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Case Report

Impression Material in the External and Middle Ear: an Overview of the Literature and a Stepwise Approach for Removal

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Here, we provide a literature overview of cases with protruding molding material for earplugs or hearing aids and subsequent required treatment, including our own cases. Patients at risk are those with impaired tympanic membranes or who previously underwent otologic surgery. Symptoms such as otalgia, tinnitus, and vertigo are alarming but do not always arise. In case of doubt, a CT scan is of additive value to prepare for adequate surgical removal and to limit potential damage. A stepwise approach for the clinician on how to address these challenging cases is presented, based upon the literature and our own experience.

KEYWORDS: (silicone) impression material, middle ear, foreign body

INTRODUCTION

Over the last two years, three cases were referred to our department with silicone material protruding into the middle ear; the silicone had been applied as a mold to create either adjusted earplugs or hearing aids. In our experience, the prevalence of these incidents is increasing due to the increasing population of hearing aid users. In the case of middle ear involvement, simply attempting to remove the silicone material may cause damage. Patients at risk are those with tympanostomy tubes, perforations, or retraction pockets of the tympanic membrane, as well as patients with a history of mastoidectomy [1]. Notably, this is often exactly the population that requires either earplugs or hearing aids. However, to date, no guidelines have been published on how to address this clinically relevant issue. Here, we describe our own experience; we also provide a review of the literature and a stepwise approach to address these incidents.

In the Netherlands, the standard procedure to create custom molds is performed by an audiology assistant. Routinely, a cotton ball is applied in the external meatus, followed by warm, colored silicone material by means of a pistol. If the cotton ball is not applied or if it insufficiently occludes the external ear canal, the silicone material can reach the tympanic membrane and beyond, as illustrated by the next three cases.

CASE PRESENTATIONS

Case 1

Our first case is a 7-year-old girl with bilateral grommets who underwent earplug adjustment for swimming lessons. Upon introduction of the silicone material, the patient immediately complained of otalgia, and the audiology assistant realized she had forgotten to apply a cotton ball before introducing the silicone impression material. The girl was referred to our center; orange silicone material was observed in both ears. Importantly, the silicone material had caused hearing loss and immediate pain, but no other symptoms. It was not yet clear how deeply the material protruded into the (middle) ear.

A high-resolution computed tomography (CT) scan was then performed in order to evaluate the protrusion of the material. The CT scan illustrated that on both sides, the external meatus was obstructed, and the material reached the tympanic membrane without protrusion into the middle ear. After informed consent was obtained, the silicone material was removed without complications. Otoscopy confirmed the (pre-existing) grommets to be in the correct position without damage to the tympanic membrane.

Case 2

Our second case is a 20-year-old male who consulted an audiologist to obtain custom earplugs because of his work in a high-noise environment as a baker. Immediately after injection, the patient suffered from otalgia and hearing loss without vertigo or tinnitus.

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The audiologist attempted to manually remove the mold; this was painful but appeared successful. After no more remnants were detected, the procedure was ceased. However, the patient was referred to our hospital because he still suffered from hearing loss. Microscopic otoscopy showed remaining silicone material surrounding a large tympanic perforation and in his middle ear.

Audiology tests confirmed a conductive hearing loss of 30 dB on the left side (Figure 1a). A CT scan was then performed, illustrating that the material had protruded into the middle ear, encasing the stapes and extending into the hypotympanum and facial recess. The material was projected against the horizontal part of the facial nerve, directly adjacent to the horizontal semicircular canal (Figure 1b).

The potential risks of hearing impairment, vertigo, and facial nerve damage were explained to the patient, and he was scheduled for surgical removal of the material by post-auricular incision and an endoaural approach six days later. After careful removal of the remaining material in the meatus, we observed the perforation in the tympanic membrane and the material that had flowed into the middle ear (Figure 1c). The remaining silicone material was completely removed, and the ossicular chain and chorda tympani were saved. The eardrum was reconstructed with an underlay fascia temporalis graft. After six weeks, the tympanic membrane was healed and intact. Auditory testing after 6 weeks showed a reduction in conductive hearing loss from 30 to 15 dB and full recovery after 6 months (Figure 1d).

Case 3

Our third case was a 41-year-old woman with a previous medical history of a canal wall up mastoidectomy and tympanoplasty of her right ear; the patient had also undergone tympanoplasty with reconstruction of the ossicular chain of the left ear. Three small tympanic membrane perforations were known to persist on the left side. To provide the patient with a conventional hearing aid, a mold was applied, and the material erroneously flowed into the left middle ear of the patient. ENT surgeon attempted to release the mold in a private outpatient clinic. However, manipulation induced vertigo and facial pain. Hence, the patient was referred to our department, and a CT scan was performed. Imaging not only showed material in the external meatus, but also in the middle ear, encasing the stapes (Figure 2a). The patient initially refused to undergo surgery; however, in less than a month, she became motivated and was scheduled for removal under general anesthesia.

By means of a combined approach, light blue silicone material was observed in the aditus ad antrum, extending inferiorly into the hypotympanum, encasing part of the previously reconstructed ossicular chain, and lying against the horizontal semicircular canal (Figure 2b). Moreover, the material protruded against the dehiscent facial nerve. Upon further exploration, the material was found to be judiciously elevated from the horizontal part of the facial nerve, the oval window, and the anterior part of the stapes footplate; the remnants are depicted in Figure 2c. Postoperatively, no vertigo was observed, and facial nerve function was normal and symmetrical (bilateral House-Brackmann scale 1). The patient's hearing impairment, measured 6 months postoperatively, was stable to her pre-operative situation; pre-operative and postoperative audiometry showed a normal perceptive threshold and an airbone gap of 20 dB.

DISCUSSION

Our described cases with molding material in their middle ear illustrate that after careful examination, diagnostic work up and microsurgical excision, a favorable audiometric result can be accomplished. However, more disadvantageous outcomes have also been reported, such as (persistent) perforations, conductive or sensorineural hearing loss [1-3], vestibular symptoms [2, 4] and a perilymph fistula [5]. This emphasizes the need for low-threshold referral to a center of expertise for this type of pathology.

Before the introduction of molding material into the external meatus, it is absolutely necessary both to be informed about the previous medical history of the patient and to perform proper otoscopic evaluation of the tympanic membrane [5, 6]. Extra caution should be taken in the presence of risk factors such as tympanostomy tubes, tympanic membrane perforations, and retraction pockets, and when the patient has a history of previous surgery, such as mastoidectomy [1]. The first case report was published in 1983 [6], and a literature search revealed 40 similar cases published in English, varying only in external or also middle ear involvement [1-17]. Table 1 provides an overview of those 34 cases in the literature with middle ear involvement and for whom the respective (surgical) removal procedures were described.

The overview provided in Table 1 includes our two presented cases with middle ear involvement. Reasonably, upon introduction, each mold will induce some conductive hearing impairment. However, other symptoms are less common. In seven cases, there was no description of symptoms upon introduction or removal of the molds [2, 3, 7-9]. Of the remaining 29 cases, acute severe otalgia was reported in 20 subjects (20/29), and 1 patient also suffered facial pain; therefore, these may be considered to be alarm symptoms. In addition, one patient suffered from hematorrhea, dizziness or vertigo was reported in seven patients, and tinnitus was reported in three patients. All of these relatively acute symptoms may be considered alarming, and referral would therefore be indicated. Notably, in cases of delayed presentation, symptoms such as perforation, persistent discharge, and conductive hearing loss may mimic chronic otitis media (n=4) [10, 11].

Manual removal of silicone material is expected to be less harmful in the absence of the risk factors mentioned above. However, cases have been reported of patients with intact tympanic membranes who suffered from hematoma, hematotympanum, or even traumatic tympanic perforation upon extrusion of molds [2, 4-6, 12]. Therefore, even in the absence of risk factors, referral to an ENT/otology department should be considered in the case of acute symptoms upon either introduction or removal of molds.

The next step in clinical decision-making is to determine whether imaging (CT scan of the mastoids) should be performed. The extent of the protrusion of material varies greatly in the described population; however, most cases were known to have a medical history of (previous) tympanic membrane perforation (n=27; Table 1). Eight perforations were caused iatrogenically upon either introduction (n=6) or

Table 1. Overview of reported cases of symptoms, location of the mold, therapy, and complications

	Author, year	Age	Sex	Side	Original indication	Symptoms introduction/ removal	Risk factor	Location in ear	Surgery	Result/remarks
1	Kiskaddon et al. (6)	70	M	L	Hearing aid, presbycusis	Pain, otorrhea, vertigo, HL	TM perforation	Middle ear surrounding ossicles	Mastoidectomy with facial recess approach, removal	
2	Syms and Nelson (2)	72	M	?	Hearing aid, mixed HL, chronic otitis media	Unknown	Perforation, no cotton ball inserted	Hypotympanum, Eustachian tube, mesotympanum	Transcanal approach under local anesthesia; manipulation of the mass was not well tolerated	Complications; acute vertigo, nausea, vomiting, and HL. Profound HL remained, vestibular symptoms resolved in months.
3		58	M	L	Hearing aid, mixed HL presbycusis, bilateral COM, perforations	Unknown	Perforations	Anterior and posterior epitympanum, entire mesotympanum, bilateral mixed HL	Transcanal approach under general anesthesia; argon laser was used. A perichondrial graft was used for the TM reconstruction.	Progressive HL of both sensorineural and conductive origin
4		75	F	R	1 year after molding presentation with discharge	Unknown	Perforations	Anterior and posterior hypotympanum, ossicular chain erosion	Facial recess approach, tympanoplasty	No complications, hearing outcome unknown
5	Hof et al. (12)	8	F	R and L	Hearing aid, mixed HL, COM and perforations	HL	TM perforations	Right: epitympanum, enclosing ossicles, chordae, and crurae of the stapes. Ossicilar chain was preserved.	Chordae on the right side had to be sacrificed, ossicles remained intact on both sides	Postoperative hearing back to baseline
6				R and L				Left: tympanotomy, tympanomeatal flap, hypotympanum and mesotympanum completely, Eustachian tube. Epitympanum and ossicles were free.	Ossicles remained intact, material could be removed without complications	Postoperative hearing back to baseline
7	Wynne et al. (5)	80	M	L	Hearing aid, presbycusis	HL, pain	TM perforation	Small impression into the mesotympanum, part of the ossicular chain	Left in place. Perforation healed, silicone material remained in the middle ear. No HL. Lost to follow-up after a year.	
8		34	M	R	Hearing aid, mixed HL	HL and pain upon removal	TM perforation	Penetration of the TM and a large amount of material resting on the ossicles	Surgical removal and tympanoplasty	Perilymph fistula. Surgical closure without relief. Complete vestibular neurectomy after 1 year due to persistent vertigo.
9	Kohan et al. (3)	80	F	R	Hearing aid, presbycusis	Severe sudden otalgia, tinnitus, worsened HL	healed TM perforation at presentation (6 months later)	intact TM, mold in attic, encased incudostapedial joint	Tympanomastoidectomy, facial recess approach, in the attic encasing the inducostapedial joint, mesotympanum, around the long incus process	No original audiogram, improvement ABG after removal. Remaining SNHL deterioration.
10		60	M	L	Hearing aid, presbycusis	Severe otalgia, HL	Traumatic anterior perforation	Hypotympanum and mesotympanum	Transcanal middle ear exploration, mold in hypotympanum and mesotympanum, from eustachian tube to stapes and round window. Tympanoplasty with perichondrium.	Complete closure of the ABG and healed perforation

Table 1. Overview of reported cases of symptoms, location of the mold, therapy, and complications (continued)

11		60	M	L	Hearing aid, mixed HL, bilateral otosclerosis	Unknown. 4-year delay to presentation.	Fenestration procedure 23 years previously on the left.		Local anesthesia, surgical excision by meatoplasty	No complications
12		9	M	L	Hearing aid, radical mastoidectomy	Acute otalgia, increased HL	Mastoidectomy	Mastoid cavity, narrow EAC	Meatoplasty and transcanal approach, retained cotton wick and mold in the mastoid, posterior to a high facial ridge	None
13		74	M	L	Hearing aid, viral-induced SNHL AD as a child on the right, presbycusis AS	Asymptomatic	Impaction in narrow external meatus	Attempt to remove under local anesthesia. Painful near TM. Manually removed in second instance by another ENT specialist.	Manually/piecemeal	Persistent subtotal perforation, 45 dB conductive HL
14		6	M	L	Hearing aid, SNHL, mastoidectomy AS	Acute otalgia, HL	Mastoidectomy	Mastoid cavity	Uncomplicated removal from the mastoid bowl without complications under general anesthesia	Increased mixed HL
16	Jacob et al. (1)	75	M	L	Hearing aid, presbycusis	HL	TM perforation	Encasing ossicular chain, extending into the hypotympanum, and protruded anteriorly into the Eustachian orifice	Tympanoplasty, middle ear exploration, and canal wall up mastoidectomy	
17		75	M	R	Hearing aid, presbycusis AD>AS	HL, new onset pulsatile tinnitus	TM perforation	Right: encased the ossicular chain, extended inferiorly into the hypotympanum, and protruded into the Eustachian orifice	Transcanal tympanoplasty and middle ear exploration, converted to tympanomastoidectomy facial recess approach because of encasement of the ossicular chain, in particular stapes	Mixed HL with a widened ABG
18		80	M	L	Hearing aid, presbycusis	HL	Attic retraction pocket	Against the pars flaccida in the retraction pocket	None. Tympanomastoidectomy was recommended, but the patient refused and was lost to follow-up.	Enlarged mixed HL
19		53	M	L	Hearing aid, mixed HL	HL	Prior left canal-wall-down mastoidectomy	External meatus only	90 minutes of microsopical removal under local anesthesia	None
20		62	M	R	Hearing aid, presbyacusis	Acute pain on removal of the mold, HL	None	Ruptured tympanic membrane, silicone material in contact with the ossicles	Refused removal. Secondary cholesteatoma developed; surgical removal was performed in two settings. Incudostapedial joint was separated and the lenticular process e roded (either due to previous removal of mold or caused by the cholesteatoma).	Persistent ABG 45 dB, hearing aid
21		8	M	L	Mold for swimming lessons	HL, acute pain	Tympanoplasty tube	Impression in the middle ear through the tympanostomy tubes, not completely around ossicles, not further into the middle ear. During surgery, a small cholesteatoma was found.	Removal of the tube, tympanoplasty and removal of ear mold material without damage. Secondary surgery due to renewed cholesteatoma was performed six months later.	Second postauricular tympanoplasty due to residual cholesteatoma, no long-term consequences

Table 1. Overview of reported cases of symptoms, location of the mold, therapy, and complications (continued)

22	Awan et al. (13)	5	M	R	Mold for hearing aid SHNL from birth. No perforations.	Hematorrhea and otalgia after introduction, traumatic perforation	Traumatic TM perforation upon introduction. Presentation after 3 months; renewed hematorrhea	Epitympanum and external meatus	Latrogenic TM perforation, transmeatal approach, embedded malleus which could not be preserved, tympanoplasty	Nine years later (patient was indicated for cochlear implantation), remnants in the mastoid antrum (was not explored before)
23	Shashinder et al. (7)	12	M	R	Hearing aid, bilateral mixed HL, perforations	Unknown	Subtotal bilateral TM perforations		Permeatal removal, chain intact, no damage. Reached into hypotympanum, mesotympanum and Eustachian tube	None
24	Dhawan et al. (14)	54	M	R	Mixed HL, four surgical procedures, including modified radical mastoidectomy	HL, extreme pain	Not known beforehand. Clinical presentation years after fitting.	Meatus, granulation tissue, a Teflon piston and eroded ossicular remnants, material in epitympanum, mastoid cavity, aditus	Mastoid exploration revealed tenacious granulations, a piston (Teflon) and ossicular remnants, causing complete occlusion of the middle ear cavity, aditus, and antrum.	Dry ear, hearing test was similar to before removal
25	Lee and Cho (10)	46	F	R	Hearing aid, bilateral mixed HL	None	TM perforation, presentation after 6 years due to chronic otorrhoea and polyp	Tympanomastoidectomy with facial recess approach, ossicular erosion, remnants in Eustachian tube orifice, erosion of the long process of the incus and superstructure of the stapes		None
26		71	M	L	Hearing aid, mixed HL, COM	Acute pain and vertigo	Central perforation	Encasing ossicular chain and extending into Eustachian tube; incus was removed and reshaped between stapes and malleus	Bilateral TM perforations	
27	Leong et al. (4)	74	F	L	Hearing aid, bilateral SNHL	Discomfort		Subluxated stapes, impaction in external and middle ear	Mold with sponge against eardrum, traumatic TM perforation and a subluxated stapes with a perilymph leak. Bony canal meatoplasty and sealing of the leak.	None, vertigo complaints 3 months after surgery; spontaneous remission. Similar hearing before and after surgery.
28	Mitchell et al. (15)	42	M	L	Occupational molds for excessive noise exposure during work, mixed HL	Severe sudden otalgia and vertigo, HL	History of multiple bilateral TM tubes, known conductive HL on the right and mixed HL on the left.	Protrusion through anterosuperior perforation,	Postauricular and transcanal approach, material in Eustachian tube orifice and sinus tympani, encasing all ossicles; resected with CO2 laser and knife. TM reconstruction with cartilage fascia.	
29	Saki et al. (16)	69	M	R	Hearing aid, bilateral severe SNHL	Otalgia, hematorrhea	None; traumatic perforation	Traumatic perforation, material in external meatus, middle ear, attic, aditus and Eustachian tube orifice	Postauricular approach, complete removal without damage	
30	Meyers et al. (17)	77	M	R	Hearing aid, presbyacusis	Acute otalgia, pulsatile tinnitus, ear fullness, HL and intermittent otorrhea for several weeks after fitting	TM perforation	Post-auricular approach, mold surrounded hearing ossicles	Mold was fixed between the stapes and the facial nerve	Perioperatively, the stapes was dislocated creating a perilymphatic leak, which was solved by means of a fascia graft. No post-operative symptoms.

Table 1. Overview of reported cases of symptoms, location of the mold, therapy, and complications (continued)

31	Algudkar et al. (11)	70	M	R	Hearing aid, presbyacusis	Severe pain and increased HL	Myringoplasty for perforation 40 years previously	Large central perforation, material in external meatus bulging into middle ear. No ossicular chain encasement.	Removal under general anesthesia, freshening of the edges of the perforation	Perforation and ABG remained, was not motivated for secondary closure
32	Jung et al. (8)	74	F	L	Hearing aid, mixed HL, chronic otitis media	Unknown	TM perforation	Completely filled left middle ear cavity, encasing ossicles, extending to Eustachian tube, dissociation of stapes-incus joint	Retroauricular approach, canal wall up mastoidectomy, removal of the incus, titanium prosthesis on the stapes foot plate, and tympanoplasty by means of fascia	
33	Suzuki et al. (9)	65	M	L	Hearing aid, bilateral mixed HL, chronic otorrhea	Otalgia and immediate vertigo upon intrusion	Perforations	Upon removal of the silicone, the apex of the impression broke off and remained in the external canal. Patient suffered a left-pointing gaze nystagmus. Material encased auditory ossicles, including stapes, hypotympanum, and Eustachian tube orifice.	Removed 5 years later due to labyrinthitis; the incus was destroyed and fistula of the lateral semicircular canal was found. Mastoidectomy showed extension into the Eustachian tube; the malleus could not be spared. Repaired the fistula with a bone chip and subdermal tissue.	
34		70	F	R	Hearing aid, mixed HL, COM and canal down mastoidectomy	Unknown	Canal wall mastoidectomy as a child	Material filled open cavity, removal under general anesthesia 8 days later		
35	Current study	20	M	L	Hearing aid, mixed HL	Otalgia and HL	TM perforation	Encasing stapes, hypotympanum, facial recess, against facial nerve, next to the horizontal semicircular canal	Removal under general anesthesia, endoaural approach, facial underlay for TM reconstruction	None
36		41	F	L	Hearing aid, mixed HL	Otalgia, HL, facial pain	TM perforation after tympanoplasty + reconstruction of ossicular chain	Middle ear encasing the stapes and in proximity to the oval window	Aditus ad antrum, hypotympanum encasing reconstructed ossicular chain, lying against the horizontal semicircular canal and dehiscent facial nerve	

ABG: air-bone gap; COM: chronic otitis media; EAC: external auditory canal; HL: hearing loss; SNHL: sensorineural hearing loss; TM: tympanic membrane

removal (n=2) of the material. This emphasizes the necessity to use material (such as an otoblock) to occlude the external meatus. To ensure a gradual increase in pressure and to ensure that the material can flow out instead of causing trauma to the tympanic membrane, the application device (such as a pistol) should not be inserted too deeply [12].

If there is clinical suspicion that material may have flowed into the middle ear, or if removal is painful and the condition of the tympanic membrane is unknown, it is advisable to perform a CT scan of the mastoid to 1) prevent collateral damage or complications and 2) establish the extent of protrusion of the molding material. This is pivotal in the presence of risk factors because the molding material can flow with relative ease into the hypotympanum, mesotympanum, and even the Eustachian tube [2, 5, 6, 10, 13].

To safely remove the impression material, four patients could be treated under local anesthesia. In one of these patients, it was necessary to convert and reschedule the procedure for general anesthesia because removal was too painful [1-3]; As a result, microscopic surgery was performed in 33 out of 36 cases. Depending on the location of the material, there was substantial risk of hearing loss and damage to the facial nerve or the semicircular canals. Encountered complications were (persistent) perforations, worsened hearing loss [1-3], and vestibular symptoms [2, 4] (Table 1). One perilymphatic fistula was reported, resulting in a complete vestibular neurectomy a year later due to persistent complaints of vertigo [5]. Transmeatal approaches could be performed in 17 cases, and in all but one case, the material was removed successfully. In the latter case, the material was encountered nine years later in the mastoid antrum when the patient was scheduled for a cochlear implant [13].

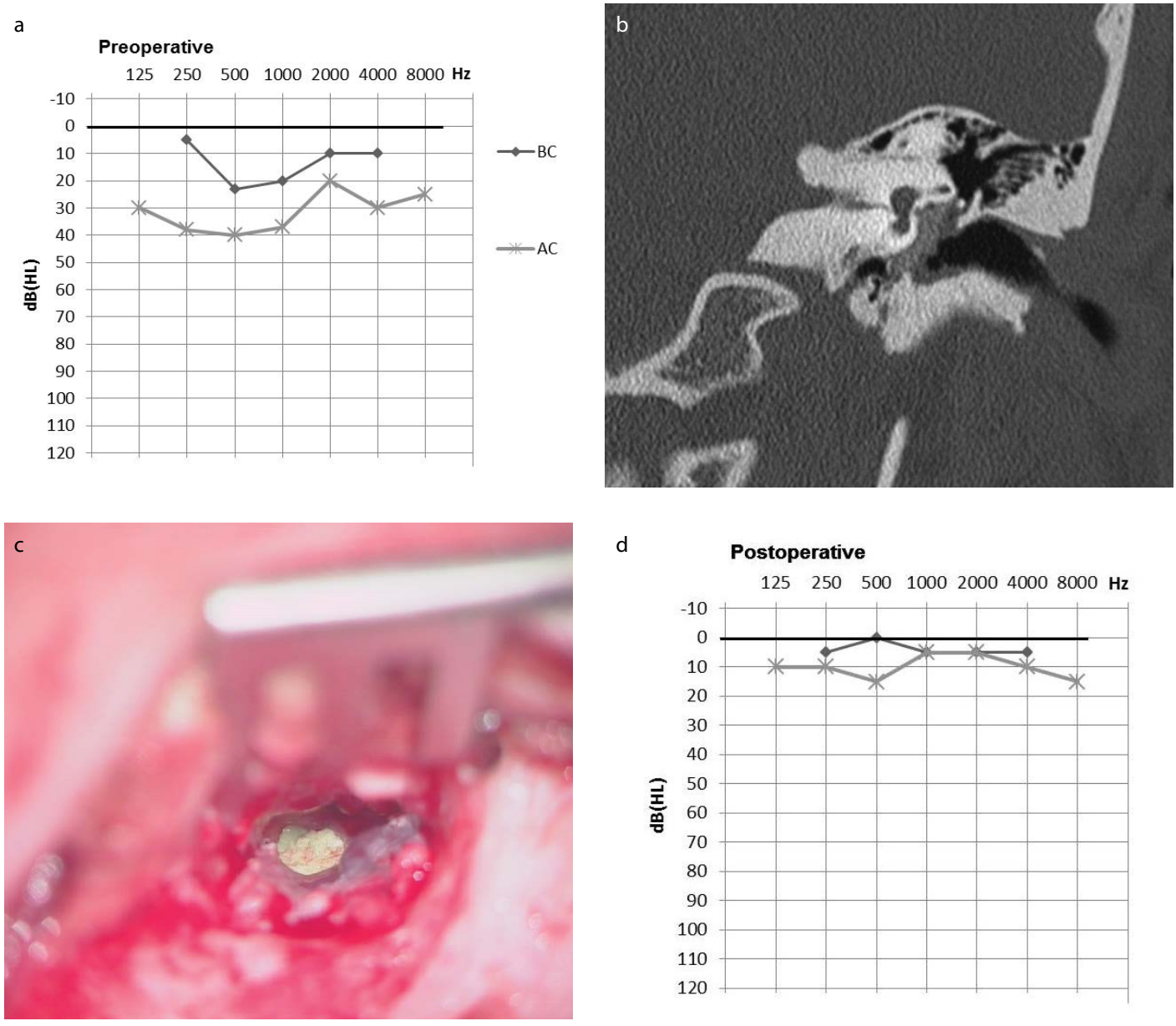

Figure 1. Illustrations of Case 2 a-d. Audiometry results showing pre-operative hearing loss (a). Coronal section of the left middle ear, showing encasement of the stapes and positioning adjacent to the facial nerve and the horizontal semicircular canal (b). Peroperative image of the perforation and silicone material in the middle ear (c). Audiometric improvement measured six weeks postoperatively (d)

To provide a stepwise approach, we created a decision-making flowchart for clinicians confronted with this intractable clinical phenomenon. It is vital for the audiology assistant applying the mold to be informed of potential risk factors. The assistant should be acquainted with the otologic medical history of the patient and should inspect the tympanic membrane by otoscopy. As mentioned, risk factors include tympanostomy tubes, tympanic membrane perforations, retraction pockets, and a previous history of mastoidectomy. When these risk factors are present, the molding material should be inserted by experienced hands. In cases of otalgia alone and in cases where an intact eardrum is observed beforehand, it can be justified to attempt to release the mold by experienced hands. However, if this procedure increases otalgia or if the condition of the eardrum is in doubt, referral to an ENT specialist is indicated, and a CT scan of the mastoids should at least be considered. When risk factors are present, even greater caution is advised, and any occurrence of symptoms at the time of application or retraction justifies referral and a CT scan, as illustrated in the flowchart in Figure 3. If the CT scan confirms that the molding material is present in the external meatus only, manual removal can be attempted by the ENT physician. However, in cases of doubt or middle ear involvement, we recommend removal under general anesthesia.

In conclusion, symptoms such as excessive pain, tinnitus, or vertigo during either insertion or removal of molding material should be considered alarming, and referral is indicated. However, the absence of these symptoms is not a guarantee of adequate placement of the mold, especially in patients with tympanic membrane perforations, retraction pockets, or with a history of otologic surgery. We have pro-

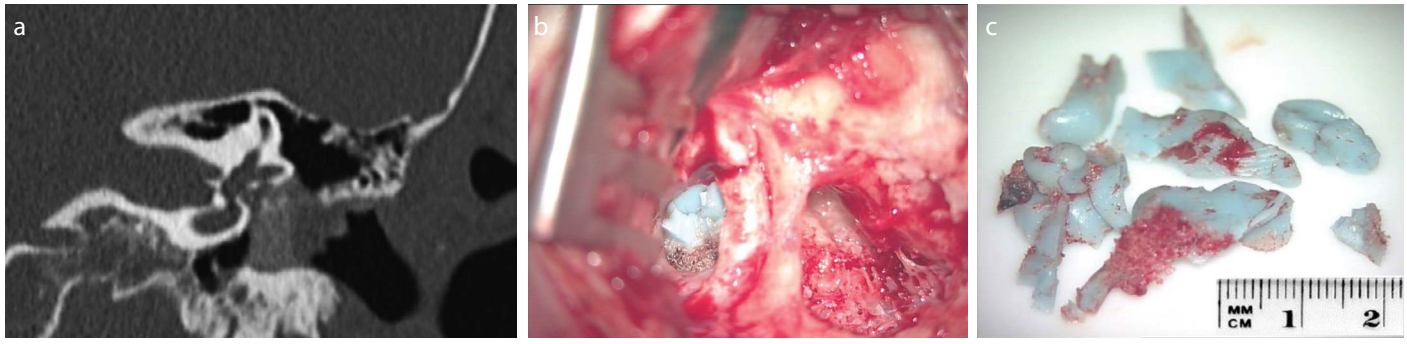

Figure 2. Illustrations of Case 3 a-c. Coronal section of Case 3, showing the stapes covered in material, adjacent to the dehiscent facial nerve and the horizontal semicircular canal (a). Combined approach showing material in the middle ear (b). The remnants after removal (c)

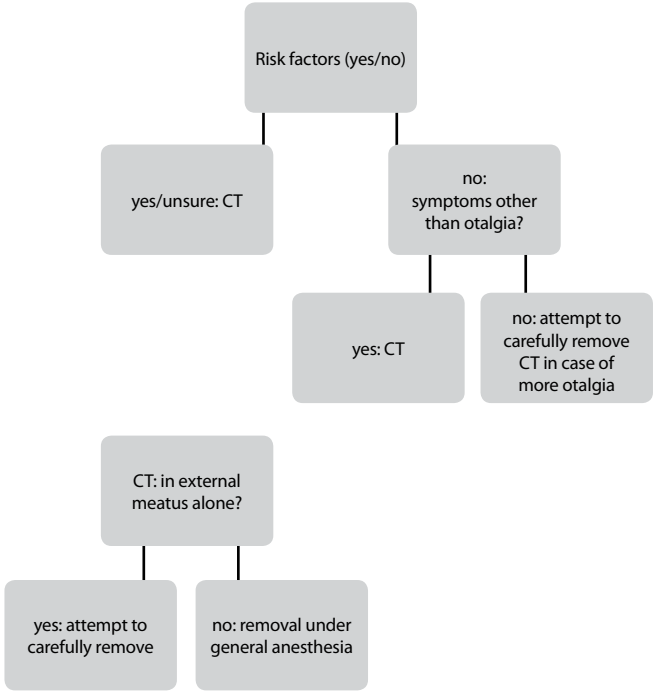

Figure 3. Flowchart as a guideline for clinicians. It is pivotal to investigate whether there are known risk factors and whether symptoms have occurred upon either insertion or removal of the molding material. In the absence of risk factors, manual removal may be carefully attempted; however, if this leads to otalgia or other symptoms, a CT scan is indicated to investigate the location of the mold and determine the proper approach for removal

vided a clinical guideline on how to address these challenging cases in a flowchart (Figure 3). In cases where middle ear involvement is suspected, a CT scan will be of additive value to determine the appropriate approach for removal.

Informed Consent: Verbal informed consent was obtained from patients and the parents of the patient who participated in this study.

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