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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22032

Source
Nationaal Trial Register

Brief title
CustomBase abutments in the posterior region

Health condition

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

Sponsors and support

Primary sponsor: Dept. Oral and Maxillofacial Surgery, University Medical Center Groningen and Dentsply Sirona Implants, Mölndal, Sweden (dental implants and crowns)
Source(s) of monetary or material Support: Dept. Oral and Maxillofacial Surgery, University Medical Center Groningen and Dentsply Sirona Implants, Mölndal, Sweden (dental implants and crowns)

Intervention

Outcome measures

Primary outcome

Peri-implant bone level change

Secondary outcome

Clinical items and patient satisfaction

Study description

Background summary

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.

Study objective

Good clinical performance compared to literature

Study design

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

Intervention

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

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2020
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
Sharing of data upon reasonable request

Ethics review

Positive opinion

Date:	12-11-2020

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

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