

Deep-Canal Ear Impressions: Medical and Clinical Concerns

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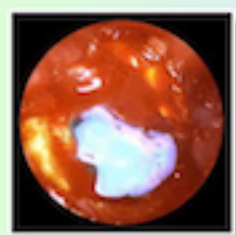
For decades audiologists have made deep-canal ear impressions for patients with severe to profound hearing losses. Since 1990 deep impressions have been made for invisible-in-the-canal hearing aids that reportedly eliminate occlusion effect, reduce feedback, assure retention and maintain pinna/concha directionality.

Less noted are reports of problems arising from these deep impressions.

This poster will review documented deep-impression problems and suggest interim and long-term recommendations to minimize these problems.

Documented Problems:

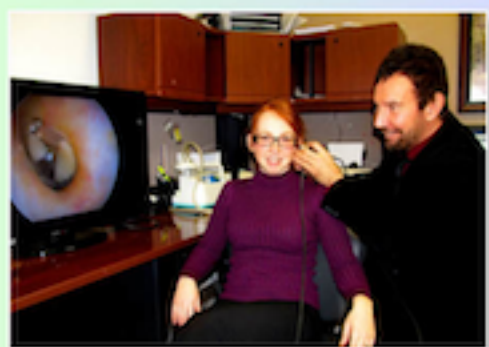
Several reports of potential medical concerns arising from deep-canal ear impressions have been published. These medical concerns include canal abrasions, trauma to the tympanic membrane and/or middle ear ossicles, progressive or long-term mixed or sensorineural hearing loss, loss/reduction of taste and smell, invasion of the impression material into the Eustachian tube, removal of PE tubes, excessive bleeding from the ear canal and ongoing vertigo.



Published Guidelines:

Conflicting clinical recommendations have been published regarding proper deep-canal impression technique. These include the following:

1. Check size and condition of the patient's ear canal (unanimous agreement).
2. An otoscope, high-quality video otoscope or surgical microscope is needed.



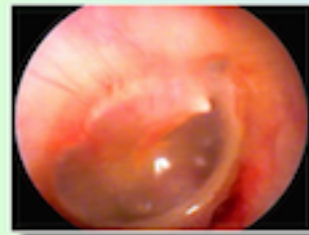
3. An ear light is needed.
4. A cotton or foam dam (vented or unvented) is needed.
5. The dam may or may not require lubrication with mineral oil or glycerin.
6. The dam is placed anywhere from 1 mm beyond the second bend of the ear canal to right on the TM.
7. Proper seal of the dam may or may not be confirmed with the otoscope/microscope.
8. An ear impression gun is recommended.
9. A high-flow, low-viscosity impression material is used.
10. The patient or the clinician removes the impression.

It is assumed if appropriate ear dams, impression tools, microscopes/video otoscopes and clinical skills are used; these aforementioned problems will be minimized or eliminated.

Our Experience:

Three ear impressions have gotten painfully stuck in our patients' ear canals. Two were unvented cotton-block design; one was vented foam rubber. Removing the two unvented cotton block impressions resulted in moderate pain for the patients. Removal of the vented foam-rubber block required a trip to two different emergency rooms.

This patient's ear canal is shown 15 hours after removal of the ear impression.



The impression causing this trauma is shown to the right.



This Leavitt-Welch fossa is not unique and may create problems for any patient and audiologist using recommended procedures.



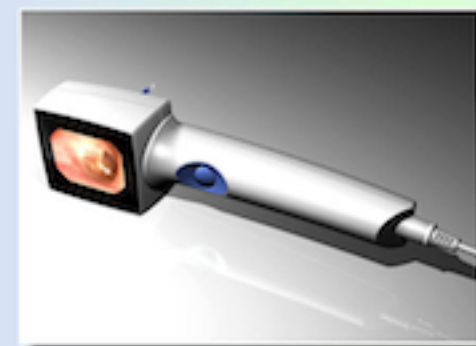
Our Recommendations:

Based on this experience, we have instituted a number of changes in protocol:

1. Each IIC candidate must sign a release of medical liability form similar to that provided at the hospital where the impression was removed.
2. We disposed of all small cotton blocks and vented foam-rubber impressions provided by manufacturers for IIC hearing aids and use only trimmed small-size foam rubber dams.



3. We look with interest to those companies developing 3D scanning technology for ear canals as we are anxious to discontinue all current recommended methods for taking deep-canal impressions.



4. We recommend FDA reconsider the classification of IIC hearing aids from Class I medical devices to Class II as deep-canal impressions do not meet Class I "reasonable" safety standards