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ORIGINAL ARTICLE

The bone shielding versus dual-zone concept in treating thin-walled fresh extraction sockets with immediate implant placement: Soft and hard tissue changes. A randomized clinical trial

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Abstract

Objectives: To evaluate the ridge alterations and esthetic outcome 1 year after immediate implant placement using the dual-zone (DZ) technique versus the bone shielding concept in patients with intact thin-walled sockets in the esthetic zone.

Material and Methods: This randomized clinical trial included 26 patients with non-restorable maxillary teeth in the esthetic zone who were randomly assigned to two groups ($n = 13$ each) to receive immediate implants using either the bone shielding concept or DZ. Definitive restorations were delivered after 2 months. Pink esthetic scores (PESs), vertical soft tissue alterations, and bucco-palatal ridge dimensional changes were measured and assessed using intra-oral digital scans at baseline and 1 year post-procedure. Labial bone thickness was measured using cone beam computed tomography scans at baseline and after 1 year.

Results: The bone shielding group provided bucco-palatal ridge thickness stability after 1 year (9.43 mm) compared to baseline values (9.82 mm), while DZ showed a significant loss in the bucco-palatal ridge thickness after 1 year (7.83) compared to baseline values (9.49). No significant difference was reported in the baseline bucco-palatal ridge thickness between the two groups ($p = 0.6$). After 1 year, the bone shielding group demonstrated 0.38 mm ridge shrinkage which was statistically significant ($p = 0.0002$) compared to 1.67 mm ridge shrinkage in the DZ group. In addition, the average total PES in the bone shielding group was 12.04 versus 10.28 in the DZ group. No significant difference was reported in the mesial papilla length between the DZ and the bone shielding group after 1 year ($p > 0.05$). However, the midfacial gingival margin ($p = 0.026$) and distal papilla were significantly higher in the DZ group ($p = 0.0025$). There was no significant difference in the mean ± SD mm bone gain at the apical level between the two studied groups after 1 year ($p = 0.06$) showing 0.85 ± 0.23 and 0.64 ± 0.32 mm, respectively. However, the bone shielding concept showed a statistically significant more bone gain mm ($p < 0.001$) at the (0.56 ± 0.43) and crestal (0.03 ± 0.8) levels after 1 year compared to DZ which revealed 0.18 ± 0.5 and 0.38 ± 0.29 mm bone loss, respectively.

Conclusion: The bone shielding concept might offer a reliable alternative for restoring thin-walled sockets by minimizing postextraction ridge dimensional alterations effect following immediate implant placement in the esthetic zone. Nevertheless, the study suffers from confounding bias since there are two systematic differences between the groups, the barrier membrane type, and the level of bone filling.
"This clinical trial was not registered prior to participant recruitment and randomization." Clinical Trial Registration: NCT05381467.

1 | INTRODUCTION

Immediate implant placement with immediate provisionalization in the esthetic zone has shown clinical predictability and a successful treatment outcome.[1,2] Substantial evidence showed variable dimensional changes following tooth extraction, ranging from 15% to 55%, in the esthetic zone.[3–5] However, immediate implants fail to halt postextraction buccal bone plate resorption, which might lead to midfacial recession and esthetic complications.[6–9] Several techniques have been proposed to preserve the buccal plate from bone resorption following immediate implant placement with no proven effectiveness.[7,10,11]

The dual-zone (DZ) concept was first described by Chu et al.[12] to minimize the amount of buccal contour change at the extraction site and enhance the thickness of the peri-implant soft tissues by filling the buccal gap with bone graft in two zones, namely, the bone zone until the crest of the socket bone and the soft tissue zone. Chu et al.[12] claimed that the graft particles are incorporated into the tissues, increasing their thickness, and providing stability and maintenance of the soft tissue volume.

Elaskary et al.[13] in 2020 introduced vestibular socket therapy (VST) as a novel, minimally invasive surgical protocol for immediate implant placement. The therapy was introduced to treat all types of fresh extraction sockets from thin-walled to compromised sockets using a flexible cortical bone membrane using the bone shielding concept. Considerably, this technique offered several advantages, including peri-implant marginal tissue stability, no delay to immediate implant placement even in severely compromised sockets, minimally invasive procedure that does not require a donor site entry, long-term stable esthetic outcomes, and total restoration of the socket defects in a shortened treatment time.[14]

There are no available randomized clinical trials comparing the efficacy of the bone shielding concept to the DZ technique in treating thin-walled intact fresh extraction sockets in the esthetic zone with immediate implants placement. Hence, the aim of the current randomized clinical trial is to compare the bucco-palatal dimensional changes, labial plate of bone thickness changes, and esthetic outcomes following placement of immediate implants in the esthetic zone using the DZ versus the bone shielding concept. Given the limited familiarity with these approaches, the results of the present study may provide additional knowledge and evidence to the literature regarding esthetics and soft and hard tissue alterations associated with the two techniques.

2 | MATERIALS AND METHODS

2.1 | Study population

This randomized clinical trial was registered at Clinical trials.gov (ID: NCT05381467), approved by the Research Ethics committee, Faculty of Dentistry, Cairo University. conducted in accordance with the Helsinki Declaration of 1975, as revised in 2013 and reported according to CONSORT guidelines 2012[15] (Figure 1). This investigation included 26 patients (6 men and 20 women, aged 19–58 years) recruited from a private clinical practice in Alexandria, Egypt between March 2022 and May2022. Participants were included if they were ≥18 years, having a single nonrestorable maxillary tooth in the esthetic zone with intact adjacent teeth, thin labial plate of bone ≤1 mm as detected by CBCT, type I socket (intact but thin labial plate of bone and intact overlying soft tissues[16]) and adequate apical bone with ≥3 mm to engage the immediately placed implants. Patients were excluded if they were smokers, with systemic diseases, periodontal disease, pregnant females, periapical pathosis, and with history of chemotherapy or radiotherapy within the past 2 years. A written informed consent with detailed description of the investigation was signed by all eligible patients.

2.2 | Randomization and blinding

Using the online sequence generator (random.org)[17] simple randomization was performed through generating numbers from 1:26 by an investigator (GN) not involved in recruitment nor treatment procedures. Allocation sequence was concealed from the surgeon (EA) and was revealed after tooth extraction according to the encoded sequence using sequentially numbered, sealed opaque envelopes. After recruitment, extraction sites of the eligible participants who agreed to be included in the study were randomly assigned into two equal parallel groups ($n = 13$ each) with a 1:1 allocation ratio to receive either immediate implant using the bone shielding concept (test group) or DZ concept (comparator) based on the generated sequence. Due to differences in techniques the operating surgeon (EA) and participants could not be blinded to the procedure. The outcome assessor (TA) and statistician (GN) were blinded.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1, 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2
	2b	Specific objectives or hypotheses	2
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	2, 3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	3
	4b	Settings and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4, 5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5, 6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	3
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	6
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	2, 3
	13b	For each group, losses and exclusions after randomisation, together with reasons	-
Recruitment	14a	Dates defining the periods of recruitment and follow-up	2, 5, 6
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	6
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	6, 7
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	7-10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	7-10
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	-

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist *Page 2*

FIGURE 1 Consort flow chart.

2.3 | Preoperative phase

Before and after tooth extraction, all patients meeting the inclusion criteria undertook a cone beam computed tomography (CBCT) images (Carestream Health, CS 8100 3D System) for diagnosis confirmation and treatment planning. With a high contrast resolution detector (high bit depth) and a field of vision 6 × 8 were taken to inspect the bone topography. The imaging protocol was standardized by radiographing the patients with a wax interocclusal record to separate the maxillary and mandibular teeth at a KVp between 5 and 10. These specifications reduce the beam-hardening effect. All patients were scanned preoperatively using an intra-oral scanner (IOS) (TRIOS, 3Shape A/S, Copenhagen K Denmark). All recruited patients underwent full mouth supra- and subgingival debridement and were prescribed 0.12% chlorhexidine HCL mouthwash twice daily for 2 weeks (The Arab Drug Company for Pharmaceutical & CHEM. IND. CO. Cairo-Egypt), including patient motivation and oral hygiene instructions. Impressions were then taken to fabricate computer-guided surgical templates on casts as well as vacuum stents on waxed-up casts to manufacture the egg-shell tooth to be fit on the temporary abutment.

2.4 | Surgical protocol

2.4.1 | The bone shielding concept (test group)

The surgical technique in the bone shielding group (Figure 2) was performed using the Elaskary VST kit (Stoma, Storz am Mark GmbH, Emmingen-Liptingen Germany). Tooth extraction was carried out using periotomes and luxators (Stoma, Storz am Mark GmbH, Emmingen-Liptingen Germany) to minimize the trauma induced to the socket-related soft and hard tissues. This was followed by a through-socket curettage and lavage simultaneously with 100 mL of anti-anaerobic infusion solution of 500 mg metronidazole (Minapharm Pharmaceuticals) using the Elaskary VST irrigation curette (Stoma, Storz am Mark GmbH, Emmingen-Liptingen Germany) that combines both curettage and flushing, thus ensures a thorough socket debridement.[18] A sub-periosteal dissection that starts from the socket orifice towards the vestibular mucosa (reaching 4–5 mm in an apical direction) not extending to the adjacent teeth is performed to create a sub-periosteal tunnel using the Elaskary T-tome periotome (Stoma, Storz am Mark GmbH, Emmingen-Liptingen Germany). Then a 1.0 mm thick flexible equine cortical membrane (OsteoBiol® Lamina®, Tecnoss®, GiavenoTorino, Italy), termed as "bone shield," was tailored and inserted into the labial tunnel using the Elaskary VST bone shield holder (Stoma, Storz am Mark GmbH, Emmingen-Liptingen Germany). A prefabricated CAD/CAM surgical guide (Surgical Guide Resin, Form 2, Formlabs) was used to insert the implant in its planned location (tapered pro Biohorizons, Birmingham, Al, USA) to benefit from its switched platform that might enhance the peri-implant tissue thickness,[19] engaging 3–4 mm of the sound intact apical bone reaching a minimum of 30-Ncm torque. The jumping gap was then filled with xenograft bone graft (MinerOss X, BioHorizons, Birmingham, Al, USA). Afterwards, a screw-retained provisional restoration was placed maintaining the graft in position.

2.4.2 | DZ technique group (comparator group)

In the comparator group; the DZ technique was performed (Figure 3). After atraumatic tooth extraction using periotomes and luxators, implant placement (tapered pro Biohorizons, Birmingham, Al, USA) along with the same bone grafting material were placed. The xenograft (MinerOss X, BioHorizons, Birmingham, Al, USA) was packed in

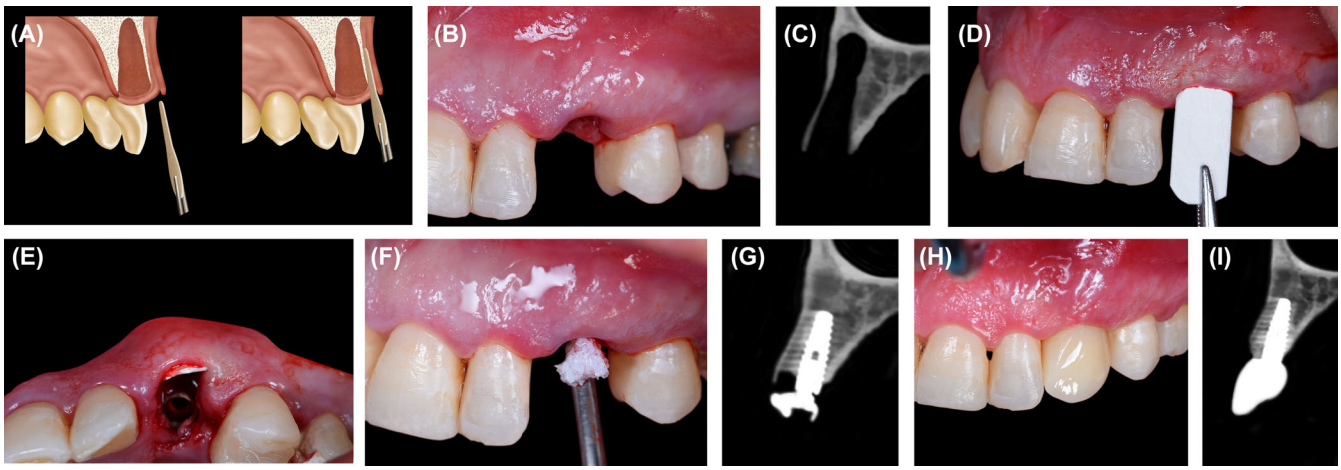

FIGURE 2 (A) The bone shielding concept, placing the bone shield above the labial plate of bone. (B) Preoperative view of a cuspid fresh exaction socket. (C) Cone beam computed tomography (CBCT) sagittal view showing an intact and thin buccal pate of bone. (D) The bone shield is introduced above the thin plate of bone. (E) The bone shield was delivered in its location. (F) Filling the jumping gap with xenograft particles. (G) Immediate postoperative sagittal view of the CBCT scan in the bone shielding group. (H) 1-year post restorative outcome with final restoration delivered showing the preserved biological contours. (I) 1 year post restorative CBCT showing the full restoration of the buccal plate and the uniformity of the grafted buccal plate of bone.

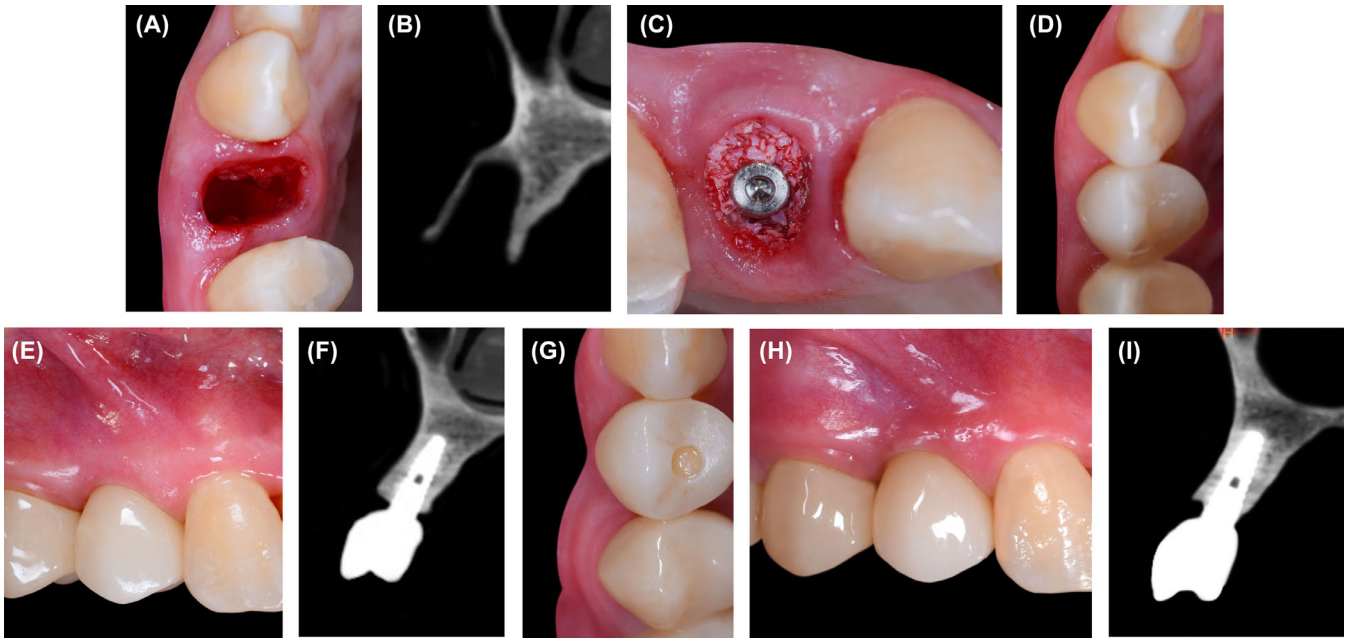

FIGURE 3 (A) Preoperative view of bicuspid fresh extraction socket. (B) Cone beam computed tomography (CBCT) showing the thin intact walled buccal plate of bone. (C) The implementation of the dual-zone concept. (D) Immediate post restorative clinical photograph incisal view. (E) Immediate post restorative clinical photograph frontal view. (F) Immediate CBCT scan post dual-zone concept. (G) 1 year post restorative clinical photograph showing the drop of the facial contour incisal view. (H) 1 year post restorative clinical photograph showing the drop of the facial contour frontal view. (I) 1 year post restorative CBCT showing reduction in the buccal bone size because of the postextraction bone remodeling.

the gap labial to the implant filling both the bone and tissue zones till the free gingival margin level as described by Chu et al.[12] Afterwards, a screw retained provisional restoration was placed maintaining the graft in position.

For both groups, immediate nonfunctional loading protocol was implemented. an anatomical customized transmucosal PEEK healing abutment (PEEK Temporary Cylinder, Biohorizons Implant Systems, Birmingham, Alabama Inc., USA) was used to seal the socket orifice and maintain the original socket architecture for few days till the original restoration delivery occurred. The socket orifice gaps were sealed with flowable composite resin around the PEEK temporary abutment (Filtek™ Supreme Ultra Flowable Restorative, 3M Corporate Headquarters, MN, USA), then finished and polished extra-orally. All subjects in both groups were scanned with an intraoral digital scanner for the final crown fabrication. The fabricated zirconia crowns were designed with S-shaped design at the transmucosal part in order to support soft tissue profile and minimize the tendency for postrestorative recession.[20]

2.5 | Postoperative phase

Patients were prescribed antibiotics including 500 mg metronidazole and 500 mg Ciprofloxacin (Minapharm Pharmaceuticals) every 12 and 24 h. preoperatively and after extraction for 5 days. Nonsteroidal anti-inflammatory drug (Catafast sachets 50 mg, Novartis) were prescribed whenever needed to relief the postoperative pain as well as Chlorhexidine mouthwash 0.12% for 2 weeks postoperatively. Patients were also instructed to place extraoral cold packs on the surgical site.

2.6 | Outcome assessment

The primary outcome assessed in this study was the buccopalatal dimensional ridge change. The buccopalatal dimensional ridge alterations were assessed via intra-oral digital scans to assess the difference and changes in the overall ridge dimensions (mm) at baseline and after 1 year. Reference points were assigned in the baseline measurements of the scans using the Standard Triangle Language (STL) files of the models obtained via IOS, to allow standardized comparisons after 1 year. The 3D software (NemoSmile Design 3D, Nemotec, Madrid, Spain) allowed the alignment of the reference points identified on the models. Similarly, the mm vertical soft tissue changes were assessed by three measurements, taken at the tip of the mesial papillae, tip of the distal papillae, and mid-facial gingival margin, on the day of the final restoration delivery and were compared to measurements after 1 year. The changes in soft tissue height in mm were identified in the three reference points by superimposing the baseline file with the postoperative file using the STL files of the models. Regarding the model superimposition, a preoperative baseline and 1-year postoperative full arch scans, including the whole teeth and palatal rugae area were taken to facilitate the superimposition. Superimposition was done using TRIOS3 shape IOS software patient monitoring tool in

which both scans were chosen and superimposed by default, after that the superimposition was confirmed and the two scans were overlapped. Measurements were performed on the superimposed models that were imported into an STL viewer (3Shape Ortho viewer, 3Shape, Denmark). Using a measurement tool, a cross-sectional section was taken at three points; mesial papilla, mid-facial gingiva, and distal papilla. At each cross-section, the most coronal gingival point was taken from the preoperative and postoperative superimposed scans, and a linear measurement was taken between these two points to measure the vertical soft tissue changes. The points were taken at the gingival line as that was drawn by the software. The best-fit algorithm of the software perfected the superimposition process (Figure 4). This was shown to be an accurate method for soft tissue volumetric measurements.[21]

After 1 year, pink esthetic score (PES),[22] was assessed from clinical photographs by two independent well-trained examiners (TA and SN) with good intra-examiner agreement (0.82 k value). The PES matches the peri-implant mucosa around an implant-supported restoration of the contralateral natural tooth. The PES includes seven variables: the mesial papilla, distal papilla, mid-facial level, mid-facial contour, alveolar process deficiency, soft tissue color, and soft tissue texture. Each variable is evaluated with a 0–1–2 score, with 2 being the best and 0 being the worst. The total PES is the sum of the scores of the seven domains, ranging from 0 to 14 (14 is the best score, indicating an almost similar appearance to the contralateral natural tooth). The mesial and distal papillae are assessed for completeness. All other variables are evaluated in comparison to a reference adjacent or the contralateral tooth. The criteria proposed by Smith and Zarb[23] were used to evaluate implant success.

The labial plate of bone thickness was assessed as the distance from the root surface to the outer labial bone surface on the sagittal section of the CBCT scan (Carestream Health, CS 8100 3D System) at baseline before extraction at three points: the implant platform (crestal thickness), half of the implant length (middle thickness) and implant apex (apical thickness). The labial bone thickness was measured again at the same locations after 1 year post restorative, then the difference between the two readings was calculated to determine the amount of bone changes (Figures 5 and 6).

2.7 | Statistical and power analysis

A total sample size of 22 patients was calculated to detect a mean difference of 1 in the buccopalatal ridge width with SD of 0.8 based on previous data,[24] with 5% level of significance and 80% power which was increased to 26 patients to account for lost to follow-up (Power and sample size program: biostat.mc.vanderbilt.edu/twiki/bin/view/Main/Power Sample Size). Normality of the data was explored using

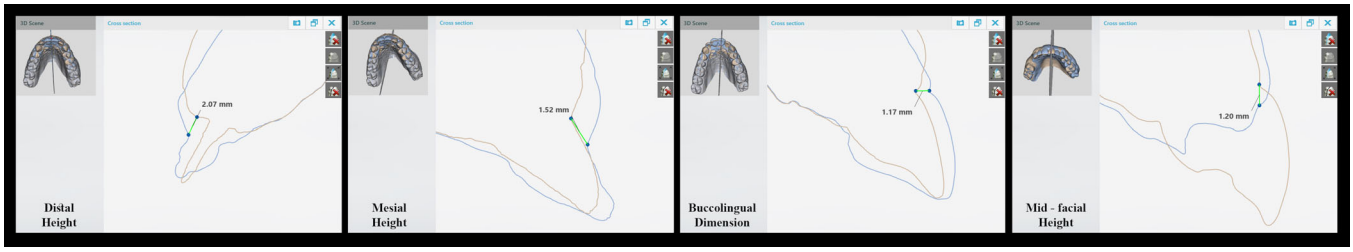

FIGURE 4 Measuring the soft tissue and ridge volumetric changes.

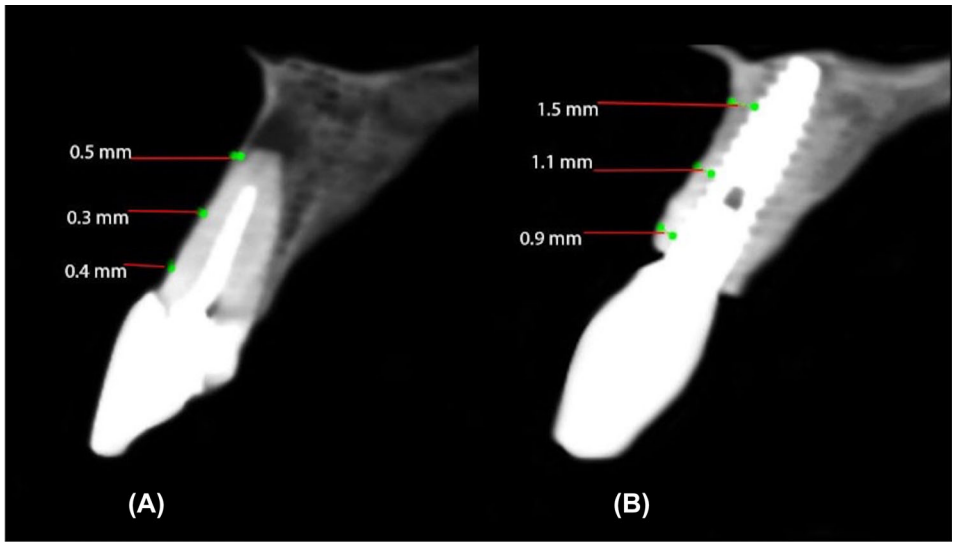

FIGURE 5 Sagittal section on the cone beam computed tomography (CBCT) scan before extraction (A) and 1 year post immediate implant placement (B) in the bone shield group. Labial bone thickness measured at three levels, crestal, middle and apical.

Kolmogorov–Smirnov and Shapiro–Wilk tests and data was described as; mean, standard deviation (SD), mean difference, 95% confidence interval, and frequencies and percentages. The unpaired Student's *t*-test was used for quantitative data and the chi-square test was used for qualitative data. The significance level was set at $p \leq 0.05$. Statistical analyses were performed using IBM SPSS Statistics (IBM SPSS Statistics for Windows Version 23.0, Armonk, NY: IBM Corp.)

3 | RESULTS

The patients demographic and clinical data are shown in Table 1. Both groups showed 100% implant survival after 1 year. Measurements of bucco-palatal ridge thickness after the two interventions at baseline and 1 year later are presented in Table 2. There were no statistically significant differences ($p > 0.05$) in baseline bucco-palatal ridge thickness between the two groups. However, the bone shielding concept demonstrated stability in the bucco-palatal ridge thickness of 9.43 (±1.29) mm after 1 year compared to 9.82 (±1.41) mm recorded at baseline. Despite showing statistical significance ($p = 0.016$), this difference was clinically insignificant. On the other hand, the DZ showed a statistically significant ($p = 0.018$) loss in the bucco-palatal ridge thickness after 1 year (7.83 ± 1.76 mm) compared to baseline values (9.49 ± 1.63 mm). Moreover, the change in bucco-palatal ridge thickness at 1 year from baseline in the bone shielding technique was −0.38 (±0.47) mm, and − 1.67 (±0.89) mm in the DZ group, which was a statistically significant difference ($p = 0.0002$).

The mm vertical soft tissue changes after 1 year in both groups are shown in Table 3. With regards to the bone shielding concept, clinical measurements after 1 year revealed soft tissue stability with minimal gingival recession at the mesial papilla, mid-facial gingival margin, and distal papilla of −0.12 (±0.24), −0.15 (±0.35), and − 0.19 (±0.26) mm, respectively. However, the DZ resulted in gingival recession in all three measurements with the mm mean (±SD) of the vertical changes of soft tissue at the mesial papilla, mid-facial gingival margin, and the distal papilla measured at −0.23 (±0.13), −0.44 (±0.23) and − 0.59 (±0.31) mm, respectively. The present statistical analysis showed no significant differences between the two protocols at the mesial papilla ($p > 0.05$) measured 1 year after the procedure, however, this was significantly different for the midfacial gingival margin and distal papilla at $p = 0.026$ and $p = 0.0025$, respectively.

The average PES in the bone shielding concept was 12.05, with the following distribution: a score of 13 in 2 cases, a score of 12 in 8 cases and a score of 11 in 3 cases. While the average PES in the DZ

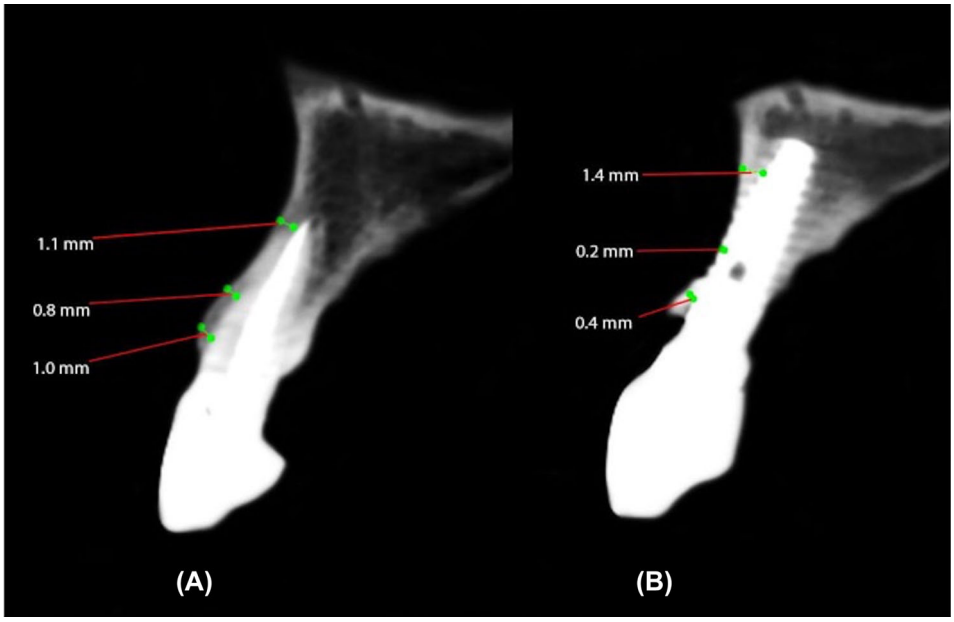

FIGURE 6 Sagittal section on the cone beam computed tomography (CBCT) scan before extraction (A) and 1 year post immediate implant placement (B) in the dual-zone group. Labial bone thickness measured at three levels, crestal, middle, and apical.

TABLE 1 Patient demographic and clinical data.

	Bone shielding $n = 13$	DZ $n = 13$	*p*-Value
Age (years) mean (±SD)	36.42 (±15.6)	33.5 (±12.57)	0.40
Male *n* (%)	4 (30)	2 (15)	0.27
Female *n* (%)	9 (70)	11 (85)	
Central incisor (*n*)	8	4	-
Lateral incisor (*n*)	3	6	
Canine (*n*)	2	3	
Implant survival *n* (%)	13 (100)	13 (100)	1

TABLE 2 Bucco-palatal ridge thickness (mm) in the two studied groups throughout the experimental period.

	Bone shielding ($n = 13$) Mean (±SD)	DZ ($n = 13$) Mean (±SD)	Mean difference [95% CI]	p-Value
Bucco-palatal ridge thickness (mm)				
Baseline	9.82 (±1.41)	9.49 (±1.63)	0.32 [−0.97, 1.61]	0.608
1 year	9.43 (±1.29)	7.83 (±1.76)	1.61 [0.30, 2.91]	0.018*
p-Value	0.016*	0.001*	-	-
Change in bucco-palatal ridge thickness (mm)	−0.38 (±0.47)	−1.67 (±0.89)	1.28 [0.68, 1.89]	0.0002*

*Significant at $p \leq 0.05$.

TABLE 3 Vertical changes (in mm) of soft tissue after 1 year in both studied groups.

	Bone shielding ($n = 13$) mean (±SD)	DZ ($n = 13$) mean (±SD)	Mean difference [95% CI]	p-Value
Mesial papilla	−0.12 (±0.24)	−0.23 (±0.13)	0.11 [−0.05, 0.28]	0.170
Mid-facial gingival margin	−0.15 (±0.35)	−0.44 (±0.23)	0.29 [0.37, 0.54]	0.026*
Distal papilla	−0.19 (±0.26)	−0.59 (±0.31)	0.40 [0.16, 0.64]	0.003*

*Statistically significant at $p \leq 0.05$.

TABLE 4 Thickness in labial bone in both groups throughout the experimental period.

	Bone shielding Mean (±SD) $n = 13$	DZ Mean (±SD) $n = 13$	Mean difference [95% CI]	p-Value
Apical bone thickness mm				
Baseline	1.26 (±0.61)	1.16 (±0.23)	0.09 [−0.27, 0.47]	0.59
1 year	2.12 (±0.56)	1.80 (±0.33)	0.31 [−0.06, 0.69]	0.10
p-Value	0.0001*	0.0001*	-	-
Bone gain	0.85 (±0.23)	0.64 (±0.32)	0.21 [−0.01, 0.44]	0.06
Middle bone thickness (mm)				
Baseline	1.06 (±0.44)	1.01 (±0.31)	0.05 [−0.26, 0.36]	0.73
1 year	1.64 (±0.50)	0.83 (±0.52)	0.81 [0.39, 1.23]	0.0005*
p-Value	0.0004*	0.22	-	-
Bone gain	0.57 (±0.43)	−0.18 (±0.5)	0.75 [0.37, 1.14]	0.0004*
Crestal bone thickness (mm)				
Baseline	0.79 (±0.39)	0.73 (±0.26)	0.06 [−0.21, 0.33]	0.64
1 year	0.82(±0.40)	0.34 (±0.33)	0.48 [0.17, 0.78]	0.003*
p-Value	0.68	0.0005*	-	-
Bone gain	0.03 (±0.28)	−0.38 (±0.29)	0.41 [0.18, 0.65]	0.001*

*Statistically Significant at $p \leq 0.05$.

group was 10.29 with the following distribution: a score of 12 in 1 case, a score of 11 in 2 cases, a score of 10 in 6 cases and a score of 9 in 4 cases.

Measurements of labial bone thickness in the two interventions at baseline and after 1 year are presented in Table 4. There was no significant difference in the baseline labial bone thickness at the apical, middle and crestal levels between the two groups ($p > 0.05$). The bone shielding concept showed a statistically significant difference in the apical and middle bone thickness ($p \leq 0.001$), while the crestal bone thickness was insignificant ($p = 0.68$) after 1 year compared to baseline values. Meanwhile, DZ revealed a statistically significant difference in the apical and crestal bone thickness ($p \leq 0.001$), while the middle bone thickness was insignificant ($p = 0.22$) after 1 year compared to baseline values. After 1 year, the bone shielding concept showed mean (±SD) mm bone gain at the apical, middle and crestal levels, reporting 0.85 (±0.23), 0.56 (±0.43) and 0.03 (±0.28) mm, respectively. While DZ demonstrated 0.64 (±0.32) mm bone gain apically, yet bone loss was revealed at the middle and crestal levels showing −0.18 (±0.5) and − 0.38 (±0.29) mm, respectively. Moreover, there was no significant difference in the bone gain at the apical level

between the two studied groups after 1 year ($p = 0.06$). Interestingly, the bone shielding concept showed a statistically significant more bone gain mm ($p < 0.001$) at the middle and crestal levels after 1 year compared to DZ which revealed bone loss.

4 | DISCUSSION

All results demonstrated herein were measured using digital three-dimensional volumetric analysis, which offers the benefits of being comprehensive and accurate,[25] to detect the post restorative midfacial gingival recession and loss of ridge contour.[26,27] That is considered the main cornerstone in the assessment of the final esthetic outcome.[28,29] Given the limited familiarity with bone shielding and DZ concepts, the results of the present study may provide additional insight and evidence to the literature in terms of esthetics and soft and hard tissue alterations.

Regarding the soft tissue difference in vertical height, the current study found that the mid-facial portion had a mean difference of −0.15 in the bone shielding group, which was statistically significantly higher compared to the in DZ group (−0.44). The enhanced soft tissue readings displayed at mid-facial gingival margin in the bone shielding group could be attributed to the minimized deleterious effect of post-extraction buccal bone resorption resulting from the use of the bone shield placed over the buccal bone at the time of tooth extraction. The DZ group results were slightly inferior to the bone shielding group, which was in line with the work conducted by Wanis et al.[30] who stated that DZ was able to impede massive midfacial recession, where the recession displayed was 0.27 mm after 12 months. The bone shielding group results of the present study were consistent with those of Ghallab et al.,[14] which confirmed that vestibular extraction using bone shield exhibited a midfacial recession of 0.39 mm. The results were also in line with studies that showed a stable midfacial soft tissue level 12 months post-VST using the bone shield and contributed to the enhanced stable esthetic results to present the facial bone crest at the implant platform.[13,31]

Concerning the papilla height, the distal papilla had a mean of −0.18 mm in the bone shielding group and −0.59 mm in the DZ group. The mean difference in papillary vertical height was significantly higher in the DZ group compared to the bone shielding group at the distal papilla, which could be attributed to the stable soft tissue profile seen in the test cases. The results of the present investigation are supported by Elaskary et al.,[32] who reported a mean of −0.64 and − 0.56 mm for the mesial and distal papillae, respectively, using the vestibular socket technique with bone shield. However, there was no statistically significant difference between the two currently studied groups for the mesial papilla, which were measured as −0.12 and −0.23 mm in the bone shielding and DZ groups, respectively. The overall improved esthetics in the bone shielding group may also be due to the final restorations that were placed at an earlier time, thereby maintaining the soft tissue contour.

In addition, the results on bucco-palatal dimension ridge alterations in the bone shielding group analysis confirmed a stability in the bucco-palatal ridge thickness after 1 year with a mean of 9.43 mm compared to 9.82 mm at baseline. Although there was a statistically significant difference between 1 year and baseline, the ridge thickness showed a mean difference of −0.38 mm which was clinically stable. In contrast, the DZ showed a statistically significant loss in the bucco-palatal ridge thickness after 1 year with a mean of 7.83 mm and a difference of −1.66 mm compared to baseline values. This indicated a significant difference in the mean bucco-palatal ridge thickness between the two groups. Tarnow et al.[33] demonstrated that bone grafting at the time of implant placement into the gap in combination with contoured healing abutment or provisional restoration resulted in the smallest amount of ridge contour change which is in line with the current findings. In addition, Chu et al.,[24] showed that the mean ± SD buccal plate dimension changes after final restoration delivery were 7.45 ± 0.95 and 10.23 ± 2.30 mm at the implant abutment interface and apically, which was also in accordance with the present study. On the other hand, Shadid[34] reported an average of 0.3 to 0.6 mm volumetric ridge reduction in the DZ concept group with an average ridge dimension of 10.93 mm. However, the results of the later study were inconsistent because of the large variations between patients.

Studies investigating the DZ concept revealed improved esthetic results as well as soft and hard tissue stability compared to several other techniques, such as immediate implants with simultaneous connective tissue grafts, the socket shield technique, and when using immediate provisional restorations alone with no bone filling.[30,35–39] Meanwhile, this clinical trial assessed esthetic outcomes using the total PES which was significantly higher in the bone shielding group (12.04) compared to the DZ group (10.28). These findings might be related to the minimal ridge alteration that occurred in the bone shielding group. Furhauser et al.[22] published that a PES of 10–12 yields good esthetic results. The enhanced PES observed may also be attributed to the use of the flexible cortical equine shield located buccally, which maintained the buccal bone architecture until bone resorption and substitution occurred, because of its superior location (being above the buccal plate), its enhanced physical character and the slow biodegradation rate of the barrier membrane that contributed positively to the overall regenerative effect. Regarding DZ concept, Chu et al.[24] recorded an average PES of 12.79, which was superior to that observed in the Wanis et al.[30] randomized clinical trial, which displayed a PES of 11.36 at 12 months. The present bone shield group PES scores were slightly higher than those of Dhande et al.[31] with a PES of 11.33 and comparable to a previous study which reported a PES of 12.67.[14] These enhanced outcomes were attributed to the intactness of the buccal plate of bone in all cases.

Since soft tissue alterations basically follow the physiological underlying alveolar bone resorption especially in thin-walled sockets,[40] the results of the present investigation could be attributed to hard tissue dimensional changes. Concerning the hard tissue changes, bone shield concept and DZ groups showed 0.85 ± 0.23 and 0.64 ± 0.32 mean ± SD mm bone gain at the apical levels respectively after 1 year with no significant difference between them ($p = 0.06$). Nevertheless, the bone shielding concept revealed mean ± SD mm

bone gain at the middle (0.56 ± 0.43) and crestal (0.03 ± 0.8) levels which was statistically significant ($p < 0.001$) at 1 year compared to the DZ group which demonstrated 0.18 ± 0.5 and 0.38 ± 0.29 mm bone loss at the middle and crestal levels, respectively. The present findings were consistent with previous clinical trials evaluating labial bone thickness after using DZ.[24,30] Chu et al.[24] reported a 0.33 mm and 0.34 loss in the crestal and middle labial bone thickness after 1 year, respectively. Likewise, Wanis et al.[30] reported mean crestal buccal bone loss at the level of implant shoulder of 0.88 ± 0.41 mm in the DZ. They concluded that the placement bone graft in the socket could not prevent the horizontal dimension reduction at 12 months and attributed this to the inevitable postextraction dimensional changes and bundle bone resorption, which support the findings presented herein.

The superior soft and hard tissue readings observed in the bone shielding group, might be explained due to the effect of using the flexible cortical bone shield which was positioned over the thin buccal plate of bone. This might have allowed partial or total postextraction buccal bone remodeling while preserving the regenerative space with no drop of the facial contour, until a *de novu* bone is formed inside the socket underneath (space preservation). The bone shield preserved the ridge dimensions by allowing buccal bone remodeling and thickening of the overlying soft tissue as well.[18] Added to that, the proven overlaying soft tissue attachment to the bone shield helps the stability of the marginal tissues.[13,31] The nature of the bone shield's slow biodegradation rate and enhanced physical character considered a contributing factor.[13,14,41] The current observations were supported by Elaskary et al.,[13,18,31,41] showing enhanced hard tissue changes after using the vestibular socket technique with bone shield and immediate implants which emphasizes the ability of this technique to regenerate, maintain, and preserve ridge dimensions for longer assessment times.

The healing period was uneventful in this investigation, evident by the absence of complications in both groups. Furthermore, this randomized clinical trial observed 100% survival for all implants which was similar to previous reports.[18,34] On the other hand, overfilling of the bone graft to the soft tissue margin was only performed in the DZ group, while in the bone shielding group the bone graft did not over fill to the marginal soft tissues. However, there are two systematic differences between the groups with a possible form of confounding bias, the membrane and the level of bone filling.

4.1 | Limitations of the study

Although the strength of the current randomized clinical trial lies in its design as well as its novelty in comparing bone shielding to the DZ concept, the core limitation of the current study is that it lacks histological analysis of the hard and soft tissues after various treatment protocols.

4.2 | Future directions

Future studies could focus more on the implementation of the bone shielding concept versus the other treatment modalities with a longer follow-up periods and larger samples of the population to validate the present findings.

5 | CONCLUSIONS

The bone shielding concept improved soft and hard tissue dimensional ridge stability compared to the DZ technique for placement of immediate dental implants in thin-walled buccal plate of bone of fresh extraction sites in the esthetic zone. Enhanced PES results, along with papillary and midfacial soft tissue stability overtime warrants the clinical application of the bone shielding concept in intact thin buccal plate of bone in fresh extraction sites.

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DATA AVAILABILITY STATEMENT

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

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