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School of Dentistry  
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This is to certify that the thesis prepared by J. Ryan Redford, D.D.S., entitled Mandibular Incisor Proclination Variability During Class II Correction has been approved by his committee as satisfactory completion of the thesis requirement for the degree of Master of Science in Dentistry.

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## **Mandibular Incisor Proclination Variability During Class II Correction**

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science  
in Dentistry at Virginia Commonwealth University.

By

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## Abstract

### **MANDIBULAR INCISOR PROCLINATION VARIABILITY DURING CLASS II CORRECTION**

By J. Ryan Redford, D.D.S.

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University.

Virginia Commonwealth University, 2014

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#### **Background**

Lower incisor proclination has been shown to increase during Class II correction with appliances such as the Forsus. This lower incisor flaring shows great variability among patients. The purpose of this study was to evaluate the effects of Class II severity, mandibular growth, and occlusal plane rotation on lower incisor flaring in patients treated with the Forsus appliance.

#### **Materials and Methods**

121 records of Class II patients treated with the Forsus appliance were analyzed retrospectively. Cephalograms were traced at three time points. ANOVA was used to compare changes in cephalometric measurements over time. Pearson's correlation was used to test for relationships between variables. Multiple regression tested for correlation between multiple variables.

#### **Results/Conclusions**

Lower incisor flaring during Class II correction with the Forsus appliance was only weakly associated with sex, molar relationship change, and occlusal plane steepening. There was no correlation between the change in lower incisor proclination and mandibular growth.

## Introduction

Class II malocclusion is a frequently encountered presentation among orthodontic patients.<sup>1</sup> Historically, a number of techniques and appliances have been used to treat Class II malocclusions effectively. These treatment modalities have evolved over time. In contemporary orthodontics, an unprecedented number of options are at the orthodontist's disposal.<sup>2</sup> Treatment modalities are chosen on a case-by-case basis with consideration of skeletal, dental, and soft tissue factors. These treatment options include but are not limited to: cervical- or high-pull headgear, bonded or removable functional appliances, interarch elastics used in conjunction with traditional full fixed appliances or aligner therapy, distalizing appliances, extraction therapy, and orthognathic surgery.

Some Class II correction modalities require patient compliance, while others do not. Class II elastics are one example of a traditional Class II correction technique which requires patient cooperation. Patients are instructed on insertion and removal of elastics and instructed to wear the elastics for a certain amount of time per day. Predicting whether and to what degree a patient will be compliant with elastic wear can be difficult.<sup>3-5</sup> Poor compliance can be a source of frustration for practitioners and patients as it can lead to poor results and increased treatment time.<sup>6</sup>

The Forsus appliance from 3M Unitek (Monrovia, CA) is an example of a compliance-free Class II correction device.<sup>7</sup> It consists of a telescoping rod in conjunction with a stainless steel coil spring that comes pre-fabricated and is easily assembled chairside by the treating practitioner.<sup>8</sup> The Forsus appliance is attached to intraoral full-fixed appliances at the maxillary first molar headgear tube and at the mandibular archwire, either mesial or distal to the first

premolar bracket. Once fixed in the mouth by the orthodontist, the Forsus appliance can be left intraorally for extended periods and it will continue to apply force to the teeth during that time. Up to 200 grams of force can be applied. The mechanism of Class II correction with the Forsus appliance has been shown in previous studies to be similar to Class II elastics.<sup>9</sup>

During orthodontic Class II correction with either functional appliances or interarch elastics, the mandibular dentition is moved anteriorly in relation to the maxillary dentition. This anterior movement of the lower dentition is accompanied by increased proclination of the mandibular incisors.<sup>9,10</sup> The degree of incisor proclination is commonly evaluated on a lateral cephalogram as an angular measurement between the mandibular plane and the long axis of the mandibular incisor. Flaring of the lower incisors from the beginning of Class II correction to the end of active treatment has been shown in patients treated with functional appliances or with other interarch mechanics. The magnitude of change in proclination within groups of treated patients has been variable, however, with large standard deviations reported. For example, Schaefer et al found  $3.8 \pm 6.8^\circ$  of lower incisor flaring with the Herbst appliance and  $4.5 \pm 6.0^\circ$  with the Twin-Block.<sup>11</sup> Ghislanzoni et al documented  $5.5 \pm 7.2^\circ$  of increased lower incisor proclination during Class II treatment with the Mandibular Advancement Repositioning Appliance (MARA).<sup>12</sup> Shoff found  $4.58 \pm 4.92^\circ$  of flaring with the Forsus appliance.<sup>13</sup>

The amount of flaring of lower incisors during Class II correction may be affected by several different factors. Three of these are: the amount of molar relationship change during treatment, the amount of mandibular growth during treatment, and the amount of occlusal plane rotation resulting from the biomechanical effects of Class II correction.

The severity of each individual's Class II malocclusion is unique. The NHANES III found that 38.8% of the U.S. population showed a mild Class II dental discrepancy with 3-4 mm

of overjet, while 10.7% of the population exhibited a moderate Class II dental discrepancy of 5-6 mm. Only 4.1% of the population presented with severe discrepancies of greater than 7 mm.<sup>1</sup> It can be inferred that correction of a more severe Class II relationship will result in greater treatment side effects such as incisor proclination and occlusal plane rotation.

The amount of mandibular growth during Class II correction is different among patients. Some patients have completed much of their forward and downward mandibular growth when Class II correction commences, while others have more potential for future growth. Previous studies have shown that the ideal timing for Class II orthopedic treatment is during the circumpubertal growth period.<sup>14,15</sup> The acceleration of mandibular growth that occurs during this time helps to resolve skeletal Class II discrepancies. Growth of the mandible is easily assessed by measurements taken on serial cephalometric radiographs.<sup>16</sup> In addition to measuring the amount of mandibular growth, there are methods to classify the stage of mandibular growth based on the morphology of the cervical vertebrae captured in a cephalogram.<sup>17,18</sup> These methods are useful in helping a practitioner time the Class II orthopedic treatment to coincide with the peak mandibular growth spurt.

The occlusal plane rotates in a clockwise direction during Class II correction with interarch elastics or functional appliances. Clockwise rotation of the occlusal plane has been shown to help a Class II dental occlusion approach a Class I relationship.<sup>19</sup> Braun and Legan showed that an end-on Class II relationship would result in a Class I occlusion when 7.2° of clockwise occlusal plane rotation occurs. This steepening of the occlusal plane has been shown in previous studies to occur within groups of patients treated with the Forsus appliance; these studies also document large standard deviations among patients.<sup>13,20</sup>

The variability in lower incisor proclination occurring during Class II correction has been well documented in the literature. More information is needed as to why this large variability exists. The present study was designed to evaluate the effects of molar relationship change, mandibular growth, and occlusal plane rotation on lower incisor flaring with the Forsus appliance. Specifically, the purpose was to evaluate the degree to which each variable affects the increase in mandibular incisor proclination.

## Materials and Methods

### **Patients and Study Design**

Before beginning the study, approval was obtained from the Institutional Review Board of Virginia Commonwealth University's Research Office. A total of 128 records were obtained from the office of Lisa Alvetro in Sidney, Ohio. These 128 records were of consecutively treated patients using the Forsus appliance for Class II correction. Inclusion criteria were: patients treated without extractions or orthognathic surgery, pre-treatment dental malocclusion of end-on Class II at least unilaterally, and radiographs of good diagnostic quality. Patients were between the ages of nine and 16 years at the beginning of treatment. After applying the inclusion criteria, seven subjects were eliminated from the study. Six of the excluded subjects had extraction therapy as part of their treatment, while one patient had poor quality radiographs.

Patients were treated orthodontically using Smartclip brackets from 3M Unitek (Monrovia, CA), with a .022 x .028" slot and a standard MBT prescription. Permanent first upper and lower molars were banded, while premolars, canines, and incisors were bonded with brackets. Before Forsus placement, each patient's dentition was leveled and aligned. Once leveling and alignment was complete, a .019" x .025" TMA arch wire was used in the mandibular arch during Class II correction. Maxillary archwires were variable from patient to patient according to individual torque needs. Class II correction was initiated by attaching the Forsus appliance intraorally. The appliance extended from the headgear tubes on the maxillary first molars to the mandibular archwire just distal to the mandibular first premolars. In 82 of the patients, the maxillary molar band headgear tube was attached near the gingival portion of the tooth, with the remaining 39 patients' tube being located at the more standard occlusal portion of the band.

The Forsus appliance was activated at the placement appointment and reactivated at each recall appointment as needed. Forsus appliances were used in each patient until correction or slight overcorrection of the occlusion was achieved. Each patient was treated to a Class I occlusion. Overcorrection of the occlusion is commonly achieved to allow for slight amounts of natural relapse of the teeth back toward their original position. The mean amount of time from Forsus placement until Forsus removal was  $5.9 \pm 2.4$  months.

Lateral cephalometric radiographs were taken at four timepoints: pre-treatment (T0), pre-Forsus appliance insertion (T1), post-Forsus appliance removal (T2), and post-treatment (T3). The cephalograms for each patient at the first three timepoints were traced using Dolphin Imaging 11.7 Software (Chatsworth, CA) by the same investigator (JRR). All bilateral structures that were detected and traced were bisected. The author was blinded to which patient was which, but could not be blinded to specific timepoints due to the presence of radiopaque fixed appliances such as bands and brackets. Any cephalometric landmarks in question were reviewed by another author (SJL) and discussed until both authors agreed upon a consensus position for the landmark. A random sample of 10 cephalograms were selected and retraced to test for the validity and reproducibility of the tracings approximately two months after the original tracings. Landmarks and their definitions are described in Table 1.

### **Cephalometric Analysis**

T0, T1, and T2 lateral cephalometric radiographs were traced to measure dental and skeletal characteristics at each stage of treatment. T0 tracings were used to evaluate pretreatment dental and skeletal relationships. T1 and T2 tracings were used to evaluate each patient's dental and skeletal characteristics at the beginning and end of Class II correction with the Forsus

appliance. Changes between timepoints were calculated. 17 skeletal and dental measurements were included in the cephalometric analysis. The nine linear and eight angular measurements are shown in Table 2. Skeletal measurements were made relative to a horizontal reference plane (SN-7°) and a vertical reference plane running perpendicular to the horizontal plane through Sella.<sup>21</sup> Occlusal plane changes were measured relative to the same horizontal reference plane described above. Mandibular and maxillary molar changes were measured along the functional occlusal plane (FOP). These planes are shown in Figure 1.

In addition to analyzing the craniofacial skeletal and dental components, cervical vertebral maturation (CVM) was recorded at T0, T1, and T2 for each patient according to the method described by Baccetti et al.<sup>17</sup> The CVM method is helpful in classifying maturational stages. Treatment timing decisions can then be made to coincide with the peak mandibular growth rate.

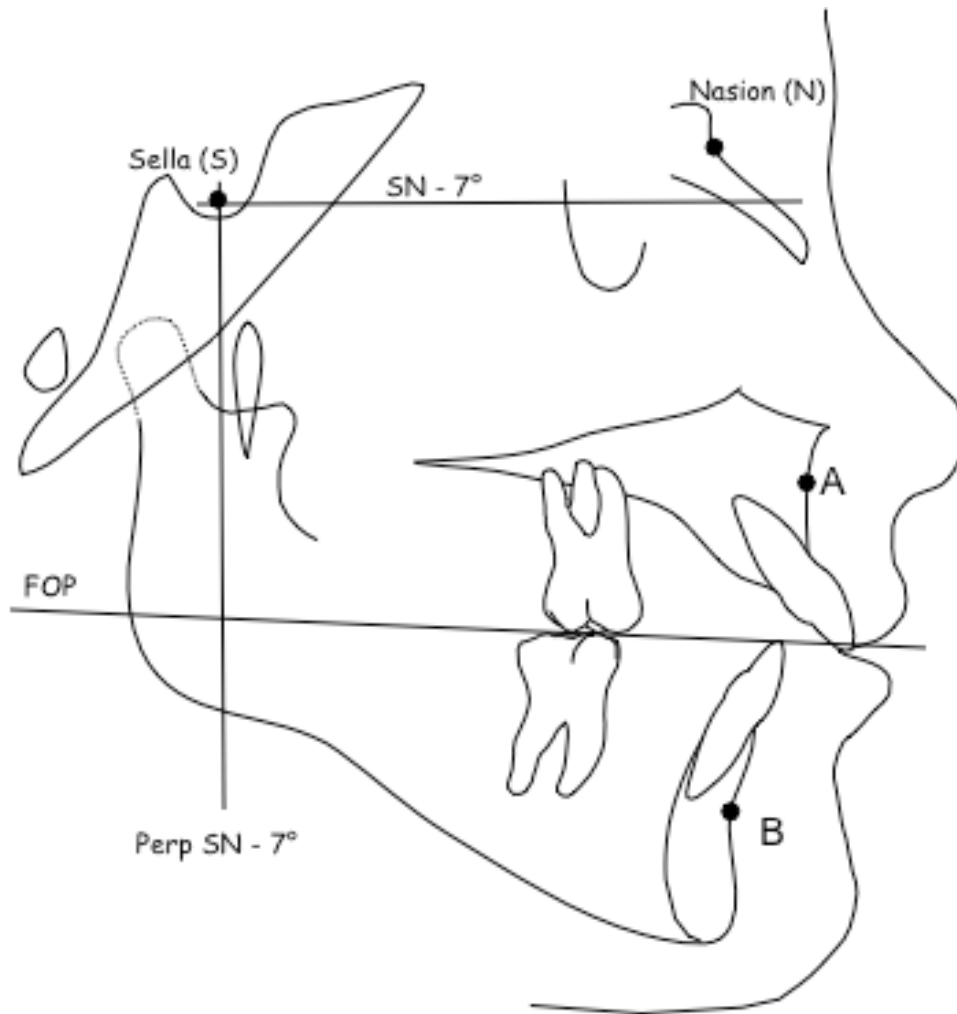


**Table 1. Cephalometric Landmarks and Definitions**

| Landmark              | Abbreviation | Definition  |
|-----------------------|--------------|---|
| A point               | A            | Deepest point on the curve of the maxilla, between anterior nasal spine and dental alveolus |
| Anterior nasal spine  | ANS          | Tip of the anterior nasal spine   |
| B point               | B            | Most posterior point in the concavity along the anterior border of the symphysis            |
| Distal U6             |              | Most distal surface of the maxillary first molar  |
| Distal L6             |              | Most distal surface of the mandibular first molar   |
| Mesial U6             |              | Most mesial surface of the maxillary first molar  |
| Mesial L6             |              | Most mesial surface of the mandibular first molar   |
| Gonion                | Go           | Most convex point where the posterior and inferior curves of the ramus meet                 |
| Horizontal Plane      | HP           | Sella to Nasion line minus 7°   |
| Lower first molar     | L6           | Mesial buccal cusp tip of the mandibular molar  |
| Lower first premolar  | L4           | Buccal cusp tip of the lower first bicuspid   |
| Lower incisor apex    |              | Root apex of the lower central incisor  |
| Lower incisor tip     | L1           | Tip of the lower central incisor  |
| Menton                | Me           | Most inferior point of the mandibular symphysis   |
| Nasion                | N            | Intersection of the internasal suture with the nasofrontal suture in the midsagittal plane  |
| Pogonion              | Pg           | Most anterior point of the mid-sagittal symphysis   |
| Posterior nasal spine | PNS          | Tip of the posterior nasal spine  |
| Sella                 | S            | Center of the pituitary fossa of the sphenoid bone  |
| Upper first molar     | U6           | Mesial buccal cusp tip of the maxillary molar   |
| Upper first premolar  | U4           | Buccal cusp tip of the upper first bicuspid   |
| Upper incisor apex    |              | Root apex of the upper central incisor  |
| Upper incisor tip     | U1           | Tip of the upper incisor  |

**Table 2. Cephalometric Measurements and Definitions**

| Measurement | Description   |
|-------------|---|
| SNA         | Angle formed by lines S-N and N-A   |
| SNB         | Angle formed by lines S-N and N-B   |
| ANB         | Angle formed by lines A-N and N-B   |
| Convexity   | Angle formed by lines N-A and A-Pg  |
| A Horiz     | Horizontal distance of A point from line through Sella perpendicular to HP              |
| A Vert      | Vertical distance of A point from HP  |
| B Horiz     | Horizontal distance of B point from line through Sella perpendicular to HP              |
| B Vert      | Vertical distance of B point from HP  |
| B Distance  | Distance of B point from intersection of HP and line through Sella perpendicular to HP  |
| Pg Horiz    | Horizontal distance of Pogonion from line through Sella perpendicular to HP             |
| Pg Vert     | Vertical distance of Pogonion from HP   |
| Pg Distance | Distance of Pogonion from intersection of HP and line through Sella perpendicular to HP |
| FOP-HP      | Angle formed by the lines of the FOP and HP   |
| U1-SN       | Angle formed by the lines of upper incisor apex-upper incisor tip and S-N               |
| U1-HP       | Angle formed by the lines of upper incisor apex-upper incisor tip and HP                |
| IMPA        | Angle formed by the lines of the upper incisor apex-upper incisor tip and Go-Me         |
| Molar Rel   | Linear distance from the mesial surface of U6 to the mesial surface of L6 along the FOP |



**Figure 1. Reference Planes Used in Cephalometric Analysis**

## Statistical Methods

Mean values were calculated for each of the obtained skeletal and dental cephalometric values. Repeated-measures mixed-model ANOVA was used to compare the mean values of these measurements across the three time points and to verify changes during treatment. Relationships between two variables were tested using Pearson's product moment correlation. Specifically, the relationship between the change in IMPA and the changes in mandibular growth, molar relationship, and occlusal plane steepness were analyzed. Multiple regression was then used to test for relationships between the change in proclination of the lower incisors during Forsus activation and pre-selected variables, including the three mentioned above. All statistical tests were accomplished using SAS software (JMP pro version 10, SAS version 9.3, SAS Institute Inc., Cary NC). Statistical significance was declared using a 5% significance level.

For  $n = 121$  subjects, this study was designed to have power  $> 95\%$  to detect a correlation as large as  $r = 0.3$ .

## Results

### Measurement Error

To ensure reliability of digital tracings, ten radiographs were selected randomly and retraced two months after the original tracing. Measurement error was evaluated with intraclass correlations between the repeated measurements. The intraclass correlation between the repeated measurements can be seen in Table 3 along with values for the maximum difference and the median absolute deviation.

**Table 3. Measurement Error**

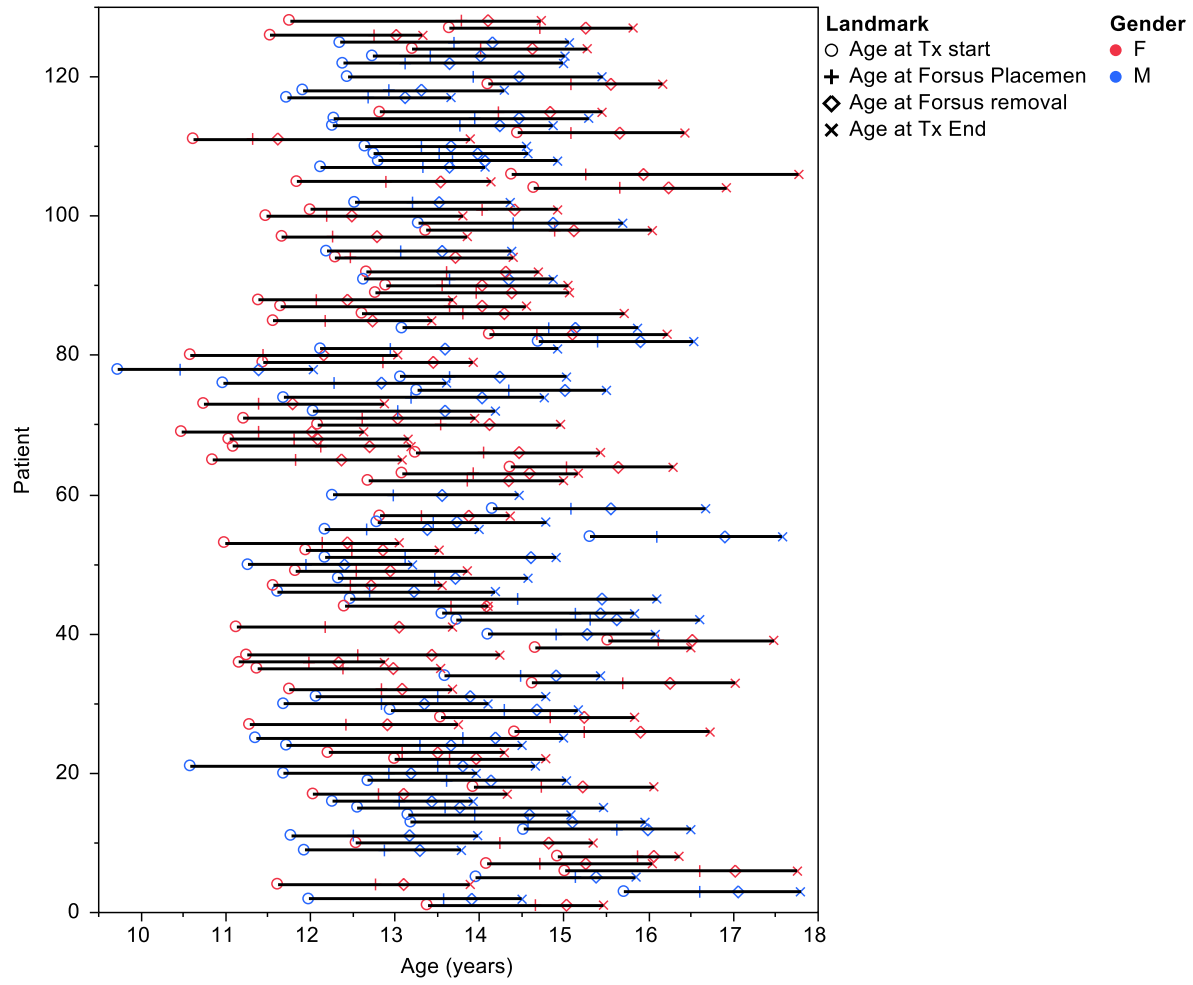
| Measurement             | ICC   | Maximum Difference | Median Absolute Deviation |
|-------------------------|-------|--------------------|---------------------------|
| SNA (°)                 | 0.984 | 1.5                | 0.25                      |
| SNB (°)                 | 0.986 | 1.3                | 0.25                      |
| ANB (°)                 | 0.945 | 1.4                | 0.20                      |
| Convexity (NA-A-Pg) (°) | 0.954 | 3.7                | 0.60                      |
| A Horiz (mm)            | 0.983 | 1.6                | 0.65                      |
| A Vert (mm)             | 0.954 | 1.8                | 0.85                      |
| B Horiz (mm)            | 0.988 | 1.8                | 0.45                      |
| B Vert (mm)             | 0.998 | 0.7                | 0.25                      |
| B distance (mm)         | 0.994 | 1.5                | 0.32                      |
| Pg Horiz (mm)           | 0.975 | 2.6                | 1.15                      |
| Pg Vert (mm)            | 0.974 | 1.7                | 1.05                      |
| Pg Distance (mm)        | 0.964 | 1.8                | 0.83                      |
| FOP-HP (°)              | 0.955 | 2.4                | 1.55                      |
| U1-SN (°)               | 0.971 | 3.1                | 1.15                      |
| U1-HP (°)               | 0.967 | 3.1                | 1.00                      |
| IMPA (°)                | 0.965 | 5.3                | 2.30                      |
| Molar Rel (mm)          | 0.962 | 1.2                | 0.45                      |

## Description of Patients

A total of 121 patients met the inclusion criteria and were included in the final analysis. The mean age of patients at the start of treatment was  $12.55 \pm 1.21$  years with a range of 9.7 – 15.7 years. The mean patient age at Forsus placement was  $13.59 \pm 1.20$  years with a range of 10.5 – 16.6 years. Patients had the Forsus appliance in place for an average of  $5.90 \pm 2.37$  months. The mean total treatment time was  $27.82 \pm 5.46$  months. Ages at the four time points are shown in Table 4. The time points and course of treatment for each patient can be visualized in Figure 2. Treatment duration and length of time between time points are shown in Table 5. The averages of the 17 measurements at T0, T1, and T2 are shown in Table 6.

**Table 4. Patient Demographics**

| Time point            | Mean      | SD   | Range |      |
|-----------------------|-----------|------|-------|------|
|                       | Age (yrs) |      |       |      |
| Treatment start (T0)  | 12.55     | 1.21 | 9.7   | 15.7 |
| Forsus placement (T1) | 13.59     | 1.20 | 10.5  | 16.6 |
| Forsus removal (T2)   | 14.08     | 1.20 | 11.4  | 17.1 |
| Treatment end (T3)    | 14.87     | 1.19 | 12.0  | 17.8 |



**Figure 2. Time Course of Each Patient**

**Table 5. Treatment Times**

| Duration                                       | Mean  | SD   | Range  |      |
|--|-------|------|--------|------|
|  |       |      | Months |      |
| Total treatment time (T0 to T3)                | 27.82 | 5.46 | 17.3   | 48.9 |
| Treatment start to Forsus placement (T0 to T1) | 12.70 | 5.00 | 2.2    | 35.0 |
| Forsus placement to removal (T1 to T2)         | 5.90  | 2.37 | 2.1    | 17.9 |
| Forsus placement to Treatment end (T1 to T3)   | 15.17 | 3.97 | 5.3    | 30.8 |

**Table 6. Average Measurements at the Three Time Points**

| Measurement             | T0     | T1     | T2     |
|-------------------------|--------|--------|--------|
| SNA (°)                 | 80.89  | 80.83  | 80.66  |
| SNB (°)                 | 75.69  | 76.04  | 76.70  |
| ANB (°)                 | 5.20   | 4.79   | 3.96   |
| Convexity (NA-A-Pg) (°) | 9.33   | 8.18   | 6.49   |
| A Horiz (mm)            | 64.50  | 65.02  | 65.44  |
| A Vert (mm)             | 47.37  | 48.80  | 49.98  |
| B Horiz (mm)            | 55.65  | 56.56  | 57.92  |
| B Vert (mm)             | 76.74  | 78.85  | 81.14  |
| B distance (mm)         | 94.95  | 97.18  | 99.86  |
| Pg Horiz (mm)           | 55.50  | 56.63  | 58.24  |
| Pg Vert (mm)            | 91.64  | 94.56  | 96.00  |
| Pg Distance (mm)        | 107.32 | 110.41 | 112.50 |
| FOP-HP (°)              | 11.15  | 9.33   | 12.17  |
| U1-SN (°)               | 101.93 | 106.49 | 102.75 |
| U1-HP (°)               | 108.93 | 113.49 | 109.75 |
| IMPA (°)                | 96.42  | 98.76  | 104.55 |
| Molar Rel (mm)          | -1.33  | -1.89  | 1.86   |



## Analysis of change over time

The goal of this study was to evaluate factors influencing the change in lower incisor inclination during Class II mechanics with the Forsus appliance. Specifically, IMPA change from T1-T2 was calculated. Three factors were hypothesized to affect the amount of lower incisor flaring: severity of the molar sagittal malocclusion, mandibular growth, and occlusal plane rotation. The severity of the Class II malocclusion was measured as “Molar Rel”. Mandibular growth was measured at B point as the horizontal and vertical components and the vector “B distance”. “B Horiz” and “B Vert” are the two components comprising “B distance”. The functional occlusal plane angulation was measured relative to the horizontal reference plane (SN-7°) and labeled as “FOP-HP”. Mean changes in recorded measurements across time can be found in Table 7.

**Table 7. Average Change Between Time Points**

| Measurement             | T0 to T1 | T0 to T2 | T1 to T2 |
|-------------------------|----------|----------|----------|
| SNA (°)                 | -0.052   | -0.230   | -0.178   |
| SNB (°)                 | 0.357    | 1.011    | 0.655    |
| ANB (°)                 | -0.412   | -1.238   | -0.826   |
| Convexity (NA-A-Pg) (°) | -1.155   | -2.838   | -1.683   |
| A Horiz (mm)            | 0.523    | 0.949    | 0.427    |
| A Vert (mm)             | 1.429    | 2.606    | 1.178    |
| B Horiz (mm)            | 0.911    | 2.273    | 1.362    |
| B Vert (mm)             | 2.106    | 4.397    | 2.292    |
| B distance (mm)         | 2.236    | 4.916    | 2.680    |
| Pg Horiz (mm)           | 1.128    | 2.734    | 1.606    |
| Pg Vert (mm)            | 2.923    | 4.365    | 1.441    |
| Pg Distance (mm)        | 3.091    | 5.183    | 2.092    |
| FOP-HP (°)              | -1.818   | 1.030    | 2.848    |
| U1-SN (°)               | 4.561    | 0.815    | -3.746   |
| U1-HP (°)               | 4.561    | 0.815    | -3.746   |
| IMPA (°)                | 2.339    | 8.135    | 5.796    |
| Molar Rel (mm)          | -0.555   | 3.196    | 3.752    |

At the start of treatment (T0), there were no differences in IMPA due to gender or age ( $P > 0.7$ ). The mean IMPA at T0 was  $96.42^\circ$ , with a range of  $81.3 - 111.1^\circ$  and a median value of  $96.7^\circ$ . Table 8 shows IMPA values at each time point and the changes in IMPA between time points. The mean change in IMPA while the Forsus was in place was  $5.80^\circ$ . This change was statistically significant.

**Table 8. IMPA Changes ( $^\circ$ ) Between Time Points**

| Time   | Min.  | 25%tile | Median | 75%tile | Max   | Mean   | SD    | 95% CI |        | P-value* |
|--------|-------|---------|--------|---------|-------|--------|-------|--------|--------|----------|
| 0      | 81.3  | 91.3    | 96.7   | 100.9   | 111.1 | 96.42  | 6.975 | 95.15  | 97.69  |          |
| 0 to 1 | -10.6 | -1.5    | 2.3    | 6.2     | 18.6  | 2.34   | 5.734 | 1.09   | 3.59   | <.0001   |
| 1      | 84.5  | 95.4    | 99.1   | 102.7   | 114.8 | 98.76  | 6.209 | 97.62  | 99.89  |          |
| 1 to 2 | -4.8  | 3.3     | 5.8    | 8.7     | 18.0  | 5.80   | 3.845 | 4.96   | 6.64   | <.0001   |
| 2      | 86.3  | 100.6   | 104.7  | 108.7   | 125.0 | 104.55 | 6.388 | 103.39 | 105.72 |          |

\* IMPA significantly increased at each timepoint ( $p < 0.0001$ )

The degree of the Class II relationship was measured along the functional occlusal plane as the distance between the mesial surface of the U6 and L6 (Molar Rel). A negative value indicated molars with a more severe Class II presentation than end-on. A positive value indicated the molar relationship being more Class I than end-on. At the start of treatment, there were no differences in molar relationship due to gender or age ( $P > 0.9$ ). Table 9 shows molar relationship values at each time point as well as differences between values at the three time points. At T0, the mean molar relationship was  $-1.33$  mm. The mean change in molar relationship during Forsus treatment, from T1-T2, was  $3.75$  mm. This change was statistically significant ( $p < .0001$ ).

**Table 9. Molar Relationship Changes (mm) Between Time Points**

| Time   | Min. | 25%tile | Median | 75%tile | Max | Mean  | SD    | 95% CI      | P-value* |
|--------|------|---------|--------|---------|-----|-------|-------|-------------|----------|
| 0      | -4.1 | -1.9    | -1.4   | -0.7    | 2.5 | -1.33 | 1.146 | -1.54 -1.12 |          |
| 0 to 1 | -4.3 | -1.3    | -0.5   | 0.2     | 4.3 | -0.56 | 1.300 | -0.84 -0.27 | <.0001   |
| 1      | -6.0 | -2.8    | -1.8   | -1.0    | 2.6 | -1.89 | 1.395 | -2.14 -1.63 |          |
| 1 to 2 | -0.9 | 2.7     | 3.7    | 4.8     | 8.1 | 3.75  | 1.481 | 3.43 4.08   | <.0001   |
| 2      | -2.9 | 1.1     | 1.8    | 2.5     | 5.1 | 1.86  | 1.236 | 1.64 2.09   |          |

\* Molar Rel changed significantly at each timepoint ( $p < 0.0001$ )

Movement of B point relative to the horizontal and vertical reference planes was used to evaluate mandibular growth. The total movement of B point (B Distance), as viewed in the sagittal plane, was calculated using B Horiz and B Vert. This variable is termed “B Distance”. Horizontal movement of B point was of most interest in this study, as forward mandibular growth would assist in correcting the sagittal Class II discrepancy. Table 10 shows mean B point horizontal measurement changes between time points. B point moved anteriorly from T1-T2 and this change was statistically significant ( $p < 0.001$ ). Vertical B point measurement changes can be found in Table 11. B Distance changes are seen in Table 12.

**Table 10. B Horizontal Changes (mm) Between Time Points**

| Time   | Min. | 25%tile | Median | 75%tile | Max  | Mean | SD    | 95% CI    | P-value* |
|--------|------|---------|--------|---------|------|------|-------|-----------|----------|
| 0 to 1 | -4.9 | -0.2    | 0.8    | 2.0     | 5.5  | 0.91 | 1.723 | 0.53 1.29 | <.0001   |
| 1 to 2 | -2.7 | 0.3     | 1.1    | 2.6     | 10.8 | 1.36 | 1.774 | 0.97 1.75 | <.0001   |

\* Differences across time ( $p < 0.0001$ )

**Table 11. B Vertical Changes (mm) Between Time Points**

| Time   | Min. | 25%tile | Median | 75%tile | Max  | Mean | SD    | 95% CI    | P-value* |
|--------|------|---------|--------|---------|------|------|-------|-----------|----------|
| 0 to 1 | -3.6 | 0.8     | 1.9    | 3.5     | 9.3  | 2.11 | 2.142 | 1.64 2.57 | <.0001   |
| 1 to 2 | -3.0 | 0.8     | 2.1    | 3.3     | 15.0 | 2.29 | 2.157 | 1.82 2.76 | <.0001   |

\* Differences across time, P < .0001

**Table 12. B Distance Changes (mm) Between Time Points**

| Time   | Min. | 25%tile | Median | 75%tile | Max  | Mean | SD    | 95% CI    | P-value* |
|--------|------|---------|--------|---------|------|------|-------|-----------|----------|
| 0 to 1 | -2.2 | 0.4     | 2.2    | 3.3     | 8.7  | 2.24 | 1.958 | 1.81 2.66 | <.0001   |
| 1 to 2 | -2.7 | 1.3     | 2.5    | 3.8     | 18.5 | 2.68 | 2.226 | 2.19 3.17 | <.0001   |

\* Differences across time, P < .0001

During leveling and alignment of teeth (T0 – T1), the mean occlusal plane steepening was 1.86°. During Forsus treatment, from T1-T2, mean opening rotation of the occlusal plane was 2.91°. The functional occlusal plane to horizontal plane means can be seen in Table 13, along with the changes across time. The occlusal plane rotation from T1-T2 was statistically significant (p < 0.0001).

**Table 13. FOP-HP (°) Changes Between Time Points**

| Time   | Min.  | 25%tile | Median | 75%tile | Max  | Mean  | SD    | 95% CI      | P-value* |
|--------|-------|---------|--------|---------|------|-------|-------|-------------|----------|
| 0      | 1.0   | 7.6     | 11.0   | 14.3    | 22.2 | 11.15 | 4.695 | 10.29 12.00 |          |
| 0 to 1 | -12.2 | -4.4    | -1.3   | 0.6     | 7.3  | -1.82 | 3.236 | -2.53 -1.11 | <.0001   |
| 1      | 1.4   | 6.3     | 9.0    | 12.0    | 18.9 | 9.33  | 3.724 | 8.65 10.01  |          |
| 1 to 2 | -4.6  | 1.1     | 3.0    | 4.6     | 9.3  | 2.85  | 2.826 | 2.23 3.47   | <.0001   |
| 2      | 0.8   | 9.1     | 11.8   | 15.0    | 23.9 | 12.17 | 4.047 | 11.44 12.91 |          |

\* FOP changed significantly at each timepoint (p < 0.0001)

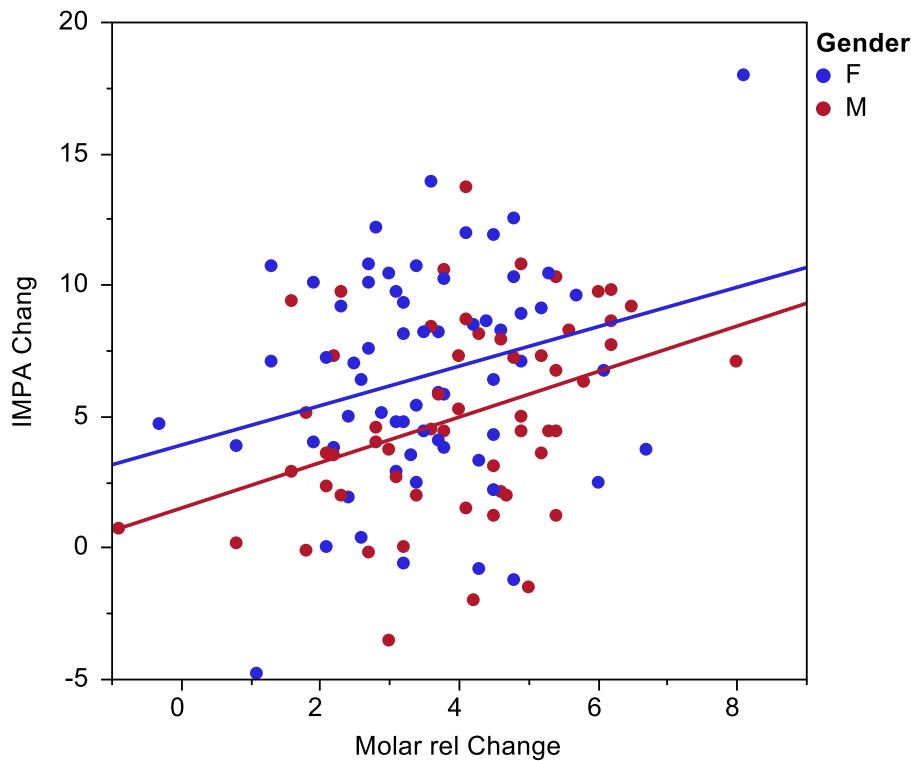
## Relationships between Change in IMPA and Changes in the Other Characteristics

Correlations between IMPA change from T1-T2 and the changes in several preselected variables during this same time period are shown in Table 14. Correlations between IMPA change and changes in each variable from T1-T2 were analyzed and used to determine which variables were significantly related to IMPA changes. The three variables that demonstrated significant correlations to IMPA change were sex, molar relationship change, and FOP rotation ( $P < .05$ ). There was no significant correlation between the change in IMPA from T1-T2 and age at T0 ( $r = -0.05$ ,  $P > 0.5$ ), or with any other variable.

Multiple regression analysis was then used to test for a relationship between IMPA change and each of the three predictors simultaneously. The P-values in the right-hand column of Table 14 show that sex, molar relationship change, and occlusal plane rotation were significantly related to IMPA changes. In spite of the relationship being statistically significant, Figure 3 shows a weak relationship. The effect of sex was that females had a significantly larger IMPA change (difference =  $1.87^\circ$ , 95% CI = 0.52 to 3.21). The effect of molar relationship was that for every one millimeter of change in molar relationship, IMPA increased by  $0.57^\circ$  (95% CI = 0.08 to 1.06). The effect of occlusal plane steepening was that for one degree of clockwise rotation of the occlusal plane, IMPA increased by  $0.28^\circ$  (95% CI = 0.019 to 0.54).

**Table 14. Relationship Between Selected Variables to IMPA Change from T1-T2**

| Predictor                          | Correlation |          | Multiple regression |          |
|------------------------------------|-------------|----------|---------------------|----------|
|                                    | <i>r</i>    | P-value  | std. Beta           | P-value  |
| Gender                             |             | 0.0278 * | 0.23                | 0.0068 * |
| Age at Tx start (T0)               | -0.05       | 0.5619   |                     |          |
| B Horizontal Change (T1-T2)        | 0.03        | 0.7117   |                     |          |
| B Vertical Change (T1-T2)          | -0.04       | 0.6949   |                     |          |
| B Distance Change (T1-T2)          | -0.01       | 0.8726   |                     |          |
| Pogonion Horizontal Change (T1-T2) | 0.05        | 0.5771   |                     |          |
| Pogonion Vertical Change (T1-T2)   | -0.03       | 0.7519   |                     |          |
| Pogonion Distance Change (T1-T2)   | -0.01       | 0.9435   |                     |          |
| Molar Relationship Change (T1-T2)  | 0.28        | 0.0018 * | 0.22                | 0.0224 * |
| FOP-HP Change (T1-T2)              | 0.30        | 0.0008 * | 0.20                | 0.0360 * |
| CVM at Forsus Insertion (T1)       | -0.02       | 0.8626   |                     |          |



**Figure 3. Relationship Between the T1-T2 Change in IMPA and the Change in Molar Relationship for Males and Females**

## Discussion

Previous articles have described the mechanism by which the Forsus appliance achieves Class II correction.<sup>9,22</sup> These same studies have shown that flaring of the lower incisors is a side effect of the treatment mechanics. The purpose of this study was not to describe how Class II correction was accomplished using the Forsus appliance. This study sought to explain the large variability in lower incisor proclination change during treatment. Three factors were hypothesized to influence the amount of change in lower incisor inclination: mandibular growth, severity of malocclusion, and occlusal plane steepening. Determining the extent that these factors contribute to lower incisor flaring would be of interest to orthodontists, as proper case selection for treatment with the Forsus appliance would be simplified for the future.

Lower incisor flaring during Class II correction is generally regarded as an undesirable side effect. It is unfavorable for two primary reasons: it can lead to negative periodontal sequelae and decreased stability. Previous studies have shown that advancing the lower incisors past the physiologic envelope of movement can lead to recession.<sup>23-25</sup> As teeth are proclined labially, bony dehiscence can be created with resultant loss of attachment.<sup>26</sup> Recession due to flaring can necessitate additional treatment and cost for the patient in the form of periodontal procedures.

In addition, it is generally agreed upon that alteration of arch form, such as with lower incisor proclination, is unstable long-term.<sup>27</sup> Årtun et al showed that stability of proclination can only be relied upon if the lower incisors are initially retroclined, a reason for the retroclination is determined, and the cause of retroclination eliminated during treatment.<sup>28</sup> For lower incisors that are normally inclined at the beginning of treatment, maintaining pre-treatment mandibular arch

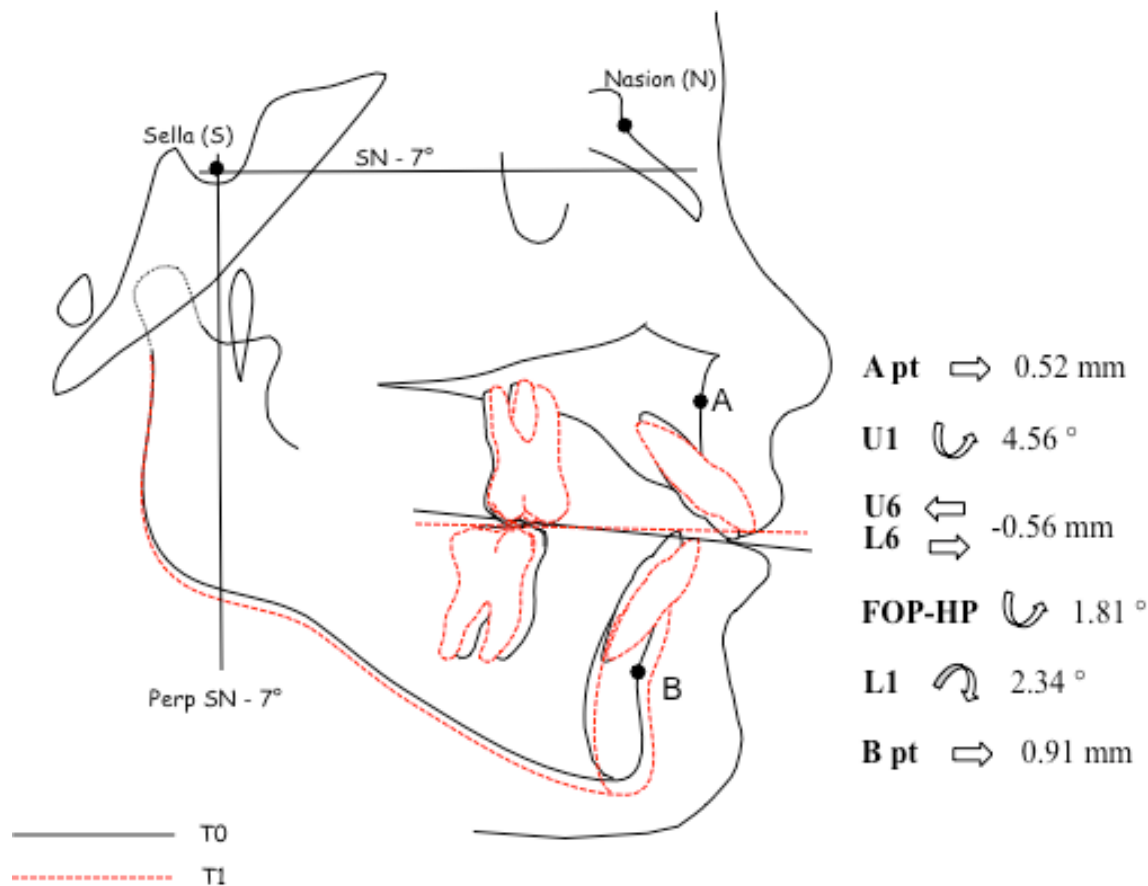
form is important for a stable result.<sup>29</sup> Stability of the outcome is an important pretreatment goal when planning any orthodontic treatment.

While previous studies have documented the increase in lower incisor proclination during Class II correction with the Forsus appliance, most have evaluated changes from pre-treatment to post-treatment.<sup>9,22</sup> Having radiographs at four separate time points of treatment was a major strength of the current study. This allowed for precise measurement of lower incisor angulation during different stages of treatment. For example, lower incisor flaring during leveling and alignment (T0-T1) was analyzed separately from flaring during active Forsus treatment (T1-T2). This allowed for an accurate representation of how much flaring could be solely attributed to the mechanics of Class II correction with the Forsus appliance, without the confounding variables of mechanics due to leveling and alignment that also flare the mandibular incisors.

Cephalograms taken at T0, T1, and T2 were traced as part of this study. T0 measurements were used to establish baseline values at the beginning of treatment. A mean IMPA value at T0 of  $96.42 \pm 6.98^\circ$ , which is similar to the norms of several cephalometric analyses, shows that pretreatment angulations were neither too upright nor too flared. The U6 to L6 molar relationship at T0 was  $-1.33 \pm 1.15$  mm. Molar relationship was measured as the distance from the mesial of the U6 to the mesial of the L6 along the functional occlusal plane. Using this method, a molar relationship of zero would indicate an approximately end-on Class II relationship. Negative values indicate an increasingly Class II malocclusion, while positive values reflect a molar relationship tending more toward Class I. The average molar relationship at the beginning of treatment was -1.33 mm, or 1.33 mm more Class II than end-on.

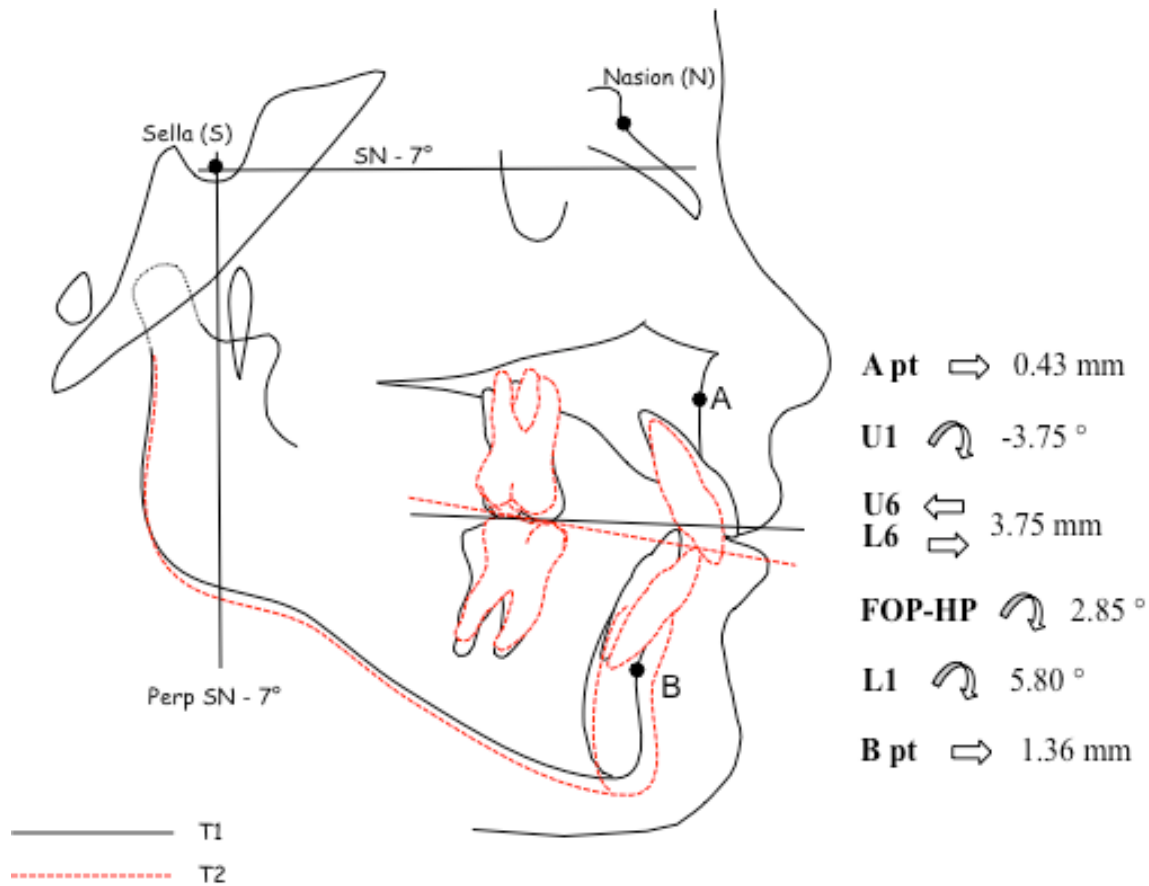


Changes in cephalometric measurements were evaluated from the T0-T1 leveling and alignment phase and T1-T2 Forsus correction phase. These changes can be seen in Figures 4 and 5. The T2-T3 finishing phase changes were not evaluated because changes during this time contributed little to Class II correction. Patients' Class II malocclusions were overcorrected to a "super" Class I position to allow slight relapse after Forsus removal and a resultant Class I occlusion. In addition, Shoff found that there was insignificant uprighting of the lower incisors from Forsus removal to treatment completion.<sup>13</sup>



**Figure 4. Mean Changes During Leveling and Alignment (T0-T1)**

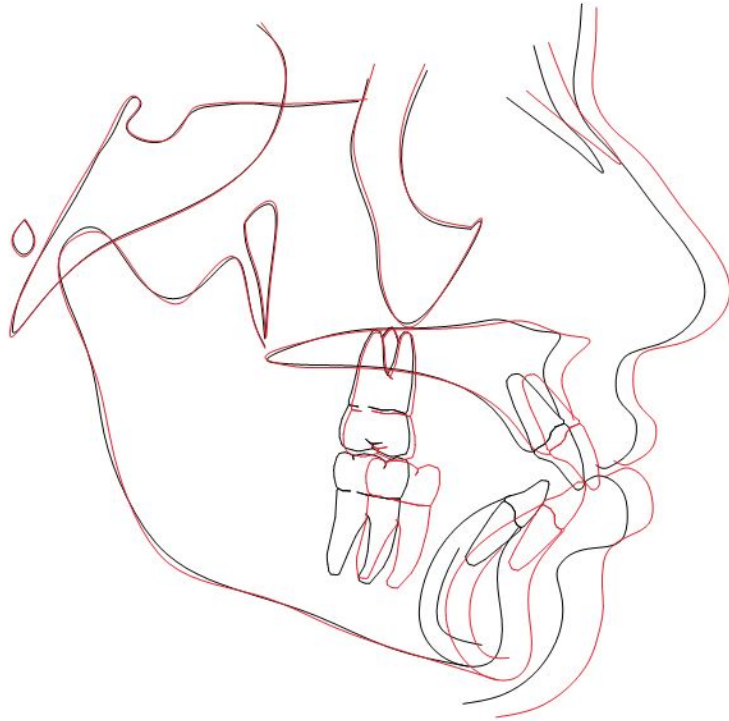
T1-T2 changes were of great interest, as this was the time coinciding with the Class II correction while the Forsus was in place. Mandibular incisors flared significantly as a result of Forsus mechanics, by an average of  $5.80 \pm 3.85^\circ$ . Molar movement, mandibular growth, and functional occlusal plane steepening were all significant during the same time period. The molar relationship was improved by an average of 3.75 mm. In relation to the vertical reference plane, B point moved anteriorly by an average of 1.36 mm. Finally, the functional occlusal plane steepened by  $2.85^\circ$ . These changes can be seen in Figure 5.



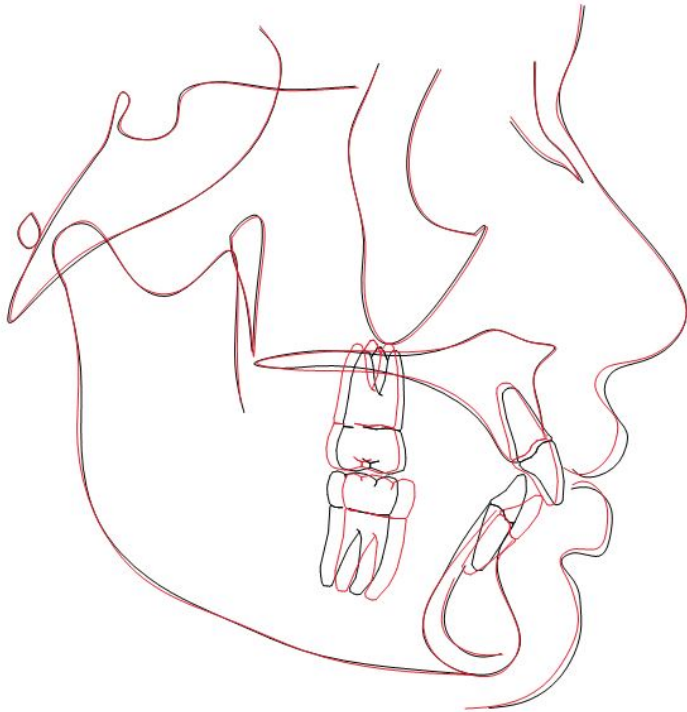
**Figure 5. Mean Changes from Forsus Insertion Until Removal (T1-T2)**

It was hypothesized that the amount of mandibular growth, the amount of Class II molar correction achieved, and the amount of occlusal plane rotation would all affect the amount of lower incisor flaring during the Forsus phase of treatment. Once a significant change in each variable was established, correlation between IMPA change and these pre-selected variables was evaluated.

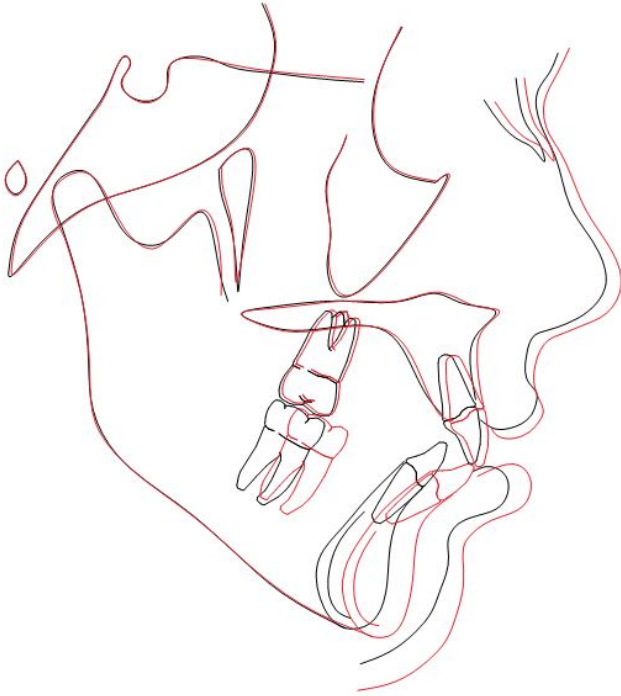
There was no correlation between the change in lower incisor proclination and the forward movement of B point. It was also investigated whether the change in lower incisor flare was correlated to other measures of mandibular growth: the vertical and total changes in B point. No correlation was found between changes in B point and proclination of the lower incisors. To further analyze the effect of growth on IMPA change, correlation analyses between lower incisor angulation change and pogonion horizontal, vertical, and total movements were performed. None showed any correlation. These findings were surprising. It was hypothesized that with favorable mandibular growth, little incisor flare would result. Conversely, it was theorized that a patient with minimal mandibular growth would experience more lower incisor flaring. Patients from the study sample that demonstrated the basis for these characteristics are seen in Figures 6 and 7. Perhaps having the Forsus in place for an average of only 5.90 months was not a long enough duration of time to take advantage of peak mandibular growth. For those patients whose mandibular growth peak coincided with the Forsus being in place, the efficiency of dentoalveolar Class II correction mechanics may have overpowered any mandibular growth contribution to correction that may have otherwise been seen. Forsus patients who demonstrated the unexpected results are shown in figures 8 and 9.



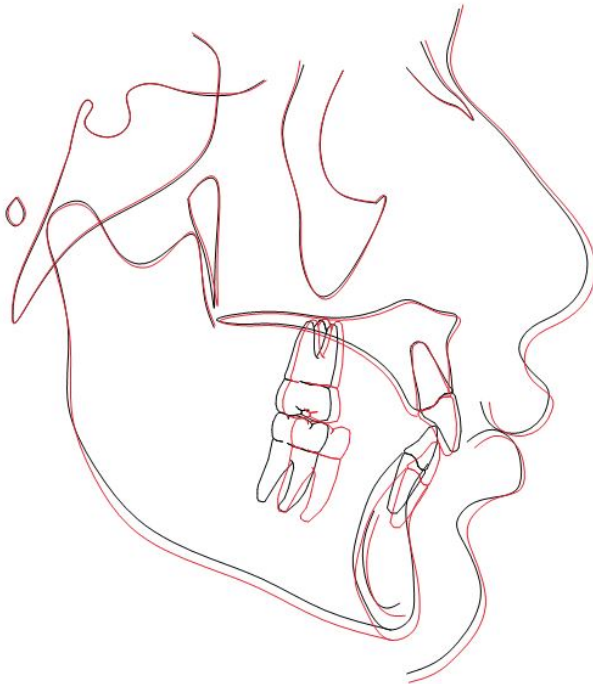
**Figure 6. Forsus Patient with Substantial Mandibular Growth and Minimal Incisor Flaring**



**Figure 7. Forsus Patient with Minimal Mandibular Growth and Substantial Incisor Flaring**



**Figure 8. Forsus Patient with Substantial Mandibular Growth and Substantial Incisor Flaring**



**Figure 9. Forsus Patient with Minimal Mandibular Growth and Minimal Incisor Flaring**

The CVM method proposed by Baccetti et al was used to classify each patient at Forsus placement into one of six stages of craniofacial growth.<sup>17</sup> According to the authors, orthopedic contribution to Class II correction is maximized when treatment is during the CS3-CS4 growth spurt stage. The results of this study showed no correlation between the amount of lower incisor flaring during Forsus correction and the CVM stage at Forsus placement. Again, these surprising findings could be explained by the short treatment time or the efficiency of Class II correction with the Forsus appliance. Other investigators have recently questioned the validity of the CVM method and its acceptability for clinical use.<sup>30,31</sup> These potential inadequacies of the CVM method may have also contributed to the lack of correlation between IMPA changes and CVM stage at Forsus placement.

During Forsus activation (T1-T2), there was correlation between the amount of lower incisor flaring and three different variables: gender, change in molar relationship, and steepening of the functional occlusal plane (Table 13).

Females had a significantly larger IMPA change during Forsus activation than males. On average, puberty and the adolescent growth spurt occur approximately two years earlier in girls than in boys. Girls typically have their growth velocity peak at age 12, while the peak for boys is closer to 14 years of age on average.<sup>32</sup> In the current study, the mean age for all patients while the Forsus was in place was 13.59 to 14.08 years old. A larger proportion of girls were therefore likely to have been past their mandibular growth peak and thus relied more upon dentoalveolar correction to achieve Class II correction. This could have resulted in greater changes in IMPA values while the Forsus was in place.

The change in molar relationship was correlated to the change in lower incisor inclination from T1-T2. It is intuitive that a more severe Class II malocclusion at Forsus insertion would necessitate more mesial movement of the lower dentition during correction, and thus result in more lower incisor flaring. Although the correlation between these two variables was significant, the strength of the correlation was weak, with an r value of only 0.28. Overall, multiple regression showed that for each millimeter of change in the molar relationship during Class II correction, the lower incisors flared by 0.57°.

Similarly, the steepening of the occlusal plane from T1-T2 showed correlation to the amount of lower incisor flaring during the same time period. This correlation was also weak. It was interesting to note that the correlation was positive, not negative, meaning that greater increases in occlusal plane steepening were associated with more incisor flaring. Braun and Legan showed that there is an approximately 0.5 mm change in the occlusal relationship for each degree of occlusal plane rotation.<sup>19</sup> Therefore, a clockwise rotation of the occlusal plane helps to correct a Class II dental relationship. It was hypothesized that the greater the magnitude of occlusal plane steepening, the less the lower incisors would flare. This study found the opposite to be true. A positive correlation can be explained by the mechanics of Forsus correction. Patients with a more significant Class II malocclusion at T0 would have had the Forsus in place for a longer period of time than those with less severe malocclusions. The Forsus works by rotating the occlusal plane clockwise and increasing anterior movement of the lower dentition and, hence, proclination of the mandibular incisors. This means that increased time with the Forsus appliance inserted would increase both the occlusal plane rotation and flaring of the lower incisors. In this sample, for every one degree of occlusal plane steepening, lower incisors flared 0.28°.

The purpose of this study was twofold. The first was to determine whether there was a correlation between lower incisor flaring and three variables during Class II correction using the Forsus appliance: mandibular growth, change in molar relationship, and occlusal plane steepening. The second purpose was to determine how much each of these factors contributed to Class II correction via multiple regression analysis. Correlation was only found between lower incisor flaring and three of the pre-selected variables. The correlations observed were weak and likely not clinically significant. The lack of strong correlation found may be attributable to large individual variation within the population studied and the influence of other factors not evaluated. Additional studies are needed to further account for the variability seen in lower incisor flaring during Class II correction with the Forsus appliance.

The findings of this investigation, however, have clinical implications. The total amount of lower incisor flaring during Forsus activation is difficult to predict. With a mean of  $5.8 \pm 3.8^\circ$ , most patients (68%) will show between  $2^\circ$  and  $9.6^\circ$  of lower incisor flaring during Forsus activation. Clinicians should be aware that the cause of increased proclination is multifactorial and dependent upon individual patient variation. Thorough diagnosis of each patient that presents with a Class II malocclusion is critical. Anatomical considerations and pretreatment lower incisor angulation should be considered. Caution should be used with the Forsus appliance in patients who can tolerate only mild to moderate lower incisor flaring during treatment. The Forsus appliance should not be used for patients in whom significant lower incisor flaring is contraindicated. Other treatment modalities should be considered as better treatment options in these cases.



## Conclusions

- The amount of lower incisor flaring observed during Class II correction with the Forsus appliance was weakly correlated to sex, molar relationship change, and occlusal plane steepening.
- There was no correlation between the change in lower incisor proclination and the amount of mandibular growth during active treatment with the Forsus appliance.
- Most of the intersubject variation in lower incisor proclination observed during treatment was not explained by the variables measured in this study.

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## Vita

Dr. Ryan Redford was born on May 9, 1984 in Provo, Utah. After graduating with honors from Timpview High School in 2002, he spent two years in Taipei, Taiwan where he became fluent in Mandarin Chinese. He returned to study biology at Brigham Young University, where he graduated Summa Cum Laude in 2008. He then matriculated to UCLA School of Dentistry and graduated Cum Laude in 2012 in addition to being inducted into OKU. Ryan subsequently gained admission to the graduate orthodontic program at Virginia Commonwealth University Department of Orthodontics and received a Certificate in Orthodontics as well as a Master of Science in Dentistry degree in 2014. After graduation, Dr. Ryan Redford will enter the private practice of orthodontics.