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Comparative Evaluation of Iso Amyl 2 - Cyanoacrylate with Braided Silk Suture After Periodontal Flap Surgery: A Randomized Controlled Trial

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KEYWORDS

Periodontal diseases, Conventional flap surgery, Cyanoacrylate, Silk Suture.

ABSTRACT:

Background: Periodontal diseases induce hard and soft tissue changes necessitating surgical intervention, commonly through flap surgeries. Primary closure of flap margins is critical for establishing a healthy dentogingival unit. Silk sutures, traditionally used for flap closure, are associated with inflammatory responses and secondary infections, highlighting the need for better alternatives. Cyanoacrylates, a group of tissue adhesives, offer potential benefits.

Aim:This clinical study compares the efficacy of Iso Amyl 2-cyanoacrylate with braided silk sutures post-periodontal flap surgery, focusing on wound healing and postoperative pain.

Materials and Methods: A split-mouth, single-blinded study was conducted on twenty sites requiring flap surgery for pocket therapy. Clinical parameters assessed included plaque index, gingival index, wound healing index, and pain using the visual analog scale. Evaluations were performed at baseline and 14 days post-surgery.

Results: Intra and intergroup comparisons were made using paired and unpaired 't' tests, respectively, with non-parametric tests applied for pain and HI scores. The intra-group comparison revealed statistically significant improvements in all parameters from baseline to the 14th day. The intergroup comparison showed significant results favoring the test group ($P \leq 0.05$).

Conclusion: N-Butyl cyanoacrylate is a reliable alternative to conventional sutures. It is easy to apply, reduces operation time, causes less inflammatory response, and decreases postoperative pain while achieving primary closure comparable to traditional silk sutures.

INTRODUCTION:

Periodontal diseases precipitate alterations in both hard and soft tissues, necessitating surgical intervention. Flap surgeries represent a standard approach to managing these periodontal disease manifestations. The primary closure of flap margins is integral to achieving favourable treatment outcomes, as it is pivotal in the development of a healthy dento-gingival unit. Periodontal surgical interventions are regularly conducted to address disease-induced changes in periodontal tissues.[1]The precise adaptation of the flap to the prepared root surface in the immediate post-surgical phase is imperative for restoring the dento-gingival unit. [2]

Sutures serve as a prevalent method to secure the flap in position post-surgery. Materials such as silk, catgut,

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nylon and polyglycolic polylactic acid derivatives are commonly used for suturing, with silk being the preferred choice. However, conventional suture materials present various drawbacks including tissue trauma from needle penetration, scar formation, susceptibility to secondary infection, the necessity for sterilization, and an additional visit for suture removal.[3] Furthermore, "wicking" associated with silk sutures increases the vulnerability of the surgical site to secondary infection.[4]

To address these complexities, there is a growing demand for alternatives such as tissue adhesives to replace sutures. Tissue adhesives have received certification from the US Food and Drug Administration and are increasingly utilized, replacing sutures in approximately 25% to 33% of emergency departments for laceration repairs and in the surgical closure of various incisions.[4]

An alternative to traditional sutures is a group of tissue adhesives known as cyanoacrylates. First synthesized in 1959 by Coover et al., cyanoacrylates are adhesive materials with a chemical structure represented as H2C=C(CN)COOR, where R- denotes an alkyl group ranging from methyl to decyl. While initial lower homologs were found to be cytotoxic, leading to their discontinuation in medical use, higher homologs starting from butyl are now considered safe. These adhesives polymerize in the presence of anions, particularly hydroxyl ions, forming a strong adhesive bond upon contact with water or tissue moisture through exothermic polymerization. Cyanoacrylates have high tensile strength, biocompatibility, and antibacterial properties, making them widely utilized in gastrointestinal and ophthalmic surgeries. Their inherent ability to adhere to moist tissues has led to numerous practical applications in dentistry.[5]

The distinctive tissue-binding characteristic of cyanoacrylate will be used in this study to assess the effectiveness of Iso Amyl 2-cyanoacrylate compared to braided silk sutures following periodontal flap surgery, focusing on wound healing and postoperative pain experienced by study subjects.

MATERIALS AND METHODS

This comparative, split-mouth, single-blinded study, was conducted at the Department of Periodontics, KAHER'S KLE V.K. Institute of Dental Sciences, Belagavi. It enrolled 20 sites with residual periodontal pocket probing depth (PPD >6 mm) in at least one quadrant post-scaling and root planning. Ethical clearance was obtained from the Institutional Ethical Committee, and was conducted in accordance with the Helsinki Declaration of 1975, as revised in October 2013. The study was registered with the Clinical Trials Registry-India (CTRI) under registration number [CTRI/2024/03/064900]. Patients meeting the study criteria were included, and informed consent was obtained from all participants.

Inclusion and exclusion criteria: The study included systematically healthy individuals aged 30 to 60 years with PPD of > 6 mm, who were willing to participate.

The exclusion criteria comprised pregnant women and lactating mothers, individuals consuming tobacco in any form, those with parafunctional habits, and subjects who had undergone periodontal therapy in the past 6 months.

Presurgical Preparation: Phase 1 therapy was carried out for all subjects and oral hygiene instructions were explained. Following completion of phase 1 therapy, subjects were scheduled for a follow-up appointment after 2 weeks for baseline measurements. Patients exhibiting residual periodontal pockets of > 6mm and subsided inflammation were selected for surgery.

Surgical Procedure: Surgical procedure was performed under Local anaesthesia (2% lignocaine hydrochloride with 1:80,000 adrenaline). A sulcular incision was made at the planned surgical site, followed by the elevation of a conventional undisplaced mucoperiosteal flap on the labial/buccal and lingual/palatal aspects of the affected teeth. Thorough debridement was carried out using curettes and ultrasonic instruments to remove local deposits and diseased granulation tissue. Subsequently, the flap was trimmed and repositioned to achieve maximal interproximal closure. The quadrant treated were randomly assigned to two groups, test group receiving iso-amyl cyanoacrylate tissue adhesive (Amcrylate® 0.25 ml) and control receiving silk sutures (Black Braided Suture), using the computer-assisted randomization technique. In the test group, following the positioning of the flap in its final closure position, Iso amyl 2-cyanoacrylate (Amcrylate) was applied

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drop-wise along the flap margins until a thin film of the adhesive was formed. In the control group, the flap was secured using simple interrupted sutures. No periodontal dressing was placed in either group. Post-operative instructions were given. Antibiotics and analgesics were prescribed to the patients for 3 days. Follow-up appointments were scheduled for clinical assessment at 3, 7, and 14 days post-surgery. Patients were recalled for suture removal after 7 days. Plaque index, gingival index, wound healing index, and pain assessment using the visual analog scale were evaluated at baseline and 14 days post-surgery.

A)Braided silk suture and B) Iso-amyl cyanoacrylate tissue adhesive

A. Pre – operative picture Conventional flap procedure -
B. and C Sulcular incision on labial side and on palatal side 13-23
D. E and F Full thickness mucoperiosteal flap reflection on labial and on palatal side 13-23
G. Braided silk sutures placed 13-11 and Iso-amyl cyanoacrylate tissue adhesive 21-23
H. Follow –up on 7th days
I. Suture removal after 7th day

RESULTS:

Statistical Analysis: The data collected was analyzed using SPSS software, version 21.Scores of different parameters in the test group and control group at different treatment time points follow normal distribution. Therefore, the parametric tests were applied. All the parameters were statistically analyzed. For intra and intergroup comparison paired and unpaired 't' test was used respectively. But for pain and HI scores the non-parametric tests were applied.

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In the comparative assessment conducted between the suture and cyanoacrylate sites, the subsequent results were obtained:

The mean value of plaque index in Group A and Group B was almost similar at the baseline.The plaque index score observed at cyanoacrylate sites was lesser as compared to suture sites with statistical significance (P = 0.0486)onthe 14th day indicating that plaque control was better when flaps were closed with cyanoacrylate when compared to silk sutures (Fig 1,2).

The mean value of Gingival index in Group A and Group B on intra group comparison was almost similar in both the groups.Gingival index score observed at cyanoacrylate sites was lesser as compared to suture sites with statistical significance (P = 0.03) at the 14th day indicating that gingival inflammation was lesser when flaps were closed with cyanoacrylate as compared to silk sutures (Fig 3,4).

Pain assessment using Visual Analog scale observed at cyanoacrylate sites was also lesser as compared to suture sites with statistical significance (P = 0.04) at 14th day indicating that less pain when flaps were closed with cyanoacrylate as compared to silk sutures. No statistically significant difference was seen on intragroup comparison among the groups. (Fig 5,6).

On inter group comparison Wound Healing index score observed at cyanoacrylate sites was also lesser as compared to suture sites with statistical significance (P=0.002) at the 14th day indicating that wound healing was better when flaps were closed with cyanoacrylate as compared to silk sutures. (Fig 7,8).

Figure 1:Comparison of Plaque Index between the study groups at different time points

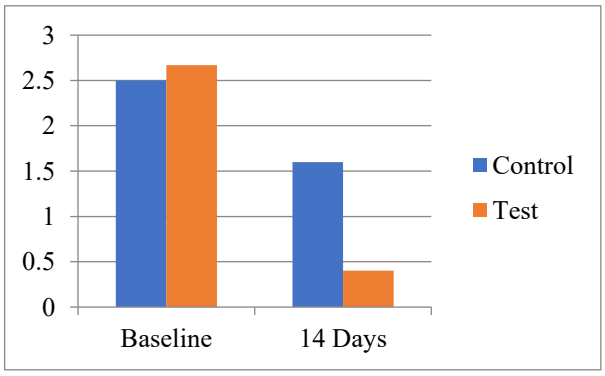

Figure 2:Intra-group comparison of Plaque Index in each of the study groups

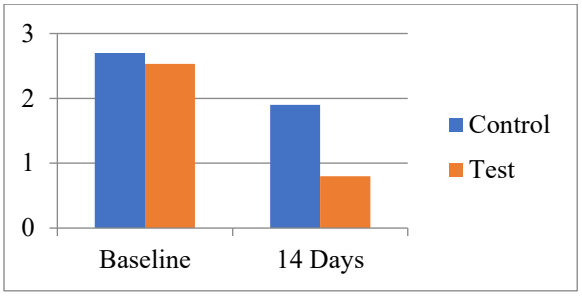

Figure 3:Comparison of Gingival Index between the study groups at different time points

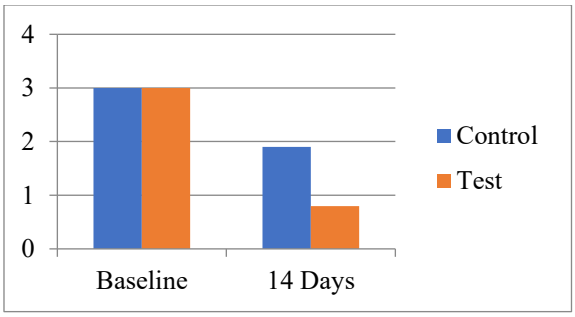

Figure 4:Intra-group comparison of Gingival Index in each of the study groups

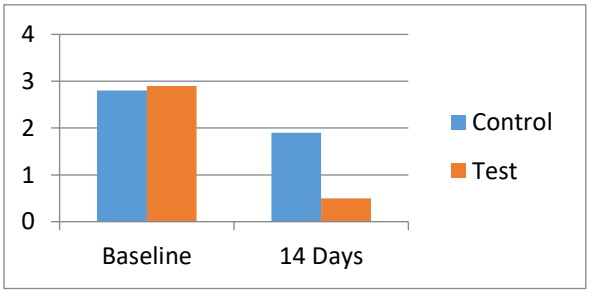

Figure 5:Comparison of Visual analogue scale between the study groups at different time points

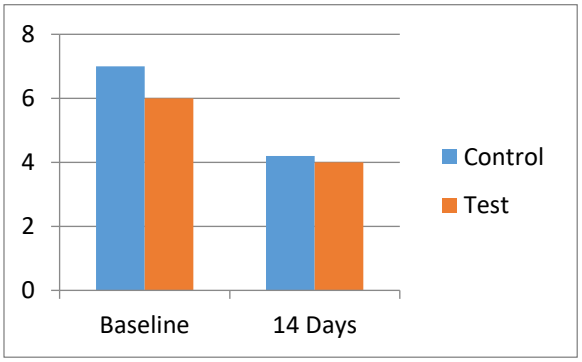

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Figure 6:Intra-group comparison of Visual Analogue scale in each of the study groups

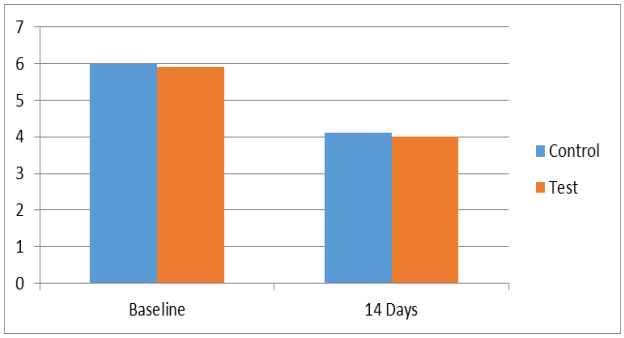


Figure 7:Comparison of Healing Index between the study groups at different time points

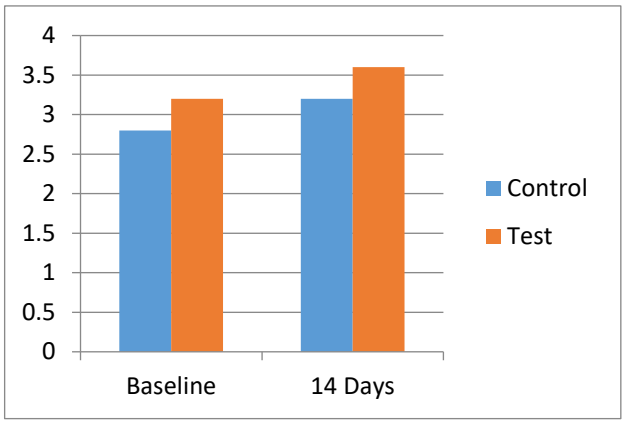
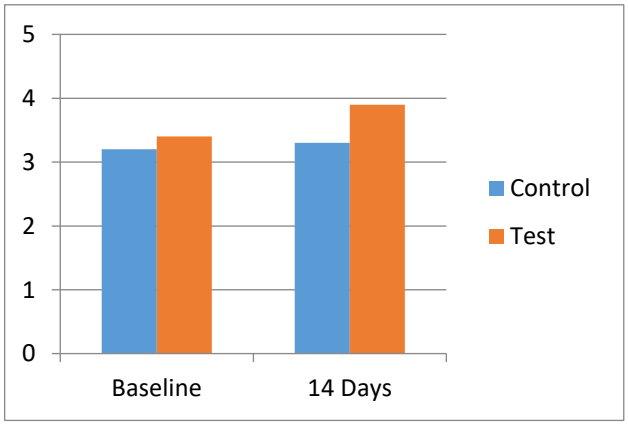


Figure 8:Intra-group comparison of Healing Index in each of the study groups



DISCUSSION:

The tissue alterations induced by periodontal disease frequently necessitate surgical intervention. Achieving primary closure and stabilization of flaps is crucial for postoperative healing. Given the inherent limitations of traditional sutures, there is a continual pursuit for more efficient and safer adhesive alternatives.[6,7]The introduction of cyanoacrylates as surgical adhesives in dentistry paves the way for future tissue adhesive innovations. Cyanoacrylates encompass short-chain (methyl and ethyl) and long-chain (butyl, isobutyl, isoamyl, and octyl) derivatives, with long-chain variants being the least histotoxic. Clinical studies highlight the advantages of cyanoacrylates, such as ease of use, reduced operative time, formation of a protective barrier, and painless application.

In this clinical study the efficacy of both silk sutures and cyanoacrylates (Amcrylates) ® were compared using various clinical parameters. In our study, 20 sitesin at least one quadrant were selected and randomly divided into group A (Conventional non-displaced mucoperiosteal flap surgery followed by flap approximation with isoamyl 2- cyanoacrylate) and group B (Conventional non-displaced mucoperiosteal flap surgery secured with 3-0 silk sutures).

On intragroup comparison, all the clinical parameters showed statistically significant improvement from baseline to 14 days. On intergroup comparison test group shows significant results than control group.

When plaque scores were recorded, on inter group comparison a significant reduction was observed in the cyanoacrylate group ($p<0.001$) compared to the silk sutures group. Patients with silk sutures showed more plaque accumulation. In contrast, cyanoacrylate, created a plaque-free environment due to the absence of suture threads in wound coaptation. These results align with the findings of Vaaka PH et al. (2018),[7]Kaur G et al. (2020).[8]

Inflammatory tissue response to the suture materials were clinically assessed by the gingival index. In our study, the inflammatory response was more pronounced in the control group at the end of 14th day, attributed to the presence of silk sutures and increased plaque accumulation and trauma during suturing. However, since sutures were removed on the 7th day, no difference in tissue response was observed between the groups on the 14th day. Our findings align with those of Chandra S et al.[9]

The wound healing index is used to evaluate post-surgical healing. In this study, the cyanoacrylate group

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exhibited significantly better wound healing at the end of 14th day. Cyanoacrylates demonstrated better tissue adaptation by securing the flap to the entire tooth surface, unlike silk sutures which provided only marginal fixation. The faster healing observed with cyanoacrylates may be due to their scab-like action, which maintains a moist surface conducive to epithelial migration and prevents secondary infection. Consequently, the healing index showed a statistically significant reduction in silk suture sites. These findings are consistent with studies by Vastani A et al. and Parmar HD et al.[10,11]

In this study, a statistically significant reduction in patient pain and discomfort on the VAS scale was observed in the cyanoacrylate group. Patients with silk sutures experienced difficulty in keeping the wound free from deposits, leading to discomfort, itching, redness, and pain.[12,13]The reduced postoperative pain and discomfort in the cyanoacrylate group can be attributed to its properties: it was painless, needleless, suture-less, stress-free, and was easy to use.[14]Additionally, the absence of seepage (wicking effect) under the cyanoacrylate covering contributed to the reduced postoperative pain.[15,16]These findings were consistent with those of other studies by Giray et al. and Khurana et al.[17,18]

CONCLUSION:

Isoamyl 2-cyanoacrylate offers several advantages over traditional sutures, making it a superior choice. It provides immediate haemostasis, is easy to apply, highly accepted by patients, and offers better aesthetics. Additionally, it is non-invasive, reduces chairside time, eliminates postsurgical pain or infection, simplifies maintenance, and prevents food lodgement. This biological sealant is well-tolerated by oral tissues with no reported side effects in studies. It promotes early initial healing and causes less intraoperative and postoperative discomfort compared to silk sutures. Consequently, isoamyl 2-cyanoacrylate is a practical and routine option for closing periodontal flap surgeries, marking a significant advancement in clinical dentistry with the advent of suture-less surgery.

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