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Better hearing rehabilitation for adult first-time users (the BEAR project)

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First-time adult hearing-aids users do not always experience the debut with success, and it is known that some give up. For the professional fitting the hearing aid, it is often a difficult to figure out, if the hearing aid is poorly fitted to the individual, and whether it is set for best performance or not. The purpose of the BEAR project is to develop a stronger framework for the diagnostics, fitting and assessment of the aided performance that will allow for a more structured, and personalized approach. The project includes several scientific efforts, incl. 1) the collection of data for almost 2.000 patients fitted according to current practice, 2) the development and assessment of new diagnostics for profiling and fitting strategies, as well as 3) development and assessment of methods for measurement of the aided performance. The on-going work includes a proposal for a differentiated fitting based on extended auditory profiles, and is accompanied by both in- and out-of-clinic options for testing and/or reporting on the aided performance experience. Future results will include an experimental validation of the proposed differentiated fitting, as well as separate efforts to investigating common denominators for patients with poor compensation benefits, and options for out-of-clinic application of the proposed methods.

1 Introduction

The BEAR project is framed on the basis of current clinical practice in Denmark (and many other places), where hearing aids are administered after medical examination and under medical supervision. For the typical adult first-time hearing aid user, the examination holds only coarse information about the individual's hearing impairment that can guide the technical fitting directly. The audiogram remains the "golden standard", which the fitting software for the various hearing aids base the dynamic amplification, compression, noise- and artefact rejection, and other functional features on. Once fitted with a hearing aid, the user will need a period of adaptation or acclimatization to the regained listening experiences, which the hearing aid offers [1]. This is a process with both successes and failures, which can be both over-whelming and fatiguing for the typical adult first-time user [2]. Most first-time users therefore needs a follow-up visit for additional consultation and possible re-fitting, which in some cases leads to a trial-and-error process, which is sub-optimal for a number of reasons: Patient frustration, sub-optimal conditions for the adaptation, and lack of confidence from both patient and professional in the solution and fitting.

The purpose of the BEAR project (sketched in Figure 1) is to develop and experimentally validate fitting strategies, which may improve the starting point for the adult first-time user, and better support the re-fitting process, if necessary. The body of work is organize in seven work-packages, accompanied by adequate management and relevant standardization.

2 The centralized clinical database (WP1)

The purpose of work package 1 (WP1) is to collect data for patients fitted with current practice in order to 1) examine the characteristics of the typical adult first-time user population, 2) identify any sub-populations that deviate in hearing characteristics, outcome or in other ways relevant for the HA fitting, and 3) have a broad starting reference for the experiments with new methods.

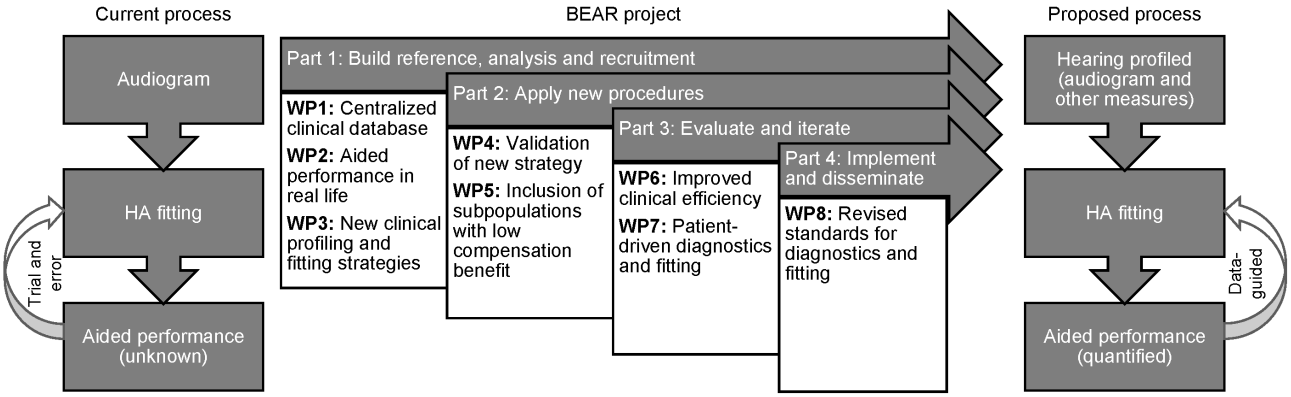

Figure 1: Sketch of current, iterative fitting process, the overall BEAR project plan and its work packages, and the proposed process involving profiling tests and measurements of the aided performance in real life, which supports any subsequent re-fitting.

In WP1, data have been collected for almost 2.000 patients (2.447 invited, 1.961 included). The general protocol included the completion of a set of questionnaires before the first visit to the clinic. The questionnaires related to the patient's general health, health-related life quality (the 15D) [5]–[9], a customized version of the Speech, Spatial and Qualities of Hearing Scale (SSQ12+4) [3]–[5], the Danish version of the Tinnitus Handicap Inventory (THI) [6], and for experienced users also the International Outcome Inventory for Hearing Aids (IOI-HA) [7]–[9]. The SSQ, THI, and IOI-HA were also administered before an obligatory follow-up around 2 months after fitting, and after at least one year post-fitting. Results confirm among other that many patients struggle and need follow-up consultations (approx. 13% before the 2-months follow-up, 74% at the 2-months follow-up, and approx. 26% after 2-months follow-up).

The self-reported health-related life quality (the 15D responses) were analysed by in the PhD study by Anne Wolff [10]. The results showed that both new and experienced users reported a higher hearing-related life quality after fitting, and new users also experienced higher overall life quality. Age, gender, degree of hearing loss, and degree of asymmetry affected the self-reported life quality. Patients with asymmetrical hearing had lower life quality improvements, and experienced users poorer space- and directional hearing (as reported in subsets of the SSQ).

The responses to the IOI-HA were analysed in the PhD study by Sabina Storbjerg Houmøller [11]. The results confirm that age, gender, and degree of hearing loss are significant factors for the effectiveness of HA treatment. It is also suggested that prior occupational noise exposure (self-reported) is related to the nature of the audiograms and poorer HA benefit in age-related hearing loss.

Key persons are, from Odense University Hospital (OUH): J. H. Schmidt (WP leader), S. S. Houmøller, R. Schnack-Petersen, from Aalborg University Hospital (AUH): A. Wolff, D. D. Hougaard, M. Gaihede, from University of Southern Denmark (SDU): V. K. Narne, L.-T. Tsai, from Aalborg University (AAU): G. Loquet, D. Hammershøi, from Force: G. Ravn, C. Daugaard, from GN Hearing: N. Bisgaard, from Oticon: Karen Wibling Solgaard, from Widex-Sivantos Audiologies (WSA): E. Schmidt.

3 Aided performance in real life (WP2)

The aided performance after fitting is in current clinical practice evaluated in the clinic using either free-field audiometry (speech audiometry) or – more often – heuristics tailored to the specific clinic's environment and options for providing relevant listening stimuli. In the present project, aided performance is assessed through 1) standardized and validated questionnaires before and after fitting (as in WP1), 2) in-clinic tests with a strong focus on speech intelligibility, 3) the use of an on-line reporting platform that probes the memory of the patient for experiences after fitting, and 4) through objective measurements of the amplification provided by the hearing aid (real-ear measurements, REM).

The in-clinic tests include among other customized versions of the Danish Hearing in Noise Test (HINT) [12], Just Follow Conversation (JFC) [13], and a few other tests inspired by the heuristics often performed in the clinics; a Sound Identification Test (SIT), a Noise Annoyance Test (NAT), and a Spatial Hearing Test of Localization. All tests were tailored for a five channel "free-field" setup in an acceptable clinic arrangement (with speakers close to the walls to avoid comb-filter effects, and situated level control). Where the speech intelligibility tests have normative reference data in many languages, the other tests will depend on the specific setup in the clinic and will likely not have options for normative

references. Even so, they may be useful in accompanying the measured speech intelligibility, and support the hearing care professional (HCP) in documenting effects of change, or when investigating given user problems.

The on-line platform [14] adds an out-of-clinic option for probing the user's memory during the first period after fitting. In the current implementation, a fixed set of experiences are presented semi-randomly (loops more than 400 experiences) and the user only have to relate to whether he or she has had a given experience or not. This makes the assignment very easy, and requires very little effort in responding. The user can log on and "swipe" through as many possible experiences, he or she care to at any time of day, where it fits the user. The data that can be collected this way carries no information about the context, settings in hearing aid, or adverse conditions, yet it provides real life data for the user experience, which may reflect the progress of a given user, and reveal systematically recurring problems (remaining challenges).

Key persons of WP2 are, from Danish Technical University (DTU): J. B. Nielsen (WP leader), S. Santurette (WP leader at start), S. G. Nielsen, T. Dau, from AAU: K. Lund, R. Ordoñez, D. Hammershøi, from Copenhagen University Hospital (CUH): J. B. Yde.

4 New clinical profiling and fitting strategies (WP3)

In current clinical practice, hearing aids are fitted almost entirely based on the pure-tone audiogram of the listener. This means that amplification, control of dynamic range, compression rate and speed, noise reduction, and other advanced features are almost entirely based on a measure based on stimuli levels close to the absolute threshold, which is quite different from the sound levels of natural communication. The clinical experience includes patients with disproportionately poor speech intelligibility [15], and it is not uncommon to see patients with near-normal thresholds (approx. 4% in the WP1 data collection), yet suffering a hearing problem they seek medical treatment for. This suggests that there may be underlying dimensions in the hearing problem, which is not well captured by the pure-tone audiogram.

In the PhD study by Raul Sanchez-Lopez, an effort was made to disentangle the underlying dimensions and categorizing the hearing problem into a two-dimensional space, configured by two independent dimensions of the "distortion": One "associated with audibility-related deficits and reduced spectral processing abilities," [16] and a second "associated with non-audibility-related deficits and reduced temporal processing abilities not reflected by the audiogram" [16]. A proposal for a such profiling was developed [17], and a revised fitting paradigm described and pilot-tested [18, 19].

Key persons of WP3 are, from DTU: R. Sanchez-Lopez, S. Santurette (WP leader at start), T. Dau, from SDU: T. Neher (WP leader), M. Wu, M. Al-Haj-Ali, from CUH: J. B. Yde, from Oticon: T. Behrens, M. S. Pedersen, S. Santurette, from GN Hearing: T. Piechowiak, from WSA: E. Schmidt, O. Hau, from Force: G. Ravn, C. Daugaard.

5 Validation of new strategies (WP4)

A second clinical trial (on-going) has been launched to investigate the potential of the stratified fitting procedure developed in WP3. Fitting procedures tailored to the fitting paradigm proposed in WP3 has been developed for existing HAs from the three participating HA companies. The fitting paradigm is based on REM-based targets, and validated for each individual patient in both the experimental fitting (categorized into four sub-populations with each their specific target), and the selected "best-practice" control (all controls fitted according to NAL-NL2 [20]).

The aided performance is measured right after fitting and at a 2-months follow-up using the methods described in WP2, enabling cross comparison of self-reported outcomes (questionnaire based), in-clinic assessments of the aided performance, and statistics from the on-line tool harvesting real-life experiences after fitting.

Key persons of WP4 are, from AAU: G. Loquet (WP leader), R. Ordoñez, P. Rye, from DTU: O. Cañete, F. Bianchi, from SDU: T. Neher, M. Wu, from OUH: J. H. Schmidt, A. T. Stubberup, from AUH: M. Gaihede, J. J. Kjærsgaard, L. Petersen, K. S. Mikkelsen, from Force: G. Ravn, C. Daugaard, from Oticon: M. Baumann, S. Santurette, from GN Hearing: T. Piechowiak, from WSA: Borys Kowalewski.

6 Sub-populations with low compensation benefit (WP5)

It is currently not part of the public Danish practice to measure the insertion gain of the hearing aids fitted, unless special circumstances require it (ear canals with abnormal geometry etc.). In WP1, measurements were made only to document the insertion gain provided by the hearing aids fitted according to proprietary rules for the given product (administered according to current practice, but with a balanced representation of hearing aids from the three participating industry

partners and only a few hearing aids from other producers). This also means that patients were effectively fitted with slightly varying fitting strategies and products, and often with minor adjustments right after first fitting, or at the follow-up. Literature suggests that applying REM for validation and verification of adequate targets increase user satisfaction and decrease the number of required follow-up consultations, e.g. [21]–[27].

It is currently analysed, how well given gain prescriptions (e.g. NAL-NL2, NAL-RP, one-third-gain, and half-gain) may predict the self-reported outcomes (SSQ and IOI-HA) for patients fitted in WP1. Cluster analysis suggests that the real-ear insertion gain deviations from target can be grouped in two main clusters, and the analyses tentatively indicate that fitting according to NAL-NL2 predicts better self-reported scores [28].

A parallel work focus on a distinct characteristic in some individuals' listening ability, where the word recognition score shows a so-called "roll-over effect", i.e. has a maximum performance peaking around a narrow level range of the reproduced words. This work is on-going, and aim at investigating the significance of the roll-over effect for optimal fitting [29], and possible relation to the profiles determined using the WP3 results.

The key persons in WP5 are, from AAU: S. K. Narayanan, D. Hammershøi (WP leader), from SDU: M. Fereczkowski, T. Neher, L.-T. Tsai, S. Klausen, from AUH: A. Wolff, from OUH: S. S. Houmøller, from Force: G. Ravn, from GN Hearing: T. Piechowiak.

7 Evaluation of clinical efficiency (WP6)

The revision of the clinical procedure aims at either improving quality, reducing costs, or simplifying procedures with the objective of reducing successive consultations and re-fittings, or ultimately eliminating some of the steps in the rehabilitation course. Yet the complexity of new procedures may also require specialized training, new instrumentation, new acoustic adaptations in test rooms, and revised administrative procedures.

In WP6, it is the intention to optimize the proposed "new" unaided and aided tests, and evaluate the impact of a revised paradigm. For better strategic planning and prioritization in the public health system, it would be desirable to be able to quantify the effects of treatment in universal life quality units, e.g. in quality-adjusted life year (QALY) [30] or similar, allowing cross-comparison of independent effects in different domains.

The on-going activities include assessment of the potential of deriving universal life quality units from the standardized outcome measures [31], and (started only recently) looking at the value proposition of treatment from the perspective of patient and hearing care professional.

The key persons in WP6 are, from SDU: J. H. Schmidt, L. N. Lorentzen, L.-T. Tsai, S. S. Houmøller, from DTU: J. B. Nielsen, S. G. Nielsen, from AAU: K. Lund, R. Ordoñez, D. Hammershøi.

8 Patient-driven diagnostics and fitting (WP7)

The use of online tools for hearing tests are growing, and it is likely that potential patients value the privacy of testing in safe environments of their own control. From a clinical perspective, reliable home tests may enable better time management of the steps that require in-clinic tests or counselling. In WP7, the potential of translating the most beneficiary tests from the WP3 profiling battery (or the WP2 aided performance tests) into tests that may to some degree give measures correlating to corresponding in-clinic tests, is addressed.

The key differences in home tests and in-clinic tests relate to i) the technical platform incl. e.g. calibration control, ii) the acoustic environment, and adequate actions (rejection) of measurements polluted by intermittent noise, and iii) user behaviour. These are mostly adverse factors, but on the positive side counts the possibility for longer or more test sessions (where the user can decide, when to conduct them), and improved motivation through ownership of some of the important steps in the rehabilitation process.

The on-going activities include an analysis of the WP1 audiograms, and user-controlled thresholds may be affected by background noise [32]. For the majority of patients, the threshold is typically more than 25 dB from normal even at low frequencies, where noise tends to dominate. The impact of background noise might therefore not critically affect the most important frequencies for initial diagnosis, and data may even provide an adequate starting point for an initial fitting.

The on-going activities also include an assessment of the impact of intermittent noise on real-ear measurements [33], and on determinations of Categorical Loudness Scaling according to ISO 16832 [34].

The key persons of WP7 are, from AAU: P. Rye, D. Hammershøi (WP leader), from AUH: A. Wolff, D. D. Hougaard, from OUH: J. H. Schmidt, S. S. Houmøller.

9 Standardization (WP8)

The results from the BEAR project are also disseminated through national guidelines and international standardization. A recent effort (by N. Bisgaard and G. Ravn) has resulted in ISO 21388, which lay down procedures for both assessment of aided performance and objective measurements (REM).

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