

# Clinical Evaluations of OSTEON<sup>®</sup> as a New Alloplastic Material in Sinus Bone Grafting and its Effect on Bone Healing

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**Abstract:** *Purpose:* The objective of this study was to clinically evaluate the use of OSTEON<sup>®</sup> as a sinus graft material and to measure the effect of healing at 4 and 6 months after surgery. *Materials and Methods:* After sinus graft using OSTEON<sup>®</sup> in 17 patients, bone specimens were collected from lateral sinus using 2.0-mm trephine bur at the time of 4 or 6 months after surgery. Histology of the bone specimens was prepared and the percentage of newly formed bone fraction, lamellar bone/woven bone ratio (LB/WB), and newly formed bone/graft material ratio (NB/GM) were measured to indicate the suitability of the materials and the successful healing of the graft. *Results:* The morphology of OSTEON<sup>®</sup> was observed to be interconnected, with 77% porosity and a pore size of 300–500  $\mu\text{m}$ . After implantation, the mean percentage of newly formed bone fraction after 4 months and 6 months surgery was 40.6 and 51.9%, respectively. Statistical analysis indicated no significant difference ( $p = 0.135$ ) in the newly formed bone fraction between the two postoperative periods. The mean LB/WB ratio after 4 months and 6 months surgery was 0.14 and 0.45, respectively, with significant difference observed between the two postoperative periods ( $p = 0.027$ ). Additionally, the mean NB/GM ratio after 4 months and 6 months surgery was 1.95 and 7.72, respectively, with significant difference observed between the two postoperative periods ( $p = 0.046$ ). *Conclusion:* It was concluded that OSTEON<sup>®</sup> is suitable for use in sinus graft application since desirable time-dependent healing was demonstrated. © 2007 Wiley Periodicals, Inc. J Biomed Mater Res Part B: Appl Biomater 00B: 000–000, 2007

**Keywords:** sinus bone graft; alloplastic material; OSTEON<sup>®</sup>

## INTRODUCTION

Placement of implant prosthesis in the maxillary posterior region is known to be difficult on many aspects and has the lowest success rate. In many clinical situations, the maxillary posterior region is made up of type III or IV bone, with porous and insufficient bones for implant placement. The advancement in implant surgical techniques, improved bone grafts, and recent developments in implant surface treatments have resulted in predictable sinus bone graft success, thereby allowing implant placement in the maxil-

lary molar region. However, controversy still exists on what constitute an ideal sinus graft materials.<sup>1–3</sup> Ideally, the bone graft material used for implant reconstruction should (a) maintain space an optimal period of time to achieve bone ingrowth and implant healing, (b) remain stable for the period of graft consideration, during implant integration, and after the implants are restored, (c) promote osteoconduction of the neighboring cells to form bone within the graft material, (d) remodel itself into long-lasting bone, (e) facilitate easy placement to avoid patient morbidity, and (f) have a predictable success rate.<sup>4</sup>

Alloplastic materials are recently used as bone substitute. They are biologically acceptable, allowing bone ingrowths and bone remodeling while maintaining volume.<sup>5</sup> Additionally, alloplastic materials have several advantages,

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such as (a) the lack of required donor site, (b) ample supply, and (c) the nonexistence of disease transmission.<sup>6</sup> Hydroxyapatite (HA) is the major mineral component in bone, and synthetic apatite has become a common osteoconductive replacement material for bone defects.<sup>7</sup> Synthetic calcium phosphate (CaP) ceramics such as beta-tricalcium phosphate ( $\beta$ -TCP) and HA are commonly used in the form of blocks, cements, pastes, powders, or granules. These bio-compatible synthetic CaP ceramics are also commonly used as alternatives to autogenous bone, xenograft, or allograft materials.<sup>8</sup> Many of the current commercially available alloplastic materials such as Bioresorb<sup>®</sup>, Chronos<sup>®</sup>, Ceros<sup>®</sup>, Cerasorb<sup>®</sup>, and Vitoss<sup>®</sup> contain  $\beta$ -TCP ceramics, whereas other commercially available alloplastic materials such as PepGen P-15<sup>®</sup>, Cerabone<sup>®</sup>, Ostim<sup>®</sup>, BioOss<sup>®</sup>, and Tutoplast<sup>®</sup> contain HA ceramics. OSTEON<sup>®</sup> is a newly developed alloplastic material containing 70% HA and 30%  $\beta$ -TCP. Two types of OSTEON<sup>®</sup> grafting materials, one with a particle size of 0.5–1.0 mm and the other with a particle size of 1.0–2.0 mm are commercially available.

As in the development of new alloplastic materials for sinus graft applications, it is critical that the healing process occurring at the graft site be evaluated. Since there are very little data on the suitability of the grafting materials for sinus graft applications,<sup>9</sup> the objective of this study was to clinically evaluate the use of OSTEON<sup>®</sup> as a sinus graft material. Histology of the bone specimens at 4 and 6 months after surgery was prepared and the percentage of newly formed bone fraction, lamellar bone/woven bone ratio (LB/WB) and newly formed bone/graft material ratio (NB/GM) were measured to indicate the suitability of the materials and the successful healing of the graft.

## MATERIALS AND METHODS

### Scanning Electron Microscopy

The morphology of OSTEON was evaluated using a scanning electron microscopy (SEM; Vega II SBH, TESCAN, Brno, Czech). The thin layer of platinum coating was performed on the samples to prevent charging. All samples were evaluated at low and high magnifications.

### Patients

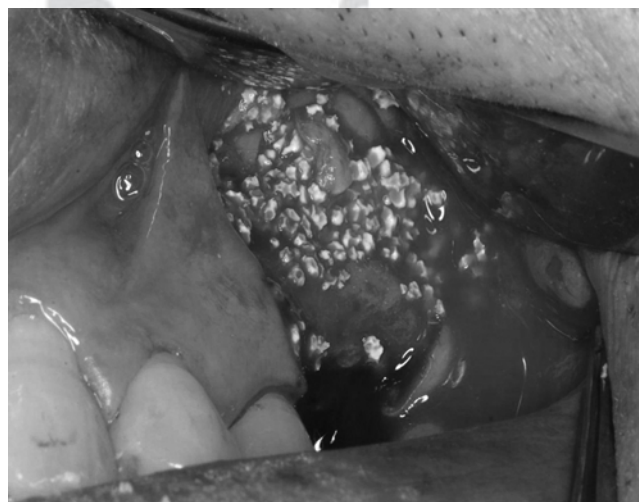
A total of 17 patients were used in this study. Informed consent from patients was obtained for all procedures performed. Additionally, approval from the Institutional Review Board at Seoul National University Bundang Hospital, Seoul, Korea was obtained prior to the onset of study.

### Surgical Procedures

Under general anesthesia and intravenous sedation, the flap was elevated via a crestal incision and a vertical releasing

incision. A small oval-shaped window was prepared in the anterior sinus wall, and the window-forming bone was then pushed-on to make the upper border of the graft site, followed by careful elevation of the sinus membrane. In this study, the two different commercially available OSTEON<sup>®</sup> grafting materials (one with particle size of 0.5–1.0 mm and the other with particle size of 1.0–2.0 mm) were initially mixed in a ratio of 1:1. The mixed OSTEON<sup>®</sup> grafting materials were then hydrated in sterile saline, followed by mixing with 10 weight % autogenous bone chips (harvested from the adjacent maxillary tuberosity area and sinus anterior wall), and stabilized with tissue adhesive (Greenplast<sup>®</sup>, Greencross, Seoul, Korea). The prepared graft and tissue adhesive mixture (0.5–2.5 cc) was then grafted as a bolus in the sinus cavity. Immediate placements or a 4 months delayed placements of implants were performed, depending on the availability of residual alveolar bone for primary stabilization (Figure 1). In all the cases, the lateral sinus window was covered by resorbable collagen membrane (Ossix<sup>®</sup>) before primary suturing. The patients were prescribed with antibiotics and analgesics for the surgical site for 5 days postoperatively. Oral rinsing with 0.12% chlorhexidine was also prescribed. To evaluate healing, biopsy of bone specimen was performed on patients in the course of connecting the healing abutment at 6 months after the sinus graft procedure for the immediately implant group, whereas biopsy of bone specimen was simultaneously performed on patients with implant placements at 4 months after the sinus graft procedure for the delayed implant group. All biopsy of the bone specimen were collected from lateral sinus using 2.0-mm trephine. Histology of the bone specimens was performed and the

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**Figure 1.** The window-forming bone was pushed-on to make the upper border of the graft site, and sinus membrane was elevated carefully. The prepared graft materials were stabilized with tissue adhesive (Greenplast<sup>®</sup>) in the bowl. The graft-adhesive mixture was grafted as a bolus in the sinus cavity. Immediate or delayed implant placement was chosen depending on whether the primary stability could be achieved. [Color figure can be viewed in the online issue, which is available at [www.interscience.wiley.com](http://www.interscience.wiley.com).]

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AQ3 **TABLE I. Summary of the Cases**

Case	Age (years)	Gender	Site (Rt./Lt.)	Volume of OSTEON <sup>®</sup> (cc)	Time of Implant Placement	Types of Implants
1	38	M	Lt.	1.0	Delayed	Implantium <sup>®</sup>
2	49	F	Lt.	2.0	Delayed	Osstem <sup>®</sup> SS III
3	49	M	Lt.	1.0	Immediate	Osstem <sup>®</sup> GS II
4	57	F	Rt.	2.0	Delayed	Osstem <sup>®</sup> SS III
5	59	M	Rt.	1.0	Delayed	Implantium <sup>®</sup>
6	47	M	Lt.	2.0	Delayed	Osstem <sup>®</sup> GS II
7	49	F	Rt.	0.5	Delayed	Osstem <sup>®</sup> US III
8	49	F	Rt.	0.5	Immediate	Osstem <sup>®</sup> US III
9	68	F	Lt.	1.5	Delayed	Implantium <sup>®</sup>
10	47	F	Lt.	1.5	Immediate	Implantium <sup>®</sup>
11	63	M	Rt.	1.5	Delayed	Osstem <sup>®</sup> US III
12	65	F	Rt.	1.0	Delayed	Implantium <sup>®</sup>
13	50	M	Rt.	1.0	Immediate	Implantium <sup>®</sup>
14	55	M	Rt.	0.5	Immediate	Implantium <sup>®</sup>
15	52	M	Rt.	1.0	Immediate	Implantium <sup>®</sup>
16	36	F	Rt.	1.0	Immediate	Implantium <sup>®</sup>
17	46	M	Lt.	2.5	Immediate	Implantium <sup>®</sup>

histologist was blind to the type of surgery and the graft material used.

**Histology and Histomorphometry**

All specimens were fixed in 10% formalin for 24 h and decalcified in Calci-Clear Rapid<sup>™</sup> (National Diagnostics, Atlanta, GA) for 12 h. The tissue were then rinsed in flowing water, treated with Hypercenter XP tissue processor (Shandon, Cheshire, UK), embedded in paraffin, sectioned to a thickness of 4.0 and 5.0 μm, followed by staining with hematoxylin-eosin and Goldner’s Trichrome. Using a light microscope to evaluate the stained sections, all images were captured using a MagnaFire digital camera system (Optronics, Goleta, CA). The density of newly formed bone, proportions of lamellar and woven bone, and residual graft materials were measured and analyzed using a Visus Image Analysis System (Image & Microscope Technology, Daejon, Korea).

**Statistical Analysis**

The percentage of newly formed bone fraction, LB/WB ratio and NB/GM ratio between 4-month specimens and 6-month specimens were statistically analyzed using the Mann-Whitney *U*-test (*p* < 0.05).

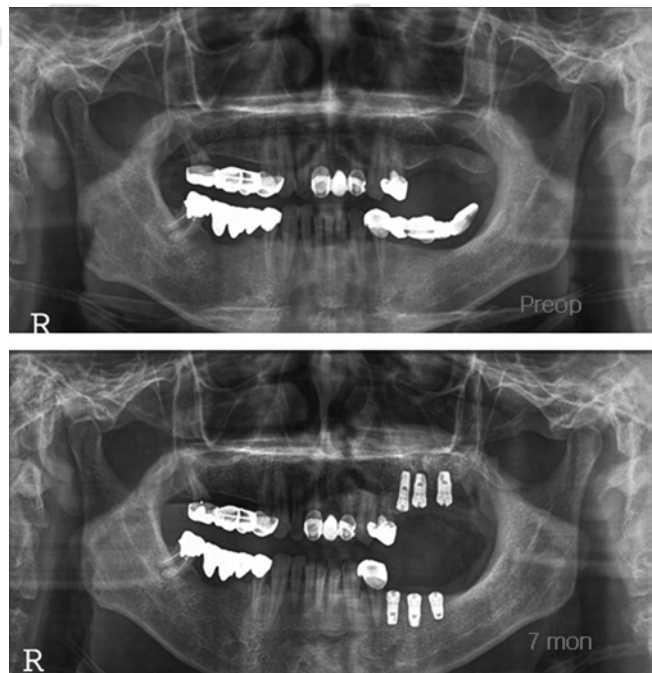
**RESULTS**

**Clinical Evaluations**

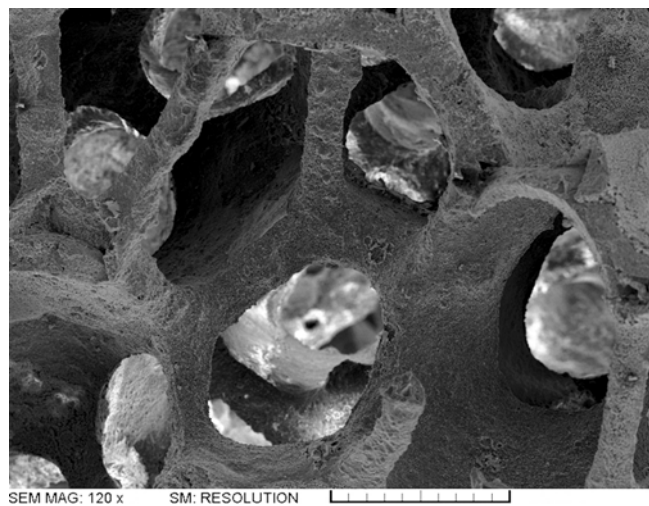
T1 As shown in Table I, nine out of the 17 patients were male. The mean age of patients in this study was 51.7 years, with patient’s age ranging from 36 years old to 68 years old. Immediate implant placement (with 6-month

biopsy specimen) was performed in eight patients, whereas delayed implant placement (with 4-month biopsy specimen) was performed in nine patients. No implant failure was observed during the study period. Additionally, normal healing process without any complication was observed in all patients, suggesting successful implant placement. A slight resorption of the grafted materials was also observed during 12 to 17 months of healing period (Figure 2).

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**Figure 2.** Panorama X-ray image before and 7 months after sinus graft on left maxillary sinus in case 1.



**Figure 3.** SEM morphology of OSTEON<sup>®</sup> with interconnected pore structure (×120). The pore size is from 300 to 500 μm, which is similar to human cancellous bone and the porous bone graft is beneficial to osteoblast cell ingrowth to OSTEON<sup>®</sup>.

**Morphology of OSTEON<sup>®</sup>**

Using the SEM, the OSTEON<sup>®</sup> graft material was observed to exhibit interconnected porous structures. Additionally, a volumetric porosity of 77% and a pore size of 300–500 μm were observed for the OSTEON<sup>®</sup> graft material (Figure 3). The stable HA in the OSTEON<sup>®</sup> grafting material was observed to be coated with the β-TCP (Figure 4).

**Histological Evaluations**

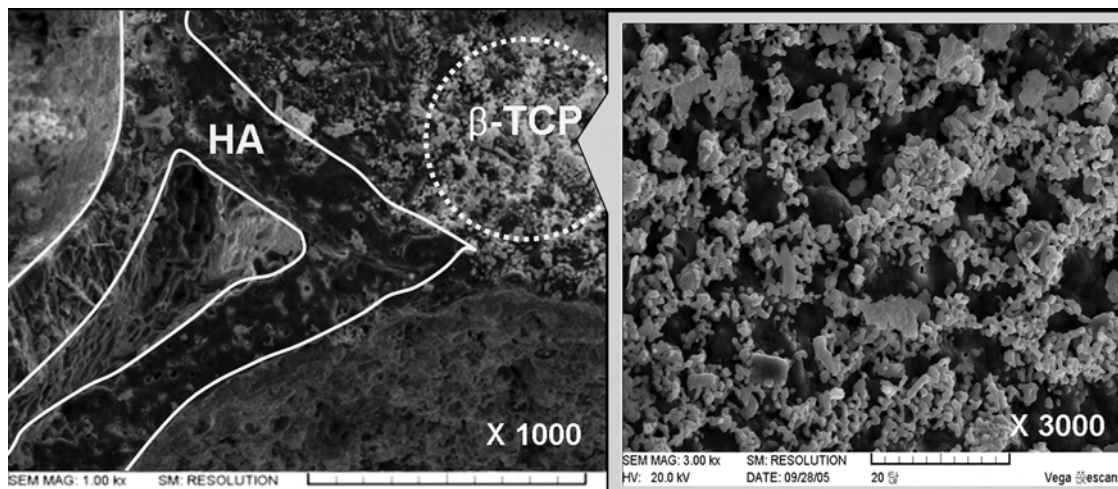
Histological evaluations were performed on biopsy of bone specimen obtained from patients with immediately placed implants at 6 months after surgery and from patients with

delayed implant placement at 4 months after surgery. Observations for the two postoperative periods were as follows:

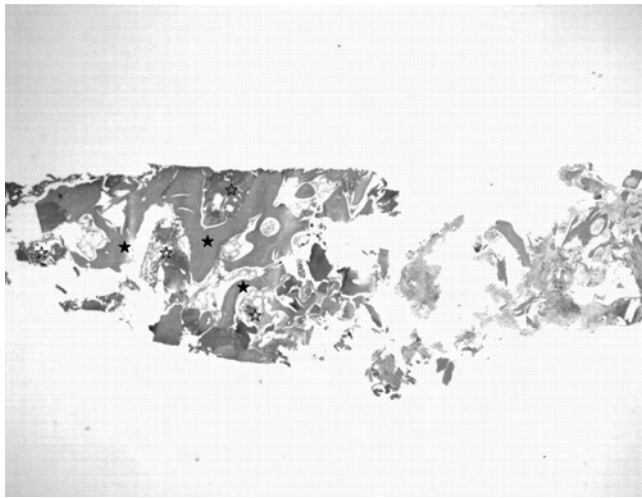
1. *4 months postoperative observations:* At a low magnification under a light microscope, a loosely organized structure was indicated for the developing trabecular bone. The trabecular bone was observed to consist of a relatively thin woven bone with foci of lamellar bone and the intervening stroma, suggesting variable degrees of fibrosis with infiltrations of chronic inflammatory cells (Figure 5). At higher magnification, the newly formed trabecular bone was observed to contain hypo- or unmineralized osteoid around the resorbing graft materials. Osteoblastic proliferation was also identified around the newly formed trabecular bone and in the osteoid (Figure 6).
2. *6 months postoperative observations:* At low magnification, a newly formed, but thickened trabecular bone around resorbing graft materials was observed (Figure 7). Higher magnification indicated a well-organized thick lamellar bone around the resorbing graft materials and with variable intervening stromal fibrosis (Figure 8).

**Histomorphometric Measurement**

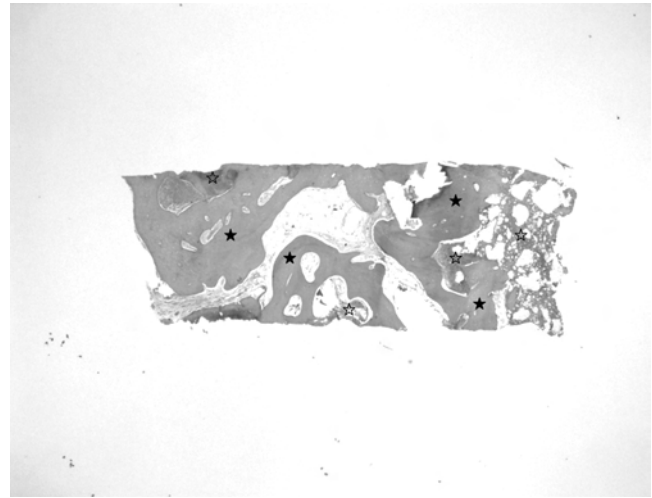
A summary of histomorphometric analysis is shown in Table II. The range of newly formed bone fraction after 4 months surgery was between 19.3 and 57.0%, with a mean percentage of 40.6%. At 6 months after surgery, the range of newly formed bone fraction was between 37.3 and 72.7%, with a mean percentage of 51.9%. Statistical analysis indicated no significant difference ( $p = 0.135$ ) in the newly formed bone fraction between the two postoperative periods. The mean LB/WB ratio after 4 months and



**Figure 4.** Cross-section view of OSTEON<sup>®</sup> (left, ×1000) and high magnification of OSTEON<sup>®</sup> surface (right, ×3000). The interconnected porous scaffold is comprised from biocompatible HA, while the surface is coated with bioresorbable β-TCP. [Color figure can be viewed in the online issue, which is available at [www.interscience.wiley.com](http://www.interscience.wiley.com).]



**Figure 5.** Newly formed trabecular bone (closed asterisks) and resorbing implant material (open asterisks) are demonstrated. H&E staining  $\times 12.5$ . [Color figure can be viewed in the online issue, which is available at [www.interscience.wiley.com](http://www.interscience.wiley.com).]



**Figure 7.** More thickened and anastomosing trabecular bone (closed asterisks) and resorbing implant material (open asterisks) are identified. H&E staining  $\times 12.5$ . [Color figure can be viewed in the online issue, which is available at [www.interscience.wiley.com](http://www.interscience.wiley.com).]

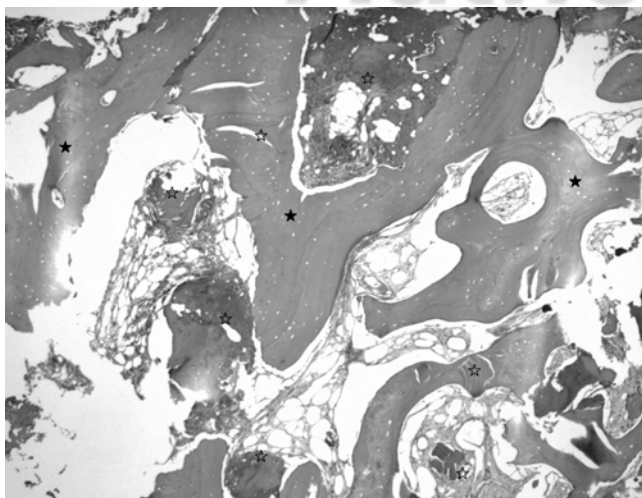
6 months surgery was 0.14 and 0.45, respectively, with significant difference observed between the two postoperative periods ( $p = 0.027$ ). Additionally, the mean NB/GM ratio after 4 months and 6 months surgery was 1.95 and 7.72, respectively, with significant difference observed between the two postoperative periods ( $p = 0.046$ ).

## DISCUSSION

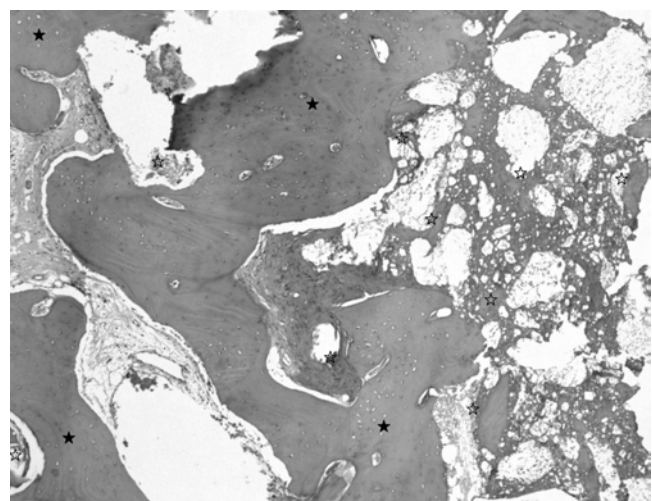
There has been no known difference in the effect of autogenous, allogenic, xenogenic, and alloplastic bone graft materials on healing process. Data on these graft materials, especially from patient studies, have been limited due to

ethical reasons. As a result, the reported use of autogenous, allogenic, xenogenic, or alloplastic bone graft materials in patients was inconclusive in demonstrating major benefits for any specific graft material.<sup>10,11</sup> Additionally, these bone graft materials are considered safe and the selection of the graft material is dependent on surgeon's preference and training. Although numerous *in vitro* and *in vivo* studies have performed to evaluate the effect of various grafting materials on healing, the efficacy and the effect of these materials on healing have to be reconfirmed through clinical trials.

Ideally, a sinus bone graft material should induce a high percentage of newly formed vital bone after graft maturation. In addition, the ideal graft material should also have



**Figure 6.** Anastomosing trabecular bone (closed asterisks) consists of woven bone and lamellar bone. New bone formation around the resorbing implant materials (open asterisks) is identified. H&E staining  $\times 40$ . [Color figure can be viewed in the online issue, which is available at [www.interscience.wiley.com](http://www.interscience.wiley.com).]



**Figure 8.** Thickened, focally lamellar trabecular bone (closed asterisks) is seen around the resorbing implant material (open asterisks). H&E staining  $\times 40$ . [Color figure can be viewed in the online issue, which is available at [www.interscience.wiley.com](http://www.interscience.wiley.com).]

AQ3 **TABLE II. Summary of the Histomorphometric Study**

NB Fraction	LB/WB Ratio	NB/GM Ratio
4-month specimens		
37.3	0.08	1.63
52.7	0.27	2.85
27.0	0.18	6.00
45.0	0.05	3.00
19.3	0.02	0.27
37.7	0.01	0.56
54.3	0.04	0.75
35.0	0.12	0.64
57.0	0.47	1.86
40.59 <sup>a</sup>	0.14 <sup>a</sup>	1.95 <sup>a</sup>
12.80 <sup>b</sup>	0.15 <sup>b</sup>	1.81 <sup>b</sup>
6-month specimens		
43.7	0.32	19.00
53.0	0.72	24.00
45.3	0.33	7.33
37.3	0.20	2.23
53.0	0.69	3.00
67.7	0.27	1.27
42.3	0.02	2.23
72.7	1.08	2.70
51.88 <sup>a</sup>	0.45 <sup>a</sup>	7.72 <sup>a</sup>
12.54 <sup>b</sup>	0.35 <sup>b</sup>	8.80 <sup>b</sup>

NB, newly-formed bone; LB/WB, lamellar bone/woven bone; NB/GM, newly-formed bone/graft material; SD, standard deviation.

<sup>a</sup> Mean.

<sup>b</sup> SD.

the ability to prevent repneumatization of the graft material. The literature has shown a wide range of different grafting materials used, with newly formed vital bone ranging from 14 to 44%.<sup>12,13</sup>

In this study, the morphology of OSTEON<sup>®</sup> was observed to be interconnected, with 77% porosity and a pore size of 300–500  $\mu\text{m}$ . This observed architecture was suggested to be similar to human cancellous bone, with the interconnected porosity and pore size capable of providing space for bone cell ingrowth. The two different commercially available OSTEON<sup>®</sup> grafting materials (one with particle size of 0.5–1.0 mm and the other with particle size of 1.0–2.0 mm) were mixed in a ratio of 1:1, hydrated, followed by mixing with 10% autogenous bone chips and stabilized with tissue adhesive. This mixture were then grafted in 17 patients and implants, either immediately or a 4 month delay placement, were performed. No significant difference in the percentage of newly formed bone fraction was observed at 4 months and 6 months after surgery. The range of newly formed bone fraction at both postoperative periods was in the range reported in the literature.<sup>12,13</sup> However, significant differences in mean LB/WB ratio and the mean NB/GM ratio were observed after 4 months and 6 months surgery. As confirmed by observations using the SEM, bone biopsy indicated more lamellar bone after 6 months surgery as compared to biopsy obtained after 4 months surgery. Significant difference in the LB/WB ratio as well as the SEM suggested the progression of bony

maturity and normal bony healing process. The significant increase in NB/GM ratio after 6 months surgery also suggested the increased accumulation of newly formed bone and resorption of graft materials during healing. Additionally, differences in NB/BM and LB/WB ratios between the two groups may also be attributable to the amount of time that the implant is present during healing. In general, these observations suggested that OSTEON<sup>®</sup> is suitable for use in sinus graft application that would allow normal healing.

Although favorable observations on OSTEON<sup>®</sup> is indicated in this short-term study, this study does not compare OSTEON<sup>®</sup> to other commercially available alloplastic materials. Further studies should be followed with a longer term evaluation for the confirmation of the effect of OSTEON<sup>®</sup> as well as to include other commercially available alloplastic materials. Additionally, since this study includes a small percentage of autografts mixed in with the allografts, it is not known if healing may be attributed to the presence of autografts present. As such, the ratio of autografts to allografts on healing may need to or may have to be further investigated in the future. However, like other commercially available xenogenic and alloplastic bone grafting materials, OSTEON<sup>®</sup> contains 70% HA and 30%  $\beta$ -TCP. As such, like most commercially available xenogenic and alloplastic bone grafting materials, bone healing during sinus graft applications is induced via osteoconduction. The host osteoprogenitor and angiogenic cells use the graft as a scaffold to generate new bone across the defect. As the host cells differentiate and mature within the graft, a functional skeletal network develops and replaces the graft through a “creeping substitution” process.<sup>14,15</sup> The reported survival rates for grafted xenografts and alloplastic materials are equivalent or better than the survival rates for grafted autogenous materials.<sup>16–20</sup> Additionally, these studies also indicated that the nonresorbed residual graft materials did not hinder osseointegration but significantly increase the bone density.<sup>16–20</sup>

In this study, two types of implants were used. Ideally, it is optimum to use the same implant system to minimize inclusion of confounding factors. However, since we are dealing with patients' bone quality that we have very little control, we have to use the different implant systems that include consideration of patients' condition such as the bony quality for the initial stabilization of implant fixtures as well as the selection of final prosthesis. Additionally, since this study was designed to evaluate the usefulness of new alloplastic material as a sinus graft material, the biopsy specimen was collected from lateral sinus using trephine, not at the implant-bone interface. As such, although implant surface and design has a huge influence over the bone quality and osseointegration at the bone-implant interface, the implant system has very little influence on bone quality in the graft material placed in the lateral sinus.

Using 1:1 mixture of xenograft (Bio-Oss<sup>®</sup>) and allograft (Interpore 200<sup>®</sup>), 1:3 mixture of autogenous bone from iliac crest and Interpore 200<sup>®</sup>, and 1:1 mixture of autogenous

bone from mandibular chin bone and Interpore 200<sup>®</sup>, Hurzeler et al.<sup>21</sup> grafted these materials in 133 patients followed by either immediate implant placements (235 implants) or delayed implant placements (105 implants). At 5 years after installing the metal ceramic prosthesis, only four implants failed, and the success rate was 98.8% for this study. It was also reported that new bone and immature connective tissue infiltrated the three sides of the raised sinus wall (mesial, periapical, distal), with the distal sides of the load-bearing wall consisting of 27.7% new bone, 31.9% connective tissue and hydrophilic lipid, and 40.4% graft particles. In patients with delayed implant placement, a more direct binding of new bone to the implant was indicated when compared to the patients with immediate implant placement. Additionally, Hurzeler et al.<sup>21</sup> also confirmed that implant loading enhanced osseointegration at the implant surface and that the porous HA in Bio-Oss<sup>®</sup> and Interpore 200<sup>®</sup> attributed to the increase in bone formation and bone-implant contact.

In another study by Smiler and Holmes,<sup>22</sup> sinus grafting of alloplastic graft materials containing porous HA on four patients resulted in the presence of 23% new bone formation, 45% connective tissue, and 32% porous HA after 4 to 5 months of healing at the graft site. In a similar study, other investigators observed the presence of 20% new bone, 47% connective tissue, and 33% graft materials.<sup>23</sup> Other studies reported an implant success of 93.7% during the 17 month period after placing 203 HA-coated implants (IMZ) following sinus graft with porous HA, and concluded that alloplastic graft materials containing porous HA was suitable for the sinus graft application.<sup>24</sup>

Using alloplastic grafting material containing 100%  $\beta$ -TCP and compared to the use of autologously harvested chin bone in 10 patients, Zijdeveld et al.<sup>25</sup> reported no significant histological difference between the two graft materials after 6 months, with no implant failure after 1 year. In comparing the use of allograft (HA and collagen) to xenograft (Bio-Oss<sup>®</sup>) for sinus graft application in patients for 4 years, implant survival rate was reported to be 97%.<sup>26</sup> It was suggested that as nonresorbing materials, the alloplastic and xenogenic materials used in this study provided adequate initial stability and were useful graft materials. Anorganic bovine bone in Bio-Oss<sup>®</sup> was reported to undergo no more than 0.5–1.0 mm resorption after 4 years and was radio-opaque on X-ray images. Other study reported the presence of 14.7% new bone formation, 29.7% residual xenograft materials, and 56.0% soft tissue at 6 months after sinus graft.<sup>19</sup> Similarly, in another study, the use of Bio-Oss<sup>®</sup> for sinus graft after 6–8 months surgery resulted in the presence of 45–50% new bone formation and 25–30% remaining graft materials, whereas the use of  $\beta$ -TCP for sinus graft after 6–8 months surgery resulted in the presence of 50–55% new bone formation and 15–20% remaining graft materials.<sup>27</sup>

In comparing xenografts (Bio-Oss<sup>®</sup>) to autografts, Schlegel et al.<sup>28</sup> reported a volumetric decrease for Bio-Oss<sup>®</sup> and autograft of 14.6 and 3.8%, respectively after 90

days surgery. Additionally, at 180 days postoperatively, the volumetric decrease of the grafts was 16.5 and 39.8% for Bio-Oss<sup>®</sup> and autograft, respectively. It was suggested that the nonresorbing Bio-Oss<sup>®</sup> prevented undesirable initial degradation and was beneficial for remodeling at the defect site. Guidelines for the use of xenogenic bone have been proposed.<sup>13</sup> It has been recommended that a 1:1 mixture of xenogenic materials with 0.25–1.0 mm particle size and 1.0–2.0 mm particle size be hydrated in physiological saline. Caution has to be taken on the mesial side of the sinus wall as the graft material is pressed against it. Too much pressure against the mesial side of the sinus wall causes small particles to obstruct new blood vessel formation and delayed resorbing large particles to retard the formation of new bone.

## SUMMARY AND CONCLUSION

In this study, OSTEON<sup>®</sup>, a new alloplastic material was clinically evaluated as a sinus graft material. The morphology of OSTEON<sup>®</sup> was observed to be interconnected, with 77% porosity and a pore size of 300–500  $\mu$ m. No significant difference in the percentage of newly formed bone fraction was observed at 4 months and 6 months after grafting in 17 patients. However, significant differences in mean LB/WB ratio and the mean NB/GM ratio were observed after 4 months and 6 months surgery. As confirmed by observations using the SEM, bone biopsy indicated more lamellar bone after 6 months surgery as compared to biopsy obtained after 4 months surgery. In this short-term study, it was concluded that OSTEON<sup>®</sup> is suitable for use in sinus graft application since desirable time-dependent healing was demonstrated.

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