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# Application of Silicone Elastomers in Extraoral Prosthesis: A Narrative Review

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## ABSTRACT

**Objectives**: The purpose of this article is to review the silicone system based on the various varieties of silicone available on the market, including classification and its properties. In addition, this article looks at the recent advancement of silicone in digital workflow as it relates to the application of extraoral prosthesis, thereby providing an overview and a guidance for practicing clinicians.

**Materials and Methods**: Electronic literature search was conducted using the PubMed and Scopus databases. There were no restrictions placed on the publication date up until December 2022. Following MeSH term keywords were used: ‘silicone’, ‘maxillofacial prosthesis’, ‘extraoral prosthesis’ Only relevant studies published in English journal articles are included and analysed in this review article.

**Results**: Silicone is an unique inorganic polymer chains. Due to its unique chemical structure, silicone exhibit skin-like elasticity, resistance to heat, biocompatibility, as well as translucency, making it suitable for fabrication of extraoral prosthesis despite its shortcomings. Several physical and mechanical properties of silicone should be taken into consideration.

**Conclusion**: The properties of silicone and its application in extraoral prosthesis, including its limitations, material considerations, and manufacturing obstacles, have been discussed. High Temperature Vulcanisation (HTV) and Room Temperature Vulcanisation (RTV) silicone are the two primary classifications for extraoral prosthesis applications. As far as is known, there are five major manufacturers of silicone for extraoral prosthesis fabrication. Silicone has considerable potential for future incorporation into digital workflows via additive manufacturing processes.

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## 1. INTRODUCTION

Extraoral prostheses and facial prostheses are interchangeable terms describing maxillofacial prostheses or alloplastic reconstructions prescribed to artificially replace individuals with facial defects due to congenital anomalies or acquired, such as trauma or oncology reason (Ferro et al., 2017). Surgical (autoplastic) reconstruction is usually favoured for any facial defects. Nonetheless, there are some limitations of surgical approach which requires prosthetic rehabilitation.

Despite several shortcomings in the properties of silicone for extraoral prosthesis , silicone is still the first material of choice and the most widely used (de Caxias et al., 2019) to fabricate extraoral prosthesis among the other alternative polymers (Beumer et al., 2011; Mitra et al., 2014) (e.g: polyurethane, chlorinated polyethylene, foaming silicones, polyphosphozenes) due to the its properties fulfilled the majority of ideal properties in fabricating extraoral prosthesis as well as its biocompatibility and skin-like texture.

Although silicone has good reputation in the application of fabricating the extraoral prosthesis, there is still no clear description on available silicone system currently used attributable to inconsistency between manufacturers and variabilities in the production of silicone itself which leads to the usage of silicones based on clinician’s preference instead of evidence based.

Digital workflow of fabricating extraoral prosthesis using silicone is still relatively new comparing to other prosthodontic works such as construction of crown and bridges. This may be contributed by the difficulty of rheological properties and viscosity in combination of setting and curing time of silicone during rapid prototyping process. It is safe to say that additive manufacturing (i.e: 3D printing) is more applicable and acceptable in the digital workflow of silicone rather than subtractive technique (i.e: milling).

The aim of this review paper is to discuss on the general properties of silicone, available silicone system in the market including its classification and properties. On top of that, this paper also will be discussing on recent advancement of silicone in additive manufacturing of digital workflow for extraoral prosthesis. Furthermore, the purpose of this review paper is to add evidence into scientific knowledge of lesser-known area of maxillofacial prosthodontics, also to serves as a guide to help clinicians with evidence-based practice for extraoral prosthesis fabrication using silicone.

## 2. DEVELOPMENT OF EXTRAORAL PROSTHESIS MATERIALS

The first extraoral prosthesis fabrication was not well recorded however it dated to even before 1600 in ancient Chinese civilization, where archaeologist found prosthesis made from waxes, clay and wood. Between 1510 – 1590, a famous French surgeon, Ambroise Pare made nasal prosthesis for wounded soldier using readily available materials such as gold, silver and glued linen cloth. Whereas loss of mandibular structure also in soldier was replaced with oil painted silver mask painted by Pierre Fauchard in his days (1678 – 1761). Between 1800 – 1900, marks the usage of porcelain and ceramic as extraoral prosthesis materials. William Morton (1819 – 1868) and Claude Martin (1889) utilised said materials for construction of nasal prosthesis (Beumer et al., 2011).

Polymers started to be the choice of materials in 19th century with the usage of vulcanite rubber and gelatine glycerine compound in 1913. Though, it is not applicable for clinical work due to its short lifespan. Since its invention in 1937, acrylic resin has replaced vulcanite rubber attributable to its ease of processing and colourability, repairability, readily obtainable, its translucency and respectable shelf life (Mitra et al.,

2014) in spite of its rigidity. The advancement of polymers in extraoral prosthesis materials followed suit by the introduction of silicone in 1960 – 1970 and is the most successful material known to date.

In more recent times, advancements in 3D printing have led to the development of new specialised material blends and crosslinking methods. These developments have allowed for the fine-tuning of the properties of these materials to optimise their suitability for 3D printing, which in turn has enabled a wide variety of mechanical and visual properties. The manufacturers of 3D printers were responsible for a significant portion of this innovation. These manufacturers have developed materials consisting of proprietary blends of polymers that are only acceptable for their machines (Crump, 1992; Kawakubo et al., 1989; Fong, 2013; Silverbrook 2011; Folgar and Folgar, 2017). For instance, one of the most successful commercial manufacturers of 3D printers, 3D Systems (located in South Carolina, United States), has over a hundred distinct polymers available for use in their 3D printing technologies. These polymers range from flexible elastomeric polymers to rigid nylons and acrylonitrilebutadiene styrene (ABS) (3D System). A good number of these designed polymers also include complicated mixtures of methacrylates, urethanes, and several other types of polymers. Their regular clinical use in prosthetics is restricted because they were just recently released onto the market, which necessitates further clinical development, biocompatibility testing, and permission from the relevant regulatory bodies (Zhu et al., 2015; Macdonald et al., 2016). However, some of these more modern polymers have been certified as biocompatible according to ISO-10993, USP Class VI, or one of the other available standards (3D System and Stratasys). Due to this, their potential for use in the routine fabrication of soft tissue prosthetics has increased, which will eventually make traditional approaches to the manufacture of prosthetics unnecessary.

Up to this date, there are several papers (Mitra et al., 2014; Abraham et al., 2018; Barhate et al., 2015; Huber and Studer, 2002; Reddy et al., 2015) discussing on available materials in fabrication of extraoral prosthesis. These literatures serve as guide for clinician to decide which materials to choose based on the advantages and disadvantages of each material and properties discussed. Nevertheless, all was in agreement on one fact; there is no current ideal material, that is available to be utilised for extraoral prosthesis fabrication.

The most commonly used materials in construction of extraoral prosthesis are acrylic resin and silicone (de Caxias et al., 2019). Though, there are other polymer or elastomer alternatives, such as polyurethane, PVC and copolymer, thermoset urethane elastomers, and chlorinated polyethylene. A more recent advanced polymer materials are silicone block copolymers, foaming silicones, polyphosphozenes and siphenylenes (Beumer et al., 2011; Mitra et al., 2014). However, they were lacking in evidence because a lot of studies were focusing on development of silicones due to its favourability. Nevertheless, there is no clear description on available silicone system used currently in extraoral prosthesis.

Table 1. Materials used for fabrication of extraoral prosthesis.

| Extraoral prosthesis material | Properties |
|---|---|
| Polyurethane (PU) | High tear and tensile strength.<br>Easy to colour.<br>Possibility of skin irritation due to polyureas. |
| Polyvinyl chloride (PVC) | Low tear strength.<br>Superior skin-like properties.<br>Great colour stability.<br>Compromised biocompatibility due to plasticizers. |
| Chlorinated polyethylene (CPE) | Better tear strength and surface wettability.<br>Easy to repair.<br>Challenging processing. |
| Silicone | Skin-like elasticity.<br>Low tear strength at the thin edge. |

| | |
|---|---|
| | Biocompatible.<br>Simple processing. |
| Siphenylenes | Improve tear strength.<br>Great colour stability. |

## 3. SILICONE

Silicone is a silicon-based or organosilicon polymers consist of inorganic backbone as chains (Si—O—Si) made up repeated units of silicon atom (Si) attached to oxygen atom (O2) with two organic groups bonds to Si centre (represents as R in Figure 1). The presence of both inorganic backbone and organic groups in one polymerized chain makes silicone a unique synthetic polymer. All silicones are known as polysiloxanes for its basic chemical name.

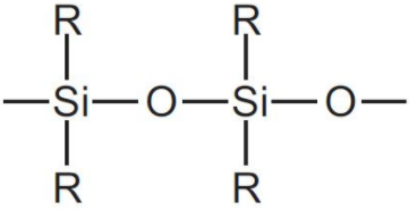

Fig. 1. Silicone chemical structure.

Silicones exist in different forms and consistency depends on the span of the polymer chain; long or short, the organic groups (i.e: methyl, vinyl, phenyl, ethenyl, trifluoropropyl) and the dimensional network. These structural determines its distinctive properties as such skin-like elasticity, resilience to heat, biocompatibility, and inherent transparency, and became the material of choice for the majority of facial prosthetics (Goiato et al., 2010; Hatamleh and Watts, 2010a; Montgomery and Kiat-Amnuay, 2010). It owes its one-of-a-kind qualities to its inorganic siloxane structure, which has structural similarities to the carbon backbone of organic polymers (Ratner et al., 2004). Condensation polymerization, free radical polymerization, and addition polymerization are the three different ways that crosslinking in silicone can take place (Colas, 2005).

For extraoral prosthesis, two silicone systems (Figure 2); liquid silicone rubber (LSR) or high consistency rubber (HCR) are commonly used. LSR is further classified into heat or high temperature vulcanised (HTV) silicone rubber, or room temperature vulcanised (RTV) silicone rubber. Some examples of HTV silicone rubber are M511 and M73 and for RTV silicone rubber are A-588, A-2000 and A-2006. The most frequent technique of production is addition polymerization at room temperature (Montgomery and Kiat-Amnuay, 2010), despite the fact that numerous other ways of manufacturing have been explored over the years. No comparison has been made to determine the superiority between HTV and RTV as material of choice for extraoral prosthesis. HCR silicone is much preferred when there is the need in extra strength and usually used for somatic prosthesis or orthotic application. However, the selection of silicones also depends on clinician’s preference based on the information provided in manufactures catalogue, material safety data sheet (MSDS) and material technical sheet (MTS) (Factor II, Inc.).

SLA techniques (vat polymerization), material jetting, and material extrusion are some of the most recent developments in the realm of 3D printing using silicone. Crosslinking can take place either through addition polymerization or UV curing (Zhou et al., 2020).

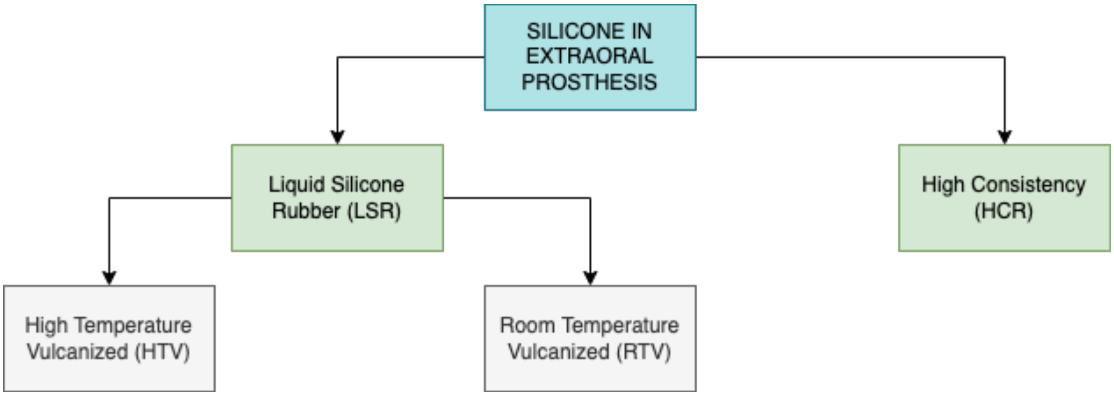

Fig. 2. Silicone system in extraoral prosthesis.

### 3.1 CLASSIFICATION OF SILICONE

Silicone does not have specific classification though, it can still classify based on chemical structures, viscosity, application and crosslinking (vulcanisation or polymerisation) process (Figure 3).

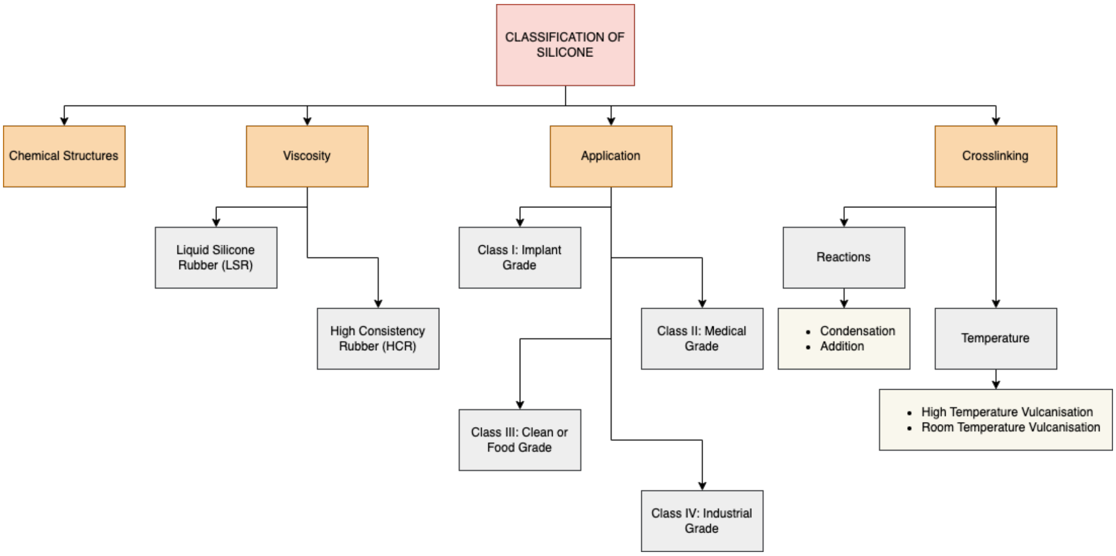

Fig. 3. Silicone classification.

Different organic groups can bond to silicone backbone which reflects to its name. For instance, polydimethylsiloxane (PDMS), the most common base for silicone, consists of two methyl group attach to backbone chain. Others are methylvinyl/dimethylsiloxanes and some examples for industrial use are phenylmethylsiloxanes and fluorodimethylsiloxanes. Fundamentally, the physical forms of silicone rely on its chemical structures which exist in four forms: silicone fluids, silicone gels, silicone elastomers (rubbers) and silicone resins. Additionally, the manufacturing and synthesis of silicone are greatly influenced by the targeted properties desired in specific industries.

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Liquid silicone rubber (LSR) and high consistency rubber (HCR) are classified based on viscosity. LSR exist in liquid form that has low viscosity. In contrast, HCR has higher viscosity and has the texture of gum (Factor II, Inc.). The processing for HCR requires compression moulding because of its consistency.

Liquid silicone rubbers are addition curing compounds which consist of two parts and can have a viscosity ranging from pourable to pasty, depending on the manufacturer (Kaira and Dabral, 2014). The rate of curing may also be adjusted, and while it proceeds at a rather sluggish pace at room temperature due to the presence of both a catalyst and an inhibitor, it accelerates rapidly between 170 and 200 degrees Celsius (Kaira and Dabral, 2014). The chemical structure of the material after polymerisation is analogous to that of HTVs that have been radical-crosslinked, although the polymer chains are shorter. One example of a 1:1 LSR that is used for prosthesis is MED-4920, which is manufactured by NuSilTM Technology LLC in Carpinteria, California, United States. Although it is utilised for prostheses, this material is most frequently found in medical equipment including balloon catheters and tubing. It has a translucent appearance, moderate strength, and the ability to imitate soft tissue. It is not possible to pour it into a mould before it cures because of its high viscosity, but it can be used for injection moulding (Aziz et al., 2003a).

The third classification for silicone is based on its application and it is graded into four grades or classes (Beumer et al., 2011; Huber and Studer, 2002; Alqutaibi, 2015). They are classified as:

(i) Class I: Implant grade

(ii) Class II: Medical grade

(iii) Class III: Clean or food grade

(iv) Class IV: Industrial grade

Class I silicone (implant grade) must be extensively researched to meet Food and Drug Administration (FDA) requirements. Breast implant is one of the examples of Class I silicone. On the contrary, Class II (medical grade) silicone is used predominantly in biomedical prostheses and used externally. Similar to Class I, Class II silicones undergo strict studies especially cytotoxic test and there should be no reporting on any side effects. As for Class III (clean or food grade) silicones, it is used for packaging and food storage, while Class IV (industrial grade) silicone is for industrial usage as the name suggested.

Finally, silicone also can be classified from vulcanisation (crosslinking or polymerisation) process; high or heat temperature vulcanised (HTV) silicones and room temperature vulcanised (RTV) silicone. HTV cured at an elevated temperature for a certain period whereas RTV silicones cured in room temperature.

In regard to classification of silicones based on crosslinking (RTV and HTV), it can be classified based on two types of crosslinking reactions: addition and condensation. Condensation reaction is a crosslinking process where polymer chains were formed from repeated condensation process between two dissimilar functional monomers. This process produced unwanted by-products such as ethyl alcohol or acetic acid other than water, that can be toxic and harm living tissues. This type of reaction requires a reactive group (e.g: silariols, a hydroxyl- terminated polysiloxanes), crosslinking agent (e.g: tetraethyl silicate), and a catalyst (e.g: dibutyltin dilaurate). The most disadvantageous properties for condensation type silicone are its high shrinkage rate with release of by-products.

For comparison, silicones undergo addition reactions are described as polymer formed from repeated addition of monomers that has double or triple bond. Similar to condensation reaction, addition crosslinking process needs catalyst usually platinum to aid addition of vinyl groups (CH2=CH—) to silyl hydride groups (—SiH).

HTV silicone can be found either in one or two component putty system (base + catalyst), or 10:1 or 1:1 ratio depending on manufacturer. It is made up of PDMS chains with 0.5% vinyl side chains. HTV silicone undergo addition reaction to form the polymers with platinum salt (chloroplatinic acid salt) as catalyst (Mitra et al., 2014), or free radical polymerization. The prolonged working period of around 30 minutes prior to polymerization is one of the advantages of high temperature vulcanizing silicones, which can be heated to temperatures between 100 and 200 degrees Celsius. However, this comes at a substantially higher cost than polymerization at room temperature and necessitates extensive milling prior to polymerization for the integration of intrinsic colours (Anusavice et al., 2013).

The production of silicones with a high consistency might benefit from free radical polymerization processes, which are also referred to as a peroxide-initiated reaction (Colas and Curtis, 2004). The radicals that are involved in crosslinking can be created at high temperatures if an organic peroxide is added to the silicone before it is heated. These silicones are typically catalysed by 2,4- dichlorobenzoyl peroxide (Craig et al., 1980), which is stable at room temperature but is activated at elevated temperatures (104–132 degree Celsius) (Colas and Curtis, 2004; Chalian and Philips, 1974; Colas, 2005). The activation of the methylene groups that form ethylene crosslinks between chains of uncured polymer occurs when the temperature is raised. The presence of vinyl groups in the polymer contributes to an increase in the rate at which this reaction takes place (Colas and Curtis, 2004; Colas, 2005). Because of their strong tear resistance as well as their outstanding thermal stability, these silicones are perfect for use in prostheses, which make use of both of these features. However, silicones that have been cross-linked with radicals have little flexibility, and as a result, they cannot be used in mobile regions like the areas that are influenced by jaw movement. Other disadvantages include opacity, yellowing after cure, odour during production and after, taste in the case of intra-oral prostheses, high friction (tacky) surface, release of peroxide split products, and the possibility of peroxide residues, which can create voids in the finished product as well as act as a catalyst for depolymerization at elevated temperatures. After the polymerization has been completed at a high temperature, additional processing may be done in order to eliminate any remnants of volatile peroxide (Colas and Curtis, 2004; Colas, 2005). The use of radical cross-linked silicones in prostheses has been stopped due to the availability of better inventions such as silicones generated via addition cure systems. This is despite the fact that radical cross-linked silicones have excellent tear resistance and thermal qualities.

High temperature vulcanization through addition polymerization operates in a manner that is analogous to that of RTV addition polymerization systems, and it results in silicones that are translucent and do not discolour, do not emit odours, are simple to demold, do not call for post-cure processing, and have high tensile and tear strengths (Aziz et al., 2003b). These are offered as either one-part systems with a shelf life of 3–6 months or two-part systems having a shelf life of 18 months while separated but only 1–7 days once mixed. The one-part systems have a shelf life of 3–6 months. Altering the ratio between the two parts of a system is one way to increase its degree of adaptability, which is another advantage of two-part structures.

Concisely, HTV silicone has a lot of advantages including excellent tear and tensile strength with high elongation percentage, and chemically, thermal and colour stable. Nevertheless, there are several shortcomings such as poor aesthetics, low elasticity with low edge strength and technique sensitive (Mitra et al., 2014). These are examples of HTV silicone system for fabrication of extraoral prosthesis; Q7-4635, Q7-4650, Q7-4735, SE-4524U, Silastic 370, 372, 373, 4-4514, 4-4515.

Differ from HTV silicone, RTV silicone can be found in condensation or addition silicone based on crosslinking reaction, and both processes need the use of a catalyst and a crosslinking agent. Plaster and gypsum (dental stone), both of which are relatively inexpensive materials, can be used to make the mould that silicone will be cured in because the reaction takes place at room temperature (Chalian and Phillips, 1974). Condensation polymerization systems can be purchased as either a one-part (designated as RTV-1) or two-part (designated as RTV-2) system. Only RTV-2 systems are found in addition polymerization systems. Two component system (base + catalyst) RTV silicone predominantly in choice of 10:1 or 1:1 ratio. Although the name suggested the curing temperature of silicone is room temperature however, it is not true room temperature vulcanisation as the temperature can be increased to fasten the curing time or to cure larger prosthesis.

Condensation polymerization can only take place in room-temperature vulcanizing systems that contain an organotin catalyst (such as stannous octoate) and a crosslinker (such as methyl triacetoxysilane) (Colas and Curtis, 2004; Colas, 2005; Aziz et al., 2003b; Lai et al., 2002). The first step in the process of crosslinking is the hydrolysis of functional groups on the crosslinker, which results in the formation of silanols. This in turn causes condensation, which leads to the production of a by-product (Colas and Curtis, 2004; Colas, 2005; Lai et al., 2002). The acetoxy and alkyloxy groups are the most frequent types of functional groups. When polymerized, these groups result in the production of acetic acid and methyl alcohol, respectively. If it is not complete, this process can be undone at temperatures higher than 90 degrees Celsius (Colas and Curtis, 2004). The use of silicones that have been cured through condensation polymerization in prosthetics has a number of drawbacks, including a lengthy curing time, the susceptibility of the material to degradation, a low tear strength, a low edge strength, and the formation of by-products that can lead to a porous structure and promote the sorption of liquids. These drawbacks can be avoided by using silicones that have been cured through other methods (Lai et al., 2002; Hulterström et al., 2008).

The condensation systems known as room temperature vulcanising-1 (RTV-1) are put to use in the commercial world as sealants and adhesives. They have to be kept in hermetically sealed cartridges because the process of crosslinking starts as soon as they come into touch with moisture in the air. Because moisture is necessary for the polymerization process, the realistic cross-sectional thickness of the object that is being created is restricted. As a result, the usage of these materials in prosthetics is restricted (Colas and Curtis, 2004; Colas, 2005; Lai et al., 2002). In spite of this, RTV-1 condensation systems have found applications in the field of prosthetics. The Dow Corning Company in Midland, Michigan, United States manufactures a product called Medical Adhesive Type A, which is also known as Silastic 891. This product is the only one of its kind to be used in external colourants on the surface of the prosthesis, and it must be applied in a very thin layer in order to permit the passage of moisture throughout its cross-sectional thickness for complete polymerization (Lai et al., 2002). In a study conducted in 1992 (Andres et al., 1992) among American prosthetists, 35.2% of the total 88 respondents indicated that they made use of Medical Adhesive Type A. A more recent poll was conducted in 2010 (Montgomery and Kiat-Amnuay, 2010), and it found that 39.5% of the 43 respondents were still using it for external detailing. RTV-1 condensation systems also have poor performance on a variety of parameters, such as taking a long time to finish polymerization, having poor mechanical qualities, and most importantly, the production process results in the generation of acetic acid, which is an irritant to the skin (Lai et al., 2002).

In RTV-2 condensation polymerization systems, the process of crosslinking is commenced when the two components, a base and curing agent (catalyst), are mixed, however the presence of moisture is not necessary for this step (Colas and Curtis, 2004; Colas, 2005). Silastic 382 and Silastic 399 are two examples of well-known silicone products that have, in the past, been marketed under the curing procedure in question (Dow Corning Company). The polymerization of Silastic 382 was catalysed by stannous octoate (Craig et al., 1980; Chalian and Phillips, 1974), which resulted in the formation of a viscous, opaque, white fluid base. The polymerization of Silastic 399 needed the use of two distinct catalysts due to the material's viscosity, which prevented it from flowing (Craig et al., 1980). These materials were often utilised up until the late 1980s in the process of fabricating implants and maxillofacial prosthesis (Chalian and Phillips, 1974). However, in the 1980s, worries over their safety began to emerge (Colas and Curtis, 2004; Lam and Hurry, 1992; Reisch, 1993; Cook et al., 1994; Wise, 2000; Segal et al., 2012) and as a result, they were withdrawn from the market (Wise, 2000; Segal et al., 2012).

In systems for vulcanizing addition polymerization that take place at room temperature (i.e., RTV platinum catalysed silicones), unsaturated vinyl (–CH = CH2) terminated poly (siloxanes) are polymerized after being initiated by a platinum catalyst to undertake a reaction with silyl hydride (–SiH) groups (Colas and Curtis, 2004; Colas, 2005; Aziz et al., 2003b; Lai and Hodges, 1999). Even though these are RTV systems, the silicones can be heat cured at temperatures as high as 100 degrees Celsius to reduce the amount of time required for curing. Because this reaction does not produce any by-products, the polymerization process does not result in any shrinking, which is one of the many key advantages of using this method (Colas and Curtis, 2004; Colas, 2005). In most cases, the basic component is made up of a polymer made of dimethylsiloxane, reinforced silica, and either a platinum or rhodium catalyst. A siloxane crosslinker, an inhibitor, and a dimethylsiloxane polymer are the three components that make up the curing agent. In the context of their application in prosthetics, the disadvantages of addition polymerization include the material's hydrophobicity, selective adhesion, inability to be extrinsically stained, short working time, and inhibition of curing by impurities (for example, amines, sulphurous, or other catalyst poisons).

Despite these drawbacks, the most majority of maxillofacial prosthesis are produced with the help of RTV platinum catalysed silicones (Montgomery and Kiat-Amnuay, 2010). The most widely used is A-2186, which is manufactured by Factor II, Inc. in Lakeside, Arizona, United States. It is a transparent two-component (10:1, base: catalyst) pourable silicone that was initially released in the year 1986 (Montgomery and Kiat-Amnuay, 2010). In 1987, Factor II, Inc. released a variant of their product known as A-2186F that had a rapid polymerization rate. In a survey that was conducted in 1992 (Andres et al., 1992) with 88 American prosthetist, it was discovered that 6.8% of respondents were using A-2186. In a survey that was conducted in 2010 (Montgomery and Kiat-Amnuay, 2010), it was discovered that this number had climbed to 32.6% with 43 respondents. The variant with a faster polymerization rate, known as A-2186F, was not included in the survey conducted in 1992; nonetheless, it was utilised by 20.9% of respondents in 2010. In the year 2000, A-2000 (Factor II, Inc.) was released as the first generation of 1:1 mixture platinum silicone. In the year 2006, A-2006 (Factor II, Inc.) was released as a follow-up to A-2000 (Factor II, Inc.) (Montgomery and Kiat-Amnuay, 2010). A survey conducted in 2010 found that 20.9 and 11.6% of respondents, respectively, used these silicones. Another clear two-part (10:1, base: catalyst) pourable silicone, MDX4-4210 (Dow Corning Company), was presented to the maxillofacial industry for the very first time in the 1970s. However, it did not reach its peak of popularity until the 1990s (Montgomery and Kiat-Amnuay, 2010). In the survey conducted in 1992, MDX4-4210 was utilised by the majority of respondents (59.1%), and it continued to be utilised in the survey conducted in 2010, by 18.6% in conjunction with catalyst A-103 (Factor II,Inc.) and by 16.3% in conjunction with Medical Adhesive Type A (Dow Corning Company).

To sum up, low tear strength, hydrophobicity, difficulty to colour extrinsically with long curing time and inhibition of crosslinking by traces of chemicals remain problems for RTV silicone (Mitra et al., 2014). These are examples of RTV silicone can be found to be use for extraoral prosthesis; Silastic 382, 399, 891 and Cosmesil/Silskin 2 system with MDX4-4210 as the most popular choice. Additionally, in area of maxillofacial or extraoral prosthesis, most literatures classify silicone into two; HTV silicone and RTV silicone (Beumer et al., 2011; Mitra et al., 2014; Abraham et al., 2018; Barhate et al., 2015; Reddy et al., 2015). To know the types of silicone available for use, it is advisable to refer to manufacturers catalogue, MSDS or MTS.

### 3.2 PROPERTIES OF SILICONE

Silicone polymers are popular in many industries due to its excellent properties which enables various applications. Not to mention its numerous physical forms in biomedical field as gels, lubricants, foams, adhesives and elastomers (Hill, 2005). Polysiloxane or silicone considered to be non-degradable polymers causes minimal body adverse reactions (Clarke et al., 2011) which makes its polymer of choice for long

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term prosthesis use in the body owing to its bioinert (chemically stable and non-reactive), biocompatibility and biodurability properties (Hill, 2005). Moreover, polysiloxane proven has long success record in biomedical application with extensive range purposes such as total artificial heart, artificial lung, intra-aortic balloon pumps, tracheal stent, tracheostomy vent, anti-reflux cuffs, extracorporeal dialysis, urethral cuffs, brain membrane, wrist joint, finger joints, hip implants, tibial cups, toe joints, oviductal plugs, chin, ear frame, eustachian tube, orbital floor, breasts implants, contact lenses, implants for reconstructive and plastic surgery, etc (Clarke et al., 2011). This proves silicone does not have any issues in eliciting negative body reactions as extraoral prosthesis.

Generally, properties of silicone depend on the chemical structures, crosslink density, type and number of side organic groups, and molecular weight (Polymer Database). Silicone has good range of tear and tensile strength properties, remarkable oxidative and temperature stability, ease of manipulation, great resistance to chemicals and weathering, high compressibility, high permeability to oxygen, nitrogen and water vapour, exceptional low temperature flexibility and freedom of motion, low in viscosity, low surface tension, low melting point and glass transition temperatures, good electrical insulators, very hydrophobic with low moisture uptake, life-like translucency and poor wetting characteristics which makes it rarely used without modification (Mitra et al., 2014; Hill, 2005; Polymer Database; Ariani et al., 2013). A proper processed and cured silicone shows it can limit microorganism proliferations by inhibiting the absorption of organic materials, source of energy to the microorganism. Subsequently, prosthesis made by silicone is relatively safe and sanitary with simple home care hygiene (Mitra et al., 2014).

The molecular weight of silicone, the degree to which it is crosslinked, and the number of fillers and colours that it contains are the three primary parameters that determine its mechanical qualities (Aziz et al., 2003a; Aziz et al., 2003b; Bellamy et al., 2003).

The polymer's tensile and elongation strengths are both directly influenced by the polymer's molecular weight distribution. A bimodal molecular weight distribution can be produced by mixing long and short chains of the same polymer (Aziz et al., 2003b). This creates a more complex structure. When polymer chains are shorter, the resulting reduced molecular weight leads to increased crosslinking, which in the case of silicone leads to a material that is brittle, inelastic, and does not mimic the properties of soft tissue. On the other hand, a high degree of elasticity in a material is accompanied with a decreased capacity for strength when there is a low degree of crosslinking. To obtain a soft tissue prosthesis that not only has a long service life but also a high degree of durability, it is essential to modify the crosslinking density so as to strike a balance between these two extremes (Azizi et al., 2003b; Bellamy et al., 2003).

The use of filler is yet another strategy that can be utilised to improve the mechanical characteristics of silicone and minimise the material's propensity for tearing. This process, which might result in a decrease in the cost of the elastomer and, consequently, the cost of the prosthesis, is commonly referred to as extending. The filler is able to perform its function by releasing stored energy as the material is deformed. This makes it possible for molecular chains to readily navigate around one another (Kong et al., 2011; Marquis et al., 2011; Momen and Farzaneh, 2011; Kong, 2003). It is important to keep in mind that very frequently the particles that are present in the intrinsic colouring pigments might have the same effect.

### 3.3 INHIBITION OF SILICONE CURING

Trace concentrations of specific sorts of substances can induce inhibition or contamination. The most prevalent causes of inhibition are sulphur or any chemical compound containing sulphur, amines and other nitrogen-containing chemicals, acitic materials, organic compounds, and certain RTV silicone catalysts. These compounds will prevent the material from curing by interfering with the curing reaction. The usage of latex gloves may result in contamination and insufficient curing.

On occasion, inhibition occurs on the exposed surface of a casting as it cures in a polluted oven. In these instances, the oven's environment contains sufficient contaminates from a previous product that was cured (for example from latex). This will manifest as a surface inhibitor and partial curing of the elastomer's surface.

Traces of amines, sulphur, nitrogen oxide, organotin chemicals, and carbon monoxide may hinder curing. These compounds should not come into touch with the uncured elastomer because organic rubbers commonly include them. Catalyst residues from silicone RTV elastomers and silicone elastomers treated with peroxide may also hinder curing (Kosor et al., 2015; Nusil, 2019).

### 3.3 CONSIDERATIONS ON THE PHYSICAL AND MECHANICAL PROPERTIES OF SILICONE

The dimensions of the material should not change when it is subjected to harsh elements such as sunshine, UV radiation, or extreme circumstances, or when it is in contact with adhesives and the solvents that they use. It is important that the fabrication process be as user-friendly as possible, including having simple processing, a low polymerization temperature, adequate working time, and the ability to easily adjust to both intrinsic and extrinsic staining techniques.

It is challenging to specify physical and mechanical properties of silicone established from the type of silicone, as physical properties of silicone can be manipulated by manufacturer during the synthesis or production of silicone. Thus, it is recommended to check with material data sheet (MSDS) or technical sheet (MTS) for further information on silicone properties of your choice in the practice. The common physical properties that can be manipulated are colour, shore A hardness, viscosity, tear strength, tensile strength, percentage of elongation and working or curing time. It is up to the purchaser to choose which specifications wanted in the silicone based on the said properties based on what is available from manufacturer.

### 3.3 Viscosity

Viscosity defines as a measurement of fluid’s resistance to flow. Viscosity is the most well-known manifestation of rheological properties, and it is used to evaluate the stability of a formulation over time as well as to improve the handling and performance characteristics. Viscosity is important in manufacturing of silicone rubber particularly liquid silicone as the polymer are designed to be process using moulding template. There is a wide variety of flow ranges available, ranging from very stiff for compression moulding to very soft for transfer moulding. Viscosity has a relatively minor impact on the chemical characteristics of silicone rubbers, but it does influence the flow behaviour and the solubility of the material.

The degree of polymerization affects the molecular weight of the material, which in turn affects the viscosity of the polymer. Viscosity increases in proportion to the length of the polymer chain. In addition, the flow of the polymer will be slowed down proportionally to the viscosity (SIMTEC).

### 3.3.2 Hardness

The surface resistance to indentation is assessed in a standard test to determine a material's hardness, which is defined as the ability of a substance to resist being deformed. Hardness is determined via this test (McCabe and Walls, 2013; Van Noort and Barbour, 2014; Sakaguchi and Powers, 2012). The form or kind of indent, the size, and the amount of load that is applied are the three characteristics that are used to characterise the most frequent types of hardness testing. The hardness numbers that are being referenced make up an arbitrary, nondimensional scale, with higher numbers denoting surfaces that are more difficult to scratch. The Brinell hardness scale and the Rockwell hardness scale are the two most often used methods for determining a material's level of abrasiveness. Each approach requires its own specialised testing apparatus and employs a different set of hardness scales. The type of material that is being evaluated will, to some part, determine the type of hardness tester that is most appropriate. When a constant force is given to a typical indenter, the dimensions of the resulting indentation change in a manner that is inversely proportional to the resistance of the material being tested to be penetrated. Therefore, lesser loads are employed for materials that are more delicate.

The Shore Durometer test is used to determine the level of hardness possessed by elastomers such as silicone. The depth to which a tiny cone can be driven into the surface of the silicone is what is being measured by this test. On the Shore Durometer scale, the value obtained is determined by converting the depth to which the cone dips into the silicone. Soft silicones cause the cone to sink more, and because of this, soft silicones have a lower value on the scale. If the silicone is hard, the cone will not sink very deep, which will result in a high score on the Shore scale. The Shore Durometer test can be performed in a number of various ways depending on the type of elastomer being evaluated. Shore Durometer A is the most common measurement for soft elastomers, while Shore Durometer D is the most common measurement for hard elastomers. The hardness value obtained from each test ranges from 0 to 100 (J-flex).

The Shore A scale is utilised for the evaluation of "softer" rubbers, whilst the Shore D scale is typically utilised for the evaluation of "harder" rubbers. There are more Shore hardness scales, such as Shore O and Shore H, although they are not commonly used in the plastics and rubber industries. The difference between 30 Shore A and 80 Shore A is significant. When a material reaches Shore 95 A, its texture will begin to more closely resemble that of plastic than that of a substance that is flexible. In this particular scenario, the Shore A and Shore D scales will briefly coincide with one another. On the other hand, the A scale refers to rubbers that may be bent, while the latter refers to hard materials.

The equipment used to determine Shore hardness is called a Durometer, which is where the word "Durometer hardness" originates from. The depth to which the indenter foot of the durometer is able to penetrate the sample being evaluated is directly proportional to the hardness rating.

### 3.3.3 Tear strength

The ability of a material to withstand damage caused by tearing is referred to as its tear strength. This can be measured for polymers such as silicone by observing how quickly pre-existing cracks spread when the material is stretched and then quantifying the rate of growth. This is expressed as the amount of tensile force in Newtons that is required to stretch a product one millimetre (N/mm). A material's abrasion and wear resistance can be gleaned from its tear strength, which not only determines how readily a material would fail by tearing when placed under strain, but also provides an indication of the material's resistance to tearing (McCabe and Walls, 2013; Van Noort and Barbour, 2014; Sakaguchi and Powers, 2012).

The ability of a material to withstand the force of tearing, which is particularly significant in thin parts such as the areas surrounding nasal and eye prostheses. When the thin prosthesis that is glued on is removed, it has a high risk of tearing, which will irreversibly damage the prosthesis. In most cases, it is evaluated using a technique known as "Trousers Tear Energy," in which a thin sheet of the elastomer is fashioned into the form of a pair of pants. After that, the legs of the pants are carefully pushed apart, and the amount of energy that is required to start a tear is determined (Mitra et al., 2014).

The risk of prosthesis failure can be reduced by choosing a silicone with adequate tear strength.

### 3.3.4 Tensile strength and percentage of elongation

The stress-strain curve is generated by stretching a piece of silicone and simultaneously measuring the amount of tensile force necessary to stretch the material as well as the amount of stretch that the material itself experiences (elongation). The silicone is pulled and stretched to the point where it breaks. The measurements of tensile force and elongation are adjusted to account for the fact that the silicone samples that are being stretched can be of varying sizes.

We can determine several crucial mechanical parameters about the silicone by analysing the stress-strain curve. These qualities will inform us how the silicone will behave. If we measure the modulus of the silicone, we can determine how rigid it is and how difficult it is to stretch. Calculating the slope of the first segment of the stress/strain curve is how this characteristic is measured. A highly steep curve will be exhibited by rigid silicones, whilst a shallower curve will be exhibited by softer silicones.

The total percent elongation, which takes into account both the elastic and plastic elongations, is useful since the elastomers must be stretched to suit the movements of various facial features. Thus, it also offers us an indication of the material's flexibility.

It is claimed that a combination of high percentage elongation and strong tear strength is the most desired for fabrication of extraoral prosthesis (Begum et al., 2011).

### 3.3.5 Wettability

It can be determined using a tensiometer to measure forces as the material is immersed and removed or by measuring the increasing contact angle of water on the surface of the set material. There are a number of elements that go into determining wettability, including the degree of cleanliness of the surfaces involved and the surface energy of those surfaces. Due to the low surface energy of the adherend (for example, maxillofacial elastomeric materials), a high contact angle is produced with liquids such as water, saliva, or glue. This prevents the materials from spreading across the surface of the adherend. Low wettability of the surface results in inadequate boundary lubrication, which in turn results in patient discomfort (Aziz et al., 2003a; Van Noort and Barbour, 2014).

### 3.3.6 Water sorption

Represents the amount of water that has been absorbed by the material, both on its surface and into its body, while the restoration is being fabricated or while it is in service. During the cleaning process, the prosthesis has the potential to absorb saliva, sweat, or water, which has the potential to alter its physical qualities, including its user's perception of colour (Aziz et al., 2003a). When boiled in water or sterilised in steam, the prosthesis shouldn't become misshapen in any way.

### 3.3.7 Stiffness

Additionally, the materials must have a low glass transition temperature in order to stop the material from becoming stiffer when it is subjected to colder temperatures (Van Noort and Barbour, 2014).

### 3.3.8 Weight and density

Patient should not experience any discomfort while wearing the prosthesis; hence, lightweight or low-density materials are essential. Additionally, this contributes to the retention of the prosthesis (Mitra et al., 2014).

## 3.4 DEGRADATION OF SILICONE

All prostheses, during the course of their service life, will experience changes, both mechanical and chemical, that will shorten their usefulness. Despite its outstanding endurance, silicone loses its colour with time, becomes stained and weathered, undergoes changes in elasticity, and tears prematurely, all of which contribute to the material's more surreal aspect and feel. In addition, interaction with the chemical environment of the skin secretions accelerates the deterioration of the polymer and promotes the growth of microorganisms, which can result in discomfort and infection for the patient as well as degradation of the polymer that is caused by microorganisms. Given the high cost and high level of complexity involved in the production of many prostheses, it is critical to investigate potential solutions to the problem of material degradation (Cruz et al., 2020).

## 3.5 SILICONE IN 3D PRINTING

It should come as no surprise that efforts are currently being made to 3D print silicone, given that it is the material that is most frequently utilised for soft-tissue prosthetics (Yeo et al., 2020). The tactics that are now being used can be roughly categorised as either indirect or direct (Eggbeer et al., 2012). Indirect methods often use the utilisation of low-cost 3D extrusion printers in order to manufacture hard polymer moulds for the purpose of curing silicone (Liu et al., 2016). The utilisation of a mould ensures that polymerization happens consistently over the majority of the silicone, creating a result that is analogous to that of more conventional methods. On the other hand, direct techniques include activities such as the extrusion, jetting, or polymerization of silicone on a layer-by-layer basis.[68] The use of direct 3D silicone printing in prosthetics is limited due to visible layering from the progressive polymerization, which could potentially render the printed prosthetic visually unappealing (Liravi and Toyserkani, 2018; Unkovskiy et al., 2018; Kenney and Zhu, 2018; Jindal et al., 2018). Although this is desirable for ease-of-fabrication, the use of direct 3D silicone printing in prosthetics is limited.

## 3.6 CHALLENGES OF SILICONE IN EXTRAORAL PROSTHESIS

The requirement that the prosthesis be attached to the patient is an important factor to consider when using silicones in prosthetics. Osseointegrated implants and a retentive structure that employs either bar clips or magnets are typically used in order to secure silicone prostheses in place once they have been attached. By serving as guides, the utilisation of clips or magnets makes the process of attaching the prosthesis much more straightforward. Acrylic resin is used in the construction of these retentive structures most of the time (Hatamleh and Watts, 2010a; Hatamleh and Watts, 2010b; Haddad et al., 2012). Therefore, it is essential that the silicone be properly bonded to the acrylic substructure so that the prosthesis may be adequately attached to the patient. This will ensure that the prosthesis will function as intended.

Due to the distinct chemical structures of silicone and acrylic, it is difficult to form a direct link between the two materials, and molecular adhesion also does not exist between them (Hatamleh and Watts, 2010a; Haddad et al., 2012; Kosor et al., 2015). It was also discovered that the adhesives were not adequate (Haddad et al., 2012). Primers that include both an organic solvent and an adhesive ingredient have been found to be effective at overcoming the challenge of increasing the binding strength between silicone and acrylic resin. This challenge was originally posed as a problem to be solved. The primer performs the function of a chemical intermediate by reacting with both materials (Hatamleh and Watts, 2010a; Haddad et al., 2012), etching into the resin in order to make it possible for the silicone to impregnate the surface of the resin by activating hydrogen bonds and covalent coupling, and by reacting with both materials. This results in the increase surface area, which increases its wettability. The hydrophilic and hydrophobic groups react and connect with the functional groups of the silicone while the adhesives are working on the silicone (Hatamleh and Watts, 2010a; Hatamleh and Watts, 2010b; Haddad et al., 2012).

### 3.7 SILICONE MANUFACTURER FOR EXTRAORAL PROSTHESIS FABRICATION

In the field of facial prosthetic fabrication, maxillofacial prosthodontists and anaplastologists are actively employing the usage of a wide variety of extraoral silicone materials. According to the findings of a survey that was carried out in 2010 by Montgomery and Kiat-Amnuay, it was discovered that the various respondents from all over the world who work in the fields of maxillofacial prosthodontics, anaplastology, and dental technology use a variety of silicone elastomer materials. The results of this investigation identified the manufacturers that now supply the prosthetic silicone materials that are most widely utilised. They are listed in Table 1. The table also summarise of the most common silicone elastomer materials that are currently utilised in the manufacturing of facial prostheses, as determined by this specific survey and the websites of the manufacturers that produce silicone that were stated before.

Table 2. List of manufacturers and its silicone material.

| **Manufacturer supplying silicone for fabrication of extraoral prosthesis** | **Country of origin** | **Commonly used silicone material** |
|---|---|---|
| Factor II, Incorporated, (Factor II, Inc.) | Lakeside, Arizona, USA | A-2186, A-2186F, A-2000, A-2006, A-103, Cosmesil M-511 |
| Technovent Limited, (Technovent Ltd.) | York Park, South Wales, UK | Techsil 25, Z004, M511 |
| Bredent GmbH & Co. (Bredent) | KG, Senden, Germany | Multsil Epithetik |
| Dow Corning Corporation, Dow Corning Corp. | Michigan, USA | MDX4-4210 with catalyst A-103<br>MDX4-4210 with Silastic Medical Adhesive Silicone Type A |
| Nusil Technology (Nusil Tech) | Carpinteria, California, USA | MED-4095, Med 4011 |

## 4. CONCLUSION

To conclude, properties of silicone has been discussed as well as its application in extraoral prosthesis including its drawbacks, material considerations, as well as challenges during fabrication. High Temperature Vulcanisation (HTV) and Room Temperature Vulcanisation (RTV) silicone are two main classifications in application of extraoral prosthesis. There are five main manufacturers that produce silicone for fabrication of extraoral prosthesis as of current knowledge. Silicone has great potential to be included in digital workflow by additive manufacturing process for future development.

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## CONFLICT OF INTEREST STATEMENT

The authors agree that this research was conducted in the absence of any self-benefits, commercial or financial conflicts and declare the absence of conflicting interests with the funders.

## AUTHORS' CONTRIBUTIONS

Nadhirah Ghazali carried out the research, wrote and revised the article. Ahmad Zafir Romli designed the research, provided the theoretical framework, supervised research progress. Tengku Fazrina Tengku Mohd Ariff conceptualised the central research idea, provided the theoretical framework, supervised research progress, anchored the review, revisions and approved the article submission

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## 5. APPENDIX

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