

## **MIDDLE EAR IMPLANTS IN PEOPLE WITH HEARING IMPAIRMENT**

### **QUESTION(S) TO BE ADDRESSED:**

1. Are middle ear implants clinically effective in children and adults with moderate to severe sensori-neural, mixed or conductive hearing loss compared with conventional hearing aids, bone anchored hearing aids or cochlear implants?
2. Are middle ear implants cost effective in children and adults with moderate to severe sensori-neural, mixed or conductive hearing loss compared with conventional hearing aids, bone anchored hearing aids or cochlear implants?

### **SUMMARY:**

#### **Background**

- Middle ear implants (MEI) are surgically implanted electronic devices which aim to correct hearing loss through stimulation of the ossicular chain or middle ear. MEIs are placed into the middle ear and generally leave the external auditory canal (EAC) open and unobstructed.
- Alternatives include conventional hearing aids of various types, bone-anchored hearing aids, and cochlear implants. A middle ear implant differs from a cochlear implant, in that the latter stimulates the auditory nerve directly.
- The basic components of MEIs are a microphone, an audio processor, a battery, a receptor and a vibration transducer which attaches to the ossicular chain. The transducer may be either piezoelectric or electromagnetic and produces vibrational energy that subsequently vibrates the ossicular chain.

#### **Clinical Effectiveness**

- The rapid evidence review by Solutions for Public Health in October 2014 found a lack of high-level, high quality evidence investigating the effectiveness of middle ear implants in both children and adults.
- In this update review, we identified one study of effectiveness of MEIs in children, one systematic review and one other study of MEIs in mixed populations of children and adults, one systematic review and two other studies of MEIs in adults.
- In children, speech outcomes, word recognition scores and speech recognition threshold appeared to improve with MEIs (VSB) compared with the unaided post-operative condition (i.e. with the implant not activated). The study did not include patient-reported outcomes.
- Studies of mixed populations of children and adults showed similar results to that in children only. The systematic review reported that significant benefits were seen between the aided and unaided post-operative condition in ease of communication, listening under reverberant conditions and with background noise. However, details of the improvements or p values were not provided.
- In adults, there was some evidence demonstrating that MEIs are effective in improving hearing from unaided pre-implantation levels in patients various types of hearing loss. There was also some evidence demonstrating that MEIs are likely to be at least as effective as external hearing aids in patients with hearing loss. Speech outcomes appear to improve with MEIs when compared with unaided hearing and are at least as good as (and in some studies

better than) the external hearing aid. However, no statistical information was reported in most of the studies.

- Patient satisfaction seemed to be greater with the MEIs than with the external hearing aid with improved sound quality, less canal occlusion, less feedback and improved quality of life.
- Overall the design of the studies, the small sample sizes and the differences in the reporting of outcomes does not allow any firm conclusions to be drawn about the effectiveness of MEIs.

### **Cost Effectiveness**

- We did not identify any studies of the cost-effectiveness of MEIs for hearing loss in children or adults.

### **Safety**

- We did not find any comparative evidence reporting on the safety of MEIs in children or adults.
- No safety issues were reported in any of the identified studies of MEIs for hearing loss in children.
- One systematic review reported on adverse effects related to the Carina® and Esteem® devices in adults. The Carina® device is associated with occasional feedback which appears to be resolved by fine-tuning of the fitting. Postoperative infection needing reoperation, fullness or pressure, middle ear effusion and partial device extrusion vertigo and tinnitus sensation were also reported. Conductive hearing loss was reported in about in 20% of subjects using Carina®.
- The most common adverse effect reported with the Esteem® device was disruption of chorda tympani nerve (61.5%). Other adverse effects related to the device include wound infection, facial palsy, temporary swelling of the lower eyelid, sore jaw, nausea, diarrhoea, elbow pain, arm and hand pain, and numbness. One study reported that 5.2% of patients implanted with the Esteem® device had revision surgeries.
- About 16% of all participants implanted with VSB were affected by an adverse event. The most common complication was floating mass transducer (FMT) extrusion. Wound dehiscence and dizziness were also reported. Device failure was observed and about 10% of participants using VSB required revision surgery.

## **1 Context**

### **1.1 Introduction**

#### **Hearing**[1]

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).

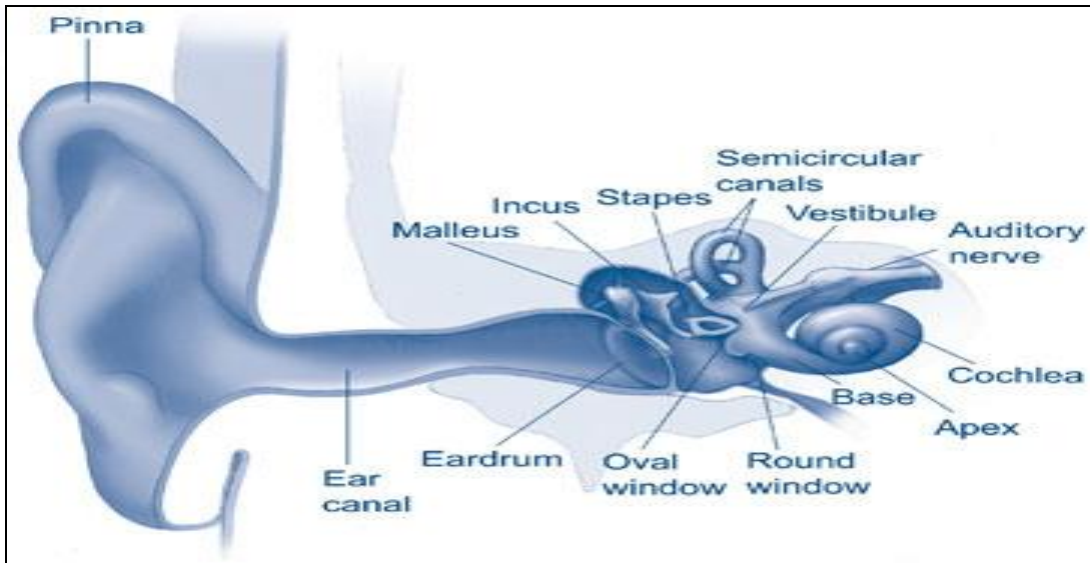


Figure 1: The sound pathway [2]

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 [2]. 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) [3].

Sound can be described in two ways: by pitch, measured by frequency in Hertz (Hz), and by loudness, measured in decibels (dB) [3].

### 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;4]. For people with normal hearing the minimal audible level (threshold) of a tone is less than 20 dB across all frequencies. People with higher thresholds are considered to have hearing loss, which may be classified into mild, moderate, severe and profound hearing loss (Table 1).

**Table 1: Classification of hearing impairment by hearing threshold [5]**

Hearing threshold (dB)	Level of hearing impairment
0-15	Normal hearing (children)
0-25	Normal hearing (adults)
15-25	Minimal hearing loss (children)
26-40	Mild hearing loss
41-55	Moderate hearing loss
56-70	Moderate-severe hearing loss
71-90	Severe hearing loss
91+	Profound hearing loss

The main types of hearing loss are:

- Sensori-neural hearing loss (SNHL) is the most common form of hearing loss [6;7]. It occurs where there is damage to the hair cells of the cochlea (sensory) or to the nerve pathway from the inner ear to the brain (neural). SNHL may be congenital (present at birth) or acquired and is usually permanent. SNHL can be caused by damage or malformation of the cochlea and

the sensitive hairs, exposure to excessive noise, vestibular schwannomas<sup>1</sup>, viral infections, temporal bone fractures, Meniere's disease, ototoxic medications and the ageing process.

- Conductive hearing loss (CHL) occurs when sound is not conducted efficiently from the external auditory canal (EAC) to the middle ear. This is generally caused by a blockage or damage in the outer or middle ear (or both) and may be transient or permanent.
- Mixed hearing loss (MHL) occurs when both sensori-neural and conductive hearing loss are present.
- Central hearing loss is caused by damage to the central nervous system that affects the processing of auditory signals.

Sometimes, hearing loss is categorised by its cause. For example, age-related hearing loss is usually (in 90% of cases) caused by SNHL due to gradual damage to the hair cells of the inner ear over time [6]. Noise-related hearing loss is the second most common form of SNHL [8]. It is caused by occupational or recreational exposure to noise, such as loud music, motorcycles or the use of firearms.

### **Management of hearing loss**

The management of hearing impairment will depend on the underlying cause. Options intended to improve quality of life include sign language, amplification, cochlear implant, auditory brain stem implant or middle ear implant [9;10].

**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 [10].

## 1.2 Existing national policies and guidance

In April 2013, the NHS Commissioning Board published a policy statement [11] on active middle ear implants. The policy stated the following as the commissioning position:

*“Active middle ear implants are not routinely commissioned except under the following circumstances, as no other alternative treatment is available:*

- *Patients with bilateral sensori-neural hearing loss in whom conventional hearing aids have been used and found to be medically unsuitable due to conditions of the external ear.*
- *Patients with a mixed hearing loss in whom conventional hearing aids have been used and found to be medically unsuitable due to conditions of the external ear [including microtia and other congenital conditions] and in whom a BAHA has been implanted and been associated with medical problems of the soft tissues or loss of fixture on more than one occasion.*

*For all other clinical indications, including all situations where inner ear function is normal, the active middle ear implants will only be used as part of a recognised and structured clinical research project.”*

## 2 Epidemiology

It is estimated that there are approximately ten million people in the UK with a hearing impairment [12]. The prevalence of deafness by severity is shown in table 2. The prevalence of deafness varies with the age of the individual. The prevalence of a permanent hearing loss is 1.65 in 1000 for newborn children and 2.05 in 1000 for children aged 9-16 years [13]. The increase in prevalence with age is related to later diagnosis, late onset or progressive hearing loss.

<sup>1</sup> benign primary intracranial tumor of the myelin-forming cells of the vestibulocochlear nerve (8th cranial nerve)

**Table 2: Estimated prevalence of hearing impairment in the UK population [13]**

Classification	Prevalence in population	Numbers in the UK
Mild/slight	16.1%	7.6 million
Moderate	4.9%	2.3 million
Severe	1%	0.5 million
Profound	0.4%	About 200,000

The Royal National Institute for the Deaf reported that approximately 2 million people in the UK wear a hearing aid [13].

Deafness may impact on all aspects of an individual's life though reducing their ability to communicate and integrate with family, friends and the broader community. It can effect education, employment and recreational activities [12]. An impact upon mental health is not unusual, with increased prevalence of anxiety and depression in the deaf population. The impact on the individual and their ability to communicate is influenced by many factors including: the age of onset, age of identification of the loss, type of hearing loss, the configuration of the hearing loss, auditory discrimination abilities, environmental factors and the introduction, correct provision and consistent use of aids or cochlear implants [12]. Family support is particularly important.

### 3 The intervention

Middle ear implants (MEI) are surgically implanted electronic devices which aim to correct hearing loss through stimulation of the ossicular chain or middle ear. MEIs are placed into the middle ear and generally leave the external auditory canal (EAC) open and unobstructed. The basic components of MEIs are a microphone, an audio processor, a battery, a receptor and a vibration transducer which attaches to the ossicular chain. The transducer may be either piezoelectric or electromagnetic and produces vibrational energy that subsequently vibrates the ossicular chain [10]. There are a variety of different types:

- Vibrant Soundbridge Middle Ear Implant System by Med-EI
- Esteem® Implantable Hearing System by Envoy Medical
- Carina® Fully Implantable Hearing System by Otologics
- Middle Ear Transducer (MET) Semi-Implantable Hearing System by Otologics

The Vibrant Soundbridge (VSB) Middle Ear Implant System is a semi-implantable device. The Vibrant Soundbridge consists of three components; an audio processor, a receiver and a magnetic component. The external audio processor is held in place on the scalp behind the ear by a magnet. The audio processor detects and amplifies sound waves and transforms them into electric signals, which are transmitted to the subcutaneous receiver component. The receiver transduces these signals into electromagnetic energy, creating an alternating electromagnetic field. The magnetic component is coupled to the ossicles of the middle ear, causing them to vibrate [10].

The Esteem® Implantable Hearing System is a fully implantable device. The Esteem® consists of two components. A piezoelectric transducer, the sensor, is placed at the head of the incus and converts mechanical vibrations detected from the tympanic membrane to an electrical signal that is amplified, filtered, and converted back to a vibratory signal by a second piezoelectric transducer, the driver. The vibrations are transmitted to the stapes [10].

The Carina® Fully Implantable Hearing System is a fully implantable device. The implant consists of a microphone, a sound processor and a transducer. The subcutaneous microphone detects sound. This is amplified and converted into an electrical signal, which is transmitted to the piezoelectric transducer. The transducer converts the electrical signal into mechanical movements, which vibrate the ossicles [14].

## 4 Findings

A search was conducted of PubMed, Embase, Cochrane, TRIP and NICE Evidence on 16<sup>th</sup> December 2015 using the search terms detailed in section 7. The search for studies in both children and adults was limited to those published from 2014 onwards in order to update an earlier SPH review of MEI in people with hearing loss [15]. The search excluded papers on middle ear prostheses and on stapes surgery. The search also excluded conference papers, letters, comment, editorials and case reports.

### 4.1 Evidence of effectiveness

#### Outcomes measured

*Functional gain* (in dB) is a measure of benefit provided by the device and was the primary outcome in most studies. It is calculated by determining the difference between the unaided preoperative and aided postoperative pure-tone average thresholds.

*Speech outcomes* were measured in a variety of standardised ways. For example, a 'speech detection level' is the softest level at which a person detects (rather than understands) speech sounds, whereas 'speech intelligibility in quiet' is determined using monosyllabic words presented at the conversational level (between 40-65 dB SPL). One error is counted each time an element is mispronounced or not repeated.

A variety of *patient related outcome* tools and scales are used. For example a 'Glasgow Benefit Inventory' was developed for otorhinolaryngological interventions and measures a patient's change in health status on an 18-item questionnaire completed by the patient. The Hearing Device Satisfaction Scale, Hough Ear Institute Profile and the Gothenburg Profile were used amongst others.

#### **4.1.1 Studies of effectiveness in children**

Our search identified one study of effectiveness of MEIs in children.

Frenzel et al [16] carried out a prospective evaluation of the safety and efficacy of the Vibrant Soundbridge (VSB) in the treatment of hearing loss in children and adolescents. The study included 19 patients from five German-speaking tertiary centres; each patient served as their own control. The authors reported significant improvements in speech outcomes. See Table 1 for summary of results.

The findings should be interpreted with caution as they do not relate to relative effectiveness compared with other devices. The sample size was also too small to be able to generalise the results.

#### **4.1.2 Studies of effectiveness in mixed populations of children and adults**

We identified one systematic review [17] and one other study [18] of MEIs in mixed populations of children and adults. See Table 2 for summary of results.



Ernst et al [17] conducted a systematic review of the safety and effectiveness of VSB in treating conductive and mixed hearing loss. The authors included 19 studies (N=294) that reported outcomes on the use of VSB, only one was a comparative study. The authors reported an average functional gain of about 30dB at three months. However, very limited statistical information was reported.

The review was well conducted with the questions clearly defined. The inclusion and exclusion criteria were clearly stated. However the findings were limited by the quality and sample sizes of the studies identified for inclusion.

Zhao et al [18] reported auditory outcomes of VSB used in nine patients with congenital oval window atresia. The authors reported improvements in functional gain as well as speech outcomes. However no statistical analysis was carried out therefore the real benefits to the patients are unclear. Also the study was too small and therefore the findings may not be generalisable.

#### **4.1.3 Studies of effectiveness in adults**

We found three studies of MEIs in adults; one systematic review [19] and two other studies [20;21]. See Table 3 for summary of results.

Pulcherio et al [19] conducted a systematic review of outcomes of the fully implantable middle ear devices Carina® and Esteem® regarding the treatment of hearing loss. This systematic review included 22 studies (N=244).

The authors concluded that due the relatively few publications available and small sample sizes, the results cannot be confidently extrapolated to a broader population. Additionally, none of these studies represented high levels of evidence (i.e. randomised controlled trials).

Ihler et al [20] carried out a retrospective study to review the results of an active middle ear implant for sensorineural hearing loss in patients who were unable to wear or did not benefit from conventional hearing aids (n=10) in comparison to patients with a matched degree of hearing loss successfully fitted with a conventional hearing aid (n=12). They reported comparable speech recognition and superior functional gain and quality of life with VBS compared to conventional hearing aids.

This study was a small retrospective study; therefore the findings should be interpreted with caution.

Maier et al [21] assessed the safety and effectiveness of the middle ear implant Vibrant Soundbridge (VSB) in patients with moderate-to-severe sensorineural hearing loss up to a mean duration of  $11.1 \pm 2.1$  years after the intervention. A total of 104 adults (for 122 implants) were included in this study. The main emphasis was on the long-term effects of VSB on residual hearing. The authors reported that bone conduction (BC) thresholds were preserved after the implantation and no indication was found of an increase over time of the small air-bone gaps introduced by the implantation. BC and air conduction thresholds worsened similarly in both implanted and non-implanted ears over time. The decrease in audiological benefit provided by the VSB was moderate and the Word Recognition Score in quiet conditions at 65 dB SPL was still largely improved with the VSB in the longest observed group. The authors concluded that the VSB does not affect the integrity of the inner/middle ear and is still beneficial in long-term follow-up.

**Table 1: Summary of evidence in children**

Study	Population	Intervention	Comparator	Outcomes
Frenzel et al 2015 [16]  Prospective, Before and after study  Five centres  Germany, Austria & South Tirol	Children (aged 5-17) with conductive and mixed hearing loss  n=19	Active middle ear implant (AMEI) – Vibrant Soundbridge (VSB)	Unaided	<p><b>Mean word recognition scores (WRS) in quiet</b></p> <p><b>Children aged 5-9 years</b> 28.9% pre-op to 80% at initial fitting p= 0.005; 95.5% at 6-month testing p=0.001</p> <p><b>Children aged 10-17 years</b> 18.5% pre-op to 80.5% at initial fitting p= 0.001; 89% at 6-month testing p=0.001</p> <p><b>Mean speech recognition threshold – SRT50<sup>2</sup></b></p> <p><b>Children aged 5-9 years</b> 57.2dB HL pre-op to 50dB HL at initial fitting p=0.175; 44.12dB HL at 6-month testing p=0.007</p> <p><b>Children aged 10-17 years</b> 62.9dB HL pre-op to 47.3dB HL at initial fitting p=0.048; 40.2dB HL at 6-month testing p=0.007</p> <p><b>Mean signal to noise ratios (SNR)<sup>3</sup></b></p> <p><b>Children aged 5-9 years</b> 0.34 pre-op to -3.01 at initial fitting -4.90 at 6-month testing p=0.006</p> <p><b>Children aged 10-17 years</b> 2.79 pre-op to -2.43 at initial fitting -3.60 at 6-month testing p=0.005</p>

<sup>2</sup>SRT50 – decibel threshold at which patients can understand 50% of monosyllables in sentences

<sup>3</sup> The difference of the sound signal level at which 50% of the words were repeated correctly with a constant noise level of 65dB



**Table 2: Summary of evidence in mixed populations of children and adults**

Study	Population	Intervention	Comparator	Outcomes
Ernst et al 2015 [17] Systematic review of 19 studies  16 before and after studies 2 concurrent cohort studies 1 non-randomised study	Children and adults with conductive and mixed hearing loss  N=294	Active middle ear implant (AMEI) – Vibrant Soundbridge (VSB)	Unaided (same patient)  Hearing rehabilitation	<p><b>Mean bone conduction threshold (12 studies)</b> No significant shift in thresholds</p> <p><b>Mean air conduction thresholds (11 studies)</b> At 3 months (4 studies): Pre-op 72dB HL to 34.2dB HL At 6 months (6 studies): Pre-op 72dB HL to 30dB HL At &gt;12months (5 studies): Pre-op 72dB HL to 26dB HL <b>No p values were reported</b></p> <p><b>Functional gain (6 studies)</b> At 3 months : 29.6dB (12.5dB to 43.4dB HL) <b>No p values were reported</b></p> <p><b>Speech outcome</b> Meta-analysis showed a significant improvement of 71.5% for Italian disyllabic scores <math>p&lt;0.00001</math> at 3 months 69% for Freiburger monosyllabic scores <math>p&lt;0.00001</math> at 6 months</p> <p><b>SRT50 (5 studies)</b> At 3 months: improvement 33dB to 41dB <b>No p values were reported</b></p>
Zhao et al 2015 [18] Retrospective study  Before and after study	Children and adults with congenital oval window atresia  n=9	Active middle ear implant (AMEI) – Vibrant Soundbridge (VSB)	Unaided (same patient)	<p><b>Functional gain</b> Mean bone conduction threshold – no change</p> <p>Mean air conduction thresholds – mean improvements of &gt;30dB <b>No p values reported</b></p> <p><b>Speech outcome</b> MSTM disyllabic recognition test<sup>4</sup> – mean score pre-op 14% to 76% post-op CMSTS sentence test<sup>5</sup> – mean score pre-op 22% to 92% post-op <b>No p values reported</b></p>

<sup>4</sup> The Mandarin Speech Test Materials (MSTM) was used to measure disyllabic speech perception.

<sup>5</sup> The Computerized Mandarin Speech Test System (CMSTS) was administered to record word recognition in sentences.

**Table 3: Summary of evidence in adults**

Study	Population	Intervention	Comparator	Outcomes
Pulcherio et al 2014 [19] Systematic review of 22 studies	Adult patients with hearing loss  N=244 (Carina®=110; Esteem® =134)	Esteem®  Carina®	Conventional hearing aids  Unaided (same patient)	<p><b>Compared with hearing aids (HA)</b></p> <p><b>Functional gain</b> Esteem® 4 out of 5 studies report some functional gain however no details were reported</p> <p>Carina® Three studies report some functional gain however no details were reported</p> <p><b>Word recognition</b> Esteem® (3 studies) <b>NS</b> Carina® SS (one study) however no details were provided NS (2 studies) Improvement (1 study) no details provided</p> <p><b>Compared with unaided (in same patients)</b> Esteem® Functional gain (2 studies) no details provided Carina® SS (2 studies) p=0.0004 &amp; p=0000001 Improvement (2 studies) no details provided</p>
Ihler et al 2014 [20] Retrospective chart review  Germany	Adult patients with sensorineural hearing loss n=22	Active middle ear implant (AMEI) – Vibrant Soundbridge (VSB) n=10	Matched population with conventional hearing aids n=12	<p><b>Mean Functional gain (VSB vs. HA) at &gt;4 months</b> 25.2 ± 8.6 vs. 14.6 ± 10.8 dB <b>No p values reported</b></p> <p><b>Speech outcome (VSB vs. HA) at &gt;4 months</b> Aided speech recognition score in noise 36.6 ± 18.4 vs. 31.2 ± 19.2 % Aided speech recognition score in quiet 66.0 ± 23.2 vs. 61.5 ± 23.8 % <b>No p values reported</b></p> <p><b>Quality of life (VSB vs. HA) at &gt;4 months</b> Glasgow Benefit Inventory total score 38.3 ± 32.3 vs. 24.8 ± 22.2 <b>No p values reported</b></p>

<p>Maier et al 2015 [21] Retrospective, single-subject repeated measurements study</p> <p>Germany</p>	<p>Adult patients with moderate to severe sensorineural hearing loss n=104 (122 ears)</p>	<p>Active middle ear implant (AMEI) – Vibrant Soundbridge (VSB)</p>	<p>Un-implanted ears</p>	<p><b>Effect on residual hearing</b> Mean bone conduction threshold immediately post-op Deterioration ranged from -2 to -3.4dB p&lt;0.001</p> <p>Deterioration no longer significant at &gt;1 year &amp; similar to un-implanted ears</p> <p>Mean air conduction thresholds immediately post-op Deterioration ranged from -1.5 to -6.9dB p≤0.001</p> <p>Deterioration no longer significant at &gt;1 year &amp; similar to un-implanted ears</p> <p>Mean ABG<sup>6</sup> deterioration -2.7dB p&lt;0.001 due to implantation</p> <p>Deterioration was transient and no longer significant at mean follow-up of 11.1 years</p> <p><b>Speech outcome</b> Significant improvement in PTA Mean unaided 59.8 dB HL vs. aided 39.9 dB HL p&lt;0.001</p> <p>no reduction in benefit observed</p>
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PTA – pure-tone average

<sup>6</sup> Air bone gap (ABG) is the difference between the thresholds for hearing when the stimuli are delivered by **air** conduction and by **bone** conduction.

#### 4.2 Trials in progress

A search of [clinicaltrials.gov](http://clinicaltrials.gov) in January 2016 did not identify any ongoing trials of MEIs.

#### 4.3 Evidence of cost-effectiveness

We did not identify any studies of the cost-effectiveness of MEIs for hearing loss in children or adults.

#### 4.4 Safety

We did not find any comparative evidence reporting on the safety of MEIs.

No safety issues were reported in any of the identified studies of MEIs for hearing loss in children.

Five studies included in the systematic review by Pulcherio et al [19] reported complications and adverse effects related to the Carina® device and three reported adverse events associated with the Esteem® device.

The Carina® device is associated with occasional feedback although this appears to be resolved by fine-tuning of the fitting. Postoperative infection needing reoperation was also reported. One study cited fullness or pressure sensation in 10% of subjects using Carina®, middle ear effusion and partial device extrusion in 15%, vertigo and tinnitus in 5% and conductive hearing loss in 20%.

One study reported that 5.2% of patients implanted with the Esteem® device had revision surgeries, 3.5% developed wound infection (one required explantation), 5.2% evolved with facial paresis. Another study reported temporary swelling of the lower eyelid, sore jaw, nausea, diarrhoea, elbow pain, arm and hand pain, and numbness. A device-related wound complication occurred that ultimately required implant removal in one subject. The minor complications reported by the third study with the Esteem® device were: temporary partial facial palsy (7.6%), disruption of chorda tympani nerve (61.5%), revision surgery because of healing difficulty (7.6%) and 23% of revision surgeries for poor functional results. The major complication was the implant removal because of wound infection (15.3%).

The systematic review by Ernst et al [17] reported adverse effects from 13 studies covering 196 patients implanted with VSB. About 16% of all participants were affected by an adverse event. The most common complication was floating mass transducer (FMT) extrusion (6.63%) This was followed by wound dehiscence (2.04%) and dizziness (1.53%). Device failure was observed in 1.53% and 10.2% of participants required revision surgery.

#### 4.5 Summary of section 4

We identified one study of effectiveness of MEIs in children, one systematic review and one other study of MEIs in mixed populations of children and adult, three studies of MEIs in adults; one systematic review and two other studies.

In children, speech outcomes; word recognition scores and speech recognition threshold appeared to improve with MEIs (VSB) compared with the unaided post-operative condition (i.e. with the implant not activated). The study did not report patient-reported outcomes.

Studies of mixed populations of children and adults showed similar results to those in children only. The systematic review reported that significant benefits were seen between the aided and

unaided post-operative condition in ease of communication, listening under reverberant conditions and with background noise, however details were not provided.

In adults, there was some evidence demonstrating that MEIs appear to be effective in improving hearing from unaided pre-implantation levels in patients various kinds of hearing loss. There was also some evidence demonstrating that MEIs appear to be at least as effective as external hearing aids in patients with hearing loss. Speech outcomes appear improve with MEIs when compared with unaided hearing and at least as good as (and in some studies reported as better than) the external hearing aid. However no statistical information was reported in most of the studies.

Patient satisfaction appeared to be greater with the MEIs than with the external hearing aid with improved sound quality, less canal occlusion, less feedback and improved quality of life.

Overall the design of studies, the small sample sizes and the differences in the reporting of outcomes does not allow any firm conclusions to be drawn about the outcomes from the findings.

We did not find any comparative evidence reporting on the safety of MEIs in children or adults.

No safety issues were reported in any of the identified studies of MEIs for hearing loss in children.

One systematic review reported on adverse effects related to the Carina® and Esteem® devices. The Carina® device is associated with occasional feedback which appears to be resolved by fine-tuning of the fitting. Postoperative infection needing reoperation, fullness or pressure, middle ear effusion and partial device extrusion vertigo and tinnitus sensation were also reported. Conductive hearing loss was reported in about in 20% of subjects using Carina®.

The most common adverse effect reported with the Esteem® device was disruption of chorda tympani nerve (61.5%). Other adverse effects related to the device include wound infection, facial paresis, temporary swelling of the lower eyelid, sore jaw, nausea, diarrhoea, elbow pain, arm and hand pain, and numbness. One study reported that 5.2% of patients implanted with the Esteem® device had revision surgeries.

About 16% of all participants implanted with VSB were affected by an adverse event. The most common complication was floating mass transducer (FMT) extrusion. Wound dehiscence and dizziness were also reported. Device failure was observed and about 10% of participants using VSB required revision surgery.

We did not identify any studies of the cost-effectiveness of MEIs for hearing loss in children or adults.

Damage to the chorda tympani nerve appeared to be the most commonly experienced adverse event. Most adverse events were relatively rare and of low severity. Serious adverse events such as facial nerve damage were rare. Technical complications related to the device, including device malfunction, migration or insufficient gain, were relatively rare. The rate of revision surgery up to 10% was reported however this varied between studies. Residual hearing loss was also reported.

## 5 Discussion and conclusions

1. *Are middle ear implants clinically effective in children and adults with moderate to severe sensori-neural, mixed or conductive hearing loss compared with conventional hearing aids, bone anchored hearing aids or cochlear implants?*

Overall, there is a paucity of high-level evidence from which firm conclusions on the relative effectiveness of MEIs can be drawn. We did not find any randomised studies. Evidence of effectiveness was from systematic reviews of non-randomised comparative studies and case series and from primary non-randomised comparative studies and case series (both children and adults).

Generally, the studies of MEIs in children and adults reported improvements in both functional gain and speech outcomes. However, statistical analyses were often not supplied. Quality of life and patient satisfaction outcomes showed benefits when reported although these were not uniformly reported across the studies.

The studies were very variable with regards to patient enrolment, study design, intervention, comparators, outcome measures and length of follow-up. The studies were very small and included patients with a range of severities and types of hearing loss, and in studies of children, a range of underlying causes of hearing loss, which made meaningful reporting of outcomes difficult.

The MEI appears to be associated with loss of residual hearing post implantation although there is some evidence to show that bone conduction (BC) thresholds were preserved after implantation and there is no indication of an increase in the small air-bone gaps introduced by the implantation over time. The majority of other complications reported were rare and of low severity. However, safety and in particular safety relative to other therapies, has not been well studied.

2. *Are middle ear implants cost effective in children and adults with moderate to severe sensori-neural, mixed or conductive hearing loss compared with conventional hearing aids, bone anchored hearing aids or cochlear implants?*

We did not identify any studies of the cost-effectiveness of MEIs for hearing loss in children or adults.

### Competing Interest

*All SPH authors have completed the ICMJE uniform disclosure form ([www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf)) and declare: grants from NHS England to SPH to undertake the submitted work, no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work*

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## 7 Search Strategy

**Table 4: Population, Intervention, Comparator and Outcomes (PICO)**

Patients/ population	Children and adults with moderate to severe sensori-neural, mixed or conductive hearing loss Children with congenital ears (microtia)
Intervention	Middle ear implant
Comparators	No intervention, Any other hearing devices including: <ul style="list-style-type: none"> <li>• air-conduction hearing aids</li> <li>• bone-anchored hearing aids</li> <li>• cochlear implants</li> </ul>
Outcome	Any, including: <ul style="list-style-type: none"> <li>• Successful implantation</li> <li>• Hearing quality (e.g. hearing threshold, sound localisation, speech recognition)</li> <li>• Quality of life, patient satisfaction</li> <li>• Functional outcomes (e.g. educational/learning outcomes)</li> <li>• Safety/Complications</li> <li>• Survival of device/its components</li> </ul> Cost/cost-effectiveness

**Search date: 16 December 2015**

**Databases searched:** PubMed, Embase, Cochrane, Trip and NICE Evidence search.

Limited to studies published in English in last two years. Papers included in the previous review of this topic (search conducted 12<sup>th</sup> August 2014) are not included in this review

Case reports, conference papers, letters and commentary and editorials excluded

Embase search:

1. (middle ear\* adj5 (implant\* or prosth\*)).ti,ab.
2. (middle ear\* and (implant\* or prosth\*)).ti.
3. ((ossicle\* or ossicular or tympanic cavity or cavum tympani or oval window\* or malleus or incus or stapes) adj5 (implant or prosth\*)).ti,ab.
4. ((ossicle\* or ossicular or tympanic cavity or cavum tympani or oval window\* or malleus or incus or stapes) and (implant or prosth\*)).ti,ab.
5. (otologics and (implant or prosth\*)).ti,ab.
6. (envoy and (implant or prosth\*)).ti,ab.
7. (med-el and (implant or prosth\*)).ti,ab.
8. (ototronix and (implant or prosth\*)).ti,ab.
9. totally integrated cochlear amplifier.ti,ab.
10. vibrant soundbridge.ti,ab.
11. Esteem® implantable hearing system.ti,ab.
12. maxum system.ti,ab.
13. (ossiculoplast\* and (implant\* or prosth\*)).ti,ab.
14. middle ear implant/
15. middle ear prosthesis/
16. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15