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Title: Osteotome sinus floor elevation without grafting material: A 10-year study.

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Background: Implant rehabilitation of edentulous atrophic posterior maxilla can be greatly extended and simplified using implants ≤ 10 mm in length and the osteotome sinus floor elevation procedure (OSFE) (Toffler 2004). Grafting is not a pre-requisite for bone formation in the atrophic maxilla because of the potential of healing and bone formation of the posterior maxilla beneath the sinus membrane (Bruschi et al. 1998, Winter et al. 2003, Lundgren et al. 2004, Nedir et al. 2006, 2009, 2010, 2013, Lai et al. 2008, 2010, Pjetursson et al. 2009, Si et al. 2013). However, the long-term outcome of implants placed in the atrophic maxilla using OSFE without grafting material has not been documented yet and the long-term stability of peri-implant bone formation remains a controversial question.

Aim: The predictability of an OSFE procedure without grafting material has been reported at 1 year (Nedir et al. 2006), 3 years (Nedir et al. 2009) and 5 years (Nedir et al. 2010). For the same patient group, it was reported herein the 10-year clinical performances of the implants and bone level measurements around implants. The study aims to evaluate the long-term success of the procedure and to analyze the long-term changes in bone levels around implants.

Material and methods: Seventeen patients received 25 ITI-SLA implants (Straumann AG) to rehabilitate 9 premolar and 16 molar sites (mean residual bone height 5.4 ± 2.3 mm). The OSFE protocol without grafting was previously described (Nedir et al. 2006). Twenty-one implants were 10 mm-long, three 8 mm-long and one 6 mm-long. The shorter implants were placed when the Schneiderian membrane was perforated. After a mean period of 3.1 ± 0.4 months, they were rehabilitated with 4 single crowns and 13 fixed partial dentures of two-to-three units. According to success criteria set forth by Buser et al. (1997), the 5-year implant success rate was 100%. Starting from 2.5 ± 1.2 mm the first year, mean bone gain was 3.2 ± 1.3 mm at 5 years. The difference in mean bone gain between 1 and 5 years was statistically significant ($p=0.001$). Crestal bone loss (CBL) was 1.2 ± 0.7 mm at 1 year and 0.8 ± 0.8 mm at 5 years ($p=0.001$). The protrusion length into the sinus decreased from 4.9 ± 1.9 mm after surgery, to 2.2 ± 1.0 mm at 1 year and 1.5 ± 0.9 mm at 5 years ($p<0.001$).

At the 10-year control, endo-sinus bone gain, CBL and protrusion were measured on apical radiographs. Descriptive statistics, mean and standard deviation were used to present values on recordings from the mesial and distal implant sides. A non-parametric Wilcoxon matched pairs signed-rank test was used to compare the

various radiographic parameters at the follow-ups. The threshold value for statistical significance was set at $p < 0.05$.

Results: Two patients (2 implants) were lost to follow-up. One patient (2 implants) was successfully treated for peri-implantitis at year 7. Fifteen patients (23 implants) attended the 10-year control. All implants were clinically stable. The survival rate was 100%. All prostheses but one were free of complications. Since the surgery time, all implants gained endo-sinus bone (mean 3.0 ± 1.4 mm). Three implants showed a complete endosseous side. The mean CBL was 1.0 ± 0.9 mm. The mean protrusion was 1.9 ± 1.2 mm. During the last five years, 10 sites have kept on slightly gaining endo-sinus bone ($+0.4$ mm) and crestal bone loss has increased for 11 implants ($+0.6$ mm). The difference in mean endo-sinus bone gain, CBL and protrusion measured at 1 and 10 years was statistically significant ($p < 0.001$, $p = 0.005$ and $p = 0.010$, respectively). The difference in mean endo-sinus bone gain, CBL and protrusion measured at 5 and 10 years was not statistically significant ($p = 0.423$, $p = 0.123$ and 0.053 , respectively).

Conclusions and clinical implications: During this 10-year follow-up, all implants fulfilled clinical and radiographic success criteria. Endo-sinus bone was mainly gained during the first years and reached 3.0 mm after 10 years. However, CBL has slightly increased between 5 and 10 years. This study is the first 10-year report that addresses the capacity of forming bone beneath the Schneiderian membrane when it is lifted without grafting. It confirms the long-term predictability of the OSFE with simultaneous implant placement.