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CLINICAL EFFECTS OF DAILY ROTARY ELECTRIC TOOTHBRUSHING ON THE PRESENCE OF GINGIVITIS AND SUPRAGINGIVAL DENTAL PLAQUE

by

B.S. December 1985, Old Dominion University A.S. May 1984, SUNY Farmingdale

A Thesis Submitted to the Faculty of Old Dominion University in Partial Fulfillment of the Requirements for the Degree of

MASTER OF SCIENCE
DENTAL HYGIENE

Old Dominion University MAY, 1987

Michele L. Darby (Director)

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ABSTRACT

CLINICAL EFFECTS OF DAILY ROTARY ELECTRIC TOOTHBRUSHING ON THE PRESENCE OF GINGIVITIS AND SUPRAGINGIVAL DENTAL PLAQUE

> Laura Jean Mueller Old Dominion University, 1987 Director: Michele L. Darby

The purpose of this investigation was to determine if statistically significant differences existed in the gingival health of subjects who brushed with a rotary electric toothbrush (Rota-dentR) when compared to a conventional toothbrush (Oral B- 35^R). A randomized, two group research design was employed using forty subjects. At baseline and at two week intervals for six weeks, gingivitis and supragingival dental plaque were measured by the Loe and Silness Gingival Index and the O'Leary Plaque Index, respectively. Multivariate analysis revealed that the Rota-dentR was superior to the conventional toothbrush in reducing dental plaque accumulation and equally effective at reducing gingival inflammation. area specific multivariate analysis was performed, superiority of the Rota-dent^R at reducing gingival inflammation in the anterior region was found. Results suggest that the Rota-dent^R is a safe and effective home care device when utilized properly.

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CHAPTER 1

Introduction

Prevention of disease and the promotion of health are the goals of many American health care consumers. In dentistry, it is acknowledged universally that periodontal diseases cannot be eliminated by mass medication with specific vaccines or chemotheraputic agents. 4

Periodontal disease prevention still remains mechanical, based on effective removal of the principle etiological factor, dental plaque.

Recently a commercially designed plaque removal instrument, the Rota-dent^R, has been developed. The Rota-dent^R is an electric toothbrush with a toothbrush head shaped similarly to the inter-space brush and with a mode of action resembling rotary instruments used in the professional oral prophylaxis.²¹ Presently, consumers may purchase this home care instrument only through dental offices for a package price of 48 dollars. Each Rota-dent^R instrument comes equiped with three interchangable brush heads. One head, designed for cleaning facial and lingual tooth surfaces, is formed like a cup with short bristles in the center. The second head is formed with longer and stiffer bristles and is designed

for interproximal cleansing. The third head is a general purpose brush, designed to cleanse tooth surfaces adjacent to the gingival margin. Before this device can be recognized as an acceptable plaque removal method, further study is required to determine its effectiveness in dental disease control. The purpose of this investigation was to determine the clinical effectiveness of the Rota-dent^R instrument as compared with a conventional toothbrush by evaluating its effect on the presence of gingivitis and supragingival dental plaque.

Statement of Problem

The intent of this investigation was to determine the clinical effectiveness of home plaque removal by a commercially available, rotary-type electric toothbrush (Rota-dent^R) on the presence of gingivitis and supragingival dental plaque, over a six week period. The specific questions addressed were:

- I. Is the Rota-dent^R electric toothbrush as effective as the conventional toothbrush in maintaining oral health as measured by the Löe and Silness Gingival Index?
- 2. Is the Rota-dent^R electric toothbrush as effective as the conventional toothbrush in reducing dental plaque scores as measured by the O'Leary Plaque Index?
 - 3. Is there an interaction between type of toothbrush

used (Rota-dent^R versus Conventional) and region of the mouth cleaned (Anterior versus Posterior) as measured by the Löe and Silness Gingival Index?

4. Is there an interaction between type of toothbrush used (Rota-dent^R versus Conventional) and region of the mouth cleaned (Anterior versus Posterior) as measured by the O'Leary Plaque Index?

Significance of the Study

Dental plaque consists of a dense, non-calcified, complex mass of bacteria known for its major role in the development of dental caries and inflammatory periodontal diseases. A position paper prepared for the American Association of Public Health Dentists by the Subcommittee on Preventive Periodontics stated that over 75 percent of adults between the ages of 18 - 79 are affected by periodontal disease. For this reason, the prevention, control and removal of dental plaque has a meaningful significance to the public and preventive professionals. This investigation examined the value of a rotary-type plaque removal instrument as a device designed to facilitate oral health maintenance.

The effective removal of dental plaque by the Rota-dent^R instrument is contingent upon its daily use. If regular usage of this rotary instrument is found to improve or maintain periodontal health, then this new

product might be recommended as a valuable self-help measure by the dental professional interested in oral health promotion. Oral health professionals need valid and reliable data on rotary instrument home care devices to make appropriate recommendations to their patients. In addition to being effective in dental disease control, dental hygienists and dentists expect home care products to be relatively easy to use, cost effective for the patient, demonstrate patient appeal and patient acceptance and meet the patient's needs for a reasonable period of time.

Since the mechanical removal of dental plaque is still the primary method of controlling dental disease, dental professionals are interested in new devices that improve mechanical control of dental plaque as part of the daily home care regimen.

Determining the effectiveness of the Rota-dent^R instrument in controlling dental disease also may have implications for its use by the physically challenged and other special populations. Since more than 75 percent of handicapped populations have some form of dental disease, devices that are effective and easy to operate are needed.⁴³ In many clients with special needs, dental care has been a low priority in relation to their major physical or mental problems.³⁷ Coupling a history of inadequate dental treatment, poor home care practices and limited access to dental care has resulted in a high

prevalence of dental disease in physically challenged individuals. Automatic toothbrushes have provided some disabled individuals with the opportunity to self cleanse their oral cavities and, hence, promote independent living skills. Additionally, electric toothbrushes have enhanced the caregivers proficiency in cleaning the oral cavities of dependent individuals. However, additional oral physiotherapy devices that could enhance the oral health status of disabled people may be a welcome addition to any existing self-help program.

Another variable that needs to be considered is cost effectiveness of the Rota-dent^R. The current market cost of a conventional toothbrush is approximately 2 dollars as compared to the 48 dollar retail price of the Rota-dent^R. The effectiveness of the Rota-dent^R instrument in the control and removal of dental plaque, as well as its longevity and repair record, must be determined in order to justify consumer purchase of the product. These implications can only be explored after clinical trials of the product are conducted.

Definition of Terms

Terms significant to the study were defined as follows:

1. Rota-dent^R--A commercially designed rotary
electric toothbrush with three interchangeable nylon brush
heads for soft deposit removal. The instrument is encased

in a white plastic shell with a brush head inserted into the upper 1/3 portion. This upper portion is bent in a 45 degree angle to facilitate complete tooth surface cleaning. The entire instrument is electrically operated providing rotary brush head movement. The Rota-dent^R was the independent variable under study.

- 2. <u>Conventional Toothbrush</u> (Oral B-35^R)--A soft, nylon bristled, multitufted toothbrush designed with a smooth flat brushing plane and used in daily soft deposit removal. This toothbrush is composed of 40 tufts; each tuft has 20 filaments of 0.007 and 0.008 inch diameter ankered to the brush handle with nickle silver. The conventional toothbrush was the control variable under study.
- 3. <u>Dental Plaque</u>—A dense, noncalcified mass of bacterial colonies in a gel like intermicrobial matrix which adheres closely to the tooth surface and is related directly to dental disease. ⁴⁷ Dental plaque accumulation was measured using the O'Leary Plaque Index.
- 4. <u>Gingivitis</u>—Inflammation of the gingival tissues characterized by redness, swelling and bleeding upon probing. Gingivitis was measured using the Löe and Silness Gingival Index.
- 5. <u>Gingival Index</u> (also referred to as the GI)-Data collection instrument, developed by Löe and Silness to
 assess the severity of gingivitis based on color,

consistency and bleeding upon probing.33

- 6. <u>Plaque Index</u> (also referred to as the PI)--Data collection instrument, developed by O'Leary to determine dental plaque accumulation.
- 7. <u>Preventive Educational Session</u>—Instructions on the concept of dental plaque, calculus, periodontal disease and use of the home care devices under study (conventional toothbrush and Rota-dent^R) were delivered by means of a standardized presentation during the initial appointment.
- 8. Preventive Professional——"An oral health educator and clinical operator who uses preventive, theraputic and educational methods to aid individuals in attaining and maintaining oral health". 47 This term is interchangeable with dental hygienist.
- 9. Home Care Regimen -- A routine performed twice daily by the subjects utilizing either a soft conventional toothbrush (Oral B-35 R) or a Rota-dent R electric toothbrush depending upon group assignment.

Assumptions

For the purpose of this study, the following assumptions were made:

- The presence or absence of gingival inflammation and gingival bleeding is an indicator of an individual's gingival health status.⁹
 - 2. The Löe and Silness Gingival Index is a valid

and reliable instrument for measuring the gingival health status of individuals.³³

- 3. The O'Leary Plaque Index is a valid and reliable instrument for measuring dental plaque accumulation. 36
- 4. All subjects received the same preventive educational instructions, understood the procedure presented to them and followed the prescribed home care instructions. Subjects' daily home care regimen was ensured by review of procedures and opportunities for questions to be answered.
- 5. The clinical examiner was a consistant scorer throughout the four appointments. The clinical examiner's evaluation techniques and knowledge of the indices were standardized prior to the study (see Appendix A).
- 6. The randomized, two group research design controlled for systematic bias in the groups with respect to attributes that may affect the dependent variables under investigation.²⁷

Limitations

The following limitations might have affected the validity or this study:

1. External and internal validity might have been threatened by the Hawthorne effect. This limitation was minimized by controlling the environmental conditions as well as subjects' knowledge of group status.

- 2. Differences in patient understanding might have caused inconsistencies in home care regimens. To minimize this problem, subjects were allowed to ask questions concerning home care procedures throughout the entire study. Written instructions also were provided.
- 3. The sample population was obtained from the Old Dominion University Student Center and Derital Hygiene Clinic. The sample consisted of 40 male and female subjects, between the ages of 18 and 55 years, with mild gingival inflammation as indicated by a score of 1.5 or greater on the Löe and Silness Gingival Index. Findings can only be generalized to similar populations.
- 4. Randomization of subjects into control and experimental groups created an unequal proportion of group gender characteristics. This limitation was minimized by establishing a baseline gingival score requirement which upon analysis revealed no significant group difference.
- 5. Exposure of the subjects to a new home care regimen might have introduced a novelty effect, thereby causing the subjects to react differently to the new technique. This was monitored by a questionnaire presented to the subjects at their last appointment.

Hypotheses

The following null hypotheses were tested:

Ho 1: There is no statistically significant

difference at the 0.05 level in the gingival health of subjects who brush twice daily with a rotary brush as compared to a conventional toothbrush, as measured by the Löe and Silness Gingival Index.

- Ho 2: There is no statistically significant difference at the 0.05 level in supragingival dental plaque accumulation in subjects who brush twice daily with a rotary brush as compared to brushing with a conventional toothbrush, as measured by the O'Leary Plaque Index.
- Ho 3: There is no statistically significant interaction at the 0.05 level between type of toothbrush used (Rota-dent^R versus Conventional) and region of the mouth cleaned (Anterior versus Posterior) as measured by the Löe and Silness Gingival Index.
- Ho 4: There is no statistically significant interaction at the 0.05 level between type of toothbrush used (Rota-dent^R versus Conventional) and region of the mouth cleaned (Anterior versus Posterior) as measured by the O'Leary Plaque Index.

<u>Methodology</u>

Multivariate analysis was used to determine the effects of two dental plaque removal techniques on the gingival health of male and female subjects between the ages of 18 and 55 years over a six week period. The sample consisted of 40 subjects with mild degrees of gingivitis chosen from

the patient pool of the Old Dominion University Dental Hygiene Clinic and Student Center.

A randomized, two group research design was used to minimize the effect of handedness on the efficiency of dental plaque removal. Subjects in the experimental group were instructed to brush with the Rota-dent^R instrument while those in the control group were instructed to brush with a conventional toothbrush. Each group brushed twice daily without the use of toothpaste. Subjects were assigned to groups randomly, to minimize systematic bias in the groups with respect to attributes that might have affected the dependent variables under investigation. Subjects participated in the study for six weeks and clinical parameters were examined at two week intervals. The first appointment included recording the initial gingival health status utilizing the Löe and Silness Gingival Index and determining dental plaque accumulation via the O'Leary Plaque Index. The principal investigator presented an individualized preventive educational session to each subject by means of standardized instructions on home care regimens (see Appendix B). All subjects in the experimental group were issued one Rota-dentR plaque removal instrument with written instructions describing its use in oral home care. Consequently, subjects in the control group were issued one soft bristled multitufted conventional toothbrush with written instructions

describing the modified bass sulcular brushing technique. The inital appointment for both groups was one hour in length. At each subsequent appointment, subjects were scored using the Löe and Silness Gingival Index and the O'Leary Plaque Index to assess clinical parameters and gingival health. Subsequent appointments required twenty minutes in length. One dental hygienist who was blind to subject group status conducted all of the scoring procedures.

CHAPTER 2

Review of Literature

Researchers have concluded that dental plaque is one of the major factors present in oral disease; elimination of dental plaque increases gingival health. 23, 28, 29, 44, 45

Recent literature supports the effectiveness of home care devices in the removal of dental plaque. Some of these devices include dental floss, conventional toothbrushes, interdental brushes and electric toothbrushes. Two of these devices, the conventional manual toothbrush and the electric rotary toothbrush, were under study in this investigation. Scientific literature related to these two devices is discussed.

Effectiveness of the Conventional Toothbrush

The manual toothbrush is a widely used plaque control device. Although studies have been conducted to determine the effectiveness of manual toothbrushing on gingival health, effectiveness of toothbrushing is related to the individual's ability to access the area with the brush bristles, manipulate the brush (dexterity) and comprehend brushing technique.⁴²

Finkelstein and Grossman 18 quantitatively assessed

the mechanical cleaning efficiency of toothbrushes. hundred ninety-nine subjects participated in an eight day evaluation of four popular toothbrushes. During the first seven days of the study, the subjects brushed their teeth at home with their assigned toothbrush, but eliminated the use of any dentifrice. On day eight of the study, a baseline evaluation of stained deposits was recorded. Subjects then were asked to brush for 60 seconds with their assigned toothbrush and a commercial dentifrice. Following this procedure, a second evaluation of stained deposits was recorded. Results of this study revealed that all toothbrush groups demonstrated significant reductions in adherent deposits; therefore, the authors concluded the importance of daily toothbrushing in plaque removal. Comparisons between toothbrush types indicated the soft and medium textured toothbrushes (angled handle and bilevel compact bristles) to be significantly more effective at removing dental plaque than the soft and medium textured toothbrushes (straight handle and level trimmed bristles). Finkelstein and Grossman 18 further concluded that design features other than bristle texture account for differences in the mechanical cleaning efficiency among toothbrushes. This investigation might have yielded more conclusive findings if subjects were provided with home care instructions on brushing techniques prior to the test period.

Smukler and Landsberg⁴² directed their research efforts toward exploring toothbrush misuse and its relationship to gingival injuries. This exploration is relevant because many health care professionals become preoccupied with the "whys" instead of the "hows" of daily toothbrushing. The clinical cases observed by Smuckler and Landsberg⁴² seemed to confirm that the method of brushing, type of brush, direction, frequency and magnitude are important factors and related to the morphology of gingival lesions. They concluded that the patient usually presenting toothbrush trauma is obsessive in nature, thus prevention of serious damage needs to be recognized in early diagnosis. This study was more intuitive than empirical because the conclusions were based on individual interpretations of clinical case reports.

Conventional versus Electric Toothbrushing

Electric toothbrushes are evaluated and classified by the American Dental Association (ADA) Council on Dental Materials, Instruments and Equipment. The Association's classification system is divided into three categories: acceptable, provisionally acceptable and unacceptable. 5,6 Currently, the rotary electric toothbrush, Rota-dent^R, is pending approval from the ADA Council. Electric toothbrushes currently approved by the ADA include: Broxodent^R Automatic Toothbrush - E.R. Squib and Sons, Inc.; J.C. Penny Automatic Toothbrush - Teledyne Aquetic

and the Sears Automatic Toothbrush - Sears and Roebuck Co., Inc.

Studies comparing electric and conventional toothbrushing have revealed conflicting results, depending upon the subjects studied, type of toothbrush used, length of study and methods of statistical analysis. Some of these studies were summerized by Ash. 7 who concluded that neither brush type is better for the average patient with gingivitis. Ash⁷ recognized, however, that one type of toothbrush, electric or manual, might be more effective for one individual than another depending on individual manual dexterity and oral facial structure. In addition, Ash concluded that one method of brushing might be more effective in one individual than another. Because of conflicting reports and the limited number of investigations on certain types of patients, no conclusive evidence could be found. Ash⁷ also reported that over 75 electric toothbrushes are being marketed today with limited data on their safety and effectiveness indicating the need for clinical research.

In 1964, a clinical study was performed by Smith and Ash, 41 to determine the effectiveness of electric toothbrushing on dental plaque. The study was conducted for 120 days using a two group crossover research design. Smith and Ash found no statistically significant difference between an electric toothbrush and a standard

toothbrush on plaque and gingival scores. The results of this study are supported by the findings of similar investigations. 13,19,25,35

Chilton, DiDio and Rothner¹³ compared the clinical effectiveness of an electric and a standard toothbrush in thirty dental students. The sample was divided into two groups. One group used the electric brush on the maxillary teeth and the standard brush on the mandibular teeth; the second group did the opposite. Generalizations of this research are limited to similar populations. The study was conducted over an eight week time period with evaluation of gingival health based on the PMA index. Results were analyzed by Chilton and El-Kashlan¹² in another report discussing analysis of variance in clinical toothbrushing experiments. The authors found no statistically significant difference in gingival health scores of individuals who used the electric or manual powered toothbrush. Analysis of variance revealed neither brush to be more effective, although the Papillary, Margingal and Attached Gingival (PMA) index scores were higher in the mandibular areas than the maxillary areas for both brush types.

Hamilton et al.²⁴ conducted a study examining the effects of automatic and hand toothbrushing on gingivitis. Seventy-one dental students were divided into three groups. One group continued its own normal oral hygiene

practices, another group used nylon hand brushes and the third group used automatic reciprocating stroke toothbrushes. The test periods were limited to one week intervals and included modified gingival and plaque indices. Subjects were evaluated for the presence of gingivitis and supragingival dental plaque, assigned to specific groups and instructed to brush. At the second evaluation, change in gingival health was determined by the gingival and plaque indices and all subjects were instructed to return to their normal oral hygiene practices. Upon reevaluation, subjects again were assigned to specific groups and instructed to brush, accordingly. The second test allowed examiners to evaluate two thirds of the entire sample population on two different brush types. The results indicated that the use of the automatic toothbrush as compared to the conventional toothbrush on patients with gingivitis removed more plaque, reduced new areas of gingivitis, was simple to use and gentle to the oral tissues. A limitation of this study was the sample population. Dental students are considered to be more conscious of oral hygiene practices than the general population and dentally oriented. 7 Results of this study, therefore, might not be reproducible in populations who are less dentally aware. Additionally, a test period of one week was inadequate for evaluating qualitative and quanitative gingival health changes. This study should be

replicated using a more representative sample over a longer period of time.

A comparison of the plaque removal effectiveness between an electric and manual toothbrush was conducted by Schifter et al. 39 Subjects were instructed to cease all personal oral hygiene for 36 hours prior to evaluation. Baseline plaque levels were obtained for all subjects via the modified Navy Plaque Index, the Circumferential Gingival Margin Plaque Index and the Interproximal Area Plaque Index. Evaluations were conducted using the same criteria after a 60 second brushing period. Results concluded both brush types to be equally effective in plague removal from facial and lingual tooth surfaces, but ineffective at interproximal line angle cleansing. This study demonstrated that the brushing time of 60 seconds or less is not sufficient for the entire cleansing procedure and that some interproximal aid should be used to supplement daily toothbrushing.

Powers, Tussing and Bradley³⁸ conducted an investigation comparing the effectiveness of interproximal plaque removal by an electric toothbrush and a conventional multi-tufted hand toothbrush, without the aid of other cleaning devices. A randomized two group crossover research design was utilized evaluating plaque removal from interproximal units. Plaque score values consisted of: 0 = no plaque; 1 = interrupted plaque and 2 = solid plaque.

Weekly evaluations were made for a total period of nine weeks. Results revealed that the electric toothbrush was superior to the conventional hand toothbrush in cleansing the exposed surfaces of "open" interproximal spaces. The investigators also noted that complete removal of plaque from the areas studied was not possible, indicating that other cleaning devices are needed to maintain oral cleanliness.

Lobene³⁰ conducted a three month study examining the effect of an automatic toothbrush on gingival health. Results indicated a highly significant reduction in gingivitis with the automatic short stroke, reciprocating action toothbrush when compared to a multi-tufted conventional toothbrush. One hundred eighty five college age women formed the sample population. Two evaluations were conducted based solely on the modified Schour and Massler Papaillary, Marginial and Attached Gingival Index (PMA). The major limitation of Lobene's study is that it was conducted solely on educated women, a population expected to be compliant and dentally sophisticated; therefore, this study might be low in external validity.

A two year comparison of hand and electric toothbrushes was conducted on 103 subjects by McKendrick et al. 35

The sample population consisted of male and female university students who were interested in dental health and who possesed low baseline periodontal scores. Using

the Oral Hygiene Debris and Calculus Index by Greene and Vermillion, a modified Russell's Periodontal Index and the Gingival Recession Index, subjects were evaluated at 3, 6, 12 and 24 month intervals. Results revealed no differences in oral debris and calculus formation, gingivitis and periodontitis and gingival recession. This study concluded that electric toothbrushing was not superior to manual toothbrushing in the improvement of oral health status. Although, these conclusions can only be generalized to similar populations of young adults with relatively little gingivitis and periodontitis, this study is relevant because of its extended time period, reducing the novelty effect limitation.

Another study by Conroy¹⁴ compared the effectiveness of four automatic toothbrush heads: toothbrush 1 had a 0.009 inch nylon filament head, used with a short stroke reciprocating action toothbrush; toothbrush 2 had a 0.012 inch nylon filament head, used with a short stroke reciprocating action toothbrush; toothbrush 3 had a 0.012-inch nylon filament head, used with a modified arcuate reciprocating action toothbrush and toothbrush 4 had a flexible brush head with 0.012-inch nylon filaments, used with a modified arcuate reciprocating action toothbrush and manual toothbrushing. Conroy's results indicated no statistically significant effect between electric toothbrushing and manual toothbrushing for two of

the four brush heads when measuring dental plaque accumulation. The modified arcuate reciprocating action brush with 0.012 inch filaments and the short stroke reciprocating action brush with 0.012 inch filaments proved to remove more plaque than manual brushing. The author concluded that effective plaque removal is directly related to the mechanical action of home care devices. The home care devices studied in Conroy's investigation were distinctive when examined in relation to brush head action and design.

Chasens and Marcus¹⁰ conducted a study to evaluate natural bristle and nylon bristle orbital stroke electric toothbrushing as compared with manual brushing in maintaining periodontally involved patients. This investigation was unique because the mechanical action of the electric toothbrush studied was orbital as compared to reciprocating in previous studies. 13,14,19,24,25,30 Twenty-seven subjects serving as their own control participated in the study. Each subject was evaluated for calculus and plague formation on the lingual and labial surfaces of the mandibular incisors and canines and the buccals of the maxillary first and second molars. evaluation was performed to measure gingival health. results showed that power brushing when compared to manual brushing was more effective in preventing calculus deposition and no statistically significant difference was noted between nylon and natural bristled brushes.

Additionally, 26 of the 27 subjects studied indicated a preference towards the power brush over the conventional brush when examined by a questionnaire. This preference might have been a result of the novelty effect.

Conventional Toothbrushing versus the Rota-dentR

The Rota-dent^R is an electric toothbrush with a rotary mode of action resembling the dental handpiece.

This new product has not been extensively studied.

Published literature relating to this device is discussed.

Horton²⁶ conducted a three week study to evaluate the Rota-dent^R instrument's ability to remove dental plaque deposits and improve gingival health. The study consisted of four dental evaluative indices: Gingival Index, Papillary Marginal Attached Gingival Index, Plaque Index and Papillary Bleeding Index. These indices were utilized to assess dental plaque deposits and gingival health. Eighteen subjects were given home care instruction on the use of the Rota-dent^R and told to brush twice daily with the instrument. Evaluations were made weekly and results indicated a 65 percent reduction in plaque and 52 percent reduction in gingival inflammation. Horton concluded that the Rota-dent^R removes plaque and reduces gingival inflammation more effectively than a regular toothbrush. Although reductions were observed in plaque and gingival scores, the pretest-posttest research design used does not and conventional toothbrushing. This study contains the limitations of a small sample size, no control group and a short three week test period, suggesting that results might be influenced by the novelty effect, selection bias or statistical regression.

In 1984. Glenwright and Walsh²² studied the relative effectiveness of rotary and conventional toothbrushing in dental plaque removal. Each of the ten subjects served as their own control; group one used the Rota-dentR on the right hand side of the mouth on days 4 and 7 and on the left hand side on days 11 and 14. The conventional toothbrush was used on the opposite side of the mouth. Group two followed the same sequence only in reverse. Results measured by the Löe and Silness Plaque Index showed no statistical difference between plaque levels on either side of the mouth, indicating that rotary powered brushing is no more effective then conventional brushing. this study utilized a crossover design minimizing the effect of handedness on the efficiency of plaque removal, the small sample size limits its conclusions. The ten subjects were also dental students who besides having knowledge of dentistry might have had gingival tissues not representative of the general population. Because of the uniqueness of the sample, results can only be generalized to populations with similar characteristics.

Galvind and Zeuner²¹ studied the effectiveness of a rotary electric toothbrush in oral cleanliness, using 40 adult subjects divided into two groups, matched according to dento-gingival plaque. The control group was given a conventional toothbrush, an interspace brush, toothpicks, disclosing tablets and home care instructions via an oral hygiene self instructional manual. The experimental group received an electric toothbrush and instruction in its use from a dental hygienist. No additional home care devices were provided. The status of oral cleanliness and gingival health was assessed on four surfaces of all the teeth and the percentage of tooth surfaces showing plague and gingival bleeding were calculated. Results of this study showed similar improvement in the oral hygiene status of both groups indicating that in the hands of patients, the electric toothbrush is just as effective as the comprehensive oral hygiene kit. The dental hygienist providing instruction and the self instructional manual were confounding variables that might have effected performance results differently, since they were not presented to both groups. Further studies are indicated to support these results and provide additional analysis.

In summary, the literature suggests conflicting information regarding the effectiveness of dental plaque removal by an electric toothbrush as compared to a conventional toothbrush. Research designs,

nonrepresentative samples, number and type of subjects and the length of experimental periods have been limitations contributing to the conflicting results. A gap in the literature exists regarding the value of the Rota-dent^R as an effective home care device for the dental consumer. Additional research is necessary to determine if the Rota-dent^R instrument is more effective at removing supragingival dental plaque and improving gingival health, when compared to conventional toothbrushing.

CHAPTER 3

Methods and Materials

This investigation was designed to determine the clinical effectiveness of a rotary-type electric toothbrush, Rota-dent^R, versus a conventional toothbrush, Oral-B 35^R, on the presence of gingivitis and supragingival dental plaque in 40 male and female subjects, 18 - 55 years of age. Over a six week period, at two week intervals the oral health status of subjects was measured by the Löe and Silness Gingival Index and the O'Leary Plaque Index.

Sample Description

Forty individuals from Old Dominion University Dental Hygiene Clinic and the Campus Student Center were invited to participate in the investigation. Participants were obtained via phone solicitation, fliers and personal communication. This sample was selected because it was likely to remain relatively stable over a six week period of time. Subjects exhibited no mental or physical disabilities, medical complexities or orthodontic appliances. In addition, the presence of gingivitis as indicated by a score of 1.5 or greater on the Löe and

Silness Gingival Index was required. Individuals excluded from the study included those presenting moderate to severe periodontitis with pocket depths greater than 5mm, rheumatic heart disease, cardiac conditions, diabetes, blood dyscrasias, pregnancy, hormonal imbalance or the use of any drugs that might alter the gingival tissue as determined by the medical history. The control group consisted of 5 females and 15 males. The experimental group consisted of 11 females and 9 males. The total sample population was 40. The sample population ranged in age from 18 - 45 years with a mean age of 25 and a standard deviation of 4.93. Analysis of individual group ages revealed the following: control group mean 25.9, standard deviation 5.9; experimental group mean 23.7, standard deviation 3.41.

Research Design

A randomized, two group research design was employed to test the effectiveness of daily rotary electric toothbrushing and conventional toothbrushing on the following dependent variables, gingivitis and supragingival dental plaque (see Table 1). Forty subjects participated in the six week study and were examined at two week intervals. The prinicpal investigator assisted the clinical examiner, a dental hygienist, in performing data collection procedures and delivered all home care

Table 1
Two Group Research Design

Evaluation Periods

	Baseline	Introduced Independent Variables	Week 2	Week 4	Week 6
Experiment Group	PI ₁ GI ₁	Rota-dent ® Electric Toothbrush	Pl ₂ Gl ₂	PI ₃ GI ₃	PI ₄ GI ₄
Control Group	PI ₁ GI ₁	Conventional Oral B-35 [®] Toothbrush	Pl ₂ Gl ₂	Pl ₃ Gl ₃	PI ₄ GI ₄

instructions. Subjects were instructed to brush their teeth without toothpaste using either a rotary electric toothbrush (Rota-dent^R) or a conventional toothbrush (Oral B-35^R) depending upon which group they were assigned. Subjects were randomly assigned to the control and experimental group by the principal investigator who alone was aware of group status. Blue and green folders represented the method of randomization. Blue folders indicated experimental group assignment and consequently, green folders indicated control group assignment. Folders were arranged by alternating color (e.g., blue, green, blue, green . . .). The subjects who met all qualifications after screening were assigned the next available folder. This method of randomization controlled for systematic bias in the groups with respect to individual attributes. Gender characteristics were not considered. The clinical examiner remained blind to group classification throughout the investigation.

This research design controlled for a number of threats to internal and external validity:

- 1. A randomized, two group research design controlled for systematic bias in the groups with respect to subject relevant attributes that might have affected the dependent variables under investigation.
- 2. To control for bias, the investigator who collected the data was blind to group status.

- Randomization was used to control for subjects' group equivalency.
- 4. Situation relevant variables were controlled by standardizing patient educational instructions and clinical scoring procedures.
- 5. Environmental conditions were controlled by use of the same dental unit, light intensity, patient position, examiner position and armamentarium at each appointment.
- 6. A randomized, two group research design equalized the effect of handedness on dental plaque removal and controlled for threats to internal validity such as history, maturation and regression.

The research design was unable to control for the following:

- 1. Pre-test sensitization might have been a factor effecting the subjects' plaque scores. Subjects knowing that they would be evaluated could have cleaned their teeth immediately prior to their scheduled appointment. This problem was minimized by using the Gingival Index.
- 2. An interrater reliability coefficient was not established for the three examiners who conducted the screenings of the potential subjects. These examiners were standardized on the screening procedures, criteria for acceptance of subjects in the study, use of periodontal probe and use of Gingival Index.

3. An intrarater reliability coefficient was not established prior to the investigation; however, the clinical examiner was standardized via a standardization excercise and the same examiner collected all of the data.

Methodology

All research was conducted at the Old Dominion University Dental Hygiene Clinic. Forty subjects participated in the investigation for a period of six weeks. The experimental group brushed their teeth using the Rota-dent^R instrument while the control group brushed with a conventional toothbrush. Clinical parameters were examined at two week intervals over a six week period. The principal investigator assisted the clinical examiner in data collection procedures and delivered home care instructions. Data collection procedures included the Löe and Silness Gingival Index and the O'Leary Plaque Index.

Required equipment for the Gingival Index included a mouth mirror, adequate light, air syringe, periodontal probe and GI score chart. Three gingival areas (buccal, mesial, lingual) were evaluated for each tooth. As recommended by Löe, only one interproximal score (mesial) was taken and then doubled to represent both mesial and distal aspects of the tooth. Löe³² states that by using this time saving procedure, analyses should show no difference in results when only one of the interproximal

surfaces is examined. The teeth and gingiva were dried and the periodontal probe was inserted into the distal line angle and wiped along the soft tissue wall near the entrance to the gingival sulcus. If the area exhibited bleeding (moderate inflammation) a score of 2 was given; tendency for spontaneous bleeding was evidence of a score of 3. If no bleeding occured the examiner evaluated the tissue characteristics based on established criteria and scored the tissue as either 0 or 1. When scoring buccal and mesial areas, the probe was inserted at the distal buccal line angle and progressed into the mesial sulcus. Lingual evaluation began at the distal lingual line angle and ended at the mesial lingual line angle.

Plaque accumulation, assessed by the O'Leary Plaque Index, was disclosed using a staining solution followed by evaluation of the facial and lingual tooth surfaces. All tooth surfaces were examined and scored based on the absence or presence of dental plaque. The presence of dental plaque in an indicated area was represented by a 1mm band located adjacent to the gingival margin. This allowed the clinical examiner to distinguish between newly formed plaque and plaque missed by toothbrushing. O'Leary³⁶ derived a final score by dividing the number of plaque containing surfaces by the total number of available surfaces. The same procedure was carried out at subsequent appointments to determine the subjects' progress.

A schedule of events in the sequence of delivery were as follows:

Phase I, Pre-Investigation. The sample group was obtained during the pre-investigation phase. Individuals who indicated a desire to participate were questioned by telephone or interviewed regarding their age and planned length of stay in the immediate area. A medical history was completed to determine any contraindications for treatment (see Appendix C). Participants who met the age, residency and medical history requirements were scheduled for a screening appointment at Old Dominion University Dental Hygiene Clinic.

Phase II, Screening. The following methods were performed to ensure that the potential subjects had supragingival plaque accumulation and gingivitis and could be classified according to the American Academy of Periodontology² as a Type II periodontal patient (no pocket depths greater than 5mm).

1. The Löe and Silness Gingival Index (GI) was used to assess qualitative changes in the gingival soft tissue. A GI score of 1.5 was the minimum requirement for subject participation since it is indicative of gingival inflammation. The GI was selected because it evaluates both visual tissue change and gingival bleeding, simultaneously.

- 2. Periodontal probing depths were used to determine subjects' periodontal status according to the American Academy of Periodontology.² Visual dental plaque accumulation also was assessed by running the periodontal probe on the clinical crown. Only those individuals who demonstrated pocket depths no greater than 5mm and moderate supragingival dental plaque accumulation were invited to participate in the investigation.
- 3. Individuals who met all criteria for acceptablity as subjects received information about the study, its purpose, procedures, risks and benefits. A written informed consent was obtained from the subjects (see Appendix C).

Phase III, Appointment One. Subjects were scheduled for an initial appointment to collect baseline data on the following variables: gingivitis and supragingival dental plaque.

- Prior to any procedures subjects' medical histories were updated.
- 2. The Löe and Silness Gingival Index was employed to assess qualitative changes in the health of the gingival soft tissue. Three gingival areas (buccal, mesial, lingual) were evaluated for all present teeth except third molars, according to the scoring criteria by Loe and Silness³³.
 - 3. The O'Leary Plaque Index was employed to determine

the amount of supragingival dental plaque accumulation.

Six tooth surfaces were evaluated as determined by scoring criteria.

- 4. Subjects in the experimental group received one Rota-dent^R appliance and instructions to brush twice daily without the use of toothpaste. The elimination of toothpaste was suggested by the manufacture to reduce the amount of foaming caused by the rotary brush head action. Following the toothbrush regimen, subjects were instructed to brush all tooth surfaces with the Rota-dent^R instrument's short pointed general brush tip. Subjects who demonstrated large embrasure spaces also were instructed to use the long pointed brush tip.
- 5. Subjects in the control group received one soft bristled multitufted conventional toothbrush (Oral B-35 $^{\rm R}$) and instructions to brush twice daily without the use of toothpaste. The elimination of toothpaste was a controlling factor in this group. Following the toothbrush regimen, subjects were instructed to brush all tooth surfaces using the modified bass sulcular brushing technique.
- 6. Each participant received verbal and written instructions on the appropriate use and maintenance of the Rota-dent^R instrument or the conventional toothbrush depending on group assignment.
- Phase IV, Re-examination (2 weeks). Subjects' medical

histories were updated prior to any procedures. Plaque Index and Gingival Index scores were measured by the same clinical examiner. Instructions for home care procedures were reviewed by the principal investigator for each subject.

<u>Phase V, Re-examination (2 weeks)</u>. This phase followed the same procedures as Phase IV.

Phase VI. Re-examination (2 weeks). This phase followed the same procedures as Phase IV. In addition, subjects were asked to complete a questionnaire regarding their likes and dislikes concering the Rota-dent^R instrument or the conventional toothbrush (see Appendix D). As a thank-you for participating in the study, subjects in the experimental group were able to keep their Rota-dent^R instruments and subjects in the control group were given Rota-dent^R instruments after the completion of the study. Furthermore, control group subjects were given instructions concering the use of the Rota-dent^R instrument.

Protection of Human Subjects

The following information was submitted and approved by the Human Subjects Committee of the College of Health Science, Old Dominion University.

1. <u>Subject Population</u> - This research investigation required the participation of 40 adult subjects between 18 and 55 years of age. The subjects were selected from the

Old Dominion University Dental Hygiene Clinic's patient pool and Campus Student Center. Screening of potential subjects was performed to ensure compliance with the subject selection criteria. Subjects had to have a minimal GI score of 1.5 and be free of any mental and physical disabilities and capable of giving voluntary informed consent for participation. No individuals who manifested any medical complexities, severe periodontal destruction or orthodontic appliances were accepted into the sample.

- 2. <u>Potential Risks</u> The potential risks were minimal.

 Trauma or injury to the gingival tissue due to
 toothbrushing could occur; however, this risk was minimized
 by providing subjects with verbal and written home care
 instructions. Review of home care instructions was
 provided at each two week appointment.
- 3. <u>Consent Procedures</u> After it was determined that the individual met the criteria for subject selection, a complete explanation of the investigation's purpose, procedures and potential risks were presented to the subjects. Voluntary informed consent was obtained after full disclosure.
- 4. <u>Protection of Subjects' Rights</u> Confidentiality of the subject's medical/dental records and individual performance throughout the study was maintained. All data were regarded as confidential and no data were released without written request of the subject. Results of the study were

presented in group form only.

- 5. Potential Benefits No claims were made that any subject would receive personal benefits from participation. Results benefited the public and oral health community by increasing knowledge of the effectiveness of rotary toothbrushing on gingival health.
- 6. <u>Risk/Benefit Ratio</u> The benefits of optimal oral health status far outweigh the minimal risks that are commonly associated with any oral physiotheraputic procedure.

<u>Instrumentation</u>

<u>Indices</u>

The O'Leary Plaque Index and the Löe and Silness

Gingival Index were used for data collection. One clinical examiner performed standardized data collection procedures to control for experimenter bias.

The Löe and Silness Gingival Index was used to obtain a valid and reliable indication of an individuals's gingival health. Gingival bleeding has been established as an early clinical sign of gingivitis and a precedent to gingival inflammation. The Löe and Silness Gingival Index was selected because it evaluates both gingival bleeding and qualitative tissue changes, simultaneously. The Gingival Index may be applied to selected teeth or the entire dentition. For this study, all teeth except third molars

were evaluated to provide a definitive evaluation. All scoring was based on the following criteria:

- 0- Normal, healthy gingival tissues.
- 1- Mild inflammation--slight change in color, slight edema. No bleeding upon probing.
- 2- Moderate inflammation--redness, edema and alazing. Bleeding upon probing.
- 3- Severe inflammation--marked redness and edema. Ulceration. Tendency to spontaneous bleeding.³³

The O'Leary Plaque Index³⁶ was used to determine the amount of plaque present on all teeth. The index measures plaque accumulation on six tooth surfaces (distal buccal, direct buccal, mesial buccal, distal lingual, direct lingual, mesial lingual). This index was chosen because the evaluation of six surfaces provides an accurate representation of plaque retention. The use of a six tooth surface index has been shown to be a valid representation of the total mouth.³⁶ All scoring was based on the following criteria:

- 0 Plaque accumulation less than 1mm.
- 1 Plaque accumulation greater than 1mm.

 Although the reliability and validity coefficients of these indices were not found in the literature they are recognized as appropriate measurement instruments in toothbrush investigations.

Questionnaire

At the conclusion of the study, a self designed questionnaire was administered to the control and experimental groups to monitor subjects' compliance and attitudes concerning the experimental procedures (see Appendix D). The questionnaire consisted of seven multiple choice and short answer questions. Questions 1, 2 and 3 assessed subject compliance with the investigation's regulations; questions 4, 5, 6 and 7 evaluated subject's attitude toward and compliance with the tooth cleaning procedures under study. The questionnaire provided room for individual responses to reflect subjects' general thoughts and perceptions concerning their toothbrush regimen. The questionnaire was not evaluated for reliability; however, content validity was established by extensive review and critical evaluation of each question by experts in the field.

Data Analysis

Multivariate analysis was performed on the data collected to determine significant effects of conventional toothbrushing and rotary toothbrushing on gingival health. This statistical analysis was chosen because of the use of multiple independent and dependent variables and because the common source of each individual observation was dependent upon the dimensions evaluated (plaque and

gingival health). The multivariate test statistic, Wilk's criterion, was used for data interpretation. Additional multivariate test statistics were evaluated resulting in similar p-values due to the investigation's sample size. In those instances where the multivariate test statistic, Wilk's Criterion, was significant, Bonferroni type simultaneous confidence intervals were formed for the mean differences between the Rota-dent^R and control groups for the three different time periods. The intervals had a family confidence coefficient of at least 0.90 for each situation evaluated. The computerized statistical analysis system (SAS) and the computer facilities at Old Dominion University were used for data analysis. The concluding questionnaire was analyzed using a standard manual tallying procedure.

CHAPTER 4

Results and Discussion

Forty subjects were selected and randomly assigned to either the Rota-dent^R (experimental group) or the conventional toothbrush (control group). Clinical parameters were examined over a six week period at two week intervals. The oral health status of the subjects was measured at baseline and at each appointment using the Löe and Silness Gingival Index and the O'Leary Plaque Index. Multivariate analyses (MANOVA) were employed to determine the main and interaction effects of the two independent variables, Rota-dent and the conventional toothbrush, on the two dependent variables, GI and PI scores.

Results

Hypothesis 1. Data were analyzed to test the hypothesis that no statistically significant difference existed in the gingival health of subjects who brushed twice daily with a rotary brush as compared to a conventional toothbrush, as measured by the Löe and Silness Gingival Index. Data analysis was based on a variable constructed from the difference between appointment means. This variable controlled for initial differences in

baseline scores. The multivariate procedure evaluated the mean differences at each interval between the two groups simultaneously (see Appendix E). The analysis revealed that the observed mean differences between the two groups were not statistically significant at the 0.05 level; therefore, the null hypothesis was retained (F= 2.32, df= 3/36, p= 0.0919) (see Figure 1). Although no statistically significant difference in gingival scores was found, the rejection region of 0.09 would have been significant if analysis was based at a 0.10 alpha level.

Although not originally hypothesized additional analyses were conducted regarding the anterior posterior differences in the subjects' gingival health. These analyses are related to the first hypothesis. Evaluation of anterior and posterior regions of the mouth revealed a statistically significant difference at the 0.05 level for anterior gingival scores (F= 3.35, df= 3/36, p= 0.0296). The mean difference scores for the experimental group (Rota-dent^R) at appointments 2, 3 and 4 were 0.6123, 0.6784, 0.7405 as compared to the control group (Oral B-35^R) with scores at appointments 2, 3 and 4 consisting of 0.6247, 0.6662, 0.6626. Based on the evaluated mean gingival difference scores for the three appointments combined, the Rota-dent^R group had significantly better gingival health than the conventional toothbrush group (see Figure 2). When Bonferroni type simultaneous confidence

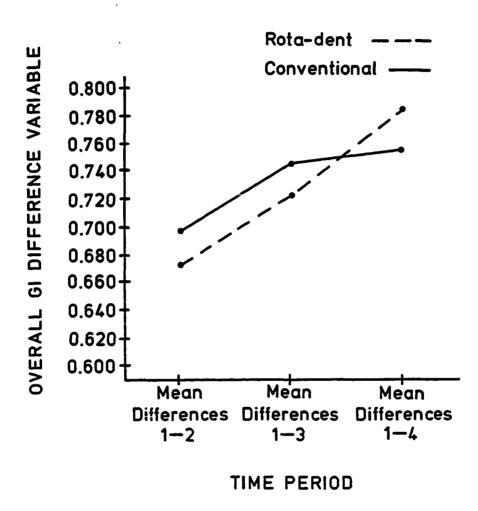


Figure 1. Comparison of Mean GI Difference Variables for Subjects in the Rota-dent^R and Conventional Toothbrush Groups at Each Appointment Interval. (Note baseline scores are not shown because the variable constructed adjusted the score for initial group differences.)

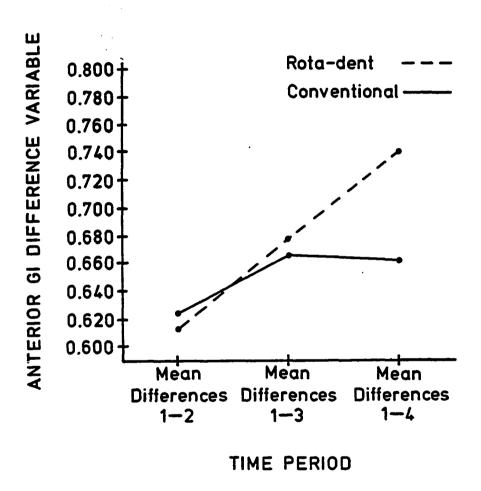


Figure 2. Comparison of Mean GI Anterior Difference Variables for Subjects in the Rota-dent^R and Conventional Toothbrush Groups at Each Appointment Interval. (Note baseline scores are not shown because the variable constructed adjusted the score for initial group differences.)

intervals were formed for this statistically significant analysis, no significant intervals were found. Posterior evaluation demonstrated no statistically significant difference between the two groups at the 0.05 level; therefore, the null hypothesis was retained ($F \approx 0.67$, df = 3/36, p = 0.578) (see Figure 3).

Hypothesis 2. Data were examined to determine if a statistically significant difference existed in the dental plaque accumulation of subjects who brushed twice daily with a rotary brush as compared to a conventional toothbrush, as measured by the O'Leary Plaque Index. data analysis evaluated the differences in mean plaque scores from the first appointment to the second appointment, third appointment and fourth appointment. These differences were then compared between the groups (see Appendix F). The analysis revealed that the observed mean differences between the two groups were statistically significant at the 0.05 level; therefore, the null hypothesis was rejected. This rejection statement was true for all regions of the mouth; overall plaque score (F= 8.42, df= 3/36, p= 0.0002), anterior plaque score (F= 3.54, df= 3/36, p= 0.0240) and posterior plaque score (F= 7.14, df= 3/36, p= 0.0007). The overall mean difference scores for the Rota-dent^R at appointments 2, 3 and 4 were 0.0954, 0.2453, 0.2578 as compared to 0.0550, 0.0967, 0.0789 in the control group. Anterior mean difference

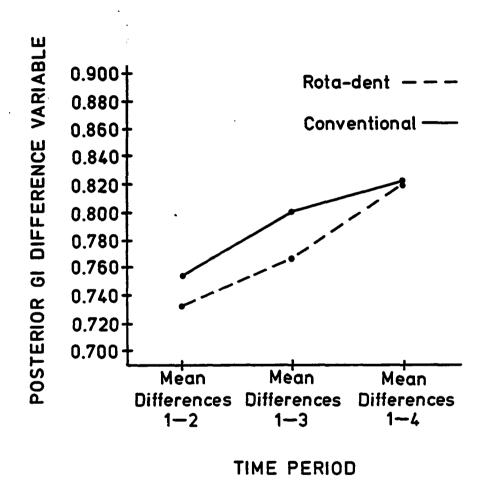


Figure 3. Comparison of Mean GI Posterior Difference Variables for Subjects in the Rota-dent^R and Conventional Toothbrush Groups at Each Appointment Interval. (Note baseline scores are not shown because the variable constructed adjusted the score for initial group differences.)

scores for the Rota-dent^R at appointments 2, 3 and 4 were 0.0434, 0.0784, 0.1376 as compared to anterior mean difference scores in the control group 0.0385, 0.0889, 0.1376. Lastly, the posterior mean difference scores for the Rota-dent^R at appointments 2, 3 and 4 were 0.1363, 0.3070, 0.3335 as compared to 0.0685, 0.1096, 0.0954 in the control group. Consequently, the significances found in these analyses are in support of the experimental group (Rota-dent^R), which demonstrated a higher mean difference score than the control group in each region of the mouth for the three appointments combined (see Figures 4, 5 and 6). When Bonferroni type simultaneous confidence intervals were formed for each statistically significant analysis, interval significances for the Rota-dentR group were found at appointments 2 and 3 for the overall plaque score and the posterior plaque score. No interval significances were found for the anterior significant plaque score.

Hypothesis 3. Data were examined to determine if a statistically significant interaction existed between type of toothbrush used (Rota-dent^R versus Conventional) and region of the mouth cleaned (Anterior versus Posterior) as measured by the Löe and Silness Gingival Index. An interaction variable was developed by subtracting the anterior gingival difference score from the posterior gingival difference score at each appointment for both groups (see Appendix G). This variable was used in the

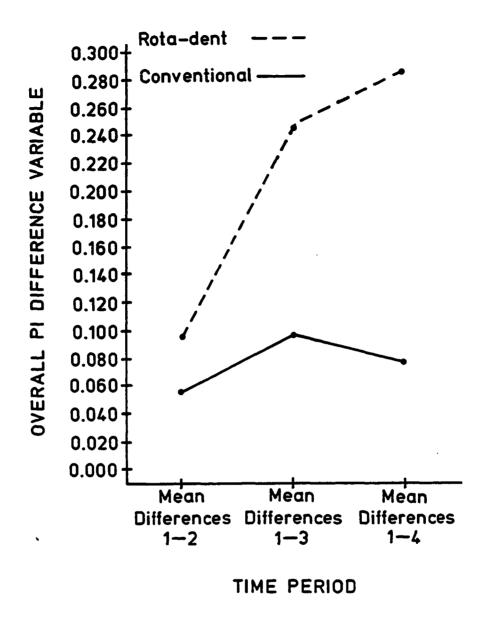


Figure 4. Comparison of Overall Mean PI Difference Variables for Subjects in the Rota-dent R and Conventional Toothbrush Groups at Each Appointment Interval. (Note baseline scores are not shown because the variable constructed adjusted the score for initial group differences.)

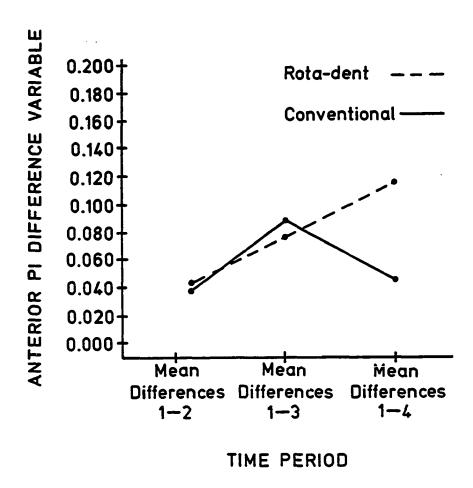


Figure 5. Comparison of Mean Anterior PI Difference Variables for Subjects in the Rota-dent^R and Conventional Toothbrush Groups at Each Appointment Interval. (Note baseline scores are not shown because the variables constructed adjusted the scores for initial group differences.)

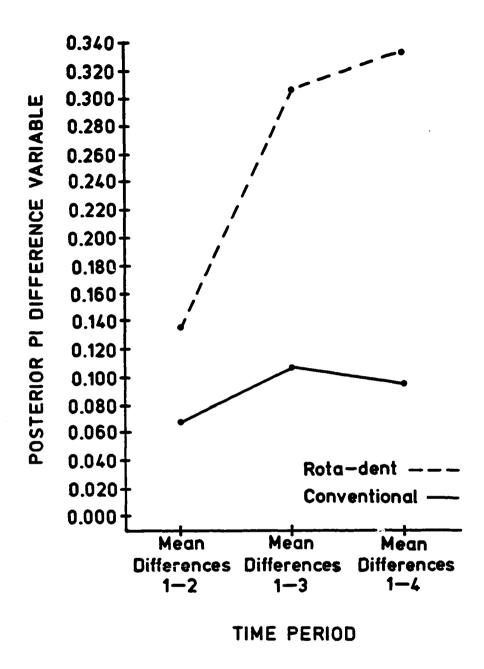


Figure 6. Comparison of Mean Posterior PI Difference Variables for Subjects in the Rota-dent^R and Conventional Toothbrush Groups at Each Appointment Interval. (Note baseline scores are not shown because the variable constructed adjusted the score for initial group differences.)

computation of the multivariate interaction statistical test. Analysis revealed no significant interaction between type of toothbrush used and region of the mouth cleaned at the 0.05 level; therefore, the null hypothesis was retained (F=2.00, df=3/36, p=0.1316).

Hypothesis 4. Data were examined to determine if a statistically significant interaction existed between type of toothbrush used (Rota-dentR versus Conventional) and region of the mouth cleaned (Anterior versus Posterior) as measured by the O'Leary Plaque Index. An interaction variable was established for this statistical procedure by subtracting the anterior plague difference score from the posterior plaque difference score for each group at each appointment (see Appendix H). Analysis revealed no significant interaction between type of toothbrush used and region of the mouth cleaned at the 0.05 level; therefore, data supported retention of the null hypothesis (F= 2.57, df= 3/36, p= 0.0693). This interaction evaluated by univariate analysis demonstrated statistical significances at each time interval, conflicting with the multivariate procedure. This occurence is common when multivariate statistics are used. If the sample size was larger, the increased statistical power of the multivariate procedure might have shown significance.

A posteriori decision was made to query the subjects regarding their perceptions about the study via a self

designed questionnaire. Inspection of the questionnaire data concerning subjects' compliance showed that 9 out of 20 subjects in the experimental group and 12 out of 20 subjects in the control group always followed the home care instructions given to them. The remaining subjects indicated a lesser response of often followed home care instructions (see Appendix D). On the average, 85 percent of the subjects in both groups claimed to have cleaned their teeth two times a day as required by the research protocol (see Appendix D). The clinical appointments were always found to be organized by 75 percent of the subjects in both groups (see Appendix D).

When evaluating subjects' perceptions about the tooth cleaning procedures under study, the questionnaire revealed 100 percent of the subjects agreeing that the home care presentation was <u>sufficient</u> (see Appendix D). Subjects in the control group indicated that they liked the instructed toothbrushing procedure because it was "more effective than their old method of brushing, felt cleaner and made their gums healthier". The two most frequent responses associated with dislikes towards the brushing procedure used in the research protocol were "the elimination of toothpaste" and "the increased length of time needed to brush". Subjects in the experimental group indicated that they liked the Rota-dent^R because it "provided a good cleaning, was easy to use and stimulated their gums". The

"elimination of toothpaste and increased length of time needed to brush". At least 95 percent of the subjects in both groups would recommend their home care procedure to others (see Appendix D). Ninety-five percent of the experimental subjects said they will continue using the Rota-dent^R, while only 85 percent of the control subjects indicated continuance of their home care regimen (see Appendix D).

Discussion

Hypothesis 1. Analysis of mean differences in posterior and overall GI scores revealed no statistically significant difference between subjects using the Rota-dent^R as compared to subjects using the conventional toothbrush. The multivariate analysis suggested that the Rota-dent^R and the conventional toothbrush are equally effective at reducing gingival inflammation. Conflicting results by Horton²⁶ indicated that the Rota-dent^R had a statistically significant effect on decreasing gingival inflammation when compared to the conventional toothbrush. The initial gingival characteristics of the sample might have been conducive for change to occur between the two groups. Although no statistically significant difference existed between the two types of home care regimens, mean GI scores showed statistically significant improvements for

both home care regimens from baseline to two, four and six weeks. These finding are supported by the literature. 21,26 Improvement in GI scores might be attributed to consistent removal of supragingival dental plaque and reinforcement of home care procedures at all two week intervals. Also, the enthusiasm of the principal investigator might have motivated the subjects in both groups to perform their daily regimens, thus confounding the effects of the independent variable.

The Rota-dent^R electric toothbrush did result in a statistically significant reduction in anterior gingival inflammation when compared to the conventional toothbrush. This finding might be attributed to the easy access of the anterior region to cleansing, resulting in the correct adaption of the Rota-dent^R toothbrush head to the tooth surface. Also, people might tend to be more concerned about the appearance of anterior teeth, investing more time in cleaning this area for cosmetic purposes.

Hypothesis 2. From baseline to two, four and six weeks, statistical analyses of PI scores revealed a statistically significant improvement in plaque reduction for all subjects. Data sugguest that the Rota-dent^R significantly reduced dental plaque accumulation in subjects when compared to the conventional toothbrush. These results are supported by the findings of Horton²⁶ and Galvind and Zeuner²¹. Although plaque accumulations

showed a statistically significant difference between brush groups, it did not correlate with the gingival findings. Pre-test sensitization might have been an influencing factor. Subjects, knowing that they would be evaluated, could have cleaned their teeth immediately before their scheduled appointment. Time of cleansing and level of patient compliance was not monitored during this study. The subjects were instructed to only use their assigned home care products; subjects using the Rota-dent^R significantly reduced dental plaque accumulation when compared to subjects using the conventional toothbrush. As with any device, successful results can be obtained only when the subject uses it regularly. Motivation still remains a critical component in the daily removal of plaque by a patient.

Hypothesis 3. Analysis failed to reject the null hypothesis that no statistically significant interaction existed between type of toothbrush used and region of the mouth cleaned as measured by the Löe and Silness Gingival Index. The MANOVA utilized an interaction difference variable (anterior minus posterior GI scores) associated with each brush type. This variable was then compared among the groups and time periods simultaneously. Although data failed to reject the null hypothesis, each of the treatments revealed clinically significant reductions in the mean GI scores from baseline to all two week

intervals. Results show statistically higher mean reductions in the anterior region for GI scores in subjects using the Rota-dent^R. The reduction, however, was not great enough to show a significant interaction effect among toothbrush type and region of the mouth cleaned.

Hypothesis 4. Data analysis failed to reject the null hypothesis that no statistically significant interaction existed between type of toothbrush used and region of the mouth cleaned as measured by the O'Leary Plaque Index. The multivariate analysis demonstrated that neither the Rota-dent^R or the conventional toothbrush was more effective in reducing subjects' plaque accumulation in specific regions of the mouth; however, the associated p-value was 0.06 indicating that the rejection region might have been reached given a larger sample size. This type of comparison analysis could not be found in the literature; therefore, a clear interpretation can not be made.

Findings from the analysis of the questionnaire indicated affirmative responses to questions of subject compliance to the home care regimens. This suggests that subjects understood the home care instructions presented to them and were motivated to implement the daily procedures. Questionnaire responses indicated that patient appeal and acceptance of the rotary electric toothbrush are positive. These findings are supported by Galvind and Zeuner, 21 whose subjects preferred the electric toothbrush over their

conventional toothbrush. Ninety-five percent of the subjects using the Rota-dent^R indicated that they will continue to use it as a daily toothbrushing procedure, further supporting patient acceptance of this new device.

When interpreting results, limitations of the study should be mentioned. Intrarater reliability of the clinical examiner was not established for GI and PI scoring before commencement of the study and, therefore, might have influenced the findings of the study. Results obtained with the GI were inconsistent when testing for interaction effects among toothbrush types and region of the mouth cleaned. These results might be attributed to failure to establish intrarater reliability. In addition, these inconsistent results might be related to the characteristics of the sample. The majority of the investigations that assessed the effectiveness of toothbrushing on gingival health utilized subjects with severe gingivitis. Subjects in the present study had mild gingivitis as opposed to severe gingivitis. Consequently, the time period of the study as well as the utilization of additional measuring instruments might yield more definitive results. This study should be continued to monitor the Gingival Index scores of the subjects over a longer time.

CHAPTER 5

Summary and Conclusions

The prevention and control of dental disease is contingent upon the patient's daily home care regimen. Many studies 10,13,14,19,24,25,35,39 have compared the effectiveness of electric toothbrushes to conventional toothbrushes for oral health self care maintanence; however, these studies have resulted in conflicting results. As technology advances, continued research must be conducted to evaluate new home care devices which may benefit consumers. The purpose of this investigation was to determine the effectiveness of rotary electric toothbrushing as compared to conventional toothbrushing as measured by supragingival dental plaque accumulation and gingivitis in subjects with mild gingival inflammation.

All research was conducted at the Old Dominion University Dental Hygiene Clinic. Forty subjects, between the ages of 18 and 55 years, who demonstrated the presence of gingivitis by a score of 1.5 or greater on the GI, were randomly assigned into the control or experimental group. The subjects in the control group were issued a conventional (Oral B-35R) toothbrush and instructed to brush twice daily without the use of toothpaste. Subjects

in the experimental group were issued a rotary electric toothbursh (Rota-dent^R) and also instructed to brush twice daily without the use of toothpaste. All subjects attended four appointments at two week intervals over a six week period. The first appointment included recording the initial oral health status (GI and PI) of each subject, presenting home care instructions and distributing the home care products. At each subsequent appointment, subjects were scored using the GI and PI and received home care reinforcement. The investigation was conducted on an examiner blind basis using a two group research design to determine the effectiveness of the independent variables, Rota-dent^R and the conventional toothbrush, on the two dependent variables. GI and PI scores.

Findings from the statistical analyses revealed no statistically significant difference at the 0.05 level for the experimental variable, toothbrush type, when evaluated on gingival health; therefore the null hypothesis that there is no statistically significant difference in the gingival health of subjects who brush twice daily with a rotary toothbrush as compared to a conventional toothbrush, as measured by the Löe and Silness Gingival Index was not rejected. However, analysis of the anterior region alone demonstrated a significant difference in subjects using the rotary brush as compared to subjects using the conventional brush. Findings from the statistical analyses revealed

statistically significant differences for the experimental variable, toothbrush type, when evaluated on plaque accumulation: therefore the null hypothesis that there is no statistically significant difference in supragingival dental plaque accumulation in subjects who brush twice daily with a rotary brush as compared to brushing with a conventional toothbrush, as measured by the O'Leary Plaque Index was rejected at the second and third appointment intervals. Results indicate that the rotary electric toothbrush Rota-dent^R was superior at reducing supragingival dental plaque when compared to the conventional toothbrush. Findings from the statistical analyses revealed no statistically significant interaction between the experimental variable, toothbrush type, and region of the mouth cleaned; therefore the null hypothesis that there is no statistically significant interaction between type of toothbrush used (Rota-dent^R versus Conventional) and region of the mouth cleaned (Anterior versus Posterior) as measured by the Löe and Silness Gingival Index was not rejected. The null hypothesis that there is no statistically significant interaction between type of toothbrush used (Rota-dent^R versus Conventional) and region of the mouth cleaned (Anterior versus Posterior) as measured by the O'Leary Plaque Index was not rejected.

Considering the discussion and limitations of the study, the following conclusions are offered:

- 1. The rotary electric toothbrush, Rota-dent^R, is as effective as the conventional toothbrush in reducing overall gingival inflammation in patients with mild gingivitis.
- 2. The rotary electric toothbrush, Rota-dent^R, is more effective than the conventional toothbrush in reducing anterior gingival inflammation.
- 3. Significant reductions in dental plaque accumulation in patients using the Rota-dent $^{\mathsf{R}}$ is dependent upon proper utilization of the instrument.
- 4. The Rota-dent^R electric toothbrush and the conventional toothbrush were equally effective at reducing gingival inflammation within subjects in anterior and posterior regions of the mouth.
- 5. The Rota-dent^R electric toothbrush and the conventional toothbrush were equally effective at reducing dental plaque accumulation within subjects in anterior and posterior regions of the mouth.

Considering the results and overall design of this research, the following recommendations for future study are made:

1. Replication of this investigation is indicated: a) using a larger sample size to assure population validity; b) using additional parameters, associated with gingival health, to determine the effectiveness of the rotary electric toothbrush and the conventional toothbrush on

gingival inflammation; and c) establishing intrarater reliability prior to the commencement of the study.

- 2. Data from this investigation should be analyzed to determine the effects of the independent variables on buccal and lingual tooth surfaces.
- 3. Further research is needed to test the abrasiveness of rotary electric toothbrushing on tooth surfaces.
- 4. Further research is needed comparing the effectiveness of a rotary electric toothbrush and a conventional toothbrush on handicapped and orthodontic patients.
- 5. Further research is needed to test the importance of home care instruction on the successful use of the ${\sf Rota-dent}^{\sf R}$.

This investigation revealed that the rotary electric toothbrush, Rota-dent^R, is a safe, effective home care device for the removal of dental plaque. Successful oral hygiene maintanence with this product is dependent upon correct adaption of the rotary toothbrush head to the tooth surface being cleaned. Results of this study support the manufacturer's recommendation, that individualized home care instructions are necessary for proper utilization of the home care device.

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APPENDICES

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APPENDIX A Clinical Examiner's Instruction Guide

Plaque and Gingival Indices Guidelines for Use in Rota-dent* Study

Gingival Index:

The Löe and Silness Gingival Index will be used to assess qualitative changes in the gingival soft tissue.

Procedure:

- A mouth mirror, adequate light and a periodontal probe will be used to evaluate tissue change.
 - 2. Evaluate one quadrent at a time:
 - a- Maxillary Right
 - b- Maxillary Left
 - c- Mandibular Left
 - d- Mandibular Right
 - 3. Air dry each quadrent before evaluating.
- 4. Three gingival areas (buccal, mesial, lingual) will be evaluated for each tooth. Score all the buccal and mesial readings first, then go back and score the lingual.
- 5. The mesial score will be doubled and a total score for each tooth is divided by 4.
 - 6. Scoring is based on the following criteria;
 - 0- Normal, healthy gingival tissues.
 - 1- Mild inflammation- slight change in color, slight edema. No bleeding upon probing.
 - 2- Moderate inflammation- redness, edema and glazing. Bleeding upon probing.
 - 3- Severe inflammation- marked redness and edema.

 Ulceration. Tendency to spontaneous bleeding.

7. Scoring Procedure:

(Buccal and Mesial) - Upon visual evaluation, determine if gingiva is a 0 or 1. If it is a 1, evaluate bleeding by inserting a probe at the distal buccal line angle and running it along the soft tissue wall near the entrance to the gingival sulcus. Continue to move the probe into the mesial sulcus, so two evaluations can be made (buccal, mesial).

(Lingual) - Upon visual evaluation, determine if gingiva is a 0 or 1. If it is a 1, evaluate bleeding by inserting a probe at the distal lingual line angle and running it along the soft tissue wall near the entrance to the gingival sulcus until reaching the mesial buccal line angle.

Scoring: If the area bleeds (moderate inflammation) a score of 2 is given, and tendency for spontaneous bleeding is evidence of a score of 3.

Plaque Index:

The O'Leary Plaque Index will be used to assess supragingival dental plaque.

Procedure:

- 1. All teeth and gingival tissues are dried.
- 2. Disclosing solution is placed on all tooth surfaces using a cotton tip applicator.
- 3. Each tooth is divided into six sections (distal buccal, direct buccal, mesial buccal, distal lingual, direct lingual, mesial lingual) and evaluated for plaque accumulation equal to

5or greater than a lmm band.

- 4. Scoring is based on the following criteria;
 - 0- Indicates the absence of plaque or the presence of plaque less than lmm.
 - 1- Indicates the presence of plaque equal to or greater than lmm.
- 5. The index is derived by dividing the number of plaque containing surfaces by the total number of available surfaces.

APPENDIX B

Educational Session Protocol

STANDARDIZED INSTRUCTIONAL SESSION

Experimental Group

- 1. Sign and Update medical history
- 2. Collect baseline data
 - a. Gingival Index
 - b. Plaque Index
- 3. View video tape
- 4. Demonstrate procedures on model
 - a. Cheek side (chin rest)
 - b. Tongue side (tooth rest)
 - c. Chew surface
- 5. Show which brush tips to use
- 6. Self practice
- 7. Distribute material
 - a. Rota-dent
 - b. New model brush tips
 - c. Written instructions

Control Group

- 1. Sign and update medical history
- 2. Collect baseline data
 - a. Gingival Index
 - b. Plaque Index
- 3. Show dental health picture book
- 4. Demonstrate toothbrushing procedure on mode!
- 5. Self practice
- 6. Distribute materials
 - a. Oral B-35 toothbrush
 - b. Written instructions

APPENDIX C Subject Consent Form and Medical History

Subject Consent Form

You are invited to participate in a study to test the effectiveness of rotary toothbrushing as compared to conventional toothbrushing in daily home care. I hope to learn if daily brushing with a rotary toothbrush has any effect on early signs of gum disease and bacterial plaque. You were selected as a possible participant in this study because you: (1) are between the ages of 18-55, (2) intend to live in this area for at least three months, (3) have early signs of gum disease and (4) are in good health as indicated by your medical history.

If you decide to participate, Laura Mueller RDH, BS, will examine your mouth for gum disease and personal oral hygiene. These examinations will be repeated at two week intervals for a total period of six weeks. Each appointment will be scheduled at the Dental Hygiene Clinic at Old Dominion University and will take a total of 20 minutes, except for the inital appointment of one hour. For the six week duration of the study, you also will be required to brush twice daily using no toothpaste with either a special rotary toothbrush or a conventional toothbrush depending upon which group you are assigned. There are no potential risks involved if you properly follow the instructions for the maintenance and use of your instruments. Improper utilization of the instruments may result in tissue trauma.

Any information that is obtained in connection with the study and that can be identified with you will remain confidential and will be disclosed only with your permission. Results of the study, if published or presented at scientific meetings, will be presented in group form so that individual participants will not be named or identified.

Subjects will receive no compensation for participation in this study; however, if you participate in the total six week study, you will be given one Rota-dent^R instrument, a market value of \$48.00.

Your decision whether or not to participate will not prejudice your future relations with the Dental Hygiene Clinic at Old Dominion University. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice.

You are making a decision whether or not to participate. Your signature indicates that you have decided to participate having read the information provided above.

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HEALTH BISTORY Rota-dant Research Study OLD DONINION UNIVERSITY

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APPENDIX D

Post-Study Subject Questionnaire and Raw Data for Both the Control and Experimental Group

Post-Study Control Group Questionnaire

<u>Directions</u>: We are most interested in your perceptions about some of the procedures used in this study. Please respond to the following questions by circling the response which most closely approximates how you feel or fill in the blank. Feel free to make additional comments.

- Did you follow the home care instructions given to you?
 Always Often Occasionally Rarely Never
- 2. On the average, how many times a day did you clean your teeth?
 i 2 3 4 >4
- 3. Did you find the clinical appointments to be organized?

 Always Often Occasionally Rarely Never
- 4. Did you feel your home care presentation was sufficient?
 Yes No Please explain?
- 5. What did you like about the toothbrushing procedure?

What didn't you like about the toothbrushing procedure?

- 6. Would you recommend the toothbrushing procedure to others?

 Yes No If no, why not?
- 7. Will you continue to use the toothbrushing procedure?
 Yes No If no, what toothbrushing procedure will you follow?

Post-Study Experimental Group Questionnaire

<u>Directions</u>: We are most interested in your perceptions about some of the procedures used in this study. Please respond to the following questions by circling the response which most closely approximates how you feel or fill in the blank. Feel free to make additional comments.

- Did you follow the home care instructions given to you?
 Always Often Occasionally Rarely Never
- 2. On the average, how many times a day did you clean your teeth?
 I 2 3 4 >4
- 3. Did you find the clinical appointments to be organized?
 Always Often Occasionally Rarely Never
- 4. Did you feel your home care presentation was sufficient?
 Yes No Please explain?
- 5. What did you like about the Rota-dent^R?

What didn't you like about the Rota-dentR?

- 6. Would you recommend the Rota-dent^R instrument to others?
 Yes No If no, why not?
- 7. Will you continue to use the Rota-dent^R as a toothbrushing procedure?

Yes No If no, what toothbrushing procedure will you follow?

Post-Study Subject Questionnaire Raw Data

Exp	erimental Group (torl Group (Oral	Rota-dent ^R) N=20 B-35 ^R) N=20	
1.	Did you follow t	he home care instruc	tions given to you?
		number of subjects experimental group	
=== 2.	Always Often Occasionally Rarely Never On the average, teeth?	9 11 seesseesseesseessees how many times a day	12 8 did you clean your
	ceech:	number of subjects experimental group	number of subjects
	1 2 3 4	17 2 1	2 17 1
3.	Did you find the	clinical appointmen	ts to be organized?
		number of subjects experimental group	
	Always Often Occasionally Rarely Never	15 5 	16 4
4.	Did you feel you sufficient?	r home care presenta	tion was
		number of subjects experimental group	
	Yes No	20	20

Questionnaire Raw Data Continued...

5. What did you like about the home care regimen?

J •	what are you tree about the home care regimen.					
		number of subjects experimental group	-			
		. =				
	Good cleaning	15	10			
	Easy to use	4	3			
	Gums Healthier	8	4			
	Liked design	3				
	Health Awareness		3			
===						
	What didn't you	like about the home	care regimen?			
		number of subjects	number of subjects			
		experimental group	_			
	Longer time	6	9			
	No toothpaste	5	8			
	Learning time	3	2			
===	=======================================					
6.	Would you recomm	end the home care re	gimen to others?			
		number of subjects	number of subjects			
		experimental group	control group			
	Yes	19	19			
	No	1	1			
===	=======================================	=======================================	=======================================			
7.	Will you continu	e to use the home ca	re regimen?			
		number of subjects	number of subjects			

experimental group control group

APPENDIX E

Mean GI Scores and Mean Differences in GI Scores for Each Home Care Regimen at All Appointments from Baseline Examination to Final Visit

Mean GI Scores and Mean Differences in GI Scores for Each Home Care Regimen at all Appointments from Baseline Examination to Final Visit

	Interval Rota-dent ^R toothbrush	Conventional toothbrush		
<u>Dascline</u>	(G1)	(G1)		
Cverall Score Anterior Score Posterior Score	1.777 1.737 1.821	1.784 1.667 1.876	Rota-dent ^R Difference Variable	Conventional Difference Variable
Appointment 1	(G2)	(G2)	$(G1) \sim (G2) = DG1$	(G1) - (G2) = DG1
Overall Score Anterior Score Posterior Score	1.104 1.124 1.087	1.085 1.042 1.121	1.777 - 1.104 = .6735 1.737 - 1.124 = .6123 1.821 - 1.087 = .7343	1.784 - 1.085 = .6994 1.667 - 1.042 = .6247 1.876 - 1.121 = .7544
Appointment 2	(G3)	(G3)	(G1) - (G3) = DG2	(G1) - (G3) = DG2
Overall Score Anterior Score Posterior Score	1.055 1.058 1.054	1.041 1.001 1.075	1.777 - 1.055 = .7224 1.737 - 1.058 = .6784 1.821 - 1.054 = .7672	1.784 - 1.041 = .7430 1.667 - 1.001 = .6662 1.876 - 1.075 = .8006
Appointment 3	(G4)	(G4)	(G1) ~ (G4) = DG3	(G1) - (G4) = DG3
Overall Score Anterior Score Posterior Score	1.002 0.996 1.001	1.028 1.004 1.052	1.777 - 1.002 = .7753 1.737 - 0.996 = .7405 1.821 - 1.001 = .8201	1.784 - 1.028 = .7564 1.667 - 1.004 = .6626 1.876 - 1.052 = .8237

APPENDIX F

Mean PI Scores and Mean Differences in PI Scores for Each Home Care Regimen at All Appointments from Baseline Examination to Final Visit

Mean PI Scores and Mean Differences in PI Scores for Each Home Care Regimen at all Appointments from Baseline Examination to Final Visit

	Interval Rota-dent ^R toothbrush	Conventional toothbrush		
Baseline	(P1)	(P1)		
Overall Score Anterior Score	0.8945 0.7530	0.8849 0.8333		
Posterior Score	0.9386	0.9244	Rota-dent ^{ll} Difference Variable	Conventional Difference Variable
Appointment 1	(P2)	(P2)	(P1) - (P2) = DP1	(P1) - (P2) = DP1
Overall Score	0.7991	0.8294 0.7948	0.8945 - 0.7991 = 0.0954 0.7530 - 0.7964 = 0.0434	0.8849 - 0.8294 = 0.0550 0.8333 - 0.7948 = 0.0385
Anterior Score Posterior Score	0.7964 0.8022	0.0558	0.9386 - 0.8022 = 0.1363	0.9244 - 0.8558 = 0.0685
Appointment 2	(P3)	(P3)	(P1) - (P3) = DP2	(P1) - (P3) = DP2
Overall Score	0.6492	0.7882	0.8945 - 0.6492 = 0.2453	0.8849 - 0.7882 = 0.0967
Anterior Score Posterior Score	0.67 46 0.6051	0.7444 0.8148	0.7530 - 0.6746 = 0.0784 0.9386 - 0.6316 = 0.3070	0.8333 - 0.7444 = 0.0889 0.9244 - 0.8148 = 0.1096
Appointment 3	(P4)	(P4)	(P1) - (P4) = DP3	(P1) - (P4) = DP3
Overall Score	0.6067	0.8060	0.8945 - 0.6067 = 0.2878	0.8849 - 0.8060 = 0.0789
Anterior Score Posterior Score	0.6154 0.6051	0.7887 0.8290	0.7530 - 0.6154 = 0.1376 0.9386 - 0.6051 = 0.3335	0.8333 - 0.7887 = 0.0446 0.9244 - 0.8290 = 0.0954

APPENDIX G

The GI Interaction Variable

The GI Interaction Variable Developed by Subtracting the Anterior DG from the Posterior DG at Each Appointment for Both Groups

	Interval	Interaction Variable Rota-dent ^R	Interaction Variable Conventional
	(anterior - posterior DG1 - DG1) IGI	IGI
Rota-dent ^R Toothbrush	0.6123 - 0.7343	0.1220	
Conventional Toothbrush	0.6247 - 0.7544		0.1296
	(anterior - posterior DG2 - DG2	I G2	1 G 2
Rota-dent ^R Toothbrush	0.6784 - 0.7672	0.0888	
Conventional Toothbrush	0.6662 - 0.8006		0.1344
	(anterior - posterior DG3 - DG3	IG3	1 G 3
Rota-dent ^R Toothbrush	0.7405 - 0.8201	0.0795	
Conventional Toothbrush	0.6626 - 0.8237		0.1610

APPENDIX H

The PI Interaction Variable

The PI Interaction Variable Developed by Subtracting the Anterior DP from the Posterior DP at Each Appointment for Both Groups

	Interval	Interaction Variable Rota-dent ^R	Interaction Variable Conventional
	(anterior - posterior DPI - DPI	IPI	IPI
Rota-dent ^R Toothbrush	0.0434 - 0.1363	0.1798	
Conventional Toothbrush	0.0385 - 0.0685		0.0300
	(anterior - posterior DP2 - DP2) IP2	IP2
Rota-dent ^R Toothbrush	0.0784 - 0.3070	0.2286	
Conventional Toothbrush	0.0889 - 0.1096		0.0206
	(anterior - posterior DP3 - DP3	IP3	IP3
Rota-dent ^R Toothbrush	0.1376 - 0.3335	0.1959	
Conventional Toothbrush	0.0446 - 0.0954		0.0507

APPENDIX I

Gingival Index and Plaque Index Scoring Chart

		Appointm	ent #		Gro	лъ ——			
poth #	Gingival Index B M M L	Sum	Plaque DB	Index B	МВ	DL	L	ML	Sum
2									
3									
4			<u> </u>						
5			·			-			
6									
7									
8									
9									
.0									
.1									
.2									
.3									
.4									
5									
.8									
.9									
20									
1									
22									
23				•					
24									
25									
26									
27									
									·
8									
9									
.0									
3]	GI Total =	1			מד דם	tal =		- 1	

APPENDIX J

Data Collection Table and Raw Data for PI and GI Scores

Group :			<u>. </u>	Data Coll Appointme	ection Tent #	Table	
Subject	GI score	GI ant	GI post	PI score	PI ant	PI post	
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16				·			

. subject #	GI score	GI	GI post	PI score	PI ant	PI post	
17							
18							
19				-			
20							

Raw Data for GI and PI Scores

```
1.69 1.93 1.75 .875
                          .805
                               .944
                                     1.14 1.12 1.10 .847 .763 .930 1.08 1.04 1.12
1 1
                               1.04
     .847
          .763 .930 1.04 1.04
                                     .764
                                          .694
                                                .833
                          .014
                                .916
     1.66 1.58 1.73
                                     1.15
                                          1.22 1.08
                                                     .660 .625 .690 .980 .958 1.00
                     .897
                                .875
     .711
                                          .472
          .666 .750
                     .903
                          -937
                                     .506
                                                -535
                                     1.08
     1.90 1.81 1.96
                     .922
                          .916
                                .927
                                          1.10 1.07 .934 .861 .989 1.00 .937 1.04
               .593 1.03
                          1.02
                               1.04
                                     .845
                                          .847
                                                .843
     .654
          .736
     1.71 1.47
                1.89
                     .898
                          .805
                                .968
                                     1.08
                                          1.14
                                                1.03
                                                     .898 .861 .927 1.02 1.08 .984
                                .984
          -597
                .666
                     .946
                          .895
                                     .535
                                           .611
                                                .479
     1.86 1.87 1.85
                     .993
                                .988
                                     .980
                                                     .705 .736 .678 1.00 .937 1.05
                          1.00
                                          .958
                                                1.00
                .630 1.00 1.02
                                .982
                                           .847
                                                .833
      .685
          -75€
                                     .839
                                                1.15
     1.75 1.70 1.79
                                .968
                                          1.06
                                                     .696 .750 .656 1.02 .958 1.07
                     .892
                          .791
                                     1.11
                .500 1.01 1.02
          .569
                               1.01
                                     .422
                                           .347
                                                .479
     .529
     1.85 1.64 2.01
                     .886
                          .013
                                .968
                                     1.10
                                          1.06
                                                1.14
                                                     .750 .722 .770 1.03 1.08 1.00
                .322 1.00
                                     .500
     . 428
          .569
                          -979
                               1.03
                                           .541
                                                .468
                                                     .845 .972 .750 1.19 1.22 1.17
     1.66
          1.66 1.67
                     .976
                          .944
                               1.00
                                     1.35
                                          1.35
                                                1.35
     •755
          .861
               .677
                     1.11 1.14
                               1.09
                                     .571
                                          .722
                                                .458
                                                     .696 .750 .656 1.03 1.06 1.01
                                     1.12 1.18
                                                1.07
                     .809
                          .694
                                .895
     1.76 1.60 1.89
      446
          .416
                .468
                     1.08
                          1.04
                                1.10
                                     .565
                                           .513
                                                -604
                     .962
    1.90 1.87
                               1.00
                                                     .814 .805 .822 1.09 1.10 1.08
                1.93
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                                     1.12
                                          1.12
                                                1.13
          .666
                .644
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                               1.03
                                     . 197
                                           .208
                                                . 188
          2.02 1.75
     1.86
                     .892
                          .888
                                .895
                                          1.18
                                                     .791 .916 .697 1.03 1.10 .984
                                     1.13
                                                1.09
      636
                          .958
          .666
                .614
                     -937
                                .921
                                     .690
                                           .722
                                                .666
1 12 1.83 1.89 1.78
                                     1.08
                                                     .910 .833 .968 1.23 1.35 1.14
                     .940
                          .916
                                .958
                                          1.06
                                                1.10
                .552 1.03 1.02
                               1.04
                                          .638
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      .642
          .763
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1 13 1.64 1.62 1.65
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                                                     .779 .763 .791 1.11 1.08 1.14
          .777
                .427
                     1.00 1.00
                               1.01
                                     .583 .680
                                                .510
      · 577
                                     .970
                                                     .813 .791 .833 .940 .854 1.01
     1.62 1.58 1.65
                     .866
                          -930
                                .807
                                          .916
                                                1.01
          .694
                .628
                     .920
                          .833
                               1.00
                                     .780
                                           .722
                                                .833
      .660
                                          1.18
          1.68 1.90
     1.81
                                .927
                                                     .755 .791 .729 1.06 1.04 1.07
                     .678
                          -347
                                     1.12
                                                1.07
                     .928
                          .833
                                .843
          .402
                .479
                                     .291
                                          .319
                                                .270
                                                .984
1 16 1.76 1.66 1.84
                          .875
                                                     .857 .847 .864 1.00 .958 1.03
                                     1.04
                     .934
                                -979
                                          1.12
                .729
                     .937
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                                .953
                                     .726
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     •755
          .791
                     .897
                          .833
1 17 1.59 1.45 1.68
                                .906
                                     1.01
                                           .950
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                                                     .884 .866 .895 .961 .950 .968
               .885
                                .984
                                           .816
           .600
                     .971
                          .950
                                     .820
                                                .875
                     .815
                          .736
                                .875
                                                     .833 .736 .906 1.07 1.02 1.10
     1.78 1.45 2.03
                                     1.08
                                          1.00
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                .885 1.03
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          .791
                                     -773
                                           .736
    1.89 1.89 1.90
                     .938
                          .888
                                -977
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                                                     .765 .791 .744 1.07 1.08 1.06
                                           1.10
                          -979
      .577 .638
               .566
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          2.37 1.78
                     .958
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                                     1.27
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                                                     .750 .750 .750 1.19 1.37 1.06
                                     . 398
                .687
                     1.16
                          1.31
                                1.06
                                          .388
                                                .406
     .726
          .777
                                                     .648 .500 .760 1.08 1.06 1.09
     1.90 1.87 1.92
                     .940
                          .930
                                -947
                                     1.04
                                           -937
                                                1.12
     .714
                     1.08 1.06
                                           .833
           .680
                -739
                                1.10
                                     .830
                                                .781
                                                     .982 1.00 .968 1.04 .979 1.09
     1.63
          1.45 1.76
                     .923
                          .916
                                -927
                                     1.12
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                .947 1.04 1.00
                               1.07
                                     .869
                                           .902
                                                .843
      .940
          .930
                     .804
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                                                     .767 .736 .791 1.03 1.00 1.06
     1.63 1.52 1.71
                          .736
                                .854
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2 3
     .898
           .763 1.00
                     1.04
                          1.08
                                1.01
                                     .827
                                           .833
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          1.62 1.91
                     .822
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                                .877
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                                                     .822 .819 .833 1.22 1.16 1.26
      .766
          .680 .844
                     1.04 1.00
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                                           .611
                                                .611
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                .020
                     .890
                          .847
                                .930
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      .791
                .819 1.19 1.20
                               1.18
                                     .840
           .763
                                           .750
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     1.86
          1.77 1.93 .880 .833
                                     1.01
                                                     .773 .791 .760 1.03 1.02 1.04
                                .916
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                                                1.03
                .802 1.06 1.00 1.10
                                          .722
      .750 .680
                                     .833
                                                .916
     1.71 1.56 1.82
                     .904 .791
                                .989
                                     1.00
                                                1.04
                                                     .851 .777 .906 .955 .833 1.04
                                           .950
          .611 .645 1.00 .958 1.04
                                     .869
                                          .847
                                                .885
      .630
                                                .883 .728 .750 .711 1.02 1.00 1.05
     1.67 1.58 1.75 .901 .833 .955 .916 .958
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     1.61 1.45 1.73 .892 .750 1.00 1.16 1.16 1.15
                                                     .797 .736 .843 .937 .833 1.01
      .821 .763 .864 .982 .979 .984 .773 .625 .885
                               .885 1.17 1.04 1.28 .839 .833 .843 1.00 .937 1.06
2 10 1.87 1.66 2.03
                     .839 .777
     .761 .694 .812 1.02 .973 1.06 .785 .722 .833
                               .854 1.10 1.04 1.15
                                                     .916 .861 .958 1.03 1.04 1.03
2 11 1.83 1.75 1.89
                    .833
                          .805
      986
          .861
                .906
                    1.04
                          1.00 1.07
                                     .845
                                          .819
                                                .864
               1.95
                     .904
                          .861
                               ·937
                                          .979 1.17
2 12 1.83 1.68
                                     1.08
                                                     .589 .486 .666 1.03 .979 1.07
               .718 1.01
                          .958 1.06
     .720
          .722
                                     .761
                                          .805 .729
2 13 1.88 1.77 1.96
                          .984 .989 1.12 1.06 1.17
                     .987
                                                     .882 .787 .947 1.11 1.02 1.17
      .882 .803
                .937
                     1.09
                          1.04 1.12
                                     .993 .984 1.00
2 14 1.72 1.58 1.82
                    .839
                          .791 .875 1.10 1.06 1.14
                                                     .690 .680 .697 1.00 1.02 1.00
                .812
                     ·973
.888
                                     -547
                                          .641
     .750
          .666
                          -979
                               .968
                                               -552
                                     .885
2 15 1.70 1.60
               1.81
                          .902 .873
                                          .791
                                               .979
                                                     .916 .902 .930 .968 .895 1.04
                     .947
                          .975 1.02 .812 .791 .833
      805 .833
                .777
                          .816
2 16 1.63 1.65
                                .964 1.04 1.00 1.07
                                                     .909 .866 .940 1.02 .950 1.07
                     .902
               1.62
      .854
          .733
                .809 1.03
                          .979 1.07
                                     .761
                                          .722
                                               .791
2 17 1.77 1.58
                          .583 .833 1.08 1.02 1.14
                                                     .863 .875 .854 1.00 1.04 .968
                1.92
                     .726
                .885 .979
                          .900 1.03
      .803 .694
                                     .893 .850 1.07
               1.67 .928
                          .833 1.00 1.10 1.02 1.17
                                                     .892 .819 .947 1.08 1.00 1.14
2 18 1.51 1.31 1.67
                                .984
      .821 .888
                          1.04
                                     .910 .902
                                                .916
2 19 1.89 1.83 1.93
                    .904
                          .916 .895 1.09 1.08 1.10
                                                    .875 .847 .895 1.02 1.04 1.01
.803 .777 .822 1.02 1.00 1.04 .958 .916 .989
2 20 2.25 2.12 2.37 .993 1.00 .988 1.25 1.29 1.21 .948 .944 .952 1.06 1.06 1.06
     .641 .611 .666 1.04 1.06 1.03 .673 .708 .642
```

APPENDIX K

Experimental and Control Group Instruction Guide

Instruction Guide for the Experimental Group

As a participant in this project, you are required to use the Rota-dent^R instrument, according to the following instructions:

- 1- Keep the Rota-dent^R instrument recharged daily for maximum performance. (see insert for details)
- 2- Brush twice daily. (morning and evening)
- 3- Eliminate the use of any oral hygiene aid or device including, dental floss, toothpick, toothpaste, mouthwash, mouth rinse etc... for the six week duration of the study. To achieve a fresh taste, toothpaste may be used on the tongue and then rinsed with water.
- 4- The Rota-dent^R brush tip should always be used at a 90 degree angle to the tooth.
- 5- Slowly and thoroughly, move the Rota-dent^R instruments' rotary tip over all tooth surfaces, between the teeth and along the gumline on the tongue side and cheek side of the mouth.
- 6- Use slight pressure. Excessive pressure will cause a slowing down of the rotary action.
- 7- Stabilize the Rota-dent^R instrument using a thumb on chin rest and a tooth rest as domonstrated in the instructional video.
- 8- Upon initial use of the Rota-dent^R you may experience a tingling sensation. This is normal and will most likly cease within 1 week to 10 days.
- 9- The Rota-dent^R and brush tips can be cleaned using normal nontoxic cleansing solutions or water.

THANK YOU for your cooperation

RDH,	BS
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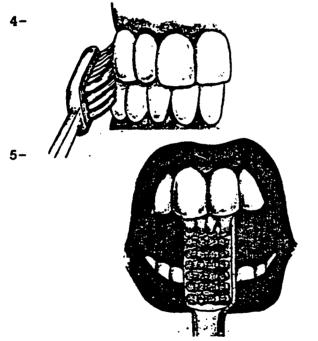
If you have any questions or comments, please call.

Dental Hygiene Clinic Old Dominion University Norfolk, Va. 23508 (804) 440-4308 or (804) 440-4310

Instruction Guide for the Control Group

As a participant in this project you are required to brush your teeth according to the standardized procedures discussed with you during your first appointment, this guide serves as a review and reminder.

- 1- Brush twice daily. (morning and evening)
- 2- Bliminate the use of any oral hygiene aids or devices including, dental floss, toothpick, toothpaste, mouthwash, mouth rinse etc. . . for the six week duration of the study. To achieve a fresh taste toothpaste may be used on the tongue and then rinsed with water.
- 3- Place brush bristles at approximately a 45 degree angle to the tooth, facing the gum tissue, then lightly press the toothbrush against the tooth so the bristle tips enter just below the gumline.



Vibrate the toothbrush back and forth; for at least ten vibrations Roll the toothbrush down towards the chewing surface of the tooth. Reposition the toothbrush and repeat.

Hold the toothbrush vertically to cleanse the tongue side of the front teeth.

6- Remember to brush all tooth surfaces on both the tongue and cheek side.

THANK YOU for your cooperation,

If you have any questions or comments, please call.

RDH, BS

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