Original Article - Prospective Study

Attached Oral Mucosal Wound Closure using Blue Glue - A Prospective Clinical Study

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Abstract

Introduction: Traditionally, sutures have been widely used to close intraoral wounds. Various alternatives have been developed amongst which newer tissue adhesives such as N-butyl-2-cyanoacrylate having accepted clinical properties are gaining popularity. The primary purpose of the present study is to evaluate the efficacy of N-butyl-2-cyanoacrylate for intraoral attached mucosal wound closure following alveoloplasty. **Materials and Methods:** In this prospective split-mouth study, 25 patients requiring alveoloplasty in either maxillary or mandibular arch bilaterally with a total of 50 sites were divided into two equal groups, namely silk suture (Group 1) and cyanoacrylate (Group 2). Each patient was evaluated on the first, third, seventh, 14th and 21st post-operative days. Parameters evaluated were time taken to close incision and to achieve haemostasis, pain, oedema, post-operative wound healing, patient discomfort and possible complications. **Results:** Time taken to close incision, time taken to achieve haemostasis, post-operative pain and oedema were found to be less in Group 2. Wound healing too was found to be better in Group 2. There was one case of adhesive peel off on the first post-operative day which was managed by reapplying the tissue adhesive. The incidence of wound dehiscence and wound infection was observed more in Group 1 on the third post-operative day. Suture breakage (16%) and adhesive dislodgement (8%) were reported on the seventh post-operative day. **Discussion:** The use of cyanoacrylates' inherent benefits, such as improved wound seal off in attached mucosa, quick polymerisation and bacteriostatic characteristics can be beneficial when performing minor oral surgical procedures on elderly, young and mentally challenged patients.

Keywords: Alveoloplasty, cyanoacrylate, polymerisation, silk suture, tissue adhesive

Introduction

Surgical wound closure with non-absorbable to absorbable suture materials is considered the gold standard.[1] Being inexpensive and easy to use,[2,3] silk sutures have been used widely in OMFS.[4] However, due to certain inherent limitations of intraoral suture usage like rapid bacterial ingress into deeper layer of operated site, tissue irritation, accumulation of food particles into suture knots[1] and longer suturing time, a need to search competent alternatives is demanded.[5] Biocompatible materials like surgical staples, tissue adhesives, surgical tapes, and fibrin sealants have also been used successfully as an alternative to silk sutures for different surgical procedures.[6]

In 1998, with approval from the Food and Drug Administration (FDA), cyanoacrylate adhesive usage for surgical and traumatic wound closure was commenced.[5,7] Reported advantages cyanoacrylates possess are good biodegradability, inherent haemostatic and bacteriostatic properties, have no systemic or geno-toxicity.[4,8,9] They increase epithelial keratinisation and have minimal inflammatory response which leads to decreased healing time.[4,8,9] They offer pain free and quick application by elimination of needle prick providing excellent cosmesis,[4,8,9] which ultimately reduces discomfort for patients and operative time for clinician.[8] Subsequently, its use in many oral surgical procedures like repair of vessels, for mucosal graft attachment, flap closure after third molar surgeries, as post extraction dressings, and in fixation of mandibular fractures has been studied extensively.[5,7,9] Alveoloplasty is one such routine minor oral surgical procedure that requires flap approximation for successful

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wound healing status post bony contouring before prosthetic rehabilitation.[7] With the goal of achieving early atraumatic and uneventful healing of intraoral wounds, the present study compared the effectiveness of N-butyl-2-cyanoacrylate versus silk sutures in alveoloplasty incision closure.

Materials and Methods

This prospective split-mouth study was conducted from September 2019 to June 2022 in the Department of Oral and Maxillofacial Surgery with prior permission from IEC (Registration no: AMC/IEC/OS/PG53/20). Twenty-five patients in the age range of 41–65 years comprising 12 males and 13 females requiring alveoloplasty in either maxillary or mandibular arch bilaterally were divided into two groups with a total of 50 sites.

- Group 1: 3-0 silk suture group (control group)
- Group 2: N-butyl-2 cyanoacrylate group (study group).

Inclusion criteria

- Class II and IV type alveolar ridges (according to Atwood, Cawood and Howell classification)[10]
- Availability of adequate soft tissue for primary approximation of flap
- American Society of Anesthesiologists Class 1, medically fit patients without any underlying systemic disease.

Exclusion criteria

- Patients with oral destructive habits which can hinder wound healing like smoking and usage of other tobacco-related products
- Patients on medications, which can impair wound healing like vasoconstrictors, e.g., ergotamine, nicotine and cocaine; selective CoX2 inhibitors; platelet aggregation inhibitors including certain antiplatelet and anticoagulant agents; corticosteroids; immunosuppressants; antirheumatic drugs; antineoplastic and anticancer drugs; antiangiogenesis agents and anti-gout drugs[11,12]
- Patients having history of allergy or contact dermatitis to formaldehyde (as cyanoacrylates contain dyes, plasticisers, polymerisation inhibitors and small amounts of formaldehyde which can act as allergens).[13]

Surgical procedure

A detailed clinical history and routine preoperative investigations were recorded beforehand. Randomisation of operating sites was done and N-butyl-2-cyanoacrylate was applied on the right side while suturing was done on the left side in all the patients. Alveoloplasty sites were infiltrated bilaterally with 2% lignocaine and adrenaline 1:80,000 after strict antisepsis with 2% Betadine. About 2-5 cm long crestal incisions were placed using BP blade #15 and full-thickness mucoperiosteal flaps were reflected using Molt's periosteal elevator. Contouring of bulbous and irregular ridges was done using bone file and round carbide burs #HP-6 or 8 followed by wound irrigation with Betadine and normal saline. On the left side, interrupted 3-0 black silk sutures were used for wound closure and were removed after seven days. Operated sites on the right side were isolated and gently dried, flaps were approximated with gentle finger pressure and N-butyl-2-cyanoacrylate tissue adhesive was applied drop by drop to cover the entire incision area in three layers with about 0.5 cm excess at each end of incision [Figure 1]. In both the groups, standard post-surgical protocol was followed, and prophylactic antibiotics and analgesics (capsule amoxicillin 500 mg, tablet diclofenac sodium 50 mg + paracetamol 500 mg and tablet ranitidine 150 mg) were administered for three days. Patients were examined on the first, third, seventh, 14th and 21st post-operative days. Parameters studied were pain, time taken for incision closure, time taken to achieve haemostasis (oozing from wound), presence of post-operative oedema (intraoral clinical observation of presence/absence of wound oedema), post-operative wound healing scored according to Landry, Turnbull and Howley index [Figure 2],[14] patient discomfort and complications like complete adhesive dislodgement, partial adhesive peel off, suture breakage, wound dehiscence and infection. The time taken for incision closure in both the groups was noted using digital stopwatch and numerical rating scale was used for assessment of pain for all the patients.

Statistical analysis

Entire data were statistically analysed using SPSS version 20.0, IBM Corporation, Armonk, NY, USA. Continuous variables are presented as mean and standard deviation, whereas discrete variables are presented as number and percentage. Normality assumption was tested using Shapiro–Wilk test. Continuous groups were compared by independent sample *t*-test and categorical groups were compared by Chi-square test. Scores of the two groups were compared by Mann–Whitney *U*-test.

Results

A total of 36 patients requiring alveoloplasty bilaterally in either jaw were initially selected for study, out of which four patients

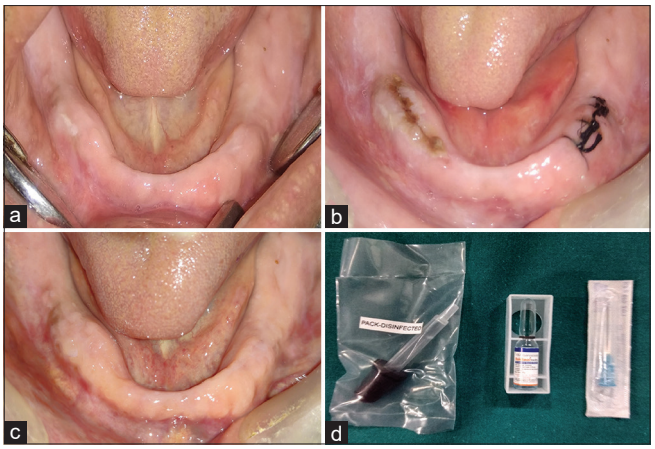


Figure 1: (a) Pre-operative edentulous mandibular alveolar ridge in a 57-year-old female patient. (b) Silk suture application on the left side versus cyanoacrylate application on the first post-operative day. (c) Wound healing on the 21st post-operative day. (d) Armamentarium for cyanoacrylate application

Very poor	Tissue color: ≥50% of gingiva red Response to palpation: Bleeding Granulation tissue: Present Incision margin: Not epithelialised, with loss of epithelium beyond incision margin Suppuration: Present
Poor	Tissue color: ≥50% of gingiva red Response to palpation: Bleeding Granulation tissue: Present Incision margin: Not epithelialised, with connective tissue exposed
Good	Tissue colour: ≥25% and<50% of gingiva red Response to palpation: No bleeding Granulation tissue: None Incision margin: No connective tissue exposed
Very good	Tissue colour: <25% of gingiva red Response to palpation: No bleeding Granulation tissue: None Incision margin: No connective tissue exposed
Excellent	Tissue color: All tissues pink Response to palpation: No bleeding Granulation tissue: None Incision margin: No connective tissue exposed

Figure 2: Landry, Turnbull and Howley index for wound healing assessment[14]

did not meet one of the inclusion criteria like similar length of alveoloplasty incision, three patients expressed their hesitations for adhesive glue usage and four patients were lost to follow-up at one week period. Hence, the final sample size for the present study was 25 patients with a mean age of 55 years, male:female ratio of 0.9:1 and approximately 56% procedures in mandible while 44% in maxilla [Table 1].

In Group 1, incision closure time was noted from the start of first suture till closure of last knot, whereas in Group 2, it was measured from the start of first layer of cyanoacrylate application from one end of incision till the last drop of third layer on the other end of the incision. Independent sample *t*-test was done to calculate difference in mean time taken for incision closure and difference in mean time taken to achieve haemostasis between both the groups too was statistically significant, $P < 0.001$ and $P = 0.000$, respectively [Table 2]. When post-operative oedema was assessed between both the groups using Chi-square test, it was statistically significant ($P < 0.05$) on the first and third post-operative days [Table 3].

Pain assessment data were analysed using Chi-square test to delineate that pain scores were statistically significant on the third and seventh post-operative days between both the groups, $P = 0.000$ and $P = 0.009$, respectively [Graph 1]. When post-operative wound healing scores were compared using Mann–Whitney *U*-test between both the groups, the mean rank in Group 2 was higher than Group 1 and it was statistically significant [$P = 0.000$, Table 4].

On assessment of post-operative complications, wound dehiscence was found more common in Group 1 (12%) than Group 2 (4%) on the seventh post-operative day. Wound infection too was more common in Group 1 (8%) on the third follow-up day. Few sutures were found broken in three patients, while complete adhesive dislodgement was observed in one patient on the seventh follow-up day, and adhesive peeled off on the first post-operative day in one patient, which was managed by reapplication of adhesive.

Table 1: Demographic distribution of patients as per age group, site and gender

Age groups (years)	Male		Female		Total
	Maxilla	Mandible	Maxilla	Mandible	
41–45	0	1	1	0	2
46–50	1	0	1	3	5
51–55	2	2	0	1	5
56–60	2	2	1	1	6
61–65	2	1	2	2	7
Total	7	6	5	7	25

Table 2: Intergroup comparison of time taken to close the incision and to achieve haemostasis (s)

Variables	Group	Mean (s)	SD	Difference, mean±SD	Independent sample *t* test *P*
Incision closure	1	232.84	24.98	232.92±5.44	0.000***
	2	100.36	10.71		
Haemostasis	1	130.76	12.23	132.92±4.97	0.000***
	2	263.68	21.65		

****P* value ≤0.001: Statistically very highly significant, SD: Standard deviation

Table 3: Intergroup comparison of post-operative oedema on days 1, 3, 7, 14 and 21

Evaluation time	Group 1, *n* (%)		Group 2, *n* (%)		Chi-square test *P*
	Present	Absent	Present	Absent	
Day 1	20 (80)	5 (20)	7 (28)	18 (72)	0.000***
Day 3	8 (32)	17 (68)	1 (4)	24 (96)	0.009**
Day 7	1 (4)	24 (96)	0	25	<0.1*
Day 14	0	25 (100)	0	25	-
Day 21	0	25 (100)	0	25	-

**P* value ≤0.1: Statistically significant, ***P* value ≤0.01: Statistically highly significant, ****P* value ≤0.001: Statistically very highly significant

Table 4: Intergroup comparison of post-operative wound healing scores according to Landry, Turnbull and Howley index[14]

Group	Number of sites	Mean rank	Mann–Whitney *U* Rank	Mann–Whitney *U*-test *P*
Group 1	25	16.3	82.5	0.000***
Group 2	25	34.7		

****P* value ≤0.001: Statistically very highly significant

Discussion

The primary tenets of wound closure place a strong emphasis on restoring soft-tissue support and function, which eventually

reduces wound tension. Timeline of wound healing ranges through four phases: haemostasis, inflammation, proliferation and maturation.[15,16]

Multiple factors like transforming growth factor-β1, saliva and infection may affect healing of fixed oral mucosa as it sustains a greater degree of physical trauma during chewing and eating.[16,17] Few studies have evaluated role of immune cells (mature mast cells) in regulation of wound healing as poor wound healing is sometimes related to protracted immunoregulation.[16] Recent approaches to manage complex wounds are polymer/biopolymer scaffold, biological graft, gel/topical ointment-fibrin glue, carbonated drink, low-intensity pulsed ultrasound, etc.[16]

Reason for widespread silk suture usage is precisely because of its nature, easy availability and cost-effectiveness[3] compared to other available alternatives. Consideration should be given to how oral tissue will react to these alternative materials[4,8,18] as majority of previous experiments are conducted mostly on skin.[8] The tissue reaction to suture material on skin differs from that of oral mucosa since epidermis does not simulate oral mucosa in terms of warmer temperatures, constant food intake (change in mechanical forces and pH), variety of microbial flora and moist environment.[8,19-21] Suturing can make wounds susceptible to infections, stitch abscesses, epidermal inclusion cysts, suture granulomas, tearing/necrosis of wound margins and increased risk of disease transmission to surgeon from an accidental needle prick.[5,19] This demanded development of newer alternatives such as staples, adhesive tapes, tissue adhesive and stripes.

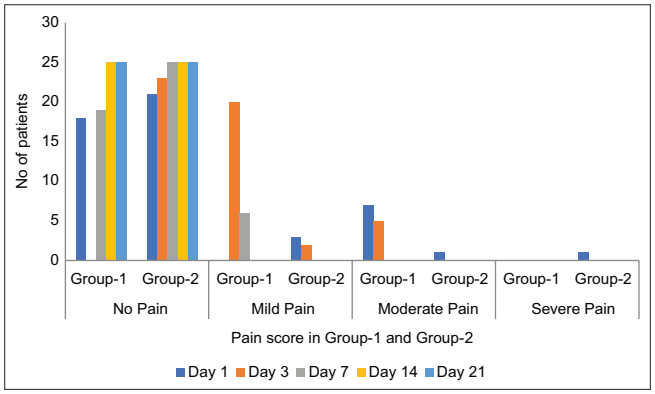
The term 'tissue adhesives' refers to any material that permits polymerisation. Cyanoacrylate was first introduced in 1949, and after 10 years, Harry Coover first established its clinical application.[1] Cyanoacrylate offers certain advantages like ease of handling and application, shorter duration of application, comfort in anxious and fearful patients, bacteriostatic property, decreased healing time, eliminated risk of needle prick injury, haemostatic property and better aesthetics.[20,22] Thus, they have widespread applications in CSF leak repair, blepharoplasty, rhinoplasty, fracture fragment stabilisation during plating, maxillary sinus membrane perforation repair, neurosurgical procedures, ophthalmic surgeries, in haemangioma management, and achieving haemostasis during intraoral and extraoral surgical procedures.[9,23]

All cyanoacrylates have same basic molecular structure, only carbon 3 side chains and alkyl group differ.[5] Cyanoacrylate monomer principally consists of cyan group, alkyl group and acrylate group. Cyan and alkyl groups are highly electronegative that cause carbons in ethylene to polarise. Ethylene in acrylate group is responsible for polymerisation of monomer in the presence of anionic structures.[24] Polymerisation changes the structure of cyanoacrylates and provides adhesive properties. The chemical reaction is exothermic and amount of heat released depends upon the chemical structure and agents (thickeners, stabilisers, etc.) added[24,25] [Figure 3].

Addition of blue dye to liquid monomer makes it apparent during application, hence popularised as 'BLUE GLUE'.[5] Moist oral tissue environment favours rapid polymerisation (within 10 seconds (s) in droplet form)[5] of cyanoacrylates which enhances its biodegradation, increases bacteriostatic properties, provides good haemostasis and imparts high tensile and adhesive strength to set glue.[5,9,26] Therefore, it requires only 30-60% of the time normally required for suturing. This signifies immediate wound margin haemostasis achieved with cyanoacrylates, while on sutured site, blood still oozes for a short period of time postoperatively.

The present study observations are in line with the abovementioned findings as the mean time required to close incision and to achieve haemostasis in Group 1 was approximately double to that of Group 2 (232.84 s and 100.36 s; 263.68 s and 130.76 s, respectively).

Kumar *et al*.,[19] and Giray *et al*.,[20] ascertained that cyanoacrylate application reduces pain in immediate post-operative period by forming a mechanical barrier against oral microflora, which is absent in suture group



Graph 1: Assessment of pain severity between both the groups on post-operative days 1, 3, 7, 14 and 21

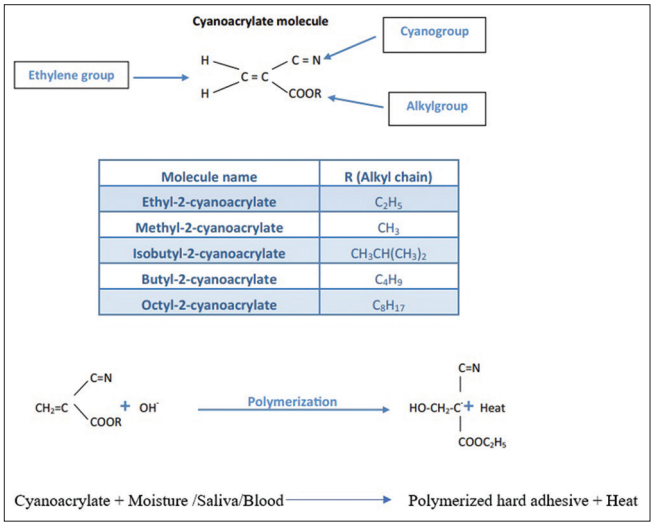


Figure 3: Chemical structure and polymerisation reaction of cyanoacrylate

because of food accumulation on suture threads and multiple microperforations posing risk of bacterial contamination causing wound infection. Barnett *et al*. also concluded that intraoral wound closure with cyanoacrylates was faster and less painful.[27] The present study too noted a statistically significant difference in pain severity on the third and seventh post-operative days between both the groups. Giray *et al*.[20] noticed marked post-operative oedema formation on sutured site compared to adhesive site during immediate post-operative period. The present study too found statistically significant oedema formation between both the groups on the first and third days postoperatively.

N-butyl-cyanoacrylates have shown bacteriostatic properties (antibacterial effects against Gram-positive bacteria and *in vitro* growth inhibition of *Bacillus subtilis*)[28] as its used vials did not show any bacterial growth even at 30 days, implying that it can be used multiple times.[5] The present study observed wound infection on the third post-operative day in one patient (4%) in Group 1 which was managed by daily wound irrigation and oral hygiene maintenance along with antibiotic regimen. On the seventh post-operative day, 1–2 randomly broken sutures were observed in four patients from Group 1, while two patients in Group 2 had adhesive dislodgement, but wound healing progression was unaffected.

Cyanoacrylates have ability to penetrate irregular tissue surfaces and form a firm union of incision line which further keeps flap margins approximated and reduces chances of wound dehiscence.[28] We observed wound dehiscence in 8% of patients from Group 1 and 4% from Group 2 on the seventh post-operative day which was in accordance with Vaaka *et al*.,[5] who reported a higher incidence of wound dehiscence with suture usage than with cyanoacrylates while in contrast to Raut *et al*.[29] who observed no significant difference in dehiscence rate. The present study observed better wound healing in 23 patients of Group 2 (very good and excellent score) which was in contrast with the findings of Suthar *et al*.[7] who noticed better wound healing in only seven out of 20 patients with N-butyl-2-cyanoacrylate usage.

Group 1 patients experienced local discomfort during daily work since suture threads and knots interfered with functional movements like speaking, chewing, sucking and swallowing. when suture threads often pull off leading to tissue tear/bleeding[19] or even suture breakage. Patient anxiety during suture removal has also been reported.[7] Accumulation of food/plaque on sutures causes halitosis and difficulty in oral hygiene maintenance. Although all these factors were absent in Group 2, some patients still showed concern regarding its efficacy as an adhesive. However, ultimate patient satisfaction was higher with cyanoacrylate usage which was similar to that noted by Vaaka *et al*.[5] Generally, adhesive peels off from mucosa or skin after seven days.[3,9] We have used two to three thin layers of adhesive which was sufficient to securely seal off the operated site from contamination similar to Singer *et al*.[30] Yet, we found adhesive peel off on the first post-operative day in one patient who was skeptical regarding efficacy of adhesive and kept on checking its adhesion with his tongue and fingernail. It was successfully managed with reapplication and counselling.

Certain positive aspects of cyanoacrylate usage are:

- Requirement of less accessory armamentarium
- Maintenance of sterilisation and asepsis by direct application
- No further visits for adhesive removal reduces patient anxiety.

One of the reported limitations of cyanoacrylate usage was its application on mobile mucosa which along with tongue interference causes its dislodgement in early healing phase. Cost of cyanoacrylates can also be a limiting factor as it is two to three times costlier than commercially available suture materials in India. Certain limitations of present study include a small sample size, wide age range where healing potential varies between different age groups of patients, patient compliance to maintain post-operative oral hygiene, and psychological bias of individual patients towards the success of new material usage.

The newer formulations like N-butyl, isoamyl and octyl cyanoacrylate degrade slower due to their longer alkyl groups compared to their previous shorter chain compounds like methyl and ethyl cyanoacrylates. Hence, lower levels of toxic compounds seeped into the body making it relatively safer and better tolerated.[31] Giray *et al*.[20] in their electron microscopic study of oral mucosa observed that N-butyl cyanoacrylate is non-cytotoxic and can be used as an alternative to sutures. Mehta *et al*.[32] reported no toxicity of butyl cyanoacrylate while studying mandibular fracture osteosynthesis as blood and urine samples were negative and chromosomal studies too revealed no change. Silk sutures have been compared with alternative suture materials like nylon, polyglecaprone, polytetrafluoroethylene, polyglactin 910, polyglycolic acid and polylactic acid.[32] for intraoral wound healing. Currently, nylon sutures outperform silk sutures, as Kavin *et al*. reported that silk sutures had five to eightfold bacterial adherence and nylon sutures had the least.[33]

Conclusion

The present study concludes that N-butyl-2-cyanoacrylate adhesive has better tensile strength on intraoral fixed tissues, has faster polymerisation rate in the presence of saliva and blood leading to reduction in duration of surgery, provides immediate haemostasis and better wound healing, is less painful, avoids multiple follow-up visits and has lower complications rates. As incorporation of various medications and growth factors with slowly degrading cyanoacrylates may hasten the healing process, present study advocates future research on its usage in minor oral surgical procedures where reduced chair-time is required such as in paediatric trauma patients, geriatric, mentally challenged and anxious patients; emergency procedures requiring immediate haemostasis as well as in aesthetic areas where a minimal scar is desired.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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