Associations between sleep bruxism and (peri-)implant complications: a follow-up study.

Published: 28-06-2012
Last updated: 15-05-2024

To investigate the time course in which (peri-)implant complications (i.e. inflammation and bone loss around dental implants and implant technical complications) develop and to identify the associations of sleep bruxism with these complications.

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

Summary

ID

NL-OMON45030

Source
ToetsingOnline

Brief title
Sleep bruxism and (peri-)implant complications.

Condition

- Other condition

Synonym
Inflammation and loss of peri-implant tissues and implant technical complications.
Inflammation and loss of mucosal and bone tissues around an implant and implant technical problems.

Health condition

Prognosis for dental implant treatments.

Research involving

Human

Sponsors and support

Primary sponsor: Academic Centre for Dentistry Amsterdam (ACTA)
Source(s) of monetary or material Support: Sunstar Suisse SA

Intervention

Keyword: Follow-up study, Peri-implant conditions, Sleep bruxism, Technical complications

Outcome measures

Primary outcome

Peri-implant inflammation and bone loss.

Implant technical complications.

Secondary outcome

Not applicable.

Study description

Background summary

Prognosis for a dental implant treatment is evaluated in terms of technical and biological aspects. Dental implant complications consist mainly of mechanical complications related to implant components or suprastructures (i.e., artificial teeth on the implants) and biological complications related to peri-implant mucosal or bone tissue. Clinical and radiographical evaluations of the peri-implant tissue conditions are generally considered to be important for detection of early signs of these implant complications.
Previous studies report that formation and development of a microbial biofilm around an implant is an important etiologic factor in the pathogenesis of peri-implant mucositis and peri-implantitis. Based on current literature, it is unclear whether mechanical implant loading contributes to the peri-implant tissue complications (i.e., inflammation and bone loss) due to the study designs (retrospective cohort study) and/or lack of definition of loading condition.
Sleep bruxism (SB), is defined as a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible during sleep. Most individuals have the manifestation

of the muscle activity, although it differs between individuals, i.e., some individuals manifest more activities, than others.. Therefore, it should be noted that virtually all individuals clench and/or grind during sleep with individual variation. SB is considered to be an important source of loading applied to implants. However, a relationship between SB and (peri-)implant complications has not yet been demonstrated, which is partly because of the large variation in the literature in terms of both the technical and the biological aspects of implants and the suprastructures. Clearly, the peri-implant complications (inflammation and bone loss) have a multifactorial etiology and therefore, in this study, all etiological factors that have been identified to date will be taken into account. SB will be monitored by measuring masticatory muscle activity during sleep. As to avoid variation in the outcomes caused by failing retention of removable suprastructures, we will confine our study population to patients treated with fixed suprastructures.

Study objective

To investigate the time course in which (peri-)implant complications (i.e. inflammation and bone loss around dental implants and implant technical complications) develop and to identify the associations of sleep bruxism with these complications.

Study design

Prospective cohort study.

Study burden and risks

Not applicable.

Contacts

Public
Academic Centre for Dentistry Amsterdam (ACTA)

Gustav Mahlerlaan 3004
Amsterdam 1081 LA
NL
Scientific
Academic Centre for Dentistry Amsterdam (ACTA)

Gustav Mahlerlaan 3004
Amsterdam 1081 LA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Planned for treatment with implant-supported fixed suprastructure.

Exclusion criteria

Opposing teeth of implant-supported fixed suprastructure are restored with a removable denture.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2015
Enrollment:	10

Type:	Actual

Ethics review

Approved WMO Date:	28-06-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 27266
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT02410681
CCMO	NL37715.029.11
OMON	NL-OMON27266