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Efficacy of the FlossPro Flosser versus Finger Flossing in Orthodontic Patients

Sharareh S. Sabet

LOMA LINDA UNIVERSITY
School of Dentistry
in conjunction with the
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Efficacy of the FlossPro Flosser versus Finger Flossing in Orthodontic Patients

by

Sharareh S. Sabet

A thesis submitted in partial satisfaction of
the requirements for the degree
Master of Science in Orthodontics and Dentofacial Orthopedics

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Each person whose signature appears below certifies that this thesis in his/her opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.

_____, Chairperson
Roland Neufeld, Associate Professor of Orthodontics and Dentofacial Orthopedics

_____
Yoon Jeong Kim, Associate Professor of Periodontics

_____
V. Leroy Leggitt, Professor of Orthodontics and Dentofacial Orthopedics

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ABBREVIATIONS

MB	Mesiobuccal
F	Direct Facial
DB	Distobuccal
DL	Distolingual
L	Direct Lingual
ML	Mesiolingual
mGI	Modified Loe and Silness Gingival Index
mQPI	Modified Quigley Hein Plaque Index
FMBS	Full Mouth Bleeding Score
Tx	Treatment
LS Means	Least Squares Means

ABSTRACT OF THE THESIS

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Sharareh S. Sabet

Master of Science, Graduate Program in Orthodontics and Dentofacial Orthopedics
Loma Linda University, September 2014
Dr. Roland Neufeld, Chairperson

Introduction: The maintenance of good oral hygiene among orthodontic patients is a challenge. The purpose of this study was to compare the oral hygiene habits, gingival health, and preference of orthodontic patients when using a floss aid compared to conventional finger flossing with a floss threader.

Methods: Thirty-four adolescent and young adult patients with fixed orthodontic appliances and poor oral hygiene were enrolled from the Loma Linda University Graduate Orthodontic Clinic. This was a single blind crossover study. The patients were randomly assigned to one of two treatment groups (floss aid or finger floss) in phase I. After prophylaxis, subjects were instructed to use the floss aid or finger floss once a day and continue brushing for 4-5 weeks. Patients then had a washout period of 4-5 weeks. In phase II, patients were assigned to the alternate treatment group for another 4-5 weeks. Clinical measurements of gingival index (mGI), plaque index (mQPI) and full mouth bleeding score (FMBS) were recorded at baseline prior to prophylaxis and after 4-5 weeks of each treatment. A survey to assess oral hygiene habits and product preference was given at the end of each treatment and results were analyzed using the McNemar and McNemar-Bowker test. Statistical analysis for mGI, mQPI and FMBS was performed

using Paired Sample t-test and a mixed model procedure.

Results: The Paired Sample t-test indicated no significant difference between baseline scores for mGI, mQPI and FMBS at phase I and phase II. The mixed model procedure analyzed data for the effects of time, treatment and treatment sequence on mGI, mQPI and FMBS. Results revealed statistically significant improvements in mGI, mQPI and FMBS for both treatment groups over time, with the floss aid showing more improvement ($P < 0.05$). Percent frequency of mGI and mQPI scores after treatment for test (floss aid) and control (finger floss) groups showed improvements in both interproximal and middle regions of the teeth. Treatment sequence was not statistically significant for any of the indices. The McNemar test indicated a statistically significant difference in the time to complete flossing between the two treatment groups ($P = 0.002$). After using both the test and control products, 85.3% of subjects preferred the test product.

Conclusions: Both the floss aid and conventional finger flossing were effective at reducing plaque, gingival inflammation and bleeding over time. Although the statistical analysis model showed more improvement in all indices with the floss aid, the improvements were small and not clinically significant.

CHAPTER ONE

REVIEW OF THE LITERATURE

It is well known that toothbrushing alone is not sufficient to adequately remove all plaque, specifically, interproximal plaque.[1] Gingivitis and periodontitis are more prevalent and frequently more severe on proximal surfaces, highlighting the importance for good oral hygiene practices especially in these regions.[1] A study by Yamamoto et al. found that the addition of flossing to toothbrushing resulted in an increase in plaque removal.[2] Addressing this concern specifically we turn to the use of dental floss. Since the early 19th century the benefits of dental floss were documented when it was thought that the source of dental disease was irritating matter between the teeth.[3] Levi Parmly, the inventor of dental floss, believed that gingival tissues could benefit favorably by regular and systematic brushing and flossing.[4]

When looking to the literature for the efficacy of dental floss as a means of interproximal plaque control, one finds conflicting data. Clinical studies, dating back to the 1970's, have shown that when dental floss is used correctly it can significantly improve proximal gingival conditions.[5-10] The American Dental Association recommends flossing at least once a day to achieve optimal oral health, and also states that flossing can help to prevent periodontal disease and carious lesions.[2,11]

Contrary to the conventional notion of the beneficial effects of flossing is the opposing argument that flossing provides no benefits as an interdental cleaning aid. Studies exist that do not show the improvements in proximal gingival conditions with the

inclusion of flossing during a short supervised program of oral hygiene.[1] Furthermore, we search a systematic review of randomized controlled clinical trials to assess the adjunctive effect of both flossing and toothbrushing versus toothbrushing alone on plaque and gingivitis. A meta-analysis was performed for the plaque and gingival index. The majority of studies showed that dental flossing provided no benefit over toothbrushing only on removing plaque and reducing gingivitis. The review concluded that a routine instruction to use floss was not supported by scientific evidence.[12]

Another systematic review of 12 randomized controlled trials assessed the effects of flossing in addition to toothbrushing compared with toothbrushing alone in the management of periodontal disease and dental caries.[13] The conclusions contrast the ones by Berchier et al.[12] The review found evidence that flossing in addition to toothbrushing was associated with a significant benefit in reducing gingivitis at 1, 3 and 6 months. However, the review could not claim or refute the benefits of floss in reducing plaque due to insufficient evidence.[13]

In reviewing the data that refute the benefits of floss, in addition to toothbrushing, one must take into consideration the studied patient population. In the systematic reviews by Berchier et al. and Sambunjak et al., the subjects were adult patients who had no orthodontic appliances.[12,13] Furthermore, some of these patients were previously treated for periodontal disease and had multiple open interproximal spaces.[12] While many interdental cleaning devices exist on the market, most studies included patients who had been treated for periodontal disease.[14,15] Ultimately, the oral hygiene regimen recommended to a patient should be unique for their dental health care needs.

It is reported that the routine use of dental floss is remarkably low, ranging from 2% to 20%, with 5-8% of youths reporting to use floss on a daily basis.[16,17] The frequency of flossing is related to patient's demographic, socioeconomic and educational factors. However, the primary problem lies in the patient's inability to incorporate flossing on a regular basis as part of daily oral hygiene, suggesting the need for alternative flossing methods. Studies have stated that research should focus on making the use of floss easier and increasing people's ability to establish a regular flossing habit, utilizing flossing aids to accomplish this goal is one technique.[16,17]

Flossing aids have been shown to be effective in preventing plaque accumulation and gingival inflammation and are generally preferred by patients for flossing.[16] Spolsky et al. compared the efficacy of a flossing aid to conventional finger flossing in adults who did not use dental floss regularly. While the study showed no statistically significant differences between groups in gingival inflammation and plaque scores, the study did show that patients preferred (56%) the flossing aid to finger flossing.[17] This preference could increase the incorporation of flossing into a daily oral hygiene routine, providing a tool that contributes to making interproximal cleaning convenient and desirable.

The ability to maintain proper oral hygiene habits is critical for patients with fixed orthodontic appliances during orthodontic treatment. However, the treatment regimen itself presents patients and orthodontists an obstacle that can ultimately influence treatment time and quality of orthodontic results. Fixed orthodontic appliances create plaque retentive sites that can lead to the accumulation of harmful bacteria, caries and decreased periodontal health.[18-22] Clinical evaluation reveals a plethora of destructive processes in the periodontium ranging from gingival hyperplasia and gingivitis to a

change in the quantitative and qualitative microbial content after the placement of fixed orthodontic appliances.[1,23]

The very nature of placing an archwire makes access to interproximal cleaning more difficult and time consuming for orthodontic patients. The accumulation of plaque on proximal tooth surfaces is consistently greater than nonproximal sites, eluding to the fact that interdental cleaning is inadequate in these regions.[1] In a study by Erbe et al., it was shown that orthodontic patients with fixed appliances had high baseline plaque values (>45%).[24] This finding has been documented in other studies, and supports the notion that removing plaque around archwires and brackets is a challenge for this patient population.[25,26]

In the literature there is evidence to support the use of dental floss in the orthodontic population. In a study by Zanatta et al., they looked for an association between dental floss use and gingival conditions in orthodontic patients. The results demonstrated statistically significant higher means of plaque index, gingival index, probing depth, and clinical attachment loss in the no dental floss group. The study concluded that flossing on a daily basis is associated with a lower likelihood of orthodontic patients having gingivitis and periodontal breakdown.[1]

Clinical signs of gingival inflammation, such as bleeding on probing and increase of pocket probing depth, have been observed during fixed orthodontic treatment.[1,18,20] This supports the need to implement an oral hygiene control system, involving interproximal cleaning aids, to provide quality care to all orthodontic patients. Kossack and Jost-Brinkmann state that the use of interdental cleaning aids should be

recommended to all patients with fixed orthodontic appliances, stressing the need to reduce plaque and gingivitis in this patient population.[27]

The use of dental floss can become challenging for adults and adolescents with the placement of fixed appliances. Studies have shown the difficulty in using dental floss, combining this with orthodontic appliances can increase the difficulty associated with the correct use of floss.[1,27] The time, effort and dexterity required to clean these sites often becomes a burden and the oral hygiene practices expected from patients are abandoned. A product that specifically aids orthodontic patients in making interdental cleaning easier may improve patient motivation and incorporation into daily oral hygiene practices. According to Waren and Chater, "There remains, however, a need for a more versatile and user friendly device that patients could adopt relatively easily, as they have the toothbrush, and which would be appropriate and effective for the majority of patients and most situations in the mouth".[4]

CHAPTER TWO

EFFICACY OF THE FLOSSPRO FLOSSER VERSUS FINGER FLOSSING IN ORTHODONTIC PATIENTS

Abstract

Introduction: The maintenance of good oral hygiene among orthodontic patients is a challenge. The purpose of this study was to compare the oral hygiene habits, gingival health, and preference of orthodontic patients when using a floss aid compared to conventional finger flossing with a floss threader.

Methods: Thirty-four adolescent and young adult patients with fixed orthodontic appliances and poor oral hygiene were enrolled from the Loma Linda University Graduate Orthodontic Clinic. This was a single blind crossover study. The patients were randomly assigned to one of two treatment groups (floss aid or finger floss) in phase I. After prophylaxis, subjects were instructed to use the floss aid or finger floss once a day and continue brushing for 4-5 weeks. Patients then had a washout period of 4-5 weeks. In phase II, patients were assigned to the alternate treatment group for another 4-5 weeks. Clinical measurements of gingival index (mGI), plaque index (mQPI) and full mouth bleeding score (FMBS) were recorded at baseline prior to prophylaxis and after 4-5 weeks of each treatment. A survey to assess oral hygiene habits and product preference was given at the end of each treatment and results were analyzed using the McNemar and McNemar-Bowker test. Statistical analysis for mGI, mQPI and FMBS was performed

using Paired Sample t-test and a mixed model procedure.

Results: The Paired Sample t-test indicated no significant difference between baseline scores for mGI, mQPI and FMBS at phase I and phase II. The mixed model procedure analyzed data for the effects of time, treatment and treatment sequence on mGI, mQPI and FMBS. Results revealed statistically significant improvements in mGI, mQPI and FMBS for both treatment groups over time, with the floss aid showing more improvement ($P < 0.05$). Percent frequency of mGI and mQPI scores after treatment for test (floss aid) and control (finger floss) groups showed improvements in both interproximal and middle regions of the teeth. Treatment sequence was not statistically significant for any of the indices. The McNemar test indicated a statistically significant difference in the time to complete flossing between the two treatment groups ($P = 0.002$). After using both the test and control products, 85.3% of subjects preferred the test product.

Conclusions: Both the floss aid and conventional finger flossing were effective at reducing plaque, gingival inflammation and bleeding over time. Although the statistical analysis model showed more improvement in all indices with the floss aid, the improvements were small and not clinically significant.

Introduction

Patients wearing fixed orthodontic appliances can accumulate food and plaque which can lead to staining, white spot lesions on the teeth, dental caries and periodontal disease. Proper oral hygiene may be more difficult to maintain during treatment, with the archwire acting as an impediment to interproximal cleaning such as flossing. Combined, these factors can contribute to a significant decline in the gingival health status of orthodontic patients. As new floss products are developed, appropriate clinical studies should be conducted to see if they can benefit the orthodontic community.

With the placement of fixed orthodontic appliances comes the challenge of increased effort and time required to clean the tooth surfaces appropriately. Oral hygiene practices become a daily struggle for orthodontic patients and it is common to see flossing abandoned all together. A tool to make flossing easier, efficient and less time consuming would be invaluable in improving the overall dental and periodontal health of orthodontic patients with poor oral hygiene.

Poor oral hygiene can directly influence the quality of orthodontic outcomes as well as treatment duration. One study showed an addition of two thirds of a month in estimated treatment time per chart entry of negative oral hygiene.[28] Another study showed an addition of 2.2 months of treatment time for patients with 3 or more "poor oral hygiene" chart entries.[29] It has been shown that those who have good oral hygiene are more likely to comply with other components of orthodontic treatment.[28] Ultimately, poor oral hygiene habits can increase the time in which dental and gingival health are at risk, in addition to the potential of jeopardizing the success of treatment with a compromised finish.

A new floss aid (FlossPro flosser, FlossPro, Chico, CA) was developed for orthodontic patients (Fig 1, A). It has a specially designed prong that can slide between the archwire and tooth embrasure, allowing the floss to easily move between interproximal tooth surfaces. The floss aid was made to offer patients a hygienic, efficient and simple way to floss to encourage hygiene compliance at home. With increased compliance, one would expect to see improvements in the gingival health of orthodontic patients with poor oral hygiene.

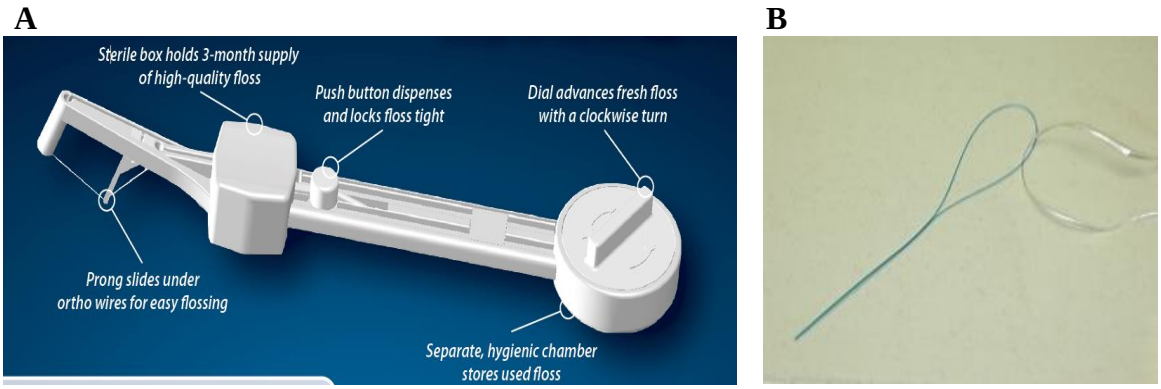

Figure 1. Floss aids: **A**, FlossPro flosser (test); **B**, Conventional finger floss with a floss threader (control).

There is currently no research data on the plaque removal efficacy and patient acceptance of the FlossPro flosser compared to conventional finger flossing with a floss threader in orthodontic patients (Fig 1). The null hypothesis was that there would be no difference between the test floss aid and conventional finger flossing when examining oral hygiene habits, gingival health and preference of orthodontic patients. The alternative hypothesis was that there would be a detectable difference between the two treatment groups.

Material and Methods

This was a randomized, examiner-blind crossover study. Patients in the Loma Linda University Graduate Orthodontic Clinic undergoing fixed maxillary and mandibular orthodontic appliance therapy who reported they did not floss regularly were screened. Patients exhibiting poor plaque control using the plaque index by Silness and Loe[30] with a score of 2 or 3 were selected for this study. After screening, 35 patients were recruited and written informed consent was obtained from all participants and/or their guardians (Appendix A). The study protocol was approved by the Institutional Review Board of Loma Linda University.

Subjects were excluded from the study if they: 1) received a professional dental cleaning within 1 month, 2) presented with pre-existing periodontal disease, 3) had excessive gingival hyperplasia, 4) used mouth rinses on a regular basis, 5) used proximal cleaning devices on a regular basis, 6) were diabetic, 7) were currently smoking, 8) were pregnant, 9) were mentally or physically disabled, 10) required antibiotic prophylaxis prior to periodontal data collection, or 11) were currently taking antibiotics.

This study employed a crossover design with 2 treatment phases. All subjects received both treatments, flossing with a test floss aid (test group) and conventional flossing (control group) (Fig 2). Initially, baseline clinical measurements were collected by a single blinded examiner. Following the collection of baseline data, each subject was provided a dental prophylaxis. Then they were randomly assigned to one of two groups for the first treatment. All subjects received standardized oral hygiene instruction regarding the proper use of the assigned floss product and provided a supply for their use at home.

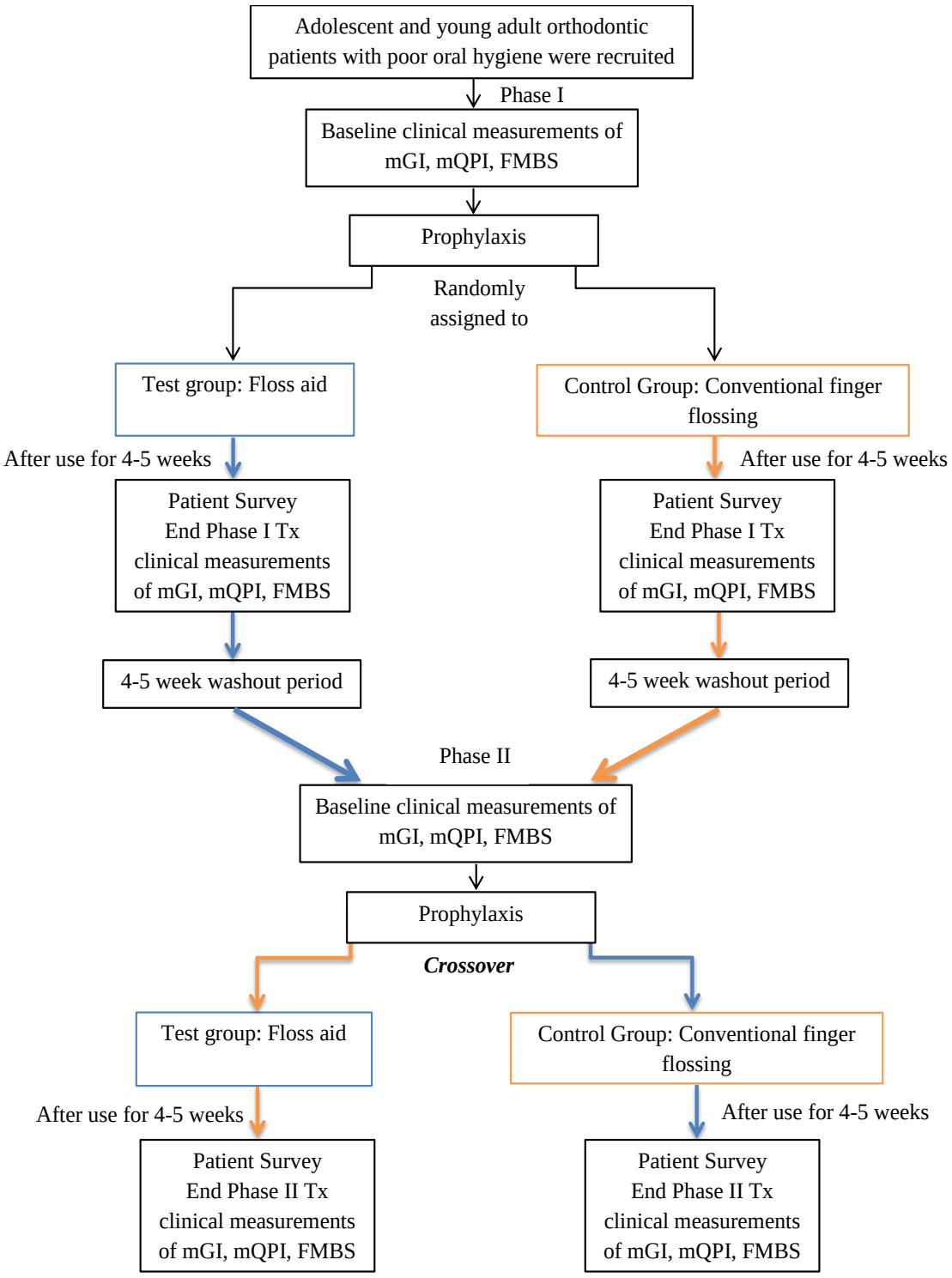

Figure 2. Study design

Each treatment phase consisted of using the assigned product, either the test floss aid (FlossPro flosser) or control with floss threaders (GUM® ButlerWeave® with GUM® Eez-Thru® floss threaders, Sunstar Americas Inc., Chicago, IL) for 4-5 weeks. At the end of the treatment phase, the patients returned for clinical measurements by the same single blinded examiner. An oral hygiene habit questionnaire was provided after use of the assigned product asking for subject's frequency of brushing and flossing, the ease of flossing with braces, the time to complete flossing, efficacy and preference of floss product and subject's intentions on changing their flossing habits (Appendix B).

There was a "washout period" for 4-5 weeks between the two treatment phases. During the washout period the patients were instructed to resume their regular oral hygiene practices (no regular flossing). The washout period allowed patients time to return to their previous oral hygiene status and establish similar baseline clinical conditions prior to the second treatment. After the washout period, baseline clinical measurements for the second treatment phase were again collected and a prophylaxis was provided. The patients were then assigned to the alternate group for the second treatment, and the assigned floss product was distributed for 4-5 weeks of use.

The Palmer Notation system was used to identify the teeth. Three measures of periodontal health were used:

1. Gingival Index (mGI). A modified version of the Loe and Silness gingival index[30], without bleeding on probing, was used to assess the gingival condition based on visual examination on a scale of 0-3: 0) Normal, 1) Mild inflammation, slight color change and edema, 2) Moderate inflammation, redness and edema, and 3) Severe inflammation, marked redness and edema, ulceration, spontaneous bleeding.

2. Plaque Index (mQPI). A modified version of the modified Quigley Hein Plaque Index[31,32] was used to score the teeth on a scale of 0-3 following the use of a disclosing solution (GUM® Red-Cote® Liquid, Sunstar Americas Inc., Chicago, IL). The disclosing solution was applied to the surfaces of the teeth using a cotton swab, followed by rinsing with water for 30 seconds. Only the gingival 1/3 of the tooth was scored. Scores were assigned as follows: 0) No plaque, 1) Separate flecks of plaque at the cervical margin of the tooth, 2) A thin, continuous band of plaque (up to 1mm) at the cervical margin, and 3) A band of plaque wider than 1mm but covering less than one-third of the crown of the tooth. Molars with metal orthodontic bands were excluded due to an inability to accurately assess the gingival 1/3 of the tooth. Prior to the next index, a wet gauze was utilized to completely clean and remove the disclosing solution.

3. Full Mouth Bleeding Score (FMBS). Defined as the percentage of sites bleeding after 30 seconds when the periodontal probe (#PAF, G. Hartzell & Son, Concord, CA) was run gently along the gingival sulcus of 6 sites of the tooth, mesiobuccal (MB), direct facial (F), distobuccal (DB), distolingual (DL), direct lingual (L), and mesiolingual (ML), with respect to the number of sites examined.

The sequence of collection was: mGI, mQPI, then FMBS. Standardized oral hygiene instruction was given to the subjects before each treatment. In order to assure the appropriate use of the floss product, each subject watched a short (~2 min) instructional video on the proper use of both products. The subject was also provided a typodont demonstration on how to use the floss products. Both verbal and visual information was provided when the test and control product was dispensed. All subjects were provided the same toothpaste (Crest Complete Multi-Benefit® Whitening + Scope®,

Procter & Gamble, Cincinnati, OH) and toothbrush (ACCLEAN® Edge, Henry Schein Inc., Melville, NY) to use during the study period.

A self-reporting compliance calendar was given to the patient when the product was dispensed and collected at the end of product use. Patients were asked to indicate flossing one time per day with a check mark on each day of the calendar. At the conclusion of product use, patients were asked to return any unused floss product.

Intraexaminer reproducibility was tested by double measurements of mGI on 12 patient photos at two different time points. Maxillary and mandibular anterior teeth were scored. No differences existed between the two time point measurements, indicating high reproducibility.

Statistical Analysis

Descriptive statistics were given as mean ± standard deviation for quantitative variables and number with percentages for qualitative variables. Paired Sample t-test procedure was used to compare the mean scores of the two baseline measurements for each outcome variable. The repeated measures analysis using a mixed model procedure was used to access the effect of treatment type, time points, and treatment sequence on each outcome variable. Post hoc tests were done on least squares means using Tukey adjustment for multiple comparisons. McNemar and McNemar-Bowker test were used to assess the relationship between the qualitative variables in the oral hygiene questionnaire. Alpha was set at 0.05 level. Statistical analyses were performed using SAS (Version 9.3: SAS Institute Inc.).

Results

Thirty-four of the original 35 subjects completed the clinical trial. One patient dropped out after phase I due to an inability to maintain follow-up appointments. There were 18 female (53%) and 16 male (47%) subjects. The average age was 15.7 years with an age range of 11 to 22 years. There were 18 subjects who started in the test group for the first treatment and crossed over to the control group for the second treatment phase. 16 subjects started in the control group for the first treatment and crossed over to the test group for the second treatment phase.

Baseline mean scores at phase I and phase II for mGI, mQPI and FMBS are shown in Table 1. There was no significant difference between baseline 1 and baseline 2 mean scores using the Paired Samples t-test for any of the indices. Hence, baseline 1 was used for baseline comparisons in Table 2.

Table 1. Baseline 1 and 2 values for mGI, mQPI and FMBS.

	Baseline 1 (N=34)		Baseline 2 (N=34)		
	Mean	SD	Mean	SD	P value
mGI	1.15	0.20	1.15	0.16	0.968 [a]
mQPI	1.21	0.19	1.14	0.19	0.132[a]
FMBS	58.73	9.02	58.28	10.62	0.814[a]

SD, Standard deviation
[a]Paired Samples t-test

The repeated measures analysis using a mixed model procedure was conducted to examine the effects of time, treatment and treatment sequence for mGI, mQPI and FMBS (Table 2). The least squares (LS) means and the difference between the means can be

seen for mGI, mQPI and FMBS in Table 2. Due to the randomized crossover design, the effect of test treatment at phase I and then control treatment at phase II vs control treatment at phase I and then test treatment at phase II was analyzed. The analysis showed no significant effect of treatment sequence for mGI, mQPI and FMBS. However, there was a significant effect of time and treatment on all indices.

Table 2. Effect of time, treatment and treatment sequence on mGI, mQPI and FMBS.

	mGI			mQPI			FMBS		
	LS Means	Difference of LS Means	P value	LS Means	Difference of LS Means	P value	LS Means	Difference of LS Means	P value
Time									
Baseline	1.15	0.67	<0.001*	1.21	0.708	<0.001*	58.75	31.20	<0.001*
End Phase I Tx	0.48	0.08	0.074	0.50	0.048	0.219	27.55	0.79	0.882
End Phase II Tx	0.40	0.75	<0.001*	0.46	0.755	<0.001*	26.76	31.98	<0.001*
Treatment									
Control	0.71	0.07	0.025*	0.76	0.075	0.003*	39.33	3.28	0.024*
Test	0.64			0.69			36.05		
Treatment Sequence									
Control-Test	0.66	-0.03	0.522	0.72	-0.001	0.985	36.34	-2.69	0.417
Test-Control	0.69			0.72			39.03		

P value for baseline represents baseline vs the end of phase I treatment, End phase I treatment represents the end of phase I treatment vs the end of phase II treatment, End phase II treatment represents baseline vs the end of phase II treatment. Mixed model analysis of variance with Tukey adjustment for multiple comparisons.
*Statistically significant at P <0.05.

mGI, mQPI and FMBS in both the control and test group decreased significantly at the end of phase I treatment and phase II treatment compared to baseline. However, there was no significant difference between the end of phase I treatment and phase II

treatment for any of the indices (Table 2). The test group with the floss aid showed statistically more improvement in all indices with a $P < 0.05$.

Evaluating the frequency of mGI scores for test and control groups in the interproximal region (MB, ML, DB, DL) at baseline reveals close to 3 times less 0 scores and an increase of an average of 2 times the number of 2 scores compared to the middle region (F, L) (Fig 3). The frequency of scores 0-3 between test interproximal and control interproximal and test middle and control middle regions at baseline and after treatment were comparable. The test and control group both increased the frequency of 0 scores and decreased the frequency of 1 and 2 scores after treatment. The middle region for both the test and control group showed a higher frequency of score 0 and lower frequency of score 1 and 2 when compared to the interproximal region after treatment.

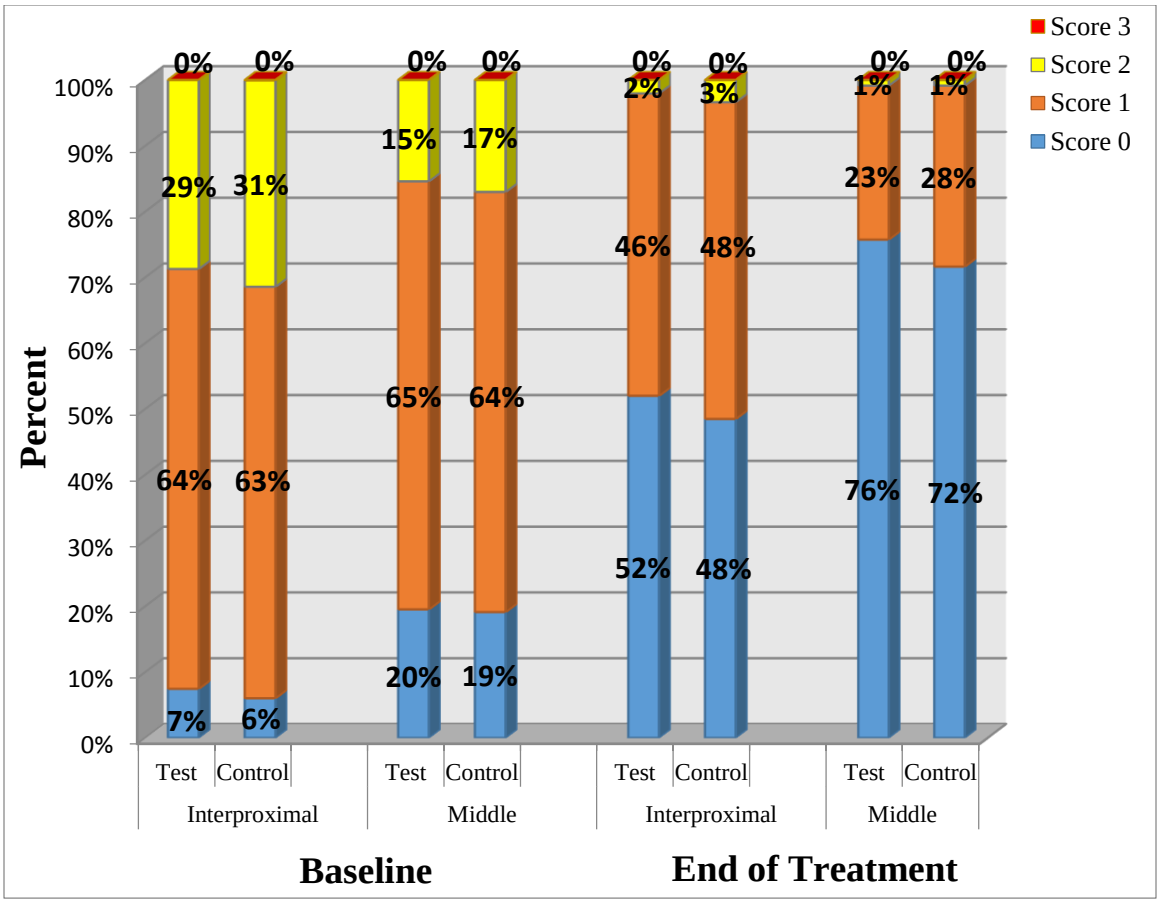

Figure 3. Frequency of mGI scores.

When evaluating the frequency of mQPI scores for test and control groups, the interproximal region at baseline had a lower number of 0 scores, close to 4 times less, when compared to the middle region for both groups (Fig 4). The interproximal region for both test and control groups had a higher frequency of 1 and 2 scores compared to the middle region at baseline. There were similar frequencies of scores 0-3 when comparing test interproximal with control interproximal and test middle with control middle regions at baseline and after treatment. The test and control groups increased the frequency of 0 scores and decreased the frequency of scores 1-3 for both interproximal and middle

regions after treatment. The middle regions after treatment for both test and control groups showed more 0 scores and less 1 scores compared to the interproximal sites.

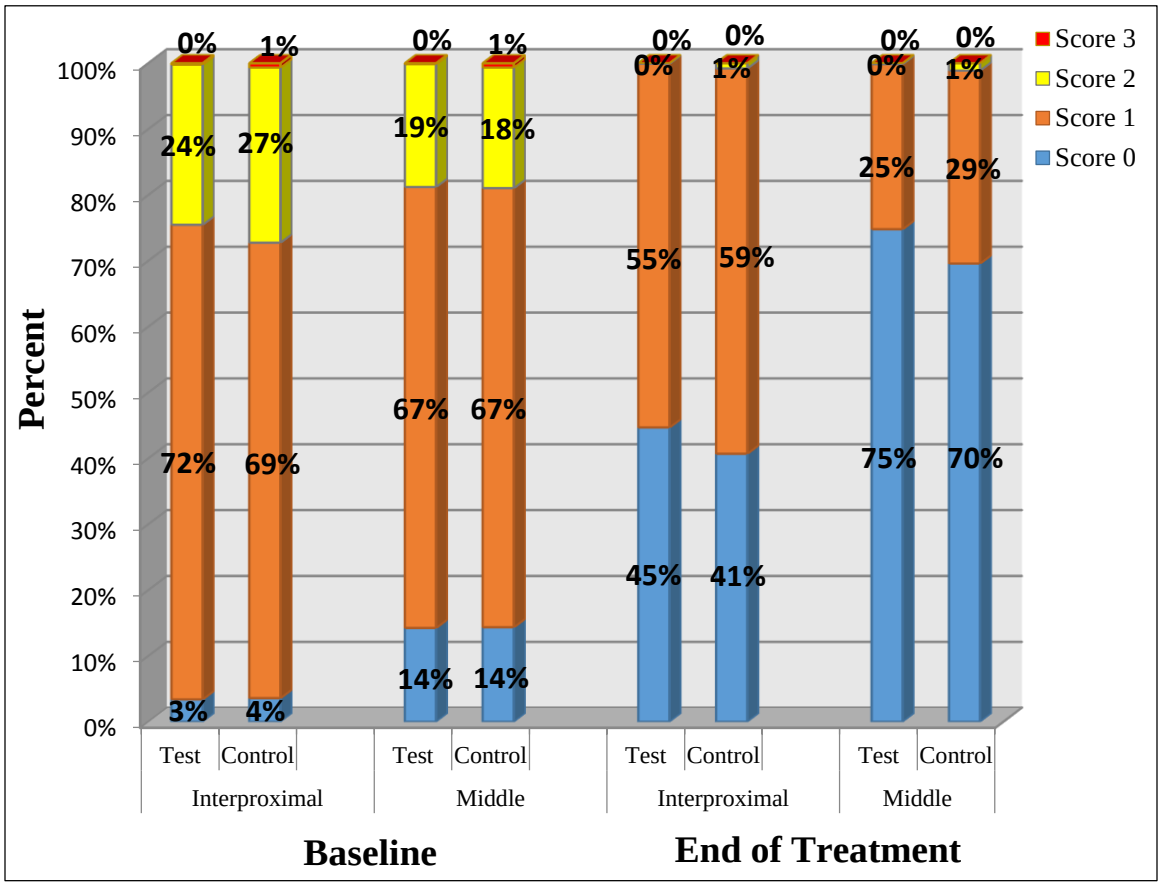

Figure 4. Frequency of mQPI scores.

The self-reported oral hygiene questionnaire results indicated a significant difference in the time to complete flossing between the two treatment groups, P =0.002 using the McNemar Test. For the test group, 15 (44.1%) subjects reported that it took them less than 2 minutes to floss and 19 (55.9%) reported it took them 2 minutes or more. For the control group, 3 (8.8%) reported it took them less than 2 minutes to floss and 31 (91.2%) reported taking 2 minutes or more to floss (Table 3).

Table 3. Oral hygiene questionnaire results.

Oral Hygiene Questionnaire	FlossPro N (%)	Control N (%)	P value
How often do you brush your teeth?			1.000[a]
2 or more times/day	28 (82.4)	28 (82.4)	
Less than 2 times/day	6 (17.6)	6 (17.6)	
How often do you floss your teeth?			0.250[a]
2 or more times/day	4 (11.8)	1 (2.9)	
Less than 2 times/day	30 (88.2)	33 (97.1)	
On a scale of 1 to 5 with 1 being easy and 5 being very difficult, how would you rate the ease of flossing with your braces?			0.514[b]
1	7 (20.6)	2 (5.9)	
2	5 (14.7)	7 (20.6)	
3	6 (17.6)	9 (26.5)	
4	10 (29.4)	12 (35.3)	
5	6 (17.6)	4 (11.8)	
How long does it take you to floss?			0.002[a*]
Less than 2 minutes	15 (44.1)	3 (8.8)	
2 minutes or more	19 (55.9)	31 (91.2)	
After using the floss product provided to me during this study I:			NA
Plan on flossing more often	34 (100)	31 (91.2)	
Will floss the same as I did before	0 (0.0)	2 (5.9)	
Will floss less than I did before	0 (0.0)	1 (2.9)	
Did you feel that the flossing product worked well in cleaning the areas between your teeth?			NA
Yes	33 (97.1)	27 (79.4)	
No	1 (2.9)	1 (2.9)	
Unsure	0 (0.0)	6 (17.6)	
If you are finished using both products, which product do you prefer using?			NA
GUM® ButlerWeave® Waxed Dental Floss	4 (25.0)	0 (0.0)	
FlossPro flosser	12 (75.0)	17 (94.4)	
Neither product	0 (0.0)	0 (0.0)	
No preference	0 (0.0)	1 (5.6)	

[a]P values were obtained by McNemar Test
[b]P values were obtained by McNemar-Bowker Test
*Statistically significant at P <0.05

Frequency of brushing and flossing was found to have no significant difference between the groups. McNemar Test P values were 1.000 and 0.250 respectively. The ease of flossing with braces was also found to have no significant difference between the groups (P =0.514, McNemar-Bowker Test).

After using the assigned floss product, all 34 (100%) subjects in the test group and 31 (91.2%) subjects in the control group reported that they planned on flossing more often than they did before. Two (5.9%) subjects in the control group reported they would floss the same as they did before and 1 (2.9%) subject reported they would floss less than they did before.

When asked if they felt the flossing product they were assigned to at the time worked well in cleaning the areas between their teeth, 33 (97.1%) subjects in the test group and 27 (79.4%) subjects in the control group stated yes. One (2.9%) subject in both the control and test group stated no and 6 (17.6%) subjects in the control group were unsure.

After using both the control and test products, 29 (85.3%) subjects preferred the test product (FlossPro flosser) compared to 4 (11.8%) subjects who preferred the control product (GUM® ButlerWeave® Waxed Dental Floss) and 1 (2.9%) subject who had no preference.

Discussion

With a crossover design, concern always lies in whether or not treatment sequence is a significant variable. Questions also arise as to whether or not the length of the washout period was enough to assure no carry over effect. The treatment sequence was analyzed and the repeated measures analysis using a mixed model procedure showed no significant effect of treatment sequence for mGI, mQPI and FMBS. Therefore, the washout period was sufficient and effective in this study.

A large number of patients in this study were adolescents. The World Health Organization defines adolescence as the period from age 10-19.[33] This time is optimal for orthodontic treatment as permanent tooth eruption is occurring and craniofacial growth is progressing. However, this period is also when patients are less compliant with treatment and less attentive to oral hygiene measures. Hence, there are higher chances of gingivitis and gingival enlargement in adolescents compared to adults. [34] The risk for increased susceptibility to decreased periodontal health supports the use of this age group in the study.

Subjects enrolled in this study had poor oral hygiene as evidenced by the high levels of bleeding, inflammation and plaque seen at baseline. The study showed improvements in overall gingival health through decreased bleeding scores, plaque and gingival inflammation over time with both floss products. This shows that the incorporation of a regular oral hygiene regimen involving interproximal cleaning aids can improve the overall gingival health of orthodontic patients with poor oral hygiene. This is similar to the conclusion by Zanatta et al. that flossing every day is associated with a lower likelihood of orthodontic patients having gingivitis and periodontal breakdown.[1]

When examining the frequency of gingival and plaque scores, the interproximal regions consistently had higher frequencies of 2 scores and lower frequencies of 0 scores at baseline for both treatment groups. After treatment, there was a substantial improvement in gingival and plaque indices that was very similar in both the test and control group in the interproximal and middle regions of the teeth.

Comparing treatment groups, the test floss aid showed statistically significant improvements in mGI, mQPI and FMBS over the control. However, when looking at the

difference of the means this improvement is small. Furthermore with such a small numerical improvement, the translation to clinical significance does not show an advantage of one treatment over the other.

The main advantage of the test floss aid is that 85.3% of subjects preferred it over conventional finger flossing with a floss threader. As seen in other floss aid studies, this preference may lead to a more consistent use and could increase the patient's ability to incorporate flossing into their daily hygiene routine.[17] The ease of using the product however was not established, possibly due to poor wording in the questionnaire. If subjects struggled with manual dexterity in navigating the proper use of conventional finger floss with a floss threader the floss aid may have been preferred since it required very minimal motor skills for its mechanical control.

The length of time subjects were in active orthodontic treatment was not considered as an exclusion/inclusion criteria in this study. Research shows that changes in gingival health can be observed 1-2 months after the placement of appliances and once established, the changes do not vary during treatment.[20] In addition, similar baseline values between the groups for all indices supports the idea that the subjects began the study with comparable gingival health.

The declining hygiene status after placement of fixed orthodontic appliances is a concern. Any method that can assist patients in the mechanical removal of interproximal plaque can prove valuable to have in one's armamentarium. The FlossPro flosser showed a statistically greater effect compared to conventional finger flossing with a floss threader in improving gingival inflammation, plaque and bleeding scores. However, this study did not establish a clinical superiority over conventional finger flossing with a floss threader.

Conclusions

1. Both the floss aid and conventional finger flossing with a floss threader were effective at reducing mGI, mQPI and FMBS over time in both interproximal and middle regions of the teeth.
2. The FlossPro flosser may confer a slight advantage over conventional finger flossing with a floss threader, however the clinical significance of this advantage cannot be established.
3. The self-reported oral hygiene questionnaire results indicated a significant difference in the time to complete flossing, with the majority of the control group taking 2 minutes or more to floss. The test group was almost evenly divided with 55.9% reporting to take 2 minutes or more to floss.
4. The majority of subjects preferred the test product (FlossPro flosser) over the control product (GUM® ButlerWeave® Waxed Dental Floss).
5. With proper oral hygiene instruction, patients improved gingival health with fixed orthodontic appliances.

CHAPTER THREE

EXTENDED DISCUSSION

Study Improvements and Future Directions

In this study, increasing the sample size could have been helpful in improving the significance of the study outcomes. Because many of the adult patients presented with one or more of the exclusion criteria, their enrollment in the study was limited.

Although the questionnaire was evaluated and edited by a psychologist, there seemed to be some confusion in the wording of the questions. Some patients were confused as to whether the questions were asking about their prior poor hygiene practices, even though the questionnaire was provided at the end of each treatment phase. Perhaps better wording to indicate present tense ("this past month") would have been helpful to the patient to indicate which portion of their oral hygiene practices they were providing feedback on.

The range of values for question 3 could reflect that it was again poorly worded since it was meant to ask in regards to ease with that particular product. The comments left on the prefrence of the floss aid consistently mentioned that it was easier to use, however this was not reflected in the answers for question 3. Perhaps adding "with the product you used this past month" to the end of the question could have provided for a better distribution or tendency towards an answer choice.

The literature supports the notion that patients with good oral hygiene may be more likely to comply with other components of orthodontic treatment.[28] A future study could

be conducted to investigate the correlation between a patient's oral hygiene status and the total length in orthodontic treatment time. In addition, one can evaluate if there is also a relationship between the level of compliance with instructions (elastics, removable appliance wear, etc.) and a patient's length of treatment based on their hygiene status.

An area of future research could also investigate the efficiency of orthodontic tooth movement in the presence of gingival inflammation and poor oral hygiene. The rate of tooth movement could be compared in patients with differing oral hygiene and periodontal status.

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APPENDIX A

INFORMED CONSENT DOCUMENTS

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in an experimental clinical procedure. Before you decide whether you want to participate in the experimental procedure, you have a right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of any signed and dated written consent form used in relation to the experiment.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

I have carefully read the information contained above in the "California Experimental Subject's Bill of Rights" and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

_____ _____

Date Patient

_____ _____

For inpatient studies, add: Time Parent/Legal Guardian

If signed by other than the patient, indicate relationship:

_____ _____

Relationship Witness

INSTITUTIONAL REVIEW BOARD
Authorization for Use of Protected Health Information (PHI)

Per 45 CFR §164.508(b)

RESEARCH PROTECTION PROGRAMS
LOMA LINDA UNIVERSITY | Office of the Vice President of Research Affairs
24887 Taylor Street, Suite 202 Loma Linda, CA 92350
(909) 558-4531 (voice) / (909) 558-0131 (fax)/e-mail: irb@llu.edu

TITLE OF STUDY:Plaque Removal Efficacy and Patient Acceptance of the FlossPro Flosser Compared to Conventional Finger Flossing in Patients with Fixed Orthodontic Appliances

PRINCIPAL INVESTIGATOR:Dr. Roland Neufeld

Others who will use, collect, orLoma Linda University Graduate Orthodontic Clinic share PHI:Dr. Sharareh Sabet

Use of the terms "I," "you" and "your" addresses, where appropriate, the study patient, the parent or legal representative if the study patient is a minor, any unborn fetus(es) and child(ren) once born. The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: name, address, telephone number, date of birth, and medical records and charts, including the results of all tests and procedures performed.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) and the Office of Research Affairs of Loma Linda University.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not be required to follow national and international "protected health information" (PHI) regulations such as the federal privacy rule.

Loma Linda University
Adventist Health Sciences Center
Institutional Review Board
Approved 11/13/13 Void after 11/12/2014
#5130339 Chair R L Rugglund

IRB 1/23/2013

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete.

- The authorization expires upon the conclusion of this research study.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at : 909-558-4616.

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

.....

I agree that my personal health information may be used for the study purposes described in this form.

Signature of Patient *or* Patient's Legal Representative	**Date**
Printed Name of Legal Representative (if any)	**Representative's Authority to Act for Patient**
Signature of Investigator Obtaining Authorization	**Date**

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#5130339 Chair R L Rigsby MD

IRB 1/23/2013

Plaque Removal Efficacy and Patient Acceptance of the FlossPro Flosser Compared to Conventional Finger Flossing in Patients with Fixed Orthodontic Appliances

School of Dentistry
Orthodontic Department

Loma Linda University

159 W. Hospitality Lane
San Bernardino, California 92408
Office: (909) 558-4616
Fax: (909) 651-3096

INFORMED CONSENT

TITLE

Plaque Removal Efficacy and Patient Acceptance of the FlossPro Flosser Compared to Conventional Finger Flossing in Patients with Fixed Orthodontic Appliances

PRINCIPAL INVESTIGATOR

Roland Neufeld, DDS, MS

For ease of reading, the word "you" or "your" will be used throughout this document to refer to the person who may enter the research program.

PURPOSE OF THIS STUDY

The department of Orthodontics and Dentofacial Orthopedics at the Loma Linda University School of Dentistry is conducting research on two different types of dental floss. The purpose of this study is to compare the oral hygiene habits, gum health and preference of orthodontic patients when using the FlossPro flosser (a flossing aid) compared to conventional finger flossing. You are being invited to participate in this study because you have started orthodontic treatment, and based on screening criteria, it appears you can benefit from improved oral hygiene practices. Approximately 40 subjects will participate in this study at the Loma Linda University Graduate Orthodontic Clinic. Your participation in this study will last up to 3 months.

Plaque Removal Efficacy and Patient Acceptance of the FlossPro Flosser Compared to Conventional Finger Flossing in Patients with Fixed Orthodontic Appliances

HOW YOU WILL BE INVOLVED

Participation in this study involves filling out a short questionnaire regarding your oral hygiene habits as completely and accurately as possible, having an intra-oral photograph of the upper and lower teeth taken, as well as having routine gum health data collected during a clinical exam. You will be expected to use regular dental floss and a flossing aid, each for 4 weeks. Two dental cleanings will be provided to you during the course of the study. A total of 4 data collection visits will be needed. The expected time commitment is about 30 minutes for both the 7 question survey and dental examination.

RISKS

The committee at Loma Linda University that reviews human studies (Institutional Review Board) has determined that participating in this study exposes you to minimal discomfort, harm or injury. However, there is a potential for a breach of confidentiality, but measures will be taken to prevent it and you may experience some discomfort during the oral exam.

BENEFITS

You may not benefit individually from participating in this study. However, we hope that this research project will help the speciality of orthodontics develop a better understanding of the effects of flossing products on the gum health and oral hygiene of patients who are undergoing orthodontic treatment. With the placement of fixed orthodontic appliances we understand that oral hygiene can become a challenge. We hope that this study will help us to see how we can help our orthodontic patients improve hygiene practices at home.

PARTICIPANT'S RIGHTS

Participating in this study is voluntary. Your decision whether or not to participate or to withdraw at any time from the study will not affect your relationship with Loma Linda University, the Loma Linda University School of Dentistry or the Graduate Orthodontic Clinic and will not involve any penalty or loss of benefits to which you are otherwise entitled. You may get a second opinion about your decision to be in this study from another doctor at your own cost. Likewise, your study doctor may withdraw you from the study for any reason without your agreement or may stop the study entirely. You are free to discontinue the study at any time.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Information about your gum and oral hygiene status will be entered into a research record. Any data or published document resulting from this study will not disclose your identity without your express permission. The information in the research records will be anonymized by removal of the participant's name and other identifying information. You will not be identified by name in any publications describing the results of this study. Your rights regarding permission to use your health information are described on the attached "Authorization for Use of Protected Health Information" form.

COSTS

There is no cost to you for participating in this study. You and/or your dental insurance must pay for those services, supplies, procedures, and care required for your routine orthodontic treatment. You will be responsible for any co-payments and/or deductibles as required by your insurance.

COMPENSATION

You will not be paid to participate in this study. However, if you chose to participate you will receive 2 free dental cleanings as part of the study. You will not be charged for any expenses incurred should you choose to withdraw from the study.

WILL STUDY STAFF RECEIVE PAYMENT?

The investigator has no financial interest nor is receiving any financial support from an external sponsor to perform this study.

IMPARTIAL THIRD PARTY CONTACT

If you wish to contact an impartial third party not associated with this study regarding any questions about your rights or to report a complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 558-4647, e-mail patientrelations@llu.edu for information and assistance.

Plaque Removal Efficacy and Patient Acceptance of the FlossPro Flosser Compared to Conventional Finger Flossing in Patients with Fixed Orthodontic Appliances

SUBJECT'S STATEMENT OF CONSENT

I have read the contents of this consent form, which is in English, a language that I read and understand. I have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. If I'm providing parental permission, this protocol has been explained to my child at a level that he/she can comprehend and I give permission for my child to participate in the study. I have received a copy of the California Experimental Subject's Bill of Rights and have had these rights explained to me. I hereby give voluntary consent to participate in this study. Signing this consent does not waive my rights nor does it release the investigator(s), institution, or sponsors from their responsibilities. I may call Dr. Neufeld (909)-558-4616 or Dr. Sabet (909)-558-4616, if I have additional concerns. I have been given a copy of this consent form.

_____ _____

Signature of Parent/Guardian Printed Name of Parent/Guardian

_____

Date

Authority to act for subject:_____

_____ _____

Signature of Subject (12 years or older) Printed Name of Subject (12 years or older)

_____

Date

Plaque Removal Efficacy and Patient Acceptance of the FlossPro Flosser Compared to Conventional Finger Flossing in Patients with Fixed Orthodontic Appliances

INVESTIGATOR'S STATEMENT

I attest that the requirements for informed consent for the dental research project described in this form have been satisfied-that the subject has been provided with a copy of the California Experimental Subject's Bill of Rights, that I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered. I will provide the subject or the legally authorized representative with a signed and dated copy of this consent form.

Date: _____

Signature: _____
(Signature Of Person Obtaining Consent)

Print Name: _____

School of Dentistry
Orthodontic Department

Loma Linda University

159 W. Hospitality Lane
San Bernardino, California 92408
Office: (909) 558-4616
Fax: (909) 651-3096

Informed Assent

Would you help one of the doctors learn more about how to keep your teeth clean and floss your teeth? Dr. Sabet is studying different ways to floss your teeth now that you have braces on them to learn more about how to keep your teeth and gums healthy.

You can help by using two different flossers. You will have to use each one the way that Dr. Sabet tells you to use it for 1 month. Before you use the flosser, and after you use it for 1 month, Dr. Sabet will take measurements in your mouth near your gums. You might feel a little pressure when she uses her gum measurement instrument, but it won't last long. Dr. Sabet will see you before you see your doctor for your braces adjustment so your appointment time will be 30 minutes longer. We will also clean your teeth twice for you.

You do not have to do this, and you have the right to say "no." If you decide not to be in the study, its okay and nothing changes. This is still your clinic for braces, everything stays the same as before. Even if you say "yes" now, you can change your mind later and its still okay. But if you don't mind flossing your teeth every night and letting me take measurements on your teeth and gums, your help in this study may help other kids keep their gums and teeth healthy when braces go on too.

Do you have any questions about this study? If so, please feel comfortable asking the person who gave you this form. If you want to say "yes" to helping the study by using our floss and letting us take measurements and look at your teeth and gums, just sign on the line below.

Thank you for thinking about this idea.

_____ _____

Child's signature Date

_____

Witness

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#5130339 Chair R L Rugglymd

APPENDIX B

ORAL HYGIENE QUESTIONNAIRE

Please circle one (1) of the following responses for each question.

1. How often do you brush your teeth?
    a. 2 or more times/day
    b. 1 time/day
    c. 2-3 times/week
    d. Less than 2-3 times/week
    e. Never

2. How often do you floss your teeth?
    a. 2 or more times/day
    b. 1 time/day
    c. 2-3 times/week
    d. Less than 2-3 times/week
    e. Never

3. On a scale of 1 to 5 with 1 being easy and 5 being very difficult, how would you rate the ease of flossing with your braces?
    a. 1
    b. 2
    c. 3
    d. 4
    e. 5

4. How long does it take you to floss?
    a. Less than 1 minute
    b. 1 minute
    c. 2 minutes
    d. More than 2 minutes

5. After using the floss product provided to me during this study I:
    a. Plan on flossing more often
    b. Will floss the same as I did before
    c. Will floss less than I did before

    Please add any comments on your selected choice:

6. Did you feel that the flossing product worked well in cleaning the areas between your teeth?

a. Yes
b. No
c. Unsure

7. If you are finished using both products, which product do you prefer using?

a. GUM® ButlerWeave® Waxed Dental Floss
b. FlossPro flosser
c. Neither product
d. No Preference

Comments:

Name: _____ Date: _____