Middle Ear Implants for the Treatment of Hearing Loss

FINAL STE REPORT

December 2011

Submitted to:
The Alberta Health Technologies Decision Process
Health Technologies and Services Policy Unit
Clinical Advisory and Research Branch
Health Policy and Service Standards Division
Alberta Health and Wellness
Edmonton, AB
Canada

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Production of this document has been made possible by a financial contribution from Alberta Health and Wellness and under the auspices of the Alberta Health Technologies Decision Process: the Alberta model for health technology assessment and policy analysis. The views expressed herein do not necessarily represent the official policy of Alberta Health and Wellness.

Acknowledgements:

With thanks for their advice and support throughout the project:

- **Ms. Kate Wagontall, Alberta Health & Wellness**
- **Dr. Nahla Gomaa, Audiologist, Edmonton**
- **Ms. Tanis Howarth, Manager Audiology Service, Glenrose Rehabilitation Hospital**
- **Ms. Jillian Ingratta, Care Manager Community Audiology, Allied Health Calgary Zone**
- **Ms. Larena Lewchuk, President, Alberta Association of Audiologists**
- **Ms. Patti-Jo Sullivan, Program Manager, Alberta Aids to Daily Living**

and to the members of the Expert Advisory Group for this assessment:

- **Dr. Hamdy El-Hakim, Pediatric Otolaryngologist, Head & Neck Surgeon, Alberta Health Services**
- **Ms. Isabel Henderson, Vice President, Glenrose Rehabilitation Hospital, Alberta Health Services**
- **Dr. Allan Ho, Tertiary Neurologist / Otologist, Covenant Health, Alberta Health Services**
- **Dr. Bill Hodgetts, Assistant Professor, Speech Pathology and Audiology, University of Alberta**
- **Ms. Brenda Huband, Senior Vice President, Metropolitan Hospitals, Alberta Health Services**
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- **Mr. Trevor Small, Director, Surgery Services, Grey Nun's Hospital, Covenant Health, Alberta Health Services**

Authors' conflict of interest statement: None declared.

Executive Summary

Introduction
This assessment is a systematic review of the evidence on middle ear implants (MEI) for the treatment of hearing loss. The objectives of this review were to determine the safety, effectiveness and cost-effectiveness of MEI in comparison to external hearing aids, bone-anchored hearing aids (BAHA), or cochlear implants; to identify particular sub-groups of patients who might benefit most from MEI, and to summarize the current criteria for using MEI versus alternative treatments for hearing loss.

Methods
This report is a systematic review of the published literature comparing MEI to alternative therapies (traditional hearing aids, BAHA and cochlear implants), for the treatment of hearing loss. A budget impact analysis and economic decision model were also prepared based on the published literature, information provided by the manufacturers, expert clinical opinion, and Alberta Health and Wellness administrative data.

Description of Technology
Middle ear implants are surgically implanted electronic devices that aim to correct hearing loss by stimulating the ossicular chain or middle ear. The devices are surgically implanted within the middle ear, leaving the external ear canal open. Implantation involves a surgical procedure performed by an otolaryngologist (ear, nose and throat surgeon) under general anesthesia. Different types of MEI are either partially or fully implantable. Middle ear implants are used to treat patients with moderate to severe hearing loss who cannot use or who are dissatisfied with conventional hearing aids.

Currently, two MEIs are licensed by Health Canada:

- **Vibrant Soundbridge®** (Med-El)
- **Esteem®** (Envoy Medical)

A third MEI, the **Carina®** fully implantable hearing aid (Otologics), is in the process of obtaining licensing in Canada. All three devices are included in this assessment.

Middle ear implants are not yet publicly funded or provided in Alberta, though they are used elsewhere in Canada and internationally.

Alternative treatments for hearing loss include conventional hearing aids, BAHA and cochlear implants. The choice of treatment is based on the type and severity of hearing loss, as well as the presence of other conditions (such as abnormal ear anatomy or chronic otitis media), and the capabilities, needs and expectations of the individual patient.

Social and System Demographics (S)
Hearing loss is a common condition that affects about 10% of Canadians. Because it usually develops gradually, many individuals are unaware that their hearing is impaired. The stigma of hearing loss and its association with old age may deter individuals from seeking treatment for this condition. Untreated hearing loss affects both physical functioning and quality of

life. It has been linked to social isolation, depression, marital and family stress, and cognitive decline. Hearing impairment also affects educational opportunities and employment. Children with hearing loss may suffer developmental and language delays.

There are various types of hearing loss, including both congenital and acquired. The most common type of hearing loss, sensorineural hearing loss, is typically age-related, though it also affects younger people. As the population ages, the number of Albertans affected by sensorineural hearing loss is likely to increase.

For most types of hearing loss, external hearing aids comprise the main and an effective treatment option. However, since hearing aids are only partially subsidized for specific populations, their cost may prevent some individuals from accessing them. In addition, problems related to discomfort, poor sound quality and feedback have been reported, although these may be related to improper fitting, rather than the hearing aid, itself. Concerns about their appearance have also been raised by some individuals. Lastly, patients with medical conditions, such as chronic ear infections or malformations of the ear, may be unable to use external hearing aids.

Technological Effects and Effectiveness (T)

Evidence of Safety

The partially implantable Vibrant Soundbridge and fully implantable Carina appear to be relatively safe. There were few reports of major complications, and these occurred at rates similar to those with BAHA. A greater number of major complications was reported with the fully implantable Esteem, including high rates of nerve damage. Revision surgeries and explantations were more frequent with the Esteem and Carina MEIs. No significant safety issues associated with conventional hearing aids were found. While in this review, the safety of MEI was not specifically compared to that of cochlear implants because of differences in eligible patient populations (cochlear implants are typically indicated for more severe hearing loss), based on previously published reviews of cochlear implants, MEI appears to be at least as safe as cochlear implants.

Evidence of Effectiveness

Middle ear implants offer functional gains comparable to those achieved with hearing aids. Based on limited evidence, MEIs appear to provide greater improvements in the perception of speech in noisy situations and in sound quality. MEI also appears to be at least as effective as BAHA in patients who may be eligible for both devices. Due to differences in the severity of hearing loss in patients eligible for cochlear implants and those eligible for MEI, the comparative effectiveness of these two devices could not be assessed

Economic Evaluation (E)

A cost-effectiveness analysis could not be conducted because for patients who are not medically able to wear a hearing aid, and who are ineligible for a BAHA, there are currently no alternative treatment options.

Budget Impact

Based on an estimated 20 patients receiving MEI per year in Alberta, the total budget impact over 5 years would be $2,677,497.

Conclusion

Although the technology has been in use for over 10 years, good quality evidence on MEI is still lacking. In patients medically able to wear conventional hearing aids, the evidence indicates that MEI offers a similar improvement in functional gain to that achieved with conventional hearing aids, but may offer greater improvement with respect to perception of speech in noise and sound quality. In the small group of patients who are medically unable to use conventional hearing aids, MEI appears to offer a viable treatment option.

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Abbreviations

AACHT = Alberta Advisory Committee on Health Technologies

AADL = Alberta Aids to Daily Living

ACSLPA = Alberta College of Speech-Language Pathologists and Audiologists

AHTDP = Alberta Health Technologies Decision Process

AHW = Alberta Health and Wellness

APHAB = Abbreviated Profile of Hearing Aid Benefit

AV = aversiveness

BAHA = bone-anchored hearing aid

BN = background noise

BTE = behind-the-ear hearing aid

CHL = conductive hearing loss

CI = cochlear implant

CIC = completely-in-the-canal hearing aid

CNC = consonant/nucleus/consonant

CROS = contralateral routing of signals

dB = decibel

DRG = diagnosis-related group

EC = ease of communication

ENT = Ear, Nose and Throat

FMT = floating mass transducer

HA = hearing aid

HINT= Hearing in Noise Test

HL = hearing loss

HRQoL = health-related quality of life

HTA = health technology assessment

Hz = hertz

iRSM = Institute for Reconstructive Sciences in Medicine

ITC = in-the-canal hearing aid

ITE = in-the-ear hearing aid

MEI = middle ear implant

MELU = Multiple Environmental Listening Utility

MET = Middle Ear Transducer

MHL = mixed hearing loss

MRI = magnetic resonance imaging

NR = not reported

PICOS = **P**articipants (**p**atients or **p**opulations) - **I**ntervention - **C**omparator - **O**utcomes – **S**tudy design (categories used in evidence-based health care to formulate research questions)

PTA = pure tone average

PTT = pure tone threshold

QoL= quality of life

RCT = randomized controlled trial

RV = reverberation

SNHL = sensorineural hearing loss

SRT = speech recognition threshold

UK = United Kingdom

US = United States

VORP = vibrating ossicular prosthesis

VSB = Vibrant Soundbridge

Glossary

Atresia = a congenital condition where a natural body opening is narrowed or closed. In congenital auditory atresia one or both of the ear canals may be closed; also called auricular atresia or aural atresia.

Audiogram = graphs that show the results of hearing tests.

Audiometry = tests that measure hearing sensitivity at different frequencies; also called pure tone thresholds.

Auditory canal = ear canal; the external auditory canal is the opening from the outer ear to the tympanic membrane (eardrum) of the middle ear.

Auditory nerve = the nerve that transmits signals from the cochlea to the brain; also called the cochlear nerve.

Audiologist = a health care professional who may assess, diagnose (depending on provincial regulations), treat and provide rehabilitation (including fitting hearing aids), for patients with hearing loss or balance disorders.

Auricle = the visible part of the external ear; also called the pinna.

Bilateral or binaural hearing loss = hearing loss in both ears.

Binaural or bilateral hearing = hearing with both ears.

Bone-anchored hearing aid = an implanted hearing aid that uses bone conduction, rather than air conduction, to transmit sound vibrations directly to the cochlea (i.e., bypassing the auditory canal and middle ear); BAHA are used to treat conductive or mixed hearing loss.

Case-control study = a study that compares individuals with a condition (cases) to those from a similar population without the condition (controls).

Case series = a study that reports on outcomes for a series of individual patients who have received an intervention (i.e., with no comparator group).

Cerumen = ear wax.

Cholesteatoma = a cyst or growth in the middle ear.

Cochlea = the fluid-filled, spiral cavity of the inner ear; from the Greek word for snail shell.

Cochlear implant = a device that is surgically implanted to treat certain kinds of deafness or severe hearing loss due to problems in the inner ear or cochlea. It consists of a

microphone, speech processer, transmitter and receiver. The cochlear implant uses an electrical current to directly stimulate the auditory nerve in response to sound.

Cohort study = an observational study where two or more groups with similar characteristics are exposed to different interventions (or an intervention versus no intervention), monitored over time, and compared.

Conductive hearing loss = hearing loss due to disorders of the outer or middle ear that affect the conduction of sound; in conductive hearing loss air conduction, rather than bone conduction, hearing thresholds are impaired.

Confidence interval = the amount of uncertainty regarding the true effect of an intervention; typically a 95% confidence interval (CI) is used, which indicates that the results are likely to be within this range approximately 95% of the time.

Contralateral routing of signals = a type of hearing aid used to treat unilateral hearing loss by sending sound from the ear with poor hearing to the ear with better hearing.

Decibel = a measure of the level of sound.

Device failure = failure of a medical technology to perform as intended.

External otitis = bacterial or fungal skin infection of the external auditory canal.

Floating mass transducer = the part of a middle ear implant that vibrates the ossicular chain of the middle ear.

Hair cells = cells within the inner ear. Tiny cilia on the hair cells act as sensory receptors that send electrical signals to the auditory nerve; damage to these cells causes sensorineural hearing loss.

Hearing aids = devices that amplify sound.

Hearing loss = a decrease or impairment in hearing sensitivity.

Hertz = a unit of frequency of change equal to one cycle per second.

Incus = one of three bones that form the ossicular chain in the middle ear.

Kappa statistic = a measure of inter-rater agreement (such as between reviewers), a value of 1 indicates perfect agreement.

Malleus = the outermost of the three bones that form the ossicular chain in the middle ear.

Mastoid bone = part of the temporal bone of the skull behind the ears; the mastoid bone contains air-filled spaces that connect to the middle ear.

Menière's disease = a condition that affects the inner ear, causing dizziness, tinnitus and hearing loss.

MeSH = the Medical Subject Headings; indexing vocabulary used by the US National Library of Medicine.

Middle ear implants = semi- or fully-implantable hearing aids.

Mixed hearing loss = the presence of both conductive and sensorineural hearing loss.

Osseointegration = bone growth that surrounds and anchors a surgical implant.

Ossicles or ossicular chain = the three small bones (the malleus, incus and stapes) that form the middle ear. These bones transmit sound from the outer ear to the cochlea, or inner ear.

Otitis externa = inflammation or infection of the ear canal (outer ear).

Otitis media = infection of the middle ear.

Otolaryngologist = an ear, nose and throat surgeon.

Otosclerosis = an abnormal bone growth in the middle ear.

Periosteum = a fibrous layer of tissue that covers bones.

Pinna = the external part of the ear; also called the auricle.

Presbycusis = age-related hearing loss; usually sensorineural hearing loss caused by permanent damage to the hair cells of the inner ear.

Pure tone = a tone that uses only one frequency.

Pure tone average = used to assess hearing level; an average, in decibels, of thresholds for pure tones at 500, 1,000 and 2,000 hertz, or the approximate level of speech reception.

Sensorineural hearing loss = hearing loss caused by damage to either or both the inner ear or the auditory nerve; the damage is usually to the hair cells (nerve endings) that transmit signals from the inner ear to the brain.

Speech recognition threshold = the lowest threshold hearing level where 50% of a list of two-syllable words can be correctly identified.

Stapes = the smallest bone in the body; one of the three bones that make up the ossicular chain of the middle ear.

Tinnitus = a constant buzzing, roaring or hissing sound in one or both ears.

Tympanic membrane = eardrum.

Unilateral hearing loss = hearing loss in one ear only; also called single-sided deafness.

Introduction

The Alberta Health Technologies Decision Process (AHTDP) is part of the Alberta Government's response to advice from the Expert Advisory Panel to Review Publicly Funded Health Services to improve decision-making regarding public funding of health technologies and services.

Under the auspices of the AHTDP, the Health Technology and Policy Unit, at the University of Alberta, was commissioned to prepare a health technology assessment (HTA) on the use of middle ear implants to treat hearing loss.

Middle ear implants were referred to the AHTDP for review by Covenant Health.

Purpose of assessment

The purpose of this assessment was to review the evidence on middle ear implants (MEI) for the treatment of hearing loss in order to support the development of policy recommendations around its provision as a publicly funded service in Alberta.

Research questions

The main question to be addressed in this review was:

> What is the role of middle ear implants in the treatment of hearing impaired patients in Alberta?

The objectives of the review were:

1. To determine the safety, effectiveness/efficacy and cost-effectiveness of MEI for the treatment of patients with hearing loss who are unable to use or are ineligible for traditional hearing aids, bone anchored hearing aids (BAHA) or cochlear implants (CI), or who are eligible for MEI as an alternative to traditional hearing aids, BAHA, or CI.
2. To determine the sub-populations of patients who might be most appropriately treated with MEI.
3. To determine the budget impact of providing MEI for the treatment of hearing loss in these patients.
4. To review the social, ethical and legal considerations for the provision of MEI for the treatment of patients with hearing loss who are unable to use, or are ineligible for traditional hearing aids, BAHA, or CI.

Background

Hearing

The human ear has three main parts:

- the outer ear (which includes the visible, external ear, the auditory canal and the tympanic membrane or eardrum)
- the middle ear (an air-filled space that contains the three small bones of the ossicular chain: the malleus, incus and stapes)
- the inner ear (cochlea, vestibule, and semicircular canals).[1]

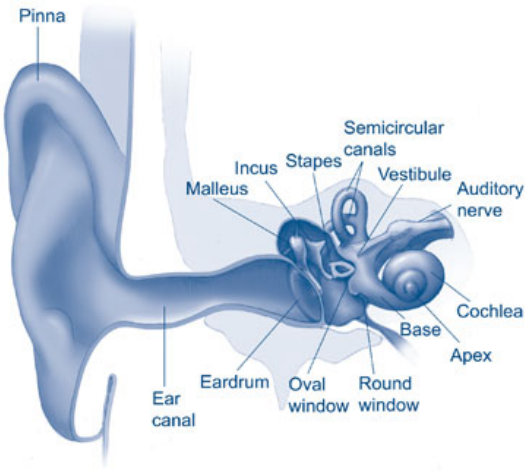


Figure 1. The sound pathway
Credit: The National Institutes of Health. National Institute on Deafness and Other Communication Disorders
http://www.nidcd.nih.gov/health/hearing/noise.html

Hearing begins with the outer ear funneling sound waves towards the middle ear. When the sound waves reach the middle ear, they cause vibrations of the bones of the ossicular chain. These vibrations move cochlear fluid and hair cells within the inner ear, generating electrical signals that are transmitted to the brain via the auditory nerve and interpreted as sound. Sound can be transmitted to the cochlea in two ways: by air conduction (through the auditory or ear canal), and by bone conduction (through the mastoid bones of the skull).

Sound can be described in two ways: by pitch, measured by frequency in Hertz (Hz), and by loudness, measured in decibels (dB).

Hearing loss

Hearing loss is diagnosed using auditory tests that compare the patient's air conduction and bone conduction hearing levels across different frequencies (high and low pitches) and thresholds (decibels).[1,2] The results of these tests plotted graphically comprise an audiogram.

Different agencies and researchers use various hearing thresholds to define the severity of hearing loss.[2-7] The Alberta College of Speech-Language Pathologists and Audiologists (ACSLPA) uses the following categories of hearing loss:

Normal hearing (children)	0-15 dB
Normal hearing (adults)	0-25 dB
Minimal hearing loss (children)	15-25 dB
Mild hearing loss	26-40 dB
Moderate hearing loss	41-55 dB
Moderately-severe hearing loss	56-70 dB
Severe hearing loss	71-90 dB
Profound hearing loss	91+ dB.[8]

The main types of hearing loss are:

- **sensorineural hearing loss (SNHL**) - the most common form of hearing loss.[9,10] It is caused by permanent damage to the hair cells of the cochlea or to the nerve pathway from the inner ear to the brain.
- **conductive hearing loss (CHL)** - which occurs when sound is not conducted efficiently from the external auditory canal to the middle ear.
- **mixed hearing loss (MHL)** - which occurs when both sensorineural and conductive hearing loss are present.
- **central hearing loss** - caused by damage to the central nervous system that affects the processing of auditory signals.

Sometimes, hearing loss is categorized by its cause, for example:

- **age-related hearing loss**, also called presbycusis, is usually caused by sensorineural hearing loss due to gradual damage to the hair cells of the inner ear over time.[9] Approximately 90% of age-related hearing loss is due to sensorineural hearing loss.[11]
- **noise-related hearing loss** is the second most common form of sensorineural hearing loss (after age-related hearing loss).[12] It is caused by occupational or recreational exposure to noise, such as loud music, motorcycles or the use of firearms.

Various medical conditions can also cause hearing loss, for example: congenital atresia that affects the ear canal, otosclerosis, Menière's disease, ear infections, head injuries, accumulated ear wax, and benign or cancerous tumours.[9]

Hearing involves auditory processes that include both the physical structures of the ear and the auditory pathways of the central nervous system. An individual can have normal hearing "sensitivity" (e.g., pure tone audiometry tests are normal), but suffer from hearing loss caused by other conditions.[2] The assessment of hearing loss and treatment incorporates outcomes from both objective (audiological tests) and subjective (patient-derived) reports. The choice of hearing loss treatment will also depend on the level of hearing loss and the structure and health of the middle and inner ears.[13]

The technology

Non-surgical treatments for hearing loss

Drug therapies (e.g., antibiotics or steroids) or alternative therapies (e.g., hyperbaric oxygen) may be used to treat some types of hearing loss. However, these therapies are not effective for sensorineural hearing loss.[14] The main treatment options for this type include external hearing aids and other assistive listening devices.

External hearing aids

External hearing aids that amplify sound are the first line of treatment for most patients. Conventional external hearing aids (referred to as 'hearing aids' in the remainder of this review), use a microphone to collect acoustic energy, which is then processed by an amplifier and transmitted into the external auditory canal to vibrate the eardrum and ossicular chain.

There are many different types, sizes and models of external hearing aids. Selection of an appropriate match for each patient is based on his or her needs, level of manual dexterity, lifestyle, expectations and budget.[5] Differences in hearing aids include the technology (air conduction or bone conduction, analog, programmable analog or digital), and the fit (behind-the-ear (BTE), in-the-ear (ITE), in-the-canal (ITC) and completely in-the-canal (CICs).[5]

Most adults with difficulties hearing have mild-to-moderate hearing loss, many of whom do not use hearing aids. This may be because they consider their hearing loss to be fairly minor or unimportant, feel there is a social stigma associated with their use (e.g., the view of hearing aids as a sign of old age) or have cosmetic concerns about wearing a hearing aid.[15-17] Studies have shown that an individual's perception of the benefit of using a hearing aid affects how much they will use one.[18]

For most patients with mild to moderate hearing loss, external hearing aids provide effective treatment. However, problems related to acoustic feedback, poor or unnatural sound quality (e.g., the sound of their own voice is distorted), discomfort, blockage of the ear canal, inadequate amplification, cleaning and maintenance requirements, and difficulty maintaining the hygiene of the ear canal have resulted in the discontinuation of their use by some patients.[16,19,20] For example, ear wax can build up behind hearing aids, reducing their effectiveness. Therefore, patients may need to have their ears cleaned regularly by a healthcare professional.[21] Other problems have been attributed to inappropriate selection and fitting of hearing aids.[17]

Developments in hearing aid technology have reduced some of the drawbacks. Digital technology has improved the sound quality achieved with external hearing aids. Newer hearing aids are also smaller. Those promoted as "invisible" or "extended wear" in-the-canal hearing aids are completely concealed within the ear canal. One example, the Lyric® invisible hearing aid (Phonak Canada Ltd), is inserted by a trained hearing professional (e.g., an audiologist, hearing aid practitioner or an Ear, Nose and Throat (ENT) physician). The insertion does not involve anesthesia or surgery, and the patient does not need to change batteries or clean the device. Individuals with a Lyric hearing aid wear the device continuously and receive a new hearing aid every three to four months. Visits for replacement procedures can require as little as 15 minutes.[22] A subscription arrangement (for

a one to three year period) includes the cost of replacement devices throughout the subscription. The cost of the Lyric device at one Edmonton hearing aid centre is $3,800 per device per year. (Note: this cost will double for patients who need hearing aids for both ears.) The subscription cost includes the replacement devices and fittings for one year. However, many patients cannot use the Lyric hearing aid because their ear canal is too small to accommodate the device. Also, some patients find the device uncomfortable. The manufacturer plans to introduce smaller devices within the coming year [personal communication: Larena Lewchuk, Audiology Clinic of Northern Alberta, Edmonton, 13 Sept 2011].

The estimated costs of traditional hearing aids in Alberta (other than the Lyric device) range from approximately $1,000 to $3,700 (including fittings). As above, this cost doubles for patients who need hearing aids for both ears. Traditional hearing aids typically last from five to seven years, and require weekly battery changes. Batteries cost approximately $40 per year per hearing aid [personal communication: Larena Lewchuk, Audiology Clinic of Northern Alberta, Edmonton, 13 Sept 2011].

Statistics Canada estimated the costs, in 2003, of additional assistive devices for individuals with hearing loss (not including installation or maintenance costs):

- telephone devices (to improve speech and hearing when using the telephone; $235 to $809)
- assistive listening devices (for example, remote microphones to pick up sounds from concerts, presentations, radio and television; $1,500 to $2,200)
- signaling or alerting devices (that use, for example, light or vibration to signal smoke alarms, doorbells or telephones; $80 to $300).[23]

In a 2005 survey of 730 Canadians with hearing loss, 63% of respondents reported using a telephone device, 47% indicated that they used an assistive listening device, and 29% used a signaling device.[23]A 2006 Statistics Canada survey found that 79.7% of those who reported hearing difficulties used hearing aids.[24]

Nevertheless, some patients do not experience a benefit from such devices. Those with high frequency (noise induced) hearing loss often have difficulty hearing with a hearing aid in the presence of significant background noise (e.g., a crowded restaurant). In other patients, blocking the ear canal with a hearing aid exacerbates conditions such as otitis externa or otitis media. Further, those with malformations of the external ear may find it impossible to wear an external hearing aid. For these patients, middle ear implants offers a possible treatment option.[25]

Surgical treatments for hearing loss

In patients with hearing loss that cannot be corrected with conservative management, surgical options may include BAHA, cochlear implants, and middle ear implants.

Bone-anchored hearing aid (BAHA)

Bone-anchored hearing aids use bone conduction (rather than air conduction) to transmit sound vibrations to the cochlea.[26] The BAHA device consists of a small titanium plate that is implanted into the patient's skull. An external "abutment" is fixed to the implant. The

vibration transducer or hearing aid component attaches to the abutment. The hearing aid detects sound and transmits it as vibratory signals to facilitate bone conducted hearing. The implantation procedure takes approximately 30 to 60 minutes.[7,27] BAHA implantation in adults is usually done as an outpatient procedure under local anesthesia.[27] A two-stage surgical procedure and general anesthesia is used for children.[27] For infants and children between the ages of six weeks and two to five years the bone-anchored hearing aid is held in place by a soft headband, rather than surgically implanted.[28] Before having the implant surgery patients can trial the BAHA to see if it is appropriate by using the device with a headband.

Bone-anchored hearing aids are intended for patients with stable conductive hearing loss or mixed hearing loss provided their bone conduction threshold is ≤65 dB HL.[7,29,29,30] BAHA are also used for some patients with unilateral or bilateral sensorineural hearing loss.[19] However, the most powerful BAHA is only able to provide 10-15 dB of compensation for the sensorineural component of hearing loss.[30,31] Some of the problems reported by BAHA users include discomfort caused by the pressure of the device against the scalp; cosmetic concerns (the external component of the BAHA is visible behind the ear), and poor sound quality due to slight movements of device.[32]

According to Oticon Medical, the Canadian cost of their BAHA devices range from approximately $3,700 to $4,300 [personal communication: Dave Gordey, Oticon Medical, Mississauga, June 9, 2011]. Replacement components for BAHA devices may include approximately 72 batteries every 6 months and a new sound processor every 5 years.[33] The headband used for young children with a BAHA may need to be replaced every year.[33] Batteries cost approximately $1.00 each; sound processors range in price from $2,150 to $4,300, and headbands cost $75.00 each [personal communication: Dave Gordey, Oticon Medical, Mississauga, 17 Nov 2011].

Cochlear implants (CI)

Cochlear implants bypass the damaged cochlear hair cells and directly stimulate the auditory nerve. The implantation procedure takes approximately two hours with the patient under general anesthetic. The implant, itself, consists of an implantable and an external portion. The external component contains a microphone that detects sound and converts it into an electromagnetic signal which is transmitted to the implanted component via magnetic coils. The implanted component then sends an impulse to electrodes placed in the cochlea, which stimulates the auditory nerve. Cochlear implants are typically indicated for patients with profound sensorineural or mixed hearing loss. Patients who receive cochlear implants need rehabilitation to learn how to recognize the sounds transmitted by their devices, as these are not the same as those heard with the normal human ear.

The Canadian cost of the Maestro Cochlear Implant System (Med-El) is $22,850. Surgical and fitting accessories, batteries, and other accessories range in price from $5 to $1,815.[34] One US state government estimated that replacement parts for cochlear implants may include approximately 72 disposable batteries every 6 months, a set of 2 rechargeable batteries each year, a battery charger and assorted other accessories every 3 years, and one headset cochlear coil, magnet and microphone each per year.[33]

Middle ear implants (MEI)

Middle ear implants are semi- or fully-implantable devices that increase sound transmission by vibrating and moving the small bones of the middle ear (the ossicular chain), transmitting sound vibrations to the inner ear. Worldwide, various models of MEI have been in use for over 10 years.[35] Middle ear implants are mainly indicated for moderate to severe sensorineural hearing loss.[35,36] While they may also be used for conductive or mixed hearing loss, they are not considered an option for patients with profound hearing loss (i.e., deafness). In these patients, cochlear implants remain the sole treatment option.[7] Recommendations for MEI include the proviso that, when possible, patients first try appropriately fitted external hearing aids.[35] Other potential MEI users are patients who have not been successfully treated with BAHA.[35] As with most surgical treatments, careful patient selection is needed.[25]

Middle ear implants may appeal to some patients, as they can be left in place while swimming or showering and do not block the ear canal. They may also be preferable for individuals in certain professions (e.g., musicians). Lastly, MEIs offer a possible treatment option for patients with severe sensorineural hearing loss who fall in the so-called "gray area" between hearing aids and cochlear implants (i.e., patients who do not have profound hearing loss and whose hearing loss is not expected to progress to profound hearing loss, but is of a high enough severity that they do not experience benefit from hearing aids).[19]

MEI is associated with surgical risks, such as damage to nerves responsible for facial movement or taste. Further, if a patient experiences problems with their MEI (e.g., feedback or device failure), removal/explantation or revision surgery is required. The Esteem fully implantable device requires surgery that alters the ossicular chain – in effect, damaging the middle ear. If the device is removed, surgery will be needed to replace the incus bone of the ossicular chain with a prosthesis. Some patients experience residual hearing loss after MEI implantation (with both the partially and fully implantable devices).[7,37] It may not be possible to fully restore the patient's previous level of unaided hearing. Patients with MEI cannot undergo magnetic resonance imaging (MRI) scans.[38]

Several companies manufacture MEIs, but not all of these devices are available in Canada.[20,35,39] The two MEIs that are currently available in Canada, and a third MEI that is expected to be available here soon, are described below.

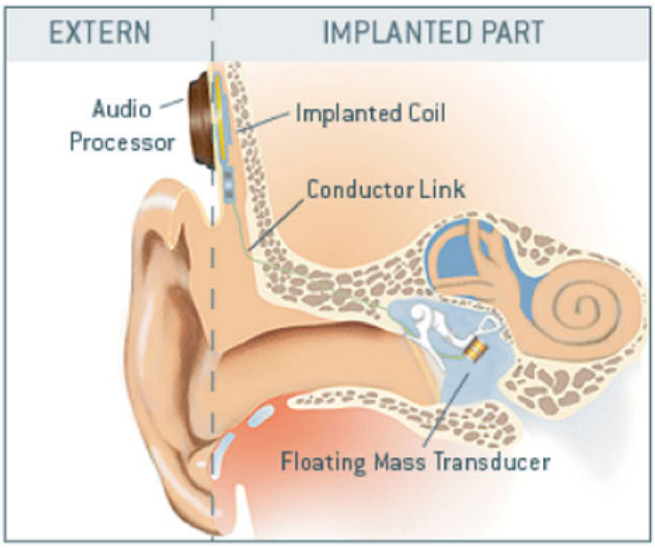
Vibrant Soundbridge® (VSB)

The Vibrant Soundbridge is a partially implantable middle ear implant with both external and implanted components. The external component is the audio processor which consists of a battery, signal processing electronics and a microphone (the most recent model has two microphones).[17] The audio processor is held on the scalp, over the implant, by magnetic attraction. The audio processor collects sound through the microphone, converts it to an electrical signal and sends it to the implanted component – the vibrating ossicular prosthesis (VORP). The VORP contains three units: a receiver which picks up the signals, a conductor which links the receiver to the floating mass transducer (FMT), and the floating mass transducer which causes the ossicular chain in the middle ear to vibrate. The VORP is usually attached to the ossicular chain, but in some patients with abnormal middle ear anatomy devices have been placed on the round window membrane instead.[17]

Initially, the Vibrant Soundbridge was recommended for use in adults with moderate to severe sensorineural hearing loss. The indications have recently been expanded to include conductive and mixed hearing loss. According to the manufacturer, several thousand people, worldwide, have been implanted with the Vibrant Soundbridge hearing system.[17] One author suggests that the Vibrant Soundbridge may be particularly useful for individuals with high frequency sensorineural hearing loss or with a hearing threshold of 70 to 80 dB of hearing loss who cannot be successfully treated with external hearing aids.[35]

The Canadian price for the Vibrant Soundbridge device is $15,000 (not including surgical and other costs). Additional accessories, such as surgical tools and magnets range in price from $55 to $800.[40] Using the device for 12 to 16 hours each day will require patients to change the battery approximately once per week (this can be done by the patient).

Figure 2. Vibrant Soundbridge middle ear implant



Source: Dr. Robert M. Traynor, Audiology Associates

Esteem®

The Esteem device is a totally implantable hearing system. It consists of three components: a sound processor (which is placed under the skin behind the ear) and two piezoelectric transducers called the "driver" and the "sensor". The "sensor" picks up sound vibrations and converts them into electrical signals. The signals are filtered by the sound processor and sent to the driver which causes the stapes to vibrate. The device can be used 24 hours per day. Depending on the level of use, the battery life is estimated to be between 5 to 7 years.[19,41] Battery changes are made during an outpatient surgical procedure under local anesthesia. One disadvantage of the Esteem system is that it requires removal of the incus bone of the ossicular chain, which is replaced by the sensor and driver of the device.[16] This alters the natural anatomy of the ear. If the device fails or the needs to be removed it may not be possible to restore the patient's pre-implant level of hearing. Further surgery to implant a device to replace the incus may be needed to recreate the ossicular chain.[19] The Esteem MEI implantation surgery takes approximately 2.5 to 3 hours, and is performed by a surgeon who has completed extensive training in the procedure.[20] The Esteem system is currently approved for use in Canada in patients with stable moderate to severe SNHL with speech discrimination test scores of ≥ 60%. Implantation is limited to patients with normal

middle ear anatomy. A Canadian price for the Esteem MEI was not available, but the US manufacturer's web site gives an estimated cost of US $30,000 for the device.[42]

Carina™

The Carina is a fully implantable version of its predecessor device, the semi-implantable Middle Ear Transducer (MET). The device is marketed in Europe as the Carina but is sometimes called the fully-implantable MET. It is currently in clinical trials in the United States. The Carina is intended for sensorineural, conductive, and mixed hearing loss (the MET V device is intended for conductive or mixed hearing loss). There are no visible external components - all components are implanted under the skin, including the microphone and the battery. Sounds are picked up by a microphone, amplified and converted into an electrical signal that is then relayed to a transducer attached to the incus. The transducer then translates electrical signals into a mechanical motion that directly stimulates the ossicular chain. To charge the device, a charging coil is placed on the skin, over the implant. The charger can be worn on a belt or waistband. If performed daily, the charging time is about 1 to 1.5 hours. A remote control placed against the skin over the magnet of the implant allows it to be turned on and off, and the volume adjusted as necessary.

Implantation surgery for the Carina requires approximately 2 hours and is performed under general anesthesia. The procedure is similar to that for cochlear implants.[16] Part of the procedure requires drilling a hole in the incus in order to attach the transducer. The microphone is implanted just behind the ear canal, and the skin that covers the microphone is thinned to allow sounds to be picked up through the skin. Patients must wait at least eight weeks after their surgery to allow healing before the device is activated.[16] Contraindications for the Carina implant are patients with chronic middle ear infections, middle ear malformation, inner ear disorders or central hearing loss.[35] The estimated US price of the Carina MEI is approximately US $15,000.[20]

Health Canada approval

Middle ear implants

Two MEIs have received medical device licenses from Health Canada, and another device is in the process of being licensed:

- Vibrant Soundbridge Middle Ear Implant System (Med-El, Innsbruck, Austria) was originally licensed as a product of Symphonix Devices Inc. in 2000.[43] The device was re-licensed in Canada under the current manufacturer, Medical-Electronics (Med-El) in 2007. It is indicated for use in patients who have moderate to severe hearing loss who cannot achieve adequate benefit from traditional therapy [personal communication: Yen Luc, Medical Devices Bureau, Health Canada, Ottawa, 15 Apr 2011]. The US Food and Drug Administration premarket approval for the Vibrant Soundbridge was issued in 2000. The US approval states that the device is indicated for adults (aged 18 years or older) with moderate to severe sensorineural hearing loss, who have first tried "appropriately fit hearing aids". However, in Europe and other countries, the device is also used for the treatment of children.

- Esteem® (Envoy, Saint Paul, Minnesota) has been licensed in Canada since 2008. It is indicated for patients with stable, moderate to severe, sensorineural hearing loss with speech discrimination scores of ≥60% [personal communication: Yen Luc, Medical Devices Bureau, Health Canada, Ottawa, 15 Apr 2011]. The Esteem device received US Food and Drug Administration premarket approval in 2010. The US approval states that the Esteem is indicated for use in adult patients (aged 18 years or older), who have stable, moderate to severe sensorineural hearing loss and unaided speech discrimination scores of ≥40%, normal middle ear anatomy and tympanic membrane, who have first tried conventional hearing aids for at least 30 days.[44]
- Carina® (Otologics, Boulder, Colorado) has not yet received Health Canada licensing. According to the manufacturer, an application is in process and licensing approval is expected within the next few months [personal communication: Alan Franklin, Otologics LLC, Boulder, CO, 7 Apr 2011]. The Carina device does not yet have US Food and Drug Administration approval, but it is available in some countries in Europe, South America and Asia. The company's web site (http://www.otologics.org) states that the Carina is indicated for the treatment of sensorineural, conductive and mixed hearing loss.

Alternative treatments

Several cochlear and BAHA implants have received Health Canada licensing approval, including:

- Clarion Multi-strategy Cochlear Implant System (Advanced Bionics, LLC)
- Cochlear Nuclear Implant Series (Cochlear Limited)
- Cochlear Nucleus Implant System for Children (Cochlear Limited)
- Pulsarci Cochlear Implant System (Med-El)
- BAHA System (Cochlear Bone Anchored Solutions)
- BAHA Divino (Cochlear Bone Anchored Solutions)
- BAHA Intenso (Cochlear Bone Anchored Solutions)

Many different models of traditional hearing aids have been licensed by Health Canada.

Social Systems and Demographics (S)

Burden of illness

Hearing loss generally develops gradually over time, and many individuals delay seeking treatment for years after they first notice some hearing loss.[5,45,46] Often it is the "stigma" – the association between hearing loss and age – that deters people from seeking treatment and from wearing their hearing aids. This may be changing, since the younger generation of seniors (baby boomers) appears to be more accepting of hearing aids.[45] In children, hearing difficulties may affect language skills and development.[7]

Statistics Canada's 2006 Participation and Activity Limitation Survey found that hearing impairment may affect an individual's education in various ways, including the choice of educational and training options, the time required to complete courses, and the level of education attained.[24] One out of five people who reported hearing limitations said that they had discontinued their education because of their condition. People with severe hearing difficulties were much more likely than those with mild hearing impairment (43.5% versus 16.8%) to withdraw from school.[24] The survey responses also indicated that hearing difficulties limited both the type of work and number of hours worked. Many individuals with hearing limitations believed that their condition made it more difficult for them to advance in their career, change jobs, or find work.[24]

A recent Australian study found an association between hearing loss and walking ability. The authors speculated that this may be due to problems with balance caused by hearing problems, together with a fear of falling, and a decline in physical and social involvement.[47] Limited social interactions may also affect the cognitive decline associated with hearing loss.[47]

A systematic review of health-related quality of life in individuals with sensorineural hearing loss and hearing aids concluded that most studies which used a disease-specific quality of life measure (i.e., specific to hearing loss as opposed to generic health measures) found improved emotional and social well-being in hearing aid users.[10] However, findings from studies that used generic quality of life measures varied. Nevertheless, the authors concluded that hearing aids provide a low-risk, relatively non-invasive treatment that improves quality of life by reducing "psychological, social and emotional effects of SNHL".[10] A systematic review of bone-anchored hearing aids found similar differences in quality of life reported by studies that used generic versus disease-specific measures.[26]

Little information is available on the economic burden of illness caused by hearing loss, and no recent Canadian information was found. A 1989 study of the costs of workers' compensation claims for noise-induced hearing loss in Alberta reported that 450 claims were submitted in the 1987 at a cost-per-claim of $14,106.[48] The authors estimated that if 80% of these claims were accepted, the cost to the Workers' Compensation Board would be $5,373,360. They also noted a substantial increase in noise-related hearing loss claims over a five year period (1979 to 1983).[48]

A US study, published in 2000, on the costs of severe-to-profound hearing loss concluded that direct and indirect costs (including medical, non-medical, educational and lost productivity costs) amounted to an average lifetime cost per individual of US $297,000.[49] Total costs varied depending on when the hearing loss began. Costs for individuals with pre-lingual onset of hearing loss exceeded US $1 million, whereas costs for those with severe-to-profound hearing loss acquired later in life averaged US $43,000.[49]

A more recent US study, on age-related hearing loss, estimated direct medical costs and lost productivity costs using national, state and city data for 2002 and projected costs for 2030. In 2002, lost productivity costs due to age-related hearing loss were approximately $1.4 billion at the national level; this was estimated to reach $9 billion by the year 2030.[50] Medical costs associated with the first year of treatment for Americans with hearing loss aged 65 and older were estimated at $1,292 per person, or $8.2 billion nationally.[50]

Prevalence and incidence

The Canadian Hearing Instrument Practitioners Society estimates that over 3 million Canadians, or approximately 10% of the population, have some level of hearing loss.[5] The prevalence of hearing loss increases with age.[1,4,51] It is considered one of the most common, chronic conditions in elderly populations.[47] The 2003 Canadian Community Health Survey found that approximately 3% of Canadians over the age of 12 experienced some level of difficulty related to hearing.[52] Canada-wide, the survey found that 11% of seniors experienced hearing difficulties. Alberta had a slightly higher prevalence, with 13% of seniors reporting hearing problems. Across the country, approximately 5% of those in the 65 to 69 years of age group reported problems hearing. This number his increased to 23% in those over the age of 80.[52] However, the Canadian Community Health Survey is based on self-reports, which may give lower prevalence rates than would be found if objective hearing tests were used.[53] In addition, many people are unaware or unwilling to admit that their hearing is impaired, further indicating that these survey results are likely an underestimate of the actual prevalence of hearing loss in Canada.[52] More recently, higher prevalence rates were reported in a Canadian Institutes of Health Research team grant, which cites a prevalence of age-related hearing loss in Canadians as 20% for those over the age of 65, and 40% for those over the age of 75.[51] No information was found on the prevalence of different types of hearing loss in Canadian adults.

European studies report slightly higher estimates of the prevalence of age-related hearing loss. A recent systematic review estimated that 30% of European men, and 20% of European women over the age of 70, had age-related hearing loss (of 30dB HL or more in their better ear), and by the age of 80, this increased to 55% of men and 45% of women.[54] In the US, one study found a prevalence rate of hearing loss (of 25dB HL or more) of 63% in US adults over the age of 70.[55] Inconsistencies in the definitions of hearing loss, ear (better ear or worse ear) in which the hearing level is measured, and the age ranges used to distinguish age-related hearing exist across the few available studies on adult onset hearing loss, making it difficult to determine the prevalence of hearing loss more precisely.[54,55]

In children, the prevalence of sensorineural hearing loss (>40 dB) is estimated to be 1 in 1,000 live births.[51] Children seem to be developing noise-induced hearing loss at increasing rates, possibly due to the use of musical instruments, audio equipment, fireworks, toy guns and telephones.[1]

Conductive hearing loss in children may be caused by congenital conditions or chronic ear infections.[28] One European study estimated that the incidence of conductive hearing loss caused by congenital atresia (narrowing or closure of the ear canal) is approximately one in 10,000 live births.[56] Of individuals with congenital atresia, about 25% have this condition in both ears.[56]

Risk factors

Risk factors for hearing loss include age, heredity, occupational or other exposure to loud noise, chronic middle ear infections, and exposure to certain drugs (including some prescription drugs often used by older adults, for example, some types of diuretics, antibiotics and anti-inflammatory agents.[57] Lifestyle factors, such as smoking, also affect hearing. A recent US study found an association between obesity and hearing loss in older women, though not in men.[53] Other health conditions, such as cardiovascular diseases and diabetes (possibly due to associated vascular damage), rheumatic and autoimmune diseases also increase the risk for hearing loss.[53,58,59]

Men experience hearing loss at higher rates than women, probably due to occupational exposures.[18,52] Socioeconomic factors do not appear to affect hearing loss, but greater social support, and higher levels of income and education were associated with an increased use of hearing aids.[18,52]

Risk factors for hearing loss in early childhood include genetic disorders, congenital atresia, intrauterine infections, preterm birth, and meningitis. Middle ear infections are common in infancy and these can also cause hearing loss.[28,51]

The 2006 Statistics Canada Participation and Activity Limitation Survey found that most Canadians who reported hearing limitations (including complete deafness and varying levels of hearing loss) also reported at least one other limitation.[18,24] The most common coexisting limitations reported were mobility, pain, agility, vision, memory and communication. A UK systematic review found that approximately 40% of people with hearing impairment also had other health problems, such as tinnitus and balance disorders, which put them at greater risk for falls and associated injuries.[46] A recent Canadian study found a "close relationship between hearing status and overall physical health, a finding which has been previously reported, but [which] remains poorly understood."[18]

Patterns of care

The type and severity of hearing loss and the level of impairment that it imposes on the individual must be weighed when determining the most appropriate treatment option. The individual patient's psychological and physical ability to adapt to and comply with the treatment is another consideration. Each patient's needs, expectations and capabilities will differ. The features and capacities of the many different devices will also be factored into the selection of treatment. When hearing loss is over 40 dB in both ears, active treatment may be recommended.[60] Traditional external hearing aids are typically the first treatment option for individuals with mild to moderate hearing loss.[19]

Sensorineural hearing loss

Sensorineural hearing loss is permanent and cannot be treated with drugs or repaired with surgery. The main treatment options are external hearing aids and assistive listening devices.

For patients with moderate to severe sensorineural hearing loss who cannot use hearing aids, BAHA, MEI or cochlear implants may be options. For patients with profound sensorineural hearing loss, cochlear implants are the only option.

Conductive hearing loss
Treatments for conductive hearing loss also include external hearing aids, BAHA or MEI. Surgery may be used for some types of conductive hearing loss.

Mixed hearing loss
Mixed hearing loss may be treated with external hearing aids, BAHA or MEI.[13] Profound mixed hearing loss may be treated with a cochlear implant.[61]

Social, legal and ethical issues

Health care delivery changes may be required to accommodate the needs of a growing number of patients with hearing loss. This includes legal issues regarding the rights of patients to receive health service interpretation services when necessary. For deaf patients, this includes the provision of sign language interpreters, but the broader interpretation is that "effective communication is quite obviously an integral part of the provision of medical services."[62]

One issue is whether an implanted MEI is suitable for a patient with hearing loss that continues to deteriorate.[20] This may be of particular concern for patients who receive totally implantable devices, since the surgical procedure for these is more complex - involving surgical alteration to the middle ear which requires surgical repair if the MEI is removed. Another concern with the Esteem totally implantable MEI is the need for surgery whenever battery changes are required (approximately every 5 to 7 years).[19,20]

Population dynamics

Younger Canadians (30 to 40 year olds) appear to be experiencing hearing loss in greater numbers.[63] Aging is a major risk factor for hearing loss.[24] Alberta's population is considered a "young" population (with a median age of 36 in 2010), but proportionately, the number of seniors in the population will likely increase as the younger population declines. In 2010, there were an estimated 396,200 seniors in Alberta (10.6% of the population). This is expected to increase to between 1.3 to 1.6 million (21.6 to 26.2% of the population) by the year 2050.[64] As the population ages, more Albertans may experience hearing loss in the future. A recent UK review estimated that their aging population will result in a 10 to 15% increase in the number of people with hearing loss over the next 15 years.[46]

Access to MEI and alternative treatments in Alberta

The cost of hearing aids can be a barrier for some individuals.[4] Hearing aids and associated costs may be partially or fully covered through programs for special populations (e.g., Veterans Affairs Canada, First Nations and Inuit Health Non-Insured Health Benefits, workers' compensation (for hearing loss due to occupational noise exposure), or through provincial programs for low income and senior citizens.[5,65,66] However, one US study found that even with partial subsidization of hearing aids, the costs of these devices still prevented

many people from obtaining this technology. Individuals with full insurance coverage were more likely to acquire hearing aids and they did so at an earlier stage of hearing loss.[15]

A Canadian study that investigated the prevalence of hearing impairment and hearing aid use found that individuals in rural areas reported a lower rate of both.[18] Difficulties in accessing hearing services may be a barrier for some rural Albertans.

The Alberta Aids to Daily Living (AADL) funds hearing aids on a cost-share basis for children (under the age of 18), full time post-secondary students (aged 18 to 24), and seniors (over the age of 65). With the cost-share patients pay 25% of the cost to a maximum of $500 per family per year.[5,65] The cost-share portion may be covered for Albertans with low-incomes.[67] With some exceptions, the program covers two hearing aids every 5 years for eligible individuals. It does not cover additional costs for upgraded hearing aids (above AADL's funding limit).[67]

Although there is a shortage of audiologists in Alberta and across Canada, the wait time to see an Audiologist is not significant (approximately two weeks), and the wait time is even less (perhaps even same-day) for appointments with Hearing Aid Practitioners. However, the wait time to see an otolaryngologist may be up to a year for non-emergency cases or about two months for urgent referrals [personal communication: Larena Lewchuk, Audiology Clinic of Northern Alberta, Edmonton, October 5, 2011].

Hearing aids are available throughout Alberta. The Alberta Aids to Daily Living program lists approximately 140 privately owned hearing aid vendors across the province.[68] Albertans pay out-of-pocket for hearing aids - unless they qualify under one of the special programs mentioned above, or have extended health insurance.

Both BAHA and cochlear implants are publicly funded in Alberta through Alberta Health Services.[69,70] The Institute for Reconstructive Sciences in Medicine (iRSM), at the Misericordia Hospital, in Edmonton (a collaboration between Covenant Health and Alberta Health Services), provides BAHA services to patients in Alberta and elsewhere in western Canada [personal communication: Kathy Packford, Glenrose Rehabilitation Hospital, Edmonton, 15 Nov 2011]. In Calgary, pediatric BAHA surgeries are performed at the Alberta Children's Hospital, and adult BAHA surgeries are performed at the Foothills Hospital [personal communication: Jillian Ingratta, Alberta Health Services, Richmond Road Diagnostic and Treatment Centre, Calgary, 16 Nov 2011].

Cochlear implant services in Edmonton are provided at the Glenrose Rehabilitation Hospital (for both adult and pediatric patients). In Calgary, adult cochlear implant surgeries are provided at the Foothills Hospital, and the pre- and post-assessment services for cochlear implants are offered at the Richmond Road Diagnostic and Treatment Centre [personal communication: Jillian Ingratta, Alberta Health Services, Richmond Road Diagnostic and Treatment Centre, Calgary, 15 Nov 2011]. Pediatric cochlear implants in Calgary are provided at the Alberta Children's Hospital.

At present, MEI are not publicly funded or available in Alberta, but they are provided at centres in Ontario (at the London Health Sciences Centre, Sunnybrook Health Sciences Centre, Ottawa Hospital and Children's Hospital of Eastern Ontario), Quebec (Centre Hospitalier Universitaire de Québec), Nova Scotia (Capital Health / Nova Scotia Hearing

and Speech Centre) and Newfoundland (Eastern Health) [personal communication: Ray Gamble, Med El, Innsbruck, Austria, 13 Jun 2011]. At 3 of these centres, a total of 15 MEIs have been implanted (in 8 patients in Nova Scotia, 5 patients at the Ottawa Hospital, and 2 at the Sunnybrook Health Sciences Centre)[personal communication: Kathy Packford, Glenrose Rehabilitation Hospital, Edmonton, 15 Nov 2011; personal communication: David Shipp, Sunnybrook Health Sciences Centre, Toronto, 21 Nov 2011].

Diffusion and demand

One Canadian manufacturer estimates that over 275,000 hearing aids are sold in Canada each year.[63] Studies indicate that people with hearing loss who use hearing aids are happier and healthier than those who do not, but, many people who could benefit from a hearing aid do not use one, or use it for only brief periods of the day.[17,71] The US MarkeTrak survey of consumer satisfaction with hearing aids found that over 12% of those with hearing aids did not use them (the "hearing aid in the drawer" problem); though non-use decreased to just over 7% in those with newer models of hearing aids.[72] Most users (over 80%) indicated overall satisfaction with their hearing aids.[72] Regarding sound quality, over 70% of those surveyed were satisfied with their hearing aid in terms of clarity of tone and sound, the sound of their own voice, and the directionality and naturalness of the sound. They were less satisfied with whistling, feedback, the ability to hear soft or loud sounds, and hearing in noisy settings.[72]

The 2003 Canadian Community Health Survey found that only 3% of seniors with hearing difficulties report uncorrected hearing problems (i.e., not corrected or not able to be corrected).[52] The rate of uncorrected hearing was higher in those over the age of 80.

Middle ear implants are significantly more expensive than external hearing aids and involve a technically difficult surgical procedure – as a result they may not appeal to many patients.[19] One US physician speculated that the market for MEIs will increase substantially as people become more aware of this treatment option.[20] However, no evidence indicating a considerable patient demand for MEI was identified in the published literature.

A 2002 chart review of 45,350 German patients with sensorineural hearing loss found that, based on pure tone audiograms, only 346 patients (0.76%) would be considered possible candidates for a middle ear implant. Of the 220 patients who could be contacted in follow-up, most were not interested in receiving an implant (their reasons included satisfaction with their existing hearing aid, anxiety about the surgery involved, or wanting to wait for further improvements to the technology).[25] Other patients were deemed ineligible when additional clinical and psychological tests were applied. Ultimately, only 42 patients (0.09% of the total study population) were considered good candidates for middle ear implants. The authors also observed that their patients' main concerns were audiological, rather than cosmetic or financial.[25]

Another German study of potential MEI candidates, this one using a database of 850 patients with mixed hearing loss who had undergone previous middle ear surgery, found that only 2.4% both met the audiological criteria for MEI and were interested in receiving an implant.[35]

Alberta Health Services data show that the number of cochlear implants provided to Alberta patients (adults and children) doubled over the 5-year period from 2006-2007 to 2010-2011. Over this period 219 adults and 200 children received cochlear implants [personal communication: Tanis Howarth and Jillian Ingratta, Alberta Health Services, 26 Jul 2011].

Based on Alberta Health and Wellness administrative data, 184 BAHA devices were implanted in Alberta patients in 2008, and 183 BAHA devices were implanted in 2007. Alberta Aids to Daily Living (AADL) covered 35 replacement BAHA processors and 18 replacement cochlear implant processors in 2010-2011. Note that AADL only covers Albertans who meet certain age or income requirements, and they do not cover the initial costs of cochlear or BAHA devices – only the replacement processors. Funding for replacement processors varies depending on the obsolescence programs offered by individual manufacturers. Total AADL funding for cochlear implant replacements in 2010-2011 was $63,490.00; BAHA replacement funding was $246,413.21. During this period the total funding for traditional hearing aids covered by AADL was $12,241,334.83 [personal communication: Patti-Jo Sullivan, Alberta Aids to Daily Living, Edmonton, 3 Sept 2011]. Alberta Aids to Daily Living has not received any requests for MEI devices, nor have they assessed this technology [personal communication: Patti-Jo Sullivan, Alberta Aids to Daily Living, Edmonton, 14 Nov 2011].

New developments

Conventional hearing aid technology continues to improve. Developments include increasingly smaller and less visible models of the devices, and open fit devices that do not block the ear canal.[72] Individuals with newer models of hearing aids (e.g., digital rather than the older analog models) have reported greater satisfaction and use of their hearing aids than those reported in previous surveys.[18,72]

A clinical trial of the Vibrant Soundbridge MEI, now underway in the US, is investigating the effectiveness of placing the floating mass transducer in the round window of the middle ear, rather than attaching it to the ossicular chain, as a treatment for mixed and conductive hearing loss.[73] Other early studies have investigated further variations on attaching the transducer to other structures indicating that MEI technology is still developing. It is possible that new groups of patients, such as those who have undergone previous middle ear surgery, may be candidates for MEI in future.[35,74]

Health system capacity

Workforce & infrastructural capacity

Otolaryngologists, or **Ear, Nose and Throat (ENT) Specialist**s are physicians with several years of specialist training.[75] They may focus on a particular sub-specialty area, such as hearing. Their scope of practice includes hearing assessment, diagnosis and treatment. An otolaryngologist may perform surgical procedures, including those associated with middle ear, BAHA and cochlear implants.

Alberta has two centres for Otolaryngology - Head and Neck Surgery - at the University of Alberta Hospital, in Edmonton, and at the University of Calgary, Foothills Medical Centre,

in Calgary.[75] Although there are currently 70 physicians in Alberta with the specialty of Otolaryngology - Head and Neck Surgery, only four of these (three in Edmonton and one in Calgary) have indicated a sub-specialty of hearing.[76]

Audiologists are health care professionals with graduate level university training in diseases of the ear and auditory system. They may perform hearing tests and prescribe hearing aids as appropriate. They may also fit hearing aids or refer this to a Hearing Aid Practitioner. A master's degree program in audiology is offered at several Canadian universities but none of these are in Alberta. In the US a doctorate of audiology degree is now required. A doctorate of audiology program may be offered in Canada soon.[77] Audiologists in Alberta are regulated under the *Health Professions Act* by the Alberta College of Speech-Language Pathologists and Audiologists (ACSLPA).[78,79] In 2008, 183 Audiologists were registered in Alberta.[80]

A **Hearing Aid Practitioner** has usually completed a two-year course of study. Grant MacEwan University, in Edmonton, offers a Hearing Aid Practitioner Program.[81] In Canada, as with audiologists, their scope of practice is defined by each province.[5] Hearing Aid Practitioners in Alberta are also regulated under the *Health Professions Act* by The College of Hearing Aid Practitioners of Alberta.[81] According to the College, the scope of practice for Hearing Aid Practitioners in Alberta includes: administering hearing tests, prescribing and fitting hearing aids, checking hearing aid fittings, recommendation of assistive listening devices, and instructing and counseling patients and their families to ensure the proper use of hearing aids.[82]

Although their qualifications differ considerably, the scopes of practice of Audiologist and Hearing Aid Practitioner overlap in Alberta. In particular, both professions can administer hearing tests, prescribe and fit hearing aids. Both health care professions may be working in either private clinics or through publicly funded Alberta Health Services.[67]

A UK guideline on BAHA for children and young adults specifies that providing this service requires a multidisciplinary team. The team should include an audiologist (for hearing and behavioural assessments); an otolaryngologist (for surgical and clinical care), a speech and language therapist (for language assessment and communication rehabilitation), and an ENT nurse specialist or nurse practitioner, who should be a qualified children's nurse (to provide the link between the family and other health care professionals). Also included on the multidisciplinary team are administrative staff and a "key (link)" worker - the main contact for the family who ensures continuity of patient care.[28] The guideline also recommends that the provision of bone-anchored hearing aids for children should be offered in a pediatric hospital or centre.[28] A 2006 Quebec assessment on bone-anchored hearing aids also emphasized the need for a multidisciplinary team that would include: at least one otolaryngologist, an audiologist, and for children a pediatric anesthesiologist and a speech-language pathologist should be included.[83] This assessment recommended that centres providing BAHA should perform at least fifteen cases per year.[83] The UK National Institute for Health and Clinical Excellence also stressed the need for a multidisciplinary healthcare team in their guidance on cochlear implants.[84] The head of the Canadian Hearing Society, recently noted the need for a "well-defined" link between the otolaryngologist who implants MEI and the audiologist who subsequently programs it.[20]

Middle ear implant surgery is technically challenging, particularly for the fully implantable devices, and there will be a learning curve as the surgeon acquires the special training

needed.[85] The surgical procedure for MEI and that for BAHA are very different (the BAHA procedure mainly involves the scalp and takes approximately 40 minutes, whereas the MEI mainly involves the middle ear mastoid and takes approximately 2.5 hours), each with distinct technical challenges [personal communication: Dr. Allan Ho, Covenant Health, Alberta Health Services]. The surgical procedure for MEI is similar to that for cochlear implants, although MEI surgery is more technically difficult due to the wider facial recess approach and the technical difficulties clipping the MEI to the ossicle [personal communication: Dr. Allan Ho, Covenant Health, Alberta Health Services, 6 Dec 2011]. A cochlear implant surgeon has the expertise to be able to perform MEI surgery, but will still need appropriate additional training. Accordingly, existing international MEI programs are typically associated with cochlear implant programs [personal communication: Cathy Creaser, Med El, Innsbruck, Austria, 16 Nov 2011]. In order to perform MEI, a surgical centre will not require any additional equipment, with the exception of specialized insertion kits, which are provided by the implant manufacturer at no cost [personal communication: Dr. Allan Ho, Covenant Health, Alberta Health Services, 6 Dec 2011].

Methodology

Technology effects & effectiveness

A systematic review of evidence from existing research on the safety and efficacy of middle ear implants was performed using well-accepted review methods.

Search for relevant studies

A search was conducted for published and unpublished studies of middle ear implants, bone-anchored hearing aids and cochlear implants in the international literature before September 2011. Search terms included controlled vocabulary terms such as MEDLINE's Medical Subject Headings (MeSH), in combination with additional terms. Two separate search strategies were run – one for middle ear implants and bone-anchored hearing aids, and the other for cochlear implants. The literature search for cochlear implants was based on the search strategy used by a 2009 UK technology assessment.[86] Based on an initial screening search of middle ear implants which identified several comparative studies to traditional hearing aids, a separate search for hearing aids was deemed unnecessary. The clinical searches were run in major biomedical bibliographic databases, including: MEDLINE, EMBASE, The Cochrane Library, Web of Science, CINAHL, PsycINFO and the Centre for Reviews and Dissemination, without date or language limits. Details of the search strategy are shown in Appendix A.

Unpublished and non-peer-reviewed literature was located through Internet searches and included manufacturer and association web sites. This search focused on middle ear implants. For completeness, the electronic search was supplemented with a manual search of the reference lists from included articles, recent health technology assessments and systematic reviews.

Selection of relevant studies

Results of the electronic and manual search were imported into a bibliographic software program (Reference Manager®). After removing duplicate entries, citations were reviewed for possible inclusion by two independent reviewers. First, titles and abstracts (where available) were screened. Secondly, full manuscripts for those articles deemed to be potentially relevant were retrieved and assessed using a pre-defined set of inclusion/exclusion criteria. Separate criteria were applied to studies of middle ear implants (Table 1) than comparator technologies (Table 2). Any discrepancy between reviewers was resolved through discussion. The level of consensus between reviewers was assessed for the second stage using kappa statistics. Kappa values were 0.90, 0.84, and 0.82 for middle ear implants, BAHA and cochlear implants respectively.

Table 1. Criteria for review protocol for Middle Ear Implants

Parameter	Inclusion Criteria	Exclusion Criteria
General	English abstracts or articles	None
Participants	Adults & children diagnosed with sensorineural, conductive or mixed hearing loss	None
Intervention	Middle ear implants (MEI): Esteem® fully implantable hearing device, Carina™ fully implantable hearing device, and Vibrant Soundbridge® semi-implantable hearing device	None

Comparator	Traditional hearing aids Bone-anchored hearing aids (BAHA) Cochlear implants (CI) No auditory support None	None
Outcomes	Any clinical outcome, including (but not restricted to): functional gain, hearing thresholds, speech reception, speech recognition, Abbreviated Profile of Hearing Aid Benefit (APHAB), self-assessment scales/patient preference, adverse events/complications	Studies without any defined clinical outcomes
Study Design	RCTs or quasi-RCTs Non-randomized controlled trials Single-arm trials Cohort studies (retrospective or prospective) Case-series and case reports Pre-surgery/post-surgery* After surgery with/without‡	Editorials and opinion pieces Case reports of the Vibrant Soundbridge

Table 2. Criteria for review protocol for BAHA and Cochlear Implants

Parameter	Inclusion Criteria	Exclusion Criteria
General	Publication date 2007-present Full-text article in English	None
Participants	Adults & children diagnosed with sensorineural, conductive or mixed hearing loss	Studies with infants (<2 years) only
Intervention	Cochlear implants Bone-anchored hearing aids	Non-implanted devices Bilateral implants only Hybrid devices
Comparator	Traditional hearing aids Bone-anchored hearing aids (BAHA) Cochlear implants (CI) Middle ear implants No auditory support	Non-comparative studies other than prospective studies reporting adverse events
Outcomes	Any clinical outcome, including (but not restricted to): functional gain, hearing thresholds, speech reception, speech recognition, Abbreviated Profile of Hearing Aid Benefit (APHAB), self-assessment scales/patient preference, adverse events/complications	Studies without any defined clinical outcomes
Study Design	RCTs or quasi-RCTs Non-randomized controlled trials Single-arm trials Cohort studies (retrospective or prospective) Pre-surgery/post-surgery* After surgery with/without‡	Editorials and opinion pieces Case series or case reports Cross sectional studies

* Retrospective or prospective comparison of pre-operative hearing assessments to post-operative assessments

‡ In studies of patients with existing implants, a comparison of hearing assessments preformed with and without the device in use

Synthesis and critical appraisal of selected studies

Information from studies was systematically extracted by one of two reviewers using a standard, pre-tested data abstraction form. The form contained elements for assessing the population, study design, methods and findings of each study (Table 3 and Appendix F). Additionally, the quality of each study was assessed using the Oxford Centre for Evidence-Based Medicine Levels of Evidence (Table 4). When required, missing data was sought from the study's author. Agreement between the two reviewers was then verified by a third party who extracted data from a random sample of studies, representing 10% of the total number.

Consensus between reviewers was assessed using the Kappa statistic and with perfect agreement (K=1.0).

Table 3. Summary of data abstraction form elements

Parameter	Description of information collected
Study design	study type, setting, length of follow-up, comparison group
Patients	number, age, gender, severity of hearing loss, eligibility for alternate treatments
Intervention	device type used, modifications in surgical technique
Outcomes	functional gain, threshold levels, speech reception thresholds, speech recognition scores, quality of life, adverse events
Study quality	Oxford Levels of Evidence

Table 4. Oxford Centre for Evidence-based Medicine Levels of Evidence

Level	Therapy / Prevention / Aetiology / Harm
1a	Systematic review (with homogeneity) of RCTs
1b	Individual RCT (with narrow Confidence Interval)
1c	All or none
2a	Systematic review (with homogeneity) of cohort studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)
2c	"Outcomes" research; ecological studies
3a	Systematic review (with homogeneity) of case-control studies
3b	Individual case-control study
4	Case-series (and poor quality cohort and case-control studies)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

See the Oxford Centre for Evidence-based Medicine web site for further explanations. Available: http://www.cebm.net/index.aspx?o=1025

Measures of effectiveness

Functional gain

Functional gain constitutes a measure of the benefit derived from the hearing device which is calculated by determining the difference between soundfield thresholds with and without the device.[87] In studies where functional gain was not reported but threshold levels were provided, gain was calculated by subtracting the post-operative aided threshold from the pre-operative unaided threshold value. When calculated, it was based on mean values at all reported frequency levels.

Some studies report functional gain stratified by frequency level, where higher frequencies represent higher pitched sounds. There may be differences in gain achieved with a hearing device across the frequencies used for audiometric testing. This may be due to the individuals hearing characteristics (ex: worse hearing at high frequencies vs low frequencies) or characteristics of the device (ex: hearing aids may be programmed to provide higher gain at certain frequencies). However, no frequencies within the range provided though audiometric tests are considered to be more clinically significant than others.

Speech reception

Can be determined in quiet and in background noise in a variety of ways, including:

- Speech reception threshold (SRT): the softest decibel level at which a person can detect sound
- Speech reception threshold 50% (SRT50): the softest decibel level at which a person can correctly identify 50% of words
- Signal to noise ratio (SNR): the softest decibel level at which a person can detect sound as a function of the amount of background noise presented

Speech recognition
Represents the percentage of words correctly identified when presented at a specified decibel level.

Quality of life
Quality of life may be measured in a variety of ways, both quantitatively and qualitatively. This report includes all reported outcome measures pertaining to quality of life. The most commonly used is the Abbreviated Profile of Hearing Aid Benefit (APHAB) which scores either the benefit derived from a hearing device, or difficulty experienced, in four subcategories:
- Ease of Communication (EC): communication in relatively favourable conditions
- Background Noise (BN): communication in settings with high levels of background noise
- Aversiveness (AV): the unpleasantness of environmental sounds
- Reverberation (RV): communication in reverberant settings.

Data analysis

Information collected from studies was summarized in tabular form to more easily identify trends and patterns in results across studies. Where results at multiple time-points were presented, the value representing the greatest number of patients was used. In cases where the number of patients was consistent, the outcome with the longest duration of follow-up was reported. The data were reviewed for potential meta-analysis.

Economic considerations

Review of economic studies

A search for economic analyses of MEI was conducted following methods similar to those described for the systematic review of clinical effectiveness. A structured search strategy, which combined relevant terms such as 'cost', 'cost effectiveness', 'financial', 'budget', and 'economic' with those used to identify clinical studies, was applied to several electronic bibliographic databases of peer-reviewed papers/studies. The databases included PubMed (MEDLINE and non-MEDLINE), The Cochrane Library, EMBASE, the UK Centre for Reviews and Dissemination databases (DARE, HTA and NHS EED), CINAHL, PsycINFO, Web of Science, and EconLit. No publication date or language limits were placed on the search. In addition to the electronic search, the reference lists of retrieved papers were hand searched. To identify unpublished studies or 'grey' literature, web-based searches using the 'Google' Internet engine were conducted.

Two researchers independently assessed the titles and abstracts of potentially relevant citations for inclusion in the review. All economic analyses that discussed MEI were selected. Information from included studies was extracted by two independent researchers

using a standard data abstraction form. In addition, the quality of each study was critically appraised using published guidelines for the assessment of economic evaluations.[88]

Decision model

According to advice received from members of the Expert Advisory Group (EAG) and findings from the systematic review of clinical effectiveness, candidates for MEI represent patients who 1) are ineligible for BAHA or cochlear implants or 2) have failed treatment with conventional hearing aids. Since there are no alternative treatment options for these patients, the introduction of MEI into the healthcare system would represent an 'add-on' service, rather than a replacement for existing ones. Therefore, a decision tree or clinical pathway was first constructed (TreeAge Pro®) using findings from the effectiveness review and input from the EAG to demonstrate the probability of a patient experiencing each event (Figure 4). Probabilities of 'events' were obtained from the literature and administrative data provided by Alberta Health and Wellness (Table 8). These probabilities were sent out for review by the EAG. Consensus among the EAG members on the probabilities was achieved. Consequently, a sensitivity analysis varying individual probability estimates was not performed. Further, because agreement among EAG members on the number of potential candidates for MEI in Alberta was also reached, the decision tree was not used to derive the number of patients who would experience each event.

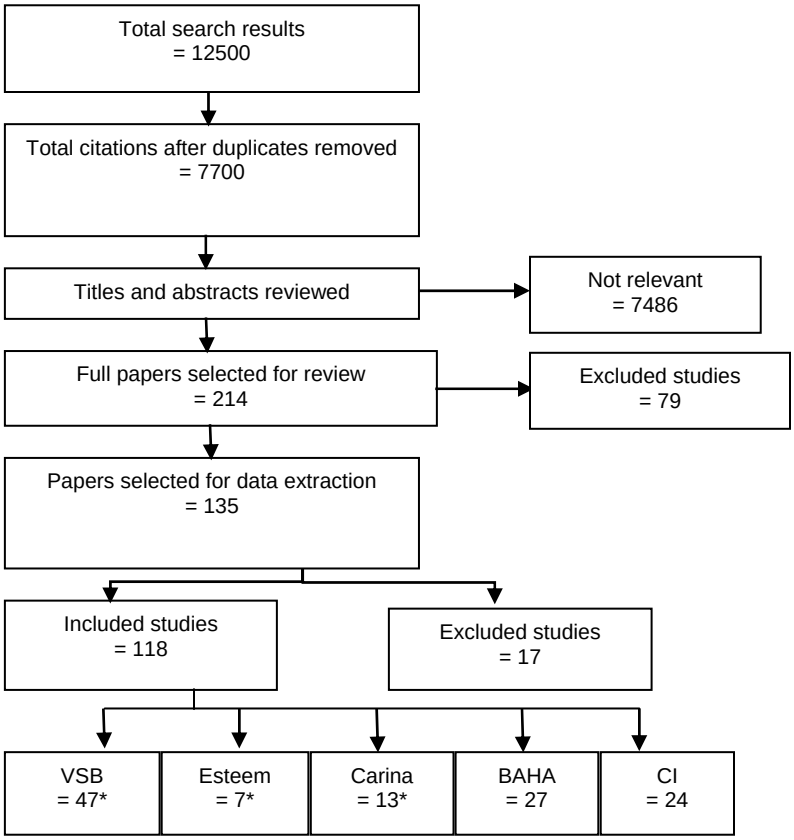
Budget impact analysis

The cost per case of MEI in Alberta was estimated under 2 different scenarios and a 5 year time horizon: 1) Using billing data from Alberta Health and Wellness and information from the clinical review and the Calgary and Glenrose Cochlear Implant Services (Alberta Health Services) and 2) Using the Alberta Health Services Operational and Financial Impact Analysis (OFIA) for Middle Ear Implants. The number of potential candidates for MEI in Alberta was determined through discussion with the Expert Advisory Group.

Technology Effects and Effectiveness (T)

The results of the literature search are shown below.

Figure 3. Literature search results & study selection for clinical review



* includes comparative studies to hearing aids

Seventy-seven hundred discrete citations were initially identified through the literature search and 214 potentially relevant articles were selected for full review (Figure 3). Of these, 47 articles (44 studies) of the Vibrant Soundbridge, 7 articles (6 studies) for the Esteem System, and 13 articles (11 studies) for the Carina Middle Ear Implant met the inclusion criteria and were, therefore, included in the review. Additionally, 27 articles (26 studies) for BAHA and 24 articles (22 studies) on cochlear implants met the inclusion criteria for the review of comparator technologies. The included studies are summarized in Appendix B. The excluded studies and reasons for their exclusion are summarized in Appendix C.

Overall description of included studies

Middle ear implants

The review of the Vibrant Soundbridge (VSB), Esteem, and Carina middle ear implants included 60 studies representing a total of 1009 patients. Except for one study reporting solely on adverse events,[89] all studies were comparative. The vast majority of studies used patients as their own controls, with only 6/61 studies employing a separate comparator

group. However, in four of these studies, the comparator groups were not useable because they comprised patients with excluded devices or normal hearing. Middle ear implants were most often compared to preoperative and postoperative unaided conditions, and traditional hearing aids. Additionally, MEIs were compared to each other, ossicular replacement prostheses, and cochlear implants (single study). There was some heterogeneity in the implantation method across studies, with the most common alternative to the traditional ossicular chain placement being placement on the round window membrane.

The VSB was investigated in 44 studies, representing 832 patients in 10 countries. The majority were European. Outside of Europe, three studies took place in the United States. No Canadian studies were found. Seven of the studies involved multiple centres, and approximately half employed a pre/post study design where a subject's performance prior to surgery was compared to that after implantation with the device. In the studies that reported patient demographics, patients ranged from 3 months to 86 years old and there were an equal number of males and females. The majority of studies were of adults patients only. However, three included both adults and children. Half of the studies included patients with sensorineural hearing loss. A small number reported on mixed and conductive hearing loss. The severity of hearing loss ranged from mild to severe, with mean preoperative air conduction threshold levels in the range of 40-80dB.

The Esteem Hearing System was investigated in 6 studies that collectively involved 105 patients in 5 countries, including the USA, Italy, Germany, Iran, and India. Of these studies, the majority were single arm trials and two were multicentre trials. In the studies reporting patient demographics, patients ranged from 18 to 88 years old and the majority were male. All studies included patients with sensorineural hearing loss, with one study also including patients with mixed hearing loss. The severity of hearing loss ranged from mild to severe with mean preoperative air conduction threshold levels in the range of 60-70dB.

The Carina Fully Implantable Hearing Aid was investigated in 11 studies, representing 72 patients, in 7 countries – the majority being European but also including the United States and China. The most common study designs were single arm trials, pre/post, and case reports. In the studies reporting patient demographics, patients ranged from 14 to 82 years old with an equal number of males and females. Patients had predominantly sensorineural or mixed hearing loss, with only 6 patients being treated for conductive hearing loss. The severity of hearing loss was moderate to severe with mean air conduction thresholds ranging from 55-80dB.

Comparator technologies

The review of comparator technologies (BAHA and cochlear implants) was undertaken to demonstrate whether these devices would provide an alternative to patients eligible for middle ear implants, and if so, to provide an indirect comparison of safety and efficacy.

There were 25 studies meeting the inclusion criteria for BAHA, which collectively included 638 patients. They took place in 12 countries, one of which was Canada (4 studies). In the studies reporting patient demographics, patients ranged from 6 months to 88 years old, and there were slightly more females than males. There were three studies that included only children. Approximately half of the studies involved patients with mixed or conductive hearing loss, and the remainder consisted of profound sensorineural hearing loss or single

sided deafness. For the studies of mixed and conductive hearing loss, the severity of hearing loss ranged from moderate to profound with mean air conduction thresholds from 50-80dB.

There were 22 studies, representing 736 patients, which met the inclusion criteria for Cochlear Implants. The studies took place in 13 countries, approximately half of which originated from the United States. In those reporting patient demographics, patients ranged from 8 months to 92 years old, and were mainly female. The type of hearing loss was predominantly unspecified, with a two studies reporting sensorineural hearing loss. The studies included patients with severe to profound hearing loss whose mean air conduction thresholds ranged from 90 – 115dB.

There were 18 studies with usable outcomes reported for hearing aids. Thirteen were comparative trials to the VSB, 3 to the Esteem, and 2 to the Carina. They included 330 patients, with approximately equal numbers of males and females. The type of hearing loss was predominantly sensorineural. However, a small number of patients had mixed and conductive hearing loss. Hearing loss severity ranged from mild to severe. Mean air conduction thresholds spanned from 40 to 80dB, with the majority being in the 50 dB range.

Table 5. Key characteristics of included studies

Treatment	Number of studies	Number of patients	Type of hearing loss	Severity of hearing loss	Mean AC threshold
VSB	44	832	Mostly SNHL, also MHL & CHL	mild to severe	50-80dB
Esteem	6	105	SNHL + 1 study of MHL	mild to severe	60-70dB
Carina	11	72	Mostly SNHL or MHL, also CHL	moderate to severe	55-80dB
BAHA	26	638	MHL or CHL, profound SNHL or single-sided-deafness	moderate to profound	50-80dB for MHL & CHL
Cochlear Implants	22	736	Unspecified or SNHL	severe to profound	90-115dB

Based on a review of the patient populations for each technology and clinical advice from a member of the expert advisory panel, it was determined that cochlear implants were not an appropriate comparator to middle ear implants. Patients receiving cochlear implants have more severe hearing loss than those who would typically qualify for middle ear implants. Therefore, results from the cochlear implant studies were excluded. However, from those same consultations, it was agreed that there would be some patient populations who would be eligible for both the BAHA and middle ear implants. Therefore, BAHA studies that could be determined to represent only patients with moderate to severe hearing loss were included in the comparative analysis of efficacy. All BAHA studies reporting adverse events were included in the comparative analysis for safety, since severity of hearing loss is not anticipated to influence adverse event rates.

Overall quality of included studies

Based on the Oxford Centre for Evidence-based Medicine Levels of Evidence, the majority of studies were level IV (representing a relatively low level of evidence), while 5/61 were considered a level IIb. The quality of evidence did not vary according to device type or outcome measure studied. Agreement on the level of evidence assigned to each study was

1.0 (i.e. perfect) among independent reviewers. While several study designs fell within the Oxford Level of Evidence grade IV (which includes case reports, case series, prospective and retrospective within patient pre/post studies, prospective and retrospective trials with and without the intervention, and single arm trials), some can be considered to be at a lower risk of bias than others. Particularly, single arm trials and prospective study designs may be more controlled and, therefore, at less risk of bias.

Two studies reported potential conflicts of interest. One VSB study received partial funding from the Institute for Implantable Electronic Hearing Systems[90] and one Esteem study was funded by Envoy Medical.[91] Other possible sources of bias include selection bias. Very few studies reported a full list of inclusion and exclusion criteria. While many reported including consecutive patients, no further details regarding selection criteria were provided. As with many surgical interventions, blinding was not possible. As a result, subjective outcomes, such as quality of life, are susceptible to bias. Also, there may be elements of measurement bias in the with or without study designs. These designs are based on a single subject repeating hearing tests under different conditions (e.g., the test is first administered while the patient's middle ear implant is turned off and then the test is repeated with the implant turned on). With repeated measures designs, there may be a learning curve effect, particularly with speech recognition tasks.

To minimize bias caused by duplicate patient populations, careful analysis was performed to identify cases in which multiple articles presented on the same study participants. Where duplicates were found, results from the most recent article were used, with the exception of outcomes only reported in the earlier article. In cases where duplicate patients were suspected but the patient populations were not identical in number between studies, this was noted in the results.

Given the overall quality of studies found and the lack of information on patient characteristics in most of the studies, a meta-analysis could not be performed.

Safety

There were 34 MEI studies that reported adverse events (Appendix D). The follow-up period for these studies ranged from 2 months – 11 years. Additionally, there were 8 BAHA studies reporting adverse events with a follow-up period ranging from 3 months - 13.5 years.

Vibrant Soundbridge

For the Vibrant Soundbridge MEI, 22 studies reported adverse events, representing 533 patients. The most common adverse event experienced was taste disturbance or damage to the chorda tympani nerve which occurred in 6.3% and was permanent in 19/33 cases. (Although this is likely an overestimate due to overlap in patient populations for two studies reporting high rates.)[92,93] Device malfunction or failure occurred in 4.8% of patients and required explantation of 19 devices and 6 revision surgeries. Of the patients who experienced device extrusion or migration (1.7%), 8/9 patients also required revision surgery. Transient pain or headache (5.7%), skin reactions (4.4%), and vertigo or dizziness (2.7%), were the most common minor complications. The sensation of aural fullness was only reported in two studies, but experienced by over 20% of those patients. Two cases of surgical errors were reported. In one case, the implant was placed upside-down and in the other, the receiver was improperly placed. Both cases required revision surgery.

Esteem

There were 5 studies reporting adverse events for the Esteem MEI, representing 87 patients. The most commonly reported adverse event, occurring in 30% of patients, was taste disturbance or chorda tympani nerve damage which was temporary in 15/26 cases. Facial weakness was reported in 8% of patients and was permanent in 2/7 cases. There was also a relatively high rate of reoperations required, including the explantation of 7 devices and 5 revision surgeries. Predominantly these were related to insufficient gain or device malfunction. Other common complications were: otitis or effusion (25.3%), pain or headache (20.7%), vertigo or dizziness (12.6%), and tinnitus (11.5%), all of which occurred at relatively high rates.

Carina

There were 8 studies reporting adverse events for the Carina MEI, representing 68 patients. The most common complication experienced was device malfunction or failure, which occurred in 17.6% of patients. In 1/12 cases, failure was related to head trauma causing disconnection of the device and in 9 cases, the device failed to charge properly. Device malfunction led to 4 explantations and 3 revision surgeries. Partial device extrusion occurred in 4 patients and resulted in 2 explantations, 1 major revision and 1 minor revision surgery. A single study reported additional conductive hearing loss in 20% of patients postoperatively.[92,93] Otitis or effusion was relatively uncommon, occurring at a rate of 4.4%. Vertigo or dizziness, pain or headache, wound infection, tinnitus, and the sensation of aural fullness all occurred in 2.9% of patients. There were no reports of taste disturbance or facial weakness.

Traditional hearing aids

There was no safety information reported on hearing aids in the included studies. Due to the non-invasive nature of external hearing aids, adverse events associated with these devices may be considered negligible. A few recently published reports of serious complications with the use of traditional hearing aids were found, all of which reported that these events are extremely rare. Reported events included complications arising from ear mold materials remaining in the ear canal after fitting for a hearing aid[96] and tissue necrosis caused by hearing aid batteries inserted into the ear by children or adults with dementia.[94]

Fitting the Lyric invisible hearing aid does not require an ear mold.[95] One US centre's report of their experience with the Lyric in 364 patients found no serious adverse events.[95] Minor complications included earache and irritation of the ear canal resulting in 65 patients (18%) discontinuing use of the Lyric within one month of insertion. Transient irritation of the ear canal caused 26 patients (9%) to have the device removed for a short period (3 to 14 days), but all patients were subsequently able to resume use of the Lyric device.[95]

Bone anchored hearing aids (BAHA)

There were 8 studies reporting adverse advents for BAHA which represented 166 patients. The vast majority of adverse events were related to skin - including 5 wound infections, 14 minor skin reactions, and 6 cases of skin overgrowth at the abutment site requiring revision surgery. A single study reported that 66.7% of patients required repair of the external processor over a 4.6 year follow-up period.[96] There was only 1 case of device extrusion reported, which occurred in the immediate post-operative period secondary to trauma and required revision surgery.[97]

Efficacy

Vibrant Soundbridge

Compared to hearing aids
There were 9 studies comparing the Vibrant Soundbridge to hearing aids. Combined, they represented 153 patients with sensorineural or unspecified hearing loss, ranging from mild to severe.

Functional gain

While the pooled average functional gain for the VSB and hearing aids was 25.9dB (range: 12.9dB to 32.5dB) and 18.6dB (range: 13.7dB to 37.6dB), respectively, the extent to which differences between interventions were statistically significant and the intervention associated with higher gains varied across studies. Luetje et al[98] noted a statistically significant benefit of VSB over hearing aids ($p<0.01$) at frequencies from 1 to 6kHz. In contrast, Sziklai & Szilvassy[99] reported a statistically significant benefit with VSB over hearing aids at 4-8kHz, but no statistically significant benefit at 1-3kHz. Todt et al found no significant difference between hearing aids and VSB.[100] Boeheim et al reported statistically significantly greater gains with VSB at 0.25-2kHz and 6-8kHz. With respect to clinical significance, a 5dB difference in gain can be considered meaningful.[104] Six of nine studies (N= 129) found clinically significant greater gains with VSB, while the remaining three studies (N=24) reported clinically significant greater gains with hearing aids. All of the studies reporting higher gain with the VSB used the patient's own hearing aid as a comparator, whereas all studies showing greater benefit with the hearing aid used specified devices.

Speech reception

Five studies reported speech reception thresholds for 50% word recognition in quiet (N=59). The pooled average SRT50% with the VSB was 47.7dB (range: 32.3dB to 57dB) and 50.6dB (range: 39.9dB to 60dB) for hearing aids. The VSB demonstrated a statistically significant improvement ($p<0.05$) over hearing aids in 4/5 studies (N=34) and no significant difference in one study (n=25).

Speech recognition

There were six studies reporting percentage speech recognition, comprising 83 patients. A statistically significant improvement ($p<0.05$) in percentage of words recognized with the VSB compared to hearing aids was found in two studies (N=64), while a non-significant difference was observed in two studies (N=12). Truy et al[105](n=6) reported a statistically significantly greater improvement with the VSB for words presented at 40dB, but no statistically significant difference at 50 & 60dB. The remaining case study[106] noted a trend towards greater word recognition with the VSB but provided no information on statistical significance.

Quality of life

Four studies compared quality of life using the VSB to hearing aids in a total of 79 patients. The Abbreviated Profile of Hearing Aid benefit was the method of assessment used in three of the four studies. Significant benefit with the VSB over hearing aids was demonstrated in two of the three studies for each subcategory (ease of communication, background noise, aversiveness to sound, and reverberation). However, results varied across studies. Luetje et al[101] (n=51) reported Profile of Hearing Aid Performance and demonstrated statistically significant improvement with the VSB over hearing aids for all subcategories ($p<0.001$). Additionally, two studies (N=58) reported a higher degree of patient satisfaction with the VSB over hearing aids using the Hearing Device Satisfaction Scale. Luetje et al[101] did not report statistical significance. In contrast, Uziel et al[107] reported statistical significance for the categories: "sound quality", "feedback", "quality of life", and "ease of communication" ($p<0.05$), but not for "mould issues" and "telephone use".

Conclusion

The functional gain and speech reception gain achieved with the VSB appear to be slightly greater than that achieved with traditional hearing aids. The VSB is at least equivalent, and possibly superior to hearing aids in terms of speech recognition. Additionally, patients experience a greater degree of satisfaction with the VSB compared to hearing aids.

Compared to unaided

There were 39 studies comparing the VSB to the unaided condition, encompassing 796 patients. The studies mainly comprised patients with mild to severe sensorineural or mixed hearing loss, with a small proportion having conductive or unspecified hearing loss.

Functional gain

Thirty-two studies reported functional gain for the Vibrant Soundbridge, representing 534 patients. The average functional gain ranged from 12.9dB to 47.2dB across studies with a pooled average of 27.1dB. There was a significant difference in functional gain reported for studies of patients with sensorineural hearing loss (N= 354) compared to those with mixed or conductive hearing loss (N= 71), with pooled averages of 25.9dB and 34.0dB respectively. Significantly higher gains were also seen for the digital version of the device (Vibrant D) compared to analog version (Vibrant P), although the vast majority of studies did not specify the device model used. (The analog version of the device is no longer marketed; patients were offered an upgrade to the digital processor at no cost [personal communication: Ray Gamble, Med El, Innsbruck, Austria, 22 Nov 2011].) There was also a trend towards greater gains in the mid-range frequencies (1-3kHz) compared to the extremes.

Speech reception

Twelve studies reported speech reception with the VSB compared to the unaided condition, representing 185 patients. All studies provided the speech reception threshold for recognition of 50% of words in quiet. The SRT50 ranged from 58dB to 94.28dB in the unaided condition and from 40dB to 61dB in the aided condition. This represents a wide variation in the speech reception threshold gain (i.e., 4dB to 40.95dB across studies). The VSB was found to be significantly superior to the unaided condition in the four studies reporting statistical evidence ($p<0.05$).

Speech recognition

Sixteen studies reported speech recognition with the VSB compared to the unaided condition, encompassing 315 patients. There was significant heterogeneity in the method of assessment across studies, with the most commonly reported outcome comprising recognition of syllables or words presented at 65dB (reported in 10 studies (N=195)). Unaided speech recognition ranged from 0% to 72%, and aided ranged from 55% to 95% across studies. There were nine studies reporting statistical significance for word recognition in the unaided compared to the aided condition (N= 200). All showed a statistically significant improvement with the VSB($P<0.05$). One exception was Rajan et al,[101] who reported non-significance when testing in noise, but a statistically significant benefit with the VSB when testing in quiet.

Quality of life

Five studies compared quality of life with the Vibrant Soundbridge to the unaided condition, representing 190 patients. The Glasgow Benefit Inventory was reported in four studies (N=182) and all reported a benefit with the VSB in the "general" subcategory. However, in the "physical" category: one study reported improvement, two reported no benefit and one reported worsening due to the VSB. Rajan et al[101] used the Abbreviated Profile of Hearing Aid Benefit and reported statistically significant improvement with the VSB compared to the unaided condition in all categories except for aversiveness ($P<0.05$).

Conclusion

Significant benefit was observed in all outcome categories with the VSB compared to the unaided condition.

Compared to hearing aids and cochlear implants

One study[31] provided a comparative analysis of the VSB to hearing aids (conventional and 'state of the art') and cochlear implants. It examined speech recognition scores across patients with sensorineural hearing loss who had been treated with one of the 4 interventions (VSB, conventional hearing aids, "state of the art" hearing aids and cochlear implants). The conclusions were: 1) conventional behind-the-ear hearing aids perform better than the VSB; 2) in patients with threshold levels >80dB, cochlear implants perform better than both hearing aids and the VSB; 3) for profound hearing loss, 90% of patient's would perform better with a cochlear implant than a middle ear implant; 4) up to a threshold level of 95dB, conventional hearing aids should be used as first line therapy for patients who are medically able to wear the device; and 5) in patients with moderate to severe sensorineural hearing loss who are medically unable to wear a conventional hearing aid (for reasons such as otitis media), middle ear implants are indicated.

Esteem

Compared to hearing aids

Three studies compared the Esteem hearing system to hearing aids, representing 67 patients with predominantly sensorineural hearing loss ranging from mild to severe.

Functional gain

The pooled average for functional gain for the Esteem was 18.1dB (range: 17dB to 33dB) and the average gain for hearing aids was 16.8dB (range: 17dB to 20dB). No studies reported statistical significance. However, one study demonstrated a clinically significant improvement in functional gain with the Esteem compared to hearing aids, while the other two showed no clinically significant difference between treatment options.

Speech reception

Kraus et al[91] reported a statistically significantly lower word recognition threshold with the Esteem compared to hearing aids ($p \leq 0.001$). Although Chen et al[109] (n=5) also reported a greater speech reception gain with the patient's "best fit hearing aid" than with the Esteem (23dB vs 7dB), no information on statistical significance was reported.

Speech recognition

Chen et al[109] (n=5) demonstrated greater word recognition with hearing aids compared to the Esteem (76% vs 47%), whereas Kraus et al[91] (n=54) reported greater benefit with the Esteem (45% vs 69.1%). However, neither study reported on statistical significance.

Quality of life

Three studies reported quality of life with the Esteem compared to hearing aids using the Abbreviated Profile of Hearing Aid Benefit (N= 68). All studies reported benefit with the Esteem over hearing aids in the categories of background noise, aversiveness to sound and reverberation. Chen et al[109] and Kraus et al[91] (N= 62) also showed benefit in the ease of communication category. However, only Kraus et al[91] reported statistical significance with $p \leq 0.01$ for all subcategories. Kraus et al[91] (n=57) also reported results of a self-assessment questionnaire, demonstrating that the majority of subjects considered the Esteem to be equal to or better than hearing aids.

Conclusion

The Esteem hearing system appears to provide similar benefit to hearing aids in term of functional gain, speech reception, and speech recognition. However, patients report greater satisfaction with the Esteem device.

Compared to unaided

Five studies compared the Esteem hearing system to the unaided condition, representing 88 patients with moderate to severe sensorineural hearing loss.

Functional gain

All five comparative studies reported functional gain. The average functional gain ranged from 11.6dB to 26.3dB across studies, with a pooled average of 18.6dB.

Speech reception

Two studies, totaling 59 patients, reported speech reception for the Esteem compared to the unaided condition. The pooled average gain in speech reception threshold with the Esteem was 26.5dB compared to the unaided condition.

Speech recognition

Four studies spanning 87 patients reported speech recognition with the Esteem compared to the unaided condition. There was significant heterogeneity in the method of assessment across studies, but all studies reported increased speech recognition with the Esteem compared to the unaided condition. However, only Memari et al[110] (n=10) reported statistical significance and found the difference to not be statistically significant (p=0.62).

Quality of life

Barbara et al[102] reported benefit in all patients with the Esteem compared to the unaided condition (n=18). Using the Glasgow Benefit Inventory and the Client Oriented Scale of Improvement, a similar degree of improvement was seen in patients with moderate and severe hearing loss.

Conclusions

There appears to be benefit in functional gain, speech reception, and quality of life achieved with the Esteem device compared to the unaided condition. However, it is unclear whether the Esteem device shows significant improvement over unaided conditions in speech recognition.

Carina

Compared to hearing aids

Three studies compared the Carina hearing system to hearing aids. Collectively, they included 21 patients with predominantly sensorineural hearing loss, which ranged from moderate to severe.

Functional gain

The pooled average for functional gain for the Carina was 10.4dB and the average gain for hearing aids was 15.6dB. Jenkins et al[94] reported that the hearing aid preformed significantly better ($p<0.05$) than the Carina at all frequencies but 4kHz and 6kHz. This study also demonstrated a clinically significant improvement in functional gain with hearing aids compared to the Carina. The remaining study[112] was a single case report demonstrating a clinically significant benefit from the Carina over hearing aids.

Speech reception

Only a single case report by Deveze et al[112] reported this outcome, demonstrating a 50% word recognition threshold gain of 20dB with the Carina and only 5dB with the patient's own hearing aid.

Speech recognition

Two studies involving a total of 21 patients reported speech recognition with the Carina compared to hearing aids. Jenkins et al[94] (n=20) demonstrated a significantly higher monoaural word recognition with the patient's own hearing aid compared to the fully-implantable MET (81% vs 67%, $P<0.001$). However, there was no significant difference between hearing aids and the MEI for recognition of phonemes or binaural words. A case report by Deveze et al[112] reported higher speech recognition with the Carina compared to the patient's own hearing aid (80% for Carina versus and 40% for hearing aids), but no information on statistical significance was presented.

Quality of life

Jenkins et al[95] (n= 20) reported Abbreviated Profile of Hearing Aid Benefit with the Carina compared to hearing aids and found the Carina to be superior in all subcategories. No information on statistical evidence was provided.

Conclusion

Evidence comparing the Carina MEI to traditional hearing aids is very limited. In existing studies, the Carina does not appear to offer a significant benefit over hearing aids in functional gain, speech reception, or speech recognition. However, patients reported a higher quality of life with the Carina device.

Compared to unaided

Ten studies compared the Carina to the unaided condition, representing 71 patients with moderate to severe sensorineural, mixed or conductive hearing loss.

Functional gain

All ten studies reported functional gain with the Carina, with values ranging from 9.3dB to 39dB and a pooled average of 21.3dB. Higher functional gain was seen in studies of patients with mixed of conductive hearing loss (N=24) compared to those of sensorineural hearing loss (N=36), with average gains of 28.2dB and 14.4dB respectively.

Speech reception

Four studies reported speech reception using the Carina as compared to the unaided condition, representing 17 patients. Speech reception threshold gain ranged from 13dB to 32dB with the Carina compared to the unaided condition, with a pooled average of 19.9dB.

Speech recognition

Four studies, encompassing 18 patients, reported speech recognition with the Carina compared to the unaided condition. Recognition of words at a presentation level of 65dB was the most frequently reported method of assessment, with three studies reporting this outcome in 17 patients. Recognition of unaided words ranged from 32.5% to 40% in the unaided condition and 68.75% to 94% in the aided condition. Improvement in percentage of words recognized was demonstrated in all studies, but none reported statistical significance.

Quality of life

Three studies used the Abbreviated Profile of Hearing Aid Benefit to compare quality of life in the unaided condition to that with the Carina (N=20). Martin et al[113] (n=7) reported a statistically significantly greater benefit with the Carina in the categories of "ease of communication", "aversiveness", and "reverberation" ($P<0.05$), but no significant difference in "background noise". In the remaining two studies, patients experienced less difficulty with the Carina in all categories except for "aversiveness", where Lefebvre et al[88] reported increased difficulty compared to the unaided condition. However, neither study reported on the statistical significance of differences.

Conclusion

The Carina appears to provide benefit compared to the unaided condition in functional gain, speech reception, speech recognition and quality of life.

BAHA

Only studies that were identified as comprising patients that would potentially be eligible to receive either a bone-anchored hearing aid or a middle ear implant were included in this portion of the review. These studies encompassed patients which were all reported to have moderate to severe, mixed or conductive hearing loss.

Compared to unaided

Five studies involving a total of 89 patients compared the BAHA to the unaided condition.

Functional gain

Three studies reported functional gain with a bone-anchored hearing aid, encompassing 53 patients. Gain ranged from 13dB to 35.2dB, with a pooled average of 24.7dB.

Speech reception

Three studies reported speech reception with a bone-anchored hearing aid compared to the unaided condition. They included a total of 46 patients. The gain in speech reception threshold with the BAHA ranged from 1.3dB to 31.7dB. Two studies (N=36) reported a statistically significant improvement in the mean speech reception threshold using the BAHA compared to unaided ($p<0.01$), whereas the remaining study did not report statistical significance.

Speech recognition

Two studies reported speech recognition with the BAHA compared to the unaided condition (N= 28). Pfiffner et al[97] reported a statistically significant improvement in the percentage of words identified at all decibel levels with the BAHA compared to without ($p=0.006$ to 0.0012). Kunst et al[115] found an increase in word recognition in noise from 51% to 74% but did not indicate whether this increase achieved statistical significance.

Quality of life

Two studies used the Abbreviated Profile of Hearing Aid Benefit to compare quality of life with a bone-anchored hearing aid to the unaided condition (N= 35). Fuchsmann et al[116] (n=15) found significantly less difficulty overall (i.e., higher quality of life) with the BAHA ($p<0.0001$), reporting improvements in all subcategories except for "aversiveness". Pfiffner et al[97] (n=20) reported significantly less difficulty with the BAHA in all subcategories ($p<0.01$).

Conclusion

There were no studies directly comparing the BAHA device to MEIs. However, based on an indirect comparison, the BAHA device appears to provide similar benefit in functional gain, speech reception, and speech recognition to the VSB and superior benefit over the Esteem and Carina devices. All devices provide a quality of life benefit over the unaided condition and it cannot be extrapolated from the available data whether higher satisfaction would be achieved with the BAHA or MEI devices.

MEI devices compared to one another

Rameh et al (2010)[103] was the only study comparing two of the MEI devices being considered in this report – the VSB and the Carina. Higher patient satisfaction and speech perception gain were observed with the VSB device.

Conclusions

Overall the quality of MEI studies conducted to date is low. Nevertheless, the findings indicate that improvement in functional gain with MEI appears to be comparable to that with hearing aids. However, evidence for functional gain with the Carina device is particularly low. Studies also suggest that MEI may offer greater improvements with respect to perception of speech in noise and sound quality.

Summary of other guidelines & assessments of MEI for hearing loss

No clinical guidelines for the provision of MEI were found in the literature review.

In their 2010 *Clinical Policy Bulletin*, the US health insurer, Aetna, determined that MEI are medically necessary for the treatment of moderate-to-severe sensorineural hearing loss in individuals who cannot tolerate a traditional ear mold due to medical conditions such as severe chronic otitis externa or auricular atresia.[104] Aetna views MEI as "experimental and investigational for all other indications". Aetna considers both BAHA and cochlear implants medically necessary for individuals who meet certain audiologic criteria.[29,105]

A 2010 systematic review for the Australian Medical Services Advisory Committee concluded that:

- good quality evidence from comparative studies is lacking
- for most types of sensorineural hearing loss MEI appeared to improve hearing over baseline levels
- the different devices, surgical procedures used and outcomes measured made it difficult to compare the safety of MEI, BAHA and CI. However, based on evidence from case series, MEI appeared to be as safe as these other surgical treatments. Expert clinical advisors noted that adverse events are likely to be higher when these devices are used in children
- they were unable to identify a particular subgroup of patients who would be suitable for MEI due to failure of hearing aids and other conservative treatment
- there was insufficient evidence to recommend MEI for public funding.[7]

The 2002 assessment of MEI by the French health technology assessment agency, CEDIT, concluded that: MEI offers a benefit for adults with hearing loss who cannot benefit from a traditional hearing aid and whose hearing impairment is not sufficient to justify using a cochlear implant.

- the indications for implanting an MEI based on "failure of a hearing aid" have not been established
- the different MEIs have not been compared to each other
- there is a risk that MEIs will diffuse into practice before best practices for their role have been properly determined.[39]

Economic Evaluation (E)

Review of existing economic analyses

Overall description of included studies

As reported in a 2010 textbook on MEI, few economic studies of MEI are available.[35] A total of four studies were found. One comprised a systematic review of studies describing the effect of MEIs on quality of life, the results of which were used to infer cost effectiveness.[106] Of the 3 remaining publications, one comprised a cost-minimization analysis[7] and one was a cost analysis.[39] The third study presented a cost-effectiveness analysis.[107] None of the studies were Canadian (Australia, France and the Netherlands). The overall quality of the evaluations (based on published guidelines for economic evaluations in health care) was low. In general, costs captured were limited to those related to the procedure (implantation of the device).

Cost analyses

The cost-minimization analysis and cost analysis were both undertaken by HTA organizations (cost-minimization analysis: MSAC (Australia)[7] and cost analysis: CEDIT (France)).[39] The MSAC report compared MEI with cochlear implants and BAHA. Since a clinical review of these treatment options concluded that the primary outcome was similar in all 3 modalities, a cost-minimization analysis was conducted, rather than a cost-effectiveness analysis. Assumptions for the evaluation included: MEI is applicable only if a traditional hearing aid is not available; only patients with hearing loss in the mild to severe range are included; the perspective of the evaluation is only partially societal, since patient co-payments are included; and only costs in the first year (including those associated with re-implantation) are considered. The analysis used unit cost estimates from various sources, such as benefits schedule rates (e.g., GP and specialist consultations, audiology services, implantation and fixation, anaesthesia, surgical assistance and CT scans), co-payments (by patients), information from manufacturers (costs of the device and battery), and expert opinion (e.g., hospital stay). Re-implantation costs due to failure were obtained from failure rates provided by clinical experts (2.5% for MEI, 5% for BAHA, and 1% for cochlear implants,). Average per case costs for MEI, BAHA, and cochlear implants were reported. The average estimated cost (converted to Canadian dollars) for MEI was $23,382, compared to $14,894 for BAHA and $23,962 for cochlear implants. A 'worst case' scenario was used to conduct a sensitivity analysis. In this scenario, ENT visits were increased from 2 to 3, 2 batteries were used per week instead of one, the number of audiologist visits were doubled, length of stay rates were estimated using diagnosis-related group (DRG) rates (instead of expert opinion) and failure rates were increased to 5% for MEI, 10% for BAHA and 5% for cochlear. The average total cost for MEI was $28,215, compared to $16,785 for BAHA and $40,309 for cochlear implants, demonstrating that the costs are relatively insensitive to the changes in parameter values. Importantly, the report also indicates that BAHA and cochlear implants may not be the appropriate comparators to MEIs for certain types of hearing loss.

Only an English summary was available for the French cost analysis.[39] Consequently, little information on methods used to estimate costs was presented. However, it concluded that

the per case cost (including pre- and post-implementation tests, the surgery itself, and a 5 day hospital stay) in Canadian dollars would be $19,173.

Cost-effectiveness analysis

The single cost-effectiveness analysis, published in 2006, was based on Dutch data.[107] Quality of life prior to and following MEI was measured in patients with severe external otitis in order to determine changes in quality of life attributable to MEI. Only direct costs related to the implantation procedure were included (ENT specialist, audiologist, anaesthesia, surgical assistance, consumable (including the device itself) and a 2 day length of hospital day). Quality of life was measured using a well-validated quality of life instrument, the SF-36 health survey. The study concluded that the cost per QALY for MEI was $25,123. Several limitations to this study were noted. Two different types of MEI devices (Vibrant Soundbridge and Otologics MET) were combined in the analysis because of small patient numbers in each group (13 and 8 respectively). No conclusions could, therefore, be drawn about the relative cost-effectiveness of the 2 devices. Also, MEI was not compared to any other treatment modality. Further, the use of a generic (as opposed to disease specific) quality of life instrument in this patient population may not be appropriate. Lastly, a sensitivity analysis was not performed.

Decision model

The decision model is based on the assumption that potential candidates for MEI comprise patients who 1) are ineligible for BAHA or cochlear implants or 2) have failed treatment with conventional hearing aids (where failure is defined as dissatisfaction with conventional hearing aids due to insignificant improvements in hearing, feedback issues, or other complications associated with their hearing aid, even after a proper fitting). A decision tree representing the probability that a single candidate patient will experience various events over a 5 year time horizon is presented in Figure 4. As mentioned in the methods section, probabilities of 'events' were obtained from the literature review and administrative data provided by Alberta Health and Wellness, and were agreed upon by the members of the EAG (Table 8).

Budget impact analysis

The estimated per case cost of MEI in Alberta, comparing costs obtained from 2 different information sources, is presented in Table 9. The first cost estimate assumes that the costs of cochlear implantation (pre-procedural, procedural, and post-procedural) reflect a conservative estimate of the costs of the MEI procedure (as suggested by clinical experts surveyed for this report and the MSAC report). These costs were obtained from Alberta Health and Wellness billing data, the clinical review, and the Calgary and Glenrose Cochlear Implant Services (Alberta Health Services). The second cost estimate is based on the Alberta Health Services Operational and Financial Impact Analysis (OFIA) for Middle Ear Implants, which does not use cochlear implantation costs. Both estimates use the cost of the Vibrant Soundbridge device, as it was agreed upon by the expert advisory group that this would be the only device likely to be used in Canada; they include pre-procedural, procedural, and post-procedural costs, and assume a 5 year time horizon.

The first cost estimate includes the cost of the device, pre-operative assessment (ENT visit, audiologic assessment, CT scan, and, in 3% of patients, counselling), implant procedure

(anesthesiologist and otolaryngologist physician fees, anesthesia supplies, surgical suite time, surgical sets and equipment, and hospital stay) and post-operative assessment/follow-up. In comparison to the cost estimate calculated from billing data, the OFIA does not include the cost of a pre-admission clinic visit, surgical liaison fees, physician fees (ENT pre-procedural, procedural, or post-procedural, or anesthesiologist), anesthesia supplies, inpatient hospital stay, or revision surgery. The cost estimate based on the OFIA includes surgical equipment as a one-time cost, while Alberta Health and Wellness hospital billing data takes these items into account on a per case basis in the procedural cost. A 5% inflation rate for the implant device and for per case (not one-time) cost items (health professional fees, procedure costs, etc.) each year for 5 years was assumed in both scenarios. The cost was calculated as an average of the inflated cost over 5 years.

Based on discussion with the Expert Advisory Group, approximately 20 patients in Alberta would be candidates for MEI (with no alternate treatment option) each year. Over a 5 year time horizon, no significant changes in prevalence or demand are expected. Therefore, approximately 100 patients would be candidates for MEI over 5 years. If all 100 patients receive an MEI, the anticipated cost over 5 years would be $2,645,231. If 5% of patients require a revision surgery, the cost of revisions would be $32,266. Therefore, the total cost of MEI over 5 years would be $2,677,497 (based on billing data). Based on the OFIA, if all 100 patients receive an MEI, the total cost of MEI over 5 years would be $1,988,165.

Conclusions

Three economic evaluations have been published on MEIs. The quality of these studies was low. They also differed in the assumptions made, conditions around the use of comparators, and sources of cost data. A French cost analysis concluded that the cost per case (including pre- and post-implant testing, the surgery and a 5 day hospital stay) would be CDN$19,173. The average estimated cost in Australia was reported in a cost-minimizations study as CDN$23,382 (MEI), CDN$14,894 (BAHA) and CDN$23,962 (cochlear implants). A 'worst case scenario' calculation produced estimates of CDN $28,215 (MEI), CDN$16,785 (BAHA) and CDN$40,309 (cochlear implants). A French cost-effectiveness study concluded that the cost per QALY for MEI would be CDN$25,123, assuming a 2 day hospital stay.

Based on an estimated 100 patients receiving MEI over 5 years, the budget would be $2,677,497.

Figure 4. Decision tree for the use of MEI in Alberta

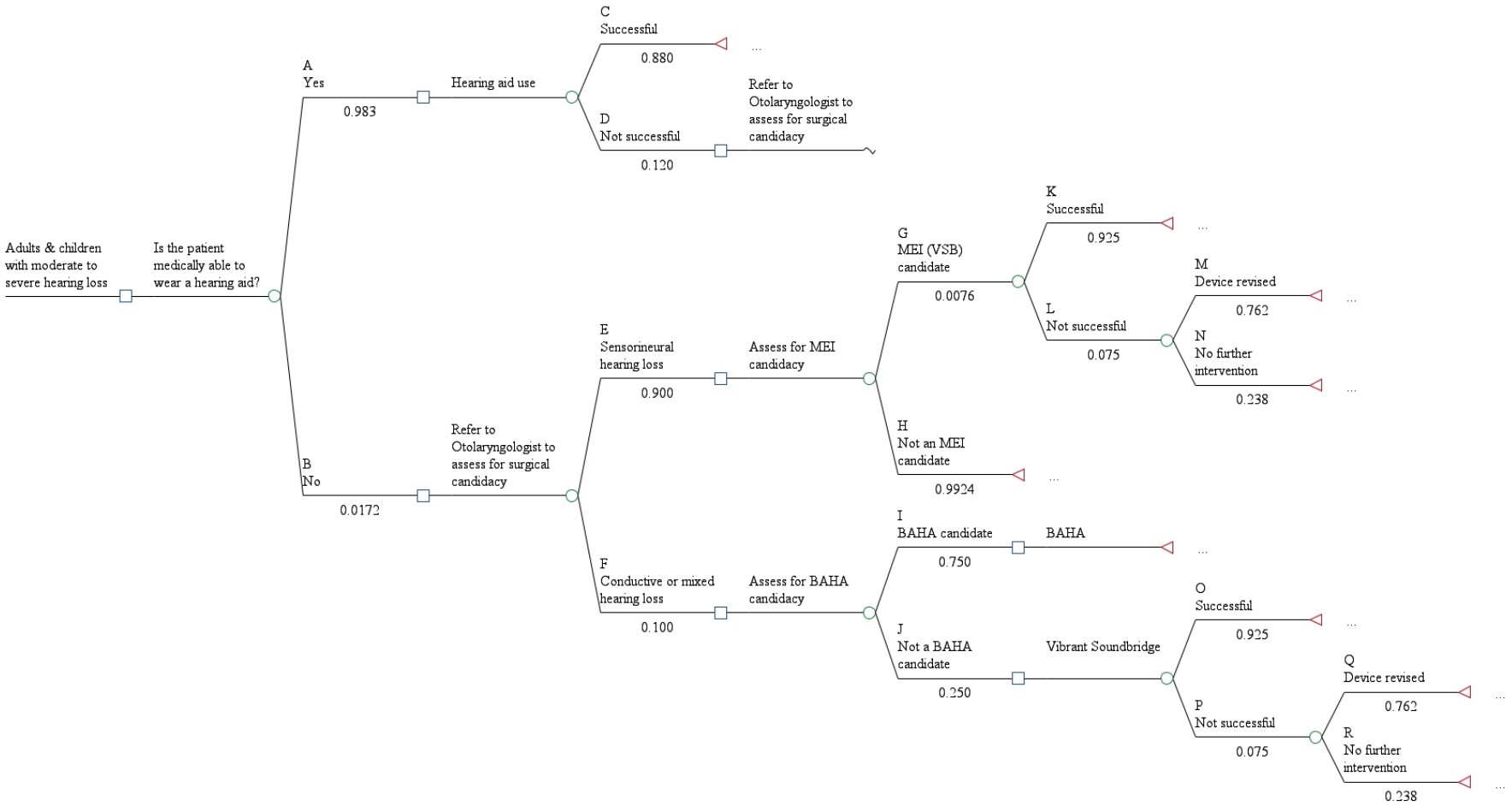


Table 6. Summary of economic analyses of MEI

Author, year, funding source	Country	Study design	Comparators	Perspective for analysis	Sensitivity analysis	Findings (Cdn$)*	Comments
Snik et al, 2010 Funding source: Not reported[106]	Netherlands	Cost-effectiveness analysis	None	Healthcare system/payer	No	Cost/QALY: $25,123	• Effectiveness (utilities) based on 'within patient' (pre-post MEI) comparison, rather than a comparison of different treatment alternatives
Australian Medical Services Advisory Committee (MSAC), 2010 Funding source: Government[7]	Australia	Cost-minimization analysis	Bone Anchored Hearing Aid (BAHA) Cochlear Implant (CI)	Healthcare system/payer	Yes (worst case scenario approach)	*Average per case cost* MEI: $23,382 BAHA: $14,894 CI: $23,962	• Assumed all three interventions were equally effective based on primary outcome (functional gain)
Snik et al, 2006 Funding source: Not reported[107]	Netherlands	Systematic review	Not applicable	Not applicable	No	Not applicable	• Systematic review of existing studies of
Le Comité d'évaluation et de diffusion des innovations technologiques (CEDIT), 2002 Funding source: Not reported[39]	France	Cost analysis (per case cost)	None	Hospital	No	$19,173/case	• Based on information in executive summary only (full report not available in English)

* In 2011 Canadian dollars

Table 7. Summary of the quality of economic studies

Author, Year, Country	Well defined analysis question	Comprehensive description of alternatives	Established program effectiveness	Identified all relevant costs and consequences	Accurately measured costs and consequences	Accurately valued costs and consequences	Discounted costs and consequences	Incremental analysis of costs and consequences	Allowed for uncertainty in costs and consequences	Comprehensive presentation and discussion
Snik et al, 2010 The Netherlands[106]	Yes	Not applicable	Yes	Yes (implicit in QALY)	Unable to determine	Unable to determine	No	No	No	Yes
Australian Medical Services Advisory Committee, 2010 Australia[7]	Yes	Yes	Yes	Yes (from payer and patient perspective)	Yes	Yes	No	Yes	Yes	Yes
Snik et al, 2006 The Netherlands[107]	Yes	No	No	No	No	No	No	No	No	No
Le Comité d'évaluation et de diffusion des innovations technologiques, 2002 France[39]	No	Yes	No	Unable to determine	Unable to determine	Unable to determine	Unable to determine	No	No	No

Based on the checklist for assessing economic evaluations by Drummond et al[88]

Table 8. Variable inputs for decision model

Branch of decision model	Variable	Estimate (probabilities)	Information sources and Assumptions
Health state			
A	• Patient medically able to wear hearing aid	0.983	• 1 – B • B is the proportion of patients medically unable to wear hearing aids (information obtained from Alberta Health and Wellness administrative data – see below)
B	• Patient medically unable to wear hearing aid Combined: -congenital aural atresia -acquired ear canal stenosis -chronic otitis media -recurrent otitis media -recurrent otitis externa	0.0172	• Incident cases of congenital aural atresia, acquired ear canal stenosis, and chronic or recurrent otitis media or externa in patients with hearing loss were identified for calendar years 2007 and 2008 from Alberta Health and Wellness administrative data, using ICD-9 and ICD-10 diagnosis codes: -congenital aural atresia: 744.01, 744.02, Q161 -acquired ear canal stenosis: 380.5^, H613 -recurrent otitis externa: 380.1, 380.2, H602, H603, H605, H608, H609 -recurrent otitis media: 381.0, 381.4, 382.0, 382.4, 382.9, H650, H651, H659, H660, H664, H669 -chronic otitis media: 381.1, 381.2, 381.3, 382.1, 382.2, 382.3, H652, H653, H654, H661, H662, H663 • An incident case was identified as a patient with a diagnosis of one of the conditions mentioned above in 2007 or 2008, with no diagnosis for that condition in the previous years going back to 2003 • For recurrent otitis externa and otitis media, recurrence was defined as ≥3 episodes in 6 months or ≥4 episodes in 12 months[108] • The number of incident cases for each condition were averaged over 2007 and 2008 and combined to obtain an overall proportion of patients medically unable to wear hearing aids
Interventions			
C D	• Hearing aid use Successful Unsuccessful	 0.880 0.120	 • Literature[72] • Literature;[72] patients who were considered to have unsuccessful hearing aid trials were those who after proper fittings were not satisfied with their hearing aid (as a result of insignificant improvements in hearing, feedback issues, etc.), or who experienced complications related to their hearing aid.
E	*Sensorineural hearing loss*	0.900	• Literature[9]
G	• Patient a candidate for a MEI (Vibrant Soundbridge)	0.0076	• Literature[25]
K L	• Vibrant Soundbridge Successful Unsuccessful	 0.925 0.075	 • Included studies in review of clinical efficacy/effectiveness for STE report • Included studies in review of clinical efficacy/effectiveness for STE report
	• Unsuccessful Vibrant Soundbridge Revision surgery No further intervention	 0.762 0.238	Due to major complications, device failure, or surgical errors; other complications were either captured in revisions, associated with a negligible costs, or required no medical intervention • Included studies in review of clinical efficacy/effectiveness for STE report (note: the review found that of patients who had failed middle ear implantation with the Vibrant Soundbridge, 47.5% had the device explanted, 40% had revision surgery, and 12.5% had no further intervention; as suggested by the Expert Advisory Group, explantation was not included as it does not reflect likely practice in Alberta and instead, the proportions of revisions and no intervention were increased to total 1.0)
H	• Patient not a candidate for a MEI	0.9924	• Literature[25]
F	*Mixed or conductive hearing loss*	0.100	• Literature[9]
I	• Patient a candidate for a BAHA	0.750	• Literature[5,6]
J	• Patient not a candidate for a BAHA (patient therefore receives an MEI)	0.250	• Literature[5,6]

Table 8. Variable inputs for decision model

Branch of decision model	Variable	Estimate (probabilities)	Information sources and Assumptions
	• Vibrant Soundbridge		• Vibrant Soundbridge is indicated for the treatment of sensorineural hearing loss in Canada; however, the use of the Vibrant Soundbridge for mixed or conductive hearing loss has been indicated in the US and was included in the review of clinical efficacy/effectiveness upon which the model is based
O	Successful	0.925	• Included studies in review of clinical efficacy/effectiveness for STE report
P	Unsuccessful	0.075	• Included studies in review of clinical efficacy/effectiveness for STE report
	• Unsuccessful Vibrant Soundbridge		Due to major complications, device failure, or surgical errors; other complications were either captured in revisions, associated with a negligible costs, or required no medical intervention
	Revision surgery	0.762	• Included studies in review of clinical efficacy/effectiveness for STE report (note: the review found that of patients who had failed middle ear implantation with the Vibrant Soundbridge, 47.5% had the device explanted, 40% had revision surgery, and 12.5% had no further intervention; as suggested by the Expert Advisory Group, explantation was not included as it does not reflect likely practice in Alberta and instead, the proportions of revisions and no intervention were increased to total 1.0)
	No further intervention	0.238	

Table 9. Estimation of average cost of MEI per case

Item	Alberta Health and Wellness administrative data				Alberta Health Services Operational and Financial Impact Analysis			
	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source
Consumables								
• Implant System Vibrant Soundbridge	16,576.89	1	16,576.89	• Literature[40] • This cost represents the average cost of a VSB implant system over 5 years, assuming a 5% inflation rate on the current cost of the VSB system ($15,000) each year for 5 years	16,576.89	1	16,576.89	• Includes implant, processor, electrode needles, battery • Literature[40] • This cost represents the average cost of a VSB implant system over 5 years, assuming a 5% inflation rate on the current cost of the VSB system ($15,000) each year for 5 years
• Surgical set/equipment (one-time cost)	-	-	-	• Costs from Alberta Health and Wellness billing data (ambulatory care and inpatient databases) take the costs of surgical equipment into account (see cost of implant procedure below)	946.58	1	946.58	• Includes beaver handle, Army and Navy retractors, cone retractors, Visao Drill, Burrs, middle ear surgical set, Bipolar Wetfield Adson set, Davis type brain retractors, custom surgical tray, alligator specials, mastoid extras, power console, Nim Monitor, and Pneumatic Chair) • Calculated from total one-time cost ($94,658) divided by the total number of cases over 5 years (N=100) • Alberta Health Services Operational and Financial Impact Analysis – Middle Ear Implants
Procedure								
Pre-procedural								
• ENT specialist visit	91.15	1	91.15	• This cost represents the average cost of a specialist visit over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: average $82.48 • Alberta Health and Wellness billing data from January 1, 2007 to March 31, 2009 for cochlear implants, as the CI procedure provides a conservative estimate of the MEI procedure (expert clinical opinion and MSAC report) • Schedule of Medical Benefits code: '03.08A'	-	-	-	-
• Pre-operative assessment (diagnostic audiology	589.34	1	589.34	• This cost represents the average cost of a pre-operative assessment over 5 years,	189.64	1	189.64	• This cost represents the average cost of a pre-operative assessment over 5 years,

Table 9. Estimation of average cost of MEI per case

Item	Alberta Health and Wellness administrative data				Alberta Health Services Operational and Financial Impact Analysis			
	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source
including hearing assessment, hearing aid evaluation, auditory brain stem response)				assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 10-12 hours at $48.48/hour (average $533.28 total) • Calgary and Glenrose Cochlear Implant Services, Alberta Health Services – personal communication with Manager Audiology Service, Glenrose Rehabilitation Hospital and Care Manager Community Audiology, Allied Health Calgary Zone				assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 3 hours at $57.20/hour ($171.60 total) • Alberta Health Services Operational and Financial Impact Analysis – Middle Ear Implants
• CT	411.70	1	411.70	• This cost represents the average cost of a CT scan over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: average $372.54; calculated from sum of average physician fee ($50.64) and average procedure cost ($321.90) • Alberta Health and Wellness billing data from January 1, 2007 to March 31, 2009 for cochlear implants, as the CI procedure provides a conservative estimate of the MEI procedure (expert clinical opinion and MSAC report) • Schedule of Medical Benefits code: 'X 9' • Canadian Classification of Health Interventions Code: '3EL20^^'	411.70	1	411.70	• Cost was not provided in Alberta Health Services Operational and Financial Impact Analysis – Middle Ear Implants, therefore the cost obtained from Alberta Health and Wellness billing data was used • Alberta Health and Wellness billing data from January 1, 2007 to March 31, 2009 for cochlear implants, as the CI procedure provides a conservative estimate of the MEI procedure (expert clinical opinion and MSAC report)
• Counselling and mental assessment	857.22*	1	857.22*	*3% of patients that meet the criteria for MEI would require counseling (by audiologist, social worker, and/or speech language pathologist) • This cost represents the average cost of counselling over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 15-17 hours at $48.48/hour (average $775.68 total) • Calgary and Glenrose Cochlear Implant Services, Alberta Health Services – personal communication with Manager Audiology Service, Glenrose Rehabilitation Hospital	202.68*	1	202.68*	*3% of patients that meet the criteria for MEI would require counselling • This cost represents the average cost of counselling over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 2 hours for social work at $57.21/hour plus 1 hour for psychology at $68.98/hour ($183.40 total) • Alberta Health Services Operational and Financial Impact Analysis – Middle Ear Implants

Table 9. Estimation of average cost of MEI per case

Item	Alberta Health and Wellness administrative data				Alberta Health Services Operational and Financial Impact Analysis			
	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source
				and Care Manager Community Audiology, Allied Health Calgary Zone				
• Surgical liaison	107.15	1	107.15	• This cost represents the average cost of surgical liason over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 2 hours at $48.48/hour ($96.96 total) • Calgary and Glenrose Cochlear Implant Services, Alberta Health Services – personal communication with Manager Audiology Service, Glenrose Rehabilitation Hospital and Care Manager Community Audiology, Allied Health Calgary Zone	-	-	-	-
• Social work*	285.98	1	285.98	*For pediatric (1-18 years of age) implant recipients only • This cost represents the average cost of social work over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 6 hours at $43.13/hour ($258.78 total) • Calgary and Glenrose Cochlear Implant Services, Alberta Health Services – personal communication with Manager Audiology Service, Glenrose Rehabilitation Hospital and Care Manager Community Audiology, Allied Health Calgary Zone	-	-	-	-
• Speech language pathology*	535.77	1	535.77	*For pediatric (1-18 years of age) implant recipients only • This cost represents the average cost of speech language pathology over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 10 hours at $48.48/hour ($484.80 total) • Calgary and Glenrose Cochlear Implant Services, Alberta Health Services – personal communication with Manager Audiology	-	-	-	-

Table 9. Estimation of average cost of MEI per case

Item	Alberta Health and Wellness administrative data				Alberta Health Services Operational and Financial Impact Analysis			
	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source
				Service, Glenrose Rehabilitation Hospital and Care Manager Community Audiology, Allied Health Calgary Zone				
• Psychology*	321.46	1	321.46	*For pediatric (1-18 years of age) implant recipients only • This cost represents the average cost of psychology over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 6 hours at $48.48/hour ($290.88 total) • Calgary and Glenrose Cochlear Implant Services, Alberta Health Services – personal communication with Manager Audiology Service, Glenrose Rehabilitation Hospital and Care Manager Community Audiology, Allied Health Calgary Zone	-	-	-	-
Procedural								
• Implant procedure (including physician fees, anaesthesia, surgical suite time, and hospital stay)	6,453.26	1	6,453.26	• This cost represents the average cost of the procedure over 5 years, assuming a 5% inflation rate on the current cost of the procedure ($5,839.39) each year for 5 years • Current cost calculated from sum of average anesthesiologist physician fee ($670.45), average otolaryngologist physician fee ($1,163.27), and average procedure cost ($28,737.17-includes: device, anesthesia supplies, surgical suite time, surgical sets and equipment, and hospital stay), subtracting the average cost of a cochlear implant ($24,731.50) • Alberta Health and Wellness billing data from January 1, 2007 to March 31, 2009 for cochlear implants, as the CI procedure provides a conservative estimate of the MEI procedure (expert clinical opinion and MSAC report) • Schedule of Medical Benefits code: '32.95A' • Canadian Classification of Health Interventions Code: '1DM53^^'	1,185.26	1	1,185.26	• This cost represents the average cost of the procedure over 5 years, assuming a 5% inflation rate on the current cost of the procedure ($1,072.51) each year for 5 years • Cost includes OR theatre time and case consumables; cost does not include physician fees, anesthesia supplies, surgical sets and equipment, or hospital stay (surgical sets and equipment incorporated as a one-time cost - see cost of consumables above) • Alberta Health Services Operational and Financial Impact Analysis – Middle Ear Implant

Table 9. Estimation of average cost of MEI per case

Item	Alberta Health and Wellness administrative data				Alberta Health Services Operational and Financial Impact Analysis			
	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source
Post-procedural								
• ENT specialist visit	57.09	1	57.09	• This cost represents the average cost of a specialist visit over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: average $51.66 • Alberta Health and Wellness billing data from January 1, 2007 to March 31, 2009 for cochlear implants, as the CI procedure provides a conservative estimate of the MEI procedure (expert clinical opinion and MSAC report) • Schedule of Medical Benefits code: '03.07B'	-	-	-	-
• Follow-up appointment post-implantation	2,140.01	1	2,140.01	• Follow-up appointments by allied health team: audiologist, social worker, speech language pathologist, and/or psychologist • This cost represents the average cost of post-operative follow-up appointments over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 10-15 hours for initial follow-up appointment, 4-6 hours for 3 month follow-up, 6-8 hours for 6 month follow-up, 6-10 hours for 12 month follow-up, and 6-10 hours for 24 month follow-up at a cost of $48.48/hour (average $1,936.44 total) • Calgary and Glenrose Cochlear Implant Services, Alberta Health Services – personal communication with Manager Audiology Service, Glenrose Rehabilitation Hospital and Care Manager Community Audiology, Allied Health Calgary Zone	252.85	1	252.85	• This cost represents the average cost of post-operative follow-up appointments over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 2 hours for post-operative tune up, 1 hour for 6 month follow-up, and 1 hour for 24 month follow-up at a cost of $57.20/hour ($228.80) • Includes post-operative tune up, device upgrade and patient follow-up • Alberta Health Services Operational and Financial Impact Analysis – Middle Ear Implant
Ongoing program delivery								
• MEI training for audiologists	-	-	-	-	4.58	1	4.58	• 8 hours at $57.20/hour (one-time cost; $457.60 total) • Calculated from total one-time cost divided by the total number of cases over 5 years (N=100)

Table 9. Estimation of average cost of MEI per case

Item	Alberta Health and Wellness administrative data				Alberta Health Services Operational and Financial Impact Analysis			
	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source
								• Alberta Health Services Operational and Financial Impact Analysis – Middle Ear Implant
• Audiology program management/coordination	-	-	-	-	138.01	1	138.01	• This cost represents the average cost of program coordination over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 3 hours per month at $69.38/hour (total cost over 5 years = $69.38/hour * 3 hours/month * 12 months/year * 5 years = $12,488.40) • Calculated from the total cost over 5 years divided by the total number of cases over 5 years (N = 100) • Alberta Health Services Operational and Financial Impact Analysis – Middle Ear Implant
• Troubleshooting equipment – maintenance, inventory, and loaners	-	-	-	-	142.43	1	142.43	• This cost represents the average cost of equipment maintenance over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: 3 hours per month at a cost of $72.60/hour (total cost over 5 years = $71.60/hour * 3 hours/month * 12 months/year * 5 years = $12,888.00) • Calculated from total cost over 5 years divided by the total number of cases over 5 years (N = 100) • Alberta Health Services Operational and Financial Impact Analysis – Middle Ear Implant
• Booths, equipment (such as computers, audiometers and programming equipment), and clerical support	-	-	-	-	27.63	1	27.63	• This cost represents the average cost of booths and equipment over 5 years, assuming a 5% inflation rate on the current cost each year for 5 years • Current cost: $500.00 per year (total cost over 5 years = $2,500.00) • Calculated from total cost over 5 years divided by the total number of cases over 5 years (N = 100)

Table 9. Estimation of average cost of MEI per case

Item	Alberta Health and Wellness administrative data				Alberta Health Services Operational and Financial Impact Analysis			
	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source	Unit cost ($Cdn)	Quantity	Total cost ($Cdn)	Information Source
								• Alberta Health Services Operational and Financial Impact Analysis – Middle Ear Implant
Other								
• Revision or re-implantation surgery	6,453.26	1	6,453.26	*5% of patients would require a revision surgery • Same as initial procedure above	-	-	-	-
Total cost per procedure								
Vibrant Soundbridge	26,774.97			• Average cost per case for adult patients, assuming: - 5% inflation rate each year for 5 years - 3% of patients receive counselling - 5% of patients have a revision surgery	19,881.65			• Average cost per case for adult patients, assuming: - 5% inflation rate each year for 5 years - 3% of patients receive counselling • Does not include pre-admission clinic visit, surgical liaison fees, physician fees (ENT pre-procedural, procedural, or post-procedural, or anesthesiologist), anesthesia supplies, inpatient hospital stay, or revision surgery as these were not included as a part of the Alberta Health Services Operational and Financial Impact Analysis
	27,918.18			• Average cost per case for pediatric patients (under 18 years of age), assuming: - 5% inflation rate each year for 5 years - 3% of patients receive general counselling - all patients receive pediatric-specific counselling by social worker, speech language pathologist, and psychologist - 5% of patients have a revision surgery				

Conclusions

Based on the findings of the review, there is a small group of patients for whom MEI comprises the only treatment option. These patients are as follows:

1. Patients with moderate to severe sensorineural hearing loss who are medically unable to wear hearing aids (e.g. patients with ear canal atresia or chronic otitis) or who have failed treatment with conventional hearing aids (e.g., patients who, after proper fittings, experience insignificant improvements in hearing, feedback issues, etc., or who experience complications related to their hearing aid).
2. Patients with moderate to severe hearing loss (with conductive or mixed hearing loss) who are ineligible for BAHA who are also either unable to wear or were unsuccessfully treated with conventional hearing aids.

Studies examining the safety and effectiveness of MEI to date are limited in both quantity and quality. Nevertheless, they present promising results. In patients who are unable to wear hearing aids, MEI appears to offer improvements in functional gain, speech perception, speech recognition, and quality of life over no treatment.

The cost of treating such patients with MEI (approximately 100 patients) in Alberta over a 5 year period is estimated to be $2,677,497.

Appendices

Appendix A – Literature searches

Two separate literature searches were run for the clinical review - one for cochlear implants, and the other for BAHA and MEI. Additional searches were run to identify economic studies and information for the "S" (social and demographic) components of the review. Searches were run during the period May 18 to June 14, 2011. Monthly update searches were run in PubMed throughout the project until September 3, 2011.

1. Cochlear implants (*search strategy reproduced from Bond, et al (2009)[86]

MEDLINE (Ovid, 1948 to May Week 1, 2011)

1	exp hearing loss/	46956
2	exp hearing loss, sensorineural/	17081
3	hearing loss, bilateral/	1473
4	exp deafness/	21758
5	severe to profound deafness.mp.	43
6	(severe adj4 deaf$).mp.	399
7	(profound adj4 deaf$).mp.	630
8	hearing loss, unilateral/	225
9	exp hearing disorders/	61653
10	deaf$.ti,ab.	24958
11	(hear$ adj5 loss).ti,ab.	25061
12	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	76910
13	exp ear, middle/ or exp ear, inner/	55112
14	12 or 13	118885
15	cochlear implants/	5398
16	cochlear diseases/	622
17	cochlear implantation/	2413
18	(cochlear adj10 (implant$ or device$)).ti,ab.	6615
19	15 or 16 or 17 or 18	8273
20	14 and 19	6649
21	limit 20 to humans	6039
22	randomized controlled trial.pt.	305548
23	controlled clinical trial.pt.	82300
24	randomized controlled trials/	72816
25	random allocation/	71302
26	double-blind method/	109663
27	single-blind method/	14889

28	exp evaluation studies/	149366
29	exp clinical Trial/	637424
30	clinical trial.pt.	461909
31	(clin$ adj5 trial$).mp.	681629
32	22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31	1063304
33	((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw.	108172
34	exp placebos/	29555
35	placebo$.tw.	128204
36	random$.tw.	514341
37	exp research design/	283392
38	33 or 34 or 35 or 36 or 37	741135
39	32 or 38	1368460
40	limit 39 to humans	1176532
41	21 and 40	661
42	(review or review-tutorial or review-academic).pt.	1602450
43	(Medline or Medlars or EMBASE).ti,ab,sh.	39997
44	(scisearch or psychinfo or psycinfo).ti,ab,sh.	4695
45	(psychlit or psyclit).ti,ab,sh.	808
46	cinahl.ti,ab,sh.	5136
47	((hand adj59 search$) or (manual$ adj9 search$)).mp.	6260
48	(electronic database$ or bibliographic database$ or computeri#ed database$ or online database$).mp.	7820
49	(pooling or pooled or mantel haenszel).mp.	32188
50	(peto or dersimonian or der simonian or fixed effect).mp.	1977
51	43 or 44 or 45 or 46 or 47 or 48 or 49 or 50	79203
52	42 and 51	36597
53	meta-analysis.pt.	28291
54	meta-analysis.sh.	28291
55	(meta-analys$ or meta analys$ or metaanalys$).mp.	48552
56	(systematic$ adj9 review$).mp.	29817
57	(systematic$ adj9 overview$).mp.	665
58	(quantitativ$ adj9 review$).mp.	2582
59	(quantitativ$ adj9 overview$).mp.	202
60	(quantitativ$ adj9 synthesis$).mp.	1699
61	(methodologic$ adj9 review$).mp.	3759
62	(methodologic$ adj9 overview$).mp.	226
63	(integrative research review$ or research integration).mp.	68

64	53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63	74689
65	52 or 64	93667
66	21 and 65	29
67	41 not 66	654
68	waiting lists/	6736
69	(wait$ adj10 (surgery or operat$ or implant$ or list$ or control$)).ti,ab.	8469
70	exp case-control studies/ or exp cohort studies/	1194848
71	68 or 69 or 70	1204536
72	21 and 71	1276
73	72 not (66 or 67)	1078
74	limit 73 to yr="2007 - Current"	359
75	limit 73 to yr="1902 - 2006	719

MEDLINE In-Process & Other Non-Indexed Citations (Ovid May 17, 2011)

1	severe to profound deafness.mp.	2
2	(severe adj4 deaf$).mp.	16
3	(profound adj4 deaf$).mp.	24
4	deaf$.ti,ab.	888
5	(hear$ adj5 loss).ti,ab.	957
6	1 or 2 or 3 or 4 or 5	1704
7	(cochlear adj10 (implant$ or device$)).ti,ab.	430
8	6 and 7	172
9	randomized controlled trial.pt.	536
10	controlled clinical trial.pt.	23
11	clinical trial.pt.	377
12	(clin$ adj5 trial$).mp.	9251
13	9 or 10 or 11 or 12	9418
14	((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw.	3109
15	placebo$.tw.	4186
16	random$.tw.	32888
17	14 or 15 or 16	34832
18	13 or 17	40592
19	8 and 18	5
20	(review or review-tutorial or review-academic).pt.	922
21	meta-analysis.pt.	33
22	(meta-analys$ or meta analys$ or metaanalys$).mp.	2626

23	(systematic$ adj9 review$).mp.	3357
24	(systematic$ adj9 overview$).mp.	50
25	(quantitativ$ adj9 review$).mp.	176
26	(quantitativ$ adj9 overview$).mp.	15
27	(quantitativ$ adj9 synthesis$).mp.	113
28	(methodologic$ adj9 review$).mp.	271
29	(methodologic$ adj9 overview$).mp.	9
30	(integrative research review$ or research integration).mp.	3
31	20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30	6427
32	8 and 31	0
33	(wait$ adj10 (surgery or operat$ or implant$ or list$ or control$)).ti,ab.	407
34	8 and 33	1

PubMed (May 18, 2011)

#5 Search #2 AND #3 AND #4	111
#4 Search Controlled clinical trial[pt] OR controlled clinical trials as topic[mh] OR clinical trial[pt] OR clinical trials as topic[mh] OR "clinical trial"[tiab] OR evaluation studies[pt] OR evaluation studies as Topic[mh] OR control[tiab] OR controlled[tiab] OR volunteer[tiab] OR volunteers[tiab] OR open label*[tiab] OR nonrandom*[tiab] OR non random*[tiab] OR quasirandom*[tiab] OR Observational stud*[tiab] OR Cohort studies[Mesh] OR cohort[tiab] OR Longitudinal studies[Mesh] OR longitudinal[tiab] OR Prospective studies[Mesh] OR prospective[tiab] OR Follow-up studies[Mesh] OR follow up stud*[tiab] OR followup stud*[tiab] OR Retrospective studies[Mesh] OR retrospective[tiab] OR Population based stud*[tiab] OR Population based analy*[tiab] OR Population study[tiab] OR Population studies[tiab] OR descriptive stud*[tiab] OR Multidimensional stud*[tiab] OR "Comparative Study"[Publication Type] OR Comparative study[tiab] OR comparative studies[tiab] OR Case-control studies[Mesh] OR case control*[tiab] OR case series[tiab] OR case comparison*[tiab] OR Case history[tiab] OR Case histories[tiab]	4916752
#3 Search publisher[sb] OR in process[sb] OR pubmednotmedline[sb]	1568137
#2 Search cochlear implant*[tiab]	6865

Cochrane Library (John Wiley; Issue 5 of 12, May 2011)

Cochrane Reviews [4] | Other Reviews [4] | Clinical Trials [87] | Methods Studies [1] | Technology Assessments [24] | Economic Evaluations [41]

#1	MeSH descriptor Hearing Loss explode all trees	728
#2	MeSH descriptor Deafness explode all trees	184
#3	MeSH descriptor Hearing Disorders explode all trees	1167
#4	(severe to profound deafness)	23
#5	(severe NEAR/5 deaf*)	28
#6	(profound* NEAR/5 deaf*)	43

#7	deaf*	723
#8	(hear* NEAR/5 loss)	1274
#9	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8)	2156
#10	cochlear implants	234
#11	MeSH descriptor Cochlear Implantation explode all trees	71
#12	MeSH descriptor Cochlear Implants explode all trees	1
#13	(cochlea* NEAR/10 (implant* or device* or prosthe*))	271
#14	(#10 OR #11 OR #12 OR #13)	272
#15	(#9 AND #14)	162

EMBASE (Ovid, 1980 to 2011 Week 19)

1	exp hearing impairment/	67750
2	exp congenital deafness/	3263
3	perception deafness/	12736
4	hearing loss/ or mixed hearing loss/ or unilateral hearing loss/	18630
5	exp ear disease/	96371
6	severe to profound deafness.mp.	52
7	(severe adj4 deaf$).mp.	480
8	(profound adj4 deaf$).mp.	750
9	deaf$.ti,ab.	27738
10	(hear$ adj5 loss).ti,ab.	29631
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10	151846
12	cochlea prosthesis/	8058
13	implantation/	30374
14	(cochlea$ adj10 (implant$ or device$ or prosthe$)).ti,ab.	8189
15	12 or 13 or 14	38111
16	11 and 15	7096
17	limit 16 to human	6462
18	randomization/	53429
19	controlled study/	3499254
20	single blind procedure/	13814
21	placebo/	177867
22	double blind procedure/	100038
23	clinical trial/	824153
24	crossover procedure/	30256
25	placebo$.tw.	156236

26	blind$ fashion.tw.	5007
27	random$.tw.	632763
28	clinical trial$.tw.	195723
29	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28	4320071
30	limit 29 to human	2720547
31	17 and 30	1466
32	exp meta analysis/	54574
33	meta#analy$.ab,sh,ti.	55284
34	methodologic$ review$.ab,sh,ti.	231
35	methodologic$ overview$.ab,sh,ti.	49
36	(integrative research adj5 review$).mp. or research integration.ab,ti.	83
37	quantitat$ synthesis.ab,sh,ti.	209
38	quantitat$ review$.ab,sh,ti.	494
39	quantitat$ overview$.ab,sh,ti.	88
40	systematic$ review$.ab,sh,ti.	58265
41	systematic$ overview$.ab,sh,ti.	502
42	32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41	92131
43	17 and 42	32
44	43 not 31	18
45	cohort analysis/	97818
46	(wait$ adj10 (surgery or operat$ or implant$ or list$ or control$)).ti,ab.	11061
47	45 or 46	108661
48	17 and 47	61
49	48 not (44 or 31)	31

Web of Science (with conference proceedings, ISI) (May 19, 2011)

# 8	168	#7 AND #6 Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 7	>100,000	Topic=((trial* or random*)) Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 6	3,592	#5 AND #4 Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 5	7,743	Topic=((cochlea* implant*)) OR Topic=((cochlea* SAME implant*)) OR Topic=((cochlea* SAME device*)) OR Topic=((cochlea* SAME prosthe*)) Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 4	56,334	#3 OR #2 OR #1 Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 3	10,100	Topic=((hear* SAME/5 loss)) Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years

# 2	30,915	Topic=((severe SAME/5 deaf*)) OR Topic=((profound* SAME/5 deaf*)) OR Topic=(deaf*) Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 1	35,169	Topic=((hearing loss or deafness or hearing disorders)) Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years

Biosis Previews (ISI) (May 19, 2011)

# 5	105	#4 AND #3 Databases=PREVIEWS Timespan=All Years
# 4	>100,000	Topic=((trial* or random*)) Databases=PREVIEWS Timespan=All Years
# 3	3,144	#2 AND #1 Databases=PREVIEWS Timespan=All Years
# 2	>100,000	Topic=(deaf*) OR Topic=((hear* SAME/5 loss)) Databases=PREVIEWS Timespan=All Years
# 1	4,897	Topic=((cochlea* SAME (implant* or device* or prosthe*))) Databases=PREVIEWS Timespan=All Years

Centre for Reviews & Dissemination (DARE and HTA databases only) (May 19, 2011)

1	(cochlea*) IN DARE, HTA	44
2	implant* or device* or prosthe*	3170
3	implant* or device* or prosthe*	3170
4	#1 AND #2	41

2. MEI & BAHA search (May 25, 2011)

PubMed (May 25, 2011)

#24 Search #22 OR #23	2935
#23 Search #21 Limits: Humans	2926
#22 Search #21 AND (in process[sb] OR publisher[sb] OR pubmednotmedline[sb])	9
#21 Search #7 AND (#16 OR #20)	3059
#20 Search #17 OR #18 OR #19	484
#19 Search bone anchored hearing[tiab]	348
#18 Search bone anchored implant*[tiab]	28
#17 Search baha[tiab]	333
#16 Search #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15	4990
#15 Search (Vibrant[tiab] OR Soundbridge[tiab] OR Sound Bridge[tiab] OR Med El[tiab] OR Envoy[tiab] OR Esteem[tiab] OR Symphonix[tiab]) AND (hearing[tiab] OR implant[tiab] OR implants[tiab] OR middle ear[tiab])	390
#14 Search Carina[tiab] AND (hearing[tiab] OR implant[tiab] OR implants[tiab] OR middle ear[tiab])	14
#13 Search implantable hearing[tiab]	199
#12 Search implantable middle ear[tiab]	58

#11	Search middle ear implant*[tiab]	192
#10	Search ear, middle/surgery	3644
#9	Search ossicular prosthesis[mh] AND (ear, middle OR middle ear[tiab])	576
#8	Search prosthesis implantation[mh] AND (ear, middle OR middle ear[tiab])	752
#7	Search #1 OR #2 OR #3 OR #4 OR #5 OR #6	62703
#6	Search hearing aids[mh]	10815
#5	Search otologic surgical procedures[mh]	12609
#4	Search deaf[ti]	5004
#3	Search deafness[mh]	21823
#2	Search hearing loss[ti]	8401
#1	Search hearing loss[mh]	46920

PubMed (broader search for device names, May 30, 2011)

#74	Search #73 NOT #70	152
#73	Search #71 AND #72	444
#72	Search hearing[tiab] OR implant[tiab] OR implants[tiab] OR implantation[tiab] OR middle ear[tiab]	231893
#71	Search Carina[tiab] OR Vibrant[tiab] OR Soundbridge[tiab] OR Sound Bridge[tiab] OR Med El[tiab] OR Envoy[tiab] OR Esteem[tiab] OR Symphonix[tiab]	13950
#70	Search ((hearing loss[mh]) OR (hearing loss[ti]) OR (deafness[mh]) OR (deaf[ti]) OR (otologic surgical procedures[mh]) OR (hearing aids[mh])) AND (((prosthesis implantation[mh] AND (ear, middle OR middle ear[tiab])) OR (ossicular prosthesis[mh] AND (ear, middle OR middle ear[tiab])) OR (ear, middle/surgery) OR (middle ear implant*[tiab]) OR (implantable middle ear[tiab]) OR (implantable hearing[tiab]) OR (Carina[tiab] AND (hearing[tiab] OR implant[tiab] OR implants[tiab] OR middle ear[tiab])) OR ((Vibrant[tiab] OR Soundbridge[tiab] OR Sound Bridge[tiab] OR Med El[tiab] OR Envoy[tiab] OR Esteem[tiab] OR Symphonix[tiab]) AND (hearing[tiab] OR implant[tiab] OR implants[tiab] OR middle ear[tiab]))) OR ((baha[tiab]) OR (bone anchored implant*[tiab]) OR (bone anchored hearing[tiab])))	3061

MEDLINE (Ovid, MEDLINE, In-process & other non-indexed citations, 1946 to present) (May 25, 2011)

1	exp Hearing Loss/	47051
2	hearing loss.ti.	8306
3	exp Deafness/	21776
4	deaf.ti.	4790
5	exp Otologic Surgical Procedures/	12633
6	exp Hearing Aids/	10939
7	1 or 2 or 3 or 4 or 5 or 6	62506
8	exp Prosthesis Implantation/	57386
9	exp Ossicular Prosthesis/	785
10	8 or 9	58016
11	exp Ear, Middle/	16609

12	middle ear.ti,ab.	14817
13	11 or 12	24217
14	10 and 13	820
15	exp Ear, Middle/su [Surgery]	3360
16	middle ear implant$.ti,ab.	190
17	implantable middle ear.ti,ab.	58
18	implantable hearing.ti,ab.	197
19	Carina.ti,ab.	1417
20	Vibrant.ti,ab.	404
21	Soundbridge.ti,ab.	83
22	Sound Bridge.ti,ab.	6
23	Med El.ti,ab.	214
24	Envoy.ti,ab.	36
25	Esteem.ti,ab.	11780
26	Symphonix.ti,ab.	15
27	hearing.ti,ab.	57465
28	implant$.ti,ab.	223063
29	middle ear.ti,ab.	14817
30	baha.ti,ab.	329
31	bone anchored implant$.ti,ab.	29
32	bone anchored hearing.ti,ab.	338
33	30 or 31 or 32	476
34	7 and 14	642
35	15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26	17422
36	27 or 28 or 29	287499
37	35 and 36	2494
38	33 or 34 or 37	3281
39	limit 38 to humans	2887

EMBASE (Ovid, 1980 to 2011 Week 20)

1	*hearing loss/	8397
2	*hearing impairment/	21521
3	*hearing aid/	5380
4	exp middle ear prosthesis/	516
5	*middle ear surgery/	631
6	1 or 2 or 3 or 4 or 5	34361
7	exp middle ear implant/	107

8	carina.mp.	1705
9	otologic.mp.	2292
10	vibrant.mp.	525
11	soundbridge.mp.	114
12	sound bridge.mp.	10
13	Med El.mp.	418
14	Envoy.mp.	130
15	Esteem.mp.	17777
16	Symphonix.mp.	46
17	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16	22859
18	(implant or implants or implantable or middle ear or hearing or deaf$).ti,ab.	199615
19	17 and 18	1921
20	6 and 17	573
21	BAHA.mp.	383
22	*bone anchored hearing aid/	131
23	21 or 22	407
24	19 or 20 or 23	2377
25	limit 24 to human	2101

The Cochrane Library (John Wiley, Issue 5 of 12, May 2011)
Cochrane Reviews [90] | Other Reviews [16] | Clinical Trials [326] | Methods Studies [1] | Technology Assessments [45] | Economic Evaluations [50]

#1	(hearing loss) or (deafness) or (hearing aids)	1979
#2	(implantation) or (implant*) or (vibrant) or (soundbridge) or (sound bridge) or (med el) or (otologic*) or (carina) or (envoy) or (esteem) or (symphonix) or (middle ear) or (baha) or (bone anchored)	15083
#3	(implantation or implant* or vibrant or soundbridge or sound bridge) or (med el or otolotic* or carina or envoy or esteem)	13232
#4	(symphonix or middle ear) or (baha or bone anchored)	1812
#5	(#1 AND (#2 OR #3 OR #4))	532

Centre for Reviews and Dissemination (DARE, NHS EED, HTA) databases (May 26, 2011)

1	(hearing loss) OR (deafness) OR (hearing aids)	259
2	(implantation) OR (implant*) OR (vibrant) OR (soundbridge) OR (sound bridge)	1378
3	(med el) OR (otologic*) OR (carina) OR (envoy) OR (esteem)	131
4	(symphonix) OR (middle ear) OR (baha) OR (bone anchored)	83

5	#2 OR #3 OR #4	1571
6	#1 AND #5	89

Web of Science (with conference proceedings, Thomson Reuters) (May 26, 2011)

# 5	1,257	#4 AND #1 Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 4	>100,000	#3 OR #2 Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 3	377	Title=(baha OR "bone anchored hearing") Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 2	>100,000	Title=(implant* OR vibrant OR soundbridge OR "sound bridge" OR "med el" OR otologic* OR carina OR envoy OR esteem OR symphonix OR "middle ear") Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 1	28,011	Title=("hearing loss" OR deaf* OR "hearing aid*") Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years

EconLit (EBSCOhost) (May 26, 2011)

S1	TI hearing loss or AB hearing loss or TI hearing aid* or AB hearing aid* or TI deaf* or AB deaf* or TI middle ear or AB middle ear	51 *took this set as none of others were relevant
S2	baha or bone anchored	13
S3	vibrant or soundbridge or sound bridge or med el or carina or otologic* or esteem or envoy or symphonix	499
S4	S2 or S3	512
S5	S1 and S4	0

CINAHL (EBSCOhost) (May 26, 2011)

S10	S7 and S8 Limiters - Exclude MEDLINE records	70
S9	S7 and S8	413
S8	S5 or S6	7066
S7	S1 or S2 or S3 or S4	16797
S6	bone anchored hearing or baha	165
S5	(vibrant soundbridge or soundbridge) or vibrant sound bridge or med el or carina or otologic* or envoy or esteem or symphonix	6901
S4	"middle ear implant*" OR (MM "Ear, Middle+")	1239
S3	(MM "Hearing Aids+")	5546

S2	(MM "Hearing Loss, Central") OR (MH "Hearing Loss, Conductive") OR (MM "Hearing Loss, Functional") OR (MM "Hearing Loss, Noise-Induced") OR (MM "Hearing Loss, Partial+") OR (MM "Hearing Loss, Sensorineural+")	2922
S1	(MM "Hearing Disorders+") OR (MM "Deafness+") OR (MM "Hearing Loss, Partial+")	11483

PsycINFO (OVID, 1987 to May Week 4 2011)

10	limit 9 to human	151
9	7 and 8	154
8	3 or 4 or 5 or 6	28980
7	1 or 2	9426
6	(baha or bone anchored hearing).mp.	21
5	(med el or carina or otologic* or envoy or esteem or symphonix).mp.	28959
4	(vibrant soundbridge or vibrant sound bridge).mp.	0
3	(vibrant soundbridge or vibrant sound bridge).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]	0
2	exp *Middle Ear/ or middle ear implant*.mp.	130
1	exp *Deaf/ or exp *Hearing Disorders/ or hearing loss.mp. or exp *Hearing Aids/	9333

3. Economics search (June 7, 2011)

Limits: middle ear implants only, 5 years

PubMed (June 7, 2011)
*using the CADTH economic filter

#16	Search (#11 OR #12) AND #2 Limits: published in the last 5 years	13
#13	Search (#11 OR #12) AND #2	25
#12	Search #9 OR #10	466
#11	Search (#3 OR #4 OR #5) AND (#6 OR #7 OR #8)	273
#10	Search (Vibrant[tiab] OR Soundbridge[tiab] OR Sound Bridge[tiab] OR Med El[tiab] OR Envoy[tiab] OR Esteem[tiab] OR Symphonix[tiab]) AND (hearing OR implant* OR middle ear)	407
#9	Search Carina[tiab] AND (hearing OR implant* OR middle ear)	60
#8	Search implantable hearing[tiab]	199
#7	Search implantable middle ear[tiab]	58
#6	Search middle ear implant*[tiab]	192
#5	Search hearing aids[mh]	10850
#4	Search hearing loss[ti]	8414
#3	Search hearing loss[mh]	47028
#2	Search "Cost-Benefit Analysis"[MeSH] OR "costs and cost analysis"[MeSH] OR "Cost Savings"[MeSH]	

OR cost-effective*[tiab] OR economics[majr] OR EC[sh] OR cost[tiab] OR costs[tiab] OR costing[tiab] OR economic*[tiab] OR "sensitivity analysis"[tiab] OR pharmacoeconomic*[tiab]

EMBASE (Ovid, 1980 to 2011 Week 22)
*using the Scottish Intercollegiate Guidelines (SIGN economic filter)

1	*hearing loss/	8431
2	*hearing impairment/	21581
3	*hearing aid/	5398
4	exp middle ear prosthesis/	518
5	1 or 2 or 3 or 4	33865
6	exp middle ear implant/	110
7	carina.mp.	1710
8	otologic.mp.	2300
9	vibrant.mp.	531
10	soundbridge.mp.	119
11	sound bridge.mp.	10
12	Med El.mp.	440
13	Envoy.mp.	130
14	Esteem.mp.	17858
15	Symphonix.mp.	46
16	6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15	22982
17	5 and 16	530
18	Socioeconomics/	90369
19	Cost benefit analysis/	55528
20	Cost effectiveness analysis/	72411
21	Cost of illness/	11398
22	Cost control/	38306
23	Economic aspect/	85399
24	Financial management/	91627
25	Health care cost/	99285
26	Health care financing/	10418
27	Health economics/	30157
28	Hospital cost/	10849
29	(fiscal or financial or finance or funding).tw.	73025
30	Cost minimization analysis/	1837
31	(cost adj estimate$).mp.	1393
32	(cost adj variable$).mp.	119
33	(unit adj cost$).mp.	1508

34	or/18-33	532843
35	17 and 34	13
36	limit 35 to yr="2006 -Current"	3

Centre for Reviews and Dissemination (DARE, NHS EED, HTA) databases (June 7, 2011)

1	MeSH DESCRIPTOR Hearing Aids EXPLODE ALL TREES	76
2	MeSH DESCRIPTOR Hearing Loss EXPLODE ALL TREES	107
3	vibrant OR soundbridge OR "sound bridge" OR esteem OR envoy OR symphonix OR carina	122
4	cost OR costs OR costing OR economic OR "quality of life"	18820
5	#1 OR #2 OR #3	261
6	#4 AND #5	137
7	* FROM 2006 TO 2011	22495
8	#6 AND #7	50

Econlit (EBSCOhost) (June 7, 2011)

S5	S2 and S4	0
S4	S1 or S3	278
S3	hearing or deaf*	278
S2	vibrant or soundbridge or sound bridge or esteem or envoy or esteem or carina or symphonix or med el	503
S1	hearing loss or hearing aid* or middle ear	25

Web of Science (with conference proceedings, Thomson Reuters) (June 8, 2011)

# 4	17	#3 Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=2006-2011
# 3	56	#2 AND #1 Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 2	>100,000	Title=(cost OR costing OR costs OR economic) Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years
# 1	28,097	Title=("hearing loss" OR deaf* OR "hearing aid*") OR Author=(vibrant OR soundbridge OR "sound bridge" OR "med el" OR otologic* OR carina OR envoy OR esteem OR symphonix OR "middle ear") Databases=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=All Years

4. Social & demographic search (June 21, 2011)

PubMed	
#64 Search #63 Limits: published in the last 5 years	120
#63 Search #27 AND (#58 OR #59 OR #60 OR #61 OR #62)	548
#62 Search equity[ti] OR inequality[ti] OR access*[ti] OR "social justice"[ti] OR value*[ti]	145913
#61 Search health services **accessibility**[mh]	70017
#60 Search healthcare disparities[mh]	3423
#59 Search bioethic*[ti]	3241
#58 Search **ethics**[mh] OR ethic*[ti]	134413
#55 Search #54 Limits: published in the last 5 years	240
#54 Search #27 AND (#52 OR #53)	680
#53 Search adherence[ti] OR **compliance**[ti] OR acceptability[ti] OR noncompliance[ti] OR satisfaction[ti] OR dissatisfaction[ti] OR motivation[ti] OR preference*[ti]	61554
#52 Search patient acceptance of healthcare[mh]	131954
#45 Search #44 Limits: published in the last 5 years	190
#47 Related Articles by Review for PubMed (Select 21300418)	36
#44 Search #27 AND #43	471
#43 Search #40 OR #41 OR #42	158350
#42 Search well-being[ti] OR wellbeing[ti] OR QOL[ti] OR HRQOL[ti] OR HRQL[ti] OR quality-adjusted[ti] OR self-rated[ti] OR "burden of disease"[ti] OR stigma[ti] OR depression[ti]	65430
#41 Search quality-adjusted life years[mh] OR qaly*[ti]	5072
#40 Search **quality of life**[mh] OR quality of life[ti]	92888
#37 Search #30 Limits: Humans, Practice Guideline, Randomized Controlled Trial, Review, Comparative Study, Consensus Development Conference, Consensus Development Conference, NIH, Evaluation Studies, English, published in the last 5 years	246
#38 Select 1 document(s)	1
#36 Search #30 AND (in process[sb] OR publisher[sb] OR pubmednotmedline[sb])	7
#32 Search #29 AND (Canada OR Alberta OR Edmonton OR Calgary)	155
#30 Search #29 Limits: published in the last 5 years	1411
#29 Search #27 AND #28	4580
#28 Search #15 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24	1754219
#27 Search #10 OR #11 OR #12 OR #13 OR #14	53398
#24 Search sex distribution[mh]	41097
#23 Search age distribution[mh]	43684
#22 Search demography[mh]	789870
#21 Search burden[ti]	9075
#20 Search prevalence[mh] OR prevalence[ti]	174256
#19 Search incidence[mh] OR incidence[ti]	181993
#15 Search /**epidemiology**	1377260
#14 Search implantable hearing[tiab]	199
#13 Search implantable middle ear[tiab]	58
#12 Search middle ear implant*[tiab]	193

#11 Search hearing aids[mh] OR hearing aids[ti]	10973
#10 Search hearing loss[mh] OR hearing loss[ti]	48504

5. Grey literature (June 9-13, 2011)
*unless otherwise shown, search terms included: hearing OR middle ear OR vibrant OR soundbridge OR carina OR esteem OR envoy OR symphonix

HTA web sites

Canada
British Columbia Centre for Health Services and Policy Research (CHSPR) www.chspr.ubc.ca/publications (scanned health technology assessment publications 1988-2004)
Canadian Agency for Drugs and Technologies in Health (CADTH) www.cadth.ca
Institut national d'excellence en santé et en services sociaux (INESSS) www.inesss.qc.ca/index.php?id=49 (scanned list of publications, currently only available in French)
Institute for Clinical Evaluative Sciences (ICES) www.ices.on.ca
Institute of Health Economics (IHE) www.ihe.ca (scanned publications lists 2006-2011)
McGill University Health Centre. Technology Assessment Unit (TAU) www.mcgill.ca/tau/ (scanned publications lists 2002-2011, and work in progress)
Ontario Medical Advisory Secretariat (MAS)
www.health.gov.on.ca/english/providers/program/mas/mas_about.html
Programs for Assessment of Technology in Health (PATH) www.path-hta.ca/ (scanned publications lists 1998-2011)

International
Adelaide Health Technology Assessment (AHTA) www.adelaide.edu.au/ahta/pubs/ (scanned publications lists 2004-2011)
Aetna Clinical Policy Bulletins http://www.aetna.com/healthcare-professionals/policies-guidelines/cpb_legal.html (search terms: middle ear / implantable hearing)
Aggressive Research Intelligence Facility (ARIF) http://www.arif.bham.ac.uk/index.shtml (search terms: "middle ear"
Australian Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)
www.surgeons.org/racs/research-and-audit/asernip-s/asernip-s-publications (scanned publications lists, various dates)
EuroScan www.euroscan.org.uk/
Joanna Briggs Institute www.joannabriggs.edu.au (search term: middle ear)
National Institute for Health and Clinical Excellence (NICE) www.nice.org.uk (search terms: middle ear / hearing)
Southern Health (formerly the Centre for Clinical Effectiveness)
http://www.southernhealth.org.au/page/Health_Professionals/CCE/Evidence_reviews/Current/ (scanned list of current and archived evidence reviews)
UK National Horizon Scanning Centre (NHSC) www.haps.bham.ac.uk/publichealth/horizon/index.shtml (scanned briefings in ear, nose & throat category)
California Health Benefits Review Program (CHBRP) www.chbrp.org/docs/index.php?action=view&op=requests (search terms: ear / hearing)
California Technology Assessment Forum (CTAF) http://www.ctaf.org/ (search terms: middle ear / hearing)
US Veterans Affairs Technology Assessment Program (VATAP) http://www.va.gov/VATAP/Phase2pubspage.asp (scanned publications lists 2001-2011)
Washington State Health Care Authority HTA www.hta.hca.wa.gov/assessments.html (scanned publications lists (2007-2011)

Regulatory
Health Canada. Medical Devices Active License Listing (MDALL) www.mdall.ca (searched for names of middle ear implant, BAHA & cochlear implant devices)
US Food & Drug Administration www.fda.gov (search terms: "middle ear implant*" / "middle ear hearing" / "Vibrant Soundbridge" / Esteem and hearing / Carina and hearing) + device name search of the MAUDE database of Manufacturer and User Facility Device Experience Database for reports of adverse events

Guidelines
BC Guidelines www.bcguidelines.ca (scanned list of guidelines)
CMA Infobase http://www.cma.ca/clinicalresources/practiceguidelines (search terms: hearing)
Guidelines.gov www.guidelines.gov
Guidelines Advisory Committee (GAC)
http://www.gacguidelines.ca/index.cfm?pagepath=About_the_GAC&id=18840 (scanned list of archived guidelines)
New Zealand Guidelines Group (NZGG) http://www.nzgg.org.nz/index.cfm?fuseaction=search (search terms: "middle ear" / hearing)
Scottish Intercollegiate Guidelines Network (SIGN) www.sign.ac.uk (scanned list of ear, nose & throat guidelines)
Toward Optimized Practice (TOP)
http://www.topalbertadoctors.org/informed_practice/clinical_practice_guidelines.html (scanned list of guidelines)

Clinical trials
ClinicalTrials.gov www.clinicaltrials.gov (search terms: "middle ear implant*" OR "middle ear hearing" OR soundbridge OR carina OR esteem OR envoy | hearing loss)
Current Controlled Trials http://www.controlled-trials.com/ (search terms: "middle ear")
CenterWatch www.centerwatch.com/clinical-trials/
Conference proceedings
Biosis (ISI Web of Knowledge, restricted to document type "meeting")
22 Topic=((hearing OR "middle ear") AND (vibrant OR soundbridge OR carina OR esteem OR envoy OR symphonix)) Refined by: Document Type=(MEETING) Databases=PREVIEWS Timespan=All Years
196 Topic=((hearing OR "middle ear") AND (vibrant OR soundbridge OR carina OR esteem OR envoy OR symphonix)) Databases=PREVIEWS Timespan=All Years

Additional web sites and sources

Hearing Loss Association of America www.hearingloss.org/convention (searched annual conference programs 2008-2011 for term middle ear)
NLM Gateway http://gateway.nlm.nih.gov/gw/Cmd (search terms: (hearing loss OR middle ear) AND (vibrant OR soundbridge OR carina OR esteem OR envoy OR symphonix))http://www.nlmgateway.gov/
Envoy Medical www.envoymedical.com
Otologics www.otologics.org
Med El www.medel.com
US National Institutes of Health. National Institute on Deafness and Other Communication Disorders
http://www.nidcd.nih.gov/ (search terms: "implantable hearing" / "implantable middle ear")
New York Academy of Medicine Grey literature collection http://www.nyam.org/library/online-resources/grey-literature-report/ (search terms: hearing loss)
NHS Evidence http://www.evidence.nhs.uk/

Google www.google.ca (hearing OR "middle ear") AND (vibrant OR soundbridge OR carina OR esteem OR envoy OR symphonix) *scanned first 25 pages of approximately 43,700,000 results

Appendix B – Evidence tables: included studies

Description of studies meeting initial inclusion/exclusion criteria

Study	Design	Patients	Outcome Measures	Quality
Middle Ear Implants				
Vibrant Soundbridge				
Babighian & Mazzoli (2005)[109]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Italy *Comparator:* preoperative unaided, Vibrant P, Vibrant D, hearing aids *Modifications:* NR *Length of F/U:* NR	*Number:* 16 VSB entered & completed *Sex:* 9 male, 7 female *Age:* mean 50.1, range 27-81 years *Type of HL:* moderate severity *Pre-op unaided threshold:* mean AC 57.8dB (range 46-68dB) *Inclusion:* consecutive patients implanted with the VSB or Otologics MET	1. Functional gain 2. Threshold levels	*Oxford level of evidence:* IV
Batman et al (2007)[110]	*Design:* retrospective case series *Setting:* single academic center *Country:* Turkey *Comparator:* preoperative unaided *Modifications:* implanted on oval window in 1 patient *Length of F/U:* 2 months	*Number:* 2 entered & completed *Sex:* 1 male, 1 female *Age:* mean 35, range 30-40 years *Type of HL:* sensorineural & mixed, moderate severity, postlingual *Pre-op unaided threshold:* mean AC 58.5dB (range 53-73) *Inclusion:* consecutive patients implanted with VSB	1. Functional gain	*Oxford level of evidence:* IV
Beltrame et al (2009)[111]	*Design:* retrospective, with/without *Setting:* 2 academic centers *Country:* Italy *Comparator:* postoperative unaided *Modifications:* FMT on round window *Length of F/U:* NA (7-9 months post-surgery)	*Number:* 12 entered & completed *Sex:* 5 male, 7 female *Age:* mean 55.7, range 32-75 years *Type of HL:* mixed, severe *Pre-op unaided threshold:* mean AC 76dB, mean BC 39dB *Inclusion:* consecutive patients implanted with VSB	1. Functional gain 2. Threshold levels 3. Speech recognition using Italian or German sentences in 55dB noise 4. Speech reception threshold using Italian or German sentences - in quiet - in 55 & 70dB noise	*Oxford level of evidence:* IV
Boeheim et al (2010)[90]	*Design:* prospective, with/without *Setting:* single academic center *Country:* Austria *Comparator:* postoperative unaided & Delta 8000 (Oticon) open fit HA *Modifications:* NR *Length of F/U:* NA (mean 25.1 months post-surgery)	*Number:* 10 entered & completed *Sex:* NR *Age:* mean 59, range 44-73 years *Type of HL:* sensorineural *Pre-op unaided threshold:* NR *Inclusion:* 1. idiopathic SNHL 2. normal middle ear function 3. implanted with VSB	1. Threshold levels 2. Speech recognition using Freiburger monosyllables @ 60 & 80dB 3. Speech reception - using Oldenburg sentences in quiet & in 60dB noise - using Freiburger numbers in quiet	*Oxford level of evidence:* IV
Boheim et al (2007)[112 +]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Austria *Comparator:* unaided *Modifications:* FMT on incus *Length of F/U:* NR	*Number:* 9 entered & completed *Sex:* NR *Age:* NR *Type of HL:* sensorineural, moderate to severe high frequency hearing loss *Pre-op unaided threshold:* NR *Inclusion:* patients with high-frequency hearing loss	1. Functional gain	*Oxford level of evidence: IV*
Bruschini et al	*Design:* retrospective, pre/post	*Number:* 12 entered & completed	1. Threshold levels	*Oxford*

Study	Design	Patients	Outcome Measures	Quality
(2009)[113]	*Setting:* single academic center *Country:* Italy *Comparator:* preoperative unaided *Modifications:* transcanal approach, FMT on incus or round window *Length of F/U:* mean 21, range 15-32 months	*Sex:* 4 male, 8 female *Age:* mean 50, range 41-71 years *Type of HL:* sensorineural & mixed, moderate severity *Pre-op unaided threshold:* mean AC 61dB *Inclusion:* consecutive patients implanted with VSB	2. Speech recognition - words & phrases in quiet @ 65 dB - words & phrases in noise 3. Adverse events	*level of evidence:* IV
Colletti et al (2006)[114]	*Design:* single arm trial *Setting:* single academic center *Country:* Italy *Comparator:* preoperative & postoperative unaided *Modifications:* FMT on round window *Length of F/U:* 1 year	*Number:* 7 entered & completed *Sex:* 3 male, 4 female *Age:* mean 56.7, range 28-74 years *Type of HL:* mixed & conductive, moderate to severe *Pre-op unaided threshold:* mean AC 72.9dB (range 65-85dB), mean BC 36.6dB (range 8-53 dB) *Inclusion:* consecutive patients with hearing loss unsuitable for treatment with other devices such as HA, BAHA & conventional MEI placement	1. Functional gain 2. Threshold levels 3. Speech reception threshold (SRT50)	*Oxford level of evidence:* IV
Colletti et al (2009)[115]	*Design:* prospective, quasi-RCT (subjects alternately assigned to intervention) *Setting:* single academic center *Country:* Italy *Comparator:* preoperative unaided & total ossicular replacement prosthesis (TORP) *Modifications:* FMT placed on round window *Length of F/U:* 36 months	*Number:* 19 VSB & 19 TORP entered & completed *Sex:* 9 male, 10 female *Age:* mean 52, range 18-74 years *Type of HL:* mixed, moderate to severe, postlingual *Pre-op unaided threshold:* NR *Inclusion:* 1. bilateral chronic otitis media without cholesteatoma 2. bilateral moderate to severe hearing loss	1. Speech recognition of disyllabic words @ 65dB 2. Adverse events	*Oxford level of evidence:* IIb
Colletti et al (2010)[116]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Italy *Comparator:* preoperative unaided *Modifications:* FMT on round window *Length of F/U:* 12- 48 months	*Number:* 12 entered & completed *Sex:* 8 male, 4 female *Age:* mean 10.2 years, range 3 months – 31 years *Type of HL:* mixed, severe, prelingual *Pre-op unaided threshold:* mean AC 69.78dB, mean BC 26.25dB *Inclusion:* 1. children & adults with severe malformations of the external auditory canal & ossicular chain 2. severe mixed hearing loss	1. Functional Gain 2. Threshold levels 3. Speech recognition using Italian disyllabic words @ 65dB 4. Adverse events	*Oxford level of evidence:* IV
Cuda et al (2009)[117]	*Design:* single arm trial *Setting:* single academic center *Country:* Italy *Comparator:* preoperative unaided *Modifications:* peizosurgery device used to attach FMT to round window *Length of F/U:* mean 12, range 6-24 months	*Number:* 8 entered & completed *Sex:* 1 male, 7 female *Age:* mean 49.4, range 28 – 59 years *Type of HL:* mixed, mild to moderate *Pre-op unaided threshold:* mean AC 62.8dB (range 21-65dB), mean BC 39.2dB (range 21-65dB) *Inclusion:* bilateral mixed hearing loss	1. Threshold levels 2. Speech recognition using disyllabic words @ 60dB 3. Adverse events	*Oxford level of evidence:* IV
Dumon et al (2009)[118]	*Design:* retrospective, pre/post *Setting:* single clinic *Country:* Italy *Comparator:* preoperative & postoperative unaided *Modifications:* FMT on stapes, incus, or round window *Length of F/U:* NR for entire cohort	*Number:* 13 entered & completed *Sex:* 7 male, 6 female *Age:* mean 56, range 17-73 years *Type of HL:* mixed, moderate to severe *Pre-op unaided threshold:* mean AC 66dB, mean BC 49dB *Inclusion:* consecutive patients receiving the VSB for mixed hearing loss	1. Functional gain 2. Threshold levels 3. Speech reception threshold for 50% & 100% correct disyllabic Fournier words 4. Adverse events	*Oxford level of evidence:* IV

Study	Design	Patients	Outcome Measures	Quality
Fisch et al (2001)[119]	*Design:* single arm trial *Setting:* multicenter (10 centers) *Country:* Switzerland, Netherlands, Germany, Italy, France, UK *Comparator:* preoperative unaided *Modifications:* None *Length of F/U:* 3 months	*Number:* 47 entered & completed *Sex:* 23 male, 24 female *Age:* mean 48.4, range 19-80 *Type of HL:* sensorineural, mild to severe, postligual *Pre-op unaided threshold:* NR *Inclusion:* 1. postlingual onset sensorineural hearing loss 2. implanted ear equal to or worse than contralateral 3. PTA for both ears within 20dB 4. ABG @ 0.5, 1, 2, & 4 kHx not >10dB at >2 frequencies 5. normal typanometry & acoustic reflexes (unless threshold >75dB) 6. normal middle ear anatomy with no previous hx of middle ear surgery 7. age > 18 years 8. unable to wear a HA or wear one for 4 hrs/day x 3 months *Exclusion:* 1. history of post adolescent chronic middle ear infection 2. inner ear disorders such as Meniere's or vertigo 3. conductive, retrocochlear or central auditory disorders 4. mental retardation, developmental delay or organic brain disorders 5. hearing fluctuation > 15dB in 2 years 6. physical, psychological or emotional disorder precluding surgery or F/U 7. Unable to complete F/U 8. skin condition precluding attachment of the processor	1. Adverse events	*Oxford level of evidence:* IV
Foyt & Carfrae (2006)[120]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* USA *Comparator:* preoperative unaided *Modifications:* some patients receiving less invasive procedure with no head shave *Length of F/U:* mean 2 years, range 7-46 months	*Number:* 9 entered & completed *Sex:* 3 male, 6 female *Age:* range 21-84 years *Type of HL:* sensorineural or mixed, moderate severity *Pre-op unaided threshold:* mean AC 53dB *Inclusion:* consecutive patients receiving the VSB	1. Functional gain 2. Threshold levels 3. Adverse events	*Oxford level of evidence:* IV
Fraysse et al (2001)[121]	*Design:* prospective, pre/post *Setting:* multicenter (5 centers) *Country:* France *Comparator:* patient's own HA, Vibrant P, Vibrant D, preoperative unaided *Modifications:* None *Length of F/U:* 6-22 months	*Number:* 25 entered & completed *Sex:* 8 male, 17 female *Age:* mean 49.3, range 20-73 years *Type of HL:* sensorineural, mild to severe *Pre-op unaided threshold:* mean AC 56dB (range 33-80dB) *Inclusion:* 1. consecutive patients receiving VSB 2. age ≥ 18 years 3. mild to severe SNHL 4. intra-aural difference in PTA <20dB 5. AC thresholds between 10 – 85dB for 0.5-6 kHz 6. ABG ≤10dB for 0.5-4kHz 7. normal ear pressure & static compliance	1. Functional gain 2. Threshold levels 3. Speech reception thresholds for 50% & 100% correct disyllabic words 4. APHAB 5. Adverse events	*Oxford level of evidence:* IV

Study	Design	Patients	Outcome Measures	Quality
		8. acoustic reflexes unless PTA >70dB 9. trial of HA but dissatisfaction 10. speech understanding >50% with HA @ 65dB 11. realistic expectations *Exclusion:* 1. history of chronic middle ear disease, inner ear disorder, or middle ear surgery 2. skin conditions preventing attachment of processor		
Frenzel et al (2009)[122]	*Design:* single arm trial *Setting:* single academic center *Country:* Germany *Comparator:* preoperative unaided *Modifications:* FMT attached to round window, stapes superstructure, incus/malleus complex, or stapes footplate. Concomitant auricular reconstruction. *Length of F/U:* 8 months	*Number:* 7 entered & completed *Sex:* 5 male, 2 female *Age:* range 10 – 25 years *Type of HL:* mixed, moderate to severe, prelingual *Pre-op unaided threshold:* mean AC 69.2dB *Inclusion:* 1. patients with unilateral microtia & osseous atresia 2. ABG from 50-60dB 3. normal inner ear function	1. Functional gain 2. Threshold levels 3. Speech reception using German two-syllable numbers 4. Speech recognition using Freiburger monosyllables - in quiet @ 50, 65 & 80B - in 60dB noise	*Oxford level of evidence:* IV
Garin et al (2002)[123] & (2005)[124]	*Design:* retrospective, cohort *Setting:* 2 academic centers *Country:* Belgium *Comparator:* preoperative unaided & normal listeners *Modifications:* NR *Length of F/U:* mean 15.6, range 9-24 months	*Number:* 11 VSB & 35 normal listeners *Sex:* 7 male, 4 female *Age:* mean 59, range 37-69 years *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* NR *Inclusion:* 1. symmetric idiopathic bilateral SNHL 2. HL stable x 2 years 3. adults with moderate to severe bilateral SNHL implanted with a unilateral VSB	1. Threshold levels 2. Speech recognition using disyllabic Fournier word lists in 55dB noise using Garin & Galle "real life sounds" with words @ 50, 55 & 60dB	*Oxford level of evidence:* IIb
Huttenbrink et al (2008)[125]& (2010)[74]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Germany *Comparator:* preoperative & postoperative unaided *Modifications:* total auricular proesthesis & FMT placed on stapes footplate *Length of F/U:* 4 weeks	*Number:* 6 entered & completed *Sex:* 3 male, 3 female *Age:* mean 67.5, range 61-75 years *Type of HL:* mixed, moderate to severe *Pre-op unaided threshold:* mean AC 75.8dB *Inclusion:* patients receiving a total auricular replacement vibroplasty	1. Threshold levels 2. Speech recognition using Freiburger monosyllabic words @ 65dB	*Oxford level of evidence:* IV
Kiefer & Staudenmaier (2010)[126]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Germany *Comparator:* preoperative unaided *Modifications:* some patients with FMT on round window, some receiving simultaneous auricular reconstruction *Length of F/U:* NR	*Number:* 15 entered & completed *Sex:* NR *Age:* range 5.7 – 45 years *Type of HL:* moderate severity *Pre-op unaided threshold:* AC range 60-70dB *Inclusion:* patients with ear malformations & hearing loss receiving VSB	1. Threshold levels 2. Functional gain 3. Adverse events	*Oxford level of evidence:* IV
Lenarz et al (1998)[127 +] & (2001)[128 +]	*Design:* retrospective, pre/post *Setting:* single center *Country:* Germany *Comparator:* preoperative unaided, hearing aids	*Number:* 34 completed *Sex:* NR *Age:* mean 47.2, range 18.9 – 80.3 years *Type of HL:* sensorineural, moderate to severe	1. Adverse events	*Oxford level of evidence:* IV

Study	Design	Patients	Outcome Measures	Quality
	Modifications: NR *Length of F/U:* ≤3 years	*Pre-op unaided threshold:* NR *Inclusion:* consecutive patients implanted with the VSB		
Linder et al (2009)[129]	*Design:* retrospective, case series *Setting:* single academic center *Country:* Switzerland *Comparator:* preoperative with hearing aid *Modifications:* FMT on round window. Concomitant subtotal petrosectomy. *Length of F/U:* mean 19, range 9 – 28 months	*Number:* 5 entered & completed *Sex:* 1 male, 4 female *Age:* mean 55.2, range 45-66 years *Type of HL:* mixed or conductive, moderate to severe *Pre-op unaided threshold:* NR *Inclusion:* patients with conductive or mixed hearing loss undergoing a subtotal petrosectomy & VSB implantation.	1. Functional gain 2. Speech Recognition 3. Glasgow Benefit Inventory 4. Adverse events	*Oxford level of evidence:* IV
Luetje et al (2002)[98] [a]	*Design:* single arm trial *Setting:* multicenter (10 academic centers) *Country:* USA *Comparator:* preoperative unaided & with patient's best fit hearing aid, Vibrant P & Vibrant D *Modifications:* NR *Length of F/U:* 3 – 4.5 months	*Number:* 53 entered & 50 completed with all comparators *Sex:* 26 male, 27 female *Age:* mean 58.7, range 28-86 years *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* mean AC 53dB *Inclusion:* 1. adults ≥18 years old 2. normal speech & language with English as first language 3. use of appropriately fitted HA x 3 months 4. SNHL 5. ear for implantation equal to or worse than contralateral 6. ABG @ 0.5 – 4kHz ≤10dB @ 2 frequencies 7. word recognition @ 40dB or most comfortable listening level ≥50% 8. normal middle ear anatomy, ossicular chain function & acoustic reflexes 9. thresholds between 30-85dB @ 0.5-4kHz *Exclusion:* 1. unilateral hearing loss 2. conductive, retorcochlear or central auditory disorders 3. hearing loss fluctiatin >15dB in either direction in last 2 years 4. physical, psychological or emotional disorders 5. mental retardation or organic brain disorders 6. physically or geographically unable to complete F/U	1. Functional gain 2. Threshold levels 3. Speech recognition using the Northwestern University Auditory test (NU-6) in quiet & in noise 4. Profile of Hearing Aid Performance (PHAP) 5. Hearing Device Satisfaction Scale 6. Soundbridge hearing aid QoL questionnaire	*Oxford level of evidence:* IV
Luetje et al (2010)[130a]	*Design:* retrospective, pre/post *Setting:* single non-academic center *Country:* USA *Comparator:* preoperative unaided *Modifications:* None *Length of F/U:* mean 7.3, range 1-11 years	*Number:* 31 entered & completed *Sex:* 19 male, 12 female *Age:* mean 56.0, range 28-74 years *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* mean AC 69.5dB *Inclusion:* 1. adults with stable SNHL 2. word recognition of ≥50% 3. normal middle ear function & absence of retrocochlear or central involvement	1. Functional gain 2. Adverse events	*Oxford level of evidence:* IV
Mosnier et al (2008)[131 b]	*Design:* retrospective, pre/post *Setting:* multicenter (19 centers) *Country:* France	*Number:* 100 entered & 77 completed *Sex:* NR *Age:* mean 51, range 19-71 years	1. Functional gain 2. Threshold levels 3. Speech recognition in quiet using	*Oxford level of evidence:*

Study	Design	Patients	Outcome Measures	Quality
	Comparator: preoperative unaided *Modifications:* None reported *Length of F/U:* 5-8 years	*Type of HL:* NR *Pre-op unaided threshold:* NR *Inclusion:* consecutive patients implanted with the VSB	disyllabic words @ 65dB 4. Glasgow Benefit Inventory 5. Self-assessment QoL questionnaire 6. Adverse events	IV
Olgun et al (2008)[132]	*Design:* retrospective, case series *Setting:* single academic center *Country:* Turkey *Comparator:* preoperative unaided *Modifications:* FMT to round window *Length of F/U:* 2-8 months	*Number:* 5 entered & completed *Sex:* 4 male, 1 female *Age:* range 23-58 years *Type of HL:* mixed & conductive, moderate to severe *Pre-op unaided threshold:* median AC 69.3dB (range 65-85dB), median BC 33.7dB (range 10.1 – 60dB) *Inclusion:* consecutive patients with VSB placed on the round window	1. Functional gain 2. Threshold levels 3. Speech recognition using open set sentences & monosyllables in quiet 4. Adverse events	*Oxford level of evidence:* IV
Pok et al (2010)[133]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Austria *Comparator:* preoperative unaided & with patient's own hearing aid *Modifications:* None *Length of F/U:* 3 months	*Number:* 54 entered & completed *Sex:* 29 male, 25 female *Age:* mean 52.3, range 30-75 years *Type of HL:* sensorineural, severe *Pre-op unaided threshold:* mean AC 50.6dB *Inclusion:* consecutive patients implanted with VSB	1. Functional gain 2. Threshold levels using warble tones 3. Speech recognition using Freiburger monosyllables @ 65 & 80dB	*Oxford level of evidence:* IV
Rajan et al (2011)[101]	*Design:* prospective, pre/post *Setting:* single academic center *Country:* Australia *Comparator:* preoperative unaided *Modifications:* round window vibroplasty *Length of F/U:* up to 12 months	*Number:* 10 entered, 8 completed *Sex:* 3 male, 5 female *Age:* mean 56.4, range 28-79 years *Type of HL:* mixed & conductive, postlingual *Pre-op unaided threshold:* NR *Inclusion:* consecutive patients undergoing round window vibroplasty for mixed or conductive HL who were otherwise unaidable	1. Speech recognition: - in quiet using monosyllabic Arthur Boothroyd words @ 65dB - in 65dB noise using the adaptive Bumford-Kowal-Bench test 2. APHAB 3. Adverse events	*Oxford level of evidence:* IV
Rameh et al (2010)[103]	*Design:* retrospective cohort *Setting:* single academic center *Country:* France *Comparator:* Carina, semi-implantable MET, preoperative unaided *Modifications:* NR *Length of F/U:* mean 3.3, range 1-11 years	*Number:* 62 VSB entered, 45 completed *Sex:* 27 male, 18 female *Age:* mean 63, range 43 -82 years *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* mean AC 60.8dB *Inclusion:* consecutive patients implanted with the VSB, semi-implantable MET, or Carina	1. Functional gain 2. Threshold levels 3. Speech reception threshold (SRT50) using disyllabic words 4. Self-assessment QoL questionnaire 5. Adverse events	*Oxford level of evidence:* IIb
Saliba et al (2005)[134]	*Design:* prospective, pre/post *Setting:* single academic center *Country:* France *Comparator:* preoperative unaided, Siemens Signia digital hearing aid *Modifications:* NR *Length of F/U:* NR	*Number:* 8 entered & completed *Sex:* 3 male, 5 female *Age:* mean 58, range 45-68 years *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* mean AC 56dB, mean BC 48dB *Inclusion:* 1. adults implanted with the VSB x 1 year 2. symmetric moderate to severe SNHL 3. stable hearing thresholds x 2 years 4. no contraindications for contralateral HA use	1. Functional gain 2. Threshold levels 3. Speech reception (SRT50) in quiet & noise 4. APHAB	*Oxford level of evidence:* IV
Schmuziger et al (2006)[135]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Switzerland *Comparator:* preoperative unaided, postoperative	*Number:* 24 entered, 20 completed *Sex:* 16 male, 4 female *Age:* mean 59, range 37-75 years *Type of HL:* NR	1. Threshold levels (unaided only) 2. Speech reception (SRT50) - in quiet using Freiburg monosyllabic words	*Oxford level of evidence:* IV

Study	Design	Patients	Outcome Measures	Quality
	with hearing aid *Modifications:* NR *Length of F/U:* mean 42, range 26-55 months	*Pre-op unaided threshold:* NR *Inclusion:* consecutive patients implanted with the VSB	- in 70dB noise using the Basler Satz-test 3. Self-assessment QoL questionnaire 4. International Outcome Inventory for Hearing Aids 5. Glasgow Benefit Inventory 6. Adverse events	
Snik & Cremers (1999)[136c]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Netherlands *Comparator:* preoperative unaided *Modifications:* NR *Length of F/U:* NR	*Number:* 7 entered & completed *Sex:* 2 male, 5 female *Age:* mean 49.4, range 33-67 years *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* mean AC 56.4dB *Inclusion:* 1. symmetric SNHL (within 15dB) 2. hearing thresholds between 30-70dB @ 500Hz & 45-80dB @ 2kHz 3. unable to use an ear mold device due to severe, therapy-resistant externa otitis	1. Threshold levels using warble tones (unaided only) 2. Speech gain @ 40, 65 & 90dB 3. Adverse events	*Oxford level of evidence:* IV
Snik et al (2000)[137c]	*Design:* retrospective, case series *Setting:* single academic center *Country:* Netherlands *Comparator:* preoperative unaided *Modifications:* None *Length of F/U:* 8-19 months	*Number:* 6 entered & completed *Sex:* 1 male, 5 female *Age:* mean 49, range 33-66 years *Type of HL:* sensorineural, moderate *Pre-op unaided threshold:* mean AC 55.2dB *Inclusion:* 1. symmetrical SNHL (within 15 db) with normal middle ear function 2. hearing thresholds between 45-80dB @ 2kHz & 30-70dB @ 0.5kHz 3. severe bilateral chronic otitis externa prohibiting use of ear molds *Exclusion:* 1. retrocochlear pathology & previous middle ear surgery	1. Threshold levels 2. Adverse events	*Oxford level of evidence:* IV
Snik & Cremers (2001)[138]	*Design:* single arm trial *Setting:* single academic center *Country:* Netherlands *Comparator:* preoperative unaided, hearing aids *Modifications:* NR *Length of F/U:* NR	*Number:* 14 entered & completed *Sex:* NR *Age:* range 33 -67 years *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* mean AC 57dB (range 40-76dB) *Inclusion:* 1. symmetrical (within 10dB) cochlear hearing loss 2. threshold levels of 30-70dB @ 500Hz, & 45-85dB @ 2kHz 3. severe external otitis prohibiting use of an ear mold *Exclusion:* 1. high frequency deafness (threshold >100dB @ 1-4kHz)	1. Functional gain 2. Speech reception 3. Speech recognition using phenomes @ 65dB	*Oxford level of evidence:* IV
Snik et al (2004)[139]	*Design:* prospective cohort *Setting:* single academic center *Country:* Netherlands *Comparator:* Otologics MET middle ear implant, preoperative unaided	*Number:* 8 VSB entered & completed *Sex:* 2 male, 6 female *Age:* mean 54.1, range 39-65 years *Type of HL:* sensorineural, severe *Pre-op unaided threshold:* AC ≥65dB	1. Functional gain 2. Threshold levels using warble tones	*Oxford level of evidence:* IIb

Study	Design	Patients	Outcome Measures	Quality
	Modifications: NR *Length of F/U:* NR	*Inclusion:* 1. patients implanted with MET or VSB with normal middle ear impedance 2. mean postoperative thresholds within 10dB of preoperative values at each frequency between 0.5-4kHz & average threshold within 5dB 3. severe SNHL with thresholds ≥65dB at 0.5-4kHz 4. chronic, therapy-resistant external otitis 5. symmetrical SNHL with thresholds of 30-70dB @ 500Hz & 40-85dB @ 2kHz 6. VSB use for ≥1 year		
Sterkers et al (2003)[140 b]	*Design:* retrospective, pre/post *Setting:* multicenter (21 centers) *Country:* France *Comparator:* preoperative unaided *Modifications:* None reported *Length of F/U:* 3 months	*Number:* 125 entered & 95 completed *Sex:* 45 male, 50 female *Age:* mean 56, range 24-81 years *Type of HL:* sensorineural, mild to severe *Pre-op unaided threshold:* NR *Inclusion:* 1. age ≥ 18 years old 2. mild to severe SNHL 3. PTA thresholds between 10 – 85dB @ 0.5-6kHz 4. ABG ≤10dB form 0.5-4kHz 5. normal middle ear pressure & static compliance 6. presently have or recently tried an optimally fitted conventional HA 7. dissatisfied with or inability to tolerate wearing a HA for a long period 8. speech understanding ≥50% @ 65dB aided or most comfortable listening level 9. stable hearing loss x 2 years 10. realistic expectations & motivations *Exclusion:* 1. history of chronic middle ear disease, Meniere's or middle ear surgery 2. skin conditions preventing attachment of processor	1. Functional gain 2. Threshold levels 3. Speech recognition in quiet using Lafont & Fournier words @ 65dB 4. Self-assessment QoL questionnaire 5. Glasgow Benefit Inventory 6. Adverse events	*Oxford level of evidence:* IV
Streitberger et al (2009)[141]	*Design:* single arm trial *Setting:* multicenter (3 academic centers) *Country:* Italy *Comparator:* preoperative unaided *Modifications:* FMT on incus, round window, stapes footplate, stapes suprastructure or cochlear fenestration *Length of F/U:* ≤9 months	*Number:* 40 entered & completed *Sex:* NR *Age:* mean 59.5, range 35-81 years *Type of HL:* mixed or conductive, severe *Pre-op unaided threshold:* mean AC 78.14dB, mean BC 44.06dB *Inclusion:* 1. severe residual conductive & mixed hearing loss after middle ear surgery 2. consecutive patients implanted with VSB	1. Threshold levels (unaided only) 2. Speech reception threshold 3. Speech recognition using Italian disyllabic word lists or German Freiburger monosyllables	*Oxford level of evidence:* IV
Sziklai & Szilvassy (2011)[99]	*Design:* single arm trial *Setting:* single academic center *Country:* Hungary	*Number:* 9 entered, 7 completed *Sex:* NR *Age:* range 21-62 years	1. Functional gain 2. Threshold levels using pure tones 3. Speech recognition using monosyllabic	*Oxford level of evidence:*

Study	Design	Patients	Outcome Measures	Quality
	Comparator: preoperative unaided, open-fit hearing aid *Modifications:* None *Length of F/U:* NR	*Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* mean AC 75.2dB *Inclusion:* 1. adults with stable, bilateral, sloping SNHL 2. >3 months experience with conventional hearing aids *Exclusion:* 1. significant alteration of middle ear function	Hungarian words in quiet @ 65dB	IV
Todt et al (2002)[142] [d]	*Design:* single arm trial *Setting:* single academic center *Country:* Germany *Comparator:* VSB HF-processor, VSB D-processor, hearing aids *Modifications:* None *Length of F/U:* 12 months	*Number:* 5 entered & completed *Sex:* NR *Age:* range 54-69 years *Type of HL:* sensorineural, mild to severe *Pre-op unaided threshold:* mean AC 55dB *Inclusion:* 1. meeting indication criteria for VSB 2. common etiology of hearing loss (ex. age & noise related) 3. gently sloping PTA loses & no progression in hearing loss x 2 years	1. Functional gain 2. Threshold levels using pure tones 3. Speech recognition using Freiburger monosyllables in quiet & in noise 4. APHAB	*Oxford level of evidence:* IV
Todt et al (2005)[100d]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Germany *Comparator:* VSB D-type, VSB Signia, hearing aids *Modifications:* NR *Length of F/U:* NR	*Number:* 23 entered & completed *Sex:* NR *Age:* range 41 -80 years *Type of HL:* sensorineural, mild to severe *Pre-op unaided threshold:* NR *Inclusion:* consecutive patients receiving the VSB	1. Functional gain 2. Speech recognition using Freiburger monosyllables in quiet & in noise 3. Self-assessment QoL questionnaire 4. Adverse events	*Oxford level of evidence:* IV
Truy et al (2008)[143]	*Design:* single arm trial *Setting:* single academic center *Country:* France *Comparator:* preoperative unaided, Signia hearing aid *Modifications:* NR *Length of F/U:* 2 months	*Number:* 6 entered & completed *Sex:* 2 male, 4 female *Age:* range 42-59 years *Type of HL:* NR *Pre-op unaided threshold:* mean AC 39dB *Inclusion:* 1. steep high frequency hearing loss within VSB inclusion criteria 2. difference in threshold levels between ears <30dB 3. normal middle ear function 4. limited satisfaction with hearing aids	1. Functional gain 2. Threshold levels 3. Speech recognition - in quiet using Lafon monosyllabic words @ 40, 50 & 60dB - in noise using Dodele meaningless words @ 55 dB	*Oxford level of evidence:* IV
Uziel et al (2003)[144]	*Design:* single arm trial *Setting:* single academic center *Country:* France *Comparator:* postoperative unaided, Signia hearing aid *Modifications:* NR *Length of F/U:* mean 17 months	*Number:* 6 entered & completed *Sex:* 4 male, 2 female *Age:* mean 56, range 32 -67 years *Type of HL:* sensorineural, moderate *Pre-op unaided threshold:* NR *Inclusion:* 1. high frequency hearing loss (normal to mild HL @ 250-500Hz, mild to moderate @ 1kHz, moderate to profound @ 2-8kHz) 2. hearing loss stable x 2 years	1. Threshold levels 2. Speech reception threshold (SRT50) 3. APHAB 4. Hearing Device Satisfaction Scale	*Oxford level of evidence:* IV
Venail et al (2007)[145]	*Design:* retrospective, case series *Setting:* single academic center *Country:* France *Comparator:* Otologics MET, preoperative unaided	*Number:* 2 VSB entered & completed *Sex:* 1 male, 1 female *Age:* mean 68.5, range 67-70 years *Type of HL:* mixed, moderate to severe	1. Functional gain 2. Threshold levels 3. Speech reception threshold (SRT50) 4. Adverse events	*Oxford level of evidence:* IV

Study	Design	Patients	Outcome Measures	Quality
	Modifications: None *Length of F/U:* 6-12 months	*Pre-op unaided threshold:* mean AC 67.5dB *Inclusion:* adults with mixed hearing loss & otorsclerosis implanted with an MEI		
Verhaegen et al (2008)[31]	*Design:* retrospective cohort *Setting:* single academic center *Country:* Netherlands *Comparator:* "state of the art" behind the ear hearing aid, second generation multichannel cochlear implants, Otologics MET *Modifications:* NR *Length of F/U:* 1 year	*Number:* 22 VSB, 47 HA, 123 CI, 10 MET completed *Sex:* NR *Age:* NR *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* NR *Inclusion:* *For MEI & Has* 1. sensorineural hearing loss with ABG ≤10dB @ 0.5- 4kHz 2. thresholds @ 0.5, 1 & 2 kHz of ≤100dB 3. thresholds of <120dB for 0.5-4kHz 4. flat or mildly sloping audiogram with ≤35dB difference in thresholds from 0.5-4kHz 5. chronic external otitis 6. experience with hearing aids x 5 years *For CI* 1. postlingually deaf adults <70 years old 2. healthy cochlear shell without otosclerosis or obliterated or malformed cochlea 3. implanted with a second generation device	1. Speech recognition using phenome scores in quiet @ 65dB (unable to extract quantitatively)	*Oxford level of evidence:* IIb
Zehlicke et al (2010)[146]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Germany *Comparator:* preoperative unaided *Modifications:* FMT attached to cartilage-perichondrium graft on stapes footplate *Length of F/U:* NR	*Number:* 7 entered & completed *Sex:* 2 male, 5 female *Age:* mean 53, range 25-69 years *Type of HL:* mixed, moderate to severe *Pre-op unaided threshold:* mean AC 79.5dB, mean BC 38.9dB *Inclusion:* adults with mixed hearing loss implanted with the VSB	1. Functional gain 2. Threshold levels	*Oxford level of evidence:* IV
Zwartenkot et al (2011)[89]	*Design:* retrospective, case series *Setting:* single academic center *Country:* Netherlands *Comparator:* None *Modifications:* transcanal approach *Length of F/U:* mean 51, range 26-73 months	*Number:* 13 entered & completed *Sex:* 7 male, 6 female *Age:* mean 59, range 44-79 years *Type of HL:* sensorineural, mild to moderate *Pre-op unaided threshold:* mean AC 45dB (range 38-57dB) *Inclusion:* consecutive patients implanted with the VSB via the transcanal approach	1. Adverse events	*Oxford level of evidence:* IV
Esteem				
Barbara et al (2009)[147] & (2011)[102]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Italy *Comparator:* preoperative unaided *Modifications:* None *Length of F/U:* NR	*Number:* 18 entered & completed *Sex:* NR *Age:* NR *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* mean AC 70dB *Inclusion:* consecutive patients with moderate to severe sensorineural hearing loss implanted with the Esteem	1. Functional gain 2. Threshold levels 3. Speech recognition @ 60 or 75dB 4. Glasgow Benefit Inventory 5. Client Oriented Scale of Improvement	*Oxford level of evidence:* IV
Chen et al (2004) [148]	*Design:* single arm trial *Setting:* multicenter	*Number:* 7 entered & completed *Sex:* 5 male, 2 female	1. Functional gain 2. Threshold levels	*Oxford level of*

Study	Design	Patients	Outcome Measures	Quality
	Country: USA *Comparator:* preoperative unaided & the patient's "best-fit" HA *Modifications:* None *Length of F/U:* 2 months	*Age:* mean 64.4, range 42 – 88 years *Type of HL:* sensorineural, mild to severe *Pre-op unaided threshold:* NR *Inclusion:* 1. age > 18 years 2. mild to severe SNHL between 500 – 4000Hz 3. implanted ear equal or worse than contralateral 4. pure tone AC thresholds between 35 – 85 dB form 500 – 4000Hz 5. use of best fit HA for 4 hrs/day x 3 months 6. normal middle ear & Eustachian tube 7. adequate space for implant, determined by CT scan 8. speech discrimination ≥60% 9. psychologically & emotionally stable with realistic expectations *Exclusion:* 1. conductive, retrocochlear or central auditory disorders 2. fluctuation in HL > 15 dB 3. physical &/or emotional disorders prohibiting testing 4. unable to complete F/U 5. hx of post-adolescent chronic middle ear infections 6. inner ear disorders 7. hx of otitis externa or eczema	3. Speech reception 4. Speech recognition - in quiet using CID-W22 word lists @ 50dB - in quiet & in 65dB noise using HINT 5. APHAB 6. Adverse events	*evidence:* IV
Kraus et al (2011)[91]	*Design:* single arm trial *Setting:* multicenter (3 centers) *Country:* USA *Comparator:* preoperative unaided, patients "walk-in" HA *Modifications:* None *Length of F/U:* 12 months	*Number:* 57 entered & completed *Sex:* 38 male, 19 female *Age:* mean 52.9, range 18-77.2 years *Type of HL:* sensorinueral, mild to severe *Pre-op unaided threshold:* mean AC 63dB *Inclusion:* 1. age ≥18 years 2. stable bilateral mild to severe SNHL 3. thresholds from 30-100dB from 0.5 – 4kHz 4. ABG ≤10dB @ 4/5 frequencies 5. word recognition ≥40% @ SRT +40dB 6. normal tympanic membrane, middle ear anatomy & Eustachian tube 7. appropriately fitted HA use for ≥4hrs/day x 3 months or 1 month for adjusted aid 8. CT showing adequate space for implant 9. English speaking 10. ability to undergo general anesthetic 11. ability & willingness to comply with study protocol *Exclusion:* 1. pregnancy 2. chronic staphylococcal skin infection 3. history of post-adolescent chronic middle ear infections, inner ear disorders, vertigo, mastoiditis, or endolymphatic hydrops 4. fluctuating AC or BC thresholds >15dB in either direction in past	1. Functional gain 2. Threshold levels using warble tones & pure tones 3. Speech reception threshold using CD spondee word list 4. Speech recognition @ 50dB 5. Self-assessment QoL questionnaire 6. Adverse events	*Oxford level of evidence:* IV

Study	Design	Patients	Outcome Measures	Quality
		2 years @ ≥2 frequencies between 0.5 – 4kHz 5. cholesteatoma or other destructive middle ear disease 6. retrocochlear or central auditory disorders 7. psychological, developmental or physical/emotional disorder preventing F/U 8. disabling tinnitus requiring treatment 9. history of keloid formation 10. hypersensitivity to silicone, polyurethane, stainless steel, titanium or gold 11. pre-existing medical conditions such as diabetes mellitus that is not well controlled or life expectancy ≤2 years 12. small mastoid of narrow facial recess 13. unable to adequately preform audiometric testing 14. history of sudden onset HL of unknown cause		
Maurer & Savvas (2010)[85]	*Design:* single arm trial *Setting:* single academic center *Country:* Germany *Comparator:* hearing aids *Modifications:* None *Length of F/U:* 3-40 months	*Number:* 10 entered & completed *Sex:* NR *Age:* NR *Type of HL:* sensorineural & mixed *Pre-op unaided threshold:* NR *Inclusion:* consecutive patients implanted with the Esteem	1. Functional gain 2. Speech recognition using monosyllabic words @ 65dB (reports range only) 3. APHAB 4. Adverse events	*Oxford level of evidence:* IV
Memari et al (2011)[149]	*Design:* single arm trial *Setting:* single academic center *Country:* Iran *Comparator:* preoperative unaided *Modifications:* None *Length of F/U:* mean 29.4, range 19-40 months	*Number:* 10 entered & completed *Sex:* 3 male, 7 female *Age:* mean 32.7 years *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* mean AC 65.6dB *Inclusion:* 1. age ≥18 years 2. moderate to severe nonfluctating SNHL from 0.5 – 4kHz 3. better or equal hearing in non-implanted ear 4. healthy middle ear with normal anatomy 5. speech discrimination score >50% 6. stable psychological & emotional condition *Exclusion:* diabetes mellitus, connective tissue disorders, chronic otitis media & external otitis	1. Threshold levels 2. Speech recognition 3. Self-assessment QoL questionnaire 4. Adverse events	*Oxford level of evidence:* IV
Murali et al (2009)[150]	*Design:* retrospective case series *Setting:* single academic center *Country:* India *Comparator:* preoperative unaided *Modifications:* None *Length of F/U:* NR	*Number:* 3 entered & completed *Sex:* 2 male, 1 female *Age:* mean 28.7, range 22-38 years *Type of HL:* sensorineural, postlingual *Pre-op unaided threshold:* mean AC 67dB *Inclusion:* 1. age ≥ 18 years 2. willing & able to comply with F/U for 1 year, understand test procedures & use of Esteem 3. mild to severe SNHL 4. Pure tone thresholds from 25 – 90dB @ 0.5- 4kHz	1. Threshold levels 2. Speech recognition for words & sentences 3. Adverse events	*Oxford level of evidence:* IV

Study	Design	Patients	Outcome Measures	Quality
		5. ABG ≤10dB @ 4/5 frequencies from 0.5-4kHz 6. unaided word recognition ≥60% @ SRT + 40dB 7. current user of properly functioning & appropriately fit HA 8. normally functioning Eustachian tube 9. normal tympanic membrane & middle ear anatomy with intact ossicular chain		
Carina				
Bruschini et al (2009)[151] & (2010)[152]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Italy *Comparator:* preoperative and postoperative unaided *Modifications:* FMT to incus, stapes, or titanium ball *Length of F/U:* mean 16.9, range 12-21 months	*Number:* 8 entered & completed *Sex:* 7 male, 1 female *Age:* mean 46.4, range 34-66 years *Type of HL:* sensorineural or mixed, moderate to severe, postlingual *Pre-op unaided threshold:* mean AC 63.44 (range 55-68.75) *Inclusion:* consecutive patients implanted with the Carina *Exclusion:* 1. vestibular or osteo-degenerative disorders 2. nonorganic hearing loss 3. central auditory nervous system disorder 4. prelinguistic onset of hearing loss	1. Functional Gain 2. Threshold levels 3. Speech recognition using disyllabic words @ 65dB 4. APHAB 5. Adverse events	*Oxford level of evidence:* IV
Deveze et al (2010)[153]	*Design:* retrospective, case report *Setting:* single academic center *Country:* Italy *Comparator:* hearing aid *Modifications:* implant coupled to footplate, concurrent reconstruction of external ear canal *Length of F/U:* 6 months	*Number:* 1 entered & completed *Sex:* 1 female *Age:* 63 years *Type of HL:* mixed, moderate, postlingual *Pre-op unaided threshold:* NR *Inclusion:* Not applicable	1. Functional gain 2. Speech recognition @ 65dB 3. Speech reception threshold (SRT50) 4. Adverse events	*Oxford level of evidence:* IV
Jenkins et al (2007)[92] & (2008)[93]	*Design*: single arm trial *Setting:* multicenter, general & academic *Country:* USA *Comparator*: pre-surgery unaided & with patient's own HA *Modifications:* None *Length of F/U*: 12 months	*Number* : 20 entered & completed *Sex:* 10 male, 10 female *Age*: mean 62.8, range 31.6 – 82 years *Type of HL:* sensorineural, moderate to severe, post lingual *Pre-op unaided threshold:* NR *Inclusion:* 1. Adults with bilateral moderate to severe HL (PTA 40-80dB) 2. Stable , non-fluctuant HL 3. NU-6 scores >40% @ 80 dB 4. Experience with HA x 3 months *Exclusion:* Concomitant disease (ex. retrocochlear HL or otitis media)	1. Threshold levels 2. Speech recognition: - in quiet using CNC words & phenomes -in 65dB noise using HINT 3. APHAB 4. Self-assessment QoL questionnaire 5. Adverse events	*Oxford level of evidence:* IV
Lefebvre et al (2009)[87]	*Design:* single arm trial *Setting:* multicenter (4 centers) *Country:* Belgium, France *Comparator:* preoperative & postoperative unaided *Modifications:* attached to round window *Length of F/U:* 12 months	*Number:* 6 entered & completed *Sex:* NR *Age:* NR *Type of HL:* mixed, moderate to severe *Pre-op unaided threshold:* NR *Inclusion:* adults (> 18 years old) with stable mixed hearing loss *Exclusion:* 1. retrocochlear, central auditory or functional components to hearing loss	1. Functional gain 2. Threshold levels 3. Speech recognition of disyllabic words in French @ 65 dB 4. APHAB 5. Adverse events	*Oxford level of evidence:* IV

Study	Design	Patients	Outcome Measures	Quality
		2. medical contraindications to surgery or MEI 3. unrealistic expectations		
Martin et al (2009)[154]	*Design:* retrospective, pre/post *Setting:* multicenter, 7 academic centers *Country:* France, Belgium, Spain *Comparator:* preoperative unaided *Modifications:* prosthesis on fascia graft on round window *Length of F/U:* 2 years	*Number:* 11 entered & completed *Sex:* 4 male, 7 female *Age:* mean 50.8, range 35-71 years *Type of HL:* mixed, moderate to severe *Pre-op unaided threshold:* mean AC 77.8dB (range 52-100), mean BC 39dB (range 17.5-62.5) *Inclusion:* 1. Consecutive patients 2. Carina placed on round window 3. Stable mixed or conductive hearing loss *Exclusion:* 1. signs or symptoms of retrocochlear, central auditory, or functional components 2. medical contraindications to surgery 3. unrealistic expectations	1. Thresholds levels 2. Speech recognition in quiet using Fournier lists of Spanish words @ 65 dB 3. APHAB 4. Adverse events	*Oxford level of evidence:* IV
Neumann et al (2010)[155+]	*Design:* retrospective, pre/post *Setting:* multicenter (2 academic centers) *Country:* Germany *Comparator:* preoperative unaided *Modifications:* None *Length of F/U:* NR	*Number:* 6 entered & completed *Sex: 2* male, 4 female *Age:* range 38-70 years *Type of HL:* sensorineural *Pre-op unaided threshold:* NR *Inclusion:* consecutive patients implanted with the Carina	1. Functional gain 2. Threshold levels 3. Speech recognition	*Oxford level of evidence:* IV
Rameh et al (2010)[103]	*Design:* retrospective cohort *Setting:* single academic center *Country:* France *Comparator:* VSB, semi-implantable MET, preoperative unaided *Modifications:* NR *Length of F/U:* mean 1.9, range 1-4 years	*Number:* 18 Carina entered, 10 completed *Sex:* 5 male, 5 female *Age:* mean 64, range 46-84 *Type of HL:* sensorineural, moderate to severe *Pre-op unaided threshold:* mean AC 69.3dB *Inclusion:* consecutive patients implanted with the VSB, semi-implantable MET, or Carina	1. Functional gain 2. Threshold levels 3. Speech reception threshold (SRT50) using disyllabic words 4. Self-assessment QoL questionnaire 5. Adverse events	*Oxford level of evidence:* IIb
Siegert et al (2007)[156]	*Design:* single arm trial *Setting:* single academic center *Country:* Germany *Comparator:* preoperative unaided *Modifications:* malleus-incus complex was removed & prosthesis attached to stapes *Length of F/U:* ≥3 months	*Number:* 5 entered & completed *Sex:* 4 male, 1 female *Age:* mean 31.4, range 18-40 years *Type of HL:* conductive, prelingual *Pre-op unaided threshold:* mean AC 72dB *Inclusion:* patients with hearing loss due to congenital auricular atresia	1. Functional gain 2. Threshold levels 3. Speech reception using Freiburger monosyllables 4. Adverse events	Oxford level of evidence: IV
Tong et al (2009)[157+]	*Design:* prospective, pre/post *Setting:* single academic center *Country:* China *Comparator:* postoperative unaided *Modifications:* NR *Length of F/U:* > 12 months	*Number:* 3 entered & completed *Sex:* NR *Age:* NR *Type of HL:* moderate to severe *Pre-op unaided threshold:* NR *Inclusion:* adults with bilateral moderate to severe hearing loss	1. Functional gain	Oxford level of evidence: IV
Tringali et al (2008)[158]	*Design:* retrospective, case report *Setting:* single academic center *Country:* France	*Number:* 1 entered & completed *Sex:* 1 male *Age:* 14 years	1. Functional gain 2. Threshold levels using pure tones 3. Speech reception threshold (SRT50)	Oxford level of evidence:

Study	Design	Patients	Outcome Measures	Quality
	Comparator: preoperative unaided *Modifications:* MEI & prosthesis attached to stapes footplate *Length of F/U:* 2 months	*Type of HL:* conductive, severe *Pre-op unaided threshold:* mean AC 70dB *Inclusion:* single patient with Franceschetti syndrome and bilateral conductive hearing loss, unable to wear a BAHA	4. Speech recognition 5. Adverse events	IV
Tringali et al (2009)[159]	*Design:* retrospective, case report *Setting:* single academic center *Country:* France *Comparator:* postoperative unaided *Modifications:* transducer attached to round window *Length of F/U:* 15 months	*Number:* 1 entered & completed *Sex:* 1 female *Age:* 48 years *Type of HL:* mixed, severe *Pre-op unaided threshold:* mean AC 80dB *Inclusion:* single case of mixed hearing loss & chronic irritation of external ear	1. Functional gain 2. Threshold levels using pure tones 3. Speech recognition	Oxford level of evidence: IV
BAHA				
Barbara et al (2010)[160]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Italy *Comparator:* postoperative unaided (subgroup analysis of bilateral conductive or mixed hearing loss & single-sided SNHL) *Modifications:* None *Length of F/U:* mean 18.4, range 3-41 months	*Number:* 30 entered, 24 completed *Sex:* 7 male, 17 female *Age:* mean 51.6, range 12-74 years *Type of HL:* all types *Pre-op unaided threshold:* for CHL & MHL mean AC 64.4dB, mean BC 21.9dB *Inclusion:* consecutive patients receiving BAHA	1. Speech reception in quiet & in noise 2. Speech recognition in quiet & in noise 3. Client Oriented Scale of Improvement 4. Glasgow Benefit Inventory 5. Entific Medical System QoL questionnaire	Oxford level of evidence: IV
Bosman et al (2009)[161]	*Design:* retrospective, with/without *Setting:* single academic center *Country:* Netherlands *Comparator:* BAHA Intenso & patient's own BAHA *Modifications:* NR *Length of F/U:* not applicable	*Number:* 23 entered & completed *Sex:* 9 male, 14 female *Age:* mean 64.7, range 43-82 years *Type of HL:* mixed, moderate to profound *Pre-op unaided threshold:* mean AC 71.2dB, mean BC 34.6dB *Inclusion:* patients with BAHA	1. Functional gain 2. Threshold levels 3. Speech reception using consonant vowel consonant phenomes - in quiet - in noise @ 60 & 70dB 4. ABHAB	Oxford level of evidence: IV
Christensen et al (2010)[162]	*Design:* single arm trial *Setting:* single academic center *Country:* USA *Comparator:* preoperative unaided (subgroup analysis of children & teenagers) *Modifications:* two-stage surgery *Length of F/U:* NR	*Number:* 23 entered & completed *Sex:* 9 male, 14 female *Age:* mean 12.6, range 6-19 years *Type of HL:* sensorineural, unilateral, profound *Pre-op unaided threshold:* NR *Inclusion:* 1. children with profound unilateral sensorineural hearing loss 2. age ≥5 years	1. Speech reception in noise using the Hearing in Noise Test 2. Children's home inventory for listening difficulties 3. Adverse events	Oxford level of evidence: IV
Christensen et al (2010)[163]	*Design:* retrospective, with/without *Setting:* single academic center *Country:* USA *Comparator:* BC transducer, BC hearing aid, BAHA with softband *Modifications:* NR *Length of F/U:* NR	*Number:* 10 entered & completed *Sex:* 3 male, 7 female *Age:* range 6 months – 16 years *Type of HL:* conductive *Pre-op unaided threshold:* mean AC 60.5dB *Inclusion:* 1. age 6 months – 18 years 2. congenital bilateral conductive hearing loss 3. initially fit with traditional BC hearing aid 4. fit unilaterally with a BAHA Compact or Divino via the Softband 5. implanted unilaterally with the BAHA system	1. Threshold levels	Oxford level of evidence: IV

Study	Design	Patients	Outcome Measures	Quality
		6. unaided & aided thresholds available for 0.5-4kHz 7. consistent full-time use of amplification		
Dumper et al (2009)[164]	*Design:* retrospective, cohort *Setting:* single academic center *Country:* Canada *Comparator:* postoperative unaided *Modifications:* NR *Length of F/U:* NR	*Number:* 50 entered & completed *Sex:* NR *Age:* NR *Type of HL:* all types *Pre-op unaided threshold:* NR *Inclusion:* 1. age >18 years 2. preoperative hearing loss fitting with defined types of hearing 3. ability to provide informed consent & participate fully in the study *Exclusion:* 1. mental handicaps	1. Speech reception in 65dB noise 2. Speech recognition in quiet 3. APHAB 4. Speech, Spatial and Qualities of Hearing Scale	Oxford level of evidence: IIb
Flynn et al (2009)[165]	*Design:* prospective, with/without *Setting:* single center *Country:* Sweden *Comparator:* Oticon Sumo DM hearing aid *Modifications:* NR *Length of F/U:* NR	*Number:* 10 entered & completed *Sex:* 5 male, 5 female *Age:* mean 59, range 32-75 years *Type of HL:* mixed, severe *Pre-op unaided threshold:* mean AC 77dB, mean BC 41dB *Inclusion:* 1. patients with mixed hearing loss (sensorineural component >25dB & ABG >30dB) 2. implanted with the BAHA	1. Threshold levels 2. Speech reception in noise	Oxford level of evidence: IV
Fuchsmann et al (2010)[166]	*Design:* retrospective, pre/post *Setting:* multicenter (2 academic centers) *Country:* France *Comparator:* preoperative unaided *Modifications:* two-stage procedure in patients <9years old *Length of F/U:* mean 6.5 years, range 10 months – 13.5 years	*Number:* 16 entered & completed *Sex:* 11 male, 5 female *Age:* mean 19.5, range 4.5 – 50 years *Type of HL:* conductive, moderate to severe, prelingual *Pre-op unaided threshold:* mean AC 58.6dB, mean BC 14.8dB *Inclusion:* bilateral conductive hearing loss due to congenital auricular atresia implanted with unilateral BAHA	1. Functional gain 2. Threshold levels 3. Speech reception 4. APHAB 5. Self-assessment QoL questionnaire 6. Adverse events	Oxford level of evidence: IV
Gluth et al (2010)[96]	*Design:* prospective, uncontrolled trial *Setting:* single academic center *Country:* Australia *Comparator:* preoperative unaided, non-implanted patients *Modifications:* None *Length of F/U:* mean 3.2, range 0.8-4.6 years	*Number:* 56 entered, 21 completed implantation, 35 were not implanted *Sex:* 10 male, 11 female *Age:* mean 51, range 30.9-68.8 years *Type of HL:* sensorineural, profound, unilateral *Pre-op unaided threshold:* NR *Inclusion:* 1. PTA (0.5, 1, 2kHz) ≤20dB &/or max. speech discrimination of ≥80% in unaffected ear 2. PTA (0.5, 1, 2kHz) ≥91dB &/or minimum speech discrimination ≤20% in affected ear 3. English as primary language 4. determined by an Otolaryngologist to be an appropriate candidate & medically suitable for BAHA 5. evaluated by an audiologist including 2 weeks trial of BAHA softband	1. Adverse events	Oxford level of evidence: IIb

Study	Design	Patients	Outcome Measures	Quality
Hol et al (2010)[167]	*Design:* single arm trial *Setting:* single academic center *Country:* Netherlands *Comparator:* preoperative unaided *Modifications:* uses contralateral routing of sound device (CROS) *Length of F/U:* NR	*Number:* 59 entered, 56 completed *Sex:* NR *Age:* mean 48, range 16-71 years *Type of HL:* sensorineural *Pre-op unaided threshold:* NR *Inclusion:* consecutive patients with unilateral inner ear deafness selected for BAHA CROS implantation	1. Speech reception in noise using Dutch sentences (SRT50) 2. APHAB 3. Glasgow Benefit Hearing Aid Profile	Oxford level of evidence: IV
Kompis et al (2007)[168]	*Design:* single arm trial *Setting:* single academic center *Country:* Switzerland *Comparator:* postoperative unaided, BAHA Compact, BAHA Divino *Modifications:* NR *Length of F/U:* > 2 years since implantation, 3 month study period	*Number:* 7 entered & completed *Sex:* NR *Age:* mean 48.6, range 19-66 years *Type of HL:* mixed & conductive *Pre-op unaided threshold:* NR *Inclusion:* patients with BAHA devices ≥2 years	1. Speech reception - using Freiburger numbers in quiet - using the Basler sentence test in noise with speech @ 50dB 2. Speech recognition using Freiburger monosyllabic words @ 50, 65 & 80dB 3. APHAB	Oxford level of evidence: IV
Kunst et al (2007)[169]	*Design:* single arm trial *Setting:* single academic center *Country:* Netherlands *Comparator:* postoperative unaided (with subgroup analysis for adults & children) *Modifications:* NR *Length of F/U: adults*: mean 17, range 10-34 weeks *children*: mean 34, range 12-38 months	*Number:* 20 entered & completed *Sex:* NR *Age:* mean 17.3, range 6-61 years *Type of HL:* conductive, moderate to severe *Pre-op unaided threshold:* mean AC 66.9dB (range 48-88dB) *Inclusion:* consecutive patients with congenital unilateral conductive hearing loss who received a percutaneous BAHA	1. Speech reception using Dutch sentences in quiet & 65dB noise 2. Speech recognition using Dutch word lists	Oxford level of evidence: IV
Lindstrom et al (2009)[170]	*Design:* prospective, cohort *Setting:* single academic center *Country:* USA *Comparator:* postoperative unaided, normal hearing controls *Modifications:* NR *Length of F/U:* 1 year	*Number:* 8 BAHA entered, 7 completed *Sex:* 2 male, 5 female *Age:* mean 49.7, range 35.3-66.7 years *Type of HL:* severe to profound *Pre-op unaided threshold:* NR *Inclusion:* 1. unilateral complete or near complete adult onset deafness 2. normal or near normal hearing in better ear 3. tympanic peak pressure ≥-50daPa 4. peak compensates static acoustic admittance between 0.35-1.30mmho 5. age 18-75 years 6. English as primary language *Exclusion:* 1. presence of developmental disorder or mental retardation 2. history of drug abuse 3. psychological disease 4. inability to follow instruction or participate in F/U appointments	1. Speech reception in noise 2. APHAB	Oxford level of evidence: IIb
Martin et al (2010)[171]	*Design:* retrospective, cohort *Setting:* single academic center *Country:* UK *Comparator:* single sided deaf controls *Modifications:* NR	*Number:* 56 BAHA completed, 67 controls entered, 49 completed *Sex:* 19 male, 39 female *Age:* mean 56, range 30-79 years *Type of HL:* single sided deafness *Pre-op unaided threshold:* NR	1. Speech reception in noise using Banfor-Kowel-Bench sentences in multi-talker babble 2. Speech, Spatial, & Quality of hearing scale	Oxford level of evidence: IIb

Study	Design	Patients	Outcome Measures	Quality
	Length of F/U: mean 28.5, range 3-41 months	*Inclusion: BAHA* 1. consecutive patients receiving BAHA for single sided deafness 2. ≥3 months BAHA use *Controls:* 1. single sided deafness without BAHA	3. Glasgow Benefit Inventory	
Mazita et al (2009)[172]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Malaysia *Comparator:* preoperative unaided *Modifications:* two stage procedure for children <12 years, all procedures under general anesthesia *Length of F/U:* mean 54.4, range 4-84 months	*Number:* 16 entered & completed *Sex:* 11 male, 5 female *Age:* mean 8.9, range 3-21 years *Type of HL:* conductive, moderate to severe *Pre-op unaided threshold:* mean AC 64.9dB(range 47-73dB), mean BC <20dB *Inclusion:* consecutive patients implanted with a BAHA	1. Threshold levels 2. Functional gain 3. Adverse events	Oxford level of evidence: IV
Newman et al (2008)[173]	*Design:* single arm trial *Setting:* single academic center *Country:* USA *Comparator:* postoperative unaided *Modifications:* NR *Length of F/U:* 18 months	*Number:* 12 entered, 8 completed *Sex:* 4 male, 4 female *Age:* mean 55.7, range 47-66 years *Type of HL:* sensorineural, profound, postlingual *Pre-op unaided threshold:* NR *Inclusion:* patients with acquired, profound, unilateral, sensorineural hearing loss	1. Speech reception in 65dB noise 2. Speech recognition in noise 3. APHAB 4. Hearing Handicap Inventory for Adults 5. Single Sided Deafness Questionnaire 6. Medical Outcomes Study SF-36v2 Health Survey	Oxford level of evidence: IV
Oeding et al (2010)[174]	*Design:* retrospective, with/without *Setting:* multicenter *Country:* USA *Comparator:* postoperative, unaided *Modifications:* NR *Length of F/U:* NR	*Number:* 19 entered, 16 completed *Sex:* 7 male, 9 female *Age:* mean 52.4 years *Type of HL:* sensorinueral, profound *Pre-op unaided threshold:* mean AC 101.6dB *Inclusion:* 1. Current BAHA user 2. unilateral profound SNHL with normal hearing in better ear 3. native English speaker 4. willing to attend visits & complete questionnaire *Exclusion:* 1. non-ambulatory 2. history of chronic or terminal illness	1. APHAB	Oxford level of evidence: IV
Pfiffner et al (2009)[175] & (2011)[176f]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Switzerland *Comparator:* preoperative unaided (with subgroup analysis for unilateral & bilateral conductive, mixed hearing loss & single-sided deafness) *Modifications:* NR *Length of F/U:* 3 months	*Number:* 114 entered & completed *Sex:* 56 male, 58 female *Age:* mean 52.8, range 18 -85 years *Type of HL:* single sided deafness, conductive or mixed *Pre-op unaided threshold:* NR *Inclusion:* 1. age ≥18 years 2. German speaking 3. three month audiologic tests in German 4. single sided BAHA	1. Functional gain 2. Threshold levels 3. Speech reception using German, French or Italian monosyllabic words or 2-digit numbers 3. Speech recognition using monosyllabic words @ 50, 65, & 80 dB	Oxford level of evidence: IV
Pfiffner et al (2011)[97f]	*Design:* prospective, with/without *Setting:* single academic center *Country:* Switzerland	*Number:* 20 entered & completed *Sex:* 10 male, 10 female *Age:* range 22 –72 years	1. Threshold levels 2. Speech reception in quiet using 2-digit Freiburg numbers	Oxford level of evidence:

Study	Design	Patients	Outcome Measures	Quality
	Comparator: preoperative unaided, BAHA Divino, BAHA BP100 *Modifications:* None *Length of F/U:* NR	*Type of HL:* mixed & conductive *Pre-op unaided threshold:* mean AC 51.5dB *Inclusion:* 1. user of BAHA Divino 2. PTC AC (0.5- 4kHz) ≥30dB, ABG ≥20dB in BAHA ear 3. PTC AC (0.5- 4kHz) ≥25dB	3. Speech recognition in quiet using Freiburg monosyllabic words @ 50, 65, & 80dB 4. APHAB	IV
Ricci et al (2011)[177]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Italy *Comparator:* preoperative with bone conduction hearing aid *Modifications:* None *Length of F/U:* >1 year	*Number:* 31 entered & completed *Sex:* 16 male, 17 female *Age:* mean 8.7, range 5-14 years *Type of HL:* conductive *Pre-op unaided threshold:* mean AC 51.2dB, mean BC 14.1dB *Inclusion:* patients with bilateral congenital aural atresia, implanted with a BAHA	1. Threshold levels 2. Glasgow Children Benefit Inventory 3. Adverse events	Oxford level of evidence: IV
Saliba et al (2010)[178]	*Design:* single arm trial *Setting:* single academic center *Country:* Canada *Comparator:* preoperative unaided *Modifications:* none *Length of F/U:* > 1 year	*Number:* 17 entered & completed *Sex:* 10 male, 7 female *Age:* mean 9.5, range 5-18 years *Type of HL:* conductive *Pre-op unaided threshold:* mean AC 64.1dB, mean BC 15.8dB *Inclusion:* consecutive patients <18years receiving BAHA	1. Functional gain 2. Adverse events	Oxford level of evidence: IV
Saliba et al (2011)[179]	*Design:* prospective, with/without *Setting:* single academic center *Country:* Canada *Comparator:* postoperative unaided *Modifications:* None *Length of F/U:* NA	*Number:* 21 entered & completed *Sex:* NR *Age:* NR *Type of HL:* sensorineural, profound, single-sided deafness *Pre-op unaided threshold:* NR *Inclusion:* 1. ≥18 years old 2. profound unilateral SNHL with BAHA implanted on deaf side 3. class A or B hearing for the contralateral ear 4. BAHA use ≥6 months	1. Speech recognition using the HINT 2. Sound locatlization 3. APHAB	Oxford level of evidence: IV
Soo et al (2009) [180]	*Design:* single arm trial *Setting:* single academic center *Country:* China *Comparator:* preoperative unaided *Modifications:* two-stage procedure under local anesthesia *Length of F/U:* mean 39.8, range 13-58 months	*Number:* 13 entered, 11 completed *Sex:* 1 male, 10 female *Age:* mean 48.15, range 36-70 years *Type of HL:* NR *Pre-op unaided threshold:* mean AC 63.5dB, mean BC 29.5dB *Inclusion:* post-irradiated nasopharyngeal carcinoma (NPC) patients with hearing impairment 2. cannot or prefer not to wear a conventional hearing aid 3. BC PTA (05-3kHz) ≤45dB 4. ABG ≥30dB 5. speech discrimination ≥60% *Exclusion:* 1. evidence of residual or recurrent locoregional NPC or de novo malignancy	1. Threshold levels (unaided only) 2. Patient satisfaction score	Oxford level of evidence: IV
Van Wieringen et al (2011)[181]	*Design:* prospective, cohort *Setting:* single academic center *Country:* Belgium	*Number:* 19 entered & completed *Sex:* NR *Age:* mean 55, range 25-72 years	1. Threshold levels 2. Speech reception (SRT50) in noise 3. APHAB	Oxford level of evidence:

Study	Design	Patients	Outcome Measures	Quality
	Comparator: postoperative unaided, subgroup analysis of single-sided deafness, unilateral & bilateral conductive & mixed hearing loss *Modifications:* NR *Length of F/U:* NR	*Type of HL:* single-sided deafness, mixed & conductive, mild to profound *Pre-op unaided threshold:* NR *Inclusion:* patients with BAHA	4. Speech, Spatial & Qualities of hearing scale	IIb
Wazen et al (2010)[182]	*Design:* single arm trial *Setting:* single academic center *Country:* USA *Comparator:* preoperative unaided *Modifications:* NR *Length of F/U:* 3 months	*Number:* 22 entered, 21 completed *Sex:* 12 male, 9 female *Age:* mean 75, range 65-88 years *Type of HL:* single-sided deafness *Pre-op unaided threshold:* mean AC 80dB (range 59 – 110dB) *Inclusion:* 1. consecutive patients with single sided deafness & mild to moderate SNHL in the contralateral ear 2. implanted with the BAHA	1. speech recognition in quiet & 55dB noise using - consonant-nucleus-consonant words - NU-6 monosyllabic words - HINT sentences 2. Hearing Satisfaction Scale 3. BAHA comparison questionnaire 4. Glasgow Benefit Inventory 5. Adverse events	Oxford level of evidence: IV
Yuen et al (2009)[183]	*Design:* prospective, with/without *Setting:* single academic center *Country:* Canada *Comparator:* postoperative unaided *Modifications:* None *Length of F/U:* mean 22.4, range 7-48 months	*Number:* 34 entered, 21 completed *Sex:* 8 male, 13 female *Age:* mean 54.5, range 33.1- 72.1 years *Type of HL:* single-sided deafness *Pre-op unaided threshold:* NR *Inclusion:* consecutive patients with single-sided deafness implanted with BAHA	1. Speech reception using the HINT in 65dB noise 2. APHAB 3. Glasgow Hearing Aid Benefit Profile 4. Adverse events	Oxford level of evidence: IV
Zeitler et al (2011)[184]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* USA *Comparator:* preoperative unaided, subgroup analysis with loading time <6weeks, <12 weeks & >12 weeks *Modifications:* some patients received device loading @ <6 weeks *Length of F/U:* NR	*Number:* 64 entered & completed *Sex:* 39 female, 25 male *Age:* mean 55, range 18- 89 years *Type of HL:* single sided deafness, mixed & conductive *Pre-op unaided threshold:* NR *Inclusion:* consecutive, adult (≥18 years) patients undergoing unilateral BAHA for CHL, MHL, or SSD	1. Speech recognition using NU-6 in noise 2. Adverse events	Oxford level of evidence: IV
Cochlear Implants				
Adunka et al (2008)[185]	*Design:* retrospective, cohort *Setting:* single academic center *Country:* USA *Comparator:* preoperative unaided, substantial vs. not substantial residual hearing loss *Modifications:* NR *Length of F/U:* 1 year	*Number:* 50 entered & completed *Sex:* 17 male, 23 female *Age:* mean 62.3, range 23.3 – 82.3 years *Type of HL:* NR *Pre-op unaided threshold:* NR *Inclusion:* 1. patients with cochlear implants 2. test group: adults with substantial preoperative residual hearing (speech reception using: CUNY test ≥60%, HINT in quiet ≥50%, or CNC word test ≥20 %) 3. control group: adults without substantial preoperative residual hearing 4. speech perception tests results @ 1 year	1. Speech reception using - HINT in quiet @ 60dB - HINT + 10dB SNR - City of New York sentence recognition in quiet @ 60dB - consonant nucleus consonant words @ 60dB	Oxford level of evidence: IIb
Aftab et al (2010)[186]	*Design:* retrospective, cohort	*Number:* 10 AIED , 12 non-AIED completed	1. Threshold levels	Oxford

Study	Design	Patients	Outcome Measures	Quality
	Setting: single academic center *Country:* USA *Comparator:* cochlear implant recipients with & without autoimmune inner ear disease(AIED) *Modifications:* None *Length of F/U:* short term (<12 months) or long term (>12 months)	*Sex:* AIED: 4 male, 6 female, non-AIED: 4 male, 8 female *Age:* AIED: mean 49.6, range 31-77 years Non-AIED: mean 56.8, range 27-83 years *Type of HL:* sensorineural, profound *Pre-op unaided threshold:* CI: mean AC 90dB, Controls: mean AC 102dB *Inclusion:* 1. patients who underwent CI for hearing loss 2. exposed group: hearing loss due to autoimmune inner ear disease (AIED) 3. non-exposed group: hearing loss from other causes *Exclusion:* 1. prelingual deafness 2. inadequate audiological data	2. Speech reception 3. Speech recognition using Northwestern University words (NU-6) 4. Adverse events	level of evidence: IIb
Arisi et al (2010)[187]	*Design:* prospective, controlled trial *Setting:* single academic center *Country:* Italy *Comparator:* preoperative unaided, "good users", "poor performers" *Modifications:* NR *Length of F/U:* 3 years	*Number:* 45 entered & completed *Sex:* 30 male, 15 female *Age:* mean 13.4, range 11-18 years *Type of HL:* severe to profound, prelingual *Pre-op unaided threshold:* NR *Inclusion:* 1. age ≥11 years at implantation 2. prelingual deafness before age 4 3. oral Italian as primary communication mode 4. auditory-oral or auditory-verbal training in school years 5. use of high-power Has until implantation 6. at least 36 months of implant use 7. "poor performers" have a mean score of ≤30% on preoperative speech tests vs "good users" have a mean score of >30% *Exclusion:* 1. associated neurologic or otologic pathology	1. speech recognition using - consonant vowel consonants - disyllabic words - sentence recognition 2. Adverse events	Oxford level of evidence: IIb
Arndt et al (2010)[188]	*Design:* single arm trial *Setting:* single academic center *Country:* Germany *Comparator:* preoperative unaided, BAHA 107ntense on heardband, CROS hearing aid *Modifications:* NR *Length of F/U:* 6 months	*Number:* 11 entered & completed *Sex:* NR *Age:* mean 43.5, range 23-68 years *Type of HL:* severe to profound *Pre-op unaided threshold:* mean AC 98.36dB *Inclusion:* 1. acquired unilateral deafness 2. PTA ≥70dB 3. word recognition using Freiburg monosyllables ≤30% @ 70dB 4. better ear PTA≤30dB & ≥80% Freiburg word recognition @ 65dB 5. CROS & BAHA not successful 6. auditory nerve intact & cochlea patent	1. Speech reception using Oldenburg sentence test in noise 2. Speech recognition using Hochmair-Schulz-Moser sentence test 3. Speech, Spacial & Qualities of hearing questionnaire 4. Health Utilities Index-3	Oxford level of evidence: IV
Budenz et al (2011)[189]	*Design:* retrospective cohort *Setting:* single academic center *Country:* USA	*Number:* 108 entered & completed *Sex:* NR *Age:* mean 63.5, range 22-86 years	1. Speech reception threshold (SRT50) 2. Speech recognition using - consonant nucleus consonant words @	Oxford level of evidence:

Study	Design	Patients	Outcome Measures	Quality
	Comparator: preoperative unaided, patients >70 years old, patients aged 18-69 years *Modifications:* NR *Length of F/U:* 2 years	*Type of HL:* NR *Pre-op unaided threshold:* NR *Inclusion:* 1. consecutive patients with cochlear implants 2. postlingual deafness 3. cochlear implant at age ≥70 years (older group) or 18-69 years (younger group) *Exclusion:* 1. English not primary language 2. hybrid or double array cochlear implant 3. without 2 years of postoperative performance data 4. different speech reception testing protocol	65dB - CNC phenomes @ 65dB - City of New York Sentences in quiet @ 65dB - CNY sentences in noise @ SNR of 10 3. Adverse events	IIb
Cosetti et al (2010)[190]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* USA *Comparator:* preoperative unaided (with subgroup analysis of adults & children) *Modifications:* None *Length of F/U:* >1 year	*Number:* 97 entered & completed *Sex:* NR *Age:* mean 44.4, range 5-92 years *Type of HL:* NR *Pre-op unaided threshold:* mean AC 91dB (range 35 -120dB) *Inclusion:* consecutive patients implanted with the Nucleus Freedom cochlear implant *Exclusion:* 1. structural cochlear abnormalities 2. simultaneous bilateral implantation 3. double array or polar insertion of standard array implant	1. Speech recognition using: - consonant-nucleus-consonants @ 65dB - multisyllable lexical neighborhood test @ 65dB - phonetically balanced kindergarten test - lexical neighborhood test - Glendmald Auditory screening procedure	Oxford level of evidence: IV
Eshranghi et al (2009)[191]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* USA *Comparator:* preoperative unaided *Modifications:* NR *Length of F/U:* NR	*Number:* 21 entered & completed *Sex:* 11 male, 10 female *Age:* mean 82.6, range 79-89 years *Type of HL:* profound *Pre-op unaided threshold:* mean AC 91dB *Inclusion:* consecutive patients implanted with cochlear implants after age 79	1. Threshold levels 2. Speech recognition using - Hearing in Noise Test - City University of New York sentences 3. Hearing Handicap Inventory for the elderly 4. Quality of Life 5. Adverse events	Oxford level of evidence: IV
Klop et al (2007)[192]	*Design:* single arm trial *Setting:* single academic center *Country:* Netherlands *Comparator:* preoperative unaided *Modifications:* NR *Length of F/U:* ≥2 years	*Number:* 8 entered & completed *Sex:* 3 male , 5 female *Age:* mean 36, range 21-55 years *Type of HL:* profound, prelingual *Pre-op unaided threshold:* mean AC 111.3dB (range 100-130dB) *Inclusion:* 1. age ≥16 years at implantation 2. aided PTA≥90dB 3. phenome recognition <40% 4. "state of the art" cochlear implant 5. properly motivated with realistic expectations 6. presence of social support in an oral-aural setting 7. normal ear anatomy 9. prelinguistic severe hearing loss *Exclusion:*	1. Speech recognition using consonant-vowel-consonant words & phenomes @ 65dB 2. Health Utility Index (HUI-MarkII) 3. Njemegen Cochlear implant Questionnaire	Oxford level of evidence: IV

Study	Design	Patients	Outcome Measures	Quality
		1. medical contraindications to implantation		
Klop et al (2008)[193]	*Design:* single arm trial *Setting:* single academic center *Country:* Netherlands *Comparator:* preoperative unaided *Modifications:* NR *Length of F/U:* >12 months	*Number:* 44 entered & completed *Sex:* 15 male, 29 female *Age:* mean 54.7, range 25-86 years *Type of HL:* severe to profound, postlingual *Pre-op unaided threshold:* mean AC 113.4dB (range 83-130dB) *Inclusion:* consecutive patients with postlingual deafness receiving cochlear implants	1. Speech recognition using consonant-vowel-consonant words & phenomes 2. Health Utility Index 3. Njemegen Cochlear implant Questionnaire	Oxford level of evidence: IV
Migirov et al (2009)[194]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Israel *Comparator:* preoperative unaided *Modifications:* supramental or posterior tympanostomy approach, or combined with subtotal petrosectomy *Length of F/U :*≥12 months	*Number:* 20 entered & completed *Sex:* NR *Age:* mean 72.3, range 65-80 years *Type of HL:* severe to profound *Pre-op unaided threshold:* mean 111.8dB (range 83.3 – 125 dB) *Inclusion:* postlingual patients aged ≥65 years at cochlear implantation with ≥12 months F/U	1. Speech recognition using - Hebrew AB monosyllabic CVC isophonetic meaningful words - Hebrew CUNY sentence test - Hebrew Early speech perception closed set speech test 2. Adverse events	Oxford level of evidence: IV
Most et al (2010)[195]	*Design:* prospective, pre/post *Setting:* single academic center *Country:* Isreal *Comparator:* preoperative unaided *Modifications:* NR *Length of F/U:* NR	*Number:* 38 entered & completed *Sex:* 12 male, 26 female *Age:* mean 36.61, range 19-71 years *Type of HL:* severe to profound *Pre-op unaided threshold:* NR *Inclusion:* adults with severe to profound prelingual hearing loss receiving cochlear implants	1. Self-assessment QoL questionnaires - Index of self esteem -satisfaction questionnaire	Oxford level of evidence: IV
Mueller et al (2011)[196]	*Design:* single arm trial *Setting:* multicenter *Country:* Germany, France, Sweden, Norway, Spain *Comparator:* None (safety only) *Modifications:* standard or supramental approach *Length of F/U:*6 months	*Number:* 50 entered & completed *Sex:* 21 male, 29 female *Age:* mean 27, range 0.7-83 years *Type of HL:* profound *Pre-op unaided threshold:* NR *Inclusion:* adults & children receiving Med-EL Sonatati cochlear implants for profound deafness	1. Adverse events	Oxford level of evidence: IV
Oyanguren et al (2010)[197]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Brazil *Comparator:* preoperative with hearing aids *Modifications:* NR *Length of F/U:* ≥1 year	*Number:* 14 completed *Sex:* 7 male, 7 female *Age:* mean 63, range 60-73 years *Type of HL:* profound *Pre-op unaided threshold:* mean AC 113dB (range 105-125dB) *Inclusion:* patients aged ≥60 years using cochlear implants for ≥1 year	1. Threshold levels 2. Speech reception using - Ling's sound detection & discrimination - Discrimination of vowels -Four choice test - Supra-segment pattern recognition tests - open sentence recognition test - monosyllable recognition test 3. Self-assessment QoL questionnaire 4. Adverse events	Oxford level of evidence: IV
Noble et al (2008)[198,199] & (2009)[200]	*Design:* Nested cohort *Setting:* single academic center *Country:* USA *Comparator:* preoperative unaided, unilateral CI, bilateral CI, CI + HA (with subgroup analysis of old vs young patients)	*Number:* 30 unilateral CI, 13bilateral CI, 17 CI + HA completed *Sex:* 28 male, 32 female *Age:* NR *Type of HL:* NR *Pre-op unaided threshold:* mean AC 101dB *Inclusion:* NR	1. Speech recognition using consonant-nucleus-consonant words 2. Speech, Spatial & Qualities of Hearing Scale 3. Hearing Handicap Inventory Elderly 4. Hearing Aid Handicap Questionnaire	Oxford level of evidence: IIb

Study	Design	Patients	Outcome Measures	Quality
	Modifications: NR *Length of F/U:* ≥12 months post insertion			
Prentiss et al (2010)[201]	*Design:* single arm trial *Setting:* single academic center *Country:* USA *Comparator:* preoperative unaided *Modifications:* extended round window approach *Length of F/U:* NR	*Number:* 18 entered & completed *Sex:* 5 male, 13 female *Age:* mean 63.17, range 26-84 years *Type of HL:* severe to profound *Pre-op unaided threshold:* NR *Inclusion:* patients to be implanted with cochlear implants	1. Functional gain 2. Speech recognition using - HINT in quiet - HINT in 10dB SNR noise - Consonant-nucleus-consonant words	Oxford level of evidence: IV
Sahli et al (2009)[202]	*Design:* retrospective, cohort *Setting:* single academic center *Country:* Turkey *Comparator:* preoperative unaided, normal hearing controls *Modifications:* NR *Length of F/U:* NR	*Number:* 30 entered & completed *Sex:* 13 male, 17 female *Age:* mean 11.8, range 7.6 – 16.0 years *Type of HL:* severe to profound, prelingual *Pre-op unaided threshold:* mean AC 104dB *Inclusion:* 1. adolescents 12-19 years olds 2. individuals with cochlear implants that have experienced hearing loss before developing speech & language skills 3. must be using a cochlear implant *Exclusion:* medical problems &/or second disability	1. Threshold levels 2. Rosenberg Self-Esteem Scale	Oxford level of evidence: IV
Sainz et al (2009)[203]	*Design:* prospective, pre/post *Setting:* single academic center *Country:* Spain *Comparator:* preoperative unaided *Modifications:* NR *Length of F/U:* 72 months	*Number:* 15 entered & completed *Sex:* 6 male, 9 female *Age:* mean 58.7 years *Type of HL:* NR *Pre-op unaided threshold:* NR *Inclusion:* patients with cochlear otosclerosis treated with cochlear implants with ≥6 years F/U	1. Speech recognition using - vowels -2-syllable words - monosyllabic words - consonants - closed words - lip reading - common phrases 2. Adverse events	Oxford level of evidence: IV
Santarelli et al (2008)[204]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Italy *Comparator:* preoperative unaided & with hearing aid *Modifications:* NR *Length of F/U:* 3 years	*Number:* 18 entered & completed *Sex:* 12 male, 6 female *Age:* mean 19.9, range 13-30 years *Type of HL:* profound *Pre-op unaided threshold:* mean AC 108.1dB *Inclusion:* 1. profound, prelingual hearing loss 2. recipients of cochlear implants with substantial functional gain 3. onset of deafness before age 3 with hearing aid use since childhood 4. age at implantation >12 years 5. better ear PTA of >90dB @ 0.5-4kHz 6. oral communication & auditory-oral training throughout school years & for ≥1 year after implant *Exclusion:* mental retardation	1. Threshold levels 2. Speech discrimination using - disyllabic words - trisyllabic words - sentences - vowels - consonants 3. Speech recognition using - trisyllabic words - sentences	Oxford level of evidence: IV

Study	Design	Patients	Outcome Measures	Quality
Shpak et al (2009)[205]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Israel *Comparator:* preoperative unaided *Modifications:* NR *Length of F/U:* 24 months	*Number:* 20 entered & completed *Sex:* NR *Age:* mean 13.02, range 8-18.5 years *Type of HL:* profound *Pre-op unaided threshold:* mean AC 112dB *Inclusion:* pre-adolescents & adolescents with prelingual profound hearing loss who received cochlear implantation	1. Speech recognition using - Hebrew AB word tests - Hebrew Central Institute of Deaf test in quiet & noise	Oxford level of evidence: IV
Souza de Souza (2011)[206]	*Design:* single arm trial *Setting:* single academic center *Country:* Brazil *Comparator:* preoperative unaided *Modifications:* NR *Length of F/U:* 2 years	*Number:* 25 entered, 23 completed *Sex:* 8 male, 15 female *Age:* mean 13.1, range 10-17.9 years *Type of HL:* sensorineural, severe to profound, prelingual *Pre-op unaided threshold:* NR *Inclusion:* 1. age 10 -17 years 11 months 2. severe to profound prelingual hearing loss 3. past use of hearing aids	1. Speech recognition using - Four choice test - vowel recognition - closed set sentences - open set sentences	Oxford level of evidence: IV
Tremblay et al (2008)[207]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* Canada *Comparator:* preimplanation & postimplantation "best aided" *Modifications:* NR *Length of F/U:* 4-13 weeks	*Number:* 17 entered & completed *Sex:* NR *Age:* mean 54, range 29-83 years *Type of HL:* NR *Pre-op unaided threshold:* NR *Inclusion:* 1. adults (>18 years) who received cochlear implants 2. speech recognition score of ≥40% in their best aided condition prior to implantation	1. Speech recognition using open set words & sentences	Oxford level of evidence: IV
Williamson et al (2009)[208]	*Design:* retrospective, pre/post *Setting:* single academic center *Country:* USA *Comparator:* preoperative "best aided" *Modifications:* NR *Length of F/U:* ≥12 months, mean 44.1 months	*Number:* 28 completed *Sex:* 15 male, 13 female *Age:* mean 75.8, range 65-89 years *Type of HL:* NR *Pre-op unaided threshold:* NR *Inclusion:* 1. consecutive patients treated with cochlear implants 2. current age ≥75 years 3. previous experience with conventional hearing aids for ≥ 6 weeks 4. audiologic F/U data for ≥12 months post-implantation *Exclusion:* patients with significant cognitive deficits, neurologic decline, cerebrovascular accidents with residual deficits or death within 12 months post-implant	1. Speech recognition using HINT sentences 2. Self-assessment QoL questionnaire 3. Adverse events	Oxford level of evidence: IV

HL:hearing loss, NR: not reported, F/U: follow-up, SNHL: sensorineural hearing loss, FMT: floating mass transducer, AC: air conduction, BC: bone conduction

[a] partial overlap of patient populations for studies [98] & [130]

[b] partial overlap of patient populations for studies [131] & [140]

[c] partial overlap of patient populations for studies [137] & [136]

[d] partial overlap of patient populations for studies [142] & [100]

[e] partial overlap of patient populations for study [97] with studies [175]& [176] is likely

[+] Data extracted from abstract only

Appendix C – Evidence tables: excluded studies

Study	Main reasons for exclusion
Middle Ear Implants	
Cayé-Thomasen et al (2002)[209]	Did not include the devices being assessed
Cremers et al (2008)[210]	Case report of the Vibrant Soundbridge
Dazert et al (2000)[211]	Did not report outcomes of interest in abstract (full-text article in German)
Dumon (2007)[212]	Case report of the Vibrant Soundbridge
Frenzel et al (2010)[213]	Case report of the Vibrant Soundbridge
Hong et al (2009)[214]	Cadaveric temporal bones with no living human participants
Jiang et al (2004)[215]	Did not report outcomes of interest
Junker et al (2002)[25]	Did not report post-operative results
Kiefer et al (2006)[216]	Case report of the Vibrant Soundbridge
Kontorinis et al (2010)[217]	Did not report outcomes of interest
Labassi & Beliaeff (2005)[218]	Review article with no primary data
Osaki et al (2008)[219]	Non-english abstract
Roman et al (2010)[220]	Case report of the Vibrant Soundbridge
Saiki et al (1990)[221]	Did not include the devices being assessed
Saiki et al (1990)[222]	Did not include the devices being assessed
Shimizu et al (2011)[223]	Cadaveric temporal bones with no living human participants
Skarzynski et al (2004)[224]	Did not report outcomes of interest in abstract (full-text article in Polish)
Skarzynski et al (2008)[225]	Case report of the Vibrant Soundbridge
Snik et al (2001)[226]	No usable outcomes
Snik & Cremers (2004)[227,227]	Unusable comparators
Snik et al (2006)[107]	Did not report outcomes of interest
Snik et al (2007)[228]	Cannot extract outcomes specific to devices of interest
Wollenberg et al (2007)[229]	Did not report outcomes of interest in abstract (full-text article in German)
BAHA	
Bovo et al (2011)[230]	Device used is BAHA headband, not implanted device
Christensen et al (2008)[231]	Case series
D' Eredita et al (2010)[232]	Unusable comparators
De Wolf et al (2011)[233]	Cross sectional study design
Deas et al (2010)[234]	Normal hearing participants
Dotu et al (2011)[235]	Full-text article in Spanish
Dun et al (2010)[236]	Did not report outcomes of interest, bilateral results only
Evans & Kazahaya (2007)[237]	Case series
Flynn et al (2008)[238]	Opinion piece with no primary data
Ghossaini et al (2010)[239]	Cross sectional study design
Ho et al (2009)[240]	Cross sectional study design
Hodgetts et al (2010)[241]	Did not report outcomes of interest, unusable comparators
Hol et al (2010)[242]	Device used is BAHA headband, not implanted device
House et al (2010)[243]	Case series
Kunst et al (2007)[169]	Cross sectional study design

Study	Main reasons for exclusion
Kunst et al (2008)[244]	Cross sectional study design
De Wolf et al (2010)[245]	Did not report outcomes of interest
Mace et al (2009)[246]	Cross sectional study design
Mani & Sheehan (2009)[247]	Letter to the editor, no primary data
McDermott et al (2008)[248]	Cross sectional study design
McDermott et al (2009)[249]	Cross sectional study design
Newman et al (2010)[250]	Unusable comparators
Nicholson (2011)[251]	Device used is BAHA headband, not implanted device
Priwin et al (2007)[252]	Unusable comparators
Romo et al (2009)[253]	Case series
Sanchez-Camon et al (2007)[254]	Cross sectional study design
Stalfors & Tjellstrom (2008)[255]	Did not report outcomes of interest
Schroder et al (2010)[256]	Cross sectional study design
Snapp et al (2010)[257]	Did not report outcomes of interest
Stewart et al (2011)[258]	Review article with no primary data
Tringali et al (2008)[259]	Cross sectional study design
Verhagen et al (2008)[260]	Device used is BAHA headband, not implanted device
Verstrasten et al (2008)[261]	Device used is BAHA headband, not implanted device
Watson et al (2008)[262]	Did not report outcomes of interest
Cochlear Implants	
Balkany et al (2007)[263]	Did not use device of interest (hybrid & totally implantable cochlear implants)
Beijen et al (2007)[264]	Inappropriate population, included toddlers <2 years old only
Bichey & Miyamoto (2008)[265]	Did not report outcomes of interest
Bodmer et al (2007)[266]	Case-control study design
Bradley et al (2010)[267]	Unusable comparators
Briggs et al (2008)[268]	Did not use device of interest (totally implantable cochlear implant)
Brown et al (2010)[269]	Did not report outcomes of interest
Budenz et al(2009)[270]	Did not report outcomes of interest (bilateral implant results only)
Chadha et al (2009)[271]	Inappropriate population & did not report outcomes of interest (children <3 years with bilateral implants)
Chang et al (2010)[272]	Did not report outcomes of interest (bilateral implant results only)
Chmiel et al (2000)[273]	Cross sectional study design
Clark et al (2011)[274]	Did not report outcomes of interest
De Raeve (2010)[275]	Inappropriate population, included children < 18 months only
Di Nardo et al (2007)[276]	Did not report outcomes of interest
Dunn et al (2010) [277]	Unusable comparators
Eapen et al (2009)[278]	Did not report outcomes of interest (bilateral implant results only)
Friedland et al (2010)[279]	Case-control study design
Gantz et al (2010)[280]	Inappropriate population & did not report outcomes of interest (children <2 years with bilateral implants)
Gordon & Papsin (2009)[281]	Inappropriate population & did not report outcomes of interest (children <3 years with bilateral implants)
Harris et al (2010)[282]	Did not report outcomes of interest
Koch et al (2010)[283]	Did not report outcomes of interest (bilateral implant results only)
Lalwani et al (2009)[284]	Did not report outcomes of interest

Study	Main reasons for exclusion
Laske et al (2009)[285]	Did not report outcomes of interest (bilateral implant results only)
Lenarz et al (2009)[286]	Did not use device of interest (hybrid device)
Low et al (2008)[287]	Inappropriate population, included children < 3 years only
Meister et al (2010)[288]	Unusable comparators
Peters et al (2007)[289]	Did not report outcomes of interest (bilateral implant results only)
Poissant et al (2008)[290]	Cross sectional study design
Ramsden et al (2009)[291]	Did not report outcomes of interest
Scherf et al (2009)[292]	Did not report outcomes of interest
Scherf et al (2009)[293]	Did not report outcomes of interest (bilateral implant results only)
Serin et al (2010)[294]	Case series
Soli & Zheng (2010)[295]	Review articles, no primary data
Valimaa & Lopponen (2008)[296]	Did not report outcomes of interest
Warner-Czyz (2009)[297]	Cross sectional study design
Wu et al (2008)[298]	Did not report outcomes of interest
Xenellis et al (2008)[299]	Case series & did not report outcomes of interest
Yoshida et al (2008)[300]	Case series
Zeitler et al (2008)[301]	Did not report outcomes of interest (bilateral implant results only)

Appendix D – Safety (adverse events)

Adverse events reported

Study	N	Device malfunction or failure	Device extrusion or migration	Damage to TM	Vertigo or dizziness	Decrease in residual hearing	Facial weakness	Taste disturbance or chorda tympani damage	Pain or headache	Tinnitus	Wound Infection	Minor Skin Reaction	Sensation of aural fullness	Skin lacerations	Insufficient gain	Otitis or effusion	Other
Middle Ear Implants																	
Vibrant Soundbridge (VSB)																	
Bruschini et al (2009)[113]	12	0	0	1(8.3%)	0	0	0	0	0	0	0	0	0	5(41.7%)	0	0	0
Colletti et al (2006)[114]	9	1(11.1%)	0	0	0	0	0	0	0	0	0	0	0	0	1(11.1%)	0	0
Colletti et al (2009)[115]	12	0	0	0	2(16.7%)	0	0	0	0	0	0	0	0	0	0	0	0
Cuda et al (2009)[117]	8	0	0	0	1(12.5%)	1(12.5%)	0	0	0	0	0	0	0	0	0	0	0
Dumon et al (2009)[118]	13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fisch et al (2001)[119]	47	0	0	0	0	0	0	7(14.9%)	0	1(2.1%)	0	0	0	0	0	0	1(2.1%)[a]
Foyt & Carfrae (2006)[120]	9	NR	NR	NR	NR	NR	NR	NR	NR	NR	0	NR	NR	NR	NR	NR	NR
Fraysse et al (2001)[121]	25	0	0	0	0	0	1(4%)	0	3(12%)	0	0	0	0	0	0	0	0
Kiefer & Staudenmaier (2010)[126]	15	0	0	0	0	0	0	0	0	0	0	0	0	0	2(13.3%)	0	0
Lenarz et al (1998)[127] & (2001)[128]	34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Linder et al (2008)[129]	5	1(20%)	0	0	0	0	0	2(40%)	0	0	1(20%)	0	0	0	0	0	0
Luetje et al (2010)[130]	31	4(12.9%)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mosnier et al (2008)[131*]	77	9(11.7%)	0	0	0	0	0	6(8%)	0	0	0	9(11.7%)	21(27%)	0	1(1.3%)	0	2(2.6%)[b]
Olgun et al (2008)[132]	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rajan et al (2011)[101]	10	0	3(30%)	0	0	0	0	0	0	0	1(10%)	0	0	0	0	0	0
Rameh et al (2010)[103]	62	4(6.5%)	0	0	0	0	0	0	18(29%)	0	0	14(23%)	0	0	0	0	0
Schmuziger et al	20	1(5%)	1(5%)	0	0	0	0	3(15%)	2(10%)	2(10%)	0	0	0	0	0	0	1(5%)[c]

Study	N	Device malfunction or failure	Device extrusion or migration	Damage to TM	Vertigo or dizziness	Decrease in residual hearing	Facial weakness	Taste disturbance or chorda tympani damage	Pain or headache	Tinnitus	Wound Infection	Minor Skin Reaction	Sensation of aural fullness	Skin lacerations	Insufficient gain	Otitis or effusion	Other
(2006)[135]																	
Snik et al & (1999)[136] & (2000)[137]	6	0	0	0	0	1(16.7%)	0	0	0	0	0	0	0	0	0	1(16.7%)	1(16.7%)[d]
Sterkers et al (2003)[140] *	95	5(5.3%)	0	0	11(11.6%)	8(8.4%)	0	13(13.7%)	7(7.4%)	0	0	0	19(20%)	0	0	0	7(7.4%)[e]
Todt et al (2005)[100]	23	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Venail et al (2007)[145]	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Zwartenkot et al (2011)[89]	13	0	5(38.5%)	1(7.7%)	0	1(7.7%)	0	2	0	0	0	0	0	1(7.7%)	0	0	1(7.7%)[f]
Total (reported)	**533**	**25(4.8%)**	**9(1.7%)**	**2(0.4%**	**14(2.7%)**	**11(2.1%)**	**1(0.2%)**	**33(6.3%)**	**30(5.7%)**	**3(0.6%)**	**2(0.4%)**	**23(4.4%)**	**40(7.6%)**	**6(1.1%)**	**4(0.8%)**	**1(0.2%)**	**13(2.5%)**
Esteem																	
Chen et al (2004)[148]	7	2(28.6%)	0	0	0	NR	0	0	2(28.6%)	0	1(14.3%)	0	0	0	4(57.1%)	4(57.1%)	4(57.1%)[g]
Kraus et al (2011)[91]	57	0	0	0	11(19.3%)	NR	4(7.1%)	25(43.9%)	15(26.3%)	10 (17.5%)	2(3.5%)	0	0	0	4(7.1%)	18(31.6%)	44(77.2%)[h]
Maurer & Savvas (2010)[85]	10	1(10%)	0	0	0	NR	0	0	0	0	0	0	0	0	0	0	0
Memari et al (2011)[149]	10	1(10%)	0	0	0	NR	2(20%)	1(10%)	1(10%)	0	0	0	0	0	0	0	2(20%)[i]
Murali et al (2009)[150]	3	0	0	0	0	NR	1(33.3%)	0	0	0	0	0	0	0	0	0	0
Total (reported)	**87**	**4(4.6%)**	**0**	**0**	**11(12.6%)**	**NR**	**7(8.0%)**	**26(29.9%)**	**18(20.7%)**	**10(11.5%)**	**3(3.4%)**	**0**	**0**	**0**	**8(9.2%)**	**22(25.3%)**	**50(57.5%)**
Carina																	
Bruschini et al (2009)[151] & (2010)[152]	8	2(25%)	1(12.5%)	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Deveze et al (2010)[153]	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Jenkins et al (2007)[92] & (2008)[93]	20	9(45%)	3(15%)	0	1(5%)	4(20%)	0	0	0	1(5%)	0	0	2(10%)	0	0	3(15%)	0
Lefebvre et al (2009)[87]	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Martin et al (2009)[154]	11	1(9.1%)	0	0	1(9.1%)	0	0	0	0	1(9.1%)	2(18.2%)	0	0	0	0	0	0
Rameh et al (2010)[103]	16	0	0	0	0	0	0	0	2(12.5%)	0	0	0	0	0	0	0	0
Siegert et al (2007)[156]	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Study	N	Device malfunction or failure	Device extrusion or migration	Damage to TM	Vertigo or dizziness	Decrease in residual hearing	Facial weakness	Taste disturbance or chorda tympani damage	Pain or headache	Tinnitus	Wound Infection	Minor Skin Reaction	Sensation of aural fullness	Skin lacerations	Insufficient gain	Otitis or effusion	Other
Tringali et al (2008)[158]	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1(100%)[i]
Total (reported)	**68**	**12(17.6%)**	**4(5.9%)**	**0**	**2(2.9%)**	**4(5.9%)**	**0**	**0**	**2(2.9%)**	**2(2.9%)**	**2(2.9%)**	**0**	**2(2.9%)**	**0**	**0**	**3(4.4%)**	**1(1.5%)**
BAHA																	
Christensen et al (2010) [162]	23	0	0	0	0	0	0	0	0	0	0	2(8.7%)	0	0	0	0	1(4.3%)[k]
Fuchsmann et al (2010)[166]	16	0	0	0	0	0	0	0	4(25%)	0	0	4(25%)	0	0	0	0	2(12.5%)[l]
Gluth et al (2010)[96]	21	0	0	0	0	0	0	0	0	0	1(4.8%)	8(38.1%)	0	0	0	0	14(66.7%)[m]
Mazita et al (2009) [172]	16	0	0	0	0	0	0	0	0	0	3(18.8%)	0	0	0	0	0	1(6.3%)[k] 2(12.5)[l]
Ricci et al (2011)[177]	31	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1(3.2)[k] 1(3.2)[l]
Saliba et al (2010)[178]	17	0	1(5.9%)	0	0	0	0	0	0	0	1(5.9%)	0	0	0	0	0	0
Wazen et al (2010)[182]	21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Yuen et al (2009)[183]	21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1(4.8%)[l]
Zeitler et al (2011) [184]	64	0	0	0	0	0	0	0	0	0	0	19(29.7%)	0	0	0	0	6(9.4%)[n]
Total (reported)	**230**	**0**	**1(0.6%)**	**0**	**0**	**0**	**0**	**0**	**4(2.4%)**	**0**	**5(3.0%)**	**33(14.3%)**	**0**	**0**	**0**	**0**	**29(12.6%)**

[a] device implanted upside-down requiring revision surgery
[b] 2 cases of fibrous tissue surrounding ossicular chair causing decrease in sound quality
[c] hematoma
[d] improper positioning of receiver requiring revision
[e] includes: headache, tinnitus, etc.
[f] external auditory canal collapse secondary to skin incisions & otitis requiring surgery
[g] includes: headache, ear pain, leg pain
[h] miscellaneous events which are not described
[i] 1 excessive bone growth in the middle ear & 1 fibrosis requiring revision surgery
[j] hematoma requiring evacuation
[k] failure of osseointegration
[l] skin overgrowth over abutment requiring revision surgery
[m] required repair of external processor
[n] major skin complications delaying device loading, 3 required longer abutment
[*] some overlap in patient populations between reference [93] & [92]

Appendix E – Efficacy/effectiveness

Table E1. Functional gain

Study	Type of hearing loss	Severity of hearing loss	Device type	N	Mean gain (dB)	Gain by frequency in kHz (dB)								
						0.25	0.5	1	1.5	2	3	4	6	8
Middle Ear Implants														
Vibrant Soundbridge														
Babighian & Mazzoli (2005)[109]	NR	moderate	Vibrant P	16	29.6	12	20	28	40	33	28	32	24	-
			Vibrant D		32.5	11	19	30	48	37	39	43	33	-
Batman et al (2007)[110]	SNHL, MHL	moderate	NR	2	22.5	-	-	-	-	-	-	-	-	-
Beltrame et al (2009)[111]	MHL	severe	NR	12	34.6	22	30	41	-	40	-	40	-	-
Boeheim et al (2010)[90]	SNHL	NR	NR	10	12.9	-9.5	1	13	-	20.5	20	14.5	22	22
Boheim et al (2007)[112]	SNHL	moderate-severe	NR	9	34	-	-	-	-	-	-	-	-	-
Bruschini et al (2009)[113]	SNHL, MHL	moderate	NR	12	27.2	-	-	-	-	-	-	-	-	-
Colletti et al (2006)[114]	MHL, CHL	moderate-severe	NR	7	13.5	-	0	13	-	22	-	19	-	-
Colletti et al (2010)[116]	MHL	severe	NR	8	41.1	-	-	-	-	-	-	-	-	-
Cuda et al (2009)[117]	MHL	mild-moderate	NR	8	30.6	-	-	-	-	-	-	-	-	-
Dumon et al (2009)[118]	MHL	moderate-severe	NR	5	32	-	-	-	-	-	-	-	-	-
Foyt & Carfrae (2006)[120]	SNHL, MHL	moderate	NR	8	13.9	-	-	-	-	-	-	-	-	-
Fraysse et al (2001)[121]	SNHL	mild-severe	Vibrant P	25	19	4	13	21	26	26	21	22	23	13.5
			Vibrant D		25	5	18	29	37	38	26	22.5	22.5	19
Frenzel et al (2009)[122]	MHL	moderate-severe	NR	7	44.6	-	-	-	-	-	-	-	-	-
Garin et al (2002)[123]	SNHL	moderate-severe	Signia & Widex	15	20.4	3	9.5	23	-	35.5	-	31	-	-
Huttenbrink et al (2008)[125]& (2010)[74]	MHL	moderate-severe	NR	6	38.2	-	14	26		47	48	56	-	-
Kiefer & Staudenmaier (2010)[126]	NR	moderate	NR	15	29.1	23	20	31	38	37	23	23	34	33
Linder et al (2008)[129]	MHL, CHL	moderate-severe	NR	5	47.2	30	39	48	-	42	-	53	-	71
Luetje et al (2002)[101a]	SNHL	moderate-severe	Vibrant P	50/53*	26.2	-	13	26	-	39	-	30	23	-
			Vibrant D		31.8	-	23	32	-	44	-	33	27	-
Luetje et al (2010)[130a]	SNHL	moderate-severe	NR	31	31.4	-	-	-	-	-	-	-	-	-
Mosnier et al (2008)[131b]	NR	NR	NR	50	26	-	18	25	-	36	-	25	-	-
Olgun et al (2008)[132]	MHL, CHL	moderate-severe	NR	4	29.5	-	-	-	-	-	-	-	-	-
Pok et al (2010)[133]	SNHL	severe	NR	54	29.1	25.7	20.9	20.5	-	23.8	30.2	36.1	37.6	37.9
Rameh et al (2010)[103]	SNHL	moderate-severe	NR	45	15.7	2	11	22	-	30	-	20	9	-
Saliba et al (2005)[134]	SNHL	moderate-severe	NR	8	16.2	12	10	23	-	30	-	10	12	-
Snik & Cremers (2001)[138]	SNHL	moderate-severe	304 processor	14	33	-	-	-	-	-	-	-	-	-
Snik et al (2004)[139]	SNHL	severe	NR	8	28.8	9	21	35	-	40	-	38	30	-
Sterkers et al (2003)[140b]	SNHL	mild-severe	NR	75	26.8	-	16	28	-	37	-	26	-	-

Study	Type of hearing loss	Severity of hearing loss	Device type	N	Mean gain (dB)	Gain by frequency in kHz (dB)								
						0.25	0.5	1	1.5	2	3	4	6	8
Sziklai & Szilvassy (2011)[99]	SNHL	moderate-severe	Model 404	7	43	-	-	-	-	-	-	-	-	-
Todt et al (2002)[142c]	SNHL	mild-severe	HF	5	18	-	1	11	-	22	21	22	25	24
			Vibrant D		27.1	-	4	17	-	37	37	38	29	28
Todt et al (2005)[100c]	SNHL	mild-severe	Vibrant D	7	23.6	-	7.9	27.1	30.7	28.6	-	26.4	20.7	23.6
			Signia	16	26.0	-	8.1	27.2	40.0	39.1	-	44.4	29.4	19.4
Truy et al (2008)[143]	NR	NR	NR	6	21.5	13.3	10.8	15	-	22.5	-	45.8	-	-
Venail et al (2007)[145]	MHL	moderate-severe	NR	2	32.5	-	-	-	-	-	-	-	-	-
Zehlicke et al (2010)[146]	MHL	moderate-severe	NR	7	29.8	22	30	40	46	28	32	20	20	-
Esteem														
Barbara et al (2009)[147] & (2011)[102]	SNHL	moderate-severe	NR	18	22	-	-	-	-	-	-	-	-	-
Chen et al (2004)[148]	SNHL	mild-severe	NR	5	17	-	-	-	-	-	-	-	-	-
Kraus et al (2011)[91]	SNHL	mild-severe	Esteem SP	54	18.8	12	18	25	-	35	25	19	10	6
Maurer & Savvas (2010)[85]	SNHL, MHL	NR	NR	10	33	-	18	34	-	41	37	35	-	-
Memari et al (2011)[149]	SNHL	moderate-severe	NR	10	11.6	-	-	-	-	-	-	-	-	-
Murali et al (2009)[150]	SNHL	NR	NR	1	26.3	10	22	50	-	38	-	29	-	9
Carina														
Bruschini et al (2009)[151] & (2010)[152]	SNHL, MHL	moderate-severe	NR	8	26.4	-	-	-		-	-	-	-	-
Deveze et al (2010)[153]	MHL	moderate	NR	1	31.8	25	30	25	25	40	25	40	45	-
Jenkins et al (2007)[92] & (2008)[93]	SNHL	moderate-severe	NR	20	9.3	2	0	10	18	15	7	12	10	-
Lefebvre et al (2009)[87]	MHL	moderate-severe	NR	6	20.8	-	-	-	-	-	-	-	-	-
Martin et al (2009)[154]	MHL	moderate-severe	NR	11	29	-	-	-	-	-	-	-	-	-
Neumann et al (2010)[155]	SNHL	NR	NR	6	26	-	-	-	-	-	-	-	-	-
Rameh et al (2010)[103]	SNHL	moderate-severe	NR	10	17.7	9	16	28	-	24	-	13	-	16
Siegert et al (2007)[156]	CHL	NR	NR	5	33.1	29	28	37	-	35	36	35	32	-
Tong et al (2009)[157]	NR	moderate-severe	NR	3	35.4	-	-	-	-	-	-	-	-	-
Tringali et al (2008)[158]	CHL	severe	NR	1	29	35	25	35	-	25	25	-	-	-
Tringali et al (2009)[159]	MHL	severe	NR	1	39	20	25	50	-	50	-	50	-	-
Hearing Aids														
Babighian & Mazzoli (2005)[109]	NR	moderate	NR	16	15.9	13	10	17	16	18	16	20	17	-
Boeheim et al (2010)[90]	SNHL	NR	Delta 8000 (Oticon)	10	20.7	-12	-5.5	6	-	15	19.5	11.5	14.5	12.5
Chen et al (2004)[148]	SNHL	mild-severe	patient's "best-fit"	5	20	-	-	-	-	-	-	-	-	-
Deveze et al (2010)[153]	MHL	moderate	patient's own	1	10.6	10	25	20	10	5	0	10	5	-
Fraysse et al (2001)[121]	SNHL	mild-severe	patient's own	25	17	3.5	11.5	23	24	23	19	18.5	17	13
Jenkins et al (2007)[92] & (2008)[93]	SNHL	moderate-severe	patient's own	20	15.8	7	9	18	25	25	20	15	7	-
Kraus et al (2011)[91]	SNHL	mild-severe	patient's own	57	17	-	11	19	20	-	16	19	-	-
Luetje et al (2002)[98]	SNHL	moderate-severe	patient's "best-fit"	53	17.8	-	12	22	-	24	-	19	12	-
Maurer & Savvas (2010)[85]	SNHL, MHL	NR	patient's "best-fit"	10	14.2	-	8	15	-	18	20	10	-	-
Saliba et al (2005)[134]	SNHL	moderate-severe	Siemens Signia	8	21.8	14	20	29	-	38	-	16	14	-

Study	Type of hearing loss	Severity of hearing loss	Device type	N	Mean gain (dB)	Gain by frequency in kHz (dB)								
						0.25	0.5	1	1.5	2	3	4	6	8
Sziklai & Szilvassy (2011)[99]	SNHL	moderate-severe	open-fit	7	37.6	-	-	-	-	-	-	-	-	-
Todt et al (2002)[142 c]	SNHL	mild-severe	patient's "best-fit"	5	13.7	-	2	14	-	20	28	26	8	-2
Todt et al (2005)[100c]	SNHL	mild-severe	patient's "best-fit"	23	15	-	18.0	7.5	-	20	24	24	20	9.5
Truy et al (2008)[143]	NR	NR	Signia	6	27.1	13.3	15.8	18.3	-	30	-	58.3	-	-
BAHA														
Mazita et al (2009)[172]	CHL	moderate-severe	NR	16	35.2	-	-	-	-	-	-	-	-	-
Pfiffner et al (2011)[97]	MHL, CHL	moderate-severe	Divino	20	13	7	16	20	-	14	-	11	10	-
			BP 100		14.2	10	16	20	-	13	-	12	14	-
Saliba et al (2010)[178]	CHL	moderate-severe	Divino	17	27.9	-	-	-	-	-	-	-	-	-

[*] only 50/53 patients were tested with the Vibrant P
[a] partial overlap of patient populations for studies [98] & [130]
[b] partial overlap of patient populations for studies [131] & [140]
[c] partial overlap of patient populations for studies [142] & [100]

Table E2. Speech reception

SRT: speech reception threshold, SNHL: sensorineural hearing loss, CHL: conductive hearing loss, MHL: mixed hearing loss, NR: not reported

Study	Type of hearing loss	Severity of hearing loss	Device type	N	Method of assessment		Speech reception threshold gain	Unaided speech reception threshold	Aided speech reception threshold
Middle Ear Implants									
Vibrant Soundbrige									
Beltrame et al (2009)[111]	MHL	severe	NR	12	SRT for Italian or German sentences	quiet	24dB	85dB	61dB
						55dB noise	-	-	66dB
						70dB noise	-	-	75dB
Boeheim et al (2010)[302]	SNHL	NR	NR	10	Oldenburg sentences	quiet	15.4dB	60.9dB	45.5dB
						60dB noise	-	4.8 dB SNR	-1.5 dB SNR
					Freiburger numbers in quiet		12dB	57.0dB	45dB
Colletti et al (2006)[114]	MHL, CHL	moderate-severe	NR	7	SRT 50%		35dB	85dB	50dB
Dumon et al (2009)[118]	MHL	moderate-severe	NR	5	Bisyllabic Fournier words	50% recognition	25dB	77dB	52dB
						100% recognition	65dB	89dB	24dB
Fraysse et al (2001)[121]	SNHL	mild-severe	Vibrant P	25	Disyllabic words	50% recognition	12dB	62dB	50dB
						100% recognition	13dB	72dB	59dB
			Vibrant D		Disyllabic words	50% recognition	12dB	62dB	50dB
						100% recognition	-	72dB	-
Frenzel et al (2009)[122]	MHL	moderate-severe	NR	7	SRT for German two-syllable numbers		38dB	59dB	21dB
Rameh et al (2010)[103]	SNHL	moderate-severe	NR	45	SRT 50% using bisyllabic words		10dB	59dB	49dB
Saliba et al (2005)[134]	SNHL	moderate-severe	NR	8	SRT 50% in quiet		14dB	58dB	44dB
					SRT 50% in noise		7dB	61dB	54dB
Schmuziger et al (2006)[135]	NR	NR	NR	10	SRT 50% using Freiburg monosyllables in quiet		4 dB	61dB	57dB
					SRT 50% using Basler Satz test in 70dB noise		-	8 dB SNR	5 dB SNR
Snik & Cremers (2001)[138]	SNHL	moderate-severe	304 processor	14	NR		22dB	-	-
Streitberger et al (2009)[141]	MHL, CHL	severe	NR	40	SRT (open field)		40.95dB	94.28dB	53.33dB
Uziel et al (2003)[144]	SNHL	moderate	Signia processor	6	SRT 50%	in quiet	-	-	32.3dB
						in noise	-	-	-8.3dB SNR
Venail et al (2007)[145]	MHL	moderate-severe	NR	2	SRT 50%		25dB	65dB	40dB
Esteem									
Chen et al (2004)[148]	SNHL	mild-severe	NR	5	NR		7dB	62dB	55dB
Kraus et al (2011)[91]	SNHL	mild-severe	Esteem SP	54	CD Spondee word list		28.3dB	58.9dB	30.6dB

Study	Type of hearing loss	Severity of hearing loss	Device type	N	Method of assessment		Speech reception threshold gain	Unaided speech reception threshold	Aided speech reception threshold
Carina									
Deveze et al (2010)[303]	MHL	moderate	NR	1	SRT50		20dB	-	-
Rameh et al (2010)[103]	SNHL	moderate-severe	NR	10	SRT 50% using bisyllabic words		13dB	75dB	62dB
Siegert et al (2007)[156]	CHL	NR	NR	5	Freiburger speech discrimination		32dB	-	-
Tringali et al (2008)[158]	CHL	severe	NR	1	SRT		29dB	75dB	46dB
Hearing Aids									
Boeheim et al (2010)[302]	SNHL	NR	Delta 8000 (Oticon)	10	Oldenburg sentences	quiet	11.2dB	60.9dB	49.7dB
						60dB noise	-	4.8 dB SNR	-0.5 dB SNR
					Freiburger numbers in quiet		6.2dB	57.0dB	50.8dB
Chen et al (2004)[148]	SNHL	mild-severe	patient's "best-fit"	5	NR		23dB	62dB	39dB
Deveze et al (2010)[303]	MHL	moderate	patient's own	1	SRT 50%		5dB	-	-
Fraysse et al (2001)[121]	SNHL	mild-severe	patient's own	25	Disyllabic words	50%	13dB	62dB	49dB
						100%	18dB	78dB	60dB
Flynn et al (2009)[165]	MHL	severe	Oticon Sumo DM	10	Understanding in noise		-	-	3.44dB SNR
Kraus et al (2011)[91]	SNHL	mild-severe	patient's "walk-in"	57	CD Spondee word list		17.7dB	58.9dB	41.2dB
Saliba et al (2005)[134]	SNHL	moderate-severe	NR	8	SRT 50% in noise		1dB	61dB	60dB
Schmuziger et al (2006)[135]	NR	NR	NR	10	SRT 50% using Freiburg monosyllables in quiet		8dB	61dB	53dB
					SRT 50% using Basler Satz test in 70dB noise		-	8 dB SNR	5 dB SNR
Uziel et al (2003)[144]	SNHL	moderate	Signia	6	SRT 50%	in quiet	-	-	39.9dB
						in noise	-	-	-8.3dB SNR
BAHA									
Fuchsmann et al (2010)[166]	CHL	moderate-severe	NR	16	NR		31.7 dB	63.4 dB	31.7 dB
Kunst et al (2007)[169]	CHL	moderate-severe	NR	10	Dutch sentences @65dB	in quiet	1.3 dB	31.1 dB	29.8dB
						in 65dB noise	-	-5.0 dB SNR	-5.3 dB SNR
Pfiffner et al (2011)[97]	MHL, CHL	moderate-severe	Divino	20	German Freiburg 2 digit numbers SRT50%		15.4	60.4	45
			BP 100				13.5	60.5	47

Table E3. Speech recognition

Study	Type of hearing loss	Severity of hearing loss	Device type	N	Method of assessment		Unaided speech recognition (%)	Aided speech recognition (%)	p-value
Middle Ear Implants									
Vibrant Soundbrige									
Beltrame et al (2009)[111]	MHL	severe	NR	12	Italian or German sentences @ SRT + 10dB in 55dB noise		-	95.8	-
Boeheim et al (2010)[302]	SNHL	NR	NR	10	Freiburger monosyllables	@ 65dB	26.3	63.0	0.003
						@ 80dB	62.3	86.5	0.004
Bruschini et al (2009)[113]	SNHL, MHL	moderate	NR	12	words & phrases	in quiet @ 65dB	55	95	-
						in noise @ SNR +10	49	69	-
Colletti et al (2009)[115]	MHL	moderate-severe	NR	19	Bisyllabic words @ 65dB		6.81	86.2	0.0004
Colletti et al (2010)[116]	MHL	severe	NR	8	Bisyllabic words @ 65dB		8.9	89.8	0.0095
Cuda et al (2009)[117]	MHL	mild-moderate	NR	8	Disylalbic words @ 60dB		-	88.3	-
Frenzel et al (2009)[122]	MHL	moderate-severe	NR	7	Freiburger monosyllables in quiet	@ 50dB	-	64	-
						@ 65dB	-	99	-
						@ 80dB	-	100	-
					Freiburger monosyllables in 60dB noise	@ 65dB	-	75	-
						@ 80dB	-	97	-
Garin et al (2002)[123] & (2005)[124]	SNHL	moderate-severe	Signia & Widex	11	Fourniers disyllabic words in 55dB noise	@ 50dB	15	40	-
						@ 55dB	37	69	-
						@ 60dB	62	86	-
Huttenbrink et al (2008)[125]& (2010)[74]	MHL	moderate-severe	NR	6	Freiburger monosyllabic words @ 65dB		0	55	-
Linder et al (2008)[129]	MHL, CHL	moderate-severe	NR	1	Freiburg syllable & number test	@ 55dB	-	35	-
						@ 60dB	-	90	-
						@ 70dB	-	100	-
Luetje et al (2002)[98]	SNHL	moderate-severe	Vibrant P	53	Northwestern University Auditory test in quiet		77	75	0.12
Mosnier et al (2008)[304 a]	NR	NR	NR	27	Disyllabic words@ 65dB		37	81	-
Olgun et al (2008)[132]	MHL, CHL	moderate-severe	NR	5	Speech discrimination		77.3	83	-
Pok et al (2010)[133]	SNHL	severe	NR	54	Monosyllabic words	@ 65Db	30	57	<0.001
						@ 80Db	58	80	<0.001
Rajan et al (2011)[101]	MHL, CHL	NR	NR	8	Monosyllabic Arthur-Boothryd word lists @ 65dB		30	94	<0.05
					Bumford-Kowal_Bench test in noise @ 65dB		50	64	NS
Snik & Cremers (2001)[138]	SNHL	moderate-severe	304 processor	14	Monosyllables & phenomes @ 65dB		21	77	-
Sterkers et al (2003)[140 a]	SNHL	mild-severe	NR	13	Lafont words @ 65dB		72	90	<0.005

Study	Type of hearing loss	Severity of hearing loss	Device type	N	Method of assessment		Unaided speech recognition (%)	Aided speech recognition (%)	p-value
				37	Fournier words @ 65dB		58	91	<0.0005
Streitberger et al (2009)[141]	MHL, CHL	severe	NR	40	Italian bisyllabic words or Freiburger monosyllables maximum intelligibility		47.75	95.75	-
Sziklai & Szilvassy (2011)[99]	SNHL	moderate-severe	Model 404	7	Monosyllabic Hungarian words @ 65dB		-	78.1	-
Todt et al (2002)[142 b]	SNHL	mild-severe	HF	5	Freiburger monosyllables in quiet		56	86	<0.05
					Freiburger monosyllables in 5dB SNR noise		48	73	-
			Vibrant D		Freiburger monosyllables in quiet		56	89	<0.05
					Freiburger monosyllables in 5dB SNR noise		48	74	-
Todt et al (2005)[100b]	SNHL	mild-severe	Vibrant D	23	Freiburger monosyllables in quiet		-	75.0	-
					Freiburger monosyllables in 5dB SNR noise		-	59.3	-
			Signia		Freiburger monosyllables in quiet		-	73.0	-
					Freiburger monosyllables in 5dB SNR noise		-	65.7	-
Truy et al (2008)[143]	NR	NR	NR	6	Lafon monosyllabic words in quiet	@ 40dB	70	95	p<0.01
						@ 50dB	85	98	
						@ 60dB	89	98	
					Dodele meaningless words in noise	-6 dB SNR	50	77	p<0.01
						-3 dB SNR	54	63	
						0 dB SNR	78	81	
						3 dB SNR	71	86	
						6 dB SNR	80	90	
Esteem									
Barbara et al (2009)[147] & (2011)[102]	SNHL	Moderate	NR	9	Speech discrimination @ 60dB		42	79	-
		Severe		9	Speech discrimination @ 75dB		30	72	-
Chen et al (2004)[148]	SNHL	mild-severe	NR	5	CID-W22 word list in quiet @ 50dB		21	47	-
Kraus et al (2011)[91]	SNHL	mild-severe	Esteem SP	54	Words @ 50dB		10.5	69.1	-
Memari et al (2011)[149]	SNHL	moderate-severe	NR	10	Speech discrimination		70.2	73.0	0.62
Murali et al (2009)[150]	SNHL	NR	NR	3	Discrimination open set		-	95	-
					Discrimination closed set		-	100	-
Carina									
Bruschini et al (2009)[113] & (2010)[305]	SNHL, MHL	moderate-severe	NR	8	Disyllabic words @ 65dB		32.5	68.75	-
Deveze et al (2010)[303]	MHL	moderate	NR	1	Words @ 65dB		-	80	-
Jenkins et al (2007)[92] & (2008)[93]	SNHL	moderate-severe	NR	20	Monaural words		-	77	-
					Monaural phenomes		-	87	-
Lefebvre et al (2009)[87]	MHL	moderate-severe	NR	6	Disyllabic words in French		-	63.33	-
Martin et al (2009)[154]	MHL	moderate-	NR	8	Disyllabic Fournier or Spanish words @ 65dB		35	94	-

Study	Type of hearing loss	Severity of hearing loss	Device type	N	Method of assessment		Unaided speech recognition (%)	Aided speech recognition (%)	p-value
		severe							
Neumann et al (2010)[155]	SNHL	NR	NR	6	Monosyllables		-	80	-
Tringali et al (2008)[158]	CHL	severe	NR	1	@ 40dB		-	0	-
					@ 50dB		-	70	
					@ 60dB		0	80	
					@ 70dB		30	90	
Tringali et al (2009)[159]	MHL	severe	NR	1	@ 40dB		-	0	-
					@ 45dB			50	
					@ 50dB			50	
					@ 55dB			60	
					@ 60dB			90	
					@ 70dB			100	
Hearing Aids									
Boeheim et al (2010)[302]	SNHL	NR	Delta 8000 (Oticon)	10	Freiburger monosyllables	@ 65dB	26.3	53.8	0.004
						@ 80dB	62.3	77.3	0.012
Chen et al (2004)[148]	SNHL	mild-severe	patient's "best-fit"	5	CID-W22 word list in quiet @ 50dB		21	76	
Deveze et al (2010)[303]	MHL	moderate	patient's own	1	Words @ 65dB		-	40	-
Jenkins et al (2007)[92] & (2008)[93]	SNHL	moderate-severe	patient's own	20	Monaural words		-	86	-
					Monaural phenomes		-	92	-
Kraus et al (2011)[91]	SNHL	mild-severe	patient's "walk-in"	54	Words @ 50dB		10.5	45	-
Linder et al (2008)[129]	MHL, CHL	moderate-severe	patient's own	1	Freiburg syllable & number test	@ 75dB	-	30	-
						@ 80dB	-	75	-
						@ 90dB	-	95	-
Pok et al (2010)[133]	SNHL	severe	patient's own	54	Monosyllabic words	@ 65dB	30	40	<0.001
						@ 80dB	58	67	<0.05
Sziklai & Szilvassy (2011)[99]	SNHL	moderate-severe	Model 404	7	Monosyllabic Hungarian words @ 65dB		-	74.2	-
Todt et al (2002)[142]	SNHL	mild-severe	NR	5	Freiburger monosyllables in quiet		56	63	-
					Freiburger monosyllables in 5dB SNR noise		48	62	-
Truy et al (2008)[143]	NR	NR	Signia	6	Lafon monosyllabic words in quiet	@ 40dB	70	83	p<0.01
						@ 50dB	85	93	
						@ 60dB	89	98	
					Dodele meaningless words in noise	-6 dB SNR	50	59	NS
						-3 dB SNR	54	60	
						0 dB SNR	78	76	
						3 dB SNR	71	80	
						6 dB SNR	80	84	
BAHA									

Study	Type of hearing loss	Severity of hearing loss	Device type	N	Method of assessment		Unaided speech recognition (%)	Aided speech recognition (%)	p-value
Kunst et al (2007)[169]	CHL	moderate-severe	NR	8	Dutch words in SNR -5dB noise		51	74	-
Pfiffner et al (2011)[97]	MHL, CHL	moderate-severe	Divino	20	Monosyllabic Freiburg words	@ 50dB	5	30	p=0.006 to 0.0012
						@ 65 dB	37	79	
						@ 80dB	74	98	
			BP 100	20	Monosyllabic Freiburg words	@ 50 dB	2	25	
						@ 65 dB	34	90	
						@ 80dB	68	99	

[a] partial patient overlap for studies [92] & [93]

[b] partial overlap of patient populations for studies [152] & [100]

Table E4. Quality of life

Study	Method of assessment	N	Results			Significance
Middle Ear Implants						
Vibrant Soundbrige						
Fraysse et al (2001)[121]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	17	EC	23		Significantly less difficulty experienced compared to hearing aids for BN (P=0.001), EC (p=0.002) and AV (p=0.002). More difficulty experienced with RV (no statistical tests reported).
			BN	39		
			AV	22		
			RV	35		
Linder et al (2009)[129]	Glasgow Benefit Inventory (% improvement due to intervention)	5	General	80		All patients reported improvement with the device in the general & physical health categories but no change in social support. No statistical tests reported.
			Physical Health	85		
			Social Support	50		
Luetje et al (2002)[98 b]	Profile of Hearing Aid Performance (% without problems)	51/ 53*	Familiar Talkers	85		Statistically significant improvement over hearing aids for all categories (p<0.001)
			Ease of Communication	79		
			Reverberation	62		
			Reduced Clues	57		
			Background Noise	59		
			Aversivenesss of Sounds	75		
			Distortion of Sounds	77		
	Hearing Device Satisfaction Scale (% of patients satisfied or very satisfied)		Clearness of tone	86		Higher satisfaction compared to hearing aids, p value not reported.
			Overall sound quality	90		
			Sound of own voice	83		
			Cleaning & maintenance	98		
Mosnier et al (2008)[304 c]	QoL questionnaire	62	77% of patients were satisfied or very satisfied with the device			The majority of patients were satisfied with the VSB.
	Glasgow Benefit Inventory (improvement due to intervention, score -100 to +100)		General	22.8		Significant improvement in the General & Social categories. No significant improvement in the Physical category. No statistical tests reported.
			Social	14.1		
			Physical	1.7		
			Overall	17.8		
Rajan et al (2011)[101]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	8		Unaided	Aided	Statistically significant improvement (p<0.05) with the VSB compared to the unaided condition in all categories except for aversiveness (p>0.05).
			EC	48	13	
			BN	53	28	
			AV	33	26	
			RV	56	28	
			Overall Average	48	23	

Study	Method of assessment	N	Results		Significance
Rameh et al (2010)[103]	QoL questionnaire	45	72% of patients satisfied with device		Patients were more satisfied with the VSB compared to the Carina. No statistical tests reported.
Saliba et al (2005)[134]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	8	EC	33	No significant difference in difficulty experienced with the VSB compared to VSB combined with a hearing aid. (P>0.05).
			BN	49	
			AV	3	
			RV	48	
			Overall Average	40	
Schmuziger et al (2006)[135]	QoL questionnaire	20	65% satisfied or very satisfied with VSB		High level of patient satisfaction with VSB.
	International Outcome Inventory for Hearing Aids (5 point Likert scale, 1=worst, 5=best)		Use	4.5	
			Benefit	3.7	
			Residual activity limitation	3.1	
			Satisfaction	3.8	
			Residual participation restriction	3.6	
			Impact on others	4.1	
			QoL	3.4	
			Overall	26.3/35	
	Glasgow Benefit Inventory(improvement due to intervention, score -100 to +100)		General	22.1	Significant improvement due to VSB in General category. Worsening in physical category due to VSB. No statistical tests reported.
			Social	5	
			Physical	-5	
			Overall	14.7	
Sterkers et al (2003)[140 c]	QoL questionnaire	95	45% "very satisfied", 38% "satisfied", 13% "a little satisfied", 4% dissatisfied		The majority of patients were satisfied with the VSB.
	Glasgow Benefit Inventory (improvement due to intervention, score -100 to +100)	56	General	20	Benefit in General & Social categories. No benefit in Physical. No statistical tests reported.
			Social	14	
			Physical	1	
			Overall	14	
Todt et al (2002)[142 c]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	4	EC	15	Significantly less difficulty experienced with the VSB compared to hearing aids for BN, RV, & EC (P<0.05). No significant difference between VSB and hearing aids in AV.
			BN	22	
			AV	48	
			RV	31	

Study	Method of assessment	N	Results		Significance
Todt et al (2005)[100c]	QoL questionnaire	23	NR		Majority of patients were highly satisfied with the acoustic characteristic of the system but wanted more technical flexibility. Highest degree of satisfaction from the open ear canal and "natural sound quality".
Uziel et al (2003)[144]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	5	EC	18	Significantly less difficulty experienced with the VSB than hearing aids in RV & AV (P<0.05). No significant difference in BN (p=0.08) & EC (p=0.068).
			BN	38.4	
			AV	32.4	
			RV	21.4	
	Hearing Device Satisfaction Scale (numeric score from -100= very dissatisfied to +100 = very satisfied)		Mould issues	67.6	Significantly more satisfied with the VSB than hearing aids in categories of : sound quality, feedback, QoL, and ease of device use (p<0.05). No significant difference for mould issues and telephone use.
			Sound quality	44.4	
			Feedback	30	
			QoL	70	
			Ease of device use	80	
			Telephone use	40	
Esteem					
Barbara et al (2011)[102]	Glasgow Benefit Inventory (improvement due to intervention, score -100 to +100)	18	Moderate hearing loss: mean 11.12 (range 2.8-25) Severe hearing loss: mean 6.83 (range 2.2-27.8)		Degree of satisfaction is similar for moderate and severe hearing loss. No statistical tests reported.
	Client Oriented Scale of Improvement (improvement in hearing due to intervention, score 5 to 25)		Moderate hearing loss: mean 17.7 in itinere, 20.6 final Severe hearing loss: 18.1 in itinere, 18.2 final		
Chen et al (2004)[148]	Abbreviated Profile of Hearing Aid Benefit (% benefit vs unaided, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	5	EC	26	Benefit from the Esteem compared to hearing aids in all categories. No statistical tests reported.
			BN	24	
			AV	-12	
			RV	32	
			Overall Average	27	
Kraus et al (2011)[91]	QoL questionnaire (% of patients reporting the device is equal or better than their hearing aid)	57	Clarity of sound	79	The majority of subjects considered the device to be equal to or better than hearing aids. No statistical tests reported.
			Speech in Noise	71	
			Natural voices	77	
			Understanding conversations	67	
			Self confidence	81	
			Active lifestyle	87	
	Abbreviated Profile of Hearing Aid Benefit		NR		Statistically significant increase in benefit in all subcategories compared to hearing aids (p≤0.01)
Maurer & Savvas (2010)[85]	Abbreviated Profile of Hearing Aid Benefit (% benefit vs unaided, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	6	EC	43	Increased benefit over hearing aids in RV, BN, & AV. No difference in EC. No statistical tests reported.
			BN	53	
			AV	3	
			RV	40	
			Overall Average	38	
Memari et al (2011)[149]	QoL questionnaire (compare sound quality with the Esteem to conventional hearing aids)	10	4/10 improved, 5/10 the same, 1/10 worse		Majority of patients felt that sound quality was equal to or improved with the Esteem compared to hearing aids.

Study	Method of assessment	N	Results			Significance
Carina						
Bruschini et al (2009)[113] & (2010)[305]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	8		Uniaded	Aided	Less difficultly experienced in the aided compared to the unaided condition in all subscales. No statistical tests reported.
			EC	54.08	10.33	
			BN	66.08	19.33	
			AV	4.33	2	
			RV	78.33	19.83	
Jenkins et al (2007)[92] & (2008)[93]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	20	EC	22		Patients experienced less difficulty with the Carina than with hearing aids in all categories. No statistical tests reported.
			BN	37		
			AV	-32		
			RV	35		
Lefebvre et al (2009)[87]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	5		Unaided	Aided	Patients experienced less difficulty with the Carina compared to unaided in EC, BN, & RV. Patients experienced more aversiveness to sound with the Carina than without. No statistical tests reported.
			EC	56.2	23	
			BN	48.6	35.2	
			AV	17.2	35.2	
			RV	46.2	35.6	
Martin et al (2009)[154]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	7		Unaided	Aided	Statistically significant improvement in EC, RV & AV with the Carina compared to the unaided condition (P<0.05). No significant difference in BN.
			EC	49.8	19.9	
			BN	45.3	44	
			AV	25.8	38.6	
			RV	57.7	44.8	
Rameh et al (2010)[103]	QoL questionnaire	10	29% of patients satisfied with device			Patients were more satisfied with the VSB compared to the Carina. No statistical tests reported.

Study	Method of assessment	N	Results		Significance
Hearing Aids					
Chen et al (2004)[148]	Abbreviated Profile of Hearing Aid Benefit (% benefit vs unaided, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	5	EC	27	Benefit from the Esteem compared to hearing aids in all categories. No statistical tests reported.
			BN	30	
			AV	-34	
			RV	27	
			Overall Average	28	
Fraysse et al (2001)[121]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	17	EC	51	Significantly more difficulty experienced compared to VSB for BN (P=0.001), EC (p=0.002) and AV (p=0.002). Less difficulty experienced with RV (no statistical tests reported).
			BN	68	
			AV	44	
			RV	52	
Jenkins et al (2007)[92] & (2008)[93]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	20	EC	31	Patients experienced less difficulty with the Carina than with hearing aids in all categories. No statistical tests reported.
			BN	53	
			AV	-37	
			RV	48	
Kraus et al (2011)[91]	QoL questionnaire (% of patients reporting the device is equal or better than their hearing aid)	57	Clarity of sound	79	The majority of subjects considered the device to be equal to or better than hearing aids. No statistical tests reported.
			Speech in Noise	71	
			Natural voices	77	
			Understanding conversations	67	
			Self confidence	81	
			Active lifestyle	87	
	Abbreviated Profile of Hearing Aid Benefit		NR		Statistically significant increase in benefit in all subcategories compared to hearing aids (p≤0.01)
Luetje et al (2002)[98 b]	Profile of Hearing Aid Performance (% without problems)	51/ 53*	Familiar Talkers	78	Significantly more patients experiencing problems compared to VSB for all categories (p<0.001)
			Ease of Communication	62	
			Reverberation	39	
			Reduced Clues	41	
			Background Noise	36	
			Aversivenesss of Sounds	57	
			Distortion of Sounds	59	
	Hearing Device Satisfaction Scale (%of patients satisfied or very satisfied)		Clearness of tone	31	Lower satisfaction compared to VSB, p value not reported.
			Overall sound quality	19	
			Sound of own voice	22	
			Cleaning & maintenance	55	
Maurer & Savvas (2010)[85]	Abbreviated Profile of Hearing Aid Benefit (% benefit vs unaided, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	6	EC	43	Less benefit with hearing aids than Esteem in RV, BN, & AV. No difference in EC. No statistical tests reported.
			BN	39	
			AV	-36	
			RV	35	
			Overall Average	20	
Todt et al (2002)[142 c]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	4	EC	38	Significantly less difficulty experienced with the VSB compared to hearing aids for BN, RV, & EC (P<0.05). No significant difference between VSB and hearing aids in AV.
			BN	62	
			AV	61	
			RV	57	

Study	Method of assessment	N	Results					Significance
Uziel et al (2003)[144]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	5	EC	36.8				Significantly less difficulty experienced with the VSB than hearing aids in RV & AV (P<0.05). No significant difference in BN (p=0.08) & EC (p=0.068).
			BN	63				
			AV	55.8				
			RV	21.4				
	Hearing Device Satisfaction Scale (numeric score from -100= very dissatisfied to +100 = very satisfied)		Mould issues	-18.2				Significantly more satisfied with the VSB than hearing aids in categories of : sound quality, feedback, QoL, and ease of device use (p<0.05). No significant difference for mould issues and telephone use.
			Sound quality	-28.2				
			Feedback	-40				
			QoL	-35.6				
			Ease of device use	-5				
			Telephone use	-25				
BAHA								
Fuchsmann et al (2010)[166]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	15		Unaided	Aided			Significantly less difficulty experienced with the BAHA than without in the Global score (p<0.0001).
			EC	86	19			
			BN	92	38			
			AV	6	47			
			RV	88	21			
			Global	90	25			
	QoL Questionnaire (Likert scale, 1=worst, 10=best)		Overall satisfaction	8.7				High degree of patient satisfaction with the BAHA.
			Improvement in QoL	8.7				
			Aesthetics	6.7				
			Sound localization	5.4				
Pfiffner et al (2011)[97]	Abbreviated Profile of Hearing Aid Benefit (% difficulty experienced, EC= ease of communication, BN= background noise, AV=aversivenss, RV=reverberation)	20		Before Divino	With Divino	Before BP 100	With BP 100	Significantly less difficulty experienced with both the BAHA Divino & BP 100 compared to the unaided condition for all subcategories (p<0.01).
			EC	56	17	64	10	
			BN	68	35	79	23	
			AV	-8	-35	-10	-30	
			RV	80	30	83	20	

* all 53 patients completed the HDSS but only 51 completed with APHAB

Appendix F – Data abstraction form

Title: _____ Reviewer: _____
Primary Author: _____ Reference ID: _____
Study Country: _____ Publication Year: _____

Type of Hearing Loss:

□ *Sensorineural* □ *Mixed* □ *Conductive* □ *Unspecified*

Severity of Hearing Loss:

□ *Mild* □ *Moderate* □ *Severe* □ *Profound* □ *Unspecified*

Timing of Hearing Loss

□ *Prelingual* □ *Postlingual* □ *Traumatic* □ *Unspecified*

Methods

Study Design:

□ Prospective	□ RCT	□ Case/clinical series
□ Retrospective	□ Controlled trial	□ Case reports
	□ Cohort	□ Single Arm Trial
□ Intra-individual	□ Pre/Post	□ With/without
□ Inter-individual		

Setting:

□ Single Center	□ General clinic/hospital
□ Multicenter : # of Centers _____	□ Academic teaching hospital
	□ Other: _____

Random Allocation to Intervention Group?

□ Yes □ No □ Not applicable

If yes, method of randomization: _____

Length of follow-up: _____

Additional Comments Regarding Study Design :

Patient Population

Was the description of the patient population:

□ clearly stated □ partially stated □ unclear or not mentioned

Inclusion Criteria	Exclusion Criteria

Eligibility:

□ clearly stated □ partially stated □ unclear or not mentioned

Is the patient population eligible for:	Yes	No	If no, provide reason(s)
Traditional hearing aids			
BAHA			
Cochlear Implantation			

MEI *(for studies on BAHA and CI)*			

Patient Characteristics

Study Group	Number of Patients		Age			Pre-op. AC thresholds	Pre-op. BC thresholds
	Entering	Completed	Range	Mean	SD		
Comparison Group 1: _____	Total: M: ____ F: ____	Total: M: ____ F: ____					
Comparison Group 2 : _____	Total: M: ____ F: ____	Total: M: ____ F: ____					
Comparison Group 3 : _____	Total: M: ____ F: ____	Total: M: ____ F: ____					
Total	Total: M: ____ F: ____	Total: M: ____ F: ____					

Reasons for drop-outs and withdrawals

Comparison Group 1: _____	
Comparison Group 1: _____	
Comparison Group 1: _____	

Additional Comments Regarding Patient Population:

Intervention:

Type of Device Used

Comparator Group 1	Comparator Group 2	Comparator Group 3

Description of Surgical Technique was:

□ clearly stated □ partially stated □ unclear or not mentioned

List Any Modifications in Surgical Technique:

Effectiveness

Outcome	How is it measured?	F/U Period (N)	Findings		
			Comparison Group 1	Comparison Group 2	Comparison Group 3
Functional Gain					
Threshold Levels					
Speech Perception (threshold)					
Speech Recognition (%)					

Quality of Life					
Other					

Additional Comments Regarding Effectiveness:

Safety

Adverse Events Reported?

□ Yes □ No

Follow-up Period: _____

Event Reported	Number of Cases	Comments

Additional Comments Regarding Safety:

Economics/Resource Utilization Comments:

Social/Ethical/Legal Comments:

Study Quality
Oxford Centre for Evidence-Based Medicine

Level of Evidence Score: _____

Funding Source: _____

Conflict of Interest Reported?

□ Yes □ No

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