



## Maxillofacial Prosthetic Materials -An Update

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### Abstract:

Body abnormalities or defects that compromise appearance, function may make an individual, incapable of leading a relatively normal life. Facial disfigurement can be the result of a congenital anomaly, trauma or tumour surgery. Surgical reconstruction may not be possible owing to size or location of the defect. The patient's medical condition or personal desires may also preclude reconstructive surgery. In such cases, prosthetic rehabilitation is indicated. A facial prosthesis restores normal anatomy and appearance, protects the tissues of a defect, and provides great psychological benefits to the patient. A number of materials are available and have been used for fabrication of maxillofacial prosthesis; the aim of this article is to provide some insight about the currently used maxillofacial prosthetic materials.

**Key words:** Polymers, Elastomers, Prosthetic materials

### Introduction:

Since the sixteenth century, acquired surgical defects have been restored by prosthetic replacements constructed from a variety of materials<sup>1</sup>. Maxillofacial prosthetics is defined as that branch of prosthodontics concerned with restoration and replacement of both of stomatognathic and associated facial structures by artificial substitutes that may or may not be removed<sup>2</sup>. It encompasses prosthetic rehabilitation of patients with oral or facial defects which may be naturally acquired or may result from disease or trauma. A number of materials are available and have been used for fabrication of maxillofacial prosthesis. These include wood, wax, metals and in recent times polymers. Polymers and elastomers are the mainstay of modern maxillofacial prosthetic reconstruction. Polymethylmethacrylate, polydimethylsiloxane and polyetherurethanes have been tested and used in meeting the demand for materials that will be biocompatible, durable, colour stable and easily manipulated.<sup>3</sup>The new materials have exhibited some excellent properties but also some frustrating deficiencies. As yet, a material has not

emerged that does not possess undesirable characteristics. Much effort has been expended recently in studying existing materials in the hopes of ameliorating their deficiencies. This article summarizes the literature about current materials applied in maxillofacial prosthodontic rehabilitation.

### Silicone:

The silicones, introduced around 1946 were used for the first time by Barnhart (1960) for extra-oral prosthesis.<sup>4</sup> Silicones are probably the most widely used materials for facial restoration nowadays.<sup>5</sup> They are a combination of organic and inorganic compounds. Silicones are categorized into implant grade, medical grade, clean grade and industrial grade based on application. Implant grade silicone should meet or exceed Food and Drug Administration requirements. More stringent testing is performed on this grade of silicones. Facial prosthesis is primarily made of medical grade silicones while clean grade silicones are used for food coverage and packing<sup>6</sup>. Reduction of silica to elemental silicon is the first step in manufacture of silicones. Silicon is combined with methyl chloride to form dimethyl dichlorosiloxane, which when

reacts with water forms a translucent watery, white polymer, Poly Dimethyl Siloxane<sup>7</sup>. Viscosity is determined by the length of the polymer chain. Fillers are added to increase the strength of the polymer. Crosslinking agents are added to silicones to make it resistant to degradation when exposed to environmental factors. The process of crosslinking is called vulcanization. The silicones are available in two forms – those requiring heat to effect vulcanization (HTV) and those that vulcanize at room temperature. (RTV)

### **RTV Silicones**

It is a type of silicone rubber made from a two-component system available in a hardness range of very soft to medium - usually from 15 Shore A to 40 Shore. RTV silicones can be cured with a catalyst consisting of either platinum or a tin compound such as dibutyltin dilaurate; advantages of RTV are esthetics, ease of coloring, easy manipulation, thin margins possible, and adhesive compatibility. The disadvantages are discoloration over time, technique-sensitivity, lack of repairability, extrinsic colors peel/fade, and lack of longevity.<sup>5</sup>

### **Silastic 382 and 399:**

In RTV Silicones like Silastic 382 and 399 the polymerization occurs via condensation reaction. It requires stannous octoate as catalyst and Ortho Alkyl Silicate as crosslinking agent; fillers such as silica or diatomaceous earth are often added to increase the tensile strength. Stone molds can be used. Opacity is the main concern of these materials.

### **MDX 4-4210:**

The elastomer is based primarily on a modified polydimethylsiloxane (PDMS) structure and the vulcanization mechanism involves the addition of Si-H groups to Si-vinyl units. A platinum catalyst initiates the cross-linking reaction; the curing reaction is sensitive to any contaminant

which is capable of coordination with the platinum catalyst. Amines, sulphur and tin compounds are especially troublesome and inhibit the cure of the material.

Because of changes in the nature of the filler, the MDX-4-4210 elastomer is not opaque as are most of the silastics and other highly filled silicones. This improvement allows fabrication of prostheses of exceptional appearance. This elastomer's most important advancement is its increased tear strength compared to that of other RTV or LTV silicones. In prosthesis of this material, unusually thin edges can be designed with minimal risk of damage during wear and removal of the prosthesis. The base polymer is essentially PDMS; thus, the elastomers are similar to the silastics in that it is heavy, does not readily accept extrinsic colouration, and does not bond well to some adhesives. These medical-grade silicone elastomers have shown to be the most popular material among clinicians. It is available as a two-component kit. This material is not heavily filled and is translucent. It has a chloroplatinic acid catalyst and hydro-methylsiloxane as a cross-linking agent. The polymerization is an addition reaction with no reaction by-products. The cured material has adequate tensile strength, increased elongation and resistance to tear. This helps in designing prosthesis with thin edges with minimal risk of damage during wear and removal of the prosthesis. The surface texture and shore hardness are within the range of the human skin. The material is non-toxic, colour stable and biologically compatible.

The base material which is clear with a honey-like consistency is weighed to obtain the required amount. Talc powder is mixed with the base material to make it opaque and until the desired translucency is obtained. Red fibres and dry earth pigments are incorporated in the base material. The patient's presence is required and the mixing is done gradually until the desired colour is achieved. This base

colour is labelled and stored in refrigerator for the next appointment. One part of catalyst, stannous octoate to ten parts of base material is added. Catalyst is thoroughly mixed with a flexible spatula. De-airing is done in vacuum at 30 psi for 30 to 40 minutes, and the material is allowed to set for 2 ½ hours. Processing is simple, as the moulds of dental stone are acceptable. A crown-mould-releasing agent or 5% solution of mild soap is applied to the mould. Care should be taken to avoid contamination of mould with petrolatum or clay residues. The releasing agent is allowed to dry for an hour. The mould is heated in a dry heat oven at 50°C for half an hour. It is then loaded with the MDX 4-4210 with a syringe and allowed to bench set for 15 minutes. The flask is placed in web clamps and cured at 80 °C for 2 hours or 150 °C for 15 minutes.

Because of its improved physical properties such as increased resistance to tear, surface texture and shore A hardness measurements being within the range of human skin and its compatibility with most skin adhesives, it is popular among the clinicians.<sup>5,6,7,8</sup> It also has proved to be quite colour stable and sufficient percentage elongation sufficient for the production of maxillofacial prostheses which will more closely stimulate the properties of facial tissues.<sup>9</sup> Recent studies on physical properties of the various silicones for maxillofacial prosthetic use have revealed that the physical properties change with the incorporation of colouring agents.

#### **A-2186 (Factor II):**

A-2186, which is made by modification of the polymer chain had greater tear resistance, tensile strength, a larger percentage of elongation and also proved to be softer at the surface than HTV silicones and many other RTV silicones. It also demonstrated absence of cytotoxicity in the cell culture tests.<sup>10</sup>

Introduced in 1986 by Factor II (Lakeside, AZ), A- 2186 was the first commercial platinum-catalyzed silicone elastomer. It is a clear-to-translucent two-part (10:1 base:catalyst) pourable silicone. A fast polymerization rate version of A-2186 with higher platinum content, “A-2186F,” became commercially available in 1987, though it was not a very preferred material for prosthesis purpose.

In 2000, Factor II introduced A-2000 as the first generation of a 1:1 mixture platinum silicone followed by A-2006 in 2006.<sup>11</sup>

Sara M. Zayed et al concluded that the incorporation of surface treated SiO<sub>2</sub> nano particles at concentration of 3% enhanced the overall mechanical properties of A-2186 silicone elastomer.<sup>12</sup>

#### **Cosmesil:**

According to G L Polyosis, Cosmesil K10 showed physical properties similar to those of MDX4-4210.<sup>13</sup> Wolfaardt et al studied that Cosmesil is acceptably biocompatible for its intended use where there may be contact with internal tissue spaces that are contiguous to external surfaces.<sup>14</sup> Begara et al studied that addition of Zn nano-oxides in lesser concentrations provided significant and consistent ultraviolet protection in Cosmesil elastomer.<sup>15</sup> Current research is more focused in improving the longevity and reducing the discolouration of silicones.

Akash et al suggest that incorporation of nano-oxides improved the color stability of silicone elastomer and also acted as an opacifier. ZnO-incorporated Cosmesil specimens showed minimal or no color change and proved to be most color stable after being subjected to outdoor weathering.<sup>16</sup> According to Mohammad S. A et al polyhedral silsesquioxane (POSS) nanoparticles have the ability to provide reinforcement to maxillofacial materials and potentially to other elastomeric systems. The POSS loading had a

significant effect on the tear and tensile properties of the maxillofacial materials.<sup>17</sup> Liu Q et al characterized its biomechanical properties of a modified silicone elastomer filled with expancel hollow microspheres and concluded that composite with a volume fraction of 5% exhibited the optimal properties for use as a maxillofacial prosthesis, though its tear strength was markedly lower than that of silicone.<sup>18</sup> Wang et al studied the cytotoxicity of Nano-TiO<sub>2</sub> Silicone Elastomer after artificial aging and showed preliminary long-term biocompatibility of the composite.<sup>19</sup>

Silicone elastomer is currently the best material available for maxillofacial prostheses; however, longevity and discoloration, which are greatly influenced by ultraviolet radiation, microorganisms, and environmental factors, remain significant problems. In the near future, the widespread availability and cost effectiveness of digital systems may improve the workflow and outcomes of facial prostheses. Patients report high satisfaction with their prostheses despite some areas that still need improvement.<sup>20</sup>

### **Siphenylenes:**

Siphenylenes are siloxane copolymers that contain methyl and phenyl groups. They are formulated as a pourable, viscous, room-temperature vulcanizing liquid. In tactual response, silphenylene elastomers feel more like skin. These polymers are transparent even when reinforced with silica fillers. These polymers possess many desirable properties of RTV silicones, including biocompatibility and resistance to degradation on exposure to ultraviolet light and heat. In addition, they exhibit improved edge strength, low modulus of elasticity and colourability.<sup>21,22,23</sup>

### **Silicone foam (Silastic 386):<sup>24</sup>**

An element in silicone, when mixed with a stannous Octate catalyst, releases a gas in the vulcanization process as bubbles are released with the resulting silicone mass

being increased and density being decreased, which presents a much lighter material. This process requires special flasks to deal with expansion problems while the gas is forming during processing. The mold also requires venting for gas release and reduction of expansion of the prosthesis.

### **High Temperature Vulcanizing (HTV) Silicones:**

HTV Silicones possess better physical properties especially tear strength than RTV Silicones.<sup>25</sup> This material may present as a one- or two-component system with a putty-like consistency. Platinum salt is used as the catalyst for addition reaction polymerization and dichlorobenzoyl peroxide for condensation reaction polymerization. A metal mold is required for processing at high temperatures. This material is not as elastic as MDX 4-4210 or other RTV silicones and is not as applicable in situations of mobile tissue beds.<sup>26</sup> These are usually white, opaque materials groups. They exhibit improved edge strength, with a highly viscous putty like consistency low modulus of elasticity and colorability. These exhibit excellent thermal and colour stability when exposed to U.V. light. Al-Harbi et al studied the mechanical behaviour and colour change of HTV(TechSil S25) and RTV(A-2186) and (MED-4210) elastomers after outdoor weathering in a hot and humid climate. The heat-polymerized elastomer showed better mechanical durability and colour stability compared with the room-temperature polymerized materials. Heat-polymerized elastomer showed the greater values of tear and tensile strengths and elongation of specimens exposed to outdoor weathering conditions. It showed the least amount of color change among the pigmented specimens exposed to outdoor weathering.<sup>25</sup> These siloxane facial materials are biologically inert and have better strength.<sup>27,28</sup>

Examples of HTV silicones- Silastic 370, 372, 373, Tech sil 25.

**Q7-4635, Q7-4650, Q7-4735, SE-4524U:** Is a new generation evaluated by Bell which is available as a single component system. It shows improved physical and mechanical properties as compared to RTVs.<sup>29,30</sup>

### **Polyurethanes:**

This maxillofacial prosthesis material is obtained by mixing a polyol component (a mixture of polyesters) which is soft, a diisocyanate component which is hard and toxic and an organotin catalyst. Prostheses can be made softer and more flexible by increasing the ratio of polyol to diisocyanate in the vulcanization mixture. These elastomers are denoted as polyurethane because they contain urethane linkages<sup>31,32</sup> The intrinsic and extrinsic coloring of this material is possible with esthetic results that exceed most currently used material. Polyurethanes can be made quite elastic without compromising edge strength, thus permitting thinning and feathering of exposed tissue margins. Their flexibility is especially well-suited to defects with movable tissue beds.<sup>6</sup> These materials are difficult to process consistently. Little margin for error is possible when measuring the constituents. The isocyanates are moisture-sensitive and, when water contamination is particularly difficult to control in humid environments. If stone molds are employed, they must be thoroughly dehydrated before processing Di-isocyanate has some toxic potential also. Polyurethane is also degraded greatly by environmental factors.<sup>33</sup> Polyurethane is not colour-stable because of the effects of ultraviolet light and surface oxidation. These materials have poor compatibility with existing adhesive systems. Cleaning the adhesive from the prosthesis is difficult and frustrating for many patients. Often, extrinsic coloration is removed during this procedure. Care must be taken when

handling the isocyanates as they are toxic. Free isocyanates have been found as cured restorations, indicating a potential for local irritation. Stone, epoxy, urethane, or metal molds can be employed for processing.

### **Acrylic Methyl Methacrylate Resin:**

Acrylic resin prostheses can be used for restoration of defects with tissue beds that are relatively non-mobile. Material is readily available and physical and chemical properties and processing techniques are familiar to dentists. Both extrinsic and intrinsic coloration can be utilized with acrylic resin. Extrinsic coloration is easily accomplished with acrylic base paints using chloroform or monomer as solvent. Alteration and feathering of exposed margins are possible due to the strength of the material. It is compatible with most adhesive systems and is easily cleansed of adhesive or derbies. Longer durability (serviceable upto 2 years) and rigidity is the primary disadvantages of acrylic resin.

Duplicate prostheses are not possible because of the destruction of the mold during removal from the flasking apparatus. It is difficult to utilize undercut areas since acrylic is a hard material. Psychologically, acrylic is less acceptable by the patient.

But still, acrylic is a favoured material for maxillofacial prosthesis such as ocular prosthesis and as a base structure for silicone prosthesis.<sup>34-39</sup>

According to Andreotti AM et al, nano particle incorporation in acrylic resin directly influenced the acrylic resin properties, providing general higher color stability and microhardness values and lower flexural strength values, after accelerated aging<sup>40</sup>. The disinfecting solution used for routine cleansing of the prosthesis can affect the surface roughness and colour of acrylic resins<sup>41, 42</sup>

### **Acrylic Copolymers (Palamed, Polyderm):**

Acrylic copolymers are soft and elastic but has not received wide acceptance because of poor edge strength, poor durability, and degradation when exposed to sunlight. Processing and coloration are difficult. The completed restorations often become tacky, predisposing to dust collection and staining. The molds are under filled (by 10%) to permit expansion of the material and formation of the foam like center.

## Recent Advances in Maxillofacial Prosthetic Materials

### Silicone Block Copolymers:

Blocks of polymers other than siloxane are positioned with the traditional siloxane polymers in an attempt to modify the current physical properties of conventional silicone.<sup>43</sup> An example of this is the intertwining of polymethyl methacrylate into the chains of siloxane.<sup>44</sup> The improvement of the bioadhesive properties of elastomeric polydimethylsiloxane (PDMS) coatings is reported. This is achieved by a surface modification consisting of the incorporation of block copolymers containing a PDMS block and a poly [2-(dimethylamino)ethyl methacrylate] (PDMAEMA) block in a PDMS matrix. Observations highlight the significant role of hydrophilic groups in the surface modification of silicone coatings.<sup>45</sup>

### Polyphosphazenes:

Polyphosphazenes fluoroelastomer has been developed for use as a resilient liner and has the potential to be used as a maxillofacial prosthetic material. Modifications of physical and mechanical properties of these elastomers may be needed to satisfy the requirements for fabrication of maxillofacial prostheses.<sup>46</sup> Researchers in New Orleans dealt with maxillofacial prosthesis, have found that compounding polyphosphazenes with little or no fillers and decreasing the ratio of acrylic to rubber yields a softer rubber, with a HD<sub>A</sub> of 25, similar to human skin.<sup>11</sup>

## Other Materials

**Colours** - There are intrinsic and extrinsic methods of colouring. Many different types of colourants have been described in the literature. They include enamel porcelain, ceramics, Artist's paint, water soluble dyes, celluloid paints, photographic stains, acrylic resin stains, food colouring oil colours, kaolin, oil paints, dry earth pigments, Nylon flocking, commercial cosmetics and ceramic pigments.

The choice of colourants depends on the preferences of the individual clinician and the type of materials used for fabrication of the facial prostheses. However, kaolin and dry earth pigments should not be used with isophorone polyurethane since there is a substantial decrease in tear and tensile strength. Similarly, artist's oils should not be used with MDX 4-4210 as it interferes with the setting reaction.

In intrinsic colouring, colours are added to the base material prior to adding catalyst to the base material. Intrinsic colouring in heat vulcanized silicone prosthesis is accomplished with a milling machine. Metallic oxides on pigmented silicone concentrates are generally used, and red fibres may be incorporated, if desired, to simulate blood vessels. According to Montgomery's survey of currently used materials for fabrication of extraoral maxillofacial prostheses in North America, Europe, Asia, and Australia (2010) silicone pigments for intrinsic and silicone pastes for extrinsic coloring were favored over artist's oil colors and dry earth pigments.<sup>5</sup> Extrinsic colouring can be done by paint on method, spraying or tattooing. The introduction of silicone colourant technology began in 1992 with Factor II's silicone intrinsic colourants. In 1999, the silicone colourants were further refined using a cross-linking fluid to maintain viscosity to allow drop-by-drop dispensing. Silicone extrinsic paste pigments (Factor II) with additional

pigment to the cross-linking fluid were introduced shortly after.

Hue et al studied the effect of pigments on dynamic mechanical properties of a maxillofacial prosthetic elastomer and concluded that the type and concentration of pigment may influence the elastic and viscous portion of the properties of the maxillofacial elastomeric materials tested.<sup>47</sup>

### Adhesives:

It is a material used to adhere external prosthesis to skin and associated structures around the periphery of an external anatomic defect. A single component RTV has been developed to serve as adhesives for silicone prosthesis. Additional research is needed to determine the compatibility of commercially available medical adhesives with different types of maxillofacial elastomers and the compatibility of cleansing solvents with maxillofacial elastomers.

### Primers:<sup>48 49</sup>

They promote bonding between silicone and other maxillofacial prosthetic material. Example: S-2260, A-4-4, DC 1205 primer and Sofreliner primer S.

### Conclusions:

All materials in use today have exhibited some excellent properties but also some frustrating deficiencies. As yet, a material has not emerged that does not possess distinct and important undesirable characteristics. Prosthesis failure is caused mainly by colour change, poor maintenance, silicone tear and delamination.<sup>50</sup> Much effort has been expended recently in studying existing materials in the hopes of ameliorating their deficiencies. Selection of a material more often depends on the individual experiences and preferences of the clinician.

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