

Randomized Controlled Comparison of Cosmetic Outcomes of Simple Facial Lacerations Closed With Steri StripTM Skin Closures or DermabondTM Tissue Adhesive

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Objective: To compare the short-term complications and long-term cosmetic outcomes of simple facial lacerations closed with 3M Steri StripTM Skin Closures or DermabondTM.

Methods: Prospective, randomized controlled trial of children ages 1 to 18 presenting to a pediatric emergency department with simple low-tension lacerations of the face. After standard wound care, patients received wound closure with either Steri Strip Skin Closure or Dermabond. Pain associated with closure was evaluated on a 100-mm visual analogue scale (0 = no pain, 100 = worst pain). A follow-up telephone call was made a week after enrollment to determine short-term complications. Patients returned 2 months after wound closure for wound photography. Cosmetic outcomes were evaluated by 2 plastic surgeons blinded to the method of wound closure on a 100-mm visual analogue scale (0 = best scar, 100 = worst scar).

Results: One hundred children aged 1 to 18 were enrolled. Ninety-seven patients had results analyzed. Forty-eight received Steri Strip Skin Closures and 49 received Dermabond. Patient demographics and wound characteristics were similar between groups. Pain scores on a 100-mm visual analogue scale were 9.0 mm for the Steri Strip group and 6.2 mm for the Dermabond group ($P = \text{ns}$). At short-term follow-up, there was one wound complication in the Steri Strip group and 7 complications in the Dermabond group ($P = 0.06$). Eighty-nine patients received 2-month evaluation (41 Steri Strip, 45 Dermabond). There was no difference in the mean visual analogue scale cosmesis scores: 37.2 mm (95% CI = 30.8–43.7) versus 43.8 mm (95% CI = 38.4–49.2) ($P = 0.12$).

Conclusions: Steri Strip Skin Closures and Dermabond provide similar cosmetic outcomes for closure of simple facial lacerations. Steri Strip Skin Closure may represent a low-cost alternative for closure of simple facial lacerations.

Key Words: laceration, tissue adhesives, skin closures

Facial lacerations are a common complaint for pediatric patients presenting to the emergency department. Traditionally, sutures have been the standard for repair of these lacerations. The advent of topical anesthetics such as lidocaine, epinephrine, and tetracaine has made the repair of simple facial lacerations almost painless.^{1,2} However, several drawbacks to the use of sutures remain. Laceration repair using sutures is anxiety producing to the child. The child often must be restrained or sedated to allow completion of the procedure. Suturing requires advanced training to ensure a good cosmetic outcome and is time intensive.

Tissue adhesives are a class of compounds known as cyanoacrylates which bind to skin surfaces via a polymerization reaction. Tissue adhesives have good tensile strength, are bactericidal and bacteriostatic, have negligible histotoxicity, and peel off spontaneously.^{3,4} Several comparative studies involving low-tension wounds of the face have shown that tissue adhesives provide equal cosmetic outcome to suturing at both 2 months and 1 year follow-up, while causing less pain as measured on a visual analogue scale,⁵ and requiring less time for the completion of the procedure.^{3,4,6,7}

Reinforced Steri Strip Skin Closures are adhesive strips with reinforcing filaments which represent another alternative to sutures for simple low-tension lacerations. They are inexpensive, easy to apply, and spare the child the need for potentially painful and anxiety-producing sutures. Adhesive strips have been shown to provide similar and, in some cases, superior cosmetic results to skin stapling.^{8–11} They also appear to decrease infection risk compared with sutures or staples.¹² Many pediatricians have used adhesive strips as an alternative to suturing for the closure of simple facial lacerations in children.

Few studies have compared adhesive strips to tissue adhesives for closure of lacerations in children.^{13,14} Mattick et al¹³ showed equivalence between the two methods but included complete data on only 44 patients, and the length

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of follow-up was not standardized. The study of Singer et al¹⁴ of 924 lacerations or incisions included 132 closed with adhesive tapes, however, only a third of the total procedures were performed on traumatic lacerations, the rest were on surgical incisions.

We hypothesized that Steri Strips would provide equivalent long-term cosmetic outcome compared with Dermabond tissue adhesive for traumatic lacerations of the face in children. We also hypothesized that the two methods would be equivalent in regards short-term outcomes (infection and dehiscence) and cause minimal pain with application.

METHODS

The primary purpose of this study was to compare the cosmetic outcome for closure of simple facial lacerations in children using Reinforced 3M Steri Strip Skin Closures[®] and Dermabond[®] topical tissue adhesive.

Patients presenting to a pediatric emergency department at a single urban children's hospital were eligible for the study. Patients enrolled were between 1 and 18 years with facial lacerations less than 2.5 cm in length and less than 12 hours old. Patients with lacerations in areas of high tension or mobility (ear, nose, mouth) or which required deep sutures or were grossly contaminated were excluded from the study. Those wounds, which were not amenable to one of the proposed methods of wound closure, were also excluded. Exclusion decisions were made by one of the investigators prior to randomization.

All treating clinicians (2 Pediatric Nurse Practitioners, 1 Physician Assistant, and 1 Physician) were experienced in wound management techniques and trained by representatives from 3M (for Steri Strip Skin Closure) and Ethicon (for Dermabond) prior to the onset of the study.

This study was reviewed and approved by the appropriate Institutional Review Board. Informed consent was obtained from all patients (assent and parent consent). Randomization was performed using a computer-generated randomization pattern. A sealed envelope contained in a consecutively numbered data packet was opened to determine whether the patient would have their wound closed with Dermabond topical tissue adhesive or Steri Strip Skin Closures. Anesthesia with lidocaine, epinephrine, and tetracaine was provided if deemed necessary by the treating clinician. Wound management was done in a routine manner including thorough cleansing and irrigation.

Patients in the Dermabond group had their wound edges manually approximated by either fingertips or forceps. The wound edges were then painted with the tissue adhesive applicator tip.

Patients in the Steri Strip group had their wound edges manually approximated by either fingertips or forceps. Skin up to the wound edges were painted with Compound Benzoin Tincture, which was allowed to dry prior to Steri

Strip placement which was perpendicular to the wound edges. A second layer of Steri Strip Skin Closures was placed perpendicular to the first layer. Subjects in both groups were told to keep the wounds dry for at least 5 days and to allow the tissue adhesive or Steri Strip Skin Closures to peel off spontaneously.

A telephone follow-up to inquire about wound dehiscence and wound infection was done a week after wound closure. The investigator who made all follow-up telephone calls was not blinded to the treatment group. Any patient with dehiscence or infection was instructed to contact the study investigator and return immediately for evaluation. Dehiscence was felt to occur if the parent or examiner felt that opening of the wound had occurred after closure. Wounds with complications were treated at the discretion of the treating clinician.

Two months following wound closure, patients returned to have wounds photographed. Photographs were completed with a single camera in a standardized fashion in regards to distance from the subject, lighting, and exposure.

Data collection included general demographic data as well as wound data. Outcome variables included time required to perform wound closure and pain of wound closure which was evaluated by the parent/guardian or the child (if greater than 5 years) using a 100-mm visual analogue scale (0 = no pain and 100 = maximal pain). Wound cosmesis was evaluated using the photographs taken at 2 months after wound closure. The assessment was completed by 2 cosmetic surgeons blinded to the method of wound repair using a 100-mm visual analogue scale (0 = best scar and 100 = worst scar).⁵

The sample size for this study was calculated on the primary outcome, wound cosmesis. It was previously determined that the minimal clinically important difference on the cosmesis VAS is 10 to 15 mm.¹⁵⁻¹⁷ The standard deviation of the cosmesis scores was estimated as 14 mm. To detect a difference in cosmesis of 10 mm, with $\alpha = 0.05$ (2-tailed) and a power of 90%, 43 patients per group would be needed.

Descriptive statistics for all variables were calculated. Differences between groups for dichotomous variables were assessed using a Fisher exact test. Exact binomial confidence limits were calculated for the 1-week follow-up evaluation of healing. Outcome variables of pain visual analogue scores, time for closure of the wound, and cost of closure did not meet the assumption of normality and were analyzed using the Wilcoxon rank sum test. In addition, 95% confidence limits were calculated around the median. Cosmesis was compared between the treatment groups using the *t* test for independent samples, as the assumption of normality was met. The 95% confidence limits were calculated around the mean. Significance for all analyses was assessed at $P < 0.05$ (2-tailed). The strength of the agreement between

the clinicians who rated cosmesis was evaluated using the intraclass correlation coefficient. This measure combines information from the *t* test and the product-moment correlation.

RESULTS

Patients were enrolled between June 1999 and July 2001. Cosmetic evaluation was completed in September 2001. One hundred patients were enrolled and randomized into the study (Fig. 1). Enrollment took place only when one of the investigators was available in the emergency department. Three patients were excluded for protocol violations (all nonfacial wounds, 2 in the Steri Strip group, 1 in the Dermabond group). A total of 97 patients met the inclusion and exclusion criteria were included in the analysis (48 Steri Strip and 49 Dermabond). Baseline demographics and wound characteristics are displayed in Table 1. There was a significant difference in topical anesthesia use between groups ($P < 0.03$).

Pain was evaluated after closure of the laceration. Forty-three percent of the pain assessments were done by the patient and 57% were done by the parent/guardian. There was no difference in mean pain assessment scores between closure methods (Table 2).

Short-term Follow-up

Short term follow-up data are shown in Table 2 and complications are listed in Table 3. Ninety-three of 97 patients had short-term follow-up. Wound complication rate was similar between groups ($P = 0.06$).

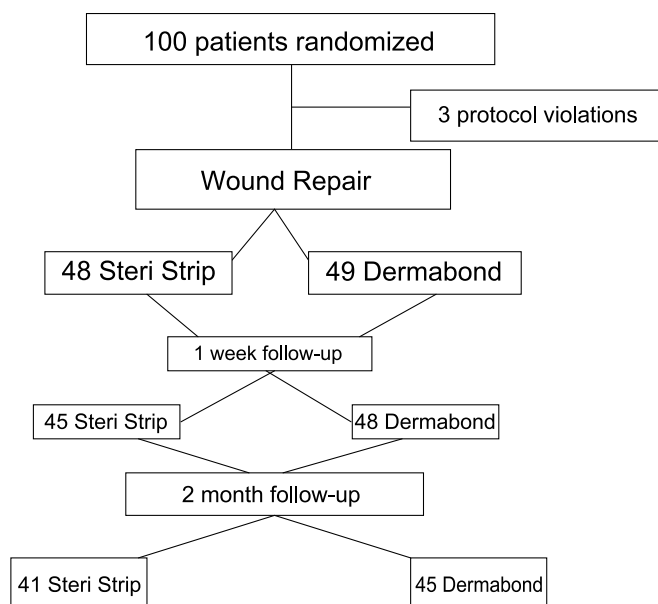


FIGURE 1. Trial profile.

TABLE 1. Demographics and Wound Characteristics

	Steri Strip (n = 48)	Dermabond (n = 49)
Age, mean [SD], y	5.2 [2.7]	5.3 [4.1]
Gender		
Male	27 (56%)	33 (67%)
Female	21 (44%)	16 (33%)
Race		
White	29 (60%)	18 (37%)
Black	8 (17%)	8 (16%)
Hispanic	11 (23%)	22 (45%)
Other/unknown	0 (0%)	1 (2%)
Length of wound, mean [SD], cm	1.4 [0.6]	1.3 [0.6]
Depth of wound, mean [SD], cm	0.4 [0.1]	0.3 [0.1]
Location		
Forehead	33 (69%)	32 (65%)
Chin	10 (21%)	11 (22%)
Upper cheek	1 (2%)	3 (6%)
Eyelid	2 (4%)	0 (0%)
Eyebrow	2 (4%)	3 (6%)
Anesthetic*		
Lidocaine, epinephrine, and tetracaine	34 (71%)	44 (90%)
None	14 (29%)	5 (10%)
Time to close, mean [SD], minutes	3.7 [2.1]	3.0 [1.9]

*Fisher exact test, $P < 0.03$.

Two-Month Follow-up

At the 2-month follow-up, 41 patients in the Steri Strip group and 45 in the Dermabond group had a photograph available for the cosmetic rating of the scar (0 mm = "best scar," 100 mm = "worst scar"). For surgeon 1, the mean cosmesis visual analogue score for the Steri Strip group was 28.0 ± 23.95 , and for the Dermabond group was 37.0 ± 23.6 , $P = 0.08$. For surgeon 2, the mean cosmesis visual analogue

TABLE 2. Pain Rating and Short-term Follow-up

	Steri Strip (n = 45)	Dermabond (n = 48)
Pain rating, mean [SD]	9.0 [15.3]	6.2 [5.8]
Median	3.0	4.0
95% CI around the median	(2.0–6.0)	(3.0–7.0)
Days to follow-up, mean [SD]	8.3 [1.6]	8.2 [2.4]
Healing uneventful*	44 (98%)	41 (86%)
95% CI	(89%–100%)	(73%–94%)
Wound infection	0 (0%)	1 (2%)
95% CI	(0%–7%)	(0%–11%)
Wound dehiscence	1 (2%)	6 (12%)
95% CI	(0%–11%)	(5%–25%)

*Fisher exact test, $P < 0.06$.

TABLE 3. Review of Short-term Complications

Closure	Complication	Day	MD Re-eval	Comment
Dermabond	Dehiscence	Day 1	yes	small—no treatment
Dermabond	Dehiscence	Day 3	no	post trauma, reported day 10
Dermabond	Dehiscence	Day 2	yes	Dermabond removed, Steri Strips applied
Steri Strips	Dehiscence	Day 3	no	not reported until day 10
Dermabond	Dehiscence	Day 2	yes	small—no treatment
Dermabond	Dehiscence	Day 3	no	not reported until day 10
Dermabond	Infection	Day 2	yes	Dermabond removed, Steri Strips applied
Dermabond	Dehiscence	Day 6	yes	post trauma, sutured

score for the Steri Strip group was 46.5 ± 21.5 , and for the Dermabond group was 50.6 ± 16.4 , $P = 0.33$. The mean cosmetic outcomes are shown in Table 4. There was no difference in cosmetic scores between groups. The intraclass correlation coefficient for the 2 evaluators was 0.48, which indicates moderate agreement.

DISCUSSION

The ideal method for closure of simple facial lacerations remains controversial. The ideal technique for laceration closure would be painless, inexpensive, easily and quickly applied, require minimal training and expertise on the part of the practitioner, and result in a cosmetically attractive repair.¹⁸

Dermabond (2-Octylcyanoacrylate) meets many of the criteria necessary for an ideal wound closure device. It is relatively easy to learn how to apply, its application can be achieved more quickly than sutures, and it does not require a return visit for removal.^{3,4,6,7} Dermabond application is also considerably less painful than sutures.^{3,4,6,7} Several comparative studies involving low-tension wounds of the face have shown that tissue adhesives including Dermabond provide equal cosmetic outcome to suturing at 2 months, 3 months, and 1-year follow-up.^{3,4,6,7}

However, Dermabond use is expensive. The cost for a vial of Dermabond ranges from 24 to 30 dollars, although the charge to the patient is usually significantly higher.¹⁹ The application of Dermabond requires hemostasis prior

to application, and some patients report a burning sensation on administration.¹⁹ Both of these issues can be remedied with the application of a topical anesthetic.

Although initial studies of cyanoacrylates have shown them to have a comparable complication rate to sutures, some studies have shown that the complication rate associated with Dermabond may be higher than previously reported. Kharasch et al²⁰ evaluated 35 lacerations closed with Dermabond. At 1-week follow-up, there was a 19% complication rate associated with Dermabond use (5/26), including 2 patients with wound dehiscence, 2 patients who picked off the Dermabond, and 1 wound infection. A recent meta-analysis found that cyanoacrylates have a higher dehiscence rate than sutures.²¹

Reinforced Steri Strip Skin Closures are adhesive strips with reinforcing filaments which represent an alternative to sutures for simple low-tension lacerations. They meet many of the characteristics of an ideal wound closure technique in that they are inexpensive, easy to apply, and spare the child the need for potentially painful and anxiety-producing sutures. They have been used for years for skin closure as an adjunctive wound support for staples or sutures. When used alone, adhesive strips have been shown to provide similar and, in some cases, superior cosmetic results to skin stapling.⁸⁻¹¹ However, these studies did not use any objective assessment parameters for comparison of wound cosmesis. Adhesive strips induce less erythema than sutures by eliminating localized areas of tension.²² They also appear to decrease infection risk compared with suturing.¹² Wounds closed with adhesive strips have been shown to have equal or superior tensile strength compared with sutured wounds 10 days after wound closure.²³ In a comparison of 7 adhesive strips, Steri Strip Skin Closures showed the best adhesion time when an artificial force was applied.²⁴

The theoretical disadvantages of adhesive tapes are that they frequently fall off, have lower tensile strength than sutures, have the highest rate of dehiscence, require the use of toxic adjuncts, cannot get wet, and cannot be used in areas of hair.¹⁸ However, several of these disadvantages are not supported. Steri Strip Skin Closures package insert indicates

TABLE 4. Cosmetic Outcome—2-Month Follow-up

Cosmetic Rating*	Steri Strip (n = 41)	Dermabond (n = 45)
Mean [SD]	37.2 [20.5]	43.8 [18.0]
Median	34.5	43.0
95% CI around the mean	(30.8–43.7)	(38.4–49.2)

0 mm = best scar, 100 mm = worst scar.

*Average of 2 evaluators.

that unless contraindicated, patients may shower 24 hours after the strips were applied. However, adhesion may be improved when bathing is limited. Some clinicians use an adjunct such as Compound Benzoin Tincture to increase adhesion, being careful to avoid contacting the wound edge. There is limited data to support the notion that adhesive tapes fall off easily. In a comparison of 2 adhesive tapes, Clearon and Steri Strip Skin Closures, which were placed on the backs of 20 adult volunteers, Clearon lasted for a mean of 3.4 days, however, Steri Strip Skin Closures lasted for a mean of 8.5 days, certainly long enough to provide effective closure of low-tension wounds of the face.²⁵ In a comparison of sutures, tissue adhesives and adhesive tape for skin closure after phlebectomy, none of the 26 of the wounds closed with adhesive tape had evidence of dehiscence or infection 10 days after closure.²⁶ Mattick's¹³ comparison of Dermabond and Steri Strips did not address short-term outcomes.

In our study, Steri Strip Skin Closures performed as well as Dermabond with regard to short-term outcomes. Only one patient in the Steri Strip group suffered a wound dehiscence. We did use Compound Benzoin Tincture and placed a second layer of Steri Strip Skin Closures perpendicular to the first layer. This layering may have improved our adherence, although a previous study found that adding a tacking strip on each end of the first layer of strips did not increase the duration of adherence.²⁷

The high rate of dehiscence in our Dermabond group is concerning. Two of the 6 patients who experienced dehiscence suffered trauma to the wound, which can be unavoidable. Only 3 of the patients who had dehiscence in the Dermabond group needed intervention. The potential that increased use of topical anesthetic in the Dermabond group led to an increase in the dehiscence rate needs to be considered. Although Dermabond was a new product when the study was started, all investigators received training in Dermabond application prior to beginning the study. In addition, the investigators had the opportunity to use Dermabond for several months as part of routine wound care prior to beginning the study.

Our evaluation of complications was limited in that we relied on parent evaluation to note dehiscence. Two of the Dermabond patients had wound dehiscence which was reported by the parents but not evaluated by a clinician. Since Dermabond is clear, parents in this group may have noted dehiscence more readily. Steri Strips impede direct observation of the wound potentially leading to an underestimation of complications.

Cosmetic outcomes for the 2 wound closure methods were equivalent as rated by 2 plastic surgeons who were blinded to the method of wound closure. Our findings are similar to Mattick¹³ who also used a visual analogue scale to assess cosmetic outcomes of lacerations closed with

Dermabond or Steri Strips. A previous study used a 5-point Likert scale to compare phlebectomy wounds closed with adhesive tape, sutures, and octylcyanoacrylate and found no difference between the groups.²⁶

Our study does have other limitations. We used a less traditional 2-month period to evaluate for cosmetic outcome. While some studies have used a 2-month period to determine cosmetic outcome, others have used a 3-month or 1-year period. Simon et al⁶ found a consistent cosmetic outcome in their patients with low-tension facial wounds at both 2 months and 1 year follow-up. Quinn et al²⁸ showed a strong association between 3-month and 1-year wound scores. There are no data to suggest that waiting an additional month to evaluate our wounds would result in a change in the outcome of this study.

Four clinicians enrolled all wounds during their clinical duties in the emergency department. Wounds, which were cared for by other clinicians or at other times, were not enrolled. This could lead to selection bias as other clinicians could have evaluated patients who were felt to be inappropriate for the study. We elected not to include a group of patients who had their facial lacerations closed with sutures. We felt that the data available at the onset of the study supported the equivalence of tissue adhesives and sutures for closure of simple facial lacerations. We did not feel it was appropriate to randomize our patients to a technique that was intrinsically more painful and time consuming, but offered no clear advantage.

The correlation between the plastic surgeons evaluating the wounds was only 0.48. Other studies have shown better intraclass correlation for the visual analogue scale.⁶ Although the visual analogue scale has been validated for wound cosmesis, our low correlation could call into question the reliability of the visual analogue scores in our study.

CONCLUSIONS

Steri Strip Skin Closures remain an inexpensive alternative to closure of simple facial wounds in children. Short-term complications and long-term cosmetic outcomes are similar in wounds closed with Steri Strip skin closures and Dermabond tissue adhesive.

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