Non surgical peri-implantitis treatment

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23755

Source
NTR

Brief title
NSPT

Health condition

Peri-implantitis

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Graduate School of Medical Sciences, Kolff institute

Intervention

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 (%);
- mPISA

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.
- Immunological biomarkers (IL-1b, IL-6, TNFa, MMP8-, MCP-1, MIP1a, OPG, sRANKL, INFgamma, G-CSF)

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 (Heitz-Mayfield 2014). 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 (Muthukuru et al. 2012). For non-surigcal treatment of peri-implantitis, air polishing has only scarcely been investigated (Sahm et al. 2011 (mild to moderate peri-implantitis), Renvert et al. 2010 (severe peri-implantitis). Sample sizes were small and study designs varied among the 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, immunological samples will be analyzed in order to evaluate the effect of therapy on 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 inflammatory parameters.

Study design

Inclusion: 2016-2019
End of followup: end 2020
Statistical anlysis: beginning 2021
Writing manuscript: 2021
Submission 2021

Intervention

Airpolishing (Perioflow® EMS), Ultrasonic device (Piezon® EMS)

Contacts

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Eligibility criteria

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;
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
- Presents of natural dentition (only for patients in heamatological study)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2016
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-01-2020
Application type:	First submission

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
NTR-new	NL8339
Other	METC UMCG : METc 2016.356

Study results