

The International Journal of Periodontics & Restorative Dentistry

Survival and Success Rates of Dental Implants Placed Using Osteotome Sinus Floor Elevation Without Added Bone Grafting: A Retrospective Study with a Follow-up of up to 10 Years



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This retrospective study with a follow-up period of 4 months to 10 years evaluated survival, success, and complication rates of implants placed using osteotome sinus floor elevation (OSFE) without added bone grafting. A total of 926 implants were placed, including 530 short implants (6 mm to 8.5 mm) and 209 implants in low residual bone height (RBH) (< 5 mm). Bone levels were evaluated at approximately 3 months and at 1, 3, and 5 years, and in some cases up to 10 years after implants were placed. The implant survival rate was 98.3% at the 5-year follow-up. Twelve of the 926 implants failed (6 preprosthetic, 6 postprosthetic). The success rate was 95.4% at a threshold of less than 1 mm of bone loss for combined systems (Straumann; Nobel Biocare). Short implant survival and success rates were statistically comparable to conventional-length implants. Low-RBH implants had a lower but acceptable survival rate of 95.7%. Adverse events were rare, with one case of infection and zero cases of vertigo reported. The findings of this study indicate that implant placement with OSFE without added bone graft is highly successful, even when short implants are used in low RBH. Int J Periodontics Restorative Dent 2016;36(suppl):s89-s97. doi: 10.11607/prd.2191

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The osteotome sinus floor elevation (OSFE) procedure is an alternative to the time-consuming and complicated lateral window sinus elevation procedure for implant placement in the posterior atrophic maxilla. Systematic reviews have reported favorable survival rates and have concluded that implant placement in conjunction with OSFE represents a predictable modality for treating the posterior maxilla, particularly when residual bone height (RBH) is greater than 5 mm.¹⁻³ However, a pilot study demonstrated that added bone graft was not necessary for OSFE,4 and a 1-year prospective study of cases with RBH of less than 5 mm revealed similar findings. 5 Few studies have reported on OSFE success without added bone graft using short implants when RBH is less than 5 mm,^{2,6,7} with one study demonstrating no significant differences in bone formation without added bone graft.8

One challenge to OSFE is elevating the sinus membrane without tearing it; cadaver studies have suggested a limit of 3 to 5 mm with membrane elevation. Another challenge of OSFE is the potential risk for benign paroxysmal vertigo (BPV). Although one meta-analysis reported a BPV frequency of 1.2%, it included 11 different studies using various drilling and osteotome designs, so there remains limited

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Table 1 Inclusion and exclusion criteria in a study of implants placed using osteotome sinus floor elevation without added bone grafting				
Inclusion criteria	Maxillary edentulous posterior sextant; RBH < 12 mm	Single edentulous site; RBH ≥ 4 mm	Multiple ^a edentulous sites; RBH ≥ 2 mm	Medically healthy; ASA 1, 2 ^b
Exclusion criteria	Maxillary anterior sextant mandibular sites	Single edentulous site; RBH < 4 mm	Multiple edentulous sites; < 2 mm	Medically compromised; ASA 3, 4

^aResidual bone height (RBH) < 4 mm for multiple sites: patients were given two options—either multiple short splinted implants with OSFE or fewer longer implants with lateral window sinus elevation. All patients chose OSFE.

blncluded patients who smoked, had controlled diabetes mellitus, were receiving bisphosphonates, or were hypersensitive to penicillin.

Table 2 Implant typ	oes, dimensions, and num	bers placed	
	Implant type		
Implants and dimensions	Straumann tissue level, 2.8 mm machined collar	Nobel Biocare replace taper, 1.5 mm machined collar	Other external hexagon Brånemark, machined 3i, partially etched
Implant width (mm)	4.1 RN, 4.8 WN	4.3, 5	3.75, 4.0, 5.0
Implant height (mm)	6 ^a , 8 ^a , 10, 12	10ª, 13	10, 11.5, 13
Total implants (n) ^b	776	88	44
Short implants (n) ^c	451	79	0

eStraumann, 6 mm and 8 mm; Nobel Biocare, 10 mm with a 1.5-mm collar, for an effective length of 8.5 mm. bN = 926.

 $^{^{}c}n = 530.$

Table 3	Summary of overall OSFE gain and low RBH subset		
OSFE gain		RB	H < 5mm
1–2.9 mm	n = 607 (65%)	2–5 mm	n = 209
3–5 mm	n = 319 (35%)	Mean	3.38 mm

OSFE = osteotome sinus floor elevation; RBH = residual bone height.

data on BPV risk using a standardized technique.

The aim of this study was to evaluate the survival and success rates in a follow-up period of 4 months to 5 years, and in some cases up to 10 years, using OSFE without added bone graft. Furthermore, a subset of short implants and low RBH sites (< 5 mm) was evaluated. Complications regarding delays, BPV, or infection were also evaluated and reported.

Materials and methods

This report is a retrospective clinical study of 926 consecutive implants placed by one periodontist (D.F.) in private practice using OSFE with no added bone between 1998 and 2010. Inclusion and exclusion criteria are listed in Table 1. Implant description and site details are listed in Tables 2 and 3. Implants were considered short if they were 6 mm or 8mm in length in the Straumann

system and 10 mm in lenght in the Nobel Biocare Replace Select system (with a 1.5-mm collar above bone, the functional implant length is 8.5 mm). Patients were made aware of the risks associated with OSFE, including infection, BPV, and the limited data for short implants in low RBH. Patients were screened 1 week after the operation for complications of infection, implant mobility, and vertigo. At 4 to 6 months after the procedures, implants were evaluated for soft-tissue health and radiographic bone level, and a forward torque test of 35 Ncm was performed. Implants that were not loose and passed radiographic tests but rotated slightly at a torque of 35 Ncm were retested at 6 to 8 months and listed as delayed if rotation was not repeated or failed if rotation was repeated. Tears, BPV, infection, and delays were recorded as adverse events. Multiple adjacent implants were typically restored with splinted crowns (Figs 1c and 2c). Patients were then followed up at approximately 1 year, 3 years, and 5 years after implant placement. In some cases, patients were followed up from 6 to 10 years if they were referred back for a complication on an existing implant or a new site.

All patients were given a pretreatment rinse and facial scrub with 0.12% chlorhexidine and then draped in a sterile wrap. A sterile saline irrigation was used.14 The patients were conscious during the procedures and had the option of mild oral sedation (1 mg lorazepam or 0.25 mg triazolam). Patients who were not hypersensitive to penicillin were given 2 g of amoxicillin 1 hour before the operation, then 250 mg three times daily for 7 days. Patients hypersensitive to penicillin were given 600 mg of clindamycin 1 hour before the operation, followed by 250 mg levofloxacin once per day for 6 days. A full-thickness flap was elevated, and a 2-mm twist drill (Implantmed, W&H) was used to drill 1 to 2 mm short of the sinus floor. A narrow, tapered-tip osteotome (p2, Aseptico Lexer) was used to create the initial fracture of the sinus floor extending only 1 mm into the sinus floor. Then, straight-walled concavetipped osteotomes (Aseptico Lexer) were used to increase the width in increments from 2.8 mm to 3.3 mm, and up to 4.0 mm if a wide implant was to be placed. Typically, the first and second osteotomes were not



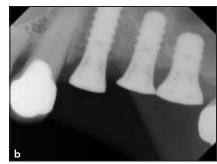






Fig 1 Bone remodeling around implants placed using OFSE, without a bone graft. (a) Instrumentation used. (b) Periapical radiograph taken immediately after implant placement in the left posterior maxilla. (c) Periapical radiograph 1 year after implant placement. (d) Periapical radiograph taken 5 years after implant placement. Note in (c) and (d) the stable dome of bone at the apex of the implants.









Fig 2 OFSE case in a patient with 2.8-mm RBH prior to implant placement. (a) Pretreatment clinical photo. (b) Surgical site preparation for three short 6-mm implants. (c) Periapical radiograph taken immediately after implant placement. (d) Radiograph taken 5 years postoperative.

used to final length but were used to provide an incremental lift of the sinus while the last osteotome was used to final length. The concave tip displaced autogenous bone and clot apically from the osteotomy walls as it was advanced (Figs 1a and 1b). The osteotome site was then sounded with a depth gauge smaller than the last osteotome to test for rebound of the sinus membrane. If rebound resistance was detected, the sinus membrane was recorded as having no tear; if no resistance was detected, it was recorded as having a tear. Whether or not a tear was detected, the implant was placed into the osteotomy site with no bone graft material added apically, and routine postoperative antibiotics were administered. Using the electric torque device, the insertion torque was recorded in increments of 5 Ncm up to 40 Ncm and then evaluated for potential effect on failure. Insertion torque was only recorded from 2005 to 2010; therefore, the data set had a limited subset of 667 implants with insertion torque data available. Where possible, partial dentures were adjusted or not worn, and complete upper dentures were relined with a soft liner.

Radiographs were taken with a parallel alignment device (DEXIS). Sinus elevation gain was determined by comparing the height where bone crossed the midbody of the implant once inserted to the apical extent of the implant on a radiograph. The apex of the implant was used as a reference point for total bone gain because bone beyond the implant apex is typically

lost.⁷ Crestal bone measures were taken from the coronal aspect of the implant shoulder or microrough surface to the most apical level of the alveolar crest, regardless of mesial or distal position. Measurements were performed by one examiner (D.F.) and calibrated to sensor dimensions (DEXIS).

Implant survival was defined as an implant that was not removed for any reason. Implant success was defined as a surviving implant with less than 1 mm crestal bone loss at 1-year recall or any subsequent follow-up when available. The threshold of less than 1 mm success criterion was chosen from guidelines provided by Sanz and Chapple.¹⁵ Implant survival and success rates were analyzed using a life table analysis as a function of time. The chi-square test was used to test the relationship between categorical variables. Effect of implant length and RBH on survival rates was analyzed at the implant level using the Cox proportional hazards model. The Kaplan-Meier analysis and logrank test were used to analyze the equality of survival functions of the three implant groups. Alpha was set at .05, and statistical significance was evaluated using SPSS statistical software (version 20.0).

Results

A total of 926 implants from 541 patients (279 women and 262 men) with a mean (range) age of 54 (18 to 88) years were included in the study. A summary of implant types placed with OSFE is presented in Table 2, and a summary of OSFE gain and the

low RBH subset is presented in Table 3. One-third of the sites had sinus elevation gain between 3 and 5 mm, and 209 sites had RBH less than 5 mm. Of the 926 implants placed, 12 failed, for a 5-year cumulative survival rate of 98.3% and a 10-year cumulative survival rate of 97% (Table 4). Six failures were preprosthetic (4 to 8 months), and six were postprosthetic. Four of the six preprosthetic failures occurred under provisional dentures on short- or low-insertion torque implants (< 15 Ncm).

Four patients with a total of six implants (< 1%) did not return for any follow-up and were deemed dropouts. These implants, as well as implants that were lost to follow-up and not yet due, were considered as censored in the survival analysis. Implants were placed over a 10-year period, so not all were available for recall up to 10 years. The follow-up distribution is presented in Fig 3, and the relative recall percentage follow-up rates are presented in Table 5. After removing implants that failed or that were lost to follow-up, 809 implants (88.5%) passed the 1-year follow-up; 610 (66.7%) passed the 2- to 3-year follow-up, and 300 (32.8%) passed the 4- to 5-year follow-up. In addition, 22 implants were available for and passed the 9to 10-year follow-up (Table 4).

The majority of short implants were restored as splinted crowns (85% vs the 15% restored as single-unit crowns). Short implants had lower survival rates than conventional-length implants, at 98.3% and 100%, respectively, but the difference was not significant (hazard ratio [HR] = 1.13; 95% confidence interval

Table 4 10-y	ear life table a	analysis			
Follow-up time (mo)	Total implants (no.)	Failed implants (no.)	Withdrawn (censored) implants (no.)	Cumulative survival rate (%)	95% confidence interval
0–4	926	4	54	99.6	100-99.2
4–8	868	2	42	99.3	99.9–98.7
8–12	824	0	15	99.3	99.9–98.7
12–24	809	1	198	99.2	99.8–98.6
24–36	610	0	141	99.2	99.8–98.6
36–48	469	2	167	98.7	99.7–97.7
48-60	300	1	106	98.3	99.5–97.1
60–72	193	2	58	97.1	99.1–95.1
72–84	133	0	62	97.0	99.0–95.0
84–96	71	0	31	97.0	99.0–95.0
96–108	40	0	18	97.0	99.0–95.0
108–120	22	0	9	97.0	99.0–95.0

[CI] = 0.36–3.57). The survival rate of implants placed in RBH < 5 mm was significantly lower, at 95.7% compared to the 99.3% obtained for implants placed in RBH \geq 5 mm (chi-square = 8.7; P = .003, HR, 4.8; 95% CI, 1.5–15.1) as shown in Figs 1b, 1c, and 4. The 5-year survival rates were 97% and 95% for Straumann and Nobel Biocare implants, respectively, and 93% for machined or partially etched implants, although none of the implant types differed significantly according to Kaplan-Meier survival analysis.

Based on bone loss < 1 mm over the period of the study, the combined mean cumulative success rate was 95.4%. By implant type, it was 97.7% for Straumann, 87.5% for Nobel Biocare, and 68.3% for other implants, with a significant difference noted between implant types (chi-square = 90.8, df = 2; P < .001). The success rate of

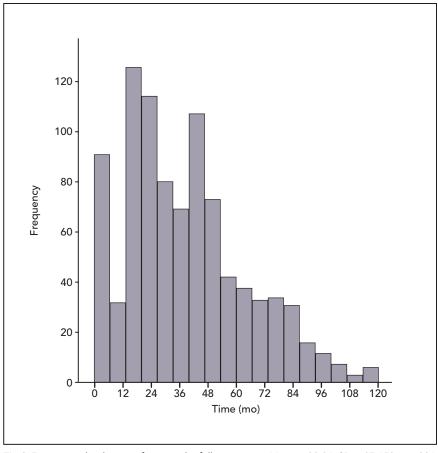


Fig 3 Frequency distribution of patients by follow-up time. Mean = 39.94; SD = 27.653; n = 926.

Table 5	Recall percentage rates by follow-up period			
Follow-up	Total implants recalled (no.)*	Implants (no. [%])		
3–6 mo	926	920 (99.3)		
1 y	926	835 (90.2)		
2-3 y	926	638 (68.9)		
4–5 y	679	327 (48.2)		
6–10 y	413	120 (29.1)		

^{*}Number of implants available for evaluation. Excludes those not yet due.

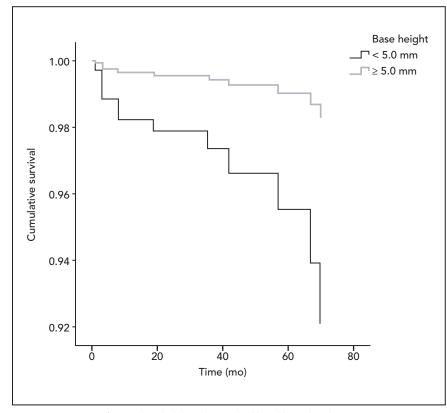


Fig 4 Comparison of survival probabilities by residual basal bone height.

surviving short implants was 97.1%, which was better than the success rate of conventional-length implants of 93.1% (P = .004). Success rates of implants placed in RBH < 5 mm were not significantly different than in RBH ≥ 5.0 mm (96.6% vs 95.1%, respectively).

When insertion torque was \geq 15 Ncm, 3 out of 455 implants (0.6%)

failed, whereas when torque was < 15 Ncm, 4 out of 212 (1.8%) failed. Because of low failure numbers, Cox analysis could not be performed. Of the seven sites that required extended healing time, four were implants placed with \geq 15 Ncm. Of the surviving implants placed with a torque of \geq 15 Ncm, the success rate was not statistically different from those

placed with a torque < 15 Ncm (96.7% vs 97.1%, respectively).

Of the 926 implants placed, one had an identified tear and ultimately failed. Zero incidences of BPV and one postsurgical infection in the sinus (0.1%) were reported (Fig 5). A delay was required for seven implants to pass the 35 Ncm test, but by 6 months all seven implants were stable at 35 Ncm, showed radiographic evidence of integration, and were restored, with none failing during later follow-up.

Discussion

Conventional-length and short implants placed using OSFE without added bone grafting were found to have good survival and success rates. Implants that failed often did so before prosthetic restoration, therefore the present study reflects both procedural failures and failures due to long-term complications. The follow-up period of 4 months to 10 years relates to the finding that half of the failure occurred in this preprosthetic phase. Patients were routinely recalled on a 1-, 3-, and 5-year schedule, after which they were typically seen only if there was a complication or a new site. After between 6 to 10 years a smaller number of implants (n = 413) were available for evaluation and a lower percentage (29%) were followed up, so a potential bias exists (Table 5). However, this is likely a bias toward overestimating complications, because complications were often the reason for the patient's visit during this follow-up period.

A systematic review of OSFE reported 5-year mean implant survival rates as high as 96%.2 Whereas another meta-analysis reported a 94% survival rate after OSFE, 80% of those cases involved added bone graft, and the RBH was between 4 mm and 9 mm.1 One large retrospective study of OSFE using the added bone technique with a sample size and follow-up period similar to the present study reported a survival rate of 97.7%.16 In the present study, no bone graft was added and a large number of short implants in low-RBH sites were used, yet the 5-year cumulative survival rate remained comparatively high at 98.3%.

The 12 implants that failed in the present study were in 11 individual patients. Six implants failed before prosthetic loading, with four of these from denture loading. Low torque on insertion (≥ 15 Ncm), 6-mm implants, and RBH < 5 mm were associated with slightly higher failure rates, so these scenarios may be considered at risk. Also in the risk group were the seven implants that required a delay to pass the torque test. Extended healing times, closed healing, and denture avoidance is advised for at risk implants. In the six postprosthetic loading failures, enough bone gain remained apically after removal of the failed implant to allow replacement with a longer implant.

Early in the study, machined or partially roughened implants had a cumulative survival rate of 93%, compared with 97% for rough-surface implants. Because of their lower survival rates, machined or partially







roughened implants were discontinued. Between Straumann and Nobel Biocare implants, survival rates were not statistically significant.

Regarding implant length, because the number of events in each

Fig 5 OFSE case with a single 8-mm implant. (a) Clinical photograph showing the low residual bone height. (b) Periapical radiograph taken immediately after implant placement. (c) Clinical photograph taken after implant placement. (d) Cone beam computed tomography ruling out a sinus perforation at 3 weeks postoperative due to the only case of infection (note the cross-sectional view of tenting of the membrane). (e) Radiograph at 1 year postoperative. (f) Radiograph at 2 years postoperative.





group as well as the hazard ratios were small, the power of the study was not sufficient to find a significant difference. However, in contrast to the present results, reports of lower survival rates for short implant use in

OSFE have been published,^{1,17} with one study reporting survival rates as low as 47% for 6-mm implants.^{6,18} The present results are similar to a systematic review reporting an implant survival rate of 94.2% in subset of low RBH (< 5 mm) sites without added bone grafting.² In that study all 6-mm implants placed in low RBH that survived were splinted (n = 76), so in the present study the high survival rate in low RBH with short implants may be due to splinting, as it reduces crestal loading in low-density bone in finite element analysis.19

Despite the lower density bone in the maxillary posterior, crestal bone levels were stable, with a success rate of 95.4% over the entire period of study (Straumann and Nobel Biocare implants combined), which is similar to conventional cases with no sinus procedure. Bone loss was significantly less in Straumann implants with a 2.8-mm collar.²⁰ Of interest, once integrated, the short implants in the present study had less progressive bone loss than the 10-mm implants, which may be because they were splinted and thus may have had less load-related loss over time.¹⁹ Although implants in RBH less than 5 mm had a lower survival rate, the success rates of surviving implants based on bone loss less than 1 mm were comparable to those of sites with RBH greater than 5 mm.

The infection rate in the present study was 0.1%, which may be a result of the routine postoperative antibiotics and the lack of graft material that has potential for graft dislodgement if a sinus tear goes

unnoticed.² In the present study, the sinus rebound test was used to reveal any maxillary sinus tears. However, this test may not reveal all tears; likewise, the Valsalva maneuver may not reveal all tears under 3 mm,9 so routine use of postoperative antibiotics in OSFE was implemented. The zero incidence of BPV in the present study suggests it is a relatively infrequent occurrence. However, case reports of BPV after OSFE have been presented in other studies,1,9,13 and a meta-analysis reported the incidence of BPV as 1.2%.1 In the present authors' experience, during the early adoption of OSFE tapered osteotomes required higher mallet forces. Therefore, the present study used predrilling of bone to within 1 to 2 mm of the sinus floor and straight-walled osteotomes to limit mallet forces, which may explain the zero incidence of BPV.

One substantial limitation in this study was the number of implants lost to follow-up. Because of the nature of a private practice, some patients did not return for recall appointments despite efforts to schedule follow-up. Another limitation was that nonstandardized periapical radiographs were used, but studies have reported 1 mm as a reasonable threshold for error range with a similar protocol.^{15,21}

Conclusions

This retrospective clinical study of 926 implants followed up from 4 months to 10 years provides evidence for successful OSFE, without added bone graft, even in cases

of RBH less than 5 mm. The high survival and success rates of short-splinted implants demonstrate that this technique could be a less invasive alternative to lateral window sinus elevation, with faster treatment time and reduced cost.

Acknowledgments

The authors reported no conflicts of interest related to this study.

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