

The Effects of Cyanoacrylate on Clinical Healing and Self-Reported Outcomes Following Free Gingival Graft Surgery: A Randomized Clinical Study

Mustafa Yilmaz¹ , Sibel Kayaalti-Yuksekk² , Burcu Karaduman³ 

¹ Istanbul Biruni University, Faculty of Dentistry, Department of Periodontology, Istanbul, Türkiye.

² Istanbul Okan University, Faculty of Dentistry, Department of Periodontology, Istanbul, Türkiye.

³ Istanbul Biruni University, Faculty of Dentistry, Department of Periodontology, Istanbul, Türkiye.

Correspondence Author: Sibel Kayaalti Yuksek

E-mail: sibelkayaalti@hotmail.com

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ABSTRACT

Objective: This study aims to reveal the effects of cyanoacrylate application at the recipient bed and the donor site in free gingival graft surgery on graft dimensions, clinical healing parameters and patient-based outcomes.

Methods: Free gingival graft operations were conducted on individuals who were randomly assigned to control or test groups. In the test group, the graft was stabilized and the donor site was coated with cyanoacrylate. In the control group, 6/0 polyvinylidene fluoride sutures were used for stabilization, while the donor site was left untreated. Variables including re-epithelization, post-operative complications, pain, bleeding and quality of life at recipient site, and color match, graft dimensions at donor site were assessed for up to 6 months.

Results: Twenty-three individuals completed the study. No differences were observed in any variable between groups except horizontal dimension loss of the graft, which was more abundant in the cyanoacrylate group at six months ($p>0.05$, $p<0.05$; respectively).

Conclusion: According to our results, cyanoacrylate can be used safely for free gingival graft surgery, but does not surpass conventional suturing with polyvinylidene fluoride.

Keywords: Cyanoacrylates, sutures, tissue grafts, patient comfort

1. INTRODUCTION

Although debatable, the presence of an 'adequate' band of keratinized mucosa, is thought to enhance the integrity of the periodontium, and to provide sufficient biofilm control (1). Hence, in cases where a lack of gingiva hinders oral hygiene practice in the region or elicits pain in chewing, soft tissue augmentation can be implemented. Free gingival grafts (FGGs) are widely preferred for augmentation since the procedure ensures predictable results (2). FGG was first described by Björn in 1963 while Sullivan and Atkins (1968) helped the technique to become widespread by stating the details and the major principles of the surgery and the expected wound healing (3). The graft is generally harvested from the palatal mucosa, which provides sufficient tissue and allows easy access for the surgeon. Although it is a relatively safe and secure procedure, secondary healing of the donor site may cause some complications such as bleeding, tissue necrosis, delayed wound healing, post-operative pain and loss of sensation. Hence, researchers focus on minimizing these complications, eventually to increase patient comfort and enhance the success of the surgery (4,5).

Cyanoacrylates (CAs) are widely used in medicine as tissue adhesives. Comprehensive hemostatic, bacteriostatic and bactericidal effects can attach tissues firmly and presumably allow healing with less scar formation (6,7). The monomer form of CA is liquid, but it starts to polymerize the moment it contacts body fluids, gaining imminent adhesive properties which allow easy application of the material (8). By considering these features, surgeons can save time and effort with CA when compared to conventional wound closure. In particular, in situations where classical suturing techniques are insufficient to ensure tissue integrity and haemostasia, the use of CA can be very beneficial. CA can also arguably act as a mechanical barrier and accelerate wound healing and epithelial keratinization (9). This may theoretically enhance healing and eventually help patients to go through a more comfortable post-operative period.

Oral health-related quality of life is a patient-based measure, exemplifying the impact of oral status on an individual's life quality (10). It is an acknowledged indicator of therapeutical need and treatment outcomes (11), whereas patient-based results do not always conform to clinical conclusions. The aim

of the study is to compare n-butyl-cyanoacrylate use in free gingival graft to conventional suturing with polyvinylidene fluoride regarding clinical healing parameters and self-reported outcomes following surgery.

2. METHODS

The study's accordance to the ethical guidelines of Helsinki Declaration was approved by the Clinical Research Ethics Committee of Istanbul Biruni University 2015-KAEK-43-18-01. The study was retrospectively registered in ClinicalTrials.gov (NCT04854902).

Sample size was calculated with G*Power 3: two-tail; $\alpha=0.05$; power $(1-\beta)=0.8$. Required size of $n=11$ for each group was determined with the actual power of 0.815. Twenty-three systemically healthy, non-smoking volunteers over 18 years of age, lacking keratinized mucosa in the mandibular anterior region (width ≤ 1 mm) with progressive gingival recession and/or discomfort in chewing or with oral hygiene practice, were recruited in Biruni University, Faculty of Dentistry, Turkey between September 2018 and June 2020. Pregnant or lactating patients, and patients on medication were excluded. Prior to enrolment, informed consent was obtained from the participants.

The participants were added to the cyanoacrylate group (CA) or to the suture group (S), based on computer-aided randomization. The surgery and 3rd day evaluation of the donor site were conducted by the same clinician (MY), while the rest of the evaluations were performed by another examiner (BK). Patient follow-up was performed for 6 months after surgery.

2.1. Parameters

Donor site assessment:

Initial mucosal thickness: The mucosal thickness of the donor area was evaluated under local anesthesia at the beginning of surgery. The measurement was conducted with the help of a 15 endodontic reamer which was inserted into the palatal mucosa 5 mm apical of the gingival margin of the second premolar and read with an electronic caliper.

Re-epithelization: The donor site was evaluated at first, second – and third-week intervals following the operation. The completion of epithelization was visually controlled and recorded dichotomously. Hydrogen-peroxide was applied to the donor area with the help of an injector, and it was accepted as complete when no foaming occurred.

Donor site complications: Complications such as pus formation or necrosis in the donor site were recorded on the third day, and at one and two weeks following the operation.

Paresthesia / hyperesthesia in the donor area: At one month control, the donor site was gently rubbed with the help of a periodontal probe, and the patients were asked to point out any difference between the symmetrical reference areas on either side, where the probe was first applied.

Self-reported outcomes:

Pain: The patients were asked to evaluate the level of pain they felt and accordingly mark a visual analogue scale (VAS), which ranged from 0 (no pain) to 10 (unbearable), at weekly intervals within the first four weeks following surgery. The number of painkiller intake was recorded.

Post-operative comfort and quality of life: The patients were asked to fill in Oral Health Impact Profile (OHIP-14) forms at baseline, 3 days, and 1 and 4 weeks (12).

Secondary bleeding: The patients were asked to report any excessive bleeding following surgery.

The evaluation of the graft

Graft dimensions: Mesio-distal (horizontal) and apico-coronal (vertical) width of the graft was measured using a Williams periodontal probe (Hu Friedy), at 1, 3 and 6 months. Measurements were rounded to the closest mm.

Color match: The color harmony of the graft with neighboring keratinized mucosa was evaluated on a scale ranging from 0 (no color match) to 10 (excellent color match).

2.2. Procedure

Dental prophylaxis, oral hygiene training and motivation, and, if necessary, occlusal rehabilitation were performed before the surgical procedure. The surgery was conducted under local anesthesia (Ultracain D-S, Sanofi Aventis) with two identical 15C surgical blades, each used separately for recipient bed preparation and for harvesting.

At the mucogingival junction in the recipient site, an initial horizontal incision was performed. A split-thickness flap was prepared and extended apically until a sufficient area ($\sim 7 \times 13$ mm) was procured. Immobile connective tissue/periosteum was left on the recipient bed where remaining muscles and loose connective tissue were excised. A 5x10 mm graft was harvested from the hard palate with the guide of a sterile aluminum foil, between the first premolar and the first molars, leaving 2 mm of safety distance with the gingival margins of adjacent teeth. Adipose tissues and irregularities were removed, paying attention to keeping the thickness at ~ 1.5 mm and the graft size as planned. Immediately after, wet gauze pressure was applied for 5 minutes to control hemorrhage in the donor site.

In the control group, the coronal part of the graft was sutured to the recipient bed with 6/0 polyvinylidene fluoride (PVDF; Trofilen, Dogsan), and a horizontal matrix suture was placed as specified by Holbrook & Ochsenbein (13). In the test group, cyanoacrylate (Indermil, Connexicon Medical) was applied only to the coronal and lateral edges of the graft for stabilization (14). Thereafter, in both groups, 5 minutes of gauze pressure was applied to minimize granulation tissue formation and to increase the surface contact between the graft and the underlying connective tissue. The donor site was left untreated in the control group, while in the test

group a thin layer of cyanoacrylate was applied as a dressing, fully covering the wound.

Chlorhexidine digluconate (0.12%) mouthwash (Klorhex, Drogan) was prescribed for use two times per day for two weeks. Flurbiprofen tablets (Majezik, Sanovel Pharmaceutical) were prescribed, and the patients were warned to note how many pills they took during the following time period. The participants were asked not to perform oral hygiene practice in the operation area for two weeks, and a soft-diet was recommended. Sutures were removed and the surgical sites were washed with saline at the end of the first post-operative week. The final evaluation of the graft dimensions was conducted at post-operative 6 months.

2.3. Statistical Evaluation

The Statistical Package for the Social Sciences (SPSS 21, Inc., Chicago, IL, USA) was used for statistical analysis. First, descriptive statistics for each variable were calculated. Prior to hypothesis testing, data were examined via the Shapiro-Wilk test for normality and the Levene test for homogeneity of variances according to parametric test assumptions. The Mann-Whitney U-Test was conducted to test the difference between the study groups and data violating the assumptions associated with parametric distribution, while the Student's t-Test for Independent Samples was used for the data meeting the assumptions. The Friedman test was applied to examine gradual changes in the measurements over time.

The Dunn multiple comparisons test was used for post-hoc testing procedure. The Spearman correlation coefficient was performed to examine the relationship between variables. $P < 0.05$ was considered as statistically significant.

3. RESULTS

28 individuals were recruited, while one patient was excluded during the recall sessions due to SARS-CoV-2 infection. 13 patients in CA (mean age 44 ± 9.31 ; 13 females) and 14 patients in S (mean age 33.36 ± 7.92 ; 9 females, 5 males) – a total of 27 patients (mean age 38.48 ± 10.04 ; 22 females, 5 males) – completed the study.

None of the patients reported any excessive post-operative bleeding. No sign of necrosis or infection was seen in the surgical areas in any timeframe.

Post-operative pain scores (VAS) in the first week were found to be highest, while they decreased gradually thereafter in both groups, with no statistically significant difference at any time point ($p > 0.05$) (Table 1). Two patients reported ongoing slight pain at the fourth week. The number of painkillers used in the first post-operative week was also similar in both groups (CA: 3.85 ± 3.58 ; S: 3.93 ± 3.83 ; $p > 0.05$), while all the patients, without any exceptions, reported that they had stopped taking painkillers following the first week. There was a negative and moderately significant correlation between mucosal thickness and pain scores in the first week ($r = 0.429$, $p < 0.05$).

Table 1. Pain (VAS) and OHIP-14 scores over time

	VAS (Mean \pm SD)			OHIP-14 (Mean \pm SD)		
	Cyanoacrylate	Control	P-value	Cyanoacrylate	Control	P-value
Baseline	-	-	-	3.77 ± 4.8^b	5.79 ± 7.01^{ab}	0.28
3 rd day	-	-	-	5 ± 4.76^b	8.5 ± 7.84^{ab}	0.18
1 st week	2.54 ± 3.45^a	2.64 ± 2.31^a	0.375	4.15 ± 4.51^{ab}	8.14 ± 7.03^a	0.105
2 nd week	1.23 ± 2.42^{ab}	0.71 ± 0.99^b	0.867	-	-	-
3 rd week	0 ± 0^b	0.21 ± 0.43^b	0.35	-	-	-
4 th week	0.15 ± 0.55^{ab}	0.14 ± 0.36^b	0.83	1.08 ± 2.22^a	4.14 ± 7.95^b	0.325
P-value*	0.001	<0.001		0.007	0.016	

VAS: Visual analogue scale scores; OHIP-14: oral health impact profile-14. SD: standard deviation. a, b: Values in the same column with different superscripts represent statistical differences at investigated timeframes in each individual group. P-value*: The significance of the differences between recall sessions in each group. P-value: The significance of the difference between groups

Table 2. The graft dimensions

	Graft dimensions (Mean \pm SD; mm)						
	Horizontal dimension			P-value	Vertical dimension		P-value
	Cyanoacrylate	Control			Cyanoacrylate	Control	
Baseline	10 ± 0^a	10 ± 0^a		5 ± 0^a	5 ± 0^a		
1 st month	9.38 ± 0.87^{ab}	9.64 ± 0.93^{ab}	0.375	4.69 ± 0.63^{ab}	4.57 ± 0.51^{ab}	0.488	
3 rd month	8.85 ± 1.21^{bc}	9.36 ± 1.08^{bc}	0.239	4.46 ± 0.66^{ab}	4.36 ± 0.5^b	0.583	
6 th month	8.15 ± 1.34^c	9.29 ± 1.27^c	0.017	4.38 ± 0.65^b	4.36 ± 0.5^b	0.83	
P-value*	<0.001	0.004		0.002	<0.001		

SD: standard deviation. a, b: Values in the same column with different superscripts represent statistical differences at investigated timeframes in each individual group. P-value*: The significance of the differences between recall sessions in each group; P-value: The significance of the difference between groups

OHIP-14 scores of CA and control also did not show any statistically significant difference with each other at any time point, with a decrease in both groups at the end of the first month relative to pre-operative values ($p > 0.05$) (Table 1). This decrease was statistically significant only in the cyanoacrylate group ($p < 0.05$). There was no loss of sensation in the donor sites of the subjects at the first month recall.

The mean mucosa thickness of the CA group was found to be $3.9 \text{ mm} \pm 0.91 \text{ mm}$, while that of the S was $4.05 \text{ mm} \pm 0.92 \text{ mm}$ ($p > 0.05$). Epithelization of the donor site was not completed in any patient in either group in the first post-operative week. At the second week recall, four patients (30.8%) in the cyanoacrylate group and three patients (21.4%) in the control group showed no more foaming at the site, whereas at the third week the remaining subjects finished re-epithelization. Mean donor site tactile scores evaluating paresthesia at the first month were 9.85 ± 0.55 in cyanoacrylate and 9.21 ± 1.81 in the suture group ($p > 0.05$).

In both study groups, a statistically significant decrease in vertical and horizontal dimensions occurred (CA: $36 \pm 8.25 \text{ mm}^2$; S: $40.64 \pm 8.09 \text{ mm}^2$) whereas only at the 6th month was the change in horizontal dimensions of the control significantly less than CA ($p < 0.05$) (Table 2). No significant difference was found between the groups in any time period evaluated in terms of color harmony ($p > 0.05$) (Table 3).

Table 3. Color harmony of the graft with the neighboring keratinized tissue at the recipient site

	Color harmony (Mean \pm SD)		P-value
	Cyanoacrylate	Control	
1 st week	4.92 ± 2.18^b	5.21 ± 1.48^b	0.867
2 nd week	6.15 ± 1.14^{ab}	6.21 ± 1.31^a	0.905
1 st month	6.62 ± 0.77^a	6.14 ± 1.03^a	0.185
3 rd month	6.31 ± 1.03^{ab}	5.86 ± 0.86^{ab}	0.169
6 th month	6.15 ± 0.9^{ab}	5.71 ± 0.91^{ab}	0.116
P-value*	0.015	0.006	

SD: standard deviation. a, b: Values in the same column with different superscripts represent statistical differences at investigated timeframes in each individual group. P-value*: The significance of the difference between recall sessions in each group; P-value: The significance of the difference between study groups

4. DISCUSSION

Suturing is considered to be effective in wound closure, but it can be time consuming. In addition, suture removal can provoke anxiety and pain in many patients. Cyanoacrylates can be used as an alternative with the advantages of fast and easy application, and of their hemostatic, bacteriostatic and bactericidal features (15). There are various forms of CA, based on the length and complexity of the chains (16). N-Butyl-2-Cyanoacrylate has been reported not to cause any immediate or long-term systemic harm, hence is deemed safe and suitable for oral surgery (17).

This study was designed to compare the clinical and patient-based results of cyanoacrylate and conventional closure with PVDF in FGG surgery, evaluating pain, quality of life, graft dimensions, re-epithelization and post-operative complications. These parameters were investigated all together, since they are all interrelated. Psychosocial factors are known to have an impact on wound healing and pain, while concurrent periodontal treatment may affect the quality of life (18). Hence, life quality was the major variable of the planned study, yet relatively low OHIP-14 scores were detected in both groups, at all sessions. This indicates that neither of the techniques drastically affect life quality. Hence, the post-operative period of both can be considered comfortable, while healing parameters come to prominence when considering which technique to apply.

Although limited in number, available studies investigating cyanoacrylate in palatal wound coverage reported less post-operative pain and less painkiller intake as a result (19,20). Tavelli and colleagues reported that only suturing the palatal site caused significantly more pain (19). Accordingly, palatal application of cyanoacrylate appears to result in better outcomes in this regard. They proposed that coating the wound with a gelatin sponge combined with cyanoacrylate constitutes the best option in reducing post-operative pain and discomfort. Stavropoulou *et al.* (5), on the other hand, reported no statistically significant difference in pain when comparing cyanoacrylate with 6-0 polytetrafluoroethylene (PTFE) sutures in the donor site of subepithelial connective tissue grafts. This can be related to the suture material used in their study inducing low inflammatory response. We left the donor site untreated in the control group, in order not to provoke more redundant inflammation, which possibly affected our results. We cannot be precisely sure of this because there are two separate surgical sites with the potential to elicit pain, and this can be considered a limitation of our study. Nevertheless, no difference was noticed between the groups regarding pain perception following surgery. This may also be due to the suture material (PVDF) used in our study, which shows relatively less plaque accumulation and bacterial contamination, procuring minimal inflammatory response (21, 22).

Immobility is particularly important during the healing of free gingival graft, while it ensures the nourishment and survival of the graft without hindrance (3). Assuming that it can be achieved with both sutures and adhesives (15), the severity of inflammatory response can be indicative in recovery performance. Suture materials can cause inflammation and foreign body reaction in the oral mucosa (23). Meanwhile, dental biofilm and debris accumulation in the surgical area and on the suture thread can adversely influence healing (21). As stated above, N-Butyl-2-Cyanoacrylate has been shown to have bacteriostatic and bactericidal effects. However, the data in the available literature regarding the effects of cyanoacrylates in oral surgery are contradictory. Some researchers reported an increase in inflammatory biomarker levels following cyanoacrylate use when compared to various suture materials such as polyglactone, silk,

and polyglactin, eventually causing poor recovery (24). On the contrary, according to a study evaluating its use in flap surgery, cyanoacrylate resulted in less inflammatory response and enhanced clinical and histological healing when compared to silk sutures (25). It has also been speculated that cyanoacrylate promotes haemostasia and rapid clinical re-epithelialization and resolution of inflammation (26,27). Yet, according to the results of another study, it does not seem to accelerate epithelization (24). These conflicting results substantiate the need of further research regarding cyanoacrylate use in periodontal surgery.

In this study, no impact of cyanoacrylate on the re-epithelization rate of the donor site was observed. In a study comparing the effects of platelet-rich fibrin and butyl-cyanoacrylate on palatal wound healing, no significant difference between cyanoacrylate (26.1%) and open wound (12.2%) groups was detected in the second week (20). Similar results for complete epithelization were observed in our study (CA: 30.8%; S: 21.4%) in the second week recalls, demonstrating no significant difference.

According to our results, free gingival graft shrinks gradually with time compared to baseline, but this decrease became statistically significant only at 3 months in both study groups. We observed relatively more reduction in the horizontal dimension at 6 months in the cyanoacrylate group. This can be related to the greater horizontal dimension of the graft, expressing the difference between the groups more significantly. Similarly, prior publications disclosed much more abundant dimension loss in width than length, which can be due to recipient bed treat or other yet unknown factors (28, 29). There are two prior publications evaluating the effects of cyanoacrylate use on graft shrinkage, with conflicting results: in one study comparing cyanoacrylate with 7-0 propylene and 5-0 propylene sutures, the researchers observed a decrease in graft size in all groups, while cyanoacrylate showed significantly less shrinkage in all control sessions (14). In addition, they reported less pain with cyanoacrylate. On the other hand, Barbosa *et al.* stated that the use of cyanoacrylate, when compared to conventional suturing, did not differ in regard to graft shrinkage, concluding that it has no impact on healing (28). Our results are not compatible with either study, suggesting a greater decrease of width in the cyanoacrylate group. The horizontal matrix suture used in our control group to stabilize the graft more stringently might have had an impact on this result, but that is yet to be proven. This is more likely due to differences in study design and measurement tools, suggesting that further standardized studies be conducted.

Another finding of our study concerns the proportionally decreasing pain scores with palatal mucosa thickness. Burkhardt *et al.* reported that thicker mucosa reduced pain, which is in accordance with our results (30). In line with this finding, further studies can be conducted in which study groups are formed according to palatal thickness and donor site treatment. Although our data did not indicate any statistically significant effect of gender and age, another

limitation of our study is the confined number of subjects, particularly regarding distribution. Another limitation of our study is that the color match and graft size were evaluated conventionally, whereas the digital methods can provide objective and consistent results comparing surgical approaches, regarding particularly graft dimensions (31). However, VAS scoring of color match by blinded examiners and measuring graft dimensions with the help of a periodontal probe, the methods applied in our study are commonly used in similar study designs (32, 33).

5. CONCLUSIONS

Within the limitations of our study, it can be concluded that cyanoacrylate use in free gingival graft does not outperform conventional suturing with PVDF with regard to healing outcomes and post-operative pain or life quality. Thus, both materials can be used in free gingival graft operations without any significant superiority to each other. Consecutive research conducted in larger populations and comparing different cyanoacrylate forms and suture materials could be beneficial.

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Conflict of interest

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