The Influence of Particulated Autogenous Bone on the Early Volume Stability of Maxillary Sinus Grafts with Biphasic Calcium Phosphate: A Randomized Clinical Trial

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ABSTRACT

Background: It is unknown whether autogenous bone impacts the grafts' stability when added to biphasic calcium phosphate (BCP) within the first six months of maxillary sinus augmentation (MSA).

Purpose: To investigate the volume stability of BCP alone and in mixtures with autogenous bone for MSA.

Materials and Methods: Bilateral maxillary sinus augmentation was performed in eight patients in a split-mouth design using BCP at the control site and adding particulated autologous bone at the test site (BCPAB). Based on 16 computed tomography (CT) the volumetric changes were evaluated using the Voxim® software (version 6.3, IVS Technology GmbH, Chemnitz, Germany) by comparing the graft volumes within two weeks of the sinus lift procedure with CT data obtained six months later. Changes of the graft volumes were calculated and statistically significant differences between the two groups were evaluated.

Results: Overall, the volumes decreased by 15% for BCP and 18% for BCPAB. The time-dependent decreases were statistically significant in both groups. Differences between the two groups were not statistically significant ($p = .065$).

Conclusions: An evident decrease of graft volume over the first 6 months of healing has to be expected irrespective of bone graft composite. Autogenous bone seems to have no evident impact on the volume decrease when added to BCP.

KEY WORDS: bone replacement materials, maxillary sinus floor augmentation, volume stability

INTRODUCTION

Maxillary sinus augmentation (MSA) as described by Boyne & James can successfully be performed before implant placement to graft the severe atrophic posterior maxilla with high predictability.[1–3] Different materials may be used for this purpose. Despite the existence of reviews and meta-analyses on this topic, the most favorable material is still a matter of controversy.[4,5] Autogenous bone still represents the golden standard for grafting material due to osteoconductive and osteoinductive properties.[6] However, grafting autogenous bone is associated with donor site morbidity, thus demanding alternatives, such as bone substitute materials.[7,8] Bone substitute materials or combinations with bone have successfully been used for maxillary sinus floor augmentation with outcomes comparative to autogenous bone.[5,6,9] Irrespective of the material used, the main issue of MSA is sufficient graft volume, allowing implant surface to be completely covered by hard tissue over time after insertion and osseointegration. The amount of grafting material required for this purpose varies depending on sinus anatomy, residual maxillary bone, and planned implant dimension.[10] Structural changes such as collapse of grafted particles, resorption, and

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bone formation may impact the graft volumes during healing. Furthermore, volume change over time may be influenced by the type of material used for grafting purposes. Nonresorbable or slowly resorbable bone substitute materials may positively influence graft stability. In contrast, autogenous bone may reduce the volume stability due to advanced resorption.[11] Apparently, there is only a little information on the time-dependent three-dimensional stability of various bone graft materials and composites used for MSA. Biphasic calcium phosphate (BCP) was successfully used for MSA and its clinical suitability has been proved in several clinical studies.[12–17] It consists of hydroxyapatite (HA) and β-tricalcium phosphate (TCP) in a 60:40 ratio, thus representing a composition of both nonresorbable and resorbable nature. It was recently shown that adding BCP to autogenous bone results in a comparable volume of newly formed bone when compared to autogenous bone alone.[16] However, the volume stability of BCP and BCP + particulated autogenous bone (BCPAB) in the first six months after MSA is unknown.

The aim of the present study was to evaluate the effect of adding particulated autogenous bone to BCP on the volume stability of the graft over a period of six months. The hypothesis is that particulated autogenous bone has a positive influence on the volume stability of BCP grafts when used for MSA.

MATERIAL AND METHODS

The study was approved by the ethics committee of the Medical University of Graz (EK-Nr.18 –213 ex 06/07) and corresponds with a recently published investigation of the same group.

Computer tomography (CT) data of eight systemically healthy patients (seven female with a mean age of 47.7 years, SD 11.7 and one male aged 58 years), who consecutively presented for bilateral MSA between 2007 and 2010 were included. The present evaluation is based on 16 augmentation sites. The prospective cohort was composed of augmented maxillary sinuses examined radiographically by taking CT scans within two weeks of MSA (scan I) and after six months (scan II) before implant placement, making a total of 32 sinus volumes. All scans ($n = 16$) were taken at the Department of Radiology, Medical University of Graz.

Preoperative bone height was <3 mm in all sites and therefore a staged surgical approach was necessary in all cases. MSA was performed with a modified lateral approach as described by Kent et al. and Lorenzoni et al.[18,19] Patients with severe systemic diseases, receiving bisphosphonate or corticosteroid medication, with a history of radiotherapy in the head and neck region and heavy smokers (>10 cigarettes/day) were excluded.

Following a split-mouth design Straumann® BoneCeramic (Institut Straumann AG, Basel, Switzerland) was used as BCP in the MSA on one side (control site). The other side was grafted with a homogenous composite of BCP (Straumann BoneCeramic) and particulated autogenous bone harvested from the linea obliqua in a relation of approximately 1:1 (test site) (BCPAB). A collagen membrane (Bio-Gide®, Geistlich Pharma AG, Wolhusen, Switzerland) was fixed with two titanium pins to cover the graft. The grafting procedure was performed by one surgeon in order to reduce bias. In two cases (one in each group) a perforation of the membrane occurred. These were closed applying a resorbable membrane (Bio-Gide®, Geistlich Pharma AG, Wolhusen, Switzerland). The individual distribution to the test and control site respectively was based on randomization. This was carried out by a Randomizer for Clinical Trials at the Institute for Medical Informatics, Statistics and Documentation of the Medical University of Graz.

Both the postoperative maxillary CT scans performed after two weeks (scans I) and the follow-up CT scans after six months (scans II) (Lightspeed QX/i, General Electric Healthcare, Waukesha, WI, USA) were performed at identical settings for each patient for the follow-up. Radiation dose was individually adjusted according to the patients' physiognomy and anatomy. The CT-data were transformed into Digital Imaging and Communication in Medicine (DICOM) format with a slice thickness of 1.25 mm. The transformed data were loaded into the Voxim® software device (version 6.3, IVS Technology GmbH, Chemnitz, Germany). For volume measurement, the surfaces of the grafted materials in the maxillary sinuses were determined and segmented manually by scrolling through each axial, coronal and transverse slice as already used in another study (Figure 1).[20] The software automatically calculated the resulting volumes in milliliters (mL). Measurements were performed blindfold and twice for each site by an experienced oral surgeon, with an interval of four weeks between the two measurements.

All data were evaluated using SPSS® software (SPSS Statistics 17.0, Chicago, IL, USA) for Windows.

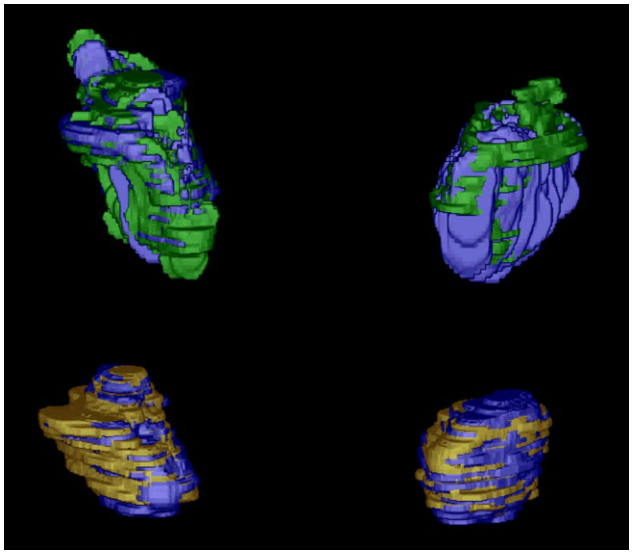

Figure 1 Representative case of a three-dimensional reconstruction of measured volumes at baseline (upper volumes) and 6 months later (lower volumes) in one patient with biphasic calcium phosphate (BCP) + particulated autogenous bone on the right side and BCP on the left side. The blue and green color indicates differences between both measurements resulting in high intraclass correlation coefficient-values.

The intrarater reliability was determined by the intraclass correlation coefficient (ICC) between the two measurements. Additional descriptive statistics of the difference between the measurements were calculated. Due to a high correlation, mean values of both measurements were used for all other statistical evaluations.

A descriptive analysis was performed. Normal distribution of data was proofed by means of a one-sample Kolmogorov–Smirnov test for both groups. Significant differences between the volumes at both time points (scans I and scans II) were evaluated for each single group with the *t*-test for dependent samples. Significance was set at $p < .05$.

Significant differences between the two sites of each group were additionally determined with the *t*-test for dependent data. Finally, volume differences between the two time points (scans I and scans II) were calculated in percent and the *t*-test for independent data was performed to evaluate significant differences between the percentage volume changes of the two groups. A bivariate scattergram was created with SPSS software for Windows.

RESULTS

The ICC revealed high intrarater correlations (range: 0.925–0.991 ICC) between the two measurements. The mean difference between the two measurements was 0.15 mL (SD 0.14).

Graft volumes showed high variances directly after grafting (scan I) with mean volumes ranging from 2.34 mL (median: 2.13 mL) for BCP to 2.86 mL (median: 2.95 mL) for BCPAB (Figure 2). The minimum was 1.38 mL for BCP and the maximum 3.75 mL for BCPAB (Table 1). After six months of healing, graft volumes decreased in all groups, ranging from a final mean volume of 1.91 mL (median: 1.90 mL) for BCP to 2.32 mL (median: 2.38 mL) for BCPAB (Table 1). The lowest measurement was 1.24 mL (BCPAB) and the highest 3.09 mL (BCPAB).

The mean volume decrease varied between 0.33 mL for BCP and 0.54 mL for BCPAB. The volume decreases between the two time points were highly significant for all groups ($p < .001$).

A comparison of the two grafts within each group showed no significant differences in decrease of volume ($p = .065$).

The percentage volume differences between the two time points ranged from 6.6% (BCP) to 29.6% for BCPAB (Table 2). An analysis of the mean percentage differences showed only slight differences between the two groups, with values ranging from 15.2% (BCP) to 18.0% (BCPAB) of decreased volume (Table 2). Differences between the two groups at either time point were not significant (t1/t2: $p = .061$/$p = .118$).

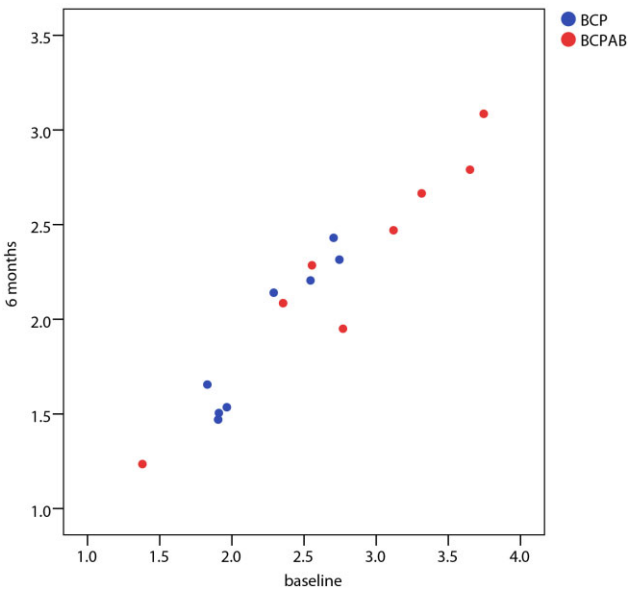

Figure 2 Scatter plots showing the different volumes (in mL) at both points in time (T1 = after Sinus lift; T2 = 6 months later).

TABLE 1 Measured Volumes for Both Groups and Time-Points

	T1					T2				
	Minimum	Maximum	Median	Mean	SD	Minimum	Maximum	Median	Mean	SD
BCP	1.83	2.75	2.13	2.34	0.38	1.47	2.43	1.90	1.91	0.41
BCPAB	1.38	3.75	2.95	2.86	0.77	1.24	3.09	2.38	2.32	0.57

BCP = biphasic calcium phosphate; BCPAB = BCP + particulated autogenous bone.

DISCUSSION

The present study revealed a statistically significant decrease in graft volume six months after MSA with BCP, irrespective of the presence or absence of autogenous bone. With regard to the hypothesis of the present study, it may be stated that particulated autogenous bone does not improve the volume stability of the graft within the first six months of healing. It can also be stated that the respective bone substitute material has no negative effect on volume stability. These results confirm findings of a similar study performed by the same working group in which bone marrow aspirates (BMA) and concentrates (BMAC) were added to deproteinized bovine bone mineral (DBBM) in a split-mouth design.[20] This study showed that neither BMA nor BMAC improved the volume stability of the grafts after six months of healing.[21] Obviously, the grafts' volume stability seems to be not so much primarily dependent on the specific (bone-substitute) material but may be influenced to a greater extent by sinus anatomy and general local factors.[20] In this context, it was recently shown that there is a positive correlation between the amount of residual bone and time-dependent percentage volume decrease of maxillary sinus grafts.[21] Unfortunately, the amount of residual bone was not assessed in the present study. Comparing our data to the literature is difficult due to the high amount of bias and the generally small number of publications on three-dimensional analyses of graft volume changes. To our knowledge, there are only four studies using three-dimensional-imaging techniques (CT) to measure time-dependent graft resorption after MSA: Wanschitz et al. investigated the volumetric changes of algae-derived hydroxyapatite substitute material (Algipore®, Dentsply Implants Manufacturing GmbH, Mannheim, Germany) and autologous bone; Sbordone et al. investigated the resorption of autogenous bony blocks and particulated autogenous bone; Arasawa et al. used crunched autologous bone. In the latter study, only one case of bilateral maxillary sinus augmentation was included in addition to the 10 unilateral sinus grafts.[15,22–24] The studies of Tetsch et al. (2010), Hatano et al. and Zijderveld et al., who used DBBM in addition to their own results, as well as the study of Riachi et al. are based on two-dimensional measurements from panoramic radiographies.[9,23–26] Prospective randomized studies using a split-mouth design with bilateral sinus augmentation to measure time-dependent graft resorption three-dimensionally have, to date, not been published for any material except DBBM + BMA and BMAC. However, taking all bias into consideration, the percentage decrease of volume in both groups – 15% in the control group and 18% in the test group – lies within the range of the above three-dimensional-based studies, with 14% for algae-derived hydroxyapatite, 15.2% for DBBM + BMA, 21.5% for DBBM + BMAC, 25% for autogenous bone and 26% for DBBM alone.[20–22,27]

TABLE 2 Volume Decreases in % for Both Groups

	Minimum	Maximum	Median	Mean	SD
BCP	6.6	22.8	14.5	15.2	6.3
BCPAB	10.5	29.6	18.6	18.0	6.9

BCP = biphasic calcium phosphate; BCPAB = BCP + particulated autogenous bone.

To conclude, and keeping in mind the limited scope of the present small-population study, a significant time-dependent volume decrease can be expected when BCP is used for MSA. Resorption seems not to be biased by the presence of autogenous bone and BCP seems to show a resorption comparative to other established materials. An overaugmentation of approximately 15 to 20% may be recommendable in two-stage MSA if BCP is used with or without autogenous particulated bone. Further studies are needed to evaluate the influence of local anatomy on the time-dependent volume decrease and to confirm the findings of the present study. The data of the present study

might be used to perform power calculations for future studies.

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