Clinical evaluation of ultrasonic subgingival debridement and ultrasonic subgingival scaling combined with manual root planning in patients with periodontitis: study protocol for a randomized controlled trial

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Study protocol

Keywords: Peridontitis, Non-surgical periodontal therapy, Ultrasonic subgingival debridement, Root planing

Posted Date: July 22nd, 2019

DOI: https://doi.org/10.21203/rs.2.11786/v1

Version of Record: A version of this preprint was published on January 28th, 2020. See the published version at https://doi.org/10.1186/s13063-019-4031-y.

Abstract

Background: Periodontal diseases are regarded as the most common diseases of mankind. The prevalence rate of periodontal disease assumes the obvious growth tendency in the whole world, increased by 57.3% from 1990 to 2010. Thereby, effective periodontal therapy is still a long-term task and tricky problem. The goals of periodontal therapy are to eliminate the infectious and inflammatory processes. Root planning, in order to eliminate the “infected cementum”, is an important step in treatment of periodontitis since 1970s. Along with the understanding of endotoxin’s feature on root surface, the necessity of manual root planing has been gradually queried. Ultrasonic instruments wouldn’t remove the cementum excessively, which are more time-saving and labor-saving compared to hand instruments as well. Hence, an increasing number of dentists prefer to scaling with ultrasonic instruments only. However, the necessity of root planing has still been emphasized in the international mainstream views of periodontal mechanical treatment. Therefore, this study is devoted to compare the clinical effect of ultrasonic subgingival debridement and ultrasonic subgingival scaling combined with manual root planing, which taking the implementation of root planing as the only variable and more in line with the clinical situation, hoping to provide some reference to dentists. Methods/design: Forty adult patients who fit the inclusion criteria are being recruited from the Peking University Hospital of Stomatology (Beijing, China). By means of randomization tables, one quadrant of the upper and lower teeth is the test group and the other is the control group. Test group: ultrasonic subgingival scaling combined with manual root planing. Control group: ultrasonic subgingival debridement. In a 24-weeks follow-up period, plaque index, probing depth, clinical attachment loss, bleeding index, furcation involvement, mobility, and patient-reported outcome (visual analog scale for pain and sensitivity) will be observed and documented. Discussion: This study evaluates the effectiveness of ultrasonic subgingival scaling combined with manual root planing and ultrasonic subgingival debridement alone in nonsurgical treatment of periodontitis with a split-mouth design after 1, 3 and 6 months. The result of the trial will potentially contribute to an advanced treatment strategy of periodontitis with ideal clinical outcome. Trial registration: The study has been registered in International Clinical Trials Registry Platform (ICTRP) under the identifier number ChiCTR1800017122. Registered on 12 July 2018. Keywords: Peridontitis, Non-surgical periodontal therapy, Ultrasonic subgingival debridement, Root planing

Background

Periodontal diseases are regarded as the most common diseases of mankind [1]. The prevalence rate of periodontal disease assumes the obvious growth tendency in the whole world, increased by 57.3% from 1990 to 2010 [2–5]. The Global Burden of Disease Study [6] reports that periodontitis is the sixth most prevalent disease. The overall prevalence rate is 11.2% around 743 million people in the worldwide. The prevalence rate of periodontitis in China was higher. According with recent released forth epidemiologic sampling survey in China, the prevalence rate of periodontal disease is 90.9% in group of 35–44 years of age. Given that periodontitis is the main cause of tooth loss in adult population worldwide that affecting their nutrition, quality of life and self-esteem as well as imposing giant socio-economic impacts and

healthcare costs [7–10]. Thereby periodontal therapy is still a long-term task and tricky problem. Periodontal treatment aims to control gingivitis and periodontitis, avoid disease progression leading to tooth loss, retain a functional dentition for a lifetime, preserve self-esteem and improve quality of life.

Subgingival plaque and calculus on the root surface in periodontal pocket are the most important local factors for the occurrence and development of periodontitis. Hence, the ultimate goal of non-surgical pocket/root instrumentation is to render the root free from microbial deposits and calculus. In the past, dentists used a variety of manual instruments (e.g. scalers, curettes) to remove these local irritants. Later, it was found that cavitation effect and microflow generated by vibration of ultrasonic instruments could effectively remove these plaque and calculus, which was widely used in non-surgical treatment of periodontitis. These methods are collectively referred to as “subgingival scaling”. In the 1970s, Hatfield and Aleo found that endotoxin could penetrate to cementum and influence the attachment of fibroblasts, leading to the concept of “root planing”, which means that root surface should be smoothed by manual instruments to effectively remove the infected cementum, so as to remove endotoxin and form a smooth, hard and clean root surface with biocompatibility, which is conducive to the attachment and healing of periodontal tissue [11–13]. By the 1980s, more studies clarified that endotoxin was only loosely attached to the surface of cementum [14, 15], and most of the endotoxin was related to the bacterial biofilm [16–18]. Therefore, it was suggested that excessive root planing for endotoxin removal was unreasonable. In 1994, the first European working conference on periodontology reached a consensus on the term “subgingival debridement”, that is, to use a gentle method to remove subgingival plaque and calculus, and to preserve the cementum as far as possible [19]. Ultrasonic instruments wouldn’t remove the cementum excessively, which are more time-saving and labor-saving compared to hand instruments as well. Hence, an increasing number of dentists prefer to scaling with ultrasonic instruments only. However, the necessity of root planing has still been emphasized in the international mainstream views of periodontal mechanical treatment; ultrasonic subgingival scaling with manual root planing is recommended after supragingival scaling.

The primary objective of scaling and root planing is to restore gingival health by completely removing elements that provoke gingival inflammation (i.e., biofilm, calculus, and endotoxin) from the tooth surface. A large number of in vivo and in vitro research have been conducted to compare ultrasonic and manual instruments, and it was found that there was not much difference between them in clinical effects, changes in microflora and root surface characteristics [20–25]. In fact, there is still a lack of research evidence comparing the clinical effects of ultrasonic subgingival scaling with or without manual root planing. On the one hand, it is difficult to distinguish subgingival scaling from root planing in traditional manual operation; on the other hand, there are fewer dentists using manual subgingival scaling and root planning. Therefore, this study is devoted to compare the clinical effect of ultrasonic subgingival debridement and ultrasonic subgingival scaling combined with manual root planing in nonsurgical treatment of periodontitis, which taking the implementation of root planing as the only variable and more in line with the clinical situation, hoping to provide some reference to dentists.

Objectives and hypotheses

The major goals of the current randomized controlled trial are to compare and evaluate the clinical outcomes of ultrasonic subgingival debridement and ultrasonic subgingival scaling combined with manual root planing.

The primary hypotheses are root planing is an important step in nonsurgical treatment of periodontitis in order to remove subgingival plaque and calculus, eliminate the “infected cementum” and promote healing.

Methods/design

Overview

The study is a prospective single-center, split-mouth randomized controlled trial. 40 patients who are with periodontitis in need of periodontal treatment will be recruited. The assessments, interventions, and follow-ups will be performed at Peking University School and Hospital of Stomatology (Beijing, China). This study has been approved by the ethics committee of Peking University School and Hospital of Stomatology (PKUSSIRB–201734032) and registered in International Clinical Trials Registry Platform (ICTRP) under the identifier number ChiCTR1800017122.

Inclusion criteria

Aggressive periodontitis (AgP): according to the AgP diagnostic criteria established by the international symposium on classification of periodontal diseases in 1999 [26];

1. Aged 18 to 35 years old;

2. Rapid alveolar bone destruction and attachment loss: the probing depth of at least 6 teeth (at least 3 of them are non-first molars and incisors) in the whole mouth is greater than 5mm, and the adjacent attachment loss is greater than 3mm. All were confirmed to have alveolar bone resorption on the adjacent surface by periapical films;

3. The participant did not receive periodontal treatment within 6 months before treatment, and did not take antibacterial drugs for nearly 3 months;

4. There are at least 20 remaining teeth in the whole mouth except the third molars, and at least one molar in each section;

Chronic periodontitis (CP): according to the CP diagnostic criteria established by the international symposium on classification of periodontal diseases in 1999 [26];

1. The patient's onset age was between 35 and 60 years old;

2. The patient was systematically healthy, had gingival bleeding, swelling, pain, halitosis, teeth mobility and occlusion discomfort;

3. At least one molar exists in each section. At least two sites in each quadrant with probing depth greater than 5mm and attachment loss greater than 3mm;

4. At least 50% of all teeth in the whole mouth have the following conditions: (a) there exists sites with probing depth greater than 5mm; (b) alveolar bone absorption is greater than or equal to 30%; (c) bleeding on probing or periodontal abscess;

5. The participant did not receive periodontal treatment within 6 months before treatment, and did not take antibacterial drugs for nearly 3 months;

6. There are at least 20 remaining teeth in the whole mouth except the third molars, and at least one molar in each section.

Exclusion criteria

1. Patients have taken antibacterial drugs within 3 months;

2. Pregnant women or women of child-bearing age who do not take effective contraceptive measures;

3. Systemic diseases such as cardiovascular and endocrine;

4. Allergic to penicillin;

5. Smokers and those who cannot give up alcohol while taking drugs;

6. Patients do not agree to participate in the test, and do not sign the informed consent.

Recruitment

Subjects will be recruited from Peking University School and Hospital of Stomatology. Subjects who are willing to join this trial will receive the study information. Before subject is included in the present study, the consent form must be signed. Figure 1 shows the procedure of participants through this trial.

Groups, randomization, and blinding

Through randomization tables, one quadrant of the upper and lower teeth is the test group and the other is the control group. Test group: ultrasonic subgingival scaling combined with manual root planing.

Control group: ultrasonic subgingival debridement. The therapist will not partake in the statistical analysis. The treatment plan and grouping will be confidential to the examiner and statistical analyst.

Interventions

Test group: ultrasonic subgingival scaling combined with manual root planing.

Control group: ultrasonic subgingival debridement.

Examination

Baseline examination

After the subjects are included, plaque index (PLI), probing depth (PD), clinical attachment loss (CAL), bleeding index (BI), furcation involvement (FI) and mobility are tested before treatment by the examiner (not the therapist).

Examination during the follow-ups

Follow-up

All subjects will be recalled for follow-up at weeks 2, 4, 12 and 24 after the treatment. At weeks 4, 12 and 24 after the treatment, PLI, PD, CAL, BI, FI and mobility will be examined. Any complications will be documented. Besides, subjects will finish a Visual Analogue Scale/Score (VAS) to evaluate pain and sensitivity during the 2 and 4 weeks after treatment.

Primary parameters

The primary parameters of this trial are PD, CAL and BI.

Secondary parameters

The secondary parameters of this trial include PLI, FI, mobility and VAS scale to evaluate pain and sensitivity after treatment.

Sample size

The sample size of this trial is calculated based on the formula: $$N = \left[\frac{\left(z\frac{\alpha}{2}+z\beta\right)\sigma}{\delta}\right]2\left(\frac{1}{Q1}+\frac{1}{Q2}\right).$$

According to the preliminary experiment results and data analysis from currently published articles, the difference of PD with and without root planning (δ) is around 0.5 mm and the standard deviation in groups (σ) is around 0.2 mm.

If the inspection level (α) is set at 0.05 and the power of test (β) is set at 90%, then 18 subjects will be required for each group. Given a loss to follow-up is around 10%, this study will require 20 subjects for each group. Consequently, this trial will require at least 40 subjects in all.

Timeline

The recruitment began in October 2018, and the intervention period will be ending in June 2020. Figure 2 shows the schedule of enrollment, intervention, and assessments.

Data collection and management

The data of the patients will be documented both on spreadsheets and databases. The statistical analysis will be performed by two experimenters independently.

Statistical analysis

Shapiro–Wilk test and Levene variance homogeneity test were performed to test the normality and variance equality, respectively. Continuous normally distributed data were expressed as mean±standard deviation (SD), and non-normally distributed data as median (lower to upper quartile). Paired-Samples T Test or Two-Related-Samples Test were used to identify any differences between groups. Statistical significance difference will be set as P value of less than 0.05. Data analyses will be performed by SPSS software.

Ethical considerations

Ethical approval

The trial has been approved by the ethics committee of Peking University School and Hospital of Stomatology (PKUSSIRB–201734032). Before subjects are officially recruited into this study, they will be given a study information and will be asked to sign a consent form.

Withdrawal

Subjects will be informed that they have the right to withdraw from this trial at any time without providing a reason. If the withdrawal occurs, treatment will also be provided to the subject.

Dissemination of results

The results of this trial will be saved at International Clinical Trials Registry Platform (ICTRP) and published in an international peer-reviewed journal which will allow for anyone access to obtain the results.

Discussion

Periodontitis is strongly associated with the presence of bacterial biofilms and dental calculus on root surfaces. Hence, the ultimate goal of non-surgical pocket/root instrumentation is to render the root free from microbial deposits and calculus. The success of periodontal treatment depends on the removal of deposits from the root surface [27–30]. All kinds of studies performed in different models and under different conditions have indicated that neither hand nor mechanical instrument is superior in removing subgingival deposits [31–37]. There was no significant difference in the changes of PD, CAL and BOP between manual subgingival debridement and ultrasonic subgingival debridement.

Previous studies demonstrated that hand instrumentation curette created the smoothest root surface, whereas mechanical instrument, such as ultrasonic scaler tended to roughen the root surface [38]. Cobb found that manual curettes were more technique sensitive and time consuming [39]. The old concept of infected cementum removal in order to provide the root surface biocompatible for soft tissue healing [11, 12] has been questioned by various studies [15–16]. The utilization of ultrasonic devices for subgingival debridement offers a less aggressive and a more comfortable therapeutic method for both the patient and therapist. But, some researches shown that the comparison between hand instruments and ultrasonic scalers did not show an advantage for machine-driven instruments [40], and tissue trauma was similar both instruments [41]. Therefore, the necessity of manual root planing cannot be completely denied. Hand instrumentation has been recommended to smooth root surface after ultrasonic debridement as the final finishing procedure in treatment of periodontitis-affected roots [42]. At present root planing is no longer to emphasize the deliberate removal of cementum, but to contribute to the removal of subgingival plaque.

This study thus intends to evaluate in vivo the effectiveness of ultrasonic subgingival scaling combined with manual root planing and ultrasonic subgingival debridement alone in nonsurgical treatment of periodontitis with a split-mouth design after 1, 3 and 6 months. We hope that the results could lead to an advanced treatment strategy of periodontitis with ideal clinical outcome.

Trial status

The trial has been registered at International Clinical Trials Registry Platform (ICTRP) under the identifier number ChiCTR1800017122 on 12 July 2018. The recruitment began in October 2018, and the recruitment will be completed in June 2020.

Abbreviations

International Clinical Trials Registry Platform: ICTRP; AgP: Aggressive periodontitis; CP: Chronic periodontitis; PLI: plaque index; PD: probing depth; CAL: clinical attachment loss; BI: bleeding index; FI: furcation involvement; VAS: Visual Analogue Scale/Score; SD: mean±standard deviation.

Declarations

Ethics approval and consent to participate

The trial was approved by the ethics committee of Peking University School and Hospital of Stomatology (PKUSSIRB–201734032). The trial complies with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Checklist. Informed consent will be obtained from all study participants. Before subjects participate in this trial, the consent form must be signed.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Funding

This trial was conducted with no external funding and was instead funded from the Department of Periodontology, Peking University School and Hospital of Stomatology.

Authors’ contributions

YY, YZ, and JH conceived the study design and drafted the protocol. YY, YZ, XW and JH participated in the recruitment and allocation. YY and YZ were the major contributors in writing the manuscript. All authors read and approved the final manuscript.

Acknowledgements

Not applicable.

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Figures

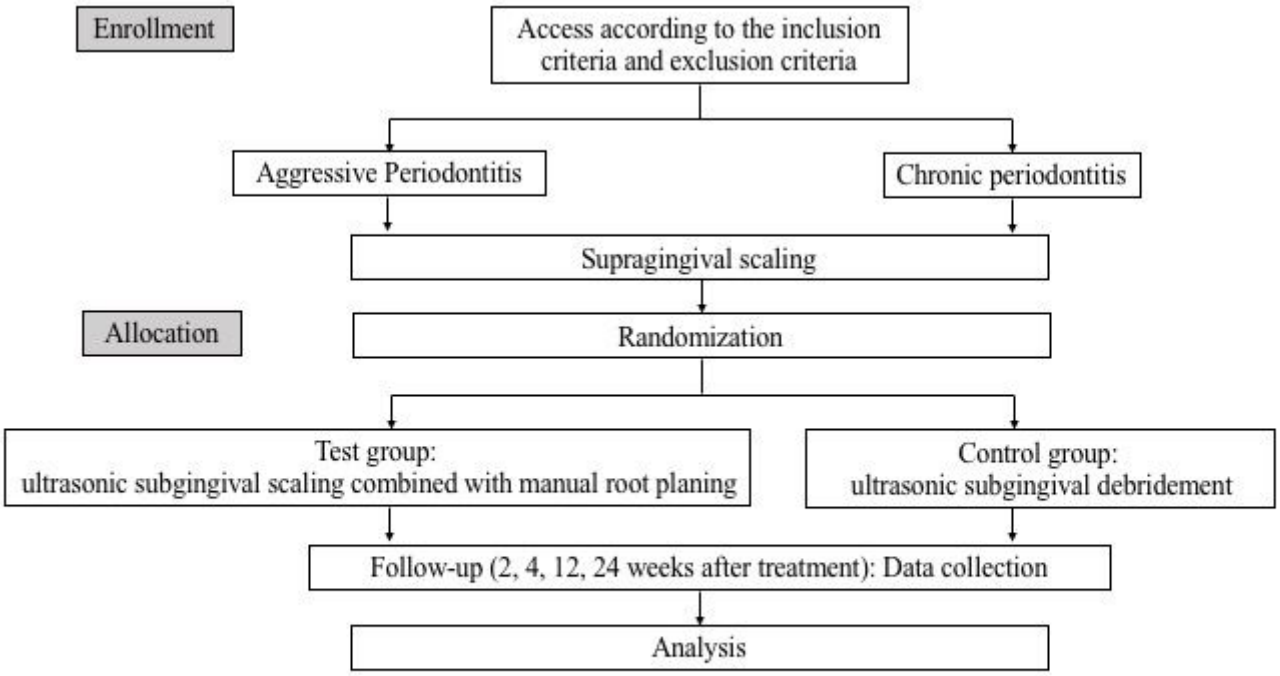

Figure 1

Consolidated Standards of Reporting Trials (CONSORT) diagram.

			STUDY PERIOD				
	Enrollment	Allocation	Baseline	Weeks after Treatment			
TIMEPOINT	**Prior to Allocation**	**0**	**0**	**Week 2**	**Week 4**	**Week 12**	**Week 24**
ENROLLMENT: Eligibility screen	√						
Informed consent	√						
ALLOCATION		√					
INTERVENTIONS: Ultrasonic subgingival scaling combined with manual root planing				←	—	—	→
Ultrasonic subgingival debridement				←	—	—	→
ASSESSMENT: PLI			√	√	√	√	√
PD			√		√	√	√
CAL			√		√	√	√
BI			√		√	√	√
FI			√		√	√	√
Mobility			√		√	√	√
VAS				√	√		

Figure 2

The schedule of enrolment, intervention, and assessments. Abbreviation: plaque index (PLI), probing depth (PD), clinical attachment loss (CAL), bleeding index (BI), furcation involvement (FI), Visual Analogue Scale/Score (VAS).

Supplementary Files

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