

A SINGLE-VISIT, SPLIT-MOUTH RANDOMIZED TRIAL OF PLAQUE SCORE
ASSESSMENTS ON TWO INTERPROXIMAL CLEANING DEVICES (GME)

by

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CERTIFICATE OF APPROVAL

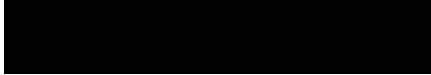
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ABSTRACT

A SINGLE-VISIT, SPLIT-MOUTH, RANDOMIZED TRIAL OF PLAQUE SCORE ASSESSMENTS ON TWO INTERPROXIMAL CLEANING DEVICES

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Background: The dental biofilm is comprised of several hundred microorganisms.

While the majority of indigenous species exhibit a commensal host relationship in health, overpopulation of these bacteria within the biofilm leads to disease. Prevention of gingival and periodontal disease is accomplished most notably with tooth brushing and flossing. Brushing effectively removes plaque on the facial and lingual surfaces but fails to completely remove interproximal plaque. Despite its benefits, many patients omit flossing because of lack of time, general discomfort and/or difficulty in reaching posterior regions. Plackers® is a flossing tool designed and marketed to alleviate the pain and discomfort of traditional floss with an additional benefit of being small and portable. **Objectives:** This randomized, split-mouth, single-visit trial compared the efficacy between traditional floss (TF) and Plackers® (PL) utilizing the O’Leary Plaque Index (PI) as the primary outcome. A secondary objective evaluated the subjects’ flossing habits, hand-domination, and flossing device preference. **Materials & Methods:** A power analysis was calculated and a total of 80 subjects were needed to reach statistical significance. Each subject was required to floss with TF on the right or left maxillary and mandibular arches and PL on the contralateral side. Group assignment was determined through computer randomization. Following use of both devices,

subjects self-administered a plaque-disclosing tablet and rinsed with water (30 seconds). Full mouth plaque scores were measured by one of two board certified Periodontists and the O'Leary Plaque Index was calculated. Prior to and following flossing with both devices, subjects were given a questionnaire regarding daily flossing habits and preference of flossing device, if any. A paired t-test was used to analyze difference between PL and TF. **Results:** This interim analysis evaluated 22 males and 7 females. T-test analysis revealed no significant difference in mean plaque scores between TF and PL ($p=0.62$). Mean plaque scores for TF and PL were $58.4 \pm 18.4\%$ and $56.9 \pm 18.63\%$ respectively. Individuals that flossed at least once/week marginally preferred TF ($P=0.07$) over PL. Higher PI individuals preferred using PL ($P=0.03$). **Conclusions:** Interim analysis found no difference in removing interproximal plaque using TF or PL.

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LIST OF ABBREVIATIONS

TF: Traditional Floss

PL: Plackers®

PI: Plaque Index (O'Leary)

REVIEW OF THE LITERATURE

Background

The dental biofilm is comprised of over 400 hundred bacterial species to include spirochetes, streptococci, actinomyces and protozoa species¹. While the majority of these indigenous species exhibit a commensal relationship with the host in periodontal health, it is the overpopulation of these bacteria within the dental biofilm, combined with alterations in the host response, that lead to the destructive sequela exhibited in gingival and periodontal diseases. Prevention of disease accomplished through several methods, most notably toothbrushing and flossing.

Development of Disease

Gingivitis is an inflammatory response of the gingiva to accumulation of bacterial plaque and has been shown to develop 21 days after cessation of oral hygiene². In another experimental gingivitis study, Friedman et al found that all participants developed gingivitis marked by inflammation, redness, and spontaneous bleeding after oral hygiene cessation³. Following the assault on the tissue by this bacterial plaque, there are morphologic changes that can be seen both clinically and histologically such as a progressive increase in inflammatory cells corresponding clinically to erythema and edema of the gingival tissues⁴. In reference to the model proposed by Page and Schroeder⁵, progression of the disease is defined by the *initial, early, established and, advanced* lesions. Histologic evidence of the early lesion can be observed 4 to 7 days after undisturbed plaque accumulation which includes a predominant infiltration of lymphocytes and macrophages. Clinically, this is marked by erythema and gingival bleeding. As the dental biofilm continues to proliferate and plaque accumulation grows, there is a significant increase of host inflammatory cells invading the gingival sulcus including plasma cells and B lymphocytes. This corresponds to the established lesion with a clinical presentation of increased redness,

gingival bleeding, and inflammation of the gingival tissues. The advanced lesion marks the stage of conversion from gingivitis to periodontitis where infiltration to the surrounding alveolar bone is exhibited and irreversible bone loss occurs.

Toothbrushing and Flossing

Removal of dental plaque can be achieved with the use of a toothbrush and employment of the Modified Bass Technique has been shown to be the most effective method^{6,7}. Although tooth brushing is an effective method for removal of plaque at facial and lingual surfaces, it fails to completely remove both supragingival and subgingival plaque in the interproximal spaces⁸. The use of dental floss has been a recognized method for removal of interproximal plaque and is shown to be more effective at plaque removal when combined with tooth brushing than tooth brushing alone^{9,10}

Flossing materials

Dental floss comes in a variety of different materials to include monofilament and multifilament and may or may not be coated with a wax material. In a study evaluating waxed versus unwaxed floss on gingival and plaque indices, observations revealed no significant difference between the two materials and concluded that reduction in interproximal plaque and inflammation is equally achievable with waxed or unwaxed floss¹¹. Additionally, even with employment of flossing by a dental professional, floss material does not appear to influence reduction of gingival inflammation¹². In a population of subjects with moderate gingival inflammation, flossing with either waxed and unwaxed floss, performed by a licensed hygienist during a 14-day period, produced no significant reduction in bleeding and inflammation indices. However, it was noted

that significant reductions in these indices were noted on the sides where flossing was employed versus the controlled, unflossed sites.

Despite the documented benefits of flossing, many patients omit this practice because of lack of time and general discomfort of maneuvering the floss both in between the fingers and between hard-to-reach posterior regions of the oral cavity. Patients with manual dexterity issues, such as those with a neurological condition or arthritic joints, may also find flossing a difficult oral hygiene task. Additionally, lack of proper flossing instruction often leads to ineffective techniques leading to both hard and soft tissue damage^{13,14} as well as inadequate plaque removal at proximal line angles.

Plackers

Plackers® is a flossing tool marketed to alleviate the pain and discomfort of traditional floss with an additional benefit of being a small, portable device. The design of Plackers®, a piece of floss suspended between a plastic holding device, appears to benefit the user by eliminating the need to wrap floss around the fingers as well as aiding in the ability to reach posterior regions. It is unclear whether this device necessitates additional instruction for flossing in order to effectively remove plaque at interproximal line angles where it tends to accumulate most^{8,15}. To date, there have been no studies reporting on the efficacy of interproximal plaque removal or preferences in patients using Plackers®.

MATERIALS AND METHODS

Subjects were recruited from the Walter Reed National Military Medical Center (WRNMMC) Dental Readiness Department and the Naval Postgraduate Dental School (NPDS) Periodontics Department. Patients were scheduled for their yearly dental examination or periodontal evaluation and, once completed, were recruited to participate in the study. A randomization table was generated by a statistician not involved in the recruitment process to allocate the devices to the right and left maxillary arches (Table 1).

Subject Number	First Treatment	Second Treatment
1	Plackers Left	Floss Right
2	Floss Right	Plackers Left
3	Floss Left	Plackers Right
4	Plackers Right	Floss Left
5	Floss Right	Plackers Left
6	Plackers Right	Floss Left
7	Floss Left	Plackers Right
8	Plackers Left	Floss Right
9	Plackers Left	Floss Right
10	Floss Left	Plackers Right
11	Plackers Right	Floss Left
12	Floss Right	Plackers Left
13	Floss Left	Plackers Right
14	Placker Left	Floss Right
15	Plackers Right	Floss Left
16	Floss Left	Plackers Right
17	Plackers Left	Floss Right
18	Floss Right	Plackers Left
19	Plackers Right	Floss Left
20	Plackers Left	Floss Right
21	Floss Left	Plackers Right
22	Floss Right	Plackers Left
23	Plackers Right	Floss Left
24	Floss Left	Plackers Right
25	Floss Right	Plackers Left
26	Floss Left	Plackers Right

Table 1: Randomization table. After assigning subject number allocation of first device in protocol sequence and side was told to patient.

The following inclusion and exclusion criteria were fulfilled:

Inclusion criteria

All military beneficiaries including active duty, retirees and dependents of active duty members were eligible for inclusion. All male and female patients, aged 18-75 with controlled systemic health (ASA I/II) were also eligible for inclusion. Finally, an inclusion criteria of at least 6 natural teeth with interproximal spacing no greater than 1 mm was applied. Patients with one lone standing implant adjacent to natural teeth within each quadrant were also eligible for inclusion.

Exclusion criteria

Patients on any antibiotic regimen and pregnant or lactating females were excluded. Additionally, prosthetic exclusions were patients with multi-unit fixed dental prostheses or any removal appliance. Patients undergoing orthodontic therapy or with any fixed maxillary or mandibular lingual retentive bars were also excluded due to the difficulty of maneuvering around brackets and wires. Lastly, if a patient reported severe difficulty flossing due to manual dexterity issues he or she was also excluded.

Study Protocol

Once these requirements were met, subjects were consented by the primary investigator (BA)
(Figure 1).

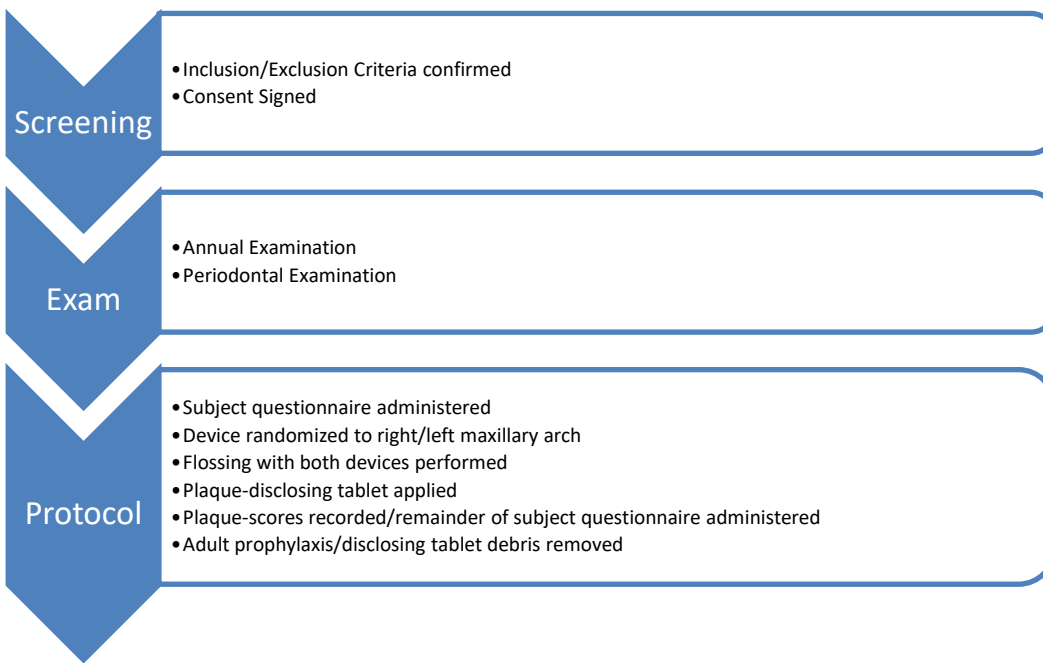


Figure 1: Flow chart of study protocol

A 4-part questionnaire was administered with two questions asked prior to flossing and two questions asked following flossing (Figure 2).

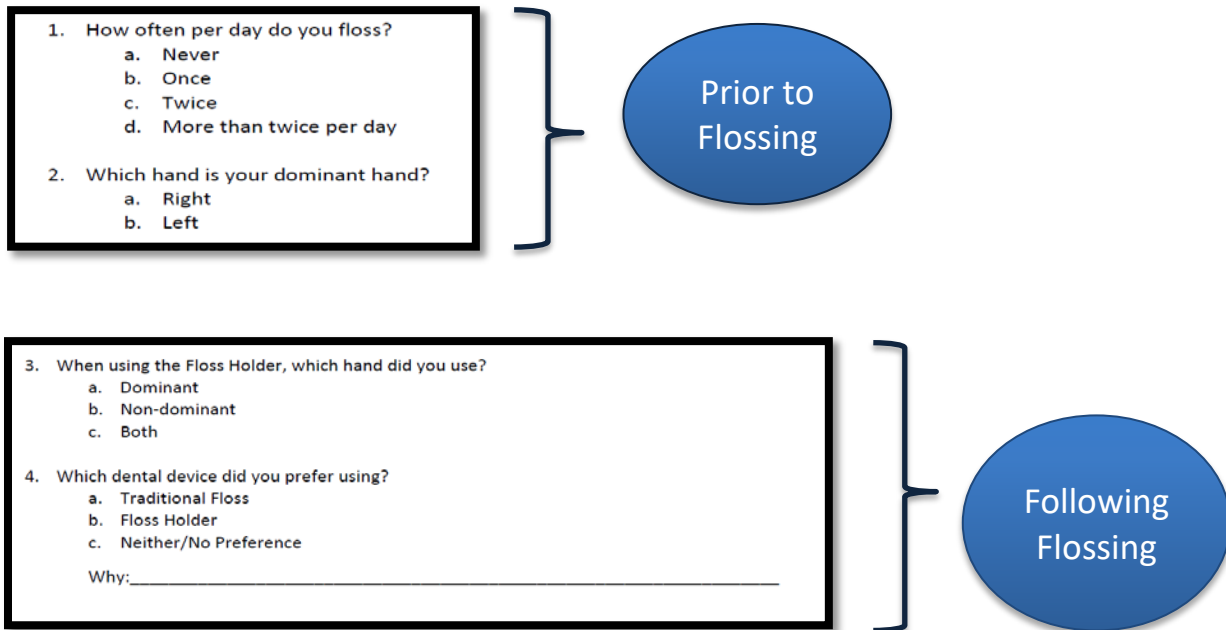


Figure 2: Study questionnaire given before and after flossing.

Subjects were given one minute of verbal instruction and instructed to use one device on the right or left maxillary and mandibular arch and the other device on the contralateral sides (Figure 3).

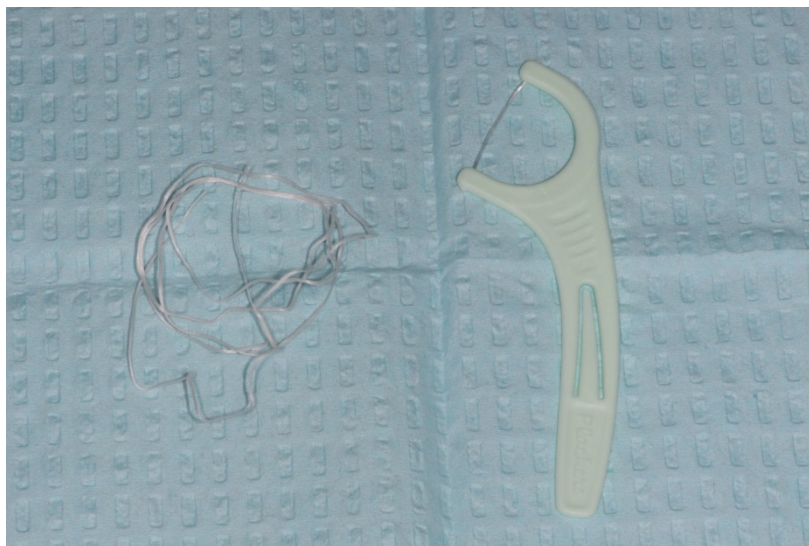


Figure 3: Unwaxed traditional floss (left). Plackers device (right)

No interventions or corrections were given to the subjects during the flossing period. Following use of both devices, subjects were given a plaque-disclosing tablet and instructed to chew it then rinse with water for 30 seconds and expectorate. The final two questions of the questionnaire were administered and inquired the subjects hand dominance while using the Plackers® and preference of device, if any. One of two, board-certified periodontist (YB or JB) completed the visual inspection and recorded plaque retention utilizing the O’Leary Plaque Index (Figure 4). Once the O’Leary Plaque Index was scored, an adult prophylaxis was administered to remove any remaining surface discolorations.

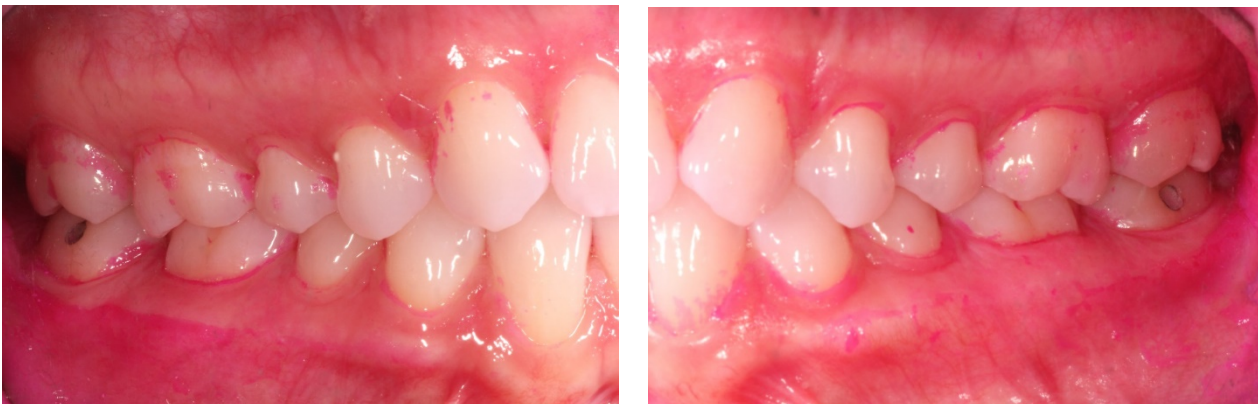


Figure 4: Plaque-retention sites following use of plaque-disclosing tablet. Left photo: right buccal. Right photo: left buccal.

RESULTS

A power-analysis determined a total of 80 subjects would be required to achieve statistical significance.

For this interim analysis, a total of 26 subjects participated. Nineteen males and 7 females with a median age of 34 were included. Table 2 describes the demographics of this military population.

Of the 26 subjects, 24 reported right-hand dominance. Flossing on a per-day basis was self-reported and 19 of 26 participants reported flossing at least once per day.

Variable	Outcome
Gender (M/F)	19/7
Age (y)	34 [27.25-42.5]
Hand Dominance [R/L]	24/2
Currently Floss? [Y/N]	19/7

Table 2: Demographic data

A paired t-test across participants revealed no significant difference in plaque index (PI) after one-time use of Plackers® (PL) and traditional floss (TF). Mean plaque scores for TF and PL were $58.4 \pm 18.4\%$ and $56.9 \pm 18.63\%$ respectively ($p=0.62$) (Figure 5).

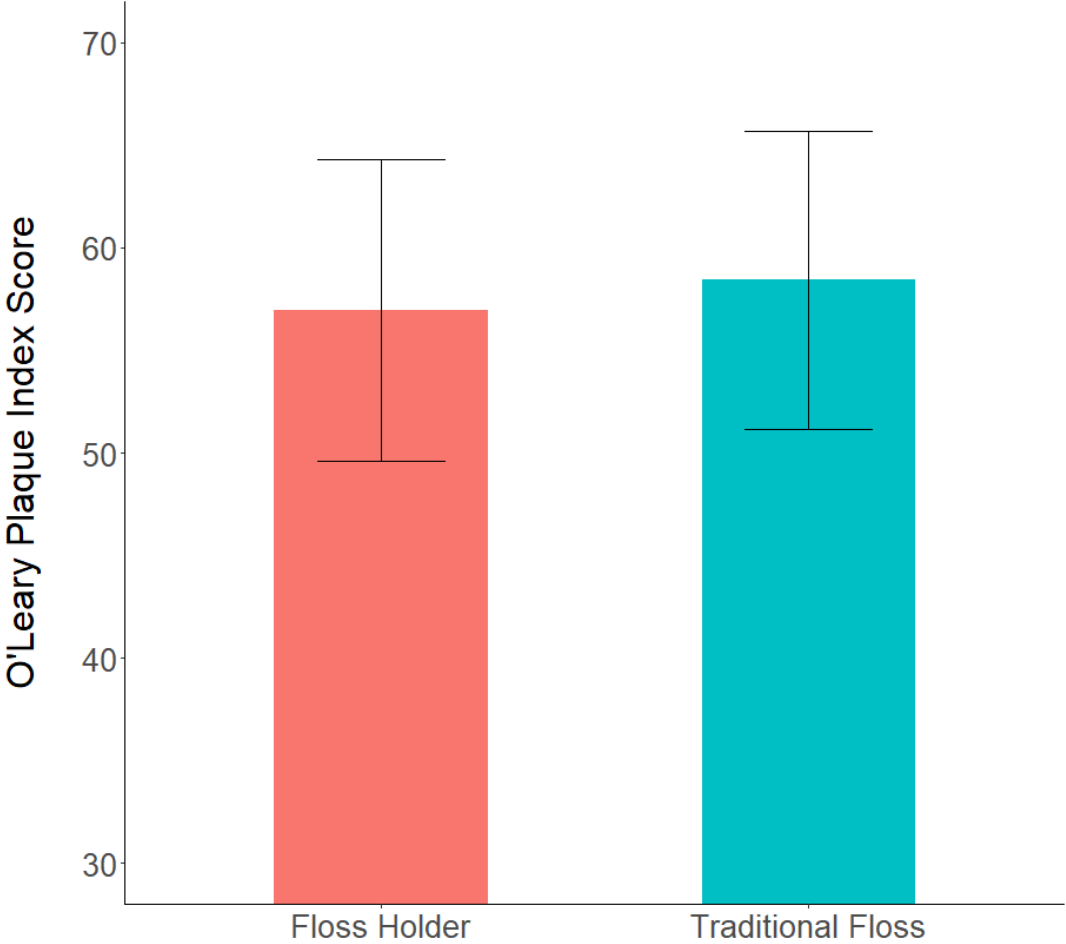


Figure 5: Mean O'Leary Plaque Scores. Floss Holders = Plackers

Mean plaque scores for individuals with each device were also correlated, $r^2=0.43$ (Figure 6).

For example, subjects with high plaque scores using TF also tended to have high plaque scores using PL and vice versa.

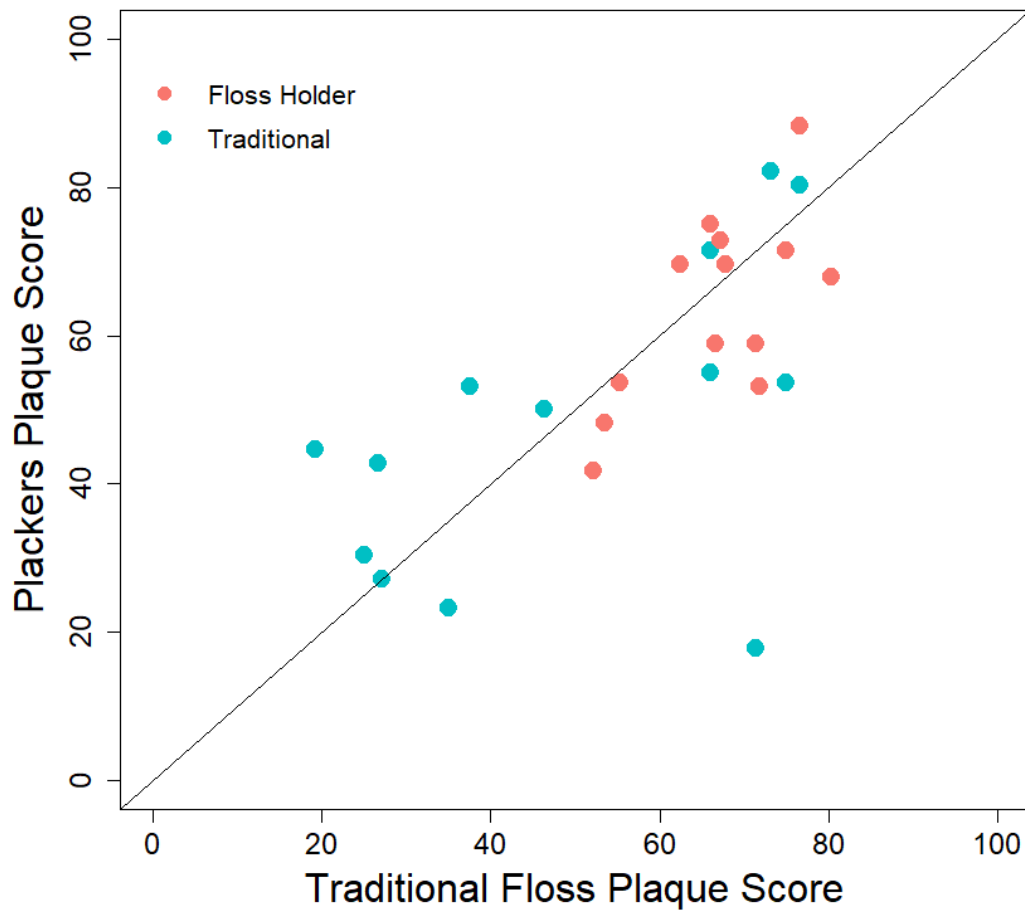


Figure 6: Scatter plot analyzing a subject's plaque score for both TF and PL in comparison with the subject's preference of device. Red=Plackers; Blue=Traditional Floss.

Additionally, it was noted that subjects who preferred using PL tended to have higher plaque scores with both devices. To investigate this trend, an average plot score across both measures for each participant was created (Figure 7). For TF, there was a wider more diffuse average of plaque scores. For PL, average plaque scores tended to higher with less distribution. An optimal, cut-point analysis was measured and a PI of $\geq 51\%$ indicated a subject might prefer PL over TF.

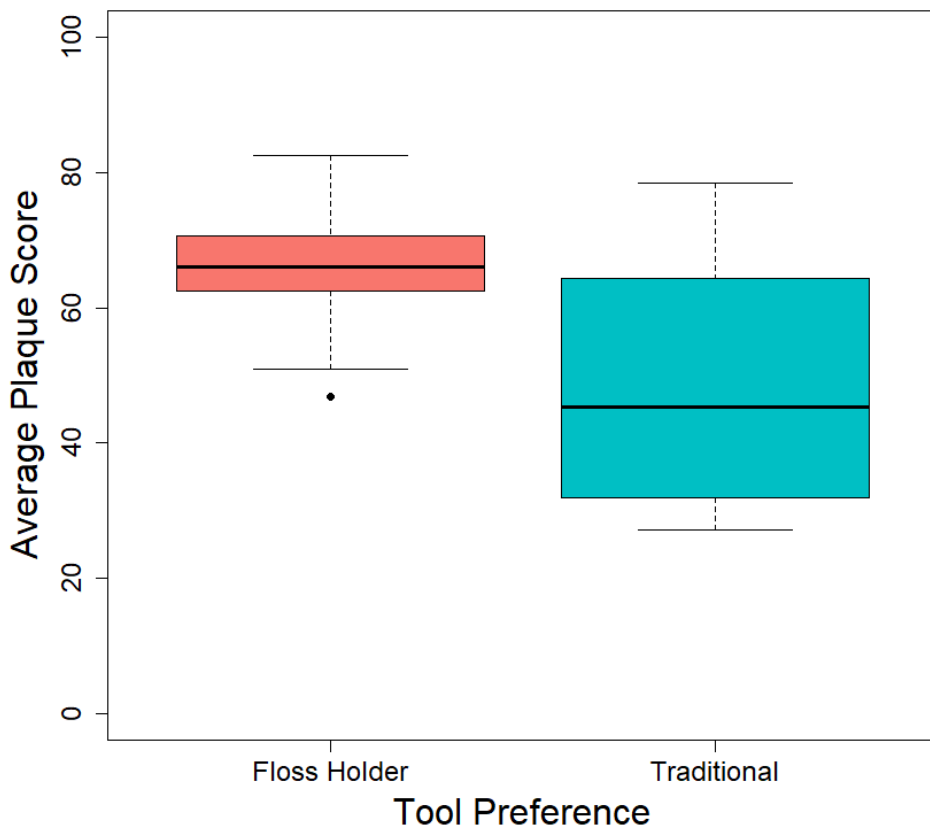


Figure 7: Average plaque scores in comparison with the subject's tool preference.

A second analysis was conducted to see if subjects were choosing their preference of device based on plaque score. Evaluation of this data revealed subjects do not have a preference of tool based on its efficacy to remove plaque (Figure 8). This indicates there is some other rationale for choosing a flossing device other than its ability to remove interproximal plaque.

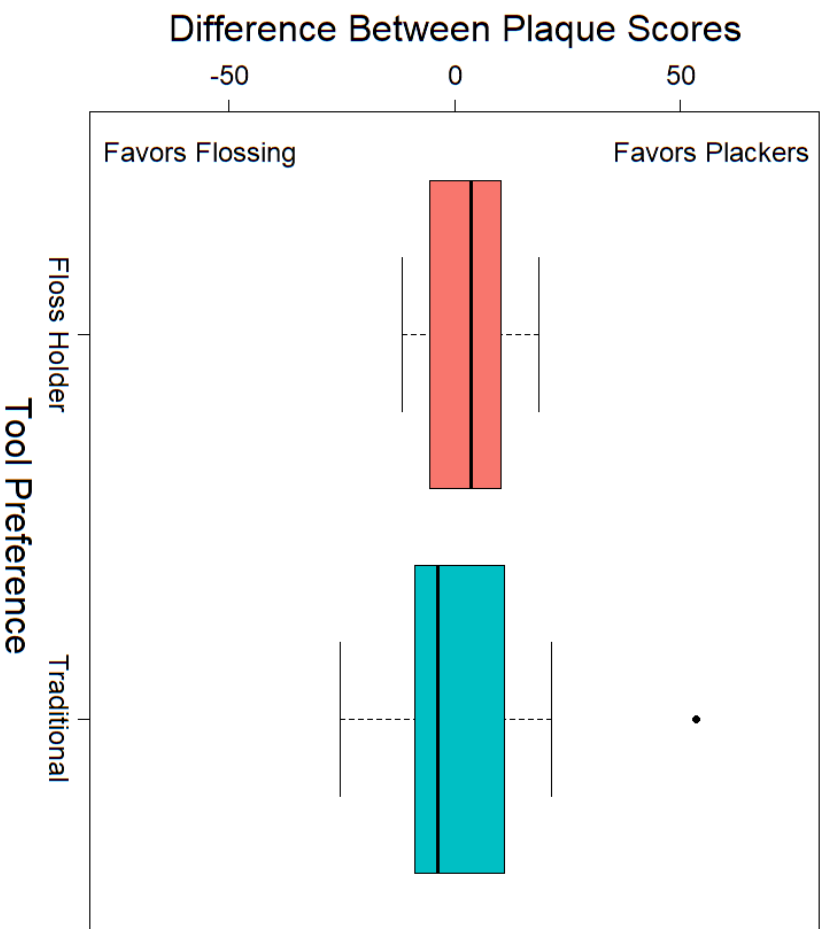


Figure 8: Differences in plaque scores compared to the subject's tool preference. This bar graph represents the finding that subjects are not making their tool preference based on tool efficacy.

DISCUSSION

From this interim analysis, the following findings were observed. First, it appears that TF and PL are equivalent in efficacy for interproximal plaque removal. Additionally, there was significant person-to-person variability in PI following one-time use. This indicates, for this military population, there is a wide range of knowledge or lack of knowledge regarding proper flossing use. Flossing instructions for this study were given to the participants according to the recommendations proposed by van der Weijden¹⁶ which includes gently wrapping the floss around the index fingers and advancing the floss through the contacts using a sawing motion. Once through the contact, the floss is to be wrapped in a “U” shape around the tooth and slightly under the gingival margin, with an additional sawing motion to remove the interproximal plaque. For the PL device, no instructions from the manufacturers were given regarding proper use. Subjects were therefore instructed to use the device similar to how traditional floss was used. While patients may view flossing as a common-sense practice, effectiveness of flossing may prove to be invalid without proper instruction. Much like toothbrushing, if patients are to see the benefits of its practice, the tool must be used appropriately and consistently. In a recent article published by the Associated Press, daily flossing practices based on scientific research were brought into question with flossing recommendations removed from federal dietary guidelines citing inconclusive evidence for benefits of flossing¹⁷. Additionally, in a 2011 Cochrane Systematic Review, Sambunjak et al determined that most flossing studies in the literature have either unclear or high risk of bias⁹. It was determined that from the 12 studies evaluated, flossing in addition to toothbrushing can reduce gingivitis but that there is weak evidence that overall plaque reduction can be achieved with toothbrushing and flossing practices. While in most of the studies evaluated, flossing instructions were administered, it should also be noted that compliance with consistent flossing practices may be difficult to measure and therefore, benefits

may be underestimated. Despite the low quality of evidence to suggest flossing practices reduce overall plaque levels, the authors concluded that given there is no evidence to either refute or support flossing and the low risk of injury while flossing, potential benefits outweigh the risks to recommend flossing to patients in prevention of gingival and periodontal diseases.

It was also noted that no individual tool was predicted by post-cleaning plaque score. However, there was no evidence to suggest tool preference is predictive of tool efficacy. Lastly, there is marginal evidence to suggest that tool preference may vary on reported flossing practice. In the current study, 73% of patients (19/26) reported flossing at least once on a daily basis. This was a self-reported measure and thus a potential bias for a high number of flossing patients may exist. In a 2015 online poll conducted by Harris Poll, 27% of respondents reported misleading their dental provider about flossing habits¹⁸. Additionally, patients also reported performing an unpleasant task such as house cleaning or sitting in traffic rather than flossing. In the current study more females than males reported preferring TF over PL however, this was not statistically significant given the unequal distribution of females and males.

Finally, a finding of a preference of PL over TF in subjects with higher plaque scores was observed in this military population. The study questionnaire asked participants to explain their preference and most who preferred the PL over TF reported its ease of use as the contributing factor. This may owe to its small design with ready to use floss in comparison with traditional floss which must be wrapped around the fingers in order to use. The clinical implication of this finding may suggest that those patients with higher plaque scores may tend to prefer a floss holding device over traditional floss, however, it must be emphasized that this does not infer superior efficacy over traditional floss. This finding might imply that these higher-plaque patients will have better compliance with a floss holding device over traditional floss.

CONCLUSION

Conclusions from this interim analysis are the following:

- (1) PL appear to be equally effective at interproximal plaque removal as TF
- (2) Patients with higher plaque scores tend to prefer PL. This might imply that patients with poor oral hygiene might have better compliance with the PL device over TF.

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