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Dental Implants

Randomised Controlled Trial

Outcomes following osteotome-mediated sinus floor elevation with Bio-Oss Collagen or no grafting material: a one-year single-blind randomized controlled trial

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Abstract. The objective of this single-blind randomized controlled trial was to test the hypothesis of no difference in implant treatment outcome and patient-reported outcome measures (PROMs) following osteotome-mediated sinus floor elevation with Bio-Oss Collagen (test) compared with no grafting material (control) after 1 year of implant loading. Forty healthy patients (27 female, 13 male) with a mean age of 49 years (range 24–74 years) were randomly allocated to the test or control group. Outcome measures included survival of the suprastructures and implants, peri-implant marginal bone loss, complications, and PROMs; the latter included the Oral Health Impact Profile-14 and a self-administered questionnaire with visual analogue scales to assess the peri-implant tissue, implant crown, function of the implant, total implant treatment outcome, and oral health-related quality of life. Mean differences were expressed with the standard deviation and 95% confidence interval. The level of significance was 0.05. Survival of the suprastructures and implants was 100% with both treatment modalities. No significant difference in any of the outcome measures was observed between the test and control groups. High patient satisfaction and a significant improvement in quality of life were observed with both treatment modalities. Consequently, no significant difference in implant treatment outcome between the test and control groups was revealed after 1 year of implant loading. Neither of the treatment modalities can therefore be considered better than the other.

Keywords: Alveolar ridge augmentation; Dental implants; Health care surveys; Maxilla; Randomized controlled trial; Quality of life; Sinus floor augmentation.

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Osteotome-mediated sinus floor elevation (OMSFE) in conjunction with the simultaneous placement of standard-length implants is a predictable and well-documented procedure to rehabilitate the atrophic posterior maxilla when the residual bone height (RBH) is > 5 mm.[1] OMSFE involves elevation of the Schneiderian membrane using a transalveolar approach. The space created between the elevated membrane and original sinus floor is maintained by the inserted implant. A grafting material is traditionally applied underneath the elevated membrane to enhance the volume supporting the implant and facilitate bone regeneration.[2] However, systematic reviews and meta-analyses have revealed no significant differences in implant survival, endo-sinus bone gain (ESBG), peri-implant marginal bone loss (PIMBL), or frequency of biological and mechanical complications following OMSFE with or without a grafting material.[3–6] Moreover, long-term case series and retrospective studies assessing OMSFE without a grafting material have demonstrated comparable clinical and radiographic implant treatment outcomes.[7–9] Consequently, the necessity for a grafting material underneath the elevated membrane in conjunction with OMSFE and simultaneous placement of implants seems debatable in relation to improving the long-term clinical implant treatment outcome.

Particulated autogenous bone is often used as a grafting material in conjunction with OMSFE due to its osteoinductive, osteoconductive, and osteogenic properties.[6] However, harvesting of autogenous bone is associated with donor site morbidity, supplementary surgery, and an unpredictable resorption of the graft material.[10,11] Xenogeneic bone substitutes with a slow substitution rate are therefore used increasingly to simplify the surgical procedure by diminishing the need for bone harvesting and improving the volumetric stability of the grafting material.[12]

Clinical and radiographic criteria are commonly used to define a successful implant treatment outcome.[13] However, these criteria do not necessarily reflect patient satisfaction with the surgical intervention, or the aesthetic outcome and function of the implant-supported restoration. Therefore, patient-reported outcome measures (PROMs) are needed to supplement the clinical and radiographic criteria in the definition of a successful long-term implant treatment outcome.[14,15]

Satisfactory clinical and radiographic outcomes following OMSFE with or without a grafting material have been reported previously in randomized controlled trials (RCTs), revealing comparable suprastructure and implant survival rates, PIMBL, ESBG, and frequencies of complications.[16–21] However, PROMs and patient satisfaction with the implant-supported restoration were not assessed in these studies. Therefore, the objective of the present single-blind RCT was to test the hypothesis of no difference in implant treatment outcome and PROMs following OMSFE with Bio-Oss Collagen compared with no grafting material after 1 year of implant loading.

Materials and methods

Study design

The study protocol was prepared and implemented in accordance with the CONSORT statement (http://www.consort-statement.org/) (Fig. 1) and was approved by the North Denmark Region Committee on Health Research Ethics (approval No. N-20180027). It has been registered at ClinicalTrials.gov (registration number NCT04618900). Patients were recruited by public invitation through Facebook or from those admitted to the Department of Oral and Maxillofacial Surgery, Aalborg University Hospital, Denmark for implant placement in the posterior maxilla. Candidates were screened for the inclusion and exclusion criteria (Table 1). The RBH was estimated by cone beam computed tomography (CBCT), and patients with a RBH between 6 mm and 10 mm corresponding to the centre of the edentulous area were included. Written and verbal information about the study was provided before the informed consent form was signed. The OMSFE, implant placement, and healing abutment connection were free of charge, but expenses for the prosthetic rehabilitation including the patient-specific abutment (Atlantis abutment; Dentsply Sirona, Mölndal, Sweden) were paid for by the patients.

Forty patients with a missing posterior maxillary tooth were included. Computer-aided block randomization was used to allocate the included patients to two groups of the same size: OMSFE with Bio-Oss Collagen (test; $n = 20$) and OMSFE with no grafting material (control; $n = 20$). Based on the sample size calculation and assuming a 10% dropout rate, 20 patients were required in each group to detect a 15% difference in long-term PIMBL between the groups, with a power of 0.8 and a significance level equal to 0.05.[22]

Surgical procedure

One hour prior to OMSFE, the patient was pre-medicated with analgesics including 400 mg ibuprofen, 1000 mg paracetamol, and a prophylactic antibiotic, either 2 g amoxicillin or 600 mg clindamycin if allergic to penicillin. All patients rinsed with 0.12% chlorhexidine solution for 1 min immediately before surgery. The surgical procedures were performed by the same trained surgeon (T.S.J.) under local anaesthesia using lidocaine (2%) with 1:200,000 adrenaline (Fig. 2).

An intraoral marginal incision was performed at the implant site, continuing into the gingival sulcus of the adjacent teeth. The mucoperiosteum was reflected exposing the alveolar process. An implant bed was prepared following the manufacturer's recommendations at 1500 rpm. The depth of the drilling process was ended at least 1–2 mm beneath the sinus floor. The Schneiderian membrane including the original maxillary sinus floor was gently elevated to the planned implant length using calibrated osteotomes combined with piezoelectric surgery and a hydraulic pressure technique (Sinus Physiolift II; Mectron, Carasco, Italy). A watertight adaptor with a tube was inserted into the prepared implant bed and connected to a syringe containing 2 ml of physiological saline solution. The membrane was safely elevated by controlling the pressure of the liquid by means of the attached Physiolift device. The integrity of the membrane was checked by Valsalva manoeuvre and the patient was asked whether they had a sensation of water in the nose or throat during use of the

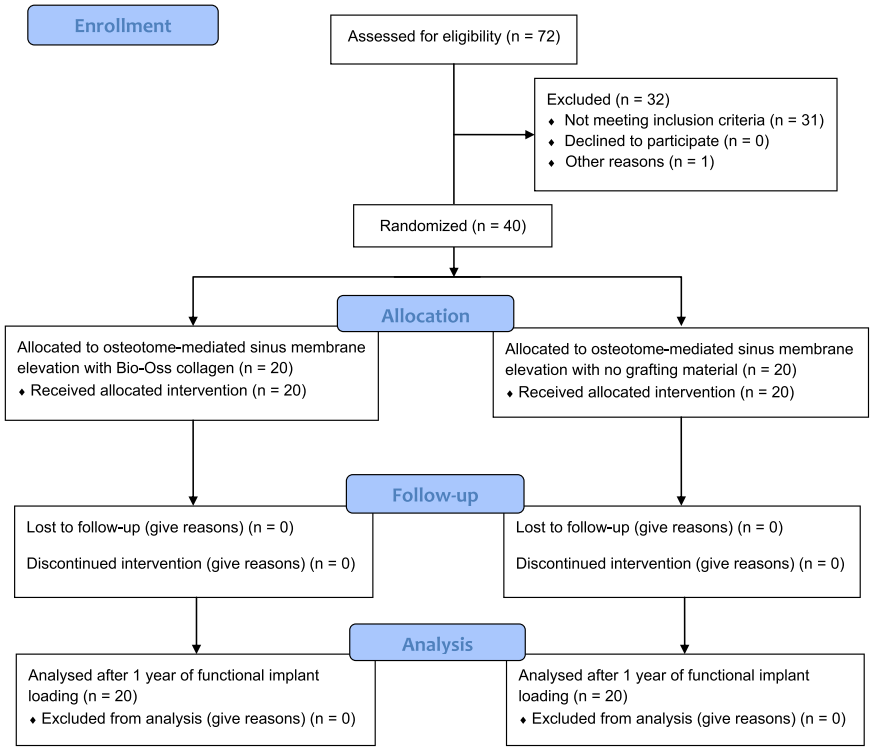

Fig. 1. CONSORT 2010 flow diagram of the study process.

Table 1. Inclusion and exclusion criteria.

Inclusion criteria:
- Age > 20 years
- Missing one posterior maxillary tooth for more than 4 months
- Residual alveolar bone height of the maxillary alveolar ridge ≥ 6 mm and ≤ 10 mm
- Width of the alveolar ridge ≥ 6.5 mm
- Mandibular occluding teeth
- Able to understand and sign the informed consent
- Single-tooth gaps, as well as free-end prosthetic solutions

Exclusion criteria:
- Absolute and relative contraindications to implant therapy, e.g. irradiated maxilla, serious systemic diseases, severe diabetes, medically compromised patients, or use of anti-resorptive drugs
- Full mouth plaque score > 25%
- Progressive marginal periodontitis
- Acute infection in the area intended for implant placement
- Parafunction, bruxism, or clenching
- Psychiatric problems or unrealistic expectations
- Heavy tobacco use, defined as > 10 cigarettes per day
- Current pregnancy at the time of recruitment
- Physical handicaps that would interfere with the ability to perform adequate oral hygiene
- Inability or unwillingness to regularly attend the scheduled follow-up visits

hydraulic technique. The implant site was also probed with an implant depth gauge to feel the presence of an intact membrane. If the membrane was largely perforated with communication to the maxillary sinus, the patient was withdrawn from the study.

A sealed randomization envelope was then opened in order to allocate the patient to OMSFE with Bio-Oss Collagen 250 mg (0.4–0.5 cm^3; Geistlich Pharma AG, Wolhusen, Switzerland) (test group), or OMSFE with no grafting material (control group). The patients were blinded to and not informed about the allocation group. In the test group, a Bio-Oss Collagen sponge was soaked in saline and applied through the implant site underneath the membrane. A straight 13 mm implant was inserted (diameter 3.6, 4.2, or 4.8 mm, Astra Tech Implant System EV; Dentsply Sirona, Mölndal, Sweden). An implant length of 13 mm was used in each case to standardize the groups. However, the implant diameter varied due to edentulism in both the premolar and molar region.

The implant stability quotient (ISQ) was determined by resonance frequency analysis using reusable MulTipeg transducers and a non-contact technique (Penguin; Integration Diagnostics Sweden AB, Gothenburg, Sweden). The measurement was repeated until the same value was recorded twice, and this was taken as the authentic value. A cover screw was then mounted before suturing (Vicryl Rapide 4–0, Ethicon FS-2; Ethicon, St-Stevens-Woluwe, Belgium). No provisional restoration was inserted.

The patients were instructed to rinse with 0.12% chlorhexidine solution twice a day until suture removal, after 7–10 days. They were also instructed to avoid any physical activity that may abruptly raise or lower the pressure in the sinus cavity, as well as to avoid vigorous mouth rinsing, smoking, and touching the gums for at least 10 days post-surgery. Postoperative analgesics were prescribed, including 400 mg ibuprofen (one tablet three times daily) and 500 mg paracetamol (two tablets four times daily), if required. Patients were prescribed postoperative antibiotics for 7 days, either 800 mg phenoxymethylpenicillin (two tablets three times daily) or 300 mg clindamycin (one tablet three times daily) in the case of penicillin allergy.

Healing abutment connection was performed under local anaesthesia, 6 months after OMSFE. The implant was exposed by a marginal incision on the alveolar process. The mucosa was reflected and the cover screw was removed. The ISQ was determined by Penguin resonance frequency analysis. A prefabricated healing abutment was mounted before suturing.

Prosthetic rehabilitation

The prosthetic rehabilitation was performed by the patient's regular dentist and was initiated 3 weeks after healing abutment connection. A definitive implant-supported restoration was fabricated using the patient-specific Atlantis abutment and a cemented or screw-retained single-crown restoration. Maintenance care and regular control of occlusion was conducted by the patient's regular dentist. The clinical procedures were handled according to the manufacturer's instructions.

Outcome measures

Outcome measures were assessed at enrolment (T0), OMSFE and implant placement (T1), healing abutment connection (T2), immediately after delivery of the prosthetic rehabilitation (T3), and 1 year after implant loading (T4). The outcome measures assessed were

survival of the suprastructure and implant, ISQ, PIMBL, PROMs, and biological and mechanical complications (Table 2).

ISQ was measured by resonance frequency analysis at T1 and T2.[23] The resonance frequency was displayed as a value ranging from 1 (lowest stability) to 99 (highest stability), where the value correlates to the micro-mobility of the implant.

PIMBL was estimated by a trained and calibrated assessor (T.S.J.) using linear measurements on digital periapical radiographs obtained at T1, T2, T3, and T4 using a photostimulable phosphor system (Digora FMX; Soredex Orion Corporation, Helsinki, Finland) and stored as.bmp files. The distance from the implant–abutment connection to the peri-implant bone level was measured mesially and distally in parallel with the long axis of the implant using open-source software ImageJ (National Institutes of Health, Bethesda, MD, USA). The linear measurement reference points were the coronal margin of the implant shoulder and the most coronal point of bone-to-bone contact.[24] Magnification, brightness, contrast, and gamma adjustment was used for image enhancement. The correction of magnification and calibration were based on the known distance of the microthreaded portion of the implant (3.5 mm), or the implant length (13 mm).

PROMs were evaluated during the consultation using the Oral Health Impact Profile-14 (OHIP-14) questionnaire at T0, T3, and T4, as well as a self-administered questionnaire to assess patient perceptions of the peri-implant soft tissue, implant crown, function of the implant, and total implant treatment, each recorded using 100-mm visual analogue scales (VAS; 0 = worst outcome to 100 = best outcome) at T3 and T4.[25–28] The OHIP-14 is organized into seven conceptual dimensions: functional limitation (Q1, Q2), physical pain (Q3, Q4), psychological discomfort (Q5, Q6), physical disability (Q7, Q8), psychological disability (Q9, Q10), social disability (Q11, Q12), and handicap (Q13, Q14) (Table 3). Two items are used to measure each dimension and consequently the OHIP-14 questionnaire consists of 14 items. The response format for the OHIP-14 was as follows: very often = 4; fairly often or many times = 3; occasionally = 2; hardly ever or nearly never = 1; never/I don't know = 0. The overall OHIP-14 score ranged from 0 to 56 and the score for each dimension ranged from 0 to 8. Values of the 14 items and each dimension were summed to calculate the OHIP-14 severity score, with higher scores indicating poorer oral health-related quality of life (OHRQoL). Instructions for completing the OHIP-14 and additional questionnaire were explained in detail. Patients completed the questionnaires by themselves, to prevent being influenced by the surgeon's or nurses' opinions and wills. Moreover, in order not to influence the responses to the questionnaire, the patients were not informed about their group allocation.

Biological and mechanical complications including infection, wound dehiscence, nasal bleeding, loss of the implant, migration of graft material, loss of the mounted crown, chipping of the ceramic, loosening of the abutment screw, or adverse events during the observation period were also recorded.

Table 2. Outcome measures.

Survival of the suprastructure; loss of the suprastructure was defined as a total loss because of a mechanical and/or biological complication
Survival of the implant; loss of the implant was defined as mobility of a previously clinically osseointegrated implant and removal of a non-mobile implant due to progressive peri-implant marginal bone loss and infection
Implant stability quotient as evaluated by resonance frequency analysis
Peri-implant marginal bone loss as evaluated by radiographic measurements
Patient-reported outcome measures as evaluated by self-administered questionnaires with visual analogue scales
Biological and mechanical complications as evaluated by clinical and radiographic assessment methods

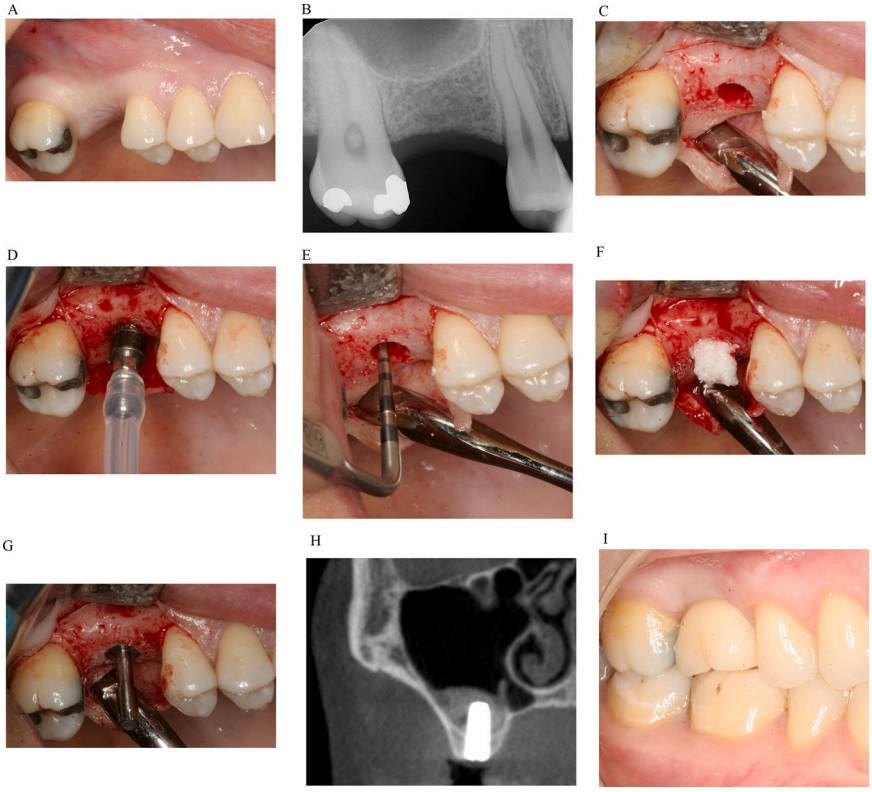

Fig. 2. (A, B) Missing right maxillary first molar with a residual bone height of 5 mm. (C) Preparation of the implant bed to the planned implant diameter, which was ended 1–2 mm beneath the maxillary sinus floor. (D) The Schneiderian membrane including the original maxillary sinus floor was elevated to the planned implant length using a hydraulic pressure technique (Sinus Physiolift II). (E) The implant site was gently probed with an implant depth gauge to feel the presence of an intact Schneiderian membrane. (F) Bio-Oss Collagen sponge was applied through the implant site underneath the Schneiderian membrane. (G) The implant stability quotient was determined by resonance frequency analysis (Penguin device). (H) Postoperative cone beam computed tomography image showing the elevated Schneiderian membrane, maintained by the inserted implant and the grafting material. (I) Final prosthetic solution after 1 year of functional implant loading.

Table 3. OHIP-14 questionnaire.

OHIP-14 dimension score	Question	
Functional limitation	Q1	Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?
	Q2	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?
Physical pain	Q3	Have you had painful aching in your mouth?
	Q4	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?
Psychological discomfort	Q5	Have you been self-conscious because of your teeth, mouth or dentures?
	Q6	Have you felt tense because of problems with your teeth, mouth or dentures?
Physical disability	Q7	Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?
	Q8	Have you had to interrupt meals because of problems with your teeth, mouth or dentures?
Psychological disability	Q9	Have you found it difficult to relax because of problems with your teeth, mouth or dentures?
	Q10	Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?
Social disability	Q11	Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?
	Q12	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?
Handicap	Q13	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?
	Q14	Have you been totally unable to function because of problems with your teeth, mouth or dentures?

Statistical analyses

The data management and analysis was conducted using Stata version 17 data analysis and statistical software (StataCorp LLC, College Station, TX, USA). The mean ± standard deviation were reported for continuous variables. Mean differences were expressed with the 95% confidence interval (CI). Comparisons of continuous variables were made by *t*-test on the mean difference, or by ordinary least squares (OLS) regression with robust variance estimation and clusters by participant ID. The level of significance was set at 0.05.

Results

Forty healthy patients underwent OMSFE with simultaneous implant placement; 27 were female and 13 were male, and their mean age was 49 years (range 24–74 years). The inclusion of patients in the study was initiated in October 2018 and the 1-year observation period was finalized in March 2022. The characteristics of the study patients in each group (OMSFE with Bio-Oss Collagen vs OMSFE with no grafting material) are outlined in Table 4. There was no significant difference in the distribution of age, smoker/non-smoker status, implant location, implant diameter, RBH, width of the alveolar process or implant diameter between the groups. The implant surface protrusion length within the maxillary sinus was significantly larger with Bio-Oss Collagen compared with no grafting material ($P = 0.026$). Moreover, significantly more female patients were included and allocated to the OMSFE with Bio-Oss Collagen group ($P = 0.041$).

CBCT obtained at enrolment revealed no maxillary sinus pathology, but mucosal thickening and sinus septa were frequently identified. A minor perforation of the Schneiderian membrane was suspected in one patient undergoing OMSFE without a grafting material, since a feeling of water in the nose was described. The patient was not excluded from the study due to the anticipated limited size of the perforation. Healing was uneventful in all patients and none of the patients needed an additional prescription of analgesics or antibiotic. No implant losses or early graft infections were observed, but five patients described minor epistaxis during the first postoperative days. A late infection occurred at 4 months following OMSFE with Bio-Oss Collagen, which was treated with an antibiotic and the removal of presumable Bio-Oss Collagen remnants underneath the buccal mucosa. All patients attended the 1-year examination and completed the OHIP-14 and additional questionnaire.

Survival of the suprastructure and implant were both 100% at T3 and T4, for both treatment modalities. All implants were restored with cemented or screw-retained single-crown restorations, which were well-functioning at T3 and T4.

The mean ISQ following OMSFE with Bio-Oss Collagen was 73.3 ± 9.7 at T1 and 80.0 ± 10.0 at T2. Corresponding measurements following OMSFE with no grafting material were 76.0 ± 8.8 and 82.1 ± 5.6. There was no significant difference in ISQ at T1 ($P = 0.351$) or T2 ($P = 0.406$) between the two treatments modalities. The ISQ increased significantly from T1 to T2 following OMSFE with Bio-Oss Collagen ($P = 0.006$) and following OMSFE with no grafting material ($P = 0.012$).

The results for PIMBL are outlined in Table 5. The implant shoulder was inserted at the same level or slightly below the surrounding bone, so PIMBL at T1 was set to zero. There was no significant difference in PIMBL at the mesial or distal implant surface at T2 ($P = 0.340$, $P = 0.279$), T3 ($P = 0.503$, $P = 0.595$), or T4 ($P = 0.936$, $P = 1.000$) between the two treatments modalities. A non-significant gradual bone loss from T1 to T4 was observed with both treatment modalities. An exposed cover screw with PIMBL and a small amount of pus secretion was found at T3 in one patient following

Table 4. Demographic characteristics of the included patients; mean ± standard deviation values.

	OMSFE with Bio-Oss Collagen $n = 20$	OMSFE with no grafting material $n = 20$	*P*-value
Sex, female/male, *n*	17/3	10/10	0.041*
Age at the time of OMSFE (years)	50.2 ± 14.2	48.1 ± 9.1	0.590
Smoking habit, *n*	0	1	1.000
Residual alveolar bone height (mm) at the implant site	6.8 ± 0.9	7.2 ± 1.1	0.356
Width of the alveolar ridge (mm) at the implant site	9.1 ± 0.6	9.1 ± 0.8	0.823
Implant location, *n*			
Second premolar	9	5	
First molar	11	12	
Second molar	0	3	
Implant diameter, *n*			0.501
3.6 mm	1	0	
4.2 mm	7	5	
4.8 mm	12	15	
Implant surface protrusion into the sinus (mm)	6.3 ± 1.2	5.4 ± 1.4	0.026*
ISQ			
T1	73.3 ± 9.7	76.0 ± 8.8	0.351
T2	80.0 ± 10.0	82.1 ± 5.6	0.406

ISQ, implant stability quotient; OMSFE, osteotome-mediated sinus floor elevation; T1, OMSFE and implant placement; T2, healing abutment connection.
*Statistically significant (*t*-test), $P < 0.05$.

Table 5. Peri-implant marginal bone loss (millimetres).

	OMSFE with Bio-Oss Collagen Mean ± SD (95% CI) $n = 20$				OMSFE with no grafting material Mean ± SD (95% CI) $n = 20$		*P*-value[a]	
	Mesial	Distal			Mesial	Distal	Mesial	Distal
T1 versus T2	0.1 ± 0.3 (−0.1 to 0.2)	0.1 ± 0.3 (−0.1 to 0.2)			0.0 ± 0.0 (0.0–0.0)	0.0 ± 0.0 (0.0–0.0)	0.340	0.279
T1 versus T3	0.2 ± 0.4 (0.0–0.3)	0.2 ± 0.5 (0.0–0.4)			0.1 ± 0.2 (0.0–0.2)	0.1 ± 0.3 (0.0–0.3)	0.503	0.595
T1 versus T4	0.2 ± 0.4 (0.0–0.4)	0.2 ± 0.5 (−0.1 to 0.5)			0.2 ± 0.4 (0.0–0.4)	0.2 ± 0.6 (−0.1 to 0.5)	0.936	1.000
			P-value[b]				*P*-value[b]	
			Mesial	Distal			Mesial	Distal
T2 versus T3	0.1 ± 0.4 (−0.1 to 0.3)	0.1 ± 0.5 (−0.1 to 0.3)	0.263	0.322	0.1 ± 0.2 (0.0–0.2)	0.1 ± 0.4 (0.0–0.3)	0.111	0.159
T2 versus T4	−0.1 ± 0.4 (−0.3 to 0.1)	−0.1 ± 0.6 (−0.4 to 0.1)	0.212	0.308	−0.2 ± 0.4 (−0.4 to 0.0)	−0.2 ± 0.6 (−0.5 to 0.1)	0.067	0.155
T3 versus T4	0.0 ± 0.1 (−0.1 to 0.0)	0.0 ± 0.2 (−0.1 to 0.1)	0.731	0.703	−0.1 ± 0.2 (−0.2 to 0.0)	−0.1 ± 0.3 (−0.2 to 0.1)	0.090	0.208

CI, confidence interval; OMSFE, osteotome-mediated sinus floor elevation; SD, standard deviation.
T1, implant placement; T2, healing abutment connection; T3, immediately after delivery of the prosthetic rehabilitation; T4, 1 year after implant loading.
[a]*P*-value for the comparison of peri-implant bone loss between the groups (inter-group comparisons).
[b]*P*-value for the comparison of peri-implant bone loss within each group (intra-group comparisons).

OMSFE with Bio-Oss Collagen, which was treated with an antibiotic and surgical debridement of the exposed implant surface, combined with autogenous bone grafting. Healing abutment connection was postponed for 3 months, until a healthy peri-implant tissue was present, as evaluated by clinical and radiographic measurements.

OHIP-14 and dimension scores in the OMSFE with Bio-Oss Collagen and OMSFE with no grafting material groups are reported in Tables 6 and 7, respectively. There was no significant difference in OHIP-14 score at T0 ($P = 0.362$), T3 ($P = 0.578$), or T4 ($P = 0.894$) between the two treatment modalities. OHIP-14 and dimension scores decreased significantly following OMSFE with Bio-Oss Collagen or no grafting material at T3 ($P = 0.005$, $P = 0.021$) and T4 ($P < 0.001$, $P < 0.001$) compared with T0, indicating significantly improved OHRQoL with both treatment modalities.

Patient perceptions of the peri-implant soft tissue, implant crown, function of the implant, and total implant treatment showed high values for all parameters at T3 and T4, with no significant difference between the two treatment modalities (Table 8).

The three-dimensional assessment of ESBG was assessed using CBCT and the results have been published in another paper.[29]

Discussion

This study demonstrated comparable survival rates of the suprastructures and implants, PIMBL, ISQ, frequency of complications, and patient satisfaction with the peri-implant soft tissue, implant crown, function of the implant, and total implant treatment following OMSFE with Bio-Oss Collagen compared with no grafting material, after 1 year of implant loading. A gradual decrease in OHIP-14 values revealed significant improvements in OHRQoL with both treatment modalities. Thus, neither of the treatment modalities can be considered better than the other. However, long-term RCTs are needed to verify this conclusion.

There are some limitations of this study that should be mentioned, including the small but statistically representative patient sample, inhomogeneous sex distribution, single-blind study design, use of non-standardized peri-apical radiographs, and the assessment of PROMs with a limited number of questionnaires. Moreover, the associations between socioeconomic status, educational background, monthly income, level of daily physical functioning and PROMs were not assessed. The conclusions drawn from the results of this study should therefore be interpreted cautiously.

OMSFE without a grafting material is associated with significant benefits for the patients and clinicians if comparable clinical and radiographic outcomes are obtained, due to reduced costs, a shortened operation time, and a reduced risk of infection or migration of the grafting material. Clinical and radiographic outcomes following OMSFE with or without a grafting material have been assessed previously in RCTs, revealing comparable clinical parameters,[16–21] which is in accordance with the results of the present study. However, these parameters do not necessarily reflect patient satisfaction with the surgical intervention or implant-supported restoration. Consequently, assessment of the implant treatment outcome should focus not only on objective criteria, but also include PROMs.[14,15]

Self-administered questionnaires are frequently used to evaluate OHRQoL and patient satisfaction with the surgical intervention or implant-supported restoration.[30,31] However, the comparison of PROMs following OMSFE with or without a grafting material has not been performed in any previous RCT using valid methods or questionnaires. In the present study,

Table 6. Oral Health Impact Profile-14 (OHIP-14) questionnaire—patients who underwent OMSFE with Bio-Oss Collagen.

Dimension		OMSFE with Bio-Oss Collagen																	
		T0						T3						T4					
		0	1	2	3	4	SDS	0	1	2	3	4	SDS	0	1	2	3	4	SDS
Functional limitation	Q1	19	1				1	19	1				1	19	1				1
	Q2	20						20						20					
Physical pain	Q3	9	9	2			29	16	4				6	17	2	1			13
	Q4	10	5	4	1			18	2					15	1	4			
Psychological discomfort	Q5	6	4	7	2	1	47	14	1	3	2		23	18		2			5
	Q6	11	1	6	2			15	1	3	1			19	1				
Physical disability	Q7	16	2	2			13	18	1	1			5	20					0
	Q8	14	5	1				18	2					20					
Psychological disability	Q9	15	1	4			39	18	2				14	20					5
	Q10	7	2	5	6			14	1	4	1			17	1	2			
Social disability	Q11	17	1	2			7	19	1				1	20					0
	Q12	19		1				20						20					
Handicap	Q13	11	5	3	1		16	18	2				2	20					0
	Q14	19		1				20						20					
		Total OHIP-14 score: 152						Total OHIP-14 score: 52*						Total OHIP-14 score: 24*					
		Mean ± SD: 7.60 ± 6.46						Mean ± SD: 2.70 ± 4.19*						Mean ± SD: 1.20 ± 2.19*					

Score: 0 = never; 1 = hardly ever or nearly never; 2 = occasionally; 3 = fairly often or many times; 4 = very often. OMSFE, osteotome-mediated sinus floor elevation; SD, standard deviation; SDS, subscale dimension score; T0, enrolment; T3, immediately after delivery of the prosthetic rehabilitation; T4, 1 year after implant loading.

*Statistically significant (*t*-test) compared with T0, $P < 0.05$.

Table 7. Oral Health Impact Profile-14 (OHIP-14) questionnaire—patients who underwent OMSFE with no grafting material.

Dimension		OMSFE without a grafting material																	
		T0						T3						T4					
		0	1	2	3	4	SDS	0	1	2	3	4	SDS	0	1	2	3	4	SDS
Functional limitation	Q1	18	2				3	20					4	20					0
	Q2	19	1					19				1		20					
Physical pain	Q3	11	5	3	1		30	16	3	1			8	18	1	1			4
	Q4	9	7	3	1			18	1	1				19	1				
Psychological discomfort	Q5	10	3	6	1		23	16	2	2			12	17	2		1		10
	Q6	16	3	1				15	4	1				17	1	2			
Physical disability	Q7	16	3	1			10	19	1				3	19	1				1
	Q8	16	3	1				18	2					20					
Psychological disability	Q9	13	4	2	1		27	18	2				8	18	2				4
	Q10	10	4	6				16	2	2				19		1			
Social disability	Q11	17	1	2			7	17	3				3	19	1				2
	Q12	18	2					20						19	1				
Handicap	Q13	15	3	2			9	18	1	1			3	19	1				1
	Q14	19		1				20						20					
		Total OHIP-14 score: 109						Total OHIP-14 score: 41*						Total OHIP-14 score: 22*					
		Mean ± SD: 5.75 ± 6.33						Mean ± SD: 2.05 ± 3.10*						Mean ± SD: 1.10 ± 2.53*					

Score: 0 = never; 1 = hardly ever or nearly never; 2 = occasionally; 3 = fairly often or many times; 4 = very often. OMSFE, osteotome-mediated sinus floor elevation; SD, standard deviation; SDS, subscale dimension score; T0, enrolment; T3, immediately after delivery of the prosthetic rehabilitation; T4, 1 year after implant loading.

*Statistically significant (*t*-test) compared with T0, $P < 0.05$.

comparable patient satisfaction with the peri-implant soft tissue, implant crown, function of the implant, and total implant treatment outcome was achieved with the two treatment modalities. A previous analysis of patient perceptions of recovery following OMSFE with Bio-Oss Collagen or no grafting material concluded that the influence of the surgical intervention on the patient's daily life activities was minimal and limited to the first post-operative days with both treatment modalities.[32] However, the numbers of days with pain, eating difficulties, and sleep disturbances were significantly increased with Bio-Oss Collagen compared with no grafting material.[32] OHRQoL relates to patient comfort when eating, sleeping, and engaging in social interactions, as well as their self-esteem and satisfaction with respect to their oral health.[33] Although OMSFE with Bio-Oss Collagen was associated with increased patient discomfort immediately after surgery, a significant and gradual improvement in OHRQoL was observed with both treatment modalities, immediately after delivery of the prosthetic rehabilitation and at 1 year of implant loading, when compared with preoperative values. Consequently, the application of Bio-Oss Collagen underneath the elevated Schneiderian membrane in conjunction with OMSFE seems not to positively improve PROMs or OHRQoL compared with no grafting material.

The placement of a grafting material underneath the elevated Schneiderian membrane in conjunction with OMSFE is intended to enhance the volume supporting the inserted implant and thereby improve bone regeneration and bone-to-implant contact.[2] The ISQ indicates the level of stability and osseointegration of the inserted implant. Previous RCTs assessing OMSFE with or without a grafting material have revealed a gradual increase in ISQ values with no significant difference between the treatment modalities used, at any time point.[16,17,34] In the present study, the ISQ values with both treatment modalities were significantly increased at healing abutment connection compared with implant placement, indicating that placement of a xenogeneic grafting material underneath the elevated membrane does not beneficially improve the ISQ compared with no grafting material, which is in accordance with the conclusions of previous RCTs.[16,17,34]

Within the limitations of this study, it can be concluded that the placement of Bio-Oss Collagen underneath the Schneiderian membrane in conjunction with osteotome-mediated sinus floor elevation seems not to improve the survival rate of the suprastructures or implants, peri-implant marginal bone loss, implant stability quotient, frequency of biological or mechanical complications, patient-reported outcome measures, or oral health-related quality of life compared with no grafting material, after 1 year of implant loading.

Ethical approval

The study protocol was approved by The North Denmark Region Committee on Health Research Ethics (approval No. N-20180027).

Patient consent

All included patients received verbal and written information about the study and signed an informed consent agreement prior to enrolment.

Trial registration

ClinicalTrials.gov registration number NCT04618900.

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Table 8. Subjective assessment of the implant treatment outcome as evaluated using a self-administered questionnaire with visual analogue scales.

Dimension	Variables (0 = no; 100 = yes)	OMSFE with Bio-Oss Collagen VAS score, mean ± SD *n* = 20		OMSFE with no grafting material VAS score, mean ± SD *n* = 20		*P*-value[a]	
		T3	T4	T3	T4	T3	T4
Peri-implant soft tissue	Satisfied with the look of the peri-implant soft tissue?	97.7 ± 4.7	99.0 ± 1.4	97.4 ± 3.7	96.4 ± 10.6	0.852	0.274
	Satisfied with the shape of the peri-implant soft tissue?	97.1 ± 6.3	99.0 ± 1.3	97.0 ± 5.4	98.5 ± 2.9	0.979	0.483
	Satisfied with the colour of the peri-implant soft tissue?	96.3 ± 10.0	99.0 ± 1.3	96.6 ± 5.1	97.0 ± 6.2	0.921	0.147
	Average score	97.0 ± 6.3	99.0 ± 1.3	97.0 ± 4.0	97.3 ± 4.4	0.992	0.098
Prosthetic solution	Satisfied with the look of the implant crown?	98.4 ± 4.2	99.0 ± 1.4	96.0 ± 10.1	97.5 ± 6.9	0.324	0.332
	Satisfied with the shape of the implant crown?	95.3 ± 8.9	97.5 ± 4.4	93.9 ± 11.7	91.8 ± 15.8	0.661	0.122
	Satisfied with the colour of the implant crown?	95.4 ± 9.1	97.5 ± 4.8	88.0 ± 20.3	92.0 ± 16.0	0.143	0.154
	Average score	96.4 ± 6.9	98.0 ± 3.3	92.6 ± 12.2	93.8 ± 12.1	0.234	0.135
Implant function	Satisfied with the function of implant?	96.2 ± 8.0	98.5 ± 2.7	92.5 ± 13.5	95.5 ± 7.6	0.298	0.107
	Experienced problems with the implant, when you speak?	97.8 ± 4.6	99.0 ± 1.7	97.5 ± 3.3	96.2 ± 11.5	0.844	0.287
	Experienced problems with the implant, when you eat?	98.2 ± 3.8	98.7 ± 1.9	98.3 ± 2.5	99.0 ± 1.9	0.883	0.510
	Experienced problems with implant, when tooth brushing?	95.8 ± 9.1	99.3 ± 1.2	98.5 ± 2.7	98.8 ± 1.8	0.222	0.407
	Average score	97.0 ± 5.2	98.8 ± 1.6	96.7 ± 4.8	97.4 ± 3.8	0.858	0.127
Treatment	Satisfied with the implant treatment outcome in general?	97.7 ± 5.2	98.3 ± 3.9	96.8 ± 8.1	97.8 ± 5.5	0.678	0.690

SD, standard deviation; T3, immediately after delivery of the prosthetic rehabilitation; T4, 1 year after implant loading; VAS visual analogue scale (0–100, with 0 indicating the worst outcome and 100 indicating the best outcome).
[a]*P*-value for the comparison between the groups at T3 and T4; *t*-test.

C-ReDiT authorship contribution statement

Thomas Starch-Jensen: Conception and design of study, Acquisition of data: laboratory or clinical, Analysis of data, Drafting of article and/or critical revision, Final approval of manuscript. **Niels Henrik Bruun:** Analysis of data, Drafting of article and/or critical revision, Final approval of manuscript. **Rubens Spin-Neto:** Conception and design of study, Analysis of data, Drafting of article and/or critical revision, Final approval of manuscript.

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Competing interests

All authors declare no financial interest or conflict of interest, either direct or indirect, in relation to the products or information reported in the article. However, Thomas Starch-Jensen gives lectures for Dentsply Sirona and Plandent (Danish distributor of Geistlich products).

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ijom.2022.12.009.

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