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Sarah Elizabeth LaRue

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CLEAR ALIGNER THERAPY VS. TRADITIONAL BRACKETS ON SMILE ARC

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Thesis submitted
to the School of Dentistry
at West Virginia University
in partial fulfillment of the requirements for the degree of

**Master of Science in
Orthodontics**

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2020

Keywords: clear aligners, smile arc, smile arc protection, smile arc flattening

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ABSTRACT

CLEAR ALIGNER THERAPY VS. TRADITIONAL BRACKETS ON SMILE ARC

Sarah Elizabeth LaRue, D.D.S.

Background and Objectives: More so than ever, the public is becoming exceedingly aware of esthetics, and will evaluate their treatment outcome based upon the improvement to their smile and overall enhancement of their facial appearance. Smile arc is considered to be a key component of facial esthetics. Literature has demonstrated that orthodontic treatment mechanics utilizing traditional brackets and wires can cause flattening of the smile arc and that smiles with flatter arcs are judged to be less attractive. The aim of this study was to determine whether clear aligner therapy can help to preserve or improve the smile arc when compared to traditional bracket orthodontics.

Experimental Design and Methods: A sample of 98 subjects that had completed comprehensive orthodontic treatment (50 treated using clear aligners, 48 treated using traditional orthodontic brackets) and had existing pre and post-treatment posed smiling photographs, were selected. 15 orthodontic experts (8 residents and 7 WVU faculty orthodontists) were asked to view a presentation of all the pre and post-treatment smiling photos and to evaluate whether orthodontic treatment had: a) improved the smile arc, b) maintained or had no clinically significant effect on the smile arc, or c) flattened the smile arc. Data was assessed to determine whether there was a difference in orthodontic treatment outcome, specifically smile arc, using the aforementioned treatment modalities. The data was analyzed using chi squared analysis, a generalized linear mixed model analysis, as well as probability testing.

Results: The results of analyses for 12 out of 15 raters demonstrated that there was a statistically significant association between treatment modality and smile arc evaluation. When all raters were considered collectively, they evaluated 17.3% of clear aligner treated subjects to have flattened smile arcs compared to 49.7% of bracket treated subjects. ($p < 0.0001$), 37.3% of clear aligner subjects were evaluated to have improved smile arc compared to 24.5% of bracket subjects ($p < 0.0001$), and 45.3% of clear aligner subjects were evaluated to have not affected smile arcs compared to 25.9% of bracket subjects ($p < 0.0001$). There was a significant effect of orthodontic treatment on smile arc evaluation ($p < 0.0001$). Patients with bracket treatment were found to be 5.259 times more likely to have flattened smile arc evaluation than those with clear aligner treatment. The probability of an orthodontic expert evaluating the smile arc as: flattened was 12% (clear aligners) and 42% (bracket treatment), maintained was 51% (clear aligners) and 48% (bracket treatment), and improved was 36% (clear aligners) and 10% (bracket treatment).

Conclusions: There is a significant effect of orthodontic treatment modality on smile arc outcome evaluation by orthodontic experts. Orthodontic expert raters evaluated a significantly lower percentage of clear aligner treated subjects to have flattened smile arcs compared to bracket treated subjects and a significantly higher percentage of clear aligner subjects to have improved smile arcs compared to bracket treated subjects. Patients treated with clear aligners have a higher probability of being evaluated to have improved or maintained smile arcs compared to those treated with brackets.

DEDICATION

To Chad, You are my #1 biggest supporter and believe in me when I can't find the courage to believe in myself. You fill me with love every day. Thank you for being my rock in life and throughout this program.

To Mom and Dad, I would not be where I am without you. Thank you for your endless love and support. You are the ones who made me believe that I am capable of accomplishing anything I set my mind to. I will always need you!

To Adam and Lauren, Thanks for always being on my side no matter what. I can count on you two to always have my back and I know you'd do anything for me. Love you both so much!

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CHAPTER 1: INTRODUCTION

BACKGROUND & SIGNIFICANCE

Orthodontic esthetics has traditionally been associated with profile enhancement. When we consider the most commonly utilized orthodontic assessments of malocclusions, including Angle classification and traditional cephalometric analyses, the focus is clearly on the profile without considering the frontal view.¹ Even though patients seek orthodontic treatment to improve their smiles, orthodontic literature contains more studies on skeletal structure than on soft-tissue structure, and the smile still receives relatively little attention.¹

Smile arc is considered to be one of the 8 components of a balanced smile along with lip line, upper lip curvature, lateral negative spaces (buccal corridors), smile symmetry, occlusal plane, angulation of the anterior dentition, and gingival margins.¹ Smile attractiveness is subjective, but there are several factors that people can agree on which constitute an attractive smile including: upper central incisors that are symmetrical & displayed during the posed smile, 1-3 mm of gingival display at rest (depending on age and gender), and maxillary incisal edges should be parallel to the curvature of the lower lip, in coordination with an ideal smile arc and proper buccal corridors.²

Several orthodontic research articles have demonstrated that flat (non-consonant) smile arcs have been judged to being less attractive when compared to consonant smile arcs.^{3,4} Studies also demonstrate that orthodontic treatment using brackets has a tendency to flatten patients smile arc.^{3,4,5} Despite the abundance of literature demonstrating that orthodontic treatment using brackets can inadvertently flatten smile arc, there are minimal recommendations of ways in which to prevent smile arc flattening in orthodontic practice. To date, there have been no studies published

about the effects of clear aligners on treatment outcome with regard to smile arc. In fact, there is a need for additional literature on clear aligner treatment outcomes in general. For that reason, this study could bring light to a treatment modality that may help to maintain or enhance smile arc in orthodontic treatment. The information revealed in this study may assist orthodontists in making recommendations and treatment planning decisions.

STATEMENT OF THE PROBLEM

Smile arc is an important contributing factor to smile esthetics. Flattened smile arcs (non-consonant) are perceived to be “less attractive” or less esthetic than a consonant smile arc. Orthodontic treatment often times inadvertently flattens smile arcs. While lots of literature exists on the effects of traditional bracket orthodontics on smile arc, there are no published studies on the effects of orthodontic treatment using clear aligners as it relates to smile arc outcomes.

PURPOSE OF THE STUDY

- To determine whether orthodontic treatment with traditional brackets flattens, maintains, or improves smile arc
- To determine whether orthodontic treatment with clear aligners flattens, maintains, or improves smile arc
- To determine if there is a difference in treatment outcomes, with specific reference to smile arc, between clear aligners vs. traditional orthodontic brackets
- To determine whether treatment using clear aligners can aid in preservation or improvement of smile arc when compared to using traditional orthodontic brackets

NULL HYPOTHESES

1. There is no treatment effect on smile arc using traditional orthodontic brackets
2. There is no treatment effect on smile arc using clear aligners
3. There is no difference in smile arc outcomes between traditional orthodontic brackets and clear aligner therapy
4. There is no improvement in smile arc outcome using clear aligners when compared to bracket orthodontics

ALTERNATIVE HYPOTHESES

1. There is a treatment effect on smile arc using traditional orthodontic brackets
2. There is a treatment effect on smile arc using clear aligners
3. There is a difference in smile arc outcomes between traditional orthodontic brackets and clear aligner therapy
4. There is an improvement in smile arc outcome using clear aligners when compared to bracket orthodontics

ASSUMPTIONS

1. All pre and post treatment photographs were taken in the “posed” smile (aka a reproducible smile made when the patient is asked)
2. Orthodontist expert panel can reliably & consistently recognize whether smile arc was flattened, maintained, or improved as a result of the orthodontic treatment rendered

LIMITATIONS

1. Other facial features may influence rater's judgement of smile arc pre and post orthodontic treatment (subjects have various races, genders, ethnicities, etc.)
2. Potential growth or adverse effects of aging may influence rater's judgement of smile arc pre and post orthodontic treatment
3. Patients had various malocclusions pre-treatment which may necessitate differences in corrective strategy (potentially more intrusive forces for deep bite correction, etc.)
4. No age restriction was placed for patient eligibility in the study, creates a treatment modality bias (majority of teenagers received traditional bracket treatment; majority of adults preferred aligners)
5. Unerupted teeth in pre-treatment photographs; there is an eruption effect on smile arc that is unrelated to the treatment

DELIMITATIONS

1. Subjects must have received comprehensive orthodontic treatment using either clear aligners or traditional orthodontic brackets and have pre and post "posed" smiling photographs that are clearly visible
2. Subjects must have no history of orthognathic surgery
3. Where aligners were utilized, subjects must have had at least 14 corrective aligners (Invisalign Lite category or higher)

CHAPTER 2: REVIEW OF THE LITERATURE

SMILE ESTHETICS

A smile is one the most important facial expressions and represents a critical component in the expression of gratitude, happiness, approval, and friendliness.⁶ Smile esthetics are becoming exceedingly important for orthodontists because more orthodontic patients assess the outcome of treatment based upon the improvement of their smiles and overall enhancement of their facial appearance. Historically, orthodontic treatment has been primarily focused on the improvement of occlusal relationships. Presently, one of the major goals of orthodontic treatment is to enhance the appearance of the anterior tooth display during smiling and speech.⁷ Today, more attention is being given to striving for optimal facial esthetics, with the enhancement of dentofacial characteristics.⁸ An article by Pitts shares that facial and smile esthetics are typically the patients primary concern and for that reason, smile esthetics should serve as the overriding standard when treatment planning as well as when evaluating the merit of orthodontic treatment outcomes. Facial attractiveness standards have evolved over the last 20 years; patients are now in search of fuller lips, more vermilion display, and broader arches. Furthermore, facially based treatment planning, with smile arc at its core, go hand in hand with occlusal goals.⁹

SMILE ARC DEFINITION

A smile esthetic characteristic that is not widely discussed or recognized is the relationship of the curvature of the maxillary anterior teeth relative to the lower lip, aka the smile arc. The term “smile arc” has various definitions depending on whether one is studying prosthodontics, orthodontics, or cosmetic dentistry literature.⁵ Cosmetic dentistry text by Goldstein describes the

“older smile,” in which the incisal edges appear straight across the smile in contrast with the “youthful smile” in which the maxillary anterior teeth are longer and create a line that comes slightly downward in the middle of the smile, traveling superiorly to the corners of the mouth.¹⁰ Frush and Fisher proposed that there should be harmony between the curvature of the incisal edges of the maxillary anterior teeth and the curvature of the upper border of the lower lip in the definition of an attractive smile.¹¹ Additionally, an article published in the Dental Press Journal of Orthodontics by Machado classifies smile arc as one of the 10 commandments of smile esthetics. He considers smile arc and the arched contour of the incisal edges of the teeth in the esthetic zone to be the most important factor of dental esthetics.¹²

According to Sarver, smile arc is defined as the relationship of the curvature of the incisal edges of the maxillary incisors and canines to the curvature of the lower lip in the posed smile.

The ideal smile arc has the maxillary incisal edge curvature parallel to the curvature of the lower lip upon smiling; the term consonant is used to describe this parallel relationship. A non-consonant, or flat, smile arc is characterized by the maxillary incisal curvature being flatter than the curvature of the lower lip on smile.⁵



Figure 1: A. Consonant smile arc; B. Non-consonant smile arc

WHY IT MATTERS/ SMILE ATTRACTIVENESS

Most people are aware that an attractive smile helps to win elections, land jobs, and form relationships; Sarver states that, “a beautiful smile sells products for companies whose subliminal message in advertising is – look better, feel younger.” However, even a well- treated orthodontics case in which the plaster casts meet every criterion of the American Board of Orthodontics for successful treatment may not produce an esthetic smile.⁵ Smile arc, as an esthetic concept, has not been fully appreciate by orthodontists.⁵

One study assessed standardized photographs of 40 subjects, 20 treated orthodontically and 20 untreated controls who were considered to have normal occlusion. Results of the investigation revealed that the curvature of the incisal edges of the maxillary anterior teeth was flatter in those who were treated orthodontically. Additionally, a panel judged the smiles with flatter arcs as being less attractive.³ Zachrisson has made similar observations that some orthodontically treated smiles are less attractive than untreated controls.¹³ Furthermore, a 2016 cross sectional study published in the Journal of Clinical and Diagnostic Research also concluded that reverse smile arc was less esthetic than parallel and straight smiles. The paper goes on to suggest that a feasible orthodontic treatment objective should be to prevent a flat or reverse smile arc and to obtain some degree of curvature resembling the lower lip line.¹⁴ A similar study by Parekh et al. evaluated the esthetic acceptability range of computer-generated variations in smile arc by laypersons and orthodontists. The analysis concluded that flat smile arcs were only deemed to be acceptable 50-60% of the time compared to smiles with ideal or excessive arcs which were significantly more acceptable 84-95% of the time. Additionally, they were able to conclude that flat smile arcs are more detrimental to smile esthetics than variations in buccal corridors. They found no significant difference between the preferences of laypersons and orthodontists.¹⁵

Ackerman et al evaluated the smile arc in both treated and untreated patients in their own practice. Almost 40% of the treated patients showed a discernible change in the smile arc; flattening of the arc occurred in 32%. In the untreated group, 13% had a change in smile arc and flattening of the arc occurred in only 5%. They noted no gender differences in the smile characteristics when treated vs. untreated controls were compared.⁴ In contrary to Ackerman's finding that there were no gender differences noted in smile characteristics, a 2008 study found that women had more consonant smile arcs than men when untreated subjects were evaluated by orthodontic specialists and laypersons.¹⁶ Another paper reported that the incisal curvature of upper anterior teeth tends to be more accentuated in females than males, but that it does flatten with age.¹⁷ In summary, smiles with flattened arcs are judged to be less attractive and orthodontic treatment has been shown to flatten smile arcs.

POSED SMILE

Smiles can be classified as either "posed" or "spontaneous." Peck and Peck classified smiles as stages I and II and Ackerman et al designated stage I as the posed smile and stage II as the spontaneous smile.^{6,4}

Posed smiles are voluntary; they need not be elicited by emotion. Posed smiles are static in the sense that they can be maintained and the lip animation is fairly reproducible; they are similar to what would be rehearsed for a photograph or school pictures.^{3,18}

The spontaneous smile is natural in that it expresses authentic emotion; lip animation is often more animated than in a posed smile and can be seen during laughter, for example. It is

involuntary and is induced by joy or mirth and is dynamic in the sense that it bursts forth and is not sustained the way a posed smile would be.⁵



Figure 2: A. Posed smile; B. Spontaneous smile

Orthodontic smile analyses typically utilize the posed smile on the basis of the following characteristics: the amount of incisor and gingival display as well as the transverse dimension of the smile.⁵

An article by Wong et al. performed an analysis of esthetic posed smiles using three dimensional analyses and visualization techniques to assess smile arcs with respect to various parameters. The results of that study determined that smile consonance depends greatly on the conversational distance and the angle of elevation between the viewer and the smile.¹⁹

HOW BRACKET ORTHODONTICS FLATTEN SMILE ARC

Orthodontic treatment often inadvertently flattens the smile arc. Orthodontic courses and programs often teach a set formula for bracket placement based on tooth measurements; this may not be appropriate for the achievement of maximum smile esthetics. For example, routinely placing the maxillary central incisor brackets 4.5 mm above the incisal edge, lateral incisors 4 mm, and canines at 5 mm, without careful consideration of the relationship of the incisal edges to the lower lip curvature, may cause the treatment outcome to leave more to be desired in the way of esthetic criteria. Patients design for appliance placement may be more appropriate if it were individualized according to soft tissue architecture and smile characteristics.⁵ Bracket placement may unintentionally lead to superior positioning of the incisal edges relative to the posterior buccal segment heights. This is especially true when emphasis is placed upon a goal to achieve canine guidance because orthodontists create relative intrusion of the maxillary incisors while extruding the maxillary canines, resulting in a flattened smile arc.⁵ In deep-bite cases, orthodontists will often position the mandibular incisor brackets closer to the gingival margin in an effort to avoid occlusal interferences that may lead to unwanted bracket loss. Mandibular incisor bracket placement at the gingival margin leads to extrusion of the mandibular incisors and a subsequent need to intrude the maxillary incisors to open the bite, which also results in a flattened smile arc.⁵ In patients with excessive gingival display on smiling, maxillary incisor intrusion is often planned to reduce the gumminess of the smile. However, if smile arc relationship is not studied and noted, undesired flattening of the smile arc may occur. To this point, maxillary intrusion arches or maxillary archwires with accentuated curves could result in flattening of the smile arc.⁵

Pitts describes a list of factors that can make it more difficult to protect existing smile arcs or enhance inadequate smile arcs during orthodontic treatment, including: inappropriate conventional bracket positioning, which typically reduces or flattens the smile arc (and wire plane) during leveling, the relative steepness or flatness of the occlusal plane (the flatter the plane, the more difficult it is to manage the smile arc esthetically), incisor proclination, whether preexisting or iatrogenic, a particularly broad anterior arch form, in which the excessive interchained span tends to flatten the smile arc, steep upper canine tips and inappropriate canine bracket positioning in relation to the incisors, and irregular shapes or size disproportions among the incisors and canines.²⁰

GROWTH PATTERN AND HABITS MAY FLATTEN SMILE ARC

Aforementioned studies have demonstrated that even though orthodontically treated patients did have a higher rate of smile arc flattening, 5% of the untreated population also experienced smile arc flattening.⁴ This indicates that a patient's inherent growth pattern may also play a role. If a patient exhibits more vertical growth in the posterior maxilla than in the anterior maxilla, it could alter the relationship between the occlusal plane and the curvature of the lower lip on smiling. In patients with this type of growth pattern, high pull headgear can help to keep the maxillary posterior teeth superior to the incisors and subsequently aid in maintaining or improving the smile arc.⁵ It is also a possibility that brachyfacial growth patterns with a low mandibular plane angle and tendency for parallelism of the sella-nasion plane, palatal plane, and occlusal plane, may lead to a flattened smile arc. In these cases, there may be a tendency for the anterior maxilla to lack the clockwise tilt necessary for an ideal smile arc.⁵ Certain habits, such as thumb sucking,

also impede anterior vertical dentoalveolar development and therefore lead to smile arc flattening.⁵

SMILE ARC PROTECTION BRACKET PLACEMENT

Pitts, with regard to his proposed bracket placement technique, stated, “Bracket positioning for Smile Arc Protection (SAP) is an innovation that blends the art of contemporary esthetics with the science behind three-dimensional control of tooth position, making superior esthetic results attainable and more predictable during orthodontic treatment.”²⁰

Pitts recommends canine reshaping (as well as incisors, when appropriate) prior to bracketing and believes that softening tooth contours, buccal/labial surfaces, incisal tips and edges and plunging cusps enhances esthetics and assists in contact relationships, bracket, and occlusal fit. He goes on to say that, “reshaping the incisal surfaces of canines assists with smile arc protection and improves contact relationships with adjacent teeth yet does not interfere with canine disocclusion.” He also suggests that reshaping the lingual surfaces of canines facilitates Class II, Class III and vertical correction when using elastics.⁹

Since the maxillary canine is the transition from the anterior to the posterior segment and establishes the sweep for the smile arc, Pitts plans positioning for the entire arch by first determining the position for this bracket. The incisal edge of the canine bracket wings must to be placed on a line drawn from the mesial to the distal contact at the height of contour interproximally (the M-D contact line). The occluso-gingival (O-G) positioning for the maxillary central and lateral incisor brackets uses the canine bracket as the reference point, with the slot of the central incisor bracket slightly more gingival (approximately 0.5 mm) than the slot of the

canine bracket (as measured from the recontoured tip) and the slot of the lateral incisor bracket slightly more incisal than the central incisor bracket (approximately 0.25 mm).⁹

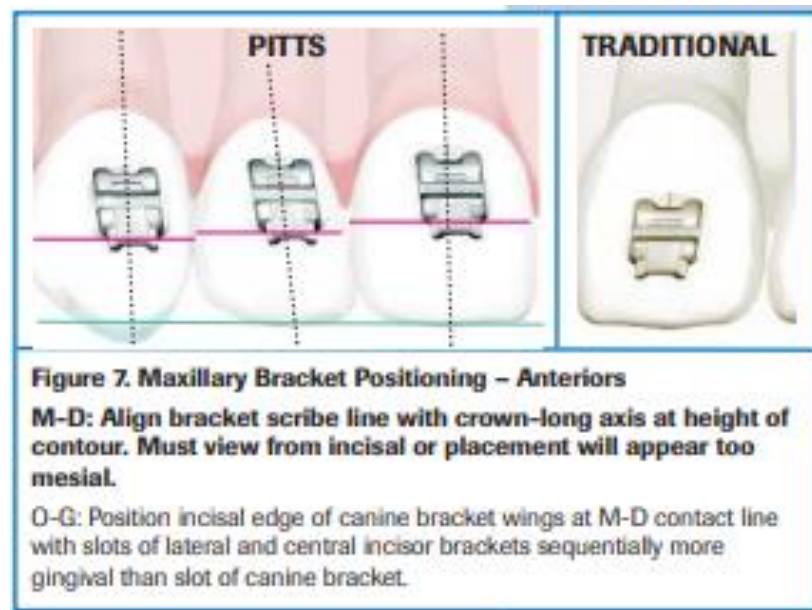


Figure 3: Smile arc protection bracket placement guide for maxillary anterior teeth

For premolar brackets, Pitts recommends aligning the scribe line of the brackets with the crown-long axis at the height of contour, paralleling the central groove and the M-D buccal line angle. Occluso-gingivally, he places the occlusal edge of the bracket at the mesiodistal contact line. For first molar bracket placement, the buccal tube pad is centered over the buccal groove of the tooth mesiodistally. For accurate cusp height transition from the first molar to the second premolar, the occlusal edge of the first molar tube pad should be placed on the M-D contact line. The M-D positioning for the maxillary second molar tube is the same as the first molar tube. In terms of O-G positioning, the bracket should be approximately 1.5 mm more occlusally than the maxillary first molar bracket.⁹

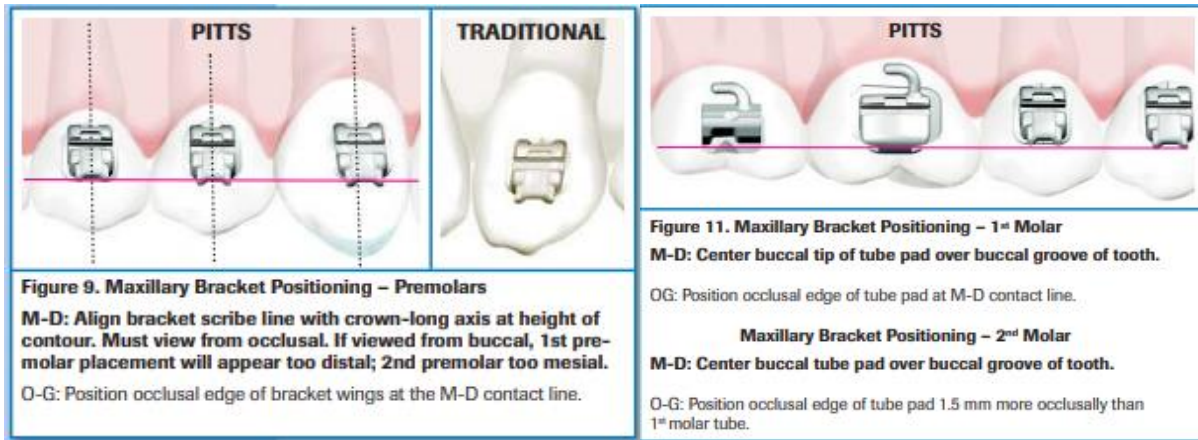


Figure 4: Smile arc protection bracket guide for maxillary premolars and molars

As demonstrated in Figure 5 below, the maxillary incisor brackets are positioned more gingivally for SAP than in traditional techniques such as bracket placement at the facial axis (FA) point.²⁰

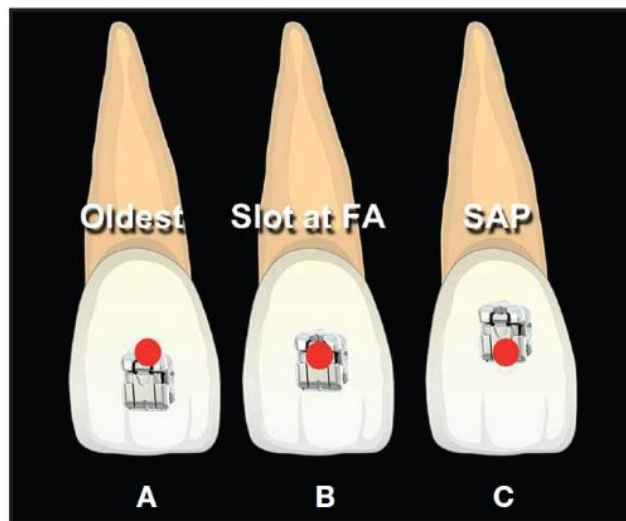


Figure 5: Comparison of traditional bracket placement techniques and SAP

With SAP bracket positioning, the divergence of the archwire from the cusp tips or incisal edges will increase from posterior to anterior, depicted in Figure 6.²⁰ This bracket placement scheme

will allow for the maxillary archwire to sit in the bracket bases parallel to the upper lip line; the upper anterior teeth will follow the lower lip with orthodontic treatment.²⁰

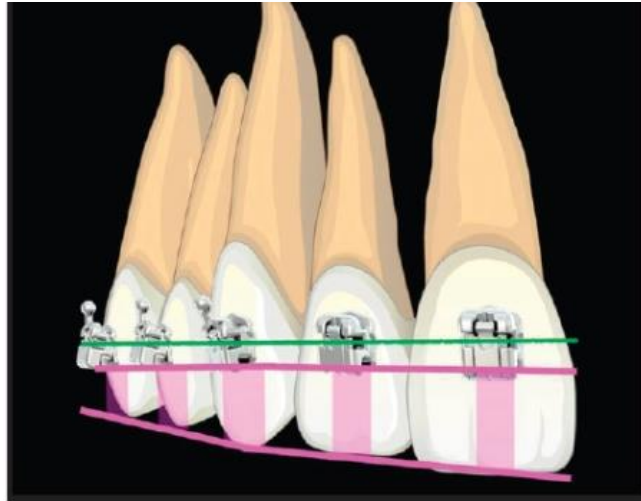


Figure 6: Divergence of the archwire from cusps tips and incisal edges increases from posterior to anterior

EARLY ELASTICS AND SECTIONAL MECHANICS TO ACHIEVE IDEAL SMILE ARC

Pitts believes that, because teeth are being erupted and/or intruded in the proper direction, early light elastics allow slight A-P correction concurrent with arch leveling. In deep bites, his general rule of thumb is to keep the elastics more posteriorly positioned in the buccal segments; in open bites, more anteriorly positioned. This protocol allows him to enhance enamel display upon smiling by changing the vertical dimension rather than by simply intruding upper anterior teeth. This use of light elastics to control the vertical dimension further enhances the opportunity to produce an esthetically pleasing smile arc.⁹

A 2016 case report in the journal of clinical orthodontics discusses the use of segmented mechanics to achieve an ideal smile arc and a rejuvenated dental appearance. The article presents a case where they chose to utilize a segmented arch technique because it could control undesirable side effects in the posterior regions while applying individual forces and moments in

the anterior segment. *Figure 7* below depicts the mechanics used for the case. They used a three-piece arch to extrude the maxillary anterior segment and an .021" × .025" heavy stainless steel archwire was placed passively for stabilization. In the anterior segment, an .019" × .025" heavy stainless-steel arch-wire with extensions distal to the center of resistance of the anterior teeth (between the canines and first premolars) was also placed passively. An extrusion force of 80g per side was applied with an .017" × .025" TMA** tip-forward spring. Although an extrusive force was thus generated anteriorly and an intrusive force posteriorly, the forces were low, minimizing the side effects associated with a counterclockwise moment.²



Figure 7: Case report details how segmental mechanics can help to achieve ideal smile arc

CLEAR ALIGNERS SEGMENTAL MECHANICS ABILITY AND INTRUSIVE EFFECTS

A 2019 systematic review article compared the efficacy of clear aligners and fixed appliances; they discovered that clear aligners had the ability to align teeth individually with one aligner moving one or several teeth. The study concluded that this gradual, segmented movement may minimize the proclination of teeth. Thus, it could be postulated that clear aligners may be suitable for patients with thin gingival biotypes to limit the risk of gingival recession. Additionally, the study found that both clear aligners and braces were effective at treating malocclusions. Clear aligners were not as effective as braces in producing adequate occlusal

contacts, controlling torque, and retention. However, clear aligners had an advantage in segmented movement of teeth and shortened duration of treatment.²¹

Clear aligners have an innate ability to intrude teeth due to occlusal coverage that may help to maintain or improve the smile arc if canines or posterior teeth are intruded to larger degree than the incisors. A 2018 study in Angle Orthodontist Journal measured intrusive forces from clear aligners on individual teeth as well as on segments of teeth. They found that when canines were intruded alone, they exhibited the largest intrusion force compared to incisors and premolars. During combined intrusion of all anterior teeth, canines still received higher intrusive forces than the incisors.²²

CHAPTER 3: MATERIALS AND METHODS

IRB APPROVAL

The protocol was approved for expedited research by the West Virginia University Institutional Review Board prior to the start of the study (See Appendix A).

SAMPLE DESCRIPTION

There were 98 subjects and 15 raters in this study. The subjects included 98 completed comprehensive orthodontic treatment cases, 48 of which were treated with traditional orthodontic bracket therapy and 50 of which were treated with clear aligner therapy. The raters included a total of 15 orthodontic experts from West Virginia University School of Dentistry Department of Orthodontics, 8 of which were orthodontic residents and 7 of which were orthodontic faculty members.

SUBJECTS

Inclusion Criteria

- Comprehensive orthodontic treatment defined by either a complete set of upper and lower brackets treating all erupted permanent teeth or a series of at least 14 clear aligners
- Subjects must have high quality pre-treatment and post-treatment smiling photographs where smile arc could be assessed

Exclusion Criteria

- Orthognathic surgery
- Pre-treatment beginning with an anterior crossbite making upper incisal edges not visible

RATERS

Inclusion Criteria

- West Virginia University School of Dentistry orthodontic faculty or resident
- HIPPA training

SUBJECT IDENTIFICATION

The 98 subjects for this study were recruited from either Sparks Family Orthodontics in Charleston, WV or West Virginia University School of Dentistry Orthodontic Department in Morgantown, WV. 48 randomly selected completed traditional orthodontic bracket cases and 50 randomly selected clear aligner therapy cases were identified as the subjects. These treatment facilities were selected because they utilize the same orthodontic treatment planning philosophy as well as the same landmark guideline for bracket placement (the FA point).

The prospective raters included 8 West Virginia University School of Dentistry orthodontic residents and 7 faculty orthodontists. A power sample size estimator was used to identify the number of raters needed for the study. All prospective raters were engaged using a recruitment script where the purpose, design, and potential risks of the study were explained and an opportunity to have their questions answered was provided. The raters were informed that they would be seeing cropped and deidentified photos from patients who had undergone orthodontic treatment.

OBTAINING PRE AND POST TREATMENT SMILING PHOTOGRAPHS

The pre-treatment and post-treatment smiling photos of the 98 subjects (48 traditional bracket therapy and 50 clear aligner therapy) were obtained from either Dolphin Imaging Software Version 11.9 (Dolphin Imaging & Management Solutions, Chatsworth, CA, USA) or from Ortho2 Edge Imaging (Ortho2 Edge Imaging, Ames, IA, USA). Photos were cropped to depict only the lips and teeth and edited to black and white in order to eliminate rater bias based on complexion, lip color, or blemishes/imperfections. A Microsoft PowerPoint™ presentation was created; one slide was dedicated to each subject with their cropped pre-treatment photo on the left and post-treatment on the right. The type of treatment the patient received was not disclosed in the presentation and the PowerPoint slide order was randomized so that those treated with brackets and those treated with clear aligners were interspersed.

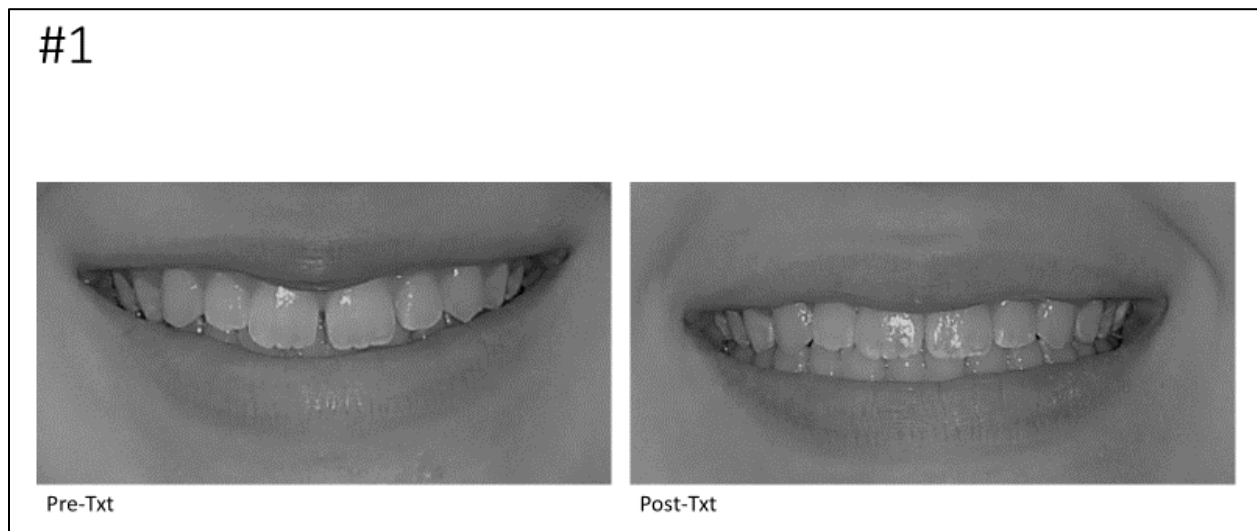


Figure 8: PowerPoint Slide of a subject pre-treatment and post-treatment smiling photos

RATING THE PHOTOGRAPHS

The raters included 15 orthodontic experts (8 residents and 7 faculty members). All raters viewed the PowerPoint presentation in the WVU Orthodontic Conference Room. Each rater was provided with a survey where they were asked to watch the PowerPoint presentation and to make a decision whether they believe orthodontic treatment flattened the patients smile arc, had no clinically significant effect on the patients smile arc, or whether treatment improved the patients smile arc. Judges noted their decisions for each patient with a checkmark.

1. <input type="checkbox"/> Smile arc was flattened <input type="checkbox"/> Smile arc was not clinically significantly affected by treatment <input type="checkbox"/> Smile arc was improved

Figure 9: Rater choices provided for each PowerPoint slide/each study subject presented

The raters did this for the 98 slides of study subjects. After a two-week time period had passed, 6 of the raters were randomly selected and asked to repeat the same survey in order to perform inter-rater reliability testing for the study.

RECORDING DATA

Each of the raters answer choices were converted into numerical values (1= flattened, 2= not clinically significantly affected, 3= improved) and entered into a Microsoft Excel workbook for statistical analysis.

STATISTICAL ANALYSIS

All statistical analyses were conducted using SAS (version 9.4, 2013, SAS institute Inc., Cary, NC). Descriptive analysis was performed for basic information of the study sample. A chi-square analysis was utilized to assess the association between treatments (bracket vs. clear aligner) and smile arc evaluation by individual rater. To examine the relationship between treatment modality and smile arc evaluation for the whole sample, a generalized linear mixed model (GLIMMIX) using rater and patient as random effects was conducted. Differences between treatment modalities was determined using an F-test. The multinomial probability distribution was used for smile arc evaluation. Intra-class correlation coefficients were calculated to evaluate the reliability of the measurements. All statistical tests were two-sided and p-value $<.05$ was considered statistically significant.

CHAPTER 4: RESULTS

RELIABILITY RESULTS

The intra-class correlation coefficient (ICC) = 0.804, with 95% CI (0.770-0.833) indicates there is acceptable evidence for the repeatability of rater evaluations between the two time points.

DATA COLLECTION

Table 1 summarizes the characteristics of the study participants. The sample of 15 total orthodontic expert raters consisted of 8 orthodontic residents and 7 WVU faculty orthodontists. That is 53% resident raters and 47% faculty raters. The subjects in the sample consisted of 98 pre and post-treatment photographs of 48 subjects treated using brackets (49%) and 50 patients treated using clear aligners (51%).

Table 1: Participants' Characteristics

Rater Characteristics (n=15)	n (%)
Orthodontic Experts:	
Residents	8 (53%)
WVU Faculty	7 (47%)
Subject Characteristics (n=98)	
Treatment Modality:	
Brackets	48 (49%)
Clear Aligners	50 (51%)

PERCENTAGE OF SMILE ARC EVALUATION OF TREATMENT MODALITY BY RATER

Table 2 summarizes the percentage of each smile arc evaluation of the treatment modalities by individual raters as well as a collective assessment of all raters. For rater 1, patients who underwent clear aligner treatment were more likely to have improved or not affected smile arc evaluation than the patients who were treated using brackets, although this difference was not clinically significant (34% vs. 25%, 50% vs. 41.7%, $p=0.08$). In addition, rater 1 evaluated 16% of clear aligner patients to have a flattened smile arc vs. 33% of bracket patients. For rater 2, patients with clear aligner treatment are more likely to have ‘improved’ or ‘not affected’ smile arc evaluation than the patients with bracket treatment (28% vs 15%, 50% vs. 29%, $p=.001$) and 22% of clear aligner patients were judged to have flattened smile arc compared with 56% of bracket patients; the differences for rater 2 were statistically significant. The results of analyses for 12 out of 15 raters showed that there were statistically significant association between treatment modality and smile arc evaluation. Patients with clear aligner treatment were more likely to have “improved” or “not affected” smile arc evaluation than patients with bracket treatment. When all raters were considered collectively, raters evaluated 50% of all bracket treated subjects to have flattened smile arcs compared to 17% of all clear aligner treated subjects and 37.3% of clear aligner subjects were evaluated to have improved smile arc compared to 24.5% of bracket subjects ($p<0.0001$), indicating a significant difference between treatment modalities on smile arc evaluation.

Table 2: Percentage of each smile arc evaluation of the treatment modalities by raters

Rater	Bracket			Clear Aligner			p-value [#]
	Flattened	Not affected	Improved	Flattened	Not affected	Improved	
1	33.3	41.7	25.0	16.0	50.0	34.0	.08
2	56.3	29.2	14.6	22.0	50.0	28.0	.001**
3	56.3	33.3	10.4	20.0	64.0	16.0	.001**
4	56.3	10.4	33.3	20.0	24.0	56.0	.001**
5	62.5	18.8	18.8	12.0	62.0	26.0	<.0001***
6	35.4	41.7	22.9	12.0	40.0	48.0	.002**
7	47.9	25.0	27.1	18.0	48.0	34.0	.02*
8	66.7	22.9	10.4	22.0	46.0	32.0	<.0001***
9	64.6	12.5	22.9	34.0	36.0	30.0	.02*
10	29.2	14.6	56.3	12.0	32.0	56.0	.49
11	52.1	29.2	18.8	14.0	54.0	32.0	.0007***
12	52.1	27.1	20.8	12.0	54.0	34.0	.0005***
13	45.8	37.5	16.7	18.0	40.0	42.0	.0008***
14	20.8	18.8	60.4	14.0	18.0	68.0	.38
15	66.0	25.5	8.5	14.0	62.0	24.0	<.0001***
All	49.7	25.9	24.5	17.3	45.3	37.3	<.0001***

[#]p-value from chi-square analysis *P-value < 0.05, **p<.01, ***p<.001

GENERALIZED LINEAR MIXED MODEL ANALYSIS FOR ASSOCIATION BETWEEN SMILE ARC EVALUATION AND TREATMENT USING RATER AND PATIENT AS RANDOM EFFECTS

The results of a generalized linear mixed model analysis for the association between smile arc evaluation and treatment using rater and patient as random effects are summarized in *Table 3*.

There is significant effect of orthodontic treatment on smile arc evaluation (p value <0.0001).

Patients with bracket treatment are 5.259 times more likely to have flattened or not affected smile arc evaluation than those with clear aligner treatment.

Table 3: Generalized linear mixed model analysis for the association between smile arc evaluation and treatment using rater and patient as random effects

Solutions for Fixed Effects							
Effect	Smile arc evaluation	Treatment	Estimate	Standard Error	DF	t Value	Pr> t
Intercept	1		-1.9635	0.3450	14	-5.69	<.0001
Intercept	2		0.5662	0.3401	14	1.66	0.1182
Treatment		Bracket	1.6599	0.3905	1356	4.25	<0.0001
		Clear aligner	0	--	--	--	

Note. DF= degree of freedom

Covariance Parameter Estimates			
Cov Parm	Subject	Estimate	Standard Error
Intercept	Rater	0.6199	0.2509
Intercept	Patient	3.3263	0.5970

Type III Test of Fixed Effects				
Effect	Num DF	Den DF	F Value	Pr > F
Treatment	1	1356	18.07	<.0001***

Note. Num DF=Numerator DF, Den=Denominator DF

*P-value < 0.05, **p<.01, ***p<.001

Odds Ratio Estimate				
Comparison	Estimate	DF	95% Confidence Limits	
Treatment (Bracket vs. Clear aligner)	5.259	1356	2.445	11.313

PROBABILITY OF TREATMENT MODALITY EFFECT ON SMILE ARC EVALUATION

Table 4 summarizes the probability of treatment modality effect on smile arc evaluation. The probability of an orthodontic expert evaluating the smile arc as flattened was 42% when patients were treated with brackets and 12% when treated with clear aligners. The probability of an orthodontic expert evaluating the smile arc as maintained was 51% when patients were treated with clear aligners compared to 48% when treated with brackets. The probability of an orthodontic expert evaluating the smile arc as being improved by treatment was 36% for the

clear aligners and 10% in the bracket group. Clear aligners treatment effected orthodontic experts to consistently evaluate the smile arc as improved to a greater degree than bracket treatment and flattened to a much lesser extent than the bracket treatment.

Table 4: Probability of treatment modality effect on smile arc evaluation

Smile Arc Evaluation	Probability	
	Bracket	Clear Aligner
Flattened	0.4247	0.1231
Not affected	0.4779	0.5148
Improved	0.0974	0.3621

CHAPTER 5: DISCUSSION

SMILE ARC EVALUATION OF TREATMENT BY ORTHODONTIC EXPERTS

Twelve out of the 15 orthodontic expert raters in this study demonstrated that there was a statistically significant association between treatment modality and smile arc evaluation and that clear aligners were more effective at maintaining or improving smile arc than brackets. This indicates that the treatment modality chosen (aka brackets bonded on the FA point vs clear aligners) does have an impact on the way orthodontic experts assess smile arc treatment outcomes. To this point, the results of this study should serve as a call to all orthodontists to pay more attention to smile arc as a factor in treatment planning decisions. This research shows that orthodontists can consistently agree on the fact that orthodontic treatment using brackets may negatively impact a crucial aspect of smile esthetics. It highlights an area on which the entire specialty of orthodontics may improve.

CLEAR ALIGNER TREATMENT SPECULATIONS

Results for all raters collectively indicated that 37.3% of clear aligner subjects were evaluated to have improved smile arc compared to 24.5% of bracket counterpart subjects ($p < 0.0001$). The difference in smile arc outcome may be attributed to the innate ability of clear aligners to intrude especially posterior teeth. To that point, if “overcorrection” is not programmed into clear aligner therapy, patients often finish with a posterior open bite – necessitating the orthodontist to section the aligners to expose posterior teeth to run settling elastics. Other studies have demonstrated that clear aligners are more effective at moving individual teeth or segments of teeth independently of the rest of the dental arch, which may have also contributed to clear aligners ability to maintain or improve smile arc. Another aforementioned study demonstrated that,

during combined intrusion of all anterior teeth, the maxillary canines received higher intrusive forces than the incisors; this may also explain clear aligners ability to maintain or improve smile arc.

BRACKET TREATMENT SPECULATIONS

When all raters were considered collectively, orthodontic experts evaluated 50% of all bracket treated subjects to have flattened smile arcs compared to 17% of all clear aligner treated subjects ($p < 0.0001$). Therefore, the results of this study are in agreement with the general consensus from the reviewed orthodontic literature that traditional bracket orthodontic treatment has a tendency to flatten smile arcs. All study subjects in the bracket treatment group for this study had their brackets placed on the facial axis (FA) point of the teeth. This formula for bracket positioning may have contributed to smile arc flattening because it does not take soft tissue architecture or lower lip line into consideration nor does it allow for much individualization between patients.

STUDY SUBJECT DEMOGRAPHICS

The majority of orthodontic patients in the region that the study was conducted (West Virginia) have Class II deep-bite malocclusions at the start of treatment. This malocclusion often necessitates reverse curves or intrusion arches which can place excessive intrusion forces on maxillary anterior teeth and subsequently be detrimental to smile arc outcome. A previously mentioned article discussed that bracketing mandibular incisors to avoid occlusal interferences in a deep bite (aka positioning brackets more gingivally) may also lead to smile arc flattening because it causes inadvertent extrusion of lower incisors and then subsequent need to intrude upper incisors to open the bite in the anterior region. It is difficult to say whether this may have

played a significant part in the outcome of this study, but deep-bite malocclusion is a very common occurrence and something that challenges orthodontists all over the world.

STUDY SUBJECT TO TREATMENT MODALITY DISTRIBUTION

An interesting point to note about the sample distribution of this study is that the majority of the bracket treated subjects were teenagers and the majority of clear aligner treated subjects were adults. Although the exact statistics of how many bracket and clear aligner subjects were teens vs. adults was not documented for this research study, the aforementioned trend was consistent. This is most likely due to the fact that it is more socially acceptable for teenagers to have braces than it is for adults. Teenagers social interactions are mostly with their peers who, chances, are, are also wearing braces or have in the past whereas adults are very self-conscious about the way metal brackets make them feel about their self esteem and have more concerns about how society will perceive them. This point could be important to an interpretation of this study's results because when we say clear aligners had a better ability to improve or maintain smile arcs, one could make an associated conclusion that it is easier to manage smile arc outcome in an adults than in teenagers. This may be the case because teenagers' teeth have more passive eruption capacity that is potentially being halted by orthodontic treatment mechanics and retention protocols (aka if nature were allowed to take its course, perhaps passive eruption over time could lead to a natural smile arc development as we mature). Adults, on the other hand, have teeth that were afforded the chance to erupt much longer before orthodontic treatment was initiated. Also, it is much easier to move teeth in teenagers due to lower bone density than adults which may explain why smile arcs are maintained better in the clear aligner (adult) population.

NULL HYPOTHESIS TESTING

1. REJECT: There is no treatment effect on smile arc using traditional orthodontic brackets
2. REJECT: There is no treatment effect on smile arc using clear aligners
3. REJECT: There is no difference in smile arc outcomes between traditional orthodontic brackets and clear aligner therapy
4. REJECT: There is no improvement in smile arc outcome using clear aligners when compared to bracket orthodontics

CLINICAL SIGNIFICANCE

The public is becoming increasingly aware of esthetics, and often evaluate their orthodontic treatment outcome based upon improvement of their smile and overall enhancement of their facial appearance. This study helps to highlight the importance of smile arc as a component of overall smile esthetics, one that is oftentimes overlooked. It demonstrates that orthodontist expert raters evaluated clear aligners as a superior treatment modality over traditional brackets when assessing smile arc outcome.

CHAPTER 6: SUMMARY AND CONCLUSIONS

SUMMARY

The aims of this study were: to determine whether orthodontic treatment with traditional brackets flattens, maintains, or improves smile arc; to establish whether orthodontic treatment with clear aligners flattens, maintains, or improves smile arc; to draw conclusions about whether there is a difference in treatment outcomes, with specific reference to smile arc, between the two treatment modalities; and finally to establish whether treatment using clear aligners can aid in preservation or improvement of smile arc when compared to using traditional orthodontic brackets.

Orthodontic experts evaluated pre and post-treatment smiling photographs of 98 randomly selected patients who had undergone comprehensive orthodontic treatment using either brackets (n=49) or clear aligners (n=50). Expert raters were asked to make a judgement about whether the patients smile arc had been: a) flattened, b) not clinically significantly affected, or c) improved by the orthodontic treatment. Statistical analyses of the evaluation from each rater and as a whole were tabulated and significant differences between the two treatment modalities were discovered.

CONCLUSIONS

Based on the results of this study, the following conclusions have been reached:

1. There is a statistically significant association between treatment modality and smile arc evaluation, thus treatment modality has a significant effect on smile arc outcome.
2. Patients with clear aligner treatment were more likely to have “improved” or “not affected” smile arc evaluation than patients with bracket treatment.
3. Patients treated using brackets were 5X more likely to be evaluated as having a flattened smile arc than those treated using clear aligners.

4. Clear aligner treatment effected orthodontic experts to consistently evaluate the smile arc as improved to a greater degree than bracket treatment and flattened to a much lesser extent than the bracket treatment.

CHAPTER 7: RECOMMENDATIONS FOR FUTURE

RECOMMENDATIONS ON SAMPLE COLLECTION & RATER RECRUITMENT

The study at hand could be improved by breaking the bracket treatment modality group in to two separate categories: those treated with brackets placed on the FA point and those treated with brackets placed using smile arc protection guidelines. Bracket placement plays a critical role in smile esthetics and especially in smile arc outcome. Adding a group of study subjects who were treated with smile arc protection bracketing would allow for a more accurate comparison of what smile arc outcomes are possible with brackets compared to clear aligners.

In addition, the study could be enhanced by including layperson judges. Previous studies have demonstrated that the general public can recognize smile arc changes. Even though they have not been exposed to the concept of smile arc, they can recognize that flat smile arcs are less attractive. Including laypersons as raters could help to support the idea that orthodontists need to pay closer attention to smile arc outcome in order to meet the expectation that orthodontists create the most beautiful smiles possible for their patients.

RECOMMENDATIONS ON METHODOLOGY

Other studies of smile arc outcomes used the average of a few photographs of the patient in the posed smile pre and post-treatment in an attempt to use the most accurate representation of the patient's lip posture in the posed smile. Since this study was retrospective, the posed pre and post-treatment smiling photographs were a one-time snap-shot. The results of the study could be strengthened and validated even further by taking an average of several photographs.

RECOMMENDATION FOR PROSPECTIVE FOLLOW UP STUDY

This study used clear aligner treatment as a modality without regard to provider preferences in ClinCheck software or specific treatment mechanics performed using the clear aligners. If the study were to be repeated, it would be beneficial to develop a standard protocol designed to use clear aligners for smile arc protection (much like the SAP bracket positioning protocol). If this were to be developed, it could be tested against the following other treatment modality groups: brackets placed on FA point, brackets placed according to SAP protocol, clear aligners with no SAP protection mechanics. In this way, a new study design could determine whether the extra effort to achieve smile arc protection via bracket positioning or prescribed mechanics on clear aligner software are worth-while. Based on the results of this study, one would anticipate that developing a protocol for this would be extremely beneficial to orthodontic practice and patient treatment outcomes.

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APPENDIX A: IRB APPROVAL LETTER



Approval of Human Research Protocol

10/28/2019

To: Chris Martin

From: WVU Human Research Protection Program

Protocol Type: Expedited

Approval Date: 10/28/2019

Submission Type: Initial

Expiration Date: 10/27/2021

Funding: N/A

WVU Protocol #: 1908675053

Protocol Title: Clear Aligner Therapy vs. Traditional Brackets on Smile Arc

The West Virginia University Institutional Review Board has reviewed and granted your request for approval of Expedited protocol 1908675053, in accordance with the Federal regulations 45 CFR 46, 21 CFR 50, and 21 CFR 56 (when applicable). Additional details concerning the review are below:

- Category 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- I am approving as an expedited category 5, but since the DUA was removed, this study can now be an exemption category 4. If you would like to create an amendment and change the review type, it can be approved as an exemption.

The following documents were reviewed and approved for use as part of this submission. Only the documents listed below may be used in the research. Please access and print the files in the Notes & Attachments section of your approved protocol.

- HIPAA Waiver Form.docx

WVU IRB approval of protocol 1908675053 will expire on 10/27/2021.

Protocol #: 1908675053
FWA: 00005078

Phone: 304-293-7073
Fax: 304-293-3098

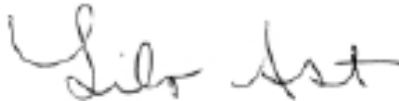
If any study related activities are to continue beyond the expiration date, a renewal application should be submitted no later than four (4) weeks prior to the expiration date. It is your responsibility to submit your protocol for continuing review.

Once you begin your human subjects research, the following regulations apply:

1. Unanticipated, serious adverse events and/or side effect(s) encountered at WVU or an affiliate site that are related to the research must be reported to the WVU IRB within five (5) days using the Notify IRB action in WVU+kc.
2. Any Unanticipated Problem or UPIRTSO or other research related event resulting in new or increased risk of harm to study subjects, occurring at WVU or an affiliate site, must be reported to the WVU IRB within five (5) days using the Notify IRB action in WVU+kc.
3. Any modifications to the protocol or informed consent form must be reviewed and approved by the IRB prior to implementation. These modifications should be submitted as an amendment.
4. You may not use a modified informed consent form until it has been reviewed and approved by the WVU IRB. Only consent forms with the WVU+kc watermark may be used to obtain informed consent from participants.

The WVU Human Research Protection Program will be glad to provide assistance to you throughout the research process. Please feel free to contact us by phone at 304.293.7073 or by email at IRB@mail.wvu.edu.

Sincerely,



Lilo Ast
IRB Administrator

APPENDIX B: RECRUITMENT OF JUDGES SCRIPT

Recruitment Script:

Hello, my name is Sarah LaRue. I am a resident at West Virginia School of Dentistry Department of Orthodontics. I am conducting research on smile arc changes associated with orthodontic treatment using traditional orthodontic brackets vs. clear aligner therapy.

Participation in this research is voluntary. It involves taking a survey about your perception of pre and post orthodontic treatment frontal smiling photos, with specific regards to smile arc. If you participate in the survey, your total time commitment will be approximately 15 minutes. There is no financial compensation for participating.

Remember, this is voluntary. You can choose to be a judge in the study or not. If you would like to participate in the research, or have any questions, please email me at laruese33@gmail.com. If selected to participate, I will reach out to you via email to arrange details on your participation.

Thank you!

APPENDIX C: RATERS SURVEY SAMPLE

Instructions:

You will be shown a series of smiling photographs of 100 patients who have undergone orthodontic treatment. You will be asked to compare the patient's pre and post treatment photographs and make a decision about how the patients smile arc was effected by treatment. Please place a check mark by one of the following choices for each patient displayed: smile arc was flattened, smile arc was not clinically significantly affected, or smile arc was improved.

1. Smile arc was flattened
 Smile arc was not clinically significantly affected by treatment
 Smile arc was improved

2. Smile arc was flattened
 Smile arc was not clinically significantly affected by treatment
 Smile arc was improved

3. Smile arc was flattened
 Smile arc was not clinically significantly affected by treatment
 Smile arc was improved

4. Smile arc was flattened
 Smile arc was not clinically significantly affected by treatment
 Smile arc was improved