Temporary Threshold Shift following Ear Canal Microsuction

A comparative analysis measuring hearing levels before, immediately and 1-week after earwax removal by microsuction

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Abstract

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Objectives:

To investigate a temporary threshold shift (TTS) of hearing and pain/discomfort caused by the microsuction procedure. Hearing loss induced by impacted cerumen was also investigated.

Design:

Impacted cerumen was removed from patients using microsuction. Hearing assessments were carried out before the procedure, immediately after and 1-week later. Hearing thresholds measured in different sessions were compared to determine the TTS caused by the microsuction procedure and hearing loss induced by impacted cerumen. A questionnaire was used to evaluate the pain/discomfort experienced by patients.

Study Sample:

30 patients (50 ears) were recruited from a cerumen removal clinic.

Results:

Significant hearing loss caused by impacted earwax was found across individual frequencies (mean 11.4dB, maximum 38.1dB). A TTS appeared in 43/50 (86%) ears, ranging from 0 to 16.2 dB averaged across frequencies between 250 and 8000 Hz, with the highest TTS at 6000 Hz. Pain and discomfort levels were both rated low, the mean levels were 1.2 (SD=0.5) and 1.6 (SD=0.5) respectively on a scale from 1-10.

Conclusions:

Microsuction appears to be a well-tolerated and preferred procedure for removing impacted cerumen. Because of the significant TTS induced by the microsuction procedure, safety concerns from a hearing perspective should be raised with the patient.

Introduction

Cerumen (earwax, or wax) is a natural physiological substance of the ear secreted from the external auditory meatus (EAM, or ear canal), which cleans, protects and lubricates the EAM. Unless the levels become excessive, it forms a coating on the EAM and then migrates using a self-cleaning process that moves the cerumen to the entrance of the meatus, where it is naturally expelled. However, cerumen or other debris in the ear (e.g., shed hairs, dirt, sand, skin, foreign objects) can become excessive and sometimes impacted. Impacted cerumen or debris can cause problems, such as conductive hearing loss, aural fullness, tinnitus and vertigo (Schwartz *et al*., 2017; Sharp *et al*., 1990; Subha and Raman, 2006). In these circumstances, removal of cerumen/debris is recommended (for the purposes of the current study, cerumen/debris will be referred to as cerumen). Approximately 2.3 million people per year in the UK seek medical treatment for impacted cerumen to alleviate the symptoms (Guest *et al*., 2004).

A variety of cerumen removal treatments are available in Ear, Nose and Throat (ENT) departments, General Practitioner (GP) surgeries and Audiological clinics. These include cerumenolytics, manual removal, syringing/irrigation and microsuction. Small, non-impacting amounts of cerumen can usually be managed using cerumenolytics or a manual method, such as a Jobson Horne or a curette. Impacted cerumen however can sometimes require a syringing/irrigation or microsuction procedure. Syringing/irrigation is a ‘wet’ method used to ‘flush out’ the cerumen from the EAM using water, traditionally performed by GPs and nurses (Sharp *et al*., 1990; Kraszewski, 2008). Historically a metal syringe was used and was then replaced with an electric oral jet irrigator (with special ear irrigator tip), as it provided better water pressure control and more precise control of water jet direction (Aung and Mulley, 2002). However, because of the water pressure within the ear canal, the practice of syringing/irrigation was deemed potentially unsafe and increased the risk of trauma to the external auditory meatus (EAM, or ear canal) or tympanic membrane (TM, or ear drum), and ear infections (Sharp *et al*., 1990; Dinsdale *et al.,* 1991; Prowse and Mulla, 2014). Therefore, contraindications for this procedure include a history of TM perforation, recurring otitis media/externa or previous ear surgery such as mastoidectomy and cleft palate.

Microsuction (whose name is derived from a combination of the word’s “microscope” and “suction”) is a method of cerumen removal that uses vacuum suction pressure to break up and extract impacted cerumen. As a result, it can be performed on cases of perforations or otitis media, without damaging

consequences. Historically it has been performed by ENTs but is now also available in audiology clinics under the visualisation of a microscope (Sarode *et al*, 2017). However, not all audiologists and ENT practitioners currently agree with the use of microsuction for cerumen removal. The main concern is noise generated at the probe of the microsuction tip, which can pose a risk of noise induced (temporary or permanent) hearing loss. The skin of the EAM can also be dragged out with the cerumen, potentially causing bleeding. Therefore, the overall comfort of the procedure and potential damage to the skin of the EAM or TM, has also been questioned in the literature.

Spencer (1980) measured the noise level generated at the probe of the microsuction unit during middle ear operations and reported a maximum sound peak level with a 2mm tube of 104.6 dB SPL. Katzke and Sesterhenn (1982) used deaf human volunteers and cadaver temporal bones with soft tissue to determine noise levels in the EAM produced by suction instruments. They found that maximum output levels recorded in the EAMs of the human volunteers, who were deaf were 108 dB SPL for a size 5 tube (0.75mm diameter), 115 dB SPL for a size 7 tube (1.5mm diameter) and 138 dB SPL for size 9 (2mm diameter), respectively. However, the duration was not mentioned for these procedures. Mendrygal and Roeser (2007) also demonstrated maximum peak sound pressure of 140 dBA using a 2mm tube and 118 dBA for a 1mm tube respectively, when a KEMAR was used. In addition, the greater noise levels were found when higher negative pressure was applied. As a result, they concluded that suction should be used for short periods of time and intermittently and if possible other methods of cerumen extraction such as hooks or forceps should be used.

More recently, in a study by Luxenberger *et al.* (2012), noise levels were measured on an artificial ear. Sound levels ranged between 97 and 103.5 dBA, with the peak sound level at 118 dBA. Moreover, when loose keratin flakes were used to simulate dry and flaky cerumen, the sound level peaked at 146 dBA, authors referred to this as the 'claret effect', which was described as the excessive noise caused by the partial obstruction of the sucker by cerumen or dermal flakes. The frequency generated by the microsuction device was characterised between 4000 and 6000 Hz for 2mm suction tubes and 3000 Hz for 4mm tubes, respectively. Similar noise levels were found by Katzke and Sesterhenn (1982), when pieces of silastic were removed from the EAM, a much louder whistling noise was reached a peak of 150 dB SPL in the size 9 and 158 dB SPL in the size 7 tubes, respectively.

However, Snelling *et al.* (2009) suggested that there was no compelling evidence to support clinically significant hearing threshold shift (TTS) of hearing, caused by the microsuction procedure. According to their results, noise levels during the procedure were largely under 100 dBA (411 out of 497 episodes, 82.70%), whereas noise levels exceeded 100 dBA 86 times (17.30%), and noise levels exceeded 120 dBA twice only. In this case, microsuction was performed using a disposable 18 gauge fine end and disposable Zoellner sucker. It is noteworthy that only BC thresholds were assessed to compare the hearing threshold shift before and immediately after the cerumen removal procedure using the microsuction. Moreover, size of suction tip and pressure levels were not carefully considered in the study. As a consequence, the results were challenged by Baguley and Knight (2009) and Roeser (2009), who expressed concern on the issues of the misled conclusion and inappropriate method of measuring hearing threshold shifts.

Furthermore, Pothier *et al.* (2006) claimed that the suction procedure was comfortable overall, using either a microscope or an endoscope, even though there were more positive patient reviews for the endoscope. In addition, Prowse and Mulla (2014) reported similar results that microsuction was generally well tolerated, with only temporary and minimal side effects. However, Addams-Williams *et al.* (2010), found that patients had negative experiences after microsuction. These included dizziness and tinnitus. The severity of these symptoms was associated with the level of experience of the practitioner undertaking the procedure.

With negative reports, (Spencer, 1980; Katzke and Sesterhenn, 1982; Luxenberger *et al.*, 2012; Mendrygal and Roeser, 2007) conflicting with positive reports (Snelling *et al*., 2009; Pothier *et al.*, 2006), it is unclear as to whether there is a temporary or permanent threshold shift of hearing associated with microsuction and how well is the procedure tolerated The overall aim of the current study was to investigate hearing threshold changes post cerumen removal using microsuction. In addition, the pain and discomfort caused by microsuction procedure were investigated.

Materials and Methods

Participants

A total of 30 patients (50 ears; 16 males, 14 females; mean age 59.1 ± 13.7years; range 25 – 86 years) were recruited from a private cerumen removal clinic. The inclusion and exclusion criteria were as follows:

1. Patients were initially booked to the cerumen removal clinic
2. They must have impacted cerumen/debris. This was defined as a hard or soft debris, full occlusion of the EAM and no part of the TM visible (Cedars-Sinai, 2019);
3. Two attempts of microsuction were made; those who failed this criterion were excluded from the study;
4. Patients who reported a history of fluctuating hearing (e.g. due to obstruction of the Eustachian tube) were excluded from the study;
5. Patients with a history of chronic middle ear disorders or previous middle ear surgery (e.g., mastoidectomy) were excluded.

Four participants (13.3%) with age-related high frequency sensorineural hearing loss used hearing aids.

Study Design and Procedure

According to the aim of the study, three steps were followed:

- **Step 1:** All participants underwent routine audiological examination consisting of otoscopy and pure-tone audiometry (PTA) - Hearing Assessment 1;
- **Step 2:** PTA was evaluated immediately after a timed cerumen removal - Hearing Assessment 2;
- **Step 3:** PTA was re-evaluated one week after cerumen removal Hearing Assessment 3, followed by a questionnaire of patients' experiences of microsuction (Appendix 1).

The same microsuction units and audiometers were consistent throughout the study.

Hearing Threshold Measurements

A *Madsen Astera 2* diagnostic audiometer was used to measure pure-tone hearing thresholds in a sound-proof booth. Pure tones were presented through *Sennheiser HDA 300* headphones, to assess Air Conduction (AC) thresholds for both ears at 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000 Hz.

Bone conduction (BC) thresholds were measured, at 500, 1000 and 2000 Hz, using a *BHM NB71* bone conductor, during *Assessment 1 only*, for those with AC hearing thresholds greater than 20 dBHL. In the present study, AC thresholds measured during the Hearing Assessments 1, 2 and 3 were compared in order to determine the TTS induced by the microsuction procedure and AC hearing threshold shift caused by the cerumen, i.e., The TTS induced by the microsuction procedure = Hearing Assessment 2 – Hearing Assessment 3;

AC hearing threshold shift caused by the cerumen = Hearing Assessment 1 – Hearing Assessment 3;

Microsuction used for Cerumen Removal

A commercial suction unit with a 2mm Zoellner suction tube attached, was used to dislodge and remove cerumen. High quality head loupes with a light source attached, were used in conjunction with a speculum, to obtain the best possible view of the cerumen inside the ear canal. Cerumen was completely removed by microsuction after participants had completed Hearing Assessment 1. When cerumen removal was complete, patients underwent Hearing Assessment 2.

Questionnaire Evaluation Following Cerumen Removal

All patients were requested to complete a questionnaire, as shown in Appendix 1. A visual analogue scale (VAS) was used to assess pain and comfort during the procedure with 1=no pain, 10=very painful and 1=no discomfort, 10=very uncomfortable, respectively. Because the participants were informed of the main objectives of this study (i.e., to investigate the risk of noise induced hearing loss caused by the microsuction procedure), the questionnaire deliberately did not include a question relating to perceived noise loudness in the questionnaire, in order to avoid any bias in regards to their preferences. However, the noise loudness and length of procedure were very likely to be included in the comfort scale. Additionally, when applicable, previous cerumen removal experience was assessed and compared to microsuction.

Data Analysis and Statistical Tests

All data was imported an *IBM® SPSS® Statistics, Version 24* software platform for analysis. Audiometric data was compared and analysed using a paired sample *t*-test. Pain/discomfort levels were analysed using a Chi-square test.

Ethical considerations

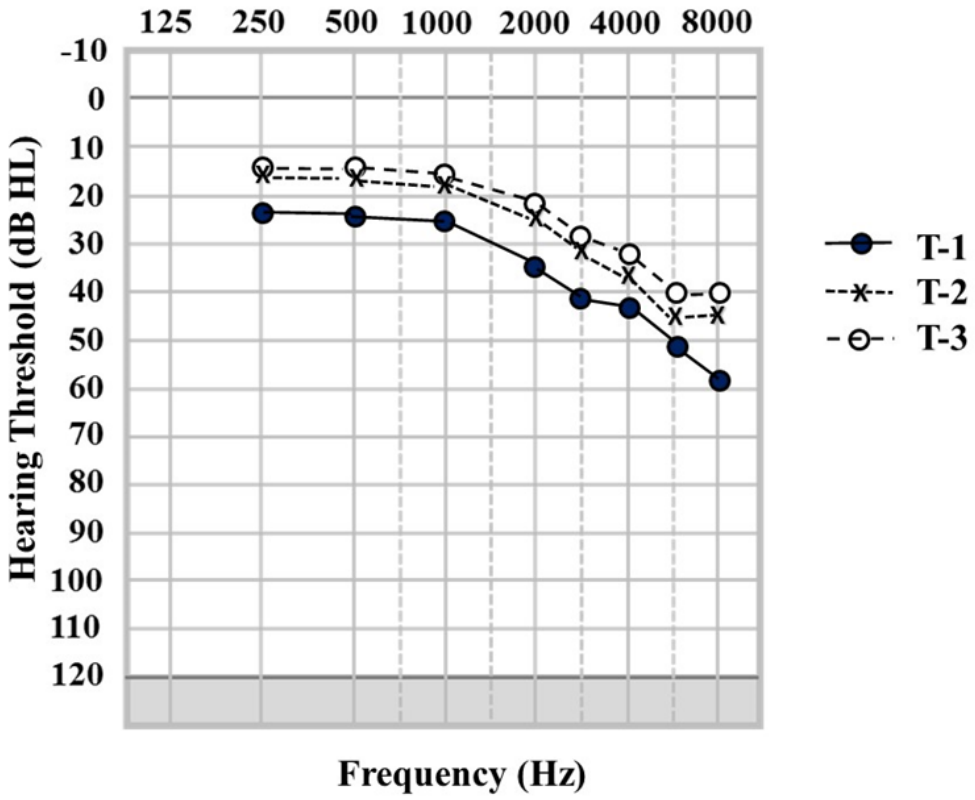
All participants were given the opportunity to read the information sheet and ask any relevant questions regarding the process. The procedure of the interviews and validation process was explained to them, prior to signing consent forms. This study was approved by the Cardiff School of Sport and Health Sciences Research Ethics Committee, Cardiff Metropolitan University, UK; Ethics Reference Number: PGT-982.

Results

Comparison of Average Hearing Thresholds Measured Over the Three Assessments

Figure 1 shows the average hearing thresholds over the three assessments. Hearing threshold change caused by cerumen removal determined by comparing the hearing assessment before cerumen was removed (Assessment 1) and the assessment 1-week following the cerumen removal procedure (Assessment 3). The range of hearing threshold changes over the individual frequencies was 8.6 - 17.7 dB. Cerumen caused the highest hearing loss at 8000 Hz (Mean: 17.7 dB; SD: 12.6), and the least at 250 Hz (Mean: 8.6 dB; SD: 12.3). Statistical analysis revealed a significant decrease in hearing thresholds across all individual frequencies (p <0.0005). Further analysis compared means for PTA at 8 frequencies ($PTA_{250\text{-}8000Hz}$) and PTA at 2 high frequencies ($PTA_{6000\text{-}8000Hz}$). Hearing loss for $PTA_{250\text{-}8000Hz}$ ranged from 0 - 38.1 dB, with a mean of 11.5 dB (p <0.0005). High frequency hearing loss for $PTA_{6000\text{-}8000Hz}$ ranged from 0 - 37.5 dB, with the mean observed at 14.8 dB (p <0.0005).

Figure 1: Comparisons of averaged hearing thresholds measured over the three assessments

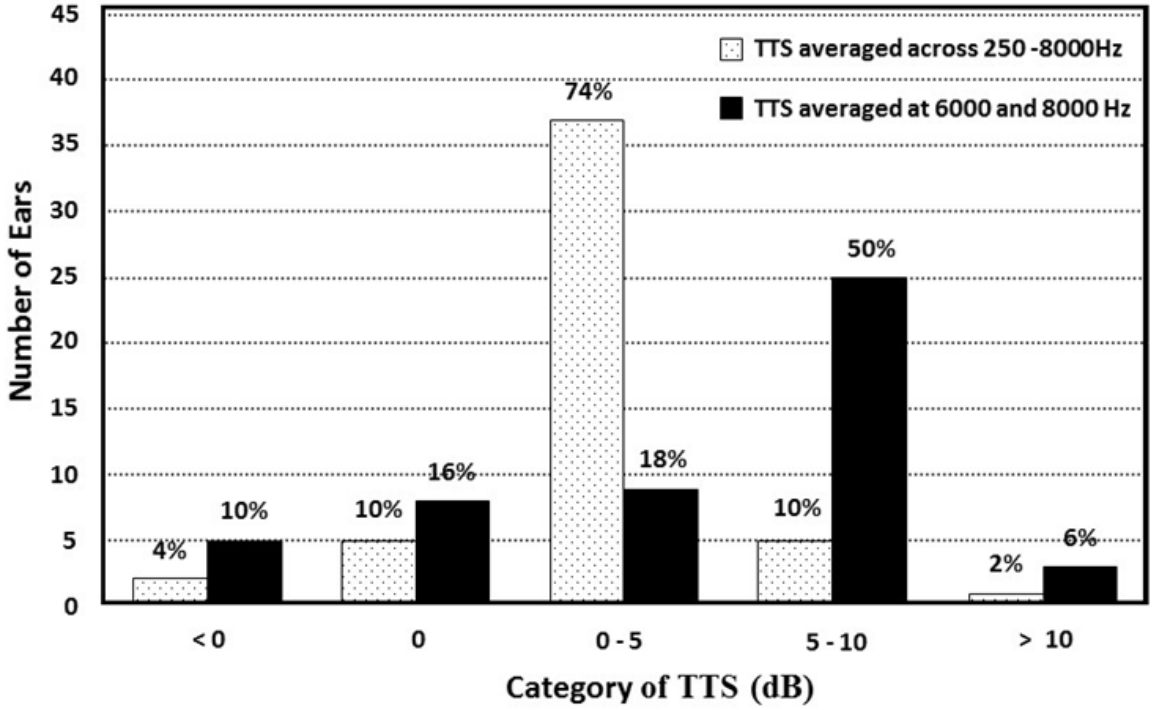


As mentioned in the methodology section, the TTS was determined by measuring the difference between the hearing threshold immediately after the microsuction procedure (Hearing Assessment 2) and that following a 1-week resting period (Hearing Assessment 3). A measured TTS appeared in 43/50 ears (86%). Figure 1 illustrates the averaged TTS by comparing Assessment 2 and Assessment 3. The range of TTS changes over the individual frequencies was 0.5 - 4.8 dB. Microsuction caused the highest temporary hearing loss at 6000 Hz (Mean: 4.8 dB; SD: 6.2), but the least at 250 Hz (Mean: 0.5 dB; SD: 3.4). The hearing loss was significant at 500 Hz (p <0.05), 3000 Hz (p <0.01) and across frequencies at 1000, 2000, 4000, 6000 and 8000 Hz (p <0.0005). However, the change in hearing thresholds at 250 Hz was not significant (p=0.302).

Figure 2 shows the distribution of TTS, averaged over 8 frequencies and compares it to the 2 high frequencies. The majority of the measured TTS, over 8 frequencies was under 5dB (88%). In contrast at 6000 and 8000 Hz, over half of the cases (28/50 ears - 56.0%), observed a TTS of 5dB or higher. Further analysis compared means for PTA at 8 frequencies ($PTA_{250\text{-}8000Hz}$) and PTA at 2 high frequencies ($PTA_{6000\text{-}8000Hz}$). TTS for $PTA_{250\text{-}8000Hz}$ ranged from 0 - 16.2 dB, with the mean observed at

2.4 dB (p <0.0005). High frequency TTS for $PTA_{6000\text{-}8000Hz}$ ranged from 0 - 17.5 dB, with the mean observed at 4.6 dB (p <0.0005).

Figure 2: Distribution and comparison of temporary threshold shift averaged across all frequencies and averaged at two high frequencies



Questionnaire Evaluation on the Tolerance and Experience Post Cerumen Removal using Microsuction

The questionnaire identified patients' previous experience of cerumen removal. Syringing/irrigation (23/30, 76.7%) was the most common method, followed by the microsuction method (5/30, 16.7%). 5 patients (16.67%) had no previous cerumen removal experience. Moreover, 75% of those who had experienced alternative forms of cerumen removal, preferred microsuction, determined after the microsuction procedure. Negative comments towards previous syringing/irrigation experiences included: *"Did not fully clean ears;" "Can be painful, uncomfortable;" "Not very impressed;" and "Didn't like it, got wet."* Four out of five (80%) patients who had prior microsuction experience preferred it to the alternate methods.

Pain and discomfort experienced during the microsuction procedure were assessed using the visual scale, with scores from 1 - 10. 25 out of 30 patients judged the microsuction procedure as having no

pain (score of 1), and 19 out of 30 patients judged the microsuction procedure as having no discomfort (score of 1). As shown in Table 1, the microsuction procedure was well tolerated, as the maximum pain score was 3 (only 1 person out of 30, 3.33%) and the maximum discomfort score was 4 (only 2 people out of 30, 6.67%). The mean pain level was 1.2 ± 0.5 / 10 and the mean discomfort level was 1.6 ± 0.5 / 10. Narrative patient comments (e.g. *"easy;" "quick;"* and *"comfortable"*) were obtained from the questionnaire from those who had not experienced the microsuction procedure previously. From those who had prior experience comments included; *"good;" "professional;"* and *"prefer microsuction"*. This further emphasised a positive patient experience towards the microsuction procedure. No negative comments were reported in the present study.

Table 1. The pain and discomfort ratings and the associations with distribution of TTS

TTS Category	**Pain Rating on a Scale of 1-10 (n)**			**Discomfort Rating on a Scale of 1-10 (n)**			
	1	***2***	***3***	***1***	***2***	***3***	***4***
<5 dB	24	3	1	17	6	3	2
5-10 dB	1	0	0	1	0	0	0
> 10 dB	0	1	0	1	0	0	0
Total	**25**	**4**	**1**	**19**	**6**	**3**	**2**

Further analysis was performed on the relationship between pain and discomfort versus the distribution of TTS using the Chi-squared test. These results showed that there was no significant correlation between either pain vs TTS ($\chi^2 = 6.87$, df = 4, $p = 0.14$) or discomfort vs TTS ($\chi^2 = 1.24$, df = 6, $p = 0.97$).

Discussion

The presence of cerumen can affect routine otology and audiology clinics. For example, hearing testing and hearing aid fitting appointments are often cancelled because of excessive cerumen blocking the EAM that can affect assessment accuracy or hinder the testing procedure (e.g., tympanometry or real ear measurement (REM)). According to Pothier and Nieuwoudt (2007), 3.3-5.3% of appointments were cancelled in a hospital over a six-week period. In this study, impacted cerumen caused an average hearing loss greater than 10 dBHL (mean: 11.4 dB, maximum hearing loss: 38.1 dB), compared over 8 frequencies (250 - 8000 Hz). The results were consistent with

findings reported by Sharp *et al.* (1990) who found an average hearing loss of 5.45 dB across the frequencies between 250 and 4000 Hz in 21 patients. In addition, Subha and Raman (2006) found an average loss of 21.19 dB across the frequencies between 250 and 2000 Hz in 109 ears. Such significant hearing loss was due to large and excessive cerumen. Therefore, given that impacted cerumen can cause a significant hearing loss, the cancellations for otology and audiology clinical appointments are inevitable.

There are advantages of microsuction for cerumen removal in terms of its effectiveness and fewer contraindications. However, concern over the TTS induced by the procedure has been raised in the literature. The results of the present study indicate a significant TTS across all frequencies, particularly in the high frequencies of 6000 and 8000 Hz. The mean loss observed (2.4 dB) was minimal but it was consistent throughout the data, as it occurred in 43/50 ears. The results partly agree with the findings of Katzke and Sesterhenn (1982) and Mendrygal and Roeser (2007). However, the primary focus of these studies was measuring noise of the suction machine in the ear and they only included minimal TTS/PTS cases in each of their studies. For example, Katzke and Sesterhenn's study included only two TTS cases who had an average TTS of 15 dB and 9.3 dB, measured over 8 frequencies (250 Hz - 8 kHz), respectively, while Mendrygal and Roeser (2007) briefly discussed permanent noise induced hearing loss of 10-15 dB in two patients. It is noteworthy that in this study the TTS at 6000 Hz was consistently the highest followed by 8000 Hz and then 4000 Hz. This is consistent with the finding by Luxenberger *et al.* (2012), whose results showed the highest frequency response between 4000 and 6000 Hz, when a 2mm suction tube was used.

Various previous studies have shown that the two major factors determining the noise sound pressure level in the EAM are the amount of negative pressure the microsuction unit generates and the size of the suction probe, i.e., the greater the suction level and the larger the size of the probe, the higher the SPL values can reach. The noise level generated from the tube of the suction machine can reach extremely high levels when using a 2mm suction tube, ranging from 114 dBA to greater than 140 dBA (Katzke and Sesterhenn, 1982; Luxenberger *et al.*, 2012; Mendrygal and Roeser, 2007). According to NIOSH recommendations (1998), considering such a noise level, there is a high risk of noise induced hearing loss for patients who undertake cerumen removal with using microsuction. Therefore, reservations should be made about the use of microsuction, regarding to the noise it emits.

Additionally, as more practitioners are using suction machines that were not originally designed to work inside the EAM, safety standards for the procedure need to be rewritten and observed.

Despite the noise of the machine and subsequent TTS, the microsuction procedure was well tolerated. There were no negative comments regarding the procedure, even when a TTS had occurred. The results agreed with the those outlined by Prowse and Mulla (2014) and Pothier *et al. (2006),* that microsuction is generally a comfortable procedure. Prowse and Mulla's study, reported results of 2.34/10 for pain and 3.03/10 for discomfort for the microsuction procedure, in 159 patients, while Pothier *et al.'s* study, found 1/10 for pain and 2.5/10 for discomfort, in 100 patients. A contributing factor is very likely that the hearing improvement after the removal of impacted cerumen greatly outweighed the observed TTS (4.75 : 1, for the present study).

Limitations

The present study needs to be considered, in light of its limitations. The primary focus of the study was to measure and compare audiometric data in order to explore the risk of hearing loss caused by microsuction procedure, so only one suction unit with one probe size (2mm) was used consistently. Due to high variability in suctioning equipment (e.g., probe size and negative pressure level), the noise sound pressure level in the EAM generated by the different equipment and settings can varies greatly. In addition, middle ear function analysis over the assessments would provide further important information that would rule out middle ear dysfunction as the cause of the hearing thresholds changes. Therefore, the present results of hearing threshold changes post cerumen removal by using microsuction need to be read with caution. A further study with additional sub-group comparisons using various microsuction equipment and settings is needed in order to provide a clear guideline for cerumen removal using microsuction. Furthermore, the preference for microsuction over other cerumen management approaches is likely to be biased by their most recent cerumen removal experience and whether it was a successful or poor experience. Another variable to be considered is that of discomfort that might be better rated by noise tolerance and procedure time separately. Giving additional opportunities for narrative comments from participants would help to minimise the inevitable bias derived from the questionnaire used in the present study.

Conclusion

The present study indicates that impacted cerumen causes an average hearing loss greater than 10 dBHL. Microsuction appears to be a well-tolerated method of removing impacted cerumen, and 75% patients preferred this procedure to alternative cerumen removal procedures. However, the noise emitted from suction machines caused a temporary threshold shift (TTS) in 43/50 ears, ranging from 0 to 16.2 dBHL averaged across all frequencies (250 - 8000 Hz), with the highest TTS at 6000 Hz. Considering the consistent TTS found in the present study, safety concerns for the microsuction procedure from a hearing perspective should be raised. As the noise sound pressure level in the EAM generated by different equipment and settings varies largely, further study with additional sub-group comparisons, using various microsuction settings is needed to provide clear guidelines for the cerumen removal management with microsuction.

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Conflict of Interest Statement

No conflict of interest to declare.

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