Evaluation of Different Methods of Indirect Sinus Floor Elevation for Elevation Heights of 10 mm: An Experimental Ex Vivo Study

Florian Stelzle, MD;* Klaus-Ulrich Benner, MD, PhD†

ABSTRACT

Objective: The aim of this study was to macroscopically and microscopically evaluate different methods of indirect sinus floor elevation regarding elevation heights of 10 mm.

Materials and Methods: Four different methods of indirect sinus floor elevation-osteotome sinus floor elevation (OSFE), bone added osteotome sinus floor elevation (BAOSFE), piezo- surgical sinus floor elevation (PSFE), and sinus floor elevation with an inflatable balloon, balloon-lift-control system (BLC) – were macroscopically and microscopically investigated *ex vivo* using 36 bisected pigs' heads.

Results: OSFE and BAOSFE perforated the Schneiderian membrane, whereas the inflatable balloon caused no laceration. PSFE elevated the mucosa without laceration as well, but was technically restricted to an elevation height of 5 mm. BAOSFE, PSFE, and BLC separated the mucosa, leaving the periosteum on the bone. OSFE completely lifted the soft tissue from the bone, including the periosteum.

Conclusions: The results of this study indicate that balloon elevation of the sinus floor may extend the indication for indirect sinus floor elevation for elevation heights of up to 10 mm. The histological elevation layer seems to be non-uniform in the different sinus floor elevation methods. Further *in vivo* experiments have to prove these findings as well as their relevance regarding the clinical outcome of sinus floor augmentation.

KEY WORDS: balloon elevation, elevated mucosa, elevation height, indirect approach, piezo surgery, separation layer, sinus floor elevation

The current state of research shows a limitation of the elevation height for indirect sinus floor elevation with classic methods like osteotome sinus floor elevation (OSFE) or bone-added osteotome sinus floor elevation (BAOSFE) (Table 1). Ultrasonic piezoelectric devices are supposed to perform an atraumatic osteotomy, as well as a gentle elevation of the sinus floor.[11] So far, the method has sporadically been used for lateral sinus floor elevation, but is not mentioned in literature regarding indirect sinus floor elevation.[11,12] Indirect sinus floor elevation with an inflatable balloon demonstrated first successful results for elevation heights of up to 10 mm.[9,13] But there are no comparative experimental studies in literature regarding this method (see Table 1).

A complete elevation of the soft tissue from the sinus floor including the periosteum when performing the sinus floor elevation is generally agreed on by clinicians.[1,4,5] First hints for a separation of mucosal layers with sinus floor elevation can be found in a histological ex vivo study.[9] The results suggest that the periosteum is left on the bone while the rest of the mucosal layers are lifted when performing the sinus floor elevation. However, there are no further studies comparing different methods of sinus floor elevation regarding the elevated mucosal layers. It was the objective of the present experimental ex vivo animal study to macroscopically and microscopically evaluate different methods of indirect sinus floor elevation – "OSFE,"

*Resident, Department of Oral and Maxillofacial Surgery, Friedrich-Alexander University of Erlangen-Nürnberg, Erlangen, Germany; †professor, Department of Anatomy, Ludwig-Maximilian University of Munich, Munich, Germany

Reprint requests to: Dr. Florian Stelzle, Department of Oral and Maxillofacial Surgery, Friedrich-Alexander University of Erlangen-Nürnberg, Glückstrasse 11, 91054 Erlangen, Germany; e-mail: Florian.Stelzle@uk-erlangen.de

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TABLE 1 Review of the Literature on Elevation Heights Regarding Indirect Sinus Floor Elevation

Authors	Elevation Method	Design	Elevation Height (mm)
Summers (1994)[1]	OSFE	Technical report	4–5
Zitzmann and Scharer (1998)[2]	OSFE	Clinical study	4–5
Ioannidou and Dean (2000)[3]	OSFE	Case report	4–5
Emmerich et al. (2005)[4]	OSFE	Meta-analysis	1–6
Summers (1994)[1]	BAOSFE	Case report	5–7
Rosen et al. (1999)[5]	BAOSFE	Clinical study	5–7
Baumann and Ewers (1999)[6]	ECOSFE	Experimental study	7–10
Nkenke et al. (2002)[7]	ECOSFE	Clinical study	2–5
Sotirakis and Gonshor (2005)[8]	Free fluid pressure	Case report	6–9
Benner et al. (2005)[9]	BLC	Technical report	10
Kfir et al. (2007)[10]	Balloon elevation	Case report	10

OSFE, osteotome sinus floor elevation; BAOSFE, bone-added osteotome sinus floor elevation; ECOSFE, endoscopically controlled sinus floor elevation; BLC, balloon-lift-control sinus floor elevation.

"BAOSFE," piezosurgical sinus floor elevation (PSFE), and sinus floor elevation with a balloon lift method (BLC) – regarding their ability to successfully elevate the sinus floor mucosa to elevation heights of 10 mm on low bone levels (<3 mm) without perforation. Furthermore, a histological analysis of the mucosal layers in the elevated region was performed to investigate if the mucosa was completely elevated from the bone or separated in a specific tissue layer through the different methods of sinus floor elevation mentioned.

MATERIALS AND METHODS

Samples

The different sinus floor elevation procedures were carried out ex vivo on 36 bisected heads of adult pigs, which had been slaughtered a maximum of 5 hours before the experiments were performed (Slaughterhouse Munich, Munich, Germany). The animals were 2 years old on average, which provided a well-developed maxillary sinus. For the surgical approach, the lateral wall of the maxillary sinus was chosen, which has a maximum thickness of 3 mm and therefore was suitable for simulating the severely atrophic ridge of the upper alveolar crest. An X-ray was taken of each half of the cadaver heads to locate the maxillary antrum and the ideal region of surgical approach, using a radiopaque benchmark (Faxitron® Cabinet X-Ray System, Series Hewlett Packard [Lincolnshire, IL, USA], 85 kV, radiation time: 1 minute).

Nine bisected heads were used for each sinus lift method. On six halves, the sinus membrane elevation was carried out under macroscopic control, after opening the sinus from medially. On three halves, the Schneiderian membrane was elevated without prior opening of the sinus. These sinuses underwent histological preparation and were used for microscopic examinations (Table 2).

Macroscopic Assessment

The elevation height was measured with a rubber-tipped depth gauge to protect the mucosa. The inward border of the osteotomy served as gauge mark. The intended height was 10 mm in the region of the osteotomy. If the intended elevation height was not reached, the maximum height of elevation was measured. During the osteotomy and the elevation procedure, the mucosa was investigated macroscopically through a medial window for the occurrence of laceration.

Microscopic Assessment

After the elevation procedure, the space under the elevated mucosa was filled with a dental impression material (Impregum™, 3M ESPE®, Seefeld, Germany). Three-dimensional bone blocks with an edge length of 7 cm including the elevated region were cut out of the cadaver skulls, using an electrical bandsaw. The samples were fixed in Schaffers's solution (two parts 96% ethanol, one part 37% formaldehyde) and dehydrated in a graded series of ethanol, acetone, and methanol. Subsequently, the decalcified sections were embedded in methyl methacrylate (900 mL of methyl methacrylate, 90 mL of phtalic acid dibutyl ester and 15 g α-α-azo-iso-butyronitrile). Ground sections with a thickness of

TABLE 2 Number of Elevated Sinuses

Elevation Method		OSFE	BAOSFE	PSFE	BLC
Macroscopic evaluation	*N*	6	6	6	6
Microscopic evaluation	*N*	3	3	3	3
All sinuses	*N*	9	9	9	9

OSFE, osteotome sinus floor elevation; BAOSFE, bone-added sinus floor elevation; PSFE, piezosurgical sinus floor elevation; BLC, balloon-lift-control sinus floor elevation.

30 µm were produced with a diamond bandsaw (Leitz®, Wetzlar, Germany) and a micro-sectioning system (EXAKT®, Norderstedt, Germany) vertically through the area of the osteotomy and elevation.[14]

After performing May–Grünwald–Giemsa staining on ground sections, and Paragon staining on microsections, the sections were magnified (5×, 10×, 25×, 40×, and 100×) and images were taken with a digital camera (FinePix S3Pro, Fujifilm®, Düsseldorf, Germany).

The microscopic evaluation included histomorphological and histomorphometrical data regarding mucosal perforations, their localization and the size of the mucosa in the perforated area (Figure 1), the size of the elevated and non-elevated mucosa, the distance of elevation from the osteotomy to the border of the elevated mucosa (Figure 2), and the elevated layers of the sinus floor mucosa.

Sinus Floor Elevation Methods

OSFE. The approach was prepared using burs with an increasing diameter up to 4.2 mm, in accordance with the manufacturer's standard protocol (Surgical Kit, ITI Dental Implant System, Straumann®, Freiburg, Germany). Cooling was provided using a saline solution with a temperature of 3°C at a rate of 100 mL/min. For the osteotomy of the inner part of the cortical bone as well as for the mucosa elevation, a tapered osteotome with a blunt tip of 4.3 mm in diameter was used in accordance with the manufacturer's standard protocol (Tapered Osteotome Kit, Replace Implant System, Steri-Oss®, Yorba Linda, CA, USA).

BAOSFE. The osseous approach to the maxillary sinus was performed similar to the OSFE method. To perform the osteotomy of the inner cortical bone and to elevate the Schneiderian membrane, plane polyacrylate globes 0.6 mm in diameter were used, serving as a surrogate for the augmentation material. Through the pressure of an osteotome, these polyacrylate globes were plugged into the bur hole and after breaking the inner cortical bone, were plugged under the elevated mucosa (Tapered Osteotome Kit, Replace Implant System, Steri-Oss).

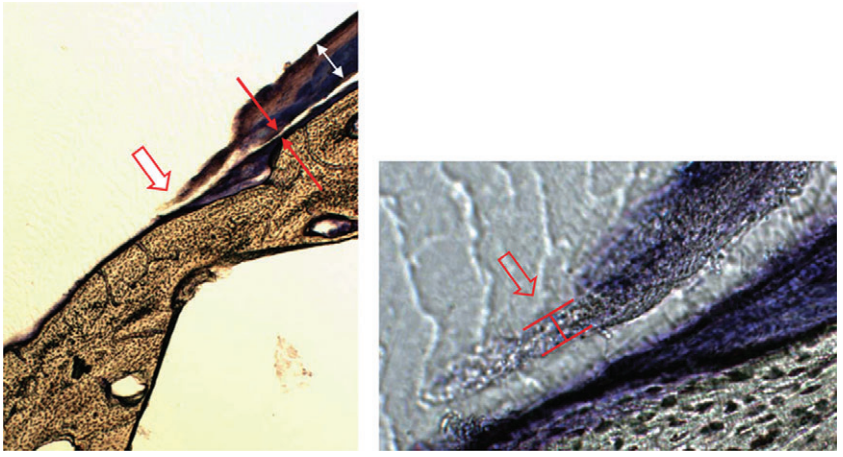

Figure 1 Assessment of the dissection layer in the mucosa (⟶; red arrow); scaling the size of the mucosa in the region of perforation (⟺; white arrow) and in the area of elevation (=>); sinus floor elevation, BAOSFE; histological microsection 30 µm, staining: Paragon, magnification 1:5.

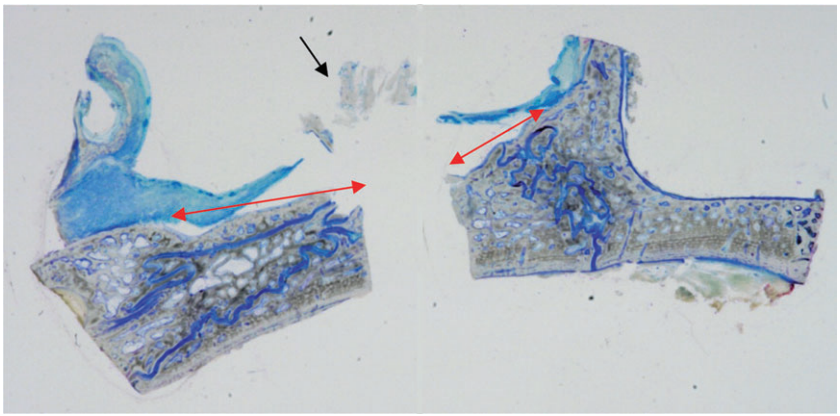

Figure 2 Assessment of mucosa perforation (⟶; black arrow); scaling of the elevation distances: edge of osteotomie – border of elevation (⟷; red arrow); sinus floor elevation, BAOSFE; histological section 100 µm, staining: H.E., magnification 1:1.

PSFE

A piezoelectric device with a curved cutting tip (Piezosurgery®, Mectron, Carasco, Italy) was used for the osteotomy of the outer cortical bone and for the cancellous bone. The inner cortical bone was ablated with a high-precision spherical grinding tip, to avoid damage to the mucosa. The settings of the piezoelectric unit were chosen: mode: boosted, power: burst c, cooling: saline solution with a temperature of 3°C with a flow rate of 40 mL/min. The sinus membrane elevation was carried out with blunt tips with different angulations (Figure 3) without water cooling, with a mode setting of: low 1. Arrangement and working steps were carried out according to the manufacturer's standard protocol for a lateral sinus lift. However, the straight-cutting device was replaced with a smaller curved cutting device (OP3) to downsize the osteotomy to a diameter of 4.5 mm.

Sinus Floor Elevation with BLC

The osseous approach was performed with burs, followed by a tubular osteotome with a diameter of 5 mm with depth control, to open the bony sinus floor. A balloon-tip catheter was inserted through a tubular osteotome under the mucosa of the maxillary sinus and was repeatedly (5×) filled with 3 mL of a contrast agent (Ultravist 240, Bayer Schering®, Berlin, Germany) (Figure 4). This procedure corresponds to the manufacturer's standard protocol (Balloon-Lift-Control-System, Hager & Meisinger®, Neuss, Germany).

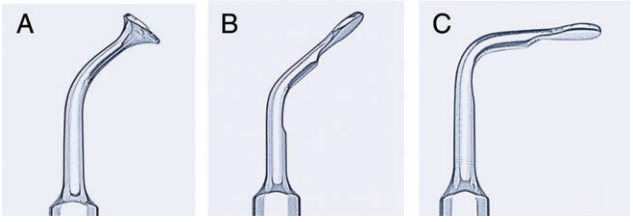

Figure 3 Blunt elevation devices, piezosurgical sinus floor elevation: elevation-device 0° (A), elevation-device 45° (B), elevation device 90° (C).

Statistics

Where appropriate, multiple measurements per sample were aggregated prior to analysis, using the mean as the aggregation measure. Mean values are given with SDs. Nominal data were compared to each other using the Fisher's exact test; metric data were compared using the Mann–Whitney *U*-test, which is appropriate for small data sets. p Values equal to or smaller than .05 were considered to be significant. All calculations were made using SPSS version 16 for Windows (SPSS®, Chicago, IL, USA).

RESULTS

OSFE and BAOSFE caused perforations of the elevated mucosa at elevation heights of 10 mm in all analyzed cases (Table 3). The perforations mainly occurred during the elevation procedure ($p = 7.16\text{e-}08$) and were mainly localized at the center of the elevated mucosa (Table 4).

During sinus lift elevations using the piezoelectric device, no perforations occurred. However, this method was limited to a maximum elevation height of 5 mm, using an indirect approach due to technical conditions regarding the length and angulations of the tips. Elevations of the sinus floor using an inflatable balloon caused no macroscopic or microscopic tearing of the elevated mucosa.

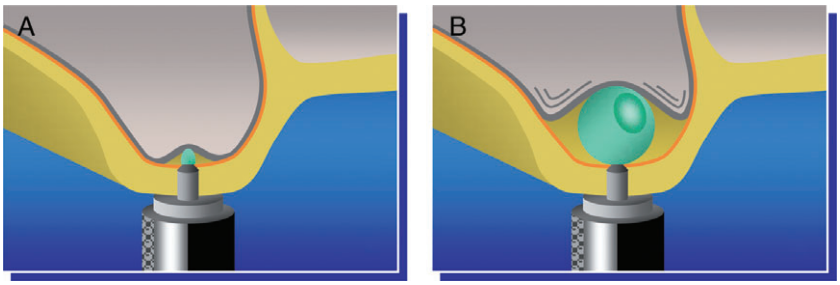

Figure 4 Diagram of the balloon-lift-control sinus floor elevation. (A) Insertion of the balloon catheter through the tubular (B) filling of the balloon/elevation of the antral mucosa.

The elevation distance showed significant differences depending on the methods of sinus floor elevation. OSFE demonstrated the lowest balloon elevation, the highest distance of mucosal separation from the sinus floor (Table 5).

The thickness of the elevated mucosa was significantly reduced in the area of perforation in the OSFE and BAOSFE samples, compared to the elevated, but intact tissue layers in PSFE and BLC samples. On the other hand, elevated but not perforated mucosa was significantly thinned out compared to native mucosa of the maxillary sinus (Table 6).

Regarding the histological examination of elevated tissue layers, the OSFE method showed a completely lifted sinus floor mucosa, including the periosteum (Figure 5). On the other hand, BAOSFE, PSFE, and BLC were found to split the mucosa within a tissue layer, which is situated near the bone and contains high rates of collagen. A thin layer of the collagen-rich tissue stayed on the bone in all histological samples, while the rest of the mucosa was elevated, containing the other part of the collagen-rich tissue, followed by a well-vascularized tissue layer and the covering epithelium (Figure 6). The histomorphometric data are provided in Table 7.

TABLE 3 Mucosa Perforation

Perforation				
Elevation method	OSFE ($n = 9$)	BAOSFE ($n = 9$)	PSFE ($n = 9$)*	BLC ($n = 9$)
Perforation (n)	9	9	0	0
Comparison of elevation methods regarding perforation (Exact Fisher's test – two way)				
Elevation method	OSFE/PSFE	OSFE/BLC	BAOSFE/PSFE	BAOSFE/BLC
p Value	6.61E-10	6.61E-10	6.61E-10	6.61E-10

*Intended elevation height (10 mm) not achieved.
OSFE, osteotome sinus floor elevation; BAOSFE, bone-added sinus floor elevation; PSFE, piezosurgical sinus floor elevation; BLC, balloon-lift-control sinus floor elevation.

TABLE 4 Cause of Mucosa Perforation

Elevation Method		OSFE ($n = 9$)	BAOSFE ($n = 9$)	OSFE and BAOSFE ($n = 18$)
Osteotomy	N	1	0	1
Elevation	N	8	9	17
Elevation (central)	N	5	9	14
Elevation (lateral)	N	3	0	3
Comparison of different causes of perforation (Exact Fisher's Test – two way)				
Osteotomy/Elevation	p Value	0.003	6.61E-10	7.16E-08
Elevation central/lateral	p Value	0.08	6.61E-10	4.12E-04

Osteotomy, perforation caused during osteotomy; elevation central, perforation in the central elevation area caused during elevation; elevation lateral, perforation at the elevation border (transition from elevated to non-elevated mucosa) caused during elevation.

TABLE 5 Elevation Distance (Osteotomy – Elevation Boarder)

Elevation Method		OSFE ($n = 3$)	BAOSFE ($n = 3$)	PSFE ($n = 3$)	BLC ($n = 3$)
Distance of elevation (mean value; one side*)	*mm*	2.25 ± 0.87	5.50 ± 3.01	10.00 ± 1.36	14.33 ± 8.76
Comparison of elevation distances (Mann–Whitney *U*-test)					
OSFE	*p* Value	/	0.015	0.004	0.024
BAOSFE	*p* Value	0.015	/	0.103	0.078
PSFE	*p* Value	0.004	0.103	/	0.107
BLC	*p* Value	0.024	0.078	0.5	/

*Elevation distance – calculated as mean of both sides from each specimen.
OSFE, osteotome sinus floor elevation; BAOSFE, bone-added sinus floor elevation; PSFE, piezosurgical sinus floor elevation; BLC, balloon-lift-control sinus floor elevation.

TABLE 6 Mucosa Size (Area of Perforation/Elevation)

Elevation Method		OSFE ($n = 3$*)	BAOSFE ($n = 3$*)	PSFE ($n = 3$**)	BLC ($n = 3$**)
Size of mucosa at the area of perforation (mean value; SD)	µm	282 ± 177	186 ± 62	/	/
Size of mucosa at the area of elevation (mean value; SD)	µm	/	/	1,133 ± 95	1,211 ± 80
Difference to native mucosa (mean value subtraction†)	µm	1468	1564	617	539
Comparison of mucosa sizes (Mann–Whitney *U*-test)					
OSFE	*p* Value	/	0.24	0.002	0.002
BAOSFE	*p* Value	0.24	/	0.002	0.002
PIEZO	*p* Value	0.002	0.002	/	0.127
BLC	*p* Value	0.002	0.002	0.127	/
Native mucosa	*p* Value	3.36E-06	3.36E-06	3.36E-06	3.36E-06

*Mucosa size – calculated as the mean of both perforated sides of each specimen.
**Mucosa size – calculated as the mean of two measurements (central elevation area – distance of measurements: 15 mm).
†Size of native mucosa – mean value: 1750 ± 154 µm ($n = 12$).
OSFE, osteotome sinus floor elevation; BAOSFE, bone-added sinus floor elevation; PSFE, piezosurgical sinus floor elevation; BLC, balloon-lift-control sinus floor elevation.

DISCUSSION

The indirect sinus floor elevation is preferred rather than the direct approach, because it causes less tissue trauma and provides faster recuperation of the patient.[2,6,15–18] However, the indirect sinus floor elevation cannot be used universally.[19,20] Poor visibility and decreased space for handling surgical instruments were found to increase the risk of mucosal perforation. Therefore, the elevation height is assumed to be limited when classic elevation methods are used.[2,4,7,21]

This study compared different methods of indirect sinus floor elevation regarding elevation heights of

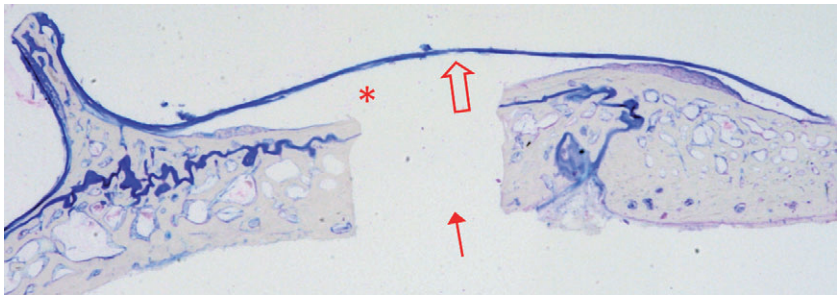

Figure 5 Elevated mucosal layers, PSFE (piezosurgical sinus floor elevation); histological section 100 µm, staining: H.E., magnification 1:1; osteotomy (⟶); elevated mucosal layers (=>); area below the elevated mucosa (*).

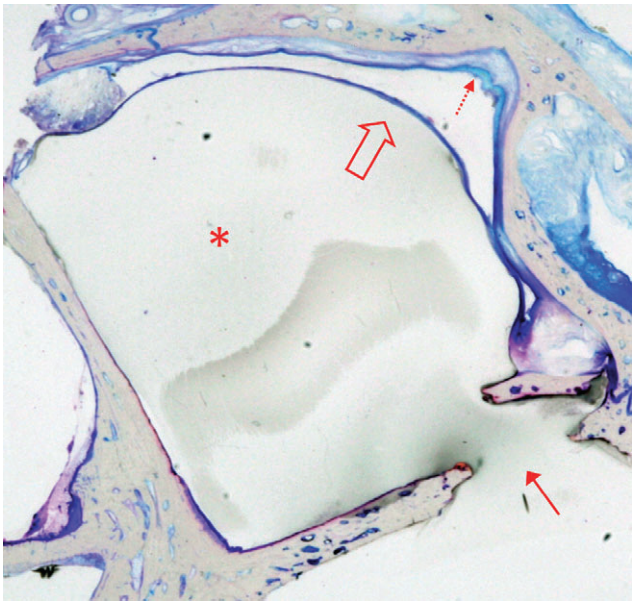

Figure 6 Elevated mucosal layers, BLC (balloon lift control system); histological section 100 µm, staining: H.E., magnification 1:1; osteotomy (⟶); elevated mucosal layers (=>); non-elevated sinus floor mucosa (⇢); area below the elevated mucosa (*).

10 mm on alveolar bone sizes equal to or smaller than 3 mm. OSFE caused mucosal tearing in all trials, as well as the BAOSFE. These results support various studies that claim a limitation of elevation height for these methods.[1,2–5] Perforation mainly occurred during the elevation process and was localized at the center of the lifted mucosa, where most of the pressure was applied by the osteotome. In the area of perforation, (OSFE and BAOSFE) the mucosa was significantly thinner than the undestroyed, elevated mucosa in PSFE and BLC samples. On the other hand, the distance of mucosa elevation from the bone was lower for OSFE and BAOSFE than for the other two methods. Therefore, uneven tension during detachment of the mucosa is assumed to be responsible for overexpansion, followed by tissue laceration.[7,22,23]

PSFE caused no mucosal tearing when performing the osteotomy and elevation of the sinus floor mucosa. These results confirm successful case reports and technical descriptions using this technique via a direct, lateral approach.[11,24] However, using an indirect approach, which was analyzed in this study, the method was technically limited. Despite a significantly greater distance of mucosa elevation compared to the classical OSFE procedure, the geometry and length of the elevation tips restricted the working range because of the small bony approach. Hence, the maximum elevation height was 5 mm on average.

The BLC method, which uses an inflatable balloon for elevation, performed the sinus floor elevation without laceration of the Schneiderian membrane in all analyzed cases. This confirms studies which successfully elevated the mucosa 8–10 mm on ex vivo human bodies fixed with formaldehyde[9] and in particular clinical cases.[9,10,13,25]

For both methods, PSFE and BLC, the thinning of the elevated mucosa was significantly higher than compared to the native mucosa. On the other hand, it remained significantly larger compared to the area of perforation in OSFE and BAOSFE samples, as mentioned. Consequently, PSFE and BLC, differing from OSFE and BAOSFE, seem to elevate the mucosa in a steadier and more even manner without overexpansion of the tissue.

A further finding of this study was that the elevated layers of the sinus floor mucosa seem to be non-uniform with different sinus floor elevation methods. OSFE, as it was performed in this study, showed a complete elevation of the soft tissue from the underlying bone, which included the periosteum (Figure 7). This fact is generally agreed on by clinicians.[1,5,26] In contrast, BAOSFE, PSFE, and BLC were found to split the mucosa. A thin collagenous tissue layer was left on the

TABLE 7 Size of Mucosal Layers According to the Elevation Method

Elevation Method		OSFE ($n = 3$)	BAOSFE ($n = 3$)	PSFE ($n = 3$)*	BLC ($n = 3$)
Stratum reticulare (remaining on bone)	µm	0	200 ± 10	156 ± 40	236 ± 32
Stratum reticulare (elevated)	µm	265 ± 60	110 ± 28	130 ± 20	160 ± 10
Stratum vasculare (elevated)	µm	1203 ± 137	1185 ± 92	1143 ± 225	1540 ± 122
Lamina epithelialis mucosae (elevated)	µm	129 ± 51	165 ± 64	110 ± 10	143 ± 12

*Intended elevation height (10 mm) not achieved.
OSFE, osteotome sinus floor elevation; BAOSFE, bone-added sinus floor elevation; PSFE, piezosurgical sinus floor elevation; BLC, balloon-lift-control sinus floor elevation.

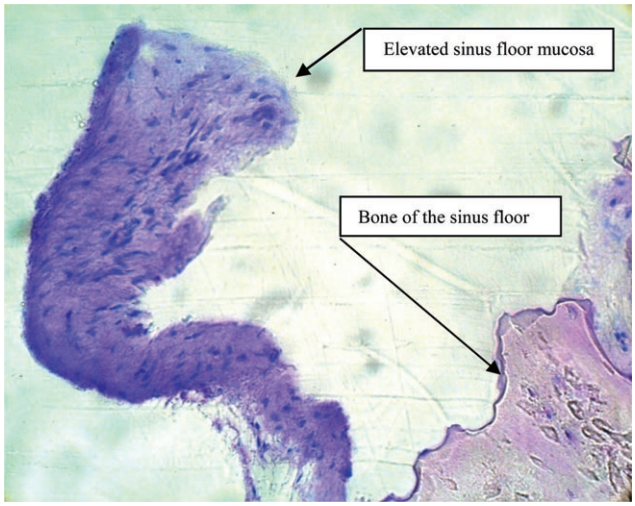

Figure 7 Inner cortical bone – entirely removed mucosa, sinus floor elevation, OSFE; histological microsection 30 µm, staining: Paragon, magnification 1:25.

bone, which can be interpreted as periosteum or parts of the periosteum. The rest of the mucosa was elevated, also including a thin collagenous tissue layer on the bottomline (Figure 8). These results support findings of prior studies regarding sinus floor elevation on human cadavers, in which splitting of the sinus floor mucosa in a collagenous tissue layer above the periosteum was demonstrated. This tissue layer was anatomically described as "stratum reticulare" and was suggested to include a "locus minoris resistentiae".[9,27,28]

To elevate just parts of the mucosa, it is necessary to perforate the periosteum or parts of the periosteum, which happened in all cases investigated in this study. However, OSFE perforated not only the periosteum, but the complete mucosa without splitting any mucosal layers. In contrast, a more proportioned pressure applied with blunt tips (PSFE) or rounded surfaces (BAOSFE, BLC) seems to lacerate the rigidly anchored periosteum by overstretching the collagenous fibers, but – after perforating the periosteum or parts of it – split the rest of the mucosa within the mentioned (locus minoris resistentiae).

The collagenous tissue of the periosteum or next to the periosteum contains osteoblast progenitor cells and therefore has the ability to build up new bone.[29–32] However, it is not known to date if both parts of a split collagenous layer, as it was found in this study – one part elevated, one part left on the bone – are able to induce proper ossification of the elevated space following sinus floor elevation.

Additionally, this study found that the elevated parts of the sinus floor mucosa, using PSFE and BLC, included an unharmed, well-vascularized layer, described as "stratum vasculare."[9] This layer is assumed to be of importance for the blood supply, assuring the vitality of the elevated mucosa.[23,33]

However, these results have to be considered with caution, regarding the fact that the experiments were performed ex vivo. Further in vivo studies have to be performed to prove an extended indication for the indirect sinus floor elevation for elevation heights up to 10 mm, using the balloon elevation method. Even though the ex vivo time was only a maximum of 5 hours, a postmortem change of tissue stability, elasticity, and

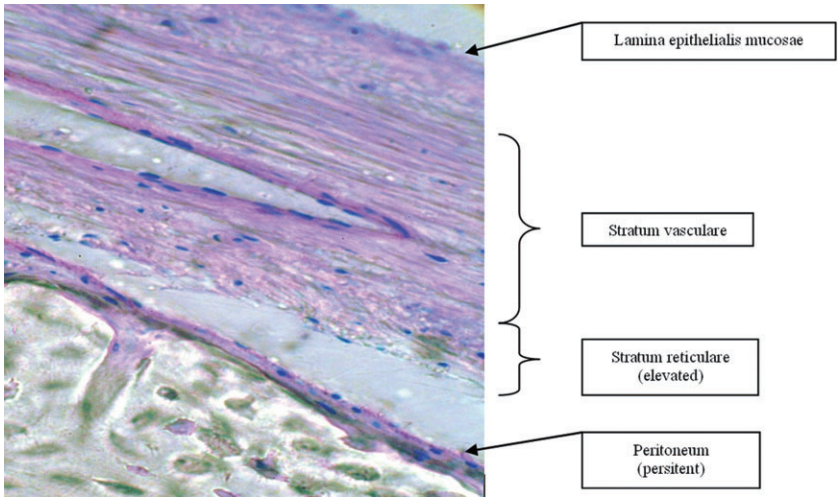

Figure 8 Elevated and persistent part of sinus floor mucosa, piezosurgical sinus floor elevation; histological microsection 30 µm, staining: Paragon, magnification 1:40.

intertissue connectivity, producing a (locus minoris resistentiae), not corresponding to in vivo conditions, cannot be excluded. This refers to the relevance of splitting of the sinus floor mucosa as well. It has to be investigated with in vivo trials if the clinical outcome of sinus floor augmentation will be altered by the elevation of just parts of the mucosa and in which way this improves the ossification pattern of the elevated space induced by both parts of the split mucosa.

CONCLUSION

OSFE as well as BAOSFE caused sinus membrane perforations on elevation heights of 10 mm, whereas the BLC lifted the Schneiderian membrane without tearing. PSFE elevated the soft tissue without laceration as well, but turned out to be limited to a maximum elevation height of 5 mm, because of geometrical restrictions of the elevation tips. OSFE completely elevated the soft tissue from the underlying bone, including the periosteum. In contrast, BAOSFE, PSFE, and BLC separated the mucosa within a clearly defined tissue layer, a locus minoris resistentiae, leaving a thin layer of osteogenic soft tissue on the bone.

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