Advances in Earmold Technology: One-Stage (Direct) Approach

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Abstract

Many hearing aid users require a customized earmold. When the hearing impairment is severe or profound, it is essential that a good fit of the earmold is achieved to avoid leakage of sound and acoustic feedback (whistling) so that the full potential of the hearing aid can be achieved. Existing laboratory technology for the production of earmolds by a two-stage process leads to dimensional inaccuracy because of (1) unsuitable materials that shrink and (2) techniques used to achieve a surface finish. Recently, a novel soft material, from which an accurate earmold can be fabricated by a one-stage process directly in the ear, has been invented by the author and patented by the United Kingdom Department of Health. This paper describes the new technology, which could provide very significant benefits in the rapid fabrication of accurate earmolds without requiring sophisticated laboratory facilities. In addition, important implications for very young infants, the profoundly deaf, and for earmold use in developing countries will be discussed.

Key Words: Earmold, instant earmold, hearing aids, materials

There is increasing concern among professionals and hearing aid users that inadequate earmolds can limit the potential benefits of wearable hearing aids (NDCS, 1985) yet very little has been accomplished to improve upon the current situation in earmold technology. Recent studies (e.g., Okpojo, 1990b) indicate that material technology is a major factor contributing to the problems of inefficient earmold production worldwide.

TECHNIQUES AND MATERIALS FOR EARMOLD MANUFACTURE

Currently, earmolds can be provided using three different approaches: standard or pre-formed earmolds, customized two-stage earmolds, or customized one-stage earmolds.

Standard or Pre-formed Earmolds

Standard or pre-formed earmolds are fabricated in several materials and supplied in about five or six different sizes for users to try out at random and then choose according to optimal fit. This is inadequate for achieving good fit and acoustic benefits because many sources of error exist in this approach. The final earmold in this system is not constructed based on an impression from the user's ear(s) and therefore it becomes impossible to obtain an accurately fitting earmold for the user. Successful fit is largely dependent on the skill of the clinician in selecting an appropriate mold, as well as the user's ability to judge what is considered “suitable.” Further, the materials used for the manufacture of pre-formed earmolds have several drawbacks (Okpojo, 1990b).

Customized Two-Stage Earmolds

Customized earmolds are ordinarily prepared by a two-stage process. The first stage involves the construction of a clinical impression of the relevant part of the ear. This is taken to a laboratory where the impression is wax dipped and invested in a matrix medium, which could be either silicone (duplicating gel) or plaster. A polymeric material is cured in the plaster or silicone thus formed, and is then drilled, tubed, and polished. Currently available two-stage earmold materials include: hard...
acrylics, usually poly (methyl methacrylate); soft acrylics, plasticized polymers; poly (vinyl chloride); silicone polymers; and visible-light curing resins.

It is virtually impossible to make an earmold fit accurately by this technique. The size of the mold may differ from that of the ear because of many factors, and undersizing will result if the impression shrinks; the impression is trimmed; the earmold shrinks during processing, for example, polymerization shrinkage; the earmold shrinks in service, shrinkage associated with long-term polymerization, or with the loss of volatile components; the earmold is polished prior to fitting; or there is growth of the ear.

To compensate, it is typical for the earmold manufacturer to dip the impression in wax. However, over-sizing can result from the procedure of wax-dipping the impression and, in view of the above, it is impossible to guarantee accuracy of dimension. Other limitations of the two-stage fabrication approach are the inherent delays in a two-stage process and lack of ready access to the manufacturing processes that are required.

**Customized One-Stage Earmolds**

It is possible to prepare earmolds by a direct (one-stage) procedure, where the ear impression becomes the final earmold. The materials employed for the one-stage earmold manufacture include poly (methyl methacrylate); Instamold; Silisoft; and Otozen. In theory, this approach can avoid many of the above problems. Until recently, however, materials technology has not been sufficiently advanced to provide a suitable material. Problems with some suggested materials are multiple. A high degree of heat can be produced as a result of the setting reaction, with danger of causing burns to the ear (e.g., with acrylic resins). A high degree of setting shrinkage may occur, mitigating against a good acoustic seal (e.g., with acrylic resins). Poor mechanical properties, for example, too great a degree of hardness, may be a hindrance leading to loss of comfort for the wearer and difficulty in processing. Poor resistance to tearing forces, as occurs with silicones, may lead to difficulties in removal of the earmold. Also, problems of degradation of the tubing in contact with the earmold material may arise, especially with silicones.

In fact, the principal materials used for direct earmold making, poly (methyl methacrylate) cold-cure materials, have been formally withdrawn from audiologic applications in the UK. In spite of these limitations, unfortunately, it is still used in most developing countries (Okpojo, 1990a). Until recently, there was little systematic research directed toward solving these problems. Impression materials have been developed mainly for dentistry, and little or no progress has been made in meeting audiologic requirements. Okpojo (1990a) has developed some criteria for desirable properties that any audiologic material should satisfy. These criteria are discussed.

**Biocompatibility with Aural Tissues**

The monomer system should be nontoxic, non-irritant, and the setting reaction should have a low exothermal release.

**Suitable Handling Characteristics**

When the powder and monomer are mixed, the consistency of the formed dough should be such that the material is easy to apply to the ear (using commercially available syringes), with a sufficient working time of about 2 to 3 minutes, and a setting time of about 4 to 7 minutes.

**Dimensional Stability**

Shrinkage should be minimal, not more than 1 to 2 percent (linear), dimensional stability should be achieved over the wide range of temperatures and humidity that would be encountered in most tropical countries.

**Suitable Mechanical and Rheologic Properties**

The set material should be elastomeric (have elastic properties with freedom from permanent deformation after strain); be resilient; have adequate strength to resist breakage or tearing on removal from the ear or during processing (e.g., core boring, insertion of sound tubes, venting); have satisfactory consistency and texture to provide comfort; be easy to use with the minimum of equipment (preferably no drilling); be compatible with available tubing material (be stable and non-interactive with tubing); be compatible with wax, if used as an impression material for the two-stage process.

**Durability**

The material should have adequate shelf life for requirements of storage and distribution.
and the final product should have an acceptably high service life (i.e., strong resistance to daily wear and tear).

**Function**

The final earmold should have potential for handling the high acoustic gain required for users of high-powered hearing aids.

**Cosmetics**

The material should be esthetically pleasing and have no offensive odor.

**Management**

The material should be capable of being easily cleaned with ordinary water and cleaning preparations.

These criteria have been applied in clinical studies and have led to the development of Otana direct audiologic material.

**CLINICAL POTENTIAL OF OTANA DIRECT AUDIOLOGIC MATERIAL**

Michael Braden (Professor of Materials Science in Dentistry) of the London Hospital Medical College and the author have invented a new soft clinical material (Otana), with great potential for the fabrication of earmolds by a one-stage process, and for impressions by a two-stage process. This new material has recently been patented by the Ministry of Defence for The United Kingdom Department of Health. It consists of a polymer powder mixed with a liquid monomer to give a syringable dough, the setting reactivity of which can be controlled by modifying chemicals. The results of preliminary pilot investigations of Otana as one-stage earmold material (see Okpojo, 1990b) indicate that this novel, soft, acrylic-based, auto-polymerizing resin would overcome the major defects of currently available direct and two-stage earmold materials as listed above. In particular, linear shrinkage of Otana may be less than 1 percent, and acoustic attenuation on a pilot group of hearing-impaired ears was on the order of 62 dB, compared with averages of 50 to 65 dB for traditional materials (Okpojo, 1990b).

This novel material, and the associated technique for its fabrication, have economic advantages over existing earmold systems. For example, the components of this acrylate system are relatively inexpensive and it requires only basic tools to process into earmolds—a core borer, tube threader, and a scalpel. The one-stage technique for earmold fabrication is reliable and sufficiently efficient that an earmold can be fitted on a single visit to the clinic. This could have very significant implications for practice in the Health Service and in particular, pediatric audiology. For example, early detection of deafness is now feasible and hearing aid fitting for young children at 6 months of age or less is possible. However, rapid growth of the external ear means a new set of earmolds may be required every 4 to 6 weeks in childhood. Therefore, the one-stage approach would be helpful in avoiding delay between the impression construction stage and the earmold processing phase.

In addition, earmolds made using Otana and the one-stage technique can be manufactured in rural areas of most developing countries where electricity and laboratory facilities do not exist. The entire process of manufacture, personnel and materials inclusive, is cost effective and could be introduced into any existing health care delivery model, for example, the Primary Health Care Approach.

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**REFERENCES**

