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SOCKET PRESERVATION USING THE ICE CREAM CONE TECHNIQUE VERSUS SPONTANEOUS HEALING IN FRESH EXTRACTION SOCKETS

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ABSTRACT

Aim: The aim of this study is to compare horizontal and vertical dimensional changes in bone occurring after socket preservation using the Ice-Cream Cone technique using xenograft and collagen membrane versus spontaneous healing of the socket without addition of bone and barrier membrane.

Subjects and methods: Seventeen patients with twenty non-restorable single or double-rooted teeth, having a buccal bone defect were enrolled to the study. Sites were randomly allocated into two equal groups; the ice-cream cone technique group (test group) and the spontaneous healing group (control group). CBCT was used preoperatively and four months postoperatively to measure horizontal and vertical bone dimensional changes. Horizontal measurements were taken at 3,6, and 9 mm below the crest.

Results: Horizontal bone loss; measured at -3, -6, -9 mm from the crest, in the test group showed a median of 1.82 mm (-3.06 - 3.45), 1.6 mm (-2.39 - -1.25) and 1.67 mm (-3.33 - -0.63) respectively, while the control group showed a loss of 2.17 mm (-4.19 - -0.83), 1.36 mm (-2.33- -0.39) and 0.72 mm (-1.57 - 0.3) respectively not showing any statistical significant difference between both groups. Moreover, vertical bone changes showed a median buccal bone height loss of 0.77 (-3.75 - 5.07) in the test group and 1.22 (-3.66 - 2.53) in the control group while the palatal bone height loss was -0.84 (-1.87 - 2.2) in the test group and -0.58 (-3.5 - 0.87) in the control group. The difference between the two groups were also non-significant.

Conclusion: The ice-cream cone technique has well preserved the buccal and palatal vertical bone height with absence of a statistical significant loss. At the crestal region, non-significant bone loss occurred in the test group compared to a significant loss in the control group. However, no statistical significant difference appeared between the two groups suggesting no apparent effect of the ice-cream cone technique.

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INTRODUCTION

One of the most commonly damaging effect that occurs to the alveolar ridge in dentistry occurs after tooth extraction, where the most change occurs in the first 2-3 months. Unfortunately, the bundle bone is highly affected due to extraction as it loses its function till it eventually disappears. These changes might lead to vertical and horizontal resorption which could reach a noticeable vertical buccal loss at 8 weeks. As for the horizontal loss it was found to be approximately 50% of the ridge where two-thirds of that loss occurs in the first three months (**Schropp *et al.*, 2003; Araújo *et al.*, 2008; Chen and Darby, 2017**).

The reason for this resorption has been explained by the socket healing process that consists of three consecutive phases. An inflammatory phase, which starts with a blood clot formed in the socket to help stop the bleeding, followed by an inflammatory cell migration process where a granulation tissue is formed and then replaced by a provisional matrix containing cells and collagen fibers. The second phase begins with the proliferative phase where the provisional matrix is invaded by bone forming cells. These cells form a finger-like projection of woven bone around blood vessels forming osteons. This woven bone is a temporary kind of bone that doesn't have a load-bearing property and will then be replaced by mature bone. The third phase follows and is known as the bone modeling and remodeling phase. Bone remodeling is responsible for exchanging the formed woven bone by a mature type of bone, this process may take several months or years. While bone modeling is the one responsible for the resorption that occurs in the socket walls altering the dimension of the ridge. The cell responsible for this mechanism is the osteoclasts which starts invading the buccal and lingual plates and cause bone resorption. The buccal plate is highly affected due to its presence in narrow thickness when compared to palatal bone (**Araújo *et al.*, 2015**).

These events hinder an uncomplicated placement of an implant to restore the lost tooth (**Van der Weijden *et al.*, 2009**). Because of these events atraumatic extraction was shown to be of crucial importance as the first aid in ridge preservation (**Bartee, 2001**). Several atraumatic extraction techniques were proposed including periotomes, powered periotomes, piezo surgery, implant drill tooth removal and vertical extraction systems.

Thus, socket preservation protocols were introduced to minimize the loss of horizontal and vertical dimensions. Several techniques were introduced including different bone graft materials as autografts, allografts, xenografts and alloplastic materials (**Jambhekar *et al.*, 2015**).

Xenograft is a non-human bone that can be derived from several sources including bovine, porcine, equine and coralline xenografts. This type of bone has a well proved osteoconductive properties for bone formation (**AlGhamdi *et al.*, 2010**). Therefore, the use of xenograft has been proven beneficial in alveolar ridge preservation (**Llanos *et al.*, 2019**).

Barrier membranes were also used whether resorbable or non-resorbable in order to act as a barrier protecting the augmented area from the outer soft tissue. However, collagen membranes were the most utilized for socket preservation as it is highly accepted by patients due to its resorbability which does not require a second retrieval surgery. It is also an important component in the connective tissue and has a chemotactic effect on fibroblasts giving it an important property in enhancing bone regeneration (**Wang and Carroll, 2001; Bunyaratavej and Wang, 2001**).

One of the evolved methods of alveolar ridge preservation is the ice-cream cone technique introduced by **Elian *et al.* (2007); (Cardaropoli *et al.*, 2014)** for the treatment of type I and II socket defects using a combination of a bone graft and a collagen membrane that it is placed inside the socket resembling the buccal wall and preventing the soft tissue intrusion, allowing bone compaction towards the buccal tissue.

MATERIALS AND METHODS

Study settings

The present randomized, controlled, parallel-grouped trial included 20 sites. Seventeen patients were recruited in this study (2 males and 15 females) with age ranging between 20 to 55 years. Two of the patients with two defects for each, did not attend their follow up appointments, and were considered dropouts, which made a total of 18 sites that had completed their follow ups and were included in this study. Sites were randomly assigned into two equal groups; test group: where extracted sockets were grafted using the ice-cream cone technique or the control group; where sockets were left to heal spontaneously.

Subjects were selected from the outpatient clinic, Department of Oral Medicine and Periodontology, Faculty of Dentistry, Cairo University between September 2019 and January 2021. Screening of patients was continued until the target sample was achieved. Identifying and recruiting potential subjects was achieved through patients' database.

Ethical Procedures

The study protocol was approved by the Ethics Committee of Scientific Research, Faculty of Dentistry, Cairo University (28-7-2019). This clinical trial was registered in U.S. National Institutes of Health Clinical Trials Registry, ClinicalTrials.gov Identifier: ID: NCT04013425. The detailed operation and follow up periods were clearly described in detail to all patients selected in this clinical trial. All subjects participated in this trial, signed a written consent, and fully agreed to participate in this work.

Eligibility criteria:

Sites included in the study were maxillary single or double rooted teeth indicated for extraction with the presence of a buccal defect (Type II sockets) **(Elian *et al.*, 2007).** Pregnant females, and patients who had radiation therapy in the head and neck region or chemotherapy during the 12 months prior to surgery and those having any habits that might jeopardize the osseointegration process, such as current smokers were excluded from the study **(Barone *et al.*, 2014, Iorio-Siciliano *et al.*, 2017)**.

Power and sample size calculation

The aim of this study is to identify the horizontal dimensional change in bone after socket preservation using the ice cream cone technique versus spontaneous healing. According to **(Iorio-Siciliano *et al.*, 2017)** the mean difference in the control group is 2.8 mm with a standard deviation of 1.1mm. The expert opinion stated that the minimum accepted difference should be 1.2mm. This makes a difference of 1.5mm between the two groups. PS power and sample size calculator software* was used to calculate the sample size with 80% power, 5% significance level leading to 8 sites in each group. The number was to be increased to a total sample size of 10 in each group to compensate for losses during follow up.

Randomization

Sites were randomly assigned to either test or control groups using computer generated randomization (www.randomizer.org) with a 1:1 allocation ratio. The numbers were allocated to each site in each patient. The two groups were equally prepared for post extraction socket preservation. A faculty member who was not involved in the recruitment executed a computer-generated randomization list, and the list was sent to the co-supervisor for the purpose of concealment. Allocation concealment was achieved by sequentially numbered opaque sealed envelopes. The sealed envelope containing treatment

* PS power and sample size calculator software version 3.1.2

assignment was opened at time of the surgery and the number was picked by another person other than the operator.

Blinding

The current investigation was a single blinded study (the evaluator of the study variables and outcomes were blinded). Due to the nature of the procedures, it was not possible to blind the researcher nor the patient for the treatment protocol as interventions were completely different. The outcome evaluators, and data analysts were blinded to group assignment. Detailed instructions on methods to maintain the blind were given to the data analysts and outcome evaluators.

Outcomes

The primary outcome was the horizontal bone dimension, while the secondary outcome was the buccal and palatal vertical bone dimension. The Outcomes were measured with **Cone Beam Computed Tomography** (CBCT). done twice, a preoperative CBCT and another one was performed after 4 months postoperatively.

Radiographic assessment

Radiographic assessment was performed according to (Temmerman et al., 2016). A Cone Beam Computed Tomography (CBCT) was performed preoperatively and 4-month post extraction. Radiographic assessment relied on registration of the pre-treatment CBCT plan upon the post-treatment CBCT results. The pre-operative and post-operative data from the CBCT scan were imported into InvivoDental Application*. The two scans were superimposed on each other. On the same coronal cut, the Buccolingual Bone Width was then measured at intervals of 3 mm, 6 mm, and 9 mm from the level of buccal crestal bone as shown in Figure (1). The exact same measurements were repeated on the superimposed "Post" scan at the same cut with the same orientation.

* InvivoDental Application v.5.3.1 (Anatomage.Inc., San Jose, CA).

Treatment Protocol

Pre-surgical phase

A thorough medical history and physical examination were done before the initiation of treatment according to dental modification of Cornell medical index **(Brightman, 1994)**. The patient's current medications as well as allergies were reviewed. Radiographic evaluation through a Cone-beam computed tomography (CBCT) was done to detect alveolar bone height and width and to ensure presence of a buccal plate defect. (Figure 1)

Surgical phase

Patients were anesthetized at the surgical site by infiltration, using Articaine Hydrochloride 4% followed by atraumatic tooth extraction performed by the aid of periotomes** as shown in Figure (2). Followed by debridement with a bone curette*** to remove any granulation tissue, then inspected to confirm the presence of buccal defects using a periodontal probe as shown in Figure (2).

Test Group

A Collagen barrier membrane**** was then shaped as an ice-cream cone and placed in the extraction socket lining the buccal tissues. The socket was then filled with a Xenograft***** and the upper part of the membrane was then used to cover the socket and stabilized in place by interrupted sutures using vicryl absorbable sutures of size 4-0******.

Control Group

Atraumatic extraction was performed in the same manner as the test group an no further procedures were carried on after tooth extraction and the sockets were left for spontaneous healing.

** Hu-friedy, Co., Rockwell St. Chicago, United States
*** Nordent, Elk Grove Village, IL, USA
**** T-Gen, Bioland, Songjeongri, South Korea
***** OsteoBiol Gen-Os, Tecnoss®, Giaveno, Italy
****** Assucryl, Assut Medical Sàrl, Pully-Lausanne, Switzerland

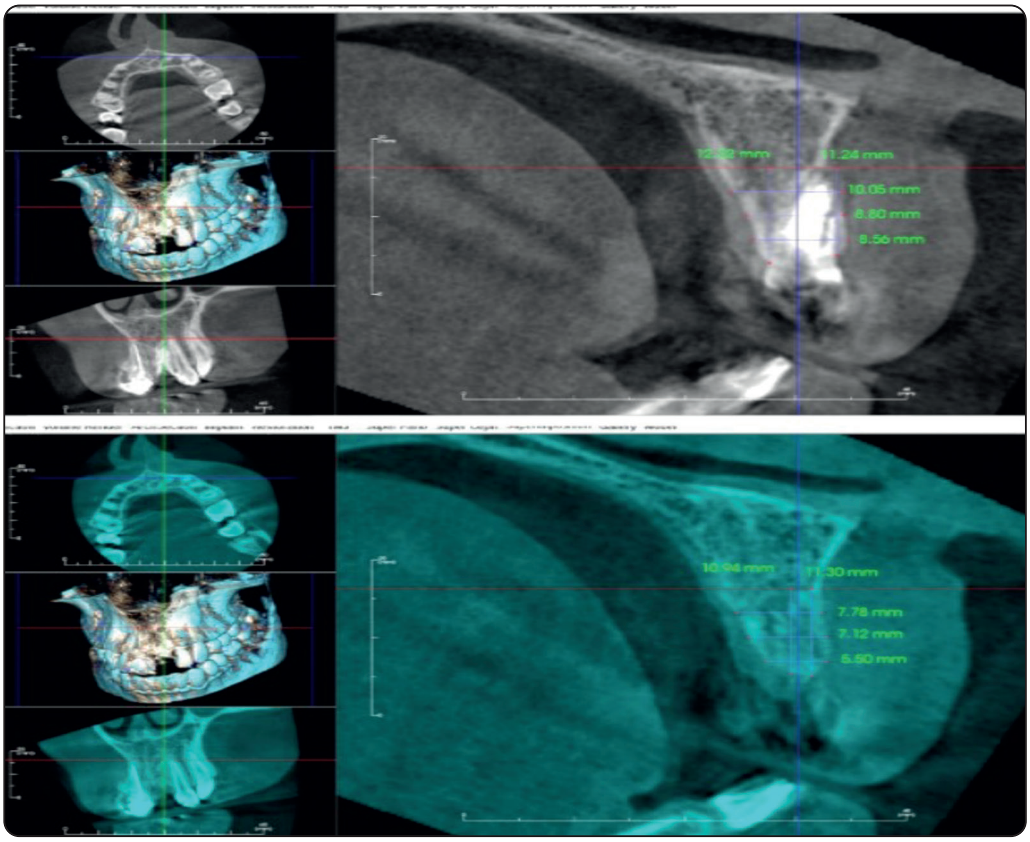

Fig. (1): Case 1 (test) Before and After CBCTs showing superimposition and measurement.

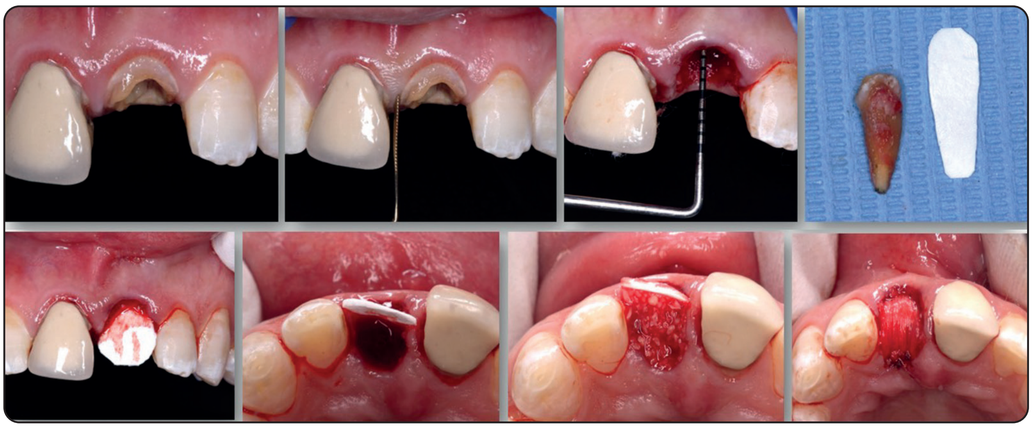

Fig. 2: Case 1 (test) Clinical photographs showing steps of the Ice-Cream Cone technique

Post-surgical phase:

Patients were placed on an antibiotic therapy of Augmentin* 1gm twice daily for 7 days. Ibuprofen** 600 mg was prescribed to be given immediately after surgery and another dose after 4 hours. A Chlorhexidine*** mouth wash (Hexitol) was to be used twice daily for two weeks postoperative. Patients were informed to attended follow up visits, 1 week and 4 months after surgery. After one week, patients attended for follow-up where suture removal was done to the test group. A new CBCT was done for each patient 4 month postoperative and readings were taken (Figure 3).

Statistical Methods

Numerical data were explored for normality by checking the distribution of data and using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). All data showed non-normal (non-parametric) distribution except for age data. Data were presented as mean, standard deviation (SD), median and range values. For parametric data; Student's t-test was used to compare between mean age values in the two groups. For non-parametric data; Mann-Whitney U test was used to compare between two groups. Wilcoxon signed-rank test was used to study the changes by time within each group. Qualitative data were presented as frequencies and percentages. Fisher's Exact test was used to compare between the groups. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics**** for Windows.

* Augmentin 1 gm, Medical Union Pharmaceuticals (MUP) – Egypt, for: GlaxoSmithKline (gsk) S.A.E. – A.R.E.

** Brufen, 600 mg tablets, KAHIRA PHARM. CO. EGYPT

*** Hexitol mouth wash 100 ml, THE ARAB DRUG COMPANY (ADCO) – A.R.E.

**** IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

RESULTS

Demographic Data:

The population in this randomized, parallel-grouped clinical trial included a total of 20 sockets with buccal bone defects in 17 patients (1 male and 16 females). The sockets were randomly assigned into two equal groups; the test group received bone grafting with xenograft and collagen membrane with the ice cream cone technique and the control group was left for spontaneous healing. Two patients (one test, one control) didn't complete the follow up period and were considered as dropouts. Accordingly, the study was completed with 9 sites per group with a total of 18 sites in 15 patients.

Patients in the test group had a mean (±SD) age of 31.9 (±11.3) while the control group had a mean (±SD) age of 44.9 (±6.6). Experimental group showed statistically significantly lower mean age than control group (p=0.009). There was no statistically significant difference between gender distributions in the two groups. The data of all examined subjects included in the present study were recorded, tabulated, subjected to statistical analysis and presented in (Tables 1,2).

Clinical outcomes

Horizontal Bone Dimension

The horizontal bone dimension was measured at 3,6 and 9 mm from the bone crest **(Table 1).**

Whether at base line or after four months; there was no statistically significant difference between median bone width at 3 mm levels in the two groups (P-value = 0.270, Effect size = 0.539) and (P-value = 0.145, Effect size = 0.731), respectively. On comparing the two groups there was no statistically significant difference regarding the mm change in horizontal bone width after 4 months at 3 mm from the bone crest (P-value = 0.965, Effect size = 0.021).

While at 6 mm level, whether at base line or after four months; there was no statistically significant difference between median bone width in the two groups (P-value = 0.508, Effect size = 0.316) and (P-value = 0.825, Effect size = 0.104), respectively. When comparing both groups there was no statistically significant difference regarding the mm change in horizontal bone width (P-value = 0.216, Effect size = 0.609).

At 9 mm level, whether at base line or after four months; there was no statistically significant

TABLE (1): Descriptive statistics and results of Mann-Whitney U test for comparison between bone width at 3 mm, 6 mm and 9 mm levels in the two groups and Wilcoxon signed-rank test for the changes within each group. *: Significant at P ≤ 0.05

Period	3 mm Level				6 mm Level				9 mm Level			
	Ice-cream Cone Technique (n=9)	*Spontaneous Healing (n=9)*	*P-value*	*Effect size (d)*	*Ice-cream Cone Technique (n=9)*	*Spontaneous Healing (n=9)*	*P-value*	*Effect size (d)*	*Ice-cream Cone Technique (n=9)*	*Spontaneous Healing (n=9)*	*P-value*	*Effect size (d)*
	Median (Range)	*Median (Range)*			*Median (Range)*	*Median (Range)*			*Median (Range)*	*Median (Range)*		
Baseline	8.56 (7.09-10.21)	7.89 (6.07-9.51)	0.270	0.539	8.8 (5.73-11.73)	8.92 (5.43-9.85)	0.508	0.316	10 (4.94-13.07)	9.17 (4.93-12.5)	0.402	0.403
4 Month	7.33 (4.52-11.86)	5.32 (3.68-8.19)	0.145	0.731	7.43 (3.34-9.46)	7.27 (3.68-9.19)	0.825	0.104	8.05 (4.01-9.74)	8.88 (4.14-10.93)	1	0
Change (mm)	-1.82 (-3.06-3.43)	-2.17 (-4.19- -0.83)	0.965	0.021	-1.6 (-2.39- -1.25)	-1.36 (-2.33- -0.39)	0.216	0.609	-1.67 (-3.33- -0.63)	-0.72 (-1.57-0.3)	0.047*	1.06
Percentage Change (%)	-19.89 (-36.25-40.69)	-23.27 (-47.27- -9.2)	0.310	0.493	-19.09 (-41.71- -13.78)	-19.4 (-32.23- -4.3)	0.825	0.104	-18.83 (-31.51- -7.19)	-12.56 (-25.41-3.48)	0.102	0.834
P-value	0.110	0.008*			0.008*	0.008*			0.008*	0.021*		
Effect size (d)	1.26	2.305			3.876	3.876			3.876	2.414		

difference between median bone width in the two groups (P-value = 0.402, Effect size = 0.403) and (P- value = 1, Effect size = 0), respectively. When comparing the amounts of change in bone width at 9 mm level between the two groups; the test group showed statistically significantly higher median decrease in bone width than control group (P-value = 0.047, Effect size = 1.06).

Vertical Bone Dimensions (Table 2):

Whether at base line or after four months; test group showed statistically significantly higher median buccal bone height than control group (P-value = 0.038, Effect size = 1.122) and (P-value = 0.019, Effect size = 1.322), respectively. As regards comparison between amounts of change in buccal bone height in the two groups; there was no statistically significant difference between the two groups (*P*-value = 0.354, Effect size = 0.448).

Regarding palatal bone height, whether at base line or after four months; test group showed statistically significantly higher median palatal bone height than control group (P-value = 0.038, Effect size = 1.122) and (P-value = 0.047, Effect size = 1.06), respectively. On comparing the amounts of change in palatal bone height between the two groups; there was no statistically significant difference between the two groups (*P*-value = 0.757, Effect size = 0.146).

DISCUSSION

The process of tooth extraction is considered a traumatic procedure, during which vascular structures are severed, soft tissue is disrupted and the periodontal ligament fibers are destroyed **(Cardaropoli *et al.*, 2003)**. Up to 50% horizontal bone loss was found to occur within the first year following extraction specially premolars and molars. However, the majority of these changes usually takes place only in the first three months' post extraction **(Schropp *et al.*, 2003).**

Some anatomical variations appear to affect the magnitude of bone loss after extraction. Out of these many factors the buccal bone thickness and tooth angulation appear to be of high value **(Misawa *et al.*, 2016)**. Also, the pattern of bone loss after 8 weeks of extraction was found to be concentrated in the middle third of the socket mesiodistally, with minimal loss at the proximal areas of neighboring healthy dentition with good periodontal ligament

TABLE (2): Descriptive statistics and results of Mann-Whitney U test showing buccal and palatal bone height in the two groups and Wilcoxon signed-rank test for the changes within each group.

	Buccal				***Palatal***			
	Ice-cream Cone Technique (n=9)	*Spontaneous Healing (n=9)*	*P-value*	*Effect size (d)*	*Ice-cream Cone Technique (n=9)*	*Spontaneous Healing (n=9)*	*P-value*	*Effect size (d)*
	Median (Range)	*Median (Range)*			*Median (Range)*	*Median (Range)*		
Baseline	12.51 (7.78-13.47)	8.15 (4.63-16.18)	0.038*	1.122		8.35 (3.81-16.13)	0.038*	1.122
4 Month	11.75 (5.59-17.93)	7.31 (3.98-12.52)	0.019*	1.322		7.78 (3.24-12.63)	0.047*	1.06
Change (mm)	-0.77 (-3.73-5.07)	-1.22 (-3.66-2.53)	0.354	0.448	-0.84 (-1.87-2.2)	-0.58 (-3.5-0.87)	0.757	0.146
Percentage Change (%)	-5.72 (-29.39-40.69)	-14.97 (-29.04-44.46)	0.310	0.493	-7.57 (-18.63-18.02)	-6.83 (-27.27-14.56)	0.453	0.359
P-value	0.678	0.139			0.515	0.173		
Effect size (d)	0.279	1.135			0.445	1.021		

**: Significant at P ≤ 0.05*

support which resulted in two-wall defects **(Chen and Buser, 2009)**. It was found that after extraction the facial bone thickness in 90% of cases showed less than 1 mm thickness while 50% had a thickness less than 0.5 mm **(Braut *et al.*, 2011)**. Moreover, sites with buccal bone of 1 mm or less showed a median vertical bone loss of 7.5 mm in comparison to sites with buccal bone thickness more than 1 mm which only showed a median vertical bone loss of 1.1 mm **(Chappuis *et al.*, 2013)**. Therefore, extraction sockets with buccal bone defects after extraction have been a challenging situation that might require further intervention for preserving the buccal bone thickness.

Minimally invasive extraction procedures were introduced to limit the trauma caused by brutal tooth extraction. The main goal of these procedures is to avoid expansion of the socket walls that may in return fracture due to the excessive laxative forces applied on the weak buccal and lingual walls of the socket. Also, rotational movements with the forceps which might cause socket expansion should be avoided as the root cross-section is not circular. **(Araújo *et al.*, 2015)**. Hence, the use of periotomes was highly encouraged in the literature due to its ability of eluding the need for a mucoperiosteal flap raising which in turn resulted in much less gingival lacerations. Also, its ability to severe the periodontal ligament fibers could make the extraction much easier minimizing the trauma caused to both hard and soft tissue **(Sharma *et al.*, 2015; Horowitz, 2005)**.

Because of the extreme esthetic demand especially in the anterior region, a 3-dimensional ridge support is needed for the peri-implant mucosal tissues. This includes sufficient bone height and width with a thick buccal bony wall supporting the soft tissue which will be in jeopardy due to the enormous changes occurring following tooth extraction **(Araújo *et al.*, 2015; Buser *et al.*, 2004)** Thus, the socket preservation attempt was approached in this clinical trial to enhance the ridge in type II sockets with buccal bone defects.

Consequently, in a systematic review by **Horváth *et al.* (2013)** it was explained that alveolar ridge preservation is the procedure of limiting and reducing the adverse effects occurring following tooth extraction allowing for bone and soft tissue contours to be maintained, aiding bone formation inside the healing socket would then facilitate accurate implant placement in a prosthetically driven position. Several clinical studies proposed the use of different grafting materials with or without the use of barrier membranes for socket preservation and have shown positive results regarding reduction of bone loss following tooth extraction **(Araújo *et al.*, 2015)**.

In this current study, a xenograft was used inside the socket based on the results from the systematic review done by **(Horváth *et al.*, 2013)** which stated that although ridge preservation procedure did not totally prevent bone loss, however the presence of a bone graft material could actually limit the vertical bone loss significantly.

The difference between using a membrane in GBR and socket preservation is that in GBR the objective is to form new bone, while in socket preservation the objective is to maintain the level of the hard and soft tissue. Therefore, in the ice cream cone technique, a collagen membrane was used and placed inside the socket since placing the membrane inside the socket could help contain the graft, prevent incursion of soft tissue inside the socket, and could prevent detachment of the periosteum from the buccal bone when compared to flap reflection techniques. Moreover, placing the membrane inside the socket before grafting allows preserving the soft tissue morphology and permits the clinician to condense the graft into the socket pushing the buccal tissues facially thus allowing an undisturbed bone formation mechanism by cells from the remaining bony walls **(Elian *et al.*, 2007)**.

Moreover, resorption of the collagen membrane occurs over a period of four months where bone will be already formed. The coronal aspect of the membrane could then act as a socket seal containing the graft and protecting the initial blood clot. The ability of collagen membranes to resorb without the need of a second stage surgery besides their hemostatic ability, its ability to stimulate platelet adhesion and improve fibrin linkage and its chemotactic effect on fibroblasts could aid in stabilizing the initial clot. Thus, collagen membranes have been the membrane of choice for several clinicians **(Wang and Carroll, 2001; Bunyaratavej and Wang, 2001; Marinucci *et al.*, 2001)**. The unfavorable mechanical characteristics of collagen membranes have been another main disadvantage which led to membrane collapse into the bony defect. Therefore, the need for using a supporting bone graft material to allow space maintenance has been widely used **(Hürzeler *et al.*, 1998)**. various advantages can make xenografts one of the best bone substitutes. These advantages include the fact that xenografts have osteoinductive and osteoconductive properties. In addition, xenografts have low immunogenicity due to different treatment techniques giving a porous, biocompatible product which has good physio-chemical properties and slow resorbability which preserve and augment bone volume efficiently **(Fuentes *et al.*, 2012; Amid *et al.*, 2020).**

In this clinical trial the follow up period was performed after 4-month post extraction. This time frame was decided based on human biopsies which examined the socket at different times post extraction and showed that the number of macrophages and other vascular structures were reduced from 2 to 4 weeks, where the osteoclastic activity showed a slow reduction over a 4-week period. On the other hand, invasion of the osteoblasts peaked at 6-8 weeks and stayed stable giving the best condition for regeneration **(Trombelli *et al.*, 2008).**

Extraction sockets with a buccal bone defect would need a barrier membrane to prevent invasion of buccal soft tissue thus allow for a normal bone formation and allow to create a 4-wall defect that would be easily filled with bone **(Elian *et al.*, 2007)**. The primary and secondary outcomes in this clinical trial were chosen based on the systematic review done by **(Horváth *et al.*, 2013)** where horizontal and vertical bone dimensions are crucial requirements for successful esthetically derived implant placement. Although direct intracortical measurement of the alveolar ridge is the most accurate way to measure changes in horizontal and vertical dimensions, Cone beam CTs (CBCT) has been considered an accurate replacement measuring tool that would not require surgical access, allowing evaluation of the hard tissue alone without involvement of the soft tissue when compared to measurements done on a cast **(Horváth *et al.*, 2013)**.

In the current study, horizontal bone loss was measured at 3, 6, 9 mm from the alveolar crest, where the test group showed a median horizontal bone loss of 1.82 mm (-3.06 - 3.45), 1.6 mm (-2.39- -1.25) and 1.67 mm (-3.33 - -0.63) respectively, while the control group showed a loss of 2.17 mm (-4.19 - -0.83), 1.36 mm (-2.33 - -0.39) and 0.72 mm (-1.57 - 0.3) respectively. The test group had a non-statistically significant loss of horizontal bone (p=0.11) at the 3 mm level while the control group had a statistically significant loss (p=0.008). Although there was no statistically significant difference between the two groups at 3 mm and 6 mm after 4 months, yet at the 9 mm level the test group showed statistically significantly higher median decrease in bone width than control group (P= 0.047).

The results of the current study are similar to a randomized controlled trial (RCT) conducted by **Iorio-Siciliano *et al.* (2017)** on 20 patients with 20 extraction sockets allocated randomly to a test group where a mucoperiosteal flap was elevated before extraction and sockets were filled with a xenograft and covered by a collagen membrane that was left exposed to the oral environment versus the control group which was left for spontaneous healing. Their results showed a statistically significant difference in horizontal bone loss of the test and control group of 1.6 (±1.3) and 2.8 (±1.1) respectively with a p-value of (0.04) in favor of the test group.

Also, the results of horizontal bone loss were consistent with another RCT by **Pang *et al.* (2014)** on 30 patients comparing the use of deproteinized bone mineral covered with a collagen membrane (trial group); where a rectangular flap was elevated to allow grafting and full closure of the socket, versus spontaneous healing (control group). After 6 months of healing, the trial group showed a mean horizontal bone loss of 1.84 (±0.35) mm which is similar to the results of the test group of this current trial, while the control group showed a statistically significant loss of 3.56 (±0.28) mm which is more bone loss than the control group of this trial that could be related to the 6 months follow up which would have subjected the socket to further bone loss over time.

The results of horizontal bone loss in the current study were more similar at the coronal aspect of the socket, while as we go apical, results were more inferior than the study conducted by **Jung *et al.* (2013)** who compared socket preservation using a xenograft with 10% collagen and covered with a collagen membrane that was sutured to seal the extraction socket without any flap elevation, versus spontaneous healing. Measurements were taken at 1, 3 and 5 mm from the crest. The xenograft-collagen group showed horizontal bone changes of -1.2, -0.6 and -0.1 mm respectively, whereas the spontaneous healing group had bone changes of -3.3, -1.7 and -0.8 mm respectively. This can be accounted to the fact that most cases included in the current study had fenestration defects which might explain the inferior results as we go apically while it was thought that the membrane would be more beneficial in such cases that require the barrier effect of the membrane. Similarly, horizontal bone loss was decreasing as far as we go from the crest, proving that the first millimeters below the crest was the most benefiting area from the applied socket preservation technique.

However, better results were obtained by **Tan-Chu *et al.* (2014)** who used the ice-cream cone technique on 11 extraction sites type II sockets with partial or complete loss of the buccal plate. A mean horizontal bone loss of 1.28 mm (0.46, 2.25) was obtained where the horizontal bone dimension was measured using CBCT. A collagen membrane was placed inside the socket lining the buccal wall; however, the sockets were filled with bone allograft rather than xenograft which could be the reason behind the superior results of their study since allografts have an osteoinductive property that might enhance bone formation.

Furthermore, superior results were obtained by an RCT by **Aimetti *et al.* (2018)** who experimented on thirty patients with non-restorable periodontally involved teeth. The test group had the sited grafted with collagenated bovine bone graft and covered with a double collagen membrane while the control group was left for spontaneous healing. Sockets were measured at 1, 3 and 5 mm from the crest on the CBCT 12-month post extraction showing horizontal bone changes of -2.6 (±1.24), -0.86 (±0.82) and 0.34 (±0.87) respectively in the test group, while the control group showed horizontal bone changes of -4.92 (±2.45), -2.01 (±0.97) and -0.61 (±1.14) respectively. The difference in results might be attributed to the long healing period compared to the current study. Also, superior results that appeared at the 3 mm level might be explained by using a double membrane while the inferior results at the 1 mm level might be induced by flap elevation and the fact that the included patients had periodontally involved teeth.

Regarding vertical bone changes, this current study showed a median buccal bone height loss of 0.77 (-3.75 - 5.07) in the test group and 1.22 (-3.66 - 2.53) in the spontaneous healing control group. While the palatal bone height loss was -0.84 (-1.87 - 2.2) in the test group and -0.58 (-3.5 - 0.87) in the control group with no statistically significant difference between the two groups. These results are consistent with a study by **Cardaropoli *et al.***

(2014) performed on 41 patients comparing grafting of the test group with xenograft and covered by a collagen membrane versus the control group where spontaneous healing took place. Vertical bone loss appeared to be -0.56 (±0.45) and -1.67 (±0.43) in the test and control group respectively showing a statistically significant difference favoring the test group. However, the difference in the sample size which is almost twice the current study could be the reason behind the slightly superior results of the test group.

The results in the present study were more superior to the study previously described by **Pang *et al.* (2014),** where the vertical bone changes at 3 months were -1.05 (±0.24) for the test group and -2.12 (±0.15) in the control group, while at 6 months the test group showed vertical loss of -1.54 (±0.25) in the test group and -3.26 (±0.29) in the control group. Their inferior results might be explained by their technique which involved flap elevation in addition to the longer follow up period leaving the area unrestored for a longer period of time which might predispose the edentulous area for further resorption. However, despite using a double collagen membrane, similar results were evident in the study early described by **Jung *et al.* (2018)**, where buccal vertical bone loss at 3 months was -0.78 mm and -1.26 mm in the test and control group respectively, while the palatal bone loss was -0.79 mm for the test group and -0.94 mm for the control group.

On the other side, results of this study came slightly inferior when compared to the previously explained study by **Iorio-Siciliano *et al.* (2017)** which showed buccal and palatal vertical bone loss of 0.3 (±0.5) and 0.1 (± 0.3) respectively for the test group, and 1.1 (±1), 0.7 (±0.7) respectively for the control group. This might be interpreted by the base line inclusion criteria which included completely intact extraction socket walls. Similarly, **Aimetti *et al.* (2018)** had superior results regarding the vertical bone changes. Their results showed buccal bone gain of 2.5 (±2.12) in the test group and 0.51 (±1.02) in the control group. Palatal bone showed a gain of 0.27 (±1.31) in the test group and a loss of 0.21 (±0.78) in the control group. The authors interpreted bone gain in their results to the flap approach accompanied by GBR procedures, where a double membrane was used fixed by pins which played an important role in preserving the volume of the augmented region.

Statistical analysis of the present data revealed a non-significant difference between the two groups regarding both horizontal and vertical bone changes. However, this statement must be interpreted cautiously, as it doesn't necessarily mean there is no difference between the clinical effect of the two procedures. It means that the difference regarding the clinical and radiographic outcomes might not be detected in the current sample size.

The results of the spontaneous healing group in the current study appeared to come in range with a systematic review that reported horizontal bone loss of 2.6-4.5 mm and vertical bone loss ranging 0.4-3.9 mm after socket healing **(Ten Heggeler *et al.*, 2011)**. Nevertheless, horizontal and vertical bone loss in the control group were superior to the findings from the systematic review by **Van der Weijden *et al.* (2009)**, who reported a mean horizontal loss of 3.87 mm and a mean vertical loss of 1.53 mm. This might be explained by the smaller sample size, or the aid of atraumatic extraction which helped preserving the socket integrity as the systematic review included studies using flap elevation for extraction **(Bartee, 2001)**.

Moreover, the results of the systematic review by **Majzoub *et al.* (2019)** are highly similar to the present study where they estimated the effect of different bone graft materials in socket preservation and compared to spontaneous healing. They stated that the average horizontal, bone loss was 1.47 (±0.92) mm in the xenograft group and the buccal and palatal height loss was 0.68 (±1.04) mm and 0.47 (±0.97) mm respectively. While the spontaneous healing group showed a horizontal resorption at 1, 3 and 5 mm from the crest as 2.98 (±2.01) mm, 1.59 (±1.23) and 0.96 (±0.69) mm respectively.

The current clinical trial showed no statistically significant difference between spontaneous healing and socket preservation. On the contrary, when the effectiveness of socket preservation in reducing the amount of bone loss in comparison to spontaneous healing was investigated by **Avila-Ortiz *et al.* (2014)** they observed that horizontal bone dimensions were affected with 1.89 mm bone loss (95% CI: 1.41, 2.36; p < .001), 2.07 mm (95% CI: 1.03, 3.12; p < .001) for mid-buccal height, 1.18 mm (95% CI: 0.17, 2.19; p = .022) for mid-lingual height. Their results concluded that a significant effect size was apparent for changes occurring in the horizontal and mid-vertical aspects of the socket, which was our concern in this present study. The authors explained that one of the reasons for improved midbuccal and midlingual height was flap elevation. They also added that one of the included studies had gain of 1.1 mm height which was unusual and might be due to measurement errors which were taken on stone casts that include soft tissue thickness in addition to the included studies which had dissimilar clinical protocols with no similar clinical conditions.

Another difference was observed when comparing the current study to that meta-analysis conducted by **Troiano *et al.* (2018)** on seven different studies which showed 2.19 mm reduction in horizontal bone loss and 1.72 mm in vertical bone loss when using a bone substitute covered with a resorbable membrane whether a flap was elevated and obtained a primary closure, or the membrane was left exposed. This can be due to larger follow-up periods that extended to 9 months in addition to several augmentation techniques included in the meta-analysis.

When comparing the results of the current study to **Barone *et al.* (2012)** and **Festa *et al.* (2013)** their results showed significant bone reduction in both width and height, while this trial wasn't able to detect any statistically significant difference between socket preservation and spontaneous healing. These studies in addition to four other studies utilizing cortico-cancellous porcine xenograft (OsteoBiol® Gen-Os; Tecnoss srl, Giaveno, Italy) and collagen membrane, were used to conduct a meta-analysis by **(Atieh *et al.*, 2015)** which claimed a significant reduction in bucco-lingual width (MD -1.97 mm; 95% CI -2.48 to -1.46; P < 0.0001; I2 = 0%) (Analysis 1.1) and height of the alveolar ridge (MD-2.60mm; 95%CI -3.43 to -1.76; P < 0.0001; I2 = 0%) (Analysis 1.2), proving a beneficial significance regarding alveolar ridge preservation using xenografts. However, this difference could be attributed to the huge amount of pooled data in comparison to the present sample size.

To the best of our knowledge, this is the first randomized clinical trial to assess the effect of the ice-cream cone technique in treating extraction sockets with a buccal bone defect. Within the limitations of this study, it can be concluded that although the difference between the two groups were statistically non-significant, the ice cream-cone technique could be more beneficial at the crestal region rather than the apical one. Also, the non-statistically significant vertical bone loss could indicate the added value of augmentation in preserving the bone height. However, future longitudinal studies with longer follow up periods and larger sample sizes are warranted to explore the potential of this technique in alveolar ridge preservation. Additional clinical and histological evaluation are required to give a full picture about the ice-cream cone technique.

CONCLUSIONS

From this study, it can be concluded that:

- Vertical bone loss was well preserved with ice cream cone technique with no statistically significant loss within each group.

- Horizontal bone loss at the crestal region was statistically non-significant in the ice cream cone group compared to a statistically significant loss with spontaneous healing group.
- When comparing both groups no statistically significant difference regarding both horizontal and vertical bone loss was observed between them.
- The ice cream cone technique could not prevent the horizontal bone loss after extraction in sockets with buccal bone defects.

RECOMMENDATIONS

Future longitudinal studies and histological evaluation with larger sample sizes should be considered with longer follow-up periods. In addition, the use of a double layers of collagen membrane or cross-linked membranes with slower degradation rate could be more beneficial in protecting the graft for a longer period to confirm the efficacy of the ice cream cone technique in preserving the socket.

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