10 Hertz, or 10 times per second. Each strip was evaluated in the same manner.

When measuring the lap-shear force, each strip demonstrated an initial peak force and then a plateau as it was being pulled apart (Figure 2). The initial peak is referred to as the maximum force required to separate the mesh-abdominal wall interface. The plateau, where the values were relatively stable, called the mean force, truly reflects the strength of tissue ingrowth between the graft and the abdominal wall. The technician marked the period of plateaued force values, and used an average of these numbers within that time frame as the mean force for that particular strip. On average, there were approximately 1500 data points per strip.

Our data indicate that cellular ingrowth and strength were attained very rapidly from implantation until the 2-week time point. For the composite mesh, the data indicate that there was a very gradual increase in strength from weeks 2 to 12; the strength at 2 weeks was measured at 0.8 pounds and increased to 1.1 pounds by week 12. The slope of the curve during this time was gradual; in fact, no significant difference existed in mean force between the 2-week and 4-week groups, the 4-week and 6-week groups, or the 6-week and 12-week groups. Only the 2-week and 12-week groups had any significant difference between them. For the pure ePTFE mesh, tissue strength peaked and reached a plateau by 2 weeks at 0.5 pounds and remained at 0.5 pounds by week 12. No statistical difference existed in mean force between any of these time points.

This study brings up several questions regarding mesh fixation and strength. One question relates to the strength of fixation to the peritoneum, which may be mobile on the overlying fascia. Our study did not specifically address this question, because typically in the porcine model, there is little preperitoneal fat and the peritoneum abuts the fascia. In cases where the peritoneum is thought to be mobile on the abdominal fascia, one potential option is to debulk the preperitoneal fat leaving the peritoneum and fascia in direct contact. In this situation, however, the placement of transfascial sutures is critical to provide adequate tissue fixation as tacks may not penetrate into the fascia.

CONCLUSION

These findings support our hypothesis that the bulk of tissue ingrowth happens quickly during the first 2 weeks after implantation. This also demonstrates a continuous increase in tissue ingrowth and strength for the composite mesh during the entire 12-week period, whereas the pure ePTFE mesh peaked and stayed relatively constant after week 2. The composite graft, for each time point, has statistically higher maximum force than the ePTFE graft per equivalent time period.

This may have clinical implications for human ventral hernia repair. Because 74% of overall lap-shear strength was reached by 2 weeks postoperatively, we question the necessity of transfascial sutures, in addition to tacks, in laparoscopic incisional hernia repair. If the mesh is well placed, with wide overlap beyond the margins of the hernia defect, there is minimal tension on the repair, and polypropylene or polyester material is used, tacks may be all that are required for adequate fixation. This change in technique results in shorter operative time and decreased postoperative pain for the patient. Additionally, rapid tissue ingrowth with the composite mesh, with almost three quarters of the ultimate strength attained by 2 weeks, suggests patients may be able to return to normal activity sooner than the commonly recommended 4 weeks to 6 weeks postoperatively. This assumption, however, needs to be validated in an independent clinical evaluation.

We acknowledge our relatively small sample size and believe that further study is warranted to discover the optimal prosthetic device and attachment method to achieve the strongest, least painful laparoscopic incisional hernia repair.

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