Critical Review Form
Therapy

Cosmetic Outcomes of Facial Lacerations Repaired With Tissue-Adhesive, Absorbable, and Nonabsorbable Sutures, *Am J Emerg Med* 2004; 22: 254-257

Objectives: **"To compare the cosmetic outcomes of lacerations limited to the face and closed with nonabsorbable nylon suture, octylcyanoacrylate , or rapid-absorbing gut suture. Our hypothesis was that there would be no clinically significant differences among them when measured at 9-months using a visual analog cosmesis scale (VACS)". (p. 254)**

Methods: **Prospective randomized trial at Regions Hospital (St. Paul, MN) between March 1999 and August 2000 enrolling consecutive patients over age 5-years presenting between 7:00am and 2:00am with facial lacerations. Exclusion criteria included bite/stellate/crush wounds, wounds > 24 hours old, immunocompromised or known keloid forming subjects, or wounds involving the vermillion border, ear, or hairline.**

All wounds were closed by one of nine PA's with 2- to 25-years experience. If two-layer closure was necessary, deep layers were closed pre-randomization. Octylcyanoacrylate (cc) closure was applied in standard fashion with wound edges held for at least 30 seconds. Rapid absorbing gut suture (RG) or nonabsorbable nylon (NG) used 6-0 suture and 48-hours of topical anti-bacterial ointment post-procedure.

Patients returned at day 4 or 5 for wound inspection and suture removal (NG group). Assessment for infection (definition = needs antibiotics) or dehiscence (definition =needs suture closure) were made at that time by the PA or physician on duty. Patients also returned at 9- to 12-months for two physician evaluators to guide the cosmetic appearance using the validated VACS score (Quinn 1995). On this scale 0 mm = worst score and 100 mm = best score. At that time patients (or parents for the < 17 year subset) evaluated wound appearance using a satisfaction analog scale. "All patients were given monetary incentives for follow-up". (p. 256)

The primary outcome was the two physician VACS, To detect a minimally clinical significant difference of 15 mm (Quinn 1998, Singer 2000) with a standard deviation of 19.4 mm, and a power of 90% with $\alpha = 0.05$ the *a priori*, sample size was 36 patients in each of the three groups.

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. "A computer-generated randomization list assigned an equal number of subjects to each closure material group". (p. 254)
2.	Was randomization concealed (blinded)?	Yes. The study used "blind outcome evaluations" by the physicians at 9- to 12-months. Patients, families, treating clinicians, and short-term follow-up clinicians were <u>not</u> blinded to subject allocation arm.
3.	Were patients analyzed in the groups to which they were randomized?	No intention-to-treat statement clearly stated.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Although the investigators do not clearly describe their statistical analyses (p-values, 95% CI), review of Table 1 (p. 255) does not suggest any clinically significant differences between treatment groups for age, gender, follow-up rates, mechanism of injury, delay to wound closure, or laceration depth/length.
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.
2.	Were clinicians aware of group allocation?	Yes. See I-a-2 above.
3.	Were outcome assessors aware of group allocation?	No. Physicians assessing wound cosmetic appearance at 9 – 12 months using the VACS scale were unaware of the subject's allocation arm.

<table>
<tr><td>4.</td><td>Was follow-up complete?</td><td>No. “ Our follow-up rate was 58%, which is similar to the follow-up rate that Quinn et al. found in their 12-month cosmetic follow-up study (57%).” (p. 256) (Quinn 1998) there was no significant difference between groups for follow-up rate (NL 57%, OC 55%, RG 62%).</td></tr>
<tr><td>II.</td><td>What are the results (answer the questions posed below)?</td><td></td></tr>
<tr><td>1.</td><td>How large was the treatment effect?

Mean VACS* Outcome Scores at 9 to 12 Months (95% confidence intervals)
<table><tr><th></th><th>NL (N =28)</th><th>OC (N =27)</th><th>RG (N =29)</th><th>P</th></tr><tr><td>Reviewer A (VACS)</td><td>77.1 (71.0–83.2)</td><td>77.2 (70.9–83.5)</td><td>73.6 (66.8–80.4)</td><td><0.65</td></tr><tr><td>Reviewer B (VACS)</td><td>88.0 (83.0–93.1)</td><td>86.0 (77.4–94.7)</td><td>88.7 (85.3–92.2)</td><td><0.79</td></tr><tr><td>Patient (VAS)</td><td>83.2 (77.3–89.1)</td><td>82.0 (75.9–88.1)</td><td>79.6 (73.1–86.0)</td><td><.0.67</td></tr></table>Abbreviations: VACS, visual analog cosmesis scale; NL, nylon suture; OC, octylcyanoacrylate; RG, rapid absorbing gut suture.

* Score of 100 = best possible cosmetic outcome.</td><td>230 subjects were eligible during study period but 40 were missed, 40 refused and 5 dropped out pre-randomization leaving 143 in the trial (49 NL, 49 OC, 47 RG).
Those lost to follow-up had shorter wounds (216 mm vs. 259 mm, p = 0.045), but did not differ by age, gender, wound width, or mechanism.
OC subjects were more likely to have a single layer closure (95% vs. 76% in NL and RG groups).
Those were no clinically significant differences between NL, OC, or RG groups (Table 4, p. 256 and at left).</td></tr>
<tr><td>2.</td><td>How precise was the estimate of the treatment effect?</td><td>Sufficiently precise since the 95% CIs above do widely overlap.</td></tr>
<tr><td>III.</td><td>How can I apply the results to patient care (answer the questions posed below)?</td><td></td></tr>
<tr><td>1.</td><td>Were the study patients similar to my patient?</td><td>Yes. ED patients with facial lacerations requiring suture repair.</td></tr>
<tr><td>2.</td><td>Were all clinically important outcomes considered?</td><td>Yes, but future trials should assess point-of-cure patient satisfaction, different wound sites more generalized populations and cost-effectiveness.</td></tr>
</table>

3.	Are the likely treatment benefits worth the potential harm and costs?	Yes. Absorbable sutures can help alleviate ED crowding and cost-ineffective, unreimbursed medical spending by obviating the need for suture removal follow-up visits after facial lacerations since glue or absorbable sutures offer similar cosmetic outcomes compared with traditional non-absorbable sutures.

Limitations

1) **Failure to reference or incorporate CONSORT guidelines.**
2) **No intention-to-treat statement.**
3) **No reporting of irrigation methods or prophylactic antibiotic use patterns.**
4) **Under-powered for primary outcomes (needed 36 per group, but had 27 to 29 per group). Post hoc power analysis still yielded 81% power. (p. 257)**
5) **Significantly different two-layered closure in OC group suggesting compromised pre-randomization allocation concealment.**

Bottom Line

Among immunocomponent ED patients > 5 years old with facial lacerations < 24 hours old, octylcyanoacrylate glue, rapid absorbing gut suture, and non-absorbing nylon sutures provided equivalent wound cosmetic outcomes at 9 – 12 months post-injury without increasing the risk of short-term dehiscence or infection. Future trials should assess cosmetic outcomes or non-facial lacerations in more general ED populations (obese, elderly, rural, and diabetic), while evaluating point-of-care patient satisfaction and cost-effectiveness.