Title:

Retrospective evaluation of clinical performance of the Astra Tech Implant System EV when used in everyday practice.

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Retrospective evaluation of clinical performance of the Astra Tech Implant System EV when used in everyday practice.

Sponsor

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Anticipated number of study sites: 7 study sites, located in EU, US and CA

Anticipated number of subjects/implants: 200 subjects

Background and overall aim

The Astra Tech Implant System EV is the next step in the continuous evolution of the Astra Tech Implant System but the foundation for this new system is still the Astra Tech Implant System. The Astra Tech Implant System EV includes dental implants in diameters ranging from 3 mm up to 5.4 mm, and lengths from 6 mm up to 17 mm. It also includes an extensive abutment assortment; patient-specific abutments as well as a wide range of pre-fabricated abutments. Utilizing a site-specific, crown-down approach, these components are designed to help support all clinical situations and soft tissue sculpturing requirements for final restorations.

The rationale for this retrospective study is to generate clinical data that supports that the OsseoSpeed EV implant is a viable treatment option that gives reliable results in everyday clinical practice.

A retrospective design is chosen because this design provides information on the everyday clinical use of the whole EV assortment rather than the controlled approach required in a prospective clinical investigation.

Study objectives

Primary objective

The primary objective is to evaluate implant survival. Survival is defined as that the study implant(s) are in situ at time of the study visit.

Secondary objectives

The secondary objectives are to evaluate:

- Implant success

Implant in situ at time of the study visit and no ADEs related to the implant or adjacent peri-implant tissues reported from the day when the study implant(s) was installed until the end of the study.

- Prosthetic success

Implant, abutment, and restoration in situ at time of the study visit and no ADEs related to the reconstruction or adjacent peri-implant tissues reported from the day when the study position(s) was permanently included in a prosthetic restoration until the end of the study.

- Bone tissue response

Marginal Bone Levels (MBL) from radiographs.

- Soft tissue response

Probing Pocket depth (PPD) Bleeding on Probing (BoP) Presence of Plaque.

- Patient reported outcomes

Subjects rate 1) Chewing function, 2) Esthetics and 3) Satisfaction.

- Adverse Device Effects (ADE) and Serious Adverse Device Effects (SADE)

Adverse Device Effects related to implant, abutment, restoration, or adjacent peri-implant tissues reported from the day when the study implant(s) was installed until the end of the study.

Study design

This study is designed as a retrospective and multi-center study. The study population consist of subjects who received one or more OsseoSpeed EV implants during the period January 1st 2015 to December 31st 2016. Two hundred subjects will be enrolled, approximately 25-30 subjects per site. The study includes retrospective data collection from subjects' medical records and data collection from one prospective study visit with clinical examination.

The active study phase, at each study site, is estimated to 6 months and includes: contacting the subjects identified and randomized during the screening phase, recalling the subjects to the clinic to perform one study visit. During this visit the informed consent form (ICF) will be signed and the clinical examination will be performed.

The study starting date for each enrolled subject will be the date the ICF is signed, and the study ends when he/she finalize the prospective study visit.

Study population

The study population will include subjects that received OsseoSpeed EV implants during January 1st 2015 to December 31st 2016. At least 6 study sites will be needed to enroll the required number of subjects.

The study subjects will be recruited from the clinics' full population of individuals previously treated with OsseoSpeed EV implants, replacing one or more teeth, anywhere in the mouth as part of their prosthetic restorations. The implants evaluated in this study will all have been placed according to the standard practice for treatment with OsseoSpeed EV implants.

Inclusion criteria

For inclusion in the study subject must meet all of the following criteria:

1. Subject ≥ 18 years at time of implant installation.
2. Subject signed and dated the informed consent form.
3. Having installed one or more OsseoSpeed EV implants between January 1st 2015 and December 31st 2016.

Exclusion criteria

Any of the following is regarded as a criterion for exclusion from the study:

1. Unlikely to be able to comply with study procedures, according to Investigators judgment.
2. Subject is not willing to participate in the study or not able to understand the content of the study.
3. Involvement in the planning and conduct of the study.
4. Simultaneous participation in another clinical study that may interfere with the present study.
5. Severe non-compliance to CIP as judged by the Investigator and/or Dentsply Sirona Implants.

Study products

The investigational product (OsseoSpeed EV implant) is already included in a restoration in the subject at enrollment, thus this study does not involve the installation of any investigational products.

Indication

Implant used for single, partial or full-prostheses.

Statistical methods

General

If nothing else is stated, descriptive statistics will be given for each variable in the study. This means number of subjects or study positions (n), mean, median, standard deviation (SD), minimum (min) and

maximum (max) values will be presented for continuous data and frequencies and percentages for categorical data.

In relation to objectives

The primary analysis of the study is to estimate the proportion of implants not failing (i.e., survive) over a fixed period of time. Each study position will be categorized as survived (Yes/No). Position will be categorized as survived = Yes, when the implant has been in situ during study. Position will be categorized as survived = No, when the implant has been lost during study. The proportion of survived study positions will be calculated by dividing the number of study positions with survived=Yes, by the total number of study positions. This proportion will be presented together with a 95% confidence interval (using the exact Binomial approach) independent of the follow-up time.

The primary analysis of the study is to estimate the proportion of implants/subjects not failing (i.e., survive).

The expected (i.e., the true) survival rate of the implants is denoted Π and is assumed to be 97 %. The null-hypothesis that the survival rate is less than 91% will be tested using the exact Binomial test, i.e. the following hypotheses will be tested:

H_0: Π < 91 %

versus

H_1: Π ≥ 91 %

Survival will be calculated on a study position level although the sample size calculation provides the number of subjects needed; this approach is chosen since we do not in advance know the number of study positions per subject. Consequently, we assume that study positions within one subject are independent of each other if more than one.

Implant survival will be analyzed on an implant level (i.e., percent of survived implants) as well as on subject level (i.e., percentage of subjects with no lost implants) i.e., if one or more implant(s) fail within a subject the subject is considered as a failure.

Primary analysis will be done on implant level.

Study timetable

Anticipated First Site Initiated:	2019 January
Anticipated Last Site Initiated:	2019 February
Anticipated First Subject Enrolled:	2019 February
Anticipated Last Subject Last visit:	2019 August
Anticipated Data Base Lock:	2019 September