REVIEW ARTICLE

A REVIEW OF MAXILLOFACIAL PROSTHESIS MATERIALS

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ABSTRACT

A facial prosthesis restores normal anatomy and appearance, protects the tissues of a defect, and provides great psychological benefits to the patient. Materials for facial prostheses over the years include latex, polymethacrylates, polyvinylchlorides, chlorinated polyethylene, polyurethanes, silphenylene and silicone elastomers. Selection of a material for a facial restoration more often is dependent on the individual experiences and preferences of the clinician.

Key words: maxillofacial, prosthesis, methacrylate, silicone

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INTRODUCTION

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 (GPT 8). Prostheses are used to restore function and/or appearance in patients who have suffered injuries or deformities, which can be caused by congenital defects, trauma and neoplasm.

In German, prostheses are called Epitheses, originating from Greek word "epithema" which means "to put something on top" in order to conceal an abnormality. Somato-prosthesis, facial prosthesis or epithesis are general terms found in literature.

History of maxillofacial prosthesis materials.

Excavations of the Egyptian tombs (1613-2494 BC) have provided evidences of artificial eyes, ears and noses. Eyes made from precious stones, earthenware, enamelled bronze, copper, and gold were found within eye sockets1of Egyptian mummies.

Chinese had used natural waxes and resins to fabricate nasal and auricular prostheses[2].

Ambroise Pare(1510-1590) can be considered as the father of facial prostheses. His work is considered to be the foundation stone of modern anaplastology. He described nasal prostheses made of silver, auricular prostheses made of papiermache´ or leather, and ocular prostheses retained by a metal band passing around the patient´s head[3,4].

In the 19th century, metals such as gold and silver, as well as ceramic materials and wood were used to create prostheses[3].Between 1800and 1900, William Morton (1819), Kingsley (1880) and Claude Martin (1889) all attempted to replace nasal defects by using ceramic material[5].

Upham (1901) reported the fabrication of nasal and auricular prostheses from vulcanite rubber. This material was, at that time, widely used for intraoral prostheses[4].

During World War I, a material based on gelatin and glycerine, called elastine, was used to fabricate facial prostheses for patients injured in the war. Because of water absorption, this material lasted only for seven or eight days, and the patients themselves were taught to make their ownprostheses[3].

Prevulcanized latex was introduced as material for maxillofacial prostheses between World War I and World War II. This material was lightweight and easy to process. However, in the early 1940s, acrylic resin replaced vulcanized rubber, due to better processing and physical properties[3].

As an attempt towards more flexible materials, polyvinylchloride was used for a period starting from the mid-1940s[3]. Barnhart, in 1960, introduced a special silicone rubber for construction of facial prostheses; this was the major revolution in the history of maxillofacial prostheses[6]. From 1970 to 1990, different authors described many types of maxillofacial elastomers. Gonzalez described polyurethane for maxillofacial prostheses[7]. Lontz described the use of modified polysiloxane elastomers[8]. Lewis and Castleberry used phenylene compound to fabricate facial prostheses[9]. By the 1990s polyphosphazenes, a class of metallo-organic polymers has also been investigated for their suitability for facial prostheses by Lawrence Gettleman [10].

The currently available facial prosthetic materials are divided into methacrylate oracrylic resins, polyurethane elastomers, and silicone elastomers. Today most maxillofacial prostheses are made of medical grade silicone elastomer (siliconerubber)[3.4.]

Ideal properties of a maxillofacial prosthesis material

Lewis et al. [9] classified three categories of ideal properties of these materials:

1. Processing characteristics that include low viscosity extended working time, capability of intrinsic and extrinsic coloration, low processing temperature, and ease of molding using reusable molds.

2. Mechanical or performance characteristics such as high tensile strength, high percent elongation and elastic modulus, high tear strength, sufficient hardness, dimensional stability, proper surface tension, coefficient of friction, and resistance to chemicals

and ultraviolet light.

3. Patient accommodation properties that guarantee a product that is nontoxic, non-allergenic, non-carcinogenic, easily cleansable, lightweight and compatible with adhesives and that has a reasonable cost.

Materials used for maxillofacial prosthesis

Methacrylates (acrylic resins)

Acrylic resin is translucent and easy to color both intrinsically and extrinsically. It is also easy to process and is relatively hard, but durable[11]. Acrylic resins are used for fabrication of prosthetic eyes in ocular or orbital prostheses, and for frameworks, as a base material or clip carrier material in silicone maxillofacial prostheses[12]. Heat-polymerized acrylic is more tissue-friendly, containing no unpolymerized tertiary amines, and therefore it is preferred over autopolymerized acrylic. A-211 is a new fleshtone (self cure) premium acrylic polymer, mixed 3 to 1 with AC-198 Fleshtone Monomer (self cure) . This final product can also be tinted to various additional colors simply by adding oil paints to the monomer.

In case of repetitive surgery, the acrylic prosthesis can be temporarily lined with soft tissue liners. Acrylic is used particularly in those cases in which little movement of the tissue bed takes place during function. It has good strength and can be fabricated with a feather margin. It has a good life of about 2 year.

Its main disadvantages are rigidity, duplicate prosthesis is not possible because of destruction of the mold during processing and water sorption which results in increased weight[13].

Acrylic Co-polymers

Oils or other plasticizers can be added to produce copolymers, which are used as flexible polymethacrylates in maxillofacial prosthodontics [14]. Polymethyl methacrylate can be plasticized with butylacrylate and methyl methacrylamide, to be used as synthetic latex (acrylic latex). However, because of the time-consuming fabrication and the short durability of the material (3-4 months) this material is not suitable for facial prostheses [12].

Acrylic co-polymersare soft and elastic but have not received wide acceptance. They possess poor edge strength and poor durability. They are subjected to degradation when exposed to sunlight. Processing coloration is difficult. Completed restoration often become tacky, predisposing to dust collection and staining[13]. Incorporation of high molecular weight acrylic polymers with molecular blocks of polymer like polyether urethane, hydrocarbon, fluorocarbon or silicone can eliminate the short comings of traditional acrylic copolymers and contain camphoroquinone as a photoinitiator[36].

Thermoplastic materials

Thermoplastic materials for dental prostheses, Valplast (Valplast Int. Corp. - USA) and Flexiplast (Bredent - Germay), were first introduced to dentistry in the 1950s. Both materials were similar grades of Polyamides (nylon plastics). Thermoplastic resins tend to have predictable long-term performance. They are stable and resist thermal polymer unzipping. They also exhibit high creep resistance and high fatigue endurance as well as excellent wear characteristics and solvent resistance. A significant percentage of the population is allergic to free monomer and these materials offer a new safe treatment alternative for these individuals. In addition, thermoplastic materials have almost no porosity, which reduces biologic material build up, odors, and stains and exhibit higher dimension and color stability.[32]

Thermoplastic resins are used for a broad variety of applications from removable flexible partial dentures, preformed partial denture clasps, fiber-reinforced fixed partial dentures, temporary crowns and bridges, provisional crowns and bridges, obturators and speech therapy appliances, orthodontic retainers and brackets, impression tray and border molding materials, occlusal splints, sleep apnea appliances, and implant abutments.[33]

Polyvinylchloride and co-polymers:

Polyvinyl chloride is produced by polymerization of the monomer vinyl chloride (VCM). Polyvinyl chlo-

ride is a rigid plastic that is clear, tasteless, and odorless, with a glass transition temperature higher than room temperature[37]. For maxillofacial application plasticizers are added to produce an elastomer at room temperature.

It is processed at 150°C and metal mold are generally used[37].A wide variation in properties can be obtained by altering the proportion of the reactant and catalyst. These properties include increased flexibility and adaptability to both intrinsic and extrinsic colouration. Recently a copolymer of 5% to 20% vinyl acetate, with the remaining percentage being vinyl chloride has been introduced. The copolymer is more flexible, but less chemically resistant than poly vinyl chloride[38].

The disadvantages of this material is the early loss of plasticisers, resulting in colour loss, increased permeability, easy tearing of the prosthetic edges and absorption of body secretion. These factors can result in rapid degradation of the physical properties of the material [13].

Chlorinated polyethylene

Lewis and Castleberry reported similarity of this material to polyvinyl chloride in both chemical composition and physical properties[13].Chlorinated polyethylene has some advantages compared to silicone elastomer: it is possible to repair, reline or recondition - factors which may extend the lifetime of the prosthesis. It is also much less expensive than silicone rubber, has greater edge strength and does not support fungus growth. The fabrication of CPE prostheses requires high temperatures and metal molds, which complicates the fabrication process [11,15]. The coloration has to be done with oil-soluble dyes by using a laminating technique, with layers of pigmented and unpigmented material[16].

According to Gettleman et al. [15], chlorinated polyethylene is suitable for making thin feather edges of the prosthesis, or to simulate cartilage while silicone elastomer is more suitable for fabricating soft facial prostheses. More recent studies have shown that aging, due to exposure to ultraviolet radiation, sebum and perspiration, leads to considerable changes in the physical properties of chlorinated polyethylene, probably due to cross-linking reactions within the material [17].

Polyurethane

Polyurethane consists of a hard segment of an extended di-isocyanate and a soft segment of polyols, and the polymerization process is performed at room temperature with an organo tin catalyst. The proportion of these segments determines the softness of the end-product Turner & Castlebury reported the development of an aliphatic polyurethane prepolymer–isophorone.. The elastomer type of polyurethane has been used as material in maxillofacial prostheses[18]. The type of polyurethane usually used in maxillofacial surgery is Epithane-3, formally marketed as Dermathane by MIP Industries[9,19].

This material allows prostheses to be lifelike in appearance[19].In general, the tear energy necessary for breaking PU elastomers is higher than the other commercially available maxillofacial materials[20]. Furthermore, polyurethanes do not injure the tissues, are hypoallergenic and have a longer longevity (9-18 months) when properly cured and handled. Thus PU elastomers can be used with success in the fabrication of facial prostheses if the casting procedure is done accurately and carefully[18].

The iso-cyanate component is toxic and it is very sensitive to moisture during the fabricating process. The presence of moisture can lead to bubbles and incomplete curing of the material [21]. Cured polyurethane contains isocyanate in a bound and nontoxic form, but it is possible that remnants of the free, toxic isocyanate component may also be present in cured material. The polyurethane composition used in maxillofacial prosthetics has been found to be toxic to human tissue cells [22].

Silicone elastomers

Silicones are a general category of synthetic polymers whose backbone is made of repeating silicon to oxygen bonds. In addition to their links to oxygen to form the polymeric chain, the silicon atoms are also bonded to organic groups, typically methyl groups. The simultaneous presence of “organic” groups

attached to an "inorganic" backbone gives silicones a combination of unique properties, making possible their use as fluids, emulsions, compounds, resins, and elastomers in numerous applications and diverse fields.

Medical use of silicone elastomer began in 1953 and it was first used for externalprostheses in 1960 by Barnhart [23]. A great variety of maxillofacial silicone products has been developed since the 1960s. It is still the most commonly used material for fabricating the surface of, or entire, facial prostheses[3,4].

Silicones are classified into 4 groups according to their applications[13]:

Class I: - Implant grade, which requires the material to undergo extensive testing and must meet FDA requirements.

Class II: - Medical grade, which is approved for external use. This material is used for fabrication of maxillofacial prosthesis.

Class III: - Clean grade

Class IV: - Industrial grade, commonly used for industrial applications.

The two major groups of poly-dimethylsiloxane silicone elastomers used for fabrication of maxillofacial prostheses are:

1) Room-temperature vulcanizing (RTV) silicones – these include a filler of diatomaceous earth particles and are composed of two main parts; a catalyst (stannous octate) and a cross linking agent, ortho-alkyl silicate. This group includes a variety of materials namely Silastic 382 and 399. They are inert, colour stable viscous polymers. MDX4-4210 is also widely used in the manufacture of maxillofacial prostheses [10]. These materials are translucent so they can be blended with suitable earth pigments to replicate the patient's basic skin colour, with higher colour stability. The material is biologically inert and processed easily. Furthermore, it can retain physical and mechanical properties at a wide range of temperatures. The main disadvantage of these materials is poor edge strength [13].

2) Heat-temperature vulcanizing (HTV) is used when higher tear strength is required. Tear strength is determined by the type and nature of the cross linking in the catalyst. Different heat vulcanized silicone elastomers exist and include: Silastic 370, 372, 373, 4-4514, and 4-4515. They are highly viscous white/opaque materials with a dichloro benzyl peroxide/platinum salt catalyst. Different amounts of silica fillers are added according to the degree of hardness, tensile and tear strength that is required. The material has thermal and colour stability but it lacks flexibility and restricts movement. It has poor aesthetic output because the material is opaque and many consider it to have an artificial or lifeless appearance. A new generation of (HTV) are Q7-4635, Q7-4650, Q7-4735, SE-4534U and these have shown improved mechanical properties compared to MDX4-4210 and MDX4-4514 RTV Silicone [10]. Lontz etal reported a new type of HTVsilicone, poly di methyl siloxane(PDM). Itwas developed by the Veteran's Administration.

Room temperature vulcanizing (RTV) silicones have been preferred because of their easy fabricating process. Stone molds can be used, and even if the polymerization reaction occurs at room temperature, the process can be accelerated at higher temperatures [9]. Heat temperature vulcanizing (HTV) silicones are generally stronger, tougher and stiffer, but the fabrication is more complicated as the material requires a milling machine and metal molds during fabrication [9].

One non-desired property is that silicone rubber is unmodifiable, which means that the whole prosthesis has to be remade due to possible changes of the underlying tissue, which may occur due to the results of healing, radiation therapy or further surgery. Silica or other fillers are added to increase the tensile strength, but the fillers may give rise to a loss of translucency. Other main disadvantages of silicone elastomers are low tear and edge strength, relatively low elongation, problems with color stability [11,14] and the potential to support bacterial or fungal growth[3,4].

Recent advances in Silicone elastomers

MDX 4 – 4210

It is a low temperature, vulcanizing silicone polymer provided as a two component kit. The polymerization reaction is addition reaction with no by product. It is very colour stable. It has a high tear strength compared to RTV silicones .Unusually thin edges can be designed in prosthesis without the risk of damage during wear & removal. Accelerated aging tests have shown that the elastomer is very colour stable[13]. According to Moore it has improved edge strength and superior coloration[34].

Sil Phenylenes

They are arylene silicone polymer. It is synthesized & formulated as a pourable, viscous, RTV liquid .It is transparent and reinforced with silica fillers. It is available as a three component kit base elastomer, tetrapropoxysilane (cross linking agent) and organotin catalyst. It has an unusual combination of high-tensile strength & low modulous (relative to other conventional RTV silicones)[13].

Silicone Block Copolymers

It has been introduced to improve some of the weaknesses of silicone elastomers, such as decreased tear strength, low percent elongation and its susceptibility to bacterial growth[13].

Polyphosphazenes

Fluroelastomer has been developed for use as a resilient denture liner, and has the potential to be used as a maxillofacial prosthetic material[13].

Cosmesil

It was described by Woofaardt[35]. It is a RTV silicone showing a high degree of tear resistance[13].

Foaming silicones

Silastic 386 is a form of RTV silicone. The gas forms bubbles within the vulcanizing silicone. After the silicon is processed, the gas is eventually released; leaving a spongy material. Formation of bubbles within the mass can cause the volume to increase by as much as seven fold. Purpose of the foam silicon is to reduce the weight of the prosthesis.

Platinum Silicones

A-2000 isthe latest in the development of elastomers specifically formulated for prosthetics. This is the first generation of1:1 mixture RTV silicone reacting well with thixotropic agents. The clinicians can control the viscosity of this silicone while working with the uncured material. A-2002 Platinum Silicone Elastomer is a new, lowdurometer, 10:1 by weight platinum, optically clear silicone elastomer[38]. This low viscosity silicone is pourable and reacts with thixotropicagents. A-RTV-40 is a new, a low durometer, shore A 40, 10:1 by weight, platinum, translucent silicone elastomer. This low viscosity silicone is pourable and reacts with thixotropic agents.

TinSil Silicone Elastomer

TinSil Silicone Elastomer [FX-108T, FX-308T] are the new condensation cure, RTV,low viscosity, translucent, low durometer, tin silicone elastomer, which has proven to be a very economical and versatile material with enhanced properties and physical characteristics.

Liquid Silicone Rubber (LSR) Systems

Liquid Silicone Rubber (LSR) Systems are two part 100% solids, pure dimethyl silicone elastomers, engineered for optimum performance in liquid injection molding (LIM) processes where high clarity, high strength molded parts. Liquid Silicone Rubber (LSR) is a pump able, colorless, translucent paste. When A and B components are mixed together in equal portions by weight, the paste will cure to a tough, optically clear elastomer via platinum catalyzed addition-cure chemistry.

Coloring agents and pigments

A maxillofacial prosthesis is characterized and colored with dry pigments, pigment suspensions, dyes or pastes to match the color of adjacent facial structures. The prosthesis should also possess a certain translucency to obtain a life like appearance. Rayon flock, thread or yarn, can be added to achieve a realistic skin appearance and texture.

Usually the combination of intrinsic and extrinsic coloring makes the color of a pigmented prosthesis match that of human skin. Intrinsic coloration plays an important part in this process since it sets the basic color and translucency. Intrinsic coloring is

less vulnerable to environmental conditions and handling than extrinsic coloring. Extrinsic coloration may be applied on the surface of a cured pigmented prosthesis which originally does not exhibit an acceptable appearance match[24].

Pigments and dyes play a key role in pigmentation and coloration of maxillofacial prosthetic elastomers. A color pigment acts as solid filler, which does not bond to the silicone. It is a finely divided colored substance that does not dissolve, but remains dispersed, when mixed or ground in a liquid vehicle. Dyes dissolve in liquid and give their color effect by staining the material [25]. Inorganic pigments are usually metal oxides while organic pigments are carbon hydrogen derivates of animal, vegetable or synthetic origin.

Adhesives for retention of prosthesis

Medical products that involve adhesion to the skin or adhesives that attach to human skin are known as pressure-sensitive adhesives (PSA), defined as viscoelastic materials, which in their dry state at room temperature can adhere strongly to a wide variety of substrates by application of slight pressure [26] for a short period of time without activation by water, heat, or solvent [27].

Nowadays, PSA for skin contact applications are mostly made of acrylic polymers because they are less irritating to skin[28]. Silicone adhesives (Holister) are a form of RTV silicone dissolved in solvent. Once applied, the solvent evaporates & a tacky surface forms that form bond with another surface. Despite their low adhesive strength, they have good resistance to moisture & weathering with low water sorption. Acrylic resin emulsions (Epithane-3, ProsAide) are composed of acrylic resin dispersed in water solvent when evaporated, leaves a rubber-like substance. Other materials include synthetic rubber, vinyl acetate, reclaimed rubber, vinyl chloride, styrene, & methacrylic. Factor II inc. A-4717 Silicone Elastomer is a two part, clear to translucent, pourable silicone system that cures at room temperature and forms a permanent high tack gel. Polymerization occurs without formation of heat RTV room temperature Vulcanizing. When used correctly it will self-attach to a silicone prosthesis as a permanent adhesive.

Adhesives has the advantages of easy application and removal from the prostheses[29]. A major limitation is achieving optimal adhesion of the prostheses for long periods of time. Another disadvantage of this method of retention is the interaction of the adhesive material with the patient's skin - perspiration, movement, sensitivity/allergy to the adhesive material. Furthermore, there is the issue of cleaning and removal of the adhesive material from the prostheses and the skin on a daily bases, which increases the possibility of tearing the prosthetic margin during maintenance [30]. Another critical problem relating to adhesive retained prostheses, and in fact prostheses in general, is colour fade. In addition to these problems, there are also concerns with alteration to the material consistency and properties with an increase in potential damage to the prosthesis[29].

Conclusion

Materials presently used for maxillo-facial prosthetics are improved and adequate but not ideal. It is highly desirable that the prosthesis be durable and has the capability of being used without significant compromise of esthetics and physical properties for at least one year [31].

The current materials used demonstrate poor long-term durability, and a prosthesis may become torn or lose its color within a short period of time. This overall deterioration has been attributed to certain environmental factors such as (1) exposure to the ultraviolet of natural sunlight, (2) wetting and drying of the elastomer, (3) surface abrasion resulting from the application and removal of cosmetics (adhesives and their solvents), and (4) secretions (sebaceous, nasal, and salivary) [31,32].

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