Ongoing Clinical Research Program on PrimeTaper EV Implant

A clinical study to evaluate the PrimeTaper EV Implant in extraction sockets and healed ridges.

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Introduction

The PrimeTaper EV implant has a tapered outer geometry and is designed to provide primary stability. The implant-abutment connection is the same as the well established Astra Tech Implant EV. Pre-clinical data for PrimeTaper EV proves the safety and performance in accordance to applicable standards. This post-market clinical follow-up study was initiated to confirm the clinical performance. More specifically, the aim is to evaluate short- and long-term survival and success rates as well as safety of the implant when used for single tooth replacements.

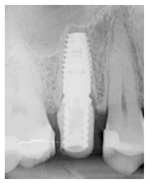
Methods and materials

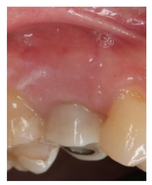
This company initiated study is an open, prospective, multicenter, international clinical investigation with a 5-year follow-up period. Subjects in need of one implant in the maxilla or mandible are recruited. The implant can be placed in extraction sockets or healed ridges, and with a one- or two-stage surgical protocol. Loading protocol can be chosen as per investigator's preference; immediate, early or delayed. Radiographic examinations take place at implant placement, at Permanent Restoration (PR), 6 months, 1, 2, 3 and 5 years after PR. Insertion Torque Values and primary stability (ISQ) are recorded at implant placement, and the surgeon's perception of the implant installation is collected. ISQ is also recorded at PR. PPD, BoP and PI is recorded at PR and at all follow-up visits. Implant success will be evaluated 1, 2, 3 and 5 years after PR and safety assessments take place throughout the clinical investigation. The primary objective is to evaluate implant survival 1 year after Permanent Restoration.

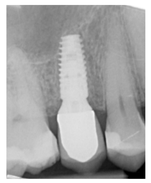
Status

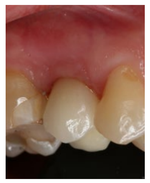
The study is ongoing with 142 subjects included. 41 subjects have reached the 6-month follow-up, and no implant losses are reported to date.


Immediate installation of PrimeTaper EV.


Immediate temporization with TempAbutment EV.


Post-op 1 week after implant placement.


Permanent restoration (PR) with TiDesign EV, 4 months after implant placement.


PR with a cement-retained Zirconia crown.

Clinical case: 36 year old female. Extraction of 15 due to trauma; gap filling and immediate placement of PrimeTaper EV Implant (Ø4.2 length 9mm) and immediate provisionalization. Courtesy of Dr. Mischa Krebs, Alzey, Germany.

Clinical comparison of non-guided vs guided surgery to immediately loaded implants in partially edentulous patients.

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[1]The McGuire Institute, USA

Introduction

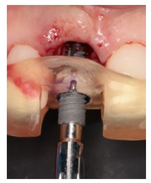
The PrimeTaper EV implant has been developed to predictably provide primary stability, allowing immediate loading in different bone qualities. Implant installation is today done with a "traditional" non-guided or a guided surgical technique utilizing digital imaging and a planning software. The aim of this study is to evaluate the short- and long-term implant survival and success rates, and safety of PrimeTaper EV using non-guided vs. guided surgery in single and multiple implant situations.

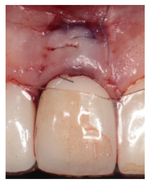
Methods and materials

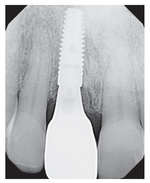
This company initiated study is a prospective, controlled, non-randomized, multicenter study evaluating single or multiple PrimeTaper EV implants restored with Atlantis abutments and fixed restorations. Non-guided vs. guided surgical techniques are used in 50 subjects in each group, followed by immediate loading and a 5 year follow-up period. Radiographic examinations take place at implant placement, impression, Permanent Restoration (PR) and 6 months, 1, 2, 3, 4 and 5 years after PR. CBCT is taken at screening for all guided cases. Primescan intraoral scanner is used for impression. Primary objective is to evaluate implant survival 1 year after PR. Secondary objectives are implant and prosthetic success and survival; implant stability; condition of the peri-implant mucosa; changes in marginal bone levels; patient reported outcomes and safety.

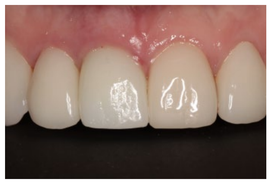
Status

The study is ongoing with 100 subjects included. 60 subjects have received the permanent restoration and 25 subjects have reached the 6-month follow-up visit.


Immediate installation of PrimeTaper EV Implant.


First provisional with Healing Abutment EV.


X-ray at final restoration.


Final restoration.

Clinical case: 54 year old male. Extraction of 11 due to severe root resorption, guided surgery with immediate implant placement of PrimeTaper EV Implant (Ø4.2 length 13mm) with a 6mm Healing Abutment EV.
Courtesy of Dr. E. Todd Scheyer, Houston, USA.

A company initiated Registry: Evaluation of use, handling and outcome of PrimeTaper EV[1,2].

[1]Dentsply Sirona, [2]The McGuire Institute, USA

Introduction

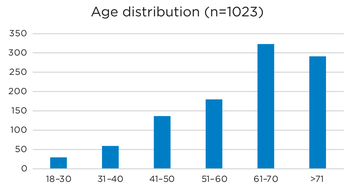
The advantages of implant systems using a tapered root form design include exceptional primary stability. The purpose of this Registry study is to confirm the concept of using a tapered dental implant system to restore a dentition. In addition, the study will describe todays implant patient, and show treatment methods and trends amongst dentists that place dental implants.

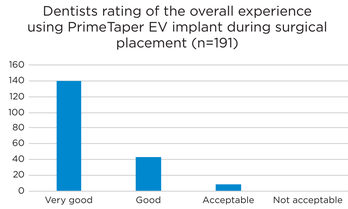
Methods and materials

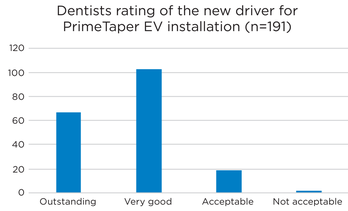
US private clinicians were invited to take part in the Registry, aiming at reaching 500 participating clinicians placing at least 2,500 implants. The Registry collects data from surveys revealing dentist feedback on the placement of PrimeTaper EV implants, restoration and treatment outcomes after 5-years of follow-up.

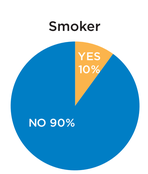
Results

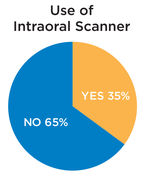
267 active clinicians have registered 1,023 patients to date.

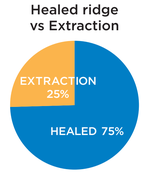


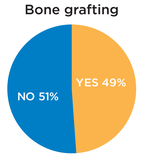


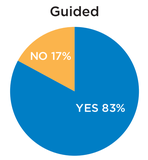


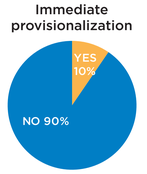












500 Clinics in US

5 years Follow-up

2,500 Implants