Maxillary implant overdentures retained by use of bars or locator attachments: 5-year findings from a randomized controlled trial.

Gepubliceerd: 03-11-2020 Laatst bijgewerkt: 13-12-2022

Satisfying results for both groups of patients, non-inferiority

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21557

Bron
NTR

Verkorte titel
TBA

Aandoening

Complaints of maxillary prosthesis

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Peri-implant bone loss

Toelichting onderzoek

Achtergrond van het onderzoek

Background
Edentulous patients wearing a maxillary denture can experience problems. Lacking prosthesis stability and retention, combined with an increased gag-reflex are the most profound complaints. Current research on implant supported overdentures shows an increased stability and retention, while decreasing gag-reflexes by reducing palatal coverage. However, consensus on treating the edentulous maxilla with an implant overdenture has not been reached. One of the aspects in overdenture treatment is the used prosthetic anchorage system. Currently literature reports on different anchorage systems, but randomised controlled trials are limited to short term results. The clinical, radiographic and patient related outcome measures were previously evaluated in 50 patients after 1 year follow-up. Patients with complaints of their conventional maxillary denture were randomly assigned to either bar (n=25) or Locator (n=25) attachment groups. All patients received four maxillary implants, placed by surgeon. After healing, the prosthesis was made by one prosthodontics. Patient related outcomes were examined through patient questionnaires before surgery and at 1 year after placement of the prosthesis. Clinical and radiographic parameters were examinated at 1 month and 1 year after placement of the prosthesis. The conclusion of the 1-years follow up results reviewed that both anchorage systems are associated with high patient satisfaction, low peri-implant bone loss and healthy peri-implant tissues (Boven GC, Meijer HJA, Vissink A, Raghoebar GM. Maxillary implant overdentures retained by use of bars or locator attachments: 1-year findings from a randomized controlled trial. J Prosthodont Res. 2020;64(1):26-33. doi:10.1016/j.jpor.2019.04.013). For the current study we want to compare the clinical, radiographical and patient related outcome measures after 5 years.

Aim: to assess the 5-year results of the clinical, radiographical and patient related outcome measures in patients treated with maxillary implant overdenture therapy, retained by bar or locator attachments.

Study design: prospective comparative trial

Study population: 50 patients

Intervention: no

Main study parameters/eindpoint: the primary outcome measure is peri-implant bone loss during the follow-up of 5 years. The secondary outcome measures are implant survival, changes in clinical (probing depth, modified bleeding index, gingiva index) parameters and patient satisfaction (validated questionnaires).

Expected results: Satisfying results for both groups of patients. The patients will have no

additional research appointments.

Doel van het onderzoek

Satisfying results for both groups of patients, non-inferiority

Onderzoeksopzet

5 years after placement prosthesis (baseline and 1-year results in previous study)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Fully edentulous patients with complaints of their maxillary prosthesis, >18y/o, at least one year fully edentulous.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Previous preprosthetic surgery in maxilla, smoking, radiation therapy in head and neck region, medical contra-indications for surgery

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-11-2020
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-11-2020
Soort:	Eerste indiening

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	NL9031
Ander register	METC UMCG : METc 2020/441

Resultaten