



EFFICACY OF CYANOACRYLATE GLUE IN COMMUNITED FRACTURES OF NON-LOAD BEARING AREAS OF MID FACE – A PROSPECTIVE RANDOMIZED CLINICAL STUDY

Maxillofacial Surgery

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ABSTRACT

Introduction-Various fracture patterns like, orbital, naso-orbital-ethmoid complex, zygomaticomaxillary complex, and Le Fort fracture, create certain problems for maxillofacial surgeons, in treating and reducing them to achieve functional and esthetic stability, specifically comminuted fragments in these areas. Different adhesives are used nowadays for many surgical procedures, among those one is cyanoacrylate and has been widely used in many surgical procedures. This synthetic glue, N-Butyl-2-Cyanoacrylate, is highly adhesive, haemostatic, biocompatible and slowly resorbed without any reaction. **Aim & Objective**- This study was aimed to evaluate the efficacy of cyanoacrylate glue in non-load bearing fractures of mid and upper face. **Methods**- Study was undertaken on 20 patients diagnosed with non-load bearing fractures of mid and upper face following trauma. **Results**- It was found that, there was adequate stability between the fractured segments based on radiographs. **Conclusion**- It was concluded that N-Butyl -2-Cyanoacrylate tissue glue was effective in stabilizing comminuted fractured segments after reduction for certain time period and allows spontaneous bone fracture healing.

KEYWORDS

Naso Orbital Ethmoid Complex, Zygomaticomaxillary Complex, Le Fort Fracture, N Butyl 2 Cyanoacrylate Adhesive, Bone Fracture Healing

INTRODUCTION

Craniofacial skeleton supports and protects vital organs. The most common cause of facial trauma is road traffic accidents and physical assault and fall, sports, gunshot wounds and occupational hazards accounts for lesser percentage. RTAs mostly lead to Panfacial fractures whereas sports injury leads to upper and midface fractures. Any high velocity force directed antero-posteriorly with an angular direction from the bottom, produces relevant bone fractures due to the presence of the pneumatic bones and sutures between the bones. The traumatic energy radiates encountering low resistance. This causes the fractures of midface in several comminuted fragments, some displaced into the maxillary sinus itself.¹

Various fracture patterns like, orbital, naso-orbital-ethmoid complex (NOE), zygomaticomaxillary complex (ZMC), and Le Fort fracture, effect the cosmetic and the functional deformity. A thorough physical examination and computed tomography (CT) scanning is required for correct and specified diagnosis.^{1,3}

Depending upon the extent of fracture, comminution, bone loss and displacement of the fractured bones, treatment varies from simple observation, conservative treatment to ORIF.² During repair, the most important point of consideration is the anatomic reduction of fractured bones and systematic fixation by the semi-rigid and rigid fixation of fractures. Fixation aids in primary healing of bone through callus formation.⁴ Open reduction and internal fixation is mostly necessary to avoid cosmetic and neurologic deformities. But it is difficult in cases of comminuted fractures to maintain the integrity of the bone as fixation with miniplates require detachment of periosteum from bone surface which usually causes bone necrosis leading into failure in fracture healing.⁵

Here, tissue adhesives play a significant role in treatment of such kind of comminuted fractures.⁶ Among one of these (fibrin adhesive,

collagen and protein-based sealants, polyurethane adhesive and bone adhesive), is N- butyl- 2- cyanoacrylate (Figure 1) and it had been widely used in many surgical procedures.⁷

An ideal adhesive should be biocompatible, non-toxic, non-irritating and not causing any hypersensitivity reactions to tissues. Also, it should be that efficient to withstand adequate external forces and provide stability to the segments till natural bone healing occurs.⁸

Literature reveals the use of N- butyl- 2- cyanoacrylate glue for different soft tissue and hard tissue repair especially in fractures of anterior wall of maxillary sinus along with the fractures of orbital-maxillary complex, fixation of orbital floor, oral dressing, cleft lip and cleft palate repair, skin graft stabilization, nasal splinting, stabilization of traumatised teeth.⁹

N- butyl- 2- cyanoacrylate glue are liquid monomers that polymerizes quickly on contact with tissue surfaces by exothermic reaction creating a strong but flexible film that bonds the wound edges. Cyanoacrylates are slow resorbing and may produce significant histotoxicity.¹⁰ It was seen that cyanoacrylates, inhibit leukocytes and possesses bactericidal properties.¹¹ When applied in humid environment, it rapidly polymerizes and creates a thin film characterized by high strength and ensures a solid adhesion of the tissues and an effective antiseptic barrier.⁶ The only precaution to be followed, is the maintenance of completely dry field during its application as any substance between cyanoacrylate adhesive and bone prevents its proper adhesion and this may lead to a thin film of blood between cyanoacrylate and bone.⁷

In our study we are evaluating the efficacy of N- butyl- 2- cyanoacrylate glue in comminuted fractures of non-load bearing areas of mid face.

AIM & OBJECTIVES

To evaluate the efficacy of cyanoacrylate glue in comminuted fractures of non-load bearing areas of mid face.

Objectives

- To reduce and align small and thin bone fragments (comminuted segments) for a complete functional and aesthetic rehabilitation.
- To evaluate the stability of fractured segments in postoperative period radiologically.
- To evaluate the efficiency of cyanoacrylate glue for its polymerisation, strength, adhesion to bony fragments and antiseptic properties.
- To propose a protocol for the use of cyanoacrylate tissue glue in fixation of comminuted, non-loaded fractured bony segments.

MATERIALS AND METHODS

This prospective randomized clinical study was conducted in the Department of Oral and Maxillofacial Surgery at People's College of Dental Sciences and Research Centre, Bhopal after getting approval from IRB/IEC with IEC no.- EC201812 on 20 patients diagnosed with comminuted fractures of non-load bearing areas of mid face following road traffic accidents from January 2019 to October 2020. All patients were informed about the surgical procedure and written informed consent was taken by them.

Inclusion Criteria

- Patients diagnosed with comminuted fractures of non load bearing areas of mid and upper face (NOE, ZMC, Le Fort & Orbital fractures) (Figure 2).
- Patients' availability to meet the follow-up schedule.
- Patients with neurologically and hemodynamically stable enough to undergo surgical procedure under general anaesthesia.

Exclusion Criteria

- Patients with non comminuted fractures of mid and upper face.
- With or without other associated Maxillofacial fractures.
- Paediatric patients with mid and upper face fractures (with/without comminuted fractures).
- Patients' refusal for informed consent.

Standard Operative Procedure

After GA administration and intubation, standard painting and draping was done under all aseptic measures. Local anesthesia (Inj. Lignocaine 2% with adrenaline) was administered at the required surgical sites. Required incisions were given and fracture sites were exposed to perform open reduction of the fractured segments (Figure 3). The fractured segments were reduced manually and kept in place by applying digital pressure. This was accompanied by proper isolation of surrounding tissues over fracture site and N butyl 2 cyanoacrylate adhesive was applied (Figure 4). The glue began to solidify in about 1–2 s and complete polymerization occurred after 60–90 s, so the glue was dried for 10 secs. At the end of this reaction, the glue reached its maximum strength. After fixation, the surgical site was thoroughly irrigated with betadine & saline (Figure 5) followed by closure of the surgical sites. Pressure dressings were applied. Post-operative radiographs were taken for radiographic evaluation (Figures 6, 7).

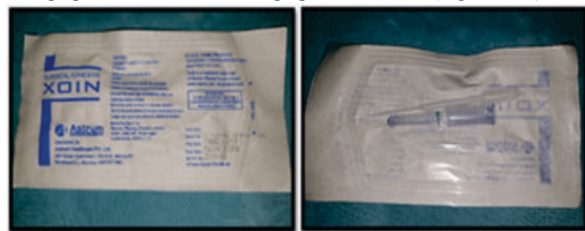


Figure 1- A & B- N-butyl-2- cyanoacrylate glue (XOIN)

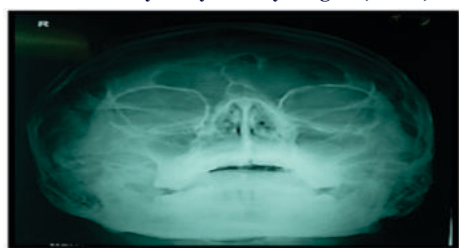


Figure 2- Pre-Op radiograph (PNS view)



Figure 3- Exposure Of Fracture

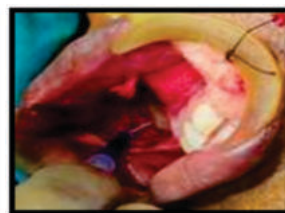


Figure 4- Placement of N butyl 2 Cyanoacrylate Glue Over Fracture Line



Figure 5- Fracture site after placement of N butyl 2 Cyanoacrylate glue

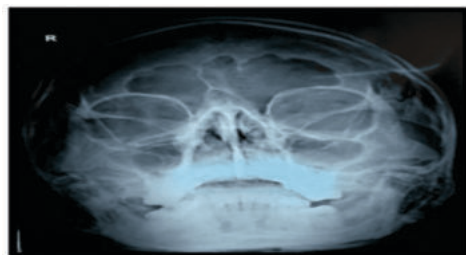


Figure 6- Immediate post-operative radiograph (PNS view)

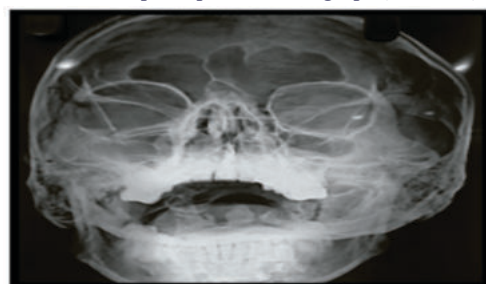


Figure 7- One-month post-operative radiograph (PNS view)

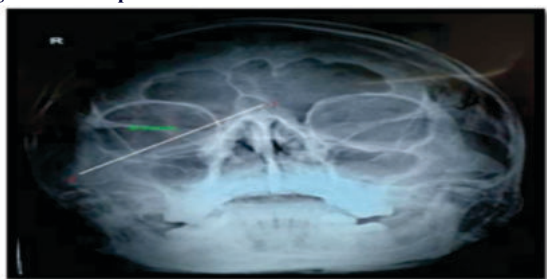
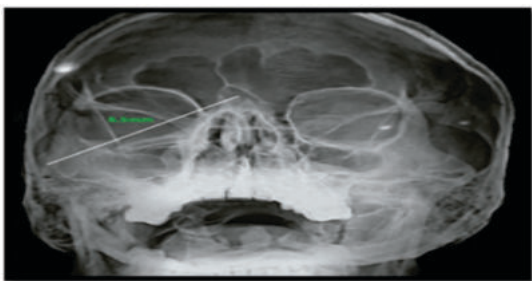
Parameters Included in The Study:

- Primary parameter- Facial symmetry (distance between NP to ZP) pre-operatively and post-operatively in PNS view.
- Secondary parameters include – pain, paraesthesia, limitation of mouth opening, occlusion, swelling, infection.

Radiographical Evaluation:

Evaluation of fixation and stability of fractures was done by radiographic evaluation (using Sidexis 4 software version 4.2 Dentsply Sirona Germany) in PNS (Water's) view, where, two radiographic points were selected pre-operatively and post-operatively. First point was taken by the intersection of nose bones (nasal pyramid) and nasal septum, called as nasal point (NP). Second point was taken from the most downward point and outside zygomatic arch, called as zygomatic point (ZP). The pre-operative distance (Figure 8) was compared to post-operative distance (Figure 9, Figure 10) and was evaluated to find increase/ decrease in the distance for statistical study in order to determine clinically possible consequences (displacement of fixed fractured segments, infection, etc.). was used for radiographic evaluation.

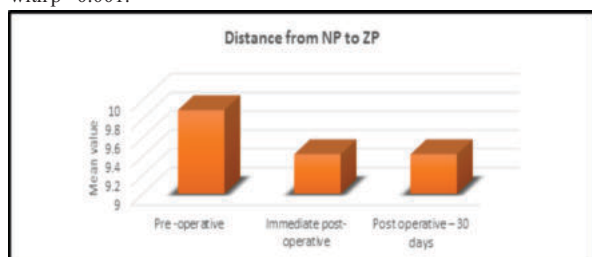


Figure 8– Pre-Op distance between NP to ZP**Figure 9 – Immediate post-op distance between NP to ZP****Figure 10– 1- month post-op distance between NP to ZP**

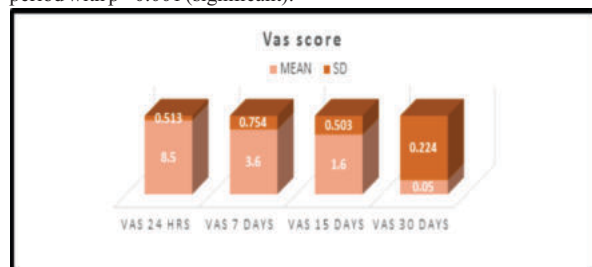
RESULTS

The mean age group of the patients included in the study ranges from 18- 53, with mean age and standard deviation of 33.55 ± 9.71 .

On radiographic evaluation, mean and standard deviation of distance measured from NP to ZP in pre-operative period was 9.89 ± 0.313 , immediate post-operative period was 9.42 ± 0.502 , 30 days post-operative period was 9.42 ± 0.502 (Graph 1) which was significant with $p < 0.001$.

**Graph 1: Radiographic evaluation mean values across time periods (Pre-op, Immediate post-op, 30 days post-op)**

Evaluation of pain in post-operative period on VAS (0 to 10) was noted in 24 hours, 7 days, 15 days and 30 days after surgery. The Mean and Standard deviation of VAS score post-operatively for 24 hours was 8.50 ± 0.513 , 7 days was 3.60 ± 0.754 , 15 days was 1.60 ± 0.503 and 30 days was 0.05 ± 0.224 (Graph 2). The Mean difference of VAS on repeated intra-group measures were found to be significant on repeated measure ANOVA test for analysis of significant differences across time periods (VAS 24 hours, VAS 7 days, VAS 15 days, VAS 30 days) in group significant differences and it was seen in all the analysed time period with $p < 0.001$ (significant).

**Graph 2: VAS score comparison across time periods**

Post-operative swelling over the surgical site was gradually reduced and subsided completely within 14 days. There were no signs of other complications like paraesthesia (except for patients having pre-

operative paraesthesia), infection, tissue toxicity, malocclusion, limited mouth opening with the use of this glue.

DISCUSSION

Road traffic accidents most commonly cause for complex facial fractures. High velocity trauma results in complex and comminuted fractures in the region of mid and upper face. These require specific surgical treatment by proper exposure of the fracture site, accurate reduction with fixation of the segments with either semi-rigid or rigid fixation techniques. The reduction of these type of fractures poses great difficulty to surgeons which requires excellent precision during its fixation. This is the most common cause that, surgeon prefers conservative management over surgical reduction, which invariably leads improper facial contour and aesthetic issues. During reflection of periosteum from over the comminuted segments may compromise blood supply to that region leading to necrosis and further infection.¹²

N- butyl- 2- cyanoacrylate glue overcome these problems and offers more stable reduction along with functional and cosmetic integrity. According to Forresta E et al.⁶ N-butyl-2-cyanoacrylate tissue glue is useful and effective in providing stability to these small fragments in comminuted fractures aiding to natural bone fracture healing in due time. Also, Kim YO¹³ and Forresta E et al.⁶ in their studies found that on displacement of small fragments following application of cyanoacrylate tissue glue, it provided adequate stability required for osteosynthesis of fractured segments and aided in spontaneous bone healing. In a study by Mehta M J et al.⁷ on treatment of mandibular fracture with cyanoacrylate adhesive found no mobility between fractured segments, no displacement of fragments was visible in radiographs and also wounds healed uneventfully and so he found this adhesive to be very promising and convenient. O' Connor D et al.¹⁰ in his study found the adhesive to be effective as there was no displacement of fractured segments in any of the cases, all of the osteotomy sites healed uneventfully. On histological examination proper bone union was seen. Although, there was mild foreign body reaction, but no necrosis or resorption was evident. This was in accordance with our study, where glue provided appropriate stability based on radiographic evaluation and reduction in the distance between NP to ZP in immediate post-operative radiograph than pre-operative radiograph and one-month post-operative after fracture healing occurred spontaneously. There were significant changes seen in pre-operative period (9.89 ± 0.313), immediate post-operative period (9.42 ± 0.502), 30 days post-operative period (9.42 ± 0.502) with the p value < 0.001 .

In literature, this tissue glue was found to be biocompatible, highly adhesive with great haemostatic property, good bonding strength and requires less effort and manipulation while application, very economical and easily polymerises in moisture.^{6,12,14} Buckley MJ et al.¹⁴ in his study found that cyanoacrylate adhesive polymerized rapidly, thus saved time, they were not completely biodegraded and induced significant inflammatory response. It formed strong bonds between tissue edges and enabled normal healing and showed antimicrobial properties. Similarly, we in our study found that the handling and application of the glue was easy and polymerisation time was just 10 seconds which was very convenient in cases of bleeding during surgeries and none of our cases had post-operative infection.

Forresta E et al.⁶ did not find a single of infection nor any adverse reaction in his study of 100 patients, only five patients reported hypoesthesia which disappeared in due time. It is in accordance with our study where post-operative complications like pain, paraesthesia, swelling, infection, tissue toxicity, etc. were negligible with the use of this glue. On pain evaluation according to VAS scores between 24 hours post-operative period and 7 days post-operative period was found to be 8.50 ± 0.513 which gradually decreased over a period of 30 days to 0.05 ± 0.224 which was negligible and with the use of glue there was significant reduction in pain in post-operative 7 or 15 days which usually lasts more in cases of conservative management.

Along with its use in hard tissues, soft tissues repair was also done like in perforations of maxillary sinus membrane, corneal perforations, to stabilize external eyelid weights, cartilage graft fixation, in gastric variceal obliteration during bleeding, tendon repair, cerebrospinal fluid fistulae, bronchobiliary fistula, skin graft fixation and was found effective in almost all of the cases as it resorbs in a period of time and rarely causes mild infection but not necrosis.^{8,17,18,19,20} In the studies by Habib A et al.¹⁵ and Cobb ARM et al.¹⁶ found cyanoacrylate glue to be

effective, rapid, safe, easy to use and economical in maxillofacial surgery as it showed good results and adaptations in orbital floor grafts, improvement in ocular symptoms in cases of external eyelid weights, provided good retention to skin grafts and successful splinting of traumatized mobile teeth.

Thus, N-Butyl -2-Cyanoacrylate tissue glue was found to be effective in stabilizing comminuted fractured segments where fixation with other modalities is very difficult with increased operating and anaesthesia time and also aids in spontaneous bone healing.

CONCLUSION

Based on the results of this study, there was adequate stability seen between the comminuted fractured segments as seen on the radiograph. There was no change noticed in the distance in post-operative period and the facial contour was also satisfactory. Since, it is very economical and easy to handle, it can be used effectively in stabilizing comminuted fractured segments following reduction for certain time period which will allow spontaneous bone fracture healing, where fixation with miniplates is very difficult.

Thus, the use of this N- butyl- 2- cyanoacrylate tissue adhesive in surgical management of comminuted fractures of non-load bearing areas of mid and upper face seems very promising but thorough study and long term follow up of large sample size is required for assured clinical results depicting possible side effects before its acceptance in regular use in Oral and Maxillofacial Surgery.

CONFLICTS OF INTEREST

There are no conflicts of interest.

FINANCIAL SUPPORT

NIL.

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