Orijinal Araştırma

Evaluation of Patients' Discomfort at the Palatal Donor Site Following Free Gingival Graft Procedures: A Randomized Controlled Clinical Trial

Serbest Dişeti Cerrahisini Takiben Palatinal Verici Alandaki Hasta Rahatsızlıklarının Değerlendirilmesi: Randomize Kontrollü Klinik Çalışma

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Abstract

Objective: The purpose of this study was to compare the effects on patients' discomfort of four different bodyguard methods for donor sites after free gingival graft (FGG) surgery.

Material and Methods: This was a 2-week randomized, controlled clinical trial in single center, comparing the effects of four different cover methods on the discomfort (pain, chewing, speaking, appearance) of patients at the donor site after the FGG surgery. This study was performed on 4 groups consisting of 12 patients each. Group A, periodontal dressing (PD); group B, Essix retainer (ER), group C, modified essix retainer (MER); and group D, modified hawley retainer (MHR). A visual analog scale (VAS) was used to measure the experienced discomfort.

Results: The mean VAS scores for pain were higher in group A than in the groups with retainers for both assessments, but there was only statistically significance at T1 ($p>0.05$). While bleeding was significantly more common in group A than in the other groups at T1 (after one week) and T2 (after two week) ($p<0.05$), the differences among groups B, C, and D were not significant ($p>0.05$). The present study showed speaking and appearance VAS scores in the PD group was lower than in the groups with retainers ($p<0.05$).

Conclusions: The complaints about the donor site after FGG surgery may be reduced with cover techniques. New approaches are needed to reduce patients' discomfort.

Key Words: Clinical Trial(S), Free Gingival Graft(S), Pain, Visual Analog Scale

Özet

Amaç: Bu çalışmanın amacı serbest dişeti grefti (SDG) cerrahisi sonrası verici sahayı korumak için kullanılan dört farklı koruyucu metodun hasta konforu açısından karşılaştırılmasıydı.

Gereç ve Yöntem: Bu çalışma iki haftalık randomize kontrollü tek merkezli SDG sonrası verici sahada kullanılan dört farklı koruyucu metodun ağrı, konuşma, çiğneme ve dış görünüş gibi hasta konforunu etkileyen etkenler açısından karşılaştıran klinik bir çalışmadır. Bu çalışma 4 gruba bölünmüş 12 kişiden oluşmaktadır. Grup A' da: periodontal pat, Grup B'de: essix plağı, grup C'de: modifiye essix plağı, grup D'de: Hawley apareyi kullanıldı. Visual analog skalası (VAS) ile rahatsızlık hissi ölçüldü.

Sonuçlar: VAS skorlarının ortalamasına göre grup A'da ağrı hissi diğer gruplardan daha fazlaydı, fakat istatistiksel anlamlılık sadece T1(1 hafta sonra) de vardı ($p>0.05$). T1 ve T2 (2 hafta sonra) 'de kanama, grup A'da diğer gruplara göre daha yaygındı ($p<0.05$), grup B, C ve D 'deki farklılıklar istatistiksel olarak anlamlı değildi ($p>0.05$). VAS skorlarına göre konuşma ve dış görünüş skorları grup A'da diğer gruplara göre daha azdı ($p<0.05$).

Tartışma: SDG sonrası verici sahayla ilgili şikayetler koruyucu yöntemin değiştirilmesiyle azaltılabilmektedir. Hasta şikayetlerinin azaltılması için yeni yaklaşımlara ihtiyaç duyulmaktadır.

Anahtar Kelimeler: Ağrı, Klinik Çalışma, Serbest Dişeti Grefti, Visual Analog Skala.

Introduction

The free gingival graft (FGG) procedure is one of the most common approaches for gingival augmentation (1-3). FGGs are used to create a widened zone of attached gingiva and reduced gingival recession (4).

A soft tissue graft is a withdrawal of soft tissue that is completely detached from its original donor site and placed in a prepared recipient bed (5). The palate is the most frequent donor site for FGGs (6).

Although it is well known that FGG is a predictable method of root coverage, the obvious disadvantages of poor color matching and donor site morbidity render it unsuitable for use as a root coverage procedure (7, 8). The donor site is an open wound that makes postoperative healing more painful for patients. Patient discomfort at the donor site after FGG surgery, pain, and bleeding are common clinical events (9-12).

To reduce complaints due to open wounds at the donor site, the palatal wound generally is protected with a periodontal dressing, covering the donor site with a periodontal pack for 1-2 weeks and repeating if necessary. To retain the dressing at the palatal site, a stent usually must be used (13). A modified hawley retainer (MHR) is useful for covering the pack on the palate and over the edentulous ridges (14). However, last two procedures have not been used often.

FGG is often used in periodontal plastic surgery; however, previously studies have documented the main disadvantages of FGG procedures associated with the donor site, including pain and bleeding due to open palatal wounds (6, 15, 16).
Today, there is no information in the literature about the effect on patients' discomfort of different cover methods that may be useful for the donor site. Thus, the aim of this clinical study was to compare the effects on patients' discomfort of four different protection methods for donor sites after FGG.

Subjects and Methods

Study population

The patient population consisted of 48 patients (24 women and 24 men) with a mean age of 30.6 years old (range: 21-38 years), who were referred to the Department of Periodontology of Inonu University in Malatya, Turkey. All of the patients approached agreed to participate in this study and signed an informed consent form approved by Inonu University's Local Ethics Committee.

The criteria used in selecting patients were the existence keratinized gingiva ≤1 mm on the facial aspect of the mandibular anterior area generally, good periodontal health, the ability to understand verbal or written instructions, no use of systemic medications (i.e., sedatives, muscle relaxants, anti-inflammatory medications, and narcotic analgesics) within the past 3 months, and no record of allergies. The exclusion criteria of this study were identified smokers and pregnancy/breast-feeding for women.

Study design and treatment protocols

The study design was a randomized, controlled clinical trial in single center, comparing the effects of four different cover methods on the discomfort of patients at the donor site after the FGG surgery.

Each patient's age, gender and date of birth were recorded and a medical history was taken. All patients clinic examinations were performed before four weeks from surgery, and they received periodontal therapy consisting of thorough oral hygiene instructions. The examination included assessing plaque index (PI) (17) bleeding on probing (BoP) (18) probing pocket depth (PPD) and clinical attachment level (CAL). Clinical parameters were measured at six sites per tooth (mesio-buccal, buccal, disto-buccal, disto-lingual, lingual, and mesio-lingual) in all teeth, except third molars, using a Williams probe (PCP- 12, Hu-Friedy, Chicago, IL, USA).

The participants in the study were selected from patients with keratinized gingiva ≤1 mm on the facial aspect of the mandibular anterior area who needed to increase the width of the keratinized gingiva. Four weeks before surgery, all patients were made SRP and were given oral hygiene instructions. The present study was performed on 4 groups consisting of 12 patients each, selected randomly, using different cover techniques to protection wounds in the palate: group A, periodontal dressing (PD); group B, Essix retainer (ER), group C, modified Essix retainer (MER); and group D, modified Hawley retainer (MHR). Two weeks before surgery, impressions were taken from 36 randomly selected patients. They were given ERs (n=12), MERs (n=12), and MHRs (n=12). The patients were asked to come back 1 (T1) and 2 weeks (T2) after surgery (Figure. 1).

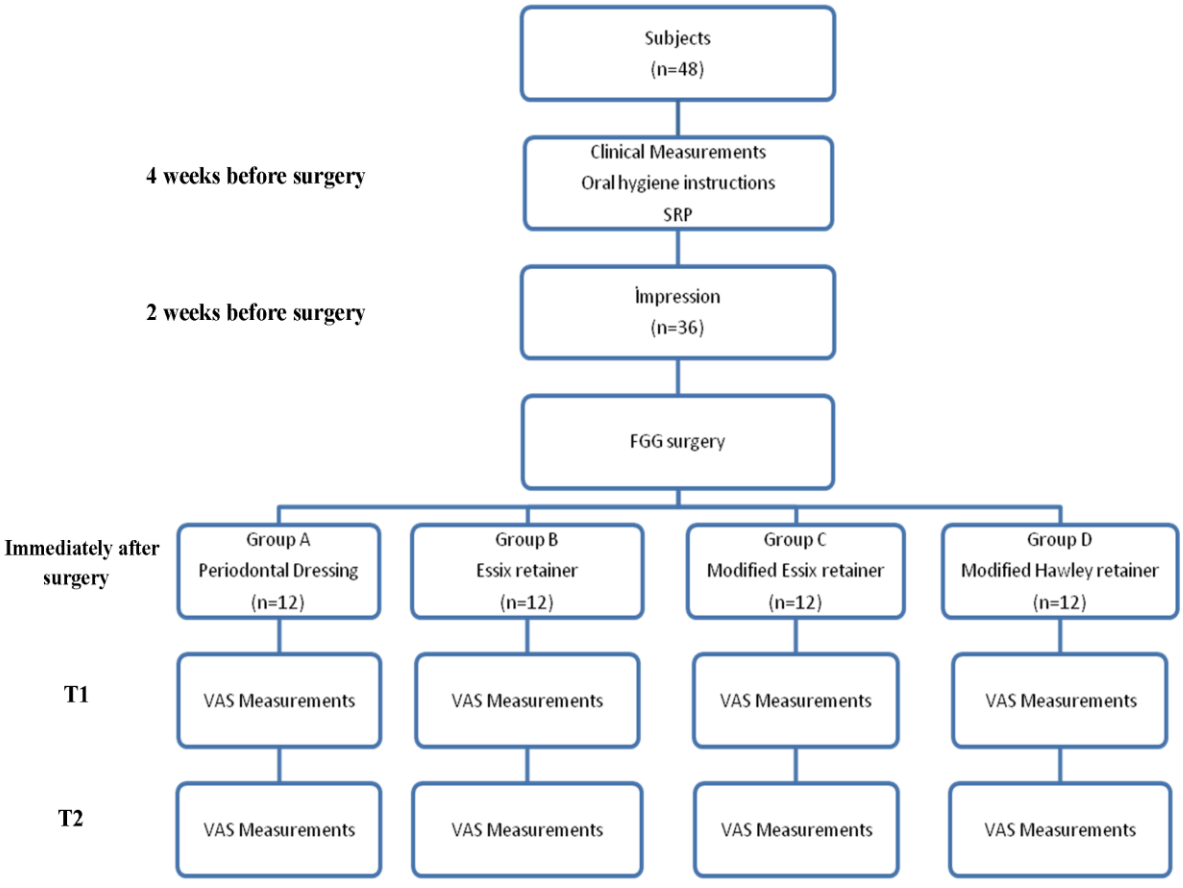

Figure 1. Study design from screening to completion of the trial

T1= 1 week after surgery; T2= 2 week after surgery; SRP= Scaling and Root Planning; VAS= Visual Anolog Scala.

Surgical procedure

All patients received same surgical technique, and to minimize variations in surgical technique, all surgical procedures were carried out by one surgeon (A.E.). Briefly, the following steps were performed in the sequence described.

Recipient site preparation

The recipient site was prepared similar to the technique described by Langer and Langer (19). After adequate local anesthesia was obtained, a marginal, horizontal, linear incision was made in the mucogingival junction with a number 15 scalpel. A split-thickness incision was extended

distally 1 to 2 teeth farther than the planned graft area (20). The raised tissue was discarded, and a periosteal bed was prepared. Gauze moistened with saline was placed over the recipient bed until graft placement.

Graft harvesting

Following the establishment of anesthesia by local infiltration (2% lidocaine with 1:100,000 epinephrine), a graft was intended to be harvested from the donor region, and the area chosen to harvest the graft was between first premolar and first molar, located ≥2 mm distant from the gingival margins of the corresponding teeth by a partial thickness incision (Figure 2). A number 15 scalpel was used to harvest the tissue at 1-2 mm of thickness. The graft thickness was immediately confirmed with a caliper at 3 points (ends and center of the graft), and if necessary, we prepared to obtain a graft approximately 1 to 1.5 mm thick, and the graft was then trimmed to adapt to the shape and size of the recipient site.

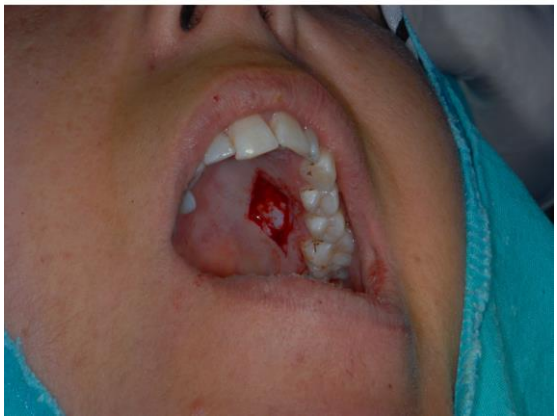

Figure 2. Image of donor area after surgery.

Graft placement

The graft was positioned and firmly adapted to the recipient area and stabilized with knotted sutures (5-0 silk). The coronal part of the graft was positioned at the MJG level, and then the suture was tied to adapt the graft firmly in this position; no attempt was made to cover the roots. A mild compress with gauze soaked in saline was also applied for 5 min.

Cover of donor site

After a gingival graft was taken from the palate, the donor area was washed with sterile saline, and hemostasis was achieved with moistened gauze in saline. Later, 4 different cover techniques were applied over the donor area to protect the surgical region. In group A, the donor area was covered with periodontal dressing **(**Coe-Pak, GC America, Alsip, IL) (Fig. 3A).

An essix retainer was adapted to the site using a regular-set periodontal dressing in group B. A modified essix retainer was adapted to the site using a regular-set periodontal dressing in group C. A modified Hawley retainer was adapted to the site using a regular-set periodontal dressing in group D.

Postoperative care

After surgery, routine written and oral postoperative care instructions were given to the patients. The patients were prescribed a non-steroidal anti-inflammatory analgesic for 1 week and 0.12% chlorhexidine rinsing. The patients were instructed to rinse gently twice daily for 3 weeks. Tooth-brushing activities in the operated sites were discontinued during this time. The sutures were removed 2 weeks after surgery. The cover methods for the donor sites were routinely used for the first 2 postoperative weeks, and the cover materials were removed 2 weeks after the surgery. Patients in groups with retainers were instructed to wear their retainers full-time for 2 weeks. In group A, a new periodontal dressing was placed 1 week after surgery.

Pain and discomfort assessments

A VAS was used to measure the experienced postoperative pain and discomfort (chewing, speaking, and appearance). The VAS was administered in a standard manner, with the initial explanation given by the same clinician to all participants (M.O.U.). All assessments were performed in the morning at the same clinic, free of extraneous noise, music, or conversation. All patients were asked to define their level of discomfort on the VAS, consisting of a scale from 0 to 100 (a 10-cm line). On this scale, 0 and 100 represented ''no pain or discomfort'' and ''the worst pain or discomfort imaginable,'' respectively.

All patients were asked to rate their bleeding experience at T1 and T2. The answers were "yes" (was bleeding) or "no" (was not bleeding). Bleeding experience was calculated as a percentage as follows:

$$\text{Bleeding Score (\%):} \quad \frac{\text{Patients who answered "Yes" (n)}}{\text{All patients (n=12)}}$$

The construction of essix, modified essix and modified hawley retainers

Maxillary and mandibular alginate impressions were taken to encompass the complete dentition and one-third of the alveolus for patients in groups with retainers. A working cast was obtained. After the estimated borders of the donor site were determined on the working cast (Fig.4A), a metal sheet was placed, which was 1 mm wider than the borders and 2 mm thick, to create a space for periodontal dressing, and this sheet was fixed on the cast with wax (Fig.4B). In addition, an Adams hook was made around the first molar and the hook dropped between the first and second premolars over the casts of MH retainers.

The retainers were formed by the action of heat from 1.00 mm (0.040 inches) on copolyester essix sheets (Dentsply Raintree Essix, New Orleans, Louisiana, USA), which was thermoformed to a thickness of 0.015 inches. The retainers for each group were shaped with burs and scissors. As the retainers in group B completely covered on the palate, they were formed in a U shape on the palate in groups C and D.

The ERs completely covered the maxillary teeth. At the same time, this retainer extended 3-4 mm onto the buccal surface of the teeth (Fig. 3B). The MER, which was on the occlusal and buccal surfaces of the premolar and molar teeth, was similar to group B; however, it covered only the palatal surface of the incisor teeth (Fig. 3C). The MHR covered only the palatal gingiva of all the maxillary teeth (Fig. 3D). The retainers were adjusted for comfort. They were polished and finished.

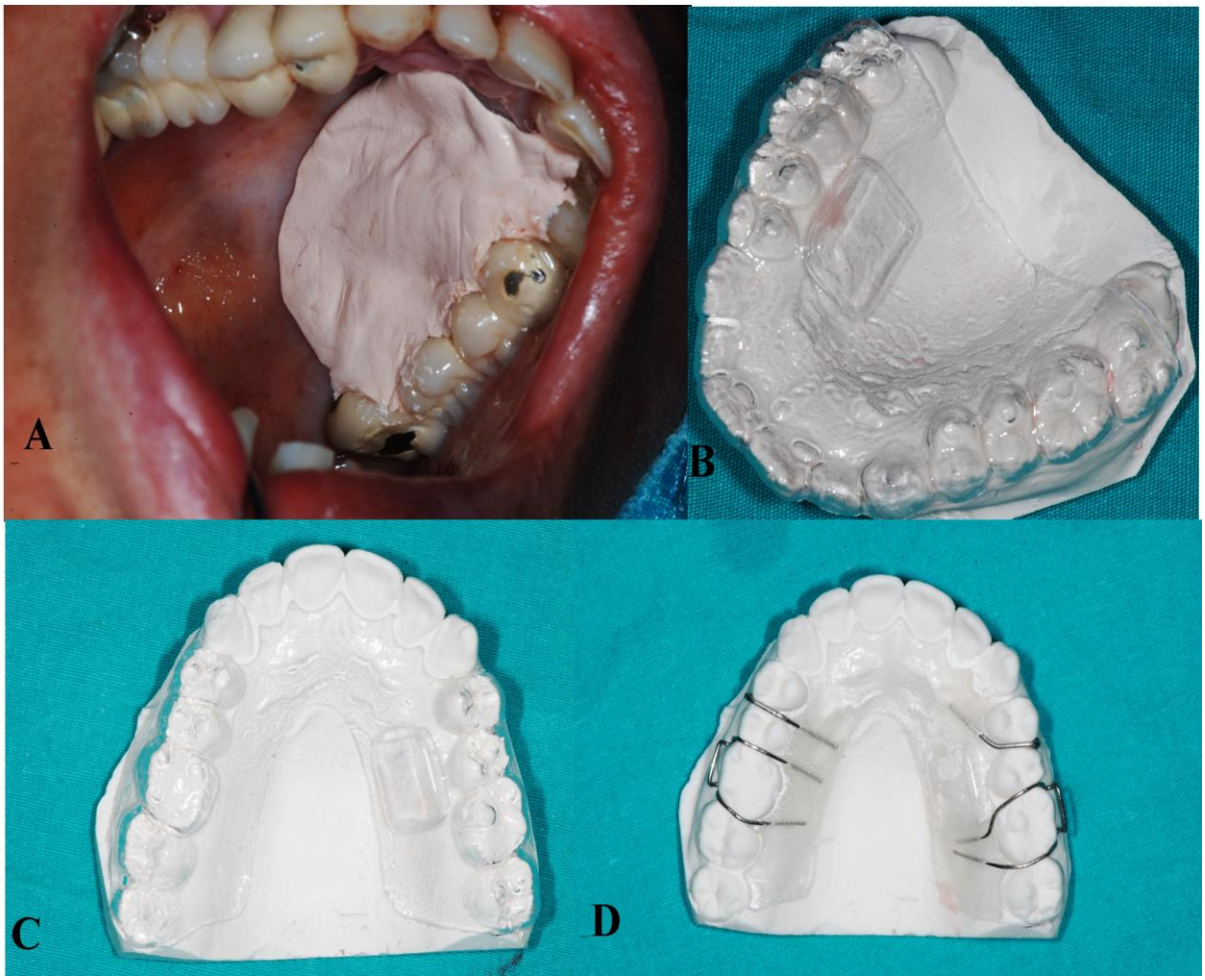

Figure 3. The application of cover teqhnicues . A- Periodontal dressing (Group A). B- Essix retainer (Group B). C- Modified essix retainer (Group C). D- Modified hawley retainer (Group D).

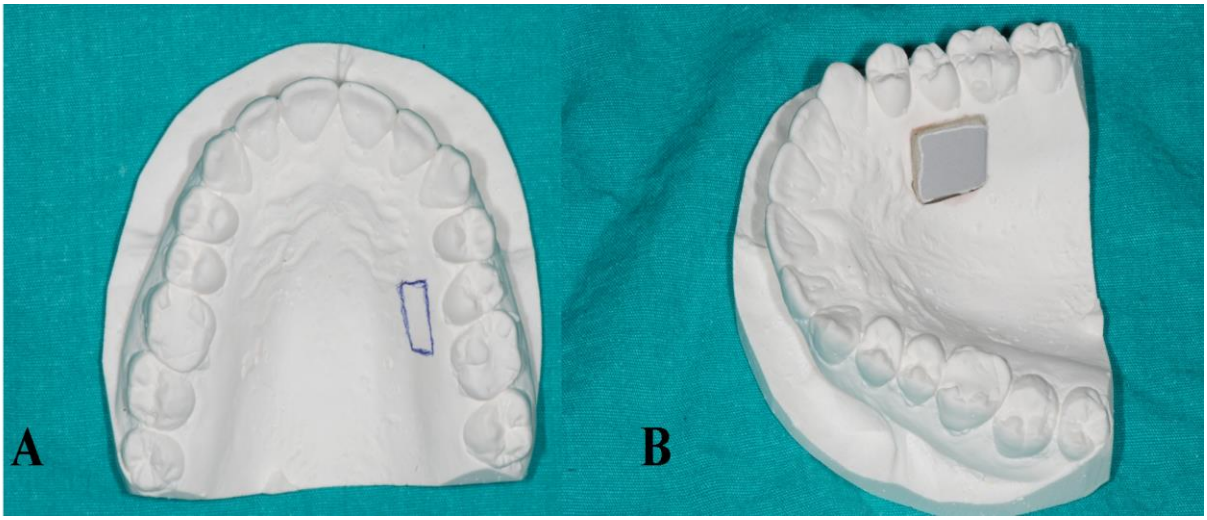

Figure 4. The working cast. A- estimated borders of the donor site, B- metal sheet was fixed.

Statistical analysis

These results were analyzed using a statistical package (SPSS statistical package version 16.0, SPSS for Windows, SPSS, Chicago, IL). A descriptive analysis was conducted (mean, standard deviation, and frequency distribution) for the collected data. Friedman and Wilcoxon tests were used to evaluate statistically the differences between T1 and T2. Differences among the groups were determined by the Kruskal–Wallis and Mann-Whitney U tests. A P-value < 0.05 was considered statistically significant.

Results

The characteristics of the patient sample are presented in Table 1. The initial statistical analysis revealed no statistical differences in age, sex, or clinical scores (PI, BoP, PPD and CAL) among the groups at the baseline examination.

Table 1. Demographic Characteristics and Clinical Parameters of study populations at Baseline (n = 48)

	Group A	Group B	Group C	Group D	p
Gender					
Male (n)	6	6	6	6	NS
Female (n)	6	6	6	6	
Age (Years; mean ±SD)	29	31	30	30	NS
Age Range (Years)	21-36	23-38	24-36	23- 37	NS
PI (%; mean±SD)	27±14	22±14	25±12	29±14	NS
BoP (%; mean±SD)	23±12	19±10	22±10	27±13	NS
PPD (mm; mean±SD)	3.2±0.4	3.5±0.4	3.2±0.4	3.3±0.5	NS
CAL(mm; mean±SD)	3.2±0.4	3.3±0.5	3.1±0.5	3.2±0.4	NS

N.S. not statistically significant at P value > 0.05.
PI= Plaque index; BoP= Bleeding on probing; PPD= Probing pocket depth; CAL= clinical attachment level.

The mean changes in the VAS scores of the groups are shown in Table 2. The reduction in the pain levels in all groups between T1 and T2 was statistically significant. It was seen that the mean VAS scores for pain were higher in group A than in the groups with retainers for both assessments, but there was only statistically significance at T1. There was no statistically significant difference in pain levels among groups with retainers at either T1 or T2 (Table 2).

Table 2. The compared inter- and intragroup VAS scores (mean ± SD)

	Group A	Group B	Group C	Group D
Pain				
T1	67±19	41±13†	44±16†	45±13†
T2	30±9 **c**	21±9 **c**	23±7 **c**	22±6 **c**
Discomfort in chewing				
T1	75±23	71±23	69±19	69±22
T2	37±11 **c**	51±14† **a**	50±16† **a**	50±14† **a**
Discomfort in speaking				
T1	34±12	56±19†	45±17†‡	46±14†‡
T2	9±6 **b**	42±13† **NS**	27±12†‡ **b**	29±10†‡ **b**
Discomfort in appearance				
T1	15±11	38±19†	18±11‡	24±14‡
T2	7±5 **NS**	29±14† **NS**	10±7‡ **NS**	13±9‡ **NS**

T1 = first week after surgery; T2 = second week after surgery.
[a] $P < .05$; *P*-values represent the difference between T1 and T2 within each treatment group.
[b] $P < 0.01$; *P*-values represent the difference between T1 and T2 within each treatment group.
[c] $P < 0.001$; *P*-values represent the difference between T1 and T2 within each treatment group.
† $P < 0.05$; *P*-values represent the difference from group A.
‡ $P < 0.05$; *P*-values represent the difference from group B.

The results of the present study demonstrated that the reduction in chewing discomfort levels in all groups between time points after surgery was statistically significant ($p<0.05$). A statistically significant difference was not found in the patients' chewing discomfort levels among the groups at T1 ($p>0.05$). The mean chewing discomfort VAS scores were significantly lower group A than in groups B, C, and D at T2 ($p<0.05$). There was no statistically significant pain level difference among groups B, C, and D at either T1 or T2 (Table 2)

The average decrease in the patients' speaking discomfort from T1 was obvious at T2 in all groups except group B ($p<0.01$). The VAS scores concerned with speaking discomfort were significantly lower in group A than in groups B, C, and D at both T1 and T2; in addition, scores were significantly lower in groups C and D than in group B at T1 and T2.

The present study showed that the average change in the patients' appearance discomfort was not statistically different between T1 and T2 in all groups. There were few complaints with regard to appearance at both assessments ofpatients with PD, and the scores of this group were lower than other groups. In the other groups, the appearance VAS scores were significantly greater in group B than in groups C and D at both T1 and T2. The complaints of postoperative bleeding in all groups are shown in Table 3. While bleeding was significantly more common in group A than in the other groups at T1 and T2, the differences among groups B, C, and D were not significant.

Table 3. Compared inter- and intragroup postoperative bleeding.

	Postoperative Bleeding			
	Group A % (n)	**Group B** % (n)	**Group C** % (n)	**Group D** % (n)
T1	58 (7)	17(2)†	17(2)†	17(2)†
T2	25 (3)	8 (1)†	8 (1)†	8 (1)†
	b	NS	NS	NS

N.S. not statistically significant at P value > 0.05.
† $P < 0.05$; *P*-values represent the difference from group A.

Discussion

This research attempted to answer questions concerning patients' discomfort with different cover methods (PD, AS, MAS, and MH) that are used to guard the donor site after FGG surgery. The outcomes showed significant differences among groups for postoperative patient discomfort. Pain VAS scores and postoperative bleeding in the groups with retainers were lower than the PD group; however, speaking and appearance VAS scores in the PD group was lower than in the groups with retainers. This was the first study designed to compare the effects on patients' discomfort of cover methods at the donor site for FGG.

The FGG surgical wound heals with secondary intention within 2-4 weeks, due to the removal of the epithelial layer of the palatal mucosa (21). Del Piezzo et al. (15) reported that complete epithelialization of the palatal wound occurred 4 weeks after FGG surgery. Our study was consistent with previous studies; palatal wounds healed in all patients completely at between 2 and 4 weeks, and no wound-healing effect was seen with any of the cover techniques in this study.

Previously reported FGG has been associated with a high incidence of donor site pain (15, 16, 22); however, investigations of this issue have been limited. There has been only one study in the literature that evaluated postoperative pain at the donor site following FGG using a VAS (16). That study's authors reported that the mean VAS pain scores at 3 days and 3 weeks postoperatively were 48 and 36, respectively, for FGG subjects. In our study, the mean VAS pain scores at T1 and T2 were 41 and 21, respectively, for the AS patients (group B). The present study results were similar to those from Vessel et al.'s (16) report for the first week; however, even the mean VAS pain score for the second week in this study was lower than Vessel et al.'s at the third week. In our opinion, this situation may have been caused by differences in wound healing. The present study showed that the mean pain VAS scores at T1 were higher in patients with PD than in other groups. According to our concept, patients who received ER, MER, and MHR experienced less pain due to a reduction in pressure over the wound at the donor site. By the second week, as epithelialization increased, it reduced pain levels in all groups. Therefore, the differences between the groups were decreasing in the second week, and these values were not statistically different. The results of this study concerning bleeding showed similar changes in VAS scores for pain, but bleeding scores saw statistically significant reduction from T1 to T2.

In recent years, patients' comfort has found an important place in healthcare (23, 24). Thus, the purposes of this study were to evaluate the effects of wound-healing at the donor site after FGG surgery, to determine which of the patients' discomfort levels were affected, and to compare the effects of the different cover techniques. According to the results of this study, important restrictions were seen of the functions related to patient comfort at the donor site. We detected that these restrictions caused pain in PD users, caused by the structure of retainers. Reducing pain via increasing epithelialization in the second week may lead to an increase in patients' comfort. In groups with retainers, patients' comfort was increased in the second week due to patients gaining more familiarity with their retainers.

In last decade, the most popular procedure for an edentulous mandible was the presence of keratinized tissue increasing in association with palatal mucosal grafts around the implants (25, 26). These patients are usually older, and this process is more difficult for them to tolerate. In this respect, the importance of patients' comfort after FGG increases further. At the end of the present study, although the use of the retainers reduced pain and bleeding, ER in particular could still lead to discomfort, seen in increases in the mean VAS scores concerning speaking and appearance. The reason for this situation is associated with their structures, but there are no data in the literature about the effects on daily life of retainers. In our opinion, the use of MER in patients with upper jaw teeth increased comfort, and the use of ER in edentulous maxilla was more useful in terms of pain.

As a result of this study, it was seen that all methods have some advantages and disadvantages. While MER and MHR are most appropriate in terms of pain and bleeding, PD is most appropriate for speaking and appearance comfort. After such surgeries patients with some particular professions which necessitate a comfort in speaking (for example a teacher) may not prefer a method, which complicates pronunciation of the words. In addition, pain and bleeding scores were higher in group A than in other groups in the first week, but scores in group A were similar to groups with retainers in the second week. Therefore, we believe there is no need for the application of retainer in the second week.

Conclusion

Complaints about the donor site after FGG surgery may be reduced with cover techniques. In particular, MER and MHR retainers showed reductions in pain and bleeding, thus increasing patients' comfort. In our opinion, new approaches are needed to reduce patients' discomfort at the donor site after FGG surgery, and patient expectations may be detrimental in selection of cover method after FGGs.

Conflict of interest: We have not a financial relationship with the organization that sponsored the research.

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