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Case Report

# Hearing Aid Silicone Impression Material Discovered During Exploration of the Middle Ear: 2 Case Reports and Literature Review

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It is unusual to see complications with the preparation of ear mold in order to get hearing aids for children who are in need. However, we came across 2 cases who had a foreign body retained in the middle ear after a long period of time from taking silicon mold impression for hearing aid fitting. One patient presented after 2 years, and the other patient presented after 10 years of hearing aid fitting. We are reporting 2 cases with silicon impression material left in the middle ear for a long period of time after taking an impression for hearing aid fitting and found unexpectedly during exploratory tympanotomy. These reported cases are among the few cases reported worldwide without clear known incidence. This necessitates proper examination by otolaryngologists and the audiologists who are responsible for taking the impression to prevent such complications.

**KEYWORDS:** Foreign body ear, hearing aid, impression mold

## INTRODUCTION

There are few reported cases in the literature about foreign bodies in the middle ear cleft. However, this rare entity may be encountered during clinical practice from time to time. The basic knowledge of the anatomy of the external auditory canal (EAC) and tympanic membrane is essential to avoid any undesired complications. Due to variability in the dimensions of EAC and in order to get the best fitting hearing aid, an impression of the exact suitable size is taken beforehand. In cases of unnoticed ear drum perforation due to any possible pathology, silicone paste may leak into the middle ear, causing adverse reaction and infection subsequently. We are reporting 2 cases of long-standing silicone foreign bodies left inadvertently inside the middle ear. Both cases had different clinical presentations. One of them resulted in a severe inflammatory reaction and persistent otorrhea developed over time from the hearing aid fitting preparation process. The other case had subtle, vague, but persistent complaints necessitating endoscopic exploratory tympanotomy. Both cases required surgical intervention to remove the foreign body material from the middle ear.

## CASE PRESENTATION

This study was approved as part of a research project by the Medical and Research Ethics Committee (MREC) of The College of Medicine and Health Sciences at Sultan Qaboos University (Approval MREC Number: 2620; Date: October 17, 2021). An informed consent was obtained from both patients to use their pictures for academic and teaching purposes as well as for publication.

### Case 1

A 13-year-old boy with bilateral moderate sensorineural hearing loss (SNHL) since early childhood and a long history of using bilateral hearing aids was considered. The patient was referred by the audiologist, who suspected right middle ear pathology. His complaints were intolerance of the hearing aid, ear fullness, and dull aching pain only in the right ear. His complaints developed after a new hearing aid fitting for 2 years. No past history of ear discharge or tympanic membrane perforation was present.

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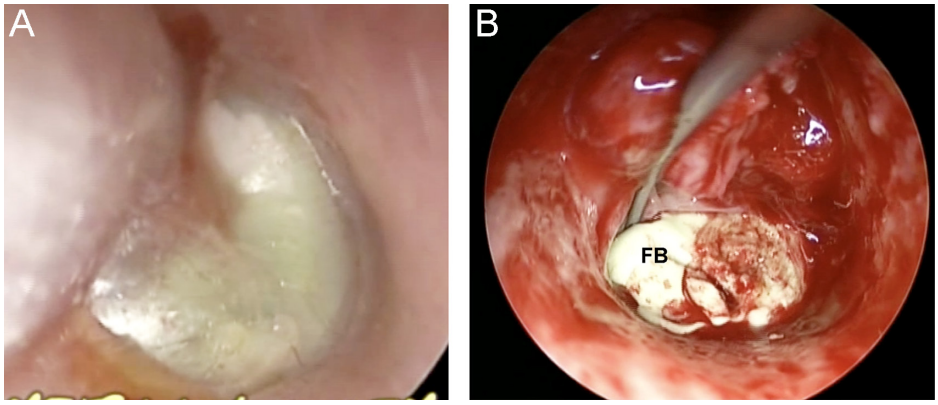


**Figure 1.** (A) Otoscopic view showing intact tympanic membrane with a greenish tint. (B) After the reflection of the tympanomeatal flap, the foreign body was found filling the middle ear.

The clinical examination showed a greenish, intact right tympanic membrane. His pure-tone audiogram revealed left stable moderate SNHL as compared to the previous audiograms, yet the right ear showed moderate mixed hearing loss. The 25 dB air–bone gap presents on the right ear raised suspicion and pushed for exploratory tympanotomy. Computed tomography (CT) scan of the temporal bones showed right middle ear opacification. Surgical exploration of the ear was offered to the parents, and they agreed.

Using the 3 mm Hopkins rigid endoscope, the tympanomeatal flap was elevated, and the tympanic membrane was reflected anteriorly to expose the middle ear. A greenish silicon foreign body filling the whole middle ear space and recesses was successfully removed endoscopically (Figure 1). Ossicular chain was preserved intact. Inflammatory fibrous band between the incus and malleus was excised. The patient made a good and fast recovery and was fitted with a hearing aid afterwards with no complaints.

**Case 2**

A 17-year-old boy was referred to our institute with a history of continuous foul-smelling discharge for 5 years duration. His mother gave a history of hearing aid fitting when he was 5 years old. He did not tolerate the hearing aid in the right ear and ended up using it only in the left ear. Five years prior to the presentation, he started to have recurrent right ear discharge, pressure sensation, and fullness. Otalgia was present from time to time as well. He was treated as mucosal chronic suppurative otitis media with ear drops and oral antibiotics. Prior to his referral to our center, he presented to the emergency department on different occasions with the same complaints.

Clinical examination revealed a very narrow, collapsing right EAC that did not improve with routine measures. Computed tomography showed soft tissue density blocking the right EAC. There was partial sclerosis of the right mastoid with complete opacification of the mastoid air cells and the middle ear. Significant bone erosions were present, including the posterosuperior aspect of the EAC, the glenoid fossa of the temporomandibular joint, the scutum, the floor of the middle ear, and complete destruction of the ossicles. Note is made on CT of a hyperdense structure occupying the middle ear cavity with lobular appearance and longitudinal extension to the right eustachian tube (ET), which was widened compared to the contralateral side (Figure 2A-B). Magnetic resonance imaging was done with suspicion of extracranial complications of chronic suppurative otitis media. Magnetic resonance imaging showed a structure of dark T1 and T2 signal intensity in the right middle ear extending to the right ET, correlating with the findings on CT. The structure was non-enhancing but surrounded by significant enhancement, indicating inflammation in the right EAC, mastoid, middle ear, temporomandibular joint, and soft tissue at the right posterior skull base (Figure 2C-D).

The patient was scheduled for tympanomastoid exploration. Due to the very severe narrowing of the EAC and the preoperative findings on CT of bone erosions of the posterosuperior aspect of the bony EAC, a canal wall-down mastoidectomy was performed. After progressive cleaning and removal of granulation as well as edematous inflammatory tissues, a greenish foreign body was seen filling the

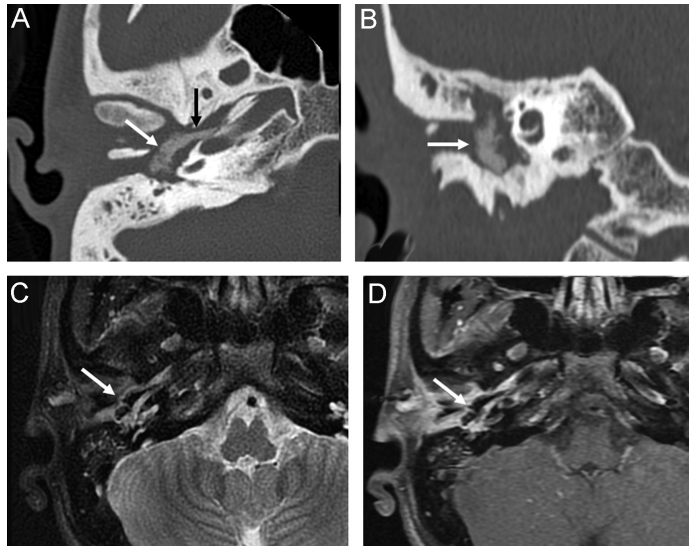


**Figure 2.** (A) Axial and (B) coronal computed tomography images with bone algorithm show a hyperdense foreign body occupying the right middle ear cavity (white arrows) and extending to the eustachian tube (black arrow in A). Bone erosion is present with the destruction of the ossicles. (C) Axial T2 weighted image with fat suppression shows the foreign body within the middle ear cavity to have low T2 signal intensity (arrow). (D) Axial contrast-enhanced T1 weighted image with fat suppression shows a lack of enhancement in the foreign body (arrow) with surrounding significant enhancement.

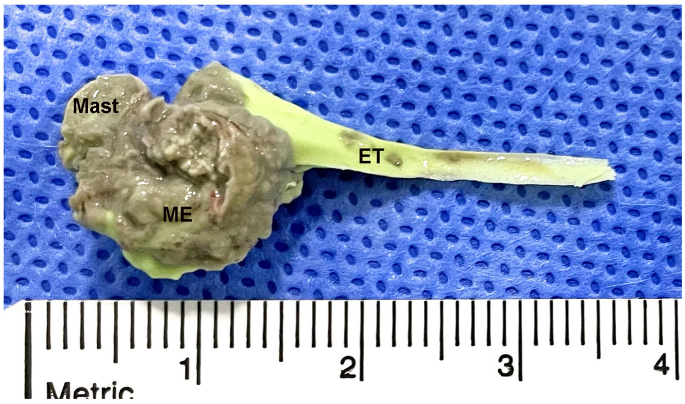


**Figure 3.** Case 2 foreign body foreign body (FB) after removal as 1 piece. The FB is seen made of greenish silicon and taking the anatomical configuration of the middle ear (ME) with anterior extension to the Eustachian tube (ET) and a posterior extension into the antrum (Mast).

whole middle ear cavity extending both backward to the mastoid and anteriorly to fill the whole ET orifice and canal. The foreign body was dislodged gently from the middle ear and removed successfully as 1 piece (Figure 3). No ossicles were found; only the footplate of the stapes could be identified under a dehiscent, overhanging facial nerve.

Because of the associated SNHL and the extensive pathologic middle ear mucosa, no attempt for ossicular reconstruction was performed. The ET was packed with a piece of muscle. A large piece of temporalis facia was placed to cover the middle ear cavity. The mastoid cavity was then partially obliterated using an inferiorly pedicled palva flap. Conchoplasty was performed to aid in the future wearing of a hearing aid. The postoperative course was uneventful.

## DISCUSSION

Among the several options for hearing rehabilitation in patients with hearing impairment, hearing aids are a straightforward, easy, and convenient option for a lot of patients. The decision to use hearing aids depends on a discussion usually happening in the clinic between the otolaryngologist and the patient. Furthermore, an audiologist will be involved in the preparation of the ear canal for the best fitting of the hearing aid. The ear mold material that is usually used is a silicon paste-like material that is injected into the EAC to ensure the best fitting. This silicon material is proven to be tissue-friendly and does not cause any adverse reactions. However, staying in the middle ear and mastoid area for long enough will lead to foreign body inflammatory response and complications.[1]

The number of cases reported in the literature is increasing with time. Suzuki et al[1] reported in their literature review 25 cases of impression foreign bodies until 2015. The total number with their cases was 27. The largest case series reported by 1 institute in the literature was by Jacob et al[2] in 2006, when he reported 6 cases of ear mold foreign bodies in the middle ear. The exact incidence of ear mold foreign bodies retained in the middle ear cleft remained unknown.[3] Van den Boer and colleagues[4] also reported 6 cases in 2019. Our literature review till 2024 revealed a total number of 42 cases including our 2 cases. The risk of such a complication is attributed mainly to external and middle ear pathology. Several papers reported that patients who have tympanic membrane perforations, grommets, retraction pockets, or mastoid cavities are at higher risk of getting such issue.[1,2,5]

The symptoms of presentation and the time of presentation as reported in the literature vary between patients. Furthermore, complications of impression material and tympanic membrane perforation can occur even in patients who had no prior ear pathology or surgical intervention.[6] An example of having an ear mold foreign body without prior pathology was observed in our first patient. Most likely, it has something to do with the technique, expertise, and force applied by the audiologist during impression taking. Sung-Dong Cho et al[7] reported 4 cases with a history of chronic suppurative otitis media prior to presentation. Two of them presented with a complaint of otorrhea, 1 with a foreign body sensation, and 1with otalgia. Manjunath D et al[8] reported a patient who presented 5 days after the impression was taken with blood discharge and worsened hearing loss.

Our first patient presented after 2 years of possibly traumatic hearing aid fitting with a complaint of intolerance to hearing aid and ear block afterward. He reported occasional dull-type otalgia as well. The second patient presented with a history of recurrent episodes of otorrhea for around 5 years before his referral to our institute. He was always managed by topical and systemic antibiotics, with which he improved for some time before the next episode of discharge. We have no definite explanation why the mold did not cause a reaction for 2 years in the first case and almost 7 years in the second case. Our guess is that it is related to the properties of the silicon material, as it is tissue-friendly, but with prolonged contact, tissue might get hypersensitive to it and complaints start.

The surgical approach for the removal of the foreign body depends on the location, accessibility, and surgeon preference. Endoscope, as a minimally invasive technique, proved its value in visualization and removal of the foreign body with preservation of anatomical structures, as in case 1. Microscopic postauricular approach was indicated when there is possible mastoid inflammation, as in case 2. The posterior canal can be preserved untouched or removed (as in case 2) if indicated. The posterior canal wall was eroded in case 2, hence the canal was removed.

The status of the ossicles as well might necessitate partial or complete removal, with possible ossiculoplasty. In our first case, it was possible to remove the foreign body endoscopically via trans-canal endoscopic ear surgery approach. The second patient had a very edematous EAC with an obscured view of the middle ear and erosion of the posterior bony canal wall. In this case, we had to choose a postauricular approach, then canal wall down mastoidectomy to have better access to the middle ear and the foreign body. The postoperative recovery period was fast and uneventful. Both patients were able to wear the hearing aid again and have a better quality of life. Table 1 summarizes the literature review with the number of cases reported between 1983 and 2024.

## CONCLUSION

Hearing aid fitting process is crucial for preventing unnecessary complications in patients with hearing impairment. It is very important to build bridges of proper communication between the patient, the audiologist, and the otolaryngologist. Basic examination skills should

**Table 1.** Summary of Literature Review with the Number of Cases Reported from 1983 to 2024

| No. | Author/Year | Number of Cases | Time Lapse Before Discovery |
|---|---|---|---|
| 1 | Kiskaddon et al, 1983[1] | 1 | 5 years |
| 2 | Mast et al, 1988[1] | 1 | 1 month |
| 3 | Syms and Nelson, 1998[1] | 3 | 1 day, 1 week, third case not mentioned |
| 4 | Wynne et al, 2000[1] | 4 | 2 cases immediate, 1 day, 1 year |
| 5 | Hof et al, 2000[1] | 1 | Not mentioned |
| 6 | Kohan et al, 2004[1] | 6 | 2 weeks, 6 months, 4 years, 3 cases not mentioned |
| 7 | Jacob et al, 2006[2] | 6 | 1 year, 5 cases not mentioned |
| 8 | Awan et al, 2007[1] | 1 | 9 years |
| 9 | Lee and Cho, 2012[1] | 2 | Immediate, 6 years |
| 10 | Meyers JA, 2013[3] | 1 | Few weeks |
| 11 | Suzuki N et al, 2015[1] | 2 | 8 days, 4 years |
| 12 | Lee HM et al, 2016[5] | 1 | 1 month |
| 13 | Van den Boer C, 2019[4] | 6 | 2 cases 3 months, 4 cases not mentioned |
| 14 | Cho SD et al, 2020[7] | 4 | Not mentioned |
| 15 | Manjunath D et al, 2021[8] | 1 | 5 days |
| 16 | Our report | 2 | 2 years and 12 years |

be acquired by all audiologists who are involved in impression taking and hearing aid fitting to reduce complications due to mold foreign bodies. Surgical intervention, once necessary, needs to be tailored toward the best outcome for the patient.

**Ethics Committee Approval:** This study was approved as part of a research project by the Medical and Research Ethics Committee (MREC) of The College of Medicine and Health Sciences at Sultan Qaboos University (Approval MREC Number: 2620; Date: October 17, 2021).

**Informed Consent:** Informed consent was obtained from the patients who agreed to take part in the study.

**Peer-review:** Externally peer-reviewed.

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