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RESEARCH ARTICLE

CLINICAL AND RADIOGRAPHIC ASSESSMENT OF BOND APATITE IN HORIZONTAL BONE AUGMENTATION AROUND DENTAL IMPLANTS: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: Bond apatite is a composite graft, composed of two-thirds biphasic calcium sulfate and one-third hydroxyapatite granules of various sizes and shapes. Oral implants are used to secure dental prostheses in cases of partial or total edentulism. The outcomes of correctly completed dental-implant procedures result in high rates of success and survival of dental prostheses.

Objective: The aim of this study was to assess Bond Apatite use in horizontal bone augmentation around dental implants, clinically and radiographically.

Materials and Methods: This research included sixteen patients, six men and ten women, with an average age of thirty years having missing maxillary anterior or premolar teeth with insufficient horizontal bone. The patients were divided into two groups: group I patients (N=8) received dental implants with Bond apatite, while group II patients (N=8) received dental implants with Bio-Oss bone graft material and pericardium bioresorbable membranes. All patients were evaluated clinically usingthe modified plaque index (MPI), modified gingival index (MGI) and probing depth (PD) and radiographically to assess bone width dimensions.

Results: There was a statistically significant difference between groups regarding MGI($p = 0.038$)andperi-implant buccal PD [mm]($p = 0.026$). There was no statistically significant difference between the tested groups regarding age($p = 0.608$), sex($p = 0.123$), MPI($p = 0.608$),orperi-implant palatalPD [mm]($p = 0.118$). There was no statistically significant difference between the two groups regarding postoperative bone width ($p = 0.187$).

Conclusion: Bond apatitemay be used as one of the materials of choice for horizontal bone augmentation around dental implants with similar promising results compared to Bio-Oss. Finally, the use of Bond apatite preparation is a straightforward, affordable, and considered successful bone graft material that could be used in osseous defect reconstruction procedure.

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Trial registration: The study is listed on www.clinicaltrials.gov with registration number (NCT06043258) 22/09/2023. The study was conducted in accordance with the seventh revision of the Helsinki Declaration in 2013 and approved by the Institutional Review Board (IRB) (M07061119) of the Faculty of Dentistry, Mansoura University, Egypt.

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Introduction:-

Tooth extraction usually leads to considerable alveolar ridge resorption. The bone resorption process begins immediately upon extraction, resulting in a 40-60% reduction in both horizontal and vertical dimensions of the alveolar ridge over the first two years.[1] The majority of postextraction bone loss is more evident on the buccal aspect of the ridge[2]and occurs mainly within the first 3 months. [3]

Oral implants are used to secure dental prostheses in cases of partial or total edentulism.[4]Because of the benefits of implant-supported prosthesis, such as improved aesthetics, improved function, improved hygiene accessibility, and osseous preservation, all at a comparable cost, single tooth implant replacement is considered a more viable option for today's patient than teeth-supported fixed partial denture, which requires preparation of adjacent teeth. [5]The outcomes of correctly completed dental-implant procedures result in high rates of success and survival of the dental prosthesis. Currently, planning the desired prosthetic reconstruction first, then placing the implants in the best three-dimensional position for achieving the intended treatment result and the regeneration of bone required to osseointegrate the implants, are the most appropriate approaches for treatment with dental implants.[4]

Advanced bone grafting techniques have helped to overcome concerns about bone deficiencies, allowing implant placement according to prosthodontic needs and achieving successful implantation. Additionally, the goals of reconstruction are to provide the proper morphology and relationship with the opposite jaw, to restore hard and soft tissue continuity, and to obtain adequate height and width of the bonefor occlusal rehabilitation. [6] The ideal bone graft substitute should have the following characteristics: biocompatibility, osteoconductivity and/or osteoinductivity, bioresorbability, and replaceability by new bone. The use of xenografts, especially bovine bone, has increased not only in ridge preservation, but also in other bone augmentation procedures. The important benefits of xenograft bone are reduction in the drawbacks associated with autograft use and their unlimited availability.[7]

Bond apatite is a composite graft; composed of two-thirds biphasic calcium sulfate and one-third hydroxyapatite granules of various sizes and shapes. There are no additives, polymers, or other compounds in the mixture, thus the chemical structure of both components remains unchanged, which gives the advantage of using each component's capabilities. The calcium sulfate component functions as a short-term space maintainer scaffold that dissolves fully in response to the rate of bone growth within 4-10 weeks. Hydroxyapatite functions as a long-term space maintainer to reduce overall graft resorption. [8]

Objective:-

The aim of this study was to assess Bond Apatite use in horizontal bone augmentation around dental implants, clinically and radiographically.

Patients, materials and Methods:-

Patient selection:

This study included sixteen patients, six men and ten women, with an average age of thirty years (ranging from nineteen to forty-five years). All patients were chosen from the Outpatient Clinic of the Faculty of Dentistry's Department of Oral Medicine, Periodontology, Diagnosis, and Oral Radiology for the replacement of lost maxillary anterior or premolar teeth (in the aesthetic zone) with dental implants. The study was conducted in accordance with the seventh revision of the Helsinki Declaration in 2013 and approved by the Institutional Review Board (IRB) (M07061119) of the Faculty of Dentistry, Mansoura University, Egypt. The study followed CONSORT guidelines for clinical trials. The study is listed on www.clinicaltrials.gov with registration number (NCT06043258) 22/09/2023.

Sample size calculation:
We hypothesized that comparison of posttest bone width between the two groups would have a large effect size (Cohen's d=0.8).

The sample size per group was calculated by using the formula by Borm et al. (2007): n * (1 - ρ2) + 1where n is the sample size if a ttest is used, (1 - ρ2) is the design effect where ρ is the correlation between baseline and outcome variables (pretest vs. posttest measures) and adding one subject to each treatment group is sufficient to attain the needed power for small clinical trials.

Using a ttest, group sample sizes of 26 patients per group achieve 80.75% power to reject the null hypothesis of zero effect size when the population effect size is 0.80 and the significance level (α) is 0.050 using a two-sided two-sample equal-variance ttest.

By applying the formula by Borm et al. (2007)[9]with n = 26 and ρ = 0.9, a sample size of 8 patients per group achieves the same power for the ttest with a smaller sample size.

Randomization:
One of the department's senior residents, who was not involved in the study and was not aware of any relevant treatment protocols, carried out the randomization using a computer-generated randomization list (SPSS v25.0). Sixteen candidates were randomly distributed into two equal groups. The distribution of the groups was as follows: each patient in Group I received an implant with Bond Apatite as bone graft substitute and each patient in Group II received an implant and Bio-Oss as bone graft substitute covered by a pericardium membrane.

Blinding
It was impossible to blind the operator as the operator was not involved in either the distribution or evaluation processes. Furthermore, all patients were unaware of which group they were in. Throughout the follow-up times, the assessor carried out each evaluation step while being entirely unaware of thetreatment protocol used. Likewise, statisticians were unaware of treatments and groups.

Criteria for Patient Selection:
Inclusion criteria:
Patients older than 28 years who were in good general health and good oral hygiene, and were available for multiple follow up appointments were selected. Every patient hadmissing tooth in the maxillary anterior or premolar area with insufficient horizontal bone at the site of the intended operation(class III according to the**Len Tolstunov** classification) [10] and was subsequently scheduled for implant supported prosthesis.

Exclusion criteria:
Patients with history of systemic disease that contraindicated intraoral surgical procedures, those on chronic treatment with any medication known to affect oral status and bone turnover, and those on long term nonsteroidal anti-inflammatory drugs exceeding 100 mg per day were excluded from the study. Furthermore, we also excluded pregnant or lactating women, patients with acute dentoalveolar infection**,** smokers more than 10 cigarettes per day and patients with poor oral hygiene.

Materials:-
Two-piece titanium dental implant system (AnyOne internal by MegaGen, co.), Bond apatite (Alloplastic bone graft material) (AugmaBio, United States of America), Bio-Oss (Xenograft bone material) (Bio-Oss, GeistlichPharmaAG, Wolhusen, Switzerland) and Pericardium barrier membrane (Tutopatch Bovine Pericardium from rti Surgical, co).

Methods:-
Preoperative measures:
All patients had a full description of all procedures (treatment protocol, steps, benefits and possible risks). Written consent was obtained beforeenrollmentin the study. Thorough medical and dental histories were recorded for all patients. Study casts were taken as a pretreatment record for all patients in the two tested groups. Intraoral photographs for the present situation were taken for all patients undergoing the surgical operations. Preoperative radiographs were obtained usingcone

beam computed tomography (CBCT) examination to measure the existing bony width and height to determine the treatment plan.

Surgical procedures:
First-stage surgery:
All surgical procedures were performed under local anesthesia (Articaine hydrochloride 68 mg/1.7 ml (Alexadricane 1: 1000 000) (Alexandria Pharmaceuticals, Egypt). A full mucoperiosteal flap was done, followed by sequential drilling with copious irrigation till reaching the needed dimensions. After implant placement: group I patients received Bond Apatite, while those in group II received Bio-Oss covered by pericardium membrane, and then suturing of the flap took place. Oral hygiene measures were given to each patient.

Second-stage surgery:
Patients recalled for the second-stage surgery after 5 months. Local anesthesia was provided, and the cover screws were removed through a minor crestal incision, followed by a two-week healing period.

Prosthetic phase:
The healing abutment was removed and a closed tray impression post was applied to take an impression with addition silicone rubber base material.Then a laboratory analog was connected to the impression post after removal from the patient's mouth to fabricate the working cast. Porcelain fused to metal restorations were fabricated and cemented to the abutments.

Evaluation of the treatment outcome:
Clinical evaluation:
All participants in both groups were evaluated for modified plaque index (MPI)[11], modified gingival index (MGI)[12] and probing depth (PD) with the aid of a blind assessor, using good light and plastic-implant probeafter the final restoration was inserted.

Radiographic evaluation:
Bone width was assessed using CBCT at baseline and 12 months after implant insertion. Bone width was measured 2mm below the crest of the alveolar ridge.

Statistical Analysis
Data were entered and analyzed using IBM-SPSS software (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp).

Qualitative data were expressed as N (%). Quantitative data were initially tested for normality using Shapiro-Wilk's test, with data being normally distributed if $p>0.050$. The presence of significant outliers (extreme values) was tested by inspecting boxplots.

Quantitative data were expressed as the mean ± SD if normally distributed; or as the median and interquartile range (Q1 or 25^{th} percentile – Q3 or 75^{th} percentile); if not.

Results:-

Demographic data:
No statistically significant difference was noted when comparing age median values among both tested groups; we found that; the group I age median value was 35.6 ± 7.5 and the group II age median value was 28.1 ± 10.5. (Table 1)

MPI:
Regarding the**modified plaque index**, four of the group I patients had a score of 0, and fourof them had a score of 1witha median value = 0.50(minimum-maximum = 0: 1). In group II, six patients scored 0, whereas only two patients scored 1 for modified plaque indexwith median value = 0.00 (minimum-maximum = 0: 1). Concerning MPI, there was no statistically significant difference between the two groups (P = 0.608). (Table 2)

MGI:
Regarding the **modified gingival index**, none of the patients in Group I scored 0, while four of them had score 1, and four patients had score 2with median value = 1.50 (minimum-maximum = 1: 2). Group II, on the other hand, contained three

patients with score 0, five patients with score 1, and none of the patients in this group had score 2 with median value = 1.00 (minimum-maximum = 0: 1). The difference between the two tested groups in median values of MGI was statistically significant (P = 0.038). (Table 2)

Peri implant probing depth:
Regarding the **peri-implant pocket depth**the study results revealedthat; the PD in the buccal aspect in group I was 2.58 ± 0.53 mm, while that ingroup II was 1.79 ± 0.73 mm. Additionally,the palatal PD mean value was 2.46 ± 0.59 mm in group I while that in group II was 1.88 ± 0.80 mm. The results showed a significantly higher buccal PD in group I versus group II (P = 0.026). Palatal PD was also higher in group I than in group II but the difference did not achieve statistical significance (P = 0.118).(Table 2)

Assessment of bone width:
Concerningthe**bone width,** intragroup comparison of bone width within each group revealed that the difference was statistically significant (paired-samples ttest was used); the p value for group I was <0.001, while the p value for group II was 0.024. Meanwhile, comparing bony width between group I and group II revealed that the difference was not statistically significant (independent-samples ttest was used); thepreintervention p valuewas= 0.769, while postintervention p value was= 0.187. (Table 2)

Discussion:-

Biomaterials have been created in recent years. They play a role in bone regeneration and reconstructive procedures. When a bone deficiency in shape and/or volume has to be fixed, a bone graft is the material of choice. [13]

This study illustrated that the median value of the MPI for group I was 0.50 (minimum-maximum = 0: 1) and for group II was 0.00 (minimum-maximum = 0: 1). There was no statistically significant difference in MPI between the two groups tested (P = 0.608). Although the difference between both groups was nonsignificant, for group II patients the MPI values were smaller than that of group I patients. This could be explained mainly in light of the differences in oral hygiene measures among the patients.In the same context,**Palachur et al.** [14]studied the efficacy of bovine-derived xenograft (Bio-Oss Collagen) in the treatment of intrabony defects and found that the mean plaque index score was reduced to 0.67 ± 0.04 with a mean reduction of 0.36 ± 0.32 (35.45%) after 9 months. Similarly,**Scabbiaet al.** [15] found a greater improvement in treatment outcome in patients treated with Bio-Ossversus patients treated with HA/collagen/chondroitin sulphate biomaterial (Biostite®) in the treatment of intra bony defects. They concluded that this result may be partly due to better plaque and bleeding scores. Furthermore, **Stein et al.** [16]assessed three approaches (biphasic calcium sulphate, autogenous bone spongiosa and autogenous bone spongiosa and open flap debridement) for treatment of intrabony defects. They found that, plaque index scores remained low from baseline throughout the whole study period with no statistically significant differences found among the biphasic calcium sulphate group and the other two groups.

In this study, the median value of the MGI for group I was 1.50 (minimum-maximum = 1: 2) and for group II was 1.00 (minimum-maximum = 0: 1). The difference was statistically significant (P = 0.038). Regarding group II patients, the MGI values were significantly less than those of group I. This could be attributed to the differences in MPI between both groups. These results were supported by**Méndez et al.** [17] who assessed xenografts for alveolar ridge preservation and concluded that this grafting material is suitable for the preservation of the alveolar ridge. Additionally, supported by study of **Kandasamy et al.** [18]made an assessment between synthetic allograft material (PerioGlas)and Bio-oss clinically and histomorphometrically, where theyfound that in Bio-Oss group, the gingival index was 0.70 ± 0.18 at the end of 1 year, while in the other group it was 0.69 ± 0.16. Clinically excellent healing was observed aftertheir placement of the implant with both allograft and xenograft material. In addition,**Baranes and Kurtzman** [19] found that Bond Apatite appears to be a predictable bone graft material. Due to the biological properties of the material, bone fill of nearly 90% has been routinely noted. The biocompatibility and bacteriostatic properties clarified the fact that the grafts are generally incorporated without pain, and the absence of an inflammatory reaction is routinely observed.

In this study it wasfound that mean peri-implant buccal probing depth in group I was 2.58 ± 0.53 and in group II was 1.79 ± 073. A statistically significant difference greater peri-implant buccal probing depth was found in group I versus that in group II(P = 0.026). Furthermore, peri-implant palatal PD was also greater in group I (with mean value was = 2.46 ± 0.59)versus that in group II(with mean value was = 1.88 ± 0.80),but the difference did not achieve statistical significance (P = 0.118). These results exceeded those obtained in previous studies evaluating the same xenograft in the treatment of deep intraosseous defects, and they reported thatpocket probing depth reduction ranged from 3.0±1.7 to 3.9±1.3. [20] On

the other hand, the findings of this study were compatible with the observations made by **Daniel et al.** [21],who found that Bio-Oss graft materials used with immediate implants resulted in excellent osseointegration.

This study compared bone width before and after intervention in each of the two tested groups. The intragroup difference was statistically significant in both group I and group II. In group I, thebone width mean value was 4.4 ± 1.2 and increased to 6.59 ± 1.03 (p value was < 0.001), while in group II it was 4.21 ± 1.4 and increased to 6.02 ± .028 (p = 0.024). However, there was no statistically significant difference between thetwo tested groups regarding bone width (p value before intervention was=0.769 and p value post intervention was=0.182). This comes in agreement with**Altaweelet al.** [22]whostudied 3 groups clinically and radiographically in which group I treated by piezoelectric ridge splitting technique (RST) and immediate implant insertion,augmented by the nano hydroxyapatite(nHA) bone graft only; group II treated by piezoelectric RST augmented by nHA bone graft and covered by amniotic membrane (AM); while group III was treated by piezoelectric RST augmentedwith PRF and nHA graft and covered by AM.They found that concomitant use of PRF with nHA graft coveredwith AM for augmentation around the dental implant in a narrow posterior mandible afterpiezoelectric alveolar ridge splitting accelerate osseointegration and significantly increase bone densityaround the osseointegrated implant and decrease bone resorption in comparison to thatachieved with the graft alone.The ridge width increased significantly in all groups. In group I,the mean ridge width was 3.99±0.4 mm preoperatively, whichincreased to 6.84 ± 1.1 mm postoperatively (P = 0.001). Ingroup II, the mean ridge width was 3.64 ± 0.3 mm preoperatively, which increased to 6.90 ± 0.6 mm postoperatively(P = 0.001). In group III, the mean ridge width was 4.17 ± 0.7 mm preoperatively, which increased to 6.65 ± 0.4 mm postoperatively(P = 0.001). The difference within group II washigher than those in groups I and III, but there were no significantpostoperative differences between groups.

Astudy done by **Atieh et al.** comparing hard tissue changes following socket preservation in groups using Bond Apatite or Bio-Oss versus no grafting. Both Bond Apatite(BCaS/HA) and Bio-Oss groups resulted in less vertical and horizontal bone loss following tooth extraction when compared to the nongrafted controlgroup. [23]

Furthermore, these findings are consistent with **Jensenetal.'s**[24]study using only Bio-Oss as a graft material. They found that Bio-Oss demonstrated high volume maintenance and new bone formation. Additionally, they reported that Bio-Oss showed higher dimensional maintenance compared to autogenous bone in the short and long term. Moreover, **Baranes and Kurtzman** [19] have also reported good clinical effectiveness of Bond Apatite in various jaw bone defects. They recommended that Bond Apatite provides added benefits clinically.

Figures:
Case No. 1 for group I:

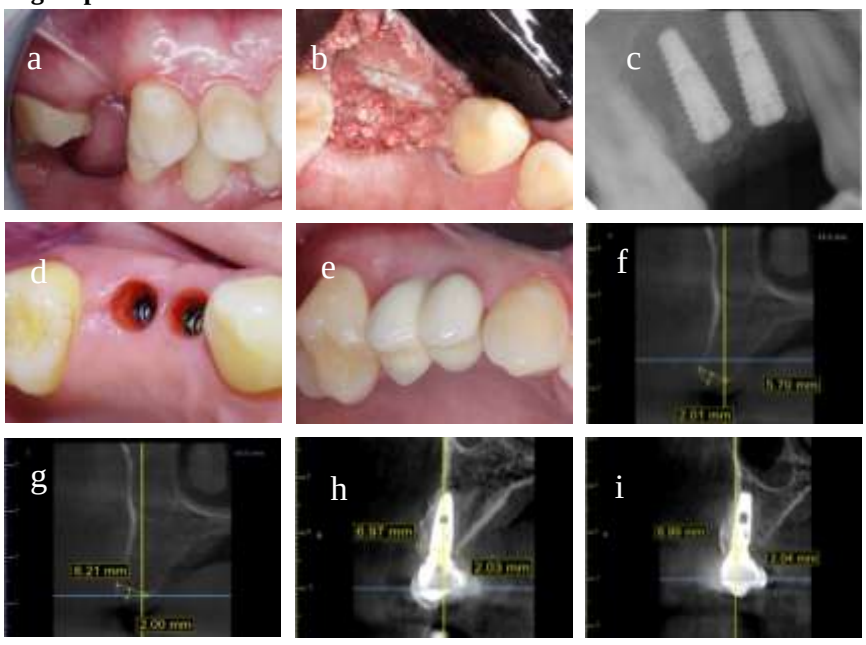

Figure (1):- (a)The buccal bone defect. (b) Bond apatite at the site of augmentation. (c) Periapical X-ray showing 2 implants in place. (d) Healing around implants. (e) 2 crowns delivered. (f) CBCT cut section showing bone width before

implant and bone graft in the 1st premolar area. (g) CBCT cut section showing bone width before implant and bone graft in the 2nd premolar area. (h) CBCT cut section 12 months after implant and bone graft in the 1st premolar area. (i) CBCT cut section 12 months after implant and bone graft in the 2nd premolar area.

Case No. 2 for group II:

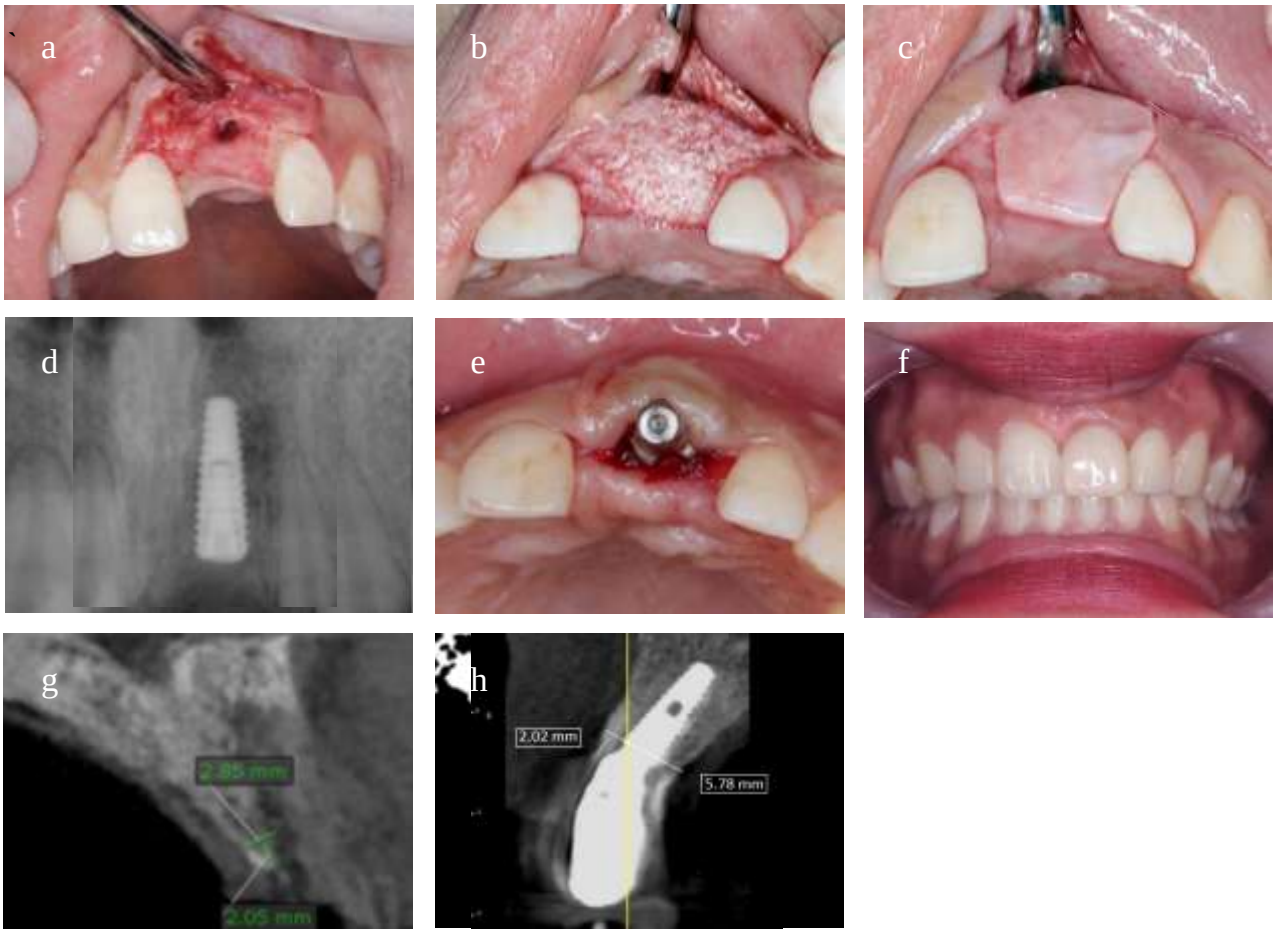

Figure (2):- (a) Flap elevation and defect. (b) Bio-Ossxenografst. (c) The pericardium membrane covering the graft material. (d) Periapical X-ray showing the implant in its planned position. (e) Transfer coping for impression. (f) Single crown delivered after healing. (g) CBCT cut section showing bone width before implant and bone graft. (h) CBCT cut section showing bone width 12 months after implant and bone graft.

Tables: -

Table (1):- Age and sex distribution in the two groups tested:

Characteristic	Group I	Group II	Pvalue
Sex			**0.608**
Male	2 (22.2%)	4 (50%)	
Female	6 (75%)	4 (50%)	
Age (years)	35.6 ± 7.5	28.1 ± 10.5	**0.123**
Notes: Data are N (%) for sex, and median (Q1-Q3) for age. Test of significance is Fisher's exact test for sex, and independent-samples ttest for age.			

Table (2):- Comparison between clinical; and radiographic parameters among two the tested groups:

		Group I	Group II	Total	P value
MPI	Score0	4 (50%)	6 (75%)	10 (62.5%)	**0.608**
	Score1	4 (50%)	2 (25%)	6 (37.5%)	
	Score2	0	0	0	
	Score3	0	0	0	
MGI	Score0	0 (0%)	3 (37.5%)	3 (18.75%)	**0.038**
	Score1	4 (50%)	5 (62.5%)	9 (52.9%)	
	Score2	4 (50%)	0 (0%)	4 (25%)	
	Score3	0	0	0	
	Score4	0	0	0	
PD	Peri implant buccal PD [mm]	2.58 ± 0.53	1.79 ± 0.73		**0.026**
	Peri implant palatal PD [mm]	2.46 ± 0.59	1.88 ± 0.80		**0.118**
Bone Width	Pre	4.40 (1.2)	4.21 (1.4)		**0.769**
	Post	6.59 (1.03)	6.02 (0.28)		**0.182**
	*P value	**<0.001**	**0.024**		
	For MPI and MGI: Data are N (%). The test of significance is Fisher's exact test.				Independent-samples ttest
	For PD: Data are mean ± standard deviation. The test of significance is Independent-Samples ttest.				
	For Bone Width: Data are mean ± standard deviation. Test of significance is *Paired-samples ttest.				

Conclusion:-

1. Bond Apatite preparation is a straightforward, affordable, and successful osseous defect reconstruction graft material.
2. Bond Apatite may be used as the material of choice for horizontal bone augmentation around dental implants with similar and sometimes even better results compared to Bio-Oss.

Abbreviations:

MPI: Modified plaque index.
MGI: Modified gingival index.
PD: probing depth.
IRB: The Institutional Review Board.
CBCT: Cone beam computed tomography.

BCS/HA: Biphasic calcium sulfate/ hydroxy apatite.

Declarations

Ethics approval and consent to participate:

The Institutional Review Board (IRB) of the Faculty of Dentistry, Mansoura University, Mansoura, Egypt, approved the current study in compliance with the seventh revision of the Helsinki Declaration in 2013 (M07061119). All of the participants gave their written consent.

Consent for publication:

All patients signed a written informed consent form for publication of their cases with the figures.

Data Availability:

The data sets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interests:

The authors declare that they have no competing interests.

Funding:

The authors received no funding for this research.

Authors' contributions:

All authors substantially contributed to the study design, drafting and revising the research, approving the submitted manuscript's final version, and accuracy of work.

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