First-Year Hearing-Aid Use and Self-Reported Outcomes in Adults

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FIRST-YEAR HEARING-AID USE AND SELF-REPORTED OUTCOMES IN ADULTS

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First-Year Hearing-Aid Use and Self-Reported Outcomes in Adults

Ph.D. Dissertation

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Abstract

By 2030, hearing loss is anticipated to rank among the top ten leading causes of disease burden. Among the various intervention strategies used to mitigate hearing loss, hearing aids are the most prevalent. To evaluate the efficacy of hearing aid intervention, it is crucial to assess their effectiveness in alleviating the limitations caused by hearing deficits, particularly from the patient's perspective. This will provide valuable insights into the hearing rehabilitation's success and identify contributing factors for successful outcomes. Self-reported outcome measures are commonly used to assess the patient's perception of hearing aid performance, and thus, they can be considered an essential indicator of the success of hearing rehabilitation.

The data collected from 1961 participants over a year as part of the Danish national Better hEAring Rehabilitation (BEAR) project was used to understand the factors contributing to successful hearing aid outcomes. The International Outcome Inventory for Hearing Aids (IOI-HA) and the short-version of Speech, Spatial, and Qualities of Hearing Scale (SSQ12) were used as the self-reported outcome measures in the study. The study investigated the impact of insertion gain, speech intelligibility index, the time taken to adapt to the new hearing aids, hearing aid adjustments, usage pattern, and other clinically relevant parameters on self-reported hearing aid outcomes.

The study found that the difference in fitted insertion gain and that prescribed by generic rationales at moderate input levels can predict HA effectiveness among experienced hearing aid users. The hearing aid users fitted with custom earmolds reported lower outcomes than those fitted with the open domes. The study showed that first-time hearing aid users with a higher speech intelligibility index at high input levels might have better hearing aid outcomes.

The study also found that the time taken to get used to hearing aids relates to the outcomes. Even after having three or more hearing aid adjustments at various time points throughout the year, the users still reported a lower outcome than users with fewer adjustments. The analysis of the self-reported situations of using and not using hearing aids showed a distinct pattern of hearing aid usage, with a concerning proportion of situational users. The importance of regular use of hearing aids for better outcomes was also confirmed in the study.

The insights from these studies can aid hearing care professionals in optimizing the fitting of hearing aids and counseling to enhance hearing rehabilitation for individuals with serviceable hearing impairments.

Resumé

I 2030 forventes høretab at være blandt de ti største årsager til sygdomsbyrde på verdensplan. Blandt de forskellige interventionsstrategier, der anvendes til at afhjælpe høretab, er høreapparater de mest udbredte. For at evaluere høreapparatbehandlingens effektivitet er det afgørende at vurdere evnen til at mindske gener forårsaget af høretab, især set fra patientens perspektiv. Dette vil give værdifulde indsigt i høreapparatbehandlingens succes og identificere de faktorer, der bidrager til de bedste resultater. Selvrapportering i form af spørgeskemaer anvendes ofte til at vurdere patientens gavn af høreapparatet og kan derfor betragtes som en vigtig indikator for hørerehabiliteringens succes.

Data indsamlet fra 1961 deltagere over et år som en del af det danske forksningsprojekt Better hEAring Rehabilitation (BEAR) blev analyseret med henblik på at forstå nævnte faktorer. *International Outcome Inventory for Hearing Aids* (IOI-HA) og den korte version af *Speech, Spatial, and Qualities of Hearing Scale* (SSQ12) blev anvendt som selvrapporterede målinger af høreapparatbehandlingen. Studiet undersøgte betydningen af forstærkning (REIG), taleforståelighedsindeks (SII), tilvænningstid, hyppighed og tidspunkt for høreapparatjusteringer, brugsmønster og andre klinisk relevante parametre på de selvrapporterede målinger af høreapparatbehandlingen.

Studiet fandt, at forskellen i generisk ordineret tilpasning og faktisk tilpasset forstærkning ved moderate inputniveauer, kan forudsige høreapparatets effektivitet for erfarne høreapparatbrugere. Høreapparatbrugere med støbte ørepropper rapporterede lavere resultater end dem, der var tilpasset med de åbne ørepropper. Studiet viste, at førstegangsbrugere af høreapparater med et højere taleforståelighedsindeks ved høje inputniveauer formentligt kan få bedre høreapparatresultater, end for den givne population.

Studiet fandt også, at den tid, det tager at vænne sig til høreapparater, kan hænger sammen med udbyttet. Selv efter tre eller flere justeringer af høreapparatet på forskellige tidspunkter i løbet af året, rapporterede disse brugere stadig et dårligere udbytte end brugere med færre justeringer. Analysen af selvrapporterede situationer ved brug og ikke-brug af høreapparater viste et bekymrende mønster af selektiv brug. Studiet bekærftede også vigtigheden af uafbrudt brug af høreapparater for bedre resultater.

Indsigten fra disse studier kan hjælpe høreapparatspecialister med at optimere tilpasning og justering af høreapparater samt rådgivning for at forbedre hørerehabiliteringen for personer med behandlingskrævende hørenedsættelse.

Contents

List of Publications

Thesis Title: First-Year Hearing-Aid Use and Self-Reported Outcomes in Adults
Ph.D. Student: Sreeram Kaithali Narayanan
Supervisors: Prof. Dorte Hammershøi, Aalborg University

The main body of this thesis consists of the following papers.

[A] Narayanan SK, Rye P, Piechowiak T, Ravn G, Wolff A, Houmøller SS, Schmidt JH, Hammershøi D., "Can real-ear insertion gain deviations from generic fitting prescriptions predict self-reported outcomes?," *International Journal of Audiology*, pp.1-9, 2022.

[B] Narayanan SK, Rye P, Houmøller SS, Wolff A, Hougaard DD, Gaihede M, Schmidt JH, Hammershøi D, "Difference in audibility provided by initial fit and NAL-NL2 and its relation to self-reported hearing aid outcomes," *International Journal of Audiology*, (Under review), 2023.

[C] Narayanan SK, Houmøller SS, Wolff A, Hougaard DD, Gaihede M, Schmidt JH, Hammershøi D, "Adapting to new hearing aids and hearing aid adjustments in adult Danish users," *American Journal of Audiology*, (Accepted with minor revisions), 2023.

[D] Narayanan SK, Houmøller SS, Wolff A, Lund K, Möller S, Hougaard DD, Gaihede M, Schmidt JH, Hammershøi D. Self-Reported Hearing-Aid Use Patterns in an Adult Danish Population. *Audiology Research*, 3(2), pp. 221-235, 2023.

In addition to the main papers, the following publications have also been made.

[1] Narayanan SK, Piechowiak T, Wolff A, Houmøller SS, Narne VK, Loquet G, Hougaard DD, Gaihede M, Schmidt JH, Hammershøi D., "Speech Related Hearing Aid Benefit Index Derived from Standardized Self-Reported Questionnaire Data," *Proceedings of the International Symposium on Auditory and Audiological Research*, vol.7, pp. 389–396, 2019.

[2] Rye P, Narayanan SK, Hammershøi D., "Effects of Intermittent Noise on Real Ear Measurements in Hearing Aid Fitting," *Proceedings of the Baltic Nordic Acoustics Meeting (BNAM)*, May 3-5, 2021.

[3] Houmøller SS, Wolff A, Möller S, Narne VK, Narayanan SK, Godballe C, Hougaard DD, Loquet G, Gaihede M, Hammershøi D, Schmidt JH., "Prediction of successful hearing aid treatment in first-time and experienced hearing aid users: Using the International Outcome Inventory for Hearing Aids," *International Journal of Audiology*, 61(2), pp. 119-129, 2022.

[4] Sanchez-Lopez R, Wu M, Fereczkowski M, Santurette S, Baumann M, Kowalewski B, Piechowiak T, Bisgaard N, Ravn G, Narayanan SK, Dau T, Neher T., "Towards Auditory Profile-Based Hearing-Aid Fittings: BEAR Rationale and Clinical Implementation," *Audiology Research*,12(5), pp. 564-573, 2022.

This thesis has been submitted for assessment in partial fulfillment of the PhD degree. The thesis is based on the submitted or published scientific papers listed above. As part of the assessment, co-author statements have been made available to the assessment committee and are also available at the Faculty. The thesis is not in its present form acceptable for open publication but only in limited and closed circulation as copyright may not be ensured.

Preface

This thesis presents the scientific work carried out as part of the PhD study titled "Identification and Characterization of Sub-Population with Low Perceived Hearing Aid Benefit," under the Better hEAring Rehabilitation (BEAR) project. The thesis is submitted to the Technical Doctoral School of IT and Design at Aalborg University in partial fulfillment of the requirements for the degree of Doctor of Philosophy. The project was funded partly by Innovation Fund Denmark Grand Solutions (5164-00011B) and partly by Aalborg University (1/3). Also, the support of all the partners in the BEAR project, Oticon, GN Hearing, Widex-Sivantos Audiology, Aalborg University Hospital, Odense University Hospital, Technical University of Denmark, University of Southern Denmark, FORCE Technology, and Copenhagen University Hospital is sincerely acknowledged. The project was carried out in the Section for AI and Sound, Department of Electronic Systems at Aalborg University.

The thesis is structured into an introduction and a collection of scientific papers. An overview of the motivation for the study, a brief introduction about the BEAR project, the adopted research framework, and the scientific contributions are summarized in the introduction. The collection of papers includes four papers that are published in or submitted to peer-reviewed journals. We have tried our best to avoid the repetition of information in the introduction section, which has already been provided in the submitted journal paper.

I want to express my sincere gratitude and respect to my only supervisor Dorte Hammershøi. Your support and guidance throughout these four years have been impeccable. Special thanks to Palle Rye for all those tremendous scientific and non-scientific discussions, and for being a great friend. I want to thank all my co-authors and colleagues in the BEAR project, especially the colleagues in work-package 1, for their massive effort in collecting the clinical data. Also, I would like to thank all the colleagues in the Section for AI and sound for creating a warm and friendly working environment. Finally, I would like to thank my family for their unconditional support. My deepest thanks to my wife, Vijaytha, for believing in me and always being beside me.

Sreeram Kaithali Narayanan
Aalborg University, March 31, 2023

Part I

Introduction

Introduction

1 Introduction

Hearing loss (HL) is one of the common disabilities, and it is estimated to affect more than 1.5 billion people globally [1]. Out of the 1.5 billion, about 466 million people may have disabling HL that requires rehabilitation. By 2050 this number is expected to reach 700 million (1 in 10 people) [1]. One of the most common causes of HL is age-related HL [2]. More than 65% of the world's population above 60 years of age have disabling HL [1]. HL is known to impact the life of the person with the impairment, and those closely associated with them [3]. Many studies have found that HL can also be linked with reduced quality of life [4, 5], cognitive decline [6, 7], dementia [8–10], and mental health problems like depression, anxiety, and stress [11]. Untreated HL results in an annual global cost of 980 billion US dollars [1].

Hearing aids (HA) are one of the most common rehabilitation options used to treat HL [12–14]. HAs help reduce the consequence of hearing impairment by providing improved audibility and also restoring other auditory cues to some degree. Modern HAs are equipped with features that use advanced signal processing capabilities to provide optimal acoustic compensation, like enhanced speech intelligibility. In a systematic review by Ferguson et al. (2017) [15], it was seen that HA use improved the ability of the hearing impaired to engage in daily life situations and increased general health-related quality of life.

Nevertheless, less than half of the people who could potentially benefit from HAs pursue having them [14, 16]. In a recent EuroTrak 2022 survey in Denmark, the adoption rate of HAs was 55% among users who had self-declared HL [17]. The survey also found that 7% of people who own HAs in Denmark do not use them, and 15% of the HA users use them less than an hour a day [17]. Similar results were observed with regard to HA usage in many previous studies [18–20]. Many previous studies [21–23] have also found HA usage time as an important factor in predicting the success of a HA treatment. If we then take HA use time as a measure of success, this could mean that the hearing rehabilitation was unsuccessful for more than 20% of the HA users in Denmark according to the EuroTrak 2022 survey [17]. From the point of view of the health system in the country, unsuccessful treatment is a social as well as a financial burden. Recent studies have also established that untreated HL or poor HA outcomes can accelerate cognitive decline [7], which may

add to the burden. The success of hearing rehabilitation using HAs is affected by multiple factors. Understanding and addressing these factors can lead to better HA outcomes, including greater adoption rates, regular use, and improved satisfaction and benefit. Although several factors influencing HA outcomes are well-established, several latent factors may have yet to be identified. In this study, we try to identify some of the factors that may affect the HA outcome in the first year of HA use among adults in Denmark.

1.1 Hearing-Aid Outcomes

Assessing the hearing impairment is the first step in the intervention using HAs, providing insight into the location and degree of impairment. After the initial assessment, considering factors like type and degree of impairment, lifestyle, and budget, the hearing care professionals (HCPs) suggest an appropriate HA solution. Often this decision is made according to the tacit knowledge and expertise of HCPs. Once the HA is chosen, an appropriate amplification strategy to counter the deficit in hearing is applied, considering the HL and other individualized information, like gender and prior experience with the HAs. This strategy can be manufacturer specific or generic. These strategies are generally referred to as prescriptive targets. The HAs, once programmed and fit with specific target prescriptions, can be verified using real-ear measurements (REMs). This helps the HCP verify the fitting against a prescriptive target and fine-tune the HA to meet the required target.

Once the HAs are fitted, it is essential to understand the efficacy of the provided treatment. HA outcome measures are used to quantify the outcomes of hearing rehabilitation. The HA outcome measures typically assess a relevant task performance to probe improvement obtained after fitting.

There are a variety of measures to assess HA outcomes both in controlled environments (like in a laboratory or clinic) and in real-world environments. Most of the measures in controlled environments assess the HA outcomes based on the aided performance in recognizing phonemes, syllables, words, and sentences [24]. Popular measures that asses aided performance in a controlled environment are Consonant-Nucleus-Consonant (CNC) [25], the Hearing in Noise Test (HINT) [26], the speech perception in noise (SPIN) test [27, 28], and speech in noise (SIN) test [29]. Some of the laboratory-based measures can also be based on the subjective impression of the HA user, like just-follow-conversation (JFC) [30], and acceptable noise level (ANL) [31, 32] test.

The HA outcome can also be measured using retrospective self-report of perceived benefit or improvement in hearing ability, often measured using standardized questionnaires. These questionnaires are intended to assess the real-world outcome of using HAs [21]. These can provide insights into the patient's experience of HL, including their perceptions of communication difficulty, social interactions, and emotional well-being. The outcome measures used in controlled environments may not reflect everyday situations, failing to capture the impact of treatment on the patient's rehabilitation journey. Moreover, these self-reported outcome measures are easily accessible and can be quickly administered to a wide range of patients. In this study, we focus

on self-reported measures to determine the outcome of hearing rehabilitation and find the correlates of having a better self-reported outcome.

Self-Reported Hearing-Aid Outcomes

Self-reported outcomes provide a personalized account of the HA user's perspective of real-world rehabilitation success with respect to the improvement in sound perception and overall quality of life. It also reflects the residual limitation that can hinder the active participation of the HA user in society [33]. Over the years, clinical practice has been moving towards patient-centered care, and assessment of the outcome of HA treatment using self-reported questionnaires in clinics has gained popularity [34]. In patient-centered care, the involvement of the patient in every stage of treatment is paramount. So the self-reported outcomes have greater relevance in patient-centered care.

Several popular instruments are used in research and clinics as self-reported outcome measures. Some of them are Client Oriented Scale of Improvement (COSI) [35], Abbreviated Profile of Hearing Aid Benefit (APHAB) [36], Satisfaction with Amplification in Daily Life (SADL) [37], International Outcome Inventory for Hearing Aids (IOI-HA) [38], and Speech, Spatial, and Quality of Hearing Scale (SSQ) [39]. These questionnaires measure the outcome across different dimensions like improvement in quality of life, hearing ability, residual limitations/restrictions, HA effectiveness, benefit, and satisfaction. Most of these are condition-specific questionnaires that are not sensitive to each individual's daily life activities and the context of HA use. However, a questionnaire like, e.g., COSI, takes such individual variations into account. The IOI-HA questionnaire overcomes this problem by becoming neutral to contextual and activity dependencies.

The self-reported measures come with their limitations while assessing the HA outcomes. The questionnaires are susceptible to recall biases, where the most recent and strong experiences may be reported, and other problems may be neglected. This may also be viewed as a favorable bias to have as this will help filter out unwanted highlights on problems that might not be of perceptual importance. The self-reported outcomes can be affected by the patient's mood, expectations, and self-assessment of residual limitations in hearing. For example, a HA user, if depressed, may not accurately report the outcome. Also, The users may report worse outcomes if they had high expectations from the HA and it is not fully met. It can also happen that HA users who are positively motivated will only report a positive outcome. Despite the limitations, the self-reported questionnaires provide deep insight into individual perceptive of outcomes from HA treatment. Ultimately, even with an improved, audiological outcome, if the end user is not satisfied with the HA, the entire rehabilitation exercise will be futile, and the HA may end up not being used effectively. The outcomes assessed in controlled environments and retrospective self-reported measures may be used in combination to best achieve a reliable estimate of the effectiveness of the HA treatment.

In the present PhD study, two self-reported measures were used; SSQ12 [40] and IOI-HA [38]. The IOI-HA has seven questions related to HA benefits and residual

activity limitations with an ordinal response scale. SSQ12 is a short version of the original 49-question SSQ [39] with 12 questions in three domains (speech, spatial, and quality of hearing). The IOI-HA is rather generic, focusing on the overall effectiveness of HA treatment, whereas the SSQ12 more specifically addresses the hearing ability in given contexts (different acoustic scenarios).

1.2 Factors Affecting Hearing-Aid Outcomes

The definition of a successful HA treatment is a subject of debate – there is no standard agreement on what constitutes success. Successful treatment should enhance speech comprehension and hearing ability in various environments. However, from a patient-focused perspective, the ultimate gauge of success is a combination of many factors, where the individual's perception of the effectiveness of the HA treatment is but one. The high functional effectiveness of the HAs (for e.g., speech comprehension) does not always translate to a comfortable experience, and users may often choose listening comfort over speech comprehension [41]. So, the determinants of HA outcomes are complex and multifaceted [42].

The factors that affect the HA outcomes may include user-related factors like the degree of HL, self-perceived hearing handicap [20, 43–47], socio-economic indicators [45, 46, 48], prior HA experience [43, 49, 50], the expectation of the user [15, 43, 51], personality [52, 53], duration of HA usage [21, 33, 54, 55], and problems associated with HA use (handling, changing battery, cleaning, etc.) [56]. The lifestyle [16] and daily usage requirements of HA users can also influence the outcomes. Some of the HA-related and other external factors that can affect the HA outcomes are, the type of HA and level of signal processing [22, 57], insertion gain [58, 59], listening situations [20, 22, 60, 61], and sound quality [56, 62, 63].

The self-perceived improvement in hearing ability in complex acoustic situations (also impacted by many of the above-listed factors) can be one of the critical factors for better HA outcomes [64].

2 Better hEAring Rehabilitation (BEAR) project

The Better hEAring Rehabilitation (BEAR) project was launched in Denmark in 2016 to study and improve HA treatment through evidence-based clinical practices. The project was a collaboration between several institutions, including three universities (the Technical University of Denmark, University of Southern Denmark, and Aalborg University), three hospitals (Odense University Hospital, Aalborg University Hospital, and Copenhagen University Hospital), three HA companies (GN Hearing, Oticon A/S, and Widex-Sivantos Audiology), and a technological service provider (the Technical Audiological Laboratory at FORCE Technology). The BEAR project consisted of eight scientific work packages (WPs) targeting different aspects of hearing rehabilitation.

The present study examined data from WP 1 of the BEAR project, which had established a centralized clinical database based on the typical adult audiological reha-

bilitation practice in Denmark (regular patient flow in two of the participating clinics). The PhD study addressed the challenges of WP 5, which focused on identifying subpopulations with inferior compensation benefits, recognizing any explaining factors, and elaborating the clinical implications, including suggesting alternative paradigms, if meaningful.

2.1 Data Collection

The participants of the WP 1 of the BEAR project were adults seeking HA treatment in either of two public clinics at Odense University Hospital and Aalborg University Hospital. Participants had to be able to read and understand Danish and had no diagnosed cognitive decline, such as dementia. Patients who met any of the following criteria were excluded from the study: being eligible for a cochlear implant or bone-anchored HAs, qualifying for other surgical procedures to treat hearing loss, having dysfunctional auricles or inner ear, or experiencing tinnitus without accompanying clinically diagnosed hearing loss [65]. Out of 2447 adults with HL that were invited to participate, 1961 consented to be part of the study. Participants included both first-time and experienced HA users; the details of the recruitment process can be found in PhD thesis of Anne Wolff [65], and Sabina Storbjerg Houmøller [66].

The data was collected from January 2017 to June 2018. The data consisted of generic information, survey results, and audiological data. The data was collected mainly in three stages: 1) At baseline (before fitting), 2) around two month after the first fit, and 3) one year after the first fit. Once the participants accepted the invitation to participate in the study, a set of questionnaires was forwarded at least two weeks before their scheduled visit to the clinic for the initial hearing examination. The questionnaires included questions on demographics (age and gender), general health-related questionnaire, HA-related questions for experienced users, self-reported noise-exposure, self-reported tinnitus, motivation-related questions, SSQ12 [40], IOI-HA [38] (only experienced users), and health-related quality of life questionnaire (15D) [67]. A browser-based Research Electronic Data Capture (REDCap) [68, 69] platform hosted by the Region of Southern Denmark was used to manage the distribution of questionnaires. A study record was established for each patient using their name and social security number (CPR number). The questionnaires were sent to the participants using a unique link via their digital mailboxes (e-boks), and the responses were directly recorded into the REDCap database. Audiometry, middle-ear diagnostics, speech-reception threshold, and word-recognition scores were performed at the first visit to the clinic - compliant with current practice. The specifics of these measurements have been detailed in the PhD thesis of Anne Wolff [65].

The diagnostic data was then used to prescribe, program, and fit the HAs in accordance with current clinical practice in the two clinics (Aalborg and Odense). A two-month follow-up visit was scheduled approximately two months after the initial fitting of the HAs. Questionnaires were sent two weeks before the scheduled follow-up to the participants to understand the self-reported HA outcome. These included standard questionnaires like SSQ12, IOI-HA, 15D, self-report on tinnitus, and a few non-standardized questionnaires about the occupation and HA use during work. Dur-

ing the two-month follow-up, a REM was performed to record the aided response/gain of the HA. The HA logging data with regard to average daily HA use time, type of HA programs used, and frequency of switching of programs were collected. The participants were offered an opportunity to have the HAs adjusted, if required, in which case the REM was repeated to document the new fitting. At the end of the follow-up visit, the information regarding any HA adjustments performed within two-month of initial fit and during the two-month follow was collected using a non-standardized questionnaire in the form of an informal interview.

Finally, a third set of questionnaires were sent after more than a year of the initial fit. This set included standard questionnaires (SSQ12, IOI-HA, 15D, self-reported tinnitus), questions related to HA adjustments, including questions on the number of adjustments after two-month follow-up visit, questions on socio-economic status (occupation status, cohabiting, income, etc.), and a non-standardized questionnaire on situations of HA use and non-use. Also, a question relating to the time taken to get used to the HA in terms of new auditory experience and HA handling was also asked. Such data collected at all three time-points have been used in the present PhD study.

2.2 REM data extraction and cleaning

In the clinical database, there were REMs from 1648 participants who attended the two-month follow-up. The REMs were performed at three input levels (55, 65, and 80 dB SPL). Also, the real-ear unaided gain (REUG) and real-ear occluded gain (REOG) were also measured as per the standard procedure. The resultant raw data from the measurement were extracted and post-processed to calculate the real-ear insertion gain (REIG) at octave-band frequencies from 125 Hz to 8 kHz for all three input levels.

Different types of anomalies in REUG and REIG were identified during the data curation. The most common anomaly was multiple unlabeled measurements. For some participants, the REM at a given input level was repeated multiple times, and the valid measurement was not labeled. So, each measurement had to be compared individually to find a logically acceptable measurement. In some cases, it was difficult to visually confirm a logically acceptable measurement and to determine the validity of these repeated measurements. There were 104 such measurements (including all levels, both ears combined) from 90 participants, which had to be excluded from further analysis. We also observed unlabeled measurements of unilateral, CROS, or Bi-CROS users of their unaided ears, which resulted in a near 0 dB insertion gain. The measurement of the untreated ear was taken to avoid any missing data; however, the missing labels on a few created confusion. This data was properly labeled to facilitate further analysis in other studies.

The REM data from a set of participants (42) with either missing REUG measurements or with some anomalies were excluded from further analysis. The most common anomaly observed in REUG measurements was an offset of approximately 5 dB at lower frequencies (12 Hz band). These offsets were hypothesized to be interference from external noise during the measurement. A study was conducted to further understand the cause of such an offset [70]. The study found that the only action that

triggered such offset was touching the probe tube during the measurement. Overall, the extensive due diligence has helped ensure the quality of such a large number of measurements included in the study.

3 Summary of Contributions

3.1 Aim of Study

The primary objective of the present PhD study was to investigate and identify the factors that contribute to the achievement of successful hearing rehabilitation among adult HA users in Denmark during their first year of use of new HAs. The success of hearing rehabilitation using HAs can be multi-dimensional; however, we try to understand it from the perspective of self-reported HA outcomes as this is most likely in the same domain as the patients' decision-making in a rehabilitation journey (success, failure, giving up, needing help, etc.). It can be hypothesized that hearing rehabilitation's success will be reflected in self-reported HA outcomes.

3.2 Research Framework

In WP 1 of the BEAR project, Houmøller et al. 2022 [43] investigated the impact of various factors like age, sex, degree of HL, word-recognition score (WRS), average daily HA use time, motivation of HA users towards HA treatment, self-reported tinnitus, and HA configuration (unilateral/bilateral fitting) on IOI-HA scores to understand the HA treatment success for both first-time and experienced HA users. Houmøller et al. [66] also studied the effect of HA technology (comparing basic and advanced HAs) and self-reported noise exposure on self-reported outcomes (IOI-HA and SSQ12). This study further extends the research of the WP 1 data and supplements it by examining the effect of other clinically relevant factors. The participants are stratified with respect to specific common characteristics derived from the clinical or self-reported measures to understand the determinants of successful hearing rehabilitation.

While commonly used objective outcome measures (typically task-performance tests with high specificity) can provide precise and consistent measures of aided listening performance in a strictly controlled environment (clinics or labs), they are less likely to reflect the everyday situations encountered by individual HA users. In contrast, self-reported HA outcomes offer a valuable testimony of the in-situ experiences of HA users, reflecting their unique hearing rehabilitation journey. Consequently, a higher self-reported HA outcome can serve as a potential indicator of successful hearing rehabilitation.

Prior research [58, 59, 71, 72] has shown that HA users fitted close to generic prescriptions have significantly better outcomes (both objective and subjective) than those fitted with a manufacturer's proprietary prescription. In Denmark, the typical clinical practice is to fit the HAs using manufacturer-specific prescriptions. It was essential to understand if there was a significant deviation from the generic prescriptions to the initial fit performed based on the proprietary manufacturer-specific prescriptions in a

large heterogeneous population like the one that participated in the BEAR WP1 [73]. We also wanted to investigate if there existed a relationship between the proximity of the current fitting to generic prescription and self-reported HA outcomes. Two studies (Study I and III) were scoped to examine these aspects of the amplification paradigms with which the HA users were currently fitted. The first study (Study I) focused on understanding the gain deviation of first-fit from three generic prescriptions (NAL-NL2 [74], NAL-RP [75], One-third gain rule [76]) at a moderate input level (65 dB SPL) and its effect on self-reported outcome measures. The second study compared the initial fit and a generic prescription (NAL-NL2) with respect to the Speech Intelligibility Index (SII) [77], a measure of audibility, at three different input levels (55, 65, and 80 dB SPL). It also examined whether the SII difference between initial fitting and generic prescription can predict self-reported outcome measures. Overall, both these studies focused on understanding the relationship between the currently fitted gain paradigm to self-reported outcome measures. Studies I and II looked at the short-term outcomes (2 months) as the REMs analyzed in these studies represented the fitted gain in the initial two months of HA use.

Adapting to new auditory experiences of the HAs, the physical presence of a device in the ear canal, and handling and managing the HAs can be challenging, especially for first-time HA users [56, 78, 79]. In adapting to the new HAs, users may fine-tune their HAs to meet individualized preferences [80]. Also, the time at which such adjustments were performed can indicate the help-seeking behavior of the HA users. All these factors can be closely linked to user behavior that can be detrimental to the success of the HA treatment. The third study in this PhD (Study III) looked into these aspects of user behavior.

The pattern of HA usage can be another aspect that links to user behavior. Previous studies have found that higher use of HAs relates to better HA outcomes [21]. There can also be a section of users who use the HAs for specific needs and still benefit from them [81, 82]. Such behaviors of HA users may result in distinct HA usage patterns, which may impact self-reported outcomes. In the fourth study (Study IV), we investigated the effect of HA usage patterns determined from the retrospective self-report of HA users about the situations in which they always took off or put on their HAs on the self-reported outcome measures. It also examined the significance of socio-economic, user-related, and demographic factors on distinct HA usage patterns. Studies III and IV looked at long-term rehabilitation success by analyzing the outcome measures recorded after at least one year of HA use.

All studies were prospective observational studies. The acoustic fitting type (HA-related), motivation (related to personality traits), HL-related (degree of HL, tinnitus, etc.), average daily use time (user behavior), and other demographic indicators (user-related) were used as covariates to understand and adjust for their effect in the model where ever applicable.

3.3 Specific Contributions

The results from the four studies were presented in four papers included in Part II of this thesis. The core strength of the studies is the large and diverse cohort recruited as

part of the typical clinical patient flow from the two Danish clinics. The background and key findings of each paper are summarized below.

Paper A: Can real-ear insertion gain deviations from generic fitting prescriptions predict self-reported outcomes?

This study examined the possibility of predicting self-reported HA outcomes from the gain deviations from the REIG to three generic fitting rationales (NAL-NL2, NAL-RP, and one-third gain rule). There were 1213 participants (884 first-time and 329 experienced HA users) with a valid real-ear measurement at 65 dB SPL input level and having answered all the questions in the IOI-HA. The gain deviations to the generic prescriptions were clustered using k-means clustering. The resulting cluster was then used as a categorical unit, effectively representing the gain slope referenced to the generic prescription of the individual HA users. The deviation from generic prescription(s) at higher frequencies defined the clusters. The results suggested that higher deviation from the generic prescriptions may result in a lower perceived benefit from the HAs for the experienced HA users than those close to generic prescriptions. For first-time users, the effect of gain deviation is statistically overpowered by the participants' motivation toward HA treatment.

Paper B: Difference in audibility provided by initial fit and NAL-NL2 and its relation to self-reported hearing aid outcomes.

This study investigated the relationship between self-reported HA outcomes and the difference in aided speech intelligibility index (SII_A) calculated from the initial fitted gain and the NAL-NL2 prescribed gain. The study included 971 participants (718 first-time HA users and 253 experienced HA users) with valid REM (55, 65, and 80 dB SPL input levels) and self-reported HA outcome data. The SII_A) was calculated using ANSI 3.5 (1997) standard. The gain provided by the initial fit was lower than NAL-NL2 at lower input levels (55 dB SPL), and at higher input levels (80 dB SPL), the NAL-NL2 was more compressive than the initial fit. The analysis showed that the difference in SII_A from initial fit to NAL-NL2 at 80 dB SPL with 0 dB SNR was a significant predictor of self-reported outcomes for first-time users. The effect of SII_Aon the self-reported outcomes for experienced HA users was not statistically significant.

Paper C: Adapting to new hearing aids and hearing aid adjustments in adult Danish users.

This study examined the effect of how long time users took to get used to the HAs, the timeline, and the number of HA adjustments performed over the first year of rehabilitation post-fitting on self-reported HA outcomes for 690 HA users. The self-reported data showed that most HA users (64%) got used to the HAs within two months of use. A minority (13%) did not get used to the HAs at all. Twelve percent of HA users never had their HAs adjusted over the first year, whereas 7% had the HA adjusted four or more times. The study showed that, for a subpopulation of participants (5%), even

after having at least three adjustments to the HAs, the self-reported outcome was still lower than for participants with fewer adjustments. We also found that the sooner the HA user got used to the HA, the better the self-reported HA outcome.

Paper D: Self-reported hearing-aid use patterns in an adult Danish population.

This study examined the daily HA usage patterns among Danish adult HA users and their relationship to HL, demographics, socio-economic status, user-related factors, and self-reported outcomes. The 1537 participants answered two questions about the situations where they always took off or put on their HAs. A latent class analysis of the responses to these questions showed distinct use patterns among the participants. The relationship between these use patterns and audiometric factors, hearing-related factors, HA-related factors, and socio-economic indicators was established. The study unveiled a high proportion of situational users and non-users and indicated the importance of consistent HA use for better outcomes.

3.4 General Discussion and Future Directions

When attempting to understand the factors influencing successful hearing rehabilitation using HAs, one has to consider the definition of treatment success. Determining HA treatment success can be intricate and lacks firmly established criteria. Nonetheless, the objective of HA treatment has always been to optimize the user's aural perception in any given context, particularly for speech comprehension. Validation measures performed in controlled settings can be used to achieve the intended HA performance, and HA can be fine-tuned as necessary. However, the paramount factor for successful hearing rehabilitation is the user's perceptual benefits and the HA's ability to solve the specific problem of the given HA user.

The present PhD study extensively investigated the effect of factors related to the insertion gain provided by the HAs derived from the REMs on self-reported HA outcomes. The REMs can be used to verify the gain provided by the HAs against a prescribed target. Many clinics (especially in Denmark) do not use REMs to ensure the match to a target gain prescription. In a recent guideline by the Danish health ministry, it has been suggested to perform REMs to record the fitted gain curves. However, using REMs to fit HAs to a given prescriptive target is still not mandated to allow tailored paradigms for a given sub-population. In a scoping review, Almufarrij et al. (2021) [83] investigated whether the use of REMs improved the HA outcomes and found that REM-based fittings were preferred even though the evidence quality varied for various outcomes in studies that were part of the review. The effect of HA fitting using REMs on outcome measures was also found to be minimal.

The results of the present PhD's first and second studies suggest that gain deviations from the current fit to the generic prescription of NAL-NL2 (at moderate and high input levels) can impact self-reported HA outcomes [73]. So, if we do not verify the fitted gain using REMs, we may not be aware of the gain deviations (to any target), which can have a critical impact on the success of HA treatment. Kochkin (2011) [84] had also found that verifying and validating the HA fitting can significantly reduce

the re-visits to the clinic. This could mean that fitting and validation may reduce the burden on a public system by reducing the number of re-visits to the clinic. The most significant concern in implementing fitting using REMs can still be economical. Further research may be warranted to establish the cost-effectiveness of routinely using REM for HA fitting, considering the effect on rehabilitation through a cost-benefit analysis [83]. Even if we do not use REMs in fitting HAs for all patients, it may possible to identify subgroups of patients who would benefit from using REMs to achieve superior outcomes. REMs can be selectively utilized in such cases to optimize the fitting for those specific sub-populations. For example, our investigations have revealed that patients with a higher degree of HL are fitted with gains that deviate significantly from the generic prescriptions, in contrast to users with milder HL. Consequently, this subset of patients can be identified as a distinct sub-population, and REM-based fitting can be selectively implemented for this group to optimize the HA performance. This may also result in a better HA outcome for that sub-population of HA users.

The population of HA users (Study III) who took more than four months to get accustomed to their HAs and those who did not get used to the HA at all constitute an important sub-population that requires attention. This sub-population reports lower self-reported outcomes than those who got used to their HA before four months of use. Additionally, HA users who, despite multiple adjustments and fine-tuning to their HA, did not have a similar level of self-reported outcomes as HA users with fewer adjustments are also an interesting sub-population to study. Stock et al. (1997) [85] suggest that HCPs should proactively understand the reasons resulting in such circumstances. The issues can be associated with audiological factors (such as suprathreshold deficits and cognitive deficits), HA-related factors (such as feedback and distortion), and other factors (such as physical comfort), as well as user behavior and lack of acclimatization. If HCPs can resolve the issues through counseling or other suitable means, these users are one and a half times more likely to be satisfied [85].

There has been much emphasis in recent research on understanding HA performance in the specific situation and its context of use [86, 87]. This will help HA manufacturers understand individual needs, and limitations can be used to tailor a solution to enhance HA performance and improve HA outcomes. HCPs can use the information about HA usage to provide more personalized counseling. The participants in the BEAR WP 1 study reported various situations where they always took off their HAs. It was observed that the HA users still have limitations in using their HAs in noisy and multi-talker situations. Even though most users stuck to the response options provided, the descriptive responses in the "other" [88] category testified to HA performance in various situations. It was interesting to observe how distinct usage patterns were linked to the socio-economic indicators that depict the state of life of HA users.

HA users come from different phases of life with varying personalities and social circumstances. The attitude of the HA users toward the HA treatment can be critical in achieving better outcomes [63, 89, 90]. Motivation, which is also a psychological aspect like attitude, is also found to be critical to the success of the treatment. Many previous studies [43, 91] have shown that motivated HA users report higher self-reported HA outcomes, especially in the case of first-time users. This study also found

a link between multiple aspects of hearing care to motivation toward HA treatment. It also showed the influence of motivation in help-seeking (Study III). Hearing-aid users with a favorable mindset may also be more likely to have a favorable outcome. Some HCPs may better understand their mindset towards HA treatment and prepare them (by setting the right expectations) for rehabilitation through effective counseling. The HCP may also find ways to promote a "growth mindset" [92] to motivate the users and to achieve a better outcome of the treatment.

The studies in the present PhD only considered people who made an effort to answer all the questions in the self-reported outcomes measures (IOI-HA and SSQ12). However, it is fair to assume that the HA users who may not have a perceived benefit from HAs and have stopped using the HAs may not have had the motivation to answer these questionnaires. This may have introduced a positive selection bias indicating a higher motivation and eagerness toward the HA treatment among the participants included in the study. Even with a positive selection bias, we could identify HA users who were discontent with their hearing rehabilitation. This became more evident when we analyzed the data in Study IV, where we identified users who were not using / sparingly using their HAs and still answered all the questions in the outcome measures. It is exceptional to notice that these users voiced their discontent in the form of detailed descriptions and also answered multiple outcomes questionnaires even when they discontinued using their HAs.

The coefficient of determination (R^2) for all the regression models considered in the present PhD study has not been very high. The maximum was 0.32 for the model predicting IOI-HA Factor 1 score [38] for the first-time users in Study I [73]. There can be various reasons for low R^2 values when predicting self-reported outcomes. The self-reported outcomes reflect complicated and multidimensional constructs that can be difficult to measure. The relationship between self-reported outcomes and some explanatory variables can be non-linear, resulting in a lower R^2 value. Also, there can be other latent variables that are not included in the model that influence the self-reported outcomes. Finally, self-reported outcomes are also subjected to measurement errors due to various biases (recall bias, response bias, etc.). All these factors may have resulted in a lower coefficient of determination for the regression models included in the study.

There can be more residual factors that can impede successful HA treatment. Identifying such factors and characterizing HA users into different subgroups according to those factors can help achieve a better HA outcome for such a subgroup of HA users. For example, a working-age HA user may have special needs in fulfilling work-related tasks and general social interaction in a professional setting. The factors that affect the overall success of rehabilitation can be similar, as found in this and previous studies. However, some latent factors could be critical in providing better HA outcomes in a specific situation of need. Understanding those factors will provide insight into improving the hearing rehabilitation experience of this specific sub-population.

Also, the research based on large amounts of data can provide comprehensive knowledge on the rehabilitation journey of HA users. We can use these large amounts of data to create complex models (rather than simple linear) to predict self-reported outcomes. This may provide insight into factors and interactions that may not be

evident when modeling a linear relationship to the self-reported outcome. The study by Suresh et al. 2022 [93] is a step forward. These predictive models can then be used to characterize the patients during the hearing screening stage itself to provide optimal care.

3.5 Conclusion

The study investigated the determinants of successful hearing rehabilitation among adult HA users, with a special interest in new users that may be more likely to give up. The key findings and conclusions from all four studies in this PhD thesis can be summarized as follows:

1. The experienced HA users fitted with an insertion gain with higher deviation from NAL-NL2 and NAL-RP at higher frequencies at moderate input levels are likelier to have a lower benefit from HA use. It is suggested that the real-ear insertion gain be determined, and fitting close to the universal target may be better for the general population of adult users.

2. The motivation towards HA treatment is a stronger predictor for benefit than the real-ear insertion gain for first-time HA users. This suggests that first-time users need different attention than experienced users and that motivational tools may help them adapt to their new situation and improve overall outcomes from treatment.

3. The HA users fitted with custom earmolds consistently reported lower outcomes than those with the open dome. Custom (vented) earmolds should provide better acoustics for all users and allow for better gain control at the lowest frequencies. This suggests that physical comfort in the ear canal is a vital factor in the individual user experience. Attention to a better physical fit of the custom earmolds in the ear canal with proper venting and better counseling on handling the earmolds may improve outcomes.

4. The insertion gain prescribed by NAL-NL2 at low and moderate (55 dB SPL and 65 dB SPL) input levels were higher than the fitted gain at octave band frequencies from 250 Hz to 8 kHz. This suggests a conservative amplification strategy for the majority of HAs fitted, which may account for part of the dissatisfaction generally observed (e.g., Eurotrak 2022 [17]).

5. NAL-NL2 gain prescription is more compressive than fitted gains at 1 kHz and 2 kHz octave bands at 80 dB SPL input level, which may have resulted in a better SII_A with NAL-NL2 prescribed gain at 80 dB SPL 0 dB SNR. A better SII_A than that provided by NAL-NL2 at higher levels could result in a better outcome.

6. A higher proportion of users with prior experience using the HAs got used to them within two months (compared to first-time users). The HA users who took longer to get used to their new HAs reported lower outcomes. This signifies

the importance of adapting to the new auditory experience and getting used to wearing the HAs post-fitting.

7. The HA users who had HA adjustments throughout the year reported a lower outcome than HA users who did not adjust their HAs for more than a year. Even after seeking help multiple times, they did not have an outcome at par with HA users who did not have any adjustments. This highlights the need for a better understanding of such patient sub-groups and a more effective course of action in clinical practice.

8. A large fraction of HA users reported taking off their HAs at home and during physical activity like running or biking. Similarly, a higher proportion of users always prefer to put on their HAs while watching TV, at work, and during social interaction. HA usage patterns may vary by demographic and socio-economic factors. The study also established a relationship between regular usage, situational usage, and non-use of HAs and self-reported HA outcomes.

The PhD study revealed significant variation in the perceived outcomes of hearing aid treatment in current clinical practice. It identified key factors that can enhance hearing rehabilitation, enabling HCPs to develop evidence-based practices that support HA users in their hearing rehabilitation journey.

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Part II

Papers

Paper A

Can real-ear insertion gain deviations from generic fitting prescriptions predict self-reported outcomes?

Sreeram Kaithali Narayanan, Palle Rye, Tobias Piechowiak, Gert Ravn, Anne Wolff, Sabina Storbjerg Houmøller, Jesper Hvass Schmidt, and Dorte Hammershøi

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Paper B

Difference in audibility provided by initial fit and NAL-NL2 and its relation to self-reported hearing aid outcomes

Sreeram Kaithali Narayanan, Palle Rye, Sabina Storbjerg Houmøller, Anne Wolff, Dan Dupont Hougaard, Michael Gaihede, Jesper Hvass Schmidt, and Dorte Hammershøi

The paper has been submitted to the
International Journal of Audiology (Under review) .

The layout has been revised.

Paper C

Adapting to new hearing aids and hearing aid adjustments in adult Danish users

Sreeram Kaithali Narayanan, Sabina Storbjerg Houmøller, Anne Wolff, Dan Dupont Hougaard, Michael Gaihede, Jesper Hvass Schmidt, and Dorte Hammershøi

The paper has been submitted to the
American Journal of Audiology (Accepted with minor revisions)

The layout has been revised.

Paper D

Self-reported hearing-aid use patterns in an adult Danish population

Sreeram Kaithali Narayanan, Sabina Storbjerg Houmøller, Anne Wolff, Katja Lund, Sören Möller, Dan Dupont Hougaard, Michael Gaihede, Jesper Hvass Schmidt, and Dorte Hammershøi

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