CLINICAL ORAL IMPLANTS RESEARCH

Sinus augmentation *via* transcrestal approach: a comparison between the balloon and osteotome technique in a cadaver study

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Abstract

Background: The transcrestal approach with osteotomes is a commonly applied and predictable technique for maxillary sinus floor elevation. However, Schneiderian membrane perforation is a common and often inevitable intraoperative complication. Recently, the use of balloons has been proposed to reduce the risk of sinus membrane perforation and to facilitate the surgical technique. The aim of this study was to determine membrane elevation height and perforation rate using the transcrestal balloon technique (B) and a conventional osteotome approach, as control (C).

Methods: Ten fresh, completely edentulous cadaver heads (seven male and three female) were selected. In a split-mouth design, each sinus was randomly assigned to either the experimental or the control technique. Pre-surgical planning was aided by cone-beam computed tomography. During the procedure, an endoscope was used to monitor the elevation procedure and the occurrence of sinus perforation. The elevation continued until either 15 mm (measured from the alveolar crest) was reached or a perforation occurred. The residual ridge and the elevated membrane height were measured and compared with the paired Student's *t*-test. Presence of sinus perforation was recorded at three cutoff points: 10, 12, and 15 mm.

Results: The mean age of the specimens was 77.7 ± 14.2 years (range 49–92). The mean initial, final, and elevated sinus membrane height for the B group was 5.3 ± 1.9, 13.7 ± 1.9, and 8.3 ± 3.1 mm, whereas the correspondent values for the C group were 5.1 ± 2.1, 13.2 ± 2.8, and 8.1 ± 3.1 mm. The incidence of sinus perforation, using 10, 12, and 15 mm as end points was 0%, 22.2%, and 44.4% in the B group, whereas in the C group the respective values were 10.0%, 20.0%, and 50.0%. No statistically significant differences were found between the two groups for all the above-mentioned variables. In addition, mean residual ridge height was not significantly different between the non-perforation and perforation sites in the B group (5.2 ± 2.2 and 5.5 ± 1.7 mm) and in the C group (5.2 ± 2.5 and 5.0 ± 2.0 mm). Three cadavers had perforations in both sinuses, accounting for 66.6% of total number of perforations.

Conclusions: Based on the findings of this study, the balloon and the conventional osteotome approach are comparable in terms of perforation rate as it relates to the elevation height. Also, the amount of residual alveolar bone was not related to the incidence of perforation and the height of sinus elevation.

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The edentulous posterior maxilla is typically characterized by unfavorable bone density (Truhlar et al. 1997) and reduced bone quantity. The latter is primarily due to bone remodeling and maxillary sinus pneumatization after tooth extraction (Smiler et al. 1992; Smiler 1997). As a consequence, rehabilitation of the edentulous posterior maxilla with endosseous oral implants is often a challenge. Many treatment alternatives, such as the use of short oral implants (less than 10 mm in length) (Felice et al. 2011) or angled implants (Jensen & Adams 2009) have been suggested in the management of atrophic maxillae. However, short implants are generally associated with higher failure rates, particularly in sites of compromised bone density compared to standard length implants (10 mm or more) (Renouard & Nisand 2006; Sun et al. 2011). Limited information is available on long-term success of angled implants, although short-term treatment outcomes appear to be acceptable (Graves et al. 2011). However, the complexity of the prosthetic phase for the fabrication of implant-supported restorations on this type of implants may discourage many clinicians.

Maxillary sinus augmentation, performed either *via* the lateral window or transcrestal approach is usually indicated to overcome limitations in residual ridge height and facilitate placement of regular/standard implants (Boyne & James 1980). In the direct approach, the Schneiderian membrane is elevated by accessing the sinus cavity through a lateral window. Implant placement can be performed simultaneously or in a staged approach depending on the features of the residual ridge, which determines the possibility to achieve primary implant stability (Pjetursson et al. 2008). The transcrestal or indirect approach involves sinus floor elevation and simultaneous implant placement (Tatum 1986; Summers 1994). The procedure consists on the in-fracture of the sinus floor by preparation of the implant bed with osteotomes of increasing diameters. It allows for condensation of the trabecular alveolar bone to increase bone density around the implant (Krafft et al. 2011), which has been demonstrated to positively influence primary implant stability (Gomes de Oliveira et al. 2011; Marquezan et al. 2011). This approach has been reported to be less invasive, have increased patient acceptance and reduced patient discomfort and morbidity (Emmerich et al. 2005).

A modification of the original transalveolar approach consisting of the use of a balloon was introduced in 2003. This method allows for the application of hydraulic pressure to elevate the Schneiderian membrane, supposedly with minimal risk of perforation (Muronoi et al. 2003). Subsequent studies have investigated the application of the sinus elevation balloon technique in human trials, reporting an incidence of Schneiderian membrane perforation ranging from 2.7% to 7.7% (Kfir et al. 2006, 2007; Kfir et al. 2009a,b; Hu et al. 2009). In all of them, antral membrane perforation was assessed intraoperatively by direct intraoral visualization or using the Valsalva maneuver, which may lead to false negative recordings. Therefore, there is limited information about the incidence of antral perforation and the dimensions of the perforation associated to maxillary sinus elevation by means of a balloon technique.

The aim of this study was to determine membrane elevation height and perforation rate using a transcrestal balloon technique and the conventional osteotome approach, as a control.

Materials and methods

Specimen selection and randomization

Ten fresh cadaver heads with fully edentulous maxillary arches were obtained from the Department of Anatomy at the University of Michigan. The mean age of the donors was 77.7 ± 14.2 years (ranged from 49 to 92 years). These specimens were harvested from human donors and kept frozen in −20°C to prevent structural changes in the tissues. The specimens were defrosted before the initiation of the experiment. In a split-mouth design, each sinus was randomly assigned to receive one of two techniques for sinus floor elevation: the balloon (B) [Experimental] or the osteotome technique (C) [Control]. The randomization was performed by blind selection of a numbered card. Number 1 indicated experimental, whereas number 2 was assigned to the control. Sinuses with relatively flat floor and free from sinus septae were chosen, as examined in cone-beam computed tomography (CBCT) scans (i-CAT; Imaging Sciences International Inc., Hatfield, PA, USA). Tenting screws (Salvin Dental Specialties, Charlotte, NC, USA) were bilaterally inserted in the canine area as references, so the sites chosen in CBCT scans could be clearly identified on the specimens (Fig. 1). Two experienced surgeons (HC and JF) performed the surgical procedures by random allocation to avoid physical fatigue.

CBCT acquisition and measurements

Prior to the surgical procedure, CBCT scans were obtained by a trained operator (JF) in the Radiology Department of the University of Michigan School of Dentistry. The specimens were stabilized using a head locator. The parameters of exposure were 120 kVp and 18.66 mAs for 20 s, resolution was set at 0.4 mm and the field of view (FOV) was 16 × 22 cm. Data images were processed using the built-in software package on a desktop computer (i-CAT; Xoran Technologies Inc., Ann Arbor, MI, USA). The DICOM files were exported to a viewer software (Osirix, aycan Medical Systems LLC, Rochester, NY, USA) to generate panoramic images that were used for site selection based on the above-mentioned criteria.

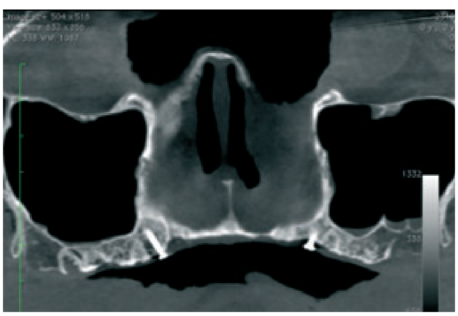

Fig. 1. Representative panoramic view reconstructed from one cone-beam computed tomography scan. Pins were used as aids to identify the surgical site clinically.

Use of the endoscope

An endoscope (ENF-V2 Rhinolaryngoscope; Olympus, Center Valley, PA, USA) that included an optical system that allows for 90° field of view and 5–50 mm depth of field was used for monitoring the procedures of sinus elevation. The insertion tube is 3.2 mm in diameter and possesses 130° up/down bending capability. Intrasurgical images were captured and transferred to a processor and viewed on a monitor connected to the processor. For time efficiency, the endoscope was inserted into the sinus via a hole (6 × 6 mm) below the inferior orbital rim. The hole was created with a diamond round bur in a high-speed hand piece. Two examiners (JF and HC) alternated between operating the endoscope and performing the surgery. During the elevation procedure, the integrity of the sinus membrane was constantly monitored via the endoscope.

Sinus membrane elevation procedures and measurements

Manufacturer instructions were followed for the use of the balloon (Sinus Lift Balloon; Zimmer, Carlsbad, CA, USA). Briefly, the balloon was connected to a syringe via a plastic line. The integrity of the balloon was evaluated by filling the balloon with 1–3 cc of air, after which the balloon was deflated. This procedure was repeated four to five times. Subsequently, the syringe was filled with 2 cc of saline. The balloon was connected with the syringe and inflated once again. Saline and air were removed out of the balloon by retracting the plunger from the syringe and disengaging the syringe from the balloon. Osteotomies were performed at the selected sites with a series of drills (SCA kit; Zimmer) of increasing diameters, specially designed to avoid trauma to the Schneiderian membrane (Fig. 2). The depth of preparation was based on the residual ridge height measured on the CBCT images. When the sinus membrane was tactilely identified, a gauge (SCA kit; Zimmer) was used to measure the residual bone height within 1 mm of accuracy. The balloon was engaged with the

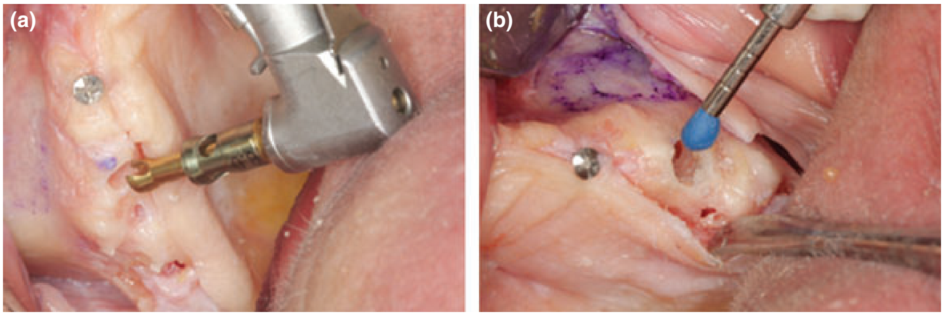

Fig. 2. Demonstration of the surgical technique. (a) A reamer drill with an appropriate stopper was used to prepare the osteotome site. (b) A balloon was used to elevate the sinus membrane.

syringe again and inserted into the osteotomy site to the level of the sinus floor, gently inflated until resistance was met, then the balloon was deflated. The inflation-deflation procedure was performed three to four times and the gauge was used to measure the amount of sinus membrane elevation (Fig. 3).

For the control group, the surgical site was first prepared with a series of the three drills, following the same procedures as described earlier for the balloon group. Subsequently, allogenic bone grafts (Puros Cancellous Particulate Allograft, Particle size: 250–1000 μ; Zimmer) were packed into the osteotomy site, followed by gently tapping an osteotome to insert the bone graft into the sinus.

For both techniques, the elevation procedure was repeated until sinus perforation was noted or 15 mm of elevation from the alveolar crest was reached. The measurements of residual ridge height and elevated membrane height were made by the gauge (SCA kit; Zimmer).

The procedure was considered to be successful when the membrane was elevated to 15 mm, as measured from the alveolar crest without any perforation; otherwise, it was considered a failure.

Statistical analysis

Clinical measurements, such as the residual ridge height and final membrane height were expressed as a mean value ± standard deviation in millimeters. The elevated membrane height was calculated as final membrane height minus residual ridge height. The mean residual ridge height and elevated membrane height were compared between the two groups with the paired Student's *t*-test. The number of successful and failed elevations was compiled for both techniques and compared with Fisher's exact test. In addition, the mean residual ridge height was compared between the successful and failed sites for both groups, using the Student's *t*-test. The percentage of perforation using 10- and 12-mm elevation (measured from the crest) as cutoff points was also calculated for each group. Statistical significance was set at 0.05 for both the Student's *t*- and Fisher's exact test. Statistical analysis was performed using specialized software (Microsoft Excel 2007, Seattle, WA, USA).

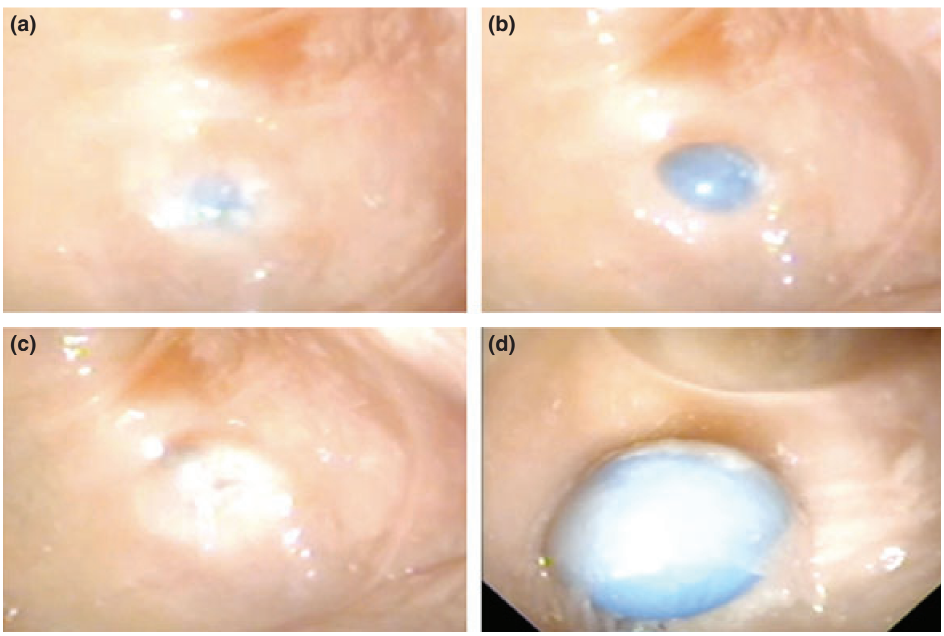

Fig. 3. Endoscopic view of sinus elevation using the balloon technique through a crestal approach. (a) Insertion of the balloon. (b) The balloon was inflated. (c) A gauge was used to measure the height of elevation and (d) Sinus membrane was perforated at the edge of the dome-shaped elevation.

Results

Twenty sites (10 for each group) on 10 specimens (7 males and 3 females) were initially selected for this study. One site was excluded in the B group because a Schneiderian membrane perforation occurred during osteotomy preparation with the pilot drill. Figure 4 shows a scatter plot illustrating distributions of elevated height as a function of residual ridge height in both groups. Only one site with 4 mm residual ridge in the C group did not reach 10 mm final height. In four sites (two in each group) the membrane was elevated 3–5 mm but failed to reach 12 mm final height. Nine sites, four in the B and five in the C group did not reach 15 mm final height.

Mean residual ridge height was 5.3 ± 1.9 and 5.1 ± 2.1 mm for the B and C group, without significant statistical difference ($P = 0.85$) (Table 1 and Fig. 5a). Mean elevated membrane height for the B and C group were 8.3 ± 3.1 and 8.1 ± 3.4 mm, respectively. The difference was not statistically significant either ($P = 0.54$). Data were subsequently stratified into successful and failed sites (based on the ability to achieve 15 mm final membrane height). Mean residual ridge was 5.2 ± 2.2 and 5.5 ± 1.7 mm for the successful and failed groups in the B group ($P = 0.83$). The correspondent values were 5.2 ± 2.5 and 5.0 ± 2.0 mm for the C group ($P = 0.89$). The results suggested that whether the membrane could be elevated successfully to 15 mm was irrelevant to residual ridge height. In failed sites, mean elevation was 6.5 ± 3.4 and 6.4 ± 3.6 mm for the B and C group, respectively.

The percentage of membrane perforation using 10, 12, and 15 mm final height as the cutoff points was 0, 22.2 ($n = 2$), and 44.4% ($n = 4$) for the B group (total $n = 9$). The corresponding values were 10 ($n = 1$), 20 ($n = 2$), and 50% ($n = 5$) for the C group (total $n = 10$). Perforation rate was not significantly different between both groups at any cutoff

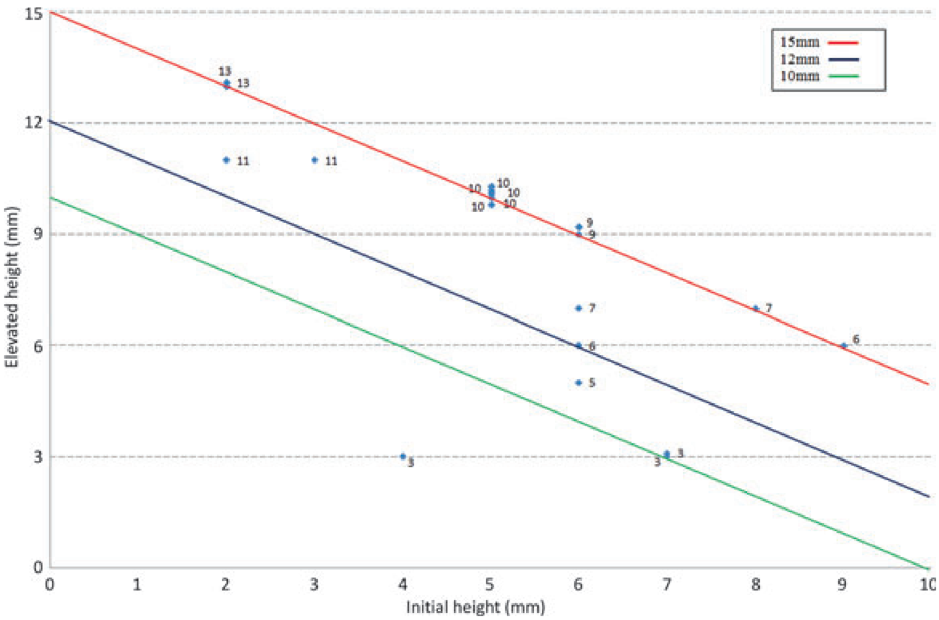

Fig. 4. Scatter plot showing the distribution of elevated height of the membrane in function of the residual ridge height for both groups. The three lines representing the 10, 12, and 15 mm final elevation were drawn to differentiate the successful and failed sites.

points (Fig. 5b). Perforations in both sinuses occurred in three specimens, which represented 66% of the total perforations.

Discussion

Transalveolar maxillary sinus floor elevation with osteotomes is a commonly indicated and predictable procedure (Tan et al. 2008). Most clinical studies (Cavicchia et al. 2001; Leblebicioglu et al. 2005; Ferrigno et al. 2006; Nedir et al. 2006; Pjetursson et al. 2009) report mean elevation between 2 and 4 mm with this approach. Hence, it is often indicated when the residual bone height is 6–9 mm (Wang & Katranji 2008). This study evaluated the efficacy and safety of transcrestal sinus elevation using two different techniques, the balloon and the osteotome approach. Results showed that both techniques were equally effective in elevating the sinus membrane. Mean initial ridge height was 5.3 mm for the balloon group and 5.1 mm for control group. After the surgical procedures, the mean elevation was 8.3 and 8.1 mm, respectively. Even in failed cases, average elevation was 6.5 and 6.4 mm for the experimental and control group. The effectiveness of the balloon technique for transcrestal sinus elevation was investigated in one case series study (Hu et al. 2009). Mean elevation height reported was 10.9 ± 2.06 mm, which is slightly superior to the findings reported in this article (Hu et al. 2009). This discrepancy may be related to differences in the characteristics of the sites where surgical procedures were performed. Although in our study cadaver heads were used, Hu and collaborators (Hu et al. 2009) conducted the study on human subjects.

Sinus membrane perforation is the most commonly encountered intraoperative complication. It may cause termination of the augmentation surgery if the perforation is large and overcomes the ability of the operator to seal it. This complication has been associated with higher incidence of sinusitis and implant failure (Schwartz-Arad et al. 2004). A systematic review found that the mean perforation rate was 3.8%, ranging from 0% to 21.4%, when using the transalveolar technique (Tan et al. 2008). This number might be underestimating the true incidence of this accident due to difficulties in identifying a membrane perforation clinically. In this study, membrane perforation was monitored with an endoscope, which allowed direct vision of the elevation from an intra-sinus perspective. The percentage of membrane perforation for both techniques was almost equal. Interestingly, in both sides of three specimens, perforations occurred before the 15 mm elevation, accounting for 66% of the total number of perforations. These results may indicate that one of the determining factors for the appearance of Schneiderian membrane perforation is its inherent properties (e.g. membrane thickness) rather than the elevation technique that was applied (Pommer et al. 2009).

The thickness of maxillary sinus membrane has been investigated by means of medical (Yilmaz & Tozum 2012) and cone-beam computed tomography (Janner et al. 2011) and also histologically (Aimetti et al. 2008). One study showed a wide range of membrane thickness (from 0.16 to 34.61 mm) (Janner et al. 2011). At similar anatomical locations, another study reported a thickness range of 0.1–2.7 mm.(Yilmaz & Tozum 2012) It has also been reported that membrane thickness is related to gingival biotype (Aimetti et al. 2008; Yilmaz &

***Table 1.* Summary of the variables, including percentage of successful elevation and initial, final and elevated height in the two groups. No statistically significant difference was found regarding the incidence of membrane perforation (*P* = 0.34) and mean elevated height (*P* = 0.54) between the two groups**

			Mean initial height		Mean final height		Mean elevated height	
Group	*N*	Percentage (%)	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range
Balloon	9	100.0	5.3 (1.9)	2–8	13.7 (1.9)	10–15	8.3 (3.1)	3–13
Balloon/S	5	55.6	5.2 (2.2)	2–8	15.0 (0.0)	15	9.8 (2.2)	7–13
Balloon/F	4	44.4	5.5 (1.7)	3–7	12.0 (1.8)	10–14	6.5 (3.4)	3–11
Control	10	100.0	5.1 (2.1)	2–9	13.2 (2.8)	7–15	8.1 (3.4)	3–13
Control/S	5	50.0	5.2 (2.5)	2–9	15.0 (0.0)	15	9.8 (2.5)	6–13
Control/F	5	50.0	5.0 (2.0)	2–7	11.4 (3.0)	7–15	6.4 (3.6)	3–11

All the measurements except the percentage were made in millimeters.
Balloon/S(F) = successful (failed) cases with the balloon technique.
Control/S(F) = successful (failed) cases with the osteotome technique.
A successful case was defined when 15 mm final height was achieved without causing membrane perforation.

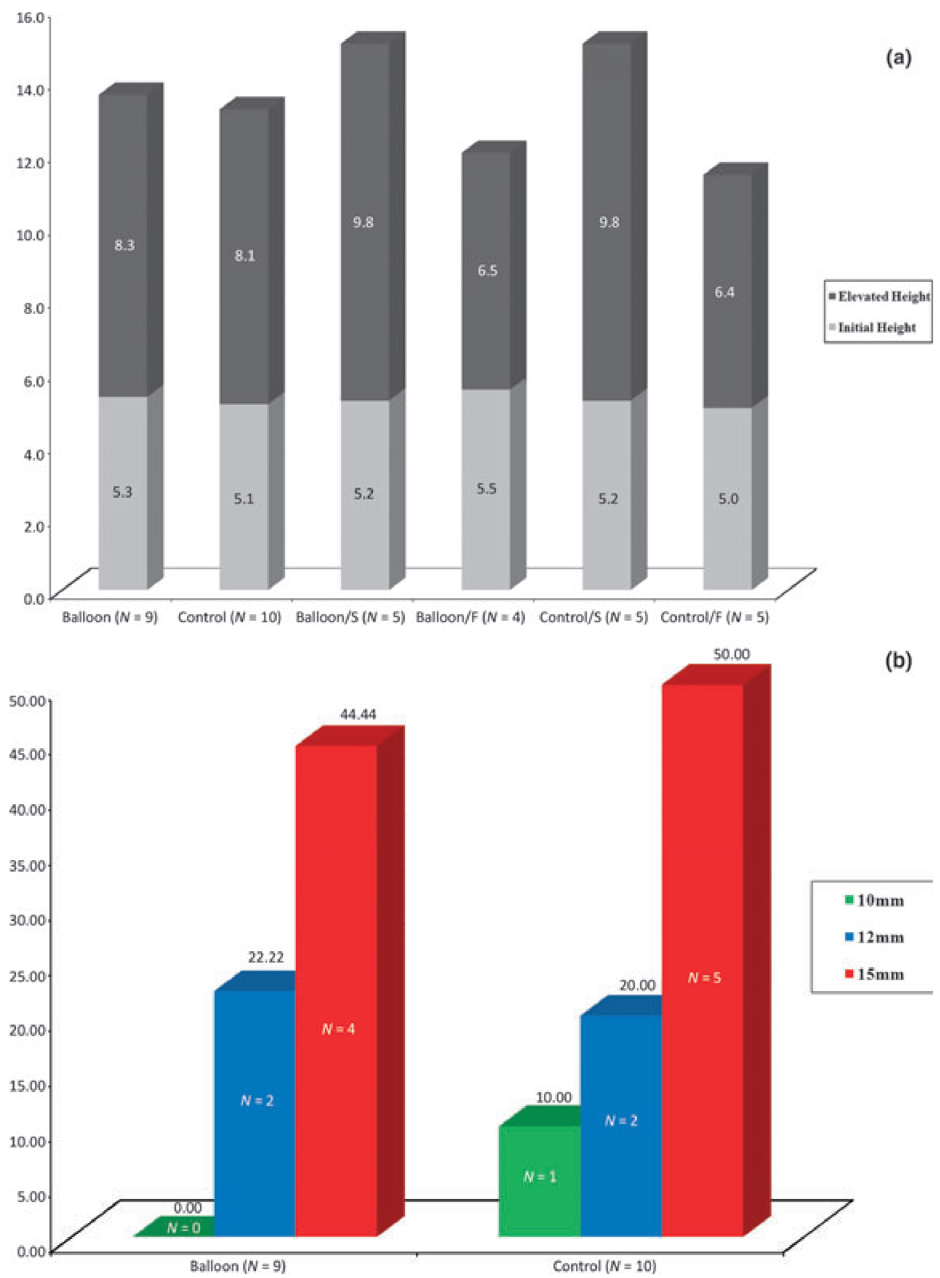

Fig. 5. (a) Bar chart demonstrating the residual ridge height and elevated height of sinus membrane in the balloon and control group. Residual ridge height was almost identical between the failed and successful cases in both groups, indicating that the occurrence of perforation was not related to residual ridge height. (b) Bar chart summarizing the percentage of membrane perforation at the cutoff points of 10, 12, and 15 mm. No difference was found between the two groups.

Tozum 2012), residual ridge height (Yilmaz & Tozum 2012), and gender (Janner et al. 2012). Current evidence suggests that increased membrane thickness might harbor a diminished risk of perforation (Pommer et al. 2009; Yilmaz & Tozum 2012). This is supported by the observations in this study. When pushed by either a balloon or osteotome, the Schneiderian membrane detached from the underlying bone to some extent. In cases of perforation, it tore at the weakest spot, usually at the periphery of the dome-shaped elevation where the membrane was still attached to the underlying bone, rather than at the center, where the elevation instruments exerted most of the pressure. Future research should focus on developing methods to accurately measure membrane thickness pre-operatively and whether the application of a collagen layer between the instruments and the membrane could decrease perforation rates.

This study was conducted following a split-mouth design. The surgical sites were randomly chosen to eliminate potential confounders, such as residual ridge height. Also, CBCT scans were used to identify suitable study sites. The reference pins further enabled the examiners to determine the mesio-distal location of the surgical site. Furthermore, the use of an endoscope was implemented to observe the dynamic process of sinus elevation, to facilitate the recording of measurements, and to reliably identify membrane perforation. However, certain limitations were present. First, fully edentulous ridges were used. It was not clear whether the results of this study could apply to partially edentulous ridges. Second, the biological and mechanical properties of the membrane might have been altered because of the nature of the samples. Third, medical history of the specimens, especially related to maxillary sinus conditions was not available; however, from CBCT scans, it was seen that all samples were free from obvious antral pathoses. Fourth, strict inclusion criteria were set for site selections, no septa and a flat sinus floor were selected, so the results may not be applied to more challenging sites. Last, in clinical situations, grafting materials undergo consolidation and resorption, which could never have been observed in cadaver studies.

Currently, short implants (<10 mm) have been used in lieu of extensive reconstructive procedures, such as sinus augmentation. A meta-analysis (Annibali et al. 2012) showed a comparable survival rate of those implants, although long-term follow-ups are still needed. Therefore, the selection of sinus augmentation should be weighed between its benefits and risks. More importantly, its alternative options should be clearly explained to the patients.

Conclusions

Similar maxillary sinus elevation height can be achieved using both the balloon and the osteotome technique (Mean height of 8.3 and 8.1 mm, respectively). In addition, the membrane perforation rate was comparable. The amount of residual alveolar bone was not related to the incidence of perforation and the height of sinus elevation. The fact that 66% perforations clustered in three specimens, coupled with the pattern of perforation as observed using the endoscope, suggests that membrane perforation occurrence is tightly related to the inherent properties of the sinus membrane, such as its thickness.

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