

Research

Role of Manual Dexterity on Mechanical and Chemotherapeutic Oral Hygiene Regimens

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Abstract

Purpose: Effective use of mechanical plaque control devices can depend on individual manual dexterity levels. The purpose of this component of a 12-week, virtually-supervised clinical trial was to investigate the role of manual dexterity on clinical outcomes for gingivitis, as measured by the relationship between manual dexterity scores on the Purdue Pegboard Test (PPT) and the effects of various mechanical and chemotherapeutic oral hygiene regimens.

Methods: This was a single-center, examiner blinded, randomized, four-treatment arm, parallel group, 12-week plaque and gingivitis study. At baseline, healthy adult volunteers with evidence of gingivitis were assessed for manual dexterity and were then examined for plaque, gingivitis and bleeding. After a dental prophylaxis, participants were randomized into four treatment groups: brush only (BO); brush/rinse (BR); brush/floss (BF); and brush/floss/rinse (BFR). The flossing groups received instruction in flossing. The PPT was used to assess manual dexterity and was performed by a licensed occupational therapist. Virtual supervision was required once each weekday and the oral hygiene regimen was unsupervised on evenings and weekends.

Results: Of the 213 subjects enrolled, 209 completed the trial. Improvements from baseline to week 12 in interproximal percent nonbleeding healthy sites (Expanded Bleeding Index (EBI)=0 and Modified Gingival Index (MGI)=0 or 1) were dependent on the participant's dexterity score. Participants with the lowest dexterity scores (9 or lower) in the BFR treatment group demonstrated the greatest improvement interproximally based on the indices (EBI and MGI). In comparison, the BF test group subjects with dexterity scores 9 or lower had limited change in improvement interproximally. There was a direct correlation between flossing effectiveness and dexterity scores.

Conclusions: Less manual dexterity can limit dental flossing effectiveness. Flossing is a difficult daily task that requires functional bilateral dexterity to be performed correctly. Individuals with lower levels of manual dexterity were shown to benefit from the addition of an essential oil mouthrinse to a regimen of toothbrushing and flossing in this clinical trial. The addition of an essential oil mouthrinse improved interproximal gingival health and mitigated the manual dexterity variable.

Keywords: manual dexterity, Purdue Pegboard Test, plaque control, flossing, toothbrushing, mouthrinses, essential oils

This manuscript supports the NDHRA priority area, **Client level: oral health care** (new therapies and prevention modalities).

Submitted for publication: 2/28/2022; accepted: 5/13/2022

Introduction

Oral disease is a global health challenge with significant health and economic burdens on populations across the lifespan.¹ Dental caries and periodontal disease are among the most prevalent and consequential diseases of the oral cavity worldwide.^{1,2} Dental biofilm (plaque) is a complex community of microbial cells embedded in an extracellular

matrix that attaches to the tooth surface. Changes in the structure of the microbial communities within biofilm (plaque) serve as a primary etiologic factor for dental caries and periodontal diseases.³ Means of plaque control include the use of mechanical and chemotherapeutic methods. Chemotherapeutic agents include toothpastes and

mouthrinses with active ingredients indicated for the control, reduction, or prevention of plaque and gingivitis. The wealth of evidence available in systematic reviews, meta-analyses, along with two recent clinical trials, reinforce the clinical relevance of adding an essential oil mouthrinse to the oral care regimen to control plaque and gingivitis.⁴⁻¹⁴ The daily removal and disruption of this biofilm has also traditionally included mechanical methods such as toothbrushing and flossing. Unfortunately, many individuals lack sufficient manual dexterity to perform proper oral hygiene methods such as daily flossing between their teeth.^{15,16}

There has been limited research exploring the relationship between dexterity and oral hygiene efficacy with mechanical devices. Niederman and Sullivan developed and validated the Oral Hygiene Skill Achievement Index (S.A.I) as a method for evaluating an oral hygiene skill. The S.A.I. evaluates a person's ability to position and manipulate an oral device (toothbrush, dental floss) and provides a format for oral hygiene instruction.¹⁷ Doherty et al. developed the Oral Hygiene Performance Test (OHPT) as a screening instrument to measure oral hygiene skills in the elderly and disabled.¹⁸

In a recent study on the clinical relevance of dexterity in oral hygiene, Barouch et al. evaluated 80 subjects ranging in age from 18 to 60 on their ability to use chopsticks to transfer 50 peas in water from one box to another within a period of one minute.¹⁹ The participants then had their plaque index score recorded before and after receiving oral hygiene instructions. Comparisons were made based on age, sex, dominant hand and the results of the chopstick dexterity test. Based on their findings, Barouch et al. concluded that dexterity might be a good predictor of improved oral hygiene and should be included as an assessment for customized education.¹⁹

The Purdue Pegboard Test (PPT) was first developed in 1948 and has been used for different ages across the lifespan in a variety of settings. The PPT takes 15 minutes to administer and involves completing a series of four subsets consisting of placing small pins into holes on a pegboard and assembling pins with collars and washers. First standardized on adult employees requiring fine and gross motor dexterity in the workplace, normative data has been collected from the PPT for children and adolescents from 5 to 19 years of age, as well.^{20,21} Additionally, the PPT has been shown to be a reliable measure of hand dexterity in individuals with multiple sclerosis, Parkinson's disease and intellectual disabilities.²²⁻²⁴ The PPT has also been used to establish validity for other hand dexterity assessments, such as the

Jebsen Hand Function Test in adults with schizophrenia and the Functional Dexterity Test for traumatic hand injury.^{25,26} The PPT was used in a study by Kenney et al. on the relationship of manual dexterity to performance of oral hygiene among university students.²⁷

The PPT is a validated instrument and considered the gold standard for measuring hand dexterity when correlated with new and existing measures in populations with and without hand function impairments.^{18,19,28-34} The PPT is also an assessment instrument because it provides separate dexterity scores for both preferred (dominant) and nonpreferred hands. Moreover, the PPT also measures small finger movements to assemble pins and washers requiring the use of both hands working together. Given its ease of use and brief administration time, the PPT was selected to further analyze manual dexterity and dental flossing skills. The purpose of this component of a 12-week, virtually-supervised clinical trial, was to investigate the role of manual dexterity on clinical outcomes for gingivitis, as measured by the relationship between manual dexterity scores on the Purdue Pegboard Test (PPT) and the effects of various mechanical and chemotherapeutic oral hygiene regimens.

Methods

This component of a randomized, controlled clinical trial was conducted from October 2020 to February 2021 at Salus Research, Inc. (Fort Wayne, IN, USA), an American Dental Association (ADA) qualified research site.³⁵ The principles of the International Council on Harmonisation Guidance for Good Clinical Practice (ICH E6 (R2)) were applied to this study. The study protocol was approved by the Institutional Ethics Committee on research involving humans (IntegReview Institutional Review Board, Austin, TX, USA) and was registered on clinicaltrials.gov (NCT04750005). Written informed consent was obtained from all subjects in accordance with the Declaration of Helsinki. Screening and baseline assessments were conducted at the same visit.

Sample

Participants were from the Fort Wayne, Indiana area and were selected for screening from the clinical test site's database. Due to COVID-19 risk at the time of the study, the age range of the sample was limited to males and females between the ages of 18 to 60 years. Participants needed to meet the following inclusion criteria: good general and oral health, no known allergies to commercial dental products, a minimum of 20 teeth with scorable facial and lingual surfaces, evidence of some gingivitis (although no minimum

score on the Modified Gingival Index (MGI) was required), absence of advanced periodontitis, and a minimum of 10 percent bleeding sites based on the Expanded Bleeding Index (EBI).^{36,37} Participants were eligible for the study if they had no sites with >5 mm probing depth, a maximum of three sites at 5 mm probing depth, and needed to be available to attend daily virtual smart-phone video sessions on weekdays for study procedures. Other inclusion criteria included absence of fixed or removable orthodontic appliance or removable partial dentures, significant oral soft tissue pathology excluding plaque-induced gingivitis, at the discretion of the principal investigator/dental examiner (PI). Participants were excluded for a variety of reasons including: dental prophylaxis within four weeks prior to baseline, requiring antibiotics prior to dental treatment, use of antibiotics, anti-inflammatory or anticoagulant therapy during the study or within one month prior to baseline, use of chemotherapeutic oral care products within the last two weeks, pregnancy or lactating, use of smokeless tobacco, vaping or e-cigarettes or suspected substance abuse, any medical or psychiatric condition that would make the participant inappropriate for the study in the judgment of the PI.

The randomization was generated using a validated program created by the Biostatistics Department at Johnson & Johnson Consumer Inc. (JJCI, Skillman, NJ, USA). Participants were assigned in equal allocation to each treatment using a block randomization with block size of four. Each participant was assigned a unique randomization number that determined treatment assignment. The PI and examiners were blinded to the treatment regimens of the subject groups. The personnel dispensing the test products or supervising their use did not participate in the examination of subjects to minimize potential bias. Other staff members, including the PI and examiners, did not have access to the area where the product was being used. Eligible subjects with evidence of gingivitis were randomized into four equal treatment groups: brush only (BO); brush/rinse (BR); brush/floss (BF); and brush/floss/rinse (BFR).

Assessments

The PPT was administered to all randomized subjects participating in a plaque and gingivitis clinical trial prior to baseline clinical examinations.¹⁴ The test was administered by a licensed occupational therapist to determine a manual dexterity score at the time of the baseline examination visit. The PPT uses a pegboard consisting of multiple holes arranged in rows. The first part of the assessment requires the subject to place as many pins as possible into the holes

using each hand separately followed by both hands together. Participants were allowed 30 seconds for each task. The last assessment requires the subject to assemble a pin, washer, collar, and additional washer and place the assembly into the holes over a 60 second period. Dexterity scores were determined by combinations of the various executions.²⁰ As the variable being examined for dexterity (dental flossing) requires the use of both hands simultaneously, pin placement using both hands was chosen as the score for analysis. Higher numerical scores on the PPT correlate with greater dexterity.

The intraoral assessments included oral hard and soft tissue safety assessment, MGI, six-site EBI, six-site probing depth, six-site bleeding on probing, six-site Turesky modification of the Quigley-Hein Plaque Index (TPI), and Proximal Marginal Plaque Index (PMI).³⁶⁻⁴¹ Each clinical assessment was performed consistently throughout the study by the same trained and calibrated clinical examiner. This calibration included an intra-examiner repeatability exercise performed yearly according to the site's standard operating procedures for the specific assessment.

Interventions

All subjects received a manual toothbrush (ADA soft, flat-trim reference toothbrush, sourced through the ADA). Subjects received toothpaste, dental floss and a mouthrinse containing a fixed combination of four essential oils (4EO) according to their assigned regimen. Instructions on product use were provided at screening/baseline; participants assigned to the flossing group received specific instructions on flossing technique and demonstrated competency. No specific toothbrushing instructions were provided except to brush for one timed minute. Similarly, participants assigned to the rinse group were instructed to rinse with 20 mL of mouthrinse for a timed 30 seconds.

Statistical analyses

A sample size of 200 completed subjects (50 per treatment group) was estimated to provide sufficient power to detect differences between BR and BF and between BFR and BF.¹⁴

The dexterity component of the clinical trial focused on the relationship between the PPT scores and the improvements from baseline to week 12 in interproximal percent nonbleeding healthy sites.¹⁴ The impact of dexterity on treatment effects was assessed using a linear model that fits regression lines with change from baseline to week 12 as the response variable, and dexterity as an explanatory variable. This model allowed for different intercepts and different slopes for the four treatment groups. Specifically,

the following linear model was applied: $y_{ij} = \mu + \mu_i + (\beta + \beta_i)x_{ij} + \varepsilon_{ij}$, where y_{ij} = change from baseline to week 12 in efficacy variable (week 12 minus baseline) for treatment i and subject j ; x_{ij} = both hands dexterity score for treatment i and subject j ; $\mu + \mu_i$ = intercept for treatment i ; $\beta + \beta_i$ = slope for treatment i ; and ε_{ij} = random error for treatment i and subject j , independently distributed as normal with mean 0 and variance σ^2 .

Treatment by dexterity interaction was assessed by testing the null hypothesis $H_0: \beta_i=0$ for all i , vs. the alternative hypothesis $H_1: \beta_i \neq 0$ for some i . H_0 describes a scenario where intercepts could be different among treatments, but the regression lines are parallel. In other words, the various treatments could have different effects on the outcome measure, but the differences among treatment effects are not dependent on dexterity of the subjects using those products. Rejection of H_0 , based on the appropriate F test, demonstrates that differences in treatment effects are dependent on dexterity. Each statistical test was performed at the 5% significance level, two-sided.

Percent nonbleeding healthy sites were calculated by taking the total number of sites with EBI=0 and MGI=0 or 1, divided by the total number of sites assessed for each subject. No imputation of missing data was performed. All other details about the statistical analysis of the clinical trial are reported separately.¹⁴ Data from all subjects at baseline and week 12 (i.e., completed subjects) were included in this analysis. SAS version 9.4 (SAS Institute, Cary, NC, USA) was used for statistical analyses.

Results

Demographics

Of the 213 randomized participants, 209 completed the study; 2 withdrew their consent and 2 were lost to follow-up (Figure 1). Participants had a mean age of 42.0 (SD 10.57) years (ranging from 18 to 59 years); means ages by group were similar (Table I). The majority of subjects were female (77.5%, n=41), Caucasian (81.7%, n=174), and non-smokers (98.6%, n=210). A summary of baseline characteristics (age, sex, PPT dexterity scores, MGI, and EBI) is shown in Table I. Most subjects (91.5%, n=195) reported right hand

Figure 1. Participant distribution (n=213)

| | Study Groups | | | | Totals |
|--------------------------------------|-----------------|------------------|------------------|-------------------------|------------|
| | Brush Only (BO) | Brush/Rinse (BR) | Brush/Floss (BF) | Bursh/Floss/Rinse (BRF) | |
| | n (%) | n (%) | n (%) | n (%) | n (%) |
| Randomized | 53 | 53 | 53 | 54 | 213 |
| Completed | 50 (94.3) | 53 (100.0) | 53 (100.0) | 53 (98.1) | 209 (98.1) |
| Discontinued | 3 (5.7) | 0 | 0 | 1 (1.9) | 4 (1.9) |
| Reason for discontinuation | | | | | |
| • Withdrawal by subject ^a | 1 (1.9) | 0 | 0 | 1 (1.9) | 2 (<1.0) |
| • Lost to follow-up | 2 (3.8) | 0 | 0 | 0 | 2 (<1.0) |

a: One withdrawal due to scheduling conflict, one withdrawal due to COVID-19.

Table I. Sample demographics at baseline (n= 213)

| Group | Brush only (n=53) | Brush/rinse (n=53) | Brush/floss (n=53) | Brush/floss/rinse (n=54) | Total (n=213) |
|--|----------------------|-----------------------|-----------------------|-----------------------------|------------------|
| Mean age, years (SD) | 42.2 (9.77) | 43.8 (9.84) | 41.4 (10.03) | 40.8 (12.43) | 42.0 (10.57) |
| Sex, n (%) | | | | | |
| Male | 12 (22.6) | 12 (22.6) | 11 (20.8) | 13 (24.1) | 48 (22.5) |
| Female | 41 (77.4) | 41 (77.4) | 42 (79.2) | 41 (75.9) | 165 (77.5) |
| Mean baseline of interproximal % EBI=0 and MGI=0 or 1 (SD) | 3.91 (6.757) | 3.28 (7.670) | 2.31 (4.843) | 1.71 (3.498) | 2.80 (5.931) |
| PPT dexterity scores – Mean (%) | | | | | |
| Declared dominant hand – Right | 47 (88.7) | 48 (90.6) | 48 (90.6) | 52 (96.3) | 195 (91.5) |
| Declared dominant hand – Left | 6 (11.3) | 5 (9.4) | 5 (9.4) | 2 (3.7) | 18 (8.5) |
| Mean right hand score (SD) | 13.7 (2.02) | 14.1 (2.05) | 14.0 (1.76) | 13.1 (2.52) | 13.7 (2.13) |
| Mean left hand score (SD) | 13.3 (1.80) | 13.2 (2.14) | 13.7 (2.14) | 12.8 (2.07) | 13.3 (2.05) |
| Mean both hand score (SD) | 11.2 (1.82) | 10.9 (1.77) | 11.4 (2.05) | 10.7 (2.03) | 11.0 (1.93) |
| Mean right + left + both (SD) | 38.2 (4.88) | 38.1 (5.17) | 39.1 (5.24) | 36.6 (6.04) | 38.0 (5.39) |
| Mean assembly score (SD) | 34.8 (6.80) | 35.1 (7.23) | 33.4 (9.37) | 33.9 (8.54) | 34.3 (8.02) |

dominance; while only 8.5% (n=18) reported left hand dominance. There were no significant differences among treatment groups for any of the demographic data.

Efficacy and dexterity

At the conclusion of 12 weeks, statistically significant treatment regimen-by-dexterity score interaction was observed for percent nonbleeding healthy sites (EBI=0 and MGI=0 or 1) ($p=0.005$). This p -value reflects differences in comparisons between treatment groups among dexterity scores. Regression line estimates for change from baseline showed greater than 60% increase from baseline (greater than 60% improvement) in the BFR treatment group in test subjects with both hands dexterity scores 9 or lower and 45-50% improvement for subjects with both hands dexterity scores 12 or higher (Figure 2). In comparison, the BF test group had slight worsening to 5% improvement from baseline to 12 weeks for interproximal percent nonbleeding healthy sites in subjects with both hands dexterity scores 9 or lower. However, the subjects in the BF treatment group with dexterity scores 12 or higher had 10-20% increase in interproximal percent nonbleeding healthy sites (EBI=0 and MGI=0 or 1).

Figures 3–6 show changes from baseline for interproximal percent nonbleeding healthy sites (EBI=0 and MGI=0 or 1) for the four treatment groups versus PPT

scores for interproximal soft tissue of individual regions of the mouth (posterior, anterior, maxillary and mandibular regions). In all regions of the mouth, the same relationships between percent nonbleeding healthy sites and dexterity were observed.

Discussion

The purpose of this component of a 12-week, virtually-supervised clinical trial was to investigate the role of manual dexterity on clinical outcomes for gingivitis, as measured by the relationship between manual dexterity scores on the Purdue Pegboard Test (PPT) and the effects of various mechanical and chemotherapeutic oral hygiene regimens. Findings from this study demonstrated significant evidence of the correlation between dexterity scores and the effectiveness of various oral hygiene regimens in reducing gingival inflammation.

Dexterity is defined as a neuromotor function that combines sensation and hand strength to produce fine, voluntary movements that can be used to manipulate small objects during a specific task.²⁸ Manual dexterity allows an individual to manipulate objects with the hand, and fine dexterity is the intricate, in-hand or digit manipulation of everyday objects. This study compared the use of various daily oral hygiene regimens to dexterity test scores. The

Figure 2. Change from baseline in the interproximal percent of nonbleeding healthy sites (%) (EBI=0 and MGI=0 or 1) versus dexterity scores by group

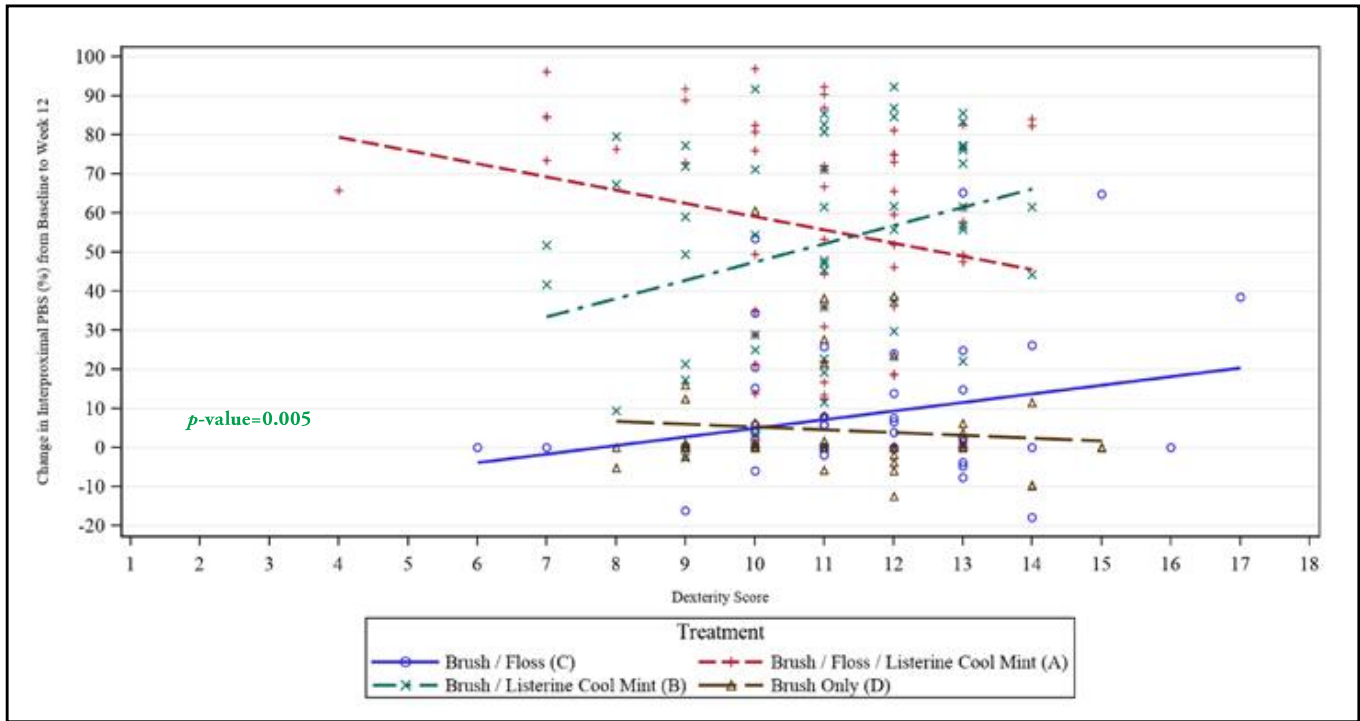


Figure 3. Change from baseline for posterior interproximal percent nonbleeding healthy sites (%) with EBI=0 and MGI=0 or 1 vs. dexterity score

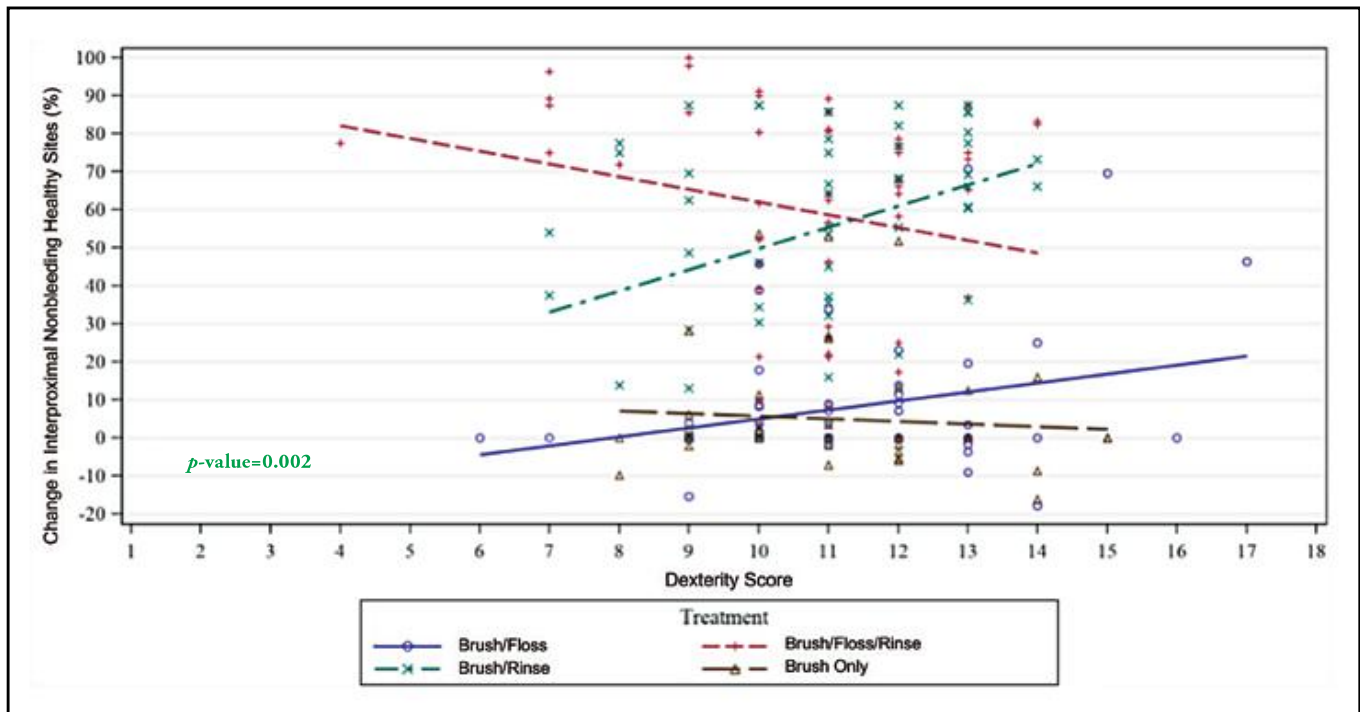


Figure 4. Change from baseline for anterior interproximal percent nonbleeding healthy sites (%) with EBI=0 and MGI=0 or 1 vs. dexterity score

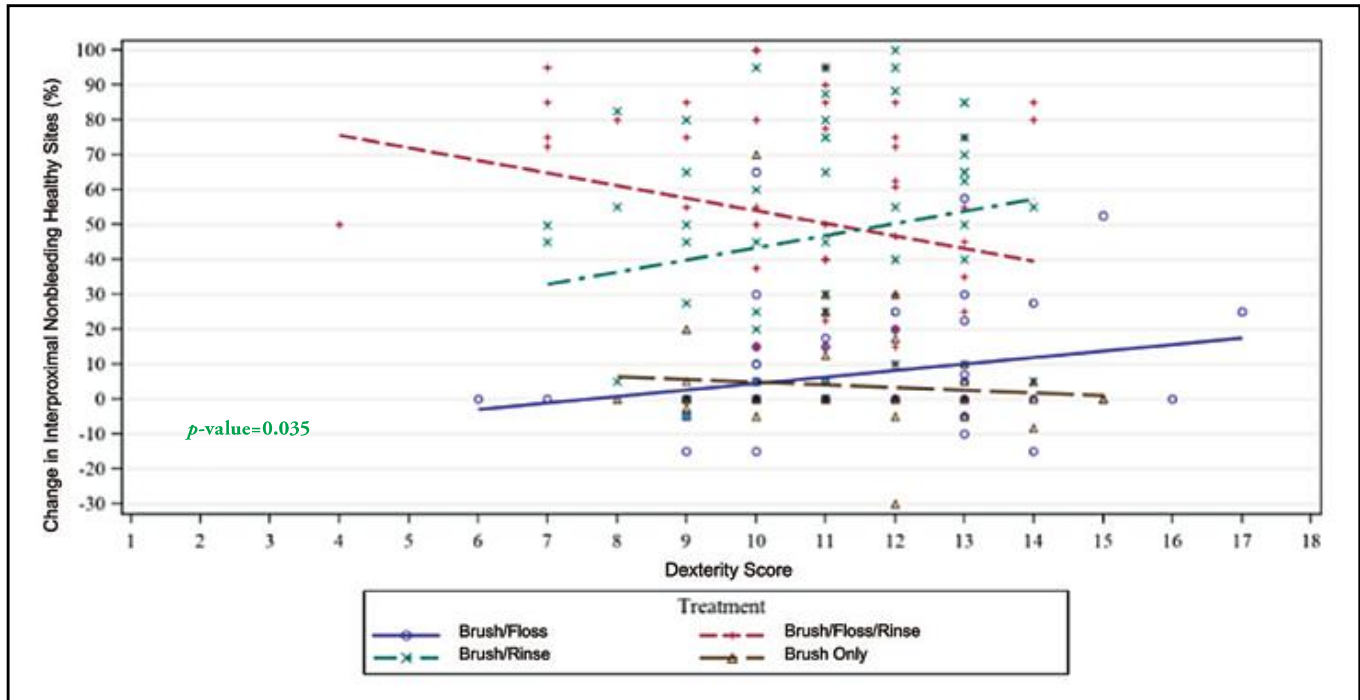


Figure 5. Change from baseline for maxillary interproximal percent nonbleeding healthy sites (%) with EBI=0 and MGI=0 or 1 vs. dexterity score

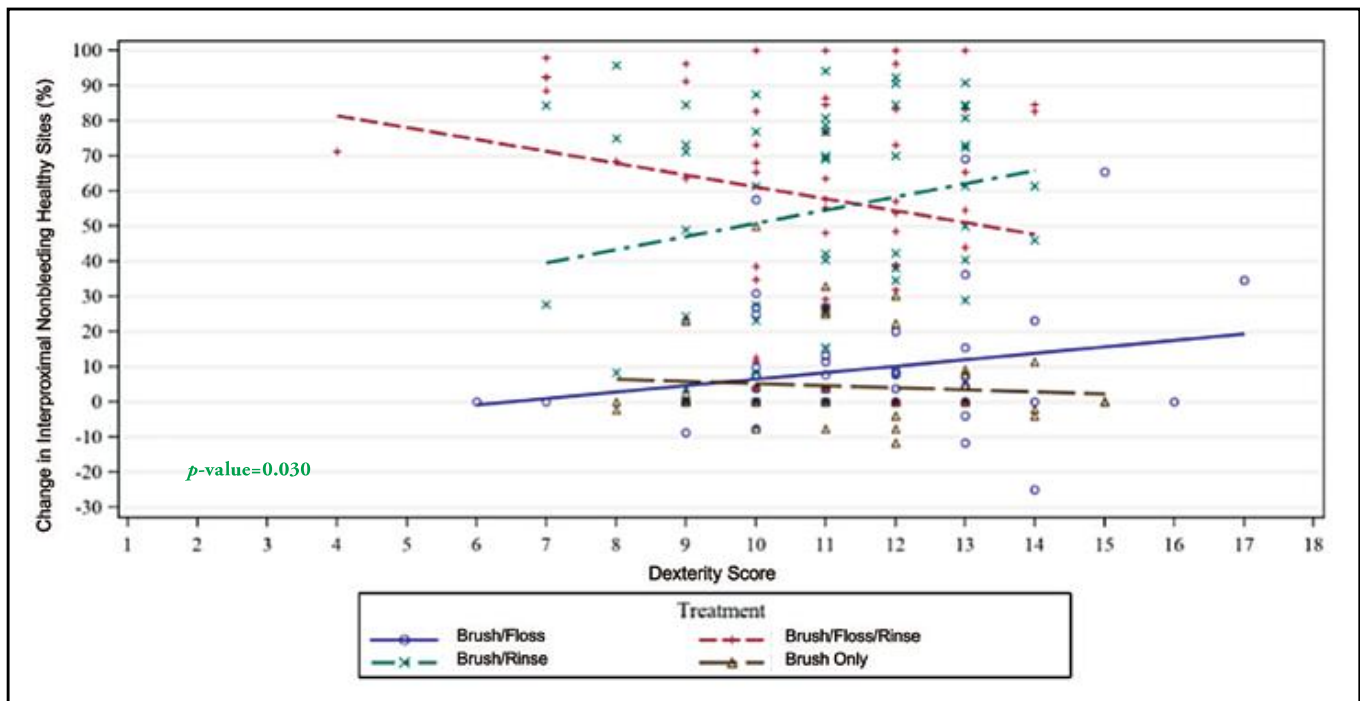
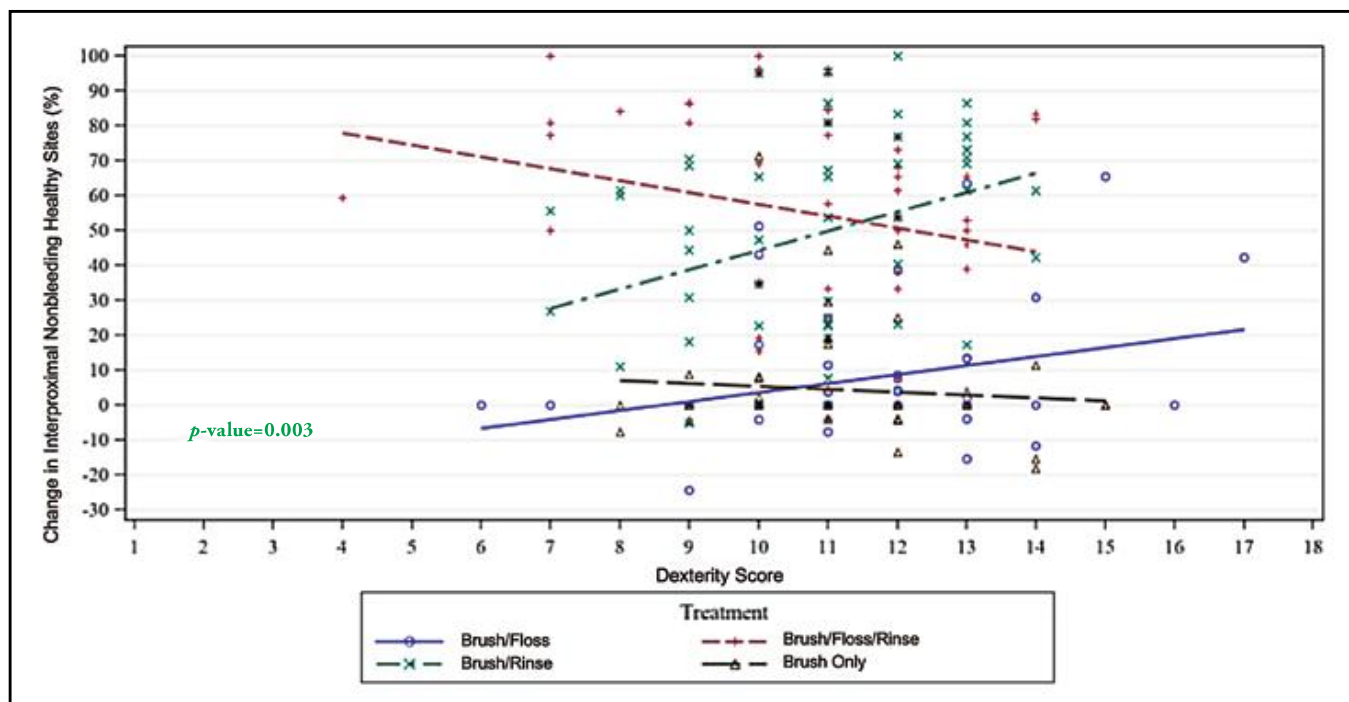


Figure 6. Change from baseline for mandibular interproximal percent nonbleeding healthy sites (%) with EBI=0 and MGI=0 or 1 vs. dexterity score



correct use of dental floss requires functional bilateral dexterity. Consider the process of extracting floss from the dispenser which requires unilateral or bilateral gross motor movement of the shoulder, elbow, forearm, wrist, and digits to obtain the product from the container. The actual flossing phase requires fine dexterity coupled with manual dexterity of the bilateral upper extremities. To be successful with this mechanical regimen, an individual must possess a certain level of bilateral gross and fine motor dexterity. Approximately 20% of participants had a both hand dexterity score ≤ 9 and approximately 22% had a both hand dexterity score ≥ 13 . In spite of being supervised daily, Monday through Friday, in this clinical trial participants in the BF group with lower dexterity scores had little or no improvement in interproximal gingivitis (EBI=0 and MGI=0 or 1). It was of interest that participants in the BFR group with lower dexterity scores demonstrated the most improvement in interproximal gingival health (>60% for participants having dexterity no higher than 9) after 12 weeks of supervised usage. The addition of a chemotherapeutic mouthrinse to a brushing/flossing regimen contributed to the improved gingival health in this group. Moreover, the participants with the highest dexterity scores in the BF group, even under supervision, demonstrated no greater than 20% improvement in their interproximal gingival health. In all regions of the mouth, the

same relationships between change in percent nonbleeding healthy sites and dexterity was observed. A mouthrinse is able to reach all areas of the mouth thus mitigating the effect that dexterity could potentially have as with dental flossing.

The BO group demonstrated little or no change during the 12-week treatment period irrespective of dexterity scores. These results were anticipated as this group was only instructed to brush for one minute using their normal toothbrushing technique. As the technique was not observed and the subjects were not instructed in a specific toothbrushing method, no changes were expected. Subjects with higher relative dexterity scores in the BR group demonstrated greater improvement in their interproximal gingival health. This result could have been due to the Hawthorne effect of being in a clinical trial. According to the findings in a systematic review by McCambridge et al., positive consequences for behaviors being investigated due to research participation have been found to exist in most studies.⁴²

Limitations

The study was conducted during the COVID-19 pandemic (October 2020 to February 2021) and restrictions may have influenced those who volunteered to participate (e.g. age, risk tolerance). The sample was restricted to people between the ages of 18 to 60 years who volunteered to be part of a

clinical study conducted at a single test site in the midwestern United States and may not be representative of the general population. Future research of interest would be to expand the age range and geographic area to be more representative of the population, to assess responses immediately following oral hygiene, and to assess plaque reduction immediately following oral hygiene, versus dexterity.

Conclusion

Findings from this component of a supervised clinical trial demonstrate that lower levels of manual dexterity, as measured by a validated assessment tool, can limit the effectiveness of dental flossing. The daily use of dental floss as a mechanical interdental cleaning device requires functional bilateral manual dexterity to perform correctly. The addition of a chemotherapeutic essential oil mouthrinse was shown to improve interproximal gingival health and mitigated the variable of manual dexterity.

Disclosures

This study was sponsored by Johnson & Johnson Consumer Inc. (JJCI; Skillman, NJ, USA), which was responsible for study design and the collection, analysis, and interpretation of data. Mary Lynn Bosma, James McGuire, Anusha Sunkara and Alicia DelSasso are employees of JJCI. Jeffery Milleman and Kimberly Milleman are principals at Salus Research, Inc., and conducted the study on behalf of Johnson & Johnson Consumer Inc. Tori York is an employee of Salus Research, Inc. Angela M. Cecil, PhD, MBA, OTR/L was a consultant to Salus Research, Inc. and contributed to the design, conduct and analysis of the Purdue Pegboard test portion of the study.

Acknowledgments

The authors would like to acknowledge Michael Lynch, DMD, PhD and Victoria Aleles of JJCI for critically reviewing the manuscript and Kathleen E. Boyle of 4 Learning Group, LLC. for managing final reviews and submission-related activities.

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