Comparison of Cosmetic Outcomes of Absorbable Versus Nonabsorbable Sutures in Pediatric Facial Lacerations

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Objective: We sought to compare cosmetic outcomes, complication rates, and patient/caregiver satisfaction of absorbable versus nonabsorbable sutures in children.

Methods: Healthy patients, 1 to 18 years old, with facial lacerations 1 to 5 cm, were randomized to repair with fast-absorbing catgut (FAC) or nylon (NYL) sutures. Patients returned in 4 to 7 days and in 3 to 4 months, at which time photographs and caregiver surveys were completed. Unlike part I, all FAC sutures were permitted to absorb rather than be removed. Using a 100-mm visual analog scale (VAS), a noninferiority (NI) design was applied, with a difference of less than 15 mm considered clinically equivalent. Caregivers and 3 blinded physicians independently rated the scars via photographs.

Results: Ninety-eight patients were enrolled, 76 caregiver surveys were completed, and 61 (29 FAC, 32 NYL) had photographs scored by physicians. The mean physician VAS scores for FAC and NYL were 57.6 and 67.6, respectively (difference, −10.0; 95% confidence interval, −19.1 to −0.4); thus, NI could not be established. The mean caregiver VAS scores for the FAC and NYL groups were 93.8 and 86.6, respectively (difference, 7.2; 95% confidence interval, −4.9 to 13.9); thus, NI of FAC was established. There were no significant differences in rates of infection, wound dehiscence, or keloid formation. In terms of future preference, caregivers favored FAC (33/33) over NYL (26/36) ($P < 0.01$).

Conclusions: Caregiver VAS scores showed NI of FAC, which were also preferred by the caregivers. However, NI for FAC could not be demonstrated by blinded physicians with respect to cosmetic outcomes.

Key Words: absorbable sutures, cosmetic outcomes, facial lacerations, caregiver satisfaction

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Facial lacerations are very common injuries seen in the emergency department (ED). All wounds that occur on the face will leave a scar regardless of how they are repaired. The ultimate goal in the management of pediatric facial lacerations is to close the wound, avoid infection, and achieve a cosmetically acceptable scar.[1] The cosmetic appearance of the scar after a repair is of particular importance to the patient and caregiver.[2] Traditional teaching recommended nonabsorbable sutures for closing the outermost layer of any laceration. This class of suture material was a good choice for skin closure as it has high tensile strength, minimal tissue reactivity, and excellent elasticity and has low cost. The less tissue reactivity with the suture material helps to decrease the likelihood of severe scar formation. These nonabsorbable sutures, however, need to be removed in 4 to 6 days. This has the added cost of an additional physician visit, and the potential for missed school days and absence from work for the caregiver. In addition, suture removal can be difficult in the already anxious and apprehensive child who may have unpleasant memories of the initial laceration repair in the ED.

In our previous study published in 2008, we were able to demonstrate noninferiority of absorbable sutures when compared with nylon (NYL) sutures in the repair of facial lacerations in children.[3] However, in that study, all remaining absorbable sutures were purposely removed at the 4- to 7-day follow-up visit. In our current study, we have allowed the absorbable sutures to dissolve within the tissue, measured the time required to be fully resorbed, and removed only the nonabsorbable sutures at the 4- to 7-day follow-up visit. The primary objective of this study was to compare the long-term cosmetic outcomes of absorbable versus nonabsorbable sutures based on physician scoring of facial lacerations in the pediatric population. Secondary objectives include analyses of complication rates and patient/caregiver satisfaction.

METHODS

This is a prospective clinical trial conducted at 2 academic, urban pediatric EDs. The enrollment period was April 2008 through April 2010, and the study was approved by the institutional review boards of the participating universities.

English-speaking pediatric patients, 1 to 18 years of age, presenting to the ED with isolated, noncontaminated linear facial lacerations, between 1 and 5 cm in length that, in the clinical judgment of the pediatric emergency medicine (PEM) physician, precluded the use of a topical tissue adhesive, were eligible. Patients were excluded if the facial lacerations were less than 1 cm or greater than 5 cm in length, had irregular borders, were the result of a mammalian bite, were more than minimally contaminated on visual inspection, were more than 8 hours old, or could be repaired with the application of a topical adhesive. Patients with complex lacerations who required repair by facial plastics (plastic surgery, otorhinolaryngology, oral maxillofacial surgery) and those with a known or suspected immunodeficiency, bleeding or clotting disorders, pregnancy, diabetes, renal dysfunction, or allergic reaction to the topical anesthetic were also excluded.

The treating physician approached eligible patients, obtained consent, and enrolled patients. All eligible patients were approached for enrollment. The suture assignments, as determined by prior randomization, were kept in sealed envelopes inside the packets with all of the study-related forms. Only after obtaining written informed parental consent in all subjects and written informed assent in children older than

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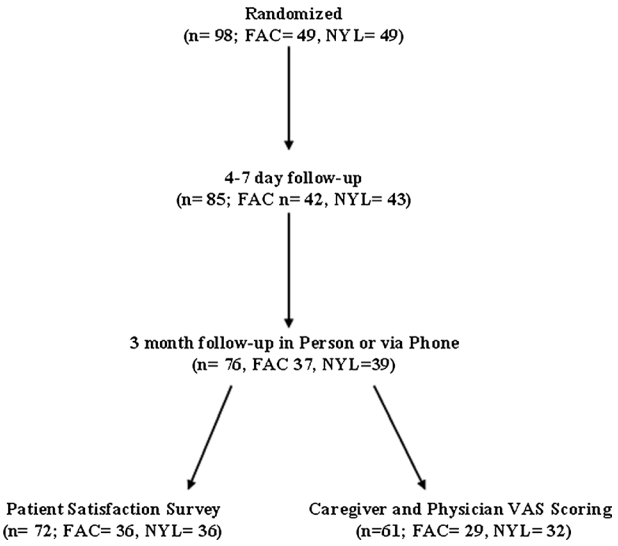

FIGURE 1. Patient allocation.

7 years was the seal broken and the type of suture material revealed.

Lacerations were repaired using a standardized approach. Local anesthesia was obtained using a topical mixture of xylocaine, adrenaline, and tetracaine and/or with local wound infiltration with 1% lidocaine with or without epinephrine. Lacerations were repaired on the surface using either absorbable suture material (5-0 fast-absorbing surgical gut [FAC]; Ethicon Inc, Sommerville, NJ) or nonabsorbable suture material (5-0 NYL; Ethicon Inc). Wounds requiring a buried suture layer were repaired with 5-0 fast-absorbing sutures in the absorbable group and with 5-0 monocryl (Ethicon Inc) in the nonabsorbable group. Only attending PEM physicians and PEM fellows on duty repaired the lacerations. All patients were given standardized wound care instructions before discharge. Patients and caregivers randomized to the absorbable suture group were given a suture log and were asked to document, on a daily basis, the number of sutures remaining.

Patients were seen for follow-up in the pediatric ED in 4 to 7 days. During these visits, the wounds were assessed by a study investigator for complications including wound infection and/or dehiscence. The nonabsorbable sutures were removed at this visit by the study investigator. Absorbable sutures still intact or that were unraveling were noted, but not removed, and recorded for analysis. Attempts by telephone were made to contact those patients who failed to return for this initial follow-up visit.

Patients were then asked to return to the ED 3 to 4 months (weeks 12-16) after the initial repair. The decision to follow up at 3 months, instead of 6, 9, or 12 months, came from the Food and Drug Administration's determination that the 3-month cosmetic outcome is the standard for evaluating success of laceration repair.[4] The caregivers and patients in the absorbable group who completed the daily suture logs were asked to return their logs at this follow-up visit. Photographs of the scars were taken using a standardized protocol with a dedicated digital camera at each institution and loaded onto a computer. The digital photographs were then printed out on photograph paper at each institution with a dedicated printer. The photographs of the scars were rated by 3 PEM physicians who were blinded to the treatment groups using a previously validated visual analog scale (VAS).[5] The VAS scale is a 100-mm continuous line that is marked at the right end with "best scar"(score 100), and on the left end with "worst scar" (score 0). The physicians were asked to mark on the line where they believe the scar "best fits." The 3 physician observers each rated the photographs of the scars once, and the mean of these ratings was used for the final comparisons. To assess interrater agreement, we calculated an intraclass correlation coefficient (ICC, 2,1).

Caregivers and patients (>15 years of age) were also asked to assess the scar using the same VAS scale at this 3- to 4-month visit. They were then asked to complete a survey to assess their level of satisfaction. The survey included questions regarding perceived complications, convenience of the suture material used, and the desire to use the same suture material if needed in the future. For those patients who did not return for the 3- to 4-month follow-up visit, the satisfaction survey was conducted by telephone interview. These caregivers were asked all the questions on the caregiver satisfaction survey, but they did not provide a VAS score for the wound repair.

Differences between groups were analyzed using the Student t test for independent samples. Proportions were compared using χ^2 and the z test for independent proportions. A significance level of 0.05 was used in all analyses. Because this was an equivalence trial, a noninferiority (NI) difference of 15 mm with the cosmesis VAS was considered clinically equivalent. Previous studies have determined that the minimal clinically important difference between 2 groups ranged from 10 to 15 mm.[5,6,7] Using the confidence interval (CI) approach, noninferiority can be concluded if the 95% CI comparing the 2 groups covers only values that do not exceed this 15-mm difference. A sample size of 37 patients per group was estimated to provide a power of 90% with an α error of 0.05 to detect this difference in the VAS. A patient attrition rate of 40% was expected and was factored in the sample size estimates.

RESULTS

A total of 98 patients were enrolled for the study (Fig. 1). Forty-nine patients were randomized to the FAC group and 49 patients to the NYL group. Twenty-two patients were lost to follow-up during the course of the study, leaving a final cohort of 76 patients (FAC, n = 37; NYL, n = 39). Eleven patients enrolled (FAC, n = 7; NYL, n = 4) in the study did not return for the 3-month follow-up visit but were contacted by telephone to answer the questions on the caregiver survey. Sixty-five patients had photographs taken of their scars at their 3-month

TABLE 1. Demographics and Wound Characteristics of the Patients Enrolled

	3-mo Visit (n = 76)		
	Group		
	FAC (n = 37)	NYL (n = 39)	*P*
Age, median (range), mo	83 (15–207)	66 (13–218)	NS
African American, n (%)	31 (84%)	30 (77%)	NS
Male, n (%)	22 (60%)	31 (80%)	$P = 0.02$
Wound length, median (range), cm	1.9 (1–3)	1.8 (1–4)	NS
No. sutures, median (range)	5 (2–12)	5 (2–11)	NS
2-Layer repair, n (%)	10 (27%)	10 (26%)	NS

NS indicates not statistically significant ($P > 0.05$).

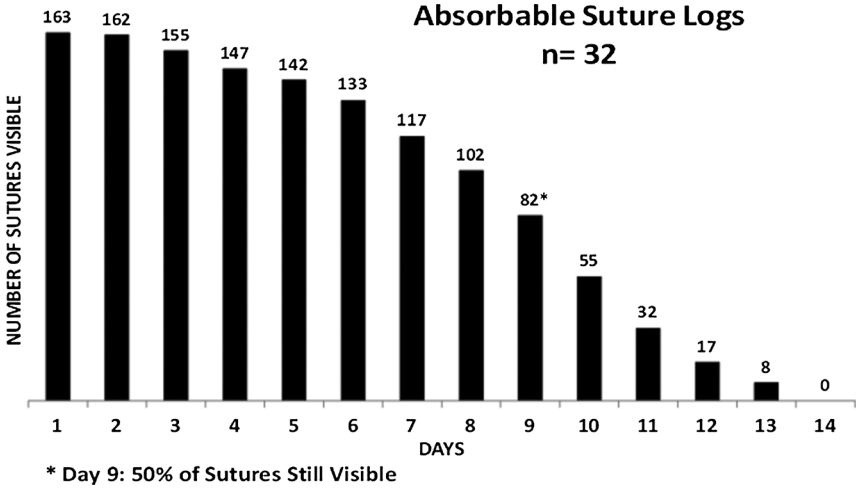

FIGURE 2. Absorbable sutures remaining in the days following laceration repair.

postrepair follow-up visit. Because of the unexpected death of the study's principal investigator, the remaining investigators were unable to locate caregiver surveys from 4 patients who completed the study. In addition, we had a different set of 4 patients who completed the study for which we were not able to locate their photographs. Therefore, we had 72 (FAC, n = 36; NYL, n = 36) patients with caregiver satisfaction surveys completed and 61 (FAC, n = 29; NYL, n = 32) patients with photographs of their scars used for VAS scoring.

A complete summary of the demographics for the 76 patients in the 2 comparison groups who completed the study is shown in Table 1. There were no significant differences in age, race, wound lengths, number of sutures, or layered repair rates between the 2 groups. Compared with the FAC group, a higher percentage of patients in the NYL group were male. Of the patients randomized to the FAC group, 32 completed and returned their suture logs (Fig. 2). A total of 168 sutures were used to repair the wounds in these 32 patients. From the information on the patient's sutures logs, 117 (70%) of the 168 sutures still remained at day 7 after repair. By day 9 after repair, 82 (49%) of the sutures were still visible in the wounds. All sutures used to repair the wounds were no longer visible at day 14 following the repairs.

Table 2 displays the VAS scores for both the physicians and caregivers. The mean physician VAS scores for FAC and NYL were 57.6 and 67.6, respectively (difference, −10.0; 95% CI, −19.1 to −0.4). This difference of −10 between the groups had a lower bound of the CI (−19.1) that was less than our NI margin of −15 mm; thus, NI could not be established for FAC with respect to the physician VAS scores. Agreement among physicians was substantial with an ICC coefficient = 0.62 (95% CI, 0.48-0.73; $P < 0.01$). The mean caregiver VAS scores for the FAC and NYL groups were 93.8 and 86.6, respectively (difference, 7.2; 95% CI, −4.9 to 13.9). The lower bound of the CI for the difference (−4.9) was greater than the NI margin of −15 mm; thus, NI of FAC was established. There was no correlation between the length of time the FAC sutures remained and the caregiver VAS scores or physician VAS scores. The correlation coefficients for the parental VAS scores and the mean physician VAS scores versus the days with remaining sutures were $r = -0.08$ ($P = 0.67$) and $r = 0.10$ ($P = 0.61$), respectively.

No patients in either group were found to have a wound infection or dehiscence during the study. Table 3 shows the results of the caregiver surveys for the 2 comparison groups. Two patients in the NYL group reported complications on the caregiver survey; both had large scar formation. Caregivers found the FAC sutures more convenient and would prefer them for future facial laceration repairs. In terms of convenience of the suture material, caregivers preferred FAC (36/36) to NYL (21/36) ($P < 0.01$). When it came to the question of using the same suture material for futures repairs, caregivers preferred FAC (36/36) to NYL (26/36) ($P < 0.01$).

DISCUSSION

Plastics surgeons, ophthalmologists, and otolaryngologists have used absorbable sutures for the repair of lacerations with good cosmetic results. Three separate studies in adult patients compared wound appearance and infection rates between absorbable and nonabsorbable sutures.[8–10] These studies found no

TABLE 2. VAS Scores for Caregivers and Physicians at 3 Months (n = 61 [FAC, n = 29; NYL, n = 32])

	VAS Scores, Mean	VAS Score Difference of the Means (95% CI)
Caregivers		
FAC	93.8	7.2 (−4.9 to 13.9)
NYL	86.6	(Equivalent)
Physicians		
FAC	57.6	−10 (−19.6 to −0.4)
NYL	67.6	(Nonequivalent)

TABLE 3. Caregiver Survey Results (n = 72)

	FAC (n = 36)	NYL (n = 36)	*P*
Convenience of suture used, n (%)	36 (100)	21 (58)	<0.01
Preference to use same sutures in the future, n (%)	36 (100)	26 (72)	<0.01
No. with perceived complication of any kind, n (%)	0	2 (6)	NS

NS indicates not statistically significant ($P > 0.05$).

significant differences in wound appearance and infection rates between absorbable and nonabsorbable sutures in adult patients. Studies comparing absorbable and nonabsorbable sutures for pediatric facial lacerations are limited. One pediatric study compared absorbable and nonabsorbable sutures for repairs in all body locations.[11] The authors found that plain gut absorbable sutures were an acceptable alternative to nonabsorbable sutures in the repair of traumatic lacerations in children. Although the majority of the lacerations in both groups involved the face, nearly 50% of the patients in both groups had Steri-Strips combined with the sutures to optimize wound approximation. Another study used tissue adhesives, absorbable sutures, and nonabsorbable sutures on both adult and pediatric patients with facial lacerations and did not detect any clinically important differences in cosmetic outcomes at 9 to 12 months.[12]

In the previous study directly comparing absorbable versus nonabsorbable sutures in pediatric facial lacerations, it was concluded that the use of FAC was a viable alternative in the repair of pediatric facial lacerations.[3] The main limitations of this study included a high attrition rate of 47% and the decision to remove the catgut sutures at the first follow-up appointment. For the current study, we again hypothesized that wounds repaired with absorbable sutures would not be clinically different from those repaired with nonabsorbable sutures in terms of cosmetic outcomes at 3 months. In this assessment, we demonstrated the actual absorption rate of FAC in pediatric facial lacerations, which, to our knowledge, is the first randomized trial to do so. Several review articles regarding suturing and suture materials report FAC suture material absorbs within 5 to 10 days.[13–17] This timeframe typically refers to the sutures present on the undersurface of the wound, whereas the outer suture material may remain longer. We found that 50% of the FAC sutures were still in place by day 9 after repair and that some sutures remained for up to 13 days.

The results in both studies showed that the difference in VAS scores for the FAC and NYL groups, as determined by the caregivers, was not statistically different with respect to cosmetic appearance at 3 months. On the other hand, our group of blinded PEM physicians rated the photographed scars with lower VAS scores for both treatment groups. They specifically rated the scars in the NYL group higher (ie, better cosmetic outcome) than those in the FAC group. This is in contrast to the findings in the previous study where the physicians found no differences between the groups.

We can only hypothesize for the observed differences in the 2 studies. First, we had only 61 patients with photographs used for caregiver and physician VAS scoring, which is below our power calculation of 37 patients in each group. Our current study may have been truly underpowered to detect noninferiority between the 2 groups. In addition, our findings may represent a simple type II error of failing to reject the null hypothesis when there are no true differences between the groups. Another contributing factor may have been the fact that 2 different groups of physicians rated the photographs in each of the studies. Still, our ICC of 0.62 for the blinded physicians indicated there was good agreement among the physicians in terms of scoring the photographed scars, making physician rater variability an unlikely contributing factor.

A fourth possibility may have been the decision to use FAC in the buried suture layer in the absorbable suture group only; perhaps the rapid absorption of these buried sutures led to more prominent scaring. Still another possible explanation is that the poorer cosmetic outcome in the absorbable suture group was due to the decision to allow all sutures to resorb at their own rate. All of the NYL sutures were removed by day 7, but 50% of the absorbable sutures were still in place by day 9. It is possible that because of the increased tissue reactivity of the absorbable sutures on the skin and having them in place for longer than the recommended period of 4 to 7 days contributed to the difference in cosmetic outcomes. Still, upon further review of the data, there was no relationship or correlation between the length of time the FAC sutures remained and the caregiver VAS scores or physician VAS scores.

Caregiver satisfaction was significantly higher in the FAC group than in the NYL group, which was not demonstrated in the first part of the study. This was true for both convenience of the suture material used for the repair and the desire for using the same suture material for future facial lacerations. One possible explanation for this may be that the first return visit was quicker and less traumatizing to the children compared with those in the previous study because the FAC sutures did not require removal. In contrast, the patients enrolled in the NYL group had their sutures removed at this 4- to 7-day visit, which took more time and required the patient to cooperate for suture removal. All of the caregivers in the FAC group were completely satisfied with the laceration repair. Thus, these caregivers may have been more likely to give the scar a higher VAS score based more on their level of satisfaction with the entire experience rather than a true objective determination of the scar appearance.

LIMITATIONS

There are several limitations in our study. First, our study involved only English-speaking patients; therefore, those non–English-speaking patients with facial lacerations were missed. Second, the technique for wound closure in our study was left to the discretion of the treating physician, who determined whether the wounds required Steri-Strips, tissue adhesives, or sutures for closure. Thus, with the increasing popularity and use of tissue adhesives in EDs, a number of patients were ineligible for our study. Another limitation was that we did not monitor or determine compliance with the wound care instructions given to the patients and caregivers. All of the patients enrolled were given standard wound care instructions that included keeping the area clean with soap and water as well as daily application of antibiotic ointment. The absorption process of absorbable sutures can be accelerated by application of warm compresses and antibiotic ointment to the sutured wound area. This, in turn, would decrease the length of time the sutures would remain visible in the sutured wound. The attrition rate of 38% was high and could also have affected the results of the analyses. Finally, with only 2 centers involved in this study, and the relatively small sample size of our final cohort, the generalizability cannot be easily determined.

CONCLUSIONS

In conclusion, although we were able to show that caregivers were extremely satisfied with the use of absorbable sutures, we are not yet able to conclude that absorbable sutures are equivalent to nonabsorbable sutures with respect to cosmetic outcomes of facial lacerations in children. Even with the limitations of our study, from the caregivers' perspective, we found noninferiority between the absorbable and nonabsorbable sutures. Potentially with a larger patient cohort, we may be able to demonstrate the same noninferiority with the blinded physicians. A larger, multicenter trial whereby standard buried sutures are applied and absorbable sutures are treated with warm compresses and antibiotic ointment, followed by manual removal when necessary by the caregiver, will address the limitations of our study as well as some of the remaining questions regarding the use of absorbable sutures in facial lacerations in children.

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