Implant-supported maxillary overdentures: a 10-years evaluation

Gepubliceerd: 14-09-2021 Laatst bijgewerkt: 13-12-2022

Simular outcomes in patients with 4 implants compared with patients with 6 implants with respects to peri-implant bone level stability

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

Samenvatting

ID

NL-OMON21260

Bron
NTR

Verkorte titel
Maxillary overdentures with 10-years follow-up

Aandoening

Edentulous patients with retention and stability problems of conventional upper denture

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Peri-implant bone level changes in 10 years

Toelichting onderzoek

Achtergrond van het onderzoek

Edentulous patients often experience problems with their complete dentures. The increase in comfort for patients wearing an implant-supported overdenture versus a conventional denture is striking, especially for those who suffer from lack of stability and retention. Since results of 6 bar-connected implants and 4 bar-connected seem comparable and with favourable one-year and 5-years results, the question raises whether this premise will hold after a longer evaluation period and whether 6 implants are needed to support an implant-retained maxillary overdenture. Yet, there are no randomized controlled trials of ≥10 years in which the treatment outcome of 4-implant maxillary overdentures are compared with 6-implant maxillary overdentures. Therefore, the purpose of this 10-years randomized controlled trial is to assess the treatment outcome (implant survival, overdenture survival, peri-implant health, radiographic bone height changes, patients' satisfaction and biological/technical complications) of maxillary overdentures supported by 4 or 6 dental implants in the maxillary region.

Doel van het onderzoek

Simular outcomes in patients with 4 implants compared with patients with 6 implants with respects to peri-implant bone level stability

Onderzoeksopzet

10-years follow-up evaluation

Onderzoeksproduct en/of interventie

Collecting 10-years follow-up data

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- at least 18 years of age;
- capable of understanding and giving informed consent;
- at least one year edentulous in the maxilla and mandible;
- bone dimensions at least 12 mm in height and at least 5 mm in width to reach initial stability of the implant;
- sufficient interocclusal space for a bar-supported attachment system.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Excluded were patients with ASA score ≥III, who were smoking, with a history of radiotherapy in the head and neck region or a history of pre-prosthetic surgery or previous implant placement.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2021
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
Upon reasonable request

Ethische beoordeling

Positief advies

Datum:	14-09-2021
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	NL9729
Ander register	METC UMCG : M18.224571 (Metc 2018/067)

Resultaten

Samenvatting resultaten
Maxillary overdentures supported by four or six implants: 10-years results from a randomized controlled trial