Body Contouring

A Multicenter Randomized Controlled Trial Comparing Absorbable Barbed Sutures Versus Conventional Absorbable Sutures for Dermal Closure in Open Surgical Procedures

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Abstract

Background: Barbed sutures were developed to reduce operative time and improve security of wound closure.

Objective: The authors compare absorbable barbed sutures (V-Loc, Covidien, Mansfield, Massachusetts) with conventional (smooth) absorbable sutures for soft tissue approximation.

Method: A prospective multicenter randomized study comparing barbed sutures with smooth sutures was undertaken between August 13, 2009, and January 31, 2010, in 241 patients undergoing abdominoplasty, mastopexy, and reduction mammoplasty. Each patient received barbed sutures on 1 side of the body, with deep dermal sutures eliminated or reduced. Smooth sutures with deep dermal and subcuticular closure were used on the other side as a control. The primary endpoint was dermal closure time. Safety was assessed through adverse event reporting through a 12-week follow-up.

Results: A total of 229 patients were ultimately treated (115 with slow-absorbing polymer and 114 with rapid-absorbing polymer). Mean dermal closure time was significantly quicker with the barbed suture compared with the smooth suture (12.0 vs 19.2 minutes; P < .001), primarily due to the need for fewer deep dermal sutures. The rapid-absorbing barbed suture showed a complication profile equivalent to the smooth suture, while the slow-absorbing barbed suture had a higher incidence of minor suture extrusion.

Conclusions: Barbed sutures enabled faster dermal closure quicker than smooth sutures, with a comparable complication profile.

Level of Evidence: 1

Keywords
sutures, mammoplasty, abdominal wound closure, wound closure techniques, absorbable barbed sutures, absorbable smooth sutures, body contouring

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An estimated 50 million surgical procedures are performed each year in the United States.1 Many of these procedures require closing a surgical incision that involves multiple layers of tissue, including muscle, fascia, and skin. The ideal closure for those incisions should be fast and easy to perform while providing optimal wound apposition with sufficient but not excessive tension, as well as a satisfactory cosmetic result.2 Surgical sutures constitute the most common method of wound closure and continue to be the method of choice for most procedures. However, outcomes with sutures can vary depending on material composition and knot selection.34 Complications associated with traditional sutures are often related to knots, including knot breakage and slippage, suture extrusion or splitting, and infection.5 In addition, tightly approximated wounds and overly taut sutures can lead to ischemia at the wound edge.

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inflammation, dehiscence, reduced wound strength, and scarring.\textsuperscript{5}

Bidirectional barbed sutures employ barbs arranged in a helical array, set in opposing directions from either side of the suture midpoint.\textsuperscript{6-8} This configuration allows the suture to be self-anchoring, permitting close approximation of the tissue while resisting the migration that can occur with swelling. Barbed sutures eliminate the need for knots during closure and mitigate some knot-associated complications. Preclinical models have indicated that knotless barbed sutures may have an advantage over smooth sutures in reduced operative time, improved tissue apposition, and more even distribution of tension across the incision.\textsuperscript{6-8}

V-Loc Absorbable Wound Closure Devices (Covidien; Mansfield, MA) consist of a unidirectional barbed absorbable suture with a welded loop end and have been approved by the US Food and Drug Administration for soft tissue approximation where treatment with absorbable sutures is appropriate. Two versions of the device have been developed: slow and rapid absorbing. Both share the same design elements but differ in material composition. The slow-absorbing device (V-Loc 180), a copolymer of glycolic acid and trimethylene carbonate, has a 180-day absorption profile; the rapid-absorbing device (V-Loc 90), composed of glycolide, dioxanone, and trimethylene carbonate, has a 90- to 110-day absorption profile. Preliminary clinical studies have indicated that V-Loc devices can reduce the time required for some surgical procedures.\textsuperscript{9-13}

This study’s objective was to compare 2 models of absorbable barbed sutures (slow and rapid absorbing) with current standard-of-care smooth sutures, assessing dermal closure time, complications, and cosmesis during abdominoplasty, mastopexy, and reduction mammoplasty procedures. We sought to compare a traditional closure method with relatively closely spaced deep dermal sutures with a method by which surgeons can use fewer deep dermal sutures. We hypothesized that the more secure barbed suture would allow the use of a continuously running subcuticular layer without the need for deep dermal closure, thus providing a secure wound closure while yielding faster closure time and a complication profile comparable with conventional absorbable sutures.

**METHODS**

**Trial Design**

This study was a prospective, multicenter, randomized, controlled trial designed to evaluate dermal closure time, complications, and cosmesis of 2 absorbable barbed sutures compared with a smooth absorbable synthetic suture (Monocryl Synthetic Absorbable Suture; Ethicon, Somerville, NJ) for dermal closure in abdominoplasty, mastopexy, and reduction mammoplasty.

Each patient who met the study criteria (outlined in the next section) had dermal closure performed on 1 side with the barbed suture (either slow or rapid absorbing) and the smooth suture on the opposite side. In this manner, the patients served as their own control. The selection of wound closure material for each side (right versus left) was randomized (through a random number table) for the barbed suture or the smooth suture. The V-Loc 90 device was not included in the beginning of the study since it was not yet commercially available. Following availability of the V-Loc 90 device, the use of the slow- or rapid-absorbing barbed suture was based upon the preference of the surgeon.

Sample sizes were determined following a review of relevant studies and using a power of 0.8 with an alpha of 0.05. The sample size was calculated with the assumption of an inferiority/superiority study to detect a minimum 10% reduction in dermal closure time with 15% of patients potentially lost to follow-up. Based on these assumptions, an estimated total of 238 patients needed to be enrolled for adequate study power.

**Participants**

The study was conducted at 9 institutions across the United States and Europe. Prior to enrollment, each patient signed an informed consent. The study procedures were approved by the Institutional Review Board or Independent Ethics Committee at each institution and performed in accordance with the ethical standards of the Helsinki Declaration of 1975. This study was registered with clinicaltrials.gov (NCT00959374).

Only patients scheduled for abdominoplasty, mastopexy, or reduction mammoplasty surgeries, as single or combined procedures, were eligible for inclusion in the study. Patients included in the study were ≥18 years of age and in good overall health. Patients were excluded from the trial if they were pregnant or breastfeeding, had a body mass index (BMI) ≥40, were diabetic requiring medication for glycemic control, had a condition that could interfere with wound healing (eg, active infectious collagen disease or history of keloid or hypertrophic scar formation), had significant anatomic asymmetry that could lead to different wound tension and/or geometry between the right and left sides, were febrile (temperature > 38°C), or had an active cutaneous or...
Interventions

Surgical procedures were based on the patient’s body type and aesthetic goals. Surgeons performed the procedure according to the appropriate standard procedures and practices at their institution. For all types of study procedures, the treatment differed with respect to the final layers of closure in the dermis on the right versus left side of the operative field.

On 1 side of the body, a standard skin closure technique was performed. This included closure of the deep dermal layer with interrupted 3-0 Monocryl sutures (Ethicon, Inc, Sommerville, NJ), spaced no further than 2 cm apart, followed by closure of the intradermal layer with running 3-0 Monocryl sutures. Based on the premise that barbed sutures would allow a more secure closure of the intradermal layer—essentially performing the function of both the running subcuticular monofilament suture and interrupted intradermal sutures—the interrupted sutures on the barbed suture side of the body were either eliminated or significantly reduced in number.

On the barbed suture side, the investigator could elect not to close the deep dermal layer with interrupted sutures; however, if deep dermal sutures were placed (based on the surgeon’s preference), then interrupted 3-0 Monocryl sutures were spaced no closer than 5 cm apart. The intradermal layer was then closed with running subcuticular barbed sutures (either slow or rapid absorbing). The same surgeon treated both sides. In this way, the protocol was designed to determine whether the more secure barbed suture would allow fewer deep dermal sutures while providing a similar complication rate as, and faster closure time than, traditional methods based on smooth sutures.

For eligible surgical procedures, certain incision lines were not included in the study. In abdominoplasty cases where a midline vertical skin resection was performed, the midline wound was not considered part of the study and could be closed in any manner selected by the surgeon. In breast procedures (mastopexy or reduction mammoplasty), closure of the areola and any vertical incision was performed according to surgeon preference and not included as part of the study.

Following the dermal closure specified above, the type of dressing administered was left to the discretion of each surgeon, and the same dressings were applied symmetrically on both right and left sides.

Outcome Measures

The primary effectiveness endpoint was total dermal closure time, measured via a calibrated stopwatch. When performed, the time required for deep dermal closure with interrupted sutures was recorded. In addition, various surgical parameters were recorded, including the number of sutures needed to close the incision.

Cosmesis was a secondary endpoint and was evaluated by an independent blinded plastic surgeon. Cosmesis photographs were taken at the 12-week follow-up visit with standard photography techniques. The cosmetic appearance of scars was evaluated on a 5-point visual analog scale (1 = worst, 5 = excellent) for parameters of color match, width, borders, and contour and distortion.

Safety was assessed through the collection of treatment-emergent adverse events (AE) and postoperative complications. Wound dehiscence, suture extrusion, granuloma, and local wound infection were evaluated according to incidence, size, and location. Wound dehiscence was defined as wound separation greater than 1 cm in depth and 1 cm in width and requiring treatment beyond standard surface dressings (office debridement, closure, wound packing, or debriding dressings). An independent reviewer adjudicated all reported events of wound dehiscence. Only events occurring from study entry and throughout the 12-week follow-up period were collected.

Statistical Methods

Baseline and surgical procedure parameters were compared with either the chi-square test, Fisher exact test (for dichotomous variables), the Mantel-Haenszel test (for ordinal variables), or the 2-sample t-test (for continuous variables).

The primary null hypothesis was that there was no difference in dermal closure time between groups (barbed vs smooth suture); this was tested with a paired t-test. Dermal closure times were evaluated overall and by dermal layer (intradermal and deep dermal). In addition, for closure times of the deep dermal layer, comparisons were made for all patients and only those who received deep dermal sutures.

For cosmesis, a composite score was calculated by summing the individual scores of each of the 4 categories of scar appearance obtained at the 12-week follow-up visit. Sign tests tested for a median difference of 0 between treatment sites.

The proportion of complications (wound dehiscence, suture extrusion, granulomas, and local wound infection) experienced by each group (barbed vs smooth suture) were
evaluated with the McNemar test. Complications were evaluated at the subject level. Similar analyses were performed for slow- and rapid-absorbing barbed suture subgroups.

Post hoc logistic regression analyses were performed on suture extrusion on barbed suture sites (either slow or rapid absorbing) and baseline parameters in which a significant difference ($P > .05$) between the groups was observed. The odds ratio and 95% confidence interval were determined for each variable.

Additional subgroup analyses were performed comparing abdominal versus breast procedures, as well as deep dermal sutures versus no deep dermal sutures for all procedures, abdominal procedures only, and breast procedures only.

**RESULTS**

**Participants**

Figure 1 provides an overview of the study’s patient flow. Consent was considered the point of enrollment. Subjects were screened for eligibility after consent/enrollment. A total of 241 patients were enrolled in the study from August 13, 2009, to January 31, 2010. Of those, 229 were randomized and treated. The slow- and rapid-absorbing barbed sutures were placed in 115 and 114 patients, respectively. Of patients receiving slow-absorbing barbed sutures, 94 completed the study. Of the 114 patients receiving rapid-absorbing barbed sutures, 110 completed the study.

All randomized patients were included in the primary efficacy and safety analyses (115 and 114 for slow and rapid absorbing, respectively). The cosmesis analysis included 190 patients (slow absorbing, $n = 88$; rapid absorbing, $n = 102$).

**Demographic and Baseline Characteristics**

A summary of the demographic and baseline characteristics of patients included in the study is provided in Table 1. Overall, patients were a mean age of 42.6 years (range, 18-70 years), predominantly white (89%) and female (93%), with a mean BMI of 28.8 kg/m$^2$ (range, 19.39 kg/m$^2$). Patients served as their own control; thus, demographic parameters...
and baseline characteristics are identical between barbed and smooth sutures. However, the patient subgroup that received slow-absorbing barbed sutures had a slight but statistically significant difference in mean BMI compared with those who received rapid-absorbing barbed sutures (29.6 vs 27.9 kg/m², respectively; \( P = .01 \)) and a higher percentage of Caucasian patients (84.3% vs 93.9%, respectively; \( P = .02 \)). No other significant differences were seen between these subgroups.

Twenty-four patients did not have any significant medical comorbidity. The most prevalent medical conditions reported were history of morbid obesity treated with bariatric surgery (52 and 24 patients receiving the slow- and rapid-absorbing barbed sutures, respectively; \( P < .001 \)) and hernia.

An assessment of certain surgical and wound-healing risk factors was performed at the preoperative visit (Table 1). In the overall study population, no risk factor was identified for 111 (49%) patients, with significantly more of those patients receiving rapid- rather than slow-absorbing barbed sutures (67 vs 44 patients, respectively; \( P = .002 \)). In the remaining patients, the following risk factors were identified: 58 (25%) patients were smokers; 50 (22%) had abdominal scarring that could have compromised blood flow to surrounding tissues; 36 (16%) were anemic; and 9 (4%) were diabetic. The majority of diabetic patients received rapid-absorbing barbed sutures (8 vs 1; \( P = .02 \)), and abdominal scarring that may have interrupted blood flow was predominantly observed in patients receiving slow-absorbing barbed sutures (43 vs 7; \( P < .001 \)). No other significant differences were observed between the groups receiving barbed suture devices.

**Procedural Parameters**

A total of 233 procedures were performed in the 229 patients, with a relatively equal distribution between abdominal procedures (either abdominoplasty or panniculectomy, \( n = 119 \)) and breast procedures (either mastopexy or reduction mammoplasty, \( n = 114 \)). A significantly higher percentage of patients receiving slow-absorbing barbed sutures underwent abdominal procedures (61.7%, \( n = 71 \)); conversely, breast procedures were more
common in those receiving rapid-absorbing barbed sutures (60.5%, n = 69).

Surgical procedure parameters are summarized in Table 2. Overall, mean operative time was 2 hours, 50 minutes, with a mean anesthesia time of 3 hours, 43 minutes. Concomitant procedures (eg, liposuction, hernia repair, and breast augmentation) were performed in approximately one-third of the patients. The most common dressing was surgical adhesive (eg, Indermil; Covidien, Mansfield, MA; and Dermabond; Ethicon, Somerville, NJ). Intraoperative drains were placed in the majority of patients (89%) and in significantly more patients with rapid-absorbing barbed sutures than slow-absorbing barbed sutures (93% vs 84.3%, respectively; \(P = .04\)).

On the barbed suture side, deep dermal sutures were placed at the surgeon’s discretion in 143 (62%) of the patients who received this treatment (Table 3). Deep dermal sutures were preferred in all but 2 subgroups (rapid-absorbing/barbed overall and rapid-absorbing/barbed in breast procedures). In patients undergoing a breast procedure with rapid-absorbing barbed sutures, 69% (n = 47) did not receive deep dermal sutures.

**Dermal Closure Time and Suture Placement**

Table 3 summarizes mean dermal closure times. Overall, mean dermal closure time was 12.0 minutes with barbed sutures, compared to 19.2 minutes with smooth sutures, a difference of 7.2 minutes (\(P < .001\); Figure 2). This difference was primarily due to the fact that fewer deep dermal sutures were applied on the barbed suture side, as the difference in time for the running closure of the intradermal layer did not reach statistical significance (8.9 minutes for barbed sutures vs 9.3 minutes for smooth sutures; \(P = .07\)). Mean deep dermal closure time was 4.9 minutes with barbed sutures, compared to 10.1 minutes with smooth sutures. When the devices were compared in just abdominal procedures or just breast procedures, a similar pattern was noted.

Differences in the number of sutures mirrored differences seen in closure times. Overall, fewer sutures were placed with barbed sutures than smooth sutures (2.0 vs 3.3, respectively; \(P < .001\)). Although suture placement was significantly less with barbed sutures than smooth sutures in deep dermal closure (1.4 vs 2.3, respectively; \(P < .001\)), there was no significant difference in intradermal closure (1.1 for both groups). A similar pattern was observed when the devices were compared in only abdominal procedures or breast procedures and in terms of whether deep dermal sutures were used.

Any sutures with loop breakage were identified before beginning the subcuticular stitch and were replaced. This did not affect the complication rate but would have increased the closure time in those cases in which it occurred. The low number of suture failures did not significantly alter the results.

**Cosmesis**

Overall, 37% of patients did not receive postoperative scar management therapy; 14% received topical treatments;
13% received a technique such as massage; and 35% received both topical treatment and a technique. An independent, blinded plastic surgeon evaluated photographs of the scars taken at the 12-week postoperative visit. Overall, the median total composite cosmesis score was 14.0 for both the barbed and the smooth suture sides. Because publication of patient photographs was not included in the study’s informed consent, they could not be included in this article; however, the evaluator observed no significant difference between treatment groups.

**Safety**

Average follow-up was 94.7 ± 45.5 days (range, 1-447 days). Of the 229 patients included in the study, 136 (59%) experienced at least 1 AE. Overall, the most common events reported among the 229 patients were minor: suture extrusion without purulent discharge or abscess, 69 (30%); wound infection, 19 (8%); hematoma, 14 (6%); edema, 13 (6%); seroma, 12 (5%); localized incision pain, 11 (5%); erythema, 7 (3%); abnormal scarring, 6 (3%); and bleeding, 4 (2%). There were no reported sinus formation or fistula AE. The majority of AE reported were either mild or moderate.

Table 4 summarizes the prevalence of AE reported at subject level according to type of barbed suture. Of the 115 patients who received slow-absorbing barbed sutures, AE—mainly suture extrusion—were more commonly reported on the barbed suture side than on the smooth suture side (30 vs 9, respectively; P = .001). Comparing...
the faster-absorbing barbed and smooth suture sides, AE were comparable, including rates of suture extrusion. Suture extrusion without purulent discharge was the only AE in which the prevalence significantly differed between slow-absorbing barbed suture side and smooth suture side (20% vs 4.3%, respectively; $P = .001$). Suture extrusion occurrence was twice as likely in patients closed with slow-absorbing sutures (Table 5). This difference continued after adjusting for potential confounding variables. The only baseline or procedural variable associated with higher odds of suture extrusion was BMI $>25$ kg/m$^2$.

AE deemed unrelated to the investigational device (barbed or smooth suture) also occurred: 3 patients developed hematoma (a severe AE) on the barbed suture side and 1 patient on the smooth suture side. In addition, 9 patients incurred severe AE of a systemic nature. Three patients experienced life-threatening events: One was a hematoma on the barbed suture side, and the others were systemic (allergic reaction and cardiac/respiratory arrest). Eight patients experienced intraoperative complications. The most common complications were greater-than-anticipated blood loss and transfusion, in 2 patients each. None of these intraoperative events were considered to be related to the investigational device (barbed or smooth sutures).

The majority of the AE were reported within 30 days postoperatively (Table 6). Wound dehiscence was most commonly reported between 11 and 30 days postoperatively. Device malfunctions were reported in 16 (7%) patients: 15 with a barbed suture and 1 with the smooth suture. The barbed suture malfunctions included 5 devices with broken or dull needles and 10 devices with suture or loop breakage. A needle break caused the single smooth suture malfunction.

### Discussion

This study was a randomized, multicenter study to compare dermal closure time, complications, and cosmesis of barbed sutures (in either slow- or rapid-absorbing versions) with smooth sutures in patients undergoing abdominoplasty, breast reduction mammoplasty, or mastopexy. All patients served as their own controls, with the test device (slow- or rapid-absorbing barbed sutures) placed on 1 side and smooth sutures used on the other. The surgical incision was closed on 1 side of the body via a modified dermal closure technique with barbed sutures in the intradermal layer and reduced or no interrupted sutures in the deep dermal layer; this was compared with a conventional

### Table 4. Prevalence of Adverse Events at Subject Level According to Type of Device, No. (%)$^a$

<table>
<thead>
<tr>
<th>Reported Term</th>
<th>Slow Absorbing (n = 115)</th>
<th>Rapid Absorbing (n = 114)</th>
<th>$P$</th>
<th>Slow Absorbing (n = 115)</th>
<th>Rapid Absorbing (n = 114)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 1 adverse event</td>
<td>30 (26.1)</td>
<td>9 (7.8)</td>
<td>.001</td>
<td>19 (16.7)</td>
<td>9 (7.9)</td>
<td>.09</td>
</tr>
<tr>
<td>Wound infection</td>
<td>4 (3.5)</td>
<td>2 (1.7)</td>
<td>.69</td>
<td>2 (1.8)</td>
<td>0</td>
<td>.50</td>
</tr>
<tr>
<td>Bleeding</td>
<td>0</td>
<td>2 (1.7)</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Granuloma</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
<td>1 (0.9)</td>
<td>1 (0.9)</td>
<td>&gt; .99</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>2 (1.7)</td>
<td>1 (0.9)</td>
<td>&gt; .99</td>
<td>4 (3.5)</td>
<td>2 (1.8)</td>
<td>.69</td>
</tr>
<tr>
<td>Suture extrusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without purulent discharge/abscess</td>
<td>23 (20.0)</td>
<td>5 (4.3)</td>
<td>.001</td>
<td>10 (8.8)</td>
<td>4 (3.5)</td>
<td>.18</td>
</tr>
<tr>
<td>With purulent discharge</td>
<td>1 (0.9)</td>
<td>0</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Seroma</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
<td>2 (1.8)</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Hematoma</td>
<td>3 (2.6)</td>
<td>3 (2.6)</td>
<td>&gt; .99</td>
<td>4 (3.5)</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Dermatitis or skin inflammation</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
<td>1 (0.9)</td>
<td>0</td>
<td>&gt; .99</td>
</tr>
<tr>
<td>Localized incision pain</td>
<td>3 (2.6)</td>
<td>1 (0.9)</td>
<td>.63</td>
<td>0</td>
<td>2 (1.8)</td>
<td>N/A</td>
</tr>
<tr>
<td>Edema</td>
<td>0</td>
<td>2 (1.7)</td>
<td>N/A</td>
<td>2 (1.8)</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Erythema</td>
<td>1 (0.9)</td>
<td>0</td>
<td>N/A</td>
<td>1 (0.9)</td>
<td>0</td>
<td>&gt; .99</td>
</tr>
<tr>
<td>Abnormal scarring</td>
<td>0</td>
<td>1 (0.9)</td>
<td>N/A</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Other</td>
<td>8 (7.0)</td>
<td>2 (1.7)</td>
<td>.11</td>
<td>4 (3.5)</td>
<td>1 (0.9)</td>
<td>.38</td>
</tr>
</tbody>
</table>

Abbreviation: N/A, not applicable.

$^a$Percentages are based on the number of total patients. Patients with multiple occurrences of the same event were counted only once within a specific reported term.
wound closure technique with running intradermal smooth sutures and interrupted smooth sutures in the deep dermal layer.

The modified technique employing barbed sutures and reduced or no deep dermal sutures resulted in dermal closure 7 minutes quicker and with comparable outcomes when compared with the conventional technique of closing deep dermal layers with smooth sutures. These results are consistent with other studies in which barbed sutures were placed in radical prostatectomies for posterior reconstruction or vesicourethral anastomoses and laparoscopic myomectomy. Because barbed sutures were used on only 1 side of the body, it could be estimated that time and suture savings could double if barbed sutures were used on both sides.

As expected, time savings was driven by a protocol-defined reduced requirement for deep dermal layer closer, made possible by treatment with the more secure barbed suture. In fact, the greatest time savings were observed in the patient subgroup that did not have deep dermal sutures. This subgroup showed a mean difference of 10.3 minutes (barbed, 9.1 minutes; smooth, 19.4 minutes; \( P < .001 \)). For patients who did receive deep dermal sutures, the barbed suture’s significant time savings reflect larger spacing between deep dermal sutures on the barbed suture side. This time savings may provide great advantages in both reduced anesthesia time and fewer required resources for surgical procedures.

The barbed suture was also associated with placement of fewer sutures. While surgical technique can influence suture conservation and number of suture packs used (length of tails, spacing, etc), if a surgeon feels comfortable placing fewer deep dermal sutures, our study shows that this can be done safely with a barbed device. However, these results should be interpreted within the context of placement guidelines predefined by the protocol. Comparable to the cost savings observed in another report on the barbed suture also used in our analysis, our results showed a difference in the barbed sutures that can potentially translate to economic savings. Barbed sutures likewise have demonstrated cost savings when used for fascial closure, although the particular barbed suture under study in this article is not approved for fascial closure. While barbed sutures cost more, it has been proposed that the time savings would offset that cost. However, further studies are needed to fully understand potential resource savings.

In this study, some significant differences were noted in terms of dressings, specifically in the application of

### Table 5. Logistic Regression of Variables Associated With Suture Extrusion Observed With Barbed Sutures

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two variables</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slow-absorbing/barbed vs rapid-absorbing/barbed</td>
<td>2.19</td>
<td>1.08, 4.44</td>
<td>.03</td>
</tr>
<tr>
<td>Barbed + body mass index &gt; 25 kg/m²</td>
<td>3.46</td>
<td>1.17, 10.24</td>
<td>.03</td>
</tr>
<tr>
<td>Barbed + white</td>
<td>2.05</td>
<td>0.57, 7.35</td>
<td>.27</td>
</tr>
<tr>
<td>Barbed + bariatric surgery</td>
<td>0.98</td>
<td>0.47, 2.04</td>
<td>.95</td>
</tr>
<tr>
<td>Barbed + diabetes</td>
<td>0.79</td>
<td>0.09, 6.70</td>
<td>.83</td>
</tr>
<tr>
<td>Barbed + abdominal scarring</td>
<td>0.45</td>
<td>0.18, 1.15</td>
<td>.10</td>
</tr>
<tr>
<td>Barbed + abdominoplasty</td>
<td>0.64</td>
<td>0.31, 1.28</td>
<td>.21</td>
</tr>
<tr>
<td>Barbed + mastectomy</td>
<td>2.05</td>
<td>0.60, 7.00</td>
<td>.25</td>
</tr>
<tr>
<td>Barbed + reduction mammaplasty</td>
<td>1.53</td>
<td>0.76, 3.07</td>
<td>.23</td>
</tr>
<tr>
<td>Barbed + Steri-Strips</td>
<td>0.43</td>
<td>0.17, 1.11</td>
<td>.08</td>
</tr>
<tr>
<td>Barbed + surgical adhesive</td>
<td>1.95</td>
<td>0.90, 4.23</td>
<td>.09</td>
</tr>
<tr>
<td>Multivariate analysis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slow-absorbing/barbed vs rapid-absorbing/barbed</td>
<td>2.33</td>
<td>1.02, 5.34</td>
<td>.05</td>
</tr>
<tr>
<td>Body mass index &gt; 25 kg/m²</td>
<td>3.15</td>
<td>0.98, 10.16</td>
<td>.05</td>
</tr>
<tr>
<td>Abdominal scarring</td>
<td>0.40</td>
<td>0.15, 1.04</td>
<td>.06</td>
</tr>
<tr>
<td>Steri-Strips</td>
<td>0.84</td>
<td>0.19, 3.84</td>
<td>.83</td>
</tr>
<tr>
<td>Surgical adhesive</td>
<td>1.35</td>
<td>0.40, 4.52</td>
<td>.63</td>
</tr>
</tbody>
</table>
Steri-Strips (Nexcare, 3M; St Paul, MN) and tissue glue in certain groups. This difference most likely reflects institutional and surgeon preference rather than differences in the type of surgical procedures performed. The study protocol did not include dressing application in the timing of the closure, so this was not considered a significant factor in the timing-related results. Though placement of specific dressings may contribute to healing and cosmesis of the wounds, no associations were noted between type of dressing and adverse healing events or ultimate cosmesis.

For this study, those AE routinely encountered with abdominoplasty or breast surgery were specifically captured. For instance, seromas are considered to be the most common complication arising from abdominoplasties. Clinical seromas have been reported to occur in as many as 35% of procedures.16-19 In our study, only 2 patients (both on the rapid-absorbing barbed suture side) reported a seroma. Seroma formation is usually not related to the final layer of skin closure and thus is not considered a device-related complication. Additionally, wound dehiscence has been reported to occur in approximately 6% of mammoplasty procedures,20,21 similar to the incidence reported in this study (range, 4.3%-8.6%).

Suture extrusion is among the most common AE arising from mastopexy procedures.22 The majority of the difference in AE reported in patients receiving barbed and smooth sutures was due to suture extrusion without purulent discharge or abscess. Furthermore, sites closed with slow-absorbing barbed sutures were twice as likely to have suture extrusion as those closed with rapid-absorbing barbed sutures. This difference remained even after adjustment for confounding variables. This difference may result from differences in either the chemical composition and/or absorption profiles of the 2 barbed suture products. In a porcine model, the rapid-absorbing barbed suture was demonstrated to have a lower reaction score when compared with either a conventional monofilament or another absorbable barbed suture.8

No significant difference between the devices was observed regarding the 12-week cosmetic outcome. This was not unexpected. In general, surgical incisions in these procedures heal relatively well with current standard-of-care closure techniques. While variations in scar management could theoretically play a role in cosmesis, we did not observe differences in cosmetic outcomes. Additionally, any differences in scar management applied to an individual patient would have been applied bilaterally. A potential study limitation is the lack of long-term cosmesis data beyond 12 weeks. In addition, this study may have been underpowered to detect a difference in scar management, as the rapid-absorbing barbed suture was not available at the start of the study.

Table 6. Adverse Events According to Date of Onset, No. (%)

<table>
<thead>
<tr>
<th>Reported Term</th>
<th>Total (n = 116)</th>
<th>Day 0 (n = 4)</th>
<th>Days 1-10 (n = 20)</th>
<th>Days 11-30 (n = 46)</th>
<th>Days 31-42 (n = 12)</th>
<th>Days 43-84 (n = 27)</th>
<th>Day &gt; 84 (n = 7)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slow-absorbing barbed sutures</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At least 1 adverse event</td>
<td>116 (100.0)</td>
<td>4 (100.0)</td>
<td>20 (100.0)</td>
<td>46 (100.0)</td>
<td>12 (100.0)</td>
<td>27 (100.0)</td>
<td>7 (100.0)</td>
</tr>
<tr>
<td>Barbed study incision side</td>
<td>68 (58.6)</td>
<td>3 (75.0)</td>
<td>9 (45.0)</td>
<td>20 (43.5)</td>
<td>10 (83.3)</td>
<td>20 (74.1)</td>
<td>6 (85.7)</td>
</tr>
<tr>
<td>Smooth study incision side</td>
<td>31 (26.7)</td>
<td>1 (25.0)</td>
<td>7 (35.0)</td>
<td>17 (37.0)</td>
<td>2 (16.7)</td>
<td>4 (14.8)</td>
<td>0</td>
</tr>
<tr>
<td>Suture extrusiona</td>
<td>49 (42.2)</td>
<td>0</td>
<td>3 (15.0)</td>
<td>16 (34.8)</td>
<td>10 (83.3)</td>
<td>15 (55.6)</td>
<td>5 (71.4)</td>
</tr>
<tr>
<td>Wound dehiscence</td>
<td>16 (13.8)</td>
<td>0</td>
<td>1 (5.0)</td>
<td>13 (28.3)</td>
<td>0</td>
<td>2 (7.4)</td>
<td>0</td>
</tr>
<tr>
<td>Wound infection</td>
<td>12 (10.3)</td>
<td>0</td>
<td>2 (10.0)</td>
<td>7 (15.2)</td>
<td>0</td>
<td>2 (7.4)</td>
<td>1 (14.3)</td>
</tr>
</tbody>
</table>

| Rapid-absorbing barbed sutures |                |              |                    |                    |                    |                    |                 |
| At least 1 adverse event      | 93 (100.0)     | 3 (100.0)    | 7 (100.0)          | 47 (100.0)         | 14 (100.0)         | 19 (100.0)         | 3 (100.0)       |
| Barbed study incision side    | 49 (52.7)      | 3 (100.0)    | 4 (57.1)           | 20 (42.6)          | 8 (57.1)           | 12 (63.2)          | 2 (66.7)        |
| Smooth study incision side    | 31 (33.3)      | 0            | 3 (42.9)           | 17 (36.2)          | 3 (21.4)           | 7 (36.8)           | 1 (33.3)        |
| Suture extrusiona             | 31 (33.3)      | 0            | 0                  | 13 (27.7)          | 8 (57.1)           | 8 (42.1)           | 2 (66.7)        |
| Wound dehiscence              | 18 (19.4)      | 1 (33.3)     | 0                  | 13 (27.7)          | 3 (21.4)           | 1 (5.3)            | 0               |

aWithout purulent discharge or abscess.
slow-absorbing suture. Finally, nonstandard application of topical skin adhesives may have affected the results; however, this variable would not have influenced the primary intraoperative outcomes of the study.

CONCLUSIONS

No single suture material will meet all the needs of the broad range of surgical procedures currently performed. Therefore, it is beneficial to have a full complement of closure devices from which a surgeon can draw to meet the needs of each procedure and patient. The results of this trial support the placement of V-Loc absorbable barbed sutures in abdominoplasty, mastopexy, and reduction mammaplasty with fewer deep dermal sutures than typically used. These barbed sutures appear to provide a more secure closure and safely close the dermal layer in a running fashion with sparsely placed or no interrupted deep dermal sutures. Furthermore, when 2 versions of this suture were compared, the version with a faster absorption profile (V-Loc 90) showed a lower minor complication rate and appeared to be more appropriate for these procedures.

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