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A SPLIT-MOUTH, MULTICENTRE RANDOMIZED CONTROLLED TRIAL COMPARING SINGLE SANDBLASTED ACID-ETCHED IMPLANTS WITH OR WITHOUT SURFACE MODIFIED WITH PH BUFFERING AGENT: RESULTS ONE YEAR AFTER LOADING

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PURPOSE. To compare the clinical outcomes of single implants with sandblasted and acid-etched (SA, control group) surface *versus* implants with SA surface modified by pH buffering agent (SOI, test group).

MATERIALS AND METHODS. This study was designed as multicentre, split-mouth, randomized controlled trial in partially edentulous subjects requiring at least two single implant-supported crowns. A one-stage implant placement procedure was performed according to the manufacturer's instructions. Patients were randomized after implant site preparation. Eight weeks after implant placement, definitive impressions were taken. Four weeks later, definitive metal-ceramic or full-ceramic crowns were cemented or screw-retained, according to the investigator's preference. Outcome measures were prosthesis and implant failures, complications, peri-implant marginal bone levels, implant stability quotient (ISQ), bleeding on probing (BoP) and plaque index (PI).

RESULTS. Overall, 62 patients from nine centres were enrolled. Thirteen patients had dropped out at one year after loading so follow-up data from 49 patients with 98 implants were analysed. In the first 12 weeks of observation, two implants were lost, both in the SA group, this difference was not statistically significant (RR = 0.200 P = 0.296, 95% CI [0.0098, 4.0830]). No prosthesis failed up to one year after crown fitting. However, during the third and fourth weeks of measurement, loss of stability was observed in two implants in the SOI group and three implants in the SA group. Mixed-effects modelling revealed a statistically significant difference in implant stability between groups (P = 0.011) over time, with slightly lower ISQ values in the SOI group (-0.65; 95% CI -1.14 to -0.15). No statistically significant differences in marginal bone levels were found between the SA and SOI groups at either implant placement (P = 0.411), prostheses fitting (P = 0.917), or 1 year after loading (P = 0.617). Likewise, there was no statistically significant difference in marginal bone loss between groups at any time point. At one year follow-up, there were no statistically significant differences in bleeding on probing (P = 0.787) or plaque index (P = 0.638).

CONCLUSIONS. The results indicate that both implant types can be successfully loaded.

CONFLICT OF INTEREST STATEMENT
Implants used in this study were donated by Osstem Implant, Osstem Global, Seoul, South Korea, but the company had no influence on the study design or outcomes. No authors have any conflict of interest to declare.