In recent years, a number of knotless, barbed, self-anchoring suture devices have become available as an alternative to closing and securing surgical wounds with knots.\(^1,2\) The purported advantages of knotless barbed sutures over conventional sutures include a reduction in operative time, improved tissue apposition, more even distribution of tension along the length of the wound (resulting in less dehiscence), better wound healing due to reduction of ischemia, and less suture extrusion.\(^1-6\)

Since barbed sutures were first patented in the United States in 1964,\(^7\) a number of papers have been published in the peer-reviewed literature describing the placement of barbed suture devices in cosmetic skin procedures; however, a thorough search of the recent literature failed to find any randomized controlled studies comparing the commercially-available barbed wound closure devices with monofilament sutures for cosmetic skin closure.

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Therefore, we present the results of our prospective, randomized, controlled in vivo study comparing two commercially-available absorbable barbed suture devices with an absorbable monofilament control suture during primary closure of surgical skin wounds. The outcomes evaluated included biomechanical wound strength and standard histological markers of wound healing.

**METHODS**

A total of 18 domestic Yorkshire pigs weighing between 13.0 and 18.6 kg (mean, 15.3 kg) were selected for this study. The Institutional Animal Care and Use Committee of the research facility (Pre-Clinical Research Services, Inc., Ft. Collins, CO) approved the study protocol; the animal welfare, housing, and research procedures for this study were in compliance with the United States Department of Agriculture (USDA) Animal Welfare Act (9 CFR Parts 1, 2, and 3) and the Guide for the Care and Use of Laboratory Animals.8

Two commercially-available barbed suture devices and one monofilament suture were compared in this study: size 4-0 V-Loc 90 (Covidien, North Haven, Connecticut), the size 3-0 Quill Monoderm (Angiotech Pharmaceuticals, Vancouver, British Columbia), and the size 4-0 Biosyn (Covidien) devices, respectively (Table 1). Biosyn is a synthetic absorbable monofilament suture, whereas the V-Loc 90 Device and Quill Monoderm are synthetic absorbable sutures that have helically-oriented barbs cut into the suture strand. The V-Loc 90 Device has unidirectional barbs, a loop end effector for anchoring, and a single swaged needle, whereas the Quill Monoderm has bidirectional bars with two swaged-on needles.

The 18 animals were randomly assigned among three in-life groups (Post-operative Days 3, 10 and 21), with six in each. In total, 192 incisions (48 incisions at each of postoperative Days 0, 3, 10, and 21) were sutured by the same surgeon (JZ). Each animal received all three test devices in a randomized, three-way matched design.

Food was withheld from each animal for 12 hours and water for three hours before surgery. The animals were premedicated with intramuscular injections of tiletamine/zolazepam (8 mg/kg; Telazol, Fort Dodge Animal Health, Ft. Dodge, Iowa) and glycopyrrolate (0.01 mg/kg; Robinul, Baxter Healthcare Corp., Deerfield, Illinois). General anesthesia was induced with an intravenous bolus of fentanyl (13.33 µg/kg; Fentanyl, Baxter Healthcare Corp.) and diazepam (0.26 mg/kg; Valium, Hospira, Inc., Lake Forest, Illinois) or midazolam (0.26 mg/kg; Versed, Baxter Healthcare Corp.). After induction of general anesthesia, the animals were intubated and maintained in a surgical plane of anesthesia with 0.5% to 5% isoflurane (Isoflo, MWI, Meridian, Idaho) in oxygen delivered through a semicircular rebreathing system. Animals were given subcutaneous carprofen (4.16-5.33 mg/kg; Rimadyl, Pfizer, New York) preoperatively; postoperatively, all animals received oral phenylbutazone (6.6 mg/kg; Equi-Phar, Vedco, St. Joseph, Missouri) twice daily for three days.

Following induction of general anesthesia, the animals were positioned in ventral recumbency on a padded heating blanket for surgery. The dorsal thoracolumbar region was clipped and aseptically prepped with 4% chlorhexidine (ChlorHex 4%; Vedco, St. Joseph, MO). A template was applied for dissecting four sublumbar 4.0-cm-long marks along either side of dorsal midline with a sterile marking pen, for a total of eight incision sites. The incision sites were positioned as shown in Figure 1, such that the

<table>
<thead>
<tr>
<th>Suture</th>
<th>Polymer Composition</th>
<th>Diameter, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-0 Biosyn</td>
<td>PGA-PTMC-PDO (60%-26%-14%)</td>
<td>0.21 ± 0.0009</td>
</tr>
<tr>
<td>4-0 V-Loc 90 device</td>
<td>PGA-PTMC-PDO (60%-26%-14%)</td>
<td>0.28 ± 0.001</td>
</tr>
<tr>
<td>3-0 Quill Monoderm</td>
<td>PGA-PCL (75%-25%)</td>
<td>0.29 ± 0.001</td>
</tr>
</tbody>
</table>

Abbreviations: PCL, polycaprolactone; PDO, polydioxanone; PGA, polyglycolic acid; PTMC, polytrimethylene carbonate.
incisions were 4 cm lateral to the dorsal midline and oriented transversely to the sagittal plane.

Each full-thickness dermal incision was made with a new number 10 scalpel and hemostasis was achieved with electrocautery. Each skin incision was closed with one of the randomly-assigned sutures in a continuous intradermal pattern. The two barbed suture devices were placed as per their respective instructions without tying knots to secure the suture line, whereas incisions closed with Biosyn (Covidien) were secured with three square knots at the beginning and termination of each suture line. Each incision was sutured for a linear distance of 3.0 cm, leaving 5 mm of unsutured skin at either end of the incision. All incisions were closed with the same number of bites. Simple interrupted sutures (USP size 3-0 SurgiPro II; Covidien) were placed at the beginning and termination of the sutured portion of each incision, so that the margins were readily ascertainable at the time of harvest for mechanical testing. The incisions were not covered or bandaged at the completion of surgery. Animals were returned to their individual pens only after they could stand and ambulate without assistance.

The incisions were assessed daily for erythema, edema, drainage, and dehiscence. Dehiscence was defined as full-thickness separation of the skin wound. Wherever possible, the underlying cause of dehiscence was recorded as being attributable to suture breakage, barb slippage, or tissue failure (suture knife through the dermis without breaking).

At the designated termination points, all animals were reanesthetized, and four additional skin incisions were made and closed primarily to provide baseline T0 samples for biomechanical testing. At the completion of the T0 incisions, the animals were euthanatized with an intravenous bolus of pentobarbital (Euthasol; Vibrac AH, Inc., Ft. Worth, Texas).

Immediately following euthanasia, the skin incisions were excised for ex vivo biomechanical testing. The interrupted marking sutures were removed and care was taken to leave 2 to 3 mm of unsutured skin at either end of the sutured incision, so that no intact skin was present in the excised test samples. The tissue samples were secured in a calibrated material testing machine (Zwick-Roell BDO-FB0.5TS; Zwick GmbH & Co., Ulm, Germany) with flat grips at 85 psi. Load was applied perpendicularly to the incision with a constant distraction rate of 40 mm per minute. Failure mode (suture breakage, barb slippage, anchor failure, or tissue failure) and maximum load (kgf) at failure were recorded for each sample.

The biomechanical data were tested for normality with the Anderson-Darling normality test. A one-way analysis of variance (ANOVA) with Tukey’s post hoc test was performed to find significant differences ($p < .05$) for maximum load to failure between the three test devices at each time point. Failure mode between the two barbed suture devices was compared with Fisher’s exact test, with significance at $p < .05$.

One incision for each test device was randomly allocated for histological analysis for each end point. The tissues were harvested and fixed in 10% buffered formalin solution. The fixed samples were embedded in methyl methacrylate, sectioned at 20 microns, and stained with Geimsa stain. Three sections for each incision were examined by a veterinary histopathologist under light microscopy to assess the relative degree of tissue reaction surrounding each suture type. Table 2 lists the histological attributes that were examined to determine an average tissue reaction score for each sample. Differences in the tissue reaction scores were analyzed through an ANOVA test, with significance at $p < .05$.

### RESULTS

All 18 animals survived the duration of the study without major complications. None of the Group I (Day 3) animals had any incisinal morbidity. Two animals in the Group II (Day 10) group experienced one incisinal dehiscence each, both due to Biosyn breakage. One dehiscence occurred as the animal was recovering from general anesthesia and the other incision dehisced on the fourth postoperative day. Both animals were treated with enrofloxacin (5 mg/kg sub-Q; Baytril; Bayer Healthcare, Shawnee Mission, Kansas).

<table>
<thead>
<tr>
<th>Attributes of the Tissue Reaction Score for Histological Analysis</th>
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<tbody>
<tr>
<td>Degree of necrosis $^a$</td>
<td></td>
</tr>
<tr>
<td>Congestion/edema $^b$</td>
<td></td>
</tr>
<tr>
<td>Cellular infiltrate $^c$</td>
<td></td>
</tr>
<tr>
<td>Neutrophils</td>
<td></td>
</tr>
<tr>
<td>Lymphocytes</td>
<td></td>
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<tr>
<td>Plasma cells</td>
<td></td>
</tr>
<tr>
<td>Macrophages</td>
<td></td>
</tr>
<tr>
<td>Eosinophils</td>
<td></td>
</tr>
<tr>
<td>Giant cells $^d$</td>
<td></td>
</tr>
<tr>
<td>Fibrosis $^e$</td>
<td></td>
</tr>
<tr>
<td>Neovascularity $^f$</td>
<td></td>
</tr>
<tr>
<td>Calcification $^g$</td>
<td></td>
</tr>
<tr>
<td>Fatty infiltration $^h$</td>
<td></td>
</tr>
<tr>
<td>Foreign body reaction (present or absent)</td>
<td></td>
</tr>
<tr>
<td>Cellular infiltrate area (μm$^2$)</td>
<td></td>
</tr>
</tbody>
</table>

$^a$0 = entity not present, 1 = entity present to a very mild degree (occasional), 2 = entity present to a mild degree, 3 = entity present to a moderate degree, 4 = entity present to a marked degree.

$^b$Number of cells scored by average of four fields at ×45 objective: 0 = no cells, 1 = 1-5 cells, 2 = 6-15 cells, 3 = 16-25 cells, 4 = >25 cells.

$^c$The cross-sectional distance of cellular infiltration (average of four fields at ×10 magnification).

$^d$Number of cells scored by average of four fields at ×45 objective: 0 = no cells, 1 = 1-5 cells, 2 = 6-15 cells, 3 = 16-25 cells, 4 = >25 cells.
Kansas) once daily for three days, and the incisions healed uneventfully by second intention. A total of 12 incisions (8.3%) in eight animals developed postoperative incisional swelling and erythema. Four of these occurred in Day 10 animals, where two incisions had been closed with Biosyn, one with the V-Loc 90 device, and one with Quill Monoderm. There were eight inflamed incisions in the Group III (Day 21) group: six incisions were closed with Biosyn, two with the V-Loc 90, device and two with Quill Monoderm. All animals were treated with enrofloxacin (5 mg/kg sub-Q Baytril; Bayer Healthcare) once daily for three to five days, with all animals responding well to the antimicrobial therapy. The remaining Day 21 animals were prophylactically treated with enrofloxacin (5 mg/kg sub-Q Baytril; Bayer Healthcare) once daily for three days.

Figure 2 summarizes the ex vivo biomechanical load to failure data for the three test articles at Days 0, 3, 10, and 21. Significant differences in maximum load to failure were observed at Day 0 ($P = .005$) and Day 3 ($P = .003$). Day 0 incisions closed with Biosyn were statistically different from those closed with the V-Loc 90 device but were not significantly different from incisions closed with Quill Monoderm. There was no significant difference in maximum load to failure between wounds closed with the V-Loc 90 Device and Quill Monoderm at Day 0. At Day 3, Biosyn wounds were not statistically different from the V-Loc 90 device wounds, but they were statistically different from incisions closed with Quill Monoderm. Although the V-Loc 90 device was stronger than Quill Monoderm at Day 3 (4.47 vs 3.80 kgf, respectively), this difference was not statistically significant. No statistical difference was observed between the test articles at Day 10 or 21.

Figure 3 shows the failure modes for the three test articles at Days 0, 3, 10, and 21. Half of the incisions closed with Biosyn failed by the suture knifing through the skin, whereas this mode of failure was relatively uncommon for either of the barbed suture devices. Pooling the mode of failures for the barbed suture devices together across all four end points revealed that the primary mode of failure for the V-Loc 90 device was suture breakage (60% of the time vs. 21% for Quill Monoderm), whereas for Quill Monoderm, the primary mode of failure was barb slippage (79% of the time vs. 33% for the V-Loc 90 device). The observed differences between barbed devices for most common mode of failure were highly significant ($P = .000$).

Table 3 shows the average tissue reaction scores for the three test articles at Days 3, 10, and 21. At postoperative Day 3, the skin incisions appeared histologically similar with the incisions being filled with a combination of fibrin and acute inflammatory cells. The cellular response to all three suture devices at Day 3 comprised neutrophils, lymphocytes, and some early macrophages. The cellular response was greatest around Quill Monoderm, with this difference being greater than both Biosyn and the V-Loc 90 device, although this observed difference was not statistically significant ($P = .209$).

Significant differences ($P = .049$) in tissue reaction were evident between the three test articles at Day 10 (Figure 4D-F). The cellular infiltrates consisted of small numbers of neutrophils and large numbers of lymphocytes and macrophages. The greatest inflammatory response was consistently seen around the Biosyn suture, whereas the V-Loc 90 device consistently had the least amount of inflammation. Giant cells were observed around both of the barbed suture devices. Mild fibrosis was observed around both Biosyn and Quill Monoderm, but no fibrosis was evident around the V-Loc 90 device. There was a mild amount of neovascularization seen around all three test articles, with no discernible differences between the three.
The V-Loc 90 device was the least reactive of the three suture devices at Day 10, with the differences between Quill Monoderm being highly significant (\(P = .017\)). Although the V-Loc 90 device had a lower average histopathology rating than Biosyn at Day 10, the difference was not statistically significant (\(P = .169\)), nor was the difference between Biosyn and Quill Monoderm significant (\(P = .617\)).

The greatest overall tissue reactions were seen at Day 21 (Table 3; Figure 4). The cellular infiltrates were similar for all three test articles and consisted of a few neutrophils and large numbers of lymphocytes and macrophages. Giant cells were observed around Biosyn and the V-Loc 90 device but not around Quill Monoderm. There was no discernible difference in the amount of fibrosis or neovascularization between the three devices at Day 21, nor was there a significant difference in the overall tissue reaction scores between the three devices.

**DISCUSSION**

The design of this prospective, randomized, controlled in vivo study was intended to demonstrate noninferiority between the V-Loc 90 device and Quill Monoderm for purposes of regulatory approval in the United States. Results from this study were included in a 510(k) submission for the V-Loc 90 Absorbable Wound Closure Device to the United States Food and Drug Administration.

The process of cutting barbs into a monofilament suture decreases the effective diameter and thereby reduces the straight pull tensile strength by as much as 60%,\(^9\) resulting in suture strength that is equivalent to that of a nonbarbed monofilament suture one size smaller.\(^5,10,11\) The labeling of the V-Loc 90 device takes into account the difference in straight pull tensile strength between barbed and nonbarbed sutures by labeling the device as being one
size smaller than the suture in which the barbs were cut, whereas the manufacturer of Quill Monoderm does not follow this practice. For this reason, the barbed suture devices (which are both created from 3-0 monofilaments; Table 1) were compared to a size 4-0 control in this study.

Differences in the design of the two barbed devices necessitated closing the incisions differently. The V-Loc 90 device, having unidirectional barbs and a single swaged needle, allows the surgeon to suture in a normal fashion, beginning at one end of the incision and progressing to the other end of the incision with a standard forehand suturing technique. The Quill Monoderm device has a bidirectional barb array with swaged needles on either end and requires the surgeon to begin in the middle of the incision and suture in opposite directions. This necessitates half of the incision being sutured with a backhand technique. For accomplished surgeons, this is not a limitation, but for surgeons in training, there will be an associated learning curve. The V-Loc 90 device requires the suture to be anchored at the beginning of the incision through the pre-formed loop, whereas Quill Monoderm, with its bidirectional barbs, is completely self-anchoring.

Table 3. Average Tissue Reaction Scores for Biosyn, V-Loc 90, and Quill Monoderm at Days 3, 10, and 21

<table>
<thead>
<tr>
<th>Test Article</th>
<th>Day 3</th>
<th>Day 10</th>
<th>Day 21</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BioSyn</td>
<td>V-Loc 90</td>
<td>Quill Monoderm</td>
</tr>
<tr>
<td>Average histopathology rating</td>
<td>0.43</td>
<td>0.38</td>
<td>0.49</td>
</tr>
<tr>
<td>p value</td>
<td>.209</td>
<td>.049</td>
<td>.419</td>
</tr>
</tbody>
</table>

<sup>a</sup>V-Loc 90 had a significantly lower average tissue reaction score than Quill Monoderm (<i>P</i> = .017).

<sup>b</sup>Biosyn did not have a significantly different tissue reaction score than either V-Loc 90 or Quill Monoderm at Day 10.

Figure 4. Photomicrographs of Biosyn (A, D, G), V-Loc 90 device (B, E, H), and Quill Monoderm (C, F, I) at Days 3 (A-C), 10 (D-F), and 21 (G-I) (Giemsa stain, ×10 magnification). Focal cellular accumulation (blue arrows) is seen opposite tissue suture gaps (red arrows) for Biosyn at all time points (A, D, G).
The overall dehiscence rate was 1.4%, and all of the dehisced wounds occurred in the control Biosyn incisions. The absence of dehiscence in either of the barbed suture groups versus the 4.2% dehiscence rate within the monofilament group would seem to substantiate prior claims that barbed devices have the potential to engender greater wound security than monofilament sutures by virtue of not relying on knots.4,6 The purported strength of barbed sutures is due to their ability to resist retrograde movement, as a result of the anchoring effect of barbs in the tissue.4,6 In comparison, nonbarbed monofilament sutures tend to migrate toward the middle of the incision, where the tension is greatest, which in turn places additional stresses on the tissues and may predispose them to wide scars or suture pull-through.4,6

The 8.3% incisional inflammation rate can be attributed to a number of factors. First, the incisions were not covered or maintained aseptically following surgery, so the incisions were exposed to unsanitary conditions during the postoperative period. Second, a significant number of the animals entered into the study with superficial abrasions along their dorsal midlines due to fighting by cage mates during the acclimatization period. Owing to the number of incisions per animal and the requisite positioning of the incisions, it was impossible to avoid incising through these abrasions at surgery and it is believed that this was largely responsible for the observed incisional site morbidity. Of interest, however, was the observation that the incidence of incisional morbidity was much higher for the control group (16.67%) than for either of the barbed devices groups (4.16% for each). Although incisional complication rate was not a primary end point in this study, the difference in infection rate suggests that barbed devices may be less prone to becoming inflamed or infected than monofilaments in the postoperative period.

The biomechanical strength of barbed suture devices is a function of barb geometry, cut angle and depth of the barbs, the total number of barbs, and the helicity.4,12-14 Increasing the number of barbs and/or the helicity increases the holding strength of barbed sutures in situ.4 The tensile strength of a barbed suture is inversely proportional to the cut depth of the barbs because as the cut depth increases, the effective diameter of the suture strand concomitantly decreases.4,13

There are significant differences in barb geometry and spacing between the V-Loc 90 device and Quill Monoderm, as demonstrated in Figure 5. The barbs on Quill Monoderm are rendered with a set cut angle, producing barbs that are apical in shape with a broad base that tapers to a point, whereas the barbs on the V-Loc 90 device are rendered with a dual cut angle. These barbs are broader, shorter, and stiffer. With finite element analysis, Ingle et al14 demonstrated that when barbs are cut with a constant high angle (like Quill Monoderm), the resultant barbs are more flexible than barbs that are devised with lower cut angles. In the latter case (as with the V-Loc 90 device), the barbs are shorter and stiffer and therefore have better tissue anchoring performance than the long flexible barbs. Figure 5 also highlights the differences in barb number and helicity between the two barbed devices: Quill Monoderm has eight barbs/cm and one helix/5.08 mm, in comparison to the V-Loc 90 device, which has 20 barbs/cm and a helix every 1.52 mm. The greater helicity and larger number of barbs should theoretically give the V-Loc 90 device an advantage over Quill Monoderm in resisting retrograde movement in situ. This was confirmed in the present study, where the primary failure mode for Quill Monoderm was barb slippage, whereas the V-Loc 90 device had a primary failure mode of suture breakage. With a much higher barb anchoring strength, the V-Loc 90 device is more prone to fail from suture breakage because the anchoring force engendered by the barbs exceeds the tensile strength of the monofilament core. In contrast, Biosyn failed either from suture breakage (50%) or by
The low incidence of the barbed devices (50%). The low incidence of the V-Loc 90 device, 0% for Quill Monoderm) reflects the fact that they are weaker in tensile strength than Biosyn. In the case of Quill Monoderm, the low anchoring force of the barbs resulted in suture slippage before the strength of the tissue was exceeded.

A final factor that influences the in situ strength of barbed devices is the ratio of the needle diameter to the suture strand diameter. To maximize axial barb engagement in tissue, the ideal situation is to couple a smallest diameter needle to the largest diameter strand, so that the tunnel left in the tissue after needle passage is as small as possible and results in the greatest amount of radial tissue compression by the barbs. Regardless of the number, geometry, or helicity of the barbs, a smaller needle-to-suture ratio will maximize barb engagement in the tissue. The Quill Monoderm in this study had a needle-to-suture ratio of 1.84, whereas the V-Loc 90 device had a ratio of 2.18. Therefore, Quill Monoderm would be expected to have better tissue purchase than the V-Loc 90 device. Further, the Quill Monoderm had a four-sided diamond tip needle, whereas the V-Loc 90 device had a reverse cutting needle. Given the viscoelastic nature of skin, the residual tissue defect following passage of the diamond point needle is likely to be smaller than the defect left after passage of the reverse cutting needle because the diamond tip will displace the collagen outward. With a cutting needle, a channel is cleanly cut through skin. The combination of a smaller needle-to-suture diameter and smaller residual tissue defect following needle passage may explain, in part, why Quill Monoderm was stronger than the V-Loc 90 device at Day 0 testing (5.01 vs 4.17 kgf). However, by the third postoperative Day, the V-Loc 90 device was stronger than Quill Monoderm, possibly reflecting the increased strength engendered by the greater barb number and helicity with the V-Loc 90 device. The more traumatic needle geometry and greater radial compression in the tissues also help explain why the average histological tissue reaction scores were consistently higher for Quill Monoderm than the V-Loc 90 device in the first 10 days following surgery. Although greater radial compression is advantageous from a barb purchase standpoint, it increases the amount of localized inflammation surrounding the suture, as was seen histologically in the current study. This may have clinically-important ramifications with respect to scar formation and warrants further investigation.

Over the critical period of wound healing, Biosyn was stronger than both of the barbed devices during ex vivo biomechanical testing (Figure 2). When an unbarbed monofilament suture is loaded in tension, it is the outer sheath that bears the majority of the applied load because of its highly-oriented, crystalline outer sheath. Cutting a barb into a monofilament suture results in two things. First, the load-bearing material that is removed by the cut consists primarily of the highly-oriented, crystalline sheath that is responsible for the tensile strength of the suture, so the ultimate tensile strength of the suture is reduced. Second, the resulting defect in the core of the suture defines the location of stress concentration and ultimately predicts the failure point. Regardless of the actual barb cut depth, the cut always removes the outer strength layer of a monofilament thread and results in a disproportionate loss in strength that is far greater than the actual loss of thread diameter. Leung et al found that cutting bars into a strand of monofilament suture reduced its strength to that of a suture that is between one to two sizes smaller. Since the control suture was only one USP size smaller than the barbed test sutures, it was not surprising that the composite strength of Biosyn was biomechanically stronger than either of the barbed devices.

One anomalous finding that warrants discussion was the observation that the incisions closed with the V-Loc 90 device increased in strength from Day 0 to Day 3, whereas the Biosyn and Quill incisions decreased in strength over the same time period. During the inflammatory phase of cutaneous wound healing, fibrillar collagen and extracellular matrix is removed by the activity of neutrophils, monocytes, and macrophages. At the end of the inflammatory phase (on the third or fourth postoperative day), the skin is actually weaker than at the time of injury because of this loss of collagen. As such, the composite strength of a sutured wound during this period is typically lower than at the time of wounding and primary repair. One explanation for why the mean biomechanical strength of incisions closed with the V-Loc 90 device increased may be that the tissue defect left by passage of the cutting needle had filled in due to inflammation, resulting in increased purchase of the barbs in the skin as compared to “time zero” testing, where the channels would have been larger. In any event, the increase in biomechanical strength during the time when primarily repaired skin incisions are typically at their weakest has obvious clinical benefits in terms of reducing the incidence of dehiscence and/or the development of unsightly scarring.

The time points for histology in this study were chosen to provide a representative sampling of histological differences during the phases of inflammation (Day 3), fibroplasia (Day 10) and maturation, and remodeling (Day 21). At Days 3 and 10, the least amount of tissue reaction was seen with the V-Loc 90 device and the greatest amount was seen with Quill Monoderm. It is plausible that the reduced barb strength of Quill Monoderm resulted in microslippage of the suture and this stimulated a greater inflammatory response in comparison to the V-Loc 90 device. Biosyn, in comparison, would not be expected to engender much inflammation since the suture freely slides within the suture tract because of its smooth surface.

The presence of giant cells around the V-Loc 90 device and Quill Monoderm (but not Biosyn) at Day 10 indicates that the barbed sutures were undergoing fragmentation. Given that Biosyn and the V-Loc 90 device are made of the same copolymer, one would expect to observe the same rate of breakage for both sutures; however, this did not appear to be the case. A plausible explanation for this discrepancy is that cutting barbs into the suture strands increases the exposed surface area of the barbed devices,
which may accelerate the rate of hydrolysis of these sutures in comparison to nonbarbed monofilaments.

The arrangement of the cellular infiltrates was markedly different between the barbed and nonbarbed sutures at all time points. For the barbed sutures, the cellular infiltrates were uniformly distributed circumferentially around the suture, whereas there was a focal accumulation of cells on one side of the suture for the Biosyn samples; it was always located directly opposite a gap between the Biosyn and adjacent dermis (see Figure 4A, D, G). The combination of localized cellular infiltrations and gap formation between the monofilament suture and skin is a manifestation of focal stress concentration attendant to wound tension. The barbed suture devices are anchored to the tissue, so the tension imparted by the distractive forces of the skin incision are borne by the helical distribution of barbs circumferentially around the suture, rather than focally. This explains why the cellular infiltrate for both Quill Monoderm and the V-Loc 90 device was uniformly distributed around the entire circumference of the suture, rather than being localized on one quadrant of the suture, as was the case with Biosyn (Figure 4).

CONCLUSIONS

Despite both knotless barbed devices engendering lower biomechanical wound strengths in the early periods of healing compared to the control monofilament suture, the absence of any incisional dehiscence and a lower incisional morbidity rate suggest that barbed sutures are clinically as efficacious as knotted monofilaments for cosmetic skin closure and may provide the added benefit of greater tension distribution along the length of the wound. No statistically significant differences existed between Quill Monoderm and the V-Loc 90 device for wound strengths. The differences between the two barbed suture devices in primary mode of failure during biomechanical testing can be attributed to differences in barb geometry, barb number, helicity, and needle-to-suture ratios. By virtue of its greater barb number, helicity, and stiffer barb geometry, the V-Loc 90 device had a higher barb-holding force than Quill Monoderm, which in turn resulted in suture breakage being the primary model of failure for the V-Loc 90 device. In contrast, Quill Monoderm was more prone to barb slippage and this resulted in greater histological tissue reaction scores during the critical period of healing. The V-Loc 90 device consistently had the lowest histological tissue reaction scores, with the difference being statistically significant to Biosyn at postoperative Day 3 and Quill Monoderm at Days 3 and 10.

Disclosures

Dr. Jeff Zaruby and Kristen Gingras are employees of Covidien Surgical Devices. Dr. Don Maul and Dr. Jack Taylor acted as paid consultants for Covidien during the course of this study.

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