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Reprint

Efficacy and Safety of BrushPicks a New Cleaning Aid, Compared to the Use of Glide Floss

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Abstract

The objective of this double-blind, four-week clinical study was to evaluate the efficacy of BrushPicks™, a new cleaning aid, and Glide floss on the reduction of plaque area, gingivitis and bleeding on probing, and to monitor safety when these products were used in addition to toothbrushing with an ADA-Accepted toothbrush (Oral-B P35) and an ADA-Accepted fluoride-containing dentifrice (Crest® Regular). No special instructions on or supervision of product use was conducted, other than requesting twice-a-day (morning and evening) use of the assigned products. Following a baseline examination, 63 qualifying adult male and female subjects from the Philadelphia, Pennsylvania area were randomized into two groups. Subjects were also told to use their assigned dental aid after each toothbrushing. Examinations for efficacy and safety were repeated after two and four weeks' use of the products. Sixty-two subjects completed all aspects of the study. There were no untoward side effects attributed to product use, reported or observed, at the two- or four-week examination times. At baseline, there were no significant differences in plaque, gingivitis or bleeding on probing mean scores between the BrushPicks and Glide floss groups. At the two- and four-week evaluation times, both the BrushPicks and Glide floss had numerically lower plaque scores compared to baseline levels. The only statistically significant reduction ($p < 0.01$) was in the BrushPicks group, comparing the week two mean with the baseline value. Gingivitis (GI) at four weeks was statistically ($p < 0.05$) lower in the BrushPicks group as compared to the Glide floss mean value. When the changes in scores from baseline to two weeks and to four weeks were assessed, the mean GI score for the Glide floss group was significantly lower at two weeks ($p < 0.01$) compared to baseline, and also from two weeks to four weeks ($p < 0.001$). The change in mean GI score for the Glide floss group from baseline to four weeks was also significant statistically ($p < 0.001$). When the changes in mean GI scores for the BrushPicks group were assessed, there was a significant decrease from baseline to two weeks ($p < 0.001$), from two weeks to four weeks ($p < 0.001$), and from baseline to four weeks ($p < 0.001$). For bleeding on probing, when the baseline to two- and four-week mean values were compared, only the BrushPicks produced significant ($p < 0.001$) decreases. At two and four weeks, the BrushPicks group mean bleeding on probing scores were significantly ($p < 0.05$ -0.01) lower than the Glide floss group scores. At the end of this four-week study, the BrushPicks product was significantly more effective than Glide floss in the reduction of gingivitis and bleeding on probing, important attributes of soft-tissue health. (*J Clin Dent* 13:125-129, 2002.)

Introduction

The interproximal area of the dentition is one of the most difficult areas for people to keep clean and free of decaying food and plaque organisms.¹ As a result, the area is prone to the

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development of periodontal disease and caries.² It has been documented that if the interproximal area can be kept clean interproximally, periodontal disease is reduced. 8-10

The manual toothbrush is the most commonly used product for the removal of plaque and cleaning the dentition. However, it has been demonstrated that standard manual toothbrushes do not effectively clean between the teeth in the difficult-to-reach interproximal spaces.¹¹ Over recent years, there has been a marked increase in the dental literature in reports of new toothbrush designs that have attempted to enhance the ability of the manual toothbrush to reach interproximal areas.¹⁴⁻²¹ One study in the dental literature by Yankell, et al.²² compared the efficacy of a variety of toothbrushes for the removal of plaque interproximally. In spite of the increasing ability of toothbrush designs to penetrate between the dentition, it is still recognized that people themselves are irregular in their brushing habits and in their ability to reach difficult areas of the mouth for cleaning with the toothbrush.^{2, 12,13}

Alternatives to the toothbrush for interdental cleaning have been on the market for a long period of time. Toothpicks have been found buried with their owners for over 5,000 years.²³ Dental floss is a commonly recommended addition to toothbrushing to focus on cleaning between the teeth. The American Dental Association considers floss not as an alternative to brushing, but a necessary component of regular dental hygiene.^{2,24} Despite its reported efficacy for cleaning, flossing is not an easy process for many people and as a result it is not used with the frequency and consistency that is needed for improved oral health.¹⁵⁻²⁹ Published studies on flossing, especially when compared to alternative forms for interdental cleaning, have not consistently produced a clear picture of its superiority.^{21,10-12} Interdental cleaning aids such as woodsticks, triangular toothpicks, rubber tips on toothbrushes and interdental brushes have also been assessed clinically for comparative cleaning and improvement in gingival health. In early efficacy studies, the evidence for the superiority of one aid over the other, or by comparison to flossing and toothbrushing alone, were not overwhelming and

often contradictory. 12,11,26,28-32. More recent studies have shown more consistent findings that interproximal brushes and aids are more effective than the use of floss when added to a toothbrushing regimen. 33-37

One important assessment of the status of gingival health is the visualized color of the soft tissues. Another important assessment is the status of the soft tissues to bleed upon stimulation. In a report by Barton and Abelson 38 it was found that the bleeding sites of a group of subjects using interdental cleaners was improved by 52.2%, compared to 8.5% for a control group that only brushed. In another study, 39 the use of interdental cleaners was compared to flossing and control, and there was a 49% improvement in the number of bleeding sites compared to control, while the floss group had a 12% improvement compared to control. While plaque reduction is important to assess for efficacy in cleaning, it is difficult to assess interproximally because it is difficult, if not impossible to visualize.

A new dental cleaning aid, BrushPicks™ (Dental Concepts, Paramus NJ, U.S.A.) has been developed. The polyethylene plastic product has two cleaning ends: one with a scored triangular-shaped tip; the other end has a flexible stem with three rows of lateral bristles (Figure 1). This study compares BrushPicks to Glide' floss (W.L. Gore and Associates, Inc., Flagstaff, AZ, U.S.A.), a commercially available ADA-Accepted dental floss, for the improvement of plaque, gingivitis and bleeding on probing, and to monitor the effects of using the assigned products on the hard and soft tissues of the oral cavity (safety evaluation). The BrushPicks and Glide floss products were used in addition to brushing with an ADA-Accepted toothbrush (Oral-B P35, Oral-B Laboratories, Belmont CA, U.S.A.) and an ADA-Accepted anticaries fluoride-containing dentifrice (Crest Regular, The Procter and Gamble Co., Cincinnati, OH, U.S.A.).

Materials and Methods

Groups

Sixty-three subjects from the Philadelphia, Pennsylvania area were randomly assigned to either the ADA-Accepted Glide floss

or the BrushPicks group. Thirty-one subjects were initially enrolled in the Glide floss group, and thirty-two subjects were enrolled in the BrushPicks group. These numbers allowed for attrition during the study and to assure that at least thirty subjects per group completed the study. One subject in the Glide floss group could not have the bleeding on probing index performed (for medical reasons), therefore there were only 31 subjects assessed for that measure only.

Subject Selection

Inclusion criteria. Females or males between the ages of 18 and 60 years, of any race, in generally normal health and mouths free from major hard or soft tissue lesions were recruited for the study. The subjects had to have at least 18 natural teeth present and to sign an informed consent form approved by the University of Pennsylvania Committee on Subjects Involving Human Beings. Subjects agreed to use only the products provided by the investigator during the study. Finally, the subjects had not had a prophylaxis within four weeks prior to the baseline examination.

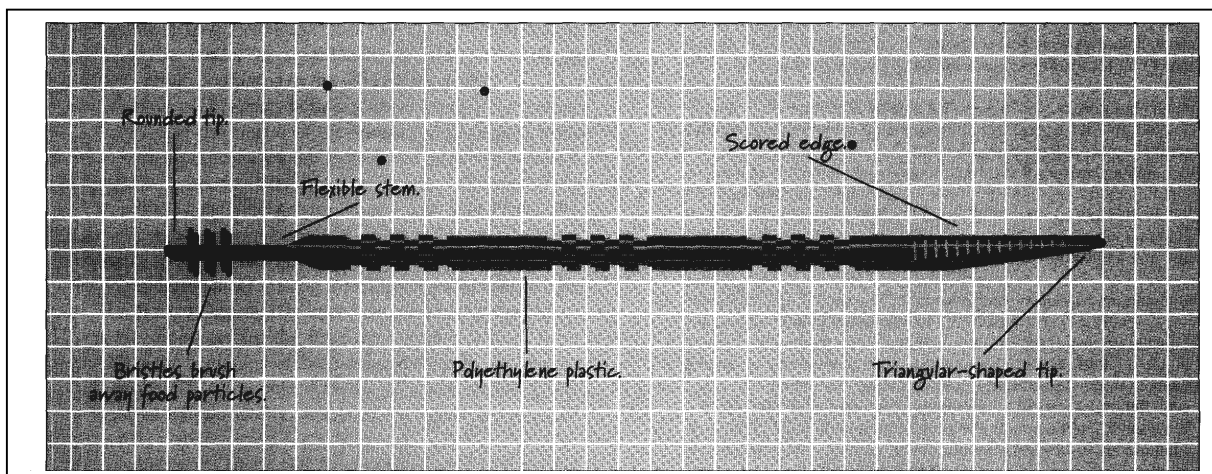
Exclusion criteria. A potential subject would be excluded from participating in the study if they used antibiotics, steroidal or non-steroidal anti-inflammatory agents. They could also not have used antibiotics within two weeks prior to the start of the study, be suffering from an acute illness, have orthodontic bands or be pregnant. Finally, they were excluded if there was a known sensitivity to, or history of oral or perioral tissue reactions or allergies to dentifrice, or if any disease or lesions of the hard or soft tissues of the mouth were present upon examination.

Protocol

Each subject had a complete oral cavity examination to determine eligibility for the study, and a medical history taken to determine the above criteria for inclusion and exclusion.

Measurements were taken at baseline (prior to the study), at an intermediate two-week point in the study, and final measurements were taken at four weeks. Safety assessments also were performed at each measurement period. Areas examined were the

Figure 1. The BrushPicks dental cleaning aid (length-65 mm, width at center-2.5 mm, width at bristle-end tip-0.6 mm).



tongue, hard and soft palate, gingivae, mucobuccal folds, the inner surfaces of the cheeks and sublingual space areas. All areas were assessed and reported as normal or abnormal, per subject. Any effects on hard tissue and/or dental restorations also were evaluated. In particular, the cervical root area was examined. Any changes noted during the oral cavity examinations or reported by the subjects were recorded on the case report form. The investigators also recorded opinions of the relationship of the study treatments to each adverse reaction or change in the oral cavity.

Plaque area was scored using the criteria of Turesky, *et al.*" Plaque was visualized using a commercially available disclosing agent. Evaluations were performed on or at the gingival areas of the facial and lingual surfaces of the Ramfjord teeth" that were not crowned or clasp-bearing. The tooth areas scored utilized the 0 to 2 scores, to evaluate only the scoring sites adjacent to the gingival margin.

Gingivitis was evaluated using the method of Lobene, *et al.*" at the facial and lingual margins of the Ramfjord teeth.

Bleeding on probing was determined at the mesial and distal gingival margins of all natural teeth anterior to the third molars using the Eastman Bleeding Index .13

At baseline, the initial plaque, bleeding on probing, gingivitis and safety examinations were performed. All subjects then received their toothbrush and fluoride-containing dentifrice and were requested to use these products twice a day (morning and evening). Subjects were randomly assigned to and given either the BrushPicks or Glide floss products, and told to use these products after they had brushed their teeth. No specific instructions were given for any of the products distributed. Between the baseline, the intermediate two-week and four-week examinations, each subject was instructed to use only the toothbrush and dentifrice, and either the Glide floss or BrushPicks. The subjects were not allowed to use any other tooth cleaning products or devices during the study.

Statistical Analysis

Mean between-group scores on plaque, bleeding on probing, and gingivitis were compared statistically using an Analysis of Variance. For the change in scores over time, within groups, an Analysis of Variance for Repeated Measures was used.

Results

Of the 63 subjects entering the study, data from 62 subjects who completed the final assessments were statistically evaluated. One subject did not report for the two- or four-week assessments and did not report dropping out of the study due to product use.

Safety

There were no untoward side effects, reported or observed, at any time during the study, attributed to any of the dental products distributed in this study.

Plaque

Plaque scores for the two products tested are presented in Table 1. While there was a numerical decline and difference between the two groups over the four weeks of the study, there were

Table I
Plaque Scores

Product	Four Weeks
Baseline	
Two Weeks	
Mean (SD)	
Glide floss	1.76(.28)
BrushPicks	1.76(.24)
1.70(.29)	1.71(.28)
1.58(.30)	1.67(.29)

no statistically significant differences between the two products at any time.

When the changes in scores over the four weeks were assessed, there was no significant statistical change in plaque mean scores for the Glide floss group. For the BrushPicks group, there was a significant statistical ($p < 0.01$) drop in mean plaque score from baseline to week two. There was no significant statistical change in mean plaque score from baseline to four weeks.

Gingivitis

Gingivitis scores are presented in Table 11. There were no significant differences in mean total gingivitis scores between the Glide floss and BrushPicks at baseline or two weeks. When total gingivitis mean scores were assessed at four weeks, there was a significant statistical difference ($p < 0.05$) favoring the BrushPicks group.

Table 11
Gingivitis Scores

Product	Baseline
Two Weeks Mean (SD)	Four Weeks
Glide floss	1.62(.36)
BrushPicks	1.58(.29)
1.54(.36)	1.42(.39)
1.43(.27)	1.21(.27)

When the changes in scores from baseline to two weeks and then to four weeks were assessed, it was found that the mean GI score for the Glide floss group was significantly lower at two weeks ($p < 0.01$) compared to baseline, and also from two weeks to four weeks ($p < 0.001$). The change in mean score for the Glide floss group from baseline to four weeks was also significant statistically ($p < 0.001$). When the changes in mean scores for the BrushPicks group were assessed, there was a statistically significant drop in scores from baseline to two weeks ($p < 0.001$), from two weeks to four weeks ($p < 0.001$), and from baseline to four weeks ($p < 0.001$)

Bleeding on Probing

The bleeding on probing mean values are shown in Table 111. There was no significant difference in bleeding on probing between the Glide floss and the BrushPicks product at baseline. At two weeks, the BrushPicks group was significantly ($p < 0.05$) lower than the Glide floss group on bleeding on probing. At four

Table III
Bleeding on Probing

Product	Baseline
Two Weeks Mean (SD)	Four Weeks
Glide floss	.26(.16)
BrushPicks	.23(.16)
.18(.18)	.16(.19)
.08(.10)	

weeks, the BrushPicks group was significantly ($p < 0.01$) lower than the Glide floss group on mean bleeding on probing scores. When the groups were assessed over time for the changes in mean bleeding on probing scores, there was no statistically significant difference in the mean scores for the Glide floss group. The BrushPicks group had a statistically significant decrease in bleeding on probing mean scores from baseline to two weeks ($p < 0.001$), from baseline to four weeks ($p < 0.001$), and from two weeks to four weeks ($p < 0.001$).

Discussion

In the published reviews located, there were no consistent differences in efficacy between waxed and unwaxed floss; however, the combination of flossing and brushing has been documented to be more effective than brushing alone, particularly in gingival responses and bleeding at interproximal sites.^{11-16,44} One published study has been located that compared waxed floss with an expanded PTFE-type (polytetrafluoroethylene) floss (Glide) in combination with brushing." Over the six weeks of the PTFE type floss study, there were no consistent significant differences between the Glide floss and the commercially available waxed floss control on the parameters monitored. Since one week of the study was conducted using a cross-over design, a questionnaire was administered to determine floss preference. Glide was the preferred floss product in several categories, including ease of use. In this study, at the two- and four-week evaluation times, both the BrushPicks and Glide floss were numerically effective in reducing plaque scores compared to baseline levels. These findings were not entirely unexpected since the plaque index used is focused on the broad tooth surfaces, which are not the primary sites where the additional tooth cleaning aides are applied.

When the changes in mean gingivitis scores from baseline were assessed, both groups exhibited decreasing mean scores over time. The BrushPicks group demonstrated a significant decrease from baseline to two weeks ($p < 0.001$), from two weeks to four weeks ($p < 0.001$), and from baseline to four weeks ($p < 0.001$). When the baseline to two- and four-week mean values were compared, only the BrushPicks product produced significant ($p < 0.001$) decreases in gingivitis mean scores. Gingivitis at four weeks was significantly ($p < 0.05$) lower in the BrushPicks group compared to the Glide floss mean.

For bleeding on probing, both groups exhibited decreasing mean scores over the course of the study. The decreases from baseline were significant for the BrushPicks group ($p < 0.01$); however, the decreases were not significantly different from baseline in the Glide floss group. At two and four weeks, the BrushPicks group mean bleeding on probing scores were significantly ($p < 0.05-0.01$) lower than the Glide floss group scores. Considering that bleeding is an important attribute of the status of soft tissue health, it is important to note that the reductions in bleeding sites for the BrushPicks subjects went from about 23% at the beginning of the study to 4% by the conclusion at four weeks. This dramatic decrease in acute bleeding was even apparent by two weeks into the study where the rate had fallen to 8%.

The reasons for the significant differences in oral health for the group using the BrushPicks group are attributed to the flexibil-

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ity and the unique design of the device, and the ease of use compared to flossing.

Summary and Conclusions In this study, both products tested decreased mean gingivitis scores compared to baseline values; however, only the BrushPicks product was significantly lower than the baseline scores. At the end of the four weeks of the study, the use of the BrushPicks cleaning device significantly improved both gingivitis and bleeding on probing compared to the ADA-Accepted interproximal flossing product tested.

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