

Crestal Sinus Floor Augmentation Using Hydraulic Pressure and Vibrations: A Retrospective Single Cohort Study

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Purpose: To evaluate the sinus membrane perforation and implant survival rate after crestal minimally invasive sinus floor augmentation using hydraulic pressure and vibrations. **Materials and Methods:** In this retrospective single cohort study, all patients who underwent minimally invasive sinus floor augmentation between 2007 and 2015 using hydraulic pressure and vibrations were included. The sinus membrane is elevated by physiologic saline at 1.5 bar. The fluid is then set into vibration to further separate the sinus membrane from the bony floor. The endpoints were sinus membrane perforation and the survival rate of implants. **Results:** The hydraulic pressure and vibration technique was applied in 156 patients. Seven patients with perforations of the sinus membrane were treated with the lateral window approach and excluded from the follow-up analysis. In the remaining 149 patients, 184 crestal sinus floor augmentations were performed and 184 implants were placed. In 10 of these 184 cases, a perforation was suspected in the postoperative computed tomography (CT) scan. In total, the perforation rate was 8.9% (17/191). Nineteen implants were lost during the follow-up period ranging from 0.2 to 8.4 years with a median of 2.3 years. The cumulative implant survival rates after 1, 3, and 5 years were 94.4%, 87.7%, and 87.7%, respectively. No severe perioperative complications were noted. **Conclusion:** The hydraulic pressure and vibration technique allows a minimally invasive crestal sinus augmentation with a perforation rate less than 10% and implant survival rates of approximately 90%. *INT J ORAL MAXILLOFAC IMPLANTS* 2018;33:1149–1154. doi: 10.11607/jomi.6478

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Severe atrophy of the posterior maxilla can render implant treatment difficult or even impossible. Sinus floor augmentation provides an implant bed by

placing bone, bone substitutes, or a combination of both between the residual maxillary bone and the sinus mucosa.¹ Depending on the residual bone height, implants can be placed simultaneously with the augmentation procedure or after a healing period of several weeks or months.² The lateral window technique^{3–5} allows the visual inspection of the integrity of the sinus mucosa, and a perforation can be closed with a resorbable membrane. However, the window technique is rather invasive and can cause swelling and pain. Minimally invasive crestal techniques have been introduced to increase patient comfort, however, at the cost of losing visual control of the sinus mucosa.

Crestal approaches include the osteotome technique,⁶ balloon techniques,^{7,8} and hydraulic pressure techniques. In particular, the hydraulic pressure techniques have led to innovations to support crestal sinus augmentation. Initial approaches were based on hydraulic pressure only such as Sinus Physiolift,⁹ iRaise,^{10,11} and others.¹² Techniques using hydraulic pressure combined with vibrations generated by ultrasonic sound were introduced, such as hydrodynamic piezoelectric internal sinus elevation.^{13,14} The strategy

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Fig 1 Surgical appliance comprising the pump, the special drill, and a connecting tubing set.

and technical fundament of the hydraulic pressure and vibration technique (Jeder-System)¹⁵ presented here is the application of 1.5 bar hydraulic pressure, whereby the respective physiologic saline is set into vibrations at 50 Hz to facilitate the separation of the sinus mucosa from the adjacent bone.

Crestal sinus augmentation can cause perforations of the sinus mucosa. Perforation rates vary considerably, ranging from 0% to 21.4%¹⁶ or even 0% to 26%.¹⁷ Sinus membrane ruptures can potentially initiate the spread of contaminants and infection processes throughout the respiratory tract, as the maxillary sinus communicates with all other sinuses of the respiratory system.¹⁸ Risk factors for ruptures are a thin sinus mucosa¹⁹ and a thin alveolar bone.²⁰ If properly managed, however, high implant survival rates are obtained in perforated sinuses.²¹ It is, nevertheless, relevant to report the perforation rates when establishing novel approaches of crestal sinus augmentation.

Implant survival rates following a crestal sinus augmentation have recently been summarized. The cumulative implant survival at 1, 3, and 5 years was 98.1%, 96.8%, and 95.8%, respectively.²² Survival rates were 92.7% when the residual bone height was < 5 mm and 96.9% above this level.²² In other reviews,^{23,24} implant survival after a minimum of 3 years loading was 97.2% and 92.8% for the crestal approach. Even though crestal sinus augmentation can be considered a predictable method in implant dentistry, implant survival rates should be evaluated when new methods for crestal sinus augmentation become accessible.

The aim of the present retrospective single cohort study was to report the sinus membrane perforation and implant survival rate after crestal minimally invasive sinus floor augmentation by application of a hydraulic pressure and vibration-based system.

MATERIALS AND METHODS

Patient Selection

To allow for a minimum follow-up of at least 1 year, patients were considered for inclusion until May 2015. The first augmentation was done in 2007, representing the starting point of this retrospective clinical study. Surgery was performed in a Private Practice for General Dentistry and Implantology, Vienna, Austria, by one of the authors (K.E.) after patients had given written informed consent. The study protocol was approved by the ethics committee of the Medical University of Vienna (ECS 2081/2016). Inclusion criteria were women and men aged 18 years or older, one or more missing maxillary premolars or molars, and bone atrophy in the posterior maxilla region with a residual alveolar ridge height of 8 mm or less. Exclusion criteria were maxillary sinus septa localized in intended implant position, maxillary sinusitis or polyposis, sinus membrane thickness greater than 5 mm, poor oral hygiene, tobacco consumption of more than 15 cigarettes per day, corticoid treatment or hypercortisolism, intravenous bisphosphonate or denosumab therapy, severe chronic diseases, immunosuppressed patients, as well as pregnant or breastfeeding women. Oral hygiene and dental status were evaluated preoperatively, the medical history was documented, and a conventional or cone beam computed tomography (CBCT) scan was done.

Surgical Procedure

Sinus augmentation was performed using a novel system first described in 2013.¹⁵ The system includes a drill, a pump, and a tubing set connecting both devices (Fig 1). The hydraulic pressure of 1.5 bar generated by the pressure-sealed system pushes the sinus membrane away from the drill. Hydraulic vibrations are generated by the pump, further separating the membrane from the sinus floor. Both hydrostatic pressure and volume of the inserted physiologic saline are constantly monitored.

The surgical procedure comprises the following steps: After a soft tissue punch (ATP punch, Dentsply, Friadent), the drill is advanced until approximately 1 or 2 mm below the sinus floor. An intraoperative radiograph can be done to verify the depth of the borehole. The drill is plugged into the pressure-sealed bore, and hydraulic pressure of 1.5 bar is built up in the pressure chamber using physiologic saline. When the drill advances through the remaining bone of the maxillary sinus, the sinus membrane is elevated by the pressurized fluid. A pressure drop visible on the display indicates this step. The saline solution is then set into hydraulic vibrations of 50 Hz to further separate the sinus membrane from the sinus floor. Physiologic saline at 0.2 mL

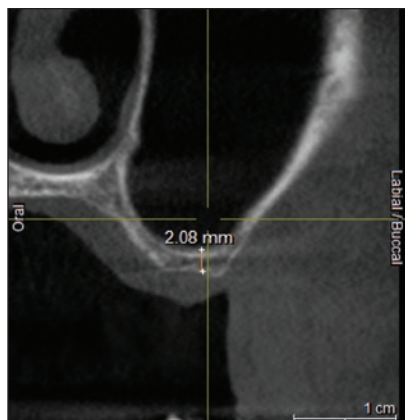


Fig 2 Left maxillary first molar site preoperatively.



Fig 3 Intraoperative radiograph for depth verification.

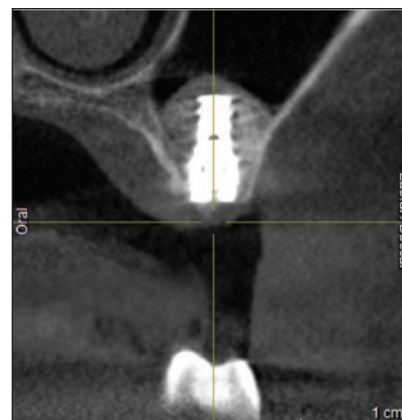


Fig 4 Left maxillary first molar site postoperatively.

per step of a total of seven steps is then pumped into the space between the membrane and the sinus floor. The rise in hydrostatic pressure is noticed each time physiologic saline is pressed against the sinus membrane. Finally, the saline solution is replaced by a bone substitute followed by implant insertion.

The type of bone substitute and implant to be used is not part of the protocol but is left to the surgeon's choice and preference. In this study, bone substitute materials were deproteinized bovine bone mineral (Bio-Oss, Geistlich Biomaterials), nano-crystalline hydroxyapatite (Ostim, Heraeus Kulzer), or a combination thereof (at a ratio of one to one). Implants placed included screw-type implants with progressive thread design and self-locking conical abutment connection (Ankylos, Dentsply Implants Manufacturing), and variable thread implants with internal connection (Nobel Replace CC, Nobel Active, and Nobel Replace, Nobel Biocare).

A clinical case with a preoperative CBCT, an intraoperative radiograph, and a postoperative CBCT is shown in Figs 2 to 4, respectively.

Preoperative and Postoperative Management

Articaine hydrochloride 4% with epinephrine 1:100,000 (Septanest with Epinephrine, Septodont) was used for local infiltration anesthesia. Following surgery, patients were prescribed either clindamycin hydrochloride 300 mg three times per day for 5 days (Clindac, Sandoz) or josamycin 500 mg twice a day (Josolid, Sandoz). Prescriptions as needed for pain control included Dexibuprofen 400 mg on demand up to three times a day (Seractil, Gebro Pharma). Stitches (when necessary) were usually removed 7 days after surgery.

Endpoints

The endpoints of this study were membrane perforation and implant survival rates. Implants were

considered successful if they were still in place and clinically not mobile at the last follow-up examination. Potential risk factors included age, sex, residual bone height, implantation site, bone substitute, implant type, implant length, implant diameter, and smoking.

Statistical Analysis

Statistical evaluation was carried out using SPSS 22.0 (SPSS) and R 3.3.1 (R Foundation for statistical computing). The data evaluated were extracted from the computer system of the aforementioned dental surgery in Vienna, Austria. Patient forms for medical history were screened to extract the relevant information. Continuous measures were described as mean values and standard deviations, and categorical data as absolute and relative frequencies. Survival time was defined as the time between implant placement and loss. In case no loss occurred, the time from implant placement to the last visit was defined as the censored survival time. The overall implant survival rate was calculated as the number of implants in situ at the last visit divided by the total number of implants placed during the whole study. For calculation of cumulative survival rates (CSRs), Kaplan-Meier analyses were applied. The log-rank test was used to analyze survival data and calculate corresponding *P* values. The following risk factors were statistically explored with regard to their potential influence on implant survival rates: age (< 60 years vs \geq 60 years); sex; residual bone height (< 5 mm vs \geq 5 mm); implantation site (premolar vs molar); membrane rupture, bone substitute, implant type (manufacturer: Ankylos vs Nobel); implant length (< 10 mm vs \geq 10 mm); implant diameter (< 4 mm vs \geq 4 mm); and smoking. For comparison of the survival distributions of the 10 different parameters, a Bonferroni correction was applied to protect from type 1 error. Therefore, the level of significance was set at $\alpha = .05/10 = .005$ for each conducted test.

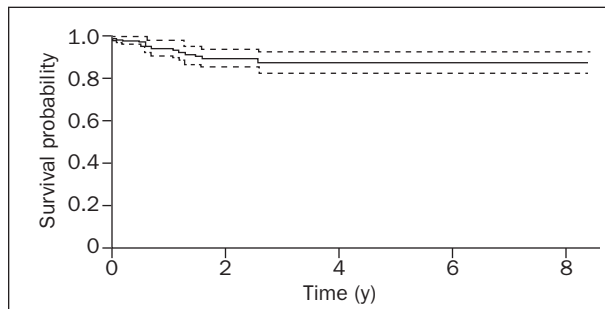


Fig 5 Kaplan-Meier cumulative survival rate (CSR) of all implants with 95% confidence interval.

RESULTS

Study Population

From January 2007 to May 2015, a total number of 156 patients were subjected to sinus floor augmentation using the Jeder-System. In seven of these patients, the surgical procedure was switched to a lateral approach due to membrane perforations detected by the hydraulic pressure and vibration system. Consequently, the statistical analyses refer to 149 patients with 184 successfully completed sinus augmentation procedures followed by implantation. In 20 of the 184 cases, a flap was elevated for implantation at neighboring sites. In three cases with residual bone heights of 1 mm, a two-stage protocol with implant insertion after 24, 28, and 53 weeks following sinus augmentation was chosen. The respective cases were included in the statistical analysis, as the sinus elevation had been performed using the hydraulic pressure and vibration system. The study population comprised 80 women (53.7%) and 69 men (46.3%). The patient ages were between 29.8 and 84.7 years (median, 61.4 years). Data regarding smoking habits were available in 144 patients, with 24 (16.7%) being smokers.

Anatomical Situation and Biomaterials

The mean residual bone height was between 1 and 8 mm (median, 4 mm). The left and the right sinus were augmented in 91 (49.5%) and 93 (50.5%) patients, respectively. The frequency of augmentation sites was 6 (3.3%), 45 (24.5%), 110 (59.8%), 20 (10.9%), and 3 (1.6%) for first and second premolars, and first, second, and third molars, respectively. The augmentation materials used were Bio-Oss in 7 (3.8%), Ostim in 8 (4.3%), and a combination thereof in 169 (91.8%) cases of sinus augmentation, respectively. The implants placed included Ankylos, Nobel Replace CC, Nobel Active, and Nobel Replace in 85 (46.2%), 68 (37.0%), 28 (15.2%), and 3 (1.6%) of cases, respectively. Implant lengths ranged from 8 to 14 mm, and implant diameter was between 3.5 and 5.5 mm. The observation time ranged from 0.2 to 8.4 years (median, 2.3 years).

Outcome Parameters

No severe perioperative complications (eg, severe hemorrhage, massive swelling, allergic reaction, etc) were noted in any patient. In 7 out of the initial 156 patients (191 cases) subjected to sinus augmentation with the hydraulic pressure and vibration system, a perforation of the sinus membrane was diagnosed intraoperatively (7/191 corresponding to 3.7%). These patients were excluded from further statistical analysis since the intended crestal procedure was switched to a classical sinus elevation using the lateral window approach. In another 10 cases (10/184 corresponding to 5.4%), a membrane rupture was suspected after completion of the procedure because of augmentation material being noticed in the maxillary sinus by conventional or cone beam CTs. Consequently, the overall perforation rate was 8.9% (17/191 cases). A total of 19 out of the 184 implants placed were lost, which corresponds to an overall implant survival rate of 89.7% (165 implants survived of 184 implants placed). The cumulative survival rates after 1, 3, and 5 years calculated by use of Kaplan-Meier analysis were 94.4%, 87.7%, and 87.7%, respectively. The respective graph with upper and lower 95% confidence intervals is shown in Fig 5. Kaplan-Meier analyses and logrank tests exploring factors with potential influence on implant survival revealed that—in the univariate statistical model— survival rates were influenced by implant type (Ankylos superior to Nobel, $P = .022$) and implant length (≥ 10 mm superior to < 10 mm, $P = .014$) but not by age, sex, residual bone height, implantation site, bone substitute, implant diameter, and smoking. However, statistical significance could not be shown for any of the analyzed parameters when using the Bonferroni correction for multiple testing (Table 1).

DISCUSSION

The first main finding was that the hydraulic pressure and vibration system is suitable for crestal sinus augmentation and can detect perforations of the sinus mucosa that require a lateral approach, which was the case in 7 out of 156 patients. Ten patients with a radiologically suspected perforation of the sinus membrane, not detected by the device or the Valsalva maneuver, could be augmented via the crestal approach, and implants were inserted. Thus, even though the overall sinus mucosa perforation rate was 8.9%, only 3.7% (7/191) of the perforations required a lateral sinus augmentation. The second main finding was that 19 implants were lost during follow-up, corresponding to a cumulative survival rate of 89.3%. These results provide the scientific fundament for the clinical reliability of applying hydraulic pressure and vibrations for crestal sinus augmentation.

If the findings are compared with those of others, the membrane perforation rate in the present study of 8.9% and 5.4% including all 191 and 184 cases where a crestal sinus augmentation was initiated or completed, respectively, are comparable to figures indicated in the literature. Tan et al¹⁶ published a systematic review of the crestal technique. In eight of the included studies, perforation rates ranged between 0% and 21.4%. In a recent meta-analysis on osteotome-mediated sinus floor elevation, perforation rates were reported in 15 of the included studies and varied between 0% and 26%.¹⁷ Perforation rates as low as 0% may be doubted, as it is surprising that this complication has not occurred in a "blind procedure." Therefore, the perforation rates of 3.8%¹⁶ and 6.3%¹⁷ have to be interpreted with care. More likely, minor perforations may have been overlooked; thus, the actual perforation rates could potentially be higher than indicated in the respective studies.^{25,26}

The overall implant survival rate of 89.7% as well as the cumulative survival rates of 94.4%, 87.7%, and 87.7% after 1, 3, and 5 years, respectively, are within the range of comparable studies. In the aforementioned systematic review, Tan et al¹⁶ estimated the mean survival rate of implants after 3 years to be 92.8% (95% confidence interval between 87.4% and 96.0%). In their recent meta-analysis, Călin et al¹⁷ reported an overall survival rate of 96.2%, whereby the lowest implant survival rate was 82.9%, and the highest reached 100%. Although in the present study patient collective, implant type and length appeared to potentially influence survival rates (univariate analysis), no statistical significance could be shown after correction for multiple testing by Bonferroni-type adjustments.

The rationale behind the choice of potential risk factors to be statistically analyzed is that not only procedure-related factors (eg, bone substitute materials and implant types) may influence implant survival but also patient characteristics (eg, age and sex) as well as site-specific factors (residual bone height and implant area). For example, regarding residual bone height, the cut-off point was set at < 5 mm versus ≥ 5 mm for comparison of the respective groups since a bone height of 4 to 5 mm is usually regarded as sufficient for primary implant stability.²⁷ In this context, it should be mentioned that the augmentation technique presented here can also be applied in sites of a residual bone height below 3 mm with an achievable height gain of up to 9 mm.¹⁵ Even in extreme cases with residual bone heights of 1 or 2 mm, the technique can be used. However, primary implant stability may not be achieved, necessitating a two-staged approach. In the present study, this was the case in three patients.

The retrospective nature of this analysis is undoubtedly the most obvious and relevant limitation of the

Table 1 Factors with Potential Influence on Implant Survival

Parameter	Implant survival rates (%) and absolute figures (in parentheses)	P value
Age	< 60 y: 87.1% (74/85) ≥ 60 y: 91.9% (91/99)	.249
Sex	Male: 93.3% (84/90) Female: 86.2% (81/94)	.102
Residual bone height	< 5 mm: 90.5% (95/105) ≥ 5 mm: 88.6% (70/79)	.567
Implantation site	Premolar: 96.1% (49/51) Molar: 87.2% (116/133)	.071
Sinus membrane perforation	Rupture: 100.0% (10/10) No rupture: 89.1% (155/174)	.286
Bone substitute	BioOss: 85.7% (6/7) Ostim: 87.5% (7/8) BioOss and Ostim: 89.9% (152/169)	.865
Implant type	Ankylos: 94.1% (80/85) Nobel: 85.9% (85/99)	.015
Implant length	< 10 mm: 66.7% (6/9) ≥ 10 mm: 90.9% (159/175)	.014
Implant diameter	< 4 mm: 85.7% (12/14) ≥ 4 mm: 90.0% (153/170)	.676
Smoking	Yes: 86.2% (25/29) No: 89.9% (134/149)	.444

No statistical significance could be shown when using the Bonferroni correction for multiple testing of all 10 parameters ($\alpha = .05/10 = .005$).

present study. The lack of a control group can be seen as another flaw. The present data allow basal conclusions on sinus membrane perforation and implant survival rates that could be advanced in larger controlled studies in a prospective setting. Furthermore, in future projects it would be advisable to consider a multi-center rather than a single-center study design.

CONCLUSIONS

The hydraulic pressure and vibration technique allows a minimally invasive crestal sinus augmentation with a perforation rate less than 10% and implant survival rates of approximately 90%.

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