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Research Article

INTRA-ORAL WOUND CLOSURE AFTER ALVEOLOPLASTY USING SILK COMPAIRED TO ISO - AMYL -2- CYANOACRYLATE

Minal Sonare, Sheeraz Badal, Gopal Nagargoje, Ajay Sorate, Paras Doshi and Dnyaneshwar sakhare

Department of Oral and Maxillofacial Surgery, in Maharashtra Institute of Dental Sciences and Research (Dental college), Vishwanathpuram, latur 413512, Maharashtra, India

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ABSTRACT

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Key words: Tissue adhesive, Isoamyl -2 cyanoacrylate, Alveoloplasty, Silk suture Title: Comparative evaluation of effectiveness of tissue adhesive (iso amyl 2-cyanoacrylate glue) and traditional sutures (3-0 silk suture) for intra-oral wound closure after alveoloplasty: A clinical study. Objective: The Aim of this clinical study is to evaluate the efficacy in terms of immediate and post-operative hemostasis, Post-operative pain and the Wound Healing Property of Iso amyl 2-cyanoacrylate glue in the closure of intraoral surgical wounds compared with 3-0 silk sutures. Material and method: A total of 15 patients requiring bilateral alveoloplasty in the same arch were included in the study. Patient with any preexisting pathology os systemic disease were excluded. after alve After alveoloplasty was performed, the wound was closed using 3-0 braided silk sutures on one side, and using Iso amyl 2-cyanoacrylate bio adhesive on the other side. Patients were evaluated based on the following parameters: The immediate and postoperative hemostasis, the Wound Healing Property the time to the use of the first rescue medication; the side where pain first arises; and the side where wound healing begins first. Results: Compared to 3-0 silk sutures, cyanoacrylate demonstrated better hemostatic properties, reduced operative time, reduced postoperative pain and better wound healing. Conclusion: These data suggest that cyanoacrylate glue is an adequate alternative to conventional sutures to close the surgical wound after alveoloplasty, and better than are 3-0 silk sutures.

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INTRODUCTION

Incision is a basic step for surgical procedures. Suitable closure and optimal maintenance of the surgical area are the most important factors that affect proper wound healing and surgical success ¹.

The traditional method of wound closure causes trauma during the needle penetration while passing through the tissues and provides a "wick down" through which bacteria can gain access to the underlying tissues. It has been proved that the presence of suture material itself increases the susceptibility to infection. It may also lead to complications like stitch abscess, epithelial inclusion cysts and railroad track scar due to the invasion of underlying epithelial layer. The wound approximation by suture is time consuming and leads to more amount of scar formation 2 . Alveoloplasty is a routine dental procedure that is associated with swelling, bleeding, and pain postoperatively. These types of surgical wounds are conventionally closed using resorbable or non-resorbable sutures and are allowed to heal by primary intention. However, suture can be challenging in this area due to inaccessibility. Suturing is time consuming, and requires adequate skill. At times, resorbable sutures must be removed

early because they can be lodged with food and be irritating to the patient. Besides these difficulties, suturing also requires an additional visit for suture removal.

In order to overcome these difficulties, a need for an alternative to sutures is always felt³. The use of tissue adhesives as an alternative to or replacement for sutures in wound closure has long been an area of interest. An ideal surgical tissue adhesive must meet the following criteria: strong binding strength, ease of application, tissue biocompatibility, biodegradable byproducts, minimal tissue reactivity, and reasonable cost. Currently available surgical tissue adhesives can be categorized as either fibrin tissue adhesives or cyanoacrylates. Although fibrin tissue adhesives and cyanoacrylates are often discussed under the general topic of surgical tissue adhesives, these two substances have different indications and mechanisms of action. Fibrin tissue adhesives use naturally occurring substrates that are part of normal endogenous clotting mechanisms. In contrast, the adhesion achieved by cyanoacrylates is a result of synthetic compounds not naturally occurring in the human body. These two types of adhesives also have different clinical indications. Fibrin tissue adhesives are typically applied below the dermis

*Corresponding author: Minal Sonare

Department of Oral and Maxillofacial Surgery, in Maharashtra Institute of Dental Sciences and Research (Dental college), Vishwanathpuram, latur 413512, Maharashtra, India

as a biologic hemostat or as a sealant for use with skin grafts and flaps. Cyanoacrylates have been shown to be histotoxic when applied below the dermis and have been used most successfully at the level of the epidermis for superficial skin closure.

Cyanoacrylates were first synthesized by "Ardis" ³ in 1949. Coover in 1959 described their adhesive properties and suggested their possible use as surgical adhesives. Various cyanoacrylate tissue adhesives are gaining popularity for closing extra oral incisions. Previously ethyl and methyl cyanoacrylate were used for wound closure, but were discarded due to their potential toxicity ³. Newer generation cyanoacrylate has come up such as N -butyl cyanoacrylate, octyl-2-cyanoacrylate and iso amyl 2-cyanoacrylate also amyl 2-cyanoacrylate has unique properties compared to other cyanoacrylates having faster tissue bonding capacity and curing than octyl cyanoacrylate. Iso amyl 2- cyanoacrylate is superior to N-butyl cyanoacrylate since it does not get brittle and fracture on long lacerations. Its excellent tensile strength, fast polymerization, biocompatibility, immediate hemostasis, ease of application, and bacteriostatic property makes it very effective in closing surgical or wound incisions⁴.

There are very few studies have been taken for the comparison of intraoral use of Iso amyl 2-cyanoacrylate synthetic adhesive. The purpose of this study is to evaluate the efficacy of Iso amyl 2-cyanoacrylate glue in closure of intraoral surgical wound when compared with 3-0 silk sutures.

MATERIAL AND METHOD OF STUDY

The study was carried out for the duration of 24 months from 2021 to 2023 in the Department of Oral and Maxillofacial Surgery.

Method of Selection of Subjects

Inclusion Criteria

- 1. Patient in the age group of 18-55 years was selected irrespective of sex, caste, religion and socio-economic status.
- 2. Patient who are indicated for bilateral Alveoloplasty, with the same length and design for removal of teeth or bony spicules will be included.
- 3. Only clean incisions which can be approximated without tension will be included.
- 4. Length of incision should be 2 to 8 centimeters.
- 5. Patients who agreed to follow the study protocol.

Exclusion Criteria

- 1. Immunodeficiency disease.
- 2. Uncontrolled systemic diseases.
- 3. Patient with anti-coagulant therapy.
- 4. Smoker.
- 5. Uncooperative patients; mentally retarded patients.
- 6. Patients, who are likely not to maintain their oral hygiene.
- 7. Patients not willing to commit to an appropriate post procedure follow-up.

Fifteen patients who required alveoloplasty (and fulfilled the inclusion and exclusion mentioned criteria) was selected. The patient withdrawal criteria was completed following the Helsinki Ethical Principles for Medical Research involving human subjects. All of the patients was informed about the

procedure and the purpose, advantages and disadvantages of the study. Valid informed written consent was obtained from every patient.

A complete detailed case history was taken . The following preoperative laboratory tests was performed: Complete hemogram, bleeding time, clotting time, and blood sugar level. After detailed evaluation case history and proper diagnosis, treatment was planned. Armamentrium required for the study was arranged as shown in figure.(fig 1 and 2) .The procedure was started with an equal volume of 2% lidocaine with 1:2,00,000 adrenaline was administered on each side. The Technique of randomization was done by a coin toss method. This was used to select sides that was treated with cyanoacrylate or sutures.

The surgical sites was divided into two treatment groups. Group A included wounds that was closed with 3-0 braided silk sutures (Trusilk / Mersilk;3-0), Group B included wounds that was closed using Iso amyl-2-cyanoacrylate bio adhesive (Amycrylate). A crestal incision with anterior release was made in all cases to expose the bony spicules. The length of incision was constant for both the sides. An envelope mucoperiosteal flap was raised. Bony projections was smoothened using a bone file/ rongeur forceps or bone bur in a handpiece. The wound was irrigated with saline. Hemostasis was achieved. Hemostatic agents, such as collagen plugs or electrocautery, was used during alveoloplasty. Wound closure was performed using either 3-0 silk or amycrylate.(Fig 3,4) The following medications was given postoperatively to all patients after wound closure: • Cap. amoxicillin 500 mg capsule three times daily for five days after the procedure. • Tab. Zerodol (Aceclofenac tablets 100 mg) twice daily for 5 days (rescue medication). • Tab. PAN D 40 mg (PAN 40; By ALKEM Laboratories ltd, India) twice daily for five days to any patients with gastric irritation. Postoperatively, patients was also be given chlorhexidine mouthwash 0.12% (Perioguard; Colgate-Palmolive India, Mumbai, India) and instructed to rinse three times per day for seven days. The intraoperative and postoperative parameters was used to evaluate the study subjects on the 1st, 3rd and 7th(Fig 5 and 6) postoperative days. These values was recorded in case history, tabulated and statistically.

Methods of Measurements

Clinical parameters was used to evaluate the study subjects on the 1 st,3rd and 7th post operative days:

- 1. Time to achieve wound closure intraoperatively in minutes/ Seconds in both groups.
- 2. Incidence of postoperative hemostasis in minutes/ Seconds in both groups.
- 3. Time to use of rescue medication postoperatively will be noted in Hours/minutes.
- 4. The side where pain first arises postoperatively in terms of dichotomous score (0/1); present or absent which was calculated in percentages.
- 5. Post-operative Wound healing according to the Landry, Turnbull, and Howley index, to describe the extent of clinical healing after periodontal surgery and it was also recently modified to be used for extraction socket healing.

The following evaluation parameters were proposed for postextraction sites by applying a dichotomic score (0/1) with a total score of 7: presence/absence of redness; presence/absence of granulation tissue; presence/absence of suppuration; presence/absence of swelling; degree of tissue epithelialization (partial/complete); presence/ absence of bleeding; presence/absence of pain on palpation and rates it from score 1 (very poor healing) to 7 (excellent healing).

RESULTS

This study was conducted in the department of Oral & Maxillofacial Surgery. This a was prospective randomized type of study. A total of 15 patients were included in this study and written informed consent was obtained from all the subjects that participated in this study. All the patients divided into two groups:

Control group- Wounds that was closed with 3-0 braided silk sutures (Trusilk / Mersilk; 3-0),

Test group- Wounds that was closed using Iso amyl-2cyanoacrylate bio adhesive (Amycrylate).

To reduce the bias in the study, the observer was blinded to the study and we choose split-mouth study. The data obtained from the study was entered in to excel sheet to prepare a master chart (Table 1) and this data was statistically analyzed using the Independent t test, ANOVA Test and Bonferroni Test on IBM SPSS 21.0 version (2015) software.

The need of requirement to take rescue medication was from 3 hours to 6 hours. This result is statistically non-significant p>0.05, (Table 2) (Graph 1).

Comparison of time required for wound closure (in secs)

From the total (n=30) sides of both archs, time required for wound closure in group A with mean of 321 seconds , standard deviation of 32.77.Time required for wound clouser in group B with mean of 237.53 seconds with standard deviation of 30.17.Time required for wound closure was significantly higher in group A (321 seconds) as compared to group B (237.53 seconds).The difference of time for wound clouser in group A to B is 83.47. This result is statistically highly significant p<0.001, (Table 3) (Graph 2).

Comparison of Time Require for Haemostasis (in secs)

From the total (n =30) sides of both arches, time required for haemostasis in group A with mean of 148.53 seconds, standard deviation of 13.67.Time required for wound clouser in group B with mean of 17.53 seconds with standard deviation of 5.07.Time required for to achieve haemostasis was significantly lower in group B as compared to group A .The Difference in time require for haemostasis is 131.This result is statistically highly significant p<0.001,(Table 4) (Graph 3).

Tables and Graphs Table 1 Masterchart

	Age	Sex	Arch	Intra-operative Assessment			Postoperative Assessment			Follow Up (Wound Healing Index) Total Score (0-7)						
Sr. No.				Evaluation of Wound Closure Time required for wound closure (in secs)		Evaluaton of Haemostasis Time required to achieve haemostasis (in secs)		Evaluation of Rescue Medication Time required to use rescue Medication. (In Hr)	The Side where pain first arises		Day 1		DAY 3		Day 7	
					Group B		-		Group A	^	Group A			Group B	Group A	Group B
1.	47	М	Maxilla	240	250	160	15	4	1	0	5	6	6	7	7	7
2.	53	F	Maxilla	328	240	140	26	3	1	0	4	5	5	6	6	7
3.	52	F	Mandible	290	220	143	19	5	0	1	5	5	5	7	6	7
4.	55	Μ	Maxilla	301	270	153	24	4	0	1	3	5	6	7	7	7
5.	54	Μ	Mandible	320	232	157	19	3	1	0	4	5	5	6	6	7
6.	53	F	Mandible	318	190	162	17	5	1	0	5	5	5	6	6	7
7.	52	F	Mandible	344	257	132	21	4	0	1	4	5	6	7	7	7
8.	48	F	Maxilla	327	208	138	12	3	0	1	4	5	6	6	7	7
9.	49	Μ	Maxilla	370	232	121	26	6	1	0	6	6	6	7	7	7
10.	55	F	Mandible	327	216	157	14	5	0	1	5	6	6	7	6	7
11.	52	М	Mandible	290	198	146	16	3	1	0	5	6	6	7	6	7
12.	52	F	Maxilla	309	234	136	10	4	1	0	4	5	5	6	6	7
13.	55	М	Mandible	350	240	165	15	5	0	1	5	6	5	6	6	7
14.	48	М	Maxilla	337	272	170	18	6	1	0	5	6	6	7	6	7
15	55	F	Mandible	364	304	148	11	4	1	0	6	6	6	6	7	7

Amongst all total (N=15) number of participants, the maximum age was 55 years old and the minimum age was 47 years old. The mean age is 51 years old with a standard deviation of and this result is statistically non-significant p>0.05. From the total (N=15) number of participants, the maximum number of females were observed and they were 53.33% (n=8) than the male i.e. 46.66 % (n=7). This result is statistically non significant p>0.05.

Amongst all total (N=15) number of participants, the alveoloplasty procedure is carried out more in mandible which is 53.33% (n=8) as compared to maxilla 46.66% (n=7). The result is statistically non-significant p > 0.05.

Time required for rescue medication

From the total (N=15) number of patients, the average time required for rescue medication by the patient was 4.27 hours.

 Table 2 Details of Time Required for Rescue Medication (in hour) (Group A and Group B).

Variable	Minimum	Maximum	Mean±SD
Time required for rescue medication	3	6	4.27 ± 1.03

 Table 3 Comparison of Time Required For Wound Closure (In Secs) (Group A AND Group B).

Variable	Groups	Mean	SD	Difference	p value	
Time required for	Α	321.00	32.77	83 47	< 0.001*	
wound closure	В	237.53	30.17	63.47	<0.001*	
Time required for	Α	148.53	13.67	131.00	-0.001*	
haemostatis	В	17.53	5.07	131.00	<0.001*	

Independent t test; * indicates significant difference at p≤0.05

Intragroup Comparison of Change in Wound Healing Within Each Group From the total (n =30) sides of both arches, Wound healing score in Group A at day 1 with mean of 4.67 and SD of 0.82 which gradually increased to mean 5.60 and SD of 0.51 at day 3. At Day 7 wound healing score with mean of 6.40 with SD of 0.51. In group B, wound healing score at Day 1 with mean of 5.43 and SD of 0.51; At Day 3, the mean was increased to 6.50 and SD of 0.52and At Day 7, score with mean of 7.00 and no SD values. This shows that there was a significant improvement in healing from day 1 to day 7 in each group. (Table 5) (Graph 4).

Pairwise Comparison of Change in Wound Healing Within Each Group

From the total (n =30) sides of both arches, In group A, there was a significant improvement in wound healing from day 1 to day 3 and from day 1 to day 7. Also, wound healing showed significant improvement from day 3 to day 7. Similar results were seen in Group B.

 Table 4 Comparison of Time Require For Haemostatis

 (In Secs) (Group A and Group B)

(III Secs) (Group A and Group B).									
0	Day 1								
Groups	Mean	SD	Mean	SD	Mean	SD	p value		
Α	4.67	0.82	5.60	0.51	6.40	0.51	< 0.001*		
B	5 4 3	0.51	6 50	0.52	7.00	0.00	<0.001*		

Repeated measures ANOVA test; * indicates significant difference at p≤0.05 **Table 5** Intragroup Comparison of Change in Wound Healing Within Each Group

Group	Day 1 to day 3	Day 1 to Day 7	Day 3 to day 7
Α	0.003*	< 0.001*	< 0.001*
В	< 0.001*	< 0.001*	0.010*

Adjustment for multiple comparisons: Bonferroni test; * indicates significant difference at $p{\leq}0.05$



Fig 1 Armamentarium used for the study



Fig 2 Materials used for the study



Fig 3 Application of Iso Amly 2- Cyanoacrylate To Achieve Primary Closure



Fig 4 Immediate Post Operative Day



Fig 5 3 Rd Day Follow up



Fig 6 Group A And B Follow Up on 7 Th Day

Intergroup Comparison of Wound Healing Between two Groups at Each Interval

From the total (n =30) sides of both arches, Wound healing score in Group A at day 1 with mean of 4.67 and SD of 0.82 which gradually increased to mean 5.60 and SD of 0.51 at day 3. At Day 7 wound healing score with mean of 6.40 with SD of 0.51.In group B, wound healing score at Day 1 with mean of 5.43 and SD of 0.51; At Day 3, the mean was increased to

6.50 and SD of 0.52and At Day 7, score with mean of 7.00 and no SD values. This results shows the comparison of change in wound healing between two groups at each interval. At day 1, day 3 and day 7, group B showed significantly better healing as compared to group A. (Table 6) (Graph 5).

 Table 6 Intergroup Comparison of Wound Healing Between Two Groups at Each Interval

Crowns	Grou	рA	Grou	n voluo			
Groups	Mean	SD	Mean	SD	p value		
Day 1	4.67	0.82	5.43	0.51	0.003*		
Day 3	5.60	0.51	6.50	0.52	< 0.001*		
Day 7	6.40	0.51	7.00	0.00	< 0.001*		
Independent t test; * indicates significant difference at $p \le 0.05$							

DISCUSSION

Understanding wound healing at multiple levels-biochemical, physiologic, cellular, and molecular-provides the surgeon with a framework for basing clinical decisions aimed at optimizing the healing response. Equally important it allows the surgeon to critically appraise and selectively use the growing array of biologic approaches that seek to assist healing by favourably modulating the wound environment. Soft tissue wounds heal in three general ways: primary intention, secondary intention and tertiary intention. Healing by primary intention is preferable as there is less scarring and the healing is rapid. The primary steps in the management of surgical wounds are haemostasis and tissue approximation. Through ages surgeons have used various materials to close incision. They are metal clips, adhesive tapes and sutures. Every material has its own advantages and shortcomings. A never ending search for a material to overcome the short comings of the various wound closure techniques led to the discovery of various tissue adhesives.

Surgeons have been using tissue sealants and adhesives since the early nineteenth century. There are presently four types of tissue adhesives: fibrin sealants, collagenbased sealants, synthetic polymer-based materials, and protein-based sealants. The creation of natural glues, surgical staples and tapes to substitute sutures has supplemented the armamentarium of wound closure techniques. The use of tissue adhesives has long appealed to surgeons and they have been extensively studied for diverse applications. Cyanoacrylates were first described in 1949 and their first reported use as clinical adhesives was 10 years later by Coover. Members of the cyanoacrylate family include methyl, ethyl, propyl, butyl, hexyl, heptyl and octyl cyanoacrylates. Methyl-2cyanoacrylate was the first cyanoacrylate compound to be used as a surgical tissue adhesive. This derivative is a shortchain cyanoacrylate compound containing a methyl group as part of its alkoxy-carboxyl subunit (R = CH3). Although methyl-2- cyanoacrylate was a breakthrough advancement in surgical tissue adhesives, its popularity and use were significantly limited when many investigations demonstrated a concerning level of histotoxicity. Thereafter, ethyl-2cyanoacrylate, containing a slightly longer carboxyl group, was developed.

In a search, for a more biocompatible tissue adhesive, cyanoacrylates with longer side chains were developed for the surgical arena. The histotoxicity of the cyanoacrylate adhesives has been found to be proportional to the length of their monomer sidechain. Further research and development produced the longer side chain derivatives and isobutyl-2cyanoacrylate was manufactured. This adhesives are known for reasonable binding strength and lesser degrees of histotoxicity when compared with their shorter-chain predecessors.

Cyanoacrylate tissue adhesives form a strong bond across tissue-wound edges, enabling normal healing to occur below the seal. These adhesives have been shown to save time and provide a flexible water resistant protective coating that will seal wounds from water exposure and contamination. They can be used safely in small wounds, but also in larger wounds where subcutaneous sutures are needed and a watertight sealant is appropriate. Favourable characteristics of N-butyl-2cyanoacrylates are that it offers several advantages over other methods of wound closure and tissue fixation like their ability to rapidly form a flexible bond, act as an occlusive protective dressing, decrease inflammation, and reduce follow-up care and medical costs.

Cyanoacrylate surgical sealant has some characteristics that make it particularly useful and reliable for the surgeon. It can be stored at room temperature, can be easily and rapidly prepared in the applicator device, and is easy to apply. Studies of wound closure have compared the cost effectiveness of suture and cyanoacrylate techniques and have demonstrated an actual cost reduction with use of the adhesives. Cost reduction is most reflected in reduced physician and ancillary services, decreased equipment needs, and fewer required follow-up visits.

The disadvantages of sutures are anxiety at the prospect of removal of sutures and the unaesthetic appearance of the vertical line of suture puncture scars. Potential advantages of cyanoacrylates therefore include reduced anxiety about removal of sutures. Reduction in the risk of a needle stick injury to the surgical team is also a potentially important consideration although this was not evaluated in this study.

We clinically evaluated each surgical wound for healing, at a time interval of 1st, 3rd and 7th postoperative day. All patients showed no wound breakdown, dehiscence, clinical signs of inflammation. In our study, wound healing score in Group A at day 1 with mean of 4.67 and SD of 0.82 which gradually increased to mean 5.60 and SD of 0.51 at day 3. At Day 7 wound healing score with mean of 6.40 with SD of 0.51.In group B, wound healing score at Day 1 with mean of 5.43 and SD of 0.51; At Day 3, the mean was increased to 6.50 and SD of 0.52and At Day 7, score with mean of 7.00 and no SD values. This shows that there was a significant improvement in healing from day 1 to day 7 in each group .This positive finding adds up to the previous human and animal study reports in which excellent bone and soft tissue healing with a mild inflammatory response is seen with an application of butyl and octyl cyanoacrylates in both intra-oral and skin wounds, ulcers.^{38,39,40}. Study performed by Kulkarni et al. $(2007)^{23}$ found that healing with the cyanoacrylate is associated with less amount of inflammation during the first week when compared to silk after periodontal flap surgery and thus concluded that cyanoacrylate aids in early initial healing. Boaz Mizrahi et al. (2011)⁵⁰ stated that tissue adhesive could also induce wound contraction and accelerate wound closure and healing. Same was noted in our study, where there was a significant difference in wound healing on the 7th postoperative day when cyanoacrylate was compared with suturing for the closure of wound after alveloplasty.

Over all our study found Iso Amyl 2- Cyanoacrylate superior to conventional suture with respect to Pain, Wound Healing, Heamostasis and Time required to achieve wound closure. The small sample size, possibility of complications other than the criteria involved in our study, shorter period of follow up, absence of an objective measurement technique, and the cost of tissue adhesive were limitations of the study. Future studies are required to evaluate long term results of intraoral usage to further its application. Research is needed for development of better tissue adhesives for usage in intraoral wounds.

CONCLUSION

The present study was conducted with an aim to evaluate the efficacy of Iso amyl 2-cyanoacrylate glue in the closure of intraoral surgical wounds compared with 3-0 silk sutures. Total 15 patients fulfilling the criteria for selection and comprising of both the genders in the age range of 18- 55 years were included in the study. Every patient satisfied the criteria necessitating particular surgery.

The study revealed that sutureless closure of intraoral wound after alveloplasty using cyanoacrylate adhesive [Amcrylate (Iso Amyl-2- cyanoacrylate)] is more beneficial when compared to the closure of wound with conventional suturing technique.

From the perusal of the collected information following conclusions can be drawn on the use of Iso Amyl-2 Cyanoacrylate.

Complete heamostasis is achieved immediately after application, there by negating the need of pressure pack over the operated site post-operatively.

No wound dehiscence, abscess formation, necrosis, granuloma formation, hematoma, clinical signs of inflammation (pain, swelling and redness) and infection, exothermic reaction was noted. Thus it is bio-compatible.

Ease of application with either needle-syringe or droppersyringe method. Thus can be practiced even by a general practitioner. No special skills are required except those for a surgical technique. This recommends its widespread use.

Being transparent permits the clinician to visualize the wound healing over the entire period of follow-up.

Less time is required for primary wound closure with Iso Amly 2- Cyanoacrylate when compared with conventional suturing.

Avoids additional visit for suture removal.

However, the cost of tissue adhesive was the only limitation of this study. Hence, We conclude that Iso Amyl-2 Cyanoacrylate is a better alternative to conventional suturing for closure of intra-oral minor surgical wounds such as closure of surgical wound after Alveloplasty.

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Author Contributions: All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Dr. Minal, Dr. Sheeraz badal and Dr Gopal Nagargoje. The first draft of the manuscript was written by Dr. Minal, Dr. Ajay, Dr. Paras and Dr. Dnyaneshwar .All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University named MIDSR Dental college, Latur Institutional Ethical Committee Meeting (Date - 14/01/2021 No - MIDSR/STU/PG/560/34/2021)."

Consent to participate

Informed consent was obtained from all individual participants included in the study. Written informed consent was obtained from the parents.

Consent to publish - Not Required.

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