Aesthetic and Functional Efficacy of Subcuticular Running Epidermal Closures of the Trunk and Extremity

A Rater-Blinded Randomized Control Trial

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**Objective:** To ascertain whether subcuticular epidermal closures of elliptical excisions of the trunk and extremities result in better functional and cosmetic outcomes than simple running epidermal closures of the same sites.

**Design:** Randomized controlled trial, with allocation of epidermal closure of elliptical excisions to 4 arms, including 1 control arm (simple running polypropylene sutures removed after 14 days) and 3 experimental arms (subcuticular running polypropylene sutures removed after 14 days, subcuticular running polypropylene sutures left in place, and subcuticular running polyglactin 910 sutures left in place). All experimental interventions were preceded by deep dermal closure with simple interrupted polyglactin 910 sutures. Interventions were delivered by 3 surgeons, who underwent 2 training sessions to minimize inter-surgeon technique variability.

**Setting:** Institutional referral practice providing ambulatory care in an urban environment.

**Patients:** A consecutive sample of 36 adult patients (ages 18-65 years), each referred for concurrent elliptical excision of at least 2 clinically atypical nevi of the trunk and/or extremity, were included in the study.

**Main Outcome Measures:** Primary outcome measures obtained at 3 and 9 months included scar width in millimeters and blinded observer ordinal scale assessment of overall scar appearance. Secondary outcome measures included ratings on the standardized Vancouver Scar Scale and the Hollander Scar Scale; an additional non-standard item was added to assess pruritus.

**Results:** No difference among groups was found in scar width at 3 or 9 months. Differences among groups were detected in overall scar appearance (3 months, \( P < .001 \); 9 months, \( P < .001 \)), vascularity (3 months, \( P = .001 \); 9 months, \( P < .001 \)), excessive distortion (3 months, \( P = .04 \); 9 months, \( P = .02 \)), contour irregularity (3 months, \( P < .001 \)), and edge inversion (3 months, \( P = .01 \)). The best overall appearance was with a subcuticular running polyglactin 910 suture left in place, and the next best was with a subcuticular running polypropylene suture left in place; differences across groups persisted but decreased in intensity at 9 months. A secondary analysis that matched high-tension anatomic sites (back and lower leg), and high and moderate tension sites (also chest and shoulder) yielded the same main effects and mostly the same results in pairwise comparisons.

**Conclusion:** While scar width does not appear to vary significantly based on choice of epidermal closure, bilayered closures of the trunk and extremity have better overall appearance and less associated erythema at 3 and 9 months after surgery with the use of a subcuticular running polyglactin 910 suture left in place.

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Among the factors that may affect the outcomes of elliptical excisions are the choices of suture type and suturing technique. Historically, the selection of technique and material has been a function of the surgeon's personal preference, informed by prior experience. With the exception of trials examining the utility of tissue adhesives, there are exceedingly few clinical trials specifically comparing the functional and aesthetic outcomes associated with different incision closure techniques. In general, the extant literature examining outcomes after elliptical excisions is focused on pretreatment prophylaxis of adverse events or posttreatment scar modification, by laser and other means, rather than on the initial choice of closure.

In this study, we systematically examined the aesthetic and functional outcomes associated with different types of sutured superficial closures used as part of bilayered repairs after elliptical excisions from the trunks and extremities. The primary means for reducing bias was a randomization protocol (see "Methods" section). Moreover, multiple surgeons participated to mitigate the effect of surgeon-specific factors, and each participating pa-
Patient was treated by 2 methods at 2 distinct sites to minimize the effect of patient-specific factors.

METHODS

PATIENT SELECTION

This study was approved by the Northwestern University institutional review board, and informed consent was obtained from all subjects. Patients were recruited from an urban university hospital dermatology practice. Specifically, consecutive adult patients (ages 18-65 years) who were determined by a staff dermatologist to have at least 2 clinically atypical nevi of the trunk and/or extremities that required excision were invited to participate. Exclusion criteria included location of the atypical nevi on the hands or feet, expected size of each suture line less than 2 cm, prior patient experience of keloids or atypical scars, and known patient hypersensitivity to any of the suture materials used in the protocol. Informed consent was obtained from all willing participants before surgery.

The period of recruitment was from August 2003 to November 2003. The period of follow-up was from August 2003 to August 2004.

SELECTION AND TRAINING OF SURGEONS

Three dermatologic surgeons, including 1 general dermatologic surgeon (M.C.M.) and 2 fellowship-trained Mohs micrographic surgeons (M.A. and D.A.W.), were the treating physicians. Each of these surgeons had obtained their surgical training at different institutions, under the mentorship of different teaching surgeons. Prior to the inception of the trial, the participating surgeons had 2 meetings to discuss the precise definitions and methodology of the 4 experimental arms and to ensure intersurgeon consistency of surgical technique; one of these meetings entailed a joint practice suturing session on pigs feet with simulated repairs. Following these meetings, each surgeon began enrollment of patients until each had accumulated 12 patients.

TECHNIQUE FOR REPAIR OF EXCISION WOUNDS

Given that each of 3 surgeons enrolled 12 subjects, each with 2 elliptical excisions, a total of 72 wounds were repaired. In every case, 2-mm margins were obtained around the visible nevus, and an elliptical excision performed with a 1.2:5 width-length ratio along minimum skin tension lines. Undermining was performed in the mid-subcutis to a width of 2 cm circumferentially around the defect. Deep dermis and subcutis were closed with vertical deep sutures of 3.0 (back) and 4.0 (all other trunk and extremity sites) polyglactin 910 (Vicryl; Ethicon Inc, Somerville, NJ) sutures placed 0.5 cm apart and no closer than 0.5 cm to each edge of the main axis (mean and median of 3 deep sutures per wound). Superficial closures were selected from 1 of the following 4 options, each of which entailed the use of a 5.0-caliber suture: (1) simple running polypropylene (Prolene; Ethicon Inc) to be removed in 14 days; (2) subcuticular running polypropylene (Prolene) to be removed in 14 days; (3) subcuticular running polypropylene (Prolene) to be left in place; or (4) subcuticular running polyglactin 910 (Vicryl) to be left in place.

OBJECTIVES AND HYPOTHESIS

The purpose of the study was to determine whether, in bilayered sutured closures of the trunk and extremities, certain superficial suture techniques would result in better opposed and less visually noticeable long-term surgical scars. Furthermore, it was hypothesized that (1) buried superficial closures would leave fewer permanent visible marks on the epidermis than would standard epidermal closures and (2) superficial sutures that were left in for long periods would be more successful at reducing long-term scar spreading than would superficial sutures that were removed at 2 weeks.

SAMPLE SIZE DETERMINATION

With a total of 36 patients in the study, each undergoing 2 different methods of wound closure, each method of closure was assigned to 18 patients. With 18 patients per method, the statistical power to detect a mean difference of 1 unit on the rating scale, assuming an SD of 0.50, was 80%. A 2-tailed test and type I error rate of 3% were assumed.

The results of this study confirmed the near accuracy of the standard deviation estimate and hence the adequacy of this sample size estimation. For the 3-month and 9-month time points, standard deviations of the study measures ranged from 0.33 to 0.74, with a median SD of 0.58. With the sample size and allocation described before, the statistical power to detect a mean difference in these measures of 0.54, assuming an SD of 0.58, was 80%. This effect size of 0.58 indicates that there is sufficient power to detect a mean difference of 1 unit on the rating scale, since the effect size of 0.58 represents an absolute difference in the means of the scales being measured.

RANDOMIZATION PROTOCOL

For each surgeon, each participating patient underwent a stratified randomization as follows (Figure 1): block randomization using 2 blocks of 6 was used to assign patients to 1 of 6 categories: (1) first site closed using option 1 and second site closed us-
OUTCOMES MEASURES

The primary outcome measures were (1) width of the surgical scar in millimeters and (2) overall appearance of the scar measured on a 5-point ordinal scale (subscale of Hollander Scar Scale). Secondary outcome measures were 2 standardized questionnaire measures, the Vancouver Scar Scale and the Hollander Scar Scale.

The Vancouver Scar Scale items measured vascularity, pliability, and height, each on a 3- to 6-point ordinal scale; pigmentation was measured on a 3-point categorical scale. Pliability was measured on a 3-point categorical scale.

Vascularity
- 0 = Normal
- 1 = Pink (slight increase in blood supply)
- 2 = Red (significant increase in blood supply)
- 3 = Purple (excessive local blood supply)

Pigmentation
- 0 = Normal color
- 1 = Hypopigmentation
- 2 = Hyperpigmentation

Pliability
- 0 = Normal
- 1 = Supple (flexible with minimal resistance)
- 2 = Yielding (giving way to pressure, offering moderate resistance, but does not behave as a solid scar mass)
- 3 = Firm (solid/inflexible unit, not easily moved, resistant to manual pressure)
- 4 = Banding (rope-like tissue that blanches with extension of scar, does not limit range of motion)
- 5 = Contracture (permanent shortening of scar producing deformity or distortion; limits range of motion)

Height
- 0 = Normal
- 1 = <2 mm
- 2 = ≥2 mm and <5 mm
- 3 = ≥5 mm

The Hollander Scar Scale items measured presence and absence of step-off borders, contour irregularities, margin separation, edge inversion, and excessive distortion and overall appearance, each on a 5-point ordinal scale (0=absence, 1=trace, 2=mild, 3=moderate, and 4=severe). An additional questionnaire item was added to assess the degree of pruritus.

DATA ANALYSIS

The live measurements by the blinded raters were used for data analysis. For reliability assessment, these live measurements were compared with post hoc ratings of all 3 sets of photographs at the end of the study. Blinded rater data were analyzed using linear model analysis, with person, surgeon, method, and the surgeon-by-method interaction in the model. For statistical analysis, SAS software (SAS Institute Inc, Cary, NC) was used. When the main effects for method and surgeon were significant (P<.05), pairwise comparisons were performed via the Bonferroni adjustment method. In this specific case, when comparing methods in a pairwise manner, the P value had to be less than .008, and when comparing surgeons in a pairwise manner, the P value had to be less than .02. Occasionally, none of the pairwise comparisons met the Bonferroni criterion even though the main effect was significant.

Separate analyses were obtained at each time point, with 11 different parameters analyzed at 3 time points. Each parameter was measured on an ordinal scale as 0, 1, 2, or 3 (some parameters had a possible response of “4,” but this was never selected by the surgeon).

Since specific anatomic locations on the trunk and extremities are associated with higher tension closures, a secondary analysis was performed by matching anatomic locations and reanalyzing the data. Matching was performed using 2 classifications of tension severity (SEV): (1) SEV1 was 1 for the upper and lower back and lower leg and 0 for all other locations; and (2) SEV2 was 1 for the upper and lower back, lower leg, shoulder, and abdomen and 0 for all other locations.
results

Of the 42 patients who were assessed for eligibility, 6 were excluded. Three did not meet inclusion criteria (planned excisions were not greater than 2 cm in length), and 3 declined to participate. A total of 36 patients with 72 surgical sites (Table 1) were randomized and allocated to intervention groups. Block randomization was devised to allocate 18 excision sites to each of 4 intervention groups. Of the randomized patients, 21 were female and the mean age of all patients was 42.6 years (range, 19-65 years). All of the allocated patients received intervention, and no patients were lost to follow-up through the end of the study (9 months after their initial surgery). Each of 3 surgeons treated 12 patients for elliptical excisions of their trunk and extremities. The intention-to-treat analysis was maintained (after randomization: 18 of 18 wounds in each of the 4 groups; 24 of 24 wounds for each of the 3 surgeons).

The mean ± SD length of initial closure was 2.52 ± 1.13 cm, and the mean ± SD width of closure immediately after suturing was 0.11 ± 0.03 cm. The mean ± SD time required for surgeons to close each ellipse was 12.9 ± 3.8 minutes, and there was no statistically significant difference between surgeons or between different types of closures. Similarly, initial postsurgery scores on the Hollander and Vancouver Scar Scales were similar across surgeons and types of closures. There were no sex-associated differences detected in overall scar appearance at 3 or 9 months, and age was not found to correlate with overall appearance.

Reliability analysis indicated no significant differences between the live and photographic ratings. Consequently, per protocol, the live ratings by blinded observers were used for the analysis.

No difference in suture line widths was detected across groups at either 3 months or 9 months. Since no overall differences were found, no pairwise comparisons of this parameter were conducted.

The overall appearance of wounds (Table 2) closed by the different methods was different at both 3 months (P < .001) and 9 months (P < .001) (Figures 2, 3, and 4). Contour irregularity (Table 3) differed across closure groups at 3 months (P < .001), but there was no residual main effect for method at 9 months (P = .33). Vascularity (Table 2), manifesting as a pink-red color, was different across groups at both 3 months (P < .001) and 9 months (P < .001). Vascularity was the only parameter that varied across different surgical techniques that was also found to vary across surgeons (Table 4). However, the significant main effect for surgeon was not associated with a consistent superiority of one surgeon or surgeons over the others. Edge inversion of scars, as manifested by partial failure of surgical eversion culminating in a depressed area, differed across closure methods at 3 months (P = .01) but not at 9 months (P = .14) (Table 3). Excessive distortion of scars differed for the various closures at both 3 months (P = .04) and 9 months (P = .02) (Table 2).

Examination of the data indicated that wounds in certain anatomic areas appeared to have greater scar width at 3 and 9 months. Post hoc analysis, which was not planned in the initial protocol, was conducted, dividing the wounds into 2 groups (back and nonback). A paired t test indicated significant differences between these groups at 3 months (P = .02) and 9 months (P < .001), with back wounds being wider. The size of the study precluded further subgroup analysis, but examination of the data did not reveal trends regarding the superiority of any suture technique for minimization of back wound scar width.

The only adverse events detected or reported were 2 cases of partial dehiscence and erosion reported in the center of wounds that were closed with subcuticular running polypropylene suture left in place (Figure 5). These were both noted at the 3-month follow-up visit and resolved subsequently.

A secondary analysis with excision sites matched for anatomic location was performed. Twenty-six of the exc-

Table 2. Overall Appearance, Vascularity, and Excessive Distortion of Scars by Closure Group at 3 and 9 Months

<table>
<thead>
<tr>
<th>Suture Closure Technique Group</th>
<th>Overall Appearance</th>
<th>Vascularity</th>
<th>Excessive Distortion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3 Months</td>
<td>9 Months</td>
<td>Score*</td>
</tr>
<tr>
<td>(1) Simple running polypropylene removed</td>
<td>2.33</td>
<td>1.96</td>
<td>Worse than (3) and (4)</td>
</tr>
<tr>
<td>(2) Subcuticular running polypropylene removed</td>
<td>2.05</td>
<td>1.89</td>
<td>Worse than (4)</td>
</tr>
<tr>
<td>(3) Subcuticular running polypropylene left</td>
<td>1.78</td>
<td>1.57</td>
<td>Worse than (4) initially; better than (1)</td>
</tr>
<tr>
<td>(4) Subcuticular running polyglactin 910 left</td>
<td>1.24</td>
<td>1.29</td>
<td>Better than (3) initially; better than (1) and (2)</td>
</tr>
</tbody>
</table>

Abbreviation: NS, no significant pairwise effects after Bonferroni adjustment for multiple comparisons.

*See the “Outcome Measures” subsection in the “Methods” section for a description of the scores.
cision sites were in anatomic locations associated with high tension (SEV1: upper and lower back and lower leg), 20 were in the moderate tension category (SEV2: chest and shoulder), and 26 were associated with low tension (all other sites). The distribution of sites by tension level and surgeon or closure method is given in Table 5.

The linear model analysis was repeated twice, once including SEV1 in the model and once including SEV2 in the model. In several instances, the results differed from the previous unadjusted analysis (Table 6). Overall, the results were the same in terms of main effects and mostly the same in terms of pairwise comparisons.

**COMMENT**

**PRINCIPAL FINDINGS**

The results of this study indicate that the choice of superficial closure technique in bilayered closures can affect short- to medium-term cosmesis and function. Immediately after closure, wounds closed by all 4 methods appeared similar in size, width, and other functional and cosmetic characteristics. However, at 3 and 9 months, these wounds differed with regard to vascularity, contour irregularity, and overall appearance.

Specifically, excisions closed by subcuticular polypropylene sutures left in place showed more contour irregularity than all the other closure methods at 3 months, but this difference was no longer statistically significant at 9 months. At 3 months, vascularity in the excisions closed by subcuticular running polyglactin 910 sutures left in place was less (less pink-red color) than in all the other groups, and vascularity in the excisions closed by simple running polypropylene sutures was substantially greater than in all the other groups; by 9 months, vascularity in all groups had
Comparison finding the following significant effects (at subcuticular running polypropylene suture (Prolene; Ethicon Inc, Somerville, NJ) left in place, this never rose to the level of significance in pairwise comparisons. At 3 months, overall appearance in the subcuticular running polyglactin 910 group persisted. At 3 months, overall appearance in the subcuticular running polypropylene suture group was better than that in all the other groups; at 9 months, this superiority was preserved except that the difference between the polyglactin 910 group and the subcuticular running polypropylene left in place group was no longer statistically significant. At both time points, the subcuticular running polypropylene suture left in place was better in overall appearance than the simple running polypropylene suture removed after 14 days.

At 3 months, edge inversion differed across methods, with the subcuticular running polypropylene suture left in place having the lowest value, which was statistically superior to that of the subcuticular running polypropylene suture removed after 14 days. Excessive distortion differed across methods at both 3 and 9 months. However, despite the trend toward lowest distortion in the subcuticular running polyglactin 910 suture left in place, this never rose to the level of significance in pairwise comparisons.

Overall scar width did not vary significantly among the 4 groups at 3 or at 9 months. In addition, while some patients complained of pruritus at various points, no systematic differences were found. Wounds at certain anatomic sites tended to have increased width regardless of the superficial closure method used; in particular, closures on the back resulted in inferior outcomes. With the exception of scar vascularity, none of the outcome parameters differed across surgical techniques or across surgeons.

### RELEVANCE AND LIMITATIONS OF PRINCIPAL FINDINGS

It appears that even in the hands of different surgeons trained in different programs, suture techniques can result in consistent differences in outcomes. We did not find that choice of superficial suture type or suture technique influenced the actual scar width. However, we did find that subcuticular superficial sutures left in place resulted in less redness during the first 9 months of wound healing, with the differences diminishing over time; possibly, the sutures that were left in place provided continuous strength at the closure site for many months and thus improved overall scar appearance. In addition, among subcuticular sutures, the absorbable variety (polyglactin 910) were associated with less redness and better overall appearance than the nonabsorbable (polypropylene) type. The nonabsorbable type were also more likely to result in contour irregularity but, if left in place, appeared to provide short-term reduction of wound inver-
sion. The observed overall superiority of absorbable sutures may derive from the relatively greater persistence of nonabsorbable sutures, which may function as foreign bodies, eliciting an increased incidence of spitting, apparent granulomas, and erosions.

These results suggest that oversimplification may undergird the folk wisdom that all elliptical excisions heal about equally well or that differences in surgeries are always of greater magnitude than differences in technique. Except for closures on the back, and possibly other high tension areas where local tissue factors may dwarf the effect of the closure method, superficial subcuticular sutures left in place appear to be a superior choice for bilayered trunk and extremity closures. The differences are subtle, primarily related to medium-term (3-month) redness and appearance, but they are real. In subcuticular closures, absorbable sutures may be less likely to cause problems associated with suture persistence.

Notably, apart from aesthetic and functional effect, overall procedure cost may be influenced by the type of bilayered closure selected. If the same caliber absorbable polyglactin 910 suture were used for deep and superficial closure of an elliptical excision, the cost of suture per closure could be reduced by at least one half. Even if a different caliber polyglactin 910 suture were used for superficial closure, this would be much less expensive than using a polypropylene suture for the top repair.

The generalizability and external validity of this study is significant, given that the relevant surgical procedures were performed by 3 different surgeons, who in turn received clinical training at different programs. However, all the surgical procedures were performed at the same referral center, and there may be systematic differences between practices here and elsewhere. Further, the generalizability of subjective evaluations is limited. For instance, what appears as a high level of “edge inversion” to one rater might systematically appear slightly less so to another. While validated measures such as the Vancouver and Hollander scales are more robust than ad hoc measures and while double-blind ratings are less susceptible to observer bias, subjective evaluations are still not likely to be as generalizable as objective measurements such as scar width.

We are not advocating a change in the standard of care, given that only the operating surgeon has adequate knowledge of the patient-specific factors that are crucial to treatment selection. We are suggesting that in the hands of a subset of surgeons and for a given group of patients, there is evidence that subcuticular closures left in place can improve scar appearance during the healing period. For younger patients and for scars at visible anatomic areas, such closures may result in decreased disfigurement and improved quality of life.

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