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## Cochlear Implants in China

### Key Words

Cochlear implant

Deafness

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### Abstract

China has approximately 6 million totally deaf people according to an official survey conducted in 1990, although the actual number is probably higher. A primary cause of deafness is the use of ototoxic drugs. There does not appear to be any emergent deaf culture in China at present. As the only available medical device that can restore partial hearing to a totally deaf person, the cochlear implant has been in development in China since 1979. This paper provides an overview of cochlear implants in China and is based on a review of published materials, visits to research institutes and hospitals, and personal communication with Chinese colleagues. As of 1993, about 1 000 deaf people, including 50 children below age 12 years, have received four types of single-electrode cochlear implants that were developed and fabricated by institutions in China. These single-electrode devices have provided an aid to lip reading, but are no longer in use due to their inability to produce open-set speech recognition. Present implant research in China focuses on development of multi-electrode devices. Basic research in electrical stimulation is relatively lacking and standardized audiological evaluation for cochlear implant effectiveness needs to be developed. The present economic growth and legal system reform in China, combined with advances in implant technology, may make it possible to produce an affordable yet effective cochlear implant system. This paper discusses cochlear implants only in China, but the social and economic factors are similar in many developing countries in Asia, South America, Eastern Europe, and Africa, where a low-cost, high-performance cochlear implant system is also needed.

The cochlear implant is the most advanced neural prosthesis. About 10000 deaf people have benefited from the use of the cochlear implant in daily life since its introduction in the 1960s. Technological complexity has also increased from single-electrode to multi-electrode implant systems and from simple filtering to sophisticated processing circuits extracting speech features. This complexity has resulted in a high-cost device that is not affordable for most deaf people in developing countries such as China.

In an attempt to modernize implant research and develop a low-cost, high-performance implant system in China, the author and professor Ming-Min Dong of Henan Medical University organized the 1993 Zhengzhou International Symposium on Cochlear Implants and Linguistics. A group of leading researchers from the United States, Canada and Australia went to China to give lectures on state-of-the-art research and applications of cochlear implants and to learn first-hand information on the status of implant research from Chinese colleagues. This interaction was fruitful in that a consensus was reached among the participants in regard to the design of a low-cost, high-performance cochlear implant system [1]. The proposed design takes advantage of recent advances in the theory and implementation of representing speech temporal cues [2-4]. The device includes a CIS-type speech processor [3], four channels of passive transcutaneous coils, and an electrode array with four monopolar electrodes.

Much has been learned about other important issues such as deafness, cochlear implant research and development, audiology, and regulations governing manufacture and distribution of medical devices in China. This paper summarizes these issues and is based on a review of published materials, visits to research institutes and hospitals, and personal

communication with Chinese colleagues. The general information on these issues is relatively unknown to the West and may be considered representational of the situation in other third-world countries.

## Deafness in China

It has been generally assumed that China, a country of 1.2 billion people, has the largest deaf population in the world, but accurate statistics were not available until recently. The 1990 official survey of the handicapped [*People's Daily*, October 20, 1990] reported that there are 23.09 million hearing-impaired people (40 dB or more in the better ear)<sup>1</sup>; among which 6 million are totally deaf adults and 3 million are deaf children. About 30000 new deaf children are expected each year with the primary cause of their deafness being the use of ototoxic drugs.

The sense of deaf culture does not seem to be strong, if existing at all, in China. The lack of deaf culture in China may be due to the following three reasons: (1) the majority of deaf Chinese people live in a hearing community – hearing neighbors, hearing parents and, most likely, hearing children; (2) signs used by deaf Chinese are not as fully developed as American Sign Language and are not uniformly recognized as a language; (3) deaf people are generally in adverse economic conditions and about two thirds of them rely on financial support from government, parents and relatives. The general public opinion in China is that deafness is a handicap and should be treated if

<sup>1</sup> For comparison, the estimate of hearing problems in the United States is about 20.99 million people or 8% of the total population [5]. The number of hearing-impaired people is likely underestimated in China; the actual number is probably at least four times greater [Wang, H.: How many are handicapped? *China Daily*, January 7, 1988].

possible. The treatment of deafness is thus the main goal for more than 300 deaf children's schools and 30 hearing-speech rehabilitation centers in China. These schools and centers are run by the National Civil Department and the Chinese Association of Handicapped Persons<sup>2</sup> and are located exclusively in metropolitan areas, even though the majority of deaf children live in the countryside. The facilities, except for a few model schools, are inadequate. The teachers in these schools and centers are usually graduates majoring in children's education and have no training in audiology and speech pathology, as these two specialties do not exist in China [for a thorough review of audiology in China, see Tyler and He, 6]. After 8–10 years of training with a combination of signing and oral approaches (though recently, oral communication has been emphasized), most graduates of these schools can read and write adequately but cannot speak intelligibly. Overall, about 80% of deaf children are not able to go to standard or deaf children's schools and 40% of the handicapped including the deaf are unemployed [Chen, Z.: Raise the level of social awareness of caring for the handicapped. *Overseas Chinese Newspaper*, September 22, 1994].

Recent economic growth in China has helped deaf people improve their employment opportunities and quality of life. During our 1993 trip to China, we encountered deaf people running printing shops, garment factories and other small businesses. This level of success by deaf people was unheard of and virtually impossible 10 years ago. A recent development is a newspaper published by the Chinese Association of Handicapped Persons

that is specifically devoted to deaf issues. TTY's (Text Telephones) are not yet available in China, but the availability of beepers with Chinese display has eased the problem deaf people encounter using telecommunication. Before the beeper era, two deaf persons who wanted to communicate over a certain distance had to either use help from two hearing people or hire someone to deliver a message personally.

However, deafness remains an obstacle for many deaf people wishing to achieve higher levels of success. An affordable but effective cochlear implant would certainly help them improve their business opportunities and quality of life. When raising the question of how much is affordable, different answers were offered depending on whom was asked. At the present time in China, some deaf people can afford the present price of a multichannel cochlear implant (about US \$15 000), but the majority cannot. Physicians from big cities such as Beijing, Shanghai, and Guangzhou think that their deaf patients can afford a US \$2 000–3 000 device, whereas physicians from smaller cities and rural areas think that US \$400–500 is a more reasonable price. To put these prices into perspective, the average yearly income for most working people in China is about US \$500 and the present Chinese-manufactured single-electrode cochlear implant costs about US \$100.

## **Cochlear Implant Development in China**

### *Single-Electrode Systems*

Cochlear implant research in China started in 1979 at Peking Union Medical College (PUMC) with experiments in cats to study biocompatibility of implant materials, electrical stimulation of the auditory nerve and the surgical approach of implantation [7, 8].

<sup>2</sup> Deng Pu-Fang, the eldest son of China's leader Deng Xiaoping, heads this organization which was established in 1988. His legs were paralyzed because of an injury suffered during the 1966–76 cultural revolution.

**Table 1.** Single-electrode cochlear implants in China

Institute	Year	Implant	Surgery	Cases (M/F)	Comments
Peking Union	1982	percutaneous	postauricular	17	15 infected
Peking Union	1988	Peking Transc.	tympanic	32 (24/8)	no infection
Hebi Hospital	1993	Peking Transc.	tympanic	85 (72/13)	80 ototoxic cases
Fujian Hospital	1993	Peking Transc.	tympanic	4	3 daily users
SMU	1987	Shanghai Transc.	facial recess	34 (19/15)	25 postlingual
Xi'an Hospital	1989	Shanghai Transc.	facial recess	50 (32/18)	30 prelingual
Air Force	1993	Xi'an Transc.	facial recess	103	adults
Air Force	1993	Xi'an Transc.	facial recess	50 (31/19)	children (6–12 yr.)
Tianjing	1986	promontory	N/A	4	mid. ear infection
Taiwan	1988	3M/House	facial recess	3 (0/3)	
Total				382	

M/F = Male vs. female; Peking Transc. = Peking Union Medical College transcutaneous device; Shanghai Transc. = Shanghai Medical University transcutaneous device; Xi'an Transc. = Lanzhou Air Force Hospital and Xi'an transcutaneous device.

Since 1980, four different groups in China have independently developed single-electrode cochlear implant systems (table 1). In 1980, researchers at Peking Union Medical College designed a percutaneous, single-electrode cochlear implant and reported 17 cases of implantation [9, 10]. However, 15 out of the 17 percutaneous devices had to be removed within 4 years of implantation due to serious local infection [11]. From 1983 to 1987, a transcutaneous version of the Peking single-electrode device was developed and 32 deaf adults (27 postlingual) received the device [8, 12]. Follow-up of these patients in 1993 showed that none of them had infection problems and the longest user has been implanted for 9 years [11]. Another 4 cases reported by Chen et al. [13] from Nanping City Hospital, Fujian and 85 cases by Zhai [14] from Hebi Hospital, Henan, all used the Peking devices. In total, about 300 deaf adults have received the Peking single-electrode device [Cao, pers. commun.]

Another transcutaneous, single-electrode cochlear implant was developed in 1987 by researchers at the Eye and Ear, Nose, Throat Hospital of Shanghai Medical University and 34 cases of implantation were reported [15]. Among these 34 cases, 25 were post-lingually deaf and 9 were prelingually deaf; 14 were implanted with a round window electrode and 20 were implanted with an electrode placed in the scala tympani. Follow-up of 14 cases after 1 year of implantation showed that 10 were daily users and 4 were infrequent users due to either inconvenience or slight dizziness. Another 50 cases using the Shanghai device were later reported in Xi'an [16], among which 30 were prelingually deaf and 20 were post-lingually deaf. All were implanted with a scala tympani electrode and all but one (due to device failure) received useful auditory stimulation. As of 1993, the Shanghai device has been used by about 500 deaf people [Wang, pers. commun.].

**Table 2.** Technical evaluations of three implant systems in China

Institute	Processor	Transmission	Receiver	Electrode
Peking Union	zero-crossing	pulse duration modulation 2-MHz carrier	17 × 6 mm silicone case	platinum ball 50 × 0.2 × 0.5 mm Silicone coating
Shanghai	compressed analog 104 × 65 × 27 mm	amplitude modulation 30-MHz carrier	22 × 5.5 mm PTFE case	platinum ball 65 × 0.2 × 0.5 mm PTFE coating
Air Force	compressed analog 100 × 65 × 25 mm	amplitude modulation 30-MHz carrier	12.3 × 4.5 mm PTFE case	platinum ball 75 × 0.2 × 0.4 mm PTFE coating

Processor size: length × width × height; receiver size: diameter × thickness; electrode parameters: wire length × wire diameter × ball diameter; PTFE: polytetrafluoroethylene.

The third type of transcutaneous, single-electrode cochlear implant was jointly developed in 1987 by the Lanzhou Air Force Hospital and Xi'an 4320 Factory. 103 adults, including 37 prelingual and 66 postlingual, have been implanted with this device [17]. Starting in 1990, this smaller device was implanted in children between 6 and 12 years old. 50 cases of child implantation and 2 cases of failure were reported in 1993 [18].

A fourth implant type that uses an extra-cochlear electrode to stimulate the promontory was developed by the Institute of Basic Medicine, Chinese Academy of Medical Sciences. Implantation of this device has been reported by Tianjing Hearing Center, the Guangzhou Red-Cross Hospital [19], and Fujian, Nanping City Hospital [13]. This extra-cochlear implant system often causes dizziness and pain sensation and is also susceptible to middle ear infection due to the opening of the tympanic membrane.

Three points are worth noting in table 1. First, the infection difference between the Peking percutaneous and transcutaneous de-

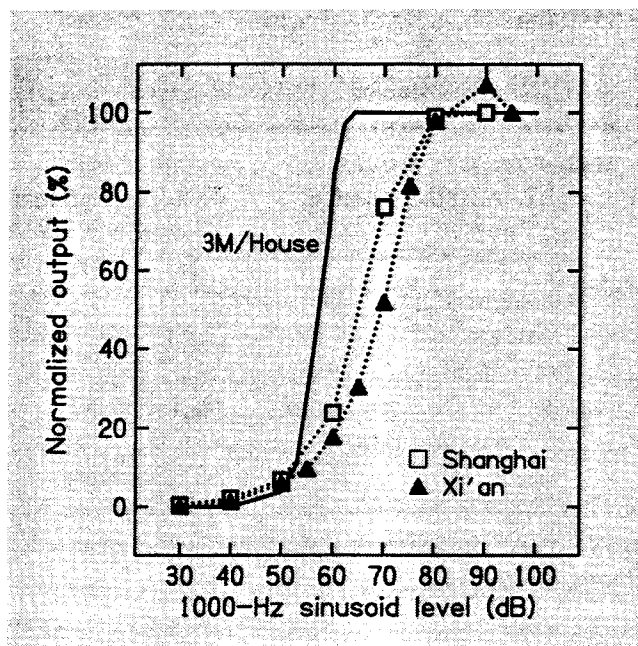
vices indicates that a transcutaneous system is more desirable in developing countries such as China where hygienic conditions are generally poor<sup>3</sup>.

Second, the absence of surgical failure in 1000 cases employing various surgical approaches indicate that the otological physicians in China have mastered the surgical implantation technique. Third, the number of single-electrode implantees described in publications is 382, but the total actual number is estimated at about 1000 cases in China.

#### *Technical Evaluations*

Table 2 shows technical parameters of the three Chinese single-electrode implant systems. Both the Shanghai and the Lanzhou Air Force device were obtained and evaluated at the House Ear Institute, whereas parameters from the Peking device were provided by Keli

<sup>3</sup> A recent communication with Drs. Wang and Cao at Peking Union Medical College suggested that the infection might also be related to the plug design and the use of materials.



**Fig. 1.** Input-output functions for the 3M/House device (the thick line), the Shanghai Medical University device ( $\square$ ), and the Lanzhou Air Force Hospital device ( $\blacktriangle$ ). The x-axis is sound pressure level of a continuous 1000-Hz sinusoid. The y-axis is normalized voltage output measured at the internal coil with an open load. The voltages at the 30- and the 90-dB input levels were (0.5, 7 V), (0.04, 5.1 V), and (0.01, 1.5 V) for the 3M/House, the Shanghai, and the Air Force device, respectively. The sensitivity was set to be maximal for the Shanghai device, whereas set to be medium for the Air Force device because a burst output occurred (20–30 ms on and 10–15 ms off) when the sensitivity was set to be maximal.

Cao [pers. commun.]. The Peking device uses a zero-crossing processing strategy. The pulse duration, defined by two adjacent zeros, is used to modulate a 2-MHz sinusoidal carrier, which is then applied to the external transmitting coil. The internal receiver has a passive decoder to retrieve the pulses, and only the pulse duration, not the amplitude, serves as a means to control the loudness level. Two silicone-coated platinum wires form two balls at the end to serve as the intracochlear electrode and reference electrode.

Different from the Peking device, both the Shanghai and the Air Force devices adopt a compressed analog-processing strategy in which the amplitude of the analog stimulus is used to modulate a 30-MHz carrier. The internal receiver has a passive demodulation circuit that restores the low-frequency speech analog waveform, which is then used to stimulate nerve fibers directly. Their electrode design is similar to the Peking electrode, except for the use of polytetrafluoroethylene (or Teflon) coating. All three devices use a mechanical headset to align the external and the internal coils.

Input-output functions and frequency responses were also measured to compare performance among the 3M/House, the Shanghai and the Air Force devices. The stimulus was a 1000-Hz sinusoid presented through a speaker (Tannoy, NFM-8) in a sound-treated room. The processor was positioned horizontally and the microphone faced at a 1-meter distance from the speaker. The internal coil had an open load and was connected to a Hewlett-Packard spectral analyzer for data collection and analysis. The external coil and the internal coil were directly attached by tape. The measured output voltage was normalized between 0 and 100% to compensate for the difference in transmission efficiency among processors. Figure 1 shows the input-output function of the three devices. The 3M/House device has a step-like function with almost no output at 50 dB SPL, reaching saturation at 60 dB SPL. The Shanghai and the Air Force devices have a 30-dB input range with a shallower slope than the 3M/House device. No data are available to evaluate whether these differences between processors may result in any performance difference in speech recognition. Frequency responses were also measured using a random noise input. Both the Shanghai and the Air Force devices have a relatively flat response between 200 and 9000 Hz.

### *Multi-Electrode Systems*

No commercial multi-electrode implant system is presently available in China<sup>4</sup>, but development efforts on one percutaneous device and four transcutaneous devices have been reported by researchers from four institutes. Tsou et al. [20] at Peking Union Medical College designed a percutaneous, four-electrode cochlear implant system and implanted it in a 46-year-old, postlingually-deaf female. Dr. Gao at Xi'an People's Hospital designed a three-electrode device [12] and researchers at Jinan University, Guangzhou, designed a four-electrode device [21]. Both devices appeared to use transcutaneous interface with no internal active electronic components. Several deaf adults in Xi'an and Lanzhou received the three-electrode device but the actual number and the audiological effects were not reported. Four deaf people received the Jinan device and two of them could obtain usable auditory stimulation. At present, both Xi'an and Jinan programs are abandoned due to either lack of financial support or personnel change.

Although no human implantation has been conducted, Peking Union Medical College and Shanghai Medical University are also developing transcutaneous, multi-electrode cochlear implant systems. With some help from researchers at the University of California at San Francisco in designing electrodes, Peking Union Medical College designed a 16-electrode device which is similar to the Clarion™ implant. A multichannel speech processor and an internal receiver/stimulator are being designed and animal experiments so far have been encouraging [11]. Shanghai Medi-

cal University received a major grant from the China Ministry of Health for developing a 22-electrode device, which appears to be similar to the Nucleus™ implant [pers. obs.]. Both the Peking and the Shanghai devices use a coding-decoding transcutaneous transmission including active components in the internal receiver. Neither of these devices is hermetically sealed, suggesting that they will have a relatively short lifetime before body fluids invade the internal electronics. Not only is hermetic sealing technology difficult for Chinese manufacturers, but it also significantly increases the price of the implant system<sup>5</sup>.

Table 3 summarizes the development and status of these multi-electrode cochlear implant systems in China. Also included are the current status of multi-electrode cochlear implants in Hong Kong and Taiwan. Since 1989, 3 males and 2 females, aged between 32 and 46, have received the Nucleus device, thanks to a joint sponsorship by University of Hong Kong and the Hong Kong Society for the Deaf [22]. Since 1990, 12 post-lingually deafened adults have received the Nucleus device at Chang Gung Memorial Hospital, Taipei [23].

### **Cochlear Implant Research in China**

#### *Patient Selection and Presurgical Screening*

Published articles indicate that patient selection and presurgical screening procedures have been standardized for cochlear implants in China [12]. These procedures are in many ways similar to standards adopted in western countries [24, 25] and include: (1) binaural

<sup>4</sup> Cochlear Pty. Ltd. is introducing its 22-electrode cochlear implant to China's market. 5 patients in Hong Kong and 12 in Taiwan have received the Nucleus device since 1989. In May, 1995, 2 patients received the Nucleus device at Peking Union Hospital.

<sup>5</sup> Hermetic sealing technology is generally assumed to be a result of pacemaker technology. The estimated price for hermetically sealing the internal device alone is at least US \$ 500. China may have a pacemaker company in Xi'an but other sources of information indicate the contrary.

**Table 3.** Multi-electrode cochlear implants in China

Institute	Year	Implant	Status	Cases	Comments
Peking Union	1980	4-electrode percutaneous	not active	1	single-channel speech processor
Xi'an Hospital	1987	3-electrode transcutaneous	not active	>5	single-channel speech processor
Jinan Univ.	1987	4-electrode transcutaneous	not active	4	1 device failure 1 no audi. response
Peking Union	1982	16-electrode transcutaneous	animal work	N/A	similar to Clarion device
Shanghai	1987	22-electrode transcutaneous	animal work	N/A	similar to Nucleus device
Hong Kong	1994	Nucleus 22	active	5	paid by charity
Taiwan	1994	Nucleus 22	active	12	paid by patients

total deafness with average pure-tone threshold higher than 95 dB HL; (2) auditory response by promontory stimulation; (3) no total cochlear ossification and no abnormal internal auditory canal as indicated by CT (computerized tomography) scan; (4) normal physical development and mental status. Most Chinese researchers think that the presently available single-electrode implants should not be placed in children less than 10 years old. It is interesting to note that a significant number of prelingually deaf adults have received implants and there is one report that the short-term performance in daily communication between implanted pre- and postlingually deaf is not significantly different [16].

#### *Materials and Morphological Research*

Biocompatibility of implant materials has been studied by placing a small piece of Teflon and a ball-shaped platinum electrode (0.2 mm diameter and 8–10 mm insertion) in the scala tympani of the cat cochlea [11, 20]. Pathological observations using scanning mi-

croscopy showed that, up to 6 months after implantation, (1) the effects of the Teflon and platinum electrode are limited to the damage of hair cells in the organ of Corti, particularly the outer hair cells from the basal part of the cochlea; (2) spiral ganglion cells and auditory nerve fibers are essentially normal except in the location of the electrode and in cases of basilar membrane rupture where both degeneration of dendrites and reduction of soma size can occur; (3) implantation of Teflon and platinum causes no toxic reaction. These results led Chinese researchers to conclude that Teflon and platinum are biocompatible materials, and safe for use in cochlear implants.

#### *Physiological and Psychophysical Research*

Little research has been done in China on the physiology and psychophysics of cochlear implants. Auditory brainstem responses evoked by electrical stimulation of the auditory nerve in cats were recorded at Shanghai Institute of Physiology and the ENT Institute



**Table 4.** Open-set, sound-only test scores (%) for 34 Shanghai Medical University single-electrode implant users

Tests	Mono-syllables	Bisyllables	Digits	Short sentences
Hearing aid (presurgical)	0.0	0.6	0.0	0.0
Cochlear implant (2-month postsurgical)	30.0	10.6	18.6	16.7

From Wang et al. [15].

of the People's Liberation Army General Hospital in Beijing [Liang, pers. commun]. Middle-latency response and its input-output function were also recorded in cats to assure that electrical stimulation evokes an auditory response [11]. Electrode impedance, threshold, and uncomfortable level were measured as a function of frequency in patients [11, 20] and the results are similar to values obtained with the Symbion device [26] and the UCSF device [27]. For those with transcutaneous implants, speech processors can be adjusted so that free-field thresholds through their processors were usually 50-60 dB HL for frequencies from 250 to 2000 Hz [8, 15, 16]. Fragmentary data on the relation between loudness and electrical amplitude and recovery from stimulation were also reported [20].

#### *Speech Recognition*

Most published articles were vague regarding methods used to train patients and evaluate speech recognition, providing largely anecdotal reports. However, two articles reported speech recognition data that were collected in controlled conditions. For a group of patients who received no benefits from hearing aids, Wang et al. [15] demonstrated the advantage of cochlear implants over hearing aids in open-set recognition of monosyllabic words, bisyllabic words, digits, and short sen-

tences (table 4). The tests were conducted in free-field, in which a microphone was placed in a calibrated position facing 100 cm from the speaker. The microphone was connected to either a hearing aid in presurgical condition or a speech processor in postsurgical condition (2 months after the processor hook-up, without special training).

Cao et al. [8] measured recognition of closed-set speech and environmental sounds for subjects using the Peking transcutaneous single-electrode implants (table 5). The tests were conducted for 21 subjects in free-field and without training. Results of all tests except for the vowel tones and the vowels showed above-chance performance levels. Table 6 shows the lip-reading enhancement by the cochlear implants for 7 subjects in recognizing a test of 100 daily-used short sentences after an average of 50 h of training (listening to the test materials on a tape recorder). Note in both tables 5 and 6 the large range of performance by the implant users. This large individual difference may be to some extent due to the degree of nerve survival but also due to other factors such as dialect, literacy, age, and pre- vs. postlingual deafness [8, 15, 16, 18]. Also shown in table 6 is the implant only and the implant plus lip-reading recognition data for open-set monosyllabic words [15]. In summary, these data demon-

**Table 5.** Closed-set, sound-only test scores (%) for 21 Peking Union Medical College single-electrode implant users

Tests	Words	Syllables	Tones	ES	SS	Vowels	Consonants
Mean	26.6	90.8	21.7	38.3	29.4	19.6	17.0
Range	0-60	50-100	0-63	0-90	0-83	0-33	0-27
Chance	8.3	33.3	25.0	10.0	8.3	20.0	8.3

ES = Environmental Sounds; SS = short sentences. From Cao et al. [8].

**Table 6.** Lip-reading enhancement (%) for single-electrode implant users

Devices tests	Peking Union (n = 7) 100 short sentences		Shanghai (n = 34) open-set words
	mean	range	mean
Implant only	42.8	25-83	30.0
Lip-reading only	75.1	42-100	NT
Implant + lip-reading	92.6	67-100	44.8

NT = Not tested. Adapted from Cao et al. [8] and Wang et al. [15].

strate that not only do single-electrode implants show a clear advantage in speech recognition over hearing aids from which these totally deaf people cannot benefit, but also enhance their ability to read lips, and even achieve open-set speech recognition with sound only in some cases. The results are generally similar to the performance of single-electrode implant users in western countries [e.g., 28, 29].

### *Role of Tones in Chinese Speech Recognition*

Chinese is a tonal language in which a vowel with different fundamental frequency variation patterns represents different meanings. A classic example is the word: *ma*, which means 'mother', 'linen', 'horse', and 'cursing' for tonal patterns of flat, rising, falling-rising, and falling, respectively. The tonal feature

should make Chinese more easily understood by implant listeners than English because fundamental frequency can be discriminated even with single-electrode stimulation [e.g., 27]. However, the tone discrimination was at the chance performance level in the study of Cao et al. [8]. This poor performance may be due to the fact that the Peking processor uses a zerocrossing strategy which does not present explicit fundamental frequency information. Xu et al. [30] directly compared Chinese and English recognition in a bilingual subject implanted with a Nucleus 22-electrode device and showed a significantly higher score of open-set word recognition for Chinese (63%) than English (42%). This difference may be partially due to a native language effect. In addition, the Nucleus implant uses the fundamental frequency to stimulate the auditory nerve and may help transmit the tonal infor-

mation in Chinese [24]. Recent data from Nucleus implant users in Hong Kong and Taiwan suggested that tonal patterns in either Cantonese or Mandarin can be effectively transmitted via the Nucleus processor extracting the pitch information and there seems to be a significant correlation between patients' ability to perceive tonal patterns and their ability to understand speech [22, 23]. However, for newer processors adopting the CIS (continuous interleaved sampling) and the SMSP (Spectral Maxima Sound Processor) strategies that do not explicitly extract the pitch information, it remains to be seen whether tonal information in Chinese can still be effectively differentiated. More controlled studies are needed to further test the hypothesis that Chinese may be easier to transmit than English via cochlear implants.

### **Manufacture and Distribution of Cochlear Implants in China**

Otological physicians in China play the most critical role in the processes of device development, manufacture, and distribution. All cochlear implant projects in China so far have been initiated by physicians who normally received initial financial support from the Ministry of Health or the Commission of Science and Technology. The physicians would normally collaborate with an engineering institute or university to design and implement a prototype device. Once the prototype device was finished and some clinical data were collected, the funding agency would organize a special committee to evaluate the effectiveness of the device. If approved, the physicians would identify a factory to manufacture the device, supervise the quality control, and receive a portion of the revenue. The physicians would then implant the device, and most likely fit the processor and conduct

the tests as well. The surgery fee (about US \$20) is much less than the device cost (US \$100 for the present single-electrode implant), whereas the surgery costs more than the equivalent single-electrode device in western countries. Most implant listeners received some form of subsidy to purchase their devices, either from their employers or the Chinese Association of Handicapped Persons. However, as the health care system undergoes reform in China, future implant users can expect higher fees for surgery and greater individual responsibility for device costs.

Regulations on manufacturing and distributing biomedical devices such as cochlear implants have been published recently, under the administration of the newly established National Institute for the Control of Pharmaceutical and Biological Products, which is part of the Bureau of Drug Administration and Policy, under the Ministry of Health. The new regulations call for tighter control of the distribution of biomedical materials and products made both in China and abroad. For imported biomedical materials and products, an application form including the following items should be submitted for consideration of approval: (1) specifications and direction of use for the imported biomedical materials and products, and a copy of the approval documents for manufacture and distribution from the exporting country; (2) the official name, chemical name, trademark, and Chinese name of the imported materials and products, accompanied by a review of the progress on research, development, and practical application; (3) chemical composition, manufacturing, quality control procedures, and samples of the imported biomedical materials and products (Chinese translation should be attached); (4) experimental data on the physical and chemical contents; (5) experimental data from animals on acute toxicity, chronic toxicity, blood compatibility, and tissue com-

patibility; (6) samples used in human clinical trials and their evaluation report; (7) samples of 3–5 consecutive products from production lines and their quality evaluation report; (8) application fee of US \$2000 for each of the imported biomedical materials and products. Similar regulations and application procedures are also applied to domestically made biomedical materials and products that intend to enter the Chinese market for the first time.

### **Issues and Comments on Future Development**

#### *Audiology and Biomedical Engineering Training*

Speech processor fitting and audiological evaluation are presently conducted by otological physicians who are already overburdened with their medical duties and receive little training in audiology and biomedical engineering. These two factors are not only responsible for the anecdotal report of the audiological evaluation results on cochlear implants, but also may have resulted in inappropriate speech processor settings that cause undesirable stimulatory effects such as dizziness, pain and facial sensation. As cochlear implants move from single-electrode to multi-electrode devices and require more complicated processor fitting techniques, the knowledge deficit in audiology and biomedical engineering will pose a more serious problem for future cochlear implant development in China. Seminars or intensive training may be a short-term cure for this deficit, but a specialized formal program in audiology is definitely needed in the long run.

#### *Speech Test Materials and Analysis*

To control speaker variance and to be able to compare between devices and between

clinic centers, it is extremely important to use tape-recorded, standard test materials to evaluate the effectiveness of cochlear implants. However, at present, this is not the case in China; different hospitals have developed their own testing materials and live voice has been used to evaluate implant patients' ability to recognize speech. The large variance in dialects, literacy and age (many deaf children are expected to be implanted) also presents a serious problem in evaluating speech recognition via implants. Thus also urgently needed are Chinese speech test materials that are less affected by dialects and require a minimal degree of literacy, such as closed-set phoneme discrimination [e.g., Iowa vowel and consonant test, Tyler et al., 31] and word intelligibility by picture identification [32].

To study what speech information can be transmitted by a communication device and to better fit an implant processor or a hearing aid, western researchers have long recognized the importance of quantitative analysis of speech recognition data [e.g. 33]. A perceptual map of speech tokens can be constructed from speech recognition data [2, 34]. Also, efficiency of transmitting specific speech features through an implant system can be analyzed [e.g. 31]. These techniques have not yet been applied to Chinese speech recognition with implants, and even if applied, modifications such as including a tonal feature are needed. These modifications, however, are relatively simple because public-domain software for multidimensional scaling applications is very flexible (e.g., SINSICAL and SINFA).

#### *Manufacture of Cochlear Implants*

Little is known about manufacturing abilities and technological levels of the present cochlear implant manufacturers in China. The Peking Union Medical College device is fabricated by Wenzhou Biomedical Instrument Factory, Zhejiang. The Shanghai Medi-

cal University device is fabricated and distributed by Liao-Yuan City Number 5 Radio Factory, Jilin. There are no official regulations for detailed manufacturing procedures of biomedical devices in China except for those described in the above-mentioned application form. Based on the observation of the obtained Shanghai and the Xi'an devices and their specifications, the devices appear to be made using outdated packaging technology and show no signs of robust testing of temperature, humidity, and vibration tolerance. Mastery of an inexpensive and reliable hermetic sealing technique will be an important factor for future manufacture of cochlear implants in China. The new laws protecting intellectual property should pave the way for potential cooperation between manufacturers in China and abroad, thus speeding the transfer of hermetic sealing technology and others.

## Conclusions

A 1990 official survey showed that China, the largest developing country in the world, has approximately 6 million totally deaf people, although the actual number is probably four times higher. A primary cause of deafness is the use of ototoxic drugs. There is no deaf culture presently in China. Cochlear implant research and development have been ongoing in China since 1979. As of 1993, about 1 000 deaf people, including 50 children below age 12 years, have received four types of single-electrode cochlear implants that were developed and fabricated by institutions in China. Present research focuses on development of multi-electrode cochlear implants. These devices may still be primitive compared to western standards, but thanks to the diligence of Chinese researchers working with limited resources, a solid foundation has been formed for further development. In addition

to device development, speech testing materials and training procedures for cochlear implant users need to be established and standardized. These developments, though costing much less than the device, can have just as important rehabilitative effects as the design of cochlear implants. The present economic growth and legal system reform in China, combined with advances in implant technology, may make it possible to produce an affordable yet effective cochlear implant system. This paper discusses cochlear implants only in China, but the social and economic factors are mirrored in many developing countries in Asia, South America, Eastern Europe, and Africa, where a low-cost, high-performance cochlear implant system is also needed.

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## Editor's Note

A test in Chinese Mandarin has been developed by R.S. Tyler, University of Iowa, Department of Otolaryngology, Iowa City, Iowa, USA, and is available to other investigators.

## Les implants cochléaires en Chine

Selon une enquête officielle récente, la Chine compte une population d'approximativement 6 millions de sourds profonds, bien que les chiffres réels soient probablement plus élevés. La cause principale de surdit  est l'utilisation de m dicaments ototoxiques. Il ne semble pas se d velopper actuellement de communaut  culturelle de sourds. En tant que seul appareil m dical qui puisse restaurer une audition partielle au sourd profond, les implants cochl aires se sont d velopp s en Chine depuis 1979. Cet article pr sente une revue des implants cochl aires en Chine et repose sur une analyse des donn es publi es, la visite de centres de recherche et d'h pitaux, des communications

personnelles avec des coll gues chinois. En 1993, environ un millier de sourds, dont 50 enfants en dessous de 12 ans, ont  t  implant s avec 4 types d'implants cochl aires mono- lectrode qui ont  t  d velopp s et fabriqu s par des institutions en Chine. Ces appareils mono- lectrode ont apport  une aide   la lecture labiale, mais ne sont plus utilis s en raison de leur incapacit    permettre la reconnaissance de la parole en liste ouverte. La recherche sur les implants se concentre actuellement sur le d veloppement d'implants multi- lectrodes. La recherche fondamentale sur la stimulation  lectrique est relativement d fici nte et il est n cessaire de d velopper une  valuation audiolinguistique standardis e de l'efficacit  des implants. La croissance  conomique actuelle et la r forme l gislative en Chine, combin es aux progr s dans la technologie des implants, permet d'envisager la production d'un syst me d'implant cochl aire accessible et n anmoins efficace. Cet article ne discute que des implants cochl aires en Chine, mais les facteurs socio- conomiques sont comparables dans beaucoup de pays en voie de d veloppement d'Asie, d'Am rique du Sud, d'Europe de l'Est et d'Afrique, o  un syst me d'implant cochl aire de haute performance mais de faible co t serait n cessaire.

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