

Research Article,

## Unilateral cleft lip closure by use of Dermabond (N-octyle-2-cyanoacrylate)

Dr Santosh Mishra<sup>1</sup>, Dr Madhuri Shukla<sup>2</sup>, Dr Amit Kumar Sahu<sup>3</sup>, Dr Sushma Mishra<sup>4</sup>

Senior Resident, Dept. Of Dentistry, ShyamShah Medical College & SGMH, Rewa  
(MP) 486001

Correspondence Address: [smdoctorsm66@gmail.com](mailto:smdoctorsm66@gmail.com)

### Abstract:

**Background:** Facial cosmetic results are one of the most concerning issues for the parents who get their children operated for cleft lip. Moreover, the postoperative care of the surgical site, the discomfort associated with the suture removal, and additional visit for suture removal are other reasons which encourages one to use any new technologies that may replace the need for suture placement. In this study, we used octyl-2-cyanoacrylate, a tissue adhesive which offers a viable alternative to traditional techniques without compromising optimal wound closure.

**Objective:** To perform a comprehensive comparison of the outcomes from the use of Dermabond in patients undergoing primary repair of congenital cleft lip ± palate anomalies.

**Materials and Methods:** Twenty patients, in the age group of 3–18 months were treated surgically for unilateral cleft lip deformity using Millard rotation-advancement flap. Pre- and post-operative photographs of the patients were taken at 1 week, 2 week, 1 month, 6 months, and 1 year postoperatively and were evaluated using Vancouver scar scale which was given by Sullivan in 1990. Paired t-test was used for statistical analysis.

**Results:** Increased vascularity (hyperemia) was seen in the 1st and 2nd week in 35% and 30% patients, respectively which gradually reduced to normal in subsequent follow-ups. The scar was flat in 85% of patients in 1st week, and the number decreased to 10% at the end of 1 year. No wound dehiscence was found in any patients. Statistical analysis showed that among all the follow-ups, only the difference between the first and second follow-ups. Comparison of the results of 1 week with all other follow-ups yielded no significant results.

**Conclusion:** Octyl-2-cyanoacrylate can be used for cleft lip closure effectively. The procedure is relatively painless and quick. Added to this are benefits of protection from wound infection since the material is bacteriostatic.

**Key words:** Congenital cleft lip, Dermabond, sutures, tissue adhesive

### Introduction:

Facial cosmetic results are one of the most concerning issues for the parents who get their children operated for cleft lip. Moreover, the postoperative care of surgical site, the discomfort associated with the suture removal, and additional visit for suture removal are other reasons which encourages one to use any new technologies that may replace the need for suture placement. Tissue adhesives are being developed which offer a

viable alternative to traditional techniques without compromising optimal wound closure. Early research was conducted on methyl cyanoacrylates, but this compound was found to produce necrosis, edema, and suppuration in treated tissues<sup>[1-3]</sup> More recent and laboratory researches and clinical testing have focused on higher homologous of cyanoacrylate, particularly the butyl forms.<sup>[4-6]</sup> Until recently, butyl-2-cyanoacrylate was the only commercially available cyanoacrylate tissue

adhesives. However, after polymerizing, the adhesive becomes brittle and is subject to fracturing when used in skin creases or long incisions. This restricts the use of adhesives in the area of low tension, thus limiting their use for incision repair. The polymer octyl-2-cyanoacrylate was formulated to correct some of the deficiency of the shorter-chain cyanoacrylates derivative.<sup>[7]</sup> Along with this, octyl-2-cyanoacrylates (Dermabond) were approved by the Food and Drug Administration in January 2001 for the use as a barrier against common bacterial microbes including certain staphylococci, *Pseudomonas*, and *Escherichia coli*.<sup>[8]</sup> There have been numerous studies on the use of octyl-2-cyanoacrylate in facial lacerations.<sup>[9,10]</sup> However, very few authors have studied its use in cleft lip cases. Therefore, the current study was undertaken to perform a comprehensive comparison of the outcomes from the use of Dermabond in patients undergoing primary repair of congenital cleft lip ± palate anomalies.



Fig 1 .Preoperative photograph showing Unilateral complete lip

### Materials and Methods:

The study was conducted on patients reporting to the Department of Oral and Maxillofacial Surgery, College of Dental Science & Hospital Indore (MP) from 2014 to 2017. After obtaining approval from the Ethical Committee, twenty patients, in the age group of 3–18 months [Figure 1] who were treated surgically for unilateral cleft lip deformity (complete or incomplete) at SGT Dental College and Hospital, Gurgaon, met the inclusion criteria for this study. The Millard rotation-advancement flap was used for all cases [Figure 2].



Fig 2. Intraoperative photograph showing Modified millard incision

The orbicularis oris was mobilized and functionally reconstructed with interrupted 3-0 Vicryl sutures. Interrupted 5-0 prolene deep dermal sutures reapproximated the skin edges. Few 4-0 chromic catgut sutures were used intraorally till the vermilion border. The adhesive (Dermabond) was then applied using the pen injection device from the nasal sill superiorly to the inferior aspect of the red zone of the lip [Figure 3]. The adhesive was directly applied in layers with 15 s delay between each application. Moist cotton was used as a swab to prevent contact of adhesive material with eyes.



Fig 3. Intraoperative photograph showing Application of Dermabond

Postoperatively, the patient was administered fluids orally as soon as they were fully conscious and could tolerate feeds. No ointment or dressing was used on the incision. Patients were advised to keep the skin adhesive dry for 48 h and then clean gently with soap and water. Patients were followed up at 1 week, 2 weeks, 1 month, 6 months, and 1 year postoperatively and were evaluated for cosmetic result, wound dehiscence, and break in white line [Figures 4-5].



Fig 4. Photograph showing follow-up after 2 weeks



Fig 5. Photograph showing follow-up after 1 year

Pre- and post-operative photographs were taken of the patients in both groups at all follow-ups. Assessment of scar was done with Vancouver scar scale (VSS) which was given by Sullivan in 1990, which assessed four variables vascularity, pigmentation, pliability, and height of the scar.[11] Table 1 depicts the values for each criterion according to VSS. Statistical analysis was done using SPSS 16.0, and paired t-test was used to test for significance for the 2 assessment tools.

**Results:**

Out of twenty patients, 80% of patients were male (n = 16) and 20% (n = 4) were female signifying male predilection. Fourteen patients presented with cleft of the left side while only six patients presented with cleft of the right side. Vascularity of scar was assessed visually by the observer. The results are shown in Table 2. The patients showed increased vascularity in the 1st and 2nd week in 35% and 30% patients, respectively which gradually reduced to normal in subsequent follow-ups.

Table 1: Vancouver scar scale

	Scar characteristics	Score
<b>Vascularity</b>	Normal	0
	Pink	1
	Red	2
	Purple	3
<b>Pigmentation</b>	Normal	0
	Hypopigmentation	1
	Hyperpigmentation	2
<b>Pliability</b>	Normal	0
	Supple	1
	Yielding	2
	Firm	3
	Ropes	4
	Contracture	5
<b>Height</b>	Flat	0
	<2 mm	1
	2-5mm	2
	>5 mm	3

Table 2: Frequencies for vascularity of scar

	1 <sup>st</sup> week	2 <sup>nd</sup> week	1 <sup>st</sup> month	6 <sup>th</sup> month	1 year
<b>Normal</b>	13	14	20	20	20
<b>Pink</b>	0	0	0	0	0
<b>Red</b>	7	6	0	0	0
<b>Total</b>	20	20	20	20	20

The scar was flat in 85% of patients in the 1st week, and the number decreased to 10% at the end of 1 year. The values for frequencies of the height of scar are tabulated in Table 3. Pigmentation was checked by visual examination, and the color was compared with the normal skin. 100% of patients showed normal pigmentation initially as well as at the end of 1 year. No wound dehiscence was found in any patients. Pliability was checked by applying pressure over the scar if the compressed scar came back to its original position within 15 s then, it was considered as normal. In all the twenty patients, scar was normal without any characteristics of supple or yielding at all times. Break in white line was seen in 100% of patients at all the follow-up appointments.

Based on the total score, the results were classified into three categories as mild (0–4), moderate (5–8), and severe (9–13). Based on this, all patients were confined to the mild category of VSS. Paired t-test was done to compare relative change in the observation measured at different time periods, and statistical analysis showed that among all the follow-ups only the difference

between the first and second follow-ups, i.e., between 1st and 2nd weeks were statistically significant (P = 0.008). Moreover, comparison of the results of 1 week with all other follow-ups yielded no significant results.

**Table 3: Frequencies for height of scar**

	1 <sup>st</sup> week	2 <sup>nd</sup> week	1 <sup>st</sup> month	6 <sup>th</sup> month	1 year
Flat	17	2	3	3	3
<2mm	3	11	12	12	14
2-5mm	0	7	5	5	3
>5	20	20	20	20	20

**Discussion:**

The concept of a surgical tissue adhesive for superficial skin closure is an attractive alternative to the use of sutures to both physicians and patients. Suture placement always requires the use of an anesthetic agent and takes significantly more time than application of octyl-2-cyanoacrylate. Although suture placement and removal rarely causes pain, patient anxiety is the main factor to worry about which is true mainly in the pediatric population.<sup>[12]</sup> In our study, we have used the cyanoacrylate glue which has eliminated the need for suture removal, the patient to undergo conscious sedation and hence reduced the number of visits. Additional benefits which we noticed in our study include ease of use, eliminating the need for additional bandages. Skin adhesives are less indicated in highly mobile areas or locations where exact skin alignment is necessary, such as the face according to Penoff.<sup>[13]</sup> In our patients, we have found that this relative contraindication does not apply to cleft lip repair. The lip is constantly moving, especially in an infant or child during feeding, sucking, crying, smiling, and grimacing. Any of the patients in our study did not show any wound dehiscence or any other wound complications.

Octyl-2 -cyanoacrylate is excellent microbial barriers as said by Narang. These films are flexible so that they do not crack, provide continuous coverage of the wound site, and they adhere strongly to the skin.<sup>[14]</sup> Our patients did not show any wound dehiscence which may indicate that the cyanoacrylate acts as a microbial barrier. This effect may have two possible explanations. First, cyanoacrylates have an antibacterial effect, possibly by the strong electronegative charge of polymer. Second, there is a lack of foreign

material in the wound. This makes cyanoacrylate an excellent alternative, not only as suture replacement but also to prevent infection.<sup>[15]</sup> Cyanoacrylate can also be used in the form of bandages as they have occlusive dressing properties; the rapid hemostatic effect is probably by sealing cuts and leaky vessels. In this regard, Histoacryl, when used as a topical adhesive over-approximated wound edges, is an effective and easily applicable local hemostatic for oral surgery in such patients.<sup>[16]</sup> In our study, we also found that bleeding was arrested immediately after the application of cyanoacrylate glue on the surgical site. The alkyl chain of the Octyl polymer is so long and hydrophobic that it can take years to degrade. The degradation products from the longer chain compounds are barely detectable on extraction studies. Thus, it is not surprising that the longer chain polymers have passed International Standards Organization (ISO) standards for a nontoxic topical medical device. FDA approved the use of first product for topical use in 1998 and second product in 2002.<sup>[17,18]</sup> As our patients did not show any toxic effect or allergic reaction to the octyl-cyanoacrylate, it can be said that octyl-2-cyanoacrylate is nontoxic to the skin. We should take proper precautions while application of cyanoacrylate glue as it can spill over the nasal area and cause blockage of nasal airway and come in contact with the eyes.<sup>[12]</sup> Hence, to avoid damage to eyes, in our patients, we used moist cotton swabs to avoid excessive spillage over the other parts. While comparing the cyanoacrylate with silk in wound closure, it is found that wound closure done by cyanoacrylate was relatively painless, quick, and the material causes less tissue reaction, achieves immediate homeostasis. There are also benefits of protection from wound infection since the material is bacteriostatic, and pain is significantly higher at the suture site in contrast with the cyanoacrylate -treated site. Sutures *per se* predispose to infection by breach of skin or oral mucosa and provide a source of infection through the suture canal and initiate foreign body inflammatory response which is not seen in case of cyanoacrylate.<sup>[19]</sup> Vastani states that the incidence of hyperemia was more on suture site.<sup>[20]</sup> Souza *et al.* also states that cyanoacrylate did not induce tissue necrosis, allergic reaction, and hyperemia and likely in our patients, we did not notice any

hyperemia which might be due to the absence of any foreign body which can cause any inflammatory change.<sup>[21]</sup> Hee *et al.* found that cyanoacrylate proved to be an effective eyelid closure method and was well tolerated by the skin surface and showed less hyperemia.<sup>[22]</sup> In our study, increase in vascularity was seen in seven patients during the first follow-up which gradually decreased during subsequent follow-up visits. Hyperemia was not noticed in any of the patients in our study as well which was in accordance with the previous studies. In addition, only two patients experienced mild pain in the postoperative period. This might have been due to the inadvertent flow of cyanoacrylate in between the wound edges causing inadequate tissue coaptation in some areas. This would have led to the collection of food debris and tissue irritation thereby causing pain. None of the patients in the study where octyl-2-cyanoacrylate was applied experienced moderate or severe pain. A hypertrophy of the scar is due to excessive amounts of collagen which gives rise to a raised scar, but not to the degree observed with keloids. Like keloids, they form most often at the sites of pimples, body piercings, cuts, and burns. They often contain nerves and blood vessels. Hypertrophic scars are red and thick. Spauwen *et al.* state that the hypertrophy of scar was present postoperatively in both of groups that were treated with monocryl 6-0 suture and cyanoacrylate for the closure of the cleft lip. They also stated that cyanoacrylate was painless, required less postoperative follow-up visits, and gave better cosmetic results.<sup>[23]</sup> In the same way, Greenhill also said that the incidence of hypertrophic scar and keloid seen with cyanoacrylate was similar with that of conventional suture. As per the hypertrophy criteria, most of our patients have shown hypertrophy of scar which is in accordance with the previous studies. Post inflammatory hyperpigmentation develops when a wound or surgical site, rash, pimple, or other stimuli causes skin inflammation, which triggers the skin to produce too much melanin. The excess melanin darkens and discolors the wound area or surgical site. David stated that the fast absorbing gut suture degrades by proteolysis which can result in an inflammatory reaction and any inflammatory reaction on the skin while healing can affect the final cosmetic outcome, i.e. postinflammatory

hyperpigmentation and which was not noticed with cyanoacrylate.<sup>[24]</sup> None of the patients presented with either hypopigmentation or hyperpigmentation during all follow-up visits. The absence of any foreign material might be the reason of the absence of inflammation that could lead to postinflammatory hyperpigmentation. The other parameter evaluated in our study was the pliability of the skin which depends on the elasticity of fibers present in the dermis. Pliability can be measured by the application of pressure by finger on the site. If the depressed skin comes to its normal position within 15 s then it can be considered as pliable. According to Mourougyan and Quinn, quality of scarring depends on the usage of dermal sutures rather than the technique of epidermal closure. Hence, the use of suture material to close the epidermis does not offer any advantage.<sup>[24]</sup> However, epidermal closure using tissue glue is simple, easy to practice, cost-effective and comfortable to the patients, parents, and the medical personnel. However, in our study, we have used suture for the closure of dermal layer and tissue glue for the epidermal closure which is in accordance with the above-stated study. In our study, in all the twenty patients, pliability of the skin was reported as normal. The skin of the lips ends in a sharp and slightly elevated line, the white line or the mucocutaneous ridge, which joins the transitional zone between the skin and mucous membrane, i.e., the vermilion border. Steffensen has listed various criteria for a satisfactory lip repair and stated the significance of the vermilion-cutaneous ridge and its importance in reproducing the normal lower border of the philtrum or “cupid’s bow.” In our study, break in white line was found in all the patients during final follow-up. As our sample size is less, further studies are required to evaluate the efficacy of cyanoacrylate in terms of break in white line criteria.<sup>[25]</sup> All the criteria of our study which includes pigmentation, pliability, vascularity, and height of scar were evaluated according to VSS. VSS was described by Sullivan in 1990.<sup>[11]</sup> It assesses 4 variables, vascularity, height/thickness, pliability, and pigmentation. Lye states that VSS remains widely applicable to evaluate therapy and as a measure of outcome in burn studies.<sup>[26]</sup> We have extended its use to assess the scar after cleft lip surgery. The score was categorized as mild, moderate, severe, and score

between 0 and 4 was considered as mild, score 5–8 was considered as moderate, and 9–13 was considered as severe. Score of all the twenty patients of our study was <4 so it comes under the mild criteria of scar assessment. In our study, there is a significant difference between the first and second follow-up visits regarding the evaluation based on various criteria as stated above. However, the difference is not significant in the subsequent follow-up visits ( $P > 0.01$ ). Thus, we can state that the efficacy of cyanoacrylate for cleft lip closure in terms of height of scar, and pliability is almost similar to closure done with other conventional methods but cyanoacrylate has many advantages over other conventional methods such as less postoperative follow-up visits, no need of suture removal, less inflammation over the surgical site, good cosmetics results, less healing time, less postoperative pain, less time required for wound closure, and less chances of infection over the surgical sites. As our sample size is less, further

studies are required to generalize our findings.

### Conclusion:

The study concluded that octyl-2-cyanoacrylate can be used for cleft lip closure effectively. The procedure is relatively painless and quick. The material causes less tissue reaction and achieves immediate homeostasis. Added to this are benefits of protection from wound infection since the material is bacteriostatic. The material is not suitable for use in high-tension areas, especially wide areas of wound closure. Further improvement in biomaterials in future might be able to address this area as well. One definite lacuna in so far as the routine use of cyanoacrylate is concerned is their cost. However, the desirability of economy of effort and better postoperative results negate this drawback. As our sample size is less, further studies are required to evaluate the efficacy of octyl-2-cyanoacrylate in cleft lip closure for better understanding of this material.

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