

A multicenter, retrospective study of the performance of a dental implant used in everyday practice

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Abstract

Background: Dental implant treatment is today state of the art to replace function and esthetics of lost teeth. Numerous clinical studies have been performed to investigate the outcome in defined patient groups, specific indications, and using certain surgical techniques.

Aim/Hypothesis : The aim of this study was to evaluate treatment outcomes of a dental implant system when used in a daily patient pool.

Material and Methods : 385 dental implants (OsseoSpeed EV, Dentsply Sirona Implants) were randomly investigated in 208 patients at 7 clinics in 6 countries. No specific inclusion or exclusion criteria were applied (other than being >18 years and willingness to participate). Primary objective was to evaluate implant survival, prosthetic success and marginal bone level changes.

Results: Patients were on average 58 years old (range 20 to 96). Forty-seven percent were male, 53% were females and 87% were non- or ex-smokers. Majority of cases were single tooth replacements, 54%, and most of the implants, 62%, were placed in the maxilla. In almost 80% of the cases, a delayed loading regimen was applied, and of the 20% of immediately loaded implants, 12% were placed in extraction sockets. Three implants were lost rendering a survival rate of 99,2% after 4 years (range 2,8 – 5,6; average 4 years), and the prosthetic success was 94%. Marginal bone levels decreased by 0.06 mm on patient level from placement/loading to 4 years of follow-up.

Conclusion and Clinical implications : Dental implant treatment using the OsseoSpeed EV implant system is a predictable treatment with high success rate when applied in daily patient pool. Single tooth replacements and delayed loading regimen were the most common indications and loading protocols.

Background and Aim

Today, treatment with endosseous titanium implants, presents high long-term success rates for the rehabilitation of edentulism and partial dentate situations. The Astra Tech Implant System has produced reliable and reproducible results with regards to both functional and esthetical outcomes, when evaluated in a comprehensive pre-clinical and clinical program^{1,2}. The Astra Tech Implant System EV is the next step in the continuous evolution of the Astra Tech Implant System

The rationale for this retrospective investigation is to generate additional large-scale clinical data to support that the OsseoSpeed EV implant is a viable treatment option that gives reliable results in everyday clinical practice.

Methods and Materials

Seven clinics in 6 countries were selected to participate in this open retrospective analysis. Each site created a 'Site Study Population List' including all eligible subjects treated from January 2015 till December 2016. There were no exclusion criteria other than being >18 years old and willingness to participate. In order to avoid bias, subjects were ordered randomly by an external statistician and put into a 'Randomized Subject Contact List'. The subjects were contacted in the specific order as specified and invited for a clinical and radiographic examination. Each investigational site was allowed to enroll up to 25-30 subjects. A sample size of 200 subjects was calculated.

Implant survival was considered the primary outcome variable and Implant success, prosthetic success, marginal bone loss and peri-implant parameters (plaque, bleeding on probing, probing pockets depth) were the secondary outcome variables.

Implant success was defined as implant in situ at time of the investigational visit and no complications related to the implant or adjacent peri-implant tissues from implant installation until the end of the investigation. Prosthetic success was defined as implant abutment and restoration in situ at time of the investigational visit and no prosthetic complications from prosthetic restoration until the end of the investigation.

Descriptive statistical analysis was performed for each variable in the investigation both with the patient and the implant as statistical unit. Bone level changes were analyzed using the Wilcoxon signed rank test.

Results

In total 385 implants were evaluated in 208 patients (110 female, 98 male; mean age 58, range 20-96) with a mean follow-up of 3.9 years (range 2.8-5.6). Most of the subjects were nonsmokers (71%), 16% were former smokers, 1% was occasional smoker and 12% were habitual smokers. Forty patients (19.2%) were bruxers and 32 (15.4%) had a history of periodontal disease. Distribution of implant length and diameter is presented in Figure 1.

The majority of the cases were single tooth replacements (223 implants), whereas 105 and 55 implants were installed for multiple-unit restorations and overdentures, respectively. Delayed loading was the most commonly applied loading regimen (306 implants, 79.5%), whereas immediate placement/immediate loading was adopted in 46 cases (11.9 %) and immediate loading in healed sockets in 31 cases (8.1%)

Distribution of implants according to retention type and prosthetic materials is presented in figure 2.

Three implants in 3 patients were lost, resulting in a survival rate of 99.2% on implant and 98.6% on patient level. Seven implants in 7 patients were failures, resulting in an implant success rate of 96.6% and 98.2% on patient and implant level. Prosthetic success rate was 92.2% on implant level and 94.0% on the level of the prosthesis.

Marginal bone level changes were evaluated comparing available baseline radiographs with the radiographs from the investigational visit. On subject level the overall mean change in MBLs for all surfaces was -0.06 0.54mm, -0.12 0.57mm with loading as baseline value, and 0.13 0.42mm with implant installation as baseline.

On implant level the mean change in the MBLs were and -0.04 0.81mm (-0.04 0.85 Mesial, -0.02 0.85 Distal). Changes were not statistically significant.

Information on plaque, bleeding and PPD was available for 382 implants in 208 patients. 168 subjects (80.8%) did not have any documented plaque on any surface. On implant level, plaque was detected in 63/382 (16.5%) implants.

Bleeding on probing was reported for 64 subjects (30.8%) and 90/382 implants (23.6%). A mean PPD of 2.6 0.79mm on subject level, and 2.7 0.84mm on implant level was found.

Six-teen complications were reported from implant placement up to completion of the investigational visit. 14 subjects (6.7%) had one event, one subject (0.5%) had two events reported. 50% of the complications were prosthesis related, 44% peri-implant tissue related, and 6% abutment related. Five events (31%) were still present or had residual effects at time of the investigation.

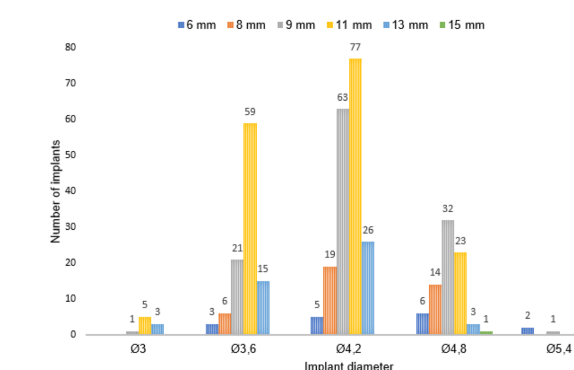


Figure 1.

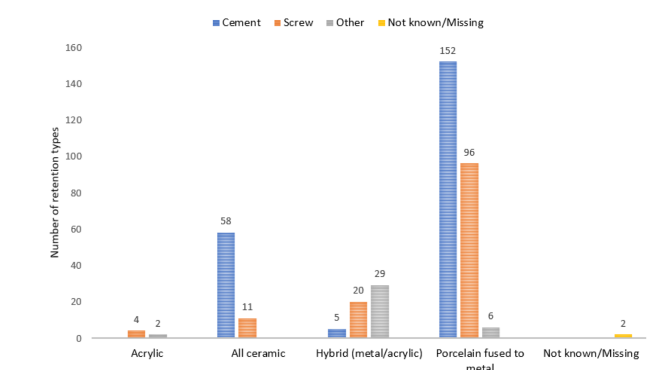


Figure 2.

Conclusion

Dental implant treatment using the OsseoSpeed EV implant system is a predictable treatment with high success rates, stable marginal bone levels and very limited complications up to 6 years of function when applied in daily patient pool. Single tooth replacement was the most common indication and delayed loading regimen the most loading protocol.

References

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