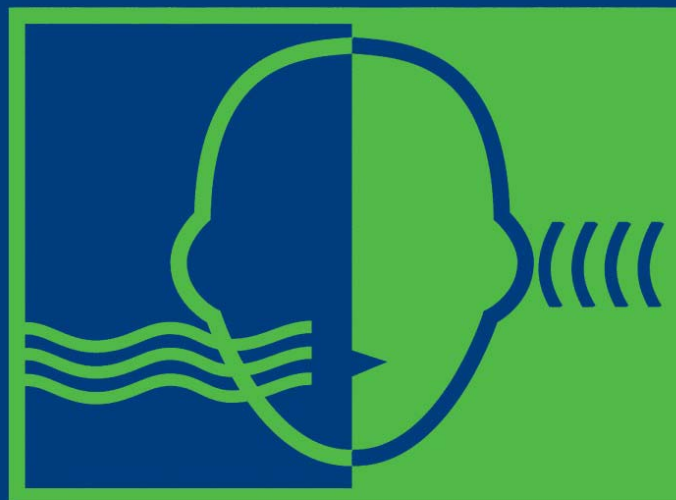


CASLPO



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**PREFERRED
PRACTICE
GUIDELINE FOR
EAR
IMPRESSIONS**

APPROVED MARCH 2005

PREFERRED PRACTICE GUIDELINE FOR EAR IMPRESSIONS

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A) Preamble

Preferred Practice Guidelines (PPGs) are necessary to ensure quality care to the people of Ontario who require an ear impression. An audiologist will be required to take an ear impression in order to achieve a number of potential different treatment options for a patient/client. It is important that the impression be an accurate representation of the external ear and ear canal to achieve the treatment goals of the patient/client.

While this guideline is recommended for the majority of cases, the College recognizes that there will arise from time to time exceptional circumstances and/or conditions when guideline procedures cannot be followed. In such instances the audiologist may be required to modify recommended procedures. This guideline is not intended to be a tutorial or to provide the audiologist with all the information required to perform ear impressions. Audiologists are ethically responsible to ensure that they are competent to make ear impressions and that their patients/clients are safe during the procedure. Audiologists should exercise professional judgment taking into account the clinical environment and the individual patient/client needs when considering deviating from this guideline. These departures from the guideline must be documented.

B) Scope of Practice

The *Audiology and Speech-language Pathology Act, 1991* states: "The practice of audiology is the assessment of auditory function and the treatment and prevention of auditory dysfunction to develop, maintain, rehabilitate or augment auditory and communicative functions." Ear impressions are necessary for audiological treatment and thus within the audiologist's scope of practice. Audiologists may take an ear impression only if they possess the appropriate training and skills to meet the standards of practice. Special considerations are necessary in taking ear impressions for infants and young children. Audiologists lacking comfort and/or experience in taking ear impressions in infants or young children should make appropriate referrals.

C) Definition of Service

Ear impressions are taken to develop end products for the treatment of disorders or protection of the auditory system. An ear impression is a physical replica of the ear achieved by injecting an impression material into the ear canal and external ear cavities (concha and helix areas of the ear). Impression materials may be either liquid-powder (ethyl methacrylate) or silicone-based materials. (Berkey, D. 1995) The nature of the ear impression is defined by the presenting concern/condition of the patient/client, and the patient/client's ability and willingness to manage the earmold. Audiologists must be aware of appropriate intervention options for presenting conditions and discuss intervention options with the patient/client. A decision to initiate an intervention option is made by the patient/client, with guidance from the audiologist.



D) Target Patient/Client Population

Any individual prone to ear infections, exposed to excessive noise levels, or presenting with a hearing loss of any degree may require an ear impression in order to initiate appropriate treatment for the presenting concern. Treatment may include but not be limited to:

1. Earmolds to prevent water from entering the ear (swim plugs).
2. Earmolds to reduce noise exposure or control sound input (earplugs/noise plugs).
3. Earmolds to couple assistive listening devices to the ear (e.g. FM systems).
4. Earmolds to couple behind-the-ear hearing instruments to the ear.
5. Custom hearing instruments.

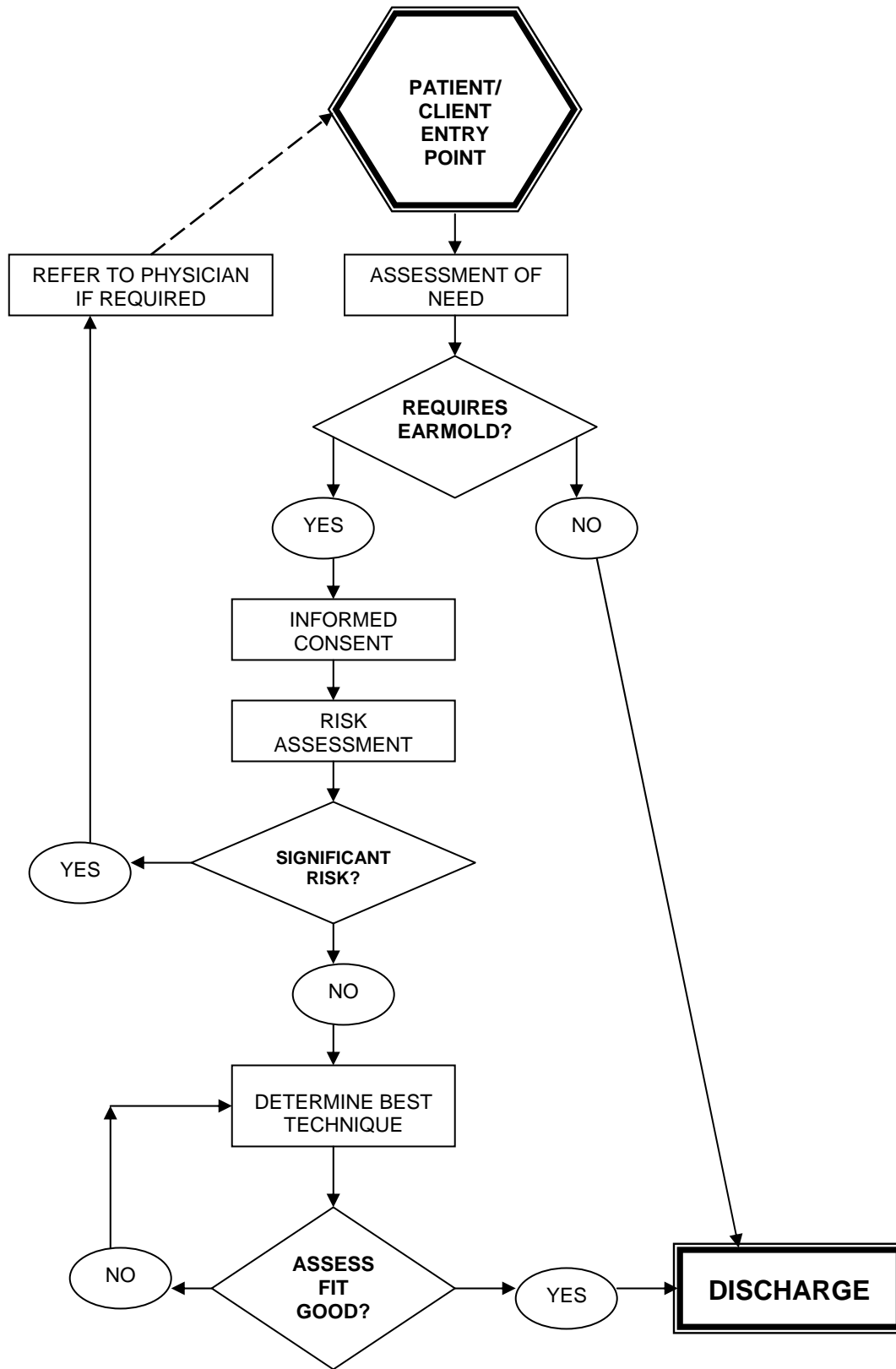
E) Resource Requirements

To take an ear impression, an audiologist requires but is not limited to:

1. An otoscope with speculum.
2. Earlight with removable tip.
3. Otoblock with thread.
4. Mixing bowl or wax pad.
5. Spatula, blunt-end tweezers.
6. Blunt-end scissors, bite-blocks.
7. Syringe or impression gun.
8. A variety of impression materials.

F) Continuum of Care

Prior to taking an ear impression for a patient/client, an Assessment of Need, Risk Assessment, and assessment of the most appropriate technique must always be performed. Risk management procedures must be in place in anticipation of any complications arising from the procedure. This is illustrated in the following flow chart:



G) Infection Control Guidelines

All components must be executed in such a way as to ensure the safety of the patient/client and clinician by adhering to infection control practices. The member must employ routine infection control practices according to Health Canada Guidelines (Canada Communicable Disease Report 1998). In addition, the member needs to implement additional precautions specific to the practice of audiology (Clark, J.G., R.J. Kemp and A.U. Bankaitis, 2003). Members should pay particular attention to the requirements for hand washing, waste management and criteria for disinfection and sterilization.

Instruments used to make ear impressions which come in contact with intact skin are considered “semi critical” and thus require cleaning and high level disinfection (soaking in a chemical solution (e.g. glutaraldehyde or hydrogen peroxide following manufacturer recommendations for concentration and exposure times) (Health Canada 1998).

Instruments used to make ear impressions for non-intact skin are considered critical which according to Health Canada present a potential risk of infection. Critical items require thorough cleaning and sterilization before use. Sterilization may be accomplished using heat (e.g. steam under pressure such as an autoclave) or soaking in a chemical solution (e.g. glutaraldehyde or hydrogen peroxide following manufacturer recommendations for concentration and exposure times) (Health Canada 1998).

H) Competencies

The audiologist demonstrates:

1. Knowledge of:
 - a) The anatomy of the external ear, ear canal and tympanic membrane.
 - b) Conditions of the external ear, ear canal and tympanic membrane that would preclude making an ear impression.
2. The ability to obtain a relevant case history from the patient/client with particular attention paid to conditions and medical/surgical procedures involving the outer and middle ear.
3. Knowledge of examination techniques of the external ear and ear canal using an otoscope.
4. Knowledge of and the ability to identify conditions of the external ear, ear canal and tympanic membrane that would prevent an ear impression from being taken safely:
 - a) Appropriate referral sources.
 - b) Conditions and circumstances that would require medical clearance to safely proceed.
 - c) Appropriate cerumen management techniques and the ability to perform this function or the capacity to refer to an appropriately regulated health professional.
5. Knowledge of and ability to utilize current ear impression techniques:
 - a) Criteria for using different techniques.
 - b) Effect of ear canal shape on the removal of the impression.
 - c) Impact of different impression materials on the patient/client and the resulting impression.
 - d) Appropriate pressure to exert when syringing ear impression materials into the ear canal.

- e) Correct procedures to mix impression material.
 - f) Appropriate procedures for safely removing impression material to preserve the integrity of the impression.
6. Knowledge of the impact of the manufacturing process on the nature of the impression:
- a) Impact of shape and size of the ear impression.
 - b) Effects of retention and acoustic properties of the earmold.
7. Knowledge of the interaction of the earmold and the end product:
- a) Acoustic properties required of end product.
 - b) Retention requirements.
 - c) Techniques to modify earmold to meet requirements of end product.

I) Referral Requirements

Where the audiologist does not feel competent to manage the risks, the patient/client should be referred to a more experienced professional (audiologist/physician). In the event of a chronic condition or an immediate need, and when the patient/client must have an ear impression taken for the purpose of treatment, medical clearance should be obtained prior to initiating the process. In addition, consultation should occur in any case where the audiologist believes that medical supervision and/or intervention may be required in the impression process.

J) Documentation

Documentation is mandatory for the protection of all parties involved in the ear impression process. The details of the intervention including Assessment of Need, Risk Assessment, techniques utilized, complications encountered and status of ear impression and resulting earmold should be documented in the patient/client's records in full. Audiologists are directed to the Proposed Records Regulation drafted by the College of Audiologists and Speech-Language Pathologists of Ontario¹ to obtain guidance for record keeping. Proper documentation is essential in the process to ensure continuity of hearing health care.

In the event of exceptional circumstances and/or conditions when guideline procedures cannot be followed, the audiologist is required to document such exceptions, including the clinical justification for the procedures used.

The patient/client's informed consent should also be documented.

K) Precautions

Audiologists must always insure that appropriate precautions are taken to prevent risk of harm to themselves. Consideration should be given to using non-latex gloves when handling impression material because of the possibility of health consequences resulting from repeated absorption of impression chemical through the skin. Members are advised to refer to material data safety sheets. In the event the end product (e.g. earmold or hearing aids) requires

¹ Draft Regulation for Records CASLPO (1996) http://www.caslpo.com/english_site/m_memregulrec.asp

modification, it is recommended that the audiologist wear eye protection and a mask to protect from hazardous airborne particles. Precautionary measures for blood- and fluid-borne pathogens should be taken at all times

L) Components of Service Delivery

Proper ear impressions involve a number of stages to ensure that the most appropriate method is employed. These stages have been identified as: Assessment of Need, Informed Consent, Risk Management Assessment, and Selection of Impression Technique.

1. ASSESSMENT OF NEED

The audiologist should obtain a relevant case history from the patient/client. The case history should include the reason for the ear impression, conditions of the outer and middle ear, or past medical/surgical procedures of the outer and/or middle ear. A thorough examination of the external ear and ear canal should be conducted with an otoscope. This, in conjunction with the case history and assessment results, will assist in determining:

- Whether or not an ear impression is necessary.
- Whether or not an ear impression can be safely taken.
- Which technique would be most suitable.

2. INFORMED CONSENT

The patient/client must be fully informed of each step of the ear impression procedure and the outcomes, benefits and risks associated with the process. The Health Care Consent Act² requires that members give patients/clients the information required to make a decision regarding ear impressions. The minimum information given must include the nature of the treatment, the expected benefits, any probable or serious risks and side effects of the treatment, alternative courses of action, and the likely consequences of not having the treatment. CASLPO requires that members document all consent to treatment discussions. (See Appendix I for an example of checklist to guide a consent to treatment discussion). Members are reminded that the crucial element in obtaining consent to treatment is a full and frank discussion of the information listed above and not the act of signing a consent form.

3. RISK MANAGEMENT ASSESSMENT

a) Components of a Risk Management Program

Improper ear impressions can result in physical harm and/or mental harm to the patient/client. It is important that the audiologist establish a risk management program.

Such a program should include:

- i. Identification of risks.
- ii. Analysis of those risks in terms of probable negative end results.
- iii. Implementation of risk control procedures.

² Health Care Consent Act, 1996 S.O. 1996, CHAPTER 2 Schedule A [online].
http://www.e-laws.gov.on.ca/DBLaws/Statutes/English/96h02_e.htm

b) Contraindications for ear impressions

- i. Ear impressions are contraindicated when:
 - Impacted or excessive cerumen is present in the ear canal.
 - A foreign body is present in the ear canal.
 - There is blood in the ear.
- ii. Other factors to be considered in deciding whether or not an ear impression can be safely taken:
 - An infection of the external ear or middle ear with active drainage.
 - Prior surgical interventions that may affect how the impression is taken, such as a tympanostomy tube.
 - Presence of perforated tympanic membrane.
 - Shape and size of the external ear canal³.
 - Skin disorders.
 - Texture of the ear.
 - Other as identified by the audiologist.
 - Age of the patient/client.

Where the audiologist does not feel competent to manage the risks, the patient/client should be referred to a more experienced professional (audiologist/physician). In the event of a chronic condition or an immediate need, or when the patient/client must have an ear impression taken for the purpose of treatment, medical clearance should be obtained prior to initiating the process. In addition, consultation should occur in any case where the audiologist believes that medical supervision and/or intervention may be required in the impression process.

c) Possible complications that may arise when taking an ear impression

(Dillon, H., 2001)

- i. Cerumen impaction.
- ii. Hematoma of the ear canal or tympanic membrane.
- iii. Perforation of the tympanic membrane.
- iv. Traumatic perforation with perilymph fistula.
- v. Impact on existing or previous surgical procedures.
- vi. Exacerbation of certain conditions (e.g. Ménière's disease, skin irritations or conditions within the external ear or canal).
- vii. Filling middle ear with impression material.

³ Observe whether the canal widens at any point sufficiently relative to the outer parts of the canal, such that removal of the impression will be difficult. It is common for ear canals to widen slightly in the anterior-posterior dimension just medial to the second bend. Ear impression materials are only able to compress slightly during removal. This is related to the elongation factor or bendability of the material (Berkey, D., 1995). Consequently, in cases of significant widening of the canal at any point, it may be difficult to remove the impression. This may necessitate taking an impression with a shorter canal portion. Impression material shore values should be taken into consideration in any case where removal may be difficult.

d) Implementation of risk control procedures

There should be a risk management plan in effect to be able to remedy any complications that may arise, or to refer to a physician, if necessary. In certain instances, this may require immediate medical intervention (e.g. impression material in middle ear, dislodged tympanostomy tube). The patient/client and significant others must be counselled appropriately if negative consequences do occur as a result of the ear impression technique.

The audiologist should be aware that the pressure that can be exerted during syringing with normal viscosity ear mold materials is sufficient to rupture the eardrum should the material flow past the canal block, or push the block down to the drum.

4. SELECTION OF IMPRESSION TECHNIQUE

The results of the Assessment of Need and Risk Management Assessment will assist the audiologist in determining the most effective technique to be utilized to minimize risk of harm and result in the best possible outcome for the ear impression. Audiologists must have competency in a variety of procedures to accommodate the range of patient/client presentations. The following factors need to be considered when choosing an appropriate procedure for making an earmold:

- a) Status of ear tissue (intact vs. non-intact).
- b) Type of end product needed (CIC (completely-in-the-canal hearing aid) /BTE (behind-the-ear hearing aid); deep vs. shallow impression).
- c) Open- vs. closed-jaw impression, taking into account mandibular movement and requirements of high-gain instruments.
- d) Type of impression material to be used, taking into account shore, viscosity, size and texture of ear canal (soft, normal, hard), mastoid cavity. (Refer to Impression Material in Glossary for a discussion of different types.)
- e) Comfort and fit of end product, taking into account the need to minimize feedback and the ability of the patient/client to handle the earmold.

5. DISCHARGE PROCEDURES

Prior to discharge, the patient/client needs to be seen by the audiologist to assess the earmold. Factors to be considered include retention, comfortable fit, interaction of end product with earmold, and the ability of patient/client to use the earmold. If the earmold does not meet the specific criteria defined by the patient/client or the function of the end product, the audiologist must determine the required course of action. This may include counselling the patient/client, making modifications to the earmold, or taking a new ear impression. If a new ear impression is required, a reassessment of the technique utilized to make the ear impression would be necessary to ensure an appropriate end product. Intervention is concluded when the earmold serves its intended function.



Appendix I: Example of Patient/Client Checklist for Discussion to Allow an Ear Impression to Be Taken by CASLPO-Registered Audiologist

- _____ is an audiologist registered with the College of Audiologists and Speech-Language Pathologists of Ontario.
- Patient/client understands that:
 - To provide audiological intervention, the audiologist must take an impression of my ear.
 - Every precaution possible will be undertaken to avoid discomfort or adverse results.
 - Taking an impression will entail introducing material into my ear and removing it to get a physical representation of my ear canal.
 - Risks associated with taking an ear impression may include:
 - Cerumen impaction (firmly wedged ear wax).
 - Hematoma (bleeding) of the ear canal or tympanic membrane (eardrum).
 - Perforation of the tympanic membrane (hole in the eardrum).
 - Traumatic perforation with perilymph fistula.
 - Impact on existing or previous surgical procedures.
 - Worsening of certain conditions such as Ménière's disease, skin irritations or conditions within the external ear or canal.
 - Filling middle ear with impression material.
- Audiologist has identified any conditions which may increase risk of taking an ear impression such as:
 - Child under the age of 12 years
 - Tympanic membrane perforation ('hole in the eardrum')
 - Myringotomy or pressure equalization (PE) tubes
 - History of ear surgery
 - Drainage
 - Prior or ongoing ear infection
 - Dizziness
 - Use of blood thinning medication (e.g. Coumadin, Heparin, high-dose Aspirin)
 - Recent earache
 - Pathological conditions of the pinna, ear canal or tympanic membrane
 - Any other health condition I feel the audiologist should be aware of before proceeding:

- Patient/client consents to procedure

Appendix II: Glossary

Otoblock with thread:

This is a small amount of cotton or foam that fills the cross-section of the ear canal to prevent impression material from flowing further into the ear canal than is required. It is also called an impression pad or eardam. Placement of the otoblock allows the impression material to fill the canal completely, allowing the best representation, and assists in protecting the eardrum.

Pressure release otoblock:

This is an otoblock that allows for venting (pressure release) when a deep impression is necessary.

Impression material:

Various types of impression material are commercially available. Ear impression materials can generally be divided into powder-liquids (ethyl methacrylate) and silicone materials. Impressions made from powder-liquid materials are generally less durable, have greater shrinkage, and are more prone to distortion and damage. Shrinkage and damage during shipping are generally not a problem for silicone-based impressions. Silicone impression materials vary in both their viscosity and shore values.

Viscosity:

Viscosity relates to the density of the material and the ease with which it flows. Lower viscosity materials flow easily, and tend not to expand the ear canal because of their lower density. Lower viscosity silicones tend to model the canal in its least expanded state. Higher viscosity silicones are more difficult to inject and are more prone to expanding the ear canal. The end product tends to fit tighter as a result. This may be a desirable feature for high-gain hearing instruments, or when better retention within the ear is required in a given device.

Shore:

This is a measure of the hardness of the impression after it cures. The shore value has no effect on the nature of the impression. It does relate somewhat to the ability to remove it from the ear, as impression materials with high shore values do not compress easily. In addition, shore affects the manufacturer's ability to make modifications to the impression.



Appendix III: Ear Impression Procedures

1. Standard ear impression technique:

Procedure A:

This procedure should be followed where a normal ear canal with intact skin is present.

1. Wash hands
2. Inspect ear
3. Consider trimming any vellus hair present in the concha that may interfere with the integrity of the impression.
4. Insert a canal block (otoblock). The resistance to flow provided by the block enables the impression material to completely fill the canal cross-section down to the desired length, rather than tapering off in width. A piece of strong thread is knotted around (through) the block to aid in removal. Blocks may be custom-made, or can be purchased in a range of sizes, with pre-tied thread. Blocks that allow for venting (pressure release) should be considered in cases where a deep impression may be necessary, or when there may be difficulty with removal. The correct size must be used in order that
 - a. it does not get pushed further down the ear canal, or
 - b. the impression material does not flow by it.
5. Insert the block with the otolith. Consider soaking block in mineral or baby oil where there is concern about removing the impression material or damage to the canal wall. The depth of insertion is important. The block should be at or past the second bend, in order to provide an accurate representation of the canal. In the case of an earmold for use with a BTE (behind-the-ear) instrument, or in the case of a custom hearing instrument, definition of the second bend allows the manufacturer to determine where the sound bore or receiver tube should be directed.
6. Mix the impression material according to the manufacturer's instructions. It is recommended that a mixing bowl or wax pad be used to avoid contamination of the impression material with sulfur-based substances that can leak from hand lotions and latex gloves, and to avoid raising the temperature of the impression material, which will decrease the setting time.
7. Make the ear impression (preferably using a syringe technique) using material appropriate to the ear canal shape, texture, and type of end product.
8. Allow the material to set before removing it from the ear. The set time will vary depending on the type and amount of material used.
9. Remove the impression by loosening the auricle area first to separate the impression material from the auricle. Rotate the impression a little to break it away from the ear, work it out of the helix curl, and pull it straight out of the ear.
10. Make a final examination of the ear to ensure that no material or cotton has been left in.
11. In the event that any injury has occurred to the ear as a result of the impression, note it in the patient/client's chart. If blood or serious injury is involved, the audiologist must recommend a medical consultation for inspection of the ear, as per the risk control procedure.

Procedure B:

This procedure should be followed when non-intact tissue is present in the ear canal, for example, perforated eardrum, tympanostomy tube or surgically enlarged ear canal. It is important to inform the patient/client of the additional risks involved where these conditions exist.

1. Wash hands; glove with sterile gloves (non-latex gloves if using silicone impression material).
2. Select sterile ear impression tools (refer to Health Canada 1998 for sterilization techniques).
3. Inspect the ear with an otoscope with sterile speculum.
4. Place sterile otoblock(s) of appropriate size at the canal opening and with a sterile earlight tip set to the desired length. Verify the placement with otoscopy.
5. Use single portioned impression material.

Steps 6-11 per Procedure A

The audiologist should be aware that the pressure that can be exerted during syringing with normal viscosity ear impression materials is sufficient to rupture the eardrum should the material flow past the canal block, or push the block down to the drum.

2. Modifications to standard technique

i. Tight or deep fitting earmold

This technique would be used for hearing instrument fittings such as completely-in-the-canal (CIC) hearing instruments and hearing instrument fittings requiring high gain to avoid acoustic feedback or to provide retention.

The second bend should be clearly visible in the impression, and preferably the impression should extend about 5 mm (in an adult) beyond this point. With the canal block inserted this deeply, the impression material is able to expand the cartilaginous canal along its entire length and provide a tighter fit.

Movement of the hearing instrument in the canal can occur because the ear canal changes shape with the movement of the patient/client's jaw. In particular, the anterior-posterior dimension of the canal between the first and second bend gradually increases as the jaw opens. (Dillon, H. 2001, Pirzanski, C. 1997). As the jaw opens, the condyle of the mandible moves forward, and this pulls the anterior wall of the canal forward. If the patient/client's back teeth are missing, the patient/client has poorly fitting dentures, or the patient/client has a temporomandibular joint disorder, the jaw can over-close, and consequently the variation in canal size with jaw movement may be greater than normal. (Excessive movement of the canal wall may preclude the use of a CIC aid.) The degree of movement can be estimated either by observing the canal wall movement with an otoscope or by feeling the degree of movement with an inserted finger.

It may be necessary in these cases to take an impression with the jaw held open until the impression hardens. This can be accomplished by positioning a bite-block in the patient/client's mouth. This will generally result in an impression where the anterior-posterior portion of the canal is wider than in a closed-jaw impression. This difference will reflect the amount by which the end product can be comfortably enlarged beyond what would be achieved with a closed-jaw impression. Providing manufacturers with both a closed-jaw and open-jaw impression can give them an indication of the maximum width of the canal for the shell or mold. Use of higher viscosity materials will also provide a tighter fit as they will tend to expand the canal more than low to medium viscosity materials.

ii. Paediatric Ear Impressions

Special considerations are necessary in taking ear impressions for infants and young children. While the technique in general is not modified, clinicians must be cognizant of the fact that the ear canal in infants and young children is smaller in diameter, shorter in length, and generally softer in texture than that of an adult. Clinicians should exercise additional caution both when inserting otoblocks and when injecting impression material into the child's ear. Impression materials with lower viscosity (including powder-liquid), while not preferred, may be necessary when taking impressions for very small ear canals. As well, a syringe with a paediatric tip may allow placement of the tip of the syringe closer to the otoblock. Audiologists lacking comfort and/or experience in taking ear impressions in children should make appropriate referrals.

iii. Manufacturer's Modification of the Ear Impression

During the manufacturing process, earmolds and custom shells are buffed in order to smooth them. Wax is applied to impressions in order to slightly enlarge them and allow for the buffing process without significantly reducing the size of the impression. Wax may also be applied to impressions to ensure better retention and reduce feedback. It is beneficial for the audiologist to know the nature of the waxing process used by the manufacturer, in order to modify the impression technique appropriately. The audiologist should also indicate whether an impression was conducted with the patient/client's jaw open or closed, to assist in determining how much waxing may be allowable.

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