

EVALUATION OF IMMEDIATE IMPLANT PLACEMENT WITH A MODIFIED SOCKET SHIELD TECHNIQUE USING XENOGENIC BONE GRAFT (A RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

BACKGROUND: Modified Socket shield technique, is an approach used to help maintain buccal bone level after implant insertion. However, the significance of bone grafting of the gap between the labial shield and the implant, in improving bone regeneration and prevention of the soft tissue ingrowth, has been described.

AIM OF THE STUDY: Evaluation of clinical and radiographic outcomes of using xenogenic bone graft on outcome of immediate dental implant placement using the modified socket shield technique.

MATERIAL AND METHOD: 16 patients were divided into two study groups. Control group received an immediate implant with modified socket shield technique. Test group received immediate implant with modified socket shield and bone graft put in the buccal gap. Outcome measurement was primary and secondary implant stability measurement and radiographic evaluation.

RESULTS: Patients in both groups experienced minimum to moderate postoperative pain and no postoperative edema was noticed. Peri-implant Bone Mineral Density (BMD) after 6 months for the test group showed to increase with a % change median of 39.4 % and this was found to be significantly higher than the control group. Implant secondary stability was found to be significantly higher in the test group with a median of 78 Implant Stability Quotient (ISQ) compared to 73 ISQ for the control group.

CONCLUSION: Deproteinized Bovine Bone Mineral (DBBM) is effective in healing of peri-implant defect and provides an appropriate stability and enhanced Bone Mineral Density (BMD). However, this technique requires proper case selection and is considered highly sensitive.

KEY WORDS: Socket shield technique, gap bone grafting, root preservation

RUNNING TITLE: Evaluation Of Socket Shield Technique Using Xenogenic Bone.

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INTRODUCTION

Increasing demand for a fast aesthetic solution between patients visiting dental clinics, caused oral implantologists to offer more immediate choices than the delayed protocol recommended by Brånemark. Those recommendations included waiting for three months after removal of the tooth and from three to six months before any loading of the implant. ⁽¹⁾ Researchers had concluded that success rate of implant placed immediately after atraumatic tooth removal had similar predictable outcomes when compared to implants placed in healed extraction sites. ⁽²⁾ Others had found positive results in implant placed immediately with recording less resorptive changes after tooth extraction. ⁽³⁾

After tooth removal, alveolar ridge alterations occur naturally leading to bone loss, the main attributing factor to this

negative effect is the loss of periodontal attachments, and trauma accompanying tooth removal. The bone loss is especially pronounced on the buccal bone plate. ⁽⁴⁾ Root preservation has been reported to help in maintaining bone at the pontic site. ⁽⁵⁾ In 2010, Hürzeler et al., has tested a new approach, at that time, called socket shield technique. Their aim was to minimize the negative effect of tooth extraction on implant outcome. ⁽⁶⁾ This technique include preservation of the labial part of the root and they concluded that buccal bone height was stabilized.

Since then, many variants and modifications of socket shield technique have been reported. These included modified socket shield technique (MSST) which recommended reducing the thickness of the labial shield to 1.5 mm, maintaining its height to the crest level and leaving the jump gap between the shield and the implant non-grafted. ⁽⁷⁾

The importance of bone grafting of the gap between the implant and the labial shield has been described. (8) A histological study was published, to compare between bone healing, with and without bone graft in sheep after preparing osteotomy sites. In both situations, bone formation was shown. However, the resultant bone without a graft material was weak and with large spaces and less trabeculae which is not suitable for bearing masticatory forces resultant from implant loading. (9) Another human histological study had shown that presence of the gap between implant and the labial shield allows for a soft tissue ingrowth. (4) Human researches regarding the importance of grafting of the jumping gap is not available in current literature. Thus, Gluckman suggested in his accordance in 2018, that further studies is recommended to investigate the importance of bone grafting of the gap described in modified socket shield technique. (10)

The primary types of bone graft material that can be used are either autograft, allograft, xenograft, and, alloplasts. All grafting materials have one or more of three mechanisms of action: osteogenesis, osteoinduction, and osteoconduction. Xenogenic grafts are typically only osteoconductive. As, they provide inert scaffold suitable for the new bone deposition from the surrounding bone or encourage growth of differentiated mesenchymal cells along the graft surface. (11) The use of this material reduces the postoperative complication by avoiding harvesting of autogenous graft from a second surgical site. Moreover, the decades of use of the Xenogenic bone graft supports its effectiveness and biocompatibility as a bone regenerative material. (12)

The null hypothesis of the study was that modified socket shield technique with bone graft was not going to significantly differ from modified socket shield technique alone with regard to implant stability, as well as biological complications.

MATERIALS AND METHODS

All study measures were accomplished with an approval from Ethics research board, Faculty of Dentistry, Alexandria University. This study has been registered at, clinicaltrials.gov and granted an ID number: NCT04489654.

Study design: The study strategy was a randomized controlled clinical trial.

Study sample: A total sample size of 16 patients who were admitted to the outpatient clinic of Oral and Maxillofacial Surgery Department. They were divided into two study groups to evaluate the clinical and radiological outcome of modified socket shield technique with bone graft, taking into consideration 5% level of significance and 1% Precision using Z-test.

Sample size has been estimated according to results of previous studies. (7)

Method of randomization: A convenient sample complying with the inclusion and exclusion criteria were assigned. Participants were randomly assigned in either group using online randomizer (www.random.org).

Sample size estimation: A minimal total sample size of sixteen male patients (Eight per group) is required to identify an average significant difference in Bone Mineral Density (BMD) and Implant Stability Quotient (ISQ) among the group

(A) and group (B) taking in consideration 80% power and 95 confidence level via a Chi Square-test. (PASS program version). (7) All measures were completed in agreement with Ethic research board, Faculty of Dentistry, Alexandria University.

Eligibility Criteria's

- Age more than 18 years old irrespective of the gender
- One or more of non-restorable (fractured or decayed) tooth/teeth in the upper aesthetic regions (incisors, premolars).
- Free from periodontal diseases. (7)
- Sufficient bone volume to allow placement of an implant. (13)
- Ability to read and sign an informed consent form
- Adequate buccolingual width to allow for a buccal gap presence.

Omission criteria

- A medical history that contraindicates oral surgical treatment (uncontrolled/untreated diabetes mellitus, immuno-compromised status, radio/chemotherapy of the oral and maxillofacial region, treatment with oral and/or intravenous amino-bisphosphonates).
- Untreated periodontal disease. (7)
- Vertical root fractures on the buccal aspect. (7)
- Tooth /teeth with horizontal fractures below bone level. (13)
- Tooth /teeth with external or internal resorptions. (13)

Materials Used:

- Superline Implant System (dentium company, Seoul, Korea.)
- implant stability measuring device : (Osstell™) , W&H Co, Gothenburg, Sweden
- Instruments for socket shield preparation: chamfer diamond bur. , long shafted carbide bur, A large-head round diamond bur.(SS White, USA)
- Instruments for removal of sectioned part: Microforceps, Periostomes. (PAK Martin International, Pakistan)
- Perimplant gap filling: OneXeno Graft. (OneGraft, Germany)

A. Presurgical Phase

Detailed history was taken from the patient which includes the following , phone number, place of living, job, and inquiries for any medical history was investigated.

The patient was examined extra and intra orally for caries examination, gingival health, and mobility or pain of tooth to be extracted

Radiographic examination of the patient included, panoramic radiograph for evaluation of sinus proximity and possibility of inserting a stable implant. A cone beam CT was done as a baseline measuring of the buccal bone height and density of the bone around the tooth to be extracted.

Pre-operative preparation of the patient included scaling and polishing if needed, an alginate impression to create a study cast for evaluation and recording

Surgical procedure^(7,8)

The crown of the hopeless tooth if presented was decoronated with a chamfer diamond bur and a large-head round diamond bur under copious irrigation, until the bone crest level. This step was skipped in already decoronated teeth due to caries or

fracture. The root was sectioned along the long axis into buccal and palatal halves with the long shank fissure bur. The lingual root fragment was carefully retrieved using microperiosteome. The remaining buccal root fragment was thinned and concaved slightly with the long shank fissure bur. Thickness of the buccal root fragment was about 2 mm to ensure resistance to fracture and resorption. The coronal part of this shield was beveled to make a lingual slope for a better emergence profile with a large head round diamond bur. The implant was inserted palatally to engage the palatal bone without contacting the socket shield. (Figure 1)

Immediately thereafter, implant stability was measured by Osstell™

Gap between the implant and the Labial shield was filled with xenogenic bone graft in the test group and was left empty in the control one. (Figure 2)

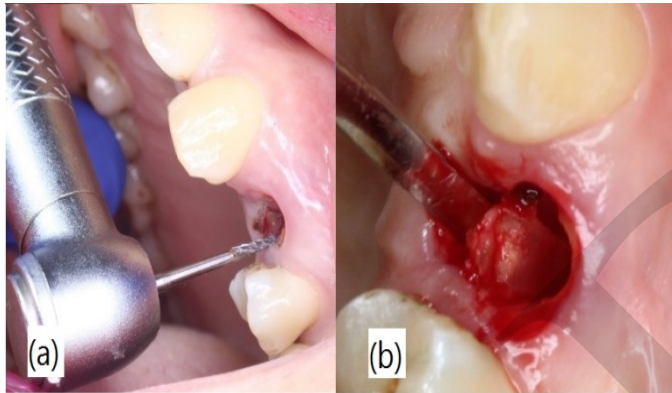


Figure 1: (a) showing fissure long shaft bur used for root sectioning (b) showing retrieval of the palatal root part after being mobilized gently with a periosteome.

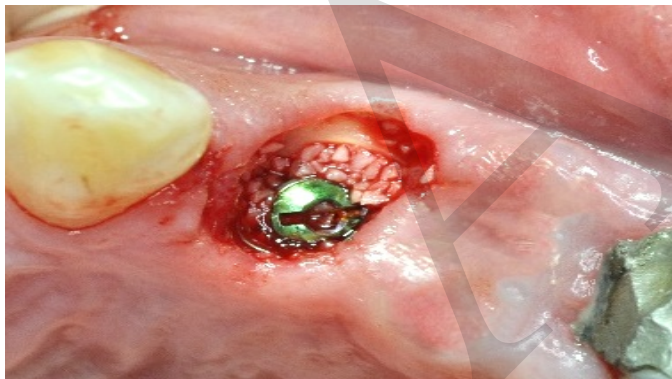


Figure 2: Clinical picture of implant placed palatal to the labial shield in study group with DBBM placed in buccal gap

Restorative procedure

All implants were immediately restored with a screw-retained provisional restoration. Aim of this is sealing the socket, and maintaining clot formation subgingivally. The gap was covered by a Teflon tape to avoid any invasion of filling material used in the procedure. A prepared acrylic crown shield with a hole at the center was then filled with flowable composite and put on the abutment after securing the screw driver in its place. After light curing the abutment is unscrewed and modified to take an s shaped profile form the gingival side. And, the occlusal surface is abundantly reduced

to ensure nonfunctional loading.

Four months postsurgically, definitive restoration was provided.

Post-operative care and follow up

Post-operative Medications:

Patients were prescribed Paracetamol 500mg (Panadol: manufactured by Uni Pharma, U.S.A.); 1 tablets every 8 hours for 5 day. In addition to Chlorhexidine Gluconate/benzylamine chloride mouth wash (Listerine: manufactured by, Johnson & Johnson, U.S.A.); twice a day. The patients were also prescribed Amoxicillin clavulanate 1gm (Augmentin: manufactured by, GlaxoSmithKline, England.); 1 capsule every 12 hours for 3 days postoperatively

Postoperative Clinical Evaluation

Patients were requested to return and were assessed for the factors of pain, wound dehiscence, facial inflammation, extreme mouth opening, dry socket development and potential harm to the lingual nerve. (9)

1. Postoperative pain:

The visual analog scale was utilized to gauge the degree of post-operative pain with a scale from 0 to 10 at 6hr, 12hr postoperatively and for 7 days after the extraction.

2. Postoperative edema (14)

Assessed in the 1st week postoperatively and measured as follows: None (no inflammation), Mild (intraoral swelling confined to the surgical field),

Moderate (extraoral swelling in the surgical zone), Severe (extraoral swelling spreading beyond the surgical zone).

3. Implant Stability

Measured by using ostell¹⁶ for both groups at implant placement time, and after 4 months postoperative at prosthetic loading phase. (15)

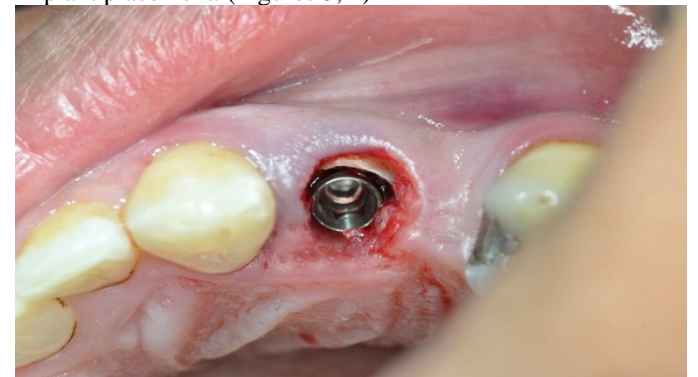
4. The biological complications(7)

This includes, Mobilization of the root fragment; Peri-implant mucositis, Peri-implantitis

Postoperative Radiographic Evaluation

Bone Mineral Density Measurement (BMD) (16)

The bone density was measured in Hounsfield units. Cone beam Computer Tomography (CBCT) (OnDemand3DTM Goddard Way, Suite 250 Irvine, CA 92618 USA) was used for all patients immediately after surgery, and at 6 months after implant placement. (Figures 3, 4)



¹⁶ Mega ISQ, Megagen, South Korea

Figure 3: Clinical picture of implant placed palatal to the labial shield in control group with the buccal gap left ungrafted.



Figure 4: CBCT measuring for BMD for a Study case. Six measurements of ROI taken along a straight line drawn in a midway between the implant and the shield. (a) Immediately, (b) After 6 months.

Buccal Bone Height ⁽¹⁶⁾

The measurements of bone height were taken immediately postoperatively and after six months. Data were collected in mm unit

Statistical Analysis of the Data

Data were fed to the computer and analyzed using Graph Pad prism. Significance of the obtained results was judged at the 5% level.

Tests performed were:

1. Mann Whitney Test

For abnormally distributed quantitative variables, to compare between two studied groups

2. Wilcoxon Signed Ranks Test

For abnormally distributed quantitative variables, to compare between two periods.

RESULTS

The selected patients were 30-51 years of age with mean age of 40.5±6.6 years and were of both sexes (6 males and 10 females). Teeth extracted in the study group were three maxillary central incisors, three maxillary first premolar, two maxillary second premolars. Teeth extracted in the control group were two maxillary central incisors, two maxillary first premolar, three maxillary second premolars.

1. Pain

Pain was evaluated daily for the first week then weekly for the first month using the VAS from 0 to 10 ("0" is pain free and "10" is extremely severe pain).

After surgery, the median of recorded values for the study group was 2.5 with maximum recorded value of 6 and minimum of 1. While the median recorded for the control group was 3.5 with minimum value 1, maximum value 6. Data was compared and found to be non-significantly different.

2. Swelling or infection

All patients did not experience any edema. No biological complications were identified upon examination within the

whole follow up period. No mobility in the tooth shield and no signs of peri-implantitis, or mucositis.

3. Measurement of Implant Stability by Osstell™

Data were collected immediately (Primary stability), and after six months from implant placement. (Secondary stability).

The median of implant primary stability for the study group was 68 ISQ with minimum value of 60 ISQ and maximum value of 73 ISQ. While the median of implant secondary stability was 78 ISQ with minimum value of 70 ISQ and maximum value of 83 ISQ.

This difference between primary and secondary stability of the study group was found to be statistically significant with p value <0.05.

The median of implant primary stability for the control group was 66.5 ISQ with minimum value of 61 ISQ and maximum value of 73 ISQ. While The median of implant secondary stability for the control group was 73 ISQ with minimum value of 66 ISQ and maximum value of 83 ISQ. This difference between primary and secondary stability was found to be statistically significant with p value <0.05.

The percentage of change of the study group was significantly higher than that of the control group. (Figure 5). The study group showed values of median 14.55% and minimum of 11 % and maximum value of 16 %, while the control group showed values of median 7.85%, minimum of 7 % and maximum value of 15.3 % (Table I)

Table I: Primary stability and secondary stability of the implant measured in ISQ of the study and control groups.

Group	Study n=8		Control n=8	
	Primary stability(ISQ)	Secondary stability(ISQ)	Primary stability(ISQ)	secondary stability(ISQ)
Minimum	60.00	70.00	61.00	66.00
25% Percentile	63.50	73.50	64.25	70.25
Median	68.00	78.00	66.50	73.00
75% Percentile	71.25	79.75	70.25	75.75
Maximum	73.00	83.00	73.00	83.00
P value	<0.05		<0.05	

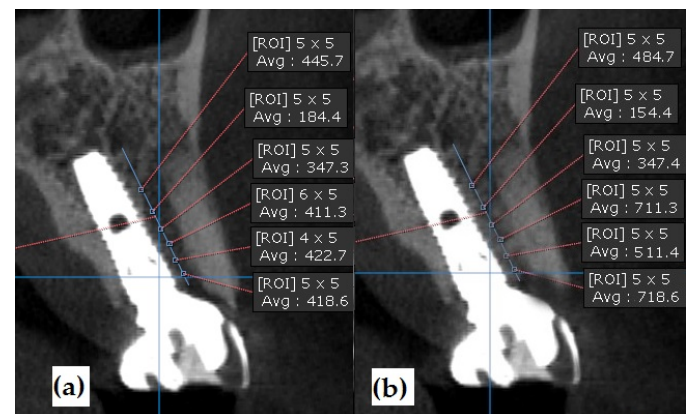


Figure 5: CBCT measuring of BMD for control case, (a) Immediately, (b) After 6 months

I. Radiographic Evaluation

Buccal Bone Level

Data of the Buccal Bone Height (BBH) were collected, immediately after implant placement (BBH-IM) and after 6 months (BBH-6ms).

Data were measured as a difference between buccal bone levels immediately post surgically and after 6 months, the median of each group was calculated and mann-whitney test was used to see the level of significance.

The median buccal bone loss for the study group was 0.24mm with a minimum recorded value of 0.09mm and a maximum recorded value of 0.4mm, while the median buccal bone loss for the control group was 0.45mm mm with a minimum recorded value of 0.1mm and a maximum recorded value of 0.5mm.

This difference in the buccal bone loss value between the study and the control groups was found to be not statistically significant with a u value 15 and p value >0.05

Bone Mineral Density (BMD)

Data of the peri-implant bone mineral density were collected, immediately after implant placement (BMD-IM) and after 6 months (BMD-6ms).

The difference in data immediately and after 6 months was calculated and compared to the initial data to analyze the percent change of each group. (Figure 6)

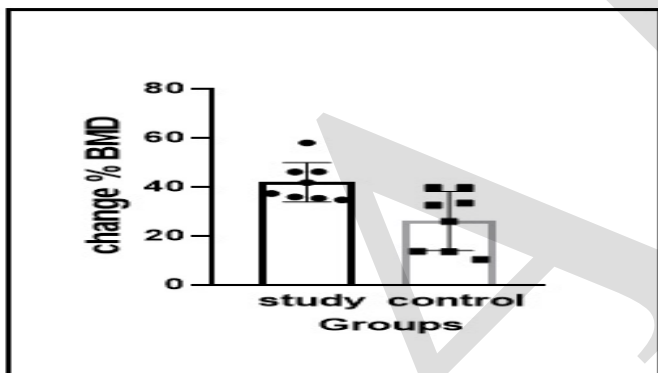


Figure 6: Bars representation of medians±interquartile ranges of both study and control groups of %change of Bone Mineral Density (BMD) , • significant difference between group, p value < 0.05

Percentage change of BMD of the study group values were, median of 39.45%, minimum value 34.6% and maximum value 57.9%. This is significantly higher than that of the control group where median is 29.10%, minimum value 10.3 % and maximum value 39.6%. (Table II)

Table II: % change in the peri-implant BMD in relation to immediate postoperative peri-implant BMD (%change BMD) of the study and control group

	Study (% change BMD)	Control (% change BMD)
Minimum	34.60	10.30
25% Percentile	35.43	13.53
Median	39.45	29.10
75% Percentile	46.08	38.03
Maximum	57.90	39.60
U	8	
P	<0.05	

DISCUSSION

Socket shield technique has been a point of interest for many researches due to its promising effect on maintenance of alveolar bone height and width, better aesthetic results, and implant survival rate. According to sirompas et al. 2014, he investigated the effect of using this technique along with implant placement, the average of alveolar bone loss at mesial and distal sides of implants were 0.18 and 0.21 mm, respectively, after 2 years of follow up. (13)

Zhang et al. in 2019, noticed that the height of buccal bone, when a labial root shield was retained, was significantly higher when compared with control groups that had the entire root removed. He investigated also the effect of putting a xenograft lingual to the root shield and compared it with a control group leaving the gap empty. He found that labial bone resorption was reduced in the group were he put xenograft 0.2mm difference. (17) Sharma et al. in 2012, recorded bone formation in his histological investigation which was newly formed on the submerged root. Cherel and Etienne et al. in 2014, found that there was perseverance of interdental septal bone when sagittal parts of two neighboring teeth were retained along with implant placement (18)

However, Gharpure and Bhatavadekar et al, stated that this technique has many complications linked to it, which includes, failure of secondary stability establishment, shield infection and mobility, and formation of cementum and fibrous tissue between the implant surface and the shield. (19) Bäumer et al, recorded mean bone loss of 0.66 mm, after 5 months follow-up. This was interpreted to be high due to absence of immediate provisionalization to shape the gingival outline which in return stabilize bone resorption.(20)

Immediately placing a provisional crown acts as a barrier for bone graft stabilization and promotion of gingival healing around the root fragment. (8) In our study, after confirming implants gained ISQ above 60, immediate loading was performed. This ISQ value, was reported to be the threshold necessary to withstand immediate loading.(21)

In our study, socket shield technique was modified and put under testing for the grafting of the buccal gap space to see its effect on osseointegration of the implant. The bone graft used

was xenogenic bone from bovine sources, the labial shield was reduced to about 2 mm in thickness and its height was flushed at the level of the labial bone.

In both, study and control groups, the technique was done without raising a flap. Patients didn't experience any kind of post-surgical swelling in either group, this is due to less invasive technique used and the preserved buccal periodontium which lead to faster and better healing. The labial shield was stable during the surgical procedure in all patients and within the follow-up period with no signs of peri-implantitis or mucositis. During the removal of the temporary custom made abutment, and before the final prosthetic loading, a healthy emergence profile was noted with no signs of scarring or loss of volume. This could be due to using microperiosteome during removal of the palatal part of the root, which made the process atraumatic and as least damaging to the surrounding hard and soft tissues, as possible, this is supported by Sharma et al. in 2015.⁽²²⁾ However, patients experienced pain post-surgically in both groups which was reported as being mild to moderate, with a median VAS score of 2.5 for the study group, and 3.5 for the control group, this was found to be non-significantly different. This agrees with the findings of Cannizzaro et al. in 2011, were flapless implant procedure was found to produce less post-surgical pain and swelling along with a significant reduction in operation time and patients' experience was more pleasant.⁽²³⁾

CBCT was used to evaluate BMD and Bone height around the implants. Many studies have supported that CBCT is a reliable in measuring small changes that doesn't significantly differ from direct measurements.⁽²⁴⁾ Bone graft used in our study was a Deproteinized Bovine Bone Mineral (DBBM), according to many years of researches it is the most used type of bone with very promising outcomes. Records of BMD was taken from the CBCT, immediately after surgery, then after 6 months. The group where DBBM was used in the buccal gap, had better BMD as compared with the control group. This finding is in accordance with the findings of Schlegel et al where he performed a histological study to compare between DBBM and other bone substitutes, greater implant to bone contact percentage was reported in the former donating for more bone gain.⁽²⁵⁾ DBBM acts as a scaffold for promoting bone formation, it has also shown the probability of being osteogenic by signaling for osteoblastic differentiation, however, the mechanism of this process is still not known.⁽²⁶⁾ DBBM placement inside bone defect shows integration on the peripheries with connective tissue presenting in the center showing the continuous bone remodeling process.⁽²⁷⁾ DBBM was also used in sockets after extraction in 15 patients and histologically examined these sites after 9 months. It was found to be a biocompatible biomaterial that helps in ridge preservation.⁽²⁸⁾ Caneva et al. in 2012 concluded that DBBM placement had shown a reduction in ridge alterations post extraction and better osseointegration of implants.⁽²⁹⁾ Another research used DBBM in filling of bone defect and left it to heal for 7 months, domination of connective tissue was noted in histological examination.⁽³⁰⁾ In another experimental study preservation of the ridge dimensions were successful although delayed healing was observed.⁽²⁶⁾ Hallman et al. 2001

found that after 6 months the amount of unresorbed biomaterial was 14.5% and that decreased to about 12% after 3 years.⁽³¹⁾ Another histological study by Hsu et al. demonstrated that DBBM had no effect on facial bone loss and integration of implants.⁽³²⁾

Bone remodeling and healing around the implant is a continuous process. The initial bone formed has loosely packed collagen fibers which later organized into thicker bundles lamellar bone and this is the desired end result. Remodelled bone increase bone to implant BIC ratio which in turn responsible for better stability.⁽³³⁾

For the purpose of investigating quality of osseointegration non-invasive methods like RFA has been documented to reflect the percentage of BIC without the need for histological retrieval, and thus, can be applied for clinical evaluation. In a study by scarano et al, in 2006, researchers investigated the relation between BIC % and RFA and found that the more the ISQ value recorded the more amount of compact bone and less trabeculae around the implant and more percentage of BIC.⁽³⁴⁾

In our study resonance frequency analysis was used for implant stability evaluation. Many studies has been using this tool as a reliable method for measurement.^(35,36)

Implants with ISQ 60 and above have been recorded to be suitable for immediate loading.⁽²¹⁾ In our study, median of primary stability for the study and control group was 68, 66.5 respectively. While secondary stability was 78 in the study group and 73 in the control group. The percentage of change for the study group was 14.5% compared to the control group with 7.8 %, this percentages were found to be significantly different.

CONCLUSION

The modified socket shield technique is efficient in maintenance of labial bone dimensions and consequently the overlying soft tissue. There have been a conflict in researches about the importance of grafting the jumping gap between the shield and the implant and its effect on osseointegration of the implant, so in our study DBBM has been used to correct the peri-implant defect to provide an appropriate stability. In addition, the custom made healing abutment helped the maintenance of the aesthetic profile. However, this technique requires proper case selection and is considered highly sensitive.

CONFLICT OF INTEREST

The writers state that they have no conflicts of interest.

REGISTRATION

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All the materials required for the study were supplied by the oral and maxillofacial surgery division in Alexandria University.

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