Technical report

Suitability of the partially implantable active middle-ear amplifier Vibrant Soundbridge® to hyperbaric exposure

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Abstract

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Introduction: Active middle-ear amplifiers represent a modern possibility to treat sensorineural, conductive and combined hearing loss. They can be in use in divers and patients who need hyperbaric oxygen therapy. Therefore, active middle-ear amplifiers have to be tested to determine whether or not they are prone to implosion or function loss in hyperbaric conditions.

Material and methods: We asked three of the companies registered by the German health authorities as manufacturers of active middle ear amplifiers to test their devices in hyperbaric conditions. Med-El agreed to support the study; Envoy stated that their devices were unable to withstand a pressure of 608 kPa; Otologics had no capacity to take part in this study. Twelve Vibrant Soundbridge® (Med-El) middle-ear amplifiers were tested in a water bath in a hyperbaric chamber. Four devices were pressurised to a maximum of 284 kPa, four devices to 405 kPa and four devices to 608 kPa, each for a maximum dive time of 78 minutes. The functions of the devices were tested in the laboratory by the manufacturer pre- and post-hyperbaric exposure.

Results: Visual inspections and laboratory function tests were normal in all 12 devices after hyperbaric exposure.

Discussion and conclusion: Hyperbaric exposure to more than one bar pressure difference can result in structural damage, implosion or loss of function of mechanical devices. The Vibrant Soundbridge® middle-ear amplifier tolerated a single hyperbaric exposure to pressures of up to 608 kPa for 78 minutes with no loss of performance.

Key words

Diving, implantable devices, hearing, equipment, pressure, barotrauma, performance

Introduction

Implantable, active middle-ear amplifiers represent an innovative option for the treatment of patients with sensorineural hearing loss, and, since the indication criteria were expanded, also for patients with mixed and pure conductive hearing loss.[1–5] Unlike conventional hearing aids that can be left behind when a patient goes into the water, active middle-ear amplifiers have parts fully or partially implanted into the patient's body.

The advantages of active middle-ear amplifiers are:

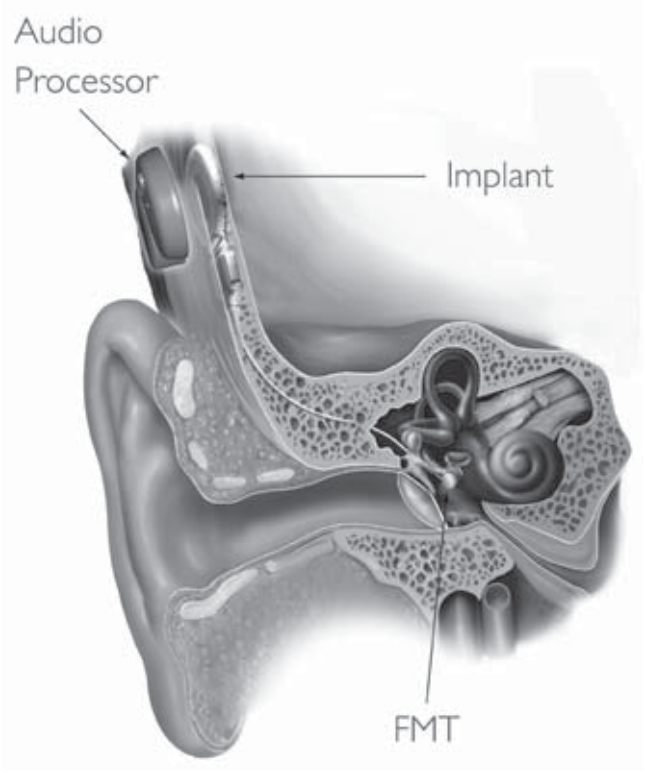
- better sound transmission into the inner ear through the direct connection to the ossicular chain or the round window membrane resulting in improved hearing, especially at high frequencies;
- increased sound transmission for patients with profound hearing loss;
- avoidance of recurrent external otitis which often occurs in patients with conventional hearing aids.

The basic principle of active middle-ear amplifiers is that they transfer the sound from the retrocochlearly implanted device through a lead that runs through the mastoid into the middle ear to a vibratory structure that activates the ossicular chain or the bone surrounding the inner ear (in the round window niche).

The products *Carina*® from Otologics, and *Esteem*® from Envoy are fully implantable devices with a microphone in the ear canal, whereas the *Vibrant Soundbridge*® (VSB) from Med-El is a partially implantable hearing system which needs an additional device on the patient's skin, kept in place by magnetic forces and which must not be worn in water. Therefore, it cannot be used underwater. The VSB uses a floating mass transducer (FMT) that is clipped to the incus or fixed in the round window niche to transmit the sound into the inner ear (Figure 1), whereas the *Carina* transmits the sound via a plunger on the incus body, while the *Esteem* transmits the sound through the stapes after the incus has been removed.

The implanted parts of the hearing devices are exposed to increased ambient pressure during diving. Since diving with compressed air involves an ambient pressure of up to 608 kPa (6 Ata) the implanted part of the active middle-ear device must be able to withstand this pressure without malfunctioning or endangering the diver through implosion-related trauma. Exposure to increased ambient pressures also occurs in situations other than diving. If it is necessary to administer hyperbaric oxygen therapy (HBOT) to a patient at some point in time after the implantation of an active middle-ear amplifier, there is a danger that the device will malfunction or that an implosion-related trauma in the hyperbaric chamber could occur.[6]

Figure 1
The Vibrant Soundbridge®, a partly implantable, active middle-ear amplifier. Only the implant and the floating mass transducer (FMT) were pressure tested as the audio processor is removed for diving or HBOT (image courtesy of Med-El)



The same problems exist for patients with cochlear implants (CI). There are patients who want to perform scuba diving after CI procedure, and the growing number of people with CIs increases the likelihood that such a patient will need HBOT at some point in time. For this reason, an American team exposed various cochlear implants to pressures up to 608 kPa.[7] The implantable parts of all the devices tested had no loss of function, leakages or implosion damage.[7]

The purpose of the current study was to expose all of the active middle-ear implants which were available on the German market in 2008 to a maximum pressure of 608 kPa.

Material and methods

The companies Envoy, Med-El and Otologics were approached to supply their devices for testing under hyperbaric conditions. Envoy advised that their *Esteem*® active middle-ear implant had already been tested up to a pressure of 608 kPa. This had led to loss of function in the implant, and for this reason they were not interested in supporting this study (Krey C, personal communication, 2006). Otologics stated that their *Carina*® implants had so far been tested up to a positive pressure of 203 kPa and to reduced pressures. This would indicate that diving up to 10 metres' sea water (msw) should be possible with this device. The package insert recommends that the patient discuss diving suitability with the surgeon. Otologics declined to have their devices tested up to an ambient pressure of 608 kPa (Teigland P, personal communication, 2007).

Med-El provided the implantable parts of 12 Vibrant Soundbridge® devices and financed the hyperbaric chamber exposure at the Heidelberg Hyperbaric Unit, Germany. The audio processor that is placed on the patient's skin was not tested as this would be removed before diving. Therefore, no function test in hyperbaric conditions was performed.

The devices were placed in a water bath and four were exposed to each of the pressure profiles:

- 284 kPa (18 msw), chosen as the maximum pressure used during HBOT;
- 404 kPa (30 msw), chosen as the pressure used for a COMEX 30 treatment table;
- 608 kPa (50 msw) chosen as the maximum pressure during air dives in the German military services.

The exposure time at the maximum depth was 60 minutes and the compression and decompression rates were both 50 kPa min^{-1}. These protocol were used to find a staged pressure tolerance of the devices in case the devices could not withstand the maximum test pressure. Pressure was measured with a diving computer, also placed in the water bath (Uwatec, Switzerland) and the hyperbaric chamber pressure measurement system (Haux Life Support, Karlsbad).

The implants were tested for normal function by the manufacturers before and after hyperbaric exposure using a Laser Doppler Vibrometer. Frequency response and signal quality were measured by means of harmonic distortion. The function tests were considered to be successful if the same criteria were fulfilled as those required for newly produced implants. Each device was also visually inspected for damage or distortion.

Results

All 12 Vibrant Soundbridge® devices were deemed fully functional prior to hyperbaric exposure. After completion of hyperbaric chamber exposure, all 12 implants exhibited no evidence of damage or distortion or loss of function.

Discussion

Implantable devices used while diving or in a hyperbaric chamber must be able to withstand increased ambient pressures. Trigano et al. examined cardiac pacemakers in vitro at pressures of 404 kPa and 606 kPa.[8] The pacemakers proved to be fully functional at both depths; however, in 15

out of the 29 tests there was damage to the housing after hyperbaric exposure at 606 kPa. Because of this, the authors recommend that patients with pacemakers dive only to a maximum of 304 kPa (20 msw).[8]

There are several theoretical risks under hyperbaric conditions following the implantation of an active middle-ear implant.

IMPLOSION

An implosion of the device in the mastoid could occur leading to pain, injury, cochleo-vestibular symptoms and even intracranial complications.

LOSS OF FUNCTION

So far, only the Med-El Vibrant Soundbridge® devices, with 12 devices tested at pressures up to 608 kPa have been shown to be completely functional after hyperbaric exposure.

INCREASED SUSCEPTIBILITY TO BAROTRAUMA

Drilling of the mastoid is necessary for the implantation of a middle-ear device, and the sound amplifying component must be coupled to the ossicular chain or placed in the round window niche. Mounting a plunger on the incus (company: Otologics) or a Floating Mass Transducer (FMT) on either the incus or at the round window niche (company: Med-El) increases the weight and inertia of the ossicular chain. However, it is unlikely that this increases the danger of barotrauma. If the ossicular chain is disrupted as with the *Envoy* devices, there is even an increased protection of the inner ear because pressure transfer from the auditory canal into the inner ear is excluded, resulting in a lowered risk for barotrauma to the inner ear. Unfortunately, these devices are not pressure-resistant according to the manufacturer.

All active middle-ear amplifiers are implanted via a 'canal-wall-up' mastoidectomy, which does not represent a contraindication for diving since the posterior outer-ear canal wall remains intact and the mastoid cavity and the labyrinth are separated from the ear canal and, therefore, protected from direct cold-water stimulation. 'Canal-wall-down' mastoidectomy (see below) is used when the posterior ear canal wall has to be removed and the mastoid cavity and the labyrinth are directly exposed to water when the patient submerges.

LOCAL SUPERSATURATION WITH LOCALISED DECOMPRESSION SICKNESS

During decompression and after a dive, nitrogen is released from the body tissues. Vann et al. determined that dives which complied with the permitted diving regulations led to gas bubble formation in breast implants and a consequent, minimal enlargement of the implant. Only diving which was not conducted in the manner of recreational diving (e.g., saturation diving) and subsequent direct altitude exposure at 10,000 metres led to significant changes in the volume of the implants.[9] Therefore, an increase in localised inert gas bubbles through supersaturation along the implanted electrode could occur. However, since active middle-ear implants and their components are contained in the middle ear and on the skull and not in the vulnerable sites of the inner ear, this danger would seem negligible.

PERIPHERAL VERTIGO FROM EXPOSURE OF THE LABYRINTH

Scar tissue can occur after a mastoidectomy, which can reduce ventilation in the mastoid. However, since the majority of patients who receive an implantable middle-ear amplifier have healthy middle ears, this seems very unlikely. Therefore, in patients with sensorineural hearing loss, when the posterior wall of the auditory canal is intact, an irritation of the labyrinth, which must be exposed while implanting the device, is unlikely and, therefore, can be disregarded. With mixed or pure conductive hearing loss, patients often have a history of 'canal-wall-down' mastoidectomy, which can represent a contraindication for diving because these patients have an increased risk for vertigo when cold water enters the mastoid. These patients need to have a cold-water provocation test (4^{o}Celsius) and, if vertigo occurs, they are not fit to dive.

Conclusions

Twelve Vibrant Soundbridge® middle-ear amplifier devices (Med-El) showed no changes in shape and no loss of function when subjected once to pressures up to 608 kPa. For this reason, the Austrian and German diving and hyperbaric medical societies recommend only this device for divers since alternatives are either not pressure-resistant or have only been tested to 203 kPa. The manufacturer should always be contacted to ensure no changes have been made to the device in the meantime. Further tests with other implants are necessary to decide whether these devices may be exposed to diving or HBOT.

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