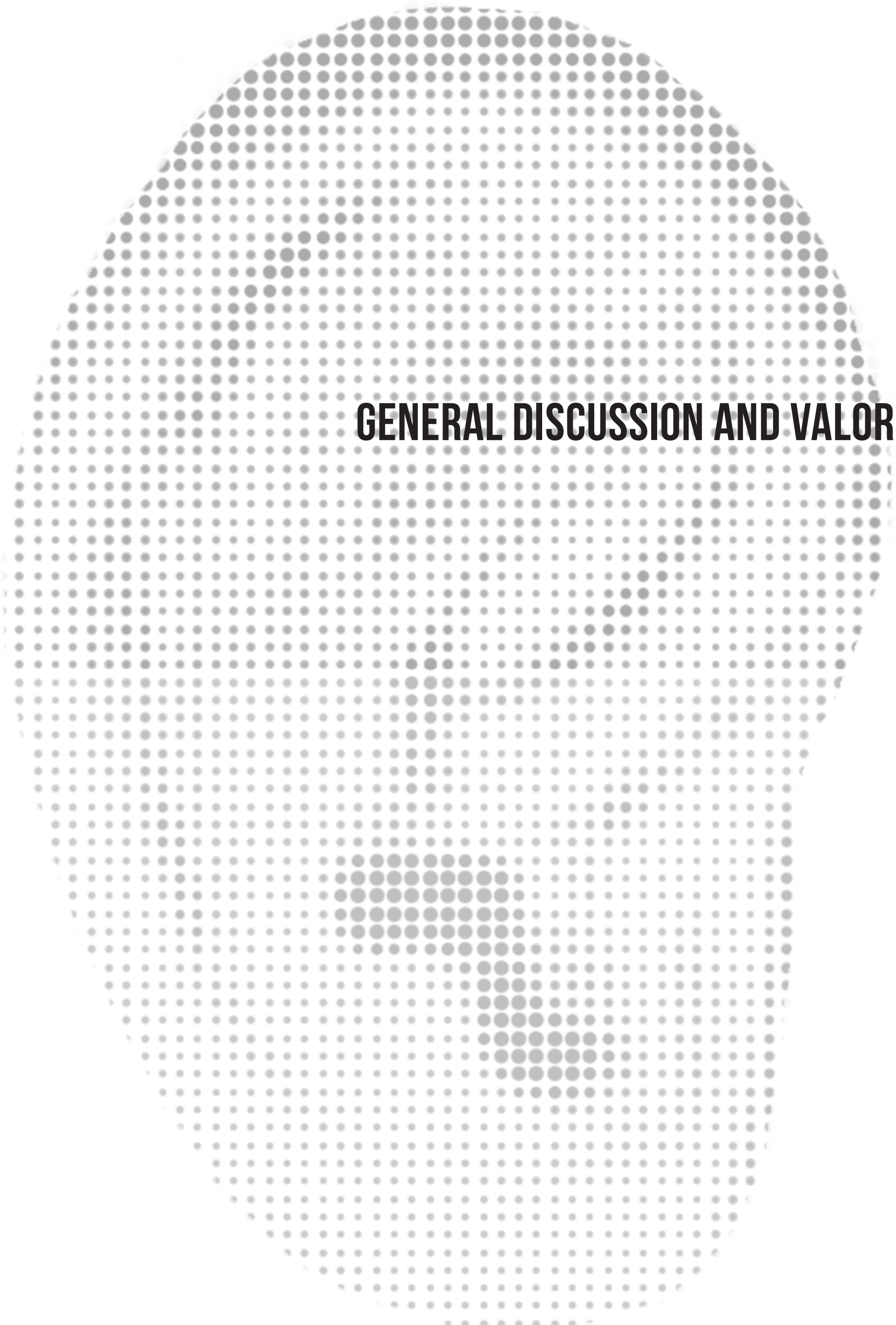
Combining a cochlear implant and a hearing aid in opposite ears



GENERAL DISCUSSION AND VALORISATION

THE RELEVANT NUMBERS

The global number of hearing impaired people keeps rising. Today more than 5% of the world population (circa 460 million people) has disabling hearing loss (> 40 dB HL in adults, > 30 dB HL in children) and this number is predicted to go up to about one in every ten people by 2050 (World Health Organisation, 2018). Contributing factors are thought to be aging, overall noise exposure and awareness of the adverse effects of hearing loss. Hearing loss namely is not only associated with incapacitating social restrictions but also has a significant cost on our economic society (Olusanya et al, 2014).

In 1995 a national UK study by the MRC Institute of Hearing Research showed that about 0.7% of the adult population (18-80 years old) had a severe hearing loss (70-94 dB HL) and 0.2% had a profound hearing loss (> 95 dB HL) (Davis, 1995). Based on these figures the number of eligible candidates for cochlear implantation (CI) may be estimated around 0.5 %, that is more than 30 million people worldwide. Today however, only a fraction of these people actually receive a CI. By the end of 2012 the total number of registered CI's worldwide was approximately 324,200 (NIDCD, 2016). In 2015 it was estimated that within Belgium and the Netherlands only about 6,6% of all eligible candidates has been implanted with a CI (De Raeve, 2015).

In the Netherlands (population 17 million) 4943 adults and 1714 children received a CI by the end of 2017 (OPCI, 2018). Even though CI selection criteria generally ask for a bilateral severe hearing loss, current reimbursement regulations in the Netherlands, as in many other countries around the world, only support unilateral cochlear implantation. Given the high costs associated with cochlear implantation (about €40 000 (Smulders et al, 2016)), bilateral cochlear implants are only reserved for children and a small group of adults with special indications (e.g. acute cochlear obliteration, severe visual impairment). Only about 10% of the CI population in the Netherlands consists of bilateral implantees (OPCI, 2018).

In case of severe sensorineural hearing loss, acoustic amplification has it limits and electric stimulation has proven its benefits. Consequently, the border between profiting from a conventional hearing aid and the potential of retrieving additional benefit from a cochlear implant has shifted. CI candidacy criteria have broadened from profound towards severe hearing loss (Gifford et al, 2010; Hughes et al, 2014), increasing eligibility of asymmetric hearing losses (Firszt et al, 2018; van Loon et al, 2017). New candidacy criteria entail new research questions related to the continuously changing CI population.

Indeed, broadening of CI criteria implies that many cochlear implant candidates today have usable residual hearing in the contralateral ear. Combined with the fact that 90% of CI candidates receive a CI in only one ear, the population of eligible candidates for bimodal hearing, making use of a CI in one ear and a conventional hearing aid in the other ear, has increased. The patient preference regarding bimodal hearing therefore was a current and clinically relevant question. As revealed in Chapter one, a recent CI-population showed a rather high bimodal hearing aid retention rate of 64% one year after implantation, while most studies in earlier years reported a bimodal use of only about 10 to 25% (Fitzpatrick et al, 2009; Syms et al, 2002; Tyler et al, 2002; Yamaguchi & Goffi-Gomez, 2013).

The profile of a bimodal user

The question arises how we can identify those CI candidates that would profit from a bimodal fitting in order to optimize counseling of eligible CI-candidates in clinical practice. Given current reimbursement regulations one often has to make a choice on which ear to implant, minding a chance to profit from bimodal hearing. Often no strong medical (contra)indications exist to implant one ear over the other. Preoperative functional hearing as well as a more comparable performance outcome between both ears have shown to be indicative factors of patient preference for bimodal hearing (Chapter 1). Therefore these factors are important to weigh when counseling CI candidates towards the best possible outcome. Especially in the light of research initiatives questioning current reimbursement regulations and investigating the benefits and associated cost-effectiveness of bilateral cochlear implantation (Smulders et al, 2016; Yawn et al, 2018), it is important to get more information on the composition of the current bimodal population in the first place (Chapter 1). If bilateral CIs might become widely available, the challenge will be to decide which devices warrant the best possible outcome given the known benefits of the bilateral and bimodal combination.

Over the years it can be seen that the characteristics of the CI population, and as a consequence the bimodal population, has changed (Chapter 1). More subjects have aidable residual hearing over a wider frequency range. The investigated bimodal population in this thesis showed aidable residual hearing up until 1kHz (Chapter 1-4). It has however been shown that not purely sound sensitivity or detection thresholds, but moreover the capacities of the residual hearing in terms of functionality or intelligibility have a major role in becoming a bimodal user (Chapter 1). It was also seen that not the degree of hearing loss but rather the functional quality of the hearing aid experience prior to receiving a CI differed between unilateral and bimodal listeners (Chapter 2). Improved speech perception was the most reported reason for bimodal users to retain their contralateral hearing aid (Chapter 2) and bimodal benefits in speech perception could be objectified using a composed test battery (Chapter 3). Speech perception is known to depend on the processing of suprathreshold information demanding a good frequency and temporal resolution, loudness and fine structure representation, as well as top-down cognitive abilities. Given an intelligibility score between 14 and 50% in the contralateral ear, the benefit of the bimodal combination should be considered (Chapter 1). If the contralateral intelligibility score rises above 50%, one stands a good chance of becoming a bimodal user after receiving a CI (Chapter 1). This criterion falls in line with the clinical procedure that often is applied when advising patients on the added value of a HA in the worse ear in case of a strong asymmetric hearing loss across ears or single-sided deafness.

Functional residual hearing could only explain part of the variation in patient preference regarding the bimodal combination (Chapter 1). It can be expected that other factors such as personal expectations, demands of the environment, aesthetics, costs or other patient characteristics could have an influence on bimodal hearing aid retention. It has for example been demonstrated that psychological factors play an essential role in the satisfaction of CI recipients (Kobosko et al, 2015). We found that the fitted outcome, the perceived handicap and the overall health status is comparable between a group of unilateral and bimodal listeners (Chapter 2). These findings could be named to suggest that the benefit of the bimodal combination in daily life listening is limited. It is however important to realize that the unilateral group and the bimodal group are most probably different in nature. The bimodal subjects needed the combined fitting of CI and HA across ears to reach the same disability rating as the unilateral group who only used a CI in one ear. Nevertheless, the outcome with CI in itself did not differ between both groups on average (Chapter 1&2). It was however demonstrated that the difference in outcome between both ears played a role in bimodal hearing aid retention (Chapter 1). Moreover it was suggested that CI expectations and the demands asked from the functional hearing could be higher for subjects in the bimodal group (Chapter 2). If the CI outcome is less satisfactory in everyday listening, this leaves room for the benefits of a contralateral hearing aid. When questioning the bimodal group in itself on the merits of one of the devices versus the bimodal combination, benefits are consistently reported across all daily listening situations (Chapter 2). Expectations, daily life activities and listening demands are still an underexposed factor in research using hearing related questionnaires. In the past years patient preference, related outcomes (Hughes et al, 2018), as well as the perspective of measuring capabilities of subjects in reaching the goals in life they which to accomplish, is gaining more interest within the field of healthcare evaluations (van Hoof et al, 2015).

The origins of bimodal benefit

By definition, bimodal hearing is associated with asymmetric hearing. For most subjects the CI ear is the primary input for speech perception, whereby the contralateral HA may be seen as a favorable side effect since speech intelligibility often drops below 50% (Chapter 1-4). Moreover, asymmetric differences regarding timing, loudness and frequency representation are inherently present across ears giving the origin of acoustic versus electrical hearing (Francart & McDermott, 2013). These differences possibly restrain the benefit from binaural cues. Despite the asymmetric deficits, an asymmetric situation also gives rise to the unique opportunity of redundancy and complementarity. Low frequent acoustic hearing encloses cues regarding voice fundamental frequency, prosody, music and more, information that (currently) cannot be captured within the domain of electrical stimulation. Furthermore, the human brain is known to be perfectly capable of analyzing and combining redundant sound information (Litovsky, 2015). Overall, the opportunities prove to conquer the pitfalls, since it has been confirmed that bimodal aiding indeed enhances multiple dimensions of speech perception, i.e. intelligibility, listening effort and sound quality (Chapter 3) in all everyday listening situations (Chapter 2). In no case bimodal interference or decrement could be objectified (Chapter 3).

The degree of bimodal benefit however appeared to be quite capricious across bimodal listeners (Chapter 3). As in many other studies the amount of residual hearing alone was not found to be able to explain the differences in bimodal benefit (Chapter 3). Results indicate that not the bimodal integration of binaural cues, based on interaural differences, but rather the basic principles of bimodal summation and therefore the access to complementary information plays an important role in the quantity, the quality and the effort of speech perception (Chapter 3) as well as the benefit of bimodal directional microphones (Chapter 4). The exact origin of the substantial variability in bimodal benefits is however still unknown and future research is warranted to expose the principles behind the degree of bimodal benefit. The small sample sizes of most CI studies however often prohibit to investigate correlations between related factors with sufficient statistical power. Combining findings by meta-analysis into larger samples and prospective follow-up of subjects whereby patients act as their own control, should therefore be considered in future research.

The clinical implications

The potential benefits of bimodal hearing are perhaps quite frequently overlooked since 50% of unilateral CI listeners reported to never have tried a contralateral HA

(Chapter 2). Clinicians need to be mindful of the opportunities which exist for patients in terms of a tailored fitting. Even though further validation of such a practical implication in other and future populations is necessary, the presented guidelines on bimodal candidacy constitute a first step towards evidence-based bimodal hearing counseling in clinical practice (Chapter 1).

After counseling, the next step entails fitting the bimodal device combination. Research has shown that the fitting of the contralateral HA often is suboptimal (Harris & Hay-McCutcheon, 2010; Yehudai et al, 2013) and that traditional fitting formulas in general support a good bimodal outcome (Vroegop et al, 2018b). Additionally, it has been demonstrated that when the CI and HA settings across ears are more adapted to each other, the benefit of the bimodal combination can be further increased. This involves the equalization of dynamic compression (Veugen et al, 2015), optimizing the frequency bandwidth according to audibility (Neuman et al, 2018), the enhancement of timing cues (Francart et al, 2014), loudness balancing (Veugen et al, 2016), as well as additional features such as bimodal directional microphones (Chapter 4). However, still more research by good quality comparative studies is needed to further develop evidence-based fitting procedures for bimodal hearing (Vroegop et al, 2018a).

It is apparent that having the CI and the HA fitted by different caregivers at different locations using different software programs, is unable to ensure the best bimodal alignment (Blamey & Saunders, 2008). Despite the fact that the indication borders between CI and HA are fading and the bimodal combination is recognized as standard care, CI centers in many countries worldwide still do not actively engage in HA fittings (Scherf & Arnold, 2014; Siburt & Holmes, 2015). As in the Netherlands, CI clinicians focus on the fitting and rehabilitation of the CI, while the HA often is left at the same preoperative setting or subjects turn to their HA dispenser for adjustments of the HA settings. If anything has been advocated by research within the bimodal field, it is that the awareness of these issues and the reduction of these distances between CI and HA fitting should be addressed more actively in clinical practice.

In order to evaluate the bimodal fitting, it is essential to apply appropriate evaluation methods to quantify the achieved benefit. A test method should be able to map the true bimodal experience and measure the value of alterations or alternatives. Moreover it should be acceptably fast, clinically applicable and administrable to the total population of bimodal users. How a person listens, communicates, and interacts with his or her environment is far more complex than the commonly used basic speech intelligibility tasks in which patients repeat lists of words or sentences (McRackan et al, 2018). A bimodal test battery regarding speech perception is investigated (Chapter 3), showing that listening effort and sound quality are also important measures to consider. These measures did not only demonstrate to represent complementary dimensions from a theoretical perspective, but also proved to be quick and suitable for the total CI population (Chapter 3). Future efforts should be made to evaluate these measures in larger and other relevant populations in order to gain more insight into the underlying mechanisms and ways to improve them. Finally, patient related outcomes are gaining importance within the evaluation of health care interventions. A set of bimodal questionnaires was assembled, applied and evaluated in a clinical population (Chapter 2). (Reduced) versions of these questionnaires (e.g. SSQ-12) are recommended to be applied within clinical conditions in order to evaluate the subjective benefits of bimodal stimulation (Chapter 2).

The future of both worlds

Subjects making use of the combination of electric-acoustic hearing bimodally as well as ipsilaterally (i.e. EAS stimulation) or every possible combination within and across ears, will become more relevant with broadening CI criteria. Moreover, it is thought that bilateral CIs will become more and more of a common practice. The trade-off between the benefit of the acoustic-electric complementarity versus the additional benefit gained by a second CI despite the high costs, is still an ongoing field of interest (Smulders et al, 2016; Yawn et al, 2018). Overall it is the aim to augment the performance of severely hearing impaired people. A unilateral CI is able to allow high levels of speech understanding in quiet conditions and can support conversations over the telephone. The performance of speech perception in complex noisy conditions is however still far from normal hearing capacities, even when supported with a contralateral HA (Chapter 3) and despite specially designed processing features (Chapter 4). Attempts should be made to further lower the effort of listening instead of the level of stagnation that is currently observed (Chapter 3).

In order to achieve a high level of speech perception, an adequate perception of pitch is required (Siciliano et al, 2010; Zhou et al, 2010). The frequency fitting of a CI nowadays however occurs in a universal manner, depicting the relevant frequency range of hearing in a standardized logarithmic manner across the electrode array, without reckoning with the individual natural tonotopy which in general is pitched about one octave lower (Chapter 5). Everyone practicing CI fittings will reckon that subjects profit from the regained access to the auditory world and most subjects over time adjust to the pitch misalignment. However, even after years of CI experience, listeners still judge the sound quality of their CI to be tinny or metallic (Chapter 2). Improving the place-pitch alignment in CI fitting therefore could perhaps not only improve speech perception, allow a faster learning phase, but also improve the quality of the sound experience. It is believed that especially in the situations where acoustic and electric stimulation is combined, as is the case with bimodal hearing, a better frequency alignment between both worlds could augment the complementary performance as well as the listening experience. The development of a new 3D analysis technique to identify the intracochlear location of CI electrodes more accurately allows us to predict a natural frequency map (Chapter 5). This map can be used in fitting the frequency allocation table of a CI. A large prospective clinical trial is warranted in order to compare the natural fitted frequency map with the standard frequency alignment. Hereby it is important that subjects act as their own control and are followed from the beginning of their rehabilitation in order to compare the learning curve between both maps while preventing first order preference. Special attention should be paid to those subjects who retain a contralateral HA as to map the perceived electro-acoustic sound image across ears and the effects it might entail regarding bimodal benefit.

Bimodal hearing brings acoustic and electric stimulation together across ears. Optimizing the combination between both worlds is however still an ongoing field of search. It could be speculated that with selection criteria shifting towards asymmetric hearing (Firszt et al, 2018; van Loon et al, 2017), more room for residual hearing in the non-implanted ear could possibly shift benefits from basic complementarity towards more true collaboration and fusion across ears. Results found so far advocate for further bimodal cooperation (Chapter 4). The future of bimodal hearing can only open new doors when a combined fitting procedure, a more enhanced inter-device communication and synchronized operation becomes available between CI and HA. Secondly, the implementation and translation of such bimodal fitting recommendations should find its way into clinical practice. This implies the simultaneous fitting of both devices by the same clinician, using the same software, allowing comparable settings in both devices in order to fully benefit from alignment and complementarity of timing, loudness and frequency information across ears. Moreover real-time exchange of information regarding the settings related to the current sound scene as well as streaming of the actual sound between both devices can open even more opportunities.

In order to improve hearing for the severely hearing impaired, efforts should be continued in order to maximize the benefit from both acoustic as well as electric stimulation and allow people to profit from the best combination of both worlds.