The Journal of Laryngology & Otology
December 2000, Vol. **114,** Supplement No. 27, pp. 50–53

Multichannel auditory brainstem implant: US clinical trial results

K. Ebinger, S. Otto, J. Arcaroli*, S. Staller, P. Arndt

Abstract

Since 1994, a US Food and Drug Administration clinical trial evaluated the multichannel auditory brainstem implant (ABI) on 92 subjects with neurofibromatosis type 2 (NF2).

The trial has shown that 85 per cent of patients receive auditory sensations. A small number of patients demonstrate a clinically significant degree of open-set sentence recognition in the sound-alone condition; however, when the ABI is combined with lip-reading cues, 93 per cent of patients demonstrate improved sentence understanding at three to six months. In addition, the majority of recipients report daily use of their devices, and satisfaction with the decision to receive the ABI.

Key words: Brain Stem; Prosthesis Implantation; Neurofibromatosis 2; United States

Introduction

Electrical stimulation of the cochlear nucleus complex in individuals deafened following removal of bilateral vestibular schwannomas (neurofibromatosis type 2, NF2) has been shown to provide beneficial auditory information.[1,2] Since June 1994, US Food and Drug Administration clinical trials of the multichannel auditory brainstem implant (ABI) have been in progress at a number of investigational sites (Table I). Evaluation of perceptual performance has shown that the multichannel ABI can provide auditory cues that are useful in sound awareness and spoken communication, including a degree of open set speech recognition in some patients.[3] Development of the multichannel ABI has provided a viable alternative to the deafness that commonly occurs in individuals with NF2.

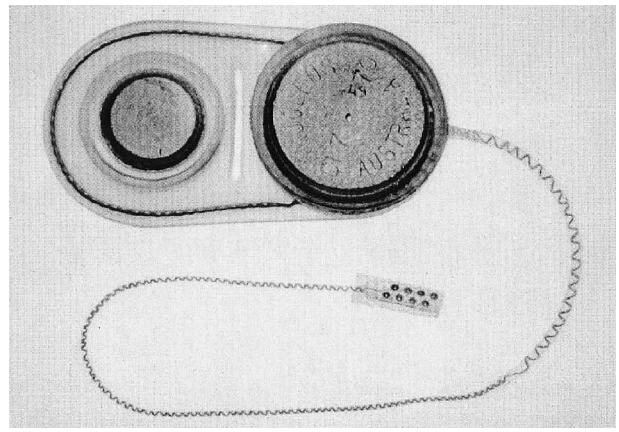
Materials and methods

Device and surgical placement

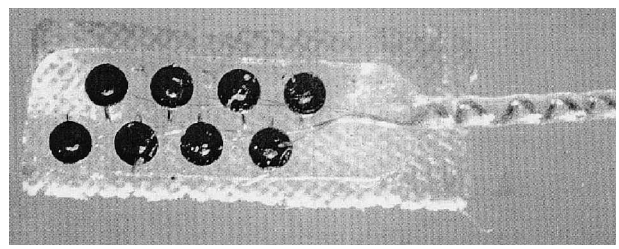
The multichannel ABI is based on the application of proven cochlear implant technology to stimulation of the central auditory system. The original single-channel ABI was developed by House Ear Institute (HEI, Los Angeles, CA) and was implanted in 25 patients from 1979–1992.[4] The multichannel ABI (Figures 1(a) and 1(b)) was developed collaboratively by HEI, Cochlear Corporation (Englewood, CO), and Huntington Medical Research Institute (Pasadena, CA). The device consisted of an array of

TABLE I
INVESTIGATIONAL SITES FOR THE US CLINICAL TRIAL OF THE MULTICHANNEL AUDITORY BRAINSTEM IMPLANT

House Ear Institute	University of Pittsburgh
New York University	University of Iowa
Baylor Hospital	Baptist Hospital
Midwest Ear Institute	California Ear Institute
Indiana University	Northwestern University



(a)



(b)

FIG. 1

(a) Receiver/stimulator and auditory brainstem implant (ABI) electrode array; (b) enlargement of ABI electrode array (actual size 2.5 × 8.5 mm).

From the Clinical Studies Department, Cochlear Corporation, and the Department of Auditory Implantable Prostheses, House Ear Institute*, USA.

eight 1-mm platinum disk electrodes interfaced with the Nucleus Mini-22 receiver/stimulator. Implantation, programming, and performance with the device in an early group of 20 patients has been reported previously.[3]

In the US clinical trials, tumour removal and placement of the ABI electrode array was achieved via a translabyrinthine surgical approach.[5] The target region of the cochlear nucleus complex in the lateral recess of the fourth ventricle was identified using anatomical landmarks, such as the taenia and root of the VIIIth nerve, and results of intra-operative monitoring of auditory evoked potentials.[6] Approximately four to eight weeks post-operatively, the electrical thresholds, comfort levels, non-auditory sensations, and pitch percepts provided by the device were assessed. Typically, patients were tested in both monopolar and bipolar stimulation modes. In monopolar (MP) mode, each active electrode on the array was paired with a remote ground on the receiver/stimulator case. In bipolar (BP) stimulation mode, each active electrode was paired with an adjacent electrode on the array that served as the ground. Using the variable (VAR) mode feature of the programming system, monopolar and bipolar stimulation modes were combined, allowing stimulation to occur between any two electrodes. This was often effective in providing additional stimulation 'channels'. For everyday listening, ABI recipients used the Nucleus Spectra speech processor with the SPEAK speech coding strategy.[7]

US clinical trial study protocol

There were no pre-operative audiological criteria indicated for clinical trial subjects since complete removal of vestibular schwannomas was expected to require transection of the auditory nerve. Besides the presence of NF2, other criteria for implantation included medical and psychological suitability, a minimum age of 12 years, reasonable expectations, willingness and ability to participate in the required follow-up, and competency in English (as all testing was conducted in English). Patients were implanted during either first or second-side tumour removal. First-side implantation offered two potential advantages: (1) recipients with bilateral hearing impairment could gain experience with the ABI prior to second-side tumour removal, and (2) there would be a second opportunity to obtain a functional ABI system in case the first-side implant did not provide auditory sensations.

Comprehensive post-operative evaluations were conducted at the time of initial stimulation, every three months during the first year after ABI connection, and annually thereafter. Every follow-up interval included psychophysical testing, programming and optimization of the speech processor, and a battery of speech perception and auditory awareness tests. The speech perception measures included vowel, consonant, word, and sentence identification tests. Vowel and consonant perception (using the Iowa medial vowels and Iowa medial consonants tests) and sentence understanding (using the City University of New York (CUNY) sentences) were assessed using laservideo disk, in sound-alone, lip-reading-alone, and sound-plus-lip-reading conditions. Testing in these three conditions allowed quantification of the degree of lip-reading enhancement provided by the device. Closed-set word recognition was measured in the sound-only condition using the Monosyllable/Trochee/Spondee (MTS) and the Northwestern University Children's perception of speech (NU-CHIPS) tests. Open-set sentence recognition ability was assessed in the sound-only condition using the Central Institute for the Deaf (CID) sentences. The tests of auditory awareness included a test of environmental sound identification (the sound effects recognition test, or SERT), and soundfield audiometry. Performance and tinnitus questionnaires were also administered at each test interval. Finally, a comprehensive neurological evaluation was conducted at each follow-up interval.

Study population

Ninety-two patients were implanted with the multichannel ABI. The average age at implantation was 33.9 years, ranging from 12.7 to 67.5 years. Two-thirds of the patients (61/92) were implanted during second-side tumour removal, with the remaining one-third (31/92) being implanted at the time of first-side tumour removal. Nearly 60 per cent of the patients were female (54/92).

Patient outcomes and clinical trial results

With respect to surgical outcome, two patients were pending initial activation at the time of writing, and two patients died prior to device activation from causes unrelated to the ABI. Of the 88 remaining patients, 75 (85.2 per cent) received auditory sensations when their ABIs were activated. In the other 13 (14.8 per cent), failure to stimulate was generally attributed to distorted brainstem anatomy, and difficulty visualizing anatomical landmarks intra-operatively.

In addition to auditory sensations, it was not uncommon during psychophysical testing for patients to report localized mild non-auditory sensations (primarily tingling) with activation of some electrodes (Figure 2). These sensations may have arisen from activation of nearby neural structures such as the VIIth and IXth nerves, or the cerebellar peduncle. The most frequent location of non-auditory sensations (60 per cent) was the head and neck on the side ipsilateral to the implant, with the remainder approximately evenly distributed to the upper extremities (10 per cent), torso (14 per cent), and lower extremities (11 per cent). Only six per cent of the non-auditory sensations occurred on the side contralateral to the ABI. Frequently, changing the reference ground electrode or increasing the stimulus pulse duration was effective in reducing or eliminating non-auditory sensations. These methods typically were used in preference to completely deactivating electrodes. Often non-auditory sensations decreased in magnitude over time, and for some patients, deactivated electrodes could be reactivated at later evaluations.

https://doi.org/10.1258/0022215001904743 Published online by Cambridge University Press

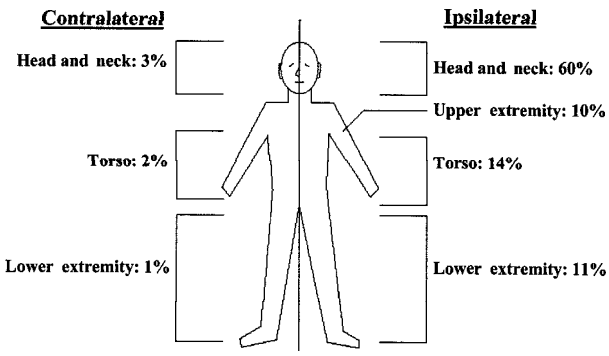


FIG. 2

Summary of side effects at initial stimulation: distribution of non-auditory sensations observed with activation of auditory brainstem implant electrodes. (n = 77 patients)

The remaining clinical trial results are reported for either the six-month or the three-month evaluation interval. Due to the poor health of many of these patients, follow-up appointments could not always be attended. For the purposes of data analysis, the six-month interval was chosen, however, for patients with no six-month evaluation, data from the three-month evaluation was substituted.

The auditory sensations provided by the multichannel ABI were useful in the discrimination and recognition of environmental sounds and speech. Figure 3 shows perceptual results at six (or three) months post-activation. Mean scores for the SERT, NU-CHIPS, and MTS tests were all significantly above chance levels. Only a few patients demonstrated any degree of 'open-set' speech recognition in the sound only condition on the CID sentence test.

The auditory information provided by the ABI, when used in combination with lipreading, was of significant benefit in enhancing speech perception as shown in Figure 4. Mean scores on the vowel, consonant, and CUNY sentence tests all improved in the sound-plus-lip-reading condition. The mean improvement of 24 per cent for CUNY sentences demonstrates the practical benefit of the device in face-to-face communication situations. A significant degree of open-set word recognition was observed on CUNY sentences for a few individuals. In subsequent testing, three patients showed further improvement in sound-only sentence scores in the

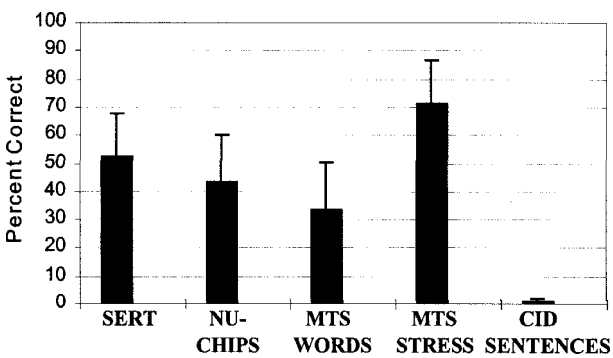


FIG. 3

Mean scores on speech perception tests at three (or six) months activation after auditory brainstem implant activation. (n = 57)

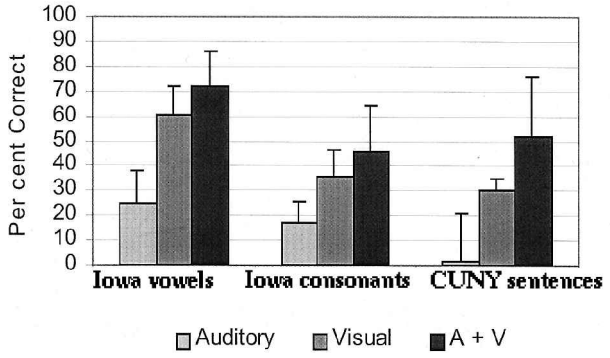


FIG. 4

Vowel, consonant and sentence recognition in auditory, visual, and auditory plus visual modes, three (or six) months after auditory brainstem implant activation. (n = 54)

order of 50 per cent correct (S. Otto, personal communication). In contrast to multichannel cochlear implants, where speech understanding abilities often improve quite quickly, it typically took three to nine months of auditory experience for ABI recipients to develop open-set speech recognition abilities.

The performance questionnaire and final survey administered as part of the clinical trials suggested a high degree of daily use and practical benefit (Tables II and III). In total, 97 per cent of patients implanted at the time of second-tumour removal reported using the device daily. Sixty-five per cent reported using the device for more than eight hours per day. Additionally, 74 per cent of recipients reported that they would recommend the ABI to others, 83 per cent indicated that they received benefit from their ABI, and 86 per cent reported that the decision to get the ABI was the right one.

Discussion

The clinical trials of the multichannel ABI have resulted in several significant findings. Multichannel stimulation of the cochlear nucleus complex is effective in providing beneficial auditory sensations that can partially restore contact with the sound environment and ease spoken communication. Many ABI recipients were able to return to their jobs and function well. Use of the ABI also helped to reduce the general disabling and isolating effects of NF2, which can be extreme for many affected individuals.

While typical ABI performance does not reach the high levels often observed with modern cochlear implants, it is apparent that several ABI recipients have some degree of open-set speech recognition. Among other factors, this may be related to the presence of electrode-specific auditory sensations (such as pitch) on multiple channels. The best

TABLE II

REPORTED FREQUENCY OF AUDITORY BRAINSTEM IMPLANT USE FOR INDIVIDUALS IMPLANTED ON THEIR SECOND ACOUSTIC TUMOUR SIDE

Hours of use:	
0 hours/day	3%
1–8 hours/day	32%
> 8 hours/day	65%

https://doi.org/10.1258/0022215001904743 Published online by Cambridge University Press

TABLE III
FINAL QUESTIONNAIRE RESULTS REGARDING BENEFIT RECEIVED FROM AUDITORY BRAINSTEM IMPLANT (ABI)

'I would recommend the ABI to others'	74% agree
'I benefit from my ABI'	83% agree
'My decision to get the ABI was the right one'	85% agree

performers with the ABI tended to experience a wider range of such sensations than average.[8] Research with microstimulating electrode arrays in animals has shown that improved access to the tonotopic gradient in the brainstem is possible.[9] A prototype penetrating ABI array, which has been developed for use in humans, may allow broader pitch perceptions, that hopefully may result in improved speech perception abilities for ABI recipients.

After initial stimulation, ABI recipients may experience slight variations in auditory or non-auditory responses that can impact use and benefit. For example, the sensitivity to stimulation on a given electrode, or its perceived sound quality, may change somewhat over time. These changes may affect the perceived quality of speech sounds or speech recognition. Particularly during the first year of use, periodic reprogramming of the speech processor to accommodate these changes can be highly beneficial.

Regular use of the ABI is highly important in increasing the rate of improvement in auditory skills and ultimate performance levels. Some ABI users implanted at the time of first-side tumour removal had useable hearing on the second, non-implanted side, and therefore did not use their devices regularly. Perceptual performance in these individuals often remained relatively low until after removal of the second-side tumour when the device was used more frequently. While cochlear implant users may experience high levels of performance very quickly, most ABI recipients (even top performers) start at significantly lower performance levels and improve much more slowly. Perceptual test scores have tended to remain low in individuals who rarely used their implants. The importance of frequent and consistent experience with the ABI should be emphasized in pre-operative counselling.

Other factors that can influence ABI use and benefit include the candidate's social activity level, motivation, general health, visual acuity, availability of a support group, and general expectations for the device. For example, since the ABI is most beneficial when combined with lip-reading cues, poor visual acuity may impact ultimate use and benefit. Addressing these issues in pre-operative counselling can help ensure more realistic expectations and promote satisfactory accommodation to and use of the implant.

Electrical stimulation of the cochlear nucleus is emerging as a safe, effective, and long-term solution to the deafness that commonly occurs in individuals with NF2. In the overall clinical study, several individuals implanted for as long as seven years are still benefiting from their implants and improving in performance. The first single-channel ABI recipient, initially implanted 20 years ago, still enjoys the daily use of her device and performs well with it.

In summary, the US clinical trial of the multichannel ABI has shown that 85 per cent of patients receive auditory sensations. A small number of patients demonstrate a clinically significant degree of open-set sentence recognition in the sound-alone condition, however, when the ABI is combined with lip-reading cues, 93 per cent of patients demonstrate improved performance on sentence understanding at three to six months. In addition, the majority of recipients report daily use of their devices, satisfaction with the decision to get the ABI, and agree that they would recommend the ABI to others who may be candidates.

Future improvements with the ABI most likely will depend upon improvements in the electrode/tissue interface and in the ability to encode sound into a form that is most meaningful to the central auditory system. Future research also will focus heavily on the development and use of alternate speech processing strategies with ABI recipients. Just as advances in cochlear implant technology have afforded an unprecedented degree of benefit for recipients, we trust that future advances in ABI technology undoubtedly will result in continued improvements in auditory performance for ABI recipients.

References

1 Hitselberger WE, House WF, Edgerton BJ, Whitaker S. Cochlear nucleus implant. *Otolaryngol Head Neck Surg* 1984;**92**:52–4
2 Eisenberg LS, Maltan AA, Portillo F, Mobley JP, House WF. Electrical stimulation of the auditory brainstem structure in deafened adults. *J Rehab Res Dev* 1987;**24**:9–22
3 Otto SR, Shannon RV, Brackmann DE, Hitselberger WE, Staller S, Menapace C. The multichannel auditory brainstem implant (ABI): Results in 20 patients. *Otolaryngol Head Neck Surg* 1998;**118**:291–303
4 Shannon RV, Fayad J, Moore J, Lo WW, Otto S, Nelson RA, *et al.* Auditory brainstem implant: II. Postsurgical issues and performance. *Otolaryngol Head Neck Surg* 1993;**108**:634–42
5 Brackmann DE, Hitselberger WE, Nelson RA, Moore J, Waring MD, Portillo F, *et al.* Auditory brainstem implant: I. Issues in surgical implantation. *Otolaryngol Head Neck Surg* 1993;**108**:624–33
6 Waring MD. Intraoperative electrophysiologic monitoring to assist placement of auditory brainstem implant. *Ann Otol Rhinol Laryngol* 1995:**104**(Suppl 166):33–6
7 McDermott HJ, McKay CM, Vandali AE. A new portable sound processor for the University of Melbourne/Nucleus multielectrode cochlear implant. *J Acoust Soc Am* 1992;**91**:3367–71
8 Otto SR, Ebinger K, Staller S. Clinical trials with the auditory brainstem implant. In: Waltzman S, Cohen N, eds. *Cochlear Implants.* New York: Thieme, 2000
9 McCreery DB, Shannon RV, Moore JK, Chatterjee M. Accessing the tonotopic organization of the ventral cochlear nucleus by intranuclear microstimulation. *IEEE Trans Rehab Eng* 1998;**4**:1–9

Address for correspondence:
Kiara Ebinger, M.S., F.A.A.A.,
Cochlear Corporation,
61 Inverness Drive East, Suite 200,
Englewood, CO 80112,
USA.

Fax: +1 303 362 2226

https://doi.org/10.1258/0022215001904743 Published online by Cambridge University Press