

Single tooth implants in the posterior maxilla and mandible: a prospective study on clinical performance of NobelBiocare Implants restored with screw-retained zirconia crowns; a 5-years evaluation

Gepubliceerd: 29-10-2021 Laatste bijgewerkt: 18-08-2022

Stable peri-implant bone levels, high implant and restoration survival rate and satisfied patients.

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

Samenvatting

ID

NL-OMON24338

Bron

NTR

Verkorte titel

NobelPosterior 5-years evaluation

Aandoening

5-years ago the patient had a missing posterior tooth

Ondersteuning

Primaire sponsor: University Medical Center Groningen

Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in marginal peri-implant bone level 5 years after placing the definitive restoration.

Toelichting onderzoek

Achtergrond van het onderzoek

- Background

There is a growing interest in restoring function in the posterior maxilla and mandible with dental implants. Next to this, these implants must be restored with crowns which are subject to minimal complications. Companies have introduced the option of screw-retaining and zirconia as crown material. The combination of posterior implants and screw-retained zirconia crowns are widely used, but prospective research on clinical performance and patient centered outcomes are scarce. Even more, 5-years data are lacking.

- Main research question

To evaluate the clinical performance of Nobel Biocare Implants restored with screw-retained zirconia crowns in the posterior maxilla and mandible. The primary objective of the study is marginal bone level changes by radiological assessments at 5-years follow-up. Secondary objectives are implant and restoration survival, condition of peri- implant mucosa and patients' satisfaction.

- Design (including population, confounders/outcomes)

The study design is an observational study of a group of patients which were treated 5 years ago with a dental implant and a screw-retained implant-supported zirconia restoration because of a missing tooth in the posterior region. Outcomes: primary outcome is the change in marginal peri-implant bone level 5 years after placing the definitive restoration. Secondary outcome measures will be implant and restoration survival, peri-implant mucosa health and patients' satisfaction using a questionnaire.

Doel van het onderzoek

Stable peri-implant bone levels, high implant and restoration survival rate and satisfied patients.

Onderzoeksopzet

5-years evaluation (5 years after placing the definitive restoration).

Onderzoeksproduct en/of interventie

Dental implant with a full-zirconia restoration

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients referred to the department of Oral and Maxillofacial Surgery 5 years ago and treated with a dental implant and a screw-retained implant-supported zirconia restoration because of having a missing tooth in the posterior region. At the time of treatment:
- The patient was 18 years or older;
- The missing tooth was a premolar or molar in maxilla or mandible;
- Sufficient healthy and vital bone to insert a dental implant with a minimum length of 8 mm and at least 4.0 mm in diameter with initial stability > 45 Ncm
- The implant site was free from infection;
- Adequate oral hygiene (modified plaque index and modified sulcus bleeding index ≤ 1);
- Sufficient mesio-distal, bucco-lingual, and interocclusal space for placement of an anatomic restoration;
- The patient was capable of understanding and giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Medical and general contraindications for the surgical procedures;
- Presence of an active and uncontrolled periodontal disease;
- Bruxism;
- Smoking
- A history of local radiotherapy to the head and neck region.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2021
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting

Upon reasonable request.

Ethische beoordeling

Positief advies	
Datum:	29-10-2021

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
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NTR-new	NL9848
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Ander register METc-UMCG : METc 2021/605 UMCG RR number 202100744

Resultaten

Samenvatting resultaten

Full-zirconia implant-supported restorations with angulated screw channel abutments in the posterior region; a 5-years prospective case series study