Experimental study of the characteristics of a novel mesh suture

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Background: The failure of sutures to maintain tissue in apposition is well characterized in hernia repairs. A mesh suture designed to facilitate tissue integration into and around the filaments may improve tissue hold and decrease suture pull-through.

Methods: In vitro, the sutures were compared for resistance to pull-through in ballistics gel. In vivo, closure of midline laparotomy incisions was done with both sutures in 11 female pigs. Tissue segments were subsequently subjected to mechanical and histological testing.

Results: The mesh suture had tensile characteristics nearly identical to those of 0-polypropylene suture. Mesh suture demonstrated greater resistance to pull-through than standard suture (mean(s.d.) 4·27(0·42) *versus* 2·23(0·48) N; P < 0.001) *in vitro*. In pigs, the ultimate tensile strength for repaired linea alba at 8 days was higher with mesh suture (320(57) *versus* 160(56) N; P < 0.001), as was the work to failure (24·6(14·2) *versus* 7·3(3·7) J; P < 0.001) and elasticity (128(9) *versus* 72(7) N/cm; P < 0.001) in comparison with 0-polypropylene suture. Histological examination at 8 and 90 days showed complete tissue integration of the mesh suture.

Conclusion: The novel mesh suture structure increased the strength of early wound healing in an experimental model.

Surgical relevance

Traditional sutures have the significant drawback of cutting and pulling through tissues in high-tension closures. A new mesh suture design with a flexible macroporous outer wall and a hollow core allows the tissues to grow into the suture, improving early wound strength and decreasing suture pull-through. This technology may dramatically increase the reliability of high-tension closures, thereby preventing incisional hernia after laparotomy. As suture pull-through is a problem relevant to all surgical disciplines, numerous additional indications are envisioned with mesh suture formulations of different physical properties and materials.

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Introduction

Sutures can fail in maintaining the apposition of divided tissues. Acute failure, as in catastrophic evisceration after a laparotomy, results from tearing of sutures through intact tissue¹⁻³. Subacute failure of laparotomy suture lines was demonstrated by Pollock and colleagues^{4,5}, and later confirmed by Burger and co-workers⁶. Early separation of metal clips placed on either side of a laparotomy closure can be seen radiographically within the first month after

surgery in patients who will later develop an incisional hernia. The Pollock hypothesis that early clip separation is associated with a 'gap [that] forms between the edges of the aponeurosis' was confirmed recently in an experimental study⁷.

Chronic failure is represented by hernia formation late after laparotomy⁸ and occurs when scar contained within the suture loop remodels and thins over time owing to the persistent tension on the sutures⁹. Cheese-wiring, the development of linear gashes in the abdominal wall, is the result of chronic suture migration through tissues.

The 3000-year-old design of the suture¹⁰ may be the limiting factor in achieving a reliable high-tension closure, as studies in cellular wound healing, suture material and suturing technique have all failed to strengthen newly sutured tissue^{11–13}. Fine thin sutures that permit atraumatic sewing present a sharp leading edge that concentrates forces at the suture–tissue interface and can act over time to cut the approximated tissues. The greater the force, such as in laparotomy closure, the greater the potential for tissue damage.

The present study investigated a novel suture designed to improve tissue hold in high-tension repairs. A cylindrical suture with an outer open mesh architecture whose braided filaments enclose an inner hollow core might permit tissue ingrowth around the filaments and thereby increase the ultimate tensile strength (UTS) of wound closure. This paper reports the laboratory characterization of a mesh suture designed for human use, in comparison with standard suture, in a clinically relevant experimental laparotomy model.

Methods

The University Council on Animal Care and Use (UCACS) and the Animal Research Ethics Board of the University of Saskatchewan reviewed and approved the project. The UCACS is a member of the Canadian Council on Animal Care and adheres to their guidelines.

Suture design

A hollow mesh suture with a macroporous outer wall was manufactured with a breaking strength equal to that of a conventional 0-polypropylene suture (Covidien, Mansfield Massachusetts, USA). After several prototypes, a cylindrical suture 1.7 mm in diameter was braided with a combination of 12 polypropylene filaments each 0.15 mm in diameter (Fig. 1). Four of the 12 filaments are aligned along the cylindrical axis in order for the suture to maintain its outer structure and avoid elongation, as shown in many textile meshes under load¹⁴. Eight additional filaments are gently braided to create the mesh pattern (Fig. 2). The filaments are bonded to one another to achieve a hollow cylindrical shape in the absence of tension. When subjected to the forces required to oppose and suture tissue, the mesh cylinder collapses perpendicular to the cylindrical axis to a flat ribbon shape (Fig. 3).

Using the standard formula of the surface area of a cylinder, the surface area of a 1-cm length of 0-polypropylene

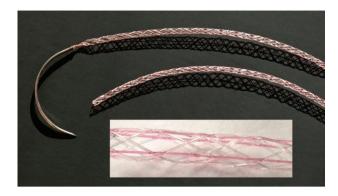


Fig. 1 Mesh suture with outer structure transilluminated. The inset shows a close-up of the mesh suture design

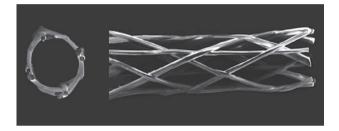


Fig. 2 Scanning electron microscopy of mesh suture end on (left) and in profile (right). Four linear filaments extend along the length of the suture and are wrapped by eight additional filaments to achieve a cylindrical mesh

is 11.0 mm^2 (0.35 mm × $3.14 \times 10 \text{ mm}$). In comparison, the surface area of a 1-cm length of mesh suture is 56.5 mm^2 (0.15 mm × $3.14 \times 12 \times 10 \text{ mm}$). Using the formula for the surface area of circles, the cross-sectional areas of the two sutures are 0.096 mm^2 ($3.14 \times (0.175 \text{ mm})^2$) for 0-polypropylene and 0.212 mm^2 ($12 \times 3.14 \times (0.075 \text{ mm})^2$) for mesh suture.

In vitro mechanical properties of the sutures

Tensometry

To determine the maximum load to failure for the mesh suture and 0-polypropylene, 3-cm segments of each suture type were extended using an Instron Tensometer (model 5542; Instron Corporation, Canton, Massachusetts, USA) equipped with a 50-N static load cell set at a crosshead speed of 10 mm/min.

Suture pull-through

Ballistics gel was prepared by dissolving 160 ml gelatine (Knox Unflavored Gelatine; Kraft Foods, Northfield, Illinois, USA) in 700 ml boiling water, and pouring the mixture into a 340×195 -mm mould. The resulting gel,



Fig. 3 0-Polypropylene and mesh suture below encircling an object, with representative knots. The mesh suture assumes a ribbon shape owing to lateral contact

used as a uniform soft tissue surrogate¹⁵, was 9.35 mm thick and cut into 60×80 -mm rectangles. A GS-25 swage needle attached to either mesh suture or 0-polypropylene pierced the gel 1 cm from the edge for atraumatic placement of the suture. Five suture pull-through tests for each suture type were performed at a pull-through rate of 500 mm/min (to mimic an abrupt force) using the Instron Tensometer.

Experimental model and *in vivo* mechanical properties of the repaired linea alba

Laparotomy was performed on 11 randomly selected commercially available pigs 130–150 days old weighing 81·8–99·8 (mean 93·0) kg. The pig stock was supplied by PIC Canada (Winnipeg, Manitoba, Canada). The pigs were allowed to drink water but not eat for 12 h before surgery. Some 30 min before induction, the pigs received an intramuscular injection of 2 mg/kg xylazine (Bayer, Toronto, Ontario, Canada), 2 mg/kg obutorphanol (Wyeth, Guelph, Ontario, Canada) and 0·04 mg/kg atropine (Rafter, Calgary, Alberta, Canada). An intravenous infusion was begun through an ear vein to deliver 6·3 mg/kg ketamine (Wyeth). The pigs were intubated and kept under general anaesthesia with isoflurane (Pharmaceutical Partners of Canada, Richmond Hill, Ontario, Canada). At the end of surgery, the animals each received 15 000 units penicillin G (Merck, Kirkland, Quebec, Canada) and $2 \cdot 2 \text{ mg/kg}$ flunixine (Merck) for analgesia. The incision was treated with Blu-Kote[®] topical spray (Naylor, Morris, New York, USA) immediately after surgery and for the following 2 days upon wound inspection.

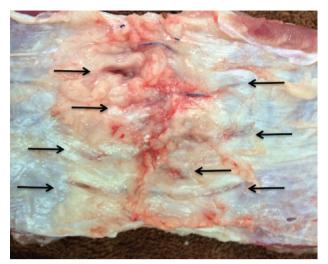
After the procedure, the animals were allowed to move and drink as desired. They received two additional intramuscular injections of penicillin within the first 24 h after surgery, but none thereafter. All animals were monitored twice a day, once in the morning and again in the afternoon. At the time of death, the pigs were sedated with an intramuscular injection of 2 mg/kg xylazine, and then killed by injection of 5000 mg pentobarbital (EuthansolTM; Schering-Plough, Kirkland, Quebec, Canada).

Laparotomy and closure

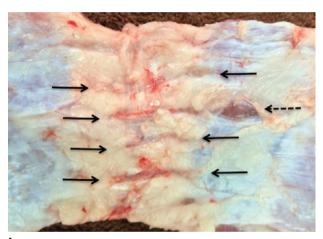
A 32-cm incision was made sharply from the xiphoid to approximately 10 cm below the umbilicus, and the subcutaneous fat was divided with standard cautery. The subcutaneous fat was cleared for 1 cm on either side of the midline and the linea alba was incised by cautery. Preperitoneal fat was left intact, and any small defects that arose (especially around the umbilicus) were repaired with a 2/0 absorbable suture. Using a standard surgical marking pen, 1-cm marks were made to guide the laparotomy closure. Abdominal wall 8-cm segments were closed with either mesh suture or 0-polypropylene in running fashion. Bites were taken 1 cm from the cut edge at 1-cm intervals. A GS-25 swage needle was used with the 0-polypropylene suture, whereas the larger mesh suture was placed using a half-circle reverse cutting French eve needle (size 2091-3; Richard-Allan, Richland, Michigan, USA). The cranial segment of the first animal was chosen randomly to start with 0-polypropylene, and each subsequent section alternated between the two suture types. The subcutaneous tissue and skin were closed with 2/0 absorbable running suture.

Laparotomy segment analysis for visual appearance, tensile strength and histology

Eight days after implantation the abdominal walls of ten pigs were harvested, with the preperitoneal and subcutaneous fat excised carefully to avoid injury to the linea alba and its suture closure. Photographs of the linea alba were taken, looking for evidence of suture pull-through. Sections of abdominal wall 6 cm wide were created, excising the knots and associated soft tissue for each of the segments for each animal. The fresh segments were placed on a customized tensometer equipped with force and position gauges (SignalExpress 2012; 1288



a 0-Polypropylene



b Mesh suture

Fig. 4 a Three-month pig laparotomy segment closed previously with running 0-polypropylene demonstrating evidence of cheese-wiring/suture pull-through (arrows); **b** 3-month pig laparotomy segment closed previously with running mesh suture demonstrating less evidence of tissue damage and cheese-wiring (dashed arrow indicates a fascial defect created during specimen preparation)

National Instruments, Austin, Texas, USA) and connected to a laptop computer. The muscle was clamped to the tensometer with specialized textured and spiked bars to limit tissue slippage. The tensometer clamps were spaced so that only the central 2.5 cm of tissue containing the sutured linea alba would be distracted. The muscle segments were extended until well past failure. The final animal was killed at 3 months, but did not yield usable distraction data. Tissue was used for histological analysis.

Table 1 Mechanical testing results

| | 0-Poly propylene | Mesh suture | P† |
|---|---------------------|----------------|---------|
| UTS of sutured linea alba (N) | 160(56) | 320(57) | < 0.001 |
| Work to UTS of sutured linea alba (J) | 7.3(3.7) | 24·6(14·2) | < 0.001 |
| Spring constant <i>k</i> (elasticity) (N/cm)* | 72(7) | 128(9) | < 0.001 |

Values are mean (s.d.). *Slope of force–elongation curve. UTS, ultimate tensile strength. $\dagger t$ test.

Definitions of mechanical properties

Failure was defined as the onset of muscle tearing. The UTS was defined as the highest force registered by the tensometer. Elongation was defined as the distance that the tissue was stretched from the point where force rose above its baseline measurement until the UTS. Work to UTS was computed as the product of force and elongation. Elasticity is defined as the force required to extend a material a unit distance. Analogous to the force constant k of a spring, the elasticity for specimens was obtained from the slope of the linear portion of the force–elongation curves (Igor Pro; Wavemetrics, Oswego, Oregon, USA).

Histology of tissue reaction to mesh suture

Transverse incisions 4 cm in length and separate from the midline incision were made over the left semilunar line in selected animals for placement of untied mesh suture within the substance of the external oblique muscle. These sutures and surrounding soft tissue were harvested at day 8 and day 90 for Masson's trichrome and picrosirius red staining for collagen.

Statistical analysis

Data are reported as mean(s.d.), unless specified otherwise. Statistical significance was defined as P < 0.050. A *t* test was used for comparison of the mechanical properties of mesh suture and 0-polypropylene.

Results

Tensometry

The force required to break the suture was similar for the mesh and 0-polypropylene sutures (38.7(3.6) *versus* 38.9(3.5) N respectively; P = 0.937, n = 6). The elasticity of the sutures was 17.0(0.8) MPa for mesh suture and 9.8(0.6) MPa for 0-polypropylene (P < 0.001).

Suture pull-through

The force required to pull through ballistics gel was higher with the mesh suture than with 0-polypropylene suture (4.27(0.42) versus 2.23(0.48) N; P < 0.001).

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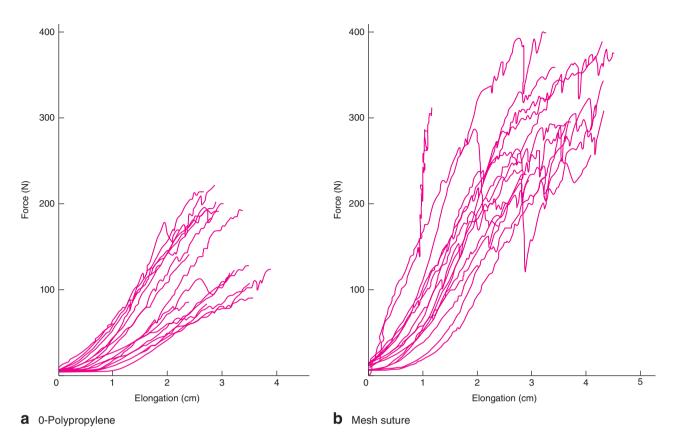


Fig. 5 Force-elongation curves for a 0-polypropylene and b mesh suture

Mechanical testing of laparotomy closure

All of the pigs survived without skin dehiscence or other wound problems, except for three small seromas seen in the 8-day specimens. All of the linea alba repairs were intact at the time of harvest, although 0-polypropylene suture was associated with longer transverse cheese-wire cuts at the suture entry points than those caused by mesh suture (*Fig. 4*).

UTS, work to UTS, and elasticity for mesh suture and conventional suture are shown in *Table 1*. The force– elongation curves for mesh suture were steeper and longer (*Fig. 5*), pointing to resistance to tearing and greater elasticity for the mesh suture tissue segments. Qualitatively, in five of the 16 mesh suture segments the UTS was the force at which the muscle lateral to the repaired linea alba tore at the tensometer clamp and not at the suture line. In comparison, all 18 of the 0-polypropylene closures failed at the suture line. The 0-polypropylene sutures were seen to unravel with the onset of failure, whereas the mesh sutures maintained their grasp on tissue even after the point of UTS.

Histology

Qualitative analysis of the mesh suture samples demonstrated complete tissue ingrowth, with all spaces between the filaments and in the central hollow core occupied by fibroblasts, collagen and capillaries (American Society for Testing and Materials level 3)¹⁶ by 8 days. Collagen was shown to be well organized in the central hollow and surrounding the filaments by day 90 (*Fig. S1*, supporting information). Collagen, stained blue with Masson's trichrome stain, was well contrasted with the muscle, stained red. Picrosirius red staining with polarized light demonstrated some collagen staining around the suture as early as day 8, and abundant collagen staining within the suture by 90 days (*Fig. S2*, supporting information).

Discussion

This study analysed *in vivo* and *in vitro* characteristics of a novel mesh suture. Although composed of the same material as standard sutures, and breaking at a similar strain, the mesh suture required a doubling of force to pull it through ballistics gel and to disrupt a newly sutured midline abdominal closure. The mesh suture was also incorporated into the surrounding tissue by 8 days after implantation.

The differences in early characteristics between the sutures are likely to be related to the novel outer design of the mesh suture, which increases the suture size, surface area and incorporation. The increased diameter and surface area of the mesh suture doubled the force required to pull it through ballistics gel. This is consistent with the effect of different sizes of solid sutures in an experimental abdominal wall burst model demonstrated by Rodeheaver and colleagues². The increased mesh suture surface area by definition increases the size of the suture–tissue interface and lowers the forces there (as shown by finite element analysis)¹⁷, potentially reducing tearing. Increases in the total surface area of scar enveloping the filaments may explain the doubling of early laparotomy strength in the present model.

Force data were analysed both for the peak force produced by the testing system and for the slope of the force-elongation curves along their initial linear lengths. This permitted the modelling of the distraction system as a straightforward Hooke spring rather than a more complex viscoelastic system. This type of analysis has been performed in human and animal tendon studies^{18,19}. The slopes of the force-elongation curve for a spring represent its tendency to return to its original length; laparotomy segments repaired with the mesh suture demonstrated a 78 per cent increase. The increased scar tissue around the filaments and within the hollow suture core created a thicker spring more resistant to stretch. Correlation between UTS and elasticity is consistent with a recent meta-analysis²⁰ of tendons. In addition to increased elasticity, the mesh suture tissue segments on average stretched further before failure (3.6(0.3) versus 3.0(0.1) cm; P = 0.027). These properties explain why the work to UTS of mesh suture segments was triple that of 0-polypropylene. Although counterintuitive to those with a working knowledge of meshes, the elasticity of the mesh suture itself was indeed higher than that of 0-polypropylene. This is due to the greater amount of polypropylene material in mesh suture, as shown by the calculation of a greater total cross-sectional area and the four longitudinal fibres that exist to prevent roping.

The experimental model is unique in many aspects. Human-sized pigs were chosen to mimic better the forces found in clinical surgery. Preliminary *in vitro* testing of suture pull-through in porcine abdominal wall using an Instron tensometer demonstrated difficulties in clamping the specimen adequately while still generating enough force to rupture a 6-cm suture line. Therefore, a custom-designed portable tensometer was created specifically for these distractions. It was decided that the benefits of immediate distraction of fresh tissue in the operating room would outweigh the benefits of using a formal tensometer in a remote facility. An 8-day testing interval was chosen so that the suture line would still be weaker than the tissue held in the tensometer clamps. Despite the early time point, when the midline tissue was still relatively fragile, five of the mesh suture samples tore at the clamps rather than at the suture line.

The experimental model required surgical expertise and precision to minimize variation. Suture placement was guided by measurements and markings. It was crucial to remove the overlying subcutaneous fat and underlying preperitoneal fat without injuring the sutured linea alba, so that the measurements would accurately reflect the breaking force of the repaired linea alba alone. Despite this attention to detail, six tissue segments were not included in the data analysis for technical reasons. In the standard suture group, one abdominal wall specimen was cut too narrowly to permit placement in the tensometer, whereas the other specimen was noted to have been closed with both mesh suture and 0-polypropylene in the same section. For mesh suture, four specimens did not undergo testing. In three of these discarded specimens, the mesh suture was inadvertently cut while dissecting off the overlying subcutaneous tissue, thereby weakening the closure. The clear/red colours of the mesh suture made specimen preparation more difficult, whereas the purple 0-polypropylene stood out against the tissues. For the fourth discarded specimen, both mesh suture and 0-polypropylene were present on tissue segment preparation.

There remain potential criticisms of this study. Rather than test the complex multidirectional forces on the abdominal wall, the tensometer obtained data from a single directional pull. Second, this was not a stressed wound healing model. The pigs were young and growing, there was no inflammation in the wounds, and the closures performed were of laparotomies rather than hernias where forces on the sutures are greater. Third, the suture bites of 10mm from the cut edge were larger than is commonly accepted now for the optimal closure of laparotomy incisions²¹. This was done intentionally to highlight differences between the sutures. It is expected that mesh suture will show optimal outcomes when a suture four times the length of the laparotomy closure is used and with small bites. Fourth, the sutures do not have identical handling characteristics. The needles for mesh suture were larger than those used for 0-polypropylene. However, a mesh suture can assume a narrow profile while in tissue; it glides through tissues surprisingly well, and handles like a standard braided suture.

The major criticism of this experimental model is the use of a single early time point for testing. Pollock *et al.*^{4,5} and Burger and colleagues⁶ showed that early stretching of a repaired laparotomy incision in humans within 1 month is a predictor of future hernia formation. Visually at 3 months the mesh suture had less associated tearing and local tissue trauma than did 0-polypropylene, but there was only a single animal at this time point. Strength testing at later time points in these young animals is not feasible, as the suture line is stronger than the abdominal wall held in the tensometer grips.

Another concern about mesh suture is whether the increased amount of foreign material could lead to unexpected local wound complications. The physical size of knots is a primary determinant of biocompatibility. Despite the large outer diameter of mesh suture, the knots have an acceptable size because the filaments collapse towards the hollow centre on tying. The filament deformation then prevents the knots from unravelling. Braided sutures tie and handle better than monofilaments, and this mesh suture can be thought of as an expanded braid. A theoretical argument against the concern over possible infections is that well incorporated foreign bodies resist becoming infected²². Sheets of polypropylene mesh are much larger in size than mesh suture and are implanted routinely in clinical surgery²³, and even used selectively in contaminated wounds²⁴. Finally, although this particular suture is made of polypropylene, there is no reason why bioabsorbable mesh sutures could not be fabricated, obviating the issue of long-term foreign body reactions.

The implications of stronger wound closure are significant. In 2009 in the USA, 181 000 patients had an incisional hernia repair with a mean total hospital charge of US $$54\,000$ (€49713; exchange rate 26 April 2015) per procedure²⁵. Although the cost of a mesh suture is likely to be higher than that of a standard suture, the mesh suture might become economically attractive if the number of incisional hernias could be reduced.

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Supporting information

Additional supporting information may be found in the online version of this article:

Fig. S1 Masson's trichrome-stained sections showing the histology of mesh suture in cross-section within muscle at 8 and 90 days (Word document)

Fig. S2 Picrosirius red staining of mesh suture seen in cross-section within muscle at 90 days (Word document)