In vitro Evaluation of Biomechanics of Orthodontic Aligners

by

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Abstract

In 2020, the dental care cost in Canada was approximately $13.89 billion and 20% of Canadians underwent orthodontic treatment. Patients seek orthodontic treatment to improve their oral functionality, psychosocial well-being, appearance, and quality of life. Aligner mechanotherapy is gaining popularity as an esthetic alternative to fixed labial mechanotherapy. However, the literature has reported limited treatment outcome with aligner mechanotherapy where 70-80% of orthodontic patients undergoing aligner treatment require midcourse correction, case refinement, or conversion to a fixed labial mechanotherapy before the end of treatment. This could be attributed to gaps in knowledge regarding aligner biomechanics that limits the predictability of orthodontic treatment outcome pointing towards the need to investigate biomechanics of the aligner mechanotherapy.

The objective of the present thesis was to utilize in vitro methods (Orthodontic Simulator) to study the force system of aligners towards gaining a foundational understanding of their expected behavior in full arch treatments. Specifically, the fundamental factors such as tooth anatomy and position, aligner materials, and auxiliaries that could influence the biomechanics of aligner mechanotherapy were evaluated in this thesis. The initial experiments assessed the force system for different teeth (central incisor, canine and second premolar) by utilizing the most used aligner materials (polyethylene terephthalate, polyethylene terephthalate glycol, and polyurethane). The biomechanical knowledge was further advanced by subsequent experiments to evaluate the effect of varying the location of auxiliaries such as divots and attachments on aligner force system for bodily tooth movement and extrusion movement, respectively.

There were several key observations made by series of biomechanical experiments. The initial experiment introduced the implication of tooth anatomy and tooth position in aligner biomechanics where mean buccal force and moment (that could tip teeth buccally/lingually) were significantly more for canine than for central incisor and premolar at 0.20 mm of lingual displacement. The similar trend was observed for other most used aligner materials: polyethylene terephthalate and polyurethane that exerted different force system on tested teeth. This experiment results highlighted the role of distinct underlying mechanical properties and variance in response of different materials to thermoforming process in aligner biomechanics. The results obtained from the experiments involving auxiliaries with aligner suggest that tactical placement of auxiliaries on buccal and lingual aspect of crown of incisors could improve the force system of aligners. This could mean possibility of extending the utility and application of aligners to difficult tooth movement such as bodily movement and extrusion.

Overall, this in vitro evidence will improve understanding of force system of aligner mechanotherapy. The results will be instrumental in guiding the future research, influence the design and protocol of the aligner mechanotherapy that will improve the delivery of care by improving treatment outcome, and reducing the treatment time for orthodontic patients.

Preface

This thesis is an original work by Harsimrat Kaur. The research design, planning, and experiment development were done by Harsimrat Kaur under the guidance and supervision of Drs. Romanyk, Major and Mah. Harsimrat Kaur has worked under the supervision of Dr. Heo for statistical analysis of this thesis project.

This thesis consists of 8 chapters and references are provided in the end of each chapter. The "literature review" of Chapter 3 was previously published as "Robertson L, Kaur H, Fagundes NCF, Romanyk D, Major P, Flores Mir C. Effectiveness of clear aligner therapy for orthodontic treatment:A systematic review. Orthod Craniofac Res. 2020;23(2):133-142. doi:10.1111/ocr.12353." As a co-first author, my responsibilities were searching for the relevant literature and extracting the key findings from the studies alongside Robertson L and Fagundes NCF. I was responsible for writing the manuscript. Drs. Major, Romanyk, and Flores Mir provided clinical insight, expertise, directed and reviewed the systematic review.

Chapter 4 of the presented thesis was published as "Kaur H, Truong J, Heo G, Mah JK, Major PW, Romanyk DL. An in vitro evaluation of orthodontic aligner biomechanics around the maxillary arch. Am J Orthod Dentofacial Orthop. 2021;160(3):401-409. doi:10.1016/j.ajodo.2021.04.005." I was responsible for conceptualization under the supervision of Drs. Romanyk, Mah and Major; Data curation and formal analysis was performed by me under the supervision of Dr. Heo. I wrote a manuscript that was reviewed by all the authors of the paper.

Chapter 5 of this thesis research was previously published as "Kaur H, Khurelbaatar T, Mah J, Heo G, Major PW, Romanyk DL. Investigating the role of aligner material and tooth position on orthodontic aligner biomechanics. *J Biomed Mater Res B Appl Biomater*. 2023;111(1):194-202. doi:10.1002/jbm.b.35145." The experiment data that was aimed to evaluate the force system for different aligner materials and to investigate the pre-thermoformed and post-thermoformed modulus of elasticity of different materials was gathered by Harsimrat Kaur and Tsolmonbaatar Khurelbaatar, respectively. I further prepared experimental protocol, performed statistical analysis, and wrote the manuscript for publication. Experimental protocol was guided by Drs.

Romanyk, Mah and Major. Statistical analysis was supervised by Dr Heo. All the authors reviewed the manuscript and provided constructive feedback.

Chapter 6 of the thesis was published as "Kaur H, Khurelbaatar T, Mah J, Heo G, Major PW, Romanyk DL. In vitro biomechanics of divot use, and their placement, in orthodontic aligner therapy. *Orthod Craniofac Res*. Published online February 1, 2024. doi:10.1111/ocr.12760." All the authors have the same roles as of chapter 5 except Tsolmonbaatar Khurelbaatar designed .STL models for the experiment.

Chapter 7 of the thesis "In-vitro biomechanics of attachment use, and their placement for extrusion tooth movement by orthodontic aligner therapy" is being prepared to be submitted to peer review journal. All the authors have the same roles as of chapter 5 except STL models were prepared by Arya Subramanian.

The in vitro apparatus, the Orthodontic Simulator, was set up with anatomical teeth by Raymond Guan. Initial experimentation and pilot testing were done by Harsimrat Kaur and Raymond Guan. Youssef Sleiman has printed 3D models that was used for thermoforming of aligners. Harsimrat Kaur has fabricated all the aligners used in this thesis project. Initial training and model preparation for aligner fabrication were provided by Keith O'Reilly.

This work is dedicated to my father, who raised me up to more than I can be, in his short time on this earth

Acknowledgements

I would like to thank all the people who have helped me throughout the course of my PhD. First and foremost, I would like to thank my supervisors Dr. Major and Dr. Romanyk for providing me with an opportunity by accepting me as their student, their constant support, and their knowledge to improve this thesis. Dr. Major is a great mentor, the amount of respect I have for him regarding his professionalism and his personality in general cannot be overstated. He has great impact on my professional and personal development over the years. Dr. Romanyk has relentlessly improved the quality of this project by constantly challenging me and helped in ensuring that I have necessary skills for my future research career.

I would like to thank my other committee members Dr. Mah and Dr. Heo who were actively involved in this research. Dr. Mah was instrumental in guiding the clinical aspect of this research and provided valuable feedback to make it clinically relevant. Dr. Heo worked closely for statistical analysis of this thesis. I appreciate all her time and efforts for ensuring that the numbers are accurate.

I would like to thank the current and previous colleagues from the Romanyk lab group for the feedback and help with the engineering aspect of this thesis. I would like to thank Susan Helwig and Keith O'Reilly for your support in equipment operation and aligner fabrication. A special thanks to Paul and Youssef Sleiman for printing 3D models for the project.

Finally, none would have been possible without my family and friends who have provided rock solid support throughout years. Papa, my personal life, and career would not have been possible without your guidance, inspiration, love, and support. I will always owe it to you. I am thankful to my brother who inspired me to travel across continents to achieve education. Words fall short to thank my husband for his love and support. Thank you, baby Gobind, for being a source of constant joy.

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Abbreviations

3D	Three Dimensional
ANOVA	Analysis Of Variance
BA	model with Buccal Attachment
BL	Model with Buccal and Lingual attachment
CoR	Center of Resistance
FE	Finite Element
Fy	Buccolingual force
Fz	Occlusogingival force
GRADE	Grading of Recommendation, Assessment, Development, and Evaluation
iMx	Initial Moment
LA	model with Lingual Attachment
MANOVA	Multivariate Analysis Of Variance
Mx	Moment that has tendency to tip teeth buccally or lingually
MPa	Mega Pascals
model GI	Divot on lingual Gingival third and buccal Incisal third
model GM	Divot on lingual Gingival third and buccal Middle third
model MI	Divot on lingual Middle third and buccal Incisal third
model MM	Divot on lingual Middle third and buccal Middle third
NA	No Attachment
N	Newton
Nmm	Newton millimeter
OSIM	Orthodontic SIMulator
PDL	Periodontal Ligament
PET-G	Glycol modified Polyethylene Terephthalate
PET	Polyethylene Terephthalate
PU	PolyUrethane
PRISMA	Preferred Reporting Items for Systematic reviews and Meta Analyses
RCT	Randomized Controlled Trial
RoB	Risk of Bias

ROBINS-I	Risk Of Bias In Non-randomized Studies of Interventions
SD	Standard Deviation
SE	Standard Error
SR	Systematic Review

Chapter 1: Introduction

This chapter introduces aligner mechanotherapy and the need for enhancing its existing biomechanical knowledge by appraising factors such as tooth anatomy, aligner materials, and aligner auxiliaries. This chapter also covers the thesis objectives and thesis outline.

1.1 Background

Patients seek orthodontic treatment to improve occlusal function, oral health, and esthetics.[1] Whilst orthodontic tooth movement could yield benefits, poor control of tooth movement during treatment could potentially pose tissue damage (such as root resorption, caries, periodontal attachment loss) and increase the overall treatment time.[2-4] Consequently, it is important to obtain more controlled tooth movements using orthodontic appliances entailing the understanding of the biomechanics (forces, moments).

Orthodontic tooth movement is the result of bone remodeling caused by force system applied through orthodontic appliances that triggers various biological pathways.[5] The magnitude and direction of applied mechanical loads directly contribute to physiologic and desired tooth movement improving treatment predictability in contrast to detrimental effects such as tissue necrosis/hyalinization and delayed tooth movement.[6] Orthodontic tooth movement such as translation (bodily movement), tipping, and root movement is dependent on the location and directions of the exerted force system from the center of resistance (CoR) (theoretically a point through which the collective mechanical effect of supporting structures is assumed to act).[7] Through the management of the applied force, tooth movement can be altered to preferentially express specific desired movement. The magnitudes of the force system should be above a minimum threshold that produces the tooth movement and below the value that can cause tissue damage. [6] Accordingly, it is imperative to comprehend the magnitude as well as the direction of the force system of orthodontic appliances.

Initial strategies to assess the biomechanics of orthodontic appliances was to simplify the force system to a determinate force system that allowed studying one-tooth and two-tooth systems.[8] Orthodontic treatment involves multiple teeth in the dental arch which increases the complexity of the system making it an indeterminate force system.[9] An in vitro Orthodontic Simulator (OSIM) was designed and validated at the University of Alberta to measure 3D force systems in real time of all teeth in a single dental arch simultaneously.[10] This experimental set up has been used to appraise the biomechanics of ligation methods,[11] anchorage control[12] and lingual orthodontic appliances.[13] There are various orthodontic appliance modalities such as conventional fixed buccal/ lingual mechanotherapy and aligner mechanotherapy to align the teeth. Biomechanics of these treatment modalities vary depending on many inherent factors unique to each modality such as means of force application where conventional mechanotherapy applies force at the bracket (small edgewise contact between wire and bracket) while aligner mechanotherapy wraps around tooth anatomy and exercise force by sequential mismatch created between teeth and aligner.[14]

Aligner mechanotherapy has become a potential alternative to conventional fixed buccal mechanotherapy as the demand for esthetic dentistry has raised.[15] A survey published in 2014 among orthodontic specialists in the United States notified that 89% of them had treated a median of 22 cases/year with aligners compared to 12 cases/year in 2008.[16] Aligners offers an esthetic substitute to fixed mechanotherapy but are limited by their treatment outcome. A survey among the European Aligner Society members pointed out that 45% of orthodontists consider that aligners have limited orthodontic treatment outcomes.[17]

A systematic review (SR),[18] including 11 articles published before 2014, that assessed the efficiency (i.e., actual achieved result of orthodontic treatment compared to the planned outcome) of aligner treatment in controlling orthodontic tooth movement concluded that aligners are not predictable for controlling anterior teeth extrusion, anterior buccolingual inclination and rotation of rounded teeth. Another SR[19] evaluated the efficiency of Invisalign® aligners, including 22 studies, concluded that Invisalign® is a viable alternative for the correction of mild to moderate malalignments in non-growing patients but had limited predictability in arch expansion through bodily tooth movement, extraction space closure, occlusal contacts correction, rotation corrections and severe malalignments. Kravitz et al.[20] has reported that most of orthodontic patients undergoing aligner treatment required case refinement (approximately 2.5 refinements), or (17.2%) conversion to a metal bracket appliance before the end of treatment. Thus, there is a substantial need to investigate biomechanics of the aligner therapy that have a direct impact on the orthodontic tooth movement. Biomechanics of aligner mechanotherapy is multifarious due to several factors such as variations in tooth/aligner surface contact mechanics,[21,22] aligner materials,[23,24] aligner activation,[25] aligner material thickness,[26] type of tooth movement,[27] aligner auxiliaries,[28] that could affect it. Most of the available literature is focused on aligner activation (increase of force system with increase in activation from 0.20 mm to 0.60 mm)[25], material thickness (increase in force system with material thickness of 0.75 mm as compared to 0.50 mm)[26], different shapes of aligner auxiliaries.[28] Factors such as tooth anatomy, aligner materials, and aligner auxiliary position that could potentially influence the aligner biomechanics and were not fully elucidated in literature were appraised through this thesis project.

1.1.1. Tooth anatomy

Incisors, canines, premolars, and molars have different crown anatomy in shape and length where incisors have more flattened tooth crown as compared to round configuration of canines and premolars (Figure 1.1).[29] It could be suggested that the contact mechanics between the aligner and the tooth vary depending on the type of teeth. Previous studies[21,22] have shown that forces exerted were distinctive when the same tooth (central incisor tooth) was moved in lingual direction as compared to buccal movement. Highlighted differences may have arisen because of different anatomy of lingual and buccal surfaces of the same tooth where aligner contacts to provide force system (Figure 1.2).[21, 22]

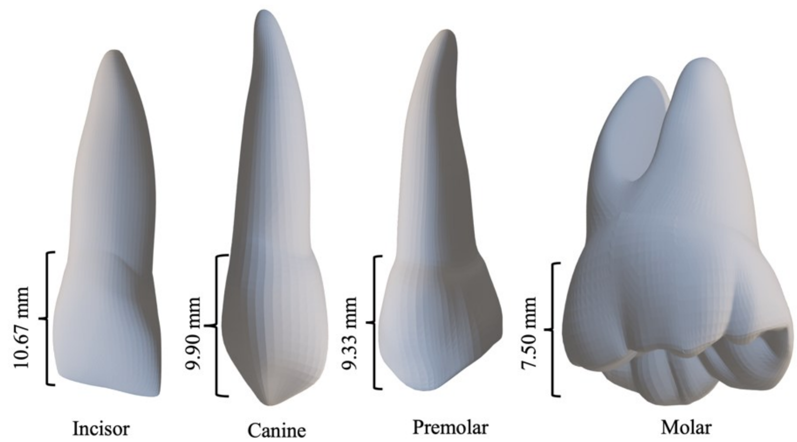

Figure 1.1 Schematic representation of incisor, canine, premolar, and molar teeth illustrating their typical anatomy and crown height

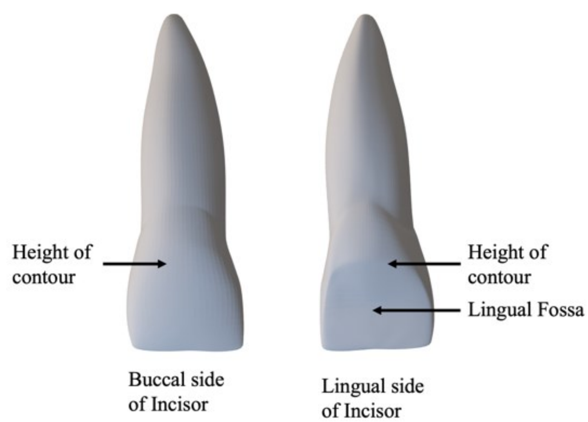

Figure 1.2 Diagrammatic presentation of the difference in anatomy of buccal and lingual side of central incisor

It is anticipated that the varying tooth/aligner engagement between different teeth can alter aligner material deformation that could result in a difference in applied orthodontic force system. In addition, there is a curvature in the arch form (primarily where canine teeth are located) that could further influence the deformation of the engaged aligner and possibly affect the force system based on the location of the teeth in the maxillary arch (Figure 1.3). There is limited literature on the possible role of anatomical configuration of teeth and force system exerted by aligners.

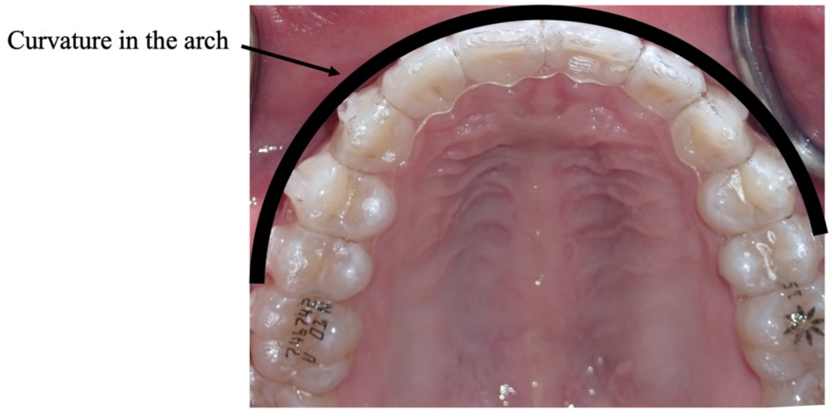

Figure 1.3 Occlusal view of maxillary arch showing curvature at canine region of the arch form

1.1.2 Aligner material

Aligner force systems are dependent on the material used for their fabrication based on the material mechanical properties. Aligners used clinically are mostly formed from polyethylene terephthalate (PET), polyethylene terephthalate glycol (PET-G), polyurethane (PU), polypropylene, polycarbonate, ethylene vinyl acetate, and polyvinyl chloride.[30] These materials have distinct features such as transparency, durability, stain resistance and elasticity that facilitate their usage as aligner material. Polypropylene is durable and stain resistant, PET-G is transparent, strong and stain resistant, PU is flexible and elastic for improved tooth movement with aligners.[31] PU based Exceed 30® material is used extensively for fabrication of aligners.[32] These aligner materials have different mechanical properties such as stress relaxation, water sorption, modulus of elasticity etc. inherently influenced by structural factors such as chemical composition that can influence the force system.[33] The previous studies[21-24] have assessed the force system limited to PET-G material. The work around other primarily used materials such as PET and PU is lacking. Additionally, the presented work has focused on a single tooth (central incisor) without providing any information on force system generated by aligner materials on other dissimilar anatomical teeth such as canine and premolars.

1.1.3 Aligner auxiliaries

Another factor that could influence the aligner biomechanics are aligner auxiliaries. Orthodontic aligner systems have evolved over time with the introduction of auxiliaries (e.g., divots, and attachments) with the proposition that aligner usage may extend to less predictable tooth movements such as bodily tooth movement and extrusion.[18,34] Different aligner system have used various auxiliaries. For example, The Sorridi® system (Sorridi srl, Latina, Italy) includes divots (and no attachments) and Invisalign system® incorporates attachments. Divots are small projects introduced in aligner trays and attachments are composite projections light cured on tooth surface engaged by aligner.

Aligner auxiliaries (divots, attachments) were supplemented to aligners to enhance its biomechanics by enabling control of tooth movement. Specifically, aligner therapy using divots or attachments are designed to have specific regions of contact between teeth and aligner. An in vitro study[28] has pointed out that tactical placement of the attachments can impose forces on specific region of the tooth surface enhancing the force delivery system by the aligners. A finite element (FE) study[34] that assessed maxillary canine movement with and without composite attachment suggested tipping movement (uncontrolled) without composite attachment and bodily tooth movement (controlled) with composite attachment. A SR[35] highlighted the importance of auxiliaries to achieve better root control for bodily movement, and extrusion with aligners.

Most of the literature is based on the influence of auxiliary shape[36-38] and very few studies have assessed the role of location of auxiliary.[39] Auxiliary location is an important factor as force (applied) variation in distance from the CoR could cause alterations in tooth movement. Therefore, it is crucial to study biomechanics of auxiliary location with aligners.

1.1.3.1 Bodily tooth movement

Bodily tooth movement involves movement of root in the same direction and distance as the crown. Controlling root position as well as the crown position provides better axial inclination of the tooth for masticatory loads which facilitates better retention after orthodontic treatment. Due to physiological limitation, tooth root is encased in bone and soft tissue (where CoR lies), only the tooth crown is available for force application. As the force is applied at distance from the CoR, this generates a moment that tends to tip the teeth. Bodily movement requires application of a force couple which is difficult with aligner treatment. Therefore, tipping is easily attainable with aligner mechanotherapy while it is limited for bodily tooth movement.[18]

Aligner with auxiliary attachments or divots can provide two-point contact with the teeth crown and extend the potential to improve treatment outcomes by establishing counter moment through a couple (Figure 1.4).[34,40] Theoretically, the couple generated will be most efficient when one divot is close to gingival margin on buccal side and other one is on incisal edge of lingual side providing the maximum distance between two divots. However, the gingival portion of aligner is suggested to apply less force as compared to the same aligner at incisal part of tooth due to thinning of aligner at gingival portion during thermoforming process.[41] Hence, it is important to explore the force system by moving the attachment along the buccal and lingual side across the crown of tooth to understand the role of location of divot placement.

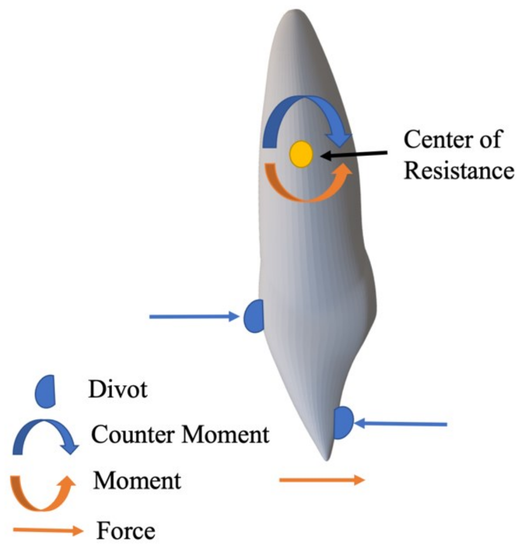

Figure 1.4 Diagrammatic presentation showing theoretical effect of adding divots to aligners where moment was generated by force applied away from CoR of tooth and counter moment was exerted by placement of divots

1.1.3.2 Extrusion tooth movement

Extrusion is moving the tooth towards the occlusal plane. A SR[18] based on clinical evidence reported that extrusion is most difficult movement with aligners. Recent retrospective studies[42-46] showed partial success of aligners with attachments for extrusive tooth movements to correct open bite. These retrospective studies identified that open bite correction was achieved by combination of anterior incisor teeth retraction, anterior teeth extrusion and posterior molar teeth intrusion resulting in counterclockwise rotation of the mandible. Absolute extrusion of anterior teeth was limited to approximately 1 mm. This is due to location of an attachment on the buccal aspect of teeth which directs the line of action of force buccal to CoR resulting in tipping of incisors lingually. An attachment added to lingual aspect of tooth could counter the moment created by buccal force, resulting in absolute extrusion. It has also been shown by FE study[39] that attachment location affects its effectiveness more than its shape where placement of a rectangular attachment on the lingual surface improved the outcome significantly.

1.2 Thesis Objectives

The overarching objective of this thesis was to utilize in vitro methods (OSIM) to study the biomechanics of aligners towards gaining a foundational understanding of their expected behavior around the maxillary arch. Factors that could influence the biomechanics of aligners such as tooth anatomy, aligner materials and aligner auxiliaries have been appraised through this project.

Aligners apply force guiding the teeth into desired position by engaging on the various surfaces of the tooth requiring intimate contact between tooth surface and aligner. Since the teeth are of different shape and surface area, it was hypothesized for first experiment that there would be differences in the force system when dissimilar teeth were displaced by the same amount using PET-G material. This aim was expanded by an additional experiment to other most used aligner materials (PET, PU) to understand their behavior on tested teeth. It was hypothesized for second experiment that various materials due to difference in their underlying mechanical properties and variance in response to thermoforming process would exert different force systems on dissimilar tested teeth.

From these two experiments, it was derived that the tested teeth experienced significant moments that could tip the teeth along with displacement leading to unpredictability of aligners for tooth movements such as bodily translation and extrusion that require root control. Therefore, the next two experiments of the project aimed at investigation of auxiliaries such as divots and attachments with aligners to analyze the force system of bodily tooth movement and extrusion, respectively that could improve predictability of these tooth movement. Further, the first two aims of the project helped us to identify the potential confounding factors (such as geometry, position of the teeth and aligner material in the force system) before evaluating the effect of auxiliaries with aligners.

For the third experiment, it was hypothesized that there would be difference in force system with varied vertical position of divots on the crown and in different combinations of lingual/buccal sides of central incisor for bodily tooth movement due to difference in the distance between the divots as well as anatomic conforms of crown of maxillary central incisor. Similarly, for the fourth experiment, it was hypothesized that change in placement of attachments on buccal and lingual side of tooth would provide alteration in the force system for extrusive tooth movement for lateral incisor due to difference in force application with respect to CoR of the tooth.

Accordingly, the following four aims were investigated for the thesis project:

- Aim 1: To evaluate the force system exerted on a central incisor, canine, and second premolar teeth around the maxillary arch using a clinically representative PET-G aligner material.
- Aim 2: To assess the force system of commonly used three aligner materials: PET, PU, and PET-G on a subset of maxillary teeth (central incisor, canine, and second premolar). In addition, the flexural modulus of pre- and post-thermoformed PET, PU, and PET-G was investigated to understand the effect of thermoforming on different aligner materials.
- Aim 3: To determine the force system of divot with its varying location on buccal and lingual sides of the crown for bodily tooth movement of central incisor using PET material
- Aim 4: To evaluate the biomechanics of attachment use, and its location on the buccal and lingual side of the crown for extrusion tooth movement of lateral incisor using PET material.

Evaluation of factors that can influence the aligner biomechanics would contribute to the existing knowledge of the aligner mechanotherapy and would be some of the first to evaluate the force system on various teeth with most used aligner materials. This will provide preliminary in vitro evidence as well as understanding to the clinicians how different aligner materials generates a force system on the various teeth in the maxillary arch. The results of this work could provide preliminary biomechanical evidence to clinicians to make more informed decisions on appliance design and treatment modalities to improve treatment effectiveness and reduce undesirable side effects.

1.3 Thesis outline

This thesis is composed of eight chapters. Chapter 2 provides a literature review on principles of biomechanics, orthodontic mechanical concepts, orthodontic tooth movement, modalities used for orthodontic force system measurement, aligner mechanotherapy history, aligner predictability of various orthodontic tooth movements, biomechanics of aligners and various factors influencing it.

Chapter 3 utilized a SR to evaluate the effectiveness of aligner mechanotherapy based on clinical evidence. This review followed "Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA)" checklist and the quality of included studies was evaluated by using "Risk Of Bias In Non-randomized Studies-of Interventions" for observational studies and "Cochrane Risk of Bias Tool" for randomized controlled trials (RCT). This SR assessed the predictability of aligner mechanotherapy for various tooth movements in all the three planes-vertical, horizontal, and transverse and compared the treatment outcome of aligners with fixed appliance therapy.

Chapter 4 evaluated the force system exerted on different teeth (central incisor, canine and second premolar) around the maxillary arch using a clinically representative 0.75 mm thick PET-G aligner material by using OSIM. As the teeth were translated in lingual direction by 0.20 mm, buccolingual forces (Fy), and moments that can tip teeth buccally or lingually (Mx) were primary outcome measures.

Chapter 5 expanded on chapter 4 where the force system for other commonly used aligner materials such as PET and PU were assessed on different teeth (central incisor, canine, and second premolar) around the maxillary arch by using OSIM. This was accomplished by lingually displacing teeth by 0.20 mm to evaluate Fy and Mx. Further, the role of thermoforming was assessed by flexural modulus estimated by 3-point bend tests.

Chapter 6 and chapter 7 explored the force system of auxiliaries used with aligners. Chapter 6 focused on evaluation of the force system of divots with aligners placed on varying position on buccal and lingual side of central incisor for bodily tooth movement. The Fy and Mx were evaluated at displacement of 0.20 mm lingually by using PET material. Chapter 7 investigated the force system of attachments with aligners located on buccal and lingual side of lateral incisor. The occlusogingival forces (Fz) and Mx were primary outcome measures at 0.20 mm of gingival displacement by using 0.75 mm PET material. Chapter 8 presented the summary and conclusions of the work with its limitations. It further discussed potential future works derived from this project.

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Chapter 2: Literature Review

This chapter introduces relevant background information regarding basic biomechanical principles with relevant topics in orthodontic treatment. Relevant literature pertaining to the biomechanics of tooth movement is presented covering biology of tooth movement, force levels for orthodontic tooth movement, and modalities to measure orthodontic force systems with elaborated discussion of OSIM (experimental set up used for this project). Aligner mechanotherapy history, its predictability with various tooth movements, and its biomechanics has been discussed in this chapter.

2.1 Principles of Biomechanics

2.1.1 Force

A force is a “push” or “pull” exerted by one body on another body. This interaction between two bodies could be direct (such as pushing an object) or indirect (for example gravitational, electric, and magnetic forces).[1] A "force" is any action that tends to maintain or alter the state of motion or rest of the body upon which it acts. Newton is a unit of the International System for measuring force, and is the force required to accelerate a one-kilogram body by one meter per second.[1] In orthodontics, magnitude of force is often expressed in grams (gm). The conversion factor from gram to Newton is 1 gm = 0.00981 N or 1 N = 101.9716 gm. Force is a vector quantity that has magnitude and direction. The direction of a force is known by observing the line of action of the vector of the force.

Force can be represented either mathematically or graphically.

Mathematical representation: $\mathbf{F}$, $\underline{F}$

Graphically, force can be represented as directed line segment (an arrow) (Figure 2.1):

- Length of the arrow represents the force magnitude
- Orientation of the arrow defines the direction or line of action
- Location of the arrowhead defines the sense

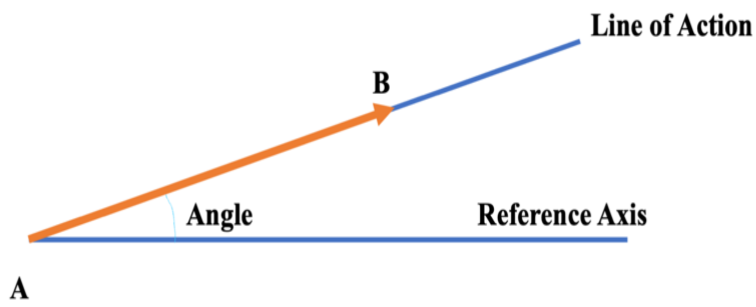

Figure 2.1 Graphical representation of force where point A defines the tail of vector F, B defines the head of vector F

Teeth are often acted upon by more than one force. The movement of teeth is determined by the net effect of all forces acting on it. Force, being a vector quantity, follows the parallelogram rule of addition (Figure 2.2). It becomes harder to evaluate net force on a tooth when multiple forces acting in various directions as is the case with orthodontic appliance.

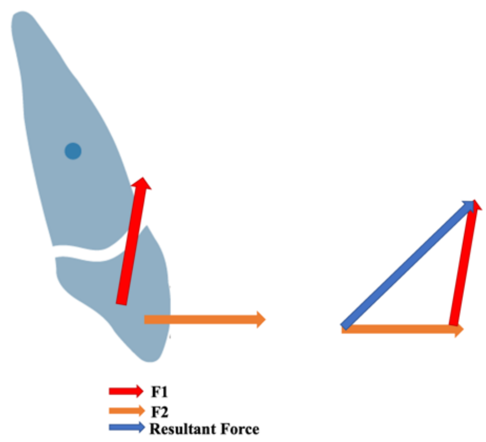

Figure 2.2 Diagrammatic presentation of the parallelogram law of addition for two forces

2.1.2 Moment

Moment of force is a measure of its tendency to produce a rotation of a body about a specific axis. Moment is created when force acts upon a body such that it does not pass through the centre of mass of the body (Figure 2.3). Moment is expressed in units of Newton-millimeters.

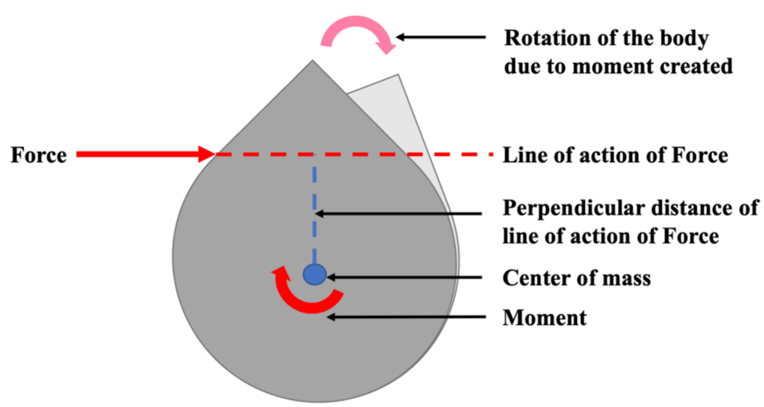

Figure 2.3 Schematic representation showing moment produced when force is applied away from center of mass of the body

The moment arm is the perpendicular distance of line of action of force and the point about which the moment is determined. A moment is increased by increasing the force and/or increasing the perpendicular distance of line of action of force.

2.2 Orthodontic mechanical concepts

Biomechanical principles play an integral part for executing efficient and successful orthodontic treatment. Orthodontic tooth movement occurs because of cascading biological reactions to the applied forces and moments with orthodontic appliances.[2] Biomechanical principles help to deduce the displacement of teeth with applied force systems. Predictable tooth movement requires favorable magnitude, direction and point of force application.[3] Therefore, it is important to understand the mechanics (forces and moments) underlying the orthodontic appliance.

Orthodontic tooth movements are frequently discussed in relation to the CoR and center of rotation.[2,3] Teeth are restrained by periodontal structures that are not uniform around the tooth. Therefore, in a restrained body such as a tooth, a point analogous to the center of mass is called CoR which is the central point of support provided by the bone and periodontal ligament (PDL) structures surrounding the tooth root. The force applied to CoR would produce translation where tooth moves bodily (Figure 2.4).[3]

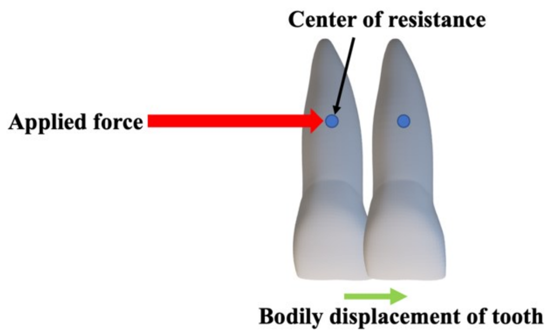

Figure 2.4 Visual illustration of theoretical scenario where a force applied through CoR of teeth

The location of the CoR is dependent on the root length, number of roots, quality, and level of supporting structures.[2,4] In a case where force does not pass through the CoR, the tooth will move in the direction of the force and there will be a moment generated that will tend to rotate (tip) the tooth in the direction of the force. In orthodontics, a moment is formed usually by two ways. Firstly, when a force is applied at the crown of the tooth away from the CoR of the tooth. Secondly, a moment can be created through a couple. A couple that is created by two parallel forces that are equal in magnitude but opposite in direction and does not have same line of action.[4] Couples produce rotation with zero resultant force. The moment of a couple is the product of the magnitude of one of the forces and the perpendicular distance between their lines of action. The orthodontist can vary the type of tooth movement by varying the ratio of moment to force applied.[4]

2.3 Orthodontic tooth movement

Orthodontic tooth movement is a combined mechanically and biologically controlled phenomenon which is achieved by applying a force system that cause stress in PDL leading to physical, chemical, and electrical signals sent to the surrounding cells and tissues.[5,6] Therefore, tooth displacement can be altered by changing the magnitude, direction and duration of the applied forces and moments.[7] Two primary mechanisms have been proposed for explaining orthodontic tooth movement[8]: 1) Pressure and tension to the PDL; 2) Bending of the alveolar bone. In 1815, Delabbare suggested the notion that pain and swelling (inflammation) following application of force is an integral part of orthodontic tooth movement. Alternatively, Farrar hypothesized that tooth movement occurs due to alveolar bone bending in response to exerted forces.[9] This was supported by Wolff's suggestion that bone internal architecture is directed by the acting mechanical forces. Histological studies[8] suggest that both extracellular components of PDL and alveolar bone respond concomitantly to the mechanical force system that results in tooth movement.

Dentoalveolar tissue remodeling during tooth movement is the result of dynamic set of events that involves cellular activity regulated by interactions between physical distortions and locally distributed humoral factors that act as endocrine, paracrine, or autocrine (Figure 2.5).[8] When stress is applied, the cells and extracellular fluid of PDL are mobilized.[2] The gradual fluid shift in PDL results in distortion of nerve fibers resulting in release of vasoactive neuropeptides, calcitonin gene related peptide and substance P leading to vasodilation of periodontal capillaries, plasma extravasation and leukocytes migration in extravascular space in the PDL.[10,11] The migrated leukocytes synthesize and secrete a variety of cytokines that are capable of stimulating fibroblasts, alveolar bone cells and endothelial cells.[8] In addition, the stress changes the shape of cells that can lead to crystallization of cytoskeletal filaments and opening or closing of stress-related membrane ion channels. Distortion of the matrix is associated with the appearance of piezoelectric spikes and the fluid flow leads to slowly dissipating streaming potentials.[9] These bioelectric phenomena can cause alterations in the polarity of plasma membranes of cells that will lead to activation of membrane enzymes and cell-matrix interactions.[8]

Cells sense the mechanical loading via cell-cell or cell-matrix adhesions. Mechanosensing induce conformational changes in cellular molecules, cytoskeletal, ion channels, and integrins that further affect gene expression regulating the orthodontic tooth movement.[12] The various cytokines and growth hormones are released in response to mechanical loading that stimulate the biological response. IL-1, IL-2, IL-3, IL-6, TNF-a, and IFN-y have demonstrated effect on bone metabolism with IL1 being most potent stimulator for bone resorption.[13] Prostaglandins are secreted when the cells are mechanically deformed with loading.[14]

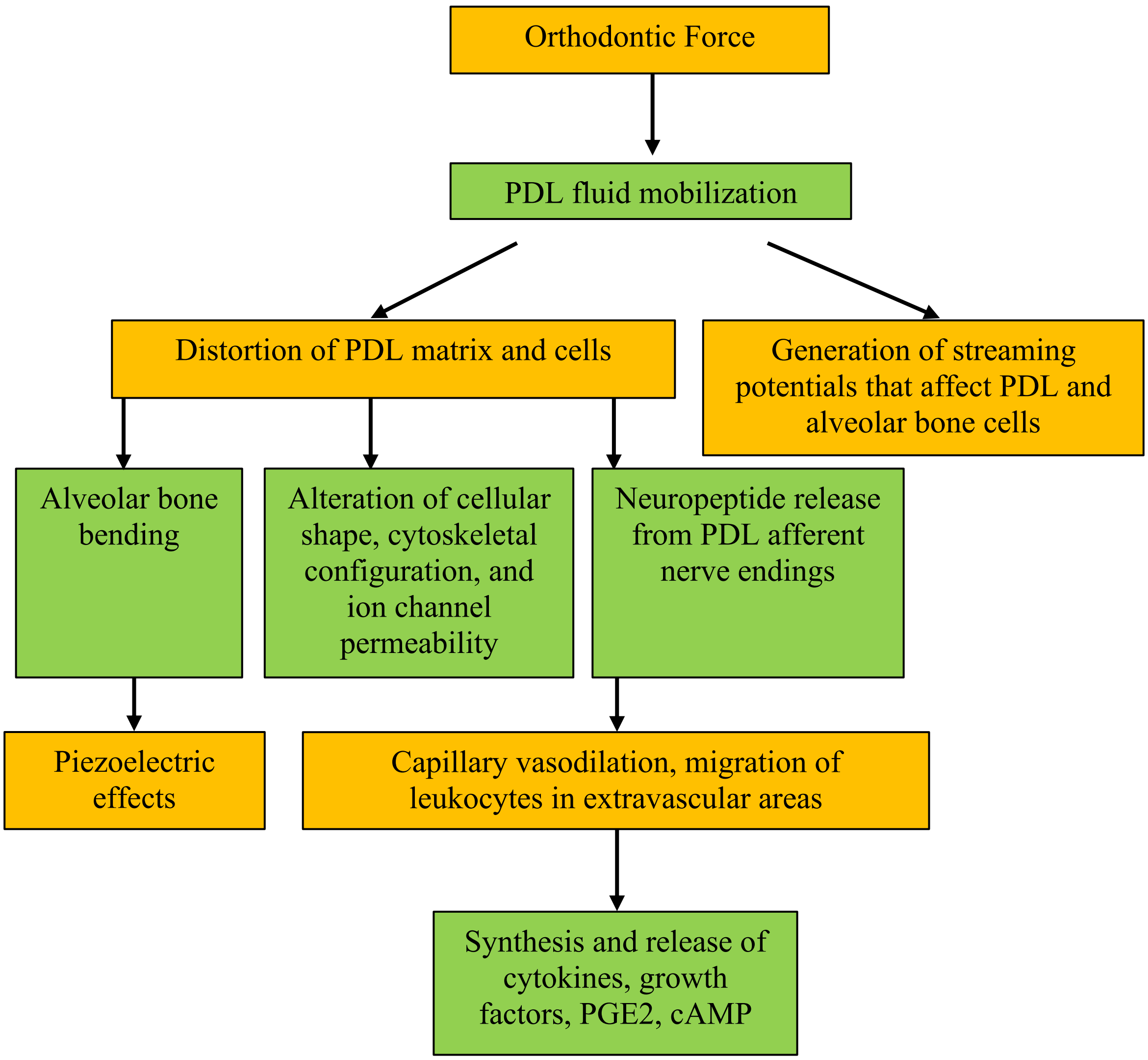

Figure 2.5 Overview of set of events involving cellular activity regulated by interactions between physical distortions and locally distributed humoral factors for tooth movement

The cells that form and degrade periodontal extracellular matrix are primarily fibroblasts and bone remodeling is in response to osteoblasts, osteoclasts, and osteocytes. Osteoblasts form the osteogenic response on the tension side (widened) zone of PDL.[2] Osteoblasts are derived from stem cells migration from blood vessels or mesenchymal stem cell precursor activation and form preosteoblasts that migrate to the bone surface to become osteoblasts.[15] The transcription factor Runx2, osterix;and proteins osteocalcin and osteopontin are significantly upregulated by tension forces.[16] On the tension side, the stress and strain are concentrated in the PDL rather than bone surface.[17] The bone adjacent to the compression side of the PDL is resorbed by osteoclasts. Osteoclasts are multinucleated cells that develop from monocyte hematopoietic cells.[18] They adhere to bone matrix and secrete acid and lytic enzymes that destroy mineral and protein structures. Osteoprotegerin, cathepsin K and chloride channel 7 are involved in osteoclast differentiation and function. RANK and RANKL are two proteins associated that regulate the osteoclast function.[18] Osteoclastogenesis is induced through up regulation of receptor activator of nuclear factor kappa-B ligand (RANKL)(Figure 2.6).[19] Cytokines and Sclerostin incites the RANKL expression to stimulate osteoclastogenesis.[20] RANKL is synthesized by osteoblast that promotes osteoclast differentiation.

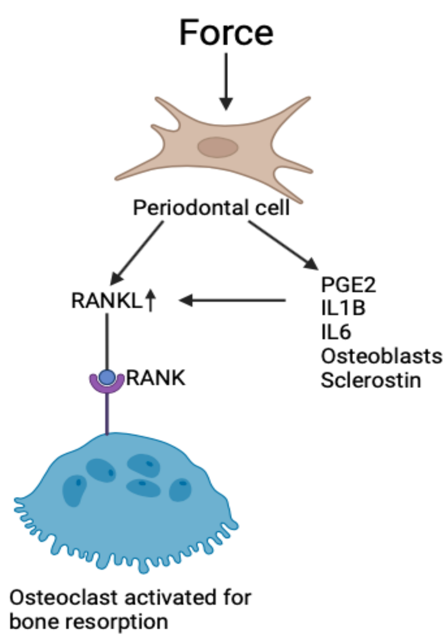

Figure 2.6 Pictorial illustration of activation of Osteoclast

Direct resorption of bone (frontal resorption) occurs when low-magnitude forces are applied that preserves tissues, cells, and vascular patency. Indirect resorption (undermining resorption) occurs because of larger-magnitude forces that necrotize periodontal tissue leading to cell death. In such cases osteoclasts are recruited from bone marrow.[2] The heavy forces could further stimulate odontoclast activity resulting in possible root resorption and increase in overall treatment time.[21-23] Therefore, the goal is to produce majority of orthodontic tooth movement with frontal resorption.

Schwartz suggested that the stress levels of 20-26 g/cm^2 were sufficient to produce orthodontic tooth movement which was based on his histological study where finger spring applied light forces (20-26 g/cm^2) showed 1mm of monthly tooth movement without any damage to the vitality of the tissue.[24] The concept of an optimal force that produces the maximum tooth movement with minimum patient discomfort or damage is discussed extensively in literature.[2,25-27] A light and continuous force is considered as optimal force in orthodontics, however, its quantification is debated. Orthodontic literature has shown force application ranging from 2cN[28] to 10N[29] for orthodontic tooth movement.

Storey[23] conducted a series of experiments on humans as well as on animals (guinea pigs) to assess the effect of magnitude of force on rate of tooth movement where different magnitudes of force was applied to the maxillary incisors. He suggested a range of force magnitudes could be termed optimal that would vary with the surface area of the tooth root. Rate of tooth movement is also dependent on the desired type of movement,[26] and individual variation[23] (sex, age, hormones etc.). Proffit *et al.*[2] suggested the force magnitudes for different type of orthodontic movement based on his interpretation of literature (Table 2.1)

Table 2.1 Force range suggested for orthodontic tooth movement by Proffit et al.

Tipping, rotation, extrusion	35 - 60gm (35 - 60cN)
Intrusion	20gm (20cN)
Bodily translation	70 - 120gm (70 - 120cN)
Root uprighting	50 - 100gm (50 - 100cN)

A SR published in 2003[30] attempted to identify optimal force or range of forces for orthodontic tooth movement. It included both animal and human studies. The included studies had a wide range of animal species, force magnitudes, teeth under study, directions of tooth movement, duration of experimental period, and force reactivation. This review concluded that no evidence could be extracted from literature about the optimal force level in orthodontics. A more recent SR[31] was conducted to evaluate the appropriate force level that should be applied during orthodontic tooth movement. This review included 12 papers (2 RCT and 10 randomized split-mouth studies from five electronic databases ((MEDLINE [via PubMed], Embase [via OVID], Cochrane Library, CINAHL, and Web of Science). The force magnitude was applied on the canine in 11 out of 12 studies and one study applied force on the second molar. This review suggested that the rate of tooth movement was similar between 50 cN and 250 cN, however, the higher forces were accompanied by adverse effects loss of canine rotation control, anchorage loss, and pain. This SR based on weak to moderate evidence proposed that forces between 50 cN and 100 cN seem optimal for tooth movement with patient comfort and fewer side effects (such as loss of canine rotation control, anchorage loss).

Force of certain minimum threshold is required for orthodontic tooth movement to overcome “active stabilization” of the PDL due to resistance provided by tissue fluid. Force below the stabilization level is expected to be ineffective.[2] The suggested threshold in literature is 5 to 10gm/cm^2.[2]

2.4 Orthodontic force measurement and prediction

The first step to allow the clinicians to move teeth predictably is to understand the relationship between appliance activation and the resultant force system produced. Presently, there are two possible ways to enhance the understanding of force system: 1) FE analysis; 2) Experimental methods.

2.4.1 FE analysis

FE analysis is an engineering approach used extensively in orthodontic research by calculating the stress and deformation of complex structures to understand force system.[32] It is based on dividing the complex structure into smaller sections termed as elements to which physical properties (e.g.

modulus of elasticity and Poisson's coefficient) can be applied to understand the response to force system.

A FE study[33] was done to understand the behavior of aligners of 0.4, 0.5, 0.6, 0.7 mm thicknesses for 0.2 mm buccal lingual translation of upper left central incisor. The Poisson's ratio was set at 0.3 for all structures while young's modulus of teeth was chosen to be 80 GPa (as that of enamel) and 1.5 Gpa for aligner. The resultant maximum forces were within the range of 1.3–18.3 N where lingual translation transmitted higher forces compared to buccal translation. The force increases with increasing the thickness of the aligner (not linear increase) and the generated forces were almost directly proportional to the rigidity of the aligner. This study suggested 4-noded tetrahedral elements for meshing of the teeth, and 10-noded tetrahedral elements for meshing of the aligner that has a flexible structure. This study is confined as it neglected the root geometry, PDL structure, and applied boundary condition of pure translation movement.

Additional FE studies have assessed different tooth movements with aligners such as rotation of second premolar,[34] retraction of maxillary incisors,[35, 36] incisor intrusion,[37] molar intrusion,[38] molar distalization[39,40] and lingual displacement of incisors.[41] The FE analysis results are affected based on the model's assumptions of material properties, physical geometry, and load application.[42] Therefore, results of FE analysis need to be interpreted with caution. Moreover, the structural morphology of the PDL, bone, and cementum is very complex. Most of the existing studies define the PDL as a homogeneous and isotropic linear material. A study has been conducted on the complex mechanical behavior of the PDL by Uhlir *et al*.[43] that established a viscohyperelastic model of the PDL. Although these models are more physiologically relevant than traditional linear models in predicting clinical tooth movement, their results lack validation by clinical data. They all used periodontal tissues of animals for their experiments, which differ from the mechanical properties of the human periodontal tissue. As a result, there is not yet an accepted ideal model for PDL FE analysis.[44] The predicted tooth movement has been shown to substantially affected by the change in the model assumptions of PDL thickness.[45] This is further complicated in case of their utility for studying biomechanics of aligners mechanotherapy (used for teeth straightening) as aligners were considered as uniform thickness but clinically aligner thickness varies after thermoforming.[45] This is an important consideration as mechanical interaction between the aligner and teeth is sensitive to the aligner thickness.[46]

2.4.2 Experimental methods

Experimental methods involve measuring an orthodontic force system intraorally or on a fabricated extraoral model using measuring devices that can be divided into optical techniques, flexible electronic sensors, and multi-axis 3D mechanical sensors.

2.4.2.1 Optical methods

These methods are based on establishing a quantitative relationship between optical parameters and stress. For instance, the pressure sensitive films evaluate the pressure applied to the film surface and corresponding degree of stain map can be obtained under various pressure loads. An in vivo[47] study placed pressure film between the aligner and tooth. A light microscope (SZ-FO Dissecting Microscope, Olympus, Japan) was linked to a digital camera (Color View Soft Imaging System, Olympus, Japan) to take pictures of the compressed film. The mean magnitude of force was 1.12N for lingually positioned first premolar moved by 0.5 mm in two weeks. The limitation of this method is: 1) the surplus force exerted due to thickness of the film; and 2) it is unable to assess the direction and dynamic changes in the orthodontic force system.[44]

2.4.2.2 Flexible electronic Sensors

In vivo strain measurement has been used to assess the biomechanics of the aligners. This assumes that the force exerted by the aligner on a tooth can be construed by the von Mises strains developed on the aligner surface that is based on the distortion energy of a structure.[48] Vardimon *et al.*[48] evaluated the force behavior of PU aligners (n=61) by analyzing the von Mises strains developed in aligners by retraction of incisors. Two identical series of aligners were manufactured, one series to be worn by patients for their treatment and another series was used for the in vivo von Mises strain measurements worn by the patient only during strain measurements. There were two strain gauge rosettes placed on the buccal surface of the maxillary central incisor and buccal surface of the maxillary premolar. Strain measurements were taken on days 1, 2, 9 and 15.

Before each measurement, strain gauge rosettes were connected to a Wheatstone bridge via a switch and balance unit to a strain indicator (P-3500, Vishay Measurements Group) and an extraoral baseline was established outside the mouth. For this study, maximum strain was developed at day 1, decreased on day 2 and maintained a plateau from days 2 to 15 days at incisor region.

Another in vivo system[49] was developed to assess the force acting on the individual tooth by specially designed brackets. The slot and base section of bracket were detachable during the measuring operation. The sensor was attached to a bracket slot which was fixed in the position relative to dental arch. Detaching the bracket isolates the force system from the tooth. The measured data was recorded, converted by means of the calibration matrix in the evaluator and processed on a computer using self-developed software. Limitations of this system is: 1) this system was developed for assessing biomechanics of fixed orthodontic mechanotherapy as sensor was attached to bracket slot and cannot be used for aligner mechanotherapy; 2) error could result from incomplete fixing of arch wires to bracket slot. Although the presented in vivo studies were able to directly measure the force system, an in vitro study designs could be beneficial for quantitative data collection in a controlled environment.

A study by Son et al.[50] aimed to assess the force system where pressure variations were measured using a series of aligners moved at intervals of 0.25 mm with a 0.75 mm thick polymer sheet. Another study by Xiang et al.[51] compared the force system of 0.75 mm thick conventional PET-G and modified PET-G (higher modulus elasticity and greater abrasion resistance) immersed in artificial saliva for two weeks with different activations (0, 0.10 and 0.20 mm) and different immersion time with the aid of thin film pressure sensor. The force sensor detection system consisted of thin film sensor (0.2 mm thick sensors), a signal acquisition circuit board, a software visually measuring the pressure and a computer. This study suggested that forces exerted by conventional PET-G appliances with 0.20 mm activation is less than the mean force applied by the modified PET-G. The force delivered by both materials decreased after immersion in artificial saliva. The limitations of these studies were the complicated contact surface between aligner and resin models due to presence of sensor in between the two surfaces that can affect the measurements.

2.4.2.3 In vitro mechanical measurement systems

Solonche *et al.*[52] established an apparatus at the University of Connecticut Health Center to measure uniplanar force systems delivered by orthodontic appliances. Various spring configurations such as alignment loops and retraction springs were tested with the apparatus. The tested appliance was mounted on two chucks that were attached to transducer (TRANSTEK, Ellington) This system was limited as it was not possible to simulate tooth movement and evaluate the force system.

An in vitro apparatus Orthodontic Measurement and Simulation System was developed by Bourauel *et al.*[53] that contained sensors to simultaneously collect the force and moment data from the teeth. Apparatus consisted of a computer, three-dimensional positional table on which two sensors were mounted, force-torque transducer, and temperature-controlled chamber. The sensor has a measuring range of 15 N and 450 Nmm for force and moment, respectively. This system has been utilized to modalities to upright molars,[54] assess the effect of bracket type on the force system[55] and levelling arch wires[56] with buccal and lingual conventional and self-ligating brackets. Mengi *et al.*[57] used an in vitro machine that was equipped with sensors to identify the force systems from orthodontic loops activated for first order corrections. This system used six incremental motors that control the rotation or translation of two sensors relative to each other at predetermined intervals. The strain gauges converted the force system exerted by different loop configurations into electrical impulses to generate a graphical analysis of the results.

A customized measuring platform with six load cells equipped with six strain gauge for analyzing the 3D orthodontic force system within the range between 0.1 and 2 N was designed by Mencattelli *et al.*[58] This system was used to measure the force system for malocclusion with a high maxillary canine treated with different super elastic wires (utilized five plaster teeth: maxillary right incisors, canine and first premolar) and effects on the rotation of a maxillary central incisor with and without a divot by aligners (utilized three teeth: maxillary right lateral incisor, central incisor, and left central incisor). Another customized platform-The Fourteen Orthodontic Sensing Device with sensor and 3 D printed resin teeth were used by Midorikawa *et al.* This appliance showed that the average force error was 2.06% and moment error was 2.00% making it feasible for various measurements for orthodontic treatment.[59]

Wu *et al.*[60] measured orthodontic forces using a wax model-based tooth movement simulation system to measure the dynamic orthodontic force system of self-ligating bracket systems. The resin teeth were arranged in wax softened in a high-temperature environment (45-65 Celsius) and connected to Nano17 sensors. The clinical tooth remodeling was simulated with the periodontal tissue remodeling under the traction of orthodontic force. The limitation of this setup was that the orthodontic force of less than 0.5 N was not enough to resist the resistance of the wax, and the temperature environment was significantly different from the oral cavity temperature.

2.4.2.3.1 Orthodontic Simulator (OSIM)

An OSIM was developed and validated at the University of Alberta to measure 3D forces and moments of all teeth in a single dental arch simultaneously and in real time.[61] The OSIM is a simplified human mouth model with a single dental arch containing 14 fixed anatomical teeth that were generated digitally using geometry reported in Linek's tooth carving manual.[62] Teeth were attached to load cells that can be used to assess the force system for various mechanotherapy (labial fixed orthodontic appliance, lingual fixed orthodontic appliance, and aligners). This system used the smallest commercially available 3D load cell® (*Nano17*, *ATI Industrial Automation*, NC, USA) that used silicon strain gauges to sense forces where resistance of the strain gauge changes as a function of the applied strain. The electronic hardware detects the change in resistance by providing six readings voltages relative to ground and the software converts these voltages to force and moment data using transducer specific calibration curves.[61] The load cells have resolution of 1/1280 for forces and 1/256 for moments with sensing range of +/- 50 N and +/- 500 Nmm for forces and moments, respectively (as provided by the manufacturer ATI automation, NC). The load cells are located at a distance from the teeth. Consequently, a coordinate measurement device was used to determine the local coordinate systems of the load cell and simulated teeth, from which a Jacobian transformation matrix to an approximated CoR was determined for each tooth (Figure 2.7).

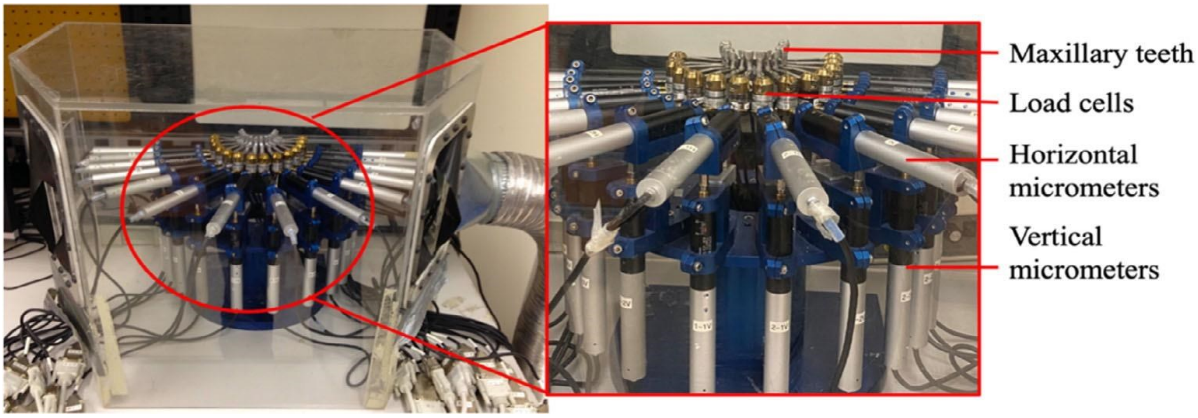

Figure 2.7 Overview of the OSIM for 3D force and moment measurements

The CoR for single- and multi-rooted teeth was approximated from the literature.[63,64] The metal teeth in OSIM were attached to horizontal and vertical micrometers for controlling their movements in buccolingual and occlusogingival directions. A heat chamber made from plexiglass can be placed over the OSIM to replicate the oral cavity with a temperature controller.

The OSIM has been used to study the biomechanics of different simulated orthodontic clinical situations since its development. Fok *et al*.[65] and Seru *et al.*[66] studied biomechanics of different modes of wire ligation to bracket for gingivally placed maxillary canine and lingually positioned maxillary incisor, respectively. Major *et al.*[67] analyzed the different sizes of copper nickel titanium wires with simulated maxillary gingivally placed canine on OSIM showed that diameter of copper NiTi archwires had a non-linear relationship with the applied force system.

The OSIM was employed by *Lee et al.*[68] to study the force system on maxillary arch when using dental and skeletal anchorage during retraction of the anterior segment in a simulated first premolar extraction malocclusion. This study concluded that skeletal anchorage transmitted lesser forces on posterior teeth with higher vertical forces on anterior teeth compared to dental anchorage. Owen *et al.*[69] assessed the biomechanics of lingual straight wires and mushroom arch wires in a vertically displaced canine and a lingually positioned lateral incisor. Lingual straight wires were shown to have a higher force system. The bend in the mushroom archwire significantly changed the force transmission between the canine and first premolar.

2.5. Aligners in orthodontics

Aligners, made up of thermoplastic material for teeth alignment, is relatively new orthodontic technique that has been built on the initial concept of Kesling's tooth positioner in 1945.[70,71] With the advancements in digital technology and patient demand of esthetics alternative for teeth alignment, aligners have gained popularity in the last decades.[72, 73]

2.5.1 History of Removable Thermoplastic Appliances

In 1945, Kesling envisioned an appliance that can guide teeth into ideal positions without the conventional use of bands and wires under the functional forces.[70,71] From this vision, he developed the one-piece rubber tooth positioning appliance fabricated based on an ideal tooth setup. He utilized his appliance after much of the major tooth movements were achieved using traditional bands and wires. He considered that teeth that were already slightly mobile from orthodontic treatment could respond more readily to the force applied by the positioner. This treatment adjunct was estimated to reduce the total treatment time in bands and wires by as much as 6 months in addition to reduced practitioner's chair side time.[74]

The first documented thermoplastic appliance was developed by Henry Isaac Nahoum in 1959 that was fabricated using an industrial-grade vacuum former described as "vacuum formed dental contour appliance." A contour appliance was formed on the set-up model that could be used as a retainer or for achieving minor tooth movements. For larger tooth movements, Nahoum suggested progressive adjustments to the teeth on the altered cast by gradually moving them through the wax and fabricated a new vacuum-formed appliance for each step.[75]

Ponitz in 1971 proposed a vacuum formed plastic appliances made from cellulose acetate butyrate, PU, polyvinylacetate polyethylene polymer, polycarbonate cycolac, and latex to be used for orthodontic finishing and retention. They preheated plastic material in an oven followed by a vacuum unit to conform the material to the shape of the dental arch on a cast.[76]

Ponitz technique was further refined by McNamara in 1985 where he used a Biostar® machine for fabrication of 1mm thick Biocryl polymer appliance. The Biostar® machine used positive air pressure to adapt the thermoplastic Biocryl® rather than the vacuum pressure technique.

The advancement of aligner therapy continues with Sheridan's utilization of Essix material (Raintree Essix, New Orleans, LA) designed to function both as a retainer and positioner.[77] Thermoplastic appliance was formed by using a positive air pressure method from a 0.030" sheet of thermoplastic copolyester. His system was based on the utility of a single appliance for in-course adjustments to achieve treatment goals rather than Nahoum's idea of using serial appliances for successive tooth movements. This was achieved by two methods; either by spot-thermoforming the aligners via Hilliard thermopliers to place a divot or dimple or by mounding (composite mound can be bonded to the patient's tooth). The mound can be incrementally increased from 1mm up to 3mm until the desired tooth position is achieved (Figure 2.8).[77]

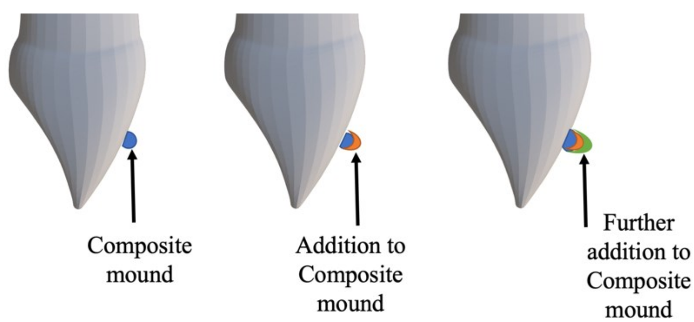

Figure 2.8 Diagrammatic presentation of crown of teeth showing incremental addition to composite mound for sequential tooth movement

The concept of using thermoplastic appliances has existed for many decades but it was limited to small subset of orthodontic treatment as appliances were fabricated manually via laborious procedures such as wax set ups. The advancements in computer-aided design and computer-aided manufacturing and rapid prototyping techniques have allowed for propagation of aligners for comprehensive orthodontic treatment through the usage of several successive aligners each designed to move teeth incrementally by a predetermined amount.

In 1997, Chishti, Kelsey Wirth and two orthodontists founded Align Technology® that developed the Invisalign system. This process involves intraoral scanning of dental arches followed by digitally moving the desired teeth in small increments (0.25-0.33mm per aligner) with the help of 3D software, print the molds at each stage and fabrication of aligners using a thermoforming process. Each aligner is worn for 1-2 weeks with approximately 0.25-0.30 mm of orthodontic tooth movement/tray.[78] This system has evolved with time. First generation of Invisalign system was dependent on its shape to achieve treatment results. To increase the effectiveness of aligner force delivery by aligner appliance, Align technology® has introduced various auxiliaries such as attachment designs, pressure points, power ridges, bite ramps and other altered aligner geometries for second generation. Simon *et al.* suggested that attachment use significantly influenced treatment predictability for incisor torque, premolar derotation, molar distalization.[79] The third generation further enhanced the system by introducing optimized attachments[78] and introduction of more flexible SmartTrack material. The fourth generation saw the introduction of Invisalign Teen designed specifically for teenagers with compliance indicators. The Invisalign system has been constantly evolving with generation five focused on pressure areas on the lingual of anterior teeth, bite ramps to facilitate correction of deep bite; generation six for anchorage control in premolar extraction cases; generation seven has molar retention attachments and generation eight has enhanced deep bite correction, flattened curve of Spee, new attachments for posterior arch expansion and buccal root activations.[80] Apart from the Invisalign system, presently there are at least 27 different aligner products commercially available for orthodontic treatment.[73] For clinical efficiency, it is important that aligners could improve patient's malocclusion and provide clinical outcome equivalent to predicted results.

2.5.2 Aligner predictability for various orthodontic movements

Numerous SRs[81-84] have been conducted to evaluate the predictability of aligner mechanotherapy. Evidence is moderate (to low) quality as it is primarily based upon matched nonrandomized studies with a few RCT. Aligner mechanotherapy does not achieve the predicted tooth movement and its effectiveness is dependent on type of tooth movement.[84]

A prospective study advised that the mean predictability of tooth movement with Invisalign aligners was at 41% in 2009 with lingual constriction being most accurate and extrusion was least accurate tooth movement.[85] A recent prospective follow up study in 2020[86] was done to provide an update on the accuracy of tooth movement with evolution of Invisalign system such as optimized attachments, pressure zones, and customized staging, and the SmartTrack aligner material. This study suggested that the system has still limited predictability with mean predictability of 50% for all tooth movements. Buccolingual tip and rotation were most and least predictable tooth movements.

A SR with meta-analysis[87] that compared aligner mechanotherapy with fixed orthodontic appliance including 11 studies (4 randomized and 7 non-randomized) suggested that aligners are associated with worse treatment outcomes compared to fixed appliances. A recent prospective multicenter study (total of 2212 teeth were measured) was conducted by Castroflorio et al.[88] to verify the predictability of aligners with respect to angulation, inclination, rotation, mesiodistal, vertical movement, and buccolingual movement. All the measured teeth showed a significant difference between the planned and achieved tooth movement: angular (lack of correction of 0.4° for every prescribed 1°), mesiodistal (0.4 loss for every 1 mm), vertical movements (lagging of 0.3 mm for every 1 mm), buccolingual (loss from 0.1 to 0.3 mm for every prescribed 1 mm).

Overall, limited efficiency and predictability of tooth movement with aligners has been identified in the literature that require multiple stages of refinement, or conversion to fixed appliances before the end of treatment.[84,89] Aligner biomechanics knowledge can play vital role in improving the predictability of tooth movement, therefore, improving the quality of the orthodontic treatment with aligners.

2.5.3 Biomechanics of aligners for orthodontic tooth movements

Aligners generate a force system due to the pre-established geometric mismatch between the aligner tray and dental arch. Tooth movement and biomechanics with aligners is dependent on various factors such as mechanical properties of the thermoplastic material, tooth/aligner surface contact mechanics, thickness of the aligners, amount of activation, and utilization of the aligner auxiliaries.[90] The following sections will discuss role of factors such as aligner materials, teeth anatomy and aligner auxiliaries appraised through this project.

2.5.3.1 Aligner materials

The material composition utilized for the fabrication of aligner influences the force delivery by the aligner affecting their clinical performance. Thermoplastic polymers can be classified as amorphous having irregularly arranged molecular structures; and semicrystalline polymers that has areas of uniformly packed chains (crystalline domains) and irregularly arranged areas (amorphous regions).[91] Based on the composition, amorphous polymers are transparent, softer, exhibit low shrinkage and possess better impact resistance. On the contrary semicrystalline polymers are opaque/translucent, exhibit good chemical resistance and has a sharp melting point.[91] The most used polymers (either individual or blended) for manufacturing of aligners are PET, PET-G, PU, polypropylene, polycarbonate, ethylene vinyl acetate, and polyvinyl chloride.[92] Polymer blends of these polymers are commonly employed in the manufacturing of aligners to improve mechanical and chemical properties.[93]

Aligner materials are viscoelastic in nature. The deflection of viscoelastic materials increases over time when exposed to constant loads.[94] Stress relaxation is a time dependent decrease in stress under a constant strain. The exponential reduction in force has been noted with aligners leading to a decrease of force in the first few hours of aligner use.[94] This material property varies with different thermoplastic materials. Lombardo et al. investigated the stress relaxation of four different aligner materials: single layered PET-G modified (Duran: SCHEU, Iserlohn, Germany), single layered PU (F22 Aligner: (Sweden & Martina, Due Carrare, Padova, Italy), double layered Erkoloc-Pro (Erkodent, Pfalzgrafenweiler, Germany) and double layered Durasoft (SCHEU), under constant load for 24 hours in a humid environment at a constant temperature. All four materials showed significant stress relaxation for the first 8 hours that tended to plateau for some materials and decreased for other materials at the 24-hour time point. Double layered materials demonstrated lower stress relaxation rates than monolayered materials. Single layered PET-G modified showed most significant stress relaxation rate during the 24 hours.[94] Different aligner materials demonstrate differing characteristics that respond varyingly to the mechanical stress (due to functional and parafunctional movements), thermal stress (caused by thermoforming and change in oral temperature) and chemical stress (owing to saliva and food consumption).[95]

The mechanical properties of aligners can be altered in an intraoral environment. A study by Ryokawa *et al.*[96] who assessed the mechanical properties of thermoplastic materials: ethylene–vinyl acetate copolymer, polyethylene, PET-G, polypropylene, polycarbonate, copolyester, polypropylene/ethylene copolymer, PU in a simulated intraoral environment. Water absorption increased with time and was in the decreasing order for PU, PET-G, copolyester, polycarbonate, ethylenevinyl acetate copolymer, polypropylene, polypropylene/ethylene copolymer, and polyethylene. The thickness of the materials decreased from 74.9 to 92.6% after thermoforming. An in vivo study[97] conducted on PET-G material considering the temperature variations, oral functions and parafunctional habits showed adequate stability of material in the oral environment.

In vitro study[98] evaluated PET-G, PET, and PU materials for distal canine movement (through wax) in typodont with first bicuspid extraction simulation. This study showed the canine with the PET-G and PU groups underwent distal crown tip movement. However, canine with PET material that displayed bodily movement. This was explained by authors based on the difference in Young's modulus between the materials, PET material having higher modulus than other two materials can wrap the tooth tightly increasing the aligner retention.

There is continuous evolution of aligner materials with the aim to produce novel materials for orthodontic appliances to mitigate the biomechanical limitations of aligners. Shape memory polymers can retain temporary shape stably and recover back to their original shape on re-application of stimulus. These materials have two traits: stable polymer network that determines the original shape and reversible polymer network that allows material to transform to an altered temporary shape.[99] The shape memory due to thermal stimuli relies on the activation and deactivation, respectively above and below transition temperature. When transition temperature is reached, the deformed shape memory shows an elastic property to recover back to its original shape leading to generation of force system for orthodontic tooth movement. These materials have substantial elastic deformation and high chemical stability. Elshazly et al.[100] conducted in vitro investigation on aligner thermoformed from ClearX sheets (0.76 mm thick, shape memory sheet material, supplied by Kline-Europe GmbH, Düsseldorf, Germany) showed the possibility of using one shape memory aligner instead of three successive conventional aligners to attain planned orthodontic tooth movement.

2.5.3.2 Role of tooth anatomy in biomechanics

Aligners wrap around the tooth crown to deliver a force system due to essential mismatch between aligner and tooth surface. Aligner's engagement with the tooth surface and the contact mechanics between the tooth and aligner may vary with different types of teeth and with different surfaces of the same tooth. [101,102]

An experimental study[101] was conducted to evaluate the force system for PET-G aligners (Duran®, Erkodur®, Track-A®) for buccal and lingual translation of an upper central incisor. There was significant difference noted in force system for buccal and lingual displacement of same tooth with mean force higher for lingual displacement compared to buccal displacement by 48 % with Erkodur®, 37 % with the Duran® and 23 % with Track-A® aligners. Another in vitro study[102] that analyzed Fy exerted by PET-G orthodontic aligners on three maxillary teeth (central incisor, canine and first premolar) by lingual displacement of 0.20 mm showed that the force system imposed by the orthodontic aligner was dependent on location of the tooth around the arch.

2.5.3.3 Aligner auxiliaries

Another significant development to overcome the biomechanical limitation inherent to aligner-based tooth movement is introduction of auxiliaries such as attachments, power ridges, intermaxillary elastics, divots. While intermaxillary elastics apply force actively, attachments are not active agents to produce a force system, instead they passively disrupt the plastic material that establishes force vector to substantially affect the tooth movement. The divots are small depressions placed on the aligners that can be used as a substitute to an attachment to guide tooth movements such as rotations, tipping and bodily tooth movements. Their utility and action are not well studied in literature besides its promising efficacy.[58]

Alternatively, attachments are protrusion of composite material polymerized onto the tooth surface whose shape and position is dependent on its function.[103] Attachments have evolved over years. Initially they have ellipsoidal in shape followed by rectangular attachments distinguished by horizontal, vertical, and beveled shapes (Figure 2.9).[104] Horizontal attachment for intrusion and extrusion, and vertical ones to derotate, and control the teeth inclination of tooth. The beveled rectangular attachment is applied along the vertical axis of the tooth in the so-called “active surface area” that prevents the sliding soap effect during placement. Recently introduced are optimized attachments in the Invisalign® system.

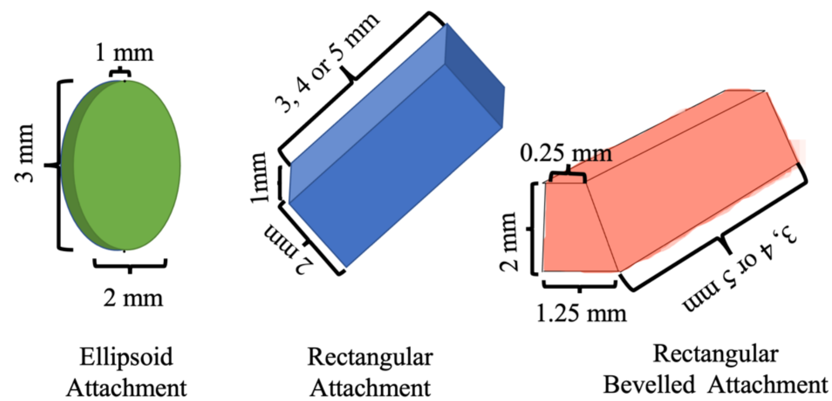

Figure 2.9 Illustration of various shapes of attachments: ellipsoid, rectangular and rectangular beveled

Evidence based on small-scale clinical studies[79] and FE analysis[38, 105-107] points out that auxiliaries improve orthodontic tooth movement with aligners.[108] A SR[109] based on five clinical trials assessed aligners with attachments for mesiodistal tipping/bodily movement; anterior buccolingual tipping/root torque; posterior buccolingual tipping/expansion; intrusion; extrusion; rotation). Aligners with attachments improved anterior root torque, rotation, mesiodistal tipping and improved anchorage. This review suggested the influence of attachments on intrusion or extrusion of teeth is lacking.

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Chapter 3: Systematic review on effectiveness of aligner therapy for orthodontic treatment

The objective of this chapter was to analyze through a systematic review the clinical effectiveness of aligner mechanotherapy by assessing: (a) predictability of aligners and (b) treatment outcome comparison of aligner mechanotherapy with conventional fixed appliance therapy. The version of this chapter is published as "Robertson L, Kaur H, Fagundes NCF, Romanyk D, Major P, Flores Mir C. Effectiveness of clear aligner therapy for orthodontic treatment: A systematic review. Orthod Craniofac Res. 2020;23(2):133-142. doi:10.1111/ocr.12353."

3.1 Introduction

With the increased demand for orthodontic treatment among adult patients, aligner mechanotherapy has become a significant aesthetic alternative in orthodontic practices.[1] One of the main limitations to aligner therapy is its apparent lack of efficiency while treating certain malocclusions. Various types of tooth movements including buccolingual inclination, interocclusal sagittal changes, closure of extraction spaces, occlusal contacts and expansion have been argued to be less efficient with aligners than with traditional fixed appliances.[2-4]

The efficiency of tooth movement is important to set up the final treatment goals, to calculate treatment times and costs based on the available evidence. There are five previous SR that discussed the effectiveness of aligners.[5-9] The first SR by Lagravere et al. published 14 years ago,[5] only included two studies with high risk of bias (RoB) so conclusions could not be made regarding the predictability of tooth movement with aligners. The second SR by Rossini et al.[6] evaluated eleven articles published prior to 2014 and suggested that aligners could be recommended for simple tooth movements. Most of the included studies (63%) had a high RoB. Another SR by Zheng et al.[7] published the same year included only four studies for qualitative analysis pointing towards insufficient evidence about the effectiveness of aligner therapy as compared to fixed appliance therapy. Two recently published SRs by Papadimitriou et al.[8] and by Ke et al.[9] included articles up to 2017. One[8] cautiously recommended aligners for non-extraction treatment with mild to moderate malocclusions in non-growing patients. The second SR[9] suggested that aligners have the advantage in treating segmented movement of teeth but are less effective in producing adequate occlusal contacts, controlling teeth torque, and increasing transverse width than fixed appliance therapy.

It is important to only evaluate recent evidence for products that are constantly evolving. There have been many new updates in aligner technology such as new materials (such as smart track®), precision cuts, precision bite ramps and tooth attachments that possibly have resulted in a more accuracy for tooth movement.[10] This could mean that some of the drawbacks previously identified with this therapy have been addressed, at least partially, in updated versions. Nevertheless, the most recently published SR[8,9] pooled all the available literature (2003 study with 2017 study) on aligners. Many of included studies in these SRs[8,9] were conducted before the introduction of the latest changes to the tray material, attachments, and treatment algorithms. Thus, it is reasonable to reevaluate the effectiveness of this treatment system by only considering studies using the latest advances in aligner materials. Accordingly, the objective of this review is to update the knowledge about aligner mechanotherapy by analyzing the 'new available evidence', published from 2014 on the predictability of orthodontic tooth movement with aligners. In addition, treatment outcome of aligners was compared to fixed appliance therapy.

3.2 Methods

This SR chapter followed the PRISMA checklist.

3.2.1 Identification of relevant studies

Articles were included if they evaluated the predictability of types of tooth movement with aligners, or if aligner treatment outcome was compared to fixed appliance therapy. We limited our search to articles published between the years of 2014-2024. No restrictions regarding language were considered. Case reports, in vitro studies, author's letters, non-human studies, reviews, summary articles, studies that used complementary treatment modalities in combination with clear aligners (e.g., temporary anchorage devices, fixed class II/III correctors, etc.), studies with surgical interventions, and studies that focus on aspects of aligner therapy other than tooth movement, were excluded. In addition, the objective of this SR was to include articles that used recent aligner technology. Therefore, we retrieved the information on patient recruitment as well as on materials used from the included papers. We excluded articles that recruited patients before 2014 'OR' have not used the latest material iterations. Articles that have missing information on recruitment date of patients were also excluded.

3.2.2 Information sources and search

Comprehensive searches were made from January 2014 to April 2024 using the following databases: MEDLINE, Embase, and Web of Science (Table 3.1).

Table 3.1 Search strategy used for SR

(Ovid MEDLINE(R) 2014-current	1) Invisalign.mp	275
	2) (aligner* adj2 (clear or plastic or therapy or removable))	506
	3) 1 OR 2	649
Embase limit: published 2014- current	1) Invisalign.mp	355
	2) (aligner* adj2 (clear or plastic or therapy or removable))	670
	3) 1 OR 2	837
Web of Science (Core collection) Indexes: SCI-EXPANDED, CPCI- S, CPCI-SSH, ESCI. Refined by: Publication Years: (2014 to 2024)	[TOPIC: (Invisalign) OR (aligner* NEAR/2 (clear or plastic or therapy))]	890
Total		2376

3.2.3 Study selection and data collection

Three reviewers independently assessed the articles for selection, and data were collected for SR. In cases of disagreement, discussions occurred among the three reviewers and further with other authors until agreements were made. This chapter was updated by Harsimrat Kaur by including the recently published literature from year 2019 to 2024 on (1) predictability of aligners; (2) comparison of treatment outcome of aligner mechanotherapy with conventional fixed appliance therapy.

3.2.4 Data items

Data collected from each article included: author, year of publication, sample size, intervention, comparison, and main findings (Tables 3.2 and 3.3). All observational studies included had retrospective study design except two studies[11, 12] that had prospective study design.

Table 3.2 Observational studies included for predictability of tooth movement

Author/ year	**Sample size**	**Age means (year)**	**Tooth prediction evaluation**	**Results**						
Grunheid, 2017	30 (28 teeth/ patient)	21.6± 9.8	M-D, B-L, O-G tip, torque, rotation	**Teeth**	**M-D mm**	**B-L mm**	**OG mm**	**Tip°**	**torque°**	**rotation°**
				Max						
				CI	-0.06	-0.45*	-0.30	0.42	1.75*	-0.33
				LI	-0.14	0.01	-0.03	0.35	0.08	0.7
				Ca	-0.11	0.11	-0.02	0.31	-0.48	0.19
				1 PM	0.02	0.15	0.06	-0.18	-0.74	-0.48
				2 PM	0.19*	0.20*	0.01	-0.82	-1.2*	-0.7
				1 Mo	0.27*	0.23*	-0.02	-1.11*	-1.5*	-0.5
				2 Mo	0.07	0.30*	-0.13*	0.41	-2.1*	0.06
				Mand						
				CI	0.12	0.11	-0.14*	-0.36	-0.66	-0.6
				LI	-0.08	0.01	-0.10*	0.51	-0.29	-0.99*
				Ca	-0.11	0.26*	-0.01	0.39	-1.6*	0.88*
				1PM	-0.02	0.05	0.09	0.16	-0.6	-1.7*
				2PM	0.13	0.09	0.04	-0.55	-0.74	-0.88*
				1 Mo	0.12	-0.08	-0.01	-0.38	-.85*	-0.30
				2 Mo	-0.02	-0.17	0.04	1.07*	-1.1*	0.29
Lombardo, 2017	16 (345 teeth)	28 ± 7	Tipping and rotation	**Teeth**	**M-D (achieved %)**	**B-L (%)**	**Rotations (%)**			
				Max						
				CI	76.6	64.5	61.5			
				Ca	78.3	54.0	62.3			
				PM	70.6	69.6	54.0			
				Mo	93.4	52.5	78			
				Mand						

				CI	87.7	86.1	67	
				Ca	86.7	66.4	54.2	
				PM	96.7	90.4	82.7	
				Mo	61.8	86.2	85.4	
Tepedino, 2018	39 (63 arch)	30.7 ± 9.3	Torque	**Achieved torque (no significant different from predicted)**				
				Max		Mand		
				Teeth				
				Ca	100%	100%		
				LI	94.4%	100%		
				CI	88.7%	98.6%		
Charalampakis, 2018	20 (398 teeth)	37.5	Horizontal and Vertical displacements, Inter Ca and inter PM widths and rotations.	**Teeth**	**Horizontal (achieved)**	**Intrusion**	**Extrusion**	**rotations**
				Max CI	79%	Extruded by 37%	36% more than predicted	57%
				Max LI	77%	Extruded by 31%	27% more than predicted	66%
				Max Ca	76%			57%
				Max PM				74%
				Mand CI & LI	98%	26%	87%	76%
				Mand canine	85%	51%		71%
				Mand PM				65%
				Max inter Ca width 77% (achieved) Mand inter Ca width 97%		Max inter PM width 78% Mand inter PM 95%		
Fan-Fan Dai,2019	30	19.4± 6.3	Max Mo tipping, translation and CI tipping and translation	**Teeth**		**Mean difference**		
				Max Mo angulation		5.86±3.51*		
				Max Mo translation in mesiodistal		2.26±1.58*		
				Max Mo translation in (mesial cusp) O-G direction		0.61±0.89*		
				Max Mo translation in (distal cusp) O-G direction		0.01±0.91		

				CI torque	-5.16 ±5.92*
				CI in B-L translation	2.12±1.51*
				CI in O-G translation	-0.50±1.17*
Haouili, 2020	38	36	M-D and B-L crown tip, extrusion, intrusion, M-D rotation	**Tooth movement**	**Accuracy**
				Rotation	46%
				Buccolingual crown tip	56%
				Mesial rotation mand first Mo	28%
				Intrusion max CI	33%
				Intrusion mand CI	35%
				Distal rotation of max Ca	37%
				Extrusion max CI	56%
				Buccal crown tip of max second PM	61%
				Labial crown tip max LI	70%
Al-balaa, 2020	22	23.74	Max and mand anterior teeth intrusion	**Teeth**	**Mean difference**
				Max Ca	-0.91*
				Max LI	-0.87*
				Max CI	-1.24*
				Mand Ca	-0.79*
				Mand incisors	-1.02*
Dai,2021	17	25.4 ±5.0	Max and mand Mo, Ca and CI angulation, inclination, and rotation	**Tooth movement**	**Mean difference**
				Max Mo angulation 4.98±2.86*	Mand Mo angulation. 1.12 ±2.34*
				Max Mo Inclination 3.27±3.35*	Mand Mo Inclination 1.47 ±3.27*
				Max Mo rotation 0.19±1.74	Mand Mo rotation 1.60 ±2.19*
				Max Ca angulation 6.00±4.44*	Mand Ca angulation 7.44 ±3.83*
				Max Ca inclination 1.08±4.58	Mand Ca inclinatio 3.28 ± 3.91*
				Max Ca rotation 0.17±4.06	Mand Ca rotation 0.23 ± 3.24
				Max CI angulation 1.89 ± 3.01*	Mand CI angulation 1.69±1.98*

				Max CI inclination 8.89±5.16*	Mand CI inclination 9.56 ± 4.04*
				Max CI rotation 0.29± 2.92	Mand CI rotation 0.75 ± 2.76
Blundell, 2021	42	>18	overbite	Pretreatment overbite	3.9±1.4
				Post treatment overbite	3.3±1.3
				Predicted (ClinCheck) overbite	1.9±0.7
Maree, 2022	30	>18	Rotation and uprighting of max CI	Difference in rotation correction	10.5±10.66*
				Difference in uprighting	2.16±3.86*
Blundell, 2023	76	>18	overbite	Pretreatment overbite	-1.48±1.09
				Post treatment overbite	0.60±1.21
				Clinically achieved as compared to ClinCheck.	66.7%
Gallucci o, 2023	28	17 ± 3.2	Maxillary arch expansion	Inter Ca width	81.99%
				Inter Ca gingival width	43.90%
				First inter PM width	93.53%
				Second inter PM width	79.43%
				First inter Mo cusp width	70.55%
				First inter Mo gingival width	55.85%
Shahabu ddin, 2023	24	32.8 ±11.9	Overbite	33.35 % of overbite correction achieved of planned correction	
Meade, 2024	355	30.14	Overjet, overbite	Planned increase in overjet 55.55%	
				Planned decrease in overjet 44.44%	
				Planned increase in overbite 108.69%	
				Planned decrease in overbite. 34.78%	
Abbreviations: Ca, canine; CI, central incisor; B-L, buccolingual; LI, lateral incisor; M-D, mesiodistal; O-G, occlusogingival; PM, premolar; Mo, molar; Max, maxillary arch; Mand, mandibular arch; SD, standard deviation *Statistically significant difference					

3.2.5 Risk of bias (RoB) in individual studies

Evaluation of the quality of the included articles was completed using RoB In Non-randomized Studies—of Interventions (ROBINS-I)[13] for observational studies and Cochrane Risk of Bias Tool for RCT (Tables 3.4 and 3.5).[14]

Table 3.3 Studies that compared outcome of aligners with fixed appliance therapy

Author/ year	**Study type**	**Sampl e size**	**Age(yea r)**	**Tooth prediction evaluation**	**Results**		
Henessy, 2016	RCT	22:SL 22:CA	26.4 ±7.7	Lateral cephalogram	Mandibular incisor proclination by CA (3.4 ± 3.2°) and FA (5.3 ± 4.3°; (p > .05)		
Jaber, 2022	RCT	20:CA 20: FA	18-25 years	ABO-OGS	Mean scores by CA 32.25 ± 4.33 and FA 33 ± 7.92; (p > .05)		
Author/ year	**Study type**	**Sampl e size**	**Age mean (year)**	**Tooth prediction evaluation**	**Variable**	**Appliance**	**Mean (°)**±SD
Sfondrini, 2018	Retro specti ve	25:FA 25:CA 25:SL	25.5±6.5	CI/PP;CI/OP;CI-TVL by lateral cephalogram	CI/PP	Conventional	6.11±3.91
						Self-ligating	5.64±3.27
						Aligner	5.13±3.23
					CI/OP	Conventional	6.88±4.28
						Self-ligating	5.17±3.10
						Aligner	4.60±3.46
					CI-TVL	Conventional	1.56±0.47
						Self-ligating	1.62±0.66
						Aligner	1.47±0.57

Abbreviations: ABO-OGS, American Board of Orthodontics Objective Grading System; CA, aligner; CI, central incisor; FA, fixed appliance; LI, lateral incisor; OP, occlusal plane; PP, palatal plane; RCT, randomized controlled trial; SL, self-ligating; SD, Standard deviation; TVL,true vertical line

3.2.6 Level of evidence

The grading of recommendation, assessment, development, and evaluation (GRADE) instrument was used to assess quality of evidence for each outcome.[15] Included studies were evaluated according to their design, study quality, consistency and directness using gradepro.org.

Table 3.4 RoB of observational studies

Author	Domains							Overall RoB Judgment
	Preintervention		intervention	Postintervention				
	A	B	C	D	E	F	G	
Charalampakis et al	Low	Serious	Low	Low	Low	Moderate	Low	Serious
Lombardo et al	Low	Moderate	Low	Low	Low	Low	Low	Moderate
Grunheid et al	Low	Moderate	Low	Low	Low	Low	Low	Moderate
Tepedino et al	Low	Moderate	Low	Low	Low	Moderate	Low	Moderate
Dai et al	Low	Moderate	Low	Low	Low	Low	Low	Moderate
Haouili et al	Low	Moderate	Low	Low	Low	Low	Low	Moderate
Al-balaa et al	Low	Moderate	Low	Low	Low	Moderate	Low	Moderate
Dai et al	Low	Moderate	Low	Low	Low	Low	Low	Moderate
Sfondrini et al	Moderate	Low	Low	Low	Low	Moderate	Low	Moderate
Blundell et al	Low	Moderate	Low	Low	Low	Low	Low	Moderate
Maree et al	Low	Moderate	Low	Low	Low	Moderate	Low	Moderate
Blundell et al	Low	Moderate	Low	Low	Low	Low	Low	Moderate
Galluccio et al.	Moderate	Moderate	Low	Low	Low	Moderate	Low	Moderate
Shahabuddin et al	Low	Moderate	Low	Low	Low	Moderate	Low	Moderate
Meade et al	Low	Low	Low	Low	Low	Low	Low	Low
Abbreviations: A, Confounding Bias; B, Selection bias; C, Bias in classifying intervention; D, Deviations from intended intervention; E, Bias due to missing Data; F, Bias in measuring outcomes; G, Selective reported result								

Table 3.5 Quality assessment of RCTS by Cochrane tool

Study	Selection bias		Performa-nce bias	Detection bias	Attrition bias	Selective outcome reporting
	Random sequence generation	Allocation concealment				
Hennessy et al	Yes (did not explain random sequence generation)	By opaque envelopes	Yes (no blinding possible)	Yes (no blinding possible)	No (90% completed study)	No
Jaber et al	Yes	By opaque envelopes	Yes (no blinding possible)	Blinding of outcome assessor	No (90% completed study)	No

3.2.7 Summary measures

Predictability of different types of tooth movement was reported as either percentage of achieved results or a numerical magnitude (in mm) using aligner therapy. The second summary was the outcome comparison between the aligners and fixed appliance therapy.

3.2.8 Synthesis of results

The results are provided in a narrative synthesis of the included studies that included study type, sample size, age of population, intervention group, comparison group and outcome.

3.3 Results

3.3.1 Study selection

The selection of articles included in this SR is shown in the PRISMA flow chart (Figure 3.1). We started the search from 2014 onwards as the latest technology developments were made in 2012 (For instance, the smart track material was introduced in October 2012) and came to the market in 2013. Most of the included studies had retrospective designs so we started the electronic search in 2014 as it is very unlikely that authors used 2013 material and published it in 2013. Our search strategy identified 2376 articles, out of which seventeen articles were finally selected for inclusion in this SR based on inclusion criteria.

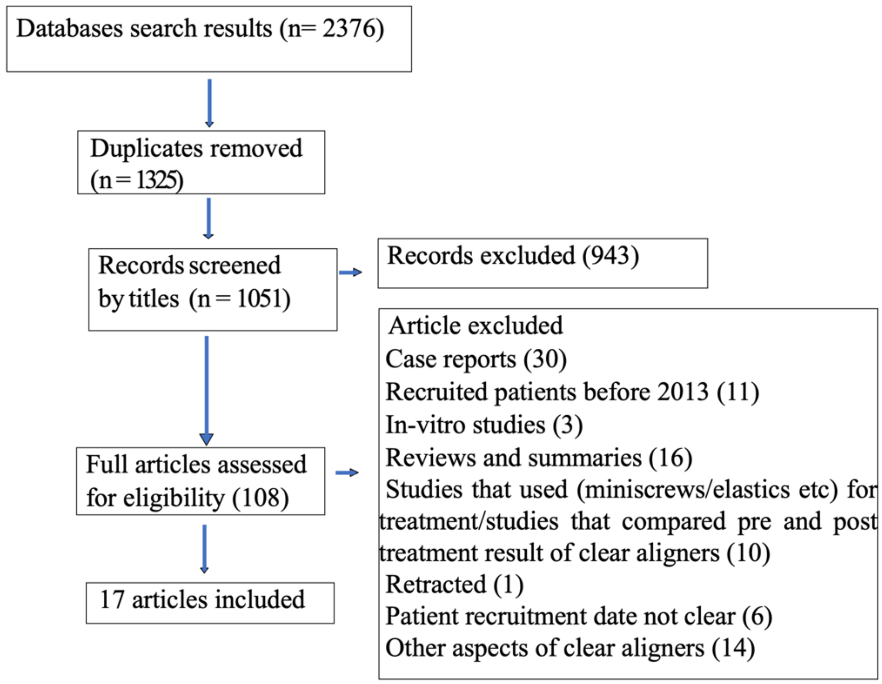

Figure 3.1 PRISMA flow chart outlining the search strategy of SR

3.3.2 Study characteristics

Of the seventeen included articles, two RCT,[16,17] two are prospective studies[11,12] and thirteen are retrospective cohort studies[18-30] All articles were written in English. Most of the included studies evaluated mild to moderate malocclusions except for four[4,10,17,19] that involved first premolar extraction cases. Most of the studies used the Invisalign® system except two studies that used Nuvola® system[20] and F22 aligners.[19]

Data collected from each of the included articles are described in Tables 3.2 and 3.3. Sample sizes ranged from 16 to 355 subjects. Most of the covered studies assessed predictability of tooth movement comparing post-treatment patient models to the predicted digital planned tooth movement models[(ClinCheck®)[18,21,22,28] (Vectra software®; Canfield Scientific,)[19,20]]. Two studies compared the aligner therapy outcome to the fixed appliance treatment outcome by using lateral cephalograms[14,20] and one RCT[17] used American Board of Orthodontics Objective Grading System for comparison.

3.3.3 RoB within studies

Among the included studies, one study[21] had a high RoB, one had low RoB,[30] and the remaining observational studies had a moderate RoB (Tables 3.4 and 3.5). For the observational studies, the most common sources of bias were related to the selection of participants (selection bias) and measurement of the outcome where the outcome assessors were not blinded (information bias). The one retrospective study[30] with low RoB selected patients randomly via a random sequence of integer generator. Further, observational studies were not likely affected by confounders as patient post treatment models were compared to 'their own' planned models. The Charalampakis study[21] was suggested to have high RoB as they selected patients that already had refinement goals which could lead to the overestimation of differences between predicted and achieved results. In addition, measurements were made with a ruler by an investigator who was not blinded to the study. On the contrary, other retrospective studies selected patients from complete records instead of all patients' records (who possibly were started but not finished with the aligner therapy). This, therefore, could overestimate the precision of achieved results.

The difficulty in identifying the stable structure when comparing the planned and achieved tooth movements could pose another source of information bias among the included studies. Palatine folds are frequently used but only apply to the upper arches. Thus, superimposition on the stable teeth was opted by various authors.[19,21] Lombardo et al[19] and Grünheid et al[18] tried to minimize this error (no statistically significant error was observed) by using the occlusal plane and best fit algorithms, respectively. Two studies[16,23] used lateral cephalograms that have been suggested to have limited precision in locating the incisor apex for the outcome assessment. However, inter-, and intra-operator errors were not significant in both the studies. Regarding the RCTs included in this SR, the Hennessy study did not describe randomization and blinding in their study.[16]

3.3.4 Level of evidence

There was 'moderate level of evidence' for predictability of tooth movement in vertical dimensions that were based on nine observational studies having moderate RoB,[11,18,19,25,26,28,29] low RoB[30] and one study has high RoB[21] as there was some uncertainty about outcome measure as measurements were made with ruler by investigator who was not blinded to the study. Also, superimpositions were done on the posterior teeth that were considered relatively stable; however, there was minimal movement of molars (0.81 mm) seen in the study. This SR presented a 'moderate level of evidence' for mesiodistal tooth movement that relied on seven observational studies[11,18,19,21,22,24,27] with moderate RoB. We also have a 'moderate level of evidence' for predictability of aligners for rotation correction, which was based on six moderate RoB observational studies[11,18,19,21,24,27] and consistent results. Three studies[11,18,19] included in this SR present low level of evidence for buccolingual tooth movement. Predictability in transverse dimension was studied by two studies- one high[21] and moderate RoB[12] observational study.

3.3.5 Results of included articles

3.3.5.1 Predictability of tooth movements with aligners

A retrospective study was conducted by Charalampakis et al[21] to determine the accuracy of specific tooth movements (n = 20; 398 teeth) in the vertical, horizontal, transverse directions and rotational movement with Invisalign® (Table 3.2). Patients for this study started treatment after 2014 when Invisalign® introduced the smart track material. Predicted and achieved models were superimposed over the initial model on posterior teeth using the software. The supervising orthodontist decided which attachments to use for each patient. Extrusion and horizontal movements of all incisors were near accurate with insignificant differences (0.20-0.25 mm) between predicted and achieved amounts. Intrusions were found to be less accurate by a median difference of 1.5 mm ($P < .001$). All achieved rotations were significantly less than those predicted, with the maxillary canines exhibiting the greatest difference of 3.05° ($P < .001$) while maxillary premolar exhibiting the lowest discrepancy of 0.9°.

Grünheid et al[18] assessed the accuracy of Invisalign® in achieving predicted tooth positions (n = 30). Records of patients treated between the years 2013 and 2016 were used for this retrospective study. Post-treatment plaster models were digitized and compared to predicted ClinCheck® model using a best fit algorithm. The software quantified the differences between achieved and predicted position for each tooth in the mesiodistal, buccolingual, occlusogingival, tip, buccolingual inclination and rotation. Statistically significant differences ($P < .05$) between predicted and achieved tooth positions were found for all teeth except maxillary lateral incisors, canines and first premolars. Anterior teeth were positioned more occlusally than predicted, rotation of rounded teeth was incomplete, and movement of posterior teeth in all dimensions was not fully achieved.

A retrospective study (n = 39) by Tepedino et al[20] evaluated the predictability of Nuvola® aligner in achieving to buccolingual inclination (torque) movements of anterior teeth presenting mild to moderate crowding. The records of patients from September 2013 to September 2017 for orthodontic treatment with aligners were screened for this study. Retention attachments were placed on buccal surfaces of first and second premolars. The digital models of upper and lower arches at T0 (pre-treatment), T1 (post-treatment) and ideal post-treatment according to setup (TS) were acquired as .STL files. The gingival points of the right and left molars in the posterior and the point on the incisal papilla between the central incisors in the anterior were used to define a reference plane. The results revealed that in the maxillary arch, central incisor achieved 88.7%, lateral incisor 94.4% and canine almost 100% of 12.7° torque predicted. In the mandibular arch, central incisor 98.6%, lateral incisor and canine achieved 100% of 20.8° torque predicted.

Lombardo et al[19] through a retrospective study (n = 16, teeth = 345) evaluated the predictability of F22 aligners for mesiodistal tipping, buccolingual tipping and rotations. Patients received aligner treatment between November 2014 and January 2017. VAM software® (Vectra, Canfield Scientific) was used to analyse and compare the pre-treatment, planned post-treatment, and achieved post-treatment models. Treatment staging (maximum movement planned was 2° rotation, 2.5° buccolingual and mesiodistal tip, and 0.2 mm linear displacement, for each aligner) and F22 Grip points were used in this study. Apart from the mesiodistal tip on the canines, premolars, molars and rotation of the molars, all the other tooth movements displayed a predictability significantly lower than 100% in the maxillary arch. On the contrary, in the mandibular arch, most of the achieved tooth movements were not statistically different from planned except for mesiodistal tipping and rotation of the canines and incisors. Among the three movements, mesiodistal tipping was most predictable (82.5%), followed by buccolingual tipping (72.9%) and rotations (66.8%). Specifically, mesiodistal movement for upper molars and lower premolars were efficacious and rotations for lower canine were least predictable.

A retrospective study (n = 30) was conducted by Dai et al[22] to compare the achieved and predicted tooth movement of maxillary molar (anchorage control) and central incisor (retraction) for first premolar extraction treatment with Invisalign®. Patients who underwent treatment between January 2014 and December 2016 were recruited for this study. This study used G6 optimized, 3mm vertical, 3mm horizontal and 5mm horizontal attachments. The achieved post-treatment model was registered with the pre-treatment model and superimposed with the planned posttreatment model using a palatal vault stable landmark with the help of Rapidform software®. There were statistically significant differences between predicted and achieved tooth movements. First molars tipped and translated mesially more than predicted by 5.86 and 2.26°, respectively. Occlusogingivally, the mesial cusp of the molar was intruded more than predicted by 0.61mm while the distal cusp was stable. Central incisor was tipped more by 5.16°, translated less by 2.12mm and extruded more by 0.50 mm as compared to the predicted. Same authors using the similar study design conducted another retrospective study[24] (n=17) where predictability of inclination, angulation and rotation of maxillary central incisor, canine and maxillary molar was assessed in first premolar extraction patients treated between August 2015 to August 2017. Maxillary molar tipped mesially (1.88°), and labially (1.49 mm) instead of planned tipping distally (-3.10°) and lingually (-1.78 mm). The similar trend was seen (but to lesser extend) for mandible molars.Canines were tipped distally in both maxilla (-7.11°in comparison to predicted -1.11°) and mandible (-9.76° as compared to predicted -2.32°); central incisors were distally tipped along with lingual inclination in maxilla and mandible but had less retraction in maxilla.

A prospective clinical trial (n=38) by Haouili et al[11] examined the predictability of all teeth treated with Invisalign. The predicted values were determined from superimposing initial and final ClinCheck models while the achieved values were attained by the difference between post treatment models and final ClinCheck models. Each tooth was superimposed by using best fit registration and compared using software®(GeoDigm, Falcon Heights, Minn). The evaluated tooth movements were mesiodistal and buccolingual crown tip, extrusion, intrusion and mesiodistal rotation. The mean accuracy was 50% with labial crown tip being most accurate movement of lateral incisor (70%) and rotation of first mandibular molar as least accurate (28%) followed by intrusion of maxillary central incisors (33%).

A retrospective study (n=22) was done by Al-balaa et al.[25] to compare the actual treatment outcome with predicted with Invisalign® for maxillary and mandibular anterior teeth intrusion using cone bean computed tomography by NewTom VGI®(Quantitative Radiology, Verona, Italy).142 teeth of 22 patients who started treatment after 2016 were assessed. The mean precision for intrusion was 51.9% with significant difference (P <0.0001) between the predicted and actual measurements of maxillary and mandibular anterior teeth.

Blundell et al.[26] assessed the accuracy of predicted outcome for deep bite with Invisalign®. This retrospective study (n=42) included patients treated between January 2014 to July 2018 with deep bite (mean initial overbite of 3.9 mm). The pretreatment, post treatment and predicted stereolithography files were taken from ClinCheck and evaluate using Geomagic Control X software® (3DSystems, Rock Hill, SC). The digital models were aligned to a horizontal reference plane (the middle of the superior margin of the incisive papilla and the interproximal papilla between the maxillary first and second molars) and the incisal edges of the maxillary and mandibular anterior teeth were identified. The vertical linear distance between incisal edge of the mandibular left central and lateral incisors and the midpoint of the incisal edge of the maxillary left central incisor was used to evaluate overbite. Overall, the results suggested overbite reduction of 39.2% where predicted overbite and post treatment overbite were 1.9 mm and 3.3 mm, respectively.

The predictability of rotation correction and uprighting of maxillary central incisors with mesiopalatal rotations was assessed by Maree et al[27] using Invisalign. The standard Invisalign treatment was followed where maximum of 2° rotation and 1° mesiodistal tip was programmed per aligner. The predicted and achieved stereolithography files were superimposed using Geomagic Control X 64® software (3D Systems, Rock Hill, SC). This retrospective study (n=30) showed shortfall of 10.5°for a mean predicted 35.27° rotation ($P< 0.001$) and shortfall of tip by 2.16° for predicted tip of 7.06° ($P< 0.001$).

Blundell et al.[28] evaluated the predictability of Invisalign® for open bite treatment by comparing the predicted outcome on ClinCheck with post treatment results. This retrospective study sourced

data from Australasian Aligner Research Database (n= 76) from patients who had treatment with Invisalign smart track aligner material since January 2014. The included patients had mean pretreatment overbite of -1.48 mm (90.8% of patients had overbite of less than 0 mm) and mean overjet of 4-6 mm. The pretreatment, post treatment, and predicted outcome regarding overjet and overbite was measured by Geomagic Control X software® in the stereolithography files for each patient. The predicted outcome was to achieve positive overbite of 0-2 mm and overjet of 2-4mm. The achieved mean overbite was 0.60 mm and mean overjet was 3.55mm. Only 66.2% of patients achieved positive overbite with only 7.9% achieving ideal overbite range.

A prospective study (n=28) by Galluccio et al.[12] that evaluated the efficacy of Invisalign system showed an average accuracy of 70.88% for expansion. The selected patients required 2-4 mm of dentoalveolar expansion. The pretreatment and post treatment arches were scanned by using intraoral Itero Flex® scanner. All linear measurements were performed by single operator for intercanine cusp width, intercanine gingival width, first and second inter premolar width, first molar width at mesiobuccal cusp and first molar gingival width for maxillary arch. Accuracy was calculated by difference between planned expansion on clincheck and post treatment expansion. The difference between predicted and achieved was not statistically significant for intercanine width, intermolar width measured at cusp tip while there was statistically significant difference for intercanine gingival width and intermolar gingival width.

Shahabuddin et al.[29] conducted a retrospective study (n=24) to investigate the predictability of deep bite correction (with initial overbite 5.20) treated between September 2016 to August 2021 using Invisalign®. The overbite was measured as per the American Board of Orthodontics grading system where vertical distance was maximum between two antagonistic teeth. The models (predicted and achieved) were superimposed using best fit surface-based registration focused on the occlusal surfaces of the first and second molars using Slicer CMF®. Overbite was measured at the incisal edge of the maxillary incisor overlapping the antagonist mandibular anterior teeth. This study demonstrated large discrepancy between the predicted (3.35 mm) and achieved (1.15mm) overbite correction with merely 33% of accuracy after the first set of aligners with no refinement.

A retrospective study (n=355) was done by Meade et al.[30] to determine achieved outcome regarding overjet and overbite matched with predicted outcome by using Invisalign®. The patients have completed treatment with Invisalign after 2018 and approximately one-third (n=101) of them have undergone extraction as part of treatment. Patients were selected from the Australasian Aligner Research Database that have information regarding approximately 14,000 patients undergone treatment with Invisalign®. Patients were selected via a random sequence of integer generator. The initial, predicted and achieved overjet and overbite measurements were obtained via ClinCheck Pro facility. The achieved overjet and overbite were 44-56% and 8.69% planned overjet and overbite changes, respectively, with statistically significant from predicted measurements ($P < 0.001$).

Studies on predictability of aligners had methodological heterogeneity as they assessed predictability of different types of tooth movement like rotation, extrusion, intrusion, bodily movement, intercanine and interpremolar width, etc. for different teeth like canines, incisors, premolars, and molars by using different materials like Invisalign®, F22 aligner® and Nuvola system®. Different material properties and aligner production processes affect the force levels and thus, the predictability of tooth movements. In addition, studies assessed outcomes differently like providing mean differences or percentage differences. Considering the heterogeneity of variables assessed and expression of outcome, we could not justify pooling the estimates through a meta-analysis.

3.3.5.2 Comparison of treatment outcome of aligners with fixed appliance therapy

Hennessy et al[16] conducted an RCT (n = 44) to compare mandibular incisor proclination produced by fixed labial appliances and third generation aligners by comparing pretreatment and near end treatment lateral cephalograms (Table 3.3). Patients were recruited between October and November 2013. The fixed appliances and aligners with optimized attachments produced 5.3 ± 4.3° and 3.4 ± 3.2°, respectively, of mandibular incisor proclination with no statistically significant ($P > .05$) differences between the groups.

A RCT (n=40) was conducted by Jaber et al[17] to compare the post treatment results between aligner and fixed labial appliance using American Board of Orthodontics Objective Grading Scores in first premolar extraction cases (Table 3.3). Patients were recruited between October 2018 to February 2019. When comparing the post treatment scores, there was no statistically significant difference between groups except for occlusal contacts that scored better for fixed labial appliance.

Sfondrini et al[23] conducted a retrospective study (n = 75) to compare buccolingual inclination (torque) of upper central incisors achieved with power ridges of aligner technology to 0.019 × 0.025inch stainless steel wire with conventional and self-ligating brackets. Patients treated with aligners were enrolled between June 2013 and June 2015. The angle formed by the upper incisor axis with palatal plane and with occlusal plane was measured on lateral cephalograms before and after treatment. In addition, linear distance of the prominent point of upper incisor from true vertical line was also measured. No statistically significant differences were seen among the three mechanotherapies ($P > .05$).

Studies on comparisons between fixed appliance therapy and aligner therapy assessed various teeth like buccolingual inclination of upper central incisors and incisors proclination of lower incisors. This hampered the potential to pool the estimates.

3.4 Discussion

3.4.1 Predictability of tooth movements with aligners

Even after various modifications of aligner therapy, there still appear to be limitations with aligners regarding most tooth movement predictability. Further, predictability of tooth movement varies with tooth, type of tooth movement and arch.

3.4.1.1 Vertical movements

Nine[11,18,21,22,25,26,28-30] assessed the predictability of occlusogingival movement out of which four studies[26,28-30] focused on evaluation of predictability of overbite correction. A low RoB[30] showed the achieved overbite was limited to 8.69% of predicted changes. This study has approximately one-third of included patients with extractions that would have further deepened the bite with retraction of anterior teeth. Other moderate RoB studies have suggested achieved overbite correction by 33.35%[29] and 66.7%[28], respectively of predicted correction.

Extrusion of maxillary anterior teeth seems to have better predictable than intrusion tooth movement.[11,21] Extrusion of maxillary incisor was 56% as compared to 33% of intrusion of maxillary incisor.[11] Maxillary central and lateral incisors underwent extrusion where intrusion was planned.[21] Lower incisors achieved 26% and canine 51% of predicted intrusion. Another two studies with moderate RoB,[18,22] also support this finding that anterior teeth were more occlusally placed than predicted and mesiobuccal cusp of maxillary molar was significantly intruded where no intrusion was planned.[22] The predictability in vertical plane remains low despite improvement in material and treatment iterations such as addition of bite ramps, optimized attachments by Invisalign and pressure areas on lingual surfaces.

3.4.1.2 Horizontal movements

A moderate RoB study[19] suggested the overall mean accuracy of mesiodistal tipping of 82.5% where lower premolars were most precise 96.7% followed by upper molar (93.4%) and lower incisors (87.7%). This agrees with high RoB study[21] that suggested 85% (canine) to 98% (incisors) of predictability in the mandibular arch and maxillary arch achieved 76% (canine) to 79% (incisors) of desired results. Another moderate RoB study[18] found statistically significant differences between predicted and achieved tooth movement in the horizontal direction for second premolars, and first molars of maxillary arch while no significant differences in the mandibular arch. Maxillary molar tipped and translated mesially (anchorage loss) where it was planned to tip distally with the help of attachments.[22] Overall, moderate levels of evidence propose that mesiodistal tipping is quite predictable in the lower arch specifically for lower premolars and incisors.

Buccolingual tipping was less accurate at 72.9% as compared to mesiodistal tipping with F22 aligners®. In the lower arch, efficiency of buccolingual tipping ranged from 90.4% (premolars) to 66.4% (canines) whereas in the upper arch, movements were less precise ranging from 69.6% (premolars) to 52.5% (molars).[19] A second moderate RoB study[18] that used Invisalign® suggested statistically significant differences between predicted and achieved buccolingual directions for upper central incisor (0.45 mm), upper second premolar (0.20 mm), upper first molar (0.23 mm), upper second molar (0.30 mm) and lower canine (0.26 mm). A study[18] showed limited torque control for central incisors, second premolars, and first and second upper molars. Torque control was also limited for lower canines and first and second lower molars. An additional moderate RoB study showed statistically significant torque loss for central incisors using the Invisalign system®.[22] Only one study[20] with moderate RoB showed good torque control with aligners for anterior teeth. This study used Nuvola® aligners and thus, cannot be compared with other aligner (Invisalign, F22)® outcomes.

Overall, rotations were found to be less predictable ranging from 28% to 76%[11,19,21] with aligners. Rotations of canines and premolars were even more difficult (lower canine 54.2% and upper premolar 54%) to achieve.[19] There were statistically significant differences between the predicted and achieved rotations for lower lateral incisors, canines, and first and second premolars.[18] One proposed suggestion is to make the bulk of these movements with auxiliary attachments like buttons and elastic chains before starting the aligner treatment.

3.4.1.3 Transverse movements

Only two recent studies (one high[21] and another moderate[12] RoB studies) assessed the predictability of transverse dimension. One observational study showed that mandibular arch width (95%-97%) is more predictable than the maxillary arch (77%-78%).[21] Other study[12] showed that no statistically significant between predicted and achieved intercanine and intermolar width measured at cusp tip while there was statistically significant difference for intercanine gingival width and intermolar gingival width. These results point at more buccal tipping of canine and molar achieved than their bodily movement with aligner mechanotherapy.

3.4.2 Comparison of treatment outcome of aligners with fixed appliance therapy

This SR suggests through the RCTs[16,17] that aligners may produce clinically acceptable results compared to fixed appliance therapy. The results were comparable for buccolingual inclination of lower incisors,[16,17] alignment,[17] marginal ridges,[17] occlusal relations,[17] overjet,[17] interproximal contacts,[17] and root angulations[17] except for the occlusal contacts.[17] Both groups required similar mean amounts of interproximal stripping (Invisalign group®, 1.9 mm; fixed group, 1.5 mm). Also, there was no significant increase in intercanine width in either group.[16]

A moderate RoB study showed similar torque control of upper central incisor with aligner and fixed appliance mechanotherapy.[23] Nevertheless, this study used 0.019 × 0.025 inch wire in 0.022 × 0.025 inch slot that itself has torque loss of 10°.

3.4.3 Limitations

There are various limitations of this review that must be taken into consideration when interpreting the results of this SR. First, even though a vast array of literature was used for the search strategy, we may have inadvertently missed a few articles. Secondly, most of the included articles were retrospective studies that have inherent limitations of selection bias, information bias and confounders that could affect the internal validity of the studies. The most common sources of bias were related to the selection of participants and measurement of the outcomes where the outcome assessors were not blinded. Sample size justification was not provided by four of included studies.[19,21-23] Thirdly, overall level of certainty/evidence ranged from low to moderate and translation of evidence into practice in a specific setting should further take into consideration factors like amount of activation present in each aligner,[21] aligner change frequency, severity of pretreatment malocclusion, expertise of the practitioner and the attachment's shape and position that could influence the success of treatment outcomes with aligner therapy. Fourthly, some of the included studies used multiple teeth for the same patient and one tooth movement was not independent from the second tooth movement, and this could have led to confounding movement expression. Lastly, as other aspects of aligners like retention of results, root resorption, treatment time and cost have not been reflected by studies included in this SR and were beyond scope of this SR, thus clear recommendations in this regard cannot be made.

3.5 Conclusions

- Current evidence with low to moderate level of certainty exists regarding efficiency of aligner therapy for certain tooth movements. The whole array of possible malocclusion types to be efficiently treated with aligners has not been covered by the included studies.
- Most of the tooth movements may not be predictable enough with aligner therapy except for minor horizontal teeth movement and dental expansion (moderate level of evidence).
- Aligners may produce clinically acceptable outcomes comparable to fixed appliance therapy for minor buccolingual inclination of upper and lower incisors. Treatment time required to achieve similar results (compared to fixed appliances) has not been investigated yet.
- Additional refinements are likely needed in almost every case to overcome current aligner therapy’s limited predictability.

3.6 References

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Chapter 4: Evaluation of aligner biomechanics for different anatomical teeth of maxillary arch

This chapter discussed the aligner biomechanics with various anatomical teeth. Three teeth such as central incisor, canine and second premolar were tested around the maxillary arch using clinically representative PET-G material. A version of this chapter has been published as "Kaur H, Truong J, Heo G, Mah JK, Major PW, Romanyk DL. An in vitro evaluation of orthodontic aligner biomechanics around the maxillary arch. Am J Orthod Dentofacial Orthop. 2021;160(3):401-409. doi:10.1016/j.ajodo.2021.04.005"

4.1 Introduction

Thermoplastic appliances have been used in dentistry as retainers, temporomandibular joint splints, bleaching trays, surgical splints, and aligners for orthodontic tooth movement.[1-4] Aligners are designed to move teeth to a desirable position through incremental movements with a series of aligners. When engaged, the slight offset of the aligner from the engaged teeth and the material resiliency imposes force system on teeth which results in their movement toward the desired position.[1] It is imperative to evaluate force system exerted by aligners as the magnitude and direction of the applied force system directly contribute to physiological and predictable tooth movement compared with detrimental effects such as tissue necrosis and unpredicted tooth movement.

A limited number of studies have investigated the force system produced by aligners. Barbagallo et al,[5] using an in vivo pressure film approach, evaluated that the initial force for buccal tipping of premolar was 5.12 N when the appliance was activated by 0.5 mm in 8 patients. An in vitro study[6] demonstrated that forces exerted by aligners for bodily tooth movement of the central incisor is dependent on the type of material (Hardcast® material applied significantly lower force than Duran® and Erkodur® [which were not significantly different from each other]), material thickness (thicker material [0.75 mm or 0.8 mm] produced significantly greater force than those fabricated from thinner material [0.4 mm or 0.5 mm]) and the amount of activation (1.0-mm activation produced significantly lower force than those with 0.5-mm activation). Several in vitro studies[7-9] have quantitatively investigated forces delivered to maxillary central incisor for derotation, tipping, torquing by 1.0 mm thick Ideal Clear®, Erkodur®, and Biolon® materials. The forces exerted by the Biolon® material was much greater than those of the other materials.

The available literature has assessed the effect of thermoplastic material choice, thickness, and amount of activation on single tooth models; however, the force systems imposed on different types of teeth (e.g., incisors, canines, premolars, and molars) has yet to be explored. Incisors, canines, premolars, and molars have different anatomy of the crown, both in terms of shape and length.[10] As a result, it could reasonably be suggested that different surface areas may be engaged by the aligner, and the contact mechanics between the aligner and the tooth may vary with different types of teeth. It is anticipated that the varying tooth/aligner engagement between teeth can alter aligner material deformation that could result in a difference in applied force system. There is a curvature in the arch form that could further influence the deformation of the engaged aligner and possibly affect the force system based on the location of the teeth in the arch. Beyond the proposed variations in mechanics based on tooth geometry and location, recent reviews have also pointed out the less predictable nature of tooth movement when using aligners.[11] Such factors point to a need to study the biomechanics of aligner therapy. Therefore, the objective of this in vitro research was to assess the forces and moments exerted on a central incisor, canine, and second premolar teeth around the arch using a clinically representative PET-G thermoplastic aligner material.

4.2 Material and methods

An in vitro OSIM was used to quantify the forces and moments generated around a simulated maxillary arch. A comprehensive description of the OSIM is provided in previous studies,[12] and chapter 2 of this thesis. Briefly, anatomic teeth were generated digitally using Linek's tooth carving manual.[13] The root portion of these anatomic teeth were reduced as cylindrical posts below cementoenamel junction to adapt and fix them on OSIM. Later, digital anatomic teeth were 3 dimensional (3D) printed using stainless steel. OSIM has horizontal and vertical micrometers that were used to move teeth in buccolingual (toward and away from the cheek) and occlusogingival (vertical) directions, respectively, to develop a symmetrical maxillary arch (Figure 4.1). The load cells (Nano17 by ATI industrial automation), capable of measuring forces and moments in 3D, were located at a distance from the teeth for OSIM. Load cell measurements were transformed to an approximated CoR of teeth by using a Faro arm (Faro, Lake Mary, Fla) coordinate measurement machine and subsequent Jacobian transformation matrices.

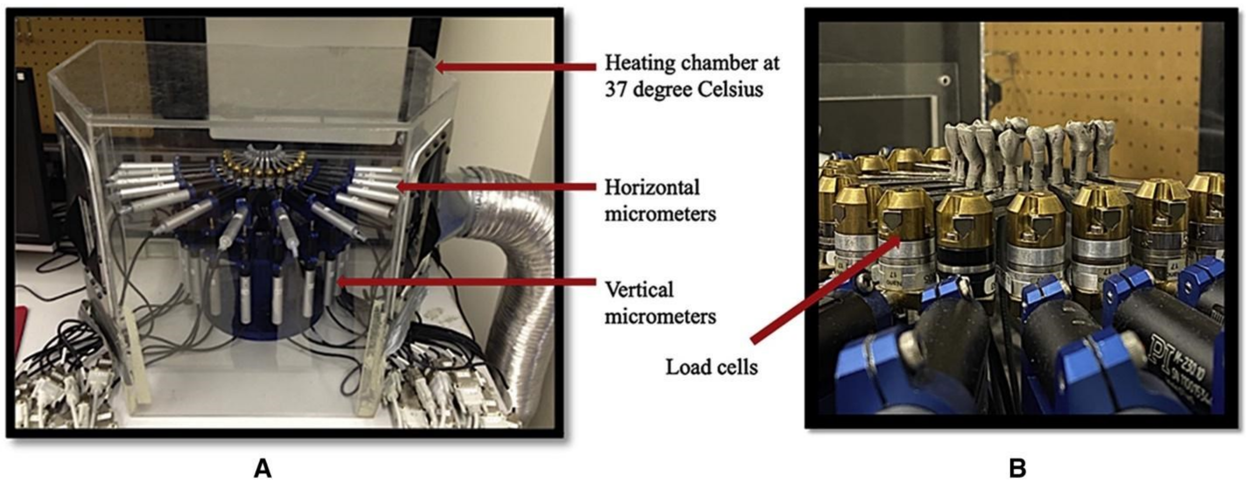

Figure 4.1 (a) OSIM overview; (b) anatomic teeth set on OSIM to simulate maxillary arch

A digital scan of the OSIM was obtained using a Lythos intraoral scanner® (Ormco, Orange, Calif) which was used to generate a plastic 3D print of the arch. The maxillary arch printed model had slight undercuts that were filled with wax and further replicated by using polysiloxane impression material to make the stone cast of high strength dental stone for aligner fabrication. Taglus material® is a US Food and Drug Administration approved PET-G material and was selected as a representative material for this chapter experiment. Sheets of 0.75 mm thickness material were randomly selected from the packet for each test. An aligner was formed through the thermoforming process with a Biostar machine® (Scheu Dental, Iserlohn, Germany) using the manufacturer specified process. As suggested by the manufacturer, a code 113 was used on the Biostar machine, which automatically set the pressure of more than 5 bar and heating time of 25 seconds (Figure 4.2).

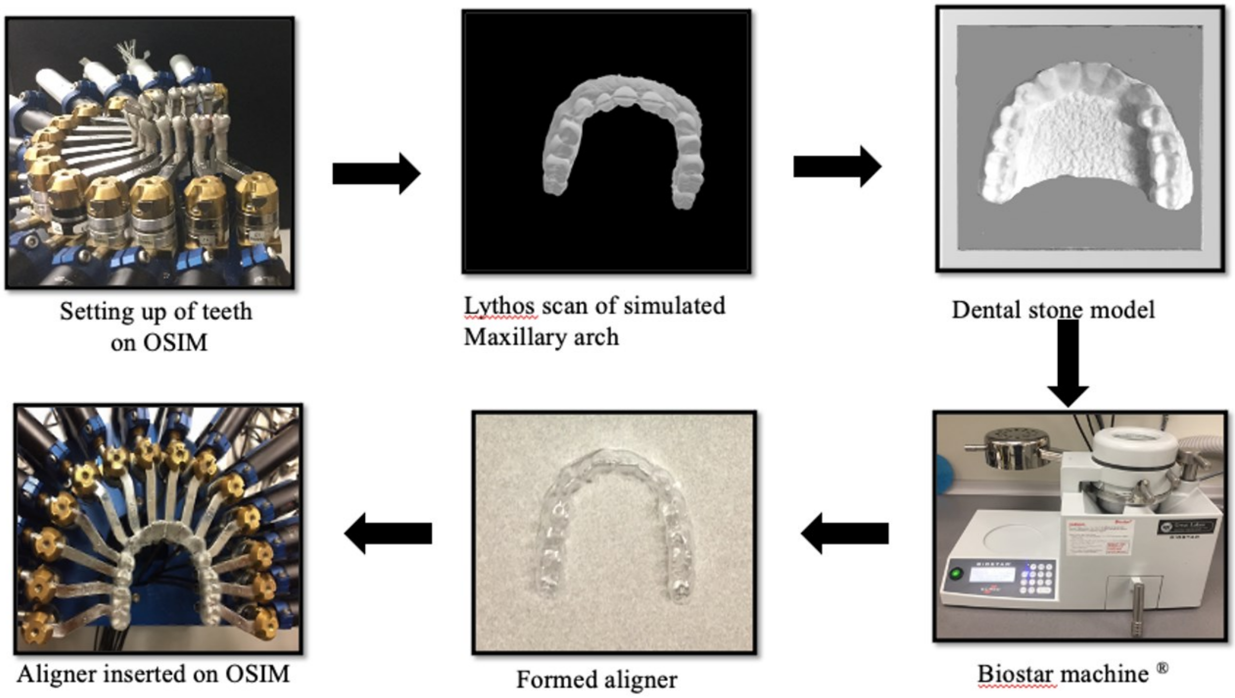

Figure 4.2 Fabrication route used for aligners: (a) setting up of teeth on OSIM;(b) Lytho scan of the OSIM arch was obtained to generate the 3D printed model; (c) 3D model was filled for undercuts and replicated to form dental stone model; (d) dental stone model was used in Biostar machine for aligner formation; (e) fabricated aligner was cut connecting the zenith of teeth; and (f) fabricated aligner inserted on OSIM

Once an aligner (n=30) was formed, it was stored for approximately 24 hours in dry conditions in the retainer box in an airtight bag before being inserted onto the OSIM. Teeth were moved with the horizontal and vertical micrometers to obtain a position for the teeth such that forces and moments in the buccolingual and occlusogingival directions on all maxillary teeth were less than 0.10 N and 5 Nmm, respectively. There are 4 types of teeth in the human oral cavity such as the incisor, canine, premolar, and molar. During orthodontic tooth movement, incisor, canine, and premolar are frequently moved, and molars are used as anchor teeth. Therefore, for this experiment, right central incisor, left canine, and right second premolar were translated individually by 0.20 mm in the lingual direction and taken back to their original position.[14] After each tooth movement, the aligner was made passive before beginning the next test. This was done so that there were no clinically relevant forces and moments acting on the system from the previous tooth movement before the start of the next tooth movement (Figure 4.3).

Initial forces and moments in the XYZ direction were recorded for the tested teeth and adjacent teeth at 0.20 mm of displacement. The variables Fy and Mx on the tested teeth were the primary outcome measures. The sign conventions for forces and moments of interest in this chapter are provided in Table 4.1. Each trial was completed at 37 Celsius to mimic the oral temperature using a heating chamber. Furthermore, to account for any variations in aligner engagement, each aligner was tested three times for each tooth movement and averaged.

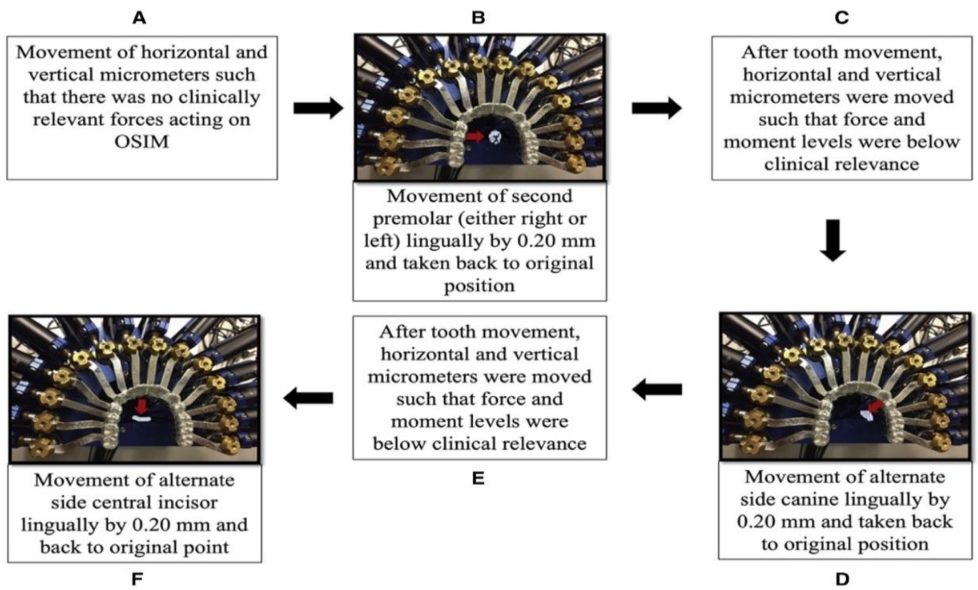

Figure 4.3 Experimental protocol: (a) once aligner was inserted on OSIM , horizontal and vertical micrometers were moved to have no clinically relevant forces and moments acting on the system; (b) second premolar (either right or left) was moved lingually by 0.20 mm, forces and moments were measured at 0.20 mm lingual displacement. The second premolar was taken back to the original position; (c) again, micrometers were moved such that no clinically relevant forces and moments was acting on the system; (D-F) other 2 teeth (canine and central incisor) were moved 0.20 mm lingually one by one

Repeated measures of multivariate analysis of variance (MANOVA) were used to assess if there was a significant mean difference in the Fy and Mx exerted on 3 teeth when the Fy and Mx were considered jointly. Statistical analysis was performed by applying repeated measures MANOVA on the 2 response variables, Fy (N) and Mx (Nmm), and a predictor variable, type of teeth (incisor, canine, and second premolar). Repeated measures of MANOVA were robust to violations of multivariate normality for this experiment as the groups were of equal size.

As the multivariate test based on Wilks' lambda rejected the null hypothesis, it was followed by repeated measures of analysis of variance (ANOVA) on each of the primary outcomes. A statistical significance was set at 0.05. A clinically significant difference was set at force levels of more than 0.10 N and moments of more than 5 Nmm. Statistical analysis was conducted using SPSS software® (version 24.0; IBM, Armonk, NY).

Table 4.1 Sign conventions for positive sense of forces and moments of the simulated arch

Fy	Fz	Mx
Buccal-directed force	Occlusal-directed force	Moment causing buccal root tip

4.3 Results

All forces and moments data were reported at the CoR for each tooth. Box plots showed the distribution of data for Fy (Figure 4.4) and Mx (Figure 4.5).

The multivariate test based on Wilks' lambda = 0.004 and $P < 0.001$ indicated that there were significant differences among the central incisor, canine, and second premolar when the 2 outcome variables (Fy and Mx) were considered jointly. The initial mean buccal force acting on the central incisor was 1.49 $\pm$ 0.18 N (Figure 4.6), canine 2.25 $\pm$ 0.38 N (Figure 4.7), and second premolar 1.50 $\pm$ 0.16 N (Figure 4.8).

Pairwise comparison with Bonferroni correction showed that there was a statistically and clinically significant mean difference in Fy between the canine and central incisor (mean difference, 0.76 N; $P < 0.001$; 95% confidence interval [CI], 0.56-0.96) and between the canine and second premolar (mean difference, 0.75 N, $P < 0.001$; 95% CI, 0.54-0.95). There was no significant difference in the Fy exerted on the central incisor and second premolar (Table 4.2).

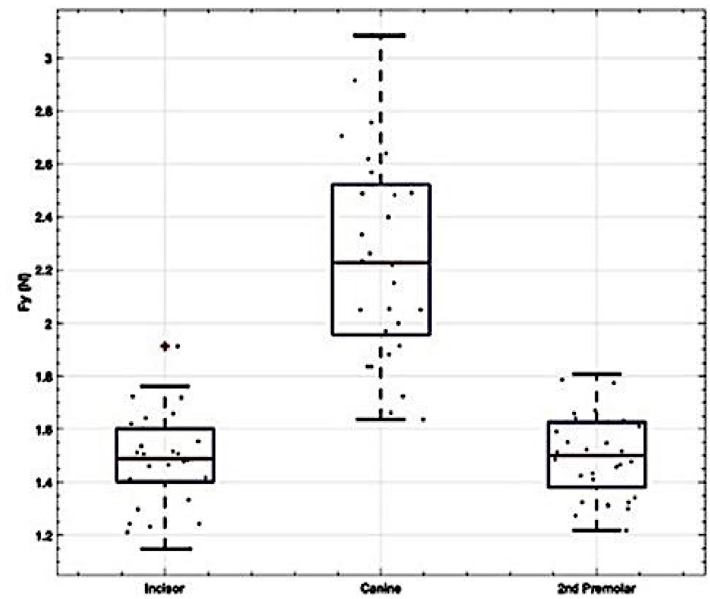

Figure 4.4 Box plot showing the distribution of Fy for each displaced tooth

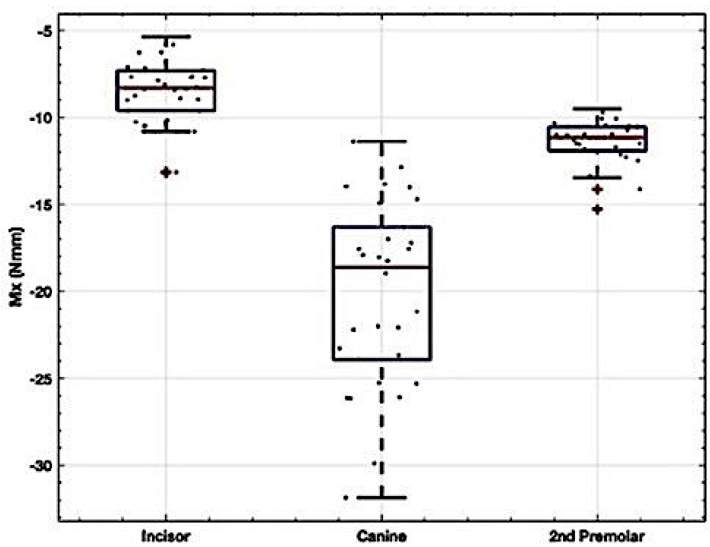

Figure 4.5 Box plot depicting the distribution of Mx that can tip displaced teeth buccally

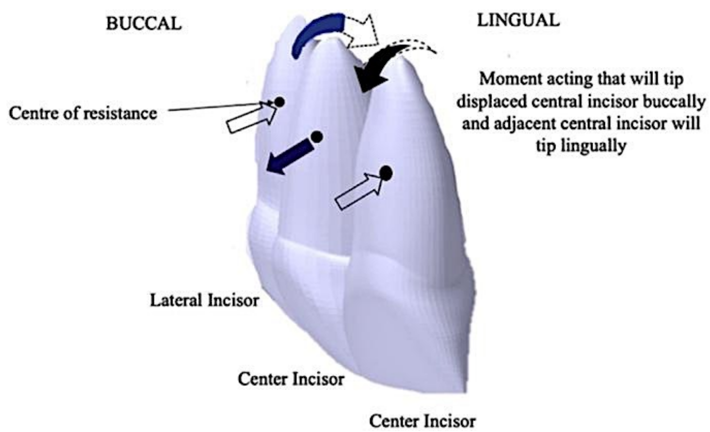

Figure 4.6 Diagram showing force system on displaced central incisor with reactionary force system on adjacent teeth

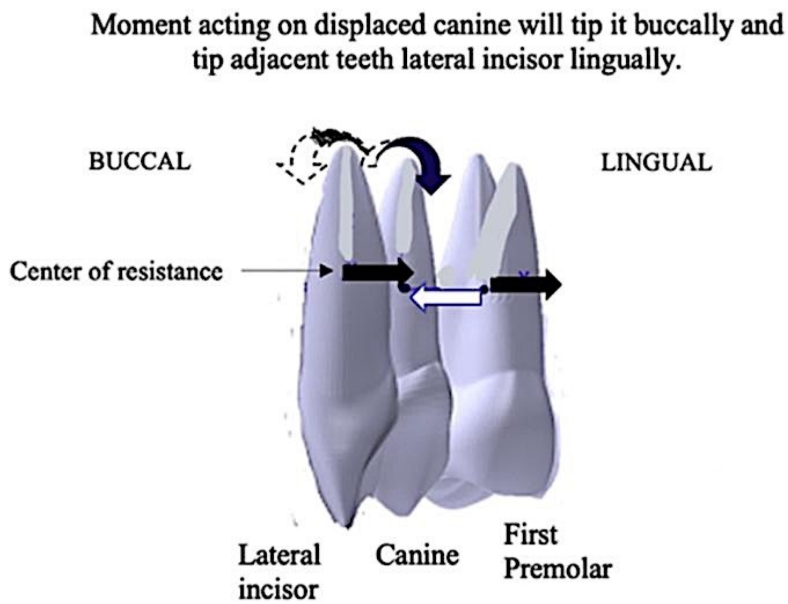

Figure 4.7 Diagrammatic illustration of force system on displaced canine with reactionary force system on adjacent teeth

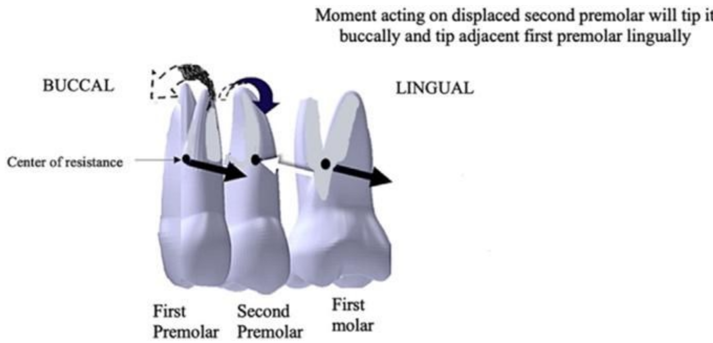

Figure 4.8 Diagrammatic representation of force system on displaced second premolar with reactionary force system on adjacent teeth

Table 4.2 Pairwise comparisons of Fy (N) between central incisor, canine, and second premolar

Buccal force on Tooth (I)	Buccal force on Tooth (J)	Mean difference between teeth (I-J)	*P* value	95% confidence interval
Canine	Central Incisor	0.76* N	<0.001*	(0.56, 0.96)
Canine	Second Premolar	0.75* N	<0.001*	(0.54, 0.95)
Second Premolar	Central Incisor	0.02 N	Approx. 0.99	(-0.08, 0.11)
* Significant mean differences				

The initial mean Mx applied on the central incisor was -8.42 $\pm$1.67 Nmm (Figure 4.6), canine -20.11$\pm$5.27 Nmm (Figure 4.7), and second premolar -11.45 $\pm$ 1.29 Nmm (Figure 4.8). The pairwise comparison with Bonferroni correction indicated that there was a statistically significant difference between canine and central incisor (-11.68; P <0.001; 95% CI, -14.09 to -9.28) and between canine and second premolar (-8.66; P <0.001; 95% CI, -11.31 to -6.01) (Table 4.3). There was a statactically significant difference between the second premolar and central incisor; however, this difference was not clinically significant (<5 Nmm).

Table 4.3 Pairwise comparisons of Mx (Nmm) between central incisor, canine, and second premolar

Moment on Tooth (I)	Moment on Tooth (J)	Mean difference in moment between two teeth (I-J)	*P* value	95% confidence interval
Canine	Central Incisor	-11.68*	<0.001*	(-14.09, -9.28)
Canine	Second Premolar	-8.66*	<0.001*	(-11.31, -6.01)
Second Premolar	Central Incisor	-3.03*	<0.001*	(-3.93, -2.13)
*Significant mean differences				

Table 4.4 Reactionary Fy (N) on teeth adjacent to the displaced tooth

Adjacent tooth	Displaced tooth	Mean force (Fy) on adjacent tooth from displaced tooth movement	Standard deviation (SD)
Central incisor	Central incisor	-0.61 N	0.16
Lateral incisor		-0.26 N	0.08
Lateral incisor	Canine	-1.09 N	0.23
First premolar		-0.16 N	0.15
First premolar	Second premolar	-0.58 N	0.08
First molar		-0.65 N	0.09

Table 4.5 Reactionary Mx (Nmm) on the adjacent tooth due to displaced tooth

Adjacent tooth	Displaced tooth	Mean moment (Mx) on adjacent tooth from displaced tooth	SD
Central incisor	Central incisor	5.87 Nmm	1.98
Lateral incisor		2.00 Nmm	1.89
Lateral incisor	Canine	11.97Nmm	2.69
First premolar		3.41 Nmm	1.84
First premolar	Second premolar	6.41 Nmm	1.33
First molar		1.57 Nmm	1.53

All the adjacent teeth to the tested teeth experienced reactionary clinically significant lingually directed force (Table 4.4, Figure 4.6-4.8) that have a tendency to move the adjacent teeth. The maximum initial reactionary moment (Table 4.5) that has a tendency to tip tooth crown lingually was found on the lateral incisor from moving canine (11.97 $\pm$2.69 Nmm). Other adjacent teeth that have clinically significant moments were the central incisor from moving adjacent incisor (5.87 $\pm$ 1.98 Nmm) and the first premolar from moving second premolar (6.41 $\pm$1.33 Nmm).

4.4 Discussion

In this experiment, the initial buccally directed force applied by the aligner on the canine was significantly greater than the central incisor and second premolar. This significant difference could be explained by altered aligner deformation because of varying tooth/aligner engagement between teeth anatomy and the location of the canine at the curvature of the arch as compared with the relatively straighter anterior and posterior arch. However, there was no significant difference observed between the initial Fy levels between the central incisor and the second premolar even though the two teeth have different anatomy of the crown.

The initial Fy exerted by PET-G at the central incisor and the second premolar was close to the optimal force range described for the translation of teeth (0.68- 1.18 N)[15] in the literature. In contrast, the Fy applied on canine was beyond the suggested range by the FE study[16] was 110- 124 g (1.08-1.24 N) for optimal buccolingual translation of canine. Although tooth movement and biological effects were not considered in this chapter, the force measurements made here compared with the optimally suggested ranges suggest further innovation into achieving force levels within the ideal range would be beneficial for aligner mechanics.

A clinically significant moment (>5 Nmm) was applied on the central incisor, canine, and second premolar that has the tendency to tip the teeth crown with translation when they were displaced. This points out the limitation of an aligner for bodily movement in a buccolingual direction. Therefore, biomechanics of the use of attachments with aligners should be investigated to prevent the tipping of teeth with aligners where bodily tooth movement is required for orthodontic patients.

There were reactionary forces exerted on all the adjacent teeth to the tooth moved during experiments. From the presented results, only the mesial adjacent tooth to the moved tooth experienced a clinically significant moment (tends to tip the adjacent tooth crown in the lingual direction). All the distal adjacent teeth to the displaced tooth did not experience any clinically significant moments. Although all the measured reactionary lingually directed forces were less than half of the applied buccal force on the displaced tooth, these reactionary forces were clinically significant and have the potential to generate orthodontic tooth movement on the adjacent teeth.

A previously published FE study[17] analyzed tooth displacement pattern, aligner deformation, equivalent stress of PDL, and stress developed on aligner for the rotational correction of 30 of mesially rotated mandibular second premolar obtained with 0.5 mm thick aligner. They showed deformation of aligner such that it could result in intrusive displacement on the right second molar area and lingual crown tipping of right lateral incisor and right first premolar with the three activation protocol for right second premolar. Another FE study[18] assessed the initial tooth displacements and stresses on PDL for the space closure of first premolar extraction where the canine was first distally moved followed by enmass retraction of the incisors. The central and lateral incisors showed extrusion and uncontrolled lingual tipping, whereas canines presented mesial crown tipping, intrusion, and minor mesial lingual rotation. With the addition of intrusion with retraction on incisors, the canine showed extrusive movement and slightly more lingual crown tipping, whereas the central incisor exhibited translation movement, and the lateral incisor underwent less tipping movement. Although these studies considered different tooth movements than what was studied here, these findings suggest that forces and moments will be transmitted to teeth adjacent to one where movement is desired. Hence, supporting teeth should be prepared during treatment planning with aligners, specifically where multiple tooth movements are performed at one time.

The tested teeth were moved in a lingual direction by 0.20 mm; consequently, the forces in the buccal direction of the tested teeth were expected. However, there was also significant intrusion Fz observed on all the tested teeth along with the buccal Fy. Maximum mean Fz was observed on the canine (0.77 $\pm$ 0.17 N), followed by the second premolar (0.46 $\pm$0.09 N) and central incisor (0.45 $\pm$ 0.13 N). The aligner wraps around the variable crown anatomy of teeth to apply forces on dentition by their elastic deformation in contrast to the point contact through the bracket in conventional metal bracket appliances. Considering the variable anatomy of the lingual surface of the teeth, the force applied to the tooth through contact with the aligners will remain perpendicular to the tooth surface, which can lead to a complex force system.[9] The imposed lingual displacement of an anterior tooth will have reactionary contact forces directed in the occlusogingival direction. The direction of the contact forces will, of course, change with tooth rotational alignment; however, the finding points to the overall complexity of aligner mechanics that differ from conventional fixed appliances.

There are various limitations that must be taken into consideration when interpreting the results of this chapter. First, the initial force system exerted by the aligner were measured, which may not be indicative of forces and moments generated over time after exposure to the oral environment (eg, humidity, temperature, and wear). Second, for this experiment, only 3 teeth (central incisor, canine, and second premolar) were assessed. It is possible that remaining teeth, with different geometry and location, could experience a difference in measured forces and moments. Third, only one representative material was chosen for this experiment to best investigate differences in aligner mechanics for teeth of different shapes and locations on the arch. The use of a different material may produce different force system. Most of the aligner manufacturers currently rely on PET-G materials for aligners, but other plastics such as thermoplastic PU and PET are used. In addition, the previous literature that has assessed the forces on single tooth model by aligner materials by Elkholy et al[19] and Hahn et al[8] have used different brands of generic PET-G materials. Therefore, we used PET-G material. Taglus material is a US Food and Drug Administration approved PET-G material and was selected as a representative material for this experiment. However, because of the lack of existing scientific data on the force system exerted by Taglus plastic on a central incisor, canine, and second premolar, it is difficult to relate the knowledge obtained from this experiment to available knowledge on plastic. Finally, the levels of clinically significant forces and moments used in this chapter are based on the evidence available in the literature. A SR,[20] which aimed to identify an optimal force range with the rate of orthodontic tooth movement as the primary outcome, suggested the force magnitude varied between 0.18 N and 3.60 N for included studies. Another biomechanical FE study[21] indicated that light bodily force of 0.1 N did not render hydrostatic stress in the canine PDL and is a lower threshold triggering orthodontic tooth movement.

4.5 Conclusions

- Canine teeth, located at the curvature of the maxillary arch, experienced significantly more mean buccal force than the central incisor and second premolar when the tested teeth were moved by 0.20 mm lingually.
- The moment that has a tendency to tip a tooth crown buccally was significantly more for the canine than the central incisor and second premolar.
- There were clinically significant reactionary forces exerted on all adjacent teeth to the lingually displaced tooth.
- Apart from buccal forces, intrusion forces were also measured when the central incisor, canine, and second premolar teeth were displaced lingually.

4.6 References

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Chapter 5: Investigating the role of aligner material and tooth position on aligner biomechanics

*This chapter was an expansion on chapter 4 where other most used aligner materials PET and PU were evaluated for three teeth – central incisor, canine and second premolar around the maxillary arch. A version of this chapter has been published as "*Kaur H, Khurelbaatar T, Mah J, Heo G, Major PW, Romanyk DL. Investigating the role of aligner material and tooth position on orthodontic aligner biomechanics. *J Biomed Mater Res B Appl Biomater*. 2023;111(1):194-202. doi:10.1002/jbm.b.35145."

5.1 Introduction

Aligners have been part of orthodontic practice since the middle of the 20th century[1,2], but have shown increased usage in the last two decades.[3] Despite their popularity, evidence has shown their reduced ability to control various orthodontic tooth movements.[4,5] An improved comprehension of force system exerted by aligners may lead to improved predictability of orthodontic tooth movements.

The force system exerted by an aligner mechanotherapy are dependent on a range of factors such as aligner material,[6-9] thermoforming process,[8] material thickness,[6,7,10] type of tooth movement[11] and amount of activation.[6] Thus, the use of an aligner appliance for orthodontic tooth movement requires an adequate understanding of these factors, aligner material being one of them. The published in vitro studies have mostly assessed the force system of PET-G material. Elkholy *et al.*[7] showed that the forces delivered on a central incisor with 0.25 mm of displacement by three different commercial brands of PET-G (Duran® 0.5/0.625/0.75 mm; Erkodur® 0.5/0.6/0.8 mm; Track A® 0.5/0.63/0.8 mm) varied for the different brands and for thickness. Hahn *et al.*[9] investigated forces applied by 1.0 mm thick aligners for three different commercial brands of PET-G material (Ideal Clear®, Erkodur®, and Biolon®) for central incisor displaced by 0.15 mm. The forces delivered by the Biolon® appliance were significantly higher ($p < 0.01$) than other studied materials. Kohda *et al*[6] investigated forces of two materials made of PET-G (Duran®, Erkodur®) and a material made of Polypropylene (Hardcast®). Hardcast® showed a significantly lower orthodontic force than the other two (Duran® and Erkodur®) materials. Apart from PET-G material, the force system generated by most used aligner materials of different structural composition such as PU and PET have not been assessed.

Structurally different materials have distinctive characteristics at the molecular level that alter their physical properties, such as flexural modulus, to exert different force system. PET is a condensation polymer produced by the esterification of ethylene glycol with terephthalic acid.[12] PET-G is a copolyester based on terephthalic acid and ethylene glycol modified with up to 50 mol % of glycol.[13] PU material is produced by reacting an isocyanate with a polyol containing a hydroxyl group in the presence of a catalyst.[14]

In addition to distinct molecular composition, any other factor that leads to considerable changes in the mechanical properties of aligners will cause changes in the applied force system. Thermoforming is one such factor wherein the aligner material is heated and drawn across the dental arch and may affect the structure of the polymer and perhaps change the material properties. It can influence the force system in two ways: (1) thermoforming process itself: the literature has shown that thermoforming of materials for aligner formation results in disparate changes in various materials before and after the process[15]; (2) thermoforming across dissimilar anatomy of teeth across arch: The various types of teeth (incisors, canines, and premolars) have dissimilar anatomy of the crown (both in shape and length) that could present non uniform surface area for drawing of the material during the thermoforming process. Previous work limited to one aligner material pointed out differences in aligner mechanics for different teeth across the maxillary arch.[16] Furthermore, the presence of curvature in the arch provides another variable that could influence the drawing of aligner around the arch. This presents a need to understand how the force system varies across the arch for different aligner materials.

The primary objective of the experiment was to evaluate the forces and moments of three materials: PET, PU, and PET-G on a subset of teeth (central incisor, canine, and second premolar). The secondary objective was to investigate the flexural modulus of pre- thermoformed and post-thermoformed PET, PU, and PET-G to understand the effect of thermoforming on different aligner materials.

5.2 Materials and methods

5.2.1 In-vitro evaluation of aligner biomechanics

An in vitro OSIM was used to simulate a maxillary arch to evaluate the forces and moments generated by representative PET, PU, and PET-G thermoformed aligners. A complete description of the OSIM has been provided in previous studies[17,18] and in this thesis chapters 2 and 4. The fixed maxillary teeth on OSIM were digitally scanned using a Lythos intraoral scanner® (Ormco, USA) to generate a plastic additively manufactured model of the arch. The posts from OSIM (and the model of the arch) do not truly replicate the surrounding tissue (e.g., gum tissue) geometry. Hence, this maxillary arch model was filled with wax that was replicated by using polysiloxane impression material to fabricate one dental stone cast for aligner fabrication. The aligner was adapted on the dental stone cast using Biostar machine®. This aligner was further poured to produce 15 dental stone models, five for each material to fabricate 6 aligners/model. Aligners were formed from randomly selected 0.75 mm thick sheets of three aligner materials—PET, PU, and PET-G material. Essix A+®(Dentsply Sirona) and Taglus®(Allure ortho) were used as a representative material for PET and PET-G, respectively, as these are available Food and Drug administration approved products. Zendura® (Bay materials) being a commonly used PU based aligner material was chosen to represent it.

Aligners were formed through a thermoforming process with a Biostar machine® (Scheu Dental). As suggested by the manufacturer, Essix A+® and Taglus® sheets were heated at 220 C for 35 and 25 s, respectively, followed by pressure of more than 5 Bar. The Zendura® sheet was heated for 40 s and was thermoformed at the same temperature and pressure. Aligners were separated from the stone model immediately after completion of the manufacturer specified protocol, that includes cool down time for aligners. The zenith of all teeth was marked, and each aligner was trimmed connecting these markings using straight lines between adjacent teeth. A formed aligner (n = 30/ material) was stored for approximately 24 h in dry conditions in a sealed airtight bag and retainer box before being tested. The sign conventions for forces and moments are same as discussed in chapter 4 (Table 4.1).

When an aligner was inserted on OSIM, teeth were moved using micrometers such that forces and moments in the buccolingual and occlusogingival directions were less than 0.10 N and 5 N mm, respectively, to generate a passive initial position. By having residual forces/moments present prior to tooth movement, it then becomes significantly more challenging to isolate the effect of tooth movement given potential confounding factors. For each aligner, the central incisor, canine, and second premolar were translated individually by 0.20 mm in the lingual direction and taken back to their original position. To account for slight variation in how the aligner may engage with the arch through individual teeth, each aligner was tested three times for each tooth movement and averaged. Similar protocol was followed for three materials.

Forces and moments in all directions were recorded at 0.20 mm of lingual displacement of the tested tooth. The variables Fy and Mx on the tested teeth were the primary outcome measures. In addition, Fz was of interest. Each trial was completed at 37C to simulate the oral temperature using the heating chamber.

5.2.2 Investigation of aligner materials' flexural modulus pre- and post-thermoforming

The flexural modulus of the thermoplastics PET, PU and PET-G were examined pre- and post-thermoforming. For pre-thermoformed samples, 40 mm long and 5 mm wide test samples were cut out of as-received sheets. As for the post-thermoformed case, the thermoplastics were formed over a simplified arch shape (Figure 5.1) using the same Biostar machine® following the manufacturer specified protocol, as detailed previously. To simulate geometry of the arch, the scanned maxillary arch was simplified into a horseshoe-like geometry using SolidWorks® (Dassault Systèmes SolidWorks Corporation, Waltham, MA, USA) with constant height of 10 mm, width of 5 mm and 9.8 mm for front (incisor) and back (molar) sides, respectively (Figure 5. 1).

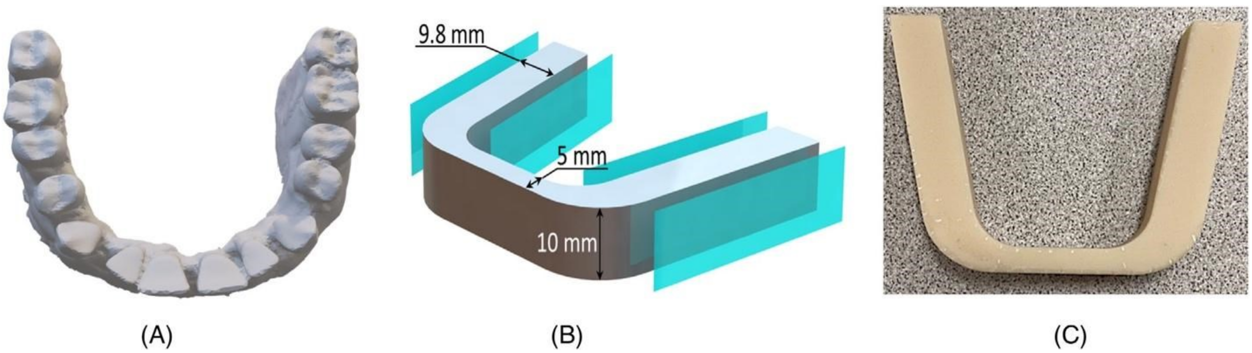

Figure 5.1 Schematic representation of the simplified geometry: (A) Digitally scanned model, (B) simplified model, the light blue planes indicate the sides of the model where specimens were cut, and (C) 3D printed simplified geometry for the thermoforming.

The complex geometry of the teeth was removed to create standardized flat samples for mechanical testing. Samples with 40 mm long and 5 mm wide dimensions were then cut from the straight, long sides of the thermoformed plastics (Figure 5.1B), with up to four samples being cut from each thermoformed plastic sheet. In total, 60 samples were prepared, 10 samples per aligner material pre-thermoforming and 10 samples per aligner material post-thermoforming. All prepared samples were stored in airtight bag in 23Celsius for 72 hr prior to testing. The thickness of the samples was measured by a digital Vernier Caliper before the mechanical testing. The measurements were done at five different locations across the sample length. Approximately, at the center of the samples, at both ends, and at the middle points between center and ends of the samples. The average of the measured thicknesses was then used for the final calculation of the flexural modulus.

The force system exerted on the tooth is generated mainly through the bending of the aligner material. Thus, the flexural modulus of aligner materials was estimated by a 3-point bend test using an ElectroPlusTM, E3000 universal testing machine (Instron, Norwood, MA, USA)® based on the ASTM standard D 790-03 (ASTM International D 790-03, 2003). The dimension of the samples was adjusted based on the size of the dental arch. Both pre- and post-thermoformed samples were tested while submerged in water at 37C temperature. Before the start of the test, each sample was given 2 min of temperature normalization time while submerged in water. The distance between the supports was 24 mm. The crosshead speed for testing was guided using the ASTM D790-03 Standard. Based on sample thicknesses, suggested crosshead speeds ranged from 1.33 to 2.51 mm/min. To keep consistency among all tests, a 2 mm/min rate was used. The initial contact of

0.02 N force was achieved by manual translation of the crosshead before the start of the test. The test setup is depicted in Figure 5.2.

The flexural modulus was estimated using two points selected in the linear region of the force-displacement curve. The linearity of the force-displacement curves was checked based on the loading rate, and the curve was linear between displacement values of approximately 0 and 2 mm for all trials. The points of the force- displacement curves at the displacements equal to 1 mm (point 1) and 2 mm (point 2) for the calculation of the flexural moduli were selected. The flexural moduli (E) were determined using Euler-Bernoulli beam theory:

$$E = (F2-F1)l^3/4bh^3(d2-d1)$$

where F1 and F2 are forces at the selected points, d1 and d2 are deflections of the selected points, b is the width, and h is the thickness of the test sample.

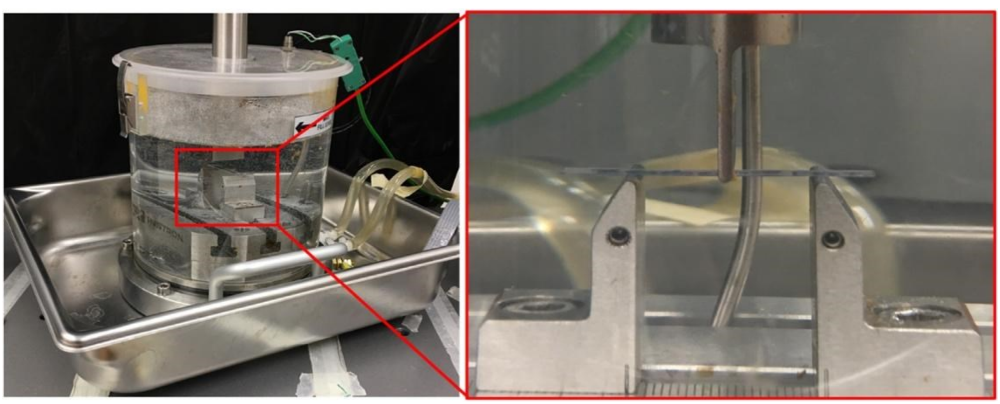

Figure 5.2 3-point bending test setup where the support span was 24 mm, and the displacement rate was 2 mm/min

5.2.3 Statistical analysis

When considering output data using OSIM, Repeated measures of MANOVA were used to assess the effect of one within subject factor: teeth (three levels: central incisor, canine, and second premolar) and one between subject factor: material (three levels: PET-G, PET, PU) on Fy and Mx. The multivariate test based on Wilks' lambda being statistically significant, it was followed by repeated measures of ANOVA on each of the outcomes (Fy and Mx). The test of sphericity was significant; therefore, it was corrected by using the Greenhouse–Geisser.

To analyze flexural moduli data obtained from 3-point bend tests, two-way ANOVA were used to assess the role of two factors: condition (two levels: pre-thermoforming and post-thermoforming) and material (three levels: Essix A+, Taglus, Zendura) on flexural modulus (continuous response variable expressed in MPa). A statistical significance was set at 0.05. Force difference of >0.10 N and moments >5 N mm was considered clinically significant. Statistical analysis was conducted using IBM SPSS version 26.

5.3 Results

The multivariate test based on Wilks' lambda $\Lambda = 0.015$, and $p < 0.0001$ suggested that at least one of the three materials was distinguishable from other two materials based on the combination of force (Fy) and moment (Mx). Similarly, Wilks' lambda $\Lambda = 0.15$, and $p < 0.0001$ indicated that there were significant differences among the central incisor, canine and second premolar when the two outcome variables (Fy and Mx) were considered jointly. The multivariate test for the interaction between material and teeth was $\Lambda = 0.810$ and $p = 0.02$ suggesting that this interaction was statistically significant at $\alpha = 0.05$. The follow up Repeated measures of ANOVA for force (Fy) suggested that mean buccal force exerted by material was dependent on teeth (interaction between material and teeth ($p = 0.013$)).

The measured Fy and Mx are summarized in Table 5.1. All the three materials, PET, PU and PET-G exerted maximum mean buccal force (2.65 ± 0.50 N), (2.53 ± 0.63 N), and (2.25 ± 0.38 N), respectively, on the canine tooth. PET-G material exerted significantly less mean buccal force as compared to PU on the canine (mean difference = -0.28 N, $p = 0.036$, 95% CI: - 0.38, 0.14) and second premolar (mean difference = -0.20 N, $p = 0.001$; 95% CI: -0.31, -0.08). PET applied significantly less mean buccal force than PU on the second premolar (mean difference = -0.15, $p = 0.012$, 95% CI: -0.26, -0.03) (Table 5.2). There was no evidence of significant difference between the three materials on the central incisor tooth.

Table 5.1 Descriptive statistics of the Fy (N) and Mx (Nmm) applied by three materials

Material	Fy central incisor [mean (SD)]	Fy canine [mean (SD)]	Fy premolars [mean (SD)]	Mx central incisor [mean (SD)]	Mx canine [mean (SD)]	Mx premolar [mean (SD)]
PET	1.42±0.20	2.65±0.50	1.55±0.16	-8.07±3.28	-26.63±5.80	-13.82±3.96
PET-G	1.49 ±0.18	2.25±0.38	1.50±0.16	-8.42±1.67	-20.11±5.27	-11.45±1.29
PU	1.53±0.54	2.53±0.63	1.70±0.32	-9.64±5.21	-24.01±7.47	-14.75±3.12

A similar trend was followed for Mx exerted by three materials. The moment exerted was dependent on the displaced tooth for all the three materials, which was maximum at canine teeth [(PET, 26.63 ± 5.80 N mm), (PET-G, 20.11 ± 5.27 N mm), (PU, 24.01 ± 7.47)]. PET-G has significantly less moment as compared to PET on canine (mean difference = 6.52 N mm, p = 0.000, 95% CI: 3.31, 9.72) and second premolar (mean difference = 2.37 N mm, p = 0.003, 95% CI:0.83, 3.91). PET-G also exerted less moment than PU on canine (mean difference = 3.90 N mm, p = 0.018, 95% CI: 0.69, 7.10) and second premolar teeth (mean difference = 3.30 N mm, p = 0.000, 95% CI: 1.76, 4.84). But there were only clinically significant differences between PET-G and PET on canine tooth (Table 5.3).

Table 5.2 Pairwise comparison with the Bonferroni correction for Fy (N)

Teeth	Material (i)	Material (j)	Mean difference (i-j)	P value	95% Confidence Interval
Central incisor	PET-G	PET	0.07	0.440	-0.11, 0.25
		PU	-0.04	0.630	-0.22, 0.14
	PET	PU	-0.11	0.213	-0.29, 0.07
Canine	PET-G	PET	-0.40	<0.001*	-0.54, -0.18
		PU	-0.28	<0.001*	-0.38, 0.14
	PET	PU	0.12	0.371	-0.14, 0.38
Second premolar	PET-G	PET	-0.05	0.394	-0.16, 0.07
		PU	-0.20	<0.001*	-0.31, -0.08
	PET	PU	-0.15	<0.001*	-0.26, -0.03
* Statistical significance was set at 0.05					

Table 5.3 Pairwise comparison with the Bonferroni correction for Mx (Nmm)

Teeth	Material (i)	Material (j)	Mean difference (i-j)	P value	95% Confidence Interval
Central incisor	PET-G	PET	-0.35	0.711	-2.24, 1.54
		PU	1.22	0.203	-0.67, 3.11
	PET	PU	1.57	0.102	-0.32, 3.46
Canine	PET-G	PET	6.52	<0.001*	3.31, 9.72
		PU	3.90	<0.001*	0.69, 7.10
	PET	PU	-2.62	0.108	-5.83, 0.59
Second premolar	PET-G	PET	2.37	<0.001*	0.83, 3.91
		PU	3.30	<0.001*	1.76, 4.84
	PET	PU	0.93	0.233	-0.61, 2.47
* Statistical significance was set at 0.05					

Apart from Fy and Mx, there were significant intrusion forces (Fz) observed in this experiment for the lingually displaced teeth. The maximum mean Fz were observed at canine tooth [(PET, 1.10 N), (PET-G, 0.77 N), (PU, 1.10 N)], followed by second premolar [(PET, 0.44 N) (PET-G, 0.46 N), (PU, 0.48 N)] and then on incisor [(PET, 0.28 N) (PET-G, 0.45 N), (PU, 0.37 N)] by all the three materials. All the adjacent teeth to the tested teeth experienced reactionary clinically significant Fy that has tendency to move the adjacent teeth in opposite direction of displaced teeth (Table 5.4). The clinically significant reactionary Mx were applied by PET and PU on lateral incisor from displaced central incisor and canine. PET-G generated clinically significant reactionary Mx on central incisor by displaced central incisor, lateral incisor for displacement of canine and on first premolar by displacement of second premolar (Table 5.4).

Table 5.4 Reactionary Fy (N) and Mx (Nmm) on teeth adjacent to the displaced tooth

Material	Adjacent tooth	Displaced tooth	Mean Fy on adjacent tooth	Mean Mx on adjacent tooth
PET	Central incisor	Central incisor	-0.28	1.92
	Lateral incisor		-0.54	5.18
	Lateral incisor	Canine	-1.08	11.08
	First premolar		-0.15	2.48
	First premolar	Second premolar	-0.46	4.06
	First molar		-0.66	3.73
PET-G	Central incisor	Central incisor	-0.61	5.87
	Lateral incisor		-0.26	2.00
	Lateral incisor	Canine	-1.09	11.97
	First premolar		-0.16	3.41
	First premolar	Second premolar	-0.58	6.41
	First molar		-0.65	1.57
PU	Central incisor	Central incisor	-0.29	2.87
	Lateral incisor		-0.59	5.23
	Lateral incisor	Canine	-0.91	8.75
	First premolar		-0.11	1.62
	First premolar	Second premolar	-0.49	3.78
	First molar		-0.63	3.29

The average thickness of aligner materials was 0.70mm (SD = 0.02) for pre-thermoforming and 0.39 mm (SD = 0.06 mm) for post-thermoforming. Two-way ANOVA showed no significant differences ($p > 0.05$) between different aligner material groups before or after thermoforming. However, there were significant within group differences ($p < 0.01$) between pre- and post-thermoforming cases in all aligner materials. On average, the thickness of the aligner material was reduced by 44%. The overall ANOVA suggested significant ($p = 0.036$) difference among the three materials for post thermoformed flexural modulus. The pre-thermoformed and post-thermoformed flexural modulus for the three tested materials is provided in Table 5.5 and comparison among the three materials is shown in Table 5.6. There were significant differences between PET and PU (mean difference = - 500.80 MPa, $p = 0.004$; 95% CI: -868.05, - 133.55) and PET-G and PU (mean difference = - 455.51 MPa, $p = 0.010$; 95% CI: - 822.76, - 88.26). There was no significant difference between PET and PET-G.

Table 5.5 Descriptive statistics for pre- and post-thermoformed flexural modulus for the three tested materials measured in Megapascal (MPa)

Material	Condition	Mean (±SD)	95% Confidence Interval
PET	Pre-thermoformed	2196.46 (±194.69)	1985.75, 2407.17
	Post-thermoformed	2412.66 (±342.53)	2201.95, 2623.37
PET-G	Pre-thermoformed	2462.36 (±41.89)	2251.65, 2673.08
	Post-thermoformed	2457.95 (±431.37)	2247.24, 2668.66
PU	Pre-thermoformed	2264.72 (±123.19)	2054.00, 2475.43
	Post-thermoformed	2913.46 (±551.82)	2702.75, 3124.17

Table 5.6 Pairwise comparison for post thermoformed flexural modulus (MPa) for three materials

Material 1	Material 2	Mean difference (1-2)	P value	95% Confidence Interval
PET	PET-G	-45.29	0.990	-412.54, 321.96
	PU	-500.80	<0.001*	-868.05, -133.55
PET-G	PU	-455.51	<0.001*	-822.76, -88.26
* Statistical significance was set at 0.05				

There was an increase in post-thermoformed flexural modulus from pre-thermoformed flexural modulus of PU material (mean difference = 648.75 MPa, $p < 0.001$, 95% CI: 350.75, 946.74). There was slight non-significant increase in flexural modulus after thermoforming for PET (mean difference = 216.20, $p = 0.152$, 95% CI: - 81.79, 514.19) (Table 5.7).

Table 5.7 Pairwise comparison for pre- and post-thermoformed flexural modulus (MPa)

Material	Condition (1)	Condition (2)	Mean difference (2-1)	P value	95% Confidence Interval
PET	Pre-thermoformed	Post- thermoformed	216.20	0.150	-81.79, 514.19
PET-G	Pre-thermoformed	Post- thermoformed	-4.41	0.990	-302.40, 293.58
PU	Pre-thermoformed	Post- thermoformed	648.75	<0.001*	350.75, 946.74
* Statistical significance was set at 0.05					

5.4 Discussion

In this experiment, the behavior of three representative orthodontic aligner materials (PET, PU, and PET-G) was studied on three subsets of teeth: central incisor, canine and second premolar. Further, the effect of thermoforming on the three aligner materials was investigated using controlled three-point bending tests. The work presented here aims to elucidate how different materials influence applied force and moment systems, how the thermoforming process affects studied materials, and how the position of the displaced tooth around the arch impacts the biomechanics.

All the three materials exhibited the similar trend where the maximum mean force (Fy) and moment (Mx) was applied on the canine. This could be due to the altered aligner deformation due to the location of the canine at the curvature of the arch. The curvature of canine perhaps supplements another dimension for deformation of aligner as compared to central incisor and second premolar that are located on comparatively straight anterior and posterior arch, respectively.

This experiment demonstrated that PET-G exerted less buccal forces compared to PU with respect to canine and second premolar. PET-G also applied less buccal force than PET on canine teeth. This is possibly due to Glycol modification of PET material that is intended to produce a softer material and lower the force levels exerted around the arch. It is also noteworthy that the pre-thermoformed flexural modulus of PET-G was larger as compared to PU and PET. However, flexural modulus remained stable for PET-G and increased for PET and PU post-thermoforming resulting in increased stiffness of materials. The previous studies[6,7,9] that assessed PET-G on central incisors had high buccal force ranges [4.49 ± 0.16 N (Duran), 7.22 ± 0.45 N (Erkodur), and 5.20 ± 0.68 N (Track-A)] as compared to PET-G representative Taglus material used for this experiment. This difference is suggested to be a result of experimental design and representative materials for PET-G used in previous studies.

PU applied statistically significant more buccal force than PET and PET-G on the second premolar. This material also exerted significantly more buccal force than PET-G on the canine tooth. These results correspond to the post-thermoformed flexural modulus of materials. The post-thermoformed flexural modulus of PU (2913.46) was more than PET (2412.66) and PET-G

(2457.95). The pre-thermoformed flexural modulus for PU (2264.72) was less than PET-G (2462.36) and close to PET (2196.46). Therefore, the findings of this chapter suggest that the mechanical properties of thermoplastic aligner materials should be evaluated after thermoforming to characterize their properties for clinical application.

A comparison of pre-thermoformed flexural modulus with post- thermoformed flexural modulus for different materials suggested that the impact of thermoforming on the mechanical properties vary according to the specific polymer. PET-G flexural modulus remained stable while there was an increase in flexural modulus of PU from pre-thermoforming to post-thermoforming. This increase in flexural modulus may be linked to the drawing of material during thermoforming where polymer materials are heated and pulled in tension resulting the polymer chains sliding over each other, unraveling, so that they become aligned with the direction of stretch.[19]

The result of present experiment is similar to previous studies that have shown an increase in flexural modulus of PU [1478 ± 88 to 1730 ± 77 MPa][19] and PET [2423.8 ± 98.8 to 2591.4 ± 152.7 MPa][20] after thermoforming. The difference in the magnitude between the results of the previous studies and present experiment could be possibly due to variance in the model used for thermoforming and different thermoforming procedures. The present experiment attempted to prepare a representative 3D arch model based on the digital scan of the simulated maxillary arch of OSIM such that the process of drawing can be closely replicated for thermoforming. In contrast, previous studies used models either to mimic a maxillary central incisor[20] [the average length (2 mm), clinical crown height (8.5 mm), and width (7 mm)] or 3D printed disk of 80 mm diameter and 12 mm height that provided flat area for thermoforming.[19] The study[19] that evaluated the flexural modulus for PU used Ministar S®(Scheu-Dental) forming machine that applies lesser pressure for thermoforming as compared to the Biostar machine® which is the pressure forming machine used in present experiment.

The buccal forces applied (away from CoR) by the three materials generated significant moments that have tendency to tip the teeth buccally. Moments generated by the materials corresponds to the applied forces across the three teeth. PET and PU would tip the canine and second premolar teeth more buccally as compared to PET-G with same amount of translation. Therefore, this experiment emphasized the need to investigate the use of auxiliaries to create a counter moment to accomplish pure translation orthodontic movement, if desired, with aligners. An in vitro study[21] evaluated the differences of various attachment designs (beveled, H ellipsoid, V ellipsoid, Hemiellip R, Hemiellip L, HRecL, HRecR, VRec- Down, VRecUp, 3Shape® box attachment, and no attachment) in their effectiveness to derotate an upper second premolar in terms of forces and moments transmitted to the tooth and showed that various geometries exert different force systems. In addition, the shapes of attachments potentially could affect the drawing of the polymeric materials during thermoforming affecting aligner material properties and the biomechanics. Thus, this experiment points out the need for future studies elucidating the effect of the drawing of the materials during thermoforming on material properties and biomechanics.

The SRs[3-5] on aligner clinical efficiency have pointed out the concerns regarding their predictability in controlling various orthodontic tooth movements. From this experiment, there were undesirable forces and moments acting with an aligner that could be one of the possible factors for its compromised results. There were undesirable significant intrusive forces observed with three tested materials when the central incisor, canine and second premolar were displaced lingually, which highlights the complexity of aligner appliance biomechanics. In addition, there were significant reactionary lingual forces observed on the adjacent teeth of the tested teeth for all the three materials that tended to move the supporting teeth.

The maximum mean clinically significant reactionary moment was generated on the lateral incisor by the three tested materials. Dissipating larger forces and moments to the smaller root surface area of lateral incisor as compared to other teeth in the arch make this tooth susceptible for root resorption.[22] Therefore, clinicians need to consider, wherever applicable, these undesirable forces and moments while doing the orthodontic treatment planning with the aligners.

The results of this experiment should be interpreted with its limitations. An in vitro OSIM was used to evaluate the forces and moments using a simplified oral environment simulation. The approximate oral temperature was replicated but other factors such as saliva and PDL compliance were not considered. It is expected that in vitro methods without periodontal simulated compliance would result in a stiffer response than the actual response. The previous in vitro research[23] comparing third order torque procedures with and without periodontal simulated compliance found small differences in measured forces and moments at low levels of simulated displacement and negligible effects of the compliance at larger magnitudes of movement. Secondly, thermoplastic aligner materials are viscoelastic in nature, which means that the force generated changes as a function of time. Therefore, only the initial force and moment levels exerted by the aligner were measured and does not represent the forces and moments generated over time after continuous exposure to the oral environment (e.g., humidity, temperature, wear). Thirdly, the samples for testing post-thermoformed flexural modulus were taken from the posterior premolar and molar region. The other regions anterior, and specifically the corner region of the arch, may behave differently owing to the process of drawing for variable anatomy. Fourthly, the clinically significant forces of >0.10 N and moments >5 N mm used in this experiment were based on the SR[24] with moderate to low level of evidence (that suggested the force magnitude varied between 0.18 and 3.60 N for included studies). An alternative biomechanical FE study[25] indicated that a force of 0.1 N is of lower threshold to trigger orthodontic tooth movement as it did not render hydrostatic stress in the canine PDL. Lastly, the oral environment presents numerous complex biologic variables such as saliva, temperature fluctuations, occlusion and others which could further affect the performance of an aligner.

5.5 Conclusions

- The maximum mean force and moment was applied on the canine located at the curvature of the arch by all the three materials. Moments generated by all three tested materials tended to tip the tested teeth buccally, emphasizing the need to investigate biomechanics of attachments for pure translatory orthodontic movement.
- PET-G applied lesser force as compared to PU with respect to the canine and second premolar. This material also applied less buccal force than PET on canine teeth.
- The impact of thermoforming on flexural modulus varied according to the specific polymer. PET-G flexural modulus remained stable while there was an increase in flexural modulus of PU from pre-thermoforming to post-thermoforming.
- There were undesirable significant intrusive forces observed with three tested materials when teeth were displaced lingually. Also, there were significant reactionary lingual forces observed on the adjacent teeth of the tested teeth.

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Chapter 6: In vitro biomechanics of auxillary (divot), and their placement, in orthodontic aligner therapy for bodily tooth movement

*The previous chapters 4 and 5 showed that there were moments generated by the applied forces when the aligner materials were tested for three subset of teeth that resulted in unwanted tipping of teeth leading to unpredicted tooth movement with aligners. This is specifically proper where bodily movement of the tooth is required. This indication led to experimental development for chapter 6 that introduces auxiliary with aligner in the form of divot. The version of this paper is published as "*Kaur H, Khurelbaatar T, Mah J, Heo G, Major PW, Romanyk DL. In vitro biomechanics of divot use, and their placement, in orthodontic aligner therapy. *Orthod Craniofac Res*. Published online February 1, 2024. doi:10.1111/ocr.12760."

6.1 Introduction

Aligners generate orthodontic tooth movement through the so-called "shape molding effect" of aligners where pre-established mismatches between the aligner shape and the dental tooth/arch geometry produces a resultant force system at the tooth/aligner contact interface.[1] Tooth movement with aligners is complex due to tooth/aligner surface contact mechanics, difference in tooth anatomy, mismatch between aligner and tooth geometries, and variations in aligner material properties.[1] As a result of such complexities, limited efficiency and predictability of tooth movement has been identified in the literature which can require multiple stages of refinement,[2] midcourse correction, or conversion to fixed appliances before the end of treatment.[3]

One of the less predictable tooth movements with aligners is bodily tooth movement, largely because an effective and well controlled force couple is required for root control to produce the bodily tooth movement.[4-6] An aligner can produce a force couple through its deformation near the gingival margin and the resulting opposite direction force produced by movement of the tooth against the inner opposite aligner surface near the incisor edge. Control of the desired force couple may be compromised as it requires consistent close fit of the aligner with the incisal edge.[5] It is further complicated by the potential deformation of the aligner with progressive tooth movement leading to change in the contact areas between the appliance and tooth.

Gomez et al.[7] suggested that tooth movement with only the aligner with no other alterations (e.g. attachments) has poor control on the inclination of teeth based on a FE evaluation. Previous in vitro research[8] considering a lingual displacement of the central incisor, canine, and second premolar with no other alterations to the aligner showed that significant moments were produced that could generate unwanted tooth tipping with displacement.

Orthodontic aligner systems have evolved over time with the introduction of auxiliaries (e.g., divots, power ridges and attachments) and improved materials with the proposition that aligner usage may extend to less predictable tooth movements such as bodily tooth movement. A SR[9] highlighted the importance of auxiliaries to achieve better root control for bodily movement, intrusion, and extrusion with aligners. An in vitro study[10] has shown that strategic placement of auxiliaries can impose forces on specific areas of the tooth surface, thereby enhancing the force delivery system by aligners towards a more controlled couple. These auxiliaries could facilitate more predictable tooth movement by providing specific regions of contact between teeth and aligner.

Divots are small dimples/projections in thermoplastic aligners introduced by Sheridan *et al.* for minor tooth movements.[11] An in vitro study[12] has verified the ability of aligners by measuring forces and moments with 1 mm thick divots to control rotational movement of the central incisor when compared to aligners without divots. Another in vitro study[13] evaluated the force delivered by aligners modified by different sized divots (heights from 0.022 to 0.142 mm) for tipping an upper central incisor in the buccal and lingual directions. This study showed that horizontal force of 0.35 to 0.60 N for tipping was reached with the divot of 0.041 mm height. In addition, there was variation in generated horizontal and vertical forces depending on the position of the divot (buccal/lingual), despite identical divot depths.

A FE study[14] of aligners without any auxiliary elements, with a single divot, double divots, vertical attachments, and horizontal attachments for movement of maxillary and mandibular incisor teeth identified that the loads elicited by the divot geometry, both in the single and double configuration, were higher than those provided by using attachments. The authors suggested that the force system delivered by a single divot was sufficient to obtain the required tooth movement, thereby potentially eliminating the need for double divot geometry. Furthermore, divots are introflexions on aligners that can substitute addition of another form of auxiliary with aligner such has composite attachment for bodily tooth movement. Composite attachment has silica as filler that has been recognized as potential occupation hazard associated with silicosis in dental supply factories[15] and dental technicians.[16]

Divots have not been studied in terms of how the placement on buccal and lingual surfaces can influence any potential moments produced to control bodily tooth movement. There is a need for a comparative analysis of the various positions of divots to understand their biomechanics for tooth movement such that the tooth may move bodily in an intended direction with no undesired tipping. Therefore, this experiment seeks to evaluate the biomechanics in terms of mean force and mean moment by varying the location of divots on buccal and lingual sides of the crown of a maxillary central incisor. Specifically, this experiment hypothesizes that the placement of divots on lingual gingival third and buccal incisal third; divots on lingual gingival third and buccal middle third; divots lingual middle third and buccal incisal third; and divots on lingual middle third and buccal middle third will have varying biomechanics due to difference in the distance between the lingual and buccal divots as well as anatomic conforms of crown of maxillary central incisor.

6.2 Materials and Methods

An in vitro OSIM[8,17] was used to measure the forces and moments generated by different placement of divots on aligners. The OSIM has the capacity to replicate a single arch, in this case the maxillary arch, with fixed anatomical teeth that were generated digitally using geometry reported in Linek's tooth carving manual.[18] OSIM has been described in detail in chapters 2 and 4 of this thesis. The fixed maxillary teeth on OSIM were digitally scanned using a Lythos intraoral scanner (Ormco, USA) to generate a. STL model, which was then modified computationally by locating divots at positions of interest on the crown of the right maxillary central incisor. The maxillary central incisor was selected as the reference tooth in this experiment as bodily movement of these teeth during orthodontic treatment is clinically relevant to ensure the proper interincisal angle that, in turn, is responsible for proper soft tissue support and harmonious profile.[19]

The scanned .STL model was taken as the base model on which the right maxillary central incisor was modified by placing a hemi-sphere shaped divot with a nominal depth of 1mm using Solidworks CAD software (Dassault Systèmes SolidWorks Corporation®).[14] Four different 3D models were designed as .STL files with variation in divot placement based on the anatomy of the maxillary incisor tooth crown which was divided into gingival, middle, and incisal thirds. Models were named after positioning of divot on anatomic location of crown of tooth. Model **GI** (**g**ingival third, **i**ncisal third) has one divot on the gingival third of lingual surface of incisor and another one on incisal third of buccal surface maintaining a difference of 8 mm between the two divots for a central incisor crown length of 10mm. Model **GM** has one divot maintained on the **g**ingival third of lingual surface and the other placed on the **m**iddle third of the buccal surface maintaining a difference of 4 mm between the two divots. Model **MI** has one divot on the **m**iddle third of lingual surface and another one is moved on the **i**ncisal third of buccal surface with distance of 4mm between the two divots; and Model **MM** has one divot placed on the **m**iddle third of lingual surface and another placed on the **m**iddle third of the buccal surface. The latter maintains a difference of 2 mm between divots (Figure 6.1).

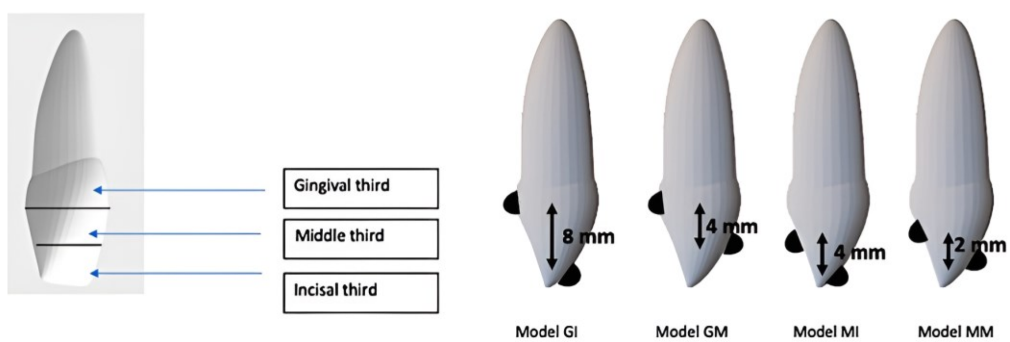

Figure 6.1 Illustration of the models prepared based on location of divot placement on anatomical crown of the central incisor

The four prepared models were 3D printed and aligners were thermoformed over the printed model using a Biostar® machine that produced aligner with introflexions. Conventionally, divot geometry can be obtained by manually stamping an aligner with plier based on visual guidance that can introduce uncertainties in its repetitive placement on various aligners used for testing in this experiment. Therefore, one model per group was prepared to physically create divot geometries in a repeatable manner onto the thermoformed aligner surface for this experiment (Figure 6.2).

Figure 6.2 Fabrication of aligner on designed model

Three aligners per model configuration were measured to confirm the divot thickness and depth. Aligners were filled with Plaster of Paris to scan using intraoral scanner and exported as a .STL file that were imported into SpaceClaim V2020R2 (Ansys, Canonsburg, PA, USA®). For measurement of divot depth, three points were created at the base of the divot and a construction circle was drawn connecting the three points. A local coordinate system was established normal to the plane that contains the constructed circle. The highest point on the divot with respect to the local coordinate system was selected as the top point. The depth was measured between the top point of the divot and the base circle (along the Z axis of the local coordinate system) (Figure 6.3).

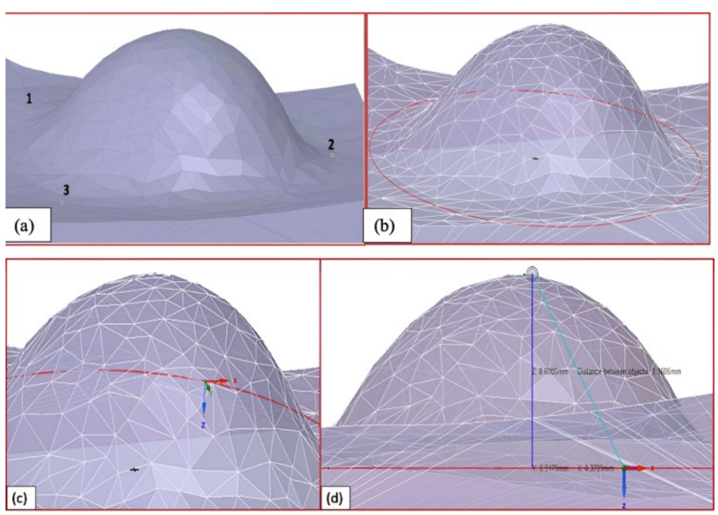

Figure 6.3 Measurement of depth of divots on aligner

For measurement of width of divots, a sphere was fit to the top spherical portion of the divot. The divot geometry diverged from the fitted sphere as it got farther from the top point. The diverging points were manually indicated on the XZ plane of the local coordinate system, and divot width was measured between those points. The width was measured along the X axis of the created local coordinate system (Figure 6.4).

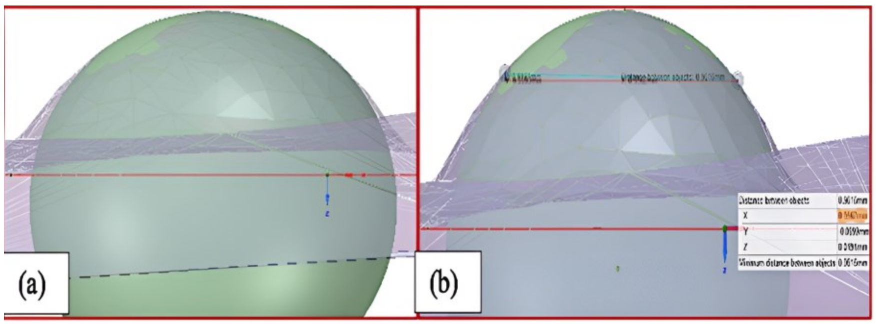

Figure 6.4 Measurement of width of divots on aligner

After confirming that the desired measurements of the divots could be achieved by thermoforming aligners on the designed models, aligners were formed using a 0.75 mm thickness of PET (Essix A+ by Dentsply Sirona®) in a Biostar® machine at 220C for 35 sec with a pressure of >5 Bar. A total of 120 aligners were formed and tested (n=30/model). Aligners were stored in an airtight container for approximately 24 hours before being tested.

Experiments began with an aligner being inserted on OSIM and teeth being moved to a passive position such that forces were less than 0.10N in the buccolingual and occlusogingival directions on all simulated maxillary teeth. For each aligner, the right central incisor was translated by 0.20 mm in the lingual direction and moved back to its original passive position.[20] To account for any variations in the experimental process (namely variable aligner engagement with the simulated OSIM arch), each aligner was tested three times and averaged. The aligner was made passive by using an in-house developed program in MATLAB after each tooth movement prior to each test. A similar protocol was followed for all four model designs and each aligner.

Forces and moments were recorded at 0.20 mm of lingual displacement of the tested right maxillary central incisor. The sign conventions for forces and moments of relevance in this experiment are provided in chapter 4. The Fy and Mx at maximum lingual displacement of the central incisor were the primary outcome measures. When an aligner was inserted on OSIM, there was an initial moment (iMx) acting on the right central incisor due to placement of divots on the aligner. Therefore, this moment on the right central incisor before displacement was also recorded. Each trial was completed at 37C to simulate the oral temperature using an air heating chamber, where the OSIM and all tested aligners were allowed to equilibrate for at least 1.5 hours prior to any testing.

One Way MANOVA was used to evaluate the effect of models (independent variable) on two continuous response variables- Fy and Mx. One Way MANOVA based on Wilks's lambda suggested significant difference between the models when Fy and Mx were considered jointly. There were two outliers present in the model GI, therefore statistical analysis was done by including as well excluding the outliers. As there was no difference observed in the analysis, results presented were with inclusion of outliers. Follow up one way ANOVA was used to assess the effect of the model on each outcome variable separately. Four designs were compared in pairwise by using Bonferroni multiple comparisons. A statistical significance level was set at 0.05. Clinically significant level used for force was >0.10 N and moments > 5 Nmm for the experiment.[21] Statistical analysis was conducted by using IBM SPSS version 26.

6.3 Results

When an aligner was inserted on OSIM before the displacement of the right central incisor there was iMx acting on the tooth due to placement of buccal and lingual divots on the aligner while making the force system passive in other directions. A clinically significant moment (>5 Nmm) was created by models GI [mean $\pm$ SD (10.48 $\pm$2.25Nmm)] and GM (11.69 $\pm$ 2.87) on the right central incisor when aligner with divots were inserted on OSIM before any displacement of the tooth. Model MI and Model MM exerted iMx of (-0.35 $\pm$ 0.70) and (2.00 $\pm$ 1.73), respectively.

One way ANOVA used to assess the effect of models (GI, GM, MI, MM) on iMx was significant (Table 6.1). No statistically significant difference was found between the moment generated by model GI and model GM. Significantly less iMx was created by model MM as compared to GI and GM. Model MI generated significantly less moment as compared to model GI, GM, and MM.

The right central incisor was displaced in lingual direction by 0.20 mm. Forces applied by displacement (away from CoR) created Mx described in Table 6.2. Three out of four designs (GM, MI and MM) had mean Mx less than clinically significant level of moment (<5Nmm). Pairwise comparisons showed no statistically significant difference for Mx between models GI and MI and models GM and MM (Table 6.3). Model GI exerted the maximum Fy of 1.87 N as compared to other models followed by GM, MI, and least force by MM (Table 6.4). Pairwise comparisons showed statistically significant differences among all four models with maximum difference of 1.58 N between models GI and MM and minimum difference of 0.40N between models GM and MI (Table 6.5).

Table 6.1 Pairwise comparisons between models for iMx(Nmm) generated by the divots

Group A	Group B	Mean Difference (Nmm)	Standard error (SE)	P value	95% CI
Model GI	Model GM	-1.21	0.53	0.150	(-2.63, 0.21)
	Model MI	10.83	0.53	<0.001*	(9.41, 12.25)
	Model MM	8.48	0.53	<0.001*	(7.06, 9.90)
Model GM	Model MI	12.04	0.53	<0.001*	(10.62, 13.46)
	Model MM	9.69	0.53	<0.001*	(8.27, 11.11)
Model MI	Model MM	-2.35	0.53	<0.001*	(-3.77, -0.93)

Table 6.2 Descriptive statistics of mean Mx (Nmm) at 0.20 mm of tooth displacement

Model	Mx (Nmm) (Mean$\pm$SD)
Model GI	-5.68 $\pm$ 7.38
Model GM	3.75 $\pm$ 5.54
Model MI	-4.27 $\pm$ 1.48
Model MM	1.96 $\pm$ 0.99

Table 6.3 Pairwise comparisons between models for Mx (Nmm) at 0.20 mm of tooth displacement

Group A	Group B	Mean difference (Nmm)	SE	P value	95% CI
Model GI	Model GM	-9.39	1.70	<0.001*	(-12.67, -6.11)
	Model MI	-1.41	1.40	0.900	(-4.70, 1.87)
	Model MM	-7.64	1.38	<0.001*	(-10.92, -4.35)
Model GM	Model MI	7.98	1.04	<0.001*	(4.69, 11.26)
	Model MM	1.75	1.02	0.930	(-1.53, 5.04)
Model MI	Model MM	-6.22	0.33	<0.001*	(-9.51, -2.94)

Table 6.4 Descriptive statistics of mean Fy (N) when tooth was displaced by 0.20 mm

Model	Force (Fy)(N) (Mean$\pm$SD)
Model GI	1.87 ± 0.75
Model GM	1.10 ± 0.47
Model MI	0.70 ± 0.23
Model MM	0.28 ± 0.08

Table 6.5 Pairwise comparisons between models for Fy (N) with 0.20 mm tooth displacement

Group A	Group B	Mean difference (N)	SE	P value	95% CI
Model GI	Model GM	0.77	0.12	<0.001*	(0.45, 1.09)
	Model MI	1.17	0.12	<0.001*	(0.85, 1.49)
	Model MM	1.58	0.12	<0.001*	(1.26, 1.90)
Model GM	Model MI	0.40	0.12	<0.001*	(0.08, 0.72)
	Model MM	0.81	0.12	<0.001*	(0.49, 1.13)
Model MI	Model MM	0.41	0.12	<0.001*	(0.09, 0.74)

6.4 Discussion

The presented experiment assessed the influence of divot placement across the crown of a maxillary central incisor on biomechanics for a simulated lingual displacement. Divots were placed in four configurations with varied vertical position on the crown and in different combinations of lingual/buccal sides. The overall goal of the experiment was to assess biomechanical differences in divot configurations for a lingually displaced central incisor, with the optimal scenario(s) resulting in a negligible moment and corrective buccal directed force.

Model GI and GM generated the largest initial moment (labelled as iMx) among the four models when an aligner was inserted on the simulated arch due to buccal and lingual divots (without any tooth displacement). The distance between the buccal and lingual divots being maximum for model GI explains the generation of the largest moment for GI among the four tested models. Model GM had divots placed on the most prominent part of the tooth, being the lingual gingival-third and buccal middle-third that could explain the generation of larger moment as compared to other models. Although model MI had a similar distance between the buccal and lingual divots as that of model GM, MI produced less moment. This outcome is possibly due to less force generation for the MI model based on the location of the divot on the crown of the right maxillary central incisor. The lingual divot was placed in the middle third that lies below the cingulum which is a prominent tooth structure on lingual side and buccal divot was placed on the incisal third that is below the prominent middle third of the tooth .

When the right central incisor was displaced by 0.20 mm, the force applied by lingual displacement (away from CoR) generated a moment that countered iMx applied by placement of buccal and lingual divots. The mean moment, Mx, for models GI, GM and MM was less than clinically significant levels which suggests that the tooth could displace bodily without unsought tipping. All generated models in the present experiment found less mean Mx as compared to a previous study[8] using an aligner without any divot in a similar experimental set up (e.g., lingual displacement and aligner material). The previous study measured a mean Mx of -8.07 ± 3.28 Nmm at maximum lingual displacement of the central incisor by 0.20 mm using an aligner without divots. This validates that divot placement could mitigate the production of unwanted tipping moments and facilitate bodily tooth movement.

These results are similar to a case report utilizing divots for a 32-year-old female with a buccally displaced lower central incisor for root control.[22] Divots were placed near the gingival edge of the buccal surface and the incisal edge of the lingual surface to create lingual root torque of the lower central incisor. Divot placement facilitated the correction of axial inclination of the lower central incisors and the roots were properly positioned within the alveolar bone.[22] A retrospective study (n=39) assessed the Nuvola aligner system® in controlling the buccolingual root movement of upper and lower teeth. The results of this study showed that the Nuvola system® approximately achieved the predicted buccolingual inclination for upper and lower anterior teeth. However, this study did not indicate if any auxiliary was used for achieving the required torque. Also, this study used small amounts of movement over a series of 12 aligners.[23]

The maximum mean buccal force, Fy, was exerted by model GI followed, in descending order, by models GM, MI, and MM. The low to moderate level of evidence in the literature suggests force levels between 70-110 g [24,25] to 254 g[21] is necessary to achieve translation. The buccal force with model GI, GM and MI was well within range provided by evidence in the literature. The Fy levels generated by models with divots in the current experiment was similar to those without divots (1.42 ± 0.20N) for the same experimental set up.[8] The present experiment found favorable biomechanics of aligner with divots as compared to aligners without divot for bodily translation. This is like results found by a FE study that analyzed standard (without auxiliary elements), single divot, double divots, vertical, and horizontal attachments located on the incisor teeth for lingual tooth movement. A preliminary analysis of the results showed orthodontics forces are better achieved by using auxiliary elements, particularly, the divots cause the highest displacement values both in single and double configurations.[14] Divots have additional benefit of reducing the risk of occupation hazard of silicosis as these are introflexions on the aligners eliminating the need of placing another form of auxiliary with aligner i.e., attachment made from composite resins. Composite resins have fillers (in the form of quartz, glass or silica) to improve their mechanical properties such as polymerization resistance and wear resistance.[26] This filler content has been increased for orthodontic attachment with aligner in order to accurately restore the shape of an attachment over time.[27] It has been shown that exposure to dust with high silica concentration presents a risk of developing silicosis among dental technicians and dental factory workers.[15,16]

These results should be construed considering the limitations of this experiment. In vitro OSIM that replicated the simplified oral environment where the approximate oral temperature was maintained with the help of heating chamber, was used to evaluate the biomechanics with no simulation of saliva and PDL. It is expected to have greater than actual response for in vitro methods without periodontal simulation. The previous in vitro research[28] that compared the third-order torque procedures with and without periodontal simulated compliance found small differences in measured forces and moments at low magnitude of stimulated displacement and negligible effects at larger magnitudes of movement. Secondly, thermoplastic aligner materials are viscoelastic in nature that suggest that force generated decreases as a function of time. Therefore, only the initial force and moment levels exerted by the aligner were measured and does not denote the forces and moments generated over time after continuous exposure to the oral environment. Thirdly, the results are limited for central incisors that generally require bodily translation in buccolingual direction. Teeth such as canine and premolars with different geometries will respond differently to placement of divots as the force system will be acting at different inclined surface tangents. Fourthly, there is large SD of data obtained. This might have been caused by potential deformation of aligners with progressive tooth movement leading to change in the contact areas between the inner surface of the appliance and the crown by slipping along the divots. Lastly, the clinically significant forces of >0.10 N and moments >5 Nmm used in this experiment were based on the moderate to low level of evidence suggested that the force magnitude varied between 0.18 N and 3.60 N for included studies.[21]

6.5 Conclusions

- Divot placement could improve the biomechanics that can facilitate bodily tooth movement of the central incisor when displaced in labiolingual direction without major root tipping especially for models GM and MI.
- All the four models were able to create the initial moment due to placement of divots on the opposite surface (buccal and lingual) of central incisor without any tooth displacement.
- The maximum moment (iMx) was applied by model GI that has maximum distance between the buccal and lingual divot followed by model GM where divots were placed on the most prominent part of lingual and buccal tooth surface of center incisor.
- Buccal force (Fy) exerted by models GI, GM and MI are within the range advised by the moderate to low level of evidence for bodily tooth movement.

6.6 References

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Chapter 7: In vitro biomechanics of attachment use, and their placement for extrusive tooth movement by aligner mechanotherapy

This was an extension of Chapter 6 where biomechanics of aligners with auxiliaries were studied. In this chapter an alternative form of auxiliary (attachment) was used to explore its biomechanics for another difficult tooth movement with aligners- extrusive tooth movement. The rationale was to understand the biomechanics for these difficult tooth movements with aligners and expand its utility to such movements.

7.1 Introduction

Extrusive orthodontic tooth movements involves moving teeth in a coronal direction that is conventionally required for dentoalveolar open bite treatment, to establish appropriate overbite for incisal guidance, and to establish adequate display of incisors during smiling.[1] Other indications include traction of impacted teeth, and exposure of teeth presenting structural damage to facilitate restorative therapy.[2] A SR[3] suggested that extrusion is one of the most difficult movements to achieve with aligner mechanotherapy as there are no substantial undercuts for retention resulting in aligners slipping occlusally/incisally, leading to lack of tooth movement.[4]

To overcome the inherent lack of predictability, different materials, design features and adjunctive strategies have been proposed to facilitate extrusion tooth movement with aligner mechanotherapy. Boyd[5] suggested reducing the amount of designed tooth movement per stage for such movements with aligner mechanotherapy. English *et al.*[6] proposed utilizing an attachment for aligner retention on the tooth. They also recommend proclination of the tooth to create interproximal space and then simultaneously extrude and retract the tooth. Glaser[7] recommended a beveled rectangular attachment for extrusion tooth movement. A recent cross-sectional study[8] aimed to determine efficacy of aligners for extrusive tooth movement of maxillary lateral incisor pointed out that despite improvements, the average clinician perceived efficacy was 4.71 on a scale of 1 to 10 (95% confidence interval, 4.28-5.14).

A SR[9] based on clinical evidence evaluated the effect of attachment when used with aligner mechanotherapy (including databases up to March 2020) and concluded that evidence regarding extrusion tooth movement is lacking. A retrospective study (n=45)[10] was done to evaluate the mechanism of anterior open bite closure using aligners with attachments by cephalometric superimposition. This study showed that open bite was relieved by combination of anterior teeth extrusion, anterior teeth retraction, and posterior teeth intrusion. Similarly, a retrospective study[11] (n=30) concluded that open bite in patients was primarily relieved by posterior teeth intrusion resulting in counterclockwise rotation of the mandible. Another retrospective study[12] that conducted cephalometric comparisons between aligners with attachments and fixed mechanotherapy (n =17 for fixed mechanotherapy and n =36 for aligner therapy) suggested that retroclination of both the upper and lower incisors appeared to contribute to open bite correction with extrusion of the upper and lower incisors limited to < 1 mm for aligner mechanotherapy.

A SR[8] reported that most of the clinicians used buccal attachment for extrusion with only 6% of orthodontists utilized lingual attachment. A FE study[13] that compared aligners without attachments, rectangular lingual attachments, rectangular buccal attachments, and ellipsoid buccal attachments showed maximum tooth extrusion potential with rectangular lingual attachments among the compared groups. In addition, if biomechanics of a lingual attachment is favorable for extrusive tooth movement, it could provide a more esthetic appearance than buccal attachments for anterior teeth. It has been shown that visual attachments detract from the esthetic acceptability of aligners.[14] It is important to recognize the moment will be generated by a force applied away from CoR that can tip the tooth in a preferential manner. Henceforth, addition of an attachment on the buccal and lingual side in combination could pose a potential solution to negating the effect of moments generated by each of the forces. Further work is necessary to evaluate the biomechanics of attachment placement towards expected responses.

The present chapter seeks to evaluate the biomechanics of attachments through force and moment measurements by varying the location of attachments on the buccal and lingual sides of the tooth. It is hypothesized that placement of attachments on the buccal side, attachment on the lingual side, and attachments on both the buccal and lingual sides would have varying mean Fz and Mx due to difference in location of attachment on anatomical conforms of crown. The results of this chapter would provide preliminary evidence to clinicians for strategic placement of attachments for extrusion of lateral incisor.

7.2 Methods

An in vitro OSIM experimental set up was used to measure the force system generated by different placement of attachments using orthodontic aligners. OSIM has been validated and described in detail in previous published work for both fixed appliances and orthodontic aligners.[15-18] In brief, the OSIM was fitted with maxillary teeth that could be displaced in buccolingual and occlusogingival directions using horizontal and vertical micrometers® (Physik Instrumente, MA, USA), respectively. The three-dimensional force system for each simulated tooth was measured using load cells® (*Nano17, ATI Industrial Automation*, NC, USA) that are located at a distance from teeth. Thus, a FARO Arm® (FARO, Lake Mary, FL, USA) was used to determine the coordinate systems of the load cells and teeth from which a Jacobian transformation matrix was developed for each pair to translate load cell measurements to forces/moments at an approximated CoR for each tooth.[19] The entire set up was enclosed in a heated air chamber to simulate the standard oral temperature of 37 Celsius.

The maxillary teeth on OSIM were digitally scanned using a Lythos intraoral scanner (Ormco, USA) to generate a .STL model that was taken as the base model. The left maxillary lateral incisor on the base .STL model was modified by placing a rectangular shaped attachment (4mm length, 2 mm breadth and 1 mm height) using Solidworks CAD software®(SolidWorks Corporation, Massachusetts, USA) at positions of interest. The maxillary lateral incisor was selected as the reference tooth in this experiment as literature has shown that this tooth generally lags the tracking in aligner sequencing because of its location between bulkier canine and central incisor teeth and overall smaller size.[8, 20]

Four 3D models were designed as .STL files with variations in attachment placement. Model NA was a control group with no attachment (Figure 7.1a); Model BA has buccal rectangular attachment placed 2 mm away from gingival margin (Figure 7.1b); Model LA was developed by placing rectangular attachment on lingual side 2 mm away from gingival margin (Figure 7.1 c); The model BL has rectangular attachments on both buccal and lingual sides (2 mm away from gingival margins) (Figure 7.1d).

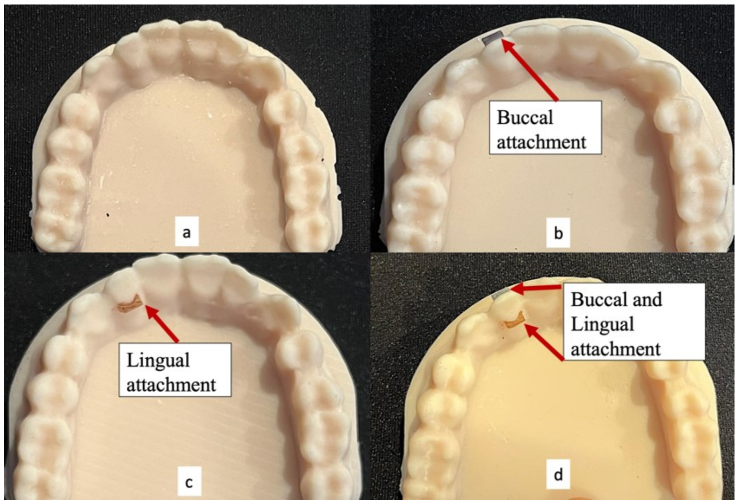

Figure 7.1 a) Model NA; b) model with BA; c) model with LA; d) model BL

Thirty aligners per model were fabricated for testing using 0.75 mm of PET (Essix A+ by Dentsply Sirona®) material using a Biostar machine (Great Lakes Orthodontic Laboratory®) following manufacturer recommendations. One extra aligner was fabricated for a model with attachment to be used as a template for attachment placement on the metal tooth of OSIM. The template aligner was brushed with olive oil and bonding composite (Transbond XT – 3M Unitak®) was packed in the template using a packing metal instrument. The metal OSIM tooth was prepared through sandblasting followed by painting metal primer. The template was placed over the metal tooth and the attachment was light cured following the manufacturer prescribed protocol.

The fabricated aligners were stored in an airtight bag for approximately 24 hours before being tested. Aligners were placed in the air heating chamber enclosing OSIM for approximately 1.5 hours to equilibrate to a temperature to 37 Celsius before being tested. Aligners were then inserted on the OSIM (Figure 7.2), and teeth were moved to a passive position such that forces were less than 0.10 N in the buccolingual and occlusogingival directions on all simulated maxillary teeth.

The passive position was achieved by using an in-house developed program in MATLAB followed by manual adjustments prior to each test. For each aligner, the left lateral incisor was translated by 0.20 mm in the gingival direction and moved back to its original passive position. Each aligner was tested three times and averaged to account for any variations in the experimental process. A similar protocol was followed for all aligners.

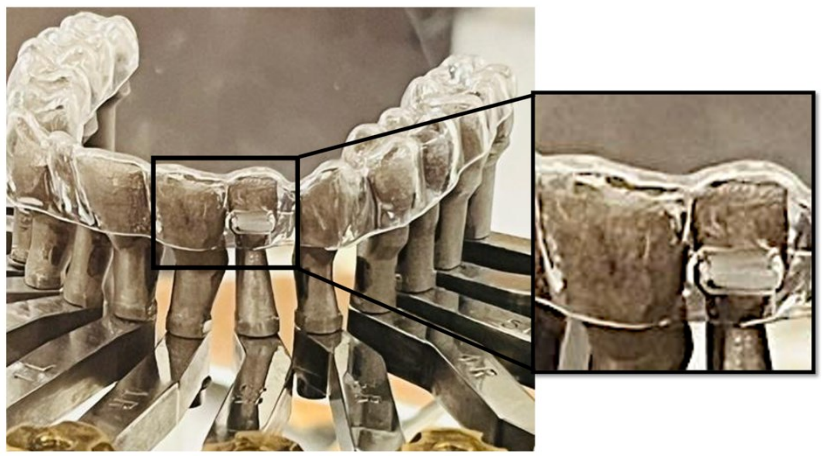

Figure 7.2 Aligner inserted on OSIM with buccal attachment

One Way MANOVA was used to evaluate the effect of models on continuous response variables which were extrusive force (Fz) and Mx. The sign conventions for response variables are specified in chapter 4. Assessment of outliers by Mahalanobis distance showed no outliers in the data. One Way MANOVA based on Wilks's lambda suggested significant difference ($p < 0.001$) between the models when Fz and Mx were considered jointly. Follow up one-way ANOVA was used to assess the effect of the model on each outcome variable separately. Four designs were compared in pairwise by using Bonferroni multiple comparisons. A statistical significance level was set at 0.05. Clinically significant level used for force was >0.10 N and moments >5 Nmm for the experiment.[21] Statistical analysis was conducted by using IBM SPSS version 26.

7.3 Results

The model BL exerted the largest extrusion force of all groups at 1.22 N followed model with BA (1.18N) and LA (1.07N). The model NA with no attachment exerted a negligible extrusion force of 0.14 N (Table 7.1).

Table 7.1 Descriptive statistics for Fz (N) on the left lateral incisor

Model	Mean force (N)	SD
NA	0.14	0.08
BA	1.18	0.25
LA	1.07	0.19
BL	1.22	0.20

There was a statistically significant difference between model NA, with no attachments, and the remaining three models (model BL, model BA, and model LA) with attachments. In addition, model BL exerted statistically significant more extrusive force, Fz, as compared to model LA. There was no statistically significant difference between model BA and model LA for extrusion forces (Table 7.2).

The model BA generated a moment, Mx, that has tendency to tip the crown of a tooth lingually (10.00 Nmm) (Table 7.3). Pairwise comparisons between the models show statistically significant difference between model BL and model BA, model LA. There was no statistically significant difference between model BL and NA (Table 7.4).

Table 7.2 Pairwise comparisons between models for Fz (N) at 0.20 mm gingival displacement

Model	Model	Mean difference	Significance	Confidence interval
BL	BA	0.04	0.990	(-0.10, 0.16)
	LA	0.15	<0.001*	(0.01, 0.28)
	NA	1.08	<0.001*	(0.95, 1.20)
BA	LA	0.11	0.140	(-0.02, 0.24)
	NA	1.04	<0.001*	(0.91, 1.17)
LA	NA	0.93	<0.001*	(-1.06, -0.80)
*The mean difference is significant at the .05 level				

Table 7.3 Descriptive statistics for Mx (Nmm) on left lateral incisor

Model	Mean Mx (Nmm)	SD
NA	2.65	1.84
BA	10.00	3.12
LA	-1.29	2.26
BL	1.86	3.71

Table 7.4 Pairwise comparisons between models for Mx (Nmm) at 0.20mm gingival displacement

Model	Model	Mean difference	Significance	Confidence interval
BL	BA	-8.15	<0.001*	(-10.11, -6.19)
	LA	3.15	<0.001*	(1.19, 5.11)
	NA	-0.80	0.990	(-2.76, 1.17)
BA	LA	11.30	<0.001*	(9.34, 13.26)
	NA	7.35	<0.001*	(5.39, 9.31)
LA	NA	-3.95	<0.001*	(-5.91, -1.98)
*The mean difference is significant at the .05 level				

7.4 Discussion

The current chapter was conducted to explore the biomechanics of four different aligner combinations by placing attachments on the buccal and lingual side of the lateral incisor for extrusion. The model without any attachment was included to serve as a control and determine if extrusive forces could be generated solely with an aligner with no added attachment. The rationale was that the anterior tooth shape itself could provide some surface retention for the aligner to aid the extrusion tooth movement. In addition, better esthetic results could be achieved by avoiding the use of attachments with aligners on the anterior dentition. However, the results of this chapter showed that the model NA did not exert clinically significant extrusion forces on lateral incisor. The model NA was significantly different from the models with attachments that exerted substantial extrusion forces. Hence, this experiment provides in vitro evidence that use of attachments is required for extrusive tooth movement with aligners.

Results from this chapter agree with those from Savignano *et al.*[13] representing a FE study that evaluated the effect of an aligner without attachments and aligners with various shaped attachments for maxillary central incisor. The aligner without attachment exerted the minimum extrusive forces of 0.4N with lowest tooth displacement as compared to the aligners with attachments. A FE study by Laohachaiaroon et al.[22] assessed displacement and stress distribution on the upper central incisor with various attachments. They reported that the model without any attachment demonstrated negligible intrusive movement instead of extrusion tooth movement. This was consistent with a clinical study[23] that included 401 anterior teeth where predicted tooth position was superimposed on achieved tooth movement, showed merely 29.6% of accuracy of extrusion tooth movement. Another in vitro study[24] that evaluated the extrusion force on left central incisor showed extrusion force of 0.94 N with PET-G representative material and very high intrusion force of 24 N instead of extrusion for PU material when no attachments were used with aligners for 0.5 mm of tooth displacement.

Rectangular shaped attachments have been reported to provide greater extrusive movement compared with ellipsoid and rectangular beveled attachments.[22] A multicenter randomized control trial showed that a horizontal attachment was significantly more effective (22%) than optimized attachments®(attachments designed by Invisalign, Align Technology, Santa Clara, Calif) for extrusion of the lateral incisor.[25] Therefore, rectangular shaped attachment was used in the present experiment to investigate biomechanics associated with varying the position of attachments. All three attachment positions resulted in significant extrusion forces acting on the maxillary lateral incisor. The extrusion forces were greatest for model BL. The increase in number of attachments and positioning them on both sides might have led to a better retention performance for aligners resulting in generation of more extrusive force in comparison to the other models with single attachments. Another FE study[26] that assessed the biomechanics of adding attachments on buccal and lingual sides of a second molar for intrusion found models with attachments on both sides had better intruding efficiency with no unsought tipping than models with only buccal or lingual attachment.

As the extrusive force was applied buccal to the CoR of the normally inclined tooth via buccal attachment for model BA, clinically significant moment was generated that has tendency to tip the crown of the tooth lingually (Figure 7.3). This is like results of an in vitro study[24] that showed significant moment generated with buccal attachment (16.19Nmm ± 5.8) that can tip the tooth lingually on 0.5 mm of displacement. This is congruent with a clinical retrospective study[27] that showed significant retro inclination of upper incisors (10.91 ± 6.95°) along with extrusion. The moment created with buccal attachment has potential to generate uncontrolled tipping of the incisor resulting in root tipping towards the buccal cortical plate of bone that could impede further extrusion of tooth as well as could lead to unwanted consequences of root resorption.[28] Hence, orthodontists should be thoughtful about the attachment position to avoid unbalanced moments in the teeth.

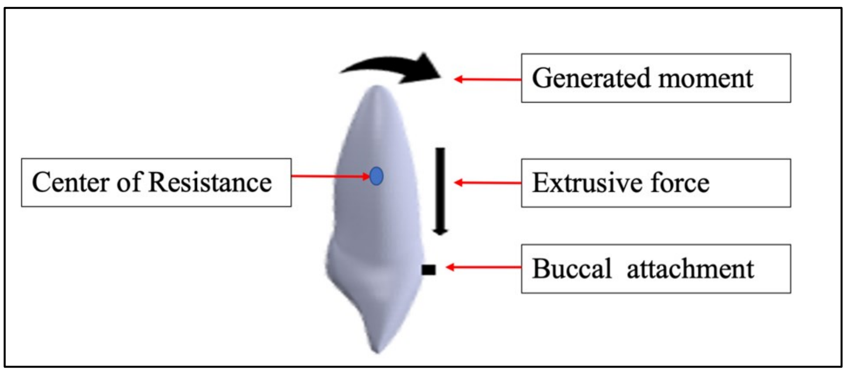

Figure 7.3 Model BA depicting the buccal attachment. Extrusive force applied on the buccal of CoR of tooth generated the moment that has tendency to tip the crown of the tooth lingually

Model LA generated a moment with extrusion force that can tip the crown of the tooth buccally as the force was applied lingual to the CoR The Mx generated was significantly less for model LA as compared to model BA that could be explained by analyzing the distance of force applied from CoR. This is consistent with results of FE study[13] which compared no attachment, rectangular lingual attachment, rectangular buccal attachment, and buccal ellipsoidal attachment on a central incisor that showed the rectangular lingual attachment showed maximum extrusive force with lower undesired moments. A SR[29] (based on included two FE studies) suggested positioning of the attachments on the lingual side of central incisor for extrusion/intrusion tooth movement.

The model BL that has attachments on both buccal and lingual sides generated negligible moment comparable to model NA (Figure 7.4) providing in vitro evidence to clinicians to utilize attachments on both sides of tooth to achieve bodily extrusion with minimum crown tip. However, it will be interesting to evaluate the patient acceptance of multiple composite attachments that can pose difficulty in insertion and removal of aligner trays in future studies.

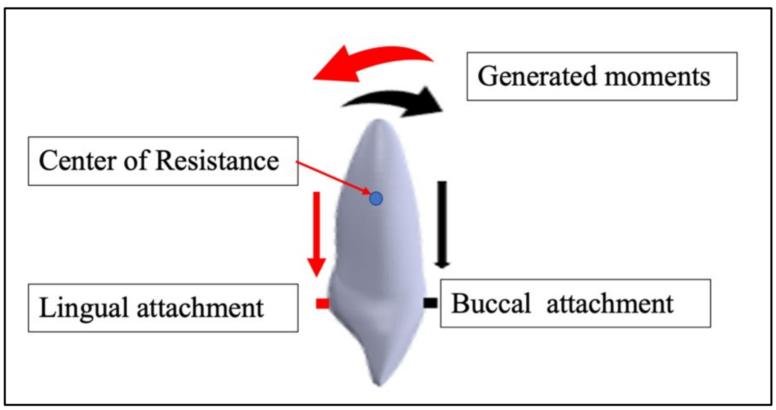

Figure 7.4 Model BL showing attachments on both buccal and lingual sides. Attachments generated moments in opposite direction negating each other effect

The results of this experiment should be considered with following limitations: 1) The initial forces and moments were assessed at 0.20 mm of displacement and does not consider the force system change over time that could be affected by stress relaxation properties of thermoplastic materials. It has been shown the load necessary to impose a constant deflection decreases over time.[30] 2) This in vitro experimental set up did not simulate the PDL and saliva. However, an in vitro study[31] reported small differences in the measurement force system at low magnitude of stimulated displacement and negligible effects at larger magnitudes of movement. 3) There was an interdental gap among the maxillary teeth set on OSIM such that loads generated by interaction between adjacent teeth were avoided. This meant that the maxillary lateral incisor was free to extrude without any interference from adjacent teeth. Clinically, it is important to evaluate if there is adequate space for the tooth to extrude. 4) Attachments were placed only on lateral incisors. Therefore, effect of multiple attachments on adjacent teeth were not studied. It will be interesting to evaluate how the force system changes when multiple teeth are involved rather than single teeth. 5) The magnitude of clinically significant forces >0.10 N was used in this experiment. This was based on the moderate to low level of evidence that suggested the force magnitude between 0.18 N and 3.60 N for included studies.[21]

7.5 Conclusions

- The presented thesis chapter provided experimental evidence to clinicians to utilize attachments for improving the predictability of extrusion forces applied with aligners as the model with no attachment did not generate clinically significant extrusion forces for normally inclined tooth.
- The model BL proved to be the best configuration to provide favorable bodily movement biomechanics by generating the maximum extrusion forces without significant tipping of the tooth.
- The model BA exerted comparable extrusion forces to model BL but generated significant moment that could tip the tooth lingually. This model could be favorable in clinical scenarios where lingual tipping of tooth is required along with extrusion.
- The model LA applied extrusion forces comparable to model BA but with less moment that could tip the teeth.

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Chapter 8: Conclusions and future work

This chapter provides a summary of the series of experiments included in the thesis along with conclusions and clinical significance of the thesis. It further discusses the limitations of the present project along with the recommendation for future work.

8.1 Summary and Conclusions

Aligner mechanotherapy has gained attention for treatment of malocclusion by providing an esthetic alternative to metal braces.[1] It can be removed by patient to perform oral hygiene practices while in orthodontic treatment.[2] On the other hand, aligner has strict requirement of patient compliance and limited ability to control various orthodontic tooth movements.[3,4] The understanding of the biomechanics of aligners could improve comprehension of their ability to exert force systems leading to improvement in predictability of treatment outcome. Therefore, this thesis was aimed to understand the biomechanics of aligners by using in vitro methods.

Prior to exploring the biomechanics of aligners, a SR was conducted to apprehend the predictability of aligners for orthodontic tooth movement. Previous SR done on the subject have pooled the studies that have utilized aligners before and after major aligner advancements. Aligner treatment have been constantly evolving, therefore, to understand the impact of advancement, only clinical studies after 2014 were included in the review. It can be deduced that predictability of tooth movement with aligners varies with tooth, and type of tooth movement. The overall mean accuracy of mesiodistal tipping was more than 75% where lower premolars were most precise followed by upper molar and lower incisors based on a moderate RoB data. Similarly, 77% to 97% of buccolingual inclination could be achieved with aligner mechanotherapy. While tipping seems to be predictable, bodily translation was shown to be limited with aligners even after altering them with auxiliaries such as attachments, and pressure points (divots, power ridges). Aligners exert force at the crown portion away from the CoR of the tooth thereby facilitating tipping movement. On the contrary, bodily translation with aligners is difficult as it entails that the applied force either must pass through the CoR of the tooth or require an equivalent system of forces and moments applied to the tooth crown. Other tooth movements such as rotation was achieved between 57% to 76% of the time, with even less rotation correction of rounded teeth (canine and premolars) at approximately 54%. Despite the improvements, most tooth movements were not predictable with aligner mechanotherapy posing the emphasis to understand the biomechanics of aligner mechanotherapy.

For this thesis, biomechanics of aligners were studied for different teeth i.e., central incisor, canine and second premolar by using PET-G material to understand the role of tooth anatomy on aligner force system. This knowledge was elaborated by the succeeding experiment that included other two commonly used aligner materials, namely PET and PU, analyzed for teeth of interest (central incisor, canine and second premolar). These initial experiments of the project provided the knowledge that different teeth anatomy, their location and material have implication in aligner biomechanics that can act as confounding factors in the assessment of the force system of aligners. In addition, the tested teeth experienced clinically significant moments for the analyzed materials that can tip the teeth when displaced, directing towards the need to supplement the aligner with auxiliaries where bodily tooth movement is required and evaluating their biomechanics. Therefore, the core factors such as teeth anatomy, aligner materials, and aligner auxiliaries that can influence biomechanics were the focus of this thesis.

Biomechanics of aligners is different from conventional fixed appliances. Where conventional fixed appliances apply forces via a wire engaged in a bracket attached on tooth, thereby applying specific point of force application to the tooth crown, aligners exert a contact force guiding the teeth into desired position by engaging on the various surfaces of the tooth requiring intimate contact between tooth surface and aligner. Aligner-tooth interface varies among teeth that have different anatomy resulting in variance in deformation of the aligner. An evaluation of the force system for aligner for different maxillary teeth such as central incisor, canine and second premolar by using 0.75-mm thick PET-G material in aim 1 of the project showed that mean Fy and Mx for canine were significantly more than for central incisor and premolar for 0.20 mm of lingual displacement. This agrees with the findings of following experiment of the thesis (aim 2) that established other two commonly used aligner materials: PET and PU (tested for central incisors, canine and second premolars) applied the maximum buccal force and corresponding moments on the canine. These findings lay emphasis that tooth anatomy and position in the arch could be an important factor when discussing the biomechanics of aligners.

An experiment 2 to assess the force system of PET, PET-G and PU aligner materials around various teeth of the maxillary arch of this project showed that these materials applied dissimilar force system on the same tooth. PET-G exerted less buccal force than PU on canine and second premolar, and less force than PET on canine. PU exerted more force than PET on the second premolar. This agreed with flexural modulus of tested materials after thermoforming that was more for PU in comparison to PET and PET-G using three point bending test on samples cut from post thermoformed aligners. It was noted that pre-thermoformed flexural modulus of PET-G was more as compared to other two materials. However, flexural modulus increased for PET, and PU increased their stiffness and force system after thermoforming. The different underlying physical properties as well alteration in response to thermoforming could lead to dissimilar force system by tested aligner materials. In addition to buccal force, intrusive force and moments that could tip teeth were generated on all the three tested teeth with three different materials in aim 2 of the project. Aligners wraps around the arch, engaging simultaneously on the occlusal, buccal, and lingual surfaces of the teeth that provide them with ability to apply compressive forces from the contact surface. Tooth surfaces are not symmetrical structures leading to creation of uneven distribution of forces and generation of moments. The tested teeth (central incisor, canine and second premolars) experienced clinically significant moment in aim 1 and 2 of the project that can tip the tooth directing towards the need to explore force system of the aligner with /auxiliaries for bodily translation. Consequently, two in vitro experiments were conducted to evaluate the biomechanics of utilizing the auxiliaries with aligner mechanotherapy for tooth movements such as bodily translation and extrusion where controlled root movement is required.

The addition of auxiliaries to aligner enhance the mismatch in specific points improving the contact area, and the force vector direction for desired tooth movement.[5] Nevertheless from a biomechanical perspective, these effects generated could be complex as the tooth has asymmetric geometry and the tooth-aligner contact changes with ongoing tooth movement.[6,7] Further, auxiliary location can influence the aligner force delivery system.[8] Therefore, effect of auxiliaries location were studied for two most difficult movements with aligners: bodily movement[9] and extrusion tooth movement[3] for this thesis project.

Bodily tooth movement and extrusion are difficult tooth movements as it depends on controlled root movement. Another challenge with extrusion is lack of undercuts for retention specially for anterior teeth that leads to slippage of aligners resulting in tooth lag.[10] Aligners with auxiliaries such as divots and attachments were utilized to analyze the biomechanics of bodily tooth movement and extrusion, respectively. For aim 3 of the project, divots (form of pressure points) were used in four configurations with varied vertical position on the crown and in different combinations of buccal/lingual sides of central incisor to assess biomechanics of varying location of divots across the crown of the tooth for bodily tooth movement. Similarly, attachments on the buccal and lingual side of the tooth were used to evaluate the biomechanics of attachment on lateral incisor for extrusion tooth movement for aim 4 of the project. These studies validated that vertical divot placement on central incisor and buccal/lingual attachment on lateral incisor from aim 3 and aim 4, respectively, has a significant effect on aligner biomechanics and their tactical arranged position could provide approximate root control.

8.2 Thesis contributions and clinical relevance

There are significant contributions made to literature because of this thesis research. The SR was conducted based on clinical evidence to highlight the efficiency of aligner mechanotherapy for various tooth movements that contribute to the existing knowledge about aligner predictability to clinicians. This provides evidence to clinician to base the selection of patients for the aligner mechanotherapy.

It was followed by series of in vitro experiments to explore biomechanics to comprehend aligner behavior with respect to varying tooth anatomy, aligner materials, and location of auxiliaries. An experimental set up (OSIM) with anatomical teeth recreated the dental arch with a temperature-controlled chamber to reproduce oral conditions to evaluate force system where other confounding factors such as individual response and related factors (compliance of wear) was omitted. The most used aligner materials with 0.75 mm of aligner thickness and 0.20 mm activation were used after thermoforming that correlates with the clinical protocol for aligners. Therefore, this project is valuable for responding to fundamental research questions for aligner biomechanics with maximum control providing guidance for future clinical testing.

This project was first to evaluate the role of tooth anatomy and tooth position in the aligner biomechanics. It improved the understanding of mechanical interaction of various teeth morphologies with aligners that will guide future clinical testing to consider anatomy and position of teeth as a confounding factor for evaluation of force system. With regards to clinical relevance, it will act as preliminary data for future research to determine the activation of aligner appliances differently for dissimilar anatomy and position of teeth across the dental arch.

The work done around aligner materials is of significance as it provided a force system of post thermoformed materials to improve our knowledge of most used aligner materials and their mechanical properties. This thesis project was one of the first to relate the force system and post thermoformed flexural modulus of aligner materials. The results guide the future in vitro studies to evaluate the aligner material mechanical properties after thermoforming that are altered by the process of thermoforming utilized for the fabrication of aligners.

To advance biomechanics knowledge, the force system was explored for auxiliaries that have become the essential part of aligners. To date, little work has been conducted on the positioning of the auxiliaries across the tooth crown that could significantly affect the force system. The results obtained from biomechanics of auxiliaries are encouraging for aligner research as strategic placement of auxiliaries could extend the utility and application of aligners to difficult tooth movement such as bodily movement and extrusion. Thus, this preliminary evidence could facilitate the design and treatment planning of aligner mechanotherapy regarding placement of auxiliaries for bodily movement and extrusion.

Overall, the results of this project will be instrumental in improving the predictability of aligners by understanding favorable location of auxiliaries for bodily translation of central incisor and extrusion of lateral incisor tooth. This biomechanical evidence will further guide the protocol and design of the aligner mechanotherapy that will improve the delivery of care by improving treatment outcome resulting in reducing the treatment time, and cost for orthodontic patients.

8.3 Limitations and future recommendations

The results of this project should be considered with its limitations. The first one was that this in vitro experimental set up did not include the PDL, tooth-to-tooth contact, and saliva.

The rigid connectors of the OSIM did not replicate the periodontal compliance. It is difficult to add periodontal simulation as periodontal compliance is non-linear, and there is wide variation of data in literature.[11, 12] The common assertion is that inclusion of periodontal compliance would significantly impact the force system resulting in less force system than predicted by in vitro studies. An in vitro study[13] validated artificial tooth-PDL-bone complex and compared its behavior with rigid dowels for third order orthodontic tooth movement. It was shown that at lower force system, the periodontal simulant borne the force system given its stiffness is less than surrounding support, however, when periodontal simulant was heavily compressed (>11 degree), the harder support system became overriding resulting in negligible effects. Having said that further investigations are needed simulating the PDL to obtain results that reflect precise tooth-PDL-bone complex behavior.

There were no interproximal contacts between metallic teeth fixed on OSIM. In normal dentition (n=15), it has been exhibited that there was anterior component of occlusal force when load was placed on the posterior teeth that progresses anteriorly through interproximal contacts and did not progress beyond contact points.[14] Accordingly, it was expected that friction and pressure from the interproximal contacts would impact the propagation and the resultant force system. Therefore, interproximal contacts were not preserved, isolating the tested tooth to prevent any interference of force system from the adjacent teeth that could bias the results.

Saliva could be another plausible factor that could affect the force system as aligners are fabricated from polymer structures that can absorb moisture causing expansion or changes in mechanical properties. Amorphous polymers possess relatively low molecular density that provides free volume for water intake leading to plasticization (increase in the molecular mobility due to reduction in internal cohesion between links of polymer chains). Water sorption is the phenomenon in the aligners that could induce dimensional changes and might affect the fit of the appliance, consequently, altering the force system exerted by aligners. An in vitro study that investigated the force system of 0.75 mm thick PET-G material by immersing the aligners in artificial saliva for seven days showed significant decay of force with increased immersion in saliva.[15] Another in vitro study pointed out decrease in force system of two aligner materials of PET-G immersed in artificial saliva.[16] However, initial force system was focus of investigation of this project that would not be predominantly affected by saliva. In future studies, the addition of oral factors such as saliva to the experimental set up could be of value as clinically, aligners are constantly subjected to saliva that is majorly composed of water.

Another limitation is related to innate aligner properties such as their viscoelastic nature and mechanical properties of aligners such as stress relaxation that decrease the force system of aligners over time of their usage.[17] As the goal of this project was to focus on initial force system, these factors, and their role were not considered in the current project.

Our experiments simulated an isolated tooth movement as compared to the clinical situation where multiple teeth were simultaneously moved which would result in complex force system. This was done to understand the role of biomechanical factors (anatomy, materials, and auxiliaries) at a tooth instead of exertion of a multiple force system by various simultaneous tooth movements. A future prospect could involve the use of more representative patient dentition models for understanding the biomechanics of aligners, but the design of such study will be complex and set up would be challenging with current OSIM equipment.

Finally, our project was focused on evaluation of force system of predominant materials used for aligners, however, there is constant progress of aligner materials with the aim to mitigate the biomechanical limitations of aligners, such as introduction of shape memory polymer and multi-layer thermoplastic material,[18] that is assumed to provide more constant force and more long-term action. It will be important to investigate their biomechanics as these materials have been utilized by commercial companies for clinical practice. Therefore, advanced aligner materials along with their varying material thickness (varies from 0.5 mm to 1.00 mm based on various manufacturers suggestions) could be an area of further research.

Apart from the improvement in the experimental set up, there are several projects that could be logical extensions of this work:

Firstly, this project focused on the investigation of the initial force system by aligner mechanotherapy that could be expanded by evaluation of the force system over extended time [such as a period of seven days (typical prescribed aligner wear time)] to make more informative conclusions in a simulated oral environment. Aligner force system might vary significantly over time due to its properties such as creep and stress relaxation. The usual supposition is that the aligner force system will decrease over time which will deteriorate its tooth movement efficiency, but this reduction is dependent on several factors such as amount of activation, aligner material, and temperature. It is therefore important to quantify the aligner force system over time to predict effective tooth movement.

Secondly, anchor teeth are another avenue of research in orthodontic mechanics. The anchor (supporting) teeth bear the reactionary forces system against the actively moving teeth to equilibrate the system, the maximum anchorage requirement being no displacement of supporting teeth from their position. Aligners can be considered to have better anchor control than conventional fixed appliance as it has extensive contact on the buccal, lingual, and occlusal surfaces of the tooth. However, studies have shown the movement of the supporting teeth with aligner therapy.[19,20] Limited literature have assessed the force system on the anchor teeth with aligner therapy. This can be an important possibility as if there is no significant force system on anchor teeth then aligner application can be extended to maximum orthodontic anchorage requirement patients.

Thirdly, it will be interesting to evaluate the force system of directly printed aligners. The conventional method of fabrication of aligner is a multiple step process that involves intraoral scanning to produce a dental model over which aligner material is thermoformed that could be time consuming. Further, thermoformed aligners have shown to have non-uniform thickness that could affect the force system posing a challenge to execute programmed tooth movement.[21] A 3D printed aligners could reduce labor time with increased dimensional stability that could possibly exert force system providing greater predictability of tooth movement.

Finally, the future work could also investigate several other factors, apart from one's studied in this project, that influence the aligner force system such as material thickness, amount of activation, type of tooth movement, different shapes of auxiliaries, and aligner auxiliaries for different tooth movement.

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