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Mould constituents in the middle ear, a hearing-aid complication

J. R. Hof, B. Kremer, J. J. Manni

Abstract
During the placement of a mould for a hearing-aid by a hearing-aid dispenser, moulding material entered the middle ear through pre-existent perforations in the tympanic membrane in both ears. Besides hearing loss, there were no other symptoms. Surgical removal of the moulding material by tympanotomy was necessary, and was complicated by encirclement of the ossicles by the material. All the material could be removed and the hearing was saved. Recommendations for an improved procedure of mould-making are made including more detailed information of the otoscopic findings at the prescriptions for hearing-aid moulds.

Key words: Hearing aids; Foreign body, migration; Ear, middle

Introduction

Hearing-aid moulds are used for several reasons. The most common indications are as protection against noise and to prevent contact with water in cases of chronic otorrhoea, grommets, or after (modified) radical operations. In most cases, these moulds are tailor-made by experienced hearing-aid dispensers, sometimes a company nurse is trained specifically for this purpose. In the Netherlands 120 000 hearing-aids per annum are prescribed and over 180 000 tailor-made moulds are produced annually. When some 25 000 moulds of the ear used for noise and water prevention are added, production exceeds 200 000 moulds annually. In the literature a few cases with complications have been described.[1,2]

We present a case report where, during the process of making a hearing aid mould, the material accidentally poured into both middle ears, making an operation necessary.

Case report

An eight-year-old, healthy girl visited our clinic frequently because of intermittent otorrhoea of both ears and a hearing loss due to perforations of the tympanic membrane. Even in periods without otorrhoea, as she had a hearing loss of 20 to 30 dB. Her speech and language development were delayed. Because of the frequency of the otorrhoea, her young age and the state of the tympanic membrane, a tympanoplasty was rejected at that time. It was decided to make use of hearing-aids in order to compensate for the hearing loss.

During the process of making the mould, the hearing-aid dispenser could not remove the moulds in their entirety from both ears and referred her to our hospital.

The girl did not complain of pain or dizziness during the procedure, she only complained about hearing loss. Inspection of the ears showed material still in the external meatus and possibly also through the perforations in the middle ear on both sides. Audiometry showed a bilateral hearing loss of 35 dB (Figure 2). There was no nystagmus. Inspection under total anaesthesia, showed the material widely spread into the middle ear. Because of the elastic consistency of the material the middle ear was explored by tympanotomy.

After elevation of the left tympanomeatal flap, it appeared that the material filled the hypo- and mesotympanum completely. The material even filled the eustachian tube; Figure 1 shows the removed mould. The epitympanum and ossicles were free. Because of the elastic character of the material, it was hard to remove. The mucosa of the middle ear was swollen and inflamed.

Exploring tympanotomy of the right middle ear showed that the material appeared to have filled the epitympanum completely. The material enclosed the ossicles and the chorda tympani and was even discovered between both crurae of the stapes. By removing the material, the chorda tympani could not be preserved, the ossicular chain however was saved.

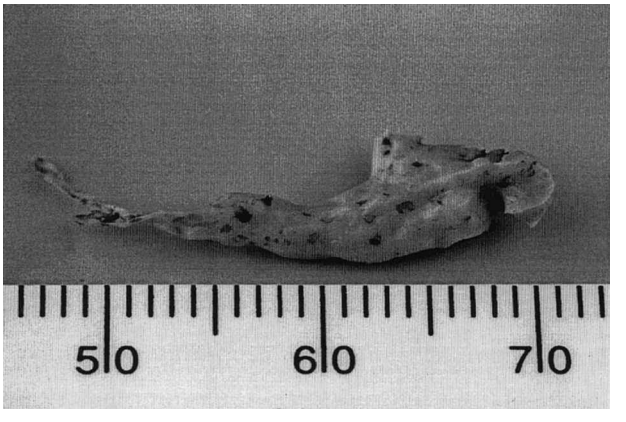

Fig. 1
Mould removed from the Eustachian tube.

From the Department of Otorhinolaryngology – Head and Neck Surgery, University Hospital Maastricht, The Netherlands.
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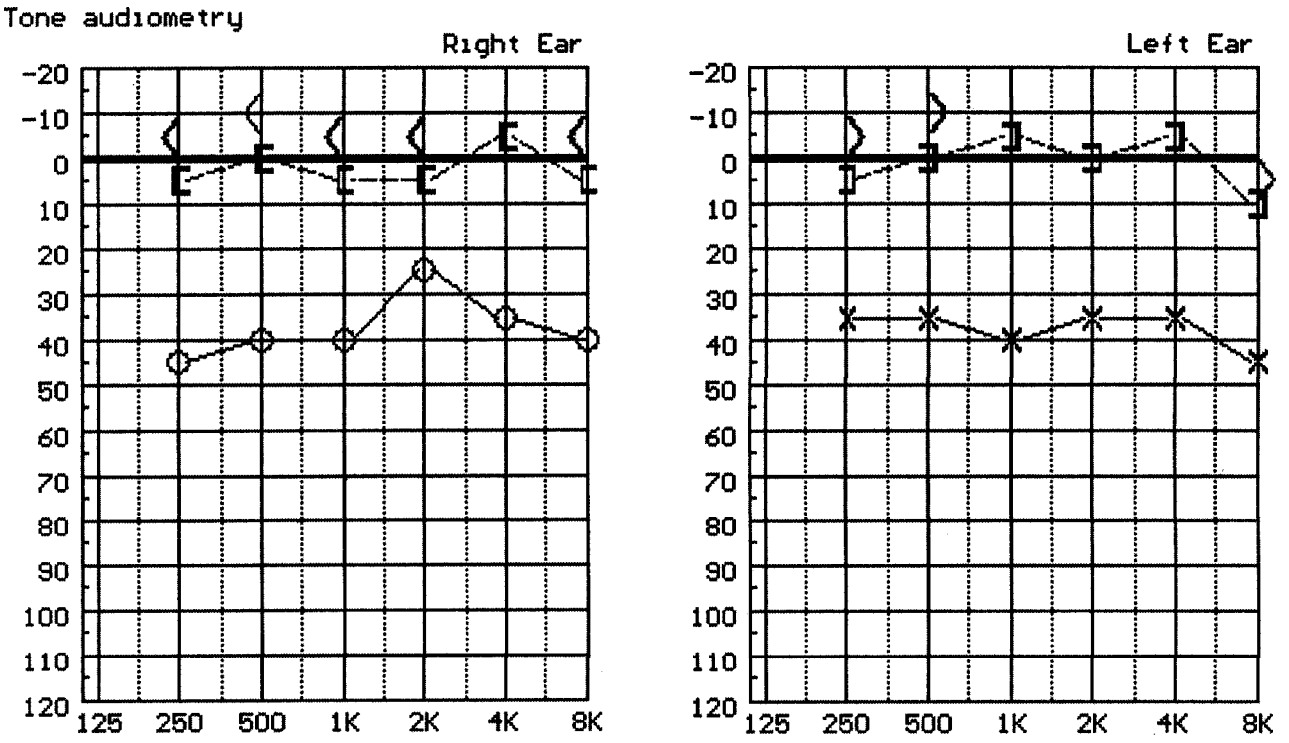

FIG. 2
Pre-operative audiometry.

There were no post-operative problems, no nystagmus, and there was no perceptive hearing loss shown by audiometry. The patient left the hospital after one day and used antibiotics orally for one week. There were no signs of inflammation or otorrhoea after these operations.

After three months, the conductive hearing loss was 25 dB, the same level as before this complication (Figure 3).

Retrospective analysis of the event showed that the procedure for making the ear mould was not optimal. It led directly to this complication. Three important points of attention are:

(1) The external meatus was not sealed with a cotton plug, although the hearing-aid dispenser knew that perforations existed.

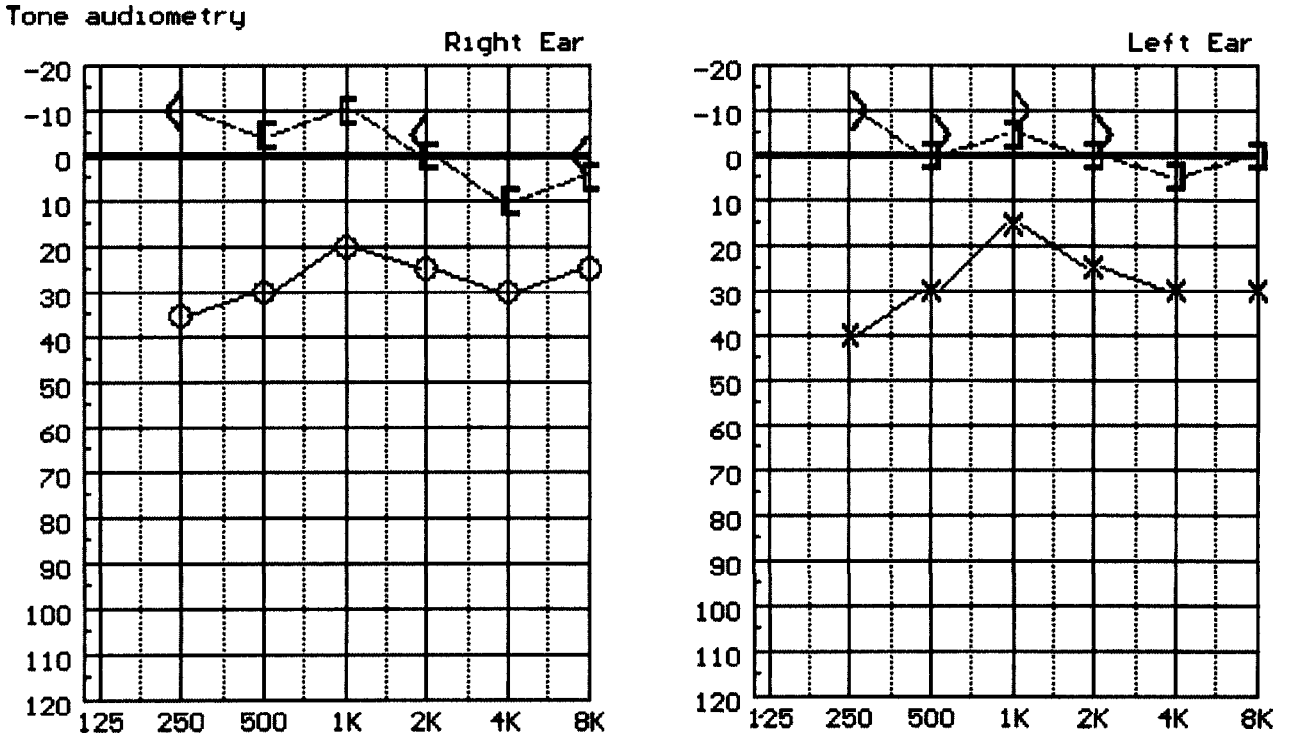

FIG. 3
Post-operative audiometry.

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(2) The mould was made with a very soft material (Otovorm A-soft, Dreven) which is frequently used for children because of the low pressure that is necessary for a good result.
(3) When the material for the mould is brought into the external meatus, there must be space left between the tip of the pistol and the introitus of the meatus. When the pressure rises in the meatus, the material will come out of the ear canal. In this case the external meatus was fully covered by the tip of the pistol so the material could only go further into the external meatus and middle ear and not out.

Discussion

This case shows that making of moulds is not entirely benign, especially in the case of perforations of the tympanic membrane, or after ear operations. Only by an exploring tympanotomy could the material be removed. However, the risk of luxation of the stapes or damage to the ossicular chain should not be underestimated.

Recommendations to improve the procedure to prevent complications like this are:

(1) The prescription for the moulds must be accompanied with more detailed information about perforations and (modified) radical operations.
(2) The mould should be made by a specialized person.
(3) If there are perforations or situations after radical mastoidectomy with canal wall down technique, the ear canal must be closed with a cotton plug.
(4) The material must not be too soft.
(5) The ear canal should not be sealed off by the tip of the pistol.

In the literature, two reported cases can be found.[1,2] These show iatrogenic perforations of the tympanic membrane by the material. By mastoidectomy (1) and middle ear inspection (2) the material was removed, in these cases resulting in a damaged hearing chain, temporal dizziness and permanent perceptive hearing loss.[1,2]

It is to be expected that these complications happen more frequently than is reported.

Addendum:

During the description of this case, a similar case has been reported.* In this case very soft moulding material passed through the cotton plug into the middle ear, in a patient with a pre-existent perforation of the tympanic membrane.

*Letter to the editor (in Dutch), Ven dan de P M *Ned Tijdschr KNO Heelk* 1999;**3:**137.

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Address for correspondence:
J. R. Hof, M.D.,
Department of Otorhinolaryngology, Head and Neck Surgery,
University Hospital Maastricht,
P. Debeyelaan 25,
Postbus 5800,
NL-6202 AZ Maastricht,
The Netherlands.

Fax: +31 43-3875580

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