Chapter 1
General introduction
The cochlear implant (CI) is one of the most successful medical implants in medical history. It has the potential to improve the hearing status of patients with severe-to-profound sensorineural hearing loss. Researchers have long sought to find a solution for individuals with these hearing losses for whom hearing aids do not provide enough benefit. Sensorineural hearing loss is often caused by damaged inner hair cells in the cochlea. CIs bypass these damaged cells by directly stimulating the auditory nerve. A CI consists of an external and an internal part (Figures 1 and 2). The external part of the CI, the sound processor, processes sound that is captured by the microphones and transmits this through the skin via a coil to the internal receiver. The internal receiver subsequently converts the signal to electrical pulses which directly stimulate the auditory nerve via electrodes in the cochlea.

Figure 1. Cochlear implant with sound processor (1), coil (2), implant (3) and auditory nerve (4). Figure retrieved from Cochlear Ltd..

The first successful implantations of a single intracochlear electrode were performed by House and Doyle in the early 1960s. House continued his work on implants in 1967 together with Urban, which resulted in the first CI system that could be used outside of the laboratory (House & Urban, 1973). A few years later, Clark developed a multichannel implant at the University of Melbourne, which was successfully implanted in 1978 (Clark, 2003). The first successful implantation of a single channel CI in the Netherlands was performed in 1985. Further research and development worldwide, and collaborations between research groups and industry partners, ultimately led to the establishment of the main manufacturers of CIs: Advanced Bionics Corp. (USA, 1993), Cochlear Ltd. (Australia, 1981), MED-EL GmbH (Austria, 1977) and Neurelec (France, 1986, has been acquired by Oticon) (Eshraghi et al., 2012). Cochlear Ltd. holds the majority of the CI market share, with approximately 60% (Intelligent Investor).
Cochlear implant candidacy

CIs and its technology have evolved considerably since their first implantation and use, from a single intracochlear electrode providing merely a sensation of sound, to a multichannel device enabling speech recognition to the majority of CI users (Eshraghi et al., 2012). These technical improvements and the success of cochlear implantation have led to changing regulations and expanding candidacy criteria (Leigh et al., 2016; Snel-Bongers et al., 2018). Initially, the criteria were very strict and only unilateral implantation was done. Then, solely adults with postlingual bilateral profound hearing loss were considered for implantation. After the successful implantation and use of CIs in adults, implantation of children with severe-to-profound hearing loss was considered and performed. Nowadays, bilateral implantation of prelingually deafened children is considered to be the standard of care. The selection criteria for adults were expanded as well and now also include adults with substantial acoustic residual hearing in one or both ears. Furthermore, bilateral implantation in adults is routinely performed in some countries (e.g., United States and Australia) (Peters, Wyss, and Manrique, 2010).

In the Netherlands, adults with postlingual bilateral severe to profound hearing impairment are considered candidates for CI if well fitted hearing aids do not provide satisfactory results. The criteria include, for instance, less than 50% speech recognition in quiet but vary slightly between implant centres. In addition, patients have to be in good health without medical obstacles for implantation (e.g., intact auditory nerve and cochlea), and must be motivated for implantation and the intensive rehabilitation program, and have realistic expectations (OPCI, 2018).
Because of technical improvements, expanding candidacy criteria and changing regulations, the number of CI users is increasing rapidly. Figure 3 shows the number of cochlear implantations worldwide. In the Netherlands, the number of CI users increased from approximately 1500 patients in 2005 to 7000 patients in 2017 (OPCI, 2018).

**Cochlear implant care in the Netherlands**

Cochlear implantations in the Netherlands are performed in each university medical centre by eight highly specialized teams. The CI teams consist of ENT surgeons, audiologists, speech and language therapists, and social workers. CI candidates have to get through an extensive selection procedure, encompassing appointments with a ENT surgeon, an audiologist, a speech and language therapist, and a social worker. Currently, adult CI candidates often find themselves on the waiting list for a prolonged period, due to limitations on the number of implantations stemming from boundaries set by the different healthcare system stakeholders.

**The clinical care pathway of new and experienced CI users**

The rehabilitation trajectory of the eight implant centres show slight differences. In this chapter, the rehabilitation trajectory offered to CI users in Amsterdam UMC, location VUmc is presented.

The first visit to the clinic for the rehabilitation trajectory after surgical implantation generally takes place three to five weeks after surgery to ensure adequate recovery of the surgical site. This visit marks the beginning of an intensive rehabilitation period, which covers the
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first three months post-implantation and is very intensive and demanding. It requires patients to frequently visit the clinic and to perform auditory training exercises at home. The schedule is often fixed and comprises weekly visits until six weeks after CI activation, followed by visits in weeks 9, 13, 28 and 52. The visits in the clinic include appointments with audiologists and speech and language therapists, in which speech recognition is assessed, the sound processor is fitted or fine-tuned, auditory training is provided, and the CI user is counselled on device use and maintenance.

The first visit after implantation comprises a fitting session with the audiologist and the first auditory training session with the speech and language therapist. The appointment with the audiologist is often split in two sessions on the same day with a break in between. The first session is aimed at providing the CI user with a basic fitting. Subsequently, the CI user is instructed to walk around the hospital and get somewhat accustomed to the sound of the CI. The basic fitting is fine-tuned in the second session, after which some patients might already be able to understand some speech. In the following sessions with the audiologist (e.g., week 1, 3, 5, 9, 12, 28, and 52 after activation of the sound processor), the fitting of the sound processor is fine-tuned. Generally, most of the adjustments to the fitting of the sound processor take place over the first few months, after which the fitting parameters remain relatively stable (Gajadeera et al., 2017).

To be able to hear sounds and understand speech with a CI, auditory training is provided by speech and language therapists in the clinic. Auditory training has been shown to improve speech recognition performance (Henshaw & Ferguson, 2013; Sweetow & Palmer, 2005). In addition to the training in the clinic, CI users are required to perform auditory training exercises at home with a training partner who is expected to attend the appointments in the clinic as well. During these appointments, training is provided by the speech and language therapist by means of exercises. The difficulty of these exercises is built up during the auditory training. The trajectory starts with the detection of sounds, followed by discrimination and identification of different sounds, and finally recognition of speech. Speech and language therapists also provide training in the use of accessories and counsel the CI user on device use and maintenance. The appointments with the speech and language therapist are provided weekly until six weeks after activation of the sound processor, followed by appointments in week 9, 12, 28 and 52.

The clinical care pathway of experienced CI users comprises annual visits to the clinic. During these visits, speech recognition is assessed and, if indicated, the fitting of the sound processor is adjusted or optimized. Training by speech and language therapists is generally no longer provided as part of standard clinical care after the first year of CI use.
**Speech recognition assessment**

Difficulties understanding speech in daily life is one of the biggest problems for people with hearing loss. As such, speech recognition ability is an important outcome measure. It is assessed approximately six times during the rehabilitation of newly-implanted CI users, and annually for experienced CI users. The results can be used both for fine-tuning of the fitting, but also to adjust the level and type of auditory training exercises.

In Dutch clinical practice, speech recognition is often assessed with monosyllable consonant-vowel-consonant (CVC) words in quiet (Bosman & Smoorenburg, 1995). Usually, the score is expressed as the percentage of correctly recognized phonemes. Speech recognition in quiet, however, does not reflect communication requirements in daily life. Therefore, speech recognition is also assessed in adverse conditions, with either sentences (Plomp & Mimpfen, 1979; Versfeld et al., 2000) or digit-triplets (Kaandorp et al., 2015; Smits, Goverts, and Festen, 2013) in a background of steady-state masking noise. These tests use an adaptive procedure to estimate the speech reception threshold (SRT), which is defined as the signal-to-noise ratio (SNR) where a listener correctly recognizes 50% of the presented stimuli. The tests are performed in the clinic with a clinician and calibrated equipment. Test administration generally occurs in a sound-treated booth, with stimuli presented via a loudspeaker. The CI user is asked to repeat the presented speech stimuli verbally, after which a clinician judges the correctness of the response.

**Fitting of the sound processor**

The process of changing or fine-tuning the CI sound processor settings is referred to as programming or fitting. Vaerenberg et al. (2014) conducted a global survey on the current state of art for CI programming and concluded that CI programming practices vary considerably, both worldwide, and within countries. Despite the importance of CI fitting and rehabilitation, there is no evidence on the existence of good clinical practice.

The goal of programming or fitting of a CI is to maximize the use of the electrical dynamic range of the auditory nerve, to ensure both the audibility of soft sounds and comfort of loud sounds. The dynamic range is the difference between the threshold level (e.g., the minimal amount of electrical stimulation that is required to perceive sound) and comfortable level (e.g., the upper limit of stimulation judged to be most comfortable, or loud but comfortable). For CIs of Cochlear Ltd., these levels are referred to as T and C levels. During fitting sessions, emphasis is put on setting T and C levels (Vaerenberg et al., 2014). The T and C levels are often psychophysically determined, thereby requiring the CI users’ feedback. T levels are determined by presenting a stimulus in a descending procedure where CI users are instructed to raise their hand or say “yes” when they hear the stimulus. C levels are determined by gradually increasing the presentation level of a stimulus where CI users are asked to indicate
their loudness percept by pointing to categories on a 10-point loudness scale. The C level is set at a level that is “loud, but comfortable”. Once the C levels are determined, the levels are decreased by a certain percentage of the dynamic range. Subsequently, the sound processor is switched to live speech mode in which the clinician increases the C levels to find the user’s most comfortable level.

The adjustment of fitting parameters is often preceded by the assessment of auditory nerve and electrode functioning at the beginning of the fitting session. Assessment of the electrode functioning occurs by means of an electrode impedance measurement. The functioning of the auditory nerve can be assessed using the electrically evoked compound action potential (ECAP) (He, Teagle, and Buchman, 2017). The ECAP represents the response of the auditory nerve after electrical stimulation and can be recorded with the intracochlear electrodes. Here, one intracochlear electrode is used to stimulate the auditory nerve and another intracochlear electrode is used to record the neural response. Cochlear Ltd. provides an automated ECAP threshold measurement, called automatic neural response telemetry (autoNRT).

Although the majority of experienced CI users are generally positive about their device, it has been well documented that speech recognition remains a challenge in many listening conditions. In particular, difficulties are often experienced in noisy listening environments. In clinical practice, the CI user can be fitted with multiple programs for various listening environments. These programs often have specific names referring to specific listening environments (e.g., quiet, noise, music). With multiple programs for various listening environments, the user is required to characterize the listening environment and subsequently select the most appropriate program using a button on the sound processor or the remote control. Although CI users are regularly fitted with multiple programs for various listening environments, research has shown that users of hearing devices often leave their devices in the default setting (Banerjee, 2011; Cord et al., 2002; Searchfield et al., 2018; Van den Heuvel, Goverts, and Kapteyn, 1997).

In addition to multiple programs for various listening environments, modern CIs have the possibility to switch automatically through multiple settings for various listening environments. Here, the sound processor analyses the listening environment and decides whether the current settings have to be changed. Recent studies have shown that automatic program selection can benefit CI users (De Ceulaer et al., 2017; Gilden et al., 2015; Mauger et al., 2014; Wolfe et al., 2015). Therefore, automatically switching programs can be a good alternative for CI users who are not able or willing to switch between multiple programs for various listening environments.
In most modern CI sound processors, the listening environments encountered by the CI user are stored in so called datalogs, together with information about the daily usage of the device and the programs used in these listening environments (Busch, Vanpoucke, and van Wieringen, 2017; Mauger et al., 2014). In clinical practice, this datalog information can help clinicians to consider which CI users benefit from multiple programs and/or an automatically switching program.

The use of telehealth in the clinical care pathway of CI users

The care as usual for both new and experienced CI users has basically remained unchanged since the first implantations in 1985 in The Netherlands. However, the growing number of CI users increases the workload of CI centres. In addition, all CI centres are located in larger cities, which requires a substantial number of patients to travel considerable distances to reach their CI centre. The current rehabilitation schedule requires patients to visit their CI centre, even if there is no clinical need. Telecare provision models, where parts of the clinical routine of CI care are being moved out of the clinic to the patient’s home, might be attractive for CI users as well as for the clinic. It could be used to monitor either progress or decline, and to identify those CI users who require visits to the clinic for further adjustments or optimization. This could result in time and cost savings for both CI centres and patients, and possibly more appropriate care adjusted to the patient’s needs. Various applications of remote tests have been studied in the past, including intraoperative testing (Shapiro et al., 2008) and programming (Botros, Banna, and Maruthurkkara, 2013; McElveen et al., 2010; Ramos et al., 2009; Wesarg et al., 2010). In addition, the assessment of speech recognition either at a remote location (Goehring et al., 2012; Hughes et al., 2012) or at home (Cullington & Aidi, 2017) has been studied. However, these remote applications have so far only been applied to a limited extent in CI care and are currently not part of care as usual for CI users in the Netherlands.

Outline of the thesis

This thesis describes studies related to improvements in the clinical care pathway of new and experienced CI users. The thesis is divided in three sections, each focusing on different aspects of CI rehabilitation. The first section focuses on home self-assessment of speech recognition via a telehealth solution. In section 2, clinical data (fitting parameters) from adult CI users are used to predict speech recognition performance with the aim to improve fitting practices. The final section focuses on the use of automatic and manual switching programs to optimally adapt settings to listening environments encountered in daily life.
Chapter 1

Section 1
This section describes the development, validation, and use of self-administered speech recognition tests at the CI users’ home. Chapter 2 addresses the technical challenges that were encountered in the development of self-administered speech recognition tests for experienced adult CI users at home. The effect of different types of masking noises (continuous versus discontinuous) on speech recognition in noise scores was examined. Furthermore, the use of an audio cable as an alternative to a loudspeaker for speech recognition testing was investigated, and a method to calibrate the home self-administered test setup was developed. Subsequently, the comparison of the self-administered speech recognition tests in quiet and in noise in the CI users’ home with the standard tests in the clinic are described in Chapter 3. Potential effects of stimuli presentation modes (loudspeaker or audio cable) and assessment (by a clinician in the clinic or self-assessment at home) on speech recognition were investigated. With the successful outcomes of the self-administered speech recognition tests in experienced CI users, we integrated the tests in the clinical care pathway of newly-implanted CI users by means of a telehealth application, the MyHearingApp (MHA). Chapter 4 presents a study that evaluated the use and feasibility of the home self-administered test functionality as part of the MHA, with newly-implanted CI users during the first three months of rehabilitation. User compliance of the newly-implanted CI users with the instructions to repeatedly perform speech recognition tests (twice a week during the first three months of rehabilitation) was evaluated. In addition, the progression in speech recognition performance during the first three months of rehabilitation is described. Chapter 5 presents the results of a study in which the home self-administered speech recognition test setup was combined with the newly developed Australian digits-in-noise test to assess speech recognition in noise of bimodal and bilateral CI users. Speech recognition in noise of bimodal and bilateral CI users was assessed in different conditions to determine the binaural benefit and the effect of different masking noises (steady-state versus 16-Hz interrupted masking noise) on speech recognition in noise. This study was conducted at the Ear Science Institute in Perth, Australia.

Section 2
This section uses clinical data that was gathered during the annual follow-up visits of adult CI users to find possible sources of variability in speech recognition outcomes. In the study described in Chapter 6 we examined the relationship between speech recognition in quiet and in noise, fitting parameters (i.e., T and C levels, dynamic range) and objective measurements (i.e., impedances and NRT thresholds) to find mapping rules to optimize speech recognition.
Section 3
Section 3 concerns the use of multimemory or automatically switching devices that are increasingly being used in clinical practice to enable CI users to use different settings for various listening environments. A review of the available literature on the use of manual and automatically switching multimemory devices by hearing aid CI users is provided in Chapter 7. This chapter further synthesizes the literature to evaluate whether hearing aid and CI users appreciate and adequately use the ability to switch between programs in various listening environments. The findings of the scoping review were used to design an experimental study which was conducted in experienced CI users to gather objective evidence concerning the use of manually or automatically switching programs for various listening environments. Datalogs are stored in the sound processor and contain information about the daily usage, encountered listening environments and program use. These data logs were used to examine whether CI users are able to select the most appropriate program in specific listening environments. The preliminary results of 15 participants are presented in the general discussion.

Chapter 8 summarizes and discusses the main findings of the studies in the different sections of this thesis. In addition, implications for clinical practice and directions for future research are presented.