Patient's perception of recovery after sinus membrane elevation and blood coagulum compared with 1:1 mixture of autogenous bone graft and deproteinized porcine bone mineral. Secondary outcomes from a single-blinded randomized controlled trial

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Patient´s perception of recovery after sinus membrane elevation and blood coagulum compared with 1:1 mixture of autogenous bone graft and deproteinized porcine bone mineral. Secondary outcomes from a single-blinded randomized controlled trial

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Author contributions

T.S-J. conceived the ideas; T.S-J. performed the surgeries and collected the data; N.H.B and T.S-J. analyzed the data; T.S.-J. led the writing; T.S.-J. and N.H.B revised and approved the final manuscript.

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Abstract

Objective: The objective was to assess patient´s perception of recovery after maxillary sinus membrane elevation (MSME) and blood coagulum (test) compared with maxillary sinus floor augmentation (MSFA) and 1:1 mixture of autogenous bone graft from the buccal antrostomy and deproteinized porcine bone mineral (DPBM) (control).

Material and methods: Forty healthy patients were randomly allocated to test or control. Oral health-related quality of life (OHRQoL) was evaluated by Oral Health Impact Profile-14 (OHIP-14) at enrolment and one week postsurgical. Recovery was estimated by questionnaires and visual analog scale assessing pain, social and working isolation, physical appearance, eating and speaking ability, diet variations, sleep impairment and discomfort after one week and one month. Mean differences were expressed with 95% confidence interval (CI). Association between OHRQoL and recovery were estimated. P-value below 0.05 was considered significant.

Results: MSME revealed 2.1 less days of pain (p = 0.03, 95% CI: 0.2-4.1) and 1.2 days of sick leave (p = 0.01, 95% CI: 0.3-2.1) compared with MSFA. No significant difference was observed in eating and speaking ability, physical appearance, work performance and sleep impairment. No significant association between impaired OHRQoL and recovery was observed. Females reported 4.77 higher OHIP-14 score compared with males (p = 0.01, 95% CI: 1.60-7.94), while association between age and OHIP-14 was -0.10 (p = 0.28, 95% CI: -0.28-0.08).

Conclusion: MSME revealed significantly less days of pain and sick leave compared with MSFA. Harvesting of autogenous bone graft seems therefore to have a significant impact on perception of recovery.

Key words

Alveolar ridge augmentation; dental implants; quality of life; randomized controlled trial; sinus floor augmentation

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Approval

The study protocol was approved by The North Denmark Region Committee on Health Research Ethics (approval no: N-20180080) and registered in Clinicaltrials.gov (registration no: NCT04667260).

1 | Introduction

Autogenous bone graft is generally considered as the preferred grafting material for maxillary sinus floor augmentation (MSFA) due to its osteoinductive, osteoconductive and osteogenic potentials (Chavda & Levin, 2018; Janssen, Weijs, Koole, Rosenberg, Meijer, 2014), and long-term studies have revealed high survival rates of suprastructures and implants, limited peri-implant marginal bone loss, few complications, and high patient satisfaction (Boven, Slot, Raghoebar, Vissink, Meijer, 2017; Maddalone, et al., 2018; Nissen & Starch-Jensen, 2019; Slot, Raghoebar, Cune, Vissink, Meijer, 2019). However, harvesting of autogenous bone graft is associated with supplementary surgery and risk of donor site morbidity (Carlsen, Gorst-Rasmussen, Jensen, 2013; Cordaro, Torsello, Miuccio, Torresanto, Eliopoulos, 2011; Starch-Jensen, Deluiz, Deb, Bruun, Tinoco, 2020). Bone substitutes of biologic or synthetic origin are therefore commonly used alone or in combination with diminutive quantity of autogenous bone graft to simplify the surgical

procedure by diminishing the need for bone harvesting (Danesh-Sani, Engebretson, Janal, 2017; Lundgren, et al., 2017; Starch-Jensen, Mordenfeld, Becktor, Jensen, 2018). Moreover, the use of a grafting material is occasionally omitted since elevation of the sinus membrane with blood coagulum formation round the exposed implant surface protruding into the maxillary cavity have revealed bone regeneration in accordance with the principles of guided tissue regeneration (Lundgren, Andersson, Gualini, Sennerby, 2004; Nyman, 1991).

Maxillary sinus membrane elevation (MSME) applying the lateral window technique without a grafting material and simultaneous implant placement have demonstrated high survival rates of suprastructures and implants, intrasinus bone regeneration, and limited peri-implant marginal bone loss, as documented in systematic reviews (Moraschini, Uzeda, Sartoretto, Calasans-Maia, 2017; Silva, et al., 2016; Starch-Jensen & Schou, 2017). These results are in accordance with a newly published long-term study revealing an overall implant survival of 95.9% and intrasinus bone gain of 4.0mm after MSME and blood coagulum (Lundgren, Johansson, Cricchio, Lundgren, 2019). Short-term studies have reported successful implant treatment outcome and high patient satisfaction with the prosthetic rehabilitation after MSME and blood coagulum compared with MSFA using different grafting materials (Altintas, Senel, Kayıpmaz, Taskesen, Pampu, 2013; Borges, et al., 2011; Lie, et al., 2015). However, patient's perception of recovery after MSME and blood coagulum compared with MSFA and autogenous bone graft alone or in combination with a bone substitutes have never previously been investigated.

From a clinical and patient perspective, it would be an advantage, if postoperative discomfort and recovery could be improved by avoiding the need for autogenous bone harvesting in conjunction with MSFA. Therefore, the objective of the present single-blinded randomized controlled trial was to assess patient´s perception of recovery after MSME and blood coagulum compared with MSFA and 1:1 mixture of autogenous bone graft and deproteinized porcine bone mineral (DPBM) using validated self-administrated questionnaires.

2 | MATERIAL AND METHODS

2.1 Study design

The protocol was prepared in accordance with guidelines for reporting randomized controlled studies (CONSORT) (http://www. consort-statement.org/). The study protocol was approved by

The North Denmark Region Committee on Health Research Ethics (approval no: N-20180080) and registered in Clinicaltrials.gov (registration no: NCT04667260). The power calculation was based on the primary outcome, which is peri-implant marginal bone loss after five years. However, the primary outcome measure used to calculate sample size is not reported in this manuscript. Hence, the reported outcome measures of the present study are considered secondary outcome measures. Based on sample size calculation and assuming a 15% dropout rate, it was planned to enrol 20 patients for each treatment group, in order to detect a 20% difference with a standard deviation of 15 between the two groups in long-term peri-implant marginal bone loss, with a power of 0.8 and a significance level equal to 0.05. Patients were recruited by public invitation through Facebook or admitted to the Department of Oral and Maxillofacial surgery, Aalborg University Hospital, Aalborg, Denmark for implant placement in the posterior maxilla. Candidates were screened for inclusion and exclusion criteria at enrolment (Table 1). Included patients received written as well as verbal information about the study protocol and signed an informed consent form before initiating the study. A total of 40 partially edentulous healthy patients with a missing posterior maxillary tooth were included and randomly allocated to MSME and blood coagulum (test group) or MSFA with 1:1 mixture of autogenous bone graft and DPBM (control group). A computer-aided block randomization (R-package "blockrand") was used to allocate included patients into two groups, with a block size of two. The randomized code was available in closed identical non-transparent sealed envelopes. Immediately before surgery, patients were randomly assigned to either test or control group, without knowing which treatment modality there were assigned.

2.2 Surgical procedure

One hour prior to surgery, patients were pre-medicated with analgesics involving 400mg Ibuprofen (Burana, Teva, Denmark) and 1000mg Paracetamol (Pamol, Takeda Pharma A/S, Denmark) and prophylactic antibiotic therapy including 2g Amoxicillin (Imadrax, Sandoz, Denmark) or clindamycin 600mg (Dalacin, Alternova, Denmark) if allergic to penicillin. All patients rinsed with 0.12% chlorhexidine solution for one minute immediately before surgery. The surgical procedures were conducted by the same trained surgeon (TSJ) in local anesthesia using Lidocaine (2%) with 1:200,000 adrenaline (Xylocaine, Amgros I/S, Denmark). A horizontal crestal incision was made from tuber maxillae with an anteriorly vertical releasing incision. A full

thickness mucoperiosteal flap was raised to expose the lateral maxillary sinus wall. A 1 x 1 cm window to the maxillary sinus was created with metal and diamond burrs. The Schneiderian membrane was carefully elevated from the sinus floor as well as the lateral sinus wall and displaced dorsocranially with blunt dissector. If a minor perforation of the Schneiderian membrane occurred, it was covered with a resorbable Symbios pre-hydrated collagen membrane (Dentsply Sirona Implants, Mölndal, Sweden). If the Schneiderian membrane was largely perforated with a huge communication to the sinus cavity, the patient was withdrawn from the study. An implant bed was successively prepared on the top of the alveolar crest following manufactory's recommendations at 1500 rpm. A straight 13 mm implant (OsseoSpeed EV, Astra Tech Implant System, diameter 3.6, 4.2, or 4.8, Dentsply Sirona Implants, Mölndal, Sweden) was inserted with a cover screw. The Schneiderian membrane with the lateral bone window was preserved in the elevated position by the apical part of the implant maintaining the created space between the elevated membrane and original floor of the maxillary sinus. In the test group, a total of 2 ml autogenous blood was aspirated from the surgical site and injected underneath the Schneiderian membrane around the exposed implant surface protruding into the maxillary cavity. In the control group, autogenous bone graft was harvested with a curved SafeScraper (Fischer Medical ApS, Glostrup, Denmark) from the buccal antrostomy. A total of 1.0 cm^3 autogenous bone graft as estimated by specially prepared stainless-steel cups (1.0 cm^3) and mixed with 1.0 ml DPBM (Symbios xenograft granules, Grain size 1.0 mm to 2.0 mm, Dentsply Sirona Implants, Mölndal, Sweden). The grafting material was soaked in autogenous blood from the surgical site and packed underneath the Schneiderian membrane around the exposed implant surface protruding into the maxillary cavity. The created window to the maxillary sinus was covered with a Symbios pre-hydrated collagen membrane (20 mm x 30 mm, Dentsply Sirona Implants, Mölndal, Sweden). Periosteum and mucosa were sutured with Vicryl 4-0 (Ethicon FS-2, Ethicon, St-Stevens-Woluwe, Belgium). No provisional restoration was inserted during the healing period. Patients were instructed to rinse with 0.12% chlorhexidine solution twice a day until suture removal has taken place after 7-10 days. Moreover, patients were instructed to avoid any physical activity that will abruptly raise or lower pressure in the sinus cavity as well as avoiding vigorous mouth rinsing, smoking and touching the gums for at least 10 days following surgery. Postoperative analgesic was prescribed involving 400mg Ibuprofen, 1 tablet 3 times daily and 500mg paracetamol, 2 tablets 4 times per day, as long as required. All patients were prescribed postoperative antibiotics involving 800mg Phenoxymethylpenicillin (Primcillin, Meda, Denmark), 2 tablets 3 times daily

for 7 days. In case of penicillin allergy, 300mg Clindamycin, 1 tablet 3 times daily for 7 days was used.

2.3 Outcome measures

Oral Health Impact Profile-14 (OHIP-14) was used to assess oral health-related quality of life (OHRQoL) at enrolment and one week after the surgical intervention. OHIP-14 is organized into seven conceptual dimensions including functional limitation, physical discomfort, psychological discomfort, physical disability, psychological disability, social disability and handicap (Slade & Spencer, 1994; Slade, 1997). Two items are used to measure each dimension and consequently the questionnaire consists of 14 items. Response format of 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 OHIP-14 scale ranged from 0 to 56 and dimension score ranged from 0 to 8. The values of the 14 items and each dimension were summed to calculate the OHIP-14 severity score, with higher scores indicating poorer OHRQoL.

Patient´s perception of recovery including pain, oral function impairments, general activity and other symptoms was assessed after one week. A self-administrated questionnaire examined social isolation, working isolation, physical appearance and mean duration of the quality of life alterations as well as questions whether they would undergo similar treatment again, if needed or if they would recommend this treatment to a friend or a relative, if indicated. Response format was yes or no. Eating ability and diet variations, speaking ability noticed, sleep impairment, pain and discomfort at suture removal was also examined through self-administrated questionnaire after one week. Each item was evaluated by means of a four-point Likert-type rating scale. Response format was as follows: Not at all = 0; close to normal = 1; almost normal = 2; a little = 3. The rating score was calculated, with higher score indicating poorer patient recovery. A self-administrated questionnaire also examined how many days they have been on sick leave or been off work, had eating and speech difficulties, and how long their sleep and physical activity have been affected.

Patient´s perception of recovery was also examined by a self-administrated questionnaire after one month and supplemented by a 100mm (0 = minimal to 100 = maximum) visual analogue scale (VAS) assessing pain, social isolation, working isolation, eating ability, speaking ability and sleep impairment.

Instructions for completing OHIP-14, self-administrated questionnaires and VAS were explained in detail to all patients. Patients completed the questionnaires by themselves, to prevent

being influenced by the surgeons or nurses' opinions and wills. Moreover, in order not to influence the compilation of the questionnaire, patients were not informed about their allocation group.

Intra- and postoperative complications including perforation of the Schneiderian membrane, bleeding, infection, wound dehiscence, nasal bleeding, explantation of implant or grafting material, exfoliation of grafting material or other adverse events were also registered.

2.4 Statistical analyses

Data management and analysis was conducted using STATA (Data analysis and statistical software, version 16, StataCorp P, Texas, USA). Patient characteristics at enrolment were reported as mean and standard deviation. Continuous data were compared by t-test and categorical by Fisher´s exact test. OHIP-14 were presented as distribution by score values, total score by dimension as well as mean and standard deviation at enrolment and after one week. Mean difference in OHIP-14 score after one week were estimated with 95% confidence interval (CI) using ordinary least square (OLS) regression and adjusted for OHIP-14 score at enrolment. Standard error was estimated by bootstrap (10000 replications and accelerated bias-corrected CI). Patient´s perception of recovery for binary and Likert scale data were reported by distribution using Fisher´s exact test. VAS and days type data were reported as mean and standard deviation. Differences in mean were estimated with OLS regression model and expressed with 95% CI. Association between OHIP-14 score at enrolment and patient´s perception of recovery was analyzed by dichotomizing OHIP-14 score into two groups (< 10 or ≥ 10) using bootstrapped t-test (10000 replications and accelerated bias-corrected CI). Association between OHIP-14 score at enrolment and age or gender was analyzed by OLS regression and bootstrap (10000 replications and accelerated bias-corrected CI). Level of significance was 0.05.

3 | RESULT

Forty patients were included and allocated to simultaneous implant placement in conjunction with MSME and blood coagulum or MSFA with 1:1 mixture of autogenous bone graft and DPBM. Patient characteristics are outlined in Table 2. One patient allocated to MSME and blood coagulum never showed up for treatment and did not respond to several calls, mails or text messages. Consequently, the patient was excluded from the study.

Minor perforation of the Schneiderian membrane occurred in seven patients (test: 3, control: 4). All perforations were covered with a resorbable Symbios pre-hydrated collagen membrane. Healing was uneventful in all patients and none of the included patients needed additional prescription of analgesics or antibiotic. All patients attended postsurgical examinations and completed OHIP-14, self-administrated questionnaires and VAS.

Mean OHIP-14 score was 9.5 (SD: 7.5) and 6.5 (7.0), at enrolment and one week after MSME (Table 3). Corresponding measurements for MSFA were 8.0 (4.5) and 8.2 (6.5) (Table 4). Adjusted OHIP-14 score (by OHIP-14 at enrolment) was 2.4 higher in conjunction with MSFA ($p = 0.21$, 95% CI: -1.4-6.1) compared with MSME, after one week. Physical pain, psychological discomfort and disability presented highest OHIP-14-dimension score, while functional limitation and social disability exhibited the lowest score indicating that self-consciousness, tension and embarrassment as well as painful aching and limitations in eating were the factors which were significantly affected in both groups.

Questionnaires after one week revealed no significant differences on patient's daily life activities between the two treatment modalities, apart from significant more patients answered that the surgical intervention has been better than expected following MSME ($p = 0.01$) (Table 5 and 6). Most patients were satisfied with the treatment and would recommend it to friends and relatives (Table 5). MSME revealed 2.1 less days of pain ($p = 0.03$, 95% CI: 0.2-4.1) and 1.2 days of sick leave ($p = 0.01$, 95% CI: 0.3-2.1) compared with MSFA, whereas no significant differences were observed in eating and speaking ability, physical appearance and sleep impairment (Table 7).

Association between impaired OHRQoL (OHIP-14 score ≥10) at enrolment and patient´s perception of recovery revealed no significant difference. However, a tendency to increase number of days with pain and sick leave from daily activities were observed in conjunction with MSME and impaired OHRQoL at enrolment (Table 8). Patient´s perception of recovery after MSFA seems to be unaffected by OHRQoL at enrolment, although number of days with deteriorated eating and speaking ability were significantly increased in patients with unimpaired OHRQoL (Table 8). Association between age and OHIP-14 score at enrolment was -0.10 ($p = 0.28$, 95% CI -0.28-0.08), whereas females revealed a 4.77 higher OHIP-14 score compared with males ($p = 0.01$, 95% CI: 1.60-7.94).

4 | DISCUSSION

Patient´s perception of recovery after MSME and blood coagulum compared with MSFA and 1:1 mixture of autogenous bone graft from the buccal antrostomy and DPBM was assessed in the present study using OHIP-14, self-administrated questionnaires and VAS. Low frequency of intra- and postoperative complications, satisfaction with the treatment and willingness to undergo the same type of surgery as well as moderate influence on daily life activities was observed with both treatment modalities. However, number of days with pain and sick leave were significantly diminished after MSME with blood coagulum compared with MSFA involving harvesting of autogenous bone graft, whereas no significant differences were observed in eating and speaking ability, physical appearance, work performance and sleep impairment. There was no significant association between OHRQoL at enrolment and patient´s perception of recovery with both treatment modalities, although a tendency to increased number of days with pain and sick leave were observed following MSME and blood coagulum in patients with impaired OHRQoL.

MSFA with autogenous bone graft from the buccal antrostomy was associated with increased postsurgical discomfort. A number of patients expressed significantly interoperative discomfort in conjunction with the use of SafeScraper indicating that the increased number of days with pain seems to be associated with the harvesting procedure and not application of the grafting material.

Implant survival rate and peri-implant marginal bone loss are the most commonly used criteria to define a successful implant treatment outcome (Papaspyridakos, Chen, Singh, Weber, Gallucci, 2012). However, clinical parameters do not necessarily reflect patient´s anticipations and satisfaction with the surgical intervention or the implant-supported restoration. Assessment of oral rehabilitation with dental implants should therefore be supplemented by patient-reported outcome measures, as suggested in a recent ITI Consensus Report (De Bruyn, Raes, Matthys, Cosyn, 2015; Feine, et al., 2018). Previous systematic reviews have revealed that patient-reported outcome measures after MSME with blood coagulum or MSFA with a grafting material are seldom reported (Raghoebar, Onclin, Boven, Vissink, Meijer, 2019; Starch-Jensen & Schou, 2017; Starch-Jensen, et al., 2018). Furthermore, patient´s perception of recovery after MSME and blood coagulum have never been assessed or compared with MSFA, phrased one study, which reported high satisfaction with the prosthetic rehabilitation after MSME with blood coagulum and a degradable poly-lactide-membrane as a spaceholder in conjunction with delayed implant placement as compared with MSFA and mixture of autogenous and Bio-Oss (Geistlich Biomaterials GmbH, Wolhusen, Switzerland) (Lie, et al., 2015).

Patient-reported outcome measures and OHRQoL reflects psychosocial parameters related to patient´s perception of the surgical intervention and recovery including pain, swelling, bruising, inability to eat and sleep, physical appearance, working and social interaction as well as their self-esteem and satisfaction with their oral health. Patient´s perception of recovery after MSFA have previously been assessed in few studies (Alayan & Ivanovski, 2018; Almahrous, et al., 2020; Farina, et al., 2018; Mardinger, Poliakov, Beitlitum, Nissan, Chaushu, 2009; Younes, Cosyn, De Bruyckere, Cleymaet, Eghbali, 2019). Mild to moderate pain and inability to participate in daily activities for 2 and 3 days have been reported after MSFA with 1:1 mixture of autogenous bone graft harvested from the buccal antrostomy and bone substitute as evaluated by questionnaire, five-point Likert-type scale and VAS (Alayan & Ivanovski, 2018). A weak of mild to moderate pain have been reported by most of the patients after MSFA with an undescribed grafting material as evaluated by four-point Likert-type rating scale and verbal rating scale (Almahrous, et al., 2020). All patients were either satisfied or very satisfied with the treatment outcome and 92% would recommend the treatment, after one year (Almahrous, et al., 2020). Pain has been reported to be most pronounced on the first postoperative day and significantly declining to presurgical values on day 7 after MSFA with a bone substitute alone as evaluated by questionnaire and VAS (Farina, et al., 2018). Mouth opening, eating and speaking ability as well as participating in routine daily activities were significantly reduced during the first week. However, most of the patients indicated willingness to undergo same type of surgery if needed (Farina, et al., 2018). Pain, restricted mouth opening and inability to participate in routine daily activities have been reported to be most pronounced on the first postoperative day and declining in most patients on days 4 and 5 after MSFA with different bone substitutes alone and simultaneous implant placement as evaluated by questionnaire (Mardinger, et al.). The median sick leave was 5 days, and more than half of the patients had 3 days off work. However, 10-20% of the patients described persisting pain, restricted mouth opening, swelling, inability to participate in routine daily activities, and had not returned to work after one week (Mardinger, et al.). Highest VAS score of pain, swelling, and hematoma had been reported on the first day after surgery with significant decline between days 3 and 7 after MSFA with a bone substitute alone and delayed implant placement as evaluated by questionnaire and VAS (Yones, et al.). Moreover, 95.5% of the patients described that they would undergo the treatment again (Yones, et al.). The results of the above studies seem to be in accordance with the results of the present study revealing that MSFA with or without harvesting of autogenous bone graft is associated with pain, sick leave as well as interference with general

activities and inability to participate in routine daily activities for approximately 3 to 5 days, which is significantly more noticeable compared with MSME and blood coagulum as described in the present study.

Patient´s perception of recovery is generally influenced by patient-related predictors, presurgical expectations and psychologic well-being involving anxiety and levels of distress (Phillips, Kiyak, Bloomquist, Turvey, 2004). A previous study assessing patient´s perception of recovery after MSFA concluded that younger age and female were patient-related predictors for delayed recovery (Mardinger, et al.). In the present study, no association between OHIP-14 score at enrolment and age was identified, but females reported significantly higher OHIP-14 score compared with men. Moreover, no significant association between impaired OHRQoL at enrolment and patient´s perception of recovery was identified with the two treatment modalities, although a tendency to increase number of days with pain and sick leave from daily activities were observed in conjunction with MSME and impaired OHRQoL.

OHIP-14 questionnaire is a reliable instrument for measuring changes in OHRQoL. However, the non-significant improvement in OHIP-14 score between enrolment and one week following MSME is not assumed to be a factual improvement in OHRQoL, but rather a symbolic phrase of patient satisfaction with the surgical intervention as well as diminished postsurgical discomfort.

The present study is characterized by following limitations including small patient sample, solely collecting postsurgical informations corresponding to one week and one month, and no systematic registration of quantity and period of need for analgesics with the two treatment modalities. Moreover, correlation between patient´s perception of recovery and socioeconomic status, educational background, and level of daily physical functioning were not assessed. Conclusions drawn from the results of this study should therefore be interpreted with caution and the above-mentioned aspects are recommended to be incorporated in future studies focusing on patient´s perceptions of recovery following alveolar ridge augmentation in the posterior part of the maxilla.

5 | CONCLUSION

Within the limitations of the present study, it can be concluded that MSME and blood coagulum is associated with significantly less days of pain and sick leave compared with MSFA and 1:1

mixture of autogenous bone graft from the buccal antrostomy and DPBM, whereas no significant difference was observed in eating and speaking ability, physical appearance and sleep impairment. High satisfaction and willingness to undergo the same type of surgery were reported with both treatment modalities and preoperative impaired OHRQoL seems not to predispose for delayed recovery.

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Competing interests

None.

Ethical approval

The study was approved by The North Denmark Region Committee on Health Research Ethics (approval no: N-20180080).

Patient consent

Included patients received written as well as verbal information about the study protocol and signed an informed consent form before initiating the study

Disclosure

The authors claim to have no financial interest, either directly or indirectly, in the products or information listed in the article.

Reference

Alayan, J. & Ivanovski, S. (2018). A prospective controlled trial comparing xenograft/autogenous bone and collagen-stabilized xenograft for maxillary sinus augmentation-Complications, patient-reported outcomes and volumetric analysis. *Clin Oral Implants Res*, 29(2):248-262. https://doi.org/10.1111/clr.13107

Almahrous, G., David-Tchouda, S., Sissoko, A., Rancon, N., Bosson, J.L. & Fortin, T. (2020). Patient-Reported Outcome Measures (PROMs) for Two Implant Placement Techniques in Sinus Region (Bone Graft versus Computer-Aided Implant Surgery): A Randomized Prospective Trial. *Int J Environ Res Public Health*, 25;17(9):2990. https://doi.org/10.3390/ijerph17092990

Altintas, N.Y., Senel, F.C., Kayıpmaz, S., Taskesen, F., & Pampu, A.A. (2013). Comparative Radiologic Analyses of Newly Formed Bone After Maxillary Sinus Augmentation With and Without Bone Grafting. *J Oral Maxillofac Surg*, 71(9):1520-1530. https://doi.org/10.1016/j.joms.2013.04.036

Borges, F.L., Dias, R.O, Piattelli, A., Onuma, T., Cardoso, L.A.G.C., Salomão, M., Scarano, A., Ayub, E., & Shibli, J.A. (2011). Simultaneous Sinus Membrane Elevation and Dental Implant Placement Without Bone Graft: A 6-month Follow-Up Study. *J Periodontol*, 82:403-412. https://doi.org/10.1902/jop.2010.100343

Boven, G.C., Slot, J.W.A., Raghoebar, G.M., Vissink, A., & Meijer, H.J.A. (2017). Maxillary Implant-Supported Overdentures Opposed by (Partial) Natural Dentitions: A 5-year Prospective Case Series Study. J Oral Rehabil, 2017;44(12):988-995. https://doi.org/10.1111/joor.12557

Carlsen, A., Gorst-Rasmussen, A., & Jensen, T. (2013). Donor site morbidity associated with autogenous bone harvesting from the ascending mandibular ramus. *Implant Dent*, 22:503-536. https://doi.org/10.1097/ID.0b013e318296586c

Chavda, S., & Levin, L. (2018). Human studies of vertical and horizontal alveolar ridge augmentation comparing different types of bone graft materials: A systematic review. *J Oral Implantol*, 44:74-84. https://doi.org/10.1563/aaid-joi-D-17-00053

Cordaro, L., Torsello, F., Miuccio, M.T., di Torresanto, V.M., & Eliopoulos, D. (2011). Mandibular bone harvesting for alveolar reconstruction and implant placement: subjective and objective cross-sectional evaluation of donor and recipient site up to 4 years. *Clin Oral Implants Res*, 22:1320-1326. https://doi.org/10.1111/j.1600-0501.2010.02115.x

Danesh-Sani, S.A., Engebretson, S.P., & Janal, M.N. (2017). Histomorphometric Results of Different Grafting Materials and Effect of Healing Time on Bone Maturation After Sinus Floor Augmentation: A Systematic Review and Meta-Analysis. J Periodontal Res, 52(3):301-312. https://doi.org/10.1111/jre.12402

De Bruyn, H., Raes, S., Matthys, C., & Cosyn, J. (2015) The current use of patient-centered/reported outcomes in implant dentistry: a systematic review. *Clin Oral Implants Res*, 26Suppl11:45-56. https://doi.org/10.1111/clr.12634

Farina, R., Franceschetti, G., Travaglini, D., Consolo, U., Minenna, L., Schincaglia, G.P., Riccardi, O., Bandieri, A., Maietti, E. & Trombelli, L. (2018) Morbidity following transcrestal and lateral sinus floor elevation: A randomized trial. *J Clin Periodontol*, 45(9):1128-1139. https://doi.org/10.1111/jcpe.12985

Feine, J., Abou-Ayash, S., Al Mardini, M., de Santana, R.B., Bjelke-Holtermann, T., Bornstein, M.M., Braegger, U., Cao, O., Cordaro, L., Eycken, D., Fillion, M., Gebran, G., Huynh-Ba, G., Joda, T., Levine, R., Mattheos, N., Oates, T.W., Abd-Ul-Salam, H., Santosa, R., Shahdad, S., Storelli, S., Sykaras, N., Santos, A.T., Webersberger, S.U., Williams, M.A.H., Jr Wilson, T.G., Wismeijer, D., Wittneben, J.G., Yao, C.J., & Zubiria, J.P.V. (2018). Group 3 ITI Consensus Report: Patient-reported outcome measures associated with implant dentistry. *Clin Oral Implants Res*, 29Suppl16:270-275. https://doi.org/10.1111/clr.13299

Janssen, N.G., Weijs, L.J.W., Koole, R., Rosenberg, P.W.J.A., & Meijer, G.J. (2014). Tissue engineering strategies for alveolar cleft reconstruction: A systematic review of the literature. *Clin Oral Investig*, 8:219-226. https://doi.org/10.1007/s00784-013-0947-x

Lie, N., Merten, H.A., Meyns, J., Lethaus, B., Wiltfang, J., & Kessler, P. (2015). Elevation of the maxillary sinus membrane for de-novo bone formation: First results of a prospective study in humans. *J Craniomaxillofac Surg*, 43:1670-1677. https://doi.org/10.1016/j.jcms.2015.07.011

Lundgren, S., Andersson, S., Gualini, F., & Sennerby, L. (2004). Bone reformation with sinus membrane elevation: a new surgical technique for maxillary sinus floor augmentation. *Clin Implant Dent Relat Res*, 6(3):165-173.

Lundgren, S., Cricchio, G., Hallman, M., Jungner, M., Rasmusson, L., & Sennerby, L. (2017). Sinus floor elevation procedures to enable implant placement and integration: techniques, biological aspects and clinical outcomes. *Periodontol 2000*, 73(1):103-120. https://doi.org/10.1111/prd.12165

Lundgren, S., Johansson, A.S, Cricchio, G., & Lundgren, S. (2019). Clinical Outcome and Factors Determining New Bone Formation in Lateral Sinus Membrane Elevation With Simultaneous Implant Placement Without Grafting Material: A Cross-Sectional, 3-17 Year Follow-Up Study. Clin Implant Dent Relat Res, 21(5):827-834. https://doi.org/10.1111/cid.12758

Maddalone, M., Mirabelli, L., Venino, P.M., Karanxha, L., Porcaro, G., & Del Fabbro, M. (2018). Long-term stability of autologous bone graft of intraoral origin after lateral sinus floor elevation with simultaneous implant placement. *Clin Implant Dent Relat Res*, 20(5):713-721. https://doi.org/10.1111/cid.12649

Mardinger, O., Poliakov, H., Beitlitum, I., Nissan, J. & Chaushu, G. (2009). The patient's perception of recovery after maxillary sinus augmentation: a prospective study. *J Periodontol*, 80(4):572-576. https://doi.org/10.1902/jop.2009.080536

Moraschini, V., Uzeda, M.G., Sartoretto, S.C., & Calasans-Maia, M.D. (2017). Maxillary Sinus Floor Elevation With Simultaneous Implant Placement Without Grafting Materials: A Systematic Review and Meta-Analysis. Int J Oral Maxillofac Surg, 46(5):636-647. https://doi.org/10.1016/j.ijom.2017.01.021

Nissen, K.J., & Starch-Jensen, T. (2019). Maxillary Sinus Floor Augmentation With Autogenous Bone Graft From the Ascending Mandibular Ramus. *Implant Dent*, 28:46-53. https://doi.org/10.1097/ID.0000000000000845

Nyman, S. (1991). Bone Regeneration Using the Principle of Guided Tissue Regeneration. *J Clin Periodontol*, 18(6):494-498. https://doi.org/10.1111/j.1600-051x.1991.tb02322.x

Papaspyridakos, P., Chen, C.J., Singh, M., Weber, H.P., & Gallucci, G.O. (2012). Success criteria in implant dentistry: a systematic review. *J Dent Res*, 91(3):242-248. https://doi.org/10.1177/0022034511431252

Phillips, C., Kiyak, H.A., Bloomquist, D. & Turvey, T.A. (2004). Perceptions of recovery and satisfaction in the short term after orthognathic surgery. *J Oral Maxillofac Surg*, 62(5):535-544. https://doi.org/10.1016/j.joms.2003.08.025

Raghoebar, G.M., Onclin, P., Boven, G.C., Vissink, A., & Meijer, H.J.A. (2019). Long-term effectiveness of maxillary sinus floor augmentation: A systematic review and meta-analysis. *J Clin Periodontol*, 46 Suppl 21:307-318. https://doi.org/10.1111/jcpe.13055

Silva, L.D., de Lima, V.N., Faverani, L.P., de Mendonça, M.R., Okamoto, R., & Pellizzer, E.P. (2016). Maxillary sinus lift surgery-with or without graft material? A systematic review. *Int J Oral Maxillofac Surg*, 45(12):1570-1576. https://doi.org/10.1016/j.ijom.2016.09.023

Slade, G.D., & Spencer, A.J. (1994). Development and Evaluation of the Oral Health Impact Profile. Community Dent Health, 11(1):3-11.

Slade, G.D. (1997). Derivation and Validation of a Short-Form Oral Health Impact Profile. Community Dent Oral Epidemiol, 25(4):284-290. https://doi.org/10.1111/j.1600-0528.1997.tb00941.x

Slot, W., Raghoebar, G.M., Cune, M.S., Vissink, A., & Meijer, H.J.A. (2019). Four or six implants in the maxillary posterior region to support an overdenture: 5-year results from a randomized controlled trial. Clin Oral Implants Res, 30(2):169-177. https://doi.org/10.1111/clr.13403

Starch-Jensen, T., & Schou, S. (2017). Maxillary Sinus Membrane Elevation With Simultaneous Installation of Implants Without the Use of a Graft Material: A Systematic Review. *Implant Dent*, 26:621-633. https://doi.org/10.1097/ID.0000000000000617.

Starch-Jensen, T., Aludden, H., Hallman, M., Dahlin, C., Christensen, A.E., & Mordenfeld, A. (2018). A systematic review and meta-analysis of long-term studies (five or more years) assessing maxillary sinus floor augmentation. *Int J Oral Maxillofac Surg*, 47(1):103-116. https://doi.org/10.1016/j.ijom.2017.05.001

Starch-Jensen, T., Mordenfeld, A., Becktor, J.P., & Jensen, S.S. (2018). Maxillary Sinus Floor Augmentation With Synthetic Bone Substitutes Compared With Other Grafting Materials: A Systematic Review and Meta-analysis. *Implant Dent*, 27(3):363-374. https://doi.org/10.1097/ID.0000000000000768

Starch-Jensen, T., Deluiz, D., Deb, S., Bruun, N.H. & Tinoco, E.M.B. (2020). Harvesting of Autogenous Bone Graft from the Ascending Mandibular Ramus Compared with the Chin Region: a Systematic Review and Meta-Analysis Focusing on Complications and Donor Site Morbidity. *J Oral Maxillofac Res*, 30;11(3):e1. https://doi.org/10.5037/jomr.2020.11301

Younes, F., Cosyn, J., De Bruyckere, T., Cleymaet, R. & Eghbali, A. (2019). A 2-year prospective case series on volumetric changes, PROMs, and clinical outcomes following sinus floor elevation using deproteinized bovine bone mineral as filling material. *Clin Implant Dent Relat Res*, 2019;21(2):301-309. https://doi.org/10.1111/cid.12730

TABLE 1 Inclusion and exclusion criteria.

Inclusion criteria:

- >20 years.
- Missing one posterior maxillary tooth for more than four months.
- Residual alveolar bone height of the maxillary alveolar ridge (as measured on a tomographic examination) ≥4 mm and ≤7 mm.
- Width of the alveolar ridge ≥6.5 mm.
- Mandibular occluding teeth.
- Able to understand and sign informed consent.

Exclusion criteria:

- Contraindications to implant therapy.
- 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 define 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.

TABLE 2 Characteristics of included patients.

	MSME with blood coagulum	**MSFA with autogenous bone graft and DPBM**
Gender (male/female)	4/16	6/14
Age at the time of MSME and MSFA, mean (SD)	51.8 year (SD: 11.1)	47.4 year (SD: 10.1)
Smoking habits	0	0
Residual alveolar bone height (mm) at implant site, mean (SD)	4.9 (0.8)	4.4 (0.9)
Width of the alveolar ridge (mm) at implant site, mean (SD)	9.4 (0.9)	9.2 (0.6)
Location of missing tooth (second premolar)	3	6
Location of missing tooth (first molar)	14	14
Location of missing tooth (second molar)	3	0
Patient drop-out before surgical intervention	1	0
Number of implants with 3.6 mm diameter	0	0
Number of implants with 4.2 mm diameter	6	7
Number of implants with 4.8 mm diameter	13	13

DPBM, deproteinized porcine bone mineral; MSFA, maxillary sinus floor augmentation; MSME, maxillary sinus membrane elevation; SD, standard deviation.

TABLE 3 OHIP-14 score in conjunction with MSME.

	Question	MSME with blood coagulum											
		Enrolment (no. 20)						One week (no. 19)					
		0	1	2	3	4	SDS	0	1	2	3	4	SDS
Functional limitation	Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?	18		2				15	3	1			
	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	18		2			8	18				1	9
Physical Pain	Have you had painful aching in your mouth?	7	9	4				8	6	5			
	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	6	6	4	3	1	42	11	3	5			29
Psychological discomfort	Have you been self-conscious because of your teeth, mouth or dentures?	7	3	5	2	3		10	3	4	2		
	Have you felt tense because of problems with your teeth, mouth or dentures?	11		8		1	49	12	2	3	1	1	32
Physical disability	Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	13	2	3	1	1		14	3		2		
	Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	17	2		1		19	15	3		1		15
Psychological disability	Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	12	5	3				13	5	1			
	Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	7	5	5		3	37	10	3	3	2	1	26
Social disability	Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	16	3	1				15	2	2			
	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	19	1				6	19					6
Handicap	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	11	1	8				13	1	4	1		
	Have you been totally unable to function because of problems with your teeth, mouth or dentures?	20					20	19					12
		Total OHIP-14 score: 181						Total OHIP-14 score: 129					
		Mean, SD: 9.5 (7.5)						Mean, SD: 6.5 (7.0)					

0 = never; 1 = hardly ever or nearly never; 2 = occasionally; 3 = fairly often or many times; 4 = very often.

MSME, maxillary sinus membrane elevation; SD, standard deviation; SDS, subscale dimension score

TABLE 4 OHIP-14 score in conjunction with MSFA.

	Question	MSFA with autogenous bone graft and DPBM											
		Enrolment (no. 20)						One week (no. 20)					
		0	1	2	3	4	SDS	0	1	2	3	4	SDS
Functional limitation	Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?	17	2	1				18	2				
	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	20					4	17	2			1	8
Physical pain	Have you had painful aching in your mouth?	9	7	4				4	6	9		1	
	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	3	8	7	2		43	4	10	5		1	52
Psychological discomfort	Have you been self-conscious because of your teeth, mouth or dentures?	6	1	9	3	1		11	4	3	1	1	
	Have you felt tense because of problems with your teeth, mouth or dentures?	9	4	6	1		51	10	5	4	1		33
Physical disability	Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	15	4	1				14	4	1		1	
	Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	14	5	1			13	17	2	1			14
Psychological disability	Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	14	5	1				11	4	5			
	Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	7	3	7	2	1	34	12	3	3	2		29
Social disability	Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	18	1	1				17	2	1			
	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	17	3				6	15	3	1	1		12
Handicap	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	13	5	2				13	3	4			
	Have you been totally unable to function because of problems with your teeth, mouth or dentures?	20					9	17	2	1			15
		Total OHIP-14 score: 160						Total OHIP-14 score: 163					
		Mean, SD: 8.0 (4.5)						Mean, SD: 8.2 (6.5)					

0 = never; 1 = hardly ever or nearly never; 2 = occasionally; 3 = fairly often or many times; 4 = very often.

DPBM, deproteinized porcine bone mineral; MSFA, maxillary sinus floor augmentation; SD, standard deviation; SDS, subscale dimension score

TABLE 5 Questionnaire assessing social and working isolation, physical appearance and quality of life alterations, at one week.

Question	MSME with blood coagulum (No. 19)		MSFA with autogenous bone graft and DPBM (No. 20)		P-value
	Yes	No	Yes	No	
Social isolation					
Did you keep your usual social activities?	16	3	12	8	0.16
Have you continued practicing your favorite sport or hobbies?	11	8	6	14	0.11
Working isolation					
Did you ask for sick leave or discontinue your work?	6	13	11	9	0.20
Did the surgery affect your performance at work?	3	16	7	13	0.27
Did anyone accompany you or drive you to work due to surgery?	2	17	0	20	0.23
Has this person discontinued his/her work to do so?	0	19	0	20	1.00
Did somebody accompany you for suture removal?	1	18	0	20	0.49
Physical appearance					
Have you noticed changes in your physical appearance?	5	14	12	8	0.05
Is it what you expected?	3	16	17	3	0.01*
Has it been worse than expected?	2	17	3	17	0.10
Has it been better than expected?	15	4	7	13	0.01*
Mean duration of the quality of life alterations					
Are you satisfied with the treatment?	19	0	20	0	1.00
Would you recommend it?	19	0	20	0	1.00

Would you repeat it?	18	1	18	2	1.00

DPBM, deproteinized porcine bone mineral, MSFA, maxillary sinus floor augmentation; MSME, maxillary sinus membrane elevation.

*Statistically significant. P-value estimated by Fisher's exact test.

TABLE 6 *Questionnaire assessing eating and speaking ability, diet variations, sleep impairment, pain and discomfort, at one week.*

Question	MSME with blood coagulum (No. 19)				MSFA with autogenous bone graft and DPBM (No. 20)				P-value
	0	1	2	3	0	1	2	3	
Eating ability and diet variations:									
Did you continue with your usual diet?		15	1	3		15	4	1	0.29
Did you notice any change in the perception of taste?	14	4	1		16	4			0.84
Did you notice any change in chewing ability?	7	4	1	7	11	3		6	0.60
Did you have problems opening your mouth?	13	3	1	2	15	3		2	0.93
Speaking ability noticed:									
Have you notice any change in voice?	15	3		1	18	2			0.49
Have you notice any change in your ability to speak?	14	4		1	18	2			0.28
When you talk with other people, do they understand you?	3	16			1	19			0.34
Sleep impairment:									
Have you had problems falling sleep?	12	4	1	2	15	5			0.44
Have you experienced interruptions in sleep?	11	3		5	17	3			0.05
Have you felt drowsy?	3	14	1	1		20			0.02*
Pain and discomfort at suture removal:									
Has the removal of suture been uncomfortable?	18			1	15	3		2	0.31
Has the appointment for suture removal caused you anxiety?	17		1	1	14	2	1	3	0.43

0 = not at all; 1 = close to normal; 2 = almost normal; 3 = a little.

DPBM, deproteinized porcine bone mineral; MSFA, maxillary sinus floor augmentation; MSME, maxillary sinus membrane elevation.

*Statistically significant. P-value estimated by Fisher's exact test.

TABLE 7 Questionnaire assessing days of recovery.

Question	MSME with blood coagulum	MSFA with autogenous bone graft and DPBM	Difference in means	Lower 95% CI	Upper 95% CI	P-value
	Mean (range), SD	Mean (range), SD				
One week:						
Days on sick leave or been off work?	0.4 (0-2), 0.7	1.6 (0-5), 2.0	1.2	0.3	2.1	0.01*
Days with eating difficulties?	1.4 (0-5), 1.4	2.1 (0-10), 2.3	0.7	-0.4	1.9	0.21
Days with speech difficulties?	0.8 (0-8), 2.0	0.4 (0-5), 1.2	-0.4	-1.4	0.6	0.46
Days sleep has been affected?	0.7 (0-8), 1.9	1.1 (0-4), 1.5	0.4	-0.7	1.4	0.51
Days with physical activity affected?	2.3 (0-14), 3.9	3.6 (0-7), 3.0	1.3	-0.8	3.5	0.23
One month:						
Days with pain after surgery?	2.3 (0-8), 2.1	4.4 (0-14), 3.9	2.1	0.2	4.1	0.03*
Days on sick leave from daily activities due to pain?	0.6 (0-6), 1.4	1.5 (0-5), 1.9	0.9	-0.1	2.0	0.08
Operation affect performance of your work? (VAS: 0-100)	12.3 (0-76), 18.8	18.6 (0-98), 28.3	6.4	-8.2	21.0	0.39
Days affected in your work?	1.7 (0-7), 2.3	2.9 (0-21), 4.8	1.1	-1.2	3.4	0.34
Able to eat a normal diet in postsurgical period? (VAS: 0-100)	70.4 (7-100), 33.7	63.5 (0-100), 35.8	-6.9	-28.5	14.6	0.53
Days unable to eat your normal diet?	1.6 (0-5), 1.7	2.5 (0-14), 3.1	0.9	-0.7	2.4	0.26
Changes in your speech after surgery? (VAS: 0-100)	5.4 (0-65), 14.9	2.3 (0-13), 3.4	-3.1	-10.0	3.8	0.38
Days with changes in your speech?	3.0 (0-30), 8.1	0.2 (0-21), 0.5	-2.8	-6.4	0.8	0.13

Trouble sleeping at night after surgery? (VAS: 0-100)	5.7 (0-52), 13.2	10.6 (0-55), 16.9	4.9	-4.4	14.2	0.31
Days night's sleep been affected?	0.7 (0-8), 1.9	0.9 (0-4), 1.3	0.3	-0.8	1.3	0.62

CI, confidence interval; DPBM, deproteinized porcine bone mineral; MSFA, maxillary sinus floor augmentation; MSME, maxillary sinus membrane elevation; SD, standard deviation.

*Statistically significant. Differences in mean were estimated by ordinary least square regression model including 95% confidence interval. P-value is for the difference being zero.

TABLE 8 Association between OHIP-14 at enrolment and patient´s perception of recovery.

Question	MSME with blood coagulum			MSFA with autogenous bone graft and DPBM		
	OHIP-14 score < 10 (no.: 10) Mean (SD)	OHIP-14 score ≥ 10 (no.: 9) Mean (SD)	P-value	OHIP-14 score < 10 (no.: 14) Mean (SD)	OHIP-14 score ≥ 10 (no.: 6) Mean (SD)	P-value
One week:						
How many days have you been on sick leave or been off work?	0.2 (0.4)	0.7 (0.9)	0.15	1.6 (1.9)	1.7 (2.3)	0.98
How many days have you had eating difficulties?	1.2 (0.9)	1.6 (1.8)	0.59	2.4 (2.6)	1.3 (1.2)	0.34
How many days have you had speech difficulties?	0.8 (2.5)	0.8 (1.3)	0.98	0.6 (1.4)	0.0 (0.0)	0.34
How many days has your sleep been affected?	0.5 (1.1)	0.9 (2.7)	0.68	1.0 (1.5)	1.2 (1.8)	0.83
How many days has your physical activity been affected?	2.2 (3.2)	2.4 (4.8)	0.90	4.2 (3.0)	2.3 (2.9)	0.21
One month:						
How many days have you had pain after surgery?	1.4 (1.8)	3.2 (2.0)	0.05	4.8 (3.1)	3.5 (5.4)	0.51
In how many days have you been on sick leave from daily activities?	0.1 (0.3)	1.1 (2.0)	0.13	1.4 (1.8)	1.8 (2.2)	0.62
Did the operation affect your performance of your daily work? (VAS)	8.0 (11.0)	17.0 (24.6)	0.31	22.6 (32.0)	9.5 (15.4)	0.36
In how many days have you been affected in your work?	1.9 (2.6)	1.6 (2.1)	0.76	3.3 (5.5)	1.8 (2.2)	0.55
In how many days have you been unable to eat your normal diet?	1.2 (1.5)	2.0 (2.0)	0.79	3.1 (3.5)	1.0 (0.9)	0.22
Have you been able to eat a normal diet in the post-operative period? (VAS)	68.3 (39.1)	72.7 (28.8)	0.33	56.9 (36.5)	78.7 (31.6)	0.17

Have you noticed changes in your speech after surgery? (VAS)	7.1 (20.4)	3.4 (4.9)	0.61	3.1 (3.7)	0.2 (0.4)	0.07
In how many days have you noticed changes in your speech?	5.1 (11.0)	0.7 (1.0)	0.24	0.3 (0.6)	0.0 (0.0)	0.27
Have you had trouble sleeping at night after surgery? (VAS)	5.2 (9.2)	6.3 (17.2)	0.86	9.1 (15.3)	14.0 (21.2)	0.57
In how many days have your night's sleep been affected?	0.5 (1.0)	0.9 (2.6)	0.68	0.9 (1.1)	1.2 (1.8)	0.64

DPBM, deproteinized porcine bone mineral; OHIP-14, Oral Health Impact Profile-14; MSFA, maxillary sinus floor augmentation; MSME, maxillary sinus membrane elevation; SD, standard deviation; VAS, visual analogue scale (0 = minimal to 100 = maximum).

P-values is estimated by bootstrapped t-test (10000 replications and accelerated bias-corrected confidence interval) comparing means for OHIP-14 score < 10 with means for OHIP-14 score ≥ 10.