Functional and clinical aspects of implant-supported, free-ending, removable partial dentures

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36010

Source
ToetsingOnline

Brief title
Implant supported partial dentures

Condition

- Other condition

Synonym
loss of chewing ability, oral dyscomfort

Health condition

kauwstelsel, orale functie en comfort

Research involving
Human

Sponsors and support

Primary sponsor: Centrum voor Tandheelkunde en Mondhygiene
Source(s) of monetary or material Support: Ministerie van OC&W,ITI Grant

Intervention

Keyword: functional aspects, implant-supported, patient satisfaction, removable partial denture

Outcome measures

Primary outcome

The primary outcome variable is the masticatory function as reflected by the so-called *mixing index* (MI). This parameter gives information about the mastication ability of the patient by analyzing the degree of mixing of a two-layered wax tablet after chewing (20 strokes).

Secondary outcome

Secondary outcome variables include patient satisfaction, clinical and radiographical parameters.

Patient satisfaction is determined by means of validated questionnaires that measures people*s perceptions of the social impact of oral disorders on their well-being (OHIP-NL49) the health related quality of life (SF36), and a Visual Analogue Scale (VAS) on general satisfaction with the function of their prosthetic appliance (range 0-100).

Clinical and radiographical parameters include:

1.probing pocket depth (PPD)

2.recession (REC)

3.bleeding on probing (BOP) is assessed at 2 sites per implant (mid-buccal and mesial). A plastic periodontal probe with 0.25 N of calibrated probing force is

used (Click-probe®, KerrHawe, Bioggio, Switzerland).

PPD is measured in millimetres from the mucosal margin to the clinical pocket.

REC is measured in millimetres from the edge of the Locator abutment to the mucosal margin. BOP is noted as absent (score=0) or present (score=1). Mean values per implant are calculated for all variables (meanPPD, meanREC and meanBOP).

4.Detailed post-insertion maintenance and restorative complications and revisions are reported by means of chart review. Mechanical complications are analyzed (MAI).

5.Marginal bone levels (MBL) are determined from standardized, long cone intraoral radiographs by measuring from the edge of the abutment to the bone-to-implant contact, both mesially and distally. Implant Survival (IS), defined as the presence of the implant at any moment of observation is also noted.

Study description

Background summary

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.

Study 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. The secondary objectives include patient satisfaction (OHIP14 and a Visual Analogue Scale), clinical and radiographical parameters (peri-implant health, marginal bone loss) and the required amount of maintenance.

Study design

a randomized cross-over trial

Intervention

Each subject will be treated with 2 implants in each posterior part of the mandible. For each subject a new RPD in the mandible and a new full dental arch prosthesis are made following a standard design. The RPD will subsequently be supported by the two most anterior implants or the two most distal implants using Locator abutments. After three months the loading conditons are changed. Data (clinical tests, questionnaires) will be gathered during the study at four time points:
1. Old RPD in situ/without RPD
2. New RPD
3. Fixated RPD on two implants
4. Fixated RPD on two other implants

Study burden and risks

Patients will benefit from this research because it is reasonable that their complaints regarding their RPD will diminish after it is retained to the locator abutments on the implants. Subsequently the costs for this treatment will only partially be charged. The risks consist of some adverse events related to the surgical procedure: pain and swelling. Patients are allowed to use analgetics after surgery if needed (Ibuprofen 600mg or paracetamol/codein 500/10mg.

Implant loss is a complication which might occur, although the prognosis is very good with nowadays techniques and materials. If so, a new implant can be placed after 3 months.

The previously described adverse events and are inherent to implant placement. There are no extra risks because of participating in this study. At the end of this study de patient is about to decide which implants he or she wants to be

used to fixate the RPD.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

4.2 Inclusion criteria
Inclusion criteria in this study are as follows:
- The patient is >= 18 years of age;
-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;
-The patient has complaints regarding his bilateral, free-ending RPD in the mandible and has a full denture in the maxilla
-The patient is capable of understanding and giving informed consent.

Exclusion criteria

-Medical and general contraindications for the surgical procedures;
-A history of local radiotherapy to the head and neck region;
-Previous implant loss
-Incapability of performing basal oral hygiene measures as a result of physical or mental disorders;
-Decreased masticatory function due to physical disorders
-Active, uncontrolled periodontal pathology of the remaining dentition;

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	dental implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25611
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL36209.042.11
OMON	NL-OMON25611