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Cochlear implants – An Overview. Are CIs world's most successful sensory prostheses?

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Abstract:

Cochlear implants (CIs) have greatly improved over the last 2 decades and now are the world's most successful sensory prostheses, that restored hearing to more than 800,000 deaf people. CIs are small electronic devices that consists of an external portion that is located behind the ear and a second portion that is surgically fixed under the skin, they replace the function of the inner hair cells in the cochlea by direct electrical stimulation of the auditory nerve. Although cochlear implantation has been used for almost 50 years, the indications for this procedure are subject to constant modifications but the main indication is the inability to achieve sufficient speech understanding. Properly implanted, fitted, and rehabilitated hearing prostheses allow to achieve open speech understanding in 70-80% of post-lingual deafness patients and very good speech development results in children. These days cochlear implantation has become the treatment of choice for people with significant hearing loss and are constantly being developed intensively.

Introduction:

Cochlear implants (CIs) are the world's most successful sensory prostheses, as shown by the outcomes from metanalyses (they are having restored hearing to more than 800,000 deaf. people and providing significantly improved speech perception to most of them[1]) and huge increase in interest, development and implantation in the last two decades[2]. CIs are the first example of a neural prosthesis that can replace a sensory organ: they bypass the malfunctioning auditory periphery of profoundly-deaf people to electrically stimulate auditory nerve fibers[3]. The first medical report of auditory perception in a deaf subject after use the electrical excitation of the cochlear nerve was described in 1957[4]. Since that discovery rapid progression in materials, electronics and digital technology have led to highly effective electrode arrays, implanted electronics, sound processors and advanced software that can receive, process, and deliver auditory information in highly efficient way to auditory neurons in the cochlea[1]. These days cochlear implantation has become the treatment of choice for people with significant hearing loss bordering on deafness, as well as deafness of sensory or parasynaptic origin in both children and adults[1,5], some outcomes after implantation shows that almost 80% of patients after rehabilitation can use the telephone, and children achieve almost normal hearing and speech development[5].

Structure of CIs:

A classical cochlear implant is a small electronic device that consists of an external portion that is located behind the ear and a second portion that is surgically fixed under the skin[6].

- The outer part is made of: microphone, which picks up sound from the environment; a speech processor, which selects and arranges sounds picked up by the microphone; a transmitter which transmit signals to internal part; and power supply[6,7].
- The internal part, which is inductively powered, contains of: receiver/stimulator, which receive signals from the transmitter and convert them into electric impulses; and an electrode array, which is a group of electrodes that collects the impulses from the stimulator and sends them to different regions of the auditory nerve[6].

Fully implantable systems are currently under intense research and development, having gained basic experience on the pros and cons with several pilot patients with first-generation devices. The advantages of fully implantable implants, such as invisibility and the possibility of use regardless of the situation, are offset by the acoustic disadvantages resulting from the placement of a subcutaneous microphone behind the ear, a limited battery life of about 10 years with the need for another re-implantation, and a technological upgrade limited to software replacement[5].

It is very important to remember that the implant does not replace normal hearing but gives the wearer some representation of the sounds and words around him and help him to understand it[6]. However, it make possible to many patients to recognize signals, understand sounds in the environment, and understand speech in person or over the telephone[6].

Way of functioning:

A cochlear implant detects ambient sound through a microphone (some versions have several) located on a sound processor outside the ear, then converts the sound into an electrical signal. This signal is sent to an external sound processor where it is converted into an electronic code according to one of several different strategies. This digital signal is transmitted through the skin via radio frequency through a transmitting coil. Finally, this signal is converted by the stimulator receiver into fast electrical impulses distributed to multiple electrodes on a chip implanted in different areas of the scala tympani in the cochlea. The electrodes in turn electrically stimulate the spiral ganglion cells and axons of the auditory nerves, which then send information via the auditory pathway to the brain for further processing, because of that for successful cochlear implant use, high residual neural survival is needed[7]. Using these signals to systematically regulate the discharges of the electrodes inside the cochlea, it is possible to transmit the time, frequency, and intensity of the sound[8]. In summary CIs replace the function of the inner hair cells in the cochlea, that have become damaged, by direct electrical stimulation of the auditory nerve using multi-channel stimulation electrodes[5].

Indication and diagnoses:

The main indication for cochlear implantation is the inability to achieve sufficient speech understanding and thus the appropriate level of communication with the use of other hearing aids. The indication therefore requires the determination of the current ability to understand speech and the possibility of its improvement with appropriate methods[5,9]. It is also necessary to check whether hearing-improving operations or acoustic implants could sufficiently improve hearing[5]. In another hand the essential condition for implantation is a functional hearing nerve and property functioning auditory pathways[7,9]. Furthermore, an anatomically impeccable cochlear must be present for insertion of the electrode carrier and the connection to the hearing nerve must be intacted[9]. Although cochlear implantation has been used for almost 50 years, the indications for this procedure are subject to constant modifications. They concern issues such as: the age of qualified patients, implantation in patients with partially preserved hearing, as well as non-standard anatomical conditions[10]. In many countries, bilateral implantations are also commonly performed, more centers now recommend this procedure also in the case of unilateral deafness or asymmetric hearing loss, especially with accompanying tinnitus in the deaf ear[10].

These days general indications for cochlear implantation are:[9,10]

- Bilateral post-lingual deafness
- Bilateral high-grade hearing impairment or sensory hearing loss near to deafness
- Binaural profound high-frequency hearing loss with low-frequency retention (without the benefit of hearing aids)
- Some cases of unilateral sensory deafness

The indications required the development of standardized diagnostic tests which, in addition to general age-independent tests, include additional elements for adults and children[9]. Currently, the individual guidelines of different countries/organizations/manufacturers slightly differ from each other, but the values are very similar[2,5,9,10]. The cochlear implant audiometric assessment is basic examination for candidates and is more comprehensive than a typical audiogram, it consists of tonal audiometry and words audiometry. There are a few recognitions test for example for adults in the U.S., candidacy is based on sentence recognition test scores, most commonly Arizona Biomedical Sentences (AzBio), with properly fitted hearing aids. Detailed indications for CIs are presented in the tables below[8]. In children candidacy group for cochlear implantation, it is first necessary to set auditory thresholds. This assessment may include auditory brainstem response testing, otoacoustic emissions test, auditory steady-state responses, and behavioral testing. In any case, before starting the process of qualification for CIs implantation, a few months trail in the hearing aid should be carried out regardless of the estimated level of hearing loss[8].

1. Severe sensorineural hearing loss or bordering on deafness
Postlingual bilateral deafness:
- Monosyllabic understanding under best-aided conditions at 65 dB SPL ≤ 60%
- or<50% without hearing aid at 80 dB
Prelingual deafness in children up to the age of 6:
- Objectively determined hearing threshold >70 dB
- Lack of or insufficient language development
Perilingual deafness (onset of severe hearing loss after birth, but before final language acquisition at around 10 years of age)
- Hearing thresholds>70 dB
- Slow, stagnant, or regressive language development
2. Single Sided Deafness or Asymmetric Hearing Loss (SSD)
3. High-frequency deafness with a hearing loss of >80 dB above 1 KHz and hearing threshold better than 50 dB at 500 Hz and below
4. Auditory Synaptopathy and Neuropathy:
- Missing brainstem responses with possibly existing otoacoustic emissions and cochlear microphonics in electrocochleography and morphologically proven auditory nerves in imaging.

Table 1. Indications for implantation of CIs according to German guidelines[5].

Indications for cochlear implantation in adults:
- bilateral post-lingual deafness
- bilateral sensorineural hearing loss - in pure-tone audiometry >70 dB HL (average 500-4000 Hz) and in speech audiometry speech understanding in hearing aids <50% for intensity stimulus of 65 dB in the absence of the benefit of hearing aids
- bilateral profound hearing loss for high frequencies with preservation of low frequencies in the absence of the benefit of hearing aids
- some cases of asymmetric hearing loss with increased tinnitus in the deaf ear
Indications for cochlear implantation in children:
- bilateral sensorineural hearing loss >80 dB HL determined based on hearing tests after approximately 6 months of rehabilitation with the use of hearing aids

Table 2. Indications for implantation of CIs according to Polish practice[10].

	Adult	Children (2–17 y)	Children (12–24 mo)
Hearing threshold	Moderate to profound SNHL in both ears (> 40 dB)	Severe to profound SNHL (> 70 dB)	Profound SNHL (> 90 dB)
Word recognition	Limited benefit from binaural amplification defined by ≤ 50% sentence recognition in the ear to be implanted (or ≤40% by CMS criteria) and ≤60% in the contralateral ear or binaurally.	Limited benefit from binaural amplification defined by ≤ 20–30% word recognition scores.	Limited benefit from binaural amplification trial based on the MAIS.

Table 3. Indications for implantation of CIs according to FDA criteria. Abbreviations: CMS, centers for medicare and medicaid services; dB, decibels; SNHL, sensorineural hearing loss; MAIS, meaningful auditory integration scale[8].

High resolution imaging, especially of neuronal structures, is very important because of small dimension of internal ear involved structures. Currently golden standard are MRI and TC of temporal bone, MRI shows the soft tissues and their relationship to each other, and CT determines the bone structure[9]. Abnormal anatomy of the inner ear is a common cause of congenital deafness; therefore, imaging is extremely important in such cases[9]. The visualization of inner ear structures requires special section planes and sequences so that for example all 4 nerves may be determined in the internal auditory meatus (acoustic, facial, superior vestibular and, inferior vestibular nerve)[9]. CT scan and it`s modification as a Cone Beam Computed Tomography allow sizing of the cochlea, especially of its length. Determination of the length is the basis for selection of the electrode carrier and for specified insertion depth in the context of individualized cochlear implantation[9,11].

Objective test of the hearing nerve and the hearing pathway is also required because the implantable hearing prosthesis uses anatomical conduction pathways. Promontory stimulation test (PST) is routinely used to assess implant candidacy, which includes measuring the electrical potentials generated in the auditory system and stimulating the inner ear electrically[12,13]. An objective functional test is possible by recording electrically evoked brainstem potentials, while the subjective test is about the patient's impressions[9,12,13]. Over last years has been much controversy over the exact role and value of this test so another testing ways of auditory nerve and pathways were considered[9,12]. Development of functional imaging methods with identification of an increased activity around the auditory cortex under electrical stimulation allow for a precise assessment of the function of nervous structures, both pre-operative and post-operative. Those are for example the positron emission tomography (PET)[14], functional magnetic resonance imaging (fMRI)[15], and near-infrared spectroscopy (NIRS)[9,16].

Many structural, functional, behavioral, or social conditions preclude the benefits of a cochlear prosthesis and are natural contraindications to its use[5]. The most common are shown in the table below.

Missing cochlea or auditory nerve
Lack of ability to participate in the overall care process, e.g. B. cognitive impairment
Missing infrastructure for CI supply
Negative subjective promontory test
Serious comorbidities that significantly impair the care process

Table 4. Most common contraindications for implantation of CIs[5].

Post-operative care: device programing

After implantation of the hearing prosthesis, the patient remains under the care of an audiologist, as the implant system needs to be adjusted to the individual stimulus conditions of the auditory nerve. There are two types of fitting: immediate, which takes place immediately after the procedure, and early, then the fitting procedure begins about 4 weeks after the operation[5,8,9]. Usually the second procedure is preferred because then postoperative swellings have disappeared and the intracochlear healing is completed[9]. During that process the "initial stimulation" and device programming, which involves setting specific parameters of stimulation (e.g., loudness levels) individualized for the recipient's ear is performed6. First, the so-called T and C values for each electrode contact are determined. This means the minimum current level at which the patient has an auditory sensation (T value) and the current at which the patient indicates a pleasant loudness of the recorded tone. The difference between the T and C level indicates the so-called the dynamic range within which the acoustic signal should be adjusted. It is important that the perceived volume is as uniform as possible across all electrode contacts in the electrode array[5,17]. Then the loudness between the contacts is optymalized, the dynamic range is defined, and the speech processing strategy is selected. The strategy speech processing is an algorithm that is transforming the acoustic signal into a defined sequence of electrical pulses that are then transmitted to the VIII nerve thru the electrode[9]. The entire frequency content of the transmitted sound signal is divided into individual frequency bands, which are then assigned to the individual contacts of the electrodes or channels of the implant. Assigning specific frequencies in tonotopic order (high-frequency components are passed near the fenestra ovalis and low-frequency components are displayed apical) brings the functions closer to a natural process[5]. Majority of patients report in first weeks that speech sounds distorted. Then the sound quality gradually improves as the brain adapts to the new sound projections over the following 3 to 6 months, depending on few factors, including age at implantation, length of deafness, previous experience with sound, rehabilitation, and therapy services[9]. In children due to lack of cooperation, fitting is more "standardized", it`s cared out based on objectively assessed parameters. So-called NRT (neural response telemetry) based maps allow an approximation of the profile over the complete electrode carrier as soon as a T and C level can be psycho-acoustically determined on an electrode contact[9]. Electrically evoked brainstem potentials and EEG are also registered in process of fitting in children group[9,18,19]. The rapid development of telemedicine has also made it possible to make changes to the implant settings remotely. Assignable to telemedicine, the specialist can directly observe the patient, analize the data collected by the implant and, in response to them, can precisely adjust selected parameters or update the software in the home environment[20]. Currently, some implants also give the possibility of adjusting directly to the user, which is called self-fitting. A person with an implant can change certain CI settings through a special interface, such as an application on a smartphone[9]. However, it is important to educate patients about adjusting, as changing them to often may hinder the rehabilitation process[9].

Post-operative care: rehabilitation

Auditory rehabilitation is a clue to the patient ‘s (re)gaining communication ability. Successful auditory rehabilitation is described as the return of speech and hearing ability[21]. This involves a dynamic learning process over several months to years and is divided into different stages of basic therapy, follow-up therapy and aftercare[22]. Basic therapy is generally the process of fitting, which is described above. Already during basic therapy (fitting), a hearing and speech training is organized[9]. First, the main aim is placed on the recognition of basic auditive categories such as loud, quiet/soft, high, low, the recognition of single syllables, of vowels and consonants, later it is overgoing to words recognition and speech understanding[9,23]. The follow-up therapy is carried out by interdisciplinary treatment team, mainly teachers, speech therapists, audiologists, and physicians using outpatient or inpatient concepts and is focused at optimizing hearing and speech outcomes[21,24,25]. Researches showed that patients of all ages and duration of deafness demonstrated the similar amount of benefit from the rehabilitation treatment[24] so even older patient need to take part in rehabilitation process, because significantly better hearing results may be achieved in this way. The implanting team is responsible to organize and perform a life-long aftercare. It refers to the technical check-up as well as the settings of the implants. Furthermore, regular updates of the software and hardware are necessary since they make progress of the implant technology useable for the patients[9]. The lifelong aftercare is concentrated at ensuring long-term hearing and speech intelligibility as well as technical support with the implant[21]. The aftercare rehabilitation is accompanied by social and professional integration measures[21]. The postoperative care and rehabilitation tasks described above require a systematic and standardized approach[5]. The patient after implantation of CIs must undergo regular examinations. For this purpose, various test methods are available that check the following parameters[5]:

- Implant function
- Electroimpedances
- Objective audiometric parameters
- Psychoacoustic methods for determining T and C levels, loudness functions, dynamic range, and frequency allocation
- Speech understanding in free field or direct feedback

Outcomes

CI care outcomes have improved significantly in recent decades, mainly due to technological developments and revised indications for patients with significantly better prognostic factors. As previously mentioned, the outcome of hearing prosthesis implantation is very variable and depends on many factors, some of which are positive factors, such as: short duration of deafness, the onset of hearing loss after speech acquisition, and good residual hearing; in turn, poor cognitive abilities, lack of family support, and a long period of deafness are negative factors[21]. For an objective evaluation of speech understanding, age-dependent test procedures are determined. They register the speech understanding for numbers and monosyllables as well as the understanding of sentences in quiet and in defined noise9. In adults usually group the Freiburg speech test is performed, which is intelligibility test for monosyllables at 65 dB without background noise[9,21]. Another speech tests which are commonly used in adults are: the Oldenburg sentence test (OLSA) or the HSM sentence test, both are performed in noise so allow for the determination of speech understanding under difficult hearing conditions[9]. On the other hand, in children group mainly the speech development is observed and documented[9]. to objectively evaluate the results which depend on the age and to perform comparative evaluations, the scale of the CAPs (categories of auditory performance) was developed[9,26]. These CAPs describe the hearing performance and its use for communication. The categories range from 0 to 9 and reach from “no auditory sensation” up to “open speech understanding” and “use of the telephone”[26].

Post-lingual deafness patients

Multiple studies have examined speech perception outcomes in elderly CI recipient and these results vary, with some showing that improvements seen in older adults are similar to that of other age groups[27]. Postoperative hearing outcomes in this group are usually associated with a rapid onset of open speech understanding[5]. Performance improves continuously over a period of usually six to twelve months, however, it may take up to three years, especially in understanding speech in noise[28,29]. About 70-80% of patients achieve open speech understanding, although there is considerable inter-individual variability depending on the previously mentioned prognostic factors[5,9,27–29]. The median value of monosyllable comprehension (Freiburg test) is approximately 65%[5,28,29]. Only single patients with good residual hearing perform worse in speech understanding and communication than before surgery under the best aided hearing aid conditions[5].

Children patients

Speech development in children with congenital deafness and implantation takes about two to six years, which corresponds to the periods familiar to people with normal hearing. As a rule, children implanted early achieve very good speech development results, which are similar to children with normal hearing[5,30]. However, speech comprehension performance in background noise is much worse, confirming the basic idea that a cochlear implant does not give a child proper hearing, but improve them from deafness to hypoacusis (median CAP, 5.5)[5,9,21,30]. The most important predictor of communication is the time of implantation and the beginning of auditory language acquisition, as this is where the critical phases of brain development occur[5,31]. If the prosthesis is inserted early enough, children can develop a true binaural hearing system[5,31]. About 70% of children with early implantation can attend regular school[32]. This percentage drops significantly in patients who are implanted later[32].

Complications:

Every surgical procedure relates to complications, generally after CIs implantation are rare, even when taking short-term and long-term events into account. Depending on the definition, rates of between 5.7% and 12.8% are reported[33,34]. The most common of them are: implant defects (1.9–3.4%), dizziness (2.2–3.9%), and wound infections (1.9%). Severe perioperative complications in the form of facial paralysis are put at 0.1–0.6% of cases, and at below 0.1% for meningitis[21,33,34].

Research and future development:

Over the past 2 decades, there has been a huge development in the field of hearing implants and as outlined above, most people with a hearing prosthesis have a good level of communication, but the results vary greatly. the ability to transmit information at the electrode-nerve interface is of fundamental importance, which is determined by the functional state of the auditory nerve and the number of effective electrode channels, as well as by central auditory processing of the basic input signal by the existing cognitive system[5]. The goal of future development is the realization of a bionic ear with extensive hearing restoration by simulating physiological hearing with technical solutions[5]. The essential elements of this bionic ear are: an improved electrode-nerve interface to restore the near-normal physiological pattern of excitation of the auditory[5]; regeneration of the peripheral auditory system through biological therapies and the appropriate use of information transmission channels created in this way through an appropriate speech processing strategy[5].

- Electrode-nerve interface - The relatively wide distance from the stimulus electrode to the hearing nerve leads to an important electric field spread and consecutively poor electric channel separation. This means that current electrode systems can only realize 6–8 separated channels what implicated the limitation of Cis[5,9]. An important improvement of the electrode-nerve interface that currently has a transmission capacity of about 1/10 of a compact disc player (60 vs. 700 kbit/s) can be achieved by positioning near the modiolus
- Regeneration of the auditory nerve - the latest research focuses on the use of nerve growth factors and the use of electrodes with a cell coating for the autoproduction of these nerve growth factors, which will result in the targeted growth of peripheral

dendrites from spiral ganglion cells on a functionalized electrode[5]. This direct neural connection improves the specificity of the electrical stimulation and thus the channel separation significantly, making it possible to realize electrode systems with much more channels[5].

- Speech processing strategy - With a significant improvement in the electrode-nerve interface with more electrically separate channels, other speech processing strategies can be used to increase the amount of information transmitted, spectral contrasting and simulate the physiological patterns of auditory nerve excitation[5].

Conclusions:

- Fully implantable systems are promising, however, due to the current technical difficulties, continuous work on their development is required, because these days their disadvantages outweigh the advantages.
- Currently used CIs have some limitations and the process of learning how to use them is demanding and long-lasting, however, for the vast majority of users, they allow to obtain measurable results that transform into an increase in the quality of life.
- Even though CIs have been used for over 40 years, the guidelines for their use are not uniform and are subject to constant change, there is no clear global guidelines.
- Despite this overall success, outcomes with Cis are very variable and depends on many factors as a: age at onset of the hearing loss and at implantation, pre/postlingual deafness, cochlear implant. experience and auditory training, residual hearing, spiral ganglion cell survival in auditory pathways, cognitive abilities, patient/family personality and motivation, parental involvement.
- A comprehensive postoperative approach, which includes both the fitting process, rehabilitation, and aftercare, is crucial for the patients' outcomes. As research shows, the benefits achieved through rehabilitation are similar at all ages.
- About 70-80% of post-lingual deafness patients after CIs implantation achieve open speech understanding, although there is considerable inter-individual variability.
- Children implanted early achieve very good speech development results, which are like children with normal hearing, however, speech comprehension performance in background noise is worse.

- The rapid development of technology allows us to assume the continuation of the dynamic development of cochlear implants. currently the focus is on improving the electrode-nerve interface, which is a major limitation of the current Cis.

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