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KOS, Maria Izabel

Abstract

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The electrical stimulation of the internal ear at the University Hospitals of Geneva

Privat-Docent Thesis

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Geneva 2010
Foreword

Multichannel cochlear implantation is a clinical technique that was introduced at the University Hospitals of Geneva (HUG) in 1985, by Prof Pierre Montandon. In 1994, I received the medical charges of the Centre Romand d’Implants Cochléaires (CRIC) that consisted of performing all surgical implantations as well as of promoting the paediatric cochlear implantation. This practice is the central focus of this thesis, which is presented in the form of a report on the experience and the lessons learned during the past 25 years within the framework of the CRIC. During this period, more than 200 implantation surgeries were performed on more than 170 patients suffering from various types of deafness.

This thesis is based on clinical studies and original data gathered between 1985 and 2009 by the multidisciplinary team of the CRIC. It includes three main parts. The first is a description of the methods and approaches followed by our team. The second part presents the results in terms of the hearing performance of the implanted patients who were classified according to three different clinical situations: post-lingually deafness, pre-lingually deafness with early implantation and some rare cases of pre-lingually deafness with late implantation. This part also includes an examination of the cases which involved complications caused by the implant, in particular those which required a reimplantation. A third and final Chapter describes the development of another type of internal ear implant by addressing the incipient question of vestibular implant. The work described in this Chapter is to my knowledge the first report on human vestibular responses elicited by electrical stimulation. I am happy to have contributed with the surgical aspects of this new development.
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1. **Introduction and objective**

The hair cells are the weakest link amongst the various connected structures forming the auditory system. Normally, when the rods of the hair cells move, they modify the transmembrane potential and these sets off action potentials that are propagated along the fibres of the auditory nerve and reach the brain through several relays. Agents such as loud noises, some congenital or acquired diseases, ototoxic products or even physiological ageing can damage these cells. All these causes lead to a type of deafness known as perception deafness. The attacks to the structures of the external or middle ear, which drive mechanically the sound to the internal ear, can also result in deafness of another type, known as conductive deafness. In this case, deafness is never complete and can be corrected by medication, surgical interventions or by the use of a hearing aid. On the contrary, perception deafness can progress and become complete. Indeed, the number of functional hair cells can decrease until the sound vibrations are no longer transformed into nervous signals, even when acoustic devices amplify the sounds. This situation, which was for a long time cause of great frustration for patients as well as for their ENT doctors, can now be redressed thanks to cochlear implantation.

The objective of this thesis is to describe in detail the experiments and the results obtained with cochlear implants in adults and children over the last 25 years in the University Hospitals of Geneva, within the *Centre Romand d’Implant Cochléaire* (CRIC).

1.1. **The history of cochlear implants**

Histological studies show that even in cases of total deafness and loss of almost all hair cells, the fibres of the auditory nerve survive and remain morphologically intact. Consequently, it should be possible, at least theoretically, to activate these cells directly by electrical stimulation. In 1957, Djourno, Eyriès and Vallancien [1957] were the first to show that the electrical stimulation of the auditory nerve produced sounds. Djourno developed a stimulating electric implant designed for animals. Eyriès, an ENT doctor, was treating a patient “who was going to receive a graft of the facial nerve” and “who had expressed the will that the impossible be tried to stop his deafness, even if only very imperfectly”. Both doctors decided to try an operation. After having fully informed the patient of the risks of failure. During the surgery for the graft of the facial nerve, Eyrïès placed the electrodes of the stimulator in the internal auditory canal, close to the remaining fibres of the severed auditory nerve. Already the first tests of stimulation, they were able to report that “… *speech is heard like a sequence of close noises: it is obvious that the patient interprets correctly the amplitudes and poorly the frequencies. However, he quickly develops a connection, a kind of coding* between syllables and words and his distorted perceptions... if after a rigorous training the coding of the words proved to be sufficient, one could certainly propose the use of a prosthesis when no other approach would allow auditory perception... “. 
On the basis of this visionary conclusion, other specialists have immediately taken the flame torch. In 1960, House [1976] was one of the first specialists to stimulate the auditory nerve by introducing an electrode into the cochlea, a technique significantly less invasive than that used by Djourno and coll. [1957]. Simmons [1966] and Michelson [1971] have followed the path traced by House. The cochlear monocular implant was born. However, at that time, the evaluation tests were rather anecdotal and based on isolated experiments. The lack of an organized multidisciplinary analysis slowed down research. A report, ordered by the National Institutes of Health (NIH) and carried out by an independent expert [Bilger, 1977], concluded that an implant with only one channel did not allow speech understanding. Nevertheless, this same report also indicated that the implanted patients communicated significantly better with their prosthesis turned on than turned off.

The NIH then decided to encourage research in this field. It was rapidly admitted that a multichannel cochlear implant was needed to integrate the principle of tonotopy which is essential when stimulating successfully the auditory system. After a few years of multichannel implantations, a team of Iowa [Gantz and coll. 1988] undertook a large comparative study. They examined the results of a group of patients who had been operated following the same surgical approach and evaluated with the same method. This team succeeded in demonstrating indisputably the superiority of the multichannel implants. Thereafter, the multichannel implants developed rapidly. Many clinical experiments were done and in 1988, at the time of the first the cochlear implant consensus set up by the NIH [1988], roughly 3’000 patients had been implanted. It was shown that patients using a multichannel implant could engage in an oral conversation without lip-reading. Even though the miracle waited by the deaf was realised thanks to the first generation of multichannel cochlear implants, such patients accounted at that time for only 5% of all the cases.

Over the following years, several research teams [Wilson and coll. 1991; Boex, 1992; Boex and coll. 1994; McDermott and coll. 1994] demonstrated that by solely improving the “sound-coding strategy” - the algorithm which transforms the auditory signals into a succession of electrical pulses distributed among the implanted electrodes – and keeping the same implanted device, most patients could follow a conversation without the assistance of lip-reading. This gave rise to the so-called second-generation multichannel cochlear implants. At the time of the next NIH consensus [1995], approximately 13’000 patients had been implanted and most of those implanted with the more recent sound processors obtained results beyond 80% of correct answers in the most difficult tests and without lip-reading.

Currently (2010), over 200’000 people have been implanted in the world. The efficiency of the cochlear implant in terms of the functional rehabilitation exceeds everything that has been achieved so far with any other nervous stimulating prosthesis. Now the born deaf children are able to develop the oral language and to attend a normal school together with their hearing peers. Nowadays, cochlear implantation is the standard treatment for severe deafness. It is refunded by the Social Security and is used as a model for the development of other neural prosthesis such as those for visual or vestibular implants [Wilson and coll. 2008].

1.2. The history of cochlear implants in Geneva
Prof Pierre Montandon, an otological surgeon, was named in 1975 head of the ENT department of the HUG. At that time only single channel implants existed. On the basis of the experimental work carried out by the Eaton Peabody Laboratory of Prof Nelson Kiang in Boston (Harvard University and Massachusetts Institute of Technology - MIT) [Montandon and coll. 1975 a, b] on the electrophysiology of the ear, Montandon got interested in the ongoing development of the multichannel implant as the only existing way of restoring adequate hearing to deaf patients and enabling them to communicate orally. The research which, at that time, seemed most promising was carried out in Salt Lake City (USA) by Eddington and Parkins and in Melbourne (Australia) by Tong and Clark. After having visited several laboratories in the United States and Europe, and advised by Kiang, Montandon choose to collaborate with Eddington and to use an implant prototype offered to our research group by the Symbion firm of Salt Lake City. This firm had already manufactured the artificial heart of Jarwick. This implant was also used Oslo (Norway) before it was marketed under the name of Ineraid®.

After the first implantations were done in Geneva (1985), it appeared necessary to set up a local multidisciplinary research team. Indeed, a highly qualified research team was needed to allow the full participation of Geneva in the international collaborative work taking place mainly among the American research centres. Marco Pelizzone who was then in a fellowship in New York was the candidate chosen to head this team.

The very successful result gotten with these implants led the American “Federal Drug Administration” (FDA) to allow the commercial use of the Ineraid implant in the USA. At the same time, Geneva received the mission of organizing, together with the Royal University of Oslo, an international training and information course. This course, which took place in Geneva in 1987, dealt with issues such as implant surgery, technical engineering and theories of the biophysics of hearing. It had a great success and received participants from the whole world, including China.

Prof Marco Pelizzone, a physicist by training, had joined the Geneva group with the mission of setting up a team of scientists and engineers whose assignment was to examine the information received by the implanted patients. At first, the research effort aimed at gathering objective data on the activation of the central auditory system through the development of techniques of evoked potentials techniques [Pelizzone and coll.1989; Kasper and coll. 1991] and recording the cerebral magnetic fields elicited by electrical stimulation of the auditory nerve [Pelizzone and coll. 1986a, 1986b, 1987]. Later on, the studies were gradually directed towards the psychophysical characterization of the perceived sounds and the development of new sound coding strategies. The Geneva team directed by Pelizzone [Boex, 1992; Boex and coll. 1994,1996] was the first to achieve an independent validation of the “Continuous Interleaved Sampling (CIS)” strategy, suggested initially by Wilson and coll.[1991]. Until then all data from the patient was gathered in the laboratory and using heavy not-portable equipment. Our team was the first to develop a portable processor that allowed measuring the performance of the implants in daily life [Pelizzone and coll. 1995]. The Geneva wearable processors were made available not only to the local patients but also to patients from Boston and North Carolina, both getting results similar to ours. This new strategy was then broadly distributed. Up to date, all currently available cochlear implants still use the basic principles developed during this phase of research.

Between 1985 and 1995, we had thus passed from the multichannel cochlear implants of the first generation to the multichannel cochlear implants of the second generation.
and the Geneva team had fully taken part in these developments. As a precaution, the implants in Geneva had been primarily proposed only for adults suffering from post-lingually deafness. These have an auditory memory of the oral language and could more easily decipher the sounds produced by their implant. But our results, like those of other international teams, suggested that the quality of the auditory information produced by the most recent devices could enable born deaf children to develop the oral language.

In the early nineties, the number of candidates for implantation increased gradually as well as the clinical activity with the implanted patients. In 1992, when I joined the ENT department, 12 implantation surgeries had already been carried out. In 1994, I was appointed physician responsible for the CRIC with the mandate to assume the surgical activities and to develop the paediatric implantation. Within this framework, I performed all the ear implantations, including children from the age of 1 up to adults aged 85 years, and using various models of implant devices.
2. Methods of cochlear implantation

Geneva is one of the pioneering centres of multichannel cochlear implantation. Since the beginning of this activity, in 1985, a multidisciplinary team was created, assembling otological and plastic surgeons, physicists, engineers, logopedists and psychologists [Montandon and coll. 1989]. In 1994, a centre for cochlear implantation, the Centre Romand d’Implant Cochléaire (CRIC) was officially created on the basis of a long time verbal agreement that existed between the university hospitals of Lausanne and Geneva. The team of this Centre worked intensely in order to overcome the difficulties resulting from the development of the implantation activity and the ever-increasing number of patients. The methodological aspects that were developed and used within this framework are presented in this Chapter.

2.1. Selection of candidates

The goal of cochlear implantation is to restore, even if imperfectly, a hearing perception that can enable an originally deaf person to communicate orally, a hearing perception of higher quality than that obtained with conventional hearing aids. It should be recalled that deafness is not a generalising term because all deafness are far from being equivalent. The time at which deafness appears is crucial because it determines the mode of communication and critically influences the decision on whether a cochlear implant is an appropriate solution. A first distinction must be made between the post-lingually deaf person who, after having learned the oral language, looses hearing gradually or abruptly and the pre-lingually deaf, who loose their hearing before having learned the oral language as a result of a congenital or an acquired affection. Being a non-for-profit organisation, motivated only by research, the CRIC has never selected candidates with the aim of getting optimal results, in a way choosing to implant only those patients who could potentially get excellent performances after implantation. Any deaf person, independently of the type and duration of deafness, the age, the mode of communication or his or her origin, was considered candidate [Montandon and coll. 1992a] as long as the implantation was particularly considered to be an appropriate treatment. The only restriction (in line with the Social Security rules) applied to cases of major intellectual deficit that would prevent the patient from benefiting from the cochlear implant, i.e. to perform oral communication.

In our Centre, the selection of candidates for implantation proceeds in the following way. The ENT doctor diagnoses deafness through the usual examination procedures. Then the patient is sent to the CRIC for a series of more specific examination. This examination aim at demonstrating that the patient will benefit from an improvement of his or her auditory perception with a cochlear implant. This preoperative step includes consultations with the otological surgeon, an imagery of the internal ear through CT or IRM, an evaluation of the auditory evoked potentials (PEA), a speech assessment by the logopedists, an evaluation of the vestibular function (balance), a
psychological consultation and finally, a practical presentation of the cochlear implant itself by the engineers. The multidisciplinary team of the CRIC discusses the outcomes of all these examinations and a proposal for treatment is made to the patient (or to the legal representative in the case of a deaf child). The decision of implanting is made jointly by the patient and the ENT specialist.

2.2. Evaluation of the excitability of the auditory nerve

It is essential to demonstrate that the deaf patient who is going to be implanted has indeed an auditory nerve which can be stimulated electrically. It is a necessary but obviously not a sufficient condition for a successful implantation.

2.2.1. The promontory test

At first there were only subjective and not very reliable tests for establishing the critical aspect of excitability. With these tests, the patient had to describe the sensation caused by an extra-cochlear electrical stimulation. The stimulating electrode was placed either on the promontory of the middle ear (using a transtympanic needle) or directly on the tympanic membrane. The patients who reported having perceived sounds during the electrical stimulation were considered as candidates.

In 1988, a study was done in Geneva to evaluate the validity of this test [Liard and coll. 1988]. One hundred nineteen individuals with normal, residual hearing or profound deafness, were evaluated. The test consisted in applying an electric current to the tympanic membrane using a small gold electrode especially designed for this test. These 119 individuals were asked to describe the auditory perception caused by the electrical pulses. Only 73% of them described them as “sounds”. The other 27% were unable to qualify it and some described it like a purely tactile perception. In addition to being inaccurate, this test was inapplicable to a great number of patients, such as those suffering from a strong tinnitus or having comprehension or communication difficulties. This was for instance the case with the very young children. To progress we had to develop an objective method which could point out without ambiguity the activation of the auditory tracts.

2.2.2. The electrically evoked auditory potentials (EABR)

Developing a test that could allow to objectively recording the electrical stimulation of the auditory pathways became a fundamental goal. Such a test should not depend on the patient’s collaboration and should also be applicable to those patients who never had auditory experience such as those suffering from congenital deafness or who are not able to describe what they hear, for example, very young children or patients under narcosis. In the area of hearing, the best objective test consists in recording the answers evoked by auditory stimulation of the brainstem which is routinely used in all ENT departments in the world. In this case, what remained to be
done was to record these answers evoked by electrical stimulation. But that was easier to say than to achieve. The auditory answers of the brainstem are signals with amplitudes of about one millionth of volt which appear in a hundredth of a second after the sound stimulus while the required signal for the electrical stimulation of the ear is about one volt, a million times stronger. Electrical stimulation thus produces at time “zero” a signal that is a million times larger than the answers that have to be detected in the next hundredth of a second. When we first started studying cochlear implants in Geneva, these engineering problems were not solved. Certain authors gave however credit to electrical responses collected in such a way which obviously corresponded to recording flaws and which did not match anything coming from the auditory system. Pelizzone and coll. [1989] managed to control these engineering problems. They succeeded in demonstrating that the recording of the brainstem evoked potentials elicited by the electrical stimulation of the internal ear (EABR for Electrically evoked Auditory Brainstem Responses) of a deaf implanted patient was very similar to the recording of the evoked potentials elicited by sound stimulation (ABR for Auditory Brainstem Responses) of a normal hearing person. In the EABR recordings, the waves sequence is identical to those of the ABR. They differ only in the latencies of the answers which are 2 ms shorter. This proves that the electrical stimulation of the internal ear activates the same auditory relays of the central nervous system (and in the same sequence) as the sound stimulations. The shortening of latencies is due to the fact that electrical stimulation “shortcuts” the process of transduction done by the internal ear during normal sound stimulation [Pelizzone and coll. 1989].

Once these developments were accomplished, we had at our disposal an objective and reliable method for evaluating the activation of the auditory pathways. But this method could only be applied to the already implanted patients and not to the patients who were candidates for an implant. For the latter, it was necessary to find a way of exploring the cochlea by introducing a stimulating electrode in order to make an objective measure before the implantation itself.

2.2.3. The EABR through exploratory cochleostomy

Exploring the cochlea through an exploratory cochleostomy is an approach that was proposed by Montandon [Montandon and coll. 1992b; 1994]. It precedes the implantation and consists in introducing a stimulating electrode into the cochlea to be able, before the implantation, to: (1) record high-quality EABR and, (2) evaluate the permeability of the cochlea (which could have been affected by ossification and fibrosis). It should be underlined that this practice is minimally invasive. Before establishing this practice, we certified by comparing the extra- and intra-cochlear stimulations within the same patient that the intra-cochlear stimulation produces indeed much more reliable results [Pelizzone and coll. 1989].

The exploratory cochleostomy is a natural extension of the oto-surgical techniques performed in Geneva. This surgery uses the transmeatal approach to reach the middle ear. This was initially proposed by Lempert in 1934 and then systematized by Schuknecht [Meltzer, 1962] at the “Massachusetts Eye and Ear Infirmary” before being brought to Geneva by Montandon. It consists in a minimally invasive surgery that uses a microscope and only local anaesthesia. We use it for almost all tympanoplasties, stapedotomies and exploratory tympanotomies. Local anaesthesia
allows communicating with the patient and getting an immediate evaluation of the surgical result. It should be noted that this technique is not very usual in Switzerland or in Europe.

A speculum is placed in the meatus and a tympano-meatal flap is lifted. While performing the exploratory cochleostomy, the round window is exposed and opened to give access to the basal turn of the cochlea. If the entrance to the cochlea is obliterated by fibrosis or ossification, those are removed using micro-instruments and micro-drills. In the cases in which there is massive ossification and no open space can be found, then an opening is tried at the cochlear apex. Once the cochlea is opened, an electrode is introduced to record the EABR. This recording technique is difficult to obtain. Indeed, the responses of the EABR are very faint and to get a clear recording it is necessary to suppress the multiple artefacts produced by the electrical environment of the operating room and of the electrical stimulation itself [Montandon and coll. 1992a, 1992b]. In the end, the patient describes the sounds perceived during the electrical stimulations while his face is also inspected in the search of an undesirable response of the facial nerve. If EABR responses are detected, the implantation surgery follows, after narcosis is induced. In some rare cases, implantation was postponed or abandoned either because no responses were detected, possibly as a result of a retro-cochlear pathology or at the request of the patient. Our experience indicates that in less than 2% of the cases there has been a stimulation with the cochlear implant while no electrical responses during the exploratory cochleostomy had been detected.

Recently we were confronted with a case that illustrates the interest of exploratory cochleostomy. One patient suffering from a profound retro-cochlear deafness caused by superficial siderosis asked for a cochlear implant. It has been reported that in some of these cases one can expect good performances from cochlear implantation even though deafness is caused by a lesion of the acoustic nerve [Hathaway and coll. 2005; Dhooge and coll. 2002]. Because of these counter-intuitive observations we accepted the patient’s request and performed an exploratory cochleostomy. During this procedure we could not record any electrically evoked potential while stimulating both ears. We postponed the implantation to inform the patient of the poor prognosis. He finally renounced to be implanted.
2.3. The implant surgery

As previously mentioned, the implant surgery is performed after the exploratory cochleostomy and induction of the narcosis. The retro-auricular incision for the access to the implant site has significantly evolved over the past years. Initially, the incision through all the layers to the periostum was broad [Balkany and coll. 1999]. Later on, it has been made with shorter alternated incisions in two layers: the cutaneous and the subcutaneous planes. This enables, at the end of the surgery, to totally cover the site away from the sutures and to protect more effectively the implanted stimulating device from the risk of exposal in case of necrosis or dehiscence of the operative wound. Currently, the incision is made according to the minimally invasive technique described by O’Donoghue and coll. [2003]. A small retro-auricular incision gives the access to the cribiforme plane of the mastoid. The opening of the bone is done through a mastoidotomy and a posterior tympanotomy. This opening is minimal because the cochlea has already been opened during the exploratory cochleostomy. This is very convenient, especially in cases of cochlear ossification, because one can then avoid making a large opening during the posterior tympanotomy. If it were not for this previous opening, one would have to extensively drill the tympanic promontory, sometimes up to the apex of the cochlea via the posterior tympanotomy,
until a space in the cochlea could be found [Montandon and coll. 1994]. Actually, an extensive drilling in this location is to be avoided because it is close to the facial nerve and implies a higher risk of damaging this nerve through of the warming of the drill or any accidental damage caused by the drill itself.

Finally, the stimulating device is placed on the temporal bone, under the temporal muscle, in a pocket opened by the elevation of the muscle. The electrode array is inserted into the middle ear via the mastoidotomy and posterior tympanotomy and then, through the cochleostomy, into the cochlea (Figure 2.1). The cochleostomy is plugged with a small piece of aponevrosis. The incision is sutured and covered with steri-strips. A compressive bandage is left in place during 24 hours. The suture stitches are removed 7 days after the surgery. Usually this type of surgery only requires two days of hospitalization.

Chapter 4 presents an analysis of the complications resulting from the implant surgeries performed in our Centre over the last 25 years.
2.4. The implants used

Figure 2.2: A cochlear implant is composed of an implanted part and an external worn carried behind the ear or at the waist. The microphone (1), the processor (2) and the antenna (3) are placed in the external device. The stimulating device (4) and the electrode array (5) are part of the implant that stimulates the auditory nerve (6). (Med-El Illustration)

The cochlear implant is composed of an internal part (the implanted device) and an external part (the vocal processor), which transforms the sounds into electrical signals that are sent to the fibres of the acoustic nerve. These two parts are connected by signals transmitted through the skin. All the most modern implants (Advanced Bionics®, Med-El®, Cochlear®) use a transcutaneous transmission of electromagnetic waves (Figure 2.2). The very first prototype used in Geneva, the Ineraid®, which was one of the first multichannel cochlear implants, used a percutaneous plug. All systems, although very different in their aspect, are based on the same principle that can be summarized in 6 points:

1. Language sounds and noises are picked-up by the microphone and transmitted to the vocal processor.
2. This processor converts the sounds into a stimulation code which is distributed among all the electrodes.
3. This information is sent to the antenna (fixed by magnetisation over the implant), and is transmitted through the skin by radio waves.
4. The implanted stimulating device receives these waves, decodes them, creates electrical pulses and sends them to the various electrodes inserted into the cochlea.
5. These electrodes stimulate the fibres of the auditory nerve that in turn transmits signals to the brain.
6. The brain analyzes them in its auditory system and interprets them as sounds.

To date, four different types of cochlear implants were used in Geneva.

2.4.1. The Ineraid® implant

The “Ineraid” implant prototype was designed by Eddington, a bio-engineer, and Parkins, an otological surgeon [Eddington and coll. 1978]. This implant was first manufactured by Symbion as a prototype. The patented device was then manufactured and marketed in the United States by Smith and Nephew-Richards. The special feature of this implant was to have a percutaneous plug, fixed at the temporal bone, which transmitted the signals through the skin. Later on, with the appearance of the transcutaneous transmitters and electronic miniaturization, this device was abandoned at the end of the 90’s and it is no longer manufactured. We will however briefly comment on it because it illustrates in an exemplary way the transition from the first to the second generation of multichannel cochlear implants.

In Europe, Prof P. Montandon made the first multichannel cochlear implantation in 1985, in Geneva. He used an “Ineraid” prototype. Already at that time this device allowed volunteered implanted deaf patients to develop a good speech understanding without the support of lip-reading [National Institutes of Health Consensus statement, 1988]. At that time, all patients used a sound coding strategy called “Compressed Analog” (CA). This strategy activated all the implanted electrodes simultaneously. With the development of a simple band-pass filtering, it was possible to selectively transmit the low frequency signals to the electrodes implanted around the apex of the cochlea and the high frequency signals to the electrodes implanted close to the base of the cochlea. Thanks to this selective distribution of signals among the electrodes the tonotopy of the cochlea, an essential condition for a good performance of the auditory system, was respected. Such a result could not have been secured with a single channel implant. It became clear that multichannel systems would be better than single channel if the various channels were able to convey independent information signals. Theoretically, it was also clear that if the simultaneously stimulated electrodes were too close together, the channels would not be able to convey totally independent information. Actually [Favre and Pelizzone, 1993], the experiments undertaken with implanted patients showed that approximately 50% of the signals transmitted to an electrode also appeared in the nearby electrode (distant 4 mm in the cochlea). Under these conditions, it was not possible to speak of real independence between the channels. The same experiments have however showed that these interferences became negligible as soon as the electrodes were activated sequentially. It was thus necessary to elaborate a sound coding strategy based on a sequential stimulation of the implanted electrodes.

Under the guidance of our colleagues in Boston, this is precisely what B. Wilson and coll. [1991] did by proposing the so-called “Continuous Interleaved Sampling” (CIS)
strategy. As in the CA strategy, the acoustic signals of the CIS were divided into wavebands by a filtering band-pass and the fluctuations of intensity in each band were transmitted to the implanted electrodes, thereby respecting tonotopy. But, contrary to the CA, the CIS strategy, as its name indicates, uses a sequential activation of the implanted electrodes to maintain as much as possible the independence of the channels and preserve the undesirable inter-actions between electrodes. Comparative experiments [Wilson and coll. 1991; Boex, 1992; Boëx and coll. 1994] were done on patients using the “Ineraid” prototype because, thanks to the flexibility offered by the percutaneous catch of this system, it was easy to compare the effects of these two coding on the same patient. All these experiments showed systematically and clearly the superiority of the CIS compared to the CA strategy. The CIS enabled the patient to perform significantly better in speech understanding. Thanks to the percutaneous plug, we had gone from the multichannel cochlear implant of first generation to the multichannel cochlear implant of second generation.

However, the then available portable vocal processors could only process the CIS using a fixed and cumbersome laboratory equipment. It was necessary to miniaturize the vocal processor. To address this challenge, an international collaboration was set up with the research centres of Massachusetts Eye and Ear Infirmary in Boston (D. Eddington), Research Triangle Institute in Durham (B. Wilson) and School of Engineers of Geneva. This team produced the first CIS portable processor: the Geneva Wearable Processor (GWP) [Pelizzone and coll. 1995]. Thanks to the sponsoring of private foundations, 70 units of the GWP were manufactured. Almost all were given to those patients in Boston, Durham and Geneva who were using “Ineraid”. Certain Geneva patients are still using them nowadays in their daily life. Unfortunately the company Smith and Nephew-Richards could not develop and market a new vocal processor because at that time it had been already purchased by a competitor that simply dropped the “Ineraid” system.

2.4.2. The Advanced Bionics® implant

The Clarion cochlear implant systems, produced by the Advanced Bionics, are manufactured in the United States. They are the result of research done by Schindler and coll. [1992]. “Clarion” was the first marketed implant with a CIS coding strategy. It was similar to the one developed in the United States and Geneva. This gave us the opportunity to make a comparative study by dismantling a “Clarion” system and temporarily connecting the output contacts of its stimulating implant to the percutaneous plugs of the “Ineraid” prototype [Boex and coll. 1996] used by a patient. At the speech understanding tests within the same patient, almost identical results were observed with the two devices. From 1995 onwards, we started to use clinically the “Clarion” system in Geneva. Since then, several models of the same brand have been produced. Some of these models carried an “Electrode Positioning System” (EPS) [Fayad and coll. 2000]. This system is made of a silicone part, which is separate from the electrode array that must be inserted between the array and the outer wall of the cochlea. Its purpose is to push the electrodes towards the inner wall of the cochlea and thus closer to the neurons located at the modiolus. Because in the United States and some European centres, some cases of meningitis in implanted children have been attributed to the use of the EPS, we immediately decided to stop using it. Fortunately we were not confronted to
any case of meningitis. Later on, for the sake of security, this model was recalled from the market.

2.4.3. The Med-El® implant

When cases of meningitis caused by some models of cochlear implant appeared, we felt that we should no longer be dependent on only one type of implant and started in 2000 to use the “Med-El” system. This system is manufactured in Austria and is based on the research done by Hochmayer-Desoyer IJ and Hochmair ES [1993]. This device uses a CIS sound coding strategy very similar to that developed originally by B. Wilson and coll. [1991].

2.4.4. The Cochlear® implant

We finally started to use in 2004 the “Cochlear” system manufactured in Australia. It is based on the research done by Clark and coll. [1986]. This implant was one of the first two multichannel implants of first generation marketed in 1985, the other being the “Ineraid” prototype. In its first conception, it comprised a transcutaneous transmission (by radio waves) device whereas the “Ineraid” implant comprised a percutaneous plug. Why didn't we use the “Cochlear” system at that time? Contrary to many other centres that from the start have favoured the most accomplished equipment, we preferred the models using a simple percutaneous plug because we wanted to avoid being restricted by the limitations inherent to an implanted stimulating device. The reason was that we believed that cochlear implantation was at its early development stages and we wanted to be able to offer to our patients other sound coding strategies as soon as they would be available and validated. Fortunately, the future has proven that we were right and our patients were immediately able to benefit from the advantages of CIS strategy. Later on “Cochlear” developed a new stimulating device (the one we use today), which was capable of carrying the most recent sound coding strategies. On the contrary, the patients using the old stimulating “Cochlear” device had to be reimplanted in order to benefit from the latest coding strategy.
2.5. The postoperative follow-up of the patients

Figure 2.3: Session for the tuning of the external processor of a child. After an auditory control, the child can collaborate by indicating the auditory threshold from each electrode. (Photo CRIC)

2.5.1. The tuning of the external processor

The tuning of the external processor can be performed approximately 4 weeks after the implantation. The first “adjustment” session aims at determining, for each implanted electrode, the intensity necessary to give a stimulus between a just perceptible sound and a strong but not unpleasant sound. It is during this session that the deaf patient experiments the new sounds emitted by his implant.

With a post-lingual deaf adult, the adjustment is easier because the patient has a hearing memory that was acquired before deafness. He can thus collaborate with the engineers and describe his sound perceptions on the basis of his memory, giving reliable indications on strength and intensity of each sound. He returns home with a standardized stimulating program on his vocal processor. The patient is then re-examined a few days later and thereafter at increasingly larger intervals until his vocal processor is tuned in an optimal way and adjusted to his personal perception. The duration of this start-up cycle of the cochlear implant varies according to each individual patient. Certain post-lingual deaf adults manage to telephone already in the first hours of implant use whereas small children adapt to the implant in a more complex procedure that requires more patience and expertise.

With very young children, the adjustment of the processor to obtain no more than the minimal threshold level may last over a month. In this case, the adjustment becomes a progressive task which is done in two stages. The first starts even before the implantation itself when the child learns to play structured games that will prepare him to play “to listen”. This will make it easier to identify during the next tuning
sessions his individual adequate stimulating levels (Figure 2.3). In doubtful cases, and this situation is rather frequent with very young children that cannot yet collaborate, low levels of stimulation are purposefully used, for safety reasons. Young children require a very steady follow-up. They have to acquire the initial steps of oral communication in order to become able to give useful indications for the fine-tuning of the vocal processor and to get a good hearing quality.

2.5.2. The medical and technical follow-up

Once the adjustment cycle of the vocal processor is completed, all patients are regularly - at least once a year- submitted to medical and technical controls of their implant and external processor. The CRIC multidisciplinary team - engineers, logopedists, physicists, doctors, and psychologists - carries out these controls, each member acting in his field of competence. In addition to such controls, the patients may visit the Centre to solve technical breakdowns (batteries, cables...) or eventual medical problems. In the event of a medical emergency or a technical failure, the CRIC has a special telephone line, which can be used 24 hours a day (orally or by SMS). Moreover, and this is particularly important for the care of the children, the therapists of the multidisciplinary team can be called to take part in school or medical meetings and have their say on the medical records or on how to proceed for an adequate integration of a newly implanted child in his school or social environment. The purpose of this assistance is to more widely disclose information about the functioning and handling of cochlear implants which is usually rather lacunar in these milieux. Finally, it should be stressed that carrying out a cochlear implant establishes a lifelong commitment between the patient and the implant centre.

2.5.3. The weekly multidisciplinary board meetings

Since the beginning, the CRIC has organised weekly multidisciplinary meetings. The participants are not only the members of the multidisciplinary team of the CRIC but also house physicians, trainees, external therapists and teachers who are somehow associated with implantation. Their objective is to establish a common language among participants with very diverse backgrounds. These meetings allow reviewing regularly the files of all the patients. Each new case is presented and an ad hoc approach is defined. In the more difficult cases, each participant adds information’s that might be useful to decide on a common procedure. Finally, such meetings are also the occasion for the members of the team to present and discuss their own research and gather elements for their own work and presentations at congresses and external workshops.

2.6. Evaluation of speech understanding

The essential goal of cochlear implantation is to improve oral communication. Thus the most rigorous way to evaluate the benefits brought by the implant is to measure
the speech understanding levels before and after implantation. But speech understanding is a complex process based on several factors [Khomsi, 1987]:

1. Capacity for hearing the elementary sounds of language, i.e. the phonemes;
2. Capacity for putting them together to form words;
3. Capacity for recognizing and identifying these words (i.e. the lexicon);
4. Capacity for building sentences as a series of words (i.e. the syntax)
5. Cognitive capacity for understanding the conveyed message.

Since we started our activity in Geneva, we were faced with the main problem of how to evaluate the efficiency of the implant in speech understanding. The first difficulty appeared with one of our first patients of French mother tongue. We had chosen to use the list of “Sentences de Fournier” (the test that is most frequently used in French speaking practices). But we immediately noted that the patient could memorize the sentences and, more than one year later, was able to repeat them by heart. We had no alternative list of sentences at hand. Another difficulty we have faced rather early in this process was the different mother tongues of our patients, notably German, Spanish and Albanian. It is not possible to translate a French text because, depending on the language, the phonetic and lexical components (as well as the syntactic rules) are very different. The essential challenge was then not only to neutralize the effects of memorization but also to find a uniform way of testing a very heterogeneous group of patients, having different mother tongues and cultural and social backgrounds. Actually, the cochlear implant acts only on the audibility of the sounds of language and does not modify (fortunately!) the phonological, lexical, syntactic, mnemic or cognitive capacities of the patient.

2.6.1. Evaluation of the performance of the post-lingual deaf patients

Almost half of the implanted patients in our Centre are adults who learned to speak before becoming deaf. These patients have a hearing memory of speech and can write. What are the tests available to evaluate this type of patient? An overview of the literature shows that there is, for each language, a series of tests for the identification of phonemes as well as for the understanding of unusual and complex sentences. How to make a choice? The implanted deaf should be submitted to tests evaluating only his hearing discrimination. Ideally these tests should avoid other sources of variability such as memorisation, lexical and cognitive levels. It should also be possible to use the same test repeatedly so as to be able to monitor and measure rigorously the performances of the patient over time. Moreover, the different centres dealing with patients of different linguistic origins should be able to use the same test to enable the comparison of the results. Rabinowitz and coll. [1992] studied a series of standardized tests largely applied in the United States. These tests include, inter alia, the identification of vowels and consonants (logatomes), of monosyllabic words (NU-6 Minimal Auditory Capacities - MAC) [Owens and coll. 1985], the recognition of words in simple sentences with important contextual contents (CUNY sentences) [Boothroyd and coll. 1985] and, finally, the understanding of very difficult and unusual sentences (IEEE Harvard sentences) [Grant and Braida, 1991]. This study showed that there is a very significant correlation (R> 0.85) between the patient’s performances in the identification of
logatomes and all other performances, i.e. the identification of monosyllabic words NU-6, words in CUNY sentences and the IEEE sentences. Rabinowitz and coll. [1992] proposed thereafter the use of a weighted index based on the score for the identification of vowels (V) and consonants (C), applying the formula \((C \times C \times V)^{0.333}\), where the consonants have a double weight because theoretically they are more relevant for speech understanding. Their study concludes and recommends that the tests of vowel and consonant identification should be used to evaluate the performances of the implanted patients because: (1) in so far as a large set of performance measures is gathered, one can be very sure that there is a strong correlation with all other speech understanding measures; (2) they minimize the effects of other variability factors and focus on the audibility of the language sounds; and (3) the test can be repeated infinitely and therefore allows the patient’s performance to be monitored over time.

**The test of vowel and consonant identification**

On the basis of these recommendations, we have developed our own test of vowel and consonant identification [Pelizzone and coll. 1993]. We voluntarily limited ourselves to work with a subset of vowels (a/an/e/i/o/ou/ü) and consonants (d,p,t,k,b,g,f,s,v,z,m,n,l,r) because they are the most important ones in the majority of languages spoken in Europe. In our test, the vowels are presented in an isolated form, without an accompanying consonant. The consonants are presented in the following form: aCa, aFa, aMa, etc. The patient is placed 1m away from the loudspeaker (Fostex ™ UP203 S) in a soundproof room. A male speaker presents the tokens in a random sequence at 75 dB SPL A. The patient must respond to each presentation using a graphic chart where all possible answers are shown (Figure 2.4). He is not told whether he gave the correct or incorrect answer.

The test is composed of a set of 56 logatomes (8x7 vowels or 4x14 consonants) and at the end of the test, the percentage of correct answers is calculated. Usually, one session consists of 3 tests of vowels and 3 tests of consonants. The performances of the patient are thus evaluated on the basis of the identification of 168 vowels and 168 consonants, which is statistically significant.
We used the “test of vowel and consonant identification” when possible, that is to say, when the patient is able to read and answer via the graphic chart. The performance results are presented using the index \((CxCxV)^{0.333}\), where \(V\) is the average of correct answers on 168 presentations of vowels and, where \(C\) is the average of correct answers on 168 presentations of consonants.

2.6.2. Evaluation of the hearing performance of children

Nowadays the deaf children are usually implanted very early in their life, typically one year old. The test of identification of vowel and consonant, as it is described above, is obviously not applicable to children aged less than 8 to 9 years. Other approaches are thus necessary. The congenitally or the pre-lingual deaf children have to learn to communicate orally with their implant. Contrary to individuals who became deaf after having acquired a hearing memory, these children have never listened and have in the beginning to learn to decipher the auditory perceptions produced by their cochlear implant. For a child who has a normal hearing capacity, 24 hours a day, learning to communicate is already a long and complex process which lasts approximately 4 years. It is also a process which varies significantly from one child to another according not only to the child himself but also to contextual factors such as the family, the school, the culture, etc. [Deriaz M, 2009]. It is therefore even more complicated to evaluate an implanted child. As we have already mentioned in connection with the very young children, the first adjustments of the vocal processor cannot be optimal and it is not even guaranteed that at the beginning the child will be able to hear completely all the
sounds of language. Moreover, even if the quality of this adjustment is satisfactory, the child will only get an imperfect hearing through the implant. Finally, the progress the child will be able to make will also depend on the quality and the frequency of the hearing training sessions he or she will be offered. If all goes well, it is only after 4 to 5 years that it he or she will fully benefit from the results of the training.

A consequence of this large variability in the children’s acquisition of oral language is the need to have a whole set of specific evaluation tests that addresses the various language aspects and a broad range of language levels. To this end Mr. Deriaz, the senior logopedist of the CRIC, gathered a comprehensive set of tests and rating scales (described below). The regular use of this battery enables us to get information on possible shortcomings in the adjustment of the implant or in the rehabilitation strategy. Thus, if the results of the tests of a child deviate from an expected norm, we try to identify the causes and rapidly propose its corrections.

Our battery of language evaluation tests for the young children has two main categories: one for the evaluation of language perception and another for the evaluation of language production.

2.6.3. The CRIC tests for the evaluation of language perception

The Minimal Pairs (MP) test

Mr. Deriaz developed a test called Minimal Pairs. It includes 18 pairs of words; the words of each pair differ only in one phoneme. The 18 pairs are divided into 3 levels of increasing difficulty (see Table 2.1). A chart with two images is shown to the child (e.g. in French: sapin-lapin, coq-phoque, château-bâteau…..) The therapist pronounces with a standard voice (and by preventing any lip reading by the child) the word corresponding to only one of the two images of the pair and the child must identify the image corresponding to the word he heard. The performance of this test is expressed by the percentage of correctly identified words. This test can be repeated infinitely since it does not allow memorization.

<table>
<thead>
<tr>
<th>Table 2.1 Test of minimal pairs (in French)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
</tr>
<tr>
<td>1. sapin-lapin</td>
</tr>
<tr>
<td>5. coq – phoque</td>
</tr>
<tr>
<td>6. balle – boule</td>
</tr>
</tbody>
</table>
The “Capacity of Auditory Performance” (CAP) scale

The CAP is a scale of auditory performance [Archbold and coll. 1998] (see Table 2.2 below). This scale has 8 performance levels: from the lowest level (0) - when the child does not react to environmental sounds - to the highest (7) - when the child is able to use the telephone with a familiar talker.

The 8 levels of the CAP are a very schematic simplification of all the possible performance levels a child can get. But thanks to this simplification, any therapist can quickly and comprehensively evaluate the auditory performance of a child. The CAP is particularly useful when it is necessary to quickly specify the auditory capacity of a child in order to take decisions at the educational or therapeutic levels. This scale also allows the therapist to monitor the patient’s progress from speech training (Deriaz, 2009).

<table>
<thead>
<tr>
<th>Level 0</th>
<th>Displays no awareness of environmental sounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>Awareness of environmental sounds</td>
</tr>
<tr>
<td>Level 2</td>
<td>Responds to speech sounds</td>
</tr>
<tr>
<td>Level 3</td>
<td>Recognizes environmental sounds</td>
</tr>
<tr>
<td>Level 4</td>
<td>Discriminates at least two speech sounds</td>
</tr>
<tr>
<td>Level 5</td>
<td>Understands common phrases without lip reading</td>
</tr>
<tr>
<td>Level 6</td>
<td>Understands conversation without lip reading with a familiar talker</td>
</tr>
<tr>
<td>Level 7</td>
<td>Can use telephone with a familiar talker</td>
</tr>
</tbody>
</table>

2.6.4. The CRIC tests for the evaluation of language production

The “Phonetically Balanced Kindergarten (PBK)” test

The PBK is a test based on the repetition of phonetically balanced monosyllabic words. It was conceived in English by Haskins (Master's thesis, North-western University) in 1949. It is regarded as one of the most difficult tests among the tests intended for children below the age of 7 [Lachs and coll. 1999]. We use this French version which was elaborated by the team of the Centre d’Implant Cochléaire of the Institute St Pierre in Palavas-les Flots (France) (personal note, Vieu A., Lupi A., Lanvin L. and Uziel A.).

This test is has 4 lists of 50 words each. Each list contains 150 phonemes (see Table 2.3; 2.4; 2.5 and 2.6). The therapist pronounces with a standard voice (and by preventing any lip reading by the child) one of the words randomly chosen from one of the lists and the child must repeat it. The score is expressed as a percentage of words (or phonemes) repeated correctly.
Table 2.3 Identification and repetition of phonetically balanced kindergarten words “PBK” (in French)

<table>
<thead>
<tr>
<th>List I</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. pou</td>
<td>19. ours</td>
<td>37. mer</td>
</tr>
<tr>
<td>2. thé</td>
<td>20. pomme</td>
<td>38. feuille</td>
</tr>
<tr>
<td>3. vol</td>
<td>21. gauche</td>
<td>39. bise</td>
</tr>
<tr>
<td>4. banque</td>
<td>22. but</td>
<td>40. rêve</td>
</tr>
<tr>
<td>5. jeune</td>
<td>23. vigne</td>
<td>41. voile</td>
</tr>
<tr>
<td>6. cinq</td>
<td>24. chut</td>
<td>42. âne</td>
</tr>
<tr>
<td>7. jambe</td>
<td>25. table</td>
<td>43. montre</td>
</tr>
<tr>
<td>8. larme</td>
<td>26. film</td>
<td>44. lettre</td>
</tr>
<tr>
<td>9. feutre</td>
<td>27. chiffre</td>
<td>45. ciel</td>
</tr>
<tr>
<td>10. griffe</td>
<td>28. nuage</td>
<td>46. truc</td>
</tr>
<tr>
<td>11. fleur</td>
<td>29. chant</td>
<td>47. aile</td>
</tr>
<tr>
<td>12. pont</td>
<td>30. ski</td>
<td>48. eau</td>
</tr>
<tr>
<td>13. faim</td>
<td>31. cou</td>
<td>49. riz</td>
</tr>
<tr>
<td>14. bleu</td>
<td>32. noix</td>
<td>50. clé</td>
</tr>
<tr>
<td>15. pot</td>
<td>33. pied</td>
<td></td>
</tr>
<tr>
<td>16. jus</td>
<td>34. bon</td>
<td></td>
</tr>
<tr>
<td>17. nuit</td>
<td>35. mordre</td>
<td></td>
</tr>
<tr>
<td>18. zoo</td>
<td>36. plat</td>
<td></td>
</tr>
</tbody>
</table>

Table 2.4 Identification and repetition of phonetically balanced kindergarten words “PBK” (in French)

<table>
<thead>
<tr>
<th>List II</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. être</td>
<td>19. croire</td>
<td>37. onze</td>
</tr>
<tr>
<td>2. os</td>
<td>20. ville</td>
<td>38. jour</td>
</tr>
<tr>
<td>3. langue</td>
<td>21. neige</td>
<td>39. seul</td>
</tr>
<tr>
<td>4. tombe</td>
<td>22. coq</td>
<td>40. chef</td>
</tr>
<tr>
<td>5. gaz</td>
<td>23. paille</td>
<td>41. niche</td>
</tr>
<tr>
<td>6. puce</td>
<td>24. sage</td>
<td>42. robe</td>
</tr>
<tr>
<td>7. douche</td>
<td>25. meuble</td>
<td>43. veste</td>
</tr>
<tr>
<td>8. tigre</td>
<td>26. souffle</td>
<td>44. barque</td>
</tr>
<tr>
<td>9. zèbre</td>
<td>27. risque</td>
<td>45. glace</td>
</tr>
<tr>
<td>10. trente</td>
<td>28. pièce</td>
<td>46. huître</td>
</tr>
<tr>
<td>11. clown</td>
<td>29. frère</td>
<td>47. vin</td>
</tr>
<tr>
<td>12. roue</td>
<td>30. chez</td>
<td>48. cru</td>
</tr>
<tr>
<td>13. deux</td>
<td>31. lit</td>
<td>49. feu</td>
</tr>
<tr>
<td>14. beau</td>
<td>32. gant</td>
<td>50. main</td>
</tr>
<tr>
<td>15. trou</td>
<td>33. drap</td>
<td></td>
</tr>
<tr>
<td>16. pré</td>
<td>34. brun</td>
<td></td>
</tr>
<tr>
<td>17. nom</td>
<td>35. fou</td>
<td></td>
</tr>
<tr>
<td>18. poivre</td>
<td>36. blé</td>
<td></td>
</tr>
</tbody>
</table>
### Table 2.5 Identification and repetition of phonetically balanced kindergarten words “PBK” (in French)

**List III**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>miel</td>
<td>19.</td>
</tr>
<tr>
<td>2.</td>
<td>droite</td>
<td>20.</td>
</tr>
<tr>
<td>3.</td>
<td>faux</td>
<td>21.</td>
</tr>
<tr>
<td>4.</td>
<td>chaud</td>
<td>22.</td>
</tr>
<tr>
<td>5.</td>
<td>tu</td>
<td>23.</td>
</tr>
<tr>
<td>6.</td>
<td>vie</td>
<td>24.</td>
</tr>
<tr>
<td>7.</td>
<td>lion</td>
<td>25.</td>
</tr>
<tr>
<td>8.</td>
<td>vrai</td>
<td>26.</td>
</tr>
<tr>
<td>9.</td>
<td>bing</td>
<td>27.</td>
</tr>
<tr>
<td>10.</td>
<td>femme</td>
<td>28.</td>
</tr>
<tr>
<td>11.</td>
<td>patte</td>
<td>29.</td>
</tr>
<tr>
<td>12.</td>
<td>goutte</td>
<td>30.</td>
</tr>
<tr>
<td>13.</td>
<td>huile</td>
<td>31.</td>
</tr>
<tr>
<td>14.</td>
<td>sol</td>
<td>32.</td>
</tr>
<tr>
<td>15.</td>
<td>sable</td>
<td>33.</td>
</tr>
<tr>
<td>16.</td>
<td>vitre</td>
<td>34.</td>
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<td>17.</td>
<td>match</td>
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<td>18.</td>
<td>boucle</td>
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<td>37.</td>
<td>course</td>
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<td>38.</td>
<td>peu</td>
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<td>39.</td>
<td>chou</td>
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<td>40.</td>
<td>pain</td>
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<td>41.</td>
<td>lait</td>
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<td>42.</td>
<td>gros</td>
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<tr>
<td>43.</td>
<td>bruit</td>
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<td>44.</td>
<td>bouée</td>
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<td>45.</td>
<td>ange</td>
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<td>46.</td>
<td>sauce</td>
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<td>47.</td>
<td>rhume</td>
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<td>48.</td>
<td>dire</td>
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<tr>
<td>49.</td>
<td>œil</td>
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<tr>
<td>50.</td>
<td>chose</td>
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</tbody>
</table>

### Tableau 2.6 Identification and repetition of phonetically balanced kindergarten words “PBK” (in French)

**List IV**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>1.</td>
<td>seau</td>
<td>19.</td>
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<td>2.</td>
<td>prince</td>
<td>20.</td>
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<tr>
<td>3.</td>
<td>moi</td>
<td>21.</td>
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<tr>
<td>4.</td>
<td>banc</td>
<td>22.</td>
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<tr>
<td>5.</td>
<td>vieux</td>
<td>23.</td>
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<tr>
<td>6.</td>
<td>lui</td>
<td>24.</td>
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<tr>
<td>7.</td>
<td>nez</td>
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<tr>
<td>8.</td>
<td>chat</td>
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<td>9.</td>
<td>arbre</td>
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<td>10.</td>
<td>ongle</td>
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<td>11.</td>
<td>canne</td>
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<td>12.</td>
<td>chance</td>
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<td>13.</td>
<td>peigne</td>
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<td>14.</td>
<td>laine</td>
<td>32.</td>
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<td>15.</td>
<td>lune</td>
<td>33.</td>
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<tr>
<td>16.</td>
<td>livre</td>
<td>34.</td>
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<td>17.</td>
<td>chambre</td>
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<td>18.</td>
<td>pitre</td>
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<td>37.</td>
<td>soif</td>
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<td>38.</td>
<td>crêpe</td>
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<tr>
<td>39.</td>
<td>coin</td>
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<td>40.</td>
<td>nid</td>
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<tr>
<td>41.</td>
<td>doigt</td>
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<td>42.</td>
<td>boue</td>
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<tr>
<td>43.</td>
<td>dé</td>
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<tr>
<td>44.</td>
<td>fruit</td>
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<td>45.</td>
<td>homme</td>
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<td>46.</td>
<td>boxe</td>
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<td>47.</td>
<td>tête</td>
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<td>48.</td>
<td>quinze</td>
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<td>49.</td>
<td>riche</td>
<td></td>
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<tr>
<td>50.</td>
<td>soupe</td>
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</tbody>
</table>
The “Repetition of Simple Sentences” (TRPS) test
This test is part of the “Test d’Evaluation des Perceptions et Productions de la Parole (TEPPP)”, elaborated by the Centre d’Implant Cochléaire of the Institute St Pierre in Palavas-les Flots (France) [Vieu and coll. 1999] (table 2.7). It has two different objectives: (1) to determine the capacity of a child for identifying current sentences comprising different morphosyntactic structures and, (2) to evaluate the quality of the child’s language production. The vocabulary and the sentences used are simple and refer to three different topics that the child can very easily identify: the bedroom, the breakfast and the school. Attached to each topic is a list of 14 sentences having increasing levels of difficulty. The structures of the sentences are divided into declaratory, imperative and exclamatory (see Tableau 2.7). The therapist pronounces with a standard voice (and by preventing any lip reading by the child) each sentence randomly selected from the list and the child must repeat it. The score is expressed as a percentage of correct repetitions relative to a total of 60 syllables and 48 words per list.
<table>
<thead>
<tr>
<th>Table 2.7 : Repetition of Simple Sentences Test – TRPS (in French)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. LE PETIT DEJEUNER</strong></td>
</tr>
<tr>
<td>Bonjour maman</td>
</tr>
<tr>
<td>Tu as bien dormi?</td>
</tr>
<tr>
<td>Va chercher un bol</td>
</tr>
<tr>
<td>Assieds-toi</td>
</tr>
<tr>
<td>Bois ton chocolat</td>
</tr>
<tr>
<td>Attention, c’est très chaud</td>
</tr>
<tr>
<td>Donne-moi le sucre</td>
</tr>
<tr>
<td>Tu veux du pain?</td>
</tr>
<tr>
<td>Mange ta tartine</td>
</tr>
<tr>
<td>Tu prends de la confiture?</td>
</tr>
<tr>
<td>Tu as fini?</td>
</tr>
<tr>
<td>Tu as encore fain?</td>
</tr>
<tr>
<td>Tu as bien mangé?</td>
</tr>
<tr>
<td>Dépêche-toi !</td>
</tr>
<tr>
<td><strong>B. LA CHAMBRE A COUCHER</strong></td>
</tr>
<tr>
<td>Bonjour</td>
</tr>
<tr>
<td>As-tu bien dormi?</td>
</tr>
<tr>
<td>Habille-toi, s’il te plaît</td>
</tr>
<tr>
<td>Où sont tes chaussures?</td>
</tr>
<tr>
<td>Brosse-toi les dents</td>
</tr>
<tr>
<td>Range tes jouets, s’il te plaît</td>
</tr>
<tr>
<td>Où est ta poupée?</td>
</tr>
<tr>
<td>Mets ton pyjama, s’il te plaît</td>
</tr>
<tr>
<td>Va au lit maintenant</td>
</tr>
<tr>
<td>Veux-tu une couverture?</td>
</tr>
<tr>
<td>Couche-toi et dors</td>
</tr>
<tr>
<td>Bonne nuit</td>
</tr>
<tr>
<td><strong>C. L’ECOLE</strong></td>
</tr>
<tr>
<td>Bonjour maîtresse</td>
</tr>
<tr>
<td>Mets ton manteau</td>
</tr>
<tr>
<td>Donne-moi le ballon</td>
</tr>
<tr>
<td>Je vais vous raconter une histoire</td>
</tr>
<tr>
<td>Chut ! Taisez-vous</td>
</tr>
<tr>
<td>Tu veux faire de la peinture?</td>
</tr>
<tr>
<td>Choisis un livre</td>
</tr>
<tr>
<td>Prends les ciseaux</td>
</tr>
<tr>
<td>Quel joli dessein !</td>
</tr>
<tr>
<td>Tu manges à la cantine?</td>
</tr>
<tr>
<td>On va dans la cour</td>
</tr>
<tr>
<td>C’est le jour de la bibliothèque</td>
</tr>
</tbody>
</table>

The “Speech Intelligibility Rating (SIR)” scale

SIR is a scale of the intelligibility of words that was elaborated by Allen and coll. [2001]. This scale (see Table 2.8) scales the intelligibility of the language production of a child into 5 performance levels, from the very lowest category (1) - when the child is only able to utter some predetermined words - to the highest level (5) - when the child can easily be understood in daily life situations. The person directly in charge of the rehabilitation of the deaf child carries out this evaluation.
This scale has the advantage of circumventing a major limitation of the clinical tests that often do not manage to evaluate rigorously the performances of the very young children. Actually, for psychological reasons, the children behave in a different way depending on whether they are at home or in school. Therefore, there is often a significant discrepancy between the various performance evaluations of the same child [Allen and coll. 2001]. The SIR scale is a practical and simple way to evaluate the development of speech intelligibility in everyday life and to monitor its evolution over time.

<table>
<thead>
<tr>
<th>Table 2.8 Speech Intelligibility Rating - SIR (in French)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
</tr>
<tr>
<td>Level 2</td>
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<tr>
<td>Level 3</td>
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<td>Level 4</td>
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<tr>
<td>Level 5</td>
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</tbody>
</table>
3. The speech understanding of implanted patients

3.1. Introduction

The post-lingual deaf can rely on the hearing memory of the oral language to decipher the sounds produced by the implant. He can therefore adapt to the cochlear implant rather easily and quickly. On the contrary, the pre-lingual deaf has to learn how to hear and communicate orally with the implant. In 1985, the multichannel cochlear implants of first generation were launched. There were no indications that the pre-lingual deaf would be able to speak with such an implant. Indeed, at that time, as a precaution and for obvious ethical reasons, we had chosen to only implant the post-lingual deaf patients. This cautious attitude turned out to be wise. In 1988, when the NIH organised the first consensus on cochlear implants [1988], it appeared that only 5% of the 3000 implanted patients could have a conversation without lip-reading. It was only around 1995, after two major events, that pre-lingual deaf patients started to be confidently implanted. The first event was the availability of the multichannel implants of second generation on a large scale. This model had transcutaneous transmission devices and the most recent sound coding strategies (CIS or SPEAK). The second was the publication in 1995 of the second NIH implant consensus [1995] informing that the vast majority of patients using the most developed vocal processors managed to reach a score of over 80% of correct answers in the more difficult tests, without lip-reading. However, at first, implanting pre-lingual deaf patients was a complex task. The group of candidates for implantation was heterogeneous. It included children of different ages but also some teenagers and adults. These deaf had an extremely variable knowledge of the oral language and often used different modes of communication. Some carried hearing aids and had benefited from an oral rehabilitation, with or without visual coding. Others were strict users of the sign language. As could be expected, the first implanted pre-lingual deaf had very different performance results and doubts were raised over the possibility that a pre-lingual deaf patient could learn the oral language with an implant. The analysis of the first sets of results led to the conclusion that the late implanted deaf were already strongly depended on visual modes of communication and that those modes remained a priority compared to the auditory information brought by an implant. It appeared to be too difficult (and maybe uninteresting) for these patients to change their modes of communication. It also appeared that their performance in oral communication was bad or very limited. These unsuccessful experiments delayed the development of the implantation of the pre-lingual deaf compared to the post-lingual deaf patients. However, after having analysed the results more carefully it appeared to the researchers that certain pioneer children - children implanted in low age and benefiting from intensive oral rehabilitation training - could indeed learn to communicate using only the oral language [Nikolopoulos and coll.1999]. As a corollary, it was also noted that if, as a precaution, the implantation had only been
made after the age of 7, the results were definitely worse and the implant was often abandoned later on [Snik and coll. 1997; Sarantz and coll. 1994]. It became clear that the earlier the pre-lingual deaf child was implanted the better would the results be [Manrique and coll.2004; Connor and coll. 2006]. It is thus necessary to implant the deaf children quite early in their lives so that they get an optimal rehabilitation.

How can that be explained? The reason seems to be that during the first years of life there is a critical phase of maturation of the auditory pathways [Harrison and coll. 2005]. This maturation phase is equivalent to that of the visual pathways, as described by Wiesel and Hubel [1963]. Indeed, these researchers showed that if the maturation period of the visual system did not proceed normally with the use of the vision of both eyes, it would lead to a phenomenon of “amblyopy”, i.e. that even a healthy eye would, if suffering from amblyopy, remain disconnected from the visual cortex. The assumption was thus made that, in the absence of auditory stimulation up to a certain age, a complete deafferentation of the deaf ear - a kind of “auditory” amblyopy – would develop and prevent the ear to benefit from the implant [Teoh, 2004]. To avoid this situation it was necessary to implant the deaf children at an early age so that they could be precociously exposed to sounds. Among the currently 200’000 implanted patients in the world, half are children implanted in low age. Approximately another half are adults that became deaf. Residually, one finds also a few teenagers or pre-lingual deaf children who were implanted late.

Given the wide diversity of cases that we came across, it was clearly not possible to consider using only a single universal hearing performance evaluation test for all the implanted patients. A post-lingual deaf implanted patient is familiar with oral communication and can be evaluated with the usual tests. The evaluation of a pre-lingual deaf child (with no writing skills) is much more delicate and requires a battery of completely different tests (see Chapter 2). A third standard case is, for example, the late implanted adolescents suffering from pre-lingual deafness. We implanted a small number of teenagers and young voluntary adults suffering from pre-lingual deafness: the results were however rather surprising [Kos and coll. 2009]!

To take into consideration this diversity of cases, the next Chapter, on the results of implantation, was divided into three parts: 1. Implantation of post-lingual deaf patients; 2. Early implantation of pre-lingual deaf; 3. Late implantation of pre-lingual deaf.

3.2. Results of implantation in post-lingual deaf patients

3.2.1. Groups of patient and the types of implant used

From 1985 to the end of 2008, 111 individuals suffering from post-lingual deafness, aged between 6 and 85 years, were implanted in the CRIC. Ninety-three of them (49 men, 44 women) had an updated file in 2008 and were included in this study. Among the 18 remaining patients, 8 died, 5 did not come back to our Centre, in spite of periodic recalls, and 5 had become too old to be tested. Among these 93 patients, 86 were implanted unilaterally, on the worse ear and with the same surgical approach. Seven of the 23 patients who had been implanted with the Ineraid prototype gave up
their old implant and asked for a new one with transcutaneous connexion on the controlateral ear. In such cases, our analysis will only consider the results obtained with the second implant.

The age of the patients at the time of the implantation ranged from 6 to 85 years (average 52 years, SD 15). The time length of implant use varied from 1 to 23 years (average 8 years, SD 6). Sixteen patients (18%) still wear the Ineraid® prototype implanted in our Centre between 1985 and 1995 with the portable vocal processor (GWP) developed in Geneva. Forty-eight (52%) wear a Clarion® model implanted since 1995. Twenty-one (22%) wear a Med-El® model implanted since 2000, and 8 (8%) a Nucleus® model, implanted since 2004.

### Table 3.1: Number of pre-lingual deaf patients, mean age at implantation, and mean time of implant use according to the type of implant (in French)

<table>
<thead>
<tr>
<th>Implant used</th>
<th>N</th>
<th>Mean age at implantation in years (SD)</th>
<th>Mean time of implant use in years (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ineraid (Prototype)</td>
<td>16</td>
<td>51 (16)</td>
<td>17 (5)</td>
</tr>
<tr>
<td>Advanced Bionics</td>
<td>48</td>
<td>53 (15)</td>
<td>7 (3)</td>
</tr>
<tr>
<td>Med-El</td>
<td>21</td>
<td>48 (15)</td>
<td>5 (4)</td>
</tr>
<tr>
<td>Cochlear</td>
<td>8</td>
<td>58 (8)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Total</td>
<td>93</td>
<td>52 (15)</td>
<td>8 (6)</td>
</tr>
</tbody>
</table>

### 3.2.2. The identification of sounds before and after implantation

Performance evaluation before the implantation was made using the vowel and consonant identification test. In this study, we considered the results of the last three vowel and consonant tests before implantation. These were gathered with the best available conventional hearing aid tuned in an optimal way. These few patients who had already given up their hearing aid before the implantation had to re-use theirs in order to be tested. The scores of the tests selected after implantation were those gathered during the last periodic control, in so far as this last control took place at least 1 year after the implantation, to respect an adaptation period. These results are in Figure 3.1. They are presented in the form of the overall performance index as proposed by Rabinowitz and coll. (1992) with the formula \( (C_{14} \times C_{14} \times V_{7})^{0.333} \).
Figure 3.1: Average performance of the 93 post-lingual deaf patients in the identification of vowel and consonant tests, before (black bars) and after (red bars) implantation. We allotted the level of “chance” (i.e. 9% of correct answers) to the completely deaf patients who had obviously not been able to complete the test before implantation.

The average score of correctly identified sounds was, for this group of patients, 23.5% (SD 18.1) before implantation and 65.4% (SD 19.5) after implantation. This increase is statistically significant (Mann-Whitney rank test, p < 0.001).

Of these 93 patients, only 3 have a lower score after implantation. Fifty-two patients were completely deaf before the implantation. We systematically encouraged them to complete the preoperative tests but the majority gave up because they either had not heard any sound or all the sounds were equally and indistinctively perceived. We allotted to these patients a performance level equivalent to the “chance” level (9% of correct answers). It is interesting to note that the average performance of these patients after implantation is not statistically different (Mann-Whitney rank test, p = 0.63) from the average performance of the patients who had a residual hearing before the implantation. Moreover, for this group as a whole, there is no correlation between the performances before and after implantation (Spearman rank order correlation, p > 0.05). This means that the patients having lower auditory performances before the implantation are not necessarily those which will show the lowest performances after implantation, and inversely.
3.2.3. Performances according to the type of implant

Almost all patients obtained an auditory gain after implantation. This gain (i.e. the difference between the percentage of correct answers after and before implantation) is of 38%, 41%, 49% and 30% for the patients using the Ineraid, Advanced Bionics, Med-El and Cochlear implants, respectively (Figure 3.2). The average gain for all the 93 patients is 42%. The users of the Med-El implant get the largest gain (49%) and those using the Cochlear implant get the smallest (30%). This difference is statistically significant (Mann Whitney rank sum test, \( p < 0.02 \)). By looking only at the set of gains after implantation, the results are somewhat different. The users of the Med-El implant still get the highest average performance level (75%) – a noteworthy level – but it is the Ineraid prototype users who get the lowest performance level (53%) (Figure 3.2). This difference is also statistically significant (Mann Whitney rank sum test \( p < 0.01 \)). This apparent inconsistency could be explained by the (statistically) significant difference between the performance levels before implantation of these two groups of patients (Mann Whitney rank sum test \( p < 0.004 \)). But we tend to reject this explanation because, as shown in the preceding paragraph, on the whole there is no significant correlation between the performance levels before and after implantation.

Concluding, we believe that it is not possible to assert on the basis of this set of measurements that there are significant differences in performance levels depending on the type of implant used. These differences are probably not very significant due to the small number of cases in some of the groups. But they could also be due to the fact that the users of the Ineraid prototype were implanted more than 15 years ago - at a time when the criteria for the selection of candidates for implantation were different and certainly not as rigorous as now.

Figure 3.2: Average performances in the vowel and consonant identification tests according to the implant used, before (black) and after (red) implantation.
3.2.4. Performances according to the aetiology of deafness

It is also interesting to analyze our results according to the aetiology of deafness (Figure 3.3). In our group, 57 patients suffered from progressive deafness, 8 from congenital deafness, 10 deafness caused by meningitis, 8 deafness caused by otosclerosis, 6 deafness caused by a disease of Menière and 4 from sudden deafness. Our analyses conclude that there is no evidence that the aetiology of deafness may affect the auditory performances of implanted patients. One should however not jump to conclusions because certain groups of patients are very small and also because it is sometimes difficult to rigorously establish the aetiology of deafness.

![Average performances in the vowel and consonant identification tests according to the various aetiologies.](image)

Figure 3.3: Average performances in the vowel and consonant identification tests according to the various aetiologies.

3.2.5. Performances according to the age at implantation

To get used to communicate orally on the basis of the imperfect sounds given by the implant requires adaptation capacity, which is easier for younger adults. Another age related factor that could have a negative impact on the performance of implants could be, for example, physiological ageing. In our patient group, the age at implantation varied from 6 to 85 years and the average age was 52 years (SD 15). In spite of a relatively scattered set of results, the analysis shows that there is a significant negative correlation ($R = -0.22, p<0.03$) between the age at implantation and the auditory performance level obtained with the implant (Figure 3.4). But we believe that this
correlation is weak and by no means a sufficiently robust argument to refuse implantation in older patients.

![Figure 3.4: Average performances of vowel and consonant identification tests after implantation according to the age at implantation.](image)

3.2.6. Discussion

Almost all patients (96%) have improved their performance in the vowel and consonant identification tests using a cochlear implant whatever the type of implant, the cause of deafness or the age at implantation. All our patients use their implant regularly [Kos and coll. 2007] and two thirds of them can communicate orally without lip-reading such as when using a telephone [Guinand and coll. 2008]. Only 3 patients (4%) had worse hearing performances than those observed before the operation. In spite of this negative result these three patients continue to use their implant on a daily basis while also carrying their conventional hearing aid on the other ear. Incidentally, it should be mentioned that in the cases of asymmetrical deafness, a large number of centres choose to implant the best ear in order to get better results. It is true that the risk to get a disappointing performance - lower than the one the patient has with a conventional hearing aid - is low. But if that would occur we know by experience that the patient feels it all the more badly if it involves his best ear. In the CRIC we implant the least good ear because, as the electrical stimulation “short-circuits” the internal ear, it can still be totally effective even when there is a significant reduction in the number of active ganglion cells [Nadol and coll. 2001].
The analysis according to the type of implant indicates that the performances of the group wearing the Ineraid prototype are not as high as that of the other groups using modern implants. This conclusion is certainly the first that comes to mind, but it should nevertheless be taken with some precaution because the gain brought by this prototype is equivalent to that brought by the more modern implants. A more detailed examination of this situation brings some interesting arguments. The majority of patients carrying the Ineraid prototype suffered from idiopathic progressive deafness. They had normal hearing at childhood and started to lose hearing at puberty to become totally deaf in adulthood. Previously (the first prototype was used in Geneva 25 years ago and the last 15 years ago), there was no satisfactory way of treating deafness and the patients were forced to adapt to deafness. As a consequence, candidacy for implantation was delayed and deafness worsened over time [Bodmer and coll. 2007]. Indeed, all the patients were implanted with an Ineraid prototype had become completely deaf (except one who had an auditory performance slightly better than the “chance” in the vowel and consonant identification test). Later on, with the success and diffusion of cochlear implantation this situation changed, particularly thanks to a decrease in tolerance to deafness. Patients started to ask for an implant much earlier, before deafness became total. Nowadays our candidates are implanted at a time when a hearing aid would still be beneficial to help supporting at least lip-reading and detect very loud sounds. However, as the quality of auditory discrimination is sharper the more excitable fibres of the auditory nerve are functional, it is crucial to be early implanted because the preservation of these fibres is inversely proportional to the duration of deafness and directly proportional to the residual hearing [Nadol and coll. 2006]. We believe that the current broadening of the implant indication as well as the fact that the patients are taken charge of much earlier resulted in implantation being done in more favourable conditions, that is, when the patient still has a larger number of surviving auditory fibres. This in our view one of the essential reasons why, in parallel to technological progress, the level of performances has increased regularly over the last three decades.

In our study, we do not find differences in patient’s performances according to the aetiology of their deafness. On the one hand, it is difficult in many cases to identify the exact type of pathology. For example, “idiopathic progressive deafness”, which affects the majority of our patients, is probably a category actually including various aetiologies, including probably genetic causes not yet totally identified [Berrettini and coll. 2008]. On the other hand, the various pathologies that attack each of the structures of the peripheral auditory system result, in the long run, in similar destructive patterns. They all firstly damage the hair cells and then cause the degeneration of the ganglion cells of the modiolus. The cochlear implant “short-circuits” the cochlea and stimulates directly the remaining fibres of the auditory nerve. It is therefore not surprising that the results with the cochlear implant are rather independent from the precise type of the hearing pathology.

The results presented in this Chapter are based on the vowel and consonant identification tests. Even if the latter are strongly correlated to other tests of
speech understanding [Rabinowitz and coll. 1992], it is difficult to compare our results to those of other centres because these tests vary from one centre to the other [Battmer and coll. 2009]. However, most studies tend to confirm a clear improvement in the quality of life of implanted post-lingual deaf patients, independently of their type of deafness, model of implant or even of their age. Three in every four patients in our group have been elderly implanted. With their implant they get a speech understanding, which is better than what they had with their conventional hearing aid. This is encouraging because, with the ageing of the population, the elder patients, suffering from presbycusis, will gradually become an increasing proportion of the candidates for implantation. We have however noticed that the potential hearing gain of a cochlear implant decreases with age. This observation is also found in many other studies [Esraghi and coll. 2009; Francis and coll. 2002; Waltzman and coll. 1993]. How to explain the effect of age on the auditory performance of an implanted person? It is difficult to answer to this question and particularly difficult to check if the influence of age results from a progressive peripheral degeneration or from a reduction in the ability to decipher the imperfect auditory messages conveyed by the implant.
3.3. Results of implantation in early implanted pre-lingual deaf patients

3.3.1. The groups of patient groups and the types of implant used

From 1998 to the end of 2008, 44 children, aged 1 to 6 years, suffering from a congenital or pre-lingual deafness were implanted in our Centre. All were operated according to the same surgical technique, 38 unilaterally on the least good ear and 6 bilaterally. Seventeen received Med-El® implants, 15 Advanced Bionics®, 11 Cochlear® and, 1 an Ineraid prototype. Of the 44 children, 27 (9 boys and 18 girls) had updated medical files in 2009 and could be included in our study. Among the not included 17 other children, 7 could not take the tests (6 had been implanted at the age of less than one year and 1 suffered from serious cognitive deficits) and 10 could not be contacted (7 moved abroad and 3 refused to be tested). Table 3.1 indicates for all the 27 children the type of implant used, the age at implantation and the length of time the implant was in use.

<table>
<thead>
<tr>
<th>Type of implant</th>
<th>N</th>
<th>Mean age at implantation years (SD)</th>
<th>Mean time of implant use years (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Bionics</td>
<td>10</td>
<td>3.2 (1.5)</td>
<td>9.0 (2.8)</td>
</tr>
<tr>
<td>Med-El</td>
<td>13</td>
<td>2.9 (1.3)</td>
<td>6.5 (1.8)</td>
</tr>
<tr>
<td>Cochlear</td>
<td>4</td>
<td>2.0 (1.2)</td>
<td>4.3 (0.4)</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>2.9 (1.4)</td>
<td>7.1 (2.6)</td>
</tr>
</tbody>
</table>

3.3.2. Evaluation of the speech understanding of young implanted children

In this part, a comprehensive view of results is presented, in the form of an “instantaneous photography” of the long term (average 7.1 years, SD 2.6) performances of implanted young children. All children had been evaluated periodically with one or more CRIC tests and (2) rating scales. As already mentioned, this battery of tests was designed to evaluate the auditory performances of young children (see Part 2.6.2). We will first present the scores of the 27 children at the time of the last session when the various tests of our battery were applied: the Minimal Pairs (PM) test, the “Phonetically Balanced Kindergarten (PBK)” test and the “Repetition of Simple Sentences” (TRPS) test. Let
us also recall that the scores of these tests are defined as the percentage of correct answers given.

In the PM test, 16 children out of 27 reached the maximum score (100%). Although this test requires a developed language sound discrimination, it appears to be a relatively easy test because the average score of the group was very high (94.8%, SD 7.5). The PBK test is more difficult. No child reached the maximum score and the interindividual variance was large. The average score of the group was 80.8% (SD 18). In the TRPS test, 15 children out of 26 got the maximum score and the average score was 91.7% (SD 16).

The results of the two rating scales of our battery, the Capacity of Auditory Performance (CAP) and the Speech Intelligibility Rating (SIR), are consistent with the results of the preceding tests. On the CAP scale, 13 children out of 27 got the maximum score and the average score of the group was of 6.14/7 (SD 0.98). On the SIR scale, 21 children out of 27 got a maximum score and the average score was also very high (4.59/5, SD 0.84).

These “gross” results show that the children suffering from pre-lingual deafness that were implanted between the ages from 1 to 6 years, from various aetiologies and receiving implants of different brands, can all, with no exception, manage to develop some control of the oral language. But it should be stressed that to reach such a level of control all these children benefited over several years (4 to 12 years) from very intensive and specific oral rehabilitation training.
Figure 3.5. Scores achieved by each of the 27 children on the PM, PBK and TRPS tests and on the CAP and SIR scales.
3.3.3. Language development after implantation

A normal child, having had since birth a perfect hearing, 24 hours a day, only delivers his first words at around one year of age and needs several years before becoming able to communicate orally in an understandable way, using simple sentences. A pre-lingual deaf child only starts to hear after being implanted and this hearing does not have the same quality as that of a normal child. At what speed can one expect this child to have the control of oral language? It is very difficult to precisely answer to this question because the existing tests to evaluate language development of newborn children only measure a subset of the various aspects (even sometimes only one aspect) of this development. It would therefore be necessary to apply an even larger and more specific battery of tests to each child and at regular intervals. Moreover, as with normal children, the interindividual variance of language acquisition among implanted children is very large because it depends on factors specific to the child as well as on other factors such as the family, the environment, etc.

We have not studied in Geneva specifically the stages of language development of implanted children. However, we will try to illustrate this development in our group of children by showing, on the basis of the most difficult test (the PBK), how their hearing scores progressed over time. For some children we have up to 11 years of post-implantation measurements. Over this period, this test was applied 100 times to 23 out of the 27 children under examination (from 2 to 9 times per child). Figure 3.6 shows, for each of these children, the evolution of the score according to the length of time of implant use. Although these data are scattered, they show that 17 of the 23 children reach a score of 80% of correct answers before the fourth year of use. The data also show that some other children clearly progress more slowly, which is an indication of the large interindividual variance of language acquisition.

Figure 3.6: Scores of 23 pre-lingual deaf children with the PBK test according to the time length the implant has been in use. Each line represents a child.
3.3.4. Discussion

At the time (1985) of multichannel cochlear implants of first generation, implantation was seldom proposed to children suffering from pre-lingual deafness. Implanting pre-lingual deaf children started in a large scale only when the multichannel cochlear implants of second generation were marketed. It should be underlined that the first studies included heterogeneous groups of children (with very different ages at implantation, suffering from various types of deafness, etc.). For this reason they have sometimes reached conflicting results [O’Donoghue and coll. 2000] to the point that some authors expressed doubts about the capacity of these implanted children to learn the oral language. It was noticed that some children implanted lately had previously developed a visual mode of communication. This communication mode remained for them a priority which hindered the development of the oral communication. At this time, most surgeons of the ENT community started to propose implantation to these children increasingly earlier because of the existence of a critical period of neuronal plasticity of the auditory system [Manrique and coll. 2004; Harrison and coll. 2001; Nikolopoulos and coll. 1999; Wu and coll. 2003; Kileny and coll. 2001; Snik and coll. 1997].

The results presented in this part concern children who were on average implanted at the age of 2.9 years (SD 1.4). The “instantaneous photography”, presented in Part 3.3.2 shows that the majority of our children acquired some control of the oral language, approximately equivalent to that of a normal child, at the age of circa 3 years. Our results also show that several years of specific oral rehabilitation were necessary to enable the deaf implanted child to acquire such a control level. Thus apparently the deaf child, as compared to a normal child, develops language with an initial delay and progresses at a somewhat slower pace. But all these originally deaf children progress to a satisfactory level of oral communication. At this level, it enabled 24 out of our 27 children to attend normal schools and communicate in oral language at school and at home. The other three children attended a school for deaf with predominant oral language and exclusive use of oral language at home.

Even if the results presented in this Part are qualitatively similar to those presented by other centres, a rigorous quantitative comparison of the hearing performances is practically impossible. In an extensive and systematic review of the recent literature, Bond and coll. [2009] show that, in this area, the quantitative comparisons suffer from important methodological limitations. Indeed, most groups under study are small and heterogeneous. They include children of different ages, with different mother tongues and different lengths of implant use; they are subject to different methods of rehabilitation, etc. This being said, there are however rather solid arguments in support for an early implantation. The first most relevant argument, in our opinion, is to avoid as much as possible a gap between the development of the cognitive and the oral language [Nicholas and coll. 2007]. If this gap is small, the child can integrate normally the oral communication to his daily needs. If this gap is large, the child’s oral communication capacities will not be, shortly after the implantation, at the level of his daily needs. He will be frustrated by this delay and will probably tend to use visual communication modes. The second argument, which has still to be verified scientifically, is the existence of a critical period of plasticity of the central auditory system.
But to lower the age for the implantation of children is not without risks. One should not underestimate the limitations related to surgical safety and, even more important, the difficulties in confirming the diagnosis of deafness in small children. The key question is thus which is the ideal age for implantation? Let us recall that the children whose results were presented in this Part were implanted on average at the age of 2.9 years (SD 1.4). That is not particularly early and our results do not seem to be worse than those of other centres. We thus think that the cochlear implantation surgery can safely be carried out in children from the age of 1 year and in any case before the fourth year of age.

3.4. Results of implantation in late implanted pre-lingual deaf patients

3.4.1. The groups of patients and the types of implants used

From 1994 to the end of 2008, 22 patients, aged from 7 to 22 years (average 14 years), suffering from congenital deafness, were implanted in our Centre. At the time of this study, only 13 (9 men and 4 women) had an updated medical file and could be included in our analysis. Among the 9 others, 4 had moved away from our centre and 5 had abandoned their implant. The 13 selected patients were implanted unilaterally on the least good ear, by the same surgeon and with the same surgical technique. Their time of use of the implant ranged from 3 to 8 years (average 4.5 years). A Med-El implant was used in 8 cases and a Clarion implant in 5 cases.

3.4.2. The modes of communication before and after the implantation

Before implantation, none of these patients used the oral language. Six patients used “cued speed” (CS) [Cornett, 1988] and attended normal schools. Seven patients used the French sign language (LS) and had been in school for deaf children with the LS as a prevalent communication mode and CS as a support for oral language. After the implantation, 4 of the 6 users adopted exclusively the oral language while only 1 of the 7 LS users did the same. We will distinguish the two user groups (LS and CS) because it is meaningful to highlight the differences in performance according to the main mode of communication used before implantation.

3.4.3. Hearing thresholds before and after implantation

Before implantation, all the patients wore conventional hearing aids with which they had a hearing threshold of 80 to 110 dB, in the frequencies between 250 and 400Hz.
After implantation, they all improved significantly their performance to an auditory threshold of 40 dB HL or higher in all the frequencies (except for a single case at 250 Hz, see Figure 3.7). There is no marked difference between the auditory benefits brought by the implant to the users of the CS and the LS.

![Figure 3.7: Hearing thresholds at the tonal audiogram for the 13 patients of this study, before and after implantation. Blue lines: Users of cued speech (CS). Red lines: Users of the sign language (SL).](image)

3.4.4. Level of oral communication *before* and *after* implantation

Before implantation, this group of patients got an average performance in the vowel and consonant identification test of 21% (SD 13), which ranged from the level of the
chance to 35% of correct answers. The evaluations of their auditory performance on the CAP scale ranged from levels 2 to 4, with one patient on level 2, ten on level 3 and two on level 4. The evaluations based on the SIR scale ranged from levels 1 to 3, with five patients on level 1, four on level 2 and four on level 3. All these results are shown in Figure 3.8.

After the implantation, the average performance of these patients in the vowel and consonant identification test rose from 21% to 47% of correct answers (SD 26). The individual performances ranged from the level of the chance to 86%. The average performances on the CAP and SIR scales improved with the use of the implant.

But the interest of this study goes beyond the simple examination of performances. We also wanted to check if the benefits brought by the implant changed according to the preferential mode of communication used before the implantation. Our results show that the users of the CS got vowel and consonant identification test scores after implantation significantly better than the users of the LS (p=0.03, t=2.34) whereas there was no difference in the scores between these two groups before implantation. In a similar way, the users of the CS got scores in the CAP scale significantly better (p=0.004, t=3.59) after implantation than the users of the LS whereas there were no differences between them before implantation. Finally, the two groups also got significantly (p=0.04, T=2.32) different scores on the SIR scale after the implantation, but such differences existed already before implantation (p=0.004, t=4.95).

![Figure 3.8](image)

**Figure 3.8:** Individual scores of the 13 patients of our study before and after the implantation. On the left: average scores of the vowel and consonant identification test. In the middle: evaluations of hearing perception according to the CAP scale. On the right: Evaluation of the word intelligibility according to the SIR scale. Blue lines: users of the cued speech (CS). Red lines: users of the sign language (SL).

### 3.4.5. Discussion

There is an important distinction to be made between the hearing gain measured with the tonal audiogram and the benefit brought by the implant. The hearing thresholds after implantation improved for all patients, whatever the mode of communication used. The hearing benefit brought by the implant is thus the same for the users of cued speech as for the users of the sign language. Both groups have improved their
performances in the vowel and consonant test and in the scale of speech intelligibility as well as in the scale of auditory performance. But such improvements were significantly larger for those patients who, before the implantation, used cued speech as compared to those who used the sign language. There is thus a significant difference in the benefits for oral communication between these two groups.

The advantages of very early implantation of pre-lingual deaf children [Manrique and coll. 2004; Kileny and coll. 2001] as well as of post-lingual deaf patients [Sterkers and coll. 2004; Proops and coll. 1999] are well established. However, there is a kind of consensus on whether the hearing results of the implanted pre-lingually deaf children are worse when implantation is done after the age of 6-7 years [Snik and coll. 1997; Sarantz and coll. 1994; Kaplan and coll. 2003]. Very seldom a pre-lingual deaf patient who was not implanted before the age of 7 will ask for a cochlear implant. Usually, these individuals are already integrated in the deaf community and have adopted a visual communication mode via the sign language [Schramm and coll. 2002]. However, there are also a few pre-lingual deaf children who were not implanted before the age of 7 who have developed (probably under pressure from their entourage) the oral language but with the support of lip-reading and cued speech. The question is then whether under these very particular conditions, the implantation can still bring benefits or if, as some authors suggest, the absence of sound stimulation during a possible critical period of hearing plasticity leads to an irreversible “visual colonization” of the hearing cortex [Teoh and coll. 2004]. This kind of “hearing” amblyopy would prevent such patients from getting any benefits from the implant [Moore, 2002; Harrison and coll. 2005; Kral and coll. 2006; Clopton and coll. 1977; Sharma and coll. 2007].

Our study throws a different look at the phenomenon of the cerebral plasticity of the central hearing system. The “real” amblyopy, the visual amblyopy, disconnects the 4c layer of the primary visual cortex from the other layers of the same cortical area (area of Brodman 17). The benefits measured with the tonal audiogram show that in spite of a long period of deafness, the implanted ear remains connected to the central hearing system, at least to the primary hearing cortex and its directly adjacent areas. We therefore believe that, strictly speaking, the hearing amblyopy does not exist! Indeed, all our observations point to the fact that the worst performances obtained by the patients using the LS are not due to the lack of hearing stimulation but to the fact that these patients are unaware of the structures of oral language. If not, why would the CS users get better results than the LS users? The training of the oral language in childhood, with the assistance of CS [Torres-Moreno and coll. 2006] or lip-reading [Moody-Antonio and coll. 2005], requires definitely a significant effort, but it makes it possible to acquire of these structures. Therefore, when these patients receive a cochlear implant they can organize the perceived sounds in a coherent way which enables them to understand the messages and to communicate. On the other hand, the users of the LS have a mode of communication that is solely visual and spatial. They decipher the information via a sequence of images or gestures by the interlocutor. Their “decoding algorithms” have nothing to do with those making it possible to decode a series of sounds making the sequence of phonemes that form words which are then put in a grammatical order to form sentences. It is extremely difficult, but not impossible, to turn from a visual and spatial communication system to one hearing [Cassandro and coll. 2003]. There was only one exception in our study. Actually, one patient succeeded in turning exclusively to oral communication while having been previously a LS user.
This does not mean that there is no plasticity in the hearing system. It is possible that higher cortical areas are prone to plasticity, such as those areas used for the segmentation of language sounds or even the area of Wernicke, which associates a series of phonemes to its symbolic significance. This is not in any way surprising because, on the issue of language production, plasticity evidently exists: a deaf person until the age of 7 will keep forever the “voice of a deaf person”. Consequently, the training of oral communication via the CS should always be envisioned for any pre-lingual deaf patient when an early implantation is not decided. This enables “the formatting” of the higher cortical areas and gives thereafter the possibility of choosing between oral and visual communication.
4. Complications resulting from implantation

The number of implanted patients has been increasing since the very first cochlear implantations. The same is true for the time length of implant use and for the number of implant related complications. The description and the analysis of these complications are an important source of information for all the professionals looking for explanations or solutions related to implantation. These analyses also allow these professionals to progress and build more reliable implants. In this Chapter we deal with all the complications faced by implanted patients that required a surgical revision, with or without replacement of the implant.

4.1. Material and methods

A complete investigation of the implant is done when a patient consults our centre for having had an accident, a clinical unexplained complaint, a dysfunction of the processor or sometimes even for not being satisfied with the hearing performance. An engineer then controls the function of the processor and of each of the electrodes. If necessary, the physical integrity of the implant, the positioning of the processor and of the electrode array are checked with radiographies. Whenever a reimplantation is necessary, we compare the hearing performances before and after the replacement using the vowel and consonant identification test.

The complications, which we treated and which are described hereafter, can be classified in 4 categories:
- Electronic failures
- Implant fractures
- Infections
- Problems in the positioning of electrodes.

4.2. The complications

Since 1985, 206 implantations were done in our Centre. We dealt with 22 complications (in 15 adults and 7 children), which required a surgical revision. In 16 of these cases (10 adults and 6 children) the implant had to be replaced. The overall results are presented in Table 4.1.
<table>
<thead>
<tr>
<th>Type of implant (n=206)</th>
<th>Adv. Bionics (n=90)</th>
<th>Med-El (n=55)</th>
<th>Ineraid (n=34)</th>
<th>Cochlear (n=27)</th>
<th>Reimplantations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic failure</td>
<td>10</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>Implant fracture</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Infections</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Positioning of the electrodes</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total des complications</td>
<td>14 (15.5%)</td>
<td>6 (10.9%)</td>
<td>1 (2.9%)</td>
<td>1 (0.3%)</td>
<td>16 (10.7%)</td>
</tr>
</tbody>
</table>

4.2.1. Electronic failures

This kind of failure occurs when the stimulating implant stops functioning, i.e. when it does not respond to any attempts of connection even when using more powerful equipment that is in principle only used for research. This breakdown is very annoying for the patient and extremely embarrassing for the medical team. There is no alternative except envisaging a new surgery to replace the defective implant.

We came across an electronic failure of the processor in 11 cases, including 10 with an Advanced Bionics® implant and 1 with a Med-El®. After reimplantation, the defective implant was returned to the factory for a thorough analysis to identify the causes of the breakdown. The most frequent cause, except when an objective structural damage is found, is a defect of the sealing of the encasement of the stimulating implant encasement. Moisture penetrates this encasement and ends up disturbing the functioning of the internal electronics.

4.2.2. Implant fractures

This kind of breakdown is characterized by a structural defect of the implant that can be identified visually (possibly by radiography or microscopy). It is usually caused either by a fracture of the encasement of the implant or by micro fractures in the internal electronic chip. In such cases the stimulating implant “is broken physically” and does not respond to attempts of connection. This breakdown is as unfortunate as the electronic failure, but as it occurs as a result of a traumatic shock we at least have the advantage of identifying the cause of the breakdown. As with the electronic failure, it is also necessary in this case to envisage a new surgery to replace the damaged implant.

We found a fracture of the implant in 4 cases, including 3 Med-El® (standard Combi 40+) and one Ineraid prototype (its percutaneous plug was destroyed in a road accident).
4.2.3. Infections

This complication is defined as an infection resulting from the implantation and resistant to all treatments. It ends up requiring a new surgical operation. We came across only one of these cases. The infection appeared 18 months after the implantation and was located around the implant and resisted to all medical treatments. The bacteriological examination of the puncture of the infected site showed a S. aureus infection. The patient was immediately treated with amoxicillin/clavulanate orally. The infection persisted and the patient then followed a treatment with ciprofloxacin and rifampicin orally during 8 weeks without success. Following these failures, the implant had to be removed. Its examination showed the formation of S. aureus biofilm around the body of the processor, located predominantly in the pocket of the removable magnet [Kos and coll. 2008]. This patient had been implanted with a device of last generation, which was sealed in a film silicone with the pocket. A reimplantation was made 3 months after the first implantation, on the same ear. Today, two years after reimplantation, the patient did not show any infectious recurrence.

4.2.4. The problems in the positioning of electrodes

This kind of failure results from a bad positioning of the electrodes, which could not be detected and corrected at the time of the surgery. When the electrodes are not properly positioned they do not function or function only imperfectly.

Implantation outside the cochlea
We had an extra-cochlear positioning of the implanted electrode array in 2 cases. They were 2 adults who had new ossification processes. This was due in one case (Figure 4.1) to a chronic otitis with S. aureus and in the other to meningitis. The two patients had received Med-El systems. In the first case, the array was placed in the Eustachian tube and in the second (Figure 4.2), in the vestibule. The 2 patients were reoperated one week after the first surgery in order to correct the positioning of the array of electrodes, without the replacement of the implant.
Figure 4.1: Tomography made before implantation of a patient who became deaf from chronic otitis with S. aureus and who had been previously operated for the complete obliteration of the middle ear. Note the relief of the promontory and of the middle ear as well as of the round window, which are erased by the neo-ossification (red arrow). The cochlea is normal.

Figure 4.2: Radioscopy made immediately after implantation of a patient who became deaf by meningitis with ossification of the basal turn of the cochlea. The electrodes array is rolled up in the vestibule in a way similar to that which one observes in a normal cochlear implantation (white arrow).

Extrusion of the array of electrodes
We had a case of extrusion of the electrode array. It was an adult who had received an Advanced Bionics (standard Clarion C2) implant together with an Electrode Positioning System (EPS). The EPS is a silicone part shaped like a “flap”, which is inserted between the electrode array and the outer wall of the cochlea. The EPS brings the electrodes closer to the inner wall of the cochlea and to the excitable cells of the modiolus [Fayad and coll. 2000]. During the first month of implant use, the patient complained that he was occasionally hearing explosions which were sometimes painful. After examination, we identified a polyp on the tympanic membrane. This polyp surrounded the end part of the EPS that had migrated out of the cochlea, traversing the tympanic membrane. Once the EPS was withdrawn and the array reinserted in the cochlea, the implant functioned normally.

Too deep insertion of the electrodes array
We had 3 patients with a too deep insertion of the electrode array into the cochlea. Two of them were Advanced Bionics systems with an EPS. At first, these two patients complained because they perceived too “low-key” sounds. This could be due to the activation of the most apical area of the cochlea [Kos and coll. 2007]. These patients were rigorously examined. It was possible to demonstrate that their identification scores in the vowel and consonant test improved when the deepest electrodes were disconnected. We were facing a completely unusual situation i.e. a situation of improvement in the hearing performance while the number of active electrodes was scaled down. It was clear that the activation of the deepest electrodes had a negative effect on the hearing performance. The radiographic images showed that these electrodes were located well beyond the average and appropriate depth (478°) for this model of electrodes array [Kos and coll. 2005]. In these 2 cases, during the surgical reoperation done under local anaesthesia, the arrays were withdrawn approximately 3 mm out of the cochlea and the EPS removed. The angle of insertion
of the apical electrode was lowered from 720° to 485° in one case and, from 675° to 433° in the other (see Figure 4.3). After this surgical correction, the patients no longer complained of perceiving too low-key sounds and the score of one of the patients in the vowel and consonant identification test improved significantly, rising from 51% to 66% of correct answers (p< 0.05). Unfortunately, we could not test the other patient because, for medical reasons, he could no longer take tests.

The 3rd case was a child implanted with a Cochlear (of type Ci 24R) implant. This implant has a preformed array of electrodes that, once inserted in the cochlea, rolls up strongly around the modiolus. To facilitate the implantation, this array is held straight by a wire which must be withdrawn during its insertion. A control radioscopy made after the operation showed that the array had been introduced too deeply, to the apex of the cochlea, beyond what is recommended by the manufacturer (see Figure 4.4). One week after the implantation, the array was withdrawn from the cochlea by approximately 3 mm during a surgery done under general anaesthesia. The follow up procedures to adapt the external processor were done in the usual way 1a) 2a) 1b) 2b).

Figure 4.3. Too deep insertion of the electrodes array in 2 adults having received the Clarion CI implant with the EPS. The wrong positioning of the electrodes array(1a and 2a) was corrected by removing the EPS and the deinsertion of the array (1b and 2b).
4.3. Hearing performance after surgical revision

Twenty-two patients had a complication that required a surgical revision. Fourteen of them were tested with the vowel and consonant identification test before and after the failure. For the other 8 we do not have tests, either before or after the revision. Among them, there were 5 patients who had the surgical revision before being tested but these patients now get identification performances close to the average (65.4% correct responses) of our group of 93 post-lingual deaf persons (see Chapter 3.2.2). Other 2 were very young children who had not been tested before the surgical revision. However, their parents and therapists reported that the children’s hearing performance after reimplantation was equal and even slightly better than before. Finally, one last patient was an adult who for medical reasons did not take part in any of the tests after the surgical revision.

Figure 4.5 shows the scores of the 14 patients having been tested, before and after the surgical revision. After implantation, eight patients improved their scores (by at least 5%, but some even more significantly), 3 had unchanged performances and 3 experienced a declining performance. In these 3 cases, reimplantation resulted in a reduction of the number of active electrodes. The reason was that the new array of electrodes could not be reinserted in the same way as in the first surgery. In 2 of these 3 cases, the patients had received an Advanced Bionics (with Helix electrode array) implant and an important intra-cochlear fibrosis prevented the whole insertion of the new array. The third patient had a cochlear ossification, which had already, in the first surgery, prevented the insertion of the whole Ineraid electrodes array.
4.4. Discussion

**Electronic failures**

The main cause for surgical revision in 11 (68%) of the 16 reimplanted patients was a defect in the sealing of the implanted case which houses the electronic device. In 10 of these 11 cases, the systems used were Advanced Bionics (6 of the model Clarion® C1 and 4 of the model Clarion® N90K/LX). The manufacturer confirmed all these sealing defects. This means that 11% of the 90 Clarion devices, which we implanted, have presented failures. Battmer and coll. [2009], on a very large series of 866 implants of this same brand, found a similar incidence (10.6%) of sealing defects in the models used in the same period. This author also points out that this type of failure was more frequent when the electronic devices were encased in ceramic cases. Our series, which is too small to allow a statistical analysis, show that both the single Med-El and 6 out of the 10 Advanced Bionics reimplanted devices had ceramic cases.

**Implant fractures**

Fractures of the body of the stimulating implant happened in 4 cases. In 3 of them (2 children and 1 adult) the implants were of the Med-El® Combi 40+ model. This model has a thin and flat ceramic body, which is not very resistant to shocks. In the
fourth case, the patient had an Ineraid® prototype with a percutaneous plug connecting the implanted electrodes to the external processor. This percutaneous plug that is screwed in the temporal bone is purposefully made out of carbon, a relatively fragile material, which acts as a fuse in the event of a violent shock. It is exactly what occurred with this patient who had cranial trauma when hit by a car.

The inherent fragility of the ceramic body has led certain authors to advise against its use when implanting children because the latter are more exposed to the risk of shocks than adults [Gosepath and coll. 2009]. In our small series, contrary to many authors [Brown and coll. 2009; Cullen and coll. 2008; Sorrentino and coll. 2008; Gosepath and coll. 2009; Ovesen and coll. 2008], we recorded an overall complication rate of children lower than that of adults. This can be due to a lack of statistics but perhaps also because we follow very strict rules with respect to the prevention of accidents: we systematically advise the parents to avoid high-risk sports and we insist on the importance of wearing a helmet when cycling and skiing.

Infections
Infections are the most frequently reported medical complication from cochlear implantation. They cause necrosis or dehiscence of the surgical wound and rejection of the implant [Harada and coll. 2003; Cunningham and coll. 2004]. This type of complication, that we had not come across so far, is relatively rare and is usually treated with antibiotics and surgery [Yu and coll. 2001].

We recently had one case of infection among our implanted patients. Because of the presence of bacterial biofilm that brought resistance to antibiotic it became necessary to remove the implant. Infection by bacterial biofilm as a cause of rejection of the implant has been underestimated because it has not been systematically investigated [Antonelli and coll. 2004]. In the literature, only two cases of persistent infection by S. aureus were clearly associated with biofilms. A large concentration of biofilm was found [Loeffler and coll. 2007] in these two cases and them both had implants carrying removable magnet pockets.

Difficulties in the positioning of the electrodes
Malpositioning of intra-cochlear electrodes constitutes the second most frequent cause of complications observed in our study. In 6 of the cases, surgical revision enabled the correction of the positioning of the electrode arrays without requiring a new implantation. This was feasible in adults, under local anaesthesia through the external hearing channel in 5 of these 6 cases. The advantage of the transmeatal approach technique deserves, once again, to be mentioned. This approach, which is minimally invasive, allows readjusting the positioning of the electrodes and preserving the implant.

In spite of an increasing surgical experience, extra-cochlear implantation is a recurrent complication [Migirov, 2007]. It is almost always associated with reossification of the cochlea [Sorrentino and coll. 2008; Cullen and coll. 2008; Venail and coll. 2008; Lassig and coll. 2005]. It was also the case in our series as we found extensive ossifications in 2 patients. They had a Med-El implant, which has an electrode array especially conceived to beatraumatically inserted. Malleability, which in most cases is very practical, can also induce a misleading impression of successful implantation. When the array does not penetrate the cochlea, it does not behave like a “spring” as other more rigid or preformed array. It adapts to any surface [Arnold and coll. 1997]. Moreover, in 1 of these cases, the per-operatory radioscopy induced an error by showing the array rolled up in the vestibule, in the same shape of a normal
implantation (Figure 4.2). A similar evaluation error is reported by Sorrentino and coll. [2008].

The only case of extrusion of the electrodes array that we observed had a special additional system - the EPS. We supposed that the extrusion of the array could result from an excess of tension imposed on the elasticity of the cochlear membranes. Migirov and coll. [2007] describe a case of extrusion of the same system preceded by several episodes of acute otitis. Green and coll. [2004], in a series of 240 cases, observed extrusions of the array of electrodes in 3 cases, but they did not specify the surgical procedure used. Connell and coll. [2008], although considering that this form of complication is rare, place it as the second cause of reimplantation. They advise surgeons to fix the array at the entry of the cochlea either with a clip or by obliterating the cochleostomy with a piece of aponevrosis and adapting the excess length of the cable in the mastoidotomy: this is the technique, which we have adopted. In our view, this is sufficient to maintain the array inside the cochlea.

The 3 cases of a too deep insertion of the electrodes array are associated with the use of devices aimed at placing the electrodes close to the modiolus. In 2 cases, the patients had been extensively examined and we had been able to show, before the surgical revision, that their sound identification improved when the deepest electrodes were disconnected [Kos and coll. 2007]. Moreover, it was impossible to only disconnect the deepest electrodes. That would result in leaving insufficient stimulation for an optimal performance. Some of the deep electrodes produce interactions, which are harmful to performance [Gani and coll. 2007]. What is the reason for that? Briaire and coll. [2006], on the basis of a digital model, show that in the event of a degeneration of the peripheral process of the ganglion cells, the body of the cells in the spiral ganglion is directly stimulated. This enhances the risk of crossed stimulation, particularly due to the electrodes located towards the apex of the cochlea, because of the anatomical distribution of the cells at this location.

4.5. Conclusion

Firstly, even if it is reasonable to expect that hearing performances will not be affected by reimplantation, there is always the risk that after a new implantation it does not reach the level of the preceding implantation [Roland and coll. 2006: Gosepath and coll. 2009; Ovesen and coll. 2008; Brown and coll. 2009; Venail and coll. 2008; Coté and coll. 2007]. This risk has many consequences, particularly for the pre-lingually deaf child who is still learning the language. The comparison of the scores of the vowel and the consonant identification test, before and after reimplantation (Figure 4.5), shows that this risk is however limited: in our group of patients, only 3 out of 14 had a significant deterioration of their performances. Fortunately, in our small series, the 7 children who had to be re-implanted maintained identical performances.

Secondly, in our series as a whole, a reimplantation was necessary in 7.7% of the cases. This rate is comparable to those reported by other implantation centres in studies already mentioned: 13.2% for Gosepath, 11% for Migirov, 8.3% for Sorrentino, 7.2% for Venail, 6.2% for Coté, 5.5% for Brown.

It should be kept in mind that the technological progress of cochlear implants is remarkable. These failure rates compare for example very favourably with that of the
paediatric pacemakers that have moreover a vital importance! Such rates can range from 8% [Tomaske and coll. 2008] to 18% [Ector and coll. 2006].

Finally, as in most other groups of patients, the most frequent cause of reimplantation is due to a “hardware failure”, i.e. a failure of the implanted stimulator that could be objectively verified with physical measurements. We never observed any failures resulting from the “software”. This kind of failure causes unexplainable performance losses or the perception of odd noises even in the absence of any identified defect in the implanted device [Balkany and coll. 2005]. It is surprising that in some centres, this type of failure ranks second among the causes of reimplantation [Venail and coll. 2008; Gosepath and coll. 2009; Brown and coll. 2009; Sorrentino and coll. 2008].

Finally, as the Swiss regulations stipulate, we have taken great care in preserving each explant and returning it for examination to the manufacturer under the best conditions. This was done each time a hardware failure could be objectively determined. The systematic analysis of the breakdowns is undoubtedly a procedure, which contributes significantly to the improvement of the reliability of the systems of implant.
5. From cochlear implants to vestibular implants: Initial steps

5.1. Context and objective

Prof J-Ph. Guyot, whose main area of expertise is otoneurology, was appointed chief of the ENT Department of the Geneva University Hospitals in 2004, after the retirement of Profs P. Montandon and W. Lehmann. Our long-standing clinical research in the field of otoneurology and of cochlear implantation has led us naturally develop the project on vestibular implants. There had been moreover nearly 40 years of close collaboration with the “Massachusetts Eye and Ear Infirmary” of the Harvard Medical School in Boston. This collaboration involved us in the research of an electrical stimulation model for the vestibular system of animals. Profs Daniel Merfeld of the Jenks Vestibular Physiology Laboratory and Conrad Wall III of the Vestibular Laboratory, were in charge of this project. We started a new collaboration with them. This was a unique opportunity to participate in the basic ongoing research on animals, which together with our original work on the electrical stimulation of the human ear, enabled us to carry out studies to determine whether what had already been partly done on the animal could be applied to humans.

It is currently estimated that in the United States more than 40% of the population consults with a doctor, at least once, because of balance disorders: more than 6 million people suffer from such a disorder chronically [National strategic research for plane balances and the vestibular system, 1991; Vital Health Statistics, 1994]. Over the next decades, the sustained ageing of the population will turn balance disorders into a growing public health problem. Yet there are not any biological ways of regenerating the damaged vestibular neurosensory structures that are the cause of such disorders.

The vestibule of the internal ear, which is close to the cochlea in the labyrinth together with the vision and the somesthetic/pathways, play a significant role in space positioning as well as in keeping the posture and stabilizing the visual image on the fovea [Guyot, 1993]. The unilateral loss of one vestibular organ does not usually cause major disorders on the long term because a compensation process results from the plasticity of the central nervous system [Curthoys and Halmagyi, 1999]. On the contrary, a bilateral loss, resulting from degeneration due to ototoxic, infectious, traumatic, congenital causes or from vestibular ageing, may lead to important imbalances that can bring a person to fall, sometimes with morbid consequences, in particular among the elderly. The bilateral loss also causes visual disturbances such as oscillopsies i.e. when it becomes difficult to stabilize the visual image on the fovea while moving. Being unable to read while walking is an example of this difficulty. In every case, the quality of life of such individuals is significantly affected [Guyot, 2003].

The development of a vestibular implant, based on a concept similar to that of a cochlear implant, could enable the rehabilitation, at least partially, of the patients suffering from bilateral vestibular loss [Guyot, 2003]. In its principle, such an implant
would consist of accelerometers fixed at the head. The latter would transform acceleration data into electrical signals that would then electrically stimulate the various branches of the vestibular nerve through electrodes implanted in the vestibule or near the emerging branches of the vestibular nerve [Merfeld and coll. 2001].
5.2. The anatomy and function of the vestibular system

The vestibular system is composed, on the one hand, of 3 orthogonal semicircular canals, which are located in each of the 3 panes of the space. They code the angular accelerations. On the other hand, it comprises 2 otolithic bodies, the utriculus and the sacculus, which code the linear accelerations [Baloh and Halmagyi, 1996] (Figure 5.1).

At one extremity, the semicircular canals have a dilatation, called the ampulla. This is where the neurosensory body is located. The latter is made of a gelatinous substance, called the cupula, which rests upon hair cells. The cupula, which is mechanically stimulated by the movement of the endolymph - which is in turn induced by the rotations of the head in the plane of the corresponding canal - moves the stereociliae of the hair cells in one or another direction, opening or closing the ionic channels which are generators of action potentials. At rest, one perceives a spontaneous activity of about 90 discharges/sec of the type I neurons, the most frequent ones in this system. This activity increases or decreases by 0.5 the action potentials/rotation degree/sec, in one or another direction [Goldberg and Fernandes, 1971]. In the
horizontal canals, the endolymph ampullipetal movements lead to a depolarization of the hair cells and thereby an increase in the frequency of discharges. In addition, the ampullifugal movements induce a hyperpolarisation and consequently a decrease of the discharges. The opposite occurs in the vertical channels [Flourens, 1830]. As early as in 1887, Ewald reported a functional asymmetry of the semicircular canals: “in the horizontal canals, the ampullipetal movement of the endolymph, resulting from an ipsi-lateral rotation, is a strong exciter while the ampullifugal movement, resulting from a contralateral rotation, is slightly inhibiting” [Ewald, 1887]. This functional asymmetry is nowadays fully understood as an electro-physiological process. Its basic activity rate ranges from approximately 90 up to 400 discharges/sec as far as the excitatory movements are concerned and, from 90 to zero for the inhibiting movements. In other words, the ear can code speeds of about 600º/sec in one direction but is not able to code speeds higher than 180º/sec in the opposite direction. A healthy person does not perceive this asymmetry in the physiological function because the vestibule responds to each movement through 2 canals operating in synergy. In the horizontal plane, it is actually the 2 lateral canals that are stimulated; in the vertical plane, depending on the position of the head, the anterior canal of one of the ears operates in synergy with the posterior canal of the other ear. This functional asymmetry of the semicircular canals is thus only perceived by subjects having only one functional vestibule [Halmagyi and Curthoys, 1988]. The otolithic bodies are sensitive to linear accelerations in the 3 planes of the space. They play a crucial role in the maintenance of the posture. The neurosensory structures of the otolithic bodies, the saccule and the utricule, are called the maculae (Figure 5.1). They are made of hair cells on top of which there is a gelatinous material and a calcareous concretion, called the otoconies, which make them heavy. The modulation of the electric activity of the bulbs and of the otolithic bodies is what generates, inter alia, the two types of reflexes: the vestibulo-ocular reflex (RVO), which stabilizes the glance, and the vestibulo-spinal reflex (RVS), which stabilizes the posture. The RVO is generated by a stimulation of the ampullary bodies. It consists of a diversion of the eyes towards the opposite direction of the head. The clinical evaluation of the function of the peripheral vestibular system is mainly done by the measurement of the RVO, through the responses to channel stimulations. The eye movements, called nystagmus, are recorded by electro or video-nystagmography. The examination of the eye movements in response to otolithic stimulations requires heavy equipment, which is only available in some specialized laboratories [Guyot and Vibert, 1999]. Measuring the RVS provides overall information on the balance but does not allow diagnosing eventual dysfunctions of the vestibule.

5.3. The determination of the stimulation sites in humans

Analogies between the cochlear and vestibular implants are numerous, but there are also critical differences. Indeed, while developing cochlear implants, the cochlea is a particularly adequate site for the insertion of electrodes and for the electrical stimulation. In addition, there is only one auditory nerve that has fibres distributed in tonotopic order along the cochlea. On the contrary, the vestibule has several sensory structures each coding a different component of the movement, and each one being innervated independently by a specific nerve branch. It is therefore not possible to
place the electrodes of the implant in only one array. They will have to be placed in different locations to stimulate separately the individual nerve branches.

In a first stage, the vestibular implant will be used to rehabilitate the function of the semi-circular canals. It will be necessary to establish implant sites for the electrodes. It is thus necessary to locate at least two implantation sites in order to enable coding movements in two orthogonal planes in space. The stimulation of the posterior ampullary nerve seemed an obvious choice to code the vertical movements of the head because this nerve is distant from the other neurosensory structures. Moreover, Gacek had already described a surgical approach to this nerve in 1974 to perform a selective neurectomy in the treatment of a benign positional vertigo [Gacek, 1974]. In a series of 252 operations done through the external hearing channel, Gacek reports that the nerve could be reached in 244 cases (97%) without effraction the ampulla of the posterior semicircular canal. While Gacek cuts the nerve to stop the vertigo, we wanted to approach it without damages and place a stimulating electrode nearby [Kos and coll. 2006]. It was thus necessary to somewhat refine this surgical technique.

For the second implantation site, we chose the area where the nerves innerving the ampullae of the lateral and superior semicircular canals emerge from the osseous labyrinth. This area is very close to the facial nerve, inside the knee formed by the geniculate ganglion (Figure 5.2) [Feigl and coll. 2009].

![Figure 5.2. Horizontal histological section at the level of the ampullae of the superior and lateral semicircular canals and the facial nerve, on the level of the geniculate ganglion. The red arrow indicates the way to approach the nerves emerging from of the ampullae of the superior and lateral semicircular canals (Illustration J-Ph Guyot).](image-url)
5.3.1. The development of the surgical approaches

In 2006, we started a close collaboration with PD Dr. Georg Feigl, at the Institute of Anatomy of the Medical School of the University of Graz in Austria. This institute is known for its long-standing practice in anatomical studies, in particular thanks to the development of a preservation method developed by Prof W. Thiel [1992]. With this method, alcohol replaces formaldehyde allowing a much better hydration of the human body, in excellent conditions of colour and flexibility. This is ideal for anatomical studies. This Institute is also extremely well equipped and benefits from a widespread tradition of body donating for science. All our studies on the surgical approaches were made jointly with Feigl, during repeated visits to this Institute.

The development of the surgical approach to the posterior ampullary nerve through the external auditory canal was achieved working on 100 half human heads. In a first stage, the nerve was identified in the canal of Morgagni by approaching the posterior fossa. Then, a coloured wire replaced the nerve. Next the nerve itself was approached through the external hearing canal. In this way the nerve was reached in 98% of the cases [Kos and coll. 2006]. The choice of this site for the coding of the vertical movements seemed appropriate.

We followed the same procedure to develop the surgery for approaching the nerves of the lateral and superior semicircular canals, at the spot where they emerge from the membranous and osseous labyrinth. The nerves were formally identified by dissection of the middle fossa and then marked with a surgical needle. Next, they were approached through the external hearing canal; in the same way we wanted to do it later in a live volunteered patient. The area was accessible in 75% of the cases. In the remaining cases, the ampulla of the two canals would have to be opened to reach the area of emergence of these nerves.

5.3.2. Confirming the adequacy of the selected implantation sites

In cochlear implantation, the electrodes are placed relatively close to the ganglion cells, which lay in the modiolus, in the centre of the cochlea. The amount of preserved function of the peripheral process connecting the ganglion cells to the ciliated sensory cells does not significantly affect the functioning of the cochlear implant. The electrodes are placed so near the ganglion cells that they stimulate them directly. The situation is different with the vestibular system. The cellular bodies of the neurons are located in the ganglion of Scarpa, which located in the internal hearing canal, away from the cupullae. Consequently, if the electrodes are placed in or near the cupullae of the semicircular canals, a specific nervous activation will only be feasible if the peripheral process of these cells connecting the neurosensory cells to the cellular bodies of the neurons is operational. If, on the contrary, this peripheral process degenerates together with the sensory cells, one would have to consider implanting the electrodes in the ganglion of Scarpa. In such a case, the specificity of the electrical stimulation would be limited because the fibres coming from the various sensory structures are, at that level, in contact one with another. To our knowledge, there is currently no anatomical or physiological evidence on the preservation of the peripheral processes. It had therefore first to be verified whether the sites selected for implantation would allow electrical stimulations to generate eye movements. Next, it
was also necessary to check whether these responses were recordable in each case of the various pathologies leading to vestibular deficit (Menière’s diseases, ototoxicity, traumas, etc).

With the hearing nerve, the effectiveness of electrical stimulation can be checked during the cochlear implant surgery thanks to the recording of the electrically evoked hearing potentials. These potentials are recordable under narcosis and are comparable to the evoked hearing potentials of a normal hearing and awakened person in response to acoustic stimulation. A similar technique is not applicable to the vestibular system. The only way to objectively measure the effectiveness of a selective stimulation of the various semicircular canals is to observe the resulting nystagmic response. But unfortunately this response disappears under narcosis. Therefore, it was essential that the stimulation of the vestibule be done under local anaesthesia. In our hospital we were in a favourable situation to meet such a condition since most surgeries of the middle ear in our department are done through the external hearing canal, under local anaesthesia [Kos and coll. 2001; Zheng and coll. 1996].

The electrical stimulation of the posterior ampullary nerve was done in 3 patients who suffered from profound deafness and were candidates for a cochlear implantation. Two of them suffered from idiopathic deafness and the other, of bilateral Menière’s disease. Stimulations were done at the beginning of the implantation surgery.

A computer generates the electrical stimulation signal. This signal is then connected to a power source, built in our laboratory that enables to produce a constant stimulating signal. For the stimulation of the posterior ampullary nerve, the power intensity of the source was set at a level that would generate a maximum current of 1 mA on the electrode. The stimulating signal consisted of a train of pulses having a negative phase of 200µs followed by a neutral phase and then a positive phase, all of the same length. The length of the fourth phase is systematically modified to lead to trains of biphasic pulses with repetition rates ranging from 25 to 400 PS (pulses per second).

The surgery starts under local anaesthesia. Once the external hearing canal is anesthetized, a speculum is placed in the meatus of the external ear and a tympanomeatal lap is elevated. The osseous overhang of the round window niche and the subiculum are drilled up to expose the whole membrane of the window. Next, the otic capsule is drilled under the membrane, in its rostral part. We used a very gradual approach in order to avoid damaging the nerve while exposing the Morgagni canal.

During the drilling, successive attempts of electrical stimulation are done until the stimulus causes a nystagmic response. The eye movements are recorded by a system of video-nystagmography. Once the stimulation experiments are over, narcosis is induced and the cochlear implant surgery can continue.

The posterior ampullary nerve was accessible in all 3 patients without having to open the ampulla of the semicircular canal. Vertical nystagmic responses were recorded. They were modulable responding to power intensity modulation, ranging from 400 µA to 1000 µA, and through the modulation of the frequency of the stimulation, which ranged from 50 to 200 PS [Wall and coll. 2007] (Figure 5.3).

This experiment showed that nystagmic responses to electrical stimulation could be obtained in the plane of the stimulated canal, as it had been previously demonstrated in animals [Suzuki and Cohen, 1964].
Figure 5.3. Nystagmus caused by the electrical stimulation of the posterior ampullary nerve in one of the three patients. Nystagmus is recorded in 4 channels, vertical right (VR) and left (VL) and horizontal right (HR) and left (HL). Stimulation causes vertical right up-beating eye movements. The lower line shows the stimulus envelope [Wall and coll. 2007].

Electrical stimulations of the lateral and superior ampullary nerves were done in 3 other patients who were candidates for a labyrinthectomy because of an invalidating Ménière’s disease, evolving for over 4 years. Under local anaesthesia, a tympanomeatal flap was elevated, as in the previous experiment. The incus and the head of the malleus were removed to open the attic. The osseous labyrinth was drilled above the horizontal part of the facial nerve, near the knee of the geniculate ganglion [Feigl and coll. 2009].

The equipment used for the stimulation of the posterior ampullary nerve was also used for the stimulation of the lateral and superior ampullary nerves. The parameters of stimulation were slightly different. The length of the phase of the biphasic pulses was of 400 µs and, the repetition rate of the pulses of 200 PS. Moreover, to facilitate the analysis of the responses, the train of pulses was modulated in “on-off” periods of 7 seconds. We observed nystagmic movements in response to electrical stimulations without any stimulation of the facial nerve in all 3 patients. The stimulation intensities ranged between 240 and 400 µA for the first patient, 120 and 240 µA for the second and 800 and 1000 µA for the third (Figure 5.4). Movements of the face by stimulation of the nerve started to appear at higher intensities.

Nystagmic response was exclusively horizontal in one patient; in the other two there was a vertical component. This is because the two nerves traverse very closely to each other when emerging from the ampullae of the lateral and superior semi-circular canals to the internal auditory canal. In spite of this vertical component, the selected location seems adequate for the coding of the horizontal movements. Indeed, one can expect that the plasticity of the central nervous system will erase this vertical component. This has already been shown in the animal in an experiment where an electrode, connected to an accelerometer sensitive to the movements in the horizontal plane, was placed in a vertical canal. A few days later, the animal adapted and the compensatory eye movements to the movements of the head were observed in the horizontal plane [Lewis and coll. 2002].
Figure 5.4: Nystagmus caused by the electrical stimulation of the lateral and superior ampullary nerve in one of the three patients. Nystagmus is recorded on 4 channels, vertical right (VR) and left (VL), horizontal right (HR) and left (HL). During the stimulation periods, a horizontal nystagmic response is observed, whereas this response is weak or absent on the vertical axis. The lower line shows the envelope of the stimulus.

5.4. The next step in vestibular implantation: Chronic electrical stimulation

A unilateral and sudden vestibular deafferentation has important effects and symptoms, which manifest themselves mainly through a body diversion in the direction of the deficient side. These disorders indicate a loss in the “vestibular tonicity” of the system, i.e. a loss of spontaneous electrical activity generated by the internal ear. These disorder regresses gradually with the emergence of central processes of compensation [Curthoys and Halmagyi, 1999]. What happens if the vestibular function suddenly recovers while compensation is active? Such a situation has been observed in a few patients, sometimes several months after the occurrence of a unilateral idiopathic vestibular deficit [Guyot and Toupet, 2007]. These patients have disorders identical to those that they had at the time of the sudden deficit but with diversions towards the opposite direction. For a proper functioning of the vestibular implant, it is necessary to restore the basic electric activity so that it can thereafter be modulated according to the direction and speed of the movements of the head, in the same way that the vestibular system does. Merfeld and his team have demonstrated that restoring abruptly an electric activity in the vestibular system will cause the same disorders as those observed at the time of sudden vestibular deficit. Generating electrical stimulation, via an electrode implanted in the cupulla of the lateral semicircular canal of a guinea pig, causes a nystagmus that regresses gradually.
in 7 days. Stimulation was then stopped, causing a nystagmus in the opposite direction that also lasted a few days. Stimulation was then re-started and the nystagmus reappeared but for a shorter length of time. These researchers noticed that the nystagmus always regressed more and more quickly when repeating the periods with and without electrical stimulation. First the time length of adaptation was of a few days but then after 4 or 5 consecutive periods fell to only a few minutes, [Merfeld and coll. 2006].

It is thus necessary to prove that this adaptation capacity also existed in humans. This demonstration should however be made without causing major discomfort to the patient. To this end, we developed strategies of electrical stimulation, which we will soon use in 3 patients to whom we have implanted an electrode near the posterior ampullary nerve. These patients suffered from profound deafness and loss of bilateral vestibular function. The engineers of the Med-El® implant manufactured at our request a special model of implant. It is similar to a Combi 40+ cochlear implant but it has an isolated electrode to be implanted close to the posterior ampullary nerve, separately from the electrodes array inserted into the cochlea. Studies of chronic electrical stimulation are currently being done with these 3 patients.

5.5. Final remarks

We have now identified two sites to implant the electrodes enabling to code of the vertical and horizontal movements. The surgical approach to these two sites can be made through the external ear canal and under local anaesthesia. This condition is important because the stimulation sites are extremely small, less than 1mm². Under local anaesthesia it is possible to record the nystagmic movements resulting from electrical stimulations and to identify in this way the most adequate location for the electrodes. Approaching the branches of the lateral and superior ampullary nerves certainly requires the removal of the incus. This unavoidably interrupts conductive hearing. But the reconstruction of the ossicular chain can be done with excellent functional results through a type III tympanoplasty [Zheng and coll. 1996]. Consequently, these sites appear to us as adequate for future vestibular implantation.
6. Overall conclusion

Over the last 30 years, the ENT specialists have had the privilege of participating in the development of implants for the human internal ear. Many professionals have contributed to the development of the artificial ear enabling the profoundly deaf to reintegrate or discover oral communication. The technology of these implants is now fully developed. In spite of its limitations, this hearing prosthesis is probably more powerful and reliable than all other neuroprosthesis designed for humans. This has been achieved thanks to the enthusiasm and expertise of several multidisciplinary teams who were fully integrated in the medical departments and whose challenge was to make the most of the technological progress to the benefit of disabled persons. This has also been achieved thanks to the many scientific exchanges which have taken place between medical teams and research laboratories at international meetings, such as, for example, at the time of the 7th European Symposium of Paediatric Implantation (2004), which our Centre had the privilege of organizing.

The results that we have reached with our patients are fully comparable to those of other centres of cochlear implantation. They show that once implanted the vast majority of deaf adults recover quickly oral communication and most deaf children are able to learn the oral language after only a few years of rehabilitation. This is a development, which was largely unimaginable 20 years ago! But this success also increases exponentially the clinical activities related to implantation. In a country like Switzerland, this has been happening not only because the number of implantations has been increasing fast but also because this activity is cumulative. An implanted person has to be monitored over the long term, if not over lifetime! To implant means guaranteeing continuous care and accepting an increasing workload.

Finally, the experience gained with the development of cochlear implantation is also extremely valuable for the development of other prostheses used for nervous stimulation. Nowadays, the stimulation of deep cerebral structures presents itself as a new and promising therapy for particular neurological diseases. Retinal implants might allow the restoration of the vision of the blind. We are pleased to have contributed with our own work to the first steps in the development of vestibular implantation.
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