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Optimal Antero-Posterior Position of the Maxillary Central Incisors and its Relationship to the Forehead in Adult Hispanic Females

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OPTIMAL ANTERO-POSTERIOR POSITION OF THE MAXILLARY CENTRAL INCISORS AND ITS RELATIONSHIP TO THE FOREHEAD IN ADULT HISPANIC FEMALES

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ORTHODONTICS

ABSTRACT

Objective: The objective of this study is to investigate the relationship of forehead inclination to anteroposterior position (AP) of the maxillary central incisors in adult Hispanic females. **Materials and Methods:** 70 participants were recruited for this study and smiling profile photographs were taken. All images were deidentified and placed in standardized dimension of 7.5" by 6.5", which were then added to a PowerPoint to be evaluated by a judging panel. 24 Adult Hispanic Females (AHF) made up the control group and were seen to have an optimal incisor AP position. 46 AHF were in the study group and were judged to not have an optimal incisor AP position. The forehead inclination and AP position of the maxillary incisors were measured. **Results:** For the control group the average AP position for the maxillary incisors in relation to Glabella Vertical (GV) was 8.40mm ± 6.94mm in front of GV. For the study group the average AP position for the maxillary incisors in relation to Glabella Vertical (GV) was 7.23mm ± 8.38mm ahead of GV. A strong positive correlation was found between forehead inclination and AP maxillary incisor position in AHF for both the control and study groups. **Conclusion:** The clinical forehead is an easily discernible and reliable landmark and can be used when determining AP positions of maxillary incisors in AHF. Different ethnicities will show different

variations in the correlation between forehead inclination and incisor position. A strong positive correlation was seen between forehead inclination and maxillary incisor position. An equation derived from the regression analysis aids in predicting the anterior limit for a maxillary incisor in AHF. For most AHF the GV should not be exceeded as a posterior limit for the maxillary incisors.

Keywords: Adult Hispanic Females, Maxillary Incisors, Clinical Forehead, Anteroposterior Incisor position, Glabella Vertical, Correlation

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LIST OF ABBREVIATIONS

AP	Anteroposterior
AHF	Adult Hispanic Female
CF	Caucasian Female
DALL	Dental Anterior Limit Line
FA	Facial Axis
FALL	Forehead Anterior Limit Line
FFA	Forehead's Facial Axis
FI	Forehead Inclination
G	Glabella
GALL	Goal Anterior Limit Line
GV	Glabella Vertical
ICC	Intra-Class Correlation Coefficient
STCA	Soft Tissue Cephalometric Analysis
TVL	True Vertical Line
TX	Treatment

CHAPTER 1

INTRODUCTION

Despite being the oldest dental specialty[2], the practice of orthodontics and dentofacial orthopaedics often bases its diagnostic and treatment norms on numbers derived from populations of Northern European descent. In particular, cephalometric as well as facial aesthetics studies focused primarily on the Caucasian population.[3],[4],[5] The Hispanic groups in the US represents 18.5% of the US population.[1]As such, they are currently considered as the largest minority. In the state of Alabama, Hispanic groups represent 4.6% of the population.[1] Therefore, it appears important to individualize treatment goals to each ethnic group when planning and delivering orthodontic care. Traditionally, treatment objectives have centered around cephalometric numbers and their definition of the skeletal, dental, and soft tissue components of the face. However, it would be useful to determine the optimal position of the upper incisor based on the soft tissue profile and its interaction with the dentition, as the soft tissue is readily available for clinical evaluation. In other words, looking at components of the profile and finding a repeatable relationship between the different elements could aid in guiding treatment, while respecting the characteristics of each population. In his six elements of orthodontic philosophy[6], Andrews introduced systematic approach to orthodontic diagnosis and planning. Element II links the optimal position of the upper incisor to that of the forehead, thus emphasizing that facial balance should be evaluated relative to the soft tissue rather

than the underlying bones. This relationship, while mainly evaluated in Caucasian population, needs to be adapted to ither ethnic groups. Therefore, the aim of this study is to evaluate the optimal position of the upper incisor relative to the forehead in a group of adult Hispanic females, to help in planning orthodontic treatment for this population group.

The Smile and its importance

It is commonly accepted that the eyes and the smile are the two main features that receive attention during an interaction or conversation with another.[7] The smile is one of the most positive influences on facial attractiveness and is a strong tool of communication.[8, 9] The importance of a smile and an individual's self-perception have been a determining factor as to why patients want treatment. Baldwin found that structural and functional considerations often took a back seat, as 80% of adults who were seeking treatment for their children or for themselves were mainly concerned with the aesthetic of the smile and overall appearance.[10] Salzmann also stated that orthodontic treatment is primarily motivated by strong aesthetic values and a societal view on attractiveness and well aligned teeth.[11] A persons psychosocial well-being is dependent on having pleasant facial appearance,[12]with anxiety, self-esteem and emotional stability being impacted by both dental and facial looks.[13]A poorly positioned upper incisor and a disturbed aesthetic will likely have a negative impact on an individual's confidence. Cunningham et al. found that a person who perceives their smile as unattractive has increased challenges thus effecting their quality of life.[14] Dahong et al concluded that a negative psychosocial effect is associated in people with excessive positive or negative overjet, as seen in class III or

class II div1 dental malocclusions respectively.[15] Bernabe et al. reinforced this narrative, concluding that increased overjet had the greatest negative impact on the quality of life.[16] .Other studies have shown that individuals who are confident and seen as attractive are regarded as both more intelligent and more successful[17]. Attractive people tend to be more satisfied with their leadership and personality[18] and have more influence over others.[19, 20]

Understanding the importance of a smile and its effect on a person's quality of life is the responsibility of the orthodontist who must be well versed on what societal standards of facial aesthetics and more specifically oral facial harmony.[21]

The smile has several important components that denote how attractive the smile is, some of which include symmetry, the smile arc, presence or absence buccal corridors and midline symmetry and angulations.[22-27] The smile arc is defined as the relationship between the curvature of the upper part of the lower lip and that of the maxillary incisors and canines in a posed smile.[22]The maxillary incisors and canines collectively are also referred to the social six; which are the most visible teeth when an individual smiles.[28] A consonant smile arc is one where the social six are in harmony with the lower lip curvature.[23] Symmetry is a fundamental key factor when determining how attractive a smile is. A dental midline that lines up with the facial midline is seen as attractive.[25] Kokich et al. concluded that a maxillary midline deviated by 4mm was detected by orthodontists who judged the smile as less attractive, however lay people and general dentists did not notice a 4mm midline discrepancy.[27] Symmetry also entails identical crown angulations on either side of the midline. As such, a 2mm difference in incisal crown

angulation is detectable by both orthodontists and lay people alike.[27] A cant of 1mm is recognisable when identified by a dentist and an orthodontist, whereas a more exaggerated cant of 3mm is more clearly discernible to the public and is seen as less aesthetic.[27] The space between the buccal surfaces of the upper teeth and the space located in the corners of the mouth when smiling is defined as the buccal corridors.[29] Studies show that these spaces add a transverse dimension to the smile and play an important role in its attractiveness.[27] Janson et al. concluded in their systematic review that most studies considered large buccal corridors to be unattractive.[9]

The position from which the smile is observed is also critically important as the smile is not unidimensional. Kerns et al. found that smiles were not deemed equally attractive when evaluated from the frontal and the profile views.[30] Pasukdee et al. also stressed the importance of including profile and three-quarter views as part of the diagnostic records when evaluating smiles, due to a large variation in observer preference.[31] Cheng et al. reinforced the need for profile and oblique views when treatment planning.[32]

The Upper Incisor and its importance

The social six teeth and in particular the upper incisors are crucial components the smile. Studies have shown that the incisors horizontal position and angulation have a direct impact on smile aesthetics. Cao et al. investigated both the anteroposterior position and inclination of upper incisors.[33] The anteroposterior (AP) position of a tooth can be

described as retruded or protruded in respect to a reference line. A retruded incisor is one that sits behind the reference line and a protruded incisor lies in front. The angulation of a tooth is termed retroclined or proclined. A retroclined incisor is one that sits more upright or inclined in a lingual direction and oppositely a proclined incisor is inclined in a labial direction. The study concluded that regardless of the AP position, a slightly lingually inclined incisor is preferred with the reference line being the long axis of the incisor to Sella-Nasion. Another conclusion from the study was that a protruded incisor is more aesthetic than a retruded incisor, the reference line here was the long axis of the maxillary central incisor to Nasion- A point.[33] Ghaleb et al. that orthodontists preferred on average a slightly labially inclined incisor as opposed to a lingually inclined or upright incisor. [34]

Schlosser et al. took a smiling profile photograph of a female who had her upper incisors in Andrews 2nd element position.[21] This photograph was then edited so that the maxillary incisors protruded and retruded in 1mm increments within the range of +/- 4mm. Orthodontist and non-orthodontists then judged the attractiveness of these profile pictures and determined that a -4mm retrusive position was the least attractive of all the AP positions. This conclusion is in line with the narrative mentioned previously by Cao et al, in that a retruded maxillary incisor is seen as unattractive.[33]

A History of Facial Beauty and Harmony

Before the modern era of orthodontics, an aesthetic ideal was likely based on sculptures, paintings, and drawings of the time. We can look to the statue of David, a masterpiece of Michelangelo, created in 1501-1504 to depict the idea of male beauty and overall harmony during the renaissance period. Sander L Gilman' book "Making the body beautiful" demonstrates how beauty is not a statically defined standard but rather a fluid concept that embodies short lived socially constructed features of desirability, power, and inferiority.[35] Sander goes on to describe how people, regardless of their background, often modify their bodies to gain a foothold in that era and its prevailing standard of beauty.

With the arrival of Dr. Edward Angle and orthodontics however, the approach to beauty and its standardization became more methodical. This is not to say that even the father of orthodontics did not look back at history and what standards of beauty had come before him. Angle often referenced the classical profile of the Greek god Apollo.[36]Later he created his own vertical line of harmony that extended from Glabella through Subnasale and to soft tissue Pogonion. If all 3 soft tissue anatomical points lined up, then Angle described this as a profile in "Perfect Harmony."

Dr. Charles H Tweed also had a heavy influence on what was deemed aesthetic focusing mainly on the mandibular arch and lower incisor position. In part, he based his philosophy upon accepting a pleasing or satisfactory a face in which the orthodontist visualizes a denture as stable and incisors in an upright and uncrowded position.[37] Tweed insisted that a lower incisor should be anywhere from 85-93 degrees to the

mandibular plane and within stable alveolar bone.[38] Artun et al. found that no difference was shown between the incisor irregularity index in patients whose lower incisors had been proclined more than 10 degrees and those who had very little change in their inclination.[39] Tweeds finished cases had profiles that seemed to fit a narrow aesthetic model, as determined by Peck et al.[40] It is unlikely that these finishes would be deemed aesthetic in today's criteria where a more full and protrusive profile seems to be the current standard, a standard that was agreed upon by Schlosser et al and Peck et al.[21, 41]

In 1947, Dr. Richard Riedel investigated profile photographs of female Hollywood stars, using a single line tracing of the soft tissue on an enlarged (to life size) profile picture. The profiles were judged by a group of orthodontists in the Midwest alongside another group of persons who displayed excellent occlusion. Surprisingly most of the Hollywood stars were judged as too protrusive. [42] A few years later, Riedel submitted groups of profile tracings with normal and abnormal occlusion again for a review by orthodontists in the Midwest. Aesthetic profiles were in a straight or flat plane with little to no incisal protrusion.[43] To decipher what the modern concepts of aesthetics were, Riedel went on to conduct another study where he asked the public to analyse 30 Seattle Sea fair Princesses and their queen. The study showed that the skeletal patterns were similar to the profiles of participants who had normal occlusion in the previous study. The beauty queens however did show a lower-than-average maxillary incisor inclination, which also was in line with his previous study.[43] Riedel concluded that the publics idea of acceptable facial aesthetics was in good agreement with the standards set by orthodontists based off normal occlusion.[42] Orthodontic literature also reinforces this narrative that the general public and dental professionals evaluate profiles similarly.[44-48]

Diagnostic Approaches

Hard tissue approach

The introduction of the lateral cephalogram by Broadbent in 1934 allowed for quantifiable measurements that could determine what the set standard and range of values could be for incisal positions and other craniofacial measurements. Dr. William B Downs was arguably the pioneer in establishing a methodical cephalometric approach to orthodontics and therefore incisor protrusion and proclination.[49]

Following the Downs Analysis, several other leading orthodontists followed suit, tweaking, and adjusting reference planes and angles to rebrand their cephalometric approach under their own respective names. Some examples include Dr. Steiners analysis released in 1953, and Dr. Tweed published tweed triangle in 1954.

One of the limitations with all the cephalometric analysis is that they were based on Caucasian norms. Downs analysis being the first, was constructed from 20 Caucasian participants aged between 17-20 years old.[49] Using only Caucasian subjects restricts the Downs analysis to this group; it cannot be used to analyse those who are from a different ethnic background. Huang et al diversified the cephalometric approach to a different ethnic minority and published a study in 1998 that looked at the norms of African Americans.[50] The study showed that African Americans had average cephalometric values that were greater than their Caucasian counter parts. It was also concluded that race amongst other factors, was extremely important when analysing cephalograms.[50] Other studies have been conducted that looked at cephalometric norms of the Mexican

American ethnicity.[51-53] Swlerenga et al. observed that Mexican American females had more protrusive maxilla's than white females, but less protrusive than African American females. Another observation showed Mexican American females had a more convex profile on average than white and African American females.[53]

Although the studies established norms for different ethnicities, the rigidity of a cephalometric approach was highlighted by Moss et al. Their study showed that good facial harmony can exist within a wide range of cephalometric values.[54] Burstone also stated that there is more to a good-looking face than taking a sample of beautiful faces, selecting a given number of cephalograms and creating averages based on these images.[3]

Another shortcoming when using a cephalometric approach is the lack of reproducibility when identifying internal landmarks; a drawback that is naturally exacerbated when different orthodontists/ examiners trace a cephalogram.[55] A study published by Silveria et al. in the Angle Orthodontist looked at 32 cephalometric measurements taken from 120 cephalograms. Only 4 showed a satisfactory reproducibility including the following: position of the maxilla relative to the anterior cranial base, inclination of the occlusal plane relative to anterior cranial base, position of the lower incisor relative to the nasion-pogonion line and soft tissue profile of the face.[56] The distinct lack of reproducibility reinforces the fragility of the cephalometric approach. All these disadvantages meant that another analytic method was necessary when evaluating the profile of an individual.

Soft tissue approach

Another consideration is to look solely at the soft tissue in a side profile shot. Currently there are 5 important analytical reference lines that evaluate the position of the lips including: Ricketts E-line,[57] Steiner's S Line (S1),[58] Holdaway's H-Line,[59] Burstone's B-Line,[60] and Sushner's S-Line (S2).[61] A study by Gonzalez et al. conducted on Mexican females showed, the lower lip thickness to be on average to be 12.5mm less than the Caucasian 14mm average.[62] As a result of this, the lower lip in Mexican females was further behind Ricketts E-line when compared to Caucasian counterparts. To clarify, Ricketts E-line runs from the tip of the nose to the soft tissue pogonion and analyses the position of the lips in respect to this line.[57] The study also stated that these norms can be applied to the Hispanic female population due to strong similarities in ethnic and anthropometric backgrounds between Hispanics and Mexican populations.[62] [41].

Although a soft tissue approach is helpful and can serve as a diagnostic aid, it is not without its limitations. The individual variability of the chin and nose, means that using a reference line such as the E line is not reliable. The variation in the soft tissue makes for poor predictability for orthodontists when deciding on upper incisor position.[63]

Furthermore there is no reliable method in determining how much a hard tissue change will affect the soft tissue as they are not always proportionally correlated.[64] Subtently et al. found that changes in the skeletal chin was closely related to changes in the soft tissue chin. However, changes in the nose were not analogous to changes in the

underling skeletal profile.[65] Burstone also stated that due to variation in soft tissue coverage there was no reliable system of hard tissue cephalometric measurements that could predict good facial aesthetics.[3]

Neither a hard tissue or soft tissue approach alone is accurate or consistent enough to diagnose and treatment plan upper incisors position. With a focus on treatment planning from the exterior soft tissue to an interior occlusion and incisal position, Dr. Larry Andrews developed a new approach, his six keys to orofacial harmony namely, element II.

Andrews Six Elements Overview

In the early 1970's, Dr. Larry Andrews identified and first reported six significant occlusal characteristics called "The Six Keys of Normal Occlusion." [66] In a collection of 120 patients with natural excellent occlusion, Dr. Andrews found that there were six characteristics that were common to all. He termed these traits the Six Keys of Optimal Occlusion, which included the following: Class I Molar Relationship; Correct Crown Inclination; No Spaces Between Teeth; Correct Crown Angulation; No Rotations of Teeth; and Flat to Slight Curve of Spee. These six keys to normal occlusion were the foundation for the development of the Straight-Wire Appliance System in the 1970s and are essential to successful orthodontic treatment as they contribute individually and collectively to the total scheme of occlusion.

The six keys of optimal occlusion now make up Andrews Element VI of the Six Elements Philosophy, which was developed in the 1980's by the Andrews Foundation.[6] The philosophy highlights six areas that are believed to be among the most important for an accurate classification system and effective and efficient rules for treating. These areas include: 1) Arch Shape and Length, 2) Anterior-posterior jaw positions, 3) Buccolingual jaw widths, 4) Vertical jaw measurements, 5) Pogonion prominence, and 6) Occlusion. Collectively, they are the fundamental components of the 6-elements orthodontic philosophy. This method generates a unique treatment plan for each individual specific to their face by using landmarks and referents to precisely position the elements.

Element II will be discussed in further detail to highlight the importance of assessing the anterior-posterior (AP) position of the maxillary central incisor in a smiling profile view of Hispanic females.

Element II Introduction

Andrews proposed the use of forehead position and inclination to determine the ideal position of the maxillary incisor teeth in 'Element II' of 'The Six Elements of Orofacial Harmony' ('Andrews analysis'). The forehead was considered a good external landmark or reference point for several reasons including the following:[67]

1. Internal landmarks are not part of the face, the forehead is and therefore more relatable when considering aesthetics of the face
2. Internal landmarks cannot be seen clinically, the forehead can be seen clinically

3. Individuals who show a harmonious profile have a strong correlation between forehead inclination and AP position of the incisor

4. The forehead is likely to be more normal in its shape and AP position when compared to external landmarks of the middle and lower third of the face

5. The AP position of the upper incisor to the forehead remains consistent throughout an individual's life, whereas the AP position relative to internal landmarks varies throughout life

Forehead types

The forehead shape and inclination is unique to each person and this tailors the incisor position specifically for each patient. Currently there are 3 accepted forehead shapes as shown below in figure 1.

Figure 1: 3 types of foreheads, from left to right: Straight, rounded, and angular

Clinical Forehead

Regardless of the forehead type, the clinical forehead must be defined as it varies according to the anatomy of the forehead. When looking at the straight forehead type, the clinical forehead begins at Trichion and Superion as they coincide with each other and naturally ends at Glabella. With the angular and the round forehead types, Trichion and Superion do not coincide and as such the clinical forehead begins from Superion and again extends to Glabella as shown in Figure 2 below.

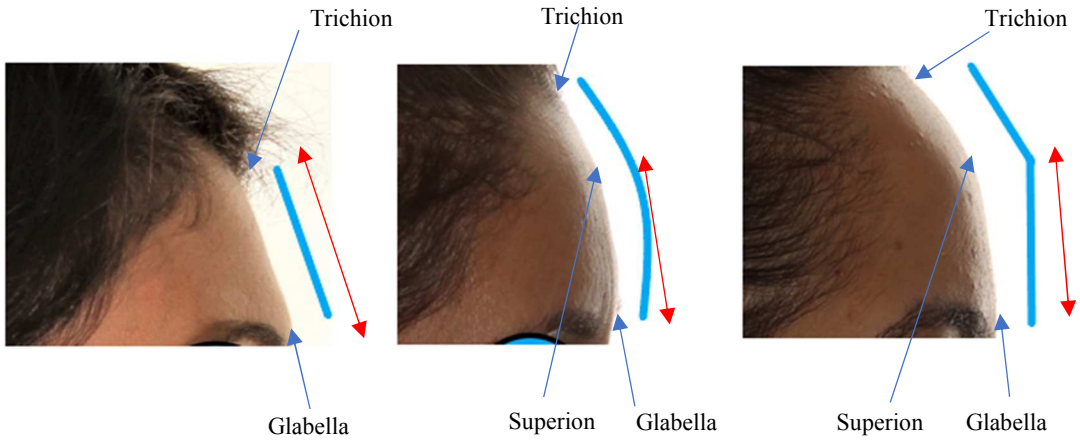


Figure 2: The clinical forehead extends from Superion to Glabella as indicated by the double ended red arrows

The GALL Line

The GALL (Goal of Anterior Limit Line, Figure 3 below) has been defined by Dr Andrews as "A line that parallels the heads frontal plane and passes through the foreheads Facial Axis (FA) point (the midpoint of the clinical forehead) when the cant of the clinical forehead is 7 degrees or less."

The vertical line drawn from soft tissue Glabella to the floor with the patient's head in Natural Head Position should be strictly adhered to for optimal aesthetics. Andrews postulated that the maxillary central incisor should be centred in anterior-posterior position approximately in line with the GALL. If the forehead is canted more than 7 degrees, then the GALL will go through a point 0.6 mm anterior to the midpoint of the clinical forehead per degree of cant. This value is then added to the FALL line to denote what the anterior limit is. However, the GALL should never exceed Glabella according to Andrews and his Caucasian norms, unless the patient expects a more protruded position and states this during an initial consultation. Understanding this formula or the second element will dictate whether the ideal maxillary incisor position can be achieved with orthodontic treatment or surgical intervention and thus helps to deciding whether both the upper and jaw and upper incisor are in an optimal position. The lower jaw and elements 3-6 from the remaining Andrews Keys can then be deduced. [6]

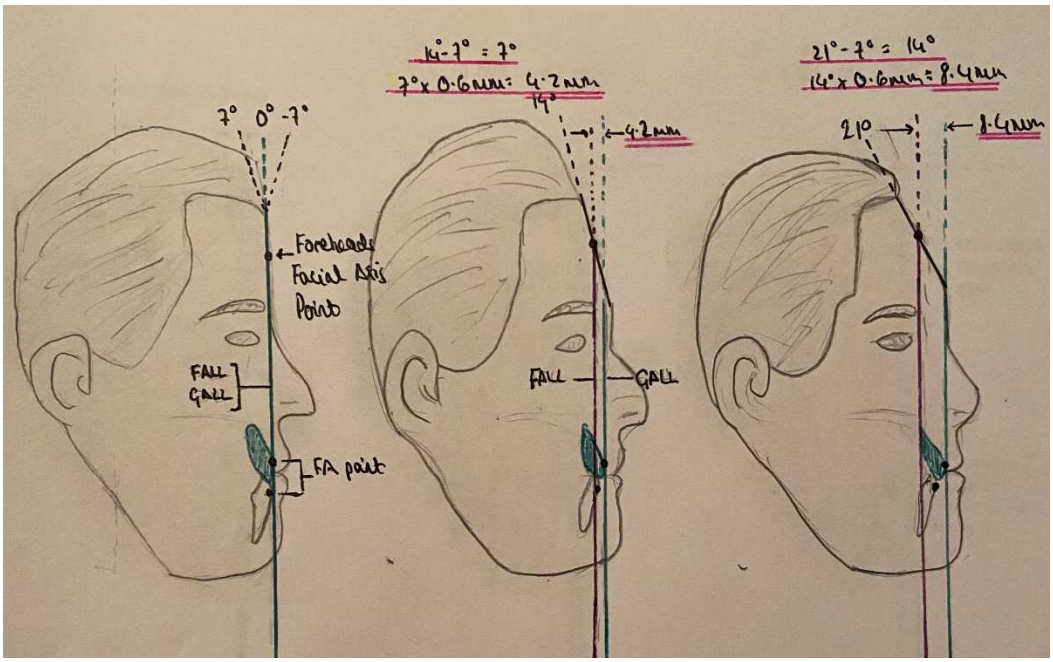


Figure 3: Dr Andrews 2nd Element, illustrating the GALL and FALL line and the equation derived from his results that determines the optimal maxillary incisor position relative to the forehead inclination in Caucasian patients

Similar Studies on Element II and Caucasians

Adams et al. found a similar result when looking at white males in a study that had 101 males in a control group who displayed good facial harmony and 97 in a study group. In the control group the upper incisors sat between the FFA point and Glabella Vertical for 91% of the group. In the sample group 59% of the incisors sat behind the FFA point. Unsurprisingly there was also a strong correlation between the maxillary central incisor position and the forehead inclination.[5]

Andrews went on to also conduct a study on 188 adult females.[4] Ninety-four (94) of these females made up the control group and were deemed to have good facial

harmony. The remaining 94 were white adult females who were seeking orthodontic treatment and made up the study sample. The upper incisor and foreheads were all in clear view in a smiling profile picture of all participants. The same reference lines FALL/FFA, Glabella Vertical and FA of maxillary incisors as well as clinical forehead inclination and AP position of the upper incisors were all included and measured. As with the male study there was a strong correlation between forehead inclination and anterior incisor position in the control group but not in the sample group.[4] Furthermore, the study showed that the upper incisors in the control group lay between the Glabella Vertical and the FFA point whereas in the sample group many of the participants had their maxillary incisors posterior to the FFA point.[4]. Several conclusions can be made from these studies but primarily it indicated the importance of using an external landmark when deciding AP positions for the upper incisors.

Tomblyn decided to explore the 2nd key further in her graduate thesis.[68] The study found that the GALL line is located within 1mm to Glabella in 95% of the Caucasian population and that with 99.7% of the population, it is 0.5mm from Glabella. As such, Glabella Vertical could be used as a vertical reference line instead of the GALL for diagnosis and treatment planning as well as dictating the limit of the upper incisor.[68]What must be re-emphasized is that this study also focused on a Caucasian patient pool, and as such conclusions from this study could not be applied to other races. This reinforced the need for further studies to investigate the second element in different ethnicities.

Studies on Element II and different ethnicities

This study aims to explore the second element for a different minority than that of Andrews Caucasians, however previous studies have been published which built upon the foundation of the second element but applied it to different ethnicities.

Gidaly et al. explored the second element further and considered the ideal position of upper incisors in female African American patients.[69] The study concluded that:

- The posterior limit is always Glabella Vertical for female African American patients and the Glabella is a reliable landmark in assessing the AP position of the maxillary incisors
- Participants with straight foreheads and zero degrees of forehead inclination, the upper maxillary central incisor was located between Glabella Vertical and 0.42mm anterior to Glabella Vertical
- For every 5° the forehead is inclined greater than 0°, the upper incisor can be correspondingly placed 1.5mm more anterior to Glabella vertical. For Example: If a Patients' forehead has a 20-degree inclination, the posterior limit for the maxillary upper incisor is still the Glabella Vertical however the anterior limit for the maxillary upper incisor is 6.4mm, based on:

  =Limit to the AP Position of Upper Incisor = 0.3(20) +0.4= 6.4mm

Carruitero et al carried out a study on a sample of 129 Peruvian participants, including both males and females.[70] The aim of this study was to establish whether Glabella Vertical line could be used as a goal for the AP position of maxillary incisors. The

study found that there was a strong correlation between the FA point of upper incisors to GALL, and the FA point of upper incisors to Glabella Vertical. It concluded that Glabella Vertical could be used as a reference point when determining the maxillary incisor AP position. Despite this study having a different ethnic minority, it agreed with Tomblyn's previously mentioned study,[68] in that Glabella Vertical can be used as a landmark when establishing AP positions of maxillary incisors.

Kim et al. explored the second element in adult Korean females.[71] The study showed a strong positive correlation between forehead inclination and AP incisor position in both control and study groups. As such, there was no significant difference in the relationship between forehead inclination and incisor position between the control and study group. This finding was different from Andrew's study on white females.[4] Interestingly in this study, the study group showed a slightly stronger positive correlation than the control group, contradicting previous publications.[4, 5, 69] The study did show that a majority of the control group (74%) had their incisors located between FFA point and Glabella; similar to Andrews' previous study.[4]

SPECIFIC STUDY AIMS

The aim of this study is to investigate the relationship of forehead inclination to anteroposterior position of the maxillary central incisors in adult Hispanic females who have good facial harmony versus those who do not have good facial harmony. The incisor position will be linearly measured against the Glabella Vertical and will be correlated to the inclination of the clinical forehead.

NULL HYPOTHESIS

Null hypothesis 1: There is no correlation between the forehead inclination and maxillary incisor anteroposterior position in the adult female Hispanic population who display facial harmony.

Null hypothesis 2: There is no significant difference in the relationship between the position of the upper incisor and forehead inclination in adult Hispanic females who display facial harmony and those who do not.

CHAPTER 2

MATERIALS AND METHODS

This study received approval from the University of Alabama at Birmingham Institutional Review Board (#IRB-300006519).

Inclusion Criteria

Seventy (70) participants were recruited for this study, based on the following inclusion criteria:

- Participant is between 18 and 60 years old
- Participant is female
- Participant is of Hispanic descent
- Participant is not currently actively receiving orthodontic treatment
- Participant has no dento-facial abnormalities

They all signed a consent form and provided their date of birth. A smiling profile photograph of each participant was taken with the upper incisors and forehead in full view. The distance between the participant and the camera was predetermined. All

images were acquired in a Natural Head Position, which has been shown to be reliable and reproducible. [72, 73] The "Universal Desktop ruler" software (manufactured by AVP software in Voronezh, Russia) was calibrated before any measurements were taken. Figure 5 shows an example of the acquired photos, including the calibration pole (Figure 5). All photographs were de-identified and placed into a standard dimension of 7.5" by 6.5" then added to a PowerPoint presentation to be evaluated by the judging panel (Figure 4). 100mm was marked on a pole located at the participants mid sagittal plane so that all photographs could be calibrated.

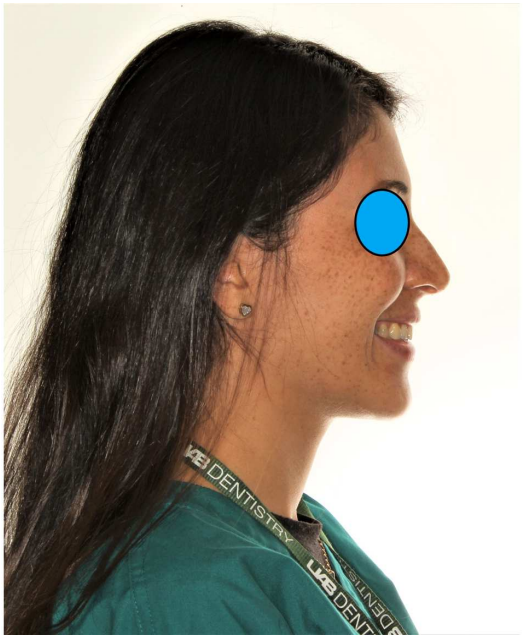


Figure 4*:* Example of a smiling photograph shown to the judging panel

A panel of 15 judges (including 9 orthodontic residents and 6 practicing orthodontists at the University of Alabama at Birmingham) were asked to evaluate the position of the upper incisors on each photograph. They needed to choose whether the upper incisor

seemed to be in a good anteroposterior position, or if an alteration of this position was needed. A tally was then made from all 15 scores.

Control and Study Groups

Based on the panel's answers, the photographs were divided into two groups:

1. The control group (N=24) consisted of images where the upper incisors were deemed to be in an optimal position for the participant, with an agreement of 14 out of 15 judges
2. The study group (N=46) consisted of the photographs where the upper incisor position was judged not to be optimal. If less than 14 judges saw the incisal position as not being optimal, the participant was placed in this group.

Measurements

The following forehead landmarks were marked on each photograph:

- FFA point: Foreheads Facial Axis point is the midpoint between Superion and Glabella in rounded and angular foreheads. In straight foreheads it is the midpoint between Trichion and Glabella.[4]
- Glabella: The foreheads most inferior anatomical landmark.[4]
- Superion: The most superior part of the forehead in round and angular forehead types.[4]

- Trichion: The most superior part of the forehead in straight forehead types.[4]

Three reference lines were included in all smiling photographs. Two vertical reference lines, Glabella Vertical and FALL/FFA were drawn parallel to the existing 100mm pole (Figure 5). These lines are defined as follows:

Line 1: Glabella Vertical: A vertical line that is parallel to the frontal plane of the head and runs through Glabella.[70]

Line 2: FALL: Foreheads Anterior Limit Line is a line that is also parallel to the front plane of the head and runs through the Foreheads Facial Axis point.[70]

The last reference line, Line 3, is the forehead gradient or inclination, connecting the most upper part of the forehead (either Trichion or Superion) to Glabella as previously defined by Andrews.[6] The intersection between reference line 2 (FFA vertical) and line 3 (forehead inclination) forms the forehead inclination angle.

Finally, the anteroposterior position of the maxillary incisors was measured from the Facial Axis of the maxillary central incisor to reference line 1 (Glabella Vertical). The Facial Axis is defined as the central point of the clinical crown.[74] All linear and angular measurements were measured using the "Universal Desktop ruler" software to two decimal places.

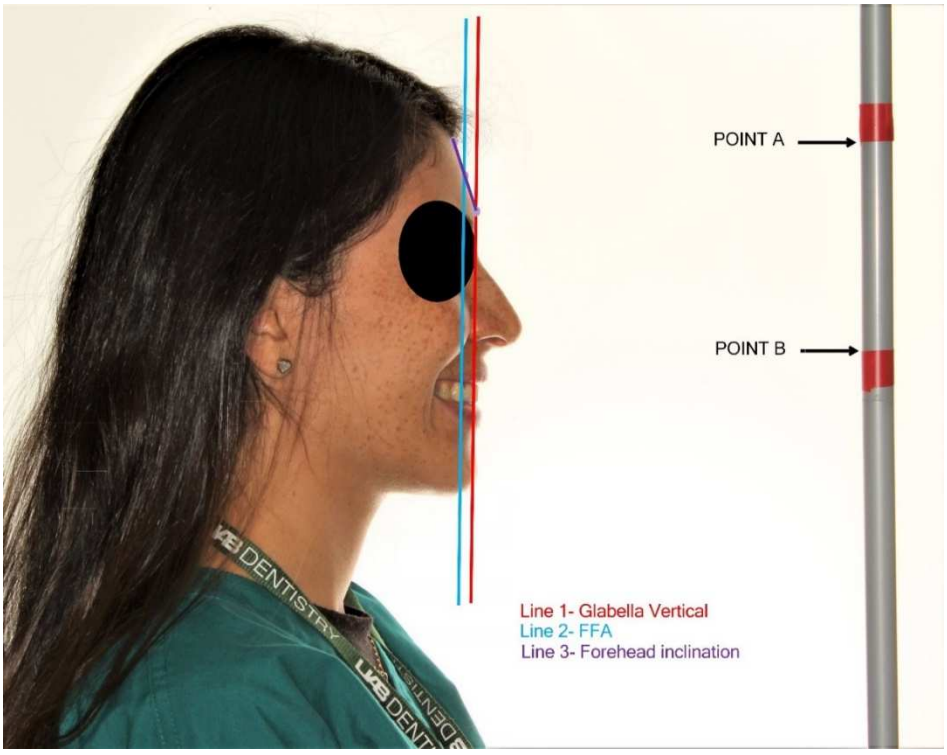


Figure 5**.** Reference Line Construction. Two vertical reference lines (Glabella Vertical and FFA Point Vertical, Lines 1 and 2 respectively). Lines 3 (Forehead inclination) and 2 (FFA vertical) form the forehead inclination angle. The distance between Point A and Point B represents 100mm/ 10 cm in distance.

Statistical Analysis

Descriptive and inferential statistical analyses were performed using SAS software (version 9.4; SAS Institute, Cary, NC, USA) software. Graphical displays were also obtained using SAS. The means, standard deviations, and ranges were calculated for maxillary central incisor AP positions in relation to Glabella Vertical, as well as forehead inclination in all subjects in each group. The means of the two groups (Control Group vs. Study Group) were compared using the two-tailed two-group t-test. Linear regression analyses were performed between maxillary central incisor position and forehead

inclination separately for both groups. Regression coefficients were tested for statistical significance. P-values of 0.05 or less indicated statistical significance.

Intra/ inter- rater reliability

10 photographs were randomly selected, and measurements were made by two independent raters for both parameters (anteroposterior position of the upper incisor and forehead inclination) at two different time points. Time points were set at two weeks apart to assess intra/inter-rater reliability and consistency of quantitative measurements made by the different raters. Intra-Class Coefficients (ICC) were calculated for both AP and forehead inclination regarding both intra/inter-rater reliability at each time point. A test was also conducted for the hypothesis on whether the ICC is 0 vs >0, with p-values of 0.05 or less indicating statistical significance.[75-77]

CHAPTER 3

RESULTS

Intra Class Correlation Coefficients

Intra-Class Correlation Coefficients (ICCs) were computed for both anteroposterior position and forehead inclination for both raters regarding intra-rater reliability (Rater A, ICC = 0.956 and 0.967, respectively; Rater B, ICC = 0.974 and 0.937, respectively). Inter-rater reliability ICCs were computed for both time points and raters for anteroposterior position (Time Points 1 and 2, ICC = 0.972 and 0.938, respectively) and forehead inclination (Time Points 1 and 2, ICC = 0.939 and 0.958, respectively). All ICCs were highly significant, with $p<0.0001$ for all.

Measurements

Maxillary Incisor AP position

Table I shows the AP position of the maxillary central incisor in relation to Glabella Vertical for the control and the study group (Control vs. Study Group). The control group showed the upper incisor to be 8.4mm in front of Glabella Vertical on average, with a range of -1.56mm and +24.19mm alongside a standard deviation of 6.94mm. The study group showed an average position of 7.23mm ahead of Glabella vertical, with a range of -10.54

and +26.28mm alongside a standard deviation of 8.38mm. The maxillary central incisor position relative to Glabella Vertical was not significantly different between the Control Group and Study Group ($p = 0.56$, as displayed in Table II).

Forehead Inclination

Table III shows the forehead inclination for the control group and the study group. The control group showed an average forehead inclination of 20.36 degrees, with a range of 11.26 – 30.21 degrees and a standard deviation of 5.2 degrees. The study group showed an average forehead inclination of 20.82 degrees with a range of 8.01 - 34.71 degrees and a standard deviation of 6.54 degrees. Forehead inclination was not significantly different between the Control Group and the Study group ($p = 0.34$, respectively, as displayed in Table II).

Regression Analysis and Correlations

Table IV shows the results of the regression analysis between the AP maxillary central incisor position and forehead inclination for both groups. In both groups, the AP position of the maxillary central incisors was strongly correlated with forehead inclination (p for β was ≤ 0.0001 for all groups, as displayed in Figures 7-8). In relation to Glabella Vertical, the AP position of the upper central incisor could be found by multiplying the forehead inclination by 1.063 and subtracting 13.242 mm for the Control Group and multiplying the forehead inclination by 1.030 and subtracting 15.249 mm for the Study Group.

The R^2 value for the Control Group was 0.634 and that for the Study Group was 0.646. This indicates that forehead inclination explains 63% of the variance in anteroposterior position for the Control Group and 65% of the variance in anteroposterior position for the Study Group.

Utilizing the formula provided from the regression analysis, foreheads sloped 0° to 5° had upper incisors located 0.5 to 2mm anterior to Glabella Vertical and for every 5° the forehead is inclined greater than 5°, the upper incisor can be correspondingly placed 1.5mm more anterior to Glabella Vertical (Figure 4).

Power Analysis

A post-hoc analysis was conducted to calculate the power of the study for the sample sizes utilized. Power calculations were performed using nQuery software (version 8.7, Statistical Solutions, San Diego, CA, USA), and assumed a two-sided statistical test and a significance level of 5%. Regarding the correlation coefficients, there was 80% power to detect ICCs of 0.79 and greater as being statistically significant, assuming a sample size of 10 measurements (AP position or forehead inclination) for each rater. All ICCs for this study were much greater than 0.79, indicating outstanding intra-rater and inter-rater reliability. Regarding the differences between the Control Group and the Study Group for AP position, there was 80% power to detect differences of 5 mm (and greater) as being statistically significant, assuming a standard deviation of 6.94 mm (from Table 1) and a two-group t-test; our differences (in mm) were much smaller than this, and as such, were not statistically significant. Regarding the differences between the Control Group and

the Study Group for forehead inclination, there was 80% power to detect differences of 3.8° (and greater) as being statistically significant, assuming a standard deviation of 5.2° (from Table 3) and a two-group t-test; our differences (in degrees) were much smaller than this, and as such, were not statistically significant. This power analysis does not imply that the study was underpowered; instead, the differences that we found imply that the results obtained for each of the study groups are statistically similar.

Tables

Table I. Anteroposterior Position (mm) of the Maxillary Central Incisors Relative to Glabella Vertical (Distance between Line 1 and the FA Point of the Upper Central Incisor, Figure 5)

Sample	n	Mean	SD	Min	Max
Control Group	24	8.40	6.94	-1.56	24.19
Study Group	46	7.23	8.38	-10.54	26.28

Table II. Differences in Anteroposterior Position (mm) and Forehead Inclination (°) Between Control Group and Study Group

Variable	Control Group	Study Group	Difference	p
AP Position, mean	8.40	7.23	1.17	0.56
Forehead Inclination, mean	20.36	20.82	-1.47	0.34

Table III. Forehead Inclination (°) for Control and Study Samples (Angle Between Line 2 and 3, Figure 5)

Sample	n	Mean	SD	Min	Max
Control Group	24	20.36	5.20	11.26	30.21
Study Group	46	20.82	6.54	8.01	34.71

Table IV. Linear Regression of Anteroposterior Position (mm) of the Upper Central Incisor and Forehead Inclination (°) for both groups

Sample	n	β	Intercept	p for β	R^2
Control Group	24	1.063	-13.242	<0.0001	0.634
Study Group	46	1.030	-15.249	<0.0001	0.646

Figures

Figure 6: Regression analysis for the Control Group

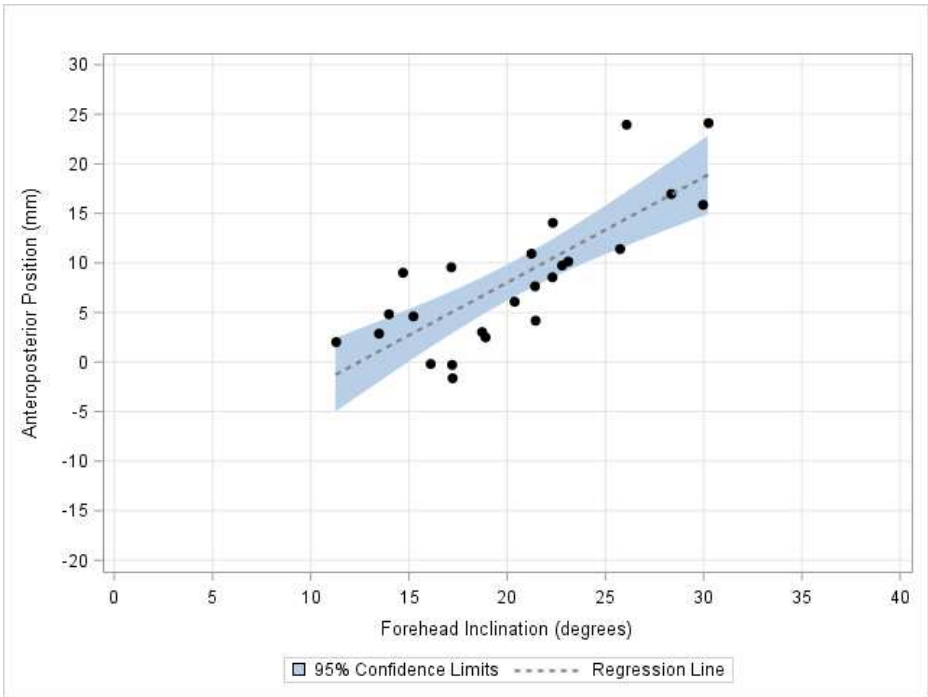
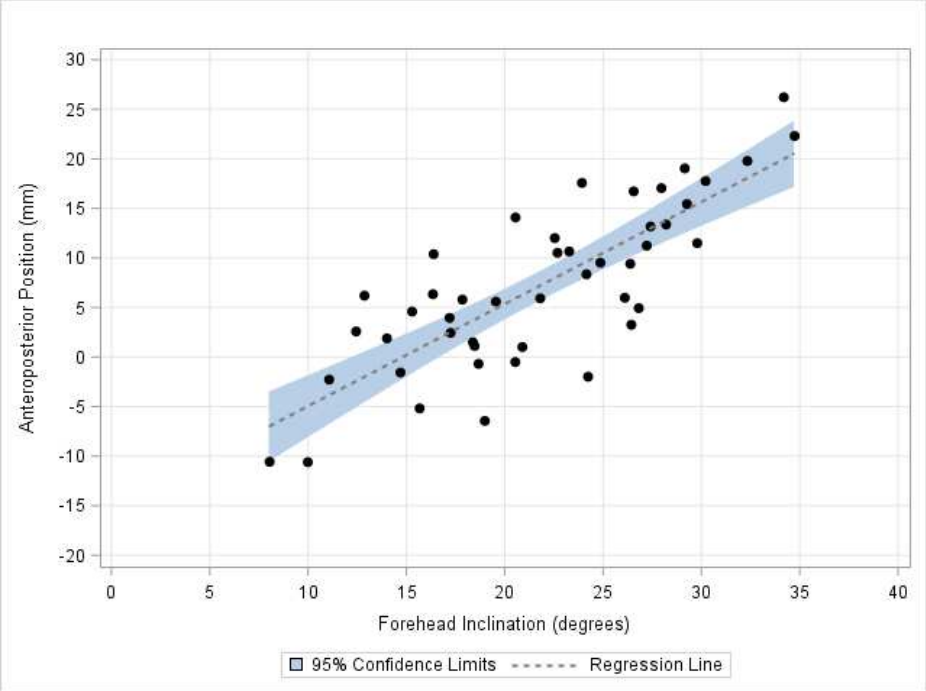


Figure 7: Regression analysis for Study Group



CHAPTER 4

DISCUSSION

The intent of this study was to investigate the second element of Andrews 6 keys of orofacial harmony when it is applied to a different ethnicity, namely a Hispanic female population.[6] Andrews himself stated the need to explore different races, ages and genders so that the second element could be diversified and used outside of a Caucasian gene pool, thus reinforcing the need for this study.[4]

The Hispanic female populations clearly differs in element II in respect to Andrews original work on Caucasian males and females, which will be explored in more detail later.[4, 6]. Previous literature states the need to incorporate smiling profile photographs as part of the diagnostic record, this is reinforced by this study. [30-32] This study also agrees with the narrative that forehead inclination and the clinical forehead, in particular the soft tissue glabella, can be used to establish incisal positions. [4-6, 67, 69, 71] This reasoning is useful for the Hispanic female population as there is not much information that dictates stable external landmarks to determine upper incisal position. Furthermore, using the forehead as a landmark helps in eliminating soft tissue references such as the nose and chin as these are subject to changing over time whereas the forehead remains stable throughout life.[65]

On average the control group showed an incisal position that was 8.4mm in front of Glabella Vertical with a standard deviation of +/- 6.94mm. The study group showed an incisal position that was 7.23mm ahead of glabella vertical with a standard deviation of +/- 8.38mm. The findings of this study found no significant difference between the AP position of the maxillary incisors in the control group and the study group. This is not in agreement with previous studies which show a significant difference between control and study groups.[4, 5, 69, 71] In the control group, 87.5% of the participants showed an upper incisor position anterior to Glabella vertical and no participants in the control group had upper incisors behind the FFA line. This finding was very similar to the results from Gidaly et al with the minority who investigated a group of African American females, showing that all participants in the control group had upper incisors anterior to Glabella Vertical.[69] In the current study, 54% of the control group had an AP position of the incisor that was less than 10.0mm ahead of GV, with an average AP position of 6.0mm within this range. Only 12.5% of participants in the control group showed an incisor behind the GV, with an average position being 0.63mm behind the GV and none falling behind or on the FFA line. Andrews study on Caucasian females showed a different outcome, with only 3% of the participants in his control group having incisors anterior to the glabella vertical, 4% behind the FFA line and 93% between the FFA line and Glabella Vertical.[4] Interestingly, the control group in the study conducted by Kim et al for adult Korean females showed on average the control group had upper incisors positioned 1.38mm ahead of the FFA line.[71] What is discernible from Gidaly et al and the current study results is that the Hispanic populations and African American female group that displayed good orofacial harmony presented a more protrusive profile in comparison to Caucasian norms. In general, when setting a goal for the AP position of the incisor

in the Hispanic female population, the clinical recommendation would be to avoid positioning the upper incisor behind Glabella Vertical, unless specifically requested by the patient. Additionally, the anterior limit for the maxillary incisor appears to be 6.0mm ahead of GV. However, the forehead inclination should still dictate the incisor position as steep foreheads can change the anterior limit and using an arbitrary value cannot be used for all Hispanic females. Therefore, one can use the equation derived from the regression analysis to dictate the anterior limit of the maxillary incisal position:

AP Position of Maxillary Incisor= 1.063 (Forehead inclination) - 13.242

A lack of significant difference was also seen between forehead inclination of both groups in this study. The control group showed a forehead inclination of 20.36 degrees and the study group showed an inclination of 20.82 degrees to the FALL line. The lack of significance in forehead inclination is also shown in studies by Kim et al and Andrews.[4, 71] Gidaly et all found a statistical significance in forehead inclination between the control group and a study group of individuals who were seeking orthodontic treatment (study group 1). Furthermore, Gidaly et al found no statistical significance between the control group and those not seeking orthodontic treatment (study group 2) as well as the control group and the combined sample of both study groups 1 and 2.[69]

The purpose of this study was highlighted in the first null hypothesis which postulated that there is no correlation between the forehead inclination and maxillary incisor AP position in the adult female Hispanic population who display facial harmony. The control group showed there is a strong positive correlation between forehead inclination and upper incisor position in Hispanic female patients who

display a good orofacial harmony. Previous studies also coincide with this finding. [4, 5, 69, 71] The strong positive correlation was also seen in the study group, which is not in agreement with most of the previous literature. [4, 5, 69] As such we can reject the null hypothesis and can accept that there is a clear positive correlation between forehead inclination and AP incisor position in Hispanic females. The linear equation of regression for both the control and study group also showed statistical significance ($p<0.0001$), reinforcing a strong correlation between both variables, supporting the argument of rejecting the first null hypothesis. Clinically this means that we can use the forehead angulation or inclination to the FALL line, to determine where the maxillary incisor should be.

In addressing the second null hypothesis, no significant differences were noted between the control group and study groups in respect to the correlation between forehead inclination and incisal position. As such the second null hypothesis in this study is accepted. Kim et al also showed a lack of significance between the control group and study groups.[71]However, the results of this current study do not coincide with the other previous studies; these studies showed a poor correlation between forehead inclination and upper incisors in the respective study groups and a significant difference between the control and study groups.[4, 5, 69]

To understand why there was no significant difference between the control and study group in respect to the correlation between forehead inclination and AP position of the upper incisors, the data must be further explored and dissected. Looking at the average upper incisor AP positions and their standard deviations between groups may give some insight. The average AP position of the maxillary incisor in the control group was 8.4mm with a standard deviation of 6.94mm.

Comparatively Gidaly et al showed a control group average AP position of 8.58mm and with a standard deviation of 3.96mm. The standard deviation indicates how much variation exists in the data around the mean.[78] This shows that this study had more variability in its data compared to Gidaly et al. One obvious reason for this the number of participants recruited, with this study having 24 participants in the control and Gidaly et al having 48. When the study sample is larger the variability decreases.[79] As such, the external validity of this study is not as strong, meaning more studies are needed with an increased sample size within the female Hispanic population. External validity examines whether the results of a sample can be applied to the greater population as a whole.[80] Other reasons for the larger standard deviations of this study could be that the Hispanic female population may inherently have more heterogeneity present or, that the sample of Hispanic females used in this study just coincidentally were vary varied in their AP incisor positions.

The R^2 values may give some insight to the lack of significance between the two groups in respect to forehead inclination and AP incisal position. Also termed the coefficient of determination, the R^2 measures the percentage of variation in the dependant variable accounted for by the independent variable.[81] The R^2 values were 63% for the control group and 65% for the study group respectively. This means that the regression line for 63-65% of the variation in AP position of the incisor is explained by the variation in the forehead inclination.[82] The R^2 for this study is considered to be moderate to substantially strong in its predictive value.[83] This illustrates that the data collected was not weak and conclusions can be drawn from it. The remaining 37-35% of the variability in upper incisor position to Glabella Vertical can be explained by the presence of factors other than the forehead inclination in this model. Other factors can also be termed confounding factors in this context.

Confounding factors are variables that can influence the independent and dependant variables.[84] The difficulty lies in establishing exactly what these confounding factors were. This is completely speculative and ultimately only the judges who participated in the study will know what these were. For example, it could vary from hair colour and style to treatment philosophies which will be discussed in more detail later. It is impossible to know, but it does show that other factors were considered.

When looking at the number of participants recruited, 46 out of the 70 fell into the study group, (almost 66% of the participants) were not found to have good oral facial harmony according to the judges. With an average forehead inclination of 20.36 and 20.82 degrees in both the control and study group respectively (Table III), the AP positions of the incisors can be quantified at this average forehead angulation (20 degrees). The control group shows an AP position of the maxillary incisors of 8.4mm whereas the study group shows an AP position of 6.2mm (Figures 7 and 8 respectively). With forehead inclinations being very similar between the groups, it appears that the judges saw the study group as having a more retrusive incisor relative to the control group or, alternatively, judged that the incisor is closer to Glabella Vertical in the study group, with both scenarios leading to a less harmonious smiling profile. The study group having a more retrusive incisor coincides with the mean AP distance of the maxillary incisors to Glabella Vertical as shown in Table 1. The mean distance of the upper incisors from Glabella Vertical in the study group was 7.23 mm, smaller than that of the control group which was 8.4mm. As previously mentioned, 54% of the control group had an AP position of the incisor that was less than 10.0mm ahead of GV, with an average AP position of 6.0mm within this range. Only 12.5% of participants in the control group showed an incisor behind the GV, with an average position being 0.63mm behind the GV and none falling behind or on the FFA line. In

the study group only 41% had an AP incisal position that was less than 10mm ahead of GV with an average value of 4.72mm in this range. 20% of the participants in the study group had upper incisors that sat behind the GV, with an average value of 5.86mm behind the GV, a value that was much more retrusive than that of the control group. In summary the study group which made up 67% of the participant sample, were seen to have more retrusive incisors. This is an interesting point of discussion: either the sample of participants truly were predominantly retrusive in their incisor position or the judges felt they were. Retrusive maxillary incisors can be seen Angle Class 2 division 2 malocclusions where they tend to be more retroclined than truly retrusive.[85] While less frequent, retrusive maxillary incisors can also be seen in smaller quantities in Angle Class 3 malocclusions.[86] Malocclusions in the Hispanic populations are overwhelmingly classified as Angle Class I (62.9%) with the second most common malocclusion being Angle Class 2 division 1 (20.3%), Angle Class III malocclusions and Angle Class 2 division 2 amount to 9.1% and 1.2% of the observed malocclusions in this group.[87] This is not unique to the Hispanic population either, other ethnicities show a similar prevalence of malocclusion.[88] As such it is highly unlikely that 67% of the participants in this study truly had maxillary incisors in a retrusive position, meaning we must consider the possibility that the judges saw the incisors as retrusive when they may not have been. This finding loops back to the need to explore confounding factors in more depth.

All the judges were affiliated with the UAB department of orthodontics, with 9 being current residents and 3 being graduated alumni. Collectively 12/15 were trained in orthodontics at the same department. We can explore the possibility that treatment philosophies may have been a confounding factor. On average, approximately 12.35% of cases are treated with extractions by the residents who

participated on the judging panel. This could point to the idea that namely a non-extraction thought process or overall training in residency may influence whether the judges saw orofacial harmony or not. In essence, retruded incisors were seen as unaesthetic by most judges of judges, perhaps reflecting their educational and cultural background which preferentially and unconsciously favours fuller profiles and more protrusive incisors. These findings are more commonly found in non-extraction orthodontic treatments. It may be that a different panel of judges in a different geographical location would have a different perception of the images. However, it is the judging panel for this study is similar to the composition of the orthodontic community in the southeast of the United States.

Future Improvements

Future studies could benefit from having Judges of Hispanic heritage evaluate smiling profile pictures of Hispanic females as they may have a different concept of what oral facial harmony consists of within their ethnicity. Furthermore, other oral healthcare professionals could be included as part of the judging panel, ranging from not only orthodontists but to prosthodontists, oral surgeons and even members of the public. This may explore a difference in the thought process behind the position of the incisor position. If orthodontists and indeed other oral health professionals trained at different institutions are included on the judging panel, it may shed more light on different training ideologies regarding aesthetic preferences and treatment philosophies. Exploring confounders or asking judges what elements steered their decisions between liking or not liking the incisor position in the face, could also explain the thought process behind judging a profile. Lastly, increasing the sample

size of the study may also be beneficial, it could increase the R^2 value, reduce the variability of the data and strengthen the external validity of the study.

Clinical Applications

Based on the data from this study, a personalized incisor position relative to the forehead inclination can be established in the Hispanic female population. Glabella Vertical should be used as the posterior limit for upper incisor. Utilizing the formula provided from the regression analysis, for patients with foreheads sloped 0° to 5°, the upper incisors should be located 0.5 to 2mm anterior to Glabella Vertical and for every 5° the forehead is inclined greater than 5°, the upper incisor can be correspondingly placed 1.5mm more anterior to Glabella Vertical (Figure 3). Alternatively, the anterior limit for the upper incisors can be calculated from the formula derived from the regression analysis, which states:

AP Position of Maxillary Incisor= 1.063 (Forehead inclination) - 13.242

For example, if a patient has a forehead inclination of 25 degrees:

AP Position of Maxillary Incisor= 1.063 (25) – 13.242 = 13mm (rounded down)

CHAPTER 5

CONCLUSIONS

- In the control group, 54% had the incisors located between GV and 10mm ahead of GV with an average value of 6.0mm
- In the control group only 12.5% of participants had upper incisors behind the GV, with an average value of 0. 63mm
- In the study group 41% had the maxillary incisors located between GV and 10mm ahead of GV with an average value of 4.72mm
- In the study group 20% of the participants had upper incisors that sat behind the GV, with an average value of 5.86mm
- Strong positive correlations were seen between the clinical forehead inclination and AP position in both the control and study groups
- For most Hispanic females, the posterior limit of the maxillary incisor in should be the Glabella vertical, unless specifically requested by the patient.
- The anterior limit for the maxillary incisor in Hispanic females can be calculated through the formular derived from the regression analysis of the control group:

AP Position of Maxillary Incisor= 1.063 (Forehead inclination) - 13.242

Andrews Caucasian norms are not applicable to patients of a different ethnic background. While the forehead is a reliable landmark to establish the AP positioning of the upper incisor, this position differs from one ethnic background to another and is best determined by using the equations derived from studies focused on a specific population group.

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APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Office of the Institutional Review Board for Human Use

470 Administration Building
701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 |
irb@uab.edu

APPROVAL LETTER

TO: Souccar, Nada M

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)
IORG Registration # IRB00012550 (IRB 03)

DATE: 03-Jun-2021

RE: IRB-300006519
IRB-300006519-007
Optimal antero-posterior position of the maxillary central incisors and its relationship to the forehead in adult Hispanic females

The IRB reviewed and approved the Initial Application submitted on 26-Apr-2021 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review:	Expedited
Expedited Categories:	6
Determination:	Approved
Approval Date:	03-Jun-2021
Approval Period:	Expedited Status Update (ESU)
Expiration Date:	05-May-2024

Although annual continuing review is not required for this project, the principal investigator is still responsible for (1) obtaining IRB approval for any modifications before implementing those changes except when necessary to eliminate apparent immediate hazards to the subject, and (2) submitting reportable problems to the IRB. Please see the IRB Guidebook for more information on these topics.

The following apply to this project related to informed consent and/or assent:

- Waiver of Consent Documentation

To access stamped consent/assent forms (full and expedited protocols only) and/or other approved documents:
1. Open your protocol in IRAP.
2. On the Submissions page, open the submission corresponding to this approval letter. NOTE: The Determination for the submission will be "Approved."
3. In the list of documents, select and download the desired approved documents. The stamped consent/assent form(s) will be listed with a category of Consent/Assent Document (CF, AF, Info Sheet, Phone Script, etc.)