SURFACE ROUGHNESS AND MECHANICAL PROPERTIES OF MAXILLOFACIAL PROSTHETIC SILICONE ELASTOMERS SUBJECTED TO OUTDOOR WEATHERING IN MALAYSIAN ENVIRONMENT

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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	micrometre
Min.	minute
mm	millimetre
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

KEKASARAN PERMUKAAN DAN SIFAT-SIFAT MEKANIKAL ELASTOMER SILIKON PROSTETIK YANG TERDEDAH KEPADA PERSEKITARAN CUACA LUARAN DI MALAYSIA

ABSTRAK

Kebanyakan elastomer silikon digunakan untuk membuat maksilofasial prostetik bagi membaikpulih kecacatan kraniofasial. Walau bagaimanapun, purata hayat perkhidmatan silikon elastomer dapat dipengaruhi oleh persekitaran tempatan iaitu cuaca. Di dalam amalan klinikal, didapati bahawa haba dan kelembapan akibat cuaca akan terus mempengaruhi jangka hayat bahan silikon dari segi degradasi permukaan dan koyak, menyebabkan penggantian prostesis kerap diperlukan. Oleh itu, matlamat kajian ini adalah untuk menilai kekasaran permukaan, kekuatan tegangan, dan peratusan pemanjangan elastomer silikon yang berbeza apabila terdedah kepada persekitaran cuaca luaran di Malaysia. Kajian eksperimen in-vitro dilakukan pada 120 spesimen berbentuk jenis-II dumbbell (kawalan = 15, kes = 15) yang dibuat daripada tiga ‘room temperature vulcanized’ (A-2000, A-2006, dan A-103) dan satu ‘heat temperature vulcanized’ (M-511) silikon (Factor II, Inc., AZ, Amerika Syarikat). Selama 6 bulan, spesimen-spesimen kes terdedah kepada cuaca luar dalam rak pendedahan yang telah diubasuaikan. Manakala spesimen-spesimen kawalan telah disimpan di dalam ‘dehumidifier’. Selepas itu, kekasaran permukaan diukur menggunakan profilometer (Surfcom Flex, Tokyo, Jepun); kekuatan tegangan dan pemanjangan peratusan telah ditentukan menggunakan Universal Testing Machine (Shimadzu, Jepun). Independant t-test dan one-way ANOVA dilakukan untuk membandingkan spesimen-spesimen yang diuji dalam setiap kumpulan silikon, dan di antara kumpulan silikon masing-masing. Setelah terdedah kepada persekitaran cuaca luaran di Universiti Sains Malaysia, Kelantan, Malaysia, hanya elastomer silikon A-2000

menunjukkan kelainan signifikan statistik dalam kekasaran permukaan di antara spesimen yang terdedah dan yang tidah terdedah kepada cuaca luaran ($p=0.005$). Bahan-bahan silicon (A-2000, A-2006, and M-511) menunjukkan kelainan signifikan statistik pada kekuatan tegangan dan nilai peratusan pemanjangan ($p<0.05$) selepas terdedah kepada persekitaran cuaca luaran berbanding dengan spesimen-spesimen yang tidak terdedah kepada cuaca luar. Dari segi kekuatan tegangan dan peratusan pemanjangan, semua elastomer telah sebaliknya terkesan dengan cuaca kecuali silicon A-103 yang mana telah mendemonstrasikan perubahan yang paling sedikit. A-2000, A-2006, dan M-511 menunjukkan nilai-nilai mekanikal yang lebih tinggi tetapi memaparkan perubahan yang lebih besar selepas terdedah kepada cuaca luar. Untuk cuaca Malaysia, A-103 boleh dicadangkan sebagai silikon yang sesuai berdasarkan perubahan yang kecil pada sifat sifat mekanikal setelah terdedah kepada cuaca luar. Walau bagaimanapun, sifat-sifat mekanikal yang lebih tinggi pada A-2000, A-2006, dan M-511 menjadikannya pilihan yang baik walaupun menunjukkan perubahan yang besar setelah terdedah kepada cuaca luar. Oleh itu, para klinisian perlu memutuskan sama ada untuk menggunakan silikon A-2000, A-2006, dan M-511 kerana sifat-sifat mekanikal yang lebih baik atau A-103 untuk daya ketahanan yang lebih baik bagi persekitaran Malaysia berdasarkan kes-kes mereka.

SURFACE ROUGHNESS AND MECHANICAL PROPERTIES OF MAXILLOFACIAL PROSTHETIC SILICONE ELASTOMERS SUBJECTED TO OUTDOOR WEATHERING IN MALAYSIAN ENVIRONMENT

ABSTRACT

Silicone elastomers are widely used for fabricating maxillofacial prostheses to rehabilitate craniofacial defect. However, the average service life of a silicone elastomer can be influenced by local weather condition. In clinical practice, it is noticed that hot and humid weathers further affects the lifespan of silicone material in terms of surface degradation and tear, thereby frequent replacement of the prostheses is required. So, the aim of this study was to evaluate the surface roughness, tensile strength, and percentage elongation of different 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=15, weathered=15) made from three room temperature vulcanized (A-2000, A-2006, and A-103) and one heat temperature vulcanized (M-511) silicone (Factor II, Inc., AZ, USA) materials. For 6 months, weathered specimens were subjected to outdoor weathering in customised exposure rack, while the non-weathered specimens were kept in a dehumidifier at 25°C ± 1°C and 50 ± 5% relative humidity. Afterwards, surface roughness was measured using a profilometer (Surfcom Flex, Tokyo, Japan); tensile strength and percentage elongation was determined using Universal Testing Machine (Shimadzu, Japan). Independent t-test and one-way ANOVA was performed to compare means of the tested properties between non-weathered and weathered specimens within each silicone group, and weathered specimens among the different silicone groups respectively. After subjected to outdoor weathering at Universiti Sains Malaysia, Kelantan, Malaysia, only A-2000 silicone elastomer showed

a statistically significant difference in surface roughness between non-weathered and weathered specimens ($p=0.005$). The silicone materials (A-2000, A-2006, and M-511) showed a statistically significant difference in tensile strength and percentage elongation values ($p<0.05$) after outdoor weathering compared to the non-weathered specimens. In terms of tensile strength and percentage elongation, all the elastomers were adversely affected by weathering, except for A-103 silicone which demonstrated the least changes. A-2000, A-2006, and M-511 showed higher values of mechanical properties but showed more changes after weathering. For Malaysian weather, A-103 can be suggested as a suitable silicone based on the least changes to its mechanical properties after weathering. However, the higher mechanical properties of A-2000, A-2006, and M-511 make them a viable option as well despite their significant changes after weathering. So, the clinicians need to decide whether to use A-2000, A-2006, and M-511 silicone for higher mechanical properties, or A-103 for better resistance in the Malaysian environment based on their cases.

CHAPTER 1

INTRODUCTION

1.1 Background of study:

Maxillofacial prosthetic rehabilitation is a process of anatomical, functional and aesthetical restoration of a craniofacial defect. Deformities can be as a result of congenital or acquired defects such as trauma, malignancy and infection. It is not uncommon 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. Prosthetic rehabilitation with silicone prosthesis for such defects could reproduce the missing structure with acceptable appearance and improved function (Beumer *et al.*, 1996).

Medical grade silicone elastomer materials had been commonly used for craniofacial defect rehabilitation (Montgomery and Kiat-Amnuay, 2010). Silicone elastomer has excellent biocompatibility, clinical inertness and acceptable esthetics which renders it the material of choice for maxillofacial rehabilitation. However, in terms of surface morphology, mechanical properties and color stability, there was still a clinical concern (Mancuso *et al.*, 2009).

The stability of surface configuration 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 namely weather has a great influence on silicone prosthesis when patients spend the time outdoor and the prosthesis exposed to the local environment. Sunlight exposure, amount of ultra-violet ray in sunlight, humidity in the local weather can affect the prosthesis (Tran *et al.*, 2004).

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 (Rosa *et al.*, 2005; White and Turnbull, 1994). The main environmental factors causing degradation of the materials are such as 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 to (Nguyen *et al.*, 2013). Thus, information is needed on the long-term outdoor performance of silicone-based maxillofacial prostheses.

An ideal maxillofacial prosthetic material should have stable surface morphology and mechanical properties, and not affected by the local environmental factors thus achieving a satisfactory lifespan for prolonged use (Ariani *et al.*, 2013; Aziz *et al.*, 2003a). Comparison in the behavior of many different silicone materials in the making of silicone prostheses is essential in relation to our local weather conditions.

1.2 Problem statement:

Environmental factors like heat, humidity, sunlight and UV light exposure in addition to natural aging and cleaning agents could cause 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 body and edge deterioration of the prosthesis, hence necessitating a replacement with a new prosthesis to restore the defect (Haug *et al.*, 1992; Haug *et al.*, 1999; Mohite *et al.*, 1994; Nguyen *et al.*, 2013).

One of the major challenges with different types of silicone elastomer is their ability to retain their properties when subjected to hot and humid outdoor weathering conditions. For long-term use, the mechanical strength of silicone elastomer exposed to different weathering situations should also be taken into consideration. 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, 1999a).

It has also been observed that in environments 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). To the best of our knowledge, experience with the longevity of a maxillofacial prosthesis in this region, it was not similar with those reported by studies done in European or North American climates.

It is therefore essential to understand the behavior of the material to allow clinicians treating Malaysian patient make the right decision on the choice of materials for the prosthesis.

1.3 Justification of the study:

There are varieties of silicone elastomer present in the market today. Different silicone elastomers have a different range of surface characteristics and mechanical properties. Silicone elastomer has different parts and components in the company packages such as base, catalyst, oil pigments, dry earth pigments and opacifier.

However, selection of proper material depends on the sustainability of a particular material regarding surface characters and physical strength in different weathering effects. Therefore, there is a need to investigate which variety of silicone elastomer has better surface characteristics and physical properties in outdoor weathering effect of the Malaysian environment.

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

Nevertheless to the best of our knowledge, there was no published data available regarding the effect on surface roughness and mechanical property of silicone elastomer in Malaysian outdoor weathering. So it was the aim of this study to investigate the surface roughness and mechanical properties of various maxillofacial silicone materials subjected to this environment.

1.4 Clinical significance and expected outcome:

The result obtained from this study would be beneficial to the maxillofacial prosthodontist in the selection of proper silicone varieties subjected to local environment for the fabrication of the facial prosthesis.

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

This study aim-

To investigate the surface roughness and mechanical properties of 3 room temperature vulcanized (RTV) and 1 heat temperature vulcanized (HTV) silicone elastomers subjected to outdoor weathering in the Malaysian environment.

1.5.2 Specific objectives

- To assess the change in surface roughness between non-weathered and weathered specimens within each silicone group, and weathered specimens of the different silicone elastomers subjected to outdoor weathering for 6 months.
- To evaluate the change in tensile strength between non-weathered and weathered specimens within each silicone group, and weathered specimens of the different silicone elastomers subjected to outdoor weathering for 6 months.

- To measure the change in percentage elongation between non-weathered and weathered specimens within each silicone group, and weathered specimens of the different silicone elastomers subjected to outdoor weathering for 6 months.

1.6 Research hypotheses:

1.6.1 Research Question

How is the outdoor weathering affecting surface roughness, tensile strength, and percentage elongation in four different maxillofacial silicones (A-2000, A-2006, A-103 and Cosmesil M-511)?

1.6.2 Null hypotheses

The Null hypotheses that were tested are summarised as follows:

- There are no significant differences in the surface roughness between non-weathered and weathered specimens within each silicone group, and weathered specimens of the four different maxillofacial silicones after exposure time in outdoor weathering.
- There are no significant differences in the tensile strength between non-weathered and weathered specimens within each silicone group, and weathered specimens of the four different maxillofacial silicones after exposure time in outdoor weathering.
- There are no significant differences in the percentage elongation between non-weathered and weathered specimens within each silicone group, and weathered specimens of the four different maxillofacial silicones after exposure time in outdoor weathering.

CHAPTER 2

LITERATURE REVIEW

2.1 Historical background:

Historians have not well reported the inception of maxillofacial prosthetic replacement. Evidence of earliest facial prostheses has been noted in Egyptian dynasty and ancient Chinese culture before 1600 A.D. In Chinese mummies, archaeologists have discovered artificial eyes, ears, and noses fabricated from wood, waxes, and clay. Similarly, artificial eyes have been reported in Egyptian mummies. However, insertion of those prostheses was perhaps done after death to fulfil the religious beliefs of that era. (Beumer *et al.*, 1996; Chalian *et al.*, 1972; McKinstry, 1995; Moore, 1994).

A renowned French surgeon, Ambrose Paré (1510-1590) described the construction of nasal prosthesis for the first time. Fabrication of the prostheses done by silver and strings were used to attach it to the face. He also used papier-mâché or leather to fabricate another prosthesis and retained it by a metal band passing over or around the patient's head. Moreover, he described the technique for producing a prosthetic eye retained by a metal band extending over the patient's head. He is called the “Father of Facial Prosthetics” due to his descriptions of the fabrication techniques of facial prostheses. However, there is insufficient evidence that his described prostheses were actually put into practice (Beumer *et al.*, 1996; Chalian *et al.*, 1972; McKinstry, 1995; Moore, 1994).

Tycho Brahe (1546-1610) was a famous astronomer who wore an artificial nasal prosthesis his whole life made from gold to cover the centre portion of his nose (Beumer *et al.*, 1996; McKinstry, 1995).

Several advancements in maxillofacial prosthodontics have been brought about by Pierre Fauchard, a father of modern scientific dentistry. He was responsible for the concept of restoring cosmetic appearance in addition to the restoration of mastication in partial dentures. He made palatal obturators for repairing palatal defects and used papier-mâché and silver to fabricate facial prostheses. His work initiated the development of facial prostheses in intraoral maxillofacial prosthodontics (Beumer *et al.*, 1996; Chalian *et al.*, 1972; McKinstry, 1995; Moore, 1994).

William Morton (1819-1868) fabricated a nasal prosthesis using enamelled porcelain for matching the patient's complexion. Norman W. Kingsley (1880) explained the technique of a combined nasal-palatal prosthesis where the obturator played an integral role in the prosthesis. Fabrication of a nasal prosthesis with ceramic material was described by Claude Martin (1889). Upham (1900) described the technique of using vulcanite rubber to construct nasal and auricular prostheses (Beumer *et al.*, 1996; Moore, 1994).

Ottofy, Baird, and Baker (1905) stated that black vulcanised rubber could be used as a base for the nasal prosthesis. The flexibility and softness of human skin were recreated in maxillofacial prostheses by the introduction of gelatin-glycerin mixtures in 1913. Bercowitsch described the fabrication technique of gelatin-glycerin facial prostheses and its coloration with water-soluble dyes. However, their lifespan was very short for applying in clinical practice. Thus, the use of vulcanised rubber was stopped in maxillofacial prostheses (Beumer *et al.*, 1996; McKinstry, 1995).

The dental profession was acquainted with acrylic resin in 1937. In both extra and intraoral prostheses, vulcanite rubber was substituted by acrylic resin soon after its introduction. Clinicians were allured by its colourability, translucency, and ease of processing characteristics. However, their use in facial prostheses was discouraged due to its rigidity (Beumer *et al.*, 1996; Chalian *et al.*, 1972; McKinstry, 1995; Moore, 1994).

From 1940 to 1960, numerous coloration techniques were proposed. Henry Bigelow colored a facial prosthesis made from acrylic resin by transparent photographic painting (Bigelow, 1943). Tylman introduced various intrinsic and extrinsic coloring stains, and also the use of resilient vinyl copolymer acrylic resin to overcome the rigidity issue of facial prostheses made with acrylic resin (Tylman, 1943). Usage of Food and Drug Administration certified colorants for staining maxillofacial prostheses was first done by Adolph Brown (Brown, 1942). Brasier achieved intrinsic coloration with stains of acrylic resin polymer and extrinsic coloration by oil color combined with acrylic resin monomer (Brasier, 1954). Fonder suggested staining auto polymerising acrylic resin using oil paints in nasal prosthesis fabrication (Fonder, 1955).

From 1960 to 1970, significant changes occurred in maxillofacial prostheses construction due to the emergence of different kinds of elastomers. Barnhart (1960) fabricated and colored facial prostheses for the first time using silicone rubber by mixing its base material with acrylic resin polymer stains (Barnhart, 1960). In 1967, Tashma performed intrinsic coloration of maxillofacial silicone prostheses by dispersing dry earth pigments in colorless powder of acrylic resin polymer (Tashma, 1967). For extrinsic spray coloration of silicone prostheses, Ouelette combined dry mineral earth pigments in a silicone base material thinned with xylene. 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 formulated base shades by making stock colors using dry mineral earth pigments and silicone based materials. However, it was claimed that prostheses colored with nylon flocking had more color stability and natural appearance than the ones stained with dry earth mineral pigments (Firtell and Bartlett, 1969).

From 1970 to 1990, facial prosthesis was fabricated using various types of elastomer. Udagama and Drane used Silastic Medical Adhesive Silicone type A for construction of maxillofacial prostheses (Udagama and Drane, 1982). Udagama lined Medical Adhesive type A with polyurethane film to overcome the problem of tearing 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 have been fabricated with various available materials, such as wood, wax, metals, and polymers most recently (Beumer *et al.*, 1996; Chalian *et al.*, 1972; Moore, 1994; Roberts, 1971). Numerous research has been conducted for eliminating undesirable properties of these materials, thus improving their characteristics. A maxillofacial prosthodontist must have a detailed understanding of properties of the materials that are used for repairing specific defects in order to attain patient acceptance and clinical success (Beder, 1974; Beumer *et al.*, 1996; Chalian *et al.*, 1972; McKinstry, 1995; Moore, 1994; Roberts, 1971).

Biocompatibility of the materials is one of the chief factors that need to be considered before fabricating maxillofacial prostheses (Beder, 1974; Beumer *et al.*, 1996; McKinstry, 1995). The materials should be devoid of any carcinogenic or toxic agents. Thus no harm can be caused to underlying tissues (Roberts, 1971). Resistance to stains is a definite advantage for allowing the use of cosmetics in order to conceal margins. A skin-like feature resembling in both appearance and tactile sensation, for instance, color, translucency, texture, and softness flexibility must be possessed by the finished prostheses for able to be used on movable tissue beds and also strong enough to avert any margin tearing when removed (Beder, 1974; McKinstry, 1995; Roberts, 1971). It should have sufficient durability of at least six months with little compromise to esthetics and physical properties due to ultraviolet radiation. The dimensional adaptability of the materials to intrinsic as well as extrinsic coloration should be stable with a service life of at least six months, and not be degraded when exposed to harmful environments or disinfectant agents (Babu *et al.*, 2018; Lemon *et al.*, 1995; Polyzois, 1999a).

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

2.3 Goals for ideal maxillofacial prosthetic materials

(Beumer *et al.*, 1996; Moore, 1994)

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 tissue
- Non-toxic components
- No polymerisation by-products
- Odourless
- 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

(Beder, 1974; Beumer *et al.*, 1996; Bulbulian, 1973; Chalian *et al.*, 1972; Roberts, 1971)

2.4.1 Acrylic resin (PMMA)

In the past, PMMA was the material of choice. It has high durability, hygiene, and easy to use. Individual skin tone can be achieved by satisfactory coloration. It can be mostly used for facial defects where minimal tissue bed movement occurs while functioning. Utilisation of both intrinsic and extrinsic coloration is possible. 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, poor edge strength and durability, easy degradation when exposed to ultraviolet light, difficulty in processing and coloring makes it less acceptable. Due to dust collection and staining, the completed restoration normally becomes tacky.

2.4.3 Polyvinylchloride and copolymers

This polymer contains various desirable properties; like flexibility, adaptability to extrinsic and intrinsic coloration, and if adequately manipulated, they show an acceptable initial appearance. Nonetheless, they easily stain and undergo degradation 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 still remain a severe 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 available polyurethane elastomer used in facial prostheses. Thinning and feathering of exposed tissue margins is possible as they can be made quite elastic without compromising edge strength. They can be colored with both 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 composed of long-chain molecules. They are useful than other polymers owing to some of the physical and chemical properties that they can retain over a wide range of environmental extremes. An alternating chain of silicon and oxygen atoms constitute the backbone of a silicone, whereas organic polymers contain chains of carbon atoms. The sides of the silicon atoms are often accompanied by organic or carbon-containing groups. Silicones can be produced in the form of elastomers (rubbers), fluids, or resins by adjusting the silicon-oxygen chain lengths. Silicone elastomers are used in numerous products, namely lubricants, waxes and polishes, water repellents, electrical insulation and non-stick coatings.

Silicones can only be produced synthetically, which might infer that the body has never developed a defence 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 product 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 vulcanising 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 (-78ºC) to higher than 570ºF (300ºC). Hence, silicones are considered ideal for various specialised 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 PC and Kiat-Amnuay S in 2010, it was observed that various silicone elastomer materials are used by the different respondents who were maxillofacial prosthodontists, anaplastologists, and dental technicians all over the world (Montgomery and Kiat-Amnuay, 2010).

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 colour 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 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.

2.5.2(b) **Medical Grade** silicones are mostly used externally. Maxillofacial prostheses are most commonly fabricated with these silicones. There has been no reported incident of any adverse reactions caused by the direct contact of medical grade silicone with human skin. Color stability of these silicones are good if the appropriate colorant pigments are used. These type of silicones are available as one or two-part systems in the market and may be found as moldable putty, pourable liquid, paste, and dispersion.

2.5.2(c) **Food Grade** is the third group. Recently, they are being utilized in the maxillofacial prosthetic field. Their similarity in composition and properties with Medical Grade silicone as claimed by the manufacturers, but being less expensive is the reason for their usage in producing facial prostheses.

2.5.2(d) **Industrial Grade** is the fourth group, which is usually used for industrial applications.

2.6 Outdoor weathering testing features:

Studies incorporating outdoor weathering tests evaluate the effects that a particular silicone or group of silicone materials experience when directly exposed to the natural environment. Whereas, artificial weathering are designed to simulate outdoor environments inside the laboratory, thus correlating the results with outdoor conditions found in nature (Rosa *et al.*, 2005).

It was noted as early in 1994 that the eventual aim of natural weathering is the prediction of the silicone material lifetime under service conditions. Therefore, the weathering exposure conditions must match the service environment. Although, the results of outdoor testing can only be used with confidence if the exposure time is equal to or greater than the expected service lifetime. On the other hand, artificial weathering that is conducted in the laboratory is easily arranged. However, the validity of the estimates of silicone material's service life under artificial weathering simulating natural conditions is questionable (White and Turnbull, 1994).

In 1992, Haug and colleagues tested the physical properties of six maxillofacial silicone materials subjected to seven environmental variables, one of which was natural outdoor weathering. The specimens in the natural weathering testing group were placed for a period of 6 months (November 1989 through April 1990) on the roof of Indiana dental school in downtown Indianapolis by hanging them from wooden racks with the help of stainless steel ligature wire. The reason behind selecting this time frame was because as per clinical observation, a facial prosthesis needs to be refabricated within this period. After the end of six months, the samples were removed from the roof and cleaned in distilled water in an ultrasonic cleaner for 10 minutes. Afterwards, they were tested for any changes in their physical properties due to weathering. However, no climatic data and average radiation of the outdoor weathering months for the testing area was summarised (Haug *et al.*, 1992). Another similar experiment was conducted in 1999 to evaluate the effect of weathering on physical properties of three silicone elastomers with its popular colorant combination. They exposed the specimens in the same manner, same place mentioned above for the same period. The samples were then tested for changes in their physical properties. But, before they were cleaned in an ultrasonic cleaner with tap water and detergent for 10 minutes, and wiped dry. In this study also, they did not mention the average monthly radiation and climatic data for the area and time of research (Haug *et al.*, 1999).

In the same year, Polyzois published an article on the effect of outdoor weathering exposure for 1 year on the color stability of three non-pigmented silicone elastomer materials. The samples were suspended by stainless steel ligature wire on plywood backed exposure rack. The exposure rack was placed on the roof of the Dental school in Athens from January 1995 through December 1995. To avoid standing water and maximize the amount of sunlight, the rack was adjusted to an angle of 5 degrees from the horizontal. The specimens were left uncovered when exposed to the environment. In this study, monthly average radiation and climatic data during environmental exposure were tabulated. The data noted were temperature, relative humidity, total solar radiation, sunshine duration, and global horizontal illuminance. The temperature ranged from 9.8˚-27.7˚C, relative humidity from 45.9 to 78.6%, and sunshine duration from 2.47-11.79 hours (Polyzois, 1999a).

Tran and colleagues in 2004, evaluated the color change of maxillofacial silicone after exposing the specimens to two different weathering sites for 4 months. The weather characteristics of the two different sites, Phoenix in Arizona and Miami in Florida were noted. The features recorded were total radiant energy, direct total UV, mean values of temperature, relative humidity, wetness time, wind speed, and rainfall. It was observed that the mean temperature, humidity, and rainfall was higher in Miami than in Phoenix (Tran *et al.*, 2004).

In 2007, Eleni and colleagues studied whether natural weather affects the mechanical properties of 4 prosthetic silicone elastomers. The weathering of the uncovered specimens were performed on the roof of the laboratory of atmospheric physics of the Aristotle University of Thessaloniki, Greece from May 2007 through May 2008 on an exposure rack similar to the previous studies. Monthly average radiation and climatic data were summarised under the following headings- temperature, summative rain height, total solar radiation, ultraviolet A and B. Temperature ranged from 6.70 to 28.20˚C, whereas rain height from 0 to 73.10 mm (Eleni *et al.*, 2009a). In the same year, another similar experiment was conducted on the rooftop of the School of Chemical Engineering of the National Technical University of Athens, Greece from July 2007 through July 2008. In this study, they included the relative humidity data of weathering in adjunct to the previous study criteria which ranged from 31-73%. Additionally, in Athens temperature reached 29˚C from 1˚C, and rain height 79 to 0 mm (Eleni *et al.*, 2011a). In 2011, Eleni and colleagues published a paper combining and correlating the results of the two studies above (Eleni *et al.*, 2011b).

Hatamleh and colleagues in 2011, published their study which they performed in 2008 investigating the effect of extraoral human and environmental conditions on the mechanical properties of Techsil- S25 silicone elastomer. Under the several conditioning aspects, one was outdoor weathering for 6 months (July 2008 through December 2008) on the roof of the Manchester Dental School (Manchester, UK) in the same manner as described in the previous studies. Monthly average climatic data and radiation were tabulated under the following headlines- mean, minimum and maximum temperature; wind speed, rainfall, global radiation and sunshine. The mean temperature ranged from 2.6-16.2˚C, and rainfall from 1.8 to 4.6 mm monthly (Hatamleh *et al.*, 2011).