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Title: Er:YAG versus Scaling and Root Planing for the Treatment of Periodontal Disease: A Single-Blinded Split-Mouth Randomized Clinical Trial

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Abbreviated Title: Treatment of Periodontitis with Er:YAG laser

BACKGROUND

STUDY PURPOSE AND RATIONALE

The purpose of this study was to examine the changes in clinical parameters 3 months after non-surgical periodontal treatment was performed with two different treatment modalities, conventional scaling and root planing and Er:YAG laser.

STUDY DESIGN

The study was conducted as a randomized, split-mouth clinical trial. Thirty subjects were recruited and right and left side (upper and lower quadrant on each side) of the patients' mouths were randomly assigned to the two treatment modalities:

1. Conventional scaling and root planing:
   Treatment was performed with Cavitron® and hand instrumentation (11/12 and 13/14 gracey's, 11/12 and 13/14 mini gracey's, 4R/4L curette and sickle scaler)
2. Er:YAG laser:
   Treatment was performed with Cavitron® and the laser set at 50 mJ and 20pps, with water irrigation (set at 10) and air cooling (set at 7). C400F and PS600T tips (J. MORITA MFG. CORP, Kyoto, Japan) were used. Er:YAG was used for further calculus removal; root debridement and decontamination; ablation of the epithelial lining to avoid downgrowth of epithelium; and ablation of diseased connective tissue, in the inner surface of the gingival epithelium and/or in any existing vertical defect. Removal of inflamed epithelial and connective tissues on the external surface was also achieved in order to promote faster inflammation reduction. Subsequently, blood coagulation was accomplished with defocused irradiation and without the cooling water spray. Irradiation was accomplished using the tip parallel to the root surfaces, starting at the deepest portion of the periodontal pocket, in a sweeping motion, slowly moving towards the coronal aspect of the pocket.

Inclusion criteria:

- Signed and dated Informed Consent
- Good general health
- Participants ≥ 18 years of age
- Participants with ≥ 20 teeth with 5 teeth, including at least 1 molar, in each quadrant of the mouth
- Participants with ≥ 30% of the present teeth with Probing depths of > 4mm and BoP
- Non-smoker and former smokers (stopped smoking > 1 year)
- Participants that have not received any periodontal treatment in the past 3 months

Exclusion criteria:

- Participants with uncontrolled systemic diseases that could affect the treatment outcome such as Diabetes with HbA1c > 7.0 percent, rheumatoid arthritis, immunosuppression, HIV with detectable viral loads
- Participants requiring antibiotic prophylaxis for any cardiovascular conditions or after any transplant and/or replacement procedures
- Pregnancy
- Patients treated with systemic antibiotic therapy of periodontal/mechanical/local delivery therapy within 6 weeks prior to study entry and throughout the study duration
- Patients being chronically (two weeks or more) treated with any NSAIDs, steroids or any medications known to affect soft tissue condition (excluding treatment with Acetylsalicylic acid < 100 mg/day)
- Presence of orthodontic appliances, or any removable appliances that impinges on the tissues being assessed
- Presence of soft or hard tissue tumors of the oral cavity
- The presence of any medical or psychiatric condition or any other condition that, in the opinion of the Investigator, could affect the successful participation of the patient in the study

RECRUITMENT

All patients seen in the pre-doctoral and post-doctoral clinics at Columbia University College of Dental Medicine were considered as potential subjects, and all students, residents and faculty were informed of this study. If any patient met the inclusion/exclusion criteria and showed interest, the study provider was contacted to provide the patient with more information.

STUDY PROCEDURES

Microsoft ® Excel software was used to generate the random sequence that allocated right and left sides (including upper and lower quadrant on each side) to the treatment modalities. Randomization was kept in an encrypted computer to which only the provider had access to. Allocation was revealed only to provider immediately prior to the first treatment appointment.

Examiner was blinded with respect to which one of the two therapies was rendered during the entire duration of the study.

VISITS:

- 1ST VISIT: Review electronic health records, including medical history, medications and dental x rays, check inclusion and exclusion criteria, solve any questions the patient may have and obtain informed consent. The following clinical parameters were recorded: clinical attachment level (CAL), pocket depths (PD), bleeding on probing (BoP) and plaque index (PI), all of them recorded in 6 sites per tooth, and tooth mobility. Patient was given oral hygiene instructions.

  2ND VISIT*: Review electronic health records, including medical history, medications. Oral inspection. Treatment of the assigned side, both upper and lower quadrants, after randomization, with conventional scaling and root planing. Patient will be given oral hygiene instructions. Anesthesia: Inferior alveolar blocks for the mandible and local infiltration for the maxilla with Lidocaine 2% 1:100,000 epinephrine for healthy patients Carbocaine 3% no epinephrine for patients with cardiovascular issues.

- 3RD VISIT*: Review electronic health records, including medical history, medications. Oral inspection. Treatment of the assigned side, both upper and lower quadrants, after randomization, with Er:YAG laser therapy. Patient will be given oral hygiene instructions. Anesthesia: Inferior alveolar blocks for the mandible and local infiltration for the maxilla with Lidocaine 2% 1:100,000 epinephrine for healthy patients Carbocaine 3% no epinephrine for patients with cardiovascular issues.

- 4TH VISIT, 1 month follow up. Review electronic health records, including medical history, medications. Patient was given oral hygiene instructions.

- 5TH VISIT, 3 months follow up. Review electronic health records, including medical history, medications. The following clinical parameters were recorded: CAL, PD, BoP and PI, all of them recorded in 6 sites per tooth, and tooth mobility. Periodontal maintenance with Cavitron ® and hand instruments (11/12 and 13/14 gracey's, 11/12 and 13/14 mini gracey's, 4R/4L curette and sickle scaler) was performed. Patient was given oral hygiene instructions.

* 2ND and 3RD appointments were given within 10 days of each other in order to complete non-surgical periodontal treatment of the whole mouth within that period of time.

INFORMED CONSENT PROCESS

Informed consent with written documentation was obtained from the research participant, by study provider. Due to the high number of Hispanic patients that were expected to be recruited, informed consent in English and Spanish was created and approved by Columbia University's Rascal.

OBJECTIVES

The primary objective of the present study was to compare periodontal clinical parameters (CAL, PD, BoP and PI) after non-surgical periodontal therapy completed with the afore mentioned treatment modalities.

Secondary objectives included record the differences in duration of treatment between the 2 arms of the study, assessing the differences in sensitivity, and evaluate subjects' modality of preference.

POTENTIAL RISKS AND BENEFITS

Therapy for periodontal disease could involve slight soreness and sensitivity, manageable with any *over-the-counter* analgesic. Soft gingival tissues could experience shrinkage due to resolution of inflammation, situation in which clinical crowns of the treated teeth could appear to be slightly longer than previous to the therapy performed.

There is no direct benefit for participating in the study; participants will be contributing to research for treating periodontal disease. However, after treatment, gingival inflammation, sensitivity, soreness, spontaneous or induced bleeding and halitosis will improve after periodontal therapy. Once the etiology of periodontal disease, bacteria, is removed, we hope to arrest the disease progression with the provided active therapy and the subsequent recall visits.

The alternative is not to participate in the study. However periodontal disease should, in all cases, be treated. The alternatives patients would have, are either to refuse all proposed treatments or to undergo therapy with only conventional hand instruments.

STATISTICAL PROCEDURES

Wilcoxon signed-rank test will be performed to assess the significance of the results pertaining to CAL and PPD (significance level of 5%). Student's t test to analyze BOP scores (significance level of 5%) SAS 9.2