ADVANCES WITH THE 22-CHANNEL COCHLEAR IMPLANT

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The Nucleus 22 Channel Cochlear Implant was developed on the basis of work at the University of Melbourne. Between 1967 and 1978, there was extensive research with animals and human temporal bones, especially regarding safety, psychophysics, histopathology and surgical approaches. As a result of this work, it was decided to develop a multi-channel intracochlear implant. The 22 channel implant has been used in more than 500 patients world-wide but there were many steps on the road to this success. Today, over one third of the post-lingually profound, deaf adults implanted with this device have significant speech understanding without lipreading.

Initially, an implant was developed, which was encapsulated in epoxy, had two separate receiver coils, one for power and data and ten bi-polar electrode pairs. This device was used in three patients in 1978. The sound and speech were analysed and coded by a main frame computer, and many different speech processing strategies were tested. From extensive testing, a speech feature extraction method was developed. This method extracted the fundamental frequency, coded as rate, the second formant, coded as place, and the sound-pressure-level coded as amplitude or loudness.

Based on early success showing predominantly improved lipreading, a wearable speech processor was developed. This was about binocular case size and was used with patients in 1979.

In 1981, an association was developed between the Australian, high technology medical firm, Nucleus Limited, and the University of Melbourne, to develop a 22-channel cochlear implant, which was safe and reliable and could be used in a world-wide clinical trial. A pocket-size speech processor with the same speech processing strategy was developed. This speech processor was operated by three penlight cells and could be programmed by a microcomputer called a Diagnostic and Programming System. The speech processor had an erasable, programmable, read-only memory (EPROM), which could allow it to be tailored to the needs of the patient. This model speech processor was accompanied by a microphone headset. The headset was held on the head by two bands, which reached over the head. Although this system worked, it was cosmetically not very acceptable.

A new hermetically sealed implant was also developed. This implant was tested extensively for reliability in environmental tests for biocompatibility. The implant was tested in dry heat, cold temperature, free fall, thermal cycling, vibration and impact shock. In addition, electrode flexing tests were done. A failure mode effects analysis was performed and electro-magnetic interference was tested for. Biocompatibility tests included physico-chemical tests, systemic toxicity tests, muscle implantation

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Transplants and Implants in Otology
Proceedings of the International Symposium
6-9 April 1987, Venice, Italy, pp. 347-348

tests, infra-red analysis, tests for ethylene oxide residuals, biocompatibility tests of assembled units and tests of cochlear histopathology after implantation. The only tissue contacting materials that were used were silastic and platinum, and these materials had been tested extensively in previous implants. The electrode array embraced a new concept, in that in addition to having 22 electrodes, there was now the possibility of stimulating any pair with reference to any other, thus giving much more flexibility in terms of stimulation strategies.

Commencing in 1982, a clinical trial was conducted in the USA, West Germany and Australia and resulted in significantly advanced clinical results. One third of the patients could understand significant speech without lipreading. There were no failures from these first 80 cases and there was no deterioration of performance. In fact, tests showed significant improvement between the results at three months and the results at 12 months. In many cases, speech understanding scores doubled over 12 months.

With this success, continual research went into speech processing strategy, and another formant, the first formant, was quasi added. This first formant was also coded into place, so that now there was almost simultaneous stimulation of two electrodes according to the first and the second formant. The system was introduced in 1985 and results of clinical trials with this new speech processing strategy on both new patients and patients with the previous speech processing strategies showed again a significant improvement. Compared with the FO/F2 strategy, results with the FO/F1/F2 strategy, for example, on CID sentence tests, showed an improvement of 30% in lipreading enhancement and similar improvements were seen in speech tracking. The percentage of patients who could now understand significant speech without lipreading was now increased to about 50%.

The next major development was to prepare the way for cochlear implants of a multi-channel, intracochlear type in children. A new 'Mini 22 System' was first implanted in 1986. The first obstacle to be overcome was that of the implant thickness. The implant was reduced from 10 mm to 6 mm thickness. The electrode and electronics were kept the same having been proven successful with adults. A second obstacle was the headset, which would be uncomfortable and poor in appearance for children. A magnetic headset was developed, which could be used with children and was much more acceptable cosmetically. The remaining potential difficulty was the uncertainty of whether a multi-channel system could be programmed with sufficient accuracy in young children. Several children, as young as 5½ years of age, have been tested and it has been shown that the system can be programmed by teaching children relevant concepts prior to surgery and then apply them to recognize differences in loudness and softness and other parameters. These children can tell the difference between electrodes. We are very optimistic that, with time, we shall be able to show greatly improved results using a multichannel implant with children.

In conclusion, it is now 20 years since the first research at the University of Melbourne on cochlear implants. Today, more than 500 patients, adult, post-lingually deaf patients, have benefited from the Nucleus 22 Channel Cochlear Implant. We are embarking on a new era with application of this very sophisticated implant to children and we hope that this is only the beginning of assisting those with impaired hearing.

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Title:
Advances with the 22-channel cochlear implant

Date:
1988

Citation:
Hirshorn, M. S., Clark, G. M., & Mecklenburg, D. J. (1988). Advances with the 22-channel cochlear implant. In Transplants and Implants in Otology: Proceedings of the International Symposium, Venice, Italy.

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