Minimally invasive transcrestal sinus floor elevation with deproteinized bovine bone or β-tricalcium phosphate: a multicenter, double-blind, randomized, controlled clinical trial


Abstract

Aims: To evaluate the outcomes of transcrestal sinus floor elevation (tSFE) performed with a minimally invasive procedure (Smart Lift technique) combined with the additional use of deproteinized bovine bone mineral (DBBM) or β-tricalcium phosphate (β-TCP).

Methods: In a multicenter randomized controlled trial, 38 sites in 38 patients were treated with the Smart Lift technique in association with DBBM (n = 19) or β-TCP (n = 19). 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.

Results: (i) Substantial aGH and SL were observed immediately after surgery and at 6 months, with no significant differences between DBBM and β-TCP groups; (ii) a significant graft remodelling was observed from post-surgery to 6-months in the β-TCP group and (iii) limited incidence of complications as well as limited post-operative pain and discomfort were associated with the use of both graft materials.

Conclusions: The Smart Lift technique in conjunction with the additional use of either DBBM or β-TCP may provide a substantial elevation of the maxillary sinus floor along with limited post-surgical complications and post-operative pain/discomfort.

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Key words: beta tricalcium phosphate; bone regeneration; dental implants; heterologous; maxillary sinus; minimally invasive; outcome assessment; surgical procedures; transplantation

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Conflict of interest and source of funding statement

The authors declare that they have no conflict of interest.

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When the dimensional alterations of the residual ridge occurring after the loss of posterior maxillary teeth limit the insertion of implants of desired length and diameter (Eufinger et al. 1997, 1999, Farina et al. 2011, Pra- 
mstraller et al. 2011), maxillary sinus floor elevation with a transcrestal approach (tSFE) represents a vali-
dated, effective option to vertically enhance the available bone through an access created in the edentulous 
bone crest (Tan et al. 2008, Del Fabbro et al. 2012). Recently, we proposed a minimally invasive pro-
cedure 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, 2010a,b) and allows for 
a predictable, apical displacement of the sinus floor (Trombelli et al. 2010b, 2012, Franceschetti et al. 2012, 
Krennmair et al. 2007, Pjetursson et al. 2009a,b, Jensen & Terheyden 2009, Del Fabbro et al. 2012). However, the only controlled clinical trial evaluating the performance of tSFE with and without graft material indicated that the apical displacement of the sinus floor obtained by tSFE may be enhanced and better maintained by placing a deproteinized bovine bone mineral (DBBM) graft under the ele-
vated sinus membrane (Pjetursson et al. 2009a). To date, DBBM is one of the most investigated graft materi-
als when used for sinus lift, in general, and tSFE, in particular (Jensen & Terheyden 2009, Del Fabbro et al. 2012). Previous studies showed its slow resorption/degradation rate follow-
ing sinus lift (Lee et al. 2006, Traini et al. 2007, Mordenfeld et al. 2010, Pettinicchio et al. 2012), and indicated that it is associated with considerable sinus floor elevation when used in combination with tSFE (Zitzmann & Schärer 1998, De-

β-tricalcium phosphate (β-TCP) graft materials may be gradually resorbed and replaced by newly 
formed bone at short time intervals (i.e. 6 months following grafting) (Ozyuvaci et al. 2003, Zerbo et al. 2004, Schulze-Späte et al. 2012). When used in conjunction with sinus floor elevation procedure with either transcrestal (Nkenke et al. 2002) or lateral approach (Meyer et al. 2009, Uckan et al. 2010), β-TCP grafts seem to effectively sustain bone regeneration resulting in a high long-
term implant survival rate. To date, no studies comparing DBBM and β-TCP when used with tSFE are 
 presently available.

Therefore, the present randomized controlled trial was conducted to compare the clinical outcomes and post-operative morbidity of the Smart Lift technique when used in association with DBBM or β-TCP.

Materials and Methods
Experimental design
The study was designed as a multicenter, double-blind, randomized, controlled clinical trial. All the clinical 
procedures were performed in full accordance with the Declaration of Helsinki as revised in Tokyo (2004) and the Good Clinical Prac-
tice Guidelines (GCPs). Each patient provided a written informed consent before participation. This manuscript 
was prepared in full accordance with CONSORT guidelines for reporting randomized controlled studies (http:// 
www.consort-statement.org/).

Patients were consecutively recruited and treated at 1 University centre and four private dental offices 
from July 2010 to October 2012. Surgical procedures were performed by five experienced clinical operators 
(L.T., C.S., L.M., O.R. and R.D.R.) with previous training in tSFE pro-
cedures. More specifically, all opera-
tors had been previously involved in research protocols on the Smart Lift technique (Franceschetti et al. 2012, 
2013).

Study population
Inclusion criteria for patient eligibility were as follows: (i) age ≥18 years; (ii) systemic and local conditions 
suitable for implant placement and sinus floor elevation procedures; (iii) indication for the placement of at least one implant with a length of 8 mm or more simultaneously with 
tSFE and (iv) patient willing and fully capable to comply with the study protocol.

Allocation and allocation concealment
All eligible patients were randomly assigned to receive DBBM (Bio-Oss® spongiosa granules 0.25–1.0 mm; 
Geistlich Pharma, AG, Wolhusen, Switzerland) or β-TCP (Ceros® β-TCP granules 0.5–0.7 mm; Thom-
men Medical, Waldenburg, Switzerland). Assignment was performed by a central study registrar according to 
a computer-generated randomization list. Block randomization was applied to obtain an equal number of 
sites with 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 as assessed with the Probe Osteo-
tome) ≤5 and ≥6 mm within each treatment group. To conceal assignment from the clin-
ical operator until the time requiring application of DBBM or β-TCP during the surgical procedure, sealed, numbered envelopes containing the treatment assignment to the specific subjects were supplied to each cen-
tre. The examiner and the patient were kept blinded as to treatment allocation.

Surgical procedure
Before sinus lift procedure, all oral diseases, including periodontal dis-
case, were thoroughly treated. The 
RBH at the site where the implant 
was supposed to be inserted was measured on a periapical radiograph 
or a CT scan prior to surgery.

The preparation of the implant 
site was performed according to a 
standardized sequence of instru-
ments which had been extensively described in previous studies (Trom-
belli et al. 2010a,b, 2012, Francesch-
As 1 g of graft material granules corresponds to a volume of the portion of a 4-mm-diameter implant protruding into the sinus for 4 mm (i.e. about 0.4 cm³). Smaller or larger amount of graft material was then used according to lower or higher, respectively, IP into the sinus.

Immediately after the completion of the sinus lift procedure, all patients received Element® RC Inicell implants (Thommen Medical AG, Waldenburg, Switzerland). The implant was inserted with either submerged or transmucosal healing protocol.

All patients were prescribed a single dose of rescue anti-inflammatory drug (i.e. ibuprofen 600 mg tablets) on the first post-operative day (evening) and were instructed to assume it pro re nata for the following six post-operative days. A 0.12% chlorhexidine mouthrinse, to be used 10 ml three times in a day for 3 weeks, was also prescribed. Sutures were removed 7 days after surgery.

**Experimental parameters**

**Surgical and post-surgical complications**

The incidence of membrane perforation was evaluated by the Valsalva manoeuvre. 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.

**Patient-centred outcomes**

The following patient-related outcomes were also recorded:

- level of discomfort perceived by the patient (VRSdiscomfort): recorded immediately after surgery on a 5-point visual rating scale (VRS) ranging from “0 – no discomfort” to “4 – very severe discomfort”;
- willingness to undergo the same type of surgery (VRSwillingness): recorded immediately after surgery on a 4-point visual rating scale (VRS) ranging from “0 – I will never undergo this type of surgery again” to “3 – no problem to repeat surgery if needed”;
- level of pain perceived by the patient (VASpain): recorded daily (evening) for 7 days following surgery on a 100-mm visual analogue scale (VAS) (ranging from “no pain” to “intolerable pain”);
- dosage of rescue anti-inflammatory drug (i.e. number of ibuprofen 600 mg tablets) assumed by the patient from the 2nd to the 7th post-operative day.

**Duration of the tSFE procedure**

The duration of the tSFE procedure was recorded as the time (in minutes) elapsed from cortical perforation with the Locator Drill (Fig. 1a) to the completion of the grafting procedure (i.e. immediately before implant placement) (Fig. 1h).

**Radiographic measurements**

Radiographs were obtained immediately after surgery and at 6 months with a paralleling technique using a Rinn film holder with a rigid film-object X-ray source, then scanned and digitized. Using an image-processing software, digitized images were stored at a resolution of 600 dpi. On radiographs taken immediately after surgery, 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;
• RBH 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 radio-opaque 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. aGH was re-assessed at 6 months after adjustment for 6-month rIL.

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

• RBH: calculated as the mean value of mRBH and dRBH;
• IP: calculated as the difference between rIL and RBH;
• extent of the sinus lift (SL): calculated as the sum of IP and aGH.

On 6-month radiographs, a qualitative assessment of the maturation of the grafted area was performed using the sinus grafting remodelling index (SGRI) (Bragger et al. 2004).

All measurements were performed by a single trained examiner (G.F.) who had previously undergone a calibration session for aGH assessment on a sample of 15 patients not included in the study (Cohen’s k-coefficient for intra-examiner agreement: 0.981) and had participated as clinical examiner in previous clinical trials using the same radiographic measurements (Trombelli et al. 2012, Franceschetti et al. 2013, G. Franceschetti, R. Farina, L. Minenna, G. Franceschetti & L. Trombelli, unpublished data).

Statistical analysis
The statistical analysis was conducted in the null hypothesis that there was no statistically significant and clinically meaningful difference between the two investigated treatments (Smart Lift with DBBM versus Smart Lift with β-TCP). Data were entered in a unique database file (STATISTICA® software version 7.1; StatSoft, Italia s.r.l., Vigonza, Italy) and expressed as median and inter-quartile range (IR). The patient was regarded as the statistical unit. Therefore, one implant was randomly chosen when two or more implants (either adjacent or not) were placed concomitantly with the tSFE procedure in the same patient. 6-month aGH and 6-month SL were regarded as the primary and secondary outcome variable respectively.

The Kolmogorov–Smirnov test was used to assess the normal distribution fitting of each variable. Within-group comparisons (pre-surgery versus 6 months) were performed with Wilcoxon test and Kruskal–Wallis ANOVA. Inter-group comparisons were performed with Fisher’s exact test, χ² test and Mann–Whitney U-test.

A multivariate model was built with 6-month aGH and 6-month SL as outcome variables and gender, type of graft and clinical operator as predictors. A Wald test was adopted to test significance of each factor, whereas the significance of the model was tested by comparing the reduction in the -2log likelihood of the model with a χ² distribution. A specific software was used (MIWin 2.27, Centre for multilevel modelling, University of Bristol, UK).

The level of statistical significance was fixed at 0.05. A web-based software (http://www.dssresearch.com/KnowledgeCenter/toolkit_calculators/statisticalpowercalculators.aspx) was used for the calculation of the statistical power of the study. According to a sample size calculation performed with a two-sided parametric test (Lehmann 2007), a per-protocol study population of 32 patients (i.e. 16 patients per treatment group) was needed to detect a significant inter-group difference (at p = 0.05) with a statistical power of 80%, assuming a standard deviation in aGH of 1.0 mm and an expected inter-group difference in aGH of 1.0 mm on the basis of data previous trials evaluating aGH following Smart Lift procedures in association with different graft materials (Trombelli et al. 2012).

Results
Study population
All 38 patients included in the study completed the experimental phase. Nineteen patients received DBBM, whereas the remaining 19 patients received β-TCP (Table 1). sWL was 6.0 (5.0–7.0) mm in DBBM group and 6.0 (5.0–7.5) mm in β-TCP group. No significant differences in sWL, implant site location, implant length and diameter were seen between groups (Table 1).

At 6 months after surgery, no implant failure was recorded, and the prosthetic rehabilitation was finalized at all implant sites.

Duration of the tSFE procedure
The duration of the tSFE procedure was 20.0 (15.5–28.0) min. and 20.5 (15.0–33.0) min. in DBBM and β-TCP group, respectively, with no significant inter-group differences.

Surgical and post-surgical complications
Membrane perforation was detected at Valsalva manoeuvre in four cases in β-TCP group and one case in DBBM group. No statistically significant difference in the incidence of membrane perforation was observed between treatment groups. Membrane perforation was treated with the insertion of a surgical haemostatic dressing (Gingistat®; GABA Vebas, S. Giuliano Milanese, Milan, Italy) through the crestal access, and systemic antibiotics (amoxicillin + clavulanic acid, 1 g t.i.d. for 6 days) was administered post-operatively. In all cases, the grafting procedure was completed, the implant was inserted and the case included for analysis.

Over the course of the first post-operative week, one patient in the β-TCP group presented with BPPV which was homolateral and spontaneously subsided within the first week following surgery.

Patient-centred outcomes
Patient-centred outcomes are reported in Table 2 and Fig. 2. VRSdiscomfort was similarly low in both groups (Table 2). VRSdiscomfort was 0 in 11 patients in the DBBM group, and 10 patients in the β-TCP group.
Table 1. Characterization of patients and implants in the DBBM and the \( \beta \)-TCP groups

<table>
<thead>
<tr>
<th></th>
<th>DBBM group ((n = 19))</th>
<th>( \beta )-TCP group ((n = 19))</th>
<th>( p ) (Mann–Whitney)</th>
<th>( p ) ((\chi^2) or Fisher’s exact test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td></td>
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</tr>
<tr>
<td>Age (years)</td>
<td>55.0 (44.5–59.5)</td>
<td>54.5 (45.0–57.0)</td>
<td>0.893</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>5/14</td>
<td>10/9</td>
<td>0.488</td>
<td></td>
</tr>
<tr>
<td>Smoking status</td>
<td>7/2/10</td>
<td>10/4/10</td>
<td>0.559</td>
<td></td>
</tr>
<tr>
<td>Daily cigarette consumption (cigarettes/day) (median and IR)</td>
<td>10.0 (10.0–15.0)</td>
<td>10.0 (10.0–20.0)</td>
<td>0.876</td>
<td></td>
</tr>
<tr>
<td>Smoking exposure (pack ( \times ) years) (median and IR)</td>
<td>13.5 (8.8–15.0)</td>
<td>10.0 (10.0–25.0)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Implant sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site location</td>
<td>1/4/14/0</td>
<td>0/5/14/0</td>
<td>0.857</td>
<td></td>
</tr>
<tr>
<td>sWL (frequency of sites)</td>
<td>3 mm</td>
<td>3 mm</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>5 mm</td>
<td>6 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7 mm</td>
<td>3 mm</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>8 mm</td>
<td>4 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>9 mm</td>
<td>1 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>sWL (mm) (median and IR)</td>
<td>6.0 (5.0–7.0)</td>
<td>6.0 (5.0–7.5)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Implants</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implant length (mm) (median and IR)</td>
<td>9.5 (9.5–11.0)</td>
<td>9.5 (9.5–11.0)</td>
<td>0.624</td>
<td></td>
</tr>
<tr>
<td>Implant diameter (mm) (median and IR)</td>
<td>4.0 (4.0–4.0)</td>
<td>4.0 (4.0–4.5)</td>
<td>0.452</td>
<td></td>
</tr>
</tbody>
</table>

\( \beta \)-TCP, \( \beta \)-tricalcium phosphate; DBBM, deproteinized bovine bone mineral.

\[ VAS_{\text{pain}} \] was similarly low over time, and significantly decreased at 7 days in both DBBM and \( \beta \)-TCP group \((p < 0.001 \text{ for both groups})\) (Fig. 2). A similarly low amount of post-surgery anti-inflammatory tablets was assumed in both groups (Table 2).

Radiographic measurements

Radiographic measurements are reported in Table 3. Post-surgery SL and aGH amounted to 6.1 (5.6–6.9) mm and 1.5 (1.2–2.3) mm, respectively, in the DBBM group, and 6.8 (6.2–7.5) mm and 2.2 (1.6–3.1) mm, respectively, in the \( \beta \)-TCP group. At 6 months, a significant reduction in aGH and SL with respect to post-surgery values was observed in the \( \beta \)-TCP group. No significant inter-group difference in aGH and SL was observed at 6 months.

SGRI was 1 (1–2) in both DBBM group and \( \beta \)-TCP group \((p = 0.488)\). The score was 0 at 1 site, 1 at 11 sites and 2 at 7 sites in the DBBM group, whereas 1 at 10 sites and 2 at 9 sites in the \( \beta \)-TCP group. The pre-surgery, post-surgery and 6-month radiographic aspect of two paradigmatic cases treated with DBBM and \( \beta \)-TCP are illustrated in Fig. 3.

Multivariate analysis

Gender was not a predictor for both outcome variables and thus not included in the final model. The type of graft material was not significant for either 6-month aGH \((p = 0.38)\) or 6-month SL \((p = 0.63)\). A significant effect of the clinical operator on 6-month aGH was observed \((p = 0.03)\), the difference between the operators with the highest and lowest 6-month aGH being 1.35 mm. The clinical operator did not have a significant impact on 6-month SL \((p = 0.08)\). The final model was significant \((p = 0.01, r^2 = 0.55)\).

Discussion

The results of the present randomized controlled trial indicated that both DBBM and \( \beta \)-TCP may be used to contribute sinus floor elevation with a transcrestal approach. The specific \( \beta \)-TCP graft material has been selected due to its positive performance when used in conjunction with sinus lift procedures (Lindemüller & Lambrecht 2006). The additional use of both graft materials led to substantial SL, whereas the use of a standardized transcrestal approach minimized post-operative complications as well as patient pain and discomfort. A significant graft remodelling was observed from immediate post-surgery to 6-months after surgery in the \( \beta \)-TCP group.

In our material, the extent of SL led to a concomitant placement of an implant of the programmed dimensions in cases where the RBH would have otherwise prevented a successful implant-supported rehabilitation. These results compared with data from previous studies where the Smart Lift technique had been used in conjunction with different graft materials in varying clinical settings (Trombelli et al. 2012, Franceschetti et al. 2012, 2013). The consistency in achieving a substantial vertical bone gain for implant placement may be ascribed to the standardized sequence of instruments of the surgical procedure. In accordance with this consideration, our multivariate analysis indicated that the clinical operator had no impact on the variability in 6-month SL. Overall, these results seem to support the predictability of the Smart Lift technique in association with graft materials to obtain a substantial sinus floor elevation.

Interestingly, the results of the multivariate analysis support the hypothesis that aGH contribution to the overall vertical extent of sinus lift (i.e. SL) may vary depending on
potential differences in operator skill and experience (in terms of number of years of clinical activity and number of treated cases prior to the involvement in this trial) in implant surgery, in general, and in the application of the Smart Lift technique, in particular. The clinical performance of many health technologies, especially those based on the intervention of an operator and/or the application of instruments/devices, varies overtime (Russell 1995). This phenomenon, defined as the learning curve, commonly shows improved performance with time, and may be influenced by several factors including the improved familiarity of the operator with the technology (Cuschieri 1995, Bouchar et al. 1996, Mowatt et al. 1998). The learning curve of the Smart Lift technique has been recently evaluated in a specifically dedicated study and the results will be reported elsewhere (G. Franceschetti, R. Farina, L. Minenna, G. Franceschetti & L. Trombelli, unpublished data).

All sites undergoing tSFE received an implant with a microrough, sandblasted and thermal acid-etched surface that was conditioned immediately before implant placement to enhance its surface energy.

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### Table 2. Patient-centred outcomes

<table>
<thead>
<tr>
<th></th>
<th>DBBM group (n = 19)</th>
<th>β-TCP group (n = 19)</th>
<th>p (Mann–Whitney)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-surgery discomfort (VRS\textsubscript{discomfort})</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 – no discomfort</td>
<td>0 (0–1)</td>
<td>0 (0–1)</td>
<td>0.707</td>
</tr>
<tr>
<td>1 – slight discomfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 – mild discomfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 – severe discomfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 – very severe discomfort</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Willingness to undergo the same surgery (VRS\textsubscript{willingness})</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 – “No problem to repeat surgery if needed”</td>
<td>18</td>
<td>15</td>
<td>0.604</td>
</tr>
<tr>
<td>2 – “I will repeat the surgery, but I would prefer to procrastinate it”</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>1 – “I will repeat the surgery, but I expect to suffer severe pain”</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>0 – “I will never undergo this type of surgery again”</td>
<td>0</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Dosage of rescue anti-inflammatory drug (ibuprofen 100 mg tablets)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd post-operative day</td>
<td>0 (0–1)</td>
<td>1 (0–1)</td>
<td>0.303</td>
</tr>
<tr>
<td>3rd post-operative day</td>
<td>0</td>
<td>0 (0–1)</td>
<td>0.363</td>
</tr>
<tr>
<td>4th post-operative day</td>
<td>0 (0–0)</td>
<td>0 (0–0)</td>
<td>0.778</td>
</tr>
<tr>
<td>5th post-operative day</td>
<td>0</td>
<td>0 (0–0)</td>
<td>0.975</td>
</tr>
<tr>
<td>6th post-operative day</td>
<td>0 (0–0)</td>
<td>0 (0–0)</td>
<td>0.975</td>
</tr>
<tr>
<td>7th post-operative day</td>
<td>0</td>
<td>0 (0–0)</td>
<td>0.975</td>
</tr>
</tbody>
</table>

*One patient in β-TCP group did not report data.

β-TCP, β-tricalcium phosphate; DBBM, deproteinized bovine bone mineral.

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Fig. 2. VAS\textsubscript{pain} in deproteinized bovine bone mineral (DBBM) and β-tricalcium phosphate (β-TCP) groups.
wettability and protein adsorption capacity (Tugulu et al. 2010). The potential benefits of this novel implant surface treatment on the early phases of osseointegration and graft maturation in the space underneath the elevated sinus membrane, however, are presently unknown and need to be investigated.

The Smart Lift procedure was associated with a low incidence of complications, post-operative discomfort and pain in both DBBM and \beta-TCP groups, and the study failed to find significant differences between groups. These findings, which were comparable to those in previous studies where different biomaterials were used in combination with the same tSFE procedure (Trombelli et al. 2010b, 2012), indicate that the graft material per se may not have a relevant influence on patient-related outcomes of the Smart Lift procedure.

At 6 months, a statistically significant decrease in both aGH and SL was observed in \beta-TCP group compared to post-surgery. The reduction in the radio-opaque area evident in the apical part of the implant in the \beta-TCP group, but not in the DBBM group, may be partly related to inter-group differences in the rate of resorption/degredation and replacement of the materials by newly formed tissues. In this respect, a recent meta-analysis on the fate of osteoconductive materials grafted into an augmented sinus at the histomorphometrical level showed that the total bone volume increased over time for both DBBM and \beta-TCP, suggesting that the two graft materials are at least partially resorbed and replaced by bone (Handscher et al. 2009). However, a variable graft remodelling was reported when the two materials had been used for sinus floor elevation, being faster for \beta-TCP (Ozyuvaci et al. 2003, Zerbo et al. 2004, Kurkcu et al. 2012, Schulze-Späte et al. 2012) and slower for DBBM (Lee et al. 2006, Traini et al. 2007, Pietursson et al. 2009a, Mordenfeld et al. 2010, Pettinicchio et al. 2012, Kurkcu et al. 2012, Trombelli et al. 2012). Recently, a histomorphometrical study on sinus floor elevation showed that DBBM resulted in a greater proportion of newly formed bone compared to \beta-TCP at 6 months (Kurkcu et al. 2012). Overall these observations seem to suggest that the differences in aGH variations observed in this study may indeed reflect the variability in the dynamics of graft replacement and subsequent newly bone formation between DBBM and \beta-TCP.

In conclusion, the results of this study indicate that both DBBM and \beta-TCP may safely support sinus lift procedures when performed with the Smart Lift technique. However, the study failed to find significant differences in clinical outcomes and post-operative morbidity between sites treated with DBBM and \beta-TCP.

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**Smart Lift** instruments for the preparation of a site with a radiographic working length (i.e. rWL, as assessed on the pre-operative periapical radiograph) of 7 mm and a residual ridge height (i.e. sWL, as assessed with the Probe Osteotome) of 7 mm. Immediately after the completion of the tSFE procedure, an implant (Thommen Medical AG, Waldenburg, Switzerland), 11 mm long and 4.5 mm wide, has been placed.

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<th>Clinical Relevance</th>
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<td><strong>Scientific rationale for the study:</strong> The study was performed to compare the effect of DBBM and β-TCP on treatment outcomes of transcrestal sinus floor elevation.</td>
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<tr>
<td><strong>Principal findings:</strong> The study failed to find significant differences in clinical outcomes and post-operative morbidity between sites treated with the Smart Lift technique in association with either DBBM or β-TCP. However, differences in post-surgery graft remodelling seem to reflect the variability in the dynamics of graft replacement and subsequent new bone formation between DBBM and β-TCP.</td>
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<td><strong>Practical implications:</strong> Both DBBM and β-TCP may safely support sinus lift procedures when performed with the Smart Lift technique.</td>
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