Critical Review Form
Therapy

Cosmetic Outcomes of Absorbable Versus Nonabsorbable Sutures in Pediatric Facial Lacerations, *Ped Emerg Care* 2008; 24: 137-142

Objectives: **"To demonstrate non-inferiority of absorbable sutures versus non-absorbable sutures as measured by cosmetic outcomes at three months. Secondary objectives include comparisons with respect to complication rates including infection, wound dehiscence, keloid formation, and parental and patient satisfaction at three months". (p. 137)**

Methods:

Prospective randomized clinical trial conducted in a single university-based urban pediatric ED (Temple University) from June 2005 to February 2006. Inclusion criteria included age > 1 years and < 18 years with 1-5 cm facial laceration. Exclusion criteria included inappropriate age or laceration length, irregular borders, mammalian bite injury, contaminated via visual inspection, wounds > 8 hours old, pre-existing immunodeficiency or clotting disorder, pregnancy, diabetes, or renal dysfunction.

Patients were randomized following consent. Both groups had wounds repaired with 5-0 or 6-0 suture with absorbable group receiving fast-absorbing surgical catgut (FAC) and non-absorbable group receiving nylon. Wounds were only repaired by attending physicians and all patients were discharged with standard wound care instructions. All patients were instructed to return at 5 – 7 days for suture removal. All remaining sutures (FAC and nylon) were removed at that time and the wound inspected by an attending physician for infection ("required systemic antibiotics") or dehiscence ("required the placement of additional sutures or tissue adhesives").

Patients were asked to return again at 3-months to evaluate wound healing cosmesis. Using a single camera and standard protocol the healed facial wounds were photographed and three pediatric EM physicians subsequently rated wound-healing using the cosmesis visual analog scale (VAS) with a minimally significant difference defined as > 15 mm (Quinn 1998). Additionally, parents and patients (> 15 years) rated their wound using the cosmesis VAS and answered survey questions about the perceived complications, convenience, and consideration of using the same suture material in the future.

Based upon as *a priori* VAS difference of 15 mm with 18.5 mm SD and 40% participant at attrition rate, this study would require 27 participants per group to

attain 90% power with one-sided α = 0.05 (non-inferiority trial). The investigators also calculated the intraclass correlation coefficient between raters for the VAS.

Guide		Comments
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. "The suture assignments, as determined by prior randomization,were kept in sealed envelopes inside the packets with all the study-related forms. Only after obtaining written informed parental consent in all subjects and written informed assent in children older than 7 years were the seal broken and the type of suture revealed". (p. 138)
2.	Was randomization concealed (blinded)?	The randomization assignments were concealed in sealed envelopes as noted above, but patients, parents, clinicians, and outcome assessors were not explicitly blinded to the allocation arm after the envelope was opened.
3.	Were patients analyzed in the groups to which they were randomized?	No clear statement of intention-to-treat. In fact, statistical analyses only preformed on the 57% with 3-month follow-up.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes. "There were no significant differences in race, sex, wound length, number of sutures, and layered repair rates in the 2 groups of patients who completed the entire study (Table 1) and in those who did not. The overall median age was 77 months (range, 23-225 months). The patients randomized to the catgut group seemed to be slightly younger (median age, 64 months) than those randomized to the nylon group (median age, 81 months), although this did not reach statistical significance". (p. 139)
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.
2.	Were clinicians aware of group allocation?	Yes.
3.	Were outcome assessors aware of group allocation?	Yes at 7-day follow-up, but no at 3-months when photographs reviewed by 3 physicians.

4.	Was follow-up complete?	" Thirty-nine patients (80%) in the catgut group and 35 patients (90%) in the nylon group returned for the 5- to 7-day follow-up. A total of 47 patients (or 53% of the patients initially enrolled) returned for the 3-month evaluation, 23 in the catgut group and 24 in the nylon group, and statistical analyses were performed on this cohort". (p. 139)
II.	**What are the results?**	
1.	How large was the treatment effect?	• From 674 patients with lacerations, 308 had non-facial and 183 non-eligible facial lacerations and another 35 refused to consent or were missed (CONSORT diagram, Fig 1, p. 138) leaving 90 subjects for randomization but one subject in each group were subsequently excluded post-randomization for ineligible lacerations (> 5 cm length). • **The 3-month ED evaluation of wound cosmesis did not differ between nylon (93.7 mm) and FAC** (92.3, difference of the means 1.4 (95%, CI – 5.3 to 8.2) with an ICC 0.42. • Parental 3-month evaluation of wound cosmesis also did not differ between nylon (91.2) and FAC (86.3, difference of the means 4.9; 95% CI 2.4 – 7.4). This had power > 90% to detect a difference between groups if one existed. • Since 47% of subjects were lost to follow-up, the investigators conducted a post-hoc analysis to determine the mean VAS necessary in this group to make FAC inferior to nylon. The result would have had to been mean VAS 66.6 mm in the 26 catgut subjects who did not finish the study. This seems unlikely given the means and 95% CI of those who did finish the study. • One patient who finished the study (FAC group) had wound dehiscence. • None of the patients in either group developed a wound infection. • 70% of FAC subjects had at least one suture in place that was removed at 5 – 7 day follow-up. • More FAC parents reported complications (13% vs. 0%) including three premature suture unraveling and one large scan for nation. • The parental survey demonstrated that FAC was more convenient (91% vs. 95%) and more likely to be requested in the future (96% vs. 79%).

2.	How precise was the estimate of the treatment effect?	95% CI are sufficiently narrow for the primary outcome. **VAS at 3 Months (n = 47)** VAS Mean (95% CI) / VAS Difference of the Means (95% CI) Observers Catgut 92.3 (89.1-95.4) 1.4 (-5.31-8.15) Nylon 93.7 (91.4-96.0) Parental Catgut 86.3 (78.4-94.1) 4.9 (2.41-7.41) Nylon 91.2 (86.9-95.4)
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 are pediatric rather than adult patients. However, is there a biologically plausible reason why adult facial laceration healing following traumatic laceration repair should differ from children?
2.	Were all clinically important outcomes considered?	No assessment of cost-effectiveness or time efficiency (lost work/school days) which will be substantially fewer with absorbable sutures.
3.	Are the likely treatment benefits worth the potential harm and costs?	Yes. With no difference in technical difficulty or time to repair, emergency clinicians can simultaneously reduce healthcare cost, patient/parental inconvenience, and ED/clinic overcrowding without negatively impacting cosmesis or complication rates by simply selecting absorbable rather than non-absorbable suture material.

Limitations

1) **Failure to reference or incorporate CONSORT guidelines for RCT.**
2) **Failure to blind outcome assessors to allocation arm.**
3) **No intention-to-treat statement or analysis.**
4) **No cost-effectiveness analysis.**

5) **Under-powered (though still > 9% power) for primary outcome which required 27 subjects in each group by *a priori* calculations. Also, not powered as an equivalence trial.**
6) **Limited external validity with large number of exclusion criteria, pediatric –age group attending-specified wound repair, and single-center design.**
7) **Significant loss to follow-up rate without attempt to identify outliers or bad outcomes.**

Bottom Line:

In healthy children with traumatic facial lacerations < 8-hours old repaired in one children's hospital ED by pediatrician or pediatric EM faculty (not residents or med students), absorbable cutgut offers equivalent wound cosmesis (as judged by parents and clinicians) at 3-months without increasing complication rates.