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, 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.

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 saignants 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

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Clinical relevance

Clinicaltrials.gov Identifier: NCT00743548

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.

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.[9,17,18] 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
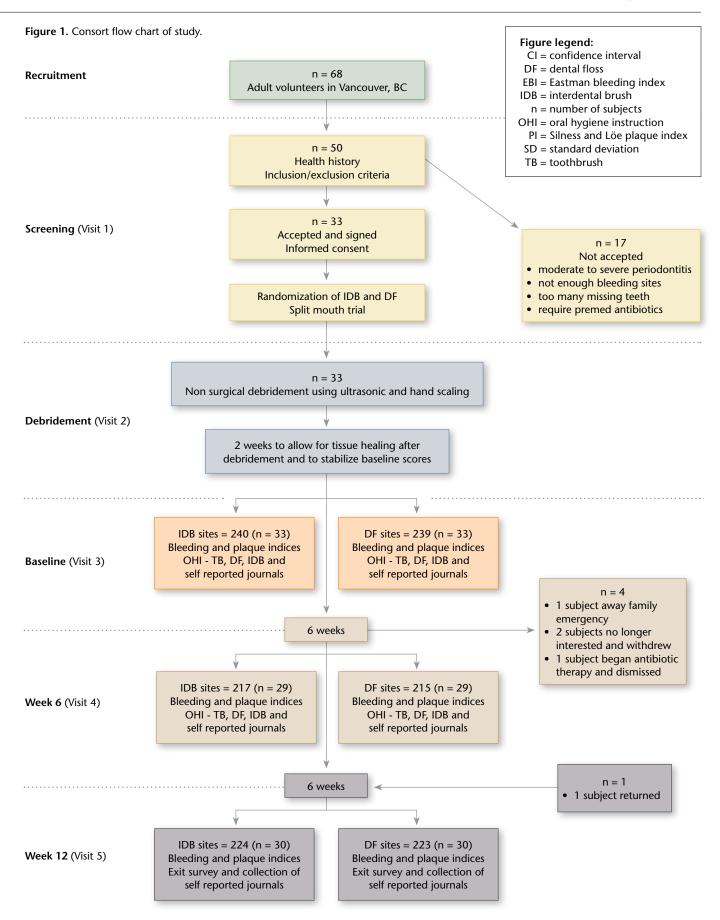4. ability to attend 5 visits.

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

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

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

n = 17
Not accepted
- moderate to severe periodontitis
- not enough bleeding sites
- too many missing teeth
- require premed antibiotics

Randomization of IDB and DF
Split mouth trial

n = 33
Non surgical debridement using ultrasonic and hand scaling

Debridement (Visit 2)

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

6 weeks

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

6 weeks

n = 1
- 1 subject returned

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

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, debridement, 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 Lőe 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.[23] 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.[22] 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™ ultrasoft 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.,[24] 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.[18] 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 reduction of plaque site mean scores at Weeks 6 and 12 (Table 2).

Table 1. Comparison of Mean Bleeding Scores Between Interdental Brush (IDB) and Dental Floss (DF) Sites at Weeks 0, 6, and 12.

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

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

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

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

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

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

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 time (SD 19.85) and the dental floss 88.93% (SD 19.70). At

Table 4. Comparison of mean plaque scores between interdental brush (IDB) and dental floss (DF) in subjects at weeks 0, 6, and 12.

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

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.

			Paired Differences				
					95% Confidence Interval of the Difference		
Weeks	Product	Index	Mean	SD	Lower	Upper	Sig (2 tailed)
0 – 6	IDB	EBI	0.19	0.49	0.12	0.25	<0.001
0 – 6	DF	EBI	0.65	0.53	- 0.01	0.14	0.07
0 – 12	IDB	EBI	0.23	0.51	0.16	0.29	<0.001
0 – 12	DF	EBI	0.08	0.52	0.01	0.14	0.03
0 – 6	IDB	PI	1.45	2.80	1.08	1.83	<0.001
0 – 6	DF	PI	1.34	2.60	0.99	1.69	<0.001
0 – 12	IDB	PI	1.49	3.02	1.09	1.89	<0.001
0 – 12	DF	PI	1.14	2.87	0.77	1.52	<0.001

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

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[24]

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.[24] 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.[24] 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.[4,15,26,29,30] Similar to Yost et al.,[18] 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.[10,32] According to one study,[32] 40% of subjects were not using proper flossing technique. The subjects in the Segelnick study[32] 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.[9,32]

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,[11–14] 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.[25] 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.

Acknowledgement

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