9-2021

Evaluating the treatment effectiveness and efficiency of the DF2 protocol using Invisalign® for treatment of Class II malocclusion: A retrospective comparison study

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School of Dentistry
in conjunction with the
Faculty of Graduate Studies

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by

Bryan J. Otis

A Thesis submitted in partial satisfaction of
the requirements for the degree
Master of Science in Orthodontics and Dentofacial Orthopedics

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September 2021

Each person whose signature appears below certifies that this thesis in his/her opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.

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ACKNOWLEDGEMENTS

I would like to express my deepest gratitude to the members of my research committee: Dr. Kitichai Rungcharassaeng, Dr. Joseph Caruso, and Dr. Andrew Ferris. Your mentorship, guidance, and support throughout this process was invaluable in making this project a reality. I would also like to thank Udochukwu Oyoyo for providing his expertise in analyzing data and interpreting results.

To my wife Jordan: thank you for your unconditional love, support, and patience. I could not have attained my professional goals without you. To my children Jack and Aria: thank you for enriching and giving my life new perspectives.

To my parents and family: thank you for being an inspiration and source of support and throughout my life and education. Finally, I would like to thank my Heavenly Father for His many blessings and providing me this opportunity to study His creation.

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ABBREVIATIONS

2D	Two-Dimensional
3D	Three-Dimensional
ABO	American Board of Orthodontics
ANB	A point-Nasion-B point
AP	Anterior-Posterior
CAT	Clear Aligner Therapy
CBCT	Cone-Beam Computed Tomography
DI	Discrepancy Index
FH	Frankfort Horizontal
G_1	Group 1
G_2	Group 2
GCG	Growth Constant Grid
Go-Gn	Gonion-Gnathion
Go-Gn – SN	Gonion-Gnathion-Sella-Nasion
ICC	Intraclass Correlation Coefficient
IMPA	Incisor Mandibular Plane Angle
IPR	Interproximal Reduction
L1-PTV	Lower incisor crown to pterygoid vertical
L6-PTV	Lower first molar to pterygoid vertical
MIP	Maximum Intercuspal Position
NBa	Nasion-Basion
OB	Overbite
OJ	Overjet

PTV	Pterygoid Vertical
SNA	Sella-Nasion-A point
SNB	Sella-Nasion-B point
T_1	Pre-treatment
T_2	Post-treatment
TAD	Temporary Anchorage Device
U1-FH	Upper incisor inclination to Frankfort Horizontal
U1-PTV	Upper incisor crown to pterygoid vertical
U6-PTV	Upper first molar to pterygoid vertical

ABSTRACT OF THE THESIS

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Master of Science, Graduate Program in Orthodontics and Dentofacial Orthopedics
Loma Linda University, September 2021
Dr. Kitichai Rungcharassaeng, Chairperson

Purpose: This retrospective study evaluated the treatment effectiveness and efficiency of the DF2 protocol for correction of class II malocclusions in comparison to conventional protocol using Invisalign®.

Materials and Methods: Clinical and cephalometric data of patients that were treated for class II malocclusion between July 30, 2014 and July 22, 2021 were reviewed and selected. The selected patients were matched for age, sex, and treatment complexity and divided into two groups: Group 1 (G_1) —DF2 protocol and Group 2 (G_2)—conventional class II Invisalign®. Clinical variables to represent the skeletal and dentoalveolar changes during treatment were assessed using pre-treatment (T_1) and post-treatment (T_2) digital study models and cephalometric tracings. Statistical analysis was accomplished using Mann-Whitney U and Spearman's rho tests ($\alpha = 0.05$). Intra-rater reliability was expressed as intraclass correlation coefficient (ICC).

Results: A total of 22 patients (6 males, 6 females in G_1 and 5 males, 5 females in G_2) with a mean age of 15.29 (14.27 in G_1, 16.52 in G_2) years of age were included in this study. Excellent intra-rater reliability was reported (ICC > .95). There were no statistically significant differences in T_1 age, discrepancy index (DI), or treatment length

between the groups ($p > .05$). There were no differences in the amount of T_1 class II or their changes (molar and canine) following treatment between the groups ($p > .05$). The amount of T_1 overjet (OJ) was statistically more in G_1 at T_1 leading to a significantly greater reduction in OJ in G_1 after treatment ($p < .05$). All other cephalometric variables at T_1 and their changes were comparable between groups ($p > .05$). No correlation was observed between treatment length and DI, molar and canine corrections ($p > .05$) except between treatment length versus canine correction in G_2 ($p < .05$).

Conclusion: The results of this study indicate the efficacy and efficiency of both protocols are comparable in class II correction. However, the lack of correlation between treatment time and the amount of class II correction in DF2 group suggests that this protocol may be beneficial when significant class II correction is required.

CHAPTER ONE

REVIEW OF LITERATURE

Class II malocclusion is defined as the mandibular first molar being distally positioned relative to maxillary first molar.[48] It is expressed by an abnormal dentoalveolar and/or skeletal configuration such as maxillary excess or more commonly, mandibular deficiency.[3] The prevalence of class II malocclusion is estimated to be approximately 15% of the total population, including 23% of children and 13% of adults.[1,2] Many individuals would benefit functionally and esthetically from orthodontic and/or dentofacial orthopedic correction for class II malocclusion. In the literature, various treatment methods are outlined to correct this malocclusion utilizing conventional edgewise appliances and clear aligner therapy (CAT).

Conventional Class II Treatment Methodologies

Due to the diverse presentation of class II malocclusion, various treatment methods are proposed based on multiple patient specific factors such as, the severity of skeletal and/or dental configuration, profile esthetics, compliance concerns, and remaining growth potential of the patient.[18] The side effects of each treatment method must also be considered while treatment planning.

Classically, the use of extra oral force with headgear was used to inhibit the sagittal growth of the maxilla while also distalizing maxillary molars and reducing overjet.[4] This allowed mandibular growth to continue while reaching a more favorable skeletal relationship.[4] However, 38% of orthodontists report not using any headgear in their practice; its utilization overall is declining.[49] This decline is partly due to observed poor compliance and availability of alternative options for class II correction.[50]

Intermaxillary elastics are a popular treatment option for class II malocclusion and are proven to be effective.[5,6] Treatment effects occur primarily at the dentoalveolar level and side effects include extrusion and retrusion of maxillary incisors, extrusion of mandibular molars, proclination of mandibular incisors and increase in vertical face height.[6] Additionally, patient compliance may be unreliable which could increase treatment time.[51,52] Overall, there are more similarities than differences between the effects of class II elastics and functional appliances.[6]

Functional orthopedic appliances are frequently employed for a skeletally deficient mandible.[8] These may be removable (Twin Block) or fixed (Herbst, MARA).[9] The aim of functional appliances is to stimulate mandibular growth by posturing it forward to correct a skeletal and/or dental relationship.[9,53] The amount of “extra” mandibular growth obtained, however, remains controversial. It has been revealed that in the short-term, functional appliances achieve greater skeletal change than class II elastics, but in long-term evaluation the effects are similar and occur at the dentoalveolar level.[6,8,9] Like class II elastics, side effects include proclination the lower incisors, retroclinination the upper incisors, and increase in vertical dimension.[6,8,9]

Another suggested method for class II correction was use of a molar distalizing appliance.[11,13,54] Reduced dependence on patient compliance is an advantage of many distalizing appliances[12,55,56] Examples include the Pendulum appliance[10] and Distal Jet.[14,15] Notable side effects include an increase in increase in vertical dimension, distal tipping of maxillary molars and loss of anterior anchorage.[13,54] These may lead to an increase in total treatment time.[13] Temporary anchorage devices (TADs) are suggested to minimize these side effects.[14] Due to the increase in vertical dimension, molar distalizing appliances are generally contraindicated in hyperdivergent patients.[35]

The Carriere® Motion 3D™ or Carriere Distalizer is a molar distalizing appliance that is growing in popularity. It uses a 2-phase treatment approach, beginning with the objective to derotate and upright the maxillary first molars while distalizing the posterior buccal segment to class I occlusion before the conventional edgewise appliances are placed.[16] During the initial phase, the mandibular arch serves as a source of anchorage, generally without active treatment. Mandibular anchorage may be a lingual arch, clear thermoplastic retainer, full fixed appliances, or TADS.[16] Unlike similar appliances, loss of anterior anchorage is not a concern since the anterior teeth are not involved. Side effects of this appliance include extrusion of maxillary canines, worsening the mandibular arch length discrepancy and relapse of derotated molars.[18] Yin et al compared the effectiveness of the Carriere Distalizer to conventional class II elastics and found that it corrected a similar class II discrepancy an average of four months faster.[18] However, overall treatment time was found to significantly longer than elastics alone while achieving similar cephalometric changes.[18] Although the Carriere Distalizer is not shown to be any more effective than alternatives in class II correction, it is gaining popularity for its rapid sagittal correction, improved esthetics and overall comfort which impacts the patient experience.[19]

Class II Treatment Methodologies using Clear Aligner Therapy

The cultural emphasis on youth and beauty has brought an esthetic paradigm shift in dentistry.[20] A resulting increase in demand for esthetic orthodontic treatment for adults and adolescents has been observed.[20,21] Clear aligner therapy (CAT) is a primary motivator of adults seeking orthodontic treatment[57] and they are willing to pay more for it.[58] This demand has driven the evolution of CAT since its inception in 1997 when Align Technology introduced Invisalign® (Align Technology, San Jose, CA).

Invisalign® was initially developed for class I malocclusions with mild to moderate crowding[23] but when applied to more complex treatments such as antero-posterior (AP) discrepancies its efficacy has been cautioned.[23,28,59] However, the use auxiliary attachments, intermaxillary elastics, sequential distalization, TADs, and/or pre-treatment distalizing appliance in adjunct with CAT has demonstrated successful treatment of AP discrepancies.[17,24-26]

A common strategy to correct class II malocclusion with CAT is “sequential distalization”. [60] In this protocol, programmed distalization begins with the second molars and once distalized two-thirds of the way, each successive tooth is moved. Auxiliary attachments and class II elastics are worn to reinforce anchorage and prevent flaring of anterior teeth.[60] Intermaxillary elastics may be attached directly to aligners with hook cut outs or attached directly to teeth with buttons, hooks, or brackets.[17]

An alternative method is use of a pretreatment molar distalizing appliance prior to CAT. Recommended appliances include Carriere Distalizer,[17,26] Distal Jet[15] or Pendulum appliance.[17] Once the sagittal correction is achieved, conventional CAT is used to complete the case and achieve treatment goals.[26]

Treatment outcome and efficacy using Clear Aligner Therapy

To test the efficacy of maxillary molar ditalization using CAT, Ravera et al treated a sample of non-growing subjects with ‘end-on’ class II malocclusion. Lateral cephalograms were analyzed before and after treatment lasting 24.3 ± 4.2 months. Each case was planned for sequential distalization. Attachments were placed on the distalizing teeth with class II elastics to reinforce anchorage. The amount of distalization observed at the maxillary first molar and second molar was 2.25 mm and 2.52 mm, respectively.[34] No significant vertical movement or tipping was noted. Overall good control of vertical dimension was achieved with little skeletal change.[34] This study demonstrates how Invisalign® is effective for distalizing molars without significant mesiodistal tipping while also maintaining vertical face height during the correction of class II 'end-on' malocclusions.

To assess predicted versus actual molar distalization achieved with Invisalign®, Simon et al evaluated the tooth movements of patients with prescribed molar distalization of >1.5mm.[32] Class II elastics were not worn and distalization of maxillary molars were supported with and without attachments. Pre- and post-treatment scans were superimposed on ClinCheck® (Align Technology, San Jose, CA) predictions to determine the efficacy of projected tooth movement. It was found that molar distalization with attachments achieved 88.4% of predicted movement which was marginally higher than the 86.9% without attachments.[32] This study demonstrates molar distalization can be achieved with Invisalign® but overcorrections may be needed to achieve full correction.

It is known that maxillary molar derotation is helpful in class II correction and can provide up to 2mm of space per side in the maxillary arch.[61] Therefore evaluating the rotational accuracy of CAT is important. Charalampakis et al found that among tooth types, all achieved rotations were significantly lower than what was predicted, however, the premolar was most accurate with a 0.9° difference between predicted and final outcomes while canines were the least accurate with a 3.05° difference.[62] Simon et al also found an overall low accuracy of premolar rotation achieving only 37.5% of projected tooth movement.[32] The authors conclude that rotational movements are one of the least accurate using Invisalign®.[61] However, when total movement and velocity are considered (below 15° and less than 1.5° per aligner) accuracy was significantly increased.[63] It should be noted that molar rotation was not specifically evaluated in the literature.

Overall, the efficacy of treatment outcomes with CAT have been assessed in the literature[27,28] and mild to moderate case outcomes are not significantly different from conventional fixed appliances[29,30] and may show a statistically significant shorter treatment time.[30,31] The average accuracy of tooth movement with Invisalign® ranged from 55-72% of projection depending on frequency of aligner change.[64] The most accurate movement is molar distalization while rotational and vertical movements are least predictable.[32,62,63] Advantages of CAT include good control of lower incisor position when pretreatment crowding is mild to moderate (<6mm)[33] and ability to maintain facial height during molar distalization without significant distal tipping.[34,35]

The DF2 Protocol

The current literature supports the efficacy of numerous class II treatment options but with continued popularity of esthetic orthodontic treatment, the present study is of significant interest. The DF2 protocol utilizes a 2-phase treatment approach with a short initial stage (~3 months) for sagittal correction.[36] In this phase, a maxillary sectional clear aligner (Invisalign®, San Jose, CA) is used in conjunction with class II elastics to achieve similar objectives to the Carriere Distalizer—molar rotation and distalization.

Unlike the Carriere Distalizer, active leveling on the mandibular arch and maxillary posterior space closure with optimal vertical control is possible in the initial phase to potentially make treatment more efficient while minimizing side effects.[36] The second phase utilizes full arch CAT to close any remaining spaces, detail and finish the patient's case.

The present literature shows class II malocclusions are effectively treated with clear aligners[17,24-26] with a high accuracy of molar distalization[34] and little increase in vertical dimension.[32] Although the effectiveness of maxillary molar rotation has not been fully realized, improved accuracy may be achieved with appropriate attachments, velocity, and movement per aligner.[63] The DF2 protocol is an intriguing esthetic treatment option for class II treatment that could prove to be efficient, cost-effective, minimize unwanted side effects while also optimizing the patient experience.

CHAPTER 2

EVALUATING THE TREATMENT EFFECTIVENESS AND EFFICIENCY OF THE DF2 PROTOCOL USING INVISALIGN® FOR TREATMENT OF CLASS II MALOCLUSION: A RETROSPECTIVE COMPARISON STUDY

Abstract

Purpose: This retrospective study evaluated the treatment effectiveness and efficiency of the DF2 protocol for correction of class II malocclusions in comparison to conventional protocol using Invisalign®.

Materials and Methods: Clinical and cephalometric data of patients that were treated for class II malocclusion between July 30, 2014 and July 22, 2021 were reviewed and selected. The selected patients were matched for age, sex, and treatment complexity and divided into two groups: Group 1 (G_1) —DF2 protocol and Group 2 (G_2)—conventional class II Invisalign®. Clinical variables to represent the skeletal and dentoalveolar changes during treatment were assessed using pre-treatment (T_1) and post-treatment (T_2) digital study models and cephalometric tracings. Statistical analysis was accomplished using Mann-Whitney U and Spearman's rho tests ($\alpha = 0.05$). Intra-rater reliability was expressed as intraclass correlation coefficient (ICC).

Results: A total of 22 patients (6 males, 6 females in G_1 and 5 males, 5 females in G_2) with a mean age of 15.29 (14.27 in G_1, 16.52 in G_2) years of age were included in this study. Excellent intra-rater reliability was reported (ICC > .95). There were no statistically significant differences in T_1 age, discrepancy index (DI), or treatment length between the groups ($p > .05$). There were no differences in the amount of T_1 class II or their changes (molar and canine) following treatment between the groups ($p > .05$). The

amount of T_1 overjet (OJ) was statistically more in G_1 at T_1 leading to a significantly greater reduction in OJ in G_1 after treatment ($p < .05$). All other cephalometric variables at T_1 and their changes were comparable between groups ($p > .05$). No correlation was observed between treatment length and DI, molar and canine corrections ($p > .05$) except between treatment length versus canine correction in G_2 ($p < .05$).

Conclusion: The results of this study indicate the efficacy and efficiency of both protocols are comparable in class II correction. However, the lack of correlation between treatment time and the amount of class II correction in DF2 group suggests that this protocol may be beneficial when significant class II correction is required.

Introduction

A common challenge among orthodontists is the treatment of class II malocclusions. The prevalence of class II malocclusions is estimated to be approximately 15% of the total population, including 23% of children and 13% of adults.[1,2] It is expressed by an abnormal dentoalveolar and/or skeletal configuration such as maxillary excess or more commonly, mandibular deficiency.[3] Due to the diverse presentation, various treatment methods are proposed based on multiple patient specific factors, such as the severity of the skeletal or dental malocclusion, profile esthetics, compliance concerns, and remaining growth potential of the patient. Many treatment modalities have been demonstrated to successfully treat class II malocclusions.[4-17]

Molar distalization is a treatment approach employed to correct class II malocclusions. Although several compliance-free intra-oral distalizing appliances demonstrate success[10-15] an increase in vertical dimension and loss of anterior anchorage are side effects.[11-13] The Carriere® Motion 3D™ or Carriere Distalizer utilizes a 2-phase treatment approach, beginning with the objective to rotate the maxillary molars while distalizing the posterior buccal segment as a unit to class I occlusion before conventional fixed appliances or clear aligner therapy (CAT) commences.[16,17] During the initial phase, the mandibular arch serves as a source of anchorage, generally without active treatment. Mandibular anchorage may be a lingual arch, clear thermoplastic retainer, full fixed appliances, or temporary anchorage devices (TADs).[16] Unlike similar appliances, loss of anterior anchorage is not a concern since the anterior teeth are not involved. Side effects of this appliance include extrusion of maxillary canines, worsening the mandibular arch length discrepancy and relapse of derotated molars.[18] Although the Carriere Distalizer relies on patient compliance and is not shown to be any more effective than alternatives in class II correction, it remains popular for its rapid sagittal correction, improved esthetics, and overall comfort which impacts the patient experience.[18,19]

With renewed focus on the patient experience, the orthodontic community has seen an increase in demand for esthetic orthodontic treatment for adults and adolescents.[20,21] Invisalign® (Align Technology, San Jose, CA), in particular, has contributed to the evolution of esthetic clear aligner therapy since its inception in 1997.[22] Although initially used for class I cases with mild to moderate crowding,[23] CAT in adjunct with auxiliary attachments, sequential distalization, intermaxillary elastics, TADs, or use of a pre-treatment distalizing appliance have resulted in the ability to treat more complex cases with antero-posterior (AP) discrepancies with success.[17,24-26]

The efficacy of treatment outcomes with CAT have been assessed in the literature[27,28] and mild to moderate case outcomes are not significantly different from conventional fixed appliances[29,30] and show a statistically significant shorter treatment time.[30,31] Clear aligners are shown to be effective at molar distalization with a mean accuracy 88.4% with the use of attachments.[32] Advantages of CAT include good control of lower incisor position when pretreatment crowding is mild to moderate (<6mm)[33] and ability to maintain facial height during molar distalization without significant distal tipping.[34,35]

With sustained popularity of esthetic orthodontic treatment, the present study is of significant interest. The DF2 protocol utilizes a 2-phase treatment approach with a short initial stage (~3 months) for class II sagittal correction. [36] In this phase, a maxillary sectional clear aligner (Invisalign®, Align Technology, San Jose, CA) is used in conjunction with class II elastics to achieve similar objectives to the Carriere Distalizer—molar rotation and distalization (Figure 1). Unlike the Carriere Distalizer, active leveling on the mandibular arch and maxillary posterior space closure with optimal vertical control can be utilized in the initial phase to potentially make treatment more efficient while minimizing side effects (canine extrusion, rotation, and distal crown tip).[36] The final phase utilizes full clear aligner therapy to consolidate space, detail, and finish.

Figure 1. DF2 aligner protocol includes sectional maxillary aligners and an intact mandibular aligner with the use of proper attachments and Class II elastics.

The DF2 protocol is an intriguing esthetic treatment option for class II malocclusions that could prove to be efficient, cost-effective, minimize unwanted side effects while also optimizing the patient experience. However, the efficacy and efficiency of this protocol in comparison to a conventional class II protocol using Invisalign® is unknown and is the subject of the present study.

Null Hypothesis

There is no statistical difference in the efficacy and efficiency between the DF2 protocol and conventional protocol using Invisalign® in the treatment of class II malocclusions.

Materials and Methods

Patient Selection

This study was approved by the Institutional Review Board (IRB) of Loma Linda University (LLU), Loma Linda, CA (#5210032). The records of patients who received comprehensive orthodontic treatment for class II correction either with DF2 protocol or conventional protocol from Ferris Orthodontic Group (Santa Barbara, California) during the time period of July 30, 2014 and July 22, 2021 were reviewed and selected according to inclusion and exclusion criteria. The DF2 protocol was defined as sectional Invisalign® class II treatment[36] while conventional protocol was defined as full arch Invisalign® class II treatment. In both groups, intermaxillary elastics were worn from maxillary canines and/or 1st premolars to mandibular molars and attachment placement and design were tailored to the patient's needs.

Inclusion Criteria

- Pre-treatment (T_1) records consisting of cephalometric radiograph (conventional or CBCT generated), digital study models and photographs.
- Post-treatment (T_2) records consisting of cephalometric radiograph (conventional or CBCT generated) and photographs.
- Pre-operative class II malocclusion bilateral or subdivision ('end-on' or more).

- Non-extraction treatment plan.

Exclusion Criteria

- Incomplete T_1/T_2 records.
- Extraction treatment plan.
- Use of extra-oral appliances during treatment.
- Severe skeletal asymmetry.
- Patients who underwent orthognathic surgery.

Data Collection Procedures

For each patient, baseline information was recorded including gender, pre-treatment age (years) and total treatment length (months) using Cloud 9 Ortho (Cloud 9 Software, Roswell, GA). Treatment length was defined as the period between the date of initial aligner delivery (T_1) and the date of attachment removal and retainer delivery (T_2). The Discrepancy Index (DI) was used to assess pre-treatment case complexity using the American Board of Orthodontics (ABO) worksheet. (https://www.americanboardortho.com/media/1186/discrepancy-index-worksheet-for-print.pdf)

Digital study models in maximum intercuspal position (MIP) were evaluated using ClinCheck® to determine pre- and post-treatment molar and canine Angle's classification. Reference landmarks for the molar were defined as the distance between the buccal groove of the mandibular first molar and the mesial buccal cusp tip of the maxillary first molar when viewed perpendicular to the buccal segment. The reference landmarks for the canine were defined as the distance between the interproximal contact point of the mandibular canine and first premolar to the maxillary canine cusp tip when viewed perpendicular to the interproximal contact point (see figure 2).

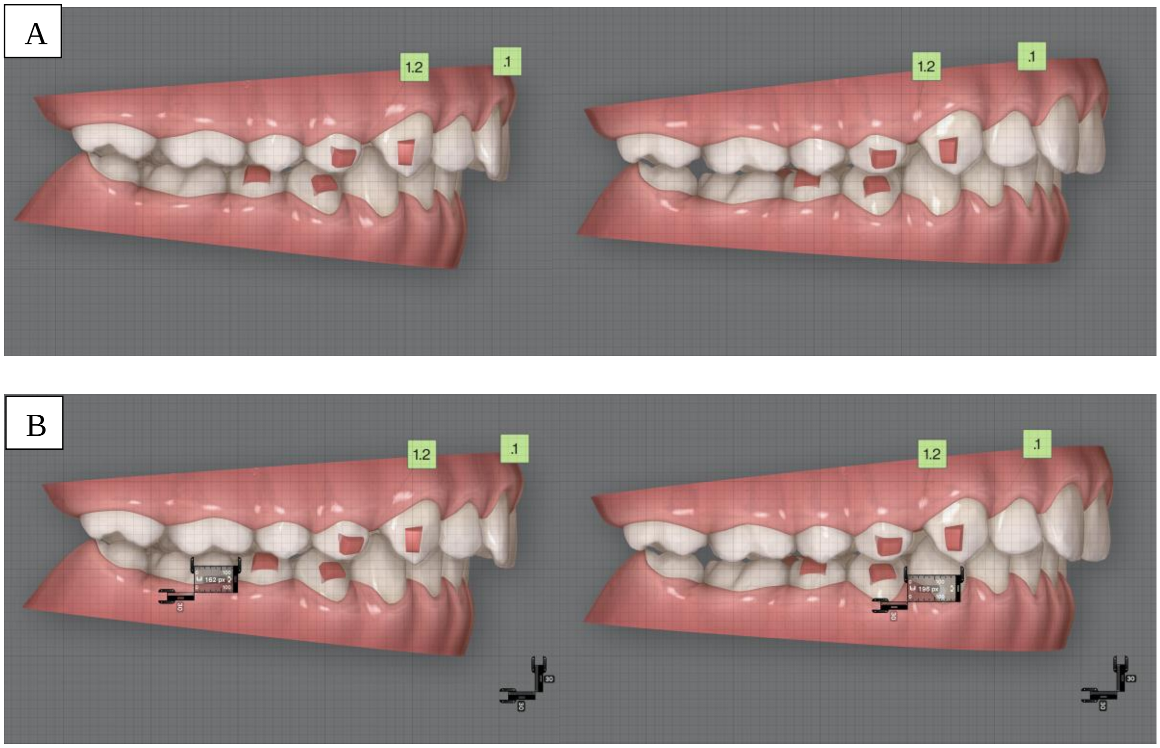

Figure 2. Digital model was rotated on ClinCheck® to proper viewing angles (A) for Class II Molar (Left) and Canine (Right) measurement using xScope® (B).

Linear dimensions were measured in pixels using xScope® (version 4.5, Iconfactory and ARTIS Software). The “Grid” feature in ClinCheck® was used as a reference length where 1mm = x pixels (x). The amount of class II present was measured in pixels (y) and then calculated in millimeters as y/x. The amount of class II distance was recorded separately for the molar and canine on the right and left of each patient (Figure 2).

The amount of class II correction was defined as the difference between the amount of pre-treatment class II and post-treatment class II. In cases of incomplete class

II correction, the amount of remaining class II present was measured and calculated on the ClinCheck® stage that best represented occlusal relationship on the post-treatment photographs.

Cephalometric data points were assessed using T_1 and T_2 conventional or Cone-Beam Computed Tomography (CBCT) generated cephalograms. All cephalograms were obtained using a Planmeca ProMax 3D Mid (Planmeca USA Inc., Hoffman Estates, IL). Pre-treatment three-dimensional (3D) files were converted into two-dimensional (2D) lateral cephalograms using Osirix MD (version 10.0.3, Pixmeo). All cephalograms were traced using Quick Ceph Studio (version 5.01, Quick Ceph Systems, San Diego, CA) using a combination of analyses, primarily Steiner and Ricketts, to represent the skeletal and dentoalveolar changes that occurred during treatment (Table 1). All variables were recorded at T_1 and T_2. Cephalometric planes used in the analysis were Frankfort Horizontal (FH)—line connecting porion and orbitale, Pterygoid Vertical (PTV)—vertical line through the posterior side of the pterygomaxillary fissure perpendicular to FH, Gonion-Gnathion Plane (Go-Gn)—line connecting gonion and gnathion and Nasion-Basion Plane (NBa)—line connecting nasion and basion. Example tracing is presented in Figure 3.

Table 1. Description of lateral cephalometric parameters.

Measurement	**Description**
SNA (°)	Angle formed between S-N and N-A
SNB (°)	Angle formed between S-N and N-B
ANB (°)	Angle formed between N-A and N-B
Go-Gn – SN (°)	Angle formed between S-N and Go-Gn
U1-FH (°)	Angle formed between maxillary incisor inclination and Frankfort Horizontal
U1-PTV (mm)	Perpendicular distance from maxillary incisor crown tip to PTV
U6-PTV (mm)	Perpendicular distance from distal surface of maxillary molar to PTV
IMPA (°)	Angle formed between mandibular incisor inclination and Go-Gn
L1-PTV (mm)	Perpendicular distance from mandibular incisor crown tip to PTV
L6-PTV (mm)	Perpendicular distance from distal surface of mandibular molar to PTV
Interincisal angle (°)	Angle formed between maxillary and mandibular incisor inclinations
OJ (mm)	Distance between the maxillary incisal edge to the facial surface of the mandibular incisor.
OB (mm)	Vertical distance between maxillary and mandibular incisal edge
Lower Lip E-Plane (mm)	Distance between the lower lip and the esthetic plane

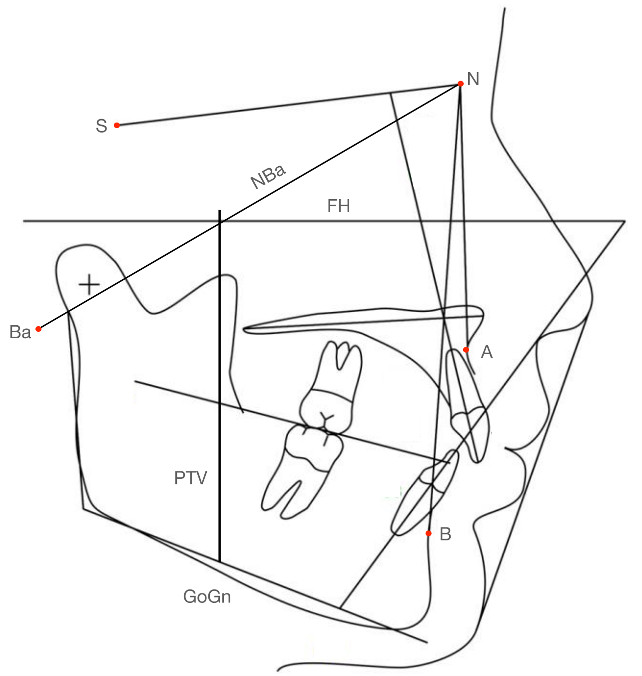

Figure 3. Lateral cephalometric landmarks and reference planes used for analysis.

To maintain consistency of landmark placement between T_1 and T_2 cephalograms, a 'Growth Constant Grid' (GCG) was constructed on the T_1 image and superimposed on the T_2 radiograph to best fit. GCG consists of FH, PTV and NBa (Figure 4).

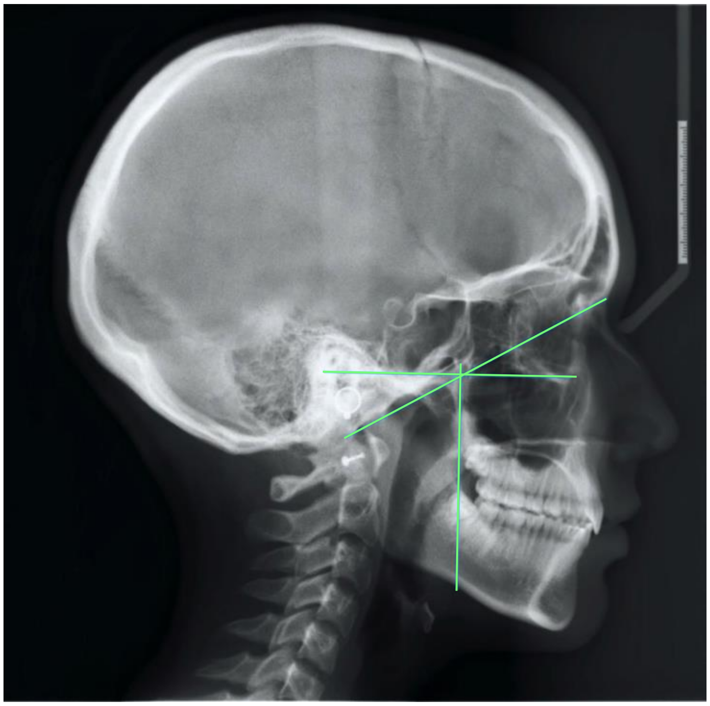

Figure 4. GCG constructed on the T_1 image consisting of FH, PTV and NBa.

Statistical Analysis

Statistical analysis was performed using jamovi (version 1.6.23.0, Sydney, Australia). Data collection procedures were carried out by a single investigator (BO) and based on the sample size, seven patients were randomly selected and repeated at an interval of at least two weeks for intra-rater reliability test, which was expressed as a intraclass correlation coefficient (ICC). Statistical analysis was accomplished using Mann-Whitney U and Spearman's rho tests ($\alpha = 0.05$).

Results

A total of 22 patients (6 males, 6 females in G_1 and 5 males, 5 females in G_2) with a mean age of 15.29 (14.27 in G_1, 16.52 in G_2) years were included in this study.

Intraclass Correlation Coefficient

High ICC (> .95) in all measurements demonstrated excellent intra-rater reliability and reproducible method of measurements (Table 2).

Table 2. The Intraclass Correlation Coefficients (ICC) of dental, and cephalometric (angular and linear) measurements.

	ICC	95% Confidence Interval	
		Lower Bound	Upper Bound
Dental	.957	.928	.975
Ceph - Angular	.999	.998	.999
Ceph - Linear	.999	.999	.999

Baseline Information

Twenty-two patients fulfilled the current study's criteria and were divided into two groups: Group 1 (G_1) — DF2 protocol (n=12) and Group 2 (G_2) — Conventional class II Invisalign® (n=10). G_1 consisted of 6 males, 6 females with a mean age of 14.27 ± 1.83 years and G_2 consisted of 5 males and 5 females with a mean age of 16.52 ± 5.36 years. The two groups were statistically comparable in T_1 age, DI, and overall treatment length (Table 3).

Table 3. Comparisons of T1 age, DI, and treatment length using Mann-Whitney U test at $\alpha = 0.05$.

	Mean (SD)		p-value
	G_1	G_2	
T_1 Age (years)	14.27 (1.83)	16.52 (5.36)	0.644
Discrepancy Index (DI)	15.50 (5.25)	14.70 (6.18)	0.741
Tx Length (months)	15.76 (3.97)	16.05 (8.56)	0.792

Note: G_1=Group 1, G_2=Group 2

Clinical Data

The comparison of the pre-treatment (T_1) amount of class II present at canine and molar and the amount of class II correction (Δ) as calculated by the pre- and post-treatment study models between the two groups are presented in Table 4. No statistically significant differences in the amount of class II at T_1 as well as the amount of class II correction was noted between the treatment groups ($p > .05$, Table 4).

Table 4. Comparison of the amount of pre-treatment (T_1) class II and their changes (Δ) using Mann-Whitney U test at $\alpha = 0.05$.

	Mean (SD)						p-value	
	G1			G2				
	T_1	T_2	Δ	T_1	T_2	Δ	G_1T_1 vs G_2T_1	$G_1\Delta$ vs $G_2\Delta$
Cl II M – R (mm)	3.27 (1.54)	0.00 (0.00)	3.27 (1.54)	3.24 (2.10)	0.91 (1.47)	2.33 (1.64)	1.000	0.129
Cl II M – L (mm)	2.73 (2.00)	0.37 (0.78)	2.36 (1.83)	2.52 (1.68)	0.43 (0.65)	2.09 (1.69)	0.619	0.624
Cl II M – RL (mm)	3.00 (1.44)	0.19 (0.39)	2.82 (1.45)	2.88 (1.44)	0.67 (0.77)	2.21 (1.20)	1.000	0.391
Cl II M – Max (mm)			3.56 (1.25)			2.95 (1.56)		0.186
Cl II C – R (mm)	4.76 (1.70)	1.10 (1.12)	3.66 (1.34)	3.86 (2.66)	1.53 (1.54)	2.33 (1.47)	0.428	0.065
Cl II C – L (mm)	3.96 (2.20)	0.97 (1.08)	2.99 (1.87)	3.35 (2.04)	1.30 (1.14)	2.05 (1.62)	0.488	0.276
Cl II C – RL (mm)	4.36 (1.60)	1.03 (0.10)	3.32 (1.21)	3.60 (1.59)	1.42 (0.75)	2.19 (1.30)	0.282	0.093
CL II C – Max (mm)			4.07 (1.50)			2.83 (1.35)		0.065

Note: G_1=Group 1, G_2=Group 2, T_1 = pre-treatment, T_2=post-treatment, $\Delta = T_1-T_2$, M = molar, C = canine, R = right side only, L = left side only, RL = average of right and left, Max=greater class II correction between right and left.

Cephalometric Data

The comparison of the cephalometric parameters between the two groups at T_1 and their changes following treatment are presented in Table 5. Nearly all cephalometric parameters compared at T_1 and the observed changes due to treatment were not statistically different ($p > .05$, Table 5). The only statistically significant difference observed at T_1 was the amount of OJ ($p = .044$. Table 5) leading to a statistically significant difference in OJ reduction between the groups ($p = .038$, Table 5).

Table 5. Comparison of pre-treatment (T_1) cephalometric parameters and their changes (Δ) using Mann-Whitney U test at $\alpha = 0.05$

	Mean (SD)						p-value	
	G_1			G_2				
	T_1	T_2	Δ	T_1	T_2	Δ	G_1T_1 vs G_2T_1	$G_1\Delta$ vs $G_2\Delta$
Mx Skeletal								
SNA (°)	81.44 (4.23)	79.56 (3.37)	-1.88 (1.65)	78.93 (3.84)	77.64 (3.35)	-1.29 (1.70)	0.176	0.575
Md skeletal								
SNB (°)	77.12 (3.05)	76.38 (2.69)	-0.74 (1.13)	74.56 (4.48)	73.81 (3.65)	-0.75 (2.02)	0.228	0.947
Mx/Md								
ANB (°)	4.32 (2.16)	3.17 (1.46)	-1.14 (1.13)	4.37 (1.49)	3.83 (1.82)	-0.54 (0.78)	0.391	0.147
Vertical								
Go-Gn – SN (°)	30.63 (5.06)	32.21 (4.56)	1.58 (2.00)	30.48 (6.78)	31.80 (6.25)	1.32 (1.87)	0.872	0.767
Mx Dental								
U1-FH (°)	113.14 (6.23)	110.62 (3.81)	-2.52 (4.03)	112.96 (5.32)	110.42 (5.72)	-2.54 (4.14)	0.717	0.766
U1-PTV (mm)	54.39 (3.52)	52.56 (4.66)	-1.82 (2.52)	52.81 (6.07)	52.06 (5.24)	-0.75 (3.18)	0.314	0.339
U6-PTV (mm)	16.29 (3.20)	15.30 (3.24)	-0.99 (2.22)	15.48 (5.79)	15.64 (4.91)	0.16 (2.90)	0.921	0.291

Md Dental								
IMPA (°)	101.69 (4.18)	98.77 (7.08)	-2.93 (5.50)	104.20 (2.94)	102.57 (3.82)	-1.63 (3.87)	0.080	0.456
L1-PTV (mm)	49.30 (3.63)	49.63 (4.38)	0.33 (2.39)	48.77 (6.19)	49.49 (5.20)	0.72 (3.56)	0.692	0.817
L6-PTV (mm)	14.34 (2.97)	15.94 (3.19)	1.60 (2.26)	14.13 (6.61)	16.41 (4.94)	2.28 (3.37)	1.000	0.692
Interdental								
Interincisal angle (°)	124.42 (7.30)	128.87 (8.78)	4.44 (6.43)	123.55 (6.54)	126.59 (7.89)	3.04 (5.18)	0.644	0.531
OJ (mm)	5.75 (1.68)	3.15 (0.723)	-2.60 (1.58)	4.38 (1.32)	2.78 (0.585)	-1.60 (1.38)	0.044*	0.038*
OB (mm)	3.00 (1.27)	1.80 (1.50)	-1.20 (1.61)	2.45 (1.00)	1.54 (1.25)	-0.91 (1.03)	0.339	0.533
Esthetics								
Lower Lip E-Plane (mm)	-1.16 (1.87)	-1.95 (1.10)	-0.79 (1.43)	-1.34 (1.91)	-2.16 (1.37)	-0.82 (1.44)	0.895	0.921

* Denotes statistical significance (p < .05

Correlation Trends

Correlations of treatment length versus amount of class II correction (molar and canine) and DI are presented in Table 6. Significant correlation was observed between treatment length and the overall molar class II correction ($p = .018$, Table 6), but not individual molar class II corrections ($p > .05$, Table 6). Nevertheless, the conventional class II Invisalign® group revealed a higher correlation ($r = .624$, Table 6) with a p-value approaching significance ($p = .06$, Table 6) compared to the DF2 group ($r = .303$, $p = .339$).

A statistically significant correlation was observed between treatment length and canine class II correction for the conventional class II Invisalign® group ($p = .016$, Table 6) but not for overall or DF2 group canine class II correction ($p > .05$, Table 6)

No statistically significant correlation was found between treatment length and overall and individual DI's ($p > .05$, Table 6).

Table 6. Correlations of treatment length versus amount of greater class II correction (molar and canine) and DI using Spearman's Rho at α=0.05.

	Treatment Length
Δ Cl II M – Overall	r = 0.500* p = 0.018*
Δ Cl II M – G_1	r = 0.303 p = 0.339
Δ Cl II M – G_2	r = 0.624 p = 0.060
Δ Cl II C – Overall	r = 0.369 p = 0.091
Δ Cl II C – G_1	r = -0.028 p = 0.939
Δ Cl II C – G_2	r = 0.758* p = 0.016*
DI – Overall	r = 0.337 p = 0.125
DI – G_1	r = 0.140 p = 0.664
DI – G_2	r = 0.396 p = 0.257

* Denotes statistical significance ($p < .05$). M = Molar, C = Canine, Δ = T_1-T_2.

Discussion

Efficacy of Class II Correction

In the treatment of class II malocclusions, dentoalveolar movement and/or orthopedic correction with reduction of overjet is expected.[6] Orthopedic correction is dependent on the treatment mechanics and growth potential of the patient.[37] The expected orthopedic correction in class II malocclusions are a decrease in the SNA angle, an increase in the SNB angle, resulting in a decrease in the ANB angle.[38] The results of this study indicate that orthopedic correction was observed in both groups: SNA decreased by 1.88° and 1.29° in G_1 and G_2, respectively and ANB angle decreased by

1.14° and 0.54° in G_1 and G_2, respectively. These differences were not statistically significant ($p > .05$; Table 5). Unexpectedly, SNB angle decreased in both groups at similar magnitude. ($p = .947$, Table 5). This could be attributed to the observed clockwise rotation of the mandible (increased SN-GoGn) measured in both groups, inclusion of some non-growing patients, and overall small sample size.

An increase in vertical face height is a known side effect of class II correction[6,7,39] and SN-GoGn is one of the most reliable indicators of this parameter.[40] Our study demonstrated a small increase in the SN-GoGn angle that was comparable in both groups ($p=0.767$, Table 5). However, previous studies using CAT, do not report any increase vertical dimension following class II correction or molar distalization.[25,36] It should be emphasized that the increases in SN-GoGn were minimal and the resultant SN-GoGn's were within normal range ($32 \pm 4°$) for both groups.

The primary objective of class II correction regularly includes distalizing the maxillary molar position while advancing the mandibular molar position optimally timed with mandibular growth.[18] The average molar corrections measured on pre- and post-treatment study models were 2.82 mm and 2.21 mm in G_1 and G_2, respectively. Similarly, the average canine corrections were 3.32 mm and 2.19 mm in G_1 and G_2, respectively. The measured changes at the molar and canine were statistically comparable between groups ($p > .05$, Table 4).

This study used the cephalometric parameter U6-PTV to compare maxillary molar position at T_1 and T_2. Pterygoid vertical (PTV) is known to be a stable reference landmark during growth.[41,42] A previous study showed U6-PTV increased an average of 1.0 mm per year between the ages of 9-19 years.[43] In our study, U6-PTV for the DF2 protocol showed a mean decrease of 0.99 mm while the conventional class II Invisalign® group showed a mean increase 0.16 mm. The difference was not statistically significant ($p > .291$, Table 5). Therefore, both treatment groups demonstrate the maxillary molar position is held against growth to assist class II correction. However, an additional 1.15 mm of molar distalization obtained with the DF2 protocol could prove to be clinically beneficial in cases of maxillary dental protrusion with crowding.

Assessing the cephalometric position of the mandibular molar was also measured in relation to PTV (L6-PTV). The DF2 group showed a mean mesialization of 1.60 mm, while the conventional class II Invisalign® group showed a larger mesialization of 2.28 mm. This difference was not statistically significant ($p > .05$, Table 5).

Although the molar corrections were comparable between the groups, the cephalometric changes showed that they were achieved with different mechanics. Molar correction in the DF2 group was more evenly attributed to distalization of maxillary molar and mesialization of mandibular molar whereas the conventional class II Invisalign® group primarily was attributed to mandibular molar mesialization. Mandibular molar mesialization in the absence of growth, existing spaces, widening of arch form, or interproximal reduction (IPR) may result in an increase in IMPA angle. Since most of the subjects in this study were growing patients, no detrimental effect was observed in the IMPA angle of either group. The use of sectional mechanics in the DF2 protocol might be advantageous in this respect. However, future studies with a larger sample size are needed to confirm or refute this trend.

An expected side effect of class II correction includes proclination of the lower incisors and retroclination the upper incisors.[6] However, previous studies using CAT treatment have demonstrated good control of lower incisor inclination in cases of mild-moderate crowding (<6mm)[25,30] This was also observed in our study. Both treatment groups observed a mean decrease in IMPA of 2.93° and 1.63° in G_1 and G_2, respectively. These changes were statistically comparable ($p > .05$, Table 5) indicating both protocols control the lower incisor inclination well. Although not statistically significant, the additional 1.30° of IMPA reduction found in the DF2 protocol could prove clinically favorable in cases with excessively proclined lower incisors.

The lower incisor position relative to PTV (L1-PTV) increased in both groups comparably ($p > .05$, Table 5), however, the magnitude of advancement was less than the mesialization observed at L6-PTV. This suggests a combination of mandibular growth, widening of arch, and/or IPR that was employed to control the lower incisor position.

Evaluation of the maxillary incisor position showed a statistically similar retraction (U1-PTV) and decreased angulation (U1-FH) between the groups ($p > .05$, Table 5). These findings suggests that a reduction in torque can be expected in either treatment protocol. This is also an expected outcome of class II correction.[6]

The inclination changes of maxillary and mandibular incisors resulted in a comparable increase in the interincisal angles between the groups ($p > .05$, Table 5). The additional increase of 1.4° observed in the DF2 group corresponded to the larger magnitude of reduction in the IMPA angle. The findings of this study suggest that control of the upper and lower incisors were comparable in either protocol; both demonstrate good control of lower incisor inclination.

Overjet reduction is an anticipated outcome of class II correction.[6] A statistically significant difference between the groups was discovered at T_1 ($p = .044$, Table 5), This is most likely because the divisions of class II malocclusion were not differentiated in this study. Due to the higher magnitude of pre-treatment OJ in the DF2 group, the magnitude of OJ correction was higher and statistically significant when compared to the conventional class II Invisalign® group ($p = .038$, Table 5). It should be noted that a normal OJ (2-3 mm) was attained in both groups. Therefore, regardless of pre-treatment OJ, one can expect to correct to a normal OJ using either protocol.

Finally, the esthetic change at the lower lip to E-plane demonstrated a similar increase in retrusion to the esthetic plane. The change was less than a millimeter in both groups and statistically comparable ($p > .921$, Table 5). This finding is comparable to previous studies which attribute the retrusion of lips to the esthetic plane to an increase in nasal tip projection accompanied by the anteroposterior growth of the chin.[44,45]

Efficiency of Class II Correction

The total treatment length and DI were statistically comparable between the groups ($p > .05$, Table 4). There was no correlation observed between treatment length and DI overall or between treatment groups ($p > .05$, Table 6). Previous studies have demonstrated a positive correlation between treatment time and DI.[46] This difference could be attributed to the small sample size.

The results indicate that longer treatment times are significantly correlated with increased AP correction at the molar for the entire sample ($p = .018$, Table 6). It is intuitive that a larger amount of class II correction will require more treatment time. However, the correlation was not significant for either group independently ($p > .05$, Table 6). It should be noted that the p-value for conventional class II Invisalign group approached significance level ($p = .06$, Table 6), but the DF2 group did not ($p = .339$,

Table 6). For the canine, the amount of AP correction was significantly correlated to treatment length for the conventional class II Invisalign® group only ($p = .016$, Table 6). These findings suggest a trend that the DF2 protocol has the potential to achieve larger AP corrections at the molar and canine without a significant increase in treatment time when compared to conventional class II Invisalign® protocol. This could be attributed to the sectional mechanics used to correct class II malocclusion early in treatment while the patient is more likely to be compliant.[47] However, future studies with a larger sample size will be needed to verify these trends.

It should be noted that Invisalign® was used in both treatment protocols analyzed in this study, however, these results are not exclusive and could be applied to any CAT system.

Conclusions

The results of this study indicate the efficacy and efficiency of both protocols are comparable in class II correction. However, the lack of correlation between treatment time and the amount of class II correction in DF2 group suggests that this protocol may be beneficial when significant class II correction is required.

CHAPTER 3

EXTENDED DISCUSSION

Study Limitations and Future Studies

There were limitations in this study that should be recognized for better understanding of the results, as well as for future studies. A primary limitation of this study was that it was based on 22 patient cases. By increasing the sample size, this would increase the power and strength of the results. Furthermore, a larger sample size would allow consideration of other variables of interest; e.g. division of class II, age, gender, compliance measures; that may elucidate trends seen in this study. The sample size of this study was limited due the overall patient population that qualified according to inclusion criteria. Over time, a larger patient data base will emerge. A prospective study with standardized records would likely yield more insightful information.

Another limitation was patient selection and data collection was done by a single person. To remove any potential bias, future studies would benefit from blinded data collection.

Finally, post-treatment study models were not available in the present study and post-treatment photographs were used to verify and best match the final occlusion on the ClinCheck® model. This could be a source of inaccuracy in cases where full class II correction was not achieved, therefore, the inclusion of post-treatment models would benefit the reliability of the results.

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