EFFECTS OF MALAYSIAN OUTDOOR WEATHER ON PHYSICAL AND MECHANICAL PROPERTIES OF PIGMENTED MAXILLOFACIAL PROSTHETIC SILICONE ELASTOMER

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by

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3D	Three dimensional
A.D	Anno Domini
AFM	atomic force microscope
ANOVA	Analysis of Variance
AZ	Arizona
C	Celsius
CFR	Code of Federal Regulations
Co.	Company
Corp.	Corporation
cps	Centipoise
F	Fahrenheit
FDA	Food and Drug Administration
gm	Gram
H	Hour
HTV	Heat Temperature Vulcanization
IBM	International Business Machines
Inc.	Incorporation
ISO	International Standards Organization
Kg	Kilogram
km/h	kilometers per hour
LP	Light protecting
Ltd.	Limited
LVDT	linear variable differential transformer
µm	micrometer
Min.	Minute

Mm	millimeter
mm/min	Millimeter per minute
mm/s	Millimeter per second
MPa	Megapascal
no.	Number
NY	New York
PMMA	Polymethyl methacrylate
ppi	Pounds per inch
psi	Pounds per square inch
PVC	Polyvinyl chloride
Ra	Roughness average
RTV	Room Temperature Vulcanization
SEM	Scanning electron microscope
SPSS	Statistical Package for the Social Sciences
SW	Silicone intrinsic white
Tech.	Technology
Thixo	Thixotropic agent
TiO_2	Titanium dioxide
TW	Titanium white
UK	United Kingdom
USA	United States of America
USP	The United States Pharmacopeia
UTM	Universal Testing Machine
UV	Ultraviolet
w/w	Weight by weight

KESAN CUACA LUARAN MALAYSIA KE ATAS BAHAN-BAHAN FIZIKAL DAN MEKANIKAL ELASTOMER SILIKON PROSTETIK MAKSILOFASIAL BERPIGMEN

ABSTRAK

Elastomer silikon digunakan dalam pemasangan prostesis maksilofasial untuk membaikpulih kerosakan kraniofasial. Tambahan lagi, keadaan cuaca tempatan boleh mempengaruhi purata servis jangka hayat sesebuah elastomer silikon. Pemerhatian semasa amalan klinikal menunjukkan cuaca panas dan lembap mempengaruhi daya tahan bahan silikon dari segi kerosakan permukaan dan koyakan, yang mengakibatkan keperluan penukaran prostesis dengan lebih kerap. Oleh sebab itu, kajian ini bertujuan untuk menilai kekasaran permukaaan, kekuatan tensil, dan peratusan kepanjangan dalam elastomer silikon yang berlainan yang mendapat pendedahan cuaca luar di persekitaran Malaysia. Suatu kajian eksperimental in-vitro telah dilakukan ke atas 120 jenis spesimen berbentuk dumbel (tanpa pendedahan cuaca=60, dengan pendedahan kepada cuaca=60) yang diperbuat pada suhu bilik vulkanik (A-2000, A-2006) (Factor II, Inc., AZ, USA). Selama 6 bulan, spesimen pencuacaan yang terdedah kepada cuaca luar diletak pada rak pendedahan khas, manakala spesimen tanpa pencuacaan disimpan dalam penyahlembap pada suhu kelembapan relatif iaitu 25°C ± 1°C dan 50 ± 5%. Selepas itu, kekasaran permukaan dinilai menggunakan profilometer (Surfcom Flex, Tokyo, Japan) sementara kekuatan tensil dan peratusan kepanjangan ditentukan menggunakan *Universal Testing Machine (*Shimadzu, Jepun). Ujian normaliti dilakukan dan didapati taburan data adalah normal. Ujian t bebas dilakukan untuk membandingkan purata bahan-bahan yang

diuji di antara kumpulan yang tidak terdedah kepada pencuacaan dan yang terdedah kepada pencuacaan dalam setiap kumpulan silikon berpigmen, dan spesimen dengan pencuacaan dalam kalangan kumpulan silikon berbeza. Selepas terdedah kepada pencuacaan luar di Universiti Sains Malaysia, Kota Bharu, Malaysia, untuk A 2000 DAN a-2006, tidak terdapat perbezaan signifikan pada kekasaran permukaan di antara sampel yang tidak mengalami pencuacaan dan yang mengalami pencuacaan (P >0.5). Dalam perbandingan di antara kumpulan-kumpulan silikon, juga tiada perbezaan signifikan yang diperhatikan(P >0.5). Untuk kekuatan tensil, terdapat perbezaan signifikan yang dijumpai di antara kedua-dua sampel A- 2000 and A - 2006, (P<0.5) yang tidak mengalami pencuacaan dan yang mengalami pencuacaan. Dalam perbandingan di antara kumpulan silikon yang sama, terdapat perbezaan signifikan yang diperhatikan (P<.001). Kesan ke atas keadaan yang tidak mengalami pencuacaan dan yang mengalami pencuacaan menunjukkan perbezaan signifikan dalam peratusan kepanjangan elastomer silikon A-2000 (P<.0.049). Tambahan lagi, sewaktu membuat perbandingan di antara kumpulan silikon, terdapat perbezaan signifikan yang diperhatikan (P<.001). A-2000 menunjukkan kekasaran permukaan yang lebih baik daripada A-2006 sebelum dan selepas pendedahan cuaca luar berbanding dengan kumpulan silikon. A-2000 mempunyai kualiti yang lebih baik dari segi kekuatan tensil dalam kedua-dua kumpulan pencuacaan dan dalam kumpulan silikon. Dalam peratusan kepanjangan, A-2006 menunjukkan nilai yang lebih baik dalam kedua-dua pencuacaan dan dalam kumpulan silikon. Secara kesimpulan, pakar klinikal perlu membuat keputusan sama ada untuk menggunakan silikon A-2000 atau A-2006 untuk bahan yang lebih tinggi faktor mekanikal, untuk kestabilan yang lebih baik dalam suasana persekitaran Malaysia berdasarkan kes dan situasi mereka.

EFFECTS OF MALAYSIAN OUTDOOR WEATHER ON PHYSICAL AND MECHANICAL PROPERTIES OF PIGMENTED MAXILLOFACIAL PROSTHETIC SILICONE ELASTOMER

ABSTRACT

Silicone elastomers are extensively used in maxillofacial prosthesis fabrication to rehabilitate craniofacial defects. The exposure to local weather conditions can influence the average service life of a silicone elastomer. It is observed in clinical practice that hot and humid weather further affects the durability of silicone material in terms of surface degradation and tear, thus requiring regular prosthesis replacement. Therefore, this study aimed to evaluate the surface roughness, tensile strength, and percentage elongation of different pigmented silicone elastomers subjected to outdoor weathering in the Malaysian environment. An in-vitro experimental study was performed on 120 type-II dumbbell-shaped specimens (non-weathered=60, weathered=60) made from three room temperature vulcanized (A-2000, A-2006) (Factor II, Inc., AZ, USA) materials. For 6 months, weathered specimens were subjected to outdoor weathering in customized exposure rack, while the non-weathered specimens were kept in a dehumidifier at 25°C ± 1°C and 50 ± 5% relative humidity. Afterward, surface roughness was measured using a profilometer (Surfcom Flex, Tokyo, Japan) whilst tensile strength and percentage elongation was determined using Universal Testing Machine (Shimadzu, Japan). Independent t-test was performed to compare the means of the tested properties between non-weathered and weathered specimens within each pigmented silicone group, and weathered specimens among the different silicone groups respectively. After being subjected to outdoor weathering at Universiti Sains Malaysia, Kota Bharu, Malaysia, for A 2000 and A -2006, there was no significant difference in surface roughness between non-weathered and weathered samples (P>0.5). Comparison within the silicon groups found that there was no significant difference observed (P >0.5). For tensile strength, there was a significant difference found between non-weathered and weathered samples in both A- 2000 and A -2006, (P<0.5). Comparison made within the silicone groups also revealed significant difference (P<.001). The effect of non-weathered and weathered conditions showed significant changes in percentage elongation of A-2000 silicon elastomer (P<.0.049). Comparison made within the silicon groups, there was a significant difference observed (P<.001). A-2000 showed better surface roughness and tensile strength than that of A-2006 before and after outdoor weathering. In contrast, for percentage elongation, A-2006 shows better value than A-2000 both in weathered condition and within the silicone group. In conclusion, the choice of silicone namely A-2000 and A- 2006 for maxillofacial prosthetics construction will depend on the clinical requirement based on mechanical properties and environmental factors.

CHAPTER 1

INTRODUCTION

1.1 Background of study

Every human has the divine right to look human. This is a quote given by a psychiatrist Dr. William J. Mayo concerning the patient with facial deformities. Taking into consideration the importance of this philosophy, a maxillofacial prosthodontist should work to ensure that the individual concerned returns to society (Rajni, 2006).

The method of repairing a craniofacial defect anatomically, functionally, and esthetically is called maxillofacial prosthetic rehabilitation. Maxillofacial prosthetic recovery plays a vital role in treating patients who have undergone severe surgery following tumor resections, trauma or congenital defects. Different kinds of deformities can result from congenital or acquired defects such as trauma, malignancy and infection. It is a common fact that a large facial defect is created as a result of surgical management of malignancy. These defects have a vast adverse influence in patient‘s quality of life such as physical asymmetry, psychological distress, and cosmetic disfigurement and often in combination of all these factors. Silicone materials have replaced conventional acrylic resins and have become the materials of choice for the fabrication of facial prostheses. Nevertheless, these prostheses must be periodically replaced owing to their color loss and deterioration of physical properties. Prosthetic rehabilitation with silicone prosthesis for such defects could reproduce the missing structure with slandered appearance and developed function (Beumer *et al.*, 1996).

In modern practice, medical grade silicone elastomer materials were more commonly used for craniofacial defect rehabilitation (Montgomery and Kiat- Amnuay, 2010). Silicone elastomer possesses excellent biocompatibility, clinical inertness and acceptable esthetics which makes it the material of choice for maxillofacial rehabilitation. However, it is difficult to achieve success with silicone prosthesis if it is not long lasting in terms of color stability and mechanical properties (Mancuso *et al.*, 2009).

The change in color following weathering of silicone elastomers has been analyzed and documented. Such investigators have reported that the key factors leading to the elastomer color change are exposure to ultraviolet radiation, changes in temperature, humidity, adhesive use, cosmetics, cleansing agents and exposure to body fluids (Sethi *et al.*, 2015). The stability and durability of pigmentation and mechanical properties depends on several factors. These factors include selection of the proper material, ability of a material to retain color, material properties, proper mixing formula and local environment namely weather. Local environment that is weather has a great influence on silicone prosthesis when patients using these prosthesis are often exposed to outdoor and as such, the prosthesis gets exposed to the local environment. Sunlight exposure, amount of ultra-violet ray in sunlight, and humidity in the local weather can affect the prosthesis (Tran *et al.*, 2004). An ideal maxillofacial prosthetic material should have good color retention and physical properties and must withstand the local environmental factors thus achieving a satisfactory lifespan for prolonged use (Aziz *et al.*, 2003; Ariani *et al.*, 2013). In order to obtain the optimum success, it is very essential to know and understand which silicone materials have better physical properties and can retain color pigments for longer period. An ideal mixing formula is required in relation to local environment and weather effect for silicone prosthesis.

The facial prostheses made from silicone materials are vulnerable to degradation in a wide variety of environments and conditions, which limits the service life of the prostheses (White and Turnbull, 1994; Rosa *et al.*, 2005). The main environmental factors responsible for degradation of the materials are the amount and duration of sunlight, the average temperature, and the moisture level to which the prostheses are exposed. Other aspects of weathering include exposure to wind, dust, and pollutants. The effect of weathering varies considerably by geographic location, season and the amount of cloud cover at which the materials are exposed (Nguyen *et al.*, 2013). Comparison in the behavior of many different silicone materials in the making of silicone prostheses is essential in relation to our local weather conditions. Thus, information is needed on the long-term outdoor performance of silicone-based maxillofacial prostheses.

1.2 Problem statement

In addition to natural ageing and cleaning agents, environmental factors such as wind humidity, sunlight and UV light penetration also cause degradation of pigmentation and deterioration in the mechanical properties of the silicone elastomer. The aesthetics of a facial prosthesis could be compromised after some time as a result of a pigmentation loss and prosthesis body and edge deterioration of the prosthesis. Hence, the need for a replacement with a new prosthesis to restore the defect (Haug *et al.*, 1992; Mohite *et al.*, 1994; Haug *et al.*, 1999; Nguyen *et al.*, 2013).

One of the major challenges with different types of silicone elastomer is their ability to retain their properties as well as preserving the color stability when subjected to hot and humid outdoor weathering conditions. The mechanical strength of silicone elastomer exposed to different weathering situations should also be taken into consideration in case of long-term use. Different studies have suggested that the service life of a silicone elastomer to be on average of six months to eighteen months (Lemon *et al.*, 1995; Polyzois, 1999). It has also been observed that in environment with hot weather, high humidity and greater ultraviolet radiation, the lifespan of the physical properties and color stability of the prostheses is limited (Al-Harbi *et al.*, 2015). Clinically, it is seen that in South Asian and Southeast Asian environment, as it is hot, humid and more occurrence of ultraviolet radiation, the life span of physical properties as well as color retention stays limited. Our experience in the field of longevity of a maxillofacial prosthesis in this region, is not similar with those reported by studies done in the climates of Europe or North America.

Based on the contributing factors discussed, clinicians need to replace the existing old prosthesis with a new one frequently. Thus, it is very costly and becomes a burden to people with low socioeconomic status. Another challenge is limited number of materials available and less specialist in this particular field.

For this reason, it is important to understand the properties of the material and determine the appropriate technique or formula for mixing of silicone elastomer that gives an ideal outcome in Malaysia weather to reduce the prosthetic error.

1.3 Justification of the study

Various forms of silicon elastomers are currently on the market. Specific silicone elastomers have specific pigmentation properties and different mechanical properties. Silicone elastomer product includes multiple components and parts such as basis, catalyst, oil pigments, dry earth pigments and opacifiers. However, selection of proper material depends on the sustainability of a particular material regarding color retentive quality and physical strength in different weathering effects. Evolution of proper manipulation formula and mixing protocols for silicon components under local environment is also a prime consideration.

Therefore, there is a need to investigate which variety of silicone elastomer has better color retention characteristics and physical properties in outdoor weathering effect of the Malaysian environment. Besides these, it is necessary to create a proper mixing protocol of silicon elastomer for local weather of Malaysia.

Most of the studies in this field have been performed in the USA and Europe. The pattern of weather of North America or Europe is different with the Southeast Asia region. While most studies were done under artificial weathering or aging chamber, there were only a limited studies that investigated outdoor weathering (Eleni *et al.*, 2009; Eleni *et al.*, 2011; Hatamleh *et al.*, 2011; Al-Harbi *et al.*, 2015).

Nevertheless, no published data is available regarding the effect on physical properties and color retentive property of silicone elastomer in Malaysian outdoor weathering till now. There is also no data available for the ideal mixing formula of silicon components for this type of weathering effect.

So, this study aims to find the suitable pigmented silicone in terms of mechanical properties for use in Malaysia as well as in Southeast Asia. The result of this study will also help in the ideal mixing protocols with different colors under the local weathering effects. The ideal mixing protocol can be transferred to ideal formula which can be later on introduced to the silicone production company.

1.4 Clinical significance and expected outcome

The outcome obtained from this analysis will be useful for the maxillofacial prosthodontist in the procurement of suitable silicone varieties according to local requirements for the manufacture of facial prosthesis, which would offer more color consistency and physical strength at a lower cost of operation. The study findings would be helpful for the clinicians to make a long-lasting and mechanically stable maxillofacial prosthesis. Thus, the expenditure of re-making a prosthesis due to premature failure and deterioration, wasting of the material and time of fabrication will be greatly reduced.

1.5 Objectives

1.5.1 General objective

To evaluate possible changes of mechanical properties of different pigmented silicone elastomers subjected to outdoor weathering in Malaysia.

1.5.2 Specific objectives

1. To analyze and compare the surface roughness of pigmented silicone elastomers subjected to outdoor weathering of Malaysia.

2. To evaluate and compare the tensile strength of pigmented silicone elastomers subjected to outdoor weathering of Malaysia.

3. To evaluate and compare the percentage elongation of pigmented elastomers subjected outdoor weathering of Malaysia.

1.6 Research hypotheses

1.6.1 Research Question

1. Are there any significant differences in surface roughness on pigmented (red, blue and yellow intrinsic color with opacifier) of two facial silicones after exposure time in outdoor weathering?

2. Are there any significant differences in the tensile strength degradation on pigmented (red, blue and yellow intrinsic color with opacifier) of two different maxillofacial silicones after exposure time in outdoor weathering?

3. Are there any significant differences in the percentage elongation on pigmented (red, blue and yellow intrinsic color with opacifier) of two different maxillofacial silicones after exposure time in outdoor weathering?

1.6.2 Null hypotheses

The Null hypotheses that were tested are summarized as follows:

1. There are no significant differences in surface roughness on pigmented (red, blue and yellow intrinsic color with opacifier) of two facial silicones after exposure time in outdoor weathering.

2. There are no significant differences in the tensile strength degradation on pigmented (red, blue and yellow intrinsic color with opacifier) of two different maxillofacial silicones after exposure time in outdoor weathering.

3. There are no significant differences in the percentage elongation on pigmented (red, blue and yellow intrinsic color with opacifier) of two different maxillofacial silicones after exposure time in outdoor weathering.

CHAPTER 2

LITERATURE REVIEW

2.1 Historical background

Maxillofacial prosthetics is a type of prosthodontics that deal with the reconstruction and replacement of stomatognathic and craniofacial structures with prostheses that may or may not be replaced on a normal or elective basis (Glossary of Prosthodontic Terms).

Before 1600 AD

Within the ancient Chinese culture, archeologists find artificial eyes, nose, and ears made from waxes, clay, and wood. They find artificial eyes in the Egyptian mummies.

1600-1800 AD

Tycho Brahe replaced his missing nose with an artificial one made of silver and gold while Ambroise Paire (Beumer et al., 1996) is known to be the first to use obturators to close palatal perforations. In 1728, Pierre Fauchard used the artificial dentures to preserve the perforations in the palate**.**

1800-1900 AD

William Morton developed nasal prosthesis using porcelain enamel. In 1889 Claude Martin used ceramic material to make nasal prosthesis. In 1894, Tetamore made an artificial nose made of "very light plastic material" that was protected with bow spectacles (Beumer et al., 1996).

1900-1940 AD

Manufacturer of Upham's vulcanite rubber nasal and auricular prosthesis. In 1905 black vulcanite rubber was used by Ottofy, Baird, and Baker. In 1913, gelatin-glycerin compounds were introduced, while Kazanjian used celluloid paints during the same time to color vulcanized rubber facial prosthesis.

1940-1960 AD

Introduced acrylic resin in 1937. Tylman (Beumer III, Curtis et al., 1996) invented durable vinyl copolymer acrylic resin foundry using self-polymerizing acrylic resin coated with oil paints for nasal prosthesis manufacture. The latex was introduced by Clarke (1945).

1960-1970

Introduction of silicone elastomers. Banhart was the first person to use silicone rubber for facial prosthesis production and colouration. Regarding the inherent decoration of silicone facial prosthesis, Tashma used dried earth pigments scattered in colourless acrylic resin liquid material. At the same time, Schaaf used artist’s oil paint tattooed into the surface of silicone facial prostheses to simulate freckles, blood vessels, and general shading.

1970-1990 AD

Lontz used adapted polysiloxane elastomers whilst Turner was known for the use of isophorone polyurethane. Udagama and Drane demonstrated the use of Silastic Medical Adhesive Type A for facial prosthesis manufacturing (Udagama 1987).

1990-present

Advances in the area of polymer chemistry have renewed interest in designing new facial prosthesis products. New forms of acrylic resins for the prostheses are being studied by Antonucci and Stansbury for the use of polyphosphazenes. Copolymers to the silicone block are still being tested.

The origin of maxillofacial prosthetic substitution has not been recorded well by historians. Before 1600 A.D., evidence of oldest facial prostheses was recorded in the Egyptian empire and ancient Chinese culture. Archeologists also uncovered fake eyes, ears, and noses made from bamboo, waxes, plaster, and metals such as gold or silver, in Chinese mummies (Chalian, et al., 1972; Moore 1994; McKinstry 1995; Beumer et al., 1996; Curtis et al., 1996).

A renowned French surgeon Ambrose Paré (1510-1590) first identified the construction of nasal prosthesis. Silver and strings design of the prostheses was used to connect it to the neck. He also used paper-mâché or cloth to make another prothesis and maintained it through a metal band that went over or across the head of the patient. In addition, he identified the procedure used to create a prosthetic eye held by a metal band that stretches over the patient's ear. Because of his knowledge of the facial prosthesis production processes, he was considered the "Father of Facial Prosthetics." There is, however, insufficient evidence that the protheses mentioned had actually been put into effect (Chalian et al., 1972; Moore, 1994; McKinstry, 1995; Beumer et al., 1996).

Tycho Brahe (1546-1610) was a prominent astronomer who wore his entire life an artificial nasal prothesis made of gold to cover his nose's central portion (McKinstry, 1995; Beumer et al., 1996).

Pierre Fauchard, a pioneer of modern medical dentistry, has brought about many developments in maxillofacial prosthodontics. In addition to improving mastication with the provision of partial dentures, he was also responsible for the idea of restoring cosmetic appearance. For restoring palatal defects, he designed palatal obturators and used paper-mâché and silver to make facial prostheses. His research pioneered the development of facial protheses in maxillofacial intraoral prosthodontics (Chalian et al., 1972; Moore, 1994; McKinstry, 1995; Beumer et al., 1996). William Morton (1819-1868) used enamelled porcelain to make a nasal prosthesis that matched the patient's complexion. Kingsley (1880) described a combined nasal-palatal prosthesis procedure in which the obturator played an important part in the prothesis. Claude Martin (1889) identified manufacturing of a nasal prosthesis with ceramic material. Upham (1900) described the technique of using vulcanite rubber to construct nasal and auricular prostheses (Moore, 1994; Beumer et al., 1996).

Ottofy, Baird, and Baker (1905) stated that black vulcanized rubber could be used as a nasal prosthesis base. In maxillofacial prostheses, the strength and softness of human skin was recreated with the advent of gelatin-glycerin mixtures in 1913. Bercowitsch identified the technique of producing gelatin-glycerin facial prostheses and their coloring with water-soluble dyes (Beumer et al., 1996).. Nevertheless, their time to engage in clinical practice was very short. Therefore, the use of vulcanized rubber in maxillofacial prostheses was discontinued (McKinstry, 1995; Beumer et al., 1996).

In 1937, the dental profession became acquainted with acrylic resin. Soon after its launch, vulcanite rubber was replaced by acrylic resin in both extra and intraoral prostheses. Clinicians were attracted by the characteristics of its color ability, translucency and ease of production. Their use in facial prostheses was however, discouraged due to their rigidity (Moore, 1994; McKinstry, 1995; Beumer etal., 1996).

Numerous coloration methods were proposed between 1940 and 1960. Henry Bigelow used translucent photographic painting (Bigelow, 1943) to colour a facial prosthesis consisting of acrylic resin. Tylman introduced various intrinsic and extrinsic coloring stains, as well as the use of resilient vinyl copolymer acrylic resin to overcome the rigidity problem of acrylic resin facial prostheses (Tylman, 1943). Adolph Brown (Brown, 1942) first made use of Food and Drug Administration approved dyes for staining maxillofacial prostheses. Brasier achieved intrinsic coloration with stains of polymer acrylic resin and extrinsic coloring by oil color mixed with monomer acrylic resin (Brasier, 1954). Fonder proposed that auto polymerizing acrylic resin be stained using oil paints in nasal prosthesis fabrication (Fonder, 1955).

From 1960 to 1970, due to the advent of different kinds of elastomers, major improvements occurred in the development of maxillofacial prostheses. Barnhart (1960) first used silicone rubber to produce and paint facial prostheses by combining its base material with acrylic resin pigment stains (Barnhart, 1960). In 1967, by dispersing dry earth pigments into colorless powder of acrylic resin polymer, Tashma performed intrinsic coloration of maxillofacial silicone prostheses (Tashma, 1967). Ouelette mixed dry mineral earth pigments into a silicone base material thinned with xylene for extrinsic spray coloration of silicone prostheses. A thin layer of catalyst covered the final coloration of the prosthesis. The final coloring of the prosthesis was protected by a thin layer of catalyst sprayed on the prosthesis, and allowing it to polymerise (Ouellette, 1969).

Firtell and Bartlett have developed base shades using dry mineral earth pigments and silicone-based materials to create stock colours. Prostheses colored with nylon flocking, however, were believed to have more color consistency and a natural appearance than those stained with dry earth mineral pigments (Firtell and Bartlett, 1969).

From 1970 to 1990, the facial prosthesis was fabricated using various elastomer forms. Udagama and Drane used Silicone type A Silastic Medical Adhesive for the production of maxillofacial prostheses (Udagama and Drane, 1982). Udagama lined Type A Medical Adhesive with polyurethane film to solve the tearing problem at the thin margins (Udagama, 1987). Since 1990, new materials have been developed in the facial prosthetic field due to the advancements in polymer chemistry.

2.2 Materials used for facial prostheses

Facial prostheses were produced using different materials available, such as wood, wax, metals and polymers (Roberts, 1971; Chalian *et al.*, 1972; Moore, 1994; Beumer *et al.*, 1996). Numerous works has been carried out to reduce undesirable properties of these materials and thus to improve their characteristics. To achieve patient acceptance and clinical effectiveness, a maxillofacial prosthodontist must have a thorough understanding of the properties of the products used to correct particular defects (Roberts, 1971; Chalian *et al.*, 1972; Beder, 1974; Moore, 1994; McKinstry, 1995; Beumer *et al.*, 1996).

Material biocompatibility is one of the key factors to consider before producing maxillofacial prostheses (Beder, 1974; McKinstry, 1995; Beumer *et al.*, 1996).

The materials should be safe from any toxic or carcinogenic agents and not harmful to the tissues underlying it (Roberts, 1971). Resistance to stains is a definite advantage for cosmetics purpose with adequate seal at the margins. A skin-like feature resembling both appearance and tactile sensation, for instance, color, translucency, texture, and flexibility must be possessed by the finished prostheses to be used on movable tissue beds and also strong enough to avert any margin tearing when removed (Roberts, 1971; Beder, 1974; McKinstry, 1995;). Even with exposure to ultraviolet radiation, maxillofacial prostheses should have sufficient longevity of at least six months. The dimensional adaptability of the material to both intrinsic and extrinsic coloration should be stable with a service life of at least six months and should not be degraded if exposed to harmful environments or disinfectants.

The finished maxillofacial prostheses must be able to reproduce in a fine detail of the lost structures, so they should be unnoticeable in general. The prosthesis texture, form, color and translucency must replicate that of the missing adjacent tissues and structures (Bulbulian, 1973; Beder, 1974; Beumer *et al.*, 1996). The clinical success depends on the finished esthetics of the prostheses.

2.3 Goals for ideal maxillofacial prosthetic materials (Moore, 1994; Beumer *et al.*, 1996)

2.3.1 Physical properties

- Dimensionally stable
- High elongation
- High resistance

- High strength
- High tensile strength
- Low friction
- Low surface tension
- Available adjusted thermal conductivity
- No water resorption
- Translucent
- Flexibility similar to human tissue
- Resistance to environmental discoloration
- Long shelf life
- The usable life of 2 or more years

2.3.2 Processing characteristics

- Ease of intrinsic and extrinsic coloring with commercially available colorants
- Ease of mold fabrication
- Ease of processing
- Ease of handling
- Long operational time
- Short functional time

2.3.3 Patient factors

- Compatible with supporting tissues
- Non-toxic components
- No polymerisation by-products
- Odorless
- Inert to solvents and skin

- Ease of adherence to living tissue
- Resistance to the growth of microorganisms
- Hygienic
- Cleansable with disinfectants
- Cleansable without loss of detail at surface or margins
- Softness compatible with tissue and maintained during use

2.4 Available materials used in fabrication of facial prostheses

2.4.1 Acrylic resin (PMMA)

PMMA has been the material of choice in the past. It is highly durable, hygienic and easy to use. Satisfactory coloration may achieve individual skin tone. Mostly, it can be used for facial defects where slight movement of the tissue bed occurs when operating. The use of intrinsic as well as extrinsic coloring is essential. By applying chloroform or monomer as a solvent, extrinsic coloration with acrylic based paints is easily accomplished. The strength of this material is very high and can be easily added when required. Most adhesive systems are compatible with it. However, its rigidity is the main disadvantage which compromises function in highly movable tissue beds, thus causing irritation of tissue and ultimately prosthesis dislodgement. Patients face discomfort during winter due to its high temperature conductivity. Its glossiness disappears after a particular service time, and any effort in restoring it is unsuccessful.

2.4.2 Acrylic copolymer (Palamed)

Prostheses made from these materials have skin like covering and sponge-like centre due to its softness and elasticity. However, it is less acceptable due to low edge strength and longevity, easy deterioration when exposed to ultraviolet light, difficulty in processing and coloring. Due to dust collection and staining, the completed restoration normally becomes tacky.

2.4.3 Polyvinylchloride and copolymers

This polymer contains various desirable properties, such as flexibility, adaptability to extrinsic and intrinsic coloration and, if properly manipulated, the initial appearance is acceptable. However, they stain easily and are degraded by ultraviolet light, ozone, peroxide and tetraethyl lead. Their flexibility is hampered due to absorption of cosmetics, solvents, and sebaceous secretion. Skin irritation is caused by under-heat of the material and darkens due to overheating. One to six months is the suggested lifespan of their prostheses. However, it can be extended to 9 to 11 months by reducing the quantity of plasticiser. Nevertheless, polymer degradation, darkening of material due to ultraviolet exposure, and poor dimensional stability remain a serious problem.

2.4.4 Chlorinated polyethylene

This material has a resemblance to polyvinylchloride in its chemical composition and physical properties. Repeatable molding and coloration by oil soluble colorant are their unique advantages. Although, a disadvantage of this material is the use of metal molds.

2.4.5 Polyurethane elastomers

Epithane-3 is the only polyurethane elastomer available which is used in facial prostheses. It is possible to thin and feather the exposed tissue edges, as they can be made very elastic without compromising the edge strength. They can be colored with intrinsic and extrinsic colorants. They are suitable for movable tissue beds due to their flexibility. However, proper processing of these materials is difficult. Water contamination is a possibility, with gas bubbles and poor curing of the material occurring due to high moisture sensitivity. Proper dehydration of stone molds is necessary before processing. Surface oxidation and effects of ultraviolet exposure result in color instability, therefore reducing the clinical use of the prosthesis to approximately three months. Moreover, they are very poorly compatible with the available adhesive systems.

2.4.6 Silicone elastomers

Silicones are synthetic materials consisting of molecules with long chains. They are useful than other polymers owing to some of the physical and chemical properties that they can retain over a wide spectrum of environmental extremes. An alternating chain of silicon and oxygen atoms form the backbone of a silicone, while organic polymers contain carbon chains. The sides of the silicon atoms are often accompanied by groups which contain organic or carbon. The silicones can be developed by adjusting the lengths of the silicon-oxygen chain in the form of elastomers (rubbers), fluids or resins. Numerous products use silicone elastomers, namely lubricants, waxes and polishes, water repellents, electric insulation, and non- stick coatings.

Silicones can only be produced synthetically, which might infer that the body has never developed a defense mechanism against it. In addition to this lack of recognition by the body, silicone polymer's lack of chemical interaction with other material or chemical reactivity to oxidise readily makes it advantageous to health science profession.

One of the most commonly used silicone products for facial prostheses is dimethyl dichlorosiloxane that forms a polymer when it reacts with water. The viscosity of these translucent, watery, white fluid polymers is determined by the polymer chain length. Poly (dimethyl siloxane), normally stated as silicone, is comprised of these silicone fluid polymers. Silicones are also supplied in rubber forms that are mostly admixed with fillers to deliver additional strength. Additives are used for coloration but with difficulty. They have a poor tear and tensile strength. Transformation of the raw mass to a rubbery resin during processing is done by the addition of antioxidants and vulcanizing agents. The network of long-chain polymers provides the silicones with reasonable resistance against degradation from ultraviolet light exposure.

Silicones possess few extraordinary properties due to the special silicon-oxygen bonds. They provide better electrical insulation and more resistance to oxidation than organic polymers owing to the higher strength of their silicon-oxygen bond than organic polymer's carbon-carbon bond. Furthermore, silicones have low surface tension, low freezing points, and weak forces of attraction. These properties have rendered silicones ideal for a variety of specialised uses. They can retain their strength, elasticity and flexibility in temperatures ranging from 108ºF (42ºC) to higher than 570ºF (300ºC). Hence, silicones are considered ideal for various specialized uses.

2.4.6(a) Current companies and their commonly used prosthetic silicone products

Numerous extraoral silicone materials are currently used by maxillofacial prosthodontists and anaplastologists in facial prosthetic fabrication. According to a survey conducted by Montgomery and Kiat‑Amnuay in 2010, it was observed that the different respondents who were maxillofacial prosthodontists, anaplastologists, and dental technicians all over the world (Montgomery and Kiat-Amnuay, 2010) use various silicone elastomer materials.

This survey revealed the current companies that supply the most commonly used prosthetic silicone materials. They are listed as follows-

- Factor II, Incorporated, Lakeside, Arizona, USA (Factor II, Inc.)
- Dow Corning Corporation, Michigan, USA (Dow Corning Corp.)
- Technovent Limited, York Park, South Wales, UK (Technovent Ltd.)
- Nusil Technology, Carpinteria, California, USA (Nusil Tech.)
- Bredent GmbH & Co. KG, Senden, Germany (Bredent)

According to this particular survey and current websites of the above-mentioned silicone supplying companies, the most popular and currently used silicone elastomer materials in the fabrication of facial prostheses are summarised as Table 2.1 (Montgomery and Kiat‑Amnuay, 2010).

Table 2.1 Current companies supplying commonly used facial silicone materials

Companies supplying silicone products	Commonly used silicone materials
Factor II, Inc.	A-2186
	A-2186F
	A-2000
	A-2006
	A-103
	Cosmesil M-511
Dow Corning Corp.	MDX4-4210 with catalyst A-103
	MDX4-4210 with Silastic Medical Adhesive Silicone Type A
Technovent Ltd.	Techsil 25
	Z004
	M511
Nusil Tech.	MED-4095
	Med 4011
Bredent	Multsil Epithetik

2.5 Classification:

2.5.1 Classification according to vulcanization reaction

The binding of the individual polymer chain is known as the vulcanization reaction. Vulcanization is generally the process of cross-linking the bonds between the polymer chains. This process is usually based on the cross-linking or catalytic agents and can occur with or devoid of heat. Vulcanizing agents and fillers are added to the silicones used for medical purpose, but they are deprived of the different additives used in organic rubber compounding.

According to the vulcanization reaction, maxillofacial silicone can be classified into two groups (Beumer *et al.*, 1996; Chalian *et al.*, 1972; Moore, 1994).

- Heat temperature vulcanization (HTV)
- Room temperature vulcanization (RTV)

2.5.1(a) Heat Temperature Vulcanizing Silicone Elastomer (HTV silicones)

In general, HTV silicones possess better physical properties than RTV silicones. Opacity, intrinsic coloration difficulty, and high superficial surface hardness are the major disadvantages of this material. Moreover, a milling process under pressure is required. It needs a high curing temperature (30 min., 180°C), which makes the lengthy fabrication process of the crucial metal mold necessary. Although application of a stone mold within a denture flask is possible, the risk of material damage during deflasking is very high.

Thermal and color stability and biological inertness are some of the noteworthy advantages of these silicones. However, they lack adequate elasticity for functioning in movable tissue beds. However, the facial prostheses stiffness and hardness may be reduced by poly (dimethylsiloxane) oligomer. Additionally, nylon reinforcement may be required at the margins to overcome the low edge strength of the material. Lifeless appearance and their opaqueness are severe objections during fabrication of facial prostheses. The intrinsic colors need to be combined into the gum stock with the help of a grinding device due to their poor acceptance of extrinsic coloration.

2.5.1(b) Room Temperature Vulcanizing Silicone Elastomer (RTV Silicones)

RTV silicones are similar to HTV silicones in many ways. The primary difference being that RTV silicones are fully cured at room temperature without the assistance of any heat. They usually require approximately 72 hours under room temperature to be fully polymerised.

The RTV silicones are much easier to process than the heat cured forms. Molds made of dental stone can be used. The RTV silicones share some of the undesirable properties of the HTV silicones in that they have poor edge strength and are difficult to color.

2.5.2 Classification according to applications

Facial silicones are classified into four groups according to their applications (Beumer et al., 1996).

2.5.2(a) Implant Grade

Implant Grade is the first classification, which has a previous successful history of implantation in humans and animals. They are synthesized under pharmaceutically uncontaminated application. Extensive testing is done on these materials and permitted to use only when they have met or surpassed FDA Regulation 21 CFR 177.2600, ISO 10993 and USP class VI requirement.