APPENDIX A

DENTAL DATA ABSTRACTION FORM

Abstraction Form

QUESTION: HOW DOES THE EFFECTIVENESS OF SCALING AND ROOT PLANING ACCOMPANIED BY ADJUNCTIVE THERAPY FOR CHRONIC PERIODONTITIS COMPARE TO SCALING AND ROOT PLANING THERAPY BY ITSELF AT VARYING LENGTHS OF TIME POST-TREATMENT?

A. Administrative Information

1. Abstractor:_____ 2.Abstract Date:_____

3. Abbreviated study citation

_____

first author *journal abbr*

_____

year *volume* *pages*

4. Abbreviated article title:

_____

5. Included?

- ❑ No

If no, excluded because: (*check one)*

- ❑ SRP different in control/comparison group than in treatment group
- ❑ No SRP-only control/comparison group/sites
- ❑ Treatment groups/sites did not also receive SRP
- ❑ Literature review or meta-analysis
- ❑ Practice guideline or editorial
- ❑ Special population/disease studied, described as: with HIV/AIDS or diabetes; localized disease; juvenile or early onset disease; in smokers; around implants;
- ❑ Other (Specify): _____

- ❑ Yes (go to ***B. Study Design Information***)

B. Study Design Information

1. Type of design (Check One):

   - ❑ *Randomized controlled trial(RCT)*
   - ❑ *Non-Randomized controlled trial*
   - ❑ *RCT with crossover*
   - ❑ *Other (Specify)*_____

   _____

2. Is it a split-mouth design?
   - ❑ *Yes*
   - ❑ *No*
3. Does study investigate (check one):
   - ❑ *Single-rooted teeth*
   - ❑ *Teeth bifurcated (molars)*
   - ❑ *Both*
   - ❑ *Not reported*
4. Does study characterize periodontal disease as (check all that apply):
   - ❑ *Mild*
   - ❑ *Moderate*
   - ❑ *Severe*
   - ❑ *Not reported*
5. Placebo used in control/comparison (SRP only) group/sites?
   - ❑ *Yes*
   - ❑ *No*
6. Number of eligible active treatment groups: _____
7. Study period (S*pecify begin and end calendar month/year in which conducted*)

   From _____ To _____

8. Study location(s) (Specify city/nation) _____

9. Study/treatment site(s):
   - ❑ *Hospital dental clinic*
   - ❑ *Graduate program university clinic*
   - ❑ *Undergraduate dental clinic*
   - ❑ *Health department clinic*
   - ❑ *Private dental practice*
   - ❑ *Not mentioned*
   - ❑ *Other* (Specify)_____

10. Duration of treatment*:*_____ *days/ weeks/months*

11. Specify eligible adjunctive therapy(ies):
   - ❑ *Amoxicillin*
   - ❑ *Augmentin*
   - ❑ *Chlorhexidine*
   - ❑ *Doxycycline*
   - ❑ *Metronidazole*
   - ❑ *Minocycline*
   - ❑ *Spiramycin*
   - ❑ *Povodine iodine*
   - ❑ *Tetracycline*
   - ❑ *Azithromycin*
   - ❑ *Clindamycin*
   - ❑ *Other* (Specify)_____

12. Dose, mode of delivery, and schedule of treatment group(s) (XX mgs, as a rinse (for local), Y times /day, week, month) and SRP only group (or with placebo if used):

    Group 1 (or only treatment group): _____

    Group 2: _____

    *Group 3:*_____

    *SRP only / or SRP with Placebo:*_____

13. Duration of evaluation period*:*_____ *days or* _____ *weeks or* _____ *months*

14. Drug use compliance monitoring:
    - ❑ *Yes*
    - ❑ *No*
    - ❑ *Not reported*
    - ❑ *Not applicable (e.g., professionally administered/applied)*
15. Describe the SRP as they performed it: _____

    _____
16. How much time on average was spent doing SRP? _____
17. Was it performed with
    - ❑ *An ultrasonic/Cavitron*
    - ❑ *By hand*
    - ❑ *Both*
    - ❑ *Not reported*
18. Describe supportive therapy provided to study participants and indicate frequency/intervals.
    - ❑ *Oral instruction How often:* _____
    - ❑ *Plaque removal How often:* _____
    - ❑ *Repeated SRP How often:* _____
    - ❑ *Other* _____
    - ❑ *Not reported*
19. Was baseline assessment performed before or after SRP?
    - ❑ *Before*
    - ❑ *After*
    - ❑ *Not Reported*
20. Number of evaluation time points (*e.g. 4 times* not including baseline) _____ and regular intervals of _____ (*e.g., every two weeks*). If intervals vary, specify evaluation points:

    _____
21. Blinding to active drug:
    - ❑ *Examiners blind*
    - ❑ *Patient blind*
    - ❑ *Patients and examiners blind (double blind)*
    - ❑ *No blinding*
    - ❑ *Not reported*

22. Outcomes (parameters measured) and citations:

CLINICAL MEASUREMENT

- ❑ *Bleeding on Probing (BOP/SBI)* *Citation:* _____
- ❑ *Plaque Index (PlI)* *Citation:* _____
- ❑ *Probing Pocket Depth (PPD)* *Citation:* _____
- ❑ *Clinical Attachment Level (CAL)* *Citation:* _____
- ❑ *Gingival Index (GI)* *Citation:* _____
- ❑ *Gingival Recession* *Citation:* _____
- ❑ *Tooth Loss* *Citation:* _____
- ❑ *Tooth Mobility* *Citation:* _____
- ❑ *Other* (Specify) *Citation:* _____

RADIOGRAPHIC TECHNIQUES

- ❑ *Bone Loss/Regeneration* *Citation:* _____
- ❑ *Other* (Specify) *Citation:* _____

MICROBIOLOGICAL METHODS

- ❑ *Chromatography* *Citation:* _____
- ❑ *DNA/RNA probe* *Citation:* _____
- ❑ *Crevicular fluid microbiota* *Citation:* _____
- ❑ *Plaque microbiota* *Citation:* _____
- ❑ *Other (*Specify*)* *Citation:* _____

PATIENT SELF REPORT

- ❑ *Patient Satisfaction* *Citation:* _____
- ❑ *Other* (Specify) *Citation:* _____

C. Sample Information

1. Description of population sampled (recurrent disease, never treated, clinic patients, private care)___

_____

_____

2. Initial sample size -- *persons (teeth)*:

   _____= Total subjects (sites)

   _____= Group 1 or only active drug group subjects (sites)

   _____= Group 2 (second active drug) subjects (sites)

   _____= Group 3 (third active drug) subjects (sites)

   _____= SRP only/SRP with placebo subjects (sites)

3. Subject/Site allocation to treatment/control conditions (Check one):

   - ❑ *Random*
   - ❑ *Systematic*
   - ❑ *Cluster*
   - ❑ *Convenience*
   - ❑ *Unknown*
   - ❑ *Other (Specify)*_____

4. Specific inclusion and exclusion criteria. (Specify tooth or person level considerations.)

- ❑ *Pregnant/breast feeding excluded*
- ❑ *Concurrent drug therapy excluded*
- ❑ *Diabetes history excluded*
- ❑ *Diagnosed systemic infection excluded*
- ❑ *Serious medical illness excluded*
- ❑ *Need for prophylactic antibiotic before dental treatment excluded*
- ❑ *Use of study drug within ____ months excluded*
- ❑ *Hypersensitivity/allergic to study drug excluded*
- ❑ *At least _____ teeth in _____ quadrant/mouth (circle one) with ____mm pocket included*
- ❑ *Age at least _____ included*
- ❑ *Other:* _____

  _____

  _____

D. Group Characteristics

Total (All Study Groups Combined)

1. Age: *mean:*_____ *median:* _____ *range:* _____

2. Gender: *number (%) male:*_____ *number (%) female:*_____

3. Race/Ethnicity: *number (%) NH White:* _____

   number (%) NH Black: _____

   number (%) Hispanic (independent of race): _____

   number (%) NH Asian/PacificIslander: _____

   *number (%) other (specify):*_____

Group 1

1. Age: *mean:*_____ *median:* _____ *range:* _____
2. Gender: *number (%) male:*_____ *number (%) female:*_____
3. Race/Ethnicity: *number (%) NH White:* _____

   number (%) NH Black: _____

   number (%) Hispanic (independent of race): _____

   number (%) NH Asian/Pacific Islander: _____

   *number (%) Other(Specify):*_____

Group 2

1. Age: *mean:*_____ *median:* _____ *range:* _____
2. Gender: *number (%) male:*_____ *number (%) female:*_____
3. Race/Ethnicity: *number (%) NH White:* _____

   number (%) NH Black: _____

   number (%) Hispanic (independent of race): _____

   number (%) NH Asian/PacificIslander: _____

   *number (%) Other(Specify):*_____

Group 3

1. Age: *mean:*_____ *median:* _____ *range:* _____
2. Gender: *number (%) male:*_____ *number (%) female:*_____
3. Race/Ethnicity: *number (%) NH White:* _____

   number (%) NH Black: _____

   number (%) Hispanic (independent of race): _____

   number (%) NH Asian/PacificIslander: _____

   *number (%) Other(Specify):*_____

SRP only/SRP plus placebo Group

1. Age: *mean:*_____ *median:* _____ *range:* _____

2. Gender: *number (%) male:*_____ *number (%) female:*_____

3. Race/Ethnicity: *number (%) NH White:* _____

   number (%) NH Black: _____

   number (%) Hispanic (independent of race): _____

   number (%) NH Asian/PacificIslander: _____

   *number (%) Other(Specify):*_____

E. Provider/Examiner information

1. Number of examiners:_____

2. Examiners received:
   - ❑ *Instruction in use of measures (written, pictures)*
   - ❑ *Standardization (Practice on patients)*
   - ❑ *Calibration (Gold standard examiner)*
   - ❑ *None/ Not reported*
   - ❑ *Not applicable (No clinical examination/measures: only one examiner)*

3. How are examiners assigned to patients at assessments?
   - ❑ *Random at each assessment*
   - ❑ *Repeat at each assessment*
   - ❑ *Not reported*
   - ❑ *Only one examiner*

F. Analysis Information

1. Analysis adjusted for clustered observations
   - ❑ *Yes*
   - ❑ *No*
   - ❑ *Not reported*
2. Type of analysis reported:
   - ❑ *Intent to treat*
   - ❑ *All with any follow-up*
   - ❑ *Full participants only*
3. Reasons/criteria for exclusion from analysis:

   _____

   _____

G. Outcome Information

1. Did study look for adverse effects?
   - ❑ *Yes, found none*
   - ❑ *Yes, but none reported*
   - ❑ *Yes, found adverse effects (number and type) by study group.*

   Specify: _____

   _____

   _____

   - ❑ *Never mentioned looking*
2. Frequency with which modified Wideman flap procedure was performed in study?
   - ❑ *Always/Often* (25% of time or more)
   - ❑ *Occasionally* (5-24 % of time)
   - ❑ *Rarely or Never* (0-4 % of time)
   - ❑ *Frequency Not Reported*

Comparison of Assessme nt 1 (Baseline) to Assessment 2

	Assessment 1 (Baseline)				Assessment 2				Group Comparisons Specify Coefficient, P-value/NS/Direction (+/-)						
Group	SRP Only	Treat 1	Treat 2	Treat 3	SRP Only	Treat 1	Treat 2	Treat 3	Statistical Test or Measure	T1 to SRP	T2 to SRP	T3 to SRP	T1 to T2	T2 to T3	T1 to T3
Number in Group															
Outcome Measures (Describe)															
1															
2															
3															
4															
5															
6															

Comparison of Assessment 2 / Baseline to Assessment 3

	Assessment 3				Group Comparisons Specify Coefficient, P-value/NS, Direction (+/-)					
Group	SRP Only	Treat 1	Treat 2	Treat 3	Treat 1 to SRP	Treat 2 to SRP	Treat 3 to SRP	Treat 1 to Treat 2	Treat 2 to Treat 3	Treat 1 to Treat 3
Number in Group										
Outcome Measures (Describe)										
1										
2										
3										
4										
5										
6										

Comparison of Assessment 3 / Baseline to Assessment 4

	Assessment 4				Group Comparisons Specify Coefficient, P-value/NS, Direction (+/-)					
Group	SRP Only	Treat 1	Treat 2	Treat 3	Treat 1 to SRP	Treat 2 to SRP	Treat 3 to SRP	Treat 1 to Treat 2	Treat 2 to Treat 3	Treat 1 to Treat 3
Number in Group										
Outcome Measures (Describe)										
1										
2										
3										
4										
5										
6										

Comparison of Assessment 4 / Baseline to Assessment 5

	Assessment 5				Group Comparisons Specify Coefficient, P-value/NS, Direction (+/-)					
Group	SRP Only	Treat 1	Treat 2	Treat 3	Treat 1 to SRP	Treat 2 to SRP	Treat 3 to SRP	Treat 1 to Treat 2	Treat 2 to Treat 3	Treat 1 to Treat 3
Number in Group										
Outcome Measures (Describe)										
1										
2										
3										
4										
5										
6										

Comparison of Assessment 5 / Baseline to Assessment 6

	Assessment 6				Group Comparisons Specify Coefficient, P-value/NS, Direction (+/-)					
Group	SRP Only	Treat 1	Treat 2	Treat 3	Treat 1 to SRP	Treat 2 to SRP	Treat 3 to SRP	Treat 1 to Treat 2	Treat 2 to Treat 3	Treat 1 to Treat 3
Number in Group										
Outcome Measures (Describe)										
1										
2										
3										
4										
5										
6										

APPENDIX B

QUALITY REVIEW CHECKLIST

QUALITY REVIEW CHECKLIST **Article:**			
Internal Validity			
1.	Random Assignment of Treatment	Y	N/NR
2	Blinding of Examiners	Y	N/NR
3	Blinding of Subjects	Y	N/NR
4	Use of Placebo	Y	N
5	Total Sample Size = 40	Y	N
6	Equal Sized Sample in Treatment and Control Groups	Y	N/NR
External Validity			
7	Judge external validity to be Good based on data reported (on disease, qualifications for participation in study, study setting, and subjects characteristics)	Y	N/NR
8	Attrition from enrolled group = 10%	Y	N
9	Multi-center Trial	Y	N/NR
Analysis			
10	Use all enrolled subjects in the analysis (or only those who completed)	Y	N
11	Reported if any Adverse Effects/Harms	Y	N
12	Are appropriate statistical techniques employed (adjust for multiple comparisons [Duncan, Scheffe, etc.], take into account lack of independence between observations [GLM, Sudaan, etc])	Y	N/NR
13	Reported means and variances (for baseline and end for T and C groups, or as change from baseline to end) as well as number of sites/teeth/people for each group or reported difference between change for the T and C groups	Y	N/NR
OVERALL RATING:			

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