Minimally invasive transcrestal sinus floor elevation with graft biomaterials. A randomized clinical trial

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Abstract

Objectives: The present study was performed to comparatively evaluate the effectiveness and post-operative morbidity of transcrestal sinus floor elevation (tSFE) performed with a minimally invasive procedure (Smart Lift technique) combined with the additional use of two graft biomaterials.

Methods: Thirty sites in 30 patients were randomly assigned to tSFE in association with either deproteinized bovine bone mineral (DBBM) (n = 15) or synthetic hydroxyapatite in a collagen matrix (S-HA) (n = 15). In both groups, the extent of the sinus lift (SL) and the height of the graft apical to the implant apex (aGH) were assessed on periapical radiographs taken immediately after surgery and at 6 months following surgery. Surgical and post-surgical complications as well as post-surgical pain/discomfort were also assessed.

Results: The results of the study indicated that (i) immediately post-surgery, both DBBM and S-HA resulted in substantial SL and aGH, which were maintained at 6 months, (ii) greater aGH and SL were observed in S-HA group compared with DBBM group at 6 months post-surgery and (iii) limited surgical complications and post-operative pain/discomfort were associated with the use of both graft biomaterials.

Conclusions: The Smart Lift technique in conjunction with the additional use of either S-HA or DBBM may provide a predictable elevation of the maxillary sinus floor along with limited post-surgical complications and post-operative pain/discomfort. SL and aGH were significantly greater at 6 months for S-HA than DBBM.

In the posterior maxillary sextants, the dimensional alterations of the residual ridge as well as the pneumatization of the maxillary sinus occurring after tooth loss may lead to vertical and transversal bone deficiencies, significantly limiting the insertion of implants of desired length and diameter [Eufinger et al. 1997, 1999; Farina et al. 2011; Pramstraller et al. 2011]. Maxillary sinus floor elevation with a transcrestal approach (tSFE) represents a surgical procedure to vertically enhance the available bone in the edentulous posterior maxilla through an access created through the edentulous bone crest. Surgical techniques for tSFE are mainly based on the fracture or perforation of the sinus floor by means of osteotomes [Coatoam 1997; Bruschi et al. 1998; Deporter et al. 2000] or burs [Tatum 1986; Cosci &uccioli 2000; Fugazzotto 2002; Le Gall 2004; Soltan & Smailer 2004; Chen & Cha 2005; Vitkov et al. 2005].

The apical displacement of the sinus floor obtained by tSFE may be enhanced and better maintained by condensing a graft material under the elevated sinus membrane. Pjetursson et al. (2009a) compared the outcomes of tSFE when performed by means of osteotomes with and without the additional use of deproteinized bovine bone mineral [DBBM]. At 1 year post-surgery, the probability to observe a radio-opaque structure apical to the implants was higher at grafted compared with non-grafted sites. After an average follow-up time of 3.2 years, a significantly greater gain in radiographic bone height was observed in grafted (4.1 mm) compared with non-grafted (1.7 mm) sites, with a two-fold higher probability to observe a substantial (≥ 2 mm) gain in height over the implant.
apex when a graft material was used (Pjetursson et al. 2009a).

Recently, we proposed a minimally invasive procedure for tSFE, 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, 2010b). The procedure represents a modification of the technique proposed by Fugazzotto (Fugazzotto 2002). However, the major novelty resides in the fact that all manual and rotating instruments are used with adjustable stop devices that restrict the working action of burs and osteotomes to the vertical amount of residual bone, thereby preventing the accidental penetration of instruments into the sinus cavity. Previous studies showed that the Smart Lift technique results in a predictable apical displacement of the sinus floor and a limited post-operative morbidity (Trombelli et al. 2010b).

With the Smart Lift technique, the vertical augmentation of the implant site is provided by the condensed trephined bone core that is displaced into the sinus. This intrusion osteotomy procedure elevates the sinus membrane, thus creating a space for blood clot formation. It is conceivable that the contribution of the bone core to the intra-sinusal bone formation may relate to the amount of residual bone at the implant site (i.e. the more the native bone pushed into the sinus, the more the newly formed bone). When a limited amount of residual bone is present with respect to the amount of bone needed for proper implant placement, bone formation may be implemented by the additional use of a graft.

Scientific evidence clearly indicates that DBBM in its granular form may effectively sustain bone regeneration when used in conjunction with sinus floor elevation procedures (Valentini et al. 2000; Valentini & Abensur 2003; John & Wenz 2004; Wallace et al. 2005; Maiorana et al. 2005; Mangano et al. 2007; Simunek et al. 2008; Felice et al. 2009, Ferreira et al. 2009; Esposito et al. 2010). Previous systematic reviews indicated that implants placed at sites augmented with DBBM in association with sinus floor elevation show a survival rate comparable or even higher than implants placed at sites augmented with other grafting materials (Wallace & From 2003; Aghaloo & Moy 2007). More specifically, when DBBM was used in association with tSFE procedures, substantial amounts of vertical bone gain (Pjetursson et al. 2009a, 2009b, Trombelli et al. 2010b) and implant survival rate (Pjetursson et al. 2009b) were reported. Similarly, a synthetic hydroxyapatite in a collagen matrix (S-HA) was successfully used in association with sinus floor elevation with either a transcrestal (Trombelli et al. 2008, 2010a, 2010b) or lateral approach (Gralini et al. 2010, Maiorana et al. 2005). A previous clinical trial comparing DBBM and S-HA in the elevation of the sinus floor with a lateral approach reported similar favourable long-term results for both graft biomaterials (Maiorana et al. 2005). To the best of our knowledge, this is the first RCT comparing the use of DBBM and S-HA in tSFE procedures.

At present, whether and to what extent the Smart Lift technique may benefit by the additional use of different graft biomaterials, and which biomaterial is the most suitable to provide conditions for new bone formation still needs to be elucidated. Therefore, the present study was performed to comparatively evaluate the effectiveness and post-operative morbidity of the Smart Lift technique when used in association with either granules of deproteinized bovine bone mineral [DBBM] or a synthetic hydroxyapatite in a collagen matrix [S-HA].

Materials and methods

Experimental design

The study was designed as a double-blind randomized clinical trial. 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.

Study population

Patients were selected and treated at the Research Centre for the Study of Periodontal and Peri-Implant 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. 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: (i) age ≥ 18 years, (ii) systemic and local conditions compatible with implant placement and sinus floor elevation procedures; (iii) indications for a single-implant placement associated with tSFE, and (iv) patient willing and fully capable to comply with the study protocol. Both smokers and non-smokers were included. The following criteria were applied to verify the site eligibility for the study: (i) at least 6 months elapsed from tooth loss; (ii) residual bone height, as the distance between the bone crest and the sinus floor ≥ 4 mm (measured on periapical radiograph or CT scan), and (iii) absence of endodontic lesions at teeth adjacent to the implant site.

Allocation and allocation concealment

All eligible patients were randomly assigned to receive either DBBM or S-HA. Assignment was performed by a central study registrar according to a computer-generated randomization list. To conceal assignment from the clinical operator until the time requiring application of DBBM or S-HA during the surgical procedure, sealed, numbered envelopes containing the treatment assignment to the specific subjects were supplied to both centres. The examiner and the patient were kept blinded as to treatment allocation.

Surgical procedure

The residual bone height at the sites where implants had to be inserted was first measured on periapical radiograph or CT scan (Fig. 2a). This measure was regarded as the radiographic working length (rWL).

Two grams of amoxicillin (Zimox 1 g; Pfizer Italia S.R.L., Borgo San Michele, Italy) were administered to each patient, 1 h prior to the initiation of the surgical procedure. The preparation of the implant site was performed according to the standardized sequence of instruments of the Smart Lift procedure (Trombelli et al. 2010a, b, 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 used to define the 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, thus providing the “surgical working length” [sWL] i.e.: the anatomical distance between the bone crest and the sinus floor in the exact location where the implant had to be placed (Fig. 2b). The working action of all manual and rotating instruments included in the succeeding surgical steps was set at the sWL using the proper adjustable stop device. 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 (Fig. 2c). The bone core [Fig. 2d] was condensed and maled to fracture the sinus floor by means of a

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According to the randomization sequence, DBBM (Bio-Oss® spongiosa granules 0.25–1.0 mm, 250 mg package; Geistlich Pharma, AG, Wolhusen, Switzerland) or S-HA (Bios-tite®, 250 mg package; GABA Vebas, S. Giulian Milanese, Milan, Italy) were grafted into the sinus with the Smart Lift Elevator by gradual increments [Fig. 2e]. An attempt to standardize the quantity of graft material placed into the sinus was made using about one half of the package content [i.e. about 125 mg]. In all cases, a cylindrical implant was inserted along with a healing abutment [Fig. 2f, g], and flaps were closed by means of 6-0 sutures.

Patients were prescribed a rescue non-steroidal anti-inflammatory agent (Nimesulide 100 mg tablets) as needed and 0.12% chlorhexidine mouth rinse, 10 mL t.i.d. for 3 weeks. The choice of a post-surgery antibiotic treatment was left to the discretion of the operator. Sutures were removed 7 days after surgery. Patients exited the study at the 6-month visit [Fig. 2h, i].

Experimental parameters

Surgical and post-surgical complications

The incidence of membrane perforation was evaluated by the Valsalva manoeuvre immediately after the fracture of the sinus floor by means of the Smart Lift Elevator and immediately after the completion of the placement of the graft biomaterial. Other surgical or post-surgical complications associated with the sinus lift procedure, including Benign Paroxysmal Positional Vertigo (BPPV), post-operative infection, post-operative haemorrhage, nasal bleeding, blocked nose, haematomas, either assessed by the operator or reported by the patient, were also recorded.

Post-surgical pain and discomfort

The following patient-related outcomes were also recorded:

- Level of pain perceived by the patient [VAS<sub>pain</sub>]: recorded immediately after surgery and at 7 days post-surgery on a 100-mm VAS [ranging from “no pain” to “intolerable pain”];
- Level of discomfort perceived by the patient [VAS<sub>discomfort</sub>]: recorded immediately after surgery on a 100-mm VAS [ranging from “no discomfort” to “maximum discomfort”];
- Dosage of rescue anti-inflammatory drug [i.e. number of Nimesulide 100 mg tablets] assumed by the patient during the 7 days following surgery.

Duration of the tSFE procedure

The duration of the tSFE procedure was recorded as the time [in minutes] elapsed

Fig. 1. Smart lift procedure: sequence of rotating and manual instruments. [a] The Locator Drill is used to perforate the cortical bone at the site where the implant has to be placed. [b] The Probe Drill is used to define the orientation of the implant, with an adjustable stop device set at least 1 mm shorter than the radiographic working length. [c] The Probe Osteotome is gently forced in an apical direction until the cortical bone resistance of the sinus floor is met, thus providing the “surgical working length” (sWL). The working action of all instruments included in the succeeding surgical steps is set at the sWL using the proper adjustable stop device. [d] A radiographic pin may be used to check the orientation of the prepared site by means of a periapical radiograph. [e] The “Guide Drill” is used to create a crestal countersink. [f] The Smart Lift Drill produces a bone core up to the sinus floor. [g, h] The bone core is condensed and malleted to fracture the sinus floor by means of the Smart Lift Elevator. A graft biomaterial may be placed into the sinus cavity by gradual increments with the Smart Lift Elevator.

Fig. 2. Clinical application of the Smart Lift technique in association with graft biomaterials. [a] Pre-operative peri-apical radiograph of an edentulous, maxillary second premolar site. [b] The surgical working length, as assessed by the Probe Osteotome, amounts to 7 mm. [c] The Smart Lift Drill is inserted with the stop device adjusted at 7 mm. [d] Bone core created by the Smart Lift Drill. [e] After the bone core has been condensed by malleting, a hydroxyapatite-based biomaterial is grafted into the sinus by gradual increments. [f] An implant [diameter: 4 mm, length: 11 mm] is placed following sinus augmentation. [g] Periapical radiograph as taken immediately after surgery. [h] Prosthetic rehabilitation at 6 months post-surgery. [i] 6-month radiograph.
from cortical perforation with the Locator Drill to the completion of the grafting procedure [i.e. immediately before implant placement].

Radiographic measurements
Radiographic measurements are illustrated in Fig. 3. All measurements were performed on the periapical radiographs taken immediately after surgery 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, and then scanned and digitized. Using an image-processing software, digitized images were stored with a resolution of 600 dpi and the following radiographic measurements were performed using a digital calliper:

- Radiographic implant length (rIL): distance (in mm) between the implant shoulder and the implant apex as assessed at the mid portion of the implant;
- Residual bone height at the mesial (mRBH) and distal (dRBH) aspects of the implant: distance (in mm) between the mesial and distal aspect of the implant shoulder, respectively, and the sinus floor;
- Height of the graft apically (aGH): distance (in mm) occupied by a radiopaque area between the implant apex and the sinus floor as assessed at the mid portion of the implant.

To account for radiographic distortion, radiographic measurements (i.e. mRBH, dRBH and aGH) on each radiograph were adjusted for a coefficient derived from the ratio: true length of the implant/rIL.

For each patient, the following derived radiographic parameters were obtained:

- Residual bone height (RBH): calculated as the mean value of mRBH and dRBH;
- Implant penetration (IP): calculated as the difference between rIL and RBH;
- Extent of the sinus lift (SL): calculated as the sum of IP and aGH.

A qualitative assessment of the maturation of the grafted area was also performed using the sinus grafting remodelling index (SGRI) (Bra¨gger et al. 2004): score 0 – no bone/grafting material visible; score 1 – cloudy structures with hazy demarcation, original sinus floor lamina dura still recognizable; score 2 – clearly visible dense structures apical to the implant and beginning resorption of original lamina dura; and score 3 – dense periapical bone graft structures with a new maxillary sinus floor outline with a well-defined new lamina dura and resorbed original lamina dura.

All measurements were performed by a single trained examiner who had previously undergone a calibration session for a GH assessment on a sample of 15 patients not included in the study. Cohen’s k coefficient (Cohen 1960) for intra-examiner agreement was 0.981.

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

Intra-group comparisons were performed using Wilcoxon test. For categorical variables, inter-group comparisons were performed with chi-squared test or Fisher’s exact test. For continuous variables, inter-group comparisons were performed using Mann-Whitney U-test.

SL was regarded as the primary outcome variable. Post hoc power analysis was performed, assuming a standard deviation in SL of 1.0 mm and an expected inter-group difference in SL of 1.0 mm, a sample of 30 patients (15 patients/group) had a power of 75% in detecting a significant inter-group difference at a level of statistical significance of 0.05.

Results

Study population
Thirty patients were included in the study and completed the experimental phase (Table 1). Fifteen implants in 15 patients received DBBM, whereas another 15 implants in 15 patients received S-HA. sWL was 6.0 mm [4.5–7.0 mm] in S-HA group and 6.0 mm [5.0–6.3 mm] in DBBM group, with no significant inter-group differences. Implant characteristics in S-HA and DBBM groups are shown in details in Table 2. No significant differences in implant length and diameter were seen between groups. Three patients in the DBBM group and one patient in the S-HA group received systemic antibiotics [amoxicillin + clavulanic acid, 1 g t.i.d. for 6 days].

At 6 months after surgery, no implant failure was recorded, and the prosthetic rehabilitation was completed in 29 of 30 implants.

Surgical and post-surgical complications
Clinical parameters are shown in Table 3. In S-HA group, one case of membrane perfora-
tion was detected using the Valsalva manoeuvre after the fracture of the sinus floor. The perforation was managed by inserting a surgical haemostatic dressing (Gingistat®, GABA Vehas, S. Giuliano Milanese, Milan, Italy) through the crestal access. At the completion of grafting procedure, the Valsalva manoeuvre was negative.

Post-surgical pain and discomfort
Post-surgery VASdiscomfort was 10.0 (0–21.0) and 0 (0–10.5) in S-HA and DBBM group respectively. Post-surgery VASpain was 2.00 (1.00–18.00) in S-HA group and 6.00 (0–13.00) in DBBM group. VASpain significantly decreased at 7 days in S-HA group (P = 0.012). No significant inter-group differences in VAS scores were observed immediately post-surgery and at 7 days [Table 3]. A limited amount of post-surgery anti-inflammatory tablets was assumed in both groups. However, no significant inter-group differences were observed in VAS scores were observed immediately post-surgery, both DBBM and S-HA group, whereas 1 at seven sites and 2 at eight sites in S-HA group. No significant differences in SGRI were observed between groups.

Table 2. Implant characteristics

<table>
<thead>
<tr>
<th>Implant type</th>
<th>Number of implants</th>
<th>Implant length (mm)</th>
<th>Implant diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-HA group (n = 15 patients)</td>
<td></td>
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<tr>
<td>Osseotite® Certain® (Biomet 3I)</td>
<td>3</td>
<td>10.0</td>
<td>5.0</td>
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<td></td>
<td></td>
<td>11.5</td>
<td>4.0</td>
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<td></td>
<td></td>
<td>8.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Osseotite® Certain® Prevail® (Biomet 3I)</td>
<td>1</td>
<td>10.0</td>
<td>5.0</td>
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<tr>
<td>Osseospeed™ (Astra Tech Dental)</td>
<td>3</td>
<td>9.0</td>
<td>4.0</td>
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<td></td>
<td></td>
<td>9.0</td>
<td>4.0</td>
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<tr>
<td></td>
<td></td>
<td>11.0</td>
<td>4.0</td>
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<tr>
<td>Implus® TTS (Leader Italia)</td>
<td>1</td>
<td>8.0</td>
<td>3.75</td>
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<tr>
<td>SPI® Element (Thommen Medical)</td>
<td>5</td>
<td>11.0</td>
<td>4.5</td>
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<td></td>
<td></td>
<td>10.00 (8.75–10.50)</td>
<td>4.00 (4.00–4.65)</td>
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<tr>
<td>Standard plus-tissue level (Straumann®)</td>
<td>1</td>
<td>10.0</td>
<td>4.8</td>
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<tr>
<td>Bone level (Straumann®)</td>
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<td>Median (interquartile range)</td>
<td>10.00 (8.75–10.50)</td>
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<tr>
<td>DBBM group (n = 15 patients)</td>
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<tr>
<td>Osseotite® Certain® (Biomet 3I)</td>
<td>5</td>
<td>10.0</td>
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<td></td>
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<td>10.0</td>
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<td></td>
<td></td>
<td>10.0</td>
<td>5.0</td>
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<td></td>
<td></td>
<td>10.00 (8.75–10.50)</td>
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<td>8.5</td>
<td>4.0</td>
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<tr>
<td>SPI® element (Thommen Medical)</td>
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<td>10.0</td>
<td>4.0</td>
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<td></td>
<td></td>
<td>9.5</td>
<td>4.0</td>
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<td>9.5</td>
<td>3.5</td>
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<tr>
<td>Standard plus-tissue level (Straumann®)</td>
<td>4</td>
<td>10.0</td>
<td>4.8</td>
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<td></td>
<td></td>
<td>10.0</td>
<td>4.8</td>
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<td>8.0</td>
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<td></td>
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<td>8.0</td>
<td>4.1</td>
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<tr>
<td></td>
<td>Median (interquartile range)</td>
<td>9.50 (9.50–10.00)</td>
<td>4.00 (4.00–4.10)</td>
</tr>
</tbody>
</table>

Radiographic measurements
Radiographic measurements are reported in Table 4. No statistically significant difference in RBH and IP were observed between groups.

Immediately after surgery, all sites showed an aGH ≥ 1 mm. SL and aGH amounted to 7.70 (6.70–8.55) and 3.00 (2.80–3.75) mm, respectively, in S-HA group, and 6.50 (5.95–7.40) and 2.60 (2.30–3.45) mm, respectively, in DBBM group. No significant inter-group differences in SL and aGH were found.

At 6 months, no significant variations in SL and aGH with respect to post-surgery values were observed in both groups. However, S-HA group exhibited a significantly greater SL and aGH than DBBM group (Table 4).

SGRI was 1 [1–2] in both groups. The score was 1 at six sites and 2 at nine sites in DBBM group, whereas 1 at seven sites and 2 at eight sites in S-HA group. No significant differences in SGRI were observed between groups.

Discussion
The present study was performed to comparatively evaluate the effectiveness and post-operative morbidity of tSFE performed with a minimally invasive procedure (Trombelli et al. 2010a, 2010b) combined with the additional use of DBBM or S-HA. Fifteen sites in 15 patients were grafted with DBBM, and 15 sites in 15 patients were grafted with S-HA. The results of the study indicated that: (i) immediately post-surgery, both DBBM and S-HA resulted in substantial SL and aGH, which were maintained at 6 months, [ii] greater aGH and SL were observed in S-HA group compared with DBBM group at 6 months post-surgery and [iii] limited surgical complications and post-operative pain/discomfort were associated with the use of both graft biomaterials.

In our study, sinus floor elevation [i.e. SL and aGH] may be regarded as the combined effect of the trephined bone core with the additional graft biomaterial displaced into the sinus cavity by the controlled action of osteotomes. SL amounted to 7.70 and 6.50 mm for S-HA and DBBM group as assessed immediately after surgery, and did not show significant variations at 6 months in both groups. The amount of bone gain was consistent with that reported in two studies, where tSFE was achieved by means of osteotomes and burs plus autogenous bone and graft biomaterial [6.75 mm] (Calvo-Guirado et al. 2006) or osteotomes plus DBBM [6.9 mm] (Kang 2008). However, the great majority of studies where
tSFE was performed by the use of osteotomes [Nkenke et al. 2002; Artzi et al. 2003; Sotirakis & Gonsor 2005] or combinations of osteotomes and burs [Horowitz 1997, Zitzmann & Schärer 1998, Toффler 2004; Leblebicioglu et al. 2005; Li 2005; Barone et al. 2008; Fermerga˚rd & Astrand 2008; Schmidlin et al. 2008; Nedir et al. 2009], either with (Horowitz 1997, Zitzmann & Gonshor 2005) or combinations of os-
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Table 3. Clinical parameters

<table>
<thead>
<tr>
<th></th>
<th>S-HA group (n = 15 patients)</th>
<th>DBBM group (n = 15 patients)</th>
<th>P-value</th>
</tr>
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<tr>
<td>Surgical and post-surgical complications Membrane perforation (Valsalva manoeuvre +) after fracture of the sinus floor</td>
<td>1</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Membrane perforation (Valsalva manoeuvre +) after grafting the biomaterial</td>
<td>0</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Other complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 patient referred “to feel trauma to the ear”</td>
<td>1 patient referred “to feel the teeth longer than before surgery”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 patient referred “to feel suture tension”</td>
<td>1 patient referred “to feel sub-orbital area numb”</td>
<td></td>
</tr>
<tr>
<td>Post-surgical pain and discomfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VASpain immediately post-surgery (expressed in mm as median and interquartile range)</td>
<td>2.00 (1.00–18.00)</td>
<td>6.00 (0.00–13.00)</td>
<td>0.902</td>
</tr>
<tr>
<td>VASdiscomfort immediately post-surgery (expressed in mm as median and interquartile range)</td>
<td>10.00 (2.00–31.00)</td>
<td>0.00 (0.00–10.50)</td>
<td>0.116</td>
</tr>
<tr>
<td>VASpain at 7 days post-surgery (expressed in mm as median and interquartile range)</td>
<td>0.00* (0.00–1.00)</td>
<td>0.00 (0.00–5.50)</td>
<td>0.540</td>
</tr>
<tr>
<td>Number of Nimesulide 100 mg tablets assumed by the patient during the first week (expressed as median and interquartile range)</td>
<td>1.00 (0.50–1.50)</td>
<td>1.00 (1.00–1.50)</td>
<td>0.683</td>
</tr>
</tbody>
</table>

*Statistically significant difference compared with post-operative VASpain (P = 0.012).

Table 4. Radiographic measurements. All values are expressed as median (interquartile range)

<table>
<thead>
<tr>
<th></th>
<th>RBH (mm)</th>
<th>IP (mm)</th>
<th>SL (mm)</th>
<th>aGH (mm)</th>
<th>SL (mm)</th>
<th>aGH (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-HA group (n = 15 patients)</td>
<td>5.25 (4.60–6.40)</td>
<td>4.70 (3.70–5.05)</td>
<td>7.70 (6.80–8.55)</td>
<td>3.00 (2.80–3.75)</td>
<td>7.50 (7.20–8.50)</td>
<td>3.35 (2.73–3.80)</td>
</tr>
<tr>
<td>DBBM group (n = 15 patients)</td>
<td>5.70 (4.33–6.35)</td>
<td>3.80 (3.30–4.45)</td>
<td>6.50 (5.95–7.40)</td>
<td>2.60 (2.30–3.45)</td>
<td>6.60 (5.70–7.05)</td>
<td>2.60 (2.10–2.90)</td>
</tr>
<tr>
<td>P-value</td>
<td>0.774</td>
<td>0.187</td>
<td>0.050</td>
<td>0.116</td>
<td>0.003</td>
<td>0.019</td>
</tr>
</tbody>
</table>
In our material, the maturation of the grafted area, as assessed by the SGR1 on peri-apical radiographs, appeared similarly incomplete after 6 months in both groups. In particular, all sites showed the presence of a radiopaque structure with or without the persistence of the lamina dura of the original sinus floor, but in none of the cases, a new maxillary sinus floor outline was observed. Our data are consistent with those by Petursson et al. (2009b), showing that the great majority of sites undergone tSFE with osteotomes, and DBBM showed a SGR1 comprised between 1 and 2 at 1 year post-surgery.

Our study showed that surgical complications and post-operative pain/discomfort were limited for both groups. Only one [S-HA] case of membrane perforation was detected by the Valsalva manoeuvre after the fracture of the sinus floor which was successfully managed with a surgical haemostatic dressing. According to the Smart Lift surgical sequence, an osteotome with a proper stop device is used to implose the trephined autogenous bone core, in such a way that the bone core determines the fracture of the sinus floor contributing to the vertical augmentation of the implant site. During the grafting procedure, only the graft biomaterial exerted the hydraulic pressure to tent the sinus membrane, whereas any direct penetration of the osteotome into the sinus cavity is prevented by the stop device. HA particles, which represent the dominant component of both graft biomaterials, have a porous interconnectivity which responds to mechanical compression with an increase in density of the biomaterial structure (Hing et al. 1999). This characteristic may have assisted the gentle apical displacement of the graft biomaterial without exceeding the critical perfusion force of the sinus membrane (Pommert et al. 2009).

The limited invasiveness of the investigated technique is reflected by low VAS scores for pain/discomfort as well as the limited assumption of rescue analgesics during the first week following surgery. It must be kept into consideration that only single-implant sites were included in the present study. It is presently unknown therefore whether the patient acceptance would remain similar if multiple adjacent sites were approached with the same procedure.

Although all implants positioned were cylindrical in shape, different implant types with variable morphology and surface characteristics were used in both treatment groups. In this respect, no evidence is at present available on the impact of implant features on the extent of sinus lift. Due to the small sample size, however, such impact could not be determined.

In conclusion, the results indicated that the application of the Smart Lift technique in conjunction with the additional use of either S-HA or DBBM may provide a predictable elevation of the maxillary sinus floor along with limited post-surgical complications and post-operative pain/discomfort. Sites grafted with S-HA sites showed greater extent of sinus lift and height of the graft apical to the implant apex at 6 months after surgery.

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