

A Prospective Comparison of Octyl-2-Cyanoacrylate and Suture in Standardized Facial Incisions

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ABSTRACT

Introduction: The cosmetic result is one key measure in the assessment of operation in the head and neck region. The principle of wound closure, should be to achieve precise wound approximation, easy handling and working properties of wound closure materials and low infection rates. In our study, we evaluated the efficiency of 2-OCA on extra oral incisions placed in the trauma patients.

Material and Methods: A total of 20 patients were enrolled and treated for open reduction and internal fixation procedures. The extra oral incisions were placed in these patients. These patients were categorized into 2 groups wherein the group I underwent suture closure with Ethilon 4-0 and group II, the incision closure done with 2-OCA. Wounds were evaluated for 24th hours, 1st week and 2nd week post operatively for pain, inflammation, dehiscence, infection, and wound closure/wound seal. The scar and the surface texture were evaluated only after a minimum follow up of 1st month and 3rd month post operatively.

Results: Clinical parameters such as pain and time taken for closure techniques were significant difference when compared to the sutured group, indicating the use of 2-OCA is beneficial in pain and application time taken for closure.

Conclusion: 2-OCA is suitable for skin closure and easy to use alternative to conventional sutures. 2-OCA is associated with good esthetic and less post operative complication.

Keywords: Octyl -2-cyanoacrylate, Suture Open Reduction and Internal Fixation, Maxillomandibular Fixation.

INTRODUCTION

The cosmetic result is one key measure in the assessment of operation in the head and neck region. The appearance of facial skin wound is relevant to the rating by patients and surgeons. If sutures are tied too tightly or left too long, they may leave permanent suture marks which affect the cosmetic results. Suture removal sometimes causes discomfort because this procedure is often associated with increased patient anxiety as the face is very sensitive.

Both the sutures and tissue adhesive have advantages and disadvantages. Principles of wound closure focus on relieving tension on the wound and bringing the skin edges together in an everted orientation. Suturing techniques may be exacting and time consuming and this stage may cause more apprehension in the conscious patient and the rest of the surgical procedures. If removed early will result in dehiscence, additional requirement of a dressing to protect the wound and suture as well. These drawback lead to discovery and development of tissue adhesive.¹

A variety of adhesive substances can be applied locally

during surgery or endoscopy for haemostasis, wound closure or fistula repair. The main classes of tissue adhesive are cyanoacrylate glues, fibrin glue and thrombin.²

Cyanoacrylate were first synthesized in 1949 and tried clinically for the first time in 1959 as agents to glue skin wounds. This procedure allows for normal wound healing and is accomplished without the need of local anesthesia or the entry of foreign material. These initial derivatives were methyl-2- and ethyl-2-cyanoacrylates. These derivatives were effective, but the shorter alkyl chains degraded rapidly, and these products had high tissue toxicity that resulted in acute and chronic inflammation. With longer alkyl chains, the toxicity decreases as a result of slow degradation, which limits accumulation of by-products.³

2-Octylcyanoacrylate, formulated with plasticizers, is even more stable, has greater flexibility and maintains a stronger bond. It degrades much more slowly, which leads to its classification as nontoxic, 2-Octylcyanoacrylates (e.g., Dermabond, Ethicon, New Brunswick, NJ) were approved for use in the United States in 1998. Studies have shown wound breaking strength to be equal to that of suture-repaired wounds at 5 to 7 days. 2-OCA has a longer 8 carbon chain compared to butyl cyanoacrylate which has 4 carbon chain, Dermabond offers greater flexibility, stronger bond and slower degradation than butylcyanoacrylate.³

2-OCA has several advantages over standard sutures. The application of tissue adhesives is relatively painless and easy to perform, no foreign material is introduced into the wound and no suture removal is required. There also is evidence that cyanoacrylate possesses inherent antimicrobial properties.⁴ 2-OCA has a higher direct cost compared with suture. But considering factors, such as equipment, medication cost, follow up visits, procedure time, patient and parent preference, and loss of parental income, 2-OCA has advantages over standard suture.

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Tissue adhesives have been used in general surgery, in the procedures related to, abdomen, eyes, kidney, liver and vascular surgeries. In dentistry, it is used in endodontics and periodontics other than oral and maxillofacial surgery.⁵

In our study, we evaluated the efficiency of 2-OCA on extra oral incisions placed in the trauma patients.

MATERIAL AND METHODS

A total of twenty patients were enrolled and treated for open reduction and internal fixation procedures. Extra oral incisions were placed in these patients. These patients were categorised into 2 groups, wherein, group I underwent suture closure with Ethilon 4-0 and group II, the incision closure was done with 2-OCA.

Twenty trauma patients were included for the study, out of which ten patients were included under Group I and the remaining ten under Group II.

Wounds were evaluated at 24th hours, 1st week and 2nd week post operatively, for pain, inflammation, dehiscence, infection, and wound closure/wound seal. The scar and the surface texture were evaluated only after a minimum follow up of 1 month and 3 month post operatively.

The ethical clearance was obtained by the Ethical committee, before this study was begun.

The patients were selected on the basis of certain preset inclusion and exclusion criteria.

Inclusion criteria

1. The patients in good general health with no significant systemic abnormalities.
2. Patch test will be done in all cases.
3. Patients from both the groups having similar lengths of incision are segregated for the study.
4. Standard facial incisions.
5. Agree to return for follow up visits.

Exclusion criteria

1. Patients who are medically/immunologically compromised.
2. Patients with a known history of allergy towards formaldehyde/cyanoacrylate.
3. Patients with Vascular diseases /collagen diseases and clotting disorders.
4. Patients with a history of keloid formation and hypertrophic scars.

Materials

In the Group I, incisions were closed by simple interrupted sutures using Ethilon 4-0 which is available under the brand name of Ethicon 4-0 from JOHNSON AND JOHNSON Limited. It is available as prepacked, presterilized single use sachets.

In the Group II, 2-Octylcyanoacrylate tissue adhesives are available as a single use sterile ampule of 0.5 ml under the brand name of DERMABOND from JOHNSON AND JOHNSON Limited was used for the study.

This study included randomized treatment of 20 patients, undergoing standardized facial incision like Submandibular or Risdon's, Infraorbital, Lateral brow, Retromandibular

incisions or Hinds incisions. On admission, case history was recorded pre operatively, as per, evaluation. The length of the Incisions varied from 2 -10cms.

In Group I, the incisions were closed with Ethilon 4-0 (Johnson and Johnson), by simple interrupted suturing technique, making sure that the skin edges were in close approximation to each other during the closure. Following the completion of suturing, an antiseptic medicated cream was applied followed with a protective dressing for the first 72 hours. The sutures were removed after an interval of 7 days.

In Group II, the incisions were closed with subcutaneous sutures using Vicryl 3-0. The skin closed with 2-Octylcyanoacrylate (Dermabond), skin edges was approximated and maintained in this position either with skin hooks/ Adson forceps. The applicator was removed from the packaging, holding the tip pointing upward. Pressure is applied at the midpoint of the ampule, crushing the inner glass tube. The applicator then was inverted and gently squeezed so as to express the adhesive through the applicator tip along the edges of the incision, all the time taking care that, the adhesive does not flow between the skin edges. Double repeated applications with an interval of 15 seconds was required to achieve maximum tensile strength across the skin edges, in the mean time, maintaining the skin approximation all along till the polymerization was completed.

Post operatively wounds were evaluated, 24 hours later, 1st post operative week and 2nd post operative week for, pain, infection, dehiscence, wound closure/wound seal, and inflammation. Surface texture and Scar was evaluated after a minimum of 1 month and 3rd month for cosmetic outcome. Surface texture was evaluated at the end of 1st and 3rd month, to check whether it was smooth or rough both visually and on palpation. Visually the wounds were evaluated for scar based on the clinical presence of linear scar, which is considered esthetically acceptable and cross hatching which is considered as esthetically unacceptable.

Results of the observations were analyzed. (Table 1). "Chi-square" test was adapted statistically for the analysis. (Table 2).

RESULTS

20 trauma patients were selected among them 19 were male patients and 1 was female. (Table 3, Fig 1). Age varied from 21 to 60 years. (Table 4, Fig 2). Etiology of trauma in most of the patients were RTA -12 Patients (60%), 5 were self fall (25%), 2 patients were assault (10%) and 1 patient was occupational (5%). (Table 5, Fig 3).

Among the 20 patients, 8 patients were associated with angle fracture of mandible, were 11 patients had ZMC fracture and 2 patients had sub condylar fracture. The incisions placed were Submandibular incision -8 patients, Lateral eye brow - 9 patients, Infraorbital incision - 5 patients and Hinds incision - 2 patients. The total number of incisions placed were 24, wherein, patients with ZMC fractures required more than one incision.

Out of these 24 incisions, 12 cases were randomly selected

Criteria		X ²	Significance
Pain		7.91	S
Inflammation		0.00	N.S
Dehiscence		0.00	N.S
Infection		0.00	N.S
Wound closure		0.00	N.S
Surface texture	Rough	0.00	N.S
	Smooth	0.00	N.S
Scar	Esthetically Unacceptable	0.00	N.S
	Esthetically Acceptable	0.00	N.S

Table-2:

Criteria		Group 1 (10) (4-0 Ethilon)	Group 2 (10) (2 OCA)
Pain		10	3
Inflammation		2	1
Dehiscence		2	1
Infection		2	1
Wound closure		2	1
Surface texture	Rough	2	1
	Smooth	8	9
Scar	Esthetically Unacceptable	2	1
	Esthetically Acceptable	8	9

Table-1:

Gender	Frequency	%
Male	19	95
Female	1	05
Total	20	100

Table-3: Gender distribution of the patients

Age(yrs)	Frequency	%
21-30	6	30
31-40	5	25
41-50	5	25
51-60	4	20
Total	20	100

Table-4: Age wise distribution of patients.

Etiology of Trauma	Frequency	%
RTA	12	60
Self fall	5	25
Assault	2	10
Occupational	1	5
Total	20	100

Table-5: Etiology of Trauma distribution.

for suturing with Ethilon 4-0(Group I) and remaining 12 were selected for Octyl-2- cyanoacrylate tissue adhesive application (Group II). The length of the incision varied from 3 to 5 cms in all the cases. The average time taken required for placement of sutures was around 12-25 minutes in group I and the average time taken for double application of 2-OCA tissue adhesive was 25-35 seconds in group II. One application required 10 seconds and the second application required another 15 seconds.

Pre operative all twenty patients complained of pain



PRE-OPERATIVE RADIOGRAPH



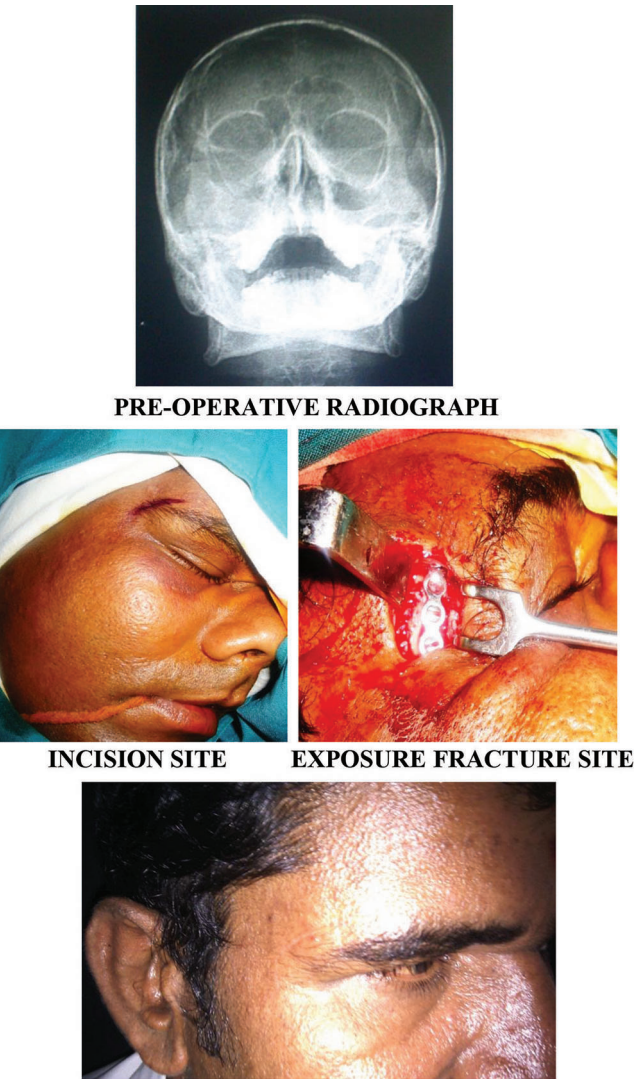
INCISION SITE

EXPOSURE OF FRACTURE SITE



Case-1:

and swelling related to the fracture site. The following parameters were taken for evaluation post operatively like Pain, Inflammation, Dehiscence, Infection, Wound Closure/ Approximation, Surface Texture and Scar. They were



Case-2:

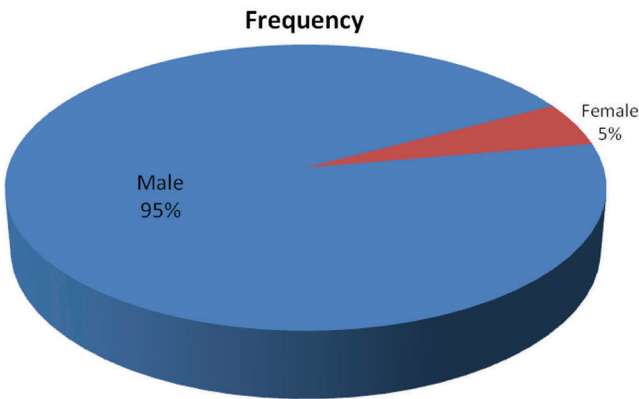
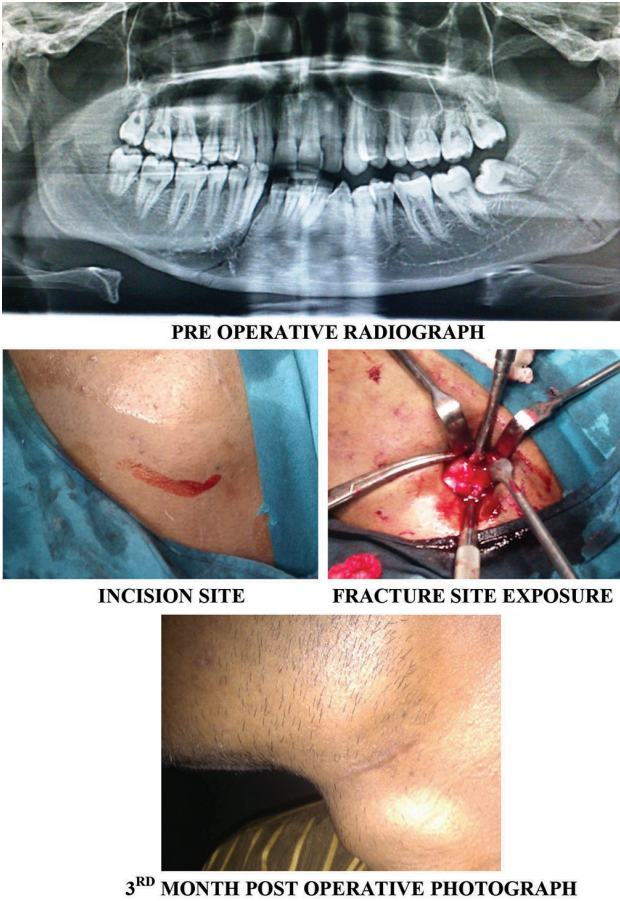


Figure-1: Gender distribution of the patients.

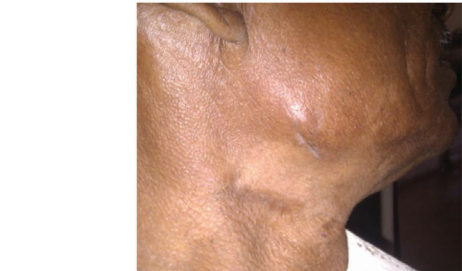
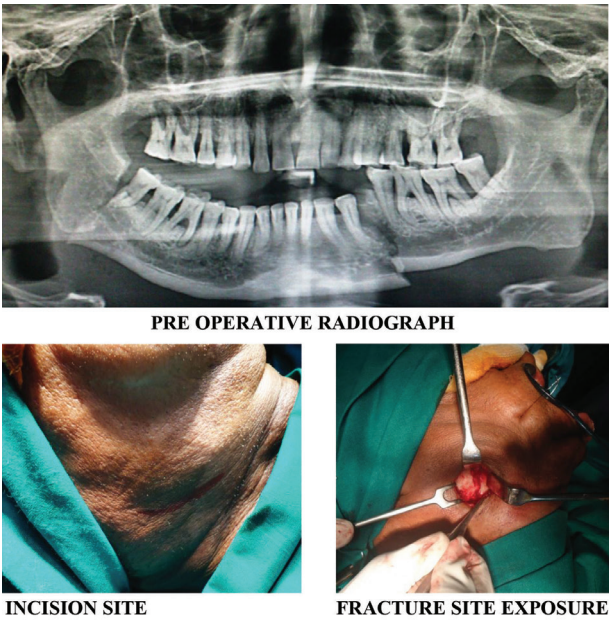
evaluated on 1st, 3rd, 7th postoperative day and end of 1st month and 3rd month.

Post operatively pain was evaluated using VAS scale in the range of 0 to 10, where 0 is considered pain free and 10 is worst pain. Pain was assessed on 1, 3rd and 7th day.

Inflammation was assessed based on signs of rubor, tumor, calor, dolor.



Case-3:



Case-4:

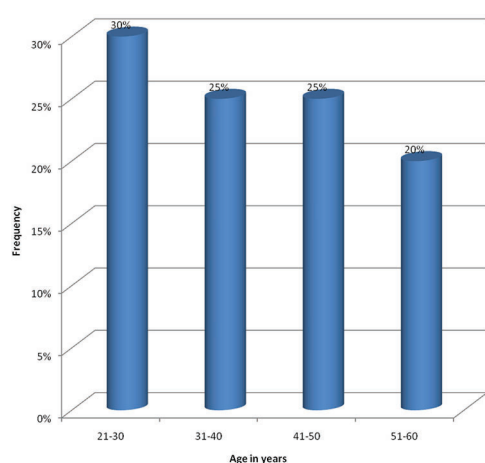


Figure-2: Age wise distribution of patients.

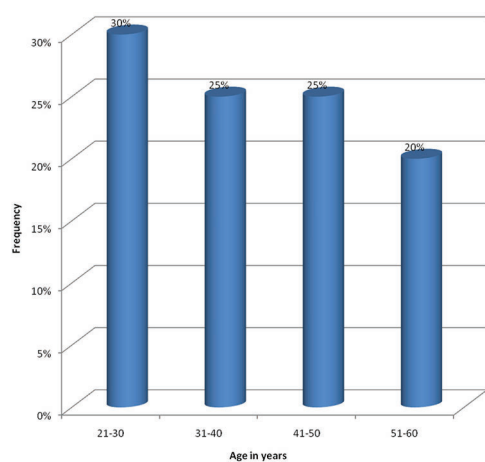


Figure-3: Etiology of Trauma distribution

Infection was assessed by presence/absence of pus.

Dehiscence and wound closure were assessed by rupture or tear of the sutured wound.

Post operatively only three patients complained of pain in the group I, on the 1st, 3rd and 7th day. Pain measured on the VAS scale measured from 1 - 5 among the three patients. Only one patient complained of pain in group II, with measurement in the range of 0 - 3 on the VAS scale. Thereby indicating that there was significantly no pain in the 2-OCA group. ($p < 0.001$, $X^2 = 7.91$)

There were no signs of inflammation observed during the first 24 hour period. Two patients under group I and one patient under group II showed signs of Inflammation at the end of 1 week. Statistically it was not significant. ($p < 0.001$, $X^2 = 0.00$).

In group I two patients presented with dehiscence at the end of seventh day whereas in Group II, one patient experienced dehiscence. Dehiscence of the sutured wound and 2-OCA group was also allowed to heal by secondary intention Statistically it was not significant. ($p = 1$, $X^2 = 0.00$),

Signs of Pus exudation from the margins, and at the point entry of the suture as well, were observed in 2 patients under Group I at the end of 7th days. Under Group II, one patient showed signs of pus exudation from the margins at the same post operative interval. Statistically it was not significant. ($p = 1$, $X^2 = 0.00$)

Patients were recalled to the OPD to evaluate the Surface texture and Scar. We preferred to not to use the photograph as the patients were ready to come for the evaluation.

Surface texture was evaluated at the end of 1st month and 3rd month, whether it was Smooth or Rough. In the groups I, 2 patients had rough surface texture and in group II, one had rough surface texture. The rest of the patients had a smooth surface texture. Statistically it was not significant. ($p = 1$, $X^2 = 0.00$).

Scar was evaluated on 1st and 3rd post operative month, to see whether it was Esthetically Acceptable or Unacceptable. Appearance of a Single Linear Scar was considered Esthetically Acceptable and appearance of Cross Hatching as Esthetically Unacceptable. Statistically it was not significant. In group I, 2 patients had Esthetically Unacceptable Scar at the end of 1st month postoperatively. There was slight roughness found visually and on palpation at the end of 3rd month.

In group II, 1 patient had an Esthetically Unacceptable Scar at the end of 1st month postoperative. But on 3rd month post operative follow up, the wound was camouflaged visually, and with a smooth surface on palpation. Thereby it was not statistically significant. ($p = 1$, $X^2 = 0.00$).

DICUSSION

Cyanoacrylate adhesive were discovered in 1949 and 10 years later, reported their use in surgical procedures. These adhesive polymerize via an exothermic reaction when coming into contact with a fluid or basic medium, thereby forming a strong bond when applied to skin.^{1,2}

Butyl cyanoacrylate is intermediate length cyanoacrylate, that is less toxic and maintains a stronger bond than the shorter chain molecules. They have not been approved for use in the United States by Food and Drug Administration (FDA).

N-butyl-2-Cyanoacrylate has been used for wound closure but it is less strong and flexible than conventional monofilament sutures. This is the reason, Octyl-2-Cyanoacrylate were developed for cutaneous application. These derivatives have a longer side chain and form a stronger and more flexible bond, with a three dimensional breaking strength, four times that of butyl- cyanoacrylate and their use has been approved by FDA.³

In our clinical study of 20 trauma patients, wherein 24 standardised facial incisions were randomly selected. 12 of the incisions were selected for 2-OCA applications and in another 12 incisions suturing was done with a standard 4-0 Ethilon.

The length of the incisions varied from 3 to 5 cms and the average time taken for wound closure with 2-OCA was 25 seconds, whereas suturing with 4-0 Ethilon took an average time of 12-25 minutes.

“A prospective comparison of octyl-2-cyanoacrylate and suture in standardized facial wounds”,¹ have shown the average length of the incision varied from 2 -3.5cm, wherein the time required for wound closure was, 3.6 mins vs 22.4mins respectively. In study showed 63mins vs 60mins.

In another study “A randomized trial comparing Octyl cyanoacrylate tissue adhesive and sutures in the management of lacerations”⁶, showed the average wound length of 12mm³ and the time required for epidermal skin closure was 5.5 seconds vs 3.5 minutes.^{1,6}

Except in studies “Closure of long surgical incisions with a new formulation of 2-octylcyanoacrylate tissue adhesive versus commercially available methods”⁷, and “Use of skin glue versus traditional wound closure methods in brain surgery: A prospective, randomized, controlled study”, it was found that the average length of the incision was ≥ 4 cm.⁸ All studies advocated an average length of incisions ≤ 4 cm in standardized facial wounds, wherein the epidermal closure with 2-OCA was faster (in seconds), compared to other standard and skin sutures/staples (in minutes). It is especially effective in children, where its use has averted the trauma of needles.

In our study post operatively there was no pain in the 2-OCA group, even though there was no difference, when compared to sutured group. There were signs of inflammation, wound dehiscence and infection in both the groups which was statistically not significant.

Similar studies was done on “A new tissue adhesive for laceration repair in children”, on paediatric patients, showed no pain, as assessed by parents in the 2-OCA group. Complications included one wound infection with no wound dehiscence.⁹ similar studies has shown that the wound closed with sutures exhibited increased inflammation and erythema around the incision site, whereas those closed with 2-OCA had significantly less tissue reaction. There were no instances of wound dehiscence, haematoma or infection in both the groups.¹⁰

In a clinical study showed, no difference in the rate of dehiscence or infection between standard suture repair and surgical adhesives.¹¹ In a similar study had also shown that, there was no difference in pain, felt in both the groups, at the end of 1st post operative week, but Infection rates were found to be similar and fewer OCA wounds were found to be erythematous with no difference in the wound dehiscence rates.¹²

Clinical study was done on aesthetic outcome of wound closure showed that no patients had wound dehiscence or infection during the first, 2 weeks of surgery and there was no evidence of prolonged healing time that could indicate that the adhesive had entered the wound.¹

In a clinical study done, wherein he evaluated the use of 2OCA in aphthous ulcers, demonstrated a statistically significant pain reduction in the patients.¹³

Cosmetic appearance of the wound was measured based on a Hollander Wound Evaluation Scale which included 6 variables like absence of step off, contour irregularities, wound margin separation greater than 2mm, edge inversion, excessive distortion/inflammation and overall cosmetic appearance.¹⁴

In our clinical study the parameters of HWES, like step off, wound margin, separation, excessive inflammation distortion, edge inversion were not taken into consideration.

This is because, two surgeons in our department, who specifically worked for this clinical study, always took care, while suturing/2-OCA application. This did not give rise to any complications like step off, contour irregularities, width of wound margin, edge inversion. Hence Surface Texture was checked Visually and on Palpation, whether it was smooth or rough. Scar was evaluated by its Esthetic Appearance. In our study, both the groups, did not show any difference.

A study showed no difference in the cosmetic outcome between both the groups.^{6,12} But in a study on the “Use of 2-OCA For Skin Closure In Facial Plastic Surgery showed that 2OCA tissue adhesive gave a better cosmetic result.¹⁰ in another group of studied showed better cosmetic results in sutured patients.^{1,15}

2-OCA showed better patients satisfaction, was faster method of wound repair and less painful, which was found to be similar in our studies too.^{6,10,12,15}

CONCLUSION

The present prospective study done on 20 patients comparing 2-OCA and suture in standardised facial incisions, clearly indicates the advantages of 2-OCA tissue adhesive which provides a relatively painless, faster method of wound closure. In conclusion our study shows 2-OCA tissue adhesive has a low rate of dehiscence, low infection rate, and provides excellent cosmetic results for closure of surgical incisions. The results are comparable to those obtained with standard wound closure techniques.

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