EARWAYS MEDICAL

# A Novel Tool for Cerumen Removal

## The EarWay® Pro Results of Clinical Assessments by Audiologists

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## Abstract

Impacted cerumen is a common condition that causes hearing loss and prevents accurate audiological assessment. Waiting time for referral to an otorhinolaryngology specialist can be long, resulting in significant delay in completion of audiological assessment.
The EarWay® Pro is designed to facilitate safe and effective cerumen removal by audiologists and general practitioners. It can reduce referrals, costs and waiting time.
Our goal was to present data from pilot assessments, and to evaluate the safety and efficacy of the device.

## Introduction

**Cerumen impaction** is a very common medical and audiological condition, accounting for 12M patient visits in the United States and resulting in about 8M **removal procedures** annually. In the UK, the number of irrigations performed is estimated at 4M per year, making it **the most common ear, nose and throat procedure performed in primary care**. Approximately 4% of primary care patients will consult their physician for cerumen impaction annually. Cerumen impaction is the number one cause of treatable hearing loss worldwide, with a direct impact on quality of life and productivity. When cerumen becomes impacted it can cause also, pain, tinnitus and sensation of fullness.
When patients with cerumen complain of otalgia or fever, physical examination of the tympanic membrane cannot be completed by general practitioners and patients are often referred to an otolaryngology specialist. **Another common source for referrals are audiologists that cannot complete audiological assessment or hearing aid fitting due to cerumen.**
The current methods used for the removal of cerumen include irrigation and manual removal under direct visualization of the ear canal. Patients can also use oil based or water-based preparations which are relatively safe. However, these tend to be only minimally effective and require multiple doses over several days to achieve results. The American Academy of Otolaryngology banned the use of cotton swabs and ear candling since they are ineffective and potentially dangerous. Recently published guidelines recommended educating populations at risk for cerumen impaction (**elderly**, children, **hearing aid users**) about proper ear canal hygiene.
**The UK's National Health Service reported on over 72,000 patients who were waiting for completion of hearing assessment during February 2020. The mean waiting time was 3.4 weeks, with data showing that 60% of patients do not complete their assessment pathway (including referral to E.N.T specialist for cerumen removal and return to audiologist evaluation afterwards) [NHS].**

## Materials & Methods

The EarWay® Pro device [figure 1] is a handheld, disposable device. Made of plastic polymer and coated by a thin layer of silicone. Its design comprises a flexible helical open profile tip and measurement markers indicating the depth of engagement.
The device is rotated inward into the ear canal, collecting the cerumen and then pulled out, extracting with it the cerumen as a single cluster.
The EarWay® Pro is intended to use without direct visualization.

### Participants

Data was collected from clinical assessments performed in 8 organizations, in 4 countries: United Kingdom, United States, Canada and Australia. Participants were all professional audiologists, hearing care specialists and all received training by EARWAYS Medical team, or by certified trainers. After each procedure, participants answered a short questionnaire. **Success** was graded according to the ability to complete audiological assessment (paitent ear canal, and at least partial exposure of the tympanic membrane allowing exclusion of gross pathology). A scale of 1 (unsuccessful procedure) to 5 (highly successful procedure) was used. **Safety** was reported based on the appreciation of safety based on participants' own experience. A scale of 1 (very unsafe procedure) to 5 (highly safe procedure) was used.
Participants were instructed to report any complications, whether device-related, procedure-related or associated with anatomical variations. Patients with known aural anomalies or patients that previously underwent otologic surgical procedure were excluded from assessment.
Since most participants had limited experience during pilot studies, interviews were held with experienced users. Four audiologists and an otolaryngologist, all with over a decade of experience in cerumen removal, who used the EarWay® Pro for a minimum of 50 cases were interviewed.

## Results

### General

The procedure success rate was approximately 70% among non-experienced users, while experienced users reported over 80% success. The safety rate was around 85% among both experienced and non-experienced users, with a 1.2% of complications reported among non-experienced users, all of them were merely minor.

### Clinical assessments by non experienced users

Our cohort includes data from 8 centers worldwide, who participated in clinical assessments between January 2020 and April 2021. A total of 43 participants (users) were included. Two hundred and fourteen patients were treated in these assessments, with a mean of 26.8 per center, and a total of 330 ears, with a mean of 41.3 ears per center. The mean duration of the procedure was 37 seconds. The mean success grade given to the use of the EarWay® Pro device was 3.45 (on a scale of 1 to 5). Figure 2, Figure 3.
A total of 4 complications were reported – a rate of 1.2% (4/330). Reported complications included slight bleeding in all four cases.
The mean safety grade given was 4.2 (on a scale of 1 to 5).

### Clinical Assessment by Experienced users

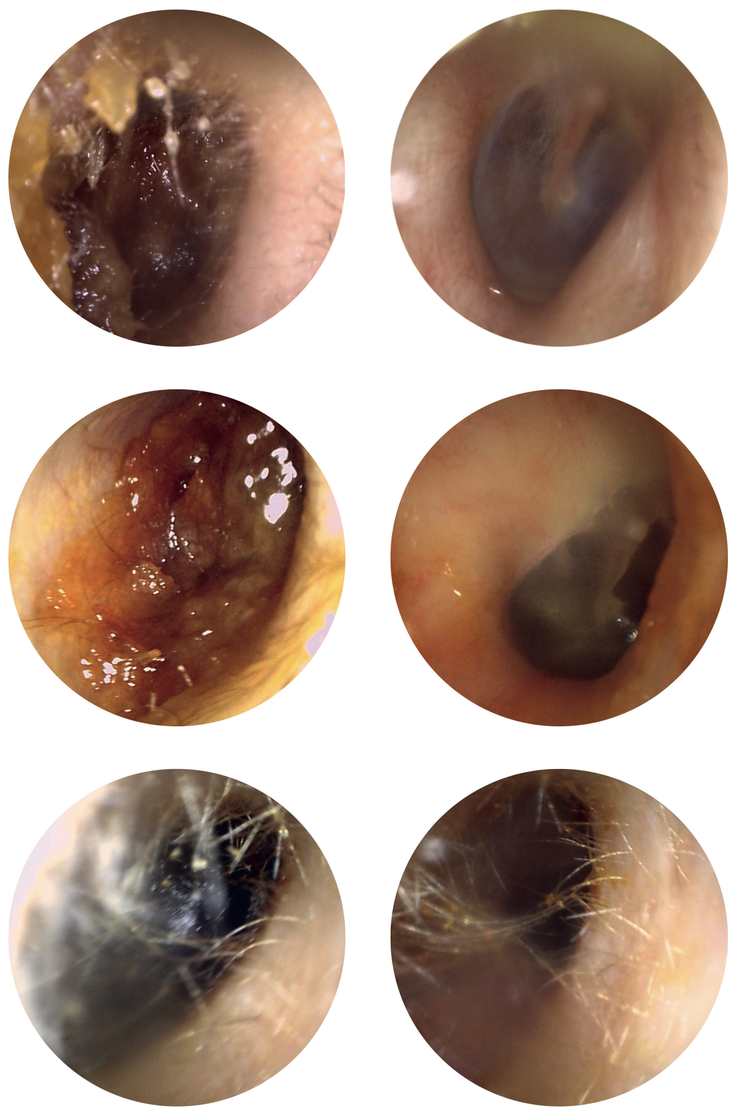
Five experienced users replied. All had over a decade of experience in cerumen removal and used the EarWay® Pro for at least 50-200 cases. Based on their experience, they rated in a 1-5 scale, device efficacy as 4.1/5, safety as 4.41/5.

### None encountered device related complications

Some patients mentioned mild discomfort or pressure sensation when the device reaches the bony external ear canal. Discomfort was tolerable and only momentary when the patient was counselled and prepared well. One responder reported less discomfort with better angling of the device. None had to abort the procedure due to discomfort.

## Cases Documentation*

**Pre-Procedure** | **Post Procedure**

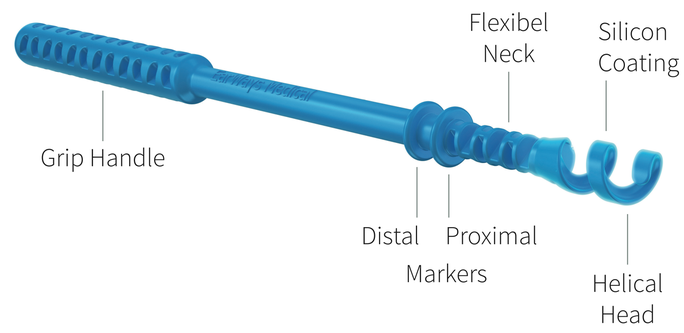


* Procedures preformed by Christiane Basilio, Canada

## Results Tables & Graphs

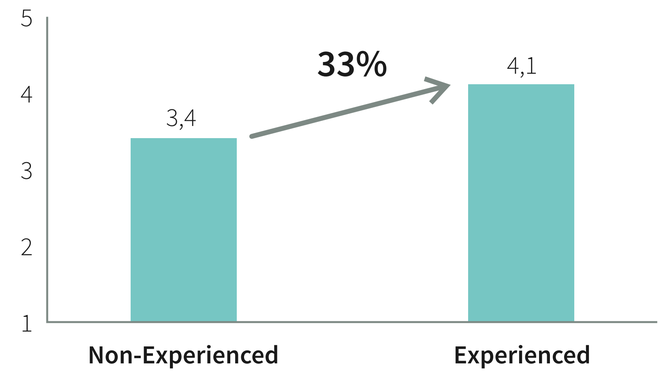
**EarWay® Pro**

Figure 1



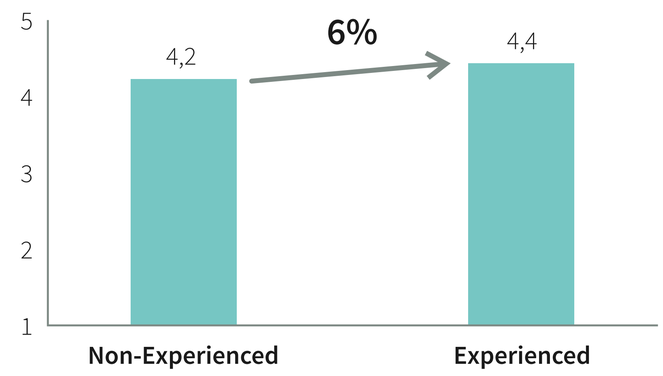

**Success**

Figure 2




**Safety**

Figure 3




## Conclusion

The EarWay® Pro device presents a safe, effective and efficient method for cerumen removal by healthcare professionals. The high success rate and safety of this device make it very useful, enabling the removal cerumen prior to audiologist evaluation without the need for referral to an E.N.T specialist, and thus significantly shortening waiting time and dropout rate of patients.

## Contact Information

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### Learn more

### Disclosure

Conflict of interest disclosure:
Prof. Ohad Hilly, author of this poster consults for the company on clinical aspects.