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Comparing three non-surgical treatments for gum disease

Submission date
27/05/2025

Recruitment status
No longer recruiting

Registration date
28/05/2025

Overall study status
Completed

Last Edited
18/07/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Non-surgical periodontal therapy (NSPT) plays a crucial role in managing gum disease, specifically periodontitis. This condition affects millions of adults worldwide, leading to inflammation of the gums and, if untreated, can result in tooth loss. The importance of effective treatment cannot be overstated, as periodontal health is vital for overall well-being.
This study aimed to compare the effectiveness of three different non-surgical treatment methods: quadrant-wise scaling and root surface debridement (Q-Sc+RSD), full-mouth disinfection (FMDis), and full-mouth debridement (FMDeb). Each of these methods has a unique approach to cleaning the teeth and gums, targeting harmful bacteria that contribute to gum disease.
The main objective was to determine which treatment method provided the best results in improving gum health for patients diagnosed with stage II and III periodontitis, according to the American Academy of Periodontology (AAP) and the European Federation of Periodontology (EFP) classification from 2017.
To achieve this, the study focused on measuring two key indicators: probing pocket depths (PD) and bleeding scores (BS). Probing pocket depth indicates the severity of gum disease, as deeper pockets suggest more advanced disease. Bleeding scores assess gum health, as bleeding can indicate inflammation. By comparing these measurements before and after treatment, the study sought to gather valuable data on the effectiveness of each treatment.

Who can participate?
To ensure the study included appropriate and relevant participants, specific inclusion criteria were established. Candidates had to be adults aged 35 years or older and diagnosed with generalized stage II or III periodontitis. This age range was selected because periodontal disease typically affects adults, and it is crucial to gather data that is applicable to this population.
In addition to age, participants needed to have at least three treatable quadrants in their mouth. Each quadrant had to contain a minimum of four teeth exhibiting deep pockets, which indicate the presence of disease. This requirement ensured that only individuals with significant periodontal issues were included in the study.
Furthermore, participants were required to consent to random assignment to one of the three treatment methods. This randomization was essential to eliminate bias in treatment assignment and ensure that the results could be fairly compared across the different groups.

What does the study involve?
The study involved a structured treatment process, where participants were randomly assigned to receive one of the three non-surgical methods. Each treatment aimed to effectively clean the teeth and gums, reducing harmful bacteria that contribute to periodontal disease.
Quadrant-wise scaling and root surface debridement (Q-Sc+RSD): In this method, treatment focused on one quadrant of the mouth at a time. Clinicians thoroughly cleaned the deep pockets around teeth, allowing for detailed attention to each quadrant.
Full-mouth disinfection (FMDis): This method aimed to disinfect the entire mouth during a single session. It involved a comprehensive cleaning process that targeted all deep pockets around teeth simultaneously, combined with the use of mouthwash containing chlorhexidine gluconate.
Full-mouth debridement (FMDeb): Similar to FMDis, this method involves cleaning all deep pockets around teeth in one visit without any chemical adjunct.
Throughout the study, participants attended regular dental check-ups to monitor their gum health closely. These visits allowed clinicians to measure the effectiveness of each treatment method. Data on probing pocket depths and bleeding scores were collected before treatment and again after treatment (after 8 weeks) to evaluate changes in gum health.
Participants also received guidance on oral hygiene practices to maintain their gum health after treatment. This comprehensive approach ensured that participants not only underwent effective treatment but also learned how to care for their gums moving forward.

What are the possible benefits and risks of participating?
Participating in this study offered several potential benefits for individuals suffering from periodontitis. One of the main advantages was receiving focused and monitored treatment from a single clinician. This continuity of care can enhance the quality of treatment and ensure that participants' specific needs are addressed throughout the study.
Moreover, participants benefited from receiving all the expected advantages of standard periodontal care. These benefits included a reduced risk of infection, alleviation of pain or discomfort, and improved maintenance of gum health. Participants had the opportunity to actively engage in their treatment and potentially achieve better oral health outcomes.
However, it was important to note that there were no additional risks, hazards, or discomforts beyond those experienced by individuals receiving periodontal treatment in a clinical setting. Participants could expect the usual side effects associated with dental procedures, such as temporary discomfort or swelling, but these were not considered unusual or unexpected.

Where is the study run from?
The study was conducted at the Division of Periodontology within the Faculty of Dental Sciences at the University of Peradeniya in Sri Lanka. This institution is well-known for its commitment to high standards of dental education and research, making it an appropriate setting for such a clinical study. The faculty provided the necessary resources, including trained personnel and facilities, to ensure that the study was conducted effectively and ethically.

When is the study starting and how long is it expected to run for?
The study began on 25/01/ 2021 and continued until 15/02/ 2022. This duration allowed sufficient time for participant recruitment, treatment implementation, and data collection. The structured timeline was important to ensure that results could be analysed comprehensively and that the effectiveness of each treatment method could be accurately assessed.

Who is funding the study?
The study was self-funded by the investigators. However, the Faculty of Dental Sciences

provided essential support by supplying necessary instruments and human resources. This collaboration helped facilitate the successful execution of the study while allowing the investigators to focus on the clinical aspects of the research.

Who is the main contact?
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Contact information

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Principal investigator

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Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

ERC/FDS/UOP/I/2021/05

Study information

Scientific Title
Management of periodontitis by three different approaches to non-surgical periodontal debridement – a comparative clinical study

Study objectives
Full mouth disinfection is more effective than Quadrant wise Scaling +RSD and full mouth debridement.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/01/2021, Ethics Review Committee, Faculty of Dental Sciences (Faculty of Dental Sciences, University of Peradeniya, Kandy, 20000, Sri Lanka; +94 (0)81 205 9390; erc@dental.pdn.ac.lk), ref: ERC/FDS/UOP/I/2021/05

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Periodontitis

Interventions
As guided by the previous literature, preliminary sample size estimation revealed that the required number of patients is 36 (12 patients in one treatment group) at partial eta squared = 0.25, alpha = 0.05, beta = 0.8 with a moderate correlation between repeated measures. This estimation was done to test the hypothesis in a factorial repeated measures model. However, a more specific re-estimation of the sample size was made with our own preliminary data after 6 months from the start of patient recruitment. Accordingly, the sample size was increased up to 45 (15 patients per treatment group).

All patients who fulfilled the inclusion criteria of the study underwent a written informed consent process, after reading the patient information sheet, followed by clarification of queries by the patients. The patients were randomized into one of the study groups, namely (Q-Sc+RSD) or (FMDeb) or (FMDis), by using a block randomization method to generate treatment groups of equal size. Randomization and allocation of patients were done by another person who was not involved in examining or treating the patients. This allocation concealment was used in order to eliminate sampling bias where the principal investigator (PI) treated all the patients in the treatment groups.

The patients underwent detailed periodontal assessments (pocket charting and radiological evaluation with a dental panoramic tomogram/DPT). After confirming the periodontal diagnosis, they were arranged with appointments by the same person who performed randomization, to commence periodontal treatment by the PI of the study.

All patients were examined for plaque score (PLS, %), bleeding score (BS, %), and probing pocket depths (PD). The parameters were recorded in plaque charts and six-point pocket charts. Prior to these periodontal assessments of patients in the study proper, intra-examiner calibration was performed on six other periodontitis patients to verify agreement within the PI for PD measurements.

Plaque (disclosed with disclosing solution) was dichotomously scored as present or absent, and the full mouth plaque score was obtained. Full mouth bleeding score was also obtained dichotomously, as present or absent upon probing. Probing pocket depths were measured in millimetres, by using a William's periodontal probe at six sites of each tooth. Probing depths of 4 mm or greater with bleeding on probing were classified as deep pockets needing root surface debridement. This is in accordance with the current recommendations for achieving endpoints of non-surgical periodontal therapy. The percentage of deep pocket distribution was obtained by dividing the total number of deep pockets (≥4 mm with bleeding) by the total number of tooth sites in the mouth.

Once the clinical measurements were completed, radiographic evaluation with DPT was carried out to confirm the detailed periodontal diagnosis as stage II or stage III periodontitis.

All patients underwent standard hygiene phase care of initial periodontal therapy (step 1 of EFP S3 guidelines, 2020), which included plaque disclosing, meticulous plaque control advice with oral hygiene instructions (OHI), followed by PMPR and removing plaque-retentive factors. Guidance on mechanical plaque removal (toothbrushing instructions and interdental cleaning) was provided to all patients, according to the individual plaque control needs. Plaque control was monitored and reinforced at the subsequent treatment visits for all patients by the same investigator who treated patients. Except for the fact that different treatment groups received three different periodontal debridement protocols, all patients received standard NSPT, with individually tailored OHI. This was to fulfil the objective of achieving optimal plaque control at step 1 of periodontal therapy, in optimizing a successful treatment outcome. Three different periodontal debridement protocols for three treatment groups were as follows.

Study Group 1 (SG1): Quadrant-wise Sc+RSD group (Q-Sc+RSD)
Each patient was treated with scaling and RSD, quadrant by quadrant, starting from the upper right jaw and proceeding clockwise over four sessions at weekly intervals. All patients received standard post-operative instructions and placebo mouth rinsing (described below) for 2 weeks.

Study Group 2 (SG2): Full Mouth Debridement group (FMDeb)
Each patient was treated with scaling and RSD in two visits, arranged on two consecutive days (within 24 hours from one another). Debridement of the right maxillary and mandibular quadrants was done on the first visit, followed by the left quadrants at the second visit. All patients received standard post-operative instructions and placebo mouth rinsing (described below) for 2 weeks.

Study Group 3 (SG3): Full Mouth Disinfection group (FMDis)
Similar to the FMDeb group, each patient received scaling and RSD in two visits, within 24 hours on two consecutive days. Debridement of the right maxillary and mandibular quadrants was done on the first visit, followed by the left quadrants at the second visit. Patients were advised

to brush their tongues with 1% chlorhexidine gel for 1 minute. Additionally, the pockets were irrigated with 0.2% chlorhexidine gluconate (CHX) at the end of each RSD session, according to the disinfection step recommended in the FMDis protocol (irrigation with a syringe, three times for 10 minutes). As the next step, the patients were instructed to use 0.2% CHX mouthwash at home (10 ml, twice daily for 1 minute, over 2 weeks. All patients received standard post-operative instructions and specific instructions regarding the use of chlorhexidine mouthwash at home.

Since the FMDis protocol (SG3) required therapeutic mouth rinsing with CHX, the patients in SG1 and SG2 were also instructed to perform placebo mouth rinsing at home (with warm water) in a similar manner over a period of 2 weeks. This was done with the intention of standardization across all three treatment groups.

Method of subgingival instrumentation (debridement)
As the step 2 treatment, scaling and RSD were performed under local anaesthesia (2% lidocaine with adrenaline 1:80,000) using periodontal curettes (Gracey) supplemented with ultrasonic scaling. All correctable local plaque-retentive factors, such as overhanging/defective restorations, untreated caries, and retained roots, were removed at the quadrant-debridement session or at the step 1 level. The patients were instructed to report any adverse events such as fever, feeling of being ill or any other discomfort to the contact person through the contact numbers provided to them at the recruitment stage.

Following the above treatment sessions for all patients in the three treatment groups, they were recalled every two weeks for oral hygiene assessment and reinforcement of OHI. Oral prophylaxis (PMPR) was also performed supra-gingivally. Plaque scores were obtained at every review visit for monitoring purposes. Eight weeks following completion of treatment, all patients underwent a full-mouth periodontal re-evaluation. These post-treatment measurements were tabulated to compare them with the pre-treatment probing pocket depths, bleeding scores, and plaque scores.

All patients continued to receive periodontal care/supportive periodontal therapy according to the identified periodontal care needs following re-evaluation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Bleeding scores and probing pocket depths were recorded at baseline and post-non-surgical periodontal therapy after 8 weeks. The parameters were recorded in six-point pocket charts. Full mouth bleeding score was also obtained dichotomously, as present or absent upon probing and calculated as a percentage. Probing pocket depths were measured in millimetres using a William' s periodontal probe at six sites of each tooth. Probing depths of 4 mm or greater with bleeding on probing were classified as deep pockets needing root surface debridement. This is in accordance with the current recommendations for achieving endpoints of non-surgical periodontal therapy. The percentage of deep pocket distribution was obtained by dividing the total number of deep pockets (≥4 mm with bleeding) by the total number of tooth sites in the mouth.

Key secondary outcome(s))

Plaque Scores (%) at baseline and post-treatment after 8 weeks. Plaque (disclosed with disclosing solution) was dichotomously scored as present or absent in a plaque chart, and the full mouth plaque score was obtained as a percentage.

Completion date
15/02/2022

Eligibility

Key inclusion criteria
1. Aged ≥35 years diagnosed with generalized stage II and III periodontitis, with at least three (03) treatable quadrants in the mouth requiring RSD, with a minimum of four teeth in any quadrant with deep pockets
2. Only those patients who consented to undergo treatment according to a random assignment into any of the three methods of periodontal debridement were included.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Those who had underlying systemic conditions (uncontrolled diabetes mellitus, leukemia /haematological disorders, pregnancy, and medication-induced gingival overgrowth)
2. Those who were current or previous smokers
3. The patients who had undergone periodontal treatment within the preceding 6 months
4. Those who were on systemic antibiotics within the last 3 months
5. Those who had used oral chlorhexidine preparations or other disinfectants within the previous month

Date of first enrolment
25/01/2021

Date of final enrolment
29/09/2021

Locations

Countries of recruitment
Sri Lanka

Study participating centre
University of Peradeniya
Faculty of Dental Sciences
Kandy
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Sponsor information

Organisation
University of Peradeniya

ROR
https://ror.org/025h79t26

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated will be available upon a request from Chathurika Padmakumari (chathurikapk@dental.pdn.ac.lk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/07/2025	18/07/2025	Yes	No

Other unpublished results			10/06/2025	No	No
Participant information sheet			28/05/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes