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Schneiderian Membrane Perforation via Transcrestal Sinus Floor Elevation: A Randomized Ex Vivo Study with Endoscopic Validation

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Abstract

Objective: To endoscopically determine the incidence of Schneiderian membrane perforation during transcrestal maxillary sinus floor elevation (SFE), in relation to the bone preparation technique, amount of bone graft, membrane elevation height and different surgical steps.

Materials and methods: Seven cadaver heads corresponding to 12 maxillary sinuses were used to perform 3 SFE via transcrestal approach per sinus (36 elevations). Each sinus was randomly assigned to either the Sinus Crestal Approach (SCA) drill kit technique (experimental group) or the conventional osteotome technique (control group). During all phases of the surgery, the integrity of the sinus membrane was monitored through endoscopic examination.

Results: A significant difference was found in the incidence of perforation ($P = 0.007$) and vertical elevation height ($P < 0.001$) between the study groups, favoring the experimental group. A safety elevation threshold of 5 mm without bone graft and implant placement was estimated. A significant correlation was observed between residual ridge height and incidence of perforation ($P < 0.001$) (OR = 0.51).

Conclusion: The SCA drill kit may demonstrate superior osteotomy preparation and membrane elevation capabilities to the osteotome technique, and significantly when 6 mm SFE is indicated. Residual ridge height and vertical elevation height are risk determinants factors.

Key words: Sinus floor elevation, bone substitutes, diagnosis, clinical assessment.

Introduction

Expansion of the maxillary sinus and resorption of the residual ridge, following upper molar and premolar extraction, may compromise dental implant placement in the maxillary posterior area. Maxillary sinus floor elevation (SFE), performed either via lateral window or transcrestal approach, is usually indicated to overcome limitations in residual ridge height (RRH) (Boyne & James, 1980). The transcrestal approach involves SFE with simultaneous placement of an implant (Tatum, 1986) (Summers, 1994). The original procedure consists of inwardly fracturing the sinus floor by preparing the implant bed with osteotomes of increasing diameters. Other techniques were later proposed, such as the balloon technique (Chan et al., 2013) (Yassin Alsabbagh, Alsabbagh, Darjazini Nahas, & Rajih, 2017) and the piezotome technique; a procedure of standardized sequence of designed drills, trephine and osteotomes (Trombelli, Franceschetti, Trisi, & Farina, 2015) (Y. K. Kim, Lee, Park, Kim, & Oh, 2017).

The transcrestal approach is a less invasive, commonly applied technique for SFE. It's reportedly associated with increased patient acceptance and reduced patient discomfort when compared to the lateral window approach (Emmerich, Att, & Stappert, 2005). The former is suitable where the relative residual ridge height is approximately 5 to 9 mm, exhibiting good long-term clinical outcomes and minimal complications (Katranji, Fotek, & Wang, 2008) (Pjetursson & Lang, 2014) (Lundgren et al., 2017). However, membrane perforation is a commonly occurring intra-operative complication, with prevalence up to 40% (Antoanela Garbacea et al., 2012).

Schneiderian membrane perforation is often undetectable by the operator during surgical transcrestal SFE procedures, and this may impact the probability of postoperative complications. Antibiotic use for postoperative sinusitis, infection and bone graft failure were shown to be significantly higher in sinuses with perforated membranes (Nolan, Freeman, & Kraut, 2014) (Schwarz et al., 2015). A small perforation within the membrane may result in communication directly between the sinus cavity and graft material. This can lead to infection and chronic sinusitis, which eventually results in loss of graft volume and/or implant failure (Katranji et al., 2008).

Detection of membrane perforations during and following transcrestal SFE is challenging. Therefore, efforts should be directed towards identifying the tools and factors associated with prevention, ultimately decreasing the likelihood of postoperative complications and improving treatment outcomes. Cone beam computed tomography (CBCT) or periapical digital radiographs seem to be less precise than the endoscope for the detection of Schnederian membrane perforations in human cadaver investigations (Antoanela Garbacea et al., 2012).

Hence, the primary aim of this *ex-vivo* study was to endoscopically evaluate the incidence of Schneiderian membrane perforation associated with the different approaches to transcrestal SFE, namely SCA and osteotome techniques. The secondary aim was to assess the association of membrane elevation height, amount of bone graft, residual ridge height and the different surgical steps on the incidence of perforation during a transcrestal SFE.

Materials and method

Study design

Seven, fresh cadaver heads with fully or partially edentulous maxillary arches were provided by the Department of Anatomy at the University of Michigan. These specimens were frozen in a temperature of -20°C, after being harvested from human donors, to prevent structural changes in the tissues. Prior to being used in this study, the cadaver heads were completely thawed for a period of 4 to 5 days at room temperature. The University of Michigan (U-M) Institutional Review Board approved this study as exempt from oversight (HUM00138166).

The included heads corresponding to 12 maxillary sinuses (5 bilateral maxillary sinuses with fully edentulous maxillary arches and 2 unilateral maxillary sinuses with partially edentulous maxillary arches) were used to perform 3 elevation procedures via transcrestal approach per maxillary sinus (a total of 36 elevations). Each sinus was randomly assigned to receive a different elevation technique: Sinus Crestal Approach (SCA) drill kit (Neobiotech, Seoul, South Korea) (experimental group) or the osteotome technique (control group). The bilateral maxillary sinuses were used in a split-mouth manner, where the test was randomly assigned to one side and the control to the opposing side. Meanwhile, the two unilateral maxillary sinus heads were each randomly assigned to one of the two study groups. The randomization was performed by a specialized software (randomized.com, Shogun Interactive Development 2006); number 1 and 2 indicated the right side be experimental and control, respectively.

With 18 sinus elevations per study group, 6 mesial elevations consisted of membrane elevation only (without graft or implant placement) (subgroup A). Meanwhile, the remaining 12 elevations comprised 6 middle 3 mm (subgroup B) and 6 distal 6 mm (subgroup C) membrane elevations with bone graft insertion and subsequent implant placement.

Eligibility Criteria

The inclusion criteria comprised the following:

- Totally or partially edentulous posterior maxillary arches
- Absence of sinus pathology evident in the three-dimensional radiological assessment
- Sinuses with a relatively flat floor as indicated to be performed in the clinical basis
- Maxillary sinus free from sinus septa as pre-surgically examined using CBCT

Specimens were excluded if:

- The posterior maxillary arch was dentate, preventing access for a transcrestal sinus lift
- The posterior maxillary arch width was < 3 mm
- The presence of a large sinus pathology was detected via the pre-procedural CBCT imaging

CBCT data acquisition

Tenting screws (Salvin Dental Specialties, Charlotte, NC, USA) were inserted bilaterally in each of the maxillary canine areas. These functioned as reference points, visible in the CBCT image, for measurements and identification of precise drilling sites to be made across the arch during the surgical procedure. The CBCT scans were obtained by a trained operator (KS) in the Radiology Department at the University of Michigan School of Dentistry. The specimens were stabilized using a head locator. Each maxillary sinus was examined pre-surgically in CBCT scans (3D Accuitomo 170 Tomograph, J Morita, Kyoto, Japan) with a voxel size of 0.08–0.16 mm. Operating parameters were set at 5.0–7.0 mA and 90 kV. Exposure time was 17.5 s. Limited FOV was selected for all images. The CBCT scans of each head were reconstructed with built-in software and analyzed on a desktop computer with a specialized implant planning software (Invivo5, InvivoDent, Anatomage, San Jose, CA, USA). The CBCT images were evaluated by one author an experienced oral surgeon (JG) on a desktop monitor (28-inch Dell 2407, resolution 1920x1200 pixels, refresh rate 59 Hz; Dell Inc., Round Rock, TX, USA) under room lighting, and at a position of approximately 30 cm from the monitor. The CBCT images were reoriented to get (1) the nasal spine and midline aligned in the center of the image in the axial slice, (2) the posterior maxillary segment in vertical position in the coronal slices and (3) the hard palate, as well as the floor of the nose in horizontal position parallel to the ground in the sagittal slices. For the evaluation of intra-examiner reliability, all measurements were performed twice at different days. The mean difference between the two measurements in bone parameters was 0.01 mm (range -0.059 to 0.079). For image assessment, each sample was conducted twice and a mean value was obtained (Janner et al., 2011). If a $\geq$ 0.2 mm difference was measured at the same point, a third assessment was performed (Bornstein, Lauber, Sendi, & von Arx, 2011; Froum, Khouly, Favero, & Cho, 2013). Similarly, a second examiner (MT) randomly selected two cases to evaluate inter-examiner reliability, where a 0.86 Interclass Correlation coefficient was obtained, indicating near absolute agreement.

Surgical procedure

An experienced surgeon (JG) performed the surgical procedures taking into account the CBCT analysis and measurements. A middle crestal incision and a mesial vertical releasing incision above the canine area were performed to elevate a full thickness flap. The CBCT measurements made from the tenting screws to the planned drill sites were extrapolated to the surgical set-up, where the same measurements were made onto the exposed bone (Figure 1). Bone preparation followed according to implant size, manufacturer guidelines and study group design. The depth of preparation was determined based on the RRH measured on the CBCT images.

Sinus membrane elevation

The experimental group osteotomies were performed using a series of increasing-diameter SCA kit drills, connected with a stopper, according to manufacturer instructions (Figure 2A). Stoppers defined the drilling length according to residual bone height and membrane elevation. In the control group, bone preparation and sinus membrane elevation were performed according to previous publications (Lundgren et al., 2017; Pjetursson & Lang, 2014). Bone preparation to 1 mm below the sinus membrane was performed using the standard implant drilling protocol (Zimmer/Biomet 3i, West Palm Beach, FL, USA), starting from the pilot-drill (ø 2.3 mm) to 3.4 mm of diameter, followed by passing with the osteotome to fracture the bony floor of the sinus and initiating membrane elevation. Initially, an osteotome of small-diameter and a light mallet were used to fracture the residual bone. Once bone preparation was complete, a second osteotome (ø 3.3 mm) (Hu-Friedy, Chicago, IL, USA) was used to elevated the sinus membrane with precise control of the penetration length (Figure 2B).

The membrane's vertical elevation height (VEH) was measured using a calibrated gauge (Neobiotech, Seoul, South Korea). Sinus membrane elevation with or without bone graft and implant placement followed, according to the designed experimental workflow. The mesial elevation site was performed without bone graft or implant placement, to the heights of 3, 4, 5 and 6 mm consecutively until perforation was achieved, at which point the final height was recorded. The middle and distal elevation sites were treated with bone graft insertion and implant placement to 3 and 6 mm, respectively. Particulate allogenic bone graft (enCore Combination Allograft, particle size: 0.25-1 mm; Osteogenics Biomedical, Inc. Lubbock, Texas, USA) was packed into the osteotomy site in the respective subgroups, before proceeding to implant placement. The amount of bone graft was measured prior to surgery using a scientific bascule (Mettler Toledo Balance AG204, Marshall Scientific, Hampton, New Hampshire, USA) to standardize the exact amount of graft material for each location:

1. 0.1 cc of bone graft in the middle site to 3 mm of elevation.
2. 0.3 cc of bone graft in the distal site to 6 mm of elevation.

Zimmer tapered screw vent dental implants (Zimmer/Biomet 3i, West Palm Beach, FL, USA) of 3.7 mm x 13 mm dimensions were placed only to the desired pre-planned height pertaining to each subgroup, when membrane perforation was not detected, in the middle and distal sites after bone graft was inserted.

Data retrieval

Residual bone height and width, and sinus membrane thickness were evaluated in each maxillary sinus and at each elevation site (mesial, middle and distal) in relation to the tenting screw reference pre-surgically viewed in the CBCT scans. An endoscope (OTV-S5 Rhinolaryngoscope; Olympus, Center Valley, PA, USA) included an optical system allowing for 90° field of view and 5–50 mm depth of field, was used by a single investigator (MT) to monitor the sinus membrane perforation during the sinus elevation procedures. The insertion tube was 3.2 mm in diameter and possesses a 130° up/down bending capability. A fiber light projector (Richard Wolf model 5119 USA Medical Instruments Corp. Vernon Hills, Illinois, USA) was used in combination with the fiberscope. Intra-surgical images were obtained and transferred to a processor that displays the visual across a connected monitor. For efficiency of time, the endoscope was inserted before starting the STE surgery into the sinus via an opening (10x5 mm) below the inferior orbital rim. At that point, the sinus membrane was exposed and checked for complete defrosting. The endoscope images were monitored by one investigator (MT) during the elevation procedure and the effect of bone graft insertion and implant placement on the membrane integrity was constantly monitored (Figure 2C and Figure 2D). The second investigator was instructed to adjourn the procedure when perforation was visually detected.

Measurements

The procedure was deemed successful when the membrane was elevated without perforation; otherwise, it was considered a failure. The elevation was measured (in millimeters) from the alveolar crest to the topmost point. The VEH was calculated as the final membrane height minus the RRH. The BPE (Bucco-palatal elevation) was the measured on a cross-sectional slice of the CBCT image (Figure 3A), while MDE (Mesio-distal elevation) was measured on a sagittal slice of the image (Figure 3B).

CBCT's before and after the surgery were obtained and a continuous endoscopy procedure, to check the integrity of the sinus membrane, were monitored during the surgery. All the following variables/measurements were obtained and recorded at each of the 3 elevation sites per sinus, amounting to 36 sites:

- Residual ridge height (RRH) (mm)
- Residual ridge width (RRW) (mm)
- Membrane Thickness (MT) (mm)
- Vertical elevation height (VEH) (mm)
- Bucco-palatal elevation (BPE) (mm)
- Mesio-distal elevation (MDE) (mm)
- The VEH to BPE ratio (VEH:BPE)
- The VEH to MDE ratio (VEH:MDE)
- Incidence of Perforation (IoP) (1-0)
- Implant Placement (IP) (1-0)
- Volume of bone graft inserted (cc)

- Stage of membrane perforation: bone preparation, bone grafting or implant placement

Statistical analysis

Statistical analysis was expressed using the mean, minimum and maximum values, standard deviations (SD). Generalized estimating equations (GEE) methods were used to test the effect of elevation technique, MT, RRH, bone graft, VEH, VEH:BPE and VEH:MDE on dependent variable IoP. Non-adjusted and adjusted odds ratio (OR) and 95% confidence intervals were obtained from univariate and multivariate binary logistic regressions using GEE to consider the clustered structure of data. GEE linear models were also used to study differences of membrane thickness or VEH between groups.

The significance level was defined as $P<0.05$, for all statistical tests. In all statistical tests involving the study groups variable, the experimental and control groups were considered groups 1 and 2, respectively. All analyses were conducted with a specialized software package (IBM SPSS Statistics 24, Armonk, NY, USA).

Results

Descriptive Analysis

A total of 7 unfixed, fresh cadaver heads (4 males and 3 females), with 10 bilateral and 2 unilateral maxillary sinuses, qualified to be included in the study. The reason for exclusion of 2 unilateral sinuses was a result of corresponding to dentate ridges, while all the included sinuses corresponded to fully or partially edentulous ridges. A total of 36 transcrestal SFE procedures were performed. The mean ridge width in the study sample was 7.13 ± 1.56 mm. A complete descriptive analysis of the data based on study groups and subgroups is summarized in table 1.

Schneiderian Membrane Thickness

The data of six sites were excluded from only the CBCT membrane measurements due to image artifacts/distortion that interfere with accurate analysis at the region of interest. Of these excluded sites, 3 belonged to subgroup A (resultant n = 9), 2 belonged to subgroup B (resultant n = 10) and 1 belonged to subgroup C (resultant n = 11). Thus, a total of 30 membrane thickness measurements were obtained from the 7 included heads. The mean membrane thickness in the total study sample was 0.93 ± 0,66 mm (0.39 to 2.91 mm), with no statistically significant difference between the subgroups (p= 0.264).

Incidence of Schneiderian Membrane Perforation

The percentage of IoP in the entire study sample was 50% (33% in the experimental group and 66.7% in the control group) (Table 1). This difference, between the two groups, was not found to be statistically significant (OR=0.25; p= 0.138). However, when the model was adjusted by other independent variables (RRH, BG) significance was reached (OR=0.04; p=0.007). Similar conclusion was obtained from the adjustment by VEH and ratios (OR=0.02; p=0.046).

Within the perforations seen in subgroups A, B and C, a total of 16.7%, 50%, 33.3% belonged to the experimental group, respectively. Although no significant difference in IoP comparing the 3 subgroups was observed, all perforations in subgroup A were at 6 mm of VEH. This demonstrates an estimated maximum safety elevation threshold of 5 mm without bone graft and implant placement.

Associated-Variables of Schneiderian Membrane Perforation

The GEE model demonstrated a statistically significant negative correlation between IoP and RRH (p<0.001) (OR = 0.51) and a lack of correlation between IoP and amount of bone graft (p= 0.229) (Table 2: model n.2). The mean RRH associated with perforations and non-perforations in the experimental group was 3.18 mm ± 1.73 and 5.38 mm ± 2.16, respectively. Contrarily, the mean RRH associated with perforations and non-perforations in the control group was 5.89 mm ± 1.82 and 8.40 mm ± 3.07, respectively. RRH associated to perforation was concluded as significantly lower in the test group (p<0.001).

Also outlined in table 2, the regression model n.3 analyzing IoP with VEH, the ratio of VEH to BPE and the ratio of VEH to MDE indicated a significant positive correlation between IoP and VEH (p = 0.004) (OR = 3.47). Correlation was also positive with VEH:BPE and negative with VEH:MDE, but statistical significance was not reached (p=0.613, p=0.525 respectively). This indicates that with increased VEH, the probability of IoP is expected to also increase.

Wald´s Chi^2 from GEE model determined a significant degree of variance between the VEH in the experimental group *versus* the control group (p< 0.001). This indicates that significantly more VEH was permitted in the experimental group, as opposed to the control group. However, no such significance was observed in terms of implant placement (p= 0.277) (Table 3).

Finally, with regards to IoP relative to the stage of surgery, 15 (83.3%) of membrane perforations were found to have occurred during the first (elevation) phase of surgery, while 0 and 3 (16.7%) of membrane perforations occurred during the second (bone graft insertion) and third (implant placement) (Figure 2D) phases of surgery, respectively. This difference was statistically significant (P = 0.005).

Discussion

Schneiderian membrane perforation is one of the most critical challenges of maxillary SFE and is associated with a higher prevalence of postoperative sinusitis (Schwarz et al., 2015). The percentage of perforations found in the present study was 50%, higher than the data reported by Garbacea *et al.(A. Garbacea et al., 2012)* and Nolan *et al(Nolan et al., 2014)*, who reported a mean IoP rate of 40% and 41% respectively. These rate was considerably less than the 58.4% reported by Alsabbagh AY(Yassin Alsabbagh et al., 2017), or the 62.5% reported by Cho *et al(Cho, Wallace, Froum, & Tarnow, 2001)*. However, perforation during transcrestal sinus membrane elevation is not always detected, indirectly impacting postoperative complications and surgical outcome. If this occurs, a number of consequences may entail: the presence of bone graft within the sinus antrum, acute or chronic sinus infection, the invasion of bacteria into the site, or disrupted maxillary sinus physiologic function (Katranji et al., 2008) (Li & Wang, 2008). With all the proposed methods of crestal SFE (Yassin Alsabbagh et al., 2017) (Y. K. Kim et al., 2017) (Chan et al., 2013), MT (Wen, Lin, Yang, & Wang, 2015) RRH (Schwarz et al., 2015), amount of bone graft inserted and VEH (Sonoda, Harada, Yamamichi, Monje, & Wang, 2017) are factors that influence the probability of membrane perforation. In this study sample, MT was not statistically significant between the two study groups, enabling a fair comparison of all other factors between test and control.

Schneiderian membrane elevation with SCA drill kit has the advantage of using a reamer to create the osteotomy in a conical shape and break the bony floor avoiding damage to the sinus membrane. However, it is important to note that although the SCA kit has shown to be superior to the osteotome technique in the present investigation, this difference was only statistically significant in subgroup C, where elevation was beyond 3 mm. Thus, it can be deduced that the two techniques are comparable when minimal elevation is necessary, however, when more than 3 mm and up to 6 mm of elevation is indicated, the SCA kit maintains membrane integrity significantly better. This could be explained by the greater VEH permitted by the SCA *versus* osteotome approach. The positive results attributed to this kit demonstrated in this study are in concordance with the results observed in the *ex-vivo* study of Yassin Alsabbagh et al., 2017, where the SCA drill kit showed to be superior to the osteotome technique in osteotomy preparation and breaking the sinus floor. These results were later corroborated in a clinical study by Kim et al., 2017, who did not report any membrane perforations using the SCA drill kit, but reported an incident of acute maxillary sinusitis 5 months after surgery. This may have been related to a possible undetected perforation during the elevation surgery. On the other hand, according to a dentists' subjective satisfaction survey performed following maxillary sinus membrane elevation via the crestal approach, 92.9% dentists were generally satisfied with the SCA approach to elevate the membrane instead of hydraulic approach (H. Y. Kim, Yang, Chung, Kim, & Yeo, 2013).

The RRH has also been described as an influencing factor that impacts membrane perforation using the transcrestal approach (Schwarz et al., 2015), where a minimal RRH of 5 mm is recommended (Pjetursson & Lang, 2014) (Lundgren et al., 2017). This data supports our results, where the RRH has been revealed as a statistically significant factor of membrane perforation. Schwarz et al., 2015 showed that RRH less than 3.5 mm was a main risk factor increasing the IoP, in agreement with the 3.18 mm ± 1.73 mean RRH associated with perforations in the experimental group observed in this study.

Most of the membrane perforations within the non-grafted subgroup (A) were obtained when the height of elevation reached 6 mm, meaning that below 6 mm represents a safe zone. Therefore, our results show the estimated 5 mm elevation height as a safe zone, prior to bone graft insertion and implant placement. These findings come in line with Lundgren et al., 2017, who described that the elevation height in transcrestal SFE should not exceed 3-4 mm.

As reported, the amount of bone graft inserted has been related to the millimeters of sinus membrane vertically elevated, obtaining elevation heights of 3 mm or 6 mm when using 0.1 or 0.3 cc of bone graft respectively (Sonoda et al., 2017). Although the findings of this study showed that VEH plays a determinant role in maintaining sinus membrane integrity, the amount of bone graft inserted was not determinant. On the other hand, the VEH:BPE and VEH:MDE displayed a different impact on membrane perforation, demonstrating that mesio-distal (MD) augmentation in relation to VEH had a positive effect on membrane perforation. Contrary to this, bucco-palatal (BP) augmentation in relation to VEH appeared to have a negative effect on maintaining membrane integrity. These ratios describe the degree of three-dimensional horizontal extension as opposed to only the vertical extension of a SFE. It is critical to address the elevation procedure from all possible directions, to better understand the tension distribution to be achieved. The findings in this study compliment those from Sonoda et al. (2017), who concluded that VEH:BPE and VEH:MDE should be ≤ 0.8 to avoid sinus membrane perforation. From a clinical standpoint, VEH:BPE and VEH:MDE may be a difficult factor to control in sinus membrane elevation via the transcrestal approach in comparison to the more invasive lateral approach, where the MD and BP bone augmentation could more practically be controlled. However, this effect requires further investigation.

According to Garbacea et al., 2012, Schneiderian membrane perforation during transcrestal sinus elevation can occur during different treatment stages: bone preparation/breaking the bony sinus floor, membrane elevation, graft insertion or implant placement. Hence, due to often being undetectable, special care is recommended during the membrane elevation phase and during the implant placement phase. With regards to implant placement, the implant may exert pressure on the bone graft that manages to perforate the sinus membrane, providing the bone graft with an escape route into the sinus cavity. However, no perforations were detected during the bone graft insertion phase in the present study, indicating that excessive perforation-inducing pressure is not exerted on the sinus membrane during bone graft insertion.

Despite the associated variables that may have an impact on the success or failure of the transcrestal SFE procedure, it must be noted that a sufficient amount of experience is a clear prerequisite. Both the technical approaches discussed in this study equally require adequate expertise prior to being performed successfully.

They are several limitations of this study, one of them is we used the cadaver to conduct this study hence the cadaver bone quality and membrane elasticity may differ from the living bone. To minimize the bias from specimen quality, we chose frozen fresh cadaver heads that have the most similar tissue situation to the actual human. Nonetheless, this remains a concern in the study. Additionally, since this is a cadaver study, so we did not conduct the power calculation to determine the proper sample size. We only used available fresh cadaver heads that qualified the study in conducting this investigation. Hence, limited sample size and lack of power calculation are limitations noted in the study.

Conclusion

The SCA drill kit may demonstrate superior osteotomy preparation and SFE capabilities to the osteotome technique, while both techniques require operator experience. This enhanced ability in elevation was especially significant when a 6 mm elevation was indicated. Also, a maximum safety elevation threshold of 5 mm without bone graft and implant placement was estimated. Finally, residual ridge height and vertical elevation height are important factors of membrane perforation.

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Table and Figure Legend

Table 1: Demographics of sinus elevation variables. IoP - incidence of perforation; RRH - residual ridge height; VEH - vertical elevation height; BPE - bucco-palatal elevation; MDE - mesio-distal elevation.

Table 2: Univariate (model 1) and multivariate (model 2 and 3) logistic regression (GEE) models analyzing association between incidence of perforation (IoP) and other variables of elevation; namely, study groups, residual ridge height (RRH), bone graft (BG), vertical elevation height (VEH), VEH:BPE ratio and and VEH:MDE ratio. VEH:MDE was excluded from the model 3 because lack of convergence of GEE estimations.

Table 3: GEE model analyzing association between the elevation technique, implant placement (IP) and vertical elevation height (VEH).

Figure 1. Bone marking measurements from the tenting screws to the planned drill sites.

Figure 2. Bone preparation: 2A: SCA drill kit (experimental group); 2B: osteotome (control group); 2C: Endoscopic image of sinus membrane elevation without perforation; 2D: Endoscopic image of membrane perforation and direct communication of the implant and bone graft with sinus cavity.

Figure 3. Cone-beam Computed Tomography of sinus membrane elevation with the vertical elevation height: 3A: bucco-palatal elevation; 3B: mesio-distal elevation.

Table 1

	IoP			RRH (mm)		VEH (mm)		VEH:BPE		VEH:MDE	
	N	*n*	*%*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*
Test	18	6	33%	4.65	2.24	6.32	1.00	0.77	0.15	0.76	0.26
Control	18	12	66.7%	6.72	2.53	3.71	0.86	0.45	0.12	0.50	0.10
A	12	6	50%	7.02	2.41	N/A		N/A		N/A	
B	12	6	50%	5.25	2.58	3.99	0.97	0.55	0.24	0.54	0.13
C	12	6	50%	4.79	2.38	6.63	0.85	0.72	0.14	0.77	0.29

Table 1: Demographics of sinus elevation variables. IoP - incidence of perforation; RRH - residual ridge height; VEH - vertical elevation height; BPE - bucco-palatal elevation; MDE - mesio-distal elevation.

Table 2

Univariate model 1					
			95% Wald Confidence Interval for OR		Hypothesis Test
Parameter	*β*	*OR*	*Lower*	*Upper*	*p-value*
Experimental Group	-1.39	0.25	0.04	1.56	0.138
RRH	-0.23	0.79	0.64	0.98	0.036*
BG	0.01	1.00	0.05	20.6	1.000
VEH	0.28	1.32	0.44	3.92	0.619
VEH:BPE	0.44	1.55	0.01	1277	0.898
VEH:MDE	-2.02	0.13	0.01	67.1	0.525
Multivariate model 2					
Experimental Group	-3.32	0.04	0.01	0.41	0.007**
RRH	-0.67	0.51	0.37	0.70	<0.001**
BG	-4.29	0.01	0.00	14.9	0.229
Multivariate model 3					
Experimental Group	-4.13	0.02	0.01	0.93	0.046**
VEH	1.25	3.47	1.50	8.05	0.004**
VEH:BPE	1.78	5.91	0.01	576.6	0.613

VEH:MDE	--	--	--	--	--

Table 2: Univariate (model 1) and multivariate (model 2 and 3) logistic regression (GEE) models analyzing association between incidence of perforation (IoP) and other variables of elevation; namely, study groups, residual ridge height (RRH), bone graft (BG), vertical elevation height (VEH), VEH:bucco-palatal elevation ratio (VEH:BPE) and VEH:mesio-distal elevation ratio (VEH:MDE). VEH:MDE was excluded from the model 3 because lack of convergence of GEE estimations.

Table 3

				95% Wald Confidence Interval for *β*	
		β	p-value	Lower	Upper
Study Groups (Experimental/Control)	VEH	2.61	<0.001***	1.91	3.31
	IP	0.80	0.277	0.53	9.44

Table 3: GEE model analyzing association between the elevation technique and implant placement (IP), as well as, vertical elevation height (VEH).

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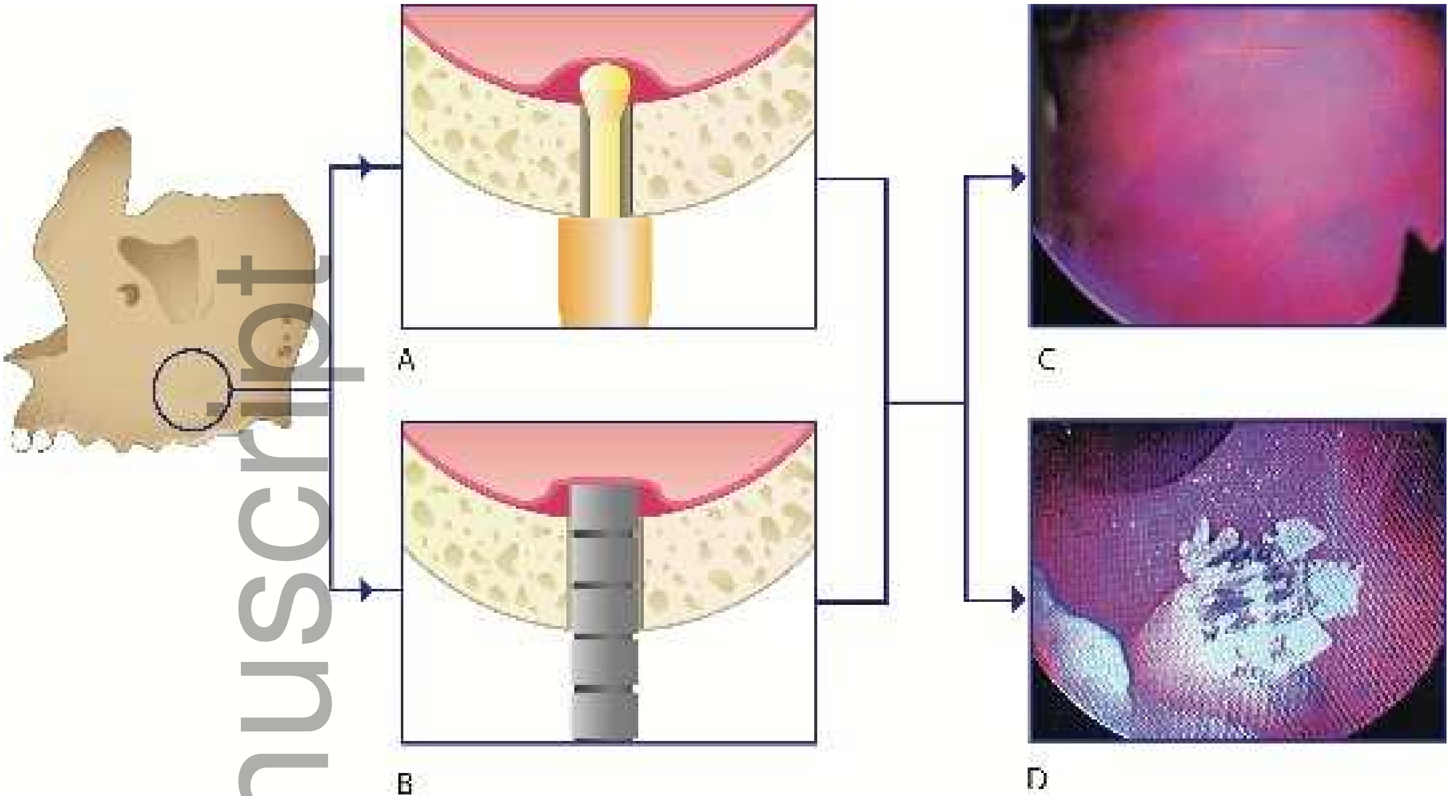

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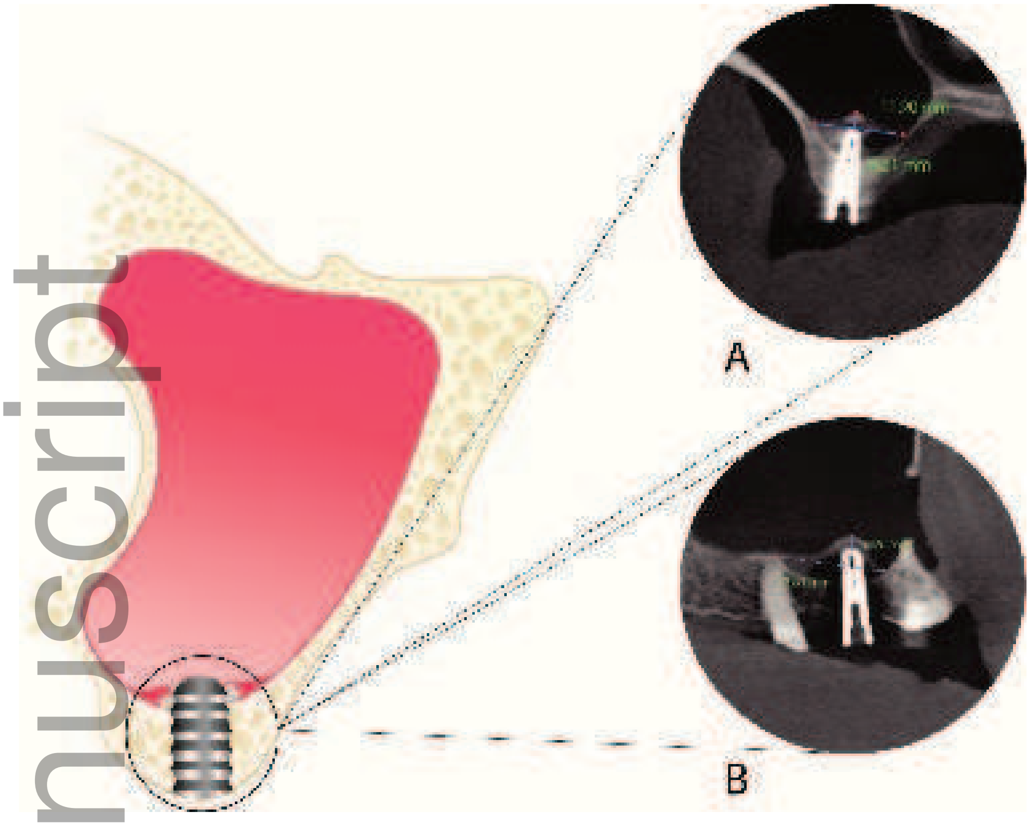

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