CLINICAL ORAL IMPLANTS RESEARCH

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Lateral approach for sinus floor elevation: large versus small bone window – a split-mouth randomized clinical trial

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Abstract

Objectives: To test whether a reduction of bone window dimension, in a split-mouth randomized study design, focused on lateral sinus floor elevations, can achieve better results than a wider window in terms of augmented bone height and a reduction of patient discomfort and surgical complications.

Materials and methods: Of the sixteen subjects enrolled in the study, each underwent a bilateral sinus lift procedure based on two different access flaps to maxillary sinus. Test side: small access window (6 × 6 mm) + bone filling using a special device. Control side: large access window (10 × 8 mm) + manual bone filling. Alveolar bone height and width were measured at pre-op and 6-month post-op CT scans; repeatable measurements were obtained using radiographic stents. Surgical intervention duration was also recorded. Patients' evaluation of surgical discomfort was assessed using a VAS diagram at 7-day, 14-day and 30-day follow-up.

Results: A significant bone augmentation in height and width of alveolar crest was obtained in both test (8.71 ± 1.11 mm, 4.70 ± 0.58 mm) and control (8.5 ± 2.02 mm, 4.68 ± 0.70 mm) sides, although no significant differences were found between the two groups. Neither any significant differences emerge in data concerning the duration of the intervention (Test 42.62 ± 6.67 min, Control 41.68 ± 8.34 min). Patients' opinion relating to surgical discomfort showed a preference for test procedure at 7-day, 14-day and 30-day follow-up.

Conclusions: A reduction of window dimensions did not affect the safety of the surgical procedure. The two testing techniques showed no statistically significant differences in surgical intervention duration. Patients' opinion at 7-day and 14-day post-op showed a preference for test procedure.

Sinus lift procedures have been demonstrated to be a reliable procedure for the treatment of maxillary posterior areas and have become routine procedures (Wallace & Froum 2003; Pjetursson et al. 2008).

Elevation of the sinus floor, mainly through the use of autogenous bone graft, can increase the bone height in the posterior area of the maxilla, (Boyne & James 1980; and Tatum 1986). In the last 20 years, this surgical procedure has been extensively investigated from several aspects: site preparation, graft materials, amount of increased bone, immediate implant placement, complication management and long-term implant success (Jensen et al. 1998; Khoury 1999; Tarnow et al. 2000; Valentini et al. 2000; Schwarz-Arad et al. 2004; Testori & Wallace 2009; Canullo et al. 2012).

Focusing on surgical aspects, the opening of the window on the lateral bone wall of the maxillary sinus and the raising of the Schneiderian membrane are probably the most complex phases of the whole procedure, presenting the risk of damage to the membrane itself (Wallace et al. 2007).

For these reasons, in order to allow an adequate visualization of the surgical area and in order to prevent complications and facilitate membrane detachment, many authors propose both a wide flap, which completely exposes the lateral wall of the maxillary sinus and a wide bone window, enabling easy access to the sinus cavity. Only a few studies have provided data on the dimensions of the bone window: A minimal length of 10–15 mm and a minimal height of 8–10 mm have been reported (Vercellotti et al. 2001) although, in many other studies, wider approaches were performed (Jensen et al. 1998; Zitzmann & Schärer 1998; Barone et al. 2008; Lambert et al. 2010). A recent

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case series (Pariente et al. 2014) showed a more conservative approach for bone window dimension: This technique consisted in the preparation of two mini windows: one mesial, of approximately 8 mm in length and 5 mm in height, and a smaller distal one. However, a more recent study (Nickenig et al. 2014) has proposed a minimally invasive approach associated with a flapless implant placement using a surgical template.

Testori & Wallace (2009) indicated 20 mm in length and 15 mm in height as the correct dimensions for the bony window, although the same authors admit that, in expert hands, a more conservative approach, reducing the dimensions of the window, may have several advantages such as better healing conditions of the graft and the preservation of a larger amount of the original bone wall.

Nevertheless, the traditional surgical approach to the maxillary sinus has been criticized, (Simonpieri et al. 2011) arguing that a wide window may reduce the healing potential of the bony wall and may facilitate a connective collapse into the sinus cavity.

We must also consider that the residual bone wall plays an important role in the healing process of the sinus graft for several reasons: From a mechanical point of view, it helps the stabilization of blood clotting and protects the graft from possible mechanical stress; from a biological point of view, it represents a source of osteoblast cells that may actively participate in the colonization of the graft itself (Schenk 1987; Mish 1993). The osteogenic process and the colonization of the graft start from the bone walls around the grafted site and progressively determine the maturation of the central part of the graft itself (Haas et al. 2002) as evidenced in animal studies (Scala et al. 2010, 2012; Favero et al. 2016).

The aim of this clinical research was to test, in a split-mouth randomized study design, whether a reduction of window dimensions can achieve the following: (i) better results than a wider window in terms of augmented bone height and (ii) a reduction of patient discomfort and surgical complications.

The null hypotheses tested were that (i) there was a higher increase of bone reconstruction when adopting a reduced window rather than a wider one and (ii) there was no difference in discomfort for the patients between the two opening procedures.

Materials and methods

Subjects for the study were recruited from a pool of patients in need of implant-supported restorations at the Department of Periodontology at the University of Siena.

Approval of the original study protocol was obtained from the Ethical Committee of the "Azienda Ospedaliera – Universitaria Senese" Ospedale "Le Scotte" Siena, Italy, and was performed in accordance with the Helsinki Declaration. All the characteristics of the protocol were explained to the patients before they signed an informed written consent form. The trial was registered on clinicaltrials.gov with the following registration number: NCT02117882.

This article is reported in accordance with the CONSORT 2010 statement for improving the quality of reporting on randomized controlled trials (Fig. 1).

Sixteen subjects (seven males, nine females; mean age 57.56 ± 8.7 years; range 44–76) were screened to participate in the study during a period of time ranging from September 2013 to June 2014.

All the patients in this study finished the 6-month examination before December 2014 with the exception of patient #13 who was unable to continue the treatment at 6-month follow-up for personal reasons. Figure 1 shows the flow diagram for this study population.

Patients were recruited for the study on fulfillment of the following inclusion criteria: non-compromised systemic health, periodontal health or healthy periodontium after periodontal therapy, condition of bilateral edentulism in the posterior maxilla with insufficient bone volume for implant placement.

All subjects received a session of prophylaxis including instructions on correct oral hygiene measures and scaling; surgical treatment was not scheduled until the patient could demonstrate an adequate standard of supragingival plaque control.

The following exclusion criteria were considered during the present protocol: systemic or immunologic diseases, recent acute myocardial pathology, coagulation disorders, metabolic disorders, bisphosphonates therapy, heavy smoking (more than 10 cigarettes/day), alcoholism, maxillary sinus pathology and former sinus surgery.

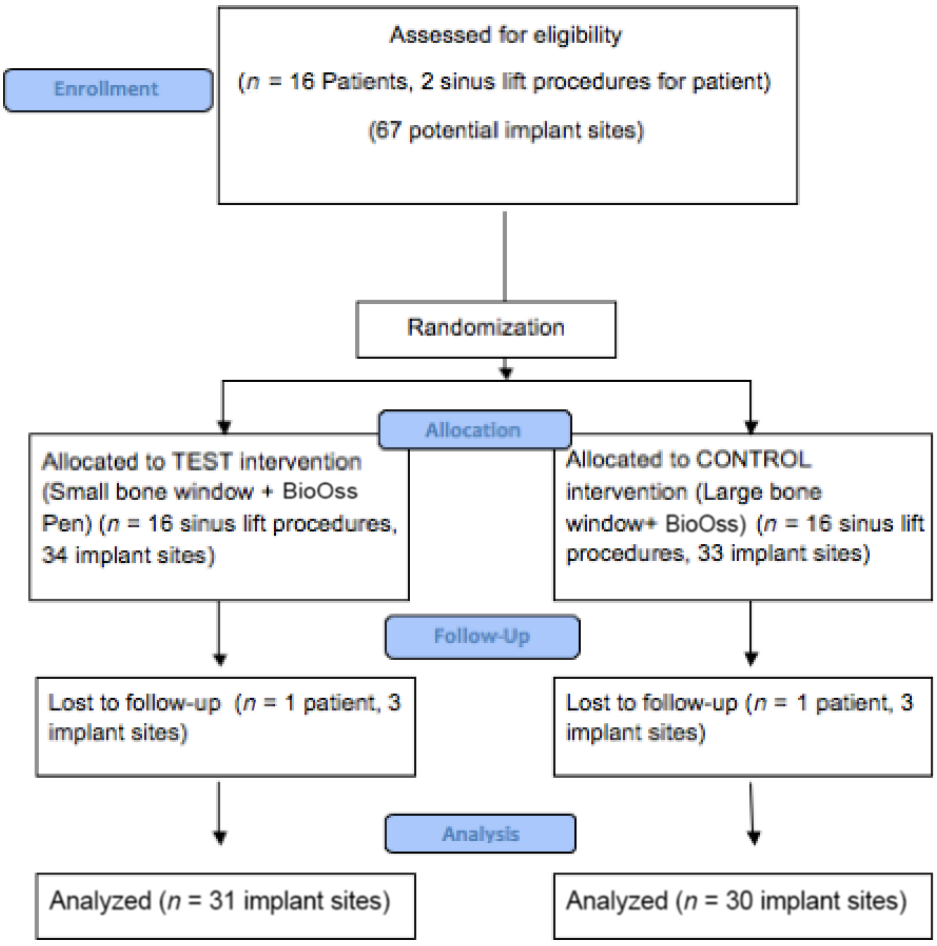

Fig. 1. Flow diagram of the study.

Study design

Each patient received a bilateral sinus lift procedure based on two different surgical procedures.

Test side: small access window to maxillary sinus + bone filling using a special device.

Control side: large access window to maxillary sinus + manual bone filling.

After making impressions, stone casts were made and a radiographic stent was prepared for each patient (Fig. 2). Radiopaque references were impressed on each stent to identify where implants were planned after bone regeneration: Using these references, repeatable measurements could be taken on CT scans performed at different time points during the protocol.

A pre-surgical CT scan focusing on the maxillary area was performed on each patient, paying special attention to the correct placement of the radiographic stent.

Prior to surgery, patients were asked to rinse with a 0.2% chlorhexidine solution for one minute.

All surgical procedures were performed by the same clinician (NB).

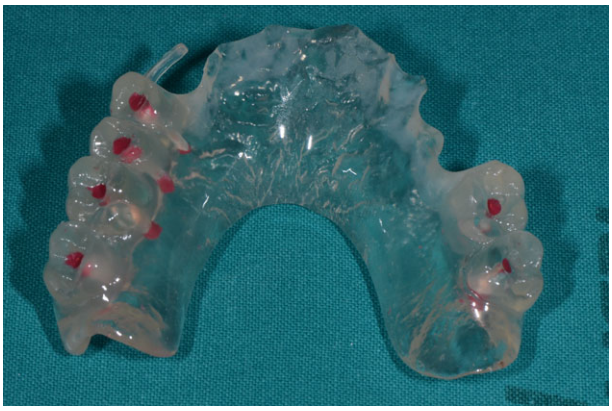

Fig. 2. Radiographic stent: radiopaque references were created in the planned implant positions.

Test side

Under local anesthesia, a full-thickness mucoperiosteal flap was elevated. Before performing the incision, the area of buccal wall of maxillary sinus had been carefully inspected to determine the more appropriate location for the bone window. The flap was made with a trapezoidal design to expose only a central area of 6 × 6 mm (the bone window) and a peripheral bone surface of a further 4 mm for each side. Crestal and releasing incisions were beveled so that an increased connective surface would be available for sutures and for collagen membrane stabilization. Once the flap was raised, a bone window of 6 × 6 mm was opened, using the Mectron Piezosurgery System (Genova, Italy), to gain access to the maxillary sinus (Fig. 3). Bone window dimensions were recorded using a periodontal probe (CPC15 Hu-Friedy, Leimen, Germany). The bony wall was reduced using a bone-shaving device until the Schneiderian membrane became evident in the fully shaved area, and bone window dimensions were approximately 6 × 6 mm. The sinus membrane was lifted starting from the inferior border of the osteotomy site, and completely and carefully dissected from the medial and inferior walls of the sinus. All surgical procedures were performed with great accuracy to avoid damage and perforation of the membrane. The sinus

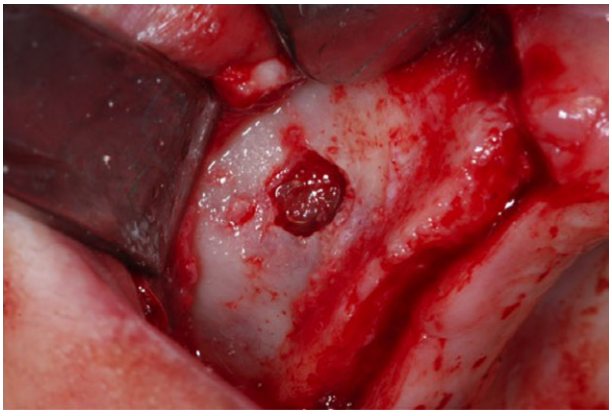

Fig. 3. Bone window for sinus access, 6 × 6 mm, test side.

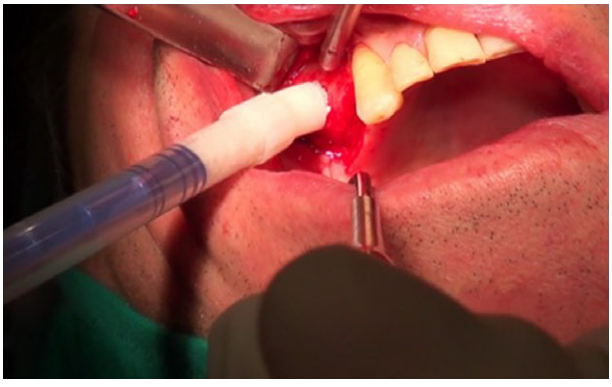

Fig. 4. Sinus filling with a special carrier, test side.

was filled with deproteinized bovine bone (1–2 mm) using a special carrier (Bio-Oss Pen; Geistlich Pharma Wolhusen Switzerland) (Fig. 4), and the bony window was covered with a collagen membrane (Bio-Gide Geistlich Pharma) (Ferreira et al. 2009). The membrane was sutured to the exposed connective surface in the peripheral area of the flap, and a periosteal releasing incision flap was sutured with sling sutures using 5/0 resorbable sutures.

Control side

Under local anesthesia, a mucoperiosteal flap was elevated and the lateral wall of the maxillary sinus was exposed. A bone window (approximately 10 × 8 mm) was opened in the lateral wall, using the Mectron Piezosurgery System, to enable the gentle elevation of the Schneiderian membrane (Fig. 5). Deproteinized bovine bone (1–2 mm) (Bio-Oss; Geistlich Pharma) was applied into the sinus cavity paying special attention to avoid

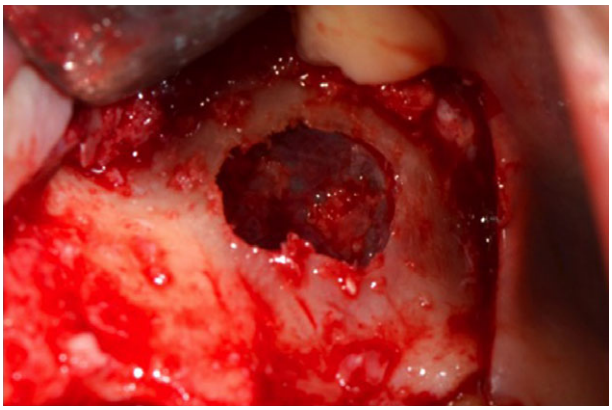

Fig. 5. Bone window for sinus access, 10 × 8 mm, control side.

Fig. 6. Sinus filling, control side.

packing (Fig. 6); the bony window was covered with a collagen membrane (Bio-Gide; Geistlich Pharma). Finally, a periosteal releasing incision flap was sutured with sling sutures, using 5/0 resorbable sutures.

Post-surgical protocol

All patients received 2 gm of amoxicillin before starting the surgical procedure and then continued for 5 days (2 gm amoxicillin per day). Chlorhexidine mouthwash was prescribed twice daily for the following 21 days. Sutures were removed after 15 days.

Dentures were not permitted for use until they had been adjusted and refitted and not before 2 weeks after surgery.

Follow-up protocol

Patients were recalled at 7-day, 14-day, 30-day and 180-day intervals.

Oral hygiene was performed every 3 months during follow-up period.

At the 6-month checkup, a CT scan was performed placing the same radiographic stent utilized for the pre-surgical scan.

Randomization and allocation concealment

Randomization of treated sites was performed immediately before the surgical intervention. An independent evaluator distributed the test and control sites according to a computer-generated randomization list. Numbered envelopes (1–16), containing the treatment indication, had been prepared before the beginning of the study and opened at the time of the surgical intervention.

Patients, measurers and statisticians were blinded about the treatment of each sinus.

Radiographic assessment

The primary objective of this study was to measure the height of augmented bone between minimally invasive procedure and traditional procedure. Measurements were taken on pre-op CT scans and 6-month post-op CT scans: Repeatable measurements were obtained using radiopaque references on radiographic stents (Figs 7–10). A blinded evaluator (CD) recorded all radiographic outcomes.

The following radiographic measurements were recorded in correspondence with

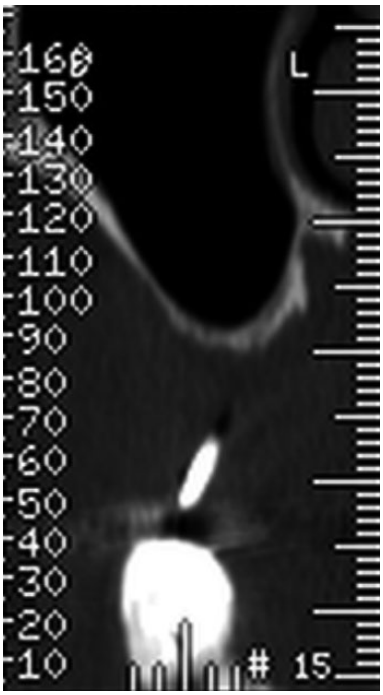

Fig. 7. Pre-op CT scan, test side.

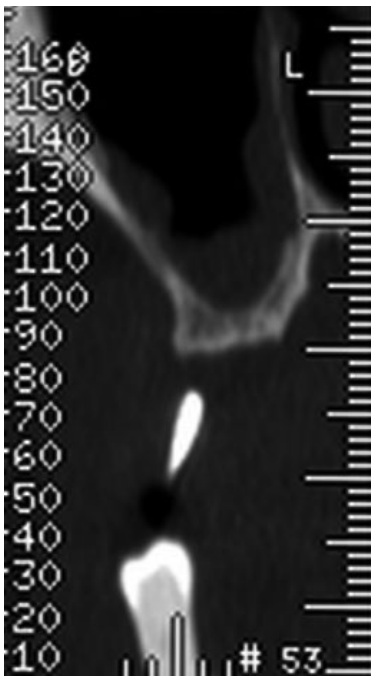

Fig. 8. Pre-op CT scan, control side.

radiopaque references: height of residual bone and width of residual bone. The thickness of the lateral wall of maxillary sinus was also measured in the center of the bone window.

Bone height increment was calculated as follows: 6-month bone height value – baseline bone height value.

The crestal bone levels were measured by means of image analysis software (NIS-elements software; Nikon, Tokyo, Japan), which scanned and calibrated the X-rays.

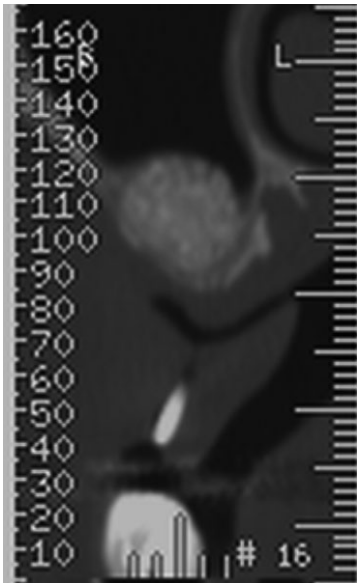

Fig. 9. Post-op CT scan, test side.

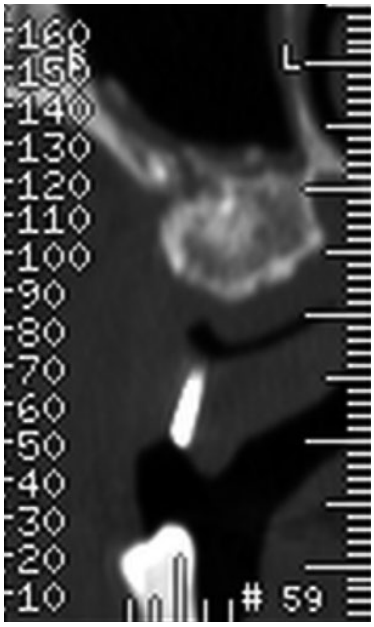

Fig. 10. Post-op CT scan, control side.

Time for surgical procedure

A secondary outcome of the study was to determine whether there were differences in surgical intervention duration between the two tested procedures. A clinician (AB), not involved in the surgical procedure, recorded all time-related outcomes. After administering local anesthesia, time was measured for each surgical procedure as follows:

- Total time of intervention from incision to the last suture (minutes)
- Partial time for bone window opening (seconds)
- Partial time for sinus elevation (seconds)
- Partial time for sinus filling (seconds)

Table 1. **Bone dimensions at baseline**

Per Group/side	Test (*N*)	Control (*N*)	*P* value
Residual bone height (mm)	3.10 ± 0.93 (34)	3.39 ± 1.22 (33)	*P* = 0.27 not statistically significant
Residual bone width (mm)	5.17 ± 1.41 (34)	5.39 ± 1.96 (33)	*P* = 0.59 not statistically significant
Lateral wall thickness (mm)	1.25 ± 0.51 (16) Median 1 Interquartile range 1–1.5	1.41 ± 0.55 (16) Median 1.5 Interquartile range 1–1.5	*P* = 0.25 not statistically significant

Patient-based evaluation

Patient opinion was assessed using the VAS. Patients were blinded about test and control side of surgical protocol. All patients were asked to complete a questionnaire concerning their discomfort after the surgical intervention on both treated sides. Patients' evaluation was requested as an overall judgment of the surgical treatment in terms of pain and swelling at 7-day, 14-day and 30-day follow-up.

The VAS consisted of a 10-cm-long line representing the spectrum of evaluation from 0% (no discomfort at all) to 100% (very relevant discomfort); the distance from the left extremity of the VAS to the mark made by the patient was measured to the nearest millimeter and reported as a value (0–10).

Statistical methods

All the statistical computations were handled by the Statistical Package for Social Sciences software (SPSS, version 18 for Windows, SPSS Inc., Chicago, IL, USA). For descriptive statistics, mean and standard deviation values were calculated for normally distributed numerical variables, while median values and interquartile ranges were provided for ordinal and non-normally distributed numerical data. To preliminarily verify that height and width of residual bone at baseline were comparable in the test and the control sites, the *t*-test was applied to each variable (Table 1). To compare maxillary sinus lateral wall thicknesses between test and control sites at baseline, the Wilcoxon signed-rank test was used as the data did not have a normal distribution. For the variables "residual bone height" and "residual bone thickness," the paired *t*-test was used to assess the statistical significance of the difference between baseline and 6-month measurements in the test and the control sites to verify whether statistically significant differences in bone height increment existed between the test and the control procedures, and the Mann–Whitney *U*-test was applied, as the compared groups were found to have unequal variances (Table 2). The same statistical test was applied to the values of bone thickness increment recorded in the test and the control sites, as these data were found to be non-normally distributed. The paired *t*-test was used to compare the times of surgery between test and control procedures (Table 3). The Wilcoxon signed-rank test was applied to assess the statistical significance of the differences in patients' discomfort between test and control side at 7, 14 and 30 days of follow-up. In all the analyses, the level of significance was set at $P = 0.05$.

Results

Every surgical procedure was successful and healed uneventfully. No major complications affected the patients, although some minor adverse events were reported as follows: In the test group, the presence of bone septa was found in two cases, membrane perforations during sinus elevation were reported in three cases and moderate hemorrhages affected two surgical interventions. In the control group, membrane perforation was reported in four cases and bone septa in three patients.

Table 1 shows residual bone dimensions at baseline in the treated sites: No significant differences were found at baseline between the treated groups in terms of residual bone height and width and lateral wall thickness.

A total number of 31 implant sites were considered for test group and 30 for control group.

In the test group, the mean dimensions for bone window length and height were 5.75 ± 0.6 mm and 5.38 ± 0.5 mm, while in the control group, they were 10.06 ± 0.93 mm and 7.31 ± 0.6 mm, respectively. Window area dimensions were 30.9 ± 4.4 mm^2 and 73.7 ± 10.1 mm^2, respectively.

Radiographic outcomes on 6-month CT scans and bone augmentation in vertical and horizontal directions are summarized in Table 2.

A significant bone augmentation in height and width of alveolar crest was obtained in both test and control sides, although no significant differences were found between the two groups.

Table 2. **Bone dimensions after sinus elevation**

Group/side	Test baseline Mean ± standard deviation (*N*)	Test 6-month Mean ± standard deviation (*N*)	Δ bone increment Mean ± standard deviation (*N*)	*P* value[1]	Control baseline Mean ± standard deviation (*N*)	Control 6-month Mean ± standard deviation (*N*)	Δ bone increment Mean ± standard deviation (*N*)	*P* value[1]
Residual bone height (mm)	2.93 ± 1.37 (31)	11.64 ± 1.59 (31)	8.71 ± 1.11 (31)	$P < 0.001$	3.24 ± 1.43 (30)	11.77 ± 1.85 (30)	8.5 ± 2.02 (30)	$P < 0.001$
P value[2]			$P = 0.88$					
Residual bone width (mm)	5.19 ± 1.51 (31)	9.99 ± 1.37 (31)	4.70 ± 0.58 (Median 4.7, interquartile range 4.30–5.15)	$P < 0.001$	5.3 ± 1.95 (30)	9.98 ± 1.74 (30)	4.68 ± 0.70 (Median 4.5, interquartile range 4–5.2)	$P < 0.001$
P value[2]			$P = 0.85$					

All measurements are in millimeters. Baseline data were recorded on pre-Op CT scans, Δ bone increment was calculated as the difference between 6-month and pre-Op data measured at the same radiopaque reference.
[1]*P* value: intragroup differences between baseline and 6-month CT scans.
[2]*P* value: intergroup differences between test and control at 6-month follow-up.

Table 3. **Treatment times: total time of the surgical interventions is expressed in minutes, and partial times are expressed in seconds**

Group	*N*	Total surgery (min)	Bone window opening (s)	Membrane elevation (s)	Sinus filling (s)
Test	16	42.62 ± 6.67	145.5 ± 62.74*	199.83 ± 73.19	158.18 ± 39.87*
Control	16	41.68 ± 8.34	208.81 ± 43.81*	220.62 ± 81.95	207.06 ± 49.68*
P value		$P = 0.722$	$P < 0.0001$	$P = 0.264$	$P = 0.003$

*Statistically significant intergroup differences.

Table 4. **Patient's discomfort. VAS diagram at 7-day, 14-day, and 30-day**

	Test 7-day	Control 7-day	Test 14-day	Control 14-day	Test 30-day	Control 30-day
Median	4	8	2	4	2	2
25%	2.5	4	2	2	1	2
75%	7	8	3	5	2	2.5
P value		0.027*		<0.001*		0.014*

*Statistically significant differences.

Surgical treatment duration is shown in Table 3: No significant differences emerged between the tested procedures in the duration of the intervention although test procedure resulted significantly quicker than control procedure in the partial times of bone window opening and sinus filling.

Patients' opinion relating to post-surgical discomfort showed a preference for test procedure at 7-day, 14-day and 30-day follow-up, as evidenced in Table 4.

Discussion

A conservative approach in bone window dimensions, during lateral sinus floor elevations, has been recently proposed by several authors. In a recent study (Pariente et al. 2014), two mini windows were proposed: The authors underlined the increased osteogenic potential of a conservative approach on lateral bone wall. They also stressed the clinical advantage of an improved stability and protection of the grafted material. A RCT study (Nickenig et al. 2014) described a mini-invasive bone window, associated with a mini-invasive flap and flapless implant insertion. They reported a reduction in post-op swelling in the test group compared to the control group where a conventional trapezoidal flap was elevated.

The reduction in window's dimensions represents an increase of surgical difficulties and as a consequence better technical skills are required. In some clinical cases, as evidenced in Figure 8, the complete elevation of the sinus mucosa can hardly be obtained and the management of surgical complications, membrane perforation, bleeding, may be more complex through a small window.

A possible advantage of a small window is a better protection of the grafted material, thus reducing the connective tissue in growth through the window. The connective tissue in growth may occur despite the use of a protective collagen membrane placed on the access window, as demonstrated in several clinical studies (Barone et al. 2011; Scala et al. 2016; Favero et al. 2016).

Focusing on the primary outcome of this study, it can be noted that a similar result in terms of bone reconstruction was obtained for test and control procedures. Each of the planned pre-op implant positions was considered adequate for implant insertion at 6-month post-op visit and radiographic control. For this reason, the first null hypothesis that there was a higher increase of sinus lift when a reduced window was made than wider window was rejected.

A significant number of membrane perforations were reported in this study (21.8% considering all the treated sites): three cases in test group and four in control group. All perforations occurred during sinus elevation. These results are similar to those reported by other clinical studies (Barone et al. 2008, Lambert et al. 2010; Pariente et al. 2014), but the incidence of membrane perforation was higher and consequently may be considered relevant if compared with other data reported in the literature (Wallace et al. 2007; Pjetursson et al. 2008). Nevertheless, in all cases of perforation, surgical procedures were completed: Perforations were managed using extreme care while continuing membrane detachment and applying a collagen membrane into the sinus cavity (van der Bergh et al. 2000).

Abnormal bleeding caused by a lesion on the subantral artery occurred in two cases of the test group for an overall incidence of 6.25% of the treated surgical sites. These data are in agreement with those reported by another clinical trial (Lambert et al. 2010). Bleeding was managed by local pressure on the bone, and in both cases, sinus elevation was completed.

One of the secondary outcomes of this study was to evaluate whether there were differences in surgical times between the two tested procedures: The overall duration of the intervention showed no significant differences between test and control groups. Partial time for bone window opening and for sinus filling showed a better result for test procedure. These aspects may be explained, respectively, by a smaller and quicker surgical approach during bone window opening, and by the use of a special carrier for bone graft that may facilitate sinus filling procedure. Time for sinus elevation showed no difference between the groups: It may be argued that a smaller window did not represent an obstacle for facilitated sinus elevation.

Time-related outcomes have to be evaluated considering a relevant limiting factor: some adverse events, such as membrane perforations and hemorrhages, or anatomical factors, such as the presence of Underwood septa within the sinus, may have had a significant influence on these results.

The management of these clinical situations surely determined a variation of treatment times, and it was not possible to quantify the delay that each single complication added to the duration of the surgical procedure.

Despite this, a split-mouth approach guaranteed the most similar anatomical conditions for the two groups and it has to be reported that the overall number of these adverse events was the same for test and control group.

Patients' opinion report at 7-day, 14-day and 30-day post-op showed a significantly better result for test procedure in terms of post-surgical discomfort. Consequently, the null hypothesis that there was no difference in discomfort for the patients between the two opening procedures must be rejected.

It may be considered that a reduction in bone window dimensions could be followed by a reduction in flap dimensions and that this could determine a further reduction of patient discomfort, as reported by a recent clinical trial (Nickenig et al. 2014). This may be a topic for other studies to reduce the surgical impact of sinus lift procedures.

In conclusion, within the limits of this study, the results of this randomized split-mouth study can be summarized as follows:

1. A reduction of bone window dimensions did not affect the safety of the surgical procedure: similar results were found in terms of height of augmented bone measured on 6-month post-op CT scans.
2. The two techniques tested showed no statistically significant differences in surgical intervention duration, although bone window preparation and bone graft filling of the sinus cavity were found to be quicker in test procedure.
3. Patients' overall opinion at 7-day, 14-day and 30-day post-op showed a preference for test procedure.

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Conflict of interest

The authors declare that they have no conflict of interests.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. CONSORT 2010 checklist of information to include when reporting a randomised trial*.