Clinical, microbiological and radiographical evaluation of implant surface decontamination using air polishing in the surgical treatment of peri-implantitis; a randomized controlled study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON43273

Source
ToetsingOnline

Brief title
Role of air polishing in the surgical treatment of peri-implantitis.

Condition

- Bacterial infectious disorders
- Soft tissue therapeutic procedures

Synonym
peri-implant disease, peri-implant infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: JSM Bench fee

Intervention

Keyword: Airpolishing, Dental implants, Peri-implantitis, Surgery

Outcome measures

Primary outcome

- Mean peri-implant bleeding score

Secondary outcome

- Full-mouth periodontal bleeding score;

- Mean peri-implant and full-mouth periodontal suppuration on probing score (%);

- Mean peri-implant and full-mouth periodontal probing pocket depth;

- Mean peri-implant and full-mouth periodontal plaque score (%);

- Marginal soft tissue recession (REC);

- Radiographic marginal peri-implant bone level and bone defect configuration

on standardized intraoral radiographs;

- Microbiological composition of the peri-implant and periodontal area;

- Implant failure, defined as implant mobility of previously clinically

osseointegrated implants and removal of non-mobile implants because of

progressive marginal bone loss or infection;

- Tooth loss, defined as removal of teeth because of progressive marginal bone

loss or infection;

- Complications and adverse events.

Study description

Background summary

Peri-implantitis is an infectious condition of the tissues around osseointegrated implants resulting in loss of supporting bone and clinical signs of inflammation (bleeding and/or suppuration on probing). Various treatment modalities have been described in the literature including mechanical debridement, pharmaceutical therapy (chlorhexidine, local or systemic antibiotics) and surgical procedures aimed at removing bacteria, smoothening of the implant surface and decontamination of the implant surface. Despite these various treatment strategies, the most effective treatment option in treating peri-implantitis lesions remains unclear. Therefore the search for a potentially beneficial treatment modality for implant biofilm removal is still imperative. One such potentially beneficial treatment might be the use of air polishing. Modern air polishing devices and their specific powders for subgingival application are becoming increasingly significant in the context of maintenance therapy. It has been shown that supportive therapy consisting of debridement and decontamination of implants and suprastructures with air polishing leads to better clinical results than conventional mechanical supportive therapy. On the basis of these considerations the aim of the present study is to investigate the clinical, microbiological and radiographical effectiveness of decontamination of the implant surface during resective surgical treatment of peri-implantitis using air polishing.

Study objective

The primary objective of this randomized controlled trial is to compare the clinical effect of decontamination of the implant surface during the surgical treatment of peri-implantitis using air polishing or hand instruments. The secondary objective is to assess the microbiological and radiographical effect of these treatment options of peri-implantitis.

Study design

This protocol consists of a single-blind, randomized, controlled clinical trial.

Intervention

All patients with peri-implantitis will be treated in a surgical way. Before surgical exposure of the affected implants suprastructures will be removed if

reasonably possible. Granulation tissue will be removed and angular bone defects will be corrected. Surgical exposure will be followed by mechanical cleansing using gauzes and cotton pellets soaked in saline and airpolishing (test) or either hand instrumentation (control). Hereafter implants are rinsed with 1 minute of saline. Finally, the gingival flap will be returned slightly apical (in order to reduce pockets) and will be firmly sutured. The surgery is followed by 2 weeks of rinsing with 0.12% chlorhexidine + 0.05% cetylpyridinium chloride without alcohol twice daily during 30 seconds. After 2 weeks the sutures will be removed. Follow-up will take place at 3, 6, 9 and 12 months.

Study burden and risks

In addition to the regular follow-up visits (after 2 weeks and 3, 6, 9 and 12 months) patients will have one additional appointment for research purposes only. All other data will be collected during the regular follow-up visits (clinical data, microbiological samples, digital intra oral pictures, x-rays).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- The patient is * 18 years of age;
- Unsuccessful treatment outcome in non-surgical treatment phase (see concomitant METC proposal). The patient has at least one endosseous implant in the oral cavity with remaining clinical and radiographical signs of peri-implantitis. Peri-implantitis is defined as probing pockets depths (PPD) of * 5mm in combination with bleeding and/or suppuration on probing and radiographic bone loss * 2 mm after placing the definitive restoration.
- The implants have been in function for at least two years;
- The patient is capable of understanding and giving informed consent.

Exclusion criteria

- Medical and general contra-indications for the procedures;
- A history of local radiotherapy to the head and neck region;
- Pregnancy and lactation;
- Uncontrolled diabetes (HbA1c < 7% or < 53 mmol/mol);
- Use of antibiotics during the last 3 months;
- Known allergy to chlorhexidine;
- Long-term use of anti-inflammatory drugs;
- Incapability of performing basal oral hygiene measures as a result of physical or mental disorders;
- Active periodontal disease at remaining dentition (Probing pocket depth*6mm, bleeding*20%) and/or insufficient oral hygiene (plaque*20%)
- Implants with bone loss exceeding 2/3 of the length of the implant or implants with bone loss beyond the transverse openings in hollow implants;
- Implant mobility;
- Implants at which no position can be identified where proper probing measurements can be performed;
- Previous surgical treatment of the peri-implantitis lesions;
- Chronic bronchitis and asthma

Study design

Design

Study phase: 3

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2017
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO

Date:	25-10-2016
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

No registrations found.

In other registers

Register	ID
CCMO	NL58447.042.16

Study results

Date completed:	22-01-2020
Actual enrolment:	58