



TO COMPARE THE EFFICACY OF INSTASEAL (ISO AMYL 2-CYANOACRYLATE, BIO-ADHESIVE) WITH 3-0, ETHICON MERSILK, IN SURGICAL WOUND CLOSURE AFTER ALVEOLOPLASTY.

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Abstract -To evaluate the efficacy of instaseal (iso amyl 2-cyanoacrylate) in closure of surgical Wound after alveoloplasty in comparison with ethicon mersilk, 3-0 sutures.

Objectives-This study was done to compare the clinical efficacy of surgical wounds in cases of alveoloplasty when wound closure was done by isoamyl 2-cyanoacrylate adhesive and 3-0 ethicon mersilk.

Methodology - The present prospective randomized study was conducted in PDM Dental College and Research Institute, Bahadurgarh in the department of oral and maxillofacial surgery after attaining the ethical committee clearance. Total number of 30 patients with age range 35-75yrs in which 17 male and 13 female were studied requiring bilateral alveoloplasty in anterior and posterior region of the lower and /or upper edentulous arch and closed randomly on one side with 3-0 black mersilk suture and on the other side with iso amyl 2-cyanoacrylate glue. The surgical sites were evaluated on the first hour of the same day and third, seventh, fourteenth postoperative days for any pain, bleeding, inflammation, infection, dehiscence and allergy.

Result-Pain and inflammation appeared to be reduced on the glued side, suggesting faster healing. Thus, it is evident from the study that iso amyl 2-cyanoacrylate glue aids in early initial healing, Is easy to apply, safe, less time consuming, less tissue reaction, no need for its removal as it is Biodegradable and no need of pressure pack. Some other advantages are simplicity, higher Speed, and excellent (grade 1) hemostasis. Based on the present study there was statistically no significant difference in p-value>0.05 between the two groups, group I and group II in relation to all the parameter evaluated and analyzed like pain, bleeding, inflammation, infection, dehiscence and allergy. Except the time efficiency which showed a significant p-value < .000 suggesting less time consumed in group II (glue site) as compared to group I (suture site). Hence the two materials are comparable in all aspects.

Conclusion-The result suggested that isoamyl-2-cyanoacrylate has better initial healing compared to suture and was easy and safe to use.

Keyword- Bilateral Alveoloplasty, Iso amyl 2-cyanoacrylate, Bioadhesive , 3-0 mersilk suture, efficacy of Instaseal

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. The conventional 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 tissues¹. 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 layer¹. Moreover the wound approximation by suture is time consuming and leads to more amount of scar formation. Although closure of wounds with sutures enables meticulous closure, sutures may cut through parenchyma and inflammatory tissues, induces tissue reactivity and may produce dehiscence of the wound. Closely spaced sutures may cause tissue ischemia with resultant necrosis of wound margins, more research focus on wound closure method with better efficiency and fewer complications² Utilization of tissue adhesives can be divided into three categories. The primary use is hemostasis. Many of the agents actually parallel the mechanisms of in vivo coagulation systems. A group of these tissue adhesives are Cyanoacrylates. Cyanoacrylate was first synthesized by ‘Adris’ in 1949. ‘Coover’ in 1959 described their adhesive properties .Some adhesives augment the local hemostasis of the patient; others achieve hemostasis as a function of general tissue adhesion, unrelated to patient clotting mechanisms. The second use of tissue adhesives is for tissue sealing. The adhesion prevents leak of various substances, such as air and lymphatic fluids. This use requires more than simple augmentation of the existing clotting system. The adhesive must seal without help from the patient. The third general use of tissue adhesives is local delivery of exogenous substances. The delivery systems proposed at this time include medications, growth factors, and cell lines. Targeted delivery is the least documented use at this time but may have the most potential in future application With these categories, the qualities specific to each adhesive help define its application in practice³. This prospective randomized study was undertaken in 30 patients reported to our department to compare the efficacy of iso amyl 2-cyanoacrylate on one quadrant and 3-0 silk sutures on other quadrant of the same patient for wound closure after alveoloplasty.

Material and Method- Total number of 30 patients with age range 35-75yrs in which 17 male and 13 female were studied requiring bilateral alveoloplasty in anterior and posterior region. Alveoloplasty was performed in the anterior or posterior region of the lower and /or upper edentulous arch and closed randomly on one side with 3-0 black mersilk suture and on the other side with iso amyl 2-cyanoacrylate glue. The surgical sites were evaluated on the first hour of the same day and third, seventh, fourteenth postoperative days for any pain, bleeding, inflammation, infection, dehiscence and allergy.

Materials -Iso amyl 2-cyanoacrylate (Instaseal tissue adhesive) 3-0 Ethicon Mersilk suture, Iso amyl 2-cyanoacrylate used in this study, is available as single-use INSTASEAL glue manufactured by Meridian Medicare limited as 0.25 ml ampoule. The system comes in a packet having an ampoule containing the glue, 1 ml syringe and a needle. It is a sterile, inert, non- toxic, biocompatible and bacteriostatic liquid topical adhesive. We used 3-0. mersilk black suture to compare its consequential healing with that of instaseal glue. This particular suture is easily available, relatively inexpensive, and provides the surgeon with the best knot security.

Data Collection Method

Pre and postoperative data and photographs were collected after obtaining consent from the patients. Medical histories, demographic information (eg, age and gender), additional patient characteristics, and blood investigations like bleeding time , clotting time, hemoglobin and random blood sugar were recorded in a case-report form. On the day of surgery, method of closure, and time needed for closure were collected.

Surgical Technique

Minimum of 30 edentulous patients who required alveoloplasty procedure were taken for the study group. The sides for Instaseal glue and suture was randomly assigned. Patient was prepared under aseptic conditions and anesthetized with 2% lignocaine with 1:80000 adrenaline. A crestal incision was made with no. 15 blade using no. 3 B.P handle. Full thickness mucoperiosteal flap will be raised to expose the bony spicules and protrubences, which was trimmed with bone rongeur and bone file. Debridement was done and adequate haemostasis was achieved. The incision was isolated with sterile cotton rolls and the tissue surface was dried with gauze sponges. The wound edges were held together by gentle finger pressure and any exudate emerging on the surface was mopped to make sure that the surface remained absolutely dry. The closure was performed on one segment with Instaseal glue. The glue was loaded in a syringe 1 ml disposable syringe (Dispovan), through the needle (.45×13mm/26GX1/2). A thin layer was applied initially and allowed to polymerize for 30 seconds, then 1 or 2 additional layers of the glue was applied on the wound in droplet form while maintaining the finger pressure. Care was taken so that the glue did not flow between the wound edges. The applied film was extended at least 3-4 mm on either side of the wound. Digital pressure was maintained till the Instaseal glue polymerized. This was evident by the transformation of the transparent bio-adhesive film into an opaque layer. Time was noted from beginning of wound closure till completion. Alveoloplasty procedure was repeated on the other segment using 3-0 mersilk ethicon suture in simple interrupted manner. Time was noted from beginning of wound closure till completion. Post-operative instructions like soft diet, cold pack for same day, no vigorous rinsing for the first 24 hrs, maintenance of oral hygiene, and warm saline rinses after 24 hrs, were given to the patients. All patients were given similar postoperative antibiotics and analgesics (Cap. Amoxicillin 500 mg thrice daily for 5 days, Tab. Diclofenac 50 mg thrice daily for three days).

Clinical evaluation

Wound was evaluated at 1st hour, 3rd day, 7th day and 14th day postoperatively for pain, bleeding, inflammation, infection, dehiscence and allergy.

Result –

The randomized prospective study was done on 30 patients who satisfied the aforementioned criteria. Surgical procedure was performed on an outpatient basis under local anesthesia during the period (Feb.) 2014-(Sept.) 2015 in 30 patients. The software used for the statistical analysis were SPSS (statistical package for social sciences) version 21.0 and Epi-info version 3.0.

The patients included in this study were of age ranging from 35-75 years. Group I and Group II with mean age value of 58.80 ± 9.50 with std. error mean of 1.73. Male and female patients were 56.7% and 43.3% respectively. Assessment of pain, bleeding, inflammation, allergy, dehiscence and infection was made clinically at the time interval of 1 hr, 3rd day, 7th day and 14th day post operatively.

Both the sutures and cyanoacrylate were statistically highly significant. ($p < 0.1$).



Fig.1. Clinical photograph showing pre-operative upper anterior edentulous sharp

bony anterior ridge

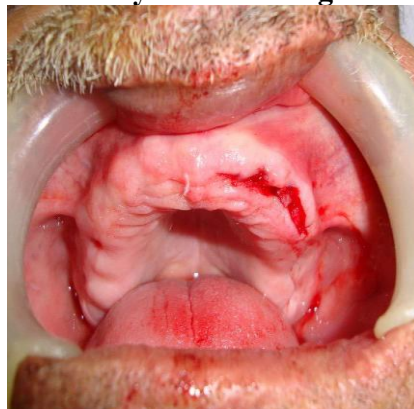


Fig.2.Clinical photograph showing crestal incision on left sharp bony edentulous ridge.



Fig.3. Clinical photograph of suturing.

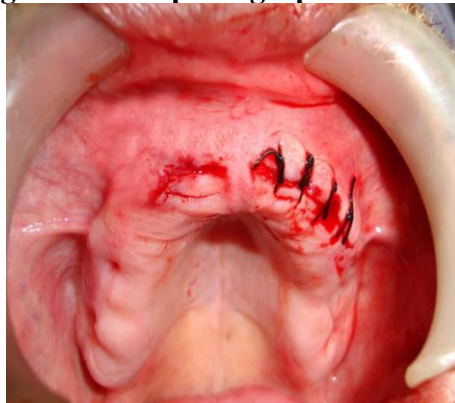


Fig.4. Crestal incision on right edentulous sharp bony ridge.



Fig.5. Clinical photograph showing application of Instaseal with needle and syringe after approximation of soft tissue flap.

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Fig.6.Clinical photograph showing Intra-operative hemostasis immediately after application of Instaseal.



Fig.6.Clinical photograph 1 hr post-operatively.



Fig.8.Clinical photograph 3rd day post-operatively.



Fig.9.Clinical photograph 7th day post-operatively.



Fig.10.Clinical photograph 14th day post-operatively.

Discussion

Many studies have been conducted on extraoral uses of cyanoacrylates but very few on intraoral applications of these cyanoacrylates. This study was done to evaluate clinically as well as histologically the intraoral wound healing when incisions were closed by Isoamyl-2 cyanoacrylate. The purpose of this study was to clinically compare the receptivity of intra-oral mucosal tissues to tissue adhesive iso amyl 2 cyanoacrylate and 3-0 mersilk sutures, following alveoloplasty. 30 patients in the age group of 35 to 75 years were included in the study, out of which 17(56.7%) were males and 13(43.3%) were females . Routine alveoloplasty procedure was carried out in all patients bilaterally maxillary or mandibular edentulous ridge. Each surgical wound was closed with tissue adhesive (Instaseal) and sutures each on either side in the same patient. There were two groups: Group I with suture site and Group II with glue site. Group I and Group II with mean age value of 58.80 and standard deviation 9.50 with std. error mean of 1.73. The method of application of adhesive in our study was needle-syringe method. The fact that the glue comes out of the needle in a fine, predictable streak allows it to get more rapidly and completely exposed to hydroxyl ions in the tissues with which it reacts and sets. Runaway” to undesired adjacent areas from the point of application is thus reduced making the procedure faster as the glue stays where you actually need it to stay and no time is wasted in re- application. Vastani and Maria⁴ used the same method of glue application in alveoloplasty done in 30 patients. Soni, Narula and kumar¹² applied same method of glue application in 3rdmolar surgery in 29 patients. Another advantage of using this method is that the glue does not flow uncontrollably into the depths of the wound about to be closed, where it can possibly cause an inflammatory reaction and impair healing. Thus its application was made very simple, easy, fast, precise and predictable. This method of application also overcomes the drawbacks of the conventionally used, spray-gun method, like burning eyes, strong smell, aspiration which required careful coverage of eyes, nose and throat. This method is also expensive compared to our method^{7,8} Quinn¹³ demonstrated that opened vials of tissue adhesive did not show any pathogenic growth even at 30 days and may be used multiple times. In our study of needle-syringe method of application there was no chance of aspiration of the glue into the respiratory system during application. However, still animal studies have been carried out by Bhaskar et al which clearly reveal no deleterious effects on the respiratory, gastrointestinal systems or on any of the vital internal organs following swallowing of this material⁹ An animal study by Douglas et al have demonstrated that if these materials in polymer form were to be inadvertently swallowed, degradation and assimilation of a significant percentage of the polymer would occur through urine⁸ The use of tissue adhesive for the closure of surgical incisions in the maxillofacial region would speed up wound closure with equal or superior cosmesis and without morbidity. The results of the study suggest that the use of iso amyl 2-cyanoacrylate produces significant decreases in the time required for the closure of incisions with mean 9.76, standard deviation 2.55 in suture site (Group I) and 3.00 mean with 0.85 standard deviation in Group II (sutures vs iso amyl 2-cyanoacrylate $P < .000$). The mean difference of 6.76 and the t test value is 13.790. The application of iso amyl 2-cyanoacrylate requires significantly less time than suturing, particularly in cases in which at least 2 incisions in the same patient are closed, because the application of tissue adhesive for another incision can be performed immediately after the application to the first incision, thus increasing efficiency in such cases. In the present study, closure with iso amyl 2-cyanoacrylate was

faster from different incisions in the same patient compared with closure with 3-0 mersilk suture. This finding is in accord with a study by Matin¹⁴ who concluded that closure with iso amyl 2-cyanoacrylate was faster with at least 3 port sites, with the differences between closure times increasing markedly when 5 ports were closed, and with incisions longer than 4 cm, with the time required for skin closure increasing more with sutures than with iso amyl 2-cyanoacrylate. Our study clinically assessed whether patient had pain over the time period of 1hrs, 3rd day, 7 days and 14 days post operatively. All 30 patients were asymptomatic over the recall period, except 5(16.7%) patients who complained of mild pain at the time interval of 1 hr in Group I with mean value of (0.57) and standard deviation of 0.82 and 3(10.0%) patients in group II who complained of mild pain at the time interval of 1 hr with mean value of (0.30) standard deviation of 0.65. In the present study post-operatively haemostatic property of tissue adhesive instaseal was evaluated by number of applications required. Out of 30 wounds bleeding stopped immediately in 18(60.0%) patients in Group I and 24(80.0%) patients in ,Group II. On post operatively 1 hr there was oozing in 12(40.0%) patients in Group I and reapplication of glue was required in 6(20.0%) patients to control bleeding from a single point in the forms of drops in Group II. On 3rd day there was accidental bleeding present in 1(3.3%) patient in Group II. No bleeding was evident thereafter over a period of follow up patients immediately after first application so no post-operative pressure pack was indicated in any of the patient. Apart from hemostasis property we clinically evaluated each alveoloplasty surgical wound for pain, clinical signs of inflammation, infection, dehiscence and allergy, at a time interval of 1 hr, 3rd day, 7days, 14 days post operatively. Thus our findings also remained consistent with the comparative study conducted by Annabelle Rajaseharans¹¹ in which Iso amyl 2-cyanoacrylate has shown tensile strength, haemostasis, hydroxyprolene levels, microscopic and macroscopic features similar to sutures and butyl cyanoacrylate after its extra oral application in animals. This material has now gained wide application in different surgical field, Traumatic closures in automobile injuries, Vascular surgeries for rejoining veins, arteries and intestines, plastic and cosmetic surgeries to remove scars, ENT surgeries for correction of earlobe punctures, cartilage implant grafts in primary and secondary nasal surgeries, hysterectomy, appendectomy, mastoidectomy, episiotomy, tubectomies, vasectomy to temporary punctual occlusion of lacrimal system. However, its intra-oral use for wound closure has not yet been reported, except for its use as extremely effective hemostatic in extraction socket^{6,11} There were no clinical signs of inflammation, change in colour, oedema from any intraoral site in all 30 patients in both Group I and Group II after 1hr, 3rd day, 7th day& 15 days Our study also assessed the presence or absence of infection at the surgical site over a time period of 1 hr, 3rd day, 7days and 14 days and found no clinical signs of pus formation in any of the surgical wound site. In our study out of 30 patients there was 1(3.3%) patient having dehiscence in wound margins in Group II on 3rd day post op, which healed by secondary intension during the 14th day follow up period. Not a single patient out of 30 showed any clinical signs of allergy in the form of discoloration, necrosis, burning sensation or redness of mucosa. This finding further holds the previous animal and human studies true^{10,28}. Cheng and Saing¹⁵ reported no statistically significant difference in the rate of wound inflammation, infection, bleeding, dehiscence or cosmetic appearance of circumcision incisions repaired with N-butyl-2- cyanoacrylate compared with suture approximation. The time required for cyanoacrylate application is less than sutures given in wound closure. The results of our study of iso amyl 2-cyanoacrylate glue indicates that it is safe, rapid, painless, and easy to use for the closure of uninfected intraoral incisions after bringing the edges together and creating a saliva-free field. Iso amyl 2-cyanoacrylate glue also proved to aid early initial healing and caused less intraoperative and postoperative discomfort to the patients, as compared with the standard suture wound closure. Although it is expensive and possesses less tensile strength than suture, there are indications for its use in primary intraoral mucosal closure. Closure of wounds without the need for sutures will be a major advancement, an opportunity to improve care for patients, especially children, and reduce pain and anxiety caused by treatment.⁵

Conclusion-The results of this study of Isoamyl-2-cyanoacrylate glue indicate that it is safe, has rapid application, painless, and easy to use for the closure of intraoral surgical wounds. Isoamyl-2-

cyanoacrylate glue caused less intraoperative and postoperative discomfort to the patients in our study, as compared with the wound closure by silk suture. The drawback is that it is expensive and possesses less tensile strength than suture and the closure has to be done while maintaining a saliva free field.

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