"COMPARISON BETWEEN N-BUTYL-2 CYANOACRYLATE TISSUE ADHESIVE & NYLON SUTURES IN MAXILLOFACIAL TRAUMA: A RANDOMIZED CONTROLLED TRIAL"

By

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Dissertation

Submitted to the
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In

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(BRANCH III)

Under the guidance of

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ABSTRACT

Introduction: A wound is defined as an injury to any of the body's tissues, particularly one caused by means of physical force and resulting in an disruption in continuity. Wound healing itself is a naturally occuring phenomenonWound care is an essential component of any surgical procedure. The general basis of wound care is relied on suturing. The injured site can be closed by using staples,tissue adhesives, tissue closure strips other than the conventional suturing technique. The main objevtive of this study was to compare N-Butyl-2-Cyanoacrylate tissue adhesive and convention nylon sutures in maxillofacial traumatic lacerations.

Material& Methods: The study was conducted in KLES DR. PRABHAKAR KORE HOSPITAL, KAHER, Belagavi, Karnataka & DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY, KLE V. K. INSTITUTE OF DENTAL SCIENCEs with due permission of the institutional ethical committee. A total of 34 patients with CLW, were included in the study who met the inclusion and exclusion criteria and with their free will gave their consent for the study. Patients were randomly divided into two groups.

Group A (case group) – N-Butyl-2-Cyanoacrylate was used for wound closure

Group B (control group) – Nylon sutures were used for wound closure

Patients were followed-up at 5^{th} and 7^{th} day respectively

On follow-up patients were evaluated for wound healing & presence of infection.

Results: In the present study, a total of 34 patients were included, requiring closure of CLW. The case group (Cyanoacrylate) included 17 patients and the control group (suture group) included 17 patients. We have found that wound healing was comparatively better in case group than the control group and the presence of infection was less in the case group when compared to the control group.

Conclusion: Cyanoacrylate tissue adhesive, has better advantages of rapid closure, no use of local anesthesia, no risk of injury from use of needles, no requirement of special equipments, better bacteriostatic activity, no necessity of wound dressing, no need of removal of material. Cyanoacrylate tissue adhesive provides satisfactory results even in emergency wound closure

LIST OF ABBREVATIONS USED

OMFS	–	ORAL AND MAXILLOFACIAL SURGERY
PRE-OP	–	PRE – OPERATIVE
POST-OP	–	POST – OPERATIVE
CLW	–	CONTUSED LACERATED WOUND

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INTRODUCTION

A wound is defined as an injury to any of the body's tissues, particularly one caused by means of physical force and resulting in an disruption in continuity. Wound healing itself is a naturally occuring phenomenon. When the tissue has been injured so badly, that it cannot heal by itself without any events, removal of non-viable tissue & foreign bodies should be done, infection to be treated. The tissues must be held in place, till the events of healing takes place, such that the injured site can withstand any external forces without any support[1].

Wound care is an essential component of any surgical procedure. The general basis of wound care is relied on suturing. The injured site can be closed by using staples, tissue adhesives, tissue closure strips other than the conventional suturing technique[1]. It has been a major concern regarding the wound closure using the conventional suturing and non-suturing techniques. Generally, the most common method used for closing any wound or injured site is by using suturing technique. The suturing technique is safe and reliable, but they require instruments to place, and create the need for removal after the injured site has healed.

The discovery of cyanoacrylates was by Ardis in 1949, followed by Coover et al using the tissue adhesive in surgical field in 1959[2], had revolutionized the non conventional closure of wound. Cyanoacrylate generally has no pigmentation, not toxic and is a biostatic tissue adhesive,that helps in faster closure of the injured site with less scarring and in the post-operative period reduces the chances of infection. In addition the advantage of the tissue adhesive includes being easy to apply to the injured site and having an established safety record, resulting in better wound healing, and reduced risk[2].

Whenever cyanoacrylate comes in contact with moisture, it turns into a polymer, and even though being an inert material, within 5-10 seconds it solidifies to rapidly providing the closure for the injured site. For the conventional suturing technique, generally it carries a need for local anesthetic injection, which is of rare use when using tissue adhesive. Literature has mixed data regarding the antibacterial effect of the cyanoacrylates. Studies conclude that the tissue adhesive has a bacteriostatic action against gram- positive bacteria, but there was no action proven against gram- negative bacteria[2].

On the contrary, the tissue adhesive provides faster wound closure, having the reduced risk of needle stick injuries. Recent literature indicates the use of tissue adhesive for both wounds sustained by trauma and incisional wounds. The results when cyanoacrylate have been used to closure wound sites is comparable with the suturing techniques.

The advantages of cyanoacrylate tissue adhesives, over the suturing techniques include ease of use, reduced healing time, better bacteriostatic activity, and better cosmetic outcome. Presently the surgical tissue adhesives can be classified under fibrin tissue adhesives and cyanoacrylates. Both these materials have different indications and have a different mechanism of action[1].

The use of cyanoacrylate tissue adhesive preparations in surgical field dates back to more than 50 years. In the initial stages it was more preferred as a surgical glue. Whenever cyanoacrylate tissue adhesive comes in contact with the proteinaceous surface of the injured site, they create strong bonds on the injured site after application of the tissue adhesive[2]. Because of this property of the cyanoacrylate tissue adhesive they are being used in different surgical branches. Other than wound

closure, cyanoacrylate tissue adhesive is used for haemostasis in cases of gastrointestinal bleeding[3], for closure of fistulae in cerebrospinal, tracheo-oesophageal regions, for fixation of skin grafts, management of head and neck arterio-venous malformations[4].

The use of cyanoacrylate tissue adhesives in other different fields of surgery is becoming more established, the use of tissue adhesives in oral and maxillofacial surgery is relatively less. So the present study has been taken up to compare cyanoacrylate tissue adhesive and nylon sutures in maxillofacial lacerations.

AIM & OBJECTIVES

AIM OF THE STUDY

To compare N-butyl-2 cyanoacrylate tissue adhesive and nylon sutures in extraoral maxillofacial incisions/lacerations

OBJECTIVES

- To evaluate & compare wound healing using N-butyl cyanoacrylate and nylon sutures.
- To evaluate & compare presence of infection using N-butyl cyanoacrylate and nylon sutures.

NULL HYPOTHESIS:

There is no significant difference between cyanoacrylate tissue adhesive and nylon sutures in wound closure.

ALTERNATIVE HYPOTHESIS:

There is significant difference between cyanoacrylate tissue adhesive and nylon sutures in wound closure.

REVIEW OF LITERATURE

Praveen Kumar Singh[5] et al in 2018 conducted a study to assess efficacy of N-Butyl-2-Cyanoacrylate tissue adhesive in closure of maxillofacial lacerations and surgical incisions. In 10 patients, which accounts for 80% of the sample size of the study, subcuticular sutures were placed. Cyanoacrylate glue was used to close the skin. As usual the pressure dressing was placed for the first 24hrs post-operatively. All the 10 patients exhibited redness, edema, ecchymosis, which reduced by post-operative 2nd week. Post-op day 1, there was no discharge from the site of surgery. 2 patients exhibited discharge from the surgical site within the 1st week. Wound gaping was seen in 1 patient on the 1st post-operative day and 2 patients had wound gaping at the end of 1st week. The study implicates the assessment of the quality of tissue adhesives, ease of use, application of cyanoacrylate, resulting in consistent and uniform results.

Abhishek Soni[6] et al in 2013, published a randomized trial correlating cyanoacrylate and conventional subcuticular skin sutures for incisions which were placed in the oral cavity and in the maxillofacial region. In this study 40 incisions were placed, in 39 patients where20 incisions were closed with 2 OCA in 14 patients and the remaining 20 incisions were closed using subcuticular suturing techniques in 15 patients. When compared to the suture group, the mean time of closure with 2-OCA was significantly faster. Assessment of wound healing was done on 5th to 10th day and 3 months post-operatively. The study demonstrated advantages and is a better material for closure.

In 2019, SudiptoSahua[1] & colleagues published a randomized prospective study comparing N-butyl cyanoacrylate tissue adhesive and Ethilon sutures for incisions which were placed made extra-orally on the facial region. Objective of the study was to compare and correlate the rates of infection, dehiscence of wound, necrosis, and requirement of time for closing incisions was observed. 24 patients was the sample size, who required wound closure extra-orally. Tissue adhesives have advantages over other wound closure techniques, such as easy to use, better bacteriostatic properties, reduced repair time, no follow-ups, and better outcomes in short and long term basis.

Sneha Setiya[7] et al in 2014 conducted A prospective controlled study comparing the efficacy of tissue glue and sutures in cases, where there is a necessity for surgical extraction of mandibular 3rdmolars which are impacted. The study included 50 patients, which were treated for similar impacted mandibular third molars on both the sides. In the control group, sutures were used to close the wound after surgical extraction of the third molar, in the case group, cyanoacrylate glue is used. The analysis of the statistical data demonstrates that on the 1st,2nd,&7th post-operative days ,the severity of postoperative pain was less with the case group, whereas postoperative bleeding and swelling were less with the case group than with suturing on the 1st postoperative day. They concluded that, Although the efficacy of cyanoacrylate and suturing in wound healing was similar, the use of cyanoacrylate resulted in better haemostasis, reduced pain & swelling.

Vishakha N. Devrukhkar[2] et al. conducted a study in 2015 to evaluate isoamyl 2 cyanoacrylate tissue adhesive in treatment of lacerations in paediatric age group. The study had follow-up for 3 months post-op, in 7 patients. Observation was done for swelling, infection, gaping, and pain on the first, third, and seventh postoperative

days, as well as scar evaluation on the first and third postoperative months. Assessment was carried out on different superficial facial wounds of average length and those with low tension. Average time taken for closure of skin was approximately, 1–2.5 minutes. Wound infection was not noted in any of the patients, and on the 3rd follow-up day, only one case had wound dehiscence. There were no suture marks, so the cosmetic was better. When the wound is clean, small and not under tension, isoamyl 2-cyanoacrylate is a better needleless method for closure of certain pediatric lacerations.

Eduardo Borie[8] et al in 2019, published a review article on the topic of oral applications of cyanoacrylate adhesives to outline the pertinent literature in context with the use of cyanoacrylate for wounds that might happen during surgical and dental operations, with the main intention on use, indications, advantages and disadvantages. The study concluded that, the literature had definitively established results about the effectiveness, ease of use, safe to use, practical and attainable use of different types of cyanoacrylate groups in both intra-oral and extra-oral procedures.

In 2021, Gabriela Vasconcelos Maia[9] et al conducted a study to compare repair of the socket after tooth extraction and closure with cyanoacrylate and nylon sutures. 20 male Wistar rats were included in this present study, and extraction of left and right molar teeth was done. On the right side, the alveolus was closed with cyanoacrylate, whereas on the left side, a single interrupted suture with Nylon 5-0 was used. Histomorphometry was done using Image J software to assess the formation of new bone on the sites. Analysis of the findings demonstrated that on the 7th postoperative day, cyanoacrylate group had a delay compared to the control side. In between post-op 15-30 days, the difference between the two groups gradually

decreased. Following statistical analysis of the histomorphometric results, there was no difference in bone neoformation in the sutured alveolus versus the other side that received cyanoacrylate glue (p = 0.902).The study concludes that the socket repair of alveolus ,closed with cyanoacrylate aids in formation of new bone, and no significant difference was found in between the two groups.

Oladega AA[10] and colleagues, organized a randomized controlled study in 2018 to compare the complications that occur during the post-op period such as swelling and healing of wound of surgical wound closure with cyanoacrylate with silk suture. The included patients were that, those have impacted lower 3rd molars, and were segregated into the study and case group randomly. The control group contains patients in which the wound was closed with silk suture and in the case group patients, cyanoacrylate was used. Observation of the patients with follow-up was done for 7 days after surgery. Post-operative pain, swelling, trismus, bleeding, wound dehiscence, and wound infection are the parameters that were observed. Both the groups had 60 patients each. No statistically evident difference was found between the two groups. On post-op day1, between the 2 groups, more bleeding was found in the control group. According to this study, cyanoacrylate tissue adhesive outperforms silk suture, as a medium for closure of wounds. Furthermore, cyanoacrylate tissue adhesive appears to have a haemostatic effect on post-op bleeding.

In 2015, Hitoshi Nemoto et al[11]. Floor of the orbit is one of the most frequently fractured bone, and reconstruction of orbit is required. For orbital floor reconstruction, various materials are used. The soft tissues were let free of any attachments and positioned back intraorbitally, by a microscope. The fragments of bone along with “ethyl-2-cyanoacrylate” are fixed to a bone board before being

transported to the orbital fracture site. This method was used for 31 (32.3 percent) of the 96 fresh orbital floor fractures. In 48 patients, simple reduction is done. In the remaining 12 patients, a bone graft with iliac crest was performed. The choice of material was alloplastic type which was used in 5 patients. Correction of diplopia in 26 cases was done. In 1 patient, the bone which was reconstructed collapse was seen into the sinus. Prior to surgery 4 cases did not show any diplopia. Postoperatively, none of the patients experienced enophthalmos, foreign body reaction, or infection. 30 of the 48 cases where grafting was done, autologous bone was used. The indications for this method are that enough bone fragments can be obtained and placed back by the orbit that will not collapse to the maxillary sinus. We obtained good results and believe this is a safe and useful method.

Vijaylaxmy Malhotra[12] and colleagues published a study in 2016 to Evaluate the application of octyl-2-cyanoacrylate in repair of unilateral cleft of lip. The most issue that is faced by the parents where operation was done, is the appearance of the faces. Furthermore, the care of the site after operating, suture removal, and the disadvantage of a follow-up for removal of sutures, are the reasons for new advancements which may replace the requirement for suture. In the present study, use of octyl-2-cyanoacrylate provides a better alternative to conventional techniques, delivering better closure of wound. To conduct a thorough comparison of the outcomes of Dermabond use in patients who were treated for cleft lip and palate defects. Millards flap technique was used in patients in the study. The sample size was 20. The patients pre- and post-op pictures were evaluated using the Vancouver scar scale at 7, 14, 30 days, 6&12 months, postoperatively. Increased vascularity (hyperemia) was observed in 35% and 30% of patients in the 1st and 2nd weeks, respectively, which was subsequently reduced. In the first week, flat scar was seen in

85% of subjects, and by the end of a year, the number had dropped to 10 percent. Dehiscence was not seen in any of the patients. The difference in-between the first and second follow-ups was statistically significant among all follow-ups. When the results of the first week were compared to the results of all other follow-ups, there was no significance. They concluded that Octyl-2-cyanoacrylate can be used for closure of cleft of lip. The application of cyanoacrylate was faster and less of pain. In addition, because the material is bacteriostatic, it protects against wound infection.

Jaydeep M Gadhavi[13] and colleagues in 2020 comparing the clinical responses of cyanoacrylate and silk sutures in incisions which were placed intra-orally. Incisions were placed in patients bi-laterally, requiring minor procedures. One side was closed with n-butyl cyanoacrylate, while control group closure was with suture. Patients were recalled on the first, seventh, fourteenth, and twenty-first postoperative days and evaluated for pain, edema, wound dehiscence, and scar. There was no statistically significant difference between suture and cyanoacrylate in terms of pain, edema, wound dehiscence, and scar formation. However, the average time required for suturing was significantly longer than the time required for cyanoacrylate application. According to this study, the efficacy of cyanoacrylate and suture in intraoral wound closure is comparable for postoperative findings such as pain, edema, wound dehiscence, and scar formation. Cyanoacrylate, on the contrary, has advantages of ease of use, takes less time, well accepted by patients.

MATERIALS AND METHODS

STUDY DESIGN

An In-Vivo double blinded Randomized Controlled Trial

STUDY POPULATION:

The study was conducted in KLES DR. PRABHAKAR KORE HOSPITAL, KAHER, Belagavi, Karnataka & DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY, KLE V. K. INSTITUTE OF DENTAL SCIENCEs with due permission of the institutional ethical committee. A total of 34 patients with CLW, were included in the study who met the inclusion and exclusion criteria and with their free will gave their consent for the study.

INCLUSION CRITERIA

- Facial incision/lacerations should be within 2-6 cm limit.
- Patients who agreed to turn up for post-operative evaluation

EXCLUSION CRITERIA

- Animal wounds or human bites, crushed wounds.
- Known allergy to cyanoacrylate.
- Patients presenting with any known medical history.
- Known history of keloid formation and scar hypertrophy

MATERIALS AND ARMAMENTARIUM

- Materials used in Disposable hypodermic syringes
- N-butyl cyanoacrylate
- 3-0 vicryl absorbable suture
- Surgical scalpel
- Tweezers
- Cotton roll
- Adson's tissue forceps
- Mosquito forceps
- Dry gauze
- Straight probe
- Skin hooks
- Mayo suture cutting scissors
- Needle holding forceps
- 4-0 nylon suture

METHODOLOGY

- The present study was conducted in DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY, KLE V. K. INSTITUTE OF DENTAL SCIENCEs and KLE DR. PRABHAKAR KORE HOSPITAL

- The subjects were allotted into 2 groups of 17 each. Equal number of chits mentioning the techniques were made and handpicked by a staff nurse with no bias.

- The basic need to achieve wound closure using non-suturing techniques for closure of skin is a dry, uncontaminated wound, of which the edges of the wound can be held in place without tension

- In the case group, after obtaining consent from the patient, the wound is debrided, and the wound is made to dry. After the wound is dried, the cyanoacrylate material is loaded into a insulin syringe. If the wound is deep then layer closure is done using 3-0 vicryl and the deeper tissues are closed After that the wound surface is held in an position such that the edges of skin are approximated and help in place and the glue is placed over the approximated wound, and held in approximated position till 1 minute. After the material is set, a dry gauze dressing is placed over the wound and patient is followed up.

- In the control group, after obtaining consent, the wound is debrided. After debridement, if the wound is deep then layer closure is done using 3-0 vicryl and the deeper tissues are closed. After closure of the deep tissues, the skin edges are approximated using 4-0 nylon sutures in an simple interrupted fashion. After closure of skin edges, a soframycin gauze pack is secured over the sutured area and patient is asked to follow up

METHODOLOGY WITH FLOWCHART

Patients reporting to Department of Oral and maxillofacial surgery and from KLE's PRABHAKAR KORE HOSPITAL with H/O trauma

↓

Patients were divided into 2 groups

↓

In one group patients will be treated with cyanoacrylate and in other nylon sutures

↓

After placement of sutures follow up (5^{th} , 7^{th} postoperative day) will be taken to check wound approximation, rates of infection, wound dehiscence

Fig.1. Armamentarium used for Cyanoacrylate group

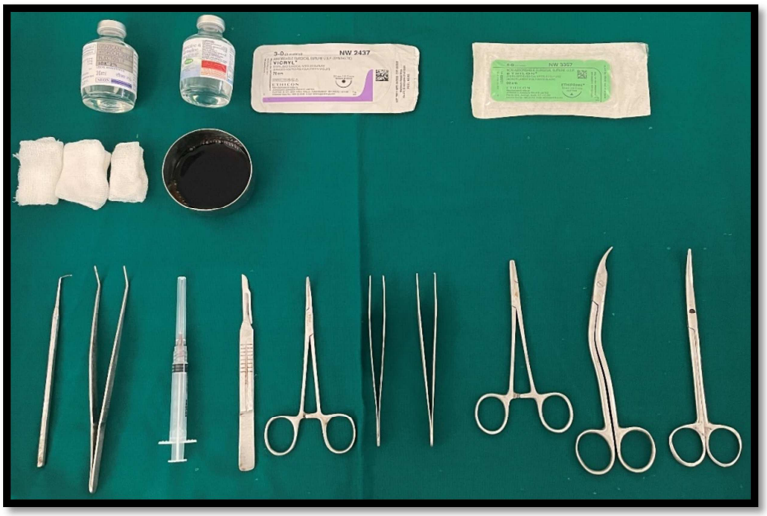

Fig.2. Armamentarium used for Suture group

Fig.3. N-Butyl Cyanoacrylate Tissue adhesive

Fig.4. CLW over right Eyebrow region

Fig.5. Immediate Closure with cyanoacrylate

Fig.6. Post-op Follow-up day 5

Fig.7. Post-op Follow-up day 7

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Fig.8. CLW present over right nasolabial fold, extending to the upper lip

Fig.9. Immediate Closure with Cyanoacrylate

Fig.10. CLW present over Right forehead region extending till Right Medial Canthal Region

Fig.11.immediate Closure done with Nylon 4-0 suture

Fig.12. Post-op follow up at 5th day

Fig.13. Post-op follow up at 7th day

EVALUATION PARAMETER

During the follow-up period the wound was assessed using the following evaluation parameter to check for any presence of infection and wound healing

Table 1 - "SOUTHAMPTON WOUND SCORING SYSTEM"

Grade	Appearance
0	Normal healing
I	Normal healing with mild bruising or erythema
Ia	Some bruising
Ib	Considerable bruising
Ic	Mild erythema
II	Erythema plus other signs of inflammation
IIa	At one point
IIb	At sutures
IIc	Along wound
IId	Around wound
III	Clear or haemoserous discharge
IIIa	At one point (≤ 2cm)
IIIb	Along wound (>2cm)
IIIc	Large volume
IIId	Prolonged for 3 days
IV	Major complication
Iva	Pus
IVb	At one point only (<2cm)
	Along wound (>2cm)
	Deep or severe wound infection with or without tissue breakdown : haematoma requiring aspiration

RESULTS

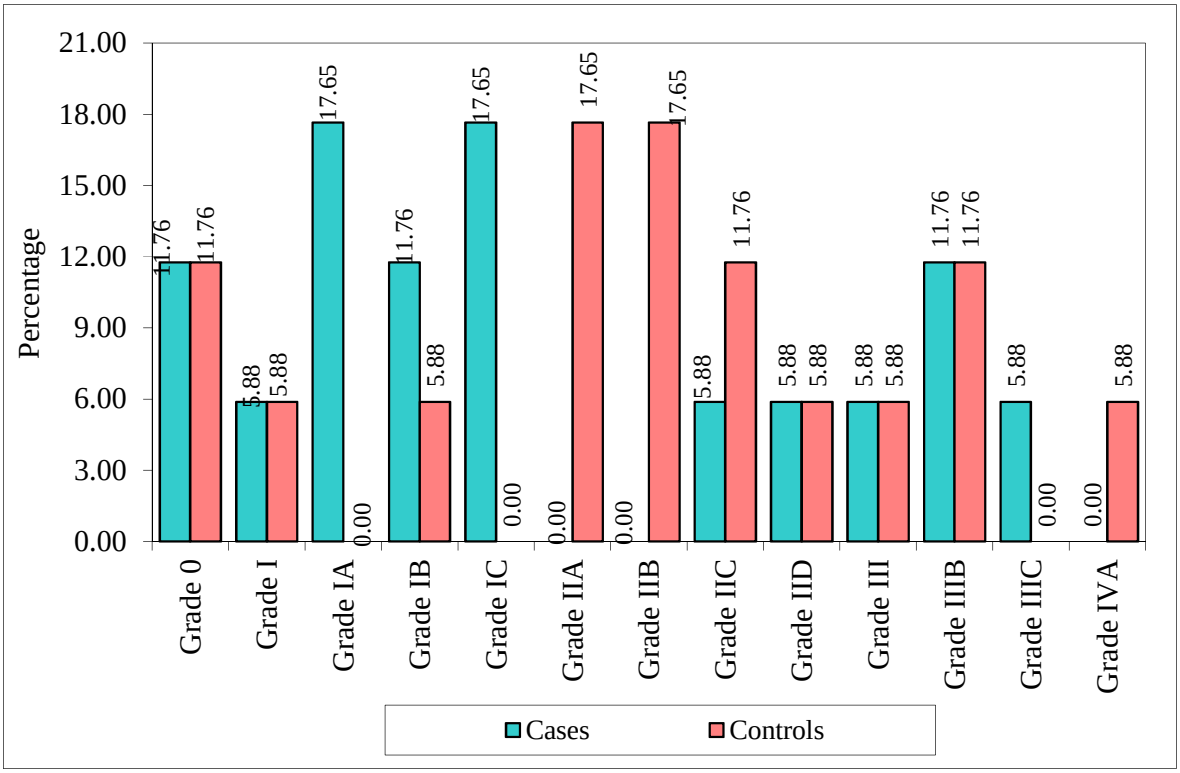
In the present study, a total of 34 patients were included, requiring closure of CLW. The case group (Cyanoacrylate) included 17 patients and the control group (suture group) included 17 patients

Table 2: Comparison of cases and controls with Grades of wound healing at day 5

Day 5	Cases	%	Controls	%	Total	%
Grade 0	2	11.76	2	11.76	4	11.76
Grade I	1	5.88	1	5.88	2	5.88
Grade IA	3	17.65	0	0.00	3	8.82
Grade IB	2	11.76	1	5.88	3	8.82
Grade IC	3	17.65	0	0.00	3	8.82
Grade IIA	0	0.00	3	17.65	3	8.82
Grade IIB	0	0.00	3	17.65	3	8.82
Grade IIC	1	5.88	2	11.76	3	8.82
Grade IID	1	5.88	1	5.88	2	5.88
Grade III	1	5.88	1	5.88	2	5.88
Grade IIIB	2	11.76	2	11.76	4	11.76
Grade IIIC	1	5.88	0	0.00	1	2.94
Grade IVA	0	0.00	1	5.88	1	2.94
Total	17	100.00	17	100.00	34	100.00
Mann-Whitney U test, Z=-0.9989, p=0.3179						

Table showing the grades of the wound on the 5th post-op evaluation day. During the follow-up period, the wounds were assessed for any erythema, presence of any discharge from the wound site, pus, along the wound and were assessed using SOUTHAMPTON SCALE

Graph 1: Comparison of cases and controls with Grades of wound healing at day 5



Bar diagram demonstrating the percentages of grades of case and control group patients on 5th post-op day.

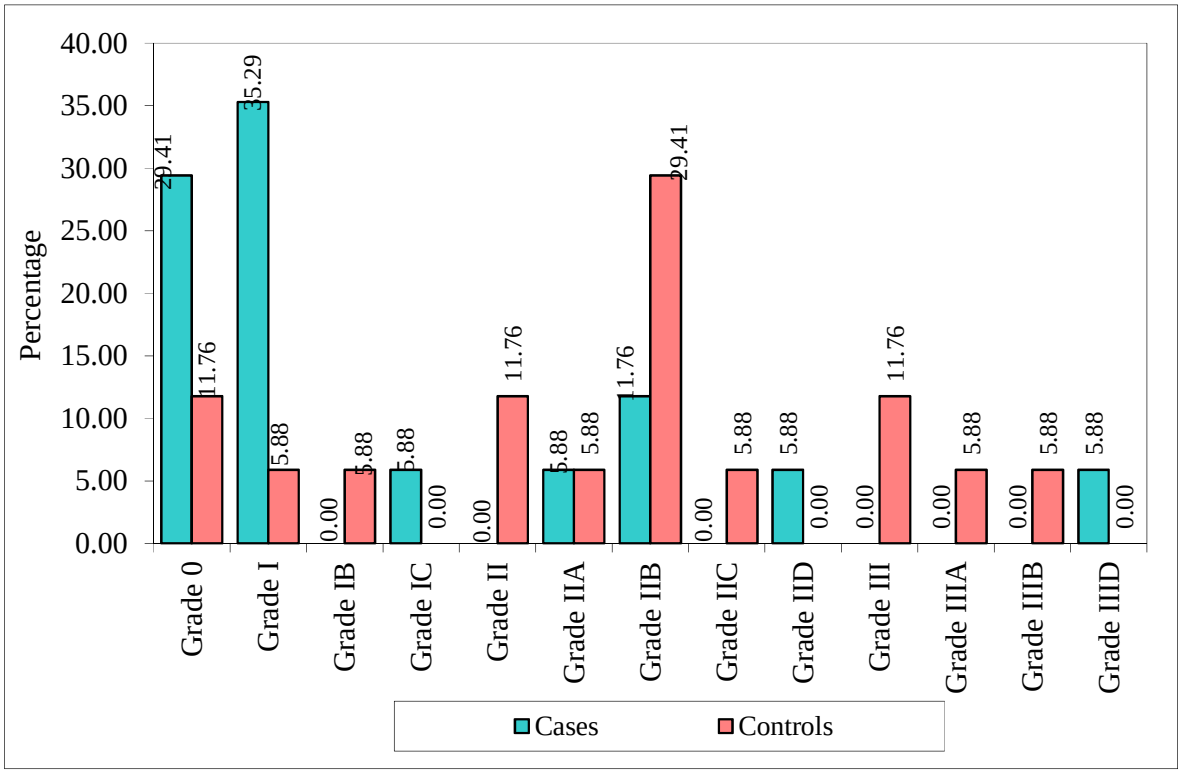
Table 3: Comparison of cases and controls with Grades of wound healing at day 7

Day 5	Cases	%	Controls	%	Total	%
Grade 0	5	29.41	2	11.76	7	20.59
Grade I	6	35.29	1	5.88	7	20.59
Grade IB	0	0.00	1	5.88	1	2.94
Grade IC	1	5.88	0	0.00	1	2.94
Grade II	0	0.00	2	11.76	2	5.88
Grade IIA	1	5.88	1	5.88	2	5.88
Grade IIB	2	11.76	5	29.41	7	20.59
Grade IIC	0	0.00	1	5.88	1	2.94
Grade IID	1	5.88	0	0.00	1	2.94
Grade III	0	0.00	2	11.76	2	5.88
Grade IIIA	0	0.00	1	5.88	1	2.94
Grade IIIB	0	0.00	1	5.88	1	2.94
Grade IIID	1	5.88	0	0.00	1	2.94
Total	17	100.00	17	100.00	34	100.00
Mann-Whitney U test, Z=-2.2216, p=0.0263*						

*$p<0.05$

Table demonstrating the grades of cases and controls on 7th post-op day

Graph 2: Comparison of cases and controls with Grades of wound healing at day 7



Bar diagram demonstrating the percentage of grades on 7th post-op day

DISCUSSION

The discovery of cyanoacrylates have revolutionized the wound closure. Cyanoacrylates are being used in various aspects of maxillofacial region

A study conducted by Oladega in 2019 where they used cyanoacrylate tissue adhesive for closure of intraoral wounds after surgical removal of 3rd molars and compared with silk suture[10]. Gabriela et al, has used cyanoacrylate in socket repair after extraction of third molars[9.] MJ Mehta et al conducted a pilot study in 1997 using the cyanoacrylate for osteosynthesis of mandibular fractures in 10 patients and concluded that it can also be used in fixation of fractures[16].Vijaylaxmy Malhotra et al, used cyanoacrylate in closure of unilateral cleft lip cases and has found it quick and the protects the wound site infection[12]. Matthew. R. Idle et al in a case report has demonstrated the use of cyanoacrylate in treating the vascular malformations of mandible[4].cyanoacrylate has also been used in the orbital floor reconstruction, a study conducted by Nemoto et al[11]. Cyanoacrylate has also been used in treating the osteochondral fractures of the knee[17].

In the present study cyanoacrylate was used for closure of lacerated wounds in maxillofacial region.

A total of 17 patients were treated with cyanoacrylate for lacerated wound closure in our study. The presence of infection and wound healing were compared to the control group. The follow up was done on 5th and 7th post-operative day, where the infection and wound healing were assessed according to Southampton scale and criteria. During the follow up period the closure sites were assessed for any erythema, presence of any discharge or pus at one or multiples sites of the closure site. After

assessment, they were graded according to the wound evaluation parameters.in this study, wound infection and healing were compared on the 5th and 7th postoperative days.

On the 5th postoperative day, the case group demonstrated more of grade Ic (17.65%), grade Ib (11.76%), grade IIIb (11.76%), which are considerable bruising, mild bruising, clear bruising along the wound. In the case group, on 5th post-operative day 2 patients showed normal healing. The other patients either had mild bruising and discharge from the wound site. Considering the control group, patients demonstrated more of IIa, IIb both accounting for nearly 35%, which are inflammation at one point and at the suture area. Grade IIc, IIIb accounted for around 23% which are inflammation along the wound and discharge from the wound site. Only 2 patients showed normal healing on the 5th post op day of control group.

Abhishek Soni et.al conducted a study comparing cyanoacrylate and subcuticular sutures for incisions where they demonstrates the presence of erythema and dehiscence of wound margins on the 5th follow-up day in cyanoacrylate group and in the suture group.

Vishaka. N. Devurkar et al conducted a study evaluating the cyanoacrylate tissue adhesive in pediatric age group, where they found wound dehiscence on the 5th follow-up day, which correlates with our present study findings that inflammation is present in the early stages of wound healing.

On the 7th post op day, by assessment of the wound, the case group demonstrated more of grade I (35.29%) & grade 0 (29.41%), which indicates normal healing with mild bruising and normal healing respectively .On the 7th post op day the

control group demonstrated more of grade IIb accounting for (29.41%) indicating the presence of erythema and other signs of inflammation. When comparing the patients of both the groups, the case group i.e., showed better wound healing on the 7th post op day and only one patient in the case group has presented with discharge from the closure site, and one patient presented with inflammatory signs all over the wound.

A study conducted by Ankita Vastani et al to compare cyanoacrylate and silk sutures in intraoral wounds demonstrated that on the 7th follow-up day, there was a reduced inflammatory response cyanoacrylate when compared to the sutured site, which corresponds with findings of our study.

Cyanoacrylate tissue adhesieves on the other hand promote epithelialization.A study done by Kumar ms[15] et al.in where he concluded that on the 3rd and 7th post-op days epithelialization was better on the sides that were treated with n-butyl-2cyanoacrylate but notable inflammation and scar in the sites closed with black silk suture.

There was no allergic reaction to N-butyl -2 cyanoacrylate in any of the patients in the case group.

Richard. A. Eiferman in 1983, published a case report of 3 cases, where n-butyl cyanoacrylate was used in cases of corneal perforations to evaluate the anti-bacterial effect. He concluded that there was anti-bacterial effect against the gram-positive organisms and no activity was present against the gram-negative organisms[1]here in this study ,the tissue adhesive was mostly used in cases where patient has sustained trauma, due to which there is a breach of the skin barrier leading

to lacerated wounds. Cyanoacrylate helps in controlling infection in cases pertaining trauma.

Abhishek soni[6] et al in 2013, conducted a study, comparing cyanoacrylate tissue adhesive and conventional subcuticular skin sutures for maxillofacial incisions, where they compared outcome, Time for closure and cosmetic outcome. They conducted a prospective randomised controlled trial, and they concluded tissue adhesive i.e., cyanoacrylate group has better outcome, patient satisfaction and lesser time for closure.

The patients in the case group showed more compliance and less anxiety, while placing the tissue adhesive

On assessment of the follow ups done on the 5^{th} and 7^{th} day, the case group, when compared to the control group, the tissue adhesive application takes less time. Higher cyanoacrylates, like n-butyl-2cyanoacrylate and isoamyl 2cyanoacrylate, disintegrate more slowly than lower side chained cyanoacrylates. Due to their delayed disintegration, these materials are less histotoxic.

SUMMARY & CONCLUSION

Cyanoacrylate tissue adhesive, has better advantages of rapid closure, no use of local anesthesia, no risk of injury from use of needles, no requirement of special, better bacteriostatic activity, no necessity of wound dressing, no need of removal of material.

Cyanoacrylate tissue adhesive provides satisfactory results even in emergency wound closure Disadvantages of the material include material cost& inability to use in areas with high tension.

- N-Butyl-2 Cyanoacrylate tissue adhesive provides satisfactory results in maxillofacial wounds.

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ANNEXURE - I - ETHICAL CLEARANCE CERTIFICATE

Research and Ethics Committee
KLE V K INSTITUTE OF DENTAL SCIENCES
KLE University
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FAX: 0831-2470640
Web: http://www.kledental-bgm.edu.in
E-mail:principal@kledental-bgm.edu.in

Sl. No. : 1342

CERTIFICATE

This is to Certify that the synopsis titled

COMPARISON BETWEEN N-BUTYL-2-CYANOACRYLATE TISSUE ADHESIVE AND NYLON SUTURES IN MAXILLOFACIAL TRAUMA: A RANDOMIZED CONTROLLED TRIAL *Submitted by*

Dr. S. MOHAN KRISHNA SAI *P. G. Student / Staff, Guided by* DR. VIJAYLAXMI SHETTAR *from Department of* ORAL & MAXILLOFACIAL SURGERY *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

Date :

Member Secretary
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURE - II - BIOSTATISTICS CERTIFICATE

KLE V.K. Institute of Dental Sciences
(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
Nehru Nagar, Belagavi-590 010 INDIA
Re-Accredited 'A' grade by NAAC (2nd Cycle) & Placed in Category 'A' by MHRD (GoI)

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FAX: 0831-2470640

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E-mail:
principal@kledental-bgm.edu.in

Biostatistics Clearance Certificate

This is to certify that the Biostatistics aspect of the Dissertation / Research work of **Dr. S. Mohan Krishna Sai,** Post Graduate Student, Department of Oral & Maxillofacial Surgery under the guidance **Dr. Vijaylaxmi Shettar** M.D.S, Reader, Department of Oral & Maxillofacial Surgery entitled **"COMPARISON BETWEEN N-BUTYL-2 CYANOACRYLATE TISSUE ADHESIVE & NYLON SUTURES IN MAXILLOFACIAL TRAUMA: A RANDOMIZED CONTROLLED TRIAL"** has been done under my guidance and considered satisfactory.

Place : Belagavi
Date : 11/12/2021

Name & Signature of Biostatistician
(Dr. S.B. Javali)

ANNEXURE - III - PLAGIARISM REPORT

Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences
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Date : 1.1.2022 Serial No. : 086

PLAGIARISM CHECK REPORT

Name of the Applicant : DR.S. MOHAN KRISHNA SAI
UG / PG / Ph.D / Staff : POST GRADUATE
Batch & Year : 2019 - 22
Department : ORAL AND MAXILLOFACIAL SURGERY

The soft copy of Research Work / Manuscript by DR. S. MOHAN KRISHNA SAI entitled "COMPARISON OF N-BUTYL-2-CYANOACRYLATE TISSUE ADHESIVE AND NYLON SUTURES IN MAXILLOFACIAL TRAUMA: A RANDOMISED CONTROLLED TRIAL"

under the guidance of DR. VIJAYALAXMI SHETTAR has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.

The scan has been carried out and the scanned output reveals a Similarity Index of 9%, which is **within** / **not within** the acceptable limits of 10% as per the UGC guidelines.

Member Secretary
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

Chairman
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi

ANNEXURE - IV - CASE HISTORY PROFORMA

NAME: **AGE/ SEX:**

OCCUPATION: **O.P.NO.:**

ADDRESS: **DATE:**

CHIEF COMPLAINT:

HISTORY OF PRESENTING ILLNESS:

PAST DENTAL HISTORY:

PAST MEDICAL HISTORY:

DRUG ALLERGY:

PERSONAL HISTORY:

Smoking/ Alcohol/ Tobacco chewing

GENERAL PHYSICAL EXAMINATION:

EXTRA-ORAL EXAMINATION:

- Facial Symmetry:
- Facial bone mal-alignment:
- TMJ:
- Lymph Node:
- Mouth Opening:

INTRA-ORAL EXAMINATION:

- Malocclusion:
- Intraoral bony mal-alignment:
- Swelling:
- Discharge:
- Pain/ Difficulty In Chewing:

PROVISIONAL DIAGNOSIS:

INVESTIGATIONS:

Complete blood count

Coagulation profile

Viral markers (hiv, hbsag, hcv)

DIAGNOSIS:

WOUND CLOSURE DONE BY :

MEDICATION:

FOLLOW UP:

ANNEXURE - V - CONSENT FORM

DEPARTMENT OF ORAL & MAXILLOFACIAL SURGERY
K.L.E. V.K. INSTITUTE OF DENTAL SCIENCES, BELGAUM

I, _____

Address:_____

Doctor's name: _____

The doctor has informed me about the suturing procedure and my involvement in it.

1. I agree to give my personal details like name, age, sex, address, medical history, previous dental history and the details required for the study to the best of my knowledge.
2. I will cooperate with the dentist for my internal and external examination.
3. I will follow the instructions given by the doctor during the treatment and take medications prescribed.
4. If the prognosis is poor, because of my tissue condition, I will not hold the dentist responsible. Anyhow the dentist can make alternative treatment plant to improve the prognosis.
5. I will pay the treatment charges to K.L.E. V.K. Institute of Dental Sciences, Belgaum at the reception counter and collect receipt of the same.
6. I will visit the dentist as and when required for the treatment, as the given appointments (date and time).
7. I permit the operator to utilize the information given by me and result obtained from this study for presentation and publication.
8. I permit the doctor to take my intraoral extraoral photographs to utilize for the study purpose, if required.
9. I will not claim any returns for my cooperation in the study, even if it is being sponsored by an agency. I am participating with my own will and wish for the betterment of the community.
10. If for any reason I am unable to participate in the study, for reasons unknown, I can withdraw from, the study.

I have read, gone through and understood the above information given by the doctor.

I have entered & signed this application.

Name: Date:

Signature: Mob. No:

Name of doctor: Dr. S.Mohan Krishna Sai

Doctor's contact: 9901782225, Hospital contact**:** 08312551732

ANNEXURE - VI - PATIENT INSTRUCTION PERFORMA

DEPARTMENT OF ORAL & MAXILLOFACIAL SURGERY.
KLE V.K. INSTITUTE OF DENTAL SCIENCES, BELAGAVI.

COMPARISON BETWEEN N-BUTYL-2 CYANOACRYLATE TISSUE ADHESIVE & NYLON SUTURES IN MAXILLOFACIAL TRAUMA: A RANDOMIZED CONTROLLED TRIAL

My name is Dr. S. MOHAN KRISHNA SAI. I am Post Graduate student in the DEPARTMENT OF ORAL & MAXILLOFACIAL SURGERY, KLE V.K. Institute of Dental Sciences, KAHER, Belagavi.

I am doing this study to evaluate & compare the N-BUTYL-2 CYANOACRYLATE tissue adhesive & nylon sutures in maxillofacial trauma.

Sutures and tissue adhesive will be placed on the same day by randomly diving the patients.

Patient is informed about the follow up procedure on 5^{th} and 7^{th} day.

During follow-ups any sign of infection and wound healing will be checked.

The sutures will be removed on 7^{th} day.

Signature of the Participant _____ Date _____

Signature of Investigator _____ Date _____

ANNEXURE - VII – MASTER CHART

CASE GROUP

Sl.no	Post-op day 5	Post-op day 7
Patient 1	IIc	IIA
Patient 2	IIIB	IIID
Patient 3	IB	I
Patient 4	IC	I
Patient 5	IID	IC
Patient 6	III	IIB
Patient 7	IIIC	IIB
Patient 8	I	I
Patient 9	IIIB	IID
Patient 10	IC	I
Patient 11	IB	I
Patient 12	IA	0
Patient 13	0	0
Patient 14	0	0
Patient 15	IA	I
Patient 16	IC	0
Patient 17	IA	0

CONTROL GROUP

Sl.no	Post-op day 5	Post-op day 7
Patient 1	IIA	II
Patient 2	IIIB	III
Patient 3	IIB	IIB
Patient 4	IIA	IIIA
Patient 5	IIA	II
Patient 6	IIC	IIB
Patient 7	IID	IIC
Patient 8	0	0
Patient 9	IIB	IIB
Patient 10	I	I
Patient 11	0	0
Patient 12	IB	IB
Patient 13	IIC	IIB
Patient 14	IIB	IIB
Patient 15	IIIB	III
Patient 16	IVA	IIIB
Patient 17	III	IIA