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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20945

Source
NTR

Brief title
Comparison of hybrid and rough implants in perio patients

Health condition

Peri-implantitis

Sponsors and support

Primary sponsor: ACTA Dental Research B.V., Gustav Mahlerlaan 3004, 1081 LA, Amsterdam, The Netherlands
Source(s) of monetary or material Support: Southern Implants, 1 Albert Road, Irene, Centurion, Re-public of South Africa

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

Secondary outcomes are implant survival, implant stability, marginal peri-implant soft tissue conditions (amount of plaque, bleeding on probing and pocket probing depths) and peri-implant microbiological composition.

Study description

Background summary

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.

Study objective

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.

Study design

Baseline, 1 year, 2 year and 3 year

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.

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-04-2020
Enrollment:	43
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	05-03-2020
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	NL8439
Other	METc VUmc : 2019.115 - NL63989.029.19

Study results