6-month Multi-clinic Treatment of Periodontal Disease Using Topical Oxidizing Agents

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Purpose
To evaluate the effects of PeriProtec Method® (PPM) over a 6-month period on the clinical outcomes of patients with periodontal disease.

Introduction
Periodontal disease is a chronic granulomatous anacrobic infection of the tooth-supporting structures (gum and bone). The gradual buildup of bacteria leads to the formation of plaque and tarter build-up on the surface of the tooth (Figure 1, Figure 7). If left untreated, bacterial toxins combined with the body’s immune response to infection can lead to gingivitis and eventually to periodontitis. Periodontal disease is characterized by inflammation of the gums, bleeding, loss of attachment, increased depth of periodontal pocket and eventual tooth loss. Naive clinical oral epidemiological studies estimate that approximately 75% of the general adult population in the US have some form of periodontal disease, with 20-30% having a severe form of the disease. 2,3,8

Current treatment of periodontal disease includes frequent brushing and flossing (traditional therapy), scaling and root planning (mechanical therapy) and antimicrobial systemic therapies. 2,3 Despite inconsistent and ineffective long-term results, scaling and root planning (SRR) is considered the gold standard treatment. Over the past 2 decades, local antibiotic treatments have been added as an adjunct to SRR regimens resulting in modest improvements to probing depth and clinical attachment levels. 2 However the question remains as to whether these improvements are clinically relevant. 2 In addition, these therapies remain inadequate interventions because they fail to maintain the long-term removal of the anaerobic bacteria that cause periodontal disease. 2,3,8,10

The PeriProtec Method® (PPM) combines a non-invasive chemical therapy with mechanical debridement. The chemical treatment commonly uses a prescribed solution of hydrogen peroxide (H2O2), an oxidizing agent that debilitates the alveolar protective coating of the biofilm and its underlying layers and also cleans the oral contours. By introducing oxygen into the anaerobic periodontal environment, the harmful anaerobic bacteria can no longer survive.

Abstract
Objectives: Determine whether use of PeriProtec Method® (PPM) in combination with scaling and root planning (SRR) over 6 months would result in improvements in outcomes measured in patients with periodontal disease (PD).

Methods: 44 patients with mild to severe PD were treated by 6 dentists in separate clinics. Dentists were trained in a 2-day training session. Subject distribution was Dentist A: 11 patients (7 male, 4 female); Dentist B: 9 patients (4 male, 5 female); Dentist C: 15 patients (9 male, 6 female); Dentist D: 4 patients (3 male, age 40, 20); all patients underwent baseline evaluation for PD to both 6 sites per month and BOP diagnosis per site. Prior to treatment, all patients received instruction on supragingival care and the use of PPM. Each Dentist administered a specific combination of PPM and SRR. Treatment Group A received four visits of PPM and Group B received four visits of SRR. All patients received PPM at baseline and PPM and SRR at 6 months.

Results: Baseline averages indicated no significant differences in PPM between Groups A and B (p>0.05), however there was 0% PPD at baseline in Group B (p=0.003). At 6 months, PPM values for 6-month patients for all parameters significantly improved from baseline and were within normal limits (p<0.05). In total, 10 patients had significantly increased BOP (p<0.05) with no significant differences noted between Dentists (p=0.65) or baseline versus treatment Groups (p>0.05).

Conclusions: An appropriately trained general Dentist can effectively administer PPM. PPM is effective for improving PD and BOP within 6 months in mild to moderate cases of periodontal disease regardless of whether full-mouth SRR is followed in PPM or PPM is followed by class-specific SRR.

Figure 1. PeriProtec Method

Figure 2. PPM Baseline

Figure 3. Figure 3. Baseline averages for PPD and BOP regardless of disease. *Indicates statistical significance

Figure 4. Group A change in PPD from baseline to 6-month follow-up regardless of disease.

Figure 5. Group B change in PPD from baseline to 6-month follow-up regardless of disease.

Figure 6. Presentation of change in Pockets-clinician change from baseline to 6-month follow-up regardless of disease

Figure 7. Sample procedure manual PeriProtec®. The key to success of this technology, in this patient population, is the patient’s ability to carry out the 30-minute activity in a day. Treatment recommendations are all per patient. In this case, we recommend twice weekly therapy.

Methods

- **Treatment physicians** – all treating dentists received prior training in administering the PPM:
  - Dentist 1 treated 11 patients (7 male, 4 female, age 52 ± 13)
  - Dentist 2 treated 15 patients (5 male, 10 female, age 57 ± 18)
  - Dentist 3 treated 15 patients (4 male, 11 female, age 55 ± 14)
  - Dentist 4 treated 3 patients (2 male, age 49 ± 20)
  - Total patients treated were 44.

- **Inclusion criteria**
  - Presence of gingival or mild to severe periodontal disease determined via periodontal examination

- **Exclusion criteria**
  - SRP treatment within 3 months prior to enrollment
  - Periodontal surgery within 6 months prior to enrollment
  - Current orthodontics
  - Physical or mental inability to utilize the dental trays for PPM
  - Less than 10% bleeding on probing (BOP) at baseline

- **PeriProtec treatment**
  - PeriProtec was custom made and delivered to each patient (Figure 2)
  - All patients received instruction on supra-gingival care and use of PPM
  - Eligible participants signed an informed consent form prior to participating

Data analysis:
- **BOP data** was converted to percentage data
- **PPD data** was stratified for some analyses:
  - > 0.3 mm – closed pockets
  - > 4.5 mm – mild disease
  - > 6.7 mm – moderate disease
  - > 9.8 mm – severe disease
- Independent t-tests were used for between treatment groups:
  - One way ANOVA's were used for comparison of data

Results

**Baseline**
- **No significant difference in PPD was seen between Groups A and B**: (p-values ranged from 0.323 to 0.552; see Figure 4)
- **Significantly more BOP was seen in Group A at baseline than Group B**: (p<0.003; see Figure 4)

**6 months**
- **PPD values for 0.5mm pockets for patients in Group A and Group B significantly improved from baseline (p<0.001 for both groups)**
- **All patients had significantly decreased BOP when compared to baseline (p<0.001)**

**Conclusions**
- An appropriately trained general Dentist can effectively administer PPM. PPM is effective for improving PD and BOP within 6 months in mild to moderate cases of periodontal disease regardless of whether full-mouth SRR is followed in PPM or PPM is followed by class-specific SRR.