Study protocol

Effect of Influence of invasiveness of subgingival debridements on attachment gain after anti-infective periodontal therapy (ATTGAIN16)

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Introduction

The main issue of non-surgical as well as surgical periodontal therapy is the elimination of vital and mineralized bacterial biofilm by mechanical plaque removal. Particularly in the context of surgical periodontal therapy, the mechanical plaque removal is accompanied by the disposal of granulation tissue.

Current studies, however, suggest that this may be a wrong approach, since the deeper, infra-alveolar soft tissue of periodontal lesions ≥ 5 mm probing depth seems to have a pronounced regenerative capacity after resolution of the periodontal inflammation[4-6].

The conventional manual instrumentation of the root surfaces with curettes or ultrasound scaler resolves the root cement in a layer thickness of on average 24 ± 18 µm, respectively 20 ± 15 µm[9]. However, the opportunity of a regenerative Reattachment would be improved significantly by the retention the root cement. Therefore, the aim of any minimal invasive periodontal therapy is the elimination of the soft/vital bacterial biofilm with the least possible preservation of the existing cement layer with the disclaim of surgical approaches and the explicit elimination of granulation tissue.

In this context the use of subgingival air polishing devices seems to be a promising option[10 11]. Various studies have confirmed the efficiency of subgingival air polishing devices for biofilm removal in a comparable magnitude to ultrasound scales or a combination of hand instruments and ultrasound scales[11-13]. By using a subgingival air polishing devices Bacterial plaque can be removed up to a pocket depth of 5 mm

without damaging the treated root surfaces[14, 15]. Also an alternative cleaning powder of smaller grain size based on the sugar alcohols Erythritols has been performed successfully in randomized clinical trials[16, 17].

Study objective

This study aims to evaluate whether a two-stage anti-infective periodontal treatment strategy, comprising a minimally invasive removal of only soft microbial biofilms with an air polish in the first step and a debridement of subgingival dental calculus with air-scaler and abrasors in a second step, results in a greater reduction of the periodontal attachment level, than a single step strategy, with a sub and supragingival mechanical debridement of soft and mineralized bacterial biofilms at the same time.

The study will be conducted with periodontal patients with deep infra-bony defects.

Material und Methoden

study population

Patients of both sexes with untreated, severe chronic or aggressive periodontitis will be recruited for the study.

inclusion criteria

- at least 15 natural teeth still in situ
- at least 1 tooth with periodontal pocket depths ≥ 6 mm and infra-alveolar bone defect
- Age ≥ 18 years

exclusion criteria

- systematic perodontal therapy ≤ 12 months before the screening time

- need for antibiotic prophylaxis before dental care
- untreated systemic diseases that interfere with periodontal healing (eg: uncontrolled diabetes mellitus).

Study design

1. Baseline examination and group assignment
All patients who meet the inclusion criteria, will be informed about the study objectives and will give their written consent.

The following parameters will be recorded at the beginning of the study on all teeth:

1. Probing Attachment Level (PAL)
(6 sites: mesiobuccal, buccal, distobuccal, mesiooral, oral, distooral)

2. Probing Pocket Depth (PPD)
(6 sites: mesiobuccal, buccal, distobuccal, mesiooral, oral, distooral)

3. Bleeding on probing (BoP) (6 measuring points / tooth)
(6 sites: mesiobuccal, buccal, distobuccal, mesiooral, oral, distooral)

4. Gingival Index (GI)
(each 1 measuring point on the buccal tooth surfaces)

5. Plaque Control Record (PCR)
(4 measuring points: mesial, buccal, distal, oral)

Subsequently, microbial samples will be taken from the deepest gingival pocket per jaw quadrant with the help of sterile paper tips and stored in Eppendorf tubes at -20 C until further analysis.

After baseline examination, the study patients will be randomly assigned to the test or the control group with a computer-generated block randomization list. Randomization will be stratified for smokers and non-smokers.

Antiinfective therapy

The anti-infective therapy will be scheduled promptly within a maximum of 10 days after the Baseline Visit.

Antiinfective therapy test group:
All patients of the test group receive a supra- and subgingival removal of all tooth adherent soft bacterial biofilms in 1-2 sessions, but within 24 h, with a low-abrasive erythritol-based cleaning powder (Air-Flow Pulver Plus, EMS, Nyon, Switzerland). Only supra- and paragingival calculus will be dislodged with sonic / ultrasonic scalers. The presence of subgingival calculus will only be documented. However, an additional mechanical subgingival instrumentation of exposed root surfaces by f scaling and root planing to remove subgingival calculus will not be performed at this time.

Antiinfective therapy control group:
All patients of the control group receive a supra- and subgingival removal of all tooth adherent soft bacterial biofilms in 1-2 sessions within 24 h too, but by using hand scalers and curettes, sonic / ultrasonic scalers, rubber cup and polishing paste.
In contrast to the test group, all exposed subgingival root surfaces will be instrumented to remove all adherent mineralized subgingival calculus.

1. Reevaluation
The 1st re-evaluation is scheduled 28 days (+ 7 days) after completion of anti-infectious periodontal therapy.

PAL, PPD, BoP, GI, and PCR will be re-recorded on all teeth and for patients from the test and the control group and subgingival microbial samples of the deepest pockets in each quadrant will be taken again. Plaque will subsequently be visualized by staining. All patient gains oral hygiene instructions to improve the efficiency of domestic plaque control by appropriate brushing techniques and aids (dental floss / interdental brushes).
All patients of in the test group, will receive a subgingival instrumentation using curettes or ultrasound scalers to subduct the subgingival calculus which just has been documented initially, but not removed.

2. Reevaluation

The 2nd reevaluation is scheduled 56 days (+7 days) after the 1st reevaluation visit.

The parameters PAL, PPD, BoP, GI and PCR will be reassessed in all study patients again. Any remaining oral hygiene deficiencies will be rediscovered by staining, and oral hygiene instructions and suitable brushing techniques will be demonstrated again. Teeth persistent bleeding on probing during reevaluation visit will be subgingivally instrumented with curettes or ultrasound scalers in the control group. The test group will receive a subgingival air polish cleaning with the low-abrasive erythritol-based cleaning powder.

Close out visit

168 days ± 7 days after the first visit (84 days after the second reevaluation), the close out visit is scheduled. The parameters PAL, PPD, BoP, GI and PCR will be reassessed again and microbial samples from the deepest gingival pocket per quadrant will be taken again.

Microbiological analyzes

The collected pooled microbiological samples will be analyzed for the presence of the periodontitis-associated microorganisms Porphyromonas gingivalis, Tannerella forsythia, Treponema denticola and Aggregatibacter actinomycetemcomitans using a commercially available bacterial gene probe test (Carpegen Perio Diagnostik, Carpegen GmbH, Münster). It is also planned to carry out a total genome sequencing of the subgingival microbiome taken from the pockets on all collected microbial samples.

Statistical analysis

Primary endpoint
The primary endpoint of the study is the reduction of the probing attachment level (PAL) between baseline and the final study after 168 days.

Secondary endpoints
As secondary endpoints the pocket depth (PPD), bleeding on probing (BoP), the gingival index (GI), the plaque control record (PCR), and changes in the composition of the subgingival pocket microflora will be evaluated.

Sample size
Assuming an average reduction of an attachment level of -2.0 mm in the control group between baseline and second reevaluation and an assumed standard deviation of ± 0.6 mm, the difference between the test and control group is 0.6 mm for a test strength of 0.9 and an error probability of $p \leq 0.05$, a group size of 2 x 22 patients is required.

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