NovafilTM A Dynamic Suture for Wound Closure

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Abdominal wound dehiscence was quantitatively studied in a rat model. Polybutester suture is a new monofilament nonabsorbable suture that has unique stress-strain properties that are potentially beneficial for abdominal wound closure. The abdominal volume at the moment of wound dehiscence was correlated with the extensibility of the suture material used for closure. Interrupted sutures of polybutester cut through the tissues at a mean abdominal volume of 212 ± 3 ml. This volume was significantly $(p \le 0.005)$ greater than the mean volumes reached with nylon $(197 \pm 3 \text{ ml})$ or polyglycolic acid $(187 \pm 4 \text{ ml})$. Closure of abdomens with continuous polybutester suture resulted in a mean rupture volume of 218 \pm 3 ml, which was significantly (p \leq 0.005) greater than that achieved with the same suture employed as simple interrupted sutures (212 \pm 4 ml). The influence of width of tissue bite, suture size, and needle configuration was also evaluated.

POLYBUTESTER (PBE) suture is a new nonabsorbable monofilament suture that has stress-strain properties that differ markedly from those of other synthetic sutures.¹ Most sutures exhibit limited elongation when exposed to increasing loads. Once their yield point is reached, they rapidly elongate until rupture occurs. In contrast, PBE sutures display a high degree of elastic stretch under low loads. After this early stretch, further elongation is limited until breakage occurs at load levels comparable to that of other sutures. This controlled stretch at low loads may offer distinct clinical advantages over that of other nonabsorbable monofilament sutures.

One clinical situation where a more dynamic suture may prove beneficial is wound closure following abdominal surgery. Wound dehiscence in vertical abdominal incisions continues to be a problem, with a reported inciFrom the Department of Plastic Surgery, University of Virginia School of Medicine, Charlottesville, Virginia

dence of 1-3%.² In almost every patient, wound dehiscence occurs when unexpected stress is placed on the wound edges, causing the sutures to cut through the tissue. The triad of abdominal distention, coughing, and vomiting appear to be the most significant causative factors of this increased abdominal pressure that leads to wound dehiscence.²

In 1968, Hoerr³ speculated that a more elastic suture might alleviate the problem of sutures cutting through the tissue. A truly elastic suture would expand as the wound tissue swelled and thus diminish the stress on the suture loop encompassing the tissue. Since an elastic suture was not available, he developed a wound closure technique in which only alternate sutures were tied. Three or 4 days after closure when the sutures began to cut into the swollen tissue, a new closure was accomplished by tying the untied alternate sutures and removing the originally tied sutures. This technique may prevent tissue cut-through, but it is tedious, time consuming, and not adjustable when the swelling subsides.

PBE sutures may possess sufficient elasticity to prove beneficial under these circumstances. It was the primary purpose of this study to evaluate the potential benefits of polybutester suture in abdominal wound closure. It was postulated that, following abdominal closure with PBE sutures, the "dynamic" properties of the suture would allow for greater abdominal expansion, less stress on the sutures, and less potential for suture cut-through and thus provide a greater margin of safety against wound dehiscence. The role of various techniques of abdominal closure on wound security was also quantitatively evaluated.

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Materials and Methods

Suture Materials

All suture materials were obtained from Davis & Geck (Danbury, CT). Three suture materials were selected for testing. The sutures were selected on the basis of their clinical applicability and on their degree of extensibility. The sutures selected were:

NovafilTM (monofilament polybutester). DermalonTM (monofilament nylon). Dexon "S"TM (braided polyglycolic acid).

Except for two studies, all experiments involved size 5/0 sutures swaged to PRE-2 reverse cutting needles. In one study, various size sutures were evaluated for their wound holding capacity. In another study, the wound holding capacity of abdominal incisions closed with sutures swaged to tapered needles was compared to that of incisions closed with sutures swaged to reverse cutting needles.

Stress-Strain Properties of Suture Loops In Vitro

The elongation of standard loops of each suture material under increasing load was determined using an Instron Universal Testing Instrument, Model 1122 (Instron Corp., Canton, MA). Loops were tied around two pins separated by a distance of 20 mm. This loop corresponded to the *in vivo* situation where a suture entered and exited a wound 10 mm from each wound edge. Each loop was secured with a four-throw square knot (1 = 1 = 1 = 1). Each loop, mounted on hooks placed in the jaws of the Instron tensometer, was elongated at a constant rate of 10 mm/min until the knot broke. The load experienced by the loop during extension was continuously plotted on a calibrated recorder.

Animal Model of Abdominal Rupture

The technique for measuring the abdominal wound bursting strength was patterned after those previously reported.^{4,5} Female Sprague–Dawley rats were fasted for 12 hours prior to surgery. After weight determinations were made, animals, within a 5 g weight variance (270–275 g), were assigned to specific treatment groups. The animals were then killed with a lethal intraperitoneal injection of sodium pentobarbital (215 mg/kg) and secured to an operating table in a supine position. A mid-line abdominal incision was made through the skin and panniculus carnosus down to the abdominal wall. This incision extended from the xyphoid to the pubis. At the caudad and cephalad ends of the mid-line incision, lateral incisions were deepened through the skin and panniculus carnosus, and the skin was reflected off the abdominal wall, permitting visualization of the underlying musculoaponeurotic tissue. A template and indelible ink were used to mark on the abdominal wall the location of the standard mid-line incision, as well as the suture entrance and exit wounds. A 6.6 cm incision was made in the linea alba, equidistant between the xyphoid and pubis. The incision was made through all musculoaponeurotic layers including the peritoneum.

A stab wound was then made in the apex of the vagina through which a polyvinylchloride cannula (2.8 mm O.D. \times 1.3 mm I.D.) was passed into the peritoneal cavity. A latex balloon was then fixed to the cannula and positioned symmetrically over the abdominal viscera just beneath the diaphram. The mid-line incision was then approximated over the undistended balloon using sutures that were introduced into the previously identified suture entrance and exit sites. The sutures were passed through all musculoaponeurotic layers, including the peritoneum, in a single layer (mass closure). The sutures were tied with a four throw square knot (1 = 1 = 1 = 1) when the cut edges of the linea alba were just approximated. Thus, the formed suture loop applied the least possible tension to the tissue within the suture loop. The ears of the knot were cut to be 3 mm long. The distance between the terminal suture loops and the ends of the incision was 3 mm. Ten suture loops spaced 6 mm apart approximated the 6.6 cm incision. Unless otherwise specified, the sutures were size 5/0 swaged to PRE-2 (13 mm) reverse cutting needles.

Abdominal pressure was steadily increased by filling the balloon with water at a fixed rate. The water was supplied from a pressurized reservoir through a metering valve that maintained the flow rate at 0.5 ml/sec, regardless of the pressure generated in the balloon. The pressure in the balloon was monitored by a Gould pressure transducer (Gould, Inc., Oxnard, CA), which was connected to a calibrated strip-chart recorder. The volume expansion in the balloon was documented by three separate procedures: the chart recorder speed was 1 mm/sec with 1 mm = 0.5ml of water; the animal was positioned on a top loading scale, and the increase in weight was monitored continuously; and the total volume in the balloon at the conclusion of the experiment was measured. For each animal, the volume and pressure were recorded until wound dehiscence occurred.

Abdominal Wound Closure Techniques

Bite width of interrupted sutures. In different groups of animals, the distance between the wound edge and the place where the suture entered the tissue (bite width) was varied. The bite widths evaluated were: 1.0 mm, 2.5 mm, 5.0 mm, and 10.0 mm. For each bite width, wounds were FIG. 1. The double-loop closure techniques involves closing the abdominal fascia, including the peritoneum, in one layer. As the abdomen expands, the outer loop of the suture expands and constricts the inner loop, which keeps the wound edges together during the periods of abdominal distention.



closed with interrupted loops of each of the three suture materials.

Suture size. Using only PBE sutures, interrupted suture loops were used for closure of the mid-line incision in which the distance between either the entrance or exit suture sites and the divided edges of the linea alba was 5.0 mm. In different experimental groups, the diameter of the suture for each mid-line closure was either 3/0, 4/0, 5/0, or 6/0.

Needle type. Using PBE sutures in size 5/0, interrupted suture loops were used for wound closure in which the distance between either the entrance or exit suture sites and the cut edge of the linea alba was 5.0 mm. In one experimental group of animals, the suture was swaged to a tapered needle (TE 1, 12 mm), while a reversed cutting needle (PRE-2, 13 mm) swaged to the same suture was employed in another group.

Continuous suture closure. Using the three different suture materials, a continuous unlocked suture was employed separately for wound closure with the knots being constructed at the proximal and distal ends of the incision. The distance between either the entrance or exit suture sites and the cut edges of the linea alba was 5.0 mm with the spacing between sutures (6 mm) being identical to that used for interrupted suture loops.

Interrupted double loop mass closure technique. With the double-loop mass closure technique, the suture entered the fascia 10 mm from the wound edge, passed through all musculoaponeurotic layers, including the peritoneum, then passed under the wound and returned through the entire abdominal wall and exited 10 mm from the contralateral wound edge (Fig. 1). The suture continued by entering the first wound edge again with a bite of 2.5 mm passing again through all the tissue layers, passing under the incision and exiting through the tissue on the contralateral side 2.5 mm from the wound edge. The loop was completed with a knot above the fascia positioned over the incision. Each of the three suture materials was evaluated separately in three experimental groups.

The statistical significance of the data for all experimental groups was determined using the Student's t-test.

Results

Load-Elongation Properties of Suture Loops

The unique low-load elasticity of PBE sutures is demonstrated in the composite load-elongation curves for the three sutures evaluated (Fig. 2). Fifty per cent of the total elongation of PBE suture occurred at loads less than 25% of its breaking strength. At a similar load, nylon suture had only elongated 25% of its total elongation at knot break. The polyglycolic acid (PGA) suture exhibited the least degree of elongation (11%) at this low load. Although PBE suture elongated considerably at low loads, its total elongation at break (10.5 \pm 0.8 mm) was similar to that of nylon (8.3 \pm 0.6 mm). Furthermore, PBE suture exhibited a knot break strength (12.55 \pm 0.65 N) that was comparable to that of nylon (13.65 \pm 0.60 N). In contrast, PGA sutures exhibited a very high knot-break load (19.20 \pm 0.65 N), but the mean total elongation of the PGA



FIG. 2. The unique ability of polybutester to elongate under small loads is demonstrated in these composite load-elongation curves. At 2.00 N polybutester suture has elongated four times more than nylon suture and ten times more than polyglycolic acid suture.

| Suture Technique | Tissue Bite* (mm) | Dehiscence Pressure (mmHg) | | | Dehiscence Volume (ml) | | |
|------------------|----------------------|----------------------------|-------------|----------------------|------------------------|-------------|----------------------|
| | | Polybutester | Nylon | Polyglycolic Acid | Polybutester | Nylon | Polyglycolic Acid |
| Interrupted | 1.0 | 186 ± 7 | 182 ± 3 | 180 ± 7 | 159 ± 2 | 161 ± 1 | 160 ± 4 |
| Interrupted | 2.5 | 220 ± 6 | 218 ± 4 | 216 ± 5 | 178 ± 2† | 170 ± 4 | 166 ± 3 |
| Interrupted | 5.0 | 239 ± 4 | 240 ± 4 | 242 ± 6 | 204 ± 4† | 190 ± 3 | 182 ± 4 |
| Interrupted | 10.0 | 240 ± 7 | 242 ± 7 | 241 ± 3 | $212 \pm 3^{+}$ | 197 ± 3 | 187 ± 4 |
| Continuous | 5.0 | 241 ± 4 | 239 ± 7 | 240 ± 6 | $218 \pm 3^{+}$ | 205 ± 3 | 192 ± 6 |
| Double loop | 2.5/10.0 | 238 ± 3 | 240 ± 9 | 239 ± 3 | $184 \pm 4^{\dagger}$ | 174 ± 4 | 168 ± 4 |

TABLE 1. Abdominal Wound Dehiscence as a Function of Suturing Technique

* Distance between the edge of the linea alba and the entrance or exit point of the suture.

† The abdominal wound dehiscence volumes of mid-line incisions

sutures at knot break (5.5 \pm 0.4 mm) was only 52% of the mean value obtained for PBE sutures at knot break (10.5 \pm 0.8 mm).

Abdominal Wound Closure

The mechanism of wound dehiscence was similar in all experiments. Wound dehiscence occurred when the stress level reached the yield point of the abdominal wall and the sutures either cut through the tissue or the entire abdominal wall ruptured. Knot slippage or breakage was never a cause of wound dehiscence.

The volume and pressure within the balloon at the time of wound dehiscence provided indices of the security of the different abdominal mid-line closure techniques. One mid-line closure technique was judged to be more secure than another if the volume and/or pressure within the balloon was greater than that encountered with another technique. The results of this experimental study dem-



FIG. 3. The relationship of abdominal pressure to abdominal volume is recorded as abdomens closed with different suture materials are continuously expanded with water. The greater abdominal volume afforded by polybutester suture resulted from its greater degree of elasticity compared to nylon suture or polyglycolic acid suture.

closed with polybutester sutures were significantly ($p \le 0.05$) greater than those encountered with abdomens closed with either nylon or polyglycolic acid sutures.

onstrated several important factors that influenced the security of the abdominal wound closure technique.

Suture material. The type of suture material used to close the abdomen had considerable influence on the abdominal volume at the time of wound dehiscence (Table 1). Closure of the mid-line incision with interrupted PBE sutures allowed the abdomen to distend to a significantly larger volume than that encountered with either PGA or nylon sutures with a comparable size suture loop (distance between entrance or exit wounds and divided edges of linea alba ≥ 2.5 mm). The influence of the type of suture material used for interrupted sutures on the pressure and volume within the balloon during expansion is illustrated in Figure 3. There was an early lag phase (0-70 ml) as the fluid filled the existing dead space of the abdomen. After this lag phase, the balloon exerted pressure on the abdominal cavity, causing stretching of the musculoaponeurotic layers. While all suture materials resisted this expansion of the abdominal wall, their unique physical properties had considerable influence on the ultimate volume and pressure within the abdominal cavity before the interrupted sutures cut through the tissues. The more elastic PBE sutures, which elongated under lower loads than the other sutures, subjected the wounds to less pressure at volume ≥ 80 ml of water than that encountered with the other suture materials. While the abdominal wound tissue closed with the three different suture materials dehisced at comparable pressures, the interrupted PBE sutures allowed the abdominal cavity to enlarge before dehiscence an additional 5 to 13%, respectively, as compared to those approximated by either nylon or PGA sutures.

The type of suture material used in the continuous and double loop closure techniques also had considerable impact on wound security as measured by the abdominal dehiscence volumes. For both closure techniques, the wound dehiscence volumes were highest with the PBE suture, followed by the nylon suture and then the PGA sutures. The dehiscence pressure for the different suture materials using either interrupted, continuous, or double loop closure techniques did not differ significantly.

Width of tissue bite. The bite width (the distance between the suture entrance and exit sites and the divided edges of the linea alba) significantly influenced the security of abdominal wounds closed with interrupted sutures, as measured by abdominal wound dehiscence pressures (Table 1). With a 1 mm bite width in the rat abdomen, the suture did not pass through the rectus muscle, and tissue cut-through occurred at a mean pressure of 183 ± 6 mmHg. By increasing the bite width to 2.5 mm, the tissue cut-through pressure was significantly (p < 0.001) increased to a mean of 218 ± 5 mmHg. With a 5.0 mm bite width, the mean tissue holding capacity was again significantly (p < 0.001) increased to 241 ± 4 mmHg. This value of 241 mmHg remained relatively constant for further increases in bite width and different suturing techniques. The pressure at which suture cut-through occurred was not a function of suture material.

Suture size. When abdominal incisions were closed with PBE sutures using interrupted sutures with 5.0 mm tissue bites, the size of the suture influenced wound security. An increase in suture size was associated with greater pressure required to cause the sutures to cut through the tissue (Table 2). The abdominal volume at the time of rupture was inversely related to suture size; the smaller the suture size the greater the abdominal volume at dehiscence.

Needle type. The suture needle configuration did not influence the security of abdominal wound closure as measured by the volume and pressure required for wound dehiscence. The dehiscence pressure $(240 \pm 3 \text{ mmHg})$ and volume $(202 \pm 3 \text{ ml})$ for wounds closed by tapered point needles did not differ significantly from the dehiscence pressure $(239 \pm 3 \text{ mmHg})$ and volume $(204 \pm 3 \text{ ml})$ encountered in wounds approximated by reverse cutting needles swaged to the same type of suture.

Continuous suture closure technique. Closure of the mid-line abdominal incision with an unlocked continuous suture allowed the abdomen to expand to a significantly (p < 0.001) greater volume before rupture than abdomens closed with interrupted sutures of the same material (Table 1). Abdominal incisions closed with PBE sutures expanded to significantly ($p \le 0.05$) greater volumes before rupture than did abdomens closed with either nylon or PGA sutures.

Double loop closure technique. The dynamics of wound dehiscence with the double loop closure technique differed significantly from that encountered with either the interrupted or continuous methods of closure. With the interrupted and continuous techniques, wound dehiscence occurred first by slight separation of the cut edges of the linea alba followed by the sutures cutting through the tissue. The distribution of forces resulting from the double

TABLE 2. Abdominal Dehiscence as a Function of Suture Size

| Suture Size | Dehiscence Pressure (mmHg) | Dehiscence Volume (ml) | | |
|-------------|-------------------------------|---------------------------|--|--|
| 3/0 | 255 ± 4 | 192 ± 3 | | |
| 4/0 | 241 ± 3 | 198 ± 5 | | |
| 5/0 | 239 ± 3 | 204 ± 3 | | |
| 6/0 | 230 ± 11 | 209 ± 5 | | |

loop technique caused the divided edges of the linea alba to come together during abdominal distention by constriction of the inner loops. Abdominal rupture did not occur at the suture sites but in the abdominal wall itself lateral to the suture line. Failure of the abdominal wall occurred at pressures identical to those encountered at the suture line in other experiments (Table 1). The configuration and dynamics of the double loop closure technique provide the least abdominal expansion volume of the closure techniques evaluated. For each suture material, the continuous suture technique provided the greatest abdominal volume before rupture, followed by the interrupted suture technique and then the double loop technique. With each technique, the use of PBE sutures provided significantly greater expansion than did the use of either nylon or PGA sutures.

Discussion

In most dehisced abdominal wounds, sutures are observed to have cut through the musculoaponeurotic layers rather than break.⁶ The resistance of the abdominal tissue against the pulling force of the sutures can be quantitated and is a measure of the security of the sutural closure technique. Several factors have been identified which significantly influence the security of abdominal wounds. One of these factors is the anatomical orientation of the abdominal incision. Using cadaver specimens, Tera and Aberg⁷ noted that the tissue holding capacity of mid-line incisions against suture pull-through was greater than that of either transverse incisions or paramedian incisions. Haxton⁸ corroborated these findings in experimental studies in cadavers demonstrating that wound dehiscence in paramedian incisions occurred at lower intra-abdominal pressures than midline incisions subjected to identical suturing techniques.

The techniques used in sutural closure also play a significant role in wound security. The importance of taking adequate bites of tissue in closing laporotomy incisions is based on both mechanical and anatomical considerations. Using a simple mathematical model, Dudley⁹ demonstrated that the mean force per unit area at the tissuesuture interface was reduced as the radius of the suture loop was increased. On the basis of this theory, we see that there is some argument to favor a single layer closure with a large bite of tissue held by the suture. From an

anatomical perspective, the size of the bite in a mid-line incision must be wide enough to extend beyond the linea alba to encompass both the anterior and posterior rectus sheathes. Tera and Aberg⁷ reported that sutures placed lateral to the transition between linea alba and the rectus sheath were two-fold more resistant to pull-through than a suture passed through only the linea alba. Using a rat model, Sanders et al.¹⁰ confirmed the importance of the size of the suture bite on the wound's ability to resist dehiscence from increased intra-abdominal pressure. The intra-abdominal pressure required to rupture a mid-line incision approximated with 4-0 silk sutures using 5 mm bites of tissue was significantly greater than that needed to disrupt incisions closed by the same caliber suture employing 1-2 mm bites. Our experimental studies likewise revealed that the tissue holding capacity against the pull of a suture was optimal when the tissue bite was ≥ 5 mm. a site that was lateral to the transition between the linea alba and the rectus muscle in the rat abdomen.

Suture diameter was another parameter in wound closure evaluated in our studies. For wider diameter sutures, the wound dehiscence pressure was significantly greater than that for more narrow diameter sutures, indicating that the narrow diameter sutures cut through the tissues more readily than the wider diameter sutures. These results are in agreement with Dudley's⁹ concept of the pressure per unit area of suture in which tissues are most prone to suture cut through by narrow diameter sutures. In Tera and Aberg's⁷ investigation, the caliber of the suture was not an important determinant of the tissue holding capacity for cadaver musculoaponeurotic tissue. The considerable interindividual variation with regard to tissue strength against suture pull and the relatively small sample size may have made it difficult to perform a reliable evaluation of the role of suture caliber in sutural wound security.

The influence of three different suturing techniques on wound security was also evaluated in this quantitative study. When compared to single interrupted sutures or interrupted double loops, the use of a continuous suture provided the greatest wound security as measured by the abdominal wound dehiscence volume. The dynamics of abdominal wound closure have been critically analyzed by Jenkins.¹¹ In measuring the abdominal wound during distention, Jenkins found that the wound may increase in length as much as 30%. Unlike interrupted sutures, only with a continuous suturing technique can the suture adjust to compensate for this lengthening. In order to provide sufficient reserve suture to accommodate wound lengthening, Jenkins found that a ratio of suture length (SL) to wound length (WL) of at least 4:1 was required. When this ratio was employed in the clinical situation, abdominal wound dehiscence was eliminated. Jenkin's clinical experiences were confirmed by the animal experiments of Poole et al.,¹² which demonstrated that closure of midline abdominal wounds with a continuous suture provided significantly greater resistance to wound disruption than closure with interrupted sutures. The results of other clinical studies are consistent with these experimental investigations and indicate that a continuous suture is less time consuming and provides security equal to or greater than that of interrupted sutures.^{13,14}

In wounds closed by either continuous or simple interrupted sutures, extensive abdominal distention caused the wound edges to separate prior to the sutures cutting through the tissue. This separation of wound edges, if it occurs, will interfere with wound healing and thus make the wound more susceptible to dehiscence. Wound edge separation can be eliminated by using a double loop technique. The distribution of forces in the double loop technique are such that as the abdomen distends the outer loop of suture expands and constricts the inner loop, which pulls the wound edges tightly together. Maintenance of approximation of the divided edges of the abdominal wound, even during periods of abdominal distention, should facilitate rapid healing and thus lessen the chances of wound dehiscence. The superiority of the double loop closure technique has been documented clinically¹⁵⁻¹⁸ and experimentally.^{19,20} Although monofilament stainless steel wire was first used for the double loop closure technique,¹⁵ later clinical studies employed nylon,²¹ polypropylene,²² and polyglycolic acid sutures^{23,24} for double loop closure and reported a remarkably low incidence of dehiscence.

When all of these parameters were controlled, it was found that the suture material itself played a very important role in wound security. In the dynamic situation of abdominal expansion, the suture determines how the stress is delivered to the tissue. The greater the ability of the suture to expand with the abdomen, the smaller the amount of stress that is transmitted to the tissue. A definite correlation between suture extensibility and abdominal wound security was demonstrated in this study. Regardless of the closure technique, the greatest abdominal volume prior to wound dehiscence was obtained when PBE sutures were used. This increase in abdominal volume was the result of the unique stress-strain properties of this new suture material. PBE sutures have the ability to elongate 50% of their length at loads of only 25% of their knot break level. In contrast, at similar loads nylon sutures elongate only 25%, and PGA only 11%. This early elongation of PBE suture is elastic so that as the abdominal volume recedes the suture continues to provide wound security. The initial ease of elongation is not a reflection of the suture's total elongation or ultimate strength. The total elongation and ultimate strength of PBE sutures are similar to those of nylon.

These results indicate that abdominal dehiscence can be eliminated when appropriate techniques are employed. Mid-line incisions, wide tissue bites, mass closure, and large sutures are techniques associated with increased wound security. These results also suggest that use of the new PBE sutures provides an extra margin of safety in closure of abdominal wounds.

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