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### **Sinus elevation with and without grafting: a 3-year prospective study.**

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**Background:** Rehabilitation of the atrophied posterior maxilla can be simplified by using implants  $\leq 10$  mm and osteotome sinus floor elevation (OSFE) technique. Peri-implant bone formation after sinus augmentation without grafting has been now well documented (Bruschi et al. 1998, Winter et al. 2003, Lundgren et al. 2004, Nedir et al. 2006, 2009, Lai et al. 2008, 2010, Pjetursson et al. 2009) but a comparison between implants randomly placed with and without grafting is still lacking.

**Aim:** 1) To evaluate the efficacy of an OSFE procedure in extremely atrophic maxillae (residual bone height (RBH)  $\leq 4$  mm) with short tapered chemically-modified hydrophilic surfaced implants. 2) To compare bone levels around randomly placed implants in grafted and non-grafted sinuses, after 1 and 3 years.

**Material and Methods:** Twelve patients requiring 1 to 2 implants per sinus with a mean maxillary RBH of  $2.4 \pm 0.9$  mm were enrolled. Through randomization, implants (TE<sup>®</sup> SLActive, Straumann AG, 8 mm) were placed without grafting (N=17, test) and with grafting (Bio-Oss<sup>®</sup>, Geistlich Pharma AG; N=20, control). Healing time was 10 weeks before functional loading with single crowns. After 1 and 3 years, endo-sinus bone gain and crestal bone loss (CBL) were measured on standardized peri-apical radiographs.

**Results:** Before loading, two control implants failed (RBH 1.4 mm and 1.2 mm). Early adverse events occurred when implants were placed in merged corticals. One osseointegrated test implant was removed after 3 years (RBH 2.8 mm) because of peri-implantitis. The overall success rate was then 91.9%. All implants gained endo-sinus bone. Bone gain was  $3.9 \pm 1.0$  mm (test) and  $5.0 \pm 1.3$  mm (control) after 1 year ( $p=0.006$ ); it reached respectively  $4.1 \pm 1.0$  mm and  $5.1 \pm 1.2$  mm after 3 years ( $p=0.012$ ). CBL was respectively  $0.5 \pm 1.0$  mm and  $0.6 \pm 1.1$  mm after 3 years; the difference in CBL between test and control groups was not statistically significant ( $p>0.05$ ). Mean endo-sinus bone gain and CBL did not statistically increase between 1 and 3 years ( $p>0.05$ ).

**Conclusions:** This study shows that grafting is not needed to reach 4.1 mm of bone gain in maxillary RBH  $\leq 4$  mm after 3 year. However, more bone is obtained when grafting material is inserted. Bone gain observed after 1-year is preserved and does not shrink over the 3-year mid-term. The OSFE procedure with immediate implant placement, while technically sensitive, might be considered as a predictable, efficient and less invasive alternative care of the atrophic maxilla.