Inadventent insertion of hearing aid impression material into the middle ear: Case report and implications for future community hearing services

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A B S T R A C T

INTRODUCTION: The creation of ear moulds for hearing aids is generally considered a safe and routine procedure for trained professionals. In the literature there are reports of otological complications caused by hearing aid mould impression material in the middle ear cavity but such complications are considered rare. PRESENTATION OF CASE: We present the case of a patient in whom impression material entered the middle ear through a perforation of the tympanic membrane during the process of making a hearing aid mould and review how this was managed. DISCUSSION: We discuss how many aspects of the British Society of Audiology guidelines were not followed during this procedure and make recommendations as to how independent community practitioners need to be closely supervised with regular review to minimise the risks of such complications. CONCLUSION: Our report demonstrates how a serious otological complication from the creation of a hearing aid impression in a community based private hearing clinic was managed. The reporting of such complications is rare but the incidence is likely to be much higher than the literature would suggest. We recommend and advise how these adverse incidents may be minimised and managed through competency reviews and formal referral links from community centres to hospital otolaryngology/audiology departments.

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1. Introduction

The creation of ear moulds for hearing aids is generally considered a safe and routine procedure for trained professionals. Producing a hearing aid is a customised process requiring skilled technicians that takes approximately 2 h.

In the literature there are reports of otological complications caused by hearing aid mould impression material in the middle ear cavity but such complications are considered rare. In reality however it is much more likely that such complications are under reported (especially in developing countries) and may be much more common than the literature would suggest.

The British Society of Audiology (BSA) has produced guidelines and recommendations on taking aural impressions and the minimum training requirements by healthcare professionals undertaking such procedures.1

We present the case of a patient in whom impression material entered the middle ear through a perforation of the tympanic membrane during the process of making a hearing aid mould and review how this was managed. We discuss how many aspects of the BSA guidelines were not followed during this procedure and make recommendations as to how independent community practitioners need to be closely supervised with regular review and assessment to minimise the risks of such complications.

2. Presentation of case

A 70-year-old man originally underwent a right myringoplasty for a perforation of the right tympanic membrane (post otitis media) 40 years previously. The operation had been successful and the patient had an intact grafted tympanic membrane on that side. His pure tone audiometry (PTA) at this stage revealed air conduction thresholds of 55–95 decibels Hearing Level (dB HL) with an air-bone gap of 20–45 dB HL in the right ear (Fig. 1a).

The patient went to a private clinic for fitting of a right sided hearing aid. During the process of producing the hearing aid mould he experienced severe pain and noticed that the hearing in the right ear had significantly worsened. He did not however experience any dizziness. At the time of the procedure the patient was not informed about any problems and was discharged from the clinic.

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One month later the patient’s reduced hearing had not improved and so he went to his general practitioner who noticed a foreign body in the right ear canal and therefore referred him to our otolaryngology department. Microscope assisted examination revealed pink impression material in the medial part of the external auditory canal. In addition to this it appeared as if there was a new tympanic membrane perforation and the impression material had passed into the middle ear. The material could not be removed under the microscope in the outpatients’ department and so the patient was listed for examination under general anaesthetic.

Under general anaesthetic the patient was noted to have a large central perforation of the right tympanic membrane. The pink impression material was visible passing through this perforation into the middle ear cleft (Fig. 2). The material was gently removed using a curved needle and micro-forceps and the edges of the perforation were freshened (Figs. 3 and 4). No obvious interruption to the ossicular chain was noted. The patient was given a two week course of ciprofloxacin drops and follow-up was arranged for him in clinic.

Two months later the right central tympanic membrane perforation persisted. However, this was dry and the edges of the perforation appeared healthy. The patient’s pain had completely resolved but PTA did reveal a worsening of his hearing on the right (Fig. 1b). The patient is currently deciding whether or not he would like a further myringoplasty on the right ear to seal this new perforation.
Reports have described how symptoms in these cases are characteristic of the length of time that the impression material is retained.\(^4\) In the acute stage, patients may suffer from otalgia, hearing loss and tinnitus while in cases of chronic retention symptoms are often similar to those of chronic supplicative otitis media with intractable otorrhoea.\(^5\)

In our case the impression material had expanded in the middle ear cavity but was removed relatively easy without having to undertake further ear surgery. However, reports in the literature have discussed how formal mastoid surgery has had to be performed to remove mould material with the material causing complications including ossicular erosion and the formation of middle ear granulation tissue and polyps.\(^6\)–\(^7\)

Symns and Nelson report the use of a trans–canal approach to remove difficult retained impression material in the middle ear cleft encasing or disrupting the ossicular chain. However, the authors discuss how in their experience this approach was suboptimal with difficult visualisation, sensorineural hearing loss and failure of the subsequent tympanoplasty graft. They instead recommend removal through a facial recess approach in these circumstances as it allows dissection in the plane of the incudostapedial joint permitting removal of material in the lateral middle ear space without jeopardising the patient’s hearing.\(^8\)

Although the reporting of middle ear complications from hearing aid fitting is rare, adverse incidents are, in all likelihood, much more common than the literature would suggest.\(^9\) Awan et al. discuss how in developing countries such as Pakistan, because of the magnitude of hearing loss and the lack of access for numerous patients to costly medical centres, many patients resort to the use of cheap hearing aids. These are often fitted by untrained individuals increasing the risk of significant complications.\(^3\) However, even in developed countries reporting of complications or recognition of a retained middle ear impression only when it is causing symptoms in the chronic setting is likely to take place significantly more than it is documented in the literature.

The BSA suggests a number of recommendations to practitioners that undertake aural impressions. In an unusual situation it is suggested that advice and supervision are sought from someone with the necessary experience and competence.\(^1\) In this case, as the patient had undergone a previous myringoplasty, it would have been preferable for the patient to be referred to an audiometry centre linked to an otolaryngology department. This would have enabled a senior technician to perform the procedure and any potential problems could have been swiftly addressed by an otolaryngologist. Despite the patient experiencing significant and unexpected pain during the impression taking, the practitioner in the private clinic did not recognise nor follow-up on the potential for a resultant complication. The patient was only referred to an otolaryngologist after subsequently being seen by his general practitioner 1 month later.

In addition the BSA recommends the use of cylindrical foam otostops during impression taking to protect the tympanic membrane and middle ear.\(^1\) Also when the material for the mould is injected into the external meatus there must be space left between the tip of the gun and the introitus of the meatus.\(^7\) This will enable the material to come out of the ear canal rather than pass medially when the pressure rises in the meatus. In our report, no otostop was used and no space was left between gun tip and meatal introitus meaning the mould material passed through the tympanic membrane and into the middle ear space.

Otoscopy is recommended before inserting the otostop, after inserting the otostop and finally after removing the impression to ensure that no impression material or otostop is left in the ear canal.\(^1\) In this case there is no record of otoscopy being performed.

In its minimum training requirements document, the Professional Practice Committee of the BSA strongly recommends that

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**Fig. 2.** Photograph of impression material passing through the tympanic membrane into the middle ear cleft.

**Fig. 3.** Photograph of the right tympanic membrane perforation post impression material removal.

**Fig. 4.** Photograph of the impression material after removal.

### 3. Discussion

We report the inadvertent perforation of a previously intact tympanic membrane and passage of impression material into the middle ear cleft during the process of hearing aid mould creation. Complications caused by this process have been documented in the literature but are considered very rare. However, patients at particular risk are those with altered anatomy such as patients with tympanic membrane perforations or retraction pockets, ventilation tubes and canal wall down mastoid cavities.\(^3\) In this case the patient had had a previous myringoplasty but the (grafted) tympanic membrane was intact pre mould fitting.
all hearing healthcare professionals, who undertake any aspect of aural care including the taking of aural impressions, submit themselves to an annual skills review and log this in their continuing professional development record.2

In this case several BSA recommendations in the taking of aural impressions were not adhered to leading to a serious otological complication. This necessitated removal of the impression material from the middle ear cleft under general anaesthetic and left the patient with a large tympanic membrane perforation and a significant worsening of his hearing in this ear.

We suggest that the BSA makes annual competency reviews a necessary requirement for all professionals undertaking community based aural care in a similar way to the annual reviews undertaken by doctors in specialty training in the United Kingdom. In addition we suggest that all private/community hearing clinics have an official link with an otolaryngology department so that any unusual or difficult cases can be referred to senior audiologists and any complications from procedures in these clinics can be swiftly assessed and managed by an otolaryngologist.

4. Conclusions

Our report demonstrates how a serious otological complication from the creation of a hearing aid impression in a community based private hearing clinic was managed. Such complications have been reported in the literature but are thought to be rare. However, these complications are likely to be under reported and probably take place more than the literature would suggest. We recommend and advise on how these adverse incidents may be minimised and managed in the future through the instigation of compulsory annual practitioner reviews of competency and clear referral links to an hospital based audiology/otolaryngology department from community or private aural care centres.

Conflict of interest

I declare that there were no competing interests from any of the authors.

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Ethical approval

Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

Contributorship

I declare that the above four authors were the only contributors to the report. The first author will act as guarantor for the work.

Author contributions

Ashwin Algudkar is the primary contributor in collection of information, literature review, writing the manuscript. Belma Maden and Arvind Singh are the secondary contributors in writing the manuscript. Taran Tatla is the secondary contributor writing the manuscript and in supervising the paper.

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