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Research

Pre-operative, chair-side Zn-containing surgical stents affect morbidity and wound healing after free gingival graft harvesting: a randomized clinical trial

Bahar Alkaya ✉ Affiliationids : Aff1, Correspondingaffiliationid : Aff1
Hamza Gokhan Kayhan Affiliationids : Aff1
Andy Temmerman Affiliationids : Aff2
Mehmet Cenk Haytac Affiliationids : Aff1
Wim Teughels Affiliationids : Aff2

Aff1 Department of Periodontology Faculty of Dentistry, Cukurova University, Adana, Turkey

Aff2 Department of Oral Health Sciences, KU Leuven & Dentistry (Periodontology), University Hospitals Leuven, Louvain, Belgium

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Abstract

Objective

To compare a AQ1 pre-operatively, AQ2 chair-side made, zinc-containing surgical stent (ZN) and suturing of a gelatin-based hemostatic agent (HA) on palatal wound healing and patient morbidity after free gingival graft surgery (FGG).

Materials and methods

Sixty patients requiring FGG were randomly divided into two groups to receive either a ZN or a sterile HA sutured on the surgical area. Patients were evaluated at 1st, 3rd, 7th, 14th, 28th, and 56th days following surgery. Overall surgical time, donor site surgical time, postoperative pain (PP), delayed bleeding (DB), changes in dietary habits (DH), burning sensation (BS), completion of re-epithelialization (CE), and patients' discomfort (PD) were evaluated.

Results

Donor site surgical time, PP, DB, DH, BS were statistically significantly lower in the ZN group together with faster completion of re-epithelialization compared to the HA group.

Conclusion

Pre-operatively, chair-side made, zinc-containing surgical stents provided significant benefits for wound healing parameters and patients' postoperative morbidity after FGG harvesting.

Clinical relevance

The results show that using Zn-containing palatal stent after free gingival graft surgery significantly reduces pain and patient morbidity during the postoperative period.

Keywords

Zinc-embedded polymer
Free gingival graft
Wound healing
Palatal stent

Introduction

Bjôrn defined AQ3 the free gingival graft (FGG) in 1963 to increase the amount of keratinized gingiva around teeth [1]. Sullivan and Atkins subsequently modified and improved the surgical approach [2]. The FGG approach is based on acquiring a palatal graft containing epithelium and connective tissue and placing it on a connective tissue bed prepared at the recipient site. It is routinely used and is a highly predictable procedure in mucogingival surgery [3]. In the presence of mucogingival problems such as insufficient attached gingival width, high frenulum attachments, and shallow vestibulum depth, FGGs are often used [4].

Numerous studies have described paresthesia, herpetic lesions, mucocele, profuse bleeding, and severe postoperative discomfort after harvesting a FGG [3, 5, 6, 7, 8]. The most pain is perceived at the palatal region after harvesting a FGG on the first postoperative day and returns to preoperative levels approximately 2 weeks later [9]. Hemostatics [10], bioactive substances [11], antibacterial and antiseptic agents [12], herbal products [5], platelet concentrates [7, 8], low-dose laser applications [13] cyanoacrylate tissue adhesives [14], hyaluronic acid [14], and palatal stents [15, 16] have been used at the palatal region to accelerate healing, prevent or decrease complications, and patient morbidity. However, the most optimal adjunct has not yet been identified. Mechanical protection of the post-harvesting palatal wound was first introduced by Langer and Langer [17]. It is the most common and accepted method and can be considered as the gold standard approach. Since it is known that the stability of the formed blood clot is one of the most crucial aspects for successful wound healing, several mechanical techniques have been used to protect the palatal clot until healing has occurred [18]. Although scientific evidence is limited, mechanical protection techniques such as palatal surgical stents are regarded as effective means to control pain and palatal bleeding [18]. Such stents should be fabricated from inert, stable, and biocompatible materials [19]. After FGG harvesting, many studies reported reduced postoperative pain and discomfort in patients utilizing such palatal stent [13, 15, 18, 20]. A disadvantage of employing palatal stents is that they must be prepared before the surgical procedure. They are often fabricated by a dental laboratory from (digital) impressions, which incurs additional costs and time investment for the patient and practitioner.

The objective of this randomized clinical study was to assess the early healing outcomes of the palatal wound following FGG harvesting with suturing a gelatin-based hemostatic agent versus the use of a pre-operatively, chair-side made, surgical stent from thermoplastic Zn-containing polymer granules.

Materials and methods

The study was approved by the Cukurova University Faculty of Medicine Clinical Research Ethics Committee (Decision No:120–55). Between March 2022 and November 2022, the study was conducted at the Department of Periodontology of the Cukurova University (Adana, Turkey), in compliance with the principles of the 2008 Declaration of Helsinki. Before enrollment in the study, patients were provided verbal and written information regarding the nature, purpose, potential risks, and benefits of the study. Informed consent forms were obtained from each patient. The study was conducted according in accordance with the Consort guidelines and registered at clinicaltrials.gov (NCT05684913).

Sample size

G*Power, 3.1.9.7 (Düsseldorf, Germany) was used to determine the sample size. The primary outcome was postoperative pain. The magnitude of the intergroup difference was chosen based on earlier evidence of reduction in palatal pain by Keceli et al. [5] (6.25 ± 1.80 in the control group versus 4.41 ± 1.58 in the test group). With the calculated effect size ($d = 1086$), 95% power, and 5% error, it was determined that a minimum of 50 persons, 25 in each group, should be included in the study. Due to possible drop-outs, 30 patients in each group were treated.

Study design

The study was designed as a 2-arm, single-center (Cukurova University, Adana, Turkey), double-blinded, randomized controlled clinical trial (RCT). The study comprised a total of 60 individuals, 31 females, and 29 males, with a single gingival recession in the anterior maxillary or mandibular region and with shallow vestibule depth and inadequate attached gingival width. All patients received root

covering surgery using a FGG harvested from the masticatory mucosa of the palate. Participants were assigned at random into two groups. In the study group, a Zn-containing polymer (Oral Surgical Granulate®, Elemental, Belgium) was used to create chair-side and pre-operatively a stent for the palatal region, whereas in the control group, an absorbable haemostatic gelatin sponge (Spongostan®, Clinisponge, Turkey) was sutured on top of the surgical area with a single compression suture. The wound healing outcomes of the palatal region, pain, and discomfort were compared between the two groups.

Inclusion criteria:

- Periodontally and systemically healthy
- ≥ 19 years old
- Amount of attached gingival width in the maxillary or mandibular anterior region < 2 mm
- Full mouth plaque score and bleeding on probing score < 15%
- A minimum of 4 mm of palatal tissue thickness (measured in the mesial, central, and distal parts of the designated area for graft harvesting by using a endodontic spreader) in order to ensure at least 2 mm remaining connective tissue after FGG harvesting [21]

Exclusion criteria:

- History of palatal graft harvesting
- Presence of systemic disease
- Utilization of medication known to impair periodontal health or delay wound healing
- Smoking

Randomization

Randomization was performed by a study coordinator (WT) who was not actively involved in the clinical trial using a computer program (www.randomizer.org). Each patient could participate in the study only once and was therefore enrolled in only one of the study groups. Allocation was concealed in opaque sealed envelopes which were opened pre-operatively after harvesting the palatal graft. For standardization, all surgical treatments were performed by the same experienced periodontist (BA).

Surgical technique and clinical procedures

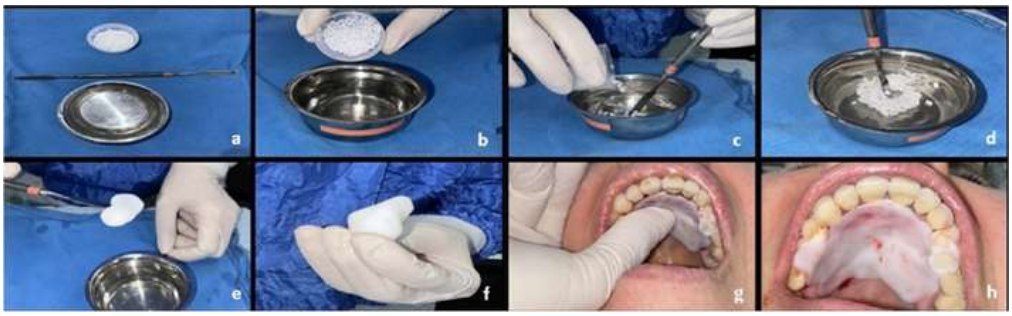
Before the procedure, all patients received oral hygiene instructions and had their teeth scaled and polished. Patients only underwent surgical treatment when good plaque control was ensured (full mouth plaque and BOP scores < 15%). The FGG was harvested from the palate of both groups using the procedure described by Sullivan and Atkins [2].

Two horizontal incisions were made, with the coronal incision 2 mm apical to the gingival margin of the adjacent teeth and two vertical incisions were traced to delineate the graft site. The blade was inserted along the coronal horizontal incision at one edge perpendicular to the bone. Once the adequate thickness of the graft was obtained (1.5 mm), the direction of the blade was changed to be parallel to the hard palate and moved in mesio-distal direction elevating the graft at one side until it became completely detached from the palate. The size (5 × 8 mm) and thickness (1.5 mm) of the graft were kept constant while the blade was advanced apically. Care was taken to avoid removing the palatal periosteum. After graft harvesting, the sealed and opaque envelope containing the to-be-applied wound management method was opened and the patients were assigned to the irrespective study group:

1. Zn-containing granulate stent (ZN): Immediately following harvesting the FGG from the palate, hemostasis was achieved with sterile moist gauzes, and a surgical stent was produced in accordance with the manufacturer's instructions. Briefly, 10 g of granulate were placed into hot water (70 °C) and then manually molded to cover the surgical site. Slight manual pressure was applied on the palatal wound to maintain hemostasis. If needed, the teeth's palatal, occlusal, and buccal surfaces were included in the stent to ensure retention. The patients were instructed on how to wear and remove the stent and informed not to chew anything while wearing the stent. They were asked to wear the stent for seven days, except during meals (Fig. 1).
2. Hemostatic agent suturing (HA): Wet sterile gauzes were used to achieve hemostasis immediately following FGG harvesting. An absorbable haemostatic gelatin sponge was then sutured with 4.0 vicryl sutures (Glikolak, Turkey) over the palatal wound. The sutures were removed on the 7th day.

Fig. 1

The preparation AQ4 of Zn-containing granulate stent. Granulates were placed into hot water (70 °C) and then manually molded to cover the surgical site



The total duration of the surgery and the graft harvesting procedure (FGG harvesting + preparation of the stent in the ZN group and FGG harvesting + suturing of the hemostatic agent in the HA group) were recorded.

The FGG was placed on sterile gauze with saline to prevent the graft from shrinking. The graft was then adapted to the recipient site and firmly anchored with two simple interrupted periosteal sutures and a crossed sling suture using 5–0 Vicryl® (Glikolak, Turkey). A saline-soaked gauze was applied to the recipient site for 2 min. All patients were instructed to use NSAID's TID if necessary and a 0.12% chlorhexidine mouth rinse (Klorhex solutions, Drogsan, Turkey) for plaque control. Tooth-brushing in the surgical sites was discontinued during this period. After 14 days, the sutures were removed from the recipient site.

Patients were re-called on day 1st, 3rd, 7th, 14th, 28th, and 56th following surgery. The patients were requested to self-report:

Postoperative pain (PP): PP experienced by the patients as a result of palatal wound was graded from 0 to 10 (0: no pain, 1: minimal pain, 10: severe pain) using a VAS. Patients were instructed to distinguish between pain at the palatal site and pain at the recipient site and to only assess the palatal discomfort. The patient's reported systemic analgesic use over a 7-day postoperative period was also documented (in milligrams) using a diary in which they recorded their daily usage of systemic analgesics.

Delayed bleeding (DB): DB of the palatal wound was described as prolonged bleeding after surgery and was documented as "yes" (presence of bleeding) or "no" (absence of bleeding) by the patient 7 days postoperatively.

Burning sensation (BS): BS was evaluated by asking the patient the degree of burning sensation of the palatal wound they experience via VAS scores (0: absent, 10: severe burning) on the 1st, 3rd, 7th, 14th, 28th, and 56th day.

Changes in dietary habits (DH): DH was assessed by inquiring about the patient's difficulties to chew due to the palatal wound via VAS scores (0: no change 10: not capable of eating) on the 1st, 3rd, 7th, 14th, 28th, and 56th day.

The following clinical evaluations were conducted by a periodontist (HGK) who was not engaged in any stage of the surgery and who was blinded (except for the first week when the sutures were in place for the control group) and calibrated.

Completion of re-epithelialization (CE): CE was clinically evaluated using the 3% hydrogen peroxide (H_2O_2) test [22]. The wound area was irrigated with 3% H_2O_2 to observe bubbling. When the epithelial barrier is intact, H_2O_2 does not diffuse into the connective tissue, preventing the release of oxygen. CE was recorded as a three-way variable (yes/no/partially) when H_2O_2 application did not result in the formation of bubbles.

Patients' discomfort (PD): PD was evaluated by applying a dental unit air spray for 5 s to the palatal region, after which patients rated their sensation on the VAS (0: no discomfort, 10: extreme discomfort).

Statistical analyses

Categorical variables were expressed as numbers and percentages, whereas continuous variables were summarized as mean and standard deviation and as median and minimum–maximum where appropriate. Chi-square test was used to compare categorical variables between the groups. The normality of distribution for continuous variables was confirmed with the Kolmogorov–Smirnov test. For comparison of continuous variables between two groups, the Student's *t*-test or Mann–Whitney *U* test was used depending on whether the statistical hypotheses were fulfilled or not. Repeated measures ANOVA was performed while comparing trend of PP between study groups. All analyses were performed using IBM SPSS20 (Armonk, NY: IBM Corp.). The statistical level of significance for all tests was considered to be 0.05.

Results

The study included sixty subjects. Age (mean ZN group: 33.9 ± 10.8; mean HA group: 33.9 ± 11.3 $p = 0.997$) and gender distribution (ZN group: 12 females, 12 males; HA group: 14 females, 14 males; $p = 0.999$) did not differ between groups. Six patients in the ZN group and 2 patients in the HA group did not attend the follow-up appointments and were therefore omitted from the statistical analysis. With 52 patients, the trial was concluded (ZN group: $n = 24$, HA group: $n = 28$). No complications were observed at the donor sites following surgery (Figs. 2 and 3). In addition, there were no reported complications related to the wearing /removal or movement or fracture of the stent in the ZN group.

Fig. 2

Clinical view of the palatal wound healing of ZN group. **a** Before surgery; **b** after surgery; **c** postop 1st day; **d** 3rd day; **e** 7th day; **f** 14th day; **g** 28th day; **h** 56th day

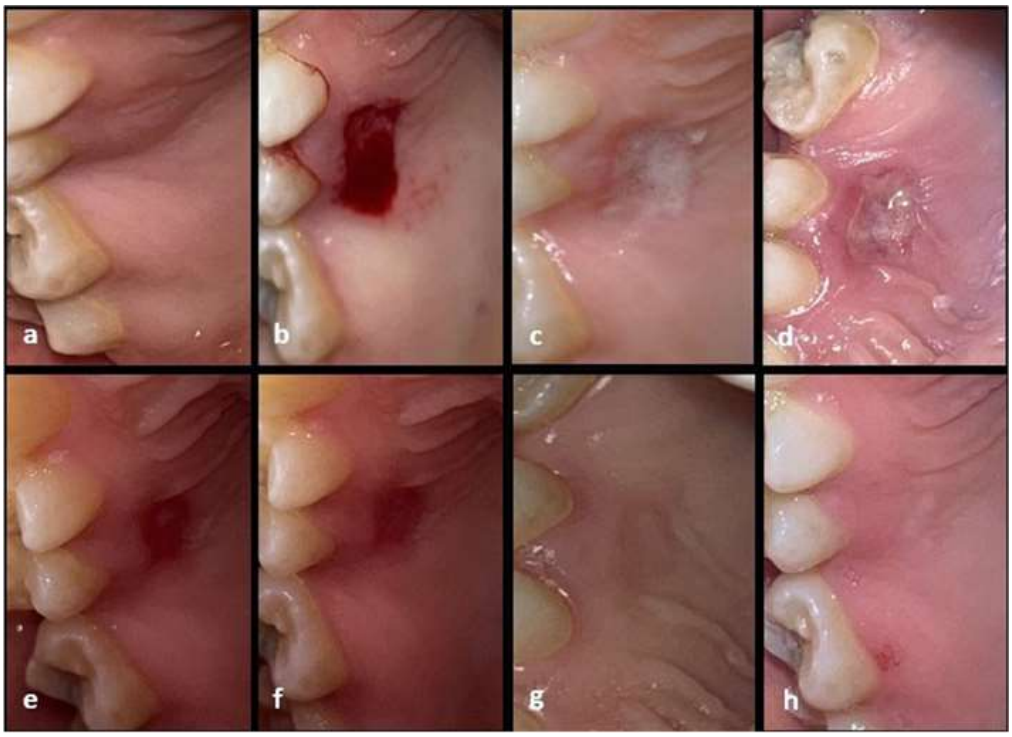
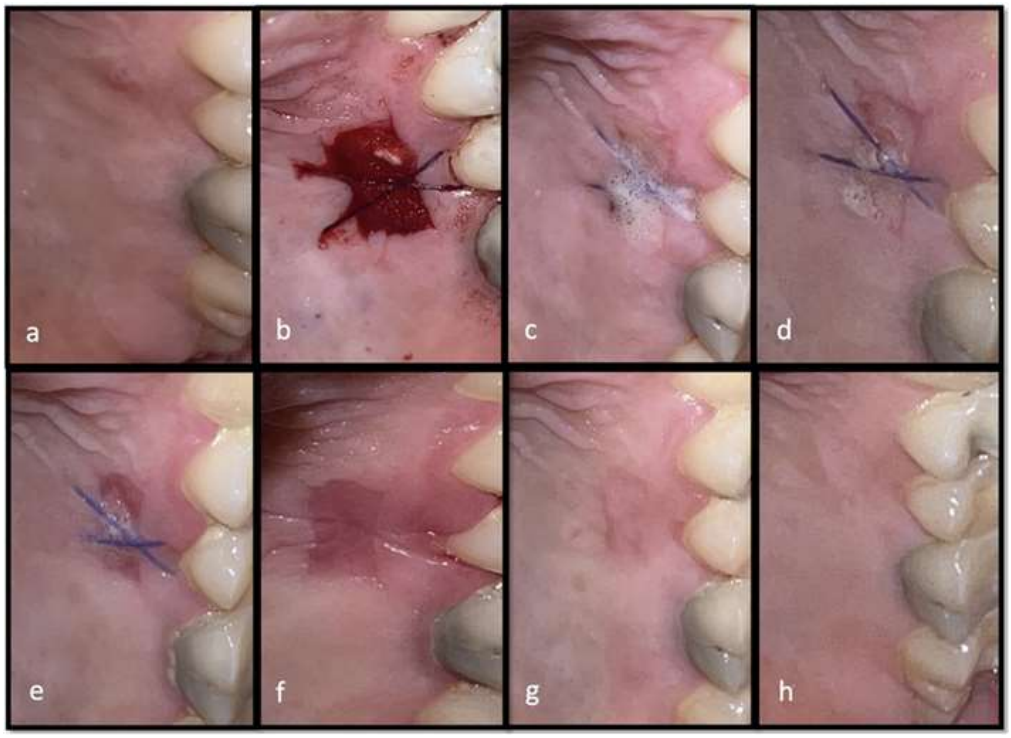


Fig. 3

Clinical view of the palatal wound healing of HA group. **a** Before surgery; **b** after surgery; **c** postop 1st day; **d** 3rd day; **e** 7th day; **f** 14th day; **g** 28th day; **h** 56th day

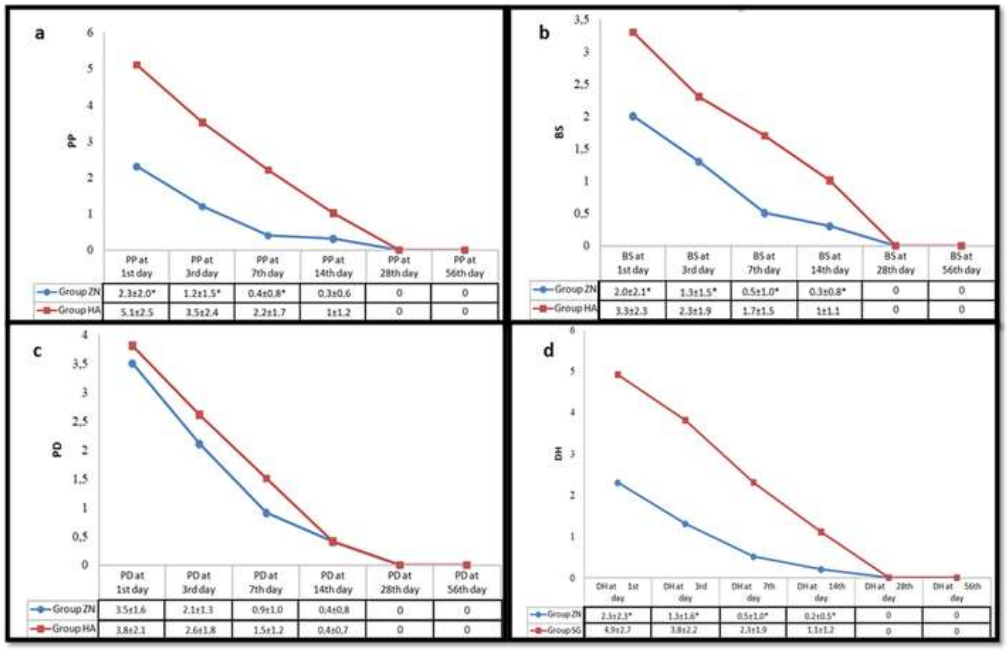


The patients in the ZN group had a considerably shorter overall surgical time (mean: 34.0 ± 4.0 min) than the patients in the HA group (mean: 39.4 ± 2.7 min) ($p \leq 0.001$). Similarly, the donor site surgical time was considerably shorter for the ZN group (median: 7 min, range: 5–9 min) against 13 min (range: 11–16 min) for the HA group ($p \leq 0.001$).

Figure 4a depicts the PP VAS scores at each time point. On day 1st, 3rd, 7th ($p \leq 0.001$ for all), and 14th ($p = 0.010$), the average pain level in the ZN group was significantly lower than that of the HA group. On day 28th and 56th, the pain levels for both groups were nil. Even though patients in the HA group took more analgesics than patients in the ZN group, there was no statistically significant difference between the two groups.

Fig. 4

a Intergroup comparison of the postoperative pain (PP) for a 56-day postoperative follow-up in FGG procedures. $^{*}p \leq 0.001$. **b** Intergroup comparison of burning sensation (BS) for a 56-day postoperative follow-up in FGG procedures. $^{*}p < 0.05$ BS, burning sensation. **c** Intergroup comparison of the patients' discomfort (PD) for a 56-day postoperative follow-up in FGG procedures. PD, patient discomfort. **d** Intergroup comparison of the parameter of changes in dietary habits (DH) for a 56-day postoperative follow-up in FGG procedures. $^{*}p < 0.05$



There was a statistically significant difference in DB on day 1 ($p = 0.003$) and 2 ($p = 0.001$) between the groups (Table 1). On the first postoperative day, four patients in the ZN group and 16 patients in the HA group reported DB. From day 2 on, there were no reports of DB in the ZN group and from day 4 in the HA group.

Table 1

$p < 0.05$ considered **AQ5** statistically significant for intergroup comparisons, Chi-square test

Number of patients (and%) experiencing DB	ZN ($n = 24$)	HA ($n = 28$)	p*
1st day	4 (16.7%)	16 (57.1%)	**0.003***
2nd day	0 (0.0%)	10 (35.7%)	**0.001***
3rd day	0 (0.0%)	1 (3.6%)	0.350
4th day	0 (0.0%)	0 (0.0%)	-
5th day	0 (0.0%)	0 (0.0%)	-
6th day	0 (0.0%)	0 (0.0%)	-
7th day	0 (0.0%)	0 (0.0%)	-
DB delayed bleeding			

Partial re-epithelialization was observed in 10 patients (41.7%) of the ZN group on the 3rd day; however, it was not observed in any patient (0%) of the HA group ($p \leq 0.001$) (Table 2). While CE was observed in all patients of the ZN group (100%) on the 28th day, CE was observed in 23 patients (82.1%) of the HA group. On the 56th day, all patients showed a CE of the grafted area (Table 2).

Table 2

$p < 0.05$ considered statistically significant for intergroup comparisons, Chi-square test

Number of patients (and %) with CE		ZN ($n = 24$)	HA ($n = 28$)	P*
1st day	**No**	24 (100%)	28 (100%)	-
	Partial	0 (0%)	0 (0%)	
	Yes	0 (0%)	0 (0%)	
3rd day	**No**	14 (58.3%)	28 (100%)	**< 0.001***
	Partial	10 (41.7%)	0 (0%)	
	Yes	0 (0%)	0 (0%)	
7th day	**No**	0 (0%)	0 (0%)	-
	Partial	24 (100%)	28 (100%)	
	Yes	0 (0%)	0 (0%)	
CE completion of re-epithelialization				

Number of patients (and %) with CE		ZN ($n = 24$)	HA ($n = 28$)	P^*
14th day	**No**	0 (0%)	0 (0%)	-
	Partial	24 (100%)	28 (100%)	
	Yes	0 (0%)	0 (0%)	
28th day	**No**	0 (0%)	0 (0%)	0.054
	Partial	0 (0%)	5 (17.9%)	
	Yes	24 (100%)	23 (82.1%)	
56th day	No	0 (0%)	0 (0%)	-
	Partial	0 (0%)	0 (0%)	
	Yes	24 (100%)	28 (100%)	
CE completion of re-epithelialization				

Both groups experienced a decrease in BS over time (Fig. 4 b). On the 1st ($p = 0.047$), 3rd ($p = 0.046$), 7th ($p = 0.003$), and 14th ($p = 0.022$) day, the average BS score was significantly lower in the ZN group than in the HA group. On the 28th and 56th day, neither group reported any BS.

Although the patients in the ZN group reported less PD than the patients in the HA group at each time point, there was no statistically significant difference between the groups ($p > 0.05$) (Fig. 4 c).

DH improved in both groups over time (Fig. 4 d). On the 1st ($p = 0.01$), 3rd ($p < 0.05$), 7th ($p < 0.05$), and 14th day ($p = 0.002$), the patients in the ZN group experienced a lower change in DH than patients in the HA group. On days 28th and 56th, the DH of both groups returned to normal.

Discussion

The purpose of this randomized controlled clinical trial was to assess the efficacy of a pre-operative, chair-side made, Zn-containing polymer palatal stent in reducing post-surgical patient morbidity following FGG harvesting. Compared to hemostatic suturing, the Zn-containing stents resulted insignificantly shorter surgical time, less pain, less bleeding, and faster re-epithelialization during the initial phase of wound healing.

The thickness of the palatal mucosa increases from incisal to molar, with an intermediate [23] and the palate mucosa in the premolar region is an ideal area to obtain grafts for anatomical reasons so that the graft is of sufficient thickness without any damage to the greater palatine artery [8, 24].

The primary outcome of the study was postoperative pain sensation, the most prevalent sequelae of FGG surgery [3, 18]. Postoperative pain is associated with increased morbidity, functional and quality-of-life impairment, delayed recovery time, prolonged duration of analgesic use, and higher health care cost [25]. In addition, the presence and intensity of acute pain during or after surgery is predictive of the development of chronic pain [20]. Patients are likely to experience intense pain during the first week following FGG surgery [5, 26]. Burkhardt et al. reported that patient-reported pain perception after palatal graft harvesting is directly related with the thickness of the graft. A thickness of ≤ 1 mm yielded significantly less pain compared to grafts with a thickness of > 2 mm. In the current study, graft thickness of 1.5 mm was standardized in all patients in order to reduce both pain and shrinkage of the graft [22]. The pain scores in the ZN group were significantly lower compared to the controls in the current study. While the average pain level of the control group was comparable to that reported in previous studies [5, 7, 16, 18], the ZN group provided significantly lower pain scores compared to a propylene mesh [18], an Essix retainer [16], cyanoacrylate [7], and medicinal plant extracts [5].

Concerning pain reduction, the current study also revealed that the Zn-containing stent promoted a faster re-epithelialization rate (up to day 28). Similarly, the duration of delayed bleeding was significantly shorter in the ZN group compared to the HA group during the initial 2 days.

The abovementioned beneficial effects of the Zn-containing stent can be attributed to 2 factors. Firstly, the physical barrier provided by the stent that provides mechanical and thermal protection of the wound, and improved stability of the blood clot at the initial stages of wound healing resulting in less postoperative pain, reduced postoperative bleeding time, and a faster re-epithelialization. Second, the integration of Zn nanoparticles in the polymer may also contribute to better healing. As an essential nutrient, zinc has many important biological functions, including wound healing, cell proliferation and division, and DNA stabilization and replication [23, 27, 28, 30]. Zinc incorporated in a polymer has been shown to increase surface hydrophilicity, inhibit the colonization and growth of bacteria, and in low concentrations increase cell proliferation [31] by passive action [32].

The result that ZN group patients experienced less pain than HA group patients in the 2 weeks following surgery may potentially also be attributable to the decreased surgical time associated with these stents. Due to the fact that there are two surgical sites, the length of the surgery is one of the downsides of the FGG procedure. Long surgical procedures can produce extensive tissue damage by prolonging the vasodilation time and causing high levels of release of biological mediators from inflammatory host cells [26]. Griffin et al. found a strong link between the duration of surgery and postoperative pain and swelling complaints in patients undergoing FGG surgery. Each surgical minute was associated with a 3% increase in swelling and a 4% increase in the risk of moderate or severe postoperative discomfort. Therefore, the use of the chair-side, per-operative made Zn stent, which led to a shorter surgical time, may have contributed to the lower postoperative pain and discomfort.

Other postoperative morbidity indicators, including burning sensation, air sensitivity, and dietary modifications, were all better in the ZN group than in the HA group. The patients in the ZN group reverted to their prior dietary patterns more rapidly than those in the HA group, from a clinical standpoint. In the study conducted by Del Pizzo et al. [33], it was found that persons who underwent FGG surgery were substantially more influenced in terms of changes in dietary habits than those who underwent CTG surgery [28]. In the study conducted by Ozcan et al. [7], the cyanoacrylate-covered group reverted to routine dietary practices more rapidly than the control group [7]. The physical covering of the palatal wound area may greatly minimize postoperative morbidity after FGG surgery, as suggested by these results.

Common limitations encountered in clinical trials evaluating donor recovery also apply to the current study. These are subjective methods, lack of histological evaluation, and wide ranges in subjective scoring systems. Additionally, since there was no stent control group without Zn, the specific contribution of Zn to these results remains to be determined. In addition, since there was not a non-application control group and since one study group received a stent while the other group had sutures, the examiner blindness was not possible for the first week when the sutures were removed. These limitations, therefore, may weaken the quality and validity of the outcomes of the study. Further randomized clinical trials with various control groups are needed to manifest the exact efficiency of zinc-containing surgical stent.

Conclusion

In conclusion, in the early phase of palatal wound healing, chair-side, pre-operatively made Zn-containing polymer stents were associated with significantly shorter surgical times and less postoperative pain and bleeding than hemostatic suturing.

Ethics approval

The study protocol, questionnaires, and informed consent forms in full accordance with the ethical principles of the Declaration of Helsinki, as revisited in 2000, were approved by Cukurova University Faculty of Medicine Clinical Research Ethics Committee and received the approval (Decision No:120–55). The study was registered at www.clinicaltrials.gov as NCT05684913.

Conflict of interest

Dr. Teughels and Dr. Haytac have received financial support for research from Elemental©-Zinkh NV. Other authors declare no conflict of interest related to the study.

Publisher's Note

Author contribution

Mehmet Cenk Haytac and Wim Teughels contributed to study conception and design. Bahar Alkaya performed all clinical procedures. Hamza Gokhan Kayhan was responsible for data collection and prepared the manuscript. Andy Temmerman performed the data analysis and prepared the manuscript. All authors critically revised the manuscript.

Data availability

The data that support the findings of this study are available on responsible request from the corresponding author.

Declarations

Competing interests Dr. Teughels and Dr. Haytac have received financial support for research from Elemental© -Zinkh NV. Other authors declare no conflict of interest related to the study.

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