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In Vivo Assessment of Clinical Performances of Commercially Available Synthetic Osteoconductive Grafts B-OSTIN HA Nano™ and OSferion™ During Direct Sinus Lift Surgical Procedures for Managing Inadequate Implant Bone Heights in Middle-Aged Patients: A Hospital Based Original Research Study

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KEYWORDS

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ABSTRACT:

Aim: This study aims to assess the clinical performance of commercially available, specific, synthetic, Osteoconductive and Biocompatible Grafts B-OSTIN HA Nano™ and OSferion™ during the Direct Sinus Lift procedure for managing inadequate Implant Bone heights in middle-aged patients

Materials and Methods: This study includes a total of 30 patients with a missing Maxillary Right Molar. Inclusion criteria required ages 35-60 and excluded those with systemic diseases, mental instability, or smokers. Significant bone resorption was noted on Cone Beam Computed Tomography (CBCT), necessitating a maxillary sinus lift. During surgery, a flap exposed the sinus's anterior wall, and graft material was packed into the sinus using the "Postage Stamp Technique." Three months later, implants were placed, with healing abutments and implant-supported prostheses installed. Patients were divided into two groups: Group 1 received Hydroxyapatite (B-OSTIN HA Nano™) grafts and Group 2 received Tricalcium Phosphate (OSferion™) grafts. Clinical parameters, including bone height increase and graft stability, were evaluated with CBCT, assessing implant stability as satisfactory, non-satisfactory, questionable, or hopeless. This study aims to evaluate the clinical performance of the grafts during sinus lift procedures for inadequate implant bone heights.

Statistical Analysis and Results: This study involved 30 patients aged 35 to 60 years, missing the maxillary right first molar and seeking implant placement. Cone-Beam Computed Tomography (CBCT) scans indicated reduced bone height, necessitating a maxillary sinus lift and alloplastic bone grafts. Implants were placed three months after the lift, with prosthesis

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fitting three months later. Patients were divided into two groups: Group 1 received Hydroxyapatite (B-OSTIN HA Nano™) grafts, while Group 2 received Tricalcium Phosphate (OSferion™) grafts. CBCT evaluations showed that Group 1 had 9 patients with satisfactory bone height increases, 8 with satisfactory scaffold responses, and 7 with satisfactory implant stability. In Group 2, 8 had satisfactory increases in bone height, 7 had scaffold responses, and 6 had implant stability. Group 1 outperformed Group 2 overall, as detailed in statistical analyses using one-way ANOVA.

Conclusion: This study concluded that Hydroxyapatite (B-OSTIN HA Nano™) significantly improves bone height compared to Tricalcium Phosphate (OSferion™), which is essential for successful implant placement. Hydroxyapatite serves as an effective scaffold for new bone tissue growth and is praised for its biocompatibility, while Tricalcium Phosphate is favoured for its biodegradability and rapid regeneration. Further research is needed to compare the efficacy of these materials.

Introduction

Placing dental implants in the posterior region of the upper jaw, known as the maxilla, presents unique challenges primarily due to the presence of the maxillary sinus, a hollow cavity that may expand over time. This expansion can complicate the adequate placement of implants, making careful planning essential. To address bone deficiency in this area, dentists utilize a variety of sophisticated techniques that enhance bone volume, resulting in notably high success rates for implant procedures.[1,2] A thorough understanding of the sinus anatomy is pivotal for effective treatment planning and execution. The maxillary sinus, or antrum of Highmore, lies within the body of the maxillary bone and is the largest and first to develop of the paranasal sinuses. The alveolar process of the maxilla supports the dentition and forms the inferior boundary of the sinus.[3,4] With the risk of bone loss from sinus expansion becoming more prevalent, maxillary sinus augmentation or sinus floor elevation has become an increasingly common solution for patients seeking dental implants. The specific approach taken can depend on both the dentist's preference and the unique bone structure of the patient, ensuring a tailored solution for each individual.[5,6] There are primarily two techniques used for sinus elevation: the direct method, which involves creating a small window in the sinus membrane, and the indirect technique, where specialized instruments are employed to gently elevate the floor of the sinus without direct access.[7,8] For a comprehensive evaluation of sinus lift procedures, imaging methods such as panoramic radiographs and cone-beam CT scans provide detailed insights into the anatomy and condition of the sinus, enabling precise treatment planning.[9,10] Bone grafting is a critical component in these procedures, as it helps in regenerating new bone to support the implants. Among the various grafting materials, autografts where tissues harvested from the patient's own body and are considered the most effective due to their compatibility and biological properties. However, other options are also available, including allografts (donor bone), xenografts (animal bone), and synthetic materials. In particular, alloplastic options like Hydroxyapatite (Synthetic, Osteoconductive, Biocompatible; B-OSTIN HA Nano™) and Tricalcium Phosphate (Synthetic, Osteoconductive, Biocompatible; OSferion™) are frequently used because of their proven benefits in promoting bone growth. Overall, continual advancements in maxillary sinus augmentation techniques are significantly enhancing patient outcomes, especially for those with insufficient bone height for implants.[10,11] This study aimed to assess the clinical performances of two specific, synthetic, osteoconductive, biocompatible grafting materials, B-OSTIN HA Nano™ and OSferion™, during direct sinus lift procedures, contributing valuable insights into improving dental implant success rates in challenging anatomical conditions.

Materials and Methods

A total of 40 patients presented with the complaint of a missing maxillary right first molar. After screening and examining these patients using a randomized sampling method, we identified 30 patients who desired implant placement and implant-supported prosthesis. The inclusion criteria for this study consisted of these 30 patients, aged between 35 and 60 years, including both males and females, who had a missing maxillary right first molar. The exclusion criteria included any systemic illness, mentally unbalanced patients, handicapped patients and smokers. Following the clinical examination, a radiographic evaluation was conducted using Cone Beam Computed Tomography (CBCT) to estimate and plan for the implant placement, as well as to assess the bone condition in the maxillary right first molar region. All interventional and non-interventional executions were performed in hospital setup only. The CBCT evaluation indicated significant bone resorption in this area, prompting the decision to perform a direct maxillary sinus lift procedure. After administering local anesthesia and preparing the surgical area, a surgical incision was made along the top of the ridge at the optimal location. Vertical curved cuts were made that extended into the vestibule, allowing for the elevation and reflection of full-thickness subperiosteal flaps on both the labial and palatal sides. The flap base was made wide with enough tissue on both buccal and palatal sides for closure. After raising the flaps, the maxillary sinus's anterior wall was exposed. A small opening was created using the "*Postage Stamp Technique*," and sinus membrane elevators were carefully used to manipulate the bony wall without damaging the *Schneiderian Membrane*. Finally, alloplastic graft material was placed and packed into the sinus. After three months following the direct maxillary sinus lift procedure, the implant placement was carried out based on the CBCT evaluation to determine bone height. Local anesthesia was administered again, and an incision was made to reflect the flap, followed by osteotomy for implant placement using the same implant kit system and performed by the same operator. After two months of implant placement, the healing abutment was installed. Subsequently, three months after the implant placement, the implant-supported prosthesis was provided. Following the placement of the implant-supported prosthesis, a CBCT evaluation was conducted for the 30 patients to assess bony details. These patients were divided into two groups. Group 1 consisted of 15 patients who received hydroxyapatite (B-OSTIN HA Nano™) alloplastic bone graft material after undergoing a direct maxillary sinus lift procedure. Group 2 consisted of 15 patients who received Tricalcium Phosphate (OSferion™) alloplastic bone graft material after the same procedure. The clinical parameters, including the increase in bone height and scaffold bone growth, were evaluated using CBCT. Implant stability was assessed through clinical evaluation, categorizing it as satisfactory, non-satisfactory, questionable, or hopeless based on observational decisions from the operators, along with statistical analysis. This study aimed to evaluate the clinical performance of commercially available grafts B-OSTIN HA Nano™ and OSferion™ during the direct sinus lift procedure for managing inadequate implant bone heights.

Statistical Analysis and Results

In this study, we used SPSS software for all our statistical analyses. SPSS version 30.0 is a useful tool for analyzing data in social and medical sciences. To assess the significance of our findings, we employed the chi-square test. This test is good for comparing differences in proportions among different groups. It helped us make thorough comparisons of categorical data, ensuring our results truly represent the trends and relationships in our dataset.

Results

This study included a total of 30 patients aged 35 to 60 years, both male and female, who were missing the maxillary right first molar and desired implant placement along with an implant-supported prosthesis. Table 1 presents a statistical description of the patients by age and gender, while Graph 1 illustrates the demographic distribution and associated details, showing a total of 16 males and 14 females among the 30 participants. After evaluating the Cone-Beam Computed Tomography (CBCT) scans, it was determined that there was reduced bone height in the area required for implant placement in the maxillary right first molar region. Consequently, a direct maxillary sinus lift procedure was carried out, followed by the placement of alloplastic bone grafts. Three months after the direct maxillary sinus lift, the implants

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were placed, and three months after that, implant-supported prostheses were fitted. Following the placement of the prostheses, CBCT evaluations were conducted on the 30 patients. The patients were divided into two groups. Group 1 consisted of 15 patients who received hydroxyapatite (B-OSTIN HA Nano™) alloplastic bone graft material after the direct maxillary sinus lift procedure. Table 2 indicates that, in Group 1 (n=15), the "increase in bone height" was evaluated using CBCT, with the data analyzed accordingly. Statistical analysis was performed using the Pearson Chi-Square test to determine the significance of the results, revealing that 9 patients showed a satisfactory response. Table 3 displays the findings for Group 1 (n=15) regarding the "Scaffold for Bone Growth," which was also assessed using CBCT. Analysis of the data indicated that 8 patients had a satisfactory response. Table 4 summarizes clinical evaluations in Group 1 (n=15) regarding the "Augmentation of Implant Stability." The statistical analysis, conducted using the Pearson Chi-Square test, showed that 7 patients had a satisfactory response based on the operators' observations. For Group 2, which also consisted of 15 patients who received Tricalcium Phosphate (OSferion™) alloplastic bone grafts following a Direct Maxillary Sinus Lift Procedure, Table 5 shows that the "increase in bone height" was evaluated using CBCT. Statistical analysis indicated that 8 patients in Group 2 had a satisfactory response. Table 6 presents findings for Group 2 (n=15) concerning the "Scaffold for Bone Growth." The evaluation using CBCT data showed that 7 patients responded satisfactorily. Table 7 details the clinical evaluation of "augmentation of implant stability" in Group 2 (n=15). Statistical analysis demonstrated that 6 patients had a satisfactory response. Upon comparison between the groups, the results were not similar; Group 1 had a higher number of satisfactory responses compared to Group 2, while Group 2 experienced a greater number of unsatisfactory responses. Table 8 presents the estimation results across all studied groups, utilizing one-way ANOVA to analyze the differences. This statistical method allows for a comprehensive comparison, highlighting variations in the measurements among the different groups under investigation.

Table 1: Age & gender based statistical description of contributing patients

Age Group (Yrs)	Male	Female	Total	P value
35-40	3	3	6	0.02*
41-45	4	4	8	0.20
46-50	2	4	6	0.01*
51-55	4	2	6	0.30
56-60	3	1	4	0.40
Total	16	14	30	*Significant
*p<0.05 significant				

Graph 1: Patients demographic distribution and associated details

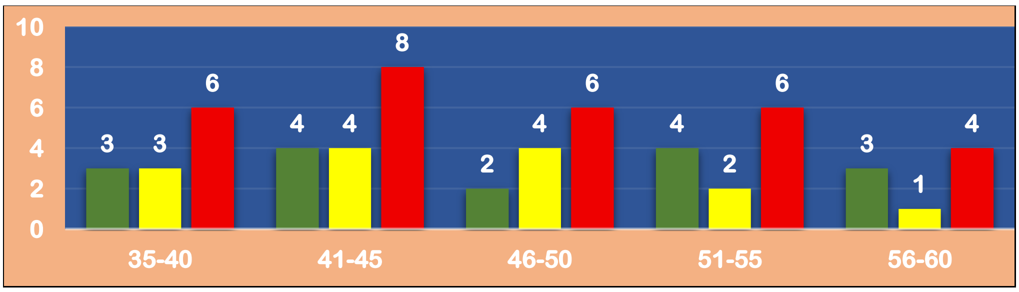

Table 2: In Group 1 (n=15), Hydroxyapatite (B-OSTIN HA Nano™) alloplastic bone grafts were placed following a direct maxillary sinus lift procedure. The "Increase in Bone Height" was evaluated using Cone-Beam Computed Tomography (CBCT), and the data were analyzed based on CBCT data. Statistical analysis was conducted using the Pearson Chi-Square test to determine the significance of the results

Performance Parameters	Operator Response	n	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square	df	p value
Increasing Bone Height	Satisfactory	9	2.30	2.453	2.234	2.45	2.367	1.0	0.02*
	Non Satisfactory	5	2.07	1.116	1.137	2.12	2.114	1.0	0.80
	Questionable	1	1.08	1.080	1.032	1.76	1.120	1.0	0.34
	Hopeless	0	-	-	-	-	-	-	-
*p<0.05 significant									

Table 3: In Group 1 (n=15), Hydroxyapatite (B-OSTIN HA Nano™) alloplastic bone grafts were placed following a Direct maxillary sinus lift procedure. The "Scaffold for bone growth" was evaluated using Cone-Beam Computed Tomography (CBCT), and the data were analyzed based on the CBCT data. Statistical analysis was conducted using the Pearson Chi-Square test to determine the significance of the results

Performance Parameters	Operator Response	n	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square	df	p value
Scaffold for Bone Growth	Satisfactory	8	2.26	2.245	2.214	2.40	2.310	1.0	0.01*
	Non Satisfactory	5	2.07	1.116	1.137	2.12	2.114	1.0	0.80
	Questionable	1	1.08	1.080	1.032	1.76	1.120	1.0	0.34
	Hopeless	1	1.08	1.080	1.032	1.76	1.120	1.0	0.34
*p<0.05 significant									

Table 4: In Group 1 (n=15), Hydroxyapatite (B-OSTIN HA Nano™) alloplastic bone grafts were placed following a Direct maxillary sinus lift procedure and clinical evaluation of "Augmentation of implant stability" and Statistical analysis was conducted using the Pearson Chi-Square test to determine the significance of the results

Performance Parameters	Operator Response	n	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square	df	p value
Implant Stability	Satisfactory	7	2.20	2.223	2.201	2.20	2.110	1.0	0.02*
	Non Satisfactory	4	2.04	1.105	1.120	2.02	2.102	1.0	0.03*
	Questionable	2	1.05	1.061	1.052	1.26	1.119	1.0	0.30
	Hopeless	2	1.05	1.061	1.052	1.26	1.119	1.0	0.30
*p<0.05 significant									

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Table 5: In Group 2 (n=15), Tricalcium Phosphate (OSferion™) alloplastic bone grafts were placed following a direct maxillary sinus lift procedure. The "increase in bone height" was evaluated using Cone-Beam Computed Tomography (CBCT), and the data were analyzed based on CBCT data. Statistical analysis was conducted using the Pearson Chi-Square test to determine the significance of the results

Performance Parameters	Operator Response	n	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square	df	p value
Increasing Bone Height	Satisfactory	8	2.26	2.245	2.214	2.40	2.310	1.0	0.01*
	Non Satisfactory	4	2.04	1.105	1.120	2.02	2.102	1.0	0.03*
	Questionable	2	1.05	1.061	1.052	1.26	1.119	1.0	0.30
	Hopeless	1	1.08	1.080	1.032	1.76	1.120	1.0	0.34
*p<0.05 significant									

Table 6: In Group 2 (n=15), Tricalcium Phosphate (OSferion™) alloplastic bone grafts were placed following a Direct maxillary sinus lift procedure. The "Scaffold for bone growth" was evaluated using Cone-Beam Computed Tomography (CBCT), and the data were analysed based on the CBCT data. Statistical analysis was conducted using the Pearson Chi-Square test to determine the significance of the results

Performance Parameters	Operator Response	n	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square	df	p value
Scaffold for Bone Growth	Satisfactory	7	2.20	2.223	2.201	2.20	2.110	1.0	0.02*
	Non Satisfactory	4	2.04	1.105	1.120	2.02	2.102	1.0	0.03*
	Questionable	2	1.05	1.061	1.052	1.26	1.119	1.0	0.30
	Hopeless	2	1.05	1.061	1.052	1.26	1.119	1.0	0.30
*p<0.05 significant									

Table 7: In Group 2 (n=15), Tricalcium Phosphate (OSferion™) alloplastic bone grafts were placed following a Direct Maxillary Sinus Lift Procedure, and clinical evaluation of "Augmentation of implant stability" and Statistical analysis was conducted using the Pearson Chi-Square test to determine the significance of the results

Performance Parameters	Operator Response	n	Mean	Std. Dev.	Std. Error	95% CI	Pearson Chi-Square	df	p value
Implant Stability	Satisfactory	6	2.09	2.110	2.121	2.12	2.090	1.0	0.03*
	Non Satisfactory	5	2.07	1.116	1.137	2.12	2.114	1.0	0.80
	Questionable	2	1.05	1.061	1.052	1.26	1.119	1.0	0.30
	Hopeless	2	1.05	1.061	1.052	1.26	1.119	1.0	0.30
*p<0.05 significant									

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Table 8: Estimation amongst all studied groups using one-way ANOVA

Variables	Degree of Freedom	Sum of Squares ∑	Mean Sum of Squares m∑	F	Level of Sig. (p)
Between Groups	4	1.312	1.804	1.4	0.001*
Within Groups	12	2.213	0.156	_	
Cumulative	17.105	6.043	*p<0.05 significant		

Discussion

Mularczyk et al reviewed in their study that the maxillary sinus (MS) stands as the largest among the paranasal sinuses, gracefully positioned on either side of the face. This remarkable cavity serves several critical functions, including amplifying sound, facilitating efficient breathing, and contributing to the reduction of the skull's overall weight. The sinus is lined with specialized respiratory tissue that plays a vital role in promoting fluid movement between the sinus and the nasal cavity, ensuring optimal respiratory function.[12,13] Juzikis et al included in their study that when there is a loss of the maxillary back teeth, it can trigger two significant types of bone loss. The first is centripetal resorption, which is a natural and expected part of the bone remodelling process. The second type involves the expansion of the sinus into areas where teeth have been lost, leading to additional bone loss. This sequential bone deterioration can diminish the bone availability necessary for dental implant placement,often necessitating the intervention of a maxillary sinus lift. This procedure is regarded as safe and effective, designed to augment both the height and width of the bone, thereby creating a solid foundation for successful dental implant placement.[14,15] Stern A et al showed in their study that the sinus lift procedure is a pivotal intervention within the field of implant dentistry, particularly instrumental in augmenting bone volume in the maxilla. This area often experiences significant bone loss following tooth extractions, making the sinus lift a crucial step in restoring dental functionality and aesthetics. Among the various techniques available, the direct and indirect sinus lifts stand out for their effectiveness in enhancing bone density in the affected region.[16,17] Kumar M et al reviewed in their study that in the direct sinus lift technique, the process begins with a carefully crafted incision that creates an opening in the maxillary sinus. This is done with precision to minimize any potential trauma to surrounding tissues. Once the opening is established, the sinus membrane is gently elevated, a delicate maneuver that requires both skill and experience to avoid rupture. Following this, bone graft materials are meticulously placed beneath the lifted membrane, serving as a scaffold that promotes new bone formation and integration over time. This method not only increases the bone volume but also lays the foundation for the successful placement of dental implants, paving the way for improved dental health and stability.[18-20] Dimitriou R et al included in their study that imaging modalities, particularly cone beam computed tomography (CBCT), are indispensable in the assessment of facial sinuses, as they produce detailed 3D images that allow for precise evaluation of the sinus structure. The incorporation of bone grafts is crucial to achieving stable dental implants; inadequate bone volume can complicate the placement process significantly. Fortunately, advancements in bone regeneration techniques and grafting materials—ranging from autografts to innovative alloplastic options such as Hydroxyapatite and bioactive glass ceramics—facilitate new bone formation and healing, effectively mimicking the structure and function of natural tissue.[21-22]

Conclusion

Within the limitations, this retrospective study was conducted to evaluate the clinical performance of two commercially available graft materials, B-OSTIN HA Nano™ and OSferion™, during direct sinus lift procedures aimed at addressing inadequate implant bone heights. The findings revealed and concluded that hydroxyapatite (B-OSTIN HA Nano™) offers a notable

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benefit compared to tricalcium phosphate (OSferion™), especially in its ability to enhance bone height, which is crucial for successful implant placement. Furthermore, hydroxyapatite serves as an effective scaffold, promoting the growth of new bone tissue and providing a supportive environment for healing. Both hydroxyapatite (B-OSTIN HA Nano™) and tricalcium phosphate (OSferion™) are widely recognized as valuable alloplastic bone graft materials, each presenting unique advantages and challenges. Hydroxyapatite is valued for its biocompatibility and similarity to natural bone, making it ideal for clinical use. In contrast, tricalcium phosphate is noted for its biodegradability and ability to promote fast bone regeneration, which benefits various surgeries. However, further investigation is needed to delve deeper into these findings and to expand our understanding of the comparative efficacy of these materials.

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