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Original Article

The influence of harvesting free gingival graft on self-reported pain perception: A randomized two-arm parallel clinical trial



Niusha Namadmalian Esfahani, Afshin Khorsand, Seyedhossein Mohseni Salehimonfared*

Periodontics Department, Dental Faculty, Tehran University of Medical Sciences, Tehran, Iran

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KEYWORDS

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Background/purpose: Free gingival graft (FGG) is used as an effective method to increase the width of keratinized tissue. However, it can cause pain at the donor site. Techniques accompanied by lesser tissue harvesting can reduce pain after surgery. The purpose of this study was to evaluate the self-reported pain perception following harvesting FGG using conventional and accordion methods.

Materials and methods: In this randomized clinical trial study, 31 patients with a deficiency of keratinized tissue around implant were investigated. Sixteen subjects in the accordion group and 15 subjects in the control group received conventional FGG. In the accordion group, FGG was harvested with a length of 60% of the mesiodistal length of the recipient area and with the same length as the mesiodistal length of the recipient area in the conventional group. The patients were asked to record their daily pain using a numerical rating scale.

Results: The severity of the pain after reaching to the peak on the second day was reduced and reached zero at day 14 in both groups. Pain severity showed no significant difference between the treatment groups. The highest level of pain was reported in the conventional group in those subjects under 50 years old, and the lowest one was in the conventional group's subjects above 50 years old. There was no difference between men and women in the reported pain between the treatment groups.

Conclusion: Harvesting graft with a smaller size in the accordion group has no effect on reducing pain.

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* Corresponding author. Periodontics Department, Dental Faculty, Tehran University of Medical Sciences, Kargar Shomali Avenue, Tehran, Iran. Fax: +98 (21) 88015800.

E-mail address: salehimo@tums.ac.ir (S. Mohseni Salehimonfared).

Introduction

Application of dental implants is a predictable method to treat patients with partial or complete edentulous. However, the faced challenge is locating implant in complicated cases who have severe bone defects. Bony defects could occur congenitally or because of trauma, pathology, infection, periodontal disease, tooth extraction, or even after implantation in the prosthetically driven position. Hence, bony defects could occur despite the presence of sufficient bone.^{1,2} In this regard, various protocols are introduced for bone augmentation, which mostly require coronal advancement of buccal flap to achieve primary closure, which could lead to the coverage of buccal area of the implant by the thin and mobile lining mucosa. Further, the width of the keratinized tissue, which is the local risk factor related to success in implant treatment, would be decreased.^{3,4}

Numerous studies have shown that the presence of a band of keratinized tissue is not necessary; however, a lack of keratinized tissue can lead to the risk of the increased probing depth, bone loss, gingival index, plaque index, bleeding on probing, and immunologic parameters.⁵⁻⁷ In clinical practice, when an appropriate plaque control is not possible and the stability of the soft tissue margin is of most importance, augmentation of keratinized tissue is invaluable.⁸ Also, the main rationale is establishing conditions that are appropriate to plaque control, facilitates making an impression, and eliminates muscular tension and frenum.

Free gingival graft (FGG) is known as a successful therapeutic method to increase attached gingiva, elimination of frenum and muscular attachments, root coverage, and vestibular extension.⁹ Moreover, gingival graft is often harvested from the palate, even though palatal tissue has anatomical limitations as the donor region. Accordingly, this limitation is the greater palatine artery at the posterior palate and at the frontier is the rugae. In order to overcome the limitation of the donor tissue in the conventional FGG, many efforts have stated to expand the tissue, of them, Accordion, Strip, and Vertical Strip techniques could be pointed.¹⁰⁻¹²

Accordion technique was firstly introduced by Rateitschak in 1985.¹² In this method, definite incisions are used to expand the tissue up to nearly 50%. In the healing process, the intervals among the incisions were covered by the keratinized epithelium followed by creeping from the surrounding keratinized tissue. Correspondingly, this tissue expanding capability leads to harvesting less tissue and subsequently the decreased pain and morbidity of the patient.

Considering the gap in studies comparison the morbidity following accordion and conventional techniques, this study was designed to investigate the effect of smaller dimensions of the graft harvested from the palate in the accordion technique on post-surgical pain of the patients.

Materials and methods

Study design

This was a randomized two-arm parallel clinical trial.

Sample size

In this study, sample size was calculated using the formula for comparing two means (two-sample *t*-test). The minimum sample size was estimated for the first type of error at 0.05 with the statistical power of 80%. The final sample size for each group was 21-patient, considering 30% of the samples to drop out.

Inclusion and exclusion criteria

This study included the patients who had more than one implant (with at least a 15-mm mesiodistal length) with the keratinized tissue width less than two mm. Patients with systemic disease or the presence of symptoms such as inflammation, bleeding on probing, or pus discharge were excluded from the study. Those with an active infection were also excluded from the study.

All the patients were informed regarding the details of this study, and the informed consent was obtained from them. The ethical committee of the Tehran University of Medical Sciences approved the study protocol (IR.TUMS.-DENTISTRY.REC.1398.071). The study was also registered in the Iranian registry of clinical trials, coded IRCT20190721044296N1.

Participants and randomization

In order to select surgical technique, the statistician prepared the list of random allocation of participants. Moreover, to produce the random allocation table, the balanced block randomization was used. The performer preserved the random allocation table until the end of the study. For each patient, the type of graft surgery was written in a thick envelope, encoded (same as the questionnaire code), and then attached to the questionnaire. The envelopes were opened prior to the surgery and acted in terms of the written surgical method in them. Since both therapeutic methods were surgical, and the surgery outcomes were detectable by the patient, the surgeon, and the investigator, there was no possibility for blinding (not for the treatment and not for the hypothesis), and only the statistician could be blinded.

Pre-surgery assessments

This study is a part of the study evaluating dimensional changes of peri-implant keratinized tissue following free gingival graft using conventional and accordion methods. Therefore, prior to performing surgery, the width of the keratinized tissue from the gingival margin to the mucogingival line was tested using the Roll test, and the distance to the mucogingival was measured using the Michigan O probe. If the implants have been exposed to the mouth, the probing depth, bleeding on probing, and plaque index were also measured.

Surgery process

At first, the patients were asked to rinse their mouth for 60s with Chlorhexidine 0.12% (Shahre Daru Lab, Tehran,

Iran). Afterward, infiltration anesthesia was done (2% lidocaine with epinephrine 1:100.000) and the recipient region was prepared as a split thickness by an incision at the mucogingival line. Subsequently, in accordion method, epithelialized graft was harvested from the palatal area with a length of 60% of the mesiodistal length of the recipient area. In the conventional method, it was harvested with the same length as the mesiodistal length of the recipient area (Fig. 1). For both groups, graft with a thickness of 1–1.5 mm was harvested. Also, donor site was sutured by silk 3-0 (Pedram Teb, Bandar Abbas, Iran). In the accordion method, the harvested graft was then expanded by intermittent incisions, so that it can cover the whole length of the recipient area. In both groups, the graft was located at the recipient area, which was then sutured by nylon or polyglycolic acid 4-0 (Nasg Teb Keyhan, Karaj, Iran) (Figs. 2 and 3). Afterward, the periodontal dressing (Coe-Pak, GC America, Alsip, IL, USA) was located on the donor site.

Both groups were prescribed to consume antibiotics (amoxicillin 500 mg, every 8 h, for 7 days), analgesics (ibuprofen 400 mg, every 6 h as long as it is painful), and mouthwash (chlorhexidine 0.12%, twice a day for a two-week period).

The patients were also asked to record their daily pain using numerical rating scale until the pain would be relieved. Notably, the number of zero was for lack of pain and the number of 10 was for the worst pain experienced by the patient.

After performing one surgery session, the patients were referred after 7 days to remove the sutures of the donor region. In addition, they were referred on day 14 to remove the suture of the recipient region.

Statistical analysis

For descriptive statistics, mean and standard deviation values were reported considering a normal distribution of the pain variable. Hypothesis testing was performed by the repeated measurement analysis of variance (ANOVA). The *post hoc* test (Sidak) was used for comparing pain level among different days. The interaction between intervention and time was not significant (p -value = 0.98). However, the interaction of the model was significant according to age group; therefore, repeated measurement ANOVA was separately performed for age group of ≤ 50 and > 50 years old. However, the interaction of the model was not significant according to gender (p -value = 0.44). The chi-square test was used to compare the day of the maximum pain (as categorical variable). Level of significance was considered as less than 0.05.

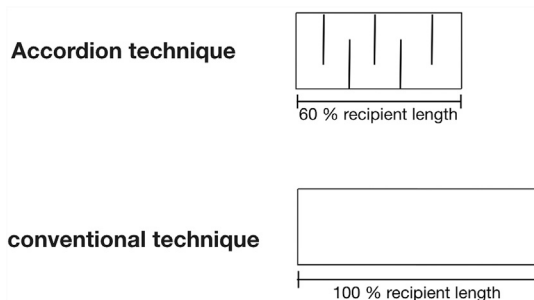


Fig. 1 Scheme of the grafts in treatment groups.

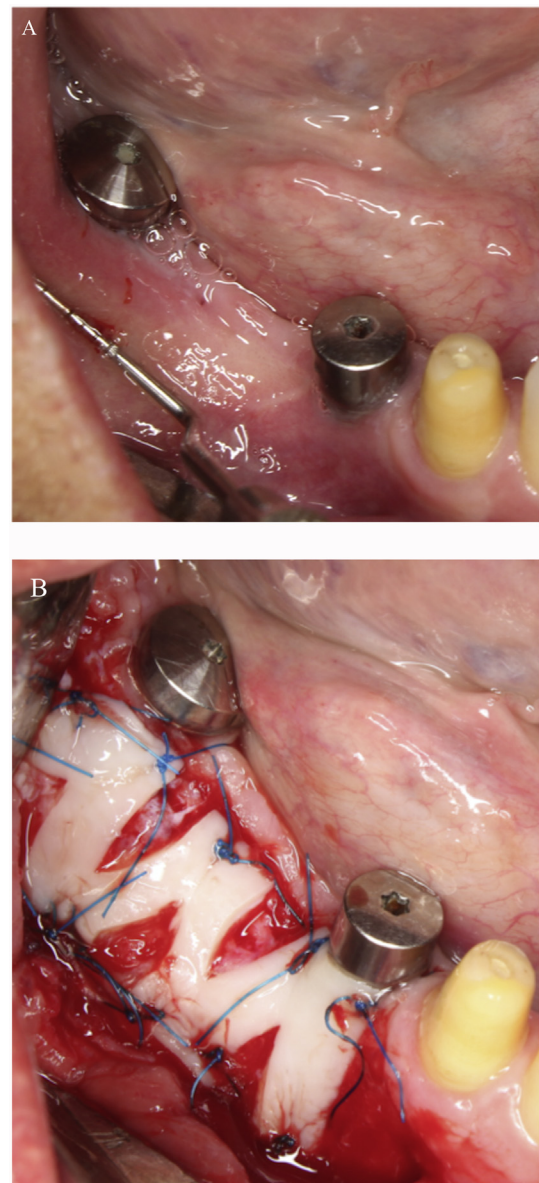


Fig. 2 Accordion technique. (A) Preoperative view (B) The FGG with a length of 60% of the mesiodistal length of the recipient area was stabilized.

square test was used to compare the day of the maximum pain (as categorical variable). Level of significance was considered as less than 0.05.

Results

In this randomized clinical trial, 56 patients with a deficiency of keratinized tissue width around the implant were investigated at the periodontology department of the dentistry faculty of Tehran University of Medical Sciences. In this regard, by considering the inclusion and exclusion criteria, 42 patients were finally enrolled in the study. Of these, 5 patients in the accordion group and 6 patients in the conventional group had no willingness to participate in filling out the questionnaire and continuing the study (Fig. 4).



Fig. 3 Conventional technique. (A) Preoperative view (B) The FGG with a length same as the mesiodistal length of the recipient area was stabilized.

Finally, 16 patients with 49 implants (8 women and 8 men), and 15 patients with 45 implants (9 women and 6 men) were recruited in the accordion group and in the conventional group, respectively.

The mean age of patients in the accordion group was 47.56 ± 12.99 years old, and in the conventional group, it was 52.73 ± 8.37 years old.

A range of 5–8 mm was considered for the graft height based on the patient's condition (Table 1).

The pain severity of the patients was assessed from the first day to the day 14. Correspondingly, comparison of the pain severity showed no significant difference between the two groups (p -value = 0.98). The pain severity was reduced from the second day until day 14, which reached zero at day 14 in both groups (Fig. 5).

Maximum pain was recorded at the first day by 56.3% of patients in the accordion group, and by 60.0% of patients in the conventional group; however, the maximum amount of pain was experienced at the second day.

The highest amount of pain was in the conventional group's subjects under 50 years old, and the lowest one was in the conventional group above 50 years old. The amount of pain in the accordion group was less different between below- and above-the-age of 50 years old (Fig. 6).

Gender did not affect the pain difference between accordion and conventional methods (p -value = 0.44).

Discussion

Past studies stated that techniques such as the accordion, accompanied by lesser tissue harvesting can reduce pain and morbidity after surgery. In the current study, a comparison was made on pain of patients in a 14-day period after surgery between accordion and conventional groups. In this study, the patients were asked to record the pain experienced in each day, for 14 consecutive days in the provided questionnaire. Both groups reported similar severity of pain with no significant differences. Approximately 60% of the patients reported the highest pain score at the first day after surgery; however, the maximum experienced pain by a patient was reported at the second day after surgery, which then reduced in descending order through later days. Moreover, no difference was observed between two groups regarding the reduction of pain, and finally, pain in both groups reached zero at day 14.

In order to find the underlying leading causes of these results, it is necessary to have a comprehensive viewpoint on pain perception. Pain perception in intra-oral surgeries is not only dependent on the factors related to the surgery, but also it is related to age and gender, as well as physical and mental statuses, which are mostly considered in medical basics studies.¹³

In a study by Keats et al., no association was found between age and pain killer use after surgery.¹⁴ While Parkhouse et al.¹⁵ reported a small significant decline in consuming pain killers at ages more than 50 years old compared to younger individuals, which was in line with the result of a recent study by Tavelli et al.¹⁶ regarding the assessment of morbidity after harvesting palatal graft. Accordingly, in the mentioned study, the inverse association with age was correlated with vascularization and anastomosis in young ages. In the current study, pain was greater in the conventional group's subjects under 50 years old and the lowest amount of pain was in the conventional group above 50 years old, hence, the age was less influential on the accordion group.

Gender was found as another effective factor. In a study by Burkhardt et al.¹⁷ that was conducted to investigate the pain severity of patients after gingival graft harvesting, no considerable difference was observed regarding pain between two genders. However, other studies that investigated pain perception in general, and not just about intra-oral surgeries, have reported a tendency to the perception of greater and more intermittent pain in women.^{18,19} However, in this study, the effect of gender on experienced pain was not statistically significant.

Other factors such as physical and mental statuses were not pointed despite their considerable effect on pain perception. This was due to not entering those patients with any systemic disease to study.

The next phase in the assessment of pain perception is considering the factors related to surgery (graft dimensions, the tissue thickness remained at the palatal area and preserving the donor area techniques), which were assessed, respectively.

Graft dimensions are assessed in three dimensions of thickness, height, and the length.

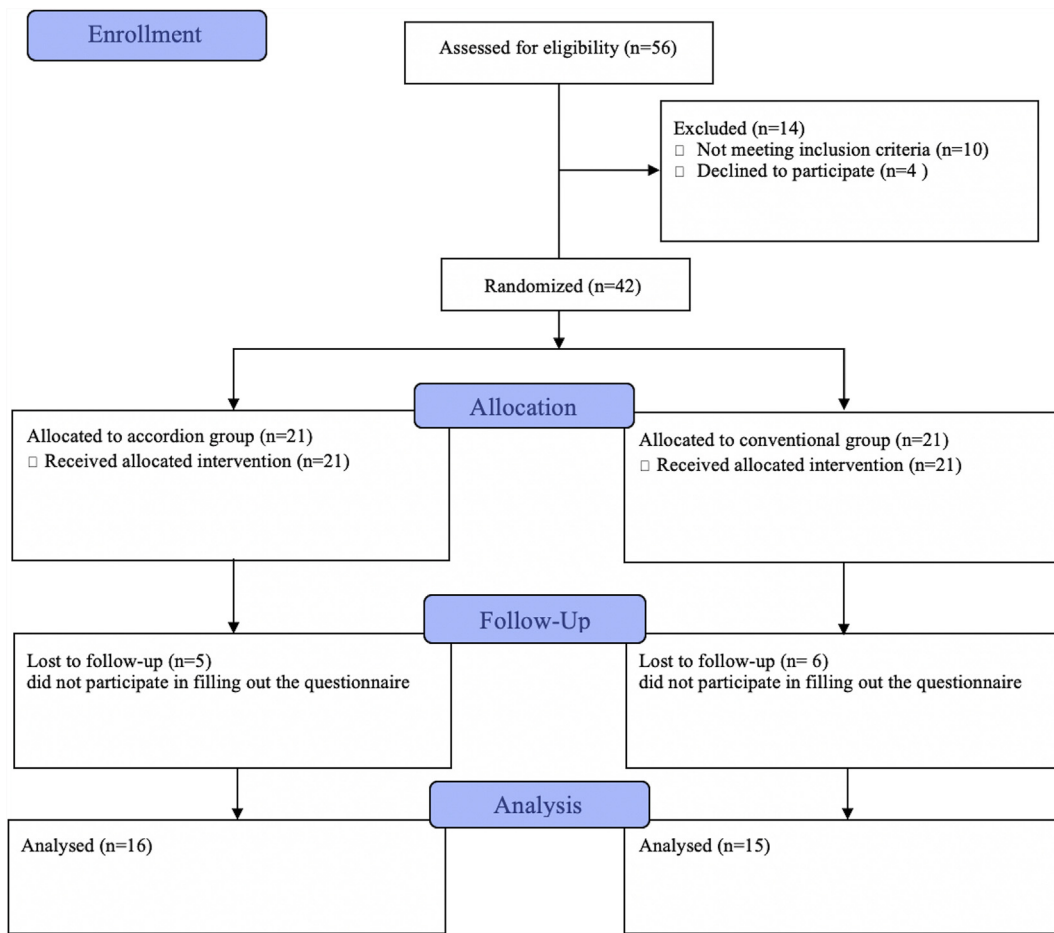


Fig. 4 CONSORT 2010 flow diagram.

Table 1 Characteristics of study participants.

	Accordion	conventional
Number of patients	16	15
Number of implants	49	45
Age (mean ± SD)	47.56 ± 12.99	52.73 ± 8.37
Gender		
Male	8 (50.0%)	6 (40%)
Female	8 (50.0%)	9 (60.0%)
Graft size		
5 mm		1 (6.7%)
6 mm		1 (6.7%)
7 mm		13 (86.7%)
8 mm	16 (100%)	

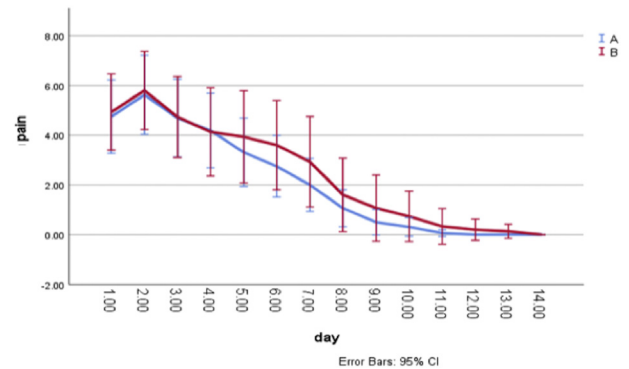


Fig. 5 Mean (standard error) numerical rating scale value changes for treatment groups for 14 days post-surgery (A: accordion technique, B: conventional technique).

In a study by Burkhardt et al.,¹⁷ it was shown that the grafts with a thickness greater than 2 mm were associated with more pain, and respectively, there was no graft thicker than 2 mm in the current study.

A study by Zucchelli et al. stated that large grafts with a thickness ≥2 mm and a height ≥4 mm are accompanied with more pain, and finally the greater height and thickness due to a higher probability of the presence of greater vessels and nerves are associated with more pain.^{20,21} In

case of the involvement of larger vessels, there is a probability of a longer bleeding during surgery. In this study, a height of 8 mm was considered to compensate the height decline following the expanding of the tissue in all cases of the accordion group. The higher graft height (approximately 1–2 mm) in the accordion group can be considered as the leading cause of more pain in this group compared to the conventional group. Moreover, regarding the length, a

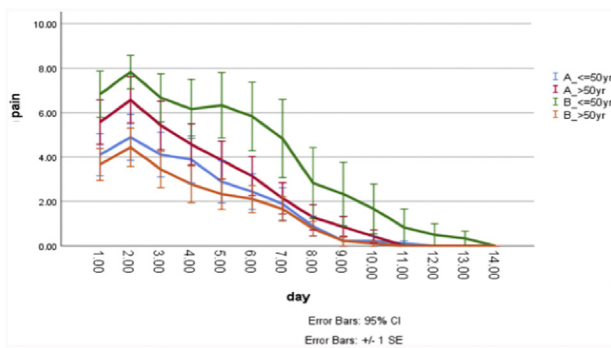


Fig. 6 Mean (standard error) numerical rating scale value changes for treatment groups in age group of ≤ 50 and > 50 years (A: accordion technique, B: conventional technique).

study by Wyrebek et al. investigated the morbidity of the patient based on graft length.²² In their study, three lengths were assessed, and it was shown that graft length cannot affect morbidity and interruption in daily activities. Accordingly, these results are in line with the current study, which concludes that increasing the length does not increase the pain. Finally, regarding the graft dimensions, it seems that large grafts with limited thickness can be used with no changes in pain perception.¹⁷

After harvesting graft with an appropriate thickness (1–1.5 mm), the wound in the palatal area is recovered by secondary healing during 2–4 weeks, and this period is accompanied with pain and distress.²¹ Previous studies showed that the remaining tissue in the palatal area considerably affects pain and morbidity. In the study by Zucchelli et al., it was reported that, greater use of pain killer is accompanied by a lower thickness of soft tissue remained on the bone.²¹ Similar results by Burkhardt et al. showed that nerve-rich periosteum plays an important role in pain perception, and remaining more thickness of the soft tissue reduces the probability of the exposure of periosteum and mechanical stimulus.¹⁷ Therefore, the primary thickness of the tissue in the palatal area and the thickness of the harvested graft are of most importance. In this regard, the primary thickness of the palatal tissue was not measured in the current study; therefore, the thickness of remaining of soft tissues on bone, the proximity to the periosteum, and subsequently the pain perception might be affected by harvesting the tissue with an identical thickness (1–1.5 mm).

In order to decrease morbidity in patients, several recent studies showed that using protective substances in the palatal region reduces patients' pain and improves recovery. A study by Eltas et al. investigated the effects of periodontal dressings, Essix retainer, modified Essix retainer, and modified Hawley retainer on pain of patients, and the comparison showed that periodontal dressing is accompanied with more pain compared to retainer. Also, retainer is the most appropriate item to reduce patient pain; however, it can interrupt talking and influence appearance.²³ Similar study by Chiu et al. showed that palatal stent reduces donor site morbidity and provides patient with a good healing.²⁴ Other studies showed that Platelet-rich fibrin, Erythropoietin, and Hyaluronic acid can improve recovery as well as reducing patient's pain.^{25–27} In

addition, a study was designed by Tavelli et al.¹⁶ to reduce morbidity of the patient after graft harvesting from the palate by considering five groups. Accordingly, suture was done in the palatal region for the first group, cyanoacrylate was used for the second group, periodontal dressing was used for the third group, gelatin sponge was used for the fourth group, and gelatin sponge combined with cyanoacrylate was used for fifth group. The results showed that protection of the palatal area has a positive effect on reducing pain and distress after surgery, and protection of palatal wound with two layers of gelatin sponge and cyanoacrylate reduces pain and distress after surgery. Although periodontal dressing was used after performing suture in the current study, due to lack of appropriate mechanical retention in a number of samples, dressings were separated in different days between the two groups before removal of sutures from the region, which can be considered to affect interpretation and comparison of results.

Given the above-mentioned discussions, the lack of significant difference regarding pain between accordion and conventional groups can be attributed to several factors. Firstly, measurement of pain in this study was performed based on the explanations of the patient, since the measurement methods were subjective and hence, increased the risk of error and bias.

Secondly, the effect of age, thirdly the effect of graft height on pain perception which was greater in the accordion group. Finally, the effect of the periodontal dressing as protective factor, which made interpretation of the results complicated, if not impossible.

Despite observing no significant difference regarding pain perception by patients in two groups, even by harvesting graft with smaller size in the accordion group compared to conventional group, it seems that using accordion technique is not reasonable to reduce pain in patients, if there is no restriction in harvesting graft from the palate. However, accordion technique is mostly helpful in those cases who require FGG and in case of limitation in donor tissue.

Authorship

Conception and design of study: Seyedhossein Mohseni Salehimonfared, Niusha Namadmalian Esfahani, Afshin Khorsand.

Acquisition of data: Niusha Namadmalian Esfahani.

Analysis and/or interpretation of data: Niusha Namadmalian Esfahani, Ahmad Reza Shamshiri.

Drafting the manuscript: Seyedhossein Mohseni Salehimonfared, Niusha Namadmalian Esfahani, Afshin Khorsand.

Revising the manuscript critically for important intellectual content: Niusha Namadmalian Esfahani, Seyedhossein Mohseni Salehimonfared.

Declaration of competing interest

The authors have no conflicts of interest relevant to this study.

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