# The importance of being flexible

### **Ingeborg Hochmair**

After a childhood in a family of university professors, during which I bred caterpillars and butterflies, grew bacteria on agar substrates, built radios and read many books, I wanted nothing more than to work in biomedical engineering from the age of 13 onwards. I wanted to make achievements in technology to improve human health and to contribute as much as I could to the development of mankind. To prepare for this, I started out studying medicine and electrical engineering in parallel and gave up medicine after two years because my main professor in electrical engineering at the Technical University in Vienna, Fritz Paschke, was the more eloquent and convincing role model.

A lot of luck is necessary in life, and I have had a good share of it, as I was allowed early on to focus on the topic that would fascinate me for my entire life. At 22, I was an able and fast student, applying to complete my electrical engineering studies earlier than was normally allowed, when my boyfriend Erwin, who later became my husband, asked me whether I wanted to join him to develop a cochlear implant at the Technical University in cooperation with the university Ear, Nose and Throat clinic.

Thus, I have been working in the field of the cochlear implants for more than 37 years. The reader may think 'how boring', but the exact opposite is true: this is the most fascinating topic one could imagine, and I have not been bored one single second of my life. The topic has grown increasingly exciting, with many further goals and plans for the future. The body of this commentary will explain why.

#### Pursuing a bold concept

The path from our first attempts in 1975 to a commercially viable device was by no means straightforward—it required a lot of flexibility.

We began our research on cochlear implants at a time when the single-channel device by William House had already been successfully implanted. Our very optimistic goal was to design an electronic implant that would enable the user not only to hear sounds but also to provide the ability to understand some speech.

Reading the literature, we came to the conclusion that, despite many unknowns, the existing knowledge (for example, ref. 1) was sufficient to guide an engineering approach to developing a multichannel cochlear implant. It was known that the pitch of tonal sensations depended on the location of the stimulated nerve fiber within the cochlea (place pitch) and on the temporal structure of the exciting signal (periodicity pitch). To make use of both features required stimulation of the auditory nerve at several locations using a signal that also represented the temporal structure of the speech wave form with sufficient detail. To use vocoder-type speech processing was a first guess. The audio signal had to be divided into a number of frequency bands, the output of which would have to be somehow converted into data for stimulation pulses applied to a multichannel electrode inserted into the scala tympani of the inner ear.

We settled for an eight-channel implant for pulsatile stimulation with a maximum stimulation rate of 10,000 pulses per second per channel as a compromise between technical feasibility and speech-processing requirements. The electronic circuitry consisted of low-power, digital standard chip devices, some of which, by some tricks, also performed analog functions; for example, the eight independent current sources drove the electrode contacts. We mounted them on a thin-film glass substrate and encapsulated the ensuing hybrid circuit in a hermetic case. We used coupling capacitors on all of the channels to prevent any direct current damaging the nerve. Stimulation data and power were supplied transcutaneously through the intact skin via inductive coupling from an external radio-frequency generator<sup>2</sup> (Fig. 1).

Developing the multichannel intracochlear electrode was quite straightforward. It was designed for 22- to 25-mm insertion into the cochlea, entering it through the round window, and it consisted of two rows of very thin Teflon insulated wires embedded in a silicone body, with ball-shaped stimulation contacts<sup>3</sup>. The wires were wave shaped for high flexibility and softness as well as to survive tensile stress. The mechanical design was such that the electrode bent in a preferred plane to ease insertion. The implant was assembled by the two of us at the Hybrid Circuits Lab of the Technical University in Vienna. All of the materials in contact with tissue were known for their biocompatibility. It is interesting to note that the design concept of this implant anticipated modern implants; it would have been well suited for the continuous interleaved sampling (CIS) strategy developed by Blake Wilson (explained below) if that strategy had been known then.

After a relatively short development time of two years, the device was implanted on 16 December 1977 and in March 1978 by Kurt Burian in Vienna. It was very exciting to have the recipients first come to our lab and be connected to the test system. Despite some existing tinnitus, place pitch could be demonstrated, and our second patient could reliably discriminate and identify stimulation channels<sup>3</sup>.

#### Achieving open-speech understanding

Reflecting on the results, we came to the conclusion that, at this stage and because we did not believe in the justification of percutaneous plugs, we had to make sure that the stimulation signal was not restricted by the implanted hardware or the transcutaneous transmission. This would also allow us to exploit periodicity pitch to a larger extent. We designed a number of simple passive, transcutaneously driven implants, and the four-channel version became the workhorse for years to come. The four channels could be stimulated simultaneously. In the early devices we could switch

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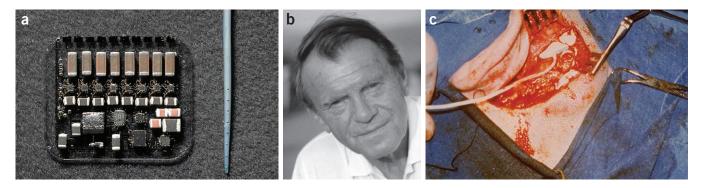


Figure 1 The first implantation of a multichannel microelectronic cochlear implant. (a) Eight-channel microelectronic cochlear implant and its long scala tympani electrode. I assembled it myself in the technology laboratory of the Technical University of Vienna. (b,c) Kurt Burian (b) performed the implant surgery (c) on 16 December 1977 in the Ear, Nose and Throat Clinic at the University of Vienna.

between several electrode configurations, and we decided, after patient tests, in favor of the less power-hungry monopolar stimulation, a concept that is now used by almost all groups. A small body-worn speech processor for daily use was adjusted to the channel, giving the best results. The first few processors generated an amplitude modulated pulsatile stimulation signal. With this signal, some open speech understanding without lip reading could be demonstrated.

These implants were very easy to assemble. During the first years, the circuits were embedded in pacemaker epoxy; later on, we used hermetic ceramic packages. Over the years, about 500 devices were implanted in adults and children.

In 1979, we spent half a year at Stanford University and met Blair Simmons and other early cochlear-implant researchers. There were rumors about a patient who could hear duck-like speech and understand a little bit of it without lip reading using analog stimulation through a percutaneous plug (the findings were later published in ref. 4). As our implants were perfectly suited for this kind of signal, we showed in that same year some open speech understanding in the laboratory through broadband analog stimulation.

Still in 1979, patients 4 (L.P.) and 5 (C.K.) received a corresponding modification to their small take-home processor that allowed them to understand speech without lip reading to a certain degree in everyday life through just one channel of the four-channel implant<sup>5</sup>. C.K. (Fig. 2) in particular was extremely motivated, and we learned a lot during the many sessions. She became well known in the cochlear-implant literature by her initials, and she is still using cochlear implants-now modern ones-bilaterally. With her and many other subjects, we learned how to individually adjust the frequency shaping and the amplitude compression to optimize speech understanding. Owing to the implant's very low

power consumption and external processing, we were able to design the very first behindthe-ear processor for a cochlear implant. We gave it the name COMFORT (**Fig. 3**).

The results achieved during the 1980s with our stimulation method, known as singlechannel broadband analog strategy, were much better than those obtained with the House implant; in fact, they were as good as results achieved with any other implant at that time, despite the fact that they do not make use of place pitch<sup>6,7</sup>. The underlying reason for their success was most likely the high flexibility and length of our electrode, allowing fairly deep insertion so that the innermost channels could reach fibers in the apical region of the cochlea.

#### Translational headaches

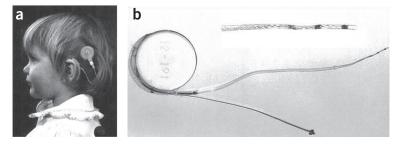
In 1981, with 17 university-built research devices implanted, we were contacted by 3M in Minnesota, who intended to enter the hearing-device market using the implant as a flagship. We signed, happy about the prospect of enabling thousands of deaf patients to understand speech using cochlear implants. Because there were ongoing discussions at that time about the safety of intracochlear electrodes, 3M decided to pursue only an extracochlear version. The implementation never worked well and did not result in product approval.

Observing the company's activities as consultants for seven years, we learned much about the challenges that huge, multiproduct companies face when trying to master high-tech, implant-specific topics. In fact, several companies have since entered and left the field: Smith & Nephew (Ineraid Device), Philips (ABS Device in the Netherlands) and Boston Scientific (Advanced Bionics).

Our relationship with 3M ended in 1988. As the project had not been successful and had delayed our own timelines compared to other groups, we decided to take advantage of everything we had learned and grow our already-existing small company MED-EL. We employed the first three people in March, 1990, and I gradually abandoned my university career to become the chief executive officer and chief technology officer of MED-EL. My husband Erwin had been appointed to a full professorship at the University of Innsbruck, Austria, where he directed the Institute of Applied Physics. This made it possible to maintain close cooperation between



**Figure 2** An important early patient. (a) C.K. has enjoyed open speech understanding from cochlear implants for the longest period worldwide: 34 years as of September 2013. Twenty-nine years after her original implantation in August 1978 and before receiving a modern PULSAR implant in 2008, she still had 25% open set monosyllabic word understanding with an analog implant, which she had wanted to keep for listening to music. Pioneer users such as C.K. worked hard and contributed a lot to the development of cochlear implants. (b) C.K.'s first four-channel implant and its take-home processor for broadband analog stimulation.



**Figure 3** The COMFORT System. (a) Child with behind-the-ear processor. (b) Implant. About 500 adults and children received the COMFORT System for broadband analog stimulation, the only transcutaneous analog system that consistently led to open speech understanding in patients with good temporal processing abilities. Most of them are using modern implants now and enjoy further increased speech understanding.

the research team at the university and the fledgling company.

Today, the research and development division at MED-EL encompasses more than 200 engineers and scientists. MED-EL has grown to be the second largest hearing-implant provider in the world and the largest in Europe in terms of cochlear-implant units.

#### The search continues

In the early 1990s, it seemed a logical development to complement the periodicity information of a low-frequency analog channel by adding place pitch information at additional channels. In 1991, an approved combined analog and pulsatile eight-channel implant was surgically placed in a patient (**Fig. 4**)<sup>8</sup>. The first results did not show a big improvement.

At this time, Blake Wilson had just published a new coding strategy called CIS (continuous interleaved sampling)<sup>9</sup>. Exercising flexibility, we decided to come up with an implant (later called COMBI 40) specifically designed for a faithful implementation of a fast CIS strategy. We communicated this plan at the third International Cochlear Implant Conference, which we organized in Innsbruck in April 1993. This conference also marked the end of the era of the broadband analog cochlear implant.

Our eight-channel system COMBI 40 was first implanted in January 1994. Thus, development had come full circle from our early eight-channel implant via the broadband analog devices to the new multichannel system, albeit at a much more sophisticated level. The development of the new implant proved to be a good move, as shown by the excellent results from a multicenter clinical trial (**Fig. 5**)<sup>10</sup>. The system provided 1,500 pulses per second per channel (12,000 pulses per second overall) and drove a 30-mm-long electrode.

In the early 1990s, cochlear implant systems like the one above were ready for global distribution for adults and children. Only four of the many early university-based research groups managed to develop commercially viable devices. Since then, the cochlear-implant field flourished, resulting in an enormous number of publications, clinical studies, basic research, rehabilitation efforts, surgical advances and improved devices.

Indications have widened considerably (**Fig. 6**). A cochlear-implant user today may be a young child of a few months of age or a centenarian; a person with bilateral implants; a patient with cochleas that are only partially deaf, using electric and acoustic stimulation simultaneously; or a person with a normal and a deaf ear (single-sided deafness). Auditory brainstem implants have also been developed for those without a functional nerve or a cochlea.

#### Concluding remarks

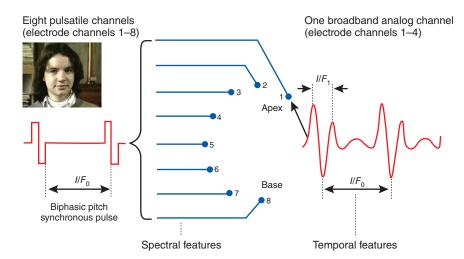
Ever since we started our work and during all these years of working on cochlear implants, four aspects have had priority over everything else. (i) Build an implant that would not pose restrictions to the signal used for stimulation, such that the intelligence of the system would reside in the component external to the body and be easily upgraded. The implant should use a stimulation signal containing a wealth of information, leaving it to the recipient's brain and not to the device to extract the sound information. In our opinion, the brain extracts features much more reliably than any electronic circuit. To our knowledge, feature extraction is no longer used in cochlear implants.

(ii) Respect for the delicate structures inside the cochlea. The electrodes we designed were soft and flexible from the beginning. The very first patient that we implanted already received wave-shaped thin wires<sup>3</sup>.

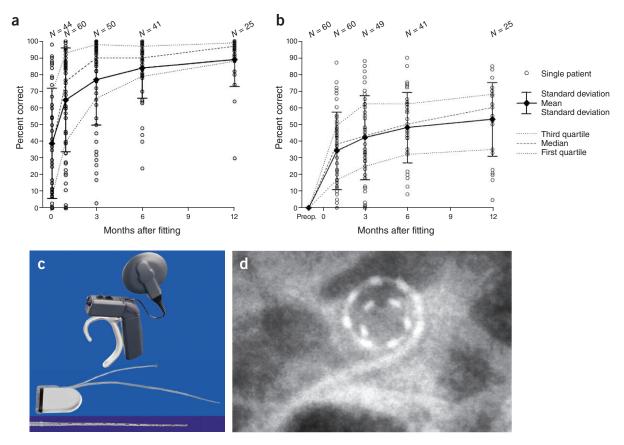
(iii) Using the entire length of the cochlea, including its apical region, for stimulation should lead to the widest range of pitch sensations, including very low pitches<sup>11</sup>, and avoid any lengthy adaptation process caused by remapping of the perceived pitch range.

(iv) Ergonomics concerning the daily use of the device by the recipients is of vital importance for the acceptance and spread of the implants. Among other things, the constant struggle for power reduction has led to the path from body-worn to behind-the-ear to off-the-ear cableless audio processors and will eventually lead to fully implantable systems.

The vision to overcome hearing loss as a barrier to communication and to quality of life has been a motivator and driving force ever since the very beginning of our journey, when it was just Erwin and me, up to today, with a team of more than 1,500 MED-EL team members that support professionals and

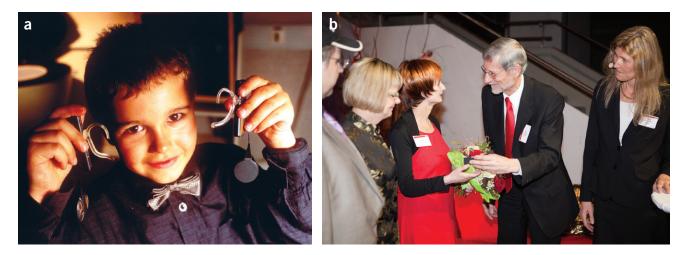


**Figure 4** A unique case. M.H. was the only patient who received an implant that combined analog and pulsatile stimulation. The analog signal conveying the temporal features is presented at one of the apical channels 1–4 together with pulses appearing on any channel depending on the spectral content of the input signal.



**Figure 5** Multicenter study results with the implant COMBI 40. This implant implemented a fast CIS strategy in postlingually deaf adults, and it showed for the first time that more than half of the patient population reached a monosyllabic word understanding higher than 50% after just 6 months. This means that these patients can talk to someone unknown to them about an unknown topic over the telephone. (a) Sentence understanding<sup>10</sup>. (b) Monosyllabic word understanding. Preop., preoperative<sup>10</sup>. (c) COMBI 40 Implant System with 30-mm-long electrode with 2.8-mm contact separation<sup>10</sup>. (d) The electrode covers most of the length of the cochlea, reaching out into its apical part, as the X-ray shows<sup>12</sup>.

device recipients around the globe and are passionate about this mission. The enthusiasm of contributing to further progress in terms of the technology and its application stands in sharp contrast to the fact that, year after year, so many deaf-born children still reach an age at which their chances to transit from a silent to a hearing world vanish as the plasticity of their auditory pathways slowly disappears.



**Figure 6** More recent pioneer patients. (a) M.R., the first bilaterally implanted (March 1996 and January 1998) child, received his implants at the ages of 2 and 4 years. Bilateral implantation for the purpose of binaural hearing was started in July 1996 (ref. 13). (b) S.S., the first electric and acoustic stimulation patient, suffered from partial hearing loss. Her low-frequency hearing was preserved despite insertion of an electrode into her cochlea for 20 mm. Electric and acoustic stimulation started with her<sup>14</sup>, as did the entire idea of preserving hearing as well as inner ear structures not only in cases with residual hearing but also in all cases. S.S. and C.K. were presented with an acknowledgement by Erwin Hochmair during the 20-year celebration.

There are still many hurdles to receiving a cochlear implant in many countries and health systems. The World Health Organization recently highlighted within its updated report on Priority Medicines for Europe and the World that hearing loss is one of the 24 priority areas of public-health importance. Hopefully, the actions derived from this report will help speed up the provision of cochlear implants and other hearing devices, especially for those who need them to exercise their human right for education.

As this personal communication has shown, certain flexibility in cochlear implant research may sometimes be advantageous and lead to distinct advances. Flexibility is even more important for one particular product of this research, the intracochlear stimulation electrodes. Important topics that are widely discussed at this time, such as hearing preservation, structure preservation, apical region and deep insertion, all depend on sufficiently flexible electrodes. At least some of these developing areas will shape the future of cochlear implants.

**COMPETING FINANCIAL INTERESTS** The authors declare competing financial interests: details accompany the online version of the paper.

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## Competing financial interests

Declaration: I.H. is the chief executive officer and chief technology officer of MED-EL.