

Comparison of effectiveness of cyanoacrylate over conventional sutures in Implant stage II recovery procedure. A randomized controlled clinical study

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TO CITE THIS ARTICLE

Kabilamurthi RS, Priya Lochana G, Thiyaneswaran N. Comparison of effectiveness of cyanoacrylate over conventional sutures in Implant stage II recovery procedure. A randomized controlled clinical study. J Osseointegr 2022;14(2):107-111.

DOI 10.23805/JO.2022.14.18

ABSTRACT

Aim Cyanoacrylates have been used in various areas of dentistry. With the growing interest in these tissue adhesives, our study aimed to compare the effectiveness of Isoamyl 2-Cyanoacryl with conventional silk sutures in Implant stage II recovery procedures.

Materials and methods Twenty systemically healthy patients requiring stage 2 Implant recovery following single posterior mandibular molar tooth implant placement were recruited in the single blinded randomized controlled clinical study. Group I comprised of 10 patients (flap approximated with Black silk sutures) and Group II (flap approximated with Isoamyl 2-cyanoacrylate) comprised of 10 patients. Wound healing was assessed using Early wound Healing Index (EHS) at day 3 and day 7. Mann Whitney U test was used to assess the early wound healing index scores at day 3 and at day 7 between the groups. Visual analog scale values were also recorded at day 0 and at day 3 between the groups.

Results When comparing the rate of healing at day 3 between the groups there was no statistically significant difference ($P=0.10$) and when comparing the healing at day 7 between the groups the healing was significantly better in the cyanoacrylate group ($P=0.01$). There was a significant difference in the VAS score at day 0 ($P=0.001$) and no statistically significant difference was noted at day 3 ($P=0.31$) between the two groups.

Conclusion Cyanoacrylate had shown to aid in early soft tissue healing around dental implants than black silk sutures for implant stage 2 recovery procedures.

KEYWORDS Cyanoacrylate, Implant, Healing, Silk suture, Wound healing.

INTRODUCTION

Dental implants are considered as a predictable treatment approach for the replacement of missing teeth. Conventional dental implant placement involves a staged approach. Following stage I implant placement, the implant recovery process is done using various techniques like scalpel, laser and soft tissue punching etc. On a routine basis, the conventional scalpel technique is carried out for implant exposure when there is sufficient keratinized mucosa around the implant.

Suturing is considered as a traditional method for wound approximation. Suture material and the techniques play a vital role in the healing following the surgical exposure of dental implants. Close post-operative approximation of the flap around the implant during the early phase of peri-implant wound healing is important for re-establishing of junctional epithelium around the implant. Various suture materials such as silk, nylon, catgut and polyglycolic-poly-lactic acid derivatives are being used for implant related surgical procedures. However the suture materials have some disadvantages such as plaque accumulation at the incision area, allergy to the materials used for suturing, suture abscess etc., leading to post-operative complications and sometimes the desired wound closure is not obtained even with advanced techniques and materials (1,2). Newer biomaterials such as cyanoacrylate have been discovered as an alternate to conventional suture materials (3). Coover et al. in 1959 commercially synthesized tissue adhesive material known as cyanoacrylates (4). Cyanoacrylates are classified into different types based on the length and complexity of their molecular chains. They are commonly available as methyl, ethyl, n-butyl, isoamyl, isohexyl, and octyl cyanoacrylates (5). Their better biocompatibility and tensile strength with fast polymerization and ease of application makes it a good choice for surgical wound closure (6). Mehta et al. conducted one of the first studies on the use of a cyanoacrylate adhesive during osteosynthesis of mandibular fractures and found no adverse effects (7). Cyanoacrylates have shown favorable results when used for correction of oral and maxillofacial defects such as cleft lip and palate (8). Literature reports have shown predictable results with the use of tissue

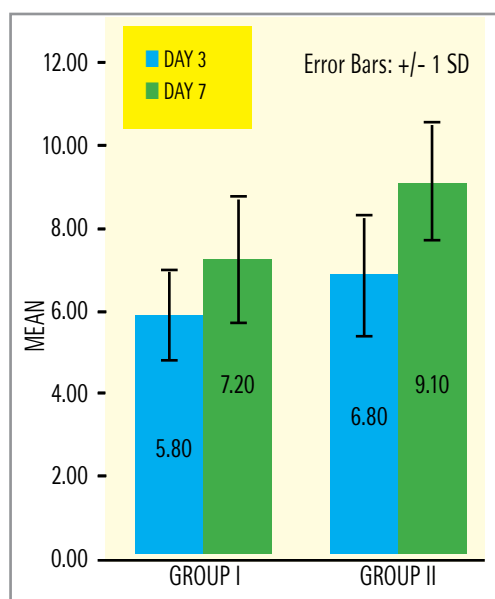


FIG. 1

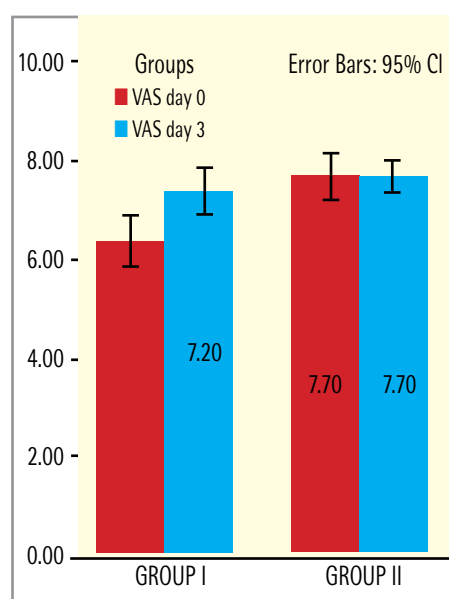


FIG. 2

adhesives in various periodontal flap surgeries and soft tissue grafting procedures (9, 10, 11). In endodontic applications apicectomy, root sectioning and bonding of fractured tooth fragments have shown good results (12, 13).

Cyanoacrylates have been used in various fields of dentistry, however there are no studies on the efficacy of this material as an alternative to sutures during implant recovery procedures. The null hypothesis states that there is no difference in wound healing when comparing cyanoacrylate and black silk suture during implant recovery procedures. Thus the aim of the present study is to compare the effectiveness of Isoamyl 2-Cyanoacrylate (AMCRYLATE) with conventional silk sutures in Implant stage II recovery procedure.

MATERIALS AND METHODS

Study setting

This single blind randomized controlled clinical study was carried out on patients who underwent surgical dental implant placement procedures at the Department of Implantology, Saveetha Dental College and Hospitals, Chennai (India). The study was carried out during the period of January 2021 to June 2021. The study was approved by the Institutional review board and ethical committee. Patients were explained about the nature of the study and an informed consent was obtained following their willingness to participate in the study. The study was performed in accordance to the Declaration of Helsinki of 1975, as revised in 2013.

Inclusion criteria

Systemically healthy patients between the age ranges of 25–45 years, requiring Stage 2 Implant recovery following single posterior mandibular molar tooth implant

placement were recruited in the study. All patients received Nobel biocare (USA) dental implants. Subjects who had no radiographic evidence of peri-implant bone loss, with adequate keratinized tissue and no signs of infection in the implant placement site were included in the study. Patients with systemic diseases such as diabetes mellitus, hypertension, anemia, smoking habit, pregnant women and a history of allergy were excluded from the study.

Randomization and study design

Sample size of 20 was calculated using the data from a previous study with a 95% confidence interval, 80% study power and 10% dropout rate for the study (9). A total of 20 patients were randomly assigned into 2 groups. Randomization of the study was done using an online random allocation software (RandomAlloc.exe. Version 1.0), where number of groups of samples, number of samples per group, and number range is fed, following which it generated random numbers. A single calibrated examiner carried out the entire study process and the data analyst was blinded during the interpretation of the study results. Group I (Control) comprised 10 patients (flap approximated with Black silk sutures) and Group II (Test) comprised 10 patients (flap approximated with Isoamyl 2-cyanoacrylate).

Methodology

The width and thickness of keratinised tissue was assessed using a UNC-15 periodontal probe was recorded prior to the beginning of the study. All the stage 2 implant recovery procedures were performed under local anesthesia with 1:1, 00,000 Lignocaine hydrochloride with 2% adrenaline. Following local anaesthesia administration, a full thickness mucoperiosteal flap was elevated. Local debridement of granulation tissue was done if present and cover screw of the implant was replaced by healing

Groups	Day 3		95 % Confidence Interval		Day 7		95 % Confidence Interval	
	Mean	Standard deviation	Lower bound	Upper bound	Mean	Standard deviation	Lower bound	Upper bound
Group I	5.80	1.13	4.98	6.61	7.20	1.54	6.09	8.30
Group II	6.80	1.47	5.74	7.85	9.10	1.44	8.06	10.13
Mann whitney test value	29.50				19.00			
P value	0.10				0.01*			

*P value less than 0.05 – statistically significant.

TABLE 1 Comparison of early wound healing index between Group 1 and Group 2.

abutments of varying size in accordance with the implant placed (Nobel Biocare, USA Regular or wide platforms) at the respective sites. Then the muco-periosteal flaps were approximated using 3-0 black silk sutures by giving simple interrupted sutures in the control group.

The same procedure was followed in the test group and Isoamyl 2-Cyanoacrylate (AMCRYLATE, Astrum Healthcare private limited, India) was applied on the test site following healing abutment placement. After complete debridement, care was taken in complete isolation of the site, following which the Amcrylate was applied on to the wound margins for approximation. Post-operative instructions and medications (analgesics) were given to the patients. The patients were asked to report on the 1st and 7th day respectively and the wound healing was evaluated using Early wound Healing Index given by Lorenzo Marini in 2018 (14). The early wound healing index assesses three parameters such as clinical sign of re-epithelisation, clinical signs of hemostasis and clinical signs of inflammation. A cumulative score was obtained for each patient with a maximum score of 10 indicating the highest score for EHS. Additionally, to assess the patient-related outcome measures (PROM) visual analog scores ranging from 0 to 10 was evaluated at immediate post-operative (day 0) and at day 3 between the groups.

Statistical analysis

Data were entered in Microsoft Excel spreadsheet and analyzed using SPSS software (IBM SPSS Statistics, Version 20.0, Armonk, NY: IBM Corp.). Descriptive statistics were used for data summarization and presentation. Shapiro-Wilk's test was used to determine the normality of the data. Mann-Whitney U test was used to compare the mean EHS values and VAS scores between Group I and Group II. Wilcoxon Signed rank test was used to compare the mean values within the Groups at day 3 and day 7. The level of statistical significance was set at a value of $P < 0.05$.

RESULTS

All the study subjects reported for the recall appointments.

A total of 12 males and 8 females were included in this study. Group I had 6 males and 4 females, similarly group II had 6 males and 4 females. All values were expressed as mean $\pm$ standard deviation. The mean age of group I was 41 ± 5 years and in group II 40 ± 4 years. No post-operative complications were seen in any of the participants. The mean width of keratinized tissue in the control group is 2.05 ± 0.17 mm and in test group 2.14 ± 0.15 mm. The mean thickness of keratinized tissue in group I is 1.05 ± 0.21 mm and in group II is 1.24 ± 0.15 mm. There was no statistically significant difference in the width of attached gingiva ($P=0.053$) and the thickness of keratinized tissue ($P=0.051$) between the study groups.

The mean EHS score at day 3 in the control group was 5.8 ± 1.13 and the mean score for the test group was 6.8 ± 1.47 . The mean EHS score at day 7 in the control group was 7.2 ± 1.54 and the mean score for the test group was 9.10 ± 1.44 respectively. When comparing the rate of healing at day 3 between the groups there was no statistically significant difference ($P=0.10$), however when comparing the healing at day 7 between the groups the healing was significantly better in the cyanoacrylate group ($P=0.010$) (Table 1). When comparing the healing between day 3 and day 7 both groups showed significantly good healing at day 7 (Table 2). The mean VAS scores at day 0 is 6.6 ± 0.70 in group I and 7.7 ± 10.67 in group II. The mean VAS scores at day 3 is 7.4 ± 0.69 in group I and 7.7 ± 0.48 in group II. There was a significant difference in the VAS score at day 0 ($P=0.001$) and no statistically significant difference was noted at day 3 ($P=0.31$) between the two groups (Table 3). Thus, based on the early wound healing index, the test group showed better healing when compared to the control group.

DISCUSSION

Cyanoacrylate adhesives have been used extensively for various intra-oral surgical procedures. These adhesives provide adequate handling time and they undergo polymerization in the presence of hydroxyl ions present in the oral tissues, leading to a slightly exothermic polymerization reaction (15). They function as mechanical barrier, accelerating epithelial keratinization favoring a

Time period	Group I	95 % Confidence Interval	Group II	95 % Confidence Interval				
	Mean	Standard deviation	Lower bound	Upper bound	Mean	Standard deviation	Lower bound	Upper bound
Day 3	5.80	1.13	4.98	6.61	6.80	1.47	5.74	7.85
Day 7	7.20	1.54	6.09	8.30	9.10	1.44	8.06	10.13
Wilcoxon signed rank test value	2.72				2.41			
P value	0.006*				0.016*			

*P value less than 0.05 – statistically significant.

TABLE 2 Comparison of early wound healing index between day 3 and day 7 within the groups.

Groups	Day 0	Day 3		
	Mean	Standard deviation	Mean	Standard deviation
Group I	6.6	0.70	7.4	0.69
Group II	7.7	0.67	7.7	0.48
Mann-Whitney test value	10		38.5	
P value	0.001*		0.31	

*P value less than 0.05 – statistically significant.

TABLE 3 Comparing the VAS scores at day 0 and day 3 between the groups.

rapid wound healing (16, 17). The current study results also suggest that early wound healing is significantly better in the cyanoacrylate group when compared with the black silk suture group. The antibacterial effects on Gram-positive organisms by these adhesives may play a vital role in the wound healing process. Cyanoacrylate adhesives also favor the coagulation process, thus providing immediate hemostasis on application (18). Although this material has gained popularity, the high cost of octyl and iso-amyl compounds and decreased tensile strength are considered as an inherent drawback of using these adhesives (16,19).

Animal and human studies comparing the various suture materials reported that cyanoacrylates can be a replacement for suture materials (9, 10). Joshi et al compared conventional suture material with an iso-amyl cyanoacrylate tissue adhesive for wound closure following third molar impactions. The authors concluded that there was significantly lesser pain due to minimal tissue manipulation in the cyanoacrylates group than the sutures (20). Similar results were noted by Vastani and Maria et al. when these adhesives were used for alveoloplasty procedures (21). Soni et al. suggested that these adhesives avoid the need for a second visit unlike sutures as the adhesive peels off after one week without causing any mucosal irritation when used for primary wound closure in the oral and maxillofacial region (22). C. Stavropoulou et al. conducted a study comparing the healing of palatal donor site after connective tissue graft harvesting between polytetrafluoroethylene

suture and cyanoacrylates. The authors concluded that there were no significant differences in the donor site healing by using the modified wound healing index (23). Giray et al conducted a study to assess the healing after root resection by using butyl cyanoacrylate adhesive in comparison with conventional sutures. Clinical and microscopic evaluation performed at 1, 2, 3, 7, 14, and 21 days after surgery concluded that scar formation was markedly greater on the sutured side (12). The present study findings also are showing significant difference in healing at day 7 favoring cyanoacrylate when compared to black silk suture.

Although cyanoacrylate has been used in the recent years, there is no clear evidence on the toxicity of the material. Avery and Ord described that butyl cyanoacrylate has no tissue cytotoxic effects and reported that all cyanoacrylates except methyl cyanoacrylate allow favorable tissue healing (24). These authors also stated that the cytotoxic effect of the adhesives is reduced as the number of lateral chains in the molecule increases. The cytotoxicity is also related to the heat released during the polymerization reaction and the presence of unreacted monomers (25,26).

Black is among the most commonly used suture material for all oral and maxillofacial procedures. It has the phenomenon of 'wicking,' which allows ingress of bacteria into the tissues leading to secondary infection (27). Kulkarni et al. concluded that the cyanoacrylates used for periodontal flap surgery have shown to aid in better wound healing than black silk (9). A recent clinical study by Mendoza et al. evaluated the efficacy of cyanoacrylate-based tissue adhesive (Periacyl® 90 HV) for socket preservation. The authors concluded that there were no post-operative complications and adequate wound closure was obtained with early healing index scores (28). To the best of our knowledge this is the first study which was done to assess the early wound healing around dental implants during stage 2 recovery using the EHS index. The study results stated that the early wound healing index was significantly better in the cyanoacrylate group at day 3 and at day 7.

The present study showed superior healing outcomes when tissue adhesives were used as an alternative to black silk sutures. The application of cyanoacrylate for implant

recovery can have greater benefits in terms of patient related outcomes. The painless application procedure for these adhesives allows their use in situations where the anesthetic effect has been diminished and for apprehensive patients (20,25). This can be proven by our study results that the VAS Scores on the immediate post-operative day was significantly higher in the tissue adhesive group than the suture group. Additionally due to early healing, this can also help clinicians to fasten the prosthetic workflow for providing the patient implant supported prosthesis. The possible limitation of the present study is a short follow up period. Hence further studies with larger follow up period and also with a larger sample size is required to extend the use of these tissue adhesive in wider areas of implant-related surgical approaches.

CONCLUSION

Based on the study findings, we can conclude that the soft tissue healing around the implants is better when using the Cyanoacrylate than the black silk sutures. Hence the use of Cyanoacrylate can provide greater benefits during the implant recovery procedures. Thus based on its safety, efficacy, ease of application these can aid in optimizing the healing outcome when used for various implant-related surgical procedures.

Financial support

The study is a self-funded study.

Conflict of Interest

Nil.

Acknowledgement

The authors would like to thank Saveetha dental college, Department of Implantology for their support in conducting and completing the study.

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