2017

Beam Study in Orthodontic Patients

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BEAM® STUDY IN ORTHODONTIC PATIENTS

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A THESIS

Submitted to the graduate faculty of The University of Alabama at Birmingham,
in partial fulfillment of the requirements for the degree of
Master of Science

BIRMINGHAM, AL

2017

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ABSTRACT

Introduction: One of the most challenging tasks of the orthodontic team is to motivate patients to maintain proper oral hygiene. In order to improve compliance, clinicians are utilizing mobile applications. The goals of this study are to determine the efficacy of an application-based approach in increasing orthodontic patient's oral hygiene compliance, as well as measure the correlation between the reported compliance and clinical parameters of gingival health.

Materials & Methods: The Beam® toothbrush and its application software (app) were selected for evaluation. Three prospective groups of 15 patients undergoing routine orthodontic treatment were evaluated as part of this research protocol (total recruitment of 45 patients) and were followed up during the early stages of orthodontic treatment. The study parameters included: oral health evaluation, application tracking, and reported compliance. Patients were recalled 3 times for a complete clinical evaluation

Results: Group 2 was the only group to show a statistically significant ($p < 0.017$) difference of plaque and gingival scores across time points. There was no significant difference in plaque and gingival scores over time across all groups. Group 2 sextants 1 & 3 showed greater increases in plaque and gingival scores. Comparing patient questionnaire responses to data collected from the Beam application software, no effective agreement was found in brushing frequency. Q2 vs Q2 app data showed a

perfect agreement with Kappa of 1. Q3 vs Q3 app data also showed a 100% raw agreement, but with a Kappa of 0.5.

Conclusions: Proper oral hygiene instructions seem to be the most important variable in achieving plaque control, as well as patient motivation and diet control. It is important for clinicians to continuously provide oral hygiene instructions throughout the course of orthodontic care. Overall brushing quality depends on brushing technique and does not seem to be device related. Frequency and duration of brushing are not as important as brushing quality. Patients that use toothbrushes with built-in timers may be more likely to brush the required time frame (2 min). The use of toothbrushes associated with apps could be promising to increase compliance within an orthodontic practice as long as a reliable app/device system can be built.

Keywords: Beam® Toothbrush, Compliance, Oral Hygiene, Gingival Scores, Plaque Scores

ACKNOWLEDGEMENTS

I would like to acknowledge Drs. Chung How Kau, Amjad Javed, and Meninder Kaur for their willingness to serve as members on my committee. I appreciate the guidance provided by each of these members throughout the entirety of my project.

I would like to express my deepest appreciation for Dr. Nada Souccar. Without her as my faculty mentor this would not have been possible. Her leadership, guidance, patience, and encouragement throughout my entire residency meant the world to me. You truly are an "Orthodontic Giant"

I would also like to sincerely thank Mr. Paul Lin for analyzing all of our data and helping translate it into valuable information, and also Dr. William Bates for providing countless hours of data entry.

I would also like to express my gratitude to my family who has supported me throughout my academic career and to the love of my life, Mallory, for her unwavering love and support.

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CHAPTER 1

INTRODUCTION

The aims of orthodontic treatment are both esthetic and functional. Currently, four out of five orthodontic patients are children and or adolescents.[1] Epidemiological studies indicate that 70% of the population is affected by some form of malocclusion. Surveys also show that nearly 50% of U.S. children would benefit from orthodontic treatment and 5% of these are seriously restricted in regards to their oral function[2]. Among those seeking treatment, it has been found that about 80% do so for cosmetic purposes[3]. While it seems reasonable to assume that the malocclusion has the potential to contribute to both dental caries and periodontal disease by increasing the difficulty to properly clean the teeth, current data shows that malocclusion in itself has little if any impact on dental disease and its supporting structures[4]. The main etiologic factor leading to periodontal breakdown and dental cavitation is dental plaque. The microbial load combined with environmental conditions, behavioral patterns and host response all play a role in maintaining oral health. While malocclusions have the ability to negatively impact periodontal health [5], the key factors in predicting the patient's oral health status rests on the individual's willingness and drive to perform proper home care[6]. These two factors determine oral hygiene much more than how well the teeth are aligned[4]. Patients' motivation plays a critical role in predicting what the status of the oral health environment will become upon the delivery of fixed appliances. Though esthetics is at

the forefront for why many individuals seek orthodontic care, one of the most challenging tasks of the orthodontic team is to motivate patients, insure that patients wear their removable appliances as instructed and brush their teeth in a consistent fashion. Despite the post-therapy advantages of orthodontic treatment, fixed appliances create many obstacles contributing to plaque retentive sites, which ultimately diminish one's ability to properly clean each tooth. Even in the most motivated patient, gingival inflammation is found in almost every case [7].

The majority of orthodontic patients are adolescents. This population group typically does demonstrate a high compliance with orthodontic recommendations throughout the course of treatment, particularly in relation to oral hygiene.[8] Several studies evaluating adolescent cooperation in health care have found that at least 25-50% of adolescence fail to comply with all aspects of treatment, and noncompliance rates up to 80% depending on the study.[9] There are several personality traits that have been found to be reliable predictors of patient compliance: Self-perception, self-confidence, gratitude, academic success, and obedience are found to be positive predictors for compliance. On the contrary, patients who are found to be self-conscious, argumentative, and depressed are those whom are found to be least compliant with orthodontic instruction [10]. Nonetheless, orthodontic treatment is highly requested by parents and adolescents, and straight teeth have been reported to have a positive impact on self-esteem, perception of attractiveness as well as social and professional success.[11-13] In a study by Shaw et al., teeth were found to be the fourth most common target for teasing among children, after height, weight, and hair[14]. It was observed that both children and

adults with normal occlusion were perceived not only as being more attractive, but also more intelligent, less aggressive and more sought-after in regards to friendship[15].

Orthodontic Risk Factors: Plaque Retention

Though there are several intraoral risk factors associated with orthodontics, the most common are enamel demineralization/caries and plaque induced gingivitis. The presence or absence of dental plaque is the major determinant of the health of both the hard and soft tissues of the mouth. Dental plaque is an essential etiological factor in the initiation and development of periodontal disease and dental caries[16]. A study by van Gastel et al. evaluating plaque biofilm, highlights the differences between various orthodontic brackets and their susceptibility to plaque retention. The focus of the investigation was to compare the microbial adhesion on various bracket types in vitro, in similar situations as they are clinically. In each case, a shift in aerobic to anaerobic species took place, which ultimately has a potential impact on the health of the soft and hard tissues[17]. Another study focused on the differences between arch wire ligation techniques: elastomeric modules versus ligature wires. It was found that elastomeric modules were associated with higher plaque scores and increased gingival bleeding, when compared to steel ligatures[18]. Contrasting results came from a more recent study evaluating the periodontal condition of the mandibular anterior teeth with the use of conventional versus self-ligating brackets. While Pandis et al. show that the lack of elastomeric module in self-ligating brackets reduced the overall plaque retention, this particular study found no difference in the anterior zone among groups[19]. Although it is not entirely clear whether the traditional edgewise or the self-ligating appliance is

superior, there is no debate that orthodontic brackets make it more difficult for patients to adequately remove all plaque from the dental surfaces.

Gingival Health

When evaluating gingival health, there are several key characteristics to be considered. The bacterial component in healthy gingiva consists primarily of gram positive aerobic bacteria: cocci and rods. With no inflammation, the presence of neutrophils within the tissue is minimal. As a patient's gingival health shifts towards being considered "unhealthy", an increased prevalence of gram negative anaerobic bacteria becomes apparent and replaces those whom were once found in the healthy tissue[20].

Gingivitis is the inflammation of the gingival tissues that does not directly result in clinical attachment or bone loss. Periodontitis, on the other hand, is inflammation of both the gingiva and its surrounding tissues resulting in connective tissue and alveolar bone loss. The American Academy of Periodontology (AAP) has established a classification system for each periodontal condition [21]. Both gingivitis and periodontitis are classified based on their primary etiology, as well as clinical and radiographic findings. Gingivitis is considered a reversible disease and its treatment is aimed primarily at eliminating the etiologic factors causing the inflammation, resulting in its ability to heal [21]. If left untreated, gingivitis has the potential to progress into periodontitis [22].

Gingivitis can be classified as being mild, moderate, or severe; localized or generalized; and marginal/papillary or diffuse[23]. The development of gingivitis can be

classified in two main categories: plaque-induced or non-plaque induced. The non-plaque induced category typically arises from any of the following: specific bacterial, viral, fungal or genetic origins, manifestation of systemic conditions, i.e. mucocutaneous disorders or allergic reactions, traumatic lesions, foreign body reactions, or not otherwise specified[21]. Plaque-induced gingivitis is the most common form of periodontal disease, and typically arises from poor oral hygiene[24], and can be modified by systemic factors (endocrine system or blood dyscrasias related), medications (drug-induced gingival enlargements or diseases) and malnutrition (ascorbic acid deficiency)[25]. A study performed by Loe et al. highlighted the role of dental plaque in the development of gingivitis. It investigated the clinical and microbiological changes that affect healthy individuals when then completely discontinue oral hygiene regimens. It demonstrated that plaque leads to gingivitis, and its maturation corresponds in a shift in bacterial colonization to include predominantly Gram-negative anaerobic rods. The key finding was that mechanical removal of plaque restored gingival health. In the absence of oral hygiene procedures, gingivitis started appearing after 4 days, and throughout the observation period, the highest accumulation of plaque occurred on the molars[26]. It is important to note that plaque biofilm must be identified early, followed by proper oral hygiene instructions as well as home care to prevent further progression. Irreversible damage occurs when the inflammatory response extends from the marginal gingiva to the bone, in which clinical attachment and bone loss occur[27].

Various theories exist in regards to the etiology and progression of periodontal disease. Whether it is specific or non-specific bacteria that ultimately lead to periodontal disease, most agree on certain ideologies. It is accepted that the primary etiology of

periodontal disease is bacterial plaque. Secondly, dental plaque that accumulates around the teeth is not of a single specific bacterium, but rather an accumulation of many types. The host response is ultimately the most important factor in determining whether periodontal disease will persist. Lastly, one must have gingivitis before having periodontal disease, but not every gingivitis turns into periodontitis [28].

The best indicator of inflammation is bleeding upon gentle probing, which indicates active and presumably progressive disease. Bleeding evaluation is crucial in that it allows the clinician to identify high-risk patients and high-risk sites. Bleeding on probing in the presence of other variables such as loss of stippling, erythema, and or edema is important when diagnosing the health of the soft tissue. Many bleeding indices have been developed in order to convert clinical findings such as changes in color, texture and form into numerical data. Alone, bleeding on probing has a low sensitivity (true positive), but has a high specificity (true negative).[20].

There are several stages of inflammation that correspond with the development of gingivitis. The formation of the initial lesion results when dental plaque has been undisturbed for at least 2-4 days. At this point, neutrophils begin to populate around the gingival margins. After about 4-7 days of undisturbed plaque, an increase vascular proliferation takes place and collagen destruction begins to occur. Once the lesion is fully established after about 2-3 weeks, further collagen damage takes place, potentially causing irreversible damage to the soft tissue. In many cases, plaque acts as a catalyst to initiating periodontal disease. Not only does the inflammatory response impact the hard and soft tissues supporting the tooth, but the enamel itself becomes compromised by prolonged retention of plaque[20].

Dental Health

As previously stated, not only does dental plaque affect the soft tissue but ultimately may directly impact the health of the tooth. The direct result of poor oral hygiene leads to enamel demineralization, also known as white spot lesions (WSL). Lesions typically develop on the gingival third of the dental crowns. Enamel decalcifications that result from the accumulation of dental plaque are the precursors of dental cavities.[29-31]

Approximately 50 percent of all orthodontically treated patients develop white spot lesions in one or more teeth, compared with only 24 percent in those not undergoing orthodontic treatment.[32-34] While any tooth in the mouth can be affected, the most common teeth affected are the maxillary lateral incisors, maxillary cuspids and mandibular bicuspids.[35] A study performed by Gorelick et al., found that half of their orthodontic patients experience at least one white spot after treatment and that they were most likely to occur on the maxillary lateral incisor.[33] White spot formations have been shown to be independent of overall orthodontic treatment duration. Several studies by O'Reilly et al. and Oggard et al. highlight the fact that while incidence and number of white spots is not dependent of length of treatment, demineralization can occur rapidly within the first month of orthodontic care[29]

The clear esthetic concerns highlight the importance of assessing each patient's caries risk and establishing proper oral hygiene prior to initiating treatment. Different treatments have been developed to reverse WSL. These include fluoride applications (gel, varnishes and pastes) and the use of various fluoride-releasing agents (elastomeric ligatures, glass ionomer cements, and sealants).[36, 37] In order to objectively record the

differences between various WSL, Gorelick established a numerical grading system to assist in classification. The scale ranges from 0 - 3, no lesion present to cavitation respectively[33]. In recent years, there have been certain regimes that have been developed in order to assist in the reversal of severe white spot lesions, such as MIPaste and Prevident. While these particular products claim to ameliorate the severity of white spots lesions, recent studies show that that are no more effective than regular oral hygiene instructions [38, 39]. In the most severe cases, the lesions need to be masked using prosthetic treatments, including veneers and full coverage crowns. This type of treatment is both invasive and expensive. The most important preventative measure in order to diminish the likely hood of negative sequelae of orthodontic care is to establish extremely high standard of oral hygiene before initiating orthodontic care.

Oral Hygiene Regimens

Establishing a proper oral hygiene regimen is essential in all cases of orthodontic treatment, and the use of supplemental tools such as electric toothbrushes, interproximal brushes, and regular professional cleaning must be encouraged throughout the course of treatment. Anecdotal experience shows that patients whom are unable to maintain adequate oral health prior to treatment are at much risk of failing with fixed appliances in place.[16]

The electric toothbrush was first introduced into the commercial market in the early 1960s. Currently there are several types of modes in which an electric toothbrush may operate: side-to-side, counter oscillation, rotation oscillation, circular, ultrasonic, ionic[40, 41]. While there have been several studies suggesting that plaque and gingival

inflammation are significantly reduced using a powered over a manual toothbrush, much debate exists[42, 43]. The lack of direct comparison between the various types of powered toothbrushes raises concern about the validity of the results.

Extensive research has been conducted to compare different manual toothbrushes using clinical parameters to identify one superior design that would be most effective in plaque removal.[40, 41, 44] Results indicate that there were no differences in plaque removal ability in the design of manual toothbrushes. From the studies it was determined that the user is the most significant variable. [41]

Other studies have investigated the differences between manual and powered toothbrushes on gingival health. While some trials showed no differences between the two devices with regards to plaque index and/or gingival index, [45-47] others found statistically better results but no necessary clinical improvement with powered toothbrushes. [48, 49] A study evaluating the effect of both manual and powered toothbrushes on clinical parameters, such as plaque and gingival indexes, as well as bleeding on probing, found that the powered toothbrush showed the greatest benefit in the mandibular and lingual areas[50]. Similarly, a study by Grender et al. found comparable results showing that power toothbrush are more effective in removal of plaque on all lingual surfaces, including interproximal, and lingual gingival margins[51]. A systematic review showed that rotating-oscillating brushes were more effective at reducing plaque scores as well as improved short and long-term protection against gingival inflammation when compared to manual toothbrushes. [43]. Interestingly, a more recent systematic review could not detect a superior mode of powered toothbrush over any other[52].

Therefore, it appears that there is no definite result proving the superiority of a powered toothbrush over a manual toothbrush.

In the same study, Deacon compared various powered toothbrushes and evaluated their ability for plaque control and gingival health. It was found that brushes with a rotation oscillation motion have a slightly improved outcome in the removal of plaque as well as reduction in gingivitis compared to those that simply vibrate[52]. While the data shows a slight difference between the two powered brushes, the clinical importance still remains unclear. Hence, further clinical trials of high quality are needed in order to establish whether one powered toothbrush is truly better than another[52]. It is also important to note that while none of the current studies comparing the various toothbrushes were performed on orthodontic patients who typically show plaque levels of 2 to 3 times higher than patients without fixed appliances[53].

Technology in Dentistry

With the evolution of technology, society has become more and more connected through their mobile devices. We are now in the time referred to as the "permanently online" era. Patient's expectations have shifted towards having access to immediate information supply and assistance. Recent studies show that upward of 80% of Americans now own smart phones[54]. In order to improve compliance, an increasing number of clinicians are turning to social media and mobile applications. There are studies in both medicine and dentistry that show text messaging as being an effective tool in modifying behavior and disease prevention[55, 56]. A systematic review performed in 2012 highlights the positive influence that text messaging has on behavioral modification

in healthcare[57]. In dentistry, text message reminders have shown to be effective by decreasing the rate of no-shows, as well as improve oral hygiene compliance in orthodontic patients[55]. Zotti et al. found that integrating an application-based approach in the oral hygiene regimen of their patients helped improve oral health during the course of treatment. [58] Other groups have found text messaging to be effective at reminding their patients about the importance of proper dental brushing. [56, 59]

With each smart phone being equipped with blue-tooth technology and the high prevalence of those owning a smart phone, it would be realistic to assume technology could play a major role in acting as patient monitoring device. Over the last several years apps such as WeChat and WhatsApp have made communication between doctor and patient ever more immediate. Apps are frequently used for appointment and hygiene reminders, as well as to manage cooperation levels with removable appliances. Currently there is ever growing evidence supporting the idea of "App based" monitoring protocols in improving oral hygiene and decreasing treatment time, bonding failures, and no-show rates.[58, 60] A longitudinal study performed by Schluter et al. evaluated the use of motivational text messages in hope that it would improve oral hygiene status of patients whom were unemployed and between the ages of 18 to 24. Through this particular study, a 23% self-reported improvement was noted[61]. In contrast, a Cochrane review was performed in 2012 evaluating mobile messaging and its role in preventative health care by improving both health status and behavior outcomes showed limited evidence to support the claim that mobile messaging is effective in preventative health care[57]. With much of the current literature supporting the use of messaging as patient reminders, much is limited to its use in managing compliance. Commercial interest regarding

patient monitoring systems has increased progressively and currently there are several apps especially designed for this purpose. Limited information is currently available on whether or not these patient monitoring devices are effective in monitoring patient compliance, specifically oral hygiene. No current literature supports or refutes the use of bluetooth equipped toothbrushes as being superior in monitoring the patient's frequency and duration of brushing. The question still exists on whether or not these apps are truly effective in monitoring patient compliance. Is it possible to use such a device to accurately record a patients brushing compliance and be able to effectively compare to what the patient is reporting. Could these systems become reliable tools in improving our treatment efficiency and quality?

The purpose of this study is to evaluate the brushing efficacy and show how it improves when using a powered toothbrush coupled to an application software (app) compared to that of a powered tooth brush alone or a manual toothbrush alone in orthodontic patients during the initial stages of treatment. The overall aims of this study were to compare the efficacy in brushing with a powered toothbrush equipped with Bluetooth technology to that of a manual toothbrush during the early stages of orthodontic treatment by evaluating periodontal parameters, as well as study the relationship between patient brushing and compliance habits and their agreement with application software recorded compliance.

CHAPTER 2

MATERIALS AND METHODS

This is a randomized prospective study aiming at evaluating brushing efficiency in participants undergoing orthodontic treatment with fixed appliances. This protocol has been approved by the UAB Institutional Review Board (150806001).

Population

Participants who were about to start orthodontic treatment with fixed appliances were prospectively enrolled in this study. Nineteen males and twenty-eight females (N=47) were randomly assigned to one of 3 groups depending on the brushing device that they were going to be using throughout the study period. The BEAM® toothbrush was selected as the powered system, specifically because it could be linked to an application software through the use of the Bluetooth technology. It is a battery powered sonic toothbrush (BEAM® technologies, Columbus, OH).

- **Group 1**: Participants using the BEAM® toothbrush and the BEAM® application to track compliance. Participants in this group registered on the company's website using their email address to be able to use the application (N=15)
- **Group 2:** Participants using the BEAM® toothbrush without the associated application (N=18)
- **Group 3:** Control group: members of this group used manual toothbrushes for their oral hygiene routine (N=14

Participants were followed-up for a period of 3 months with orthodontic appointments every 6 weeks (regular orthodontic appointment sequence). At each appointment, they were evaluated for study parameters. Two periodontal indices were used to evaluate oral health: The plaque index (PI) and the Gingival Index (GI), both defined below[26, 62]. Their compliance was also recorded through paper logs or BEAM® application recording.

Inclusion Criteria

1. 12 years and older
2. Participants requiring orthodontic treatment
3. At least 8 permanent teeth erupted on each arch
4. Participant with fair oral hygiene (defined as plaque index <2)
5. Participants who possess a smart phone/tablet compatible and able to download the BEAM® application

Exclusion Criteria

1. Participants who are taking medications that are known to enlarge the gingival tissues (anti-epileptics, calcium channel blockers, etc…)
2. Participants who are planning to move out of Birmingham, AL in the next 6 months
3. Participants currently enrolled in a different hygiene research project

Method

Subjects were recruited through the Orthodontic Postgraduate Clinic at the University of Alabama at Birmingham School of Dentistry. Each participant was approached by a

member of the research team (Principal Investigator, Co-Investigator) before bracket placement and the study was presented to him or her. If they agreed on participating, they signed a consent or an assent form, based on their legal age. Participants who signed an assent form had a consent form signed by their legal guardian.

Each participant was randomly assigned to one of the 3 groups at the bonding visit by puling the group's number out of a closed envelope:

1. BEAM® brush with BEAM® app
2. BEAM® brush without BEAM® app
3. Manual toothbrush (control)

At each study visit, intra-oral photographs were taken using a standard intra-oral photographic camera in a light controlled environment (frontal shot, left and right buccal shots). A clinical examination recording Plaque Index and Gingival Index was also performed. Participants were recalled every 6 weeks, to preserve the regular orthodontic treatment sequence. Initial hygiene instructions were delivered using an educational video to standardize the message among the three groups. This video consisted of spoken instructions over an animated simulation of manual brushing of teeth with braces and wires. At the second and third visits, each participant also filled out a compliance questionnaire (Figure 1). A summary of the procedures conduced at each visit is presented in Table 1.

Table 1: Study timeline for each participant

Time point	# of weeks	Procedure
T0	0	Initial evaluation: Consent form, Intraoral photos, Random assignment to one of the 3 groups, Brackets placed, oral hygiene instructions given, measurements of plaque index and gingival index
T1	6	Intraoral Photos, measurements of plaque index and gingival index, fill out paper questionnaire
T2	12	Intraoral Photos, measurements of plaque index and gingival index, fill out paper questionnaire

Studied parameters

1. *Oral Health evaluation*

Two periodontal indices were used to track oral health: the Plaque Index [62] (Table 2) and the Gingival Index [26] (Table 3). Each tooth was evaluated at 4 sites for each index: mesial, mid-buccal, distal and mid-palatal.

PI and GI were calculated for each group at each time point as an overall score for the entire mouth, score per sextant (6 sextants: teeth #2-5; 6-11; 12-15; 18-21; 22-27; 28-31), for all buccal sites (mesial, mid-buccal, distal), then per specific site: mid-buccal scores and lingual/palatal sites scores.

PI and GI are expected to be low in health. The scores were used to compare baseline (T0) oral health to T1 and T2 health status within each group and between groups.

2. *Application tracking*

The frequency and duration of brushing in Group 1 was tracked using the BEAM® application. The app interface is shown in Figure 2. For each participant in Group 1, instructions were provided on how to install the "BEAM® App" onto their mobile device. With the investigator present, each toothbrush was then

synced to the application to ensure that the application was working properly. For participants in Group 2, there was no information provided about the Bluetooth capability of the toothbrush. The compiled app data for Group 1 was given to the Investigators by the BEAM® Company.

Reported compliance of all participants was tracked using a paper brushing and compliance questionnaire filled out by participants (Figure 1). The questionnaire allowed them to describe their brushing habits (type of toothbrush used, frequency of brushing, duration of brushing) as well as to track behavior linked to brushing (use of reminders, suggested compliance aids). The answers for questions 2 and 3 were compared to the data generated by the app.

Figure 1. Participant Brushing and Compliance Questionnaire

The Beam System: Effect on Dental Hygiene and Compliance in Orthodontic Patients

IRB #: X150806001

QUESTIONNAIRE

Please fill-out the questionnaire below by checking the appropriate box(es) or writing down your comments. A member of our study team will be happy to assist you should you have any questions

1. **Do you use a manual or powered toothbrush?**
    1. Manual
    2. Powered
2. **How often do you brush your teeth?**
    1. One time per day
    2. Two times per day
    3. More than 2 times a day
    4. When I remember
3. **On average, how much time do you spend brushing your teeth?**
    1. One minute
    2. 2 minutes
    3. I don't know
    4. I use a timer
4. **Do you need to be reminded to brush your teeth?**
    1. Yes
    2. No

    If yes, which of the following would be helpful to you?

    1. An alarm
    2. A text message
    3. A phone app
    4. A family member
5. **Do you think an app may be useful to help you take better care of your teeth? Why?**
    1. Yes
    2. No
6. **What is the best way to encourage your friends brush their teeth?**
    1. Video
    2. App
    3. Text
    4. Show them how
    5. Give them rewards

Table 2. Plaque Index [62]

Score	Description
0	No plaque in the gingival area
1	A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be recognized only by running a probe across the tooth surface.
2	Moderate accumulation of soft deposits within the gingival pocket and on the gingival margin and/or adjacent tooth surface that can be seen by the naked eye.
3	Abundance of soft matter within the gingival pocket and/or on the gingival margin and adjacent tooth surface.

Table 3. Gingival Index [26]

Score	Description
0	Normal gingiva
1	Mild inflammation, slight change in color and edema, no bleeding on palpation
2	Moderate inflammation, redness, edema, glazing, bleeding on probing
3	Severe inflammation, marked redness and edema, ulcerations, tendency to spontaneous bleeding

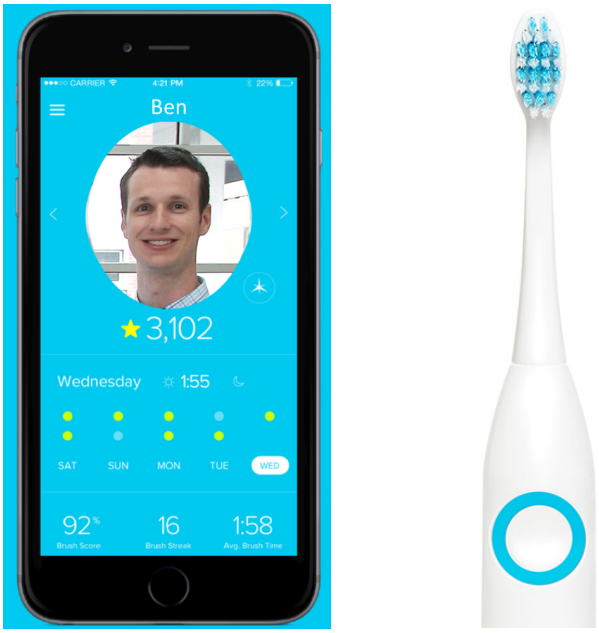

Figure 2.
BEAM®[®] Application Interface and BEAM®[®] Toothbrush: Application interface as seen on a mobile device.
Once the participant is registered and the toothbrush is turned on (left picture), it connects to the BEAM® App through Bluetooth (right picture). The parameters of interest are duration and frequency of brushing.

Statistical Methods

Descriptive statistics (mean and standard deviation) were used to summarize the plaque indexes at all sites, straight buccal sites, buccal sites plus interproximals and plaque indexes of 6 sextants for each study groups at baseline (T0), 6 weeks (T1) and 12 weeks (T2). A linear mixed model with compound symmetry covariance structure was used to examine the plaque index differences between time points for each group. The differences in plaque indexes between groups at various time points were assessed using an ANOVA. Post-hoc comparisons were performed using t-tests. Similarly gingival scores at all sites, straight buccal sites, all buccal sites and palatal sites as well as gingival scores by sextants were compared between groups and across time points using the same methods as described above. A chi-squared (or Fisher's exact) test was used to compare the questionnaire responses between the three groups at T1 and T2. Percent agreement and Cohen's Kappa were computed to assess the consistency of responses to the questionnaires at T1 and T2 for the entire cohort and individual group, as well as comparisons of questionnaire responses against the data captured by the application. To correct for multiple testing for the post-hoc comparisons, a Bonferroni corrected p-value of 0.017 was used as a threshold to determine statistical significance in two-tailed statistical tests. All analyses were conducted using SAS 9.4 (SAS Institute, Cary NC) software.

CHAPTER 3

RESULTS

Periodontal parameters: Plaque Index and Gingival Index

The PI and GI were measured at 4 sites on each tooth. The periodontal parameters data were analyzed as follows for each group across time points and between groups:

1- Overall scores for each parameter for the entire mouth

2- Score per sextant for each parameter

3- Score for all buccal sites for each parameter

4- Mid-buccal scores for each parameter

5- Palatal/lingual scores for each parameter

Overall scores (All Sites, All Teeth)

Plaque Index (overall score)

When evaluating plaque indexes at all sites on all teeth between time points for each group, *Group 2* was the only group that showed a significant increase in PI between baseline (T0) and last visit (T2) ($p=0.006$). All other groups showed no significant differences between time points. At each time point, there was no significant intragroup difference. (Table 4)

Table 4. Plaque Scores of All Teeth, at All Sites

PI	T 0	T 1	T 2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Group 1	1.28±0.44	1.29±0.33	1.38±0.28	0.95	0.37	0.4
Group 2	1.08±0.59	1.27±0.45	1.36±0.4	0.06	0.006*	0.38
Group 3	1.27±0.49	1.51±0.4	1.46±0.37	0.03	0.09	0.65
(G1-G2) p value	0.19	0.91	0.89			
(G1-G3) p value	0.94	0.16	0.61			
(G2-G3) p value	0.22	0.12	0.5			

*Denotes statistical significance at $p < 0.017$ with Bonferroni correction, G= group

Gingival Index (overall score)

When evaluating gingival scores between all groups at all time points, *Group 2* showed a significant higher gingival score at T1 and T2 as compared to baseline (T0). A significant increase was also noted in *Group 3* from baseline to T1 and T2. Lastly, when comparing all three groups at each timepoint, a significant difference was noted in the gingival score only at T0 between Group 1 and Group 2, with Group 1 exhibiting a higher baseline GI score (p=0.010). (Table 5)

Table 5. Gingival Scores of All Teeth, at All Sites

GI	T 0	T 1	T 2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Group 1	1.44±0.29	1.64±0.29	1.55±0.22	0.06	0.28	0.4
Group 2	1.12±0.56	1.51±0.35	1.59±0.29	<.0001*	<.0001*	0.39
Group 3	1.31±0.41	1.57±0.32	1.54±0.31	0.013*	0.028	0.76
(G1-G2) p value	0.010*	0.3	0.79			
(G1-G3) p value	0.3	0.61	0.92			
(G2-G3) p value	0.14	0.62	0.71			

*Denotes statistical significance at $p < 0.017$ with Bonferroni correction, G= group

Scores by Sextants

PI and GI scores for each group were calculated by sextants across time points:

Sextant 1: teeth #2-5;

Sextant 2: Teeth #6-11

Sextant 3: Teeth #12-15

Sextant 4: Teeth #18-21

Sextant 5: Teeth #22-27

Sextant 6: Teeth #28-31

Plaque Index per Sextant

Plaque indexes for each group per sextant were compared across time points.

Group 1: no difference was found in plaque scores between each of the sextants over any of the time points (T0, T1, T2).

Group 2: Sextant 1 (tooth #2-5) showed a significant increase in PI between T0 and T1 ($p=0.011$) as well as between T0 and T2 ($p=0.003$). *Sextant 3* (tooth #12-15) also showed a significant increase in PI between T0 and T2 ($p=0.006$)

Group 3: no significant difference was found between sextants over time points (T0, T1, T2). (Table 6)

Table 6. Plaque Scores for All Sites Within Each Sextant for Groups 1, 2, & 3

Group 1

PI	T0	T1	T2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Sextant 1	1.26±0.61	1.26±0.52	1.42±0.33	0.99	0.22	0.23
Sextant 2	1.2±0.57	1.09±0.38	1.26±0.28	0.41	0.68	0.22
Sextant 3	1.51±0.5	1.55±0.37	1.67±0.47	0.78	0.22	0.35
Sextant 4	1.33±0.47	1.42±0.47	1.37±0.29	0.55	0.81	0.72
Sextant 5	1.16±0.53	1.16±0.43	1.3±0.34	0.97	0.32	0.34
Sextant 6	1.3±0.48	1.42±0.29	1.41±0.31	0.38	0.44	0.91

Group 2

PI	T0	T1	T2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Sextant 1	1.09±0.63	1.4±0.46	1.45±0.45	0.011*	0.003*	0.67
Sextant 2	0.94±0.77	1.17±0.61	1.2±0.55	0.06	0.038	0.85
Sextant 3	1.25±0.67	1.53±0.52	1.58±0.46	0.018	0.006*	0.67
Sextant 4	1.11±0.66	1.31±0.53	1.41±0.49	0.11	0.021	0.45
Sextant 5	0.9±0.62	1±0.43	1.2±0.45	0.44	0.02	0.13
Sextant 6	1.36±0.65	1.42±0.49	1.49±0.39	0.62	0.3	0.58

Group 3

PI	T0	T1	T2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Sextant 1	1.38±0.31	1.51±0.31	1.47±0.26	0.35	0.54	0.75
Sextant 2	1.22±0.59	1.44±0.6	1.4±0.54	0.13	0.22	0.78
Sextant 3	1.49±0.58	1.62±0.34	1.61±0.45	0.31	0.34	0.94
Sextant 4	1.26±0.5	1.57±0.43	1.46±0.4	0.029	0.17	0.41
Sextant 5	1.14±0.72	1.45±0.51	1.4±0.6	0.038	0.09	0.7
Sextant 6	1.27±0.57	1.61±0.4	1.5±0.43	0.022	0.11	0.46

*Denotes statistical significance at $p < 0.017$ with Bonferroni correction

Gingival Index per Sextant

Gingival scores for each group per sextants were compared across each time point.

Group 1: no difference was found in gingival scores between each of the sextants over any of the time points (T0, T1, T2).

Group 2: All sextants except Sextant 5 (tooth #22-27) at time interval T0-T1 showed a statistically significant increase in gingival score across time points.

Group 3: *Sextant 5* (tooth #22-27) showed a significant difference between time points T0 and T1 as well as T0 and T2 (p=0.001). All others sextants showed no significant difference. (Table 7)

Table 7. Gingival Scores for All Sites Within Each Sextant for Groups 1, 2 and 3

Group 1

GI	T0	T1	T2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Sextant 1	1.48±0.37	1.51±0.25	1.53±0.28	0.8	0.72	0.91
Sextant 2	1.27±0.37	1.53±0.34	1.37±0.21	0.04	0.44	0.2
Sextant 3	1.6±0.33	1.76±0.34	1.74±0.27	0.16	0.22	0.85
Sextant 4	1.43±0.3	1.66±0.47	1.58±0.31	0.05	0.2	0.49
Sextant 5	1.45±0.37	1.71±0.34	1.56±0.29	0.039	0.36	0.24
Sextant 6	1.52±0.26	1.66±0.32	1.63±0.31	0.26	0.36	0.82

Group 2

GI	T0	T1	T2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Sextant 1	1.21±0.64	1.56±0.43	1.65±0.28	0.002*	<.0001*	0.38
Sextant 2	1.03±0.63	1.43±0.55	1.42±0.28	0.0006*	0.0007*	0.94
Sextant 3	1.2±0.59	1.75±0.35	1.82±0.34	<.0001*	<.0001*	0.47
Sextant 4	1.12±0.55	1.51±0.32	1.57±0.33	0.0004*	<.0001*	0.6
Sextant 5	1.05±0.61	1.32±0.37	1.5±0.43	0.02	0.0002*	0.11
Sextant 6	1.17±0.55	1.64±0.35	1.7±0.29	<.0001*	<.0001*	0.59

Group 3

GI	T0	T1	T2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Sextant 1	1.47±0.17	1.52±0.3	1.48±0.28	0.73	0.99	0.74
Sextant 2	1.3±0.54	1.55±0.37	1.48±0.38	0.05	0.16	0.57
Sextant 3	1.39±0.47	1.68±0.43	1.64±0.45	0.018	0.039	0.76
Sextant 4	1.31±0.46	1.54±0.36	1.57±0.34	0.06	0.038	0.83
Sextant 5	1.16±0.58	1.61±0.44	1.6±0.4	0.001*	0.001*	0.93
Sextant 6	1.36±0.45	1.55±0.35	1.51±0.37	0.11	0.21	0.73

*Denotes statistical significance at $p < 0.017$ with Bonferroni correction

Periodontal Parameters for all Buccal Sites

All buccal sites, including interproximals, were evaluated to investigate the impact of brackets and wires on gingival parameters.

Plaque Index for all Buccal Sites (mesial, mid-buccal, distal)

Group 2 plaque scores were significantly higher at T2 than T0 (p=011). All others groups and time points were reported as being non-significant (Table 8).

Table 8. Plaque Scores for All Buccal Sites, Including Interproximals

PI	T 0	T 1	T 2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Group 1	1.31±0.46	1.26±0.35	1.42±0.34	0.71	0.37	0.2
Group 2	1.1±0.63	1.26±0.48	1.4±0.46	0.18	0.011*	0.22
Group 3	1.28±0.61	1.55±0.48	1.51±0.43	0.04	0.07	0.81
(G1-G2) p value	0.23	0.99	0.91			
(G1-G3) p value	0.87	0.12	0.61			
(G2-G3) p value	0.32	0.1	0.52			

*Denotes statistical significance at $p < 0.017$ with Bonferroni correction, G= group

Gingival Index for all buccal sites (mesial, mid-buccal, distal)

Group 1 did not show any significant difference in gingival scores across all time points.

Group 2 showed a significant increase in GI between T0 and T1 as well as between T0 and T2 ($p=0.0002$ and $p<0.0001$ respectively)

Group 3 showed a significant increase in GI between T0 and T1.($p=0.014$)

No significant group difference was detected at each time point. (Table 9)

Table 9: Gingival Scores for All Buccal Sites, Including Interproximals

GI	T 0	T 1	T 2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Group 1	1.41±0.3	1.6±0.33	1.52±0.24	0.08	0.29	0.48
Group 2	1.12±0.56	1.5±0.37	1.59±0.32	0.0002*	<.0001*	0.39
Group 3	1.31±0.52	1.59±0.37	1.56±0.37	0.014*	0.027	0.81
(G1-G2) p value	0.038	0.47	0.66			
(G1-G3) p value	0.49	0.93	0.81			
(G2-G3) p value	0.18	0.54	0.85			

*Denotes statistical significance at $p < 0.017$ with Bonferroni correction, G= group

Periodontal Parameters per Tooth Aspect

Each periodontal parameter was independently evaluated per tooth aspect.

Plaque Index at Mid-Buccal Sites

When evaluating the mid-buccal sites only, there was no significant difference in plaque index values between groups at any time point. Also, no difference was observed when comparing the mid-buccal sites of each group across each time points. (Table 10)

Table 10. Plaque Scores for Mid-Buccal Sites Only

PI	T0	T1	T2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Group 1	1.33±0.47	1.24±0.31	1.38±0.32	0.49	0.66	0.26
Group 2	1.09±0.6	1.22±0.46	1.34±0.43	0.27	0.027	0.26
Group 3	1.25±0.6	1.5±0.48	1.46±0.44	0.05	0.11	0.73
(G1-G2) p value	0.16	0.87	0.82			
(G1-G3) p value	0.66	0.14	0.66			
(G2-G3) p value	0.35	0.09	0.49			

*Denotes statistical significance at $p < 0.017$ with Bonferroni correction, G= group

Gingival Scores at Mid-Buccal Sites

When comparing the gingival scores at mid-buccal sites of each group, *Group 2* gingival scores showed a significant increase from T0 to T1 and T0 toT2 (p=0.005 and p<0.0001 respectively) All other groups showed no significant difference across time points. Gingival scores between groups did not differ at any time point (Table 11).

Table 11**:** Gingival Scores for Mid-Buccal Sites

GI	T 0	T 1	T 2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Group 1	1.43±0.31	1.59±0.28	1.51±0.3	0.18	0.47	0.53
Group 2	1.11±0.56	1.43±0.39	1.56±0.36	0.005*	<.0001*	0.22
Group 3	1.25±0.49	1.47±0.41	1.51±0.36	0.079	0.038	0.75
(G1-G2) p value	0.026	0.25	0.74			
(G1-G3) p value	0.23	0.41	0.96			
(G2-G3) p value	0.35	0.78	0.71			

*Denotes statistical significance at $p < 0.017$ with Bonferroni correction, G= group

Plaque Index at Palatal/Lingual Sites

When comparing plaque indexes from the palatal sites alone, *Group 2* was the only group to show a significant increase between T0 and T1 (p=0.002) (Table 12)

Table 12. Plaque Scores for Palatal and Lingual Sites Only

PI	T 0	T 1	T 2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Group 1	1.19±0.55	1.36±0.34	1.24±0.15	0.1	0.6	0.26
Group 2	1±0.51	1.3±0.44	1.22±0.28	0.002*	0.017	0.41
Group 3	1.23±0.28	1.41±0.35	1.30±0.32	0.09	0.51	0.29
(G1-G2) p value	0.16	0.65	0.86			
(G1-G3) p value	0.77	0.71	0.69			
(G2-G3) p value	0.09	0.4	0.56			

*Denotes statistical significance at $p < 0.017$ with Bonferroni correction, G= group

Gingival Index at Palatal/Lingual Sites

Gingival scores from the palatal sites only were compared between groups and across time points.

Group 1 showed no significant time point difference

Group 2 showed a significant increase in GI scores between T0 and T1 as well as T0 and T2 ($p<0.0001$).

Group 3 showed no difference across time points.

When comparing each group to one another, *Group 1* and. *Group 2*'s gingival scores were significantly different at T0 (baseline), with Groups 1's score being higher ($p=0.0006$) (Table 13)

Table 13. Gingival Scores for Palatal and Lingual Sites Only

GI	T 0	T 1	T 2	p value (T0-T1)	p value (T0-T2)	p value (T1-T2)
Group 1	1.54±0.3	1.75±0.3	1.64±0.3	0.06	0.38	0.29
Group 2	1.11±0.59	1.53±0.36	1.59±0.28	<.0001*	<.0001*	0.52
Group 3	1.29±0.16	1.52±0.35	1.48±0.31	0.041	0.1	0.68
(G1-G2) p value	0.0006*	0.07	0.69			
(G1-G3) p value	0.06	0.09	0.23			
(G2-G3) p value	0.14	0.98	0.38			

*Denotes statistical significance at $p < 0.017$ with Bonferroni correction, G= group

Questionnaire and Application Results

Participant Paper and Compliance Questionnaire

Paper questionnaires were administered to all participants at T1 and T2. They comprised questions about brushing habits as well as questions investigating compliance.

A total of 33 participants were given the electric toothbrushes (Groups 1 and 2) and 14 used manual toothbrushes throughout the course of the study. When considering all three groups (Groups 1, 2, & 3) and comparing them over time (T1 & T2) differences were noted in the responses to the questionnaire. Kappa scores were used as a way to account for random chance in a sample of data. It allowed for the discernment between factual data and reported data.

At both T1 and T2, 87% of all participants reported brushing at least 2 times or more per day and 72% (T1) to 74% (T2) of the participants reported brushing 2 minutes each cycle. A decrease in the number of participants needing a reminder to brush their teeth was recorded between T1 and T2 (91% and 95% respectively). In 100% of the cases, participants reported a family member as being their reminder to brush their teeth, versus the use of an alarm, a text message, or a phone app. From T1 (68%) to T2 (66%), a slight decrease is noted in the number of participants reporting to find the app as being useful. All participants reported that the "tell, show, do" technique was the best way to learn how to brush their teeth, reported in the questionnaire as "show them how" option for question 6.

Comparisons of Responses to Questions Between the Three Groups (T1)

There was no statistically significant difference between the three groups' responses at T1. A total of 93% of Group 1 perceived the app as being useful, while 45% of those whom were not utilizing the app did not think it would be beneficial.

Comparisons of Responses to Questions Between the Three Groups (T2)

The percentage of participants reporting a brushing time of 2 minutes was higher in Groups 1 (100%) and 2 (72%) than in Group 3 (50%). Participants in Group 3 (42.8%) reported not knowing for how long they were actually brushing their teeth. This percentage was higher than any of the 3 groups. Group 1 had the highest percentage overall that found the app to be useful, 93%. Overall 66% of the participants in the study perceived the app as being useful. Group 3 had the highest percentage of those that believed the app would not be beneficial (57% of group 3, and 34% overall)

Comparison of Change in Responses to Questionnaire From T1 to T2 for all Participants

There was no significant difference in change in response to questions at T1 and T2 when comparing all groups to one another over time.

Comparison of Change in Response to Questionnaire From T1 to T2 by Group

There was no significant difference in change of response to the questions within each group over time points T1 and T2. This finding applies to Groups 1, 2 and 3.

Participant Application Software Data: Group 1

Participants enrolled in Group 1 were asked to synchronize their phones and toothbrushes in order to allow the BEAM® application to record the frequency and duration of their brushing. The recorded data was compared to the reported data on the paper questionnaire through questions 2 (frequency) and 3 (duration).

Comparison of Application Data to Questionnaire

When comparing the data retrieved from the application to the responses reported on the questionnaire, it was noted that 4 of the 11 participants in Group 1 were not recorded due to a failure in communication with the Bluetooth technology and the application. The duration of brushing time in Group 1 was recorded as a range from 1.4- 4.4 minutes, with an average brushing time of 2 min. 91% of the participants were recorded as brushing 2 times a day and 9% were recorded as brushing 3 times a day.

When focusing on the frequency of brushing at T1, an agreement of 81.8% with a kappa of -0.0476 was found. There was no effective agreement between questionnaire and app in regards number of brushing cycles per day. At T2, a 100% agreement was seen between questionnaire and app data (Kappa =1).

In regards to brushing duration, an agreement of 100% with a Kappa of 0.5 was found at both T1 and T2. This shows a fair agreement between questionnaire and app in regards to length of each brushing cycle. The reason there were only 9 data points recorded was due to the fact that two participants spent more than 2 minutes brushing their teeth and there was not an answer choice for longer brushing time within the questionnaire.

CHAPTER 4

DISCUSSION

The aims of this study focused on comparing the efficacy in brushing with a powered toothbrush equipped with Bluetooth technology to that of a manual toothbrush during the early stages of orthodontic treatment by evaluating periodontal parameters (plaque and gingival scores), as well as study the relationship between patient brushing and compliance habits, and their agreement with application software recorded compliance.

Recent studies have shown that technology has an increasing role in many forms of healthcare. Whether be motivational messaging or simple reminders, text messaging has shown to be effective in improving patient compliance[56, 61]. When evaluating the BEAM® System, the Bluetooth technology was used solely as an objective way to record oral hygiene compliance, through tracking frequency and duration of brushing. Only participants in Group 1 received the BEAM® application.

In our study, participants who used the app reported finding it useful, and participants who did not could not really perceive an advantage to it, as they had not tried it. It is however interesting to note that overall, Groups 1 and 3 performed better than Group 2, based on the periodontal parameters. If Group 3 (manual toothbrush) is considered the control, then using an app would make powered toothbrush users more similar to the control, as the group who did not use the app but had the powered toothbrush had worse periodontal scores. This finding could be explained by random

chance since each participant was randomly distributed among the groups. Another explanation is that the app does in fact motivate participants, by turning a hygiene habit into a game. The concept of gamification is very novel in the medical field. It consists of transforming a repetitive action into a positive experience so that candidates engage in an activity with a higher duration and intensity[63-65]. From this standpoint, dental hygiene, a repetitive and mandatory activity for oral health, would be the perfect candidate for gamification.

At baseline, plaque levels were similar in the 3 groups. While not statistically significant, the plaque scores increased steadily in all 3 groups throughout the observation period. Group 2 had a statistically significant increase in plaque and gingival scores between baseline and T2. However, at the end of the study, there was no difference between the groups. This finding is an indication that plaque removal is more challenging when patients are undergoing orthodontic treatment with fixed appliances. Plaque scores in orthodontic patients have been shown to be as high as 2-3 times that of patients without orthodontic fixed appliances[53]. Plaque accumulates readily on bonded attachments, elastomeric ligatures, and patients are more prone to gingivitis throughout the course of treatment[17-19, 53]. Moreover, Oggard found that due to increased plaque and gingival scores, demineralization occurs rapidly within the first couple months of orthodontic treatment[30]. These facts highlight the significance of installing exceptional oral hygiene habits at the start of orthodontic care, and reinforcing them throughout treatment[53]. The expectation was that participants enrolled in an oral hygiene study protocol would do their best to clean their teeth, but the results show otherwise, thus the importance of properly installing the habit since treatment start.

The selection of a toothbrush is primarily dependent on personal preference, affordability, and/or professional recommendation. While much debate still exists over the effectiveness of manual versus powered toothbrushes, several studies hold firm on the claim that powered brushes reduce plaque and gingival health scores more than a manual toothbrush[42, 43, 53]. Through this study, it was found that plaque accumulation, which could result in gingivitis and enamel decalcification, was very similar whether using a manual or a powered toothbrush. The gingival indexes were statistically increased between Groups 1 and 2 at baseline, for Group 2 between T0-T1 and T0-T2, and for Group 3 for T0-T1. They were also increased on the palatal side only between Groups 1 and 2 but not on the buccal side, suggesting that the statistically significant difference in GI scores between these 2 groups was due to inflammation on the palatal side at the start of treatment in Group 2. As gingival bleeding is a sign of inflammation, close monitoring of oral hygiene habits and performance would also serve to reduce inflammation. The Beam toothbrush is a sonic toothbrush, and similar to previous studies, it did not show a particular advantage in overall plaque removal, as shown by the clinical parameters. This finding is in agreement with previously published reports [40, 52] that state that the difference between different types of powered toothbrushes is not clinically significant, even though the rotation oscillation brushes might show a slight advantage at reducing gingivitis in the short term.

It is interesting to note that plaque removal was more challenging for Group 2, with sextants 1 and 3 showing an increase in plaque scores for T0-T1 and T0-T2. These sextants correspond to the maxillary posterior segments. The gingival indexes were increased for Group 2 in all sextants throughout the study. The posterior buccal segments;

specifically sextants 1, 3, 4, 6; are more difficult to properly clean and show higher plaque and gingival scores[66]. Previous studies have shown an advantage for powered toothbrushes for the lingual aspects and the mandibular teeth[50, 51]. While the sextant location for Group 2 is different, it nonetheless emphasizes the need to orient the toothbrush bristles adequately to achieve good oral hygiene. Interestingly, Group 2's performance led to higher PI and GI scores for both the mid-buccal and the palatal measurements throughout treatment, implying that their brushing was really affected by their technique rather then by the presence of bonded attachments. Patients may perceive powered toothbrushes to be more effective than they really are and hold more stock in the idea that the powered motion of the toothbrush requires less patient hand movement.

Another key point in the design of the study is that no interproximal cleaning devices were prescribed to the participants. Toothbrushes typically do not target interproximal areas, and the presence of orthodontic wires makes this task even more challenging. Based on the results, plaque and gingival indexes worsened when the interproximal surfaces were included in the overall scores. Interestingly, a recent systematic review found low-quality evidence in the need to use interproximal aids or a reduction in gingivitis and plaque at one month[67]. However, orthodontic treatment typically spans a duration of 24 months. Interproximal brushes alone have been shown to reduce overall plaque [68, 69] and are recommended for use in all patients[40]. Some authors also found them to be more effective than dental floss[70, 71], whereas others say that there was low levels of evidence pertaining to the difference between dental floss and interproximal brushing[67]. In the presence of wires that do not allow for an easy

flossing motion, interproximal brushes might be a more attractive choice for patients undergoing orthodontic treatment with fixed appliances.

Studies have shown that optimal brushing time is at a minimum of 2 minutes[66]. While the electric toothbrush may not necessarily be more effective, individuals using a toothbrush with a built-in timer were more likely to brush for consistent duration of time. For instance, the average brushing time recorded by the application for participants in Group 1 was 2 minutes. It was also found that those same patients were brushing at least 2 times per day. Of the three groups, Group 3 was the only group to show variation among reported duration of brushing. It is likely that patients who do not use a timer perceive themselves as brushing longer than they really do, even though epidemiologic studies recommend the use of self-reported brushing habits as a proxy measure for oral hygiene indices such as the plaque index[72]. However, given the difference in sample size, this was not applicable in our study. It is also important to consider the fact that brushing for 2 minutes, 2 times per day does not necessarily translate into good oral health. As stated earlier, proper technique is key, as a patient could simply turn the device on with little effort into working the bristles underneath the brackets themselves.

Cumulatively, 91% of the participants reported not needing a reminder to brush. Of those that did require a reminder, 100% reported their parents as being their source, rather than an electronic device. This finding is contrary to what has been found to be most effective in serving as reminder for patients. Many studies have found that messaging devices as well as applications are highly effective in reminding patients to brush[55, 57-59]. It may be that young patients are used to rely on their parents, and that electronic reminders work better with adults. While all participants were provided oral

hygiene instruction at the beginning and throughout treatment, difficulty in adequately removing plaque build-up remained persistent. It also important to note that 89% of patients reported that "tell, show, do" was the best way to learn. This technique is commonly used with pediatric patients and combines verbal and non-verbal communication coupled with positive reinforcement[73]. A recommendation would therefore be to spend time presenting oral hygiene techniques to patients using this technique, even though in a busy orthodontic practice setting, a voice over video seems more practical.

Kappa scores were calculated to compare recorded and reported compliances in Group 1, as it was the only group to use both paper questionnaires and the BEAM® application. The kappa test has been used in many studies to assess the reliability and agreement of self-reported brushing frequency and duration[72, 74]. Both frequency and duration were tested.

Of the three groups, Group 1 was the only group to register their toothbrush with the BEAM® application, providing opportunity to compare reported frequency and duration of brushing by each participant via the questionnaire, to the objective data collected by the Bluetooth technology. After comparing the data retrieved from application software and the questionnaires by each participant several key findings were highlighted. There was a lack of agreement between reported and recorded frequencies of brushing at T1 that increased to a fair agreement at T2. There was a fair agreement between reported and recorded durations of brushing at T1 and T2, as indicated by kappa values of 0.5. The discrepancies between the reports could be explained by a lack of good communication between the toothbrush and the application, as duration is preset in the

toothbrush timer. Though the data shows that subjects using an electric toothbrush were more likely to brush for 2 minutes, no direct correlation can be made suggesting the increased duration of brushing directly improves plaque scores and gingival health. It was also recorded that 100% of those using the BEAM® application were recorded as brushing at least 2 times or more per day. Taking into consideration frequency and duration of brushing, it appears that the quality of brushing is the most important factor in regards to plaque reduction and improved gingival health. This finding is in accordance with previously published reports[67, 71].

Limitations

Some aspects of the study could be refined. From a design standpoint, it would be interesting to recruit a larger number of participants in each group and follow them up over a longer period of time to see the changes that would affect the measured periodontal parameters. Getting the participants to fill-out the paper questionnaire would also have been of value, to see if any changes in their habits occurred as a result of the study. In the questionnaire, diet questions could be incorporated, as the nature of the ingested food and drinks can have an effect on plaque formation. Moreover, a question about being left or right handed would have allowed to increased comparisons between the participants and the time points. From a technical standpoint, The BEAM® system showed inconsistencies in data transfer, as the toothbrush sometimes did not synchronize with the application. In addition, there were multiple instances throughout the course of the study where the BEAM® toothbrush failed due to water damage inside the unit. Corrosion of the batteries leading to failure in the communication between devices led to

toothbrushes having to be replaced and re-synced throughout the course of the study. This limitation could be easily addressed by building a more robust system.

A comparison between scripted live dental brushing demonstration and voice over video instructions would be of value, to discern any major advantage of one technique over the other. Finally, linking the app to a rewards system is worth exploring, as it might increase compliance and motivation.

CHAPTER 5

CONCLUSIONS

Proper oral hygiene instructions seem to be the most important variable in achieving plaque control, as well as patient motivation and diet control. It is important for clinicians to continuously provide oral hygiene instructions throughout the course of orthodontic care. Overall brushing quality depends on brushing technique and does not seem to be device related. Frequency and duration of brushing are not as important as brushing quality. Patients that use toothbrushes with built-in timers may be more likely to brush the required time frame (2 min). The use of toothbrushes associated with apps could be promising to increase compliance within an orthodontic practice as long as a reliable app/device system can be built.

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APPENDIX A

IRB APPROVAL FORM

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Institutional Review Board for Human Use

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on January 24, 2017. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator:	SOUCCAR, NADA M
Co-Investigator(s):	SAMUELSON, BENJAMIN
Protocol Number:	**X150806001**
Protocol Title:	*The Beam System: Effect on Dental Hygiene and Compliance in Orthodontic Patients*

The IRB reviewed and approved the above named project on 8/22/16 The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This Project will be subject to Annual continuing review as provided in that Assurance.

This project received EXPEDITED review.

IRB Approval Date: 8/22/16

Date IRB Approval Issued: 8/22/16

IRB Approval No Longer Valid On: 8/22/17

Expedited Reviewer
Member - Institutional Review Board
for Human Use (IRB)

Investigators please note:

The IRB approved consent form used in the study must contain the IRB approval date and expiration date.

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

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