Comparison of clinical and radiographical outcomes following placement of hybrid and moderate rough implants in the posterior mandible of periodontally compromised patients: a 3-year randomized clinical trial

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Hypothesis: Periodontally compromised patients can possibly benefit from the placement of hy-brid dental implants, because of less biofilm and less pathogenic bacteria will attach to the smooth upper portion of the hybrid implant. As a result, less...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20945

Bron
NTR

Verkorte titel
Comparison of hybrid and rough implants in perio patients

Aandoening

Peri-implantitis

Ondersteuning

Primaire sponsor: ACTA Dental Research B.V., Gustav Mahlerlaan 3004, 1081 LA, Amsterdam, The Netherlands
Overige ondersteuning: Southern Implants, 1 Albert Road, Irene, Centurion, Re-public of South Africa

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measure is the radiographical change in implant mean marginal bone level (MBL) on the mesial and the distal site 36 months after delivery of the fixed partial dentures (FPDs).

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY

Rationale: Successfully treated periodontitis patients are generally receiving the same dental im-plants as patients without a history of periodontitis. However, these patients have significantly high-er risk of implant failure with an increased marginal bone loss when compared with periodontally healthy patients. It is important to have the most favorable implant placed in these patients for oral rehabilitation purposes. There are some limited evidences present showing that implants with a ma-chined surface were less prone to bone loss related to peri-implantitis compared with rougher im-plants.

Objective: The primary objective is to investigate the change in marginal bone level of hybrid im-plants and moderate rough implants in the mandible of periodontal compromised patients. The secondary objective of this study is to investigate hybrid dental implant performance in implant sur-vival rate, implant stability and peri-implant microbiological composition. Lastly, in this study the prosthetic workflow will also be evaluated in terms of impression taking, materials used and occlusal wear.

Study design: The study is set up as a multicentre randomized within-subjects controlled clinical trial.

Study population: Volunteer patients of 18 years and above who are periodontally compromised with partial edentulism in the posterior mandible.

Intervention: Each patient will receive two types of implants with different surface roughness from the Southern Implants system. The implants are to replace single partially edentulous spaces in the mandibular premolar and molar region.

Main study parameters/endpoints: The main study endpoint is the change in marginal bone level between the hybrid and the moderate rough dental implants after 3-years follow-up.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The tax in terms of time for the patient will be equal with the time re-quired in a regular dental office or referral practice for oral implantology. There is no increased risk associated with participation, because we follow the standard protocol for oral implantology.

Doel van het onderzoek

Hypothesis: Periodontally compromised patients can possibly benefit from the placement of hy-brid dental implants, because of less biofilm and less pathogenic bacteria will attach to the smooth upper portion of the hybrid implant. As a result, less biofilm induced peri-implantitis will develop. If peri-implantitis unfortunately develops, it will be easier to remove biofilm from the hybrid implant.

Onderzoeksopzet

Baseline, 1 year, 2 year and 3 year

Onderzoeksproduct en/of interventie

Each patient will receive two types of implants with different surface roughness from the Southern Implants system. The implants are to replace single partially edentulous spaces in the mandibular premolar and molar region.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age at least 18 years
- Provision of written informed consent
- Agree to return for follow-up visits after 1, 2 and 3 years
- Periodontally compromised patients having a history of proximal attachment loss of > 5mm in > 30% of teeth present and enrolled in a supportive periodontal therapy (SPT) program after active periodontal treatment
- Requirement of two single-unit fixed partial dentures (FPDs supported by two implants in mandibular premolar and/or molar region
- Adjacent natural tooth/teeth
- In antagonistic jaw natural teeth, partial prosthesis, or implant supported (partial) prosthesis in contact with planned FPD
- History of edentulism in planned implant area > 4 months
- At planned implant area, a minimum of 12 mm bone in vertical dimension and minimum of 6 mm in horizontal dimension available
- Acquiring a primary stable implant situation assumed by investigator

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- History of local radiotherapy to the head and neck region
- History of chemotherapy < 5 years prior to surgery
- Smoking > 10 cigarettes a day
- Uncontrolled diabetes mellitus
- Known or suspected current malignancy
- Pregnancy at time of inclusion
- Alcohol or drug abuse
- Any systemic or local disease that would compromise postoperative healing and/or osseointegration
- Need for systemic bisphosphonates, corticosteroids or any other medication that would compromise postoperative healing and/or osseointegration
- History of systemic bisphosphonates
- Presence of active clinical periodontal disease expressed by probing pocket depths > 5 mm and bleeding on probing
- History of necrotic or rapid progressive periodontitis
- Untreated caries and/or endodontic disease
- Previous implant loss
- Previous bone augmentation in planned implant area
- Severe grinding/clenching habits
- Incapability of performing oral hygiene as a result of physical or mental disorders
- During any period of the study, if any mandatory procedures and measurements are missing by the investigator, the dataset of that subject will be removed from the final results.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-04-2020
Aantal proefpersonen:	43
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	05-03-2020
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	NL8439
Ander register	METc VUmc : 2019.115 - NL63989.029.19

Resultaten