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Long-term crestal bone changes in implants placed in augmented sinuses with minimal or moderate remaining alveolar bone: A 10-year retrospective case-series study

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Abstract

Objectives: To evaluate long-term clinical and radiographic outcomes of dental implants placed after lateral window sinus augmentation utilizing the sagittal sandwich technique.

Materials and Methods: Patients treated with sinus augmentation were included in this retrospective case-series study. The surgical procedure was performed with particulate autogenous bone- and anorganic bovine bone-derived mineral (3:7 ratio). Implants were grouped based on baseline residual alveolar ridge height: group S (residual alveolar ridge height of 0.1–3.5 mm), group M (height of 3.5-7mm), and group C (native bone). Radiographs were taken at baseline (abutment installation) and annually throughout the 10-year follow-up.

Results: A total of 86 patients (92 sinus lifts) and 209 implants were included. Ten sinus membrane perforations were recorded (11% incidence), and graft infections occurred in 3 cases (3.2% incidence). During the 10-year follow-up, 3 implants (1.4%) failed. No significant differences in the mean implant marginal bone loss (MBL) between the three groups were found after 1-, 2-, and 5-year follow-up ($p > .05$). At 10 years, group C exhibited more MBL than group M with a mean difference of −0.53 mm ($p = .01$). After 10 years, MK III implants displayed significantly more bone loss in native bone than those in augmented bone with a mean difference of 0.48 mm ($p = .02$). Five patients and 7 implants developed peri-implantitis with no significant differences between the groups ($p = .570$).

Conclusion: Implant placement after two-stage sinus grafting utilizing the sagittal sandwich technique is a relatively safe and predictable procedure with minimal complications and MBL after 10-year follow-up.

KEYWORDS

clinical trial, dental implants, posterior maxilla, sinus grafting, staged procedure

1 | INTRODUCTION

The consequences of tooth loss involve vertical and horizontal resorption of the alveolar process which may compromise future insertion of a dental implant (Pietrokovski & Massler, 1967; Schropp et al., 2003). In addition to the regular pattern of bone loss expected after extraction, the expansion of the sinus may result in inadequate bone height to place implants. Loss of teeth in the posterior maxilla typically induces vertical expansion of the maxillary sinus toward the alveolar ridge crest (Sharan & Madjar, 2008; Wehrbein & Diedrich, 1992). This pattern of bone loss in many instances creates a situation that necessitates bone augmentation to allow for implant placement (ten Bruggenkate & van den Bergh, 1998; Lundgren et al., 2017). A wide range of augmentation procedures can be utilized for either sinus augmentation or vertical and horizontal ridge augmentation. Nevertheless, not all of these procedures are associated with the same level of patient morbidity (Abi Najm et al., 2013; Chiapasco et al., 2009; Fontana et al., 2011).

Sinus augmentation using the lateral window technique is the most common technique to overcome limitations associated with proximity of the sinus (Esposito et al., 2014; Starch-Jensen & Jensen, 2017). Boyne & James were the first to describe a staged approach for implant placement following lateral sinus floor augmentation (Boyne, 1993). In his study, Boyne used autogenous iliac bone graft for sinus augmentation. Autogenous grafts have been considered the gold standard for years (Lundgren et al., 1996) due to their osteogenic, osteoinductive, and osteoconductive capabilities (Burchardt, 1987; Fillingham & Jacobs, 2016). Due to the fact that harvesting autogenous bone poses an increased risk of morbidity, a range of alternative grafting materials have been proposed to be used alone or in combination with autogenous bone grafts (Esposito et al., 2010; Hallman et al., 2002; Wheeler et al., 1996). Contemporary literature suggests that the best implant survival rates have typically been achieved with particulate autogenous bone grafts, anorganic bovine bone–derived mineral (ABBM), or a combination of both (Bornstein et al., 2008; Pjetursson et al., 2008). Due to their different biological and osteoinductive properties, a fundamental difference was discovered histologically. Autogenous bone graft resulted in a considerably higher percentage of vital bone after 6 months, whereas ABBM took around 9 months to reach a comparable level of vital bone (Froum et al., 1998; Hallman et al., 2002).

Layered grafting techniques aim to strategically maximize the benefits of each biomaterial while minimizing the disadvantages. For example, autogenous bone possesses osteogenic potential but is resorbed relatively rapidly compared with xenograft which possesses a low substitution rate. The addition of a protective layer of ABBM combines the osteogenic properties of autogenous bone with the space maintaining properties of ABBM xenograft (Buser et al., 2013; Wen et al., 2018). A number of mixtures using various grafting materials have been utilized for ridge augmentation (Leong et al., 2015), as well as sinus augmentation (Jovanovic & Hunt, 1999; Urban & Lozada, 2010). The sagittal sandwich technique involves placing autogenous bone in the area of future implant placement and protective layers of ABBM at the medial and lateral borders (Urban & Lozada, 2010). This grafting technique allows the dental implant to be placed exclusively in autogenous bone (composed of residual bone and autogenous bone graft), while utilizing the low turnover rate of the ABBM to protect the bone volume medially and laterally from accelerated resorption (Piattelli et al., 1999; Valentini & Abensur, 2003).

Implant failure rates have been found to be slightly higher in augmented sinuses. Aghaloo and Moy conducted a systematic review assessing 5,128 implants placed in augmented sinuses and reported that implant survival was 92% when composite autogenous and ABBM grafts were utilized (follow-up from 10 to 102 months) (Aghaloo et al., 2016). In a recent systematic review and meta-analysis analyzing 1,517 implants, Raghoebar et al. reported a 5-year survival rate that varied between 88.6% and 100%, with a cumulative 5-year survival rate of 97.8% (Raghoebar et al., 2019). In particular, the annual rate of implant loss was higher for implants placed in a mixture of autogenous bone and bone substitute (mostly ABBM) compared with placement of implants in either type alone (0.81 or 0.23 per year, respectively).

There is limited data assessing the long-term outcomes of implants placed in sinuses grafted with the sagittal sandwich augmentation technique. Hence, the primary aim of this study was to assess the clinical and radiographic outcomes of dental implants placed in a two-stage procedure after sinus augmentation using sandwich bone grafts. The effect of baseline residual crestal bone height on clinical and radiographic outcomes was also evaluated, where minimal residual crestal bone was defined as ≤3.5 mm and moderate was defined as >3.5 and ≤7 mm.

2 | MATERIAL AND METHODS

2.1 | Ethical approvals and consent

The Research Ethics Committee at University of National Institute of Pharmacy and Nutrition, Budapest, Hungary, provided ethical approval for the present article (approval number: OGYÉI/42850/2019). This retrospective case-series study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2013. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were followed during the preparation of the manuscript. The physical and digital records that fell under the predetermined eligibility criteria were screened and evaluated by two examiners (IU and SF).

2.2 | Primary and secondary study objectives

Primary objectives:

1. To evaluate marginal bone loss around placed implants.
2. To assess the survival of implants placed in augmented maxillary sinuses.

3. To compare implant survival in minimal and moderate residual bone heights.

Secondary objectives:

1. To evaluate the incidence of peri-implant disease and complications associated with implant placement in conjunction with sinus augmentation.
2. To assess the incidence of biological complications related to the sinus lift procedure.

2.3 | Inclusion and exclusion criteria

To be considered eligible for the study, the following inclusion criteria had to be met:

1. Over 25 years of age at the time of surgery.
2. Bone deficiency in the maxilla which requires sinus floor elevation to enable placement of one or more dental implants.
3. Residual alveolar height of the maxilla below the sinus floor ≤7 mm and ≥0.1 mm (as measured by pre-operative radiographs).
4. Residual bone width ≥6 mm (as measured clinically intra-operatively).
5. Generally healthy and able to undergo required surgical procedures.
6. Implants followed for a minimum of 10 years with radiographs and periodontal charting taken at 1, 2, 5, and 10 years post-surgery.
7. Patients compliant with regular visits for supportive periodontal therapy.

Patients were excluded based on the following criteria:

1. Uncontrolled systemic medical conditions that might interfere with required surgical procedures.
2. History of local radiation therapy within previous 5 years.
3. Sinus pathology including but not limited to acute maxillary sinusitis, sinus tissue thickening, or sinus opacification.
4. Residual bone width ≤6 mm (as measured clinically intra-operatively) or cases requiring horizontal bone augmentation. In such instances, the surgery took place, but the case was excluded from the study.
5. Patients with missing or incomplete charts.
6. Patients with follow-up period less than 10 years.

2.4 | Data collection and study group allocation

All patient records were initially screened and evaluated against the eligibility criteria. Subsequently, the selected implant sites were allocated to different study groups based on the residual alveolar ridge height prior to surgery:

- **Test group S** (severe bone atrophy): residual alveolar ridge height of more than 0.1 mm but less than 3.5 mm.
- **Test group M** (moderate bone atrophy): residual alveolar ridge height of more than 3.5 mm but less than 7 mm.
- **Control group C** (implants placed in pure native bone): implants from participants of groups S or M that required additional implants in the canine or premolar areas without sinus augmentation.

All patients were treated in a private practice setting (Urban Regeneration Institute, Budapest, Hungary), and all surgical procedures including sinus augmentation and implant placement were performed by the same experienced practitioner (IU). Patient treatment occurred from May 2001 to 2008. All relevant patient-level information including age at the time of implant placement, smoking, and gender were collected. Additionally, the number and location of implants, residual bone height, mechanism of crown retention, as well as the implant brand, length, and diameter were collected.

2.5 | Surgical Procedures

2.5.1 | Pre-surgical preparation

Surgical procedures including potential risks and benefits were thoroughly explained to all patients, and written consent was obtained from all patients prior to surgery. All participants received prophylactic systemic antibiotic coverage (500 mg amoxicillin t.i.d. or 150 mg clindamycin q.i.d. in the case of penicillin allergy) 24 hr prior to grafting surgery.

2.6 | Clinical procedures

Both test groups were treated with sinus floor elevation and subsequent sinus floor augmentation utilizing the lateral window approach as described by Boyne (Boyne & James, 1980). A full-thickness mucoperiosteal flap was elevated exposing the lateral sinus wall. A sinus window was then prepared. The size, shape, and location of the window were determined on a case-by-case basis and were tailored based on site-specific characteristics and the number of implants to be installed. The sinus membrane was dissected and lifted carefully to create an intra-sinus space allowing grafting material to be packed to at least 15 mm from the alveolar bone crest. Autografts were harvested from intra-oral sites based on the amount of graft needed, the available bone, and anatomic limitations. Autogenous grafts were particulated in a bone mill (R. Quétin Bone-Mill, Roswitha Quétin Dental Products). A sandwich bone augmentation technique using particulate autogenous bone in an ABBM sandwich (30:70 autograft/ABBM ratio) was applied for both test groups. A sagittal layer of ABBM (Bio-Oss; Geistlich Pharma, AG) was placed at the medial

wall of the sinus. Autogenous bone was then placed superiorly to the planned implant sites, making up the bulk of the graft material. A final layer of ABBM was placed to cover the autogenous bone layer laterally until flush with the lateral wall. Both graft materials were carefully packed to ensure maximum contact with native bony walls while avoiding over-packing.

A resorbable porcine collagen membrane (Bio-Gide, Geistlich Pharma, AG) was applied in a bilayer fashion to protect the sinus windows (Jung et al., 2018). The flaps were sutured with ePTFE (expanded polytetrafluoroethylene) sutures (GORE-TEX, CV-5 Suture; W. L. Gore & Associates) using a combination of single interrupted and continuous sling techniques. Primary closure was efficiently achieved in all cases.

2.7 | Post-surgical procedures

A post-operative regimen of amoxicillin 500 mg t.i.d. for 7 days (or if allergic, 150 mg clindamycin q.i.d. for 6 days) was prescribed. An anti-inflammatory medication (50 mg diclofenac potassium or ibuprofen 200 mg, t.i.d.) was prescribed for one week following the surgery.

All patients were evaluated at 7 and 14 days following sinus surgery. Intra-operative and post-operative complications were carefully recorded, including Schneiderian membrane perforation size and incidence, severe intra-operative bleeding, and graft infection.

2.8 | Dental implant placement

For both test groups, the surgical site was left to heal for approximately 7 months to allow for bone maturation. After this healing period, patients returned for implant placement surgery. Implants in the control and test groups were placed at the same visit. Osteotomy preparations were completed using a standard surgical technique and adhering to the manufacturers' recommended guidelines. Implant selection for each case was based on sensible clinical judgment according to the bone quality at the recipient sites. Osteotomies were started with a 2-mm twist drill, which allowed the clinician to assess the quality of the bone. The following implant systems were used: MK III (Brånemark System, Nobel Biocare), MK IV (Brånemark System, Nobel Biocare), Nobel Speedy (Nobel Biocare), and Nobel Replace (Nobel Biocare). In all cases, the implant platform was positioned at the level of the crestal bone. At implant placement, the following parameters were recorded: implant dimension, the need for further vertical augmentation (using a crestal approach for instance), and lack of primary stability. All implants were fully submerged for a mean healing time of 6.5 months prior to abutment connection. Final restorations were placed within 6 weeks after second-stage surgery. All cases received fixed implant-supported restorations.

2.9 | Radiographic assessment of marginal bone level changes

Intra-oral periapical radiographs were taken using a conventional paralleling technique, utilizing position holders and a dedicated intra-oral radiographic unit (Rinn XCP film holder; Dentsply) at baseline (abutment installation) and 1-, 2-, 5-, and 10-year follow-up. Intra-oral radiographs were taken with a paralleling technique using Digora® photostimulable phosphor plates and the MinRay® intra-oral radiographic system (Soredex). Mesial and distal marginal bone level changes were assessed by direct comparison between radiographs taken at baseline and 10 years later. The selected reference point was the implant-abutment connection for all implants. Bone levels were measured as the distance from the reference point to the first bone-to-implant contact using Adobe® Photoshop software (Adobe Systems Incorporated) (Figure 1). In case of bony craters, both apical and coronal bone levels were recorded and analyzed. Whereas measurements were initially made in pixel format, linear measurements (in mm) of abutment and implant diameter were used for calibration of the images, translating pixel values into mm. In order to eliminate inter-examiner variations, a clinician independent from the clinical aspects of the study performed all radiographic analysis of marginal bone loss. Bone levels were subsequently measured mesially and distally and then pooled.

2.10 | Follow-up protocol

All included patients were enrolled in a tightly controlled maintenance program starting after abutment connection. Maintenance included a biannual clinical examination and an annual radiographic examination. Major complications related to post-surgical peri-implant and bone graft healing, such as infection of the bone graft or sinusitis, were recorded. For the current study, the definition of peri-implantitis (PI) according to the American Academy of Periodontology (AAP)/European Federation of Periodontology (EPF) 2017 World Workshop was employed (Berglundh et al., 2018). Periapical radiographs were taken in accordance with the aforementioned radiographic protocol.

2.11 | Statistical analysis

Bone level changes were analyzed using a linear mixed model utilizing the patient as a fixed variable. Two main factors were investigated: implant type and crestal bone height. In the first model, time of evaluation was added as a fixed factor. In the second model, the analysis was based on implant type and crestal height and three groups were constructed: MK III placed after sinus lift, MK III placed in native bone, and MK IV placed after sinus lift. These three groups were also compared in a third linear mixed model where the time of evaluation was added as an extra factor. Inter-group comparisons of radiographic and clinical variables were conducted for each

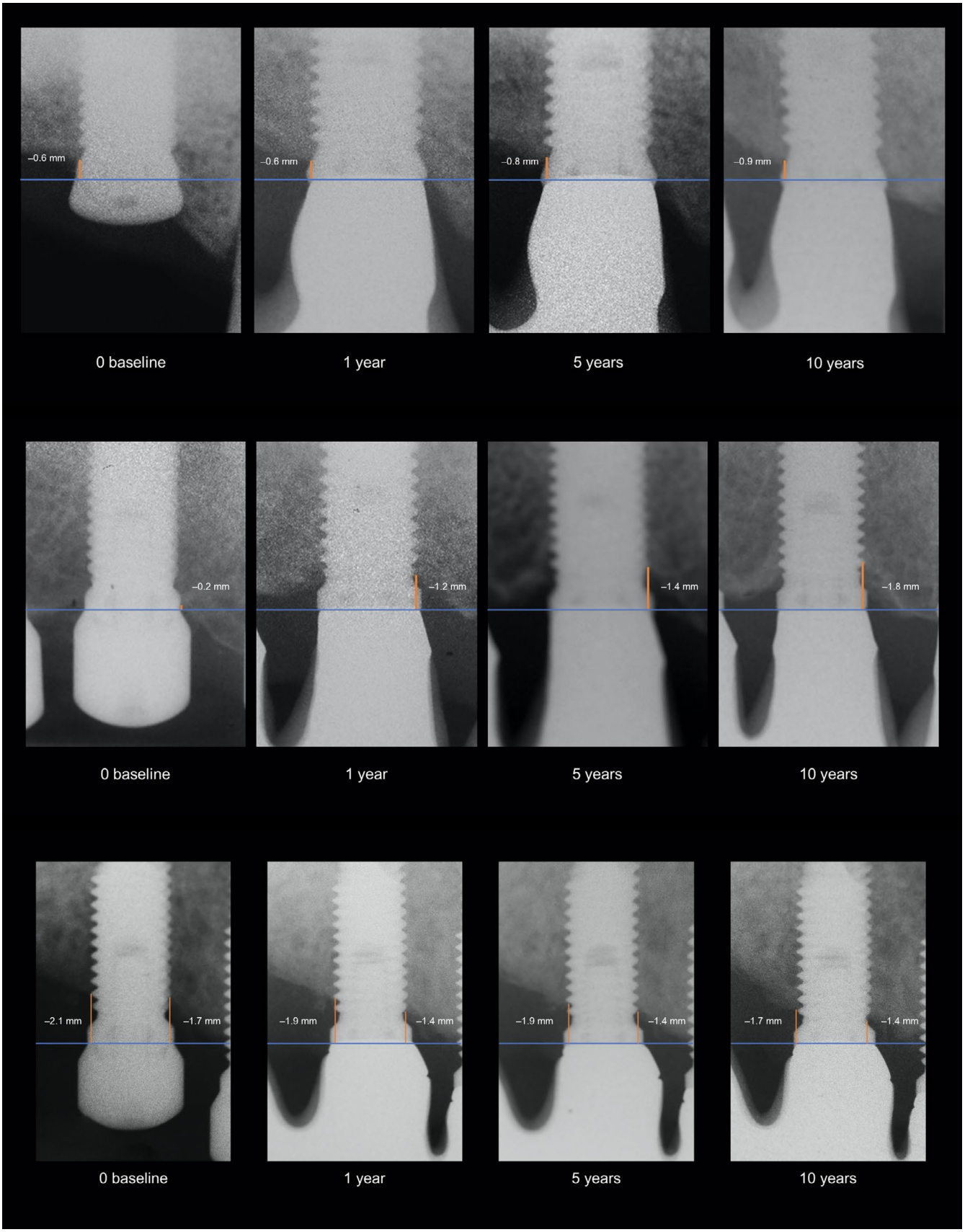

FIGURE 1 Measurements of the bone level (distance from the implant–abutment connection to the first bone-to-implant contact) around the implants during the follow-up period

TABLE 1 Demographic data at the implant-level characterizing the control, severe bone atrophy, and moderate bone atrophy groups

		GROUP		
Implant-Level Data	**Total**	**Control**	**Severe bone atrophy**	**Moderate bone atrophy**
n (implants)	209	27	114	68
Age at IP (years)	52.8 ± 8.0	54.0 ± 6.8	52.4 ± 7.2	53.0 ± 9.7
Gender				
Male	95 (45.5)	10 (37.0)	55 (48.2)	30 (44.1)
Female	114 (54.5)	17 (63.0)	59 (51.8)	38 (55.9)
No. of implants				
1	8 (3.8)	1 (3.7)	2 (1.8)	5 (7.4)
2	54 (25.8)	1 (3.7)	32 (28.1)	21 (30.9)
3	111 (53.1)	14 (51.9)	65 (57.0)	32 (47.1)
4	36 (17.2)	11 (40.7)	15 (13.2)	10 (14.7)
Mean ± *SD*	2.84 ± 0.75	3.30 ± 0.72	2.82 ± 0.67	2.69 ± 0.82
Implant type				
Branemark MkIII	100 (47.9)	25 (92.6)	46 (40.4)	29 (42.6)
Branemark MK IV	77 (36.8)	2 (7.4)	48 (42.1)	27 (39.7)
Nobel Speedy groovy	10 (4.8)	0 (0.0)	8 (7.1)	2 (2.9)
Nobel Replace select	22 (10.5)	0 (0.0)	12 (10.4)	10 (14.7)
Bone Height (mm)			1.89 ± 0.83	4.63 ± 0.81
Position				
Canine	4 (1.9)	4 (14.8)	0 (0.0)	0 (0.0)
PM1	38 (18.2)	17 (63.0)	11 (9.6)	10 (14.7)
PM2	56 (26.8)	6 (22.2)	32 (28.1)	18 (26.5)
M1	73 (34.9)	0 (0.0)	44 (38.6)	29 (42.6)
M2	38 (18.2)	0 (0.0)	27 (23.7)	11 (16.2)
Harvest site				
None	27 (12.9)	27 (100)	0 (0.0)	0 (0.0)
Chin	12 (5.7)	0 (0.0)	6 (5.3)	6 (8.8)
Posterior Maxilla	26 (12.4)	0 (0.0)	15 (13.2)	11 (16.2)
Ramus	144 (68.9)	0 (0.0)	93 (81.6)	51 (75.0)
Diameter				
3.75 mm	57 (27.3)	20 (74.1)	24 (21.1)	13 (19.1)
4 mm	128 (61.2)	7 (25.9)	78 (68.4)	43 (63.2)
4.3 mm	18 (8.6)	0 (0.0)	9 (7.9)	9 (13.2)
5.0 mm	6 (2.9)	0 (0.0)	3 (2.6)	3 (4.4)
Length				
<13 mm	2 (1.0)	1 (3.7)	0 (0.0)	1 (1.5)
13 mm	89 (42.6)	21 (77.8)	47 (41.2)	21 (30.9)
15 mm	112 (53.6)	5 (18.5)	66 (57.9)	41 (60.3)
16 mm	6 (2.9)	0 (0.0)	1 (0.9)	5 (7.4)

Note: IP, implant placement.

individual time point and also for all time points together. The latter was possible because there were no significant interaction effects. A correction for simultaneous hypothesis testing according to Sidak was performed for the comparisons that evaluated each time point separately. A correction according to Tukey was performed when the groups were compared for all time points together. A residual analysis by means of a normal quantile plot and a residual dot plot showed that the data were homoscedastically and normally distributed

around the mean. Implant survival was assessed by means of a frailty model using the patient as a random variable, and either implant time or crestal height as a fixed variable. A detailed description of the statistical models can be found in the Appendix A.

3 | RESULTS

3.1 | Clinical characteristics and demographic profiles

A total of 86 patients (37 males; 49 females) with a mean age of 52.36 years (range: 30–67) were included, and 92 sinus lifts were performed. None of the included patients were smokers. Overall, 209 implants were placed in the three study groups. Autogenous bone was harvested from the chin (8 patients), ramus (61 patients), and posterior maxilla (17 patients). When multiple implants were placed, their crown was always splinted. All the implants were screw retained. Complete implant-level data of the three groups are shown in Table 1.

3.2 | Healing of the sinus grafts

Ten sinus membrane perforations were recorded in this study (11% incidence). No perforations exceeded 5 mm in size. Perforations were sealed with a Bio-Gide collagen barrier (Bio-Oss, Geistlich Pharma, AG) and subsequently treated following the aforementioned grafting protocol. Post-operative swelling in almost all patients followed a routine pattern, reaching its maximum 48 hr post-surgery, and gradually subsiding over approximately one week.

Eighty-nine out of the 92 augmented sinuses healed without any complications. Graft infections occurred in three patients (3.2% incidence). For these patients, systemic antibiotics were prescribed, surgical exploration was conducted, graft rinsing was performed, and an additional healing period was implemented (Urban & Lozada, 2010). Although these patients suffered loss of a limited portion of the graft, signs of infection were eliminated through our treatment protocol, and implant placement was successful without the need for additional grafting.

3.3 | Marginal bone loss (MBL)

3.3.1 | Overall bone level changes

For all implants, radiographs were available and readable at all examination intervals. The mean peri-implant bone level changes that occurred during the 10-year follow-up are shown in Figure 2a–c, Supplementary Table 1, and Figure 3a–c. No statistically significant inter-group differences in the mean MBL around implants between

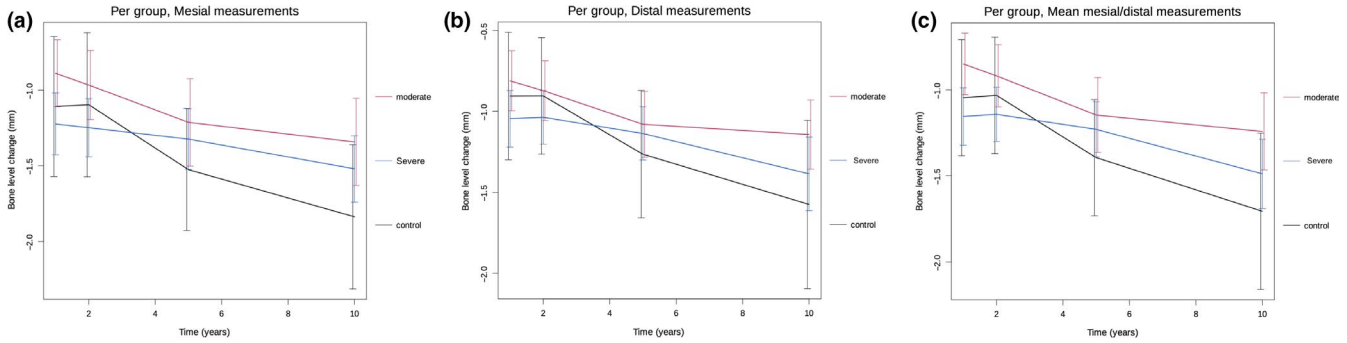

FIGURE 2 Mean peri-implant bone level changes occurring during the 10-year follow-up. Mesial (a), distal (b), and mesial/distal (c)

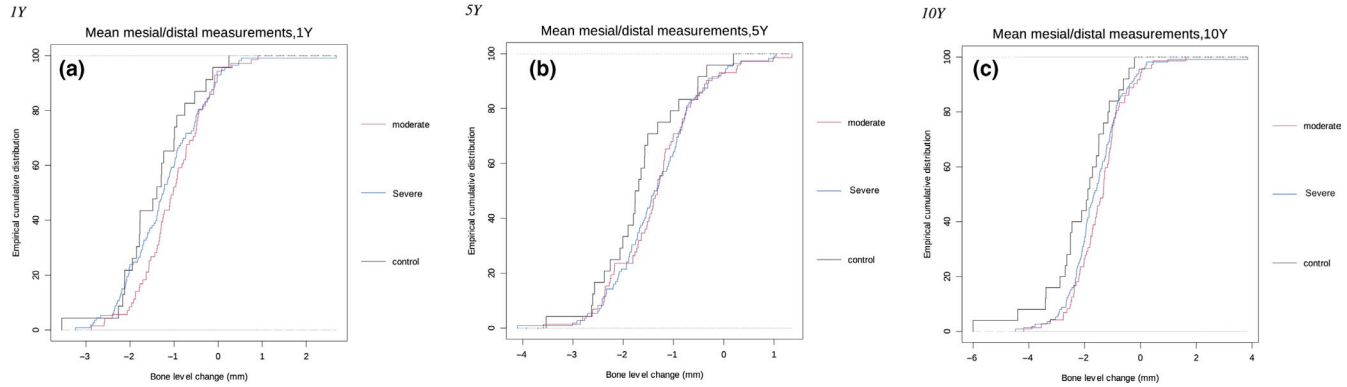

FIGURE 3 Cumulative distribution of the mean peri-implant bone level change at 1(a), 5 (b), and 10 (c) years

TABLE 2 Mean marginal bone loss comparison among the three groups at each interval during the studied follow-up period

Time point	Comparison	Difference (mm)	P-value
1Y	Control–Severe	−1.1182	0.9997
1Y	Control–Moderate	−0.2562	0.8217
1Y	Severe–Moderate	−1.1381	0.9941
2Y	Control–Severe	−0.1129	0.9998
2Y	Control–Moderate	−0.2047	0.9617
2Y	Severe–Moderate	−0.0919	0.9999
5Y	Control–Severe	0.2638	0.747
5Y	Control–Moderate	0.2327	0.8877
5Y	Severe–Moderate	−0.0311	0.9999
10Y	Control–Severe	−0.4272	0.1001
10Y	Control–Moderate	−0.5312	0.017
10Y	Severe–Moderate	−0.1039	0.9996
Between-patient variability		Within-patient variability	
0.6508		0.6614	

TABLE 3 Mean marginal bone loss (only MK III implants) comparison among the three groups at each interval during the studied follow-up period

Time point	Comparison	Difference (mm)	P-value
1Y	Control-Severe	−0.1289	0.9993
1Y	Control–Moderate	−0.3193	0.6527
1Y	Severe–Moderate	−0.1904	0.9853
2Y	Control–Severe	−0.1553	0.9958
2Y	Control–Moderate	−0.3403	0.5592
2Y	Severe–Moderate	−0.185	0.9886
5Y	Control–Severe	0.2663	0.7595
5Y	Control–Moderate	0.4697	0.1201
5Y	Severe–Moderate	−0.2034	0.9765
10Y	Control–Severe	−0.4587	0.0748
10Y	Control–Moderate	−0.7457	0.0007
10Y	Severe–Moderate	−0.287	0.7806
Between-patient variability		Within-patient variability	
0.6601		0.576	

the three groups were recorded after 1-, 2-, and 5-year follow-up ($p > .05$). At 10 years, group C showed more MBL than group M with a mean difference of −0.53 mm ($p = .01$) which was the only significant inter-group comparison (Table 2). Similarly, when differences among groups were analyzed only for MK III implants (Table 3 and Figure 4a–c), statistically significant differences occurred at 10 years where group C showed more MBL than group M with a mean difference of −0.7 4 mm ($p < .01$).

3.3.2 | MK III–MK IV comparison

The mean bone level changes during the 10-year follow-up of MK III and MK IV implants are reported in Figure 5a,b. Mean mesial/distal measurements at each individual time point are reported in Table 4. After 10 years, MK III implants placed in native bone displayed significantly more MBL than those placed after sinus lift procedures with a mean difference of −0.48 mm ($p = .02$).

3.4 | Survival rate

Overall, 3 implants (1.4%) failed during the 10-year follow-up period. Statistically significant differences among groups were not found since one implant was lost in each group ($p > .05$). In groups S and M, the implants were lost during the first year of follow-up, while in group C, one implant was lost during the second year (Figure 6a). Analysis of different types of implants (MK III versus. MK IV) showed no statistically significant difference ($p > .05$) (Figure 6b).

3.5 | Peri-implantitis

Five patients (6.17% incidence; 95% CI: 2.03%–13.82%) developed PI around at least one implant. A total of 7 implants (3.35%) were diagnosed with PI (95% CI: 0.91%–5.79%). Overall, no statistically significant differences were found between the three groups ($p = .570$). Moreover, none of the implant- and patient-related

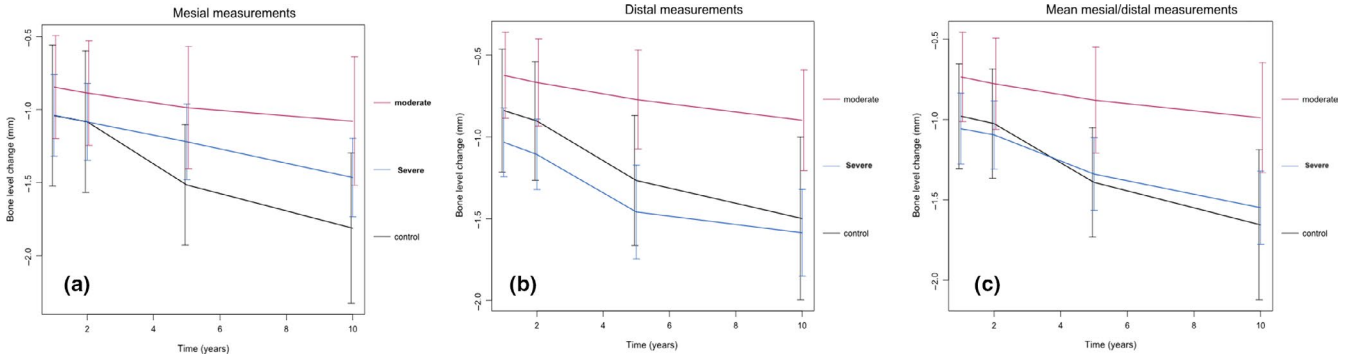

FIGURE 4 Mean peri-implant bone level changes for MK III implants over 1, 2, 5, and 10 years. Mesial (a), distal (b), and mesial/distal (c)

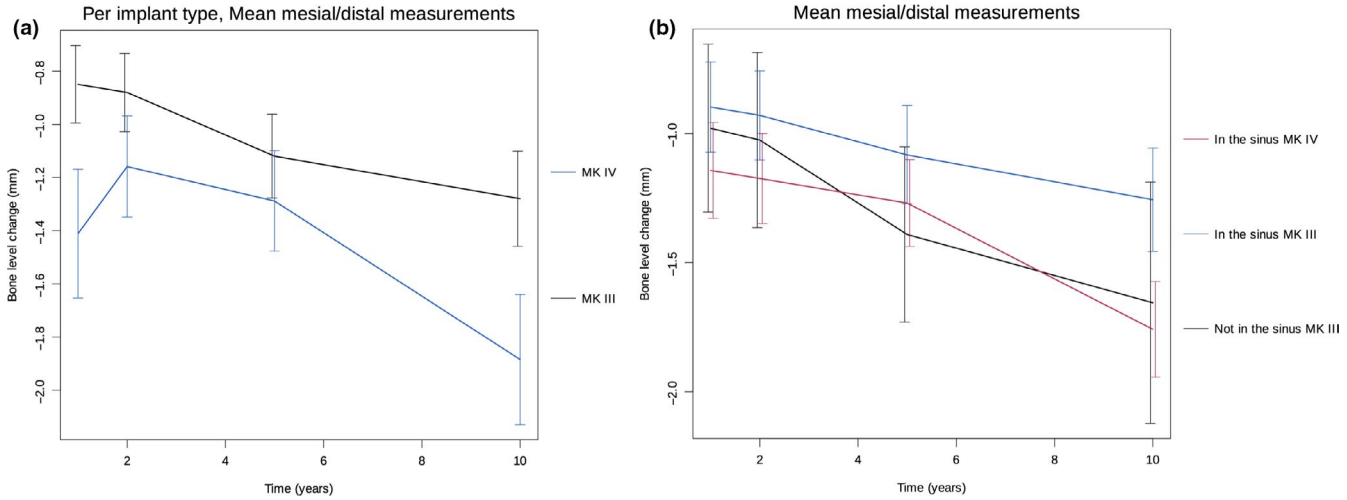

FIGURE 5 Mean bone level changes during the 10-year follow-up of MK III and MK IV implants (a). Figure 4b shows a comparison among implants placed either in native bone or after a sinus lift procedure

TABLE 4 Mean marginal bone loss of MK III and MK IV implants at each studied time point from baseline to 10-year follow-up

Time range	Comparison	Difference	P-value
1Y	MK III in native bone–MK III after sinus	−0.1375	0.9971
1Y	MK III in native bone–MK IV after sinus	−0.0328	0.9999
1Y	MK III after sinus–MK IV after sinus	0.1047	0.9895
2Y	MK III in native bone–MK III after sinus	−0.1617	0.9879
2Y	MK III in native bone–MK IV after sinus	−0.0509	0.9999
2Y	MK III after sinus–MK IV after sinus	−0.1107	0.9835
5Y	MK III in native bone–MK III after sinus	−0.2572	0.693
5Y	MK III in native bone–MK IV after sinus	−0.1476	0.9925
5Y	MK III after sinus–MK IV after sinus	0.1096	0.9855
10Y	MK III in native bone–MK III after sinus	−0.4836	0.0201
10Y	Not in the sinus MK III–MK IV after sinus	−0.278	0.5816
10Y	MK III after sinus–MK IV after sinus	−0.2056	0.4657
Between-patient variability		Within-patient variability	
0.6411		0.6172	

factors were associated with increased incidence of PI (Table 5). Only a weak trend (p = .093) of increased PI associated with the 15-mm compared with the 13-mm implants was found (OR: 4.98; 95% CI: 0.77–32.4).

4 | DISCUSSION

Restoration of edentulism in the posterior maxilla with dental implants is often challenging due to inadequate quality and quantity of alveolar bone. After tooth loss, the alveolar bone and the floor of the maxillary sinus experience increased remodeling, resulting in alveolar bone resorption and sinus pneumatization. Ultimately, this limits the available bone for implant placement. To handle this challenge, multiple treatment solutions have been proposed, including maxillary sinus floor elevation with or without grafting procedures (Aghaloo et al., 2016), as well as the use of short implants (Ravida, Wang, et al., 2019; Thoma et al., 2015). Despite high success rates, short implants have obvious limitations in cases of severely atrophied maxillary bone (Ravida, Majzoub, et al., 2019; Ravida, Wang, et al., 2019).

Sinus floor elevation has been shown to be the most predictable augmentation technique for bone volume enhancement in compromised sites (Aghaloo & Moy, 2007). Moreover, the predictability of the procedure and the overall survival rate of implants placed in augmented sinuses have improved over time. In a systematic review, the reported implant survival rate in augmented sinuses was significantly higher in articles published in 2003 or later (96.21%) compared with older studies (85.66%; $p < .001$) (Del Fabbro et al., 2013). There is little available evidence evaluating the long-term outcomes of peri-implant bone levels in augmented sinuses. Galindo-Moreno et al. reported that implants placed in augmented maxillary sinuses exhibited significantly greater MBL than implants placed in native bone (roughly 0.4-mm difference) (Galindo-Moreno et al., 2014, 2015).

Our study included a total of 86 patients with 209 implants that were successfully placed and followed up for 10 years. Implants were allocated into one of three groups: placement in severely atrophied ridges (ridge height of 0.1–3.5 mm), moderate bone atrophy (ridge height of 3.5–7 mm), and a third group of implants placed in non-augmented native bone in the canine or premolar areas. Our results showed that overall there were no significant differences in

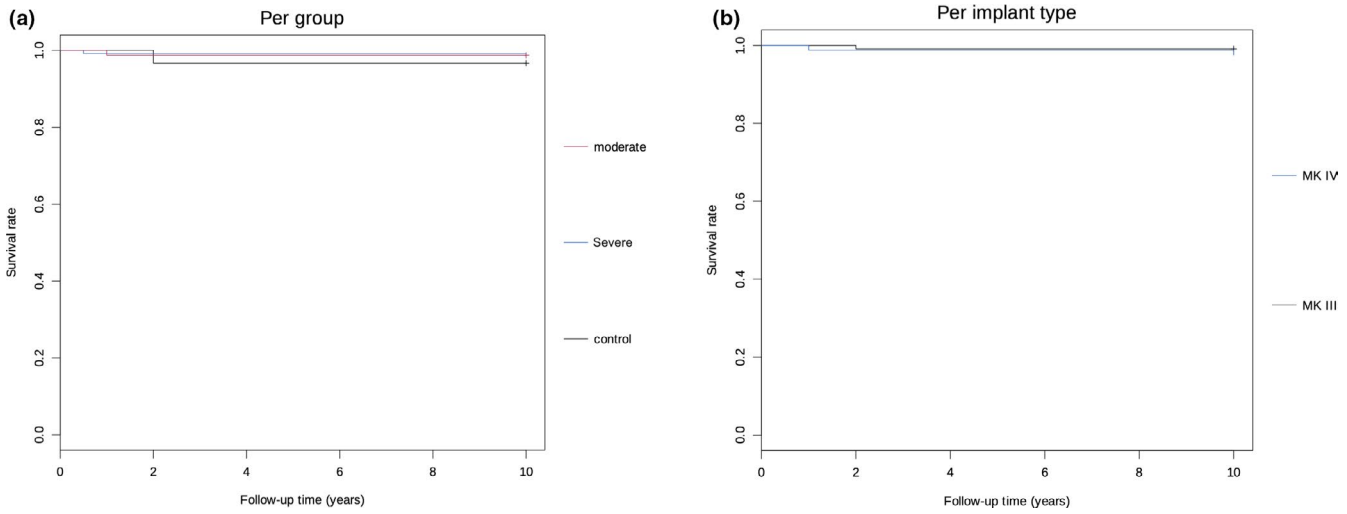

FIGURE 6 Implant survival rate according to the group (a) or type of implants (b) during the 10-year follow-up period

the mean MBL around implants between the three groups at 5 years. The only significant inter-group comparison was at 10 years, where group C showed more MBL compared with group M (mean difference = 0.53 mm). Though the reason for the disparity in MBL between both groups is unclear, we assume this might be related to the available bucco-palatal bone thickness. Typically, the edentulous posterior maxilla has abundant bone thickness, while the bone width at the premolar area is comparably thinner. To constrain MBL around implants, it has been suggested that the bone thickness around an implant should not be less than 2 mm (Spray et al., 2000). Similarly, a randomized clinical trial by Wennstrom and coworkers found significantly greater MBL around implants placed in thinner maxillary bone (Wennstrom et al., 2004).

Our results fall in agreement with previous investigations, substantiating that when ideal soft and hard tissue management is accomplished, bone gain can be predictably maintained over time (Donos et al., 2008). Previous reviews reported a 5-year implant survival rate ranging from 75% to 100% after sinus augmentation, irrespective of the grafting material used (Corbella et al., 2015; Nkenke & Stelzle, 2009). The results of a recent systematic review showed a similar finding, where studies using a similar technique had the highest long-term implant survival rate (Raghoebar et al., 2019). In the present study, only 1.4% of implants failed over a period of 10 years, confirming that implant placement in conjunction with the sagittal sandwich technique allows for predictable long-term survival rates.

The combination of ABBM with autogenous bone has been reported to act in a mutually supportive manner. On one hand, it employs the osteogenic potential and growth factor release from autogenous bone. On the other hand, ABBM successfully maintains the grafted space, owing to its slow substitution rate. The faster bone turnover associated with autogenous bone is believed to facilitate the migration of osteoblasts via creation of a newly formed Haversian system (Galindo-Moreno et al., 2011). When using this combination, less volumetric changes occur compared with the use of autogenous bone alone (Shanbhag et al., 2014).

Although maxillary sinus augmentation is the gold standard for rehabilitation of the atrophied posterior maxilla, several intra- and post-operative complications are commonly encountered (Schwartz-Arad et al., 2004; Stacchi et al., 2017; Urban et al., 2012). It is widely recognized that sinus membrane perforation is the most common complication during sinus floor elevation surgery, with an average incidence of around 20% (Pjetursson et al., 2008; L. Schwarz et al., 2015). In the present study, the incidence of sinus perforations was 11%, and all perforations were less than 5 mm. Perforations were corrected at the time of surgery with a Bio-Gide collagen barrier (Bio-Oss; Geistlich Pharma, AG) and exhibited no further complications. While other studies reported an increased implant failure rate after sinus perforation (Hernandez-Alfaro et al., 2008; Proussaefs et al., 2004), none of the cases with perforation experienced implant failure in our study, which is in agreement with the findings reported in a recent systematic review (Raghoebar et al., 2019).

Though uncommon, graft infection is one of the major post-operative sinus augmentation complications that can lead to catastrophic loss of the graft (Testori et al., 2019). The incidence of graft infection in the present study was relatively low (3.2%), which is in accordance with other studies (Zijderveld et al., 2008). All cases with graft infection were managed according to a prescribed protocol, and all patients healed uneventfully, allowing implant installation without the need for additional grafting (Urban et al., 2012). We presume that our overall low complication rate might be due to the standard protocol utilized in this study and the clinical expertise of the operator (IU).

In the present study, minimal peri-implant bone changes occurred, with minor variances between different implant types. MK III implants placed in native bone had significantly less MBL than those placed after sinus lift procedure at 10-year follow-up (mean difference of 0.48 mm). This might be attributed to the lack of wound dehiscence due to adequate soft tissue management and optimal biomaterial selection.

TABLE 5 Prevalence of PI according to independent factors: mean ± standard deviation or *n* (%). Result of linear regression models or simple logistics using generalized estimation equations (GEEs) or chi-square test of independence

		PI		
	Total	No	Yes	P-value
Number of Implants	209	202 (96.6)	7 (3.4)	
Age (years)	52.8 ± 8.0	52.6 ± 8.0	59.1 ± 5.5	0.542
Gender				
Male	95	88 (92.6)	7 (7.4)	0.597
Female	114	114 (100)	0 (0.0)	
Groups				
Control	27	26 (96.3)	1 (3.7)	0.570
Group S	114	109 (95.6)	5 (4.4)	
Group M	68	67 (98.5)	1 (1.5)	
Type of implant				
Branemark MK III	100	98 (98.0)	2 (2.0)	0.261 (4 types) 0.285 (MK III versus. MK IV)
Branemark MK IV	77	72 (93.5)	5 (6.5)	
Nobel Speedy groovy	10	10 (100)	0 (0.0)	
Nobel Replace select	22	22 (100)	0 (0.0)	
Position				
Canine	4	4 (100)	0 (0.0)	0.983
PM1	38	37 (97.4)	1 (2.6)	
PM2	56	54 (96.4)	2 (3.6)	
M1	73	70 (95.9)	3 (4.1)	
M2	38	37 (97.4)	1 (2.6)	
Sinus lift				
No	27	26 (96.3)	1 (3.7)	0.900
Yes	182	176 (96.7)	6 (3.3)	
Harvest site				
None	27	26 (96.3)	1 (3.7)	
Chin	12	12 (100)	0 (0.0)	0.800
Posterior Maxilla	26	25 (96.2)	1 (3.8)	
Ramus	144	139 (96.5)	5 (3.5)	
Diameter				
3.75 mm	57	57 (100)	0 (0.0)	0.475
4 mm	128	121 (94.5)	7 (5.5)	
4.3 mm	18	18 (100)	0 (0.0)	
5.0 mm	6	6 (100)	0 (0.0)	
Length				
<13 mm	2	2 (100)	0 (0.0)	0.093 (13 mm versus. 15 mm)
13 mm	89	88 (98.9)	1 (1.1)	
15 mm	112	106 (94.6)	6 (5.4)	
16 mm	6	6 (100)	0 (0.0)	

The prevalence of PI falls within a wide range (approximately 10%–50%) depending on several factors (Derks & Tomasi, 2015; Koldsland et al., 2010). Multiple risk factors have been identified which contribute to the development of PI (Monje et al., 2019; F. Schwarz et al., 2018). In the present study, 6.1% of patients presented with PI associated with at least one of their implants, and

a total of 7 implants (3.3% of implants) were diagnosed with PI. In a 5-year prospective study, Krennmair and coworkers reported almost the same results, with an implant-level rate of peri-implantitis of 3.3%, and 6.6% at the patient level (Krennmair et al., 2019). While there is no available evidence to support the assumption that implants placed in augmented sinuses might have an increased incidence of peri-implantitis, a few studies suggest that the development of PI may increase the risk of post-operative complications associated with sinus augmentation. A recent report suggested that the progression of PI into sinus floor augmented bone may lead to maxillary sinusitis (Park et al., 2019). Another study reported that if the peri-implant infection reaches the grafted material inside the sinus, it can potentially spread throughout the graft, leading to graft failure (Scarano et al., 2017).

The strengths of the present article include the long-term follow-up, blinded radiographic analysis, and that the same expert surgeon performed the procedures. On the other hand, the present article is not exempt from limitations including the fact that bone density was not recorded and different implant systems were used. To control for the different implant systems used, a separate statistical analysis was performed for MK III implants alone, which was the predominant system utilized, and confirmed the overall results at 10 years. In addition, only data gathered from patients following the recall program with at least 10-year follow-up were included in the present analysis. This means that patients with less follow-up or that dropped out of the recall program were not considered. Further studies are required to verify the clinical efficacy and limitations of the sagittal sandwich augmentation technique. Future randomized controlled studies should define defect size and total augmented volume of the defects.

5 | CONCLUSIONS

Within the limitations of this retrospective case-series study, it can be concluded that two-stage sinus grafting utilizing a sagittal sandwich approach appears to be a safe and predictable procedure with minimal complications. After 10-year follow-up, the differences in marginal bone loss among groups were minimal, and the limited difference among the moderate and severe groups, even if statistically significant, may not be impactful clinically. Thus, peri-implant marginal bone loss does not appear to be influenced by the pre-surgical residual ridge height.

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CONFLICT OF INTEREST

The authors do not have any financial interests, either directly or indirectly, to the products or information identified in the paper except Dr. Urban occasionally received honorarium for speaking on behalf of Nobel BioCare and Geistlich Pharma.

AUTHOR'S CONTRIBUTION

IAU performed treatment, collected the data, conceived the ideas, and led the writing. SF collected the data and helped with patient management. AR, MAH, and MG collected the data, analyzed the data, and drafted manuscript. JL and HLW conceived the ideas, analyzed the data, and revised manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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APPENDIX A

General linear models are suitable for solving a wide range of problems in statistics, including ANOVA and regression. In formula notation, they can be expressed as $Y = X\beta+\varepsilon$, where Y is a matrix of n rows and 1 column, containing the response data, where n equals the number of responses, and β is a nx1 column matrix of coefficients that make sure that the sum of the square values of the residuals in the nx1 column matrix ε are as small as possible. X is the design matrix, containing one or more independent variables. For linear regression, for example, X consists of n rows and 2 columns. The first column is filled with the value of 1 on every row, the second column contains the values of the independent variable. For an ANOVA model with 1 factor containing three groups, X has 3 columns and the values of the different lines in the columns depend on the group. There are multiple possibilities to construct design matrix X. The so-called "sum to zero contrasts," for example, fills the design matrix as follows: in a first instance, the first column has the value of 1 for every row, like is the case in linear regression. The values in the second and third columns depend on the group each observation belongs to. The second column has a 1 for an observation belonging to the first group, a 0 for an observation belonging to the second group and a −1 for an observation belonging to the third group. The last and third column has a value of 0 for an observation belonging to the first group, a value of 1 for an observation belonging to the second group, and a value of −1 for an observation belonging to the third group. The residual values in ε are assumed to be independently from each other and follow a normal distribution with mean 0 and population standard deviation σ.

The independence of the values is often a problem for data analysis. Often, the data can be grouped into subgroups that are independent from each other. For example, when multiple data are collected from patients, like measurements at different implants, the data from multiple implants within the same patient are dependent on one other because they arise from the same patient. Mean values per patient are independent. In order to model dependency between the data, the general linear models need to be extended. In formula notation, we have:

$$Y = Xb + Zu + e$$

The matrices Y, X, β, and ε are the same as for general linear models. The matrices Z and u are new and contain the information about the random effects. Z is defined in the same way as X is defined, but now for the random effects. The matrix u contains the random effects, which are supposed to be normally distributed around 0 and with population standard deviation σ_p, which represents in this text the between-patient variability.