Implantable microphones as an alternative to external microphones for cochlear implants

Abstract

Totally implantable cochlear implants may be able to address many of the problems cochlear implant users have around cosmetic appearances, discomfort and restriction of activities. The major technological challenges that need to be solved to develop a totally implantable device relate to implanted microphone performance. Previous attempts at implanting microphones for cochlear implants have not performed as well as conventional cochlear implant microphones, and in addition have struggled with extraneous body or surface contact noise. Microphones can be implanted under the skin or act as sensors in the middle ear, however, evidence from middle ear implants suggest body and contact noise can be overcome by converting ossicular chain movements into digital signals. This article reviews implantable microphone systems and discusses the technology behind them.

Search strategy

The review was performed using databases with independently developed search strategies, including Medline, Embase, the Cumulative Index to Nursing and Allied Health Literature, and the Cochrane Library, in addition to conference proceedings and a manual search of the literature, with the last search conducted on 12th June 2017. Relevant articles were subsequently reviewed from reference lists. We considered all studies, including bench studies, retrospective case series and prospective cohorts. Key words utilised in the search included the following: 'cochlear implant', 'microphone', 'implantable', and 'middle ear'.

Introduction/Background

Cochlear implants have increasingly become an effective treatment for patients with severe to profound hearing loss and implantation rates are rising with around 13,000 people currently using cochlear implants in the UK and around 650 adults and 650 children implanted each year (*Cochlear implants*, The Ear Foundation, 2015). Despite this, more than 900,000 people in the UK are estimated to be severely or profoundly deaf (Action on Hearing Loss, 2016) meaning many more could potentially benefit from implantation. A lack of national health funding and awareness accounts for the majority of this disparity (Raine, 2013). Some potential users, however, are deterred by the cosmetic appearance of cochlear implants because of the perceived stigma of hearing loss (Wallhagen, 2010). Commercially available cochlear implants currently consist of three parts: an external sound processor that typically sits behind the ear, an internal receiver/stimulator connected to electrodes in the cochlea, and a radio link that enables the transcutaneous transmission of signals and power across the skin. The external sound processor contains the microphone for transducing the sound signals into electrical signals, the electronic circuitry for digital signal processing (DSP) and the battery, which powers both the external and internal components. Having an external sound processor has many functional and psychological disadvantages. Because of the visibility and prominence of the external sound processor it can act as a "stigma symbol" (Goffman, 2009) that draws attention to a negative identity and can also be easily damaged by unpredictable impacts – manufacturers therefore advise against wearing them during vigorous exercise. Moreover, the sound processor cannot be worn in bed, which has clear

safety implications and can further heighten self-awareness of hearing loss. There is also a functional disadvantage of having a microphone that is external to the ear, or just at the entrance of the outer ear canal (Frohne-Büchner, Büchner, Gärtner, Battmer, & Lenarz, 2004), because users are not able to exploit the passive gain of the external ear canal over the frequencies relevant to speech (Shaw, 1974). Users also cannot fully benefit from the shadow effect of the pinna, which attenuates sounds from the rear and may provide directional cues (Byrne & Noble, 1998). Finally, the external sound processor restricts the use of standard headwear, such as earphones and helmets, which can be inconvenient and act as yet another reminder of hearing loss.

Uptake of cochlear implants could be increased by having a totally implantable cochlear implant, which would require the microphone, DSP, and battery to all be internal. Although the technology already exists for implantable batteries and speech processors, the best technology for implantable microphones is yet to be determined. This is exemplified by the wide variety of technological approaches that have undergone preliminary investigations and the paucity of devices that have reached human trials. Broadly, implantable microphones can be split into subcutaneous and middle ear microphones with further subdivisions based on exact location, coupling and method of transduction (e.g., piezoelectric vs capacitative), which in turn determines whether it is the displacement, velocity or acceleration that is transduced. Middle ear microphones are either fixed within the middle ear or mastoid and have a probe in contact with an ossicle or they involve a free-floating device attached solely to the ossicles; the former can lead to a force on the ossicles even without stimulation and the latter adds to the inertial load of the ossicles.

Essential requirements for implantable microphones

The microphone must be sufficiently sensitive so that the equivalent input noise is similar to external microphones. For middle ear microphones this means that the microphone must be responsive to the small displacement, low velocity or low acceleration of the ossicles (according to the mode of transduction). The largest amplitude of vibration occurs at the umbo (Vlaming & Feenstra, 1986; Zurcher, Semaan, Megerian, Ko, & Young, 2010). For an 80 dB SPL sinusoidal stimulus, the maximum displacement of the umbo is about 2 – 10 nm, the maximum velocity is about 2 μm/s (0.1 mm/s/Pa) (Vlaming & Feenstra, 1986; Voss, Rosowski, Merchant, & Peake, 2000) and the maximum acceleration is about 0.1 g (Zurcher et al., 2010).

Operation should not greatly change the transfer function of the middle ear and so lead to a conductive hearing loss. The addition of mass to the ossicles will increase the inertia and impede the transmission of higher frequencies (Gan, Wood, Dyer, & Dormer, 2001; Needham, Jiang, Bibas, Jeronimidis, & O'Connor, 2005; Nishihara, Aritomo, & Goode, 1993). Any additional mass should therefore be substantially less than the total mass of the ossicles, which is about 65 mg(Nummela, 1995). Nishihara et al (1993) found that the addition of just 5 mg to the long process of the incus could decrease stapes displacement at 4 kHz by about 10 dB. In contrast, any change that increases the stiffness of the ossicular chain will impede the transmission of lower frequencies. In addition, surgical insertion must not substantially damage the middle ear or lead to a loss of residual hearing.

The microphone must be biocompatible and robust. An intrinsic feature of a microphone is that at least one part moves and the microphone must therefore be able to cope with the repeated small movements over the lifetime of the implant, which could be decades. It is a tenet of electronic design that the root cause of failure is usually mechanical and the microphone is potentially the weak point of the whole implant. The microphone must be robust to impacts such as a blow to the head. The housing must also be impervious to surrounding body fluids.

Finally, the microphone should be irresponsive to body noise, caused for example by scratching the head and the microphone must be low power to minimize the size and maximize the life of the internal battery.

Here, we review the technologies that have been tested to date and discuss the surgical implications of using them. We have included microphones developed for implantable hearing aids and middle ear implants because microphones developed for these devices could also potentially be used for cochlear implants. To enable a better assessment of implantable microphones we have also reviewed the current technology for external microphones.

External microphones

Standard cochlear implant microphones are electret microphones (Wolfe & Schafer, 2014). Electret microphones are essentially capacitor (condenser) microphones that transduce sound into an electrical signal through changes in the distance between the two parallel plates of the capacitor as sound energy moves one of the plates, the diaphragm. In contrast to other types of capacitor microphones, they eliminate the need for a polarizing voltage across the plates by using a material on one plate that is permanently charged, although a power supply will still be needed for the internal amplifier.

Speech intelligibility for the best performers in quiet with external microphones is approaching that of normal listeners (Ebrahimi-Madiseh, Eikelboom, Jayakody, & Atlas, 2016; Wilson & Dorman, 2008), but in background noise speech intelligibility drops substantially for all cochlear implant users(Wilson & Dorman, 2008). Although most noise reduction strategies involve DSP, microphones may have a role to play. Externally, microphones can be placed in a directional housing unit to attempt to eliminate background noise or more than one microphone can be fitted. Using a second microphone pointing backwards allows speech processors to filter out unimportant background noise. This provides limited benefit monaurally but more speech intelligibility in particular is gained with binaural dual microphones (Kokkinakis, Azimi, Hu, & Friedland, 2012). External microphones, like subcutaneous microphones, do not take advantage of the natural amplification and directionality cues provided by the external ear (Blauert, 1983), and have increased susceptibility to impact over middle ear microphones.

Subcutaneous microphones

So far, research on implantable microphones has concentrated on placement directly under the skin, behind the pinna or in the middle ear. Attempts have also been made to implant a microphone beneath the canal wall skin (Zenner et al., 2000). Placements close to the pinna might be expected to lead to sensations closest to normal hearing, but this has not been tested. To compete with external microphones subcutaneous microphones must compensate for the loss in sensitivity and signal filtering that result from sound passing through skin. Placing the microphone under thin skin would improve sensitivity but risks extrusion.

The first implantable microphone was trialled in Japan as part of the Rion T-MEI (Kodera, Suzuki, & Ohno, 1988; Yanagihara, Suzuki, Gyo, Syono, & Ikeda, 1984). The microphone was an extremely fragile electret condenser microphone. It was initially trialled in cats and implanted for one year. Microphone sensitivity was found to vary based on skin thickness and position and ultimately, having found no benefit from implanting it in the mastoid, they recommended implanting it in the external auditory canal (EAC). These findings are backed up by more recent studies on porcine

models that found sound attenuation was directly proportional to skin thickness within the range of 0.5-3mm (Deddens, Wilson, Lesser, & Fredrickson, 1990). Jenkins and Uhler (2014) found that adding 6mm of soft tissue over a microphone reduces its effectiveness by a factor of ten(Herman A. Jenkins & Uhler, 2014) and the sensitivity of microphones to physiological noise is also increased by a factor of 100, so a degree of cushioning is required to limit this interference. To increase microphone sensitivity at speech frequencies, one bench study used a subcutaneous electret microphone attached to an acoustic tube (E. S. Jung, Seong, Lim, Lee, & Cho, 2011). Different lengths of tubing were trialled with correspondingly different resonant frequencies in the high-frequencies of human hearing (the frequencies filtered most when sound passes through soft-tissue thus partially overcoming the soft-tissue filtering effect). Results were promising with a significant improvement in the frequency response.

Aside from sound filtering, subcutaneous microphones must be unresponsive to sounds generated by soft-tissue movement such as head-turning (Bruschini, Forli, Passetti, Bruschini, & Berrettini, 2010) or scratching the scalp; even moving hair can lead to signal interference. In addition, sound localisation in subcutaneous microphones is likely to be limited. To avoid these issues, Kodera designed a microphone implanted in the EAC, therefore shielding the microphone from contact noise whilst benefiting from the naturally thin canal wall skin and the directionality cues of the external ear. Results in implanted cats at nine months showed excellent device durability and performance characteristics (Kodera et al., 1988). Leysieffer developed this concept producing a miniaturised version that was subsequently trialled on 20 patients (Leysieffer, Muller, & Zenner, 1997). Two patients had partial skin necrosis above the microphone requiring fascial grafts, but otherwise results showed that auditory canal skin could be drawn over the microphone diaphragm without harming the transmission quality of the microphone.

This idea was integrated into a middle ear implant with a microphone sensor under the EAC wall skin (Zenner et al., 2004). The sensor was then coupled to a hermetically sealed processor connected to an actuator attached to the incus. Interestingly, participants scored 89% on horizontal sound localisation tests in their implant ear, which was significantly better than the non-test ear suggesting the implanted microphone did encode some directional cues provided by the external ear. In two cases, however, there was partial skin necrosis above the microphone membrane corrected with fascia, and two patients had ear canal scar formation.

Finally, an electret microphone was developed in Korea which was placed in the middle ear cavity, and has been tested in experimental studies on three temporal bones (Woo et al., 2015). The microphone receives sound from the outer ear canal through a ventilation tube in the tympanic membrane and an acoustic duct across the middle ear cavity (Figure 1). Although the microphone sensitivity was flat and surgery straightforward, the authors accepted that wax, water contamination

and device migration are all potential limitations.

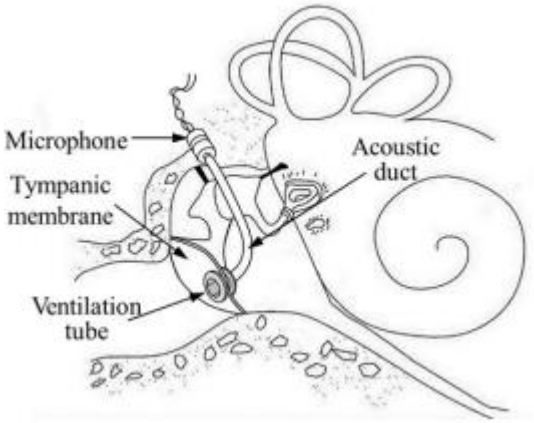

Figure 1. Subcutaneous microphone in the middle ear cavity that connects to the outer ear canal via an acoustic duct and ventilation tube (Woo et al., 2015)

Perhaps because of problems with microphone extrusion, the only commercial active middle ear implant with a subcutaneous microphone has reverted to one placed behind the pinna (Pulcherio et al., 2014). The Otologics Carina (now Cochlear Corporation) relies on a standard subcutaneous omnidirectional electret microphone. There is no consensus on where the microphone should be placed (Martin et al., 2009) but traditionally it is implanted directly behind the EAC. Positioning it here avoids problems with acoustic feedback as well as noise generated by contraction of the temporalis and sternocleidomastoid muscles. The microphone then sends a signal via the speech processor to the electromagnetic transducer, which is usually attached to the body of the incus by drilling a recess or by direct application. The degree of incus loading is adjusted during surgery to enable maximal compliance of the system and placement can be at one of multiple locations on the ossicular chain or round window (Martin et al., 2009). Most trials showed that the Carina system gave hearing that was equivalent to conventional hearing aids (Bruschini et al., 2010; Martin et al., 2009) but again due to complicated surgery and limited additional benefit few devices have been implanted in the UK.

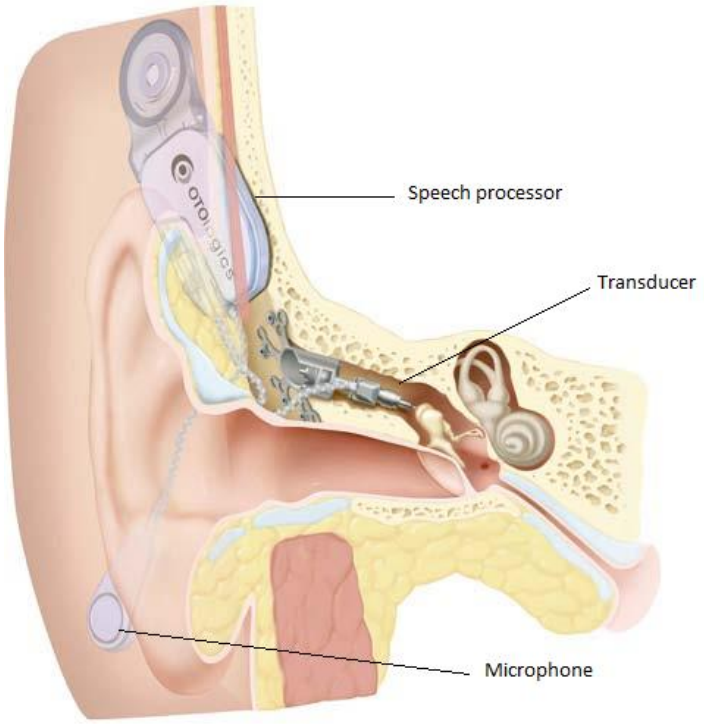

Figure 2. Cross-section of the ear showing fixation of the microphone behind the pinna for the Otologics Carina middle ear implant (Modified from image courtesy of Cochlear).

Middle ear microphones

Middle ear microphones convert movement of the tympanic membrane or ossicles into an electrical signal. In addition to advantages conferred by a subcutaneous microphone over external microphones, a middle ear microphone is able to use more of the ear's natural directionality cues and amplification provided by the pinna and ear canal. A further advantage for cochlear implants is that the middle ear reflex may be activated by electrical stimulation during vocalization, chewing, and swallowing; this feedback mechanism would act to decrease movement of the ossicles and so reduce the microphone signal, in turn reducing self-stimulation of the cochlea.
Yanagihara's group again trialled the first middle ear sensor with a piezoelectric sensor receiving ossicular vibrations from the malleus in three human temporal bones (Gyo, Yanagihara, & Araki, 1984). Sensitivities were sufficient at around -60 dB re 1 V/Pa at 1 kHz (see review by Lewis for an excellent explanation of microphone sensitivity(Lewis, 2012)).

Coupling

Measurements of the displacement transfer function using laser doppler vibrometry suggest that the malleus head or incus body are the optimal sites for coupling to middle ear microphones (Chung, Song, Sim, Kim, & Oh, 2013). Despite straightforward access to the umbo, however, standard cochlear implant surgery requires a cortical mastoidectomy and therefore the incus is more appealing. One drawback of using the incus, however, is that incus displacement naturally reduces with increasing frequency (Goode, Killion, Nakamura, & Nishihara, 1994). This may be crucial given the importance of high frequencies in speech discrimination. Although controversial, there is also some evidence that there are frequency-dependent changes in the rotational axis of the malleus-incus complex, (Schön & Müller, 1999). If confirmed, this would impair the ability of any middle ear microphone to produce a flat frequency response.

The contact point between a middle ear microphone and the ossicles is crucial as both too much or too little force will result in a conductive loss and therefore reduce sensitivity (Bruschini et al., 2010). Some middle ear implants therefore use intraoperative loading devices to improve coupling efficiency and consistency (e.g. Herman A. Jenkins & Uhler, 2014). The mass of the coupling between a middle ear microphone to the ossicles must also be considered because the displacement of the ossicular chain decreases with added mass, thereby decreasing sensitivity (Nishihara et al., 1993). A further consideration is ambient pressure changes, which can lead to relatively large displacements of the ossicular chain. If a transducer or microphone is fixed to the temporal bone then this ossicular displacement will lead to a sustained increased force on the ossicles at the contact point and there is the potential for bone resorption and a subsequent loose fit. To circumvent this problem, a hydroacoustical transmission device with a soft contact to the ossicles has been developed, which consists of a flexible, water-filled tube covered on the ossicular side by a soft balloon with a thin wall (Huttenbrink, Zahnert, Bornitz, & Hofmann, 2001). The authors recommend placing it on the short process of the incus for surgical simplicity. Frequency responses for the microphone characterised normal middle ear transmission with an improved high frequency response due to the high-frequency resonance of the water-filled tube.

Patient selection

The success of implanted middle ear microphones relies on patients having a reliable middle ear transfer function. Any loss of energy transmission through the ossicular chain secondary to middle ear disease or otherwise will lead to reduced microphone sensitivity. Patient selection is therefore important, but unfortunately very little literature exists on optimal patient selection. One previous study compared thresholds of direct vibration using an ossicular vibration device coupled to the umbo in awake patients to approximate function of a middle ear transducer and therefore guide patient selection using laser Doppler vibrometry (Maassen et al., 2004). Results were reliable and repeatable between ears, however the authors pointed out that the device did not exactly replicate linkage between a middle ear microphone and the ossicles. Tympanometry provides a crude measurement of middle ear function, but no information on ossicular movement. It is likely that a reliable measurement device will be needed to accurately predict which patients will benefit most from middle ear microphones should the technology become widely accepted.

Microphone type

Conventionally, microphones transduce sound waves in air into an electrical signal. In contrast, middle ear microphones convert the displacement or velocity of the ossicular chain into an electrical signal. The overall function is the same but the transfer of energy is very different. A middle ear transducer transfers energy from a high impedance to a lower impedance system (unlike traditional hearing aids). The two main types of middle ear transducers have centred on piezoelectric and electromagnetic devices. Most middle ear microphones are confined to piezoelectric systems, but electromagnetic systems, accelerometers and capacitor microphones can also be used.

Piezoelectric materials generate a voltage when compressed (and deform when voltage is applied). Piezoelectric microphones exploit this with excellent resolution by using ossicular movement to compress the piezoelectric material thus generating the electrical signal (for review see (Mukherjee, Roseman, & Willging, 2000). Most piezoelectric microphones are built as a “bimorph” in which two crystals are sandwiched together to multiply the deformation. Ideally, the resonant frequency of the microphone should be above the range of human hearing. There is, however, a trade-off between sensitivity and the frequency of the resonance: The shorter the device, the higher the resonant frequency is for an equivalent mass, but conversely the longer the device is the more force it generates. Piezoelectric microphones must be built to precise dimensions to optimise its resonance

frequency and sensitivity. Nonetheless, it is not currently possible to have both sufficient sensitivity and a resonant frequency below the range of normal hearing (Chi et al., 2009).

In contrast to piezoelectric microphones, which convert displacement of the ossicles into a voltage, electromagnetic microphones convert the velocity of the ossicles into a voltage. A magnet is placed in close proximity to an electromagnetic coil thus generating an electrical signal via electromagnetic induction. Electromagnetic microphones tend to have a smoother frequency response and particularly respond better at low frequencies compared with piezo electric microphones. Their placement in the middle ear is difficult, however, as the greater the distance between the driven magnet and coil, the greater the power requirement and within the confines of the middle ear there are limited configurations possible. Unlike piezoelectric microphones, electromagnetic microphones are not compatible with magnetic resonance imaging (MRI) because of the intrinsic magnet. Moreover, electromagnetic microphones have a power requirement in the order of 100 to 1000 times more than an piezoelectric transducer (Kroll, Grant, & Javel, 2002), and would therefore require a larger internal battery to get equivalent performance.

Envoy Esteem

The only implantable middle ear microphone in commercial use is for the active Envoy Esteem middle ear implant developed by Envoy Medical Corporation. Its development started in 1985 (see Kroll et al 2002 for review) and has been marketed in Europe since 2006 obtaining U.S. Food and Drug Administration approval in 2010. It relies on a speech processor and battery situated in a subcutaneous pocket over the mastoid (see figure 3). Normal movement of the ossicular chain is picked up by a piezoelectric sensor coupled to the incus body with bioglass cement and fixed to the mastoid floor. This transduces the movement into an electrical signal conveyed to the speech processor. A further signal is then sent to a piezoelectric transducer attached to the stapes head, which crucially is disarticulated from the incudostapedial joint to avoid feedback. The stapes is therefore mechanically moved, which in turn stimulates the cochlea. During surgery, the ossicular chain is tested with vibrometry before disarticulation, and once the system is in place tested again to ensure the device is working. The device has been approved by the FDA for adults with a moderate-severe sensorineural hearing loss with word recognition scores over 40%. Three trials showed some improvement over best-aided condition in word recognition scores and quality of life scales (Kraus, Shohet, & Catalano, 2011; Memari, Asghari, Daneshi, & Jalali, 2011; Monini, Biagini, Atturo, & Barbara, 2013), but none reached significance on mean gain in dB. A combination of device failures, surgical complications and limited audiological benefit over conventional hearing aids has led to few devices being implanted.

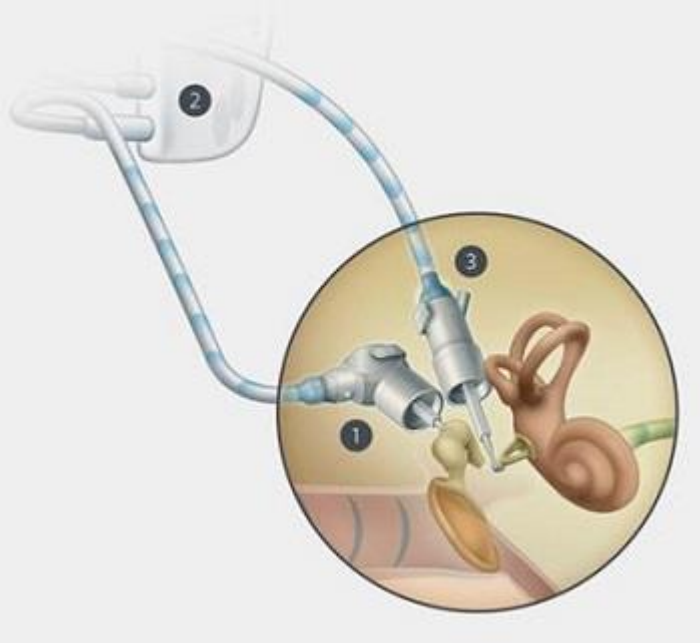

Figure 3. Middle ear microphone in the Envoy Esteem middle ear implant (From Envoy Medical Corporation)

Previous trials of implanted microphones for cochlear implant users

In Australia, a feasibility study with three patients placed the entire cochlear implant package under postaural skin (Briggs et al., 2008). All had a standard (external) cochlear implant sound processor (ESPrit 3G – Cochlear Corporation) as well as the research device and were able to switch between devices as needed. Although the research device used the same packaging and electrode technology identical to the commercial CI24RE receiver stimulator, the sound processing and stimulator electronics were designed specifically for the device and the microphone was a subcutaneous microphone based on a conventional electret microphone incorporated into the body of the stimulator (Figure 4). Hearing thresholds were tested with warble tones and after training were found to be worse in the research device mode (29, 42 and 37 dBHL for subjects 1, 2 and 3 respectively) compared with losses between 15 and 25 dBHL across all frequencies for the Esprit 3G. Speech intelligibility was tested using open set monosyllabic consonant-vowel nucleus-consonant (CNC) words at 60 dBSPL in quiet and CUNY sentences at 65 dBSPL in multi-talker babble. Again, results were unfavourable for the research device with CNC scores in quiet of 77% for the ESPrit 3G versus 33% for research device, and CUNY sentences scores in noise of 72% for ESPrit versus 34% for the research device. The authors surmised that one patient's hearing suffered due to a thicker skin flap. There were no complications and all three subjects continue to use the implant on a limited basis finding additional benefits over the standard cochlear implant (as introduced earlier). The main factor limiting their use is the significant increase in body/physiological noise over and above their existing external microphone.

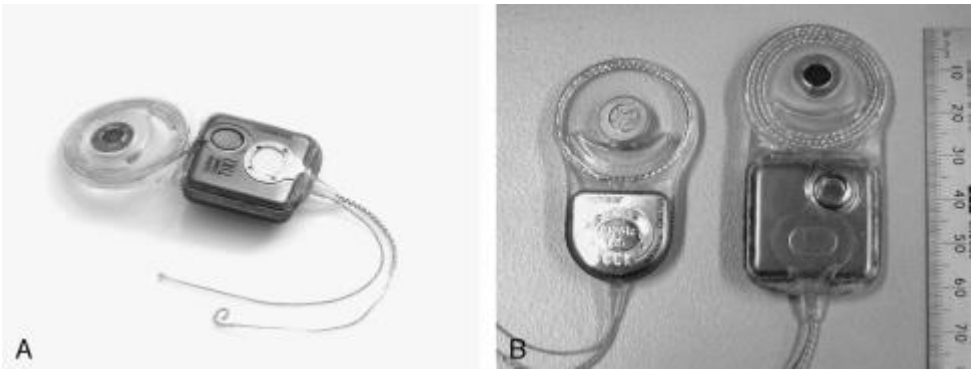

Figure 4. a) Prototype totally implantable cochlear implant (TIKI) with a subcutaneous microphone. b) Comparison between the commercial CI24RE Freedom receiver/stimulator (left) the TIKI (right) (Briggs et al, 2008).

In America, four cochlear implant users were implanted with a Carina microphone (see Figure 5), linked via a percutaneous plug to the external sound processor of their Freedom (Cochlear Corporation) sound processor (H. A. Jenkins & Uhler, 2012). This enabled switching between both microphones. All patients had used a Freedom Cochlear implant for over twelve months and had CNC scores of 40 % or more in quiet. Hearing tests included sound-field pure-tone thresholds which were substantially lower when using the Freedom microphone (around 25 dB average) in comparison with around 45 dB average with the implanted Carina microphone. Speech testing was carried out using open set monosyllabic CNC in quiet at 50 and 60 dB SPL (as per FDA guidelines), and BKB-SIN at 70 dB SPL. Results favoured the external Freedom microphone with CNC scores averaging 67 % correct for the Freedom microphone and only 35 % for the Carina. The BKB-SIN scores equally were better throughout for the Freedom device. In the discussion, the authors mentioned improved software signalling for the second two patients and this is reflected in Abbreviated Profile of Hearing Aid Benefit (APHAB) scores, which are equivalent for the second two patients comparing Freedom with Carina microphones. For the first two patients, the Freedom scores are substantially better.

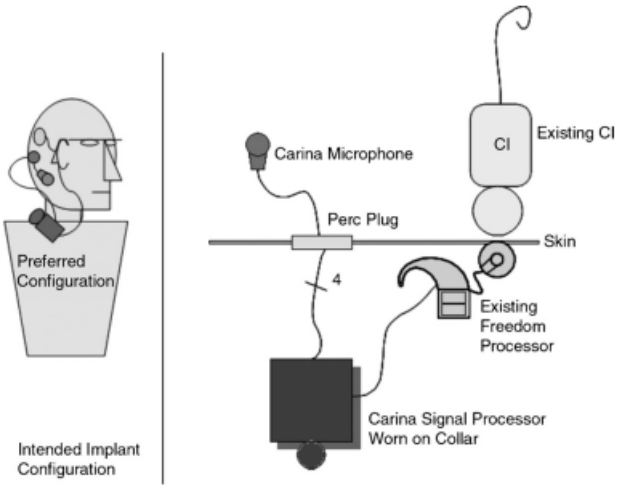

Figure 5. Test configuration for the implanted Carina microphone, which was used as the direct audio input to an external Freedom sound processor via a percutaneous plug and an external signal processing worn on the collar (Jenkins et al, 2012)

The subjects in Briggs' study obtained mean warble tone thresholds of 36 dB HL with their research device, in comparison with subjects in the Jenkins study reaching pure-tone thresholds of 45 dB HL. CNC scores in quiet were equivalent (33% and 35%, respectively). Comparisons are difficult to make for speech in noise due to differences in speech material and reporting.

Finally ten patients in Belgium were implanted in 2016 with the same setup as Jenkins and Uhler except the Carina microphone was attached to an existing cochlear implant device placed at least *two* years previously. Improved sound processing allowed a reduction in the perception of body noise and improved pure-tone thresholds and speech recognition scores. Pure-tone audiometry thresholds with the implanted microphone were 44.9dB compared with 36.4dB for the external microphone. Under good listening circumstances speech recognition scores reached approximately 90% of the performance level reached with the external microphone. Hair movement and hearing one's one voice remained a concern for some recipients but was reduced by the installed body noise cancellation function.

Bench studies

A number of bench studies have investigated a variety of microphones that warrant discussion. The majority of bench microphones studies have investigated piezoelectric or electret devices, with a few attempts trialling electromagnetic, accelerometer and hydrophone microphones. More recently the concept of an intracochlear microphone has also been investigated.

Various different ways of maximising microphone performance for piezoelectric devices have been trialled. By placing a piezoelectric sheet in the gap between a disarticulated incudostapedial joint on a temporal bone model a sensitivity of about -60 dB re 1 V / Pa for sound between 20-120 dB SPL was achieved (Koch, Esinger, Bornitz, & Zahnert, 2014). In a previous temporal bone model, however, it was difficult to avoid the sheet touching the middle ear which led to significantly reduced sensitivity. An alternative method was developed by Chi et al (2009) using a piezoelectric bimorph element microphone implanted on the malleus of cats (Chi et al., 2009). The frequency response curve of the piezoelectric microphone mirrored the standard external microphones but sensitivities were different (−38.7 dB re 1 V/Pa at 1,000 Hz and -1.5dB re 1V/Pa at 1,000Hz respectively). The same group developed a piezoelectric microphone implanted in cats and tested its sensitivity when placed on the malleus, and in comparison to an external microphone but also when hung in the tympanic cavity (Kang et al., 2012). Despite efforts to reduce the weight of the sensor, when attached to the malleus, the authors noticed a dramatic decrease in microphone sensitivity in the low frequencies, which they postulated was due to a mass-loading effect. Poor sensitivity was achieved with the microphone hanging in the tympanic cavity. Most recently, a piezoelectric microphone was designed housed in a biocompatible unibody with a titanium clip allowing attachment to the long process of the incus (Jia et al., 2016). Using human cadaveric heads, the microphone sensitivities were flat with an average sensitivity of -56.58dB RMS ref 1V at 1000 Hz using an acoustic stimulation strength of 90dB SPL ref 20 µPa.

Park et al 2007 and Zurcher et al 2010 have investigated using an accelerometer that can be attached to the ossicular chain (Park et al., 2007)(Zurcher et al, 2010). Unlike other piezoelectric or electromagnetic middle ear sensors which rely on the body of the sensor to be fixed and then use the displacement of the diaphragm to transduce signals, accelerometers are fixed only to the moving

ossicles and therefore rely on the displacement of a “proof mass” within the accelerometer relative to fixed sensors within the body of the accelerometer. This has the obvious surgical advantage that only one fixation point is needed which will most likely make surgery more straightforward. These sensors can be piezoelectric (Park et al., 2007) or capacitative (Zurcher et al, 2010)(Young, Zurcher, Semaan, Megerian, & Ko, 2012). The sensor in Youngs experiment detected sounds around 60dB at 500Hz but they suggest that until micro electro-mechanical (MEMS) systems significantly reduce in size, the mass-loading effect of an accelerometer attached to the ossicular chain is likely to reduce sensitivity beyond useful levels.

Maniglia et al (1999) used an electromagnetic transducer in reverse in human temporal bones (Maniglia et al., 1999). A small magnet was fixed either to the incus or malleus, whilst the magnetic coil was fixed 0.5 mm away using a fixation device attached to the mastoid cortex. The average signal-to-noise ratio was 37 dB with the magnet placed on the incus, and 44 dB when placed on the malleus. Higher power consumption and difficulties in placing the coil near to the magnet makes this system less favourable.

The idea of intra-cochlear microphones or sensors is inherently attractive as it allows full utilisation of both the external and middle ear. If possible, future integration with the electrode array may leave much of the external ear and middle ear untouched. There are multiple technical challenges to overcome not solely limited to device size, but there are currently three patented cochlear microphones. Zhang et al designed a piezoelectric sensor which is placed in perilymph to pick up pressure waves within(Zhang, Seligman, Klein, & Cowan, 2009). Jung et al (2015) designed an artificial basilar membrane with an integrated piezoelectric sheet allowing detection of fluid movement within an artificial cochlear chamber. The design was capable of frequency separation between 450 Hz and 5 kHz (Y. Jung, Kwak, Kang, Kim, & Hur, 2015). Finally nanorods have been trialled to simulate outer hair cells. Nanorod length was found to be the most critical parameter in improving sensitivity with increasing nanorod length leading to greater drag force and therefore sensitivity (Manson & Shen, 2013).

Conclusion

The potential benefits of a fully implantable cochlear implant system are obvious. The single remaining challenge in achieving this relates to implantable microphone technology and recent technological advances have created a variety of implantable microphones that in the future could challenge or replace conventional external microphones. To be accepted as a mainstream alternative, however, implantable microphones must also provide cochlear implant patients with a sound quality that matches or exceeds their external counterparts. The majority of commercial products to date are confined to subcutaneous devices and although most have equivalent hearing thresholds, sound quality is affected by surface contact or physiological noise. Positioning implantable microphones in the middle-ear may avoid this and be able to take advantage of directionality cues and amplification provided by the pinna and external ear canal.

References

Blauert, J. (1983). Spatial Hearing—The Psychophysics of Human Sound Source Localization: Cambridge, MA: MIT Press.

Briggs, R. J., Eder, H. C., Seligman, P. M., Cowan, R. S., Plant, K. L., Dalton, J., Money D., Patrick, J. F. (2008). Initial clinical experience with a totally implantable cochlear implant research device. *Otology & neurotology, 29*(2), 114-119. doi: 10.1097/MAO.0b013e31814b242f

Bruschini, L., Forli, F., Passetti, S., Bruschini, P., & Berrettini, S. (2010). Fully implantable Otologics MET Carina™ device for the treatment of sensorineural and mixed hearing loss: Audio-otological results. *Acta oto-laryngologica, 130*(10), 1147-1153

Byrne, D., & Noble, W. (1998). Optimizing sound localization with hearing aids. *Trends in Amplification, 3*(2), 51-73

Chi, F. L., Wu, Y., Yan, Q. B., Shen, Y. H., Jiang, Y., & Fan, B. H. (2009). Sensitivity and fidelity of a novel piezoelectric middle ear transducer. *ORL; journal for oto-rhino-laryngology and its related specialties71*(4), 216-220. doi: 10.1159/000229301

Chung, J., Song, W. J., Sim, J. H., Kim, W., & Oh, S.-H. (2013). Optimal ossicular site for maximal vibration transmissions to coupled transducers. *Hearing Research, 301*(0), 137-145. doi: http://dx.doi.org/10.1016/j.heares.2013.01.007

Cochlear implants. (2015). Retrieved from http://www.earfoundation.org.uk/hearing-technologies/cochlear-implants/cochlear-implant-information-sheet

Deddens, A., Wilson, E., Lesser, T., & Fredrickson, J. (1990). Totally implantable hearing aids: the effects of skin thickness on microphone function. *American journal of otolaryngology, 11*(1), 1-4

Ebrahimi-Madiseh, A., Eikelboom, R. H., Jayakody, D. M., & Atlas, M. D. (2016). Speech perception scores in cochlear implant recipients: An analysis of ceiling effects in the CUNY sentence test (Quiet) in post-lingually deafened cochlear implant recipients. *Cochlear implants international, 17*(2), 75-80

Frohne-Büchner, C., Büchner, A., Gärtner, L., Battmer, R. D., & Lenarz, T. (2004). Experience of uni- and bilateral cochlear implant users with a microphone positioned in the pinna *International Congress Series* (Vol. 1273, pp. 93-96): Elsevier.

Gan, R. Z., Wood, M. W., Dyer, R. K., & Dormer, K. J. (2001). Mass loading on the ossicles and middle ear function. *Annals of Otology, Rhinology & Laryngology, 110*(5), 478-485

Goffman, E. (2009). *Stigma: Notes on the management of spoiled identity*: Simon and Schuster.

Goode, R. L., Killion, M., Nakamura, K., & Nishihara, S. (1994). New knowledge about the function of the human middle ear: development of an improved analog model. *Otology & Neurotology, 15*(2), 145-154

Gyo, K., Yanagihara, N., & Araki, H. (1984). Sound pickup utilizing an implantable piezoelectric ceramic bimorph element: application to the cochlear implant. *American Journal of Otology, 5*(4), 273-276

Huttenbrink, K. B., Zahnert, T. H., Bornitz, M., & Hofmann, G. (2001). Biomechanical aspects in implantable microphones and hearing aids and development of a concept with a hydroacoustical transmission. *Acta Otolaryngologica, 121*(2), 185-189

Jenkins, H. A., & Uhler, K. (2012). Speech perception comparisons using an implanted and an external microphone in existing cochlear implant users. *Otology & Neurotology, 33*(1), 13-19. doi: 10.1097/MAO.0b013e31823c9335

Jenkins, H. A., & Uhler, K. (2014). Otologics Active Middle Ear Implants. *Otolaryngologic Clinics of North America, 47*(6), 967-978. doi: http://dx.doi.org/10.1016/j.otc.2014.08.007

Jia, X.-H., Gao, N., Xu, X.-d., Wu, Y.-Z., Kang, H.-Y., & Chi, F.-L. (2016). A new floating piezoelectric microphone for the implantable middle ear microphone in experimental studies. *Acta Oto-Laryngologica*, 1-7

Jung, E. S., Seong, K. W., Lim, H. G., Lee, J. H., & Cho, J. H. (2011). Implantable microphone with acoustic tube for fully implantable hearing devices. *IEICE Electronics Express, 8*(4), 215-219

Jung, Y., Kwak, J.-H., Kang, H., Kim, W. D., & Hur, S. (2015). Mechanical and Electrical Characterization of Piezoelectric Artificial Cochlear Device and Biocompatible Packaging. *Sensors, 15*(8), 18851-18864

Kang, H. Y., Gao, N., Chi, F. L., Jin, K., Gao, Z., & Pan, T. Z. (2012). Feasible Pickup from intact ossicular chain with floating piezoelectric microphone. *Biomedical Engineering Online, 11*(1), 10. doi: 10.1186/1475-925x-11-10

Koch, M., Esinger, T. M., Bornitz, M., & Zahnert, T. (2014). Examination of a mechanical amplifier in the incudostapedial joint gap: FEM simulation and physical model. *Sensors, 14*(8), 14356-14374

Kodera, K., Suzuki, J., & Ohno, T. (1988). Evaluation of the implantable microphone in the cat. *Advances in Audiology, 4*, 117-123

Kokkinakis, K., Azimi, B., Hu, Y., & Friedland, D. R. (2012). Single and multiple microphone noise reduction strategies in cochlear implants. *Trends in Amplification, 16*(2), 102-116. doi: 10.1177/1084713812456906

Kraus, E. M., Shohet, J. A., & Catalano, P. J. (2011). Envoy Esteem Totally Implantable Hearing System Phase 2 Trial, 1-Year Hearing Results. *Otolaryngology--Head and Neck Surgery*

Kroll, K., Grant, I. L., & Javel, E. (2002). The Envoy® Totally Implantable Hearing System, St. Croix Medical. *Trends in Amplification, 6*(2), 73-80. doi: 10.1177/108471380200600208

Lewis, J. (2012). Understanding microphone sensitivity. *Analog Dialogue, 46*(2), 14-16

Leysieffer, H., Muller, G., & Zenner, H. P. (1997). [An implantable microphone for electronic hearing aids]. *HNO, 45*(10), 816-827

Maassen, M. M., Rodriguez Jorge, J., Herberhold, S., Vonthein, R., Zimmermann, R., Baumann, I., . . . Zalaman, I. M. (2004). Safe and reliable sound threshold measures with direct vibration of the ossicular chain. *The Laryngoscope, 114*(11), 2012-2020

Maniglia, A. J., Abbass, H., Azar, T., Kane, M., Amantia, P., Garverick, S., . . . Falk, T. (1999). The middle ear bioelectronic microphone for a totally implantable cochlear hearing device for profound and total hearing loss. *The American Journal of Otology, 20*(5), 602-611

Manson, R. D., & Shen, I. (2013). Preliminary Modeling of an Intracochlear Piezoelectric Microphone *ASME 2013 International Design Engineering Technical Conferences and Computers and Information in Engineering Conference* (pp. V001T009A024-V001T009A024): American Society of Mechanical Engineers.

Martin, C., Deveze, A., Richard, C., Lefebvre, P. P., Decat, M., Ibanez, L. G., . . . Tringali, S. (2009). European results with totally implantable carina placed on the round window: 2-year follow-up. *Otology & neurotology, 30*(8), 1196-1203. doi: 10.1097/MAO.0b013e3181c34898

Memari, F., Asghari, A., Daneshi, A., & Jalali, A. (2011). Safety and patient selection of totally implantable hearing aid surgery: Envoy system, Esteem. *European Archives of Oto-Rhino-Laryngology, 268*(10), 1421-1425. doi: 10.1007/s00405-011-1507-0

Monini, S., Biagini, M., Atturo, F., & Barbara, M. (2013). Esteem middle ear device versus conventional hearing aids for rehabilitation of bilateral sensorineural hearing loss. *European Archives of Oto-Rhino-Laryngology, 270*(7), 2027-2033

Mukherjee, N., Roseman, R. D., & Willging, J. P. (2000). The piezoelectric cochlear implant: concept, feasibility, challenges, and issues. *Journal of biomedical materials research, 53*(2), 181-187

Needham, A., Jiang, D., Bibas, A., Jeronimidis, G., & O'Connor, A. F. (2005). The effects of mass loading the ossicles with a floating mass transducer on middle ear transfer function. *Otology & Neurotology, 26*(2), 218-224

Nishihara, S., Aritomo, H., & Goode, R. L. (1993). Effect of changes in mass on middle ear function. *Otolaryngology--Head and Neck Surgery, 109*(5), 899-910

Nummela, S. (1995). Scaling of the mammalian middle ear. *Hearing research, 85*(1), 18-30

Park, W. T., O'Connor, K. N., Chen, K. L., Mallon, J. R., Jr., Maetani, T., Dalal, P., . . . Kenny, T. W. (2007). Ultraminiature encapsulated accelerometers as a fully implantable sensor for implantable hearing aids. *Biomedical Microdevices, 9*(6), 939-949. doi: 10.1007/s10544-007-9072-4

Pulcherio, J. O. B., Bittencourt, A. G., Burke, P. R., Monsanto, R. d. C., de Brito, R., Tsuji, R. K., & Bento, R. F. (2014). Carina® and Esteem®: A Systematic Review of Fully Implantable Hearing Devices. *PLoS ONE, 9*(10), e110636. doi: 10.1371/journal.pone.0110636

Raine, C. (2013). Cochlear implants in the United Kingdom: awareness and utilization. *Cochlear implants international, 14*(sup1), S32-S37

Schön, F., & Müller, J. (1999). Measurements of ossicular vibrations in the middle ear. *Audiology and Neurotology, 4*(3-4), 142-149

Shaw, E. A. (1974). The external ear *Auditory System* (pp. 455-490): Springer.

Vlaming, M. S., & Feenstra, L. (1986). Studies on the mechanics of the normal human middle ear. *Clinical Otolaryngology and Allied Sciences, 11*(5), 353-363

Voss, S. E., Rosowski, J. J., Merchant, S. N., & Peake, W. T. (2000). Acoustic responses of the human middle ear. *Hearing Research, 150*(1-2), 43-69

Wallhagen, M. I. (2010). The stigma of hearing loss. *The Gerontologist, 50*(1), 66-75

Wilson, B. S., & Dorman, M. F. (2008). Cochlear implants: current designs and future possibilities. *Journal of rehabilitation research and development, 45*(5), 695

Wolfe, J., & Schafer, E. (2014). *Programming cochlear implants*: Plural Publishing.

Woo, S. T., Shin, D. H., Lim, H.-G., Seong, K.-W., Gottlieb, P., Puria, S., . . . Cho, J.-H. (2015). A New Trans-Tympanic Microphone Approach for Fully Implantable Hearing Devices. *Sensors, 15*(9), 22798-22810

Yanagihara, N., Suzuki, J., Gyo, K., Syono, H., & Ikeda, H. (1984). Development of an implantable hearing aid using a piezoelectric vibrator of bimorph design: state of the art. *Otolaryngology--Head and Neck Surgery, 92*(6), 706-712

Young, D. J., Zurcher, M. A., Semaan, M., Megerian, C. A., & Ko, W. H. (2012). MEMS capacitive accelerometer-based middle ear microphone. *IEEE Trans Biomed Eng, 59*(12), 3283-3292. doi: 10.1109/tbme.2012.2195782

Zenner, H. P., Leysieffer, H., Maassen, M., Lehner, R., Lenarz, T., Baumann, J., . . . McElveen, J. T., Jr. (2000). Human studies of a piezoelectric transducer and a microphone for a totally implantable electronic hearing device. *Am J Otol, 21*(2), 196-204

Zenner, H. P., Limberger, A., Baumann, J. W., Reischl, G., Zalaman, I. M., Mauz, P. S., . . . Maassen, M. M. (2004). Phase III results with a totally implantable piezoelectric middle ear implant: Speech audiometry, spatial hearing and psychosocial adjustment. *Acta Oto-laryngologica, 124*(2), 155-164. doi: doi:10.1080/00016480310016055

Zhang, L. A., Seligman, P. M., Klein, A., & Cowan, R. (2009). Implantable acoustic sensor: Google Patents.

Zurcher, M. A., Semaan, M., Megerian, C. A., Ko, W. H., & Young, D. J. (2010). A MEMS capacitive accelerometer design as middle ear microphone based on ossicular chain micromechanic characterization at umbo for fully implantable cochlear prosthesis. *Sensors and Materials, 22*(6), 297-312