Single tooth implants in the posterior maxilla and mandible: a prospective study on clinical performance of Atlantis CustomBase solution with full-contour zirconia Atlantis Crowns.

Gepubliceerd: 12-11-2020 Laatst bijgewerkt: 13-12-2022

Good clinical performance compared to literature

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22032

Bron
Nationaal Trial Register

Verkorte titel
CustomBase abutments in the posterior region

Aandoening

One missing or failing tooth being a molar in the maxilla or mandible;

Ondersteuning

Primaire sponsor: Dept. Oral and Maxillofacial Surgery, University Medical Center Groningen and Dentsply Sirona Implants, Mölndal, Sweden (dental implants and crowns)
Overige ondersteuning: Dept. Oral and Maxillofacial Surgery, University Medical Center Groningen and Dentsply Sirona Implants, Mölndal, Sweden (dental implants and crowns)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Peri-implant bone level change

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Nowadays, the use of dental implants for oral rehabilitation is a generally accepted treatment modality. During the first years of implant dentistry, dental implants were used mainly for the restoration of edentulous mandibles with implant-supported prostheses. Yet, there is a shift towards the application of dental implants for single-tooth replacements, supported by long-term studies reporting excellent survival rates (Den Hartog et al. 2008). Not only in the aesthetic region, but also in the posterior maxilla and mandible there is a growing interest in restoring function. Dental implants show a good performance in the posterior region (Telleman et al. 2011); in recent years attention has been shifted towards a better initial stability to reduce treatment time. Next to this, implants must be restored with crowns which are subject to minimal complications. Specially for the posterior region, companies have introduced the option of screw-retaining and zirconia as crown material, of which less technical complications are mentioned. The combination of posterior implants and screw-retained zirconia crowns are widely used, but prospective research on clinical performance and patient centered outcomes are lacking.
Objective: To evaluate the clinical performance of Astra Tech Implants EV and Atlantis CustomBase Abutments with full-contour zirconia Atlantis Crowns in the posterior maxilla and mandible.
Study design: A prospective case series.
Study population: a total of 50 participants.
Intervention: All patients will be treated with a Astra Tech Implant EV and an Atlantis CustomBase Abutments with full-contour zirconia Atlantis Crowns.
Main study parameters/endpoints: The main study parameters are: changes in marginal peri-implant bone loss and clinical performance. Additional parameters are: mucosal changes and patient satisfaction.

Doel van het onderzoek

Good clinical performance compared to literature

Onderzoeksopzet

Tpre = before treatment: patient satisfaction
T1 = 1 month after restoration placement: radiographic bone level and clinical items

T12 = 12 months after restoration placement: radiographic bone level, clinical items and patient satisfaction

Onderzoeksproduct en/of interventie

All patients are treated with an Astra Tech Implant EV. After a period of 3 months a screw-retained zirconia restoration is placed.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients referred to our department for single-tooth implant therapy in the maxillary and mandibular posterior region are considered for inclusion.

The following inclusion criteria are applied:
- one missing or failing tooth being a molar in the maxilla or mandible;
- enough bone to reach initial stability of the dental implant;
- at least 18 year of age;
- ASA score ≤ 2 (Smeets et al. 1998);
- adequate oral hygiene, i.e. Plaque Index Score (Silness and Loë, 1964) and Gingival Index Score (Silness and Loë, 1964) ≤ 1;
- mesial-distal width of diastema at least 8 mm;
- patient is capable of understanding and giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are:
- presence of active clinical periodontal disease as expressed by probing pockets depths ≥ 4 mm and bleeding on probing;
- presence of peri-apical lesions or any other abnormalities in the posterior region as determined on a radiograph;
- smoking;
- a history of radiotherapy to the head and neck region;
- use of intravenous bisphosphonates shorter than 10 years ago.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2020
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
Sharing of data upon reasonable request

Ethische beoordeling

Positief advies

Datum:	12-11-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9059
Ander register	METC UMCG : METc 2017-295 Non-WMO study

Resultaten

Samenvatting resultaten
1-year results to be published in international peer-reviewed journal