CASE WESTERN RESERVE UNIVERSITY

SCHOOL OF DENTISTRY

GRADUATE STUDIES

We hereby approve the thesis of

David Ervin Harmon, Jr.

candidate for the degree Master of Science

in Dentistry.

Signed: G. T. Terezhalmy, DDS, MA
(Chairman)

Sachiko Nelson

Date: July 8, 1996

THE EFFECTS OF AN ULTRASONIC TOOTHBRUSH ON ESTABLISHED GINGIVITIS IN ORTHODONTIC PATIENTS AGED ELEVEN THROUGH SEVENTEEN

by

DAVID ERVIN HARMON, Jr.

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School of Dentistry

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THE EFFECTS OF AN ULTRASONIC TOOTHBRUSH ON ESTABLISHED GINGIVITIS IN ORTHODONTIC PATIENTS AGED ELEVEN THROUGH SEVENTEEN

Abstract

by

DAVID ERVIN HARMON, JR.

The purpose of this double-blind clinical study was to investigate and determine the effectiveness of an ultrasonic toothbrush on established gingivitis in full-banded orthodontic patients aged eleven through seventeen. Forty-eight subjects (equal proportion of male and females) were randomly selected and assigned to two groups; ultrasonic toothbrush and placebo toothbrush. The groups were evaluated initially to establish a baseline (T_1), and subsequently at 6-weeks (T_2) and 12-weeks (T_3). The parameters examined were the gingival index of Loe and Silness, the Turesky plaque index and the Eastman Bleeding Index .

Repeated measures ANOVA was calculated. Significant reductions in the gingival index ($p = 0.000$ at time period T_3) and bleeding index ($p = 0.000$ at time periods T_2 and T_3) were found in the group using the ultrasonic toothbrush. At the end of this three-month study the group using the ultrasonic toothbrush showed an 83% reduction of gingival bleeding compared to 21.0% for the placebo toothbrush group. A 46% reduction in the gingival index was also seen in the ultrasonic group compared to 23% in the placebo group. Reduction of overnight plaque accumulation in the ultrasonic group was 27.1% versus 16.1% in the placebo group. Although reductions of overnight plaque formation were clinically apparent by week-twelve, it was not statistically significant. A comparison of intraoral photographs taken of each subject at baseline and twelve-weeks, demonstrated clinically apparent reductions in gingival swelling and gingival redness in the ultrasonic toothbrush group when compared to the placebo toothbrush group.

An ultrasonic toothbrush when used twice daily for three minutes, proved to be an important therapeutic device in controlling gingival inflammation, bleeding, and plaque accumulation in orthodontic patients ages eleven through seventeen years of age with established gingivitis.

DEDICATION

I would like to dedicate this thesis to my mother Rosalind C Harmon, who has for thirty-years tolerated me, all of my dreams and ideas. I would like to thank her for all of the sacrifices she has made for me and Carla to reach our goals. Now in the years to come it is my turn to start giving back.

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INTRODUCTION

Effectively removing plaque is a skill many people are unable to perfect. Orthodontic patients with fixed appliances have a much more difficult time cleaning their teeth than individuals without orthodontic appliances. Periodontal problems following the placement of orthodontic bands, brackets, and archwires are enhanced by the inherent surface irregularities on the bands and brackets. Surface irregularities also allow for the collection and retention of food and debris. Orthodontic appliances also protect plaque from the actions of brushing, mastication and the antimicrobial activities of saliva (Zachrisson, Zachrisson 1972). It would be beneficial if a toothbrush could be used during the active stages of orthodontic treatment which would reduce bacterial plaque accumulation, improve the gingival health, reduce the incidence of bleeding, and minimize the progression of periodontal disease in these patients (Lundstrom, Krasse 1987).

Sonic and ultrasonic devices have many clinical applications in the field of dentistry. Such devices include dental scalers and sonic toothbrushes; both aid in the removal of harmful plaque and calculus. Sonic frequencies are described as sound frequencies which fall below 20,000 Hz. Sonic scalers operate between frequencies of 2,000 to 6,000 Hz. Ultrasonic scalers and cleaners operate

at frequencies between 25,000-45,000 Hz. (Figure 1). Sound intensity can range from low to high depending on the magnitude of ultrasound (Bueche 1988) Most humans cannot hear frequencies above 20,000Hz. Sound intensity is defined as the power passing thorough a unit area perpendicular to the direction of wave propagation. As ultrasonic energy propagates through a medium its energy is transferred to the medium as heat. The rate or the amount of heat transferred is directly proportional to the frequency and intensity of the ultrasound (Bueche 1988). High and low frequency, high intensity ultrasound transfers significant energy which is often expressed as heat to the medium it propagates through (Bueche 1988). High frequency, low intensity ultrasound transfers significantly less energy and heat to its medium.

The use of ultrasound in medicine has many applications. The frequency often employed in medical ultrasound is around 1.5 MHz. High frequency, low intensity ultrasound has been shown to have a synergistic effect on the rate of healing in damaged tissues (Pilla, Mont 1992). The mechanical effects of ultrasound on dental plaque and calculus is well understood. However, the biological affects on the microbiological environment of dental plaque and the mechanism of how ultrasound effects the rate of gingival healing, or regulate gingival responses to bacterial challenges is not well established. The ultrasonic toothbrush operates at a frequency of 1.6 MHz. Its safety and effectiveness, versus a manual toothbrush

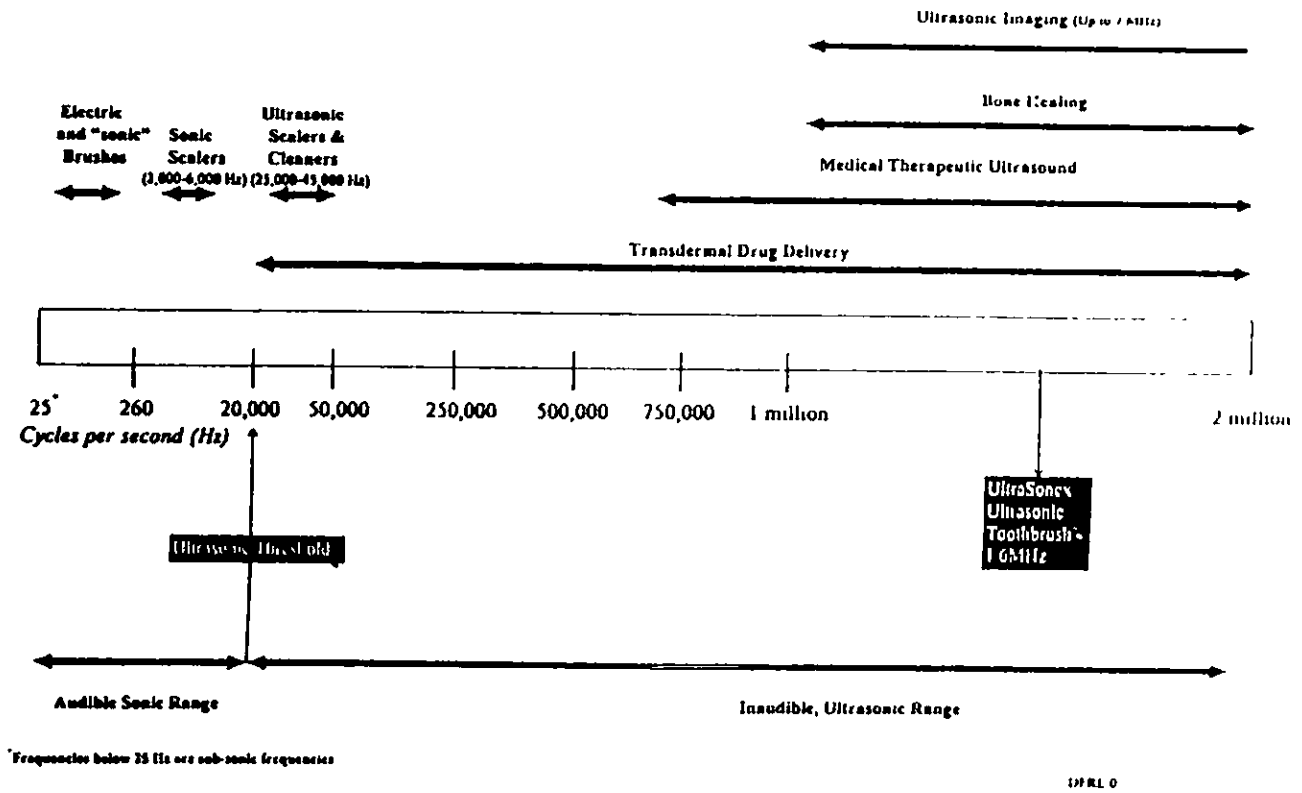


Figure 1. The differences of frequencies of sonic versus ultrasonic devices.

(Figure Courtesy of Sonex International Corporation)

has been well documented (Terezhalmy et al , 1994). This study was designed to evaluate the effectiveness of the ultrasonic toothbrush in orthodontic patients ages eleven through seventeen with established gingivitis in a double blinded clinical study over a three month period.

LITERATURE REVIEW

Gingivitis

Although there are many causes for gingivitis, clinicians and investigators believe that microorganisms and their metabolic by-products play the most significant role in the initiation of the inflammatory process. Similarly, a variety of metabolic and immunologic factors determine host response to these irritants (Goldman, Cohen 1990). The infectious process of gingivitis often represents a dynamic interrelationship that is modulated by the changing equilibrium between the defense mechanisms of the host versus the destructive forces of the irritant

Inflammatory processes involving the gingiva usually encompass the sulcular epithelium, col area, the gingival corium, the junctional epithelium, and the outer epithelial covering. According to Goldman and Cohen (1990), the initial lesion occurs in the col site, with a subjacent accumulation of inflammatory cells seen in the corium. Most of the cells present are lymphocytes and plasma cells, with some histiocytes and polymorphonuclear leukocytes. The lesion will later show ulceration of the sulcular epithelium, disruption of gingival fibers, and the dissolution of the collagen fibers by the collagenase type enzymes that are liberated by inflammatory cells (Loesche, Laughon 1980).

One of the earliest and most significant clinical sign of gingival inflammation is the presence of bleeding on probing Other signs include changes in the texture and color of gingival tissues, enlargement of the crestal portion of the gingivae with a tendency for disengagement of the margin with retraction and edema (Goldman, Cohen 1990). Furthermores, the gingival margins become irregular, with deepening of the interdental col, and craterlike lesions begin to develop. Because of increased vascularity, the slightest gingival manipulation of afflicted tissues initiates bleeding from the gingival sulcus The inflammation and destruction of gingival fibers accounts for the loss of the stippling effect which is often apparent in normal gingival tissues.

Many scientific experiments have consistently shown that prolonged accumulation of bacterial plaque can produce gingivitis in otherwise healthy patients and there is also a strong correlation between the type and number of organisms present in the plaque and the amount of gingival inflammation (Loe, et al , 1965). The persistence of bacterial plaque on tooth surfaces as well as its toxic by-products, represent the most important link in the chain of events that lead to both periodontal destruction and tooth decay (Loe, Silness 1973). Normally, inflamed gingival tissues are quickly repaired by the recruitment of fibroblasts, and within a few days the tissues are restored to their original form. If, however, plaque control is inadequate, the immune system and the body's reparative mechanisms are impaired, the infectious process of gingivitis can progress rapidly as a function

of the causative agent, time, age, and the resistive and reparative powers of the patient (Goldman, Cohen 1990).

A variety of bacteria are indigenous to the mouth. This is attributed to the diversity of surfaces available for colonization, and the comparatively unselective conditions that prevail in the mouth (Holmberg, Hallander 1973; Socransky, Manganiello 1971). Moore et al., (1982) detected 166 bacterial species and subspecies in periodontally healthy patients. Of these bacteria, Actinomyces naeslundii, Actinomyces odontolyticus, Lactobacillus species D-3, Fusobacterium nucleatum, Streptoccocus angiosus, Veillonella parvula and Treponema species A appeared to be the most likely etiologic agents of gingivitis.

Members of the genus Actinomyces are gram positive and appear to be strict parasites. A. israelii , found in the human mouth and in salivary calculi, is thought to be non-pathogenic. A. viscous has also been isolated from the oral cavity of man, and is associated with gingival plaque and periodontal disease (Wilson, et al., 1983). The physical association of certain Streptococci and Actinomyces have the ability to convert lactic acid into propionic acid and may be the necessary prerequisite for the colonization by Villanelle, Fusobacteria and Treponema species (Ritz 1967) which produce stronger and more destructive irritants such as propionic acid, butyric acid or both (Moore et al., 1982). Loesche, Laughton (1980) reported the presence of low to moderate levels of Treponema species even in healthy subjects. When the number of Treponema organisms exceeds the

subjects threshold level, a gingival response occurs (Loesche, Laughton 1980). Similarly, the presence of high quantities of spirochetes have been detected in individuals suffering from an acute case of gingivitis, and daily mechanical removal of these irritants resulted in resolution of the gingival inflammation (Goldman, Cohen 1990).

Most patients who undergo orthodontic therapy receive fixed appliances. The components of the appliance create new retention areas for microorganisms and impede proper access to the tooth surfaces (Sakamaki, Bahn 1968). Increased retention of bacterial plaque contributes to unfavorable gingival conditions (Balenseifen, Madonia 1970). Zachrisson and Zachrisson (1972) also found that the placement of bands and arch wires in orthodontic patients often leads to an increase in the number of harmful odontopathic and periodontopathic organisms on tooth surfaces. Others (Balenseifen, Madonia 1970; Corbett et al., 1981; Scheie et al., 1984) have shown that the number of Streptococcus mutans and Lactobacilli in dental plaque is significantly higher during than before and after orthodontic treatment. Although some orthodontic patients may have good or even excellent plaque control, they are still susceptible to developing gingivitis and decalcification (Lundstrom, Krasse 1987).

According to Theilade et al., (1966), prolonged accumulation of bacterial plaque can produce gingivitis in otherwise healthy patients, and it is usually resolved with the mechanical removal of plaque and reinstitution of oral hygiene practices. The three basic approaches to the prevention of gingivitis are to (1) eliminate all clinically detectable plaque, (2) reduce the level of plaque below the individual's threshold for disease, and (3) alteration of the microbial composition of plaque (Korman 1986).

The first approach has shown that frequent prophylaxis and good oral hygiene will inhibit plaque formation and gingivitis, and it will prevent loss of periodontal attachment (Axelson, Lindhe 1987) However, most individuals do not efficiently remove plaque The second approach involves the reduction of plaque below the individual's threshold for disease. It must be realized that the threshold may change because of alterations in the host's ability to deal with the microbial burden. The third approach is to alter the microbial composition of plaque such that disease does not develop. All three of the above approaches may be attainable by mechanical means since repeated disruption of plaque maturation could result in a plaque with lower levels of certain bacterial groups (Korman 1986).

Manual Toothbrushes

The first toothbrush, made of ivory and bristles made from horse's mane, appeared in China around 1000 A.D. However, the term "toothbrush" was not introduced to the English vocabulary until the early 19th Century By 1920 there were well over a hundred different brands of toothbrushes on the market in the United States, with variable designs (Mandel 1993). In the early 1920s and 1930s toothbrushes all had hard to very hard bristles. It was believed the harder the bristles the greater the effectiveness in cleaning teeth. Many of the bristles in the early days were made from animal hair, generally horse's hair. Nylon bristled toothbrushes did not appear on the market until 1938. According to Mandel, the appearance of the nylon bristle revolutionized the toothbrush industry. Mandel also stated that nylon bristles offered many advantages over natural bristles such as homogeneity, elasticity, resistance to fracture, repulsion of water, and most importantly less susceptibility to microbial contamination. Even with the advent of the new nylon bristles, many health care practitioners believed that natural "hard textured" bristles along with very aggressive brushing techniques were truly superior in cleaning the dentition than the nylon bristled toothbrushes (Mandel 1993).

By the late 1950's and early 1960's there appeared to be a widespread shift towards soft-bristled nylon toothbrushes and the 1970s and 1980s witnessed the evolution of accepted criteria for the design of the adult toothbrush (Mandel 1993).

Design specifications included (1) a relatively small head (30 mm X 10 mm) for easy access to all areas of the mouth including the molar regions, (2) a wide and long handle to ensure a firm grip, (3) soft nylon bristles 0.2 mm in diameter and 10 mm long with rounded ends to minimize gingival damage, and (4) a multituffed straight trimmed brush head for optimal cleaning (Fransen 1986). These criteria were arbitrary, and Park et al., (1985) believed that no particular toothbrush design was superior for plaque removal, instead the thoroughness and dexterity of the brusher was by far the most important determinant. By the late 1980s a variety of brushing techniques have also been (Bass, Charter, and Roll) advocated by clinicians, with the Bass method being the most widely used (Manson, Eley 1989)

Electro-Mechanical Toothbrushes

The notion that all manual toothbrushes were relatively equal and that the effectiveness of plaque removal was dependent upon the manual dexterity of the user, spawned the advent of the electric toothbrush, which made its debut in 1939. According to Mandel (1993) the electric toothbrush had very little effect on the market until its resurgence in the 1960s, and again in the late 1980s. Three of the most successful electromechanical toothbrushes introduced include the Interplak® (Bausch and Lomb), Braun's Oral-B® (Epident EPI™ Products) and the Sonicare® (Optiva Corporation) toothbrushes (Table 1).

Table--1. Types of Toothbrushes

Type	Representative brands	Motion type and technique	Motion controlled by	Motion powered by
Manual	Butler® Gum® Crest Complete® Colgate® Precision™ Oral-B® Advantage™	Bass, Charters, Stillman, etc.	user	user
Electro-Mechanical	Panasonic® Teledyne Water Pik®	sideways vibrating brush head	machine	electric motor with circular to linear converter
	sonicare™	sideways vibrating brush head	machine	electric magnet with pivoted linear linkage
	soniplak™	vertically vibrating brush head	machine	electric motor generating harmonic vibrations
	Interplak®	rotating tufts	machine	electric motor with gears and linkage
	Braun® Oral-B® Omron™ Oralgiene™ Rota-dent®	rotating brush-head	machine	electric motor circular motion
Ultrasonic	UltraSonex®	Bass, Charters, Stillman, etc.	user	user, adjunct ultrasound generated by piezo-electric crystal

(Table Courtesy of Sonex International Corporation)

The Inteplak® toothbrush uses rack and pinion gearing to produce an oscillating, counter-rotational motion with tufts whirling at 4,200 revolutions per minute. The Braun Oral-B® toothbrush also uses an oscillating motion with tufts moving at a rate of 2,800 rotations per minute. A four-week clinical evaluation of the effects of the Interplak® toothbrush was conducted by Yankel et al , (1985) on eleven orthodontic patients with established gingivitis. Although this study lacked a control group and a large sample size, they reported that the InterPlak® toothbrush had an important and positive impact on the status of the gingiva on orthodontic patients. A 60-day blinded crossover study design, also tested the effects of the Interplak® toothbrush versus a manual toothbrush on orthodontic patients. Wilcoxon et al., (1991) reported the Interplak® toothbrush to be statistically superior in reducing gingivitis and plaque accumulation when compared to a manual toothbrush. Although this study used a control group and a cross-over study design, the sample size was again relatively small, and the control and the experimental toothbrush had apparent physical and mechanical differences. Interplak® toothbrush does not have a timer system, the amount of time spent brushing is user dependent.

A four-month double-blinded cross-over clinical study of the effectiveness of a Sonicare® toothbrush versus a manual toothbrush, (White 1996) reported clinically significant reductions of plaque, gingival swelling, and bleeding by the Sonicare®

group. Although it was considered double-blind, the participants could see physical and mechanical differences between the two toothbrushes. The Sonicare® toothbrush recommended brushing time is two-minutes. According to the manufacturer the brush uses a Smartimer™ system that divides the two minutes into thirty-second intervals, which encourages the patient to give equal attention to all four quadrants of the mouth. After the two-minute duration is over the brush automatically shuts off.

Ultrasonex™ Ultrasonic Toothbrush

The Ultrasonex™ Ultrasonic toothbrush is a manual toothbrush with a piezo-electric ultrasonic (transducer) embedded in the brush head (Figure 2). The ultrasonic emitter is driven by a power supply located in the handle that operates at 1 6 MHz. The transducer contracts and expands volumetrically in tune with the impulses provided by the power supply, converting the electric energy into ultrasonic waves. The ultrasonic waves are transmitted from the transducer to the brush head and the bristles. The bristle vibration amplitude is microscopic and does not provide any tactile feedback to the user Dentifrice is used to conduct the ultrasonic waves to the teeth and soft tissue. According to the manufacturer, gingival fluids in the sulcus can also conduct the ultrasonic waves into subgingival environment.



Figure 2. The Ultrasonex™ ultrasonic toothbrush
(Courtesy of Sonex International Corportation)

The 1.6 MHz, high-frequency, low-intensity sine-wave ultrasound was specifically chosen by the manufacturer to avoid tissue heating and to provide a noninvasive modality with a capability of complete tissue penetration. The system is fully automated, all solid-state electronics. A unique, large-scale integrated microcircuit monitors and controls the ultrasonic output of the device. It turns off automatically (three-minutes) when the preset dosage is achieved. The brush head is tapered anteriorly (12 mm x 30 mm to 10 mm x 30 mm) for easy access. The brush also has a long handle (8.5 inches) with a circular diameter (7/8 inch) to ensure a firm grip The standard bristles are ultrasoft, multitufted, straight trimmed, polished with round ends, and made of 5mL (0.13 mm) Tynex® Nylon Monfilament (Dupont Corporation) for optimal cleaning. Special bristles of 4mL (0.10 mm) are available for patients with highly sensitive gingival, severe inflammation, erythema, and a tendency toward spontaneous hemorrhage and ulceration.

In a thirty-day clinical study designed to determine the efficacy of the ultrasonic toothbrush in reducing the levels of subgingival bacteria, quantification by DNA probe analysis demonstrated statistically significant reductions ($p=0.005$) of the mean total subgingival flora from 3.9×10^6 CFU/sample at baseline to 1.3×10^6 CFU/sample at 4 weeks (Besselar 1994) Another thirty day study evaluating the efficacy and safety of an ultrasonic toothbrush versus a conventional toothbrush concluded that the ultrasonic toothbrush was significantly more effective in

removing plaque (p=0.001) and reducing the proportion of high plaque surfaces (p=0 005) following overnight plaque formation (Terezhalmy, et al., 1994). A long-term (six-month) study reported that although there was no significant reduction in overnight plaque formation and proportion of high plaque surfaces from baseline to day-thirty, significant reduction in overnight plaque formation (p=0.0001) was observed with the ultrasonic toothbrush at the six-month follow up (Terezhalmy et al , 1995). Since a necessary first step in plaque formation is bacterial adherence to oral surfaces, this observation suggests that the high-frequency, low-intensity sine wave ultrasound (1.6 MHz) not only removes bacteria already bound to a tooth more efficiently than a conventional toothbrush (Terezhalmy et al., 1995), but may also alter cell surface components belived essential for bacteria to attach to tooth surfaces and other cells (McInnes et al , 1992), and consequently, reduce overnight plaque formation.

It is universally accepted that there is a direct correlation between plaque accumulation and gingival inflammation (Loe et al., 1965). If supragingival plaque is allowed to grow and mature it will produce inflammatory changes that modify the anatomical relationship between the gingival margin and the tooth surface. Gingivitis is characterized clinically by changes in the color, form, position, and surface apperarance of gingival tissue and may be assessed by the gingival index. In a short-term evaluation of an ultrasonic toothbrush, the gingival index did not differ significantly between baseline and the fifteen-day visit, but was

statistically smaller at thirty-days (Terezhalmy et al., 1994). In the long-term study, there was a significant difference in the gingival index ($p=0.0002$) between the experimental group and the control group at the thirty-day visit, this improvement in the gingival index ($p<0.001$) continued in the experimental group for the duration of the study and following cross-over of the control group to the ultrasonic group at thirty-days a similar reduction in the gingival index ($p<0.001$) was observed at six months (Terezhalmy et al., 1995).

Supragingival plaque appears to be necessary for the initial colonization of the subgingival environment (Korman 1986). Studies have demonstrated that subgingival recolonization will occur within two months following root surface instrumentation if the supragingival deposits are not controlled (Magnusson et al , 1982). The end result is a new ecologic subgingival setting protected from and independent of the supragingival environment. The subgingival bactera can induce one or more aspects of periodontal diseases including inflammation and vasculitis, and manifest clinically as gingival bleeding, increased sulcular temperture, pocket formation (apical migration of the functional epithelium along the root surface), alveolar bone loss, and tooth mobility. Bleeding on probing reflects an inflammatory lesion in the connective tissue below the junctional epithelim. Although bleeding does not differentiate between gingivitis and periodontitis, its presence provides an objective diagnostic sign that can be easily monitored and

used to evaluate areas inaccessiable for visual inspection Its absence is a reliable negative predictor of future attachment loss (Lang et al., 1990)

A short term study found that by day-thirty the bleeding index improved significantly in the experimental group versus the control group. In a long term study, the significant improvement noted in the bleeding index ($p<0.001$) in the experimental group at day-thirty could not be maintained long-term, however, following the cross-over of the control group on day-thirty, the bleeding index of that group did not deteriorate further while the patients were using the ultrasonic toothbrush (Terezhalmy et al., 1994, 1995). In the above study, a professional prophylaxis and root surface instrumentation was not performed for at least sixty-days prior to baseline until the six-month follow up. Although at the six-month visit, reduced supragingival plaque accumulation and reduction in the gingival index was supported by the data, the presence of subgingival colonization during the first six-months of the study is supported by the finding that the bleeding index was highest at six-months. This suggests the possibility that significant subgingival colonization has occured prior to the initiation of the study which requires professional root surface instrumentation for complete removal. However, once the subgingival environment is appropiately instrumented, the ultrasonic toothbrush can significantly slow down recolonization (Terezhalmy et al., 1995).

Ultrasound in Medicine and Dentistry

Low Frequency, High Intensity Ultrasound

The results of a study designed to assess the effects of ultrasonic scalers on supragingival plaque in vivo and in vitro concluded that ultrasonic scalers can have a profound effect on microorganisms both in vitro and in vivo (Mousques et al., 1980). Mousques et al., observed a reduction in the number of spirochetes and motile rods with a subsequent increase in coccoid cells. According to Thilo and Baehni (1987), ultrasonic plaque and calculus removal is primarily mechanical, causing fracture of the attached deposits through the resultant shock waves. The disintegrated calculus deposits and plaque form a slurry which further assist in removal of additional plaque and other hardened deposits

Walmsley (1985) postulated that bacterial cell destruction may also occur by a mechanism he termed "acoustic cavitation". He believed that acoustic cavitation involves the pulsation of gas or vapor-filled voids in a sound field. He identified two types of cavitation, stable and transient. Stable cavitation causes cavities to pulsate for many cycles in the sound field, transient cavitation involves the spontaneous generation and collapse of cavities. He also stated that cavities may be present already, or they may grow from pre-existing nuclei as a result of rectified diffusion. Sound bubbles will oscillate in resonance with the frequency of the sound field and act as powerful concentrators of acoustic energy into shearing forces and harmful microstreaming fields.

Acoustic energy may also attack objects such as cells in the irradiated medium by radiation forces. Rapidly forming bubbles begin to collapse violently; local temperatures approaching 10^4 K result, causing thermal decomposition of water (Nyborg, Ziskin 1985) and the release of free hydroxy radicals. The biological effects of free radicals are quite severe. Free radicals can cause wide array of damage to biological systems such as severely damage or weaken cell membranes and cause irreparable genetic damage to susceptible cells and tissues.

High Frequency, High Intensity Ultrasound

High frequency, high intensity energy ultrasound is also known to generate destructive cavitational forces as well as extreme heating of the medium through which the energy propagates (Walmsley 1985) The ultrasonic waves are generated when particles of the medium are energized causing them to violently vibrate and transfer energy to adjacent particles (Walmsley 1985). Ultrasonic energy travels either in a longitudinal or transverse fashion. Longitudinal propagation travels in the direction of the wave, while transverse propagation causes particles to be displaced at right angles of the direction of the wave. Transverse waves can only travel in solids, whereas longitudinal waves travel most effectively in fluids. The human body can transmit both longitudinal and transverse waves, however, soft tissues can only transmit longitudinal waves while transverse waves are usually being dissipated as heat (Walmsley 1985).

Cavitation energy requires the presence of gaseous bodies or bubbles in the fluid, known as cavitational nuclei (Davies 1959). As the bubbles pulsate, transverse waves are set up on its surface (Davies 1959) which become distorted and more unstable as the ultrasonic amplitude increases. According to Nyborg and Ziskin (1985) microbubbles will occur around the original bubble. The formation of microbubbles are usually associated with a transient cavitational field, where the bubbles demonstrate the collapse phenomenon (Davies 1959). Gases in these bubbles reach temperatures of thousands of degrees Celsius and several thousand atmospheres of pressure. The final cavitational effect is caused by the collapse of the bubble which in turn generates high velocity destructive shock waves that can severely damage the cell wall of biological tissues (Nyborg, Ziskin 1985).

High Frequency, Low Intensity Ultrasound

Contrary to the previous discussion, numerous user friendly and safe high frequency, low intensity devices are being used in medicine today. They have been proven safe and effective in the hands of laymen. Bone healing accelerators, fetal monitors and an ultrasonic toothbrush have been declared safe by the FDA for unsupervised home use.

The ultrasonic toothbrush is a manual toothbrush with an ultrasonic component. The bristles of the ultrasonic toothbrush are designed to contact and remove plaque from tooth and gingival surfaces, thereby reducing the level of harmful organisms and subsequently reducing inflammation. The ultrasound

emitted from the bristles is postulated to aid in the loosening of the bond of the bacterial plaque, thus improving the plaque removal capabilities of the bristles (McInnes et al ,1992). In addition, the ultrasound liberated may heighten the immune response by stimulating macrophages to release potent chemotactic and phagocytic agents that could increase the rate of destruction of harmful microorganisms within the oral cavity.

Extensive research has been conducted on how ultrasound accelerates the rate of healing in bone fractures and soft tissue. It is believed that ultrasound's mechanical pressure waves may mediate biological activity directly by mechanical deformation of the cell membrane or indirectly by some sort of electrical effect caused by cell deformation (Heckman, Ryaby 1994). The cell membrane appears to be the target, with various second-messenger systems proposed as the initiators of the biological response (Pilla and Mont 1992). While low frequency, high intensity ultrasound propagates through the biological medium (tissue system) causing drastic pressure and temperature changes, high frequency, low intensity ultrasound causes negligible temperatures changes because of the low incident of power dissipation.

A study conducted by Wang and Lewallen (1994) demonstrated that ultrasound (1.5Mhz) significantly increased the mechanical parameters of healing fracture calluses in adult rats without causing damaging thermal or pressure effects. It has been observed that the predominant cells at the site of tissue injury are

initially polymorphonuclear leukocytes followed by monocytes. Monocytes that arrive at the site of injury develop into activated macrophages, these cells are believed to work very closely with developing fibroblasts. This close relationship suggests that there may be an interaction between the two cell populations (Young, Dyson 1990). It is therefore postulated that macrophages can liberate fibroblastic and mitogenic products High frequency, low intensity ultrasound appears to be effective in amplifying the release of various mitogenic products from activated macrophages. The most likely cause of cell permeability changes are due to the effects of cavitation, in which the gas bubbles, a few microns in diameter, oscillate in a regular fashion for many cycles (Young, Dyson 1990). The enhanced microstreaming around these cells may be responsible for some changes in membrane permeability (Mortimer, Dyson 1988). Although caviational forces may be hazardous, some investigators have demonstrated that cavitational forces can also stimulate collagen synthesis. Moreover they noticed an increase in the rate of protein synthesis and did not report harmful effects to the cells irradiated (Duarte 1983).

In a normal subject complete vascularization of a surgical wound site is generally achieved in 6 -7 days. Since capillary growth occurs during inflammation and the formation of granulation tissue is accompanied by an increased accumulation of leukocytes and macrophages, it has been suggested that initiation of the process of angiogenisis may be due to the release of some angiogenic

stimulating type substances from these cells (Young, Dyson 1990) Therapeutic levels of high frequency, low intensity ultrasound have been reported to effect the rate of angiogensis. It has been postulated that changes in cell membrane permeability, induced by the ultrasound, cause an acceleration in the rate of repair (Diegelmann et al., 1982; Mortimer, Dyson 1988). Changes in cell permeability to calcium ions may have a dramatic effect on cell behavior. Calcium ion fluxes, in response to membrane permeability changes, act as chemical signals (second messengers) which influences the rate of tissue response and influence biological activity of inflammatory cells present in the area (Diegelmann et al.,1982)

The relationship between the mechanical removal of plaque and the reduction of gingivitis has been well established. The ability to effectively remove plaque with a manual toothbrush appears to be directly related to the level of dexterity of the user. According to Terezhalmy et al., (1995) the effects of ultrasound coupled with mechanical plaque removal appears to be more beneficial in reducing bleeding, swelling, and plaque accumulation than the effect of a manual toothbrush, and the ultrasonic toothbrush has been shown to be safe in maintaining optimal oral hygiene in adult non-orthodontic patients. Orthodontic patients are especially susceptible to gingivitis because of inherent surface irregularities of the brackets. Surface irregularities make effective plaque removal very difficult and presents a significant challenge to the patient, as well as, the orthodontist. The

effects of the ultrasonic toothbrush on orthodontic patients, has not been established.

Department of Orthodontics

OBJECTIVE OF THIS STUDY

The purpose of the present study is to examine the effects of the ultrasonic toothbrush on orthodontic patients aged eleven through seventeen with established gingivitis. Specifically to determine the effectiveness of an ultrasonic toothbrush in the reduction of overnight plaque formation, gingivitis, and gingival bleeding over a twelve-week period, were studied

Null Hypothesis

The following null hypotheses will be tested:

1) The placebo and ultrasonic toothbrush groups are similar in reducing gingival swelling at six-weeks and at twelve-weeks.

2) The placebo and ultrasonic toothbrush groups are similar in reducing bleeding at six-weeks and at twelve-weeks.

3) The placebo and ultrasonic toothbrush groups are similar in reducing overnight plaque formation at six-weeks and at twelve weeks

MATERIALS AND METHODS

Experimental Design

This study was conducted as a randomized, double-blinded, placebo-controlled, clinical trial. The blinding process (Chamlers et al., 1983) ensured that there was no way to predict or influence which treatment any of the subjects received. The placebo and experimental toothbrushes were physically similar, however, the ultrasonic component of the placebo toothbrushes were inactive. This did not provide any mechanical clues to the patients or the investigator since ultrasound is silent and "motionless". This study design was chosen to allow for the collection of data free of bias, which can be a concern in a clinical study since it can potentially alter the results and lead to false conclusions (Chamlers et al, 1983).

Criteria for Patient Eligibility

Forty-eight subjects randomly selected from the patient pool of the Department of Orthodontics at Case Western Reserve University School of Dentistry, Cleveland, Ohio qualified for this study based on the following criteria:

1) They were at least eleven years of age but no older than seventeen years of age.

2) They had evidence of gingivitis, but no evidence of periodontitis.

3) They were undergoing full-banded and bonded extraction or non extraction orthodontic treatment with brackets on their anterior teeth and bands on the molar teeth

4) They had no evidence of decay on their teeth.

5) They were not taking any systemic antibiotics or had any significant systemic disease

6) They had no known allergies to Crest® regular toothpaste.

7) They were not scheduled to have their orthodontic appliances removed before the end of the study.

Equal proportions of males and females were selected for participation in this study. The age range is representative of the population of orthodontic patients in active treatment in the Department of Orthodontics.

Treatment Administration

The placebo and experimental toothbrushes were supplied by Sonex International Corporation of Brewster, New York. The Crest® regular toothpaste was supplied by Proctor and Gamble Company, Cincinnati, Ohio. All of the toothbrushes and toothpaste were dispensed at Case Western Reserve University School of Dentistry. The subjects were instructed to contact the principle investigator in case they needed more toothpaste. The patients were each instructed to use the assigned toothbrush once in the morning, and once at night for three minutes.

Subject Recruitment and Randomization Procedure

The clinical records administrator of the School of Dentistry, supplied a master listing of all active orthodontic patients aged eleven through seventeen. A total of 214 subjects fit the initial criteria. The pool of candidates were then divided based on gender (n = 110 females and n = 104 males)

Using the table of random numbers, a total of fourty-eight patients (twenty-four males and twenty-four females) were selected by a third-year periodontal resident to prevent selection bias. The guardians of the forty-eight subjects were then contacted by phone to request permission to participate. Five subjects were excluded for various reasons such as appliances to be removed before the end of study, antibiotic therapy for acne, etc. Consequently, five subjects were selected from the remaining pool of candidates, and subsequently contacted for permission to participate. The forty-eight candidates were scheduled for an initial screening visit to ensure that gingivitis was present. Three candidates were excluded because of the lack of established gingivitis and were replaced by three subjects who fit the criteria. The guardians of each of the forty-eight subjects were requested to sign a informed consent form supplied by the principle investigator

Study Groups

Twenty-four females and twenty-four males were evenly assigned to either the experimental toothbrush or placebo toothbrush group. All of the assignments were done in a double-blinded fashion This was accomplished by packaging, labeling, and dispensing the experimental and placebo toothbrushes in an identical manner. Each subject was provided with a large tube of Crest® regular toothpaste with fluoride. Crest® regular toothpaste was selected because it does not have any active ingredients that would directly effect the outcome of the results

Experimental Group

The active toothbrushes contained a transducer, which was responsible for producing the ultrasound, and a built in timer, which stayed on for three minutes. After the three minute time limit, the operation light, located on the handle turned off automatically signaling the termination of the brushing procedure.

Control Group

The twenty-four subjects in the control group were given an Ultrasonex™ toothbrush which had the same physical attributes as the experimental toothbrush except the ultrasonic transducer was inactivated.

Reports and Measurements

Each subject received a complete oral examination at baseline to determine eligibility for the study Various evaluations were performed at baseline and at the follow-up visits at six-weeks, and twelve-weeks. Clinical measurements for the plaque index, gingival index, and bleeding index were recorded at all visits Between baseline and twelve weeks, subjects were instructed to perform oral hygiene twice daily by the assigned method. A professional prophylaxis had not been performed on any of the subjects within one month of the baseline measurements or at any point during the study. Subjects were instructed not to brush their teeth for twelve to fourteen hours before each follow-up visit, so that overnight plaque formation could be assessed.

A safety assessment was made at each visit. The areas examined were the hard and soft palates, gingivae, muccobuccal folds, the inner surface of the cheeks, sublingual areas, and possible damage to orthodontic appliances. Intraoral photographs were taken of all of the subjects at all three time periods to serve as photographic evidence. Clinical measurements were recorded after the safety examination at each of the three visits. The plaque index was measured using the Turesky Plaque Index (Turesky et al., 1970) (Figure 3). Evaluations were performed at the gingival areas of the facial and lingual surfaces and interproximally for the Ramfjord teeth (Ramfjord 1967).

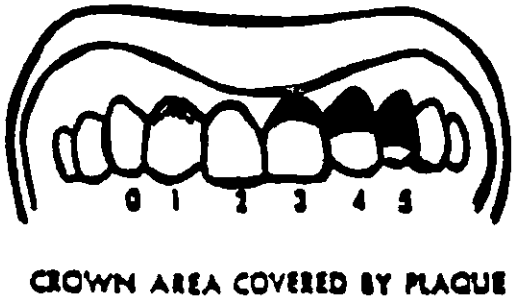


Figure 3 Diagram (After Turesky Plaque Index) used for measuring plaque accumulation.

0 = No plaque near the gingival area

1 = Separate flecks of plaque at the cervical margin of the tooth

2 = A thin continuous band of plaque (up to one mm) at the cervical margin of the tooth

3 = A band of plaque wider than one mm but covering less than 1/3 of the crown of the tooth

4 = Plaque covering at least 1/3 but less than 2/3 of the crown of the tooth

5 = Plaque covering 2/3 or more of the crown

The Gingival Index was recorded using the method of Loe and Silness (1967) at the facial and lingual gingival margins and interproximally for the Ramfjord Teeth. If no bleeding occurred a score of 0 or 1 was recorded according to tissue appearance. If bleeding was present, a score of 2 or 3 was selected.

0= Absence of inflammation

1= Mild inflammation, slight changes in color and minor changes in texture

2= Moderate inflammation, moderate glazing, redness, edema, and hypertrophy, bleeding, on probing.

3= Severe inflammation, marked redness, and hypertrophy. Tendency to spontaneous bleeding, ulceration's

The bleeding index was determined at the mesial and distal of the premolar and molar teeth using the Eastman Bleeding Index (Caton, Polson 1985). A wooden Stim-U-Dent® (Johnson and Johnson™) was inserted interproximally from the facial depressing the papilla 1 mm to 2 mm. Following a horizontal path insertion, the Stim-U-Dent® was removed and inserted four times. If bleeding occurred within fifteen seconds a score of 1 was assigned for that tooth surface. If no bleeding occurred within fifteen seconds a score of 0 was assigned for that tooth surface.

Compliance

Each subject was given a compliance chart and instructed to mark over the corresponding day only after they had completed brushing twice daily for three minutes. Subjects were instructed to bring their chart with them to each appointment. Each subject was instructed to change the toothbrush head after one month or if the bristles had became frayed. Subjects were instructed to return the compliance chart along with the toothbrush at the end of the study.

Data Collection

The plaque index, gingival index, and bleeding index were recorded for each tooth examined. To obtain a single index value per subject, the total score for each of these clinical measurements was divided by the number of surfaces examined. The data at baseline, six-weeks, and twelve-week data were collected by the investigator, blinded to the subject's treatment.

After all of the data was collected, it was transcribed and entered onto Microsoft™ Excel© software program. The final data was then processed by the SPSS™ (Statistical Programing for Social Sciences) in the Department of Orthodontics at Case Western Reserve University.

Statistical Analysis

Descriptive statistics for clinical measurements are summarized as mean and standard deviation by visit for each group. Repeated measures analysis of variance (ANOVA) was performed (baseline, six-weeks, and twelve-weeks); factors were included in the model to test for group differences, subject differences, visit differences, and interaction between the group and the visit.

Additionally t-test were performed to analyze group differences at each visit, as well as differences from baseline. For this procedure the Bonferroni correction was utilized to account for the problem of multiple comparisons. Thus, alpha was

set as 0 006 for this procedure, and was calculated by dividing the alpha value by the number of tests (9) which constitutes a significance level of $p < 0.006$.

Reliability

All of the initial and subsequent oral examinations, safety assessments and study compliance were performed by the principal investigator The gingival index, plaque index, and bleeding index were recorded by the principal investigator. The principal investigator was calibrated to measure gingival, bleeding, and plaque indices at The Cleveland Clinic Foundation's Department of Dentistry, Cleveland, Ohio. The principal investigator was blind to which device the subjects were using throughout the study.

RESULTS

A total of twenty-two subjects in placebo the toothbrush group and twenty-one subjects in the ultrasonic toothbrush group completed the study. Five subjects did not complete the study due to non-compliance The mean age of the experimental group was 15.11 (±1.53), and the mean age of the control group was 15.21(±1.71). The mean percent cooperation for the experimental group was 86.81% and 91.6% for the control group. The cooperation percentage was determined from the daily compliance charts each subject was instructed to keep during the study.

The baseline descriptive data for all of the indices recorded in this study showed that the two groups were comparable at the onset of the experimental period (Table 2).

Table 2. -- Descriptive Data at Baseline

Index	Ultrasonic Toothbrush (N = 21) Mean Scores (S.D.)	Placebo Toothbrush (N = 22) Mean Scores (S.D.)
Plaque Index	3 148 (±0.67)	3.107 (±0 71)
Gingival Index	1.658 (±0.38)	1.679 (±0.36)
Bleeding Index	0.804 (±0 17)	0.765 (±0.21)

Comparisons of the six-week data between the ultrasonic group and placebo group showed reductions in the mean values of all three indices. However, none of the reductions were statistically significant. Although both groups experienced overall reductions in each clinical measurement, statistically significant results were only observed in the ultrasonic group at the twelve-week visit for the bleeding index $p<0.000$ and gingival index $p<0.000$ as shown in (Table 3).

Table 3.-- Results of Clinical Measurements at each Visit for the Gingival, Bleeding and Overnight Plaque Index

Measurement	Visit	Ultrasonic Toothbrush Mean (S.D.)	Placebo Toothbrush Mean (S.D.)	p-value
Plaque Index	Baseline	3 148 (0.67)	3 106 (0.71)	0.841
	6-weeks	2.312 (0.61)	2.720 (0.61)	0.022
	12-weeks	2.279 (0.64)	2.609 (0 76)	0.135
Gingival Index	Baseline	1.652 (0.38)	1.679 (0 38)	0.820
	6-weeks	1.050 (0.36)	1.256 (0 36)	0.069
	12-weeks	0.893 (0.36)	1.323 (0 36)	0 000*
Bleeding Index	Baseline	0.803 (0.17)	0.765 (0.21)	0.525
	6-weeks	0.309 (0 22)	0.511 (0 27)	0.011
	12-weeks	0.137 (0.21)	0.596 (0.42)	0.000*

*Significant at $p<.0006$ using Bonferonni Correction
Correction = 0.05/ number of visits (9) = 0.006

Repeated measures ANOVA tests (Table 4) reported the "effect of the group by time"(interaction), which relates to the effectiveness of the toothbrush over time, and the "effect of time"(time) relates to the effectiveness of the time factor

alone. The overall results for the bleeding and gingival index were statistically significant for both interaction and time effects At T_2, Significance for the plaque index, was observed only for the time effect at T_2 Statistical significance for interaction and time effect was observed for the bleeding index, while only the time effect was significant for the gingival and overnight plaque indices. At T_3, all three indices demonstrated statistical significance for time, while significance for interaction was observed only for the gingival and for the bleeding index.

Table 4.-- Results of p-Values from Repeated Measures Analysis of Variance (ANOVA)

Measurement	Overall Effect	T_2 Effect	T_3 Effect
Plaque Index			
Interaction	0 241	0.184	0.494
Effect by time	0 000*	0.000*	0.001*
Gingival Index			
Interaction	0.001*	0.084	0.000*
Effect by time	0.000*	0.000*	0.000*
Bleeding Index			
Interaction	0.000*	0.000*	0.000*
Effect by time	0 000*	0.000*	0.000*

*Significant at $p<0.05$

Comparisons of mean differences from baseline to six-weeks, observed statistical significance only for the bleeding index ($p=0.000$). Baseline to twelve-

weeks showed statistically significant differences in the mean values for the bleeding index (p=0.000) and gingival index (p=0.000), but not for the plaque index (p=0.184). Week-six to week-twelve results demonstrated statistically significant differences in the mean value for the bleeding index, however no statistical significance was observed for the mean differences in the gingival, plaque indices (Table 5).

Table 5.-- Results of Clinical Measurement at each Visit for Gingival Index, Bleeding Index and Overnight Plaque Index.

Measurement	Visit	Ultrasonic Mean s.d. (±)	Placebo Mean s.d. (±)	Mean Difference (X2-X1)	p-value
Gingival Index	Baseline to 6-weeks	0.602 (0.32)	0 422 (0.35)	-0.180	0.084
	Baseline to 12-weeks	0.761 (0 31)	0.379 (0.36)	-0.407	0.000*
	6-weeks to 12-weeks	0.158 (0.32)	-0.069 (0 26)	-0 227	0.014
Plaque Index	Baseline to 6-weeks	0.836 (0.85)	0.386 (0.87)	-0.451	0.094
	Baseline to 12-weeks	0.869 (0.88)	0.497 (0.92)	-0.372	0.184
	6-weeks to 12-weeks	0.033 (0.60)	0.111 (0.84)	0.781	0.728
Bleeding Index	Baseline to 6-weeks	0.494 (0.22)	0.253 (0.16)	-0.240	0.000*
	Baseline to 12-weeks	0.666 (0.20)	0.166 (0.26)	-0.498	0.000*
	6-weeks to 12-weeks	-0.172(0.26)	-0.085 (0.26)	-0.257	0.004*

*Significant at p≤0.006 using Bonferonni correction
Bonferonni correction = 0.05/number of tests (9) = 0.006

Table 6 represents comparative results expressed as percent reductions from baseline to six-weeks, baseline to twelve weeks, and six-weeks to twelve weeks.

Noticeable reductions were found in the ultrasonic group in all of the three clinical measurements from baseline to twelve weeks, however, the most notable reductions were observed at 82.93% for the bleeding index, 46.8% for the gingival index, and 27.55% for the plaque index. Noticeable reductions were also found in the placebo group from baseline to six weeks in the bleeding index at 33 2% and in the gingival index at 23.97%. Despite positive reductions, the placebo group showed increases from six-weeks to twelve weeks for the gingival index at -5.6%, and the bleeding index at -16.6%.

Table 6.--Results of Percent Reduction from Baseline to Six-Weeks, Baseline to Twelve-Weeks, and Six-Weeks to Twelve-Weeks

Index	Visit	Ultrasonic Toothbrush Group % Percent Reduction	Placebo Toothbrush Group % Percent Reduction
Gingival Index	Baseline to 6-weeks	37.42%	23.97%
	Baseline to 12-weeks	46.78%	19.73%
	6 weeks to 12-weeks	14.95%	-5.57%*
Plaque Index	Baseline to 6-weeks	26.51%	12.43%
	Baseline to 12-weeks	27.55%	16.01%
	6 weeks to 12-weeks	1 43%	4 08%
Bleeding Index	Baseline to 6-weeks	61.52%	33.20%
	Baseline to 12-weeks	82.93%	22.09%
	6 weeks to 12-weeks	35.66%	-16.63%*

* A minus indicates an increase in the particular index observed
Percent difference calculated by = Baseline - Time Period x 100/Baseline
Percent difference calculated by = 6-Weeks - Time Period x 100/ 6-Weeks

Figures 4, 5 and 6 are a graphical representations of the mean overnight plaque scores, mean gingival scores and mean bleeding scores repsectively, for the ultrasonic and placebo group from baseline to twelve weeks.

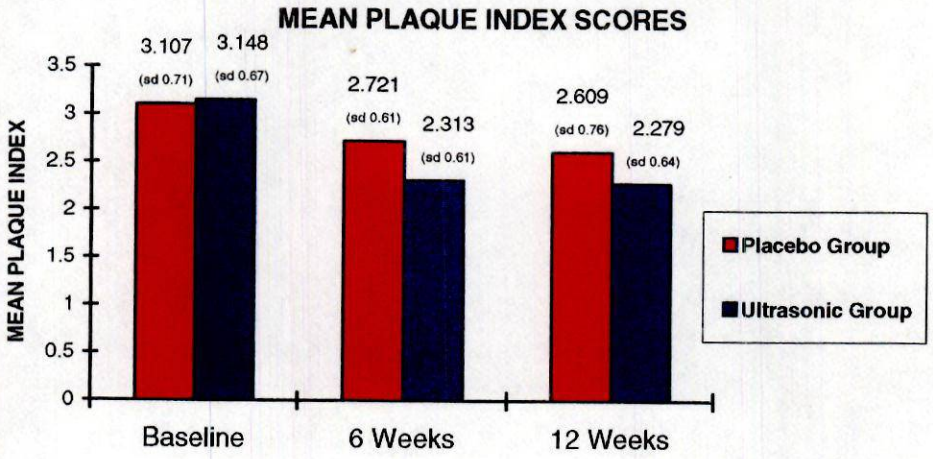


Figure 4. Mean Overnight Plaque Scores for the Ultrasonic and Placebo Group from Baseline to Twelve Weeks.

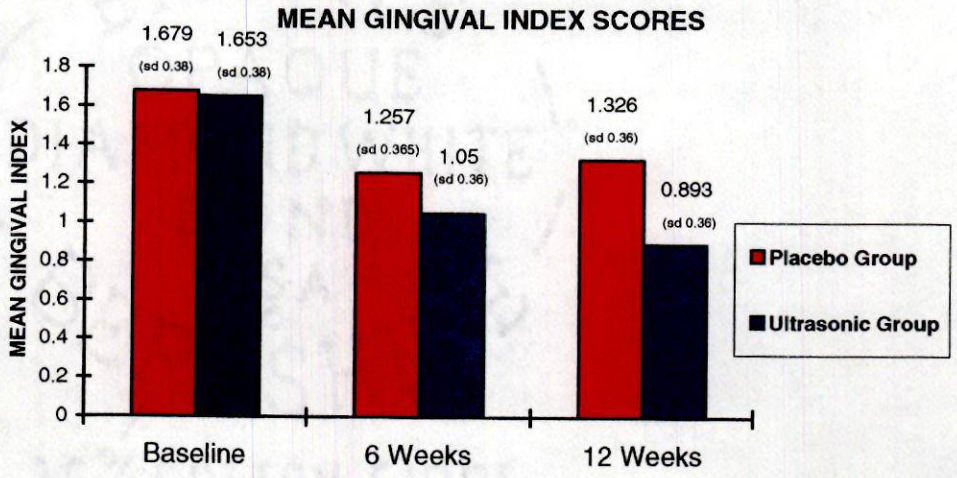


Figure 5. Mean Gingival Scores for the Ultrasonic and Placebo Group from Baseline to Twelve Weeks.

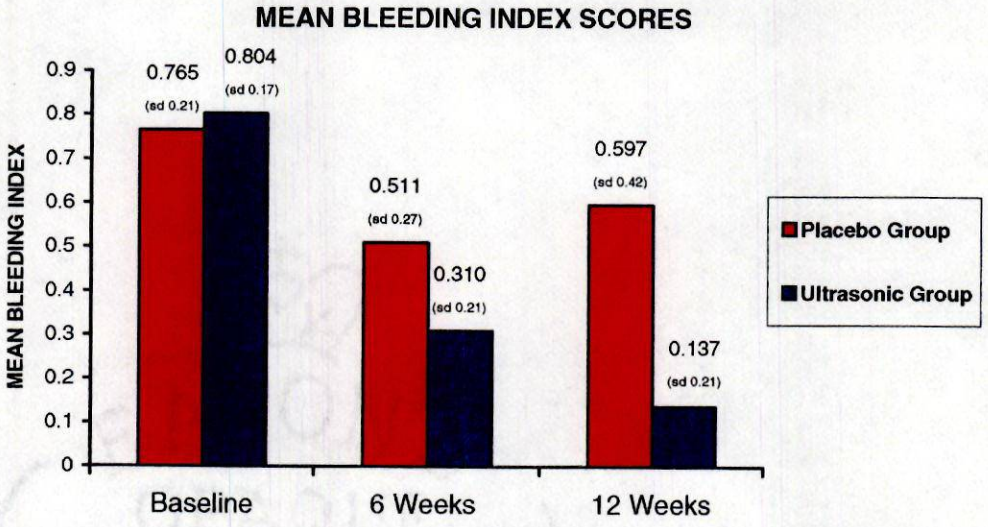


Figure 6. Mean Bleeding Scores for the Ultrasonic and Placebo Group from Baseline to Twelve Weeks.

Photographs were obtained for both the ultrasonic and placebo toothbrush groups for baseline, six-weeks and twelve-weeks. Baseline photograph representing subject #1 in the placebo group, demonstrates evidence of significant edema and slight redness around the gingival margins (Figure 7). Week-twelve photograph of the same patient shows edema is still present (Figure 8).

A photograph of subject #2 in the ultrasonic group at baseline showed significant edema and redness along the gingival margins.(Figure 9) Twelve-week photographic evidence demonstrated clinically apparent reductions in both gingival edema and redness (Figure 10).

Figure 7. Photograph of subject #1 in the placebo group at baseline; note the presence of significant gingival enlargement and redness

Figure 8. Photograph of subject #1 in the placebo group at twelve-weeks; note that gingival enlargement is still present.



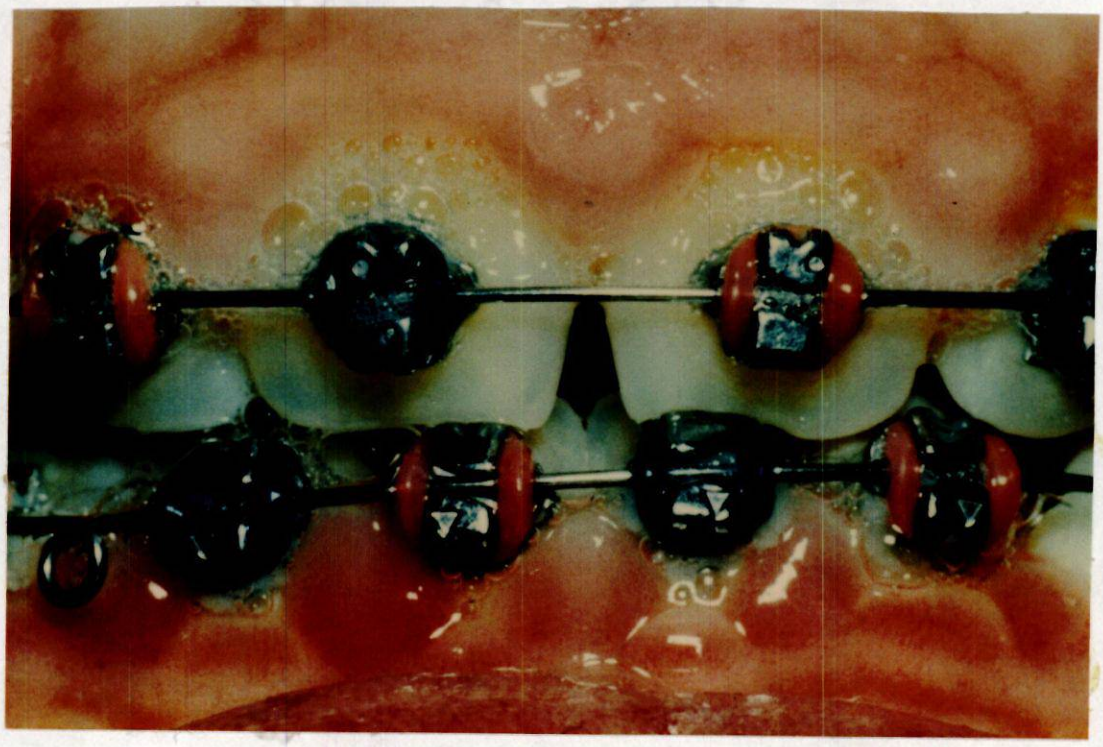
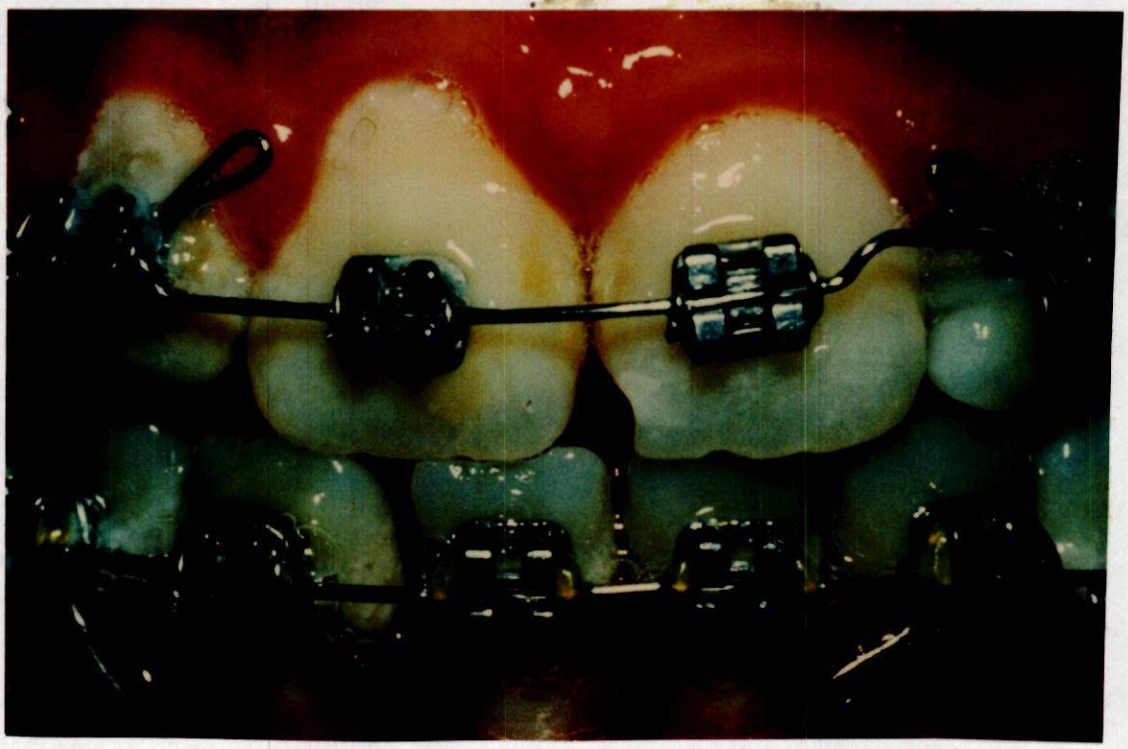
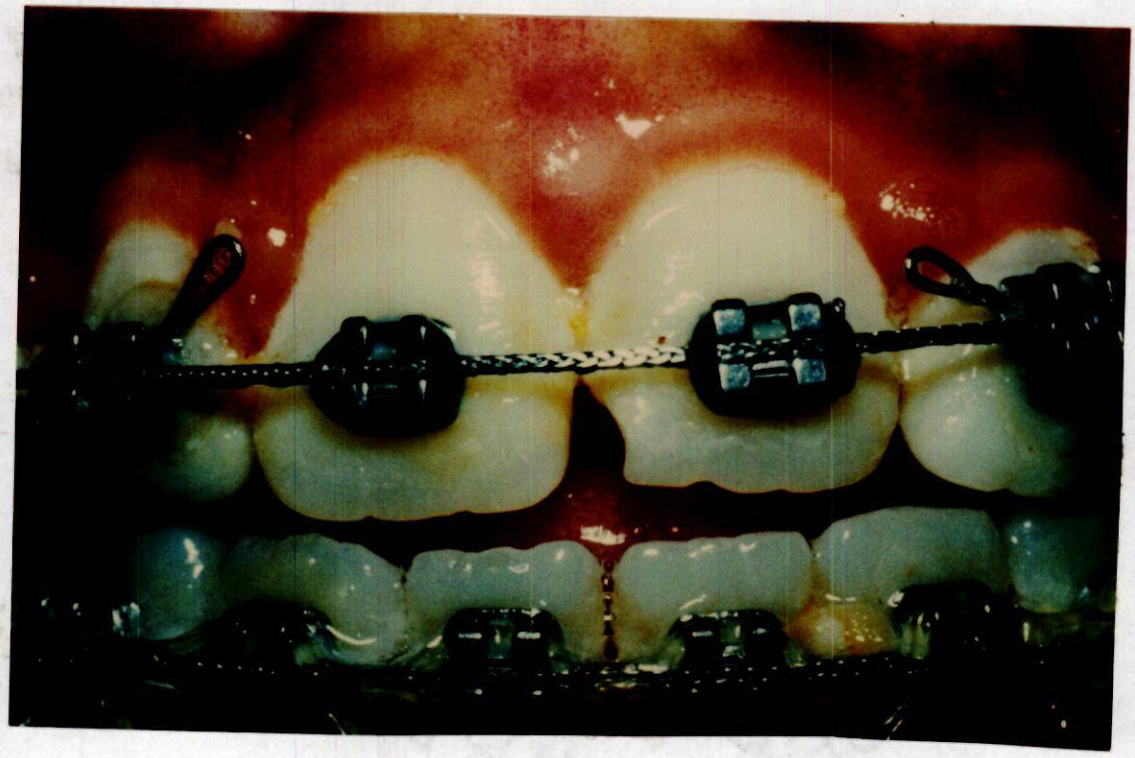


Figure 9. Photograph of subject # 2 in the ultrasonic group at baseline; note the presence of gingival enlargement and redness.

Figure 10. Photograph of subject # 2 in the ultrasonic group at twelve-weeks; note the reduction in enlargement and gingival redness.



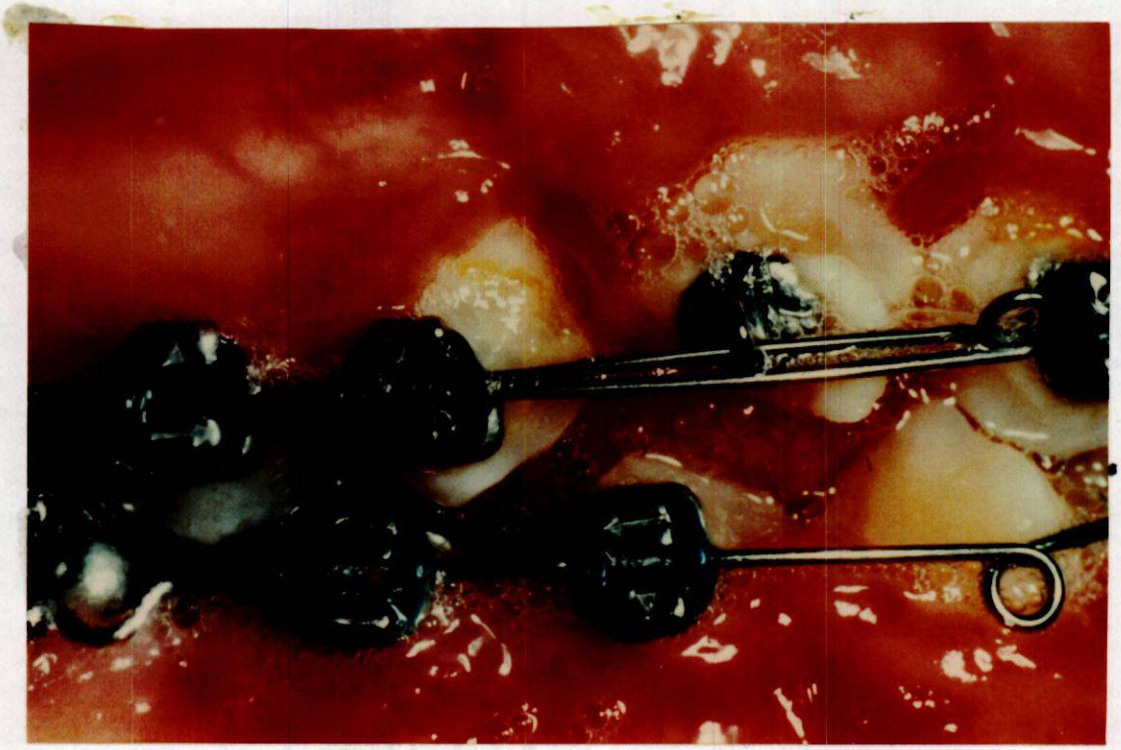


Baseline lateral photographs of subject #1 demonstrates the presence of significant gingival edema and gingival redness (Figure 11) A photograph of subject #1 provide evidence that marked gingival edema and redness are still present at twelve-weeks (Figure 12). Baseline photographs of subject # 2 (Figure 13) demonstrate the presence of significant gingival edema and gingival redness. Photographic evidence of subject # 2 provide evidence of clinically apparent reductions in gingival edema and gingival redness at twelve weeks (Figures 14).

All forty-three toothbrushes were collected and tested using an oscilloscope in order to determine the identity of the toothbrushes. The results showed that twenty-one toothbrushes tested positive for ultrasound (Figure 15), and twenty-two toothbrushes tested negative (Figure 16). This was consistent with the number of subjects present in each group; twenty-one ultrasonic subjects and twenty-two placebo subjects

Figure 11. Photograph (Lateral) of subject #1 in the placebo group at baseline, note the presence of gingival enlargement and redness.

Figure 12. Photograph (Lateral) of subject #1 in the placebo group at twelve-weeks, note the presence of gingival redness and enlargement



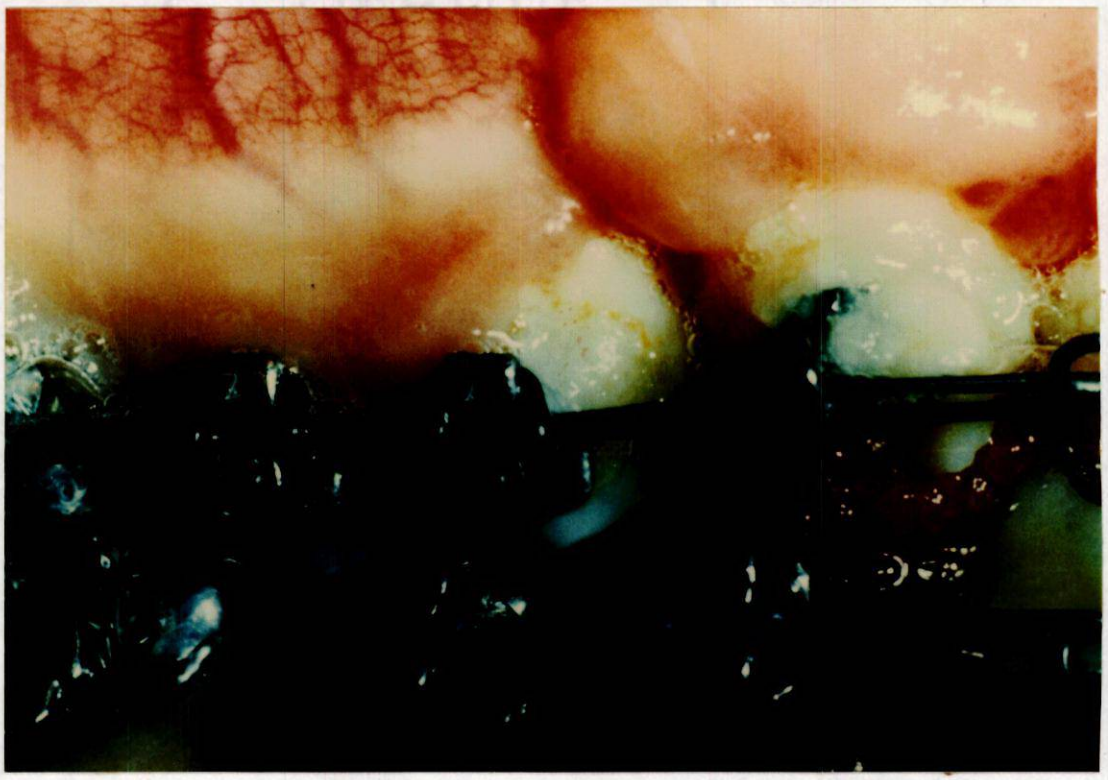
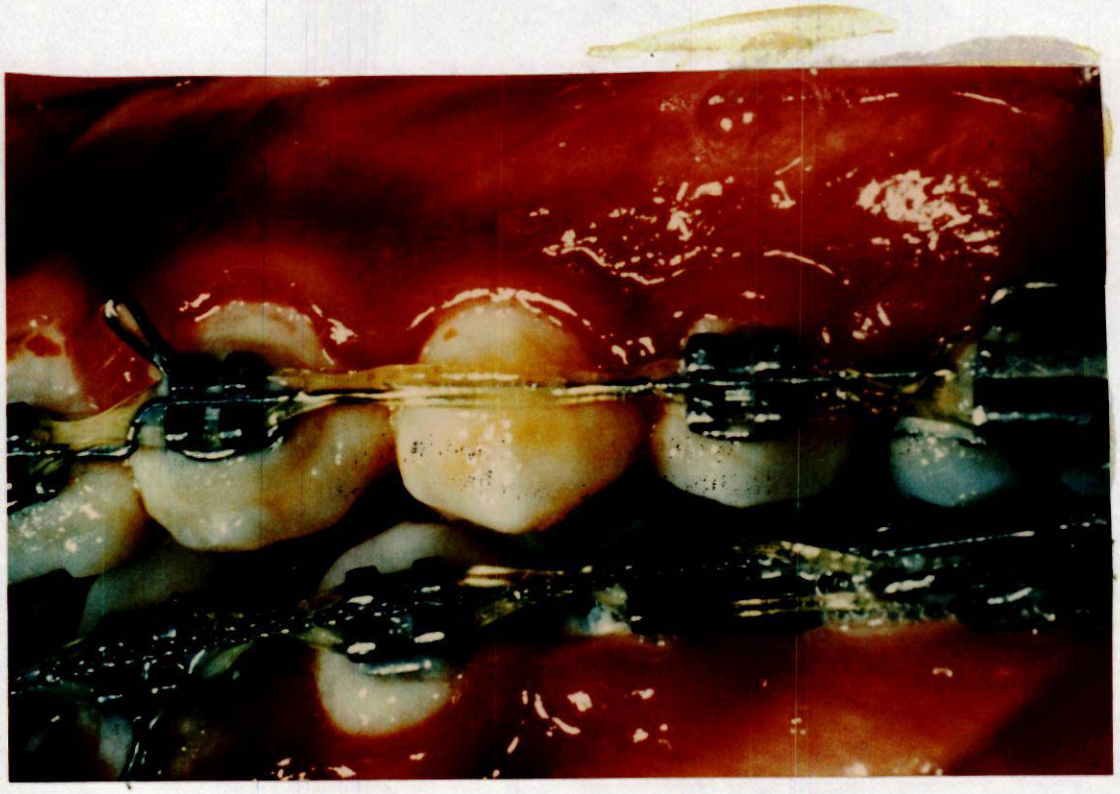


Figure 13. Photograph (Lateral) of subject # 2 in ultrasonic group at baseline; note the presence of gingival enlargement and redness.

Figure 14. Photograph (Lateral) of subject #2 in ultrasonic group at twelve-weeks; note reduction of gingival redness and enlargement.



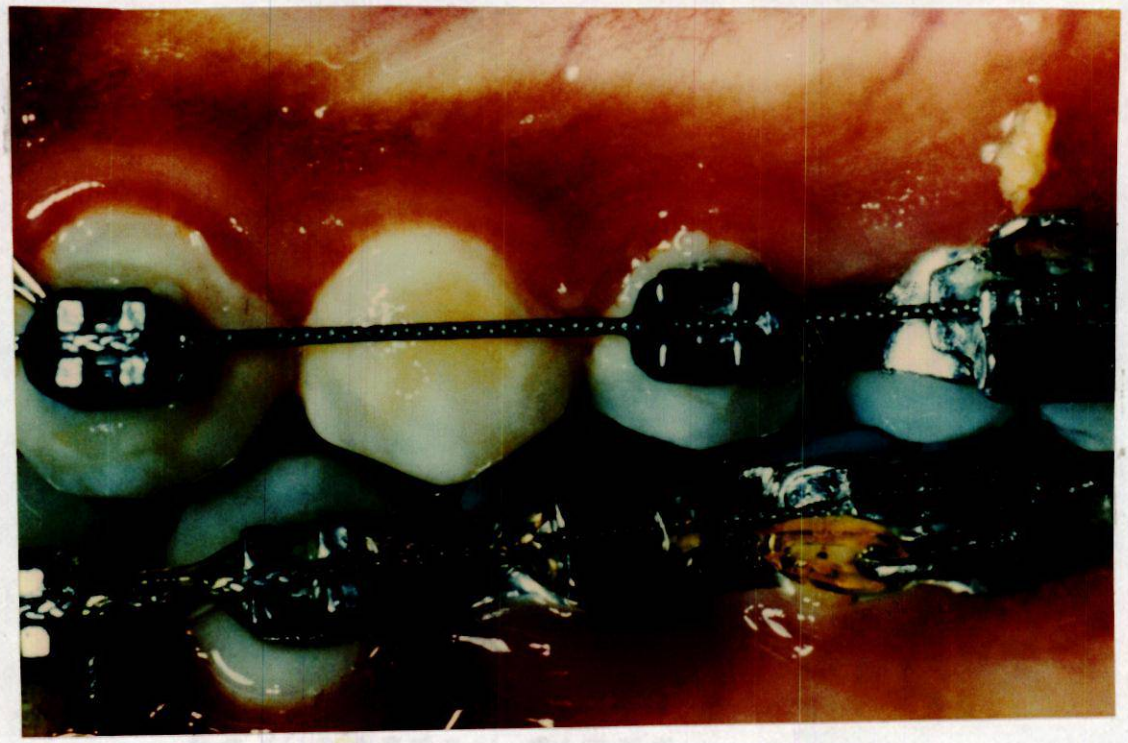
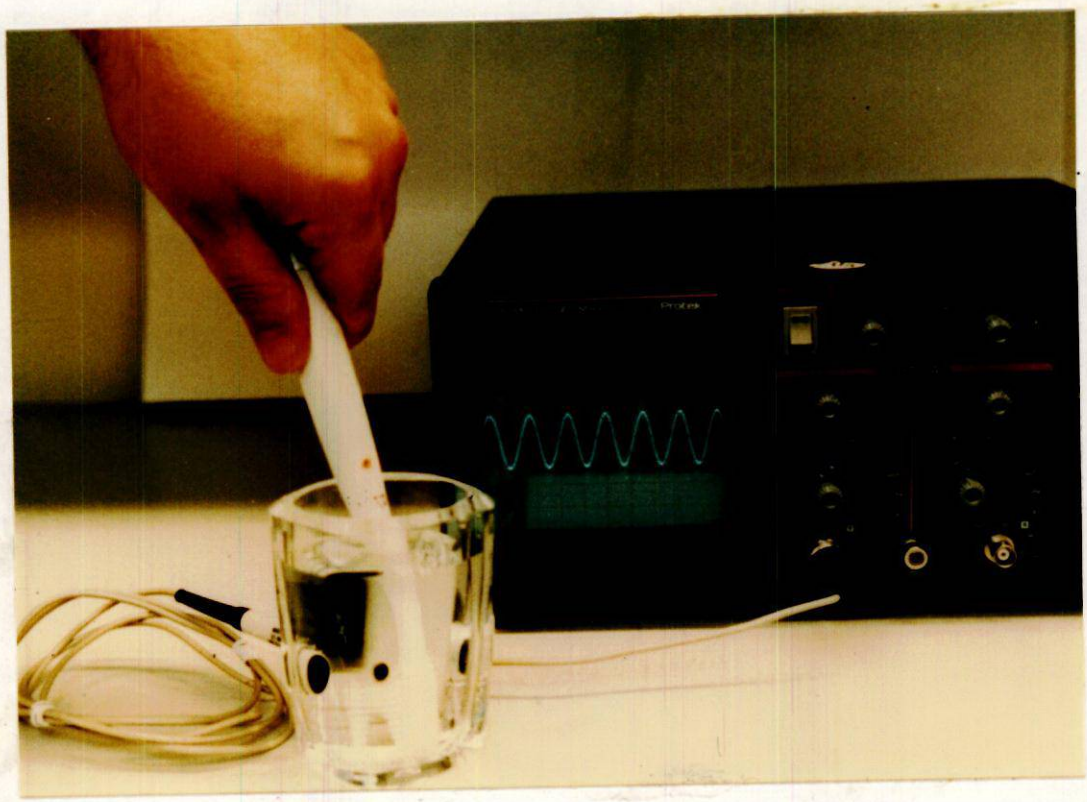


Figure 15. Photograph of toothbrush in group B being tested by an oscilloscope, to determine the identity of experimental group; note that the **unit tested positive for ultrasound**

Figure 16. Photograph of toothbrush in group A being tested by an oscilloscope to determine identity of experimental group; note that the **unit tested negative for ultrasound.**





DISCUSSION

Orthodontic patients are especially susceptible to gingivitis because of inherent surface irregularities of the brackets. Surface irregularities make effective plaque removal very difficult and presents a significant challenge to the patient as well as the orthodontist. The effects of the ultrasonic toothbrush on orthodontic patients, has not been established. The purpose of the present study was to examine the effectiveness of the ultrasonic toothbrush on orthodontic patients aged eleven through seventeen with established gingivitis. Specifically the effects of an ultrasonic toothbrush on overnight plaque formation, gingivitis, and bleeding over a twelve-week period, were studied.

The baseline descriptive data for all of the indices recorded in this study showed that the two groups were comparable at the onset of the experimental period. The results for clinical measurements at each visit for the gingival, plaque, and bleeding indices comparing the ultrasonic group and the placebo group showed reductions in the mean values for all three indices at six-weeks, however, none of the reductions were statistically significant. At the twelve-week visit, statistically significant reductions in the mean values were observed in the bleeding

index and gingival index for the ultrasonic group. Conversely, the mean values for all three clinical measurements in the placebo group showed no improvement, in fact, increased above the values obtained at week-6. This observation could be the result of the testing effect.

The results of a thirty-day study comparing the effects of an ultrasonic toothbrush (experimental) versus a manual toothbrush Oral B-40® (control) reported statistically significant reductions in the bleeding index for the ultrasonic group at the end of the thirty-day period (Terezhalmy et al., 1994). The results from the present study, using repeated measures ANOVA tests showed dramatic reductions in the bleeding index at six-weeks and twelve-weeks. Statistical significance for interaction and time for the bleeding index was observed at T_2 and T_3 The results obtained in a 6-month cross-over study also conducted by Terezhalmy reported statisitically significant reductions in the bleeding index at day-thirty in the ultrasonic group, that persisted thoughout the six-month study period. The results obtained for the bleeding index in the present study were consistent with Terezhalmy's study which suggest that the effects of the ultrasonic toothbrush on bleeding were immediate and persisted throughout the study, therefore the first clinical measurement expected to improve in subjects using the ultrasonic toothbrush was the reduction in the bleeding index.

Results of a thirty-day and six-month study (Terezhalmy et al., 1994 ,1995) reported significant reductions in the gingival index for the ultrasonic group at day-

thirty and also at the end of the 6-month study. The results reported from previous studies (Terezhalmy et al., 1994, 1995), as well as, the results obtained in the present study suggest that the overall effect of the ultrasonic toothbrush on gingivitis was cumulative and became statistically significant at the end of the twelve-week period.

A 6-month cross-over study conducted by Terezhalmy reported no significant reductions in the plaque index (overnight) in the ultrasonic group (experimental) versus the Oral B-40 group (control) at day-thirty. However, following the cross-over, statistically significant reductions for overnight plaque formation were observed in the ultrasonic group at the six-month period. Although statisitically signficant results for overnight plaque reduction were observed at the end of Terezhalmy's study, the results observed in the present study were not significant. However, a trend was identified, which could suggest that given a longer test period significance in overnight plaque reduction might have been observed. Since neither group had a statistically significant effect on overnight plaque formation at any time period, this could suggest that ultrasound did not interfere with the formation of plaque but, enhanced its removal by the mechanical actions of the toothbrush. McInnes et. al , (1992) Consequently, any improvement observed in the gingival and bleeding indices can be attributed to improved plaque removal by the ultrasonic toothbrush.

Intraoral photographs comparing subjects in the control and experimental groups show clinical improvements in both groups. The ultrasonic group appears to show the most clinically significant reductions in gingival redness and gingival edema at the end of twelve weeks

The mechanism of how high intensity, low frequency ultrasound effects plaque formation, bleeding and gingivitis is not well understood, additional studies are needed utilizing larger treatment groups and longer testing periods

All of the baseline and follow-up examinations were performed by the principle investigator, this prevented inter-examiner variability and ensured reliability. The principle investigator was blinded to which group received the active or placebo toothbrush, which eliminated examiner bias.

Compliance was a major concern for this type of study, the subjects were given instructions on brushing as well as a compliance chart to track their brushing habits. Because the subjects were not in a controlled environment, it is impossible to control for compliance in this type of study. Since both the experimental toothbrush and control toothbrush were physically and mechanically similar the design of the brush should have not affected the results. Although each brush was equipped with a running indicator light, (three-minutes) the length of time spent brushing was solely based on the subject's discretion.

Despite the positive results of this study, it could have been improved in the following areas: larger sample size, longer test period, cross-over study design and

the use of a conventional toothbrush as the control. A larger sample size would have been more representative of the actual population being observed The use of a longer test period would have further validated the accuracy of the results. The cross-over design would have prevented group error, and ensured that the toothbrush caused the observed results. The use of a conventional toothbrush as the control, would ensured that the mere design of the ultrasonic toothbrush did not have some effect on the results For future research in this area the above mentioned adjustments should be made.

SUMMARY AND CONCLUSIONS

The purpose of the present study was to evaluate the effects of an ultrasonic toothbrush on orthodontic patients aged eleven through seventeen with established gingivitis. Specifically to determine the effectiveness of an ultrasonic toothbrush on overnight plaque formation, gingivitis, and gingival bleeding over a twelve-week period, were studied.

The overall results for repeated measures ANOVA tests showed statistical significance for both time and interaction for the bleeding index at T_2 The gingival index was statistically significant for time throughout the 12-week period, but interaction was significant only at T_3. The results observed for the overnight plaque formation was statisitically significant for time at T_2 and T_3 No significance was observed for interaction in the overnight plaque formation at any point throughout this study.

Comparisons of intraoral photographs shows that subjects in each group had clinically apparent reductions at the end of twelve-weeks, however subjects in the ultrasonic group appeared to show greater clinical improvements when compared to the placebo group.

When used twice daily for three minutes as a part of a oral hygiene regimen, the ultrasonic toothbrush was significantly more effective than the placebo toothbrush in reducing bleeding and swelling over a twelve-week period. The ultrasonic toothbrush should be considered a safe, effective, and superior oral hygiene alternative for patients undergoing active orthodontic treatment.

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