Maxillary sinus augmentation is a predictable technique to increase bone volume in the posterior maxilla prior to implant placement.\textsuperscript{1,2} Dental implants placed in sites previously augmented via a lateral wall approach result in an overall implant survival rate of 97.7% after 3 to 6 years.\textsuperscript{3}

Different materials were studied, as sole materials or in combination with autogenous bone. Only minor differences in implant survival rate were reported for autogenous bone combined with various bone substitutes (92% to 94.8%) compared with bone substitutes alone (95.9%).\textsuperscript{4} Likewise, Jensen et al\textsuperscript{5} reported that implants placed in maxillary sinuses that were augmented with deproteinized bovine bone mineral had a survival rate of 96%, while similar rates (94%) were obtained with a composite graft (20/80 ratio) of autogenous and deproteinized bovine bone mineral graft. However, Froum et al\textsuperscript{6} reported significantly greater vital bone formation when as little as 20% of autogenous bone was added to the graft. Also, implants placed in such composite hybrid graft sites had lower annual failure rates compared with bone substitutes alone (1.47% and 2.59%), respectively.\textsuperscript{7}

Moreno Vazquez et al\textsuperscript{8} reported a low postoperative complication rate (< 15%) in 200 consecutive maxillary sinus augmentation procedures. In cases that presented complications, treatment included additional antibiotic therapy, implant removal, or sinus reentry and total removal of the grafting material. In three cases, biopsy specimens were taken from the sinuses, and histologic analyses were performed. \textbf{Results:} The prevalence of postoperative complications was 32.8% (22 of 67 cases) in 18 of the patients (29.5%). The most prevalent symptoms were persistent pain (68.2%), swelling (63.6%), and oroantral fistula (54.5%). Radiographic signs appeared in 45.5% of the complications. A total of 24 implants failed; thus, an overall 80.3% survival rate was established at 19 months. The vast majority of complications (86.4%) were treated eventually with reentry surgery and revealed that the sinus was full with granulation tissue surrounding pieces of a nonossified rubber-like material. In cases where implants were placed, nonosseointegrated implants were surrounded by soft tissue. The sinus was cleaned thoroughly; the graft material remnants were removed together with inflamed parts of the sinus membrane, followed by chlorhexidine and saline lavages. In the biopsy specimens taken from the sinus cavity, there were no histologic features of new bone formation around the grafted material. \textbf{Conclusion:} Lateral wall maxillary sinus augmentation using PBB was associated with an acute sinus infection histologic appearance and with a 7-times-higher failure rate compared with previous reports. This serious adverse event suggests that PBB cannot be recommended for maxillary sinus augmentations.

\textbf{Keywords:} complication, implant failure, infection, graft failure, PLCL (poly L-lactide-co-ε-caprolactone) coated bovine bone, sinus elevation

\textbf{Purpose:} To describe the postoperative complications following lateral wall sinus augmentation using (poly L-lactide-co-ε-caprolactone; PLCL) and natural polysaccharides polymers–coated bovine bone (PBB). The secondary aims were to examine histologic findings and to propose complication management alternatives. \textbf{Materials and Methods:} This retrospective study included 61 subjects who underwent 67 lateral wall sinus augmentation procedures using PBB in the standard protocol. In cases that presented complications, treatment included additional antibiotic therapy, implant removal, or sinus reentry and total removal of the grafting material. In three cases, biopsy specimens were taken from the sinuses, and histologic analyses were performed. \textbf{Results:} The prevalence of postoperative complications was 32.8% (22 of 67 cases) in 18 of the patients (29.5%). The most prevalent symptoms were persistent pain (68.2%), swelling (63.6%), and oroantral fistula (54.5%). Radiographic signs appeared in 45.5% of the complications. A total of 24 implants failed; thus, an overall 80.3% survival rate was established at 19 months. The vast majority of complications (86.4%) were treated eventually with reentry surgery and revealed that the sinus was full with granulation tissue surrounding pieces of a nonossified rubber-like material. In cases where implants were placed, nonosseointegrated implants were surrounded by soft tissue. The sinus was cleaned thoroughly; the graft material remnants were removed together with inflamed parts of the sinus membrane, followed by chlorhexidine and saline lavages. In the biopsy specimens taken from the sinus cavity, there were no histologic features of new bone formation around the grafted material. \textbf{Conclusion:} Lateral wall maxillary sinus augmentation using PBB was associated with an acute sinus infection histologic appearance and with a 7-times-higher failure rate compared with previous reports. This serious adverse event suggests that PBB cannot be recommended for maxillary sinus augmentations.
L-lactide-co-ε-caprolactone and natural polysaccharides polymers (PLCL) designed to increase hydrophilicity, cell adhesion, and osteogenicity. In a recent in vitro study, this PLCL-coated bovine bone (PBB) was compared with deproteinized bovine bone mineral: Higher vitality and proliferation rate of both mesenchymal stem cells and human osteosarcoma cells were found in the PBB group. In another in vivo study of ridge preservation in rats, a higher percentage of new bone and lower residual scaffold were found in the PBB compared with the deproteinized bovine bone mineral control. Histologic analysis of the biopsy specimens demonstrated an intensive new bone formation occurring around this graft, indicating good osteoconduction. Few human cases also reported successful bone reconstruction using PBB.

To the best of the authors’ knowledge, this study constitutes the first report of the significant adverse events associated with PBB.

The objective of this retrospective study was to describe the postoperative complications following lateral wall sinus augmentation using PBB at either the Department of Periodontology, School of Graduate Dentistry, Rambam Health Care Campus, or in one private practice. All cases were treated by highly experienced periodontists (more than 10 years of experience). The study was conducted according to the ethical principles for medical research (IRB approved 0249-19-RMB).

All the patients who underwent unilateral or bilateral open sinus augmentation procedures using PBB alone or simultaneously with implant placement are included in this report (provided that they had a preoperative CBCT taken prior to the procedure and postoperative panoramic radiographs taken immediately postoperatively). Additional panoramic or CBCT images were taken at the time of reported signs or symptoms (5 to 12 months from surgery). Patients with at least a record of two surgical radiographs were included.

A standard lateral wall sinus augmentation protocol was employed (Figs 1a and 1b) with preoperative antibiotics (2 g amoxicillin or 600 mg clindamycin) that was administered 1 hour prior to surgery and followed for an additional 1-week course.

In addition, a single dose of 8 mg dexamethasone was administered 1 hour before the surgery and a daily dose of 4 mg for the first 2 days after surgery along with analgesics as necessary. The patients received postoperative instructions that included mouthrinse with chlorhexidine gluconate 0.2% for 3 weeks.

**MATERIALS AND METHODS**

This is a retrospective two-center report of subjects who underwent lateral wall sinus augmentation procedures using PBB at either the Department of Periodontology, School of Graduate Dentistry, Rambam Health Care Campus, or in one private practice. All cases were treated by highly experienced periodontists (more than 10 years of experience). The study was conducted according to the ethical principles for medical research (IRB approved 0249-19-RMB).

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Suture removal was performed 2 weeks postoperatively, and follow-up visits were performed at 6 weeks, 3 months, and 6 months following the surgical procedure. Implant placement in these sites was performed either with sinus augmentation or 6 to 9 months postoperatively.

In cases that presented complications (see the results section), additional antibiotic therapy was prescribed, and if this failed to resolve the problem, the implants were explanted. In persistent cases, a reentry surgery was performed, in which the lateral window was exposed, and the infected grafting material was completely removed. In two of those persistent cases, biopsy specimens were taken from the sinuses during the reentry surgery. In one asymptomatic case 8 months after sinus augmentation, a core biopsy specimen was obtained by using a trephine bur during osteotomy preparation for implant placement (Fig 2b). The histologic slides were stained with hematoxylin and
eosin solution (Fig 3a) and with immunohistochemistry to identify CD68 (Fig 4a), a marker for cells of the macrophage lineage. Furthermore, a microbial sampling was taken during one of the reentry surgeries.

RESULTS

A total of 67 sinuses in 61 patients were included in the study. Patients’ ages ranged from 29 to 83 years, with a mean age of 60.1 ± 11.16 years. Fifty-four percent of patients were women (28 men and 33 women). Three patients (4.92%) were light smokers (< 10 cigarettes a day).

Fifty-five patients received unilateral and six patients received bilateral lateral wall sinus augmentation procedures. The prevalence of postoperative complications was 29.5% in patient-based calculation (18 patients out of 61) and 32.8% in sinus-based calculation (22 sinuses out of 67). Of those complications, 59.1% occurred in two-stage cases and 40.9% occurred in one-stage cases.

Symptom appearance ranged from 2 to 19 months (mean: 8.38 ± 4.9 months). The most prevalent symptoms were persistent pain, swelling, and oronasal fistula (Table 1; Fig 1c); those occurred in > 50% of the patients. Radiographic signs appeared in 45.5% of the complications and included partial or complete disappearance of the graft (13.6%) and radiolucency within the grafting material (31.8%; Figs 5b and 5d) or surrounding the implants (Figs 6d and 6e). In most cases, failures presented themselves by implant spontaneous exposure, mobility, oronasal fistula, or deep probing pocket depth following implant restoration.

For the sinuses that presented with complications (22 sinuses), 24 implants in 15 sinuses have failed, resulting in a 20.1% survival rate in those sinuses.

All 22 failing sinuses were operated on by three surgeons. An interoperator comparison showed that the failure rate was comparable: E.E.M., 27.3% (6/22 sinuses), E.G., 33.3% (5/15 sinuses), and Y.M., 36.7% (11/30 sinuses).

Management of Complications

The initial treatment in 63.6% of the cases was a prescription of a second antibiotic course; this resulted in a temporary improvement. One case was treated with chlorhexidine lavage via the oroantral fistulation. In 36.4% of the cases, implants were removed (Figs 1d and 1e). The aforementioned treatments did not solve the problems in most of the cases, and therefore, a reentry procedure was needed in 19 cases (86.4%). Following flap elevation and lateral window exposure, the sinus was exposed. It was found to be full with granulation tissue surrounding pieces of a nonossified rubber-like material (Figs 2a and 7a). Some cases presented widespread inflammation, inflamed sinus membrane, and severe resorption of the buccal plate and the bone crest (Figs 1e and 6f). In cases where implants were placed, nonosseointegrated implants were surrounded by soft tissue (Fig 1d). In most cases, the sinus was cleaned thoroughly; the graft material remnants were removed together with inflamed parts of the sinus membrane, followed by chlorhexidine and saline lavages (Fig 7b).

<table>
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<th>Characteristics</th>
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<tr>
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<tr>
<td>Implant failure</td>
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Fig 5  Radiographic appearance of maxillary sinus augmentation complication III. (a) CBCT before maxillary sinus augmentation. (b) CBCT 9 months following the procedure. (c) CBCT immediately following the reentry surgery that included sinus clearance from granulation tissue. A dome shape was evident in the superior aspect of the augmentation with a communication area to the sinus cavity. A collagen membrane was applied on that area. LPRF membranes were used to fill the sinus cavity, and another collagen membrane was applied on the lateral window. No bone was augmented at this stage. Note the significant thickening of the sinus membrane. (d) CBCT 6 months following sinus clearance. Partial bone fill was evident; however, the communication area to the sinus was still evident. (e) Panorex immediately following second maxillary sinus augmentation procedure. The procedure was performed guided, and implants were placed in the maxillary left first and second molar positions in the areas filled with bone.

Fig 6  Radiographic appearance of maxillary sinus augmentation complication I. (a) Panorex before maxillary sinus augmentation. (b) CBCT before the procedure. (c) Panorex following the procedure. (d, e) CBCT 6 months following the procedure demonstrating radiolucency surrounding the implants in maxillary left first and second molar positions. (f) Radiographic appearance in 3D bone model CBCT following 6 months from reentry surgery demonstrating complete loss of the buccal bone.
Histology

Two biopsy specimens were taken from asymptomatic patients who presented radiographic radiolucency in the grafted sinus. Histologic analysis revealed mainly mild chronic inflammation (Figs 3a and 3b), fragments of xenograft, loose connective tissue, and fibro-adipose tissue. No vital bone was evident (Figs 4a and 4b).

One biopsy specimen was taken from a patient with an acute sinus infection. In this case, severe inflamed fibrous tissue surrounded the residual graft lacking vital bone, and focal cholesterol clefts, giant cells, and granulation tissue were found in the histologic slide. In microbial sampling, no anaerobic bacteria could be detected in the culture; also, no bacteria growth was

Fig 7 Clinical appearance of maxillary sinus augmentation complication III. (a) 9 months following the procedure, probing in the lateral wall demonstrated soft tissue material in the sinus cavity. (b) Following sinus clearance, a dense solid tissue was evident instead of the sinus membrane with big communication to the sinus cavity. The sinus was washed with saline. (c) A collagen membrane was applied on the communication. (d) LPRF membranes filled the compartment. (e) Another collagen membrane was applied on the lateral window. Primary closure was achieved. (f) 7 months later, reentry surgery was performed. (g) The sinus cavity was not completely filled bone as expected, and the communication area to the sinus was still evident. (h) The sinus membrane was very thick but not hard as before. (i) The procedure was performed guided, and implants were placed in the maxillary left first and second molar positions in the areas filled with bone. (j) Again, a collagen membrane was applied on the communication area. (k) Repeated sinus augmentation using xenograft (Bio-Oss). (l) Another collagen membrane was applied following implant placement in the maxillary left first and second molar positions.
found in the direct smear. However, *Streptococcus salivarius* was found.

**DISCUSSION**

In the present retrospective analysis, an overall 32.8% postoperative complication rate was documented following lateral wall sinus augmentation using PBB.

Infection of the grafted sinus is generally considered a rare complication, with a mean incidence of 2.9% (range: 0% to 7.4%). This usually develops 3 to 7 days postsurgically. However, >20% of the present cases using PBB presented signs of active infection (such as oroantral fistula and suppuration), which correspond to at least 7-times-higher incidence of infections compared with the literature.

Askar et al use the six-level postoperative classification system to assess the incidence and severity of postoperative complications following dental surgical procedures. It was found that patients who underwent lateral wall sinus augmentation had a 30% chance to develop some type of complication. Similarly, in the present study, the patients had a complication rate of 29.5%.

Regarding the severity of complications, it seems that in the present study, the Grade III complication rate is 1.7-fold higher (24.6% in comparison to 14.3%).

The implant survival rate was reported to be 90% to 97.7% following 3 to 6 years of function. However, in the present study, the implant survival rate was 80.3% following 19 months, which is significantly lower. Infection is considered the leading cause of implant failure since 61.4% of failed implants were reported to have an infection. In the present study, 79.9% of the implants in infected sinuses failed, a much higher rate than reported in the literature following infections.

Other postoperative complications were also higher than in previous publications.

In three cases, implants have not yet been placed, so further complications might still occur. The complications were detected within a variable time range and could be detected even following more than a year and a half. Therefore, the authors expect to have more complications in the future.

The failures presented a spectrum of symptoms and could be detected radiographically in <50% of the cases. Pain and implant failure were the most prevalent complications (68.2% and 68.2%, respectively).

Few cases presented a dome-shape appearance, known as the “Dome Phenomenon” (Figs 2c and 2d), which was detected during the reentry procedure and was also evident radiographically (Fig 8c). Mahler et al reported that after removal of infected grafting material and resolution of the inflammation, the bony dome may present itself in the apical extension of the sinus.

![Radiographic appearance of maxillary sinus augmentation complication II.](image)

*Fig 8* Radiographic appearance of maxillary sinus augmentation complication II. (a) CBCT before maxillary sinus augmentation. (b) CBCT 9 months following the procedure. (c) CBCT 1 month following reentry surgery. The surgery included implant placement in the maxillary right second premolar and first and second molar positions with LPRF membranes to fill the sinus cavity. The dome shape is evident in the superior aspect of the augmentation. (d) Panorex immediately following the reentry surgery. (e) Panorex following stage-two surgery, 6 months following reentry surgery, demonstrating good primary stability of all the implants with no pathologies.
previously grafted area. The present study, therefore, left the "dome-shape" solid tissue in the sinuses following reentry and filled the sinus with LPRF membranes (Figs 2e and 2f). However, in the present cases, this did not ossify (Figs 7g and 7h). One case required a second reentry surgery, and therefore, the authors might recommend in those cases a complete removal of the sinus content during reentry (Figs 5c and 5d).

Biopsy specimens demonstrated histologically severe inflamed fibrous tissue with giant cells or mild chronic inflammation with loose fibrin-connecitive tissue and fibro-adipose tissue.

There were no histologic features of new bone formation around the grafted material.

Several limitations should be noted in this study. First, it was a retrospective study. There are different specialists who performed the procedure, and therefore, the technique was not uniform.

Reports of multiple failures following sinus augmentations are rare. One study reported multiple implant failures following the use of demineralized bone matrix allograft in maxillary sinus augmentation. Biopsy specimens taken from the failed sinuses during reentry demonstrated mild to severe inflammatory reactions, and histologic examination revealed no features of new bone formation around the graft. The results reported there are very similar to the present study, especially the histopathologic picture.

CONCLUSIONS

Lateral wall maxillary sinus augmentation using PBB was associated with a histologic appearance of acute sinus infection and with a 7-times-higher failure rate compared with previous reports and only an 80.2% implant survival rate. This serious adverse event suggests that PBB cannot be recommended for maxillary sinus augmentations.

ACKNOWLEDGMENTS

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