Comparison of Soft Toothbrush and New Ultra-soft Cleaner in Ability to Remove Plaque from Teeth

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ABSTRACT

In this single-blind, crossover study, the difference between a brushless tooth cleaner and a soft toothbrush was studied to compare plaque removal efficiency. The sample was composed of 15 human subjects who were categorized into two groups. Group 1 was composed of subjects randomly assigned to the brushless tooth cleaner for the first two weeks. Group 2 was composed of those randomly assigned to begin the study using the soft toothbrush. After two weeks of brushing with their assigned device, subjects returned to their normal modality to brush their teeth for one week. For the last two weeks of the study, subjects were told to brush with the opposite device they were originally assigned to at the beginning of the trial.

Investigators recorded the subjects' gingival indices (based on probe depths) and Quigley scores (based on plaque indices using disclosing solution) at the beginning of week one, the end of week two, the end of week three and the end of week five. The main outcomes in this study were the Silness Loe Index (SLI) and the Quigley Hein Index (QHI). The SLI was assessed on the buccal, lingual, mesial and distal surfaces of six teeth, for a total of 24 surfaces. The QHI was assessed on the buccal and lingual surfaces of six teeth, for a total of 12 surfaces. Each index was measured at each visit by the sum total score divided by the total number of surfaces. The data were analyzed separately using a mixed-effects repeated measures analysis of variance (RMANOVA) for crossover designs. Results indicate that, according to the SLI, there is no significant difference between the two treatments after the first or second weeks. However, based on the QHI, statistically significant differences existed between the two treatments after week one and two. After week one, the soft toothbrush use had a higher QHI than the brushless tooth cleaner. After week two, the brushless tooth cleaner had a higher QHI than the soft toothbrush.

Toothbrushes have been the gold standard for cleaning plaque from teeth for generations. They have ranged in texture from hard to soft and natural to synthetic materials. A recent study by David Pashley, et al., the Medical College of Georgia School of Dentistry, Augusta, GA, entitled "Consensus-Based Recommendations for the Diagnosis and Management of Dentin Hypersensitivity,"

The ultra-soft cleaner that is the subject of the study described here was invented by Jack Gruber, D.D.S., a periodontist affiliated with North Shore University Hospital and New York University College of Dentistry.

introduced the term "toothbrush disease." The term means gingival recession and wear of the root surface caused by overuse of toothbrushes and toothpaste, which contribute to hypersensitivity of the teeth to touch and temperature change.

The PeriClean was designed to eliminate the deleterious effects of the standard toothbrush while being as effective as the toothbrush in removing plaque buildup. The bristles on a toothbrush can cause gum recession and sensitivity, hence the move from hard bristles to soft bristles over recent years. As of this date there are no studies we know of that compare a brushless cleaner (the PeriClean) to a soft toothbrush for effectiveness in removing plaque from teeth.

The aim of this study was to observe whether a brushless cleaning device can be equally as effective at removing plaque from teeth as a soft toothbrush. The aim was to give people an alternative to bristle brush cleaning if they find they are brushing too hard. The hypothesis was that it is possible to maintain healthy teeth and gingiva by using brushless methods in conjunction with flossing.

Materials

The toothbrush being used was a standard soft-bristled toothbrush that is FDA approved. The PeriClean is made of all materials that are FDA approved as well. The handle will be made from polypropylene.

Polypropylene (PP) Total 3824WZ is a versatile thermoplastic used in a variety of applications, among them, food packaging, textiles, laboratory equipment and automotive components. Its particulars are as follows:

- Antibacterial properties.
- FDA approved.
- Made in USA.
- Recyclable.
- Excellent flexibility to assist in minimizing force applied to teeth and gums.
- Suitable tensile and tear strength to avoid product deterioration.
- High elongation before breaking but reasonable stiffness.
- Low taste and odor concerns.
- Low density light weight compared to other materials.
- Weight: 24 grams.

The pad

The pad is made of soft thermoplastic rubber. It is GLS CL2000X. Generally, thermoplastic rubbers are considered a high-tech, space-age material. It possesses the following properties:

- FDA approved.
- Made in USA.
- Recyclable.
- Crosslink bond in its structure contributes to high elastic properties and soft and rubbery "feel."
- Its softness assists in minimizing force applied to teeth and gums.
- Its softness also conveys being non-destructive to teeth and gums.
- Excellent tear strength (relative to this application).
- Good wear resistance (relative to this application).
- Low taste and odor concerns.
- Weight: 3 grams.

Cement

The adhesive is Loctite 4011. It is very strong, water resistant and FDA approved.

Methods

The Quigley Hein Index (QHI) and the Silness Loe Index (SLI) were obtained at each study visit. For the Quigley scores a disclosing solution was used, which colored the plaque. This disclosing solution is in general use in dentistry to highlight plaque. It is made from vegetable dyes and is not a permanent coloring agent. The Silness gingival uses periodontal probing gently between the gum and tooth and is also in general use by hygienists and dentists. Subjects selected needed to be 18 years of age or older and have healthy gingiva. Those with braces on their teeth were excluded. Also excluded were people who are decisionally impaired and need authorized representatives to sign consent forms.

Recruitment was done via direct contact from our patient population. If a subject was found to be eligible to participate, she or he was approached by someone from the research team during a scheduled visit. Patients were screened at 400 Community Drive, Manhasset NY 11030. A total of 15 subjects were recruited for this study.

No forms of advertising were used. If in the future advertisements are to be used, approval will be obtained from the Institutional Review Board (IRB) prior to use. The recruitment methods used provided equitable selection of subjects.

Informed consent was obtained by study personnel approved by the IRB. The consent form conformed to 45 CFR 46.116, 21 CFR 50.20, and institutional requirements. The informed consent process was a comprehensive discussion between the study doctor and a prospective subject about the nature of the research study, risks and benefits, alternatives to research and rights of a study subject.

All potential research participants were provided with the information in the IRB-approved consent form both verbally and in a copy of the consent form. They were given ample time to think about whether they wished to participate, and had the opportunity to ask questions. If the potential subject needed more time, she or he was given the form to take home and was advised to think about participating and to discuss it with family and friends. If

consent was obtained on the same day that research procedures were initiated, the investigator documented in the research record the date that consent was obtained and that it occurred prior to initiation of the research procedures.

The study investigator then ensured, to the best of his or her ability, that prospective subjects understood why the research was being done and why they were being asked to participate. The study investigator documented the process in the subject's medical record and/or research record. A subject's autonomy was respected at all times; and the consent process was free of all elements of coercion.

Obtaining initial informed consent was documented by the use of a written consent form approved by the IRB and signed and dated by the subject, a witness and the study doctor. One copy of the signed consent form was given to the subject and a second copy was placed in the subject's medical chart (if appropriate). The original signed consent form was retained with the principal investigator's research records.

After consent was obtained, subjects were randomly assigned by a 1:1 ratio to the toothbrush or PeriClean (brushless tooth cleaner). During the first visit, the subject's teeth were washed with a disclosing solution. Investigators also did periodontal probing gently between the gum and tooth to look at the gingival index. Subjects brushed their teeth for two weeks (at home) with the PeriClean or toothbrush, depending on which one they were randomized to. After two weeks, subjects came for a second study visit. At this visit, the following occurred: 1. teeth were washed with a disclosing solution; and 2. periodontal probing was done.

After their week two visit, subjects were advised to return to the normal modality they used to brush their teeth. They did this for one week. At week three, subjects came back into the office; their teeth were again washed with a disclosing solution. Investigators also did periodontal probing gently between the gum and tooth to look at the gingival index again. This was used as the baseline measure for the crossover period. After this wash-out period, subjects crossed over to the other toothbrushing method. If subjects were originally randomized to the PeriClean, they then used a toothbrush for the last two weeks of the study (weeks three through five). If subjects were originally randomized to a toothbrush, they switched over to the PeriClean for the last two weeks of the study (weeks three through five).

Two weeks later (five weeks from the beginning of the study), subjects returned for the final study visit. At this visit, all of the previous exams were done.

Statistical Methods

The Biostatistics Unit developed a randomization procedure using a permuted block design. The randomization assignment was opened and provided the subject with the assigned PeriClean or toothbrush, to be used at home. All patients involved in this crossover trial were randomly allocated, in a 1:1 ratio, to two sequences:

1. PeriClean followed by soft toothbrush; or
2. soft toothbrush followed by PeriClean.

Descriptive statistics (means ± standard deviation [SD] and frequency [%]) were calculated for baseline patient characteristics (i.e., age and sex).

The primary outcomes variables in this study were the SLI and the QHI. The SLI was assessed on the buccal, lingual, mesial and distal surfaces of six teeth (3, 7, 12, 14, 23, 28), for a total of 24 surfaces. The QHI was assessed on the buccal and lingual surfaces of six teeth, for a total of 12 surfaces. Each index was measured at each visit by the sum total score / total # of surfaces. All measurements were recorded by a single, experienced examiner.

SLI and QHI data were analyzed separately using a mixed-effects, repeated measures analysis of variance (RMANOVA) for crossover designs, with treatment (PeriClean or soft toothbrush) and period (one or two) as factors in the model. A carryover effect was excluded in the model, as it was assumed that any carryover effects were minimized with the washout period between switching modalities.

A result was considered statistically significant at the $p<0.05$ level of significance. All analyses were performed using SAS version 9.3 *(SAS Institute Inc., Cary, NC)*.

Methodology

The Gingival Index (GI) was developed by Loe and Silness to describe the clinical severity of gingival inflammation, as well as its location.

Teeth examined:

1. Maxillary right first molar
2. Maxillary right lateral incisor
3. Maxillary left first bicuspid
4. Mandibular left first molar
5. Mandibular left lateral incisor
6. Mandibular right first bicuspid

Appearance	Bleeding	Inflammation	Points
normal	no bleeding	none	0
slight change in color and mild edema with slight change in texture	no bleeding	mild	1
redness, hypertrophy, edema and glazing	bleeding on probing/ pressure	moderate	2
marked redness, hypertrophy, edema, ulceration	spontaneous bleeding	severe	3

Surfaces examined on each tooth:

1. Buccal
2. Lingual
3. Mesial
4. Distal

- Gingival Index for a specific tooth = AVERAGE (points for the four surfaces).
- Gingival Index for type of tooth (first molar, first bicuspid, lateral incisor) = AVERAGE (Gingival Indices for the two teeth).
- Gingival index for patient = AVERAGE (Gingival Indices for all six teeth).

Average Gingival Index	Interpretation
2.1 - 3.0	severe inflammation
1.1 - 2.0	moderate inflammation
0.1 - 1.0	mild inflammation
< 0.1	no inflammation

For the Quigley scores, a disclosing solution was used, which colored the plaque. This disclosing solution is in general use in dentistry to highlight plaque. It is made from vegetable dyes and is not a permanent coloring agent.

The Silness Gingival Index uses a periodontal probe gently between the tooth and gum and is also in general use by hygienists and dentists. It is not invasive to the tissues of the gums and teeth.

Results

The average age of the 15 subjects in this study was 34.7 ± 8.1. There were 11 females (73.3%) and 4 males (26.7%).

SLI

The estimated "treatment" difference between PeriClean and soft toothbrush mean SLI was -0.121 [95% confidence interval:-0.219, -0.0235]. This treatment effect was significant ($p<0.0189$). However, the period effect was not statistically significant ($p<0.1504$), implying that it does not seem to matter whether the patients used the soft toothbrush or the PeriClean in the first period or the second period.

QHI

The estimated "treatment" difference between PeriClean and soft toothbrush mean QHI was 0.166 [95% confidence interval: 0.069, 0.262]. This treatment effect was significant ($p<0.0026$). The period effect was also statistically significant ($p<0.0001$), implying that it does matter whether the patients used the soft toothbrush or the PeriClean in the first period or the second period.

The table below contains a breakdown of the SLI mean ± SD and QHI mean ± SD for each treatment at the end of each period.

Period	Treatment	N	SLI	QHI
1	PeriClean	7	0.05 ± 0.09	0.58 ± 0.32
	Toothbrush	8	0.19 ± 0.17	0.91 ± 0.48
2	PeriClean	8	0.14 ± 0.13	0.83 ± 0.53
	Toothbrush	7	0.24 ± 0.16	0.18 ± 0.18

Discussion

This comparison of the soft toothbrush versus the brushless cleaner is significant to the oral health field because it showed us that both are equally effective in their ability to remove plaque from teeth. The statistics suggest that while it does not matter which device was used when, the brushless cleaner can stand up to the conventional soft toothbrush in plaque removal. Because this device is still in the beginning stages, there are gaps in the literature. However, the brushless cleaner appears to be gentler on the gingiva and may show promise in the future for preventing gingival recession.

As with many other research endeavors, this study had limitations. While a larger sample size would have been more desirable, only 15 subjects were used in conducting this research. Using subjects from a larger age range may also provide more comprehensive results. And while gender did not prove to be a factor, 73.3% of the subjects were female, which may have given skewed results.

Future research in this topic could be invaluable for the field of oral health. In order to get a better understanding of the brushless cleaner, more studies should be done without the pre-existing limitations. A much larger sample size that incorporates a more even distribution of males to females, as well as a much more varied age range should be used. Other relevant studies that could be done in the future should determine the effects of the brushless cleaner on the regrowth of gingiva.

Queries about this article can be sent to Dr. Gearity at dr.gearity@gmail.com.

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