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Transcrestal maxillary sinus floor elevation with bone substitutes. A prospective case-control study

Rialzo del pavimento del seno mascellare con approccio transcrestale associato a biomateriali sostituti dell'osso. Studio prospettico caso-controllo

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Summary

The effectiveness and postoperative morbidity of 2 hydroxyapatite-based bone substitutes (Biostite® vs Bio-Oss®) when used for sinus floor elevation with a transcrestal approach were compared. Results indicated a greater extent of sinus lift and height of the graft apical to the implant apex for the Biostite® group at 6 months. Surgical complications and post operative pain/discomfort were limited for both groups.

Riassunto

In questo studio si sono confrontate efficacia e morbidità post-operatoria di due biomateriali base di idrossiapatite (Biostite® vs Bio-Oss®) usati in associazione a rialzo del seno transcrestale. I risultati hanno mostrato nel gruppo Biostite® a 6 mesi una maggiore entità di rialzo del seno e maggiore altezza dell'innesto apicalmente all'apice dell'impianto. In entrambi i gruppi complicanze chirurgiche e dolore/discomfort post-operatorio sono stati limitati.

Introduction

Maxillary sinus floor elevation represents a surgical procedure to vertically enhance the available bone, thus permitting the positioning of implants with adequate length in the edentulous posterior maxilla. Sinus floor elevation technique through a transcrestal (or transalveolar) approach was first published by Tatum in 1986 (Tatum 1986) and then modified by Summers (Summers 1994a, b) who introduced the use of a specific set of osteotomes.

Sinus floor elevation procedures are generally associated with grafting the sinus cavity with autogenous bone, bone substitutes or combination of the two. Pjetursson et al. (2009) compared the transcrestal sinus floor elevation by means of osteotomes with and without the additional use of deproteinized bovine bone mineral (Bio-Oss® Geistligh Pharma, AG, Wolhusen, Switzerland). A significantly greater gain in radiographic bone height was observed in grafted compared to non-grafted sites (4.1 mm and 1.7 mm, respectively).

Recently, a hydroxyapatite-collagen based bone substitute, (Biostite®, Vebas s.r.l., S. Giuliano Milanese, Milan, Italy) was successfully used for sinus floor elevation procedures with a transcrestal approach (Trombelli et al. 2010a). In this particular study, we proposed a minimally-invasive procedure, namely the *Smart Lift* technique, which is characterized by a transcrestal access to the sinus cavity by means of specially-designed drills and osteotomes (Trombelli et al. 2008, Trombelli et al. 2010a, b).

To date, however, there is still controversy regarding the most suitable graft biomaterial to provide conditions for new bone formation after elevating the sinus membrane. Thus, the aim of the present study was to comparatively evaluate the effectiveness and postoperative morbidity of the *Smart Lift* technique in association with 2 different HA-based bone substitutes.

Materials and Methods

Patients were selected and treated at the Research Centre for the Study of Periodontal and Periimplant Disease, University of Ferrara, Italy or Unità Operativa Complessa di Odontostomatologia, Ospedale "Casa Sollievo della Sofferenza", S. Giovanni Rotondo, Foggia, Italy, from January 2008 to May 2009. All the clinical procedures were performed in full accordance with the Declaration of Helsinki and the Good Clinical Practice Guidelines (GCPs). Each patient provided a written informed consent before participation.

Before sinus lift procedure, all oral diseases, including periodontal disease, were thoroughly treated. The following criteria were applied to verify the patient eligibility for the study:

indications for implant-supported prosthetic rehabilitation;

systemic and local conditions compatible with implant placement and sinus floor elevation procedures;

- patient where the sinus lift procedure was to be applied to a single implant;
- patient willing and fully capable to comply with the study protocol;
- age ≥ 18 years.

The following criteria were applied to verify the site eligibility for the *Smart Lift* technique:

- at least 6 months elapsed from tooth loss;
- absence of endodontic lesions at teeth adjacent to the implant site;
- length of the residual bone height (i.e. the distance from the bone crest to the sinus floor) of at least 4 mm.

Surgical procedure

The residual bone height at the sites where implants had to be inserted was first measured on periapical radiographs or CT scan. This measure was regarded as the radiographic working length (rWL).

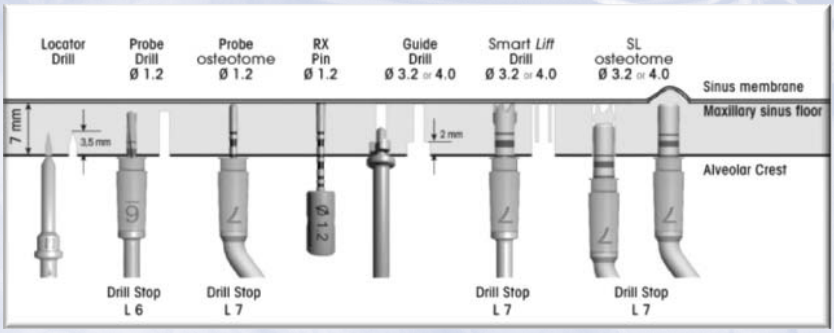
The preparation of the implant site was performed according to a precise sequence of instruments (Trombelli et al. 2010a, Fig. 1). After full-thickness flap elevation, a first drill (*Locator Drill*) was used to perforate the cortical bone at the site where the implant had to be placed. A second drill (*Probe Drill*), was utilized to define the position and orientation of the implant, with an adjustable stop device set at least 1 mm shorter than the rWL. Then, the "*Probe Osteotome*" was gently forced in an apical direction until the cortical bone resistance of the sinus floor was met. It provided the "surgical working length" (sWL), (i.e.: the anatomical distance from the bone crest to the sinus floor in the exact location where the implant had to be placed). Thus, the working action of all manual and rotating instruments was set at the sWL by using the proper adjustable stop device. Bone width (i.e. the bucco-lingual diameter of the alveolar crest), was measured with a periodontal probe (UNC 15, Hu Friedy, Chicago, IL) at site of implant placement. A "*Guide Drill*" was then used to create a crestal countersink, where the trephine bur (*Smart Lift Drill*) was subsequently inserted producing a bone core up to the sinus floor. The bone core was condensed and malleted to fracture the sinus floor by means of a calibrated osteotome (*Smart Lift Elevator*).

According to a randomization sequence, either Biostite® (Group A) or Bio-Oss® (Group B) was grafted into the sinus by the Smart Lift Elevator.

The duration of the *Smart Lift* procedure, i.e. the time (in minutes) elapsed from cortical perforation with the *Locator Drill* to the completion of the sinus lift procedure (i.e. immediately before implant placement) was recorded.

Patients were prescribed a rescue non-steroidal anti-inflammatory agent (nimesulide 100 mg tablets) as needed, and 0.12% chlorhexidine mouthrinse, 10 ml t.i.d. for 3 weeks. Sutures were removed 7 days after surgery.

Fig. 1. Smart lift procedure: sequence of rotating and manual instruments



Clinical parameters

The following clinical parameters were assessed during and after the surgical procedure.

Surgical complications:

- membrane perforation: evaluated by the Valsalva maneuver, (i) after the fracture of the sinus floor by means of the *Smart Lift Elevator*, and (ii) after grafting the biomaterial (prior to implant placement).
- other complications and/or adverse events associated with the sinus lift procedure

Patient-related outcomes

- intra-surgery complications and/or adverse events perceived by the patient during the surgical procedure;
- level of pain perceived by the patient immediately after surgery and at 7 days post surgery, recorded on a 100-mm VAS (ranging from "no pain" to "intolerable pain");
- level of discomfort perceived by the patient immediately after surgery, recorded on a 100-mm VAS (ranging from "no discomfort" to "maximum discomfort").
- dosage of nimesulide (i.e. number of 100 mg tablets) assumed by the patient during the 7 days post surgery.

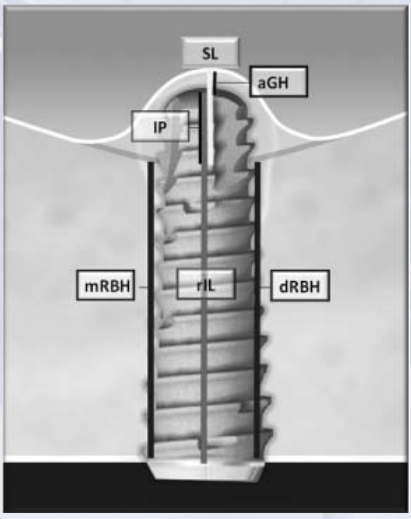
Radiographic measurements

Radiographic measurements were performed on periapical radiographs as taken immediately after the surgical procedure and at 6 months following surgery. Radiographs were obtained with a paralleling technique using a Rinn film holder with a rigid film-object X-ray source. All radiographs were scanned and digitized. Using an image-processing software, digitized images were stored with a resolution of 600 dpi, and displayed on a monitor. The following linear measurements were performed with the help of a caliper (Fig. 2) on the post-operative periapical radiograph, approximated to the nearest mm:

- *radiographic implant length* (rIL): as the distance from the implant shoulder to the implant apex assessed at the centre of the implant along its longitudinal axis. This measure was referred to the true length of the implant and used to calculate the distortion of all other radiographic measurements;
- *residual bone height* (RBH): as the distance between the bone crest, as assessed at the implant shoulder, and the sinus floor. The *residual bone height* at the centre of the implant was derived as the mean of the distances between the bone crest (at the implant shoulder) and the sinus floor as assessed on both mesial (mRBH) and distal (dRBH) aspects of the implant;
- *extent of the sinus lift* (SL): as the distance between the sinus floor and the top of the radio-opaque grafted area measured at the centre of the implant along its longitudinal axis;
- *implant penetration* (IP): as the difference between IL and RBH;
- *height of the graft apically* (aGH): as the difference between SL and IP. This measure was considered as positive if the top of the radio-opaque grafted area was located apically to the apex of the implant, and viceversa.

All measurements were performed by a single trained and calibrated examiner.

Fig. 2. Radiographic measurements



See text for acronymes.

Statistical Analysis

Data were entered in a unique database file and all analyses were performed with STATISTICA® software version 7.1 (StatSoft, Italia s.r.l., Vigonza, Italy). The patient was regarded as the statistical unit.

Data were expressed as median (interquartile range). Intra-group comparisons were performed by Wilcoxon test. Inter-group comparisons were performed with χ^2 test and Mann-Whitney U test. The level of significance was set at 5%.

Results

30 patients participated in the study. Fifteen implants in 15 patients received Biostite® (Group A), while 15 implants in 15 patients received Bio-Oss® (Group B). The study population is described in Table 1. Smokers were higher in Group A. Implant characteristics are shown in table 2. All implants were cylindrical and at least 8 mm long. All implants were in place at six months, the prosthetic rehabilitation was performed on 29 implants. No differences in implants length and diameter were seen between groups.

Clinical parameters are shown in Table 3. Only one perforation was detected by a positive Valsalva maneuver after fracturing the sinus floor, in the Group A. The site was managed by inserting a surgical haemostatic dressing (Gingistat® GABA Vebas s.r.l., S. Giuliano Milanese, Milan, Italy), and then grafted (the Valsalva maneuver resulted negative following grafting).

Post-surgery VAS scores pain and discomfort as well as the assumption of post-surgery analgesic tablets were limited for both groups. VAS pain significantly decreased from post-surgery to 7 days for Group A.

Radiographic measurements are shown in Table 4. In both groups, a substantial SL was observed post surgery which was maintained at 6 months. In all cases, a positive aGH was recorded. At 6 months, Group A showed a significantly greater SL and aGH compared to group B.

Table 1. Study population

	Group A (n = 15 patients)	**Group B** (n= 15 patients)	**p-value**
Gender	5 males 10 females	6 males 9 females	0.598
Age (years) (mean, min-max)	50.1 (37 - 69)	51.0 (33 - 67)	0.367
Smoking status	7 smokers 2 former smokers 6 non-smokers	3 smokers 3 former smokers 9 non-smokers	**0.036**
Cigarettes/day	20 (14 - 20)	10 (8 - 14)	0.117

Table 2. Implant characteristics.

	Implant type	Number of implants	Implant length (mm)	Implant diameter (mm)
Group A (n = 15 patients)	Osseotite® Certain® (Biomet 3I)	3	10.0	5.0
			11.5	4.0
			8.5	4.0
	Osseotite® Certain® Prevail ® (Biomet 3I)	1	10.0	5.0
	Osseospeed™ (Astra Tech Dental)	3	9.0	4.0
			9.0	4.0
			11.0	4.0
	Implus® TTS (Leader Italia)	1	8.0	3.75
	SPI® Element (Thommen Medical)	5	11.0	4.5
			11.0	4.0
			9.5	4.0
			8.0	4.0
			8.0	4.0
	Standard Plus-Tissue Level (Straumann®)	1	10.0	4.8
	Bone Level (Straumann®)	1	10.0	4.8
		Median (I.R.)	**10.00 (8.75 - 10.50)**	**4.00 (4.00 - 4.65)**
Group B (n= 15 patients)	Osseotite® Certain® (Biomet 3I)	5	10.0	4.0
			10.0	4.0
			10.0	5.0
			10.0	3.25
			8.5	4.0
	SPI® Element (Thommen Medical)	6	9.5	4.0
			9.5	4.0
			9.5	4.0
			9.5	4.0
			9.5	3.5
			9.5	3.5
	Standard Plus-Tissue Level (Straumann®)	4	10.0	4.8
			10.0	4.8
			8.0	4.1
			8.0	4.1
		Median (I.R.)	**9.50*** **(9.50 - 10.00)**	**4.00**** **(4.00 - 4.10)**

* no statistically significant difference between groups (p=0.683)

** no statistically significant difference between groups (p=0.512)

Table 3. Clinical parameters.

	Group A (n = 15 patients)	Group B (n= 15 patients)	p-value
SURGICAL COMPLICATIONS			
Membrane perforation (Valsalva manouvre +) after fracture of the sinus floor	1	0	-
Membrane perforation (Valsalva manouvre +) after grafting the biomaterial	0	0	-
Other surgical complications	0	0	-
PATIENT - RELATED OUTCOMES			
Intra-surgery complications perceived by the patient	1 patient referred "to feel trauma to the ear"	1 patient referred "to feel suture tension"	
	1 patient referred "to feel the teeth longer than before surgery"	1 patient referred "to feel sub-orbital area numb"	-
VAS pain immediately post surgery (mm)	2.00 (1.00-18.00)	6.00 (0.00-13.00)	0.902
VAS discomfort immediately post surgery (mm)	10.00 (2.00-31.00)	0.00 (0.00-10.50)	0.116
VAS pain at 7 days post surgery (mm)	0.00* (0.00-1.00)	0.00* (0.00-5.50)	0.540
Nimesulide 100 mg tablets assumed by the patient during the first week (N)	1.00 (0.50-1.50)	1.00 (1.00-1.50)	0.683

* statistically significant difference intra-group compared to post-operative VAS_{pain} **(p= 0.012)**

\# no statistically significant difference intra-group compared to post-operative VAS_{pain} (p= 0.266)

Table 4. Radiographic measurements.

			Immediately post-sugery		6-month post-surgery	
	RBH (mm)	**IP** (mm)	**SL** (mm)	**aGH** (mm)	**SL** (mm)	**aGH** (mm)
Group A (n = 15 patients)	5.25 (4.60-6.40)	4.70 (3.70-5.05)	7.70 (6.70-8.55)	3.00 (2.80-3.75)	7.50§ (7.20-8.50)	3.35♀ (2.73-3.80)
Group B (n= 15 patients)	5.70 (4.33-6.35)	3.80 (3.30-4.45)	6.50 (5.95-7.40)	2.60 (2.30-3.45)	6.60° (5.70-7.05)	2.60θ (2.10-2.90)
p-value	0.774	0.187	0.050	0.116	**0.003**	**0.019**

§ no statistically significant intra-group difference compared to post-surgery value (p= 0.753)

♀ no statistically significant intra-group difference compared to post-surgery value (p= 0.780)

° no statistically significant intra-group difference compared to post-surgery value (p= 0.079)

θ no statistically significant intra-group difference compared to post-surgery value (p= 0.079)

Conclusions

In conclusion, the results indicated that the Smart Lift technique appeared to be a surgical option for transcrestal sinus floor elevation in association with HA-based biomaterials. Surgical complications and post operative pain/discomfort were limited for both groups. A greater extent of sinus lift and height of the graft apical to the implant apex were observed for the Biostite® group at 6 months.

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