

# **NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE**

## **INTERVENTIONAL PROCEDURES PROGRAMME**

### **Interventional procedures overview of auditory brain stem implants**

#### ***Introduction***

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by one or more Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

#### ***Date prepared***

This overview was prepared by Bazian Ltd in December 2002.

#### ***Procedure name***

- Auditory brain stem implants.

#### ***Specialty societies***

- British Association of Otorhinolaryngologists, Head and Neck Surgeons
- Society of British Neurological Surgeons

#### ***Description***

##### **Indications**

Deafness caused by damage to the vestibulocochlear nerve resulting from tumours or surgery.

Tumours of the vestibulocochlear nerve (acoustic neuromas) are rare and generally benign. The most common cause is a rare genetic condition called neurofibromatosis.

In people with vestibulocochlear nerve damage, hearing is not improved by hearing aids or cochlear implants.

##### **What the procedure involves**

Auditory brain stem implants are electrodes placed in a part of the brain (the cochlear nucleus) responsible for processing sound signals carried from the ear through the

vestibulocochlear nerve. This nucleus lies in the lower part of the brain, called the brain stem.

Removal of vestibulocochlear nerve tumours and placement of auditory brain stem implants is often done at the same time. The surgeon makes an incision in the skin of the side of the head, and removes some of the bone behind the ear. This exposes the tumour so that it can be removed and also allows access to the brain stem beneath it. Sometimes the surgeon approaches the brain stem through the back of the head.

People with auditory brain stem implants wear an external receiver and speech processor. This device converts sounds into electrical signals, which are then sent to the implant.

## ***Literature reviews***

### **Appraisal criteria**

Studies of auditory brain stem implants were included if they examined clinical outcomes.

### **List of studies found**

No systematic reviews, randomised controlled trials or non-randomised controlled studies were found.

Twelve publications were found describing case series.<sup>1-4</sup> The four largest are described in the table.

References to smaller studies are given in the Appendix

## Summary of key efficacy and safety findings

| Study details                                                                                                                                                                                                                   | Key efficacy findings                                                                                                                                                | Key safety findings                                                                                                            | Key reliability and validity issues                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| <p>Ebinger<sup>1</sup></p> <p>Case series</p> <p>USA</p> <p>1994 to 2000</p> <p>92 people, age range 13 to 68 years</p> <p>88 people with follow up data<br/>Most followed up at 6 months; some only 3-month data available</p> | <p>Received auditory sensations: 75/88</p> <p>Used device daily: 97% (denominator not clear)</p> <p>Reported having benefit from it: 83% (denominator not clear)</p> | <p>Tingling in various parts of the body 'not uncommon'</p>                                                                    | <p>Uncontrolled case series.</p> <p>Short follow up.</p>                                                          |
| <p>Otto<sup>2</sup></p> <p>Case series</p> <p>Los Angeles, USA</p> <p>1992 to 2000</p> <p>61 people, age range 12 to 71 years</p> <p>Follow up to 7 years</p>                                                                   | <p>Mean improvement in communication over lip-reading alone: 26% (range 0-66%)</p> <p>Improvements continued up to 7 years after implantation</p>                    | <p>Cerebrospinal fluid leak: 2 people</p> <p>Meningitis: 1 person</p> <p>'Severe or serious non-auditory sensations': none</p> | <p>Uncontrolled case series..</p> <p>Same centre as in Ebinger<sup>1</sup>; likely to be overlap of patients.</p> |

| Study details                                                                                                                                                                                    | Key efficacy findings                          | Key safety findings                 | Key reliability and validity issues                                                                                                                        |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Hitselberger<sup>3</sup></p> <p>Case series</p> <p>Los Angeles, USA</p> <p>1979-2000</p> <p>More than 100 people</p>                                                                          | <p>Restoration of limited hearing: 80%</p>     |                                     | <p>Uncontrolled case series.</p> <p>Data extracted from abstract only.</p> <p>Same centre as in Ebinger<sup>1</sup>; likely to be overlap of patients.</p> |
| <p>Sollman<sup>4</sup></p> <p>Case series</p> <p>1 Asian and 9 European countries (main author Germany)</p> <p>1992-2000</p> <p>54 people, mean age 33 years</p> <p>Follow up: up to 7 years</p> | <p>Some hearing: 94%</p> <p>Daily use: 89%</p> | <p>Pulmonary embolism: 1 person</p> | <p>Uncontrolled case series.</p>                                                                                                                           |

| Study details                                                                                              | Key efficacy findings                                                                                                                                                      | Key safety findings                            | Key reliability and validity issues                                                                                                                                                                                                                                                                       |
|------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Schwartz M (2003)<sup>5</sup></p> <p>Case Series</p> <p>86 consecutive patients – 60 were evaluable</p> | <p>Patients had significant improvement in scores on several audiologic tests compared to baseline.</p> <p>Improvement was also seen when used to augment lip reading.</p> | <p>Authors did not report on complications</p> | <p><b>This study was identified during the consultation process in June 2004.</b></p> <p>Same centre as in Ebinger<sup>1</sup>; likely to be overlap of patients.</p> <p>Number of patients (n=16) were excluded from analysis.</p> <p>Limited outcomes (no absolute numbers were given in the paper)</p> |

## **Validity and generalisability of the studies**

All the studies found are case series.

All are small, so do not provide precise estimates of risk of complications.

## ***Bazian comments***

It appears that there are two main centres publishing work on auditory brain stem implants, one in the USA and one in Germany.

## ***Specialist Advisor's opinions***

*Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.*

The best results allow conversation using the device, and lip reading. At worst, the device at least gives contact with environmental noise.

They listed the potential adverse effects of the procedure as death, damage to lower cranial nerves, intracranial haematoma/brainstem stroke, meningitis, and infection of device.

## ***References***

Ebinger K, Otto S, Arcaroli J, Staller S et al. Multichannel auditory brainstem implant: US clinical trial results. *Journal of Laryngology & Otology* 2000, 114: 50-3.

Otto SR, Brackmann DE, Hitselberger WE, Shannon RV, et al. Multichannel auditory brainstem implant: update on performance in 61 patients. *Journal of Neurosurgery* 2002, 96: 1063-71.

Hitselberger WE, Brackmann DE, Day JD, Shannon R, et al. Auditory brain stem implants. *Operative Techniques in Neurosurgery* 2001, 4: 47-52.

Sollmann W-P, Laszig R, Marangos N. Surgical experiences in 58 cases using the nucleus 22 multichannel auditory brainstem implant. *Journal of Laryngology & Otology* 2000, 114: 23-6.

Schwartz, M.S., Otto, S.R., Brackman, D.E., Hitselberger, W.E., Shannon, R.V. Use of a multichannel auditory brainstem implant for neurofibromatosis Type 2. *Stereotactic and Functional Neurosurgery* 2003, 81 (1-4) 110-114.

## Appendix: References to studies not described in the table

Note: these studies are carried out by a small number of authors (the Otto [USA] group and the Sollmann [Germany] group in particular). It is possible that some of the people included in the series are reported on more than once.

| Reference                                                                                                                                                                                                                                | Number of study participants |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| <b>The Sollmann group</b>                                                                                                                                                                                                                |                              |
| Nevison B, Laszig R, Sollmann W P, Lenarz T, et al. Results from a European clinical investigation of the Nucleus multichannel auditory brainstem implant. <i>Ear &amp; Hearing</i> 2002; 23: 170-183.                                   | 27                           |
| Marangos N, Stecker M, Sollmann W-P, Laszig R. Stimulation of the cochlear nucleus with multichannel auditory brainstem implants and long-term results: Freiburg patients. <i>Journal of Laryngology &amp; Otology</i> 2000; 114: 27-31. | 18                           |
| Laszig R, Marangos N, Sollmann W-P, Ramsden R T. Central electrical stimulation of the auditory pathway in neurofibromatosis type 2. <i>Ear, Nose, &amp; Throat Journal</i> 1999; 78: 110-117.                                           | 14                           |
| Marangos N, Laszig R, Sollmann W P. [Long-term results of multi-channel stimulation of the cochlear nucleus with auditory brain stem prostheses] [German]. <i>Wiener Medizinische Wochenschrift</i> 1997; 147: 259-263.                  | 11                           |
| <b>The Otto group</b>                                                                                                                                                                                                                    |                              |
| Otto SR, Shannon RV, Brackmann DE, Hitselberger WE, et al. The multichannel auditory brain stem implant: performance in twenty patients. <i>Otolaryngology - Head &amp; Neck Surgery</i> 1998; 118: 291-303.                             | 20                           |
| Otto SR, Brackmann DE, Staller S, Menapace CM. The multichannel auditory brainstem implant: 6-month coinvestigator results. <i>Advances in Oto-Rhino-Laryngology</i> 1997; 52: 1-7.                                                      | 15                           |
| Otto, S. Staller, S. Multichannel auditory brain stem implant: case studies comparing fitting strategies and results. <i>Annals of Otology, Rhinology, &amp; Laryngology - Supplement</i> 1995; 166: 36-39.                              | 12                           |
| Soussi T, Otto SR. Effects of electrical brainstem stimulation on tinnitus. <i>Acta Oto-Laryngologica</i> 1994; 114: 135-140.                                                                                                            | 18                           |
| Otto SR, House WF, Brackmann DE, Hitselberger WE, et al. Auditory brain stem implant: effect of tumor size and preoperative hearing level on function. <i>Annals of Otology, Rhinology &amp; Laryngology</i> 1990; 99: 789-790.          | 15                           |
| <b>Other groups</b>                                                                                                                                                                                                                      |                              |
| Vincent C, Zini C, Gandolfi A, Triglia JM, et al. Results of the MXM Digisonic auditory brainstem implant clinical trials in Europe. <i>Otology &amp; Neurotology</i> 2002; 23: 56-60.                                                   | 14                           |
| Lenarz M, Matthies C, Lesinski-Schiedat A, Frohne C, et al. Auditory brainstem implant part II: Subjective assessment of functional outcome. <i>Otology and Neurotology</i> 2002; 23(5): 694-7.                                          | 11                           |
| Lenarz T, Moshrefi M, Matthies C, Frohne C, et al. Auditory brainstem implant: part I. Auditory performance and its evolution over time. <i>Otology &amp; Neurotology</i> 2001; 22: 823-33.                                              | 14                           |