Title:	**Middle ear implant for sensorineural, conductive and mixed hearing losses**
Agency:	Medical Services Advisory Committee (MSAC) MDP 853 Commonwealth Department of Health and Ageing GPO Box 9849 Canberra ACT 2601 http://www.msac.gov.au
Reference:	MSAC Application 1137 First printed November 2010
	ISBN (print) 978-1-74241-347-1 ISBN (online) 978-1-74241-348-8

Aim

To assess the safety, effectiveness and cost-effectiveness of the middle ear implant (MEI) in (a) patients with mild, moderate or severe sensorineural hearing loss, (b) patients with mild, moderate or severe conductive hearing loss, and (c) patients with mild, moderate or severe mixed hearing loss.

Results and Conclusions

Safety

No comparative evidence was available to inform on safety of the MEI compared with either the bone anchored hearing aid (BAHA) or the cochlear implant (CI). For the MEI device safety outcomes were drawn from comparative, case series and case report data for a total of 1222 patients. There were no deaths associated with MEI implantation. Most adverse events were relatively rare and of low severity. Serious adverse events such as facial nerve damage were reported to have occurred rarely. Damage to the chorda tympani nerve was reported more commonly; however, some instances of resulting taste disturbance were reported to have been transient and to have resolved over time. Technical complications related to the device, including device malfunction, migration or insufficient gain were relatively rare. Residual hearing loss after MEI implantation was reported on by most studies, with 13 studies reporting that patients suffered significant declines in mean residual hearing loss after MEI implantation. In summary, due to the absence of comparative evidence it is not possible to accurately compare the rates of adverse events between patients receiving MEI, CI or BAHA. However, on the limited evidence that is available, it appears that MEI implantation is at least as safe as CI or BAHA implantation.

Effectiveness

One comparative study was available to assess the effectiveness of the MEI versus the CI, and no comparative studies were available to assess the effectiveness of the MEI versus the BAHA. Three comparative studies of the MEI device alone were identified; however, these studies generally involved an internal comparator such as MEI attachment method. Hence, most of the evidence for the effectiveness of the MEI has been derived from level IV evidence.

Generally, MEI implantation and/or activation led to improvements in patients with mild, moderate and severe sensorineural hearing loss; sensorineural hearing loss of undefined severity; mild, moderate and severe mixed hearing loss; mixed hearing loss of undefined severity; and conductive hearing loss. The MEI appears to be at least as effective as the external hearing aid. However, these conclusions are limited by the paucity of high-level evidence. Many effectiveness outcomes were reported in case series, and subject to bias. The lack of high quality studies may be related to the relative youth of the MEI procedure.

Cost-effectiveness

The total estimated first year cost of an MEI, BAHA and CI is $23,873, $15,207 and $34,466, respectively. The incremental cost of using an MEI as opposed to a BAHA is $8,666. The incremental cost saving of using an MEI as opposed to a CI is $10,593.

Based on 2006-07 MBS data, the total cost of BAHA would be $1,611,957 (106 patients) and the total cost of CI would be $11,270,250 (327 patients). This gives a total cost of $12,882,207. If MEI was used instead of BAHA and CI the total cost would be $10,336,916. Hence the cost savings of performing MEI as a direct replacement for BAHA and CI would be over $2.5 million.

Expert opinion endorsed by the Advisory Panel indicated that MEI would not just replace current CI and BAHA use, but would become another option in meeting the pool of unmet need of those with hearing loss. Expert opinion was that these individuals, currently persisting with hearing loss or a less than optimal

hearing aid, may consider MEI implantation while they are not considering or accessing BAHA or CI. The previously mentioned variability in HA management prior to consideration of MEI, and limited data on the pool of ‘unmet need’, makes this number difficult to quantify. Sensitivity analysis suggests that if one per cent of the estimated pool of individuals with moderate or severe hearing loss elected to have MEI, the additional cost would be $2,291,787. These estimates are based on prevalence data of hearing loss in Australia and include a large portion of older Australians for whom an MEI would not be viable.

Methods

The evidence regarding the use of the MEI in patients with sensorineural, conductive or mixed hearing losses was systematically assessed. PubMed, EMBASE, the Cochrane Library and Current Contents were searched for relevant literature from database inception to August 2009.

Studies were included in the review using pre-determined PICO selection criteria and reasons for exclusion were documented. The quality of studies was assessed, data were extracted in a standardised manner, and results were reported narratively.