# Critical Review Form
## Therapy

**A Randomized, Controlled Trial Comparing Long-term Cosmetic Outcomes of Traumatic Pediatric Lacerations Repaired with Absorbable Plain Gut versus Nonabsorbable Nylon Sutures, *Acad Emerg Med* 2004; 11: 730-735**

**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". (p. 731)**

**Methods:** **This was a randomized controlled clinical trial conducted at the McGill University Montreal Children's Hospital from January 1999 thru December 2001. Eligible subjects were < 18-years with lacerations < 12-hours old requiring sutures as judged by the Pediatric EM physician who served as both the clinician and the researcher. Exclusion criteria included: animal or human bites, heavily soiled wounds, keloid-prone patients, wounds crossing joints or high tension areas, tender/nerve/cartilage/bone involvement, collagen vascular disease, prolonged corticosteroid use, immunodeficiency, diabetes or clotting disorder, or scalp lacerations. Wounds amenable to tissue adhesive closure (< 5 cm length and < 0.5 cm width) were also excluded.**

**Pediatric EM fellows and six full-time board certified faculty recruited all subjects during clinical shifts. Eligible subjects were randomized to Group A (absorbable plain catgut sutures) or Group NA (non-absorbable nylon sutures), but otherwise received wound management at the discretion of the EM physicians:**

- 1% lidocaine local anesthesia (up to 4 mg/kg)
- Facial wound closure with 5-0 or 6-0, extremity or torso wound closure with 4-0 or 5-0.
- Simple interrupted suturing using a cutting needle.
- Deep wounds (beyond dermal layer) deep layers with plain gut sutures using a buried knot.
- Steri-strips, topical and systemic antibiotics at the physician's discretion.

**Within 5-10 days all subjects had follow-up at the outpatient clinic where a single research nurse who specialized in wound care evaluated all wounds using a validated wound evaluation score (WES) on six variables: presence of step-off, contour irregularities, margin separation, edge inversion, extensive distortion, and overall cosmetic appearance. A WES score of 6/6 is considered optimal. The**

**research nurse also noted the presence of infection (purulent discharge, excessive erythema/pain or fever) or wound dehiscence at that time. Non-absorbable sutures were removed at the time so the study nurse was not blinded to group allocation. At 4- or 5-months, the patients were also evaluated by a single plastic surgeon who repeated the WES score evaluation and evaluated the wound using a validated visual analog score (VAS) from 0 (worst) to 100 (best outcome). Standardized study questionnaires were used at each stage.**

**The primary outcome was the 5-month VAS and the sample size was computed based upon $\alpha = 0.05$, $\beta = 0.90$, and a minimally significant difference on the VAS of 12 mm Hg (ref) so that 13 patients would be required in each group.**

| Guide | | Comments |
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| **I.** | **Are the results valid?** | |
| **A.** | **Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?** | |
| 1. | Were patients randomized? | Yes. "Subjects were randomized (by block numbers of six) into one of two groups". (p. 732) |
| 2. | Was randomization concealed (blinded)? | No. Patients, clinicians, and research nurse (at 5-10 d follow-up) all knew which treatment was received. Therefore, co- intervention bias and ascertainment bias are possible.<br><br>Although blinding of each group would have been technically feasible using identical appearing suture material, doing so would have increased the expense and logistical complications of the trial immensely. |
| 3. | Were patients analyzed in the groups to which they were randomized? | Unknown since no clear statement of intention-to-treat. |
| 4. | Were patients in the treatment and control groups similar with respect to known prognostic factors? | Yes. "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)". (p. 732) |
| **B.** | **Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?** | |
| 1. | Were patients aware of group allocation? | Yes. See I-A-2 above. |

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| 2. | Were clinicians aware of group allocation? | Yes. See I-A-2 above. |
| 3. | Were outcome assessors aware of group allocation? | Yes and No. The research nurse at 5-10 days was aware since he or she had to know which had nylon sutures to remove. The plastic surgeon who assessed outcomes at 4-5 months, however, was blinded to subjects' group allocation. |
| 4. | Was follow-up complete? | "All 95 patients presented for short-term follow-up". (p. 733)<br>However, only "Sixty-three of the 95 patients (66%) 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". (p. 733) |
| **II.** | **What are the results (answer the questions posed below)?** | |
| 1. | How large was the treatment effect? | • Among 147 eligible subjects, 95 were enrolled (50 Group A, 45 Group NA).<br>• Wounds were primarily face (78%) and hands.<br>• No differences were noted in short-term optimal WES (6/6 score) between Group A and NA (62% vs. 49%, relative risk 0.73, 95% CI 0.45 to 1.17).<br>• No difference s noted in dehiscence rates (2% A vs. 11% NA, p = 0.07) though trend suggested higher rates with nylon.<br>• At 4-5 months plastic surgery evaluation, VAS was 79 mm (95% CI 73 – 85) for Group A vs. 66 mm (95% CI 55 – 76 for Group NA. There was again no significant difference between groups for the WES score at that time (optimal WES 36% A vs. 28% NA, RR = |

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| | | 0.88, 95% CI 0.62 to 1.26).<br>• Three patents had wound revisions recommended, none choose to. |

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| 2. | How precise was the estimate of the treatment effect? | See 95% CI above. |
| **III.** | **How can I apply the results to patient care (answer the questions posed below)?** | |
| 1. | Were the study patients similar to my patient? | No, these patients are pediatric laceration victims so uncertain external validity in adults. |
| 2. | Were all clinically important outcomes considered? | No. The investigators did not assess patient discomfort with suture repair or satisfaction with cosmetic outcome or inconvenience with follow-up requirements. Further, cost-effectiveness was not assessed. |
| 3. | Are the likely treatment benefits worth the potential harm and costs? | Yes. Compared with traditional nylon suture repair, "the use of plain gut absorbable suture material in pediatric traumatic lacerations affords good long-term cosmesis and similar complication rates". (p. 733) |

## Limitations

1) **Failure to reference or use CONSORT reporting guidelines.**
2) **Failure to blind patient, clinician or nurse outcome assessor to allocation arm increases risk of bias.**
3) **No intention-to-treat statement.**
4) **No reporting of irrigation methods or prophylactic antibiotic use.**
5) **No reporting of reasons for excluding subjects.**
6) **Under-powered for primary outcome (needed 86 to complete follow-up, had 63) and not designed to evaluate therapeutic equivalence.**
7) **External validity limited to pediatric patients in pediatrics ED.**

## Bottom Line

**Among immunocompetent pediatric patients with lacerations not amenable to tissue adhesive wound closure (i.e. wounds > 5 cm length or > 0.5 cm width are not amenable to glue) closed with simple interrupted sutures, plain catgut provides similar or better cosmetic outcomes at 1-week and 5-months as traditional non-absorbable nylon suture. Future appropriately powered analyses should assess these outcomes on adult patients while using more contemporary absorbable sutures.**