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- Title:** Comparison between short implants placed with or without grafting in atrophic posterior maxilla: The 5-year results of a prospective randomized controlled study.
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- Key-words:** Posterior maxilla, graft material, bone regeneration, crestal approach, osteotome sinus floor elevation, sinus augmentation, no grafting
- Learning objectives:** The osteotome technique is predictable in very low residual bone height over a 5-year period. A grafting material is not required to promote osteogenesis and gain endo-sinus bone volume. More endo-sinus bone is gained when grafting material is added.

Abstract:

Background: Sinus floor elevation and implant placement allow the rehabilitation of the edentulous atrophic posterior maxilla. Sinus floor elevation through the lateral approach is the recommended treatment (Jensen et al. 1998). The osteotome sinus floor elevation (OSFE) technique has gradually gained popularity because of its minimal invasiveness. However, two questions necessitate further investigation: first, the minimal residual bone height (RBH) allowing the predictable use of OSFE and, second, the behavior of the peri-implant bone tissue in extreme clinical conditions.

Purpose: Over an observation period of 5 years: 1) to evaluate the clinical efficiency of short implants placed with the OSFE in RBH ≤ 4 mm, 2) to compare bone levels around implants placed with and without grafting.

Material and Methods: TE® SLActive implants (Straumann AG, 8-mm long) were placed in atrophic maxilla (RBH ≤ 4 mm). Prior to surgery, sinuses were randomized to receive Bio-Oss® (Geistlich® Pharma AG; control group) or not (test group). After 10 weeks of healing, implants were functionally loaded with single crowns. Bone levels were measured from standardized peri-apical radiographs after surgery, at 1, 3 and 5 years. Data were statistically analyzed using mixed linear models which included a random effect (random intercept) for each patient, and a fixed effect for the treatment group. Fixed effect was treatment year for the analysis along time. The p-values took into account random patient effect. The comparison of success rates between implant groups was tested by means of Fisher test. The threshold value for statistical significance was set at $p < 0.05$.

Results: Twelve patients (19 sinuses) were enrolled. The mean RBH was 2.4 ± 0.9 mm (0.9 - 4.0 mm). Through randomization, 17 implants were placed without grafting (test group, 9 patients, 9 sinuses) whereas 20 implants with graft material (control group, 10 patients, 10 sinuses). Three failures (two early and one late) were recorded. The early failures were related to the implant placement in fused corticals regardless of presence or lack of graft material (Nedir et al. 2012). The late failure was due to the recurrence of the periodontal disease treated before implant placement. The overall implant success rate was 91.9% after 5 years (94.1% test, 90.0% control; $p=0.66$).

All implants gained endo-sinus bone. After 1 year, mean gain was 3.9 ± 1.0 mm (test) and 5.0 ± 1.3 mm (control; $p < 0.001$); after 3 years, it reached respectively 4.1 ± 1.0 mm and 5.1 ± 1.2 mm ($p = 0.001$) and after 5 years, respectively 3.9 ± 1.0 mm and 4.6 ± 1.2 mm ($p = 0.001$). Mean crestal bone loss was limited to 0.6 ± 1.1 mm after 5 years, without statistical difference between the groups ($p = 0.564$). The mean bone gain and crestal bone loss did not statistically change between 1 and 5 years (respectively $p = 0.550$ and $p = 0.304$).

The dome formed by the graft material above control implants showed a mean height of 1.6 ± 0.9 mm after surgery. At 5 years, 11 implants were completely embedded in peri-implant bony material (mean

dome height 1.1 ± 0.7 mm). The difference between dome height measured after surgery and at 5 years was not significant ($p = 0.132$).

Conclusions: In the extreme conditions presented hereby - very low RBH, use of short implants, reduced healing time, single crown rehabilitation -, both the *de novo* bone and the composite regenerated mineralized tissue showed an ability to support loading stress. Grafting was not needed to reach 3.9 mm of bone augmentation, but more bone was gained with graft material. However, when implants were placed with graft material, a limited decrease in the dome height above the implant apex has been observed after 5 years. Bone gains measured after 1 year were preserved. The extremely atrophic posterior maxilla could be predictably rehabilitated using OSFE with the simultaneous placement of 8-mm long implants.