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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29507

Source
Nationaal Trial Register

Brief title
Flexible versus acrylic partial dentures

Health condition

Missing teeth

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: ZonMW, Boeringstichting

Intervention

Outcome measures

Primary outcome

OHRQoL (5-point Likert-type scale)

Secondary outcome

overall satisfaction (VAS 1-100), function, comfort and esthetics (5-point Likert-type scale)

Study description

Background summary

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.

Study objective

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

Study design

0 months, 1,5 months, 3 months

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• 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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-09-2020
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable

Application type:	Not applicable

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	NL8868
Other	METc UMCG : TBA

Study results