

Comparative Clinical, Radiographic and Histomorphometrical Assessment Between Two Different Xenografts in The Maxillary Sinus Floor Augmentation During Dental Implants Procedure

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Abstract

Aim and Objective: The objective of the study was to compare clinical, radiographic, and histomorphometrically parameters of maxillary sinus lift using Lumina-Bone Porous[®] against those of Bio-Oss[®] in a split-mouth model through the sinus lift technique.

Materials and Methods: A total of 83 patients underwent implant dentistry program were included in the study. 1–2 mm granules of Bio-Oss[®] Large (BO cohort; n = 41) or Lumina-Bone Porous[®] (LB cohort; n = 42) was used for the sinus lift technique. The clinical, radiographic, and histomorphometrically parameters were collected and evaluated.

Results: Six-months after sinus lift the bone ridge heights were 9.89 ± 2.11 mm and 9.31 ± 2.23 mm for BO and LB cohorts ($p = 0.228$). The rate of survival of implants was the same between both cohorts (100 % vs. 93 %, $p = 0.241$). There was no statistical difference reported between BO and LB cohorts for histomorphometrically evaluation ($p > 0.05$ for all parameters).

Conclusion: Both Lumina-Bone Porous[®] and Bio-Oss[®] Large can be used for reconstructive procedures in sinus lift.

Keywords: Bio-Oss[®]; Dental implant; Lumina-Bone Porous[®]; Sinus lift procedure; Xenograft.

Introduction

Dental implants are use as the 'gold standard' process to replace the missing teeth and further, to support the dental prostheses, to get aesthetic view, and proper functioning of the teeth [1]. The posterior part of the maxilla, the loss of alveolar bone height, and lower density of maxillary sinus region has created a lot of issues for oral surgeons during implant surgeries [2]. The lateral window

technique has been generally adopted approach for the augmentation purposes [3].

Sinus lift surgical technique increases the height of residual bone in the posterior maxilla through the reposition of the maxillary sinus floor towards upward direction and creating bone height that to accommodate dental implant(s) properly [4]. Alternatively surgical technique could be performed for implants for augmented directions, zygomatic implants, and 4-8 mm short implants [2].

Due to osteoinductive, osteoconductive, and osteogenic properties of autogenous bone, it has been used preferred material for implant [5] but it has limited availability at donor site and required more time for surgery [6]. Numbers of bone substitutes made from natural biomaterials and xenograft with similar collagen composition and bone architecture made from bovine or swine available [7] that are safe and biocompatible [8]. Histomorphometry parameters for the grafted sinus are not correlated to survival rate of the implants but it is a measuring tool to assess the materials of the graft [9].

There are several xenografts available in market

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Funding support: This study was supported by National Natural Science Foundation of China 81771117

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for clinical practice. They might have similar origin but may act differently in different requirements. Therefore, it has been necessary to analyze clinical, radiographic, and histomorphometrically parameters among them [1].

Bio-Oss[®] has osteoconductive property and generally used for sinus lift procedures [10] but Lumina-Bone Porous[®] is available at comparatively low cost and prepared from bovine inorganic bones [11]. It has been manufactured from sinter-free process and chemically sterilized. The chemical sterilization maintains collagen chain and provides 75 % porosity of the surface of the particles that improves the osteoconductive property [1].

The objective of the retrospective study was to compare clinical, radiographic, and histomorphometrically parameters from maxillary sinus lift of Lumina-Bone Porous[®] against those of Bio-Oss[®] in a split-mouth model through the sinus lift technique.

Materials and Methods

Ethics approval and consent to participate

The designed protocol (GMUCL151420 dated July 20, 2020) of the established study was approved by the institutional review board. The study adhering to the law of China and V2008 Declarations of Helsinki. All participating patients signed an informed consent form regarding treatment, pathology, and publication of the study during hospitalization.

Study population

Patients underwent implant dentistry program were included in the study. Patients with compromised general health were excluded from the study.

Sample size calculation

A power calculation of 80 % ($\beta = 0.1$) and considering type I error 5 % ($\alpha = 0.05$) at 95 % of confidence level, the sample size was found minimum 80 in each cohort [1].

Cohorts

1–2 mm granules of Bio-Oss[®] Large (Geistlich Pharma AG, Wolhusen, Switzerland) was used in a total of 41 patients under the sinus lift technique (BO cohort). 1–2 mm granules of Lumina-Bone Porous[®] (Critéria Ind. e Com. de Produtos Mediciniais e Odontológicos Ltda) was used in a total of 42 patients under the sinus lift technique (LB cohort).

Surgical procedure for sinus lift

The maxillary sinus floor was augmented bilateral method [12]. Surgery was performed under local anesthesia (2 % lidocaine with adrenaline, Xylocaine 2% with 1:200,000 Adrenaline, AstraZeneca PLC, Cambridge, United Kingdom) by the same surgeon. 1 g Amoxicillin plus clavulanic acid (Augmentin[®], Pfizer Inc., New York, NY, USA) before operation and 625 mg thrice in a day for 7 days after operation was given for prophylactic purposes. The patients were used chlorhexidine (Hexidine, Johnson & Johnson Pvt. Ltd., New Brunswick, New Jersey, USA) for mouth rinse 1 min prior surgery and twice in a day for 7 days after surgery.

The full-thickness flaps were elevated, through a round diamond bur under irrigation (normal saline, Baxter Inc., IL, USA) to create a bone window. Schneiderian membrane was elevated and the bone window was pushed inside the cavity. The material was added to fill the gap. The gap between maxillary alveolar process and sinus floor was filled with particles of bone xenograft. Patients were examined in the followed up at 1-week, 2-week, 1-month, and 3-month after operations. The implantation was made 6-months after sinus floor augmentation.

Radiographic analysis

Cone beam computed tomography (GE Healthcare, Chicago, Illinois, USA) was performed 6-months after sinus lift for morphology and residual alveolar bone height.

Dental implant surgery and biopsy retrieval

Under local anesthesia (2 % lidocaine with adrenaline) biopsy samples were collected 6-months after sinus lift. Histology and histomorphometry analysis were performed from biopsy samples.

Statistical analysis

SPSS v25.0 IBM Corporation, Armonk, NY, USA was used for statistical analysis purposes. Constant data demonstrated frequency (percentage) and continuous data demonstrated mean \pm SD. Two tailed unpaired t-test for continuous data and Fisher's exact test for constant data were performed for statistical analysis. A *p*-value less than 0.05 was considered significant.

From 15 August 2018 to 15 January 2020, a total of 83 patients underwent implant dentistry program at the parent hospital and the referring hospitals. Among them three patients with compromised general health (American Society of Anesthesiology III or IV), two patients had chronic

sinusitis, and one patient had drug abuse. Therefore, data of these patients were excluded from the study. Data of 212 patients underwent implant dentistry were retrospectively collected

and analyzed (Fig. 1).

Results

Study population

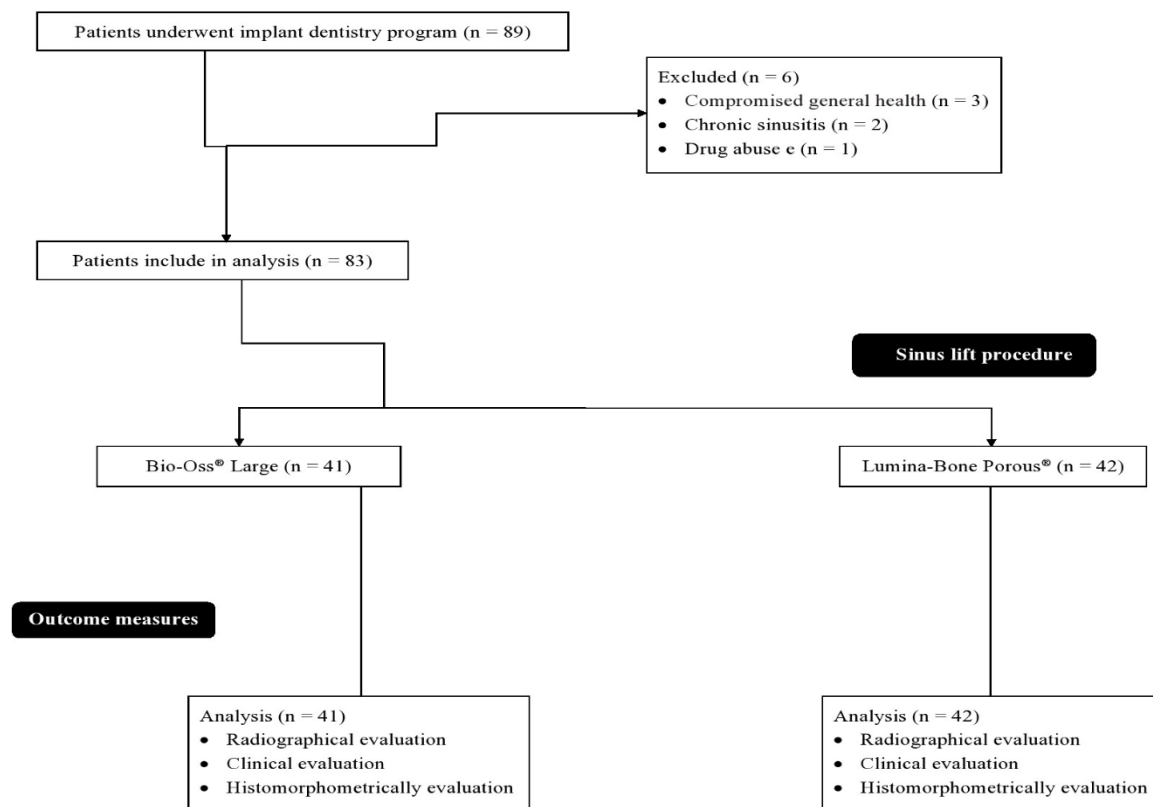


Figure 1. Flow diagram of the study.

Clinical and demographical conditions

Included patients have 35–65 years of age. The

other Clinical and demographical conditions of included patients are reported in Table 1.

Table 1. Clinical and demographical conditions of included patients

Parameters	Cohorts		Comparisons between cohorts
	BO	LB	
Numbers of patients included	41	42	<i>p</i> -value
Age (years)	Minimum	35	0.292
	Maximum	65	
	Mean ± SD	42.15±4.15 43.52±7.18	
Sex	Male	20(49) 18(43)	0.662
	Female	21(51) 24(57)	
Ethnicity	Han Chinese	36(88) 35(84)	0.818
	Mongolian	4(10) 6(14)	
	Tibetan	1(2) 1(2)	
Hypertension	1(2)	1(2)	0.998
Hypotension	1(2)	2(5)	0.997
Depression	1(2)	1(2)	0.998
Resident bone ridge height in the deepest portion of maxillary sinuses floor prior to sinus grafting (mm)	2.95±0.88	2.72±0.82	0.221

Constant data demonstrated frequency (percentage) and continuous data demonstrated mean ± SD.

Radiographical evaluation

Resident bone ridge height in the deepest portion of maxillary sinuses floor prior to sinus grafting were 2.95 ± 0.88 mm and 2.72 ± 0.82 mm

for BO and LB cohort ($p = 0.221$). Six-months after sinus lift those were 9.89 ± 2.11 mm and 9.31 ± 2.23 mm ($p = 0.228$, Fig. 2).

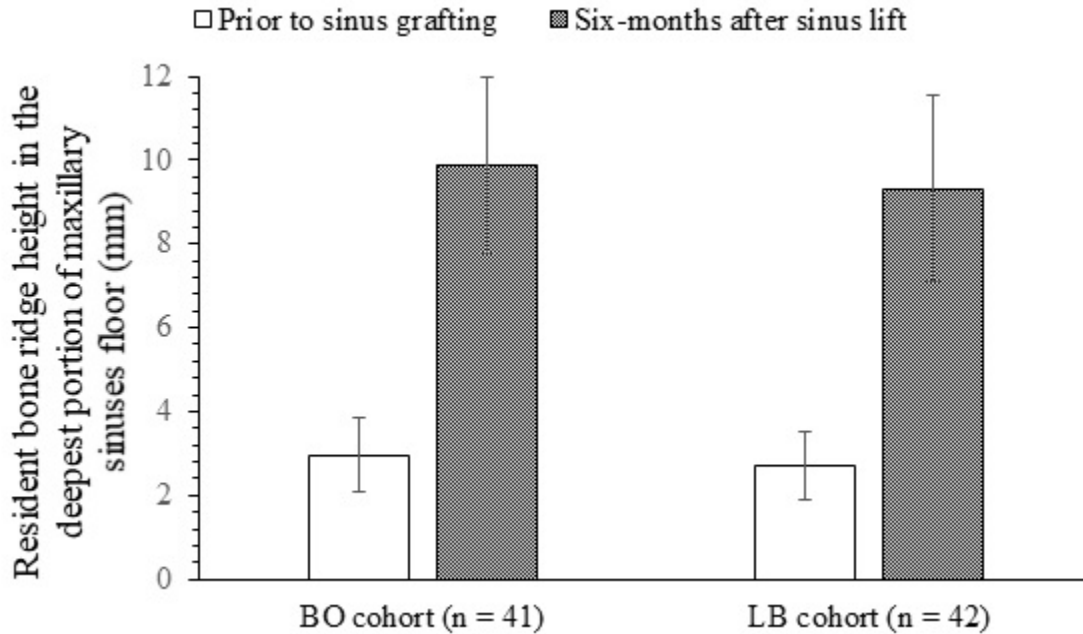


Figure 2. Resident bone ridge height analysis. Data demonstrated mean \pm SD.

Clinical evaluation

The survival rate of implants was the same between both cohorts ($p = 0.241$, Table 2). None of patients had postoperative complications.

Table 2. Implants survival

	Cohorts		Total
	BO	LB	
Implant installed	41	42	83
Implant loss	00	03	03
Survival	100%	93%	96%

Data demonstrated frequency.

Histomorphometrically evaluation

There was no statistical difference reported between BO and LB cohorts for histomorphometrically evaluation (Table 3).

Table 3. Histomorphometrically evaluation

Histological parameters	Cohorts		Comparisons between cohorts
	BO	LB	
Numbers of patients included	41	42	<i>p</i> -value
Newly formed bone	19.15 ± 4.15	20.12 ± 4.59	0.316
Non-resorbed material	18.15 ± 7.15	19.13 ± 6.45	0.514
The connective tissue	55.14 ± 8.17	57.42 ± 9.15	0.235
The total bone	38.15 ± 5.14	39.41 ± 6.45	0.329

Data demonstrated mean \pm SD.

Discussion

There was no statistical difference for bone height 6-months after sinus lift ($p = 0.228$) between both cohorts. The results of the study were agreed with randomized prospective trials [1, 8]. The study concluded that Lumina-Bone Porous® and Bio-Oss® Large can be used for reconstructive procedures in sinus lift.

The study reported 93 % implant survival for Lumina-Bone Porous®. The results of the study were agreed with randomized prospective [1] and prospective non-randomized [13] trials and clinical research [14]. Lumina-Bone Porous® does not support sufficient amount of new bone formation.

Lumina-Bone Porous® exhibited similar

histomorphometrically evaluation to Bio-Oss® The results of the study were agreed with randomized prospective trial [1]. This is because Lumina-Bone Porous® and Bio-Oss® have the same particle size (1–2 mm) and the condition of biomaterial substitution is related to particle size materials [15]. Lumina-Bone Porous® can be used as alternate of Bio-Oss®.

In the limitations of the study, for example, retrospective analysis and lack of randomized trial. The right and left sinus difference analysis did not report. Future studies with more patients correlating different properties in maxillary sinus floor augmentation procedure like long-term effects on sinus bone grafts and dental implants are needed.

Conclusions

Both Lumina-Bone Porous® and Bio-Oss® Large can be used for reconstructive procedures in sinus lift.

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