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## **Auditory Outcomes in Tumor vs. Nontumor Patients Fitted with Auditory Brainstem Implants**

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### **Abstract**

Auditory brainstem implants (ABIs) are currently indicated for patients older than 12 years with neurofibromatosis type 2 (NF2) who had bilateral schwannoma removed. Over the last 10 years, we have extended the indications for ABIs to nontumor children and adult patients with cochlear or cochlear nerve injuries or malfunctions who would not benefit from a cochlear implant. We have provided ABIs for patients with cochlear nerve aplasia and other injuries, and patients in whom any benefit was, or would be, severely compromised as in extensive cochlear ossification. In the present chapter we report our recent findings in adult ABI patients and compare the psychophysical and speech perception outcomes in tumor with those in nontumor patients. We demonstrate that the ABI can stimulate the central auditory system in a way that gives the ability of open set speech understanding, and can thus be indicated in nontumor adult patients who are not candidates for a cochlear implant. From April 1997 to January 2006, a total of 80 patients, 62 adults and 18 children, were fitted with ABIs in the University of Verona ENT Department; age ranged from 14 months to 70 years. Twenty-six patients had NF2 with bilateral vestibular schwannoma removal, and 54 had nontumor diseases of the cochlear nerve or cochlea. The retrosigmoid approach was used in all patients. All patients had a functioning implantation, and no complications were observed during the operation, activation as well as long-term use of the ABI. All patients, except 1 (NF2), reported auditory sensations with activation of various numbers of electrodes (from 5 to 21). Different electrodes elicited different pitch sensations. At 1 year after implantations nontumor adults scored from 12 to 100% in open set speech perception tests (average 59%), and tumor (NF2) patients scored from 5 to 30% (average of 11%). The differences between these results are statistically significantly ( $p < 0.01$ ). To investigate the cause of the differences in performance between tumor and nontumor ABI recipients, a series of psychophysical tests were done consecutively in 39 adult patients with implants (25 nontumor and 14 tumor patients) from May 1999 to April 2004 and with a follow-up of at least 1 year. The outcome of this study shows that: (1) The ABIs allow most tumor and nontumor patients to experience improved communication as well as awareness of environmental sounds. (2) Nontumor patients had better hearing outcomes than tumor patients when the variation in the

auditory benefit with the ABI in relation to the patient's underlying pathological conditions were taken into consideration. (3) A significant number of nontumor patients are able understand speech at a level comparable to that of the most successful cochlear implant users including conversational telephone use. (4) The ABI represents the tool for hearing rehabilitation in patients with profound hearing loss who cannot be fitted with cochlear implants.

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Approximately 400 neurofibromatosis type 2 (NF2) patients have received multichannel auditory brainstem implants (ABIs) worldwide, and obtained a functionally beneficial level of auditory input to assist them with their communication needs. Patients with other diseases involving the cochlear nerve or the cochlea, with a similar disconnection of the central auditory systems from sound, have so far not been considered to be candidates for treatment with an ABI. The cochlear nerve may be congenitally absent, or destroyed due to acquired disorders (e.g. posttraumatic cochlear nerve avulsion) or, the cochlea may be so severely compromised that fitting of a cochlear implant becomes difficult, inappropriate, or even impossible as is the case with cochlear aplasia, and postmeningitis cochlear ossification. In view of the site and the nature of such lesions and the ability of modern ABI devices to provide stimulation directly to the first central auditory station (cochlear nucleus-CN), it is surprising that the indications for the ABI have been limited to tumor patients. Indeed, lack of intervention condemns such individuals to a dramatic inability to communicate. Fear of unsatisfactory auditory results, risk of complications, surgical limitations and ethical reasons were, and probably still are, the reasons for limiting the indication of ABIs to patients with NF2 [1–3]. For a detailed analysis and discussion of these issues, see Colletti et al. [4].

One major reason why the use of ABIs was restricted to patients with NF2 and who had had bilateral vestibular schwannoma removed is probably that the ABI yields poor hearing results, and certainly not comparable to those which can be achieved with cochlear implants. The overall ABI performance in such tumor patients is in fact no better than that achieved by single-channel cochlear implants, whereas multichannel cochlear implants can restore speech understanding to a level where most patients can converse on the telephone. However, in view of the worldwide acceptance of the use of ABI in such patients, it must be assumed that the improvement in communication skills through the use of ABIs in patients with NF2 is not negligible. This is supported by the progressive increase in the number of centers providing ABIs. In Europe, the number of centers that treat NF2 patients with ABIs has increased from 9 in 1998 to 22 in 2005. Absence of a significant improvement in communication skills from ABIs in such patients must have rapidly discouraged its application with a decline of interest in the device.

In this paper we review our recent findings in the use of ABI, and we compare the outcome of psychophysical and speech perception tests in tumor patients with that obtained in nontumor patients. We present evidence that ABIs can provide sufficient stimulation of the central auditory system for open set speech understanding to justify the extension of the indication to patients without tumors.

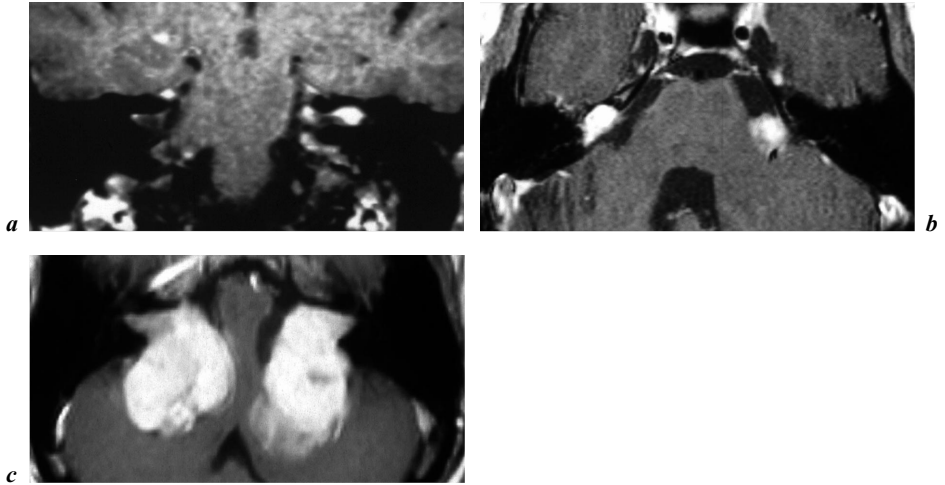
## Methods

### *Patients*

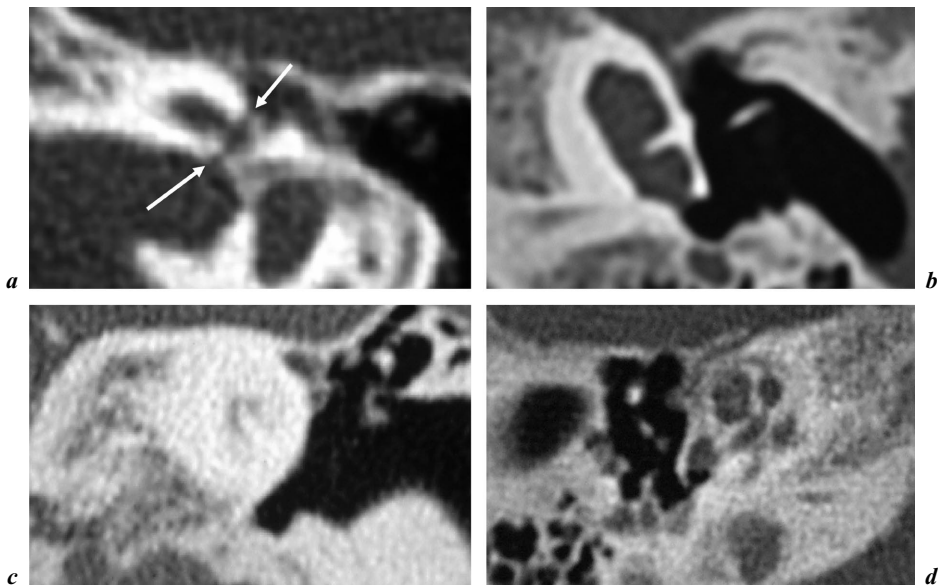
From April 1997 to January 2006 a total of 80 patients (62 adults and 18 children; age range: 14 months to 70 years) were fitted with ABIs in the ENT Department of the University of Verona. These patients were suffering from tumors of the cerebellopontine angle (26 patients) and from a variety of nontumor diseases (54 patients) of the cochlea or cochlear nerve. The retrosigmoid-transmeatal approach was used in tumor patients and the retrosigmoid approach in all nontumor patients. Seventy patients (16 tumor and 54 nontumor) were fitted with a Nucleus 24 Cochlear ABI (Cochlear Co., Lane Cove, Australia), 6 tumor patients were fitted with a Nucleus 21 Cochlear ABI (Cochlear Co.); 1 nontumor and 3 tumor patients received a Med-El Pulsar ci100 ABI (Med-El Co., Innsbruck, Austria).

Twenty-six patients, 20 adults and 2 children, had NF2 with bilateral vestibular schwannoma removed, and 4 adults had solitary unilateral vestibular schwannoma in the only hearing ear. Ten children had bilateral cochlear nerve aplasia; four with associated cochlear malformations, two with associated unilateral facial nerve agenesis and 1 with combined microtia and aural atresia. Two of these children had been fitted with a cochlear implant elsewhere. Two adults and 3 children presented with cochlear malformations. One child, who had previously been fitted unsuccessfully with a cochlear implant, and 2 adults had auditory neuropathy. One child and 29 adults showed bilaterally altered cochlear patency: 17 patients had complete bilateral cochlear ossification, and 13 patients presented with cochlear derangement of the turns caused by meningitis (7), otosclerosis (15), or autoimmune disease (8). Four adults of this group had not received any benefit from a previously fitted cochlear implant. Six patients, 5 adults and 1 child, had profound hearing loss after head trauma with different degrees of cochlear fractures. For a detailed description of the patient population, see Colletti et al. [4–8].

To investigate differences in performances between tumor and nontumor patients, 39 adult ABI patients (25 nontumor and 14 patients with NF2 who had had bilateral vestibular schwannoma removed), were selected for a series of psychophysical tests. These patients were operated upon consecutively from May 1999 to April 2004. The sizes of the tumors ranged from 4 to 52 mm: 4 tumors were judged to be small, 5 medium and 5 large (fig. 1). The 25 nontumor patients had different types of diseases; 4 patients had bilateral labyrinthine fractures (fig. 2a), 1 had a bilateral temporal bone fracture, 2 had cochlear malformations characterized by incomplete cochlear partition (type II or Mondini malformations; fig. 2b), 18 had different alteration of the cochlear patency, 10 had complete bilateral cochlear ossification (fig. 2c) and 8 presented with cochlear derangement of the turns (fig. 2d) due to meningitis (3 patients), otosclerosis (2) and autoimmune diseases (3). Two of these patients had been previously fitted with a cochlear implant elsewhere.



**Fig. 1.** Encephalic MRIs with gadolinium enhancement showing CPA tumors of different sizes. *a* Small tumors in coronal view. *b* Medium tumors in axial plane. *c* Large tumors in axial plane; the large bilateral tumors compress the brainstem.



**Fig. 2.** *a* A transverse fracture line (arrows) involving the cochlea is visible on CT scan in axial view. *b* CT scan shows in coronal view an incomplete cochlear partition (type II or Mondini malformation). *c* A left complete cochlear ossification (T.L.; for details, see text) is evident on CT scan (coronal view). *d* CT scan (coronal view) shows a cochlear derangement.

Approval of the study was obtained from the ethical Committee of the University of Verona Hospital, and the patients gave informed consent for the implantation and the subsequent studies.

The auditory performances of the patients that were selected for this study were comparable with those obtained in the remaining ABI population for both tumor and nontumor patients. Average open-set sentence recognition score in the auditory only mode obtained 1 year after implantation was 6% in the tested tumor group, 11% in the remaining tumor patients ( $p = \text{n.s.}$ ), 46% in the tested nontumor group, and 59% in the remaining nontumor patients ( $p = \text{n.s.}$ ).

#### *Description of the ABI Devices*

A Nucleus 21 Cochlear ABI was used in the first 6 patients who received implants. It was based on the Nucleus 22-channel Cochlear Implant System. It had a silicone elastomer electrode carrier 8.5 mm long, 3.0 mm wide and 0.6 mm thick. Twenty-one platinum disk electrodes, 0.7 mm in diameter, arranged in three diagonally offset rows were on one face of this carrier. The electrodes were connected to a Nucleus cochlear implant 22 M\* receiver-stimulator by a silicone elastomer lead 1.2 mm in diameter and 11 cm long containing 21 individually insulated, helically wound, 25- $\mu\text{m}$  platinum/iridium (90/10%) wires. A special narrow-weave mesh cut into the shape of the letter T was attached to the rear surface of the carrier with the aim to promote fibrous tissue growth helping and fixing the array in situ. It had one reference electrode. The receiver/stimulator was identical to the Nucleus 22 M cochlear implant with a single monopolar plate electrode added to the top surface electronics capsule. A Spectra 22 speech processor controlled the stimulation [9]. The Nucleus 24 cochlear ABI is based on the nucleus 24 M cochlear implant systems.

The Nucleus 24 cochlear ABI has been used since 1999 and differs from the Nucleus 22 ABI in its possibility to use different stimulation strategies, and to utilize the neural response telemetry for performing intraoperative electrical monitoring of the neural interface, and the possibility of removing the magnet from the internal receiver/stimulator of the device.

The use of the neural response telemetry that provides a near-field monitoring of evoked potentials from the cochlear nucleus might be useful in verifying the correct positioning of the ABI in the lateral recess and to define the stimulus level to be used at ABI activation. This should be particularly advantageous in children.

The Nucleus 24 cochlear ABI has speech processing strategies such as continuous interleaved sampling and advanced combination encoder (ACE), see Introduction and the paper by Loizou [this vol, pp 109–143]. The impulses that are delivered to the implanted electrodes with the SPEAK strategy have a modest rate of 250–300 pulses/s (pps). The number and location of the electrodes to be stimulated are selected based on the intensity and frequency of the incoming signal. The continuous interleaved sampling strategy employs a high fixed rate of stimulation (600–1,800 pps) delivered to a small number of channels. The ACE strategy combines the advantages of both the SPEAK and cochlear implant strategies. It has a high rate of stimulation (600–1,800 pps), a large dynamic electrode selection and numerous available electrodes, improving the transmission of temporal and spectral speech information. For further discussion of processor strategies, see Introduction and the paper by Loizou [this vol, pp 109–143].

The electrode array of the Nucleus 24 cochlear ABI device has a flat silicone carrier ( $3 \times 8$  mm), where the 21 platinum electrodes are arranged in 3 rows and 3 electrodes as reference. The individual electrode diameter is 0.7 mm. A T-shaped Dacron mesh is attached

to the electrode carrier to stabilize the device intraoperatively and to permit tissue growth for further postoperative stabilization.

Implantable portions of the Med-El Pulsar ci100 ABI consist of a processor with a stimulus generator, the active electrode array, and the reference electrode. The stimulator measures approximately  $3.5 \times 2.4$  cm and is less than 0.4 mm thick. All electronic components are contained in a compact ceramic case. It consists of the implant circuitry and a powerful microchip that is encapsulated in the hermetically sealed ceramic housing. The implant housing and electronics of the ABI are identical to those of the C40+ cochlear implant (Med-El Co.). The ABI can process large amounts of data and it can provide updated information in each pulse at a high rate of up to 18,180 pps. This capability makes the stimulator compatible with a wide range of pulsatile coding strategies for future developments in speech processing. Telemetry features enable device function to be analyzed within seconds. Telemetry can assist in confirming the correct functioning of the implant and provide additional information that may be useful for programming the external speech processor. Information provided by telemetry includes impedances of the individual electrodes, ground path impedance, electrode status, voltage distribution, identification of short-circuits, and overall implant integrity.

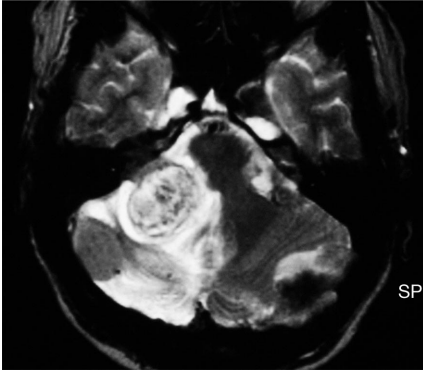
The implanted electrode array of the Med-El Pulsar ci100 ABI consists of 12 active platinum contacts that are partially embedded in a flat oval-shaped silicone paddle. Soft and pre-shaped, the paddle is designed to fit onto the curved surface of the floor of the lateral recess of the brainstem. A polyester mesh embedded in silicone exceeds the size of the paddle, allowing tissue growth that will stabilize the electrode array onto the surface of the brainstem, thus minimizing the possibility of electrode movement or migration. The diameter of the electrode lead increases from 0.7 mm at the silicone paddle to 1.3 mm over a length of 10 mm.

## **Postoperative Procedures**

Patients were followed postoperatively in the intensive care unit and returned to the ENT Department the day after the operation. CT scans were performed to evaluate electrode placement before discharge. Imaging showed the ABI in the proper position and no displacement occurred in any of the patients. On average, patients were hospitalized for 6 days after implantation. The ABIs were activated approximately 4–6 weeks after implantation. Because of the possible risks involved in stimulating brainstem structures, activation was done in the intensive care unit with electrocardiographic monitoring and with an anesthesiologist present.

### *Complications and Unwanted Effects of Stimulation*

No complications were observed during the operation or on activation or during long-term use of the ABI in any of the patients who received implants. One patient (H.K.) who had extensive brainstem compression from multiple tumors (fig. 3), reported no auditory sensations, while other patients had



*Fig. 3.* Gadolinium-enhanced encephalic MRI demonstrating in the axial plane multiple tumors in the only patient (H.K.) with no auditory sensation at ABI activation. Extensive compression and displacement of the brainstem are evident.

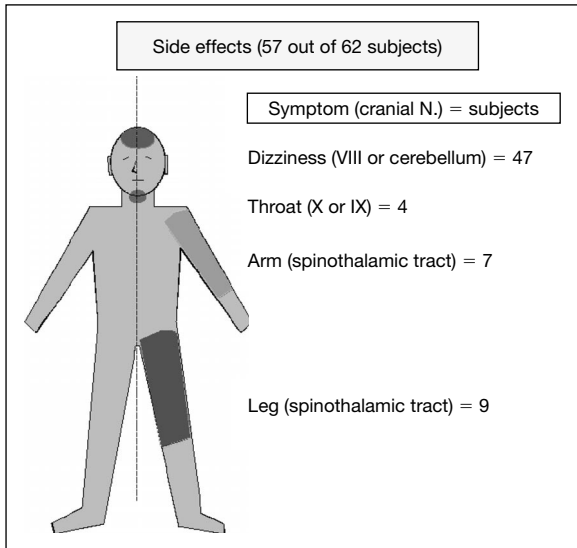
auditory sensations for activation of 5–21 electrodes. The number of electrodes the activation of which induced nonauditory sensations varied from 1 to 8 among the patients. These electrodes were inactivated. Side effects were noted in 57 of 62 patients. The most common side effect was transitory dizziness that occurred in 47 patients. Tingling sensations in the leg, arm and throat were reported by 9, 7 and 4 patients, respectively (fig. 4). No contralateral side effects were observed. These nonauditory sensations often decreased in magnitude over time, and in 9 patients the electrodes that initially were associated with such side effects could be reactivated at a later session.

#### *Results at the Time of Activation of the ABI*

At activation, all patients except one (H.K.) could detect and recognize environmental sounds. Activation of different electrodes elicited different pitch sensations. A substantial variability of perceptual performance was characteristic for the group of patients we studied. This was true of all the different tests performed (closed-set vowel and consonant confusion test, closed-set word recognition, open-set sentence recognition and speech-tracking responses in the auditory mode alone and in the visual-auditory mode). These observations in ABI users are thus similar to the experience of cochlear implants where the results also vary greatly between individuals without the reason being known (see Introduction).

#### *Processor Fitting and Programming*

The protocol used for the activation and testing of the ABI and the evaluation of the auditory results differed between adults and children and has been detailed



**Fig. 4.** Location and incidence of nonauditory side effects after ABI activation. For description, see text.

elsewhere [4–5]. Briefly, the threshold level and maximum comfortable levels of each electrode were first assessed to select the optimal electrode configuration. The monopolar mode was initially utilized to identify the electrodes that elicit auditory sensations. Electrodes that induce unpleasant sounds or nonauditory effects were excluded from future use. To determine an ABI recipient’s perception of pitch and to define the appropriate tonotopic order of the electrodes, the place-pitch scaling and ranking procedures [4–5] were used. The processor was then programmed according to the pitch scaling and ranking results were obtained. On average, for the first 6 months from activation, the SPEAK encoder strategy was applied in all patients using the Investigational Protocol for the Clinical Trial of the Multichannel Auditory Brainstem Implant [10]. When the patients reach an auditory performance level without any improvement for 3 months, i.e. a ‘plateau phase’, the ACE strategy is utilized. ACE processors have higher stimulation rates, which allows better spectral and temporal resolution of speech signals and improvement in open-set speech recognition scores within a short period of time [11].

### *Follow-Up Tests*

Patients were followed regularly for assessment of the efficacy and safety of their implants. Patients returned to our center for medical follow-up at 1 month,