A Comparison of the Force Degradation of Marketed

Latex Elastics in Varying Normal Resting pHs

By

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### THESIS

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Dr. Maria Therese Galang Dr. Budi Kusnoto Dr. William Hohlt Dr. Ana Bedran-Russo Grace Viana, Msc This thesis is dedicated to my loving fiancée, Cristina, and my parents Mark and Marguerite. Their endless love and support have guided me through all of my successes. I would also like to dedicate this thesis to Dr. William Hohlt and his wonderful wife Judi. They treated me like a son and their support guided me through dental school and my residency in orthodontics.

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## LIST OF ABBREVIATIONS

RMO®	Rocky Mountain <sup>®</sup> Orthodontics (Denver, CO)
$G\&H^{\mathbb{R}}$	G&H <sup>®</sup> Wire Company (Franklin, IN)
3M <sup>®</sup>	3M <sup>®</sup> Unitek (Monrovia, CA)
$\operatorname{OO}^{\mathbb{R}}$	Ortho Organizers <sup>®</sup> (Carlsbad, CA)
$\operatorname{AO}^{\mathbb{R}}$	American Orthodontics <sup>©</sup> (Sheboygan, WI)

#### SUMMARY

This study analyzed the effect of pH on latex elastics produced by two different manufacturers, RMO<sup>®</sup> (Denver, CO) and G&H<sup>®</sup> (Franklin, IN). The objective of this study was to determine the difference in force degradation seen in 1/4", 4.5 oz elastics from two manufacturers, at five different timepoints, in three different pH environments. The null hypothesis tested was that there were no mean differences in the percent of initial force of 1/4", 4.5 oz latex elastics among the five different timepoints, regardless of pH or manufacturer. The sample size was 15 for each manufacturer in each pH. Each elastic was stretched to three times their diameter without relaxation. They were tested in artificial saliva at 37° C that was adjusted to the pH of 5.60, 6.75, and 7.60. The force (N) was measured using a Chatillon (Largo, FL) DFM 10 Force Gauge and the results were presented in percent of initial force loss at five timepoints: 0.5 hours, 1 hour, 4 hours, 8 hours, and 12 hours. The factors pH and manufacturer were statistically analyzed by a two-way repeated-measures ANOVA with a Greenhouse-Geisser correction. Results indicated a statistically significant effect of time, F(3.48, 292.57) = 330.44, (p < 0.001). There was a statistically significant mean difference among the three pHs, F (2, 84) = 22.03, (p < 0.001). There was a statistically significant mean difference between the two manufacturers, F (1, 84) = 5.44, (p = 0.022). The interaction between pHs and the manufacturers was also statistically significant, F (2, 84) = 4.58, (p = 0.013). At the pH of 5.60, RMO<sup>®</sup> latex elastics had a mean percent of initial force that was significantly higher than when they were placed in the pH levels of 6.75 and 7.60 among the five timepoints (p < 0.001). There was also a significant difference at the pH of 5.60 between the two manufacturers with RMO<sup>®</sup> having a higher percent of initial force among the five timepoints when compared to  $G\&H^{\mathbb{R}}$  (p < 0.001).

# SUMMARY (continued)

The results of this study indicate that the factors pH and manufacturer have a statistically significant effect on force degradation.

#### **1. INTRODUCTION**

#### 1.1 Background

Elastics are used in orthodontics to correct anterior-posterior discrepancies because of the force they produce when stretched. Orthodontic patients are commonly given instructions to wear elastics from their first molar to their canine bilaterally to correct anterior-posterior discrepancies. They are often instructed to change elastics up to three times a day over a 24 hour period. The practitioner relies on the patient to change the elastics throughout the day in order to maintain the marketed force listed on the package of elastics. If the patient is not compliant or there is substantial force degradation, the treatment objective of correcting the anterior-posterior discrepancies cannot be achieved. The elastics lose their force over time due to their properties and the environment within the mouth. One of the properties that could possibly affect the force degradation is the pH of the oral environment.

Elastics have been shown to lose a substantial amount of force over time (Kersey *et al.*, 2003a; 2003b; Wang *et al.*, 2007; Gioka *et al.*, 2006; Beattie and Monaghan, 2004; Liu *et al.*, 1993; Wong, 1976; Kanchana and Godfrey, 2000). The degradation of force is directly related to how often patients change their elastics during the day to keep a constant force for appropriate physiological tooth movement. The degradation of the elastics can be caused by a variety of factors. Water absorption, pH, the length of wear, and diet are all factors that could possibly affect elastic force. As Kersey *et al.* (2003a) reported, there was also a difference in the force loss of latex and non-latex elastics, which can further complicate predicting the rate of degradation. Wong (1976) explained that synthetic elastics have elasticity from macromolecular

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chain entanglements, whereas natural rubbers, like latex, have covalent bonding and crosslinking of chains for their elasticity. This makes them more resilient to force degradation when used intraorally.

Most studies on elastics have focused only on comparing the force degradation between different manufacturers, the difference in degradation between latex and non-latex elastics, and static versus dynamic environments. There are many variables affecting the degradation of the elastics that need to be analyzed individually. In *in vivo* testing, it is difficult to compare manufacturers or evaluate the load that is placed on the elastics based on the highly variable intraoral environment and the inability to rule out other variables, such as pH, in each individual.

Artificial saliva (Beattie and Monaghan, 2004) and distilled water (Kersey *et al.*, 2003a; 2003b; Kanchana and Godfrey 2000) have been shown to increase the rate and amount of degradation seen when compared to a dry environment. This may possibly be due to water absorption. However, there is another major component that is variable in the population. This variable is pH. The range of normal resting salivary pH is 5.60 to 7.60 with an average pH of 6.75 as found in the 3405 cases analyzed by Brawley (1935). Normal resting salivary pH has been defined by Brawley (1935) as saliva that is secreted without any form of induced stimulation. It is saliva that is secreted under normal body conditions such as normalized metabolism of the glands, breathing, and muscle movements. A paper by Ferriter *et al.* (1990) showed that polyurethane chain elastics in a basic pH degraded more than if the pH was acidic.

Previous studies have not analyzed the effect of the normal resting salivary pH on the force degradation of latex elastics. Beattie and Monaghan (2004) conducted an *in vitro* study on diet but this was found not to affect elastic force degradation. However, studying diet is not necessarily a good determinant for examining degradation in terms of pH because the pH change in the oral cavity during meal intake is only for a short period of time.

#### 1.2 **Objective of the Study**

The objective of this study was to determine if 1/4", 4.5 oz latex elastics have a different rate of force degradation in patients with different normal resting salivary pHs. A secondary objective was to determine if the force degradation was different among two manufacturers.

#### 1.3 <u>Null Hypothesis</u>

There are no mean differences in the percent of initial force of 1/4", 4.5 oz latex elastics among five different timepoints regardless of pH or manufacturer.

#### 2. REVIEW OF LITERATURE

#### 2.1 Latex Properties

Latex comes from the species *Hevea brasiliensis* which is in the Euphorbiaceae family. A review of natural rubber by Blackley (1997) mentioned that the tree can grow up to 30 meters and has a trunk that is three to four meters in diameter. The tree grows in four regions: tropical South America, India, the Far East, and tropical Africa. He mentioned that the process of obtaining latex is called tapping and it is usually done manually with a knife to cut the tree and a cup to collect the latex. A single tree can withstand being cut in the same place every other day, indefinitely.

Natural rubber is made up of *cis*-1,4-polyisoprene chains and has a Carbon backbone with side chains that can include aldehydes, esters, and fatty acids. A small percentage of natural rubber is made up of proteins and amino acids. Vulcanization, or the production of rubber, is performed with the addition of sulfur (Higgins, 1994). Each polyisoprene chain has unstable double bonds where molecules can use the electrons in the double bond to react with the chain. Sulfur is used to form covalent bonds between these polyisoprene chains (Higgins, 1994).

Wong (1976) evaluated orthodontic elastic materials. He explained the elasticity of latex elastics is from the coiled structure of long and folded polymer chains. When these chains are extended, the coiled chains are elongated from a random to a more ordered structure consisting of linear chains. There is a tendency to revert back to the disorganized coils upon removal of the elongation stress. This is why latex elastics have an elastic behavior. Synthetic latex materials are cross-linked rather than covalently bonded as with latex. They tend to have increased strength but permanently distort more than latex causing them to lose their elastic properties sooner than latex elastics.

#### 2.2 Degradation of Latex

Higgins (1994) explained that the hardness and elasticity of rubber production is controlled by the amount of sulfur added to the polyisoprene chains. If a high concentration of sulfur is added, more of the double bonds react with the sulfur to form more covalent bonds. This causes the chains to be more unreactive and much more rigid and resistant to degradation since the chains cannot move as freely relative to the neighboring chains. The elastomeric properties of the rubber disappear when all of the bonding sites are used up. Rubbers that are more elastic, such as latex elastics used for orthodontics, do not have as much sulfur added in their production. The chains are not as covalently bound together and have more freedom to move. They also have more reactive double bonds and this can lead to their degradation.

Latex is susceptible to sunlight and it needs to be stored properly or cracks will appear in the material. Oxidation, or ozonolytic degradation, is one of the most common ways that natural rubber degrades causing crack formations under stress. This degradation creates the byproducts levulinic aldehyde and acid (Blackley, 1997). Oxidation reduces the elasticity by forming crosslinks between chains with the remaining unreacted double bonds. This makes the rubber more brittle and subject to cracks. The cracks in the rubber then cause more double bonds to be exposed, thus increasing the amount of oxidation (Higgins, 1994). Latex is able to absorb water and this is one of the main problems faced with intraoral use. When latex takes up the water, the unsaturated double bonds are broken down, weakening the polymer chains (Wong, 1976). Swelling and staining occurs with the absorption of fluids and bacteria. The swelling causes a change in hardness, modulus of elasticity, tensile strength and elongation in elastomers. They also lose soluble constituents when in the presence of fluid (Nagdi, 1993).

Hydrolysis is the reaction between water and molecules that have polar groups like esters and amides (Nagdi, 1993). If the backbone of a polymer is made up of these polar groups, hydrolysis can cause chain scission. This chain scission occurs much faster when there is an acid or alkali present (Nagdi, 1993). Water provides oxygen for the degradation of the molecular chains as hydrogen peroxide is produced, which causes a sticky layer on the surface and the loss of carbon groups like those seen in rubber (Zhang, 2004).

#### 2.3 Static vs. Dynamic Testing

A study by Kersey *et al.* (2003a) tested 1/4", 4.5 oz AO<sup>®</sup> (Sheboygan, WI) latex and nonlatex elastics in distilled water at 37° C. They used a computer model generated by Peck *et al.* (2000), which was based on intraoral movements, to determine that during a maximal opening of 50 mm, the distance from the canine to the molar increased by 24.7 mm. They stretched the elastics from three times the diameter, which was 19.05 mm, to 43.75 mm at a rate of one cycle per minute. The stretching lasted one second and the elastics were returned to the initial distance of 19.05 mm for the rest of the minute. Twelve latex and 12 non-latex elastics were tested from AO<sup>®</sup>. The cycling in this experiment was also consistent with Liu *et al.* (1993). Kersey *et al.* (2003a) showed that there was an increase in force loss in the first 30 minutes. Latex elastics were found to be at 74.55%  $\pm$  2.91% of their initial force when cycled at 24 hours. Static tests showed that the latex elastics were at 82.74%  $\pm$  1.90% of their initial force at 24 hours. Non-latex elastics were at 53.16%  $\pm$  4.31% of their initial force for dynamic tests and at 68.73%  $\pm$  6.12% for static tests at 24 hours. They found that cyclic testing showed the greatest force loss in the first hour but afterwards there was a similar rate of force loss as seen in the static tests. The initial force loss in the first hour was greater in the non-latex elastics. After 200 cycles, there were no differences in the rate of force loss at each timepoint. This test is consistent with other studies, showing that the largest amount of force loss for latex and non-latex elastics occurred within the first hour (Wong, 1976; Liu *et al.*, 1993; Gioka *et al.*, 2006; Wang *et al.*, 2007; Beattie and Monaghan, 2004). After the second hour in the static tests, the latex elastics had almost no change over the course of the 24 hour test.

Liu *et al.* (1993) also examined the force degradation characteristics of orthodontic latex elastics. They tested Ormco<sup>®</sup> (Orange, CA) elastics, size 4F, which have a diameter of 7.09 mm and a marketed force of 170 g (1.7 N). This size was used to evaluate intermaxillary wear. Ormco<sup>®</sup> products have been shown to react differently than other manufacturers (Ferriter *et al.*, 1990; Gioka *et al.*, 2006). The study by Liu *et al.* (1993) stretched the elastics from two centimeters to five centimeters. The elastics were cycled for one cycle per second, which was similar to the study by Kersey *et al.* (2003a; 2003b), however, the stretching was done before the initial reading. All elastics were stretched to three times the diameter such as Gioka *et al.* (2006) and Kersey *et al.* (2003a; 2003b). Their sample size was five in each group. The tests

were static and they were done in a dry environment. The elastics for the control were stretched for 48 hours with measurements being taken at 10 seconds, 1 minute, and 3, 5, 24, and 48 hours. The control elastics were not pre-stretched. The experimental groups were pre-stretched 200, 500, or 1000 times before they began their initial readings. When pre-stretching more than 200 times, there was no statistical difference in force degradation, which was consistent with Kersey *et al.* (2003a). After 1 hour, the control group showed  $91.3\% \pm 1.7\%$  of the initial force and at 24 hours the force decreased to  $86.2\% \pm 1.7\%$  of the initial force. The percent of initial force 1 hour after 200 cycles was  $87.5\% \pm 3.1\%$  and 24 hours later, it was  $85\% \pm 2.6\%$ . For 500 cycles, it was  $87.2\% \pm 0.9\%$  at 1 hour and  $82.1\% \pm 2.3\%$  at 24 hours. For 1000 cycles, it was  $86.7\% \pm$ 2.0% at 1 hour and  $82.2\% \pm 2.9\%$  at 24 hours. The latex elastics kept more force in a dry environment than when water or artificial saliva was present such as in the studies by Beattie and Monaghan (2004) and Kersey *et al.* (2003a).

The study by Wong (1976) examined the changes of force in a 3/16", 4.5 oz. latex elastic. The brand was not mentioned in this study. They were stretched 17 mm, which was supposed to represent the distance from the cuspid to the 2<sup>nd</sup> bicuspid, for 21 days in a dry and static environment. After 24 hours, there was approximately 83% of the initial force, which was similar to the static test in distilled water evaluated by Kersey *et al.* (2003a), which had 82.74 ± 1.90% of the initial force after 24 hours.

#### 2.4 Determination of Marketed Forces

Kersey *et al.* (2003a; 2003b) and Beattie and Monaghan (2004) used consistent techniques such as stretching the elastics to the initial distance of three times the marketed internal diameter for 1/4", 4.5 oz latex elastics. Similarly, Polur and Peck (2010) pointed out that orthodontists and manufacturers have been arbitrarily stretching elastics to three times the diameter to approximate the marketed force. This has become an unregulated standard for measuring orthodontic elastic forces.

Gioka et al. (2006) attempted to address this problem by determining if stretching the elastics to three times the diameter is an appropriate approximation of the marketed force for elastics. Gioka et al. (2006) measured 7 different size and force variations of latex elastics. They ranged in size from 3/16" to 3/8" in diameter with varying force levels from Ortho Technology<sup>®</sup> (Tampa, FL), Ormco<sup>®</sup>, and Glenroe<sup>®</sup> (York, PA). The sample size consisted of five elastics for each sample tested. They were tested in a dry and static environment. A dynamometer was used to record the data in real-time. Each elastic was extended until the force was equal to that reported by the manufacturer. Their conclusion was that the force of the elastics labeled by the manufacturer might not be the actual force when they are stretched to three times the diameter. Most distances stretched within a range of 2.7-3.0 times their diameter reproduced the manufactured force, but two of the seven cases fell out of the norm. A 5/16" diameter elastic that had 6.0 oz of force (170 g) by Ormco<sup>®</sup> needed to be stretched five times the diameter to reach the reported force. They found that 1/4", 4.5 oz elastics, could be stretched to three times the internal diameter to reach the marketed force, but that this distance should not be applied to all sizes of elastics. This is consistent with other studies such as Kersey *et al.* (2003a; 2003b) that stretched the elastics to three times the diameter for force measurement. They also found that the decay rate increased rapidly in the first three to four hours and most of the relaxation was complete after five hours. The decay rate leveled off soon after and became less of a factor for the remaining 24 hours. They reported that the mean percent of force loss was  $24.08\% \pm 1.90\%$  from the initial force. Based on this study, it is reasonable to stretch 1/4", 4.5 oz. elastics to three times the diameter to obtain the marketed force.

A study by Kanchana and Godfrey (2000) evaluated Ormco<sup>®</sup>, Unitek<sup>®</sup> (Monrovia, CA) and Tomy<sup>®</sup> (Tokyo, Japan) 3/16", 1/4", and 5/16" latex elastics with various marketed force levels. They examined the initial force of the latex elastics stretched to various extensions starting at five millimeters up to 60 mm in five millimeter increments in dry and wet environments. The elastics for the wet test were mounted between stainless steel pins at different fixed distances including the distance of 20 mm. The elastics were submerged in filtered tap water at 37° C. They measured at six timepoints including: 1, 6, 12, 24, 48, and 72 hours. They used tweezers to transfer the elastics to an Instron machine at each timepoint. The sample was 15 for each manufacturer in the dry environment, but only ten in the wet environment because of the time it took to transfer the elastics out of the water bath for measurement. They found that 1/4" latex elastics in a wet environment matched the marketed force at three times the diameter. Other sizes in the wet environment and all of the sizes tested in the dry environment did not match the marketed force at three times the diameter. They found an approximately 30% force loss after one hour, but only an additional 7% of force loss over 72 hours, which was very similar to what was found by Kersey et al. (2003a). They found that elastics with a higher initial force tended to lose less percentage of force than elastics that are lighter in force. This study observed

that a study was needed to look at pH changes and the effect the changes could have on the degradation of natural rubber elastics. They found significant differences among the manufacturers between the comparable sizes that they examined (p < 0.0001), but they did not feel that the differences were clinically significant. They found several non-significant differences in force after 24 hours. It was suggested to use a force that was 1.3 to 1.6 times the reported manufacturer's force to account for the force loss at the end of the first hour.

#### 2.5 In Vivo Studies

Wang et al. (2007) reported the degradation of 3M<sup>®</sup> (Monrovia, CA) latex elastics in vivo and *in vitro*. This test examined the amount of degradation between intermaxillary wear and intramaxillary wear. They examined the elastic wear of 12 students between the ages of 12 and 15 years old. The students were selected from a boarding school and their diet was controlled. They found that intermaxillary elastics had greater force loss because intermaxillary wear is cyclic in nature compared to intramaxillary wear. They also stretched the elastics to a fixed distance of 20 mm in artificial saliva at 37° C to compare to the *in vivo* intramaxillary traction. After 48 hours, the remaining force was 61% of the initial force for the elastics worn by the students in intermaxillary traction. For intramaxillary traction, with the elastics placed in the students and in the static test with artificial saliva, the percent of initial force was 71% after 48 hours. In this study, the percent of initial force in the *in vivo* test with intramaxillary traction matched the *in vitro* test so the static test was a good evaluation of how elastics placed in intramaxillary traction degrade in patients. At 12 hours, intramaxillary traction and the static test in artificial saliva were 75% and 76%, respectively. This study also reinforced the results reported by other studies that the greatest amount of force loss was within the first hour, with

approximately 14% of the force being lost in the first 30 minutes and another 6% being lost after 1 hour for the *in vivo* intramaxillary traction test and the static test in artificial saliva (Kersey *et al.* 2003a; 2003b; Beattie and Monaghan, 2004; Gioka *et al.*, 2006; Liu *et al.*, 1993).

#### 2.6 <u>Studies on Diet</u>

An in vitro study by Beattie and Monaghan (2004) found that diet had no effect on the degradation of latex elastics. Latex elastics with a diameter of 3/16<sup>°</sup> from 3M<sup>®</sup>, AO<sup>®</sup>, and RMO<sup>®</sup> were tested. They were stretched initially to 15 mm, which is approximately three times their lumen diameter, similar to the study by Gioka *et al.* (2006). The sample size had 10 elastics per group that were tested in artificial saliva. This study stretched the elastics at a rate of 500 mm/min from three times their initial diameter to a total of 25 mm. In this study, the measurements were taken with the elastics stretched to 25 mm and the results were reported in Newtons and not in percent of initial force. The control group in this study was placed for 24 hours in artificial saliva without any diet exposure. Another group had the elastics placed in the artificial saliva for 12 hours, then replaced by new elastics for another 12 hours to represent a compliant patient who changes their elastics. They tested different food exposures over a 24 hour period using a sample of 10 elastics. Meals were given in 20 minute intervals and the elastics were exposed to snacks at 8 minute intervals. They found no significant difference between the daily dietary changes. They found that RMO<sup>®</sup> latex elastics had the least amount of initial force degradation after 24 hours and AO<sup>®</sup> had the most degradation. This study tested other brands of elastics and found a difference between them. This shows that different brands exhibit different properties and need to be tested in varying environments to analyze how they respond.

#### 2.7 pH Effects

A study by Ferriter *et al.* (1990) and Brawley (1935) showed that pH changes in diet were not as important as looking at the normal resting salivary pH. Brawley (1935) studied the normal resting salivary rate seen in patients. He defined the normal resting salivary rate as saliva that is secreted without any form of induced stimulation. It is saliva that is secreted under normal body conditions such as normalized metabolism of the glands, breathing, and muscle movements. In this study, Brawley took saliva from 3,405 patients and tested the pH. The pH range for the population sampled was 5.60 to 7.60 and the average pH was found to be 6.75. He found no significant difference in the mean pH values between males and females, except in older age groups that were 50 years old or higher.

Ferriter *et al.* (1990) referred to Brawley's study to help him design a study for the degradation of polyurethane c-chain elastics in different pH levels. Seven different brands of elastomeric chain were tested for force degradation. These were not made of latex but rather polyurethane. The force degradation rates were tested statically for four weeks. The elastics were extended to equal distances for the first test. For the second test, they were stretched to different distances to produce identical initial force levels. The force derived from the chain elastics depended on the magnitude of the initial force and the length of time the elastics were activated. The manufacturers that were tested included: A Company<sup>®</sup> (San Diego, CA) medium, gray chain; AO<sup>®</sup> Memory Chain, short, gray chain; GAC<sup>®</sup> (Bohemia, NY) Chainette, gray, and narrow chain; Ormco<sup>®</sup> power chain II, gray, and close space; RMO<sup>®</sup> Energy Chain, narrow, gray chain; TP Orthodontics<sup>®</sup> (LaPorte, IN) E-chain, medium, gray; 3M<sup>®</sup> Alastik gray spool chain, C-1. Artificial saliva was used, which simulated a more realistic environment for testing when

compared to a dry environment or distilled water. They tested a pH of 4.95, as this is the pH value seen clinically in dental plaque in the presence of starchy foods. They also tested a pH of 7.26 because it is slightly basic, but well within the normal saliva and plaque pH levels. Six of the seven products that were tested behaved very similar during a four week activation period with the exception of Ormco<sup>®</sup>. After the first week, the decay rates of the chain elastics in the acidic solution slowed significantly, while the force continued to decay at a more rapid rate in the basic solution. Ormco<sup>®</sup> had a force decay rate that was greater in the acidic solution for the first week, however, after one week, the force decay rate significantly slowed down in the acidic solution. After two weeks, the elastics had more force in the acidic solution than in the basic solution like the other manufacturers. Overall, the study concluded that the force decay rate was directly proportional to the pH of the oral environment. As the pH became more basic, the force decay rate increased.

A study by Sauget (2011) examined the effect of pH on non-latex and latex elastics. They examined 3/16", 6.0 oz non-latex elastics from Aurodontics<sup>®</sup> (Riverside, NJ) and  $AO^{\text{®}}$  and included 3/16", 6.0 oz  $AO^{\text{®}}$  latex elastics for a material comparison. This study was structured similar to the study by Beattie and Monaghan (2004). They stretched the elastics on pins 15 mm apart and took their measurements at a distance of 25 mm from a force gauge by hooking the elastic from one of the pins to the hook of the force gauge at each of the timepoints. They had a sample size of 10 elastics in artificial saliva at the pH levels of 5.0, 6.0, and 7.5. The timepoints that they tested were 10 seconds, which represented the initial timepoint, 4 hours, 8 hours, and 12 hours. They found that  $AO^{\text{®}}$  non-latex elastics produced significantly higher force than Auradonics<sup>®</sup> non-latex elastics. Non-latex  $AO^{\text{®}}$  had a significantly higher force measurement when compared to latex  $AO^{\text{(B)}}$  elastics at 4, 8, and 12 hours. This differs from other studies mentioned in that latex  $AO^{\text{(B)}}$  elastics had more force degradation than the non-latex  $AO^{\text{(B)}}$  elastics. At 10 seconds, the latex  $AO^{\text{(B)}}$  elastics had a higher initial force but had significantly less force than the non-latex  $AO^{\text{(B)}}$  elastics as time progressed. They did not find a significant decrease in force for the first four hours in their non-latex groups, which was contrary to the findings of Kersey *et al.* (2003a; 2003b). However, they did find a statistically significant decrease in force during the first four hours for  $AO^{\text{(B)}}$  latex elastics. In regards to pH, they found no significant correlation between pH and force decay. They mentioned that their large variability came from inconsistencies in the manufacturing of the elastics in both size and quality between samples from the same manufacturer.

#### 2.8 <u>Non-Latex</u>

A study done by Kersey *et al.* (2003b) compared 4 brands of non-latex orthodontic elastics from AO<sup>®</sup>, GAC<sup>®</sup>, OO<sup>®</sup>, and Masel<sup>®</sup> (Carlsbad, CA). They included 1/4", 4.5 oz AO<sup>®</sup> and OO<sup>®</sup> elastics and 1/4", 4.0 oz Masel<sup>®</sup> and GAC<sup>®</sup> elastics. All were stretched to two times and three times the marketed diameter. All forces were still less than the marketed force at three times the marketed diameter (19.05mm) except GAC<sup>®</sup>, which was higher. To compensate for the variations in initial forces and the size of the elastics due to their production, the percent of initial force was measured for each elastic. A pilot study was conducted and it was determined to test 12 elastics per group. Each group was tested cyclically in the same manner as the previous study by Kersey *et al.* (2003a). At 24 hours, AO<sup>®</sup> had a force that was 48.0%  $\pm$  6.0% of the initial reading. Ortho Organizers (Carlsbad, CA) was 49.2%  $\pm$  4.9% of the initial force and GAC<sup>®</sup> was 53.5%  $\pm$  4.7%. Masel had a reported mean percent of initial force of 41.1%, but no standard deviation could be calculated due to the amount of breakage that occurred. There were no significant differences among brands except for Masel. Prior to eight hours, all the elastics behaved with similar force degradation rates. Most of the degradation occurred in the first 30 minutes. After 24 hours, nearly 50% of the initial force was lost in all non-latex elastics. Nearly 25% of the force loss occurred in the first 30 minutes. Kersey *et al.* (2003a) referenced a study by Baty *et al.* (1994) which reported that a difference in 10% of force is clinically significant for c-chain elastics and may be the case for elastics although no studies have been done to show this. Kersey *et al.* (2003a; 2003b) also monitored visual changes in non-latex elastics that were not seen in latex elastics. There was permanent deformation, swelling, and color change from transparent to opaque. Also noted by this author was that in non-latex elastics, the initial force readings were highly variable when compared to the marketed force on the packaging among the manufacturers, but the percent of force degradation was similar between the manufacturers despite this.

#### **3. METHODS**

#### 3.1 Design

The percent of initial force loss for G&H<sup>®</sup> and RMO<sup>®</sup> 1/4", 4.5 oz latex elastics was evaluated in three different pH levels. The normal resting salivary pH, as defined by Brawley (1935), was the basis for the three pH levels. The average normal resting salivary pH was found to be 6.75 and the range was 5.60 to 7.60. The elastics were placed in artificial saliva adjusted to these three pH levels at a temperature of 37° C for a period of 12 hours. Beattie and Monaghan (2004) suggested that 12 hours of wear represented a compliant patient. Kersey et al. (2003a; 2003b) showed that there was not much change in degradation after 2 hours, thus a study for anything greater than 12 hours was deemed unnecessary to yield significant data regarding differences in force degradation between manufacturers. A sample size of 15 elastics was used in this study. This was based upon previous literature, which ranged from the sample size of five elastics in the study by Liu et al. (1993) to 12 elastics used in the studies by Kersey et al. (2003a; 2003b). Kanchana and Godfrey (2000) used 15 elastics in their dry environment, but when they studied the elastics in a wet environment, they used 12 elastics. The data was collected in percent of initial force so that the force loss would be comparable despite the varying initial forces.

The control consisted of a bath of artificial saliva at 37° C with a pH of 6.75 since this was the average normal resting salivary pH found by Brawley (1935). The elastics were then tested at 37° C in artificial saliva adjusted to the pH of 5.60 and then to the pH of 7.60, which were the range of normal resting salivary pH found by Brawley (1935). Fifteen 1/4", 4.5 oz latex

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elastics from each of the two independent manufacturers were stretched to three times the internal diameter in each pH to approximate the marketed force, which has been shown to be an appropriate distance by Gioka *et al.* (2006) and by Kanchana and Godfrey (2000). One quarter inch, 4.5 oz elastics are commonly used for class II or class III correction in the clinic at the University of Illinois at Chicago and have been tested in other studies (Kersey *et al.*, 2003a; 2003b; Gioka, 2006; Kanchana and Godfrey, 2000). The elastics were tested in a static environment to decrease any unwanted variables that could be introduced by cyclic testing.

The force levels were manually recorded in Newtons in a Microsoft Excel (Redmond, WA) spreadsheet. The percent of initial force was then calculated from this data and plotted in graph format against time in hours. The forces in Newtons at the initial time, 30 minutes, 1 hour, 4 hours, 8 hours, and 12 hours were recorded. Figure 1 shows the conceptual framework of the experimental design.

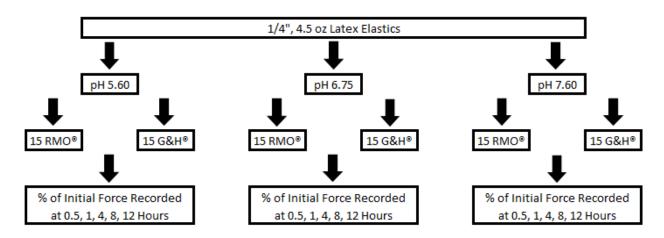


Figure 1. Conceptual Framework

#### 3.1.1 <u>Time Measurements</u>

The time at 30 minutes and 1 hour has been documented in several studies such as Kersey *et al.* (2003a; 2003b), Gioka *et al.* (2006), and Wang *et al.* (2007) to show the greatest amount of degradation in the elastic force.

It is often convenient for the patient to change the elastics at breakfast, lunch, and dinner over a 12 hour period. These patients are only getting approximately 4 hours of wear between changing their elastics so the force at four hours was recorded. Eight hours is an important time for analysis since the patients at the University of Illinois at Chicago are often instructed to change their elastics three times a day to maintain an appropriate force level. The degradation at 12 hours represented compliant patients in the study by Beattie and Monaghan (2004) so this was the final timepoint recorded.

The time was started when the elastics were initially stretched to 19.05 mm as they were being placed on the force gauge for the initial measurement. Since the elastics were being measured one by one, the elastics were measured in 30 second intervals for each elastic to allow for them to be picked up, stretched, and placed to and from the force gauge. This process took less than 30 seconds for each elastic. This allowed for the elastics to be kept in the artificial saliva for approximately the same amount of time.

The setup included two aluminum blocks to test 30 elastics with steel pins approximating the size of bracket hooks at 0.80 mm. The pins were set 19.05 mm apart from each other measuring from the outside of one pin to the outside of the other as seen in Figure 2. The distance 19.05 mm is three times the internal diameter of the elastics at rest.



Figure 2. Aluminum blocks with 0.80 mm diameter pins set 19.05 mm apart.

### 3.1.2 <u>Temperature</u>

The temperature was kept at 37° C by cycling the artificial saliva in and out of the water tank with a VWR Scientific (West Chester, PA) Model #1104 Heated Water Bath as pictured in Figures 3 and 4.



Figure 3. VWR Scientific Model #1104 Heated Water Bath



Figure 4. Water tank with two aluminum blocks submerged. The tubes are for water flow in and out.

#### 3.1.3 Randomization

The elastics were designated into bins using a random number generator in Microsoft Excel (Redmond, WA). Three lots were donated by RMO<sup>®</sup> and two lots were donated from G&H<sup>®</sup>. Each lot from G&H<sup>®</sup> had approximately 5000 elastics placed in 50 packages and each lot from RMO<sup>®</sup> had approximately 2000 elastics placed in 20 packages. Three packages of 1/4", 4.5 oz elastics, one from each lot, were used for RMO<sup>®</sup> and two packages from each of the two lots for G&H<sup>®</sup> were used. The principal investigator was blinded as to which manufacturer was being measured. The order that the elastics were measured in was also randomized at the beginning and this same order was used at each timepoint when measuring the elastics.

#### 3.1.4 Measuring the Elastics

Preliminary runs of this experiment, where the elastics were allowed to relax during their transfer to and from the force gauge, had highly variable results. There were several increases and decreases in force for each of the elastics over the 12 hours. The amount of rebound seen was not comparable to previous studies so the method of handling the elastics was altered. For this study, the elastics were placed using separating pliers that were adjusted to create a jig to transfer the elastics at exactly 19.05 mm to and from the aluminum blocks and the force gauge. This avoided any relaxation and maintained the same distance during the entire experiment by simply squeezing the separating pliers to maximal opening for the desired stretched distance of 19.05 mm as pictured in Figure 5. A study by Josell *et al.* (1997) used a transfer jig measured to the same distance that elastic chains were stretched in order to transfer the chains to and from a force gauge.

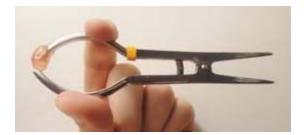


Figure 5. Separating pliers adjusted to open to 19.05 mm upon maximal opening.

To initiate the test, separating pliers were used to lift and stretch the elastics to 19.05 mm. They were then immediately placed on the Chatillon (Largo, FL) DFM 10 Force Gauge for the initial reading and directly transferred to the appropriate number on the aluminum blocks submerged in the artificial saliva.



Figure 6. Chatillon (Largo, FL) DFM 10 Force Gauge and latex elastic being stretched to 19.05 mm.

The hooks on the force gauge were marked so that the placement of the elastics could be repeated. The diameter of both hooks on the force gauge was 0.80 mm, which matched the pins on the aluminum block. This is the same testing apparatus that  $G\&H^{\ensuremath{\mathbb{R}}}$  uses to test their elastics for quality control.

### 3.2 <u>Materials</u>

#### 3.2.1 <u>Sample</u>

15 RMO<sup>®</sup> 1/4", 4.5 oz latex elastics for each pH tested

Lot#: 250142, 247498, 248649

15 G&H  $^{\ensuremath{\mathbb{R}}}$  1/4", 4.5 oz latex elastics for each pH tested

Lot#: 211823, 229127

#### 3.2.2 Instrumentation

Beckman Phi 71 pH Meter (Brea, CA)

Two aluminum boards with 15 pairs of pins 0.80 mm in diameter, set apart at a distance

of 19.05 mm for each aluminum board

Artificial saliva at 37° C at a pH of 6.75 for control

Artificial saliva at 37° C at a pH of 5.60 for basic experimental pH

Artificial saliva at 37° C at a pH of 7.60 for acidic experimental pH

Artificial saliva recipe:

Hepes: 20.000 mmol

CaCl<sub>2</sub>PO<sub>4</sub>: 0.538 mmol

KH<sub>2</sub>PO<sub>4</sub>: 0.451 mmol

KCl: 43.330 mmol

Adjusted to appropriate pH by adding 2M HCl or 2M NaOH.

1/4", 4.5 oz elastics by RMO<sup>®</sup> (Denver, Co) and G&H<sup>®</sup> Latex Elastics (Franklin, IN)

VWR Scientific (West Chester, PA) Model #1104 Heated Water Bath

Chatillon (Largo, FL) DFM 10 Force Gauge (calibrated by Tangent Labs (Indianapolis, IN) on September 6th, 2011)

Mitutoyo (Aurora, IL) HDS Digital Height Gauge

#### 3.3 Data Collection

The force in Newtons was used to calculate the percent of initial force loss of RMO<sup>®</sup> and  $G\&H^{\$}$  1/4", 4.5 oz latex elastics as they degraded in varying normal resting salivary pH levels in a static environment. The data was reported in percent of initial force.

### 3.4 <u>Statistical Analysis</u>

A two-way repeated measures ANOVA with Greenhouse-Geisser correction using SPSS Version 19 (Chicago, IL) to analyze the data in percent of initial force loss over the five timepoints: 0.5 hour, 1 hour, 4 hours, 8 hours, and 12 hours. A paired samples *t*-Test was run to compare the differences in the mean percent of initial forces between each of the five timepoints for results that were found to be significant by the two-way repeated measures ANOVA test. The confidence interval was set at 95%.

#### **4. RESULTS**

#### 4.1 <u>Descriptive Statistics</u>

Table I through Table III show the descriptive statistics used to calculate the Within-Subjects Effects and the Between-Subjects Effects of the factors. Table I shows the total means and standard deviations of the percent of initial force for the factor pH among five timepoints. Table II shows the total means and standard deviations for the factor of manufacturer among five timepoints. Table III shows the total means and standard deviations for the factors pH and manufacturer among five timepoints.

#### TABLE I

MEAN AND STANDARD DEVIATION OF THE PERCENT OF INITIAL FORCE FOR PH LEVELS AMONG FIVE TIMEPOINTS (HOURS)

рН	0.5	1	4	8	12
5.60	$82.38 \pm 3.14$	$80.11 \pm 3.04$	$78.89 \pm 2.96$	$77.71 \pm 2.64$	$77.22\pm3.32$
6.75	$80.74 \pm 3.34$	$77.74\pm2.69$	$74.72 \pm 2.54$	$72.70\pm2.80$	$72.15\pm2.66$
7.60	$82.32\pm2.84$	$79.73 \pm 3.59$	$75.17 \pm 2.77$	$73.14 \pm 2.73$	$73.30\pm2.50$

#### TABLE II

### MEAN AND STANDARD DEVIATION OF THE PERCENT OF INITIAL FORCE FOR RMO<sup>®</sup> AND G&H<sup>®</sup> AMONG FIVE TIMEPOINTS (HOURS)

Manufacturer	0.5	1	4	8	12
$G\&H^{\circledast}$	$82.49 \pm 3.13$	$79.47 \pm 3.23$	$75.50\pm3.03$	$73.14\pm3.19$	$72.71\pm3.08$
RMO®	$81.13 \pm 3.09$	$78.92 \pm 3.31$	$77.02\pm3.45$	$75.89 \pm 3.33$	$75.73 \pm 3.39$

#### TABLE III

	[	0.5	1	4	8	12
	pН					
	5.60	$81.57\pm3.47$	$78.96 \pm 2.86$	$77.31 \pm 2.47$	$75.96 \pm 2.21$	$74.95\pm2.73$
$G\&H^{\mathbb{R}}$	6.75	$82.47\pm3.41$	$78.58 \pm 2.88$	$74.41 \pm 2.84$	$71.79\pm3.08$	$71.17\pm2.92$
	7.60	$83.45\pm2.29$	$80.88 \pm 3.63$	$74.79\pm3.06$	$71.67 \pm 2.23$	$72.01 \pm 2.33$
	5.60	$83.19\pm2.64$	$81.26\pm2.85$	$80.47\pm2.59$	$79.46 \pm 1.73$	$79.48 \pm 2.11$
RMO®	6.75	$79.02\pm2.25$	$76.90\pm2.29$	$75.02\pm2.27$	$73.61 \pm 2.25$	$73.12\pm2.03$
	7.60	$81.19\pm2.95$	$78.59 \pm 3.27$	$75.55 \pm 2.48$	$74.60\pm2.42$	$74.60 \pm 1.98$

#### MEAN AND STANDARD DEVIATION OF THE PERCENT OF INITIAL FORCE FOR RMO<sup>®</sup> AND G&H<sup>®</sup> AMONG FIVE TIMEPOINTS (HOURS) AT THREE DIFFERENT PH LEVELS

#### 4.2 Between-Subject Effects and Within-Subject Effects of Variables

Table IV shows the within-subjects effects of the following variables and interactions: time; time and pH; time and manufacturer; and time, pH and manufacturer on the mean percent of initial force. The results showed that all the variables time; time and pH; and time and manufacturer had a statistically significant effect on the percent of initial force (p < 0.001). The interaction among time, pH, and manufacturer also had a significant effect on the percent of initial force (p = 0.040).

Table V shows the interaction between pH levels, manufacturers, and the main effects of pH levels and manufacturers, on the mean percent of initial force. There was a statistically significant main effect of pH on the mean percent of initial force, F(2, 840) = 22.03, (p < 0.001). There was a statistically significant main effect of manufacturer on the mean percent of initial

force, F(1, 84) = 5.44, (p = 0.022). There was also a statistically significant interaction between pH and the manufacturers on the mean percent of initial force, F(2, 84) = 4.579, (p = 0.013).

These tests indicate that time, pH, manufacturer, and their interactions affect the mean percent of initial force among the five timepoints over 12 hours.

#### TABLE IV

#### ANOVA TEST OF WITHIN-SUBJECTS EFFECTS ON THE MEAN PERCENT OF INITIAL FORCE

	df	Mean Square	F	p-value*		
Time	4	949.84	330.44	0.000*		
Time and pH	8	37.36	13.00	0.000*		
Time and Manufacturer	4	86.68	30.16	0.000*		
Time, pH, and Manufacturer	8	6.15	2.14	0.040*		
* p-value statistically significant at $p \le 0.05$ .						

#### TABLE V

#### ANOVA TEST OF BETWEEN-SUBJECTS EFFECTS ON THE MEAN PERCENT OF INITIAL FORCE

		10	Mean	F	1 .4
		df	Square	F	p-value*
	pН	2	525.14	22.03	0.000*
	Manufacturer	1	129.67	5.44	0.022*
	pH and Manufacturer	2	109.13	4.58	0.013*
10	1		10.05		

\* p-value statistically significant at  $p \le 0.05$ .

### 4.3 <u>Two-Way Repeated Measures ANOVA Test</u>

Table VI shows the overall results of the two-way repeated measures ANOVA test evaluating the statistical differences between RMO<sup>®</sup> and G&H<sup>®</sup> at each pH tested. This shows that there is a statistically significant mean difference in percent of initial force between the two manufacturers at a pH of 5.60 ( $p \le 0.05$ ). There was no difference found between the manufacturers at the pH of 6.75 and 7.60.

#### **TABLE VI**

	VA TESTS OF BETW				
PERCE	NT OF INITIAL FOR	CE BET	WEEN RM	O <sup>®</sup> AND	G&H <sup>ℝ</sup>
	AT DIFFER	ENT PH	LEVELS		
			Mean		
		df	Square	F	p-value*
Mar	ufacturer pH 5.60	1	342.62	17.14	0.000*
Mar	ufacturer pH 6.75	1	0.82	0.03	0.855

4.48

0.16

0.690

Manufacturer pH 7.601\* p-value statistically significant at  $p \le 0.05$ .

# 4.4 <u>Comparing RMO<sup>®</sup> and G&H<sup>®</sup> Percent of Initial Force at the pH of 5.60</u>

Table VII shows the mean percent of initial force as time increased for the experimental test at the pH of 5.60. This shows that RMO<sup>®</sup> had more remaining force than G&H<sup>®</sup> at each of the five timepoints measured. Tests of the Within-Subjects Effects indicated a significant main effect of time (p < 0.001). The interactions of time and manufacturer were also significant (p = 0.035). Tests of Between-Subjects Effects indicate a significant main effect for the manufacturer (p < 0.001).

This indicates that as time increases, the mean percent of initial force decreases and this is statistically significant. The mean percent of initial force differences between the two manufacturers were also statistically significant at the pH of 5.60.

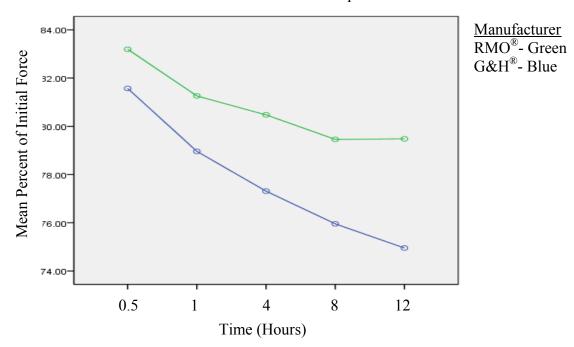
The first 30 minutes showed the most degradation with approximately 18.5% of the initial force being lost for G&H<sup>®</sup> and 16% being lost for RMO<sup>®</sup>. From one hour to 12 hours, G&H<sup>®</sup> lost 4% of its force and RMO<sup>®</sup> only lost approximately 2% of its force.

#### **TABLE VII**

THE PERCENT OF INITIAL FORCE OF RMO <sup>®</sup> AND G&H <sup>®</sup> 1/4", 4.5 OZ
LATEX ELASTICS IN ARTIFICIAL SALIVA AT A PH OF 5.60 AMONG
<b>FIVE TIMEPOINTS</b>

TIME (HOURS)	MANUFACTURER	Ν	MEAN % <b>± SD</b>
0.5	G&H	15	$81.57 \pm 3.47$
	RMO	15	$83.19 \pm 2.64$
1	G&H	15	$78.96 \pm 2.86$
	RMO	15	$81.26 \pm 2.85$
4	G&H	15	$77.31 \pm 2.47$
	RMO	15	$80.47\pm2.59$
8	G&H	15	$75.96 \pm 2.21$
	RMO	15	$79.46 \pm 1.73$
12	G&H	15	$74.95 \pm 2.73$
	RMO	15	$79.48 \pm 2.11$

Figure 7 graphically shows the Table VII. The elastics degraded for both G&H<sup>®</sup> and RMO<sup>®</sup> over time except at the 12 hour timepoint, where RMO<sup>®</sup> was approximately the same force from 8 hours to 12 hours.



Mean Percent of Initial Force at the pH of 5.60

Figure 7. Mean Percent of Initial Force at the pH 5.60

# 4.5 <u>Comparing RMO<sup>®</sup> and G&H<sup>®</sup> Percent of Initial Force at the pH of 6.75</u>

Table VIII shows the results for the control data set of RMO<sup>®</sup> and G&H<sup>®</sup> latex elastics in a pH of 6.75. Tests of the Within-Subjects Effects indicated a significant main effect of time (p < 0.001). The interaction of time and manufacturer was also significant (p < 0.001). Tests of Between-Subjects Effects indicate that there is not a significant main effect of the manufacturer on the percent of initial force (p = 0.855).

This means that the mean percent of initial force significantly decreased over time but that there was no statistically significant difference in the mean percent of initial force between the two manufacturers at the pH of 6.75 among the five timepoints.

#### **TABLE VIII**

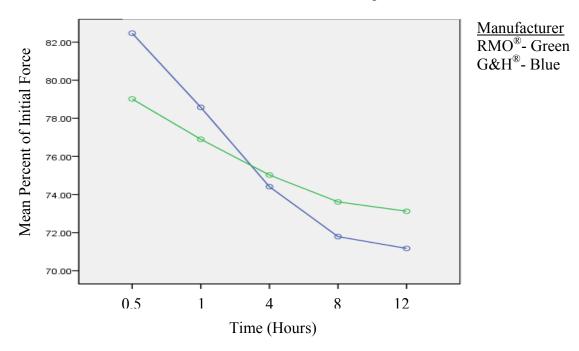
# THE PERCENT OF INITIAL FORCE OF RMO<sup>®</sup> AND G&H<sup>®</sup> 1/4", 4.5 OZ LATEX ELASTICS IN ARTIFICIAL SALIVA AT A PH OF 6.75 AMONG FIVE TIMEPOINTS

TIME (HOURS)	MANUFACTURER	Ν	MEAN $\% \pm SD$
0.5 HOURS	G&H	15	$82.47\pm3.41$
	RMO	15	$79.02\pm2.25$
1 HOUR	G&H	15	$78.58 \pm 2.88$
	RMO	15	$76.90\pm2.29$
4 HOURS	G&H	15	$74.41 \pm 2.84$
	RMO	15	$75.02\pm2.27$
8 HOUR	G&H	15	$71.79\pm3.08$
	RMO	15	$73.61 \pm 2.25$
12 HOURS	G&H	15	$71.17\pm2.92$
	RMO	15	$73.12 \pm 2.03$

Figure 8 graphically shows the percent of initial force for both RMO<sup>®</sup> and G&H<sup>®</sup> at each timepoint. The graph shows that both manufacturers lose force over time, but their force loss is not statistically different at a pH of 6.75.

Before the four hour timepoint, G&H<sup>®</sup> had a higher mean percent of initial force at each timepoint when compared to RMO<sup>®</sup>. After four hours, RMO<sup>®</sup> had a higher mean percent of initial force at each timepoint. However, this difference was found not to be statistically significant among the five timepoints.

The first 30 minutes showed the most force loss for both manufacturers with approximately 17.5% of force loss for  $G\&H^{\ensuremath{\mathbb{R}}}$  and 21% of force loss for  $RMO^{\ensuremath{\mathbb{R}}}$ . After 1 hour, the amount of force degradation leveled off with approximately 7% of force being lost from 1 hour to 12 hours for  $G\&H^{\ensuremath{\mathbb{R}}}$  and 4% for  $RMO^{\ensuremath{\mathbb{R}}}$ .



Mean Percent of Initial Force at the pH of 6.75

Figure 8. Mean Percent of Initial Force at the pH 6.75

# 4.6 <u>Comparing RMO<sup>®</sup> and G&H<sup>®</sup> Percent of Initial Force at the pH of 7.60</u>

Table IX shows the results collected for RMO<sup>®</sup> and G&H<sup>®</sup> at a pH of 7.60. Tests of the Within-Subjects Effects indicate a significant main effect of the variable time (p < 0.001) and the interaction time and manufacturer (p < 0.001). Tests of Between-Subjects Effects indicate that there was not a significant main effect between the manufacturers (p = 0.690).

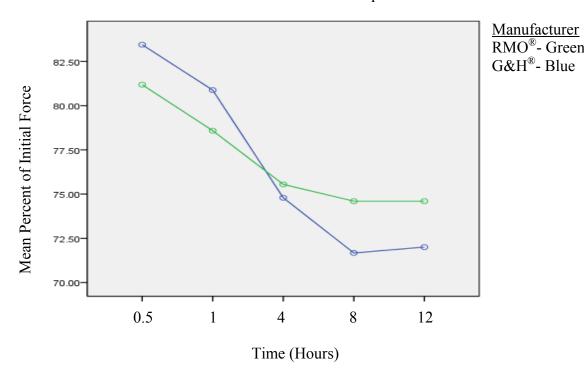
This means that as time increased, the mean percent of initial force significantly decreased for both manufacturers. However, there is no statistically significant difference on the elastic force degradation between the manufacturers and the five timepoints at a pH of 7.60.

# TABLE IXTHE PERCENT OF INITIAL FORCE OF RMO® AND G&H® 1/4", 4.5 OZLATEX ELASTICS IN ARTIFICIAL SALIVA AT A PH OF 7.60 AMONG FIVE TIMEPOINTS

TIME (HOURS)	MANUFACTURER	N	MEAN $\% \pm SD$
0.5	G&H	15	$83.45\pm2.29$
	RMO	15	$81.19 \pm 2.95$
1	G&H	15	$80.88 \pm 3.63$
	RMO	15	$78.59 \pm 3.27$
4	G&H	15	$74.79\pm3.06$
	RMO	15	$75.55 \pm 2.48$
8	G&H	15	$71.67 \pm 2.23$
	RMO	15	$74.60 \pm 2.42$
12	G&H	15	$72.01 \pm 2.33$
	RMO	15	$74.60 \pm 1.98$

Figure 9 graphically shows the force degradation for RMO<sup>®</sup> and G&H<sup>®</sup> at a pH of 7.60. The graph shows that both manufacturers lose force over time except at the 12 hour timepoint where RMO<sup>®</sup> had the same percent of initial force as the 8 hour mark, and G&H<sup>®</sup> had a slight increase in percent of initial force from 8 to 12 hours.

The two manufacturers behaved similarly to when they were placed in the pH of 6.75. G&H<sup>®</sup> had a mean higher percent of initial force at each timepoint before the four hours and RMO<sup>®</sup> had a higher mean percent of initial force at each timepoint after four hours. However, among the five timepoints, the two manufacturers were found not to be statistically different.



Mean Percent of Initial Force at the pH of 7.60

Figure 9. Mean Percent of Initial Force at the pH 7.60

#### 4.7 <u>Post Hoc Scheffé Test for pH</u>

A Post Hoc Scheffé Test was run to determine which of the pH levels had statistically significant differences in their mean percent of initial force among the five timepoints. Table X shows the results with the pH of 5.60 showing a statistically significant difference in the mean percent of initial force from the pH of 6.75 and the pH of 7.60. Further statistics were run to see if this finding was significant for one or both of the manufacturers.

#### TABLE X

### POST HOC SCHEFFÉ TEST FOR COMPARISON OF EFFECT ON PERCENT OF INITIAL FORCE

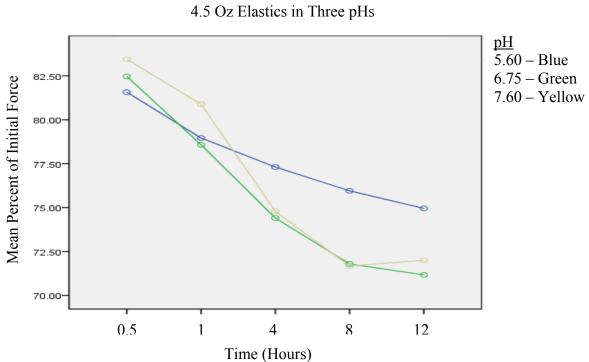
		Mean Difference		
pH(a)	pH(b)	(a-b)	Std. Error	p-value*
5.60	6.75	3.65	0.56	0.000*
5.60	7.60	2.53	0.56	0.000*
6.75	7.60	-1.12	0.56	0.144

\*p-value statistically significant at  $p \le 0.05$ .

#### 4.8 <u>Mean Difference of Percent of Initial Force Within G&H<sup>®</sup></u>

Figure 10 shows the mean percent of initial force for  $G\&H^{\ensuremath{\mathbb{R}}}$  at all three pH levels. Tests of the Within-Subjects Effects indicated a significant main effect of variable time (p < 0.001) where as time increased, the percent of initial force decreased for  $G\&H^{\ensuremath{\mathbb{R}}}$ . The interaction of time and pH was also found to be significant (p < 0.001).

The Tests of Between-Subjects Effects indicate a border limit significant main effect of pH on the elastic force degradation for  $G\&H^{\ensuremath{\mathbb{R}}}$  (p = 0.059). This was considered not to be significant for this study.



# Mean Percent of Initial Force for G&H<sup>®</sup> 1/4", 4.5 Oz Elastics in Three pHs

Figure 10. Mean Percent of Initial Force for G&H<sup>®</sup> at each pH

The amount of force degradation that G&H<sup>®</sup> elastics lost ranged from 16.5% to 19.5% in the first 30 minutes. From 1 hour to 12 hours they all lost an approximately 2% to 4% of force.

### 4.9 <u>Mean Difference of Percent of Initial Force Within RMO<sup>®</sup></u>

Figure 11 graphically shows the mean percent of initial force for all three pH levels tested for RMO<sup>®</sup>. Tests of Within-Subjects Effects indicated a significant main effect of variable time (p < 0.001) where as time increased, the percent of initial force decreased for RMO<sup>®</sup>. The interaction of time and pH also had a significant main effect (p < 0.001).

Tests of Between-Subjects Effects indicate a significant main effect of pH (p < 0.001). The pH levels show statistically significant mean differences on the percent of initial force among the five timepoints for RMO<sup>®</sup>.

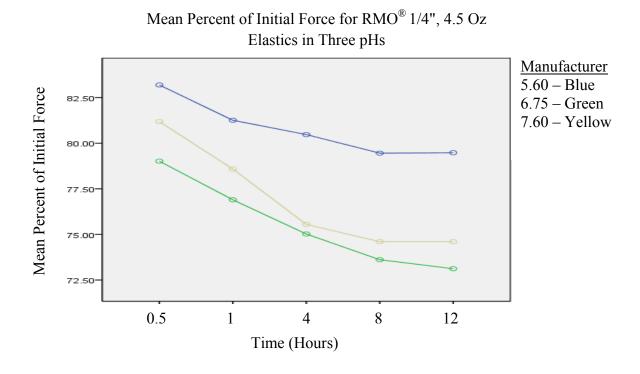


Figure 11. Mean Percent of Initial Force for RMO<sup>®</sup> at each pH

A Post Hoc Scheffé Test was run within the manufacturer RMO<sup>®</sup> to find out which pH was significantly different. Table XI shows the pH level of 5.60 was significantly different from the pH levels of 6.75 and 7.60 for RMO<sup>®</sup> latex elastics. Looking at Figure 11 and the outcome of the Post Hoc Scheffé Test, the mean percent of initial force was significantly higher for RMO<sup>®</sup> latex elastics over the five timepoints.

#### TABLE XI

POST HOC SCHEFFE TEST FOR							
COMPARISON OF EFFECT ON PERCENT OF							
INITIAL FORCE WITHIN RMO <sup>®</sup>							
Mean							
		Difference					
pH(a)	pH(b)	(a-b)	Std. Error	Sig.			
5.60	6.75	5.24	0.75	0.000*			
5.60	7.60	3.87	0.75	0.000*			
6.75	7.60	-1.37	0.75	0.199			

\*p-value statistically significant at  $p \le 0.05$ .

The RMO<sup>®</sup> latex elastics in the pH of 5.60 did not degrade as much in the first 30 minutes and had a slower rate of force degradation when compared to when they were placed in the 6.75 and 7.60 pH levels. After the first 30 minutes, the RMO<sup>®</sup> elastics lost only 17% of their initial force at the pH of 5.60, whereas at the pH of 6.75 and 7.60, they lost 21% and 18%, respectively. From 30 minutes to 1 hour, the elastics degraded approximately 2% for all pH levels but after 1 hour, the elastics began to behave differently. From 1 hour to 12 hours, the elastics in the pH of 5.60 lost just over 1% of force and 20.5% overall for the entire study. From 1 hour to 12 hours, the pH levels of 6.75 and 7.60 lost 4% of their force. Overall, the pH levels of 6.75 and 7.60 lost 27% and 26.5% of their initial force.

# 4.10 Paired Samples *t*-Test for RMO<sup>®</sup> at the pH of 5.60

A paired samples *t*-test for RMO<sup>®</sup> latex elastics at the pH of 5.60 was run to evaluate the different timepoints since RMO<sup>®</sup> latex elastics were significantly different at the pH of 5.60 from the other pH levels tested, and significantly different from G&H<sup>®</sup> at this pH. Table XII shows the paired samples *t*-test which compared the different timepoints to see if there are any significant differences.

Only the timepoints at 30 minutes and 1 hour had mean percents of initial force that were significantly different from each other when looking at successive timepoints (p < 0.05). From one hour to four hours (p = 0.152), four hours to eight hours (p = 0.125), and eight hours to twelve hours (p = 0.955), there were no statistically significant differences found. This shows that after one hour, there is no significant amount of force loss for RMO<sup>®</sup> latex elastics at the pH of 5.60.

When all of the timepoints were paired up with each other, additional statistically significant differences could be found. When examining Table XII, one can see that all pairs of timepoints were significantly different except the successive timepoints mentioned above ( $p \le 0.05$ ). It was worth noting that the timepoint at 30 minutes was the only timepoint that had a mean percent of initial force that was significantly different than all other timepoints.

IE DU OE	5 60	
1E PH OF	3.00	
t	df	p-value*
3.23	14	0.006*
4.15	14	0.001*
5.10	14	0.000*
5.21	14	0.000*
1.52	14	0.152
2.69	14	0.018*
3.48	14	0.004*
1.63	14	0.125
2.23	14	0.043*
-0.06	14	0.955
	t 3.23 4.15 5.10 5.21 1.52 2.69 3.48 1.63 2.23	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

# **TABLE XII**PAIRED SAMPLES T-TEST FOR RMO®

\*p-value statistically significant at  $p \le 0.05$ .

#### **5. DISCUSSION**

This study was conducted to examine the effects of the normal resting salivary pH on 1/4", 4.5 oz latex elastics. The normal resting salivary pH was defined by Brawley (1935) as saliva that is secreted under normal body conditions such as normalized metabolism of the glands, breathing, and muscle movements. The average pH found by Brawley (1935) within his sample of 3405 was 6.75 and the range that was found was 5.60 and 7.60. These were the three pHs used to determine the effect of pH on the degradation of latex elastics. It was found in the study by Ferriter *et al.* (1990) that polyurethane chain elastics degrade less in an acidic pH when compared to a more basic environment. After investigating 1/4", 4.5 oz latex elastics from RMO<sup>®</sup> and G&H<sup>®</sup>, the null hypothesis was rejected. There was a difference in the mean percent of initial force among the five timepoints when looking at different pH levels and between two manufacturers. RMO<sup>®</sup> latex elastics at the pH of 5.60 were found to have a significantly higher percent of initial force when compared to G&H<sup>®</sup> at the pH of 5.60.

#### 5.1 <u>Comparison of the Degradation in Force Seen in Other Studies</u>

Several studies have examined the degradation of elastics (Kersey *et al.*, 2003a; 2003b; Gioka *et al.*, 2006; Wang *et al.*, 2007; Wong *et al.*, 1976; Beattie and Monaghan, 2004; Liu *et al.*, 1993). These studies showed that latex elastics lose force over time and that most of the degradation occurred in the first 30 minutes. This current study supported the published results with a majority of the force degradation occurring in the first 30 minutes for all three pH levels tested.

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In the first 30 minutes, the drop in mean percent of initial force was the highest between any of the timepoints for all three pH levels tested. Interestingly, Kersey *et al.* (2003a) observed a 10.6% force loss after 30 minutes when latex elastics were tested statically, which was less than what was found in the current study. Kersey *et al.* (2003a) used AO<sup>®</sup> 1/4", 4.5 oz. elastics in distilled water. Since significant differences were found between RMO<sup>®</sup> and G&H<sup>®</sup> under certain conditions in this study, there may also be differences in how AO<sup>®</sup> latex elastics degrade when compared to other manufacturers. There may be a difference in force loss when using distilled water versus artificial saliva with more force loss being seen with distilled water.

Upon studying G&H<sup>®</sup> elastics in the three pH levels, which were found not to be significantly different, the elastics only lost approximately 4% to 9% of force from 1 to 12 hours. RMO<sup>®</sup> elastics lost approximately 4% of force from 1 hour to 12 hours for the pH levels of 6.75 and 7.60, which were also found to not be significantly different. However, the elastics in the pH of 5.60 were found to be significantly different among the five timepoints and it was found that they only lost 2% of force from 1 to 12 hours. This 2% loss in mean percent of initial force was less than what was found at all the other pH levels between the two manufacturers.

As mentioned in the results, the mean percent of initial force for successive timepoints from 1 hour to 12 hours were found not to be significantly different from each other by the paired samples *t*-test for RMO<sup>®</sup> at the pH of 5.60. The amount of force lost after one hour is so small that it may not be clinically significant. Baty *et al.* (1994) stated that a clinically significant change in force only occurs when the change in force is at least 10%. This means that the loss in force after one hour may not be clinically significant and the force loss in the first 30 minutes may be the most important for the clinician in deciding what size and force of elastic is needed. The force degradation in the first 30 minutes is clinically significant since the change in force is greater than 10% for all of the elastics tested. Whether the elastics from either manufacturer at any timepoint provide an optimal force or not is up for debate.

In contrast to the study by Sauget *et al.* (2011), a statistically significant correlation between pH and percent of initial force was found. The variability inherent in elastic production most likely produced the varying initial forces reported by the authors. To counter this variability, the current study was modeled after Kersey *et al.* (2003a) by performing the statistical analysis on the percent of initial force rather than the actual force recorded. An elastic within a group could theoretically have a different initial force due to the manufacturing variability, but have a comparable percent of initial force at successive timepoints if the rate of degradation was similar between elastics from the same manufacturer.

#### 5.2 <u>Artificial Saliva</u>

Artificial saliva may have an added effect when compared to distilled water in terms of degradation of the elastics since studies in artificial saliva seem to have a higher amount of force loss. Wang *et al.* (2007) used artificial saliva and showed a force loss of 13.3% in 3/16" latex elastics manufactured by  $3M^{\ensuremath{\mathbb{R}}}$  in the first 30 minutes in static tests. This amount of degradation was larger than the static tests in distilled water at  $37^{\circ}$  C reported in the study by Kersey *et al.* (2003a). The study by Liu *et al.* (1993) showed that there was less degradation in a dry and static environment than there is in an artificial saliva environment. His study showed a percent of initial force of 85% in a dry and static environment after 24 hours and the current study was

85% after only 30 minutes when artificial saliva was used. Using artificial saliva may increase the amount of force degradation when compared to dry environments and the use of distilled water.

#### 5.3 Degradation Pattern

When examining the latex elastics in the 6.75 pH and the 7.60 pH there was an interesting shift in the degradation pattern seen at the four hour timepoint. Before four hours,  $G\&H^{\circledast}$  had a higher mean percent of initial force and after this point,  $RMO^{\circledast}$  had a higher mean percent of initial force, as seen in Figures 8 and 9. It appears that there is a trend, where  $RMO^{\circledast}$  1/4", 4.5 oz latex elastics may be more advantageous to use in patients who wear their elastics for over eight hours at a time, but  $G\&H^{\circledast}$  1/4", 4.5 oz latex elastics may be better to wear for patients who change their elastics more frequently since there is less degradation initially. Although this pattern was seen when the elastics were placed in the 6.75 pH and the 7.60 pH, the mean percent of initial force for each manufacturer was not statistically significant among the five timepoints in either pH environment. This pattern was not seen at the pH of 5.60 where RMO<sup>®</sup> had a statistically significant higher mean percent of initial force among the five timepoints.

Since only RMO<sup>®</sup> elastics were significantly different at the pH of 5.60 and significantly different from G&H<sup>®</sup> elastics at the pH of 5.60, further testing was conducted via a paired samples *t*-test at this pH as seen in Table XII. Beattie and Monaghan (2004) also found less percent of initial force loss with RMO<sup>®</sup> latex elastics. When studying successive timepoints, the difference in the mean percent of initial force from 30 minutes to 1 hour was significantly

different, but the successive timepoints were not statistically different through the remaining 12 hours. This shows that there was no statistically significant difference in the mean percent of initial force after one hour for successive timepoints using RMO<sup>®</sup> 1/4", 4.5 oz. elastics at the pH of 5.60. Kanchana and Godfrey (2000) reported that elastics with a higher initial force showed less force degradation. When analyzing Tables XIII-XVIII, RMO<sup>®</sup> tended to have a higher initial force so they would be expected to have a lower rate of force degradation as was seen at the pH of 5.60. The actual sizes of the elastics were not measured by the investigator, but an observation was made that the RMO<sup>®</sup> elastics tended to appear thicker in size than G&H<sup>®</sup>, which also may have caused a difference in the percent of initial force loss.

#### 5.4 Force Recovery

Multiple studies show that the rate of force degradation slows as time increases. (Kersey *et al.*, 2003a; 2003b; Gioka *et al.*, 2006; Wang *et al.*, 2007; Wong *et al.*, 1976; Beattie and Monaghan, 2004). This study showed a similar effect on the rate of degradation. After the initial force loss, the amount of degradation began to stabilize. Tables VII, VIII, and IX exhibit a minor change in the percent of initial force between the timepoints 8 and 12 hours. A phenomenon occurred between 8 hours and 12 hours where some of the elastics increased in force slightly. Liu *et al.* (1993) talked about this occurrence and called it a "recovery phenomenon". They found that it was not statistically significant, but it could be seen in all groups except the control. Their explanation was that there was a time dependent reorganization of the crosslinks within the elastic. In their study, the force increased from 87.5%  $\pm$  3.1% of the initial force at 1 hour to 88%  $\pm$  3.0% at 3 hours. Table VII shows a slight increase at the pH

of 7.60 during this same time interval for G&H<sup>®</sup>, where RMO<sup>®</sup> remained at the same force as seen in Table IX. However, the differences between the two timepoints were well within the range of the standard deviation of each measurement so the "recovery phenomenon" may also possibly be attributed to measurement error.

In a preliminary test by the principal investigator, the elastics were allowed to relax during the transfer from the bath of artificial saliva to the force gauge. The raw data was variable with increases and decreases in force seen randomly throughout the timepoints. Allowing the elastics to relax could have allowed the polyisoprene chains to reorganize, thus causing the variability seen in the results of this preliminary test, much like what was reported by Liu *et al.* (1993). It is recommended to keep the latex elastics stretched the same initial distance at all times when analyzing the force degradation in a static environment so that the "recovery phenomenon" described by Liu *et al.* (1993) is limited. However, there may not be any clinical significance to this since the change in percent of initial force was found not to be clinically significant by Liu *et al.* (1993) and was not mentioned in the *in vivo* study by Wang *et al.* (2007).

#### 5.5 <u>Characteristics of Latex and Force Degradation</u>

Water absorption and oxidation contribute to the degradation of the elastics. The water absorption occurs due to impurities in the rubber that are hydrophilic (Eng and Ong, 2001). This leads to the swelling of the elastics, which in turn exposes more double bonds to react and causes chain scission.

The pattern of this degradation has two phases (Eng and Ong, 2001). The first phase is over a short period of time and appears to be present in the current study mostly in the first 30 minutes for all of the elastics tested. This phase results from an actual physical relaxation where the polymers rearrange. The degradation in this phase is a linear function of log time. The second phase of degradation occurs over a longer period of time and is more of a chemical relaxation. This is from chain scission and reformation of the polymers. The relaxation in this phase is a linear function of time. This explains the slower rate of degradation after one hour in the current study where phase one of degradation has diminished and the properties of the rubber begin to slowly change due to the environment that they are placed in.

#### 5.6 Isoelectric Point and Degradation

RMO<sup>®</sup> had significantly less force loss at the normal salivary resting pH of 5.60 than at 6.75 or 7.60. One reason for the differences in elastic degradation may be due to an increased rate of hydrolysis. The presence of alkalis (OH<sup>-</sup>) and acids (H<sup>+</sup>) increases the rate of hydrolysis. These groups attack the double bonds thus leading to the degradation of the rubber (Higgins, 1994).

In artificial saliva, at the pH of 5.60, the rubber molecules in the latex elastics may be closer to their isoelectric point. Hertz (1994) explained that the isoelectric point is the point where the molecule has an overall charge of zero. It is the pH where the molecule is not attracted to hydrogen ions or hydroxide ions, thus making the molecule less reactive. This is not necessarily at the neutral pH of 7.0. Hydrogen ions are positively charged and are in higher concentrations to react with the molecule in an acidic environment. Hydroxide ions are

negatively charged and are in higher concentrations to react with the molecule in a basic solution. Chain scission, or the breakdown of the polyisoprene chain, happens in the presence of both acids and alcohols. Both can break down the double bonds making the rubber more brittle (Higgins, 1994). This isoelectric point can be altered by oxides, proteins, or other molecules attached to the carbon backbone of the rubber molecule to make it more reactive (Hertz, 1994). It makes sense that the latex elastics could vary in their force degradation because they may have different oxides, proteins or other molecules that alter their polarity. Phinyocheep (2005) showed that the polarity of the backbone in rubber may shift based on the molecules attached leaving fewer double bonds open for attack, thus, less degradation. In this study RMO<sup>®</sup> latex elastics at the pH of 5.60 may be closer to their isoelectric point than any other elastic in any other pH, thus making them less reactive.

It is difficult to evaluate and compare the manufacturers because there are no standards for their production or testing as mentioned by Polur and Peck (2010). Any type of regulation or control in the chemical makeup of the latex would add cost to the production of the latex elastics that may not be necessary since Baty *et al.* (1994) showed that force differences less than 10% are not clinically significant. The differences in the production of the latex elastics from both RMO<sup>®</sup> and G&H<sup>®</sup>, whatever they may be, were not great enough to have more than a 10% difference in percent of initial force.

#### 5.7 <u>Clinical Applications</u>

One quarter inch, 4.5 oz RMO<sup>®</sup> latex elastics were found to be the superior elastic in a lower pH environment. They were shown to have less force loss over time than G&H<sup>®</sup>. If the

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pH of the mouth is at the normal resting salivary pH of 6.75 or a more basic pH, the elastics were not significantly different so either brand would be suitable for a typical patient. Patients with a normal salivary pH of 5.60 would probably not be recommended for continued orthodontic treatment if the patient has decalcifications and carious lesions associated with having a lower intraoral pH. In this clinical scenario, the choice between manufacturers may not even have to be made since it would not be recommended for patients with an acidic intraoral pH to continue with orthodontic treatment until their risk of caries diminishes.

The recommendation from this study is to either choose an elastic with an approximately 20% higher force than is needed to allow for the degradation that occurs within the first 30 minutes and instruct the patient to wear them for 12 hours. If the clinician does not want to start with a higher force during the first 30 minutes, it is recommended to give the patient the elastics with the required force to start with, but change them at least every 4 hours so that they are not treated for an extended period of time at a force that is at least 20% less than the initial force.

Patients that are not wearing their elastics due to the soreness that they experience when they first place them can be informed to continue wearing their elastics since the force that they experience will decrease significantly in the first 30 minutes. If the pain persists every time the patient starts a new elastic, the patient could be instructed to reuse their elastics since they do not lose much force after the first hour.

Whether the force being produced by the elastics from either manufacturer at any timepoint, and in any pH, is optimal or not is up for debate. Just because an elastic provides

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more force does not mean that the elastic moves the teeth at a faster rate or a greater distance. Hixon *et al.* (1969) discussed that there is no proof as to what amount of force is optimal. Little is known how age or gender can change the effect that a force has on the rate of tooth movement. The force that moves the teeth at an optimum rate can vary between individuals. It can vary with intermittent or continuous forces. There is no force established that is optimal to move teeth among the consensus of orthodontists. Little information is known on how all of these variations within a population change the rate of tooth movement. RMO<sup>®</sup> latex elastics may have more force than G&H<sup>®</sup> at the pH of 5.60 but this does not necessarily mean that the rate of tooth movement is faster with RMO<sup>®</sup> latex elastics.

#### 5.8 <u>Conclusion</u>

The null hypothesis was rejected. There was a statistically significant mean difference in the percent of initial force of 1/4", 4.5 oz latex elastics among five different timepoints for pH and manufacturer. RMO<sup>®</sup> latex elastics had a significantly higher percent of initial force over five timepoints at the pH of 5.60 when compared to the pH levels of 6.75 and 7.60. RMO<sup>®</sup> latex elastics also had a significantly higher percent of initial force over five timepoints than G&H<sup>®</sup> latex elastics at the pH of 5.60.

#### 5.9 Limitations and Future Studies

This experiment focused on the effect that pH had on 1/4", 4.5 oz latex elastics from two manufacturers. A weakness of this study is that the elastics had to be handled manually in order to measure them. They had to be removed from the artificial saliva and be placed on hooks outside the wet environment into dry air to be measured at each timepoint. Care was taken to

keep them stretched at 19.05 mm but inconsistencies could arise during the manual transfer to and from the force gauge.

The elastics appeared to vary in size despite the label showing that the diameter was 1/4". Others were cut at an angle so the width of the elastics was not always symmetrical. It may be beneficial to individually measure the size of the elastic so that they are similar and control the initial force so that it is also the same for each of the elastics tested. This test tried to compensate for this variation by randomizing the elastics from different lots to get a better sample of what an orthodontist may actually use.

A future study could test the isoelectric points of different rubber materials and determine, by adding different molecules to the carbon backbone, how the polarity and reactivity of the rubber changes. It may be possible to alter the make up of the side chains of the natural rubber to create a superior product that resists degradation.

The intraoral pH of a large sample of orthodontically treated patients versus a general population would improve this study. The pH levels that were tested were from an old study by Brawley (1935) and the consumption of fast food and acidic beverages have escalated since then.

A study looking at the consistency of the production of latex elastics in terms of the accuracy of the diameter, thickness, and force production would aid in answering why RMO<sup>®</sup> appeared to have a higher initial force as seen in Tables XIII-XVIII.

After statically testing RMO<sup>®</sup> and G&H<sup>®</sup> in the three different pH levels, it would be beneficial to see how they degrade when they are being cycled similar to the study by Kersey *et al.* (2003a; 2003b). An *in vivo* study would also be valuable to derive more clinically relevant observations.

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# APPENDIX

# TABLE XIII

# G&H<sup>®</sup> FORCE IN NEWTONS ACCORDING TO TIME IN HOURS AT THE NORMAL RESTING SALIVARY PH OF 5.60

Specimen	0	0.5	1	4	8	12
1	1.00	0.85	0.85	0.80	0.75	0.75
2	1.00	0.80	0.80	0.80	0.75	0.75
3	1.00	0.80	0.80	0.75	0.75	0.75
4	1.00	0.75	0.75	0.75	0.75	0.70
5	1.00	0.80	0.75	0.75	0.75	0.75
6	1.05	0.90	0.85	0.85	0.80	0.80
7	0.95	0.75	0.75	0.75	0.75	0.70
8	1.00	0.80	0.80	0.75	0.75	0.75
9	0.90	0.75	0.70	0.70	0.65	0.65
10	1.00	0.80	0.80	0.75	0.75	0.75
11	0.90	0.70	0.70	0.70	0.70	0.70
12	1.10	0.95	0.90	0.90	0.90	0.90
13	1.00	0.80	0.75	0.75	0.75	0.75
14	1.05	0.90	0.80	0.80	0.80	0.75
15	1.05	0.90	0.85	0.80	0.80	0.80

# TABLE XIV

# RMO<sup>®</sup> FORCE IN NEWTONS ACCORDING TO TIME IN HOURS AT THE NORMAL RESTING SALIVARY PH OF 5.60

Specimen	0	0.5	1	4	8	12
1	1.25	1.00	1.00	1.00	1.00	1.00
2	1.45	1.25	1.25	1.20	1.20	1.20
3	1.25	1.05	1.05	1.00	1.00	1.00
4	1.25	1.00	1.00	1.00	1.00	1.00
5	1.25	1.00	1.00	0.95	0.95	0.95
6	1.45	1.25	1.20	1.20	1.15	1.15
7	1.10	0.90	0.90	0.90	0.90	0.90
8	1.45	1.25	1.20	1.15	1.15	1.15
9	1.60	1.30	1.25	1.30	1.25	1.25
10	1.30	1.05	1.05	1.05	1.05	1.05
11	1.15	1.00	1.00	1.00	0.90	0.95
12	1.30	1.05	1.00	1.00	1.00	1.00
13	1.25	1.05	1.00	1.00	1.00	1.00
14	1.25	1.05	1.00	1.00	1.00	0.95
15	1.40	1.20	1.10	1.10	1.10	1.10

### TABLE XV

# G&H<sup>®</sup> FORCE IN NEWTONS ACCORDING TO TIME IN HOURS AT THE NORMAL RESTING SALIVARY PH OF 6.75

Specimen	0	0.5	1	4	8	12
1	1.10	0.95	0.90	0.85	0.80	0.80
2	1.00	0.85	0.75	0.75	0.75	0.70
3	1.00	0.85	0.80	0.75	0.70	0.75
4	0.95	0.70	0.70	0.70	0.65	0.65
5	1.00	0.85	0.80	0.75	0.75	0.75
6	1.05	0.90	0.85	0.80	0.80	0.75
7	1.05	0.90	0.85	0.85	0.80	0.80
8	1.00	0.80	0.75	0.70	0.70	0.70
9	1.10	0.90	0.90	0.80	0.80	0.80
10	1.05	0.85	0.80	0.75	0.75	0.75
11	1.10	0.90	0.85	0.80	0.80	0.75
12	1.05	0.85	0.85	0.80	0.75	0.75
13	1.00	0.80	0.80	0.75	0.70	0.70
14	1.00	0.80	0.75	0.70	0.65	0.65
15	1.00	0.85	0.80	0.75	0.70	0.70

# TABLE XVI

# RMO<sup>®</sup> FORCE IN NEWTONS ACCORDING TO TIME IN HOURS AT THE NORMAL RESTING SALIVARY PH OF 6.75

Specimen	0	0.5	1	4	8	12
1	1.50	1.10	1.10	1.05	1.05	1.05
2	1.25	1.00	1.00	0.95	0.95	0.95
3	1.40	1.10	1.05	1.05	1.00	1.00
4	1.50	1.20	1.15	1.15	1.10	1.10
5	1.40	1.10	1.05	1.00	1.00	1.00
6	1.50	1.20	1.20	1.15	1.15	1.10
7	1.45	1.15	1.15	1.10	1.10	1.05
8	1.30	1.00	1.00	1.00	0.95	0.95
9	1.45	1.15	1.05	1.10	1.05	1.05
10	1.35	1.10	1.05	1.05	1.00	1.00
11	1.25	1.00	0.95	0.90	0.90	0.90
12	1.55	1.25	1.20	1.15	1.15	1.20
13	1.55	1.20	1.20	1.15	1.10	1.10
14	1.45	1.20	1.15	1.10	1.10	1.10
15	1.30	1.00	1.00	1.00	1.00	0.95

### TABLE XVII

# G&H<sup>®</sup> FORCE IN NEWTONS ACCORDING TO TIME IN HOURS AT THE NORMAL RESTING SALIVARY PH OF 7.60

Specimen	0	0.5	1	4	8	12
1	1.00	0.85	0.85	0.80	0.75	0.75
2	1.00	0.80	0.75	0.70	0.70	0.70
3	1.10	0.90	0.85	0.80	0.75	0.75
4	1.00	0.85	0.85	0.75	0.75	0.75
5	1.10	0.90	0.90	0.85	0.80	0.80
6	1.00	0.85	0.85	0.75	0.70	0.75
7	1.05	0.90	0.85	0.80	0.75	0.75
8	1.00	0.85	0.80	0.75	0.75	0.75
9	1.05	0.90	0.85	0.75	0.75	0.75
10	1.10	0.90	0.90	0.85	0.80	0.80
11	1.10	0.90	0.90	0.85	0.80	0.80
12	0.95	0.75	0.70	0.65	0.65	0.65
13	1.05	0.90	0.85	0.80	0.75	0.75
14	1.15	0.95	0.90	0.85	0.80	0.80
15	1.05	0.90	0.90	0.80	0.75	0.75

### TABLE XVIII

# RMO<sup>®</sup> FORCE IN NEWTONS ACCORDING TO TIME IN HOURS AT THE NORMAL RESTING SALIVARY PH OF 7.60

Specimen	0	0.5	1	4	8	12
1	1.35	1.15	1.10	1.05	1.00	1.05
2	1.35	1.15	1.15	1.10	1.10	1.05
3	1.40	1.15	1.10	1.05	1.05	1.05
4	1.40	1.15	1.10	1.05	1.05	1.05
5	1.80	1.40	1.40	1.35	1.35	1.35
6	1.55	1.30	1.25	1.20	1.15	1.15
7	1.35	1.10	1.05	1.00	1.00	1.00
8	1.40	1.15	1.15	1.05	1.05	1.05
9	1.40	1.05	1.00	1.00	1.00	1.00
10	1.55	1.20	1.20	1.15	1.15	1.15
11	1.30	1.05	1.00	1.00	0.95	0.95
12	1.50	1.25	1.20	1.15	1.15	1.15
13	1.40	1.10	1.05	1.00	1.00	1.00
14	1.25	1.00	1.00	0.95	0.95	0.95
15	1.45	1.20	1.10	1.10	1.05	1.05

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