A STUDY OF SHORT-TERM SKELETAL, DENTAL, AND SOFT TISSUE EFFECTS
OF CLASS II MALOCLUSIONS TREATED WITH INVISALIGN® WITH
MANDIBULAR ADVANCEMENT FEATURE OR TWIN BLOCK APPLIANCE
COMPARSED WITH HISTORICAL CONTROLS

by

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D.M.D., Southern Illinois University, 2017

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THE FACULTY OF GRADUATE AND POSTDOCTORAL STUDIES

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THE UNIVERSITY OF BRITISH COLUMBIA

(Vancouver)

July 2020

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The following individuals certify that they have read, and recommend to the Faculty of Graduate and Postdoctoral Studies for acceptance, a thesis entitled:

A study of short-term skeletal, dental, and soft tissue effects of Class II malocclusions treated with Invisalign® with Mandibular Advancement Feature or Twin Block appliance compared with historical controls

submitted by Spencer Sonntag Blackham in partial fulfillment of the requirements for the degree of Master of Science in Craniofacial Science

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Abstract

Introduction: The purpose of this retrospective cephalometric study was to compare short-term skeletal, dental, and soft tissue effects in Class II malocclusions treated with Invisalign® with Mandibular Advancement Feature (IMAF) as compared to Twin Block (TB) appliance, and age and gender matched historical controls.

Methods: 64 Class II malocclusion patients received phase I treatment with IMAF or TB, 32 in each group. Comprehensive phase II treatment was then completed for 19 of the IMAF group with Invisalign® clear aligner therapy and 19 patients of the TB group with full fixed edgewise appliances (FEA). 32 longitudinal historical controls were age and gender matched to the IMAF sample. Lateral cephalograms were obtained and intraoral photographs reviewed before treatment (T1), immediately following end of the active advancement of phase I (T2), and at completion of comprehensive phase II orthodontic treatment (T3). Radiographs were randomly traced by a single investigator blinded to group allocation. ANOVA and Tukey tests were used for inter-group comparisons. Intraclass correlations, t-tests, Dahlberg’s error, and scatter plots were utilized for reliability testing.

Results: After phase I treatment, both TB and IMAF decreased the ANB angle, facial convexity, and overjet significantly more than the controls. IMAF decreased the overjet through significant retraction of the upper incisor and protrusion of the lower incisor. IMAF also impeded the vertical eruption of the lower incisor. TB decreased the overjet via retraction and retroclination of the upper incisor and protrusion of the lower incisor. Following phase II comprehensive
treatment both treatment groups decreased the Wits Appraisal and overjet significantly more than the control sample. The lower incisor was significantly proclined and protruded in the TB and FEA group, and the lower incisor significantly protruded in the IMAF and Invisalign® group. Only the TB and FEA group significantly decreased the facial convexity more than the control group.

**Conclusions:** IMAF with Invisalign® treatment and TB followed by FEA are effective in correcting a Class II malocclusion. Treatment with IMAF may result in less proclination of the lower incisors compared to the TB appliance.
Lay Summary

Growing orthodontic patients may present with a small lower jaw that is set back relative to the upper jaw. In these cases growth modification is attempted to create a harmonious relationship between the two jaws. The Twin Block appliance has commonly been used to treat a malocclusion with a small mandible; Invisalign® with Mandibular Advancement Feature is a novel appliance that proposes to accomplish the same. The present study reviewed radiographs before and after treatment with the two appliances, as well as patients who received no treatment with a similar observation period. Both appliances were able to decrease the discrepancy between the two jaws, decrease the overjet, and correct the dental malocclusion.
Preface

The present study concept was identified by Dr. Sandra Tai. The methodology for carrying out the project was developed by Dr. Benjamin Pliska, Dr. Sandra Tai, Dr. Bingshuang Zou, and myself. I then completed the appropriate ethics approvals, with assistance from Dr. Benjamin Pliska, prior to initiating data collection. I collected the entirety of the data set, Eleanor Cawthorne performed the blinding and randomization, and then I completed data review and analysis. I concluded the study by performing statistical analysis with suggestions and input from Dr. Benjamin Pliska, Dr. Bingshuang Zou, and Mary Wong.

This study was reviewed and approved by the University of British Columbia Clinical Research Ethics Board per approval number H18-00443 and subsequently H19-00644.
Table of Contents

Abstract .................................................................................................................. iii
Lay Summary .......................................................................................................... v
Preface ................................................................................................................... vi
Table of Contents ................................................................................................. vii
List of Tables ......................................................................................................... xiv
List of Figures ......................................................................................................... xv
List of Abbreviations ............................................................................................. xvi
Acknowledgements ............................................................................................... xix
Dedication ................................................................................................................ xx

Chapter 1: Introduction .......................................................................................... 1
  1.1 Presentation and Etiology ................................................................................... 1
  1.2 Prevalence ........................................................................................................ 3
    1.2.1 Prevalence Specific to Ethnic Population .................................................. 4
  1.3 Growth Related Changes .................................................................................. 6
  1.4 Treatment Alternatives ................................................................................... 9
    1.4.1 Non-Growing Patients .............................................................................. 9
    1.4.2 Growing Patients .................................................................................... 13
  1.5 Functional Appliances .................................................................................... 15
    1.5.1 Fixed Functional Appliances .................................................................. 15
    1.5.2 Removable Functional Appliances .......................................................... 17
      1.5.2.1 Twin Block Appliance ....................................................................... 21
1.6 Clear Aligner Therapy.................................................................29
1.6.1 Invisalign® ..............................................................................30
1.6.1.1 Invisalign® with Mandibular Advancement Feature ..........31
1.7 Research Question .......................................................................32
1.7.1 Hypotheses................................................................................33
1.7.2 Study Aims ...............................................................................33

Chapter 2: Methodology .....................................................................35
2.1 Project Introduction .......................................................................35
2.1.1 Sample Size Calculation..........................................................35
2.1.2 REB Approval ...........................................................................36
2.2 Treatment Protocol .......................................................................36
2.2.1 TB Protocol .............................................................................36
2.2.2 IMAF Protocol .........................................................................38
2.3 Sample Collection .........................................................................41
2.3.1 IMAF Sample ..........................................................................43
2.3.2 TB Sample ...............................................................................44
2.3.3 Control Sample ........................................................................45
2.4 Cephalometric Tracing .................................................................46
2.4.1 Tracing Method .........................................................................47
2.4.2 Reliability & Tracing .................................................................50
2.5 Cephalometric Analyses ...............................................................50
2.5.1 Major Outcomes .......................................................................52
2.5.2 Minor Outcomes .......................................................................52
2.6 Statistical analyses ................................................................. 52
2.7 Method error/reliability ........................................................... 53

Chapter 3: Results ........................................................................ 55

3.1 Pooling of Sub-Groups ............................................................... 55
  3.1.1 Males and Females ............................................................... 55
  3.1.2 Phase 1 Patients (with T1 & T2 only) Compared to Comprehensively Treated Patients (with T1, T2, & T3) ................................................................. 57
3.2 Reliability Testing .................................................................... 59
3.3 Initial (T1) Presentation ............................................................. 66
  3.3.1 Skeletal Presentation ......................................................... 66
    3.3.1.1 Maxilla ........................................................................ 67
    3.3.1.2 Mandible ..................................................................... 67
  3.3.2 Dental Presentation ............................................................ 68
    3.3.2.1 Maxillary Incisors ......................................................... 68
    3.3.2.2 Mandibular Incisors ...................................................... 68
    3.3.2.3 Molar Presentation ....................................................... 69
  3.3.3 Soft Tissue .......................................................................... 69
3.4 Phase 1 Treatment (T1 to T2) Results ...................................... 69
  3.4.1 Skeletal Outcomes .............................................................. 70
    3.4.1.1 Maxillary Changes ......................................................... 70
    3.4.1.2 Mandibular Changes ...................................................... 71
  3.4.2 Dental Outcomes ............................................................... 71
    3.4.2.1 Maxillary Incisors ......................................................... 71
3.6.4.1 IMAF Correlations ........................................................................................................79
3.6.4.2 TB Correlations ........................................................................................................80
3.6.5 Lower Incisor Protrusion (L1-NB & L1-APo) and Vertical ........................................80
  3.6.5.1 IMAF Correlations ....................................................................................................80
  3.6.5.2 TB Correlations ........................................................................................................81
3.6.6 Molar Movements .......................................................................................................81
  3.6.6.1 IMAF Correlations ....................................................................................................81
  3.6.6.2 TB Correlations ........................................................................................................82
3.6.7 Facial Convexity ..........................................................................................................82

Chapter 4: Discussion ........................................................................................................93
4.1 Initial (T1) Presentation ....................................................................................................93
  4.1.1 Significant Variables: IMAF and TB to Control .......................................................94
  4.1.2 Significant Variables: TB and Control .........................................................................95
  4.1.3 Significant Variables: IMAF and TB ..........................................................................98
4.2 Advancement (T1 to T2) Changes ....................................................................................98
  4.2.1 Skeletal Outcomes ......................................................................................................99
    4.2.1.1 Maxillary Changes .................................................................................................103
    4.2.1.2 Mandibular Changes .............................................................................................104
  4.2.2 Dental Outcomes .......................................................................................................106
    4.2.2.1 Maxillary Incisors .................................................................................................108
    4.2.2.2 Mandibular Incisors .............................................................................................111
    4.2.2.3 Molar Changes .....................................................................................................114
  4.2.3 Soft Tissue Outcomes ...............................................................................................116
4.3 Phase 2 (T2 to T3) Changes ................................................................. 118
  4.3.1 Significant Variables: TB and Control ............................................. 119
  4.3.2 Significant Variables: IMAF and Control ....................................... 119
  4.3.3 Significant Variables: IMAF and TB ............................................. 120
4.4 Overall (T1 to T3) Changes ............................................................. 121
  4.4.1 Significant Variables: TB and Control ............................................. 121
  4.4.2 Significant Variables: IMAF and Control ....................................... 123
  4.4.3 Significant Variables: IMAF and TB ............................................. 125
4.5 Variable Correlation ........................................................................ 126
  4.5.1 Lower Incisor Proclination ............................................................. 127
    4.5.1.1 IMAF Correlations .............................................................. 127
    4.5.1.2 TB Correlations ............................................................... 128
  4.5.2 Overjet ....................................................................................... 128
    4.5.2.1 IMAF Correlations ............................................................. 128
    4.5.2.2 TB Correlations ............................................................... 129
  4.5.3 Mandibular Length ...................................................................... 130
    4.5.3.1 IMAF Correlations ............................................................. 130
    4.5.3.2 TB Correlations ............................................................... 130
  4.5.4 Upper Incisor Protrusion ............................................................. 131
    4.5.4.1 IMAF Correlations ............................................................. 131
    4.5.4.2 TB Correlations ............................................................... 132
  4.5.5 Lower Incisor Protrusion (L1-NB & L1-APo) and Vertical ............ 132
    4.5.5.1 IMAF Correlations ............................................................. 132
4.5.2 TB Correlations ............................................................................................................. 133
4.5.6 Molar Movements ........................................................................................................ 134
  4.5.6.1 IMAF Correlations ................................................................................................. 134
  4.5.6.2 TB Correlations ..................................................................................................... 136
4.5.7 Facial Convexity ......................................................................................................... 137
  4.5.7.1 IMAF Correlations ................................................................................................. 137
  4.5.7.2 TB Correlations ..................................................................................................... 138
4.6 Strengths of This Study ................................................................................................. 138
4.7 Limitations ....................................................................................................................... 139

Chapter 5: Conclusion ........................................................................................................... 141

Bibliography ......................................................................................................................... 143

Appendices ............................................................................................................................ 163

Appendix A .............................................................................................................................. 163
  A.1 ABO Analysis ................................................................................................................ 163
  A.2 McKee Analysis .............................................................................................................. 164
  A.3 Additional Measurements ............................................................................................. 165

Appendix B .............................................................................................................................. 167
  B.1 Cephalometric Tracing Points ...................................................................................... 167
  B.2 Examples of Cephalometric Tracings ......................................................................... 169

Appendix C .............................................................................................................................. 171
  C.1 Significant Intraclass Correlation Coefficients (ICC) .................................................. 171
  C.2 Dahlberg’s Error Test Results ...................................................................................... 172
List of Tables

Table 1.1 Class II Prevalence in Varying Ethnicities .................................................................6
Table 2.1 IMAF Sample Practice Distribution ..............................................................................44
Table 2.2 Example of Data Excel Sheet ..........................................................................................51
Table 3.1 Males and Females – Significant Variables at T1 .............................................................57
Table 3.2 Patients With or Without T3 – Significant Variables at T1. ..............................................59
Table 3.3 Significant IMAF Correlations .........................................................................................83
Table 3.4 Significant TB Correlations .............................................................................................84
Table 3.5 T1 Presentation. NS: Non-significant, *: p ≤ 0.05, **: p ≤ 0.01 ....................................86
Table 3.6 Advancement Phase Changes (T2-T1). NS: Non-significant, *: p ≤ 0.05, **: p≤ 0.01 88
Table 3.7 Phase 2 Changes (T3-T2). NS: Non-significant, *: p ≤ 0.05, **: p ≤ 0.01 ..................90
Table 3.8 Overall Changes (T3-T1). NS: Non-significant, *: p ≤ 0.05, **: p≤ 0.01 ....................92
Table 3.9 Molar Movements: *: p ≤ 0.05, **: p ≤ 0.01, ***: p ≤ 0.001 ........................................115
Table C.1 Significant Intraclass Correlation kappa values .............................................................171
Table C.2 Dahlberg’s Error Test Results .........................................................................................172
Table C.3 Dahlberg’s Error Test Results Continued .................................................................173
List of Figures

Figure 2.1 Twin Block Appliance Design. Courtesy Dr. Sandra Tai.........................................................38

Figure 2.2 Invisalign® with Mandibular Advancement. Courtesy Dr. James Andrews & Dr. Spencer Blackham........................................................................................................................................40

Figure 2.3 Invisalign® with Mandibular Advancement Feature with Mandible in the habitual Retruded Position (Left) and Advanced Position (Right). Courtesy Dr. James Andrews & Dr. Spencer Blackham ........................................................................................................................................41

Figure 3.1 SN-MP Angle with Almost Perfect Correlation Repeat Tracing Scatter Plot .............62

Figure 3.2 L1-NB (mm) with Almost Perfect Correlation Repeat Tracing Scatter Plot ..............63

Figure 3.3 Midface Length (Co-A, mm) with Moderate Correlation Repeat Tracing Scatter Plot ........................................................................................................................................64

Figure 3.4 Nasolabial Angle with Substantial Correlation Repeat Tracing Scatter Plot..............65

Figure B.1 Sample Cephalometric Tracing with Numbered Points. Key on Following Pages...167

Figure B.2 Sample Cephalometric Tracing with Analysis Lines ......................................................169

Figure B.3 Sample Cephalometric Tracing with Molar Measurement Lines..............................170
List of Abbreviations

A: A-Point
AAO: American Association of Orthodontists
AAOF: American Association of Orthodontists Foundation
ABO: American Board of Orthodontics
ABO-OGS: American Board of Orthodontics – Objective Grading Scale
ANS: Anterior Nasal Spine
Ar: Articulare
B: B-Point
Ba: Basion
CAT: Clear aligner therapy
CEJ: Cementoenamel Junction
Co: Condylion
CVMS: Cervical Vertebral Maturation Stage
D: Distal
FEA: Fixed Edgewise Appliance
FH: Frankfort Horizontal
FMA: Frankfort to Mandibular Plane Angle
Gn: Gnathion
Go: Gonion
IMAF: Invisalign® with Mandibular Advancement Feature
IPR: Interproximal Reduction
L1: Lower Incisor
L6: Lower First Molar
LFH: Lower Face Height
LL: Lower Lip
M: Mesial
MA: Mandibular Advancement
MARA: Mandibular Anterior Repositioning Appliance
Mn: Menton
MP: Mandibular Plane (Go-Gn)
N or Na: Nasion
OP: Occlusal Plane
Or: Orbitale
Pg: Pogonion
PNS: Posterior Nasal Spine
Po: Porion
PP: Palatal Plane
PT Point: Pterygomaxillary Fissure Point
RCT: Randomized clinical trial
S: Sella
Sn: Subnasale
ST: Soft Tissue (may also be denoted by an apostrophe)
TB: Twin Block
TFH: Total Face Height
U1: Upper Incisor

U6: Upper First Molar

UBC: University of British Columbia

UFH: Upper Face Height

UL: Upper Lip
Acknowledgements

First and foremost I would like to express my boundless appreciation and love to my parents for their continual support during this 31-year journey. I would not be here without you.

To my committee:

- Dr. Sandra Tai, I am most appreciative of your insight and clinical knowledge.
- Dr. Bingshuang Zou, your encouragement and support have been without equal.
- Dr. Benjamin Pliska, thank you for your guidance throughout this project.

To Dr. David Kennedy, your suggestions and wisdom have been invaluable during the entirety of the program.
Dedication

To my wife Angela Rose. You’ve been my rock and support since Day 1. You are my sounding board. You entertain my wildest goals and aspirations without question. Without you, I would be far from the true potential you’ve helped me achieve through thick and thin.

Here’s to:

beginning the next chapter in life with you, after closing this book of a thesis.

taking long drives, just you and I.

sharing more quality time, as a family and as a couple.

loving you forever and always,

Spencer
Chapter 1: Introduction

1.1 Presentation and Etiology

An ideal Angle Class I occlusion can be described as the maxillary canine occluding interproximally between the mandibular canine and first premolar, and the mesiobuccal cusp of the maxillary first molar set over the buccal groove of the mandibular first molar. This is contrasted with an Angle Class II dental malocclusion where the maxillary canine is occluding mesial to the distal edge of the mandibular canine, and the mesiobuccal cusp of the maxillary first molar is mesial to the buccal groove of the mandibular first molar. This has also been referred to as a distal occlusion because the mandibular dentition is set distal to the maxillary dentition. The Angle Class II classification has been subdivided into two classes based on incisor positioning – division 1 and division 2. An accompanying characteristic of a Class II division 1 malocclusion is an increased overjet. While in a Class II division 2 classification the maxillary incisors are retroclined and the overjet is not as excessive, thus camouflaging the severity of the anterior-posterior discrepancy. The Class II division 2 malocclusion is not as prevalent (as will be discussed in the following section), and will not be the focus of the ensuing study. Class II malocclusions have varying degrees of severity and a variety of etiological causes.

An Angle Class II malocclusion can be readily predicted early on in life. A patient presenting with a distal step in the primary dentition is highly likely to present in the future with a Class II malocclusion of the permanent dentition as Bishara found that cases with a well interdigitated distal step in the primary dentition result in a Class II permanent dentition malocclusion. This
The concept of “once a Class II always a Class II” will be revisited in Section 1.3 Growth Related Changes.

The premature loss of maxillary primary second molars without supervision or orthodontic intervention can result in space loss and the mesial drifting of the maxillary first molars. As the maxillary first molars drift forward, the outcome is a mandibular dentition that is set distal relative to the maxillary dentition, thus leading to a Class II dental malocclusion with crowding.

Occasionally, approximately 15% of Class II malocclusions, the maxillary skeleton may factor into a Class II malocclusion.60 Drelich, Altemus, and also Rothstein confirmed this to be the case – a prognathic maxilla relative to the mandible – is a major contributing factor.1,39,100 The dentition is prognathic and often protrusive as a byproduct of a prognathic maxilla, and an Angle Class II malocclusion is often seen. This is substantiated by McNamara in 1981 who reported that the vast majority of investigators (7 of 8) found the maxillary incisors to be protrusive in Class II cases.39,58,60,61,80,99,100,103

A diminutive mandible, one that is small in size and retrusive in position, can lead to a Class II dental malocclusion. McNamara reports the retrusive mandible to be “the most common single characteristic of the Class II”.80 When the mandible is set back – or retrognathic – relative to the maxilla, the alveolar bone and therefore the mandibular dental complex is set back as well: a distal occlusion results. A retrognathic mandible is one of the major factors contributing to a Class II dental malocclusion and is well agreed upon in the dental literature.23,39,53,58-61,80,86,99,103
The vertical proportions of a patient may contribute to a Class II presentation to some extent. While a patient may have a mandible of relatively normal length, it has the potential to be positioned more inferiorly due to excessive vertical growth. This vertical growth can occur in the maxilla and be seen as vertical maxillary excess, or in the mandible as seen in any of the seven indicators studied and composed by Dr. Bjork. The seven indicators of increased mandibular vertical growth, and therefore rotation are: “(1) inclination of the condylar head, (2) curvature of the mandibular canal, (3) shape of the lower border of the mandible [antegonial notching], (4) inclination of the symphysis, (5) inter incisal angle, (6) interpremolar or intermolar angles, and (7) anterior lower face height”.22 Patients with a significant vertical growth pattern are commonly seen with long lower facial third dimensions and are often referred to as dolicocephalic. As the maxilla grows excessively in a downward direction, or as the mandible grows more vertical than forward, the mandible tends to rotate down and back, carrying the dentition with it, contributing to a Class II malocclusion. Drelich, Henry, and Hunter all reported longer facial heights with steeper mandibular plane angles to be more common in retrognathic patients as compared to orthognathic patients.39,59,61 The samples of these studies were predominantly white and so are only able to speak with relation to the sample population.

1.2 Prevalence

After an Angle Class I malocclusion – one in which the molars are in an orthodontically ideal anteroposterior relationship but malignment is present – and a normal Angle occlusion, an Angle Class II malocclusion has been reported to be the most prevalent.97 Published data ranges from 5% to 32% depending on the ethnicity of the sample population.43,91 And while “available data are not as extensive as for American populations, it seems clear that Class II problems are
most prevalent in whites of Northern European descent”. The difficulty with prevalence reports is that there is little differentiation from a mild Class II molar relationship on a Class I skeletal base, to a severe Class II molar relationship on a severely Class II maxillomandibular discrepancy with a retrognathic mandible, both of which are classified as a Class II malocclusion. It may be of comfort however that Dr. Proffit reports, citing the NHANES III survey, that a Class II malocclusion severe enough such that surgery is warranted occurs in only about 4% of the general population.

1.2.1 Prevalence Specific to Ethnic Population

A review of the pertinent literature reveals there is a significant amount of variation among different ethnic groups. The findings have been summarized in the following Table 1.1 Class II Prevalence in Varying Ethnicities. As seen, there is quite the discrepancy that can occur between studies despite reporting the same ethnicity. What can also be appreciated is the predilection for Caucasians and Middle Eastern ethnicities to trend towards Class II malocclusions. With reference to the Asian population in the Vancouver, British Columbia region that potentially is a large portion of our sample, Lin et al, conducting a systematic review and meta-analysis, found that of a sample of 92,517 school age children, a Class II malocclusion was found 9.91% of the time. It should also be noted to be fairly well accepted that the prevalence of Class II malocclusion typically does not decrease with age, as Arya et al found that a distal occlusion (Class II in primary dentition) did not self-correct. Aslam et al however did find a slight increase of the prevalence as the age of untreated sample increased which will be discussed in the coming section.
<table>
<thead>
<tr>
<th>Year</th>
<th>Author(s)</th>
<th>Ethnicity</th>
<th>Age Range</th>
<th>Sample Size</th>
<th>% Angle Class II</th>
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<td>1959</td>
<td>Altemus</td>
<td>Black</td>
<td>12-16</td>
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<tr>
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<td>Emrich, Brodie, and Blayney</td>
<td>Black</td>
<td>6-8</td>
<td>903</td>
<td>5</td>
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<tr>
<td>1964</td>
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<td>Black</td>
<td>12-14</td>
<td>1,476</td>
<td>7</td>
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<tr>
<td>1951</td>
<td>Massler &amp; Frankel</td>
<td>Caucasian</td>
<td>14-18</td>
<td>2,758</td>
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<tr>
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<td>6-8</td>
<td>10,133</td>
<td>11</td>
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<tr>
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<td>13,475</td>
<td>15</td>
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<tr>
<td>2019</td>
<td>Lin et al</td>
<td>Chinese</td>
<td>6-12</td>
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<tr>
<td>1928</td>
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<td>German</td>
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<td>643</td>
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<tr>
<td>1928</td>
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<td>German</td>
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</tr>
<tr>
<td>2001</td>
<td>Silva &amp; Kang</td>
<td>Hispanic</td>
<td>12-18</td>
<td>507</td>
<td>21.5</td>
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<tr>
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<td>Oshagh et al</td>
<td>Iranian</td>
<td>6-14</td>
<td>700</td>
<td>32.6</td>
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<tr>
<td>1915</td>
<td>Chiavaro</td>
<td>Italian (Rome)</td>
<td>3-6</td>
<td>1,000</td>
<td>14.19 of malocclusions</td>
</tr>
</tbody>
</table>
Table 1.1 Class II Prevalence in Varying Ethnicities

<table>
<thead>
<tr>
<th>Year</th>
<th>Authors</th>
<th>Ethnicity</th>
<th>Age Range</th>
<th>Sample Size</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1985</td>
<td>Garner &amp; Butt</td>
<td>Kenyan</td>
<td>13-14</td>
<td>505</td>
<td>7.5</td>
</tr>
<tr>
<td>2009</td>
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<td>1,681</td>
<td>27.7</td>
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<tr>
<td>2014</td>
<td>Aslam et al</td>
<td>Pakistani</td>
<td>15-50</td>
<td>600</td>
<td>27.1</td>
</tr>
<tr>
<td>2004</td>
<td>Sayin &amp; Türkahraman</td>
<td>Turkey</td>
<td>13.57 ± 3.16</td>
<td>1,356</td>
<td>24</td>
</tr>
</tbody>
</table>

1.3 Growth Related Changes

The question must be asked, is there a difference in growth of an untreated Class II malocclusion compared to the ideal Class I? Briefly, Dr. Bishara has completed quite a bit of work regarding the diagnostic and clinical presentation of malocclusions. In 2006 he reported, “the overall growth patterns of untreated Class II division 1 individuals do not seem to differ from those observed in normal subjects”. But will a Class II malocclusion self-resolve or persist? And will the prevalence of Class II malocclusions change with age? These questions will drive the following discussion.

Dr. Bishara analyzed the concept of anteroposterior discrepancies and their carryover from primary to permanent dentition initially in 1988. He found that distal steps, or a Class II, in the deciduous dentition invariably leads to a Class II presentation in the permanent dentition. Furthermore, once a well interdigitated full cusp Class II dental relationship develops in the primary, mixed, or succedaneous dentition, the probability of self-correction is highly unlikely.
Dr. Moyers discussed and expounded on the concept earlier in his 1973 work where he outlines the progression of a distal step primary second molar relationship into a Class II permanent dentition malocclusion. The best outcome one can hope for would be the progression of a full step Class II to a cusp-to-cusp Class II relationship with forward growth of the mandible and forward shifting of the mandibular dentition. Dr. Bishara’s work in 1988 outlined his findings of a less severe Class II malocclusion, one that is cusp-to-cusp, is more likely to result in a Class I molar relationship at 55% of the time, as compared to a Class II molar relationship that occurs only 45% of the time. A decade earlier Dr. Arya et al found the percentages to be 69% of edge-to-edge malocclusions will result in a Class I and 31% will result in a Class II. This change from a cusp-to-cusp molar relationship to a Class I is likely due to both the forward growth of the mandible and forward shifting of the mandibular dentition due to more leeway space in the mandible as suggested by Dr. Moyers. Dr. Bishara revisited the Class II malocclusion in 2006 and claimed that they “are often present early and are maintained unless corrected orthodontically”. This is in line with Emrich et al who in a longitudinal study of 7,654 children at two time points (6-8 and again at 12-14 years old), found that if the child was Class II at the first exam, 96.73% of these were class II at the second exam. Therefore with a good amount of certainty, a clinician can determine a Class II malocclusion early on and anticipate the same anteroposterior malocclusion in the future if no orthodontic intervention occurs.

Certain changes can be expected as patients grow older. In 1959, Moore found that facial profiles improved in orthodontically treated subjects, but the facial convexity was maintained in untreated subjects. This suggests, similar to the aforementioned data, that the anteroposterior condition will not improve without intervention. Aslam et al “found that the prevalence of
malocclusion is not dependent on age”, however they also reported that of their 600 person sample, those younger than 20 years of age had a Class II prevalence of 27.5% and those over 50 years of age had a Class II prevalence of 34%, yet no statistics were run on these numbers to assess significance. This may suggest a trend for an increasing number of Class II patients as the age increases. Aslam et al findings were in agreement with Korkhaus’ work despite being in an older demographic. Korkhaus found that at age 6 the Class II prevalence was 7.2% yet at age 14 the percentage increased to 13.2%. This percent increase is similar to Dr. Angle who found 16.6% prevalence at age 6 and 23.8% at age 14. The increase of Class II presentations in the younger ages may be due to the primary second molar being present at the initial 6 year exam and a good Class I molar occlusion, then if premature loss of the maxillary primary second molar occurred the potential for space loss and presentation of a Class II malocclusion could contribute to the increase in Class II prevalence. A caveat to these concepts is the Class II malocclusion is a dental determinate, which can change with space loss, location of crowding, or similar factors. Therefore in defense of the above data, Emrich’s reports on the literature found conclusively that jaw relationships do not change with growth. A patient with a Class II maxillomandibular discrepancy will not outgrow the discrepancy, and similarly, the Class II dental malocclusion is unlikely to self-correct.

Briefly, Dr. Proffit reporting on data from the NHANES III survey found that an “overjet of 5 mm or more, suggesting Angle’s Class II malocclusion, occurs in 23% of children, 15% of youths, and 13% of adults”. These numbers suggest a decreasing occurrence, which would fit with our understanding of the influence of the cephalocaudal gradient growth and the effect this may have on facial shape and occlusal relationships. However a limiting factor can be that this
data is based on overjet, which is dependent on inclination of the anterior teeth, which may not necessarily reflect the molar relationships assessed in previous studies cited above.

1.4 Treatment Alternatives

In order to understand the underlying cause(s) of the patients’ malocclusion, a thorough review of the patients’ records, including but not limited to chief complaint, clinical photographs and radiographs, must be performed. Depending on the severity, etiology, and age of the patient, Class II malocclusion treatment options range from the common inter-arch elastic to the surgically invasive bilateral sagittal split osteotomy (BSSO) for a mandibular advancement. The following review has two sections: those patients who have finished somatic growth, and those who have growth remaining.

1.4.1 Non-Growing Patients

In a non-growing individual, the clinician may recommend a number of treatment alternatives, depending on the severity of the Class II malocclusion. A common therapy in a mild Class II dentition where the discrepancy from ideal is less than or equal to half a cusp width is the classic inter-ach elastic used in a Class II pattern from the maxillary anterior region to the mandibular posterior dentition. The use of elastics has been found to have side effects when correcting a Class II malocclusion as documented recently by Jayachandran et al. These side effects include:

- the extrusion and retroclination of the maxillary incisors that can increase the gingival display upon smiling and unaesthetic torque of the maxillary incisors,
- the proclination and protrusion of the lower incisors that can lead to significantly proclined lower incisors if used for an extensive period of time and even gingival recession if periodontal support is eroded,

- the extrusion of the mandibular posterior teeth which then causes a downward and backward rotation of the mandible leading to a shallow overbite and increased mandibular plane angle and the potential to increase the severity of the Class II malocclusion.

Dr. William Proffit recommends that Class II elastics be avoided in non-growing patients with facial features that would not tolerate some downward and backward rotation of the mandible. The length of time should be minimized such that the elastics are used to titrate the buccal interdigitation rather than be the driving force of anteroposterior correction. A recommendation of “3 or 4 months at the completion of treatment… is often acceptable”.

The use of elastics may be used in concert with a maxillary posterior distalizer – springs, clear aligners, or temporary anchorage devices (TADs) – in order to move the maxillary molar distal sufficiently to achieve a Class I molar relationship. The space opened by pushing the molar distally is then closed by retracting the premolars and incisors into a Class I relationship as well.

A clinician could potentially elect to use a Class II dental correction which is affixed to the archwire when using buccal fixed edgewise appliances (FEA) should patient compliance with elastic use become an issue, or some of the aforementioned side effects of elastics wish to be avoided. These correctors include appliances such as the Powerscope® and Forsus Fatigue.
Resistant Springs®. Another option that is similar but affixed to the teeth is the Herbst appliance. While the effects on the maxillary incisors and mandibular posterior teeth may be avoided, the proclination of the lower incisors can become more pronounced than had elastics been used, and the maxillary posterior may relatively intrude which can cause an increase in the overbite. Other adverse effects include the potential for a midline deviation if one side of the corrector is activated more than the other and increased emergencies due to breakage or patient discomfort.

A non-growing patient with a half cusp or more Class II molar and canine malocclusion may be presented with the treatment option of extraction of maxillary first premolars and space closure in order to camouflage the anterior-posterior discrepancy. By extracting the first premolars the maxillary canines can be retracted into the extraction space sufficiently to interdigitate into a Class I canine relationship. The remaining extraction space is then utilized to protract the maxillary posterior teeth until the molar settles into a full cusp Class II relationship – where the mesiobuccal cusp of the maxillary first molar occludes precisely between the mandibular first molar and second premolar. Although not an ideal Class I molar relationship, a well-interdigitated full cusp Class II molar relationship is stable and presents less occlusal interferences than a half cusp Class II relationship. Furthermore the Class I canine creates an ideal overjet situation as well as the possibility for a canine rise or group function excursive pattern. Proffit reports the extraction of upper first premolars to “be an excellent treatment method” when used in the right situations.

Should the clinician desire to complete treatment for the patient in a Class I molar and canine relationship, or sufficient crowding or other factors warrant extraction of dental units in the
mandibular arch, the clinician may opt for the extraction of not only the maxillary first premolars but also the mandibular second premolars. Such an extraction pattern allows the maxillary canines to be retracted as previously outlined, and the mandibular molars to be protracted into the extraction space of the second premolar. As long as the maxillary first molars are held in their initial position, or mesialization controlled relatively well, the mandibular molar will outpace the mesial movement and complete treatment with the mesiobuccal cusp of the maxillary molar occluding directly above the buccal groove of the mandibular first molar. Such an extraction pattern has the potential to increase the treatment time as each premolar extracted tends to increase the length of treatment by nearly 5 months, as reported by Janson et al. The two aforementioned treatment options of extractions also have the potential to adversely affect the facial profile if care is not taken during closure of the extraction sites; the upper lip may become more retrusive, the nasolabial angle more obtuse, the upper incisors excessively retrusive and or retroclined. As with any orthodontic treatment, case selection is critical in order to achieve ideal esthetic and functional outcomes when dental extractions are employed.

A BSSO mandibular advancement is a treatment modality with the potential to increase mandibular length and improve the facial profile in patients who present with mandibular retrognathia and a large overjet greater than 10 mm, or who are dissatisfied with their convex facial profile. Orthognathic surgery can be carried out in coordination with orthodontics that may or may not include extractions. A Class II skeletal discrepancy with minimal dental crowding, relatively acceptable maxillary and mandibular incisor positioning, and upper lip support can be treated with a BSSO advancement without extractions. Should the patient have a shorter lower facial third, the leveling of the Curve of Spee would be performed after the surgery.
in order to rotate the mandible down during the advancement, thus increasing the anterior lower face height.\textsuperscript{97} If attempting to maximize the amount of mandibular advancement or there is severe dental crowding, extraction of the maxillary second premolar and mandibular first premolars can be performed. By extracting the maxillary second premolar the maxillary first molar can be protracted, increasing the severity of the Class II molar relationship. The extraction of the mandibular first premolar allows for the mandibular incisor to be retracted, thus increasing the overjet and creating a more severe Class II canine relationship. This pre-surgical occlusion allows the oral surgeon to advance the mandible more than the initial overjet would have permitted.

As outlined, there are a plethora of treatment considerations to take into account when treating a non-growing orthodontic patient with a Class II malocclusion. Taking into consideration both the etiology – skeletal or dental – as well as the severity of the malocclusion will guide the treatment alternatives. Alternatives range from elastics requiring patient compliance, to a fixed Class II corrector requiring increased patient adaptability, to extractions in one or both arches, and to surgery with or without extractions. An open discussion and informed consent regarding the outcomes, both positive and adverse, will aid the clinician and patient in accomplishing a pleasing orthodontic finish.

1.4.2 Growing Patients

While some, if not all, of the previously discussed in Section 1.4.1 Non-growing Patients may be applicable to the growing patient, there is an additional treatment alternative that may be employed in the treatment of a Class II malocclusion: growth modification. Growth modification
is the effort to favorably induce a change in the patients’ growth pattern to create a more harmonious maxillomandibular relationship.

One method of growth modification is the use of a headgear appliance. Initially appearing in orthodontics in the late 19th century, only to be reintroduced in the mid-20th century with Dr. Kloehn demonstrating the clinical effects substantiated by cephalometric measurements.\(^3,70,71\) Headgear utilizes the cranium as an extra-oral anchor to pull against the maxilla. The goal is to control the forward (and occasionally the downward) growth of the maxilla. By controlling the forward growth of the maxilla, the mandible is given the opportunity to catch up in growth to the maxilla, thereby creating a more harmonious maxillomandibular relationship, even if both are retrusive.\(^122\) Interestingly enough, Keeling et al. found a slight increase in the amount of mandibular length increase when headgear and biteplane (sufficient to disarticulate the occlusion) was used.\(^68\)

Another method employed in an effort to improve the skeletal balance is the use of functional appliances. This group of appliances encourages the anterior or forward posturing of the mandible. The theory is that by posturing the mandible forward for an extended period of time, there will be favorable changes in the growth pattern of the mandible, the temporomandibular joint, and the maxilla.\(^33,104\) Such appliances have a history in the European orthodontic community and were subsequently adopted in North America.\(^97\) A brief review of some of the more commonly used appliances, their design, and effects will be carried out in the subsequent section: Section 1.5 Functional Appliances.
Growth modification is an attempt to achieve a favorable growth environment. Often the changes to either jaw induced by the appliances are relatively insignificant alone, but the combination of several factors result in a clinically acceptable result. Simply put “even though growth modification [alone] cannot be expected to totally correct an adolescent Class II problem [malocclusion], some forward movement of the mandible relative to the maxilla does contribute to successful treatment of the average patient. The rest of the correction must occur from some combination of retraction of the upper incisors and forward movement of the lower arch”.\textsuperscript{97}

1.5 Functional Appliances

1.5.1 Fixed Functional Appliances

There are various types of functional appliances; some of them are cemented to the teeth; such as the Mandibular Anterior Repositioning Appliance (MARA), and Herbst. Others are attached to the arch wire or bands on teeth, such as the Powerscope\textsuperscript{®} or Forsus\textsuperscript{®} appliances.

The MARA is considered an active appliance; it requires the patient to posture forward without the help of a spring/plunger to achieve a Class I occlusion.\textsuperscript{97} The Herbst on the other hand is a passive activator as the plunger/tube forces the mandible forward, removing patient compliance.\textsuperscript{97} Both appliances can be used without fixed edgewise appliances.

The Powerscope and Forsus\textsuperscript{®} appliances require the use of fixed edgewise appliances, on to which they are affixed. These appliances are further complicated by the fact that a sufficiently stiff arch wire needs to be in place prior to placement of the functional appliance. This delays the
treatment of the Class II relationship until the arches are sufficiently aligned to allow a straight stainless steel archwire to be placed.

Dr. Proffit suggests appliances that are tooth borne tend to produce more dental effects including retroclination of upper incisors and proclination of lower incisors. This claim is supported by the meta-analysis by Vaid et al in 2014 that found the lower incisors were significantly protruded with fixed functional appliances, but no similar significant effect occurred with removable appliances. As the fixed functional appliances eliminate non-compliance, their effects by being attached to the teeth can be more profound.

Zymerdikas et al found a “small inhibition of maxillary growth, small stimulation of mandibular growth, and with more pronounced dentoalveolar and soft tissue changes” but that these effects of fixed functional appliances were “small and probably of minor clinical importance”. The mean difference in common cephalometric variables between the changes observed in the functional and control groups were -0.83 degrees for SNA, +0.87 degrees for SNB, and the ANB was -1.74 degrees; the treatment groups showed an ANB decrease of 1.95 degrees.

A meta-analysis of the Herbst appliance found a mean decrease of 1.5 degrees in the ANB angle that rebounded, or rather, the ANB angle was found to increase by 0.2 degrees over the 34 months following active treatment. The overjet also decreased by an average of 6.5 mm during treatment, yet after 5 years had relapsed by 1.8 mm. The difference between Zymerdikas et al
and Bock et al of 0.65 degrees for ANB changes can be considered within the realm of tracing error, or due to the inclusion of multiple fixed appliances in the Zymperdikas et al review.

1.5.2 Removable Functional Appliances

Not all appliances are cemented to teeth or attached to arch wires. Some of these removable type of appliances include the Bionator, Functional Regulator-II (FR-II), and Twin Block appliances.

The Bionator appliance is a mono-block appliance made up of a single piece of acrylic that is worn intraorally. It uses an acrylic pad positioned lingual to the mandibular dentition that places an uncomfortable pressure on the friable mucosal tissues, thus encouraging the patient to posture the mandible forward. Furthermore posterior bite blocks and guide planes are commonly included in the appliance fabrication to encourage forward positioning of the mandible and mesial eruption of the mandibular posterior dentition.

The FR-II is similar to the Bionator but incorporates buccal and labial acrylic pads to relieve the soft tissue pressure of the cheeks and lips to allow passive expansion of the arches in both anteroposterior and transverse planes. It is also a mono-block appliance, with multiple acrylic portions interconnected via metal wires.

The Twin Block appliance, as its name suggests, is composed of two pieces – one removable appliance for the maxilla and one for the mandible. The maxillary and mandibular portions interdigitate via ramps or inclined planes on the molar region, typically manufactured at a 70-degree angle. It is considered an active appliance due to the requirement of the patient posturing
the mandible in an anterior position to engage the inclined planes. Expansion may be incorporated into the appliance in order to match the maxillary arch width to the mandibular arch width as the mandible is advanced. This expansion occurs by means of a midline expansion screw in the maxillary appliance with expansion occurring at a single quarter turn weekly to prevent the appliance expansion from outpacing the expansion expressed by the maxillary arch, and thus an inability to seat the appliance intraorally.

Early systematic reviews “found no significant difference between the untreated control group and the group treated with functional appliances”. The included studies primarily used the Bass, Bionator, and FR-II appliances with one study using the Twin Block appliance. Treatment varied from 6 months to 2 years with a wide variety of appliance wear instruction (14 hours per day to full-time). A review of the soft tissues later by Flores-Mir & Major reported that there is no evidence to suggest that Twin Block improves, nor negatively impacts the face, lips, or soft tissue. More recently D’Antò et al, reviewing systematic reviews, agreed by finding insufficient evidence to warrant any claims regarding the soft tissue profile effects of Class II functional appliances. They also found that small amounts of skeletal changes were reported but most studies consistently reported dentoalveolar changes to reduce the overjet and Class II relationship.

In a similar systematic review Cozza et al found the increase in mandibular length to be greater with the Herbst appliance (3.36 mm increase per year) than the Twin Block appliance (average increase of 2.76 mm per year) in randomized clinical trials (RCT), yet still reported no significant increase in mandibular length. However most of the included studies were
conducted on patients in the pre-pubertal stages of growth, and from Marsico et al it is evident that improved skeletal outcomes can be achieved in pubertal patients. The Herbst is a fixed appliance and therefore has some degree of bias and compliance variance compared with the Twin Block. Further undermining the idea that functional appliances do not significantly increase mandibular length, Cozza et al reported “two-thirds of the samples in the 22 studies reported clinically significant supplementary elongation in the total mandibular length”. More recently the Twin Block appliance was reported to increase mandibular length greater than any other appliance, with the exception of the Sander Bite Jumping appliance. The Sander Bite Jumping appliance was only described in 1 RCT while the Twin Block was investigated in 2 RCTs. Santamaria-Villegas et al also “found a statistically significant increase in mandibular length in the treated individuals” and stated “functional appliances have a favorable effect on the correction of mandibular retrognathia”. And compared to fixed functional appliances Pacha et al found that removable appliances (Twin Block & Activator) tended to decrease the ANB angle, increase the mandibular length, and offer less proclination and protrusion of the lower incisors than the fixed functional appliances (Herbst, Twin Force Bite Corrector, Forsus®). Such results are encouraging to the clinician looking to obtain an improved skeletal relationship in patients with a retrognathic mandible. This data is tempered however by a long-term study of removable and fixed functionals (Activators, Bionator, Functional Regulator-II, Herbst, and Forsus®) found that at age 18 (or when growth was completed as determined by the CVM) the ANB was a single degree less than the controls, the SNA angle was a degree less, the Co-Gn was 3 mm longer, the Wits had improved 2.5-3.5 mm and there was no significant positional changes for the mandible. As a caveat, the Twin Block was not included in this study. However in a systematic
review and meta-analysis of the short-term effects of the Twin Block appliance, an average increase in the mandibular length of 3 mm was reported.\textsuperscript{41}

A critical factor of functional appliance treatment is timing the initiation of treatment with the pubertal growth spurt of the patient. Marsico et al found that “when functional appliance treatment is provided in early adolescence, there are small beneficial changes in skeletal patterns, but these are probably not very clinically significant”.\textsuperscript{78} Early adolescence can be considered younger than 10 as the “two studies [that were] homogeneous [were] 9.57 years, whereas the others reported mean ages of 8.5 and 11.6 years”.\textsuperscript{78} This would suggest that treatment when the patient is compliant is better than no treatment at any age. Thus encouraging the clinician to treat the child when he or she is willing to undergo, and is motivated, to complete treatment. On the other hand, Baccetti et al in comparing an early-treated group (CVM 1 & 2) and a late-treated group (CVM 3-5) found that “optimum treatment timing for Twin-block therapy of Class II disharmony appears to be during or slightly after the onset of the pubertal peak in growth velocity” suggesting CVM 3 or later.\textsuperscript{12} This recommendation stems from their findings of 1) “greater skeletal contribution to the correction of the molar relation”, 2) clinically significant increases in mandibular length that were larger than the early-treated group, and 3) an improved distal direction of growth of the condyle.\textsuperscript{12} Their late-treated group started treatment at 12 years 11 months ± 1 year 2 months.\textsuperscript{12}

Utilizing the Cervical Vertebral Maturation method as a review and meta-analysis standard rather than chronological age, Perinetti et al stated “it appears that treatment outcomes favor initiation of treatment during puberty, when the CVM is Stage 3 or greater as the mandibular
length increases and the ANB decreases due to SNB and SNA changes were greater in the pubertal group as compared to the pre-pubertal group (CVM Stages 1 and 2)”.

No matter the timing or choice of appliance, “generally, full appliances supported by Class II elastics are the next step in treatment”.

1.5.2.1 Twin Block Appliance

The literature on the Twin Block appliance is quite extensive, partly due its popularity and ease of use, despite the inconclusive evidence supporting its effectiveness. Šidlauskas suggests the differing data may be due to “the use of not reliable reference lines and/or structures for cephalometric analysis before and after treatment”. The greater issue may lie in the fact that the cephalometric or clinical variables reported across studies vary nearly as much as the number of studies. Few studies use common variables to assess changes; for the upper incisor angulation there are those that measure the angle to Sella-Nasion, others to Frankfort Horizontal, other still to the Palatal/Maxillary plane or even the lower incisor. As such, systematic reviews are hard pressed to offer up any firm conclusions as each investigator uses different analysis.

Nevertheless, the soft tissue, dental, and skeletal effects of the Twin Block appliance, as reported in the literature, will be presented below for consideration.

Elfeky et al most recently found a significant improvement in facial soft tissue in both the anteroposterior and vertical planes – this was largely due to an increase in the mandibular length. Unfortunately this study looked solely at female patients and each was characterized as having a “steep” mandibular plane, with the average being 43 degrees. However Baysal & Uysal 2014,
looking at a mix of males and females with a more common mandibular plane angle (SN-MP of 31.2 degrees) also found the facial soft tissue to have improved in the vertical dimension, accompanied by a significant increase in the mandibular length (as measured from Co-Gn).\textsuperscript{16} The improvement in the anteroposterior direction is corroborated by Quintão et al who found the soft tissue pogonion was significantly advanced.\textsuperscript{101} Incorporating a portion of the retention period, the study of 28 patients treated with Twin Block for 9 months by Lee et al found the soft tissue pogonion came forward 5.11 mm relative to the tragus – pogonion line.\textsuperscript{75} In the following 3 months when the appliance was removed, the soft tissue pogonion relapsed 0.65 mm.\textsuperscript{75} Curiously enough, at the end of the 12 months of observation, the soft tissue pogonion was 6.99 mm forward of its initial position, suggesting growth occurred to supplement to the 5.11 mm of forward movement.\textsuperscript{75}

Lund and Sandler found a slight increase in the lower facial height that proved to be significant.\textsuperscript{77} Illing et al similarly found a significantly increased lower facial height with restraint of A-point in combination with an increased total facial height as well.\textsuperscript{63} According to Morris et al reporting on the same sample as Illing et al (1998), “the most significant effect found was the advancement and lengthening of the lower lip combined with some forward movement of the chin point and increase in all the facial height parameters”.\textsuperscript{83} This lengthening of the lower lip as a result of the lower face height increase decreases the amount of lower lip eversion. Baysal & Uysal support this in finding a statistically significant decrease in the convexity of the labiomen tal fold, corroborated by Varlik et al stating the labiomen tal fold “flattened”.\textsuperscript{17,120} This visually results in a more esthetic lower face by reducing the protrusion of the lower lip creating a balanced profile. Unfortunately Varlik et al also reported an increase in the nasolabial angle,
which if too obtuse can result in an unaesthetic facial profile. Therefore the Twin Block appliance offers a great many soft tissue improvements when treating a patient with a retrognathic mandible, however it also walks a fine line with regards to having an adverse effect on the nasolabial angle.

Baysal et al said it succinctly when they found the soft tissue profile improved with the use of the Twin Block appliance. No need to distinguish how much was anteroposterior or vertical, simply put, the profile improved. Their findings were with regards to a highly significant improvement in the Glabella – Subnasale – Soft Tissue Pogonion in the Twin Block treated group as compared to the control group. The Glabella – Subnasale – Soft Tissue Pogonion angle can be influenced by forward growth of the nose and chin, as well as forward and downward movement of the mandible (and thus soft tissues as well).

The Twin Block appliance is used in growing patients exhibiting a Class II skeletal and dental malocclusion. The goal is to establish a Class I dental occlusion and improve the skeletal relationship. Lund & Sandler (1998) in a study of 36 patients who wore the Twin Block appliance for on average a little over 10 months concluded the majority of Class II malocclusion correction was dental. O’Brien et al confirmed this in 2003 by stating the overjet reduction was “mainly due to dentoalveolar change (73%), with a small element of favorable skeletal change”. Šidlauskas on the other hand found the molar and overjet correction to be roughly 50% dental changes (44% and 60% for the molar and overjet, respectively). No matter the percentages the question remains, where does the dental correction occur?
Effects on the upper incisor vary but some report it only moves palatally. Unfortunately this claim falls short of providing sufficient information as the study used the Pitchfork analysis and therefore did not differentiate between retroclination and bodily movement of the upper incisor. Other investigators claim the only effect of the Twin Block appliance on the upper incisor is retroclination. Still others more recently have reported both retroclination and palatal movement of the upper incisors. As an aside, Gill & Lee in 2005 studied a modified Twin Block against the traditional Twin Block appliance. One of the modifications included the use of torquing springs on the palatal aspect of the upper incisors in an effort to avoid overly retroclining them; it was a success as the modified Twin Block showed a reduced amount of retroclination. A systematic review and meta-analysis of the Twin Block appliance in 2015 by Ehsani et al revealed an average of 9.2 degrees of retroclination for the upper incisor.

Effects on the lower incisor vary as much as the reports on the upper incisor. Jena et al in 2006 reported only labial movement of the incisor, but again use of the Pitchfork analysis prevented differentiation from proclination. Nevertheless their findings are corroborated by Baysal & Uysal in 2013. Interestingly enough, studies tend to conclude only labial repositioning of the lower incisor despite significant amounts of proclination. The amount of proclination ranges from 0.92 to 8.2 degrees, with an average across 11 studies of 3.37 degrees. Finally, Ehsani et al reported an average of 3.9 degrees of proclination of the lower incisor from their systematic review and meta-analysis.

Molar movement is corroborated by Elfeky et al, Tümer et al, and Ehsani et al finding the maxillary first molar distalizes and the lower first molar moves mesially. The vertical
movement of the molars on the other hand is quite variable as there is the option to trim the acrylic of the appliance in the posterior to allow for eruption of the molars. Baysal & Uysal in 2014 documented that the upper incisors, as well as molars did not extrude significantly as compared to the control sample.\textsuperscript{16} However the lower incisor extruded in the control group but not in the Twin Block group. There was also a significant decrease in the overbite in the Twin Block group, potentially from the lower incisor control of vertical eruption or leveling of a Curve of Spee. There was no acrylic coverage on the lower incisors but the Hawley used during retention had a bite plate, adding a confounder to the study.\textsuperscript{16}

Therefore it can be stated that the Twin Block appliance tends to retrocline and retrude the maxillary incisors, procline and protrude the lower incisors, distalize the maxillary first molar, and mesialize the mandibular first molar.

In the same year, and in contrast to Lund & Sandler (1998) who concluded the majority of Class II correction was dental, Mills & McCulloch (1998) concluded, “two-thirds of reduction in overjet could be accounted for by the forward growth of the mandible”.\textsuperscript{77,81} However Baysal & Uysal have thus far been the greatest proponents that the effects of the Twin Block appliance are skeletal by reporting in their 2014 article that at least 70% of the overjet and molar correction come from skeletal effects.\textsuperscript{16}

Various researchers have found the Twin Block appliance to have a headgear-like effect on the maxilla, causing restraint, inhibition or forward growth, or retracting the maxilla.\textsuperscript{17,25,81,101,117} However Jena et al in 2006 found that the Twin Block appliance did not restrict the maxilla.
significantly. Use of the Pitchfork analysis limits the variables through which the maxilla can be assessed, and furthermore, the sample was purely female which is not the only sex the Twin Block appliance is used on.

As the Twin Block postures the mandible forward, one would expect significant changes to the mandible as related to Sella-Nasion (SNB angle). Interestingly enough, while the SNB angle is reported to improve, there are also studies finding no difference in the SNB angle. This increase in SNB may be from a repositioning of the condyle within the temporomandibular joint to a more forward position as Elfeky et al reported when comparing the condyle of Twin Block patients to control subjects. However this forward repositioning is only one of multiple factors at play increasing the SNB angle. A significant increase in the mandibular length is also commonly reported in the literature and would improve the SNB angle. These increases range from 2.4 mm to 4.2 mm more than the average mandibular length increase seen in control samples during the adolescent growth period.

After reviewing its effects, how does the Twin Block appliance compare to other functional appliances? In the late 20th century, Illing et al reported the Twin Block appliance provided the most anterior movement of mandible as compared to both the Bass and Bionator appliances. A little less than a decade later in 2006, Jena et al found the Twin Block to be more adept than the Bionator in all variables related to Class II correction. Even more recently, Baysal & Uysal suggest the Twin Block appliance offers better skeletal correction than the Herbst appliance (a fixed Class II functional corrector). Some slight variations to the Twin Block appliance have popped up in an effort to extract more skeletal changes or mitigate the dental side effects. One
such technique involves incrementally advancing the mandible by adding acrylic to the bite ramps at recall visits. However, both Banks et al and Gill et al found that an incremental bite jump offered no better skeletal changes than a single maximum bite jump.\\(^{13,52}\)

Growth modification can be undertaken with various appliances and at varying times. The cervical vertebral method is a simple and reliable method of quantifying the skeletal maturation stage of a patient based on the shape of the cervical vertebrae.\\(^{12}\) There are six stages of vertebral maturation as identified by O’Reilly & Yanniello; 1-3 corresponds to accelerating growth, and 4-6 to the decelerating period.\\(^{90}\) “Pubertal growth peak occurs on average between vertebral stage 3 and 4”.\\(^{12}\) Some researchers report, “cervical spine growth stage does not influence the outcome of Twin-block functional appliance treatment”.\\(^{13}\) However, the focus of this study was not on the timing of treatment but rather incremental versus maximum bite advancement. Furthermore, there was no data shared, no confidence intervals, no explanation of how such a conclusion was made. Singh et al in 2010 looked specifically at the CVM and how it relates to Twin Block therapy outcomes in three groups with increasing skeletal maturity. Their first group was CVM 1 & 2, group 2 contained CVM 3 & 4, and group 3 cases were CVM 5 & 6. Unfortunately, their groups were poorly distributed and likely underpowered. Group 1 contained only 5 subjects, while the second group contained 29. As such their conclusion of ideal timing for functional therapy with the twin block appliance to be “during or slightly after pubertal growth spurt” should be viewed with caution.\\(^{113}\) Baccetti et al also looked specifically at the CVM and its influence on Twin Block treatment outcomes. Their finding of the “optimum treatment timing for Twin-block therapy of Class II disharmony appears to be during or slightly after the onset of the pubertal peak in growth velocity” corroborates Singh et al.\\(^{12}\) The claim corresponds to their
group of patients with CVM stages 3-5 with an average age of 12 years 11 months, which had 16 patients. Their early treatment group (CVM 1 & 2) sample of 21 was also much stronger than the sample size of 5 reported by Singh et al. Some of the recorded benefits of initiating treatment shortly after the onset of the pubertal peak include improved skeletal changes to support the molar change to Class I as well as significantly more increases in both mandibular length and ramus height. One possible explanation for the improved skeletal outcomes is the improved compliance of the older patients. However this is in stark contrast to Banks et al who found the younger patients (those younger than 12.3 years old) were three times more likely to complete treatment as compared to older patients. It may be that Baccetti et al only looked at patients who successfully completed treatment while Banks et al performed an intent-to-treat protocol, including patients who were non-compliant and did not have ideal outcomes.

Relapse is inevitable with any orthodontic treatment and Twin Block is no exception. As recently as 2020 it was reported that a year after 12 months of active Twin Block therapy, 75% of patients had overjet relapse (increase) of less than or equal to 1 mm. The average overjet reduction in this sample of 64 patients was an impressive 6.22 mm. Lee et al in 2007 found that among 28 patients on average only 1 mm of overjet relapse occurred during the 3 months immediately following appliance removal when no retention is given. Similar to Oliver 2020, the average relapse correction was 6 mm, however the range was 1 – 11 mm of overjet reduction – a byproduct of an intent-to-treat analysis. Although relapse does occur, the Twin Block appliance offers a considerable amount of correction with a minimal amount of relapse.
The overall treatment effects are summarized by Illing et al quite succinctly – the Twin Block appliance demonstrates changes, both dentally and skeletally, towards a Class I occlusion above that which controls exhibit.\textsuperscript{63}

1.6 Clear Aligner Therapy

An esthetic alternative to conventional metal fixed edgewise appliances for treatment of malocclusions is clear aligner therapy (CAT). These aligners are a series of removable appliances fabricated from thermoplastics, or similar materials, that are formed to models of the teeth. Each aligner is formed from a model with the teeth in incrementally improved positions, thus, as the patient transitions from one aligner to the next, the teeth are systematically moved to correct the malocclusion. Aligners are available through fabrication by the clinician, or through third party companies. As CAT is a relatively new treatment modality in comparison to the FEA (Invisalign\textsuperscript{®} released their initial product in 1999) research continues to be reviewed to provide the most current scientific evidence.\textsuperscript{67} Papageorgiou et al conducted a systematic review and meta-analyses of CAT as compared to FEA. They found that FEA offered superior outcomes based on the American Board of Orthodontics – Objective Grading Score.\textsuperscript{93} However this is clouded by the fact that overall the treatment length for CAT was shorter than FEA.\textsuperscript{93} Two of the studies reported four months more treatment time with FEA.\textsuperscript{93} This introduces a level of bias as all things being equal, the CAT patients could have undergone additional refinements, but the treatment was terminated. Of the eight components in the ABO-OGS (alignment, marginal ridges, buccolingual inclination, occlusal contacts, occlusal relationship, overjet, interproximal contacts, and root angulation) the FEA was moderately favored in the root angulation, overjet, and occlusal relationship.\textsuperscript{93} As the torque of the upper incisors may influence the overjet, it
should be noted that torque planned in CAT simulated outcomes is only expressed at 42%, with a range of 27.4% to 51.5%. There was no clarification on labial or palatal crown torque, nor on if the case was addressed with extractions or non-extraction. However the current data suggests that a reduction of overjet via retroclination of proclined upper incisors, without loss of torque control, is extremely difficult to accomplish with CAT.

### 1.6.1 Invisalign®

Align Technology is one of many companies supplying clinicians with CAT orthodontic appliances. Using a patented SmartTrack™ (LD30) material, present day Invisalign aligners are touted to be significantly improved from the previous aligner material Exceed30 (EX30). As previously mentioned, CAT continues to have difficulty with certain types of movements. Simon et al in 2014 found that specifically “upper incisor torque and pure premolar derotation are challenging movements” (with no indication of whether the incisor torque was facial or palatal. While molar distalization of more than 1.5 mm was quite effective with averages between 88.4% and 86.9%, with and without attachments, respectively. Molar distalization is one method of correcting the buccal occlusion of mild to moderate Class II to an ideal Class I in growing and or non-growing patients. By distalizing the upper molar an improved molar relationship is attained; premolars and anterior teeth are then retracted to close the space. A follow up in 2016 of the molar distalization effects, Ravera et al found the maxillary first molar was distalized on average 2.25 mm without significant changes to the vertical as measured by the SN-MP angle. There was no reference to the intended amount of distalization in this study.

Treatment with Invisalign® aligners continues to expand its range from cases with minor
malocclusions to cases requiring orthognathic surgery, dental extractions, and now to functional appliances for growing individuals exhibiting “mild to severe Class II” malocclusions.\textsuperscript{47}

1.6.1.1 \textbf{Invisalign® with Mandibular Advancement Feature}

Dr. Proffit states, “there is no reason that growth guidance with a functional removable appliance cannot be combined with active tooth movement produced by springs or screws”.\textsuperscript{97} If functional appliances can be conceivably be combined with hardware, why not with another medium such as plastics? Align Technology developed a functional appliance using their patented materials that combines the concepts of growth modification with active tooth movement in the anterior region. Released in late 2017, the Invisalign® with Mandibular Advancement Feature (IMAF) replicates the mechanism of action of functional appliances as it postures “the lower jaw forward”\textsuperscript{47}. It does so with inclined planes built into buccal “precision wings placed between the 1\textsuperscript{st} molar and premolars” which can only interlock when the patient postures the mandible forward – much like a Twin Block appliance.\textsuperscript{47}

According to Align Technology the IMAF is indicated in growing patients with mild to severely retrognathic Class II malocclusions who present in the permanent dentition or a very stable late mixed dentition where it is anticipated the primary second molars will persist for the duration of the advancement phase. One major contraindication is if there are any supernumerary teeth present buccal to the premolars or permanent first molar. This may be due to the position of the wings on the buccal surface of the aligners and thus potentially placing unwanted pressure in the region of the supernumerary teeth.
In addition to the contraindication regarding supernumerary teeth, there are certain conditions that require correction prior to treatment with the mandibular advancement feature. These include a posterior crossbite, an overbite $\geq 8\text{ mm}$, maxillary first molars rotated mesial in by $>20$ degrees, or an Angle Class II division 2 subdivision with minimal overjet. In each of these situations a pre-advancement phase of aligners are prescribed to correct the malocclusion to the degree that aligners with precision wings may be placed to advance and posture the mandible forward.

As the IMAF is a novel appliance, there currently is no independent data that has been published on the effectiveness of treatment. Align Technology released data from a multi-center (10) study of 40 patients who underwent orthodontic treatment with the IMAF. Their findings suggest a significant improvement in the overjet, molar relationship, ANB angle, Wits Appraisal, Convexity, Mandibular Length, and SNA angle.\textsuperscript{55} These results were secured online via a presentation by Dr. Barry Glaser at the American Association of Orthodontists conference in Los Angeles, California, U.S.A. in May of 2019. No control sample was included in the review, nor was there a comparison to any other functional appliance. As such, this study is positioned to increase the depth of review and comparison of the IMAF appliance.

1.7 Research Question
The purpose of this study is to compare the short-term skeletal, dental, and soft tissue effects of Invisalign® with the Mandibular Advancement Feature as compared to the Twin Block appliance and historical controls immediately following advancement as well as following
complete orthodontic treatment. The IMAF cases will complete orthodontic treatment with Invisalign® clear aligner therapy, and the TB cases with full fixed edgewise appliances.

1.7.1  Hypotheses

Null Hypothesis 1: There is no difference in the skeletal, dental, or soft tissue effects of the Invisalign® with Mandibular Advancement Feature as compared to the Twin Block appliance.

Null Hypothesis 2: There is no difference in the skeletal, dental, or soft tissue effects of the Invisalign® with Mandibular Advancement Feature as compared to historical controls.

Alternative Hypothesis 1: Invisalign® with Mandibular Advancement Feature has significant differences in the skeletal, dental, or soft tissue effects when compared to the Twin Block appliance.

Alternative Hypothesis 2: Invisalign® with Mandibular Advancement Feature has significant differences in the skeletal, dental, or soft tissue effects when compared to historical controls.

1.7.2  Study Aims

The effects of the two appliances and historical controls will be assessed using cephalometric measurements at three time points (T1 – pre-treatment, T2 – post-advancement, T3 – completion of comprehensive treatment) with the major outcome variables being the SNB and ANB angles, the overjet, the L1-MP angle, lower incisor protrusion (L1-NB, mm), and the Facial Convexity angle.
The SNB angle change will indicate the amount of anteroposterior improvement of the mandibular skeletal position in correcting the maxillomandibular discrepancy. The overjet will provide a measurement of dental improvement based on the treatment modality. The L1-MP angle and L1-NB (mm) will demonstrate the amount of deleterious effects the appliances had on the lower incisor angle with relation to the mandibular plane to provide dental compensation of a skeletal Class II maxillomandibular discrepancy. And finally the Facial Convexity angle will reveal the amount of improvement in the soft tissue profile as a result of treatment and/or growth.
Chapter 2: Methodology

2.1 Project Introduction

This project was conceived by Dr. Sandra Tai during her testing of the Mandibular Advancement Feature with Invisalign®. Development of the project occurred among Dr. Spencer Blackham, Dr. Benjamin Pliska, Dr. Sandra Tai and Dr. Bingshuang Zou.

2.1.1 Sample Size Calculation

Review of current literature regarding correction of Class II malocclusion with removable functional appliances indicated a change in ANB is commonly used to assess improvement in skeletal relationship. The change reported in ANB by three articles was 0.8, 2.3, and 2.46 degrees.\textsuperscript{14,63,65} The standard difference for these same articles was 1, 1.8, and 2.08 degrees, respectively.\textsuperscript{14,63,65} The average standard difference of these articles was 1.63 degrees. Using this value and a sample calculation \[N=2/(d^2) \times C\], (N is the number in each group, \(d\) is the standard difference, and \(c\) is a constant based on power and confidence), a sample size of at least 14 subjects per group was determined. The value of the constant is 17.8 for \(p = 0.01\) and a 95% Confidence Interval.\textsuperscript{121} A sample size of 14 subjects per group may be deemed sufficient with a homogeneous sample population. However due to the non-homogenous mix of the patient groups in Vancouver, British Columbia, Canada – being Asian, Middle Eastern, and Caucasian, among other, and in order to improve the Confidence Interval, as many as 50 consecutively treated subjects per group (roughly three times the sample size of 14) were proposed to be collected.
2.1.2 REB Approval

Ethical approval was acquired through the University of British Columbia Clinical Research Ethics Board portal (RISe) via approval numbers H18-00443 and H19-00644 with final approval occurring on March 21st, 2019.

2.2 Treatment Protocol

Dr. Sandra Tai treated all TB cases. IMAF cases were treated at the offices of Dr. Sandra Tai and Dr. Sam Daher. Lateral cephalometric radiographs and intraoral buccal photographs were taken prior to the initiation of treatment (T1), immediately following discontinuation of active advancement (T2), and at the completion of comprehensive treatment (T3) when applicable.

Protocol consistent between the IMAF and TB groups included the following:

- Correction was considered complete when the patient was in an anterior edge-to-edge relationship and the canine and molar relationship was corrected to Class I or super Class I without the appliance in place and without the ability to retract the mandible.
- Once correction was complete the appliance was discontinued entirely unless the premolars were in an Angle Class I relationship, at which point the appliance was worn at nighttime only until the initiation of Phase 2.

2.2.1 TB Protocol

The Twin Block appliance (Figure 2.1) was fabricated such that the inclined planes were 70 degrees to the plane of occlusion. The mandibular portion of the appliance had Adams clasps on the first premolars and a labial bow with acrylic from lateral incisor to lateral incisor. The maxillary portion of the appliance had Adams clasps on the first molars and first premolars. The
acrylic facing the occlusal surface of the lower dentition was periodically trimmed to theoretically allow for the eruption of the mandibular molars. There was a midline expansion screw (Hyrax type) that was activated one quarter turn by the patient once a week until the maxillary palatal cusps were over the mandibular buccal cusps, at which point expansion was discontinued but appliance wear continued as needed. Some appliances had a labial bow from canine to canine while some did not in order to accommodate brackets on the upper anterior teeth from lateral-to-lateral, or canine-to-canine if permanent canines were erupted. Some appliances also had ball clasps soldered to the maxillary first molar and mandibular first premolar Adams clasps for nighttime elastics worn from the ball clasps to keep the mandible engaged forward while the patient was sleeping. Furthermore, appliances for patients with a Class II division 2 classification – one with a Class II molar relationship but minimal overjet due to retroclined upper incisors – had an expansion screw in the anteroposterior direction just distal to the maxillary anteriors in order to increase the overjet. This increased overjet then matched the anteroposterior discrepancy of the molars. The advancement protocol was a single advancement taking the patient to an anterior edge-to-edge relationship (unless the overjet was larger than 6 mm, then advancement was carried out in 2 incremental advancements).

Once correction of the anteroposterior discrepancy was complete (as described in the protocol consistent between the TB and IMAF on page 36), a minimum of a two month pause in treatment was prescribed to allow the occlusion to settle and Phase 2 comprehensive treatment with Ormco Orthos (0.018” slot size) fixed edgewise appliance brackets was initiated when a complete permanent dentition (both upper and lower first molar to first molar) was present. The archwire sequence was 0.016” NiTi, 0.016” x 0.016” stainless steel, 0.016” x 0.022” stainless steel
finishing wire. There were very few exceptions when a larger finishing wire (0.017” x 0.025” stainless steel) was utilized. Class II elastics worn from the maxillary canine to the mandibular first molar were prescribed as needed. No interproximal reduction (IPR) was performed.

![Twin Block Functional Appliance](image)

Figure 2.1 Twin Block Appliance Design. Courtesy Dr. Sandra Tai

### 2.2.2 IMAF Protocol

The Mandibular Advancement Feature with Invisalign® performed on the included cases consisted of no pre-mandibular advancement (pre-MA) aligners. Align Technology currently offers pre-MA aligners without precision wings if any of the following 4 criteria are met:

1) Posterior crossbite – aligners provided to correct crossbite,

2) Deep bite $\geq 8$ mm – aligners provided to decrease overbite,
3) Maxillary first molars are rotated mesial in by $\geq 20$ degrees – aligners are provided to derotate the molars as during MA there is no movement on the first molars or second premolars/primary molars due to precision wings on the aligners,

4) Patient presents with an Angle Class II division 2 malocclusion with minimal overjet – aligners are provided to procline the upper incisors to provide at least 2 mm of overjet to accommodate advancement of the mandible.

The Invisalign® ClinCheck software expands the maxillary arch in order to create an ideal buccal overjet during advancement of the mandible, however no overcorrection is prescribed. Leveling and aligning – including the lower incisors – occurs during the MA phase without any IPR neither prescribed nor performed. The first molars and second premolars (or second primary molars) have no movement prescribed during the MA phase as the IMAF precision wings interfere with attachment placement and engagement (see Figure 2.2 and Figure 2.3). Dr. Sandra Tai had global preferences set for her ClinCheck software to expand in the posterior (premolars and molars) but to not have any expansion occur at the canines. No extrusion was programmed into the molars or premolars. Patients were instructed to change aligners every 7 days. The advancement protocol for the IMAF group was an advancement of 2mm every eight weeks. Advancement was discontinued when the molars were in an Angle Class I relationship and the patient could no longer retracted the mandible into a position of excess overjet. If the patient completed the supplied aligners but the aforementioned criteria was not met, additional aligners were requested until the patient was corrected to Class I molar with the inability to retract their mandible.
If the patient was overcorrected (Class III molar) then the mandibular advancement aligners were discontinued. If the patient was a Class I molar then the patient was instructed to wear the mandibular advancement aligners at nighttime only. There was an eight-week gap from the completion of the MA phase and Phase 2 treatment with Invisalign® clear aligner therapy in order to process the scan data, fine tune the ClinCheck software plan, and receive additional aligners. During Phase 2, patients were instructed to wear Class II intraoral elastics from a hook on the maxillary tray to a button bonded to the mandibular first molar buccal surface. The hook on the upper tray was in order to theoretically transmit the Class II force to the entire maxillary arch and therefore aid in overjet correction. The elastic was connected to a button on the mandibular first molar in order to minimize the amount of mesial force placed on the lower incisors as compared to if the elastic was connected to the mandibular aligner tray. When interproximal reduction was programmed into the treatment, there was either 0.2 mm (diamond embedded strip) or 0.5 mm (Brassler Extra Fine Needle Diamond #8392.31.016 bur) prescribed and performed.

Figure 2.2 Invisalign® with Mandibular Advancement. Courtesy Dr. James Andrews & Dr. Spencer Blackham
2.3 Sample Collection

The treatment sample (both TB and IMAF groups) were collected based on consecutively treated patients over a defined time period. Spencer Blackham went to the Richmond, British Columbia, Canada office of Dr. Sandra Tai for acquisition of records. General inclusion criteria stipulated that cases treated with IMAF must be treated in Phase 2 with Invisalign® and those cases treated with TB should have been treated with full fixed edgewise appliances. Furthermore, cases should have no missing radiographic records and no medical conditions, including but not limited to, a craniofacial syndrome, missing teeth, damage to jaw before/during treatment, bone metabolism conditions, etc.

Selected lateral cephalometric radiographs with a radiographic ruler taken on either a Sirona XG (if treated at Dr. Sandra Tai’s office) or a Sirona Orthophos SL (if treated at Dr. Sam Daher’s office) were exported from Tops Software (tops Software, Atlanta, Georgia, U.S.A.) using an anonymized naming system beginning with the IMAF sample as 001, 002, 003… 070 and TB.
sample beginning at 071, 072, 073… 126. Each radiograph was further named with a .1, .2, or .3 based on the associated time point (T1, T2, or T3, respectively). Radiograph files were uploaded to the secure University of British Columbia (UBC) Workspace server from the private practice for subsequent cephalometric tracing at the University of British Columbia. Photos from each time point were reviewed, when available, and molar classification noted in quarter cusp increments. Positive values signified an Angle Class II relationship, negative values signified an Angle Class III relationship, and 0 identified an Angle Class I molar relationship. A Microsoft® Excel® (Version 12.3.6/Microsoft® Excel® for Mac 2008) spreadsheet was created to record the following data:

- Anonymized subject number
- Date of Birth
- Sex
- Treatment Group
- Date of T1, T2, and T3 records
- Date of Initiation of Treatment, Discontinuation of Advancement, Initiation of Phase 2 (if different than discontinuation of advancement), and Removal of Appliances
- Molar classification at T1, T2, and T3

Anonymized files were downloaded and saved to the University of British Columbia Graduate Orthodontic server.
2.3.1 IMAF Sample

The IMAF sample was taken from two private practices located in Vancouver, British Columbia, Canada – Dr. Sandra Tai and Dr. Sam Daher. 70 IMAF cases were identified – 16 from Dr. Sam Daher’s practice and 54 from Dr. Sandra Tai’s – that had treatment initiated no earlier than January 1, 2015 and the last record taken no later than March 21, 2019. The following cases were excluded for the associated reasons:

- 26 were ongoing and thus only had T1 radiographs,
- 5 had no post-advancement records,
- 5 had previously been treated with the Twin Block appliance and were now attempting IMAF,
- 1 patient had been treated with headgear before IMAF and between the T1 and T2 radiograph, thus confounding the IMAF results,
- and 1 patient was transitioned from IMAF to fixed edgewise appliance without completing advancement and no T2 record was taken.

Following the application of exclusion criteria, 32 IMAF cases remained with T1 and T2 records, 19 of these also having T3 records following completion of treatment with Invisalign®. This final sample was derived from the two practices as follows:
## Phase 1 Cases with T1 & T2 Records

<table>
<thead>
<tr>
<th></th>
<th>Phase 1 Cases with T1 &amp; T2 Records</th>
<th>Comprehensive Cases having T3 Records As Well</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Sandra Tai</td>
<td>19</td>
<td>13</td>
</tr>
<tr>
<td>Dr. Sam Daher</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>19</td>
</tr>
</tbody>
</table>

Table 2.1 IMAF Sample Practice Distribution

### 2.3.2 TB Sample

The patient records of the practice of Dr. Sandra Tai were searched for children treated with a Twin Block appliance followed by fixed edgewise appliances between January 1, 2010 and December 31, 2015. A total of 81 patients who received treatment with the Twin Block appliance were identified. The following cases were excluded for the associated reasons:

- 2 were excluded due to having been previously treated with a Twin Block,
- 4 began treatment before the selection criteria and were receiving a repaired Twin Block,
- 35 had records which were unable to be located due to surname truncation,
- 1 had incomplete records (missing T2 record),
- 2 received confounding treatment (1 via headgear, 1 via upper first premolar extraction),
- and 5 received Invisalign® as a Phase 2 treatment.
A total of 32 TB cases remained with T1 and T2 records, 19 of these also having T3 records following completion of comprehensive orthodontic therapy with fixed edgewise appliances. The entirety of the TB sample was treated at Dr. Sandra Tai’s office.

2.3.3 Control Sample

The samples for the Control Group were acquired online from the American Association of Orthodontists Foundation (AAOF) Craniofacial Growth Legacy Collection. A digital search of the database was conducted to identify all Class II patients, as categorized by the Craniofacial Growth Legacy Collection. A thorough review of all the returned patients was carried out to identify a control sample that would longitudinally match the IMAF group by age and sex. Matching the Control sample to the IMAF sample was to allow for direct comparison to the novel Mandibular Advancement Feature, as no previous studies have compared its effects to controls at this time, and the fact that the Twin Block appliance has previously been compared to historical controls.\textsuperscript{12,81,109} The Control sample was the composite of patients from the following growth studies:

- Bolton Brush Growth Study Center at Case Western University,
- The University of Toronto Burlington Growth Study,
- The Oklahoma Denver Growth Study,
- The University of the Pacific Mathews Growth Study,
- The Michigan Growth Study at the University of Michigan,
- and The Oregon Growth Study at Oregon Health and Science University.
There were so few historical records that met the sex and age criteria at T1, T2, and T3 that was necessary to utilize multiple growth studies, furthermore, it was not feasible to also match the Controls to the IMAF group by ANB. To allow linear measurement comparisons despite differences in scaling between radiographs, the Control sample was preferentially selected for those with a Sella to Nasion distance provided (subsequently used as the tracing “ruler”) via the AAOF Craniofacial Growth Legacy Collection.

2.4 Cephalometric Tracing

Randomized numbering was generated by a research assistant. If each patient was given a random number but their multiple radiographs (XXX.1, XXX.2, and XXX.3) were still grouped under the random patient number, the observer (Spencer S. Blackham) could conceivably determine which radiograph was T1, T2, and T3. Therefore each file was assigned a random number instead of each patient in order to avoid the observer from becoming biased by the aforementioned concept. Anonymized files were copied into a second folder in order to avoid inadvertently deleting the original anonymized file during the renaming process. The copied files were then renamed according to the randomization, and randomization key was secured with password protection.

Mock patient files were created in Dolphin Imaging 11.7 Premium (Dolphin Digital Imaging and Management Solutions, Chatsworth, California, U.S.A.) with last name as the Ethics Approval numbers H18-00443 and H19-00644. Each radiograph file was then added to the mock patient under a new Time Point Tab. Each Time Point Tab contained a single radiograph. The Time Point Tab was named with the randomized number associated with the file being loaded into the
Additional “patients” with first names X, Y, and Z were created when the limit of 100 Time Point Tabs was reached within the first mock patient file within the Dolphin program.

2.4.1 Tracing Method

All radiographs were traced on the same computer under the same lighting conditions using contrast, gamma, and emboss image enhancers provided by Dolphin software. More specifically, by increasing the Gamma setting to approximately 80-95%, the soft tissue outline was enhanced. Increasing the Emboss setting to approximately 75-90% enhanced the mandible and hard tissue. Each setting was reverted to default before proceeding and/or saving the tracing. Dr. Spencer S. Blackham traced all the lateral cephalometric radiographs using the following cephalometric points in order:

- Ruler Point 1
- Ruler Point 2
- Porion
- Orbitale
  - The orbital and porion outline secondary points were adjusted at this point to line up with the associated structures
- PT (pterygomaxillary) point
- Sella
- Nasion
  - Cranial vault floor secondary points adjusted at this time
- Basion
  - Cranial base secondary points adjusted at this time
- Soft Tissue (ST) Glabella
- ST Nasion
- Bridge of Nose
  - Nasal bone secondary points adjusted at this time
- Tip of Nose
- Subnasale
- ST A Point
- Upper Lip
- Stomion Superior
  - Upper face ST secondary points adjusted at this time
- Stomion Inferior
- Lower Lip
- ST B Point
- ST Pogonion
- ST Gnathion
- ST Menton
  - Lower face ST secondary points adjusted at this time
- Throat Point
  - Throat secondary points adjusted at this time
- B Point
- Pogonion
- Gnathion
- Menton
- Gonion
- Ramus Point
- Mid-Ramus
- Sigmoid Notch
- Articulare
- Constructed Gonion
- Condylion
  - Mandible secondary points adjusted at this time
- A Point
- Anterior Nasal Spine
- Posterior Nasal Spine
  - Pterygomaxillary fissure secondary points adjusted at this time
- Upper 6 (1st Molar) Occlusal (meaning the mesiobuccal cusp)
- Lower 6 (1st Molar) Occlusal (meaning the mesiobuccal cusp)
- Distal (Cemento-enamel Junction) CEJ of the Upper 6 (1st Molar)
- Mesial CEJ of the Upper 6 (1st Molar)
- Distal CEJ of the Lower 6 (1st Molar)
- Mesial CEJ of the Lower 6 (1st Molar)
  - The 1st molar outlines were adjusted at this time
- Labial gingival border of the lower incisor
- Lower incisor tip
- Lower incisor apex
- Lingual gingival border of the lower incisor
Mandibular symphysis secondary points adjusted at this time

- Labial gingival border of the upper incisor
- Upper incisor tip
- Upper incisor apex
- Lingual gingival border of the upper incisor
  - Maxilla secondary points adjusted at this time
  - Overall tracing was reviewed at this point to identify errors prior to analysis

### 2.4.2 Reliability & Tracing

Approximately one-quarter of the x-rays were traced twice for reliability testing purposes. Five patients having T1, T2, and T3 lateral cephalometric radiographs, and three patients having T1 and T2 radiographs were randomly selected from each group. This totaled eight T1, eight T2, and five T3 radiographs retraced per group for a total of 63 radiographs with two sets of tracings for comparison. The duplicate radiographs were included in the randomized tracings such that there was no bias as to knowing which radiographs were being traced twice.

### 2.5 Cephalometric Analyses

Upon completion of tracings, a custom analysis (Blackham Analysis) was created by merging the American Board of Orthodontics (ABO) and the McKee analyses (See Appendix A), in combination with millimetric vertical and horizontal molar positioning measurements as follows:

- U6-PP vertical,
- L6-MP vertical,
- H-Perpendicular to the Mesial of the U6,
- U6 Distal to Occlusal Plane Perpendicular,
- H-Perpendicular to the Mesial of the L6,
- and L6 Distal to Occlusal Plane Perpendicular.

Each lateral cephalometric radiograph was then subjected to the custom analysis and results were exported to a Microsoft Excel spreadsheet with the randomized radiograph number in column A, and each subsequent variable in columns B, C, D, etc. De-blinding took place at this point by inserting a new column to the left of Column A (randomized number) and noting the anonymized patient and time point. This was accomplished by referencing the password protected coding sheet. Repeated subjects were noted with an asterisk (*) and appeared on a separate row immediately following the initial tracing. The measurements were then copied into a new sheet within the same file (thereby protecting the original data from deletion) and organized such that each subject occupied a single row, with each variable occurring as T1 in Column C, T2 in Column D, and T3 in Column E, and the Delta T2-T1 in Column F, Delta T3-T2 in Column G, and Delta T3-T1 in Column H; repeated until all variables were organized in said manner. (See Table 2.3) The document was password protected to prevent accidental and/or unwanted changes to the data.

<table>
<thead>
<tr>
<th>Anonymized</th>
<th>Randomized</th>
<th>Variable 1 T1</th>
<th>Variable 1 T2</th>
<th>Variable 1 T3</th>
<th>Delta T2-T1</th>
<th>Delta T3-T2</th>
<th>Delta T3-T1</th>
<th>Variable 2 T1</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>46</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>001*</td>
<td>29</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2.2 Example of Data Excel Sheet
2.5.1 Major Outcomes

Major outcomes include final or change in ANB angle (as well as SNB angle), overjet, lower incisor proclination (as measured by Lower Incisor to Mandibular Plane angle), lower incisor protrusion (as measured by Lower Incisor to NB, mm) and soft tissue facial convexity. An alpha (α) of 0.050 was set for statistical significance, while changes larger than 2 mm and 2 degrees were considered clinically significant, mirroring the clinical significance suggested by Vaid et al.\textsuperscript{119}

2.5.2 Minor Outcomes

Minor outcomes include final or change in overbite, upper incisor proclination and protrusion, mandibular length, skeletal convexity, and molar positioning. The other variables included in the ABO and McKee Analyses were included for completeness of the study.

2.6 Statistical analyses

A copy of the final data sheet was saved into a new, unprotected file for import into the statistical software. Statistical analyses were performed using IBM SPSS Statistics 25 (SPSS Inc., Chicago, Illinois, U.S.A.). Descriptive statistics (minimum, maximum, mean, standard deviation, Skewness Z-score, Kurtosis Z-score) for each group were run for each time point and saved. Paired Sample t-tests for testing the differences between time points, as well as between deltas, within each group were performed and saved. Because the set comparing T1 to T2 contained 32 subjects per group, and the set comparing T1 to T3 had the 19 completed subjects per group, no Bonferroni Correction on the p-value was necessary. An Analysis of Variance (ANOVA) was
performed for each variable, testing the differences between groups at each time point, as well as each delta, and saved. If statistical significance (set at \( p \leq 0.050 \)) was determined by the ANOVA test, a Tukey test was then performed to determine between which groups existed statistical significance (again set at \( p \leq 0.050 \)), and subsequently saved. Pearson Correlation Coefficient statistics were performed comparing select outcomes (T3-T1 and T2-T1) with select T1 variables. Box-plots of all variables were reviewed to identify outliers. The radiograph associated with each significant outlier was reviewed to determine if a landmark associated with the variable, or ruler point, was placed inappropriately. In order to minimize introduction of unwanted bias, no other landmarks were moved, nor was there an effort to “correct” the outlier if the observer (SSB) determined the landmark to be adequately placed from first impression. New cephalometric analyses (titled “Blackham Research”) were run and exported if any changes were made to the radiograph. The new measurements were copied into the data sheet that was subsequently saved as a post-outlier modified data file. Following completion of outlier review, the modified data sheet was imported into IBM SPSS Statistics 25 and statistics were re-run according to the aforementioned methodology.

2.7 Method error/reliability

Reliability testing was conducted using IBM SPSS Statistics 25 and Microsoft Excel. Scatter plots for the visualization of variability between repeat tracings (see Figures 3.1 through 3.4) were created in Microsoft Excel as recommended by Donatelli & Lee.\(^{37,38}\) Using Microsoft Excel, a Dahlberg’s Error was calculated for each variable by subtracting the first tracing value from the second tracing value and squaring the result; the squared value was then divided by twice the retraced sample size (N, sample size of 24 for T1 and T2, 15 for T3). The square root
of the sum of the squares/2N was calculated to give the final Dahlberg’s Error value. Further reliability testing was carried out using IBM SPSS Statistics 25 for Intraclass correlations (ICC), and an Independent Sample t-test for comparison of the differences of means between the initial and repeat tracings.
Chapter 3: Results

After running the statistical analysis, a review of the results should be completed. The average initial cephalometric measurements will be presented first, followed by the mean cephalometric changes as a result of growth and the advancement phase (phase 1 treatment). Subsequently the overall changes for those subjects who completed comprehensive (phase 2) orthodontic treatment will be outlined. A presentation of the correlations between variables will conclude this section.

3.1 Pooling of Sub-Groups

In order to assure consistency and allow for pooling, male and female cephalometric variables at T1 were compared. Furthermore, the initial presentation of those subjects who had only T1 and T2 records were compared to those who had T1, T2, and T3 records.

3.1.1 Males and Females

When all 96 (32 from each treatment group) males and females were compared at T1, there was no significant difference between them, suggesting that males and females may be pooled without significant confounding factors. For completeness, the males and females within each group were compared. The significant findings are shown in Table 3.1.

Within the TB group there was no significant difference between males and females.
In the IMAF group, the two sexes had significant difference of ANB and skeletal convexity values (p-value of 0.026 and 0.030 respectively). Despite being statistically significant the mean ANB and skeletal convexity values were of no clinical significance (< 2 degrees), and so pooling males and females of the IMAF group was deemed appropriate.

Males and females within the Control group showed significant differences of upper incisor protrusion (U1-APo), Lower 6 Distal to Occlusal Plane Perpendicular, as well as the Nasolabial Angle. Tracing of the most labially positioned incisor can be a confounder when a single incisor is blocked out and thus not be indicative of the true anterior dental positioning. Furthermore, the upper incisor to the Nasion – A-Point measurement showed no significant difference between males and females and so therefore, the upper incisor protrusion was not considered a significant variable. The Lower 6 Distal to Occlusal Plane Perpendicular (L6D to OPP) while statistically significant can be influenced as the occlusal plane tips clockwise or counter-clockwise, and again, the H-Perpendicular to Mesial of the Lower 6 was not significant, therefore L6D to OPP was not considered a significant variable between males and females. Finally the Nasolabial angle had such a wide standard deviation and was not a major outcome that it was not a weighty variable when deciding to pool the males and females. Therefore, with redundancies in place, the pooling of the males and females of the Control group was considered appropriate.
<table>
<thead>
<tr>
<th>Group; Variable</th>
<th>Male Mean ± SD</th>
<th>Female Mean ± SD</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMAF; ANB</td>
<td>5.52 ± 1.28</td>
<td>5.87 ± 2.35</td>
<td>0.026</td>
</tr>
<tr>
<td>IMAF; Skeletal Convexity</td>
<td>10.01 ± 4.30</td>
<td>10.25 ± 6.47</td>
<td>0.030</td>
</tr>
<tr>
<td>Control; U1-APo, mm</td>
<td>5.83 ± 1.60</td>
<td>7.18 ± 2.91</td>
<td>0.019</td>
</tr>
<tr>
<td>Control; L6D to OP Perp</td>
<td>40.00 ± 6.13</td>
<td>41.67 ± 3.40</td>
<td>0.039</td>
</tr>
<tr>
<td>Control; Nasolabial Angle</td>
<td>116.92 ± 7.09</td>
<td>115.23 ± 11.10</td>
<td>0.036</td>
</tr>
</tbody>
</table>

Table 3.1 Males and Females – Significant Variables at T1.

3.1.2 Phase 1 Patients (with T1 & T2 only) Compared to Comprehensively Treated Patients (with T1, T2, & T3)

All treated patients in this study underwent a Phase I treatment of mandibular advancement growth modification, and some of these patients went on to complete a second phase (Phase 2) of comprehensive treatment at the time of data collection. Overall the cases that had T3 records as compared to those that had only T1 and T2 records generally agreed with each other and were quite similar at T1 (See Table 3.2). The only significant difference between the two sub-groups at T1 was the CVMS (With T3: 3.18 ± 1.14; Without T3: 2.46 ± 1.27). The difference was deemed to not be clinically significant as both were near the growth spurt and the standard deviation was greater than one stage of maturation. Therefore the two sub-groups were pooled for analysis of the effects of Phase 1 treatment. It is assumed that all patients will eventually receive a second phase of comprehensive treatment as they further mature, as some were simply not yet old enough for Phase 2 treatment at the time of data collection.
The TB group showed significant differences between those patients with T3 records and those that did not have T3 records for both CVMS and the Left Molar Relationship at T1. While there was a difference between the CVMS means, both were prior to the pubertal growth spurt (CVMS 3) and therefore were pooled. The left molar relationship was also statistically different between the two sub-groups at T1, however the difference was approximately a quarter cusp and the standard deviations were both larger than a quarter cusp. The variable was not considered clinically relevant as to prohibit pooling of the groups. As all the cephalometric variables were statistically non-significant, the sub-groups were pooled.

The IMAF group showed a significant difference for the CVMS at T1 between patients with a final (T3) record and those who had only T1 and T2 records. Both sub-groups were near the growth spurt, therefore pooling could be considered appropriate.

The Control group showed no significant differences at T1 between those with T3 records and those without. Therefore there were no qualms about pooling the two sub-groups for T1 and T2 comparisons.
<table>
<thead>
<tr>
<th>Group; Variable</th>
<th>With T3 Mean ± SD</th>
<th>T1 &amp; T2 Only Mean ± SD</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All; CVMS</td>
<td>3.18 ± 1.14</td>
<td>2.46 ± 1.27</td>
<td>0.005</td>
</tr>
<tr>
<td>TB; CVMS</td>
<td>2.50 ± 1.25</td>
<td>1.62 ± 0.65</td>
<td>0.027</td>
</tr>
<tr>
<td>TB; Left Molar</td>
<td>0.92 ± 0.25</td>
<td>0.65 ± 0.38</td>
<td>0.022</td>
</tr>
<tr>
<td>IMAF; CVMS</td>
<td>3.63 ± 1.11</td>
<td>2.54 ± 1.27</td>
<td>0.016</td>
</tr>
</tbody>
</table>

Table 3.2 Patients With or Without T3 – Significant Variables at T1.

3.2 Reliability Testing

Reliability testing with paired t-tests resulted in no significant findings. This is expected as each of the samples consisted of the same radiographs. The tracing errors would need to be quite significant to produce significance with the paired t-tests.

In order to be thorough, intraclass correlation coefficients (ICC) were examined for the two data sets. Landis & Koch in 1977 report the following kappa values should be used when evaluating ICC results:

- Poor       $< 0.0$
- Slight     $0.0 – 0.20$
- Fair       $0.21 – 0.40$
- Moderate   $0.41 – 0.60$
The vast majority of kappa values for all variables at all time points were almost perfect correlation. Again, this is to be expected as the two sets of data are derived from the same radiographs traced by the same investigator. Ideally all variables should have an ICC value of 1.0, indicating perfect consistency in landmark identification, however there were six variables with less than “almost perfect” correlation. The significant results can be found in Appendix C.1 Significant Intraclass Correlation Coefficients.

The initial tracings were only “moderately” (kappa value: 0.506) correlated for the Midface Length (Co-A, mm). This less than ideal correlation could be due to A-point being a narrow spicule of bone, making it easily washed out under poor radiographic conditions. However, more than likely the landmark at fault is condylion as the initial mandibular length variable was also less than perfect (“substantial”, kappa value: 0.672). Mandibular length also uses condylion as a reference point. Condylion is likely the landmark that proved inconsistent due to its location at the most posterior superior position of the condylar head. This places it in the petrous portion of the cranium, leading to considerable overlap of osseous structures and therefore difficulty in consistently identifying its location. Curiously enough, the lower incisor extrusion relative to the mandibular plane was only “substantially” correlated (kappa value: 0.774) between repeated measurements.
After active advancement the only variable with a less than ideal correlation coefficient was the maxillary skeletal position (A-Na Perpendicular, mm) with a kappa value of 0.660. As previously discussed, A-point may be at fault here. The other possibility is the nasion perpendicular could become erroneous if the reference plane (Frankfort Horizontal) varies sufficiently. Frankfort Horizontal could be slightly off as porion, the distal landmark, sits in a very radioopaque area of the skull leading to difficulty in identification.

The final duplicate cephalograms showed less than “almost perfect” correlation in the nasolabial angle and the distal of the lower 6 to the occlusal plane perpendicular line, kappa values of 0.733 and 0.789, respectively. The nasolabial angle is the angle created by the upper lip, the subnasale, and the columella. The columella is likely the inaccurate point as the columella is long and begins an upwards turn at the tip, creating variability in placement. Finally, while the horizontal measurement for the lower 6 was found to be less than perfect, it was in the substantial category. Furthermore, there was redundancy built into the cephalometric analysis performed during this study by also using the H Perpendicular to the mesial of the lower 6, which was found to be almost perfect correlation between repeated measurements.

Donatelli & Lee suggest a scatter plot to be a highly effective way to assess consistency and reliability between repeat data sets.\textsuperscript{37-38} Below are two examples of variables with high correlation coefficients (SN-MP and L1-NB, mm; see Figure 3.1 and Figure 3.2, respectively), as well as two with low correlation coefficients (Midface Length and Nasolabial Angle; Figure 3.3 and Figure 3.4, respectively). As can be seen, high correlation variables tend to have the first and
second tracing measurements closely clustered. While in the low correlations there is a greater degree of separation between the two points.

Figure 3.1 SN-MP Angle with Almost Perfect Correlation Repeat Tracing Scatter Plot
Figure 3.2 L1-NB (mm) with Almost Perfect Correlation Repeat Tracing Scatter Plot
Figure 3.3 Midface Length (Co-A, mm) with Moderate Correlation Repeat Tracing Scatter Plot
The final reliability test performed was the Dahlberg’s Error test. This test gives a value indicative of the amount of discrepancy between the two samples, not just a significance value, correlation coefficient, or visual of the data. The results can be found in Appendix C.2

Dahlberg’s Error Test Results. The present study uses the criterion set by Cozza et al who stated that 2 mm was deemed clinically significant. In this light there were three variables with clinically significant error in reliability. The first was the nasolabial angle, which had variations between 3.7 and 5.3 degrees. As previously stated, the placement of columella is the most probable explanation. The upper incisor angle with Frankfort Horizontal varied between 1.77 and
2.44 degrees as well. However the upper incisor to both sella-nasion and palatal planes had deviations less than 2 degrees and so the redundancy of measurements was beneficial. Finally, the mandibular skeletal anteroposterior position varied by as much as 3.44 mm. Therefore not only should the changes of the sagittal position of the mandible be considered with their accompanying standard deviations, but the fact that this measurement can carry as much as 3.44 mm of error more anterior or posterior should be taken into consideration as well.

3.3 Initial (T1) Presentation

The IMAF group and Control group were age and gender matched; therefore there was no significant difference between the aforementioned two groups, yet they both differed significantly from the TB group – the TB group being significantly younger.

In general the patients of all three groups presented with Class II maxillomandibular discrepancies of varying degrees with associated dental compensations. A review of the specific characteristics follows as well as in Table 3.5.

3.3.1 Skeletal Presentation

Overall, the IMAF and TB groups initially presented with a significantly more Class II maxillomandibular discrepancy than the Control group. ANB, Skeletal Convexity, and Wits Appraisal were more Class II in the treatment groups than the controls, however the IMAF and TB groups were relatively similar to each other.
With regards to the vertical skeletal components, the SN-MP, FMA, and P-A Face Height had insignificant statistical differences between all three groups. Only SN-MP was slightly lower angle than the norm for all three groups. The LFH/TFH however – and subsequently the UFH/TFH – showed significant differences between the Control group and the other two groups.

All three groups were circumpubertal in skeletal maturation as measured by the CVMS. As the IMAF and Control groups were older chronologically, their CVMS was also significantly more advanced as compared to the TB group.

3.3.1.1 Maxilla

At T1, there were no significant differences in SNA or A-Na Perpendicular between any of the groups, with the maxilla being relatively well positioned. Yet the IMAF and TB groups (while statistically similar) were significantly shorter in Midface Length than the Control group, and all were shorter than the norm.

3.3.1.2 Mandible

The mandible at T1 was relatively retrusive (with regards to SNB norms) across all three groups, with no significant differences existing for the variables SNB or Pg-Na Perpendicular. The Mandibular Length of the IMAF and TB groups was statistically similar, but significantly shorter than the Control group. However, all three groups were shorter than the norm.
3.3.2 Dental Presentation

All three groups presented with more overjet than is ideal, yet the TB group presented with a severe overjet that was significantly more than the IMAF and Control groups (which were statistically similar). The overbite among the three groups was relatively similar, while being deeper than the ideal.

3.3.2.1 Maxillary Incisors

The upper incisors were relatively well positioned (compared to norms) in both anteroposterior and angulation measurements and showed no significant differences across the groups except for the U1-PP angulation and U1-APo positioning. In the aforementioned variables the TB group was significantly more proclined and protrusive as compared to the Control group. Of note is the redundancy of two additional variables reporting the upper incisor angulation, as well as an additional variable for the anteroposterior positioning, all showing no significant differences between the three groups.

3.3.2.2 Mandibular Incisors

As for the lower incisors, the IMAF group presented the most proclined and significantly more than the Control group, but relatively similar to the TB group. With regards to protrusion, all three groups were statistically similar (L1-NB was slightly more protrusive than normal but L1-APo was slightly retrusive). The Control groups showed significantly more extruded lower incisors at T1 as compared to the IMAF and TB groups.
3.3.2.3 Molar Presentation

IMAF and TB groups presented with approximately the same mean molar relationship on the right and left (three quarter cusp Class II, more than half cusp but less than full cusp Class II).

At T1 the U6’s of all groups began relatively similar to the norm with TB being significantly more intruded than the Control group but relatively similar to the IMAF group. The Control group U6’s were also significantly more anteriorly positioned as compared to the IMAF and TB groups. All three groups had L6’s that were relatively intruded as compared to the norm. IMAF and TB were significantly more intruded as compared to the Control group. Again, the L6’s of the Control group were significantly more anterior versus the IMAF and TB groups.

3.3.3 Soft Tissue

All three groups were more convex facially than the norm, and the TB and IMAF groups were significantly more convex than the Controls. The NLA was more obtuse than normal, but no significant differences between the groups. The UL to E-Plane was more protrusive than normal and only TB and the Controls differed significantly. LL to E-Plane was also protrusive as compared to the norm and all three groups were similar.

3.4 Phase 1 Treatment (T1 to T2) Results

Overall most variables showed improvement towards correction of a Class II maxillomandibular discrepancy through skeletal changes and dental compensations. Both IMAF and TB groups underwent active advancement for approximately the same amount of time (356 days, no statistically significant difference), although the standard deviation was quite large for each
The general changes as a result of the advancement phase are presented below. The exact values (T2 cephalometric measurement minus the T1 cephalometric measurement) can be found within Table 3.6 at the conclusion of this chapter.

3.4.1  **Skeletal Outcomes**

Use of IMAF or TB resulted in a significant decrease in the Skeletal Convexity, Wits Appraisal, as well as the ANB angle as compared to the Control group, and a significant improvement from T1 to T2 for the two treatment groups.

SN-MP, FMA, and P-A Face Height showed no significant changes for any of the groups, however the Control group showed a decrease in the vertical, while the TB showed an increase in the vertical skeletal component (SN-MP & FMA), causing the two groups to be significantly different from each other.

While all three groups increased in LFH/TFH (and therefore UFH/TFH decreased) there was no significant difference between any of the groups. However only the TB and Control groups showed significant increases in LFH from T1 to T2.

3.4.1.1  **Maxillary Changes**

SNA and A-Na Perpendicular were reduced in the treatment groups (IMAF & TB) while the Control group showed an increase. There was no significant difference between the groups or change from T1 to T2 for any of the groups. The Midface Length increased in all 3 groups and
although there was no significant difference in the amount of change, only the TB and Control groups changed significantly.

### 3.4.1.2 Mandibular Changes

With regards to the mandible, all groups showed a statistically significant increase in the SNB angle from T1 to T2. The anteroposterior position of the mandible (Pg-Na Perpendicular) showed increases across all groups but only IMAF and Control increased significantly. Finally, the mandibular length increased significantly for all groups, and TB increased significantly more than the IMAF and Control groups.

### 3.4.2 Dental Outcomes

The overjet showed significant differences between all groups with TB and IMAF decreasing significantly – TB significantly more than IMAF, and the Control group relatively unchanged. Similarly, the overbite was reduced in all groups but only the TB and IMAF groups decreased significantly, resulting in the TB being significantly more reduced than the Control group.

### 3.4.2.1 Maxillary Incisors

The upper incisors in treatment groups (IMAF and TB) tended to retrocline and become more retrusive, with the TB group showing the greatest, and significant, amount of retroclination and retrusion. The Control group became slightly more protrusive and proclined during the same time period (T1 to T2).
3.4.2.2 Mandibular Incisors

The lower incisors in the IMAF group showed no significant degree of proclination (L1-MP), protrusion with regards to L1-NB (mm), or extrusion (L1-MP, mm). The IMAF lower incisors however did show a significant amount of protrusion based on L1-APo (mm). The TB group became significantly more protrusive and showed a significant amount of extrusion that was similar to that of the Control group. The TB group did not procline significantly. The lower incisors within the Control group showed minimal change in proclination and protrusion yet extruded a statistically significant amount.

3.4.2.3 Molar Changes

The U6 showed minimal extrusion in the IMAF group, but a significant amount of extrusion in the TB group that was comparable to the Control group. The U6 tended to move in a mesial direction in all groups. The L6 showed a significant amount of extrusion and mesial movement in all groups.

Both IMAF and TB groups demonstrated a significant improvement towards a Class I molar relationship with TB showing a statistically significant greater improvement.

3.4.3 Soft Tissue Outcomes

Facial Convexity was significantly decreased in both IMAF and TB groups while the Control group showed minimal changes. The NLA and LL to E-Plane was relatively unchanged in any of the groups. The UL to E-Plane however showed significant retraction in all groups with TB
showing the greatest amount. However, there was no significant difference in the amount of change between the groups.

3.5 Final (T1 to T3) Results

Most variables showed a continued improvement towards correction of a Class II malocclusion through both skeletal changes and dental compensations. The Phase 2, or time between T2 and T3 was significantly longer for the TB group as compared to the IMAF group, and therefore the Control group (as the Control was age matched to the IMAF group). As would be expected, all groups aged significantly both chronologically and skeletally (CVMS) over the course of the study. The overview of the changes as a result of growth and continued orthodontic treatment are presented below. The exact values of T3 minus T2 for the Phase 2 change, and T3 minus T1 for the overall change can be found within Table 3.7 and Table 3.8 at the conclusion of this Chapter.

3.5.1 Skeletal Outcomes

Both IMAF and TB groups decreased in Skeletal Convexity and ANB values during Phase 2 and the resultant change overall was significant. The control group demonstrated similar changes, also significant, over the same time period as the IMAF group. The Wits Appraisal also continued to improve towards a Class I value during Phase 2 or observation, however only the treatment groups (IMAF and TB) showed significant improvements overall.

There was minimal change in the SN-MP, FMA, and P-A Face Height during Phase 2 and no significant changes overall. (As a caveat, there may be a case for statistical significance in the overall change of FMA in the Control group). The LFH/TFH increased in Phase 2 for the
treatment groups and remained relatively unchanged in the Control group. The overall increase in LFH was statistically significant for IMAF and TB groups. (The opposite change in the TFH also holds true).

3.5.1.1 Maxillary Changes
The SNA angle continued to decrease during Phase 2, but only the TB group showed a significant decrease in the SNA angle overall. While there were minimal changes in the Maxillary Skeletal position (A-Na Perpendicular) during Phase 2, overall the treatment groups tended to become more retrusive and the Control group became more protrusive, although no statistically significant changes occurred. The Midface Length increased in all groups and demonstrated a significant change from T1 to T3.

3.5.1.2 Mandibular Changes
With regards to mandibular positioning, during Phase 2 the SNB angle was relatively unchanged in the IMAF group, the TB group became slightly smaller (more retrusive), and the Control group increased (more protrusive). Overall only the IMAF and Control groups showed statistically significant increases in the SNB angle. The Pg-Na Perpendicular values increased during Phase 2, and overall, for all groups. The only statistically significant increase overall occurred within the Control group. The mandibular length increased significantly in all groups during the course of the study, and increases occurred in all groups during Phase 2, though not significantly more than during the advancement phase.
3.5.2 Dental Outcomes

The overjet and overbite continued to decrease during Phase 2 among all groups. The overjet reduction during Phase 2 was significantly less than during the advancement phase for the IMAF and TB groups. Overall only the IMAF and TB groups demonstrated significant decreases in the overjet and overbite from T1 to T3.

3.5.2.1 Maxillary Incisors

The upper incisor angulation remained relatively unchanged during from T2 to T3, however overall the treatment groups showed some retroclination and the Control group demonstrated some proclination. None of these changes were significant. Upper incisor positioning relative to the NA line during Phase 2 tended to become more protrusive but from T1 to T3 the treatment groups tended to become more retrusive while the Control group become more protrusive. None of these changes were significant. However upper incisor relative to APo showed all groups becoming more retrusive during both Phase 2 and overall. Only the treatment groups showed significant retraction from T1 to T3.

3.5.2.2 Mandibular Incisors

Lower incisors tended to procline during Phase 2. Overall the IMAF group angulation remained relatively unchanged, the TB group proclined, and the Control group was retroclined. Only the TB group showed a significant change from T1 to T3. The AP position of the lower incisors tended to become more protrusive during Phase 2 and overall, yet only the treatment groups protruded significantly. All groups demonstrated extrusion during Phase 2 and overall, however only the TB and Control groups showed significant extrusion from T1 to T3.
3.5.2.3 Molar Changes

Right and left molar relationships continued to improve in the IMAF group but relapsed slightly with the TB group during Phase 2. Overall there was a significant improvement in both groups. Upper and lower first molars continued to extrude during Phase 2 and overall there was significant extrusion in all groups. Upper and lower first molars moved mesial during Phase 2 and overall all groups had a significant amount of mesial movement – one of two measurements for the upper first molar was not statistically significant for overall mesial movement, while the other was.

3.5.3 Soft Tissue Outcomes

The Facial Convexity continued to decrease during Phase 2 for all groups but only the treatment groups showed significant improvements at T3 over T1. The NLA became more acute during Phase 2 but overall tended to become more obtuse throughout treatment – the IMAF group at T3 was approximately the same NLA as at T1. Both upper and lower lips became more retrusive to the E-Plane during Phase 2 as well as overall. Only the Control group demonstrated significant retraction of the lower lip from T1 to T3, however all three groups retracted the upper lip significantly from T1 to T3.

3.6 Variable Correlation

Pearson Correlation statistical analysis was performed to determine correlation between specific overall (T3-T1) changes and various initial variables for both IMAF and TB groups. These outcome variables were chosen because they had clinically relevant changes that occurred as a
result of treatment. The T1 variables selected for correlation testing were chosen with the express purpose of exploring the explanation of variance of said variables on the outcome. Charts with the outcome variables and the T1 variables showing significant correlation for IMAF group and TB group, along with the r-value and significance can be found in Tables 3.3 and 3.4, respectively. Evans suggests interpreting Pearson Correlation absolute r-values based on the following ranges and associated strength of correlation:

- 0.00-0.19 “very weak”
- 0.20-0.39 “weak”
- 0.40-0.59 “moderate”
- 0.60-0.79 “strong”
- 0.80-1.0 “very strong”

3.6.1 Lower Incisor Proclination

3.6.1.1 IMAF Correlations

Lower incisor overall proclination was correlated with the following initial characteristics:

- Strong Correlations:
  - The more proclined the incisors began, the less proclination occurred, and
  - the more protruded (L1-APo) the incisors began, the less they proclined.

- Moderate Correlations
  - The more protruded (L1-NB) the incisors began, the less they proclined,
  - the larger the overjet, the more the incisors proclined,
the greater the ANB angle, the more the incisors proclined, and
the longer the patient wore the advancing appliance, the more the lower incisors proclined.

3.6.1.2 TB Correlations

- Strong Correlations:
  - The greater the initial proclination of the lower incisor, the less the lower incisors proclined during treatment.

3.6.2 Overjet

3.6.2.1 IMAF Correlations

Overjet reduction was found to correlate with the following initial variables:

- Very Strong Correlations:
  - The larger the overjet, the greater the reduction.

- Moderate Correlations:
  - The more Class II the Wits Appraisal, the larger the overjet reduction, and
  - the more protruded (U1-APo) the upper incisors, the greater the overjet reduction.

3.6.2.2 TB Correlations

- Very Strong Correlations:
  - The larger the initial overjet, the more reduction occurred.

- Strong Correlations:
The more protrusive (U1-APo) the upper incisor began, the greater the amount of overjet reduction during the course of treatment.

3.6.3 Mandibular Length

3.6.3.1 IMAF Correlations
Mandibular length increase was correlated with the following initial variables:

- Moderate Correlations:
  
  o The longer the initial length of the mandible the less the mandible increased in length, and
  
  o the older the patient the less the mandible increased in length.

3.6.3.2 TB Correlations

- Moderate Correlations:
  
  o The longer the initial mandibular length, the less the mandible tended to increase in length,
  
  o the older patients tended to demonstrate less mandibular length increase, and
  
  o the greater the extrusion of the lower incisor, L1-MP (mm), resulted in a smaller amount of mandibular length increase.

3.6.4 Upper Incisor Protrusion

3.6.4.1 IMAF Correlations
Upper incisor protrusion (U1-APo, mm) correlated with the initial variables found below:

• Very Strong Correlations:
  o The larger the overjet, the greater the retraction of the upper incisor, and
  o the greater the Wits Appraisal (more Class II), the more the upper incisor was retracted.
• Moderate Correlation:
  o The more protrusive the upper incisor was at initial resulted in a greater amount of retraction of the upper incisor.

3.6.4.2 TB Correlations

• Moderate Correlations:
  o Upper incisors that started treatment more protrusive tended to demonstrate a greater reduction in upper incisor protrusion,
  o a patient with a larger overjet exhibited a larger reduction in upper incisor protrusion, and
  o the more proclined the lower incisor, the more the upper incisor was retracted.

3.6.5 Lower Incisor Protrusion (L1-NB & L1-APo) and Vertical

3.6.5.1 IMAF Correlations

Lower incisor positioning correlated with the following initial variables:

• Strong Correlations:
  o The greater the L1-MP angle, the less the incisors protruded (L1-APo & L1-NB).
• Moderate Correlations:
  o The more Class II the Wits Appraisal, the less the incisors extruded, and
  o the greater the mandibular plane angle the more the lower incisor protruded (L1-APo).

3.6.5.2 TB Correlations

• Strong Correlations:
  o The greater the L1-MP angle, the less the incisors protruded (L1-NB & L1-APo).

• Moderate Correlations:
  o The older the patient, the less the incisor protruded (L1-NB & L1-APo) and extruded,
  o the greater the overjet, the more the incisor protruded (L1-NB),
  o the deeper (greater) the overbite, the less the lower incisor extruded relative to the mandibular plane, and
  o the longer the mandible, the less the lower incisor extruded relative to the mandibular plane.

3.6.6 Molar Movements

3.6.6.1 IMAF Correlations
Molar positioning correlated with the following initial variables:

• Moderate Correlations:
  o The steeper the mandibular plane angle, the more the lower first molar extruded,
o the longer the mandible and older the patient, the less mesial movement of the maxillary and mandibular first molars occurred, and

o the further the upper and lower first molars began from the occlusal plane perpendicular, the less they moved mesially over the course of treatment.

3.6.6.2 TB Correlations

• Moderate Correlations:

o The longer the mandible and older the patient, the less extrusion of the maxillary molar occurred,

o the greater the initial distance of the upper first molar to the palatal plane, the less the maxillary first molar extruded,

o the longer the second phase of treatment, the more the lower first molar erupted relative to the mandibular plane,

o the greater the ANB angle and Wits Appraisal, the more the lower first molar erupted relative to the mandibular plane, and

o the further the lower first molar started from the occlusal plane perpendicular, the less it tended to move mesially.

3.6.7 Facial Convexity

Facial Convexity changes for either IMAF or TB were not found to significantly correlate with any of the tested initial variables.
### IMAF Correlations

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>T1 Variable</th>
<th>r; Pearson Correlation</th>
<th>p Value</th>
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Table 3.3 Significant IMAF Correlations
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<th>( p ) Value</th>
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<td>-0.597 &amp; -0.654</td>
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<tr>
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Table 3.4 Significant TB Correlations
### T1 Presentation

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<th>IMAF</th>
<th>TB</th>
<th>CONTROL</th>
<th>IMAF v. TB</th>
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<th>TB v. Control</th>
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<tr>
<td>CVMS</td>
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<td>3.32 ± 0.98</td>
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<td>**</td>
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</tr>
<tr>
<td><strong>SKELETAL</strong></td>
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<td>ANB</td>
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<td>29.0</td>
<td>27.86 ± 3.05</td>
<td>27.57 ± 2.90</td>
<td>29.61 ± 2.50</td>
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<tr>
<td>H Perpendicular to MU6</td>
<td>38.86 ± 4.01</td>
<td>39.41 ± 4.52</td>
<td>43.82 ± 4.62</td>
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<tr>
<td>U6D to OP Perpendicular</td>
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<td>37.75 ± 4.33</td>
<td>41.58 ± 4.37</td>
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<td>** **</td>
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<tr>
<td>H Perpendicular to ML6</td>
<td>34.77 ± 4.79</td>
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<td>L6D to OP Perpendicular</td>
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<td>35.27 ± 4.46</td>
<td>40.78 ± 5.03</td>
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<td>Facial Convexity</td>
<td>22.50 ± 4.93</td>
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<td>Nasolabial Angle</td>
<td>118.30 ± 10.85</td>
<td>116.13 ± 9.07</td>
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<td>UL to E-Plane</td>
<td>-1.13 ± 2.93</td>
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<td>LL to E-Plane</td>
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Table 3.5 T1 Presentation. NS: Non-significant, *: p ≤ 0.05, **: p ≤ 0.01
### Phase 1 Changes (T2-T1)

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<tr>
<th>VARIABLE</th>
<th>IMAF</th>
<th>TB</th>
<th>CONTROL</th>
<th>IMAF v. TB</th>
<th>IMAF v. Control</th>
<th>TB v. Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.98 ± 0.40</td>
<td>1.33 ± 0.61</td>
<td>1.02 ± 0.39</td>
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<td>**</td>
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<tr>
<td>Advancement Period</td>
<td>356.53 ± 145.41</td>
<td>356.75 ± 154.65</td>
<td>NS</td>
<td>** NS</td>
<td>**</td>
<td>**</td>
</tr>
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</tr>
<tr>
<td>ANB</td>
<td>-1.11 ± 0.96 **</td>
<td>-1.16 ± 0.98 **</td>
<td>-0.20 ± 0.90</td>
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<tr>
<td>Skeletal Convexity</td>
<td>-2.54 ± 2.35 **</td>
<td>-2.38 ± 2.20 **</td>
<td>-0.60 ± 1.94</td>
<td>NS</td>
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<td>**</td>
</tr>
<tr>
<td>Wits Appraisal</td>
<td>-2.42 ± 1.99 **</td>
<td>-2.24 ± 2.04 **</td>
<td>0.41 ± 2.22</td>
<td>NS</td>
<td>**</td>
<td>**</td>
</tr>
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<td>SN-MP</td>
<td>-0.03 ± 1.78</td>
<td>0.68 ± 2.02</td>
<td>-0.58 ± 2.06</td>
<td>NS</td>
<td>NS</td>
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<tr>
<td>FMA</td>
<td>0.00 ± 1.81</td>
<td>0.68 ± 2.36</td>
<td>-0.65 ± 1.97</td>
<td>NS</td>
<td>NS</td>
<td>*</td>
</tr>
<tr>
<td>P-A Face Height</td>
<td>0.20 ± 1.73</td>
<td>0.28 ± 1.85</td>
<td>0.55 ± 1.82</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
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<tr>
<td>LFH/TFH</td>
<td>0.34 ± 1.05</td>
<td>0.64 ± 1.23 **</td>
<td>0.51 ± 1.00 **</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
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<tr>
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<td>-0.34 ± 1.05</td>
<td>-0.64 ± 1.23 **</td>
<td>-0.51 ± 1.00 **</td>
<td>NS</td>
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<tr>
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<td>SNA</td>
<td>-0.20 ± 1.71</td>
<td>-0.33 ± 1.13</td>
<td>0.24 ± 1.41</td>
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<td>NS</td>
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<tr>
<td>A-Na Perpendicular</td>
<td>-0.24 ± 2.01</td>
<td>-0.27 ± 1.82</td>
<td>0.48 ± 2.34</td>
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<td>NS</td>
<td>NS</td>
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<tr>
<td>Midface Length</td>
<td>0.77 ± 2.57</td>
<td>2.28 ± 2.60 **</td>
<td>1.65 ± 3.05 **</td>
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<td>SNB</td>
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<td>0.83 ± 1.14 **</td>
<td>0.44 ± 0.99 *</td>
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<tr>
<td>Pg-Na Perpendicular</td>
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<td>0.93 ± 3.40</td>
<td>1.42 ± 3.94 *</td>
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<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Mandibular Length</td>
<td>3.35 ± 3.40 **</td>
<td>5.57 ± 3.19 **</td>
<td>3.02 ± 3.10 **</td>
<td>*</td>
<td>NS</td>
<td>**</td>
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</tr>
<tr>
<td>Overjet</td>
<td>-1.83 ± 1.52 **</td>
<td>-3.57 ± 2.29 **</td>
<td>-0.02 ± 0.95</td>
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<tr>
<td>Overbite</td>
<td>-1.13 ± 1.65 **</td>
<td>-1.67 ± 1.80 **</td>
<td>-0.21 ± 1.25</td>
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<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>U1-SN</td>
<td>-0.52 ± 7.13</td>
<td>-4.42 ± 5.66 **</td>
<td>0.73 ± 3.11</td>
<td>*</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>U1-FH</td>
<td>-0.56 ± 7.43</td>
<td>-4.46 ± 5.94 **</td>
<td>0.96 ± 3.14</td>
<td>*</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>U1-PP</td>
<td>-0.14 ± 7.13</td>
<td>-4.45 ± 5.77 **</td>
<td>0.56 ± 3.11</td>
<td>**</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>U1-NA (mm)</td>
<td>-0.06 ± 1.88</td>
<td>-1.24 ± 1.63 **</td>
<td>0.16 ± 1.20</td>
<td>*</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>U1-APo (mm)</td>
<td>-0.92 ± 1.56 **</td>
<td>-1.98 ± 1.68 **</td>
<td>-0.09 ± 0.69</td>
<td>**</td>
<td>*</td>
<td>**</td>
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<tr>
<td>L1-MP</td>
<td>-0.58 ± 4.33</td>
<td>1.48 ± 4.50</td>
<td>-0.69 ± 3.22</td>
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<td>NS</td>
<td>NS</td>
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<td>L1-NB (mm)</td>
<td>0.41 ± 1.33</td>
<td>1.08 ± 1.16 **</td>
<td>-0.06 ± 0.71</td>
<td>*</td>
<td>NS</td>
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</tr>
<tr>
<td>L1-APo (mm)</td>
<td>1.09 ± 1.36 **</td>
<td>1.77 ± 1.41 **</td>
<td>-0.09 ± 0.83</td>
<td>NS</td>
<td>NS</td>
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</tr>
<tr>
<td>L1-MP (mm)</td>
<td>0.25 ± 1.68</td>
<td>1.16 ± 1.15 **</td>
<td>0.95 ± 1.25 **</td>
<td>*</td>
<td>NS</td>
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<tr>
<td>Right Molar</td>
<td>-0.63 ± 0.38 **</td>
<td>-0.85 ± 0.42 **</td>
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<tr>
<td>Left Molar</td>
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<td>-0.80 ± 0.41 **</td>
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<tr>
<td>U6-PP</td>
<td>0.46 ± 1.56</td>
<td>1.13 ± 1.13 **</td>
<td>1.38 ± 1.60 **</td>
<td>NS</td>
<td>*</td>
<td>NS</td>
</tr>
<tr>
<td>L6-MP</td>
<td>1.37 ± 1.45 **</td>
<td>2.22 ± 1.41 **</td>
<td>0.84 ± 1.32 **</td>
<td>*</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>H Perpendicular to MU6</td>
<td>0.94 ± 1.96 *</td>
<td>0.79 ± 2.20 *</td>
<td>1.32 ± 2.10 **</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
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<tr>
<td>U6D to OP Perpendicular</td>
<td>1.84 ± 3.13 **</td>
<td>2.03 ± 1.73 **</td>
<td>0.50 ± 2.53</td>
<td>NS</td>
<td>NS</td>
<td>*</td>
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<tr>
<td>H Perpendicular to ML6</td>
<td>2.78 ± 2.29 **</td>
<td>3.48 ± 2.10 **</td>
<td>1.92 ± 2.61 **</td>
<td>NS</td>
<td>NS</td>
<td>*</td>
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<tr>
<td>L6D to OP Perpendicular</td>
<td>4.01 ± 3.55 **</td>
<td>5.12 ± 2.15 **</td>
<td>0.85 ± 2.87</td>
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### SOFT TISSUE

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<th>Δ</th>
<th>p</th>
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<td>Facial Convexity</td>
<td>-1.43 ± 2.59 **</td>
<td>-1.60 ± 2.92 **</td>
<td>0.44 ± 2.63</td>
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<td>*</td>
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<tr>
<td>Nasolabial Angle</td>
<td>1.33 ± 6.31</td>
<td>-0.78 ± 7.39</td>
<td>2.12 ± 7.19</td>
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<tr>
<td>UL to E-Plane</td>
<td>-0.77 ± 1.51 **</td>
<td>-1.50 ± 1.20 **</td>
<td>-0.88 ± 1.75 **</td>
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<tr>
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<td>-0.54 ± 1.52</td>
<td>-0.60 ± 1.78</td>
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Table 3.6 Advancement Phase Changes (T2-T1). NS: Non-significant, *: p ≤ 0.05, **: p ≤ 0.01
### Phase 2 Changes (T3-T2)

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<th>VARIABLE</th>
<th>IMAF</th>
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<th>CONTROL</th>
<th>IMAF v. TB</th>
<th>IMAF v. Control</th>
<th>TB v. Control</th>
</tr>
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<tr>
<td>Age</td>
<td>1.21 ± 0.50</td>
<td>2.89 ± 0.97</td>
<td>1.25 ± 0.56</td>
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<td>NS</td>
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</tr>
<tr>
<td>ANB</td>
<td>-0.25 ± 0.71</td>
<td>-0.17 ± 1.43</td>
<td>-0.63 ± 0.79</td>
<td>NS</td>
<td>NS</td>
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</tr>
<tr>
<td>Skeletal Convexity</td>
<td>-0.59 ± 1.65</td>
<td>-0.63 ± 3.10</td>
<td>-1.71 ± 1.77</td>
<td>NS</td>
<td>NS</td>
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<tr>
<td>Wits Appraisal</td>
<td>-0.22 ± 1.81</td>
<td>-0.32 ± 1.92</td>
<td>-0.75 ± 1.82</td>
<td>NS</td>
<td>NS</td>
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<td>SN-MP</td>
<td>-0.34 ± 1.63</td>
<td>0.37 ± 2.54</td>
<td>0.13 ± 1.79</td>
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<td>FMA</td>
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<td>-0.17 ± 2.39</td>
<td>0.07 ± 1.62</td>
<td>NS</td>
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<tr>
<td>P-A Face Height</td>
<td>0.48 ± 1.10</td>
<td>-0.31 ± 1.41</td>
<td>-0.02 ± 1.76</td>
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<tr>
<td>LFH/TFH</td>
<td>0.22 ± 0.71</td>
<td>0.52 ± 1.25</td>
<td>-0.03 ± 0.66</td>
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<tr>
<td>UFH/TFH</td>
<td>-0.22 ± 0.71</td>
<td>-0.52 ± 1.52</td>
<td>0.03 ± 0.66</td>
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<tr>
<td>SNA</td>
<td>-0.25 ± 1.35</td>
<td>-0.42 ± 1.01</td>
<td>-0.42 ± 1.12</td>
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<tr>
<td>A-Na Perpendicular</td>
<td>-0.09 ± 1.88</td>
<td>0.09 ± 2.48</td>
<td>-0.30 ± 2.33</td>
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<td>NS</td>
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<tr>
<td>Midface Length</td>
<td>0.27 ± 1.87</td>
<td>1.37 ± 2.62</td>
<td>1.55 ± 2.93</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
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<tr>
<td><strong>MANDIBLE</strong></td>
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<td></td>
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</tr>
<tr>
<td>SNB</td>
<td>0.02 ± 1.04</td>
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<td>0.22 ± 1.13</td>
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<tr>
<td>Pg-Na Perpendicular</td>
<td>0.16 ± 3.25</td>
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<td>0.73 ± 4.38</td>
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<tr>
<td>Mandibular Length</td>
<td>1.29 ± 2.42</td>
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<td>3.94 ± 3.24</td>
<td>NS</td>
<td>*</td>
<td>NS</td>
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<tr>
<td>Overjet</td>
<td>-0.39 ± 1.20</td>
<td>-0.45 ± 1.44</td>
<td>-0.34 ± 1.33</td>
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<td>Overbite</td>
<td>-0.27 ± 1.22</td>
<td>-0.62 ± 1.64</td>
<td>-0.30 ± 1.80</td>
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<tr>
<td>U1-SN</td>
<td>0.00 ± 3.33</td>
<td>0.20 ± 6.42</td>
<td>-0.47 ± 3.76</td>
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<tr>
<td>U1-FH</td>
<td>0.18 ± 3.76</td>
<td>0.75 ± 5.81</td>
<td>-0.40 ± 3.78</td>
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<td>U1-PP</td>
<td>0.18 ± 3.19</td>
<td>0.54 ± 6.51</td>
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<td>U1-Na (mm)</td>
<td>0.01 ± 1.28</td>
<td>0.14 ± 1.90</td>
<td>0.35 ± 1.29</td>
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<tr>
<td>U1-APo (mm)</td>
<td>-0.14 ± 1.28</td>
<td>-0.02 ± 1.63</td>
<td>-0.26 ± 1.12</td>
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<tr>
<td>L1-MP</td>
<td>0.28 ± 4.71</td>
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<td>-0.06 ± 2.19</td>
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<td>L1-NB (mm)</td>
<td>0.16 ± 0.90</td>
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<td>-0.07 ± 0.74</td>
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<tr>
<td>L1-APo (mm)</td>
<td>0.25 ± 0.99</td>
<td>0.47 ± 2.39</td>
<td>0.19 ± 0.93</td>
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<td>NS</td>
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</tr>
<tr>
<td>L1-MP (mm)</td>
<td>0.48 ± 1.43</td>
<td>1.09 ± 1.72</td>
<td>0.89 ± 1.41</td>
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</tr>
<tr>
<td>Right Molar</td>
<td>-0.11 ± 0.27</td>
<td>0.21 ± 0.30</td>
<td>**</td>
<td></td>
<td></td>
<td>**</td>
</tr>
<tr>
<td>Left Molar</td>
<td>-0.03 ± 0.23</td>
<td>0.16 ± 0.30</td>
<td>**</td>
<td></td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>U6-PP</td>
<td>0.97 ± 1.19</td>
<td>1.87 ± 1.59</td>
<td>0.79 ± 0.92</td>
<td>NS</td>
<td>NS</td>
<td>*</td>
</tr>
<tr>
<td>L6-MP</td>
<td>0.91 ± 1.57</td>
<td>1.61 ± 1.97</td>
<td>1.07 ± 1.35</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>H Perpendicular to MU6</td>
<td>0.15 ± 1.83</td>
<td>1.86 ± 2.30</td>
<td>1.51 ± 1.78</td>
<td>*</td>
<td>NS</td>
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</tr>
<tr>
<td>U6D to OP Perpendicular</td>
<td>0.48 ± 2.40</td>
<td>3.19 ± 3.64</td>
<td>1.72 ± 1.50</td>
<td>**</td>
<td>NS</td>
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</tr>
<tr>
<td>H Perpendicular to ML6</td>
<td>0.73 ± 1.52</td>
<td>2.66 ± 2.86</td>
<td>1.57 ± 2.36</td>
<td>*</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>L6D to OP Perpendicular</td>
<td>0.82 ± 2.93</td>
<td>3.58 ± 4.15</td>
<td>1.91 ± 1.81</td>
<td>*</td>
<td>NS</td>
<td>NS</td>
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<tr>
<td>SOFT TISSUE</td>
<td>T1-T2</td>
<td>T2-T3</td>
<td>T3-T2</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>----------------------</td>
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</tr>
<tr>
<td>Facial Convexity</td>
<td>-0.93 ± 1.81</td>
<td>-1.46 ± 3.04</td>
<td>-1.05 ± 4.10</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
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<tr>
<td>Nasolabial Angle</td>
<td>-1.46 ± 4.66</td>
<td>-0.74 ± 7.80</td>
<td>-4.11 ± 9.07</td>
<td>NS</td>
<td>NS</td>
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<tr>
<td>UL to E-Plane</td>
<td>-0.57 ± 1.19</td>
<td>-1.11 ± 1.24</td>
<td>-0.88 ± 1.99</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>LL to E-Plane</td>
<td>-0.58 ± 1.36</td>
<td>-0.16 ± 1.98</td>
<td>-0.67 ± 1.70</td>
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Table 3.7 Phase 2 Changes (T3-T2). NS: Non-significant, *: p ≤ 0.05, **: p≤ 0.01
## Overall Changes (T3-T1)

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>IMAF</th>
<th>TB</th>
<th>CONTROL</th>
<th>IMAF v. TB</th>
<th>IMAF v. Control</th>
<th>TB v. Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>2.12 ± 0.61**</td>
<td>4.19 ± 1.09**</td>
<td>2.19 ± 0.59**</td>
<td>**</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>CVMS</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td><strong>SKELETAL</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANB</td>
<td>-1.29 ± 0.90**</td>
<td>-1.36 ± 1.26**</td>
<td>-0.79 ± 0.87**</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Skeletal Convexity</td>
<td>-2.82 ± 2.32**</td>
<td>-2.96 ± 2.48**</td>
<td>-2.23 ± 1.78**</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Wits Appraisal</td>
<td>-3.03 ± 2.42**</td>
<td>-2.83 ± 1.65**</td>
<td>-0.14 ± 1.89</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>SN-MP</td>
<td>-0.21 ± 2.22</td>
<td>1.27 ± 3.71</td>
<td>-0.72 ± 2.17</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>FMA</td>
<td>-0.33 ± 2.81</td>
<td>0.66 ± 2.84</td>
<td>-0.90 ± 1.85 *</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>P-A Face Height</td>
<td>0.58 ± 1.81</td>
<td>-0.20 ± 2.51</td>
<td>0.77 ± 2.34</td>
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<td>NS</td>
<td>NS</td>
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<tr>
<td>LFH/TFH</td>
<td>0.58 ± 1.02 *</td>
<td>1.21 ± 1.19 **</td>
<td>0.53 ± 1.28</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>UFH/TFH</td>
<td>-0.58 ± 1.02 *</td>
<td>-1.21 ± 1.19 **</td>
<td>-0.53 ± 1.28</td>
<td>NS</td>
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<tr>
<td><strong>MAXILLA</strong></td>
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<tr>
<td>SNA</td>
<td>-0.36 ± 1.39</td>
<td>-0.74 ± 1.32 *</td>
<td>-0.04 ± 1.17</td>
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<td>NS</td>
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<tr>
<td>A-Na Perpendicular</td>
<td>-0.39 ± 1.85</td>
<td>-0.21 ± 2.31</td>
<td>0.52 ± 2.33</td>
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<td>NS</td>
</tr>
<tr>
<td>Midface Length</td>
<td>1.39 ± 2.87 *</td>
<td>3.14 ± 2.71 **</td>
<td>3.31 ± 3.31 **</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td><strong>MANDIBLE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNB</td>
<td>0.94 ± 1.52 *</td>
<td>0.61 ± 2.03</td>
<td>0.76 ± 1.31 *</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Pg-Na Perpendicular</td>
<td>1.11 ± 3.69</td>
<td>1.24 ± 4.25</td>
<td>2.77 ± 4.19 **</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Mandibular Length</td>
<td>4.81 ± 3.68 **</td>
<td>8.81 ± 3.03 **</td>
<td>6.90 ± 4.26 **</td>
<td>**</td>
<td>NS</td>
<td>NS</td>
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<tr>
<td><strong>DENTAL</strong></td>
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<td></td>
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</tr>
<tr>
<td>Overjet</td>
<td>-2.55 ± 2.18 **</td>
<td>-4.48 ± 2.13 **</td>
<td>-0.34 ± 1.63</td>
<td>*</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td>Overbite</td>
<td>-1.54 ± 1.20 **</td>
<td>-2.56 ± 1.82 **</td>
<td>-0.16 ± 2.30</td>
<td>NS</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>U1-SN</td>
<td>-1.09 ± 8.41</td>
<td>-4.34 ± 10.16</td>
<td>0.04 ± 3.65</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>U1-FH</td>
<td>-1.08 ± 8.36</td>
<td>-3.79 ± 9.66</td>
<td>0.54 ± 3.83</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>U1-PP</td>
<td>-0.76 ± 8.46</td>
<td>-3.57 ± 9.15</td>
<td>0.25 ± 3.82</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>U1-NA (mm)</td>
<td>-0.26 ± 2.50</td>
<td>-1.22 ± 2.85</td>
<td>0.38 ± 1.63</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>U1-APo (mm)</td>
<td>-1.17 ± 2.34 *</td>
<td>-2.05 ± 2.22 **</td>
<td>-0.43 ± 1.23</td>
<td>NS</td>
<td>NS</td>
<td>*</td>
</tr>
<tr>
<td>L1-MP</td>
<td>-0.05 ± 4.62</td>
<td>3.61 ± 5.65 *</td>
<td>-1.52 ± 3.60</td>
<td>NS</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>L1-NB (mm)</td>
<td>0.84 ± 1.29 *</td>
<td>1.99 ± 2.48 **</td>
<td>-0.23 ± 1.03</td>
<td>NS</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>L1-APo (mm)</td>
<td>1.60 ± 1.17 **</td>
<td>2.64 ± 2.08 **</td>
<td>0.00 ± 1.04</td>
<td>NS</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>L1-MP (mm)</td>
<td>0.60 ± 1.87</td>
<td>2.03 ± 2.05 **</td>
<td>1.97 ± 1.53 **</td>
<td>*</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Right Molar</td>
<td>-0.78 ± 0.30 **</td>
<td>-0.78 ± 0.34 **</td>
<td>-</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left Molar</td>
<td>-0.69 ± 0.36 **</td>
<td>-0.79 ± 0.34 **</td>
<td>-</td>
<td>NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>U6-PP</td>
<td>1.08 ± 1.45 **</td>
<td>2.99 ± 1.32 **</td>
<td>2.13 ± 1.43 **</td>
<td>**</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>L6-MP</td>
<td>2.42 ± 1.79 **</td>
<td>3.74 ± 1.57 **</td>
<td>1.75 ± 2.00 **</td>
<td>NS</td>
<td>NS</td>
<td>**</td>
</tr>
<tr>
<td>H Perpendicular to MU6</td>
<td>1.07 ± 2.34</td>
<td>2.12 ± 2.77 **</td>
<td>2.48 ± 2.30 **</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>U6D to OP Perpendicular</td>
<td>3.03 ± 3.66 **</td>
<td>4.75 ± 3.85 **</td>
<td>1.57 ± 2.82</td>
<td>NS</td>
<td>NS</td>
<td>*</td>
</tr>
<tr>
<td>H Perpendicular to ML6</td>
<td>3.69 ± 2.52 **</td>
<td>6.05 ± 3.05 **</td>
<td>3.38 ± 2.96 **</td>
<td>*</td>
<td>NS</td>
<td>*</td>
</tr>
<tr>
<td>L6D to OP Perpendicular</td>
<td>5.79 ± 4.13 **</td>
<td>8.82 ± 4.31 **</td>
<td>2.05 ± 3.02 **</td>
<td>*</td>
<td>*</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td>T3 - T1</td>
<td>T2 - T1</td>
<td>T1 - T0</td>
<td>NS</td>
<td>NS</td>
<td>*</td>
</tr>
<tr>
<td>-----------------------------</td>
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<td>----</td>
</tr>
<tr>
<td>Facial Convexity</td>
<td>-2.18 ± 2.28 **</td>
<td>-3.31 ± 2.90 **</td>
<td>-0.66 ± 3.86</td>
<td>NS</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Nasolabial Angle</td>
<td>0.26 ± 6.67</td>
<td>-0.16 ± 8.25</td>
<td>-2.16 ± 10.01</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>UL to E-Plane</td>
<td>-1.21 ± 1.69 **</td>
<td>-2.57 ± 0.96 **</td>
<td>-1.51 ± 1.97 **</td>
<td>*</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>LL to E-Plane</td>
<td>-0.46 ± 1.54</td>
<td>-0.56 ± 1.82</td>
<td>-1.24 ± 1.52 **</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

Table 3.8 Overall Changes (T3-T1). NS: Non-significant, *: \( p \leq 0.05 \), **: \( p \leq 0.01 \)
Chapter 4: Discussion

A review of the results will be discussed within this section beginning with how the groups significantly differed at T1. Following the initial presentation, the changes that significantly differed between the groups during the advancement period (T1 to T2), the Phase 2 (T2 to T3), and finally the overall changes (T1 to T3) will be compared and contrasted with other investigative findings, in said order. The pertinent correlations among the treatment groups will conclude this section.

As previously mentioned in the Methodology section (Sections 2.3.1 and 2.3.2), 70 IMAF and 81 TB cases were identified as having been consecutively treated within the defined time frame. Despite ethical approval allowing for the collection of records from as many as 50 patients, application of the eligibility criteria resulted in a final sample size of 32 for each treatment group due to exclusion of cases with missing records, cofounding treatment modalities, or because the patient was currently undergoing Phase 1 treatment.

4.1 Initial (T1) Presentation

In an ideal study comparing the effects of two treatment alternatives and a Control group there would be no differences between any of the groups at baseline. However, even with randomized allocation to different groups there is the possibility of statistically significant differences.\textsuperscript{16,17,83,120}
A Control group was included in this study in order to demonstrate what would potentially happen with no treatment. Because the two treatment groups had a significant age difference, it was decided to match the Control sample to the age and gender of the IMAF group. This was because investigation of the IMAF group was the primary purpose of the study; furthermore, TB has previously been compared to controls. The use of historical, longitudinal Control samples made it extremely difficult to precisely match the ages of the sample to that of the IMAF. Ideally groups would have been matched by age, gender, as well as the ANB angle, however due to the limited supply of Class II historical controls (as identified by the AAOF search engine), this was not feasible. The resulting Control sample, though identified with the AAOF search engine as Class II, was significantly less Class II than the IMAF as well as the TB sample. What this means is that there was less of a Class II malocclusion to correct, had the controls been treated, and therefore less dramatic changes would have been expected. Further details regarding the differences will be outlined in the following sections.

4.1.1 Significant Variables: IMAF and TB to Control

The primary difference in Class II presentation between the Control and treatment groups was exhibited in the ANB angle, Skeletal and Facial Convexity, as well as the Wits Appraisal, which were all a mild Class II maxillomandibular discrepancy in the Control group. These Control samples were also slightly longer in the lower face height, had longer midfaces, and longer mandibular lengths. Taking the milder skeletal discrepancy into consideration, this spilled over into a few dental presentations that were significantly different from the treatment groups. Because the mandible was longer, and the ANB and Skeletal Convexity was less, the lower
incisors did not have to dentally compensate as much for the Class II skeletal base and so therefore were not as proclined (99.7 versus 94.8 degrees, IMAF versus Control, respectively). Finally, with the Control group exhibiting a longer lower face height, the lower incisors were further, or rather, exhibited more eruption from the mandibular plane as compared with the IMAF and TB groups (37.7, 37.9, and 40.3 mm, IMAF, TB, and Control, respectively). The TB group was fairly similar to the average of 17 studies.\textsuperscript{13,16,17,25,42,52,63,75,77,81,83,87,89,101,109,117,120} The present study TB group had the following differences compared to the published TB samples:

- Mandibular Length being slightly shorter,
- SN-MP being slightly lower (however this, and the eruption levels of the first molars are skewed by the selective sample of Elfeky 2018 for high angle patients, an average SN-MP of 43 degrees)\textsuperscript{42},
- L1-MP being more proclined,
- overjet 2 mm less, and
- less facially convex but with more obtuse nasolabial angles.

4.1.2 Significant Variables: TB and Control

There were select variables that the TB was found to be significant compared to the Control group when the IMAF group was not. They are as follows:

The overjet was significantly greater in the TB group compared to the Control group and was also found to be significantly more than the IMAF group as well. This is a dental expression of the fact that while both treatment groups started significantly more Class II than the Control
group, the TB group was *highly* significant in ANB and Skeletal Convexity (while IMAF was moderately significant), thus suggesting a more *severe* Class II presentation in the TB group. This could be an indication of selection bias as it is possible clinicians preferentially select the TB for severe cases until the IMAF has proven its ability to correct such severe Class II malocclusions. A randomized clinical trial may have mitigated this selection bias.

The TB mean upper incisor angulation related to the palatal plane was significantly different from the Control group, but angulation related to the sella-nasion line and Frankfort Horizontal were not significantly different. The TB to Control differences in upper incisor angulation to sella-nasion, Frankfort Horizontal, and palatal plane were 4.2, 4.3, and 5.5 degrees, respectively. The upper incisor protrusion relative to A-Pogonion was also significantly different from the Control group (but not the IMAF group), yet there was no difference among the groups with respect to upper incisor protrusion relative to NA. This could be due to the fact that the mandible was more retrusive in the TB group, thereby positioning pogonion farther posterior and effectively making the upper incisor more protrusive. There could also have been a disproportionate amount of individually protrusive incisors, and when tracing a cephalometric radiograph the most protrusive tooth is traced. Therefore, if the TB cases tended to be more crowded anteriorly with a blocked out incisor positioned more facially, the TB cases would then be found to be more protrusive. Wrapping up the variations in angulation and AP position, the redundancy of upper incisor angulation and protrusion measurements while helpful is also a hindrance as after running statistical analysis on so many variables, something is bound to be found significantly different.
Another variable that was significantly different to the Control group, and unique to TB, was the upper lip to E-plane measurement. The TB group tended to have a more protrusive upper lip, which may or may not coincide with the more protrusive upper incisor relative to A-Pogonion. Ultimately as this was not a major outcome variable, it was of little concern.

Wrapping up the variables significantly different to the Control group, and unique to TB, is the upper first molar vertical position relative to the palatal plane. While statistically significant, it may be of little clinical significance as the difference between TB and Control means was only 1.6 mm, with TB being less erupted. The upper first molar being 1.6 mm less erupted may have more to do with the age of the patient. When the distance from palatal plane to the cusp of the upper first molar and the distance from the mandibular plane to the cusp of the lower first molar is summed, the results for IMAF, TB, and Control are 47.5, 46.8, and 50.4 mm, respectively. This, combined with the fact that the skeletal vertical components were insignificant, helps assuage concerns regarding an impact the vertical position of the molars may have on treatment. Of note is that the control had the largest sum distance, and also had the largest SN-MP angle. This is consistent with the knowledge that eruption in the posterior has a wedge like effect, opening the mandibular plane, but begs the question: is the patient high angle due to skeletal growth and compensatory eruption of the molars, or are the high angle due to eruption of the molars thereby opening and creating a steep mandibular plane angle?

When we take into consideration the fact that the Control sample was a mild Class II presentation the importance of the change, and not the final value, is highlighted. The change between each time point in the Control group can be attributed to the average growth that can be
anticipated. Any significant changes above and beyond, or less than the Control group changes seen in the treatment groups, are then attributed to be due to a significant contribution by the treatment appliance.

4.1.3 Significant Variables: IMAF and TB

Unfortunately the IMAF and TB groups were not age matched. IMAF tended to be older and this is largely due to the requirements set forth by Align/Invisalign® to have stable second primary molars (very young patient) or a full permanent dentition (older patient). Because a portion of the IMAF patients were part of the initial/beta testing of the MA feature, there were more stringent requirements (no primary teeth present). As the age was significantly different, the CVMS was also significantly different. However apart from the age and CVMS the IMAF and TB groups were well matched with only the overjet being significantly different. The TB group had a significantly larger overjet with a difference of 1.4 mm. This could be attributed to the slightly more proclined and protrusive upper incisors and the slightly more retroclined lower incisors of the TB group. With an increased overjet, it will be anticipated to see a significantly greater amount of overjet reduction in the TB group. This was the totality of the difference between the two treatment groups.

4.2 Advancement (T1 to T2) Changes

Overall most variables within the treatment groups showed improvement towards correction of a Class II maxillomandibular discrepancy via skeletal changes and dental compensations. Both IMAF and TB groups underwent active advancement for approximately the same amount of time (no statistically significant difference), although the standard deviation was quite large for each
group, reflecting a high degree of individual variation and response to treatment. In general, the vast majority of significant Class II correction came from dental compensations. However, there were not very many variables with significant changes in the IMAF group compared to the Control group. The general trend among variables in the IMAF group was towards a Class II correction, yet many variables did not reach statistical significance. One thing that will continue to repeat throughout the discussion is the idea that multiple small and statistically insignificant changes will result in a clinically significant outcome. What can be visualized is a dental compensation for a Class II maxillomandibular discrepancy,

The TB group on the other had had quite a few more variables that were significantly different from the Control sample. This may indicate a greater lack of controlled forces on the teeth during the advancement phase, or greater treatment correction required to achieve the Phase 1 objectives. The greater number of statistically significant variables may also be confounded by the fact that the TB patients presented generally with slightly more severe class II malocclusions allowing for a greater degree of correction, and started treatment at a younger age and earlier CVMS, which may have allowed active treatment to occur during a greater portion of the pubertal growth spurt.

4.2.1 Skeletal Outcomes

When a review of what IMAF accomplished skeletally, it is evident that between the IMAF and TB, not much differs. This lends to the idea that the appliances have similar methods of skeletal growth modification. However, when IMAF changes are compared to those from growth alone
(Control group), there are three primary outcomes that are significant: ANB, Skeletal Convexity, and Wits Appraisal.

ANB improved by 0.9 degrees more than what growth provided, the question of clinical significance remains, as tracing error could be a contributing factor – yet across 32 samples in the IMAF and an additional 32 in the Control group, tracing error would become less of a factor. Still, the questions remains, is a single degree more of improvement in the relationship of maxilla to mandible grounds to claim clinical significance? When other functional appliances are systematically reviewed in the literature, Cozza et al report that “a statistically significant difference… had to be greater than 2.0 mm to be regarded also as clinically significant”. A review of the literature with regards to angular measurement consistency reveals that Iacob et al encountered a 1.6528 degrees difference in ANB between the same radiographs traced twice. While the ANB angle showed the greatest variability, the SN-MP angle showed the least with only 0.0102 degrees of difference between the first and second tracings. Furthermore, the average change seen in 11 studies was 2.66 degrees. For the present study, a cut off of greater than 2 degrees was set for the amount of change required for a clinically significant angular difference to have occurred. Following this criterion, a single degree of improvement is not grounds for claiming clinical significance.

The Skeletal Convexity was significantly improved in the IMAF group as compared to the Control group. This was expected as the ANB improved significantly as well. The change was much greater than the improvement in ANB – nearly 1.9 degrees more than growth alone for Skeletal Convexity. The reason that more improvement could be seen is that while ANB uses A-
point and B-point for the lower two points, Skeletal Convexity utilizes the ANS and Pogonion. While ANS is restrained with appliance use, the mandible is advanced, and so pogonion moves anteriorly. Not only is the mandible advanced, but the chin also continues to grow – as it does throughout life. Therefore with chin growth and continued restraint of the maxilla, greater improvement in Skeletal Convexity, as compared to ANB improvement, is valid and anticipated.

While Skeletal Convexity was chosen to be included for review, few others have included this variable in their outcomes. Mills & McCulloch reported the convexity decreased by 5.7 degrees, a year later Tümer et al found an improvement of 3.89 degrees, and most recently in 2013 Baysal & Uysal reported an improvement of 5.25 degrees. As the outlier reporting only 3.89 degrees improvement, Tümer et al also had 7 months between initial and post-advancement cephalograms while Mills et al and Baysal et al waited an average of 14 and 16 months, respectively. The present study found TB to decrease the skeletal convexity by $2.38 \pm 2.20$ degrees and the IMAF group by $2.54 \pm 2.35$ degrees. The treatment time of approximately 12 months was more than Tümer et al but less than either Mills et al and Baysal et al. At nearly 5 months of standard deviation in the treatment time, this is reflected in the similarly large standard deviations of skeletal convexity improvement.

Finally, between IMAF and the Control group, the Wits Appraisal was significantly improved. This was expected, as a Class II corrector should improve the Wits Appraisal. The Wits Appraisal relates the dental malocclusion to the skeletal malocclusion by utilizing the occlusal plane as the reference plane for lines drawn perpendicular through A-point, and then again through B-point. This reflects the discrepancy between the maxilla (A-point) and mandible (B-point). The IMAF improved the Wits Appraisal by 2 mm more than what the Control group
exhibited. While there are no studies currently published comparing the IMAF to Control groups, it will now be expedient to compare the IMAF appliance to the TB appliance in an effort to elucidate the efficacy of the novel IMAF appliance.

As previously established, there was a significant age difference between the IMAF and TB groups. Therefore, any significant changes exhibited by one appliance over the other should be viewed with a critical eye as either the younger or the older group, in relation to peak growth velocity of the mandible, could have affected the outcome. Skeletally the IMAF did not present outcomes significantly different from the TB appliance. This was expected as both appliances work to posture and hold the mandible in an anterior position. On one hand the IMAF may have had the advantage of being more widely accepted by patients due to being less invasive than the bulk of the TB acrylic, however both appliances are similarly advancing the mandible and so therefore potentially are equally uncomfortable to the patient. In 2009, Brunharo et al reported a decrease of 3.09 mm in the Wits Appraisal, their sample size was only 19 but the decrease in the present study, being 2.24 mm for the TB is relatively similar. Our sample size being considerably larger as well corroborates their findings.

TB differed slightly from the IMAF appliance in its significance when compared to the Control group. The TB group tended to steepen the mandibular plane (by 0.68 degrees) while the Control group had a trend of flattening the mandibular plane (by approximately 0.60 degrees). This is contrasted to the IMAF group that had relatively no effect on the mandibular plane. This was not expected from the TB group as efforts were made to control the vertical by trimming the posterior acrylic in the low angle cases to allow posterior dentition eruption to increase the lower
face height, and by leaving the acrylic unchanged in the high angle cases to impede posterior dentition eruption. By doing so in some but not all cases, it was expected that the results would cancel each other out, but this was not seen. However when other studies are reviewed comparing the effects of TB to growth/control groups, the effects are corroborated by Baccetti 2000 who found the SN-MP increased by the same degree as the present study (0.68 degrees), and Šidlauskas in 2005 reported an increase in SN-MP of 0.50 degrees. However Brunharo et al and Illing et al found the exact opposite, a decrease of 0.50 and 1.5 degrees in the SN-MP, respectively. These results are variable largely because of the variations in treatment modalities and philosophies regarding the TB appliance, its activation, and modification.

Ultimately, while there was a significant increase in the mandibular plane angle of the TB group as compared to the Control group, there was no significant increase in the lower facial height, suggesting that either the soft tissue changes from the mandibular plane steepening were negligible or that the soft tissue dimensions counteracted the effects of the skeletal change. In all three groups the lower facial height increased, one possibility is that the soft tissue increased in all three groups, but more in the Control group to counteract the flattening of the mandibular plane. In any case, no significant changes in lower facial height were seen, which is contrary to Tümer as well as Lund and their findings (increase of 1.3% and 1.5%, respectively). Again, this could be due to the variations in practitioners approach to TB treatment.

4.2.1.1 Maxillary Changes

The maxilla did not show a significant difference between the changes occurring in the three groups. However, the treatment groups showed a mild reduction in the SNA angle and A-Na
Perpendicular. This was anticipated because both appliances are advancing the mandible by using the maxillary dentition to hold the mandible in an anterior position. This force of holding the mandible forward reciprocally restrains the maxilla. Therefore, over the course of a year – the average length of time the appliances were worn – the maxilla was retruded with respect to the cranial base (SNA) and Nasion (A-Na Perpendicular). This is contrasted by the minor advancement that occurred in the maxilla in the control group with respect to the SNA angle the A-Na Perpendicular distance. Again, anticipated, as there was no external force on the maxilla that generally grows in an anterior and inferior direction. These findings are corroborated by the literature reporting decreases in the SNA angle ranging from 0.1 to 1.4 degrees with TB treatment.\textsuperscript{63,77}

4.2.1.2 Mandibular Changes

With regards to the mandible, each group demonstrated an increase in the SNB angle. The mandible tends to maintain its initial vector of growth along the Y axis, yet the treatment groups demonstrated a slightly greater amount of SNB increase.\textsuperscript{49} And while the increase of the IMAF and TB were not significantly more than the Control group, when all the small and seemingly insignificant changes are summed, there is a clinically significant change exerted by these two devices. The present findings are most similar to Illing et al who in 1998 reported an average increase of only 0.8 degrees in the SNB angle following 9 months of treatment.\textsuperscript{63} In contrast, Šidlauskas, Singh, Mills, and Baysal 2013 found the TB did in fact cause a significant increase in the SNB angle over Controls, however the subjects in the Singh et al study wore the appliance for 2 years full time in comparison to the present study where patients were in active advancement for an average of 1 year.\textsuperscript{17,81,109,113}
Mandibular length change demonstrated some significant differences between groups. The mandibular growth that occurred in the Control group amounted to a mean of 3.02 mm. In contrast the TB mean was 5.57 mm, which was significantly more than the Control group as well as the IMAF group (mean of 3.35 mm). While the amount of mandibular length increase seen in the TB group was more than the other two groups, there is the major confounding factor of age. With a significantly younger patient pool in the TB group, there is the possibility that the advancement period for the TB encompassed a greater section of the pubertal growth spurt. It may also be that the TB group were entering the pubertal growth spurt while the other two groups, being older in terms of more advanced CVMS, were exiting the pubertal growth spurt and therefore were unable to capitalize on the peak height velocity changes that occur within the pubertal growth spurt.

Curiously, despite the mandibular length increase being greatest in the TB group, the Pg-Na Perpendicular change was the smallest in the TB group. This may be a reflection of differences in the anterior-posterior position or direction of remodeling that occurs with the glenoid fossa during the treatment period. Another possibility for this occurrence is because there was a slight trend to open the mandibular plane by 0.68 degrees. This opening of the mandible rotates the entire complex down and back, in a clockwise manner. What then happens is that the boney chin projection (Pogonion) rotates a greater relative distance compared to the rest of the complex because it is farther from the point of rotation in the temporomandibular joint. Because pogonion rotates more clockwise, it becomes more retrusive relative to the Na Perpendicular. This opening of the mandibular plane was not seen in the IMAF nor the Control groups and therefore the
pogonion was able to move mainly anteriorly instead of rotating away from the Nasion Perpendicular.

Difference in ages between the TB and Control group can make drawing conclusions of direct comparisons difficult. Such age differences however do not exist between the IMAF and Control groups. As previously stated, the Control group had a mean increase of 3.02 mm in mandibular length, contrasted with the mean increase within the IMAF group of 3.35 mm. This equates to no statistically significant difference in the changes exhibited within the IMAF group as compared to the Controls. However in actuality, it may be through small positive incremental changes towards correction of a Class II malocclusion, through which treatment is successful. This can be encouraged especially as the sum of small and non-significant changes result in correction of a Class II dental malocclusion as demonstrated by the successful correction of the dental malocclusion in all the included cases, and an improvement in the skeletal Class II disharmony. At the time of publication, there were no studies comparing the effects of the IMAF appliance to a set of longitudinal Control subjects, as such further investigation is encouraged to identify and or increase the knowledge on these outcomes.

4.2.2 Dental Outcomes

As expected, there was minimal change that occurred from T1 to T2 in both overbite and overjet in the Control group. The IMAF group on the other hand demonstrated nearly 2 mm more reduction than the Control group, which was a statistically significantly improvement. Even more impressive was the amount of reduction that occurred with the TB group – 3.57 mm! This amount of overjet reduction was significantly more than both the Control and the IMAF group.
This impressive reduction may be related to the initial overjet as the TB group had significantly more initial overjet than the other two groups (7.3 mm TB, 5.9 mm IMAF, 4.8 mm Control). Pearson Correlation Coefficient of -0.933 showed correlation to the amount of initial overjet to the amount of overjet reduction. This makes sense, as the more there is to reduce, the more reduction that should occur in order to reach the Phase 1 treatment objectives. Both IMAF and TB reduced the overjet to approximately 4 mm of overjet, 4.09 mm and 3.75 mm, respectively.

As previously mentioned, the mandibular plane was opened in the TB group and the mandible rotated down and back. This movement causes an increase in the overjet, which suggests that had there been an improved control of the vertical component then the amount of overjet correction may have been even greater. What is comforting is the fact that both appliances were able to successfully reduce the overjet significantly more than the Control groups. Among 11 studies\textsuperscript{13,16,42,52,63,75,77,81,87,89,109}, the average percentage of overjet reduction was 60.7% with a range of 48.6% – 95.1\%\textsuperscript{42,77}. The present study found a 48.9% reduction of overjet in the TB and 31.0% in the IMAF group during the advancement phase of treatment. A reduction of 61.4% when the TB appliance and FEA are used, and a 43.2% reduction with IMAF and Invisalign\textsuperscript{®} use was found from initial presentation to completion. As such, the findings of this study align well with those reported in the literature for the use of TB.

Contemplating the outcomes of the overbite, the only significant difference in the amount of change was between the TB and Control groups. At nearly 1.5 mm more reduction in overbite as compared to the Control group, the TB may have accomplished this via the opening of the mandibular plane. By rotating the mandible clockwise, the lower incisors also rotate down and back which would aid in the decrease in overbite. The reduction of 1.67 mm by the TB group
aligns well with the findings reported by Elfeky et al and Illing et al who found 1.87 mm and 1.8 mm of reduction, respectively.\textsuperscript{42,63} Again, the evaluation of the TB as compared to the Control group in the present study may be an unfair comparison as the two groups were so poorly matched at the initiation of the study.

The IMAF appliance also decreased the overbite more than the Control but not to a significant amount. Because there was no change in the mandibular plane, this was not a contributing factor to the overbite correction. Therefore, when looking at the lower incisor vertical position as related to the mandibular plane, the IMAF group erupted significantly less than the Control group (difference of 0.70 mm between the two groups). The amount of eruption control of the lower incisors in the IMAF group was 76% of the overbite reduction. While no vertical measurement of the upper incisor was established during this study, a possibility is that by having complete coronal coverage of both the upper and lower incisors through clear aligner therapy, the vertical eruption of the incisors was impeded and therefore overbite reduction occurred.

4.2.2.1 Maxillary Incisors

The maxillary incisor angulation had multiple redundancies built into the cephalometric measurements. The more common measurement referenced in the literature and at the University of British Columbia is the upper incisor angulation to the Sella-Nasion line. This may be for a litany of reasons, however the fact that the American Board of Orthodontics utilizes this angle in cephalometric evaluation of the upper incisor angulation is likely the forerunner. In any case, upper incisor to the Frankfort Horizontal, as well as to the palatal plane, was also measured. The
Frankfort Horizontal has the potential to be erratic in its measurement due to the dense osseous structures in the region of porion – one of the points used in determining the Frankfort plane. Palatal plane also can be inconsistent due to the Anterior Nasal Spine (ANS) being a narrow spicule of bone that can be washed out by exposure errors. The vertical placement of the Posterior Nasal Spine – the second point of palatal plane – is also prone to inconsistencies due to mottling in the region, significant soft tissue overlays, as well as third molar presence or absence.

The TB group showed consistent agreement in the retroclination of the upper incisor that occurred during the advancement phase. Each plane of reference recorded approximately 4.45 degrees of retroclination. This was significantly more than both the IMAF and Control groups. The TB group did start approximately 4 degrees more proclined than the other two groups, though this was not significant statistically. A reason for the significantly more retroclination than the other two groups could be the result of the Hawley bow of the TB appliance. Another reason for the greater degree of retroclination in the TB group could be that the incisors began proclined compared to the ideal and so 4 degrees of retroclination was considered acceptable to reach a normal position.

The IMAF upper incisors tended to retrocline by only 0.50 degrees. There was some variability across the three planes with U1-PP showing only 0.14 degrees of retroclination and U1-FH demonstrating the most at 0.56 degrees of retroclination. None of the changes for the three variables (U1-SN, U1-FH, U1-PP) were significantly different from the Control group. The greater degree of upper incisor torque control may be due to the active movement from first premolar to first premolar the ClinCheck software prescription builds into the aligner trays the
IMAF patient wears. Actively moving and torquing the teeth would be the equivalent to all of the TB patients also having brackets from first premolar to first premolar and orthodontic treatment carried out. Furthermore, the upper incisors started at approximately the ideal angulation for the IMAF group and so therefore not changing their positioning was the goal, which was accomplished. While in the TB group retroclination was the treatment objective to achieve an ideal upper incisor angulation. Therefore, both appliances were able to exhibit torque control of the upper incisors in accomplishing the specific treatment objective.

The angulation of the upper incisors within the Control group tended to increase. The proclination ranged from 0.56 to 0.96 degrees among the three reference planes (U1-PP with the least amount of proclination and U1-FH with the most amount of proclination). Baysal & Uysal reported 0.38 degrees of proclination over the course of 15.5 months.16 Lund reported retroclination of 0.2 degrees; Mills reported proclination of 0.2 degrees.77,81 This may be due to the length of time between record taking, or a difference in initial proclination values. If the general trend is to increase in proclination, the longer the amount of time between records, the more change of proclination potentially will be recorded.

Upper incisor protrusion among the three groups was highly variable. The two treatment modalities tended to decrease the protrusion, and the Control group generally did not change in protrusion. The U1-NA protrusion decreased the most in the TB group (1.24 mm) and increased the most in the Control group (0.16 mm). The IMAF group remained relatively unchanged at 0.06 mm of retraction. The increased amount of retraction in the TB group can be easily explained by the increased amount of retroclination that occurred. Because the angulation
changed significantly more than any other group, the incisal edge moved significantly more as it traveled along an arc of closure while retroclining.

Similar to the U1-NA anteroposterior measurement of the incisal edge, the U1 was also measured in relation to the A-point to Pogonion. The outcomes were relatively similar to those of previously mentioned but in greater magnitudes and all measurements indicating retraction of the upper incisors (0.92, 1.98, and 0.09 mm retraction for the IMAF, TB, and Control groups, respectively). Each group was significantly different in the amount of retraction from the other groups. TB however was highly significantly different from the two other groups. Again, with a greater degree of retroclination, a greater degree of retraction of the incisal tip is expected. The difference in measured amount of retraction could be explained by the movement of pogonion due to active advancement of the mandible. Moving the mandible forward (and therefore pogonion) inadvertently causes the upper incisor to become more retrusive to pogonion. The greater degree of retroclination and retraction that occurred in the TB group is a component of correcting the significant amount of overjet when compared to the IMAF and control groups.

### 4.2.2.2 Mandibular Incisors

While there was no statistically significant difference between the proclination of the lower incisors among the groups, there was what could be considered a clinically significant change between them. The TB group proclined by 1.48 degrees during the advancement phase but the IMAF group retroclined by 0.58 degrees. The proclination exhibited by the TB group is similar to that reported by Gill in 2005 (1.3 degrees), Varlik in 2008 (1.86 degrees), as well as Baysal in 2013 (0.92 degrees). However the present study reported less proclination than a number
of studies as well.\textsuperscript{25,75,63,77,81,109,113,117} It is important to note that the IMAF group started nearly 3 degrees more proclined than the TB group and approximately 5 degrees more proclined than the Control group. It also stands to mention that the IMAF group had the increased possibility of interproximal reduction, allowing for resolution of incisor crowding, retraction, retroclination, or a combination of the three to occur during Phase 1 treatment. These considerations must be taken into account when selecting a treatment modality. While retroclination of proclined incisors may be possible, it is at the expense of enamel and potentially intercanine width. Furthermore, expansion at the canines has been demonstrated to be highly unstable with the vast majority of expansion being lost to relapse occurring post-treatment.\textsuperscript{26} Therefore, while resolution of crowding and minor correction may occur during treatment, the final post-retention result may be a return of significant crowding, leaving the patient in a similar state as they presented in and therefore no better off.

The Control group lower incisors retroclined the most of any group by 0.69 degrees. This was not expected however due to the decrease in the mandibular plane (SN-MP) the lower incisor may have tipped (retroclined) back, become more crowded, and more retrusive as the lower incisors were pushed up against the upper incisors with increased mandibular length, and deepening of the mandibular plane. The lower incisors did in fact become more retrusive, but not by a significant statistically nor clinically amount.

Both IMAF and TB treatment groups exhibited more protrusive lower incisors but only significantly more than the Control group (which became more retrusive); the TB group was highly significant. This result is expected with the use of Class II functional appliances due to the
forward pressure placed on the mandibular dentition during treatment. Additionally, the slight rotation of the mandible in a clockwise rotation, due to steepening of the mandibular plane relative to sella-nasion, causes B-point and pogonion to rotate a greater distance than the lower incisor tip because their distance from the center of rotation in the temporomandibular joint is greater than the lower incisor tip. The result is that the chin and B-point are more inferior and more posterior than the lower incisor tip – effecting a relative protrusion of the lower incisor tip even if no actual protrusion occurred. Other investigators have also found the lower incisors to become more protrusive as compared to a Control group.¹⁷,²⁵,¹⁰¹

With regards to the eruption of the lower incisor, the Control group erupted by 0.95 mm from T₁ to T₂. In contrast, the TB group extruded by 1.16 mm and the IMAF group extruded by only 0.25 mm. The TB extruding slightly (but insignificantly) more than the Control group could again be attributed to the steepening of the mandibular plane and the incisors erupting to compensate for said rotation, or alternatively the age differences between groups. This finding of more, but a statistically insignificant amount, extrusion in the TB group compared to the Control group is contradicted by Illing et al and Baysal et al who both found the TB group had minor amounts of intrusion of the lower incisor while the control groups had mild amounts of extrusion.¹⁶,⁶³ Curiously, the IMAF group extrusion was controlled to such a degree that there was significantly less extrusion in said group compared to the Control group. This restraint may be due to the complete facial, incisal, and lingual coverage of the lower incisor for an extended period of time (T₁ to T₂), a period of active somatic growth. It could further be explained by the potential for the clinician to design a ClinCheck software plan such that incisor intrusion is prescribed and an intrusive force is in place during treatment.
4.2.2.3  Molar Changes

Correction of a Class II molar classification occurred significantly more with the TB appliance (as measured in quarter cusp increments from clinical photos). The average improvement in molar classification in the TB group was approximately 83% of a full cusp while the IMAF improvement was approximately 63% of a full cusp. The increased correction in the TB appears to be the result of slightly greater restraint of the mesial movement of the maxillary first molar and a greater amount of mesial movement of the mandibular first molar (measured cephalometrically), as compared to the IMAF group. Though the TB was not significantly greater than the IMAF, it did in fact effect a significant change in molar movements as compared to changes in the Control group. While clinical photos of the Control group were not available due their being longitudinal historical controls, the IMAF group did restrain the maxillary first molar mesial movement, and increased the mesial movement of the mandibular first molar (as measured on cephalometric radiographs) more than the Control group, though not to a statistically significant degree. However due to the clinical outcome, it can therefore be advantageous to use either appliance if the goal is to restrain the maxillary molar and advance the mandibular molar for the correction of a dental Class II malocclusion. A comparison of molar movements of the present study as compared to reports in the literature can be found below in Table 4.1 Molar Movements.
<table>
<thead>
<tr>
<th>Author</th>
<th>Reference Line</th>
<th>Maxillary First Molar</th>
<th>Mandibular First Molar</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Twin Block</td>
<td>Control</td>
</tr>
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<td>Blackham et al 2020</td>
<td>Occlusal Perpendicular</td>
<td>2.03 ± 1.73*</td>
<td>0.50 ± 2.53</td>
</tr>
<tr>
<td>Blackham et al 2020</td>
<td>Occlusal Perpendicular</td>
<td>IMAF: 1.84 ± 3.13</td>
<td>IMAF: 4.01 ± 3.55***</td>
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<td>Brunharo et al 2011</td>
<td>Sella-Nasion Perpendicular through Sella</td>
<td>1.45 ± 1.96</td>
<td>2.60 ± 4.64</td>
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<td>Jena et al 2006</td>
<td>Pitchfork Analysis</td>
<td>0.07 ± 1.21*</td>
<td>-1.18 ± 0.53</td>
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<tr>
<td>Mills et al 1998</td>
<td>True Vertical through Sella</td>
<td>-1.0 ± 1.4***</td>
<td>1.5 ± 1.9</td>
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<tr>
<td>Tümer et al 1999</td>
<td>Pterygomaxillary vertical</td>
<td>-0.54 ± 1.65**</td>
<td>1.50 ± 1.95</td>
</tr>
</tbody>
</table>

Table 4.1 Molar Movements: *: p ≤ 0.05, **: p ≤ 0.01, ***: p ≤ 0.001

Vertical control of the molars, as measured on cephalometric radiographs relating the mesiobuccal cusp of the maxillary first molar to the palatal plane and the lower first molar to the mandibular plane presented interesting outcomes. The Control group demonstrated extrusion of the maxillary first molar of 1.38 mm that was significantly more than the IMAF group – but not the TB – suggesting that the maxillary molar was relatively intruded by use of the appliance.
Interestingly enough, the IMAF groups lower first molar extruded 1.37 mm. This was more, though not significantly, than the Control group (0.84 mm). If the amount of maxillary and mandibular molar extrusions are calculated, the IMAF extruded a total of 1.83 mm and the Control group 2.22 mm. Again, this decreased amount of extrusion in the IMAF group may be due to the occlusal coverage by the aligners effecting an intrusive force on the posterior dentition.

The TB group on the other hand demonstrated a highly significant amount of lower first molar extrusion (2.22 mm) and a total molar extrusive value of 3.35 mm. If the total molar extrusion exceeds the vertical growth of the ramus, then clockwise rotation of the mandibular plane may occur. With respect to appliance design, efforts were made by the clinician to trim the acrylic covering the posterior molars to allow for preferential extrusion during the course of treatment to correct the curve of Spee and rotate the occlusal plane clockwise. However, the severity of the initial overbite in each patient may play a role in the amount of posterior openbite that occurred as a result of advancement – by either TB or IMAF. The greater the initial overbite, the more the mandible would be rotated clockwise with the patient in an edge-to-edge anterior relationship. The more the mandible rotates clockwise, the larger the posterior openbite, and the greater the potential for additional extrusion beyond that typically seen in growth alone.

4.2.3 Soft Tissue Outcomes

Facial Convexity was significantly decreased in both treatment groups compared with the Control group. A decrease of 1.60 and 1.43 degrees was measured for the TB and IMAF groups, respectively. There were no significant differences between the changes effected by either
appliance; this is contrasted by the Control group that increased in Facial Convexity (0.44 degrees). This relative difference of approximately 2 degrees for each treatment group could be considered clinically significant and is statistically significant. The changes seen among the groups were all expected. Active advancement of the mandible should theoretically decrease the convexity as the mandible is actively postured forward, and this was validated in the cephalometric outcomes. The present results are most similar to Morris et al who reported a mean decrease of 0.8 degrees while their control group increased convexity by 1.7 degrees, a difference of 2.5 degrees.3 Baysal & Uysal reported greater improvements by TB; a decrease in convexity by 4.02 ± 2.46 degrees and the controls decreased by 0.12 ± 2.67 degrees, a difference of 3.90 degrees.17 Morris et al patients wore the Twin Block appliance for 9 months while Baysal & Uysal patients wore the appliance an average of 16.2 months. This may contribute to a greater change exhibited in the soft tissues. The average patient wore the Twin Block appliance for 12 months in the current study.

Nasolabial angle changes showed no significant differences amount the three groups, however the TB group decreased the angle slightly (0.78 degrees) while the IMAF and Control groups both increased the angle (1.33 and 2.12 degrees, respectively). These results should be interpreted with caution as the age difference between the groups results in difference in growth, including the nose. Furthermore the nasolabial angle is calculated not from the tip of the nose but rather the Columella – which is not a point placed by the investigator in this study but rather automated by the cephalometric analysis program (Dolphin Imaging). Other investigators found increases as large as 6.23 degrees with regards to the nasolabial angle and TB.120
All groups showed retraction of both upper and lower lips relative to the E-plane. There were no significant differences among the groups. The retraction of the lips may have more to do with the growth of nose and chin rather than the effects of the appliances. Being highly critical, the lower lip in the treatment groups were retracted less, suggesting the possibility that the advancement of the mandible, or increase in lower face height, as caused by the appliances moved the lower lip closer to the E-plane. The upper lip showed a similar amount of movement in the IMAF group compared to the Control group. On the other hand, the upper lip was retracted by nearly twice the amount as exhibited in the Control group. Again, these results should be viewed with caution as none of the groups changes were significantly different and the values so small as to be clinically insignificant. The present findings of upper lip retraction with TB use is in line with the findings of Baysal & Uysal, Varlik et al, Morris et al, and Lee et al.17,75,83,120

4.3 Phase 2 (T2 to T3) Changes

Most variables showed a continued improvement towards correction of a Class II malocclusion through both skeletal changes and dental compensations. The Phase 2, or time between T2 and T3, was significantly longer for the TB group as compared to the IMAF group, and therefore the Control group (as the Control was age matched to the IMAF group). All groups aged significantly both chronologically and skeletally (CVMS) over the course of the study. The overview of the changes as a result of growth and continued orthodontic treatment are presented below. The exact values of T3 minus T2 for the Phase 2 change, and T3 minus T1 for the overall change can be found within Table 3.7 Phase 2 Changes and Table 3.8 Overall Changes.
4.3.1 Significant Variables: TB and Control

The only significant difference between the TB group and Control group was the extrusion of the upper first molar relative to palatal plane. The TB group extruded significantly more (1.87 versus 0.79 mm) however this is confounded by the significantly longer length of time between T2 and T3 for the TB group (2.89 years versus 1.25 years) which would allow the upper first molar to continue to develop vertically. Therefore it is difficult to draw any conclusions from comparing the two groups.

4.3.2 Significant Variables: IMAF and Control

There was a solitary variable with significant differences between the IMAF group and Control group: mandibular length. Curiously enough, the Control group had a greater increase in mandibular length compared to the IMAF group (3.94 versus 1.29 mm). An explanation for this would be murky at best. The possibility of confounding factors such as ethnicity – it is presumed that the Control sample was predominantly Caucasian, while the IMAF group was more diverse with Asian, Middle Eastern, and Caucasians, to name a few – could skew outcomes one way or the other. Another confounding factor may be the era in which the information was collected – the Control sample was historical and the IMAF sample was current – causing a difference in nutrition, health, and extraneous influences. Because of the difference in length of time between T2 and T3 for the TB and IMAF groups, it is difficult to say what the mandibular length change would be for TB group. If both groups were matched for age at T2 and T3 and the mandibular length change was similar, while the Control remained greater, it might suggest a difference in
the sample population. Alas this project was unable to match the two treatment groups for age and therefore such discussions are purely conjecture.

4.3.3 Significant Variables: IMAF and TB

Having prefaced the age change difference between the TB and IMAF group, the following discussion regarding significant difference in variables should be approached with caution. A greater amount of time between the discontinuation of the functional appliance and Phase 2 treatment initiation within the TB group may have allowed more relapse of anteroposterior correction to occur. This would then make the TB Phase 2 correction include more anteroposterior correction than the IMAF group. The majority of the Class II correction occurred during the advancement phase for both groups, with IMAF correcting less. However the IMAF corrected more during the Phase 2 than the TB group did, thereby effectively “catching up” to the TB correction.

The horizontal molar measurements were all statistically significant between the IMAF and TB groups, with the TB group measuring a greater mesial movement than the IMAF group. Again, it should be noted the vastly greater amount of time between T2 and T3 for the TB group which would allow more mesial migration of the molars and anterior growth of the maxillomandibular complex, thereby accentuating the distance from the H Perpendicular and Occlusal Plane Perpendicular for the TB group.
4.4 Overall (T1 to T3) Changes

As previously iterated, it is important to keep in mind the idea that multiple small and statistically non-significant changes result in a dramatic change in the dental malocclusion. There were very few variables that showed significant differences in overall changes; and those that did were found mainly within the dental – and not skeletal – variable groups.

4.4.1 Significant Variables: TB and Control

Once again, the following discussion regarding TB outcomes as compared to Control outcomes should be taken cautiously due to the study duration for the TB group (4.19 years) versus the Control group (2.19 years). During the observation period (T1 to T3), skeletally there was only a significant difference between the two groups with regards to the Wits Appraisal. For the TB group it decreased by 2.83 mm while the Control group decreased by a mean value of 0.14 mm. This is anticipated as the TB has a restraining effect on the maxilla and advances the mandible. Therefore a reduction in the Wits Appraisal was expected and indeed necessary for successful treatment. In the study by Brunharo et al, where the Control groups were well matched, a significant decrease was seen in the Wits (Twin Block reduction of -3.09 ± 2.66 mm versus 0.95 ± 2.79 mm in controls).25

With a decrease in the Wits Appraisal comes the anticipated significant decrease in overjet that also proved significantly more than the Control group (4.48 mm reduction compared to 0.34 mm). This is well substantiated by a plethora of other investigators.12,13,16,17,42,52,63,66,75,77,81,87-89,109,113
As expected with successful orthodontic treatment, the overbite was reduced significantly more in the TB group as compared to the Control group. In the current literature the average overbite correction with TB therapy is 3.8 mm with a wide range (1.8 – 8.64 mm reduction; Illing et al\textsuperscript{63} – Singh et al\textsuperscript{113}). \textsuperscript{16,42,63,77,109,113}

The upper incisor was retracted over 1.50 mm more than the mild (0.43 mm) retraction that occurred in the Control group. This retraction occurs primarily due to the posterior application of force not only on the entire maxillary dental complex by the TB in Phase 1, but also from the fixed edgewise appliances which were used during Phase 2 treatment. The combined effect produces retroclination and retraction of the upper incisors. While in the Control group the upper incisors only experience lip musculature exerting a posterior force vector – quite a bit less than an entire jaw (mandible) exerting posterior forces on the incisors. The lower incisors in the TB group demonstrated Class II dental compensations in both angulation and anteroposterior positioning. The incisors were protruded and proclined significantly more with the use of the Twin Block appliance compared to the retroclination and mild retraction that occurred in the Control group. This expression of dental decompensation is expected as the entire dental complex shifts mesially to compensate for a Class II skeletal discrepancy. Overall these changes must also be understood to occur from a combination of effects of the TB and fixed edgewise appliances, as well as from growth during the study period.

The lower first molar of the TB group extruded and moved mesial a significantly greater amount than the Control group. Again, much of this change can be attributed to the combined effects of TB and then fixed edgewise appliances used during Phase 2 treatment, as well as the two years
of growth that occurred during the observation period of the TB subjects. However the findings of various studies who had well matched Control samples to the TB sample found that the upper molar extrudes 0.50 mm more than controls and the lower molar was restrained from extruding by 0.96 mm, yet neither difference was significantly different.\textsuperscript{117}

The final variable demonstrating significant differences between the TB group and Control sample was Facial Convexity. The TB sample showed a decrease of 3.31 degrees while the Control sample decreased only 0.66 degrees. Due to the extra two years of growth in the mandible and then chin button, this may not be an appropriate comparison. Morris et al and Baysal & Uysal found no significant difference between subjects treated with a Twin Block appliance and a well-matched control sample.\textsuperscript{17,83} Therefore in all likelihood poor matching of the Controls to TB may confound the present study.

4.4.2 Significant Variables: IMAF and Control

There were only four variables that were found to be significant between the IMAF and Control groups and the four were previously discussed in Section 4.4.1 Significant Variables: TB and Controls as these same four were also significant in the TB group. In an effort to be brief the discussion will be kept light as similar principles and concepts are at play, however with Phase 2 treatment occurring with removable aligners instead of fixed edgewise appliances. Differences between the two treatment groups will be elucidated at length in the following Section 4.4.3 Significant Variables: IMAF and TB.
The decrease in Wits was greater in the IMAF than the Controls. The overjet reduction was significantly more than the Control group but also significantly less than the reduction that occurred in the TB group.

The lower incisor protruded significantly compared to the Control group but only with respect to L1-APo; L1-NB (mm) was not found to be statistically significant. Therefore as the redundancy of L1-NB (mm) was not found to be significant, the likelihood that the lower incisor became more protrusive with clinical significance due to treatment may not be a valid conclusion.

Finally, the distal of the lower first molar to the occlusal plane perpendicular was found to be significantly different but was also highly variable between the three groups and therefore may not be the strongest indicator of lower first molar movement. Furthermore, none of the remaining three redundant checks on molar positioning were significant. Thus due to the plethora of measurements regarding molar positioning and the gross difference of the L6D to OP perpendicular measurement between all three groups, there should be no cause for alarm at this difference. As stated previously, small incremental changes in dental and skeletal variables, that individually are not statistically significant, combined amount to an important and clinically significant correction in the dental malocclusion and improvement in the skeletal relationship as compared to the Control group.
4.4.3 Significant Variables: IMAF and TB

As outlined multiple times previously, the overall length of treatment for the TB group was significantly longer than the IMAF group and so therefore more growth is incorporated into the TB group overall changes that are unable to be calculated from the existing data set.

Mandibular length change may have been the variable most affected by difference in observation periods. There was a significant difference between the two groups with the TB increasing in length 4.00 mm more than the IMAF group. Again, with a clear understanding of the influence of growth, it would be reasonable to expect the observed differences between the two groups. Specifically, TB was observed for 4.19 ± 1.09 years and IMAF only 2.12 ± 0.61 years.

The reduction of overjet was also significantly different between the two groups with the TB demonstrating nearly 4.5 mm of overjet reduction and the IMAF group exhibiting 2.55 mm of reduction. The TB group started with significantly more (1.4 mm more) than the IMAF group, yet even if this difference is taken into account, the TB group still demonstrated an overall greater reduction of overjet. This is due to the increased retroclination of the upper incisors as well as proclination and protrusion of the lower incisors that occurred in the TB group.

The lower incisor extrusion was also significantly different between the two groups – specifically the TB group lower incisor extruded significantly more (1.43 mm difference). This could be due to differences in the observation time leading to increased eruption of the lower incisor in the TB sample, or the use of fixed edgewise appliances instead of removable aligners.
Another explanation is due to the complete incisal coverage from the Invisalign® aligners, there was a greater impediment to vertical eruption of the lower incisors and thus vertical control.

The lower first molar also tended to move significantly more in a mesial direction in the TB group as compared to the IMAF sample. Again a component of this may in fact be growth, however the fact that more protrusion occurred in the TB group may also suggest that the entire dental complex underwent a mesialization. Therefore while there may be growth confounding this comparison, it remains that the TB dentoalveolar unit may have moved more in a mesial direction as compared to the IMAF group.

The final variable that was significantly different between the two groups was the upper lip to E-Plane. The upper lip was retracted a mean of 2.57 mm in the TB group and only 1.21 mm in the IMAF group. This difference of 1.36 mm is unlikely to be clinically significant and is also confounded by the increased amount of growth the TB group underwent. The extra growth could result in the nose and chin growing more than the IMAF group, thus creating an E-plane more anterior to the upper lip sufficient to cause a significant difference between the two groups.

4.5 Variable Correlation

Pearson Correlation statistical analysis was performed to determine correlation between specific overall (T3-T1) changes and various initial variables for both IMAF and TB groups. Significant correlations and discussion are found below.
4.5.1 Lower Incisor Proclination

4.5.1.1 IMAF Correlations

Lower incisor proclination was found to strongly correlate with the initial degree of proclination; the more proclined the lower incisors began, the less overall proclination occurred. This is interesting because suggests there may be a physiological limit to the degree of proclination the lower incisors will tolerate. As some cases started proclined, they may have already been at the upper limit and therefore the mandibular symphysis and periodontal support prohibited further proclination. Another possible explanation for the fact that less proclination occurred if the incisors started more proclined is that they had already dentally compensated for the Class II maxillomandibular discrepancy. In a dental compensation for an increased ANB angle the lower incisors will procline and protrude while the upper incisors will retrocline and retrude in an effort by the dentition to decrease the overjet and create anterior incisal contact. Another strong possibility is that with increased initial proclination, the clinician was acutely aware of the need to control the lower incisor position and therefore incorporated IPR in order to create space to alleviate crowding, level the Curve of Spee, and mitigate the lower incisor proclination.

Both the aforementioned arguments are similar and in line with those that can be made for the strong correlation between protrusion and proclination; which is that the more protrusive the lower incisors began, the less they proclined. As the lower incisors become more protrusive, they effectively are shifted forward out of the mandibular symphysis and alveolar housing. This in turn creates an unstable dentition, one that may have been predicted by the clinician who
specifically chose to limit proclination via incorporating interproximal reduction or lower arch expansion for the management of lower incisor inclination.

One moderate correlation that should be fairly self-explanatory is that the longer the patient wore the IMAF appliance, the more the incisors tended to procline. This is likely the result of the appliance placing a continuous (as long as the patient was wearing the appliance) mesial force on the mandibular dentition. This mesial force would posture the mandible forward but also shift the entire dentition mesially. As the dentition moved forward, correcting the Class II molar relationship, the lower incisor proclines.

4.5.1.2 TB Correlations

The amount of proclination of the lower incisor within the TB group was found to strongly correlate with the degree of initial proclination of said incisor in a similar manner as the IMAF group. Refer to the preceding Section 4.5.1.1 IMAF Correlations for a discussion of this subject.

4.5.2 Overjet

4.5.2.1 IMAF Correlations

Overjet reduction within the IMAF group was found to have a strong correlation with the initial presentation of the upper incisor protrusion. The more protruded the upper incisor relative to A-Pogonion, the more the overjet reduction occurred. In a similar, but reverse application of the concepts revolving around the mesial movement of the entire mandibular dentition, the entire maxillary complex was retracted. The mandible was postured forward with the maxilla
experiencing a distal force as it supports the posture. This force is expressed on the dentition and
the protruded upper incisors are effectively retracted. Another explanation involves the treatment
objective to expand the maxillary dentition to coordinate with the mandibular dentition as the
mandible is advanced. Each millimeter of expansion offers an increase of 0.7 mm of arch length.
This increased arch length could then be utilized (similar to IPR in the lower anterior) to retract
or retrocline the upper incisors. Another rationale for the amount of overjet reduction correlating
to the initial protrusion of the upper incisors is that occasionally a solitary upper incisor will be
crowded facially/labially out of the arch. This results in proclination and protrusion to a larger
degree than the surrounding teeth. On a cephalometric tracing and subsequent measurement, the
most protrusive upper incisor (and lower incisor for that matter) is traced and used for measuring
purposes. This can essentially over exaggerate the overjet, as a single tooth that is crowded
facially out of the arch is not indicative of the overjet across the majority of the incisors.
Furthermore, this single tooth protrusive overjet is a far cry easier to resolve as compared to an
overjet of the same amount that is uniform across the entirety of the incisors.

4.5.2.2 TB Correlations

Similar to the correlations found within the IMAF group, the TB group exhibited correlations
with upper incisor protrusion as well. See Section 4.5.2.1 IMAF Correlations.
4.5.3 Mandibular Length

4.5.3.1 IMAF Correlations

Mandibular length increase was correlated with a few variables that could have some interrelationship as well. It was found that the older the patient was at the beginning of treatment, the less the mandible tended to increase in length. In a review of the other variables with correlations to the amount of mandibular length increase, there was statistical significance between the increase in length and the initial length; the longer the mandible at T1, the less it increased during the treatment period. A thoughtful approach to these two variables finds that they are saying the same thing. As the patient ages, the mandible increases in length. Therefore older patients have longer mandibles, in general. This could be the effect of the pubertal growth spurt. There is no radiographic method for determining the exact moment at which the growth spurt begins and ends, however it may be that the younger patients incorporated some, or more, of the growth spurt into the observation period than the older patients. For example, the younger patients may have been entering the growth spurt a month or two into treatment and therefore had nearly the entirety of treatment with high growth potential. On the other hand the older patients may have been on the tail end of their pubertal growth spurt and therefore only incorporated the growth spurt into the first three months or so of treatment.

4.5.3.2 TB Correlations

TB correlations for mandibular length changes were in agreement with those found within the IMAF group but there was an additional variable: L1-MP (mm). This variable was not expected to correlate with the mandibular length change as it has a more vertical connotation. The
correlation states that the further the initial distance from the mandibular plane to the lower incisor tip resulted in a smaller amount of mandibular length increase. This could be due to the fact that as the distance from the mandibular border to the incisal tip increases the patient may be more likely to be classified as having a vertical growth pattern. Supposing the patient exhibits a vertical growth pattern there would be a poor horizontal growth or lengthening of the mandible during the observation period. Therefore if a patient presents with a higher than normal distance from the mandibular border to the incisal tip of the lower incisor, there may be a poorer prognosis for the outcome of TB use with regards to mandibular length.

4.5.4 Upper Incisor Protrusion

4.5.4.1 IMAF Correlations

Upper incisor retraction correlated with initial overjet and initial incisor protrusion in such a way that the greater the initial values, the greater the incisor was retracted. This discussion can be very similar to the discussion revolving around overjet. And therefore referring back to Section 4.5.1.2 Overjet is encouraged.

The initial Wits Appraisal was also correlated – the greater the Wits Appraisal (meaning more Class II) the more the upper incisor was retracted. This correlation has both a skeletal and dental component. The Wits Appraisal takes the difference between the A point and B point perpendicular to the occlusal plane difference, thus reflecting the skeletal component. But as the reference plane is the occlusal plane, the dentition can influence the Wits Appraisal. The steeper the occlusal plane (posterior portion is higher than the anterior), the greater the distance between
the A and B point perpendicular will be. While the occlusal plane flattens, the two points will tend to converge. Furthermore, a Class II reading from the Wits Appraisal would tend to tie hand in hand with a larger overjet. And a larger overjet requires greater amounts of dental camouflage to reach an appropriate overjet and overbite. To decrease the overjet, the retraction and retroclination (furthering the amount of relative retraction) must occur. Thus it is expected and should be anticipated in clinical scenarios to see reduction in overjet via retraction of the upper incisor.

4.5.4.2 TB Correlations

While TB exhibited the same correlations as the IMAF group regarding upper incisor protrusion changes (Overjet and U1-APo), the TB group also demonstrated a correlation with the L1-MP initial proclination. Specifically, the more proclined the lower incisor, the more the upper incisors was retracted. This is fairly straightforward and self-explanatory. The lower incisor had already dentally compensated for a Class II maxillomandibular skeletal discrepancy and was at what could feasibly be considered its physiological limit. Therefore the remaining distance between the upper and lower incisors (overjet) was corrected via upper incisor retraction; a clear-cut example of dental compensation.

4.5.5 Lower Incisor Protrusion (L1-NB & L1-APo) and Vertical

4.5.5.1 IMAF Correlations

The lower incisor angle relative to the mandibular plane was found to correlate with the lower incisor protrusion (L1-NB and L1-APo). The proclination has previously been discussed with
regards to physiological limits in Section 4.5.1.1 Lower Incisor Proclination. This concept applies similarly to the amount of protrusion a lower incisor can physiologically accept.

Of greater interest is the moderate correlation between the mandibular plane angle (SN-MP) and the amount of lower incisor protrusion – specifically, the steeper the mandibular plane angle, the more the lower incisor protruded. While a curious concept at first, this is relatively well explained by the idea that as the mandibular plane rotates and becomes steeper, the lower incisor is relatively protruded in front of the mandible without any movement of the incisor occurring. The reverse is also true, as one auto-rotates the mandibular complex in a counterclockwise, or up and forward direction, the incisor becomes relatively retruded with relation to the Nasion to B-Point and A Point to Pogonion lines. Therefore the clinician can anticipate with relatively good certainty that in a patient with a steeper mandibular plane angle, the lower incisor will tend to become more protrusive with IMAF treatment. It should be noted that patients with a high mandibular plane angle tend to present with lower incisors that are retroclined relative to the normal lower incisor to mandible plane. The clinician should therefore take the appropriate steps to control, counteract, or treat the sequela of lower incisor protrusion resulting from treatment and proclination that may include, but is not limited to, gingival recession, mobility, black triangles due to inadequate periodontal support interdentally, etc.

4.5.5.2 TB Correlations

There was a plethora of differences between the two treatment groups regarding correlations surrounding the lower incisor movements. While the initial L1-MP angle continued to be predictive protrusive movements of the lower incisor, the age and overjet were also moderately
correlated. The older the patient, the less the incisor protruded and also extruded, suggestive of more proclination occurring in these patients to decrease the overjet and also a decrease in the amount of vertical compensatory growth occurring at the incisal region in response to vertical growth of the face. The overjet suggests that the greater the overjet at T1, the more the lower incisor protruded relative to NB. Once again it should be fully anticipated for said change to occur as an amalgam of small and statistically non-significant changes, both skeletal and dental, occur in correction of the Class II malocclusion.

The longer the mandible at T1, the less the lower incisor extruded relative to the mandibular plane. And furthermore, the deeper (greater) the overbite, the less the lower incisor extruded. This could be that the eruption of the lower incisor was controlled in a deep bite patient in order to decrease said overbite. The longer mandibular length can be related to the age as well which stated similarly that the older the patient (and potentially the longer the mandible) the less the incisor extruded.

Therefore while there were multiple variables that were potential predictors of incisor changes throughout treatment, many may hold references to each other.

4.5.6 Molar Movements

4.5.6.1 IMAF Correlations

Correlations of note with regards to the molar movements include how both age and mandibular length were predictors of the mesial movement of both the upper and lower first molars –
specifically, the older the patient and longer the mandible, the less the molars tended to move in a mesial direction away from the occlusal plane perpendicular. This correlation is to be anticipated because as the patient ages, the mandible becomes longer, so the two are slightly redundant. Secondly, as the patient ages the molars are less likely to experience mesial drift in comparison to a patient in a late mixed dentition, or a dentition with leeway space remaining. Furthermore, resolution of any crowding would preferably occur with anterior displacement of the mandibular dentition in order to decrease the overjet by protruding and proclining the teeth. Should the resolution occur by distalizing the mandibular molars the Class II molar relationship would remain uncorrected. Similarly in an older patient it would be a goal to distalize the maxillary dentition to reduce overjet and improve the molar relationship. Any distalization would result in less mesial movement and or a net negative movement with respect to initial maxillary molar position relative to the occlusal plane. Therefore, in older patients and those with longer mandibles, it can be anticipated that minimal molar movement will occur when compared to patients who are younger and have shorter mandibles.

Finally, patients with steeper mandibular planes tended to exhibit greater amounts of mandibular first molar extrusion. This is may be a result of the vertical growth pattern and the dentition compensating for said growth. It may be a result of Class II elastics which are connected to the mandibular first molar and the maxillary canine. The elastic exerts a mesial and extrusive force vector on the molar, thus extruding the mandibular first molar.
4.5.6.2 TB Correlations

The amount of molar movements within the TB group had multiple variables with interesting connotations. While both age and mandibular length were self-explanatory in that the older the patient and longer the mandible at T1 (potential relationship between these two), the less the maxillary molar extruded throughout treatment. This is well within the realm of sound reasoning because as the patient ages, less vertical growth occurs and therefore less extrusion of the molars (maxillary in this instance) occurs to compensate for vertical skeletal growth.

What held more interest, and also held potential relationships between the variables, was the length of Phase 2, the ANB angle, and Wits Appraisal. The longer the treatment and greater the Class II maxillomandibular discrepancy the more the lower first molar erupted relative to the mandibular plane. There are two specific reasons to explain this correlation. First and foremost, the worse the Class II maxillomandibular discrepancy (as measured by the ANB angle and Wits Appraisal) the longer the patient would potentially undergo treatment in order to satisfactorily treat the malocclusion. A longer treatment would result in a greater amount of vertical skeletal growth and therefore the mandibular first molar would erupt to compensate for said growth. Secondly, and theoretically relative to the clinicians’ mechanics, is the use of Class II elastics that are connected to the maxillary canine and the mandibular first molar. The Class II elastic has not only a horizontal vector used to correct the anteroposterior dental malocclusion but also a vertical component. This vertical component has the potential to extrude the mandibular first molar. In a more severe Class II discrepancy (again as measured by the ANB angle and Wits Appraisal), the Phase 1 treatment of advancement with the TB appliance may not have been sufficient to completely treat the malocclusion. Therefore during the Phase 2 (T2 to T3), elastics
would have been employed. Again, if elastics are used for a prolonged period of time, there is the potential to extrude the mandibular first molar beyond what growth would have caused. What is interesting to note is that the mandibular plane (SN-MP) became slightly steeper over the course of treatment. This supports the theory that Class II elastics were used and caused extrusion of the lower first molar, resulting in an opening of the mandibular plane as the mandibular rotated clockwise (down and back) to accommodate the extruded molar.

4.5.7 Facial Convexity

4.5.7.1 IMAF Correlations

Curiously, Facial Convexity changes were not found to significantly correlate with any of the tested initial variables. This could easily be viewed with frustration in the inability to predict which patients will respond favorably to IMAF treatment. Yet it can also be viewed as the possibility that there are a plethora of variables at play that result in significant improvements to the Facial Convexity. There are plenty of confounding variables in determining what variables predict positive outcomes, one of which is the presence or absence of a chin button. A chin button, or projection of the mandibular symphysis, that is prominent gives the illusion of a longer mandible, longer chin to throat length, and less convex profile. The converse is also true. Therefore it is difficult to separate patients and outcomes based solely on the chin button size and projection. This concept of chin projection is also hampered by any rotational effects on the mandible because as the mandible rotates down and back in a clockwise rotation, the chin projection relative to B point is decreased. A more in-depth study into the relationship of chin button projections as indicators for outcomes – such as horizontal or vertical growth patterns,
treatment outcomes related to functional and or fixed appliances, or facial patterns – may be of interest to future investigators.

4.5.7.2 TB Correlations

As with the IMAF group, the TB group had no initial variable that was run for correlation demonstrate any significant correlation with Facial Convexity changes. See Section 4.5.7.2 IMAF Correlations for discussion on the matter.

4.6 Strengths of This Study

Some strengths of the study that allow the project to review and compare the IMAF to TB and Controls with minimal bias include first, the absence of 3rd party supported data and secondly, lack of 3rd party financial support. Also of note, is that at the time of project initiation, no independent research had been conducted regarding the treatment effects and outcomes when using the Mandibular Advancement Feature with Invisalign® for the treatment of a Class II malocclusion.

Furthermore, with only two treating practitioners, there is minimal variation in treatment protocol. Another strength is that there is minimal selection bias within the Twin Block group because at the time of treatment for these cases the IMAF was not a treatment modality. The tracings were completed by a single, blinded operator (SSB) and contained a respectable amount of re-tracings in order to verify tracing validity.
The owners and practitioners were present to elucidate clinical techniques regarding treatment with the respective orthodontic appliances, and were not involved in the tracing and analysis of records. Furthermore, the owners and private practice colleagues were not involved in the independently conducted analysis. As such, risk of inducing bias from recognition of patient lateral cephalometric radiographs or otherwise was minimized.

A major strength of the control group is that they are longitudinal and therefore each patient is matched with a control subject that remains consistent for each time point.

4.7 Limitations

Some of the weaknesses of this study include the fact that the Control group is historical in nature, does not come from the same locale (multiple growth center studies included), and is less severe Class II skeletal relationship. Furthermore, the amount of crowding was not precisely assessed, but thought to be evenly distributed between groups. Therefore changes and differences between groups may be partially due to correction of crowding.

Another limitation relates to the retrospective nature and the associated potential biases. One bias may be selection bias within the IMAF group as the practitioners could imagine a patient to be more compliant with the IMAF, and therefore provide more favorable results. However all patients self-selected the appliance after being shown an example of each (IMAF and TB) on a typodont. Furthermore, none of these patients were randomly assigned, as this is a retrospective chart study. However, this project may lead to prospective randomized clinical trials in the future.
In response to the fact that one patient may be more compliant with IMAF than TB, all patients were treated to correction, therefore there is no difference in compliance as the treatment time in advancement phase was the same (mean). While having only two treating clinicians is considered strength, it could also be a limitation as there could be subtle differences between the treatment protocol in both practices. The lab fee associated with the IMAF and subsequently Invisalign® aligner treatment is more in comparison to the TB appliance and FEA treatment and so this could also be a complicating factor when the decision to treat is made. This would be offset if TB treatment was followed by Invisalign® aligner treatment as the IMAF treatment is included in certain Invisalign® aligner plans.
Chapter 5: Conclusion

The purpose of this study was to compare the short-term skeletal, dental, and soft tissue effects of Invisalign® with the Mandibular Advancement Feature to the Twin Block appliance and fixed edgewise appliances when used for the treatment of a Class II malocclusion in a growing orthodontic patient. A longitudinal historical control sample was age and gender matched to the IMAF group for additional comparisons.

Following a review of cephalometric radiographs and clinical photographs, both Invisalign® with the Mandibular Advancement Feature followed by Invisalign® treatment, and Twin Block therapy followed by fixed edgewise appliances are effective in the correction of a Class II malocclusion.

Invisalign® with the Mandibular Advancement Feature may impede lower incisor eruption during the advancement phase as compared to the Twin Block appliance. While the Twin Block appliance may improve the molar relationship, overjet (primarily through retroclination of the upper incisors), and increase mandibular length to a greater degree than Invisalign® with the Mandibular Advancement Feature during the same period from T1 to T2.

Neither Invisalign® or fixed edgewise appliances as a treatment modality in the second phase of treatment offered any significant dental or skeletal outcomes over the other.
Invisalign® with the Mandibular Advancement Feature followed by treatment with Invisalign® removable aligners can effectively treat Class II malocclusions, significantly decreasing the Wits Appraisal, overjet, and improving the skeletal and soft tissue convexity, through a combination of small and non-statistically significant effects on both skeletal and dental components of the malocclusion.
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Appendices

Appendix A

Cephalometric Analyses: ABO, McKee, and Additional Measurements

A.1 ABO Analysis

Maxilla to Cranial Base

SNA: Sella – Nasion – A-Point Angle

Mandible to Cranial Base

SNB: Sella – Nasion – B-Point Angle

SN-MP: Sella – Nasion to Mandibular Plane Angle

FMA: Frankfort Horizontal to Mandibular Plane Angle

Maxillo-mandibular

ANB: A-Point – Nasion – B-Point Angle

Maxillary Dentition

U1-NA (mm): Upper Incisor to Nasion – A-Point

U1-SN: Upper Incisor to Sella – Nasion Angle

Mandibular Dentition

L1-NB (mm): Lower Incisor to Nasion – B-Point

L1-MP: Lower Incisor to Mandibular Plane Angle

Soft Tissue

Upper Lip to E-Plane (mm)

Lower Lip to E-Plane (mm)
A.2 McKee Analysis

Maxilla Skeletal

SNA: Sella – Nasion – A-Point Angle

A-Na Perp (mm): Maxillary Skeletal (A-Point – Nasion Perpendicular)

Co-A (mm): Midface Length (Condylion – A-Point)

Mandible Skeletal

SNB: Sella – Nasion – B-Point Angle

Pg-Na Perp (mm): Mandibular Skeletal (Pogonion – Nasion Perpendicular)

Co-Gn (mm): Mandibular Length (Condylion – Gnathion)

Maxilla to Mandible Skeletal

ANB: A-Point – Nasion – B-Point Angle

Maxillary/Mandibular Difference (Condylion-Gnathion – Condylion-A-Point) (mm)

Wits Appraisal (mm)

NA-APo: Skeletal Convexity (Nasion – A-Point – Pogonion) Angle

Maxilla Dentoalveolar

U1-SN: Upper Incisor to Sella – Nasion Angle

U1-FH: Upper Incisor to Frankfort Horizontal Angle

U1-PP: Upper Incisor to Palatal Plane Angle

U1-NA: Upper Incisor to Nasion – A-Point Angle

U1-NA (mm): Upper Incisor to Nasion – A-Point distance

U1-APo (mm): Upper Incisor to A-Point – Pogonion distance

Mandible Dentoalveolar

L1-MP: Lower Incisor to Mandibular Plane Angle
L1-NB: Lower Incisor to Nasion – B-Point Angle
L1-NB (mm): Lower Incisor to Nasion – B-Point distance
L1-APo (mm): L1 to A-Point – Pogonion distance

*Vertical Dimensions*

FMA: Frankfort Horizontal to Mandibular Plane Angle
SN-MP: Sella – Nasion to Mandibular Plane Angle
UFT/TFH (%): Nasion – Anterior Nasal Spine:Nasion – Menton
LFH/TFH (%): Anterior Nasal Spine – Menton:Nasion – Menton
P-A Face Height (%): Sella – Gonion:Nasion – Menton
U6-PP (mm): Upper First Molar Mesiobuccal Cusp to Palatal Plane distance
L1-MP (mm): Lower Incisor Tip to Mandibular Plane distance
L6-MP (mm): Lower First Molar Mesiobuccal Cusp to Mandibular Plane distance

*Soft Tissue*

Upper Lip to E-Plane (mm)
Lower Lip to E-Plane (mm)
Nasolabial Angle (Columella – Subnasale – Upper Lip)
Facial Convexity (Soft Tissue Glabella – Subnasale – Soft Tissue Pogonion) Angle

**A.3 Additional Measurements**

*Horizontal Molar Movements*

H Perpendicular to Mesial of Upper 6
Upper 6 Distal to Occlusal Plane Perpendicular
H Perpendicular to Mesial of Lower 6
Lower 6 Distal to Occlusal Plane Perpendicular

*Incisor Relationship*

Overjet

Overbite
Appendix B

Appendix B contains cephalometric tracing points and lines used for cephalometric analysis.

B.1 Cephalometric Tracing Points

Figure B.1 Sample Cephalometric Tracing with Numbered Points. Key on Following Pages.
| 1. Ruler Point 1          | 24. B-Point            |
| 2. Ruler Point 2          | 25. Pogonion           |
| 4. Orbitale              | 27. Gnathion           |
| 5. PT Point              | 28. Gonion             |
| 7. Nasion                | 30. Ramus Point        |
| 8. Basion                | 31. Articulare         |
| 10. Soft Tissue Nasion   | 33. Sigmoid Notch      |
| 11. Bridge of Nose       | 34. Mid-Ramus          |
| 12. Tip of Nose          | 35. Posterior Nasal Spine |
| 15. Upper Lip            | 38. Labial gingival border of U1 |
| 16. Stomion Superior     | 39. Lingual gingival border of U1 |
| 17. Stomion Inferior     | 40. Root Apex of U1    |
| 18. Lower Lip            | 41. Incisal Tip of U1  |
| 19. Soft Tissue B-Point  | 42. Incisal Tip of L1  |
| 20. Soft Tissue Pogonion | 43. Labial Gingival Border of L1 |
| 21. Soft Tissue Menton   | 44. Lingual Gingival Border of L1 |
| 22. Soft Tissue Gnathion | 45. Root Apex of L1    |
| 23. Throat Point         | 46. Distal CEJ of U6   |
B.2 Examples of Cephalometric Tracings

Figure B.2 Sample Cephalometric Tracing with Analysis Lines
Figure B.3 Sample Cephalometric Tracing with Molar Measurement Lines
Appendix C

Appendix C contains supplemental statistical analyses.

C.1 Significant Intraclass Correlation Coefficients (ICC)

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Variable</th>
<th>ICC kappa value</th>
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<tbody>
<tr>
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<td>Midface Length</td>
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<tr>
<td>T1</td>
<td>Mandibular Length</td>
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<tr>
<td>T1</td>
<td>L1-MP (mm)</td>
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<td>T2</td>
<td>Maxillary Skeletal Position</td>
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<tr>
<td>T3</td>
<td>Nasolabial Angle</td>
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<tr>
<td>T3</td>
<td>L6 Distal – OP Perpendicular</td>
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Table C.1 Significant Intraclass Correlation kappa values
### C.2 Dahlberg’s Error Test Results

<table>
<thead>
<tr>
<th></th>
<th>SNA</th>
<th>SNB</th>
<th>ANB</th>
<th>SN - MP</th>
<th>FMA (MP-FH)</th>
<th>U1 - NA (mm)</th>
<th>U1 - SN</th>
<th>L1 - NB (mm)</th>
<th>L1 - MP</th>
<th>Overjet (mm)</th>
<th>Overbite (mm)</th>
<th>Lower Lip to E-Plane (mm)</th>
<th>Upper Lip to E-Plane (mm)</th>
<th>Maxillary Skeletal (A-Na Perp) (mm)</th>
<th>Midface Length (Co-A) (mm)</th>
<th>Mand. Skeletal (Pg-Na Perp) (mm)</th>
<th>Mandibular length (Co-Gn) (mm)</th>
<th>Wits Appraisal (mm)</th>
<th>Convexity (NA-APo)</th>
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<tbody>
<tr>
<td><strong>T1</strong></td>
<td>0.47</td>
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<td>0.84</td>
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<td><strong>T2</strong></td>
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<td>1.96</td>
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Table C.2 Dahlberg’s Error Test Results
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<tr>
<th></th>
<th>U1 - FH</th>
<th>U1 - Palatal Plane</th>
<th>U-Incisor Protrusion (U1-APo) (mm)</th>
<th>L1 Protrusion (L1-APo) (mm)</th>
<th>UFH/TFH (N-ANS:N-Me) (%)</th>
<th>LFH/TFH (ANS-Me:N-Me) (%)</th>
<th>P-A Face Height (S-Go:N-Me) (%)</th>
<th>U6 - PP (UPDH) (mm)</th>
<th>L1 - MP (LADH) (mm)</th>
<th>L6 - MP (LPDH) (mm)</th>
<th>H Perp to Mesial U6 (mm)</th>
<th>H Perp to Mesial L6 (mm)</th>
<th>U6 Distal to Occ Plan Perp (mm)</th>
<th>L6 Distal to Occ Plan Perp (mm)</th>
<th>Nasolabial Angle (Col-Sn-UL)</th>
<th>Facial Convexity (G'-Sn-Po')</th>
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</thead>
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Table C.3 Dahlberg’s Error Test Results Continued