The Maxillary Sinus Floor Elevation Using a Poly-L-Lactic Acid Device to Create Space Without Bone Graft: Case Series Study of Five Patients

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Maxillary sinus floor elevation using autologous or alloplastic bone grafting is often performed for implant treatment of maxillary molars; however, issues related to the donor site and complications such as infection have been reported. We performed maxillary sinus floor elevation using poly-L-lactic acid (PLLA) as a space-making material in patients with an insufficient bone mass (<3 mm) for simultaneous implantation between the alveolar crest and floor of the maxillary sinus and evaluated the newly formed bone. Conventional antrostomy of the maxillary sinus from the lateral wall was performed, and PLLA was placed on the floor of the maxillary sinus after elevating the sinus membrane. Six months after surgery, the bone mass and density were measured using quantitative computed tomography, and histological evaluation was performed. No complications were recorded. Radiological findings showed a bone-like radiopaque appearance, and histological examination revealed new bone formation in all patients. In cases with insufficient bone mass prior to simultaneous implant placement, this method of maxillary sinus augmentation allows for sufficient bone augmentation without bone grafting.

Key Words: without bone graft, bone mineral density, maxillary sinus floor elevation, poly-L-lactic acid, maxillary molar implant

INTRODUCTION

Maxillary sinus floor elevation using bone replacement methods—such as autogenous or alloplastic bone grafting or combinations thereof—is required during implant treatment of the maxillary molars because of expansion of the maxillary sinus and resorption of the alveolar bone associated with the loss of teeth.

Maxillary sinus floor elevation using the lateral-window technique was first reported by Tatum in 1977 and first published in a scientific paper by Boyne and James1 in 1980. Despite great advances in bone regeneration techniques, we have not been able to eliminate the need for autogenous and alloplastic grafting surgeries. The types of bone replacement materials currently used include (1) autogenous bone grafts from the oral cavity or iliac bone; (2) allograft bones collected from cadavers and subjected to freeze-drying treatment, such as demineralized freeze-dried bone allografts; (3) xenogeneic bones derived from bovine bones and seaweed; and (4) artificially created alloplastic bone grafts, such as synthetic hydroxyapatite (HA) and beta-tricalcium phosphate (β-TCP).

In 1993, Boyne et al1 performed sinus floor elevation in monkeys without the use of bone graft materials and identified the formation of a cancellous bone-like tissue. In 2004, Lundgren et al2 reported that the creation of space under the maxillary sinus membrane alone was sufficient to induce the formation of new bone without the use of graft materials, and in 2007, Hatano et al3 reported that after an observation period of 12–34 months to allow the space under the maxillary sinus membrane to fill with venous blood, the implant survival rate was 92.9%. Cricchio et al4 reported in 2011 that the implant survival rate after an observation period of 1–6 years was 98.7%.

Bone grafts in the maxilla and mandible have a high success rate, but the morbidity associated with harvest sites makes the concept of “graftless” augmentation appealing. While these techniques have yielded relatively stable results, the simultaneous insertion of implants is required to make space. Radiological or histopathological evaluation of the newly formed bone resulting from this method in humans has proved insufficient for the following reasons: (1) This method is contraindicated when the bone thickness is insufficient to...
achieve primary stability; (2) issues such as metal artifacts resulting simultaneous implantation have made it difficult to perform three-dimensional radiological evaluation, as reported in previous studies; (3) only two-dimensional evaluation using periapical and panoramic radiographs have been performed; and (4) no quantitative evaluation of bone density has been conducted thus far.

In this study, we report our histological and radiological study of newly formed bone after performing maxillary sinus floor elevation using a lateral-window technique. This technique employed a poly-L-lactic acid (PLLA) device to create space in patients in whom simultaneous implant placement would have been difficult because of insufficient bone mass between the alveolar crest and the floor of the maxillary sinus.

**Materials and Methods**

This study was approved by the Ethics Committee of the hospital attached to the Faculty of Dentistry at Tokyo Medical and Dental University (approval number 406).

The study group included 5 healthy patients (3 men and 2 women between the ages of 56 and 61 years). These patients presented with edentulous posterior maxilla of less than 3 mm. Sinus augmentation, insertion of 11 implants, and final restoration were achieved in these patients. Follow-up ranged from 19 to 38 months, with a mean period of 26.2 months. All patients provided informed consent.

Five patients were excluded from the study due to a history of bone metabolism disorder or nasal disease, the presence of a markedly thickened maxillary sinus membrane (≥5 mm), the presence of uncontrolled diabetes, and heavy smoking (20 cigarettes per day).

The materials used consisted of 0.3-mm-thick HA 40% PLLA mesh plates (Figure 1). The PLLA mesh plate was made from composites of uncalcined hydroxyapatite (u-HA) particles and poly-L-lactide (PLLA) with a 40/60 (wt %) ratio of u-HA/PLLA. The mechanical properties of the PLLA mesh plates were as follows: bending strength, 270 MPa; bending modulus, 9.1 GPa; tensile strength, 110 MPa; tensile modulus, 2.3 GPa; compressive strength, 107.3 MPa; compressive modulus, 6.1 GPa. The plates had a modulus of elasticity close to that of natural cortical bone, and due to their radiopacity and thermoplasticity, the plates also demonstrated optimal degradation and resorption behavior, osteoconductivity, and bone bonding capability.

Sinus augmentation was performed under intravenous sedation combined with local anesthesia. A flap was reflected to expose the lateral plate of the maxilla, and an oblong bony window, approximately 5 × 10 mm in dimension, was created using a diamond round bur with continuous sterile saline irrigation (Figure 2a). The sinus membrane was then carefully elevated from the lateral wall and sinus floor through traditional instrumentation. The plate size of the PLLA mesh plate was determined using a preoperative CT image. The PLLA mesh plate was heated and bent along its central axis; this modification made it easier to attach the plate using a titanium screw. If the 3D dimensional maxillary sinus was larger than the plate size of the PLLA mesh plate was inserted. The plate was then positioned 15 mm from the residual ridge and fixed with a microscrew (3 mm long) to the lifted sinus membrane under the lateral access window (Figure 2b). Finally, the mucoperiosteal flap was repositioned and fixed in place using 4-0 Nylon sutures. The PLLA mesh plates were removed at the time of implant insertion (6–9 months after surgery).

Six months after the sinus augmentations, we used a quantitative computerized tomography (QCT) method for the quantitative and objective assessment of the jaw bone quality. The QCT method was developed by Genant et al and has been widely used in lumbar vertebrae and the femur for the diagnosis of osteoporosis. Similar to our previous studies, the bone mineral density (BMD) of the mandible was measured using QCT with Siemens Somatom Sensation 64 (Siemens, Munich, Germany) at 120 kV and 125 mA with a slice thickness of 1 mm.

The CT values obtained with the calibration phantom were converted based on the linear relationship between the X-ray attenuation coefficients and the CT values to calculate the value of the BMD (mg/ml).

Patients were evaluated for differences in the amount of newly formed bone, which were then reported as mean percentages ± standard deviations. The difference between the preoperative bone height and postoperative bone height was analyzed using the paired t-test, and P < 0.05 was considered significant (SPSS Statistics 21).

At the time of implant insertion (6–9 months after sinus augmentations), bone tissue was collected from the antrostomy site using 3-mm trephine burs and fixed in a 10% neutral buffered formalin solution. Next, the specimens were washed, dehydrated, and defatted, and a methyl methacrylate resin block was prepared. After trimming using a precision saw (IsoMet 1000, Buehler, Lake Bluff, Ill), the specimens were cut into 6-μm slices using a microtome (Leica RM2255, Leica Microsystems, Buffalo Grove, Ill) to prepare samples for Goldner and hematoxylin and eosin (H&E) staining. Thereafter, the percentage of newly formed bone area was calculated using the area measurement software (Scion Image, Scion Corporation, Frederick, Md) based on the Goldner-stained samples.

**Results**

The Table presents data pertaining to the patients in this study. Complications such as inflammatory symptoms, infection, implant loss and peri-implant bone resorption were not found during the observation period (mean observation period, 26.2 months; range, 19–38 months) (Figure 3a and b).

However, invagination of the soft tissue into the antrostomy site was detected in all of the patients at the time of removal of the mesh plate (Figure 4).

Radiological examination showed that the mean increase in bone thickness and BMD by QCT method 6 months after surgery was 7.4 ± 1.5 mm (Figure 5a and b) (P < 0.01) and 181 ± 41 mg/ml. Neof ormation of cancellous bone-like tissue was found in all patients.

The histopathological finding of newly formed bone in all patients and the presence of a large number of osteoblasts distributed in a well-aligned pattern confirmed new bone formation (Figure 6a, b, and c). In addition, neoangiogenesis...
and loose connective tissue were observed. The average level of bone formation, which was measured using Scion Images, was as high as 42.5 ± 8.7%.

**DISCUSSION**

This study focused on a new surgical method for maxillary sinus floor elevation that does not involve the use of bone replacement materials or implants, in which an absorbent PLLA mesh plate is used to create space.

The PLLA mesh plate used in this study is a complex formed by uncalcined HA particles, comparable to HA found in vivo, and PLLA at a ratio of HA/PLLA = 40/60 (wt %). The osteosynthetic material is bioabsorbable, has good bone conduction, and is widely used mainly in the fields of orthopedic and craniomaxillofacial surgery for the cooptation of bone fragments at fracture sites and the fixation of bone grafts. In this study, the plates were softened with heat and bent to adapt to the dimensions of the maxillary sinus, which varied among patients.

Scala et al reported that elevation of the sinus membrane without any grafting materials would not leave sufficient space for new bone formation. Such augmentations require devices that create space under an elevated sinus membrane. In the present study, the PLLA mesh device was not absorbed at the time of implant insertion; it remained fixed to the residual ridge and elevated sinus membrane and was therefore considered sufficient for the creation and maintenance of sinus space.

Fuerstn et al and Srouji et al have reported evidence supporting the osteogenic capacity of the sinus membrane. Asai et al and Xu et al reported no evidence of any influence of the sinus membrane on endo-sinus bone formation. In the present study, following 6–8 months of healing, the presence of new bone was detected between the PLLA mesh device and the sinus floor. A cross-sectional computerized tomography (CT) scan conducted 6 months postoperatively showed incomplete bone filling above the PLLA mesh plate. Najman...
et al\textsuperscript{14} reported that the tissue reaction to polylactides was characterized by formation of a capsule around the material and the presence of fibroblasts, macrophages, polymorphonuclear cells, and other cells characteristic to a foreign body reaction. Therefore, the PLLA mesh plate with apatite deposition may lead to the bone being nonconductive.

The histologic specimens obtained after a healing period of 8 months showed new bone formation in all patients. All of the

\begin{table}
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\begin{tabular}{|c|c|c|c|c|c|c|c|c|c|c|c|c|}
\hline
Patient & Age (Sex) & Implant Insertion Site & Existing Bone Mass (mm) & Time of Biopsy (mo) & Increase in Bone Thickness (mm) & Bone Mineral Density (mg/mL) & Rate of bone formation (%) & Implant Length (mm) & Insert Torque (Ncm) & Implant Loss (n) & Observation Period (mo) \\
\hline
1 & 61 (M) & 15 & 1.5 & 8 & 7 & 152 & 48.5 & 10b\textsuperscript{†} & 15 & 0 & 38 \\
& 16 & & 1 & & & & & 10a & 20 & 0 & \\
2 & 58 (M) & 15 & 2 & 8 & 10 & 157 & 31.1 & 11.5a & 20 & 0 & 30 \\
& 16 & 1.5 & & & & & & 10a & 20 & 0 & \\
3 & 58 (F) & 25 & 2 & 9 & 7 & 246 & 46.6 & 10a & 20 & 0 & 23 \\
& 26 & 2.5 & & & & & & 8.5a & 20 & 0 & \\
4 & 56 (M) & 25 & 2 & 6 & 7 & 197 & 50.8 & 10a & 20 & 0 & 21 \\
& 26 & 2.5 & & & & & & 10a & 20 & 0 & \\
5 & 58 (F) & 25 & 2.5 & 7 & 6 & 153 & 35.5 & 10a & 20 & 0 & 19 \\
& 26 & 2 & & & & & & 10a & 20 & 0 & \\
& 27 & 2 & & & & & & 10a & 20 & 0 & \\
\hline
Mean values & 58.2 & 1.91 ± 0.1 & 7.6 & 7.4 ± 1.5\textsuperscript{*} & 181 ± 40.8 & 42.5 ± 8.7 & 19.5 & 0 & 26.2 & & \\
\hline
\end{tabular}
\caption{Patient and clinical data}
\end{table}

\*P < 0.01

\textsuperscript{†}Implant: (a) φ4.0 mm MKIVTi-unite, (b) φ3.75mm MKIIITi-unite, Brånemark, Nobel Biocare.

\textbf{FIGURES 3 AND 4.} FIGURE 3. X-rays show implants in place before superstructure. (a) Case 3. (b) Case 4. FIGURE 4. Invagination of soft tissue into the antrostomy site.
analyzed specimens demonstrated a large number of osteoblasts and adequate signs of vital bone formation in the sinus cavity, starting from the sinus floor and extending coronally toward the apex.

In all patients, the shape of the plate was found to have been maintained up to the time of implant insertion, which was performed 6–9 months after surgery. Because this was a clinical study, the PLLA mesh plate was removed in all the patients; in actual clinical practice, however, implant insertion can be performed without removing the plates because these are naturally degraded and absorbed in approximately 2–4 years.

In the future, controlling the rate of degradation and absorption might also be possible using plates of varying thicknesses.

When bone graft materials are used in sinus floor elevation, complications such as infection of the grafted bone and maxillary sinusitis due to leakage may occur, regardless of the bone graft material selected surgical procedure often becomes more cumbersome, and there is a risk of postoperative leakage into the paranasal sinus.

Relatively stable outcomes have been achieved in studies of sinus floor elevation without the use of bone graft materials in humans. In a study by Lundgren et al., the authors inserted 19 implants with a 4- to 10-mm (average, 7 mm) distance between the alveolar crest and the maxillary sinus floor, and they reported that all of the implants remained intact 12 months after placement of prostheses. In contrast, Ellegaard et al.15 used a similar method to fill the space in a blood clot in patients with an existing bone thickness of ≥3 mm and reported that over an average 5-year observation period, the survival rate of 131 inserted implants was 90%.

In radiological studies of the changes in bone thickness over successive years, Cricchio et al.4 carried out examinations using radiological CT and periapical radiograph during an observation period of 1–6 years and reported that the mean increase in bone thickness after 6 months was $5.3 \pm 2.1$ mm and that there was little change thereafter.

In our study, the mean BMD of the newly formed bone was $181 \pm 41$ mg/mL, a value significantly higher than that of mandibular trabecular bone in postmenopausal women (as identified in our previous study8) and similar to the mean BMD
of mandibular trabecular bone in menopausal women. Based on this finding, when cutting through the tissues at the time of implant insertion, the bone quality may be sufficient to achieve primary stability.

In our study, the increase in bone thickness after 6 months was 7.4 ± 1.5 mm, which was better than that reported by Lundgren et al; however, because this result is likely to vary depending on the location of the PLLA device and the method of placement, there may be a need to consider better contours, fixation methods, and placement locations of PLLA devices that would allow for an appropriate increase in bone mass.

Previous histopathological studies have shown poor results when implants were not used. In particular, Cricchio et al\textsuperscript{16} conducted a study on monkeys in which they used PLLA for creating space after elevation of the floor of the maxillary sinus. The authors reported that in most cases, there was no formation of new bone at the site where PLLA alone had been placed. In another study conducted on 8 patients, with a distance of 4–5 mm between the alveolar crest and the floor of the maxillary sinus, Ahn et al\textsuperscript{17} used only absorbable collagen for filling after maxillary sinus floor elevation. They reported that histopathological evaluations performed on biopsy specimens collected 6 months after surgery using a trephine bur showed no formation of new bone in 6 of the 8 patients. Cricchio et al\textsuperscript{16} stated that the cause of failure was that the space-making materials did not achieve strong fixation.

In our study, formation of new bone was observed in all patients (mean, 42.5 ± 8.7%). A compilation of previous studies on the issue of the bone formation rate associated with maxillary sinus floor elevation using various types of bone graft materials in humans\textsuperscript{18–23} has shown that the bone formation rates were as follow: (1) 38–49% over 6–9 months with autogenous bone graft alone, (2) 28–29% over 8–9 months with DBA or FDBA alone, (3) 21–36% over 6–9 months with \(\beta\)-TCP alone, and (4) 20–42% over 6–9 months with bovine-derived HA. The findings from our study reveal a bone formation rate higher than that associated with the use of bovine bone-derived HA alone and comparable to that...
associated with the use of autogenous bone grafts. Because there is no need for a donor site, a sinus floor elevation technique that uses no graft material could be a very useful method of treatment. However, because invagination of soft tissue into the antrostomy site was observed in all patients in this study, methods for treatment of the antrostomy site may need to be investigated in the future, and there is a need to establish surgical procedures that would allow for maxillary sinus floor elevation in a reliable and simple fashion without the use of graft materials or simultaneous implant insertion.

**CONCLUSION**

The findings of this study suggest that even in patients in whom the bone mass between the alveolar crest and the floor of the maxillary sinus is insufficient for maxillary sinus floor elevation and in whom simultaneous insertion of implants is difficult, sufficient new bone formation can be achieved using a PLLA device as a space-making material. In addition, since this technique does not involve the use of bone graft materials, there is no need for a donor site, our sinus floor elevation technique could become the surgical method of choice for maxillary sinus floor elevation using the lateral window technique. As PLLA has thermoplasticity, it is not difficult to handle the material, and the guided bone regeneration method could be applied. However, the difficulty of 3D positioning and the potential for soft tissue invasion to the bone window should be addressed. Considering the relatively limited number of cases and short follow-up periods, further studies using larger samples and with longer periods of data collection are needed to determine the long-term stability of the newly formed bone.

**ABBREVIATIONS**

BMD: bone mineral density  
CT: computerized tomography  
DFDBA: demineralized freeze-dried bone allografts  
H&E: hematoxylin and eosin  
HA: hydroxyapatite  
PLLA: poly-L-lactic acid  
QCT: quantitative computerized tomography  
β-TCP: beta-tricalcium phosphate

**REFERENCES**