Flexible versus Acrylic Removable Partial Dentures (RPDs) for Provisionalization in the Anterior Region: Oral Health-Related Quality of Life and Patient Satisfaction

Gepubliceerd: 11-09-2020 Laatst bijgewerkt: 18-08-2022

Flexible RPD's have a higher impact on OHRQoL compared to acrylic RPD's.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29507

Bron
NTR

Verkorte titel
Flexible versus acrylic partial dentures

Aandoening

Missing teeth

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: ZonMW, Boeringstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

OHRQoL (5-point Likert-type scale)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: During the healing period after ridge preservation/ridge augmentation procedures prior to implant placement, an acrylic resin tissue-supported removable partial denture (RPD) can be used as a provisional restoration in the anterior region for esthetic and functional reasons. Patients are only moderately satisfied with an acrylic RPD as a provisional restoration. A flexible design RPD might prove beneficial for patients with regard to Oral Health-related Quality of Life (OHRQoL), overall satisfaction, function, comfort and esthetics. Therefore, the aim of this within subject comparison study is to compare the patient satisfaction between a flexible RPD and an acrylic RPD with regard to OHRQoL, overall satisfaction, function, comfort, and esthetics. Objective: The primary objective is to compare OHRQoL with regard to a flexible RPD and an acrylic RPD. The second objective is to compare patient satisfaction between a flexible RPD and an acrylic RPD with regard to overall satisfaction, function, comfort, and esthetics. Study design: The study is designed as a within subject comparison study. Study population: Adult patients with a missing incisor, canine or premolar in the maxilla are included in this study. Intervention: The ridge preservation/ridge augmentation procedure will be performed according to standard protocol. During the 3-month healing period after surgery, the patients will receive a flexible RPD or acrylic RPD as a provisional restoration for the first 1.5 months according to the assigned study group. After 1.5 months, the RPD is switched. Main study parameters/endpoints: The main study parameter is OHRQoL. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The patients will receive one extra appointment for research purposes only in addition to the regular treatment protocol. The described parameters will be collected during regular appointments.

Doel van het onderzoek

Flexible RPD's have a higher impact on OHRQoL compared to acrylic RPD's.

Onderzoeksopzet

0 months, 1,5 months, 3 months

Onderzoeksproduct en/of interventie

Flexible RPD (1,5 month), acrylic RPD (1,5 month)

Contactpersonen

Publiek

University Medical Center Groningen
Vincent Donker

+31681723511

Wetenschappelijk

University Medical Center Groningen
Vincent Donker

+31681723511

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• One missing or failing tooth (for at least 3 months), being an incisor (central or lateral), canine or premolar in the maxilla, the adjacent teeth are natural teeth;
• Large bony defect that requires a ridge preservation/ridge augmentation procedure for implant placement;
• Adequate oral hygiene (modified plaque index and modified sulcus bleeding index);
• Sufficient mesio-distal, bucco-lingual, and interocclusal space for placement of an anatomic restoration;
• The patient is 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:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	11-09-2020
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8868
Ander register	METc UMCG : TBA

Resultaten