The Journal of Laryngology & Otology (2007), ***121***, *110–113*.

doi:10.1017/S0022215106002222
Printed in the United Kingdom
First published online 29 September 2006

Main Article

Prospective study of the microbiological flora of hearing aid moulds and the efficacy of current cleaning techniques

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Abstract

Introduction: Wearing hearing aid earmoulds has been implicated as a predisposing factor in the development of chronic otitis externa. Audiologists come into contact with a large number of hearing aid earmoulds and these could potentially harbour pathogenic micro-organisms, with the risk of subsequent cross infection. Cleaning with dilute alcohol is widely used in an attempt to break the chain of infection.

Objective: To determine the presence and nature of microbial flora on hearing aid earmoulds and the efficacy of cleaning methods used to prevent cross infection.

Setting: Secondary health care within the audiology department of Addenbrooke's Hospital, Cambridge, UK.

Design: A prospective, observational study.

Methods: Hearing aid earmoulds were swabbed before and after cleaning. Samples were cultured to determine qualitatively and quantitatively the microbiological flora present before and after cleaning.

Results: Twenty out of 21 (95 per cent) earmoulds had microbes present and, of these, 19/20 (95 per cent) had a polymicrobial profile. Coagulase negative staphylococci and diphtheroids were the most frequent microbial isolates, but pathogenic bacteria and fungi were also demonstrated on earmoulds both before and after cleaning.

Conclusions: The polymicrobial flora, including recognized pathogens, that colonizes earmoulds may lead to chronic otitis externa. Cleaning with 70 per cent alcohol solution was ineffective, in particular for pathogenic fungi on earmoulds.

Key words: Hearing Aids; Equipment Contamination; Otitis Externa

Introduction

Otitis externa can represent a recurrent problem for the patient and a significant workload for otolaryngology departments (up to 20 per cent of patients seen).[1] Although the precise pathogenesis of otitis externa has not been elucidated, studies have identified predisposing factors, such as water exposure and increased humidity in the external auditory canal (EAC).[1–3] Patients who need to wear earmoulds for hearing aids have been shown to have a predisposition to developing chronic otitis externa.[1] Although these patients have chronically elevated humidity within the EAC,[2] it is also possible that the hearing aid mould itself could provide a potential reservoir of pathogens, leading to recurrent and chronic otitis externa.

Hearing aid audiology clinics have a large throughput of patients, and it is important to maintain asepsis to prevent cross infection. Hearing aid moulds are often handled by both patients and audiologists during consultations, and efforts are made to prevent potential contact transmission of pathogens by cleaning the earmoulds.

The purpose of this study was to determine the presence and nature of the microbiological flora of hearing aid moulds and also the efficacy of current cleaning methods.

Patients and methods

Patient inclusion and exclusion criteria

Patients prospectively attending the walk-in hearing aid repair clinic at the audiology department were given an explanation of the study purpose and procedure and informed consent was obtained. Only 'behind the ear' (BTE) acrylic hearing aid moulds (both soft and hard) were included in this study as all the patients attending the clinic had this particular kind of hearing aid mould. The size and configuration of the BTE aid allowed sampling without staff having to touch the mould with their fingers.

All patients with current, chronic or recent otitis externa (within the last three months) were excluded from the study, as were those with otorrhoea due to any cause. Any hearing aid mould that was not in

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Accepted for publication: 23 February 2006.

situ or that had been handled by the patient in the clinic was also excluded from sampling.

Methods

Sampling and transport. The BTE hearing aid was removed by the primary author without any contact with the earmould itself, and a dry, sterile, cotton-tipped swab was used to rub the surface of the mould which lies within the external auditory canal. The swab was then immediately placed in an enclosed tube containing sterile Amies transport culture medium with charcoal (Sterile Transport Swab, Sterelin, Stone, UK). The specimen was labelled with demographic data and marked as a 'pre-clean' sample. The hearing aid mould, after being handed back to the audiologist, was then cleaned with either an Alcowipe (Seton Prebbles, Bootle, UK) or Azowipe (Vernon-Carus, Preston, UK) antiseptic wipe (70 per cent isopropyl alcohol solution) for 20 seconds and left to dry for 60 seconds. The detailed cleaning method used was left to the audiologist but care was taken not to allow any contact of the hearing aid mould with hands or non-sterile surfaces after cleaning. Another dry, sterile, cotton-tipped swab was used to sample the same portion of the mould and was then placed in a fresh, enclosed tube of sterile Amies transport medium, labelled with demographic data and marked as 'post-clean'; both samples were then sent to the microbiology laboratory.

Culturing technique. Samples were received and culturing began within two hours of the specimen being taken in the clinic. Each sample was inoculated to one plate each of blood agar, chocolate agar with bacitracin disc, and a CLED (Cysteine Lactose Electrolyte Deficient) plate (Oxoid Ltd., Basingstoke, UK). All plates were incubated at 37°C in 5 per cent CO_2 for 48 hours and examined at 24 and 48 hours. Samples were also inoculated to one neomycin anaerobe agar plate with metronidazole disc (inoculated anaerobically in a N_2, H_2 and CO_2 mixture for 48 hours at 37°C and examined at 24 hours, 48 hours and five days) in addition to a Sabouraud dextrose agar plate with added chloramphenicol (incubated at 30°C in air for five days and examined daily). Microbial growth was quantitated by recording colonies extending to the first set of streaks on the agar as 'light', to the second set as 'moderate' and to the third as 'heavy'.

Identification of organisms. Standard UK diagnostic laboratory identification techniques were used, following the Health Protection Agency standard methods (see http://www.hpa-standardmethods.org.uk/). Staphylococcal isolates were differentiated by coagulase status by use of the tube coagulase method. Any isolates of *Staphylococcus aureus* would have been tested for methicillin resistance by the disc method using Iso-sensitest agar. Provision was made for identification of coliforms using chromogenic agar and analytical profile index (API 20E or API 20NE). The X and V factor disc test on Columbia agar and the optochin disc test were used to identify haemophilus and *Streptococcus pneumoniae*, respectively. Pseudomonas was identified primarily by the oxidase test and then by use of API 20E and API 20NE as necessary. Fungi were identified by microscopy and the germ tube test, and further differentiation was performed with biochemical testing kits.

Results

Twenty-one BTE hearing aid moulds were sampled from 10 male and seven female patients (age range 51–92 years, mean 68.3 years). All moulds tested were vented. In four male patients, both the right and left hearing aid moulds were sampled on the same visit to the audiology clinic. None of the patients attending the clinic had suffered from acute otitis externa in the last three months.

Microbes were present on 20/21 (95.2 per cent) moulds, with two or more species being present on 19 of the 20 moulds (95 per cent) with positive cultures. In many cases, there was colonization with multiple species of microbe on the hearing aid moulds (Table I). Bacteria were the most frequently encountered type of microbe (present on 95 per cent of moulds with positive cultures), but yeasts were present on over one-third of moulds (35 per cent). Coagulase negative staphylococci were the predominant form of microbe, but a number of known pathogens, such as *Pseudomonas aeruginosa* and *Candida albicans*, were also isolated (Table II). *Staphylococcus aureus* and haemophilus species were not obtained from any earmould sampled. It was noted that, in the four patients who had earmoulds from both ears sampled, there were differences in the microbiological flora and degree of colonization between the right and left earmould.

There was heavy growth of 14 cultured organisms, moderate growth of 24 and light growth of 17. Only one hearing aid mould sampled during the study (4.8 per cent) yielded no growth of organisms after two days of incubation. Results of macroscopic observation of debris had no bearing on the type of organism cultured or the degree of growth in culture.

Analysis of the efficacy of the cleaning methods utilized revealed that only in one hearing aid mould out of 20 (5 per cent) was there eradication of all the microbes present prior to cleaning. Wiping the earmould with either Alcowipes or Azowipes (both being cloths soaked with 70 per cent isopropyl alcohol) made no difference to the efficacy of microbe removal, despite the mould appearing

TABLE I

MICROBIAL SPECIES CULTURED FROM HEARING AID MOULDS

Species cultured (*n*)	Hearing aid moulds [*n* (%)]
0	1 (4.8)
1	1 (4.8)
2	10 (47.6)
3	5 (23.8)
4	2 (9.5)
5	2 (9.5)

https://doi.org/10.1017/S0022215106002222 Published online by Cambridge University Press

TABLE II

MICRO-ORGANISMS OBTAINED FROM HEARING AID MOULDS

Micro-organism	Frequency [*n* (%)]	Culture growth (*n*)		
		Heavy	Moderate	Light
Bacteria				
Coagulase negative staphylococci	19 (95)	4	10	5
Diphtheroids	15 (75)	7	4	4
Pseudomonas aeruginosa	3 (15)	1	1	1
Klebsiella sp	3 (15)			
K oxytoca	2		1	1
K pneumoniae	1		1	
Proteus sp	2 (10)	1	1	
Peptostreptococcus sp	2 (10)			
P magnus	1			1
P micros	1		1	
Enterobacter cloacae	1 (5)			1
Citrobacter koseri	1 (5)			1
Fungi				
Candida parapsilosis	7 (35)	1	4	2
Candida albicans	1 (5)		1	

macroscopically clean in all cases before post-clean sampling. Although cleaning did not eradicate micro-organisms, it did have the effect of reducing the bacterial load on the hearing aid mould (shown as downgrading from heavy to moderate or moderate to light growth when comparing pre- and post-cleaning cultures). Even this effect was not apparent in the majority of earmoulds colonized by fungi (Table III).

Discussion

This study demonstrated that over 95 per cent of the patient hearing aid moulds sampled harboured micro-organisms and that there was polymicrobial colonization of earmoulds in the vast majority of cases (95 per cent). There do not appear to be any similar studies specifically sampling the portion of the hearing aid mould which fits inside the EAC. A smaller study has demonstrated polymicrobial colonization in seven of 10 (70 per cent) hearing aids (however, the entire outer surface of the hearing aid was swabbed as opposed to the mould specifically).[4] A much earlier investigation of stock earmoulds (used in hearing aid evaluation), revealed colonization of 20/36 (56 per cent) of moulds sampled.[5] The authors of that study were reassured by the 'small quantities' of non-pathogenic bacteria isolated (only four species were identified and no fungi were sought) and suggested that this may have been due to frequent cleaning of the earmoulds.

TABLE III

EFFECT OF CLEANING

Outcome	Pre-clean swab (*n*)*	Post-clean swab (*n*)*
Colonized with microbes	20	19 (95%)
Heavy growth of ≥1 species	8	2†
Pseudomonas cultured	3	2 (66.7%)
Fungi cultured	7	6 (85.7%)

*Number of earmounds; †6 downgraded to moderate or light growth but no eradication.

There was cerumen visible on many of the earmoulds, and it follows that the microbial flora demonstrated should be consistent with that found in human cerumen. This was not the case; although studies (including ours) have demonstrated that coagulase negative staphylococci and diphtheroids are frequently cultured, streptococcus species[6] and *S. aureus*[7] are also frequently found in cerumen. The pathogens demonstrated on our earmoulds, such as klebsiella species, yeasts and *Ps. aeruginosa*, are either absent or present at low levels in normal cerumen.[6–8] It could be argued that the microbiological flora grown may be consistent with that found in the EAC specifically, as opposed to that of cerumen, but, again, our study demonstrated altered microbial flora, with an increased variety and frequency of pathogenic organisms.[6,9,10] It is interesting to note that the microbiological flora of the right and left earmoulds of four of the patients differed; no obvious explanation can be given for this finding.

The occlusal effect of the hearing aid mould, with increased humidity, despite venting of all earmoulds sampled, could lead to increased quantities of micro-organisms within the EAC. This effect has been demonstrated in earlier studies, with substantial increases in the number of micro-organisms in the EAC after just 25–30 minutes of occlusion.[11,12] Polymicrobial flora within the cerumen is found more frequently in those with chronic otitis externa.[13] The increased humidity of the EAC in hearing aid wearers[2] may lead to changes from normal to polymicrobial floral (as demonstrated in our study), with a preponderance of pathogenic microbes and subsequent development of chronic otitis externa.

The cleaning method routinely used in hearing aid audiology clinics, i.e. wiping the earmould with 70 per cent alcohol solution, was shown to be inadequate. Only 5 per cent of the earmoulds with a previous positive culture showed no growth on the post-clean culture. Alcohol solution is normally considered to be a useful antiseptic for hand hygiene as part of an infection control strategy, and it is also

https://doi.org/10.1017/S0022215106002222 Published online by Cambridge University Press

frequently used for disinfection of the hard surfaces of critical medical equipment. However, in our study, not only did it not remove pathogenic bacteria consistently (merely reducing the load from heavy to moderate or moderate to low culture growth), but it was particularly ineffective in reducing the fungal load of the earmoulds sampled. These findings are not in agreement (with regard to effects on bacterial colonization) with those of Lankford and Behnke,[5] who thought that the cleaning methods utilized in the audiology departments they sampled were sufficient. In their study, earmoulds were used intermittently for hearing assessment and cleaned regularly by a variety of methods, including soap and water, soaking in antiseptic solutions, or washing with 70 per cent isopropyl alcohol. Previous publications also suggest that using alcohol to clean acrylic earmoulds can denature the material, leading to cracks in the mould.[5] The comparatively longer insertion time of the earmould in the EAC, and the difficulties many patients encountered in trying to regularly clean them, meant that the moulds sampled in our study had large numbers of microbes present (many of them pathogenic) when they were removed to give to the audiologist. Unfortunately, this study shows that, even when cleaning was attempted with 70 per cent alcohol solution, the risk of transmitting pathogens to the next patient's earmould was not eliminated. Clearly, a more robust infection control strategy needs to be developed, with more effective cleaning techniques, and staff should perform hand hygiene carefully between decontamination of each earmould.

The bacterial and fungal load on earmoulds, demonstrated by this study, may lead to increased potential for the development of otitis externa, and this may be of concern in those patients with compromised immune systems. Furthermore, the frequently observed patient behaviour[4] of licking an earmould (to lubricate it with saliva to aid insertion) should be discouraged.

- **Wearing hearing aid earmoulds has been implicated as a predisposing factor in the development of chronic otitis externa**
- **This study aimed to determine the presence and nature of microbial flora on hearing aid earmoulds and the efficacy of cleaning methods used to prevent cross infection**
- **Ninety-five per cent of earmoulds had microbes present and, of these, 95 per cent had a polymicrobial profile. Coagulase negative staphylococci and diphtheroids were the most frequent microbial isolates**
- **Cleaning with 70 per cent alcohol solution was ineffective, in particular for pathogenic fungi on earmoulds**

It would be useful for future studies to assess the effect on the microbiological flora of leaving the earmould out of the EAC for prolonged periods of time (as advised for patients with acute otitis externa). It would also be interesting to demonstrate, in those with hearing aid moulds, whether it is the increased humidity in the EAC or some foreign body effect that leads to the development of chronic otitis externa. Studies demonstrating optimal cleaning methods would be very welcome.

Conclusion

Patients with hearing aid moulds have a varied and polymicrobial flora on their earmoulds in the vast majority of cases, and the current cleaning method of rubbing with 70 per cent alcohol solution is ineffective.

Acknowledgements

Other members of the departments of audiology and clinical microbiology, especially Mr N Bentley, are warmly thanked for their help and cooperation.

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Mr N Ahmad takes responsibility for the integrity of the content of the paper.
Competing interests: None declared