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MAXILLARY SINUS AUGMENTATION BY DIRECT IMPLANT VALVE APPROACH VERSUS BALLOON TECHNIQUE

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ABSTRACT

Objective: This study was designed to evaluate the efficacy of the Direct Implant Valve Approach (DIVA) versus the transcrestal approach assisted with a balloon for the rehabilitation of posterior atrophic posterior maxilla with implant-supported fixed prostheses. **Subjects and methods:** This prospective clinical study included 14 patients (7 males and 7 females). They ranged from 29 to 69 years with the posterior atrophic edentulous maxilla. All patients underwent clinical and radiographic examinations, including full-mouth intra-oral photographic series and cone-beam computed tomography (CBCT), which were performed to assess the maxillary sinus floor. The predictor variables were intraoperative primary stability and level of sinus membrane lifting. The outcome variables were secondary implant stability (Osseointegration) and the level of bone height gained. **Results:** The mean bone height before surgery was 5.814± 0.669mm, 6.84± 0.861mm for DIVA and Balloon groups respectively which became 12.78± 0.526 and 10.81 0.671after 6 months postoperatively. ISQ was 39.00±2.160, 40.00±2.160 which became 71.71±1.604, 70.43±1.272 after 6months for DIVA and Balloon groups respectively. **Conclusion:** The Balloon approach was an effective approach to augment alveolar bone height without causing maxillary sinus membrane perforation. However, the DIVA approach was used in the limited residual alveolar bone height and required meticulous surgical procedures.

KEYWORDS: Sinus membrane, bone height, crestal approach, Direct Implant Valve Approach, Balloon technique.

INTRODUCTION

After tooth extraction, resorption and pneumatization of alveolar ridges are common occurrences in the posterior maxillary region. These may cause not only a quantitative reduction but also a qualitative deterioration of bone leading to a skeletal bone segment inadequate for implant placement. In these situations, the residual vertical bone height is diminished making standard dental implant placement difficult [1-6]. Several techniques and procedures have been proposed to address this challenge and to obtain adequate bone dimensions for dental implant insertion. Boyne and James [1] introduced the maxillary sinus augmentation by lateral approach, a modification of the known sinus procedure according to Caldwell- Luc, to allow proper implant insertion into an atrophic maxillary ridge. Subsequently, sinus augmentation with lateral access has been widely studied as a safe and predictable treatment [7,8].

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In 1986, a sinus floor elevation by crestal approach was suggested by Tatum [9]. Summers, [10] proposed the osteotome technique to place dental implants in a simpler, more conservative, and less traumatic procedure than the lateral approach [11]. Some authors [12-14] suggested different modifications to Summers' technique based specifically on the use of different biomaterials and on the expansion and compression of the alveolar bone crest to lift the maxillary sinus membrane.

The Direct Implant Valve Approach was designed from inside with an internal screw that may be used for bone augmentation delivery and possible direct observation by an endoscope. The DIVA was used in cases when the dental implant insertion may be combined with the maxillary sinus membrane elevation and bone augmentation [15,16]. The new dynamic implant valve approach simplified dental implant procedures and reduced treatment time [16].

Accordingly, the present study was a trial to compare DIVA and Balloon elevation techniques in augmentation of the posterior atrophic maxillary alveolar ridge.

SUBJECTS AND METHODS

The present study was a randomized clinical comparative study continued from September 2018 to August 2020 in the Faculty of Dental Medicine, Department of Oral and Maxillofacial Surgery, Al-Azhar University. The sample included 14 patients,7 males, and 7 females with age (29-69 years) with single or multiple missing teeth in the sinus zone of the posterior maxilla in which the sub antral bone height ranged from 4mm to 9 mm for the one-stage sinus floor elevation surgery.

Clinical evaluation: At the initial visit, all patients underwent clinical and radiographic examinations, including full-mouth intra-oral photographic series and cone- beam computed tomography CBCT (Planmeca ProMax 3D Classic, Helsinki, Finland), which were performed to assess the maxillary sinus. Medical consultation was undertaken when necessary (ENT) Department in faculty of medicine in Assuit branch, Al-Azhar University).

Radiographic examination: Pre-operative CBCT was used to assess the residual bone height (RBH) below the sinus lining, fig (1A). Digital periapical radiographs also were taken during implant bed preparation. Before surgery, a surgical guide template made up of clear acrylic was used and a metal sleeve was used to decide the location of implant placement.

Surgical procedure:

Anesthesia: All surgical procedures in both two groups were performed using maxillary nerve block technique local anesthesia, with strict aseptic conditions. The procedure was performed under local anesthesia; Art pharma Anesthesia (4% Articaine with Epinephrine 1/200000 as a vasoconstrictor) (1.8 ml cartridge) was administered to the patient. Middle and Posterior superior alveolar nerve block along with greater palatine nerve block was given to ensure optimal anesthesia of the surgical site.

Surgical exposure: An alveolar mid-crestal horizontal incision was performed in the edentulous site and connected with the sulcular incision of adjacent teeth. Muco-periosteal envelope flap was elevated exposing alveolar bone. A surgical guide template was used to guide the pilot drill.

Group one: (DIVA group): After using a pilot drill, a 2mm drill was used to move up to 1-2 mm from the sinus floor (according to the CBCT image). Following the drilling, a 2.8 mm curved osteotome was used to reach a 1-2 mm level from the sinus floor. The implant was inserted in the bone till the primary stability was reached, Fig (1A). After that, the internal screw was removed and saline irrigation via the internal port was used. This procedure was performed until the vertical level needed for the length of the implant was obtained. The integrity of the maxillary sinus membrane was assisted by the movement of the saline level via the implant

coronal space. Injection of gel form bone graft via the DIVA injection adaptor kit (DIVA system Paltop - Germany), fig(1D). Wound closure was performed utilizing a non-absorbable suture gauge (4/0). The post-operative vertical bone height was measured in the axial view of CBCT, table (1).

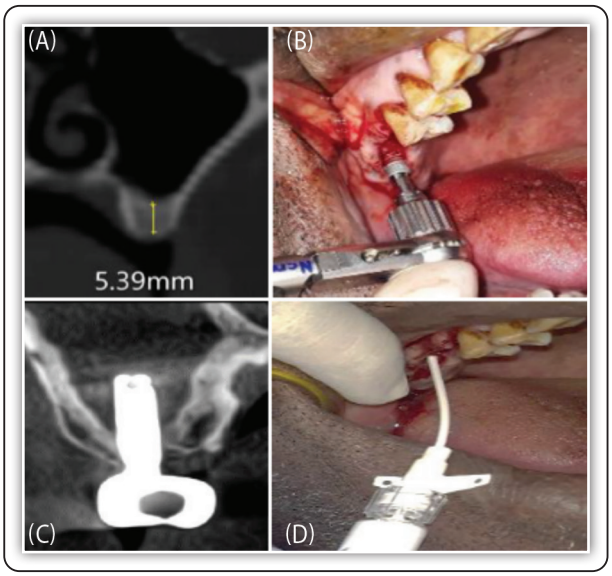

FIG (1) Showing preoperative vertical bone height measurement (A), implant insertion (B), new vertical bone height after 6 months implant insertion(C), bone graft injection (D).

Group two: (Balloon group): After exposing the alveolar bone, a pilot drill was used, followed by a 2 mm twist drill with a stopper set for the desired osteotomy length, leaving a 1 -2 mm inferior to the maxillary sinus floor (according to the CBCT image). An osteotome tip No D2.1 mm, No D3.1 mm, and/or No D3.7 mm from surgical osteotome kit (Dentium company, Korea) was inserted, and gentle tapping applied by a surgical mallet to allow for controlled greenstick bone fracture of the sinus floor, fig (2A). Entrance into the sinus membrane space (SMS) was manifested by changes in the voice resonance and tactile sense of the operator. A balloon-harboring device tip (MiambeLTD, Korea) consists of a plastic tube, three mm in diameter, that connects on its proximal end to the inflation syringe, and its distal portion had an embedded silicone balloon was used. The balloon device inserted carefully in the subantral space (beneath the maxillary sinus lining) and then inflated. The balloon was inflated with saline (1.5ml) that pushed up the maxillary sinus membrane, creating the future space for implant insertion. Subsequently, the balloon was inflated with a progressively controlled higher volume of normal saline. A gel form bone grafting material βTricalcium phosphate sterile resorbable bone substitute in hyaluronic acid (Genoss Company, Korea) was inserted, Fig (2C) After placement of the required amount of bone substitute for elevation, table (3) the dental implants (ROOTTS implant SWESS Dental Inc.) were

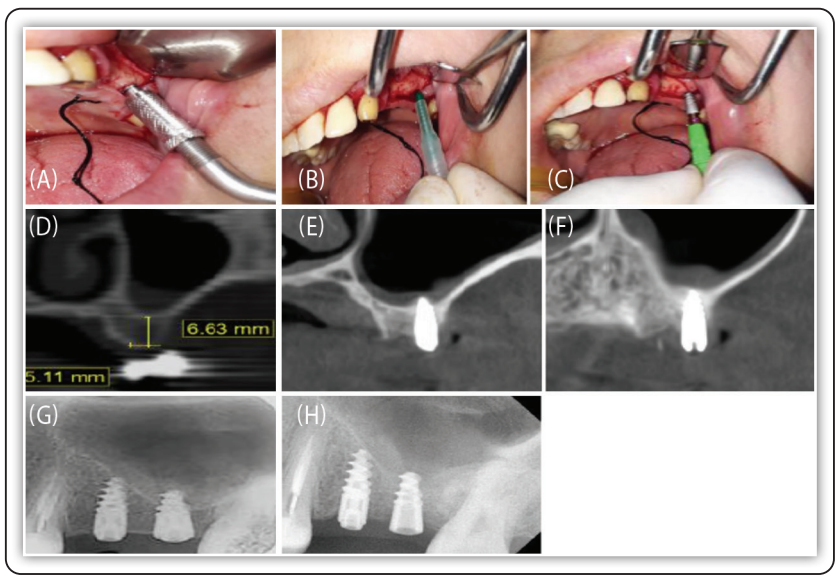

FIG (1) Showing osteotome application (A), balloon device application (B), Implant insertion (C), preoperative vertical bone height measurement(D), CBCT showing endo sinus bone gained after 3 months of Implant insertion (E), CBCT showing endo sinus bone gamed after 3 months of implant insertion(F), periapical x-ray showing endo sinus bone gamed after 3 months of implant insertion(G), periapical x-ray showing endo sinus bone gamed after 6 months of implant insertion (H).

placed. A dental implant (10 and 12 mm in length) and diameter were (3.7, 4.2, 4.8, and 5 mm) was installed into osteotomy site using hand screwdriver till coronal thread of implant into the bone.

CBCT Examination and Data Processing: The scanning parameters were configured as follows: 360_ rotation, 300 frames, 125 kV, 5 mA, 3.8s, voxel size 0.44 mm, the field of view (FOV) 15mm _ 7 mm/15 mm _ 10 mm. All CBCT images were saved in the Digital Imaging and Communications in Medicine (DICOM) format. These data were then imported into the Blue Sky Bio software (Libertyville, IL 60045 United States). version 21.0 (NV, Technologielaan, Leuven, Belgium) where all the processed measurements were performed. The results of the examined groups of this study were recorded, tabulated, and statistically analyzed using SPSS Version 21.0 software program where the paired t-test was used within each group and an unpaired t-test was used for comparison between the groups.

RESULTS

A total of 14 adult patients aged 29-69 (mean 47.5 years), 7 males and 7 females participated in this study. The patients were divided randomly to equal two groups, a group I (Balloon group) and group II (DIVA group). Six patients underwent unilateral sinus floor elevation surgery and eight patients underwent bilateral procedures. The total performed sinus floor elevation sites were 22 with a total of 22 dental implants. A total of two implants (one of Balloon group and one of DIVA group) were lost in two patients during the first three months after implant placement. All data of these two patients (2 sites with 2 implants) were excluded from the analyses. Post-operative complications were recorded in the table (4). DIVA was performed in 11sites (test group) and standard technique with a balloon with bone grafting was done in 11sites (control group).

Changes in vertical bone height: Vertical bone height means, standard deviations, t-values, and p-values within each group illustrated in the table (1) and fig (4). *Paired t-test* showed a highly statistically significant difference in comparing pre-operative versus post-operative vertical bone height in both two groups. The mean value of vertical bone height in the Balloon group was 6.84 mm ±0.86 at immediate that increased to 10.81 mm ±0.67. The mean value of vertical bone height in group DIVA was 5.81 mm ±0.66 at immediate that increased to 12.78 mm ±0.66. *Unpaired-test was* used for comparing pre-operative & post-operative vertical bone height between groups; it showed a highly statistically significant difference between the two groups pre-operatively & post-operatively.

TABLE(1) Illustrating mean ± SD values of Pre-&: post-operative alveolar ridge height among studied groups, alone with significance level using paired a: unpaired t-test.

Follow Up / Periods Studied	Preoperative	3 month	6 month	3 month Vs preoperative		6 month Vs preoperative	
	Mean ± SD	Mean ± SD	Mean ± SD	Paired t-test			
				t	P	t	P
Groups I	5.814±0.669	13.28±0.50	12.78±0.53	-36.87	0.00**	-28.89	0.00**
Groups II	6.840±0.861	11.39±0.60	10.81±0.67	-41.94	0.00**	-31.44	0.00**

	Unpaired t-test					
	t	P	t	P	t	P
G II Vs GI	-2.49	0.03*	6.36	0.00**	6.11	0.00**

TABLE(2) Illustrating mean ± SD values of ISQ scores among studied groups at two evaluation periods, along with significance level using paued & unpaired t-test.

Follow Up / Periods Studied	Preoperative	3 month	6 month	9 month	3 month Vs preoperative		3 month Vs 6 month		9 month Vs 6 month	
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Paired t-test					
					t	P	t	P	t	P
Groups I	39.00±2.16	69.07±69	70.43±2.17	71.71±1.60	-38.06	0.00**	-1.27	0.253	-1.59	0.11
Groups II	40.00±2.12	54.57±412	65.71±2.69	70.43±1.27	-14.59	0.00**	10.07	0.00**	-1.37	0.11

	Unpaired t-test							
	t	P	t	P	t	P	t	P
G II Vs GI	-4.57	0.00	8.62	0.00**	1.27	4.23	1.66	.012

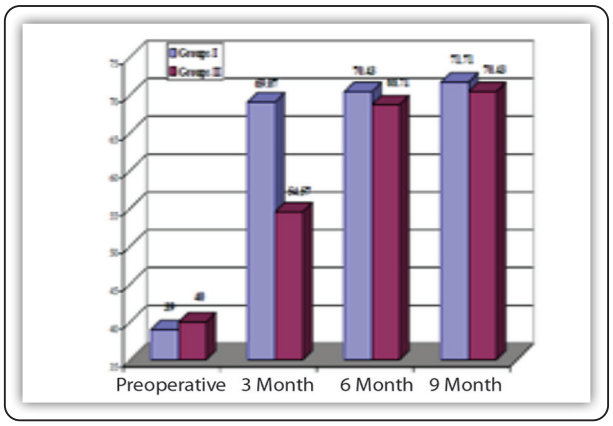

FIG (3) Bar chart showing means of implant stability quotient (ISQ) in the two

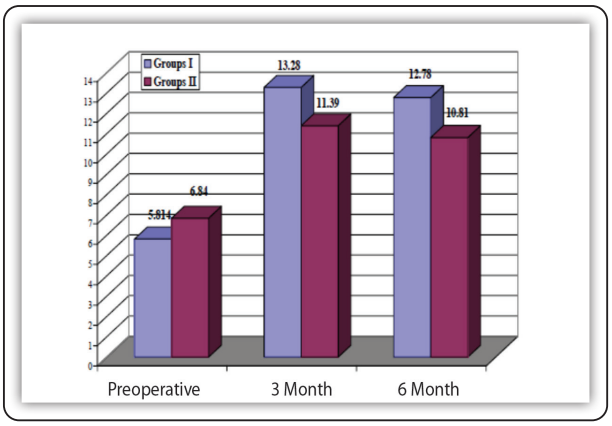

FIG (4) Bar chart showing means of Pre-& post-operative alveolar ridge height in the two groups.

Implant Stability Quotient (ISQ): Implant stability was checked for all implants using osstell (Osstell Co. Sweden) intraoperatively, 3, 6, and 9 months postoperatively. The mean ISQ measured values in both two groups increased during the observation period. RFA measurements demonstrated that the mean ISQ value at the time of implant placement in the DIVA group was 39.00 ± 2.16

The corresponding value for implants in the Balloon group was 40.00 ± 2.16. Nine months after implant placement, the mean ISQ value of DIVA group was 71.71±1.60, for implants placed in balloon group was 70.43 ± 1.27 Patients were seen at 3rd, 6th, and 9th months for the clinical follow-up sessions, and all patients completed the 9 months' clinical observation period. Table (2) presents the mean and standard deviations of ISQ values of each group.

There were no statistically significant differences in the primary stability between the two groups immediately after implant placement The only significant difference in the mean ISQ values between the two groups was found at 3rd month after implant placement (p = 0.048). Otherwise, no other significant differences were found in the mean ISQ values between the balloon and the DIVA groups during the observation period, fig (3). *Paired t-test* showed a high statistically significant difference at 9 months of observation interval when compared to the immediate observation period in the two groups.

Unpaired-test used for comparing ISQ between two groups, showed no statistically significant difference at immediate of observation period; when it compared the two groups with each other. While it showed a high statistically significant difference in comparing G II vs. G I at 3 months of observation interval. **The time during surgery:** Meantime of procedure was measured in minutes from flap reflection to complete surgical site closure, table (3) In the case of the DIVA group, the main surgical time was 17.36±1.82 minutes while in the case of the Balloon group was 24.36±2.79 minutes which was statistically significant resulted in decreased chair time and patient discomfort.

Bone graft and adjunctive instruments. The mean amount of bone graft used for each group was illustrated in the table (3). In the case of the DIVA group, no additional specialized tools or accessories to facilitate membrane elevation procedure, where the implant itself made the elevation and maintained to making tenting affect the delivery of bone grafting materials. Also, the mean amount of bone graft that was used was 0.51 cc ± 0.13. In the case of the Balloon group, a certain armamentarium (bone graft condenser, specially designed balloon for membrane elevation with barometric control) should be used. Also, the mean amount of bone graft that was used was 0.80 cc ± 0.26.

Complications: All complications that were noted during surgery and post-operatively for both two groups were presented in table (4). During surgery: one case with sinus membrane perforation, discharge from the nose (blood and bone graft residuals). Short-term postoperative: two cases presented by benign paroxysmal positional vertigo and sinusitis. One case for each group was presented by the failed implant to osseointegrate, no cases presented by long- term post-operative complications such as chronic sinusitis, mucocele, or oroantral fistula.

TABLE (3) Illustrating range, min, maximum, and mean ±SD values of surgical time and bone graft materials among studied groups, along with significance level using paired & unpaired t-test.

Studied groups	Variant	Range	Min	Max	Mean	SD	Between Group Comparisons	
							Unpaired t—test	P
DIVA	Time (minuet)	5.50	15.50	21.00	17.36	1.82	-5.55	0.00**
	Boe graft materials (cc)	0.40	0.30	0.70	0.514	0.13	-2.60	0.02*
Balloon	Time	8.50	21.50	30.00	24.36	2.79	-5.55	0.00* *
	Materials	0.70	0.50	1.20	0.800	0.26	-2-60	0-02*

TABLE (4) Illustrating the cornplications during different treatinent periods.

Time	Complication	DIVA group	Balloon group
During surgery	Membrane perforation	No	One case
	Discharge from the nose (blood or bone graft substitute)	No	One case
Short term postoperative	Benign paroxysmal positional vertigo and presented by sinusitis	Yes, One case	Yes, One case
Long term post—operative	Chronic sinusitis and loss of the graft material	No	No
	Mucocele,	No	No
	Oroantral fistula	No	No

DISCUSSION

Rehabilitation of the posterior edentulous maxilla with dental implants may be a challenge because of insufficient bone volume resulted from buccolingual and/or apical-occlusal atrophy of the edentulous alveolar bone and pneumatization of the maxillary sinus [1-8]. Hence, the vertical height of the residual bone is reduced which makes placing a standard dental implant difficult. To resolve this situation, Maxillary sinus membrane elevation is one possible solution [5,6]. In this study, Osstell™ was used to measure (primary) dental implant stability at the day of surgical placement, after 3,6, and 9 months to evaluate the degree of osseointegration (secondary implant stability). RFA measurements demonstrated that the stability of implants increased during the healing period, and the mean ISQ values became 71.71±1.60 for the DIVA implant group and 70.43±1.27 for the balloon group, after 9 months' implant placement. This finding was in line with several studies that reported an increase in stability of implants placed simultaneously with SFE procedures during the healing period. This increase in the implant stability during the healing period represents the changes in the bone-implant interface during the process of Osseo integration [11-16].

In this study, the mean initial implant stability quotient (ISQ) values at the surgery in both two groups were 39.00 and 40.00 respectively. The implant stability quotient (ISQ) values at the time of the surgery can be viewed as a low number in comparison with values after 6 months 70.43 and 68.71, this was expected since the implants placed immediately after the sinus lifting procedure may have lower primary stability due to main bone contact originated from the apical aspect of the osteotomy site (in regular implant osteotomy bed), which in both groups was absent, only lateral friction was present. This compatible with Turkyilmaz & McGlumphy [18] histomorphometric study showed that resonance frequency analysis (RFA) values correlated well with the amount of bone-to-implant contact. At 3 months, this observation showed a higher implant stability quotient (ISQ) in group I in comparison with group II.

These results might be explained by a correlation between the amount and distribution of bone grafts around the dental implant as gel form bone graft resorbed and replaced by natural bone in group I giving semicircular and symmetric distribution around the DIVA implant which was seen in periapical x-ray investigation during the study. On the other hand, the balloon group had an uncontrolled spread of bone graft insertion so it creates a wide area distribution in the horizontal plane only not in the vertical one. In the same point, the mean amount of bone graft materials that was used 0.80±0.23 while in the DIVA group was 0.51±0.13which was a clinically significant result so, the membrane liability to perforate and (or folded) due to overfilling was possible in the Balloon group. On the other hand, membrane in the case of the DIVA group, there was no membrane folding or perforation due to sequential insertion and stabilization of membrane by a tenting effect that made the need for less amount of bone graft injection.

The mean vertical bone height after sinus lifting in the DIVA group was 13.28mm±0.50 after 3 months from implant insertion in the other hand, in the Balloon group was 11.39mm±0.60, which was a clinically significant. In a group I, due to sequential insertion and gradual membrane dissecting by injection of saline through the implant, and injection of gel form bone graft at the same time of implant installation that made the needed vertical bone height was done. These results were in the same line with Yassin et al [19] where the vertical bone height 7mm after membrane elevation but this results from an animal study. On the other hand, in group II due to the multiple entrances of the balloon device, multiple inflation, and deflation to make membrane dissection (prolonged time) and then injection of gel form bone graft materials followed by implant insertion that made the bone graft distribution unequal and lead to horizontal dissecting more than the vertical direction.

CONCLUSION

Although, the small sample size of this study, the results suggested that:

1. The DIVA implant was an effective, safe procedure for maxillary sinus lifting
2. Both DIVA and Balloon groups had comparative results with superiority to DIVA in primary stability and vertical bone height.
3. The DIVA implant simplified the sinus lifting procedure and reduced surgical time.
4. This newly designed implant can be used in a standard fashion and also intraoperative delivery for gel form bone grafts.
5. Trance-crest osteotomy and using a balloon for the sinus membrane elevation in the posterior maxilla for simultaneous implant placement provide predictable results concerning primary stability and implant surveillance.

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