EAR MOULD MATERIALS - A REVIEW

Reg.No.02SH0021

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Independent Project as a part of fulfillment of First year M.Sc, (Speech and Hearing), Submitted to the University of Mysore, Mysore.

ALL INDIA INSTITUTE OF SPEECH AND HEARING MYSORE - 570006 May, 2003

CERTIFICATE

This is to certify that this Independent project entitled "EAR MOULD MATERIALS - A REVIEW" is a bonafide work in part fulfillment for the degree of Master of Science (Speech and Hearing) of the student with **Register No.02SH0021**.

Mysore May,2003

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Dr.M.JAYARAM Director All India Institute of Speech and Hearing Mysore - 570006

CERTIFICATE

This is to certify that this Independent project entitled

"EAR MOULD MATERIALS - A REVIEW" has been prepared under my

supervision and guidance.

Koleyilah

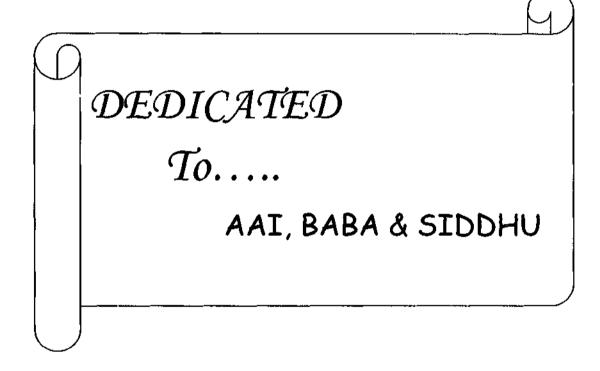
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Mysore May,2003

DECLARATION

I hereby declare that this Independent project titled "EAR MOULD MATERIALS - A REVIEW" is the result of my own study under the guidance of Dr.K. RAJALAKSHMI, Lecturer in Audiology, All India Institute of Speech and Hearing, Mysore and has not been submitted in any other diploma or degree.

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INTRODUCTION

The earmold is an integral part of the wearable hearing aid, but while it is easy for all of us to get excited about the latest digital technology we often forget about earmolds, which will make the instrument a success. To discuss the role of the earmold for hearing aid fitting according to Blue (1975) is somewhat like" discussing the role of the engine to the successful operation of an automobile" and this success of the mold will only be achieved, if we use good mold materials, starting with a good impression, a good impression material and a good earmold material.

In earlier days making and wearing an earmold used to be a dreadful experience for the patient because plaster of paris was the material of choice for impression and hard rubber used to be the mold material. But over the years different earmold laboratories have developed many satisfactory materials and now plaster of paris is replaced with soft impression materials and hard rubber is replaced with soft silicone. Many new accessory materials are also developed over the period, which enhances the properties of the mold.

Today earmold material technology has become dynamic and we have a variety of choice to match the client's need. Audiologists are able to match the needs of patients like feedback problem, aesthetic appearance, and in case of allergic reactions.

For better fit, soft molds can be used, for feed back problems Polyvinylchloride materials can be used, for aesthetic problems invisible molds can be used. So acoustic modifications like venting, horning and tubing, earmolds can also be subjected to further acoustic modifications with the use of appropriate earmold material. But still the literature has a very little information about the acoustic characteristics of the mold materials. And also the ear mold laboratories in India have been slow to exploit this vast reservoir of knowledge about the materials. The reason for this is perhaps the poor resource and financial condition of our country. As material is a part of the ear mold technology, it is our responsibility to make awareness about the latest technology and to encourage them to meet the challenge of new material technology.

The consecutive chapters deal with the variety of impression materials, ear mold materials, and other accessory materials along with their composition, manipulation, properties, advantages and disadvantages to make a successful ear mold.

METHOD

The information required was collected from sources like

- Books,
- Journals,
- Internet and
- earmold laboratories established in different countries. For this letters were written to the laboratories requesting the information. The information obtained is categorized under following headings.

Impression Materials

With hearing aids becoming smaller and more powerful than ever, ear mold labs are increasingly emphasizing the importance of anatomically accurate ear impressions. "Some experts contend that as many as 50% of unsuccessful fittings are the result of inappropriate impression materials or techniques being used" (Pirzanski, 1997).

The role of the impression material is to accurately record the dimensional and spatial relationship of the constituent parts of the external ear to make an impression mold. (Pirzanski1999, 2000). There are mainly three impression materials available in market for impression making:

- 1. Powder and liquid
- 2. Silicone materials
- 3. Alginate material.

If an ear impression material is to be acceptable for clinical use it must satisfy a number of requirements as listed out by Loavenbruck and Madell (1981).

- It should have appropriate viscosity required to accurately register the detailed contours of the ear.
- 2) It should possess dimensional stability and retain its shape from the time of removal from the patients ear until its processing. The texture of the cartilage in the ear canal can be firm, normal or soft. The softer the tissues, the more it will be stretched by the impression material injected into the ear leading to distorted final mold. Therefore the dimensional accuracy and stability of the materials used to

produce both impressions and earmold fit is crucial for good earmold fit. (Parker, Okpojo, Nolan, Combe, and Bamford, 1992).

- 3) 3. Material should be non-toxic and non-irritant.
- 4) Should have sufficient elasticity when removed from the ear.
- 5) Should be easy to use.
- 6) It must set in a reasonable time without undesirable effect eg. (no exothermic)
- 7) It must have sufficient mechanical strength, not to tear or permanently deform upon removal.
- 8) Must not be too expensive.
- 9) Should be biocompatible.

Because of availability and different properties of these different impression materials, "one of the still controversial and widely debated issue, in hearing instrument fitting is whether using soft or firm ear impression materials result in better ear impressions" (Pirzauski, 2000).

According to Pirzauski (1997) following parameters of any ear impression materials should be specified on the materials, container/packages by the manufacturers.

- Value of after mix viscosity.
- After cure hardness (shore value).
- Tensile strength.
- Stress relaxation.

Contraction ratio (for 7 days period).

Effectiveness of release agent.

Mixing ratio of the components.

Polymerization time.

This information is vital for the clinician to make appropriate decision regarding choice of impression material. (Nolan and Combe, 1989). However not all the manufacturers give this information. The properties which are mainly considered are

Viscosity:-

"Viscosity of impression materials is defined as a measure for the consistency of the material before polymerization"'(Pirzanski,1999).

The lower the viscosity, the easier the material flows and the less pressure that is developed during injection into the ear canal (Staab &Martin, 1995). (Viscosity is important for taking impression because, if hard material is used then soft tissues of cartilage part of ear canal will stretch more which will lead to snug fitting of the ear mold and if a very soft (runny) impression material is used, the cartilage will not be expanded adequately and the earmold may become loose (Pirzauski, 1999).

The viscosity of currently available impression materials varies significantly from one material to another and manufacturers generally do not provide a description of viscosity, but describes according to the colour. Example: Blue Silicone is easy flowing than pink one. But actually viscosity is independent of colour (Pirzauski, 2000). Viscosities of some of the types of impression materials given by different companies are as follows.

- a. Gun applied silicone— Lowest viscosity (most runny)
- b. One to one silicone for deep canal fitting: Harder but less than "C".
- c. General applications,
 - Light putty and catalyst silicone
 - Acrylic (liquid and powder) both has more viscosity than B.
- d. Stiff paste and catalyst silicone high viscosity)
- e. (Acrylic materials viscosity may vary depending on the mixing ratio. / (Pirzanski; 1999, 2000)

Shore Value:-

"It refers to the material's after cure hardness and does not define the flow characteristics of the material" (Pirzanski, 1999). The higher the shore value, the harder the material and the more the resistance against deformation of impression) (Staab and Martin, 1994). The manufacturers usually specify it.

Guessing materials viscosity based on its shore value is not recommended, because it refers to the materials after cure hardness and does not define the flow characteristics of the material (Pirzanski, 1997).

I This hardness of the elastic material is measured with an instrument called as durometer] and is expressed in units of shore (Staab and Martin, 1994,1995). Silicone materials have shore values in the range of 20 s to 70 sj Majority have 40s (Staab and Martin, 1995).

Bur usually shore values of impression material is virtually irrelevant while taking impression (Pirzauski, 2000).

Dimensional Stability:-

Dimensional stability of earmold impression depends on materials/tensile strength, stress relaxation and, shrinkage ratio (Pirzanski, 1999).

Tensile Strength:-

"It is, how much pull can be extorted on the final impression before it tears (Pirzauski 1999). A good material should have more tensile strength:

Stress relaxation: -

It describes the viscoelastic nature of the cured material. A finished impression having good stress relaxation should compress somewhat when pulled through a narrow part of the ear and then fully recover (Pirzanski, 1999).

• Silicone have good stress relaxation but acrylic impression materials have inferior stress relaxation: When forced out through a narrow ear aperture, an acrylic impression can lengthen and become permanently distorted (Pirzanski, 1999).

Shrinkage: -

It is the tendency of impression material to shrink with respect to time and occasionally with temperature (Pirzanski, 1999).

Audiological impression materials having a contraction ratio less than 2% over a period of seven days are most satisfactory for earmold preparation (Pirzanski, 1997).

Acrylic materials are prone to shrinkage but usually acrylic impression materials with a contraction ratio higher than recommended limit often yield adequate ear impression due to their moderate after mix viscosity, so can achieve satisfactory fitting. (Pirzanski, 1999).

Elongation :-

"It refers to the "stretch" of the finished impression.

If an ear impression has more elongation, it can compress somewhat when pulled through a narrow part of ear canal.

Details of each material is as follows:

1. Ethyl methacrylate

It is the common material used for ear impression. Commonly called as powder and liquid material as it is made up of two components powder and liquid.

It is composed of long chains of ethyl methacrylate monomer units (Agnew, 1986).

Composition:-

Ethyl methacrylate is chemically very similar to polymethyl methacrylate (Lucite acrylic). It has higher molecular weight and ethyl ester group as a side molecule instead of methyl groups, which results in a polymer that is softer and more flexible. (Agnew, 1986).

It is supplied as powder and liquid in which powder is a prepolymer that is capable of further polymerization upon the addition of more monomer. The powder also contains a chemical catalyst to initiate polymerization when the liquid monomer is added.

A polymerization inhibitor is also added to the monomer to prevent polymerization from occurring until the liquid and powder are mixed together.

Reaction time can be altered by altering the proportion of inhibitior (Koran;as cited in Craig and Powers, 2002).

Manipulation:-

Take a premeasured unit of powder and liquid as specified by the company and put it in a non absorbent mixing container, preferably a glass bowl. Pour all of the liquid provided into bowl first and then add the powder. By using a metal spatula mix till all of the powder is saturated. This process should be complete within 20-30 seconds from the time the powder and liquid contact each other. When the polymerization starts i.e., when the powder and liquid start sticking together, transfer the material into the syringe to take impression. (Morgan, 1987; Koran, 2002).

Properties:-

1. *Dimensional Stability: A* combination of time and temperature affects the dimensional stability of ethyl metacrylate. Agnew (1986) reported that ethyl methacrylate impression materials are subjected to warpage even at room temperature.

The softening temperature of ethyl methacrylate is 149°F, however significant dimensional changes have been reported as low as 100° F (Agnew, 1986).

Ethyl methacrylate impression often demonstrates warpage and droop of the canal towards the body. Sideways shift of the canal of 0.040" to 0.045" have been measured after five days by Agnew (1986).

2. *Shrinkage:* Agnew (1986), studied stability of ear impressions of ethyl methacrylate and he found, standard ethyl methacrylate impression materials are more subjected to inherent shrinkage than silicone. Additional factors such as exposure to elevated temperature or inconsistent mix ratios can accelerate the shrinkage. In addition to this, Pirzanski (1999) found, if the recommended liquid to powder mixing ratio is not observed, or if the finished impression is not processed promptly then the material will shrink. In support of this Agnew (1986) conducted one experiment and showed that 'shrinkage measured for the group with 10% additional liquid added, was approximately 12% more than for the recommended mix ratio and the shrinkage for the group with 20% additional liquid added was approximately 22% more than for the recommended mix ratio.

Agnew (1986) also noted that Ethyl methacrylate ear impression materials tends to shrink with time as a part of its curing processes. Volume shrinkage of about 6% to 8% during polymerization is seen.

Agnew (1986) measured the ethyl methacrylate impressions by double exposed photography and showed that, these materials revealed typical volume shrinkage of about 2% to 3% after 24 hours, increasing to about 4% to 5% in 5 days. Nolan and Combe (1997) observed contraction of 2% of ethyl methacrylate materials within 48 hours.

Temperature is also important for shrinkage of ethyl methacrylate materials.

Agnew (1986) exposed ethylmethacrylate impression materials for 115°F for 17 hours and found shrinkage of 7.6%.

3. *Stress Relaxation:* Acrylic impressions have inferior stress relaxation. When forced out through a narrow ear aperture, an acrylic impression can lengthen and become permanently distorted. A whitish mark will appear at the spot where maximum distortion occurred (Pirzanski, 1999).

Advantages' .-

- Adequate shelf life.
- It is a good impression material for making ITE hearing aid shells.

Disadvantages'. -

- Dimensional stability is very poor.
- Ambient temperature has a lot of effect on this material.

2. Silicone impression materials

Silicone materials are widely used for impression taking in the provision of earmolds. (Nolan, Elzemety, Tucker and Mc Donough,1978).

In dental science the silicone materials are called as non-aqueous elastomeric impression materials.

Basically silicone is a synthetic polymer based on a backbone of alternating silicone and oxygen atoms. We can create a wide variety of silicones with different properties by attaching different organic chemical side groups to the backbone(Johnson; as cited in Craig & Powers, 2002). Viscosity of silicone impression

material varies from supplier to supplier, usually it ranges from 20 shore to 70 shore value, although majority of materials used have about a 40 shore end hardness (Pirzanski, 2000).

Silicone is usually available in two forms:

- i. Paste type (available in semisolid form) and
- ii. Putty type (available in lump form)(Agnew, 1986).

Composition

Silicone impression materials consist of two parts—base and catalyst, which are mixed immediately before use.

The base material is called prepolymer which is a partly polymerized material of controlled and limited molecular weight which is capable of further polymerization

Polymerization is initiated by the addition of a suitable chemical catalyst,

typically an organometallic salt.

Inert fillers are used to modify the characteristics of the starting materials and the tensile strength of the final materials(Johnson ;as cited in Craig & Powers,2002).

Usually silicone impression materials contain 30% to 40% of filler content for syringe able pastes and upto about 75% filler content for putty material. (Agnew, 1986)

Properties :-

1. *Dimensional stability* — Silicone materials have greater dimensional stability and resistance to creep due to cross-linking with in the material itself which eliminates canal slump and warpage. (Agnew, 1986). Viscosity also plays an important role in dimensional stability. Pirzanski (1997) studied 16 deep canal impressions taken with a low viscosity silicone and compared with 16 deep canal impressions taken with moderately viscous silicone. 13 of the low viscosity impressions were satisfactory in terms of their dimensional stability. The other 3 are dimensionally inferior, their diameter measured at the acoustic seal was at least 0.4 mm smaller compared to their moderate viscosity counterparts.

2. *Tensile strength:* According to Staab and Martin (1994) a fairly low viscosity silicone material that has little pressure when inserted into the ear has good tensile strength, compresses fairly easily, does not expand during set-up time and holds its shape well.

3. *Shrinkage* : Silicone materials have minimum shrinkage. Paste type silicone shrinkage is higher than for the putty silicone because of the lower filler content of the paste type material (Johnson; as cited in Craig & Powers, 2002).

4. *Heat Resistance :* Silicone polymers have typical heat resistance temperature of 500°F which eliminates distortion due to temperature exposure.

When vulcanized, silicone impression forms a firm rubbery polymer that has excellent mechanical properties and retention of shape (Agnew, 1986).

5. Absorption of liquid: Humidity has very little effect on silicone impression as cross linked polymers do not absorb liquids (Agnew, 1986).

There are two types of silicone materials, which are classified according to the reaction between the silicone molecules, with terminal hydroxy group and an alkoxy orthosilicate, which are used for impression taking.

They are

- a) Condensation reaction silicones
- b) Addition condensation silicones

Condensation reaction silicones

It is one of the most commonly used silicone impression material.

Composition: -

It is supplied as a base and an accelerator. Base contains a linear silicone called a polydimethysiloxane, which has reactive terminal hydroxy group. Fillers like calcium carbonate or silica having particle size from 2 to $8\mu m$, and in concentrations from 35% for low consistencies to 75% for putty like consistencies are present. The accelerator may be a liquid consisting of stannous octoate suspension and alkyl silicate, or it may be supplied as a paste by adding a thickening agent (Johnson; as cited in Craig & Powers,2002.,Craig,Powers & Wataha, 2000).

Reaction: -

The available products set by a condensation reaction between silicone molecules with terminal hydroxy groups and an alkoxy orthosilicate, in the presence of an organotin compound as a catalyst (Nolan & Combe, 1985).

A cross-linked rubber is produced since more than one silicone molecule can react with alkoxy orthosilicate. An alcohol by product is produced with an endothermic temperature rise of about 1°C. This release of byproduct causes shrinkage of the material which is a cause for poor dimensional stability. (Nolan and Combe, 1985).

Manipulation:-

In paste type condensation silicone base paste and a liquid catalyst or reactor is provided. A length of the base is dispensed from the tube onto a graduated mixing pad and then one drop of the liquid catalyst is added for each unit length of base. A homogenous mixture is to be obtained.

In putty type material - a putty material as a very thick paste and a liquid accelerator is supplied(Johnson; as cited in Craig & Powers, 2002).

Some manufacturers have formulated a two paste putty system, which should be taken in equal amount and mixed to get a homogenous mixture (Dreve Otoplastic Product Catalogue).

The polymers do not have characteristic colour. Condensation silicone paste materials and putty can be made in variety of colors. Pastel pink, blues, greensand purple are common and varies depending on manufacturers. (Dreve Otoplastic Product Catalogue).

Temperature has a significant influence on the rate of curing for condensation. Chilling the materials or mixing on a cool slap slows the reaction rate. Altering the base catalyst ratio is another effective and practical method of changing the curing rate of this impression materials (GowriSankar, 2002).

Properties:

 Dimensional stability:- They show less dimensional stability compared to addition condensation silicone because of more shrinkage (Nolan and Combe, 1985). Pirzanski (1997) investigated the effect of time on dimensional stability of condensation reaction silicone and addition cure silicone and found that the condensation cure silicone contracted 0.5% and addition cured silicone contracted for 0.1% within 48 hours.

- Shrinkage :- condensation materials shrink over a period of approximately one week. Weight loss occurred for condensation materials, presumably is related to the loss of volatile reaction byproducts.
- Stress:- distortion may occur if the material is stressed too much at any time.
 Eg. On removal from the ear or during transporting to the laboratory.
- Elasticity:- The material is more likely to respond as elastic if it is strained quickly so that the deformation is elastic and recoverable. Prolonging the strain by removing the impression slowly increases the change for permanent deformation.
- 5. Tear resistance:- Tear resistance is high .do not tear easily as alginates
- 6. *Biocompatibility:* one of the most biologically inert materials.
- 7. Shelf life:- Shelf life is not very good.

Advantages

- Adequate working time
- Pleasant odor and no staining
- Adequate tear strength
- Better elastic properties on removal
- Less distortion after removal

Disadvantages

- Poor dimensional stability
- Potential for significant distortion
- Slightly more expensive
- Poor to adequate shelf life

Addition condensation Silicone

Addition silicones are frequently called as polyvinyl siloxane or vinylpolysiloxane impression materials. In contrast with condensation silicones, the addition reaction polymer is terminated with vinyl groups and is cross linked with hydride groups, activated by a platinum salt catalyst and no volatile byproducts are formed after the reaction (Johnson; as cited in Craig &Powers, 2002).

Composition :-

The addition type is available in extra low, low, medium and heavy and very heavy (putty) consistencies. It is available in base-catalyst form and two paste putty form.

Both base and catalyst parts contain a form of the vinyl siloxane.

Base paste contains - polymethyl hydrogen siloxane and also other siloxane polymers. Ctalyst paste contains - divinyl polydimethyl siloxane and other siloxane prepolymer. The accelerator / catalyst also contains a platinum catalyst which consists of platinum and 1,3 divinyltetramethyldisiloxane If the catalyst paste contains the platinum paste activator then the paste labelled 'base' must contain the hybrid silicone.Both parts contains fillers(Johnson; as cited in Craig and Powers, 2002).

Reaction:

Here volatile byproducts are not formed as in case of condensation silicone materials (Nolan & Combe 1985).

Setting takes place in the presence of platinum - containing 'catalyst' by an addition reaction between an organo-hydrogen siloxane and a compound with a vinyl siloxane group.

Cross linked products are produced, since the organo-hydrogen siloxne has more than one hydrogen atom capable of undergoing addition reaction, the volatile byproducts are not formed. (Nolan & Combe, 1985).

Manipulation

The light body and medium body vinyl polysiloxanes are supplied as two pastes and putty is supplied as two jars of high viscosity base and catalyst materials.

As both base and catalyst contains similar materials and have nearly equivalent viscosities, so are much easier to mix. The similarity of the paste consistencies and the shear thinning behaviors of these impression materials make the vinyl polysiloxane suitable for an automatic dispensing and mixing device.

This apparatus has certain advantages compared with hand dispensing and spatulation.

The two components are mixed homegenously in ratio of 1:1 to get a precise paste which is then filled in the syringe to take impression (Dreve Otoplastics Product Catalogue).

Curing rate of addition silicones appears to be more sensitive to ambient temperature than condensation silicones.

Cooling has little effect on the viscosity (Craig, Powers & Wataha, 2000)

Properties

- 1. *Elasticity:* The vinyl polysiloxane impression materials are the most ideally elastic of all the material available. Distrotion on removal is virtually nonexistent because these materials exhibits the lowest strain in composition values (Johnson; as cited in Craig and Powers,2002).
- 2. *Tear Energy:* Resistance to tearing is adequate, similar to that of the condensation silicones.
- 3. *Dimensional stability:* These are the most dimensionally stable of all existing materials because no volatile byproducts are formed resulting in no shrinkage (Nolan & Combe, 1985).
- 4. *Biocompatibility:* These materials are highly inert and does not cause any allergic reactions (Nolan & Combe,1985).

Advantages:

- Elasticity is more than condensation type silicone.
- Good dimensional stability as shrinkage is minimum.

• Can be used with all kinds of ages.

Disadvantages:

No significant disadvantage are found in this material, except that the cost is high.

3. Alginate hydrocolloid impression material

It is the cheapest and effective impression material.

Algin is a mucous extraction from brown sea weed (algae). This natural substance algin is a linear polymer with numerous carboxyl acid groups called as ALGINIC acid. Algenic acid is insoluble in water but salts obtained with sodium; potassium and ammonium are soluble in water, which forms alginate hydrocolloid.

It is also called, irreversible hydocolloid because once it changes from sol phase to gel phase, the material cannot be reliquidified (Johnson; as cited in Craig and

Wataha,2002). The principal factors responsible for the success of this type of impression material is that it is (1) easy to manipulate (2) comfortable for the patient (3) relatively inexpensive (Better molds for more people-A project for upgrading earmold technology in India, 1992). *Composition*

It is a two-component system of powder and water, which need to be mixed.

There is no reaction till the water is added to the powder. The chief active ingredient of the irreversible hydrocolloid impression material is one of the soluble aliginate such as sodium, potassium or triethanolamine alginates.

Diatomaceous earth is also added as filler which increases the strength and stiffness of alginate gel. It produces a smooth texture and a firm gel surface, which is not sticky.

Zink oxide also acts as a filler which aids in forming the sol by dispersing alginate powder particles in the water (Craig, Powers and Wataha, 2000).

Manipulation:

It is prepared by adding premeasured powder into premeasured water kept in a clean rubber bowl. The powder is slowly added into the water. Metal spatula is used for mixing. Care should be taken to avoid whipping air into the mix. A vigorous figure eight motions is best with the mix being swiped or stropped against the sides of the rubber mixing bowl with intermittent rotation (180°) of the spatula to press out air bubbles.

A mixing time of 45 sec to 1 minute is sufficient. A smooth creamy impression should be expected (Better molds for more people-A Project for upgrading earmold technology in India, 1992).

Reaction:

The typical sol - gel reaction of soluble alginate with calcium sulphate results in the formation of an insoluble calcium alginate gel.

Once the gelation starts, the impression material should not be disturbed because the growing fibrils will fracture and the impression would be significantly weakend. Optimum gelation time (The time interval between mixing of the material and the time until the material is no longer sticky when touched by clean, dry hand) is between 3-4 minutes at room temperature (20°C).

In clinical settings, gelation time can be altered by changing the water: powder ratio or mixing time. But this slight modification can have marked effects on the properties of gel, impairing the tear strength and elastic nature of material (Johnson; as cited in Craig and Powers,2002.,GowriSankar,2002.).

Properties:

- Dimensional Stability: Alginate impressions lose water by evaporation and shrink on standing in air. Impressions left on the bench for as short time as 30min may become inaccurate enough to require remaking the impression. The dimensional stability is good if the impression is casted immediately.
- 2. Tear resistance: It is very low.
- 3. *Strength:* It has poor strength and the manipulative factors that are under the control of the clinician affect the gel strength.

Overmixing breaks up the calcium alginate gel network and reduces its strength.

Insufficient spatulation results in failure of the ingredients to dissolve and complete reaction does not take place, which reduces the strength.

4. *Shelf life* : Storage temperature and moisture contamination from ambient air are the 2 major factors that affect the shelf life of alginate impression material.

Materials stored for 1 month at 65 to 70°C are unsuitable for use because alginate depolymerizes. Usually has a good shelf life.

Advantages:

- > Cheaper material than any other material
- Easy to use and manipulate.
- No harmful byproducts are formed.
- Adequate shelf life.

Disadvantages:

• Poor dimensional stability

Ear mold materials:

Earmold can be made with many different materials ranging from hard acrylic (Lucite) to much softer materials, such as silicone. These materials vary considerably in the types of finishing techniques they undergo, as well as the extent of shrinkange during the 'curing' process and also over a period of time(Ross ,2001). A range of earmold materials is available in market. They are

- Hard acrylic
- Soft acrylic
- Light cured acrylics
- Vinyl
- Polyvinylchloride

- Silicone
- E-compound
- Foam material
- Composite mold materials.

Usually the Earmold material selection depends on the person's and degree of hearing loss, canal tissue hardness, and allergic reactions to the earmold material. So keeping all these points in mind the audiologist should choose an appropriate material.

An ideal material should have following properties (Stakeholder forum on hearing enhancement (n.d.) http://cosmos.ot.buffalo.edu.).

- Flexibility to adapt to dimensional changes within the ear.
- Long term stability.
- Not susceptible to oils and wax.
- Will not shrink over time.
- Does not induce increased oil and wax production in the ear canal.
- Easy to clean.

But the problem is that there is no single material that will be effective for all people. Trial and error and a very careful observation is required to get an effective earmold for the particular patient. It should also be noted that each earmold manufacturer company labels the material with different product names, making it difficult for the consumer to determine the actual material type (Pakulski, 1999).

Let us consider each material in detail.

Acrylic

Also called, as Lucite. It is the most popular polymer material available for preparation of earmold. It is a plastic resin, which is rigid at all temperatures and can be recommended for mild to moderate hearing loss (www.rayshearing.com/earmold.htm). There are different types of acrylic materials available, which differ by their curing procedures. They are

- 1. Heat cure
- 2. Chemical cure or cold cure
- 3. Ultra Violet Cure

These materials can also be classified, depending on the texture as Hard acrylic and Soft acrylic.

Acrylic material is usually provided in a powder (polymer) and liquid (monomer) form, which needs to be mixed. Powder is provided in sealed packets and liquid in dark bottles.

Composition

Dusie contents of powder and riquid are	
Powder	Liquid
Poly methyl methacrylate or polymer	Methylmethacrylate(monomer)
Organic peroxide (initiator)	Hydroquinone (inhibitor)
Dyes & Pigments	Organic amine(Accelerator)
Plasticizer	Plasticizer
Inorganic particles	Cross-linking agent

Basic contents of powder and liquid are

Powder: Most of the commercial materials contain polymethyl methaacrylate modified with small amounts of ethyl, butyl or alkyl methacrylate to make it stronger. Initiators like benzoyl peroxide or diisobutylazonitrils is added to initiate polymerization when monomer is added. Various dyes can be added to obtain different colours.

Liquid :The liquid monomer contains resin like methyl methacrylate. A different kind of monomer can also be added which can change the curing procedure like heat curing ,chemical curing or photo curing. Inhibitors are added to give the liquid adequate shelf life and to inhibit premature polymerization (Craig, Powers and Wataha,2000).

1) Heat cured acrylic :

In this type, heating the material at about 100°C for 2 hours of duration cures the Acrylic material. (Better molds for more people-A project for upgrading earmold technology in India,1992). The final product is a hard acrylic material.

Manipulation

Manipulation is same as in case of any powder liquid material. Sufficient amount of liquid(monomer) is poured in a glass container to which powder (polymer) added. The liquid should be sufficient enough to completely wet the polymer powder. The liquid and the polymer are allowed to physically react in the same closed glass jar, until a doughy consistency is reached. During the reaction, mixture goes through many stages (1) sandy (2) stringy or sticky (3) doughy or putty like (4) rubbery (5) stiff.

The mixture is ready to pack in the flask when it separates cleanly from the walls of the glass jar. This takes around 15 minutes. Then the mixture is packed into plaster cast under pressure, clampled and kept in over temperature of 100°C for 2 hours.

During mixing, little polymerization takes place but no substantial polymerization occurs until the flask is heated to about 70°C(Craig,Powers,Wataha,2000. Better molds for more people- A project for upgrading earmold technology in India, 1992).When heating is done for given hours, the flask is brought to room temperature and then deflasking is done.

Common material used is poly methyl methacrylate.

Reaction :

Here a basic polymerization reaction occurs in which monomer and polymer reacts with each other forming the bonds and giving rise to a final hard product.

Advantages

- Does not shrink over time.
- Easy to grind and buff.
- Tubing can be easily glued.

Disadvantages

- can cause allergic reactions to the technicians as it releases harmful fumes while mixing of monomer and polymer.
- cannot recommend for children because the hardness of the mold might be harmful in case of a blow on the ear.

2) Chemically accelerated acrylic materials

When polymerization is done at room temperature by chemical accelerator, it is called as chemical curing. Also called as self curing or autopolymerization or cold curing (Gowrisankar, 2002., Koran ; as cited in Craig and Powers, 2002). Some of the acrylic materials can be cured by this procedure.

. . .

Composition:

It is same as for basic polymer materials, only the additional accelerator like tertiary amine and sulfinic acids are added (Koran; as cited in Craig and Powers, 2002). *Reaction:*

The accelerator reacts with the initiator at room temperature. Sufficient free radicles are produced which initiates polymerization reaction. Except for initiation rest of the reaction is same as heat cured type.

In earmold technology ethyl ethacrylate is the material used by cold curing. The reaction is exothermic.

It is available in powder and liquid form which is mixed and filled in the syringe to take the impression. The material is filled in the ear canal with the help of syringe and is kept till it becomes hard. It is mentioned that this material should be removed from the ear before body temperature is reached, but this results in distortion of mold with consequent loss of acoustic seal (Tucker, Nolan, Colclough, 1978). Owing to the presence of this difficulty Nolan, Elzemety, Tucker and McDonough (1978) noted that this material has proved to be the most difficult to work with. The main difficulty was encountered in knowing the ideal time at which the earmold should be taken out before it reaches the body temperature, and because of inter subject variability many impressions were distorted when taken out.

This mold can also be made by 2 stage process by filling the material in a negative form of plaster. .Bulmer (1973) found no statistically significant difference between quality of cold cure molds when made directly or indirectly.

Acoustic Properties

This material is a faithful representation of the ear contours with no shrinkage and provides a close contact with the contours of the ear providing a better acoustic seal (Bulmer ,1973 .,Tucker, Nolan and Colclough, 1978). In an unreported study by Huntingdon and Powell (as cited in Bulmer ,1973) has indicated that cold cure molds permit use of higher gains from hearing aids than do conventional mould, as the feedback problem reduces.

Huntingdon; as cited in Bulmer (1973) also noted a significant increase in the amplification of the aid was possible with the cold cure ear mould.

In another study by Tucker, Nolan and Colclough (1978), the mean gain for soft acrylic was found 55 dB which was more than 45 dB SPL of hard acrylic earmould. Nolan, Elzemety, Tucker and McDonough (1978) found mean, H.A.I.C. gain of 52 dB for hard acrylic and 51 dB for direct and indirect cold cured acrylic mold but this difference is not very significant.

Advantages

- No change of shape during processing
- Forms a good acoustic seal
- Improves hearing aid performance
- It is subjected to acoustic modification like Venting (Bulmer, 1973).
- It can be used with silicon to form a composite mould. Cold cure acrylic can be used in pinna part and silicone in canal part.

Disadvantages

The setting time of the material is inconsistent and mainly depends on the room temperature (in case of 2 stage processing). Colder the room longer will be the setting time. A room temperature of 70° F was found to be most satisfactory.

- It emits fumes from its monomer which causes excessive dryness of skin, while handling the material (Bulmer, 1973).
- If it is allowed to cure directly in ear canal, then causes irritation in the skin as the reaction is exothermic because of this it is not a material of choice..
- One of the major problems is physical irritation caused due to the roughness of the surface of the mould. The material is capable of very finely replicating small surface irregularities. Hence each pore on the skin is reproduced on the mold as a tiny raised area which acts as a irritant. (Bulmer, 1973).
- The sound bore drilling is a problem, as the material melts during drilling(Better molds for more people-A project for upgrading earmold technology in India,1992)
- The material cost is three times that of heat cure acrylic material(Better molds for more people-A project for upgrading earmold technology in India,1992)

3. Light cured/Ultra Violet cured/ Photo cured earmould materials

These are the current available earmould materials for the production of precise, high quality and biocompatible earmoulds. It has a great potential for the rapid production of earmoulds (Evans,Nolan,Combe,1991).

In this system, a photo initiatior molecule is present in the material (resin) which is activated by light rays of particular wavelength.

Previously ultraviolet light was used for activation. However, it had drawbacks such as retinal damage, limited penetration depth of light, reduction of intensity of U.V. light with time. Recently a new resin system is developed which can be activated by a visible light with a wavelength of 470 nm for activation. (Gouri Sankar,2002.,Craig, Powers, Wataha, 2000).

Evans ,Nolan and Combe (1991) evaluated, manipulative variables in the use of light curing and to comment on their potential for earmould fabrication. They found that the efficacy of polymerization of photo material is dependent on the degree of illumination which inturn depends on (i) choice of light box (ii) location within light box and depth and age of the resin in the box.

Box which has more light intensity, polymerization is rapid. If the material is kept near the source, results in rapid polymerization. If the depth of the material is around 12mm - 17 mm the light reaching reduces typically by about half and a third respectively (Gouri Sankar,2002).

Composition:

There are two types of materials available . One is hard UV cured material, resulting in hard earmold and other is soft U.V. cured material, resulting in soft earmold.lt is a semiliquid material, available in dark coloured bottles to protect it from sunlight. Commonly urethane dimethalycrylate is used for light activated curing. (Bettermolds for more people. A project for upgrading earmold technology in India, 1992). It is a composite having the matrix of urethane dimethyacylate fillers such as micro fine silica and high molecule weight acrylic resin monomer. (Craig, Powers & Wataha, 2000). A photoinitiator molecule is added called camphoroquinone.

Manipulation :

A finely cut final ear impression is kept in the cuff (a flask)containing photogel which is then cured. After the material is set, scoop out the impression and fill the material (methane acrylic) in the space and put it in light curing system for hardening. Working time is around 10 minutes (Dreve Otoplastics Product Catalogue).

Reaction:

The photo initiator molecule, camphoroquinone gets activated by light rays and reacts with dimethylamino methacrylate an amine, which releases free radicles and inturn initiates polymerization and the material becomes hard.

Advantages

- The residual monomer content of these materials is lower (0.4%) compared with conventional materials where it is around 0.7% to 7% (Kubicke,2000).
- These materials offer a good possibility of correction (Kubicke, 2000).
- The material is supplied as a single liquid so convenient to use
- Working time is under control as we can change the working time.
- There is less chance of air entrapment during mixing and insertion.

Disadvantages

• When the polymerization is occurring, shrinkage of the material takes place towards the light source, pulling it from marginal areas which are away from the light source (Gowri Sankar, 2002).

- Sometimes the area facing the light source gets polymerized but the area underneath might remain under polymerized as intensity of light will not reach there.
- In addition, furnished UV earmoulds requires surface buffing and polishing to make them cosmetically appealing. (To overcome this ultraviolet cured varnishes are available which provides surface with high density (Pirzanski, Chasin, Kenk, Maye, Purdy, 2000).

Properties of Acrylic materials

- 1) *Strength* : Pure acrylic materials are low in strength, brittle on impact and fairly resistant to fatigue failure (Craig, Powers and Wataha, 2000).
- 2) *Tensile and Compressive strength* : Heat cured and chemical cured, both have adequate tensile and compressive strength.
- Compressive creep : when the material is placed under load they will deform (creep) with time.

The lowest compressive creep rates are found for heat polymerized materials. Chemically accelerated acrylics have higher values for compressive creep (Gowri Sankar, 2002).

 Heat distortion temperature : Heat distortion temperature is a measure of the ability of a plastic to resist dimensional distortion by heat. It is 71°C to 91°C for polymethyl methacrylates. 5) Polymerization shrinkage : The light cured material has low polymerization shrinkage of 3%, because higher molecular weight oligomers are used. Also 2% of shrinkage for heat cured acrylic was seen (Gowri Sankar, 2002)
Combe and Nolan (1989) stated that for hard acrylic, the shrinkage depends on the curing process.

In terms of shrinkage, Quick cure > over night cure >overnight dry.

- 6) *Dimensional stability* : Chemically activated materials have more dimensional accuracy than heat cured (Craig, Powers & Wataha,2000).
- 7) Shelf life : Acrylic plastic packed in the powder liquid form have excellent shelf life as the liquid is well protected the powder is very stable ultra violet cured materials have less shelf life.
- 8) Allergic reactions: Meding and Ringdahl (1992) conducted a skin patch test for allergy contact dermatitis for 22 patients wearing methyl methacrylate earmolds and found six of the twenty two patients having allergy to the earmold material. The main cause for this is that it leaves 0.2% residual monomer even after curing. In 106 first time users of hearing aids, MacKenzie et al. (1989) describe itching among 40% of these patients using traditional acrylic earmolds. For 90 patients using UV cured ear mold ,Nielsen and Paden(1993) found 11 of the patients showing sensitization towards this material.
- 9) *Acoustic properties:* Attenuation : Any earmould should have good attenuation property so that it will provide less feedback for high gain hearing aids.

Parker, Okpojo, Nolan, Combe and Bamford (1992) calculated the Feedback transmission path attenuation (FTPA) for several materials and found that FTPA magnitude decrease with increase in hardness of mold material and found maximum for soft molds and minimum for acrylic material.

In an overall Noise Reduction Ratings (NRR) determined according to U.S. Environmental Protection Agency (EPA) method (1978) varied among traditional earmolds between 2.0 dB (vinyl) and 3.3 dB (Lucite). But according to Frank (1980) material did not differentially influences the attenuation provided by the earmoulds.

Kolpe (2002) found the attenuation provided by hand acrylic is 35dB.which is less than silicone and pvc material.

Vinyl or Polyvinylchloride (PVC) material

According to Pakulski (1999) vinyl and polyvinyl chloride is taken as the same material in earmold technology because they give almost the same quality final product. Chemically vinyl is poly ethyl methacrylate and PVC is polyvinylchloride.

Vinyl is a soft material that provides good acoustic seal and can be modified by special techniques. (Pakulski, 1999) and also provides greater wearing comfort (Martin,1996).

In a survey conducted by Pakulski (1999) 47% of the manufacturers in united states recommend vinyl as a material of choice.

It is recommended for children as well as adults with severe to profound hearing loss (http://www.rayshearing.com/earmold.htm).

PVC has added cross linking agents to add more strength (Craig, Powers and Wataha, 2000). It is supplied as a finely divided PVC particles suspended in a solvent. When this solvent is heated above a critical temperature of 150°C, the particles dissolve in the solvent .when the liquid is cooled finally an elastic solid is formed.

There is another derived material of vinyl called as thermoplastic vinyl. It softens with body temperature. It is less expensive than silicone and can be a alternative for it. It is a good material for children to improve the acoustic seal. It is available in different skin colours, (http://www.bradingrao.com).

Properties

- 1. Soft texture because of which it gives good acoustic seal
- 2. High Shelf life.
- 3. Shrinkage is present over a period of time.
- 4. Good tensile strength.
- 5. Good tear resistance but less than silicone.
- 6. Acoustic properties : It provides a better seal and greater wearing comfort (Martin 1996). Trychel and Haas (as cited in Pirzanski, Chasin, Klenk, Maye & Purdy, 2000) compared several vented earmoulds made of Lucite PVC and observed greater attenuation by PVC than by Lucite.

There are little published information examining the effect of PVC or vinyl earmould available (Pakulski, 1999)

Advantages

- Can be subjected to various acoustic modifications like vents and horns (Better molds for more people-A project for upgrading earmold technology in India, 1992).
- Can be used in composite moulds (soft quality)to form a soft power seal.
- Much more stable than soft acrylic as does not change shape with body temperature (http://LIU%20info%sheets%20%Ear%20mould%20materials.htm)
- Easy to insert and remove as tend to grip less in the ear canal.
- Can be made into any style of mold

Disadvantages

 Shrink and harden over time so frequent replacement is needed (http://www.brandingrao.com.).

Silicone earmould materials

Latest advancement in earmold technology is the use of silicone materials. It is softer material and is usually recommended for feedback reduction as it provides maximum seal (Pukulski 1998).

Pakulski (1999) conducted a survey of earmold labs and found that 30% of labs indicate silicone as a material of choice for children with seve re to profound hearing impairment.

A silicone mould can be made either by two step procedure or by one step i.e direct fitting procedure.

In two step procedure it is either heat vulcanized or room temperature vulcanised material.

Heat vulcanized silicone material

Here the silicone material is cured by heating it, therefore called as heat vulcanized.

Composition

It is a putty like material available in lump. The material present is polydimethyl vinyl siloxane copolymer with 0.5% vinyl side chains. Initiators like benzoyl peroxide is added. Filler is silica particles.

Here vulcanization means, the initiator undergoes thermal decomposition to form free radicals that cross link the copolymer into a three dimensional structure.

Manipulation:

First a negative form is formed in the cast with the help of impression material, to which the material is packed with pressure, which is then put at 180°C temperature for around half an hour. Later the flask is brought to the room temperature, which is then deflasked and mold is taken out

Advantages:

- Adequate shelf life
- Flexible material
- Good strength
- Available in many colours.

Disadvantages :

Manufacturing requires many machines (Gouri Sankar, 2002).

Room temperature cured silicone:

It is a high quality silicone which is vulcanized at room temperature within a span of 20-30 minutes with little heat evolution and minor shrinkage.

It is available in double cartridges which gets mixed in the nozzle of the syringe which comes out with pressure (Dreve Otoplasics Product Catalogue).

These materials are similar to addition silicone impression materials consisting of vinyl and and hydride - containing siloxane and are polymerized with chloroplatinic acid catalyst (Gowri Sankar, 2002).

Manipulation

Take out the ear impression and make it as a final trimmed earmould. Coat the impression with impression wax and embed the impression in the brass flask containing plaster. Close the flask and produce the counterpart. Negative impression will be formed in the other part of the cast. After curing the plaster, remove the impression and fill the place with silicone material with the help of a syringe. Close the flask to let it cure for 20-30 minutes at room temperature. Take out the mould for further treatment. Final hardness of this material varies between 20-70 Shore (Dreve Otoplastics Product Catalogue).

Advantages over traditional hot vulcanizing silicones:

- Easy processing of the material in double cartridges.
- No tempering is required.
- Polymerization time is less (20-30 minutes)
- Material is available in many colours and final hardness.

Direct fitting silicone earmould materials.

Here the earmoulds are made directly in the ear, without prior impression taking.

This is same as the silicone impression material where addition - vulcanizing silicone is used.

Polymerization takes place within ear canal with little heat evolution and the final mould is obtained which is further subjected to lacquering and then tubing.

The material is available in two cartridges which get mixed in the nozzle of the syringe.

This mould can be obtained only by syringing techniques (Dreve Otoplastics Product Catalogue).

Properties

- 1. It has minimum shrinkage.
- 2. Has good shelf life.
- 3. Dimensional stability is good.

- 4. Most non allergic material. Cockerill(1987)conducted skin patch test on 25 subjects out of which only one of it showed allergic reaction to the silicone.
- 5. Acoustic Properties : Silicone earmolds provide maximum acoustic seal thereby reducing the feedback.

Letowski and Burchfild (1991) compared sound attenuation provided by silicone and Lucite material earmould which was done by functional attenuation, real ear in situ attenuation, KEMAR-EAR-IN-SITU attenuation and found that silicone provides more attenuation than Lucite.

Pirzanski, Chasin, .Klenk, Maye and Purdy (2000)found, soft silicone attenuates more than hard acrylic, the difference between the two was around 4dB to 8.8 dB at 125 Hz to 2000 Hz. But with this it should also be noted that silicone provides more attenuation at high frequencies, so one should not prescribe silicone where attenuation of high frequency consonant is not desirable (Letowski and Burchfield, 1991).

Kolpc (2002) found that silicone attenuates 46 dB of noise.

Advantages:

- Provides the best acoustic feedback control.
- No polishing required hence no loss of accuracy.
- Comfortable to the wearer.
- Good cosmetic appearance.
- Do not change the shape and do not shrink or harden over time.

(http://LIU%20info% sheets%20-% ear% 20mould% 20 material.htm.)

- Hypoallergenic
- It has good shelf life.

Disadvantages

- Difficult to modify using grinding, venting or horning.
- Can be difficult to insert and remove so require some form of lubrication
- Ring fixing is not possible
- Sometimes the cured material has unpleasant odour.
- They are more expensive.

E - compound

In 1987 Emtech laboratories, Roanoke VA announced a new material for ITE shell earmoulds, commercially called as E-compound (<u>www.Emtech.com</u>).

It is produced by filling a polymeric matrix like Lucite, silicone or vinyl with hollow glass microspheres of various diameters. These glass microspheres increases the input impedence of the material which results in less sound energy entering the material. As a result E-compound provides better attenuation to external noises outside a frequency range amplified by the hearing aid (Letowski, Richards and Burchfield, 1992) and depending on this property, Ridenhour (1988) reported that 54% of this listeners demonstrated improved word recognition in noise with ITE aids having Ecompound shell compared with Lucite shells. Letowski, Richards, and Bunchfield (1992) conducted one experiment and compared viscoclastic properties of ITE shell materials made of polymethyl methacrylate (Lucite) and E-compound of Lucite called E-Lucite. Measurements were done with the help of a viscoelastometer Autovibron and found that mechanical loss in plain Lucite was greater than those in E-Lucite. This is attributed to greater mobility of a polymetric chain in the plain Lucite than in the E-Lucite.

In the second experiment by Letowski et al., (1992) comparison of mechanical vibrations passed through Lucite and E-Lucite was done. Here the mechanical properties were compared by measuring the amount of each material placed between a bone vibrator and a mechanical coupler. Frequency response from the bone vibrator was measured for direct coupling, indirect coupling through Lucite , indirect coupling through E-Lucite for a signal from beat frequency Oscillator. The results showed there is slightly more effective transmission of vibrations through E-Lucite than through Lucite.

In the third experiment by Letowski (1992) possible difference between the Lucite and E-Lucite in the transmission of sound pressure levels were assessed. The results of this study were contradictory to the previous studies. They found that both E-Lucite and E-Silicone, presented greater obstruction to sound wave transmission than respective plain materials. The mean difference in transmission loss between E-Lucite and Lucite was around 3 dB across the low and mid frequencies while for silicone and E-Silicone the difference increased to around 10 dB in the same frequency range.

Foam earmold material

Here viscoelastic foam is used to make the earmold. The foam is a slow recovering foam. It provides good sound attenuation. Oliveria, Hawkinson and Stockton (1992) tried the foam earmolds on ten BTE users and found that these molds were superior to the conventional earmolds. Kolpe (2002) found that these mold attenuates around 52 dB of noise.

Composite earmold materials.

Here the earmolds are made with hard backplate of acrylic and soft canal part of silicone.

The outer hard portion gives ease of removal and insertion ,while inner soft portion gives maximum acoustic seal and comfort.

Tucker, Nolan and Colclough (1978) experimentally found that the composite molds give a better performance in prevention of acoustic feedback than soft acrylic and hard acrylic molds.

Accessory materials:

In making a successful mold other than impression materials and mold materials, we need accessory materials to carry out processes like coating of impression material, polishing, grinding buffing, tubing and repairing of ear moulds. For this we need accessory materials.

All hard-body earmolds require sanding and polishing to facilitate insertion in the canal and for cosmetic purposes. The surface of soft earmolds in treated chemically for these same reasons. But these finishing techniques may slightly alter the outer dimensions of the earmold which might result in poor acoustic seal (Ross, 2001).

Accessory materials used in the laboratory are :

1. Plaster:

The first accessory material model for taking impression is plaster. It helps to form a negative form of the mould.

There are two varieties of plaster available for flasking.

Stone plaster which is more expensive but will have better finish and dental plaster which is less expensive.

Manipulation: The plaster is added in water, and the reaction takes place after which the plaster hardens..

For 20 gm of dental grade and for 50 gms of stone plaster, need 15 ml of water.

Then measured quantity of water and plaster powder are taken in the flexible rubber bowl mixed with a rigid metal spatula while mixing it is important to avoid air bubbles. Keep the impression mould in flask and pour plaster on it. Let the plaster set or harden(Better earmold for more people-A project for upgrading of earmolds in India,1992).

In case of photocuring, instead of plaster, a gel which is ultra violate rays permeable is used to form a negative form.

It is a addition silicon with gel consistency, tear resistance and cloudy in Appearance (Dreve Otoplastica Product Catalogue).

2. Separating medium

After the impression mould is removed from the cast a thin layer of separating get is applied with a brush so that any small cavities will be filled. The liquid contains chemical called sodium alginate.

Silicone lacquer is also available as a separating medium of silicone impressions and forms. (Better earmold for more people-A project for upgrading of earmolds in India,1992).

3. Polishing

After the mould is grinded, the next step would be polishing. It can be done in following ways.

Cloth polish/buffing with the help of fine powder called as pumice powder. (Better earmold for more people-A project for upgrading of earmolds in India,1992)

As an alternative sometimes chemical solution is used instead of powder polish, which cures in 30 seconds by Ultra Violate rays Mainly used for hard molds (Microsonic labor product catalogue2001. Dreve Otoplastica Product Catalogue).

A special silicone - lacquer which cures at air humidity containing dimethyl polysiloxane acetoxylan (e), phenylmethan (e) is used for lacquering silicone molds. (Dreve Otoplastica Product Catalogue)

4. Cement:

This cement or a thick cement is required to give a secure bond between the acrylic earmould and the tubing.

Thick cement is same as thin cement but it has acrylic powder in suspension (Frisch Labor System Product Catalogue). Vinyl cement is also available for tubing for all soft earmoulds except silicons.

5. Repairing material:

For repairing of acrylic hard mould cold cure acrylic is used. This allows it to act as a gap filler on the earmould where the sound bore diameter has been universed due to repeated retubing.

6. Wax:

Paraffin work is used for dipping the silicone mould into it which forms a thin layer over it. So when the final mould is hummed or polished, its dimensions will be change (Dreve Otoplastica Product Catalogue).

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