Pocket irrigation in peri-implantitis treatment

No registrations found.

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

Summary

ID

NL-OMON25224

Source
NTR

Brief title
GUMOZ

Health condition

Peri-implantitis

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: UMCG

Intervention

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);
- 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.
- Patient satisfaction

Study description

Background summary

The most effective approach to treat peri-implantitis remains to be found. Recently, a new pocket irrigator/evacuator device, The Fluxion®, based on an alternated interplay between vacuum and fluid (water), has been introduced. A periodontal study showed decreased probing pocket depths and reduced bleeding on probing1. Moreover patients reported less pain after treatment compared to conventional treatment. Whether the pocket irrigator can be used for treatment of peri-implantitis seems unknown.

Study objective

The aim of the present prospective cohort study is to assess the clinical and microbiological effects and patient-reported pain in the non-surgical treatment of peri-implantitis using a pocket irrigator/evacuator device

Study design

Start inclusion; march 2018
Data collection; march 2018 - march 2019
Data analysis; april 2019
Writing manuscript; june 2019
Submission; july 2019

Intervention

All patients receive extensive oral hygiene instructions (using an electric toothbrush, interdental brushes and floss (Oral-B® superfloss or Meridol® floss, at implants in the esthetic zone only) and mechanical non-surgical debridement of the remaining dentition and the supramucosal areas of the implants using ultrasonic instrumentation (EMS®) and hand

instruments (scalers and curettes) in one session. The submucosal areas of the infected implants will be irrigated using the Pocketirrigator for 25 seconds per site (4 sites per implant), twice weekly during a period of 3 weeks.

Contacts

Public
University of Groningen
Diederik Hentenaar

(+31) 503613846
Scientific
University of Groningen
Diederik Hentenaar

(+31) 503613846

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 (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;
- Uncontrolled diabetes (HbA1c < 7% or < 53 mmol/mol);
- Smoking
- Use of antibiotics during the last 3 months;
- Long-term use of anti-inflammatory drugs;
- Active periodontitis of the remaining dentition (PPD > 5 mm);
- 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 treatment of the peri-implantitis lesions during the last 3 months (scaling or curettage)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2018
Enrollment:	24
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	16-05-2019
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	NL7746
Other	METC UMCG : METC2017.644

Study results