Prevention of Scar Spread on Trunk Excisions

A Rater-Blinded Randomized Controlled Trial

Kevin F. Kia, MD; Molly V. Burns, MD; Travis Vandergriff, MD; Sarah Weitzul, MD

Importance: Wounds that heal under tension lead to wider and more conspicuous scars and result in decreased long-term patient satisfaction. We hypothesized that prolonged intradermal suture lifetime can decrease scar spread in wounds under tension.

Objective: To determine whether prolonged intradermal support would help decrease scar spread.

Design: Prospective, randomized, controlled, rater-blinded, split-scar trial.

Setting: Outpatient dermatology clinic at Dallas Veterans Affairs Hospital, Dallas, Texas.

Patients: Patients presenting with skin cancer on the trunk were considered for the trial. We included 25 distinct surgical sites on a total of 22 patients.

Intervention: After excision, the wounds were closed with polyglactin 910 and poly-4 hydroxybutyrate (P4HB) sutures in opposite halves of the same wound.

Main Outcome Measures: Quantitative scar spread at 12 months and qualitative assessment using a visual analog scale and Hollander Wound Evaluation Scale.

Results: We found a statistically significant difference in scar width between the 2 suture materials, with a mean difference of 2.3 (95% CI, 1.0-3.6) mm (P < .001) favoring P4HB. A clinically significant difference on the visual analog and Hollander Wound Evaluation scales was not identified. Suture reactions were more common with P4HB.

Conclusions and Relevance: Prolonged intradermal suture support leads to significantly decreased scar spread. However, the use of a longer-acting absorbable suture increases the rate of suture reaction noted at 3 months. Further studies into less reactive, longer-acting biomaterials are needed. In clinical practice, excisions in high-tension areas that are classically known to spread over time can benefit from longer-acting intradermal sutures.

Trial Registration: clinicaltrials.gov Identifier: NCT00938691

Participants received financial compensation for completion of the trial were included in all statistical analyses (1 death from pneumonia and 1 patient becoming homeless). The total number of participants undergoing analysis was 20.

Figure 1. Patient flowchart using CONSORT criteria. A total of 22 participants were enrolled in the study and intervention assignments were randomized. Because 3 participants had multiple (2) wounds (sites of intervention), a total of 25 wounds were enrolled in the study. Allocation consisted of wound suturing with polyglactin 910 (intervention A) and wound suturing with poly-4 hydroxybutyrate (intervention B). All wounds received interventions A and B in a split-scar design, with each wound divided into halves and individual halves assigned a suture material in a random fashion. Two participants were lost to follow-up before the final follow-up period; one died of pneumonia, and the other was homeless. The total number of participants undergoing analysis was 20.

ate circumstances favoring scar spread. If this hypothesis is true, prolonged intradermal support would help to decrease scar spread. To test this hypothesis, we conducted a prospective trial comparing polyglactin 910 with the novel long-acting absorbable suture material poly-4 hydroxybutyrate (P4HB). A naturally occurring polyester produced by bacterial fermentation, P4HB is approved by the US Food and Drug Administration for soft-tissue ligation and approximation. The suture consists of a translucent monofilament that is reported to have initial tensile strength comparable to that of polydioxanone. The key characteristic of this new suture material is its retention of tensile strength; at 24 weeks after placement, the material retains 30% of its original strength and is not completely resorbed until 1 year.

**METHODS**

We used a single-center, prospective, randomized, rater-blinded clinical trial design to evaluate whether extended intradermal support would have a clinically significant effect on scar outcome. Written informed consent was obtained from all patients, and the study was approved by the institutional review board of the Dallas Veterans Affairs Hospital. We followed the protocols of the Declaration of Helsinki during the study. All veterans presenting to the dermatology clinic at the Dallas Veterans Affairs Hospital with biopsy-proven skin cancer located on the upper trunk necessitating local excision were eligible for the trial. Exclusion criteria included current or planned pregnancy; current breast-feeding; a history of ionizing radiation therapy, keloid or hypertrophic scarring, bleeding, or a collagen or an elastin disorder; current internal malignant disease; and current use of immunosuppressants. Participants received financial compensation for completion of the study. Patient enrollment took place from March 1 to June 30, 2009.

A split-repair design was created by repairing one-half of the elliptical excision with 3-0 intradermal polyglactin 910 and the other half with 3-0 intradermal P4HB. The side to which the specific suture was assigned was randomized (using a random number generator [http://www.random.org]), and the halves were designated as sides A and B. A polypropylene suture was used to align epidermal edges in each closure. Each wound was repaired by the same dermatologist (K.F.K.). Allocation of suture side was kept in a sealed envelope by the clinic support staff and not revealed to the surgeon until after the patient had consented to and been positioned for the procedure. The patient was not able to physically visualize which sutures were being used and was never informed of the randomization allocation.

The primary outcome measure was scar width, measured in millimeters. Width was measured using standardized high-resolution photographs by a blinded reviewer (T.V.). A separate measurement was also obtained in person (by K.F.K.). Scar width was measured using calipers at the midpoint of each half of the wound. Secondary outcome measures included measurement of scar aesthetics by blinded dermatologists (T.V. and S.W.) applying the Hollander Wound Evaluation Scale (HWE) and visual analog scale (VAS). The HWE addressed the following 5 clinical variables: width greater than 2 mm, presence or absence of elevation, color, presence or absence of hatch marks, and overall appearance. A score of 5 is the best possible score. The VAS is a 100-mm line with the worst possible scar represented by a score of 0, located at the far left end, and the best possible scar represented by a score of 100, located at the far right end. The HWE and VAS have been previously validated for use on photographs of scars. The scores assigned by both reviewers were averaged. All measurements were taken at 3 and 12 months after surgery. Adverse events, such as pruritus, pain, infection, suture reaction, dehiscence, and bleeding or hematoma, were also recorded and treated appropriately.

A power analysis performed before enrollment predicted that, with 25 participants (and an expected dropout rate of ≤20%), the study would have greater than 80% power to detect a 1-mm reduction in scar width. The study would have greater than 90% power to detect a 15-mm difference on the VAS and a 1-U difference on the HWE. These values were previously determined to represent the mean numerical differences indicative of a clinically significant difference.\(^7,8\) We used a paired \(t\) test for all continuous variables. Unless otherwise indicated, data are expressed as means (with 1 SD).

**RESULTS**

During the study, we examined 25 lesions on a total of 22 participants, with all lesions located on the back (Figure 1). Two patients were unavailable for follow-up before the 3-month postoperative examination (1 death from pneumonia and 1 patient becoming homeless). Consequently, data from the remaining 23 lesions were used for a per-protocol statistical analysis. The patients were all men, with a mean age of 69 years. The mean excision diameter was 2.3 cm, and the mean final length of closure was 7.2 cm. The 23 patients who remained in the trial were included in all statistical analyses (Table). The scar spread measured by rater-blinded review of standardized photographs was found to be significantly different between the 2 halves at both assessments. At the 3-month analysis, the P4HB sutures had...
a mean spread of 0.7 (0.7) mm and the polyglactin 910 had a mean spread of 1.7 (2.5) mm. The mean difference between these 2 scar spreads was 0.98 (1.61) (95% CI, 0.28-1.67 mm (P = .008). At 12 months, the mean scar spread for PH4B was 0.9 (1.5) mm and for polyglactin 910 it was 3.2 (4.3) mm, with a mean difference of 2.3 (3.0) (95% CI, 1.0-3.6) mm (P < .001) (Figure 2 and Figure 3).

At 3 months, the VAS and HWE were used to evaluate the scar as a secondary outcome. The VAS resulted in a score of 69 for P4HB sutures and 62 for polyglactin 910 sutures, with a mean difference of 7 (14) (95% CI, 1.0-3.6) mm (P = .02). Although this line represent patients whose scars were wider on the polyglactin side compared with the P4HB side. A, Scar spread at 3 months after surgery. B, Scar spread at 12 months after surgery.

for PH4B sutures was 0.8 (1.3) mm and for polyglactin 910 sutures it was 2.3 (2.7) mm, with a mean difference of 1.5 (2.3) mm (P = .004). We found no statistically significant difference between the mean differences noted by the primary investigator and the blinded reviewer.

Complications were classified as minor and major, depending on whether they were symptomatic to the patient. The side sutured with P4HB included 8 complications (35% of the 23 wounds analyzed). Seven of these complications were minor asymptomatic focal areas of erythema suggestive of local suture reaction. One reaction defined as major was a significantly inflamed suture reaction with sterile abscess formation and drainage. Two complications were noted on the polyglactin 910 side (9% of 23 wounds analyzed). One minor asymptomatic visible suture reaction was noted. One additional patient receiving aspirin and warfarin sodium developed a hematoma; however, his secondary dehiscence was completely isolated to the side of the wound with polyglactin 910 sutures.

### Table. Primary and Secondary Outcome Measure Results

<table>
<thead>
<tr>
<th>Suture</th>
<th>Scar spread, mm</th>
<th>Difference</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>P4HB</td>
<td>3 mo 0.7 (0.7)</td>
<td>1.0 (1.6)</td>
<td>.008b</td>
</tr>
<tr>
<td></td>
<td>12 mo 0.9 (1.5)</td>
<td>2.3 (3.0)</td>
<td>.001b</td>
</tr>
<tr>
<td>Polyglactin 910</td>
<td>3 mo 4.2 (1.1)</td>
<td>0.4 (0.9)</td>
<td>.07</td>
</tr>
<tr>
<td></td>
<td>12 mo 4.8 (1.2)</td>
<td>0.3 (0.7)</td>
<td>.02d</td>
</tr>
<tr>
<td>HWEc</td>
<td>3 mo 4.2 (1.1)</td>
<td>0.4 (0.9)</td>
<td>.07</td>
</tr>
<tr>
<td></td>
<td>12 mo 4.8 (1.2)</td>
<td>0.3 (0.7)</td>
<td>.02d</td>
</tr>
<tr>
<td>VAS, mmd</td>
<td>3 mo 69 (16)</td>
<td>7 (14)</td>
<td>.03d</td>
</tr>
<tr>
<td></td>
<td>12 mo 72 (13)</td>
<td>10 (12)</td>
<td>.001d</td>
</tr>
</tbody>
</table>

Abbreviations: HWE, Hollander Wound Evaluation Scale; P4HB, poly-4 hydroxybutyrate; VAS, visual analog scale.

a Unless otherwise specified, data are expressed as mean (SD).

b Indicates a statistically significant difference.

c Indicates measured on a scale of 1 to 5.

d Indicates a statistically significant difference, but that difference did not reach a predetermined clinical significant difference.

e Indicates measured on a scale of 1 to 100 mm.
In the choice of suture for high-tension wounds, a surgeon must consider not only the initial tensile strength necessary to bring the wound together but also the duration of action to keep the wound supported over time. The most commonly used suture in dermatologic surgery, polyglactin 910, provides excellent initial tensile strength but does not retain sufficient integrity to prevent long-term scar spread in high-tension wounds. Our study demonstrates that prolonged intradermal support is necessary to decrease scar spread.

Many studies have attempted to examine the relationship between scar spread and tension in a wound. Authors have attempted to prove this relationship by comparing single- vs double-layer closure. In a randomized controlled trial, a comparison between single- and double-layer closure in facial lacerations showed no significant difference in scar outcome. A similar study evaluated postlaminectomy wounds and found no significant difference in scar width after 2 to 3 months regardless of intradermal sutures. A study in Japan comparing 20 inguinal wounds repaired with polydioxanone and nylon sutures found no significant difference in scar width. Chantarasak et al found little difference in scar quality between polyglycolic acid and polydioxanone sutures in wounds under minimal tension. The common variable among these studies is that their closure was conducted on lacerations and incisional wounds, both of which exist under minimal tension. This scenario is different than most cutaneous oncologic surgery in which adjacent skin is being stretched to cover a defect.

Several studies support the idea that wounds under tension heal better with more intradermal support. A study with methods similar to those of the present study compared scar quality after closing wounds under tension with polyglycolic acid or polydioxanone. Polyglycolic acid, having a much shorter duration of action, produced significantly wider scars. Another study by Wray found that scar width and appearance correlated with the amount of tension required to close skin incisions after breast reconstruction.

Our study has several limitations that merit discussion. First, this study was performed in a uniformly white population, and therefore the results may not generalize to other skin types. In addition, the follow-up reported herein was restricted to 1 year after surgery. Additional follow-up may be necessary to determine long-term scar appearance.

The visible suture reactions were significantly more common on the P4HB side than on the polyglactin 910 side. Most of these reactions were asymptomatic to the patient (ie, erythematous macule visible within scar line [Figure 4]). However, a similar reaction on a more visible area (the face or extremities) may have been more distressing to the patient. In addition, 1 patient had a very significant inflammatory response on the P4HB side leading to a significantly poorer outcome, with a VAS of less than 10 of 100. This result demonstrates that, even if an inflammatory reaction is infrequent, its consequences can be clinically significant.

Overall, this study demonstrated significantly decreased scar spread favoring the longer-acting absorbable P4HB sutures. However, the use of a longer-acting absorbable suture increased the rate of suture reaction noted at 3 months. This study serves as proof that prolonged intradermal support will reduce scar spread in high-tension areas. Further studies into less reactive, longer-acting biomaterials are needed.

Accepted for Publication: December 6, 2012.
Published Online: April 17, 2013. doi:10.1001/jamadermatol.2013.3004
Correspondence: Kevin F. Kia, MD, Department of Dermatology, The University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd, Dallas, TX 75390-9069 (kevinfka@gmail.com).

Author Contributions: Dr Kia had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Kia, Vandergriff, and Weitzul. Acquisition of data: Kia and Vandergriff. Analysis and interpretation of data: Kia, Burns, and Vandergriff. Drafting of the manuscript: Kia and Vandergriff. Critical revision of the manuscript for important intellectual content: Kia, Burns, Vandergriff, and Weitzul. Obtained funding: Kia. Administrative, technical, and material support: Kia, Burns, and Vandergriff. Study supervision: Kia, Vandergriff, and Weitzul.

Conflict of Interest Disclosures: None reported.
Funding/Support: This study was supported by a grant from the American Society of Dermatologic Surgery. Sutures samples (P4HB) were donated by Tepha, Inc.

Role of the Sponsors: The sponsors had no role in the design and conduct of the study; in the collection, analysis, and interpretation of data; in the preparation of the manuscript; or in the review or approval of the manuscript.

References