

Clinical and radiographic changes at titanium dental implants with a modified transmucosal neck surface: a 3-year multicenter randomized controlled trial

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Background: Outcomes of an experimental study in humans indicated that implant surface modification may have the potential to enhance soft tissue attachment to titanium abutments of dental implants.

Aim/Hypothesis: To compare the 3-year clinical and radiographic changes following placement of titanium-zirconium alloy (TiZr) implants with a modified sandblasted and acid-etched (mSLA) neck with those with a machined (M) neck.

Material and Methods: Tissue level TiZr implants with a mSLA (test) or M (control) transmucosal neck were randomly inserted in pristine bone according to manufacturer's instructions. The implants had a length of 8–12 mm, an endosseous diameter of 4.1 mm and a neck height of 1.8 mm and were placed in the posterior maxilla or mandible. The implants were restored with screw-retained single-unit crowns 8–12 weeks following implant placement (baseline, BL). The modified Gingival Index (mGI) served as primary endpoint and was assessed at BL and after 6, 12 and 36 months. Secondary clinical parameters included the assessment of probing depth (PD), mucosal recession (REC) and attachment level (AL). Standardized radiographs were taken at time of implant placement, at BL and after 12 and 36 months. The patient was masked with respect to the study device.

Results: Data from 43 patients (22 test and 21 controls) with 1 implant each were available for the 3-year analysis. No statistically significant differences ($P > 0.05$) were observed with respect to any clinical and radiographic parameters throughout the study period. The implant survival rates amounted to 95.5% in the test and to 100% in the control group, respectively. At the 3-year follow-up, 22.4% of the test and 21.1% of the control implants yielded ≥ 1 bleeding site, respectively. After 3 years, mean PD was 3.2 ± 0.8 mm in the test group and 3.0 ± 0.6 mm in the control group. Mean bone level changes of 0.33 ± 0.69 mm in the test group and of 0.12 ± 0.30 mm in the control group were measured between BL and the 3-year follow-up. The combination of clinical and radiographic parameters yielded 3-year success rates of 90.5% in the test and 94.7% in the control group, respectively.

Conclusions and clinical implications: Tissue level implants with a mSLA transmucosal neck failed to show clinical and radiographic superiority compared with commercially available implants with a machined transmucosal neck up to 3 years.