

EFFECTIVENESS OF INTERDENTAL BRUSHING ON BLEEDING REDUCTION IN PERIODONTAL HEALTHY POPULATION- A CONTROLLED CLINICAL TRIAL

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ABSTRACT

Objectives: This prospective randomized clinical trial investigated the impact of interdental brushing in adults free of periodontal diseases.

Material & methods: Sixty adults healthy subjects (mean age of 22 years) were enrolled in this 12-week, blinded, parallel-group randomized clinical trial with an equal patient allocation to the two groups. Test group used twice daily a manual toothbrush (Curaprox ultra soft 5460[®], Curaden International AG, Kriens, Switzerland) and daily interdental brush (Curaprox[®] CPS, Curaden International AG, Kriens, Switzerland). Control group used only manual toothbrush. At each visit, during the evaluation period, the colorimetric probe (IAP CURAPROX[®], Curaden International AG, Kriens, Switzerland) was used in all interdental spaces for all subjects in the two groups. After probing, the corresponding brush was introduced in the interproximal space and the presence of bleeding was recorded. All the subjects were evaluated at one week, one month and 3 months after the baseline visit.

Results: 1446 sites out of 1560 can be used for analyses. The overall preventive fraction (PF) was 46% at one week and 72% at 3 months. Results are better in anterior sites than in posterior sites (80% and 69% respectively). Subjects with baseline low periodontal risk present less bleeding (OR=2.3). An inverse relationship between brush diameter and presence of bleeding was found.

KEYWORDS

Interdental brushes, interdental cleaning, gingival bleeding, controlled clinical trial

Introduction

Health promotion activities include periodontal disease as part of Healthy People 2020 by focusing on the reduction of moderate and severe periodontitis in the adult population. Effective interproximal oral hygiene is a crucial factor in maintaining and promoting good oral health. Dental floss has been used for many years in conjunction with toothbrushing for removing dental plaque in between teeth. However, interdental brushes have been developed which many people find easier to use than floss, providing there is sufficient space between the teeth. An interdental brush, sized correctly for each interdental space, is easy to handle, atraumatic to the papillae and will allow gingivitis patients to monitor their own progress, while at the same time performing a beneficial oral hygiene procedure and removing any interdental plaque present. An IDB with an adapted diameter can be considered as a preventive factor in the disruption of the dental pellicle. In a recent study, 92.3% of interproximal sites can be used for IDB in a 18-35 yrs old adults without periodontal diseases according to the CDC-AAP cases.

There is a need for high-quality research to improve the evidence base in the barriers and facilitators to the delivery of oral hygiene interventions in primary care; the behaviour change interventions to improve inadequate oral hygiene; the provision of dental prophylaxis and effectiveness of optimal timescales for manage gingival condition in a daily practice. Cochran review advances a low-quality evidence that toothbrushing with interdental brushing was better than toothbrushing alone. There was also very low-quality evidence for a reduction in gingivitis and plaque at one month.

There is also a need to support the dental team to manage periodontal conditions in primary care appropriately, to improve the overall oral health of the population. Encourage patients to modify other lifestyle factors that may impact on their oral health. As an adjunct to tooth brushing, interdental brushes (IDBs) are more effective in removing plaque as compared with brushing alone or the combination use of tooth brushing and dental floss. [J Evid Based Dent Pract. 2012]. Few studies have evaluated clinical outcomes following IDBs using on gingival bleeding in 3 months period that reflect risk assessments performed during routine practice.

The aim of this study was to evaluate on the one hand the interdental cleaning efficiency on bleeding status vs. toothbrushing alone.

Material and Methods

The indications of the CONSORT Statement [Moher et al., 2001] were followed in this clinical trial.

Study design and treatment groups

This study was a 12-week, blinded, single-centre, stratified, parallel-group randomized clinical trial with an equal patient allocation to the two groups:

- Test group: manual toothbrush and interdental brushes (IDB)
- Control group: manual toothbrush only

Ethical approval

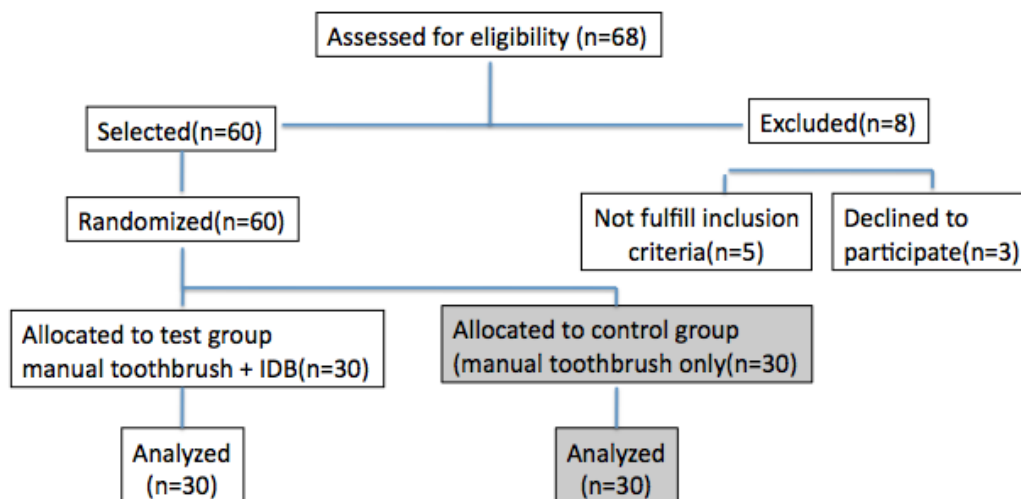
The ethics committee of the dental faculty of the University of Lyon approved the study protocol. The study conformed to the Declaration of Helsinki and was performed according to the guidelines of Good Clinical Practice. Before participation, all the participants received full oral and written information on the aims of the study and signed a written form of consent.

Study setting and eligibility criteria

All subjects were dental students at the University of Lyon. The inclusion criteria were 1. healthy periodontal condition (pockets less than 2 mm) 2. at least tooth brushing twice per day, 3. no clinically significant dental anomalies or prosthetic restoration, and 4. consent. The exclusion criteria were 1. risk of infection or major haemorrhage, 2. immunosuppression, diabetes, haemophilia, those taking anti-platelet or anti-coagulant agents, 3. history of periodontal illness or treatment, and 4. subjects undergoing a course of dental or orthodontic treatment. The use of antibiotics during the study period led to exclusion.

Randomization

In order to achieve the same sample size in both groups and, at the same time, we have balanced groups in terms of the most relevant variables –sex and basal periodontal risk – a stratified (two levels for sex and two levels for baseline periodontal risk) and block randomization – computer assisted –method was used. Baseline periodontal risk was defined according to % of bleeding sites by subject : high-risk if subject had $\geq 30\%$ of bleeding sites, and low-risk if subject had $< 30\%$ of bleeding sites. Two examiners collected the data and were blinded to patient allocation. The examiners were trained beforehand in the use of the IAP CURAPROX© probe and obtained a minimum kappa value of 0.82 compared to the gold standard examiner (excellent agreement according to Landis scale)[Landis, 1977].



Protocol

The clinical trial consisted of three stages: screening examination (visit 1), baseline examination (visit 2), and evaluation period: the latter consisted of three further visits (3, 4, and 5) over a 12-week evaluation period. The observer was 'blinded' to group allocation. During the first visit, patients were screened for suitability and consent was obtained. At the second visit, all the interproximal spaces (excepting those between the 2nd and 3rd molar) were evaluated by a colorimetric probe and then the corresponding interdental brush was introduced. Presence of bleeding was recorded at this time for each interdental space. Subjects of group 1 were instructed in the correct use of interdental brushes. During the 3-month observer-blinded evaluation period, all the subjects were given recall appointments at one week, one month and 3 months after the baseline visit.

Interventions

Toothbrushes and interdental brush. Patients of test group used a manual toothbrush (Curaprox ultra soft 5460[®], Curaden International AG, Kriens, Switzerland) and an interdental brush (Curaprox[®] CPS, Curaden International AG, Kriens, Switzerland). Patients of control group used manual toothbrush only.

Tooth brushing protocol

After randomization, participants were given verbal instructions on brushing. The verbal instructions were supported by practical demonstration on a plastic model. No further oral hygiene instructions were given subsequently.

Tooth brushing technique

Manual toothbrush. Patients were advised to use moderate pressure, according to the recommendations of Bass, including small horizontal shifts back and forth, twice a day.

Interdental toothbrush. Participants of test group: according to the different size of IDBs determined at baseline, participants are instructed to introduce the IDB one time and once a day.

Clinical protocol during evaluation period At each visit, during the evaluation period, the colorimetric probe (IAP CURAPROX[®], Curaden International AG, Kriens, Switzerland) was used in all interdental spaces for all subjects in the two groups. The procedure consists in introducing the IAP CURAPROX[®] probe (CPI) into the vestibular interdental space, inserting it fully, then noting the colour emerging from the interdental space on the vestibular side. The pressure used to place the probe tip at the base of the interdental sites was approximately 50 N/cm² (0.20 gram force). This corresponds to the colour code of the IDB most suitable for the space in question. The probing protocol was always the same, starting in the 16-17 interdental space and finishing in the 46-47 interdental space. This information concerning the IDB diameter for each interdental space is recorded in a chart and a copy is given to the subject. After probing, the corresponding brush was introduced in the interproximal space and the presence of bleeding was observed.

The IDBs used are from the CPS range of CURAPROX[®]. This pack comprises 5 cylindrical IDBs with the following characteristics:

- A colour code related to the size of the brush
- An access diameter defined by the gauge of the CURAL[®] wire core used for stiffening the IDB
- An effective cleaning diameter defined by the length of the synthetic bristles covering the working part of the device.

Statistics

SPSS Windows 20.0 (IBM, Chicago, IL, USA) was used for the descriptive statistics (mean values with SD and percentages) and for analytical statistics (p-values calculation) in those analyses with the patient as the unit of analysis. SUDAAN 7.5 (RTI, RTP, NC, USA) was used for analytical statistics (p-value calculation) in those analyses with the interproximal site as the unit of analysis, to adjust for clustering (multiple sites within the patients). The output variable is interproximal bleeding after IDB at interproximal site level. The statistical methods are indicated in the table footnotes.

Results

Sixty subjects completed the study (30 subjects in test group and 30 subjects in control group). Baseline comparison of patients according to the group shows no difference for the principal variables (Table 1).

Table 1. Baseline comparison of patients according to group (n=60 patients).

Variable	Control	Test	p-value
	(n=30)	(n=30)	
	n (%)	n (%)	
Sex			0.757 ^b
Male	21 (70.0)	18 (60.0)	
Female	9 (30.0)	12 (40.0)	
Age (yrs.), mean±sd	22.8±3.8	22.0±1.8	0.409 ^c
Basal patient's periodontal risk ^a			0.768 ^b
High	16 (53.3)	13 (43.3)	
Low	14 (46.7)	17 (56.7)	
Tobacco			0.314 ^b
Yes	10 (33.3)	5 (16.7)	
No	20 (66.7)	25 (83.3)	

a: High if $\geq 30\%$ bleeding sites, and Low with $< 30\%$ bleeding sites.

b: Chi square, Yates' corrected.

c: Student's t-test

Table 2 shows the evolution of bleeding during the trial period. At baseline (T0), the % of bleeding sites was 34.8% in control group and 35.8% in test group ($p=0.88$). During T0-T3 the evolution of % of bleeding sites was no significant in control group (34.8% at T0 and 37.6% at T3; $p=0.10$). In test group the % of bleeding sites decreases from 35.8% at T0 to 14.5% at T1, 10.9% at T2 and 10.4% at T3 ($p=0.008$). Preventive fraction (PF) was 46% at T1 (1 week), 64% at T2 (1 month) and 72% at T3 (3 months).

Analysis of PF according to localization (anterior sites or posterior sites) shows better results of effectiveness for anterior sites: PF in anterior sites was 80% and 69% in posterior sites, at 3 months.

Table 2. Bleeding along the time in sites corresponding to 60 patients (30 control and 30 test).

Zone and Time	Control		Test		Comparison (<i>p</i> -values) ^c	Preventive Fraction (PF) ^d (95%-CI) ^e
	n (sites) ^a	%±se ^b	n (sites)	%±se		
<i>Anterior</i>						
T ₀ (Baseline)	222	28.4±6.2	246	28.8±6.4	0.956	
T ₁ (+1 week from T ₀)	222	17.6±6.1	246	10.6±3.8	0.335	40 (17-71)
T ₂ (+1 month from T ₀)	222	28.8±6.4	246	8.1±3.0	0.005	72 (48-96)
T ₃ (+3 months from T ₀)	222	29.3±6.4	246	6.0±2.9	0.001	80 (59-100)
Global <i>p</i> -value ^c		0.057		0.019		
Pairwise comparison ^f				T ₀ ≠T ₁ ,T ₂ ,T ₃		
<i>Posterior</i>						
T ₀ (Baseline)	482	37.7±4.9	496	39.5±6.5	0.841	
T ₁ (+1 week from T ₀)	482	31.1±4.7	496	16.5±4.2	0.026	47 (15-78)
T ₂ (+1 month from T ₀)	482	30.7±4.8	496	12.3±3.0	0.002	60 (37-83)
T ₃ (+3 months from T ₀)	482	41.3±6.2	496	12.5±5.3	0.001	69 (43-96)
Global <i>p</i> -value		0.227		0.007		
Pairwise comparison				T ₀ ≠T ₁ ,T ₂ ,T ₃		
<i>Anterior+Posterior</i>						
T ₀ (Baseline)	704	34.8±4.5	742	35.8±6.2	0.886	
T ₁ (+1 week from T ₀)	704	26.8±4.1	742	14.5±3.6	0.028	46 (15-76)
T ₂ (+1 month from T ₀)	704	30.2±4.7	742	10.9±2.5	<0.001	64 (44-84)
T ₃ (+3 months from T ₀)	704	37.6±5.8	742	10.4±4.2	<0.001	72 (49-96)
Global <i>p</i> -value		0.102		0.008		
Pairwise comparison				T ₀ ≠T ₁ ,T ₂ ,T ₃		

a: Effective sample size for each estimation. For example, the first figure (n=222) comes from the following calculation: 30 control patients x 10 anterior sites/patient= 300 sites, minus sites with diasthema (n=16), lack of tooth (n=9) or with no space to introduce the interproximal brush along the follow-up (n=53), gives effective sample = 222 sites (=300-16-9-53).

b: Standard errors corrected for complex sampling (multiple sites within the mouth), by using DESCRIPT procedure in SUDAAN 7.0.

c: *p*-values corrected for complex sampling (multiple sites within the mouth), by using chi-square (CROSSTAB procedure in SUDAAN 7.0).

d: Preventive fraction (PF): percent difference between Controls and Tests = $[(\%_C - \%_T) / \%_C] \times 100$.

e: 95%-CI = $\% \pm 1.96 \times se$, where se (standard error) is calculated, after correcting for multiple sites within the mouth with DESCRIPT procedure in SUDAAN 7.0), according to Dubey et al. 1965 [Dubey SO, Lehnhoff RW, Radike AW. A statistical confidence interval for true percent reduction in caries - incidence studies. J Dent Res 1965;44: 921-923].

f: When global *p*-value is significant, paired comparisons (by using chi-square, corrected for complex sampling) where the symbol "≠" means significantly (*p*<0.05) different groups.

Table 3 shows multivariate association between studied variables and bleeding at 3 months of interdental brushing. Odd ratio (OR) for control group was 4.3 (that means 4 more time bleeding in comparison to test group). The interdental brushing obtains poorest results in high-risk periodontal patients than in low-risk periodontal patients (OR= 2.3). Results are better in anterior sites than in posterior sites (OR= 2.2). Finally we found an inverse relationship between diameter of interdental brush and bleeding: higher is the diameter; less is the bleeding.

Table 3. Multivariate associations^a between studied variables and Bleeding at 3 months after interproximal brushing (n=1446^b sites from 60 patients).

Variable	n	OR ^c (95%-CI)	p-value
<i>Patient's variables:</i>			
Group			0.006
Control (no interproximal brushing)	704	4.3 (1.6-12.1)	
Test (interproximal brushing)	742	1.0	
Basal patient's periodontal risk			0.065
High	686	2.3 (0.9-5.5)	
Low	760	1.0	
<i>Site's variables</i>			
Zone			<0.001
Posterior	978	2.2 (1.5-3.3)	
Anterior	468	1.0	
Interprox.Brush at 3 months			0.005
5 (1.1 mm.)	146	0.0 (0.0-0.2)	
4 (0.9 mm.)	207	0.1 (0.0-0.5)	
3 (0.8 mm.)	328	0.5 (0.3-1.1)	
2 (0.7 mm.)	529	0.6 (0.3-1.0)	
1 (0.6 mm.)	236	1.0	

a: Backward stepwise based on statistical significance (p>0.15 to exclude a variable). Initial variables included also age, sex and tobacco. p-values and 95%-CI calculated with LOGISTIC PROC in SUDAAN 7.0, to account for clustering (multiple sites within patients).

b: These data refer to 60 patients x 26 sites/patient= 1560 sites; excluded sites for diasthema (n=16), lack of tooth (n=34), or lack of space to introduce the interproximal brush along the follow-up (n=64); thus, available sites for this table = 1446.

c: Odds ratio.

Discussion

The subjects in this study were homogenous, including only young and healthy periodontal subjects, with a high level of standard mechanical toothbrushing (at least 2 times/day). In line with the aim of this study, the criteria for inclusion chosen are logical according to it. The choice of age (mean age of 22 years-old) is associated with the attempt to select subjects without periodontal disease. The need for IDB in periodontal patients has been extensively described previously (Poklepovic et al). However, the current literature is less clear on the relevance of IDB in periodontal healthy population. Dental students have been chosen as sample because: 1. we consider it's a very well motivated population, from dental health behaviour point of view and 2. in order to prevent dropout during follow-up. This randomized clinical study followed the CONSORT statement (Moher et al., 2001). We chose a parallel-group design, which is beneficial for trials of longer duration (Zingler, 2014). Regarding sampling method, several points are important for discussion. First, the analysis is mainly carried out including all interdental sites, using SUDAAN program, that allows and adjustment of p-values and standard errors due to clustering (multiple sites within the mouth). Second, in order to achieve a correct randomization in the two groups, a balanced selection was used in terms of sex and baseline periodontal risk, as described in Material and Methods. The verification of the main variables used in the study shows that subjects have been

well balanced between the two groups, tests and controls. It can be said therefore that the allocation has been made without any bias.

Bleeding has been used as dependent variable. However, the reproducibility of the diagnosis of bleeding has been widely discussed in the literature (Leroy et al). The force applied to the probe, the angle of insertion and the experience of examiner are cited as factors of misdiagnosis. Bleeding index can be also influenced by the initial oral hygiene standard of the participants (Kossack and Jost-Brinkmann, 2005). For this reason, subjects were stratified according to baseline levels of bleeding to ensure equal distribution. The mean difference of bleeding between controls and test was the effect measures used (PF). We calculated the corresponding 95% confidence intervals. The unit of analysis was interproximal sites. Unlike other studies, the evaluation of bleeding was performed in all interproximal sites not using indexes teeth (partial versus full mouth examinations) [Cobb 2009; Savage 2009].

The internal validity of the study has been guaranteed through a calibration process. The two examiners who participated in data collection have been previously trained in a workshop calibration. The same examiners had participated in a previous study using a similar protocol. Blinding of the examiners was guaranteed throughout the study.

There has been no drop out throughout the study in either group. That was certainly due to the specific characteristics of the sample (dental students).

Results in this study allow us to postulate that interdental bleeding represent a very prevalent problem. In our particular sample, with periodontal healthy and young patients, with high level of standard mechanical toothbrushing, 35% of sites present bleeding after IDB. At subject level, 50% of the sample corresponds to high baseline periodontal risk (>30% of bleeding sites). Even, in this kind of subjects, the need for IDB is high. It could be hypothesized a higher prevalence in general population. Furthermore, this figure is still more conservative. Whilst the most severe forms of periodontal disease, with alveolar bone loss, are much less common, gingivitis is prevalent at all ages and is the most common form of periodontal disease (Mariotti 1999). Therefore disruption of the oral biofilm via mechanical methods remains one of the best treatment options (Chandki 2011).

Our results show an increasing PF in reducing bleeding in healthy periodontal population, from 46% (after one week) to 72% (after 3 months). Multivariate analysis shows a odd ratio (OR) of 4.3 for control group at 3 months. The effectiveness of IDB in reducing bleeding for interdental spaces is evident. Better results are achieved in low periodontal risk patients (OR=2.3). Probably, the baseline amount of gingivitis is an important factor. IDB reduce more bleeding in anterior sites than in posterior sites (OR=2.2). Access to interdental hygiene in posterior sites is much more complicated than in anterior sites. It seems clear that the interdental cleaning is not part of daily oral hygiene, for the majority of the population. So far, dental floss has been the method of removal of interdental plaque most used. The introduction of interdental brushes as part of the daily oral hygiene should be accompanied by proper training of dentists and dental team first, and then spread to the health education of the general population.

The diameter of the brush is inversely related with the bleeding. The larger the diameter of the brush, the lower the occurrence of bleeding. In interdental spaces where it is only possible to introduce a brush of small diameter, resistance causes increased bleeding. Conversely, in those large spaces, which can use larger diameter brushes, the resistance is very low and less bleeding appears.

An interesting discussion is to associate bleeding with the need for periodontal care in the medium and long term. The reduction of gingivitis in the general population results in more than merely the cosmetic improvement following the reduction of the gingival bleeding. There is overwhelming evidence that gingivitis is linked to periodontitis, and the elimination of gingivitis

will result in the reduction of attachment loss in the majority of the population (Robinson). Therefore, the overall reduction of gingivitis is a good way to improve oral health. The absolute magnitude could be enormous or modest. At this stage no scientific evidence can quantify this magnitude.

Originally, interdental brushes were recommended by dental professionals to patients with large embrasure spaces between the teeth (Slot 2008; Waerhaug 1976), caused by the loss of interdental papilla mainly due to periodontal destruction. However, with the greater range of interdental brush sizes and cross-sectional diameters now available, they are considered a potentially suitable alternative to dental floss for patients who have interdental papillae that fill the interdental space (Imai 2011). Daily dental flossing adherence is low among patients because it requires a certain degree of dexterity and motivation (Asadoorian 2006), whereas interdental brushes have been shown as being easier to use and are therefore preferred by patients (Christou 1998; Imai 2010). Furthermore, when compared to dental floss, they are thought to be more effective in plaque removal because the bristles fill the embrasure and are able to deplaque the invaginated areas on the tooth and root surfaces (Christou 1998; Imai 2011; Jackson 2006). However, there are conflicting study results regarding the efficacy of interdental brushes in the reduction of clinical parameters of gingival inflammation (Noorlin 2007) and whether they are only suitable for patients with moderate to severe attachment loss and open embrasures, or whether they are a suitable aid for healthy patients to prevent gingivitis who have sufficient interdental space to accommodate them (Gjeramo 1970; Imai 2011).

As in any preventive measure, it is important to have information on the degree of compliance of the subjects. A questionnaire was distributed to all subjects in the test group to determine the frequency with which they used the IDB throughout the study. All subjects in the test group used daily IDB. The same questionnaire was used to collect data on acceptability of interdental brushing method studied. Twenty-six subjects (86%) reported that the acceptability of the IDB method was good or very good and only two patients did not consider it acceptable. Finally, regarding possible adverse effects, no subject considered the technique of IDB as traumatic, painful or iatrogenic. Nine subjects (30%) however consider that the technique is a little difficult at first, but proper training can simplify it.

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