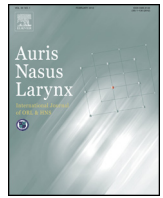




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## In-ear medical devices for acoustic therapies in tinnitus treatments, state of the art

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### ABSTRACT

Cochrane reviews indicate there is very limited support for all forms of sound therapy and cognitive behavioral therapy has the strongest support. American Academy of Otolaryngology (AAO) recently published some guidelines which recommends Cognitive Behavioral Therapy (CBT) for tinnitus intervention, and only indicates that sound therapy should be considered an “option” for intervention.

Nevertheless, acoustic therapy could lead to cause changes in the tinnitus perception and has been appreciated by the affected people for years. In the last decades, the use of sound or sound enrichment has become a central part of many tinnitus management programs used by audiologists, whether the intention was to mask tinnitus, suppress tinnitus, or interrupt the tinnitus generating neural activity.

Several acoustic therapies have been developed and implemented in the last 40 years, but how can we determine which one is the most effective? We can determine the effects based on the results reported in many research studies, but in those studies are many factors that differ from one study to another, like in-ear medical devices used to apply acoustic therapy for tinnitus treatment.

In this article, we review and analyze the different types of in-ear medical devices used in the most recently acoustic therapies in treatments against tinnitus, allowing us to identify the pros and cons. By our analysis, an optimal medical device could be characterized to enhance the application of acoustic therapies and in consequence the global results of the sound therapies that already exist. In this review, it was considered acoustic therapies, the technology implemented in medical devices and the clinical needs.

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## 1. Introduction

Tinnitus is known to affect between 5% and 15% of the population [1]. About half of the people with tinnitus are concerned about it, and it is reported that about 2% indicate that

tinnitus significantly affects their life. Tinnitus may have a direct effect on a person’s emotional wellbeing, their hearing, and ability to sleep and to concentrate. These in turn impact basic life functions such as socialization and relaxation [2]. In severe cases, it can interfere with the individual’s ability to perform adequately on the job, or contribute to psychological disorders such as depression, suicide ideation, posttraumatic stress disorder, anxiety, and anger [3].

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The Committee on Hearing, Bioacoustics, and Biomechanics (CHABA) defined tinnitus as “the conscious experience of a sound that originates from the patient’s own head.” It can be distinguished between objective tinnitus (somatosounds) due to peripheral vascular abnormalities, among others, detected by stereoscopic inspection, and subjective tinnitus that cannot be heard by others [4]. From an acoustic point of view tinnitus is characterized by its intensity and its frequency content [5].

Generally speaking, sound therapy is the appropriate and conscious use of sound energy to promote well-being in humans and also the expansion of consciousness. The therapy through sounds is based on the knowledge that all matter is vibrating at specific frequencies. These therapies can influence physiological, cognitive and even psychological variables [6].

Many different acoustic therapies for Tinnitus approaches have been marketed over the last 40 years though with varying success. Some of the most widely used therapy approaches for which positive results have been reported include tinnitus masking (wearing an ear level masking device), Tinnitus Retraining Therapy (which includes counseling and sound therapy principles), and Neuromonics (a music-based approach combined with counseling) [7]. However, no single treatment is 100% effective. Shortly afterwards, we will explain these therapies and their sound generators more in detailed.

Audiologists have always known that sounds could interfere with tinnitus [8–11], though there is no consensus on how to measure the effectiveness of the outcomes of tinnitus treatments so that they remain inconclusive [12–14].

Beck explains that some medical devices are effective in assisting people with tinnitus by helping the brain to distinguish between true sounds and pseudo sound (tinnitus), increasing neural activity and assisting the brain in correcting for the potential negative effects of disinhibition, partial masking of tinnitus, and improving the ability to cope with tinnitus by reducing the stress in their lives [15]. In the Audiological Tinnitus Management (ATM) protocol, Henry et al. [16] recommended the use of a combination of instruments (amplification and noise generator in the same device) for a blended benefit of amplification and constant broadband noise to achieve this enhanced soundscape.

## 2. In-ear medical devices

Hearing aids were programmed to assist hearing instead of a focus on tinnitus. They have become common therapeutic tools in the audiological management of tinnitus [17]. However, there is currently no evidence to support or refute the provision of hearing aids as a primary intervention in the management of tinnitus in patients with co-existing hearing loss [18]. The lack of information about the head causes directivity reduction and distortions. The signals that arrive at the array are distorted by the so-called head shadow effect, which must be considered in the design of hearing aids [19].

It is only fairly recently that the potential physiological origins of tinnitus [20] and mechanisms of sound-based treatments have become clearer [21,22]. Moreover, some of the patients suffer from psychiatric comorbidities as depression or anxiety.

Nevertheless, hearing aids have been a popular choice for tinnitus intervention, Kochkin and Tayler [17] did a survey study of 230 hearing care professionals suggests that six out of 10 patients (60%) experienced minor to major relief of tinnitus when wearing hearing aids, and a total of one in five (22%) receive major relief. Less than 2% of patients experience a worsening of their tinnitus when wearing hearing aids, while 39% receive no benefit. Due to the most effective settings of hearing aid for tinnitus suppression may not be same as for enhancing communication [23]. For example, hearing aids can lead to habituation of tinnitus for patients with tinnitus and hearing loss but not with hyperacusis [24].

Most of the devices that exist in the commercial market for tinnitus treatment are hearing aids, which have a masking signal implemented in the device for the therapy in the majority of the cases [25]. In the case of hearing aids used in tinnitus treatments should be open ear hearing aids [26], because with a partial occlusion is possible to avoid an increase in the perception of the tinnitus instead of a complete occlusion in the ear canal with other kind of hearing aids.

Other type of implemented technology is the cochlear implantation, which allows the preservation of residual hearing after cochlear implantation and the synergistic use of electric and acoustic stimulation (EAS). EAS is a well-accepted therapeutic treatment for subjects with profound hearing loss in the higher frequencies and no or mild hearing loss in the low frequencies. Several manufacturers offer individual soft electrodes specially designed for hearing preservation as well as combined electric-acoustic audio processors for tinnitus treatment [27].

### 2.1. Types of in-ear medical devices

Any device that amplifies sound might be helpful for tinnitus management. There are numerous articles underlining this effect, and even the AAO guidelines support the use of hearing aid for tinnitus management. Most in-ear medical devices for tinnitus treatment are hearing aids that are classified depending of the characteristics of the treatment and the needs of patient [28]. The classification of different types of in-ear medical devices in Tinnitus Management is showed in Fig. 1.

Behind-the-ear (BTE) medical devices consist of a hard plastic case worn behind the ear and connected to a plastic ear mold that fits inside the outer ear. The electronic parts are held in the case behind the ear. Sound travels via the hearing aid through the ear mold and into the ear. In a study performed by Munhoses Dos Santos et al. [29], 66% of the patients prefer BTE hearing aids with open molds than the other kind of molds.

In-the-ear (ITE) medical device fits completely inside the outer. The case holding the electronic components is made of hard plastic. Some ITE devices may have certain added features installed, such as a telecoil, which is a small magnetic coil that allows users to receive sound through the circuitry of the hearing aid, rather than through its microphone.

In the canal (ITC) medical device is made to fit the size and shape of a patient’s ear canal. A completely in canal (CIC) medical device is nearly hidden in the ear canal. Because they are small, canal aids may be difficult for a patient to adjust and

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