Long-term Effects of Cleaning Methods on Properties of Vivera and ACE Clear Retainer Materials

BY

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THESIS

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MA

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF FIGURES (continued)

LIST OF ABBREVIATIONS

ADA	American Dental Association
ANSI	American National Standard
CNC	Computer Numerical Control
GSK	GlaxoSmithKline
SD	Standard Deviation
SEM	Scanning electron microscopy
UIC	University of Illinois at Chicago

SUMMARY

Orthodontic relapse is one of the most commonly seen sequela post orthodontic treatment, which emphasizes the retention period as one of the most crucial phases for successful long-term treatment. One of the only effective approaches to prevent orthodontic relapse is long-term retainer wear. Clear retainers have increased in popularity due to their "clear" esthetic nature (Chang et al., 2014). Crucial to maintaining the "clear" nature of these retainers is an effective cleaning technique. Until now, few scientific studies have been performed that focus on the proper maintenance for "clear" retainers.

This preliminary study aims to evaluate long-term light transmittance, surface roughness, and flexural modulus, of two clear retainer materials: Vivera® (Align Technology, Inc.) and Essix® ACE (Dentsply® International Inc.) using 7 different cleaning methods including: Invisalign® cleaning crystals, Polident®, Listerine® mouthwash, 2.5% vinegar, 0.6% sodium hypochlorite, 3% hydrogen peroxide, and toothbrushing with distilled water over a 6-month period.

1. INTRODUCTION

1.1 Background

Clear retainers have increased in popularity due to their near invisible appearance (Mai et al., 2014; Singh et al., 2009; and Hichens et al., 2007). The most common polymers used to fabricate clear retainers are polyester, polypropylene, and polyurethane (Zhang et al., 2011). Because retainers are essential in preventing orthodontic relapse, it is crucial to have an effective cleaning technique to maintain long-term use of the retainers. Coupled with long-term use of clear retainers comes disadvantages including loss of translucency and material integrity, discoloration, and plaque and calculus retention (Zafeirdiadis et al., 2014; and Gardner et al., 2003). If an effective cleaning method can be formulated, it will allow for increased life span of the retainers and overall better retainer compliance.

1.2 Objective

This preliminary study aims to evaluate long-term light transmittance, surface roughness, and flexural modulus, of two clear retainer materials: Vivera® (Align Technology, Inc.) and Essix® ACE (Dentsply® International Inc.) using 7 different cleaning methods including: Invisalign® cleaning crystals, Polident®, Listerine® mouthwash, 2.5% vinegar, 0.6% sodium hypochlorite, 3% hydrogen peroxide, and toothbrushing with distilled water over a 6-month period. Ultimately, the goal of this study was to observe the long-term effects of various cleaning methods on the physical and mechanical properties of the clear retainer materials.

1.3 Hypotheses

H(1) – There is no mean difference in the light transmittance, surface roughness, and flexural modulus between Vivera® and Essix® ACE thermoplastics at baseline.

H(2) - There is no mean difference in the long term light transmittance, surface roughness, and flexural modulus of Vivera® or Essix® ACE between baseline and six months when exposed to seven cleaning methods.

H(3) – There is no long term mean difference between seven cleaning methods in the light transmittance, surface roughness, and flexural modulus of Vivera® or Essix® ACE.

1.4 Eligibility

Inclusion Criteria

- Retainer materials – 0.040” thickness
    - Vivera® - Invisalign®
    - Essix® ACE - Dentsply® International Inc.
- 7 cleaning methods and a storage solution
    - Invisalign® cleaning crystals
    - Polident®
    - Listerine®
    - 2.5% vinegar
    - 0.6% sodium hypochlorite
    - 3% hydrogen peroxide
    - Artificial saliva (storage)
- Tooth-brushing cleaning method

Exclusion Criteria

- Non Vivera® or non Essix® ACE retainer materials
- Any cleaning method not listed above

2. REVIEW OF LITERATURE

2.1 Importance of Retention

Orthodontic retention is one of the most important aspects of orthodontic treatment to prevent relapse. Studies have shown that if the periodontal structures surrounding orthodontically treated teeth do not remodel, the teeth will have a higher tendency to relapse (Thilander, 2000). Post treatment, it is often difficult to distinguish between relapse due to continued growth of the patient and associated structures, or relapse due to remodeling of the periodontium or orthodontic treatment (Thilander, 2000). The final occlusal outcome is a combination of effects of facial growth in conjunction with dental development. However, facial structures and the dento-alveolar process continue to change throughout one's lifetime, therefore being in a constant state of turnover (Thilander, 2000). The issues behind retention become much more pronounced in adults who may have had a malocclusion that developed over many decades and was corrected in a matter of 18-24 months. It becomes more difficult to retain a malocclusion in an adult versus in a growing patient due to the amount of time that the adult patient had the malocclusion (Arvystas, 1996). In adulthood, the time required for transeptal, supracrestal, supra-alveolar connective tissue fibers to stabilize is much more than in childhood. Therefore, retention becomes even more important once patients are treated as adults. (Arvystas, 1996). Once orthodontists understand the interplay between relapse and continued physiological changes, they can better understand the best methods of retention. It is important however, for patients to understand that retention is a continuation of orthodontic treatment and is meant to maintain the teeth and occlusion in a steady state. (Thilander, 2000). In addition, based on each patient's individual condition, the options for retention are numerous.

Though the options for retention vary greatly, studies still remain inconclusive with regards to the efficacy of one retention protocol over another.

2.2 Retention Options

Recently, more options for orthodontic retention have been introduced aside from the traditional Hawley metal retainer. Thermoplastic clear retainers have increased in popularity due to their esthetic and clear properties. Though often preferred because of their clear nature, the physical properties of these clear retainers undergo constant transformation due to intraoral temperature and load deflection changes (Kwon et al., 2008). These clear retainers are fabricated from thermoplastic material, mainly composed of polyethylene or polypropylene. Previous studies have reported poor wear resistance of thermoplastic materials, and similar studies on mouth guards made from comparable materials have demonstrated dimensional changes (Kwon et al., 2008). Vivera®, a polyurethane blend is known to show sensitivity to heat, humidity and salivary enzymes though it has been shown to be biocompatible (Gracco et al., 2009).

Orthodontists differ extensively in their retention post orthodontic treatment. In a recent systematic review, the effectiveness of Hawley retainers compared to vacuum formed retainers was investigated. Seven studies were reviewed including five randomized control trials and two controlled clinical trials. Though there was some evidence suggesting no significant difference between Hawley retainers and vacuum formed retainers in regards to post treatment changes in intermolar and intercanine widths, there was no evidence recommending one over the other with respect to occlusal contacts, cost, patient satisfaction and lifetime (Mai et al., 2014). Furthermore, some studies show that Hawley retainers allow for better posterior occlusion settling, a process that is hindered by thermoplastic retention (Rinchuse et al., 2007).

In a study by Lindauer and Shoff, clear retainers were compared to Hawley retainers in their effectiveness at maintaining orthodontic correction. Both types of retainers proved to be suitable in maintaining teeth alignment post orthodontic treatment (Lindauer and Shoff, 1998). On the other hand, a prospective randomized controlled trial showed more incisor irregularity after six months of Hawley retainer use compared to thermoplastic vacuum formed retainer use (Rowland and Williams, 2006).

Apart from removable orthodontic retention appliances, fixed retainers are another suitable retention option. A twisted flexible wire such as a 0.0175" steel wire can be bonded to the six anterior front teeth. However, if only bonded to the canines and not the incisors, some rotation and/or labio/lingual movement of the incisors may occur. Heat treatment of the wire prior to bonding may prevent these unnecessary movements (Rinchuse et al., 2007). Though fixed retention prevents the need for patient compliance with retainer wear, it does introduce other problems such as gingival inflammation and plaque buildup due to the difficulty in cleaning. Furthermore, occlusal interferences and forces may distort the wire causing unwanted movement of the teeth (Rinchuse et al., 2007).

Ultimately, the appropriate retention protocol is determined based on the individual patient in conjunction with goals set by the orthodontist (Mollov et al., 2010).

2.3 Advantages of Clear Retainers

The advantages of clear thermoplastic retainers are numerous. Apart from being more esthetic, cost effective, and durable when compared to Hawley retainers, there is no adjustment needed upon delivery. Furthermore, less lab time and knowledge of dental laboratories/wire

bending is needed to fabricate clear retainers compared to traditional Hawley retainers (Gardner et al., 2003).

The durability of clear thermoplastic retainers was tested in a study conducted by Gardner et al. In order to determine the wear capability of retainer thermoplastics, three thermoplastics, Raintree Essix® C+, Great Lakes Orthodontics Invisacryl® C and a TR® (hard polyethylene terephthalate glycol (PETG) copolymer) sheet were examined. The three polymers underwent 1000 cycles in a wear apparatus with steatite ceramic abraders. Results showed that the TR® thermoplastic material had four times less wear compared to Essix® C+ and Invisacryl® C. Furthermore, there was no difference in wear between Essix® C+ and Invisacryl® C (Gardner et al., 2003).

2.4 Maintenance of Clear Retainers

Though clear retainers have become more popular due to their esthetic nature, proper cleaning and maintenance of this type of retainer is difficult. There are two main methods for cleaning clear retainers, mechanical and chemical. Mechanical cleaning includes tooth brushing and/or using an ultrasonic device. Chemical cleaning on the other hand involves submerging retainers in refreshing/antimicrobial cleaning solution (Chang et al., 2014). Along with cleaning of the clear retainers, it is important to understand that the integrity of the clear plastic material may become compromised after repetitive use and cleaning cycles. If orthodontists understand the extent to which plastic retainers can undergo wear and deformation before fracturing, this can ultimately help prevent relapse due to broken retainers.

In a study by Pascual et al., 2010, two different clear plastic retainer materials were tested, polyethylene-terephthalate-glycol (PETG; Tru-Tain Splint) and polypropylene/ethylene-

propylene rubber (PP-EPR) blend (Essix C+). The materials were stored either in dry air, distilled water, Listerine® mouthwash, mint Crest® ProHealth mouthwash, 3% hydrogen peroxide, or Polident®. The specimens were then fractured under tension to determine their essential work of fracture and plastic work of fracture. Results of this study showed that compared to distilled water, none of the cleaning solutions decreased the energy needed to initiate fracture in both orthodontic thermoplastic retainers (Pascual et al., 2010).

2.5 Relevant Studies

In a recent study, the force and energy delivery properties of three Essix® thermoplastic materials, A+, ACE and C+ were investigated using a three-point bend test. These materials underwent thermocycling for 1000 cycles or 1mm repeated load cycling for 100 cycles. The materials were then tested at baseline and after cycling. Results of this study showed the force delivery after thermocycling was not statistically different from that at baseline, however it was different after repeated loading (Kwon et al., 2008).

In a similar study, 30 flat specimens of Vivera® retainer material were divided randomly into one of four test groups. Each group consisted of a specific solution in which the retainer samples were immersed. The four different solutions were coffee, tea, red wine, and Coca-Cola®. The fifth group was distilled water, which was used as the control. The specimens were immersed in their appropriate solution for an unspecified amount of time. After immersion, a spectrophotometer was used to measure the CIE color parameters. Results of this particular study showed that coffee and tea both had a significant impact on the color staining of the Vivera retainer material, and to a lesser extent, red wine (Zafeiriadis et al., 2014).

A study by Chang et al., examined the mechanical and chemical effectiveness of bacteria removal on Essix® ACE plastics. In the first study retainers were brushed with Colgate® toothpaste, brushed with distilled water and then rinsed with distilled water to determine the effectiveness of removal of *Streptococcus mutans*. In the second study, retainers were brushed with fluoridated toothpaste, chlorhexidine gel, and immersed in a chlorhexidine solution to determine the mechanical and chemical effectiveness of removal of multispecies biofilm. Results of the first study showed a 99% reduction in S. mutans when brushing with toothpaste alone. Conversely, in the second study, all techniques significantly reduced all microorganisms except for methicillin-resistant *S. aureus* (Chang et al., 2014).

A study by Ryokawa et al., evaluated water absorption with a 2-week water absorption test, thickness changes tests with thermoforming and water absorption, and tensile tests in simulated intraoral environment of eight different thermoplastic materials. Results of this study demonstrated a significant increase in water absorption of the materials, a decrease in thickness after thermoforming, and an increase in elastic moduli of some of the materials with a decrease in the others. There was a decrease in tensile yield stress of the materials in the simulated oral environment. (Ryokawa et al., 2006). This study suggests that significant environmental factors may influence the mechanical and physical properties of dental thermoplastics.

Few studies have investigated the effects of intra-oral conditions on the deterioration of clear aligners. One study by Gracco et al., evaluated the short-term optical, chemical, and morphological changes in Invisalign® aligners when exposed to the oral environment. This study investigated one ‘as-received’ Invisalign® aligner, one aligner submerged in artificial saliva for 2 weeks, and one aligner that was intra-orally used. Infra-red analysis was used to determine molecular degradation, spectrophotometry was used to evaluate color and translucency changes,

and scanning electron microscopy was used to evaluate surface morphology. Results revealed significant molecular changes on the surfaces of all three different aligners, no surface damage to the 'as-received' aligner, but significant damage to the intra-orally used aligner. Translucency was greatest for the 'as-received' aligner and least for the intra-orally used aligner suggesting that human saliva contributes to discoloration of clear retainers (Gracco et al., 2009).

3. METHODOLOGY

3.1 Study Design

All testing was completed at the UIC School of Dentistry and the ADA building. Based on the current literature and what orthodontists most commonly recommend to clean retainers, seven different clear retainer cleaning methods were chosen for this study: Invisalign® cleaning crystals, Polident® denture cleaner, Listerine® mouthwash, 2.5% vinegar, 0.6% sodium hypochlorite (NaClO), 3% hydrogen peroxide (H_2O_2), and toothbrushing with distilled water with a standardized toothbrushing machine.

All of the cleaning experimental procedures and storage of samples was performed at the laboratory at UIC and the property testing was performed at the ADA building. At baseline when the samples had not been treated, and after soaking at 6 months, the physical properties: light transmittance, surface roughness, and flexural modulus of the two clear retainers, Vivera® and Essix® ACE were measured using a spectrometer, profilometer, and an instron three-point bend test, respectively at the ADA.

3.2 Specimen Preparation

The two clear retainer materials chosen for this study were Vivera® from Align® Technology and Essix® ACE from Dentsply International Inc. Vivera samples, a polyurethane blend of methylene diphenyl diisocyanate and 1,6-hexanediol, were prepared by Align® Technology at the standard dimension of 50.8mmx12.7mmx1mm as recommended by the ANSI/ADA Standard No 139 for Dental Base polymers (Figure 1). Essix® ACE, a copolyester of 0.040mm thickness from Lot 00022419 and was generously provided by Dentsply International Inc. The Essix® ACE material was first processed over a stainless steel block

(Figure 2) with the following dimensions 55mm x 18mm x 6mm (Figure 3) using the Biostar® from Great Lakes Orthodontics, Ltd (Figure 4). The samples were cut from the processed sheet into the standard dimensions (Figure 5) using a diamond saw and automated CNC milling machine at the ADA. In a similar study, flat stone models were used instead of stainless steel blocks to fabricate flat specimen of standard dimensions (Kwon et al., 2008).

Figure 1: Photo of Vivera® sample

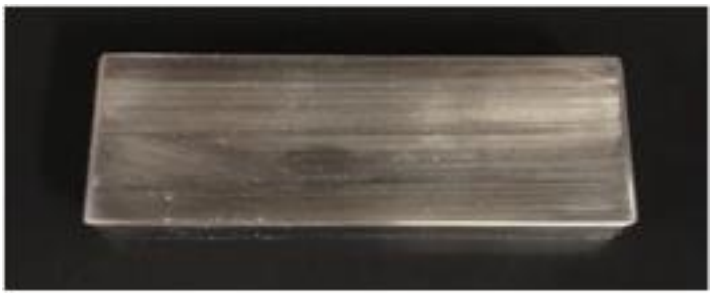

Figure 2. Photo of stainless steel block used for material processing

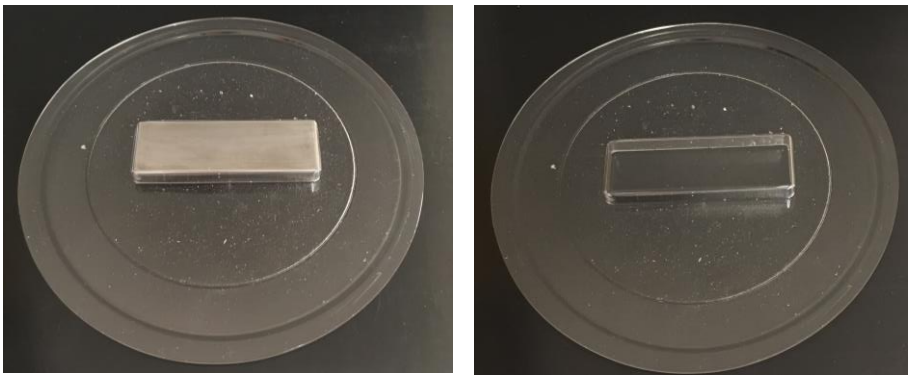

Figure 3. Photo of processed Essix® ACE material

Figure 4. Photo of Biostar® from Great Lakes Orthodontics, Ltd.

Figure 5. Photo of Essix® ACE material in the standard testing dimension

Ten specimens of each prepared material were randomly divided into seven groups for each cleaning solution and the toothbrushing group. Five of the specimens in each group were tested for flexural modulus and the other five were tested for light transmittance and surface roughness. One specimen was taken at random from each cleaning group for SEM testing. The specimens for SEM only came from the specimens used for light transmittance and surface roughness. The labeling scheme for each individual specimen consisted of a letter and two numbers to designate the material, specimen number, and cleaning method. A "V" or an "A" was used to represent Vivera® or Essix® ACE respectively. The first number represented the specimen number (1-0) with the final number representing the solution (1-8). The specimen numbers, 1-5 were used for the flexural modulus test and 6-0 were used for the light transmittance and surface roughness tests. The solution numbers represented the cleaning groups as follows. Group 1-Invisalign® cleaning crystals, group 3-Polident®, group-4 Listerine®, group 5-2.5% vinegar, group-6 0.6% sodium hypochlorite, group 7-3% hydrogen peroxide and group-8 toothbrushing. As an example, V61 would represent Vivera®, specimen number 6 used for transmittance and surface roughness, and cleaning method Invisalign® cleaning crystals. A05 would represent, Essix® ACE, specimen number 10 used for transmittance and surface roughness, and cleaning method vinegar (Figure 6). Note: Group 2 was a different solution used in a similar experiment but excluded from the current study. Five samples of each material were used in each cleaning solution to account for any fracture or breakage throughout the project.

Each group of five specimens was wrapped in a 10"x10" piece of Regency Natural Ultra Fine 100% cotton cheesecloth, with each specimen separated from the next by a glass bead in order to allow the material to be completely exposed to all solutions. The bundle was tied tightly with twine (Figure 7). Each group of ten specimens, separated into two separate bundles was

stored in artificial saliva in a glass jar appropriately labeled with the retainer material and solution (Figure 8) and stored at 37°C.

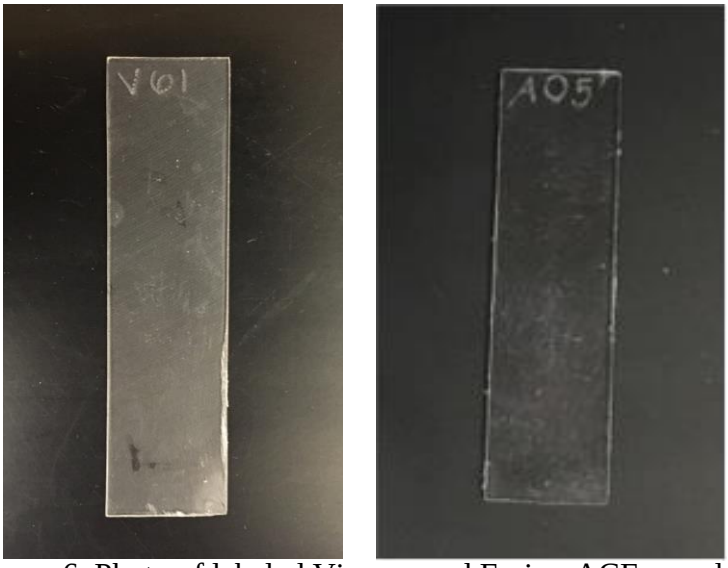

Figure 6. Photo of labeled Vivera® and Essix® ACE samples

Figure 7. Specimens wrapped in cheesecloth

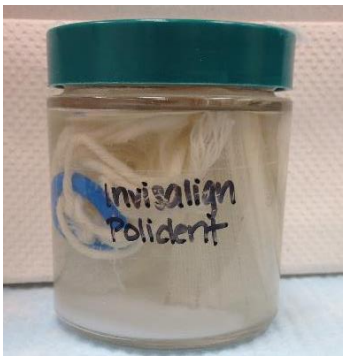

Figure 8. Labeled specimens stored in artificial saliva

Figure 9. 37°C Incubator

3.3 Cleaning Solutions and Artificial saliva preparation

Large volumes of 2.5% acetic acid (vinegar) and 0.5% sodium hypochlorite (NaClO) were prepared at a time to reduce the variation from solution preparation. To create the vinegar, 25 mL of 99% glacial acetic acid was added to 800mL of Double-distilled water. Additional Double-distilled water was added up to a final volume of 1000 mL. 60 mL of 5% concentrated (splash less) Clorox® bleach was added to 540 mL of Double-distilled water to a final volume of 600 mL to create 0.5% NaClO during the experiment. 3% hydrogen peroxide (H_2O_2) was

prepared on the experiment day with 60 mL of 30% H_2O_2 and 540 mL of Double-distilled water. 600 mL of vinegar, 0.5% NaClO, and 3% H_2O_2 solutions were used each experiment day.

Artificial saliva was prepared with 1.6g sodium chloride, 1.6g potassium chloride, 3.18g calcium chloride dehydrate, 2.76g sodium dihydrogen phosphate monohydrate, 0.02g sodium sulfide nonanhydrate, 4g urea, and 4000 mL distilled water (Nakagawa, 1999) (Figure 10). The saliva was thoroughly mixed overnight on a magnetic stir plate. The day following saliva preparation, potassium hydroxide was added to the saliva to achieve a final pH of 6.75.

Figure 10. Artificial saliva

3.4 Experimental process

Throughout the study period, specimens remained in artificial saliva at 37°C. Twice a week, each group of specimens was removed from the artificial saliva, rinsed with Double-distilled water, and then immersed in 600 mL of the appropriate cleaning solution. According to

the manufacturer's instructions, six packets of Invisalign® cleaning crystals were dissolved in 600 mL of distilled water and four tablets of Polident® denture cleaner were dissolved in 600 mL of distilled water. Specimens were suspended from glass rods atop the beakers (Figure 11) filled with each of the six solutions for 15 minutes, with the exception of Polident®, which was used for 3 minutes per GSK manufacturing recommendation. The beakers were placed on magnetic stir plates with stir rods to facilitate cleaning.

Figure 11. Specimens submerged in Invisalign® cleaning crystals

For the seventh cleaning method, specimens from each material were brushed with a standardized tooth-brushing machine custom-fabricated by the ADA staff (Figure 12) and Double-distilled water for 2 minutes twice weekly over the same 6-month period. The tooth-brushing machine speed control was set at 15%, which was equal to 300 strokes per minute, and the load was set at 50 grams. The machine was run for 2 minutes using a standard soft bristle

toothbrush. Over the course of the two minutes, Double-distilled water was sprayed through a plastic syringe on the specimen every 15 seconds to maintain moisture.

Figure 12. Standardized toothbrushing machine

Following soaking and toothbrushing each day, specimens were replaced in the cheesecloth and returned to the appropriate glass jars with a fresh batch of artificial saliva and replaced in the incubator at 37°C.

3.5 Data Collection

The three physical properties that were measured for each of the specimens tested included: 1.) light transmittance, 2.) surface roughness, and 3.) flexural modulus.

Light Transmittance was measured using a system (Figure 13) consisting of a miniature spectrometer (Flame, Ocean Optics Inc.), a broadband quartz tungsten halogen light source, a six-inch diameter integrating sphere (Labsphere Inc.), a custom designed specimen holder, and associated fiber optic cables (QP100-2 UV VIS, Ocean Optics Inc.). Light transmission measurements were collected with *Oceanview* software (Ocean Optics version 1.5) using a built-in transmission measurement algorithm. Prior to testing, the light source was allowed to stabilize for approximately 15 minutes. The system was then initialized with this light source by taking

light energy measurements without a specimen inserted into the specimen holder. After inserting the specimen, light energy measurements were taken and transmission measurements were automatically calculated for wavelengths from 380nm to 740nm.

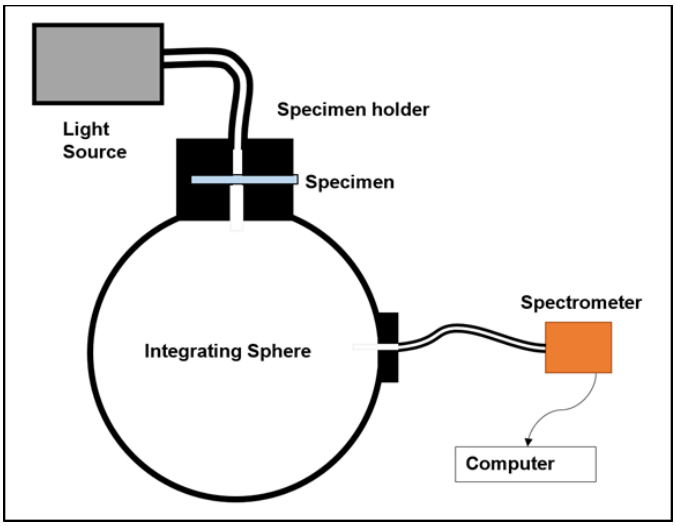

Diagram courtesy of Henry Lukic, ADA Science Institute, Research and Standards
Figure 13. Diagram of light transmission measurement system

Surface roughness was measured using a Surtronic 3+ profilometer (Taylor Hobson, Inc.) (Figure 14) placed on a Thorlabs motorized XYZ stage controlled by Thorlabs APT software. The parameters on the profilometer were set so that the cutoff length, L_c, was set to 0.25mm and the evaluation length, Ln, was set to 2.5mm (Figure 14). The resolution of measurements was set to 0.02 micrometers. Each sample was placed into the holder shown in Figure 15 with the engraved label side facing up and furthest away from the researcher.

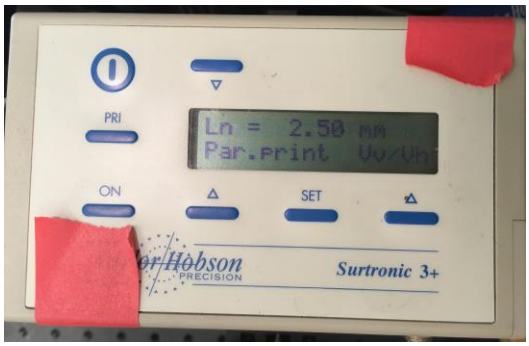

Figure 14. Surtronic3+ Profilometer Display

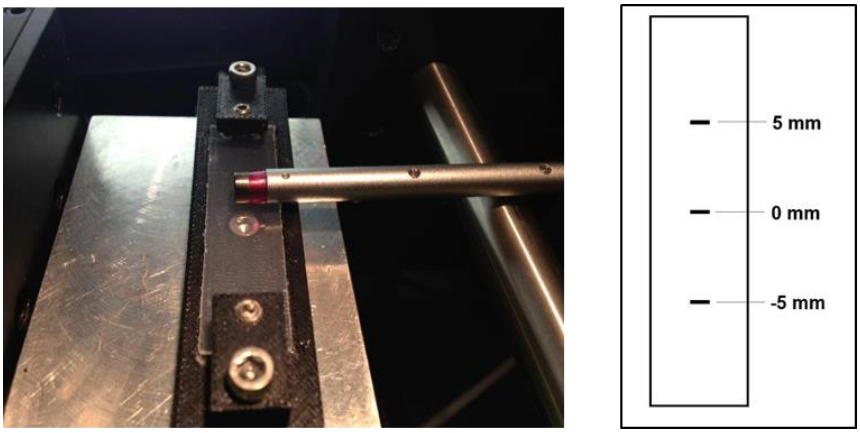

Figure 15. Photo showing profilometer stylus and specimen holder (left) and diagram showing specimen measurement locations (right)

The APT software (Figure 16) was used to position the stylus of the profilometer to measure the surface roughness at three locations on each specimen. The measurements were located 5mm above the center, at the center, and 5 mm below the center along the length of the specimen (Figure 15). After the stylus was positioned, surface roughness measurements were taken by depressing the “measurement start key” located at the top left corner of the profilometer. The resulting output was electronically transferred to the Microsoft HyperTerminal application (Figure 16).

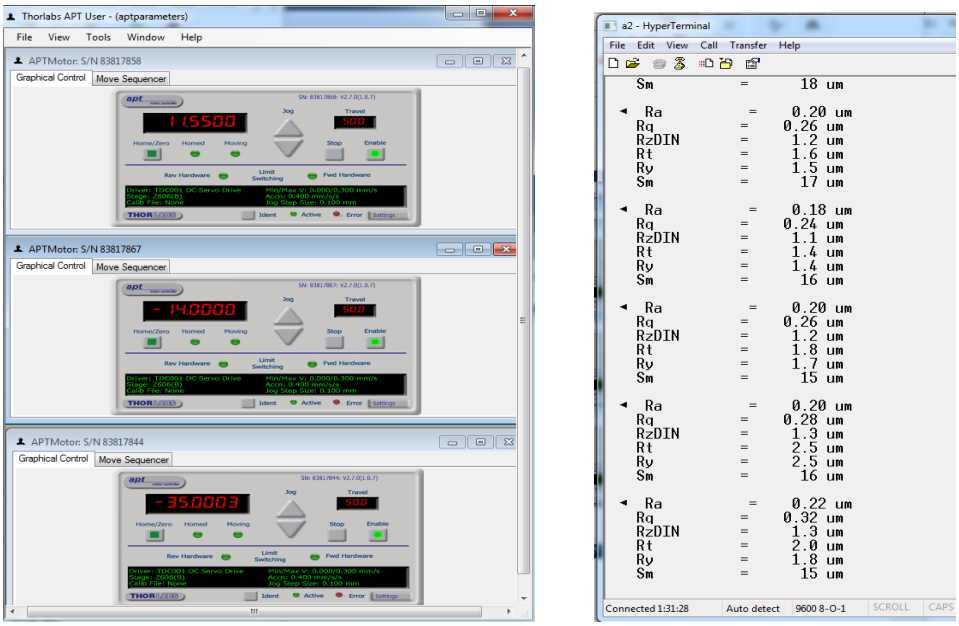

Figure 16. Thorlabs APT software interface (left) and hyperterminal output (right)

The following six roughness values were recorded during each measurement: R_a, R_q, R_zDIN, R_t, R_y, and S_m, but for the purposes of this testing, only the arithmetic average roughness, R_a, was analyzed for surface roughness.

A universal testing machine (Instron 5582) (Figure 17) was used to conduct a three-point bend test, in conjunction with the program *Testworks*. Prior to starting any testing, each individual specimen was measured three times using calipers and a C-clamp for width and thickness respectively. The measurements were made on either end of the specimen and directly in the center. These measurements were used consistently throughout the entire six months of testing.

In the *Testworks* program, the width and thickness were entered for each individual specimen in the first tab labeled “Test”. All other values (test speed, endpoint, and length)

remained constant. Each specimen was oriented with the labeled side face up and to the right of the positioner. The specimen was held between two black blocks in order to center itself on the fixture. Once inserted properly, only the block on the right side remained during the test (Figure 17).

Figure 17. Photo of Instron setup

The plunger was lowered using the down arrow on the remote (Figure 18) until it just touched the sample.

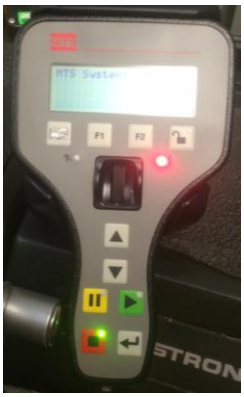

Figure 18. Photo of Instron remote

The LOAD value on the “Test” tab changed from negative to positive, after which the lowering of the plunger was halted and the machine was locked via the remote. The green arrow on the remote was pushed to begin the test after locking the machine. The plunger depressed the specimen until it reached 1% strain after which it stopped. Once 1% was reached, the plunger was released from the specimen. The “Review” tab on *Testworks* revealed the modulus of elasticity in MPa (Figure 19). The data was then exported to excel.

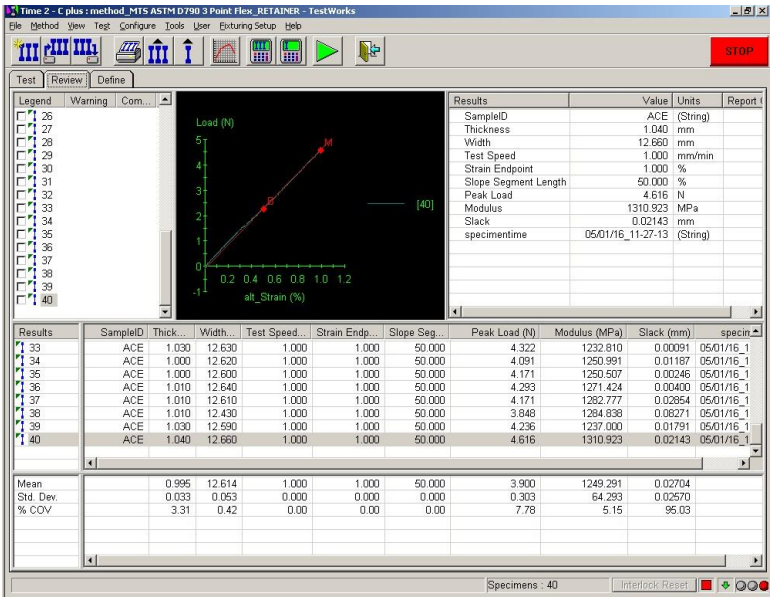

Figure 19. Testworks interface (Young's modulus)

The JCM-6000 Neoscope II Benchtop Scanning Electron Microscope (JEOL Inc.) was used to obtain qualitative image data to supplement the quantitative findings of the three previously described tests (Figure 20). The scanning electron microscope (SEM) images were taken only at the end of the 6-month testing period. One specimen was randomly chosen from each specimen group for a total of 15 samples. Each specimen was plated with a layer of gold approximately 10 nm thickness on both sides using the Cressington Sputter Coater (Figure 21).

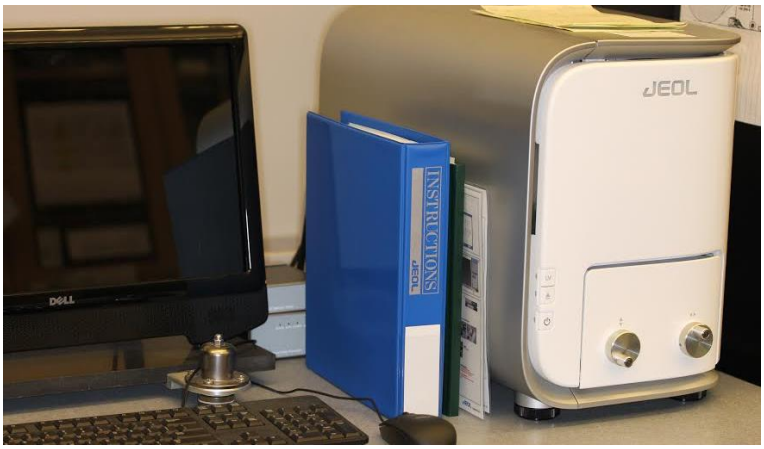

Figure 20. JCM-6000 Neoscope II Benchtop SEM (JEOL, Japan)

Figure 21. Cressington sputter coater (left) and Gold plating chamber (right)

Gold plated specimens were placed into the JEOL chamber (Figure 22) and inserted into the machine. Qualitative analysis was taken in the center of each specimen at 50 microns scale and 500 times magnification.

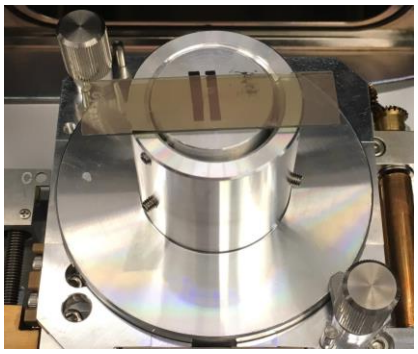

Figure 22. Photo of specimen holder for SEM

3.6 Data Analysis and Statistical Analysis

Once the light transmittance (%), surface roughness (μm), and flexural modulus (MPa) values were obtained from their respective machines, the raw data was recorded in an excel spreadsheet. The mean differences were calculated. Assumption of normality of the data was evaluated using the Shapiro-Wilk test. Shapiro-Wilks test of normality showed that the majority of the variables had a normal distribution. The study hypotheses were evaluated using parametric tests and non-parametric tests depending on the type of data distribution. For the comparison of the mean difference, independent student t-tests and one-way ANOVA were performed to compare the cleaning methods on the three properties of each material. For the comparison of the mean difference between each experimental method, Post-hoc Bonferroni multiple comparison tests were used when needed. Statistical significance was set at 0.05. All calculations and tests were performed with IBM SPSS Statistics for Windows (version 22.0, IBM Corp., Armonk NY).

4. RESULTS

4.1 Normality

The Shapiro-Wilk test showed that the majority of the variables in this study had a normal distribution. Descriptive statistics were computed for all of the variables. Non-parametric and parametric tests were performed. Both parametric and non-parametric analyses demonstrated similar results. Based on the distribution of the raw data, mean differences were investigated using independent t-tests for each cleaning method between baseline and 6 months. The results are reported based on the parametric test procedures. The mean differences among all cleaning methods were investigated by one-way ANOVA with post hoc Bonferroni tests when needed.

To test for any inherent difference in light transmittance, surface roughness, and flexural modulus between Vivera® and Essix® ACE at baseline, an independent student t-test was run to test the mean differences. Data from the tests indicate that Vivera® had less initial transmittance compared with Essix® ACE and greater initial flexural modulus. The surface roughness between the two specimens was comparable (Table I, Figures 23-25).

TABLE I

INDEPENDENT STUDENT t-TEST FOR MEAN DIFFERENCES AT BASELINE (NO SOLUTIONS) FOR VIVERA® AND ESSIX® ACE – DESCRIPTIVES RESULTS ($\overline{X}$,SD)

Variables / Groups	Light Transmittance (%)	Surface Roughness (µm)	Flexural Modulus (MPa)
Vivera® (n=35)	92.2± 0.8*	0.14±0.05	2760±89*
Essix® ACE (n=40)	95.2±0.9*	0.14±0.02	2045±84*

*Statistically significant at: $p \leq 0.05$

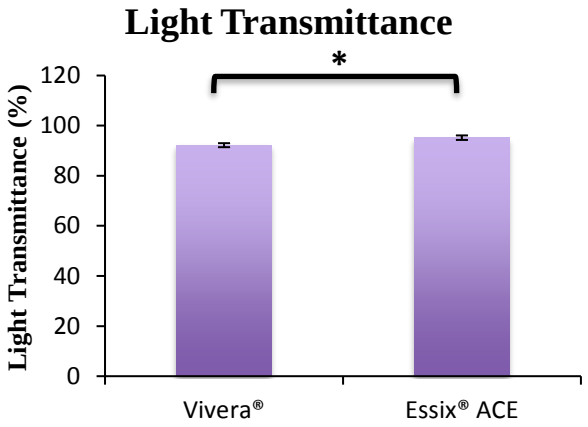

Figure 23. Graph of light transmittance at baseline

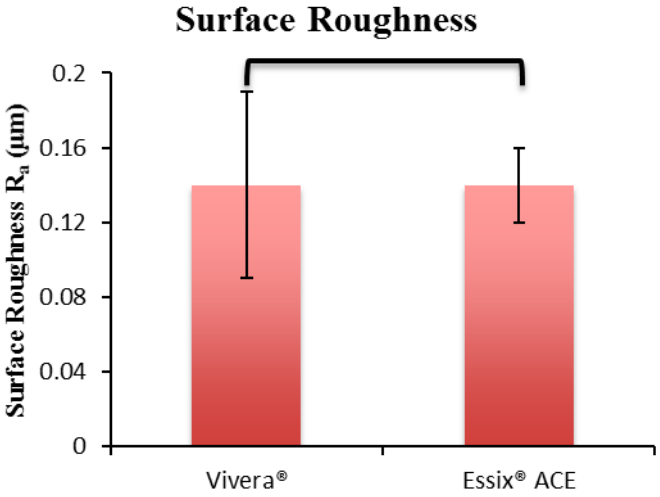

Figure 24. Graph of surface roughness at baseline

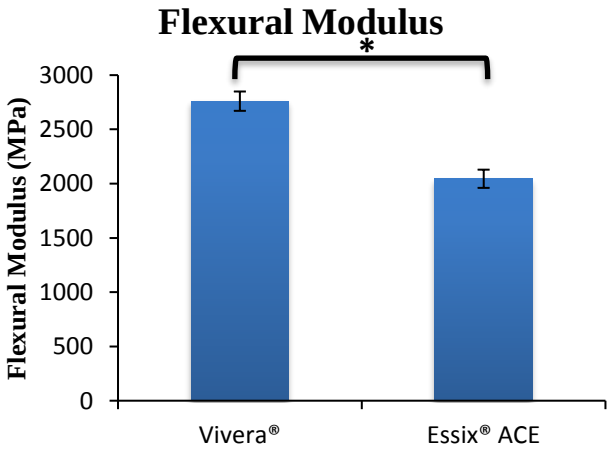

Figure 25. Graph of flexural modulus at baseline

4.2 Vivera®

Results of the independent t-test between baseline and six months indicate that there was a consistent loss of transmittance in Vivera® retainer materials when immersed in all cleaning methods compared to baseline. Independent student t-tests between baseline and each of the cleaning methods on light transmittance at baseline and six months showed significant mean differences for all cleaning methods ($p<0.05$) (Table II, Figure 26). All methods produced similar roughness values when comparing baseline and six months except for NaClO (Table II, Figure 27). Qualitative analysis with SEM of NaClO showed no difference in surface texture at 50 microns and 500x magnification between baseline and six months (Figure 28). All cleaning methods showed similar effects on flexural modulus comparing baseline to six months except for vinegar and toothbrushing which both decreased the flexural modulus of Vivera® (Table II, Figure 29).

TABLE II

INDEPENDENT STUDENT t-TESTS AT 6 MONTHS COMPARED TO BASELINE FOR VIVERA® (N=5) – DESCRIPTIVES RESULTS ($\overline{X}$,SD)

VARIABLE / CLEANING METHOD	Light Transmittance (%)			Surface Roughness (µm)			Flexural Modulus (MPa)		
	Baseline	6 months	P-value	Baseline	6 months	P-value	Baseline	6 months	P-value
Invisalign® cleaning crystals	91.7±1.0	88.5±0.5	<0.001*	0.14±0.03	0.12±0.03	0.309	2752±60	2757±150	0.942
Polident®	92.7±0.8	89.3±0.8	<0.001*	0.13±0.02	0.15±0.06	0.480	2769±108	2870±125	0.235
Listerine®	91.8±0.8	89.1±0.4	<0.001*	0.12±0.01	0.12±0.02	0.829	2725±70	2900±199	0.101
2.5% vinegar	92.0±0.7	87.8±1.3	<0.001*	0.12±0.01	0.12±0.01	0.572	2704±90	2852±43	0.011*
0.6% sodium hypochlorite	92.1±0.5	87.9±0.9	<0.001*	0.14±0.02	0.11±0.01	0.018*	2793±120	2917±151	0.186
3% hydrogen peroxide	92.3±0.3	87.5±0.9	<0.001*	0.18±0.12	0.22±0.14	0.633	2758±104	2863±141	0.217
Toothbrushing	92.5±0.9	85.6±1.9	<0.001*	0.13±0.02	0.12±0.01	0.840	2823±51	2911±45	0.020*

*Statistically significant at: $p \leq 0.05$

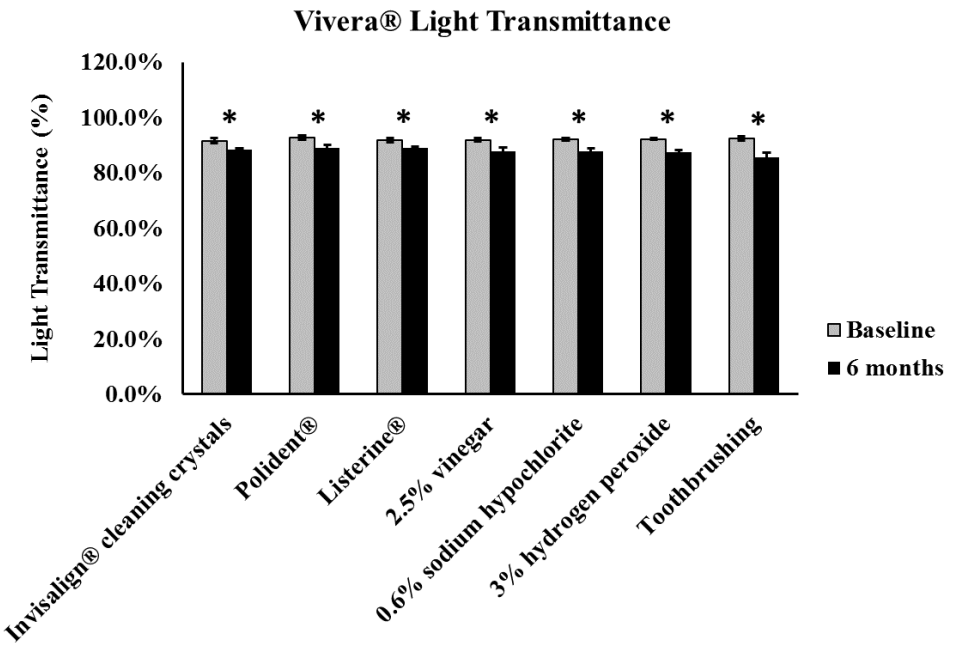

Figure 26. Graph of Vivera® light transmittance between baseline and 6 months (*P<0.05)

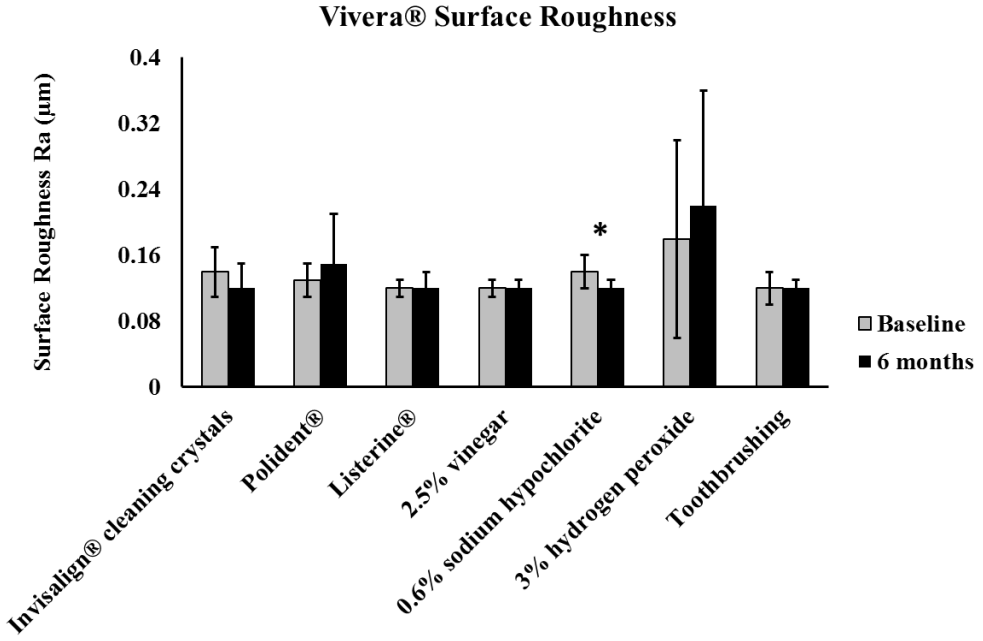

Figure 27. Graph of Vivera® surface roughness between baseline and 6 months (*P<0.05)

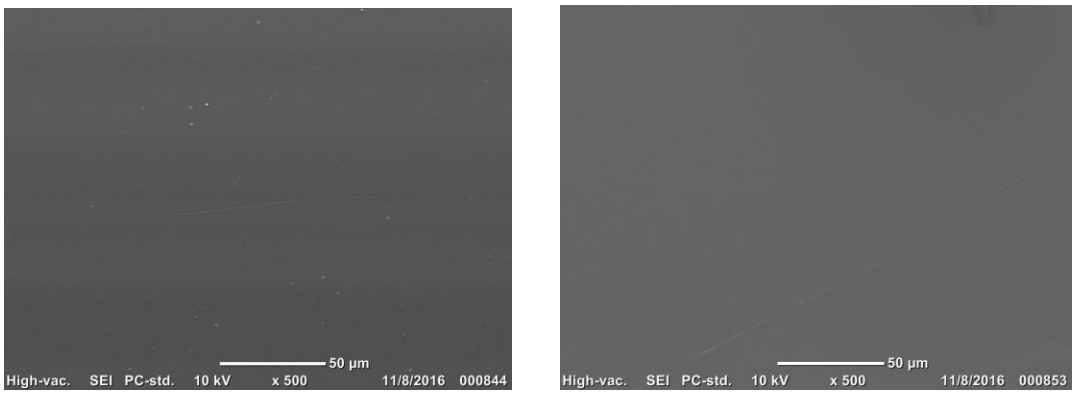

Figure 28. SEM of Vivera® no treatment (Left) and Vivera® with NaClO (Right)

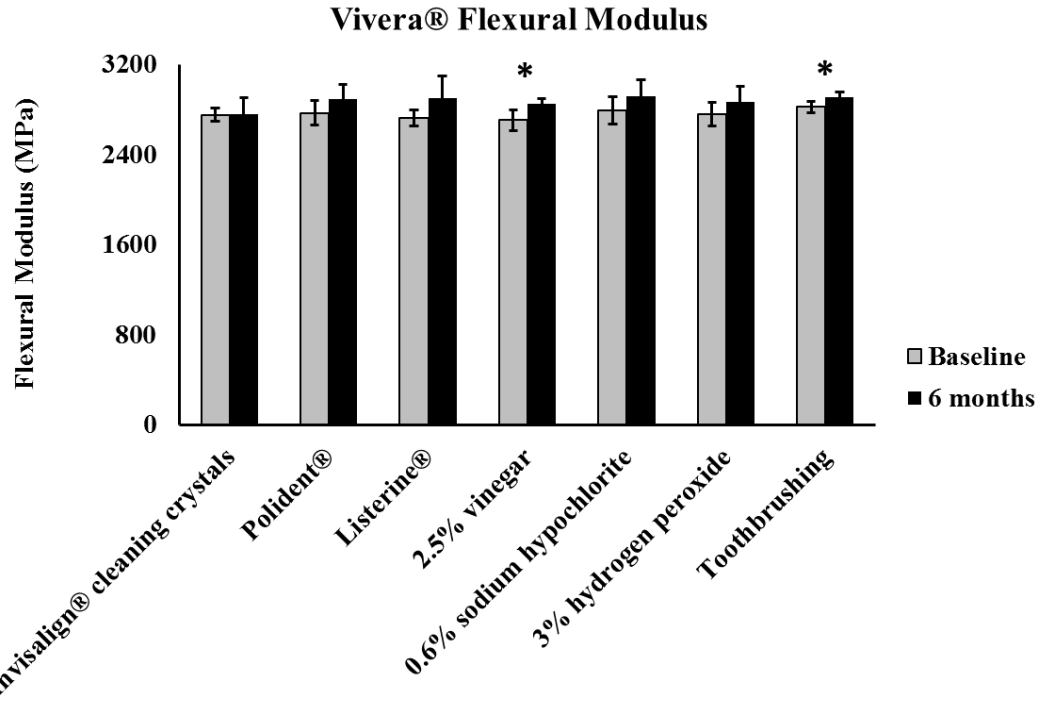

Figure 29. Graph of Vivera® flexural modulus between baseline and 6 months (*P<0.05)

Results of the one-way ANOVA on cleaning methods for Vivera® showed that a statistically significant difference was found in light transmittance among the cleaning methods

(Table IV). Post hoc Bonferroni tests on transmittance indicated that toothbrushing had the greatest decrease in transmittance while Invisalign® cleaning crystals, Listerine®, and Polident® showed good transmittance at 6 months (Table V). There was no difference among the cleaning methods on surface roughness and flexural modulus (Table IV).

TABLE III

VIVERA® (N=5) – DESCRIPTIVES RESULTS ($\overline{X}$,SD)

VARIABLE / CLEANING METHOD	Light Transmittance (%)	Surface Roughness (µm)	Flexural Modulus (MPa)
Invisalign® cleaning crystals	-3.2±0.8	-0.02±0.02	5±152
Polident®	-3.4±1.3	0.02±0.06	88±127
Listerine®	-2.7±1.0	0.00±0.01	175±162
2.5% vinegar	-4.2±1.0	-0.00±0.01	149±79
0.6% sodium hypochlorite	-4.2±1.3	-0.03±0.01	125±176
3% hydrogen peroxide	-4.8±1.0	0.04±0.14	105±70
Toothbrushing	-7.0±2.4	-0.00±0.02	88±52

TABLE IV

VIVERA® ONE-WAY ANOVA RESULTS

VARIABLE AND SOURCE	F Statistic	P-value
Light Transmittance (%)	5.368	0.001*
Surface Roughness (µm)	0.789	0.586
Flexural Modulus (MPa)	0.929	0.49

*Statistically significant at: $p \leq 0.05$

TABLE V

VIVERA® PAIR-WISE MEAN-DIFFERENCE RESULTS – LIGHT TRANSMITTANCE

CLEANING METHOD	Invisalign® cleaning crystals	Polident®	Listerine®	2.5% vinegar	0.6% sodium hypochlorite	3% hydrogen peroxide	Toothbrushing
Invisalign® cleaning crystals		1.000	1.000	1.000	1.000	1.000	0.003*
Polident®	1.000		1.000	1.000	1.000	1.000	0.005*
Listerine®	1.000	1.000		1.000	1.000	0.461	0.001*
2.5% vinegar	1.000	1.000	1.000		1.000	1.000	0.072
0.6% sodium hypochlorite	1.000	1.000	1.000	1.000		1.000	0.068
3% hydrogen peroxide	1.000	1.000	0.461	1.000	1.000		0.353
Toothbrushing	0.003*	0.005*	0.001*	0.072	0.068	0.353	

*Statistically significant at: $p \leq 0.05$

4.3 Essix® ACE

Results of the independent t-test indicate that there was a consistent loss of transmittance with Essix® ACE in all cleaning methods at six months compared to baseline (Table VI, Figure 30). Independent student t-tests between baseline and each of the cleaning methods on light transmittance at baseline and six months showed statistically significant mean differences for all cleaning methods ($p<0.05$) (Table VI). All methods produced similar roughness values at six months except for Listerine® (Table VI, Figure 31). Qualitative analysis with SEM of Listerine® showed no difference between baseline and six months (Figure 32). All cleaning methods increased flexural modulus at six months except for Invisalign® cleaning crystals (Table VI, Figure 33).

TABLE VI

INDEPENDENT STUDENT t-TESTS AT 6 MONTHS COMPARED TO BASELINE FOR ESSIX® ACE (N=5) – DESCRIPTIVES RESULTS ($\overline{X}$,SD)

VARIABLE / CLEANING METHOD	Light Transmittance (%)			Surface Roughness (µm)			Flexural Modulus (MPa)		
	Baseline	6 months	P-value	Baseline	6 months	P-value	Baseline	6 months	P-value
Invisalign® cleaning crystals	95.4±0.8	92.4±1.4	0.003*	0.14±0.03	0.14±0.04	0.930	2088±57	2187±78	0.050
Polident®	95.4±1.4	91.9±0.6	0.001*	0.14±0.02	0.15±0.04	0.565	2067±58	2250±59	0.001*
Listerine®	94.8±0.8	87.4±1.8	<0.001*	0.14±0.01	0.12±0.01	0.034*	2025±115	2220±130	0.036*
2.5% vinegar	95.1±0.7	93.0±0.9	0.003*	0.13±0.01	0.13±0.01	1.000	2047±97	2231±70	0.009*
0.6% sodium hypochlorite	95.3±0.3	92.5±1.0	<0.001*	0.14±0.03	0.12±0.01	0.260	2018±58	2222±70	0.001*
3% hydrogen peroxide	95.3±0.7	92.6±0.9	0.001*	0.14±0.02	0.14±0.02	0.849	1976±56	2259±72	<0.001*
Toothbrushing	95.5±0.8	90.7±0.8	<0.001*	0.14±0.02	0.14±0.03	0.714	2032±72	2285±59	<0.001*

*Statistically significant at: $p \leq 0.05$

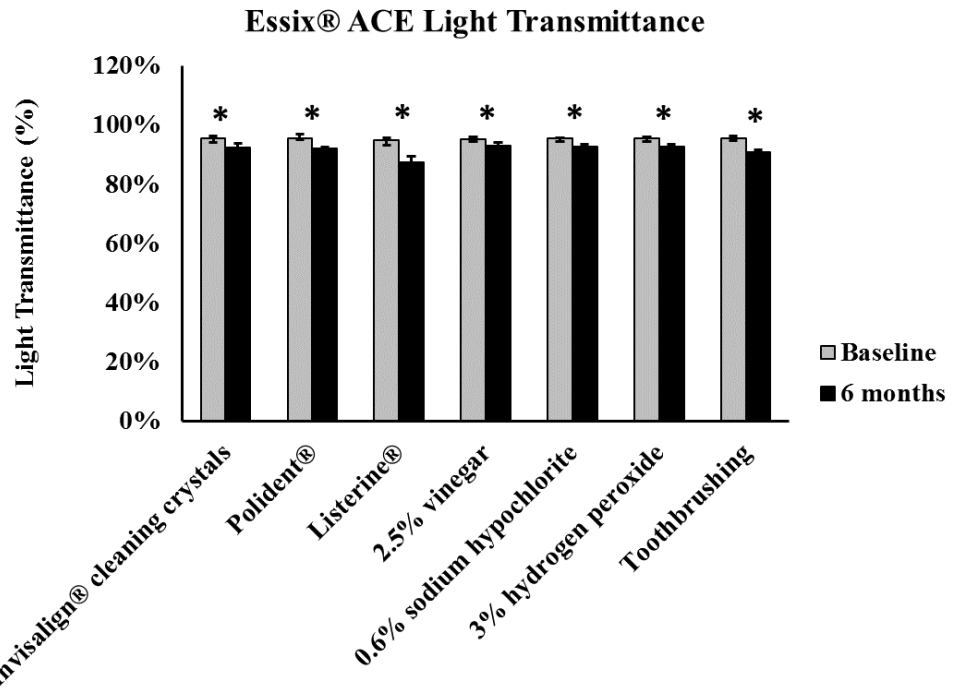

Figure 30. Graph of Essix® ACE light transmittance between baseline and 6 months

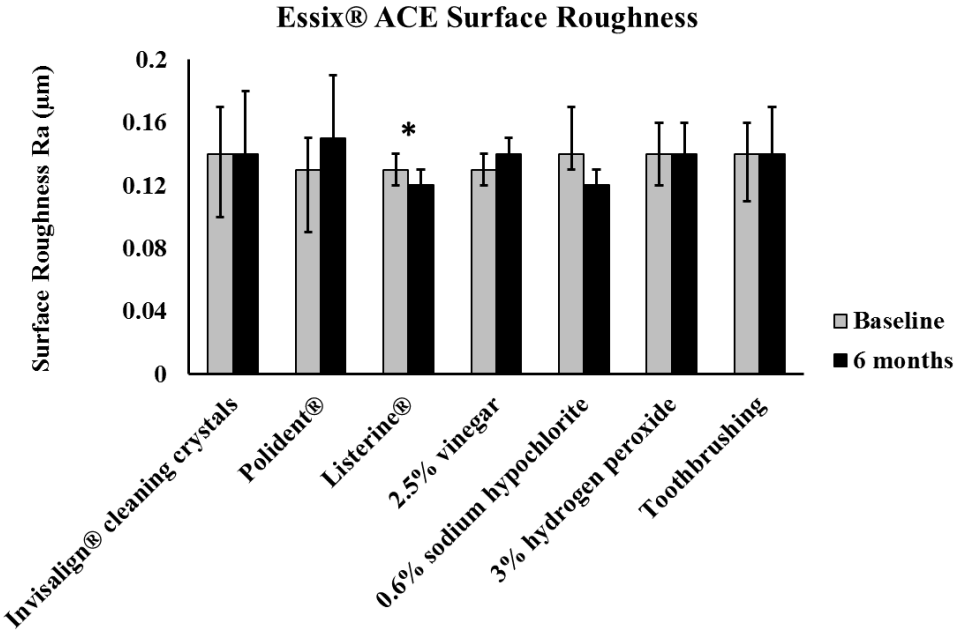

Figure 31. Graph of Essix® ACE surface roughness between baseline and 6 months

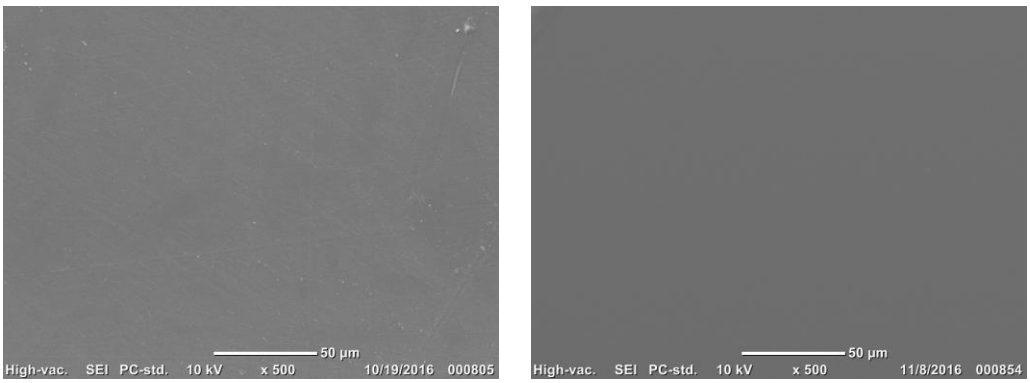

Figure 32. SEM of Essix® ACE no treatment (Left) and ACE with Listerine® (Right)

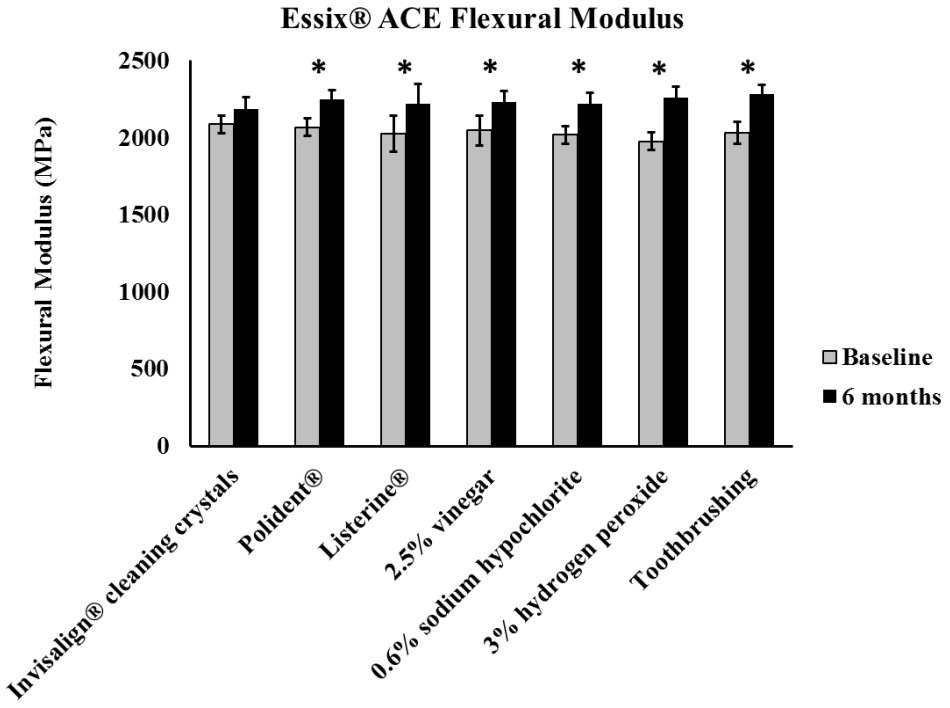

Figure 33. Graph of Essix® ACE flexural modulus between baseline and 6 months

One-way ANOVA was performed to compare the methods on the three properties of each material. A statistically significant difference was found in light transmittance and flexural modulus changes among the cleaning methods (Table VIII). Post hoc Bonferroni tests on transmittance indicated that Listerine® had the lowest transmittance compared to all other solutions which showed better transmittance. There was no difference however between transmittance in Listerine® and toothbrushing (Table IX). Post hoc Bonferroni tests on flexural

modulus changes indicated 3% H_2O_2 had the greatest increase in stiffness compared to Invisalign® cleaning crystals which did not show much change (Table X). Toothbrushing also had an increase in stiffness that was different from Invisalign® cleaning crystals. There was no difference among the cleaning methods on surface roughness changes (Table VIII).

TABLE VII

ESSIX® ACE (N=5) – DESCRIPTIVES RESULTS ($\overline{X}$,SD)

VARIABLE / CLEANING METHOD	Light Transmittance (%)	Surface Roughess (µm)	Flexural Modulus (MPa)
Invisalign® cleaning crystals	-3.0±1.6	0.00±0.01	99±98
Polident®	-3.5±1.2	0.01±0.05	184±8
Listerine®	-7.4±1.5	-0.01±0.02	195±58
2.5% vinegar	-2.1±1.3	0.00±0.01	185±32
0.6% sodium hypochlorite	-2.8±0.8	-0.02±0.03	204±27
3% hydrogen peroxide	-2.7±0.8	0.00±0.02	283±39
Toothbrushing	-4.7±1.0	0.01±0.01	253±21

TABLE VIII

ESSIX® ACE ONE-WAY ANOVA RESULTS

VARIABLE AND SOURCE	F Statistic	P-value
Light Transmittance (%)	9.282	<0.001*
Surface Roughness (µm)	0.963	0.474
Flexural Modulus (MPa)	6.656	<0.001*

*Statistically significant at: $p \leq 0.05$

TABLE IX

ESSIX® ACE PAIR-WISE MEAN-DIFFERENCE RESULTS – LIGHT TRANSMITTANCE

CLEANING METHOD	Invisalign® cleaning crystals	Polident®	Listerine®	2.5% vinegar	0.6% sodium hypochlorite	3% hydrogen peroxide	Toothbrushing
Invisalign® cleaning crystals		1.000	<0.001*	1.000	1.000	1.000	0.890
Polident®	1.000		0.001*	1.000	1.000	1.000	1.000
Listerine®	<0.001*	0.001*		<0.001*	<0.001*	<0.001*	0.061
2.5% vinegar	1.000	1.000	<0.001*		1.000	1.000	0.061
0.6% sodium hypochlorite	1.000	1.000	<0.001*	1.000		1.000	0.499
3% hydrogen peroxide	1.000	1.000	<0.001*	1.000	1.000		0.443
Toothbrushing	0.890	1.000	0.061	0.061	0.499	0.443	

*Statistically significant at: $p \leq 0.05$

TABLE X

ESSIX® ACE PAIR-WISE MEAN-DIFFERENCE RESULTS – FLEXURAL MODULUS

CLEANING METHOD	Invisalign® cleaning crystals	Polident®	Listerine®	2.5% vinegar	0.6% sodium hypochlorite	3% hydrogen peroxide	Toothbrushing
Invisalign® cleaning crystals		0.301	0.124	0.274	0.056	<0.001*	0.001*
Polident®	0.301		1.000	1.000	1.000	0.089	0.939
Listerine®	0.124	1.000		1.000	1.000	0.219	1.000
2.5% vinegar	0.274	1.000	1.000		1.000	0.098	1.000
0.6% sodium hypochlorite	0.056	1.000	1.000	1.000		0.457	1.000
3% hydrogen peroxide	<0.001*	0.089	0.219	0.098	0.457		1.000
Toothbrushing	0.001*	0.939	1.000	1.000	1.000	1.000	

*Statistically significant at: $p \leq 0.05$

5. DISCUSSION

5.1 Discussion

This study evaluated the long-term effects of cleaning methods on light transmittance, surface roughness and flexural modulus of Vivera® and Essix® ACE clear retainers. The main composition of Vivera® is polyurethane and Essix® ACE is a copolyester, consisting mainly of polyethylene (Invisalign Appliance Materials, 2013 and ACE Plastic, 2005). Aligner materials are generally composed of resin polymers and subject to changes when exposed to humidity, warmth, and salivary enzymes (Eliades et al., 1999).

Results of our baseline analysis of light transmittance, surface roughness, and flexural modulus of Vivera® and Essix® ACE reveal that they differ in transmittance (Figure 23) and flexural modulus (Figure 25) but are comparable in surface roughness (Figure 24). Vivera® had a decreased initial transmittance compared to Essix® ACE and an increased modulus. Therefore, we reject the first null hypothesis for light transmittance and flexural modulus. Both materials are made up of different polymers. Vivera® is a polyurethane and comes from methylene diphenyl diioscyanate and 1, 6-hexanediol with additional additives (Invisalign® Appliance Materials, 2013). The literature reports that polyurethanes are particularly susceptible to light degradation (Thomson, 2013). Furthermore, aging of polyurethanes has been shown to increase modulus (Boubakri et al., 2010) supporting the results of our first hypothesis. Essix® ACE is a copolyester, primarily consisting of polyethylene tetraphalate and additives (ACE Plastic 2005). Because each material is made up of a different polymer, their baseline properties are expected to differ.

Aromatic polyurethane, the specific type of polyurethane in Vivera® is extensively used in medical devices and known to have superb mechanical properties. These properties include

high tensile strength and high melting points, abrasion resistance, chemical resistance, ease of processing and tensile strength (A guide to thermoplastic polyurethanes). Despite good physical properties, polyurethanes are susceptible to light degradation over time (Thompson, 2013). Furthermore, they are susceptible to water hydrolysis and oxidative degradation ultimately leading to cracking when left in vivo for extended periods of time. Polyurethane is not inert, and is known to be affected by heat, moisture, and enzymes (Schuster et al., 2004). According to the MSDS sheet from Align® Technology, Vivera® is meant to be thermally stable at most temperatures. However, surface degradation is expected when exposed to sunlight. On the whole however, no large amounts of biodegradation are expected (Align Technology, 2013).

Copolyesters are known to have high light transmittance, excellent mechanical properties, great fatigue resistance, and dimensional stability (Zhang et al., 2011). Primarily composed of polyethylene, copolyesters have good chemical resistance and have been shown to exhibit less wear than other softer thermoplastics (Gardner et al., 2003). Similar to polyurethane, copolyesters do contain low hydrolytic stability (Modjarrad and Ebnesajjad, 2014). As supported by the literature above, there is an inherent difference in the composition of Vivera® and Essix® ACE.

The second hypothesis is rejected for light transmittance in both retainer materials. Both Vivera® and Essix® ACE showed similar loss of light transmittance among all cleaning methods. These results agree with previous studies examining the deterioration of properties of aligner materials overtime (Gracco et al, 2009). Based on the results of the current study, it is evident that there is a consistent decrease in translucency in both Vivera® and Essix® ACE retainer materials due to immersion in different cleaning solutions. Polyurethane, the primary component of Invisalign® aligners has been known to have loss of transmittance inherent in its

physical properties which could have attributed to the decrease in transmittance compared to Essix® ACE (Gracco et al., 2009). Furthermore, artificial saliva will accelerate discoloration of polyurethane material despite daily toothbrushing (Gracco et al., 2009). Previous studies have also found that polyurethanes are particularly vulnerable to pigment adsorption and have poor color stability supporting the fact that there was a decrease in translucency (Kim and Lee, 2009).

The second hypothesis is accepted for surface roughness of Vivera®. Vivera® showed to be relatively unchanged in surface roughness at 6 months compared to baseline except with NaClO. Though NaClO did cause a statistically significant increase in surface roughness, qualitative assessment with SEM (Figure 28) showed no difference, indicating that the results may not be clinically significant. Similarly, the surface roughness of Essix® ACE was relatively unaffected by the cleaning methods. Though Listerine did cause a statistically significant increase in roughness, SEM results showed no difference (Figure 32) indicating little clinical significance. Furthermore, the human tongue cannot detect surface roughness less than 0.5 microns (Sarrett, 2010), suggesting further lack of clinical significance in surface roughness results. All surface roughness values for Vivera® and Essix® ACE were well below 0.5microns, suggesting that the roughness caused by the solutions was not enough to have clinical significance even though it did have statistical significance.

The second hypothesis is rejected for flexural modulus of Vivera® with vinegar and toothbrushing. All other cleaning methods had no effect on flexural modulus. Both vinegar and toothbrushing increased the modulus of Vivera®, thereby increasing stiffness and decreasing flexibility. Polyurethanes have been seen to undergo physiochemical changes due to water hydrolysis, thereby causing swelling and irreversible degradation, which may support this result of increased stiffness with vinegar and toothbrushing (Zhang et al., 2011). Likewise, the second

hypothesis was rejected for flexural modulus of Essix® ACE with all cleaning methods except for Invisalign® cleaning crystals. Invisalign® cleaning crystals had little effect on flexural modulus of Essix® ACE. This increase in flexural modulus or stiffness of Essix® ACE could be attributed to the oxidation of the polymer. Oxidation is synonymous with aging or degradation of polymers. Polymers undergo oxidation at certain temperatures, but this oxidation often results in an increase in modulus or stiffness (Sepe, 2014).

The third hypothesis is rejected for light transmittance of Vivera® and Essix® ACE. Toothbrushing Vivera® with Double-distilled water elicited the greatest change in light transmittance. Results of the post hoc Bonferroni test indicated that Invisalign® cleaning crystals, Listerine® and Polident® are all different from toothbrushing, and therefore suitable cleaning reagents for Vivera® retainers. The scratches that toothbrushing elicited in Vivera® in (Figure 34) can be speculated to have contributed to the decrease in transmittance overtime. Results of the post hoc Bonferroni test for Essix® ACE indicated that Listerine® caused the greatest decrease in transmittance, similar to toothbrushing. One of the two main components of Listerine®, ethanol has been shown to cause slight yellowing at 50% in copolyesters (Eastman Spectar copolyester). Though ethanol is only present at about 20% in Listerine®, it can be thought that the alcohol content could still cause some discoloration in Essix® ACE. This result is further supported by results of a previous study which showed color changes in clear retainers when exposed to wine, suggesting that alcohol may lead to color changes in retainer thermoplastics (Zafeiriadis et al., 2014).

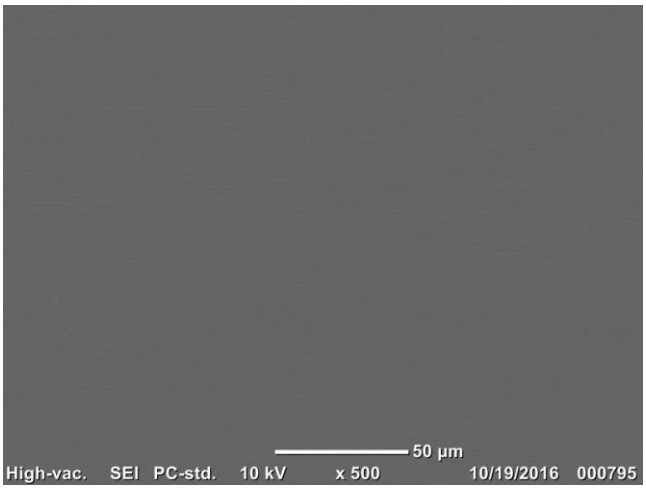

Figure 34. SEM of Vivera® with toothbrushing

The third hypothesis is accepted for surface roughness of Vivera® and Essix® ACE and accepted for flexural modulus of Vivera® as no cleaning method appeared to be superior to the other. This hypothesis is rejected for flexural modulus of Essix® ACE. Results of the post hoc Bonferroni for flexural modulus in Essix® ACE indicate that H_2O_2 had the highest flexural modulus and differed significantly from Invisalign® cleaning crystals and toothbrushing. H_2O_2 is a powerful oxidizer, and as mentioned previously, oxidation has been known to increase stiffness in polymers which supports the results of the hypothesis. Oxidative degradation has been known to increase stiffness of polymers over time as a result of surface polarity changes in polyesters (Caudill, 1992).

5.2 Limitations of this Study

One of the most significant limitations of this study is that the specimens that were used were flat and did not reflect the real shape of orthodontic clear retainers. Clear orthodontic retainers are fabricated over a model of a patient's teeth and therefore assume a much less uniform shape. For the purpose of this study, flat specimens were used for ease of manipulation

and to create a basis for future studies. Though the specimens were flat, they were processed which eliminated the variable of heat effect on the material due to processing.

Align® Technology processed and cut the material before donating it for the study. Because of this, we are unaware of the method they use for processing and cutting the material. The process that the material went through could have played a factor and effected our results.

The profilometer machine proved to be an inefficient test for this particular study. Not only was the sensitivity too small, but generally for this type of test, there is a "control" sample that is measured before each test sample to ensure that the machine is recording the surface roughness accurately at each time.

5.3 Future Research

In future studies, the sample size should be increased to enhance the power and validity of the study. Future studies would also benefit from testing real thermoformed retainers instead of flat specimen. This study demonstrates that the largest differences were seen in the translucency of the retainer materials. It would be beneficial to further investigate the degree of discoloration and decrease in translucency to better determine at what point new retainers should be fabricated.

Until now, most studies have focused on in vitro evaluation of retainer materials. Few studies have been in vivo, or evaluating the effects of the intraoral environment on clear retainers. Attempts to evaluate retainer thermoplastics intra-orally would have better validity and more clinical relevance as it is virtually impossible to simulate intra-oral environments and expect to have comparable results. Examining how the intraoral environment effects physical properties of clear retainers would have more clinical validity.

Generally, orthodontists recommend full time retainer use for six months to one year after removal of appliances. After the first year, nighttime use is recommended. Therefore, a longer term study evaluating effects on retainers over a few years may hold more validity as it would simulate real world applications better than a 6-month trial.

6. CONCLUSION

The light transmittance of Vivera® and Essix® ACE clear retainers appears to decrease over time. Toothbrushing appears to affect clarity of Vivera® the most while Listerine® appears to have the most detrimental effect on Essix® ACE. Surface roughness does not change over the 6-month period of study. Qualitative analysis with SEM confirms the fact that the studied cleaning methods have a minimal effect on the surface roughness of these clear retainers. In addition, since the human tongue cannot detect surface irregularities below 0.5microns, the results of the profilometer test are not clinically relevant. Flexural modulus of Essix® ACE appears to be affected by strong oxidizers, leading to an increase in modulus and decrease in flexibility. Overall, Invisalign® cleaning crystals appear to have the least effect on light transmittance in Vivera® and little effect on flexural modulus in Essix® ACE suggesting that it is a likely an efficient cleaning method for clear retainers. However, future studies with an increased sample size and simulated intraoral conditions should be carried out to increase the validity and relevance of the findings.

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APPENDICES

APPENDIX A

Material Safety Data Sheet *Align Technology, Inc.*

Title: MSDS for Invisalign Appliance Materials – EX15, EX30, and EX40		ECO Number: SJ003732
Doc Number: 2088	Rev: C	Last Print Date: 01/07/13

MATERIAL SAFETY DATA SHEET

ALIGN TECHNOLOGY, INC.
2560 Orchard Parkway
San Jose, CA 95131
USA
(888) 822-5446

1. CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Product names:
EX30 – Invisalign® Aligners
EX40 – Vivera® and Invisalign® Retainers
EX15 – Invisalign® Templates

2. COMPOSITION/ INFORMATION ON INGREDIENTS

2.1. Polyurethane from methylene diphenyl diisocyanate and 1, 6-hexanediol. CAS# 137873-51-9
2.2. Additives

3. HAZARDS INDENTIFICATION

3.1. EMERGENCY OVERVIEW
3.1.1. This product consists primarily of high molecular weight polymers which are not expected to be hazardous.
3.1.2. Can burn in a fire creating dense, toxic smoke.
3.1.3. Molten plastic can cause severe burns.
3.1.4. Odorless.
3.1.5. No significant immediate hazards for emergency response are known.

3.2. POTENTIAL HEALTH EFFECTS (See Section 11 for toxicological data.)
3.2.1. EYE: Solid or dust may cause irritation or corneal injury due to mechanical action. Elevated temperatures may generate vapor levels sufficient to cause eye irritation.
3.2.2. SKIN: Essentially nonirritating to skin. Mechanical injury only. Molten material may burn skin. Skin absorption is unlikely due to physical properties.

APPENDIX A (continued)

Material Safety Data Sheet *Align Technology, Inc.*

Title: MSDS for Invisalign Appliance Materials – EX15, EX30, and EX40		ECO Number: SJ003732
Doc Number: 2088	Rev: C	Last Print Date: 01/07/13

3.2.3. INGESTION: Single dose oral toxicity is considered to be extremely low. No hazards anticipated from swallowing small amounts incidental to normal handling operations.

3.3. INHALATION: Dust may cause irritation of the upper respiratory tract. At room temperature, Exposure to vapors is unlikely due to physical properties: normal-processing temperatures may generate vapors which may cause irritation if ventilation is inadequate.

3.4. SYSTEMIC (OTHER TARGET ORGAN) Effects: No specific data: however, repeated exposure to the unheated material are not anticipated to cause significant adverse effects. Processing fumes may cause eye and respiratory irritation upon repeated exposure.

3.5. CANCER INFORMATION: No relevant information found.

3.6. TERATOLOGY (BIRTH DEFECTS): No relevant information found.

3.7. REPRODUCTIVE EFFECTS: No relevant information found.

4. FIRST AID

4.1. EYES: Flush eyes with plenty of water.
4.2. SKIN: Wash off the following water or shower.
4.3. INGESTION: No adverse effects anticipated by this route of exposure incidental to proper industrial handling.
4.4. INHALATION: Remove to fresh air if effects occur. Consult a physician.
4.5. NOTE TO PHYSICIAN: If burn is present, treat as any thermal burn, after decontamination. No specific antidote. Supportive care. Treatment based on judgment if the physician in response to reactions of the patient.

5. FIRE FIGHTING MEASURES

5.1. FLAMMABLE PROBERTIES

5.1.1. FLASH POINT: Not applicable

5.1.2. METHOD USED: Not applicable

5.2. FLAMABLE LIMITS

5.2.1. LFL: Not applicable

5.2.2. UFL: Not applicable

APPENDIX A (continued)

Material Safety Data Sheet *Align Technology, Inc.*

Title: MSDS for Invisalign Appliance Materials – EX15, EX30, and EX40		ECO Number: SJ003732
Doc Number: 2088	Rev: C	Last Print Date: 01/07/13

5.3. HAZARDOUS COMBUSTION PRDUCTS: Under fire conditions polymers decompose. The smoke may contain polymer fragments of varying compositions in addition to unidentified toxic and/or irritating compounds. Hazardous combustion products may include and are not limited to Carbon monoxide and Carbon dioxide and trace amounts of aromatic hydrocarbons as hydrogen cyanide.

5.4. OTHER FLAMABLE INFORMATION: Dense smoke is emitted when burned without sufficient oxygen. Mechanical handling can cause formation of dusts. To reduce the potential for dust explosion, do not permit dust to accumulate.

5.5. EXTINGUISHING MEDIA: Water, Carbon dioxide or Dry chemical.

5.6. FIRE FIGHTING INSTRUCTIONS: Keep people away. Isolate fire area and deny unnecessary entry. Cool surroundings with water to localize fire zone. Hand held carbon dioxide or dry chemical extinguishers may be used for small fires. Soak thoroughly with water to cool and prevent re-ignition.

5.7. PROTECTIVE EQUIPMENT FOR FIREFIGHTERS: Wear positive-pressure-self-containing breathing apparatus (SCBA) and protective fire fighting clothing (includes fire fighting helmet, coat, pants, boots, and gloves). If protective equipment is not available or not used, fight fire from a protected location or safe distance.

6. ACCIDENTAL RELEASE MEASURES (See Section 15 for Regulatory Information)

6.1. PROTECT PEOPLE: Pellets or beads may present a slipping hazard.

6.2. PROTECT THE ENVIRONMENT: Spills should be collected to prevent contamination or Waterways. Material is heavier than water and had limited water solubility. It will collect on the lowest surface. See section 13 for more specific information.

6.3. CLEANUP: Sweep up.

7. HANDLING AND STORAGE

7.1. HANDLING: Good housekeeping and controlling of dusts are necessary for safe handling of product.

7.2. STORAGE: Store in a dry place.

APPENDIX A (continued)

Material Safety Data Sheet *Align Technology, Inc.*

Title: MSDS for Invisalign Appliance Materials – EX15, EX30, and EX40		ECO Number: SJ003732
Doc Number: 2088	Rev: C	Last Print Date: 01/07/13

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. ENGINEERING CONTROLS: Good general ventilation should be sufficient for most conditions. Local exhaust ventilation may be necessary for some operations.

8.2. PERSONAL PROTECTIVE EQUIPMENT

8.3. EYE/FACE PROTECTION: Use safety glasses. If there is a potential for exposure to particles which could cause mechanical injury to the eye, wear chemical goggles. If vapor exposure causes eye discomfort, use a full-face respirator.

8.4. SKIN PROTECTION: No precautions other than clean body-covering clothing should be needed. Use gloves with insulation for thermal protection, when needed.

8.5. RESPIRATORY PROTECTION: For most conditions, no respiratory protection should be needed; however, if handling at elevated temperatures without sufficient ventilation, use an approved air-purifying respirator. In dusty atmospheres, use an approved dust respirator.

8.6. EXPOSURE GUIDELINE (S): None established

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. APPERANCE: Clear to pale yellow pellets.

9.2. ODOR: Odorless.

9.3. BOILING POINT: Not applicable.

9.4. VAP. PRESS: Not applicable.

9.5. VAP. DENSITY: Not applicable.

9.6. SOL. IN WATER: Insoluble.

9.7. SP. GRAVITY: 1.1 – 1.2

10. STABILITY AND REACTIVITY

10.1. CHEMICAL STABILITY: Thermally stable at typical use temperatures.

10.2. CONDITIONS TO AVOID: Avoid temperatures above 500F (260°C).

10.3. INCOMPATIBILITY WITH OTHER MATERIALS: Non known

10.4. HAZARDOUS DECOMPOSITION PRODUCTS: Processing may release fumes, which may include polymer fragments and other decomposition products. Fumes can be irritating. At temperatures exceeding melt temperatures, polymer fragments can occur. Hazardous decomposition products may include and are not limited to aliphatic and aromatic compounds, carbon dioxide and trace amounts of hydrogen cyanide.

10.5. HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

11.1. ACUTE INGESTION: Single dose oral LD50 has not been determined.

APPENDIX A (continued)

11.2. MUTAGENICITY (EFFECTS ON GENETIC MATERIAL): No relevant information found.

12. ECOLOGICAL INFORMATION

12.1. ENVIRONMENTAL FATE

12.2. MOVEMENT & PARTITIONING: No bio-concentration is expected because of high molecular weight (MW > 1000). In the terrestrial environment, material is expected to remain in the soil. In the aquatic environment, material will sink and remain in the sediment.

12.3. DEGRADATION & PERSISTENCE: This water insoluble polymeric solid is expected to be essentially un-reactive in the environment over a period of many years. Surface photo degradation is expected with exposure to sunlight. No appreciable biodegradation is expected.

12.4. ECOTOXICITY: Not expected to be acutely toxic, but pellets, if ingested by waterfowl or aquatic life, may mechanically cause adverse effects.

13. DISPOSAL CONSIDERATIONS

13.1. DISPOSAL: DO NOT DUMP INTO ANY SEWERS, ON THE GROUND, OR INTO ANY BODY OF WATER. All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

13.2. FOR UNUSED & UNCONTAMINATED PRODUCT, the preferred options include sending to a licensed, permitted: recycler, re-claimer, incinerator or other thermal destruction device, or landfill.

14. TRANSPORT INFORMATION

14.1. UNITED DOT INFORMATION: This product is not regulated by D.O.T. when shipped domestically by land.

14.2. CANADIAN TDG INFORMATION: This product is not regulated by TDG when shipped domestically by land.

15. REGULATORY INFORMATION (Not meant to be all inclusive—selected regulations represented)

15.1. NOTICE: The information herein is presented in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied is given. Regulatory requirements are subject to change and may differ from one location to another; it is the buyer's responsibility to ensure that its activities comply with federal, state or provincial, and local laws. The following

APPENDIX A (continued)

specific information is made for the purpose of complying with numerous federal, state, or provincial, and local laws and regulations. See other sections for health and safety information.

15.2. U.S. REGULATIONS

15.2.1. SARA 313 INFORMATION: To the best of our knowledge, this product contains no chemical subject to SARA Title III Section 313 supplier notification requirements.

15.2.2. SARA HAZARD CATEGORY: This product has been reviewed according to the EPA "Hazard Categories" promulgated under Section 311 and 312 of the Superfund Amendment and Reauthorization Act of 1986 (SARA Title III) and is considered, under applicable definitions, to meet the following categories:

15.2.2.1. Not to have met any hazard category

15.2.3. TOXIC SUBSTANCES CONTROL ACT (TSCA):

15.2.3.1. All ingredients are on the TSCA Inventory or are not required to be listed on the TSCA inventory.

15.2.4. STATE RIGHT-TO-KNOW: This product is not known to contain any substances subject to the disclosure requirements of

15.2.4.1. New Jersey

15.2.4.2. Pennsylvania

15.2.5. OSHA HAZARD COMMUNICATION STANDARD:

15.2.5.1. This product is not a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

15.2.6. COMPREHENSIVE ENVIRONMENTAL RESPONSE COMPENSATION AND LIABILITY ACT (CERCLA, OR SUPERFUND):

15.2.6.1. To the best of our knowledge, this product contains no chemical subject to reporting under CERCLA.

16. CANADIAN REGULATIONS

16.1. WHMIS INFORMATION: The Canadian Workplace Hazardous Materials Information System (WHMIS) Classification for the product is:

16.1.1. This product is not a "Controlled" Product: under WHMIS.

APPENDIX B

DENTSPLY GAC

MATERIAL SAFETY DATA SHEET

Form W104-11A Rev. 1

Product Name: Ace Plastic

Part Number(s):
25-025-35,25-420-41,25-450-45,25-325-30,25-020-35,25-050-35,25-478-40,25-425-40,25-320-31,25-350-35,25-347-30,25-347-35

Release Date: December14, 2005

1. Product and Company Identification

Trade Name & Synonyms Ace Plastic	**MSDS Code Number** Refer to part number
Chemical Name NA	**Manufacturer / Distributor** GAC International Inc.
C.A.S. Number NA	**Address** 355 Knickerbocker Ave. Bohemia, NY USA 11716
Grades or Minor Variant Identities NA	**Information Telephone Number** 1-631-419-1700
Product Use (for Canada) Plastic	**Emergency Telephone Number** 1-631-419-1700

2. Composition of Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Trade Secret	Proprietary	NA	5
Copolyester	Proprietary	NA	95

3. Hazard Identification

Emergency Overview

Molten material will produce thermal burns.

Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	NA	NA	NA	NA	NA
Skin	NA	NA	NA	NA	NA
Inhalation	NA	NA	NA	NA	NA
Ingestion	NA	NA	NA	NA	NA
Other	NA	NA	NA	NA	NA

Medical Conditions Aggravated by Exposure
NA

Carcinogenicity (IARC, NTP)
NA

Potential Environmental Effects
NA

4. First Aid Measures

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	If molten material contacts the eye, immediately flush with plenty of water for at least 15 minutes. If easy to do remove contact lenses.	Get medical attention immediately.	NA
Skin	If burned by contact with molten material, cool as quickly as possible. Do not peel material from skin.	Get medical attention.	NA
Inhalation	If symptomatic, move to fresh air.	Get medical attention if symptoms persist.	NA
Ingestion	Material is not expected to be absorbed from the gastrointestinal tract so that induction of vomiting should not be necessary.	NA	NA
Other	NA	NA	NA

APPENDIX B (continued)

DENTSPLY GAC

MATERIAL SAFETY DATA SHEET

Form WI04-11A Rev. 1

Product Name: Ace Plastic

Part Number(s):
25-025-35,25-420-41,25-450-45,25-325-30,25-020-35,25-050-35,25-478-40,25-425-40,25-320-31,25-350-35,25-347-30,25-347-35

Release Date: December14, 2005

Note to Physicians (Treatment, Testing, and Monitoring)
Burns should be treated as thermal burns. The material will come off as healing occurs; therefore, immediate removal from the skin is not necessary.

5. Fire and Explosion Data

Flashpoint & Method:	**Flammable (Explosive) Limits in Air**	**Autoignition Temperature**	**Other**
°C / °F NA; combustible solid	LEL: NA UEL: NA	NA	NA
Flame Propagation or Burning	**Properties Contributing to Fire Intensity**	**Flammability Classification**	
NA	NA	Health- ,Flammability-1, Reativity-0	
Extinguishing Media		**Extinguishing Media to Avoid**	
Water spray, dry chemical		NA	

Protection and Procedures for Firefighters
Wear self- contained breathing apparatus and protective clothing.

Unusual Fire and Explosion Hazards
Powdered material may form explosive dust- air mixtures. Hazardous combustion products: Carbon dioxide, carbon monoxide

6. Accidental Release Measures

Containment Techniques
NA

Spill/Leak Clean-Up Procedures and Equipment
Sweep or scoop up and remove.

Evacuation Procedures
NA

Special Instructions
NA

Reporting Requirements
NA

7. Handling and Storage

Handling Practices and Warnings
Personal Precautionary Measures: Avoid contact with molten material.

Prevention of Fire and Explosion: Keep from contact with oxidizing materials. Minimize dust generation and accumulation. In the United States of America refer to NFPA 8 Pamphlet No. 654, " Prevention of Fire and Dust Explosions in the Chemical, Dye, Pharmaceutical and Plastics Industries".

Storage Practices and Warnings
(°C / °F). Keep container closed.

8. Exposure Control/Personal Protection

Ventilation	**Other Engineering Controls**
Good general ventilation (typically 10 air changes per hour) should be used.	Ventilation rates should be matched to conditions. Supplementary local exhaust ventilation, closed system, spaces mechanical generation of dusts, heating, drying etc.

Routes of Entry:	Personal Protective Equipment (PPE) for Normal Use:	PPE for Emergencies:
Eye/Face	Wear a face shield when working with molten material.	NA
Skin	When material is heated, wear gloves to protect against thermal burns.	NA

APPENDIX B (continued)

DENTSPLY GAC

MATERIAL SAFETY DATA SHEET

Form: WI04-11A Rev. 1

Product Name: Ace Plastic

Part Number(s): 25-025-35,25-420-41,25-450-45,25-325-30,25-020-35,25-050-35,25-478-40,25-425-40,25-320-31,25-350-35,25-347-30,25-347-35

Release Date: December14, 2005

Inhalation	If engineering controls do not maintain airborne concentrations to an acceptable level, an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to insure compliance with OSHA Standard 63 FR 1152, January 8, 1998. Respirator type: Dust, organic vapor.	NA
General Hygiene Considerations and Work Practices	Recommended Decontamination Facilities: Eye bath, washing facilities.	
Protective Measures During Repair and Maintenance of Contaminated Equipment	NA	
Other Protective Measures and Equipment	NA	

9. Physical and Chemical Characteristics

Appearance Solid (pellet). Color: Varies with formulation		**Odor** Odorless
Normal Physical State: ☐ Liquid ☐ Gas ☒ Solid ☐ ____ (Other)		**Boiling Point** °C / °F NA **Melting Point** °C / °F NA **Freezing Point** °C / °F NA
Specific Gravity or Density (H_2O=1) >1	**Solubility in Water** Negligible	**pH** NA
Vapor Pressure (mm Hg @ 20°C) NA	**Vapor Density (AIR= 1)** NA	**Evaporation Rate (Butyl Acetate = 1)** NA
Other Thermal Decomposition Temperature: Thermal stability not tested. Low stability hazard expected at normal operating temperatures.Softening point: Varies with formulation.		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid) Material reacts with strong oxidizing agents.		
Hazardous Products Produced During Decomposition NA		
Hazardous Polymerization? ☐ May Occur ☒ May Not Occur		**Conditions to Avoid** °C / °F NA
Stability? ☒ Stable ☐ Unstable		**Conditions to Avoid** °C / °F NA

11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic or Reproductive Effects, or Structure Activity Data

Acute toxicity data if available are listed below. Additional toxicity data may be available on request.

APPENDIX B (continued)

DENTSPLY GAC

MATERIAL SAFETY DATA SHEET

Form WB4-11A Rev. 1

Product Name: Ace Plastic

Part Number(s): 25-025-35,25-420-41,25-450-45,25-325-30,25-020-35,25-050-35,25-478-40,25-425-40,25-320-31,25-350-35,25-347-30,25-347-35

Release Date: December14, 2001

12. Ecological Information

Toxicity, Environmental Fate, Physical/Chemical Data, or Other Data Supporting Environmental Hazard Statements

Acute toxicity data if available are listed below. Additional toxicity data may be available on request. This material has not been tested for environmental effects.

13. Disposal Considerations

Regulations

Discharge, treatment, or disposal may be subject to national, state, or local laws. Incinerate.

Properties (Physical/Chemical) Affecting Disposal

NA

14. Transport Information

Regulated for shipping?	Proper Shipping Name	Packing Group	
☐ Yes ☒ No	Ace Plastic	None	
Do changes in quantity, packaging, or shipment method change product classification?		**Hazard Class**	**Identification Number**
☐ Yes ☒ No		None	None

Other

DOT (USA): Class not regulated. ICAO Status: Class not regulated. IMDG Status: Class not regulated

15. Regulatory Information

Federal Regulations

WHMIS (Canada) Status: noncontrolled.

SARA 313: None, unless listed below.

International Regulations

NA

Other

Carcinogenicity Classification (components present at 0.1% or more): none, unless listed below.

TSCA (US Toxic Substances Control Act): This product is listed on the TSCA inventory. Any impurities present in this product are exempt from listing.

DSL (Canadian Domestic Substances List) and CEPA (Canadian Environmental Protection Act): This product is listed on the DSL. Any impurities present in this product are exempt from listing.

EINECS (European Inventory of Existing Commercial Chemical Substances): This product is listed on the EINECS. Any polymer present in this has regulatory clearance under Directives of European Union.

AICIS/NICNAS (Australian Inventory of Chemical Substances and National Industrial Chemicals Notification and ASSESSMENT Scheme): This product is listed on AICS or otherwise complies with NICNAS

MITI (Japanese Handbook of Existing and New Chemical Substances): This product is listed in the Handbook or has been approved in Japan by new substance notification.

ECL (Korean Toxic Substances Control Act): This product is listed on the Korean inventory or otherwise complies with the Korean Toxic Substances Control Act.

APPENDIX B (continued)

DENTSPLY GAC

MATERIAL SAFETY DATA SHEET

Form W304-11A Rev. 1

Product Name: Ace Plastic

Part Number(s): 25-025-35,25-420-41,25-450-45,25-325-30,25-020-35,25-050-35,25-478-40,25-425-40,25-320-31,25-350-35,25-347-30,25-347-35

Release Date: December14, 2005

16. Other Information	
Supplier Number: 40/25	**Supplier Release:** December 8, 2005

N/A = not applicable, NA = not available, N/E = not established, N/D = not determined.

APPENDIX C

ALIGN TECHNOLOGY

May 14, 2015

Align Technology Awards $310,000 as Part of Its University Research Award Program 2015 for Orthodontic Therapy and Intraoral Scanners

SAN JOSE, CA -- (Marketwired) -- 05/14/15 -- Align Technology, Inc. (NASDAQ: ALGN) today announced awards totaling $310,000 in new funding to four universities in North America and eight international universities for projects seeking to better understand orthodontic treatment and use of intraoral scanners.

"The number of applications for the Research Award Program increased tremendously this year. The topics and quality of the proposals received from around the world are very impressive making the program even more competitive than in previous years. We eagerly await the results of the university research efforts funded by this program as we endeavor to advance the field of clinical orthodontics," said John Morton, Align Technology director, research and technology.

The North America research award recipients for 2015 are:

- Dr. Joel Gluck, Dr. Marion Messersmith, and Dr. Sonia Rabangdale at Vanderbilt University (Nashville, TN), $25,000
- Dr. Phimon Atsawasuwan, Dr. Manika Agarwal, and Dr. Spiro J. Megremis at University of Illinois at Chicago (Chicago, IL.), $25,000
- Dr. Carlos Flores-Mir, Dr. Camila Pacheco-Pereira, and Dr. Terry Carlyle at University of Alberta (Edmonton, AB), $25,000
- Dr. Miroslav Tolar, Dr. Robert Boyd, Dr. Mohammed Fallah, Dr. HeeSoo Oh, and Dr. Marie Tolarova at University of the Pacific (San Francisco, CA), $25,000

The International research award recipients for 2015 are:

- Dr. Ali Darendeliler and Dr. Alexandra K. Papadopoulou at University of Sydney (Sydney, Australia), $25,000
- Dr. Graciela J. Barreda, Dr. Elizabeth A. Dzierewianko, Dr. Karina A. Muñoz, and Dr. Gisela I. Piccoli at S.A.O. - U.C.E.S. (Buenos Aires, Argentina), $25,000
- Dr. Jana B. Chabke, Dr. Waddah Sabouni, and Dr. Philippe Chanavaz at Paris Decartes University (Paris, France), $25,000
- Dr. Isabelle Graf, Dr. Bert Braumann, Dr. Jorg Schwarze, Dr. Carolin Keller, Dr. Julia Supke, and Dr. Andreas Stippig at University of Cologne (Cologne, Germany), $25,000
- Dr. Bin Cai, Dr. Tingting Ai, Dr. Lixiang Mai, Dr. Xiaonan, and Dr. Lusai Xiang at Sun Yat-sen University (Guangzhou, China), $25,000
- Dr. Phanomporn Vanichanon, Dr. Supranee Vichiennet, and Dr. Thanaporn Sowithayasakui at Chulalongkorn Univeristy (Bangkok, Thailand), $25,000
- Dr. Wenli Lai, Dr. Hu Long, Dr. Renhuan Huang, Dr. Rui Xu, and Dr. Rui Zhao at Sichuan University (Chengdu, China)
- Dr. Mimi Yow, Dr. Linton J. Nash, and Dr. Jason C. Sheng at National University of Singapore (Singapore), $25,000

"As we further expand our growth in the international markets, especially in the APAC regions, more universities are now engaging in advanced research to further the capability of Invisalign treatment in all types of malocclusion and orthodontics. Align Technology is honored to be able to provide this funding to enable universities to better understand the issues involved in orthodontic treatment around the world today," said Dr. Mitra Derakhshan, Align Technology clinical international director.

The research study proposals approved for funding in 2015 consist of evaluating long term flexibility, and translucency of clear retainers; understanding of the factors that influence patients' satisfaction with their Invisalign orthodontic treatment outcomes; quantifying the amount of tooth movement achieved; evaluation of the magnitude of force applied by an aligner; evaluating the efficacy, effectiveness and treatment results and stability of open bite treatment; evaluating attachment surfaces; evaluating treatment duration for surgical class II patients; evaluating occlusal characteristics and oral health-related quality of life; examining the effect of orthodontic treatment on speech; analyzing occlusion in patients before and after Invisalign treatment; comparing tooth movement efficacy and comfort with Invisalign treatment.

In 2013, Align introduced a intraoral scanner research award component in recognition of the rapid increase in the utilization of intraoral scanning technology. The following are the scanner award recipients for 2015:

APPENDIX C (continued)

- Dr. Emiliya D. Taneva at University of Illinois at Chicago (Chicago, IL.), $5,000
- Dr. Jing Guo at Shandong University (Shandong, China), $5,000

The two intraoral scanner award proposals include evaluating palatal rugae patterns using 3-dimentional digital models obtained with the iTero intraoral scanner; evaluating the repeatability and reliability of digital intraoral scanning by different operators under clinical conditions.

All proposals received were reviewed and prioritized by an independent academic committee in a blind evaluation. The 2015 academic committee is comprised of six members: Dr. Sunil Wadhwa (Chair), director of the Division of Orthodontics at the Columbia University; Professor Donald Burden, director of the Centre for Dentistry at the Queen's University at Belfast, Ireland; Dr. Emile Rossouw, chairman of the Department of Orthodontics at University of North Carolina; Dr. Glenn Sameshima, chairman of the Advanced Orthodontic Program at University of Southern California; Dr. Allen Firestone, associate professor of orthodontics at Columbia University; and Dr. Timothy Wheeler, professor of orthodontics at University of Florida, previous academic committee chair, and committee advisor.

The 2016 Align Research Award Program submission details are to be announced later this year.

About Align Technology, Inc.
Align Technology is the leader in modern clear aligner orthodontics that designs, manufactures and markets the Invisalign® system, which provides dental professionals with a range of treatment options for adults and teenagers. Align also offers the iTero 3D digital scanning system and services for orthodontic and restorative dentistry. Align was founded in March 1997 and received FDA clearance to market the Invisalign system in 1998. Visit www.aligntech.com for more information.

For additional information about the Invisalign system or to find an Invisalign provider in your area, please visit www.invisalign.com. For additional information about the iTero 3D digital scanning system, please visit www.itero.com.

Source: Align Technology

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VITA

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	M.S., Oral Sciences, University of Illinois at Chicago, Chicago, Illinois, 2017
	Certificate, Orthodontics, University of Illinois at Chicago, Chicago, Illinois, 2017
HONORS:	Research Honors Distinction, University of Pennsylvania, Philadephia, Pennsylvania 2014
AWARDS/ SCHOLARSHIPS:	Align Technology® Research Award, 2015
PROFESSIONAL MEMBERSHIP:	American Association of Orthodontists American Dental Association Illinois Society of Orthodontists Chicago Dental Society