External and Middle Ear Trauma Resulting From Ear Impressions

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Abstract

When taking an impression of the external ear canal and ear, the audiologist is engaged in an invasive procedure whereby a foreign body is first placed into the ear canal and then removed. There is always an element of risk for significant medical problems when a clinician is performing an invasive procedure. Although some minor patient discomfort and, at times, some slight trauma to the ear canal occur when taking ear impressions, the incidence of significant trauma to the external or middle ear appears to be low. The purpose of this report is to provide some illustrative cases of significant external and middle ear trauma as a result of taking impressions of the external ear. Audiologists are advised to develop and implement an appropriate risk management program for taking ear impressions to reduce the potential risks associated with this procedure to their patients and to their practices.

Key Words: Case study, ear impressions, foreign body, hearing aids, hearing protection devices, litigation, physical trauma, risk management, tympanic membrane perforation

Abbreviations: CIC = completely in the canal, HPD = hearing protection device, OR = operating room, PROS = pressure relief oto-dam system

Ear trauma is a common problem in emergency medicine and may occur as an outcome of a number of mechanisms, including exposure to loud noises or blast injuries, chemical exposures, thermal injuries, and penetrating or blunt traumas (Turbiak, 1987). Some minor discomfort or slight trauma to the ear canal is common when taking ear impressions. For example, the placement and removal of the otoblock dam may scratch the ear canal walls, which may then result in some slight bleeding. In other cases, hair in the external ear canal may adhere to the hardened impression material and be accidentally but forcibly torn from the canal walls, or there may be some stretching or bending of the external ear when the impression material is removed from the canal. However, the incidence of more serious trauma to the external and middle ear systems from ear impressions seems to be low. The purpose of this article is to provide six illustrative case reports of significant external and middle ear trauma secondary to taking impressions of the external ear. All six cases were managed by the authors; however, the authors were not the individuals who took the impressions leading to the consequences described in these reports.

When taking an impression of the external ear canal and ear, the audiologist is engaged in an invasive procedure whereby a foreign body is first placed into the ear canal and then removed. Technically, all ear impressions, earmolds, hearing aids, and hearing protection devices (HPDs) inserted into the ear canal can be considered foreign bodies. There are few published reports of difficulties associated with taking impressions of the ear. In 1983, Juneau advised caution when packing canal blocks and taking an impression of a postoperative ear, particularly if the ear canal is surgically enlarged. Specifically, if the impression mater-
ial is extruded into the enlarged area, the impression may not be able to be withdrawn, at which point a physician's services would be required. Clinicians are routinely advised to use caution when taking impressions of ears with tympanostomy tubes as there is a risk of the impression material adhering to the tube itself. Consequently, when the impression is removed, the tube may be moved and, in some cases, forcibly displaced from the tympanic membrane.

In the American Speech-Language-Hearing Association's technical report on professional liability and risk management (ASHA, 1994), the liability insurance broker for this association received 11 claims between February 1985 and August 1993 due to earmold impression material breaking off or being left in the ear canal. When faced with this scenario, Manning (1992) has advised that clinicians use forceps or blunt-nosed tweezers to remove an otoblock or separated earmold materials. In addition, he recommended that clinicians not attempt to grasp the block at the margin where it contacts the wall of the canal as damage to the canal wall may occur. Clinicians must be conscious of the proximity of the instrument to the tympanic membrane at all times and should use extreme caution as the insertion of hard-shafted instruments into the ear canal may cause severe and immediate damage to the skin lining of the canal and the tympanic membranes.

In 1992, Schimanski described a case study of an 81-year-old man who suffered a rupture of the tympanic membrane while receiving an impression for a hearing aid fitting. The silicone impression material apparently ruptured the tympanic membrane and a large amount of impression material penetrated into the middle ear cavity, requiring surgical treatment to remove the impression material. More recently, Syms and Nelson (1998) described four cases of impression-material foreign bodies of the external canal and middle ear. The authors stressed that even in experienced hands, adverse outcomes are common when trying to remove ear impression material from the ear canal and/or middle ear.

CASE REPORTS

Cerumen Impaction on the Tympanic Membrane

HL, a 69-year-old retired autoworker, had impressions made for both ears prior to an evaluation with binaural digitally programmable in-the-ear hearing aids. This gentleman had normal tympanograms just prior to when the audiologist made the ear impression. His audiogram obtained before the procedure is presented in Figure 1. Although the ear canals were inspected otoscopically prior to the impressions, the clinician believed that the small amount of wax present in the ear canals did not pose any risks to the patient for this procedure and would not interfere with the opportunity to obtain a good impression for the hearing aids. Foam otoblock dams were inserted beyond the second bend of each ear canal and ear impressions were obtained. After removal of the right ear impression, the patient reported a sensation of fullness and a mild deterioration of hearing in the right ear, although there were no reports of pain or discomfort during the procedure. An otoscopic inspection of the right ear canal and tympanic membrane suggested that cerumen appeared to have adhered to the right tympanic membrane. Audiologic testing immediately after the impressions were made indicated a Jerger Type A tympanogram (abnormally high compliance peaking at normal tympanometric pressure) and the addition of a slight conductive component to the high-frequency thresholds in the right ear. The results are illustrated in Figure 2. The patient was referred to an otologist who removed the cerumen adhering to the patient's right tympanic membrane. The tympanogram
returned to normal and the conductive component was resolved. The subsequent hearing aid evaluation and fitting proceeded without any further incident regarding the status of the patient's external and middle ear systems.

Hematoma of Tympanic Membrane from Deep Impression

PS, a 56-year-old lobbyist, volunteered to participate in a study investigating the efficacy of digital hearing aids. The initial audiogram is presented in Figure 3. After otoscopic inspection, foam otoblock dams were placed at least 2 mm beyond the second bend of the external ear canals. The audiologist introduced silicone impression material into the ear canals with a manual impression gun. After the material had properly set, the clinician removed the impressions. The subject reported significant discomfort when the impression material was removed from the left ear canal. He also reported a sensation of fullness and a decrease in hearing in his left ear. Subsequent otoscopic examination by a staff neuro-otologist revealed a large hematoma on the left tympanic membrane, as illustrated in Figure 4. Apparently, the tympanic membrane was bruised by the otoblock during the impression process. An audiologic work-up at that time indicated a flat tympanogram and a significant conductive compo-
normally. In some cases, hematomas can result in the deterioration of the integrity of the tympanic membrane and ultimately lead to a large perforation. At the 6-month follow-up, the tympanic membrane had healed normally, the conductive component had resolved as illustrated in Figure 6, the patient no longer complained of any fullness in his left ear, and he was successfully fit with binaural digital completely-in-the-canal (CIC) hearing aids. However, due to this history and the patient's reluctance to have any additional impressions taken of his ear canals, the audiologist stored his impressions and the investments of his hearing aids permanently to address any future needs for additional or replacement CIC hearing aids.

Large Central Perforation in the Left Tympanic Membrane

MC, a retired 63-year-old secretary, participated in a hearing aid evaluation for a possible fitting of CIC hearing aids. According to patient report, the hearing aid dispenser did not examine the ear canals before or after taking the ear impression nor did the dispenser insert any otoblock dams into her ears when making the ear impressions. She reported severe pain during the removal of the impression material from her left ear canal. After the impression material was removed, she experienced bleeding and a significant decrease in her hearing sensitivity of her left ear, severe vertigo, and an intense headache. The audiogram obtained during her otologic work-up 2 days later is presented in Figure 7 and indicated a profound hearing loss in her left ear. The patient was diagnosed with a large, dry central perforation of the left tympanic membrane. The perforation is illustrated in Figure

Figure 5 Postimpression audiogram for PS.

Figure 6 Audiogram demonstrating the recovery of hearing thresholds for PS.

Figure 7 Postimpression audiogram for MC.
8. Although a tympanoplasty successfully repaired the perforation, there was no recovery of any hearing in this patient's left ear, and she chose to continue with a monaural hearing aid fitting for her right ear with an audiologist at her otologist's office. Subsequent litigation resulted in a large cash settlement for the patient and the loss of the hearing aid dispenser's license and practice.

Tympanic Membrane Perforation and Foreign Body in Middle Ear Cavity

TC, an 80-year-old male with a long history of bilateral symmetric sensorineural hearing loss, was being seen by a hearing aid dispenser for a CIC hearing aid fitting for his left ear. An example of his audiograms prior to the incident described below is presented in Figure 9. He had no previous history of ear surgery or injury prior to this appointment; however, an otoscopic inspection by a different hearing aid dispenser 3 years earlier suggested that his left tympanic membrane may have had an "old scar" or what appeared to be a "perforation closed over." The dispenser reportedly inspected the external ear canals and tympanic membranes before the ear impressions but there was no written note of the otoscopic inspection. The patient reported that he had significant pain and decreased hearing when the silicone impression material was placed in his left ear. Otoscopic inspection by the hearing aid dispenser after the impression material was removed from this patient's left ear suggested that some of the impression material and the otoblock dam had penetrated through the tympanic membrane and was resting in the middle ear cavity. The patient's primary care provider placed TC on oral antibiotics and he was referred for otologic care.

Upon examination, the otologist noted a perforation in the inferior-posterior quadrant of the left tympanic membrane with a yellow plastic substance bulging out of the perforation. Upon closer inspection, the impression material apparently had flowed into the mesotympanum and had adhered to the ossicles and walls of the middle ear cavity. The otologist removed the exophytic material external to the tympanic membrane and placed the patient on Blephamide drops. After discussing the case with several other otologists and discovering that the silicone was considered to be "nontoxic," the otologist chose not to explore the ear surgically.

At a follow-up visit 1 month post-trauma, the patient was found to have a healing perforation and a profound sensorineural hearing loss in his left ear. This audiogram is presented in Figure 10. Subsequent examinations have shown an intact left tympanic membrane and a consistent profound sensorineural hearing loss in TC's left ear. TC reports no ear pain or drainage and currently wears a CROS postauricular hearing aid to the right ear with acceptable results.
Traumatic Perforation with Perilymph Fistula

RH, a 34-year-old male with a mild bilateral sensorineural hearing loss (consistent with his history of noise exposure as illustrated in Fig. 11), received ear impressions of both ears at his place of employment in order to be fit with custom HPDs. After a technician inspected the ear canals and mixed the silicone impression material, the audiologist introduced the impressions into the ears of the patient without examining the ear canals himself. The patient reported that upon removal of the impression material in his right ear, he felt a great deal of pain and heard a loud pop. Visual inspection, by the technician removing the ear impression and then by the supervising audiologist, revealed that a large amount of impression material remained deep inside RH’s right ear canal. After several attempts to manually remove the silicone impression material from the ear canal with a wax pick, the audiologist had RH return to his worksite without instruction or caution regarding his ear care or the use of any HPDs. Approximately 30 minutes later, the audiologist had RH return to the front office of the plant and again made several attempts to remove the impression material with no success. RH was then referred to a local otologist the next day to have the impression material removed.

At his office, the otologist also had difficulties removing the silicone impression material from RH’s right ear canal and he was referred for ear surgery at a regional hospital later that day. At the hospital, the patient was sedated and underwent examination with a microscope in the operating room (OR). The otologist noted that the impression material had penetrated the tympanic membrane and a large amount of the material was resting on the ossicles. He successfully removed the impression material from the external ear canal, tympanic membrane, and middle ear cavity and subsequently examined the middle ear system for any additional complications. Finding none, he performed a tympanoplasty to repair the perforation in the tympanic membrane.

Upon recovery, RH suffered from severe vertigo and reported that he had no hearing in his right ear. After 2 days of observation, RH was returned to the OR for repair of a possible perilymph fistula. Although there was no change in RH’s complaints regarding severe vertigo and no measurable hearing in his right ear, he was dismissed from the hospital after a short stay and was monitored by the otologist for 3 months. After 3 months, there was no relief of these symptoms. He was unable to return to work due to the severe vertigo and found that simple activities, such as climbing stairs to a second floor bedroom, resulted in an incapacitating episode.
of vertigo. Consequently, he spent most of this time on his living room couch sleeping and watching television. He was referred to a neuro-otologist who also performed a fistula repair with no success. Ultimately, the patient was required to undergo a complete vestibular neurectomy that addressed but did not completely resolve his vertigo and balance disorder. His hearing sensitivity for the right ear failed to show any recovery (Fig. 12). Through this period, he became permanently disabled and suffered marital and parental difficulties as his family tried to cope with the physical and psychological changes secondary to the trauma to his external, middle, and inner ears. RH ultimately settled for a very large cash settlement from the audiologist's liability insurance carrier as well as from the audiologist. Unfortunately, RH continues to have difficulties with vertigo and hearing loss.

**Tympanic Membrane Perforations during Student Training**

While fulfilling an externship, her last practicum site prior to receiving her graduate degree, a student in a private practice setting perforated the tympanic membranes of two patients while taking impressions. The first of these patients experienced immediate extreme pain, whereas the other patient's symptoms were unknown to the audiologist until she came in for her fitting and mentioned that she felt air blowing through her ear. Prior to these events, the student had completed approximately 80 ear impressions without incident but was frequently supervised by the audiologist. Although the student's university and ASHA required only 25% supervision for therapy sessions and 50% for diagnostics, this student received supervision by the audiologist for approximately 90% of the direct service provided. The last 2 days of the externship were less closely supervised as the audiologist believed that the student, having done well to this point, would benefit from an opportunity to practice "independently." The student was allowed to perform the otoscopic inspections, place the otoblocks, mix and "shoot" the impression material, and remove the impression material from her patients without the close supervision of the private practice audiologist.

Fortunately, the patient who experienced the pain had spontaneous recovery, the perforation healed, and she was fit with a CIC hearing aid. The second patient was less fortunate. She soon underwent a tympanoplasty to repair her perforated tympanic membrane. This patient requested that her medical bills and lost wages be reimbursed, the total bill not exceeding $8750.00. The student was required by the university to carry liability insurance and her insurance carrier covered the medical costs, lost wages, and an additional $1500.00 over the amount the patient had requested.

Six weeks after the patient accepted her check from the student's insurance company, the private practice audiologist received a letter from a law firm representing the student's insurance carrier. This letter directed this audiologist to cover the carrier's cost, $11,192.39, for this patient's medical care. The law firm stated that if they did not hear from the audiologist, they would file legal action and begin proceedings for the revocation of her driver's license until these costs were recovered. The audiologist's insurance carrier stated that there was no need to worry, especially if the student's policy stated that the student's insurance carrier was the primary insurer, as was the case for this episode.

The university that contracted the audiologist to supervise the student was determined by the university's legal counsel to have no liability in this case due to a revised state code that waived its sovereign immunity and consented to be sued only under certain circumstances, specifically "the University may only settle a matter after a civil action is filed and then only with the
approval of both the Attorney General and the Court of Claims." After receiving the letter from the law firm, the private practice audiologist never heard from the student or the university.

Two years later, on the last day before the statute of limitations expired, the audiologist was named as a defendant in a lawsuit brought against her by the student's insurance company. The student was deposed approximately 3 years after that event and could not recall any of her experiences with these patients. The student did, however, recall that she and the audiologist attended a manufacturer's CIC certification course a few weeks prior to the incidents and were both certified for CIC hearing aid fittings.

Two months after the student's deposition, a notice of dismissal of the suit was issued with the threat of a refile within 1 year. There was no cash settlement at that time. Had there been a cash settlement, it would have resulted in the audiologist being reported to the National Practitioner's Data Bank. However, the audiologist had difficulties maintaining a contract with a preferred provider organization because of the case being reported incorrectly with her malpractice insurance carrier's files.

As a side note, the patient who had the tympanoplasty also required an additional ear surgery as she developed a cholesteatoma and stenotic ear canal as a by-product of the tympanoplasty.

**SUMMARY AND CONCLUSIONS**

Although most clinicians may never encounter a serious trauma to the external or middle ear when making ear impressions, the cases described above indicate that procedures currently used to take an impression of the ear pose significant risks to the patient, and these procedures must be considered invasive. Although ear traumas as described in these seven cases are not life threatening, they may account for significant morbidity (Turbiak, 1987). It is not uncommon that various techniques used to remove cerumen such as ear syringing or the introduction of swabs or other instruments into the external ear canals can result in direct trauma lesions to the tympanic membrane and ossicles (Silverstein et al, 1973; Brahe and Vendelbo, 1986; Huang and Lambert, 1997). In addition, foreign bodies can extend through the tympanic membrane, resulting in disruption of the labyrinthine membrane leading to perilymph fistula that may manifest itself as a long-standing sensorineural hearing loss or, in many cases, a fluctuating or progressive sensorineural hearing loss (Goodhill, 1980; Brookhouser, 2000). Finally, temporary and permanent threshold shifts can result from the concussive inner ear trauma due to large pressure perturbations from the mechanical manipulation or the subluxation of the ossicles (Pender, 1992; Canalis et al, 2000).

Risk exposure increases when taking deep canal impressions for CIC hearing aids or for deep-fitting earmolds or HPDs. Risk exposure also increases when taking ear impressions of surgically altered ears. Establishing and following an appropriate risk management program when making ear impressions may not only protect the financial assets of the audiologist or audioligic practice, it also may reduce the probability that a sequence of events may result in significant trauma to the ear and consequently reduce the total risk exposure to the patients (ASHA, 1994). ASHA (1994) recommends five steps for the implementation of a risk management program:

1. Identification of pure risks;
2. Analysis of those risks in terms of probable loss, frequency, and severity;
3. Development of alternative risk control and risk financing techniques and choice of the proper technique or combination thereof;
4. Improvement of chosen techniques; and
5. Monitoring the program's effectiveness and modifying it as risks change over time.

Although at the time of this writing, the American Academy of Audiology has published several manuscripts discussing various legal and professional issues for audiologists (e.g., Ison and Ison, 1993; Wilson and Roeser, 1997; AAA, 1997a; Decker, 1999), the organization does not yet have any published guidelines or policies addressing risk management other than the scope of practice for the audiologist (AAA, 1997b).

There currently is a paucity of data describing the various risk factors associated with making impressions of an ear. For example, what are the risks associated with blow-bys of the impression material? A blow-by occurs when the impression material has pushed by the otoblock dam and the impression material covering at least two sides and possibly up to all four sides of the otoblock dam. It does not traditionally or conventionally refer to any impression material left in the external ear canal after the impression has been removed from the ear. Although blow-bys
are not a typical consequence, they do occur occasionally when making ear impressions. Blow-bys occur because (1) the clinician has failed to adequately seal the ear canal with an appropriately sized otoblock dam, (2) too much force was exerted during the introduction of the impression material into the ear canal, (3) the patient exercised excessive jaw movement during the introduction of the impression material into the ear canal, and/or (4) the clinician selected and placed an otoblock dam to seal the ear canal when the patient's mouth was closed but perhaps took the impression with the patient's mouth open. An open mouth impression can result in a significant change in the shape or diameter of the ear canal (Pirzanski, 1996, 1997). Most blow-bys do not result in any trauma to the ear canal or to the tympanic membrane, but it is possible to have a blow-by scratch the canal wall, resulting in some bleeding in the external ear canal. It also is possible for the impression material to adhere to the tympanic membrane or even penetrate the tympanic membrane as a consequence of a blow-by. Until appropriate epidemiologic studies are completed and reported in the literature, the identification and analysis of the nature, frequency, and severity of risks to patients as a consequence of blow-bys remain largely unknown to most clinicians.

Because the risk data of ear impressions are not established, audiologists should take a very conservative approach when taking impressions of ears as the procedures are invasive. Consequently, the patient should be fully informed of the procedures, outcomes, benefits, and risks associated with taking ear impressions. A signed patient informed consent must be obtained prior to the procedure. The audiologist can reduce the risks posed to their patients by providing an appropriate standard of care that is consistent with current preferred practice patterns, guidelines, and position statements (Dybala and Thibodeau, 1998; ASHA, 1999). Thus, audiologists should employ materials and techniques that can reduce discomfort or injury. For example, audiologists should consider using pressure relief oto-dam systems (PROS) whenever inserting material beyond the second bend of the ear canal. These systems may allow better ventilation of the cavity between the impression material and tympanic membrane, reducing the risk of pressure discomfort or injury. Furthermore, audiologists should consider 100% supervision when students are making ear impressions simply due to the invasive nature of this activity and the severity of the risks involved. Finally, audiologists should only attempt to resolve any negative consequences of making ear impressions when they have the necessary knowledge, expertise, and credentials to provide a needed service. The patient must be counseled appropriately regarding the necessary strategies and actions needed to address any of the negative consequences from an ear impression. Audiologists should also implement any policies that address the hazardous risks to their patients. Clearly, allowing the worker in the fifth case study to return to the work environment with ear impression material still present in the ear, even if he/she received appropriate instructions and counseling before he/she received medical attention, posed significant medical risks to this employee. In this case, the employer should have been informed of the situation and the employee referred to or transported to the emergency room of the local hospital to address any risks due to the presence of the ear impression-material foreign body in the ear canal. This could include the employee trying to remove the foreign body himself once he was discharged by the audiologist.

Perhaps the best means of addressing the risks associated with making ear impressions is establishing and maintaining effective communication with the patient, the patient's family or caregivers, and other health care professionals. Effective communication starts with the development and adoption of a plan for risk management (before the act) related to ear impressions. Everyone who provides this service delivery should have an opportunity to help develop policies regarding ear impressions and agree to follow these policies. Both formal policies such as obtaining signed informed consent statements and informal policies such as the selection of the type of ear impression material should be addressed fully. These policies should specify that the audiologist must carefully record that informed consent was obtained, document the nature and extent of services the patient received, and describe any observed outcomes and recommendations arising from the delivery of the service to the patient.

Both formal and informal policies also should be developed that limit risk exposure (after the incident) in the event that something happens. There should be a succinct and well-delineated plan of action that has sufficient flexibility to meet the individual needs of each patient at the time and following the incident. All actions and discussions should be documented fully, dated, signed, and filed for future reference, whether
or not there may be future litigation. Although keeping excellent records will not eliminate risk or litigation, it can significantly improve the quality of patient care and reduce the risk exposure of those involved in the service delivery (Kibbee and Lilly, 1989; Paul-Brown, 1994).

REFERENCES


