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Maxillofacial Prosthesis materials: A Review

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***Abstract*---**As the human face constitutes a center of attention in human relationships, the emotional pressure because of facial disfigurement can produce a high degree of handicap. These disfigurements can be congenital deformities such as cleft lip, cleft palate or acquired deformities such as accidental injuries. The rehabilitation needed is more because of patient's psychological and emotional demands rather than their physical deficits. The purpose of this article is to give a piece of in-depth knowledge and discussed the various maxillofacial materials and their recent advances. Although the current clinical scenario concerning the field of a maxillofacial prosthesis is promising, improvement in material and techniques to be expected in the future to have better results.

***Keywords*---**emotional pressure, facial disfigurement, cleft lip, accidental injuries, psychological.

Introduction

Maxillofacial prosthodontics is an art and science of cosmetic reconstruction for the regions in the maxilla, mandible, or face employing non-living substitutes that are missing or defective because of surgical intervention, trauma, pathology, or developmental or congenital deformities. However, to restore these defects surgeries can be performed. But surgeon work is limited by various factors such as limited availability of tissue, compromise local vascular bed, periodic visual inspection of the defect, and physical condition of the patient[1]. So, rehabilitation falls in the hands of prosthodontics. Maxillofacial prosthodontics is the branch of

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prosthodontics concerned with restoration or replacement of the stomatognathic and craniofacial structure with a prosthesis that may or may not is removed on a regular or elective basis[2]. Materials that are used for rehabilitation are not ideal, but they have been perfected to the point of practical use. In evolving a successful prosthetic facial replacement, three factors are necessary:

1. Creative ability
2. Technical knowledge
3. Materials that will allow the prosthodontist to fully exploit these talents.

Historical Background

Before 1600 A.D. Ambroise Pare (1510-1590), fabricated a nasal prosthesis using gold, silver, paper & linen cloth glued together. Pierre Fauchard (1678 – 1761) made a mask for facial reconstruction with silver for replacement of lost part of mandible. William Morton (1819-1868) fabricated a nasal prosthesis using enameled porcelain. In 1889, Claude Martin used ceramic material. Vulcanized rubber was introduced in 1900 and was used for a facial prosthesis. In 1913 gelatin-glycerin compounds were introduced. From 1940 to 1960 Acrylic resin was introduced and is still used for prosthesis fabrication. Adolf Brown used colorants. Brasier used acrylic resin polymer stains. Lontz used modified polysiloxane elastomers in the late 1970s. Gonzalez introduced and described the use of polyurethane elastomers[3]. Lewis and Castleberry described the use of siphenylenes. Udagama & Drane introduced Silastic Medical Adhesive Silicone Type A. After 1990 new generations of acrylic resins are being investigated by Antonucci and Stansbury. Gentleman described using polyphosphazenes for the facial prosthesis.

Materials

Acrylic Resins

They became popular after world war II and was employed for specific types of facial defects that are which required little movement in tissue bed during the function. Acrylics are best suited to temporary facial restorations due to being porous in nature. However, it is favor as a permanent material as it is durable, color stable, easily repaired, relined, and easily processed

Advantages

- Easily available.
- Both intrinsic and extrinsic coloration utilized.
- Strength -feather expose margins.
- Easily repaired, relined & processed.
- Serviceable -up to 2 years.
- Compatible with most adhesive systems and easily cleansed of adhesives or debris.

Disadvantages

- Rigid.
- High thermal conductivity.
- The duplicate prosthesis is not possible

Acrylic Copolymers

These are soft and elastic material and due to this they have not received wide acceptance. Other objectionable properties like Poor edge strength, subject to degradation when exposed to sunlight, Processing & coloration difficult, completed restoration become tacky due to predisposing of dust collection, or due to staining.

Palamed

It is a Copolymer of methacrylics and acrylics. It consists of base powders and stain concentrates, the solvent liquid that combined to form a dough like material. The shade guide is provided for base shade powders and stain concentrates. It is packed into close molds and cured in a hot water bath. The molds are underfilled by 10% to permit expansion & formation of the foam-like center. In Palamed ratio of ingredient must be proportioned with utmost care because too much irregularity in ratio will result in a stiff heavy unstable product or too little will result in the incomplete filled mold with large pores[4].

Visible Light Cure resins

It underwent polymerization without substantial exothermic reaction. Biologic testing indicated they are non-toxic and biocompatible. They are useful in the replacement of large full-thickness defects in the cranium & other regions and in cases of mandibular augmentation.

Advantages

- Accuracy of fit
- Ease of fabrication
- Ease of manipulation

Vinyl polymers and copolymers (Realistic, Mediplast, Prototype *III*)

It is a combination of polyvinyl-chloride & plasticizers. A copolymer of 5%-20% vinyl acetate with vinyl chloride was introduced for making it more flexible. Extensively used in the beginning but use decreased due to excessive shrinkage, long processing time, discoloration, hardening of the margins due to plasticizer migration and loss, and absorb sebaceous secretions[4]. However, efforts to improve polyvinylchloride were made by limiting the amount of plasticizer which increases the lifespan of the prosthesis up to 9 to 11 months. But problems remain relative to polymer degradation & darkening of the material secondary to UV exposure.

Advantages

- Flexible
- Adaptable to both intrinsic and extrinsic coloration process.
- Acceptable initial appearance

Disadvantages

- Loss of plasticizer-discoloration & hardening of the prosthesis.
- Poor edge strength.
- Easily stained & degraded.
- Lack-life like translucence.
- Absorb sebaceous secretions.
- Soil easily because of surface tackiness.
- Clinical usefulness extends 1-6 months.
- Poor dimensional stability of polyvinylchloride

Chlorinated Polyethylene

They are similar to polyvinyl chloride in both chemical composition and physical properties. But their processing procedure involves high heat curing of pigmented sheets of the thermoplastic polymer in metal molds.

Advantages

- Coloration, using oil soluble dyes possible
- repeated molding possible

Disadvantage

Use of metal mold

Polyurethane Elastomers

They have been used for over 50 years now to fabricate facial prostheses for individuals missing facial anatomy due to resection, trauma, or even congenital anomalies· Available for commercial and medical uses. Only one (Epithane-3) is available for facial restoration. It is synthesized with a wide range of physical properties by varying reactants & their amounts[4].

Components

- Hard segments-extended diisocyanates
- Soft segments-polyesters and isocyanates
- Catalyst-stannous octate or dibutyltin diacetate
- Coloring agents-inorganic colorants

Juan B.Gonzalez (1978)[5] conducted a study to evaluate the effect of altering the component ratio of polyurethane on its various physical and mechanical

properties, such as surface hardness, tensile strength, initial modulus of elasticity, and percentage of elongation. He concluded that-

- with every increase of 0.1 gms of Part B or the addition of the catalyst, there was an increase in surface hardness, tensile strength, initial modulus of elasticity.
- Whereas there was a decrease in percentage elongation with the same alterations in formulations.

Advantages

- Elastic
- Good edge strength
- Can be colored both intrinsically and extrinsically.
- Good cosmetic results

Disadvantages

- Difficult to process consistently.
- Are moisture sensitive.
- Not color stable.
- Poor compatibility of the material with an existing adhesive system.
- Cleansing the adhesive from the prosthesis can be difficult.
- Isocyanates cause local irritation.

Silicone Elastomers

Barnhart (1960) first use silicone elastomers for extraoral prostheses. They are chemically termed as polydimethylsiloxane. They are a combination of organic or inorganic compounds. The first step is the reduction of silica to silicon that is in elemental form. Then by various reactions the silicon is combined with methyl chloride to form Dimethyl dichloro siloxane, which, when it reacts with water, forms a polymer (polydimethylsiloxane).

- **Usage-** broad range of maxillofacial and anatomic prosthetic devices where flexible tissue.
- **Production:** can only be produces synthetically. It is a two-step process that creates a carbon-silicon bond, then making the silicon-oxygen bond that forms the chain.

In the first step, reaction between chloride vapor and silicone powder in the presence of a copper catalyst series of molecules (carbon, silicon, and chlorine atoms) take place. In the second step, by the process of hydrolysis and distillation the chlorine is replaced with oxygen to produce the silicone. **Mark A. Pigno, Millicent C. Goldschmidt, and James C. Lemon (1994)[6]** evaluated the efficacy of antifungal agents incorporated into facial prosthetic silicone elastomer. The study was conducted -

- to determine if the fungal growth is affected by the black discoloration of the prostheses.
- to determine the inhibitory effect of antifungal agents' nystatin and clotrimazole upon their incorporation into the silicone.
- to determine the life of the antifungal action with silicon.

Disadvantages

- Poor strength
- Receive colors with difficulty
- Some are opaque resulting in prosthesis that are cold and lifeless.
- Microbial growth
- Poor wet ability
- Good only with silicone adhesives

Silicones according to their applications are categories into 4 groups:

- Implant Grade
- Medical Grade
- Clean Grade
- Industrial Grade

Polymers have fillers for additional strength. Antioxidants & vulcanizing agents are added to transform the raw mass into a rubbery resin during processing. The silicone undergoes vulcanizing that is the process of crosslinking the silicone. Silicone polymer is vulcanized; this changes it from a liquid or putty-like paste to solid rubber. Depending up on the activation of the vulcanizing process, silicones are classified as:

- Room Temperature- Vulcanizing (RTV)
- Heat- Vulcanizing (HTV)

RTV Silicone Elastomers (Example: Silastic 382 & 399)

They continue to serve the needs of the maxillofacial restorations but with has limited aspects. They are available as clear solutions. A silicone polymer that is viscous includes a filler and a catalyst (Stannous octoate). Mixing stock elastomers with catalyst for curing, air entrapment in finished cured prosthesis - initiate tear & accumulation of skin exudates. Silica fillers (diatomaceous earth) enhance tensile strength and mask yellowing or discoloration sacrifices considerable translucency- difficult to attain internal (intrinsic) coloration. Dough corning manufacturers different kinds of RTV silicones.

- clear or translucent MDX4-4210
- semitransparent silastic 399
- opaque and white silastic 382.
- The Difference among these RTV is in their curing time and strength.

Advantages

- Color stable
- Biologically inert
- Easier to process
- Retain physical and chemical properties at a wide range of temperature
- Stone molds can be used

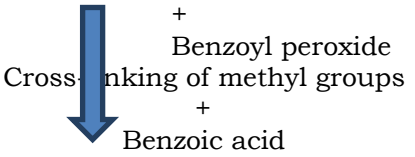
Disadvantages

- Poor edge strength
- Costly
- Cosmetic appearance of the material - inferior to that of polyurethanes, acrylic resins, polyvinyl chloride.

HTV Silicon Elastomer (Examples: Silastic 4-4514, SE- 4524U, Q7- 4635). It consists of 1 or 2 component systems with putty-like consistency. Two primary catalysts - platinum salt (addition) and dichlorobenzoyl peroxide (condensation) are used. The filler used is very pure, finely divided silica (size 30 μ). Processing of heat-cured silicones requires sophisticated instrumentation and high temperature[4].

Mechanism for formation

Polydimethylsiloxane (diorganopolysiloxane)



Advantages

- Excellent thermal stability
- Biologically inert
- Color stable when exposed to ultraviolet light

Disadvantages

- Opaque, lifeless appearance
- Not adequate elasticity in function
- Metal Molds

Advantages of HTV over RTV

1. Fewer chances of air bubble entrapment, since hand mixing of catalyst and pigments with the elastomer, is avoided.
2. Increased tear strength mechanical durability, and chemical resistance.
3. Increased biocompatibility and flexibility.

SilPhenylenes

Introduced by Dr. Castle Burry. They are the arylene silicone polymer which is synthesized and formulated as a pourable, viscous, RTV liquid. They are combinations of carbon and silicone polymers and therefore they have many advantages of both the polymers. It is transparent, reinforced with silica fillers. It consists of a kit that includes a Base elastomer, Tetrapropoxysilane (cross linking agent), and Organotin catalyst (Stannous octate)

Advantages

- The unusual combination of high-tensile strength & low modulus (relative to other conventional RTV silicones)
- Improved edge strength
- It is a high temperature- resistant organosilane for improved thermal stability of material for high-temperature molding
- Superior coloration
- Feel like skin

Disadvantage: require special metal molds

FOAMING SILICONES (Silastic 386)

It is a form of RTV silicone with stannous octate as a catalyst for the release of gas

Application

- Large maxillofacial prosthesis
- Lighter weight of the prosthesis

Advantages: The formation of the bubbles within the mass can cause the volume to increase by as much as 7 times.

Disadvantages: The foamed material has reduced strength and is susceptible to tearing.

MDX4 – 4210

Most popular among clinicians. In a survey by Andres, 41% of clinicians use this material. It is available as a two-component kit. The polymerization reaction is an addition reaction with no by product and hence, very color stable.
Dorsey J. Moore et al[7] in their study evaluated a polymeric material MDX-4-4210 Elastomer (which was not in use at that time) for its modulus of elasticity, resistance to tear propagation, and hardness. They compared this material to foaming silicon (commonly used for maxillo-facial prostheses). It was concluded that:

- The modulus of elasticity of MDX 4-4210 is one-fourth of Silastic 382.

- The resistance to tear propagation of MDX 4-4210 was better than Silastic 382.
- MDX-4-4210 was softer than silastic 382.

Advantages

- Polymerization addition reaction - no reaction by products.
- Adequate tensile strength.
- Improved qualities re relative to coloration and edge strength.
- Increased elongation and resistance to tearing – no reinforcement of thin edges.
- Surface texture and shore A hardness measurements - within the range of human skin.
- Unusually **thin edges** can be designed in a prosthesis without the risk of damage during wear and removal.

MPDS - Silicone Block Copolymers

(Methacryloxy propyl-terminated poly dimethyl siloxane)
They were introduced to overcome the weakness of silicone elastomers such as decreased tear strength, low percent elongation & bacterial growth over prosthesis. The silicone block co polymers has more tear resistance than conventional cross linked silicone polymers. Methacrylate located at the side chain undergoes free radical thermal polymerization and crosslinking and responsible for improved mechanical and bonding characteristics. The presence of methacrylate groups in MPDS-MF reduces the hydrophobicity which enhances its adhesion to non-silicone based adhesive[8].

Recent advances

Various advancements have occurred in the field of maxillofacial prosthesis not only in terms of imaging and prosthesis fabrication but also in impression materials and attempts have also been made to regenerate the lost parts.

Digital fabrication

A physical model can be manufactured based on the data received by CBCT or MRI. The digital fabrication methods can be divided into two categories: subtractive and additive. It is initiated with the scanning of the anatomical area or model known as computer aided design (CAD).

The **subtractive technique** used is the conventional numerically controlled machining known as milling which can be 3 axis, 4 axis, or 5 axis. The prosthesis is fabricated in the shape of the model by milling from a block of polyurethane or other foam. The **advantages** of using it includes low material costs and the possibility that these models can be worked on with surgical instruments. However, this method has two **limitations**. These are restricted motion capabilities which can be difficult to program complex geometries that can result in tool/workpiece collisions, and they are often the cases in medical application. The other disadvantage is that the materials used to fabricate the physical model.

The material to be used should be hard, tough, and sterilizable. The quality of the milled models was limited because the polyurethane foam is brittle and soft and the material is not sterilizable[9].

Additive methods are advantageous over subtractive method in the fabrication of the physical models of anatomical details. The main advantage of rapid prototyping is that medical models can be created that have undercuts, and complex internal geometries such as neurovascular canals or sinuses in no time and less effort. They are translucent and the internal geometries can be easily seen. The main problem with milling is that very small geometries are difficult to make, and it is expensive[10].

The development of rapid prototyping systems has led to the creation of customized 3-dimensional anatomic models that exhibit a level of complexity unknown with conventional numerically controlled based equipment primarily because the rapid prototyping method includes the building an object in layers defined by a computer model that has been virtually sliced. This helps in the production of complex shapes with detailing in internal and undercut areas. By incorporating 3-D scanning as a modeling technique, the user obtains a digital model of the proposed anatomic part. The data perceived can be manipulated to create a reproduction of facial surface features, mirror anatomic parts, and produce models in various scales to compensate for patient growth or material distortions. The main advantages of rapid prototyping technologies are reduced operating time and, which leads to a greater quality of prosthesis, increased patient comfort, greater patient satisfaction, and a lower cost of treatment in the long term[11].

Tissue engineering

Stem cells are unique types of cells that have a specialized capacity for self-renewal to give rise to one or sometimes many different cell types. Rehabilitating facial expression is more delicate and complex. This method has now gained popularity with the introduction of stem cells into regenerative dentistry. Tissue engineering is mainly composed of 3 units: stem cells, signaling molecules, and a scaffold[11]. Stem cells can be divided as-

- Embryonic stem cell
- Adult stem cell
- Heamatopitc stem cell
- Mesenchymal stem cell
- Induced pluripotent stem

Clinical application of stem cells

These cells can be used to correct the larger craniofacial defects by regeneration of bone and soft tissues. Surgical correction can be done by transfer of tissue which might result in all or either of the following:

- Loss of function of the lost part
- Donor site morbidity

- Scarring
- Infection

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Stem cells from dental pulp has the probability for osteoblast formation that is a good source of bone formation. Stem cells can be obtained from bone marrow and dental pulp can be used to correct larger defects. Stem cells obtained from exfoliated deciduous teeth (SHED) have the ability to promote wound healing.

Newer impression materials (J series alginates and Elastomer)

1**. J -603 Special formula alginate**

- Special formula for making an impression of ophthalmic area as it has neutral pH that prevents irritation
- It has fine grain particles.
- It is creamy in consistency, bubble free material

2. J – 6390 alginates

- Ideal for making an impression of hands, feet, or small objects
- Bright pink in color or white
- White has setting time for two-three minutes

3. **J – 6370**

- Introduced for making an impression for socket duplication and smaller impressions
- Alginate sets within 3 min 20 sec

4. J – 6380 alginate (6 minutes)

- For making an impression of Head and larger areas
- Smooth, strong, firm, and flexible

5. J – 604 Fiber gel alginate

- 40 % stronger than conventional
- Adds tear strength, prevents run and drips
- Retains moisture, Reduces shrink rate
- Remains soft and flexible
- Delayed pouring without loss of details

Elastomers

FX – 302-1 clone silicone impression material

- Ideal for quick impression and multiple pours
- Available in two parts
- 8 minutes Room temperature vulcanization
- Expensive

Nanoparticles incorporation

In 2008, Hang Yu conducted a study to evaluate the effect of different concentrations of nanosized oxides of various compositions on the mechanical properties of a commercially available silicone elastomer. The incorporation of Titanium, Zinc, or Cesium nano-oxides was added in various concentrations to a commercial silicone elastomer (A-2186). It was found that with their incorporation the overall mechanical properties of the commercial silicone (A-2186) maxillofacial elastomer[13].

Cleaning of Prosthesis

The care and cleaning of the maxillofacial prosthesis improved the success of the treatment. But for this, the patient should be motivated and correctly instructed. Both acrylic and silicon harbor microorganisms. Silicone retains these on its surface. Therefore, for external use, use water and any neutral soap. Besides these, chlorohexidine is also an excellent mode for cleaning. Other auxiliary methods include the use of isopropyl alcohol, hydrogen peroxide[14].

Conclusion

Although wide varieties of materials are in use, to date none of the materials shows desirable properties and duplicates of human skin. Currently, the most widely accepted materials are silicones (Room Temperature Vulcanization). Most common among them is MDX4-4210. The selection of a material for a facial restoration is dependent on the individual experiences and preferences of the clinician. Prosthodontist work tends to be limited to the inadequate material available for facial restorations, movable tissue below, difficulty in retaining large prosthesis, and patient capability to accept the final result. However, Newer materials and techniques have improved the esthetics, life like appearance, and ease in duplication with the incorporation of even the slightest and minutest details. Planning of the prosthesis, the impression making, sculpting the model, and selection of the material, all these factors contribute to a successful prosthesis.

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