

# Surgical removal of hearing aid ear mold impression material from the middle ear: a report of two cases

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## Abstract

A hearing aid effectively improves the quality of life of hard-of-hearing people, but complications after obtaining an ear mold to facilitate fitting the hearing aid have been reported. We treated two patients in whom we surgically removed ear mold impression material from the middle ear. The first patient was a 78-year-old man with persistent right otorrhea. He was initially diagnosed with chronic otitis media and was treated conservatively. The otorrhea did not resolve. Further examination revealed a foreign body in the tympanic cavity, which was identified as impression material based on material analysis. The patient then remembered that a mold for a hearing aid ear had been prepared for him about 15 years ago. Tympanoplasty was performed successfully. The second patient (case 2) was an 84-year-old woman who had undergone canal wall down tympanoplasty. Impression material was introduced into her left ear but could not be removed. Foreign body extraction was performed through an incision behind the ear, with the impression material found embedded in the mastoid cavity. It was successfully removed. In both cases, we considered it crucial to obtain the patient's medical history, thoroughly examine the tympanic membrane, be aware of the risk associated with hearing aid fitting in a postoperative ear, and avoid injecting impression material to aid hearing aid fitting without careful consideration.

**Keywords:** Hearing aid, Ear mold, Impression material, Chronic otitis media, Middle ear foreign body

## Introduction

A hearing aid is an essential tool for improving the quality of life of hard-of-hearing people. The volume of hearing aids sold in Japan tends to increase with our aging society. However, whereas a hearing aid is beneficial to many people, adverse incidents surrounding hearing aid fitting, particularly accidents during the process of making a mold in the ear canal, are occasionally reported. Here we report and discuss two cases in which surgery was necessary to remove ear mold impression material from the middle ear.

## Case reports

### Case 1

A 78-year-old man presented to our clinic with a 6-month history of persistent otorrhea in the right ear. Physical examination revealed accumulated purulent otorrhea in the right ear. In addition, the space between a perforated tympanic membrane and the tympanic cavity was occupied by granuloma-like material. Although the patient had been seeing his local doctor regularly for acute exacerbation of chronic otitis media and had been treated with ear cleaning and antibacterial agents for 2 months, the otorrhea did not stop. He was subsequently referred to our hospital for more radical treatment.

Figure 1a shows that the patient's right tympanic membrane at

the initial visit had become sclerotic. Calcified and indurated material was also found in the tympanic cavity. The epitympanum was full of granulomas, and purulent otorrhea was apparent. According to the pathological examination, the granuloma was inflamed and composed of degenerated and cornified material associated with calcification. Computed tomography (CT) of the temporal bone (Figure 1b) showed that the mastoid antrum in the right ear was poorly pneumatized, and there were soft tissue shadows within the tympanic cavity. They were particularly obvious in the uniformly high-density area from the tympanic cavity toward the Eustachian tube. Based on these findings, the diagnosis was chronic otitis media and suspicion of tympanosclerosis.

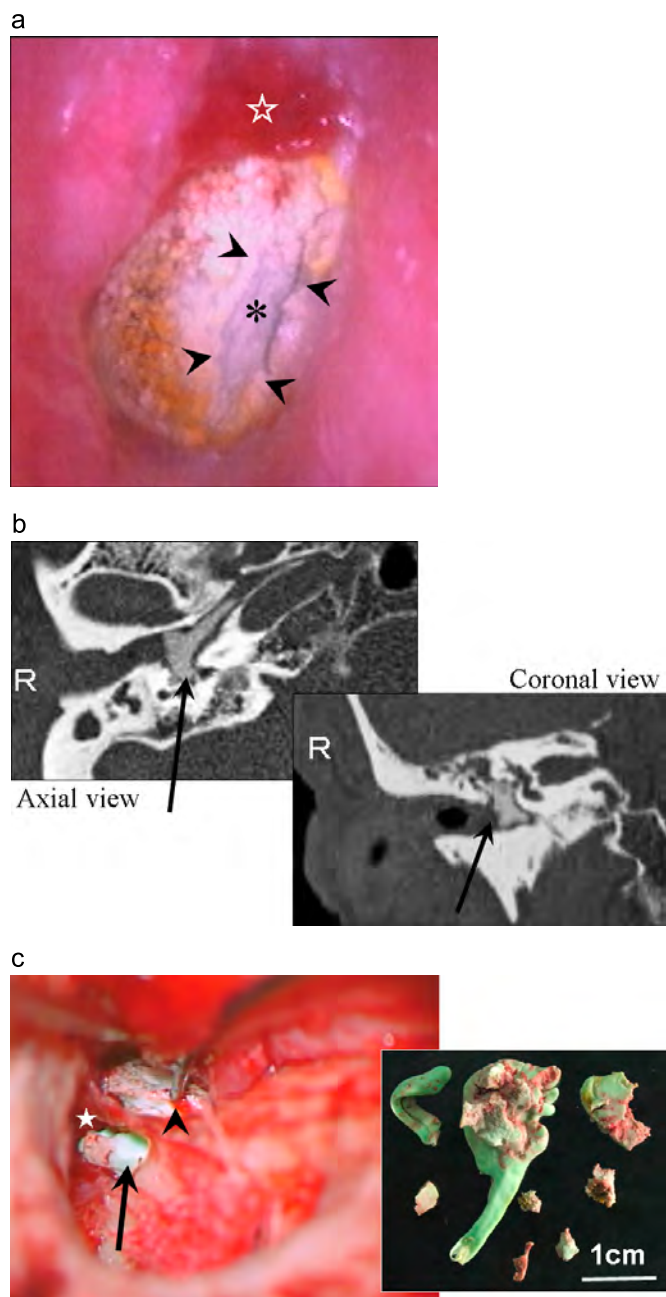
We recommended conservative therapy to address the infection. The patient, sensitive to cefotiam and clindamycin, underwent a course of injections and was treated with daily ear cleaning, but the otorrhea did not resolve. He then underwent tympanoplasty for diagnosis and radical treatment. Figure 1c shows the surgical findings. We performed mastoidectomy and approached the tympanic cavity through the mastoid antrum. The mastoid air cell was full of purulent discharge and granulomas, but no bone defects were found between the mastoid antrum and the epitympanum. There were no cholesteatomas or tumors. The tympanic cavity was full of a tough, elastic, rubber-like, light green foreign body that occupied and clung closely to the inside wall between the epitympanum and the mastoid antrum and extended anteriorly into the Eustachian tube. Because the malleus and incus were embedded in the foreign body, they were removed along with the foreign body during surgery. Although we surgically removed the chorda tympani nerve as well as the foreign body in the Eustachian tube, the stapes was saved. Canal wall up tympanoplasty with reconstruction of the tympanic cavity was performed.

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**Figure 1** Case 1. a: Patient's right tympanic membrane has become thickened and sclerotic. Perforation (arrowhead) was found behind the tympanic membrane. A calcified and indurated plate-like substance (asterisk) was identified in the tympanic cavity. Granulomas (star) were seen in the epitympanum. Purulent otorrhea has accumulated. b: Dorsal view after mastoidectomy. Computed tomography (CT) shows the temporal bone without contrast. Note the uniformly high-density area (arrow) in the tympanic cavity. c: Perioperative findings and foreign bodies. The incus (star) and chorda tympani n. (arrowhead) are seen. The light green foreign body (arrow) occupied the space between the tympanic cavity and mastoid antrum. Right: The foreign bodies have been removed from the middle ear.

Postoperatively, the otorrhea was rapidly alleviated, and the patient has been making satisfactory progress. The foreign body removed from the middle ear looked like ear impression material. According to the quantitative analysis, C and Ci were major components of this foreign body, which is the same material as is

commercially available in impression material. According to our patient's postoperative interview, he remembered having purchased a hearing aid from a traveling salesperson about 15 years prior to developing otorrhea but did not remember the details. The hearing aid had not been used for many years, and the patient did not remember it until he was reminded of it when we brought up this issue.

#### Case 2

An 84-year-old woman had visited a hearing aid dealer because of a hearing impairment due to canal wall down tympanoplasty surgery on her left ear 18 years ago for chronic otitis media. She had not seen an otorhinolaryngologist before shopping for the hearing aid but conveyed to the hearing aid dealer that she had undergone ear surgery. Because a high-powered hearing aid was proposed as an alternative to the one she already had, a hearing aid ear mold was made at the hearing aid shop. With the aim of fitting the hearing aid properly, the hearing aid dealer injected impression material into her left ear after inserting a sponge stopper to prevent accidental pouring. The dealer then tried to remove the solidified impression material from the ear, but it fractured due because of a difficult removal. The foreign body remained within the ear. She immediately went to a clinic, where a doctor also could not remove it. She was referred to our hospital.

Physical examination revealed foreign body-like impression material projecting from the external orifice of the left ear. CT showed that the foreign body fully occupied the mastoid cavity (Figure 2a). Instead of removing it from the opening of the external ear canal, which would have been difficult because the inside of the mastoid was larger than the inlet, we designed a surgical treatment, which we performed 10 days later.

Figure 2b shows surgical findings. An incision was made behind the ear, which revealed a green foreign body occupying the mastoid cavity. The foreign body was incarcerated in, and clung closely to, the external ear canal and mastoid cavity. We dichotomized the foreign body and began a two-pronged removal: one part of the foreign body through the posterior incision, and the other part from the external ear canal. None of the ossicles was broken. The patient made good progress and left the hospital on the third day after surgery.

#### Discussion

The volume of hearing aids sold has increased with Japan's aging society. In 1990, the annual shipment into Japan was 300,000. By 2014, that volume increased to about 525,000 hearing aids per year. Among all types of hearing aids, the shipping volume of behind-the-ear (BTE) hearing aids is remarkably high,<sup>1</sup> and most of the BTE hearing aid users have ear molds. The purpose of wearing an ear mold is to prevent howling sounds, make it difficult to remove the hearing aid, and stabilize its acoustic properties. The ear mold is particularly easy for hard-of-hearing people to fit securely. However, cases of erroneously injecting impression material into the outer and middle ears during the fitting process are occasionally reported. A previous study showed that there were about 35 patients who required surgical removal of impression materials from the ear.<sup>2</sup> Furthermore, according to a national study that was conducted for the past 12 years by the Japan Audiological Society,<sup>3,4</sup> 28 of 300 accidents involving residual impression material filling the ear space required general anesthesia to remove it.

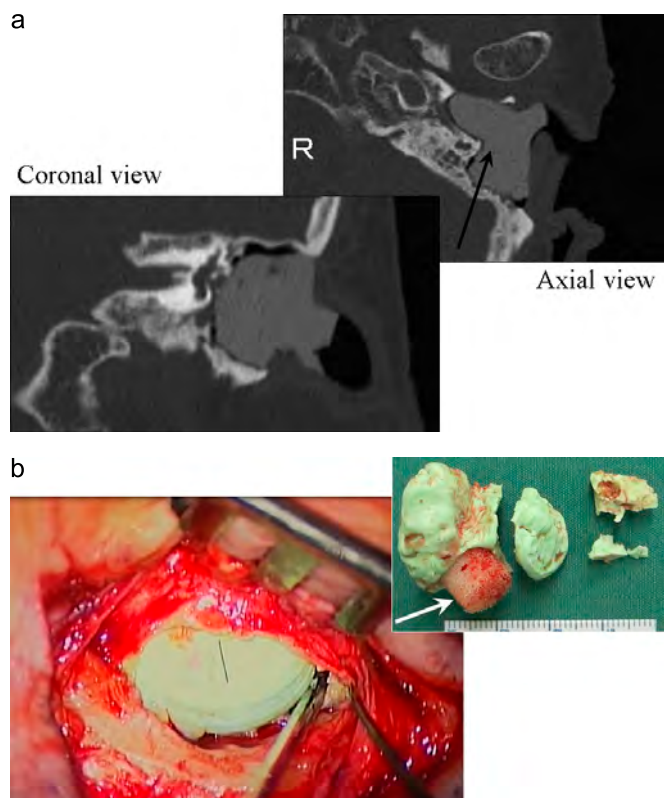


Figure 2 Case 2. a: CT of the temporal bone without contrast. A uniformly high-density area (arrow) is seen from the mastoid cavity to the external ear canal. b: Surgical findings and removed materials. The mastoid cavity was fully occupied by a foreign body. A sponge stopper (arrow), which is used to prevent erroneous injection of impression material, was attached to the removed material.

The major causes of these accidents were anatomical issues, including a perforated tympanic membrane, the precarious condition of the postoperative mastoid cavity, retraction into the epitympanum, and epitympanum deficiency. Technical issues include injection without a sponge stopper to prevent accidental pouring and injection of too much impression material. To prevent such accidents, the following points must be considered<sup>2,5,6</sup>: obtaining an accurate medical history of the patient, thoroughly examining the tympanic membrane, being aware of the risks associated with hearing aid fitting in the postoperative ear, and avoiding injection of impression material without careful consideration, among others.

Until 2005, a hearing aid dealer in Japan did not need a license to sell hearing aids. The constitution was amended in 2005 to required registration by local governments, establishment of a management system, and attendance at courses conducted by the Ministry of Health, Labour, and Welfare.<sup>7</sup> To become a hearing aid specialist, the following requirements must be met: Candidates must have a certain amount of experience and attend a 4-year hearing aid practitioner program. He or she then must pass an examination. Those who pass the examination are certified by the Association for Technical Aids. Hearing aid specialty shops, where the certified specialists are employed, are then able to join the Japanese Association of Hearing Aid Dealers.<sup>7</sup> These are not mandatory certifications, but they potentially will become effective indicators of safe, secure hearing aid sales.

Regarding the responsibility of the patients, previous reports

indicated that most patients who encountered accidents similar to that described for our first patient (case 1), after erroneous injection of impression material, immediately saw an otorhinolaryngologist. Some patients, however, go untreated for many years after the injection. The longest time reported, according to our literature review, was 9 years before removal of the impression material after erroneous injection.<sup>8</sup> In our case, the foreign material was removed after 15 years—possibly the longest time between injection and removal. This case—in which the impression material not only entered the middle ear and had been unnoticed for many years but was also recognized and diagnosed at the time of surgery to remove it—is particularly rare. This case is also peculiar because even the patient's family members, as well as the patient himself, had entirely forgotten that the patient had been fitted for a hearing aid.

If a middle ear infection lasts a long time without identifying the cause from the patient's medical history, and if its shadows within the tympanic cavity are also observed on CT, we must bear in mind that a foreign body in the middle ear may be the cause. In fact, foreign bodies remaining in the middle ear for a long time have been described in cases of chronic otitis media caused by persistent otorrhea,<sup>9</sup> which is similar to this case; broken and melted auditory ossicles<sup>10</sup>; and severe dizziness and anacusis resulting from a semicircular canal fistula.<sup>2</sup> It has also been thought that complications increase as time progresses if foreign bodies remain in the middle ear for a prolonged time.<sup>9</sup> In our case, unfortunately, although we were forced to remove the ossicles and chorda tympani nerve together with the foreign body, we believe that our surgical treatment was appropriate because the otorrhea stopped immediately after the operation. From a social point of view, one important issue in this case was that the hearing aid fitting was performed by an unlicensed hearing aid dealer, so we can neither identify the distributor in charge nor refer to the record of that time. It was probably unavoidable, however, because 15 years ago hearing aid dealers could sell hearing aids to anyone without being registered anywhere or having a license as a hearing aid specialist.

Injecting impression material into the mastoid cavity after canal wall down surgery seems to be the most common type of mistake,<sup>2,5,6</sup> as in our second patient (case 2). According to the hearing aid shop where the accident occurred, a hearing aid dealer knew from the patient interview that she had undergone ear surgery, and knew from visual observation that her ears were not in good condition. It seems, however, that this dealer did not have knowledge about and/or recognition of the patient's previous surgery. This dealer also did not recognize a large cavity located posterior to the external ear canal and so never imagined that the injected impression material was incarcerated in the cavity. The shop is a local eyeglass shop where they sell hearing aids in addition to eyeglasses. The shop was registered to a local government, but this dealer did not hold a license as a hearing aid specialist. Hence, the hearing aid shop did not have enough knowledge or recognition of unusual ear anomalies, including the postoperative ear in this case, resulting in the erroneous injection.

Precautions are recommended for hearing aid fitting by the U.S. Food and Drug Administration,<sup>11,12</sup> which stipulates, "a hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician" in case of "visible congenital or traumatic deformity of the ear." Likewise in Japan, when any one of the eight contraindications for hearing aid fitting (Table 1) established by the Japanese Association of



Table 1 Contraindications to a hearing aid fitting

- Presence of visible deformities or injuries of the ear caused by ear or other surgery
- History of otorrhea caused by otitis media or other problems during the previous 90 days
- History of sudden or progressive hearing loss during the previous 90 days
- History of unilateral hearing loss during the previous 90 days
- Acute or chronic dizziness
- Significant cerumen accumulation in the ear
- Eczema, injuries, or discomfort in the external ear canal
- Audiometric air–bone gap  $\geq 20$  decibels at 500, 1000, and 2000 hertz (Hz)

When any of these eight factors is present, the prospective user must see an otorhinolaryngologist before being fitted for a hearing aid.

Hearing Aid Dealers<sup>13</sup> is present, the hearing aid dealer should first advise prospective users to see an otorhinolaryngologist. In our case 2, the patient had undergone ear surgery, which is one of the contraindications. Therefore, the hearing aid shop should not have performed a hearing aid fitting. Fortunately, the patient recovered completely. To avoid similar incidents, otorhinolaryngologists, in collaboration with hearing aid shops, must enlighten more people to increase awareness about the risks associated with hearing aids.

In conclusion, we presented two patients for whom we were forced to surgically remove impression material. In case 1, the patient was originally diagnosed with chronic otitis media, but a foreign body was later identified in the middle ear during surgery. We learned from an extended patient interview that a foreign body had been in the patient's middle ear for the past 15 years without his knowledge. In case 2, we considered a case in which hearing aid dealers with insufficient understanding of the postoperative ear erroneously injected impression material into the middle ear. Both patients underwent surgery and completely recovered. We must be vigilant to prevent similar accidents, and we need to enlighten people about the possibility of this problem.

## References

1. Japan Hearing Instruments Manufacturers Association. The shipment number of the hearing aid in Japan. (<http://hochouki.com/about/report>). (Accessed Apr 9, 2017). (in Japanese).
2. Suzuki N, Okamura K, Yano T, Moteki H, Kitoh R, Takumi Y, Usami S. Silicone impression material foreign body in the middle ear: two case reports and literature review. *Auris Nasus Larynx* 2015; 42: 419–23.
3. Sugiuchi T, Kodera K, Zusho H, Asano Y, Kanesada K, Hayashida M, Kanaya K, Tokumaru T. [Complications resulting from taking ear impressions.] *Nippon Jibiinkoka Gakkai Kaiho* 2015; 118: 1058–67 (in Japanese).
4. Sugiuchi T, Zusho H. [Ear injuries caused by auditory canal impression in hearing aids fitting: second report.] *Audiology Japan* 2002; 45: 75–81 (in Japanese).
5. Jacob A, Morris TJ, Welling DB. Leaving a lasting impression: ear mold impressions as middle ear foreign bodies. *Ann Otol Rhinol Laryngol* 2006; 115: 912–6.
6. Kohan D, Sorin A, Marra S, Gottlieb M, Hoffman R. Surgical management of complications after hearing aid fitting. *Laryngoscope* 2004; 114: 317–22.
7. Inoue K. Present situation of hearing instruments in Japan—Japan Trak 2012. *Otolaryngol Head Neck Surg (Tokyo)* 2015; 87: 278–86 (in Japanese).
8. Awan MS, Iqbal M, Sardar ZI. Iatrogenic insertion of impression mould into middle ear and mastoid and its retrieval after 9 years: a case report. *J Med Case Rep* 2007; Feb 2: 1–3.
9. Lee DH, Cho HH. Otologic complications caused by hearing aid mold impression material. *Auris Nasus Larynx* 2012; 39: 411–4.
10. Leong SC, Banhegyi G, Panarese A. Serious complications during aural impression-taking for hearing aids: a case report and review of the literature. *Ann Otol Rhinol Laryngol* 2012; 121: 516–20.
11. Meyers JA, Ardeshirpour F, Hilton CW, Levine SC. Complication from hearing aid mold material: a case report and review of legal matters. *Am J Otolaryngol* 2013; 34: 739–42.
12. Code of Federal Regulations: Warning to hearing aid dispensers: hearing aid devices; professional and patient labeling, 21 CFR Sect. 801.420 2012.
13. Japan Hearing Instruments Dispensers Association. Contraindications associated with hearing aids. ([http://www.jhida.org/kyoukaitowa/kensyo/kinki8\\_a4.jpg](http://www.jhida.org/kyoukaitowa/kensyo/kinki8_a4.jpg)). (Accessed November 11, 2016) (in Japanese).

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