Mechanical Properties and Patient Perceptions of Commonly Used Clear Aligner Systems As-Received and After Clinical Use

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MECHANICAL PROPERTIES AND PATIENT PERCEPTIONS
OF COMMONLY USED CLEAR ALIGNER SYSTEMS
AS-RECEIVED AND AFTER CLINICAL USE

by

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ABSTRACT
MECHANICAL PROPERTIES AND PATIENT PERCEPTIONS
OF COMMONLY USED CLEAR ALIGNER SYSTEMS
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Lauren Teske, D.D.S.
Marquette University, 2015

Background/Objectives: This study aimed to investigate the viscoelastic properties of two clear aligner systems, Invisalign (Align Technology, Inc, Santa Clara, CA, USA) and Simpli5 (Allesee Orthodontic Appliances, Sturtevant, WI, USA), and determine if there was a difference after use. A survey assessed patients’ perceptions of the aligner material and post-treatment satisfaction.

Materials/Methods: Mandibular aligners were collected from two patients after 2-3 weeks of use (n=6). Duplicate, unused aligners were obtained for each patient (n=6). Dynamic mechanical analysis (DMA) characterized the viscoelastic properties of the materials. Three tests were done on separate specimens: frequency scan (0.1-10 Hz under 25 µm displacement at 37°C), creep-recovery (1 N, 2 N and 3 N at 37°C) and temperature ramp (28°-120°C at 5°C/min under 1 Hz and 25 µm displacement). The survey was given to sequential patients (n=7) after completing aligner therapy. Repeated measures of multivariate analysis of variance were performed.

Results: No statistically significant difference in storage modulus, loss modulus, tan δ, creep compliance, or strain recovery was found comparing the materials in as-received and after-use states, and no significant difference was found between Invisalign and Simpli5 (p>0.05). The tan δ (loss modulus/storage modulus) values for as-received Invisalign and Simpli5 at 1 Hz were 0.056±0.01 and 0.093±0.03. The creep compliance (µm²/N) for as-received Invisalign and Simpli5 were 300±50 and 155±36. Strain recoveries were >94%. Patients’ survey responses were predominately positive, as all were pleased with the esthetics, comfort, and performance of the aligners.

Conclusions: While there was no significant difference between the materials before or after use, both Invisalign and Simpli5 demonstrated favorable qualities, including low tan δ values and positive patient perception of the material.
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CHAPTER 1
INTRODUCTION

Patient demands for esthetic orthodontic treatments have grown to include esthetic appliances, such as ceramic brackets, lingual orthodontics, and clear aligner therapy (Rovall et al. 2009, Ziuchkovski et al. 2008, Jeremiah et al. 2011). If a patient’s orthodontic treatment motivation is esthetically driven, they may prefer a more attractive appliance as well. More Invisalign patients reported seeking treatment to improve their appearance (85% vs. 67% for fixed appliance patients), where more fixed appliance patients reported seeking treatment because their dentist referred them (26% vs. 3% for Invisalign patients) (Miller et al. 2007).

Companies including Align Technology (Santa Clara, CA) and Allesee Orthodontic Appliances (Sturtevant, WI) have developed a method of fabricating custom-made, clear aligners designed to gradually and sequentially move teeth to their desired positions (Kuo and Miller 2003). The short-term chemical and physical changes, as well as the structural conformation and leaching before and after use, have been previously studied on Invisalign (Align Technology) (Gracco et al. 2009, Schuster et al. 2004). However, Invisalign has recently changed the material they use in making their aligners to SmartTrack Aligner Material, which continues to be a polyurethane based material, claimed to have increased elasticity and a more precise fit (Align Technology MSDS).

No studies to date have investigated the mechanical properties of the clear aligners manufactured by Allesee Orthodontic Appliances (AOA), including Simpli5 and Red, White and Blue.
A better understanding of the material properties could lead to better sequencing of tooth movement and more efficient treatment (Drake et al. 2012). As treatment efficacy with clear aligners has been reported to be 41% to 59%, further investigation in material behavior is needed for improvement (Kravitz et al. 2009, Chisari et al. 2014, Simon et al. 2014a). The force delivery properties of aligners are influenced by both the direction of displacement and the stiffness of the material used (Hahn et al. 2010a, Hahn et al. 2010b). A recent study has found that the orthodontic force produced by a thermoplastic material is strongly correlated with its hardness and elastic modulus; therefore, any significant differences in the properties of clear aligners may have an impact on what aligner system the practitioner chooses to use (Kohda et al. 2013).

Material properties may even affect the treatment outcome, as it was found that patients wearing a harder aligner material for a two week activation time showed the best results in all measurements of occlusal and alignment improvement, although the difference was not statistically significant (Clements et al. 2003).

It is also important to determine if the material’s properties change after use, as biofilm modification and oral environmental conditions may have effects on the hardness and viscoelasticity of the material (Eliades and Bourauel 2005). Previous studies have detected changes in the Invisalign material after use, including increased hardness, abraded cusp tips, integument adsorption, biofilm calcification, micro-cracks, delamination, and loss of transparency (Schuster et al. 2004, Gracco et al. 2009).

This study aimed to investigate the mechanical properties of two clear aligner systems, Invisalign and Simpli5, and determine if there was a difference in the aligner properties after being worn intra-orally for 2-3 weeks. Dynamic Mechanical Analysis
(DMA) was used to characterize the viscoelastic and creep compliance properties of the used and unused aligners under conditions encountered during their typical use (i.e. intraoral temperature and mastication frequency). Previously, DMA has been used to investigate denture soft lining materials, dental composites, nickel-titanium closed coil springs, titanium orthodontic wires and mouthguard materials (Hong et al. 2012, Murata et al. 2002, Waters et al. 1996, Thorat et al. 2013, Vouvoudi and Sideridou 2013, Ryou et al. 2013, Khan et al. 2008, Mesquita et al. 2006, Emami and Söderholm 2005, Cox et al. 2014, Laino et al. 2011, Gould et al. 2009). However, DMA has not yet been used to investigate clear aligner materials.

Additionally, a survey assessed patients’ perceptions of the aligner material, as well as post-treatment satisfaction. While practitioners prefer increased treatment efficacy with clear aligners, patient satisfaction should also be assessed. Patient preferences with treatment process and esthetic needs can drive treatment decisions despite appliance shortcomings. Patients have reported positive responses on quality of life surveys during aligner wear, but their perceptions of the aligners during wear and post-treatment satisfaction have not yet been assessed (Miller et al. 2007, Shalish et al. 2012, Tuncay et al. 2013).
CHAPTER 2
LITERATURE REVIEW

**Esthetic Treatment Demands**

Patient demands for esthetic orthodontic treatment have grown to include esthetic appliances, such as ceramic brackets, lingual orthodontics, and clear aligner therapy (Rosvall et al. 2009, Ziuchkovski et al. 2008, Jeremiah et al. 2011). The appearance of orthodontic appliances plays a significant role in patients’ decisions to receive orthodontic treatment: a recent survey found that 33% of young adults would be unwilling to wear visible braces if needed (Bergstrom et al. 1998). Another study found that while traditional metal brackets were found to be esthetically acceptable to only 55% of adults, clear aligners were acceptable to over 90% (Rosvall et al. 2009). Furthermore, they showed no difference in acceptability ratings when considering the appliances for their own treatment or for their children’s treatment, and they were willing to pay more for appliances they deemed more esthetic. Clear aligner preference extends to adolescents as well, as surveyed 15-17 year olds rated clear aligners most acceptable and attractive over ceramic, self-ligating, traditional, and shaped brackets (Walton et al. 2010).

As more adults are seeking orthodontic treatment, esthetic improvements of appliances may be a major factor in the increase in acceptability of orthodontic treatment for adults. Perceived personal characteristics of adults may be influenced by their dental appearance and orthodontic appliance design: greater perceived intellectual ability was associated with the appearance of no appliance or aligner appliances compared to steel or ceramic appliances (Jeremiah et al. 2011). This could likely influence the patient’s orthodontic appliance choice. If their treatment motivation is esthetically driven, they
may prefer a more esthetic appliance as well. More Invisalign patients reported seeking
treatment to improve their appearance (85% vs. 67% for fixed appliances patients), where
more fixed appliance patients reported seeking treatment because their dentist referred
them (26% vs. 3% for Invisalign patients) (Miller et al. 2007).

**Clear Aligner Therapy**

Companies including Align Technology (Santa Clara, CA) and Allesee
Orthodontic Appliances (Sturtevant, WI) have developed a method of fabricating custom-
made, clear aligners designed to gradually and sequentially move teeth to their desired
positions (Kuo and Miller 2003) (Figure 1). The short-term chemical and physical
changes, as well as the structural conformation and leaching before and after use have
been previously studied on Invisalign (Align Technology) (Gracco et al. 2009, Schuster
et al. 2004). However, Invisalign has recently changed the material they use in making
their aligners to SmartTrack Aligner Material, which continues to be a polyurethane
based material (Align Technology MSDS). Align Technology states that the SmartTrack
material delivers a lower initial insertion force for improved patient comfort, while
maintaining more constant force over the two-week treatment period. Additionally, it is
claimed to have higher elasticity and a more precise fit. This is beneficial in that it
improves tracking and control of tooth movements (Align Technology brochure). No
studies to date have investigated the mechanical properties of the clear aligners
manufactured by Allesee Orthodontic Appliances (AOA), including Simpli5 and Red,
White and Blue. Both systems use AOA’s highly esthetic proprietary material and are
designed to treat minor to intermediate anterior misalignment, only differing in the number of aligners the patient has to wear to correct the misalignment (AOA brochure).

**Figure 1.** Unused Invisalign (left) and Simpli5 (right) mandibular aligners.

The aligner manufacturing process differs for the two companies. Align Technology uses stereolithography technology to create plastic resin models from photoactivated polymer (Kuo and Miller 2003). The patient’s polyvinyl siloxane (PVS) impressions are scanned and converted into 3-dimensional electronic models, where the teeth are electronically separated and moved by a technician. Alternatively, the models can be fabricated directly from the patient’s intraoral scan (Garino and Garino 2012). Each stage of treatment is converted into a physical model with a stereolithography apparatus, and an automated aligner system heats, forms and laser-marks sheet plastic over each model (Kuo and Miller 2003). Ridges from the model formed by stereolithography can be seen in the finished aligner material, and the tray is scalloped
along the gingival margin (Figure 2). Conversely, Allesee Orthodontic Appliances fabricates their aligners from stone models where the individual teeth are manually sectioned by lab technicians and repositioned with wax (McNamara and Brudon 2001, Kim and Echarri 2007). The finished product is highly transparent with a straight-line finish instead of scalloping the gingival margins (Figure 2). Each system produces clear aligners from the models, each corresponding to a 2-3 week interval of treatment. Progressive alignment of 0.25 to 0.5 mm is designed into each aligner (Simon et al. 2014b). Aligner systems including ClearSmile and Raintree Essix allow more displacement in each aligner (0.5 to 1 mm) compared to the Invisalign system (0.25 to 0.33 mm) (Kwon et al. 2008, Simon et al. 2014b).

Figure 2. Aligner material. A. Invisalign aligner. Notice the generalized ridges from the stereolithographic manufacturing process, the impression of the attachments on the premolars and how the aligner is scalloped along the gingival margin. B. Simpli5 aligner. The material appears more translucent in comparison to Invisalign and the edge is trimmed straight across the gingival margins of the teeth.

Benefits of clear aligner therapy include esthetics, comfort, oral hygiene improvement and reduced chair time (Boyd et al. 2000). Adult Invisalign patients have reported less pain and fewer negative impacts on their lives than those with fixed
appliances (Miller et al. 2007, Shalish et al. 2012). Those with fixed appliances took more pain medication during the first week of orthodontic treatment than the Invisalign patients (Miller et al. 2007). Adolescents also have positive responses to aligners. The vast majority did not limit foods, avoid communication or feel self-conscious while wearing the aligners (Tuncay et al. 2013). After three months, 70% had seldom or never experienced discomfort, and 80% had seldom or never used pain relievers. As treatment progressed, the patients reported even less discomfort (Tuncay et al. 2013). In addition to improved comfort, clear aligners also show favorable consequences for periodontal health compared to fixed appliance treatment (Kluckowska et al. 2011). After 24 months, the plaque index decreased 15.1% in the maxilla and 16.6% in the mandible in teenagers using Invisalign Teen aligners (Tuncay et al. 2013).

Orthodontic appliances must be selected on the basis of more than appearance, as the appliances must have desirable functional properties and treatment outcomes. A systematic review in 2005 determined there was not sufficient evidence to adequately evaluate Invisalign treatment effects, and that high-quality clinical evidence was needed (Lagravère and Flores-Mir 2005). Since then, there have been numerous studies that have looked at the efficacy and treatment outcomes of Invisalign treatment. Treatment efficacy with clear aligners has recently been reported to be 41% to 59% (Kravitz et al. 2009, Chisari et al. 2014, Simon et al. 2014a). While the reported treatment efficacy numbers are low, case reports have shown successfully completed moderate to difficult orthodontic malocclusions, including open bite, extraction and surgical cases (Hönn and Göz 2006, Womack 2006, Boyd 2005, Boyd 2008, Marcuzzi et al. 2010, Schupp et al.)
Furthermore, resolving moderately severe anterior crowding can be successfully accomplished with Invisalign (Krieger et al. 2012).

Treatment outcomes of Invisalign have been compared to fixed appliances using the objective grading system of the American Board of Orthodontics. Compared to traditional braces, Invisalign lost an average of 13 more points and had a 27% lower passing rate (Djeu et al. 2005). While the strengths of Invisalign included its ability to close spaces and correct anterior rotations and marginal ridge heights, it was deficient in correcting large anteroposterior discrepancies and occlusal contacts (Djeu et al. 2005). Kuncio et al. evaluated casts from patients treated with Invisalign, and compared them to patients treated with fixed appliances immediately after treatment and 3 years post-treatment (Kuncio et al. 2007). They found that patients treated with Invisalign relapsed more than those treated with fixed appliances, particularly in the maxillary anterior region. Even though the Invisalign group relapsed more, the mean alignment was superior to the fixed appliance group before and after the retention phase (Kuncio et al. 2007).

**Orthodontic Tooth Movement with Clear Aligners**

The type of desired tooth movement influences the efficacy of treatment with clear aligners. When looking at dental improvements, aligners were most successful in improving anterior alignment, transverse relationships and overbite (Clements et al. 2003). Aligners were least successful at improving buccal occlusion and only moderately successful at improving midline and overjet (Clements et al. 2003). One study reports lingual constriction to be the most accurate movement (47.1%) and extrusion to be least
accurate (29.6%) (Kravitz et al. 2009). Additionally, they determined that canine rotation accuracy was significantly lower than for other teeth and lingual crown tip was significantly more accurate than labial crown tip. This study was done without auxiliaries in order to provide a baseline value of what can be achieved with aligners alone. A recent study investigated the efficacy of Invisalign aligners in tooth movements deemed difficult with aligners and analyzed the influence of auxiliaries, including attachments and Power Ridges (Simon et al. 2014a). They found that premolar derotation showed the lowest accuracy (40%), while molar distalization was the most effective movement (87%). No statistically significant difference was found with the use of attachments in the efficiency of premolar derotation or molar distalization. Additionally, no substantial difference was observed if incisor torque (42% mean accuracy) was supported with a horizontal ellipsoid attachment or a Power Ridge.

Other factors can influence orthodontic tooth movement with clear aligners, such as age, gender, root length, and bone levels. A quadratic (u-shaped) relationship between age and tooth movement was found for women, indicating an increase in tooth movement in younger and older women (Chisari et al. 2014). However, a more linear relationship was found for men, with decreased movement at older ages. The study also found a significant negative correlation between tooth movement and the measurement of the apex to the center of rotation, but bone quality was not correlated with tooth movement (Chisari et al. 2014). This may account for individual differences in treatment efficacy during clear aligner therapy.

As tooth movement with aligners has been distance-based as opposed to force-based with fixed appliances, recent studies have attempted to quantify the force delivery
properties of aligners. Initially it was determined that median force values for intrusion
during rotation of an upper central incisor at the low activation range of ±0.17 mm were
between 0.0 N and -0.8 N, with the highest intrusive force being -5.8 N for a rotation of
-0.51 mm (Hahn et al. 2010a). Recently, it has been reported that initial mean moments
were 7.3 N·mm for maxillary incisor torque, 1.0 N for distalization and 1.2 N·mm
(without attachments) to 8.8 N·mm (with attachments) for premolar rotation (Simon et al.
2014b). While the recent findings suggest that bodily tooth movements and torque can
be performed with aligners since they deliver the necessary force systems, the ideal
values given by Proffit (0.35 to 0.6 N for rotation and tipping, and 0.1 to 0.2 N for
intrusion) were exceeded (Proffit et al. 2013).

The force delivery properties of aligners are influenced by both the direction of
displacement and the stiffness properties of the material used (Hahn et al. 2010a, Hahn et
al. 2010b). At lower activation ranges, different chemical and physical material
properties might be responsible for the different force levels. The local deformations of
the material and friction at the contact areas may be of relevance (Hahn et al. 2010a).

**Material Properties of Clear Aligners**

A better understanding of the material properties could lead to better sequencing
of tooth movement and more efficient treatment (Drake et al. 2012). It has been found
that there is great variety in mechanisms among the initial force systems during clear
aligner therapy, as an aligner with high initial force may be followed by an aligner with a
low force, resulting in tooth movement that is not constant (Simon et al. 2014b).
Additionally, as the order of sequential aligners increase, aligner strains relating to force
delivery increase (Vardimon et al. 2010). A recent study has found that the orthodontic force produced by a thermoplastic material is strongly correlated with its hardness and elastic modulus; therefore, any significant differences in the properties of clear aligners may have an impact on what aligner system the practitioner chooses to use (Kohda et al. 2013). Material properties may even affect the treatment outcome, as Clements et al. found that patients wearing a harder aligner material for a two week activation time showed the best results in all measurements of occlusal and alignment improvement, although the difference was not statistically significant (Clements et al. 2003).

It is also important to determine if the material’s properties change after use, as biofilm modification and oral environmental conditions may have effects on the hardness and viscoelasticity of the material (Eliades and Bourauel 2005). During the time the aligners are worn, they are exposed to salivary enzymes, byproducts of oral flora, liquids, and trauma caused by swallowing, speech and bruxism (Gracco et al. 2009). In vitro testing conditions are unable to simulate the intraoral conditions the aligners are exposed to, including plaque accumulation. Therefore, retrieval analysis obtains critical information since it investigates the material in its intended environment (Eliades and Bourauel 2005).

Previous studies detected changes in the Invisalign material after use. Differences were found in the surface morphology of aligners after use, including abraded cusp tips, integument adsorption, biofilm calcification, micro cracks, delamination, and loss of transparency (Schuster et al. 2004, Gracco et al. 2009). Delamination of the material can lead to loss of mechanical strength of the aligner (Gracco et al. 2009). The loss of transparency may be caused by trauma from chewing and bruxism (Gracco et al. 2009).
Additionally, buccal segments showed an increase in hardness, which may be caused by masticatory-induced cold work (Schuster et al. 2004).

Although polyurethane is biocompatible, it is not an inert material, as it is sensitive to heat, humidity and salivary enzymes (Gracco et al. 2009). No traceable byproducts were detected after Invisalign aligners were stored in artificial saliva or an ethanol aging solution (Schuster et al. 2004, Gracco et al. 2009). Furthermore, no evidence of cytotoxicity or estrogenicity was found at various concentrations of aligner eluents (Eliades et al. 2009). This could be related to the material’s structure, as it is composed of polyurethane with added methylene diphenyl diisocyanate and 1,6 hexanediol (Schuster et al. 2004). The diphenyl structure provides stability and sufficient reactivity to form a polymer free of byproducts (Schuster et al. 2004). Also, unlike the aromatic rings in BisGMA, polyurethane has short rigid portions joined by short flexible hinges and long flexible portions (Eliades et al. 2009). However, the in vitro testing conditions may have underestimated the material’s chemical stability and future in vivo studies are needed.

**Dynamic Mechanical Analysis**

Dynamic mechanical analysis (DMA) involves applying an oscillating force or displacement to a sample and analyzing the material’s response. DMA is especially appropriate for viscoelastic materials, as it determines both the elastic and viscous response of the material. When a sinusoidal stress is applied to an entirely elastic material, the deformation occurs exactly in phase with it. A completely viscous material will respond with the deformation lagging 90° behind the applied stress. However, when
the stress is applied to a viscoelastic material, it will not behave as a perfectly elastic or viscous material, and the deformation will lag behind the stress by some angle <90° (Mesquita et al. 2006).

The properties measured under the oscillating load are storage or elastic modulus (E’), loss or viscous modulus (E’’), and tan δ (ratio of loss to storage modulus). The storage modulus represents the stiffness of the material and is proportional to the energy stored during a loading cycle (Vouvoudi and Sideridou 2013). The loss modulus is related to the amount of energy lost due to viscous flow (Vouvoudi and Sideridou 2013). Therefore, a greater storage modulus indicates greater stiffness, while a greater loss modulus indicates a greater tendency to undergo time dependent deformation. Tan δ is a measure of how well the material can disperse energy throughout its mass and is related to molecular mobility. While a high tan δ indicates high molecular mobility, a low tan δ indicates less molecular mobility, which means the material will quickly respond to load and return to its original shape faster (Vouvoudi and Sideridou 2013).

Previously, DMA has been used to investigate denture soft lining materials (Hong 2012, Murata 2002, Waters 1996), dental composites (Thorat et al. 2013, Vouvoudi and Sideridou 2013, Ryou et al. 2013, Khan et al. 2008, Mesquita et al. 2006, Emami and Söderholm 2005), nickel-titanium closed coil springs (Cox et al. 2014), titanium orthodontic wires (Laino et al. 2011), and mouthguard materials (Gould et al. 2009). However, DMA has not yet been used to investigate clear aligner materials.

A DMA instrument is also able to perform tests utilizing a constant load rather than an oscillatory load, thus allowing creep-recovery testing. Creep-recovery testing examines a material’s response to a constant load and its behavior on removal of that load.
An advantage of this creep test is the ability to mimic the conditions seen in use. Comparing materials after multiple cycles can be used to magnify the differences between materials, as well as predict long-term performance (Menard 2008).

Objective

This study aimed to investigate the mechanical properties of two clear aligner systems, Invisalign and Simpli5, and determine if there was a difference in the aligner properties after being worn intra-orally for 2-3 weeks. Dynamic Mechanical Analysis was used to characterize the viscoelastic and creep compliance properties of the used and unused aligners under conditions encountered during their typical use (i.e. intraoral temperature and mastication frequency). A creep-recovery test, frequency-scan, and temperature ramp were done to characterize these mechanical properties that directly affect the performance of the aligners, as it has been found that the orthodontic force produced by a thermoplastic material is strongly correlated with its hardness and elastic modulus (Kohda et al. 2013).

Additionally, patient satisfaction with the esthetics and performance of the aligners was assessed with a survey. While practitioners may prefer increased treatment efficacy with clear aligners, patient satisfaction should also be assessed, as any shortcomings of clear aligner therapy might have little clinical significance if patients are satisfied with the treatment process and their post-treatment smile. Patients have reported positive responses on quality of life surveys during aligner wear, but their perceptions of the aligners during wear and post-treatment satisfaction have not yet been assessed (Miller et al. 2007, Shalish et al. 2012, Tuncay et al. 2013).
Sample retrieval and preparation

Representative samples of three mandibular aligners were collected from two patients after being worn in the oral cavity for 2-3 weeks. One patient was treated with Invisalign, while the other patient was treated with Simpli5. Duplicate, unused (as-received) aligners were obtained for each patient.

The as-received and after-use mandibular aligners were cut into 3 segments (2 posterior and 1 anterior) and then sectioned in order to better approximate rectangular beams (30 to 39 mm in length, 6 to 10.5 mm in width, and 0.5 mm in thickness), as shown in Table 1 and Figure 3. Prior to testing, the length, width, and thickness of the specimens were measured with a caliper. The specimens’ width was measured at 8 to 11 different points, posterior and anterior segments respectively, and averaged. Both materials were uniform in thickness.

The lengths were variable because the sections from the aligner were cut interproximally rather than through a tooth imprint. However, this differing length is rather inconsequential as the stress state in 3-point bending is determined by the testing span length. The width varied between aligner products because of the scalloped versus non-scalloped nature of the aligners. For all measures mentioned below except creep compliance, actual dimensions were factored in so as to normalize results, i.e. modulus takes into account the dimensions of the specimen to determine stress and strain values.
Table 1. Sample preparation

<table>
<thead>
<tr>
<th></th>
<th>As-received/ before use</th>
<th>After 2-3 weeks of intraoral use</th>
<th>Creep-Recovery Sample Dimensions (mm)</th>
<th>Frequency Scan Sample Dimensions (mm)</th>
<th>Temperature Ramp Sample Dimensions (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Invisalign</strong></td>
<td>3</td>
<td>3</td>
<td>35 x 6.3 x 0.5</td>
<td>39 x 7.5 x 0.5</td>
<td>32 x 6.0 x 0.5</td>
</tr>
<tr>
<td>(Align Technology)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Simpli5</strong></td>
<td>3</td>
<td>3</td>
<td>32 x 8.0 x 0.5</td>
<td>35 x 10.5 x 0.5</td>
<td>30 x 6.5 x 0.5</td>
</tr>
<tr>
<td>(Allesee Orthodontic Appliances)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 3. Sample preparation. A. The as-received and after-use aligners were cut into 3 segments: 2 posterior and 1 anterior. B. The segments were then sectioned into rectangular beams. C. The buccal segments of the specimens were used for testing. D. Prior to testing, the specimens’ length, width and thickness were measured. Because of the scalloped gingival margins, the widths were measured at 8-11 points and averaged.
Dynamic Mechanical Analysis

A Q800 DMA (TA Instruments, New Castle, Delaware, USA) was calibrated using a standard block of stainless steel. All testing was done in three-point bending mode, and the support separation was 20 mm (Figures 4 and 5). The specimens were preloaded to 0.0100 N to stabilize prior to testing. Three types of tests were done on separate aligner specimens: frequency scan, creep-recovery, and temperature ramp.
Figure 4. Q800 DMA (TA Instruments, New Castle, Delaware, USA). A. Liquid nitrogen tanks. B. Furnace closed. C. Furnace open. D. Three-point bending fixture and stage.
Figure 5. Experimental set up. A. Invisalign specimen on three-point bending fixture, prior to loading (frontal view) B. Simpli5 specimen on three-point bending fixture, prior to loading (sagittal view).

For the frequency scan, testing was performed over a frequency range of 0.1 to 10 Hz under 25 µm displacement at 37°C. The frequency value of 0.1 Hz simulates behavior at rest, while the frequency value of 1 Hz simulates behavior during mastication (Murata et al. 2002). The isothermal temperature of 37°C was chosen to simulate intraoral conditions.

During the creep-recovery test, the specimens had static forces of 1 N, 2 N, and 3 N applied during the creep-recovery test at an isothermal temperature of 37°C. The stress was applied for 1 minute, and the specimens were allowed to recover for 3 minutes. This sequence was done three times for each force value.

A temperature range of 28-120°C was selected for the temperature ramp to cover intraoral temperature, observed to be up to 60°C, and the material’s likely glass transition temperature ($T_g$) (Moore et al. 1999). The temperature was ramped from 28°C to 120°C.
at 5°C/min under a frequency of 1 Hz and 25 µm amplitude. The T<sub>g</sub> will be determined from the peak of the tan δ curve.

**Survey**

A brief survey of 9 questions with three choices per question was given to 7 sequential patients undergoing clear aligner treatment (Figure 6). Approval was obtained from the Institutional Review Board at Marquette University. The survey asked for comment on their satisfaction with the esthetics and performance of the aligners.
Figure 6. Survey used to assess patient satisfaction.

Statistical Analysis

For the frequency scan, storage modulus, loss modulus, and tan δ at three frequencies (0.1, 1 and 10 Hz) were selected for statistical analysis. For the creep-recovery test, the creep compliance value and the strain recovery (%) at the end of the
first 1 N application were selected for statistical analysis. The temperature scan obtained a single plot for each specimen category; therefore, no statistical analysis was done.

Repeated measures multivariate analysis of variance (MANOVA) was performed to analyze the frequency data with as-received vs. used as a within subject factor and Invisalign vs. Simpli5 as a between subject factor. A significance level of 0.05 was considered to be significant. If the p-value of the multivariate test resulted in $P < 0.5$, inferences on univariate tests were further made with a significance level of 0.05. If the p-value of multivariate test resulted in $P > 0.05$, the results of univariate tests were only considered descriptive and no significant conclusions were drawn. Univariate tests were performed using the non-parametric Wilcoxon Rank Sum test.

Survey responses were given the values of +1 for a positive reply, 0 for a neutral reply and -1 for a negative reply. The overall survey responses were averaged. A score $< 0$ can be interpreted as patient dissatisfaction with clear aligners, with the lowest value of -1 being highly dissatisfied. A score $> 0$ can be interpreted as patient satisfaction with clear aligners, with the highest value of +1 being highly satisfied.
CHAPTER 4
RESULTS

Based on the repeated measures MANOVA, the difference between as-received and used samples was not significantly different when comparing the frequency test results for Invisalign with Simpli5. Further, at each frequency (Table 2, Figures 7-9), the difference for storage modulus, loss modulus, and tan δ between Invisalign and Simpli5 was not statistically significant (P=0.104 at frequency 0.1 Hz, P=0.404 at frequency 1.0 Hz, and P=0.120 at frequency 10 Hz). When using univariate tests (Wicoxon Rank Sum), no significant difference (P>0.05 for all tests) was found. For storage modulus at frequency 1 Hz and 10 Hz, a p-value of 0.10 was found. This suggests that non-significance could be due to the small sample size. The tan δ (loss modulus/storage modulus) values for as-received Invisalign and Simpli5 at 1Hz were 0.056±0.01 and 0.093±0.03. Frequency scans of representative samples are displayed (Figures 10-13).
<table>
<thead>
<tr>
<th></th>
<th>Storage Modulus (MPa)</th>
<th>Loss Modulus (MPa)</th>
<th>Tan δ</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>As-received</td>
<td>Used</td>
<td>As-received</td>
</tr>
<tr>
<td><strong>Invisalign</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.1 Hz</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>4599 (1592)</td>
<td>3944 (1354)</td>
<td>241 (72)</td>
</tr>
<tr>
<td></td>
<td>4817 (1657)</td>
<td>4120 (1330)</td>
<td>262 (76)</td>
</tr>
<tr>
<td>10 Hz</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>5135 (1774)</td>
<td>4261 (1168)</td>
<td>308 (119)</td>
</tr>
<tr>
<td><strong>Simpli5</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.1 Hz</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>4902 (4007)</td>
<td>2892 (198)</td>
<td>413 (392)</td>
</tr>
<tr>
<td></td>
<td>4857 (3912)</td>
<td>5137 (3946)</td>
<td>456 (406)</td>
</tr>
<tr>
<td>10 Hz</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>4744 (3646)</td>
<td>5039 (4004)</td>
<td>575 (523)</td>
</tr>
</tbody>
</table>

Table 2. Frequency scan descriptive statistics.

Figure 7. Mean storage modulus values with standard error bars.
**Figure 8.** Mean loss modulus values with standard error bars.

**Figure 9.** Mean tan δ values with standard error bars.
Figure 10. Frequency scan of Invisalign as-received sample.

Figure 11. Frequency scan of Invisalign used sample.
Figure 12. Frequency scan of Simpli5 as-received sample.

Figure 13. Frequency scan of Simpli5 used sample.
For the creep test data, the repeated measures MANOVA did not yield any significance when comparing Invisalign with Simpli5 (P = 0.219) (Table 3, Figures 14 and 15). The univariate test (Wilcoxon Rank Sum test) also did not yield any significance for creep compliance and strain recovery. However, the p-value for the creep compliance was 0.10, which indicates that non-significance could be due to lack of sample size. The creep compliance (µm²/N) for as-received Invisalign and Simpli5 were 300±50 and 155±36, respectively. Strain recoveries were >94% for all groups. Creep compliance curves for representative samples are presented (Figures 16-19).

<table>
<thead>
<tr>
<th></th>
<th>Creep Compliance (µm²/N)</th>
<th>Strain Recovery (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>As-received</td>
<td>Used</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invisalign</td>
<td>300 (50)</td>
<td>374 (57)</td>
</tr>
<tr>
<td>Simpli5</td>
<td>155 (36)</td>
<td>136 (11)</td>
</tr>
</tbody>
</table>

Table 3. Creep-recovery test descriptive statistics.
Figure 14. Mean creep compliance values at the end of the first 1N application with standard error bars.

Figure 15. Mean strain recovery values three minutes after the first 1N application with standard error bars.
Figure 16. Invisalign as-received sample during creep recovery testing.

Figure 17. Invisalign used sample during creep recovery testing.
Figure 18. Simplified as-received sample during creep recovery testing.

Figure 19. Simplified used sample during creep-recovery testing.
The temperature scan revealed that the storage modulus slightly decreased with increasing temperature within clinically relevant temperatures (Figure 20). Additionally, the used samples of each system exhibited greater storage moduli than the as-received samples (Figure 20). Representative storage modulus, loss modulus, and tan δ plots over the full temperature range are shown in Figures 21-24. Invisalign’s storage modulus gradually decreased over the temperature range of operation, whereas Simpli5 exhibited a more dramatic decrease starting at approximately 60-70°C. The testing parameters did not reveal the materials’ glass transition temperature (T_g) (Figures 21-24). At the glass transition temperature, E’ (storage modulus) decreases dramatically over a short temperature range, E” decreases initially and then increases, and tan δ reaches its peak.

![Storage Modulus vs. Temperature](image)

**Figure 20.** Storage modulus plot from temperature ramp test.
Figure 21. Temperature scan of as-received Invisalign.

Figure 22. Temperature scan of used Invisalign.
Figure 23. Temperature scan of as-received Simpli5.

Figure 24. Temperature scan of used Simpli5.
The mean survey score was 0.44±0.25, which indicates the patient satisfaction is somewhere between neutral and highly satisfied (Table 4). All surveyed patients were pleased with the esthetics and comfort of the aligners (Figure 25). Additionally, they all noticed that the aligner made improvements in the alignment of their teeth, and most would highly recommend aligner therapy to friends and family. There was no significant correlation between the responses to Q1-8 with Q9 about their recommendation of clear aligner therapy to others. About half did perceive changes in the aligner material as they progressed through them, including color changes, loss of transparency, and surface texture defects.

<table>
<thead>
<tr>
<th></th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average score Q1- Q8</td>
<td>0.13</td>
<td>0.75</td>
<td>0.43 (0.28)</td>
</tr>
<tr>
<td>Average score Q1- Q9</td>
<td>0.22</td>
<td>0.78</td>
<td>0.44 (0.25)</td>
</tr>
</tbody>
</table>

**Table 4.** Survey satisfaction scores.
Figure 25. Survey responses collected from patients after receiving clear aligner therapy (N=7).
Past studies have shown that clinical recommendations can be determined from results of materials studies. One study found that as the order of sequential aligners increase, aligner strains relating to force delivery increase. They concluded that final aligners should be thicker or worn for a longer period of time (Vardimon et al. 2010). However, another study determined that thin material (0.508 mm) can deliver higher energy than thick materials (0.762 or 1.1016 mm), and they therefore recommend that thin material be selected to move teeth efficiently (Kwon et al. 2008).

Other studies have found changes in the aligner material after use. In the deflection ranges of optimal force delivery (0.2-0.5 mm), the force delivery properties of aligners were different after repeated load cycling, but were not different after thermocycling (Kwon et al. 2008). Additionally, both thermocycling and load cycling influenced Vickers hardness values. This may be significant because if aligners become hard during use, they may cause discomfort to the patient and induce changes in their force delivery properties. Another study has found that intraoral aging adversely affected the mechanical properties of Invisalign. Contrary to the previous study, used aligners had significantly lower hardness values, with higher elastic index and creep indentation values (Bradley et al. 2015). The decreased hardness indicates a less wear resistant material, where the increased elastic index implies the material became more brittle (Bradley et al. 2015).

While changes in material properties after clinical use have been reported, it has also been found that neither material fatigue nor difference in stiffness play a significant
role in the rate or amount of tooth movement. No significant difference was found in the amount of orthodontic tooth movement between those who wore the same aligner for two weeks compared to those who changed to a new duplicate aligner after one week (Drake et al. 2012). Another study did not find a substantial difference in the treatment completion rate when comparing hard and soft appliances, with completion rates being 32% and 27%, respectively (Bollen et al. 2003). However, neither material was the same as the material used by Align Technology. The hard material used was twice as stiff as the commercial material, while the soft material was one-tenth as stiff.

These differing and sometimes contradicting findings suggest that orthodontic tooth movement with clear aligners needs further study. A better understanding of the clear aligner material properties remains pivotal to this ongoing investigation and could potentially lead to better sequencing of tooth movement and more efficient treatment. However, comparisons between studies may be a challenge, as the material used in future studies may not be the same material used in past studies, since the companies continue to evolve the material and its characteristics.

As this is the first study to use DMA to characterize the clear aligner material and examine a previously uninvestigated material, there are limited studies for results comparison. The most comparable study is one that recently conducted DMA to investigate the glass transition temperature, storage modulus, and loss modulus of five commercial mouth guard materials (Gould et al. 2009). While no differences were found between the materials for the mean glass transition, storage modulus or loss modulus, the glass transition of all the materials fell well below the targeted, end-use intraoral temperature. The materials exhibited a maximum tan δ at ~ -10°C and a transition range
from ~ -5° to 40°C. The authors concluded that the materials are problematic in that they are not functioning as optimal mechanical damping materials, as ideally they should be exhibiting a high tan δ value (>0.3) but exhibited a tan δ value of less than 0.2 at 37°C.

In contrast to mouth guard material, clear aligner material would ideally have a low tan δ value, a high storage modulus and a low loss modulus. The elastic or storage modulus (E’) reveals the ability of the material to store elastic energy and is associated with recoverable elastic deformation. The viscous or loss modulus (E”) indicates the material’s ability to dissipate mechanical energy through conversion into heat by molecular motion, and is associated with unrecoverable viscous loss. Therefore, a greater storage modulus indicates greater stiffness, while a greater loss modulus indicates a greater tendency to undergo time dependent deformation. A low tan δ would result from a low loss modulus and a high storage modulus, since it is the ratio of loss modulus to storage modulus. A material with a low tan δ will quickly respond to load and return to its original shape faster, which would be ideal for efficient tooth movement with clear aligners. The fact that the tan δ approached zero in the temperature range of operation for the clear aligners means the materials have almost no viscous component over the temperature and frequency ranges investigated. This is suggestive of more elastic-like materials (Mesquita et al. 2006).

A material’s elastic modulus varies as a function of frequency. The elastic modulus of more elastic-type materials tends to increase toward higher frequencies. The low frequency range is where the viscous-like behavior predominates since the material will have time to flow. At higher frequencies, the material does not have enough time to flow, which decreases its energy dissipation capacity through internal friction and lowers
the viscous modulus (Mesquita et al. 2006). Occasionally, conditions are found where the material-instrument system resonates like a guitar string at certain frequencies, which is dependent upon the sample geometry or dimensions (Menard 2008). This occurred at frequencies of 6-8 Hz in the present study.

For the creep-recovery test, as the stress \( (\sigma_0) \) is applied, there is an immediate response by the material. The point at which \( \sigma_0 \) is applied is when time is equal to zero for the creep experiment. When the force is removed, there is an immediate recovery of the material, which is recorded as percent recovery. From a molecular perspective, this can be considered the elastic deformation of the polymer chains, angles and bonds (Menard 2008). Polyurethane materials tend to offer superior mechanical properties, especially in relation to tear and abrasion, and flex-fatigue life (Kanyanta et al. 2010).

During clear aligner therapy, the placement of a new active aligner results in initial deformation of the material, as the aligner does not fit the current conditions of where the teeth are. Rather, it is made to fit passively only when the teeth have moved the desired 0.25-0.33 mm that was programmed into that aligner. Therefore, the material deformation exerts a force on the teeth, which results in orthodontic tooth movement. While a constant force on the teeth may be beneficial for efficient movement, the biological implications of a constant force should also be considered, as it has been shown to cause more root resorption compared to intermittent force (Ballard et al. 2009, Roscoe et al. 2015).

It has also been found that clear aligners have internal stresses in them, even when they are intended to fit passively (Vardimon et al. 2010). The von Mises strains during the two-week aligner wear did not decrease to zero, indicating that they still exerted
pressure even in a passive form. The authors speculated that this could be related to undersized aligner manufacturing due to minor shrinkage of the impression material (<0.5% for polyvinyl siloxane), as well as stereolithographic apparatus model shrinkage during polymerization (<0.6%) (Vardimon et al. 2010). This evidence shows that creep compliance is an important material characteristic, as the aligners have the potential to deform during the entire two to three week period that they are worn.

While no statistically significant difference was found comparing the two materials, Invisalign showed a trend of having greater creep compliance than Simpli5; therefore, it deformed more under constant stress. This may be in agreement with Align Technology’s claims that their SmartTrack material delivers a lower initial insertion force, while maintaining more constant force over the two-week wear period. Further, regarding the strain recovery percentage, Simpli5 may show a trend to recover to a slightly greater amount and/or faster than Invisalign, as more of its recoveries are closer to 100%. These findings may have important consequences for ensuring the teeth are tracking with the aligner progression appropriately. It has been found that reasons why patients do not complete their initial series of aligners include refusal to proceed to the next appliance, excessive pain, inability to fit the next appliances, or recommendation to do a mid-course correction (Bollen et al. 2003).

Although the creep compliance and strain recovery differences were not significant between used and unused samples, testing intra-orally aged viscoelastic specimens remains important. It has been found that in-vivo aged elastomeric ligatures express much higher creep than their in-vitro aged counterparts (Eliades 2005). Adsorption of lipids during intraoral use has been shown to cause structural alterations on
polyurethane material. The lipids act as nuclei for calcification, which lowers the glass transition temperature. This induces a plasticizing effect and decreases the free energy for crack propagation (Schubert et al. 1995).

While the frequency scan revealed no statistical difference comparing storage moduli values before and after use, the temperature ramp test demonstrated the potential that the storage modulus of the materials may increase after use. This is in agreement with previous studies’ findings (Schuster et al. 2004, Kwon et al. 2008). If the aligners become hard during use, they may cause discomfort to the patient and induce changes in their force delivery properties.

The testing parameters did not reveal the materials’ glass transition temperature ($T_g$), although DMA has greater sensitivity in measuring the $T_g$, compared to using differential scanning calorimeter (DSC) (Menard 2008). A 10-20°C difference between DMA and DSC is often seen (Menard 2008). While both methods have more than one way to determine the $T_g$, the peak of the tan δ curve was chosen to determine the $T_g$ in this study due to its less subjective nature. It appears that the tan δ begins to dramatically increase at ~60°C for Simpli5, but it is unclear for the Invisalign samples. Factors including contact point slippage or excessive creep at the loading points as the temperature was increased could have caused the difficulties in testing the specimens.

Future research should continue to investigate the $T_g$ of the materials, as it represents a major transition for polymers and corresponds to the expansion of the free volume. The free volume, $v^f$, of a polymer is known to be related to viscoelasticity, aging, penetration by solvents, and impact properties. Unless enough free volume exists, the motions of a polymer chain cannot occur (Menard 2008). As free volume increases with
increasing temperature, its molecular mobility increases, which results in a lower elastic modulus. The specific temperature of this softening as the material goes from a glassy to a rubbery state helps determine the end use of the material. Changes in $T_g$ are used to monitor changes in the polymer such as plasticizing by environmental solvents and increased crosslinking from thermal or UV aging (Menard 2008).

Certain material characteristics can be determined by examining the tan δ peak and $T_g$ value. A more homogeneous material presents a narrower tan δ peak, while a heterogeneous material with filler particles has a broadened tan δ curve (Vouvoudi and Sideridou 2013). Additionally, a higher cross-link density would yield a higher $T_g$ (Emami and Söderholm 2005). The presence of an additional peak is often due to the specimen’s unreacted sites becoming thermally cured during the DMA test (Emami and Söderholm 2005, Vouvoudi and Sideridou 2013).

This was the first study to investigate patient perceptions of the clear aligner material, as well as their satisfaction with the results. Previously, patients had been questioned on pain, communication interference, and food limitations (Miller et al. 2007, Shalish et al. 2012, Tuncay et al. 2013). This study’s survey responses were predominantly positive, which is consistent with previous positive responses on the mentioned quality of life surveys. All surveyed patients were pleased with the esthetics and comfort of the aligners. Additionally, they all noticed that the aligner made improvements in the alignment of their teeth, and most would highly recommend aligner therapy to friends and family. About half did perceive changes in the aligner material as they progressed through them. They noticed color changes, loss of transparency, and surface texture defects. Furthermore, half of the patients responded that the aligners
were not easy to keep clean, which is likely related to their perception that the color of
the aligner had changed.

The patients’ perceptions of the material changes are consistent with previous
retrieval studies. Differences were found in the surface morphology of aligners after
intraoral use, including abraded cusp tips, integument adsorption, biofilm calcification,
micro cracks, delamination, and loss of transparency (Schuster et al. 2004, Gracco et al.
2009). This shows that these patients that desire esthetic appliances can be very aware of
the unattractive changes in the material.

One of this study’s limitations involved the sample preparation and geometry. The
specimens were carefully sectioned and measured, but a small error in a sample
measurement can result in a significant change in the modulus value (Menard 2008).
Additionally, for DMA it is ideal that the four sides of the specimen are parallel to the
opposite side and perpendicular to the neighboring sides with no narrow parts (Menard
2008). The material would ideally be formed over a flat rectangular shape instead of
tooth models in order to make standardized flat specimens, but this would make
comparison between used and unused samples impossible. The importance of retrieval
analysis was discussed previously. The samples in this study were sectioned into
rectangular beams, but the Invisalign samples in particular did contain some narrow parts
due to the trimming process of the manufacturer. It remains unknown whether the
macroscopic material variations, i.e. attachment impressions and stereolithographic
ridges on Invisalign’s material, influence the material’s stiffness or force delivery.

The experimental set up has the potential to be modified. The clamped cantilever
mode is preferred for materials with low to medium elastic moduli (10 to 10,000 MPa),
whereas the supported mode (including three point bending mode) is more suitable for high modulus materials, such as ceramics and metals (Emami and Söderholm 2005). The aligners have medium elastic moduli, so the cantilever mode may be preferred. However, the supported mode generally yields the greatest accuracy for the storage modulus, and the clamped mode yields more accurate loss modulus data (Emami and Söderholm 2005). While neither precisely reflects what is occurring during three-dimensional tooth movement with clear aligners, the data produced from either mode is sufficient to compare unused and aged materials and/or different materials.

In addition to modifying the experimental set up, future research should consider an increased sample size. Threats to conclusion reliability and validity depend on sample size. Treatment effects need to be large before significance can be determined. Usually previous studies can be used to determine this, but as stated previously this is the first study to use DMA to characterize clear aligner material. Many p-values are close to being significant, which may imply that a larger sample size would have shown a significant impact. While it is recommended that at least three samples should be run to confirm that the data is correct, many DMA studies use three to five samples (Menard 2008, Gould et al. 2009, Mesquita et al. 2006, Cox et al. 2014). The current study’s advances include establishing a protocol for using DMA to test clear aligner materials and providing comparative data.

It is important to keep in mind that the behavior of polyurethane material is dependent on humidity and temperature. It has been found that the elastic modulus of a biomedical polyurethane material changed drastically when the testing conditions were altered. The modulus was 40% less in wet conditions at 37°C than it was in dry
conditions at room temperature (Kanyanta et al. 2010). While temperature control is possible with dynamic mechanical analysis, it may not be possible to test the aligner properties directly in the conditions that completely mimic their intended application.

Once various clear aligner materials have been characterized according to their viscoelastic properties, this research should extend into a clinical setting to determine if materials with more ideal properties (a low tan δ value, for example) produce more efficient tooth movement. The consistency of force delivery, as well as clinical outcomes, should also be analyzed. Any significant differences may have an impact on what aligner system the practitioner chooses to use.
CHAPTER 6
CONCLUSION

No statistically significant difference was found for the investigated mechanical properties of Invisalign and Simpli5 when comparing the materials in their as-received and after clinical use states. Additionally, no statistically significant difference was found between Invisalign and Simpli5; however, certain trends were observed. These include Invisalign exhibiting greater creep compliance and Simpli5 demonstrating greater and/or faster strain recovery. As many p-values were close to being significant, a larger sample size should be considered in future studies.

While there was no significant difference between the materials before or after use, both Invisalign and Simpli5 demonstrated favorable clinical qualities, including low tan δ values and patient satisfaction with the material. Patients’ survey responses were predominately positive, as all were pleased with the esthetics, comfort and performance of the aligners. Clear aligner material should continue to be studied, as a better understanding of the material properties could lead to better sequencing of tooth movement and more efficient treatment.


