Implant Placement in Combination with Sinus Membrane Elevation without Biomaterials: A 1-Year Study on 15 Patients

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ABSTRACT

Background: Membrane elevation in combination with implant placement without biomaterials is a rather new technique proposed for sinus lifting.

Purpose: This study assessed the clinical outcome of such technique during the first year of loading.

Material and Methods: Fifteen patients with a mean residual bone height of 6.2 mm were consecutively recruited for sinus lifting. After opening a replaceable bone window, the membrane was dissected from the sinus walls. A total of 28 implants were placed in the residual crest and they kept the membrane lifted upwards. After window repositioning, the flap was sutured. A 6-month healing period was allowed. Patients were re-examined after 12 months of loading.

Results: All the implants survived at the end of the follow-up. The 5.5 mm mean bone reformation was significantly lower than the 8.2 mm mean membrane lift achieved after implant placement. Regeneration at the distal surface of the most posterior implants was significantly less than at other aspects. The height of membrane lift was not correlated with the amount of regenerated bone.

Conclusions: All of the 28 implants placed in combination with sinus membrane elevation were stable during the first year of loading. No extra costs for biomaterial or morbidity for bone harvesting were necessary.

KEY WORDS: bone reformation, minimal intervention, sinus membrane

INTRODUCTION

The majority of the implant rehabilitative alternatives for edentulous posterior maxillas are little invasive for the patient and successful also in the majority of cases presenting with reduced bone volumes.[1] Unfortunately, in some patients, posterior areas of the upper jaws may lack bone for adequate implant stability. When this severe atrophy is due to the pneumatization of the maxillary sinuses at the expenses of the alveolar crest, grafting of the sinus floor is generally performed. Although several techniques and grafting materials have been used for this purpose, as a general rule, grafting techniques should be as simple, less invasive, complication free and with the shortest healing time as possible.[2] The rather novel sinus augmentation technique presented by Lundgren and colleagues[3–5] seems to satisfy the above-mentioned requirements. When the sinus membrane is carefully dissected and maintained lifted by implants placed in the residual bone volume, spontaneous bone regeneration results around the implants. Without any grafting material, the new bone formation is promoted by the coagulum in the isolated compartment created around the implants. Animal studies have shown histological evidence of osseointegration around implants placed in combination with this technique.[6] In addition, the health of the sinus mucosa has been shown not to be compromised after the lifting and implant placement procedure.[7] This technique has already been subjected to some clinical investigations from a few different centers with

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similarly good results.[3,4,8–10] However, more clinical data seem to be desirable to document the effectiveness and predictability of the sinus membrane elevation technique in combination with placement of dental implants without grafting material.

The aim of this report is to describe the survival rate of Astra Tech implants that were placed in combination with the sinus membrane elevation technique in a series of 15 patients with atrophic posterior maxillas that were followed up clinically and radiographically for the first year of loading.

MATERIALS AND METHODS

Patients

Fifteen patients (11 men and 4 women; mean age 46 years) were consecutively treated. Ten of them needed a rehabilitation of atrophic posterior maxillas, while the others needed maxillary first molar replacement. All the patients signed an informed written consent to the treatment. Preoperative panoramic radiographies or tomograms showed healthy sinus conditions and atrophy of the residual bone crest that was unsuitable for conventional implant placement (Figures 1 and 2). One experienced operator treated all the patients from January 2007 to February 2008.

Treatment

A mucoperiostal flap was raised to access the lateral wall of the sinus. A bone window was then opened into the sinus using a reciprocating surgical microsaw (BBraun, Milan, Italy) and a piezoelectric handpiece (Surgybone, Silfradent, Cesena, Italy). Whenever possible, angled osteotomies were made so that the bone window had bevelled margins to facilitate its repositioning at the end of the procedure. After removal of the bone window, small elevators were used to carefully dissect the sinus membrane free from the sinus floor. The membrane was then lifted upwards, so that a separate compartment for the implants was created. In three cases, a tear of the sinus membrane occurred during the dissection procedure. Two cases were managed by gently laying down a piece of resorbable membrane (Bio-Gide, Geistlich, Wolhusen, Switzerland) on the perforated sinus membrane, where it adhered after blood absorption; the remaining case was left untreated given the small tear size. In the residual alveolar crest, implant position was marked with a round bur and then 2, 2.5, and 3.2 mm diameter twist drills were used to prepare the sites aiming at high primary stability. The residual bone height (Figure 3A) was measured with a depth gauge (Depth Gauge Fixture, Astra Tech, Mölndal, Sweden) at

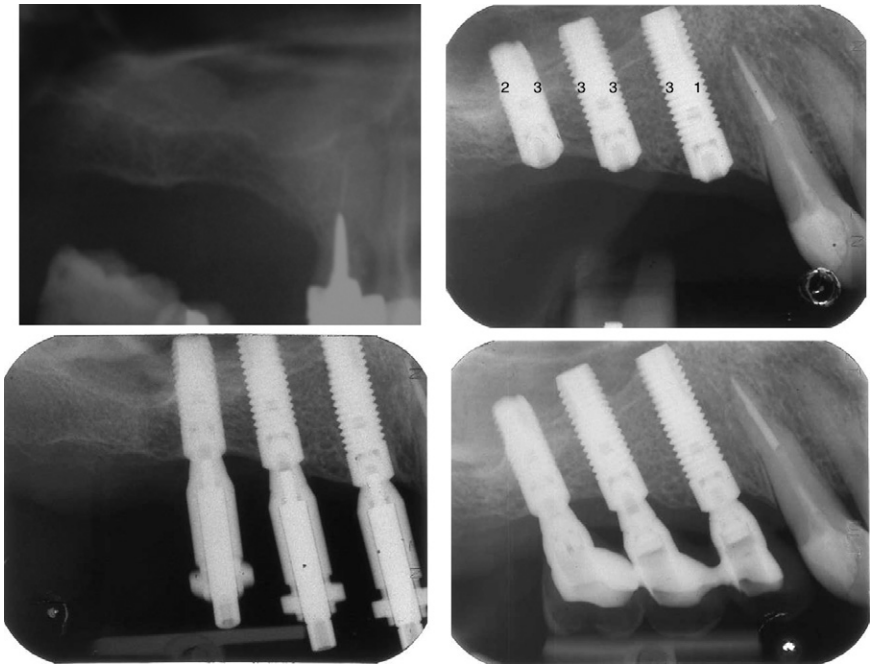

Figure 1 Preoperative situation before extraction of the bicuspid. Further controls at 4 months of healing, abutment connection, and 1 year of loading. The numbers in the 4-month x-ray indicate the grouping of the implant aspects to evaluate bone regeneration distribution.

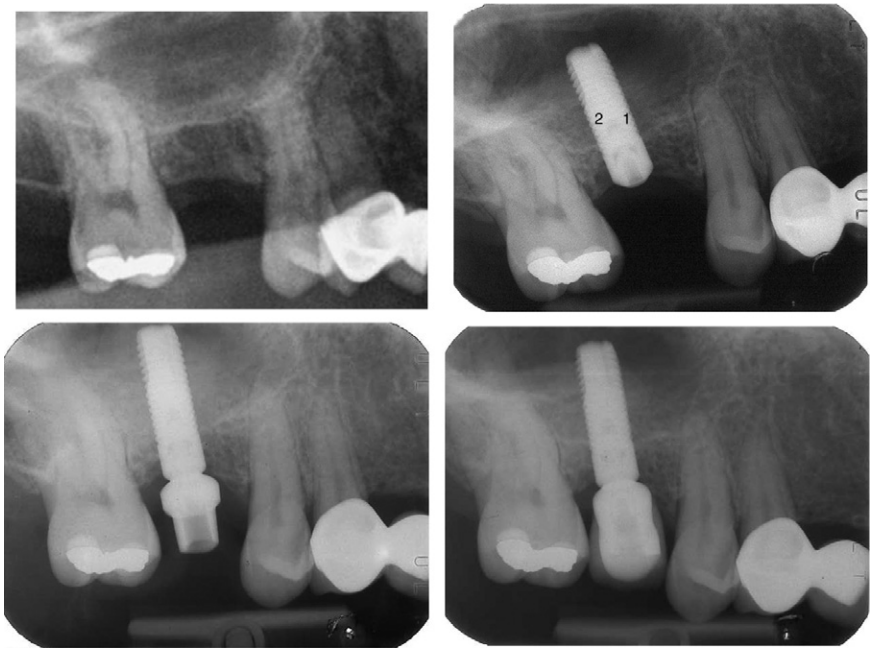

Figure 2 Preoperative bone volume and following controls at 4 months of healing, abutment connection, and 1 year of loading. The numbers in the 4-month x-ray indicate the grouping of the implant aspects to evaluate bone regeneration distribution.

the mesial and distal aspect of each site and recorded in patient's chart. These intra-operatory data were then used to determine the height of the membrane lift achieved, that is, the implant protrusion inside the sinus (Figure 3B), and was used as a baseline to calculate bone formation around the implants at the end of the follow-up (Figure 3C). Patients received one to three implants that acted like tent poles in lifting the sinus membrane with their apical surfaces (Figure 4). A total of 28 implants (Osseospeed, Astra Tech, Mölndal, Sweden) were placed in combination with membrane elevation. In addition, one implant in four of the treated patients was placed in the native bone volume next to the site in need of augmentation; such implants were not the subject of study. One implant had a length of 11 mm, nine implants had a length of 13 mm, and the remaining 18 were 15 mm long. In nine sites, because of the limited space available, 3.5-mm-diameter implants were used, while the remaining 19 implants had a 4 mm diameter. After placement, the bone window was repositioned on the sinus wall; the bevelled margins and few drops of cyanacrilate-based surgical glue (Glubran2,

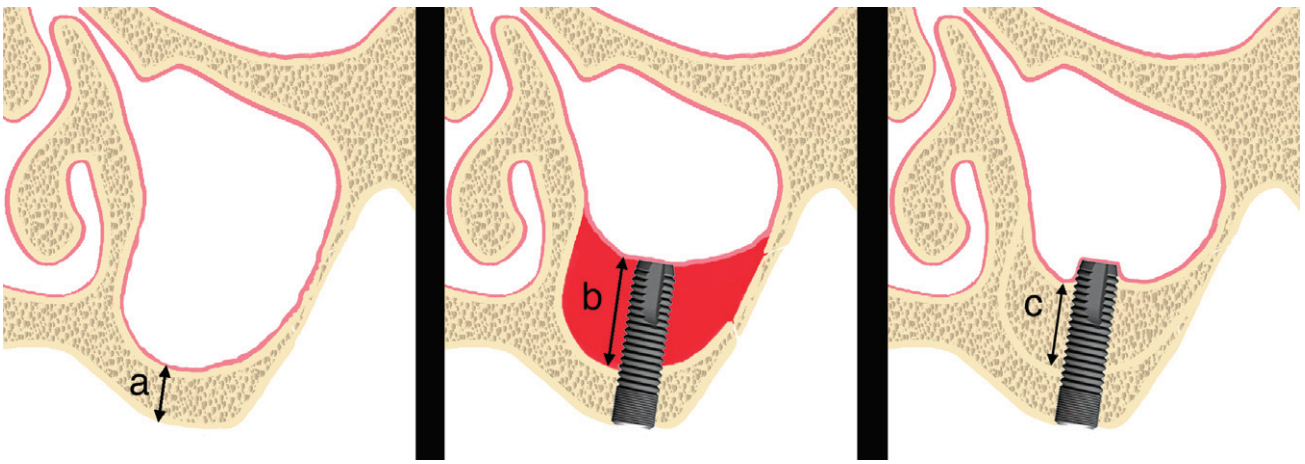

Figure 3 Schematic representation of the lifting sequence and of the investigated parameters. *A*, residual bone height; *B*, membrane lift achieved after implant placement; *C*, sinus bone regeneration after 1 year of loading.

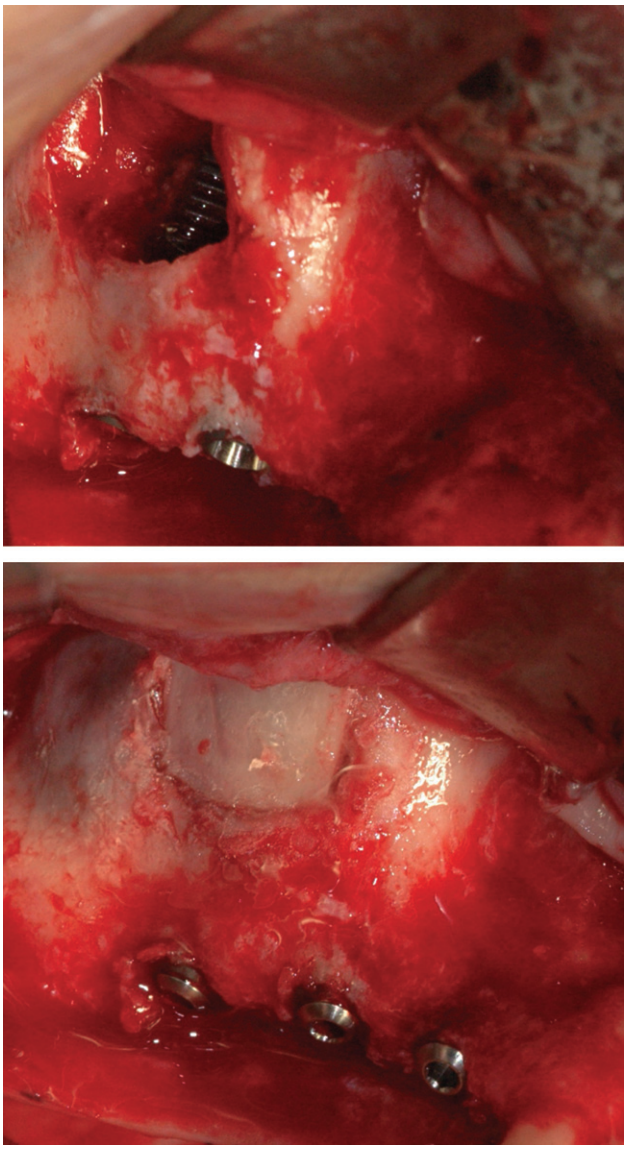

Figure 4 Implants maintain the membrane lifted upwards. The bone window replaced and glued to seal the access.

Gem, Lucca, Italy) helped to achieve its firm stabilization (Figure 4). The flap was then sutured (Vicryl 3-0; Ethicon Inc, Somerville, NJ, USA). Patients were sent back home with a prescription of antibiotics (Rocefin, Roche, Milan, Italy) and analgesics (Toradol, Recordati, Milan, Italy). They were also instructed not to blow their nose. After 2 weeks, all of the patients were reviewed and sutures removed. A 6-month healing period was allowed before performing abutment surgery. The patient received screw-retained bridges or single crowns that were either cemented or screw retained.

Follow-Up

At the 1-year follow-up, the following clinical variables were recorded: absence of pain, discomfort, or infection associated with the implants. A surviving implant was defined as an implant that was in function and symptom-free. Prostheses were not removed to check individual implant stability.

Radiographic examinations (Figures 1–2) were made after 4 months of healing, at abutment connection, and after 1 year of loading when recall of the patients and clinical examination was also performed. Such follow-up x-rays were all intraoral periapical images exposed with the aid of a film holder. X-rays were then digitized and evaluated with a freeware image analysis software (ImageJ; http://rsb.info.nih.gov/ij/). The sinus bone regeneration after 1 year of loading (Figure 3C) was calculated from the baseline value measured at surgery (Figure 3A). To evaluate its distribution, bone regeneration was measured at the mesial surfaces of the most anterior implant, including single implants (group 1), at the distal surfaces of the most posterior implant, including single implants (group 2), and at all the remaining implant surfaces (group3) (Figures 2–3). In addition, crestal bone level changes from abutment connection to the first year of loading were measured at the mesial and distal side, and then a final mean value was calculated for each implant.

Statistical Analysis

Data distribution was normal (Kolmogorov-Smirnov test, $p > .05$) and group variances were homogeneous (Levene test, $p > .05$). Differences in distribution of bone regeneration between the groups 1, 2, and 3 were assessed with an analysis of variance and Tukey's post-hoc comparison. In addition, a *t*-test was used to find differences between the height of the membrane lift achieved and the bone regeneration after 1 year of loading. A Pearson's correlation test was applied to check correlation between sinus lift obtained and new bone formation. Statistical significance was set at $\alpha = 0.05$.

RESULTS

Clinical Outcomes

The wound healing was uneventful. The overall procedure was well tolerated by the patients who reported only little postoperative swelling and minor discomfort.

The mean residual bone height was 6.2 mm (range 4–10 mm) as measured intraoperatively. Five patients received a single implant, seven received two implants

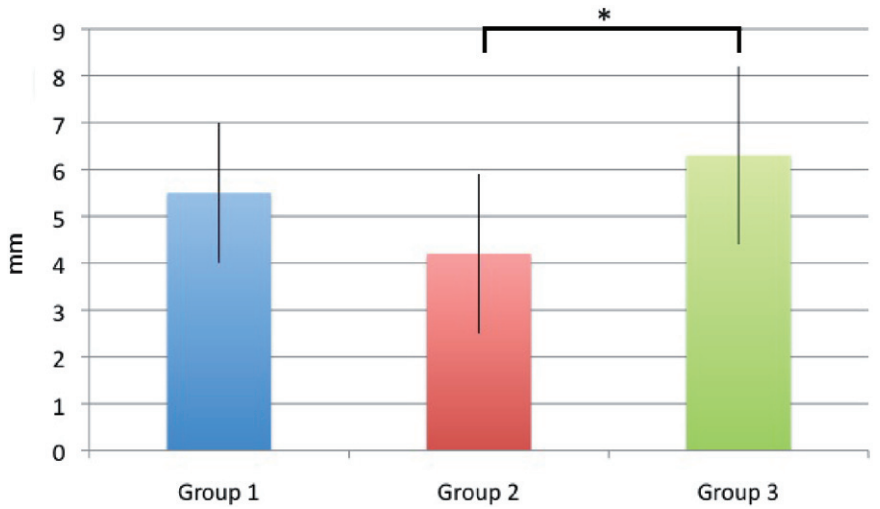

Figure 5 Distribution of bone regeneration. Group 1 represents the mean regeneration at the mesial surface of the most anterior implants, including single implants. Group 2 represents the mean regeneration at the distal surface of the most posterior implants, including single implants. Group 3 represents the mean regeneration at all the remaining implant surfaces. * = significant difference.

each, and the remaining three received three implants each. All the patients could be restored with the planned prostheses.

All the implants were in function and symptom-free at planned follow-up visits, and no intervening dropouts occurred.

Radiographic Outcomes

The mean bone regeneration after 1 year of loading was 5.5 mm. Table 1 shows the distribution of the heights of the residual bone and the corresponding bone regeneration achieved. Table 2 shows the distribution of the membrane lift achieved after implant placement and the corresponding bone regeneration. The mean regeneration achieved (5.5 mm) was significantly less ($t = 5{,}616$ $p < .05$) than the mean lifting (8.2 mm) obtained with implant placement. No significant correlation resulted

TABLE 1 Distribution of the Heights of the Residual Bone and Corresponding Bone Reformations Achieved. Data in millimeter

	Residual Bone	*N* of Implants	Mean Final Bone Regeneration
	3	3	7.6
	3.5	3	6.2
	5.5	1	4
	6	2	6
	6.5	5	6
	7	7	5.3
	7.5	5	4.4
	8	2	4.4
Mean	6.2		5.5
SD	1.6		1.6

TABLE 2 Distribution of the Membrane Lift Achieved after Implant Placement and Corresponding Bone Reformation

	Membrane Lift	*N* of Implants	Mean Final Bone Regeneration
	5	1	3
	5.5	3	3.5
	6	3	4.2
	7	1	5.8
	7.5	2	5.8
	8	4	6
	8.5	5	6
	9	2	6
	9.5	2	4.6
	10	1	6.3
	11.5	2	6.8
	12	2	8.2
Mean	8.2		5.5
SD	2		1.6

Membrane lift achieved was significantly greater than the final bone reformation ($p < .05$). No correlation resulted between the two parameters. Data in millimeter.

between membrane lift and new bone formation. Figure 4 illustrates significant differences in the distribution of regenerated bone ($F = 6.92$, $p < .05$). The amount of bone regenerated at the distal surface of the most posterior implants or at the distal surface of single implants (group 2) was significantly less than the regeneration achieved at implant aspects that were next to other implants (group 3) (Tukey's test $p < .05$; Figure 5). Finally, the mean crestal bone change after 1 year of loading was 0.36 mm (SD 0.2).

DISCUSSION

Implant placement, in combination with sinus membrane elevation technique without additional biomaterials, has been recently presented as an effective alternative when bone is insufficient for implant support in the posterior maxilla.[3–5] Actually, it has been recently proven that Schneiderian membrane contains osteoprogenitor cells and it is associated with a genuine osteogenic potential that might sustain bone formation in the absence of any osteoconductive material.[11] The technique seems particularly appealing because it is relatively simple, little invasive, has low complication risk, and requires a relatively short healing time. The present study reported the 1-year outcome of 28 implants that were placed according to the above-mentioned surgical technique. No complication occurred and a very satisfactory 100% survival rate resulted after the 1-year loading period. These data are in accordance with the outcomes already reported in the available clinical literature.[3,4,8–10]

Another interesting finding of the present study comes from the radiographical analysis. A mean of 5.5 mm of bone regeneration around the implant threads was obtained. Fermergård and Åstrand[12] documented the outcome of TiO Blast Astra Tech implants placed in the posterior maxilla with the osteotome sinus floor elevation technique without grafting material. With a mean residual bone height of 6.3 mm, the bone regeneration achieved was 4.4 mm. Although the surgical technique was quite different from the one investigated here, the involved principle is equal: elevation of the membrane to create a coagulum space around the implant without additional biomaterial. Therefore, given the similarity of the residual bone height, the results of the above-mentioned and the present study might be well comparable. Conversely, Thor and colleagues[8] reported slightly greater regeneration when using TiO Blast Astra Tech implants in combination with sinus membrane elevation exactly as done in this study. In fact, they obtained 6.5 mm of regenerated bone with a greater bone gain at most resorbed sites (2 to 5.5 mm of residual crestal bone). Slightly smaller preoperative bone volumes as compared with the patients investigated here are a possible explanation for this difference. Nevertheless, the new bone formation here obtained was enough to guarantee stability to the implants during the first year of loading. A second difference with the above-mentioned study is the lack of correlation between membrane lift and new bone reformation. This could be again due to differences in residual bone volumes between the two studies. On the other hand, this lack of correlation is in accordance with a dog study where no relationship could be demonstrated – after sinus membrane elevation – between length of implant protrusion into the sinus cavity and height of reformed bone.[13] It seems that more studies will be necessary to understand what is the amount of regeneration achievable for a given residual bone volume.

It is also interesting to note that the bone gain around the implants (5.5 mm) was significantly lower than the mean lifting height obtained after surgery (8.2 mm) with the implant apexes that were often left uncovered by the regenerated bone. The reason for the incomplete ossification of the coagulum space seems to be that implants do not provide a lifting action sufficient to completely resist the intra-sinus air pressure. As a result, a partial collapse of the membrane and a consequent decrease of the amount of regenerated bone are unavoidable. The instability of the newly formed bone after elevation of the sinus membrane was already described in a rabbit model.[14] The pressure caused by respiration was thought to be cause of resorption of the new-formed bone during the first 6 weeks after surgery. After 6 weeks, the shrinking process stopped and after 10, a new cortical border reformed under the elevated membrane.[14] Similar results were described in other animal studies where new bone formation occurred up to the mid-third portion of the implants, while the membrane alone was covering the apical portion.[6,15]

Some of the most recently marketed implants have been reported to enhance new bone apposition at their surfaces showing potential for bioactivity.[16–18] It would be interesting to compare these surfaces in terms of new

bone formation when used in combination with the membrane elevation technique.

Noteworthy of attention is also the variation in bone regeneration due to position. In particular, it resulted that at the distal aspect of the most posterior-placed implant, including single implants, smaller bone regeneration occurred. This is probably explained because the distal aspect of posterior-placed implants is more exposed to the pneumatization of the sinus, while a better support of the membrane is possible in the area between two adjacent implants. However, a limitation in the present study is the pooling of implants facing on the distal aspect edentulous areas and dentate areas. In fact, theoretically, implants facing on the distal aspect a dentate area would be in a more advantageous situation where the tooth helps in keeping the membrane lifted. This aspect guarantees further investigation. In any case, regardless of the difference in bone regeneration, all the implants had a satisfactory outcome after the first year of loading. It has also to be considered that intraoral radiography is not able to provide comprehensive data on bone regeneration; nevertheless, tomography scans were not performed for ethical reasons.

As far as crestal bone levels are concerned, it resulted a resorption after 1 year of loading a resorption slightly greater than the 0.06 mm previously reported[19] for the Astra Tech system resulted. Although less pronounced, this seems consistent with the "push out" from the original marginal bone level described for some implants in a previous similar study.[8]

A final aspect to consider is the surgical management of the mucosal membrane. Dissecting the membrane is a delicate phase of the technique; it has been shown experimentally that when accomplished successfully, there are no variations in the physiology of the sinus ostium and mucosa.[13] Unfortunately very thin, easy-to-tear membranes are sometimes found; as a consequence, lacerations have been described in the previous literature.[3,8] Possible strategies in these cases might be the suturing of the membrane,[3,8] periostal grafts,[8] use of surgical glues,[20] or biomaterials, however, the best approach for perforation repair has still to be established. In the present study, a smaller perforation was left untreated while two bigger ones were repaired with a resorbable membrane that allowed the creation of the secluded space for clot formation around the implants. In all three cases, the complication did not affect the stability of the implants over the first year of loading. It has been nicely suggested that, with the investigated surgical technique, tearing of the membrane seems not to be catastrophic as long as an isolated compartment around the implants can be created, for instance, by suturing the membrane.[21] If the repair is not accomplished, bone regeneration will be most likely minimal.[21] In fact, it has been observed in animal studies[13,20] that when implants perforate the membrane and protrude inside the sinus, the membrane adheres to a more cervical portion of the implant, while sinus health and osseointegration in the residual bone are not jeopardized. Therefore, it could be speculated that the present technique is little harmful also in cases of poorly managed perforations.

One last technical-related remark is deserved to the use of a surgical glue to stabilize the bone window once replaced at the end of the procedure. Its use is probably unnecessary from a strictly regenerative point of view, as previous publication that relied only on the effect of the coagulum for stabilizing the window showed similar results to the present study.[3,4,8] However, the glue, being harmless, seems helpful in firmly and rapidly stabilizing the bony window after its replacement, therefore guaranteeing its immobility during flap repositioning and suturing. This could be an advantage especially when the stability of the window once back in place is not excellent because the osteotomies are not neatly angled and therefore its margins are little beveled.

One limitation to the application of the technique is finding adequate primary stability for the implants in the residual bone. A carefully adapted surgical technique with the use of thinner drills than the implant diameter has therefore been recommended in previous report on this technique.[4,8] By following this recommendation it was feasible to successfully apply the membrane elevation technique also in cases where preoperative bone volumes were much less than in the cases here presented.[8]

In conclusion, this study confirms that the placement of dental implants in combination with membrane elevation could be advantageous when a sinus lifting is required. A satisfactory outcome can be obtained without extra costs for biomaterial or morbidity for autologous bone harvesting. Also, the new bone formation occurs contemporary to osseointegration, therefore keeping the overall treatment time short.

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