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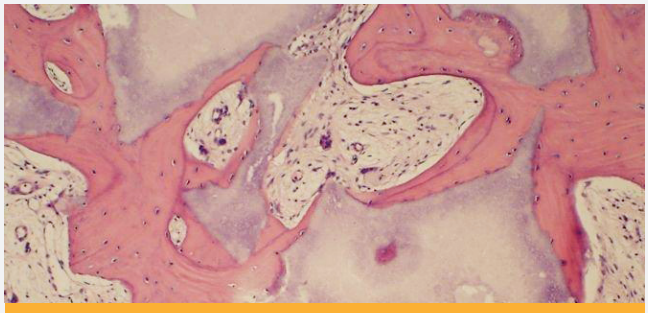
Clinical Radiographic and Histomorphometrical Analysis of Maxillary Sinus Augmentation Using Synthetic Bone Substitute - 4Bone.



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Clinical Radiographic and Histomorphometrical Analysis of Maxillary Sinus Augmentation Using Synthetic Bone Substitute – 4Bone.

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Introduction

Insufficient bone height often prevents placement of standard dental implants in the posterior edentulous maxilla. This pathological condition is most commonly the result of alveolar bone loss due to severe periodontitis, tooth loss, sinus pneumatization, or a combination of these.[1] Maxillary sinus augmentation is a surgical procedure that compensates for this pathological condition by increasing the alveolar bone height prior to or simultaneous with endosseous implant placement. [2,3] The procedure was first presented by Tatum in the late 1970's[4] and was first published by Boyne in 1980[5]. The technique has been repeatedly modified.[6-10]

Sinus lift procedure adequately increases the vertical dimension of the resorbed alveolar process in the posterior maxilla. thus enabling placement of implants of sufficient length at this site. Grafting materials, including autogenous bone,[5,9] demineralized freeze-dried bone allograft (DFDBA),[11-14] mineralized freeze-dried bone allograft (FDBA),[14] xenografts,[15-18] hydroxyapatite preparations,[7,15] calcium sulfate preparations,[19] and growth factors embedded in different carrier materials [21-23] have been successfully used to augment the floor of the maxillary sinus. The fear of bovine spongiform encephalopathy (BSE) ("Mad cow disease") transferring to humans (although no report of this has been made in the literature)[24] and the discovery of human immunodeficiency viruses surviving in allogenic bone after tissue processing [25,26] have drawn attention to the possibility of disease transmission from xenografts and allografts to humans. However, the use of alloplast materials is a viable alternative and is well accepted by the patients. Bioceramics made of a mixture of hydroxyapatite and beta tricalcium phosphate have demonstrated bioactivity and osteoconductivity.[27-29]

The aim of the present case report is to radiographically histologically and histomorphometrically evaluate the regenerative potential of 4Bone in sinus lift procedures.

Materials and Methods

M.D a 57 year old male nonsmoker with no systemic disorders and no history of sinusitis, required rehabilitation of the maxillary edentulous posterior maxilla. The patient, after being informed about alternative treatment plans, preferred maxillary sinus elevation followed by the placement of endosseous implants. The patient signed an informed consent form in which the procedure was explained in detail. Evaluation of the medical history, intra and extra oral examination, panoramic radiographs and a relevant CT scan showed that the patient was suitable for the treatment plan (Fig. 1).

The sinus lift procedure was performed using 4Bone, a fully synthesized homogenous hydroxyapatite and beta tricalcium phosphate (HA : ß-TCP) 60 : 40 as a filler bone substitute. Biopsies were harvested from the proposed implant site immediately prior to implant placement.

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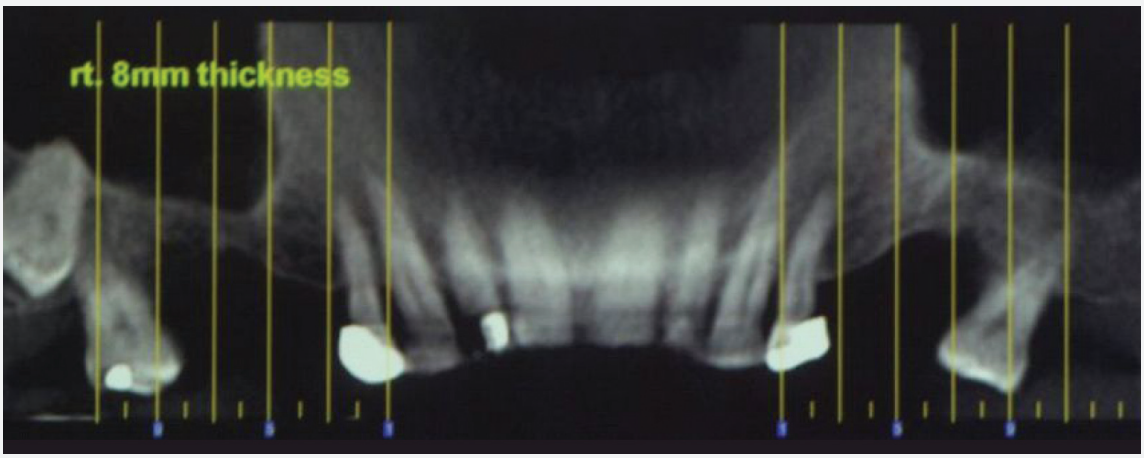

Fig. 1 MD- Initial radiographic presentation showing the enlarged sinus cavity.

Surgical Technique

The patient was premedicated 1 hour before surgery with 8 mg Dexamethasone† [30] and 875 mg amoxicillin-clavulonate potassium. Local anesthesia included 3% Lidocaine HCl (2-6 cc) and base norepinephrine§ (0.04 mg). The patient rinsed his mouth with 0.2% chlorhexedine gluconate solution for 1 minute, immediately preoperatively, to obtain a better surgical antiseptic environment.

Surgical procedures were performed according to the technique described by Smiler and Holmes.[7] Briefly, at the edentulous region distal to the position of the first premolar, a mucoperiosteal buccal flap was elevated, exposing the lateral bony wall of the sinus antrum. A round diamond bur, 2 mm in diameter, was used to outline the demarcation of the lateral window that was removed, completely exposing the underlying Schneiderian membrane. The membrane was separated from the housing bone, and a tension-free reflection exposing the sinus walls was achieved by gently pushing it away using large flat curette#. An inner occlusive native collagen membrane** was placed underneath the reflected Schneiderian membrane, serving as a "roof" to the augmented space prior to graft placement, as previously described[31]. The membrane was adapted to the Schneiderian membrane "roof" thus defining a space limited by peripheral bony walls, an osseous floor below, and an upper border created by a collagen barrier covering the Schneiderian membrane.

The established void was filled with 4 cc of saline-wet 4Bone grafting material, followed by placement of a collagen membrane** over the lateral window[32] and primary soft-tissue closure using 4/0 silk sutures Φ. Postoperatively, systemic antibiotic (amoxicillin-clavulonate" , 875 mg) was prescribed twice daily for 1 week. and naproxen sodiumx (one 275 mg tablet every 6-8 hours for 24 hours)was used for pain control. Dexamethasone Φ (4 mg daily) was administered for an additional 2 days[30] to minimize edema. Antiseptic mouth wash (0.2% chlorhexidine gluconate δ) was used twice daily (30 seconds each time) for 2 weeks. Sutures were removed after 14 days, followed by uneventful soft-tissue healing.

A CT scan performed 9 months after sinus augmentation demonstrates radiographic stability of the graft material and normal thickness of the Schneiderian membrane (Fig. 2). At this stage, immediately prior to implant placement,a biopsy measuring 2 mm in diameter and 14 mm in length was harvested from the proposed implant site using a surgical guide and a trephine drill[a]. The biopsy specimen was fixed in 10% neutral buffered formalin for 96 hours, decalcified in 5% formic acid for 14 days, and embedded in paraffin.[33]

Blocks were cut to 5um-thick slides and stained with Hematoxylin & Eosin (H&E). The biopsy site was enlarged into a regular osteotomy and two Lance implants 16 mm in length and 5 mm in diameter were placed[T].

Histomorphometric Analysis

Histomorphometric measurements were taken using a microscope millimeter eyepiece grid, at x200 magnification. Each grid was composed of 121 intersections and the slide was measured at 10 different sites (for a total of 1,210 readings per slide). Measurements were taken from both the pristine bone, which was identified according to lack of graft material, and from the newly formed tissue superior to it. The relative percentages of newly formed bone, graft particles, and connective tissue were calculated by counting the number of recordings of each tissue type on every grid intersection. The total count of all points of each tissue type divided by 1,210, represents the relative percentage of each component involved in the area of the newly regenerated tissue.

Histomorphometry

Bone surface area was calculated using a microscope equipped with a drawing tube (Leitz, Wetzlar, Germany), connected to a computer using Axioplan II (Zeiss, Kontron, Image Analysis Division, Oberkochen, Germany).Only the grafted area was considered; the border between the newly regenerated area and the pristine bone was clearly indicated by the presence of remaining 4Bone granules (Fig. 5).

The contact length of the new bone/graft particles was divided by the circumference and multiplied by 100. thus expressing the osteoconductive value as a percentage (Fig 5).

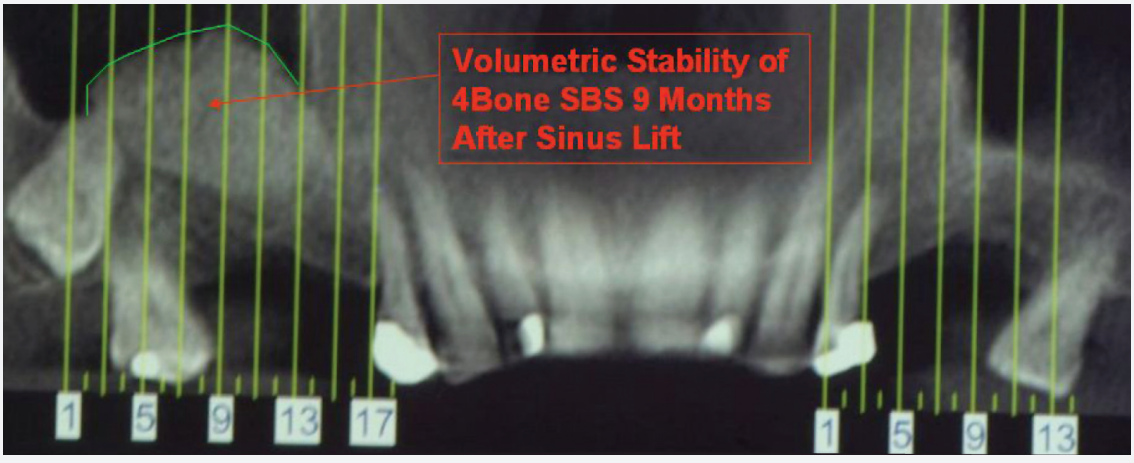

Fig. 2 MD- 9 months after sinus grafting showing stability of the grafted material.

Results

A CT scan performed 9 months later demonstrated volumetric stability of the radiopaque zone covered by a thin layer of soft tissue (Fig. 2).

Histology

The biopsy included both pristine and newly formed bone. Newly formed bone was equally dispersed along the biopsy (apically-corronally). The graft particles were surrounded by and showed intimate contact with the bone and the connective tissue surrounding it (Figs. 4, 5). Osteoblasts were seen lining graft particles in conjunction with newly formed bone (Fig. 5). There was no evidence of inflammatory infiltrate.

Histomorphometry

New bone formation accounted for 28% of the total surface. The percentage of connective tissue was 31% and residual graft particles averaged 41%. In comparison to pristine bone, the mineralized material (new bone formation and graft particles) was higher (59% vs. 39%). The connective tissue compartment of the pristine bone was 61% (Fig. 3). The interface between bone and 4Bone particles surface was 61% of the total particles surface.

Discussion

New bone formation in the present study averaged 28%. This value is lower than the 41% and 36% recorded by Cammack,[14] who used FDBA and DFDBA respectively for the same procedure. The results of the present study are equal to the new bone formation fraction reported by Kolerman et al.[31] who used FDBA (oragraft) and internal collagen membrane for sinus augmentation (29%), and to the (28.3%) reported by Froum et al [34]. of new bone formation using a mineralized cancellous bone allograft for the same procedure. This fraction is lower than the 40.33% of new bone formation reported by Noumbissi [35] using the same bone allograft. Deproteinized bovine bone mineral is well documented as augmentation material for sinus floor elevation.[15,17,33-35] In a study in which Bio-Oss was used for sinus augmentation, newly formed bone increased from 21.1% to 27.6% between 6-12 months[17], The graft particles compartment decreased from 39.2% to 27% in the same period. The mineralized area (which is new bone and graft particles) remained constant around 60%. This is equal to the value achieved in the present study. Ample data was reported regarding new bone formation in sinus floor elevation procedures; however, very few articles dealt with the osteoconductive values of the materials grafted.[35-37] Proussaefs et al.[36] found that 40.17% of the Bio-Oss particles were in contact with bone. whereas Tadjoedin et al. [37] found that only 34%-38% of the Bio-Oss surface was in contact with bone. Noumbissi et al.[35] reported the same values for Bio-Oss (34.75%) and higher values using puros (54.33%). All the above mentioned values are lower than the 61% found in the present study using 4Bone. The advantages of using a barrier membrane in sinus augmentation over the lateral bony window (i.e. increasing the amount of vital bone formation) are well documented.[32,38,39] In contradiction, Fugazzotto and Vlassis[40] reported on a 98.6% success rate when placing a resorbable membrane over the lateral window, while a similar success rate (99.2%) was observed when an external membrane was not used. Using an internal collagen membrane underneath the Schneiderian membrane as a routine procedure has never been investigated. In the present case, a collagen membrane was placed underneath the reflected Schneiderian membrane, although the membrane appeared clinically intact. Care was taken not to cover the peripheral bony walls. The use of an internal membrane offers an additional barrier that may help to prevent passage of graft particles and bacterial contamination to and from the sinus cavity through potential small tears.[40-42]

Within the limits of the present case, it is suggested that 4Bone, is biocompatible and osteoconductive permitting new bone formation similar to deproteinized bovine bone mineral and allograft materials when used in conjunction with an internal sub-Schneiderian collagen membrane for sinus augmentation procedures. Although our data are based on a single case, the 4Bone seems to be an accepted material for sinus augmentation.

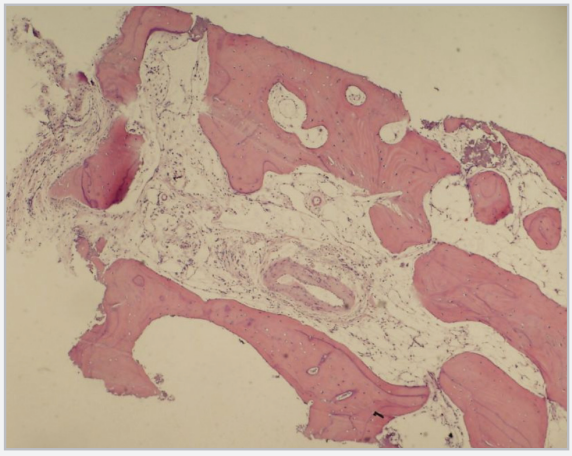

Fig. 3 MD- 9 months biopsy. Pristine bone. (Hematoxilyn & Eosin, x100 magnification)

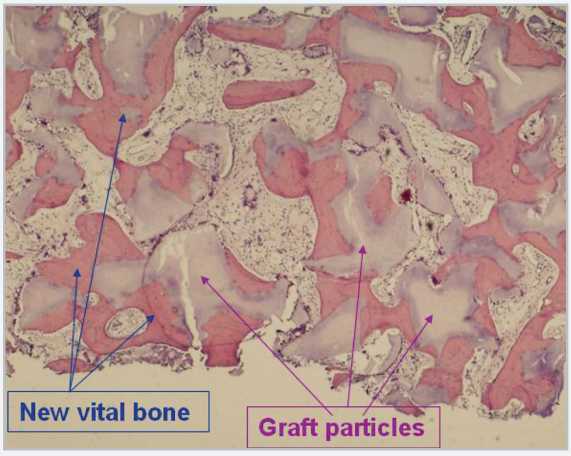

Fig. 4 MD- 9 months biopsy after grafting with 4Bone. Graft particles surrounded by vital bone and connective tissue. (Hematoxilyn & Eosin, x100 magnification)

References

1. Tallgren, A. The continuing reduction of the residual alveolar ridges in complete denture wearers: A mixed-longitudinal study covering 25 years. J Prosthet Dent 1972;27:120-132.
2. Wallace SS, Froum SJ. Effect of maxillary sinus augmentation on the survival of endosseous dental implants. A systemic review. Ann Periodontol 2003;8:328-343.
3. Peleg M, Mazor Z, Chaushu G, Karg AK. Sinus floor augmentation with simultaneous implant placement in the severely atrophic maxilla. J Periodontol 1998; 69:1397-1403.
4. Tatum OH. Maxillary sinus grafting for endosseous implants. Presented at the Annual Meeting of the Alabama Implant Study Group, Birmingham, AL.1997.
5. Boyne PJ, James RA. Grafting of the maxillary sinus floor with autogenous marrow and bone. J Oral Surg 1980;38:613-616.
6. Misch CE. Maxillary sinus augmentation for enosteal implants. Organized alternative treatments plans. Int J Oral Implantol 1987;4:49-58.
7. Smiler DG, Holmes RE. Sinus lift procedure using porous hydroxyapatite: a preliminary report. J Oral Implantol 1987;13:239-253.
8. Wood R, Moor P. Grafting of the maxillary sinus with intraorally harvested autogenous bone prior to implant placement. Int J Oral Maxillofac Implants 1988; 3:209-214.
9. Kent JN, Block MS. Simultaneous maxillary sinus floor bone grafting and placement of hydroxylapatite-coated implants. J Oral Maxillofac Surg 1989;47: 238-242.
10. Misch CE, Dietsh F. Bone grafting materials in implant dentistry. Implant Dent 1993;2:158-162.
11. Jensen OT, Shulman LB, Block MS, Iacono VJ. Report of the sinus consensus conference of 1996. Int J Oral Maxillofac Implants 1998;13(supplement).
12. Garey DJ, Whittaker JM, James RA, Lozada AL. The histologic evaluation of the implant interface with heterograft and allograft material - an eight months autopsy report. Part II. J Oral Implantol 1991;17:404-408.
13. Whittaker JM, James RA, Lozada J, Cordova C, Garey DJ. Histological response and clinical evaluation of heterograft and allograft materials in the elevation of the maxillary sinus for the preparation of endosteal dental implant sites. Simultaneous sinus elevation and root form implantation. An eight month autopsy report. J Oral Implantol 1989;15:141-144.
14. Cammack G, Nevins M, Clem DS, Hatch JP, Mellonig JT. Histologic evaluation of mineralized and demineralized freeze dried bone allograft for ridge and sinus augmentation. Int J Periodontics Restorative Dent 2005;25:231-237.
15. Artzi Z, Nemkovsky CE, Tal H, Dayan D. Histopathological morphometric evaluation of 2 different hydroxyapatite bone derivates in sinus augmentation procedure: a comparative study in humans. J Periodontol 2001;72:911-920.
16. Testori T, Wallace SS, Del Fabbro M, Taschieri S, Trisi P, Capelli M, Weinstein R. Repair of large sinus membrane perforations using stabilized collagen barrier membranes: surgical techniques with histologic and radiographic evidence of success. Int J Periodontics Restorative Dent 2008;28:9-17.
17. Valentini P, Abensur D. Maxillary sinus floor elevation for implant placement with demineralized freeze dried bone and bovine bone (Bio-Oss). A clinical study of 20 patients. Int J Periodontics Restorative Dent 1997;17:232-241.
18. Orsini G, Scarano A, Piatteli M, Piccirilli M, Caputi S, Piattelli A. Histologic and ultrastructural analysis of regenerated bone in maxillary sinus augmentation using a porcine bone-derived biomaterial. J Periodontol 2006;77:1984-1990.
19. Pecora GE, De Leonardis D, Cornelini R, Della Rocca C, Cortesini C. Short term healing following the use of calcium sulfate as a grafting material for sinus augmentation: a clinical report. Int J Oral Maxillofac Implants 1998;13:866-873.
20. Landi L, Pretel RW, Hakimi NM, Setayesh R. Maxillary sinus floor elevation using a combination of DFDBA and Bovine derived porous hydroxyapatite: a preliminary histologic and histomorphometric report. Int J Periodontics Restorative Dent 2000;20:575-583.
21. Hanisch O, Tatakis DN, Rohrer MD, Wohrle PS, Wozney JM, Wikesjo UME. Bone formation and osseointegration stimulated by rhBMP-2 following subantral augmentation procedure in non human primates. Int J Oral Maxillofac Implants 1997;12:785-792.
22. Groeneved EHJ, Van der Bergh JPA, Holzmann P, ten Bruggenkate CM, Tuinzing DB, Burger EH. Histological observations of a bilateral maxillary sinus floor elevation 6 and 12 months after grafting with osteogenic protein 1 device. J Clin Periodontol 1999;26:841-846.
23. Groeneved EHJ, Van der Bergh JPA, Holzman P, ten Bruggenkate CM, Tuinzing DB, Burger EH. Histomorphometrical analysis of bone formed in human maxillary sinus floor elevation grafted with op-1 device, demineralized bone matrix or autogenous bone. Comparison with non grafted sites in a serial of case reports. Clin Oral Implants Res 1990;10:499-509.
24. Sogal A, Tofe Aj. Risk assessment of bovine spongiform encephalopathy transmission through bone graft material derived from bovine bone used for dental applications. J periodontal. 1999;70:1053-1063.
25. Simonds RJ, Holmberg SD, Hurwitz RL, et al. Transmission of human immunodeficiency virus type 1 from seronegative organ and tissue donor. N Engl J Med. 1992;326:726-732.
26. Marthy S, Richter M. Human immunodeficiency virus activity in rib allografts. J Oral Maxillofac Surg. 1998;56:474-476.
27. Frayssinet P, Trouillet JL, Rouquet N, Azimus E, Autefage A. Osseointegration of macroporous calcium phosphate ceramics having a different chemical composition. Biomaterials. 1993 May;14(6):423-9.
28. Daculsi G, Laboux O, Malard O, Weiss P. Current state of the art of biphasic calcium phosphate bioceramics. J Mater Sci Mater Med. 2003 Mar;14(3):195-200
29. Le Nihouannen D, Saffarzadeh A, Aguado E, Goyenvalle E, Gauthier O, Moreau F, Pilet P, Spaethe R, Daculsi G, Layrolle P. Osteogenic properties of calcium phosphate ceramics and fibrin glue based composites. J Mater Sci Mater Med. 2007 Feb;18(2):225-35.
30. Misch CM. The pharmacologic management of maxillary sinus elevation surgery. J oral Implantol. 1992;18(10):15-23.
31. Kolerman R, Tal H, Moses O. Histomorphometric analysis of newly formed bone after maxillary sinus floor augmentation using ground cortical bone allograft and internal collagen membrane. Accepted for publication. J Periodontol. 2008 Nov;79(11):2104-11.
32. Tawil G, Maula M. Sinus floor elevation using a bovine bone mineral (Bio-Oss) with or without the concomitant use of a bilayered collagen barrier (Bio-Gide): a clinical report of immediate and delayed implant placement. Int J Oral Maxillofac Implants 2001;16:713-721.
33. Artzi Z, Kozlovsky A, Nemcovsky CE, Weinreb M. The amount of newly formed bone in sinus grafting procedures depends on tissue depth as well as the type and residual amount of the grafted material. J Clin Periodontol 2005;32:193-9.
34. Froum S.J, Wallace SS. Elian N. Cho SC, Tarnow DA. Comparison of mineralized cancellous bone allograft (Puros) and anorganic bovine bone matrix (Bio-Oss) for sinus augmentation: Histomorphometry at 26 to 32 weeks after grafting. Int J Periodontics Restorative Dent 2006;26:543-551.
35. Noumbissi S.S, Lazada J.L, Boyne P.J, Rohrer M.D, Clem D., Kim J.S, Prasad H. Clinical, histologic, and histomorphometric evaluation of mineralized solvent-dehydrated bone allograft (puros) in human maxillary sinus grafts. Jornal of Oral Implantology 2005;4:171-178.
36. Proussaefs P, Lozada J, Kim J, Rohrer MD. Repair of the perforated sinus membrane with a resorbable collagen membrane: A human study. Int J Oral Maxillofac Implants 2004;19:413-420.
37. Tadjoedin E. S, De Lange E. S, Bronckers A. L. J. J, Lyaruu D. M and Burger E. H. Deproteinized cancellous bovine bone (Bio-Oss) as bone substitute for sinus floor elevation. Journal of clinical Periodontology 2003;30 (3), 261-270.
38. Tarnow DP, Wallace SS, Froum SJ, Rohrer MD, Cho S-C. Histologic and clinical comparison of bilateral sinus floor elevations with and without barrier membrane placement in 12 patients: Part 3 of an ongoing prospective study. Int J Periodontics Restorative Dent 2000;20:116-125.
39. Froum SJ, Tarnow DP, Wallace SS, Rohrer MD, Cho SC. Sinus Floor elevation using anorganic bovine bone matrix (OsteoGraft/N) with and without autogenous bone: A clinical, histologic, radiographic, and histomorphometric analysis- Part 2 of an ongoing prospective study. Int J Periodont Rest Dent 1998;18:529-543.
40. Fugazzotto PA, Vlassis J. A simplified classification and repair system for sinus membrane perforations. J Periodontol 2003;74:1534-1541.
41. Avera SP, Stampley WA, McAllister BS. Histologic and clinical observation of resorbable and non-resorbable barrier membranes used in maxillary sinus graft containment. Int J Oral Maxillofac Implants 1997;12:88-94.
42. Van den Bergh JPA, ten Bruggenkate CM, Disch FJM, Tuinzing DB. Anatomical aspect of sinus floor elevation. Clinic Oral Implants Res 2000;11:256-265.
43. Kolerman R, Samorodnitzky G, Barnea E,Tal. Histomorphometric analysis of newly formed bone after bilateral maxillary sinus augmentation using two different osteoconductive materials and internal collagen membrane: Case series.
Accepted for publication. Int J Periodontics Restorative Dent.

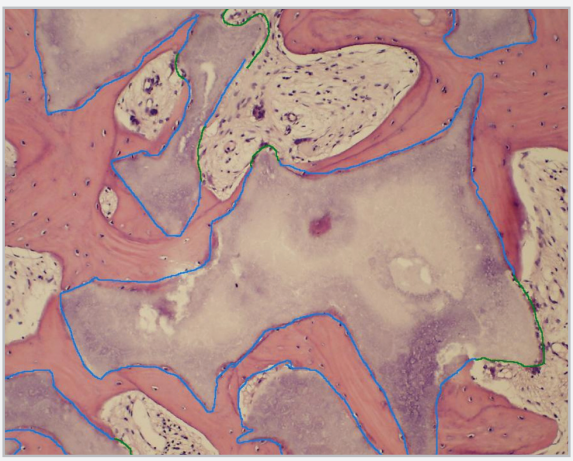

Fig. 5 MD- 9 months biopsy after grafting with 4Bone. Graft particles surrounded by vital bone and connective tissue. (Hematoxilyn & Eosin, x400 magnification)

1 4Bone: Biomatlante, France. Distributed by: MIS implants, Shlomi Israel.
† Rekah Pharmaceutical Products Ltd. Holon, Israel
Augmentin - Glaxo Smith Klein, Brentford, UK
§ Novocol Pharmaceutical of Canada, Inc., Cambridge, Canada
Tarodent mouthwash, Taro Pharm Ind Ltd., Haifa, Israel
Kramer-Nevins Hu-Friedy
** Bio-Gide, Geistlisch Pharma AG, Wolhusen, Switzerland
ǁ Augmentin - Glaxo Smith Klein, Brentford, UK
Ж Narocin, Teva Pharm Ind Ltd., Petah-Tikva, Israel
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