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Effectiveness of Maxillary Molar Intrusion With the Invisalign System for Correction of anterior Open Bites

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EFFECTIVENESS OF MAXILLARY MOLAR INTRUSION WITH THE INVISALIGN SYSTEM FOR CORRECTION OF ANTERIOR OPEN BITES

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ABSTRACT

Objective: The purpose of this study is twofold: To assess the amount of molar intrusion that can be predictably be achieved with clear aligners (Invisalign, Align Technology, Santa Clara, CA, USA) and to quantitatively document the dental and skeletal changes resulting from anterior open bite correction. **Methods:** This retrospective case-series study analyzed lateral cephalograms of 23 adult anterior open bite patients treated with Invisalign. Pre-treatment (IN) and post-treatment (FN) cephalograms were traced to determine changes as a result of treatment. 13 different variables were measured, 6 angular and 7 linear. All patients were treated consecutively by a single, experienced Invisalign provider in their private practice. Inclusion criteria included: anterior open bite (overbite < 0.0 mm), patients at least 18 years of age at the initiation of treatment, both arches treated with Invisalign, and good quality pre-treatment (IN) and post-treatment (FN) lateral cephalograms. Paired t-tests were used to analyze the data and determine significant changes that occurred as a result of treatment. **Results**: A total of 23 patients met the inclusion criteria and were included for data analysis with an average pretreatment age of 38.5 years [standard deviation (SD) = 12.95] and pretreatment open bite of -1.6 +/- 1.2 mm. Statistically significant ($P < 0.05$) differences were found in 8 of 13 variables. These variables included an increase in overbite (+2.6mm), a decrease in lower anterior facial

height (LAFH) (- 0.62mm), intrusion of the maxillary 1st molar (U6-PP) (-0.66mm), intrusion of the mandibular 1st molar (L6-MP) (-0.68mm), extrusion of the maxillary incisor (U1-PP) (+ 0.90mm), retroclination of the maxillary incisor (U1-PP) (-5.2°), extrusion of the mandibular incisor (L1-PP) (0.67mm), and retroclination of the mandibular incisor (L1-MP) (-5.2°). **Conclusion**: Invisalign is an effective treatment modality for adult non-growing anterior open bite patients. This system can effectively control and even reduce the vertical dimension, but does not seem to change the skeletal face significantly. Open bite closure with Invisalign occurred due to a combination of tooth movements: maxillary and mandibular incisor extrusion, maxillary and mandibular incisor retroclination, and maxillary and mandibular molar intrusion, leading to a slight decrease in lower anterior facial height.

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CHAPTER 1

INTRODUCTION

In 1998, Align Technology (Invisalign, Align Technology, Santa Clara, CA, USA) introduced the Invisalign appliance, a series of computer designed clear removeable plastic aligners that fit over the teeth and move them incrementally into a desired position [1]. From the beginning, Invisalign was marketed to the adult patient as an esthetic alternative to traditional appliances and has been a driving factor for its increase in demand ever since [2]. Originally, the Invisalign appliance was designed to treat mild orthodontic cases with mild to moderate crowding and no skeletal discrepancies [3]. Over the last 23 years, Invisalign's consistent improvement in virtual planning and plastic materials coupled with increased clinical experience has resulted in successful treatment of more complex malocclusions [4–6]. Throughout orthodontic history, treatment of anterior open bites has been one of the most difficult malocclusions to treat due to its multifactorial etiology, the tendency for traditional fixed appliances to extrude teeth, and high potential for relapse [7–9]. More recently, there have been reports of successful correction of anterior open bites with Invisalign but the mechanism by which correction is achieved is not completely understood [10–12]. This study evaluated specific tooth movements contributing to open bite correction with Invisalign.

Definition and Etiology

"Anterior open bite" is a malocclusion often defined in textbooks as "no overlap of the incisors" [13]. Although this definition is generally accepted, others define the malocclusion as "no vertical overlap of the incisors when buccal segment teeth are in occlusion" [9]. Even others claim malocclusions are defined according to missing function, suggesting patients of this type cannot incise with their incisors [14]. The prevalence ranges from (1.5-11 %) and varies with age and ethnicity [15]. A health examination on US children ages 6-11 reported a 5.7% prevalence of anterior open bites. In the same report, the prevalence in African American children was 16% while only 4% in Caucasian children [16]. Numerous studies indicate a higher prevalence in the deciduous and mixed dentitions compared to the permanent dentition, suggesting a decrease in prevalence as one nears adolescence[15,17].

The etiology of an anterior open bite is complex and multifactorial. The malocclusion can be caused by a variety of environmental factors, genetic predispositions, and or skeletal growth abnormalities [7]. More broadly, they can be described as dental or skeletal in origin. When an anterior open bite is caused by a local force such as digit sucking, pacifier use, forward tongue position, or tongue thrusting there is often spontaneous closure of the open bite if the force is removed before transitioning from the mixed dentition to the permanent dentition [15,17,18]. Studies have shown 40-80% of mixed dentition anterior open bite cases resolve without intervention [17,19] . For this reason, early interceptive treatment for correction of anterior open bites is controversial and may have little value. Anterior open bites caused by irregular anterior tooth position may be resolved

with dental extrusion or retroclination of the incisors [12]. While these previously mentioned malocclusions appear as open bites, they are dental not skeletal open bites. Skeletal open bites are more complex and result from genetic predisposition, allergies, syndromes, hypertrophy of lymph tissue, airway obstruction, and super-erupted posterior teeth [7]. In these patients there is often a clockwise (viewed from patient's right) downward and backward rotation of the mandible. This can be a result of shorter rami or excessive vertical growth of the maxilla. When eruption of the posterior teeth or molar region outpaces the growth at the condyle a backwards rotation of the mandible will occur and often times result in an anterior open bite [20]. Any genetic or environmental factor that promotes vertical growth in the posterior region will result in an anterior open bite unless there is compensatory growth at the condyle or rami [7].

Anterior Open Bite Treatment Modalities

Anterior open bite cases, like all cases in orthodontics, require proper diagnosis of the malocclusion in order to facilitate successful treatment. According to Ng et al., there are four general treatment modalities used by orthodontists in treatment of an anterior open bite: (i) orthodontic observation and advice on early problems; (ii) interceptive treatment; (iii) camouflage treatment by orthodontics only; (iv) a combined orthodontic and surgical approach [15]. The appropriate treatment modality is chosen based on a variety of factors that include: etiology of the open bite, age of the patient, severity, and the patient's functional and esthetic concerns.

The first two modalities can be successful interventions for the growing patient. If a local environmental factor such as tongue thrusting or digit sucking is recognized as the cause of the anterior open bite early enough and stopped, often times the bite will spontaneously close without any intervention. However, some patients require orthodontic intervention to help break the habit. There are habit-therapy options such as a tongue crib, chemical aversion, and hand wraps that can aid in resolution [7,13]. While habits may require orthodontic intervention for resolution, abnormal vertical skeletal growth seen in young children may also be helped by orthodontic treatment.

Vertical growth of the jaws continues into the late teenage years. If an anterior open bite is diagnosed in the early permanent dentition with no associated habit and a hyperdivergent growth pattern, interceptive treatment may be warranted [13]. Growth modifying appliances like the vertical pull chin cup, high pull headgear, and vertical holding appliance may be offered as treatment options. The goal of these appliances is to arrest or slow dental eruption, control the vertical dimension, and in some cases redirect growth [21–23]. Early diagnosis of the skeletal abnormality is key and successful treatment may aid in avoiding more complex orthodontic therapy or surgery later in life. Early intervention can be helpful in resolving or slowing the progression of an anterior open bite, but often times the underlying etiology goes undetected or the malocclusion does not develop until after adolescence or into adulthood [13].

Mild to moderate anterior open bites in post adolescent and non-growing patients can be corrected by treatment with traditional appliances. Usually, “camouflage treatment” with traditional appliances is used in these cases and can be supplemented with elastic

wear, extractions, and/or temporary anchorage devices (TADs). Vertical elastic wear is commonly used by clinicians to close mild anterior open bites by extrusion and retroclination of the incisors and is purely dentoalveolar compensation [15]. On the other hand, extractions of premolars, is believed by many clinicians to close the bite via a reverse wedge effect [24]. However, some research suggest the lower anterior facial height does not decrease with premolar extractions [25,26]. Up until 1985, when the first mini-implant was used for additional anchorage, elastics and extractions were the only forms of camouflage treatment for anterior open bites. Over the last 35 years, various techniques have emerged which utilize TADs to facilitate intrusion of posterior teeth and minimize unwanted side effects when treating anterior open bites [27,28]. Active orthodontic molar intrusion via TADs has offered an alternative to treatment of moderate and even some severe anterior open bite cases which would have been treated with orthognathic surgery in the past.

Non-growing patients with severe skeletal anterior open bites have traditionally been treated with a combined orthodontic and surgical approach [7]. These patients often have maxillary excess and require maxillary impaction via a Le Fort osteotomy [7]. Superior repositioning of the maxilla facilitates forward and upward rotation of the mandible as well as closure of the anterior open bite. Additionally, maxillary impaction followed by autorotation of the mandible decreases the patient's anterior facial height [29]. Some patients may require a genioplasty to reduce the increased chin projection accompanied by the autorotation. Maxillary impaction is the one of the more stable orthognathic surgical movements [30]. In a classic study by Proffit and White, 61 patients had Lefort 1 osteotomies with at least 2 mm of maxillary impaction, 95% were stable, 5% experienced relapse [30].

While surgery offers an opportunity for ideal correction and has long been considered the "gold standard" for severe skeletal anterior open bites, the patient assumes the associated risks including significant cost, partial or permanent anesthesia, pain, swelling, and bruising typically associated with any procedure under general anesthesia [8,9]. Timing of surgical intervention coincides with the completion or near completion of growth, so any remaining growth will not undo correction achieved by surgery. Females tend to complete growth earlier than males and therefore can often have surgical intervention at an earlier age [13].

Until the advent of clear aligner technology, orthodontic camouflage was accomplished with traditional appliances supplemented by extractions, elastics, or mini-implants [15]. In fact, early studies showed limitations of Invisalign's ability to treat complex malocclusions. These early shortcomings can likely be attributed to the fact that these studies were conducted in the first few years of Invisalign's development [31,32]. Consistent advances in clear aligner materials, attachments, and virtual planning have expanded the scope of aligners from treatment of simple cases to more complex malocclusions such as anterior open bites [10,11]. A few case reports document successful treatment of severe anterior open bites with Invisalign[10,33]. However, the evidence is limited and the mechanism of bite closure of this new treatment modality is not well understood.

Stability

The anterior open bite is a challenging malocclusion to treat and if bite correction is achieved the correction is difficult to maintain [34]. Typically, the goal of anterior open

bite treatment is to achieve positive overlap of the incisors. Relapse is common and refers to the tendency for overbite correction to be lost posttreatment [35].

A variety of treatment modalities are available for the clinician to optimally correct anterior open bites. Habit correcting appliances or habit cessation may result in spontaneous resolution of the open bite[36]. Correction can also be achieved via orthodontic movement of the teeth in the alveolar housing. In severe cases combined orthodontic and surgical intervention are necessary to achieve bite closure. With a multitude of therapy options, determining the relative stability of each treatment modality is important in diagnosis and treatment planning.

Anterior open bite correction by non-surgical orthodontic intervention and surgical intervention has shown similar long-term stability. In a metanalysis of 21 studies, published by Greenlee et. Al., non-surgical correction showed 75% stability while surgical correction showed 82%[35]. Stability success was defined as positive overlap of the maxillary and mandibular incisors. Each group had a similar pre-treatment overbite (non-sx: -2.6mm, sx: -2.8 mm)[35]. Mean posttreatment overbite was 1.4 mm and 1.6 mm respectively[35]. The metanalysis excluded studies with follow-ups of less than 12 months and the mean follow-up time was 3.2 years for the non-surgical group and 3.5 years for the surgical group[35]. At follow-up, mean overbite was 0.8 mm in the non-surgical group and 1.3 mm in the surgical group with no statistical difference between the amount of overbite reduction from pre-treatment to follow-up in the two groups [35]. The results of this study suggest non-surgical and surgical intervention have similar short-term results and long-term stability.

Traditional teachings have suggested orthognathic surgery is indicated for non-growing patients with moderate to severe open bites due to stability concerns. The aforementioned metanalysis indicates there is some vertical relapse with surgical intervention and that relapse is not statistically different than the relapse found in non-surgical orthodontic intervention of a similar population. The additional small amount of relapse in the non-surgical group could have been attributed to growth posttreatment. The average initial age of the non-surgical group at the beginning of treatment was 16 compared to 23 in the surgical group [35]. Due to limitations in this analysis, there needs to be more exploration of stability in treating this malocclusion, but it does suggest there is no difference in stability of anterior open bite treatment in non-surgical and surgical orthodontic intervention.

At this time, very little research exists on stability of clear aligner therapy in correction of anterior open bites. In a study of 112 anterior open bite patients treated with aligners, fixed appliances, fixed appliances with TADs, and surgery, stability was assessed. At a mean of 1.2 years posttreatment, there was no statistical difference in stability between the groups [37]. There is limited evidence assessing stability of anterior open bite treatment with clear aligners and additional research is needed.

Biomechanics: Invisalign vs. Traditional Appliances

It has been suggested that Invisalign therapy may serve as a superior non-surgical orthodontic treatment modality for correction of anterior open bites compared to traditional appliances [38]. Mechanically, traditional fixed appliances have a tendency to

extrude teeth leading to a worsening of the malocclusion [39,40]. Contrarily, some hypothesize Invisalign may inherently be an effective treatment option in correcting anterior open bites due to the intrusive effect of the aligners resulting from the increased interocclusal distance created by the thickness of the trays [41]. The increased interocclusal distance may help close the bite by providing a "bite block effect" created by the patient's normal bite force [42]. In fact, there are multiple case reports of successful closure of anterior open bites using Invisalign [10–12,33]. Unfortunately, the current research is not strong enough to definitively determine the mechanism by which Invisalign is able to close an anterior open bite.

Purpose

Invisalign may offer a promising alternative of a non-surgical approach to treatment of anterior open-bite malocclusions. Yet, the current evidence-based research on how Invisalign could successfully correct this challenging type of malocclusion is limited and shows conflicting results. It is important for the clinician to know what movements are contributing to bite closure. Posterior intrusion is effective in correcting anterior open bites, but the extent and predictability with which Invisalign can accomplish this movement is still unclear. The purpose of this study is twofold: To assess the amount of maxillary and mandibular 1st molar intrusion that can be predictably be achieved with clear aligners by comparing pre-treatment (IN) and post-treatment (FN) lateral cephalograms and to quantitatively document the dental and skeletal changes resulting from anterior open bite

correction with clear aligners. Our null hypothesis is that there is no difference between pre and post treatment molar position in the vertical position with Invisalign therapy.

CHAPTER 2

MATERIALS AND METHODS

The study's protocol was designed as a retrospective case-series study. Approval was obtained by the Institutional Review Board (IRB) of the University of Alabama at Birmingham (UAB) (Protocol #IRB-300006639).

This study was an evaluation of the mechanism of anterior bite closure with Invisalign clear aligners. The study sample consisted of adult patients consecutively treated with Invisalign by one, experienced Invisalign diamond plus provider. The provider (J.S.) has treated over 6,700 Invisalign cases and is in the top 1% of Invisalign providers nationwide, which awards him diamond plus status. Patient records were screened at two private practices in Warner Robins, GA and Macon, GA. All consecutive Invisalign records were screened from each office with no preference in case selection from the providing clinician. The de-identified records were reviewed at the Department of Orthodontics, University of Alabama at Birmingham, from January 2021 to September 2021 by one primary investigator (L.I.) and one secondary investigator (T.C).

All patient data was collected from the provider's database, generating one report through OrthoTrac practice management software with the words "anterior open bite" and treatment completion between 1/1/2013 and 9/1/2021 as a search key and timeframe. After conducting a preliminary search, a total of n0 = 140 cases were retrieved from the computer search within the entire Invisalign clinical database as possible anterior open bite cases.

From the 140 cases, a total of 23 cases were selected for evaluation based upon the following inclusion and exclusion criteria:

Inclusion criteria:

- Male and female between 18-100 years of age
- Anterior open bite >0 mm prior to treatment
- Treated consecutively with Invisalign in both arches
- Initial and final lateral cephalograms taken within 6 months of initiation and completion of treatment
- Treatment completed between 1/1/2013 – 9/1/2021
- All patients treated by the same provider (Dr. J Don Spillers Jr.)

Exclusion criteria:

- Incomplete or poor-quality records
- Patients with significant medical histories (syndromes, etc)
- Treatment involving orthodontic appliances other than Invisalign system
- Treatment involving extractions
- Patients who had restorative work or surgery done prior to final scan
- Non-completion of treatment

Each patient who met the inclusion and exclusion criteria was assigned a random number. The following records were then de-identified with the newly assigned random number. The data collected included (1) lateral cephalograms from two time points: pre-treatment (IN) and posttreatment (FN), (2) the Invisalign Treatment Overview report, (3) treatment length, (4) age at initiation of treatment, and (5) patient's sex. The Invisalign Treatment Overview is a document generated by Align Technology for each patient summarizing all case specific treatment information. Data collected from the report for the purposes of this study were the number of aligners, number of refinements, planned interproximal reduction, and planned molar intrusion. All data was encrypted and kept on a password-protected computer locked in the secondary investigator's (T.C) office at University of Alabama at Birmingham (UAB).

All eligible cases with de-identified pre-treatment (IN) and post-treatment (FN) lateral cephalograms were imported into Dolphin software (Dolphin Imaging, Chatsworth, Calif) to perform cephalometric analyses. Fourteen landmarks were identified on the pre-treatment and post-treatment cephalograms and can be seen on Figure 1. Seven linear and six angular measurements were evaluated to assess the changes during treatment and can be seen on Figures 1-2. All measurements with their definitions are presented in Table 1. The mandibular plane, palatal plane and occlusal plane were used as reference lines. Measurements were taken from these lines in order to assess changes as the result of treatment. The mandibular plane was defined as a line drawn through menton (Me) and gonion (Go) [43]. The palatal plane was defined as a line drawn through anterior nasal spine (ANS) and posterior nasal spine (PNS) [44]. The occlusal plane was defined as a line drawn

through the bisection of the mesiobuccal cusp tips of the first molars and the incisal edges of the most anterior incisors [45].

To assess dental changes in the anterior and posterior vertical dimensions the palatal plane and the mandibular plane were used as reference lines. The following measurements were recorded. Vertical position of the incisors (U1-PP and L1-MP), defined as the shortest millimetric distance from the tip of the maxillary incisor to the patalal plane and tip of the lower incisor to mandibular plane. Vertical position of the molars (U6-PP and L6-MP) defined as the shortest millimetric distance from the mesiobuccal cusp of maxillary and mandibular first molars to their respective reference lines.

To assess changes in the angulation of the maxillary and mandibular incisors two measurements were used. U1-PP angle was created by a line drawn through the long axis of the maxillary incisor to the palatal plane, and L1-MP angle was created by a line drawn through the long axis of mandibular incisor to the mandibular plane.

Lastly, 5 angular measurements were recorded to assess skeletal change as a result of treatment. These include SNA, SNB, ANB, LAFH, and SN-MP. Dolphin software computed the linear and angular measurements used in our statistical analyses.

All cephalometric landmarks were identified by the principal investigator (L.I.) and checked for accuracy by the secondary investigator (T.C). Landmarks for pretreatment and posttreatment radiographs were traced sequentially for each patient in order to minimize landmark identification error. Approximately three weeks later, ten radiographs were randomly selected to be retraced by the principal investigator to ensure accuracy and determine intra-rater reliability.

Statistical Analyses

All statistical analyses were performed with SAS software Version 9.4 (SAS Institute, Inc,, Cary, NC, USA). Measurements for pre-treatment and post-treatment variables as well as differences are summarized by means and standard deviations. Pre-treatment (IN) and post-treatment (FN) differences for all variables were compared using paired t-tests. A 95% confidence interval of the mean difference was reported, p-values less than 0.05 were considered statistically significant. The intra-class correlation coefficient value was calculated using linear mixed models, accounting for between-patient and between-timepoint variation.

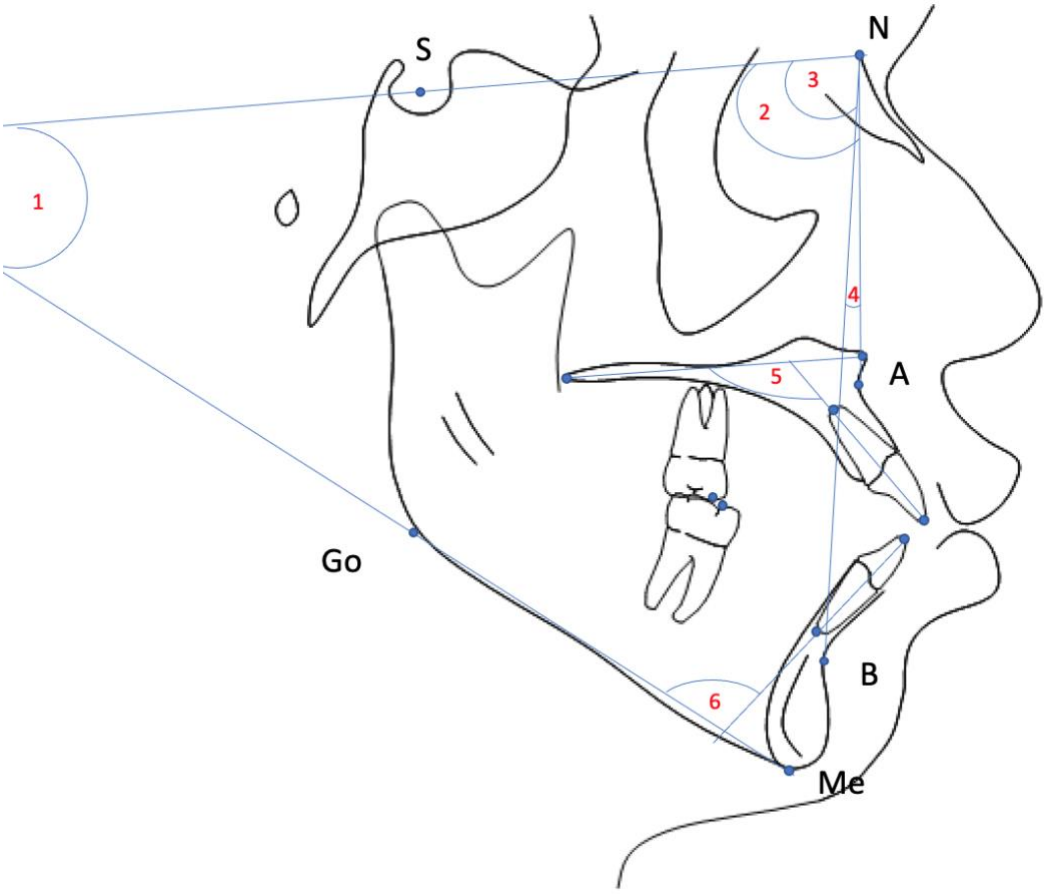

Figure 1. Angular measurements. 1, SN – MP: angle between SN plane and mandibular plane (Go-Me); 2, SNA: angle between SN plane and NA plane; 3, SNB: angle between SN plane and NB plane; 4, ANB: angle between NA plane and NB plane: 5, U1-PP: angle between long axis of the U1 and palatal plane (ANS-PNS); 6, L1-MP: angle between the long axis of the L1 and mandibular plane (Go-Me).

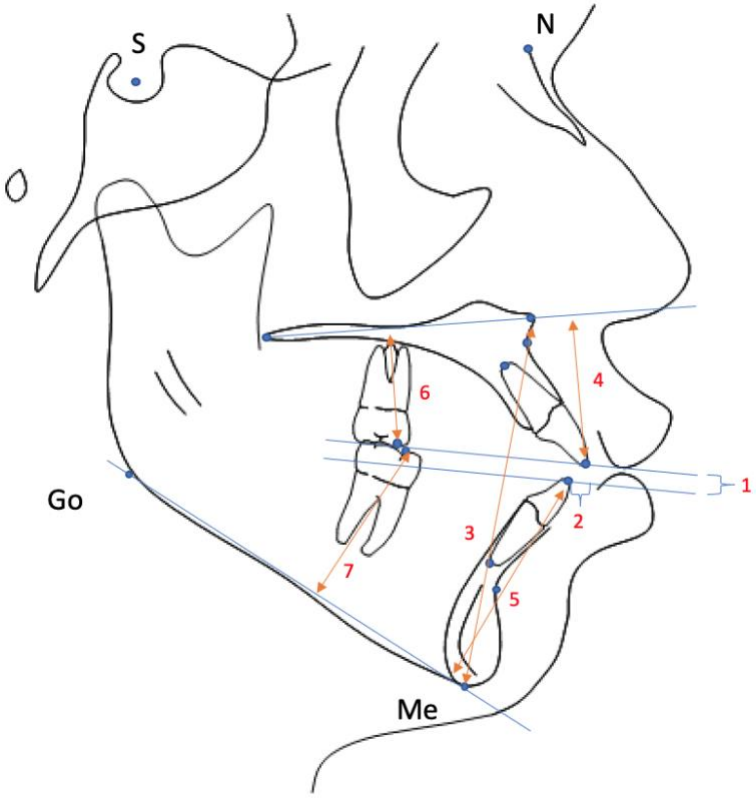

Figure 2. Linear measurements. 1, overbite: shortest distance from U1 tip and L1 tip perpendicular to the occlusal plane; 2, overjet: distance from the tip of U1 to tip of L1; 3, LAFH: shortest distance from ANS to Me; 4, U1-PP: shortest distance from U1 tip to palatal plane; 5, L1 – MP: shortest distance from L1 tip to mandibular plane; 6, U6-PP: shortest distance from mesiobuccal cusp tip of U6 to palatal plane; 7, L6-MP: shortest distance from mesiobuccal cusp tip L6 to mandibular plane.

Table 1. Definitions of Variables Used as Measurements in Current Study.

Variable	Definition
Overjet (mm)	The horizontal millimetric distance from U1 tip to L1 tip
Overbite (mm)	The vertical millimetric distance from U1 tip and L1 tip perpendicular to the occlusal plane
SNA (degrees)	This angle indicates the horizontal position of the maxilla relative to the cranial base. A point is the most anterior measure of the maxillary apical base.
SNB (degrees)	This angle indicates the horizontal position of the mandible relative to the cranial base. B point is the most anterior measure of the mandibular apical base.
ANB (degrees)	This angle measures the relative position of the maxilla to the mandible. The ANB angle is calculated from the following formula: ANB = SNA- SNB
LAFH (mm)	The millimetric distance between ANS and menton
U6 – PP (mm)	The millimetric distance between the mesiobuccal cusp tip of the U6 and the palatal plane (ANS - PNS)
U1 – PP (mm)	The millimetric distance between U1 tip and the palatal plane (ANS - PNS)
U1 – PP (degrees)	Angle measured by the intersection of the long axis of U1 and palatal plane (ANS – PNS)
L6 – MP (mm)	The millimetric distance between the mesiobuccal cusp tip of the L6 and the mandibular plane (Go - Me)
L1- MP (mm)	The millimetric distance between L1 tip and the mandibular plane (Go – Me)
L1 – MP (degrees)	Angle measured by the intersection of the long axis of L1 and mandibular plane (Go – Me)
SN – MP	Angle measure by intersection of a line connected sella-nasion (SN) and a line connecting mandibular plane (Go-Me)

CHAPTER 3

RESULTS

An overall of 140 cases were initially identified and screened for inclusion. Data from 23 patients met the preselected criteria and were included in the study. Within the sample, 18 were females and 5 were males. The average pretreatment age of the sample was 38.5 years [standard deviation (SD) = 12.95]. The mean treatment time for the Invisalign patients was 1.7 years. The mean number of refinements was 2 +/- 2.

Intra-class correlation coefficients were calculated for intra-rater reliability and are presented in Table II. For intra-rater reliability, the ICC ranged from 0.86 to 0.99. An alpha error of 0.05 was used as the level of statistical significance for the analysis.

All pre-treatment (IN) and post-treatment (FN) values are presented in Table III, together with their means and SD's. The measurements depicting the differences between the means of the pre-treatment (IN) and post-treatment (FN) scores of each of the thirteen variables within the Invisalign group are presented in Table IV, together with the relevant P values and SD's, as well. Most of the pre-treatment (IN) to post-treatment (FN) differences showed to be significantly different during Invisalign therapy. These variables included the overbite (mean difference = +2.6mm), the lower anterior facial height (LAFH) (mean difference = - 0.62mm), the upper molar vertical position (U6-PP) (mean difference = -0.66mm), the lower molar vertical position (L6-MP) (mean difference = -0.68mm), the upper incisor vertical position (U1-PP) (mean difference = + 0.90mm), the upper incisor

inclination (U1-PP) (mean difference = -5.2°) , the lower incisor vertical position (L1-MP) (mean difference =+0.67mm), and the lower incisor inclination (L1-MP) (mean difference = -5.2°). The changes in the overjet (mean difference = + 0.26mm, P =0.50), SNA (mean difference = +0.02°, P =0.89), SNB (mean difference = + 0.02°, P = 0.91), ANB (mean difference = +0.02°, P = 0.92) and mandibular plane angle (mean difference = -0.01, P =0.95) did not reach statistical difference.

Table II. Intra-rater reliability.

Variable	ICC intra-rater
Overjet (mm)	0.86
Overbite (mm)	0.86
SNA (deg.)	0.99
SNB (deg.)	0.99
ANB (deg.)	0.99
LAFH (mm)	0.99
U6_PP (mm)	0.92
U1_PP (mm)	0.95
L1_MP (deg.)	0.86
L6_MP (mm)	0.99
L1_MP (mm)	0.99
U1_PP (deg.)	0.90
SN_MP (deg.)	0.99

Table III. Pre-treatment (IN) and post-treatment (FN) values.

	Pre-treatment (IN)		Post-treatment (FN)	
Variable	Mean	(SD)	Mean	SD
Overjet (mm)	2.55	(1.76)	2.81	(0.68)
Overbite (mm)	-1.63	(1.21)	1.02	(0.74)
SNA (deg.)	83.04	(6.01)	83.07	(5.92)
SNB (deg.)	79.72	(5.00)	79.74	(4.98)
ANB (deg.)	3.30	(3.45)	3.33	(3.64)
LAFH (mm)	69.19	(5.42)	68.56	(5.17)
U6_PP (mm)	23.70	(2.40)	23.03	(2.23)
U1_PP (mm)	28.41	(2.87)	29.31	(6.67)
L1_MP (deg.)	99.50	(9.99)	94.27	(9.06)
L6_MP (mm)	32.93	(4.04)	32.25	(3.89)
L1_MP (mm)	41.34	(4.42)	42.02	(4.60)
U1_PP (deg.)	118.29	(7.69)	113.02	(6.47)
SN_MP (deg.)	35.83	(7.28)	35.81	(7.34)

Table IV. Mean Difference.

	Post-treatment (FN) - Pre-treatment (IN) Mean Difference		
Variable	Mean	(SD)	P-value
Overjet (mm)	0.26	(1.83	(0.50)
Overbite (mm)	2.66	(1.19)	(<.0001)*
SNA (deg.)	0.02	(0.79)	(0.90)
SNB (deg.)	0.02	(0.71)	(0.91)
ANB (deg.)	0.02	(1.05)	(0.92)
LAFH (mm)	-0.63	(1.67)	(0.018)*
U6_PP (mm)	-0.66	(0.74)	(.0003)*
U1_PP (mm)	0.90	(0.89)	(<.0001)*
L1_MP (deg.)	-5.24	(5.24)	(<.0001)*
L6_MP (mm)	-0.69	(0.79)	(.0004)*
L1_MP (mm)	-0.68	(1.07)	(.0059)*
U1_PP (deg.)	-5.27	(5.22)	(<.0001)*
SN_MP (deg.)	-0.01	(1.17)	(0.96)

*denotes changes are significant at $p < 0.05$

CHAPTER 4

DISCUSSION

The current retrospective case-series study evaluated skeletal and dental changes in a group of non-growing anterior open bite patients treated with Invisalign. More specifically, this study attempted to quantify tooth movements and any skeletal effects of those tooth movements in correction of anterior open bites with the Invisalign system. The age amongst the participants of the group ranged from 19.5 to 59.8 years of age with a mean average of 38.5 years. From the 23 participants that were selected for this study, 18 (78%) were females and 5 (22%) were males. Previous studies had similar distribution of sex frequency in their sample sizes with females that underwent Invisalign treatment to surpass males [46,47]. In terms of treatment duration, our participants needed 0.8 to 2.4 years to complete treatment. During their Invisalign treatment, an average of 90 clear aligners were used for each treatment. The participants needed between 0 and 4 refinements (mean of 2.0). A refinement is an additional set of clear aligners made for the purpose of making small changes to tooth positions. Two similar studies reported mean treatment times of 14.04 months and 21 months [47,48]. The mean treatment time found in our study was 19.6 months. One of the possible reasons for the 5-month discrepancy in treatment time between our study and the one reported by Harris et al is the number of refinements. Their study reported a range of 0 to 3 refinements with a mean of 1 refinement [47]. No other studies have reported the number of refinements used. Fewer refinements may explain the decrease in

total number of aligners used as well as the decreased treatment time. A greater number of refinements found in our study could be related to overcorrection, and it could have altered the statistics. Other studies that looked at treatment of complex malocclusions with Invisalign have reported comparable treatment times. A retrospective study of sequential distalization of molars using Invisalign had an average treatment time of 22.8 months, while a case-report of a 4 first premolar extraction case treated with Invisalign found a 20.5 month treatment time [49,50]. These findings suggest correction of anterior open bites may be less challenging to treat than sequential distalization and 4 premolar extraction cases with Invisalign.

The differences in 13 pre-treatment (IN) and post-treatment (FN) cephalometric measurements were compared within the group (Table IV). The statistical analysis used to quantify the differences was a paired t-test. With regard to differences in pre-treatment (IN) and post-treatment (FN) outcomes within the group of participants, 8 out of 13 variables showed to be different; overbite (mean difference = +2.6mm), the lower anterior facial height (LAFH) (mean difference = - 0.62mm), the upper molar vertical position (U6-PP) (mean difference = -0.66mm), the lower molar vertical position (L6-PP) (mean difference = -0.68mm), the upper incisor vertical position (U1-PP) (mean difference = + 0.90mm), the upper incisor inclination (U1-PP) (mean difference = -5.2°) , the lower incisor vertical position (L1-MP) (mean difference =+0.67mm), and the lower incisor inclination (L1-MP) (mean difference = -5.2°).

In terms of anterior open-bite correction, our results indicated Invisalign treatment significantly deepened the bite. The severity of initial overbite in our study ranged from (-

2.84) to (-0.42) mm with a mean of (-1.63) mm. Our initial overbite values were greater than those reported by similar studies done by Harris et al. (-1.21mm) and Khosravi et al (-1.1mm) [47,51]. Harris et al. performed a retrospective case series study on 45 adult anterior open bite patients treated with Invisalign [47]. Similarly, Khosravi et al.'s study was a retrospective case control study evaluating Invisalign's ability to manage overbite in three groups; normal overbite (68) patients, deep bite (40 patients), and open bite (12) patients [51]. Our average pretreatment overbite was similar to that of Moshiri et al. and Garnett et al. who reported average initial overbites of (-1.8mm) and (-1.57mm), respectively [48,52] Like our study, Moshiri et al. designed a retrospective case-series study evaluating cephalometric changes in 30 adult anterior open bite patients treated with Invisalign [48]. Garnett et al was a retrospective case control study comparing cephalometric changes in adult anterior open bites patients treated with clear aligners (36) and fixed appliances (17) [52]. Our study showed an average of 2.7 mm overbite correction during treatment. In comparison to the two studies with similar initial open bite severity, our overbite change was more than the 2.28 mm reported by Garnett et al. and less than the 3.4 mm Moshiri et al [48,52]. The range of bite closure (1.3 - 3.27mm) was much greater in the two studies with less severe initial open bites [47,51]. Our study found the mean final overbite value to be (1.02 +/- 0.74) mm and ranged from 0.28 – 1.76 mm. According traditional orthodontic literature, an overbite of 0-2mm is considered normal[13]. On average, the patients' final overbite (1.02 mm) in our study was in the middle of this range. From the above, it is reasonable to assume Invisalign treatment can have a positive effect of anterior open bite correction, and can achieve what is considered a normal overbite.

Several studies have agreed, extrusion of the maxillary and mandibular incisors is one of many tooth movements critical to Invisalign's success in treating anterior open-bites [47,48,52]. On the contrary, one study concluded extrusion of the incisors (U1-PP =0.9mm, L1-PP 0.8 mm) was the primary mechanism by which correction was achieved [51]. Khosravi's study evaluated cephalometric changes in three groups of overbite patients treated with Invisalign. In the open bite group, comprised of 12 patients, overbite and L1-MP were the only statistically significant changes found [51]. Due to the small population size in Khosravi's open bite group, no strong conclusions can be made using this data. In our study, maxillary and mandibular incisors vertical position increased relative to palatal plane and mandibular plane (U1-PP +0.90 mm) and (L1-MP +0.68 mm) respectively. Both of these movements were beneficial for the correction of the open bite. These results were similar to those reported by others using palatal plane and mandibular plane as reference lines [48,51,52]. Those results ranged (0.5-0.97 mm) for U1-PP and (0.53-0.82 mm) for L1-MP [48,51,52]. The average pre-treatment (IN) vertical position of the maxillary incisor (U1-PP mm) for our sample was 28.41 +/- 2.47 mm. U1-PP mm norms, determined by Burstone, are 27.5 +/- 1.7 mm and 30.5 +/- 2.1 mm for females and males respectively [53]. Our study was comprised of 78% females. With this in mind, the mean initial U1-PP mm should be closer to the average female norm which ours was. This suggests a normal distance of U1-PP at pre-treatment (IN). The average post-treatment (FN) U1-PP value was 29.31 +/- 6.67 mm. This would suggest an increased vertical position (U1-PP) for females, but our population was not all females and can be considered a normal value for our population. L1-MP norms are 40.8+/-1.8 and 45 +/-2.1 mm for females and males respectively [53]. In our study, the mean pre-treatment (IN) L1-MP value was 41.34 +/- 4.42. This initial value

is within the normal range and is what we would expect with a sample comprised largely of females. We reported a mean post-treatment (FN) L1-MP value of 42.02 +/- 4.60 mm, which is within the normal range. While our data suggests incisor extrusion to be beneficial for open-bite correction, it is not the only tooth movement involved in bite closure with clear aligners. Mechanically, it is very difficult to move teeth vertically without tipping them forward or backward, and therefore, it is important to measure the change in inclination of the maxillary and mandibular incisor.

Changing the inclination, or tipping, of maxillary and mandibular incisors can bring the incisal edges closer together or farther away depending on the direction of movement. When treating an anterior open bite, it may be beneficial to upright the incisors. Uprighting, or more appropriately termed retroclining, brings the edges of the teeth closer together and effectively deepens the bite. Two studies have reported retroclination of the maxillary and mandibular incisors in anterior open bite correction with clear aligners [47,52]. In these studies, retroclination of the maxillary incisor (U1-PP°) ranged from 4.76 - 10.91°, while retroclination of the mandibular incisor (L1-MP°) ranged from 3.73 – 5.75°. The results of our study demonstrated that the maxillary (U1-PP°) and mandibular incisor (L1-MP°) retroclined 5.27 and 5.24° respectively. Each of these values were a statistically significant difference. According to Burstone, the normal upper incisor inclincation (U1-PP°) is 112 +/- 5.30° and 110 +/- 4.30° for females and males respectively [53]. The subjects in our study had an initial U1-PP value of 118.49 +/- 7.69°. This value is more than 1 standard deviation above the norm and suggest the initial inclination of the upper incisor was proclined, or increased, prior to treatment. The mean post-treatment (PN) U1-PP

inclination in our study was 113.02 +/- 6.47°. This value falls within an acceptable range for U1-PP inclination. Lower incisor to mandibular plane norms for males and females is 95.9 +/- 5.2° [53]. The mean initial L1-MP° in our study was 99.50 +/- 9.99°. Despite our study's initial L1-MP° value falling within 1 standard deviation of Burstone's norm, it suggests a tendency for a proclined lower incisor prior to treatment. Our report found a post-treatment (FN) L1-MP inclination of 94.27 +/- 9.06°. Initial values for incisor inclination (U1-PP and L1-PP°) show definitive a dento-alveolar problem. The post-treatment (PN) values for these two measurements are very close to the ideal norms. Therefore, our results suggest retroclination of the upper and lower incisors can be accomplished effectively with Invisalign.

Controlling the vertical dimension when correcting anterior open bites in adult non-growing patients with hyperdivergent growth patterns is critical to achieving a successful treatment outcome [54]. Traditional fixed appliances have the tendency to extrude posterior teeth. Extrusion of posterior teeth can create a larger anterior open-bite and may require more anterior extrusion to obtain positive overlap of the incisors [55]. Therefore, it is imperative when treating an anterior bite, whether skeletal or dental, to intrude, or at a minimum maintain, the maxillary and mandibular molars in the vertical dimension. Our study found significant molar intrusion was achieved [(U6-PP) and (L6-MP)] during treatment and contributed to a counter clockwise rotation of the mandible and decrease in the lower anterior facial height (LAFH). Vertical position of the maxillary 1st molar decreased (U6-PP) by 0.66 mm and the mandibular 1st molar (L6-MP) 0.69 mm. These

findings indicate aligner therapy can successfully maintain and, in fact, reduce the skeletal and dental vertical dimension.

Our findings may be the result of the "bite block" effect attributed to the increased vertical dimension created by the thickness of the aligners coupled with consistent biting force produced by the patient. Our findings agree with two similar retrospective studies evaluating the mechanism by which clear aligners close anterior open bites. These studies reported significant intrusion of the 1st molars ranging from 0.4 – 0.47 mm and 0.39 – 0.60 mm in the maxilla and mandible [47,48]. Approximately, one third of the patients in Harris et al. study had planned molar intrusion. Interestingly, the authors observed more intrusion in the patients who had molar intrusion planned than those who did not, but the difference was not statistically significant [47]. This result suggests clear aligner therapy has a bite deepening effect on all patients. In our study, 17 of 23 patients had molar intrusion of 1 mm or more planned in their virtual prediction and could be a reason we observed more molar intrusion than the aforementioned studies. 6 patients did not have intrusion planned in their virtual setup. We did not compare patients with planned molar intrusion to those without due to the small number of patients with no intrusion planned, but in 5 of the 6 patients who did not have intrusion planned, intrusion was observed. This finding indicates clearly aligners may have an inherent "bite block" effect. However, the findings in our study and Harris et al. contradict what Moshiri et al. reported. Their study reported posterior intrusion with aligners had to be planned in the virtual setup, but the author presented no evidence to support this claim nor was it explicitly stated whether all patients

in his study had molar intrusion planned [48]. More research with larger sample sizes is required to make this determination.

Little research measuring the accuracy (percent achieved vs. percent planned) of molar intrusion using clear aligners exist. One study reported 1st molar intrusion to be 35.1% accurate in the maxilla and 41.2% in the mandible [56]. Interestingly, 2nd molar intrusion was more accurate (50.3% and 51.3%) [56]. This study consisted of 38 patients and there was no mention of any patient having an anterior open bite. More research needs to be done in order to quantify the amount of molar intrusion one can predictably achieve using Invisalign. Additionally, verification of molar intrusion accuracy would be a beneficial tool for the clinician when treatment planning more complex cases with Invisalign.

The lower anterior facial height (LAFH) demonstrated a significant decrease of 0.63 mm. This value indicates significant maxillary and mandibular molar intrusion leading to a shortening of the lower anterior facial height and correction of the open bite malocclusion. The average post-treatment (FN) LAFH reported was 68.56 +/- 5.17 mm. McNamara determined LAFH was directly correlated to midfacial length [44]. Our study did not report this length. Therefore, it is not possible to compare the LAFH to that of a norm. Despite a statistically significant decrease of 0.63mm in LAFH, this is likely of little clinical significance. An additional indicator for Invisalign's ability to have a true skeletal effect is SN-MP angle. Our study found a 0.01 degree decrease in this angle as a result of treatment and was not statistically significant. These results indicate if a patient desires not only dental change but facial change, surgery should be the preferred treatment option.

In addition to the mandibular plane angle (SN-MP), four more values did not change significantly, post treatment: ANB, SNA and SNB angles and the overjet (OJ). The first three angles indicate an anterior posterior relationship of the jaws to the cranial base and the jaws to each other. Our study was conducted on adult patients with an average age of 38.59 years. We did not expect the maxilla, and therefore A point and subsequently SNA, to move in the anterior-posterior (AP) dimension pre-treatment (IN) to post-treatment (FN) because our population was comprised of adult non-growing patients. The same logic can be applied to SNB and ANB, except with a substantial decrease in the vertical dimension a forward rotation of the mandible could increase the SNB angle and change the ANB angle. Although we reported a statistically significant decrease in lower anterior facial height, it was not enough to significantly change the AP position of B point. Hence, we reported no statistically significant change in SNA, SNB, and ANB. Additionally, overjet (OJ) did not significantly change. This value increased 0.26mm post-treatment. Normal overjet is considered to be 2-3 mm [13]. Both the initial and final mean overjet values (2.55 mm and 2.81 mm) fall within the normal range and therefore we would not expect to see a significant decrease in this value.

CHAPTER 5

CONCLUSION

1. Invisalign system is an effective treatment modality for non-growing anterior open bite patients.
2. Anterior open bite closure with Invisalign aligners occurred due to a combination of tooth movements: maxillary and mandibular incisor extrusion, maxillary and mandibular incisor retroclination, and maxillary and mandibular molar intrusion, leading to a decreased lower anterior facial height and a counter clockwise rotation of the mandible. The null hypothesis was rejected.
3. The Invisalign system is effective in reducing and controlling the vertical dimension in anterior open bite patients but does not seem to change the skeletal face significantly.
4. Further studies are necessary to corroborate our findings.
5. Long-term evaluation of these cases should be continued to assess the stability of correction.

CHAPER 6

LIMITATIONS

The sample size of this study was small and retrospective in nature; there were 23 patients. This study also lacks a control group. Therefore, the results should be interpreted with caution. This limited sample size also means that our study's results may not be generalizable to the populations; studies with larger sample sizes may include individuals with more severe open bites. Thus, this study may better serve as a preliminary insight for higher powered studies in the future.

Furthermore, approximately 78% of the patients were female and 22% were male. In addition, our study did not exhibit an even distribution of race and ethnicities. In order to avoid possible confounders, future studies should strive to include an equal gender, race and ethnicity distribution in the participant pool.

While all participants started treatment with an anterior open bite, there was a distribution in severity. For this reason, the amount of open bite correction necessary to achieve a successful result varied from subject to subject. In addition, treatment compliance is not an absolute measurement and is difficult to measure.

Despite a general protocol being used for all cases, each malocclusion was uniquely treatment planned based upon the patient specific details. Therefore, features prescribed in each patient's virtual prediction varied.

A cephalogram is a 2-dimensional radiograph of a 3-dimensional space. For this reason, cephalometric analysis may be limiting. A 3-dimensional measurement taken from a CBCT could be more accurate.

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APPENDIX

IRB 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

NHSR DETERMINATION

TO: Icenhour, Logan Garrett

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-300006639
Effectiveness of maxillary molar intrusion with the Invisalign system for correction of anterior open bite

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The Office of the IRB has reviewed your Application for Not Human Subjects Research Designation for the above referenced project.

The reviewer has determined this project is not subject to FDA regulations and is not Human Subjects Research. Note that any changes to the project should be resubmitted to the Office of the IRB for determination.

if you have questions or concerns, please contact the Office of the IRB at 205-934-3789.

Additional Comments:

Coded data from a non-research source, documentation that source will not release the code