A removable partial denture on implants.

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

Samenvatting

ID

NL-OMON25611

Bron
Nationaal Trial Register

Verkorte titel
RPD, implants

Aandoening

dysfunction of bi-lateral, free-ending removable partial dentures
Loss of oral function due to nonfunctional RPD

Ondersteuning

Primaire sponsor: UMCG, Groningen, The Netherlands
Overige ondersteuning: ITI

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The masticatory function as reflected by the so-called ‘mixing index’.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Free-ending mandibular removable partial dentures yield poor patient acceptance and are generally considered uncomfortable by the patient. Problems caused by the rotational movement of the denture become more frequent. Implants placed in the posterior parts of the mandible can help overcome these problems. Fixed, implant-supported non-removable restorations are not always feasible, both from a surgical and from a financial point of view. As an alternative, implants can also provide retention and support for a Removable Partial Denture (RPD).

There is a lack of evidence in the literature to demonstrate the effectiveness of implant-supported RPD. Well-controlled clinical trials, to the best our knowledge, have not been performed. For a selective population of patients, implant-supported RPD's may well be a viable treatment option that thus far has not yet been fully explored.

Objective: The primary objective of this study is to investigate the improvement of masticatory function of implant-supported RPD treatment in free-ending, bilateral mandibular partial edentulism depending on the implant position. The secondary objectives include patient satisfaction (OHIP-NL49, SF36 and a Visual Analogue Scale), clinical and radiographical parameters (peri-implant health, marginal bone loss) and the required amount of maintenance.

Doel van het onderzoek

We expect an improvement in function, denture stability and patient satisfaction whereas prosthetic maintenance and implant complications are minor.

Onderzoeksopzet

1. TIntake: Before active treatment: MI both with and without current RPD, if present, OHIP-NL49, SF36, VAS;

2. T0: Implant placement, X-ray, submerged healing;

3. T3: 3 months after implant placement: Second stage surgery, placement locator®abutments and start procedure new RPD;

4. T5: 5 months after implant placement: Placing new prostheses (RPD in mandible in conjunction with complete maxillary denture). No measurements;

5. T8: 8 months after implant placement: MI with new RPD without attachment, OHIP-NL49, SF-36, VAS. Changing loading conditions of RPD. Mounting 2 matrices into RPD (A or P) to give support and retention to RPD;

6. T11: 11 months after implant placement: MI with new RPD with attachment, OHIP-NL49, SF36, VAS, PPD, REC, BOP, MBL. Changing matrices;

7. T14: 14 months after implant placement: MI with new RPD with changed attachment, OHIP-NL49, SF36, VAS, PPD, REC, BOP, MBL (X-ray). Changing locator abutments depending on wish subject.

Onderzoeksproduct en/of interventie

The present study is a randomized cross-over trial.
For this study two groups of fifteen patients with complaints regarding their RPD in the mandible and a maxillary complete denture are selected. In all patients four single implants are placed in the mandible: two directly behind the most distal abutment teeth and two at the location of the first molar. The implants are first provided with covering screws conform a two stage surgery approach.

Three months after placing the implants the second stage surgery takes place. All four implants will be provided with locator abutments. Subsequently a new RPD in the mandible and new complete maxillary denture are made. The first three months after placement of the RPD, none of the locator®abutments will provide retention and support to the RPD. After another three months two locator®abutments are loaded (A or P) by mounting the matrices into the RPD. And after another three months the loading conditions are changed to the other 2 locator®abutments. The sequence of loading depends on the group the patient will be directed to at random.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. The patient is ≥ 18 years of age;

2. The bone volume distal from the most posterior abutment teeth should allow the placement of implants with a minimum length of 8 mm and minimum diameter of 3.3 mm;

3. The patient has complaints regarding his bilateral, free-ending RPD in the mandible and has a full denture in the maxilla;

4. The patient is capable of understanding and giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Medical and general contraindications for the surgical procedures;

2. A history of local radiotherapy to the head and neck region;

3. Previous implant loss;

4. Incapability of performing basal oral hygiene measures as a result of physical or mental disorders;

5. Decreased masticatory function due to physical disorders;

6. Active, uncontrolled periodontal pathology of the remaining dentition.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-06-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36010
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2815

Register	ID
NTR-old	NTR2956
CCMO	NL36209.042.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36010

Resultaten

Samenvatting resultaten
N/A