CLINICAL INVESTIGATIONS

A Randomized, Controlled Trial Comparing Long-term Cosmetic Outcomes of Traumatic Pediatric Lacerations Repaired with Absorbable Plain Gut versus Nonabsorbable Nylon Sutures

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Abstract

Objectives: To show that the use of absorbable sutures in pediatric traumatic lacerations affords good long-term cosmesis and no increase in complications (infection, dehiscence rates, and need for surgical scar revision) when compared with wounds sutured with nonabsorbable sutures. Methods: This was a randomized clinical trial conducted in a pediatric emergency department. Patients 1-18 years of age who presented to the emergency department with lacerations <12 hours old were recruited between January 1999 and December 2001. Exclusion criteria were the following: wounds that could be approximated by tissue adhesives, animal/human bites, gross contamination, puncture/crush wounds, wounds crossing joints, lacerations of tendon/nerve/cartilage, collagen vascular disease, immunodeficiency, diabetes mellitus, bleeding disorder, and scalp lacerations. Patients were randomized into one of two groups: those receiving absorbable plain gut sutures (group A) and those receiving nonabsorbable nylon sutures (group NA). Board-eligible/certified pediatric emergency physicians or clinical fellows performed laceration repair in a standardized approach. All wounds were reevaluated within ten days by a single research nurse who assessed the wounds using a previously validated wound evaluation score (WES) composed of six items (presence of step-off, contour irregularities, margin separation, edge inversion, extensive distortion, and overall cosmetic appearance). A score of 6/6 was considered optimal. The study nurse also noted the presence of infection and dehiscence. The patients were then seen by a single blinded plastic surgeon at four or five months who evaluated the wound using a previously validated visual analog scale of cosmesis (VAS). In addition, the surgeon repeated the WES and assessed the need for surgical scar revision. Results: A total of 147 patients were

eligible, and 52 patients declined to participate. Of the 95 patients enrolled, 50 were randomized to group A and 45 to group NA. The two groups had similar ages, gender distributions, rates of use of sedation or steri-strips, wound lengths and widths, mechanisms of injury, and wound locations. At the short-term follow-up, no difference was found in the proportion of optimal WES scores between group A (63% of patients) and group NA (49% of patients) (relative risk = 0.73; 95% confidence interval [95% CI] = 0.45to 1.17). No difference was found in the rates of infection and dehiscence between the two groups. Sixty-three of the 95 patients presented for long-term follow-up. The groups remained similar with respect to patient and wound characteristics as well as wound location. The average VAS score at four months was 79 (95% CI = 73 to 85) for group A and 66 (95% CI = 55 to 76) for group NA. In addition, no differences were found in the proportion of optimal WES between group A (36% of patients) and group NA (28% of patients) at four months (relative risk = 0.88; 95% CI = 0.62 to 1.26). Surgical scar revision was recommended for only three patients, of whom two were in group A. No patients chose to have their scars revised. No differences were found between group A and group NA for the rates of dehiscence (2% vs. 11%; p = 0.07) and infection (0 vs. 2; p = 0.3). Conclusions: The use of plain catgut absorbable sutures in the repair of traumatic lacerations in children appears to be an acceptable alternative to nonabsorbable sutures because the long-term cosmetic outcome seems to be at least as good. In this study, plain gut suture material seemed to provide slightly better cosmesis. In addition, no difference was found in the rate of dehiscence or infection between the groups. Key words: wounds; sutures; pediatrics; cosmesis; traumatic lacerations. ACADEMIC EMERGENCY MEDICINE 2004; 11:730–735.

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Traumatic lacerations are among the most common reason children and their families visit the emergency department (ED). Annually, more than two million traumatic wounds are treated by emergency physicians in North America. In our institution alone, more than 2,500 children presented to the ED for repair of traumatic lacerations in 1997. Fortunately, we estimate that a large majority of these wounds are repaired by tissue adhesives in our institution. This affords less pain and discomfort for the child and eliminates the need for suture removal. Although a minority of lacerations are repaired using sutures, the experience can be very traumatic to a child, particularly when the patient must return for suture removal.

In our opinion, an ideal method of laceration closure would be one that is relatively painless, non-traumatic, rapid, without need for follow-up, associated with low rates of wound complications, and associated with optimal long-term cosmesis. Such an ideal method clearly does not exist. However, several clinical trials have shown that tissue adhesives have the potential to be less traumatic to the patient, to be more cost-effective, and to produce good cosmetic results when compared with sutures. ^{1–5} Unfortunately, these products cannot be applied to all laceration repairs. A significant proportion of lacerations still require suturing because of their location, size, depth, or width. ⁶

There seems to be no universal agreement among authorities in choosing the ideal type of suture material for wound repair. In particular, controversy exists as to when to use the absorbable type of suture materials as opposed to the nonabsorbable types in the repair of traumatic lacerations in children. 6-11 In the traditional teaching, nonabsorbable sutures have been recommended as the material of choice for closing the outermost layer of any laceration, particularly those under tension. More recently, many surgeons have challenged this notion and have recommended that all pediatric lacerations requiring sutures, including facial lacerations, should be repaired with absorbable-type suture material, with the exception of lacerations over areas of tension.^{2,3,7,12–16} This new trend stems from case series, retrospective studies, and small uncontrolled prospective studies in the plastic surgery, otolaryngology, and general surgery literature. These studies attempted to show that there is no appreciable difference with respect to cosmetic outcome and wound complications (infection and dehiscence) in operative wounds closed with absorbable suture material, compared with those closed with nonabsorbable suture material, even in the closure of facial wounds in cosmetic surgery. 12-17 In addition, the use of absorbable sutures afforded the benefit of not having to return to the clinic or to the operating room for suture removal. Obviously this is of great benefit to the patient as well as to possible cost containment for the health care system.

Although one may extrapolate findings from the data provided by elective wound closure to traumatic lacerations seen in the ED, the fact remains that traumatic lacerations differ from operative incisions. First, operative wounds are created and repaired under sterile conditions; therefore, the risk of infection and resultant poor cosmesis are probably less than with traumatic lacerations. Second, the incision produced in the operating room tends to have straight, even edges that are easily approximated, thus affording optimal scarring. Third, the closure of operative incisions is performed by surgeons whose level of skill in performing suture closure technique may be greater than that of emergency physicians.

Our objective was to show that the use of absorbable sutures in pediatric traumatic lacerations affords good long-term cosmesis and no increase in complications (infection, dehiscence, and need for surgical scar revision) when compared with wounds sutured with nonabsorbable sutures.

METHODS

Study Design. This was a randomized clinical trial. The scientific committee and the institutional review board of our center approved this study; informed consent was obtained before enrollment.

Study Setting and Population. The study was conducted in a pediatric tertiary referral center. Its ED has an estimated volume of 65,000 patient visits per year. All children younger than 18 years of age who presented to the ED with lacerations <12 hours old requiring suture repair as judged by the recruiting emergency physician on duty were enrolled. Patients were excluded for the following reasons: wounds caused by animal or human bites; heavily soiled wounds requiring debridement; stellate crush wounds or contaminated puncture wounds; wounds in patients with a known history of keloid formation; wounds crossing joints or in areas of high tension; lacerations involving tendon, nerve, cartilage or bony injuries; and a history of collagen vascular disease, prolonged corticosteroid use, primary or secondary immunodeficiency, type 1 diabetes mellitus or clotting disorders, and scalp lacerations (difficult-to-evaluate cosmesis). All patients with wounds that could be approximated by tissue adhesives (e.g., <5 cm in length or <0.5 cm in width) were also excluded.

Study Protocol. All eligible patients were recruited consecutively by six designated full-time emergency physicians (board-certified/eligible) and by pediatric emergency fellows while they attended in the ED. All fellows are at least fourth-year residents whose suturing technique was previously supervised and deemed good to excellent by one of the recruiting physicians. Once eligibility and exclusion criteria

were confirmed and informed consent was obtained, subjects were randomized (by block numbers of six) into one of two groups: patients in group A received absorbable plain catgut sutures (Ethicon Inc./Johnson & Johnson Co., Sommerville, NJ), and patients in group NA received nonabsorbable nylon sutures (Ethicon Inc./Johnson & Johnson Co.). Patient data were recorded on standardized study data sheets so that all patient information was as complete and consistent as possible. Patient data on all eligible patients who refused to participate were also collected for analysis.

After randomization, patients were treated using a standardized care plan, which was reviewed in detail with all recruiting physicians before the start of the study. The use of prophylactic antibiotics, however, was left to the discretion of the treating physician. Laceration repair was performed using sterile technique. The wounds were infiltrated with 1% lidocaine solution (maximum dose, 4 mg/kg).^{8–11} Wounds in patients in group A were sutured with 5.0 or 6.0 plain catgut suture material if the laceration was on the face. Lacerations on the extremities or the torso were repaired with either 4.0 or 5.0 plain gut. Similarly, wounds in patients in group NA were sutured with 5.0 or 6.0 nylon suture material for facial lacerations and 4.0 or 5.0 nylon for lacerations in the extremities or the torso. Simple interrupted suturing technique using a cutting needle was used in both groups. Sutures were placed 4-5 mm apart. In deep wounds (i.e., beyond the dermal layer) requiring multilayer closure and for wounds under some tension, deep layers were closed with plain gut sutures using a buried knot. Steri-strips were used at the physician's discretion in both groups to optimize wound approximation. The use of a topical antibiotic was allowed if deemed necessary by the recruiting physician, as is currently the practice in our institution. Once suturing was completed, a dry dressing was applied to the wound in both groups and patients were given standardized wound care instructions.

All patients had a follow-up visit in the outpatient clinic, where they were assessed by a single research nurse specialized in wound care. Patients with facial lacerations were seen within five to seven days after repair, and patients with lacerations in the extremities or the torso were seen within seven to ten days after repair. During the visit, the research nurse assigned a wound evaluation score (WES) using a previously validated wound evaluation scale.¹⁸ The WES is composed of six items (presence of step-off, contour irregularities, margin separation, edge inversion, extensive distortion, and overall cosmetic appearance). This WES was used as a tool to evaluate short-term cosmesis. A score of 6/6 was considered optimal. The presence of infection was noted if the patient showed signs of any gross purulent discharge, excessive wound erythema, and/or pain and/or fever. The presence of dehiscence was also noted if the wound edges at any point in the wound seemed separated. Patients with nonabsorbable sutures had their sutures removed at that time. Patients were then seen in the plastic surgery clinic within four to five months by a single plastic surgeon blinded to the patient's study group. The wounds were evaluated using a previously validated visual analog scale (VAS) of cosmesis where 0 represents the worst possible cosmetic outcome and 100 the best possible cosmetic outcome. The plastic surgeon also repeated the WES and noted whether surgical scar revision was recommended for any of the wounds.

Measures. The primary outcome measure was the previously validated VAS of the wounds at four months after repair. Secondary outcome measures were WES of the wounds at five to ten days and at four months, complication rates (infection and dehiscence), and need for surgical scar revision.

All demographic information was obtained from the patient's record. A standardized study question-naire was completed prospectively by the recruiting physician; this questionnaire provided detailed data regarding the description of the wound as well as patient characteristics (inclusion/exclusion criteria). The research nurse collected the data, such as the WES, at the short-term follow-up visit. Long-term data were recorded by the blinded plastic surgeon on a standardized study sheet containing the VAS, the WES, and a space to check if scar revision was recommended.

Data Analysis. Patient characteristics and outcomes were compared using Fisher's exact test and the chi-square test for categorical variables and Student's t-test for continuous variables. A p-value less than 0.05 was considered significant. Relative risk ratios, with 95% confidence intervals (95% CIs), were calculated. Our sample size was calculated based on the potential long-term follow-up of our patients. Sample size was calculated based on a power of 90% ($\alpha = 0.05$; $\beta = 0.90$) to detect a difference of 12 mm on the previously validated scale of cosmesis.²⁰ We calculated that at least 43 patients were required per group ($\alpha = 0.05$; $\beta = 0.90$).

RESULTS

A total of 147 eligible patients were seen during the study period. Fifty-two patients declined to participate, mainly because of their inability to return for long-term follow-up. Of the 95 patients enrolled, 50 were randomized to group A and 45 to group NA.

The two groups were similar in age, gender, use of sedation and steri-strips, wound size, and mechanism of injury (Table 1). The locations of the laceration in the two groups were similar (Table 2). Data on missed

TABLE 1. Patient and Wound Characteristics in Included Patients

Characteristics	Group A (n = 50)	Group NA (<i>n</i> = 45)	p-value
Median age (yr)	8.1	9.5	0.15
Female (%)	20 (40)	17 (37)	0.15
Deep sutures (%)	2 (4)	2 (4)	1.00
Sedation (%)	6 (12)	4 (9)	0.75
Steri-strips (%)	24 (48)	22 (49)	0.92
Median wound length (cm)	2.0	2.0	0.63
Median wound width (cm)	0.5	0.5	0.61
Mechanism of injury (% sharp)	26 (53)	26 (58)	0.38

patients were also collected and analyzed. No differences were found between missed patients and those recruited with regard to patient and wound characteristics (Table 3).

All 95 patients presented for short-term follow-up. No differences were found in the proportion of optimal WES (6/6) between group A and group NA (62% vs. 49%; relative risk = 0.73; 95% CI = 0.45 to 1.17). No differences were found between group A and group NA for the rates of dehiscence (2% vs. 11%; p = 0.07) and infection (0% vs. 2%; p = 0.3). None of the patients with wounds repaired with plain gut absorbable sutures required suture removal.

Sixty-three of the 95 patients presented for long-term follow-up at four months: 34 in group A and 29 in group NA (Figure 1). The groups remained similar with regard to patient and wound characteristics (Table 4). In addition, the data on patients who presented for follow-up were compared with those who did not. No differences were noted in patient or wound characteristics in patients who presented for long-term follow-up versus those who did not.

The VAS at four months was 79 mm for group A (95% CI = 73 to 85) and 66 mm for group NA (95% CI = 55 to 76). In addition, no significant difference in the proportion of optimal WES was detected between group A (36% of patients) and group NA (28% of patients) at four months (relative risk = 0.88; 95% CI = 0.62 to 1.26). Surgical scar revision was recommended for only three patients: two were in group A, and one was in group NA. No patients chose to have their wounds surgically revised.

TABLE 2. Wound Locations in Included Patients

Location	Group A (n = 50)	Group NA (n = 45)
Face (%)	30 (60)	21 (47)
Lip (%)	0 (0)	1 (2)
Arms (%)	3 (6)	5 (11)
Torso (%)	1 (2)	0 (0)
Hands (%)	10 (20)	9 (20)
Legs (%)	5 (10)	7 (16)
Feet (%)	1 (2)	2 (4)

TABLE 3. Characteristics of Included versus Missed Patients (Refusals)

Characteristics	Included (n = 95)	Missed (n = 52)	p-value
Median age (yr)	8.8	8.5	0.72
Female (%)	37 (39)	13 (25)	0.1
Sedation (%)	10 (11)	4 (8)	1.0
Steri-strips (%)	46 (48)	21 (40)	0.4
Median wound length (cm)	2.0	3.0	0.6
Median wound width (cm)	0.5	0.5	0.96
Mechanism of injury (% sharp)	52 (55)	23 (45)	0.58
Location (% face)	51 (54)	29 (55)	0.72

DISCUSSION

Our study suggests that the use of plain gut absorbable suture material in pediatric traumatic lacerations affords good long-term cosmesis and similar complication rates as in traumatic wounds repaired with nonabsorbable, nylon suture material.

To our knowledge, this is the first study that has analyzed the cosmetic outcomes and complications of wounds repaired using absorbable versus nonabsorbable sutures in pediatric traumatic lacerations in the setting of the ED. A review of the literature from 1966 to the present shows two studies that conducted comparisons of absorbable and nonabsorbable sutures in patients with traumatic lacerations and compared

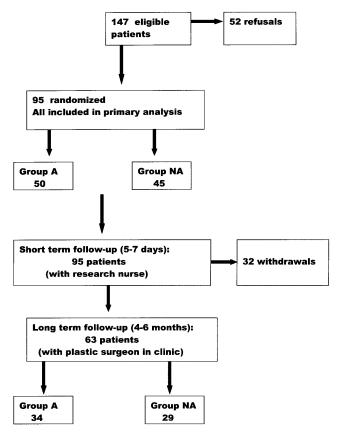


Figure 1. Patient allocation.

TABLE 4. Patient and Wound Characteristics at Four Months

<u>Characteristics</u>	Group A (n = 34)	Group NA (n = 29)	p-value
Median age (yr)	7.8	9.9	0.06
Female (%)	13 (38)	13 (45)	0.59
Sedation (%)	2 (6)	3 (10)	0.65
Steri-strips (%)	18 (55)	13 (45)	0.44
Median wound length (cm)	2.0	2.3	0.29
Median wound width (cm)	0.5	0.5	0.40
Mechanism of injury (% sharp)	15 (44)	18 (62)	0.15
Location (% face)	21 (62)	12 (41)	0.35

clinical cosmetic outcomes in these patients. Start et al. conducted a prospective clinical trial that examined the benefits of using absorbable sutures for the closure of scalp wounds in children.²¹ A total of 100 children were studied: 50 were randomized to repairs with chromic catgut and the other 50 to repairs with silk. At five-day follow-up, neither group of patients had complications. This particular study attempted to address the issue of cosmetic outcomes; however, cosmesis was assessed in a part of the body that may not be clinically relevant (the scalp) and results may not be generalizable to other more important areas such as the face. More recently, Sheety et al. conducted a five-year retrospective review of 102 adult patients with hand lacerations and compared the quality of scar formation in those patients repaired with 5.0 Vicryl versus those repaired with 5.0 nylon.²² They recommended absorbable suture material as an acceptable alternative to nonabsorbable sutures in the repair of hand lacerations in this age group. Unfortunately, this last study has several limitations, the most important being that the investigators did not use a standardized scale of cosmesis for comparisons.

When wounds require sutures, repair with absorbable sutures is clearly advantageous in that any further emotional and physical trauma for the patient is avoided. An important factor is the degree of distress and discomfort experienced during a laceration repair and during subsequent suture removal. At the suture removal follow-up, the use of certain instruments, such as needles and syringes, may frighten the already-traumatized child and result in the development of long-term negative interactions with health professionals in the future. ²³ Ideally, absorbable sutures should be used in children to avoid suture removal.

In addition, the costs associated with follow-up can be substantial. The repeat visit may result in missed workdays for the caregivers.

LIMITATIONS

Our study has some limitations. Its generalizability could be limited to the pediatric population. Further-

more, suture repairs were performed by trained pediatric ED personnel whose level of expertise in the management of pediatric lacerations may be different from physicians in other institutions without similar training. In addition, we had a large number of refusals (52 of 147 eligible patients). Often patients were reluctant to come for follow-up or, after presenting our study to them, insisted on absorbable sutures. In an attempt to detect any sample bias, we compared the patients who refused with the group of patients included in the study and found no difference with regard to patient and wound characteristics. Finally, we chose the most basic of absorbable sutures, namely, plain gut, and we cannot comment on possible results with other type of absorbable sutures. We chose plain gut, however, because it is widely available in most, if not all, EDs. In theory, many would agree that other more sophisticated types of monofilament or rapidly dissolving absorbable suture materials are designed to provide at least as good or better cosmetic results.

At present there may still be some individuals who believe that nonabsorbable material offers a slightly better alternative to absorbable sutures because it tends to result in fewer wound complications, such as dehiscence, and better wound cosmesis. There is no strong evidence to support this belief.

CONCLUSIONS

This prospective study of pediatric patients offers data suggesting that long-term cosmetic outcomes in wounds repaired with simple plain gut sutures seem to be at least as good as in wounds repaired with nonabsorbable nylon sutures.

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