# Preliminary Data on Periodontal Disease Treatment Using Topical Oxidizing Agents

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## Purpose

The aim of this study was to evaluate preliminary data of a multi-year, multi-clinic study of the Perio Protect Method™ (PPM) in treating periodontal disease at 3 separate dental clinics.

## Introduction

Periodontal disease is characterized by the presence of pathogenic bacteria that affects the tissues surrounding and supporting a tooth. Detrimental effects can arise if the cause of the disease is not alleviated and host responses including inflammation, loss of attachment, increased depth of the periodontal pocket to the affected tooth, and bleeding of gums continue to occur (Soikkonen K et al, 2000; Needleman et al, 2004). When the condition becomes chronic, correlation with other systemic diseases exists: cardiovascular disease, obesity, low birth weight, and uncontrolled diabetes to name a few (Colhoun et al, 2008; Agueda et al, 2008; Al-Zahrani et al, 2003). To date, periodontal disease continues to be prevalent worldwide which impacts individuals by impairing their ability to function, reduces quality of life and creates a financial burden onto communities (Jain et al, 2008; Cunha-Cruz et al, 2007).

Current treatments to help manage periopathogens include traditional therapies (brushing and flossing), mechanical therapy (scaling and root planing; SRP), and antimicrobial delivery systems (Graham, L., 2003). SRP is considered the "gold standard" for treatment of periodontal disease. While these therapies have resulted in improvements in periodontal disease in the short term, they are ineffective interventions because they do not maintain long term removal of bacteria (Greenstein, G. et al, 2004; Hanes et al, 2003; Mombelli et al, 2004; Swierkot, K et al 2009).

## Abstract

**Objectives**: Presentation of preliminary data from multi-year, multi-clinic study on use of Perio Protect Method™(PPM) - prescription medical device placing oxidizing agents into periodontal pockets in combination with SRP - to treat periodontal disease (PD). This study examines 3-month outcomes on subjects with mild to moderate PD among 3 dentists; one being the inventor of PPM, Dentist 3. **Methods**: 35 subjects were divided: 11 with Dentist 1 (7 females;52.8± 12.7 years;group 1), 10 with Dentist 2 (6 females;56.5±11.0 years;group 2), and 14 with Dentist 3 (10 females;59.5±15.7 years;group 3). Baseline and 3-month follow-up evaluations measured PPDs (6 per tooth) and bleeding on probing (BOP; dichotomous for each tooth). All subjects received instructions in supra-gingival care and PPM use with oxidizing agent (1.7% hydrogen peroxide). Post H2O2 treatment initiation, Dentist 1 and 2 performed quadrant and/or site-specific SRP while Dentist 3 performed only site-specific SRP. Percentage of closed pockets (<4mm) for each subject was calculated. Data analysis used Wilcoxon Signed Ranks and Kruskal-Wallis with post-hoc Kolmogorov-Smirnov. **Results:** No significant difference in closed pockets and BOP among groups was observed at baseline. All groups showed significant improvement from baseline in PPD and BOP ($p<0.05$) except for group 2 which was unchanged on BOP. At follow-up, all groups improved in closed pockets with no significant differences among groups (group 1= 96.0±5.0%; group 2=94.0±4.3%; group 3=96.6±9.7%). All but one subject (Group 3) showed improvement in closed pockets (range all groups=0.5-45.7%). Group 3 had significantly greater improvement in BOP (0.0±0.0%) at follow-up than group 1 (17.8±18.3%;p=0.003) and group 2 (49.9±31.2%;p<0.001). **Conclusion:** Dentists can achieve good results in PPDs in 3 months using PPM. PPD changes along with group 3's decrease in BOP suggest that PPM has the potential to decrease need for extensive invasive dental procedures in early stage PD.

## Method

•Patient Selection: Subjects included both males and females from ages 25-80 obtained from 3 general practice dental clinics.

- Inclusion factors: Subjects committing to a one year study by signing an informed consent form prior to treatment, presence of gingivitis or periodontal disease (determined by periodontal examination) which has not been treated for 3 months pre-study, and available dental records for 1 year pre-study.
- Exclusion factors: SRP within the last 3 months, periodontal surgery in the last 6 months, current orthodontia, and physical or mental inability to use dental trays associated with PPM.

•**PPM Treatment Protocol:** All subjects received instructions in supra-gingival care and PPM use with an oxidizing agent (1.7% hydrogen peroxide). Custom-made Perio Trays® were fabricated and delivered to each subject (Figure 1). Post $H_2O_2$ treatment initiation, Dentist 1 performed quadrant and/or site-specific SRP, Dentist 2 performed full mouth SRP prior to initiating PPM protocol, and Dentist 3 performed only site-specific SRP (Table 1). Daily usage varied by disease severity and doctor preference - most commonly trays were used twice daily for 10 minutes per session.

35 subjects entered the study

Group 1/Dentist 1: 11 subjects (7 females; 52.8 ± 12.7 years)
Group 2/Dentist 2: 10 subjects (6 females; 56.5 ± 11.0 years)
Group 3/ Dentist 3: 14 subjects (10 females; 59.5 ± 15.7 years)

•Outcome measures collected include disease severity measured by pocket probing depth (PPD) and BOP at baseline and 3 month follow-up:

•PPD measured at lingual and facial sites as well as distal, central and mesial. Disease severity was coded as follows:

| Classification | Probing depth |
|---|---|
| Normal | 1-3mm |
| Mild | 4-5mm |
| Moderate | 6-7mm |
| Severe | >8mm |

•BOP was graded as a dichotomous measurement per site.
•Data analysis was blinded to doctor and clinic.
•PPD and BOP measurements were converted to percentages for analyses.
•Changes in gingivitis were noted by examining changes in 1-3 mm pocket depths from baseline to 3 month follow-up (Table 2).

•Analysis: Data analysis used Wilcoxon Signed Ranks and Kruskal-Wallis with post-hoc Kolmogorov-Smirnov.

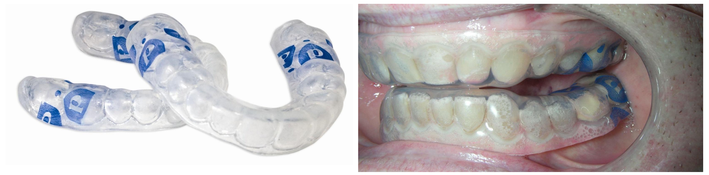


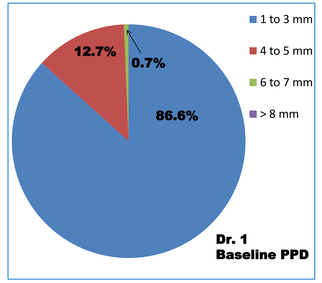
**Figure 1:** Sample of trays. These Perio Trays® are prescription medical devices.

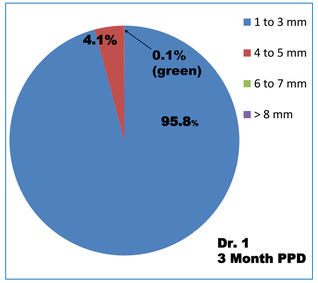
| | Total Patients | No SRP | Site Specific SRP | Full mouth | 1Q | 2 Q | 3 Q |
|---|---|---|---|---|---|---|---|
| **Doctor 1** | 11 | 9 | 1 | 0 | 0 | 1 | 0 |
| **Doctor 2** | 10 | 0 | 0 | 10 | 0 | 0 | 0 |
| **Doctor 3** | 14 | 12 | 2 | 0 | 0 | 0 | 0 |

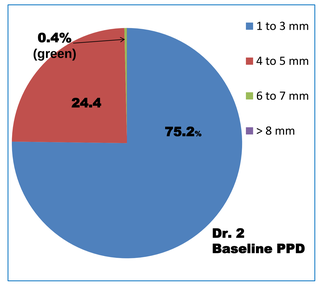
**Table 1**: Amount of scaling and root planing performed at each dental clinic. (Scaling and root planing –SRP; Quadrant -Q)

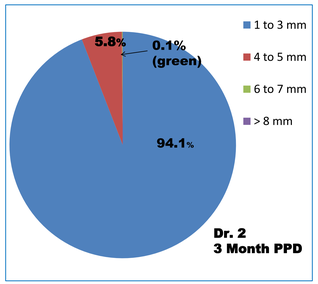
## Results

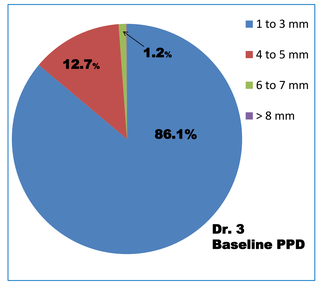
No significant differences in closed pockets and BOP among groups were observed at baseline. All groups showed significant improvement from baseline in PPD and BOP ($p<0.05$) except for group 2 which was unchanged on BOP (Figure 2 and 3). At follow-up, all groups improved in closed pockets with no significant differences among groups (group 1= 96.0±5.0%; group 2=94.0±4.3%; group 3=96.6±9.7%). All but one subject (Group 3) showed improvement in closed pockets (range all groups=0.5-45.7%). Group 3 had significantly greater improvement in BOP (0.0±0.0%) at follow-up than group 1 (17.8±18.3%;p=0.003) and group 2 (49.9±31.2%;p<0.001).



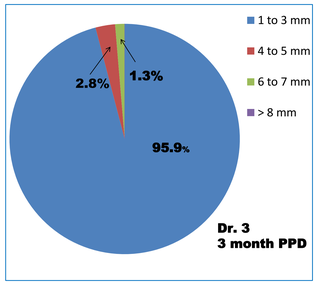




**Figure 2:** Percentage of PPD classification from baseline compared to 3 months from each clinic site

| | Total 3 mm PPD initial | No change | Worse | 3mm to 2mm | 3mm to 1mm |
|---|---|---|---|---|---|
| Doctor 1 | 478 | 49.79% | 1.46% | 45.19% | 3.56% |
| Doctor 2 | 671 | 49.48% | 3.44% | 45.29% | 1.79% |
| Doctor 3 | 752 | 9.71% | 3.59% | 34.97% | 51.73% |

**Table 2**: Data of 3mm PPD from initial compared to 3 months at each clinic site

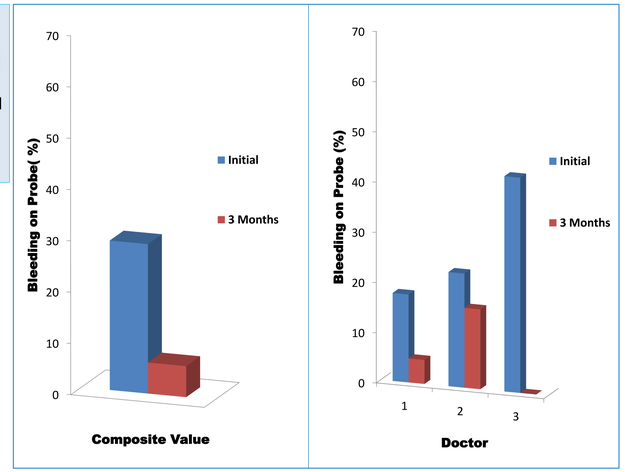



**Figure 3:** Percentage of bleeding on probe compared between doctors and overall.

## Conclusion

This study shows that good results can be obtained within 3 months regardless of dental practitioner. In addition, by performing only site specific SRP when indicated as done in Group 3, PPM has the potential to decrease need for extensive invasive dental procedures in early stage periodontal disease

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