Interdental brush in Type I embrasures: Examiner blinded randomized clinical trial of bleeding and plaque efficacy

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ABSTRACT

Background: Daily oral biofilm disruption is necessary for periodontal health; however, clients’ dental flossing compliance is low. This study explores the interdental brush for bleeding and plaque reduction in sites of intact interdental papillae. Methods: Examiner blinded, randomized, split mouth, 12 week clinical trial comparing interdental brush (n = 224 sites) to dental floss (n = 223 sites) for bleeding and plaque reduction in thirty volunteers with a minimum of 4 bleeding sites per side. Non surgical debridement performed at Week 2 with oral hygiene instructions at Weeks 0 and 6. Bleeding and plaque indices at Weeks 0 and 6. Bleeding and plaque indices at Weeks 0, 6, and 12. Results: One way ANOVA comparing interdental brush mean bleeding sites 1.08 (SD 0.27, CI 1.04 to 1.12) to dental floss sites, mean 1.19 (SD 0.39, CI 1.14 to 1.25), demonstrated statistical significance, p = 0.01. There was no statistical difference between interdental brush mean 5.14 (SD 2.62, CI 4.80 to 5.49) and dental floss mean of 5.12 (SD 2.51, CI 4.79 to 5.45) for plaque sites, p = 0.93. Post hoc analyses at the subject level, interdental brush mean bleeding was 0.08 (SD 0.02, CI 0.07 to 0.09) and dental floss mean was 0.2 (SD 0.04, CI 0.18 to 0.21) at Week 12, p = 0.01. Conclusion: Interdental brush significantly reduces bleeding sites in subjects with Type I embrasures. Both interdental aids significantly reduced plaque over 12 weeks.

Key words: interdental cleansing, dental devices, plaque and bleeding indices, gingivitis, oral hygiene

RéSUMÉ

Contexte : La rupture quotidienne du biofilm buccal est nécessaire pour la santé parodontale, mais la clientèle utilise rarement la soie dentaire. Cette étude examine le brossage entre les dents pour réduire le saignement et la plaque dans les sites de la papille interdentaire intacte. Méthodes : Examen à l’insu, randomisation, scission de la bouche, 12 semaines d’essais cliniques comparant la brosse interdentaire (n = 224 sites) à la soie dentaire (m = 223 sites) pour réduire le saignement et la plaque chez trente volontaires ayant un minimum de 4 sites sanguins de chaque côté. Débridement non chirurgical effectué dans la Semaine 2 avec enseignement de l’hygiène buccale durant Semaines 0 et 6. Indices de saignement et de plaque durant les Semaines 0, 6 et 12. Résultats : La comparaison ANOVA à sens unique des sites de saignement au brossage interdentaire, moyenne de 1,08 (ÉT 0,27, CI 1,04 à 1,12) et des sites nettoyés à la soie dentaire, moyenne de 1,19 (ÉT 0,39, CI 1,14 à 1,25), a démontré une statistique importante : p = 0,01. Il n’y avait pas d’écart statistique entre la moyenne de 5,14 (ÉT 2,62, CI 4,80 à 5,49) du brossage interdentaire et la moyenne de 5,12 de la soie dentaire (ÉT 2,51, CI 4,79 à 5,45) pour les sites de plaque, p = 0,93. Aux analyses ultérieures au niveau du sujet, la moyenne de saignement au brossage interdentaire était de 0,08 (ÉT 0,02, CI 0,07 à 0,09) et la moyenne de la soie dentaire était de 0,2 (ÉT 0,04, CI 0,18 à 0,21) dans la Semaine 12, p = 0,01. Conclusion : Le brossage interdentaire réduit de façon significative le saignement des sites chez les sujets avec embrasure de type 1. Les deux modes de nettoyage interdentaire ont réduit considérablement la plaque sur la période de 12 semaines.

Key words: interdental cleansing, dental devices, plaque and bleeding indices, gingivitis, oral hygiene

Clinical relevance

Scientific rationale for study: Dental floss is usually recommended for type I embrasures, but few clients floss daily. The interdental brush is easy to use, but has not been studied in Type I embrasures. Principal findings: The interdental brush reduced bleeding and plaque, and was preferred by subjects. Practical implications: The novel interdental brush system:
• is time and cost efficient for oral health professionals to select an optimal sized interdental brush for their client’s oral self care needs, and
• provides an evidence based alternative for clients who do not comply with dental floss.

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Introduction

Daily effective disruption of the oral biofilm by mechanical self care such as tooth brushing and dental flossing is a common method for achieving and maintaining oral health. The accumulation and maturation of the oral biofilm results in a shift in the health–disease equilibrium such that periopathogens proliferate and the host responds with inflammatory processes that results in periodontium destruction.1–2 Although professional mechanical therapy, such as non surgical debridement is effective for lowering the microbial load and creating a more favourable subgingival environment for health,3–4 effective daily plaque disruption by clients is also necessary to slow the colonization of supragingival biofilm, and thus, its extension subgingivally.4–6

Tooth brushing is the primary and most widely accepted mechanical method for disrupting the oral biofilm, but it cannot effectively reach the interproximal areas where periodontal disease is prevalent.7–10 Dental floss is a common interdental mechanical method for interdental oral biofilm disruption; however, daily compliance ranges from 11% to 30% due to clients’ lack of ability and motivation.11–14 Subjects in previous studies indicated that dental flossing was difficult and time consuming to use,15 therefore, follow up studies have focused on other interdental self care aids such as interdental brushes. Studies comparing interdental brush to dental floss have demonstrated client preference for the interdental brush because of its ease of use.15,16 Furthermore, the interdental brush has effectively demonstrated reductions in dental plaque and bleeding in subjects with clinical attachment loss, and thus, open embrasure areas.8,17,18 However, there is no information on the efficacy of interdental brushes in subjects with Type I embrasures because these subjects were not considered suitable candidates for the large diameter interdental brushes that were previously available. Type I embrasures are defined as interdental papillae that fill the interdental spaces between adjacent teeth that are in contact.19 For the purposes of function and esthetics, preserving the interdental papillae with daily interdental oral self care is desirable.20

Since the prevention and early treatment of periodontal disease is preferred, oral health professionals need to encourage their clients, who have gingivitis, to comply with daily interdental oral self care. Therefore, the purposes of this study were two fold:

i. to determine the interdental brush’s effectiveness for reducing plaque and gingival inflammation as indicated by gingival bleeding upon stimulation in subjects with intact interdental papillae, and

ii. to determine whether the subjects’ perceptions of the interdental brush’s ease of use would have a positive influence on their daily self care compliance.

The study subjects’ preference for interdental self care products may be found in the article, Encouraging client compliance for interdental care with the interdental brush: the client’s perspective.21 This paper will focus on the clinical parameters of the randomized controlled trial.

Materials and methods

Study design

The study was an examiner blinded, split mouth, 3 month, randomized controlled trial comparing interdental brush (Curaprox Prime Series, Curaden Swiss, Amlehnstrasse, Switzerland) to dental floss on premolars and 1st and 2nd molars in 33 healthy adults with bleeding Type I embrasures (Figure 1). The study’s primary outcome parameter was reduction of bleeding, and the secondary outcome was reduction of plaque.

Study recruitment and enrollment

The study protocol was reviewed and approved by the University of British Columbia Clinical Research Ethics Committee in Vancouver, Canada. Subjects were recruited from the general population via a newspaper advertisement in the local paper, Vancouver Craigslist, and flyers posted on UBC campus from September 2008 to February 2009. Subjects were not dental or dental hygiene students. Participation was not limited by race or gender, and all subjects signed a consent form.

The target population was adults with plaque induced gingivitis, as determined by having red, bleeding upon stimulation gingival tissues, and probing depths of 4 mm or less. The inclusion criteria consisted of:

1. a minimum of four interproximal areas per side with intact interdental papillae that could accommodate a minimum 0.6 mm interdental brush width as determined with the colour coded probe (Curaprox Prime Series, Curaden Swiss, Amlehnstrasse, Switzerland);
2. a minimum of four interproximal bleeding sites per side upon stimulation with a Stimu-Dent™ inserted horizontally four times;
3. dexterity to use waxed dental floss without any additional aids, and
4. ability to attend 5 visits.

Subjects were excluded from the study if: 1) they required premedication with antibiotics prior to dental therapy; 2) used chlorhexidine or over-the-counter mouthwash during the study; 3) used tobacco products; 4) had full orthodontia and/or 5) had taken antibiotics one month prior to the study (Figure 1).

Blinding

This was an examiner blinded trial. Blinding was achieved by keeping all the clinical records collected by the examiner separate from the enrollment and randomization process conducted by the study organizer. Only the examiner, who was unaware of the product randomization throughout the study, collected the clinical measurements at baseline, 6, and 12 weeks.

Confidentiality and randomization

Upon entering the study, subjects were assigned an individual identification number. Only the medical health history form contained the subjects’ personal information, and this was separated from the clinical data collection forms by the study organizer. The interdental brush was randomly assigned to the left or right side of the subjects’ mouths with the dental floss assigned to the remaining
Interdental brush in Type I embrasures

Recruitment

n = 68
Adult volunteers in Vancouver, BC

n = 50
Health history
Inclusion/exclusion criteria

Screening (Visit 1)

n = 33
Accepted and signed
Informed consent

Randomization of IDB and DF
Split mouth trial

n = 33
Non surgical debridement using ultrasonic and hand scaling

2 weeks to allow for tissue healing after debridement and to stabilize baseline scores

Baseline (Visit 3)

IDB sites = 240 (n = 33)
Bleeding and plaque indices
OHI - TB, DF, IDB and self reported journals

DF sites = 239 (n = 33)
Bleeding and plaque indices
OHI - TB, DF, IDB and self reported journals

n = 4
1 subject away family emergency
2 subjects no longer interested and withdrew
1 subject began antibiotic therapy and dismissed

Week 6 (Visit 4)

IDB sites = 217 (n = 29)
Bleeding and plaque indices
OHI - TB, DF, IDB and self reported journals

DF sites = 215 (n = 29)
Bleeding and plaque indices
OHI - TB, DF, IDB and self reported journals

Week 12 (Visit 5)

IDB sites = 224 (n = 30)
Bleeding and plaque indices
Exit survey and collection of self reported journals

DF sites = 223 (n = 30)
Bleeding and plaque indices
Exit survey and collection of self reported journals

n = 1
1 subject returned

Figure 1. Consort flow chart of study.

Figure legend:
CI = confidence interval
DF = dental floss
EBI = Eastman bleeding index
IDB = interdental brush
n = number of subjects
OHI = oral hygiene instruction
PI = Silness and Löe plaque index
SD = standard deviation
TB = toothbrush
side (Figure 1). Subjects used both products. Randomization of products to left or right side of the mouth was determined by a flip of coin by the study organizer. All subjects were right handed as determined by observing them write in their medical health histories, and confirmed later when subjects participated in the oral hygiene instruction sessions.

**Study schedule**

Subjects had a minimum of 5 visits: screening, debride ment, baseline, week 6 and week 12 data collection (Figure 1). At baseline, week 6, and week 12, the examiner collected the subjects’ plaque and bleeding scores. Subjects’ teeth were disclosed using disclosing solution (Trace disclosing solution, Young Dental Manufacturing, Earth City, MO, USA) and the Silness and Löe plaque index, which was modified to determine plaque scores on four interproximal surfaces (mesial–buccal, distal–buccal, mesial–lingual, and distal–lingual) of the premolars and 1st and 2nd molars using an ordinal scale of 0 to 3; 0 indicated no plaque, 1 was light plaque, 2 was moderate plaque, and 3 was heavy plaque accumulation. The Eastman Bleeding index was used to determine the presence or absence of interproximal bleeding posterior to the canines; score of 0 was no bleeding, and 1 was presence of bleeding. The study organizer measured the subjects’ embrasures with the colour coded probe (Curaprox Prime Series, Curaden Swiss, Amlehnstrasse, Switzerland), which was inserted horizontally from the buccal aspect until snug and observing the visible colour. Each colour on the probe corresponds to a matching colour coded interdental brush. The interdental brush diameters range from 0.6 mm (dark green on the probe) to 1.1 mm (light green). Five brush diameters were available: 0.6 mm, 0.7 mm, 0.8 mm, 0.9 mm, and 1.1 mm. A maximum of three interdental brush sizes were chosen per subject. When more than three brush sizes were required, a smaller already identified diameter was used for that site.

Subjects were instructed, with no time limit, in the use of:
- the modified Bass tooth brushing method using a soft manual toothbrush (Curaprox CS 5460 Prime™ ultrasonic toothbrush, Curaden Swiss, Amlehnstrasse, Switzerland),
- manual flossing with waxed dental floss (Johnson & Johnson Inc., NB, Canada), and
- interdental brush (Curaprox Prime Series, Curaden Swiss, Amlehnstrasse, Switzerland).

Subjects were instructed to brush their teeth twice a day, once in the morning and again at night, and to use the dental floss and interdental brush once a day on the assigned side, preferably at night. Subjects were instructed in dental flossing techniques to ensure maximum floss adaptation around the interproximal tooth surfaces. Interdental brush instruction consisted of inserting the interdental brush from the facial aspect, slightly apical until the tip passed under the contact point then horizontally through the embrasure area. The interdental brush was inserted once and removed. Subjects were cautioned not to thrust the interdental brush interproximally and repeatedly in a brushing motion. The study organizer demonstrated the difference between a new and worn interdental brush, and encouraged subjects to replace their interdental brush as needed. Based on the manufacturer’s prospectus, this occurred between 10 and 14 days. Subjects received enough supplies to last 6 weeks, but could request more supplies from the study organizer at any time. All subjects were instructed to only use these products and the provided toothpaste (Colgate Cavity Protection Regular toothpaste, Colgate-Palmolive Canada Inc., Canada), and to refrain from professional dental hygiene services, and over-the-counter and prescription mouthwashes during the study period.

Subjects were also given a daily journal at baseline to self report their daily compliance with interdental brushing and dental flossing (Figure 1). The journal, which the subjects were encouraged to place in their bathroom as a reminder, included a diagram of the teeth and indications as to where to use the specific interdental brush and dental floss.

Throughout our study, the examiner assessed the subjects for soft tissue trauma as indicated by clinically visible gingival cuts, redness, abraded areas, or damaged interdental papilla, and the study organizer addressed subjects’ concerns.

**Statistical analyses**

According to a study by Jackson et al., who demonstrated positive results with a parallel randomized controlled trial comparing interdental brush and dental floss over 12 weeks, 34 participants per group were needed to detect a 15% difference between the products for mean plaque index at 12 weeks. Yost et al. had approximately 30 subjects per group, and demonstrated statistically greater reductions in gingival index for the interdental brushes compared to dental floss. Our study enrolled 33 subjects to compare interdental brush to dental floss. Descriptive statistics, one way ANOVA, and paired t-tests (SPSS 17) were used to analyze the quantitative data. One way ANOVA compared interdental brush to dental floss sites at Weeks 0, 6, and 12. Paired t-tests were used to monitor the reduction in bleeding and plaque from baseline to week 12 for interdental brush and dental floss sites. Post hoc analyses were conducted at the subject level for the primary outcome of bleeding reduction between interdental brush and dental floss at Week 12. All analyses were conducted with alpha set at 0.05 and 95% confidence intervals.

**Results**

Thirty adults (20 women, 10 men) completed the three month study, contributing 224 interdental brush sites and 223 dental floss sites. All participants were right handed.

At baseline (Week 0), there was no statistically significant difference between the interdental brush and dental floss sites for bleeding and plaque scores (Tables 1 and 2). Comparing interdental brush to dental floss sites at Weeks 6 and 12, demonstrated statistically significant differences between the products for reduction in bleeding sites (Table 1). However, both products performed similarly for
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reduction of plaque site mean scores at Weeks 6 and 12 (Table 2). Post hoc analyses at the subject level continued to support the interdental brush for statistically significant reduction in bleeding compared to dental floss at Week 12 (Table 3), but maintained the non significant differences between the products for plaque scores (Table 4).

From baseline to Week 6, as well as baseline to Week 12, mean bleeding and plaque scores were significantly reduced in interdental brush sites (Table 5). Mean plaque scores were also significantly reduced in dental floss sites from baseline to Week 6 and baseline to Week 12 (Table 5). Although mean bleeding scores did not reach statistical significance for dental floss sites from baseline to Week 6, it became significant over the 12 weeks (Table 5).

Subject compliance with interdental brush and dental floss, determined by self reported journal entries, and approximation of product use was high. At Week 6, subjects were using the interdental brush 89.13% of the

Table 1. Comparison of mean bleeding scores between interdental brush (IDB) and dental floss (DF) sites at weeks 0, 6, and 12.

<table>
<thead>
<tr>
<th>Product</th>
<th>Week</th>
<th>n (sites)</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI (lower, upper bound)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDB</td>
<td>0</td>
<td>240</td>
<td>1.32</td>
<td>0.47</td>
<td>1.26, 1.38</td>
<td>0.243</td>
</tr>
<tr>
<td>DF</td>
<td>0</td>
<td>239</td>
<td>1.27</td>
<td>0.45</td>
<td>1.22, 1.33</td>
<td></td>
</tr>
<tr>
<td>IDB</td>
<td>6</td>
<td>217</td>
<td>1.11</td>
<td>0.31</td>
<td>1.06, 1.15</td>
<td>0.035</td>
</tr>
<tr>
<td>DF</td>
<td>6</td>
<td>215</td>
<td>1.18</td>
<td>0.38</td>
<td>1.13, 1.23</td>
<td></td>
</tr>
<tr>
<td>IDB</td>
<td>12</td>
<td>224</td>
<td>1.08</td>
<td>0.27</td>
<td>1.04, 1.12</td>
<td>0.001</td>
</tr>
<tr>
<td>DF</td>
<td>12</td>
<td>223</td>
<td>1.19</td>
<td>0.40</td>
<td>1.14, 1.25</td>
<td></td>
</tr>
</tbody>
</table>

Table 2. Comparison of mean plaque scores between interdental brush (IDB) and dental floss (DF) sites at weeks 0, 6, and 12.

<table>
<thead>
<tr>
<th>Product</th>
<th>Week</th>
<th>n (sites)</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI (lower, upper bound)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDB</td>
<td>0</td>
<td>240</td>
<td>6.43</td>
<td>2.82</td>
<td>6.07, 6.79</td>
<td>0.262</td>
</tr>
<tr>
<td>DF</td>
<td>0</td>
<td>239</td>
<td>6.14</td>
<td>2.78</td>
<td>5.79, 6.50</td>
<td></td>
</tr>
<tr>
<td>IDB</td>
<td>6</td>
<td>217</td>
<td>5.06</td>
<td>2.39</td>
<td>4.74, 5.38</td>
<td>0.344</td>
</tr>
<tr>
<td>DF</td>
<td>6</td>
<td>215</td>
<td>4.85</td>
<td>2.29</td>
<td>4.54, 5.15</td>
<td></td>
</tr>
<tr>
<td>IDB</td>
<td>12</td>
<td>224</td>
<td>5.14</td>
<td>2.62</td>
<td>4.80, 5.49</td>
<td>0.928</td>
</tr>
<tr>
<td>DF</td>
<td>12</td>
<td>223</td>
<td>5.12</td>
<td>2.51</td>
<td>4.79, 5.45</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Comparison of mean bleeding scores between interdental brush (IDB) and dental floss (DF) in subjects at weeks 0, 6, and 12.

<table>
<thead>
<tr>
<th>Product</th>
<th>Week</th>
<th>n (subjects)</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI (lower, upper bound)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDB</td>
<td>0</td>
<td>30</td>
<td>0.30</td>
<td>0.05</td>
<td>0.28, 0.32</td>
<td>0.31</td>
</tr>
<tr>
<td>DF</td>
<td>0</td>
<td>30</td>
<td>0.27</td>
<td>0.06</td>
<td>0.25, 0.29</td>
<td></td>
</tr>
<tr>
<td>IDB</td>
<td>6</td>
<td>29</td>
<td>0.11</td>
<td>0.03</td>
<td>0.10, 0.12</td>
<td>0.14</td>
</tr>
<tr>
<td>DF</td>
<td>6</td>
<td>29</td>
<td>0.17</td>
<td>0.04</td>
<td>0.15, 0.18</td>
<td></td>
</tr>
<tr>
<td>IDB</td>
<td>12</td>
<td>30</td>
<td>0.08</td>
<td>0.02</td>
<td>0.07, 0.09</td>
<td>0.01</td>
</tr>
<tr>
<td>DF</td>
<td>12</td>
<td>30</td>
<td>0.20</td>
<td>0.04</td>
<td>0.18, 0.21</td>
<td></td>
</tr>
</tbody>
</table>

Table legend: CI = confidence interval; DF = dental floss; EBI = Eastman bleeding index; IDB = interdental brush; n = number of subjects; OHI = oral hygiene instruction; PI = Silness and Löe plaque index; SD = standard deviation; TB = toothbrush
Table 4. Comparison of mean plaque scores between interdental brush (IDB) and dental floss (DF) in subjects at weeks 0, 6, and 12.

<table>
<thead>
<tr>
<th>Product</th>
<th>Week</th>
<th>n (subjects)</th>
<th>Mean</th>
<th>SD</th>
<th>95% CI (lower, upper bound)</th>
<th>p- value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDB</td>
<td>0</td>
<td>30</td>
<td>1.68</td>
<td>0.36</td>
<td>1.55, 1.82</td>
<td>0.20</td>
</tr>
<tr>
<td>DF</td>
<td>0</td>
<td>30</td>
<td>1.55</td>
<td>0.30</td>
<td>1.44, 1.67</td>
<td></td>
</tr>
<tr>
<td>IDB</td>
<td>6</td>
<td>29</td>
<td>1.23</td>
<td>0.18</td>
<td>1.17, 1.30</td>
<td>0.47</td>
</tr>
<tr>
<td>DF</td>
<td>6</td>
<td>29</td>
<td>1.23</td>
<td>0.18</td>
<td>1.16, 1.29</td>
<td></td>
</tr>
<tr>
<td>IDB</td>
<td>12</td>
<td>30</td>
<td>1.26</td>
<td>0.24</td>
<td>1.17, 1.35</td>
<td>0.43</td>
</tr>
<tr>
<td>DF</td>
<td>12</td>
<td>30</td>
<td>1.28</td>
<td>0.22</td>
<td>1.20, 1.37</td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Comparison of mean bleeding and plaque scores of interdental brush (IDB) and dental floss (DF) sites from baseline to week 6 and baseline to week 12.

<table>
<thead>
<tr>
<th>Weeks</th>
<th>Product</th>
<th>Index</th>
<th>Mean</th>
<th>SD</th>
<th>Lower</th>
<th>Upper</th>
<th>Sig (2 tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 6</td>
<td>IDB</td>
<td>EBI</td>
<td>0.19</td>
<td>0.49</td>
<td>0.12</td>
<td>0.25</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>0 – 6</td>
<td>DF</td>
<td>EBI</td>
<td>0.65</td>
<td>0.53</td>
<td>-0.01</td>
<td>0.14</td>
<td>0.07</td>
</tr>
<tr>
<td>0 – 12</td>
<td>IDB</td>
<td>EBI</td>
<td>0.23</td>
<td>0.51</td>
<td>0.16</td>
<td>0.29</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>0 – 12</td>
<td>DF</td>
<td>EBI</td>
<td>0.08</td>
<td>0.52</td>
<td>0.01</td>
<td>0.14</td>
<td>0.03</td>
</tr>
<tr>
<td>0 – 6</td>
<td>IDB</td>
<td>PI</td>
<td>1.45</td>
<td>2.80</td>
<td>1.08</td>
<td>1.83</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>0 – 6</td>
<td>DF</td>
<td>PI</td>
<td>1.34</td>
<td>2.60</td>
<td>0.99</td>
<td>1.69</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>0 – 12</td>
<td>IDB</td>
<td>PI</td>
<td>1.49</td>
<td>3.02</td>
<td>1.09</td>
<td>1.89</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>0 – 12</td>
<td>DF</td>
<td>PI</td>
<td>1.14</td>
<td>2.87</td>
<td>0.77</td>
<td>1.52</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Table legend: CI = confidence interval; DF = dental floss; EBI = Eastman bleeding index; IDB = interdental brush; n = number of subjects; OHI = oral hygiene instruction; PI = Silness and Löe plaque index; SD = standard deviation; TB = toothbrush

time (SD 19.85) and the dental floss 88.93% (SD 19.70). At Week 12, compliance remained high with subjects using the interdental brush 92.70% of the time (SD 7.77) and the dental floss 92.34% (SD 8.70). There were no statistically significant differences between interdental brush and dental floss for subject compliance at Week 6 (p = 0.97) and Week 12 (p = 0.88). There were no adverse events or side effects at any of the time points for interdental brush or dental floss.

Discussion

Daily oral self care is an essential part of the health disease equilibrium,9 and this study demonstrated the positive effects of daily interdental oral self care. The absence of bleeding, which is a clinical sign of gingival health,25 was significantly better in interdental brush sites. Interdental brushes are effective for the central part of the interdental space compared to dental floss, which cannot effectively remove plaque from the invaginated axial cervical tooth surfaces.15,26 The bristles of an appropriately sized interdental brush are able to disrupt the interdental oral biofilm, especially in the concave tooth and root anatomy of premolars and molars.27–29 This study used a measuring tool to determine the best fitting interdental brush per site. The result was effective disruption of the oral biofilm interproximally compared to other studies that used a one-size-fits-all interdental brush for the subjects’ interdental sites, and thus, demonstrated no statistical difference among the products for bleeding scores.18,30 Similar to other studies, our study demonstrated plaque reduction over the 12 weeks for interdental and dental floss sites, but no statistical difference between the products.18,30 Only Jackson et al.24 demonstrated a statistical
difference between interdental brush and dental floss for plaque scores. Subjects in Jackson et al.'s study were diagnosed with chronic periodontitis and recruited from a periodontal waiting list. As such they were likely to have open embrasures, which may have enhanced the subjects’ ability to remove interproximal plaque with the interdental brush, and increased the examiner’s visibility for plaque scoring. In our study, subjects had intact interdental papillae, which limited the subjects’ and examiner’s visibility of the disclosed plaque on interproximal tooth and root surfaces.

Also, subjects in our study received professional debridement prior to the intervention phase unlike those in Jackson et al. Professional debridement has been shown to have positive influences on gingival health by removing the oral biofilm and altering the interproximal and subgingival environments, especially in the root grooves and concavities of molars and premolars, areas that dental floss cannot effectively deplaque. Similar to Yost et al., the lack of plaque score differences between the interdental brush and dental floss in our study may be related to the pre-intervention debridement.

The repeated nature of the oral hygiene instructions may have also had an effect on the clinical improvements demonstrated in our study. In order for dental floss to be effective, clients must have effective flossing techniques. According to one study, 40% of subjects were not using proper flossing technique. The subjects in the Segelnick study demonstrated similar difficulties with dental floss at the baseline oral hygiene instruction sessions such as incorrect adaptation of the floss around the teeth, and inadequate mechanical motions to remove the disclosed plaque deposits. However, after receiving repeated, intensive one-on-one instructions, most subjects demonstrated effective dental flossing technique and were able to remove the visible, disclosed plaque deposits. Evidence for this improvement in flossing technique is demonstrated by the statistically significant reductions of plaque scores over time. This finding supports the conclusions of other studies, namely that dental flossing technique plays a significant role in effective plaque biofilm disruption.

Subjects who participate in a study often exhibit compliance with behaviours that may or may not continue beyond the study’s parameters. Daily compliance with dental flossing is historically low, but subjects in this study had high compliance with daily dental flossing, which had positive influences on the clinical parameters. Therefore, one must consider that it may not be the specific interdental aid that has a significant effect on the client’s oral health status, but rather their compliance with daily self care. Oral health professionals need to provide continual oral health education and support for clients who demonstrate a readiness to change their oral self care behaviours to demonstrate the clinical benefits of daily interdental oral self care.

Although our study demonstrated no statistical difference between the interdental brush and dental floss for plaque scores, the interdental brush demonstrated statistically significant reductions in bleeding, a histological supported clinical manifestation of gingival inflammation. It would appear that the interdental brush was disrupting the interproximal oral biofilm sufficiently to cause a shift in the equilibrium towards gingival health compared to the dental floss sites. The results of our study support the recommendation of the interdental brush for oral self care in clients with intact interdental papillae, especially for clients who prefer not to use dental floss to achieve and maintain oral health.

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References

Encouraging client compliance for interdental care with the interdental brush: The client’s perspective

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ABSTRACT

Background: Toothbrushing for daily oral biofilm disruption is well accepted by clients, but dental flossing is not, due to poor dexterity or lack of motivation or both. The interdental brush is considered an easy to use alternative, which may influence daily self care compliance; however it has only been studied in subjects with open embrasures. Purpose: To determine whether interdental brush’s ease of use influences willingness for daily compliance in subjects with intact interdental papillae. Methods: This paper focuses on the secondary outcome of a randomized controlled trial comparing interdental brush to dental floss in 32 adults with intact but bleeding interdental papillae. Subjects received non surgical debridement two weeks prior to intervention phase, and instructions to use toothbrush, dental floss, and interdental brush at baseline (week 0) and week 6. Subject compliance was measured with self reported journals and amount of products used. Exit survey collected information about subjects’ perceptions and preferences for interdental brush and dental floss. Results: Subjects were more than twice as likely to “strongly agree” that interdental brush was easy to use compared to flossing, with 40% having neutral opinions about dental floss’s ease of use. They were also willing to use the interdental brush daily (43.3% strongly agreed and 50% agreed). The subjects’ opinions regarding daily dental flossing ranged from “disagree” to “strongly agree” (6.7% to 30.0% respectively). Discussion: Study results were similar to other studies that demonstrated client compliance with interproximal oral self care is associated with clients’ perceptions of ease of use and motivation. Conclusion: Interdental brush is easy to use and well accepted by study subjects, which may positively influence daily interproximal self care compliance.

RESUME

Contexte : La clientèle accepte bien le brossage des dents pour le nettoyage quotidien du biofilm, mais il n’en est pas ainsi de l’usage de la soie dentaire. La brosse interdentaire est choisie comme alternative plus facile à utiliser, qui peut influencer la pratique des soins personnels quotidiens; toutefois, cela n’a pas fait l’objet d’études chez les sujets ayant des embrasures ouvertes. Objet : Établir si la facilité d’utilisation de la brosse interdentaire influence la propension au brossage quotidien chez les sujets dont les papilles interdentaires sont intactes. Méthode : Cet article se concentre sur les effets secondaires d’un essai contrôlé et randomisé, comparant le brossage interdentaire à l’utilisation de la soie dentaire chez 32 adultes ayant des papilles interdentaires intactes, mais saignantes. Les sujets ont reçu un débridement non chirurgical deux semaines avant la phase d’intervention et des instructions sur la façon d’utiliser la brosse à dents, la soie dentaire et la brosse interdentaire au départ (semaine 0) et à la 6e semaine. La propension des sujets a été mesurée à partir de comptes-rendus quotidiens et de la quantité de produits utilisés. Le dernier questionnaire a permis de recueillir de l’information sur la perception et les préférences des sujets concernant la brosse et la soie dentaire. Résultats : Les sujets étaient au moins deux fois plus enclins à être “vivement d’accord” sur la facilité d’utilisation de la brosse interdentaire comparativement à la soie dentaire, et 40% se sont dit neutres sur la facilité d’utilisation de la soie dentaire. On était aussi d’accord à utiliser la brosse interdentaire quotidiennement (43,3 % étaient très d’accord et 50 %, d’accord). L’avis des sujets concernant l’usage quotidien de la soie dentaire variait entre « d’accord » et « y êtes d’accord » (6,7 % à 30,0 %, respectivement). Discussion : Les résultats de l’étude ressemblent à ceux des autres études qui ont démontré que la propension des clients aux soins buccaux interproximaux personnels s’associe à la perception de facilité d’usage et à la motivation des clients. Conclusion : La brosse interdentaire est facile à utiliser et bien acceptée par les sujets de l’étude, ce qui peut influencer positivement la propension aux soins interproximaux personnels et quotidiens.

Key words: dental home care devices, client compliance, oral hygiene, interdental cleansing/ aids

INTRODUCTION

Oral biofilm, known as dental plaque, is a complex bacterial community that naturally develops on a tooth surface, and contributes to the host’s defences by preventing the colonization of exogenous species.1 However if left undisturbed, there is a gradual shift in the bacterial flora to Gram-negative anaerobes that have been associated with periodontitis.2–4 Plaque induced gingivitis is the early, reversible stage of periodontal disease.5 Although not all sites with gingivitis will progress to periodontitis, oral health professionals are unable to predict the level or rate of progression,2–4 which necessitates the prevention and treatment of gingivitis.2 Daily mechanical disruption of the oral biofilm remains the primary self care method for achieving and maintaining oral health because studies have demonstrated that bacteria are protected in the biofilm from orally delivered antimicrobial agents.5–8 Although toothbrushing is well accepted, interdental self care is not.7 The toothbrush is unable to penetrate intact interdental areas to disrupt the biofilm where periodontal disease is prevalent.7,8 Dental hygienists commonly recommend dental floss for their client’s interproximal oral biofilm disruption, but clients’ compliance for daily flossing is usually low, ranging from 10% to 30%, due to lack of dexterity and motivation.7 Studies have demonstrated that individuals who experience difficulties with dental floss are less motivated to floss daily.7

Other interdental aids have been developed to facilitate easier oral self care and thus, attempt to address the compliance issue.9,10 The interdental brush is a small cylindrical or cone shaped brush that is inserted interproximally. Usually the interdental brush is studied in subjects with clinical attachment loss who present with
larger interdental embrasure spaces. In subjects with large embrasure spaces, the interdental brush reduced probing depths, bleeding scores, and had superior plaque reducing abilities compared to dental floss. However there is no published literature on the efficacy of interdental brush for clients with intact interdental papillae. Since it is desirable to treat gingivitis with the aim to prevent possible progression to periodontitis and clinical attachment loss, oral health professionals need alternative, evidence based interdental oral self care aids to recommend to their clients who are adverse to or cannot floss.

This paper focuses on the subjects’ perceived ease of use with the interdental brush and dental floss, as well as how this perception may influence their willingness for daily self care compliance. A separate paper will be published later reporting the clinical findings surrounding the relative effectiveness of interdental brush to dental floss in individuals with intact interdental papillae.

MATERIALS AND METHODS

Study design

The study was an examiner blinded, split mouth, three month, randomized controlled trial comparing interdental brush to dental floss on premolars, first and second molars in thirty-two healthy adults with intact, but bleeding interdental papillae. Clinical outcomes and subjects perceptions were measured. This paper will focus on the subjects’ perceptions in the exit survey. The study protocol was reviewed and approved by the University of British Columbia’s Clinical Research Ethics Board. The study is registered with www.Clinicaltrials.gov (Identifier NCT00743548).

Study recruitment and enrolment

Subjects were recruited via a newspaper ad in the local paper, Vancouver Craig’s List, flyers posted on the University of British Columbia’s (UBC) campus, and orally through the Vancouver Westside dental community. Participation was not limited by race or gender. Study subjects were not dental or dental hygiene students, but were recruited from the general population. All study visits were held at the Nobel Biocare Oral Health Centre, which is the dental clinic located on UBC’s Point Grey campus in Vancouver, Canada.

All potential subjects were screened to inform them of the nature of the study and to determine whether they met the inclusion/exclusion criteria. Inclusion criteria consisted of:

1. a minimum of four interproximal areas per side that could accommodate a minimum 0.6 mm interdental brush width as determined with the Curaprox probe™ (Curaden Swiss, Amlehnstrasse, Switzerland),
2. a minimum of eight interproximal bleeding sites upon stimulation with a Stimu-Dent™ (Johnson & Johnson Inc., NB, Canada) inserted horizontally four times,
3. dexterity to use waxed dental floss without any additional aids, and
4. ability to attend five study visits.

Subjects were only required to present with interdental papillae filling the interdental spaces of adjacent teeth that are in contact. Interdental brush width was determined by horizontally inserting the Curaprox coloured probe™ from the buccal aspect until snug, and by observing the colour left visible as shown in Figure 1. Each colour on the probe corresponds to a brush diameter. The diameters range from 0.6 mm (dark green on the probe) to 2.0 mm (light green). Subjects were excluded from the study if they:

1. required premedication with antibiotics prior to dental therapy,
2. used chlorhexidine or over the counter mouthwash during the study,
3. used tobacco products, and/or
4. had full orthodontia.

Subjects who met the study’s inclusion/exclusion criteria were invited to participate in the study, and they signed informed consent.

Figure 1: Coloured probe and corresponding interdental brush inserted interproximally. A. The coloured probe is inserted horizontally into the interproximal site until snug. B. The visible colour on the buccal aspect corresponds to the best fitting interdental brush for the site.
Maintaining client anonymity and randomization

The subjects were assigned an individual identification number upon study enrolment. Only the medical health history form contained the subjects’ personal information. All data collection forms, compliance forms, and surveys were coded and separated from the medical history form to maintain the subjects’ confidentiality and anonymity.

The non blinded examiner randomized subjects upon initial subject contact, before screening information was collected. The non blinded examiner randomized the subjects without knowledge of any subject information such as dominant hand, number of bleeding sites, and size of interdental spaces. The left side of the subjects’ mouths was randomly assigned by flip of coin to interdental brush or dental floss with the right side receiving the remaining oral self care aid. There was no attempt to balance the distribution of interdental brush or dental floss to left side of the subjects’ mouths, but the resulting distribution was fairly equal.

Study schedule

Upon enrolment and prior to the intervention phase of the study, all subjects received non surgical periodontal debridement using a combination of ultrasonic and hand instrumentation with no time limit, by an experienced dental hygienist two to three weeks before baseline data collection.

Subjects were given verbal and hands on oral hygiene instructions by the non blinded examiner at baseline and Week 6. Modified Bass tooth brushing method using Curaprox CS 5460 Prime ultra-soft compact toothbrush™ (Curaden Swiss, Amlehnstrasse, Switzerland), spool flossing with waxed dental floss and no flossing aids (Johnson & Johnson Inc., NB, Canada), and Curaprox Prime IDB™ (Curaden Swiss, Amlehnstrasse, Switzerland). Instructions were provided until the subject was comfortable with the techniques and had no unanswered questions. During the oral hygiene instructions the subjects’ dominant hand was noted as the one the subjects used to brush, floss, and interdentally brush. Subjects were instructed to brush their teeth twice a day, morning and before bed; floss once a day on the assigned side preferably at night, and use the appropriate colored interdental brush inserted once in and out on the assigned side, once a day, again preferably at night. All subjects were instructed to use only these products and the toothpaste provided, Colgate Cavity Protection Regular toothpaste, (Colgate-Palmolive Canada Inc.) and to refrain from using professional dental hygiene services and over the counter and prescription mouthwashes during the study period. Subjects were given a compliance folder to note their daily progress with the interdental brush or dental floss. The compliance folder included a diagram of the teeth and indications as to where to use the dental floss and specific interdental brush, which included a maximum of three colours representing differing diameters. Subjects were encouraged to place this diagram in their bathroom as a reference and reminder. Subject compliance was evaluated through the self reported journal, and product wear and usage at Weeks 6 and 12.

The exit survey was distributed and collected by the non blinded examiner at the end of the Week 12 visit. A 5-point Likert scale, ranging from “Strongly agree” to “Strongly disagree”, was used for the exit survey to capture the study subjects’ opinions regarding the interdental brush or dental floss. The survey consisted of four closed item statements and one open ended question to provide subjects with an opportunity to add their own comments.

Figure 2: Frequency of subjects’ responses to exit survey. The coloured bars represent the five point Likert scale ranging from “Strongly Agree” to “Strongly Disagree” that subjects used. The length of the bars represents the frequency of the subjects’ responses for each statement.
Thirty adults completed the three-month study. Two adults were unable to be contacted upon completion of the debridement, and did not enter the intervention phase of the study.

The exit survey results indicated 50% of the study subjects strongly agreed and 46.7% agreed that the interdental brush was easy to use (Figure 2). In the survey, subjects stated that the “interdental brush was easier to use even with a busy schedule and was faster than dental floss.” Other subjects commented, “I like the interdental brush over flossing because of the ease of use; I can reach parts [with the interdental brush] that I find difficult to clean with dental floss.” Subjects had no prior experience with the Curprox™ IDB system because this product is unavailable in western Canada.

Fewer subjects agreed that dental floss was easy to use (Figure 2). Although there was no statistically significant difference between interdental brush and dental floss for ease of use, $X^2(1, n=30)=0.9, p<0.05$, forty per cent of subjects were neutral about dental floss’s ease of use. Study subjects comments included, “the dental floss is slippery and difficult to grasp, which made it less convenient than the interdental brush. I found dental floss irritating to use, especially trying to maneuver it in the back teeth.” The majority of subjects (97%) entered the study with no history of daily flossing, but by the end of the study, 30% of the subjects strongly agreed and 36.7% agreed that they were willing to use dental floss every day (Figure 2). These subjects attributed their willingness to floss daily to learning the proper flossing technique and the structure created within the study. The other 26.7% held neutral opinions on daily flossing, and 6.7% were not willing to floss daily beyond the study because they found it difficult to use and time consuming (Figure 2). Subjects “strongly agreed” (43.3%) and “agreed” (50.0%) that they were willing to brush interdentally daily (Figure 2). In particular, the majority of the subjects’ open comments indicated they would more likely use the interdental brush daily although there was no statistically significant difference between interdental brush and dental floss for daily use preference in the closed items, $X^2(1, n=30)=0.87, p<0.05$. Ease of use was a major theme, and this may have influenced the subjects’ willingness to continue and use the interdental brush daily. Subjects commented, “I really prefer the interdental brush; I can still clean my teeth before bed, even in a busy daily schedule, with the interdental brush, but this is not the case with dental floss.” Two subjects, who were neutral about using the interdental brush daily, commented they had difficulty accessing the interproximal site between the last two molars and did not like changing the brush tips for the various sites.

**DISCUSSION**

Many dental hygienists focus on instructing their clients in the use of dental floss for oral health maintenance and treatment of gingival diseases because they have been taught flossing in their dental hygiene education, and are familiar with the product. However client compliance with dental floss is historically low in spite of dental hygienists providing oral health education and flossing instructions. Clients frequently choose not to floss because of lack of motivation and ability. Motivation to change behaviour may be imposed externally, which may then develop into an internally valued belief that is sustained. In this study, subjects became keenly aware of the sites that were bleeding, and became interested in monitoring these sites while using the interdental brush and dental floss. The presence of bleeding, which is an objective sign of gingival inflammation, became an effective external motivator for the subjects. Subjects commented that they were motivated to brush interdentally and floss to attain non bleeding status, and began to equate non bleeding sites with gingival health. In this study, several subjects stated they now understood the importance of self care for oral health. The internalization of health beliefs, such that external motivators no longer play a role in compliance, needs further investigation.

Simply being in the study may have also motivated the study subjects to comply with interdental brush and dental floss. The Hawthorne Effect occurs when subjects are immersed in an environment that supports positive behaviours. In this study, subjects were required to report their daily use of interdental brush and dental floss in a journal. The journal had to be submitted to the non blinded examiner along with the subjects’ dental products at Weeks 6 and 12 to be inspected for usage, and thus, subjects may have been motivated to please the examiners.

Study subjects were also motivated by the frequent, intensive oral hygiene instructions that encouraged them to continue to improve their oral self care techniques as well as their daily use of interdental brush and dental floss. According to Stewart and Wolfe, subjects who received two 30-minute sessions of oral hygiene instruction were able to maintain their newly acquired self care skills a year later, but other studies have shown that educational attempts at modifying client behaviour for daily flossing is unsuccessful. Since the present study had no long term follow up, it is unknown if these study subjects would continue their daily interdental self care routine. A long term study is needed to observe whether intensive, continuous oral hygiene instructions in self care skill acquisition and oral health knowledge would assist clients in achieving long term interdental self care compliance.

According to Asadoorian, motivation to self care
interdentally is closely linked to the individual’s ability to use the aid. Although there was no statistically significant difference for subjects’ product preference in the present study, the overall theme collected from the subjects’ comments was that “ease of use” played a significant role in their willingness to continue the daily use of the interdental brush. In this study, almost all subjects agreed that the interdental brush was easy to use. The interdental brush could be used with one hand and subsequently, without the use of a mirror. The study findings were similar to those reported by Slot et al., in which patients considered the interdental brush to be simpler to use, in spite of the brush’s tendency to bend and distort.

While subjects were familiar with dental floss, and had received flossing instructions previously from their oral health professionals, the majority of the subjects did not floss daily prior to enrolling in this study because they did not like dental floss, found it difficult to use, and/or were not motivated to use it. Dental floss takes a certain amount of dexterity and instruction to achieve optimal interproximal oral biofilm disruption and this was apparent in this study. Subjects received intensive one-on-one flossing technique instructions at baseline and week 6, and even with repeated instructions, two subjects were unable to master the skill as evidenced by their stable interproximal plaque scores. For some subjects, the repeated flossing instructions not only assisted them with achieving the correct technique, they became more accustomed to dental floss, and thus indicated that they were more willing to continue with daily flossing on the exit survey. These findings support Asadoorian’s comment that ability and motivation are closely linked.7

There are numerous health behavioural theories, such as the Health Belief Model, Trans Theoretical Model, Stages of Change, Self Efficacy, and Locus of Control Model that have explored oral health behaviour modification.16,17 These models focus on individuals assuming responsibility for their own health.16,17 A complete review of oral health behaviour models can be found elsewhere.16,17 Having a clear understanding of these models and the clients’ stage of behaviour are critical for identifying, modifying or changing behaviours that contribute to optimal oral and overall health.

This study demonstrates the importance of assessing the client’s abilities and source of motivation prior to making an oral self care recommendation for optimal compliance. Frequent client centred oral hygiene instruction and support is necessary to nurture the new behaviour until the client becomes accustomed to the technique and routine. Dental hygienists must consider their own biases and preferences in addition to the scientific evidence when recommending oral self care products to their clients.

CONCLUSION

The interdental brush is an easy to use alternative, interdental self care aid for clients with gingivitis and intact interdental papilla in the posterior sites, who cannot or choose not to use dental floss as part of their oral self care preventive routine. Study subjects were more willing to use the interdental brush than dental floss for their daily interdental self care due to its ease of use, which may enhance oral self care compliance.

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