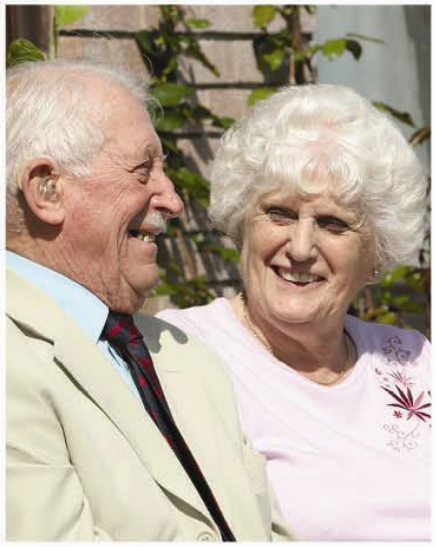
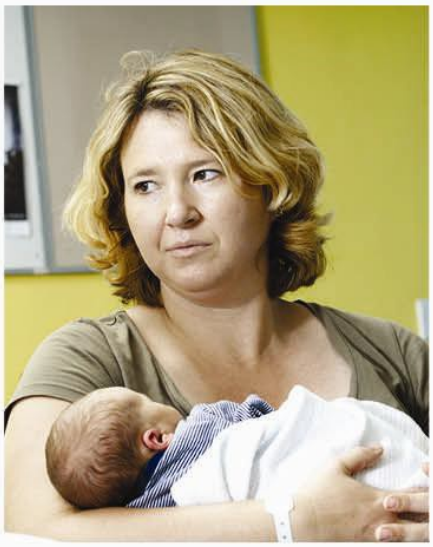
NHS Commissioning Board

Clinical Commissioning Policy Statement: Active Middle Ear Implants

April 2013

Reference: NHSCB/ D09/PS/a





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NHS Commissioning Board Clinical Commissioning Policy Statement: Active Middle Ear Implants

First published: April 2013

Prepared by the NHS Commissioning Board Clinical Reference Group for Specialised Ear Surgery

First published April 2013
Published by the NHS Commissioning Board, in electronic format only.

POLICY STATEMENT: Active Middle Ear Implants	Policy Ref: NHSCB/ D09/PS/a

Treatment:	Active Middle ear implants are surgically implanted hearing aids, which are placed within the middle ear, and are suggested as a therapy for certain patients with conductive, sensorineural or mixed hearing loss for whom alternative treatments (e.g. conventional hearing aids, bone anchored hearing aids etc.) are unsuitable. Active Middle ear implants can be fully implantable or semi-implantable and work via electromagnetic or piezoelectric transducers.
For the treatment of:	Patients with moderate to severe conductive hearing loss, sensorineural hearing loss or with a mixture of the two types of hearing loss who are unable to benefit from conventional prosthetic devices. Device implanted surgically
Background:	It is estimated that there are approximately nine million people in the UK with a hearing impairment. The prevalence of deafness varies with the age of the individual. The prevalence of a permanent hearing loss is 1 in 1000 for newborn children, and 2 in 1000 for children aged 9-16 years. The difference in prevalence with age is related to later diagnosis, late onset or progressive hearing loss. Hearing loss may be broadly grouped into three categories. Hearing loss may be caused by interference with the transmission of sound from the outer and middle ear to the inner ear, and is called conductive hearing loss. Conductive hearing loss may be transient or permanent and congenital (e.g. malformation of the outer or middle ear) or acquired. Acquired causes include blockage of the external auditory canal by cerumen or foreign objects, otitis externa, otitis media, perforation of the tympanic membrane and otosclerosis. The second category of hearing loss occurs when there is damage to the organ of hearing (cochlea), auditory nerve or auditory centres in the brain, and is called sensorineural hearing loss. Sensorineural hearing loss is usually permanent and may be congenital (e.g. genetic causes or malformation of the inner ear) or acquired. Acquired causes include the ageing process (presbyacusis), acoustic trauma (prolonged exposure to excessive noise), Meniere's disease, ototoxic

medications, viral infections of the inner ear (e.g. measles or mumps), viral infections of the auditory nerve (e.g. rubella or mumps), vestibular schwannomas, multiple sclerosis, meningitis, encephalitis and cerebrovascular accident.

Finally, mixed hearing loss occurs when an ear has a combination of both conductive and sensorineural hearing loss. An example would be a patient with presbyacusis who also has chronic ear disease.

The management of hearing impairment will depend on the underlying cause, the communication needs and preferences of the patient as well as their general medical condition. Options available to improve quality of life include sign language, amplification, bone anchored hearing aid, cochlear implant, middle ear implant and auditory brain stem implant.

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 sensorineural 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.

Effective from:

1 April 2013

Evidence summary:

The Specialised Ear Surgery CRG requested and was granted a review of the evidence for the clinical and cost effectiveness of middle ear implants as, at 1 July 2012, there were no known documented commissioning policies.

An evidence review was performed by an independent reviewer. Their report reviewed and referenced some 32 documented pieces of evidence, which are quoted as the references here.

In summary the review found that there were major limitations in the evidence available. There was a lack of high-level

evidence on the relative effectiveness and safety of the middle ear implant compared with other recognised treatments. The evidence available consisted of comparative studies and case series that were all subject to bias and confounding. Findings must be interpreted cautiously.

Most studies are of the Vibrant Soundbridge device. It cannot be stated that one device is superior to another.

Evidence assessing the effectiveness of the middle ear implant compared with the external hearing aid demonstrated that the middle ear implant was at least as effective in patients with sensorial neural hearing loss and patients with mixed hearing loss.

Speech discrimination in quiet and in noise with the middle ear implant was improved when compared with the unaided groups and at least as good as or better than the external hearing aid.

Patient satisfaction appeared greater with the middle ear implant than with the external hearing aid with improved sound quality, canal occlusion, feedback and quality of life. However, the confidence in these findings is limited by the quality of the evidence base.

The middle ear implant appears to be associated with loss of residual hearing post implantation. The majority of complications reported were rare and of low severity. However, safety and in particular safety relatively to other therapies, has not been well studied.

No studies had been conducted to determine the clinical effectiveness of the middle ear implant compared to bone anchored hearing aids.

No studies had been conducted to determine the cost effectiveness of the middle ear implant.

Evidence Level – unable to grade as the evidence is absent

Further information is required to achieve a definitive position on this technology.

Equality impact:

The NHS CB has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB will have due regard to the

	different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which they are responsible, including policy development, review and implementation.
Responsible CRG:	Specialised Ear Surgery CRG
Date approved by NHS CB Board:	1 April 2013
Policy review date:	From April 2014 To be confirmed
Version:	V1 1
	N/A

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