
RESEARCH NOTES

ISSUES IN COCHLEAR PROSTHETICS FROM AN INTERNATIONAL SURVEY OF OPINIONS

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Abstract

Cochlear prostheses are beginning to be implanted regularly to restore hearing in profoundly deaf patients, but there is little agreement on the relative merits of the many different designs and rehabilitative procedures. We report on the responses to a technology assessment questionnaire that was sent to 120 researchers and clinicians worldwide who have been at the forefront of research in this field.

Most patients with profound sensorineural deafness (no useful hearing) have lost the hair cells that transduce acoustic vibrations into electrical activity in the auditory nerve. A cochlear prosthesis uses a surgically implanted electrode to excite the remaining auditory nerve fibers electrically according to a speech processing algorithm that is driven by the signals picked up by an external microphone, thus inducing sensations of sound in the patient. For reviews of the technology, see Banfai (1) and Loeb (10).

After 25 years of active basic and applied research, cochlear prostheses are starting to attract widespread interest from both clinicians and the medical device industry. The rate of implantation is rising rapidly throughout the world as clinical centers acquire the necessary technical and clinical experience to handle the sophisticated technology involved in screening, implanting, fitting, and rehabilitation. However, the many parallel but independent development efforts around the world have resulted in a great variety of device designs (Table 1) and clinical protocols. Attempts to compare results across devices in standardized test protocols (2;7) have been hampered by the large variability among patients with respect to their inner-ear pathology (8) and cognitive abilities. Thus, as with many emerging medical technologies, it seems likely that the practices of individual clinicians and the policies of health care agencies will continue to be driven by informally perceived consensus rather than by definitive studies.

This survey was designed to facilitate the consensus process by soliciting frank opinions from those researchers and clinicians with the most experience in this area, using a forum where their anonymity was ensured.

METHOD

In early 1989, a technology assessment questionnaire was mailed to 120 leading researchers and clinicians who had been working and publishing for at least several years

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Table 1. Cochlear Prostheses

Device name	P.I./institute/city	Manufacturer/city	First desc.	Est. no. implants	Approx. cost (US \$)	Availability ^a	Electrode		Stimulus		Coupling ^f
							Contacts ^b	Depth (mm) ^a	Channels ^d	Waveform ^e	
—	Djourno/Eyries/Paris	—	1957	1	—	Never	1	M	1	Pulse	Perc.
—	Doyle/Univ. Southern California/Los Angeles	—	1964	1	—	Never	1	?	1	AM	Trans.
—	Simmons/Stanford/Calif.	—	1966	4	—	Superseded	8	M	8	Pulse	Trans.
Bioear	Simmons, White/Stanford	Biostim/Brooksville, FL	1984	7	4,500	Defunct	1	X-3	1	Analog or pulse	Trans.
UCSF	Michelson/Univ. California/San Francisco	—	1971	5	—	Superseded	2	15	1	Analog	Trans.
UCSF-Storz	Merzenich, Schindler/UCSF	Storz/St. Louis, MO	1984	18	12,000	Withdrawn	16	24	4	Analog	Trans.
Clarion	Schindler, Merzenich/UCSF + Wilson/Research Triangle/Durham, NC	Minimed/Sylmar, CA	1988	0	13,000	R&D	16	24	8	Analog	Trans.
3M-House	House/House Hearing Inst./Los Angeles	3M Corp./St. Paul, MN	1973	3,000	6,500	Withdrawn	1	6	1	AM or pulse	Trans.
Chorimac	Chouard/CHU Saint-Antoine/Paris	Bertin/Paris	1973	150	9,000	Superseded	8, 12	0-3 ^g	8,12	Analog	Trans.
Monomac	Chouard/CHU Saint-Antoine/Paris	Bertin/Paris	1987	?	?	Local	1	X-10	1	Pulse	Trans.
Minimac	Chouard/CHU Saint-Antoine/Paris	Bertin/Paris	1988	?	?	Local	15	? ^h	15	Pulse	Trans.
EPI	Douek, Fourcin/Guy's Hosp./London	—	1978	9	?	Local	1	X	1	Pulse	Ext.
UCH-RNID	Fraser/Univ. College Hosp./London	Fine Tech./London	1988	45	1,100	Local	1	X	1	Analog	Ext.
Vienna	Hochmair/Innsbruck	—	1978	70	?	Local	8	14	1	Analog	Trans.
3M-Vienna	Burian/Hochmair/Tech. Univ./Vienna	3M Corp./St. Paul, MN	1978	80	9,500	Withdrawn	1	X	1	Analog	Trans.
Implex	Banfai, Hortmann/Cologne-Duren Group	Hortmann, GmbH/Cologne	1978	100	6,000	Europe superseded	1, 4, 8	X	1, 4, 8	Analog	Perc./trans.

Exco-16	Banfai, Hortmann/ Cologne-Duren Group	Hortmann, GmbH/ Cologne	1985	60	?	Europe	16	X	16	Pulse	Perc./ trans.
Ineraid	Eddington/Univ. Utah/ Salt Lake City	Symbion/Salt Lake City, UT	1980	100+	11,000	IDE	6	22	4	Analog	Perc.
Nucleus	Clark/Univ. Melbourne	Cochlear-Nucleus/ Sydney	1980	1,500	12,200	PMA	22	25	2/21	Pulse	Trans.
—	Dillier, Spillman/ Universitatsspital/Zurich	—	1982	10	?	Local	1	X	1	Pulse	Trans.
MSR-UCL	Gersdorff, Sneppe/Catholic Univ. Leuven/Brussels	Siemens	1985	9	?	Local	1, 2	X-5	1, 2	Analog	Trans.
Laura	Marquet Peeters/Univ. Instelling/Antwerp	Forelec/Antwerp	1988	2	?	R&D	16	18	8, 16	Analog or pulse	Trans.
Prelco	Cazals/INSERM/Bordeaux	Racia/Bordeaux	1985	23	2,000	Local	1	X	1	Analog	Trans.
Medtronic	Frayse/Toulouse	—	—	17	?	Local	1	X-2	1	Pulse	Trans.
—	Gerhardt/Humboldt Univ./Berlin	—	1987	10	?	Local	2	X	2	Analog	Trans.
Omina	Bosch/Hosp. de la Cruz Roja/Barcelona	—	—	12	?	Local	1, 6, 8	?	1, 6, 8	?	?
ECME	Bochanek/Acad. Med./ Warsaw	—	—	3	?	Local	1	X	1	?	?
—	Valvoda, Tichy/Acad. Science/Prague	—	1988	3	?	Local	1	X	1	Analog	Trans.

^a U.S. Food and Drug Administration designations: IDE = investigational implants only at approved centers; PMA = approved for marketing to licensed practitioners.

^b Number of electrically separate, active contacts, excluding reference or ground.

^c M = directly in auditory nerve in modiolus; X = extracochlear.

^d Number of channels commonly activated in parallel; nucleus device sweeps 2 output channels among 21 bipolar sites.

^e Analog = band-pass filtered acoustic signal; pulse = brief stimuli, usually at F_0 rate, amplitude-modulated by acoustic envelope; AM = unrectified carrier modulated by acoustic signal.

^f Perc. = percutaneous plug; trans. = transcutaneous inductive coupling; ext. = exteriorized, removable appliance.

^g Electrodes inserted through individual fenestrations in the lateral wall of the cochlea.

^h In Scala tympani via round window.

Source: Adapted from review by Loeb (10). For references, see Loeb (10).

in the field of cochlear prosthetics. We solicited opinions on the present status of the field, the potential for application of cochlear prostheses beyond profoundly deaf adults (including prelingually deaf children), and the obstacles that exist to this expansion. Questionnaires were numerically encoded to ensure confidentiality and anonymity during the review process. Sixty-one of the 120 questionnaires mailed were returned (most with detailed comments). Of these, 7 were incomplete, leaving 54 useful responses. Numbers given below in brackets indicate the number of respondents for each comment.

RESULTS AND DISCUSSION

Respondents' Backgrounds

Respondents were distributed among the following disciplines in relatively equal proportions: otology, audiology, biomedical engineering, and neurophysiology and psychophysics. The majority had been acquainted with the field of cochlear prosthetics for 6-18 years. Greater than 60% cited personal research activities, scientific literature and colloquia, and/or clinical experience as their major sources of information. At least 40% of the respondents were well acquainted with at least one of the following devices: Melbourne-Nucleus/Cochlear (5), House-3M (6), Vienna-3M (3), Utah-Symbion (15), and/or UCSF-Storz (17). Except as noted below, respondents from each field had a similar distribution of opinions.

Issues of Clinical Acceptance. The following items were ordered by the respondents according to their importance for clinical acceptance: speech processor design [38], transmitter/receiver/stimulator design [33], electrode design [26], cost reimbursement [19], diagnostic/prognostic screening [17], and clinical fitting procedures [17]. Physiologists and engineers gave priority to device issues, in keeping with their fields; similarly, audiologists ranked clinical issues more highly. Otologists and engineers were least concerned with costs. Some ranked these criteria from the client's perspective as efficacy, cost, fitting time, design with respect to cosmetics, and, last, screening.

The criterion for clinical acceptance most commonly written in under "Other" was efficacy (speech perception). Other priority issues listed were cosmetic considerations such as size and absence of a percutaneous plug, and rehabilitation, with a need for the development of in-home training equipment.

Barriers to Wider Application. Two-thirds [34] of the respondents listed economics, that is, insufficient third-party coverage [6] for devices that are costly [4] due to the limited market size, as one of the main barriers to the widespread clinical application of cochlear prostheses. The lack of measurable prognostic determinants, such as nerve survival [6], was seen by some to compound the problem of limited efficacy of the device [16] (which limits the population of candidates to those with less residual hearing than the worst possible prosthetic performance). Educational barriers [22] include inadequate auditory rehabilitation facilities [6] and unaware or overzealous clinicians [7]. The major political barriers noted were resistance from the deaf community [9], and professional prejudice on the part of administrators and educators [3], some of whom were perceived as spreading misinformation and negatively influencing policy, funding, and regulatory agencies. While some otologists and audiologists [4] felt that restrictive selection criteria were needlessly limiting access, concern was expressed that cochlear implantations should be conducted only by dedicated implant teams and not by individual entrepreneurs.

Therapy: Quantity, Quality, and Limits. Most implant recipients have expectations for improvement beyond the "hard-of-hearing" level, a common performance

plateau with the current generation of devices. Thus, counseling is important so that the enthusiasm of patients (or their parents) is tempered by realistic expectations [10] and adequate psychological support [5]. The extent of therapy required beyond the initial fitting apparently varies greatly among individual patients (adult vs. child or postlingual vs. prelingual) [3] and devices [3]; while proficient users of the better devices have required less training [4], it is a matter of debate whether extensive training would enable those who do poorly to improve, or only to attain their ultimate performance level more rapidly [6]. The relationship between auditory training and patient performance has not been studied formally [3]. While prognostic measures might advise clinicians regarding the optimal duration of formal therapy, in practice this is now limited mostly by the patient's perception of benefit [3]. Excessive therapy requirements could increase patient costs and ultimately discourage interest in cochlear prostheses [3], which would be unfortunate considering the relatively greater burden of poor performance [3]. Costs could be reduced through the use of home training (such as the House Ear Institute Home Program for Children with Cochlear Implants) [9], or for children, recouped eventually through educational mainstreaming. Although opinions varied regarding the ideal structure for training programs, it was agreed that therapeutic regimens ought to focus on auditory training [4], accurate speech recognition and audio-visual integration [6], improved confusion-matrix performance [2], and speech correction. It was felt that such training should be provided to prelingually deaf children by the schools for the hearing impaired [3]. There is a general shortage of trained personnel, which might be partially alleviated by self-administered test materials [3].

Beyond the Profoundly Deaf. Whether the respondents were optimistic [23], detachedly factual [16], or pessimistic [12] regarding implant use in the moderately deaf, all listed the same obstacles. The greatest hindrance to the use of cochlear implants in the severely or moderately deaf populations is the lack of a guarantee of sufficient efficacy in a given patient [12]. While overall efficacy is expected to continue to increase through improved coding and electrode design [6], results for individuals remain quite variable and unpredictable [7]. It may be difficult to compete against improved (digital) hearing aids [12], which present no surgical risk. (Nucleus was reported to have begun a study of efficacy in moderately deaf patients.) While hair cells in the vicinity of a cochlear electrode are invariably destroyed, in one study, patients implanted with a short, single-channel intracochlear electrode did not lose their residual (presumably apical) hearing [16]; thus, implantation related losses of useful residual hearing may be less than feared [14], and such residual hearing may indicate good nerve survival and a better prognosis for the prosthesis. To avoid permanent damage while providing useful stimuli, a number of European groups have favored the use of extracochlear devices. It was claimed that a synergistic fusion of signals has been noted when a hearing aid in one ear (for low frequencies) is combined with an implant in the other (to restore high-frequency perception) [4]. The effort required by a hearing-aid user to adjust to a new type of perceptual distortion will be the greatest obstacle to overcome, even if the implant produces greater speech discrimination alone or in combination with a hearing aid [4]. The greater cost of a cochlear implant compared to a hearing aid would affect many of such patients' choices [6].

The Prelingually Deaf and Children. A few respondents were pessimistic [5] and many noncommittal about prospects for the prelingually deaf, but half [23] were frankly optimistic, suggesting that prelingually deaf children may ultimately obtain the greatest benefit from this technology. (The prognosis is poorer for prelingually deafened adults, who will require more training than their postlingually deafened counterparts (5).) However, important research questions remain regarding the possibility

of learning auditory processing after the developmental period for language acquisition (about age 4 (4)), the appropriateness of existing coding strategies for children, and the extent of central nervous system (CNS) plasticity (9). Long-term, well-controlled, and limited clinical trials seem necessary [10]. Sound awareness from early stimulation should enhance learning of aural and oral skills [6], aiding patient integration into hearing society, and preventing entrapment in the deaf community. Extracochlear stimulation may prevent atrophy of spiral ganglion neurons and central pathways (11;18), preserving them for later intracochlear stimulation.

Certain clinical issues must be addressed if prelingual pediatric implantation is to achieve the status of an accepted therapy, as it is now for adults. Cochlear prostheses must be shown to provide more than minimal sound awareness [12]. While the ultimate measure of efficacy is speech recognition, intermediate evaluative criteria need to be developed, because the present language-dependent measures are inappropriate in very young patients. Audiologists emphasized the need for prognostic measurement techniques, possibly based on cochlear patency and nerve survival and distribution. Regarding pediatric candidates, critical ethical conflicts arise from the need for diagnostic surety (which requires time-consuming trials to prove nonbenefit from both hearing and tactile aids [9]), the desire to implant before age 4 [11] and safety concerns related to bone changes (14), the effects of chronic electrical stimulation on a developing nervous system, the frequency of otitis media in young children [9], and the effects of reimplantation, all of which will require much study [7].

The greatest resistance could prove to be sociopolitical, as attempts to remove deaf children from the closely knit deaf community could raise a strong emotional response [6]. Only with the interest, acceptance, and involvement of parents, teachers, related professionals, and institutions for the deaf [24] can the necessary intensive aural and oral rehabilitation techniques be developed and implemented [9]. For example, sign language training provides essential language skills, such that learning to use an implant becomes similar to acquiring a second language (4). Such cooperation would lessen the economic impact of implant related programs on both private and governmental agencies and families [6].

Are Intracochlear Devices Sufficient? Most respondents believed that, with device refinements including stimulation of more apical neurons, improved VIIIth nerve coding [3], electrodes matched to the patient's nerve survival pattern [2], and improved signal-to-noise ratios, the present intracochlear strategy would be sufficient for at least 75% of the deaf patient population [35,8]. While some felt CNS stimulating prostheses (for either the ventral cochlear nucleus or the cerebral cortex) would eventually replace cochlear devices [8], all who favored their development [20] considered it as potentially the only means of restoring functional hearing in the 25% of the severely hearing impaired with poor nerve survival or true nerve deafness from causes such as otosclerosis or meningitis. However, extensive research into the functional organization of the cochlear nuclei and the auditory cortex will be required [8]. Those objecting to the idea of central stimulation [20] cited safety [2] and the view that auditory cognition depends both on central processing and primary processing by the periphery [3], presaging even greater coding problems in central structures that might be less able to adapt to unusual activity patterns than the periphery [4].

SUMMARY AND CONCLUSIONS

While the development of multichannel devices and various new speech processing algorithms have been major advances, expansion of the potential patient population

from the profoundly deaf to the severely deaf should not be expected until the efficacy of cochlear implants for functional hearing (as demonstrated by speech tracking and performance on vowel and consonant confusion tests) can be guaranteed to exceed that of hearing aids. Variations in patient performance are thought to be dependent on variations in nerve survival. Thus, the development of prognostic assessment techniques is essential for determining the best processing strategy, the speech cues to be presented, and patient suitability for implantation. Selection protocols could be modified to include those severely deaf patients who have measurable audiometric responses but no usable hearing, which is considered to be a sign of good nerve survival. Costs for the device and rehabilitation may severely limit enthusiasm for this therapy, especially in the absence of third-party coverage. Rehabilitation requirements and their associated costs might be decreased if device refinements result in enhanced speech perception performance from the outset.

Some special considerations must apply to the application of cochlear prostheses to the prelingually deaf, especially children. In addition to good prognostics, the degree of impairment must be assessed accurately, lest useful hearing be lost iatrogenically. More intensive, and thus expensive, rehabilitation is required to develop oral and aural language skills. Much research will be required to determine the salient vocal cues, effective coding strategies, and the optimal implantation age while minimizing the associated risks from surgery, infection, and bone growth. Resistance from the deaf community must be addressed by sympathetic dialogue and education.

While the present cochlear implants appear sufficient to restore useful hearing in the majority of profoundly deaf patients, some patients may require stimulation of the auditory nuclei, an approach that is presently in the early research stage (12;13).

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