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EVALUATION OF DENTAL IMPLANT STABILITY IN REGENERATED SOCKETS USING BIHYBRID COMPOSITE BONE GRAFT VERSUS NORMAL HEALED SOCKETS IN THE MAXILLARY ESTHETIC ZONE (RANDOMIZED CONTROLLED CLINICAL TRIAL)

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ABSTRACT

BACKGROUND: Alveolar ridge preservation using bihybrid composite bone graft as an intra-socket osseous graft is one of the techniques used to preserve alveolar ridge from resorption after extraction. In addition, dental implants became a mandatory choice in prosthetic treatment plan nowadays. Bone dimensions and quality are considered an important factors to insure the stability and success of an implant.

AIM OF STUDY: To clinically compare the stability of delayed loaded dental implants in sockets regenerated using bihybrid composite bone graft versus implants that were installed in nongrafted sockets.

MATERIAL AND METHODS: This study was conducted on twenty-two sockets, 11 of them with preplaced bihybrid composite bone graft after extracting unrestorable teeth and the other group with native bone. After 6 months, osteotomy was prepared and implant was placed. Primary stability was measured using resonance frequency analysis (osstell device). After 4 months secondary stability was also measured.

RESULTS: Twenty-two implants were inserted in extraction sockets of twenty patients, 8 males, 12 females. No statistically significant difference in primary and secondary stability between both groups was found. The mean primary stability for the study group was 56.00 ±5.98, while for the control group was 51.18 ±7.96 (P= 0.124). The mean secondary stability for the study group was 61.82 ±3.31, while for the control group 58.82 ±7.19 (P=0.223).

CONCLUSION: Grafting sockets using bihybrid composite bone graft does not enhance implant stability.

KEYWORDS: Dental implant, Bihybrid composite bone graft, Primary stability, Secondary stability, Osstell instrument

RUNNING TITLE: Implant stability in preserved sockets using bihybrid bone.

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INTRODUCTION

Alveolar bone resorption after tooth extraction became an inevitable true fact that should be avoided as soon as possible to preserve the dimensions of the ridge (1). Kim et al. reported that the average amount of bone loss was between 5-7 mm, and 2/3 of this reduction occurs within the first three months after dental extraction (1).

Ridge dimensions could be preserved by several techniques including immediate implant placement after extraction, socket preservation or ridge augmentation as a delayed modality. Immediate implant placement was found to be the best choice not only for preserving ridge dimensions but also preserving the natural architecture of the peri-implant mucosa (2). However, in some situations it is not recommended to place an immediate implant as in cases with purulent infection or lack of apical bone availability or presence of large peri-apical lesions which may compromise the prognosis of the implant (3). In such cases socket preservation followed by delayed implant placement become the ideal treatment plan for restoring the missed teeth (4).

Socket preservation is a technique where a bone graft material is placed into the empty socket at the time of extraction. A wide variety of bone graft materials can be used including autogenous, allograft, xenograft, and synthetic bone grafts with different techniques (5).

Autogenous bone combines osteoconductive, osteoinductive, osteogenic properties in comparison to other bone substitute. Another important advantage of autogenous graft is the absence of immunological reactions, that's why it has been considered the gold standard. However, there are

some limitations for using autogenous bone graft including restricted donor sites and possible harvesting morbidity, and limited available bone volume had been reported for intraoral bone grafts (5).
The allogenic bone graft is a bone substitute obtained from different individuals of the same species, having full osteoconduction and partial osteoinduction capabilities. The Advantages of allograft use is that there is no donor site morbidity or complications associated with harvest and that the needed quantity is readily available. Allograft disadvantages include delayed vascular penetration, slow bone formation, accelerated bone resorption, extrusion, infection, and a higher incidence of nonunion (6).
Xenograft material is widely used in guided bone regeneration field and the most common source is the bovine bone. Deproteinized bovine bone had an architectural geometry that is similar to that of human bone which facilitate new bone formation in direct contact to the graft (7).
Bovine bone had undergone several advanced tissue engineering technologies resulting in a new hybrid bioactive bone substitute. In this new concept bovine mineral bone matrix was combined with bioactive resorbable polymers and collagen fragments resulting in a bihybrid composite bone graft. Collagen fragments promote blood cell adhesion and colonization resulting in a quick growth of the patient's cells into the graft material. Biodegradable polymers provide perfect integration and osteogenesis and protect the bone from early resorption (8).
In 2023, Rateb et al. performed a study to evaluate the effectiveness of bihybrid composite bone graft in preserving the socket dimensions after tooth extraction. They concluded that this composite material has the ability to preserve the alveolar ridge height and width (9).
Implant success evaluation could be done by several techniques. One of the most common non-invasive techniques is measuring the implant stability (10).
Primary implant stability must be achieved immediately after implantation indicating a good mechanical retention of the implant into the surrounding bone. In contrast, secondary stability is measured after osseointegration indicating a biological stability in which a new structural and physiological contact between the implant and the pre-existing bone as well as newly-formed surrounding bone tissues formed by inherent osteogenic activities (10).
Vallecillo-Rivas et al. (2021) compared primary and secondary stability between preserved sockets using xenograft material and native bone. He has reported that higher ISQ values are obtained in implants placed in native bone than in bone regenerated with xenograft (11).
Therefore, this study aimed to measure and compare clinically the primary and secondary stability of delayed loaded dental implants in sockets regenerated using bihybrid composite bone graft and delayed loaded implants in non-grafted sockets

MATERIALS AND METHODS

Research design: The current research is a randomized controlled clinical trial. Twenty-Two patients were recruited from the Outpatient Clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University, Egypt. Parallel design with allocation ratio of 1:1 research had been approved by the ethics committee at the faculty of Dentistry Alexandria University. Approval number: 0660-04/2023 -30/4/2023.
The patients were divided into two groups. The study group included eleven patients who underwent socket preservation after extraction using bihybrid composite bone graft (Swiss Bone®) 6-8 months ago. While the control group included eleven patients with native bone that did not underwent socket preservation after extraction.

Eligibility criteria

The inclusion criteria for the case selection were patients requiring dental implants after performing socket preservation using bihybrid composite bone graft (Swiss Bone®) 6-8 months ago and patients did not underwent socket preservation in the maxillary esthetic zone. Age range 18-40, with good oral hygiene and good compliance to the treatment.
Patients were excluded if there was any infection present in the indicated area, if they were suffering from a systemic disease or disorder contraindicating the treatment or receiving a head and neck radiotherapy. Also they were excluded if they were heavy smokers or alcohol abusers, or suffering from parafunctional habits

Pre-operative evaluation

History was recorded and clinical examination was performed via inspection to detect any failure in the regenerated bone, presence of infection, presence of acute discharge.
Preoperative CBCT was performed for all patients for diagnosis and treatment planning by assessing the quantity of bone, proximity to vital structures and selection of the appropriate implant size.
Preoperative preparation including scaling and root planning for all patient (Figure 1). An alginate impression (Cavex Holland BV, Haarlem, The Netherlands) was taken and poured by stone forming a stone model and then scanned using digital scanner (Omnicam, Dentsply Sirona, USA).
Implant planning and surgical guide fabrication using computer software (Blue Sky Plan, Blue Sky Bio, USA). The surgical guide was then 3d printed (Photon S, Anycubic, China) (Figure 1).

Surgical procedure

Starting the procedure by injecting labial and palatal infiltration using 4% articaine with 1:100:000 epinephrine (Alexadricaine anesthetic solution, Alexandria Company for Pharmaceuticals, Egypt). A paracrestal incision including the labial papilla of the adjacent teeth was made using scalpel no.15 and bard parker handle no.3. A full thickness mucoperiosteal flap was then reflected. The surgical guide was placed to facilitate drilling in a proper location and proper orientation. Osteotomy was prepared using drills supplied by the implant surgical guide kit. C-tech implant (C-Tech Implant, C-Tech Company, Italy) was inserted in group I where the bone graft was placed (Figure 2). In group II C-tech implant was inserted in native bone (Figure 2). After the complete insertion of the implants, smart peg was attached to the implants to measure the primary stability using osstell ISQ device (Osstell ISQ device, W&H Company, Sweden) (Figure 3). The cover screw was then placed. The flap was finally sutured using polypropylene suture (Polypropylene suture, ghatwary medical GMS, Egypt) (Figure 4).

Post-Operative phase

Postoperative medication included clindamycin 300 mg every 12 hours for 4 days. (Dalacin C, Pfizer, Egypt) and Non-steroidal anti-inflammatory drug; Diclofenac potassium 50 mg tablets every 8 hours for 5 days for all patients (Cataflam, Novartis, Egypt).

Post surgical instructions included cold fomentation for the first 24 hours to reduce anticipated postoperative swelling and pain, rinsing with 0.12% chlorohexidine mouthwash starting from the next day (Hexitol, The Arab Drug Company, Egypt). Patients were instructed to maintain a good oral hygiene. After 10 days the sutures were removed.

Follow-up phase

Clinical evaluation was done daily for the first week, and monthly for any signs of failure, infection or any complications by intra oral and extra oral inspection of all patients in both groups. After four months, another paracrestal flap was incised and reflected. Cover screw was removed and healing abutment was placed and suturing of the flap was performed. After complete healing and suture removal secondary stability was measured using osstell ISQ device. (Figure 5)

Statistical analysis

Data were analyzed using IBM SPSS version 23 for Windows, Armonk, NY, USA. Normality was tested using Shaprio Wilk test and Q-Q plots. Age and implant stability values (ISQ) were normally distributed while percent change in ISQ values were not normally distributed. Percent change was calculated according to the following formula:

$$\frac{Secondary\ Stability - Primary\ Stability}{Primary\ stability}\ x\ 100$$

Intention to treat analysis was employed as a case was dropped out among the control group. The *Independent t test* was used to assess difference between groups regarding age and 1ry and 2ry implant stability while *Mann Whitney U* test was used to analyze percent change in ISQ values. *Pearson Chi Square* was employed to compare gender distribution. All tests were two tailed and the significance level was set at p value<0.05.

RESULTS

Twenty-two implants were placed in twenty patients (8 males, 12 females; with average 36.4% for males and 63.6% for females) (Figure 6). In the study group the mean age was 30.45 ±5.32 years, while the control group the mean age was 30.64 ±6.14 years (Table 1, Figure 6). These patients were enrolled in this randomized controlled clinical trial and the follow up time was four months.

Primary stability was measured directly after implant placement using Resonance Frequency Analysis device (Osstell ISQ device, W&H Company, Sweden). The mean primary stability for the study group was 56.00 ±5.98, while for the control group was 51.18 ±7.96 (P= 0.124) (Table 2, Figure 6). There was no significant difference between the two groups in primary stability. Secondary stability was measured after 4 months. The mean secondary stability for the study group was 61.82 ±3.31, while for the control group 58.09 ±7.98 (P=0.176) (Table 2, Figure 6). There was no significant difference between the both groups.

When comparing the percent change in implant stability between both groups it was found that the mean in study group was 11.54 ±13.33, while in control group was 14.81 ±14.49 (P= 0.491) (Table 3, Figure 6).

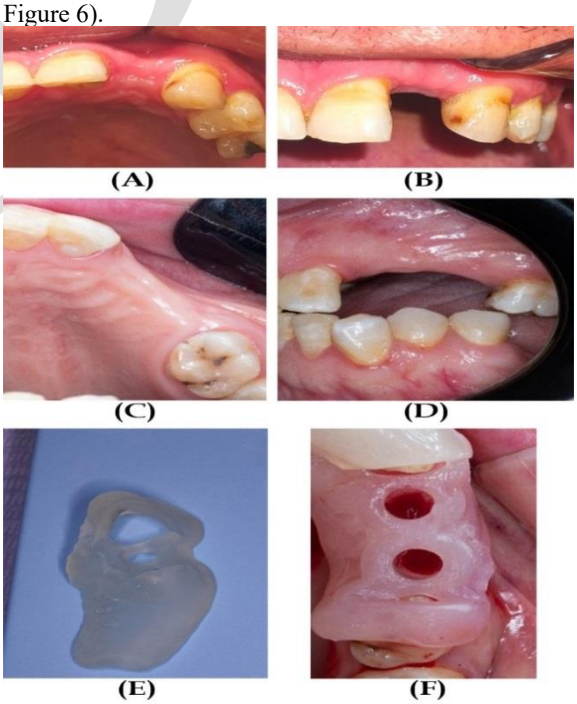

Figure (1): A,B) Occlusal and frontal view of ridge with pre-placed bone graft. C,D) Occlusal and frontal view of ridge with native bone. E) Surgical guide used in study case. F) Surgical guide used in control case.

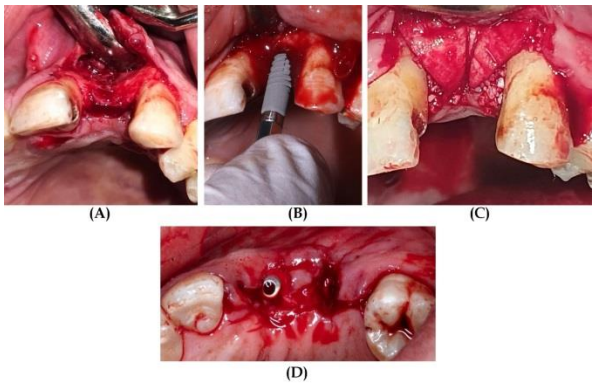

Figure (2): A) Bone width available after 6 months from socket preservation. B) Implant placement in previously preserved socket. C) Bone graft addition was needed to cover the implant and prevent implant dehiscence. D) Implant placed in native bone.

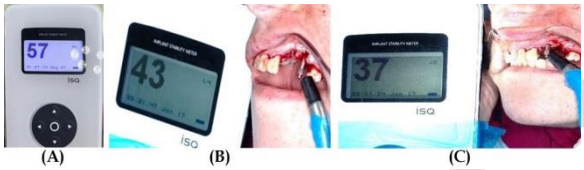

Figure (3): A) Primary stability in implant placed in preserved sockets. B,C) Primary stability in implants placed in native bone.

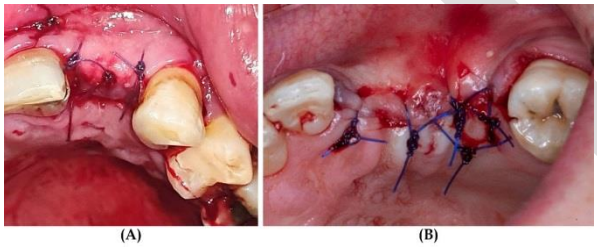

Figure (4): A,B) Suturing using polypropylene sutures.

Figure (5): A) Secondary stability in study case. B, C) Secondary stability in control case.

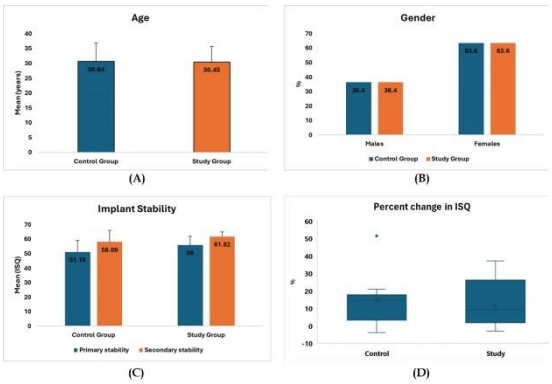

Figure (6): A,B) Mean of age and gender of the two groups. C) Primary and secondary implant stability in the two groups. D) Percent change in implant stability between the two groups.

Four cases were reported with complications. In one case in study group, an infection was observed as a peri-implant radiolucency at the follow up stage with neither clinical mobility nor pain upon percussion. In this case antibiotics were prescribed in the form of Amoxicillin + clavulanate 1 gm every 12 hours for 5 days (Augmentin, GlaxoSmithKline, UK) and Metronidazole 500mg (Flagyl, GlaxoSmithKline, UK.) every eight hours for 5 days.
Another case in control group, complained from implant loosening after 1 week of implant insertion and this case was excluded and replaced by another one.
The other two cases in both study and control groups, were suffering from insufficient bone width, with primary stability accounts for 37 in control case and 46 in study case. Therefore, bone graft was placed to compensate this deficiency in dimensions.

Table 1: Demographic data of the study sample

Variables		Control Group (n=11)	Study Group (n=11)	Test value (*p* value)
Age in years	Mean ±SD	30.64 ±6.14	30.45 ±5.32	0.074 (0.942)
Gender: n (%)	Males	4 (36.4%)	4 (36.4%)	0.00 (1.00)
	Females	7 (63.6%)	7 (63.6%)	

Table 2: Comparison of primary and secondary implant stability (ISQ) between groups

		Control Group (n=11)	Study Group (n=11)	Test value (*p* value)
Primary stability	Mean ±SD	51.18 ±7.96	56.00 ±5.98	1.605 (0.124)
	Median	50.00	58.00	
	Min – Max	37.00 – 62.00	46.00 – 63.00	
Secondary stability	Mean ±SD	58.09 ±7.98	61.82 ±3.31	1.431 (0.176)
	Median	56.00	61.00	
	Min – Max	47.00 – 69.00	56.00 – 67.00	
Test value (*p* value)		4.117 (0.002*)	3.030 (0.013*)	

*Statistically significant difference at *p* value<0.05

Table 3: Comparison of percent change in implant stability between groups

		Control Group (n=11)	Study Group (n=11)	Test value (*p* value)
% Change	Mean ±SD	14.81 ±14.49	11.54 ±13.33	0.689 (0.491)
	Median	14.58	9.09	
	Min – Max	-4.00 – 51.35	-3.23 – 36.96	

DISCUSSION

Socket preservation has been proven to be the best modality to minimize post-extraction resorption that occurs naturally after losing the teeth. This technique provides better dimensional stability and thus decreases the need for bone augmentation at restoring time (9).

On the contrary, Morjaria et al. (2014) found that the socket intervention therapies did not prevent the resorption but reduce the dimensional changes that occur post-extraction (12).

Various bone grafts had been used as a socket preservation material, the one has been chosen to be examined in this study was the swiss bone®. A bihybrid composite material composed of a xenograft bovine bone substitute enriched with collagen and biopolymers. This material was found to be effective in preserving alveolar ridge dimensions and providing better bone density when compared with non-grafted sockets (9).

The selected patients were free from any uncontrolled systemic diseases that may complicate the healing process of the implant. Bornstein et al (2009) reported that systemic diseases whether with or without systemic medications decrease the success and survival rate of implants and increase failure risk. Also patients with parafunctional habits, and patients receiving chemotherapy or radiotherapy and immunosuppressed patients were excluded from this study as Gomez de Diego et al (2014) stated that head and neck radiotherapy show lower levels of osseointegration throughout the time (13,14). Heavy smokers (>14 cigarettes per day) were also excluded because high risk of failure was documented to occur in smokers when compared with non-smokers (15,16).

In the present study, implant stability either primary or secondary was measured in grafted sockets and non-grafted sockets. A comparison was performed for implant stability between the study and control groups using an osstell device.

Most of the implants osseointegrated without any clinical complication neither mobility nor purulent infection with no pus discharge. However, the complications that occured in some cases show an equal distribution among the study and control cases.

Primary stability is related to the mechanical attachment of the implant in the surrounding bone at time of insertion, while Secondary stability is related to the response of tissues to the inserted implant.

Implant stability was measured using the Resonance frequency analysis (RFA) via the Osstell ISQ system. RFA is the measurement of the frequency with which a device vibrates. It reflects the micro-mobility of dental implants, which in turn is determined by the bone density at the implant site. Bafijari et al. stated that there is a strong relationship between implant stability and ISQ value that can be estimated by resonance frequency analysis (17,18).

After obtaining ISQ values, it was clear that implants in grafted and non- grafted sockets showed similar stability values, either primary or secondary stability.

In this study, after measuring primary and secondary stability using RFA via osstell device for both groups, the analysis of the values showed no significant difference in implant stability between grafted sockets using swiss bone® and non-grafted sockets.

Hashmi et al. (2020) compared the primary implant stability of implants placed in preserved sockets using autogenous dentin graft and implant stability in preserved sockets using alloplastic hydroxyapatite [HA] crystal. It was found that the primary stability of implants placed in sockets with autogenous dentin graft showed better results than the other group with alloplastic graft (19).

Similarly, in 2021, Santos et al. performed ridge preservation in two groups of post-extraction sites, the first group was preserved using autogenous mineralized dentin matrix, and the second group preserved using xenograft granules. Primary and secondary implant stability were assessed and the results showed similar measurements between both groups and no statistically significant difference was detected (20).

Also, a study was done by Taman et al. (2017) in which socket preservation was performed in the first group using autogenous bone graft mixed with hyaluronic acid and the other group only with autogenous bone, followed by delayed implant placement. Primary and secondary stability were assessed and it was concluded that there is no statistically significant difference in ISQ between both groups (21).

In addition, a comparison was performed by Chenchev et al. (2019), comparing primary and secondary stability of implants placed in three groups of sockets. The first group was preserved using allograft, the second group preserved using PRF as a sole grafting material, and the third group was left without socket preservation substitute. The study revealed no statistically significant difference in primary stability between the two preserved

groups, while it was significantly lower in the control group. In the three groups, secondary stability values were higher when compared to their primary stability (22).

Mayer et al. in (2020) applied a study on sheeps comparing primary stability in two groups of sockets preserved using xenograft (Bio-Oss, Bio-Active bone) and the third group was left for natural healing. It was found that there is no statistically significant difference between the three groups. Therefore, it was concluded that preserving sockets using xenograft did not influence primary stability in delayed implant stability (23).

On the other hand, Vallecillo-Rivas et al. in 2021 compared the implant stability between grafted and non-grafted sockets. The assessment of stability was done using the osstell device. They revealed a significant difference between implants placed in regenerated sockets and those placed in native bone. High stability was obtained in native bone in comparison with grafted sockets using xenograft bone substitute (11).

The difference in results between the current study and Vallecillo-Rivas et al. study could be referred to the larger sample size were used by them. In addition, the difference in study location, as the most frequent site in their study was the posterior mandible and the least frequent site was the anterior maxilla, thus entails using larger implant diameters. While the current study was performed in the maxillary esthetic zone, thus require the using of smaller implant diameter size.

Socket preservation is a technique that has been widely used lately and was proved to preserve ridge dimensions and limit amount of resorption occur after extraction. Some grafts succeeded in achieving the purpose of the technique and also in providing the implants inserted in the preserved sockets with the optimum stability that enhance and prolong the success of the implant. On the other hand, some other grafts maintain the ridge dimensions only without enhancing the rigidity of the ridge and thus affect the stability of the implant placed in these preserved sockets.

CONCLUSION

Within limitations of this research, we concluded that grafting the sockets using bihybrid composite bone graft does not enhance implant stability.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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