LOMA LINDA UNIVERSITY
School of Dentistry
in conjunction with the
Faculty of Graduate Studies

Custom Application of Peroxide Gel as Adjunct to Scaling/Root Planning in Treatment of Periodontitis

by

Joseph J. Kim

A Thesis submitted in partial satisfaction of
the requirements for the degree
Master of Science in Periodontics

September 2019

Each person whose signature appears below certifies that this thesis in his/her opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.

Chairperson

Yoon Jeong Kim, Associate Professor of Periodontics,

Erik Sahl, Associate Professor of Periodontics

Tord Lundgren, Professor of Periodontics

ACKNOWLEDGEMENTS

I would like to thank Loma Linda University and the entire Advanced Specialty Education Program in Periodontics, LLUSD, for this opportunity to pursue and earn my Master of Science in Periodontics.

A very special ‘Thank You’ to my research guidance committee for their direction with this research. I would also like to thank Dr. Oyoyo and Dr. Alqahtani for their help with the statistical analysis.

To my wife, Susan, for her unending love and support.

CONTENT

Approval Page iii

Acknowledgements iv

List of Figures vi

Abstract viii

Chapter

1. Introduction 1

2. Materials and Methods 4

Trial Design 4
Screening and Recruitment of Patients 4
Eligibility Criteria 5
Exclusion Criteria 5
Interventions 6
Therapy 7
Treatment 7
Maintenance 8
Standardized OHI 8
Non-Surgical Periodontal Therapy 9
Custom HP Tray Fabrication 9
Custom HP Tray Application 10
Outcomes of Clinical Assessment 10
Clnical Periodontal Parameters 10
Examiner Reproducibility 12
Randomization; Sequence, Allocation, and Implementation 12
Follow Up Care 13
Study Schedule 13
Statistical Analysis 16

3. Results 17

4. Discussion 28

5. Conclusion 29

References 30

FIGURES

Figures Page

1. CONSORT Flow Diagram....15
2. Mean PD in each group, SRP, HP13, and HP26 18
3. Mean R-Rec in each group, SRP, HP13, and HP26 19
4. Mean RAL in each group, SRP, HP13, and HP26....20
5. Baseline MQH scores for SRP, HP13, and HP26....21
6. 4-Week MQH scores for SRP, HP13, and HP26....22
7. Re-Evaluation MQH scores for SRP, HP13, and HP26 23
8. Final MQH scores for SRP, HP13, and HP26 24
9. Mean BOP in each group, SRP, HP13, and HP26....25
10. BOP % in pockets initially <5 mm 25
11. BOP % in pockets initially >5mm 26

ABBREVIATIONS

HP	Hydrogen Peroxide
HP13	13-Week Hydrogen Peroxide Group
HP26	26-Week Hydrogen Peroxide Group
OHI	Oral Hygiene Instruction
SRP	Scaling and Root Planing
PD	Pocket Depth
R-Rec	Relative Recession
RAL	Relative Attachment Level
BOP	Bleeding on probing
MQH	Modified Quigley-Hein Plaque Index

ABSTRACT OF THE THESIS

Custom Application of Peroxide Gel as Adjunct to Scaling/Root planning in Treatment of Periodontitis

by

Joseph J. Kim

Master of Science, Graduate Program in Periodontics
Loma Linda University, September 2019
Dr. Yoon Jeong Kim, Chairperson

Aim: This study was aimed to evaluate and compare the clinical effects of scaling and root planning (SRP) combined with local delivery of 1.7% HP in customized trays to that of SRP alone.

Materials and Methods: Sixty patients with generalized moderate to chronic severe periodontitis will be assigned to three groups treated by SRP plus HP gel with a custom prescription tray application. The test groups will receive twice daily 1.7% HP gel in custom trays four weeks prior to SRP and will continue to application for up to 3- and 6-months post-SRP. Baseline data that is collected at the start of the study will be collected again at 4, 13, and 26 weeks post-SRP and analyzed for any changes and thus main outcome variables will include changes in pocket depth (PD), relative recession (R-Rec), relative attachment level (RAL), and changes in bleeding (BOP) using ANCOVA of main effects.

Results: Repeated measure ANOVA showed significant difference in pocket depth among all time points in all treatment groups. Mean BOP was significantly reduced in all groups between 4-week examination and re-evaluation with mean BOP scores at final

examination staying similar to levels at re-evaluation for HP13 and HP26 groups. Mean BOP scores at final examination group for SRP group was similar to baseline.

Discussion: The use of adjunctive HP in custom fabricated trays presents with no adverse effects. Significant improvement was evident in pocket depth and attachment level in both treatment groups between after 4 weeks of using the tray. No significant effect found in SRP group between baseline and 4 weeks. After SRP, significant difference was seen in all three groups between 4 weeks and 3 months.

CHAPTER ONE

INTRODUCTION AND REVIEW OF THE LITERATURE

Currently, the primary non-surgical treatment for chronic periodontitis consists of supra- and subgingival plaque (biofilm) removal and mechanical debridement to reduce the periodontal bacterial load [1-3]. This localized, professionally administered therapy, commonly referred to as scaling and root planing (SRP), usually results in clinical improvement and decreases the progression of the disease [4-6].

SRP alone has significant limitations since studies showed that it is impossible to eliminate subgingival calculus completely and bacteria in dentin tubules [7-10]. Consequently, viable bacteria that remain after SRP repopulate subgingivally, and bacteria constantly introduced into the mouth result in new biofilm formation [11, 12]. As a result, it is necessary to repeat mechanical debridement at least every three months during periodontal maintenance. For these reasons, numerous adjunctive treatments have been investigated and many sustained or controlled-release local delivery of antimicrobial or chemotherapeutic agents are used in the treatment of periodontitis[13]. In addition, there are several problems and limitations associated with the adjunctive therapies for both patients and clinicians, including home care restrictions for brushing and flossing around treated sites, unsuitability for shallow pockets (<5mm), biofilm resistance to antibiotics, and etc. [13, 14].

Topical hydrogen peroxide (HP) application can circumvent many of the limitations and has been shown to reduce plaque and gingival inflammation [15, 16]. Aqueous HP at low concentrations, which has long been used as a debriding agent and wound cleanser, also has an extensive history of topical application with SRP [17-20]. Perio Protect® is a treatment

method combining mechanical and chemical debridement with 1.7% HP gel [21]. The HP gel is directed into periodontal pockets via a custom tray, as an aid to manage biofilms better for patients with gingivitis and periodontitis. The FDA approved ≤3% HP gel as an oral debriding agent and an oral wound cleanser. The FDA also cleared the prescription tray branded as the Perio Tray® (Perio Protect, St. Louis, MO) as a subgingival delivery medical device in 2004 (21 C.F.R. § 872.6870). Customized extensions of the tray support the customized seal to direct the gel deep down into the sulcus or periodontal pocket and overcome the crevicular fluid flow [22].

Custom tray application of the HP gel as an adjunct to SRP in the treatment of chronic periodontitis has been investigated. In randomized controlled studies, it was demonstrated that significant reduction of probing depth (PD) and bleeding without mechanical intervention were seen after two weeks of HP prescription tray regimen followed by SRP and the results were maintained for up to six months with the daily use of HP prescription trays for 10 weeks [22, 23]. The prescription tray delivery of HP gel as an adjunctive to SRP was effective before and after full-mouth SRP in reducing PD about 1mm over SRP alone for six months in chronic periodontitis patients [23, 24]. However, there is currently no randomized control clinical study evaluating the differences in the duration effects of the treatment in chronic periodontitis patients with customized delivery of hydrogen peroxide gel.

The primary objectives of this randomized, controlled, single-blind, parallel clinical study are: (1) to examine if the prescription tray delivery of HP gel adjunctive to SRP results in a greater clinical improvement than SRP alone over a six-month period; and (2) to

evaluate whether the custom tray delivery of the HP gel can decrease inflammation prior to SRP.

The secondary objective is to compare if there is a difference between the length of treatment of adjunctive HP gel (3-months versus 6-months). It is hypothesized that adjunctive HP therapy will provide additional clinical benefits in PD reduction, attachment gain, and reduction of bleeding on probing (BOP) compared to SRP alone.

Null Hypotheses:

There is no significant difference between the treatment groups (SRP + HP_{13} vs. SRP + HP_{26} vs. SRP alone) with regards to reduction in PD.

There is no significant difference between the treatment groups with regards to attachment gain.

There is no significant difference between the treatment groups with regards to BOP.

CHAPTER TWO

MATERIALS AND METHODS

Trial Design

This study is a single-blinded, randomized, controlled, parallel clinical trial. This study has been approved by the Institutional Review Board of Loma Linda University. This protocol is written in concordance to the CONSORT 2010 statement for improving the quality of reports of randomized controlled trials.

Screening and Recruitment of Participants

A study population of sixty qualifying adults was selected by screening from patients who were referred to the Graduate Periodontics Clinic at Loma Linda University School of Dentistry. All patients received a comprehensive periodontal examination and those diagnosed generalized moderate to severe chronic periodontitis [25] showing minimum of one site with PD of ≥5 mm and bleeding on probing (BOP) in at least two quadrants was considered for subject recruitment. Patients who met the inclusion and exclusion criteria were eligible to participate in the study (see Eligibility and Exclusion criteria) and the patients were asked if they were willing to be a subject. Verbal and written informed consent were given to the subject outlining the purpose, timeline, as well as potential risks and benefits of participation. Once the patient accepted and was recruited as a subject they were randomized into groups by a predetermined random group assigner (see Randomization: Sequence, Allocation, and Implementation).

Eligibility Criteria

1) Volunteers who can read and sign the Research Information and Consent Form

2) Male and female adults, aged ≥18 years.

3) Presence of twenty or more (at least 2 posterior teeth in contact per quadrant, one of which is a molar), natural teeth in good state of repair with scorable surfaces.

4) Show evidence of chronic periodontitis, minimum of one site with PD ≥5mm and BOP in at least two quadrants and no mechanical debridement for six months prior to the start of the study.

5) Agree to comply with the conditions and schedule of the study, i.e., willing to use the assigned products (see Treatment Phase and Standardize Oral Hygiene Instruction) according to instructions and be available for appointments.

6) Agree not to have a dental prophylaxis, professional whitening treatment, or any other elective, non-emergency dental procedure (other than those provided) at any time during the study.

7) Willing to refrain from using mouth rinses and tooth whitening products for the duration of the study.

Exclusion Criteria

1) Any systemic conditions or medication intake that can alter periodontal status (e.g. uncontrolled diabetes (with <3-month recent HbA1c of >8.5%), anti-seizure medication, immunosuppressant, and calcium channel blockers with clinical sign of gingival overgrowth.

2) Immune-compromised state.

3) Any current heavy smoking habits (>10 cigarettes/day)

4) Any medical condition or history requiring prophylactic antibiotic coverage prior to dental treatment.

5) Females who are lactating or pregnant (as determined by medical history) or planning to become pregnant for the duration of the study.

7) Physical limitations/restrictions compromising oral hygiene procedures.

8) The presence of significant oral soft tissue pathology and/or lesions associated with ill-fitting appliances or restorations.

9) Tooth mobility associated with advanced periodontal disease (e.g. score of >2 using Miller Classification).

10) Any temporomandibular joint disorders.

11) Grossly carious, orthodontically banded, and third molars will not be included in the tooth count.

12) Presence of any significantly tipped, crowded, or largely defective restorations.

13) Any extreme adverse events relating to the use of HP gel (e.g. prolonged tooth hypersensitivity or aberrant soft tissue/mucosal reaction)

All participants were screened and evaluated at Loma Linda University School of Dentistry Graduate Periodontics Department. There are three groups of 20 patients, two therapy test groups and the control group.

Interventions

The overall study was divided into three phases consisting of: 1) a therapy phase, 2) a treatment phase, and 3) a maintenance phase.

Therapy Phase

The therapy phase consisted of establishing baseline periodontal parameters and implementation of standardized oral hygiene instructions. All subjects were given verbal and visual instructions and demonstrated whether or not they can perform adequate oral hygiene with repeated instructional sessions throughout the study (see Fig. 1). Oral hygiene instructions (OHI) included use of plaque disclosing agent and proper use of indicated oral hygiene aids. The remaining areas of disclosed plaque assessed the quality of oral hygiene. Subjects in the two therapy test groups were given their customized prescription tray along with supervised instructions during their first try-in. The therapy consisted of initiation of 1.7% HP gel delivered in these customized trays (Perio Protect Tray, Perio Protect, LLC, St. Louis, MO, USA) four weeks prior to non-surgical periodontal treatment, SRP, at week 0. Subjects were instructed to deliver the gel 2-times daily for 15 minutes. These subjects also received calendar journals and will be asked to log entries of when they have used their trays.

Treatment Phase

The treatment phase began with non-surgical periodontal treatment. The two therapy test groups will have used their customized application HP gel for four weeks prior to the start of treatment. Non-surgical periodontal treatment consisted of 1-, or 2-visit SRP using ultrasonic and hand instrumentation with local anesthesia. Surfaces were to be deemed clean and debrided when subgingival deposits cannot be tactilely detected and the root surface feels smooth to the operator. Re-evaluation of SRP was done 8 weeks after the last session of SRP, at week 13. One therapy test group stopped using the HP

therapy at the re-evaluation visit (HP13). Whereas the other test therapy group received impressions for a new customized tray to continue application of HP therapy for an additional 13 weeks (HP26) to the termination of the study.

Maintenance Phase

All subjects were recalled 4 weeks after re-evaluation of SRP was done for periodontal maintenance and again 3 months later for their final maintenance. In the HP26 group, subjects continued to use twice-daily HP gel for 15 minutes until the termination of the study, at week 26. Measurements for all subjects, correspondingly, were taken at week 26. Patients enrolled in the study were maintained with 3-month maintenance intervals for the duration of the study (See section Follow Up Care).

Standardized OHI

Subjects were instructed to brush twice daily (morning and evening) with a dentifrice (Crest® Cavity Protection Toothpaste, Procter & Gamble Co., Cincinnati, OH, USA) and an adult, single end-tapered bristle toothbrush (Nimbus®Microfine®, Nimbus Dental, Los Altos CA). Patients will also perform interdental cleaning with aids including standard dental floss, threaded floss (Superfloss®, Oral-B®, Proctor & Gamble, Cincinnati OH), and interproximal brushes (Proxabrush®, TePe® USA, Anaheim CA) of varying sizes depending on embrasure sizes of the patient. Proper technique for each cleaning aid were demonstrated and reiterated at each appointment. Oral hygiene aids were dispensed to the patient four weeks prior to initiation of SRP. Patients have agreed

to refrain from the use of any prescription or over-the-counter mouth rinses and tooth whitening products.

Non-Surgical Periodontal Therapy

All subjects received SRP by periodontal residents, either in their 2nd or 3rd year of specialty training, without time restriction. SRP was conducted with local anesthesia using ultrasonic instruments (Cavitron®, Dentsply® International, York PA) devices and hand instruments (Gracey Curettes, Hu-Friedy®, Chicago IL). Supra- and subgingival surfaces were determined "clean" when the surfaces felt smooth with the use of a periodontal explorer (11/12 After-Five™ Explorer, Hu-Friedy®, Chicago IL). Supragingival surfaces were polished with a rubber cup and polish paste.

Custom HP Tray Fabrication

For subjects enrolled and assigned to the two test therapy groups, impressions of both maxillary and mandibular arches were made using polyvinyl siloxane (PVS) (Exafast™ NDS, GC America, Alsip IL) on stock plastic impression trays. Heavy viscosity vinyl polysiloxane (VPS) (Splash! ®, DenMat®, Lompoc CA) was used to first capture the dental arch and tooth surfaces then the resulting impression trays were impregnated with low viscosity PVS (Exafast™ injection). The impressions was sent to an FDA-registered dental laboratory for fabrication of custom, ethylene-vinyl copolymer trays (Perio-Trays®).

For subjects assigned to HP26, a second impression was taken at the re-evaluation appointment (Visit 5, Week 13) with the same methods as previously described. Once the

new tray was received from the dental laboratory, the patient was recalled and given the new custom tray along with any refills of HP gel.

Custom HP Tray Application

The principal investigator supervised first use of trays and HP gel and, if needed, adjustment were made to trays so that it seated completely and comfortably in the subject's mouth while maintaining an adequate seal. Each subject applied a thin ribbon of gel throughout tooth indentations to provide a dosage of ~0.75 gram in each tray using a mass scale. Treatment frequency will be fixed throughout the study duration:

Start of Treatment (Visit 2, Week 0) to 8-weeks following SRP (Visit 5, Week 13): two treatments per day, 15 minutes each

Subjects in the treatment groups documented tooth brushing and the gel tray applications in calendar journals for the entire duration of the study. Subject compliance was estimated throughout the study by reviewing diaries and by massing gel tubes at each visit. Patients were instructed to bring in their treatment tubes to each visit.

Outcomes of Clinical Assessment

The following clinical assessments were performed throughout the study by the same examiner who was blinded to the treatment rendered to the subjects.

Clinical Periodontal Parameters

When collecting data, the examiner was blinded to treatment groups. Using the same PVS (Exafast™ NDS, GC America, Alsip IL) impressions to fabricate stone models

(Microstone, Whipmix Corp., Louisville, KY) a customized stent was fabricated using a positive pressure thermoplastic mold device (Biostar® Scan/Biostar® V, Great Lakes Orthodontics, New York). This 1-mm thick, semi-rigid stent was used as reference[26] for the linear measurements using a periodontal probe (15 UNC Color-Coded Probe, Hu-Friedy, Chicago IL). All the measurement will be at 1 mm increments. Clinical parameter measurements was taken at six sites (mesio-buccal, mid-buccal, disto-buccal, mesio-lingual, mid-lingual, and disto-lingual) of each tooth. Relative gingival recession (R-REC) was measured from a margin of the stent to the most coronal height of the gingival margin. PD was measured as the distance from the gingival margin to the depth of the pocket. The probe was held flat against the tooth near the gingival margin and inserted into the periodontal pocket in a path that is parallel to the long axis of the tooth and advanced using light pressure until slight resistance is felt. Relative attachment level (RAL) was measured from a margin of the stent to the bottom of the pocket.

Bleeding on probing (BOP) was measured with sites that show any bleeding within 30 seconds of probing and was recorded as a percentage.

Oral hygiene level was measured by using the Modified Quigley-Hein Plaque Index (MQH) [27] with disclosing solution that measures plaque on all teeth except 3rd molars at 4 surfaces on the buccal and lingual surfaces where:

Score 0 has no plaque

Score 1 has separate flecks of plaque along the cervical margin of the tooth

Score 2 has a ≤1 mm band of plaque at the cervical margin of the tooth

Score 3 has a band of plaque >1 mm but <⅓ of the crown of the tooth

Score 4 has plaque that is covering ≥⅓ but <⅔ of the crown of the tooth.

Score 5 has plaque covering ≥⅔ of the crown of the tooth

Full mouth series of periapical and bitewing radiographs was captured for all patients for standard periodontal diagnostic procedure as a part of the comprehensive periodontal evaluation. Radiographs of patients that were referred other clinics taken within a year of the comprehensive periodontal evaluation was used.

Examiner Reproducibility

Collection of clinical periodontal parameters was repeated in 6 patients for inter-examiner reproducibility. This was accomplished by randomly recalling some subjects for a second exam during the same session, as scheduling permits. Scoring at least one other subject before doing the repeat exam minimized the likelihood of the examiner recalling individual scores. Interclass/inter-examiner correlation (ICC) of overall variability was calculated and represented as an ICC score (SPSS, IBM Corporation, Armonk New York U.S.).

Randomization; Sequence, Allocation, and Implementation

Subjects were assigned randomized identification (ID) numbers during enrollment (Visit 1), which will be recorded on all Case Report Forms (CRF) and the Product Accountability Log. Immediately following the preliminary clinical parameter recording the investigators randomly allocated subjects in a group using a predetermined random group assigner (SAS, SAS Institute, Cary NC) based upon subjects' ID numbers. Each subject received non-surgical periodontal therapy (SRP) as indicated in areas with increased probing depths.

Follow Up Care

Patients enrolled in the study will be monitored for any changes in their periodontal status. If deterioration of periodontal conditions is noted (i.e. PD deepening and losing RAL >1.5mm with or without bleeding on probing), re-treatment of sites was recommended to the patient. Any sites requiring re-treatment, either non-surgical or surgical intervention will be excluded in final study data and will be treated as indicated.

Study Schedule

A study schedule summary follows for HP group arms:

- Visit 1: Screening, recruitment, randomization and periodontal consultation was completed. PVS impressions were taken for fabrication of both prescription trays and customized stents created for clinical measurements if patient accepts and were recruited as subjects.
- Visit 2, Week 0: Data collected for clinical measurements with custom stents for RAL, PD and R-rec (Baseline). Delivery of prescription tray and first supervised instructions and placement of the gel for the treatment groups. OHI.
- Visit 3, Week 4: 4 weeks after the delivery of the tray and the gel; data collection of periodontal parameters with stent, 2 quadrants of SRP, reinforcement of OHI. Inquire if subjects had any adverse events with the use of hydrogen peroxide gel
- Visit 4, Week 5: No more than 1-week elapsed time since visit 4; SRP of 2 remaining quadrants, reinforcement of OHI.

- Visit 5, Week 13: Periodontal re-evaluation 8 weeks after last quadrant of SRP; data collection of periodontal parameters with stent, SRP on residual sites with detectable calculus, termination of peroxide use in HP13. For subjects enrolled in HP26 , new impressions were made for new prescription tray.
- (Visit 6, Week 14 [HP26 only]): New prescription tray delivery
- Visit 6, Week 17: Periodontal maintenance, reinforcement of OHI.
- Visit 7, Week 26: Data collection of periodontal parameters with stent (final exam), periodontal maintenance, reinforcement of OHI.

A study schedule summary follows for SRP arm:

- Visit 1: Screening, recruitment, and randomization. Data collection of periodontal parameters by residents and verified by attending periodontists. PVS impressions will be taken for fabricating of customized stents for clinical measurements if patient accept and are recruited as subjects.
- Visit 2, Week 0: Clinical measurements with stents (Baseline).
- Visit 3, Week 4: SRP and OHI
- Visit 3, Week 5: Remaining quadrants of SRP, reinforcement of OHI
- Visit 4, Week 13: Periodontal re-evaluation 8 weeks after last quadrant of SRP; data collection of periodontal parameters with stent, SRP on residual sites with detectable calculus, reinforcement of OHI
- Visit 5, Week 17: Periodontal maintenance, reinforcement of OHI
- Visit 6, Week 26: Data collection of periodontal parameters with stent, periodontal maintenance, reinforcement of OHI.

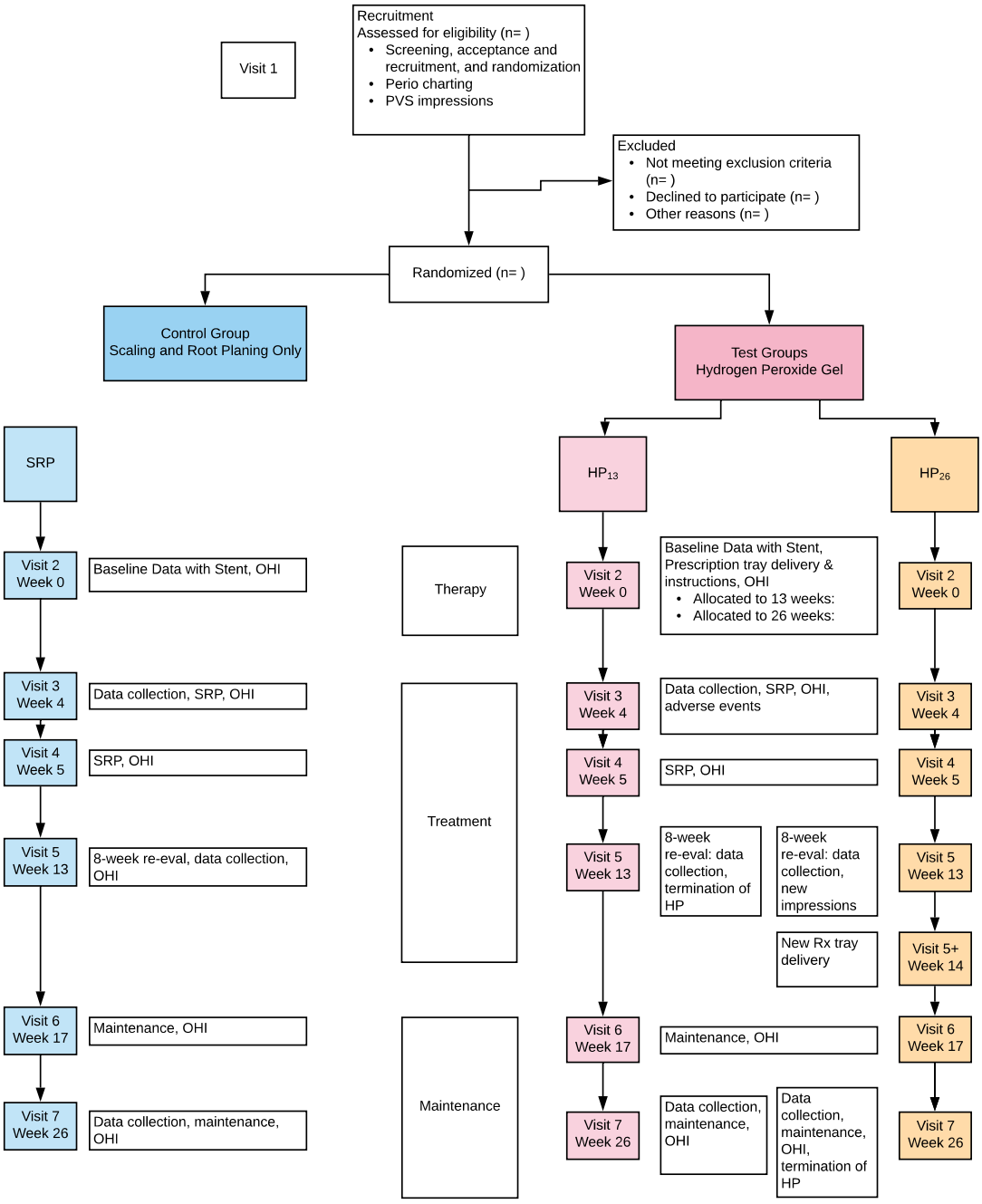


Figure 1. CONSORT Flow Diagram

Statistical Analysis

The primary outcome variables are PD reduction, RAL gain, and reduction in BOP. PD data was computed to provide a mean score per mouth. Secondary efficacy variables were BOP, and MQH. BOP was computed to provide a mean score per mouth for each clinical assessment and were analyzed using repeated measures (ANOVA). Outcome variable data analysis consisted of between-treatment and within-treatment (longitudinal) comparisons of PD and CAL at all examination time points using parametric procedures. Between-treatment and within-treatment comparisons employed baseline data and analysis of covariance (ANCOVA) for follow-up data. All comparisons were performed using two-sided hypothesis tests, and employed a 0.05 level of significance.

CHAPTER THREE

RESULTS

There were total 15 subjects who completed the 6-month trial. There were 10 males with an mean age of 55.6 years and 8 males with an mean age of 51.1 years. There was a total of 3 patients in SRP group, 3 patients in HP13 group, and 9 patients in HP26 group. The mean pocket depth (PD) shown in figure 1 at baseline for SRP group was 3.88 ± 0.06 mm (std. error), 4.11 ± 0.06 mm for HP13, and 3.83 ± 0.04 mm for HP26. At the 4-week examination, PD for SRP group decreased to 3.67 ± 0.06 mm, 4.06 ± 0.06 mm with HP13, and 3.55 ± 0.04 mm for HP26. At the re-evaluation examination, PD for SRP group was 3.30 ± 0.06mm, 3.43 ± 0.06 mm for HP13, and 3.14 ± 0.04 mm for HP26. The final examination, PD were 3.43 ± 0.06 for SRP, 3.40 ± 0.06 mm for HP 13, and 3.23 ± 0.04 mm for HP26. Repeated measure ANOVA showed significant difference in pocket depth among all time points in all treatment groups. In SRP group, no significant difference between baseline and 4 weeks in pocket depth and relative attachment level.

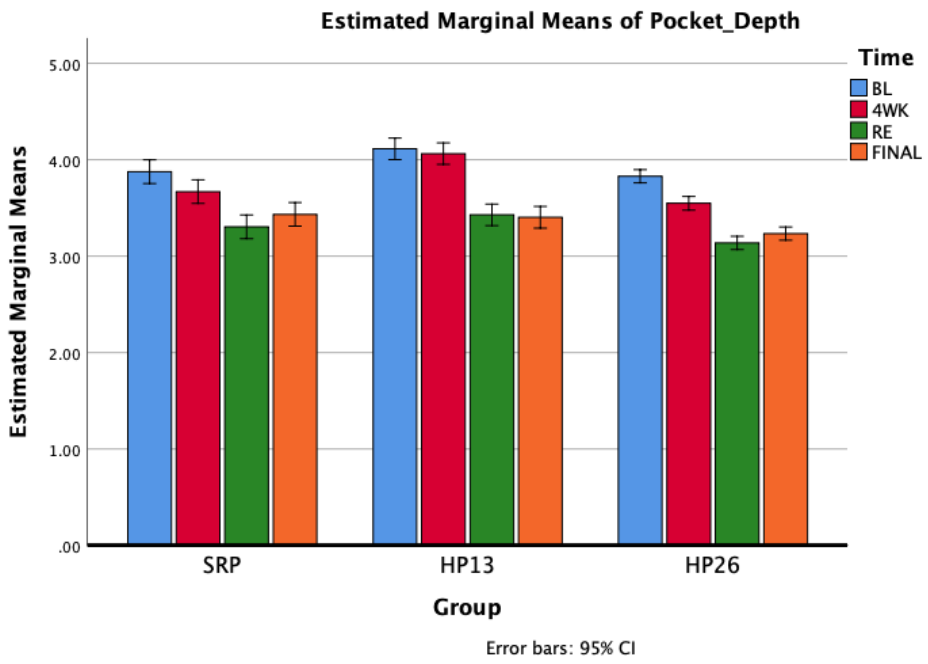


Figure 2. Mean PD in each group, SRP, HP13, and HP26.

Figure 2 shows the mean relative recession over time. The mean relative recession at baseline was 3.28 ± 0.06 mm for SRP, 2.87 ± 0.06mm for HP13, and 3.21 ± 0.03 mm for HP13. At 4-weeks, it was 3.35 ± 0.06 mm for SRP, 3.23 ± 0.05 mm for HP13, and 3.15 ± 0.03 mm for HP26. At re-evaluation it was 3.33 ± 0.06 mm for SRP, 3.27 ± 0.05 mm for HP13, and 3.29 ± 0.03 mm for HP26.

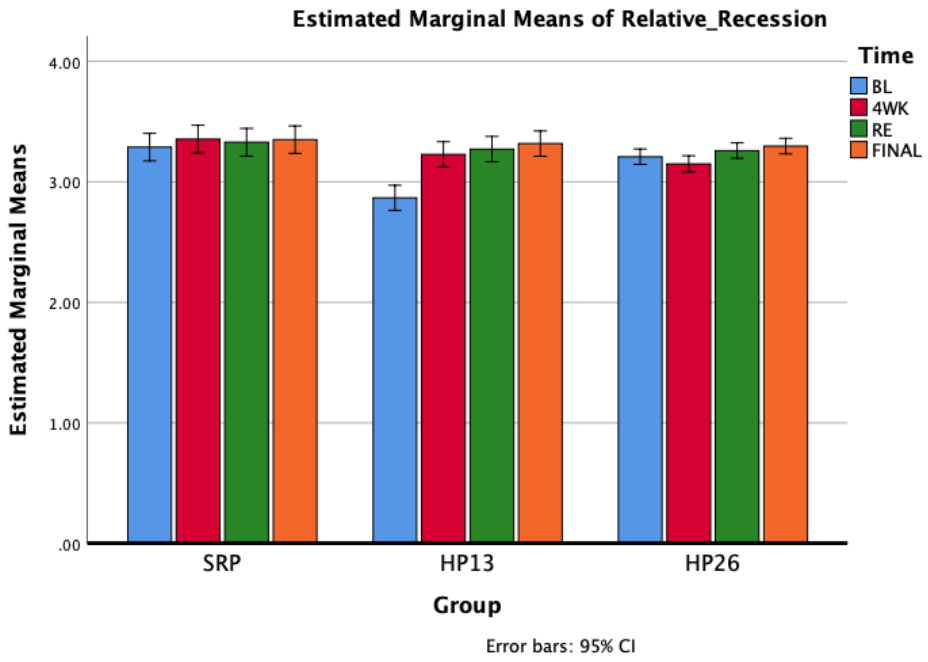


Figure 3. Mean R-Rec in each group, SRP, HP13, and HP26.

Figure 3 shows the mean relative attachment level. The mean RAL at baseline was 7.16 ± 0.08 mm for SRP, 6.97 ± 0.07 mm for HP13, and 7.04 ± 0.04 mm for HP26. At 4-weeks, the RAL was 7.02 ± 0.08 mm for SRP, 7.29 ± 0.07 mm for HP13, and 6.69 ± 0.05 mm for HP26. At re-evaluation the RAL was 6.63 ± 0.08 mm for SRP, 6.15 ± 0.07 mm for HP13, and 6.39 ± 0.04 mm for HP26. At the final exam RAL was 6.79 ± 0.08 mm for SRP, 6.71 ± 0.07 mm for HP13, and 6.53 ± 0.04 mm for HP26.

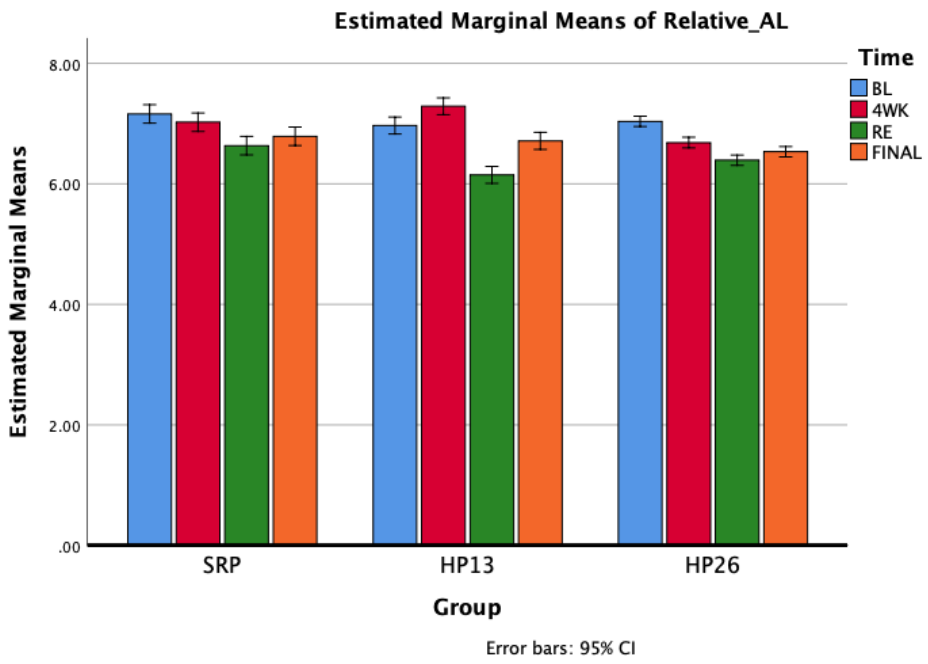
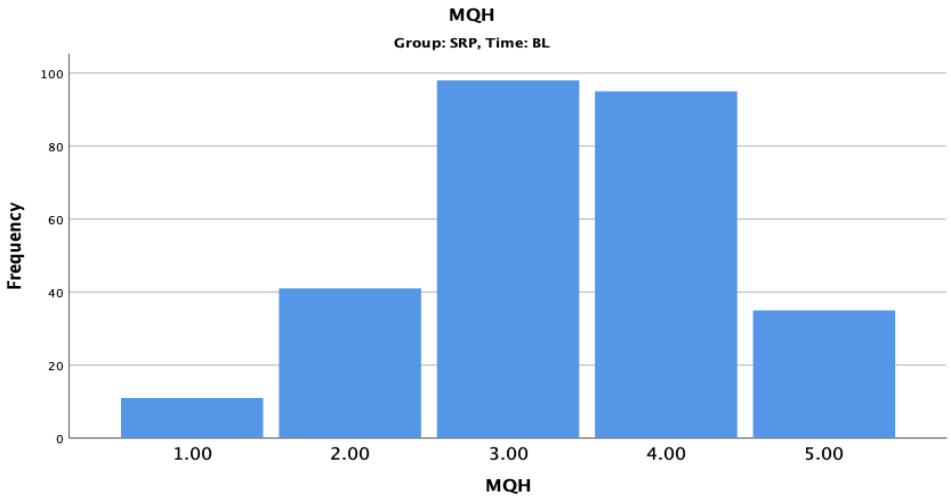
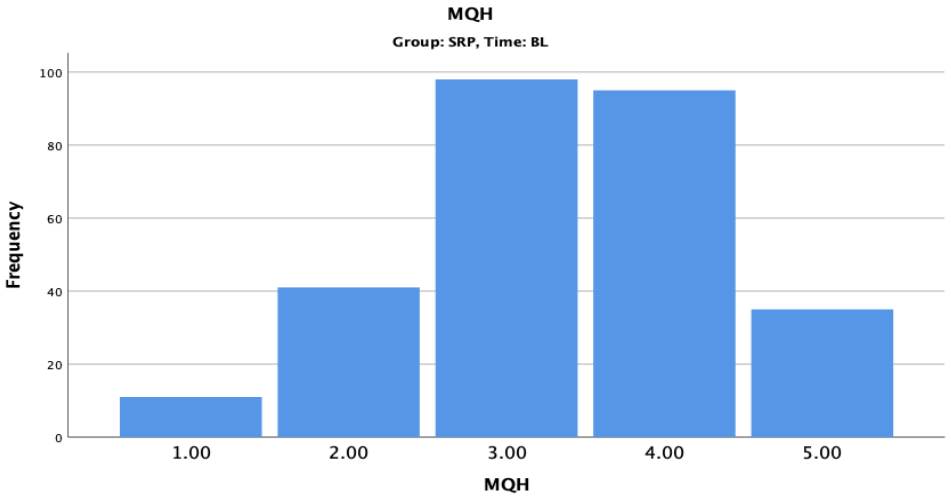


Figure 4. Mean RAL in each group, SRP, HP13, and HP26.

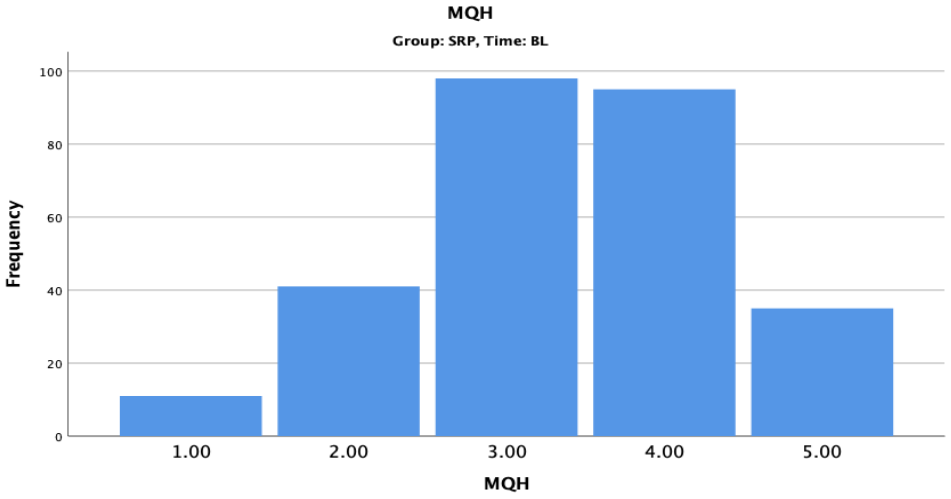
Figures 4, 5, 6, and 7 show baseline, 4-week, re-evaluation, and final MQH plaque scores. Plaque scores varied throughout the four timepoints with no obvious differences between groups.



A)

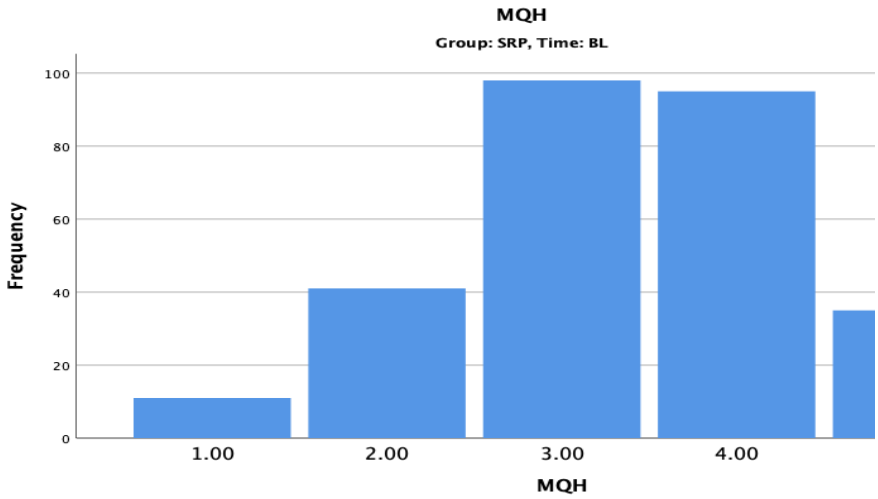


B)

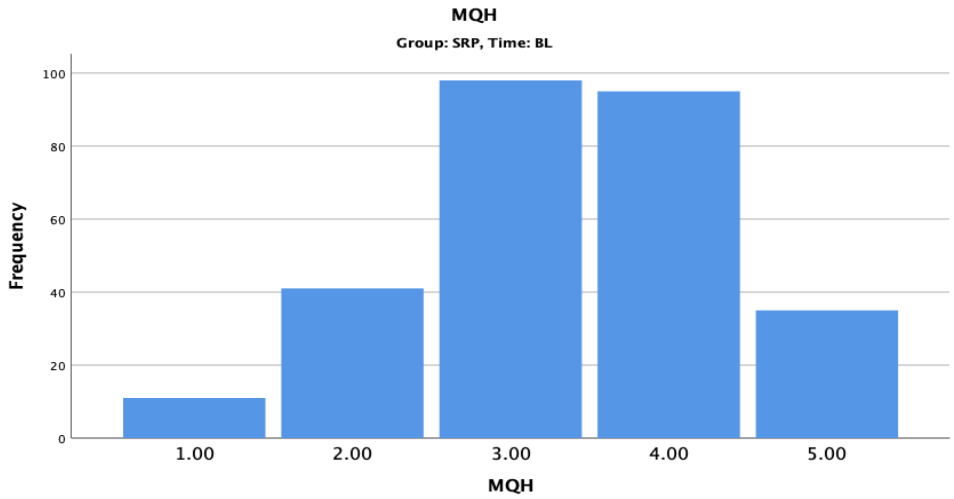


C)

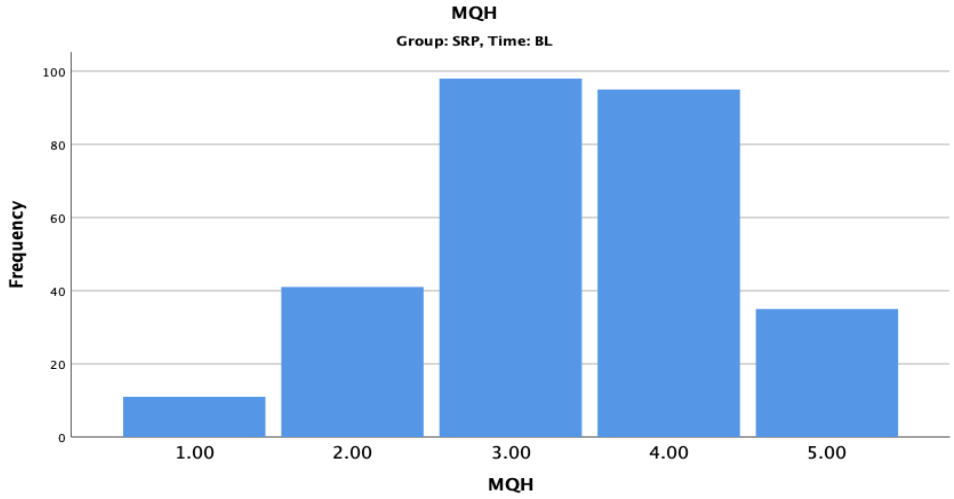
Figure 5. Baseline MQH scores for A) SRP, B) HP13, and C) HP26



A)

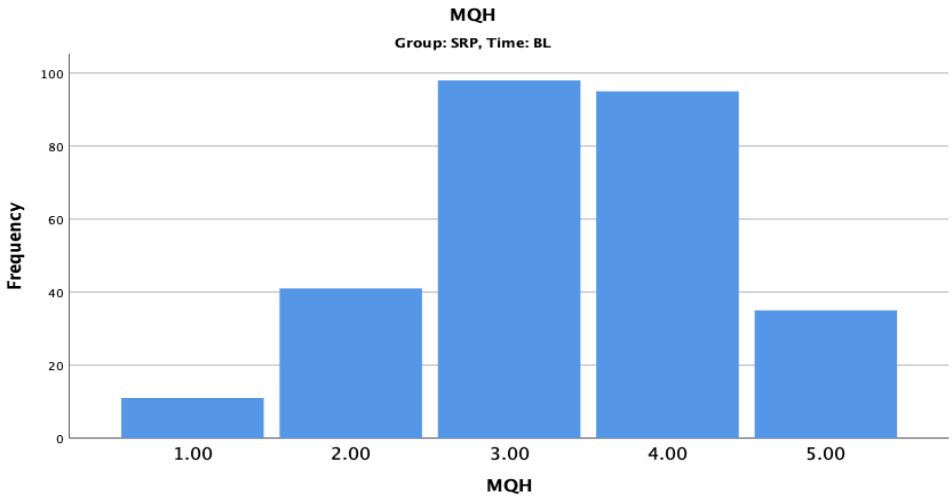


B)

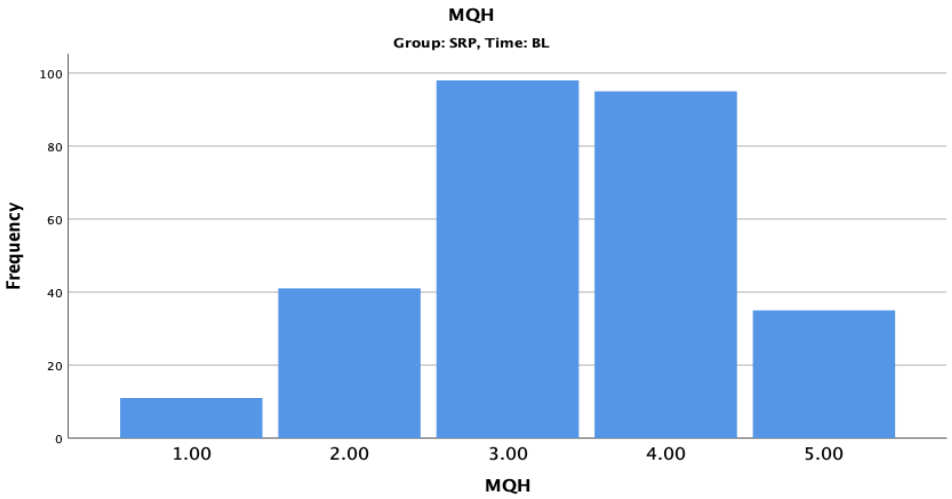


C)

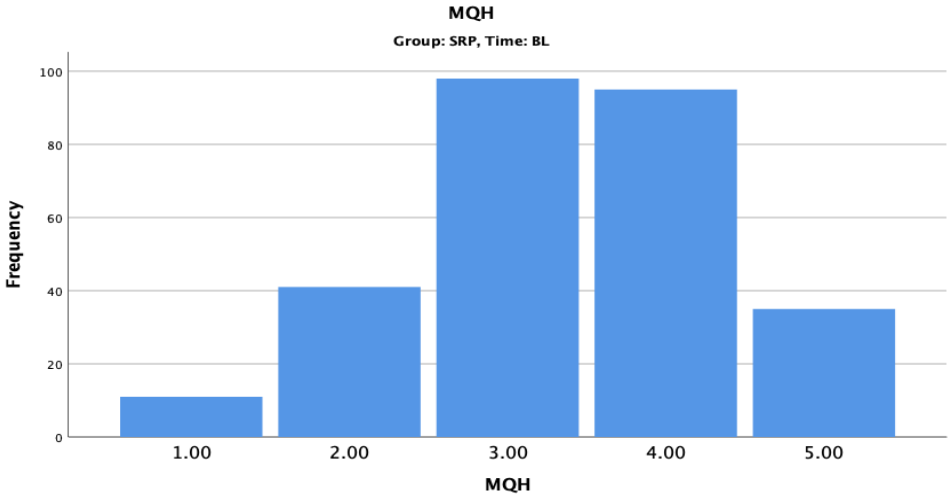
Figure 6. 4-Week MQH scores for A) SRP, B) HP13, and C) HP26.



A)

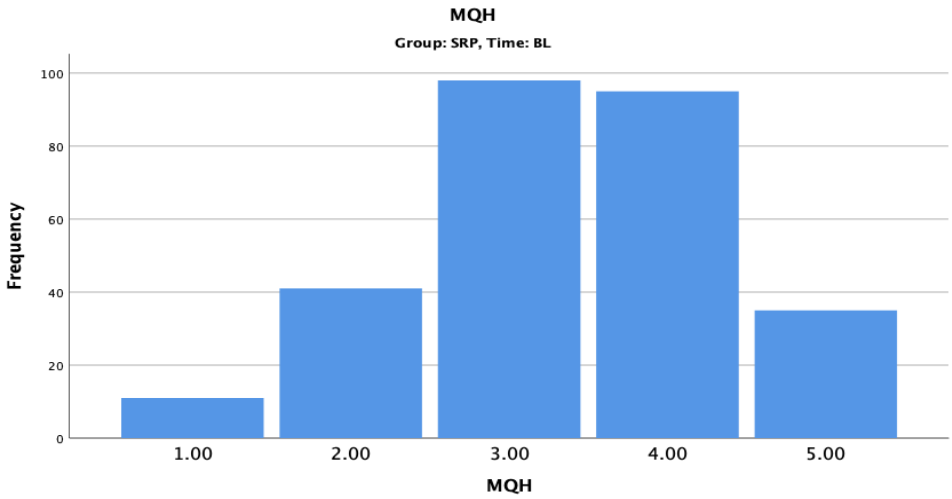


B)

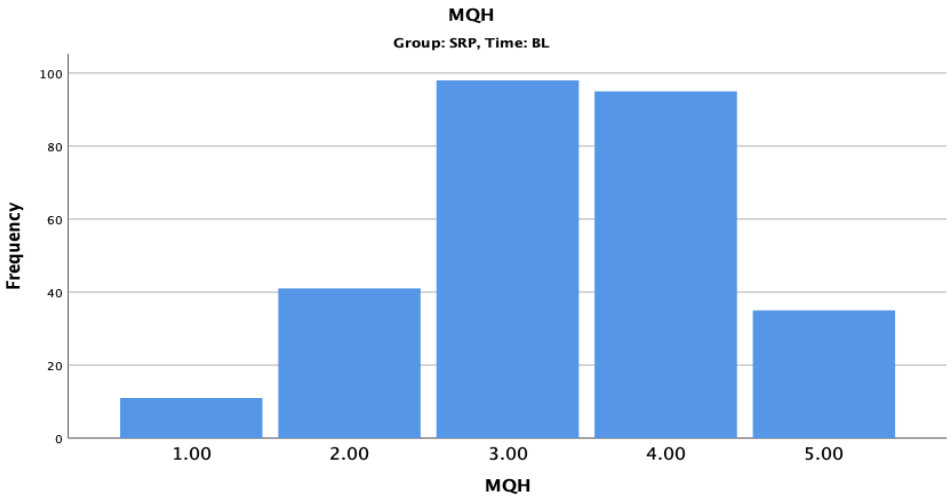


C)

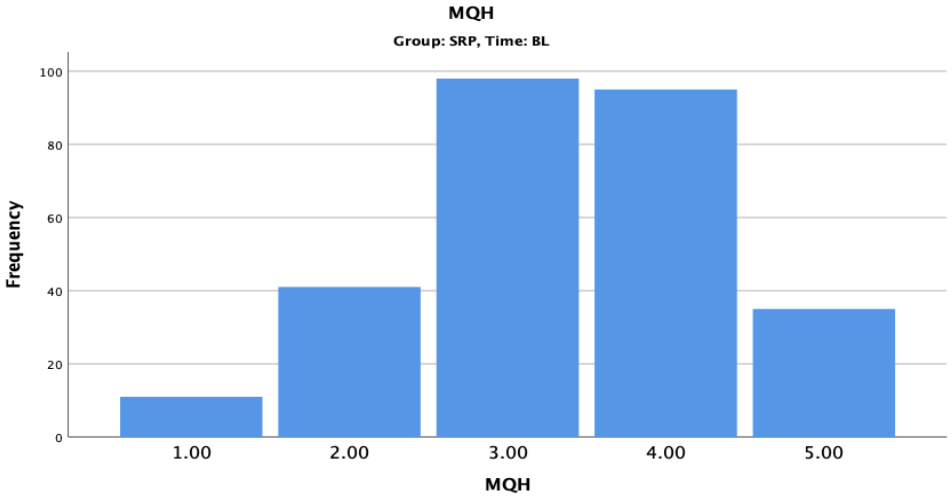
Figure 7. Re-Evaluation MQH scores for A) SRP, B) HP13, and C) HP26.



A)



B)



C)

Figure 8. Final MQH scores for A) SRP, B) HP13, and C) HP26.

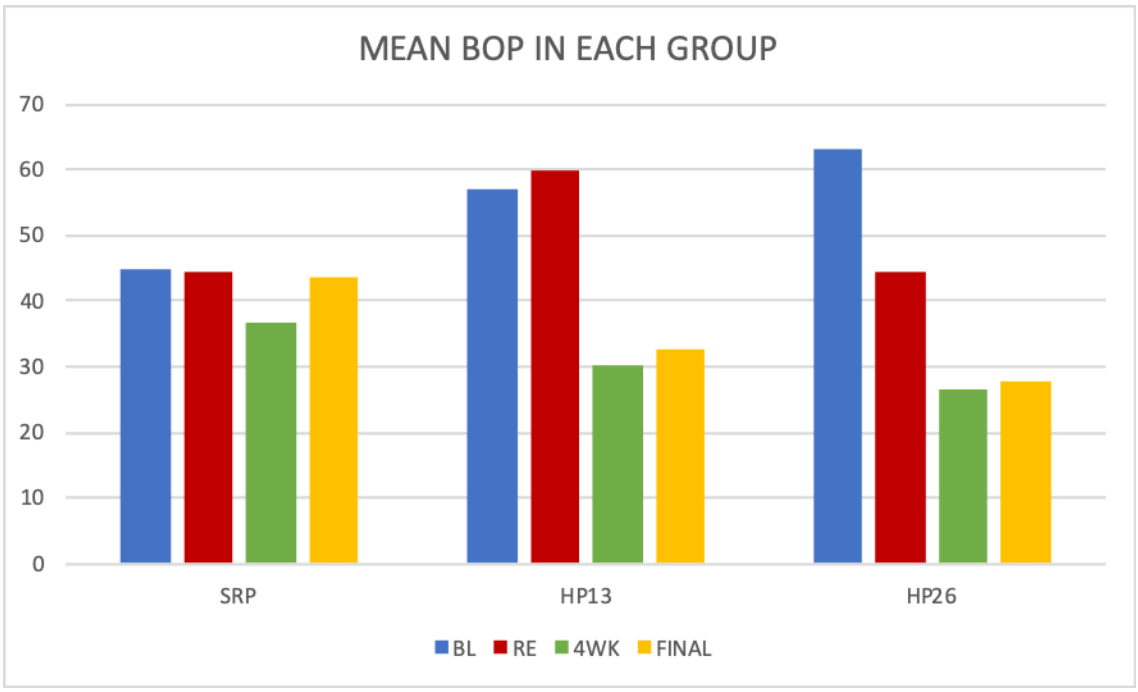


Figure 9. Mean BOP in each group, SRP, HP13, and HP26

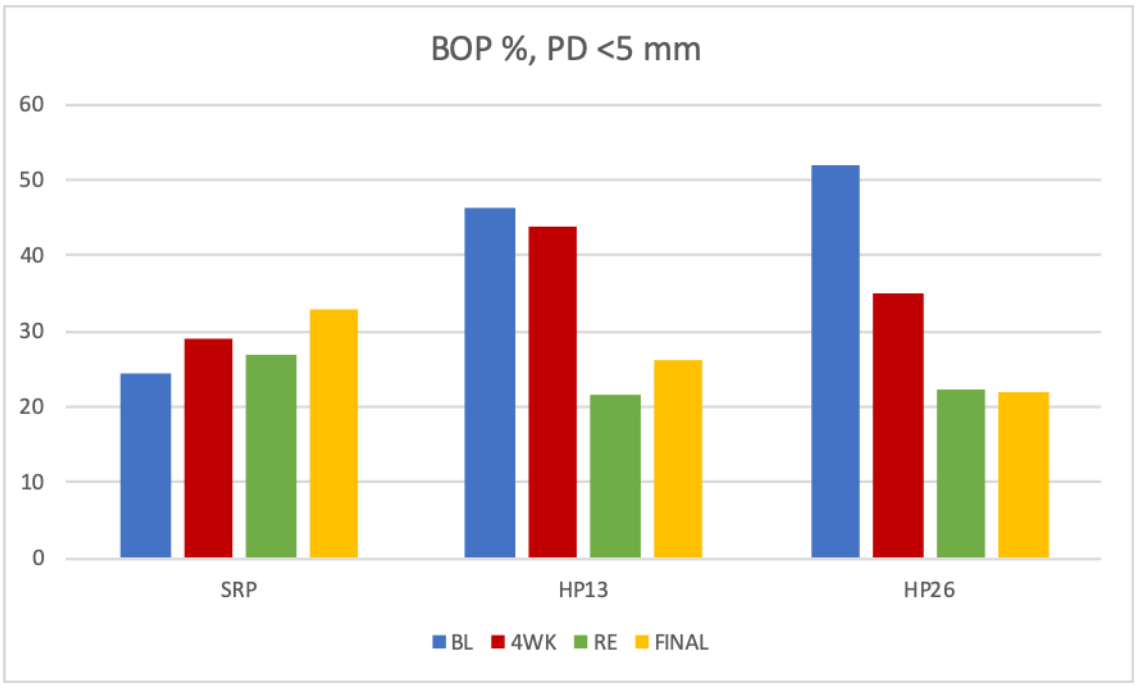


Figure 10. BOP % in pockets initially <5 mm

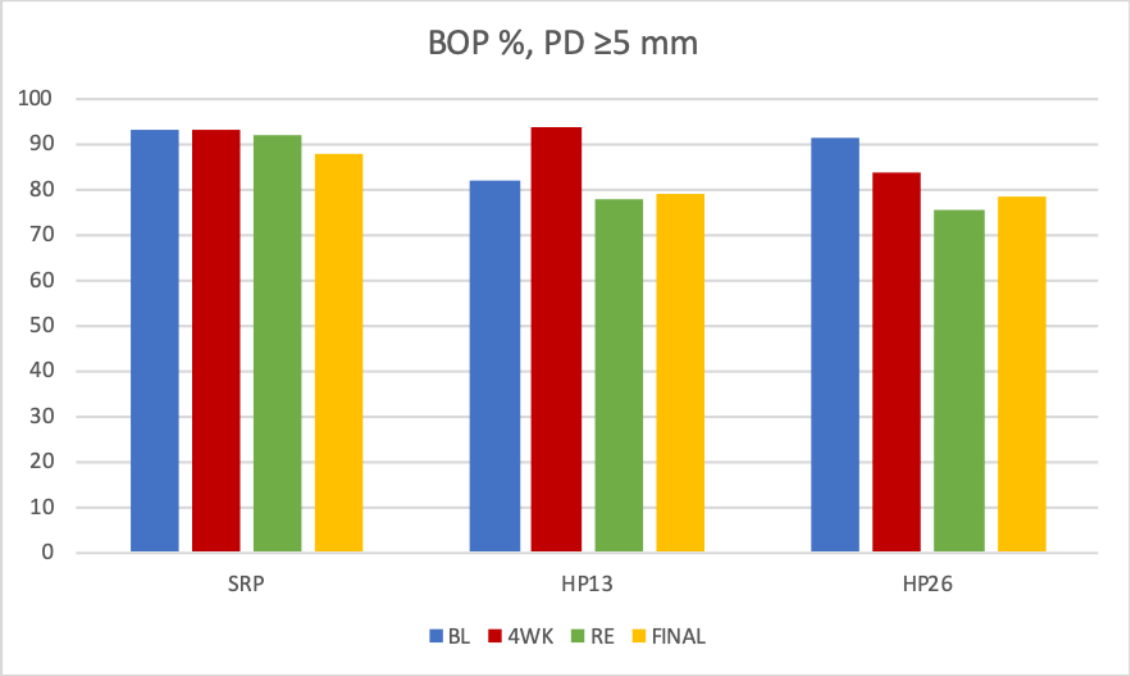


Figure 11. BOP % in pockets initially ≥5mm

Figure 8 shows mean BOP. Baseline mean BOP was 45% for SRP, 57% for HP13, and 63.1% for HP26. At 4-weeks, mean BOP was 45% for SRP, 60% for HP13, and 44% for HP26. At re-evaluation, mean BOP was 37% for SRP, 30% for HP13, and 27% for HP26. Final mean BOP scores were 44% for SRP, 33% for HP13, and 28% for HP13. Mean BOP was significantly reduced in all groups between 4-week examination and re-evaluation with mean BOP scores at final examination staying similar to levels at re-evaluation for HP13 and HP26 groups. Mean BOP scores at final examination group for SRP group was similar to baseline.

Figure 9 shows BOP % in pockets initially <5mm. At baseline, 24% of pockets <5mm were BOP for SRP, 47% for HP13, and 52% for HP26. At 4-week examination BOP % were 29% for SRP, 44% for HP13, and 35% for HP26. At re-evaluation, BOP %

was 27% for SRP, 21% for HP13, and 22% for HP26. At the final exam, BOP % was 33% for SRP, 26% for HP13, and 22% for HP26.

Figure 10 shows BOP % in pockets initially ≥5mm. At baseline, BOP % was 92% for SRP, 81% for HP13, and 91% for HP26. At 4-week examination, BOP % was 91% for SRP, 93% for HP13, and 83% for HP26. Re-evaluation BOP % was 91% for SRP, 78% for HP13, and 75% for HP26. At final examination, BOP % was 88% for SRP, 79% for HP13, and 78% for HP26.

CHAPTER FOUR

DISCUSSION

This randomized, examiner-blind, parallel-design, clinical trial compared the effectiveness of SRP to daily treatment with 1.7% hydrogen peroxide using prescription, custom-fabricated dental trays as an adjunct to SRP. The results of this study demonstrate that the peroxide/prescription tray treatment regimen in combination with SRP is statistically significant in terms of reduction of BoP

In contrast to prior studies (Putt 2012, 2013 Journal of Clinical Dentistry), this study did not provide evidence to show that the use of peroxide/prescription tray regimen prior to SRP would reduce pocket depths without mechanical intervention. According to Putt 2012, the mean difference between test and control group after two weeks of 4-times daily use hydrogen peroxide was 0.44 mm in sites >5mm. The difference between test and control groups for all sites was 0.18mm. The difference that was seen between our study was that the subjects were instructed to use twice daily hydrogen peroxide, therefore the total "contact time" of peroxide is effective half.

The amount of marginal tissue recession over time did not demonstrate an increase of soft tissue recession over time with the use of the prescription trays indicated that the physical seal along the gingival margin does not induce or propagate recession.

CHAPTER FIVE

CONCLUSION

In conclusion, the use of adjunctive HP in custom fabricated trays presents with no adverse effects. Significant improvement was evident in pocket depth and attachment level in both treatment groups between after 4 weeks of using the tray. No significant effect found in SRP group between baseline and 4 weeks. After SRP, significant difference was seen in all three groups between 4 weeks and 3 months.

REFERENCES

1. Cugini MA, Haffajee AD, Smith C, Kent RL, Jr., Socransky SS. The effect of scaling and root planing on the clinical and microbiological parameters of periodontal diseases: 12-month results. *J Clin Periodontol* 2000;27:30-36.

2. Heitz-Mayfield LJ, Lang NP. Surgical and nonsurgical periodontal therapy. Learned and unlearned concepts. *Periodontol 2000* 2013;62:218-231.

3. Van der Weijden GA, Timmerman MF. A systematic review on the clinical efficacy of subgingival debridement in the treatment of chronic periodontitis. *J Clin Periodontol* 2002;29 Suppl 3:55-71; discussion 90-51.

4. Badersten A, Nilveus R, Egelberg J. Effect of nonsurgical periodontal therapy. I. Moderately advanced periodontitis. *J Clin Periodontol* 1981;8:57-72.

5. Drisko CH. Nonsurgical periodontal therapy. *Periodontol 2000* 2001;25:77-88.

6. Konopka L, Pietrzak A, Brzezinska-Blaszczyk E. Effect of scaling and root planing on interleukin-1beta, interleukin-8 and MMP-8 levels in gingival crevicular fluid from chronic periodontitis patients. *J Periodontal Res* 2012;47:681-688.

7. Fleischer HC, Mellonig JT, Brayer WK, Gray JL, Barnett JD. Scaling and root planing efficacy in multirooted teeth. *J Periodontol* 1989;60:402-409.

8. Jepsen S, Deschner J, Braun A, Schwarz F, Eberhard J. Calculus removal and the prevention of its formation. *Periodontol 2000* 2011;55:167-188.

9. Parashis AO, Anagnou-Vareltzides A, Demetriou N. Calculus removal from multirooted teeth with and without surgical access. II. Comparison between external and furcation surfaces and effect of furcation entrance width. *J Clin Periodontol* 1993;20:294-298.

10. Rabbani GM, Ash MM, Jr., Caffesse RG. The effectiveness of subgingival scaling and root planing in calculus removal. *J Periodontol* 1981;52:119-123.

11. Quirynen M, Vogels R, Pauwels M, et al. Initial subgingival colonization of 'pristine' pockets. *J Dent Res* 2005;84:340-344.

12. Tribble GD, Lamont RJ. Bacterial invasion of epithelial cells and spreading in periodontal tissue. *Periodontol 2000* 2010;52:68-83.

13. Smiley CJ, Tracy SL, Abt E, et al. Systematic review and meta-analysis on the nonsurgical treatment of chronic periodontitis by means of scaling and root planing with or without adjuncts. *The Journal of the American Dental Association* 2015;146:508-524. e505.

14. Zijnge V, Meijer HF, Lie MA, et al. The recolonization hypothesis in a full-mouth or multiple-session treatment protocol: a blinded, randomized clinical trial. *J Clin Periodontol* 2010;37:518-525.

15. American Academy of Periodontology statement on the local delivery of sustained or controlled release antimicrobials as adjunctive therapy in the treatment of periodontitis. . *J Periodontol* 2006;77:1458.

16. Behle JH, Sedaghatfar MH, Demmer RT, et al. Heterogeneity of systemic inflammatory responses to periodontal therapy. *J Clin Periodontol* 2009;36:287-294.

17. Boyd RL. Effects on gingivitis of daily rinsing with 1.5% H2O2. *J Clin Periodontol* 1989;16:557-562.

18. Gomes DC, Shakun ML, Ripa LW. Effect of rinsing with a 1.5% hydrogen peroxide solution (Peroxyl) on gingivitis and plaque in handicapped and nonhandicapped subjects. *Clin Prev Dent* 1984;6:21-25.

19. Gusberti FA, Sampathkumar P, Siegrist BE, Lang NP. Microbiological and clinical effects of chlorhexidine digluconate and hydrogen peroxide mouthrinses on developing plaque and gingivitis. *J Clin Periodontol* 1988;15:60-67.

20. Marshall MV, Cancro LP, Fischman SL. Hydrogen peroxide: a review of its use in dentistry. *J Periodontol* 1995;66:786-796.

21. Dunlap T, Keller DC, Marshall MV, et al. Subgingival delivery of oral debriding agents: a proof of concept. *J Clin Dent* 2011;22:149-158.

22. Putt MS, Proskin HM. Custom tray application of peroxide gel as an adjunct to scaling and root planing in the treatment of periodontitis: a randomized, controlled three-month clinical trial. *J Clin Dent* 2012;23:48-56.

23. Putt MS, Proskin HM. Custom tray application of peroxide gel as an adjunct to scaling and root planing in the treatment of periodontitis: results of a randomized controlled trial after six months. *J Clin Dent* 2013;24:100-107.

24. Putt MS, Mallatt ME, Messmann LL, Proskin HM. A 6-month clinical investigation of custom tray application of peroxide gel with or without doxycycline as adjuncts to scaling and root planing for treatment of periodontitis. *Am J Dent* 2014;27:273-284.

25. Armitage GC. Development of a classification system for periodontal diseases and conditions. *Ann Periodontol* 1999;4:1-6.

26. Nylund K, Egelberg J. Antimicrobial irrigation of periodontal furcation lesions to supplement oral hygiene instruction and root debridement. *J Clin Periodontol* 1990;17:90-95.

27. Turesky S, Gilmore ND, Glickman I. Reduced plaque formation by the chloromethyl analogue of victamine C. *J Periodontol* 1970;41:41-43.