

Onderzoek naar relaties tussen nachtelijk knarsetanden en complicaties rond tandimplantaten.

Gepubliceerd: 18-12-2014 Laatste bijgewerkt: 15-05-2024

Excessive mechanical load can cause complications of dental implants and their suprastructures, as well as the peri-implant soft and hard tissues. Sleep bruxism is considered as an important source of mechanical load in the oral environment...

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

Samenvatting

ID

NL-OMON27266

Bron

NTR

Aandoening

Inflammation of peri-implant tissues, marginal bone loss, implant technical complications, suprastructure complications, implant mobility, loss of osseointegration.

Ondersteuning

Primaire sponsor: Academisch Centrum Tandheelkunde Amsterdam (ACTA)

Overige ondersteuning: Sunstar Suisse SA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Peri-implant inflammation and implant technical complications (modified gingival index, probing depth, implant mobility, marginal bone height, suprastructure complications,

abutment complications, implant fracture, other complications)

Toelichting onderzoek

Achtergrond van het onderzoek

This prospective cohort study was designed to answer the question: "Is sleep bruxism a risk factor for (peri-)implant complications?". The study is a single-centre, double-blind, prospective cohort study with a follow-up time of two years. 98 participants fulfilling inclusion criteria (planned treatment with implant-supported fixed suprastructure(s) and age 18 years or older) will be included. Sleep bruxism will be monitored at several time points as masticatory muscle activity during sleep by means of a portable single-channel electromyographic device. Our main outcomes are biological complications (i.e., related to peri-implant bleeding, probing depth, marginal bone height, quality of submucosal biofilm, and loss of osseointegration), and technical complications (i.e., suprastructure, abutment, implant body, or other). The results of this prospective cohort study will provide important information for clinicians treating bruxing patients with dental implants. Furthermore, it will contribute to the body of evidence related to the behaviour of dental implants and their complications under conditions of high mechanical loadings that result from sleep bruxism activity.

Doel van het onderzoek

Excessive mechanical load can cause complications of dental implants and their suprastructures, as well as the peri-implant soft and hard tissues. Sleep bruxism is considered as an important source of mechanical load in the oral environment. Therefore, it is hypothesized that sleep bruxism could be associated to implant and peri-implant complications.

Onderzoeksopzet

Exam 1: at appointment of impression for suprastructure

- Peri-implant conditions
- Oral hygiene
- Quality of plaque
- Occlusal force
- Awake bruxism
- Smoking

- Occluding pairs
- Indicators of parafunctions
- Periodontal parameters
- Sleep bruxism (3 nights)

Exam 2: at appointment of placing the suprastructure, 2 weeks after exam 1

- Peri-implant conditions
- Oral hygiene
- Occlusal force
- Prosthetic characteristics
- Opposing element characteristics
- Indicators of parafunctions
- Periodontal parameters

Exam 3: 4 weeks (+/- 3 days) after exam 2

- Peri-implant conditions
- Implant technical complications
- Sleep bruxism (3 nights)

Exam 4: 6 weeks (+/- 1 week) after exam 3

- Peri-implant conditions
- Implant technical complications
- Quality of plaque

Exam 5: 9 months (+/- 2 weeks) after exam 4

- Peri-implant conditions
- Oral hygiene
- Quality of plaque
- Awake bruxism
- Smoking
- Occluding pairs
- Opposing element characteristics
- Implant technical complications
- Indicators of parafunctions
- Periodontal parameters
- Sleep bruxism (3 nights)

Exam 6: 6 months (+/- 3 weeks) after exam 7

- Peri-implant complications
- Implant technical complications

Onderzoeksproduct en/of interventie

Placement of one or more dental implants which will support fixed suprastructures.

Contactpersonen

Publiek

Academic Centre for Dentistry Amsterdam
Magdalini Thymi

0205980802

Wetenschappelijk

Academic Centre for Dentistry Amsterdam
Magdalini Thymi

0205980802

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Planned for treatment with implant-supported fixed suprastructure(s).
- 18 years of age or older.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Opposing teeth of implant-supported fixed suprastructure(s) are restored with removable artificial teeth.
- Patients categorized in the classes 3 or higher according to the ASA system for classification of physical status.
- Use of occlusal splint, mandibular repositioning appliance or any other bruxism mitigating device during sleep.
- Active periodontitis at the time of implant placement.
- Known allergy to Grindcare® electrode material.
- Patients with a pacemaker.
- Swollen, infected or inflamed tissues or skin eruptions, e.g. phlebitis, varicose veins etc. in the placement area of the Grindcare® electrode.
- Pregnant women will not be treated with dental implants. Pregnancy after placement of implants will not be a reason to stop participation of the subject in the study.

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Anders

Blinding:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	09-01-2015
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	18-12-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45030
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4790
NTR-old	NTR4930
CCMO	NL37715.029.11

Register

OMON

ID

NL-OMON45030

Resultaten