A COMPARISON OF THE MECHANICAL PROPERTIES OF PIGMENTED SILICONE ELASTOMERS USED IN MAXILLOFACIAL PROSTHESES

by

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The following individuals certify that they have read, and recommend to the Faculty of Graduate and Postdoctoral Studies for acceptance, a thesis/dissertation entitled:

A comparison of the mechanical properties of pigmented silicone elastomers used in maxillofacial prostheses

Submitted by Nora El-Mowafy in partial fulfillment of the requirements for the degree of Master of Science in Craniofacial Science

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Abstract

Purpose: To evaluate and compare the mechanical properties of various commercially available pigmented polydimethylsiloxane elastomers (silicone elastomers) utilized in the fabrication of maxillofacial prostheses.

Materials & Methods: Three commonly used silicone elastomers were evaluated: A-2000 (Factor II), A-2186 (Factor II), A-103 (Factor II). The silicones was combined with opacifier: Titanium White (Factor II), and pigment: Intrinsic Pigment in Naturelle (Factor II). Specimens were fabricated through the use of aluminum and stone moulds to form trouser- and dumbbell-shaped specimens. From each material 20 specimens were prepared, 10 dumbbell-shaped and 10 trouser-shaped (n=10) for a total of 60 specimens. Mechanical properties evaluated included: Shore-A hardness, tear strength, tensile strength, and percent elongation. These properties were tested according to ASTM protocols. Data was statistically-analyzed with one-way ANOVA of each property at the 95% level of confidence as well as Tukey’s post-hoc tests for specific identification of significant differences between materials.

Results: ANOVA indicated statistically-significant differences among the three materials for each of the four outcomes tested. Further statistical analysis with Tukey’s post-hoc tests showed significantly lower tensile strength and tear strength and higher % elongation for A-103 when compared to both A-2000 and A-2186. No statistically significant differences were found between A-2000 and A-2186 with respect to tensile strength, percent elongation or tear strength. All three groups were found to be significantly different from each other in terms of Shore-A hardness. A-103 exhibited the lowest hardness values, whereas A-2186 was found to have the highest hardness.
Conclusions: Material A-103 exhibited the lowest tensile and tear strengths as well as hardness, however, it displayed the greatest percent elongation. Material A-2000 and A-2186 displayed similar characteristics with regard to tensile and tear strengths, but differed in terms of Shore-A hardness with A-2186 exhibiting the greatest hardness.
Lay Summary

Maxillofacial prostheses are of great value for the restoration of head and neck defects in affected patients. Various commercially available silicone materials are used for the fabrication of these prostheses, however no one material possesses all the necessary characteristics of the ideal material for this application. Pigments and opacifiers are added to these materials in an effort to reproduce a natural likeness and esthetic result. The literature examining the effects of these additives on the mechanical properties of silicones is limited. The aim of this project was to evaluate and compare the mechanical properties of various commercially available pigmented silicones that are used in the fabrication of maxillofacial prostheses. In addition, the mechanical properties of a silicone material that has yet to be reported on in the literature were evaluated.
Preface

This thesis is an original intellectual product of the author, Nora El-Mowafy. This project was conducted under the direct supervision of Dr. Caroline Nguyen. The other members of the research committee were Dr. Rick Carvalho and Dr. Adriana Manso.

The custom-made aluminum molds were fabricated by Dr. Caroline Nguyen at the UT MD Anderson Cancer Center in Houston, Texas. The fabrication of the resin molds was carried out at Frontier Dental Laboratories (325 W 6th Ave, Vancouver, British Columbia) by David Bird and his team of lab technicians. Shore- A Hardness testing was conducted by Jeffrey Mount at UTHealth, School of Dentistry (7500 Cambridge St, Houston, Texas). Statistical analyses were conducted with the help of Anton Svendrovski. With the exception of the above mentioned, the lead investigator, Nora El-Mowafy, completed all components of this project independently including: research, specimen preparation and testing, data analysis and dissertation writing.

Ethical approval from the UBC Ethics Board was not required, as this study did not involve the of use human or animal subjects and bio-hazardous materials.
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<tr>
<td>HTV</td>
<td>High temperature vulcanizing</td>
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<tr>
<td>IRHD</td>
<td>International rubber hardness number</td>
</tr>
<tr>
<td>MFPs</td>
<td>Maxillofacial Prostheses</td>
</tr>
<tr>
<td>PDMS</td>
<td>Polydimethylsiloxane</td>
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<td>RTV</td>
<td>Room temperature vulcanizing</td>
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Dedication

For my cherished parents Wafa and Omar. If I could dedicate the world to you I would, but for now, one of my greatest accomplishments is in your honour.

“Do it for them”
Chapter 1: Introduction

0.1 Introduction

Maxillofacial prosthodontics, as defined by the American Academy of Maxillofacial Prosthetics, is a subspecialty of prosthodontics concerned with the art and science of anatomic, functional, or cosmetic reconstruction by means of nonliving substitutes, of those regions in the maxilla, mandible, and face.¹ Maxillofacial prostheses (MFPs) are utilized to restore defects of the head and neck region resulting from congenital malformations, developmental anomalies, and trauma or cancer resection.² These prostheses are of great value as they serve to restore patients’ function as well as improve appearance, which in turn have a positive psychological impact on those affected. They are especially beneficial in cases when surgical reconstruction cannot otherwise be performed to restore a defect.³ Such is the case with large defects, defects in a region of irradiated tissues, or when the risk of tumor recurrence is high. Furthermore, surgical reconstruction of defects resulting from malignant tumor is often delayed for a year after resection. Throughout this time, patients are rehabilitated with maxillofacial prostheses.³ Despite the advantageous applications of these prostheses, the pursuit of the ideal material to use for their fabrication remains a challenge.

0.1.1 History of Materials Used for Maxillofacial Prostheses

Various materials have been used throughout history for the fabrication of maxillofacial prostheses. As early as 1510, Ambroise Paré described the use of gold, silver, paper and linen cloth for the fabrication of a facial prosthesis.³ Toward the end of the 19ᵗʰ century, vulcanite rubber was widely used within the profession.³ After its introduction, latex was incorporated into
the vulcanized rubber to overcome the issue of the material’s rigidity. In 1937, vulcanite rubber was replaced after the introduction of acrylic resin. Acrylic resin offered the advantages of translucency, colorability and ease of processing and repairs. However, the issue of rigidity of the material remained, which led to the development of resilient vinyl copolymer acrylic resins for the fabrication of maxillofacial prostheses. In 1960, Barnhart introduced the use of silicone elastomer for the fabrication of these prostheses.

The use of other types of elastomeric materials has been documented in the literature: modified polysiloxanes elastomers, chlorinated polyethylene and polyurethane elastomers. They were initially promising, as polyurethanes offer excellent cosmetic results as well as exhibit desirable elastic properties for the restoration of moveable tissues. However, despite their unsurpassable esthetics, fabrication of polyurethane prostheses is difficult and highly technique-sensitive. Moreover, the material’s extremely short service life of three to six months limit its’ long-term clinical application. Advances in polymer chemistry have led to further investigation of these materials’ applicability in the field of maxillofacial prosthodontics. Despite these advances, silicone elastomers remain the most commonly used material for the fabrication of maxillofacial prostheses.

0.2 The Ideal Material

The final esthetic result of a maxillofacial prosthesis is the most important factor in determining clinical success. Maxillofacial prostheses should reproduce a natural cosmetic appearance to the finest details as well as adequately restore patient function. However, the
prosthodontists ability to provide patients with a prosthesis that fulfills these requirements is limited by the properties of the materials available for their fabrication.³

Materials employed for the fabrication of maxillofacial prostheses should fulfill the ideal handling, processing, biological, physical and mechanical properties. With regards to processing of maxillofacial prostheses, the material should be easily manipulated with an acceptable working and curing time, accept colorants, and remain dimensionally stable during processing.³ The cured material should be non-toxic, non-allergenic, non-irritant, non-porous, and should not support the growth of microorganisms.³ The processed prostheses should be chemically inert, dimensionally stable over a range of temperatures (-40°F - 140°F) and should not transfer heat or cold to the supporting tissues.³ The material should adequately reproduce a realistic translucency and the incorporated colorants should remain stable. The ideal material should be inexpensive, cleansable, repairable and have a minimum service life of 6 months.³

Ideally, materials employed for the fabrication of maxillofacial prostheses should possess high tear strength, tensile strength and percent elongation at break as well as hardness similar to that of the tissue being replaced. Clinically, the most critical property is the material’s tear strength.¹⁰ Maxillofacial prostheses are fabricated with very thin margins to ensure favourable blending with the surrounding facial tissues.¹⁰ Although implants can sometimes be placed to aid in the retention of these prostheses, medical adhesives remain widely used for this purpose.³,¹⁰ Upon removal of the prosthesis, the thin margins are highly susceptible to tearing.¹⁰,¹¹ For this reason, maxillofacial materials should exhibit a high resistance to tearing. The tensile strength is the maximum stress a material can withstand before failing. A high tensile strength of
Maxillofacial materials is necessary for prosthesis durability.\textsuperscript{10} Hardness provides a measure of the materials flexibility and it’s ability to accommodate facial movements.\textsuperscript{11} Maxillofacial prostheses should be fabricated from a material with a similar hardness as the missing facial tissue in order to accurately replicate the lost structures.\textsuperscript{3,10,11} Lewis et al., reported that hardness values ranging from 25-35 hardness numbers would best mimic facial features.\textsuperscript{12} In addition, the material selected should possess low water sorption to resist staining and color deterioration when the prosthesis comes into contact with sweat or saliva.\textsuperscript{10}

Despite the various maxillofacial materials available, with each offering it’s own advantages and limitations, no one material possesses all the necessary ideal properties.

0.2.1 Silicone Elastomers

Since their introduction in 1960s, the advantages of silicone materials have led to their widespread use in maxillofacial prosthodontics.\textsuperscript{9} These include their biocompatibility, chemical inertness, ease of manipulation, durability and relative strength.\textsuperscript{2} However, silicone elastomers are not without their deficiencies. These include color instability, deterioration of physical properties over time, difficult repairs, and short periods of prosthesis serviceability.\textsuperscript{2} Silicone prostheses remain esthetic and serviceable for an average of only one to two years and patient's satisfaction declines within three years of service.\textsuperscript{2} The deterioration of these materials occurs due to the effects of weather, environmental factors, smoking, tobacco chewing, and cleaning agents.\textsuperscript{2} The components of weather that affect the degree of prosthesis deterioration are the amount of sunlight, temperature fluctuations, moisture level and the presence of air pollutants.\textsuperscript{2}
Silicones (polydimethyl siloxane elastomers) are a combination of organic and inorganic compounds. The quality of these materials depends on their two basic components: the polydimethyl siloxane (PDMS) chains and the silica fillers. The overall strength and service life of the material depends on the interactions between these two components. The mechanical properties of silicone elastomers depends on the molecular weight distribution, the degrees of cross-linking of the PDMS chains, as well as the incorporation of silica fillers.

The length of polymer chain determines the viscosity of the silicone. The degree of cross-linking also affects the mechanical properties, highly cross-linked silicones are brittle with little elasticity, while low cross-linked silicones are weak with low tear and tensile strength. Polyzois et al., evaluated the mechanical properties of room-temperature vulcanizing elastomers after altering the molecular architecture by controlling the proportions of cross-linking. The authors reported a reduction in tensile strength, elongation at break and tear strength with increasing degrees of cross-linking. They hypothesized the reduced tear strength resulted from stress concentration, which could not be dissipated due to the reduced segmental mobility of PDMS chains. Furthermore, the degree of cross-linking also affected the nature of the tearing. Conversely, increasing cross-linking proportions resulted in increased elastic modulus and hardness properties of the material. Fillers are added to the silicone to improve its’ strength, while additives are used to provide color. Polyzois et al., concluded that although fillers are added to these materials in an effort to enhance the mechanical and physical properties, excessive fillers ultimately weaken the material.
Chapter 1: Review of Literature

1.1 Review of Literature

Despite the evident value of silicone elastomers in the field of maxillofacial prosthodontics, the evidence with respect to their mechanical properties is scarce. Few publications are available which make comparisons between the commercially available materials.\(^{10,11}\) In addition, due to the limitations in comparing the research available, it is challenging to ascertain which material is the most ideal for this application. In the past, research has been centered on the color stability and physical properties of these materials.\(^{15-17,18}\) Moreover, the prostheses short service life resulting from deterioration due to weather and environmental factors has led to a focus on the effects of weathering on the physical properties of these materials. Several studies have evaluated the effects of both natural and artificial weathering, which depend on the amount of sunlight exposure, temperature and moisture levels, and presence of air pollutants.\(^{2,19-21}\) An evaluation of the mechanical properties of the most commonly used commercially available silicones should be combined with an assessment of the physical properties as well as the effects of aging on the materials to identify an ideal material or to aid in developments of a novel material with improved properties.

A recent study examined the effect of opacifiers and pigments on the mechanical properties of one commonly used silicone material, MDX4-4210/type-A before and after an artificial aging process. The authors investigated the effects of a UV mineral-based light-protecting agent (LP), two opacifiers; titanium white dry pigment (TW) and silicone intrinsic white opacifier (SW) as well as pigments on the mechanical properties of silicones after their
incorporation. The LP agent, which claimed to improve color stability from environmental degradation, was found to cause considerable degradation of the mechanical properties of the silicone tested. The opacifiers and aging process had statistically significant effect on the hardness, tear strength, tensile strength, and percent elongation. Of the two opacifiers tested, the findings indicated TW best preserved the mechanical properties. In addition, the results demonstrated the aging process decreased hardness, tear strength, tensile strength, and percent elongation for all groups. It is worth noting that artificial weathering is not a true representation of the weathering environment prostheses are normally subject to. Furthermore, it can also lead to incorrect estimates of the lifetime of a polymer as they may cause greater changes than normal outdoor aging and prosthesis use.

Aziz and colleagues evaluated the properties of five commonly used maxillofacial silicone materials. Tear strength, tensile strength, percentage elongation, hardness, water absorption and water contact angles. The authors evaluated four commercially available silicones: Cosmesil HC, Cosmesil St, A-2186, Prestige, and Nusil. This evaluation of silicone materials demonstrated that no one material fulfilled all the necessary criteria of an ideal material used for MFPs. The differences observed can be attributed to the differing compositions of each material, such as differences in the cross-linking systems (addition or condensation), molecular weight of the polydimethylsiloxane (PDMS), cross-link density, grade and concentration of the silica filler. The authors reported statistically significant differences in the mean tear strengths found between all commercial materials evaluated. A-2186, Nusil and Cosmesil HC demonstrated greater tear strengths that were statistically significant from those exhibited by Cosmesil St and Prestige.
Both Cosmesil materials, HC and St, exhibited the greatest hardness values, which were significantly harder when compared with the other materials. Materials composed of high molecular weight polymers that are highly cross-linked coupled with a high filler content resulted in a material with a considerable hardness. Correspondingly, materials with a lower filler content, or reduced cross-link density are softer. A reduced cross-link density allows the polymer chains to deform for a greater distance, while a lower filler concentration reduces the polymer/filler interactions and increases the mobility of the chains.\textsuperscript{10}

Statistically significant differences of the mean tear strengths were reported between all commercial materials evaluated. Statistically significant resistance to tearing was found with Cosmesil HC, Nusil, A-2186. This is likely due to the silica fillers with high surface area, which allows for maximized polymer/filler interactions. Moreover if the silica filler is modified with dimethyl silyl or trimethyl silyl groups the resulting polymer withstands greater deformation without rupture or tearing. A-2186 demonstrated the highest tear strength. The authors proposed this could be attributed to the broader bimodal PDMS molecular weight distribution, which increases the resistance to tearing while maintaining the materials flexibility. Bimodal network silicones consist of a blending of long and short chains of the same polymer. The advantages of silicones with bimodal networks are illustrated by their enhanced mechanical properties owing to a high cross-link density with a low incidence of chain irregularities. Elastomers with bimodal polymer networks possess superior tear and tensile behaviors coupled with resilience when compared to monomodal ones.\textsuperscript{10,13}
With respect to percent elongation, Nusil exhibited a greater elongation at break, which was statistically significant when compared to other materials. Despite Nusil exhibiting a high elongation at break owing to the high molecular weight PDMS chains achieving a greater degree of crystallization, its decreased resistance to tearing was evidenced by a greater distance between the cross-links. This explanation was confirmed as Cosmesil HC, which is composed of a lower molecular weight PDMS, however, exhibits reduced distance between the polymer cross-links, exhibited superior tear strength in spite of its reduced tensile strength. Superior tear, tensile and percent elongation at break with Nusil, Cosmesil HC, A-2186 was found. The authors attributed this finding to these materials’ composition of high molecular weight PDMS chains in combination with surface-treated silica fillers. However, cross-linking of a high molecular weight material results in an increased viscosity of the base polymer. The significance of the viscosity of the polymer is the effect on the handling properties of the material since a higher viscosity material is more difficult to manipulate. Nusil, Cosmesil HC and St displayed increased viscosities when compared with A-2186 and Prestige. The decreased viscosity of Factor II could be attributed to the cross-linking reactions. A low viscosity material results when a low molecular weight PDMS chain is combined with an addition cross-linking reaction. The authors concluded that while A-2186 demonstrated adequate mechanical properties, it may be problematic with respect to patient comfort as it had the poorest wettability. The authors concluded that none of the commercially available silicones tested were able to satisfy the requirements of an ideal silicone material used for maxillofacial prostheses.

Similarly, Hatamleh and Watts conducted an investigation of three widely used silicone elastomers. The materials assessed were Techsil (S25), and two types of Cosmesil (M511/HC
and Z004/St). The authors evaluated their tear strength, tensile strength, elongation, and hardness. With respect to tear properties, they found no statistically significant differences between the materials. Cosmesil Z004 exhibited the greatest tear strength of 7.04 kN/m, followed by Techsil and finally Cosmesil M511 with tear strengths of 6.55 kN/m and 6.52 kN/m, respectively. However, tensile properties were statistically significantly different between the silicones with Techsil displaying the greatest strength of 4.85 MPa. Cosmesil Z004 was superior to M511 with tensile strengths of 3.86 MPa and 1.86 MPa, respectively. Techsil also exhibited superior percent elongation at break of 941.25%, which was a statistically significantly different when compared to both Cosmesil materials. The percent elongation of the Cosmesil silicones was 608.55% for Z004 and 580.93% for M511. Statistically significant differences for hardness values were reported between all materials. The hardest material was Cosmesil Z004 with a shore A hardness of 36.44, followed by Techsil with a hardness of 25.42 and lastly Cosmesil M511 demonstrating a hardness of 12.64. The authors acknowledged that a standard cross-linker was used for the purpose of this investigation. As a result lower hardness values for Cosmesil M511 could be expected since the material was not formulated according to the manufacturer’s recommendations, which requires the use of corresponding cross-linker in order to achieve hardness values between 35-40.\textsuperscript{11}

Haug and colleagues evaluated various materials used for the fabrication of maxillofacial prostheses. They investigated four room temperature vulcanizing (RTV) silicone elastomers (Factor II A-2186, Factor II A-102, Medical Adhesive Type A, and Silastic 4-4210), and one high temperature vulcanizing (HTV) silicone elastomer (Silastic 4-4515) as well as one polyurethane elastomer (Epithane-3). The authors tested the six materials (control groups) to
evaluate ultimate tensile strength, percent elongation, tear strength, and hardness. They also evaluated the effects of outdoor weathering, 2 prosthesis adhesives (Pros-Aide and Secure Medical Adhesive), cleaning agents, cosmetics and time passage on the mechanical properties of these materials. However, as this paper is focussed primarily on evaluating mechanical properties of silicones in the absence of variables, these results will not be discussed in an effort to allow comparisons with the literature. The authors found that Silastic 4-4515 demonstrated a superior tensile strength of 9.52 MPa, 50% higher than second-strongest material, Factor II A-2186. The materials with the lowest tensile strength were Medical Adhesive Type-A (1.13 MPa) and Epithane-3 (0.83 MPa). Factor II A-2186 and Silastic 4-4515 exhibited the highest percent elongation, 448% and 476%, respectively, while Factor II A-102 exhibited the lowest percent elongation of 130%. In regards to tear strength, the authors found that Factor II A-2186 was superior when compared with the other materials’ control groups. The hardest materials were Silastic 4-4515 and Epithane-3 with Shore-A hardness values of 50.16 and 46.62, which were statistically significantly superior when compared to the other materials. The softest material was Factor II A-2186 with a Shore-A hardness of 22.84. This study included polyurethane materials as well as an HTV elastomer, which both are not routinely used in the fabrication of these prostheses due to their drawbacks as well as their difficult and technique sensitive fabrication. Moreover, the evidence supports the wide use of RTV silicone elastomers for these prostheses when compared to alternative materials. The authors concluded, in line with other publications, that no single ideal material exists and none of the materials tested fulfilled the criteria of an ideal material for MFPs. They reported Silastic 4-4515, a HTV elastomer, was the strongest material, in spite of this, RTVs are the preferred silicones owing to their ease of fabrication.22,23
The primary focus of the literature investigating silicone elastomers for the fabrication of MFPs has centered on the physical properties and color stability of these materials.\textsuperscript{15, 17, 19, 21, 24, 25} The limited available evidence, coupled with variations in the studies poses a challenge in comparing the conclusions in the literature. The results of mechanical testing of silicones are dependent on the materials tested, specimen preparation, the specimen shape (trouser, angle, crescent), and the test methods, protocols and conditions. For instance, different materials, standard mechanical test protocols, testing equipment and scales of measure were used in the studies by Aziz et al., and Hatamleh et al. Despite these two publications evaluating two common materials, both authors described dissimilar curing temperatures and times for the same materials. Similarly, a lack of adherence to the manufacturer’s instructions for material preparation was evidenced in the study by Hatamleh et al., which is not clinically applicable. In addition, variations in the findings result with differing crosshead testing speed since the higher the rate of stressing, the less time available for molecules to redistribute the stress, which results in early tearing of the specimen. For this reason, the literature evaluating tear strength should be carefully evaluated. Despite the challenges in comparing results and identifying a superior material, there is a consensus among the literature that further improvements of both physical and mechanical properties of silicones used for maxillofacial prostheses is required and that no one material possess the ideal characteristics required for a maxillofacial silicone.\textsuperscript{10, 11}

Bellamy and colleagues set out to overcome the inadequacy of the currently available silicone materials by testing a new formulation of a silicone rubber. The authors tested the base material of a novel three-layered polymeric system as well as evaluated its mechanical properties when compared with two widely used silicone materials. The commercial materials tested were
Factor II (A-2186) and Technovent. The authors prepared four formulations of the novel bimodal silicone rubber material, each with varying proportions of the constituents that would affect the mechanical properties. They conducted hardness, tear, and viscosity testing of the four formulations as well as of the commercially available silicones. After the initial testing, the authors determined which formulation demonstrated the optimum compromise of tear strength, hardness, and viscosity. The tensile properties of the selected formulation were then evaluated by finite element analysis. The selected novel material was formulation 2, with a filler content of 30 and a polymer content of 70 of which 80% were high molecular weight and 20% were low molecular weight polymers. When compared with the commercially available silicones, the novel material exhibited hardness values that were not statistically significantly different when compared to the two commercial materials. However, the novel material demonstrated superior tear strengths that were statistically significant when compared to the commercially available silicones. No significant differences were found between the selected novel formulation and the other materials. The authors were able to demonstrate that by varying the ratios of low molecular and high molecular weight polymers, it was possible to optimise the material’s tear strength. As this was a preliminary study of a novel material, further development of the material and testing of the remaining two layers are required.

It is evident that in the field of maxillofacial prosthodontics, silicone elastomers play a key role in providing patients with a prosthesis that fulfills both the patient’s need as well as the standard of care we strive to provide. Although these materials enable maxillofacial prosthodontists to make a considerable impact in the lives of those with head and neck defects, shortcomings in these materials limit the serviceability of these prostheses. In an effort to address
these concerns, maxillofacial literature has been centered on assessing silicone elastomers. The available evidence concerning silicone elastomers used for the fabrication of MFPs initially was focused on evaluating the mechanical properties of the commercially available materials – with a spotlight specifically on material MDX4-4210 (Dow Corning Corp.; Midland, Michigan). Further research concentrated on assessing the effects of aging on the colour stability as well as its effect on the mechanical properties of these materials to simulate the conditions MFPs are exposed to while in service. While recently, research has been centered on enhancing the mechanical properties of the existing materials by incorporating inserts. Various materials have been suggested for this purpose including the incorporation of nano-oxides (Ti, Zn, or Ce), agents used for colorization (intrinsic pigments, rayon flocking fibers, artist’s oils, or kaolin). In addition, improvement of the mechanical properties has been suggested by varying the cross-linker to resin ratio. While current research is still investigating both mechanical properties as well as the effects of aging, attention is being directed to the development of new silicone materials with enhanced properties.\textsuperscript{26} Despite the increasing interest in maxillofacial silicone elastomers and increased numbers of publications in recent decades, variability in the available evidence obstructs the ability to compare and draw conclusions from the literature.

This review of the available literature revealed, as confirmed by a recent review of literature conducted by Hatamleh et al., that although there has been an increase in the research conducted with regard to the existing maxillofacial prosthetic materials as well as advancements and developments of these materials, the ability to make comparisons between the evidence remains an obstacle. The authors of this review made a legitimate suggestion that in an effort to overcome the shortcomings and variability of the available evidence, efforts should be focused
on developing and instituting international standards and specifications for the testing and evaluation of materials used for the fabrication of MFPs.²⁶

1.2 Aims

The objective of this study was to evaluate and compare the mechanical properties of various commercially available pigmented polydimethylsiloxane elastomers (silicone elastomers) utilized in the fabrication of maxillofacial prostheses. In addition, this study aimed to provide the first report of the mechanical properties of silicone elastomer material A-103 (Factor II Inc.; Lakeside, Arizona).
Chapter 2: Materials and Methods

2.1 Material Selection

This study utilized three RTV silicone elastomers: A-2186, A-2000, and A-103 (Factor II Inc.; Lakeside, Arizona). From each material 20 specimens were prepared, 10 dumbbell-shaped and 10 trouser-shaped (n=10) with a total of 60 specimens. Each silicone elastomer was combined with an opacifier, Titanium White dry pigment (Factor II Inc.; Lakeside, Arizona) and intrinsic pigment, FI-SK01 in Naturelle (Factor II Inc.; Lakeside, Arizona). (Figures 1-5)

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<tr>
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<tr>
<td>Functional Intrinsic Skin Colours- Silicone Coloring System in Naturelle (30ml)</td>
<td>Factor II; Lakeside, AZ</td>
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</table>

Table 1: Silicone materials and additives used in the fabrication of silicone specimens for this study.
Figure 1: A-2000 Platinum RTV Silicone Elastomer (Factor II Inc.; Lakeside, Arizona).

Figure 2: A-2186 Platinum RTV Silicone Elastomer (Factor II Inc.; Lakeside Arizona).

Figure 3: A-103 RTV Silicone Elastomer (Factor II Inc.; Lakeside, Arizona).
Figure 4: Titanium White Dry Pigment (TW) (Factor II Inc.; Lakeside, Arizona).

Figure 5: Functional Intrinsic Skin Colours- Silicone Coloring System in Naturelle (Factor II Inc.; Lakeside, Arizona)
2.2 Mold Fabrication

Four custom-made aluminum molds were utilized to fabricate gypsum stone and resin molds. The custom molds were designed as dictated by ASTM International standard test methods for tear strength (D624-00) (Figure 6) and tension (D412-98a) (Figure 7) of conventional vulcanized rubber and thermoplastic elastomers. Stone molds were fabricated using ISO type 3 dental stone, Microstone (Whipmix; Louisville, Kentucky), which was combined with water in a ratio of 28ml/100g and was mixed under vacuum. The custom molds for the dumbbell-shaped specimens were filled with the stone mixture under vibration. The stone molds were left to completely set for forty-five minutes before removal from the aluminum molds. After their removal, the bases of the stone molds were sanded using 60grit sandpaper (3M; Maplewood, Minnesota) to ensure completely flat bases. The custom molds for trouser-shaped specimens were filled with a mixture of resin material, Smooth Cast 300 (Smooth-On; East Texas, Pennsylvania), wherein part A and part B were mixed in a 1:1 ratio and titrated for 1 minute. The resin mixture was then poured into the aluminum molds and left to set for ten minutes before removal from the aluminum molds. The bases of the resin molds were trimmed using a model trimmer to ensure they were completely flat. All molds were then notched at non-critical edges, using a super-coarse acrylic bur (H79SGE, Brassler USA; Savannah, Georgia). This was done to provide an area for wedging of an instrument to facilitate opening of the molds. Each completed mold allowed for the fabrication of two silicone specimens. (Figures 8 & 9)
Figure 6: Custom-made trouser shaped aluminum molds used for the fabrication of resin molds.

Figure 7: Custom-made dumbbell shaped aluminum molds used for the fabrication of stone molds.
Figure 8: Stone dumbbell-shaped mold with notches.

Figure 9: Resin trouser-shaped mold with notches.

2.3 Specimen Fabrication

For each material, a total of 540g of silicone, 22.5g of titanium white dry pigment and 8.25ml of functional intrinsic pigment was needed to fabricate 20 specimens. To simplify and contain manipulation, the silicone was mixed in batches. A total of three batches were required to produce 10 dumbbell-shaped specimens, while a total of two batches were needed to yield 10 trouser-shaped specimens. Overall, five mixture batches were required to yield 20 specimens for
each group. Each batch mixture consisted of 108g total silicone content (base & cross-linker), 4.45g of TW, and 1.65ml of intrinsic pigment. Material A-2000 required a 1:1 ratio of silicone base to cross-linker; meaning for each batch 54g of Part A (base) was combined with 54g Part B (cross-linker). In contrast, both Material A-2186 and A-103 required a mixture ratio of 10:1; meaning each batch for these materials consisted of 98g base combined with a 10g cross-linker.

The silicone was mixed by spatulating on a large plastic slab to allow for gradual incorporation of the additives and to eliminate air bubbles. The base and cross-linker of the silicone were mixed first, to which the intrinsic pigment was added. Prior to its incorporation, Titanium White dry pigment was passed through a sieve to prevent the formation of lumps and avoid incomplete mixing. Once the material was thoroughly mixed, it was spread evenly in thin layers across the slab. This was done to facilitate elimination of bubbles by atmospheric pressure. The silicone was then loaded into a 60ml Monoject syringe and injected directly into the molds. Prior to the introduction of the silicone mixture into the stone molds, a separating medium was applied. No separating medium was required for the resin molds. After injection loading of the silicone, air bubbles were eliminated using a sharp instrument. The filled molds were then covered with metal lids, stacked on top of one another and clamped together using C-clamps. The silicone-filled molds were left to completely vulcanize at room temperature for 48 hours. After the initial vulcanization, the lids were removed from the molds and the silicone material was left to further vulcanize at room temperature for an additional 24 hours. Once completely set, the silicone specimens were retrieved using a blunt instrument. The excess silicone material (flash) was trimmed using a no.11 blade.
2.4 Specimen Identification

Specimens were notched with a no. 11 blade at non-critical edges for identification purposes as follows:

Group A: Baseline A-2000, no notch
Group B: Baseline A-2186, two notches on the same side
Group C: Baseline A-103, two notches on one side, one notch on other side

(Figures 10-15)

Figure 10: Trouser-shaped specimen fabricated from material A-2000 (group A).

Figure 11: Dumbbell-shaped specimen fabricated from material A-2000 (group A).

Figure 12: Trouser-shaped specimen fabricated from material A-2186 (group B).
Figure 13: Dumbbell-shaped specimen fabricated from material A-2186 (group B).

Figure 14: Trouser-shaped specimen fabricated from material A-103 (group C).

Figure 15: Dumbbell-shaped specimen fabricated from material A-103 (group C)
2.5 Mechanical Testing

2.5.1 Tensile Strength

Tensile strength testing was conducted according to ASTM D412 guidelines using an Instron Universal testing machine (model 4301 Instron; Norwood, Massachusetts). Each dumbbell-shaped specimen was secured between the grips of the universal testing machine and separated at a rate of 500mm/min. A total of ten specimens were tested. Tensile strength (MPa) was calculated using the following formula: TS=F/A; where F is the force at the time of specimen rupture and A is the mean cross section calculated from three measurements with an electronic caliper (Neiko; Taiwan, China). The mean cross section of the dumbbell-shaped specimens was determined to be 52mm$^2$. (Figure 16)

2.5.2 Percent Elongation

Percent elongation testing was conducted simultaneously with tensile strength testing. Percent elongation (%) was calculated after recording the initial distance between the grips (Lo), which was equal to 30mm, and determining the distance between the grips at the time of specimen failure (Lf). The following formula was used to calculate percent elongation: %E= 100 x (Lf-Lo)/Lo, where Lf = distance between grips at failure and Lo = original distance between grips. (Figure 16)
2.5.3 Tear Strength

Tear strength testing was conducted according to ASTM D624 guidelines using the Instron Universal testing machine model 4301 (Instron; Norwood, Massachusetts). Trouser-shaped specimens were secured between the grips of the universal testing machine and separated at a rate of 500mm/min. A total of ten specimens were tested. Tear strength (MPa) was calculated using the following formula: $Ts = F/d$; where $d$ is the median thickness of each specimen measured three times with an electronic caliper (Neiko; Taiwan, China) and $F$ is the force at the time of rupture. The median thickness of the trouser-shaped specimens was determined to be 3.09mm.
2.5.4 Shore-A Hardness

Shore-A hardness testing was conducted according to ASTM D2240 guidelines. Two trouser-shaped specimens were stacked to achieve a thickness of 6mm as required by the test protocol. The readings that were obtained were of the specimen on top. Using a standard durometer (1600 Standard Dual Durometer; Rex Gauge Company Inc., Buffalo Grove, Illinois), vertically placed with the indenter tip 12mm away from specimen edges, the indenter tip was applied to the specimen surface and maintained in position for three seconds before the indentation dimensions were measured. A total of five indentations were made and five readings were obtained, each 6mm apart. The mean of the five readings was determined. The specimen positions were then reversed and the same was repeated. (Figures 17-19)

![Image of 1600 Standard Dual Durometer](image.jpg)

Figure 17: 1600 Standard Dual Durometer (Rex Gauge Company Inc., Buffalo Grove, Illinois)
Figure 18: Two trouser-shaped specimens stacked to achieve a thickness of 6mm.

Figure 19: Shore-A Hardness testing readings conducted 6mm apart on trouser-shaped specimens.

2.6 Statistical Analysis

An Excel file with the raw data was generated and loaded into SPSS. A one-way analysis of variance (ANOVA) of each property at the 95% level of confidence was conducted. To identify differences between specific groups, Tukey’s post-hoc tests were subsequently conducted.
Chapter 3: Results

3.1 Tensile Strength

Table 2 shows tensile strength test values of each specimen for each of the materials tested. In addition, Table 2 shows the mean and standard deviation values of each material tested. For group A (A-2000), the tensile values ranged from 1.61 to 2.44MPa with a mean value of 2.01MPa and standard deviation of 0.25MPa. For group B (A-2186), the tensile strength values ranged from 1.62 to 3.16MPa with a mean value of 2.34MPa and standard deviation of 0.44MPa. For group C (A-103), the tensile strength values ranged from 0.97 to 2.21MPa with a mean value of 1.57MPa and standard deviation of 0.37MPa. Figure 17 shows a box and whisker plot of the data. Figure 18 shows bar graphs of the data. Figures 20-25 show images of the specimens of each group after testing.

Analysis of variance (ANOVA) revealed statistically significant differences among the means of the three groups (p<0.001). Further statistical analysis with Tukey’s Post Hoc test revealed statistically significant difference between the means of group C and group A (p=.047); and between means of group C and group B (p < .001). No statistically significant difference was found between the means of groups A and B (p= .15). (Table 6)
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Table 2: Tensile strength values, means and standard deviations in MPa for specimens made from materials A-2000, A-2186, and A-103. (*) Represent the highest and lowest values for each material.

Figure 20: Box & whisker plot of tensile strength values of the three materials displaying range, median and first and third quartiles.
Figure 21: Bar graph representing mean tensile strength values of the three materials and displaying statistically significant differences.

3.2 Percent Elongation

Table 3 shows percent elongation test values of each specimen for each of the materials tested. Additionally, Table 3 displays the mean and standard deviation values of each material tested. For group A (A-2000), the percent elongation values ranged from 253.66% to 391.66% with a mean of 310.26% and a standard deviation of 37.49. For group B (A-2186), the percent elongation values ranged from 183.6% to 378% with a mean of 262.88% and a standard deviation of 66.5. For group C (A-103), the values ranged from 257.33% to 677.33% with a mean of 441.16% and a standard deviation of 123.40. Figure 19 shows a box and whisker plot of the data. Figure 20 shows bar graphs of the data. Figures 21-26 show images of the specimens of each group after testing.
Analysis of variance (ANOVA) revealed statistically significant differences among the means of the three groups (p<0.001). Further statistical analysis with Tukey’s Post Hoc test revealed statistically significant difference between the means of group C and group A (p< .01); and between the means of group C and group B (p < .001). No statistically significant difference was found between the means of groups A and B (p= .46). (Table 6)

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Table 3: Percent elongation values, means and standard deviations for specimens made from materials A-2000, A-2186, and A-103. (*) Represent the highest and lowest values for each material.
Figure 22: Box & whisker plot of percent elongation values of the three materials displaying range, median and first and third quartiles.

Figure 23: Bar graph representing mean percent elongation values of the three materials, and displaying statistically significant differences.
Figure 24: Group A (Material A-2000) specimens #1-5 after tensile strength and percent elongation testing.

Figure 25: Group A (Material A-2000) specimens #6-10 after tensile strength and percent elongation testing.
Figure 26: Group B (Material A-2186) specimens #1-5 after tensile strength and percent elongation testing.

Figure 27: Group B (Material A-2186) specimens #6-10 after tensile strength and percent elongation testing.
Figure 28: Group C (Material A-103) specimens #1-5 after tensile strength and percent elongation testing.

Figure 29: Group C (Material A-103) specimens #6-9 after tensile strength and percent elongation testing.
3.3 Tear Strength

Table 4 shows tear strength test values of each specimen for each of the materials tested. Additionally, Table 4 displays the mean and standard deviation values of each material tested. For group A (A-2000), the tear strength values ranged from 15.05MPa to 29.39MPa with a mean of 23.45MPa and a standard deviation of 4.4. For group B (A-2186), tear strength values ranged from 18.52MPa to 30.1MPa with a mean of 27.31MPa and a standard deviation of 3.99. For group C (A-103), the values ranged from 10.7MPa to 18.4MPa with a mean of 14.34MPa and a standard deviation of 3.16. Figure 27 shows a box and whisker plot of the data. Figure 28 shows bar graphs of the data. Figures 29-40 show images of the specimens of each group after testing.

Analysis of variance (ANOVA) revealed statistically significant differences among the means of the three groups (p<0.001). Further statistical analysis with Tukey’s Post Hoc test revealed statistically significant difference between the means of group C and group A (p< .001); and between group C and group B (p < .001). No statistically significant difference was found between groups A and B (p=.66). (Table 6)
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Table 4: Tear strength values, means and standard deviations in MPa for specimens made from materials A-2000, A-2186, and A-103. * Represent the highest and lowest values for each material.

![Simple Boxplot of Tear strength in MPa by Group](image)

Figure 30: Box & whisker plot of tear strength values of the three materials displaying range, median and first and third quartiles.
Figure 31: Bar graph representing mean tear strength values of the three materials and displaying statistically significant differences.

Figure 32: Group A (Material A-2000) specimens #1-5 after tear strength testing.
Figure 33: Group A (Material A-2000) specimens #6-10 after tear strength testing.

Figure 34: Group B (Material A-2186) specimens #1-5 after tear strength testing.
Figure 35: Group B (Material A-2186) specimens #6-10 after tear strength testing.

Figure 36: Group C (Material A-103) specimens #1-5 after tear strength testing.
3.4 Hardness

Table 7 shows the mean Shore-A hardness numbers of each specimen for each of the materials tested. For each specimen, five hardness readings were obtained and mean value calculated. Furthermore, Table 7 shows the overall means and standard deviation values of each material tested. For group A (A-2000), the Shore-A hardness numbers ranged from 28 to 29 with a mean of 28.48 and standard deviation of 0.32. For group B (A-2186), the hardness numbers ranged between 31.8 and 34 with a mean of 32.94 and a standard deviation of 0.73. For group C (A-103), the hardness numbers ranged from 25.4 to 28.2 with a mean of 26.88 and a standard deviation of 0.97. Figure 40 shows a box and whisker plot of the data. Figure 41 shows bar graphs of the data.
Analysis of variance (ANOVA) revealed statistically significant differences among the means of the three groups (p<0.001). Further statistical analysis with Tukey’s Post Hoc test revealed statistically significant differences between the means of group A and group C (p < .001); and between the means of group B and group C (p < .001); as well as between the means of groups A and B (p < .001). (Table 6)

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<tr>
<th>Specimen #1</th>
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<th>Group B: A-2186</th>
<th>Group C: A-103</th>
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<td>28*</td>
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<td>27</td>
</tr>
<tr>
<td>Specimen #3</td>
<td>28.6</td>
<td>31.8*</td>
<td>27.8</td>
</tr>
<tr>
<td>Specimen #4</td>
<td>28*</td>
<td>33.2</td>
<td>27.8</td>
</tr>
<tr>
<td>Specimen #5</td>
<td>28.4</td>
<td>34*</td>
<td>28.2*</td>
</tr>
<tr>
<td>Specimen #6</td>
<td>29*</td>
<td>34*</td>
<td>26.8</td>
</tr>
<tr>
<td>Specimen #7</td>
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<td>Specimen #8</td>
<td>28.6</td>
<td>32.4</td>
<td>25.4*</td>
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<td>Specimen #9</td>
<td>28.6</td>
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<td>25.4*</td>
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<tr>
<td>Mean</td>
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<td>32.94</td>
<td>26.88</td>
</tr>
<tr>
<td>S.D.</td>
<td>0.32</td>
<td>0.73</td>
<td>0.97</td>
</tr>
</tbody>
</table>

Table 5: Hardness values, means and standard deviations for specimens made from materials A-2000, A-2186, and A-103. * Represent the highest and lowest values for each material.
Figure 38: Box & whisker plot of Shore-A Hardness numbers of the three materials displaying range, median, outliers and first and third quartiles.

Figure 39: Bar graphs representing mean Shore-A Hardness numbers of the three materials and displaying statistically significant differences.
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Group</th>
<th>Mean</th>
<th>SD</th>
<th>One-way ANOVA results &amp; Tukey’s HSD post-hoc tests</th>
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<tr>
<td><strong>Tensile strength in MPa</strong></td>
<td>Group A: A-2000</td>
<td>2.01</td>
<td>0.27</td>
<td>$F(2,27) = 9.91, p = .001$</td>
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<td></td>
<td>Group B: A-2186</td>
<td>2.34</td>
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<td></td>
<td>Group C: A-103</td>
<td>1.57</td>
<td>0.39</td>
<td>A vs B $p = .15$, A vs C $p = .047$, B vs C $p &lt; .001$</td>
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<tr>
<td><strong>Percent elongation</strong></td>
<td>Group A: A-2000</td>
<td>310.26</td>
<td>39.52</td>
<td>$F(2,27) = 10.93, p &lt; .001$</td>
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<tr>
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<td>Group B: A-2186</td>
<td>262.94</td>
<td>70.15</td>
<td>Tukey HSD test:</td>
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<td>Group C: A-103</td>
<td>441.16</td>
<td>130.08</td>
<td>A vs B $p = .46$, A vs C $p &lt; .01$, B vs C $p &lt; .001$</td>
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<tr>
<td><strong>Tear strength in MPa</strong></td>
<td>Group A: A-2000</td>
<td>23.54</td>
<td>4.63</td>
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<td>25.06</td>
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<td></td>
<td>Group C: A-103</td>
<td>14.34</td>
<td>3.33</td>
<td>A vs B $p = .66$, A vs C $p &lt; .001$, B vs C $p &lt; .001$</td>
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<tr>
<td><strong>Shore A Hardness</strong></td>
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<td>0.32</td>
<td>$F(2,27) = 188.64, p &lt; .001$</td>
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<tr>
<td></td>
<td>Group B: A-2186</td>
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<td>0.73</td>
<td>Tukey HSD test:</td>
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<tr>
<td></td>
<td>Group C: A-103</td>
<td>26.88</td>
<td>0.97</td>
<td>A vs B $p &lt; .001$, A vs C $p &lt; .001$, B vs C $p &lt; .001$</td>
</tr>
</tbody>
</table>

Table 6: Summary of statistical analysis
Chapter 4: Discussion

Three room-temperature vulcanizing (RTV) silicone elastomers were selected for testing based on the results of a survey conducted by Montgomery & Kiat-Amnuay. The authors conducted a survey among 260 members of the American Anaplastology Association and the American Academy of Maxillofacial Prosthetics (AAMP) to identify the most commonly used silicone elastomers used for maxillofacial prosthetics. From a total of 43 respondents, the authors determined that RTV-type silicones developed by Factor II (Lakeside, Arizona) were preferred; and the most commonly used material was A-2186 (Factor II). The top four most commonly used silicones were: A-2186, A-2186F, A-2000 (Factor II) and MDX4-4210 with catalyst A-103 (Dow Corning Corp.; Midland, Michigan).²⁷

In an effort to provide clinically relevant information, this survey was the basis for the materials selected in this study. For this reason, RTV silicones A-2186 and A-2000 manufactured by Factor II were included in this study. The material A-2186F (Factor II) was excluded from this study for the reason that its formulation is similar to A-2186 as it was developed as a faster polymerizing version of A-2186 with higher platinum content. Finally, the material A-103 (Factor II) was selected as an alternative to MDX4-4210 (Dow Corning Corp., Midland, Michigan). Both materials A-103 and MDX4-4210 exhibit identical formulations; the elastomer components of these materials both consist of a dimethylsiloxane polymer, a reinforcing silica and platinum catalyst. In addition, the curing agents for both materials are also alike with both consisting of a dimethylsiloxane polymer, an inhibitor and a siloxane cross-
linker. As a result of the indistinguishable formulation of these two materials, as well as the fact that MDX4-4210 was unobtainable, A-103 was selected as the third material to be tested.

According to Han et al., the addition of 10% volume of opacifier to silicones was found to maintain color stability.\textsuperscript{15} Based on this finding, a comparison of the effect of two opacifiers and one UV absorber on the mechanical properties of pigmented silicones was conducted by Nguyen et al. The authors reported that both opacifiers, one of which is TW, in addition to the UV absorber were found to adversely affect the mechanical properties of pigmented silicones. The authors reported that of the three materials tested, TW was found to best preserve the mechanical properties of pigmented silicones.\textsuperscript{2} In addition, functional intrinsic skin color (Factor II, Lakeside, Arizona) was selected to provide colorization of the silicone materials. The survey conducted by Montgomery & Kiat-Amnuay evaluated the most commonly used pigments used as intrinsic opacifiers in the fabrication of MFPs. The authors reported that intrinsic pigments were more commonly used when compared with oil pigments and dry earth pigments.\textsuperscript{27} Furthermore, the assessment of the mechanical properties of pigmented silicones as opposed to evaluating the materials in the absence of colorization provided more clinically applicable results. For these reasons, the present study examined the mechanical properties of pigmented silicones with the addition of 10% volume TW.

The importance of developing a silicone elastomer that can be used for the fabrication of MFPs that fulfills the criteria of the ideal material cannot be denied. The dramatic effects of structurally durable and highly esthetic MFP can have over a patient’s life should not be minimized. Patients with head and neck defects may experience an array of negative emotions
including shame, anxiety, reduced self-esteem and inferiority that in turn have adverse effect on their psychological well being if left unrehabilitated. Ideally, materials employed for the fabrication of maxillofacial prostheses should possess high tear strength, tensile strength and percent elongation at break as well as hardness similar to that of the tissue being replaced. Lewis & Castleberry suggested desirable values for mechanical properties of silicone elastomers used for the fabrication of MFPs. The authors suggested tear strength should fall within a range of 30 to 100 ppi, tensile strength ranging between 7 to 14 MPa, percent elongation of 400% to 800% and Shore-A hardness number between 25-35.

Tensile strength provides an indication of the materials overall durability and resistance to rupture, while percent elongation demonstrates the materials flexibility. Flexibility is an important property for MFPs as it suggests how well the prosthesis will be able to accommodate dynamic facial movements. Hardness numbers are significant, as they should mimic the hardness of the natural tissues to be restored. It is also important to consider the site of the tissue that is being replaced as the head and neck region exhibits varying degrees of hardness. Finally, adequate tear strength is paramount in fabricating prosthesis to ensure the thin prosthesis margins are able to resist tearing. This property also relates to the overall serviceability of the prosthesis, since one of the most common indications for replacement of an MFP is due to torn margins as a result of repeated placement and removal.

The results of this study indicated that A-2186 exhibited the greatest tensile strength, while A-103 demonstrated the least. However, all the tensile strength values reported in this study were below 3 MPa, which suggests that none of the materials exhibit the “ideal” tensile
strength. Nevertheless, it is essential to appreciate that it is unlikely that any one material would possess all the ideal characteristics for the fabrication of an MFP. Similarly, tear strength results exhibited the lowest values for A-103 while A-2186 exhibited superior values when compared with A-2000. Percent elongation values ranged from 262.88% to 310.26%; again all below the suggested ideals outlined by Lewis et al. A-103 exhibited the greatest percent elongation while A-2000 represented the lowest value. Lastly, the results demonstrated Shore-A hardness numbers all within the range of 25-35, with A-2186 as the hardest material, while A-103 was the softest. It has been suggested that the viscosity of the material may illustrate a relationship with the filler content. Silicone elastomers with superior strength qualities could be attributed to higher filler content or higher molecular weight of the dimethylsiloxane polymer, which in turn affects the materials viscosity. During manipulation of the silicones for specimen fabrication for this study, it was recognized that materials A-2000 and A-2186 were considerably more viscous when compared to A-103. Additionally, the lower tensile and tear strength values for A-103 are suggestive of a low cross-link density. The superior percent elongation exhibited by A-103 may further confirm this hypothesis, since materials with a low cross-link density exhibit greater elasticity while those with a high cross-link density are less elastic.

Aziz and colleagues evaluated the properties of five commonly used maxillofacial silicone materials, one of which was A-2186. The authors reported mean tear strength of 17.63 (N/mm²), mean tensile strength of 4.23 (N/mm²), percent elongation of 650.8%, and a hardness of 16.62 in international rubber hardness degrees (IRHD). It is significant to note that this study utilized different testing protocols for tensile strength, percent elongation and hardness testing. In addition, hardness values in this article were reported in IRHD. When comparing hardness
numbers reported in IRHD with Shore-A, it is critical to appreciate that testing procedures also differ with respect to the indentor geometry, the force applied and the time before a hardness reading is obtained. Tear strength testing was carried out according to ASTM D624 guidelines, the same protocol used in the present study. This study found mean tear strength of material A-2186 to be 27.31MPa, considerably higher than what the authors reported. Although the same protocol was used, Aziz and colleagues employed a crosshead speed of 20mm/min, which could explain the discrepancy between the values reported. Respectively, comparisons between the results of these studies are not valid.¹⁰

Conversely, a study conducted by Lai et al., reported similar findings for pigmented A-2186 silicone elastomer when compared to the results of our study. All the outcomes tested yielded similar results with the exception of tear strength. However, the tear strength testing in their study utilized a trouser shaped specimen with a thickness of 1mm, as opposed to the 3mm trouser-shaped specimens that were fabricated for the present study. In addition, a reduced crosshead speed of 10in/min was applied. Both of these variations in the test method could explain the disparity observed in tear strength results.⁹

The results of this study showed mean tensile strength values for A-2000 of 2.01MPa. Cevik & Eraslan, who evaluated A-2000 with the incorporation of TiO² nanoparticles and reported a mean tensile strength of 2.23MPa, reported a similar result. In contrast, the values they reported for Shore-A hardness were higher: 38.5, while percent elongation and tear strength values were lower than those reported in the present study, 178.67% and 17.17MPa, respectively. One explanation for this difference may be the fact that the authors did not provide colorization
of the specimens. Nguyen et al., evaluated the effect of pigments on MDX4-4210 and reported that the addition of pigments did not have a statistically significant effect on the Shore-A hardness, tear strength or percent elongation of silicone specimens. Paradoxically, the authors did find colorization of silicones had a significant effect on tensile strength. Conversely, a dynamic mechanical analysis evaluating the effects of intrinsic pigments on A-2000 reported a significant influence on the mechanical properties of the silicone elastomer. In addition, a publication by Yu & Craig assessed the effect of pigments on the mechanical properties of silicones. Although this study examined a different RTV silicone elastomer, Silastic 44210 (Dow Corning Corp., Midland, Michigan), the authors reported the incorporation of pigments influenced the mechanical properties of the silicone. The contrasting findings among the available literature regarding the effect of opacifiers and pigments on mechanical properties of silicones suggests that further research is required to provide clarity on this relationship.

Nguyen et al reported pigmented MDX4-4210 specimens with the addition of 10% volume TW to exhibit Shore-A hardness of 22, tensile strength of 1.6MPa, percent elongation of 539% and tear strength of 11.8kN/m. Although this was an evaluation of MDX4-4210, these findings are similar to the results exhibited by A-103 in the current study, with the exception of percent elongation. As this is the first study to analyze and report the mechanical properties of A-103, no direct comparisons can be made with the available literature. However, the comparison with the study by Nguyen et al., which followed the same protocol and utilized the same materials with the exception of the type of pigment used, supports the theory that A-103 and MDX4-4210 are analogous materials.
A study by Haug et al., compared the physical properties of six silicone elastomers in the absence of pigments and opacifiers. Two of the silicones evaluated in this article were A-2186 and MDX4-4210. Despite the absence of pigments and opacifiers, the authors reported similar results for the mechanical properties of A-2186 when compared with the present study. Notably, hardness was significantly lower than the number reported in the current study. The data reported for MDX4-4210 was also comparable to our findings for A-103, with the exception of tensile strength. In addition, when comparing the studies findings of A-2186 and MDX4-4210; a similar relationship was reported as was found in our study. A-2186 exhibited greater tensile strength, percent elongation, and tear strength. However, MDX4-4210 exhibited a higher hardness number. The present study found that A-2186 exhibited higher tensile strength, tear strength, and hardness but a lower percent elongation when compared to A-103.

The manufacturer, Factor II, recommends exposing the silicone mixture to a vacuum to reduce the entrapment of air within the polymerized material, however, this is not described as a mandatory step in the handling of the material. In the present study, the absence (lack of availability) of a vacuum machine and the use of manual mixing may have been a limitation as this led to incorporation of small voids in some specimens that were visually undetectable and only observed after testing. This occurred most commonly with material A-103 which was the least viscous of the three materials and exhibited the greatest predisposition to air bubble formation during mixing and manipulation of the silicone material.

Another possible limitation of this study was the inability to obtain material MDX4-4210. Despite the identical formulations of materials MDX4-4210 and A-103, a different manufacturer
produces each material. Although both manufacturers do supply a list of the material constituents, the exact proportions of the contents are not included, hence it cannot be confirmed that the two materials are truly one in the same. It is unlikely that these, if any, minor variations would have a profound impact on the mechanical properties, however, this should still be taken into consideration.

In the present study, stone and resin molds were utilized for the fabrication of the silicone specimens. Although custom-aluminum molds were available for the fabrication of the stone and resin molds, metallic molds are seldom used for the fabrication of test specimens or MFPs, as they are more expensive and complicated to construct. Stone molds are often favored owing to their ease of fabrication and reduced cost. Lai & Hodges compared the physical properties of A-2186 when cured in steel molds with those fabricated in stone molds. The authors assessed tensile strength, tear strength, percent elongation, and hardness and reported statistically significant differences for all outcomes tested except tear strength. The vulcanization of platinum-based silicones, such as A-2186 and A-103, occurs as result of crosslinking reaction whereby a silyl hydride group is added to a vinyl group promoted by a platinum catalyst. Any chemical compounds that interfere in this reaction could inhibit the complete curing of the silicone. The authors hypothesized that trace amounts of sodium phosphate on the stone molds’ surface after application of a separating medium may be responsible for this finding. No reports on the effect of aluminum molds on the physical properties of silicone materials are currently available in the literature. Again, the discrepancy this may have caused in the data obtained is likely to be minor, however, this distinction is still noteworthy and may suggest that metallic molds should be utilized when fabricating MFPs as opposed to stone ones.29
The available literature is unable to infer which silicone material is superior, nor does it provide recommendations for which materials may be suitable for specific applications. For instance, human skin varies in elasticity among different individuals as well as among different maxillofacial regions. Site-specific recommendations of materials with respect to hardness values could be of value for the practical application of silicone materials for MFPs. In the available literature that investigated these materials in the absence of pigments, which are incorporated to achieve a satisfactory esthetic appearance, the resulting data does not provide a true clinical perspective of the material properties since the addition of pigments has been shown to have an effect on the properties. Further research examining the mechanical properties of the various commercially-available pigmented RTV silicone materials when subject to aging should be conducted to determine which material demonstrates superior mechanical properties for long-term clinical use.

In addition, research focusing on silicone alternatives or advancements in silicone materials could be of value in identifying a material with more optimal properties for this application. Silicone block copolymers, which have higher tear strength when compared with cross-linked polymers have been suggested for the fabrication of MFPs. Polyphosphazenes resilient denture liners have also been suggested as a potential material to be used for MFPs. However, the use of new materials for this application requires long-term evidence that is pertinent to their clinical use.
Chapter 5: Conclusions

The objective of this study was to evaluate and compare the mechanical properties of various commercially available pigmented polydimethylsiloxane elastomers (silicone elastomers) utilized in the fabrication of maxillofacial prostheses. In addition, this study aimed to provide the first report of the mechanical properties of silicone elastomer material A-103 (Factor II Inc.; Lakeside, Arizona).

Within the limitations of this study, statistically significant differences were found between the three materials for each of the four outcomes tested. Statistical analysis with Tukey’s post-hoc tests showed significantly lower tensile strengths for material A-103 (group C) when compared to both A-2000 (group A) and A-2186 (group B) materials. Similar findings were revealed with regard to tear strength; wherein significantly lower tear strength values were found for material A-103 when compared to both A-2000 and A-2186. Conversely, material A-103 exhibited statistically significant higher percent elongation when compared to materials A-2000 and A-2186. No statistically significant differences were found between materials A-2000 and A-2186 with respect to tensile strength, percent elongation or tear strength. All three groups were found to be significantly different from each other in terms of Shore-A hardness. Material A-103 exhibited the lowest hardness values, whereas material A-2186 was found to have the greatest hardness.

The available literature poses difficulties in providing conclusions regarding the optimum maxillofacial material. The available evidence is limited owing to the challenges in comparing
the results of the literature coupled with limited studies focussing on the mechanical properties of these materials. Further research should focus on investigating the commonly used commercially available materials according to standard protocols. In addition a comprehensive investigation of the effects of weathering on these materials with respect to both mechanical and physical properties would be of value for clinical application.
Bibliography


Appendix

Raw Data of Mechanical Testing Conducted

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Group</th>
<th>Group</th>
<th>Tensile strength in MPa</th>
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<th>Tear strength in MPa</th>
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