SCIENTIFIC ADVANCES

Prospective, Randomized, Controlled Trial of Tissue Adhesive (2-Octylcyanoacrylate) vs Standard Wound Closure Techniques for Laceration Repair

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ABSTRACT

Objective: To compare a new tissue adhesive, 2-octylcyanoacrylate, with standard wound closure techniques for the repair of traumatic lacerations.

Methods: A prospective, randomized, controlled clinical trial enrolled consecutive patients >1 year of age with non-bite, non-crush-induced lacerations who presented <6 hours after injury. Structured closed-question data sheets were completed at the time of laceration repair and suture removal. Patients were randomly assigned to treatment with either 2-octylcyanoacrylate or standard wound closure. Infection was determined at the time of suture removal. Long-term cosmetic appearance (>3 months) was assessed by physicians using a previously validated categorical cosmetic scale and by patients using a 100-mm visual analog scale.

Results: There were 63 patients randomized to the octylcyanoacrylate group and 61 patients treated with standard wound closure techniques. The 2 treatment groups were similar with respect to age, gender, race, medical history, and wound characteristics. At the 5-to-10-day follow-up, only 1 wound was infected and only 2 wounds required reclosure due to dehiscence. These 3 patients received treatment with octylcyanoacrylate. At long-term follow-up, the cosmetic appearances were similar according to the patients (octylcyanoacrylate, 83.8 ± 19.4 mm vs standard techniques, 82.5 ± 17.6 mm; $p = 0.72$) and the physicians (optimal cosmetic appearance, 77% vs 80%; $p = 0.67$).

Conclusions: Wounds treated with octylcyanoacrylate and standard wound closure techniques have similar cosmetic appearances 3 months later.

Key words: wounds; lacerations; tissue adhesives; sutures; staples; infection; cosmetic appearance; cyanoacrylate; octylcyanoacrylate.

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Each year, >12 million patients sustain traumatic lacerations necessitating repair in the United States.[1] In the United States, suturing is the most common method of laceration repair. Suturing generally requires the painful injection of a local anesthetic, is time-consuming, requires specialized instruments, carries the risk of a needlestick

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injury to the practitioner, usually requires the patient to return for suture removal.

The ideal method of wound closure should be simple, rapid, inexpensive, painless, and bacteriocidal, and should achieve optimal cosmetic results. Tissue adhesives, which are available outside the United States, offer many of these characteristics. Until recently, the only commercially available tissue adhesive was n-2-butylcyanoacrylate (Histoacryl Blue, B. Braun Melsungen AG, Germany); however, it has not received widespread acceptance.

A new tissue adhesive, 2-octylcyanoacrylate, offers several advantages over n-2-butylcyanoacrylate. It is more pliable and less brittle. Therefore, it is less likely to fracture and can conform to irregular body contours. Additionally, 2-octylcyanoacrylate has been found to have 3 to 4 times the breaking strength of n-2-butylcyanoacrylate (unpublished data, Dimensional Analysis Systems, Inc., Leonin, NJ). The purpose of this study was to compare the outcome of lacerations repaired with 2-octylcyanoacrylate with the outcome of those repaired by standard wound closure techniques.

METHODS

Study Design: We performed a prospective, randomized clinical trial to compare a new tissue adhesive (2-octylcyanoacrylate, Dermabond, Closure Medical Corp., Raleigh, NC) with standard closure of traumatic lacerations. The main outcome measures for this trial were the patient's and physician's assessments of cosmetic appearance of the healed lacerations ≥3 months following repair. The study was approved by the University Medical Center Research Committee and the Committee on Research Involving Human Subjects at the State University of New York at Stony Brook.

Setting and Patient Population: The study was performed at the ED of University Medical Center at Stony Brook. The ED has an annual census of 47,000 patients. Consecutive patients who presented when 1 of 8 participating investigators was working were evaluated for study inclusion. Participating physicians all worked day, evening, night, and weekend shifts during the study period. More than 50% of all hours were covered during the study period. Hours were covered in proportion to the circadian pattern of patient presentation. Because we previously demonstrated that the level of training and experience is related to cosmetic outcome, all investigators were full-time academic emergency medicine faculty.[2] Combined, the investigators had repaired >1,000 lacerations between 1992 and 1996. Investigators reviewed a 20-minute instructional video on the application of tissue adhesives and practiced applying tissue adhesives to frankfurters 2 to 3 times prior to study commencement. None of the physicians had any previous experience with octylcyanoacrylate tissue adhesives. One had previously used butylcyanoacrylates.

Patients were eligible for inclusion in the protocol if they were ≥1 year of age; were of generally good health without significant systemic abnormalities; agreed to return for 5–10-day and 3-month follow-up; and provided written informed consent. Specific exclusion criteria were patients with multiple trauma, previously diagnosed peripheral vascular disease, insulin-dependent diabetes mellitus, known bleeding diathesis, known personal or family history of keloid formation or scar hypertrophy, and known allergy to cyanoacrylate compounds or formaldehyde.

In addition to inclusion and exclusion criteria for patients, the study also had specific criteria based on laceration etiology, degree of contamination, and location. Eligible wounds were those that would require 5-0 or smaller sutures for skin closure. Determination of appropriate suture size was left to the judgment of the study physician. This size suture was chosen because the functional tensile strength of 2-octylcyanoacrylate is comparable to that of 5-0 sutures (Dimensional Analysis Systems, Inc.). Wounds secondary to animal or human bites, punctures, decubitus ulcers, or crush injuries that resulted in a burst (stellate) laceration were excluded. Wounds with visual evidence of active local or systemic infection, with gangrene, with visible contamination or devitalized tissue, or within active rashes were also excluded. In addition, wounds located at the vermilion border of the lip, in the mucosa, or in areas covered by natural hair (precluding an assessment of cosmetic outcome at 3 months) were excluded. All other wounds were included in the study.

Treatment Group Assignment: Patients meeting all eligibility requirements were randomized to treatment with either topical application of 2-octylcyanoacrylate (Dermabond) or standard wound closure (sutures, adhesive tapes, or staples). Randomization occurred after informed consent was obtained but prior to wound preparation and closure. There were 2 sets of randomization codes. Lacerations necessitating subcutaneous and percutaneous closure and lacerations necessitating only percutaneous closure were randomized separately to ensure approximately equal numbers of cases in the treatment groups.

Measurements: A wound registry data sheet was prospectively completed for all patients sutured in the ED using a closed-question format.[3] Information recorded included patient demographics (age, sex, race); medical history and medications; wound characteristics (etiology of wound, time of injury, wound location, length, shape, and margin, degree of contamination, and presence of foreign bodies); wound preparation (type of anesthetic, method of irrigation or scrub and solution used, and wound debridement); and wound closure techniques. In addition,

TABLE 1 Demographic Characteristics

	Octylcyano-acrylate (n = 63)	Standard Closure (n = 61)	p-value
Age—mean ± SD	20.8 ± 19.4 yr	15.2 ± 13.5 yr	0.07
Gender—male	60%	62%	0.82
Race—white	83%	85%	0.39
Past history			
Obesity	2%	5%	0.36
Skin abnormalities	0%	0%	1.00
Cardiovascular disease	3%	2%	1.00
Gastrointestinal disease	2%	2%	1.00
Hepatic disease	0%	0%	1.00
Renal disease	0%	0%	1.00
Endocrine abnormalities	0%	0%	1.00
Hematologic abnormalities	0%	0%	1.00
Extremity abnormalities	2%	0%	1.00
Allergies	3%	2%	1.00
Other	13%	10%	0.88
Available for short-term follow-up	90%	93%	0.54
Available for long-term follow-up	97%	90%	0.13

time required for skin closure was measured and recorded by the suturing physician using his or her own wrist watch.

At the time of suture removal (5–10 days after wound closure), patients were evaluated for the presence of infection. Observers were blinded to the identity of the practitioner who sutured the wound. At this time, the progress of wound healing was assessed based on edge apposition, epidermal separation, and dehiscence to original depth. Dehiscence was considered to occur if the wound required retreatment. Infection was assessed with respect to erythema, edema, pain, and temperature using a 4-point scale for each. The overall clinical impression of infection has been shown to be reliable with high interobserver concordance.[3] Cosmetic appearance was not assessed at the time of suture removal because short-term appearance does not correlate with long-term cosmetic outcome.[4]

At long-term follow-up, the cosmetic appearance was assessed by both the patient and a study physician different from the study physician who repaired the laceration. Physicians rated the cosmetic appearance of the wound using a previously validated 6-point scale.[3–5] Lacerations were assigned 0 or 1 point each for the presence or absence of the following: a step-off of borders; contour irregularities; wound margin separation; wound edge inversion; excessive wound distortion; and overall appearance. A total cosmetic score was then calculated by adding the individual scores for the 6 categories.[3] Wounds receiving a score of 6 were considered to have an optimal cosmetic appearance. All other wounds were considered to have a suboptimal appearance. This scale has excellent interphysician concordance for total cosmetic score.[3,4] Patients were asked to "Draw a line across the diagram below to show how satisfied you are with the way your laceration looks" by completing a 100-mm visual analog scale with the ends labeled "most satisfied" and "least satisfied" with cosmetic outcome. Physician evaluation of cosmetic outcome using the 6-point categorical scale has been shown to be related to patient satisfaction with the outcome of laceration repair.[5]

Data Analysis: Data were entered into Access 95 (Microsoft, Inc., Redmond, WA) and imported into SPSS 6.0 for Windows (SPSS, Inc., Chicago, IL) for statistical analysis. Categorical variables are expressed as the percent frequency of occurrence, and the study and control groups were compared using χ^2 tests. Continuous variables are reported as means ± SDs (or medians with interquartile ranges [IQRs]), and comparisons were performed using t-tests. The main outcome was the long-term cosmetic appearance, as assessed ≥3 months after wound repair. Secondary outcome measures were the rates of wound infection and dehiscence as assessed within 5 to 10 days of wound repair. All tests were 2-tailed with α preset at 0.05. This study had a power of 80% to detect a 10-mm difference in the patient's assessment of cosmetic appearance at the time of suture removal. Previous studies have shown that an 11-mm difference in patient perceptions of wound appearance is analogous to the difference between the physician assessments of optimal and suboptimal cosmetic appearance using the categorical scale described above.[5]

RESULTS

There were 124 study participants: 63 patients were treated with octylcyanoacrylate and 61 patients were treated with standard wound closure techniques (54, sutures; 1, staples; and 6, adhesive tapes). Six patients in the octylcyanoacrylate group and 3 patients in the standard care group received subcutaneous sutures. The 2 treatment groups were similar with respect to age, gender, race, and medical history (Table 1). Overall, 38 patients (31%) were 1–5 years of age; 31 (25%) were 6–17 years of age; and 55 (44%) were ≥18 years of age. Wound characteristics were also similar between the treatment groups (Table 2).

Comparison of wound preparation techniques found that the patients treated with octylcyanoacrylate less frequently received local anesthesia (21% vs 89%, $p < 0.001$). The 2 groups were similar with respect to decontamination with normal saline (81% vs 75%; $p = 0.36$),

irrigation (50% vs 65%, p = 0.13), and the use of a scrub (48% vs 31%, p = 0.08). Wounds that were sutured received a mean (±SD) of 3.8 ± 1.6 sutures. No patients received prophylactic antibiotics. The mean time required for skin closure alone (not including injection of anesthesia, waiting for adequate anesthesia to develop, and wound cleansing) was 5.98 ± 6.40 minutes for the octylcyanoacrylate group vs 10.02 ± 6.90 minutes for the standard closure group (p = 0.001).

For the 114 (92%) patients who returned for evaluation 5 to 10 days after laceration repair, only 1 wound infection was noted (octylcyanoacrylate group). The infection was considered secondary to poor cleansing and failure to remove a piece of wood from the wound. Two wounds treated with octylcyanoacrylate required reclosure due to dehiscence: a 2-year-old boy manually removed the octylcyanoacrylate from his chin, and an adult female had sloughing of the octylcyanoacrylate from her calf. Neither had received deep sutures. Both required a second wound closure.

Of the 116 (94%) patients who returned for long-term follow-up assessments at a median of 93.5 days (IQR 87–118) following laceration repair, there were no differences between groups. Patient assessments of cosmetic appearance were similar for the 2 groups. The mean ± SD cosmetic score for patients whose wounds were closed with octylcyanoacrylate was 83.8 ± 19.4 mm. The mean ± SD cosmetic score for patients whose wounds were closed with standard techniques was 82.5 ± 17.6 mm. These scores were not different (p = 0.72).

Physician assessments of cosmetic appearance were also similar for the 2 groups. The percentage who received an optimal cosmetic score was 77% for the octylcyanoacrylate group and 80% for patients whose wounds were closed with standard techniques. These percentages were not significantly different (p = 0.67).

TABLE 2 Wound Characteristics

	Octylcyanoacrylate (n = 63)	Standard Closure (n = 61)	p-value
Mechanism of injury			0.92
Glass	9%	13%	
Wood	4%	2%	
Non-glass sharp object	24%	23%	
Blunt object	64%	63%	
Location of laceration			0.13
Face	56%	71%	
Scalp	11%	1%	
Hand/fingers	22%	18%	
Other upper extremity	3%	7%	
Lower extremity	8%	3%	
Length of laceration—mean ± SD (range)	2.1 ± 0.9 cm (1–5 cm)	1.9 ± 1.0 cm (1–7 cm)	0.31
Width of laceration—mean ± SD (range)	3.2 ± 1.9 mm (0–10 mm)	2.9 ± 2.0 mm (0–10 mm)	0.44
Aligned with tension lines—yes	40%	50%	0.31
Shape—linear	82%	88%	0.70
Gross contamination	0%	0%	1.00
Foreign body identified	0%	0%	1.00

DISCUSSION

The ultimate goals of wound closure are avoiding infection and achieving a functional and cosmetically appealing scar. To date, most clinical studies have focused on wound infection rates despite the fact that wound infection rates are low[6–13] and patients are more concerned with the ultimate cosmetic appearance of their wounds.[14] With the development of a reliable and valid cosmetic scale, emphasis is shifting toward measuring cosmetic appearance as the primary outcome measure of wound repair.[3–5,14,15]

Use of cyanoacrylates as tissue adhesives was first described in 1959.[16] Cyanoacrylates are liquid monomers that polymerize into a solid material on contact with tissue anions, forming a thin film that causes adherence of the 2 opposed wound edges. While the short-chain cyanoacrylates (methyl and ethyl forms) have been associated with tissue toxicity due to rapid degradation, the higher-chain derivatives (such as n-2-butylcyanoacrylate and 2-octylcyanoacrylate) have been shown to have minimal if any cytotoxicity.[17]

Mizrahi et al. described the use of n-2-butylcyanoacrylate in >1,500 children with minor lacerations of the scalp, face, and limbs.[18] Only 28 children developed wound infections and 10 required sutures for dehiscence. In a prospective, observational study of 143 patients conducted at an urgent care center in Israel, wound infection rates and dehiscence rates were similar in patients treated with and without tissue adhesives.[19] On follow-up, cosmetic results of wounds repaired using tissue adhesive were judged to be good. Similarly, good results have been reported when tissue adhesives were used for closure of various plastic and reconstructive surgeries, urologic procedures, general surgical procedures, and application of split-thickness skin grafts.[20–24]

Recently, Quinn et al. performed the first Canadian prospective, randomized controlled clinical trial that compared the effectiveness of n-2-butylcyanoacrylate and suturing for the repair of facial lacerations in 75 children who presented to the ED.[25] All lacerations were <4 cm long and none required deep sutures. The use of tissue adhesive was faster and less painful than the use of sutures. Similar cosmetic results were obtained at a 3-month follow-up. Quinn et al., in a randomized, controlled clin-

ical trial of 136 adult patients treated with sutures or 2-octylcyanoacrylate, found similar results.[26]

In our prospective, randomized, controlled clinical trial, we found that 2-octylcyanoacrylate performs as well as standard wound closure techniques in terms of wound infection rates, wound dehiscence, and long-term cosmetic outcome. We also found that patients who received wound closure with 2-octylcyanoacrylate were less likely to require anesthesia, did not require the physician to wait for the onset of anesthesia prior to closing the wound, and had faster wound closure times. Differences between our study and that of Quinn et al. were the patient population and the choice of outcome measurements. Our study included children and adults, while Quinn et al.'s evaluated only adults. Our outcome parameters were assessed by direct observation of the healed wounds by physicians and patients, while Quinn et al. assessed cosmetic appearance by direct observation of trained research nurses and photographic observation by plastic surgeons.[26] Both studies used validated cosmetic scales.

A cost-effective analysis in Canada, which compared the costs of wound repair using tissue adhesives and sutures, demonstrated significant cost savings using adhesives.[27] These cost savings were due to reduced physician and ancillary services, reduced equipment needs, and elimination of the need for suture removal. In addition, tissue adhesives have bacteriostatic properties. In an in-vitro model, Quinn et al. demonstrated antimicrobial effects against gram-positive organisms for both n-2-butylcyanoacrylate and 2-octylcyanoacrylate.[28] Noordzij et al. demonstrated that wounds treated with n-2-butylcyanoacrylate have considerable resistance to bacterial growth compared with wounds closed with sutures.[29]

LIMITATIONS AND FUTURE QUESTIONS

This study has several limitations that deserve comment. Although the study was a randomized, controlled clinical trial and patient enrollment occurred during all hours of the day and night, investigators were not present 100% of the time during the study period. Wound preparation was not standardized; however, we did not detect statistical differences in irrigation, scrubbing, and other wound care practices. The inclusion of staples and adhesive tapes in the control group would have biased the study toward more favorable outcomes in that group because the use of staples has been associated with improved cosmetic outcomes[30] and the use of adhesive tapes has been associated with decreased infection rates.[31] The inclusion of these patients may have biased the study against tissue adhesives.

Several disadvantages of tissue adhesives merit discussion. The wound bursting strength of the cyanoacrylates is less than that of sutures. However, it is not clear how much tensile strength is required to avoid wound dehiscence. To date, increased rates of wound dehiscence have not been reported with the use of tissue adhesives. Although sutures provide a more immediately secure wound closure than adhesives, the breaking strengths in wounds are similar 7 days after injury.[29] Until clinical studies specifically address the use of tissue adhesives in areas of skin subjected to large static and dynamic tensions (e.g., over joints), we would not advocate their use unless the tension is eliminated by deep sutures.[32]

CONCLUSION

New tissue adhesives such as 2-octylcyanoacrylate offer many of the advantages of the ideal wound closure devices. They have previously been shown to be inexpensive and painless, and have antimicrobial activity against gram-positive organisms. We have shown that they have a low rate of dehiscence and a low infection rate, and provide excellent cosmetic results.

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