

Initial Study of the Perio Protect™ Treatment for Periodontal Disease

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Purpose:

To objectively evaluate outcomes of Perio Protect Method™ relative to the treatment of periodontal disease.

Introduction:

Periodontitis is an oral disease process initiated by pathogenic bacteria in the oral cavity leading to inflammation, increased periodontal pocket depth (PPD) and clinical attachment loss.^{8,10} Periodontitis affects about 30% of the adult population, 10% of which develop chronic periodontitis.⁵ Consequences of disease progression can also negatively impact the patient's quality of life physically, socially and psychologically.⁹

To date, periodontal disease (PD) treatment includes the traditional therapy of brushing, flossing and supragingival irrigation, the "gold standard" mechanical therapy of scaling and root planing (SRP), antimicrobial delivery systems i.e., antimicrobial microspheres and combination therapy using antimicrobial delivery systems as an adjunct to SRP.^{4,7,11} While these therapies have resulted in PD improvements, they are ineffective in yielding long-term benefits, completely removing bacteria, decreasing treatment frequency, duration and costs and reversing the disease process.^{1-3,9,11}

This pilot study retrospectively evaluated the outcomes of the Perio Protect Method™ developed by Dr. Duane Keller. This FDA approved treatment utilizes periodontal prescription trays containing tetracycline and hydrogen peroxide. Subjective feedback from Dr. Keller, staff and patients suggests improvement in PD prevention and reversal. Quantitative data analysis have not been performed to date.

Abstract:

A new treatment regimen, Perio Protect Method™, is being used to treat all stages of periodontal disease. While subjective clinical response has been positive, no studies have systematically examined this method that uses prescription trays to direct medications into the gingival sulcus.

Objective: To evaluate outcomes of the Perio Protect Method™.

Methods: A retrospective analysis compared pre-treatment and six months post-treatment records for 11 patients with periodontal disease and 2 with gingivitis (56.2±10.1 years; 8 females, 5 males; 5 smokers =39%). Sequential subjects with at least one molar in all quadrants and no standard periodontal treatment for 6 months pre-study were chosen to complete 6 months of the Perio Protect™ program. Disease severity was assessed by probing pocket depth (PPD) and bleeding and established treatment frequency and duration. Teeth exhibiting the worst symptoms of periodontal disease (PPD=5.7±1.8; range= 4-9) and those with the least evidence of disease (PPD=1) were considered in the subsequent analysis. Data was analyzed using paired t-tests. **Results:** Nine patients exhibited bleeding pre-treatment (mean = 20.7±14.0 sites). A significant decrease occurred post-treatment with only three patients exhibiting bleeding (mean = 2.7±4.4 sites; p=0.002). No patients developed any new bleeding sites post-treatment. A significant change in PPD occurred in the most severely diseased teeth with post-treatment PPD of 3.0±2.1 (p<0.00010). The percentage of closed pockets (PPD≤3 mm) in this group post-treatment was 70.8%. All teeth in the least severe range stayed within the normal range post-treatment (PPD≤3 mm).

Conclusions: Treatment outcomes indicate the Perio Protect Method™ is effective in treating periodontal disease. Further studies are necessary to examine its effect on different patient populations over longer treatment times and to compare it to gold standard treatments.



Figure 1. Evaluation of Probing Pocket Depth (PPD) used to determine the severity of PD. The colored markings on the probe indicate the depth (mm) of the respective pocket.



Figure 2. Sample photo illustrating bleeding on probing during pre-treatment evaluation before implementing treatment with Perio Protect Method™.



Figure 3. Sample photo of five month post-treatment evaluation of same patient (Fig. 2) after using Perio Protect Method™. Photo illustrates improved gingival appearance and lack of bleeding on probing.



Figure 4. Perio Protect Method™ Prescription Tray, brush, and medication set-up.

Perio Protect Method™ Protocol:

Prescription Tray Formation

- A stock tray is selected and customized with wax to fit the patient's mouth.
- Impressions are taken of the patient's mouth from the tray selected.
- Prescription trays are fabricated by the lab according to the patient's diagnosis.
- Trays are delivered to the patient and checked for fit by dental staff.

Treatment Application

- With trays tooth side up, one drop each of hydrogen peroxide gel and Sumycin is placed into every other tooth indentation and then spread evenly with a small brush (Figures 4, 5).
- Patient education includes dental staff instruction and in-office video viewing.
- Trays are fully seated with all teeth covered and sealed against gingiva.
- In this study, the trays were worn two times a day for 15 minutes.
- Post-treatment, trays are rinsed with cool water. The mouth may be rinsed with water or mouthwash or the teeth may be brushed.

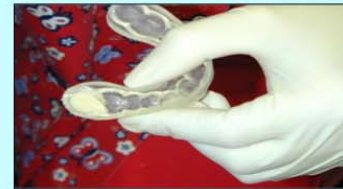


Figure 5. Prescription tray containing hydrogen peroxide gel and Sumycin.

Methods:

- This study was retrospective in nature.
- Subjects consisted of 13 patients, 11 with periodontal disease and 2 with gingivitis (8 females, 5 males; 56.2±10.1 years) seen by a general practice dental clinic between 2003 and 2005. Two subjects did not receive SRP while the remainder underwent the procedure 1-2 times during the 6 month treatment period.
- Patient selection required all subjects to have at least one molar in all quadrants and no standard periodontal treatment for 6 months pre-study.
- Patient records were coded by a staff member of the Keller Professional Group, PC to maintain patient confidentiality.
- Patient records were obtained on basic demographics, pre-treatment and 6 month ±1 month post-treatment evaluation results.
- Disease severity for analysis was determined using probing pocket depth (PPD) and bleeding frequency.
 - Each tooth was evaluated by probing its facial and lingual portion as well as the distal, mesial and central aspect of the respective tooth.
 - PPD was assessed using the following scale:
 - Type 1 – Normal (1-3mm pocket)
 - Type 2 – Mild (4-5mm pocket)
 - Type 3 – Moderate (6-7mm pocket)
 - Type 4 – Severe (8mm pocket)
 - Bleeding was graded a "1" if present, and "0" if absent.
- Two teeth exhibiting the worst symptoms of periodontal disease (PPD=5.7±1.8; range=4-9) and one tooth with least evidence of disease (PPD=1) were considered in the analysis for each subject.
- Data were analyzed using paired t-tests for pre and post treatment values.

Results:

Refer to Figure 6:

- Nine of thirteen patients exhibited bleeding pre-treatment with Perio Protect Method™ (mean = 20.7 ±14.0 sites).
- Significant difference in bleeding occurred with three of nine patients exhibiting post-treatment bleeding (mean = 2.7 ± 4.4 sites; p = 0.002).
- No patients developed any new bleeding sites post-treatment.

Refer to Figures 7 and 8:

- Significant difference in PPD in teeth with worst symptoms with post-treatment PPD of 3.0 ± 2.1 (p < 0.0001).
- The percentage of closed pockets (PPD < 3mm) in this group post-treatment was 70.8%.

Additional results:

- All teeth with least symptoms remained in normal range post-treatment (PPD < 3mm).
- No significant differences occurred between smokers and non-smokers for post-treatment bleeding or PPD.

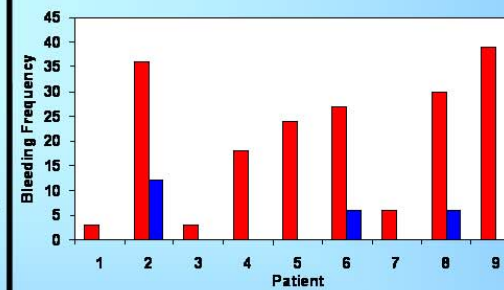


Figure 6. Bleeding frequencies before (red) and after (blue) treatment with Perio Protect Method™. Bleeding frequency = number of bleeding sites at distal, mesial, and central portion of the tooth for both the facial and lingual aspect of the respective tooth.

Conclusions:

Treatment outcomes regarding improvements in bleeding frequency and probing pocket depth indicate the Perio Protect Method™ is effective in treating periodontal disease over a six month period of time. Further studies are necessary to examine its effect on different patient populations over longer treatment times and to compare it to gold standard treatments.

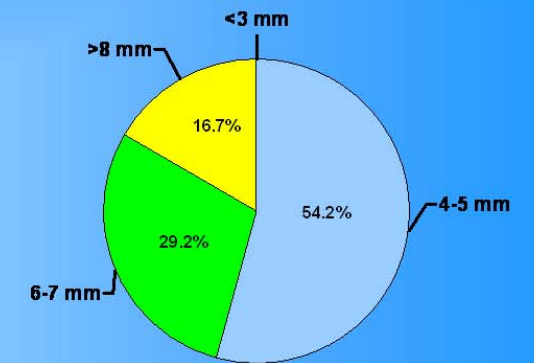


Figure 7. PPD in teeth with worst symptoms before treatment with Perio Protect Method™. Labels represent amount of PPD (mm). Normal = <3 mm, Mild = 4-5 mm, Moderate = 6-7 mm, Severe = >8 mm.

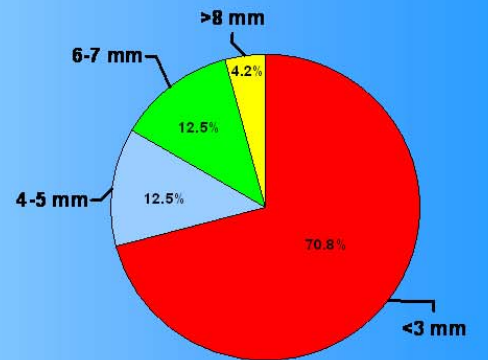


Figure 8. PPD in teeth with worst symptoms after treatment with Perio Protect Method™.

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