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Trifactorial classification system for osteotome sinus floor elevation based on an observational retrospective analysis of 926 implants followed up to 10 years

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Objective: A novel osteotome trifactorial classification system is proposed for transcrestal osteotome-mediated sinus floor elevation (OSFE) sites that includes residual bone height (RBH), sinus floor anatomy (contour), and multiple versus single sites OSFE (tenting). **Method and Materials:** An analysis of RBH, contour, and tenting was retrospectively applied to a cohort of 926 implants placed using OSFE without added bone graft and followed up to 10 years. RBH was divided into three groups: high (RBH > 6 mm), mid (RBH = 4.1 to 6 mm), and low (RBH = 2 to 4 mm). The sinus "contour" was divided into four groups: flat, concave, angle, and septa. For "tenting", single versus

multiple adjacent OSFE sites were compared. **Results:** The prevalence of flat sinus floors increased as RBH decreased. RBH was a significant predictor of failure with rates as follows: low-RBH = 5.1%, mid-RBH = 1.5%, and high-RBH = 0.4%. Flat sinus floors and single sites as compared to multiple sites had higher observed failure rates but neither achieved statistical significance; however, the power of the study was limited by low numbers of failures. **Conclusion:** The osteotome trifactorial classification system as proposed can assist planning OSFE cases and may allow better comparison of future OSFE studies. (*Quintessence Int* 2015;46:523–530; doi: 10.3290/j.qi.a33935)

Key words: classification, observational study, osteotome, retrospective, sinus elevation, transcrestal

The osteotome sinus floor elevation (OSFE) procedure is a proven alternative to the more complicated lateral window sinus augmentation technique, with implant survival rates of more than 94% when there is sufficient residual bone height (RBH) \geq 5 mm.^{1,2} To date RBH has

been the only determinant used to classify OSFE sites. Early OSFE classification systems divided cases into four groups based on their RBH: Group A \geq 10 mm, B = 7 to < 10 mm, C = 5 to 6 mm, and D \leq 4 mm.³ With the advent of shorter and micro-rough implants demonstrating survival rates for 8-mm implants comparable to 10-mm implants,⁴ the prior classification divisions are less valid. Furthermore, under the prior classification systems the \leq 4-mm category was restricted for lateral window sinus elevation but these can now be treated with OSFE using 6-mm implants.

The "contour" of the sinus floor can also facilitate or complicate the OSFE procedure. Elevating a flat sinus floor creates tension of the sinus membrane, but most studies still report a 3-mm elevation as a safe thresh-

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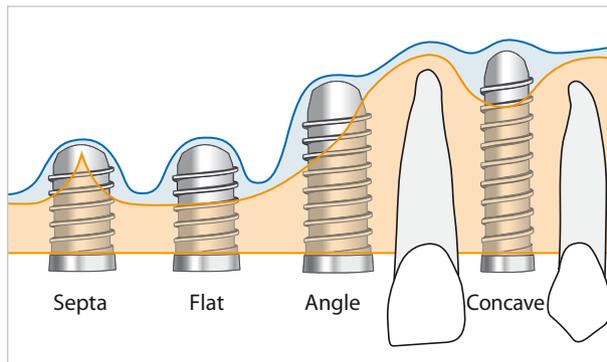
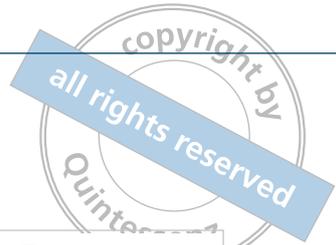


Fig 1a The four sinus contour groups.

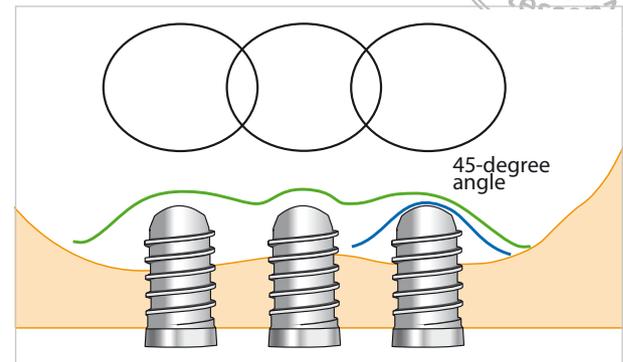
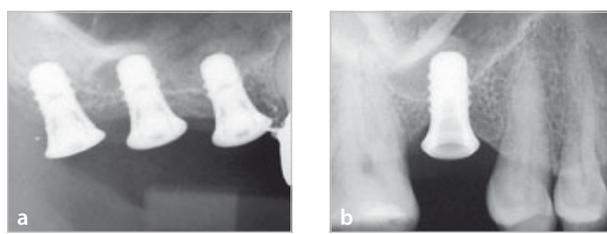


Fig 1b Multi-site OSFE tenting.



Figs 2a to 2d Radiographs at the time of implant placement in the four sinus contour groups. (a) Flat sinus floor with multiple implants. (b) Concave sinus floor of 3 mm elevated 5 mm to accommodate 8-mm implant. (c) Angle sinus floor elevated only at distal. (d) Septa with implant aligned to peak and bone gained laterally.



old.^{1,2,5,6} On the other hand, a floor with a 3-mm concavity may be elevated 3 mm with minimal membrane tension, then elevated an additional 2 to 3 mm for a net gain of 5 to 6 mm with similar membrane tension to a flat floor elevated 3 mm (Figs 1a and 2b). Steep angles such as anterior walls or septa may increase complexity as they may require increased mallet force; while on the other hand, the apical cortical density may provide good fixation for the OSFE site (Figs 1a, 2c, and 2d).

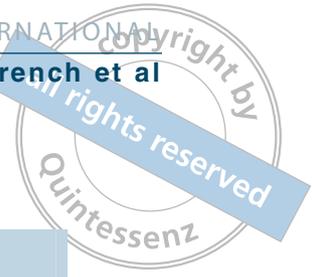
With adjacent OSFE sites, membrane “tenting” can be achieved which may facilitate OSFE as has been described in both a clinical study and a cadaver study (Figs 1b and 2a).^{5,7} Furthermore, adjacent OSFE sites allow for prosthetic splinting of implants, which in low-density bone reduces crestal bone load.⁸⁻¹⁰ Recent studies of non-grafted OSFE sites have shown that multiple OSFE combined with short splinted implants result in high success rates even in low RBH.^{11,12} However, to date, “tenting” from adjacent OSFE sites has not yet been included in an OSFE classification system.

The purpose of this paper is to propose a classification system for OSFE. This trifactorial analysis using

RBH, sinus contour, and tenting was evaluated retrospectively using a large cohort of implants placed using the OSFE procedure. The classification system can be used to assist in treatment planning OSFE and as a guide to assessing the complexity of the procedure.

METHOD AND MATERIALS

A retrospective analysis of RBH, contouring, and tenting of 926 implants, placed using OSFE without added bone graft, and followed up to 10 years was performed. This cohort further included subsets of 530 short implants and 209 sites with RBH < 5 mm. This cohort is the subject of survival and success analysis of OSFE with no added bone currently in preparation.¹¹ A summary of implant type and dimension is shown in Table 1. Implants were placed and insertion torque was recorded. All implants were not loaded until 3 months after insertion, then a forward torque test to 35 Ncm and periapical radiograph were performed to verify integration, and implants were then restored. All implants that were removed for any reason were recorded as failures.



Implant type, dimensions, placed	Straumann, tissue level, 2.8-mm machined collar	Nobel Biocare, Replace Taper, 1.5-mm machined collar	“Other” external hexagon; Brånemark, machined, Biomet 3i, partially etched
Implant width (mm)	4.1 RN, 4.8 WN**	4.3, 5.0	3.75, 4.0, 5.0
Implant height (mm)	6*, 8*, 10, 12	10*, 13	10, 11.5, 13
n (N = 926)	792	90	44
n short* (N = 530)	451	79	0

*Straumann 6 and 8 mm, Nobel Biocare 10 mm with 1.5-mm collar for effective length of 8.5 mm.
 **RN and WN denote implant neck width of 4.8 mm and 6.5 mm respectively.

Factor	Group			
RBH	High (> 6 mm)	Mid (4.1–6 mm)		Low (2–4 mm)
Contour*	Flat (sinus floor contour < 10 degrees)	Concave (dual sided 10 to 45 degrees)	Angle (one or two angles > 45 degrees)	Septa (narrow peak > 45 degrees)
Tenting**	Single-site (no adjacent OSFE)		Multi-site (1 or more adjacent OSFE)	

*Angle determined by angle at which sinus floor crosses the circumference of implant at time of placement.
 **Adjacent implants counted only if placed with adjacent OSFE.

The osteotome trifactorial classification system is based on three surgical site factors: RBH, sinus contour, and tenting. RBH was divided into three groups:

- High (RBH > 6 mm)
- Mid (RBH = 4.1 to 6 mm)
- Low (RBH = 2 to 4 mm).

The sinus floor “contour” was divided into four groups: flat, concave, angle, and septa (Table 2 and Figs 1 and 2). “Tenting” was evaluated by recording whether single versus multiple adjacent OSFE were performed (Figs 1b and 2a). It was only considered “tenting” when adjacent OSFE procedures were performed, as opposed to including all adjacent implants. Statistical analysis was utilized to evaluate the associations between every two site characteristics and then evaluated for failure rates of different levels in each site characteristic.

RESULTS

Overall the implant survival rate was 98.3% at the 5-year follow-up. Twelve implants (12/926) failed (6 pre-prosthetic, 6 post-prosthetic). There were no

implants placed and removed within the surgical visit as none failed to achieve primary stability, but there were 212 implants with low primary stability (5 to 10 Ncm) and within these there were 4/6 pre-prosthetic failures. There was one membrane tear recorded and this implant failed later so counted as a post-prosthetic failure. There was one infection which was treated with antibiotics and the implant remained successful, and there were no cases of vertigo reported.

Based on bone loss < 1 mm over the period of the study, the combined average cumulative success rate was 95.4%. Of the surviving implants, short implants and sites with RBH < 5 mm had success rates that were comparable to conventional length implants. Technical complications were not recorded since the study was done in a surgical office and restorations were performed by a variety of restorative offices.

Regarding the trifactorial analysis, the associations between any two site characteristics was strong in that there was an association between RBH and contour, RBH and tenting, as well as contour and tenting. The majority of sites were flat or concave in all RBH groups

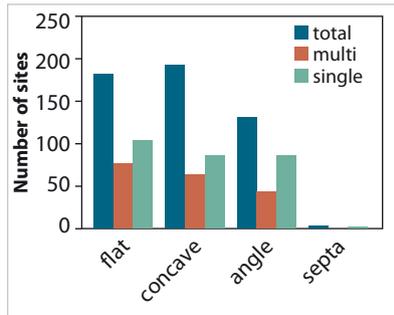
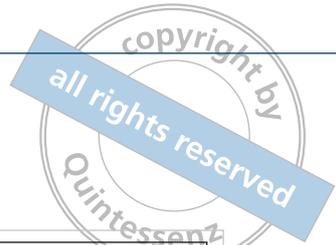


Fig 3 Distribution of sites as a function of contour and tenting for high-RBH (> 6 mm).

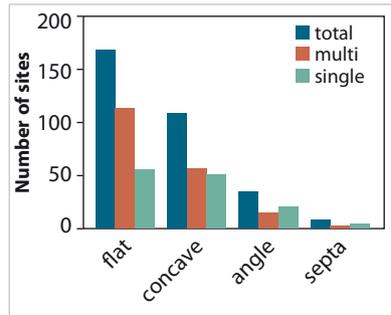


Fig 4 Distribution of sites as a function of contour and tenting for mid-RBH (4.1 to 6 mm).

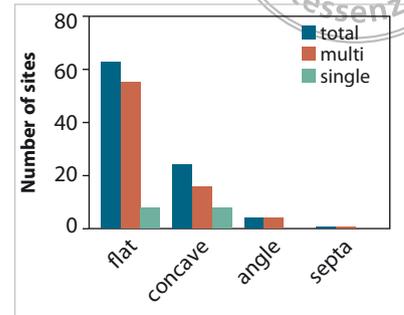


Fig 5 Distribution of sites as a function of contour and tenting for low-RBH (2 to 4 mm).

Contour and tenting*	RBH			Subtotal	Total
	High (> 6 mm)	Mid (4.1-6 mm)	Low (2-4 mm)		
Flat and single-site	1/106	3/56	0/8	4/170	8/415
Flat and multi-site	0/77	0/113	4/55	4/245	
Concave and single-site	1/128	1/52	1/8	3/188	3/325
Concave and multi-site	0/64	0/57	0/16	0/137	
Angle and single-site	0/45	1/21	0/0	1/66	1/172
Angle and multi-site	0/87	0/15	0/4	0/106	
Septa and single-site	0/4	0/5	0/0	0/9	0/14
Septa and multi-site	0/1	0/3	0/1	0/5	
Subtotal (single-site)	2/283	5/134	1/16	NA	NA
Subtotal (multi-site)	0/229	0/188	4/76	NA	NA
Total	2/512	5/322	5/92	NA	12/926

*Tenting is present when there are adjacent OSFE sites (ie, in the "multi-site" scenario, but not for "single-site" scenarios).

but the prevalence of flat sites increased as the RBH was reduced. There was also a significant trend to more angle and concave forms in areas with greater RBH ($\chi^2 = 65.453$, degrees of freedom [df] = 6, P value = .000). There were nearly even amounts of multiple and single sites overall ($N = 494$ and 434 , respectively) but concave and septa locations tended to be single sites, while flat or angle sites tended to be multiple sites ($\chi^2 = 28.192$, $df = 3$, $P = .000$). The number of sites treated with multiple OSFE increased in lower RBH sites compared to single OSFE sites, such that in the low-RBH group, the vast majority were multiple OSFE sites ($\chi^2 = 50.205$, $df = 2$, $P = .000$).

Distribution of surgical sites and failures relative to each individual factor

RBH, contour, and tenting is seen in Figs 3 to 5 as well as Table 3. There were 12 of the 926 implants that failed (1.3%). The failure rate of RBH was greatest in the low-RBH group at 5.1%, while in the mid-RBH group it was 1.5%, and rare in the high-RBH group at 0.4% (Table 4). The differences among failure rates of three levels in RBH are statistically significant ($\chi^2 = 15.768$, $df = 2$, $P = .000$). Evaluating the failure rate of sinus contour revealed a trend to higher failure rates in flat sites at 1.9% compared to 1% for concave and 0% to 1% for the septa and angle groups, respectively (Table 5). Evaluating the failure rate of single versus multiple adjacent sites by tent-



Table 4	Failure distribution as a function of RBH group			
	RBH group			Total
	High (> 6 mm)	Mid (4.1–6 mm)	Low (2–4 mm)	
Failure	2	5	5	12
Success	510	317	87	914
Total	512	322	92	926

Table 5	Failure distribution as a function of sinus contour				
	Flat	Concave	Angle	Septa	Total
Failure	8	3	1	0	12
Success	407	322	171	14	914
Total	415	325	172	14	926

Table 6	Failure distribution as a function of tenting (single- vs multi-site)		
	Single	Multiple	Total
Failure	8	4	12
Success	425	489	914
Total	433	493	926

ing revealed a trend to lower failure for adjacent OSFE at 0.8% compared to 1.8% for the single sites (Table 6). It was then evaluated if tenting, contour, and RBH had any interaction (Table 3). The highest failure rate of 7% was seen in the low-RBH groups with multiple implants in flat sinus floor sites. The next highest trend to failure at 5% was single OSFE sites for mid-RBH in flat sinus floor. The differences among failure rates of different levels both in contour and in tenting were not statistically significant.

DISCUSSION

A retrospective observational analysis, with respect to RBH, sinus contour, and tenting was performed on 926 OSFE sites and is presented in Table 3 and Figs 3 to 5. A high survival rate is reported and this may in part be due to the consideration of sinus contour and tenting with adjacent OSFE sites in addition to the well-established consideration of RBH. Based on this, a trifactorial classification system is proposed herein (Table 2).

The analysis of the distribution of site characteristics revealed that there was an increase in flat sites and a reduction of concave or angled sites as the RBH decreased, with a trend toward flat sinus floors in the mid- and low-RBH groups. The flattening of the sinus floor is as expected since, over time, in large edentulous spaces with no adjacent roots, the sinus is pneumatized and RBH is lost. Most concave sites were between adjacent teeth or between a tooth and septa, which preserves RBH such that when comparing RBH groups the relative percent of concave sites was 37% and 34% in high- and mid-RBH groups respectively, but 26% in the low-RBH group. There was also a higher relative percentage of angled sites in the high-RBH group as a result of bone preservation, typically seen at the distal of an adjacent root (Fig 3 and Table 3).

In the present analysis, RBH was the strongest predictor of survival, with a statistically significant lower failure rate of 0.4% for high RBH as compared to 1.6% for mid RBH, and 5.4% for low RBH. That RBH is a pre-

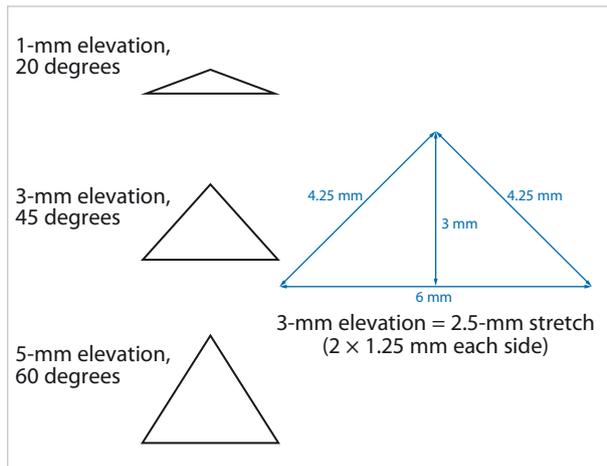
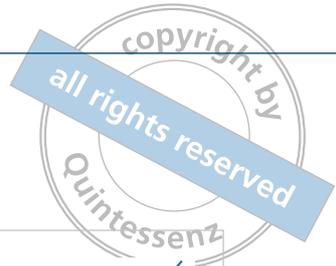


Fig 6 Expected angle of sinus membrane for a 1-mm, 3-mm, and 5-mm elevation as based on observation that a 4-mm-wide implant has about 6 mm circumferential “impact”.

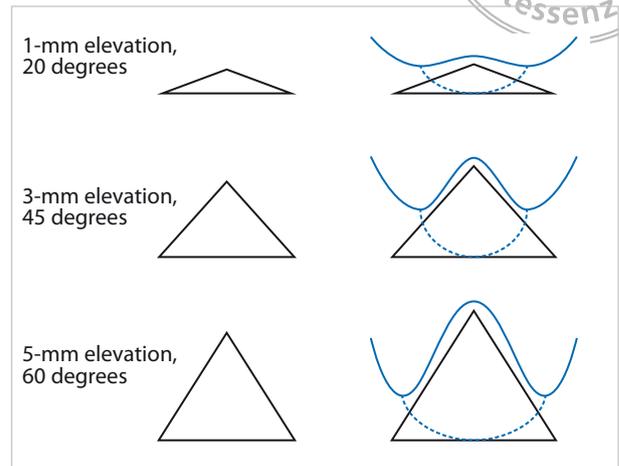


Fig 7 Schematic depicting the benefit of a concave floor for 1-mm, 3-mm, and 5-mm elevation.

dicator of survival is in keeping with other studies showing lower survival rates in RBH < 5 mm, with typical survival of 85% to 92% being reported;^{2,3} one study even showed failure as high as 47% for 6-mm implants in OSFE sites.⁴ However, as stated above, a better than expected survival rate of > 94% can be reported for this cohort, even for the most at risk low-RBH group,¹¹ which may be partly due to the trifactorial classification used when optimizing the OSFE procedure.

Individually, the effects of contour and tenting on failure were not found to be statistically significant; however, the power of the study was limited by low numbers of failures. It is still of interest to note that more failures were observed in flat sinus floors, with a rate of 1.9%, which was about twice that compared to all other contours, at 0% to 1% (concave, angle, septa). The flat sinus risk remained apparent in the low-RBH group, with failures of 6.3% (4/63) compared to 3.4% (1/29) for all other contours (concave, angle, septa) (Table 3). This may be because angle and concave sites have at least one high wall to assist the elevation and the walls may provide better fixation for the implant.

On radiographs taken after OSFE, it was observed that the bone flexed about 1 mm peripheral to the implant, thus providing an approximate 6-mm diameter for a 4-mm width implant. From this an expected sinus membrane angle was proposed (Figs 6 and 7). For example, for

a flat floor a vertical elevation of 1 mm translates into about a 20-degree membrane angle and therefore has minimal vertical tension. On the other hand, an elevation of 3 mm has a 45-degree angle and therefore about half the force of the elevation is vertical, which may explain why a 3-mm elevation is considered a safe limit for OSFE.^{1,5} Elevating the sinus up to a typical maximum of 5 mm in a flat floor has an angle of 60 degrees, with two thirds of the tension being vertical, which may increase tear risk where all other factors are equal (such as membrane elasticity). For a concave floor, a 5-mm elevation may be at less risk, since at the periphery it is already higher than the center and thus a 5-mm elevation is more like a 3-mm inversion with an added 2-mm elevation (Figs 2b and 7). Flat sinus floors also offer the least potential for implant stability compared to concave or angled sites since flat sites have no bone at the periphery of the implant on one side to assist with primary stability.

For flat sinus contours there were more adjacent OSFE sites represented: 67% of mid-RBH and 87% of low-RBH, respectively. This trend reflects the treatment planning whereby multiple adjacent short implants, making use of the tenting effect to reduce the risk for tear, together with splinting to reduce crestal bone loading, was used in lieu of lateral sinus elevation.^{8,9} This is in contrast to the situation of a single OSFE site in a flat sinus floor of 2 mm, which would not be a can-

didate for OSFE since an elevation of 6 mm in a flat floor would be needed to place an 8-mm implant.

There were more single units in the high-RBH group, which is as expected since an implant of proven length (ie, 8 to 10 mm) for single sites can be utilized.⁴ Steep angle sites were also more prevalent in the high-RBH group and did not, therefore, require as much vertical elevation for the standard 8- to 10-mm implants; this was typically limited to 1 to 3 mm (Fig 2c). On the other hand, it was observed that steep-angled walls and septa sites required higher mallet forces and as such, the OSFE technique was modified by angled pre-drilling along the sinus wall as close to final depth as possible, and then increasing the width and height to a lesser extent so the osteotome functioned as both a lateral and vertical displacement versus a purely vertical elevation. The modified OSFE technique, which enabled an otherwise unconventional OSFE case, had a low failure rate of 1% and no incidence of benign paroxysmal vertigo (BPV), which compares favorably to a previously reported BPV risk for OSFE of 1.3%.¹ It is also noteworthy that straight-walled osteotomes were used as standard protocol since it was observed early in the study that higher forces were needed with tapered osteotomes.

The presence of septa on the sinus floor is well described in the literature and the coronal peak represents an area of high bone density that may be of use in supporting more load with a smaller implant.¹³ Despite the widespread prevalence of septa and its potential value as a site for OSFE, septa are only recently described in case reports.¹³ For septa the protocol was also modified, drilling up to the apex of septa but then not using OSFE to elevate past the apex; rather using osteotomes to displace the sinus floor laterally to accommodate implant width (Fig 2d). In the present study, there was 100% survival of implants aligned to septa, thus indicating that septa may be recommended as a favorable site for OSFE. However, despite the 100% survival, there were only 14 septa sites in total and of these only 5 sites were in the low-RBH group (septa or steep-angled combined). Furthermore, these low-RBH sites had implants placed in conjunction with adjacent

implants; therefore, further study of septa is warranted and septa as a standalone site in low-RBH is not advised.

The beneficial effect of adjacent vs single OSFE is best illustrated in the 332 sites with mid-RBH where both single and adjacent sites were used routinely in high numbers. In this case, we found 5/134 single sites failed compared to 0/188 adjacent sites. Theoretically, there may be a similar advantage in the low-RBH group but it is difficult to evaluate because, as part of the precautionary planning, there were minimal numbers of single sites in this group. Despite this, it can be seen that there are good survival rates in low-RBH sites treated with adjacent OSFE in this study, which demonstrates that when short implants are placed in low-RBH, the sinus elevation may be facilitated by the tenting effect. An effect of implant splinting, which typically accompanies adjacent OSFE sites, may also play a role in improved survival as described below. In prior studies, short 6-mm implants with OSFE were considered higher risk, with up to 47% failure;⁴ but in this cohort, survival of 6-mm implants was near comparable to that of the 8- to 10-mm implants. Thus, in a 3-mm flat sinus floor for example, the use of three splinted 6-mm implants may provide a viable alternative to two 8-mm implants done either with OSFE using aggressive 5-mm elevation or the more invasive lateral sinus elevation technique.

Based on the clinical impression of complexity for surgical placement and on trends observed in failure analysis, Table 7 was developed as a guide for planning potential OSFE sites and assessing degree of difficulty and the trifactorial classification system. An SAC classification similar to that introduced in 1999 by the Swiss Oral Implantology Society was used, wherein the S represents straightforward, A advanced, and C complex sites. In this case, a straightforward site for OSFE may be a case that with suitable training in OSFE procedure could be managed by most operators with a good result. An advanced case would be for clinicians with more advanced training and years of experience in OSFE, again with good results expected. A complex case would be advised for clinicians with significant training and experience, and even then the results may vary such that patient expectations would need to be carefully discussed.



Table 7 Osteotome complexity rating following the osteotome trifactorial classification system. In the SAC coding, S denotes a straightforward procedure, A an advanced procedure, and C a complex procedure; X denotes a scenario in which OSFE would not be advised.

Contour and tenting*	RBH		
	High (> 6 mm)	Mid (4.1–6 mm)	Low (2–4 mm)
Flat and single-site	A	C	X
Flat and multi-site	S	A	C
Concave and single-site	S	A	C
Concave and multi-site	S	A	C
Angle and single-site	A	C	X
Angle and multi-site	A	C	C
Septa and single-site	A	C	X
Septa and multi-site	A	C	C

*Tenting is present when there are one or more adjacent OSFE sites (ie, in the “multi-site” scenario, but not for “single-site” scenarios).

CONCLUSION

In conclusion, a new osteotome trifactorial classification system is presented that considers sinus contour and tenting from adjacent sites in addition to RBH. This system provides improved characterization of surgical sites, and thus enables the practitioner to tailor their osteotome procedure, with modifications described herein, in order to improve implant survival. RBH remains the strongest predictor of failure in this study, as in most other OSFE studies. Although the failure analysis of this cohort did not reveal a statistically significant effect of contour and tenting, the power of this analysis was low due to the low number of failures, and this warrants further study. Furthermore, a trend to better survival in septa, angle, and concave sites compared to flat sinus floor was observed, and a trend to better survival for adjacent OSFE sites was also noted. A guide for planning and assessing the complexity of the OSFE procedure, based on clinical observations as well as the trifactorial classification, is also presented.

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