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Comparative Evaluation of Bone Regeneration Using Synthetic Hydroxyapatite *Versus* Commercially Available Xenograft in Lateral Wall Sinus Augmentation: Non-Blinded, Randomized Controlled Trial

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ABSTRACT

Aim: To evaluate and compare bone regeneration in lateral sinus wall augmentation with indigenous hydroxyapatite and commercially available bovine hydroxyapatite graft in healthy subjects over a period of 6 months follow-up.

Material and Method: 20 cases were enrolled for the study, 10 in each group, control group wherein, Bio-Oss® bone graft and 10 in test group where G-bone graft was placed respectively. Standard of Care (SOC) protocol was followed in performing sinus lift procedure. Followed by placed secured by tissue tags and sutures. 6 months post-operatively, bone core with trephine was obtained of size 3.2 mm for histological examination and implants were placed at the same surgical site. Bone core was then histologically evaluated for: new bone formation, Residual graft material, Particle size of new bone, Vascularity and Inflammation.

Results: G-bone showed higher percentage for new bone formation, Residual graft material, Particle size of new bone, Vascularity and Inflammation at 6 months.

Conclusion: G-bone is a useful substance for sinus augmentation.

Keywords: Sinus augmentation, Bone graft, Bone formation, Xenograft, Hydroxyapatite.

INTRODUCTION

In past few years, apart from Tatum's sinus lift [1,2], many techniques such as tilted implants, all-on-4 technique, zygomatic implants, short implants and CAD/CAM assisted customized implants have come into

practice [3], yet, sinus lifts (direct/ indirect) to facilitate proper implant integration remains as one of the most widely performed procedures for overcoming deficient bone, allowing implant placement [4]. It is unrealistic to expect one graft material to possess all the necessary characteristics needed for regeneration such as volume maintenance, acceleration of bone remodelling, osteoconductivity and but not limiting to growth factors or scaffolds for tissue engineering [3,5-6]. Still, a huge variety of bone graft materials are available which can produce predictable results and can be categorized in four groups: (A) autogenous bone graft (B) allogenic grafts (ALLs), (C) xenogenic grafts (XENs), and (D) alloplastic, synthetically produced grafts (SYNs). Yet all of these graft categories have their own share of disadvantages, leaving clinicians to choose the one which has predictable results over long period of usage.

G Bone graft, an advanced synthetic bone grafting material, presents a potential alternative that may offer superior results. It is a mixture of HA, TCP and other forms of calcium such as calcium carbonate and bicalcium phosphate, Where in Its granules are made of synthetic calcium hydroxyapatite in low crystalline form. This innovative grafting material ensures successful implant placement even in cases of limited bone volume. Bio-Oss® bone graft widely used biomaterial in the field of dental implantology. Derived from bovine bone, it offers excellent biocompatibility and osteoconductive properties, making it an ideal choice for bone regeneration and augmentation procedures. Hence, the rationale for conducting this comparative study lies in the need to evaluate and compare the efficacy and outcomes of G Bone graft and Bio-Oss® xenograft in lateral sinus wall augmentation.

MATERIAL AND METHOD

A non-blinded randomized controlled trial was conducted at the dental office wherein, a total of 20 subjects were selected for the study, 10 in test group and 10 in control group calculated using G Power Software (version 3.0.10). 15 subjects were needed to achieve 80% power at a two-tailed alpha of 0.05 for an effect size of 0.8, when using the Paired t-test, as calculated by the G*Power 3.1.9.2 program. Based on the calculated effect size of 0.80, 5% level of precision, 95% confidence level and 80% power of the study. The minimum sample size was calculated as 18. Hence the final sample size for the study was 20, with 10 in each test and control group (Table 1).

Patients for the study were selected based on the flowing inclusion and exclusion criteria:

Inclusion Criteria:

- Patients between 18-80 years of age.
- Reduced alveolar bone height in the maxillary posterior segment.
- Compliant patients.

Exclusion Criteria:

- Patients having uncontrolled systemic diseases and/or presence of infection.
- Patients on medication known to interfere with periodontal tissue health and healing.
- Pregnant or lactating women.
- Patients with habit such as smoking/ tobacco chewing/ parafunctional habits.
- Patients with known allergies to any product/medications used in the study.

All the patients were treated keeping Helsinki declaration [7] (2019) into consideration and institutional ethical guidelines for biomedical research as per ICMR guidelines. For All subjects participating in the study signed a

consent form to willingly participate in the study. All patients were pre-examined with standard protocols and intraoral photographs, dental models, panoramic radiographs and CBCT (Figure 1) scans along with Consent forms. After 6 months, biopsy was taken to study the histological section of the augmented sites.

Table 1: Study of control group.

Study Groups	Number of Subjects	Treatment
Group I (control)	10	Treated using Bio-Oss® bone graft
Group II (Test)	10	Treated using G-Bone bone graft.

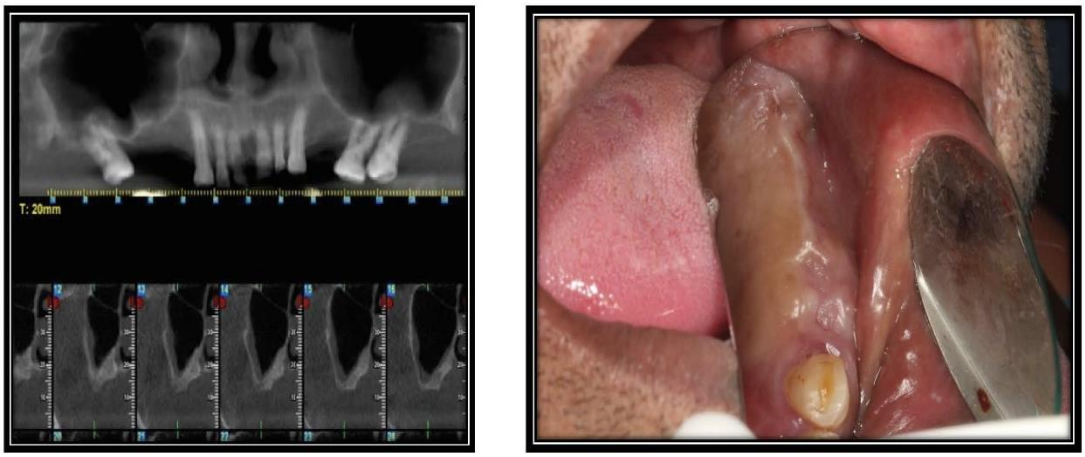

Figure 1: Radiographic and clinical image.

In all the cases a bony window was prepared with a large round bur under copious irrigation with saline (Figure 2). Once the bone was thin enough to be lifted, to expose the membrane, bone window was carefully removed and the membrane was slowly lifted (Figure 3) to make space for the bone graft, Bio-Oss® (Geistlich Pharma AG, Wolhusen, Switzerland) in control group and G-bone in test group, was placed in order to increase the height. Ossix collagen membranes used to close the openings after bone grafting. The membrane was secured using tissue tags (Figure 4). All sites were then sutured with the 3-0 silk sutures/ Vicryl suture which were then removed after 10 days. To obtain A bone core for histological study after 6 months, surgical site was reopened and core was obtained with the help of trephine with the diameter of 3.2 mm. Implant of size 4 mm diameter (in all cases) was placed at the same site from where the core was harvested. Post-operatively, Patients were advised to maintain proper oral hygiene for which they were prescribed Chlorhex plus mouthwash twice daily along with antibiotics and analgesic SOS. Other routine post-surgical instructions were given. Biopsy was taken by harvesting a core from the augmented site for histological examination and the following parameters were evaluated:

- New bone formation
- Residual graft material
- Particle size of new bone
- Vascularity
- Inflammation

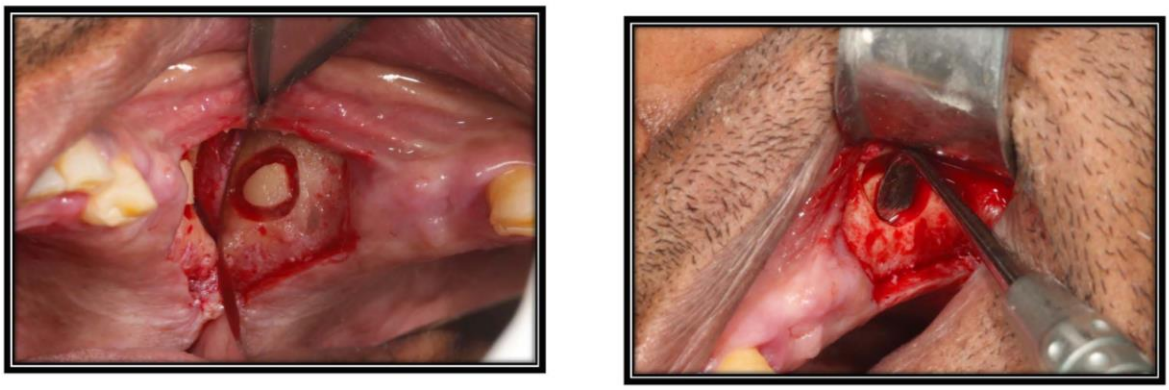

Figure 2: Surgical procedure.

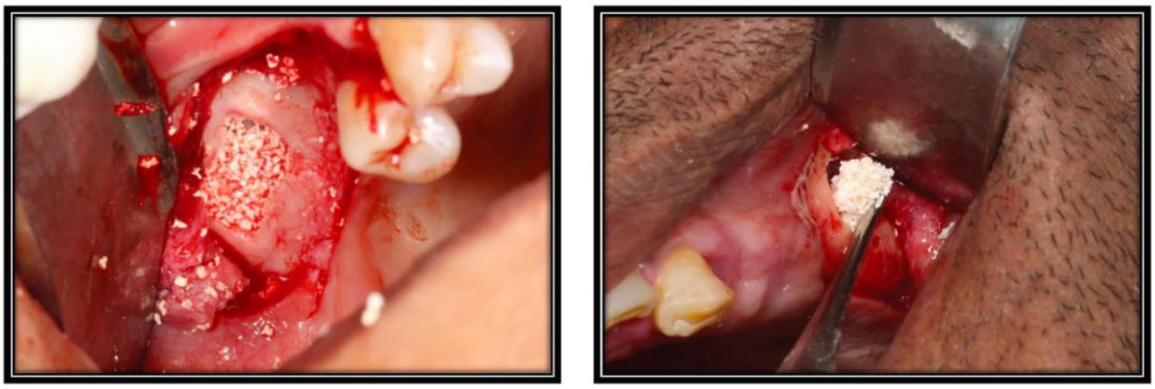

Figure 3: (a) Placement of Bio-Oss® bone graft. (b) placement of G-bone graft.

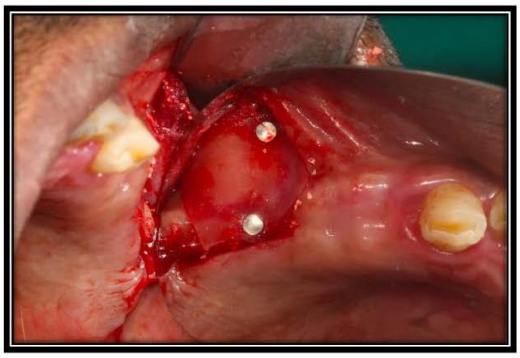

Figure 4: collagen membrane with tissue tags.

Statistical analysis

Statistical Package for Social Sciences (SPSS) version 21, IBM Inc. was used to analyse data. Descriptive data (Frequency distribution) was reported for each variable. Summarized data was presented using Tables and Graphs. Chi square test was used for categorical variables. Level of significance was set at $p < 0.05$.

RESULTS

For test group, 100% patients showed histological evidence of new bone formation (Figure 5). For control group 60% patients showed histological evidence bone formation, and it was found to be significant (Figure 6). Significantly Higher number of patients in test group reported new bone formation as compared to control group

(Figure 7). For test group, 100% patients showed presence of residual bone graft and for control group 70% patients, the difference was statically not significant (Figure 8). Coming to vascularity, 100% patients showed vascularity in test group whereas 60% in control group. The comparison was done using chi square test and it was found to be significant (Figure 9). No inflammation was observed in test group which was in 100% of patients, whereas, for control group in 80% patients no inflammation was seen (Figure 10). The comparison was not found to be significant. Figure 11 shows 100% results at particle size of 1 mm -2 mm in test as compared to control group.

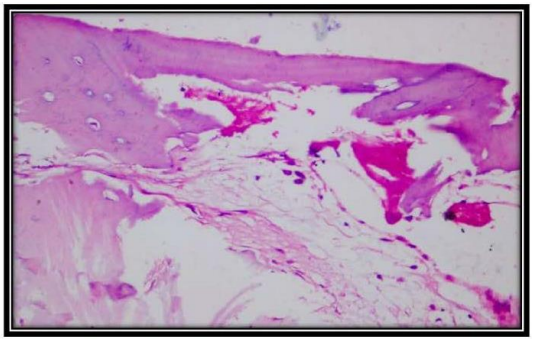

Figure 5: Histology of new Oss® placement (control group).

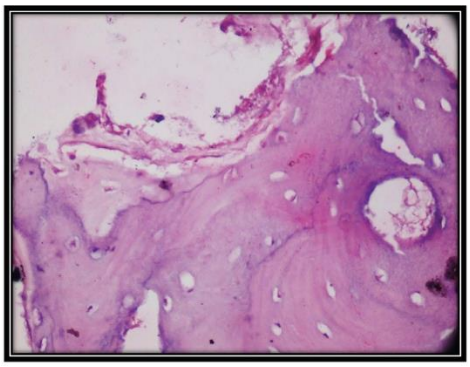

Figure 6: Histology of bone formation after Bio-bone formation in G-bone graft (test group).

DISTRIBUTION OF PATIENTS ACCORDING TO NEW BONEFORMATION

	Test group: G Bone		Control group: BIO-OSS	
	N	%	N	%
NO	0	0	4	40
YES	10	100	6	60
p value	0.043*, sig			

Chi square test, level of significance set at p <

0.05Ns: non-significant, sig: significant

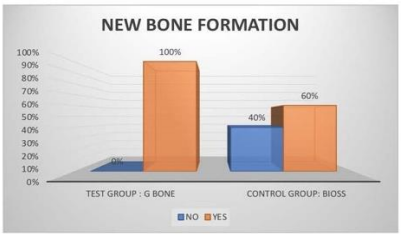

Figure 7: Patient distribution based on new bone formation.

DISTRIBUTION OF PATIENTS ACCORDING TO RESIDUALBONE GRAFT MATERIAL

	Test group: G Bone		Control group: BIO-OSS	
	N	%	N	%
ABSENT	0	0	3	30
PRESENT	10	100	7	70
p value	0.105,ns			

Chi square test, level of significance set at p <

0.05Ns: non-significant, sig: significant

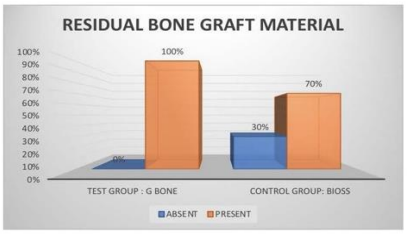

Figure 8: Patient distribution based on residual bone graft.

DISTRIBUTION OF PATIENTS ACCORDING TO VASCULARITY

	Test group: G Bone		Control group: BIO-OSS	
	N	%	N	%
NOT SEEN	0	0	4	40
SEEN	10	100	6	60
p value	0.043*, sig			

Chi square test, level of significance set at p <

0.05Ns: non-significant, sig: significant

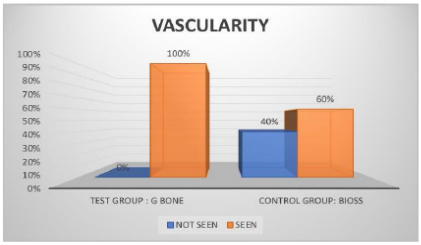

Figure 9: Patient distribution according to vascularity.

DISTRIBUTION OF PATIENTS ACCORDING TO INLFLAMMATION

	Test group: G Bone		Control group: BIO-OSS	
	N	%	N	%
NO	10	100	8	80
YES	0	0	2	20
p value	0.237, Ns			

Chi square test, level of significance set at p <

0.05Ns: non-significant, sig: significant

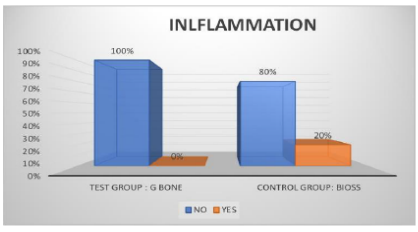

Figure 10: Patient distribution according to inflammation.

DISTRIBUTION OF PATIENTS ACCORDING TO PARTICLESIZE

	Test group: G Bone		Control group: BIO-OSS	
	N	%	N	%
1-2 mm	10	100	6	60
2-3 mm	0	0	2	20
3-4 mm	0	0	2	20
p value	0.046*, sig			

Chi square test, level of significance set at p <

0.05Ns: non-significant, sig: significant

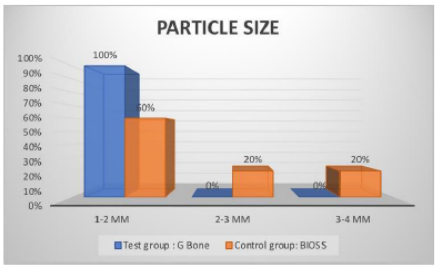

Figure 11: Patient distribution according to particle size.

DISCUSSION

The evolution of bone grafts from 1920s, has come a long way in the manner of their procurement, understanding and predictability of results, irrespective of the choice of the graft material used, bone regeneration should be achievable keeping the properties of the graft into consideration. Having said so, today, any implant procedure is not complete without the use of bone grafts. A sinus lift is a common and safe procedure to produce height of the posterior maxillary region. Even though bone has a unique potential of modelling and remodelling itself, in cases of sinus augmentation, it poses few challenges such as (1) compromised blood supply, (2) instability (mechanical), (3) large defects and (4) competing with tissue of high proliferative activity8 which is the membrane. The prognosis of the treatment also depends upon its perforation-free implant placement9 which is largely dependent upon technique used for making the lateral window.

When round burs are used for making lateral window, 20%-30% chance of membrane perforation has been noted [10]. In 1998, Torrella et al. [11], described use ultrasound instruments for opening of the lateral window, which reduced risk of perforation up to 95%. In a metanalysis comparing perforation rates, conventional instruments such as a round bur have 24% as compared to piezoelectric with 8% [12] respectively. However, Atieh et al. [13], in a systematic review, stated no significant difference between the two surgical techniques. Similarly, Geminiani et al. [14], in a meta-analysis, found no statistically significant difference between the types of devices. Another author Esposito et al. [15], in a Cochrane review did not find any evidence of piezoelectric for sinus surgery to be superior. Hence it can be safely stated that occurrence of perforation is relative to the experience of the operator.

Choice of the graft is of utmost importance. Apart from the obvious properties of each aforementioned types of grafts, other properties of individual graft substitute should be considered such as ‘geometry’ favouring blood vessels ingrowth, paramount for bone formation [16]. Meaning, that the material along with being porous needs to have macropores as well, a critical aspect of revascularization of bone filler materials [17]. Surface

characteristics of graft materials such as chemical composition, microporosity, surface roughness, crystallinity and crystal size [17] are important for initial attachment of cells (osteoblasts and osteoclasts) and therefore formation of new bone layer by layer [18-20]. In a systematic review by Baghban et al. [21], between autogenous bone and Bio-Oss®, authors found no significant difference. In fact, authors stated that Bio-Oss® may be considered superior to autogenous, because of the obvious disadvantages of the autogenous bone. Kim et al. [22], stated that Bio-Oss® showed superior properties in comparison when used alone or in combination with autogenous bone at a proportion of 25%. One of the advantages of using Bio-Oss® is delayed bone formation. In comparison between Bio-Oss® and non-grafted controls in human subjects it was found that Bio-Oss® particles instead of resorbing, became surrounded by less mineralized bone and more fibrous tissue than the control sites suggesting delayed osseous healing [23]. Coming to G-Graft, or G-bone, is a synthetic graft contains natural low crystalline hydroxyapatite with collagen. It is available in form of granules, dowels and blocks. Studies have stated that G-Graft treated defects attain density and enhanced bone healing in early stage of regeneration. Johnson et al. [24], reported better regeneration with Collagen-hydroxyapatite composite graft as compared to tricalcium phosphate, and hydroxyapatite used alone.

Current study shows both bone graft substitutes present with good bone formation. The new bone formation was at the rate of 60% in Bio-Oss® and 100% in case of G-bone but this difference is attributed due to delayed bone formation with Bio-Oss®. Araujo et al. [25], found de novo hard tissue formation after 3 months, when he used hydroxyapatite/ collagen composite (Bio-Oss Collagen) on healing of an extraction socket of dogs. In the current study the biopsy has been done at 6 months, hence the difference in bone formation. also, defects treated with G-Graft initially gain greater density, which promotes early bone healing. When it comes to collagen-hydroxyapatite composite graft, the take-up in the current study was good, and there was no discernible host inflammatory response. Additionally, some regions had newly formed bone with osteocytes imprisoned within osteocytic lacunae. Therefore, it is a useful substance for sinus augmentation. Also, the particle size, shows more bone formation with 1 mm - 2 mm of graft particle size.

CONCLUSION

G-bone, made of multiphasic calcium hydroxyapatite, is an advantage as it is absorbed faster by the body compared to xenografts. The graft take-up in the current study was good, and there was no discernible host inflammatory response. Additionally, some regions had newly formed bone with osteocytes imprisoned within osteocytic lacunae. Therefore, it is a useful substance for sinus augmentation.

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