A Randomized Controlled Comparison of Guardian-Perceived Cosmetic Outcome of Simple Lacerations Repaired With Either Dermabond, Steri-Strips, or Absorbable Sutures

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Objectives: The aim of this study was to compare the guardian-perceived 3-month cosmetic outcome for pediatric lacerations repaired with absorbable sutures, Dermabond, or Steri-Strips. Secondarily, pain and satisfaction with the procedure from both guardian and provider perspectives were compared.

Methods: In this randomized controlled trial, we enrolled a convenience sample of children aged 0 to <18 years who presented with simple linear lacerations (≤5 cm in length, ≤0.5 cm in width, and <12 hours old) to a pediatric emergency department. Children were randomized to receive laceration repair with absorbable sutures, Dermabond, or Steri-Strips. Topical L.E.T. solution (lidocaine, epinephrine, tetracaine) was applied to wounds which were then closed by the primary team. Guardians and providers completed questionnaires regarding perceived pain and satisfaction with the procedure. Guardians were contacted 3 months after the repair and asked to email a picture of the scar with their perception of cosmesis rated on a visual analog scale from 0 to 100.

Results: Fifty-five patients were enrolled, of whom 30 completed 3-month follow-up (12 suture, 7 Dermabond, 11 Steri-strips). There was no statistical evidence of an association between scar appearance and closure method based on medians and interquartile ranges for cosmetic ratings of scar: suture median 70.5 (IQR 59.8–76.8), Dermabond median 85 (IQR 73–90), Steri-strips median 67 (IQR 55–78) ($P = 0.254$). Guardian satisfaction with length of stay, guardian and physician satisfaction with the procedure, and guardian and physician-perceived pain also showed no differences.

Conclusions: No differences were observed in guardian-perceived cosmesis of simple lacerations repaired with sutures, Dermabond, or Steri-Strips when evaluated 3 months after intervention. In addition, there were no differences in guardian or physician-perceived pain or satisfaction with the closure methods. The results of this study suggest that all 3 closure methods appear to be clinically equivalent, which is largely consistent with other evidence. Further study should be expanded to a larger demographic.

Key Words: laceration, sutures, absorbable sutures, Dermabond, Steri-Strips, tissue adhesive, surgical tape, simple pediatric laceration, cosmesis, pain, satisfaction, guardian, guardian-perceived, cosmetic outcome

(*Pediatr Emer Care* 2024;40: 700–704)

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Disclosure: The authors declare no conflict of interest.

This study was supported in part by the Vanderbilt CTSA grant UL1TR002243 from NCATS/NIH, a $6500 grant to support subject compensation, statistical support and administration costs of the study.

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ISSN: 0749-5161

Each year approximately 9 million people are seen in emergency departments (EDs) in the United States for lacerations.[1,2] Lacerations are a common chief complaint in the pediatric ED.[3–5] Historically, sutures have been the preferred method of closure for lacerations; however, this method of repair can be painful and traumatic for children.[2,5] Less invasive methods of wound closure are available including surgical tape and tissue adhesives.[6–8] In addition to being faster

they are also less expensive and may reduce sedation needs leading to decreased length of stay (LOS) in the ED.[9–14]

While suture alternatives have been shown to adequately close wounds, there are few studies that directly evaluate the cosmesis of suture alternatives for lacerations specific to the pediatric population.[14–17] Most studies have used older versions of tissue adhesives, had small sample sizes, or were used on iatrogenic lacerations such as laparoscopic trocar incisions.[18–26] A 2020 meta-analysis, evaluating both adults and children with surgical and nonsurgical wounds, compared tissue adhesives, surgical tape, and sutures, and showed that surgical tape appeared to convey the best clinician-rated cosmesis.[27] This evidence suggests that good cosmesis is possible with alternative suture methods.

This study provides a comparison of the 3-month cosmetic outcome for pediatric lacerations closed with suture versus a tissue adhesive, Dermabond, or surgical tape, Steri-Strips. The aim of this study is to compare how different methods of pediatric laceration repair affect cosmetic outcome from the perspective of the patient's guardian. Secondarily, the study assesses pain and satisfaction with the procedure from both guardian and provider perspectives, guardian satisfaction with LOS, and provider comfort with the procedure.

METHODS

Study Design and Setting

We performed a randomized controlled trial of a convenience sample of children who presented to a pediatric ED at a single children's hospital.

Selection of Participants

Patients were included if they were age 0 to <18 years, English-speaking, and their ED visit was for a simple linear laceration. Simple linear laceration was defined as ≤5 cm in length, ≤0.5 cm in width, and <12 hours old. Patients were excluded if they had medical history that may impact wound healing (defined as hematologic or oncologic diagnoses requiring chemotherapy, ichthyosis, or epidermolysis bullosa). Additional exclusion criteria included use of oral steroids (defined as more than 5 days in the past month), history of keloid formation, allergy to tissue adhesives or topical anesthetic, or lack of access to photographic capabilities and email. Lacerations were excluded if they required subcutaneous sutures, were

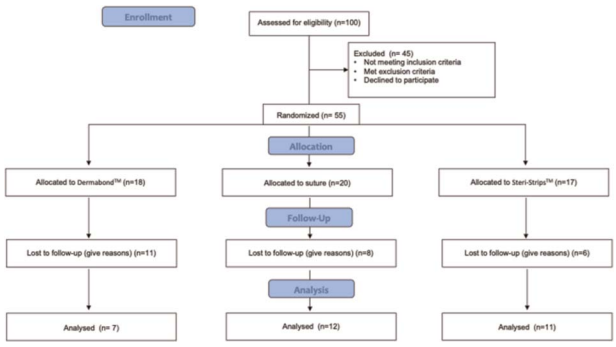

FIGURE 1. Enrollment flow diagram.

caused by animal bites or scratches, and were located on the scalp, eyebrow, eyelid, lip, mucosa, nailbed, or overlying a joint.

Study Procedures

This research was reviewed and approved by the institutional review board of Vanderbilt University Medical Center (IRB# 171108). This trial was registered in advance at clinicaltrials.gov (NCT03280628). Written consent and assent, when applicable, were obtained for any child meeting inclusion and exclusion criteria before laceration repair in the ED. The participant was then randomized to 1 of the following 3 arms: Dermabond, Steri-Strips, or absorbable sutures. The randomization sequence was generated using randomizer.org and implemented using sequentially numbered, sealed, opaque envelopes. On completion of consent/assent, the envelope was opened, and the participant assigned a study group.

For all lacerations, topical L.E.T. solution (lidocaine, epinephrine, tetracaine) was placed on the laceration for analgesia and wound irrigation performed with sterile normal saline. The wound was closed by the primary ED team according to the patient's assigned study group (Dermabond, Steri-Strips, or absorbable sutures). The proceduralist was a pediatric or emergency medicine resident, an ED-based advanced practice nurse practitioner, or a pediatric emergency medicine fellow or attending. Given the nature of the study, neither the patient, guardian, nor health care provider was blinded to the method of closure. Injected anesthetics, anxiolysis, or the use of sedation were left to the provider's discretion.

After the procedure, the patient's guardian was asked to fill out a questionnaire about pain control, satisfaction with the procedure, and satisfaction with the ED LOS. The healthcare provider was also asked to fill out a questionnaire with similar questions. Demographics were extracted from the patient electronic medical record and from the guardian questionnaire. The laceration location and size and the level of training of the provider were recorded at the time of the ED visit. All data were recorded directly into a REDCap database housed at Vanderbilt University Medical Center.[28]

At discharge, the patient and guardian were provided with standardized verbal and written return precautions by the study staff. Each participant's guardian was sent an online REDCap survey via email at 3 months after the initial ED visit. The survey prompted them to rate 6 preselected scars to help standardize guardian responses. They were also asked to take a picture of the child's scar and upload and rate the child's scar through the REDCap survey. If they were unable to take or upload a photo then they were asked to meet with study staff and fill out all questions on paper, and at that time a photo of the child's scar could be taken and recorded. The participant was compensated with $15 after completion of all study requirements.

Primary Outcome Variable

The primary outcome of this study is the cosmetic appearance of the resultant scar as rated by the patient's guardian at 3 months after closure. The appearance was measured on a 100-mm sliding visual analog scale (VAS) where a score of 0 corresponds to "worst scar appearance" and a score of 100 corresponds to "best scar

TABLE 1. Baseline Demographics and 3-Month Follow-up by Closure Method

	Dermabond		Suture		Steri-Strip	
Characteristic	**Enrolled**	**Follow-up**	**Enrolled**	**Follow-up**	**Enrolled**	**Follow-up**
n	18	7	20	12	17	11
Age, median (IQR)	4.00 (3.00, 5.00)	5.00 (3.50, 5.00)	3.50 (2.75, 5.00)	4.00 (3.00, 5.25)	3.00 (2.00, 5.00)	3.00 (2.00, 5.00)
Male, no. (%)	14 (77.8)	5 (71.4)	17 (85.0)	10 (83.3)	12 (70.6)	8 (72.7)
Race, no. (%)						
White	9 (50.0)	5 (71.4)	12 (60.0)	8 (66.7)	12 (70.6)	8 (72.7)
Black	4 (22.2)	1 (14.3)	5 (25.0)	3 (25.0)	3 (17.6)	1 (9.1)
Other	4 (22.3)	0 (0.0)	3 (15.0)	1 (8.3)	1 (5.9)	1 (9.1)
Unknown	1 (5.6)	1 (14.3)	0 (0.0)	0 (0.0)	1 (5.9)	1 (9.1)
Proceduralist, no. (%)						
Resident	10 (55.6)	2 (28.6)	7 (35.0)	5 (41.7)	11 (64.7)	7 (63.6)
PEM fellow	1 (5.6)	0 (0.0)	4 (20.0)	2 (16.7)	2 (11.8)	2 (18.2)
Nurse practitioner	4 (22.2)	3 (42.9)	6 (30.0)	4 (33.3)	3 (17.6)	2 (18.2)
PEM attending	3 (16.7)	2 (28.6)	3 (15.0)	1 (8.3)	1 (5.9)	0 (0.0)
Laceration length (cm)						
Mean (SD)	1.46 (0.59)	1.46 (0.74)	1.55 (0.42)	1.60 (0.45)	1.28 (0.33)	1.30 (0.29)
Median (IQR)	1.50 (1.00, 2.00)	1.50 (1.00, 1.50)	1.50 (1.19, 2.00)	1.75 (1.19, 2.00)	1.00 (1.00, 1.50)	1.50 (1.00, 1.50)
Laceration width (cm)						
Mean (SD)	0.46 (0.07)	0.50 (0.00)	0.42 (0.12)	0.44 (0.10)	0.40 (0.13)	0.45 (0.13)
Median (IQR)	0.50 (0.50, 0.50)	0.50 (0.50, 0.50)	0.50 (0.30, 0.50)	0.50 (0.38, 0.50)	0.50 (0.30, 0.50)	0.50 (0.50, 0.50)

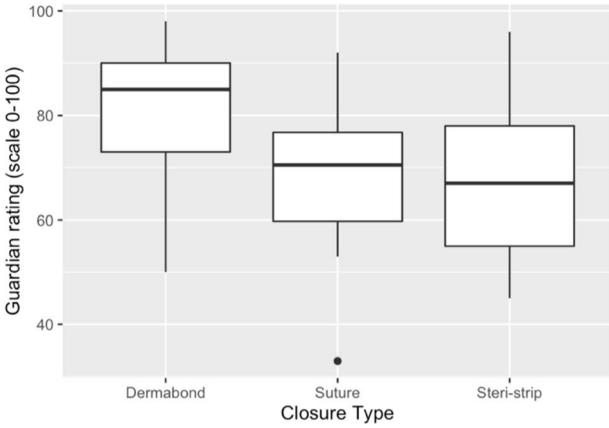

FIGURE 2. Guardian cosmetic rating of scar at 3-month follow-up by closure method.

appearance." This scale has been validated as a scoring method to evaluate cosmesis of scars; it is sensitive to small changes allowing for smaller, more practical sample sizes to show clinically significant differences in populations.[22,25–28] Before rating their own child's scar, guardians also rated 6 preselected, standard scars to provide an individualized scoring benchmark.

Secondary Outcome Variables

Secondary outcomes included pain experienced by the patient separately evaluated by the guardian and provider at the time of the ED visit. Guardians and providers were each asked to score how much pain they felt the patient experienced on a 100-mm sliding VAS with a score of 0 corresponding to "no pain" and a score of 100 corresponding to "terrible pain." Guardian satisfaction with LOS and provider comfort with procedure were also measured on a 100-mm sliding VAS with a high score being anchored with "very satisfied" and "very comfortable" respectively.

Statistical Analysis

Initial analysis characterized the study cohort overall and grouped by assignment. Categorical variables are presented as counts with percentages and continuous variables as median (interquartile range [IQR]) or means (standard deviation). For the primary outcome, a proportional odds model was fit to determine if there was an association between closure method and cosmesis. Unadjusted and adjusted odds ratios (ORs) quantifying the association of closure type and a better cosmetic rating of scar by guardian were estimated from the ordinal logistic regression models. The model for the primary outcome was adjusted for the guardian's individual scoring benchmark. Associations between closure method and secondary outcomes were also assessed using proportional odds models. For secondary outcomes, the covariates were child's age and the training level of the proceduralist. Models are reported with 2-sided 95% confidence intervals; the critical *P* value was set at 0.05. There were no missing variables for covariates or outcomes. All analyses were conducted using R version 4.0.2, including the rms extension package.

Sample Size Considerations

In previous studies, cosmesis scored with a standard deviation of 15 mm on the 100-mm VAS, and the minimal clinically important difference between 2 scars has also been declared as 15 mm on a 100-mm VAS.[29] Assuming a variance among mean VAS of about 70 reflecting at least 1 of the closure methods deviating by 15 mm from another, 15 participants per group have 90% power for an overall effect of closure method. With a sample size of 15 in each group, the study would have 90% power to detect a meaningful difference in a 2-group comparison using a Wilcoxon rank sum test. We aimed to recruit 20 patients per group to allow for lost to follow-up.

RESULTS

Between September 2017 and December 2020, a total of 100 patients were approached and 55 patients were included in the study. Thirty patients completed 3-month follow-up (12 suture, 7 Dermabond, 11 Steri-Strips) (Fig. 1). Median age was 3.0 years (IQR 2.8–5.0), 78% were male, and 60% were White (Table 1). Laceration closure was most often performed by resident physicians (51%). Patients who presented for follow-up were older with median age of 4.0 years (IQR 2.6–5.0) and more commonly White (70%). Laceration length and width between the ED group and follow-up group were similar. In those completing follow-up, patients closed with Steri-Strips were younger (median 3.0 years [IQR 2.0–5.0]) than the suture (median 4.0 years [IQR 2.0–5.3]) and Dermabond (median 5.0 years [IQR 3.5–5.0]) groups (Table 1). There were more black patients in the suture follow-up group (25%) compared with Steri-Strips (9%) and Dermabond (14%).

Figure 2 shows the median and IQR for cosmetic ratings of scar by guardians using the VAS between 0 and 100. Dermabond was given a median score of 85 (IQR of 73–90), suture was given a median score of 70.5 (IQR 59.8–76.8), and Steri-Strips were given a median score of 67 (IQR 55–78). There was no statistical evidence of an association between scar appearance and closure method whether adjusted for the guardian's average rating of the 6 standard scars or unadjusted (Table 2). In 2 group comparisons, the OR was 0.33 (95% CI: 0.06–1.70) for suture versus Dermabond, 0.23 (95% CI: 0.04–1.38) for Steri-Strips versus Dermabond, and 0.71 (95% CI: 0.16–3.08) for Steri-Strips versus suture.

For the secondary outcomes, guardian satisfaction with LOS did not differ by closure type (Table 3). When an adjustment was made for proceduralist and age of the patient, there was still no difference in satisfaction of LOS. Guardian and physician-perceived pain of each closure type did not differ. Overall, guardian

TABLE 2. Proportional Odds Model of 3-Month Cosmetic Outcome by Closure Method

	Unadjusted			Adjusted		
	OR	**95% CI**	***P* Value**	**OR**	**95% CI**	***P* Value**
Suture: Dermabond	0.30	0.06–1.54	0.148	0.33	0.06–1.70	0.185
Steri-strip: Dermabond	0.20	0.03–1.16	0.073	0.23	0.04–1.38	0.108
Steri-strip: suture	0.68	0.16–2.86	0.594	0.71	0.16–3.08	0.644

TABLE 3. Secondary Study Outcomes by Closure Method

Characteristics	OR (CI)	*P* Value
LOS satisfaction		
Suture vs Dermabond	0.51 (0.16–1.60)	0.249
Steri-Strips vs Dermabond	1.03 (0.32–3.26)	0.964
Steri-Strips vs suture	2.01 (0.63–6.42)	0.240
Guardian perceived pain		
Suture vs Dermabond	1.14 (0.35–3.68)	0.824
Steri-Strips vs Dermabond	1.97 (0.65–5.98)	0.234
Steri-Strips vs suture	1.72 (0.54–5.53)	0.362
Physician perceived pain		
Suture vs Dermabond	1.99 (0.64–6.18)	0.235
Steri-Strips vs Dermabond	1.61 (0.52–5.02)	0.412
Steri-Strips vs suture	0.81 (0.24–2.71)	0.732
Guardian overall satisfaction		
Suture vs Dermabond	0.80 (0.24–2.68)	0.723
Steri-Strips vs Dermabond	0.78 (0.24–2.54)	0.685
Steri-Strips vs suture	0.97 (0.30–3.15)	0.966
Physician comfort with procedure		
Suture vs Dermabond	0.97 (0.3–3.12)	0.958
Steri-Strips vs Dermabond	0.57 (0.17–1.91)	0.360
Steri-Strips vs suture	0.58 (0.18–1.87)	0.366

satisfaction with the closure method did not differ by closure type. All 3 closure types result in high satisfaction scores by guardians on the VAS: Dermabond 99.5 (IQR 94.5–100.0), sutures 99.5 (88.0–100.0), and Steri-Strips 99.0 (95.0–100.0). Provider comfort with the procedure did not differ by closure type. Refer to Table 4 for additional data regarding secondary outcomes.

DISCUSSION

There was no evidence for differences when comparing the guardian-rated cosmetic outcomes closure of simple pediatric lacerations with absorbable sutures, tissue adhesives, or surgical tape. The findings of this study suggest providers can have confidence using alternatives to traditional sutures given their comparable cosmetic outcomes for simple linear lacerations, as well as safety and low cost.[17,30,31]

As previously described, other studies have shown mixed results regarding cosmesis as rated by clinicians but there is limited data regarding cosmesis as rated by guardians. For instance, tissue adhesives and surgical tape were shown to have similar cosmetic outcomes in children with simple lacerations when rated by plastic surgeons.[14] One study showed that tissue adhesives have better cosmesis than sutures as rated on the Hollander Cosmesis Scale because no suture marks are noted on the scar.[19] A meta-analysis showed that surgical tape conveys better cosmesis than tissue adhesives in pediatric wound closure as rated by clinicians.[27] The equivocal findings of this study are unique given that guardian-perceived cosmesis has largely not been evaluated.

Aside from cosmesis, there are other factors that influence choice of laceration repair method including procedural satisfaction, perceived pain, and LOS. For instance, tissue adhesives have been shown to be easy to use and perceived as nonpainful.[13] In addition, the need for sedation often increases ED LOS.[10] While this study did not explicitly measure LOS or the cost of procedures, this study did highlight that all 3 closure methods were associated with high overall satisfaction scores by guardians. For all 3 closure methods, there was no significant difference in LOS satisfaction, guardian or physician-perceived pain, guardian overall satisfaction, and physician comfort with the procedure. Interestingly, 1 study showed that the strongest predictor of parental satisfaction for laceration repair in the ED was considered to be provider performance, which is comprised of physician communication, caring attitude, confidence, and hygiene.[5] Therefore, increasing physician confidence in any

TABLE 4. Secondary Outcomes by Closure Method Additional Data

Characteristic	Dermabond	Suture	Steri-Strip
	Enrolled	Enrolled	Enrolled
n	18	20	17
LOS satisfaction			
Mean (SD)	85.00 (17.73)	72.80 (31.19)	85.12 (20.94)
Median (IQR)	94.00 (71.25, 100.00)	89.50 (45.25, 98.50)	92.00 (83.00, 100.00)
Parent perceived pain			
Mean (SD)	16.50 (19.28)	26.74 (31.25)	23.94 (23.35)
Median (IQR)	11.00 (3.00, 24.50)	17.00 (1.50, 51.50)	22.00 (9.00, 28.00)
Physician perceived pain			
Mean (SD)	8.44 (10.03)	24.25 (27.66)	17.82 (19.26)
Median (IQR)	5.50 (3.00, 9.25)	6.50 (1.50, 48.75)	15.00 (0.00, 27.00)
Parent satisfaction			
Mean (SD)	93.78 (11.88)	84.45 (29.69)	92.00 (20.25)
Median (IQR)	99.50 (94.50, 100.00)	99.50 (88.00, 100.00)	99.00 (95.00, 100.00)
Physician satisfaction			
Mean (SD)	91.89 (16.27)	92.45 (9.63)	92.59 (10.31)
Median (IQR)	99.00 (91.50, 100.00)	97.50 (83.75, 100.00)	98.00 (92.00, 100.00)
Physician comfort			
Mean (SD)	94.00 (7.84)	94.10 (8.70)	91.94 (8.23)
Median (IQR)	99.00 (88.75, 100.00)	97.50 (91.50, 100.00)	96.00 (86.00, 100.00)

*All numbers are on a 100-mm sliding VAS (eg, a score of 0 corresponds to "no satisfaction" where a score of 100 corresponds to "most satisfied").

laceration repair method may increase guardian satisfaction in addition to possibly providing an overall less traumatic and less expensive experience. As clinical landscapes change, it will be important to evaluate the cost, LOS, and sedation needs associated with each closure method because these all 3 methods are associated with high rates of guardian perceived satisfaction and ensure provider competence and confidence in each procedure as this may also increase guardian perceived satisfaction.

There are multiple limitations of this study. The study could not be double-blinded. Providers varied in their level of training, which has an indeterminate effect on cosmetic outcomes. There was a 45% lost to follow-up rate and this may have biased our results. The original projected sample size of 90 was not met, with a final sample size of 30 related both to ongoing low census and increased regulations around permissible patient contact during the global COVID-19 pandemic. Given the small sample size, this study may not have had the ability to detect more rare complications from various suture methods such as wound dehiscence. While this study had no adverse events, future larger studies are needed to help compare the relative safety of each closure method.

In addition, preformed preferences of guardians influenced enrollment in this study. Some guardians declined participation in this study to request a specific repair method recommended by an outside provider who referred them to the ED. Some guardians requested tissue adhesive because they did not want their child to undergo 'painful stitches,' and some declined Steri-Strips because they were worried their child would remove the surgical tape. These findings speak to the continued variability of management and the need for evidence surrounding simple laceration repairs.

There are many factors to consider when choosing a method of laceration closure in children including cosmesis, perceived pain, provider comfort with the procedure, and resources needed. This study was unable to detect any differences in guardian perceived cosmesis measured 3 months after closure between simple linear lacerations repaired with sutures, Dermabond, or Steri-Strips. Guardians generally appeared satisfied with all approaches. Larger studies will allow for further evaluation of perceived cosmesis based on repair method. Overall, the results of this study suggest that all 3 closure methods appear to be clinically equivalent which is largely consistent with other evidence.

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