Clinical, microbiological, radiographical and heamatological evaluation of implant surface decontamination using air polishing in the non- 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-OMON43349

Source
ToetsingOnline

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

Condition

- Bacterial infectious disorders

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, Non-surgical, Peri-implantitis

Outcome measures

Primary outcome

- Mean peri-implant 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 (%);

Secondary outcome

Full-mouth periodontal bleeding score;

- Marginal soft tissue recession (REC);

- Radiographic marginal peri-implant bone level

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

- Need for additional surgery at teeth and implants;

- 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.

- Haematological parameters (only for 20 edentulous patiënts already

participating in the non-surgical RCT):

- number of leucocytes,

- number of erythrocytes,

- erythrocyte sedimentation rate (ESR),

- number of thrombocytes,

- level of interleukin 6,

- concentration of C-reactive protein (CRP).

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 non-surgical and surgical treatment modalities have been described in the literature including mechanical debridement and/or pharmaceutical therapy (chlorhexidine, local or systemic antibiotics), aimed at removing bacteria and decontamination of the implant surface. Despite these various treatment strategies, the most effective treatment option for treating peri-implantitis lesions in a non-surgical way remains unclear. Therefore the search for a potentially beneficial treatment modality 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. For non-surigcal treatment of peri-implantitis, air polishing has only scarcely been investigated. Studies that evaluated air polishing as non-surgical treatment had small sample sizes and study designs varied among these studies. If peri-implantitis is left untreated it may ultimately lead to implant loss. Moreover, it is thought that peri-implantitis, like periodontitis, may extort systemic effects. The inflammatory burden, consisting of bacteria and inflammatory mediators entering the systemic circulation, is thought to be related to the amount of inflamed peri-implant tissue. The greater the amount

of inflamed peri-implant tissue, the greater the amount (and the chance) of bacteria and inflammatory mediators entering the systemic circulation may be. 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 non-surgical treatment of peri-implantitis using air polishing. In addition, haematological samples will be analyzed in order to evaluate the influence of peri-implantitis on systemic inflammatory parameters (compared to standard values) and to evaluate the effect of therapy on systemic inflammatory parameters.

Study objective

The primary objective of this randomized controlled trial is to compare the clinical effect of decontamination of the implant surface during the non-surgical treatment of peri-implantitis using air polishing or ultrasonic treatment. Secondary objectives are to assess the microbiological and radiographical effects of these treatment options of peri-implantitis and to evaluate the influence of peri-implantitis and its treatment on systemic inflammatory parameters.

Study design

This protocol consists of a single-blind, randomized, controlled clinical trial. A select group of fully edentulous patients (patients with upper and lower full dentures) participating in the RCT will additionally be selected for hematological evaluation.

Intervention

All patients with peri-implantitis will be treated in a non-surgical way. Patients will receive a full mouth periodontal and peri-implant treatment by a professional oral hygienist in one or multiple sessions (depending on the periodontal health status) Patients will be randomly assigned to a test or control group. In the test group implants will be cleaned with the use of an air abrasive device. In the control group implants will be cleaned with an ultrasonic device (=care as usual). In both the test and control group, the remaining dentition (teeth) will be cleaned using an ultrasonic device and hand instrumentation. Immediately before subgingival debridement, all patients will rinse their mouth with 0.12% chlorhexidine + 0.05% cetylpyridinium chloride without alcohol (Perio-aid®) for 30 sec in order to reduce the intra oral bacterial load. Clinical, microbiological and radiographical data will be collected before treatment (T0) and 3 months after treatment (T3). Patients with a successful treatment outcome at T3 (no bleeding/suppuration on probing and pocket depth < 5 mm) will be re-evaluated at 12 months after treatment. Patients with an unsuccessful outcome will continue with a surgical treatment protocol (see concomitant METC proposal)

Additionally, in a subset of patients, samples for haematological evaluation will be collected at baseline (before non-surgical treatment, T0) and at 3 months (T3) after the non-surgical treatment.

Study burden and risks

In addition to the regular visit (intake and 3, 6, 9 and 12 months follow-up) all patients will have one additional appointment for research purposes only. Other data will be collected during the regular follow-up visits (clinical data, microbiological samples, digital intra oral pictures, x-rays). The selected group of patients that will participate in the heamatological evaluation will have another two additional appointments for research purposes (before and after treatment (see flow chart page 13). This select group of patients will have 8 instead of 6 appointments in total.

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;
- The patient has at least one endosseous implant in the oral cavity with clinical and radiographical signs of peri-implantitis. Peri-implantitis is defined as progressive loss of marginal bone >= 2mm, as compared to the baseline radiograph (after placing the definitive restoration) in combination with bleeding and/or suppuration on probing (Lang and Berglundh 2011);
- 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 contraindications for the procedures;
- A history of local radiotherapy to the head and neck region;
- Pregnancy and lactation;
- Uncontrolled diabetes mellitus (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;
- 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;
- Previous non-surgical treatment of the peri-implantitis lesions during the last 3 months (scaling or curettage)
- Chronic bronchitis and asthma

Study design

Design

Study phase:	4
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):	27-10-2016
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO Date:	25-10-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-06-2017
Application type:	Amendment
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	NL58438.042.16

Study results

Date completed:	20-11-2019
Actual enrolment:	80