

Grant Application Form 2008

Date of application: Resubmitted June 15, 2008

Project Title: Comparison of Inter-dental Brush to Dental Floss for Reduction of Plaque and Bleeding in Areas with Intact Papillae: A clinical trial.

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Host Institution/Organization:

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Title:

Organization: Address: Phone: Fax:

E-mail address:

Designated Authority:

Name: Title:

Institution: Address:

1.0 Abstract (max. 300 words)

Background: Periodontal disease is linked to systemic conditions such as diabetes¹ and cardiovascular disease² and left untreated, may result in loss of teeth which impacts quality of life.³ Periodontal disease is highly prevalent interproximally^{4,5} but is reversible as gingivitis with meticulous plaque control. Dental floss is the gold standard for interproximal deplaquing but few people floss daily because it is difficult to use.⁶ Previous studies demonstrated interdental brushes as effective and acceptable to subjects, but were limited to subjects with moderate to severe periodontitis, who had periodontal surgery and/or attachment loss and thus, large embrasure spaces.^{7,8} Interdental brushes have not been studied in subjects with gingivitis and smaller and/or intact embrasures.

<u>Objective:</u> To determine whether the Curaprox interdental brush is an effective, easy to use alternative to dental floss for reduction of plaque and bleeding in subjects with gingivitis and thus, smaller embrasure spaces.

Study design: 12 week, examiner-blinded, split mouth clinical trial.

<u>Measurements</u>: Silness and Lőe Plaque and Eastman bleeding indices at baseline, 6 and 12 weeks. All subjects receive scaling and oral hygiene instructions. Questionnaire to determine subjects' preference for product, ease of use, and willingness to use daily.

<u>Subjects</u>: 32 adults with gingivitis recruited using sample calculations 20% beta and 5% alpha. Inclusion: Minimum 4 posterior sites accommodating 0.6 mm interdental brush, minimum 8 posterior bleeding sites, dexterity for manual flossing, and attend 4 study visits. Exclusion: Premedication with antibiotics for dental treatment, using chlorhexidine or over-the-counter mouthrinses, smokers, and/or have orthodontia.

<u>Statistical analyses</u>: Paired t-tests comparing products as well as exploring changes from baseline to 6 weeks and to 12 weeks. Equivalency tests may indicate subject preference is the deciding factor for product selection and not product efficacy. Descriptive statistics for questionnaire data. 95% CI.

Sponsors: Curaden Swiss in-grant aid, BCDHA partial funding.

2. 0 ORGANIZATIONAL INFORMATION (max. 2 pages) 2.1, 2.2

UBC Vision and Mission

The University of British Columbia will provide its students, faculty, and staff with the best possible resources and conditions for learning and research, and create a working environment dedicated to excellence, equity, and mutual respect. ⁹ It will cooperate with government, business, industry, and the professions, as well as with other educational institutions and the general community, to discover, disseminate, and apply new knowledge, prepare its students for fulfilling careers, and improve the quality of life through leading-edge research. ⁹ The graduates of UBC will have developed strong analytical, problem-solving and critical thinking abilities; they will have excellent research and communication skills; they will be knowledgeable, flexible, and innovative. ⁹ As responsible members of society, the graduates of UBC will value diversity, work with and for their communities, and be agents for positive change. ⁹ They will acknowledge their obligations as global citizens, and strive to secure a sustainable and equitable future for all. ⁹

UBC alignment with CDHA Research Agenda and CFDHRE Mission

UBC is an internationally renowned research university that conducts leading edge research in areas such as, but not limited to, biomedical, clinical, health services, and social, cultural, environmental, and population health. UBC's vision and mission statements align with the CFDHRE mission of enhancing the overall well being of all Canadians by providing the best possible resources and conditions for learning and research for faculty, staff, and students.

2.3, 2.4 Project participants' names, background, roles, and qualifications to conduct the project.

Principal Investigator (PI):

Co-Investigator (CI):

2.5 Other participants

3.0 PROJECT PROPOSAL INFORMATION (max. 6 pages)

3.1 Project objectives

- 1. To determine whether the Curaprox® interdental brush system is effective for removing interdental plaque and reducing interproximal gingivitis as determined by a reduction in bleeding compared to the gold standard, dental floss.
- 2. To determine whether the subjects find the interdental brush easier to use than dental floss and thus, are more willing to use the interdental brush daily.
- To provide evidence of an effective alternative for interdental oral self care which dental hygienists can recommend to their clients who cannot or choose not to dental floss.

Project objectives support:

- CFDHRE mission statement of "enhancing the oral health and well-being of Canadians" by exploring an alternative oral self-care aid that could be beneficial for the majority of the population who cannot or choose not to floss.
- CDHA research agenda in Biological Research, the testing of devices to improve health: study is using the interdental brush in areas of intact papilla which has not been studied before.
- CDHA Clinical Research: testing the interdental brush's efficacy for plaque removal and bleeding reduction and hence, treatment and prevention of gingivitis and encouragement of oral health promotion.
- CDHA Health Services: filling in the knowledge gap by providing evidence that the interdental brush is effective for intact papilla areas.

3.2 Target audience/target of the research

- Adults with gingivitis, who cannot or choose not to dental floss daily.
- Targeted because the interproximal area is susceptible to periodontal disease.^{4,5}

3.3 Project need or significance

Periodontal disease is linked to systemic conditions such as diabetes¹ and cardiovascular disease² and left untreated, may subsequently result in loss of teeth, which impacts quality of life.³ Periodontal disease is highly prevalent in the interproximal area^{4,5} where the toothbrush is unable to penetrate,¹² thus necessitating an interdental deplaquing method. Gingivitis is reversible by mechanically disrupting the biofilm which in turn reduces inflammation and allows for gingival healing.¹³ Presently researchers are unclear as to which gingivitis sites may progress to periodontitis.¹⁴ In human models, inadequate plaque control increases the development of anaerobic flora within 3 to 4 weeks, which may result in periodontitis.¹⁴ However, animal models with experimentally-induced gingivitis usually progress to periodontitis.¹⁵ Therefore, the literature continues to support the early treatment of gingivitis as a proactive practice for optimal oral health.^{6,13,14,15}

Dental floss is considered the gold standard for interproximal deplaquing, but few people use dental floss daily because it is difficult to maneuver intra-orally. Other interdental self-care aids, such as interdental brushes have been shown to effectively deplaque interproximal areas and have a higher rate of acceptability by subjects because of ease of use, but these studies focused on moderate to severe periodontitis subjects with large embrasure spaces. Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies which used the smaller diameter GUM Soft-Picks Other studies of the smaller diameter GUM Soft-Picks Other studies of the smaller diameter GUM Soft-Picks Other studies of the smaller diameter GUM Soft-Picks Other Soft-Picks Other

¹²and BrushPicks^{™16} on subjects with smaller embrasure spaces demonstrated no statistically significant differences *between* the GUM Soft-Picks[®] ¹²and BrushPicks^{™16} to dental floss. The diameter of the GUM Soft-Picks[®] ¹²and BrushPicks^{™16} may have been too small to demonstrate a significant difference for interproximal plaque removal because studies have shown that the interdental brush must fit snugly, yet atraumatically, into the embrasure space to achieve better plaque removal than floss.¹⁷ Therefore, this study explores the use of an appropriately sized interdental brush in subjects with smaller embrasure spaces to treat gingivitis.

3.4 Approach or methodology

Study Design:

- Study explores the adjunctive benefits of oral self-care. Compares interdental brush to gold standard, dental floss.
- Split-mouth, examiner-blinded 12 week clinical trial.
- Measurements at baseline, week 6 and week 12.
- Differences among interdental aids have been demonstrated from baseline to 4-6 weeks in other studies,^{7, 8, 16} however, this study will also collect data at 12 weeks to control for the debridement's positive effects on gingival health.^{18,19}
- Subject is own control; uses experimental intervention and positive control.

Study Schedule:

Screening Visit:

- Screening by Principal Investigator (PI).
- Description of study and subject expectations explained. Subject consent form given (Appendix A).
- Subject meets inclusion/exclusion criteria :
- Minimum 4 sites that can accommodate at least 0.6 mm are identified for interdental brush. If more than 4 sites can accommodate the interdental brush, the sites will be grouped by sextants to reduce subject confusion as to where to use the brush and randomized using a computer generated random table. Sites identified by inserting Curaprox colored probe into the embrasure space. Color that is visible buccally corresponds to interdental brush most appropriate for site. (Appendix B). Preferred interproximal test sites are those distal to the canines to reduce the possibility of adverse effects in the aesthetic zone. Overzealous use of overly large interdental brushes may traumatize the interdental papilla; however, this adverse effect will be minimized with appropriately sized brushes, oral hygiene instruction, and limiting the sites to the less visible posterior areas.
- Minimum of 8 bleeding sites as determined by inserting a Stimudent interproximally in a horizontal plane 4 times.
- 30 minute visit.

<u>Visit 1 (Week -2)</u>:

- Subject enrolled in study after submitting signed consent form.
- Debridement by Co-Investigator (CI) at UBC clinic.
- 60-90 minute visit, depending on amount of debridement required.

Visit 2 (Week 0):

- Study begins.
- CI collects baseline plaque & Eastman bleeding scores (Appendix C). CI will remain blinded for data collection purposes.
- PI provides oral hygiene instructions for toothbrush, floss, interdental brush and assigns floss and interdental brush to previously identified test sites. Subjects receive Oral-B #35 soft manual toothbrush (Oral-B Lab Inc, Redwood city, CA), waxed dental floss (Johnson & Johnson Inc., NB, NJ), Colgate Cavity Protection Regular toothpaste (Colgate-Palmolive Canada Inc.), and appropriate interdental brushes (Curaden Swiss) and are requested to only use these products to reduce confounding variables. Colgate Cavity Protection Regular toothpaste chosen to reduce possible confounding from triclosan (antiplaque and antigingivitis) and sodium pyrophosphate (reduces calculus formation) found in other formulations. Subjects given diagram indicating where to use the color-coded interdental brush.
- 30 45 minute visit.

Visit 3 (Week 6):

- Compliance check. Check wear of interdental brushes (splayed bristles, frayed tips, bent or broken wire, loss of brush shape), floss used, toothpaste used.
 Replenish oral hygiene supplies as needed.
- CI mid-study data collection: plaque and bleeding indices (see Appendix C).
- PI reinforce floss and interdental brush techniques. Address any subject concerns.
- 30 45 minute visit.

Visit 4 (Week 12):

- CI collects final plaque and bleeding data (see Appendix C) and administers subject questionnaire (see Appendix D). Subjects fill in questionnaire at the end of the visit and may submit to CI or mail to PI.
- Subject exited from study.
- 30-45 minute visit.

The research intervention: The interdental brush is the test product and the dental floss is the positive, gold standard. The curaprox interdental brush is cylindrical and is attached to an angled, long handle that facilitates access to the posterior areas of the mouth. Curaprox brushes are chosen because the system allows the clinician to select a brush diameter that fits snugly but atraumatically into the embrasure without guessing for optimal time efficiency and plaque removing efficacy. A range of brush diameters are available (0.6 mm to 2.0 mm), increasing the likelihood of finding a suitable fit.

<u>Subjects</u>: 32 adults with mild to moderate gingivitis. Literature cites 26-30 subjects per treatment to demonstrate equivalency or better for plaque removing ability of the interdental brush to dental floss.^{7,20} Sample calculations using 20% beta and 5% alpha supports a sample size of approximately 30-34 subjects per treatment. 32 subjects will be recruited to offset possible attrition, which ranged from 0 to 6% in other studies.^{7,12,20}

<u>Recruitment:</u> Subjects recruited via newspaper ad in local paper, Craigslist (on Internet), UBC campus-wide student list serves, and community outreach clinics. Ads will indicate length of study, number of visits, interdental brush versus dental floss comparison,

inclusion/exclusion criteria, honorarium offered but not specified as per ethics guidelines, and have Principal Investigator's contact information. UBC ethics approval for clinical trials will be obtained prior to recruitment of subjects.

<u>Inclusion criteria</u>: To be considered for inclusion in the study, subjects require:

- 1. Minimum of 4 interproximal areas that can accommodate a minimum 0.6 mm interdental brush width
- 2. Minimum of 8 interproximal bleeding sites upon stimulation
- 3. Dexterity to use manual waxed dental floss
- 4. Attend all 4 study visits

Exclusion criteria: To control for possible confounding variables, subjects cannot:

- 1. Require premedication with antibiotics prior to dental therapy
- 2. Use chlorhexidine or over-the-counter mouthwash during the study
- 3. Smoke
- 4. Have orthodontia

<u>Subject Honorarium</u>: Subjects receive complimentary debridement (approx. value \$160) and \$75 for data collection visits (UBC recommends \$25 per study visit; honoraria offered for 3 data collection visits).

Measurements:

a) Plaque index (modification of Silness and Löe, 1964)

The gingival area and teeth are dried with triplex syringe air; disclosing solution applied to teeth. All teeth, except 3rd molars, are scored at four interproximal sites per tooth (MB, DB, ML, DL) according to the following criteria:

- 0 = No plaque. No pink visible on tooth surface.
- 1 = A light film of plaque. The plaque may be seen in situ only after the application of disclosing solution and will appear as light pink flecks.
- 2 = Moderate accumulation of plaque. Plaque will disclose as a medium pink solid line or area, and/or can be seen with the naked eye and will extend from the interproximal surface to the line angle.
- 3 = Heavy accumulation of plaque. Plaque will disclose as deep pink/red, will be thick and extend from the interproximal surface past the line angles of the teeth.

Plaque score per tooth = sum of scores ÷ number of surfaces scored Plaque score per subject = sum of tooth scores ÷ number of teeth scored

b) Eastman Bleeding Index (Caton & Polson, 1985)

All interproximal areas except between the 2nd and 3rd molars will be scored. A wooden interdental cleaner is inserted horizontally between the teeth from the facial aspect, depressing the interdental papilla 1-2 mm, then removed. The process is repeated 4 times. The presence of absence of bleeding within 15 seconds is noted.

0 = no bleeding 1 = bleeding

Eastman Bleeding Score = number of interdental spaces that bled ÷ number of interdental spaces studied

Oral Hygiene Instructions (OHI):

a) Modified Bass Tooth Brushing (TB)

Toothbrush angled at 45 °to gingival margin. Small circular motion at gingival margin followed by a sweeping motion away from the gingival margin. **Toothbrush twice a day, morning and night.**

b) Dental Flossing (DF)

18" piece of waxed dental floss wrapped around the middle fingers of each hand. Floss held by pinch-like grip between index finger and thumb with approximately 1" of floss between the hands. Floss gently inserted through the contact point and wrapped around the tooth. Floss rubbed against the tooth surface in an up and down motion 2-3 times between the contact point and the base of the sulcus. Repeated with the adjoining tooth surface. Then removed from the interproximal area. **Floss once a day in identified areas only.**

c) Interdental Brush (ID)

Appropriate color-coded interdental brush is attached to handle. Interdental brush is inserted horizontally into the interproximal area. Brush is inserted in once then removed. Subjects will receive a diagram indicating where to use the color-coded interdental brush. Interdental brush once a day in identified areas only using appropriate color-coded brush.

Statistical Analyses:

Paired t-tests will be used to compare the differences between the products (i.e., one side average versus the other side average) for the plaque and bleeding indices as well as baseline to Week 6 and baseline to Week 12 mean differences. Equivalency testing such as Levene's will be done to determine whether the products are similar in distributions of efficacy clinical endpoints, which will support the efficacy of interdental brush to dental floss such that subject preference determines product choice. Descriptive statistics will be used for the subject questionnaire.

3.5 Products or outputs

Study will explore whether the interdental brush is effective as dental floss for interproximal deplaquing and reducing gingivitis to provide evidence to support the dental hygienists' recommendation of the interdental brush for his/her client who cannot or chooses not to floss for treating gingivitis and/or maintaining oral health.

Results of the studies will be published in a dental hygiene or clinical periodontal journal. As recommended by CFDHRE, first consideration will be given to the Canadian Journal of Dental Hygiene (CJDH), where we are most likely to reach our target audience.

3.6 Intended results/outcome/impact of the project

Intended Outcomes: The interdental brush will be as effective as dental floss in removing interproximal plaque, but will be easier to use and have higher subject acceptability for daily use. The interdental brush will reduce bleeding sites as effectively as dental floss, indicating that interproximal inflammation has been resolved.

Expected long-term results: To provide evidence to support the recommendation of interdental brush for clients who cannot/choose not to floss and thus, support evidence-based clinical decision-making by dental hygienists. To introduce a systematic, time efficient method for determining the ideal interdental brush size for optimal plaque control for clinicians providing oral health education and promotion to their clients. To explore the future possibilities of using interdental brushes, a subject friendly method, for applying anti-microbials interproximally for individuals who require adjunctive therapies to use at home in conjunction with professional therapies to treat their periodontal disease. The overall long term objective is to develop a centre for dental hygiene research that is specialized in comparing oral health products.

3.7 Work plan

Month	Activity	Progress
Jun-	Consultation with Biostatistician for final sample size	Jun 08:
Sep	determination.	Application being
2008	Ethics Approval from UBC Clinical Research Ethics Board	filled in.
		Jul 11, 08:
		Target date for
		application
0 00	9 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	submission
Sep 08-	Ongoing recruitment until 32 adults with gingivitis enrolled	
May 09	or until Feb 1, 2009, whichever comes first. As subjects are	
	enrolled, they will begin the study following the study schedule as described in Section 3.4. Subjects may be at	
	various visits within the study during this time period.	
	Principal Investigator will do data entry as the subjects	
	complete the study; co-investigator will remain blinded	
	during data collection of remaining subjects. Study will close	
	May 3, 2009.	
May 09	Data analyses with biostatistician	
Jun 09	Submit report to CFDHRE: summary and evaluation of	
	study, attainment of objectives and intended results, and	
	lessons learned	
Jul –	Write paper for publication	
Dec 09		
Spring	If the study results are positive, introduce Curaprox system	
2010	to UBC faculty for consideration into clinical curricula.	
	Disseminate results to study clubs, submit to CDHA website	

3.8 Knowledge dissemination plan

The results of the study will be published in a refereed journal such as the CJDH or other refereed periodontal journal and dental hygiene study clubs for the purpose of disseminating evidence to support the recommendation of interdental brushes as an alternative interdental oral self-care aid for clients who cannot/choose not to floss but require a method for treating gingivitis and/or maintaining optimal oral health.

We would also like to include the results of the study on the CDHA website in the "Oral Care Centre" which provides information to dental hygienists about health promotion procedures and therapeutics that they may consider in their dental hygiene practices.

The results will also be presented to the dental and dental hygiene faculty at UBC with the purpose of integrating the method into the undergraduate dental and dental hygiene curricula, i.e., to teach dental and dental hygiene students how to use the system and to increase the students' awareness of alternative evidence-supported interdental aids that can be used for specific clientele.

3.9 Evaluation plan

The Principal Investigator will compare the study outcomes such as the results, effectiveness of the study design, subjects recruited, and study measurements to the literature to determine whether the study fills in the knowledge gap and supports or refutes the evidence for interdental brush use in intact papillary areas. In addition we will collaborate with our former supervisors and current colleagues at UBC, Dr. Edward Putnins, Associate Dean Research and Graduate Studies, Professor in Periodontics and Professor in Oral Biology, who may provide suggestions related to study designs, clinical measurements, data interpretation, and extensions of the approach to other target populations. The long term objective is to develop a centre for dental hygiene research that is specialized in comparing oral health products. The paper will include these suggestions for future studies.

4. BUDGET

I) Non-Salary Costs

3900
1500 500 660
5600 200
200 0

Total costs: 12,560

Other Sources of funding: In-grant aid from Curaden Swiss, BCDHA \$500

Total Requested from the CFDHRE: \$12,060

Budget Narrative:

Brief explanation for each budget item:

- la) Travel support to the International Federation Dental Hygiene conference in Glasgow, Scotland July 1-3, 2010, which will be showcasing new technologies and methods for treating oral disease would be greatly appreciated as a means of showcasing dental hygiene research to the larger dental hygiene community and to provide an opportunity to meet other dental hygiene researchers. Estimates only: round trip airfare 1800, conference fee 600, accommodation/transportation 1500.
- lb) Clinic sundries are all items required in a clinical setting for universal precautions (personal protection, barriers, disinfectant wipes, sterilization fee), clinical dental hygiene procedures (gauze, saliva ejectors, bibs, cotton swabs), and study items such as disclosing solution, Vaseline, etc.

Study supplies are distributed to study subjects to control for possible confounding variables such as the use of different toothpastes, floss, toothbrushes, which may affect the study results. Supplies must be sufficient to cover the 12 week study period.

Study instruments: Approximately 8 curettes at \$45 each need to be replaced for this clinical trial (I have the instrument kits from a previous clinical trial and just need to replace worn curettes for this study) and two Cavitron inserts at approximately \$300.

Ic) UBC strongly recommends \$25 honorarium per study visit to be paid to study subjects. The study has 3 visits (not including screening and debridement) and is targeting 32 volunteers.

Newspaper advertisement in local paper (Vancouver Courier) for one weekend for the purposes of subject recruitment is approximately \$200 for a 2"x3" box ad.

II) A biostatistician is required to assist with the statistical analyses. \$50/hour, which is a typical fee charged by biostatisticians in Vancouver. Approximately 4 hours consultation would be required for study design and analyses. Principal investigator, co-investigator, and clinic manager are not allowed to draw a salary or receive monetary compensation from grants for studies conducted at UBC as per UBC policy #87 section 3.2.8 because research is considered a responsibility of faculty in the Faculty of Dentistry.

5. REQUIRED ATTACHMENTS

Ethics

Please note: All methodology involving human subjects requires ethics approval. Ethics approval must either accompany this application, or follow if the proposal is accepted.

This project requires an ethics approval:	YES <u>√</u> _	NO
Ethics approval attached:	YES	NO <u>√</u>
Ethics approval will be sent at a later date:	YES <u>√</u>	NO
Curriculum Vitae Lead Principle Applicant CV attached:	YES <u>√</u>	NO
Co-Principle Applicant CV attached:	YES √	NO

6. OTHER ATTACHMENTS

- 1. Appendix A: Subject consent form
- 2. Appendix B: Screening form
- 3. Appendix C: Data collection form
- 4. Appendix D: Subject questionnaire

7. DESIGNATED AUTHORITY

The designated authority(s) is responsible for overseeing the project and the funds.
Name:
Title: Director
Institution/Organization: Research Services, UBC
Address: 102-6190 Agronomy Road, Vancouver, BC, V6T 1Z3
Phone number:
Fax:
E-mail address:
Designated Authority Signature
Principal Investigator Signature
Co-Investigator Signature
Department Head Signature
Dean Signature

Note: all signatures are on hard copy, which were already sent by Canada post with the original application.

References

- 1. Moles DR. Evidence of an association between diabetes and severity of periodontal disease. Evid Based Dent. 2006;7:45.
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Subject Information and Consent Form

Study: Comparison of Inter-dental Brush to Dental Floss for Reduction of Plaque and Bleeding in Areas with Intact Papillae: A Clinical Trial.

Principal Investigator: Pauline Imai, Dip DH, BDSc, MSc, RDH

Co-Investigator: Penny Hatzimanolakis, Dip DH, BDSc, MSc (candidate), RDH

Sponsors: Curaden Swiss in grant aid, BCDHA

Emergency Telephone Number:

1. Introduction:

You are being invited to take part in this research study to determine whether an interdental brush, which is a small cylindrical brush that fits in-between your teeth, is effective for removing plague and reducing bleeding gums in-between your teeth.

2. Your Participation is Voluntary:

Your participation is entirely voluntary. You may decide whether or not to take part in this study. Before you make your decision, it is important for you to understand what the research study involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study, and the possible benefits, risks, and discomforts.

If you wish to participate in this study, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time without giving any reasons for your decision.

If you do not wish to participate in this study, you do not have to provide any reasons for your decision. Under no circumstances should you feel pressured or obligated in any way to participate in this study.

Please take the time to read the following information carefully. You can discuss it with your family, friends, dentist, and dental hygienist before you decide.

3. Who is sponsoring the study?

The British Columbia Dental Hygienists Association is partially funding this study. Curaden Swiss® is generously supplying the inter-dental brushes. The investigators do not receive any financial gain or benefits from the study or Curaden Swiss and are not employed by Curaden Swiss.

4. Background information about gingivitis, dental floss, and inter-dental brushes:

Gingivitis is reversible, inflammation of the gums caused by the presence of plaque on the teeth. Gingivitis is characterized by red, puffy gums, which bleed with brushing or flossing. Untreated, gingivitis may lead to periodontal disease. Periodontal disease usually involves the destruction of the bone and surrounding tissues around the teeth. Severe periodontal disease can result in tooth loss. The best method for treating gingivitis is to remove the plaque from the teeth everyday.

Tooth brushing is effective for removing the plaque from the outside and inside surfaces of the teeth, but it cannot reach the in-between areas where gingivitis is prevalent. Dental floss is the most common method for removing plaque in-between the teeth, but some people have problems maneuvering the floss in their mouths and thus, choose not to floss. Other methods for cleaning in-between the teeth include toothpicks, rubber tips, and interdental brushes. In previous studies, interdental brushes were used in large spaces where there wasn't any in-between the teeth gums. The large spaces were caused by severe bone loss, gum surgery or missing teeth. This study explores the use of interdental brushes in smaller spaces between the teeth, where the gums may still be present. By studying the use of interdental brushes in mild cases of gum disease, we hope to find an alternative method that people can use for cleaning in-between the teeth.

5. What is the purpose of the study?

The purpose of this study is to determine whether the interdental brush is an effective, alternative oral self-care aid to dental floss for removing plaque and reducing gingivitis in-between the teeth.

6. Who can participate in the study?

You must meet the following criteria to be considered for inclusion into the study:

- Have 4 areas that can accommodate the smallest inter-dental brush width.
- 2. Have 8 areas in-between your teeth that bleed with stimulation.
- 3. Have the dexterity to use manual waxed dental floss.

4. Able to attend all 4 UBC sessions.

7. Who should NOT participate in the study?

You cannot take part in the study if you have the following:

- 1. You require antibiotics before every dental visit.
- 2. You are using chlorhexidine mouthwash.
- 3. You choose to use an over the counter mouthwash during the study.
- 4. You smoke.
- 5. You have orthodontic braces.

8. What does the study involve? What procedures and visits can I expect?

If you agree to take part in this study, the procedures and visits you can expect will include the following:

Screening Visit: During this 30 minute visit, dental hygienist #1 will check your medical history and examine your mouth to see if you have at least 4 areas in the posterior areas of your mouth, between your teeth that can accommodate an interdental brush. She will use a color probe to measure the space between your teeth to determine if you have enough space for the brush. Dental hygienist #1 will also check for bleeding gums by inserting a toothpick between your teeth. Any questions you have about the study will be answered. You will be given this consent form to take home to read thoroughly before you make your decision. If you decide to participate, you will be asked to sign this consent form and to return it with you for visit 1.

Visit 1: You will return this signed consent form when you come for this visit and will have your teeth cleaned by dental hygienist #2. This visit can vary from 60 minutes to 90 minutes depending on the amount of tartar you have on your teeth. You will then be asked to <u>return in 2 weeks</u> for visit 2.

Visit 2: Dental hygienist #2 will examine your mouth to determine your plaque and bleeding scores. Your teeth will be disclosed with a disclosing solution. The pink stain is temporary and is easily removed with brushing. The bleeding scores are assessed by inserting a toothpick between your teeth.

You will then receive instructions on how to brush, floss, and use the interdental brush by dental hygienist #1. Dental hygienist #1 will tell you where to floss and where to use the interdental brush. You will be given a guide to remind you where to floss and where to use the interdental brush because you cannot interchange the products in your mouth. You are asked not to tell dental hygienist #2 where in your mouth you are using the floss and interdental brush. This is called examiner-blinding and is done to reduce examiner bias when she examines your mouth at visit 4.

You will receive a manual soft toothbrush (Oral-B #35), Johnson & Johnson waxed dental floss, Colgate Cavity Protection Regular toothpaste, and appropriate interdental brushes. You are asked to only use these products for the next 12 weeks because other types of toothpastes and toothbrushes may affect the study results. This visit is approximately 30-45 minutes. You will return in 6 weeks for visit 3.

Visit 3: Dental hygienist #2 will check your plaque and bleeding scores at this mid-study visit. Your teeth will be disclosed again and a toothpick will be used to check for bleeding.

You will be asked to bring your toothbrush, floss, interdental brushes, and toothpaste so dental hygienist #1 can check for wear and give you replacements as needed. Any questions or concerns about techniques and/or the study in general are addressed. You will return in 6 weeks for the final visit. This visit is approximately 30-45 minutes.

Visit 4: The final visit is with dental hygienist #2 for 30-45 minutes to collect your plaque and bleeding scores. Your teeth will be disclosed again and the toothpick will be used to assess your bleeding scores. You will be asked to fill in a one page questionnaire on the products which you can submit to dental hygienist #2 or mail to the principal investigator. You are then exited from the study.

Where is the study taking place?

How many people will be in the study?

32 volunteers

How long will the study take?

The study is 14 weeks long, from the teeth cleaning visit to the final data collection visit. Each study visit is approximately 30-45 minutes, except the teeth cleaning visit which can vary in length depending on the amount of tartar on your teeth.

9. What are my responsibilities?

You will be asked to use the dental floss and inter-dental brush daily for 12 weeks in the identified areas of your mouth. You will need to attend all 4 study visits and fill in the short questionnaire. If you begin using chlorhexidine mouthwash or over the counter mouthwashes during the 12 week study, you must inform the Principal Investigator as soon as possible.

10. What are the possible harms and side effects of participating in this study?

Some people can be overly vigorous with the dental floss and inter-dental brush and may cause some gum irritation and/or slight gum bleeding, but with proper instruction this possible harm is greatly minimized. Interdental brushes that are too large for the space between your teeth and are forced into the space may cause the gum to shrink creating a space between the teeth; however, this possible side effect will be minimized by choosing the correct sized brush for you. The interdental brush will not be used in the front teeth as a precaution to maintain your smile.

11. What are the benefits of participating in this study?

No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study. We hope that the information learned from this study can be used in the future to benefit other people with a similar condition.

12. What are the alternatives to the study treatment?

If you choose not to participate in this study, the following interdental treatment options may be available to you: rubber tip stimulators, floss holders, and toothpicks. You can

discuss these alternative options with your dentist or dental hygienist before deciding whether or not to participate in this research project.

13. What if new information becomes available that may affect my decision to participate?

If new information arises during the research study that may affect your willingness to remain in the study, you will be advised of this information as soon as possible by telephone. If a more effective treatment becomes available, it will be offered to you.

14. What happens if I decide to withdraw my consent to participate?

Your participation in this research study is entirely voluntary. You may withdraw from this study at any time. If you decide to enter the study and then withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis. By law, this data cannot be destroyed.

15. What happens if something goes wrong?

Signing this consent form in no way limits your legal rights against the sponsor, investigators or anyone else.

In case of a serious medical event, please report to an emergency room and inform them that you are participating in a clinical study and that the following persons can be contacted for further information: Ms. Pauline Imai at

16. Can I be asked to leave the study?

If you are not complying with the requirements of the study or for any other reason, the study investigators may withdraw you from the study. You may be asked to leave the study if you develop one of the study's exclusion criteria or if unexpected serious adverse events, which affect your safety, become known. The investigators may decide to discontinue the study at any time, or to withdraw you from the study at any time, if they feel that it is in your best interests.

17. What happens after the study is finished?

You may not be able to receive the inter-dental brush after your participation in the study is completed. There are several possible reasons for this, some of which include:

- The inter-dental brush may not be effective in removing plaque.
- The inter-dental brush may not be commercially available.
- Your oral health professionals may not feel it is the best option for you.

18. What will the study cost me?

You will have to pay for parking or bus fares to participate in the study. There is no reimbursement for study related expenses. However, you will receive a dental cleaning (approximate value \$160), an honorarium of \$75, and toothbrush, toothpaste, dental floss, and interdental brushes for participating in this study.

19. Will my taking part in this study be kept confidential?

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate and the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices.

20. Who do I contact if I have any questions about the study?

If you have any questions or desire further information with respect to this study, you may contact Ms. Pauline Imai, Principal Investigator, at

21. Who do I contact if I have any questions or concerns about my rights as a subject during the study?

If you have any concerns about your rights and/or experiences as a research subject, you may contact the Research Subject Information Line in the University of British Columbia Office of Research Services at

Subject Consent to Participate

I have read and understood the subject information and consent form.

I have had sufficient time to consider the information provided and to ask for advice if necessary.

I have had the opportunity to ask questions and have had satisfactory responses to my questions.

I understand that all of the information collected will be kept confidential and the result will only be used for scientific objectives.

I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the student-teacher relationship.

I understand that I am not waiving any of my legal rights as a result of signing this consent form.

I understand that there is no guarantee that this study will provide any benefits to me.

I have read this form and I freely consent to participate in this study.

I have been told that I will receive a dated and signed copy of this form.

I, (print your name)	, consent to
	, consent to ntal Brush to Dental Floss for Reduction of
Plaque and Bleeding in Areas with Intact P	•
Your Signature	Date
Witness: (Print name)	
Witness: (Signature)	Date
Principal Investigator: Pauline Imai, Dip Dh	H, BDSc, MSc, RDH,
(Signature)	Date
Note: ESL Translator: (Print name)	
Translator: (Signature)	Date
Language consent form translated into:	

Appendix B: Screening Form

9 SB	
	Place
Interdental Brush vs Dental Screening	FIOSS
Screening	EBI
Subject:Assigned Code:	
Assigned Code:	CODE
Date:	
Color Code Brush	MANNININININININININININININININININININ
Dark green G 06 Red R 07	
Red R 07 Pink P 08	
Yellow Y 09	MANAMMANAME
Lt green LG 011	
	CODE
Eastman Bleeding Index	
(EBI)	EBI
+ = Bleeding present	
- = No bleeding	
	EBI CONTRACTOR OF THE PROPERTY
- i	The state of the s
	CODE
	MAN
is .	
	עטעטועועועועועועועועועועועועועועוע
	CODE
	EBI
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Comments:	
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Appendix C: Data Collection

Interdental Brush vs Dental Data Collection	Floss						
Subject Code:	EBI						
Date: Visit: Baseline Final	PI			1 1			
Plaque Index (PI) 0 = No plaque. No pink visible. 1 = Light film plaque. Light pink flecks. 2 = Moderate plaque. Medium pink solid line/area. Extend interproximal to line at a series of the s	ngle.		8000	3000			
0 = No bleeding 1 = Bleeding after 15s							
	EBI						
	PI	e de la composition della comp		1 1			
28			PR	7 A	AA	PQ	PARR
					0 0	00	
		MN	\	1 4	AlA	IAIAI	AAMU
	PI						
	EBI						
Observations/comments:	1						
				•			
						-	
,							

Appendix D: Study Questionnaire

Subject Questionnaire: "Comparison of Inter-dental Brush to Dental Floss for Reduction of Plaque and Bleeding in Areas with Intact Papillae: A Clinical Trial."

Your <u>anonymous</u> comments about the inter-dental brush and dental floss are greatly appreciated for increasing our understanding of the products' acceptability for patients to use at home.

I. Please place a check mark ($\sqrt{}$) in the box that best describes your response to each statement.

Statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
I found the inter-dental brush easy to use.					
I found the dental floss easy to					
I will continue to use the inter-					
dental brush every day.					
I will continue to use dental					
floss every day.					

II. Please describe any discomfort or problems, if any, that you experienced wh				
using the inter-denta	brush or dental	floss:		
III. Please write any a	dditional comme	ents here:		

Thank you for completing this questionnaire. Your responses are important to us!