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INVITRO EVALUATION OF FORCES DELIVERED BY ALIGNERS FABRICATED USING POSITIVE AIR PRESSURE VERSUS NEGATIVE AIR PRESSURE

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ABSTRACT

Objective: To evaluate the difference in force delivery between aligners fabricated using positive air pressure versus negative air pressure.

Material and methods: A series of clear aligners of similar material composition (PET-G), manufacturer (Scheu Dental), thickness (0.75mm) and activation of 0.2mm uncontrolled palatal tipping on the upper left central incisor were designed and fabricated using two different methods of fabrication. The first set of aligners (n=5) were fabricated via positive air pressure using MiniStarS pressure thermoforming and the second set (n=5) were fabricated via negative air pressure using the PlastVac P7 vacuum forming machine. A force change measurement system was used to measure changes in the forces delivered by the pressure formed and vacuum formed PET-G materials. Statistical analysis was carried independent samples t test to compare between pressure formed and vacuum formed force values using Significance level was considered at $P < 0.05$.

Results: There was a statistically significant increase in force values delivered by aligners thermoformed using positive air pressure compared to aligners fabricated using negative air pressure. Forces delivered by vacuum formed aligners averaged to **0.40N** compared with **1.01N** for aligners thermoformed using positive air pressure.

Conclusions: The forces delivered by aligners are influenced by the fabrication process; aligners fabricated using positive pressure showed increased fit and adaptation on the resin model which led to an increase in the delivered forces compared to aligners fabricated using negative pressure.

KEYWORDS: Aligners, Force, Positive air pressure

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INTRODUCTION

Clear Aligner therapy (CAT) is an orthodontic technique that uses a series of custom plastic aligners manufactured on computer generated models to guide teeth gradually into proper alignment. The concept of clear aligners was first introduced by Kesling in 1945. Originally, clear aligners were used as a complimentary treatment for finishing orthodontic treatment. However, their laboratory fabrication was tedious, so they didn't gain much popularity.[1]

As the esthetic demands for orthodontic patients increased, the demand for CAT rocketed over the last few years. With the obvious benefits of being invisible; hence being more aesthetic, removable; so they are easier to clean and more convenient to the patient, CAT is now competing to take place of conventional fixed appliance therapy altogether.[2]

Currently with development of dental materials and computer science, manufacturing of clear aligners is much easier. Furthermore, all types of tooth movement are now possible with better understanding of how clear aligners work and the factors controlling their performance.[3]

Clear Aligners are made from viscoelastic thermoplastic materials. Their material composition mostly consists of polyethylene terephthalate glycol-modified (PET-G), polypropylene, polycarbonate, thermoplastic polyurethanes, or ethylene vinyl acetate polymer blends.[4]

Viscoelastic materials have intermediate properties between viscous and elastic materials. This means that the material properties vary considerably over time even if there is no load applied to the aligner. They experience creep and stress relaxation. Therefore, they deliver forces in a less constant manner compared to stainless steel and nickel titanium wires.[5]

Aligners have been widely used in clinical settings. Few studies, though, have examined their applied force. Orthodontists' clinical experiences largely determine how much tooth movement occurs at various stages. If too much or too little force is used to correct a tooth, it may hurt or have little effect. Therefore, a more effective final design depends on the force delivery capability of clear aligners. [6]

One major step of advancement is the introduction of different thermoforming techniques using plastic sheets to fabricate the appliance in an efficient manner.[7] There are two commonly known thermoforming techniques to mold the aligner sheet on the dental model: Pressure forming (positive air pressure) and Vacuum forming (negative air pressure). The pressure forming method employs positive pressures up to 100 psi, which produces a more exact fit, whereas the vacuum forming approach uses negative pressures between 3 and 14 psi.[8]

Weir et al. explained that the inner fit of the aligner and its ability to generate forces on the surface of the tooth is dependent on the air pressure of its fabrication to some degree. Aligners that are fabricated using positive air pressure are hypothesized to have more precise fit on the tooth and hence more efficient force delivery.[3]

The purpose of this study was to investigate the effect of different thermoforming techniques (positive pressure and negative pressure) on the force levels of aligners made from similar material composition, thickness and activation.

MATERIALS AND METHODS

A series of clear aligners were designed and fabricated in the Orthodontic Department Digital Center of the Faculty of Dentistry, XXX, XXX, XXX. Two types of thermoforming techniques were used in the fabrication of the aligners: positive air pressure and negative air pressure. Within each group the aligners used were made from same the polymer composition, manufacturer, thickness and activations. Most manufacturers use PET-G aligners; therefore PET-G was selected for this study[6]. The aligner sheets used in this study were manufactured by Duran, Scheu Dental, GmbH, Iserlohn, Germany, which are incorporated by the Clear-Aligner System.

To investigate the effect of different thermoforming pressures on force delivery of aligners, 5 Duran PET-G aligner sheets each of 0.75mm thickness were thermoformed on a 0.2mm activation model using positive air pressure. Another five aligner sheets of the same mentioned criteria were thermoformed using negative air pressure.

A stone model of a well aligned maxillary dental arch was randomly selected from a pool of post-treatment patient records obtained from the Department of Orthodontics at Faculty of Dentistry, XXX. The stone model was scanned using the 3-shape R-750 scanner* to obtain a digitized version of the model via Autolign** software.

To obtain the activation model, 0.2mm activation of the upper left central incisor was performed in the palatal direction. This model was labelled NH1 while the zero model that harbored no movement of the central incisor was left unlabeled.

Using the Autolign sculpting tool, a trim line 2mm above the gingival margin of teeth was applied to both models, both models were then 3D printed using the PhotonMono*** 3D printer

All samples were thermoformed according to the manufacturer's instructions using the same parameters.

a) Positive Air Pressure:

Five Duran PET-G aligner sheets were thermoformed with positive air pressure using the MinistarS**** pressure forming machine. Pressure at 4bar/58psi, infrared heat at 160°C for 30 seconds, then cooling for 45 seconds was applied to thermoform the aligner sheets on the 0.2mm activation model.

b) Negative Air Pressure:

Another 5 Duran PET-G aligner sheets were thermoformed with negative air pressure using the PlastVacP7***** vacuum forming machine on the 0.2mm activation model. This machine was used at a pressure of 2.5bar at 120°C for 30 seconds.

All aligners were then trimmed 2mm above the gingival margin using the trim line on the model as a reference.

A 0.2mm thick Hi-Precise pressure sensor was used to detect force level changes (Fig.1). This sensor, the thinnest sensor ever created, was designed and fabricated by TekScan (Massachusetts, USA)[9]. This sensor had superior specifications compared to conventional sensors such as a soft and flexible material structure, minimal thickness, small size and high sensitivity. A specific working circuit was prepared and connected to the sensor.

Fig. (1)

The sensor used in this study is a force sensitive resistor that detects pressure by changing its resistive

* 3shape, Copenhagen, Denmark.
** Diorco Co., Ltd., Korea.
*** HongKong ANYCUBIC Technology CO., Limited
**** Scheu-Dental Gmbh, Iserlohn, Germany
***** Bio-art, Sao Carlos SP, Brazil

value. The more pressure felt by the sensor the more its resistance goes down. The resistance of the sensor without load was greater than 8KW. The pressure detected by the sensor is read by the working circuit in Voltages. This data was then read by a supporting software and an equation provided by the software is used to convert the voltage values to Force values measured in Newtons. An illustration of the signal acquisition unit is displayed in (Fig.2). The circuit equation was as follows: VO = VCC (R/(R+FSR)).

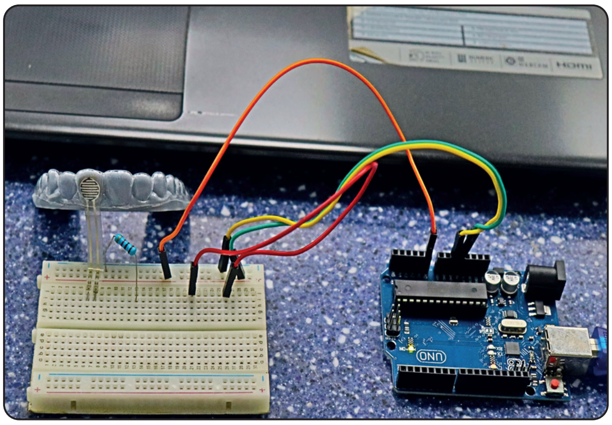

Fig. (2)

The sensors' effectiveness was assessed by using 10 calibrated forces. The results had a 95% maximum precision rate, demonstrating their remarkable reproducibility.

To measure the corresponding orthodontic force for each aligner, a supporting software visually displayed pressure data (ArduinoIDE 2.0.4, Ivrea, Italy). All measurements were taken under room temperature of 25°C and low humidity after the sensor was calibrated.

For both experimental groups, all readings were recorded by placing the thermoformed aligner on the zero-activation model to measure the force delivery by the aligner.

A conversion equation was inserted into the software to convert the readings from resistance units to force units in Newtons. The results were then submitted to statistical analysis.

RESULTS

Aligners thermoformed using negative pressure showed lower force values than aligners thermoformed using positive pressure. The mean force value with the negative pressure thermoformed aligners was found to be **0.4000N** and the mean force value with the aligners thermoformed using positive pressure was found to be **1.1000N.** A bar chart of the measured force changes is shown in (Fig.3)

The percentage increase of mean force relative to the force at negative pressure was found to be 175.00%.

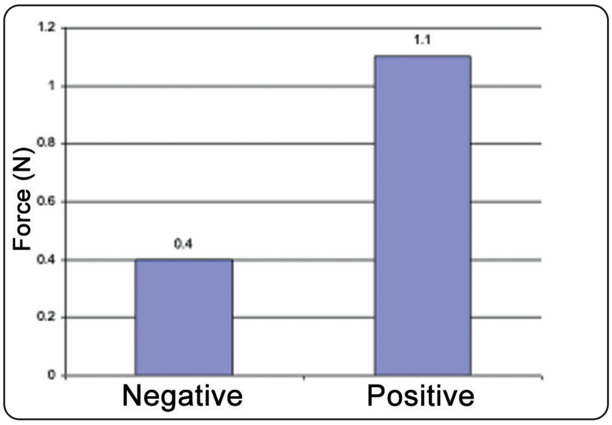

Fig. (3)

Statistical analysis

All data were collected, tabulated and subjected to statistical analysis. Statistical analysis was performed by IBMÒ SPSSâ (version 20 for Windows; IBM, Armonk, NY). Microsoft office Excel was used for data handling and graphical presentation.

A Shapiro-Wilk test of normality was applied and showed that the data were normally distributed.

Each measurement's averages and standard deviations were determined, and an analysis of variance for between-subject effects was carried out to establish the degree of significance between the results (95% confidence level: significant at $P<0.05$).

Independent samples *t* test was carried out to compare between two non-numeric values.

The results of this test showed a statistically highly significant difference between the force levels of positive and negative pressures with $P<0.01$ which is considered highly significant.

DISCUSSION

Clear Aligner Therapy (CAT) is the most current and exponentially growing treatment technique in the field of Orthodontics. This is largely due to the increase in public awareness of dental esthetics which has led to a rise in the demand for more esthetically appealing orthodontic treatment modalities.[10] This directly corresponded with the reported jump in the number of dental professionals offering CAT.[11]

CAT is marketed as a more convenient and esthetic alternative to fixed orthodontic therapy, more *adults* are now more interested in getting comprehensive orthodontic treatment. This also contributed to the leap in popularity of CAT among patients of different age groups.[3, 10]

As a result of the increased popularity in use of clear aligners in orthodontic offices combined with the relative deficiency in available research, the scope of interest in this study was to have a closer look at the force delivery of clear aligners.

This study focused on one of the most versatile systems in the market nowadays; the **Clear-Aligner® system**.The Clear-Aligner System is the most popular system after Invisalign which is why it was used in this study[12]

The method of fabrication of aligners and the magnitude of air pressure used in their fabrication is an important predictor of the forces delivered by aligners as it directly affects the aligner fit and adaptation on the teeth. **Nahoum** stated that the air pressure's magnitude determines the aligner's inner details and fit to a certain point. The more intricately detailed the inner surface of the aligner is, the more force is generated and the higher precision of tooth movement is expected by the aligner.[13]

Despite increased popularity of CAT, there are no previous studies that compared the force delivery of aligners fabricated using negative versus positive air pressure. Therefore, this study was carried out.

However, previous studies investigated force values in different settings and parameters, for instance, **Barbagallo et al.** studied the force that thermoplastic appliances applied to maxillary first premolars in vivo using a pressure-film.[14] A German study team investigated the force delivery characteristics of thermoplastic aligners during tipping and intrusion of teeth and reported the impacts of several materials and their thicknesses.[15-17]

The force levels delivered by aligners fabricated using positive air pressure versus aligners fabricated with negative air pressure were compared. The results showed that aligners thermoformed using positive air pressure deliver higher forces than aligners made with negative air pressure by almost 175% increase. This suggests that the increase in air pressure used in thermoforming aligner sheets improves the fit of the aligner inner surface in contact with the teeth. Our results align with **Hahn et al.**, who concluded that vacuum formed (negative air pressure) aligners deliver lower forces at *higher activations* compared with pressure formed (positive air pressure) aligners confirming that the method of fabrication has measurable effect on the forces delivered.[16] This result might be explained by the greater friction applied by aligners fabricated using positive pressure, which leads to increased resistance to lifting up forces that are caused by the progressive deflection of the aligner on the measuring tooth.

Forces delivered by vacuum formed aligners were only slightly higher **(0.40N)**, than the optimum recommended levels for uncontrolled tipping as recommended by Proffit (0.3N – 0.6N), compared with **1.01N** with pressure formed aligners.[18] This means that using negative air pressure for thermoforming aligners may not be efficient in producing the sufficient force levels needed to achieve uncontrolled palatal tipping.

CONCLUSIONS

The method of aligner fabrication affects the forces delivered by the aligner. Using positive thermoforming pressure increases aligner fit and adaptation on the resin model leading to a statistically highly significant increase in force delivery. While using negative pressure delivered forces that lie within the biologic force range for uncontrolled tipping, however, these forces were in the lower bound of the range.

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