Research Article

2 Octyl Cyanoacrylate Tissue Glue (Dermabond Tm) Versus Polypropylene Skin Closure in Primary Unilateral Cleft Lips

Saadia Nosheen Jan[1], Umer Nazir[2], Hamid Hussain Ansari[3], Muhammad Sohail[4], Afzal Basheer[5], Muhammad Mustehsan Bashir[6]

[1]Assistant Professor, Department of Plastic Surgery, KEMU/ Mayo Hospital, Lahore; [2]Assistant Professor, Department of Plastic Surgery, KEMU/ Mayo Hospital, Lahore; [3]Associate Professor, Department of Plastic Surgery, KEMU/ Mayo Hospital, Lahore; [4]Assistant Professor, Department of Plastic Surgery, KEMU/ Mayo Hospital, Lahore; [5]Assistant Professor, Department of Plastic Surgery, KEMU/ Mayo Hospital, Lahore; [6]Professor and Head of Plastic Surgery Department, KEMU/ Mayo Hospital, Lahore

Abstract

Introduction: Suture-less skin closure for better scars is fast gaining popularity. We compared the scar outcome of tissue adhesive closure and the standard Polypropylene 6/0 suture.

Objective: To compare the results of tissue glue with Polypropylene 6/0 in wound closure of primary unilateral cleft lips.

Patients and Methods: The randomized control trial was held in the Plastic Surgery department, Mayo Hospital Lahore from February 2013 till October 2018. 300 patients with primary unilateral cleft lips, aged 3 months to 5 years were included. The patients were randomly allotted Group A (Polypropylene 6/0 closure) or Group B (2 octyl cyanoacrylate closure). Modified Mohler technique was used for repair. Follow-up was at 5 days, 3 months with final scar score at 6 months. The infection rate and need for revision were evaluated. Scars were rated using Visual Analogue Scale (VAS) by the patients and Hollander Wound Evaluation Scores (HWES). One Sample Kolmogorov Smirnov test,Mann Whitney U test and chi square tests were applied as relevant. p-value < 0.05 was considered significant.

Results: There were 15 (10%) infections in Group A and 4 (2.67%) in Group B. In Group A, 35 (23.33%) patients had hypertrophic scarring against 10 (6.67%) in Group B. In Group A, 12 (8%) patients needed revision versus 3 (2%) revisions in Group B. The mean VAS score for Group A was 81.22 and Group B 82.58 while the HWES mean score was 4.67 and 5.3 respectively.

Conclusion: Superior results were achieved with with 2-octyl-cyanoacrylate closure compared to Polypropylene 6/0.

Received | 08-02-2019: **Accepted** | 21-02-2020

Corresponding Author | Dr. Saadia Nosheen Jan, Assistant Professor, Department of Plastic Surgery, KEMU/ Mayo Hospital, Lahore. **Email:** saadia_jan@yahoo.com

Keywords | Octyl-2- cyanoacrylate, Polypropylene 6/0, Hollander Wound Evaluation Score and Visual Analogue Score, Infection, Hypertrophic scarring.

Introduction

The pursuit for minimal scarring in cleft lip repair has challenged plastic surgeons for many decades. Many factors are involved in creating an optimal cleft lip repair scar and optimal scarring has been termed one of the most important requirements in a cleft lip repair.[1] Whatever technique is employed to bring the cleft elements together, it is the proper dissection and release of the aberrant cleft tissue

attachments, meticulous approximation of the orbicularis muscle as well as accurate dermal apposition that sets the basis for an optimal result. Once the deeper components of the repair have been properly executed, a tension free and watertight epidermal repair with a relatively inert material, able to withstand the forces of facial animation is required that creates a wound that is impervious to surrounding pollutants and convenient to handle. Many materials, amongst them sutures both absorbable and non absorbable), tissue adhesive glues and adhesive strips have been proposed for epidermal closure in a cleft lip repair.

In an attempt to find a material compatible with the best scar possible in an otherwise assiduous repair, suture less skin approximation with tissue glues is fast gaining popularity. 2-octyl cyanoacrylate tissue glue was approved by the FDA in 1998[2] for use on body tissues and is being used for epidermal closure in cleft lip repairs for sutureless skin closure in a bid to improve the scar outcome. The incidence of the cleft lip/palate population in Pakistan is high at 1.9 per 1000 births.[3] Suboptimal scarring is one of the most common complications in cleft lip surgery[4]. Though people have described the use of tissue adhesive for epidermal closure in cleft lip repairs and others have compared its results with absorbable sutures and surgical adhesive strips, there has been no study comparing the results of tissue adhesive with the non-absorbable Polypropylene suture in epidermal closure of cleft lips. Due to the high incidence of cleft lip and palate in our population, we felt it pertinent to compare the results of tissue adhesive with the commonly used Polypropylene 6/0 sutures. Our aim was to find out which one of the two would produce the best scar, simplify wound care, minimize revision surgeries, the need for additional anaesthesia, hospital stay and overall ease burden on the economy, most of or patients belonging to the lower socioeconomic strata.

Methods

The study period ranged from February 2013 till October 2018. The total number of patients in the study was 300. To minimize the effects of the severity of the cleft on the overall result of the repair, only primary unilateral cleft lips (193 complete and 107 incomplete) were included in the study. 180 patients were male and 120 were female. Age range was from 3 months to 5 years. All patients in the study had Fitzpatrick 3 or 4 skin types. The patients were randomly allotted Group A (epidermal closure achieved with Polypropylene 6/0) or Group B (epidermal closure achieved with 2-octylcyanoacrylate tissue adhesive) using sealed envelopes so as to divide the patients into 2 groups of n=150 each. To exclude bias, only those patients were included who had not received NAM or any presurgical procedure prior to the lip repair. All repairs were done by the same surgeon. The modified Mohler repair with the Noordhoff flap for vermilion reconstruction was performed. Meticulous mobilization of the cleft elements with detachment of all aberrant tissue attachments was ensured. In both groups the same suture type and surgical technique was used for approximation of each layer except the epidermis. Thus, the lip mucosa was closed with interrupted Vicryl 5/0 sutures from the buccal sulcus up to the red line superiorly. Everting mattress sutures of Vicryl 4/0 were used to approximate the orbicularis muscle. The dermis was then carefully repaired with Vicryl 5/0 interrupted sutures from the nasal sill until the red line inferiorly. Special attention was given to accurately align the white roll.

After closure of the deeper layers had been achieved, in Group A patients, epidermal closure was achieved with interrupted Polypropylene 6/0 sutures and the wound was dressed with adhesive strips (Steristrips TM). In Group B, two temporary single knot key sutures of Vicryl 6/0 were placed in the epidermis at the tip of the advancement flap and at the white roll. The wound was dabbed to remove any moisture before application of the glue. The epidermis was held in approximation with two fingers to prevent seepage of tissue glue into the wound that could incite an inflammatory reaction to the glue. Care was also taken to minimize dribbling of the glue into the surrounding areas, especially into the wet lip mucosa as moisture can cause excessive glue polymerization. Next, the glass ampoule containing the glue was crushed by pressing gently on the encasing plastic cylinder. The glue was applied from the nasal sill to inferior margin of the red lip uniformly with wound edges held together for 30 seconds to allow the glue to set. The two temporary holding sutures were then pulled out before the glue had polymerized fully. Any

inadvertent drifting was patted dry before complete polymerization had taken place. 2-3 layers of the glue were applied, at 30 second intervals. No ointment or dressing was applied on top of the tissue glue layer. The wound was advised to be kept dry for at least 24 hours to prevent premature peeling.

In the absence of any post-operative complications, patients in Group A were discharged on the 2nd post operative day after change of Steristrips™. while patients in Group B were discharged on the 1st postoperative day as no dressing change was needed. They were asked to come back once the glue had peeled off around the 10-14th day, to keep the wound dry for another 24 hours and not to pick at or apply any emollient over the glue. 1st follow up for Group A was on the 5th postoperative day when stitches were removed under general anaesthesia and surgical adhesive strips (SteristipsTM) were applied to maintain apposition of the wound edges. Parents were advised to reapply the adhesive strips for another 2 weeks if they came off or became dirty. The wound was also assessed for any gaping or infection at the time of 1st follow up in both groups. All patients were asked to follow the same scar therapy regime with scar massage starting on the 21st post-operative day. They were asked to report immediately in case of any pain or redness around the wound, discharge from the incision or a shortening or thickening of scar.

The patients were thereafter followed up at 3 and 6 months to assess for development of hypertrophic scarring and treatment for hypertrophic scars instituted where needed. Hypertrophic scarring was defined as thickening or shrinkage of the lip scar that remained 6 months from the lip repair.[5] The scars were finally assessed at 6 months by a plastic surgeon oblivious to the epidermal approximation technique used, using the Hollander Wound Evaluation Score6. Scars were also assessed by the patients' parents using the Visual Analogue Score.[7] The scar revision rate due to suboptimal scarring after skin closure with Polypropylene 6/0 and 2ocytyl cyanoacrylate was recorded and compared in the 2 groups.

All data was entered and analyzed using SPSS version 22. Mean ± S.D and Median ± IQR was calculated for quantitative data while frequency (%) was used for qualitative data. Normality of quantitative data was checked using One Sample Kolmogorov Smirnov test where we found data was not-normal. So instead of parametric application of test we applied Mann Whitney U test to compare median ± IQR in both groups. Chi-square test was applied to compare categorical responses in both groups. P-value < 0.05 was considered as significant.

All data was entered and analyzed using SPSS version 22. Mean ± S.D and Median ± IQR was calculated for quantitative data while frequency (%) was used for qualitative data. Normality of quantitative data was checked using One Sample Kolmogorov Smirnov test where we found data was not normal. So instead of parametric application of test we applied Mann Whitney U test to compare median ± IQR in both groups. Chi-square test was applied to compare categorical responses in both groups. P-value < 0.05 was considered as significant.

Results

In all 300 cases the mean age of cases was 14.56 ± 12.80 months (Table 1). 180(60%) male and 120(40%) females were taken with equal male to female ration both groups (90 male and 60 females in each group). The mean visual analogue score and the Hollander wound evaluation scores for Prolene 6/0 and DermabondTM groups are shown in Table 1. On comparing their median ± IQR we found no significant difference, p-value = 0.069 (Table 1). In Prolene 6/0 and DermabondTM group there were 15(10%) cases and 4(2.67%) cases who had infection, p-value 0.009 (Table 2). There were 5 cases of allergic reactions to the SteristripsTM that presented as redness and cellulitis (Figure 1A,B). In Group A, 9 of the infections resolved with an antibiotic course of 5-7 days with no further untoward phenomena. However, in 6 of the patients the wound scars became hypertrophic. In Group B comparatively, only 4 infections were reported. Though 2 resolved with an antibiotic course, the wounds in the other 2 proceeded to heal with hypertrophic scarring. All infections were with Staphylococcus Aureus bacteria. Wound gaping following suture removal occurred in 78 (52%) patients in Group A, mostly in the area of the C-flap, while the same occurred in 4 (2.66%) patients in Group B in whom the glue had partially peeled off prematurely. There were 12(8%) cases in Polypropylene 6/0 group and 3(2%) cases in DermabondTM group who needed revision of the procedure, p-value

Table 1: *Comparison of age, visual analogue and Hollander wound evaluation score*

		Mean	S.D	Median	IQR	p-value
Age (months)	**Prolene (n=150)**	14.59	13.00	14.59	11	0.708[a]
	Dermabond (n=150)	14.52	12.64	10	10	
	Total (n=300)	14.56	12.80	10	10	
Visual analogue Score	**Prolene (n=150)**	81.22	4.30	82	5	0.08 [a]
	Dermabond (n=150)	82.58	2.99	83	3	
	Total (n=300)	81.90	3.76	82	3	
Hollander wound evaluation score	**Prolene (n=150)**	5.47	0.59	6	1	0.069 [a]
	Dermabond (n=150)	5.60	0.49	6	1	
	Total (n=300)	5.53	0.54	6.00	1	

[a] Mann Whitney U test was applied

0.017.

Table 2: *Comparison of Outcome of procedure in both groups*

		Study groups		p-value	Odds ratio (95% CI)
		Prolene group	Dermabond group		
Infection	**Yes**	15(10%)	4(2.7%)	0.009[b]	**4.05** (1.31, 12.52)
	No	135(90%)	146(97.3%)		
Hyper-trophic scars	**Yes**	35(23.3%)	10(6.7%)	< 0.0001 [b]	**4.26** (2.02, 8.97)
	No	115(76.7%)	140(93.3%)		
Revision needed	**Yes**	12(8%)	3(2%)	0.017 [b]	**4.26** (1.18, 15.42)
	No	138(92%)	147(98%)		

[b] Chi-square test was applied

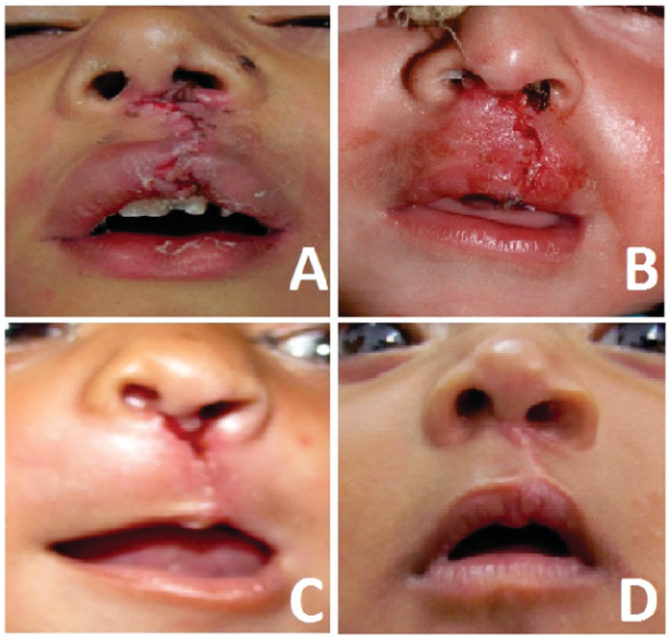

Figure 1: *Maceration and Cellulitis after Applying SteristripsTM (Fig.A&B). Wound Deshisence after Stich Removal in Area of C-flap (Fig C). Hypertrophic Scarring in the same Patient (Fig D)*

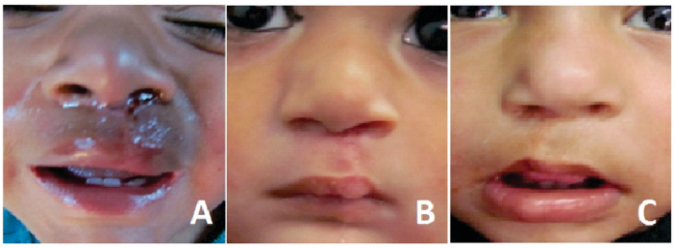

Figure 2: *Results with 2-Octylcyanoacrylate Tissue glue. Scar Quality Fared better on all Parameters as Compared with Group A Patients.*

Discussion

The study showed better results for the tissue adhesive group ($p<0.05$) than for the Polypropylene 6/0 group on all parameters. Many factors contribute to a narrow, flat and nearly imperceptible cleft lip repair scar. Good dermal approximation is one of the key elements that determine the eventual physical characteristics of the scar[8], especially so when closure of the epidermis is to be done with tissue adhesives. In our study, dermal closure was achieved with Vicryl 5/0 in both groups.

The traditional method for epidermal closure is with sutures. These sutures have to be removed usually under general anesthesia necessitating surplus hospital costs and stay, valuable operative time and additional anesthesia. To preempt these factors absorbable sutures, tissue adhesives and surgical adhesive strips (SteristripsTM) have been used for suture less epidermal closure in cleft lip repairs.

2octyl-cyanoacrylate (DermabondTM) is a popularly used tissue adhesive in the market today. It consists of a monomer of cyanoacrylate and formaldehyde in a liquid acid stabilizer, which when comes into contact with moisture converts into a polymer that binds the epidermal layers together. The longer chain of this

newer derivative of cyanoacrylates as compared to its predecessors not only lends increased pliability during facial animation, but also acts as a stent stabilizing the wounds against distractive forces[5], the face being the most mobile part of the body. It is used in uncontaminated wounds to close the epidermis where a suture of 5/0 diameter or less would be required.[9]

Our study reported better scar cosmesis on both the HWES and VAS scores with DermabondTM as compared to Polypropylene 6/0. Many elements contributed to the better scar. The wound, once the sutures are removed on the 5th postoperative day to prevent cross-hatch marks, tends to gape (Figures 1A and C). SteristripsTM are inadequate substitutes in providing sufficient wound strength and approximation, especially during animation. The majority of the gaping occurs in the area where the C-flap meets the advancement flap in the Mohler technique (Figure 1). DermabondTM once applied peroperatively imparts sufficient wound approximation and strength, persisting until it peels off around the 10th to 14th day, thus obviating suture removal. The tissue adhesive attains its maximum bonding strength within two and a half minutes, with a strength equivocal to what a healed wound achieves at 7 days.[9] As such it would be expected to produce a better wound. However, Spauwen et al[10] reported equivalent cosmesis when comparing epidermal closure of cleft lips with Octyl-2-cyanoacrylate tissue glue and Monocryl 6/0.

In this study, the incidence of infection in the Polypropylene 6/0 group was significantly higher than in the DermabondTM group. We attribute our increased infection rate in Group A to the humid environment prevalent in our country as well as the lack of awareness in wound care and hygiene in our population. Also, SteristripsTM that are relied upon to maintain epidermal approximation after suture removal are not an effective impediment against nasal secretions, environmental bacteria and other causative agents of infection. In our hot and humid climate, they frequently come off when in contact with moisture that not only decreases their efficacy in apposing the epidermis but also require a more frequent change. Given our climate conditions, moisture accumulates underneath the occlusive strips causing wound maceration posing an increased infection risk (Figure 1B). Also, there is occasional seepage of blood through the suture line that further predisposes the wound to infection and attentuates the adhesive powers of the strips.

DermabondTM on the contrary, acts as an impermeable protective barrier against nasal secretions, food, saliva and other extraneous agents that might contribute to wound infection. Additionally, DermabondTM has intrinsic antimicrobial properties.[11]The electronegative charge it possesses reacts against the positively charged carbohydrate capsule of gram positive bacteria, consequently conferring bactericidal properties.[12]

The hot, damp climate conditions as well as poor awareness of suture line care and hygiene necessitated discharge on the 2nd postoperative day after an initial wound cleaning and 1st change of SteristripsTM that are usually loosened and soiled by this time. Patients were educated on re-application of SteristripsTM once they became dirty or loose and about wound hygeine. SteristripsTM may also cause local allergic/ hypersensitivity reactions per se[13,14] and this was noted in 5 of our patients as well.

When comparing infection rates of sutures versus DermabondTM cited by similar studies, in a study comprising 306 patients by Wilson et al[5], no infections (0%) were reported in 121 patients when DermabondTM was used to close the skin in cleft lips compared to 5 (4%) infections amongst 186 patients when SteristripsTM were used. Infection can also result from a tissue reaction to the suture. Shinohara et all[15] in a series of 103 patients, reported stitch abscesses in 14% (out of a total of 56 patients) when epidermal closure was achieved with monofilament nylon as compared to no abscesses in 47 patients (0%) in lips repaired with absorbable polydiaxone/ polyglyconate sutures.

The partial wound dehiscence at the time of suture removal could also be a likely factor in predisposing the wound to hypertrophic scarring in addition to infection. As described above, the decreased the efficacy of the SteristripsTM to maintain the same level of wound approximation after sutures are removed in the Group A and an increased infection incidence in Group A contributed to a higher incidence of hypertrophic scarring in this study. Magee et

al16 cited no complications, shorter operative time, protective barrier formation by the glue facilitating incision care, no suture removal need and good scar outcome in 64 patients using 2-octylcyanoacrylate for epidermal closure of a cleft lip . Concomitantly the revision rate in our study was also lower in the DermabondTM epidermal closure group as compared to the Polypropylene 6/0 group.

Malhotra et al[17] studied the use of 2-cyanoacrylate glue in closing unilateral cleft lips and expounded on the additional benefits of Dermabond as a haemostatic agent by virtue of its occlusive properties that seals bleeding vessels.

Though the cost of DermabondTM is frequently debated, when the inconvenience and additional costs incurred for suture removal, the higher revision rate requiring general anaesthesia that mandates hospital stay and the risk of anaesthesa itself are accounted for, DermabondTM appears to be a much more cost effective and attractive alternative than Polypropylene 6/0.

Conclusion

Octyl-2-cyanoacrylate proved to be a superior alternative to Polypropylene 6/0 suture closure in epidermal closure of unilateral cleft lips regarding all the parameters evaluated in our study.

Ethical Approval: Given
Conflict of Interest: The authors declare no conflict of interest
Funding Source: None

References

1. Tamada I, Nakajima T.Detailed assessment of cleft lip scar following straight line repair. J Plast Reconstr Aesthet Surg. 2010;63(2):282-8.
2. Singer AJ, Quinn JV, Hollander JE. The cyanoacrylate topical skin adhesives. Am J Emerg Med. 2008;26(4):490-6.
3. Elahi MM, Jackson IT, Elahi O, Khan AH, Mubarak F, Tariq GB et al. Epidemiology of cleft lip and cleft palate in Pakistan. Plast Reconstr Surg. 2004; 113(6): 1548-55
4. Cheema SA, Asim M. An analysis of deformities in revision surgeries for secondary unilateral cleft lip. J Coll Physicians Surg Pak. 2014;24(9):666-9.
5. Wilson AD, Mercer N. Dermabond tissue adhesive versus Steri-Strips in unilateral cleft lip repair: an audit of infection and hypertrophic scar rates. Cleft Palate Craniofac J. 2008;45(6):614-9.
6. Singer AJ, Arora B, Dagum A, Valentine S, Hollander JE. Development and validation of a novel scar evaluation scale. Plast Reconstr Surg. 2007;120(7): 1892-7.
7. Mattick A, Clegg G, Beattie T, Ahmad T. A randomised, controlled trial comparing a tissue adhesive (2-octylcyanoacrylate) with adhesive strips (Steri-strips) for paediatric laceration repair. Emerg Med J. 2002;19(5):405-7.
8. Mourougayan V. Sutureless skin closure for cleft lip repair. Cleft Palate Craniofac J. 2006;43(6):656-8.
9. Bruns TB, Worthington JM. Using tissue adhesive for wound repair: a practical guide to dermabond. Am Fam Physician. 2000; 1;61(5):1383-8.
10. Spauwen PH, De Laat WA, Hartman EH. Octyl-2-cyanoacrylate tissue glue (Dermabond) versus Monocryl 6 × 0 Sutures in lip closure. Cleft Palate Craniofac J. 2006;43(5):625-7.
11. Mertz PM, Davis SC, Cazzaniga AL, Drosou A, Eaglstein WH. Barrier and antibacterial properties of 2-octyl cyanoacrylate-derived wound treatment films. J Cutan Med Surg. 2003;7(1):1-6.
12. Rushbrook JL, White G, Kidger L, Marsh P, Taggart TF. The antibacterial effect of 2-octyl cyanoacrylate (Dermabond®) skin adhesive. J Infect Prev. 2014; 15(6):236-39.
13. Howard BK, Downey SE. Contact dermatitis from Dermabond. Plast Reconstr Surg. 2010;125(6):252e-3e.
14. Ricci JA, Parekh NN, Desai NS. Diffuse cutaneous allergic reaction to Dermabond. Prehosp Disaster Med. 2014;29(5):546-8.
15. Shinohara H, Matsuo K, Kikuchi N. Absorbable and nonabsorbable buried sutures for primary cleft lip repair. Ann Plast Surg. 1996;36(1):44-6.
16. Magee WP Jr, Ajkay N, Githae B, Rosenblum RS. Use of octyl-2-cyanoacrylate in cleft lip repair. Ann Plast Surg. 2003;50(1):1-5.
17. Malhotra V, J., Rao JKD, Arya V, Sharma S, Singh S, P Luthra. Evaluating the use of 2-cyanoacrylate in unilateral cleft lip repair. Natl J Maxillofac Surg. 2016;7(2):153–158.