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Short-Term Effects of the Poliswab^R on Supramarginal Bacterial Plaque Removal and Gingival Health in a Spinal Cord Unit Population

Beth Elaine McKinney
Old Dominion University

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SHORT-TERM EFFECTS OF THE POLISWAB^R
ON SUPRAMARGINAL BACTERIAL PLAQUE REMOVAL AND GINGIVAL HEALTH
IN A SPINAL CORD UNIT POPULATION

by

Beth Elaine McKinney
B.S., 1986, University of Maryland at Baltimore

A Thesis Submitted to the Faculty
of Old Dominion University
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Approved by:

Deanne Shuman. Director

Michele L. Darby

Angela C. Martin

ABSTRACT

SHORT-TERM EFFECTS OF THE POLISWAB^R ON SUPRAMARGINAL BACTERIAL PLAQUE AND GINGIVAL HEALTH IN A SPINAL CORD UNIT POPULATION

Beth Elaine McKinney
Old Dominion University, 1991
Director: Deanne Shuman

The purpose of this investigation was to determine the short-term efficacy of a mechanical device (Poliswab^R) on supramarginal bacterial plaque removal and gingival health. The sample consisted of 15 residents in a spinal cord unit at the Hampton Veterans' Affairs Medical Center. A single blind, split-mouth, pretest-posttest design was used in the study with each subject serving as his own control. Over a two week period, each participant had his teeth cleaned once daily by a dental hygienist using a Poliswab^R containing sodium bicarbonate and dentifrice on one side of the mouth and a toothbrush without dentifrice on the opposite side. The Navy Plaque Index and the Loe and Silness Gingival Index were recorded on each participant at baseline and two weeks after initiation of the study. Data were analyzed using t-tests for dependent samples (alpha set at 0.05) to determine the effectiveness of the Poliswab^R as compared to the toothbrush in removing supramarginal bacterial plaque and its effect on gingival health. Results showed the Poliswab^R to be as effective as the toothbrush in supramarginal bacterial plaque removal. No statistically significant changes in gingival health were noted in either group.

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CHAPTER 1

Introduction

As medical technology extends longevity, greater numbers of individuals require specialized long-term care. Special populations of individuals include the elderly, those with cancer and heart disease, the mentally and physically impaired, children with severe illnesses, patients with spinal cord injuries, and patients on multiple, long term, drug therapy. Dental hygiene professionals are challenged to promote oral wellness for these patients. Modifications in oral health techniques and products are often necessary to accommodate these patients' special oral health needs. When recommending oral hygiene therapy for individuals with special needs, the dental hygienists must consider the unique aspects of the client's situation, such as time required for effective oral hygiene, manual dexterity, skill level, motivation of the caregiver, and the environment for delivery of oral hygiene care. Generally, the easiest regimen will produce the greatest client adherence; however, that regimen may not be the most efficacious for achieving optimal oral wellness. Each clinician must decide, along with the patient and/or the caregiver, what constitutes an acceptable regimen.

One oral hygiene aid commonly used in institutions as a substitute for the toothbrush is a Toothette^R. A Toothette^R consists of a cylindrical piece of foam sponge attached to the

top of a thin plastic rod. Toothettes^R are inexpensive, easy to use and disposable. The foam may contain glycerin, flavoring or baking soda (the Poliswab^R), or be ingredient free. The sponge portion of the Toothette^R is rubbed onto the teeth for supramarginal bacterial plaque removal.

Since Toothettes^R were developed and marketed by a medical company, little dental research exists to verify their efficacy. In addition, the Toothette^R is not well recognized among oral health professionals because it has not been marketed to them. A dental hygiene research base for this product would not only attempt to determine its effectiveness, but also enable dental hygienists and other health care professionals to promote the Toothette^R, if warranted, to special needs populations who might benefit from it.

Statement of the Problem

The two research questions to be investigated were:

1. Does an oral hygiene device, the Poliswab^R by Halbrand, Inc., provide effective removal of supramarginal bacterial plaque?
2. Does the Poliswab^R affect gingival health status?

Significance of the Problem

Research is lacking on oral health care products not commonly marketed to, and used by, oral health professionals. Products such as the Toothette^R are used commonly in many long term care facilities, despite the fact that few studies exist which verify their effectiveness. Nurses and other caregivers

desire a regimen of oral hygiene care for their clients that is quick and convenient, yet which promotes an adequate level of oral health. The Poliswab^R, a Toothette^R with baking soda and dentifrice, meets the criteria for ease of use and is a popular choice for oral hygiene care. Poliswabs^R require no water or toothpaste and are simple to use with bedridden patients who have difficulty expectorating or commonly swallow toothpaste. In addition, the Poliswab^R is disposable, thereby avoiding infection control issues inherent in toothbrush storage. This study will contribute in determining the product's effectiveness which has heretofore remained uninvestigated by oral health professionals.

Patients with cervical injuries high on the spinal column require assistance with daily oral hygiene care. These individuals usually have no fine motor coordination and often have poor or no gross motor coordination below the neck. Manipulation of oral hygiene aids becomes impossible for these individuals. Since patients with spinal cord injuries rely on their dentition to maintain independence in performing daily activities, dental health is critical for meeting basic human needs. The Poliswab^R, because of its availability and ease of use frequently is selected as the oral hygiene aid of choice in this patient population. This study assists in determining if the Poliswab^R is of benefit in maintaining the oral health of spinal cord patients.

The Poliswab^R contains a small amount of sodium

bicarbonate; however, no contraindications to the use of the product in hypertensive individuals are identified, mentioned by the manufacturer, or in the literature. This study contained one patient under treatment for hypertension. Although secondary to the research questions, daily blood pressure measurements were recorded in order to assist in establishing the safety of the product's use in hypertensive individuals.

Definition of Terms

The following terms were defined operationally for the purpose of this investigation:

Supramarginal Bacterial Plaque: a soft dense matrix of bacteria that accumulates every 24 hours and adheres firmly to the clinical crown of the teeth and soft tissues. Bacterial plaque is the etiological agent in all dental and periodontal diseases. This factor was one dependent variable in the study and was measured using the Navy Plaque Index.

Gingival Health Status: a state of the periodontium at the clinical level characterized by the presence or lack of erythema, edema, and bleeding. This factor was the second dependent variable in the study which was measured using the Gingival Index developed by Loe and Silness.

Gingival Index: an index developed by Loe and Silness (Loe 610) to assess the severity of gingivitis based on color, consistency, and bleeding on probing.

Navy Plaque Index: an index developed by the U. S. Navy

(1968) to assess the formation of supramarginal bacterial plaque with an emphasis on the gingival area. Supramarginal bacterial plaque is assessed with the aid of disclosing solution. All teeth are scored on both facial and lingual surfaces, with a total of eight scores recorded on each tooth.

Poliswab^R: an oral hygiene aid which consists of a 2.5 by 2 centimeter cylindrical piece of foam sponge attached to the tip of a thin, 15 centimeter plastic rod (Figure 1). The foam is impregnated with a mint flavoring and baking soda. This product was the independent variable in the study.

Toothbrush: a Butler 311 toothbrush served as the control in this study. The Butler 311 toothbrush is an adult toothbrush consisting of three rows of soft bristles. It was applied to the teeth using the modified Bass technique for debris and bacterial plaque removal. This product was the control variable in the study.

Assumptions

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

1. The Navy Plaque and Gingival Indices are valid and reliable methods for assessing the presence of supramarginal bacterial plaque and gingival health, respectively (Elliott et al. 221, Elliott et al. 41, Loe 610).
2. The degree of gingivitis present at the baseline examination was a true indicator of the subjects' periodontal

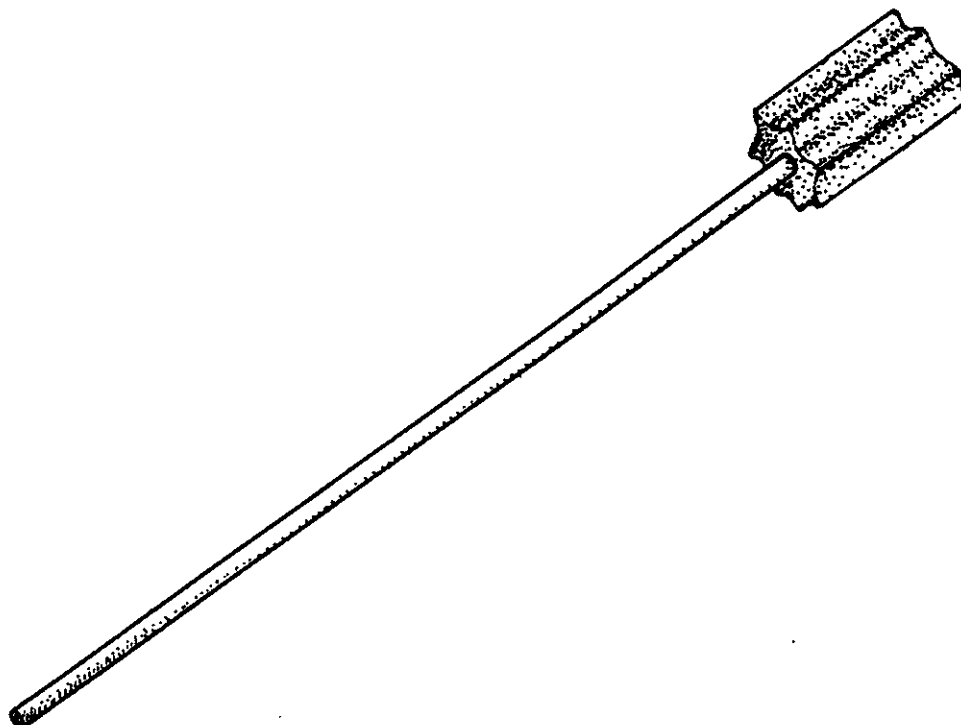


Figure 1. The Poliswab^R by Halbrand, Inc.

health.

3. The amount of bacterial plaque on the subjects' teeth at the baseline examination was an indicator of their routine oral hygiene status.

4. The subjects, friends and relatives of the subjects, and the nurses would comply with the study protocols, specifically not providing any additional oral hygiene care for the two week duration of the study.

5. All data were collected by a dental hygienist who had established intrarater reliability and was blind to the location of experimental and control variables; therefore, data collection techniques and measurements were valid and reliable.

8. The subjects in the study are representative of spinal cord residents in other Veterans' Affairs long term care facilities.

10. Subject relevant extraneous variables were controlled by the use of the "split mouth" experimental design since each subject acted as his own control.

11. Situation-relevant variables were controlled by performing data collection at the same time of day and under the same conditions for all subjects. Furthermore, the subjects were all residents of the same long term care facility.

Limitations

The validity and reliability of the results of this study

might have been limited by the following factors:

1. The subjects were drawn from a homogenous group of residents in a spinal cord unit at a Veterans' Affairs' center; therefore, generalization of the results of this study may only be made to similar sample populations under similar conditions.

2. Results might have been affected by inconsistent provision of oral hygiene care. To minimize this, all oral hygiene care was provided by one dental hygienist using standardized procedures. However, in providing care for 15 patients, fatigue may still have caused this to be a limitation.

3. Results may have been limited by the two week time period of the study. A three month time span commonly is recommended in clinical trials to adequately assess changes in gingival health.

4. The subjects' awareness of being in a study might have caused them to change normal oral health care behaviors. To minimize this concern, patients were asked to refrain from using any other oral hygiene aids during the study.

5. Subject cooperation was a limitation in this study since the oral hygiene care at this particular Veteran's Administration facility is provided routinely at 4 a.m. During this study, the 4 a.m. regimen was suspended and oral hygiene care was provided in the evening. Every attempt was made not to interfere with the subjects' daily routine.

6. Non-resolution of gingival symptoms could be due to side effects of medications commonly taken by spinal cord patients and not to the independent variable. Care was taken to identify and exclude where possible subjects taking such medications.

Hypothesis

The following null hypotheses were tested: There is no statistically significant difference at the 0.05 level in the supramarginal bacterial plaque status of spinal cord patients who receive oral hygiene care with a Poliswab^R in one half of their mouths, and a soft-bristled toothbrush in the other half, as measured by the Navy Plaque Index. There is no statistically significant difference at the 0.05 level in the gingival health status of spinal cord patients who receive oral hygiene care with a Poliswab^R in one half of their mouths, and a soft-bristled toothbrush in the other half, as measured by the Gingival Index by Loe and Silness.

Methodology

A "split-mouth" randomized subjects, pretest-posttest design was used to test the hypotheses. In addition, the experiment was conducted in a single blind manner, meaning that the rater was unaware which side received the experimental or control treatment. Each subject's mouth was visually divided at the midline and randomly assigned to the control (toothbrush) or the experimental (Poliswab^R) variable. The principle investigator retained a record of this

assignment. The side of the mouth that received oral hygiene care with the toothbrush was the control, since the toothbrush is the standard of mechanical supramarginal bacterial plaque removal for facial and lingual surfaces. The toothbrushing technique used was the modified Bass method since this is an accepted standard. No recommended technique for using the Poliswab^R could be found in the literature, so it was applied in the manner of a toothbrush. The rater scored both the Navy Plaque Index and the Gingival Index prior to beginning the study (baseline), the plaque index after oral hygiene care had been rendered, and the gingival index again at two weeks (endpoint). Analysis of the data was performed using t-tests for dependent samples with alpha set at 0.05.

CHAPTER 2

Review of the Literature

The Toothette^R has been a popular oral hygiene aid in long-term and acute care facilities since its introduction in 1964 (Halbrand, 1990). Its popularity with nursing staff and patients is well documented in the literature (DeWalt 104, Gordon 1985, Seto 9). However, few scientific studies exist which document the effectiveness of the product. Patients with spinal cord injuries often require assistance with daily oral hygiene care. Because the Poliswab^R is a common item in many acute and long-term care facilities, it may be selected by caregivers rendering oral hygiene care to patients with spinal cord injuries. Since no scientific literature could be located concerning the Poliswab^R, a relatively new product, this review will present those studies in which its precursor, the Toothette^R, was utilized for investigation. Information regarding the Toothette^R will be considered as representative of the Poliswab^R as well. A review of the current literature in these areas will include: composition of the Toothette^R and Poliswab^R, advantages and disadvantages of the products, marketing of the Toothette^R products, indications for use of the products, efficacy of the product, and the specific oral health needs of spinal cord patients.

Composition of the Toothette^R and Poliswab^R

Both the Toothette^R and Poliswab^R consist of a cylindrical

polyester foam head attached to a 15 centimeter polystyrene handle. Toothettes^R and Poliswabs^R are available in a variety of product versions (see Figure 2). The Poliswab^R with dentifrice and sodium bicarbonate is the product selected for evaluation in this study. The sodium bicarbonate was added to the Poliswab^R in order to, "neutralize acidity in the mouth, breakdown debris, and aid in reducing mucous" (Halbrand, 1988). This Poliswab^R is approximately 35% sodium bicarbonate and 65% mint flavored dentifrice. The total amount of additives is 0.0002 grams per Poliswab^R with the sodium bicarbonate accounting for approximately 0.07 milligrams of the total product (Halbrand, 1990). There is no fluoride in any of the Toothette^R or Poliswab^R products.

Advantages and Disadvantages of the Poliswab^R

The Toothette^R and Poliswab^R products are reported to have several significant advantages to nurses and other primary care givers. These advantages include expediency of care, maintenance of an aseptic environment, cost-effectiveness, convenience and patient comfort. Frequently, oral hygiene care is neglected in hospitals and long-term care facilities due to other more urgent patient needs (Maurer 671, Napierski and Danner 257, Wilentz and Kleinman 118). Because Poliswabs^R require no preparation or the addition of water, dentifrice or other ingredients, they provide a quick and efficient means of providing oral hygiene care for a patient. This increases the chance that oral hygiene care will be provided and allows more

Product and Component Ingredients

Toothette^R untreated

Toothette^R with mint dentifrice impregnate

Toothette^R with lime and glycerine impregnate

Poliswab^R untreated

Poliswab^R with lime and glycerine impregnate

Poliswab^R with sodium bicarbonate/dentifrice impregnate

Figure 2. Oral Swabs Manufactured by Halbrand, Inc.

patients to be given care in a limited amount of time.

Poliswabs^R are an individually packaged, disposable product. Unlike a toothbrush which must be stored and harbors microorganisms, a new Poliswab^R is used each time patient oral hygiene care is rendered. Since the Poliswab^R does not require the patient to expectorate, a more sanitary environment is maintained during oral health care delivery. This advantage can be of particular benefit when caring for infectious patients (Daeffler 31).

When ordered in bulk, these oral hygiene products are cost effective for large institutions to provide to patients. The Poliswab^R used in this study is the most costly of the Toothette^R products. When purchased in bulk, Poliswabs^R cost approximately nine cents apiece (Halbrand, 1990), 37 cents less than that of a toothbrush ordered in a similar amount (Healthco, 1991). Savings for an acute care hospital, which experiences a relatively rapid patient turnover, would be more dramatic than for a long-term care facility.

Poliswabs^R are convenient for nursing personnel to use, making their selection over other oral health products such as toothbrushes more likely. Poliswabs^R require no special application technique, are easily portable, sanitary, quick and disposable. They are easy to use in patients who are uncooperative or unresponsive (Wasserman et al. 264, McClain 503). They may also be more gentle than other products (DeWalt 108, Daeffler 31, Seto et al. 12). Their precursor,

the Toothette^R, has consistently rated popular with nurses (Harris 341, Shepherd et al. 26, Warner 82).

In addition to popularity with nursing staff, the Toothette^R consistently has been shown to be popular with patients, often ranking highly in comparison to other methods of providing oral hygiene care (Harris 341, Daeffler 432, Seto et al. 11). The foam heads of the products are reported to be gentler and less irritating to the tissues. Patients also prefer the taste of the product.

The primary disadvantage of the use of Toothettes^R and Poliswabs^R centers around the unanswered question of efficacy since evaluation of the product has been subjective and highly contradictory. For example, considerable discrepancy exists among researchers on whether the products provide an adequate level of oral hygiene care. Some studies emphasize that the product is superior to the toothbrush in improving oral tissues other than the gingiva (DeWalt 107, Daeffler 81, Shepherd et al. 26), while other studies rank the Toothette^R as being effective in removing debris (DeWalt 108, McClain 503). The majority of researchers, however, question the product's effectiveness in removing supramarginal bacterial plaque and debris (Daeffler 81, Seto et al. 11, Shepherd et al. 26, Gordon et al. 1985). No studies could be located which evaluate the Poliswab^R containing sodium bicarbonate.

Although the product's popularity with nurses and patients provides useful information for the oral health care

professional, discrepancies in the manner of application and operator technique may influence recommendations of products far more than the product's usefulness in and of itself. Therefore, a product may be recommended for use because it requires relatively little skill to manipulate as opposed to its benefit to the patient.

Marketing of the Toothette^R Products

The Toothette^R was developed in 1964 by a medical products company. Toothette^R products are marketed throughout the United States and Canada to hospitals and long-term care facilities. They are advertised primarily in nursing literature, so it is not surprising that dental professionals may be unfamiliar with the product. They are commonly referred to in advertisements as a "disposable toothbrush".

Toothette^R products are sold by the manufacturer directly to over 3,000 hospitals in the United States (Halbrand 1990). In addition, the products are available through all major medical distributors in the United States and Canada. Sales volume is approximately five million dollars per year, attesting to the products' popularity among nursing personnel.

Although Toothettes^R have been marketed for general use and have been researched in a variety of populations, there are patient groups for whom the products are particularly suggested in the literature. These include oncology, intensive care, cardiac care, renal care, pediatric, post-oral surgery, geriatric, stroke, comatose and physically or

mentally disabled patients.

Oncology patients are a patient population frequently targeted in the literature involving Toothettes^R. Foremost among oral hygiene concerns for these patients is the risk of inducing bacteremia. Toothette^R products are considered the standard of care for post-chemotherapy patients due to their gentle cleansing ability and, therefore, reduced risk of inducing a bacteremia (Gordon et al. 1985).

Recently, mention of the Toothette^R has been made in dental hygiene texts addressing special needs populations (DeBiase 1990). Although the product is recommended for use, no information is offered regarding its efficacy.

Efficacy of the Toothette^R

While most of the references to Toothettes^R in the literature are anecdotal, there exist a few scientific studies. The earliest of these is a 1975 study by DeWalt, a registered nurse. Using a randomized time-series design, she studied the effects of a Toothette^R and a toothbrush on 48 geriatric patients for nine months. The subjects were randomly assigned to one of six experimental or control groups. The primary purpose was not to assess the effectiveness of one product versus the other, but to discover if the frequency of the oral hygiene care was a factor in improved oral health. The researcher assumed that she was examining two oral hygiene aids that were equivalent in their effectiveness.

Interestingly, this study is one of only two reported studies that attempted to calibrate the caregivers by providing instructions on how to use the oral hygiene devices. In this study, caregivers (nursing personnel) were instructed to apply the toothbrush and the Toothette^R by using six vertical strokes on each tooth. The type of Toothette^R used in the study is not stated in the research. DeWalt used the Oral Assessment Tool developed by the University of Nebraska Medical Center as the data collection instrument. The Oral Assessment Tool uses numerical and descriptive ratings to assess voice, swallow, lips, tongue, saliva, mucous membranes, gingiva and teeth/dentures, and is a common index in the nursing literature (Eilers et al. 325). Data were analyzed using multiple regression analysis and variances with alpha set at 0.05. DeWalt concluded that the toothbrush was superior in stimulating the gingival tissue and removing debris; however, the Toothette^R was superior at improving all other evaluated oral tissues (such as the tongue, mucosa and lips).

There are several limitations to DeWalt's study. The first is that the instructions provided to the caregivers were restrictive and time-consuming (six vertical strokes on each tooth). It is questionable whether these instructions were explicitly carried out by all nurses for all 48 patients on each tooth every two to eight hours for a period of nine months. No information was supplied on the amount of time it

took the caregivers to provide this regimen and the amount of time allotted for oral hygiene care on a daily basis. DeWalt stated that "oral care was not considered a care priority in the setting" (106). Many of the geriatric patients were reported to be on medications that have oral side effects such as xerostomia. This significant relevant variable was not mentioned as a factor in the results; a particularly important limitation since the data collection tool evaluated such things as salivation. Although DeWalt's methodology and statistical analysis appear well selected and valid, the Oral Assessment Tool is not a recognized instrument for assessing the efficacy of oral hygiene aids; therefore, conclusions regarding both the Toothette^R and toothbrush must be viewed in a conservative manner.

Harris, another nurse, conducted a study in 1980 to evaluate four oral hygiene aids: toothbrush, Toothette^R, forceps with swab and swabbed gloved finger. The study was conducted in geriatric acute care units of three hospitals with the purpose to assess the acceptability and efficacy of the four products. The sample population was comprised of 100 patients selected at random; 68 patients were edentulous. The primary caregivers were the nursing personnel. No attempt was made to alter the practices or frequency of oral hygiene care currently in use by the nursing staff. Nurses were allowed to select their instrument of choice when providing oral hygiene care to their patients. No attempt was made to calibrate the

caregivers. After the next five sessions of providing oral hygiene care for patients, a posttest in the form of a questionnaire was administered to the nurses. The type of Toothette^R used was not specified in the study. Nurses' preferences were reported only in terms of frequencies. Harris offered the conclusion that the Toothette^R was the most acceptable product among the nursing staff. Data concerning patients' opinions of the products also were collected during the study. All attempts at providing oral care, regardless of the product used, were reported by patients as being effective.

Despite an attempt by Harris to employ acceptable scientific methods in comparing the products under consideration, this study has several limitations. There is little control over the majority of extraneous variables, including effect of medications on oral health, technique of the caregivers, selection of independent variables by the caregivers, and time and frequency of oral hygiene care. Measurement of the efficacy and acceptability of all products was subjective. Results could be due not to the validity of the product, but rather to the opinion or bias of the caregiver. In addition, conclusions based on such a high percentage of edentulous patients cannot be inferred to a dentate population. Although this study provides insight to nurses' perceptions of the value of various oral hygiene aids used in hospital settings, its design and methods do not allow

the study to substantiate the efficacy of any particular product.

A 1985 study (unpublished) by Gordon, a registered nurse, along with other nurses and a dental hygienist, evaluated the Toothette's^R use with oncology patients undergoing chemotherapy for leukemia. Chemotherapy patients become immunocompromised due to low white cell counts resulting from the drug therapy. The Toothette^R is the standard of care for oral hygiene recommended to these patients because it is a more gentle means of providing care than the toothbrush. Some medical professionals believe that the use of a toothbrush could induce a potentially fatal bacteremia in oncology patients. Gordon's one year investigation was conducted at Johns Hopkins Hospital where 80 patients with aplastic leukemia were studied in a randomized two group, pretest-posttest research design. Each patient was evaluated over a period of three weeks immediately following chemotherapy. The purpose of the study was to assess if the toothbrush and Toothette^R compared in effectiveness and to assess if the toothbrush could be used safely by leukemia patients undergoing chemotherapy. All subjects provided their own home care and were given brushing instructions. The type of Toothette^R used was not specified in the study. Several data collection tools were used: the Oral Assessment Tool previously described, the Plaque Index, Gingival Index, and Bleeding Index. Of the 80 patients initially enrolled only 16

completed the study. Data on the 16 patients who completed the study were analyzed by the Wilcoxin matched pairs sign test, t-tests and Chi-square analysis. The authors tentatively concluded that the toothbrush is safe for use in this population and that it was more effective for maintaining a high level of oral health than the Toothette^R. This study is one of only two in the literature that assesses the effects of the Toothette^R with the use of a dental index. The mortality rate of the study is a serious limitation that hinders conclusions drawn from the results.

The only study published in a dental journal with regard to a Toothette^R was done by Seto et al. in 1987. The authors' purpose was to investigate the efficacy of several oral hygiene aids commonly used by nursing personnel in the hospital environment. Thirteen volunteers who worked in a hospital were recruited. Oral health aids evaluated included an untreated Toothette^R, a lemon-glycerine swab, cotton gauze, cotton swabs, and a toothbrush. Subjects provided their own home care, but were given instructions on the proper use of all oral products under study. The research design was a randomized, single blind, pretest-posttest study that lasted two days. Measurements were made using the Plaque Index; subjective comments by the participants also were noted during verbal interviews by the examiners. Data were analyzed by analysis of variance and the Student Newman-Keuls tests. The researchers concluded that the toothbrush was the superior

oral hygiene aid; however, comments from the subjects indicated that the Toothette^R was well liked.

Extraneous variables were controlled; however, the experimental time frame of two days was extremely short and limits the conclusions that may be drawn from the study. There are many unique aspects to the study that enhance its credibility, including the provision of home care instructions to the subjects by research personnel on all oral hygiene aids, identification of the type of Toothette^R and the use of a dental index.

Although the Toothette^R also is recommended for use in populations that require assistance with oral hygiene due to physical disabilities, no such studies could be located in the literature search.

Oral Needs of the Spinal Cord Injury Patient

There are approximately 150,000 quadriplegic and paraplegic persons in the United States. This number grows by 10-11,000 per year (Schubert 1). Spinal cord injury patients present unique dental challenges. Multiple drug therapy; spasticity; autonomic dysreflexia; and bowel, bladder and skin care programs must all be considered when planning home or professional dental care for these patients.

Quadraplegic patients who have limited mobility of arms and no fine motor coordination in the hands often rely on various oral prostheses, commonly referred to as mouthsticks, to accomplish tasks of daily living, for example, activating

electrical appliances, writing, using a telephone, turning pages, and other similar activities. Usually such a prosthesis will be constructed of a soft acrylic resin in the shape of a mouth rim which holds a long, lightweight metallic rod. Patients with cervical injuries high on the spinal column often rely on their mouth prostheses as the sole means of living independently. For these patients the maintenance of a sound dentition is a basic human need.

There are a number of concerns regarding the potentially deleterious effect of mouthsticks on the periodontium and the masticatory system (Leinbach 221). Research at The Ohio State University (Rodeghere et al. 251) demonstrated that with a properly fashioned mouthstick, good home care and regular professional care, mouthsticks have no adverse effects on the periodontium.

Oral hygiene care is, therefore, of vital importance to the spinal cord injury patient. The majority of these people cannot maintain an adequate level of oral hygiene without assistance. For those who are in frequent contact with the dental professional, have regular professional care and are living independently at home, their needs are most likely met with toothbrushes, floss holders and other items familiar to the dental professional. For the spinal cord patient in a hospital or extended care facility, who may have more infrequent contact with oral health care professionals, oral needs most likely are addressed by nursing staff who may be

less familiar with items such as floss holders and more familiar with items such as the Toothette^R or Poliswab^R. Since Toothettes^R and Poliswabs^R have been well received for their gentleness and simplicity in application by both nurses and patients, they frequently may be given to or used on spinal cord patients in extended care facilities. Due to the importance of maintaining a disease-free periodontium in the spinal cord patient, contradictory literature concerning the Toothette's^R benefits, and a lack of studies that assess the use of Toothette^R products in such a population, research is warranted in this area.

Summary and Conclusions

The Toothette^R is a common oral hygiene aid used in hospitals and long term care facilities. Popular among nurses and patients alike, the Toothette^R is easy to use, economical, disposable and pleasant for the patient. Few scientific studies have examined the efficacy of the product. No studies could be located which investigated the Poliswab^R. Anecdotally, much controversy exists regarding the product's efficacy in supramarginal bacterial plaque removal and oral health promotion. Toothettes^R are recommended specifically for several types of patient populations, one of which is persons with cervical injuries high on the spinal column who are unable to maintain their own oral health. Maintenance of the dentition is of vital importance to these individuals in order to provide a level of independence. All oral health

care products used with these patients, therefore, should provide for optimal oral health. Investigation of the Poliswab^R in this population may provide valuable information on the product's efficacy and indications for use.

CHAPTER 3

Methods and Materials

The use of oral hygiene aids by nursing professionals in special patient populations is a subject on which little scientific research exists in the literature. This study was designed to evaluate one of these products, the Poliswab^R, in a population with spinal cord injuries. A single-blind, randomized, split-mouth design was used with pre- and post-test measures to ascertain the effectiveness of the tested product, the Poliswab^R with sodium bicarbonate and dentifrice. A conventional toothbrush served as a control on each patient.

Sample Description

The sample was drawn from a convenience population of spinal cord injury residents at the Hampton, Virginia Veteran's Affairs Medical Center. A random group of spinal cord injury individuals is unrealistic to obtain; therefore, the use of an intact group was necessary. All members of the intact group had similar background, diets and daily routines. The use of the split-mouth design attempted to control for lack of randomization among the subjects.

There were a total of 14 men, aged 40 to 65, and one woman who participated in the study. Ten men and one woman completed the study. All subjects were long term residents at the Medical Center for various personal and physical reasons. Fourteen subjects were quadriplegics with injuries at the sixth cervical vertebrae or higher (see Figure 3); one participant was a paraplegic. Most of the participants'

Cervical Lesion Level	Functional Expectations for Complete Lesions
C-4	Incapable of voluntary function in arms, trunk, or legs. Poor respiratory reserve. Totally dependent.
C-5	Can stabilize and rotate neck; has rhontoids and deltoids, allowing some shoulder movement. Elbow flexion; biceps and brachiocardialis partially innervated.
C-6	Can move shoulders well. Strong elbow flexion. Wrist muscles allow weak closure of hand - can use large-handled light-weight objects. Can sit up in bed with help, and roll over. Still needs attendant.
C-7	Patient can lift own body weight. Can use hands, which are weak and lack dexterity. Can eat independently, with some asistance. Most often confined to wheelchair.

Figure 3. Functional Significance of Lesion Levels.
adapted from Schubert, M.M. et al. Dental Treatment of the Spinal Cord Patient. Project Decod. University of Washington, School of Dentistry. Seattle, Washington. 1977.

injuries were due to automobile or alcohol related accidents. Some injuries to the spinal cord were complete and others incomplete; therefore, participants demonstrated a wide variety of physical abilities. Some were able to provide their own oral hygiene with the aid of a hand brace; others were completely incapable of even gross motor coordination.

An attempt was made to approach all qualified subjects to participate in the study. Reasons for disqualification included: fragile medical status, need for premedication, severe or uncontrolled hypertension (defined as a diastolic pressure of over 110), fewer than six remaining natural teeth, untreated root caries, severe untreated coronal caries, xerostomia, current treatment with chlorhexidine products, severe gingival hyperplasia, and past refusal of dental treatment. Only fifteen volunteers were identified from a selection of approximately 60 residents.

This population was targeted because it was identified through the literature as one of the categories of patients for whom use of Toothette^R products is recommended. Due to potential spasticity problems, the spinal cord patient requires a gentle method of rendering oral hygiene care; therefore, the Poliswab^R is a likely choice of nursing staff who provide oral hygiene care for these patients. In addition, since the natural dentition is important to the spinal cord patient to maintain independence, effective oral home care is vital. Therefore, this population is ideal to

assess the efficacy of the Toothette^R products. No similar study could be found in either medical or dental literature.

Research Design

This clinical trial employed a randomized, split-mouth, pre-test, posttest design (see Figure 4). The experimental variable was the Poliswab^R containing sodium bicarbonate and dentifrice. Since a toothbrush is the generally accepted mode of mechanical bacterial plaque removal, it served as the control variable. Dependent variables, the presence of supramarginal bacterial plaque and gingival inflammation, were evaluated by the Navy Plaque Index and the Loe and Silness Gingival Index, respectively. Both pre-tests were performed prior to the commencement of the study. The Navy Plaque Index posttest occurred immediately following provision of the oral hygiene regimen; the Gingival Index posttest was performed at two weeks after commencement of the oral hygiene regimen.

Methodology

Patients with spinal cord injuries at the Veteran's Affairs Medical Center have access to regular professional dental care, and had previously received at least periodic examinations by a staff dentist. Prior to approaching the prospective subjects, the principal investigator screened the dental records of all the residents in the spinal cord unit. Health histories, medications, number of natural teeth and

Groups	Pretest	Independent Variable	Posttest
(R)E	Y ₁	X	Y ₂
(R)C	Y ₁	-	Y ₂

(R)	Randomized (split mouth)
E	Poliswab side of mouth
C	Toothbrush side of mouth
Y1	Navy Plaque Index and Gingival Index
X	Treatment with the Poliswab
-	Treatment with the toothbrush
Y2	Navy Plaque Index and Gingival Index

Figure 4. Randomized Subjects Pretest-Posttest Design

date of last dental treatment were reviewed to determine eligibility for inclusion in the study.

Flyers describing the investigation were posted in the spinal cord units. Potential subjects for the study were recruited during their lunch time. At that time the purpose of the study was explained to the residents. Follow up recruitment was conducted on a room by room basis for those residents whose dental charts indicated their appropriateness for participation in the study.

Brief bedside oral screenings were conducted for those who verbally showed an interest in participation in order to identify potential disqualifying factors. If no disqualifying factors were noted, the risks and benefits of the study were more fully explained to the subject (see Appendix A) and a written informed consent was obtained by the principal investigator (see Appendix B). Appointments were then scheduled with the principal investigator for prophylaxis two weeks prior to the start of the study.

The principal investigator met with the dental hygienist who scored the indices for a calibration session prior to the start of the study. Exercises were conducted on both dental indices prior to data collection. The rater was familiar with the Gingival Index, but not with the Navy Plaque Index. Intrarater reliability was established for the rater.

The first evening of the experimental procedure, the rater (dental hygienist A) assessed Navy Plaque and Gingival

Index levels on all patients at bedside to obtain baseline measures. The scoring was conducted using a headlight as a light source and a standard number four, dental mouth mirror. Disclosing solution, applied using cotton tip applicators, was used with the Navy Plaque Index. A Williams probe was utilized for the Gingival Index. The Gingival Index was scored first, and then the Navy Plaque Index so that disclosing solution would not interfere with the scoring of the Gingival Index. Dental hygienist B acted as recorder and scored both indices on a data collection form designed for this study (see Appendices D and F).

The experimental side of the mouth was determined by the investigator by flipping a coin prior to the initiation of the study. Following the scoring of both indices, the experimental oral hygiene regimen was instituted by the primary caregiver, dental hygienist C. Following completion of the oral hygiene care, the posttest Navy Plaque Index was scored by the rater. The primary caregiver was not present during the scoring, and the rater was not present during the oral hygiene care.

During the following two weeks, all oral hygiene care was provided by a hygienist who acted as primary caregiver. Oral hygiene care was provided every evening following the evening meal. Each patient received care on one side of the mouth with the Poliswab^R and on the other side of the mouth with a conventional Butler 311 toothbrush. Tap water, but no

dentifrice was used with the toothbrush. The tap water in Hampton, Virginia is fluoridated at the rate of 1 ppm. The dental hygienist was the only person to provide oral hygiene care during the two week period. No other oral health care or aids were permitted to be used for the duration of the study by either the nursing personnel or the patients themselves. A reminder to this effect was posted by the nursing staff above each resident's bed. The subjects in this study had a passive role.

Neither the manufacturer nor the literature recommend a technique for using the Poliswab^R. Therefore, the Poliswab^R was applied to the teeth in a manner approximating the modified Bass brushing technique. Toothbrushing was done using the modified Bass technique. Neither oral hygiene product was timed in its use during the procedure. No flossing was provided or permitted during the investigation.

The sample group contained one resident who was undergoing treatment for hypertension. Blood pressure measurements were recorded for this subject every evening by the primary caregiver at the same visit when rendering oral hygiene care. No attempt was made to calibrate blood pressure equipment.

Two weeks after oral hygiene care was instituted, the posttest was recorded using the Gingival Index at approximately the same time of evening for each subject. The index was recorded in the same manner as the pretest, by the

same rater, at bedside and using the same equipment. Upon completion of the measures, subjects were allowed to return to their normal oral hygiene regimen as provided either by themselves or by a staff member.

Protection of Human Subjects

A spinal cord unit at the Hampton, Virginia Veteran's Affairs Medical Center was selected for this study. The population was convenient and accessible. In addition, many logistical problems such as travel and coordination of schedules were avoided by utilizing an intact population located in one facility. Many mitigating factors, such as subject variability, were eliminated by selecting such an intact group. Even though the participants are permanent residents of the Veteran's Affairs Medical Center, they were able to give voluntary consent and were free to refuse to participate.

The principal investigator met with all potential subjects in the spinal cord unit to discuss the study and answer any questions. The cover letter and a copy of the consent form were given to all subjects (see Appendices A and B), with duplicates filed in the subjects' medical records where the information was available to the staff. A third copy of both forms was filed with the resident physician. Two separate meetings were held with the resident physicians and the head nurses to acquaint them with the study and solicit input.

Prior to recruitment of subjects, the research proposal and protection of human subjects information were subject to review by the Veteran's Affairs Research and Development Committee, the Veteran's Affairs Human Subjects Committee and the Old Dominion University Human Subjects Committee. The proposal was passed by all committees without revisions.

Data collection sheets did contain subject names. The data sheets were coded prior to being subjected to statistical analysis. Only the principal investigator had access to data which contained subject names. Once the group data was entered for statistical analysis, the patient sheets were filed and no longer consulted. They were not referred to in reporting the data in any form. All subjects' data were coded with a letter; therefore, a breach of confidentiality with regard to a subject was of minimal risk.

Risks to the subjects were minimal, but included worsening of gingival conditions due to possible inadequate cleansing, the inconvenience of the care provided by a second party, the annoyance of not using other oral hygiene aids, and the possible development of hyperplastic tissue (if subject was taking the medication, nifedipine). In addition to the above, residents who were being treated for hypertension had a slightly increased risk of elevated blood pressure due to the sodium bicarbonate contained in the product under investigation. Physicians in the spinal cord unit felt that any risk was negligible; however, blood pressure was monitored

on the one hypertensive individual in the study. Toothettes^R are currently used by staff at the Veteran's Affairs Medical Center and some patients expressed a familiarity with them.

Benefits from participation in the study included an additional professional prophylaxis and daily oral hygiene care by a dental hygienist. Oral hygiene care delivered by nursing personnel was sporadic, often provided only at the insistence of the patient. During the study the participants received two weeks of diligent oral hygiene care from a dental hygienist. The time and effort required to provide oral hygiene care might have been of educational benefit to the nursing staff where informal training and/or conditioning might have occurred as a result of the dental hygienist's daily presence.

In addition, the Veterans' Affairs Medical Center would be recognized and acknowledged for their participation in any publications. The residents, by their participation, might help establish for the medical and dental professions the efficacy of the product. Additionally, results of this study may benefit the nursing community, improving their knowledge of the importance of proper oral hygiene, proper home care methodologies and identification of effective/ineffective products.

Since the product is already in common use with no adverse sequelae reported in the literature, the risks were minimal in relation to the benefit of daily oral hygiene

care, and the information gained which could be applied directly by the health care professionals and those dental professionals who have contact with special patient populations.

Instrumentation

This study used two dental indices, the Navy Plaque Index (NPI) and the Gingival Index (GI). The Navy Plaque Index was developed in 1968 to screen and monitor the dental health of Navy personnel (Grossman 41). A disclosing solution and adequate light must be used when administering the index. Only the Ramfjord teeth may be scored or all teeth may be scored. Both facial and lingual surfaces are scored in the index. The tooth is divided into four sections (see Appendix C) and scores are assigned based on the presence or absence of bacterial plaque. The scores range from zero to three. By assigning higher numbers to the gingival portion of the tooth, the gingival area is weighted. The NPI total score is derived from adding all scores on evaluated teeth. This index has been tested in several trials at the Naval Academy, analyzed by the National Naval Dental Center and found to be reliable and valid (Elliott et al. 221, Elliott et al. 41). The index is still in use at Naval Dental Centers worldwide. In this study all teeth were scored for data analysis.

The Gingival Index was developed by Loe and Silness in 1967. With the use of a periodontal probe and adequate light, it assesses the gingiva based on bleeding on probing and

tissue changes in color and appearance. Gingiva is rated on a scale of 0-3 (see Appendix E). All teeth are examined and a score is assigned for facial, mesial, distal and lingual areas. Those four scores are averaged to derive a score for the tooth, and all scores are averaged to derive a score for the subject. This index has been used in multiple trials since its creation and has proved reliable and valid (Loe 610). In this study, all teeth were scored for data analysis.

Statistical Treatment

Since the sample size was only 15 for the Plaque Index and 11 for the Gingival Index (due to subject mortality), the data collection tools provide ratio-type data, and subjects served as their own controls, t-tests for dependent samples were performed to identify differences in the effectiveness of the Poliswab^R and the standard manual toothbrush. Data for the blood pressure measurements were not analyzed in this study, but rather were collected to monitor general health. The alpha level for all calculations was set at the 0.05 level. All data were analyzed by computer using the SPSSX statistical software package.

CHAPTER 4

Results and Discussion

Fifteen subjects from a spinal cord unit at the Hampton Veteran's Affairs Medical Center participated in a study to determine the effectiveness of an alternative oral hygiene aid, the Poliswab^R in removing supramarginal bacterial plaque and its effect on gingival health. Two weeks prior to the study, all subjects received a prophylaxis by the principal investigator. For two weeks, a dental hygienist performed oral hygiene care once daily for the subjects. A split-mouth design was used; on one side of the mouth the patient received care with the Poliswab^R and on the other side with a Butler 311 toothbrush. Presence of supramarginal bacterial plaque was measured using the Navy Plaque Index; gingival health was measured using the Gingival Index by Loe and Silness. The Navy Plaque Index was performed prior to oral hygiene care and immediately afterwards. The Gingival Index was performed prior to the start of oral hygiene care and at two weeks. One rater, a dental hygienist, performed all indices and was blind to the side receiving the experimental treatment. A computerized, statistical package, SPSSX, was used for data analysis.

Results

The first hypothesis in this study stated that there was no significant difference between the Poliswab^R and a toothbrush in removing supramarginal bacterial plaque. Data

obtained from the Navy Plaque Index were analyzed to test this hypothesis. Data from 15 subjects were analyzed by t-tests for dependent samples in order to assess how well both aids removed supramarginal bacterial plaque. Raw data for both pretest and posttest measurements are listed in Appendix G. The mean scores for both pre- and post-test groups are listed in Tables 1 and 2. Results of the t-tests are listed in Table 3. There was no significant difference in the groups' supramarginal bacterial plaque status at baseline as revealed by the t-tests ($t=-0.29$, $df=14$, $p=0.776$). Results of the t-tests revealed that the side treated with the Poliswab^R, the experimental group, showed a significant reduction in the presence of supramarginal bacterial plaque ($t=5.21$, $df=14$, $p=0.000$). In addition, t-tests revealed that the side treated with the toothbrush, the control group, also had a significant decrease in the amount of supramarginal bacterial plaque ($t=6.88$, $df=14$, $p=0.000$). When comparing the posttest results of the experimental versus the control group, the t-test revealed that there was no significant difference between the two methodologies ($t=0.65$, $df=14$, $p=0.525$).

In comparing mean scores for the experimental and control groups, there was a 5.76 incremental difference in the experimental group as opposed to a 6.3074 incremental difference in the control group (see Table 4 and Figure 5). Although not statistically significant, this difference suggests that the toothbrush might be slightly superior at

Table 1

Mean Scores for the Navy Plaque Index-Experimental Group

	Mean	Standard Deviation
Pretest	9.8847	.824
Posttest	4.1247	.805

Table 2

Mean Scores for the Navy Plaque Index-Control Group

	Mean	Standard Deviation
Pretest	10.0327	3.212
Posttest	3.7253	3.469

Table 3
t-Values for Navy Plaque Index Scores

Comparison	t-value	p-value
Experimental and control pretests	- 0.29	0.776
Experimental pretest and posttest	5.21	0.000 *
Control pretest and posttest	6.88	0.000 *
Experimental and control posttests	0.65	0.525

df=14

* significant at the 0.05 level

Table 4
 Summary Statistics of NPI Scores for Experimental
 and Control Sides at Baseline and Two Weeks

Interval	Poliswab ^R Side (Experimental)			Toothbrush Side (Control)		
	\bar{x}	\bar{x} reduction	t-value	\bar{x}	\bar{x} reduction	t-value
Baseline	9.8847			10.0327		
Two Weeks	4.1247	5.76	5.21*	3.7253	6.3074	6.88*

df=14

* significant at the 0.05 level

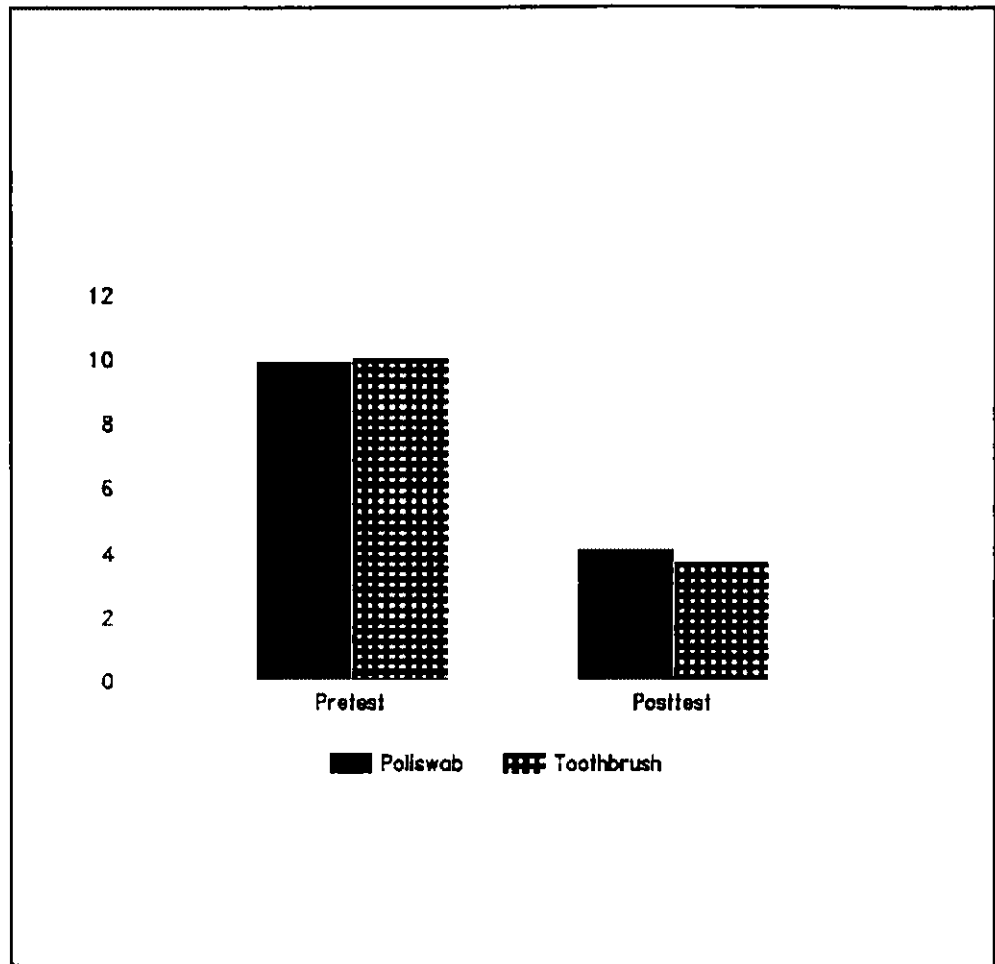


Figure 5. Mean Values for Navy Plaque Index Scores for Experimental and Control Variables

supramarginal bacterial plaque removal to the Poliswab^R. The null hypothesis that there is no statistically significant difference in the supramarginal bacterial plaque removal ability of the toothbrush and the Poliswab^R was retained based on the results of the t-tests.

The second hypothesis stated that there was no significant difference between the Poliswab^R and the toothbrush in their effect on gingival health. Data from 11 subjects on the Gingival Index were analyzed to test this hypothesis. t-Tests for dependent samples were used to determine statistical differences in gingival health scores. Raw scores for both pre- and post-test Gingival Index scores are listed in Appendix H. Mean scores for the experimental and control groups are listed in Tables 5 and 6. Results of the t-tests are listed in Table 7. There was no significant difference in the gingival health status of both groups at the start of the study as revealed by the t-test ($t=1.80$, $df=10$, $p=0.102$). t-Tests also revealed that there was no significant change in either the experimental or control group during the duration of the study ($t=-0.77$, $df=10$, $p=0.460$ and $t=-0.60$, $df=10$, $p=0.563$ respectively) (see Figure 6). In addition both groups were statistically equivalent at the end of the study as well ($t=1.77$, $df=10$, $p=0.107$). The obtained p-values were greater than or equal to 0.10 for all tests. A summary of

these results is presented in Table 9. The null hypothesis that there is no statistically significant difference in the gingival health of spinal cord patients who receive oral hygiene care with a Poliswab^R in one half of their mouths, and a soft-bristled toothbrush in the other half was retained based on the results of the t-tests.

Table 5
Mean Scores for the Gingival Index-Experimental Group

	Mean	Standard Deviation
Pretest	0.1691	0.237
Posttest	0.2400	0.267

Table 6
Mean Scores for the Gingival Index-Control Group

	Mean	Standard Deviation
Pretest	0.1055	0.172
Posttest	0.1509	0.154

Table 7
t-Values for Comparison of Gingival Index Scores

Comparison	t-value	p-value
Experimental and control pretests	1.80	0.102
Experimental pretest and posttest	-0.77	0.460
Control pretest and posttest	-0.60	0.563
Experimental and control posttests	1.77	0.107

df=10

* = significant at the 0.05 level

Table 8

Summary Statistics of Gingival Index Scores for Experimental
and Control Sides at Baseline and Two Weeks

Interval	Poliswab ^R Side (Experimental)			Toothbrush Side (Control)		
	\bar{x}	\bar{x} reduction	t-value	\bar{x}	\bar{x} reduction	t-value
Baseline	0.1691			0.1055		
Two Weeks	0.2400	0.0709	-0.77	0.1509	0.0454	-0.60

df=10

* significant at the 0.05 level

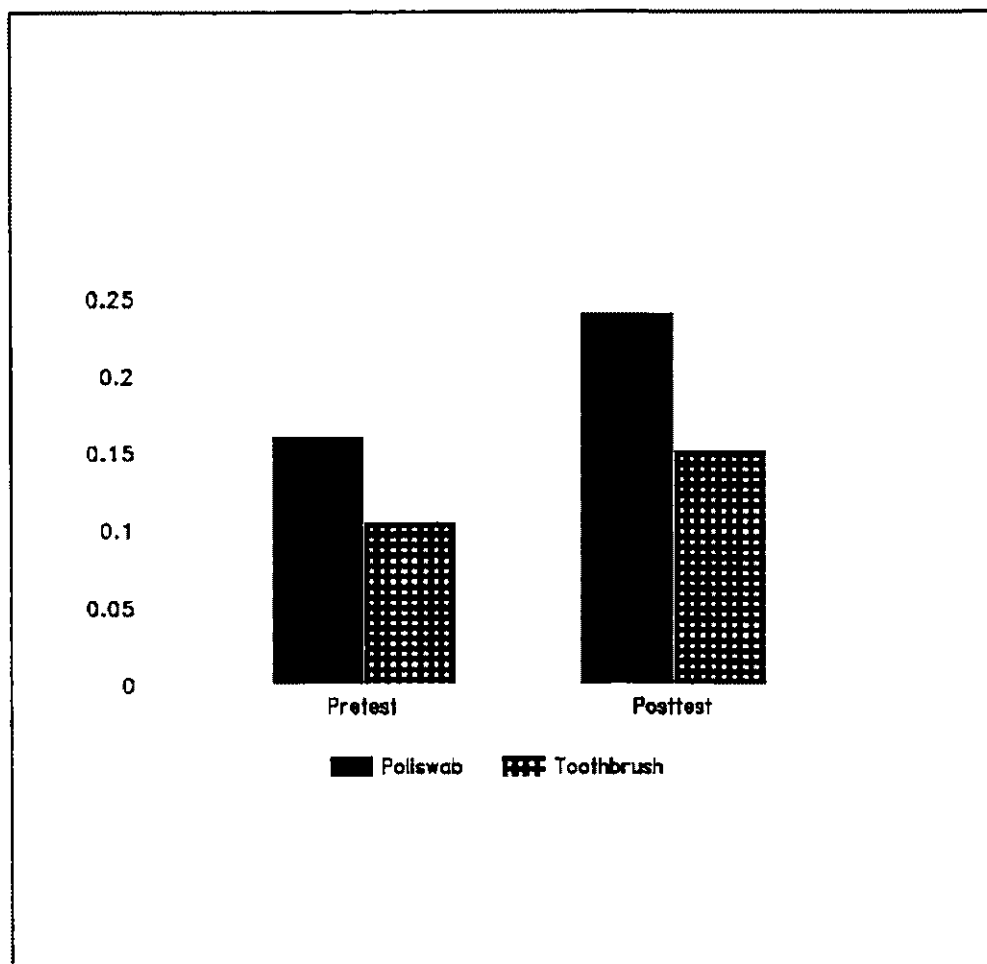


Figure 6. Mean Values for Gingival Index Scores for Experimental and Control Variables

Discussion

Based on the results of the t-tests, the first hypothesis could not be rejected at a confidence level of 0.05, leading to the finding that both oral hygiene aids were similarly effective in removing supramarginal bacterial plaque. This result contradicts findings in other studies which evaluated the supramarginal bacterial plaque removal capabilities of the Toothette^R and found that the toothbrush was superior (DeWalt, Gordon et al., Seto et al.). This difference may be due to several factors. All of the previous researchers evaluated the Toothette^R product. No studies evaluating the Poliswab^R could be located in the literature; hence, the Toothette^R was used for comparison purposes. The Poliswab^R differs from the Toothette^R in the addition of sodium bicarbonate to the product, which may have enhanced supramarginal bacterial plaque removal.

In the studies conducted by Gordon et al. and Seto et al., subjects provided their own oral hygiene care. In this study, both methods of supramarginal bacterial plaque removal were applied by a dental hygienist. The effectiveness of the aids, therefore, may be confounded, or masked, by the heightened professional training and motivation of the caregiver. Supramarginal bacterial plaque removal using the same tools, but with a less trained or less motivated

caregiver, might yield different results. The comparison between this study and DeWalt's study is weak since DeWalt's study used multiple caregivers and assessed the frequency of oral hygiene rather than the methodology. The studies are not comparable either in indices or statistical tests used.

Plaque removal assessment was difficult in this study due to the confinement of the subjects to hospital beds. Artificial light was used to perform the Plaque Index. Data might have been unreliable due to the difficulty in its collection. For one subject, the raw scores presented a posttest plaque index that was actually greater than the pretest for the experimental side, despite the use of a single calibrated examiner. This occurrence may have been due to inadequate lighting, or inadequate disclosing for the pretest.

Neither the Poliswab^R nor the toothbrush accomplished complete supramarginal bacterial plaque removal as evidenced by the Navy Plaque Index. The majority of the remaining supramarginal bacterial plaque was noted at the mesial and distal aspects of the tooth which, although assessed by the index, are areas where bacterial plaque is normally best removed by the use of dental floss. The data would seem to reinforce the necessity of using dental floss for complete plaque removal.

It was noted during the study that Poliswabs^R are easy to

manipulate and convenient to use. The Poliswab^R quickly becomes moist once introduced into the oral cavity, thereby making it appear less resilient and abrasive when applied against tooth structure. The moist foam head of the product collapsed easily against tooth surfaces when any pressure was applied. This observation may account for the small difference in the supramarginal bacterial plaque removal ability when compared to the toothbrush which was not similarly affected by contact with saliva. Subjects overall had positive comments regarding the product. Many found it more gentle than the toothbrush and the flavor to be pleasant. Only one subject dropped out of the study over dissatisfaction with the Poliswab^R. He complained that it "drys out my mouth" and "makes my food taste bad".

Traditionally, dental hygiene has paid little attention to alternative oral hygiene aids in favor of the toothbrush and floss. If the Poliswab^R is as effective as a toothbrush in removing supramarginal bacterial plaque, then the product bears consideration as a valid alternative for use in hospitals, long term care facilities, home health care with oncology patients, and those instances where infection control or patient comfort is a primary consideration. Its use should not be discouraged, but rather recommended by the dental hygiene profession.

Based on the results of the t-tests performed on the Gingival Index scores, the second null hypothesis was not rejected. There was no difference found in the gingival health of either the experimental or control sides of the subjects' mouths. In addition, no change in gingival health was noted in either sides of the subjects' mouths. This finding contradicts those of DeWalt and Gordon et al. who concluded that the toothbrush resulted in more gingival improvement than a Toothette^R. As discussed earlier, because of differences in research methodology and patient populations (DeWalt studied nursing home residents, Gordon studied leukemia patients), their findings might not be directly comparable to this study.

Raw data indicate that the subjects were in relatively good gingival health prior to the study. Such an assessment might be due to the prophylaxis prior to the inception of the study. In addition, some of the participants had Type II-III periodontal disease (American Academy of Periodontology) which is not measured by the Gingival Index. The presence of fibrotic tissue resulting from chronic periodontal disease may have resulted in lower Gingival Index scores due to the lack of acute inflammation present, rather than the actual lack of a disease state.

Since the Navy Plaque Index indicated that both products

were effective in removing supramarginal bacterial plaque (except for interdental areas), some improvement in gingival scores might be anticipated. However, no improvement (or significant deterioration) was noted in the two week period of the study as revealed by the posttest Gingival Index scores. A greater difference in gingival health might have been noted if the study had extended over a longer span of time and if more data collection measurements had been taken during the study. Additionally, there were many factors not identified at the beginning of the study, such as alcoholism and antibiotic regimens, which probably positively influenced the subjects' gingival condition and hence, the results of this portion of the investigation.

During the investigation several subjects developed urinary tract infections, a common complication among spinal cord patients (Stover et al. 47). Two subjects were compelled to withdraw from the study for this reason. The potent antibiotics used to treat recurrent urinary tract infections also affect bacterial colonization of the oral cavity and, therefore, the scores on the Gingival Index. Lack of bleeding and edema in these subjects could have been due to the antibiotics rather than the method of plaque control.

Several subjects in this investigation were identified during the study as suffering from alcoholism. Alcoholism has been identified in the literature as a common problem among

people with spinal cord injuries (Heinemann et al. 619). The active practice of alcoholism made these subjects difficult to work with during the study. They often were not available for their oral hygiene care, missing between one to three sessions during the two week period. In addition, the direct effects of alcohol on the oral tissues may have adversely affected the subjects' gingival health resulting in lower Gingival Index scores. Alcoholics, showing little interest in food and nutrition, often have poor diets. Improper nutrition can have an impact on gingival health as well, adding another extraneous variable influencing the Gingival Index scores. One subject dropped out of the study due to his alcoholism.

Several of the subjects in the study had various mental disorders, such as schizophrenia and bi-polar disorder. Such mental disabilities also are not uncommon to spinal cord patients (Cushman and Dijkers 191). In addition to anti-psychotic medications which are known to cause xerostomia, these subjects were sometimes difficult to work with during the investigation, e.g., one to two sessions of oral hygiene were missed during the two week period. This might have caused an increase in the Gingival Index scores.

Although the nursing staff was instructed not to provide any oral hygiene care for these patients, many of the participants in the study did become dissatisfied with the limited schedule of oral hygiene care. Many of the subjects

were strongly suspected of using various types of therapeutic and non-therapeutic mouthrinses during the duration of the investigation, despite having agreed not to do so. These mouthrinses could have affected the oral tissues by decreasing supramarginal bacterial plaque and gingivitis, thereby, influencing the results of the Gingival Index and the Plaque Index.

Patients with spinal cord injuries often experience involuntary spasticity of the musculature (Katz 108 and Maynard et al. 566). If a person is experiencing such an episode during the rendering of oral hygiene care, that care can be expected to be compromised regardless of the method used. In addition, these subjects were on numerous medications, such as diazepam to control spasticity. Many of these medications are known to cause xerostomic changes in the oral cavity. The spasticity and oral side effects of such medications may have resulted in increased plaque formation and gingivitis leading to higher Gingival Index scores.

Despite the results of the Gingival Index, a slight increase in supramarginal calculus was observed by the caregiver over the two week period of the study on the side where the Poliswab^R was used. It may be that the Poliswab^R did not remove the supramarginal bacterial plaque sufficiently to prevent supragingival calculus formation. It is also possible

that the fatigue involved for the caregiver in providing care to these subjects contributed to a decline in the quality of supramarginal bacterial plaque removal over the two week period. Patients with spinal cord injuries can be demanding of caregivers' time since they are able to perform very few functions themselves. The average amount of time spent providing oral hygiene care for 11 residents varied from three to five hours each evening, depending on the subjects demands and availability. Since the subjects were seen in approximately the same order every evening, it is possible that fatigue resulted in less thorough care for those who received oral hygiene last.

One resident with hypertension was included in the study. Blood pressure measurements were taken daily in an effort to establish if the Poliswab^R with its addition of sodium bicarbonate affected blood pressure measurements in any way. Although the data were not statistically analyzed, blood pressure measurements stayed within normal limits for this subject during the duration of the study (see Appendix I). Since only one person with hypertension was included, no conclusions regarding the safety of the product's use in hypertensive individuals are offered.

Although the results of this investigation indicate that the Poliswab^R effectively removes supramarginal bacterial

plaque, the gingival health of these subjects did not change despite the oral hygiene care they received. This study only measured supramarginal bacterial plaque; however, submarginal bacterial plaque, which is not easily removed by the Poliswab^R, might be a more critical factor as an etiologic agent in periodontal disease. There are many factors in persons with spinal cord injuries that may affect gingival health in addition to the type of oral hygiene aid utilized. Both the Poliswab^R and the toothbrush were shown to be similar in their ability to remove supramarginal bacterial plaque; however, additional therapies are needed to maintain or improve gingival health.

Chapter 5

Summary and Conclusions

Many types of alternative oral hygiene aids used by the nursing profession have not been researched to determine their effectiveness in special patient populations requiring oral wellness. The aim of this investigation was to determine if one of these non-traditional aids, the Poliswab^R, was effective at removing supramarginal bacterial plaque and improving gingival health in a spinal cord unit population. No research in the literature could be located which evaluated the Poliswab^R. Studies which evaluated its precursor, the Toothette^R, differed in their assessment of its effectiveness.

A single-blind, split-mouth study was designed with the toothbrush serving as the control. Oral hygiene care was provided for two weeks by a dental hygienist for 15 volunteer residents from a spinal cord unit at a local Veterans' Affairs Medical Center. The Navy Plaque Index was used to assess supramarginal bacterial plaque removal and the Gingival Index was used to assess gingival health status. The t-test for dependent samples was used to analyze all data at the 0.05 level of significance.

Summary

Contrary to other studies investigating the Toothette^R, this investigation found that the Poliswab^R was as effective as the toothbrush in removing supramarginal bacterial plaque

from the facial and lingual aspects of tooth surfaces. Findings from statistical analyses revealed no statistically significant differences between the experimental and control variables at the 0.05 alpha level; therefore, the null hypothesis that there is no difference in the effectiveness of the Poliswab^R and the toothbrush in removing supramarginal bacterial plaque was not rejected.

This investigation also revealed no improvement or deterioration in gingival health status between either the Poliswab^R or toothbrush groups. This finding is contrary to other investigations reported in the literature which found that the toothbrush is superior to a Toothette^R in improving gingival health. Based on statistical analyses which showed no statistically significant differences between the experimental and control variables at the 0.05 alpha level, the null hypothesis that there is no difference in the effect on gingival health status between the Poliswab^R and the toothbrush was not rejected.

Conclusions

Based on the results of this investigation, the following conclusions are offered.

1. The Poliswab^R is as effective in removing supramarginal bacterial plaque on facial and lingual tooth surfaces as the manual toothbrush.

2. Neither the Poliswab^R nor the toothbrush are effective alone in promoting optimal gingival health in a spinal cord unit population.

Considering the limitations and design of the study in relation to the results, the following recommendations are offered:

1. Replication of this study using a larger population sample and a longer time period is necessary in order to verify validity of the results.

2. Similar studies should be conducted using other caregivers besides dental hygienists to establish the effectiveness of the Poliswab^R when used by multiple non-professional caregivers.

3. Further research is needed to determine the effectiveness of the Poliswab^R for other special patient populations.

4. Further research is needed to establish the safety of the Poliswab^R with sodium bicarbonate for use in hypertensive patients on sodium restricted diets.

5. Additional studies are needed in other populations of persons with spinal cord injuries, those with less severe injuries and those who are not institutionalized, to verify these results.

This investigation revealed that the Poliswab^R is as

effective as the toothbrush in removing supramarginal bacterial plaque in a spinal cord unit population. Neither the Poliswab^R nor the toothbrush was found to have any effect on gingival health. Results of this study suggest that dental hygiene professionals may want to consider the Poliswab^R as a valid substitute for the toothbrush in special patient populations where ease of application, patient comfort, or infection control are important. However, the Poliswab^R may not be the aid of choice in populations with periodontal probings exceeding normal limits due to its inability to remove submarginal bacterial plaque. As with the toothbrush, other appropriate interdental aids, chemotherapeutic mechanisms and professional care are recommended as essential compliments to the Poliswab^R in maintaining oral health.

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APPENDIX A
INFORMED CONSENT
PATIENT INFORMATION SHEET

Appendix A

Informed Consent
Patient Information SheetVETERANS AFFAIRS MEDICAL CENTER
HAMPTON, VIRGINIA 23667

Title of Study: Effects of the Poliswab^R on Supramarginal Bacterial Plaque Removal and Gingival Health in a Spinal Cord Unit Population

Investigators: Beth E. McKinney, BSDH (Principal Investigator)

General Nature and Purpose of Study: You are being requested to participate in a study to assess the effectiveness of a Poliswab^R, a commonly used oral hygiene product, in removing plaque and in improving the health of the gum tissue. Although Poliswabs^R have been used in hospitals and other facilities for many years, there have been very few studies that show if they are effective.

Specific Procedures: For two weeks a dental hygienist will come every day to do your oral hygiene care. Half of your mouth will be cleaned with a Poliswab^R and the other half will be cleaned with a toothbrush. You will be asked not to use any other oral hygiene aids during the study. Before and after the three weeks, a dental hygienist will do an oral exam to assess whether the products have been effective.

Prior to the study, a brief oral exam will be done to determine if you are a suitable candidate. If you have not had your teeth cleaned recently, you will be provided with a cleaning. The Poliswab^R is constructed of soft foam on a handle. The foam contains a mint flavoring and a small amount of baking soda. The toothbrush will be used with water but not with any type of toothpaste. The hygienist will come daily to do the home care for you. The dental hygienist who will conduct the oral exams during the study will perform two measurements that assess how much plaque and gum inflammation are present. To do the measurements, she will be visually looking at the teeth with the aid of a coloring agent and rubbing a dental instrument over the tooth. At the end of two weeks, you may go back to your normal dental care routine.

Risks: Poliswabs^R have been used routinely in hospitals and long-term care facilities since 1964, with no adverse effects

reported to the patients. In fact, they are very popular among some nurses and patients. It is possible that you have already encountered the Poliswab^R in your stay at the V.A. since Poliswabs^R are used there as well. Known risks for this study, however, do include the following:

1. Because the Poliswab^R and the toothbrush do not adequately clean between the teeth, and because you will need to refrain from other oral hygiene measures for two weeks, you may be at a slightly increased risk for developing or worsening existing gum disease that is between the teeth.

2. Having your teeth cleaned for you daily by someone else may be an inconvenience to you.

3. Not being allowed to use other oral hygiene aids may be an inconvenience and/or annoyance to you as well, especially if you feel that cleaning is not adequate or you would wish cleaning more often than once a day.

4. If you are taking a drug for high blood pressure called Procardia (nifedipine), there is an increased chance that you may develop gingival hyperplasia (enlarged, fibrous gum tissue) as a result of the possibly less effective home care regimen in this study.

5. If you have high blood pressure, you may be at risk for elevated blood pressure since the Poliswab^R contains a small amount of baking soda. Your blood pressure will be monitored daily by the dental hygienist.

6. There may be other risks not yet identified.

Benefits: There are several benefits that you may receive by participation in this study. They include:

1. You will be provided with an additional professional cleaning and exam if one is needed.

2. Your participation will help establish for the nursing and dental hygiene professions if the Poliswab^R is an effective product whose use should be encouraged, or if its use should be discouraged because it is ineffective.

3. As a group you will be acknowledged and recognized for your participation in any resulting publications.

4. Oral hygiene care will be provided for you by a dental hygienist daily for two weeks. This may contribute to an improvement in your oral health.

Alternative Therapy: Since this study is not a treatment protocol, there is no alternative therapy except the routine oral hygiene regimen at the V.A. which you are now receiving.

APPENDIX B
INFORMED CONSENT
PATIENT STATEMENT

Appendix B

Informed Consent
Patient Statement

"I have read this consent form; I understand what will be done to me; my questions have been answered; and I give my consent to participate.

"I understand that I may withdraw from this study at any time without penalty or prejudice. I understand that withdrawing from the study will not affect my future care at the Veterans Affairs Medical Center.

"If data resulting from this study are published or presented at meetings, I will not be identified without my prior written permission. I understand that all results are confidential with regard to my identity, and that no individual data will be released to persons outside the research team without the team first obtaining my written permission.

"I acknowledge that I was informed about any possible risks and benefits to my health and well being that may be associated with my participation in this research. I understand that in the event I am physically injured as a result of participation in this research study, if I am eligible for medical care as a veteran, all necessary and appropriate care will be provided. If I am not eligible for medical care as a veteran, humanitarian emergency care will nevertheless be provided.

"I acknowledge that I have been advised of how I may obtain a copy of the results of this research project and that upon my making such a request, a copy will be provided without charge.

"If I have any additional questions about the study, I may call the principal investigator, Beth McKinney, phone # 683-4310. If I have any complaints about the study or the manner in which it is conducted, I may call Dr. Richard Atkinson, ACOS/R&D, phone #722-9961 ext. 683."

Participant's Signature

Date

Witnessed by

Date

I have explained the above to the subject, who in my opinion, understands the procedures and the risks involved.

Principal Investigator

Date

APPENDIX C
NAVY PLAQUE INDEX PROCEDURE

Appendix C

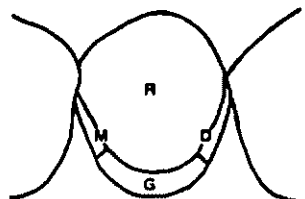
Navy Plaque Index Procedure
by Grossman & FediEquipment

adequate light
disclosing solution
mouth mirror or tongue blade

Procedure

Both facial and lingual surfaces are evaluated for the presence of plaque. Plaque is assessed as being either present or absent. The amount of plaque is not assessed. By placing higher weighted scores on certain sections of the tooth, the gingival portion of the tooth is emphasized. The facial and lingual surfaces are divided into the following sections.

Diagram of surface areas:
M--mesial; G--gingival; D--
distal; and R--remaining

Criteria for Scoring

- 0 if no plaque is present on the entire surface
- 1 if plaque is present in area R
- 2 if plaque is present in area G
- 3 if plaque is present in area M or D

Scoring

Sum of scores for each section
----- = score per tooth
4

Sum of scores of teeth
----- = Navy Plaque Index
Number of teeth examined

Interpretation of Scores

No specific interpretation of scores is offered by the authors.

Appendix D

Navy Plaque Index Chart

Directions: For each tooth examined, circle the letter/number combination corresponding to the areas where plaque was found. Add the numbers for each area on the tooth to obtain a total score for the tooth. Add all scores and divide by the number of teeth examined to get a score for the entire mouth.

	Facial					Lingual				Total Score
1	M3	G2	D3	R1		M3	G2	D3	R1	
2	M3	G2	D3	R1		M3	G2	D3	R1	
3	M3	G2	D3	R1		M3	G2	D3	R1	
4	M3	G2	D3	R1		M3	G2	D3	R1	
5	M3	G2	D3	R1		M3	G2	D3	R1	
6	M3	G2	D3	R1		M3	G2	D3	R1	
7	M3	G2	D3	R1		M3	G2	D3	R1	
8	M3	G2	D3	R1		M3	G2	D3	R1	
9	M3	G2	D3	R1		M3	G2	D3	R1	
10	M3	G2	D3	R1		M3	G2	D3	R1	
11	M3	G2	D3	R1		M3	G2	D3	R1	
12	M3	G2	D3	R1		M3	G2	D3	R1	
13	M3	G2	D3	R1		M3	G2	D3	R1	
14	M3	G2	D3	R1		M3	G2	D3	R1	
15	M3	G2	D3	R1		M3	G2	D3	R1	
16	M3	G2	D3	R1		M3	G2	D3	R1	
17	M3	G2	D3	R1		M3	G2	D3	R1	
18	M3	G2	D3	R1		M3	G2	D3	R1	
19	M3	G2	D3	R1		M3	G2	D3	R1	
20	M3	G2	D3	R1		M3	G2	D3	R1	

21	M3	G2	D3	R1	M3	G2	D3	R1
22	M3	G2	D3	R1	M3	G2	D3	R1
23	M3	G2	D3	R1	M3	G2	D3	R1
24	M3	G2	D3	R1	M3	G2	D3	R1
25	M3	G2	D3	R1	M3	G2	D3	R1
26	M3	G2	D3	R1	M3	G2	D3	R1
27	M3	G2	D3	R1	M3	G2	D3	R1
28	M3	G2	D3	R1	M3	G2	D3	R1
29	M3	G2	D3	R1	M3	G2	D3	R1
30	M3	G2	D3	R1	M3	G2	D3	R1
31	M3	G2	D3	R1	M3	G2	D3	R1
32	M3	G2	D3	R1	M3	G2	D3	R1

APPENDIX E
GINGIVAL INDEX PROCEDURE

Appendix E

Gingival Index Procedure
by Loe & SilnessEquipment

adequate light
periodontal probe
mouth mirror

Procedure

A periodontal probe is gently inserted approximately one millimeter into the gingival sulcus and dragged from the distal line angle to the mesial line angle. Afterwards the gingiva is assessed based on the following criteria. Both facial and lingual surfaces are evaluated. Mesial and distal evaluations are made from the facial surface. A separate score is assigned at each point.

Criteria for Scoring

0 normal gingiva
1 mild inflammation, slight color change, no bleeding
2 moderate inflammation, redness, edema, bleeding
3 severe inflammation, redness, ulceration, spontaneous bleeding

Scoring

$$\frac{\text{distal} + \text{facial} + \text{mesial} + \text{lingual}}{4} = \text{score per tooth}$$

$$\frac{\text{Sum of scores for all teeth}}{\text{Number of teeth examined}} = \text{Gingival Index}$$
Interpretation of Scores

0.1-1.0 Mild gingivitis
1.1-2.0 Moderate gingivitis
2.1-3.0 Severe gingivitis

23								
24								
25								
26								
27								
28								
29								
30								
31								
32								

APPENDIX G
NAVY PLAQUE INDEX
RAW DATA

Appendix G
Navy Plaque Index
Raw Data

Subject	Experimental		Control	
	Pretest	Posttest	Pretest	Posttest
A	10.69	1.54	7.67	2.25
B	10.93	2.13	8.53	3.87
C	13.00	6.64	13.60	5.20
D	3.33	1.33	4.20	1.20
E	4.33	3.67	5.33	0.00
F	9.60	0.00	7.00	1.00
G	11.77	11.23	13.00	12.17
H	11.00	3.00	10.33	3.00
I	12.60	2.40	12.64	1.50
J	13.34	6.21	14.14	2.50
K	7.50	8.40	11.75	8.25
L	13.86	0.36	13.12	2.50
M	10.00	4.92	9.00	8.77
N	6.50	5.40	7.60	0.50
O	9.82	4.64	12.58	3.17

Appendix H
Gingival Index
Raw Data

Subject	Experimental		Control	
	Pretest	Posttest	Pretest	Posttest
A	0.63	0.00	0.33	0.00
B	0.00	0.15	0.00	0.07
C	0.09	0.25	0.09	0.32
D	0.08	0.02	0.05	0.00
E	0.08	0.50	0.04	0.38
F	0.00	0.15	0.00	0.21
G	0.00	0.09	0.00	0.10
H	0.00	0.19	0.04	0.08
I	0.36	0.88	0.07	0.41
J	0.57	0.41	0.54	0.09
K	0.05	0.00	0.00	0.00

APPENDIX I
BLOOD PRESSURE MEASUREMENTS
RAW DATA

Appendix I
Blood Pressure Measurements
Raw Data

Day 1	186/114 *
Day 2	170/110 *
Day 3	130/86
Day 4	134/88
Day 5	126/72
Day 6	128/80
Day 7	138/82
Day 8	136/82
Day 9	subject unavailable
Day 10	138/88
Day 11	132/84
Day 12	128/88
Day 13	136/86
Day 14	132/82

* measurements taken with a suspected broken sphygmomanometer