ASPECTS OF HEARING AID FITTING PROCEDURES

R.M. Metselaar

Aspects of hearing aid fitting procedures

Thesis: Erasmus University Rotterdam, the Netherlands

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ASPECTS OF HEARING AID FITTING PROCEDURES

ASPECTEN VAN AANMEETMETHODEN VAN HOORTOESTELLEN

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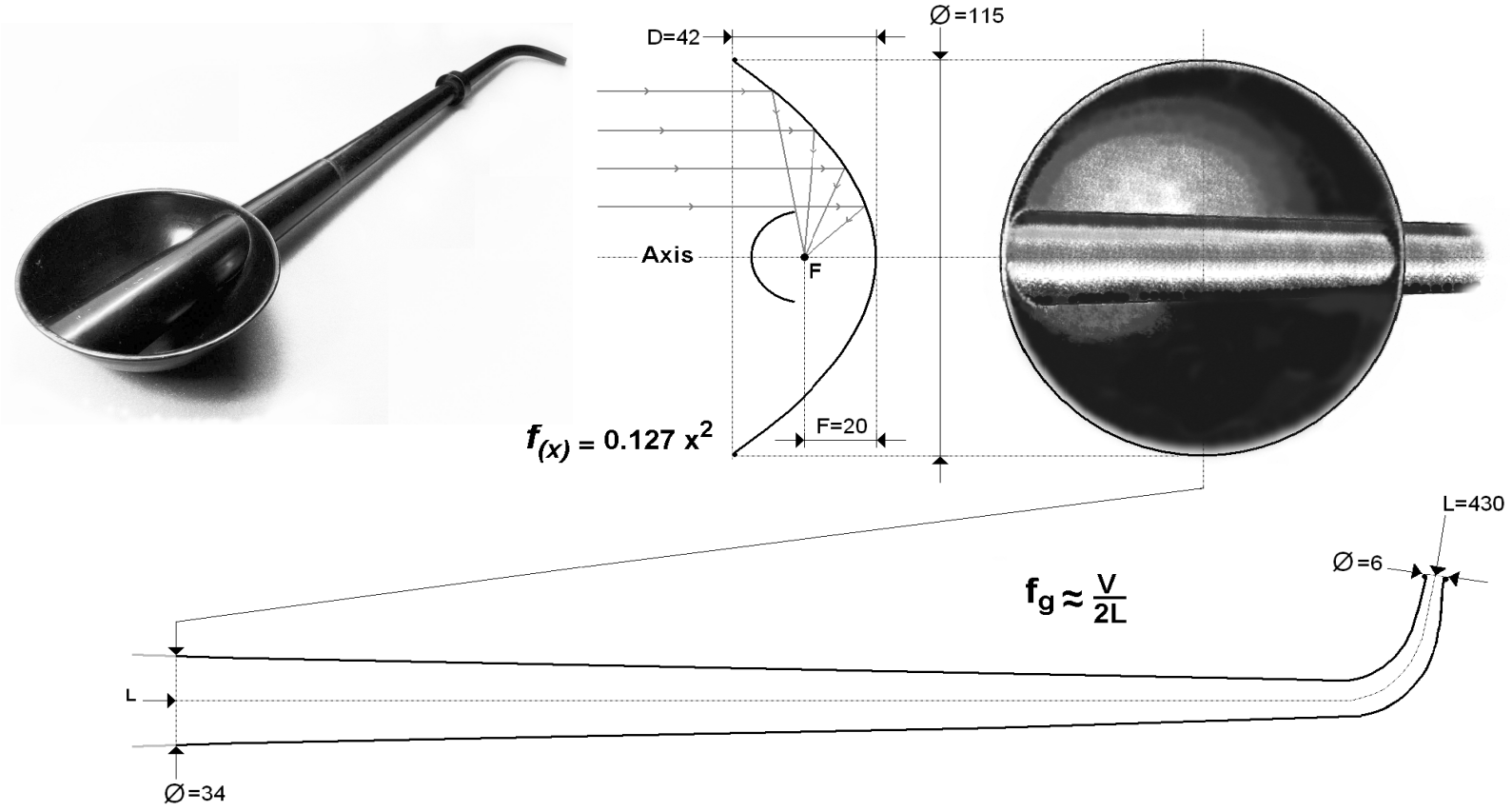

Figure 1-0: An acoustic ear horn made of brass, probably dating from the 1920s. This example consists of two parts: (1) Sound is collected by a parabolic reflector (mathematical function given in the figure) that transforms an incoming plane wave travelling along the axis into a spherical wave converging toward focus “F”. The reflector is mounted on a conical horn (2) that converts the acoustical impedance. The wavelength of the ground frequency is approximately two times the length of the horn as is given in the formula. All sizes in millimeters. Photograph and drawing by the author.

Chapter 1

General introduction

Introduction

Sensorineural hearing loss is a common and chronic disorder that affects almost ten percent of the world population. In the Netherlands, it is also the major disorder in the working population [NCvB, 2008]. Hearing loss leads to restriction in the interaction with others and withdrawal from participation in (social) activities. Due to the size of the problem and the vast impact on the function, hearing rehabilitation is an important issue. Although hearing rehabilitation focuses on many more aspects such as learning of communication strategies and adaptation to the acoustical environment, hearing aid fitting is one of its first essential steps. Hearing aids have to amplify sound to a level above the hearing threshold to utilize the residual hearing capacity of the ear as much as possible. In the 20th century, a number of technological advances have taken place in amplification devices. These started from nonelectronic ear horns that were replaced by electronic hearing aids. Amplification was initially achieved by analogue circuits, while from the 1990s digital signal processors have entered the market. An enormously wide variety of hearing aid models has become available since [Bentler & Duve, 2000].
Aside from differences that have to do with the sound that is being produced, hearing aids can be classified with respect to type. While the technological development started with body-worn hearing aids, we nowadays distinguish behind-the-ear (BTE), in-the-ear (ITE) and hearing aids that fit partly or completely in the ear canal (CIC). These types are available in a wide variety of models, colours and sizes and are of various brands. A classical feature is the telecoil for use with induction loops. Options that are available for modern hearing aids are remote controls, infrared and fm-receivers, the use of multiple programs and water resistant housings. Last but not least, every hearing aid has its own price. It is obvious that the search for the hearing aid that is most suitable for the individual patient can be regarded as a real challenge. It is not only based on measures like speech perception but may also be determined by listening comfort, wearing comfort and functionality. This is all devised during the selection phase of a hearing aid fitting.
Aside from differences in the exterior and the above-mentioned features, hearing aids can be distinguished with respect to the sound that they produce. For a long time the amount of amplification and the frequency characteristic were the main issues. Later on, electronic compression circuits were added to limit the maximum output and/or gain of the hearing aid. More recently developed features are feedback reduction, noise cancellation and the use of directional microphones. To adjust the various controls of the hearing aid in order to optimally compensate for

the affected cochlea is a challenge on its own. This is done during the adjustment phase of a hearing aid fitting.
Procedures for hearing aid fitting have been invented in parallel with the development of hearing aid technology.

Types of hearing loss

Two main types of hearing loss can be distinguished depending on the localization of the cause. These can usually be diagnosed by pure-tone audiometry. A hearing loss is conductive when the cause is located somewhere between the outer ear canal and the stapes footplate. The cause of a sensorineural hearing loss is located between the stapes footplate and the auditory cortex. This type of hearing loss can roughly be differentiated into a cochlear and a retrocochlear cause. Other tests have been developed for this purpose, like the measurement of oto-acoustic emissions and auditory brainstem responses. Central causes of hearing loss are difficult to locate.
The discrimination between the types of hearing loss is of clinical importance because the options for treatment differ. A conductive hearing loss can probably be solved with surgery of the middle ear, the tympanic membrane or the ear canal, depending on the location of the cause. Otherwise, a hearing aid can be helpful to overcome the loss of acoustic energy between the entrance of the ear canal and the cochlea. In case of a sensorineural hearing loss, no surgical therapy is available to improve the natural function of the cochlea. In fact, almost every mechanical impact on the cochlea will result in (some) loss of function. The suitable treatment for mild to moderately severe sensorineural hearing loss is to amplify sound to a level above the hearing threshold with a hearing aid.

Procedures for hearing aid fitting

In the process of a hearing aid fitting a selection phase and an adjustment phase can be distinguished. Taking into account the vast amount of hearing aids that is currently available on the market, it can be regarded a challenge to adequately fit a hearing aid which means that it compensates the hearing loss as much as possible. Several approaches have been developed to perform these actions according to various theories on amplification for hearing loss. The basic approach of many linear hearing aid fitting procedures is to calculate the desired amount of amplification, the so called “target gain”, from the hearing thresholds. This is done according to some arithmetic formula. Since the prescribed gain is independent from the input level of sound, these fitting procedures are regarded as linear. A

classic example of a threshold-based formula is the Australian National Acoustic Laboratory (NAL) procedure [Byrne & Dillon, 1986]. A more recently developed approach is to calculate the amplification from loudness judgments levels. The Desired Sensation Level input/output (DSLi/o) procedure [Cornelisse et al, 1994] is a well-known example such procedure. This procedure is nonlinear because the amount of amplification is dependent on the level of the input signal.
A hearing aid must then be chosen that is able to deliver the desired amount of gain and it has to be adjusted to the target. Prescriptive fitting procedures are attractive because they offer a clear outcome that is objective and controllable while the result is fairly independent on the quality of the person who fits the hearing aids. Moreover, they can easily be automated and are as a result nowadays usually incorporated in the fitting software that accompanies a modern hearing aid.
Comparative fitting procedures take a different approach. Supposed that the main goal of a hearing aid fitting is to restore speech intelligibility as much as possible, one can also try a number of aids with different adjustments and test the outcome by means of speech tests. Results can be compared with each other so that the hearing aid fitter is able to choose the best hearing aid for the client. Other criteria can also be taken into account like, for example, the sound quality. This gives the fitting process an interactive character. Although this way of fitting will be more demanding and requires a certain amount of knowledge and experience from the fitter, it offers the opportunity to directly test the aim of the fitting procedure with the hearing aid in situ. Moreover, the demonstration of the sound of the hearing aid is a part of the process of counselling. The usual method of selecting and fitting hearing aids in the Netherlands was a comparative and interactive process between the prescriber and the patient with emphasis on speech recognition scores in quiet and in noise and the clients' judgment about the sound quality.
Prescriptive fitting formulas offer an objective and controllable result that is less dependent on the quality of the fitter. Moreover, they can be automated and (therefore) require relatively little time. These are drawbacks of a comparative procedure for hearing aid fitting for such an approach takes a relatively large amount of effort and time while the quality of the fitting depends on the level of competence of the hearing aid fitter. The advantage of a comparative procedure can be the direct testing of the objective (e.g. speech intelligibility) with the hearing aid in situ. Furthermore, demonstrating the hearing aid sound is part of the process of counselling.
We were interested in the quality and the efficiency of the comparative fitting procedure that we used in the Netherlands in comparison with a hearing aid fitting according to a prescriptive formula that is used in many countries. We took one of

the best-known and widely validated linear fitting formulas that was developed by the National Acoustic Laboratories, the revised NAL-rule [Byrne & Dillon, 1986] with the modification for profound hearing losses, NAL-RP [Byrne et al, 1990]. Corrections for an air-bone gap were performed by adding 25% of the difference between the air and bone conduction thresholds to the gain at each specified frequency [Lybarger, 1963]. The following research questions were formulated:

1. What is the quality and efficiency of prescriptive fitting formulas like the NAL-RP rule and can this method be introduced in the Netherlands without loss of quality of care to all hearing-impaired people?
2. Is there a necessity to distinguish between groups of patients in which the prescriptive fitting method gives no optimum quality? Can we identify groups in which the application of the Dutch comparative fitting method should be continued?
3. Can we reduce the costs of hearing aid provision by optimizing the practical implementation of the above-mentioned procedures and distinguishing hearing-impaired candidates for who these procedures are suitable?

We designed a study according to a double-blind randomized design that was performed in a large-scale clinical population of potential hearing aid candidates. Patients were randomly assigned to one of the two methods. Stratification was performed based on the maximum score in the speech audiogram. After having used the hearing aids for about twelve weeks each fitting was assessed using speech tests in quiet and in noise, measurements of real-ear insertion gain and questionnaires investigating the benefit of the prescribed hearing aids and the effects on hearing-related and overall health-related quality of life. Also the costs of both procedures were assessed.
The characteristics of these outcome measures are briefly explained in the next paragraphs.

Outcome measures

Several aims can be set when fitting a hearing aid, depending on the hearing aid fitter and the hearing-impaired client. These can be divided into objective and subjective. The property of objective outcome measures in the evaluation of hearing aid fitting procedures is that they can be obtained by psychophysical or entirely physical measurements. When the result of the test is to a certain extent dependent on the cooperation of the client, it is characterized as psychophysical. Speech intelligibility testing and loudness measurements are examples. Entirely physical measurements can be carried out without the interference of the client. Examples are brainstem audiometry and performance tests of hearing aids,

consisting of measurements of coupler gain and real-ear measurements. Many objective outcome measures are available, from amplification values measured on a 2cc coupler to the understanding of speech in background noise.

Speech intelligibility

Since the ability to understand speech can be regarded the most important quality of the human auditory function, the benefit with hearing aids in everyday life is probably best expressed as the improvement of the intelligibility of speech especially in the presence of background noise. Numerous tests for the evaluation of speech understanding have been designed since the Western Electric 4A test that was developed by Fletcher at Bell Telephone Laboratories in 1929 [Fletcher, 1929], while each test uses its own recorded speech material. In the Netherlands, speech recognition in quiet is usually measured with the use of consonant-vowel-consonant (CVC) words. Lists of phonetically balanced words have been recorded in Dutch and are widely used for clinical applications [Bosman, 1989]. These tests are performed in laboratory conditions which benefit the reproducibility of the test results, but also limit the consequence for everyday life circumstances with background noise and reverberation. Outcome measures for clinical evaluation of hearing aids should therefore encompass the testing of speech intelligibility in noise. Several tests have been developed for this purpose [Hagerman, 1984; Plomp & Mimpen, 1979; Nilsson et al, 1994]. Various standardized acoustic everyday life background noise have been recorded to simulate realistic sound environments [Dreschler et al, 2001] for speech testing in noise. Tests on the speech reception threshold show high test-retest reliability and a small standard deviation.

Hearing aid gain

The acoustical output of a hearing aid is usually expressed as coupler gain. An acoustical coupler between the hearing aid and the microphone of the measuring instrument simulates the ear canal and earmould. Since the volume of a normal ear canal is approximately 2 cm^3, a widely used coupler model is indicated as the 2cc coupler. Several specifications for couplers are available according to ANSI 3.7 [1973], IEC 126 [1973] or IEC 711 [1981]. An example of a coupler is given in figure 1-1. Coupler gain measurements for hearing aids are carried out under strictly standardized conditions. These measurements offer the advantage of a direct technical comparison between hearing aids. A number of prescriptive fitting

procedures, including the NAL-RP, calculate a target expressed in 2cc coupler gain.

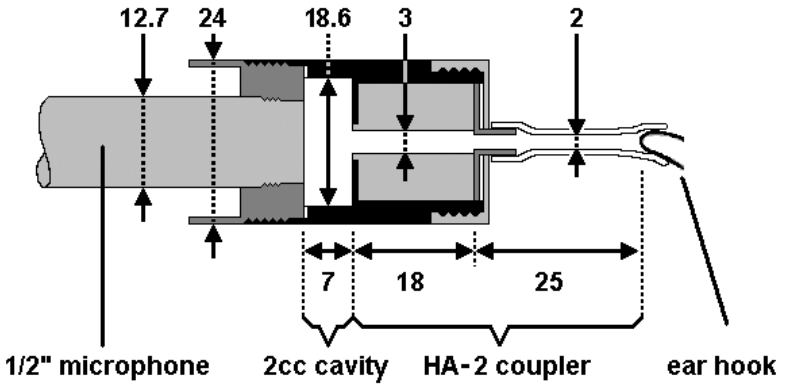

Figure 1-1: *Drawing of a HA-2 2cc coupler according to the specifications of IEC126 made by Bruel & Kjaer. The coupler is mounted on a ½ inch microphone. Sizes in millimeters. Drawing by the author.*

The problem with coupler measurements is that they do not take into account the acoustical characteristics of the different earmould configurations and the normal variations in ear canal geometry and eardrum immittance. This latter issue becomes particularly important in children. As a consequence, the desired in-situ gain will not always be obtained even though the requested 2cc coupler values of a prescriptive fitting procedure are closely matched. To prevent these discrepancies, the real-ear unaided gain (REUG) should be measured during fitting. This can be performed by real-ear measurements.
Real-ear measurements offer the possibility to evaluate the amount of gain that is present at the level of the eardrum. This is possible by the use of two microphones of which one is situated near the entrance of the ear canal while the other is connected to a small silicon tube (“probe”) that ends near the eardrum. This is illustrated in figure 1-2.The difference between both microphones is defined as the real-ear gain. When no hearing aid is present, the real-ear unaided gain (REUG) is measured. The REUG reflects the acoustical characteristics of the ear canal of the patient. This includes a “natural” resonance resulting in a gain of about 10 to 16 dB between 2 and 4 kHz. When an in-the-ear (ITE) hearing aid or an earmould with a behind-the-ear (BTE) hearing aid is placed in the ear canal, the real-ear aided gain (REAG) is measured.

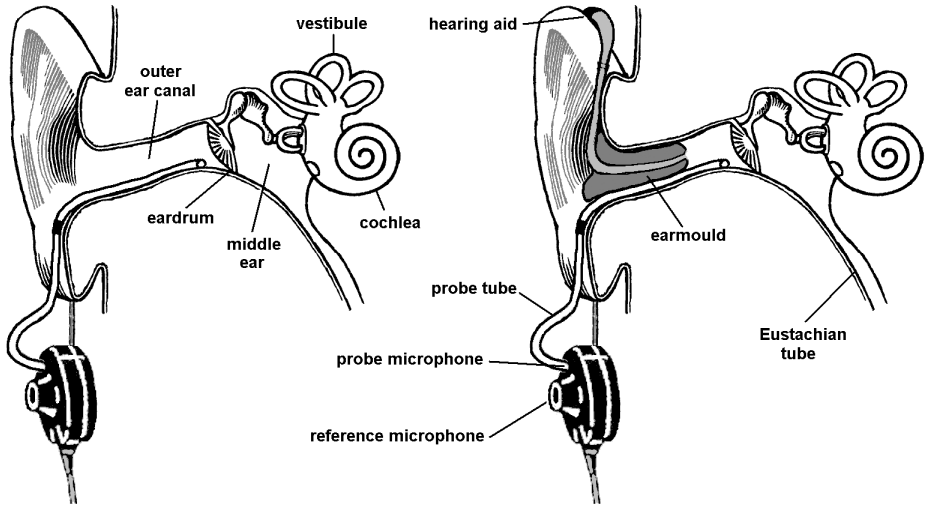

Figure 1-2: *Equipment and position during real-ear measurements. Left: when only the probe microphone is placed near the eardrum, the unaided gain (REUG) is measured. Right: with the hearing aid in situ, the aided gain (REAG) is measured. Drawing by the author.*

However, with the insertion of a mould in the ear canal, its natural resonance disappears. The resulting amount of gain, delivered by the hearing aid in situ, is therefore given by the difference between the REAG and the REUG and is called the real-ear insertion gain (REIG). A visual representation of these curves is given in figure 1-3.

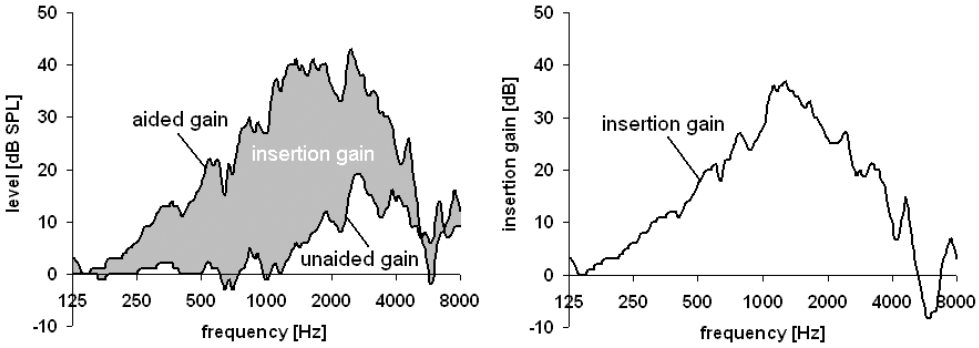

Figure 1-3: *Example of real-ear curves. The shaded area between the aided gain and unaided gain (left panel) is depicted in the right panel as the insertion gain.*

Questionnaires

The effect of a hearing aid fitting can be evaluated within several different domains. Cox distinguished seven different categories of self-report outcome data [Cox, 2003]. Four of these are related to the use of the hearing aid itself: satisfaction, quality of life, benefit and use of the hearing aid. These categories are related to hearing and communication and can be investigated by the various questionnaires that have been designed and validated for this purpose. Hearing aid benefit obviously is the most traditional dimension of these. It has been widely explored in a large number of different acoustical situations by the various hearing-specific questionnaires [Cox & Alexander, 1995; Kramer et al, 1995; van den Brink et al, 1996; Gatehouse, 1999; Gatehouse & Noble, 2004]. The other three categories are related to the individual that is fitted with hearing aids: the impact of the hearing impairment on others, the experience of limitations of activities and restrictions of participation. The latter two domains have been defined by the International Classification of Functioning, Disability and Health of the World Health Organization [WHO, 2001]. The former WHO conceptual framework of 1980 defined the consequences of hearing impairment in the domains of disability and handicap [WHO, 1980]. Subjective hearing disability and handicap are indicators of hearing-specific quality of life.
For an economic evaluation of the effect of hearing aids should be expressed in terms of a change in overall health-related quality of life (HRQoL). Various generic inventories are available for this purpose. Aspects of general HRQoL can range from physical status (e.g. daily life activities) to the domain of social well-being and depression. Some well-known examples are the Sickness Impact Profile [Gilson et al, 1975], the Medical Outcomes Study SF-36 [Ware & Sherbourne, 1992], the EuroQol-5-Dimensions (EQ5D) instrument [EuroQol Group, 1990] and the Health Utilities Index Mark III (HUI3) [Feeny et al, 1995]. However, the problem with generic questionnaires is that items related to hearing and communication are under-represented. These measures are therefore relatively insensitive to changes resulting from the use of hearing aids.

Costs

To compare the efficiency of hearing aid fitting procedures, an analysis of costs was done to compare the costs of the two hearing aid fitting procedures: the Dutch comparative procedure and the procedure according to the NAL-RP formula [Polder et al, 2000]. We presumed the implementation of a fitting formula to be cheaper than a comparative fitting approach. The use of a prescriptive formula can

be supposed to require fewer visits which take less time and, because of a high level of standardization, make lower demands of the hearing aid fitter. At the same time, we expected the quality of a prescriptive fitting approach to be equal to our comparative fitting procedure. The analysis of costs was performed according to the guidelines designed for this purpose [Drummond et al, 1997; CVZ, 1999; Oostenbrink, 2000]. Three categories of costs were distinguished:

1. Direct medical costs. These are costs of visits to the hospital and the audiological centre for examination, pure-tone and speech audiometry, all visits necessary for the selection, the fitting and evaluation of hearing aids and the costs of the hearing aids that were fitted.
2. Direct, non-medical costs. These are costs for travelling, time that was spent on visits and out-of-pocket costs of the hearing-impaired patient and his/her companion.
3. Indirect costs. These are costs that are generated as a consequence of being absent because of illness, getting disabled for work and being dependent on others because of hearing impairment.

Aim of the thesis

To investigate the quality and efficiency of hearing aid fitting procedures was the main purpose of our studies. This was done by focusing at different aspects of the phases of hearing aid selection and fitting. We started with a search through the literature to discover what was known about the effectiveness of the various fitting procedures that have been developed up in comparison with each other. This review of the literature can be read in **Chapter 2**.

Chapter 3 describes the results of two important objective outcome measures of a hearing aid fitting: the intelligibility of speech in quiet and in noise. This was done for two different fitting procedures, the well-known NAL-RP prescriptive procedure and a comparative procedure that has been used for a long time in the Netherlands.

The subjective outcome of the same two fitting procedures was described in **Chapter 4**. We used different inventories to investigate hearing disability and handicap after hearing aid fitting and the benefit of hearing aids. This was done in two groups that were fitted according to the two above-mentioned procedures. The effects of the degree of hearing loss, the previous experience with hearing aids and the effect of a unilateral and bilateral fitting have been analyzed.

In **Chapter 5** we focus on the degree of improvement of speech intelligibility in noise after hearing aid fitting. The question is if the improvement is due to the

characteristic of the sound that is delivered by the hearing aid, or if it is specified by the characteristic of the hearing loss.
Chapter 6 finally discusses the results of the study that was performed for this thesis. Also included are the results of the costs-effectiveness analysis that was performed with the study.

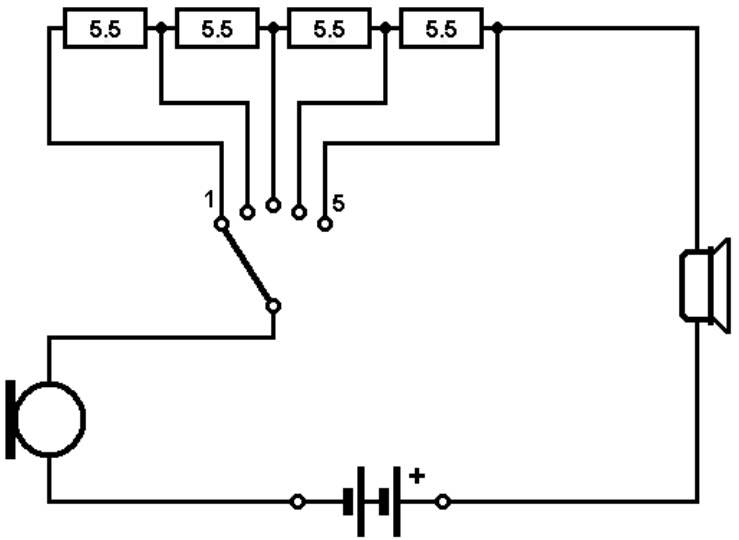

Figure 2-0: Early electric hearing aid with carbon microphone by Ardente, dating from around 1930. The volume can be set by a switch that is situated at the back of the microphone. The box below contains two 1.5 Volt batteries. Electrical diagram reconstructed by the author (resistor values in Ohms). Hearing aid from the historical collection of Beter Horen, Doesburg, the Netherlands. Photograph by the author.

Chapter 2

Comparative studies on hearing aid selection and fitting procedures: a review of the literature

Metselaar RM, Maat A, Verschuure J, Dreschler WA, Feenstra L

Eur Arch Otorhinolaryngol. 2008;265(1):21-29

Abstract

Although a large number of fitting procedures have been developed and are nowadays generally applied in modern hearing aid fitting technology, little is known about their effectiveness in comparison with each other. This paper argues the need for comparative validation studies on hearing aid fitting procedures based on the design of a randomized clinical trial and carried out in a large-scale clinical population. These studies are hard to conduct but can provide detailed information on the various aspects of the rehabilitation with hearing aids. The design of several recently reported comparative studies of hearing aid fitting procedures will be reviewed. This gives rise to a number of comments on aspects like, study design, composition of the study population and definition of outcome measures rather than on the outcome or conclusions of these studies themselves.

Introduction

Since the development of electronic hearing aids, several procedures have been designed for fitting them to the degree and type of hearing loss of the individual hearing impaired user. A hearing aid fitting procedure can actually be divided into a phase of hearing aid selection and a phase of adjustment or fine tuning. Evaluation of the performance of the hearing aid can be carried out immediately after the selection and adjustment phase. Therefore, a hearing aid fitting procedure can basically be regarded as an iterative process.
Evaluation can be performed according to a wide variety of criteria, including psychophysical tests (e.g. performance tests of speech intelligibility), electro acoustic measurements (output characteristics in a standard coupler) and (self-report) inventories on hearing disability, handicap and health-related quality of life. Hearing aid fitting procedures can be classified by the manner in which the result of the fitting is being assessed. Theoretically, this can be done according to comparative and prescriptive procedures. In a purely comparative procedure, hearing aid selection and/or adjustment is based on comparison of some outcome measure among various potentially suitable hearing aids and/or hearing aid settings. Here, hearing aid selection, adjustment and evaluation are closely linked which gives these procedures a highly iterative character. Various criteria can be used for evaluation. Some procedures make use of aided speech intelligibility tests [Carhart, 1946; Verschuure, 1994]. Modern examples that are suitable for fitting nonlinear hearing aids like ScalAdapt [Kiessling et al, 1996] use loudness scaling data with different noise bands while the Camadapt procedure [Moore et al, 1998]

is based on the loudness perception of speech signals. These latter two procedures are referred to as “adaptive”.
Prescriptive procedures are based on a formula that calculate target gains derived from the clients audiometric data (e.g. pure-tone thresholds and/or loudness judgement levels). A growing number of these procedures, both generic and proprietary, have been formulated [Hawkins, 1992] while it has become common practice to implement at least one target formula in the fitting software of modern digital hearing aids. Both types of fitting procedures have pros and cons that are listed in table 2-1.

Table 2-1: *Advantages and drawbacks of comparative (adaptive) and prescriptive fitting procedures.*

procedure	**advantages**	**drawbacks**
comparative / adaptive	Objective can directly be tested with the hearing aid in situ.	Relatively large amount of effort and time required for fitting.
	Demonstrating the hearing aid sound is part of the process of counselling.	Quality of fitting depends on level of competence of hearing aid fitter.
prescriptive	Objective and controllable procedure depends to a much smaller extent on quality of the hearing aid fitter.	May not be suitable for each individual patient.
	Quick procedure that can be automated to a large extent.	Correlation between calculated target and actual performance with hearing aid not clear.

However, with all the various fitting procedures to choose from, there is still limited information available to guide a clinician in determining which of these will provide the best amplification characteristics for a specific client. To clarify this issue, validation on appropriately large and appropriately stratified clinical samples of competing fitting procedures can be regarded as a research priority [Gatehouse, 1993].
Such studies are hard to conduct for a number of reasons of which the main three are listed below:

- They require a sufficiently large and heterogeneous group of hearing-impaired listeners.
- They should be performed according to the design of a double blind randomized clinical trial.

- A number of validation instruments have to be available that are sufficiently stable and sensitive to differentiate between outcomes.

Also for new fitting strategies that have been and will be developed and implemented in the fitting software of modern hearing aids, it would be advisable to validate and compare these procedures in clinical studies among a heterogeneous group of hearing-impaired listeners. The present article reviews the recent literature on comparative studies on hearing aid fitting procedures and intends to give good recommendations for setting up such studies.

Comparative studies – review of the literature

SELECTION OF PUBLICATIONS

In order to review the characteristics of comparative studies on hearing aid fitting procedures, we performed a Medline search of English language studies that compared the outcome of two or more hearing aid fitting procedures. All kinds of fitting procedures were included. As search terms were used: ”hearing aid fitting procedures”, “fitting formula” and “hearing aid prescription” in combination with either the term “comparison” or “differences”. Studies on fitting procedures for cochlear implants, implantable hearing aids and bone-anchored hearing aids were excluded. The initial search yielded 17 articles published between 1990 and 2005. Two studies that were dealing with differences between hearing aids instead of fitting procedures were excluded. Three publications referred to (partly) the same study population and study design [Moore et al, 2001; Alcántara et al, 2004; Marriage et al, 2004]. Some basic features of these studies are summarized in table 2-2.

All reviewed studies were conducted in adult populations. In all but two studies prescriptive fitting procedures were evaluated. In a study by Parsons & Clark [2002] a prescriptive procedure was compared with an intuitive procedure, while Moore et al compared two adaptive procedures [Moore et al, 2005].

We will comment on a number of important aspects on comparative studies on hearing aid fitting procedures in the next paragraphs.

STUDY DESIGN

In general, the most appropriate way of comparing two different treatment modalities in a clinical population is by means of a prospective double-blind randomised trial. When trying to apply this for the comparison of fitting procedures for hearing aids, some problems are likely to arise in the practical implementation.

Probably the most difficult one has to do with blinding, both to the client and to the investigator. Different factors can provide clues to the client about the kind of procedure that is being used. The hearing aid itself and the way in which it is actually being fitted are likely to be different for the competing fitting procedures. These issues can be especially relevant for experienced hearing aid users. On theoretical grounds, one could prefer the aid that realizes an output characteristic most similar to some target response. However, with the modern digital techniques in the current hearing aids it becomes more and more indistinct which aid to select for a certain hearing loss. The type and size of hearing aid and the presence of specific features available can then become more relevant. Practical considerations can be based on price or size of the available hearing aids, or the presence of, for example, a telecoil. In case of a bilateral hearing aid fitting, it can be useful to aim for similar aids or at least for a match with respect to manufacturer or battery size. Some of these hearing aid related issues are likely to be regarded as relevant factors during the statistical analysis of the study results.

It may be due to the reasons listed above, that we did not find publications reporting about the results of randomized trials according to a double-blind procedure. In fact, we found no randomised trials that met our inclusion criteria for review.

In just one study by Smeds [2004] part of the data has been obtained according to a double-blind procedure.

Of the 11 studies that were reviewed for this publication and have been conducted in real populations, only the study by Sammeth et al [1993] has been designed according to the parallel design. All other studies were performed according to a crossover design. This approach decreases the number of subjects necessary for analysis while it enables both objective and subjective comparison to be matched within individuals. Self-report benefit of hearing aids can easily be investigated using paired-comparisons or rankings, which was done in most of these studies. Although the crossover study design has specific advantages over the parallel design, its applicability for clinical evaluation may also have some limitations. Clients have to become used to the hearing aids they are fitted with during the study. They may need some time to acclimatize to the sound of different tone settings or programs that are being evaluated. Furthermore, one has to consider the audiological memory of the clients, which is complicating a direct comparison between the alternatives to be tested. Finally, the evaluation of a number of sound samples delivered by the different programs of tone settings may easily become demanding for the participants. With a growing number of alternatives to choose from, they may tend to stick to just one or two of the available alternatives.

We would therefore argue for a parallel study-design in favour of a crossover design.
When a crossover design is being applied, the number of available alternatives should be kept very limited. The participants should then be provided with a sufficient amount of time to become acclimatized to the different alternatives to compare. A simplified proposal for a study design according to a randomized controlled trial is given in figure 2-1.

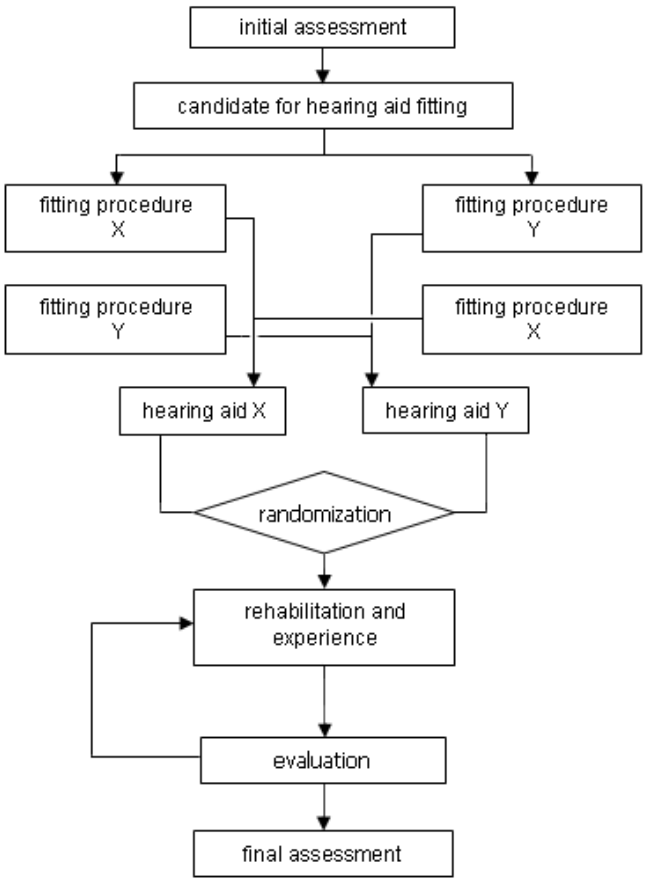

Figure 2-1: *Simplified layout of a design for a randomized clinical trial for comparison of two hearing aid fitting procedures.*

POPULATION

The following three aspects concerning the study population necessary for comparison of hearing aid fitting procedures will be considered:

1. Size of the population. It is essential that the clinical study achieves its objectives. A small negative study might not have had adequate statistical power to find important differences between fitting procedures. Therefore, a statistical power analysis has to be part of the design of the study. In general, one has to be able to detect a minimum clinical relevant difference with a probability (statistical power) typically set to at least 0.80. Therefore, the number of subjects that has to be included in a study will depend on the outcome measures that are chosen. Of all 15 publications reviewed, the size of the study population was argued only in the study performed by Parsons & Clark [2002].
2. Characteristics of the population. The patients to be included in the study should be representatives of the intended target population. That means that they fulfil certain characteristics with respect to hearing impairment, although non-hearing related issues could be relevant as well, like age and life style. These will depend on the fitting procedures that are being compared and on the research question and should therefore explicitly be mentioned. Distinction can also be made depending on the cause and the degree of the hearing loss. This will enable statistical analysis on relevant subgroups. First-time hearing aids users should be distinguished from experienced users as it is obvious that their reactions on the wearing of hearing aids can be rather different.
   Only in a minority of the studies reviewed, exclusion criteria were explicitly mentioned. Most of the studies drew a distinction between (steeply) sloping and flat losses or between low frequency, mid-frequency and high frequency hearing losses. In all studies, almost entirely sensorineural types of hearing loss were included.
3. Stratification. When for a prospective randomized clinical trial, a consecutive number of hearing impaired patients is included, one will usually obtain a representative sample of the clinical population. However, one could also be interested in differences between fitting procedures within a certain subgroup of hearing impaired patients. In order to include a relatively larger number of the intended category, stratification could be applied. This will facilitate the statistical analysis of the data, as sufficient numbers of a (less common) category can be included while unintentional inclusion of more common patients will be restricted. Various criteria for stratification can be applied,

depending on the research questions. Stratification has not been carried out in the studies that we reviewed for this publication.

OUTCOME MEASURES

Evaluation of a hearing aid fitting encompasses assessment in a wide range of audiological situations, from the verification of the electroacoustical characteristics of a hearing aid in a standard coupler to the application of psychophysical measures and inventories addressing hearing related issues as well as concerns in the public health domain. Relevant responses can include the performance of the hearing aid itself and the degree to which a hearing aid resolves the hearing disabilities experienced by an individual or a specific group of hearing impaired persons.

In considering appropriate outcome measures for evaluation of hearing aid fitting procedures in large-scale clinical populations, one has to realize that these have to be relevant for the population in general and that the test conditions have to meet everyday life acoustical situations.

An extensive list of well-defined and validated measures for the evaluation of hearing aid fittings is available. These can be characterized as being more or less objective or subjective, depending on the way the data are obtained. Purely objective measures (e.g. insertion gain data) share the property of being entirely physical. Performance data (e.g. like speech tests) can be regarded as psychophysical because they are dependent on the client's ability to deal with a certain acoustical situation. Subjective measures are based on questions asking for the experience of the client. Three frequently used types are (self-report) questionnaires / inventories, ratings / rankings and diaries. The problem with objective and subjective measures is that they sometimes may match poorly. Several studies have shown that the correlation between self-report benefit from hearing aid and improvement of speech intelligibility is weak [Haggard et al, 1981; Cox & Alexander, 1991].

A principal problem arises with respect to outcome measures to be chosen. This will be encountered when an outcome measure is chosen that is similar to or the same as the main fitting criterion of one of the investigated procedures ('golden standard'). In this situation, comparison will obviously be in favour of the procedure that uses the corresponding measure. This seems to be the case in the study by Smeds [2004] who evaluated the overall loudness of two prescriptive procedures that were different with respect to the prescribed amount of gain and compression. Overall loudness itself obviously correlated with the procedure. However, the main

outcome measure in this study was the preference of loudness by the hearing impaired clients.
For clinical evaluation of fitting procedures, we would recommend the use of a mix of well-defined objective and subjective outcome measures.
A number of commonly used outcome measures will be discussed below.

HEARING AID GAIN

Prescriptive hearing aid fitting procedures usually suggest a set of target gains, based on audiometric threshold data or on suprathreshold loudness judgments (uncomfortable loudness or most comfortable loudness). Differences between prescriptive formulas have been investigated in several studies. Ricketts [1996] compared the prescribed gain, compression ratios, compression thresholds and the relative predicted speech intelligibility index of one linear (NAL-R) and four nonlinear (DSL i/o, VIOLA, FIG6, RAB) fitting procedures. The gains provided by these procedures were calculated for a number of patients with sensorineural hearing losses, of which audiometric thresholds and loudness-growth data were obtained. However, no actual hearing aid fittings were performed in this study.
Stelmachowicz and co-workers [1998] compared the user gains at the levels of 50 and 80 dB for 49 adults who were fitted with a WDRC-hearing aid according to the LGOB algorithm with the recommendations that were prescribed by two threshold based procedures for fitting of nonlinear hearing aids (DSL 4.0 and FIG6). However, the latter two procedures were not actually applied to the study population so that the comparison should be regarded as theoretical.
Although these studies reveal considerable differences between gains prescribed by different fitting procedures, their clinical relevance is limited because they do not provide any psychophysical measurements or data on client satisfaction. This is an important issue as little is known about the correspondence between a given similarity to some target and the extent to which hearing aids fitted according to that target for an individual or a population group are able to alleviate the consequences of the domains of auditory disability (activity limitation) and handicap (participation restriction).
Target gains are usually expressed as coupler gains assuming a standard earmould that enables easy comparison. Hamill & Barron [1992] compared the target frequency response differences of four linear prescription formulae. They used a number of audiograms from actual hearing loss cases as well as a small number of hypothetical audiograms. Due to the design of this study no patients had been fitted with hearing aids.

Although the high degree of standardization is one of the practical advantages of coupler gain measurements, they do not take into account the acoustical characteristics of the earmould and ear canal of the patient. This issue becomes particularly critical in children. Target coupler gains should therefore be translated into real-ear gains which can be performed most accurately by measurement of the real ear to coupler differences (RECD) for each individual patient, as has been described in detail by Cornelisse et al. [1995].
Parsons & Clark [2002] used the same procedure when they compared the calculated DSL 4.1 target gains with the real-ear responses measured after fitting according to the 'intuitive' NHS fitting procedure.
Differences between the prescribed gains and the amounts of gain that were actually measured after fitting cannot be avoided completely. Sammeth and co-workers [1993] investigated differences between prescribed and measured 2cc coupler gains and between prescribed and measured real-ear insertion gains. They compared the NAL-R, POGO II and MSU formulas with respect to prescribed gains and frequency responses. The results of actual hearing aid fittings on 110 ears were used for analysis. They found that for both 2-cc coupler and real-ear insertion gain (REIG) data, all three prescription formulas had a mean deviation from target of less than or equal to 10 dB in the frequency range from 250 to 4000 Hz. Their data indicated that too much gain was provided in the mid frequencies and too little gain in the high frequencies. To explore whether these deviations would be responsible for significant deficits in speech intelligibility or not, they calculated modified Speech Transmission Indices (mSTI). They found that in almost 50 percent of the cases the mean difference between the mSTI for the obtained REIG was poorer than that for the prescribed REIG, but within the 95 percent confidence interval. In almost 12 percent the mSTI calculated for obtained REIG fell outside the 95 percent confidence interval for the mSTI calculated for prescribed REIG. The mean difference in these fittings was 18.7 percent (SD=3.6).
The best way to compare the sheer physical result of fitting procedures is by means of real-ear measurements. These data have been reported in a number of more recent studies [Moore et al, 2001; Alcàntara et al, 2004; Marriage et al, 2004].

SPEECH INTELLIGIBILITY MEASURES

Testing of speech intelligibility has an attractively high degree of face validity because the improvement of speech understanding is probably the most desired outcome of a hearing aid fitting. The aim of assessing how well a particular hearing aid fitting procedure is able to reduce speech perception deficits of the impaired listeners requires measurements of aided speech intelligibility. Various procedures

have been developed for this purpose. Speech testing in quiet is usually performed with standardized lists of monosyllabic words or sentences.
When these standardized tests are being used to differentiate between hearing aid fittings, the investigator has to realize that they are performed in laboratory conditions. This benefits the reproducibility of the test results, but also raises the problem of the uncertainty with which the results can be generalized to everyday life circumstances with a varying amount of background noise and reverberation. The effects of these factors have been investigated by Cox & Alexander [1991]. They tested intelligibility of speech in the following three different listening conditions: a favourable one with a low level of background noise and reverberation and with visual cues available, a situation with relatively low background noise but reduced availability of speech cues due to reverberation, low speech intensity and limited or absent visual cues and a situation with a high level of background noise and available visual cues. They found that benefit from hearing aids, which was defined as the improvement of the intelligibility score, was highest in the favourable test condition and poorest in the situation with highest background noise. In contrast, no beneficial effect on speech intelligibility was measured in either listening condition.
The improvement of understanding of speech will also apply to different everyday acoustic situations. It is therefore obvious that outcome measures for clinical comparison of hearing aid fitting procedures should encompass speech testing in noisy circumstances. Standardized procedures for testing speech intelligibility in noise have been developed [Plomp & Mimpen, 1979; Hagerman, 1984; Nilsson et al, 1994]. These tests are characterized by high test-retest reliability and very small standard deviations of the speech reception threshold (SRT). Supplementary sentence lists have been recorded In order to prevent learning effects [MacLeod & Summerfield, 1990; Versfeld et al, 2000]. Others have developed nonsense sentences with a syntactically fixed structure [Hagerman, 1982; Wagener et al, 1999] which has the advantage of repeated usability with the same person. Speech materials have been recorded in different languages. Various standardized acoustic everyday life background noises are available to simulate realistic sound environments [Dreschler et al, 2001].
In a substantial number of the studies reviewed for this publication, speech testing indeed forms part of the outcome measures. Lunner et al [1997] measured speech in noise (S/N) ratios by using the Hagerman procedure. Alcántara et al [2004] and Marriage et al [2004] measured speech reception thresholds (SRT's) in steady and modulated noise, using the ASL sentence lists.

QUESTIONNAIRES

Subjective evaluations of hearing aid fitting encompass a wide range of outcome measures. Cox [2003] distinguished seven different categories of self-report outcome data. Four of these are related to the use of the hearing aid itself: satisfaction, quality of life, benefit and use of the hearing aid. The other three domains are related to the individual that is fitted with hearing aids: the impact of the hearing impairment on others, the experience of limitations of activities and restrictions of participation. The latter two domains have been defined by the International Classification of Functioning, Disability and Health of the World Health Organization [WHO, 2001]. The former WHO conceptual framework of 1980 defined the consequences of hearing impairment in the domains of disability and handicap [WHO, 1980].

With the exception of the domain of quality of life, the other categories of outcome parameters are hearing-specific and can be investigated by the various questionnaires that have been designed and validated for this purpose. Hearing aid benefit obviously is the most traditional dimension of these. It has been widely explored in a large number of different acoustical situations by the various hearing-specific questionnaires. A well-known example is the Abbreviated Profile of Hearing Aid Benefit (APHAB) by Cox & Alexander [1995] that investigates the hearing aid benefit in a variety of acoustical circumstances. The Glasgow Hearing Aid Benefit Profile [Gatehouse, 1999] also investigates the relevance of each of the proposed acoustical situations to the individual and also the degree of hearing aid use in each situation. This is especially an important factor to be regarded when a study is conducted with a large-scale clinical population as the need for acoustic rehabilitation can differ significantly among the many users. The Speech, Spatial and Qualities of Hearing Scale (SSQ) was developed more recently by Gatehouse & Noble [2004]. The SSQ investigates the hearing of speech in a variety of competing contexts, spatial hearing, segregation and recognition of sounds, quality of sounds and the amount of listening effort. The Hearing Handicap and Disability Inventory (HHDI) [van den Brink et al, 1996] is an example of a questionnaire that was especially designed according to the former WHO definitions of disability and handicap.

Various generic inventories are available that are able to investigate the domain of health-related quality of life in general. Aspects can range from, for example, physical status (e.g. daily life activities) to the domain of social well-being and depression. Well know examples are the Sickness Impact Profile [Gilson, 1975], the Medical Outcomes Study SF-36 [Ware & Sherbourne, 1992], the EuroQol-5-Dimensions (EQ5D) instrument [EuroQol Group, 1990] and the Health Utilities

Index Mark III (HUI3) [Feeny et al, 1995]. The problem with these generic questionnaires is that hearing or communication-related items are under-represented in most of them. As a consequence, these measures do not tend to be sensitive enough to document changes that result from hearing aid use [Bess, 2000].
Although health-related quality of life encompasses many aspects of functioning of the individual in various daily life circumstances, we feel that hearing or communication-related aspects are of greater influence than is recognized by most generic questionnaires.
The impact of hearing loss on the quality of life has been investigated in a population of elderly individuals [Dalton et al, 2003]. The authors found a significant association between the severity of hearing loss and impaired activities of daily living and decreased mental and physical function that was measured with the SF-36 questionnaire. Joore et al [2003] could not establish an improvement in overall quality of life measured with the EQ5D after fitting with hearing aids, while the social functioning did improve significantly according to the SF-36.
Barton et al [2004] found that the gain in utility that was measured after fitting with hearing aids according to the EQ5D, the SF-6D (derived from a subset of questions from the SF-36 questionnaire) and the HUI3 was highest for the HUI3. The HUI3 is indeed the only questionnaire that contains a number of communication-related issues like hearing, speech and vision.
We recommend application of a (limited) set of self-report hearing-specific questionnaires. These should be able to investigate health-related quality of life according to the International Classification of the WHO (2001) and must have been validated in clinical populations. The impact of the provision of hearing aids on health related quality of life could probably be investigated best by the HUI3.

Conclusions

Comparative studies of hearing aid fitting procedures that have been conducted according to a prospective design on a large-scale clinical population are hard to find in the literature.
We feel that more of this kind of studies are necessary to provide information about quality and efficiency of hearing aid fitting procedures. We propose the following recommendations that such studies should meet:

1. designed according to a prospective double-blind randomised trial,
2. preferably designed according to a parallel setup,
3. when a crossover design is used, the number of alternative procedures should be kept small,

4. the size of the study population should be derived from a power analysis,
5. stratification should be applied in order to include sufficient numbers of subjects in each of the relevant subgroups,
6. a set of different outcome measures should be chosen, containing at least:
    - real-ear measurements,
    - speech intelligibility tests in noise, preferably performed according to a procedure that assesses the speech reception threshold in an adaptive way, and
    - validated illness-specific questionnaires that have been designed according to the WHO-definitions.

Table 2-2: *Study characteristics*

authors	population	fitting procedures	study design	pro-/retrospective	blinding	outcome measures
Humes, 1990	12 hearing impaired patients	NAL-R POGO MSU (Cox)	field test according to crossover design	prospective	no	CUNY nonsense syllable test H.A. gain
Hamill, 1992	81 measured audiograms 8 hypothetical audiograms	NAL Berger Lybarger POGO	comparison of calculated outcome measures for each procedure	retrospective	no	H.A. frequency response predicted modified STI
Sammeth, 1993	75 hearing impaired adults	NAL-R POGO II MSU (Cox)	parallel design (50 NAL-R + 14 POGO II + 11 MSU)	prospective	no	insertion gain 2-cc coupler gain predicted speech intelligibility
Ricketts, 1996	20 hearing impaired patients	DSL i/o VIOLA FIG6 RAB NAL-R	comparison of calculated outcome measures for each procedure	retrospective	no	gain, compression ratio, compression threshold, relative predicted SII

Table 2-2 (continued): *Study characteristics*

authors	population	fitting procedures	study design	pro-/retrospective	blinding	outcome measures
Lunner, 1997	8 experienced hearing aid users	POGO II LinEar	field test according to crossover design	prospective	no	S/N threshold for speech questionnaire: sound quality
Stelmachowicz, 1998	49 hearing impaired patients	LGOB DSL 4.0 FIG6	fitting according to LGOB compared with calculations according to DSL & FIG6	retrospective	no	user-gain
Peters, 2000	9 hearing impaired patients	NAL-R Cambridge	paired comparison for H.A. settings according to both fitting procedures	prospective	no	subjective loudness, tone quality, intelligibility speech in quiet & noise. SRT quiet & noise
Keidser, 2001	24 experienced hearing aid users	IHAFF NAL-NL1	laboratory test & field test according to crossover design	prospective	no	paired comparison of subjective judgements of speech intelligibility & preferred overall gain
Moore, 2001	10 experienced hearing aid users	CAMEQ CAMREST DSL i/o	field test according to crossover design	prospective	no	H.A. gain, difference gain to initial fit, APHAB, SRT quiet & noise

Table 2-2 (continued): *Study characteristics*

authors	population	fitting procedures	study design	pro-/retrospective	blinding	outcome measures
Wesselkamp, 2001	21 hearing impaired patients	DSL i/o "prescriptive"	field test according to crossover design	prospective	no	SRT, sound quality rating, paired comparison of sound quality
Parsons, 2002	33 inexperienced hearing aid users	"intuitive" DSL 4.1	comparison of calculated (DSL) and measured (NHS) outcome	retrospective	no	H.A. gain
Alcántara, 2004	10 experienced hearing aid users	CAMEQ CAMREST DSL i/o	field test according to crossover design	prospective	no	H.A. gain, difference gain to initial fit, APHAB, SRT quiet & noise
Marriage, 2004	20 experienced & 20 inexperienced hearing aid users	CAMEQ CAMREST DSL i/o	field test according to crossover design	prospective	no	H.A. gain, difference gain to initial fit, APHAB, SRT quiet & noise
Smeds, 2004	21 inexperienced hearing aid users	NormLoudn LessLoudn	field test according to crossover design	prospective	partially	paired comparison of preference, loudness, calculated loudness, measured speech recognition
Moore, 2005	16 inexperienced hearing aid users	Camadapt Eartuner	field test according to crossover design	prospective	no	insertion gain, subjective rating, APHAB

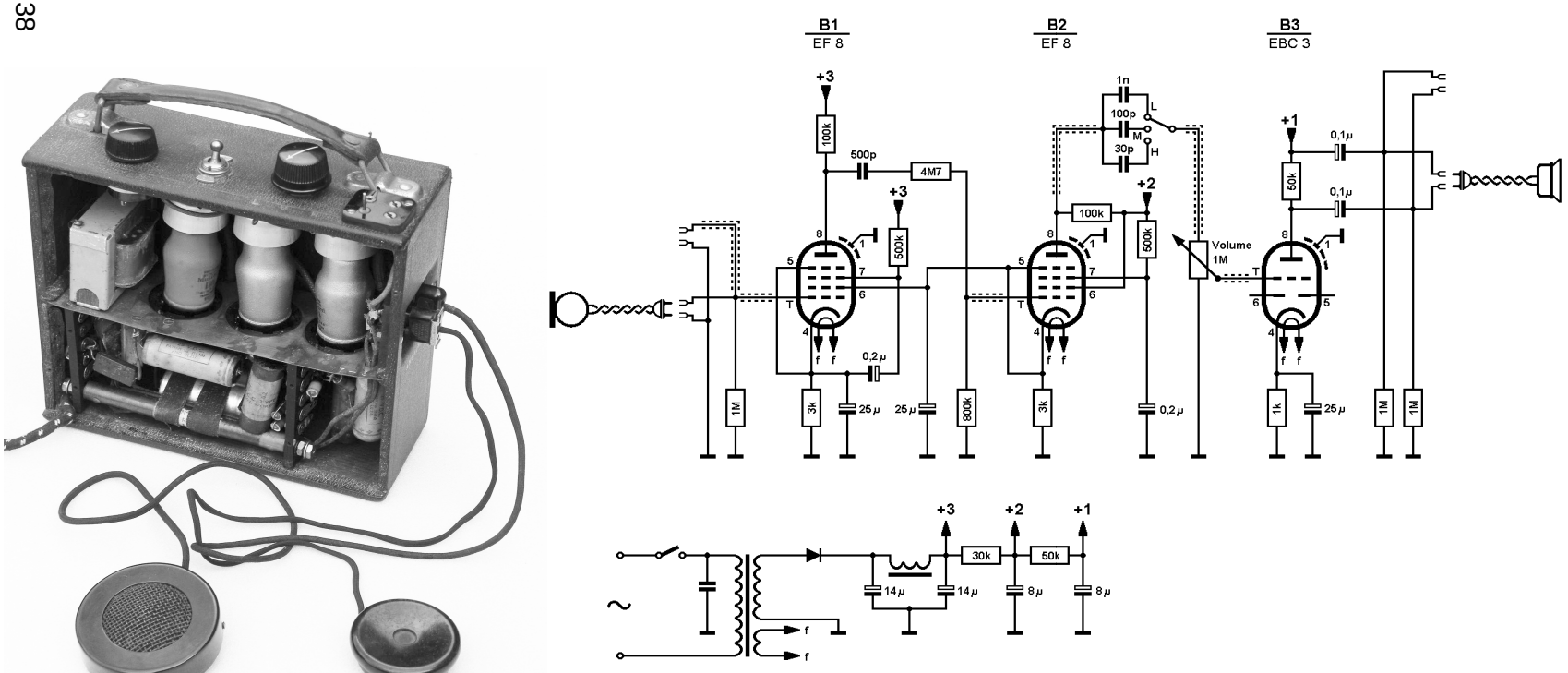

Figure 3-0: An early electronic hearing aid by the English company Amplivox with 3 vacuum tubes (made by Mullard). This table model (dimensions 19x18x7.5 cm) with external microphone dates from 1938. Tone switch (right) and volume wheel (left) are located on top. Mains cord for power supply (220V AC). Circuit diagram reconstructed by the author (resistor values in Ohms, capacitor values in Farad). Hearing aid from the historical collection of Beter Horen, Doesburg, the Netherlands. Photograph by the author.

Chapter 3

Comparison of speech intelligibility in quiet and in noise after hearing aid fitting according to a purely prescriptive and a comparative procedure

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Abstract

We compared two different types of hearing-aid fitting procedures in a double-blind randomized clinical study. Hearing aid fittings based on a purely prescriptive procedure (the NAL-RP formula) were compared to a comparative fitting procedure based on optimizing speech intelligibility scores. Main outcome measures were improvement of speech intelligibility scores in quiet and in noise. Data were related to the real-ear insertion responses that were measured after fitting. For analysis purposes subgroups were composed according to degree of hearing loss, characterized by unaided speech intelligibility in quiet, previous experience with hearing aids, unilateral or bilateral fittings and type of hearing aid.
We found equal improvement of speech intelligibility in quiet, while fitting according to the prescriptive formula resulted in a somewhat better performance as expressed by the speech-to-noise ratio in comparison to the comparative procedure. Both procedures resulted in comparable real-ear insertion responses.

Introduction

Within the actual process of hearing aid fitting a selection and evaluation phase can be distinguished [Gatehouse, 1993], although the degree of distinction between these phases will vary according to the fitting procedure. A prescriptive formula initially selects a hearing aid according to some target characteristic, which is usually derived from psychophysical measurements (e.g. pure-tone audiometry or loudness scaling). In a comparative procedure, where the hearing aid is selected by comparison according to some criterion (e.g. speech intelligibility, sound quality), the selection process has a more iterative character. Here, the selection and evaluation phase are more closely linked.
Prescriptive procedures can easily be automated and offer a quick and reproducible method for the initial hearing aid selection. However, although the design of some of these procedures are based on speech intelligibility data, a conscientious implementation of this approach implies that pure-tone thresholds or loudness data directly or indirectly entail all the information required to alleviate hearing impairment, including psychophysical factors like spectral and temporal resolution and ecological factors like lifestyle and acoustics. A comparative procedure principally approximates the primary criterion chosen as close as possible and offers direct clinical evaluation with the hearing aid in place. However, this way of fitting could be expected to be more time-consuming and to be dependent on the knowledge and experience of the hearing aid fitter.

While the number of prescriptive formulae is gradually increasing, little is known about the quality and efficiency of this kind of fitting procedures in comparison with a comparative fitting approach which seems to steadily loose popularity. Quality can be defined as the extent to which a fitting procedure will succeed in alleviating limitations in performance, suffered by an individual or a population group and encourage participation in society. Efficiency has to do with the amount of labour, knowledge and money that needs to be invested in an optimum hearing-aid fitting procedure. Comparison of these kinds of fitting procedures in a clinical setting can reveal differences concerning these aspects.
We designed a prospective double-blind randomized clinical trial. Aim of the study was to compare the quality of a prescriptive hearing aid fitting procedure with a comparative method. Prescriptive fittings were carried out exactly according to the NAL-RP method, as this is one of the best known and extensively documented and validated prescriptive procedures for linear amplification [Byrne & Cotton, 1988; Byrne & Dillon, 1986; Byrne et al, 1990; Byrne & Tonisson, 1976]. We based the criterion of the comparative procedure on speech intelligibility tests, more or less according to the procedure described by Carhart [1946]. Although these measurements are relatively time-consuming, they can provide useful information since improving the intelligibility of speech is one of the main goals in hearing rehabilitation. We defined quality in terms of improvement of speech intelligibility score in quiet and in noise. Insertion responses from the two fitting procedures were compared and related to changes in speech perception data.

Material and methods

POPULATION

Hearing-impaired patients were primarily recruited from the audiological centers of two university hospitals. Experienced as well as inexperienced hearing aid users were included after informed consent was obtained. Mean pure-tone audiometric thresholds (1, 2 and 4 kHz) had to be at least 35 dB HL at one ear (insurance company criterion for partly reimbursing the expenses in the Netherlands), predominantly or entirely sensorineural. Exclusion criteria were:

- maximum unaided speech score less than 50 percent at the best ear
- suspicion of retrocochlear cause of hearing loss
- Meniere's disease (active phase)
- (severe) tinnitus
- significant co-morbidity

Patients that were included in the study were stratified according to unaided maximum speech intelligibility score in quiet measured at the better ear. Stratification was done in an attempt to achieve a more equally distributed population with respect to the range of hearing impairments. Patients were stratified according to maximum speech intelligibility score at the better ear. Three strata were distinguished: a lower stratum containing speech scores between 50 to 74%, a middle stratum between 75 and 89%, and a high stratum with scores at and beyond 90%.
The number of clients necessary was calculated in a power analysis. Based on a former pilot study (unpublished) we assumed an improvement in aided vs. unaided speech intelligibility scores at 65 dB SPL of 15%, 11% and 5% in the lower, middle and higher stratum respectively. For calculation of group-sizes a student t-test was applied with a standard significance (p-value <0.05). When the power is set at 80% the clinical relevant differences between improvement in speech intelligibility for both fitting procedures is 6%, 4% and 1.25% in the three strata. These should contain 124, 176, and 180 patients respectively, requiring a total number of 480 participants.

GENERAL PROCEDURE

Standard pure-tone audiometry was performed with the Madsen OB-822 clinical audiometer and TDH-39 earphones. Speech audiometry was performed with the same equipment for each ear separately. Lists of 11 phonetically balanced CVC-words [Bosman, 1989; Smoorenburg, 1985] were offered at 10 dB intervals. Each consonant or vowel added 3 percent to the total score.
Hearing aid fittings were carried out according to the NAL-RP formula and the comparative procedure as well. A detailed description of these procedures will be given in the next paragraphs. After inclusion each patient was fitted according to the two hearing aid selection and evaluation procedures in succession, each carried out by a different hearing-aid fitter. Both fitters were not informed about each others results, except for the type of hearing aid prescribed (BTE or ITE) and unilateral or bilateral fitting which was kept the same in both prescriptions in order to keep the procedure masked to the patient. Unilateral as well as bilateral fittings were carried out, depending on the user's hearing and preference. All hearing aids used in the study had analogue electrical circuits and were adjusted to linear amplification. No digital circuits and/or WDRC compression algorithms were used as clear fitting procedures for these hearing aids and amplification-mode were emerging at the time of the study and would make it impossible to apply the strict design of the project.

The hearing aids selected according to both fitting procedures were specified in a prescription, which also included indications concerning the tone settings and the desired type of earmould and ear hook.
One of either prescription was randomly selected by an independent person and given to the patient who subsequently consulted the hearing-aid dispenser for conveyance of the hearing aid and earmould according to the specifications of the prescription. The patient was unaware of the type of hearing-aid fitting that was selected.
A 12-weeks period of rehabilitation and experience followed during which the patient was able to get used to the sound and wearing of the aid. Evaluation of the hearing aid was performed once in the middle of this period (after 6 weeks) in order to optimize its setting. At the end of the try-out period (12 weeks), final assessments were performed by a researcher who was not aware of the type of procedure the patient had been fitted with. The measurements consisted of measurements of aided and unaided speech intelligibility in quiet and in noise and real-ear measurements. Several self-report questionnaires had to be completed also at the beginning (t=0), halfway (t=6 weeks) and at the end of the acclimatization period (t=12 weeks).
The blinding ended after having assessed whether the hearing-aid has been satisfactorily fitted or not. This was done according to audiological and client criteria. For approval on audiological grounds, the speech intelligibility in quiet with hearing aid(s) had to be equal or better than the maximum speech score measured in the speech audiogram before fitting. The patient could also indicate whether (s)he was satisfied with the result. NAL-RP prescriptions could then be changed and optimized according to the comparative procedure if necessary. This was required by the Medical-Ethical Committee of the participating hospitals and ensured that patients were provided with at least the same care as when they would not have participated in the study.

NAL-RP FITTING

Prescriptive hearing aid fittings were strictly carried out according to the NAL formula [Byrne & Dillon, 1986] with the modification for profound hearing losses [Byrne et al, 1990]. Corrections for an air-bone gap were performed by adding 25% of the difference between the air and bone conduction thresholds to the gain at each specified frequency [Lybarger, 1963]. Ear canal characteristics were taken into account by measuring the open ear response (‘real-ear unaided response’) to correct for the standard coupler response (IEC 126) [IEC, 1973] by the individual

real-ear to coupler difference. This procedure has been described by Cornelisse et al [Cornelisse et al, 1995].
Hearing aid selection was performed by means of a computer program that has been exclusively designed for this study. Coupler responses of all hearing aids available in our centers with different settings of tone-controls had been measured in advance on a 2cc coupler according to the IEC-standard 126, 2nd edition [IEC, 1973] using a PortaRem-2000 (RD Rastronics Division, Denmark). These had been stored in the database of the program. The actual selection process consisted of matching the calculated target gain of the patient with all coupler responses in the database. The hearing aid that was able to generate a response most similar to the target gain was selected. Correction factors for open ear response and type of earmould were also included in the selection program, the exact type of hearing aid and tone settings and also the specifications of the earmould were prescribed.
After the specified hearing aid had been delivered to the patient, it was adjusted as close as possible to the NAL-RP target real-ear insertion response. This was done by real-ear measurements with the hearing aid and earmould in the ear.

COMPARATIVE FITTING PROCEDURE

The comparative fitting procedure that was used in this study has been described in detail by Verschuure [1994]. The aim is to improve speech perception as much as possible; to at least the maximum speech intelligibility found in the (unaided) speech audiogram. Hearing aid selection was therefore performed in a comparative procedure in which evaluation of speech intelligibility in quiet with each of the selected hearing aids in the ear was used as the primary selection criterion. A second criterion was used, based on sound quality judgments by the patient.
After a six-week period of initial acclimatization to the sound and the wearing of the hearing aid, evaluation and, if necessary, adjustment of hearing aid settings was performed in order to optimize speech intelligibility.
Final assessments were done after a second six-week period of rehabilitation and experience. Hearing aid fitting was considered finished when both the hearing aid fitter and the patient were satisfied with the result. In case of an unsatisfactory result after 6 or 12 weeks, re-selection of hearing aids took place, which was again followed by fine-tuning and acclimatization.

Outcome measures

The following primary outcome measures were defined:

- improvement of speech intelligibility scores in quiet. Speech intelligibility scores were measured in a free-field condition at 55, 65 and 75 dB SPL, using the recorded NVA lists, each containing 11 CVC-words. These were presented through a loudspeaker at a distance of 1 meter from the patient in a sound-treated booth with a reverberation radius of about 1.5 m. Correctly reproduced consonants and vowels (33 for each list) were scored as a percentage score. The aided speech score used for analysis was the highest speech score at one of the levels 55, 65 or 75 dB SPL. Unaided intelligibility was defined as the highest speech score for any sound level measured at the better ear in the speech audiogram.
- improvement of the critical speech-to-noise ratio (SN ratio). Speech intelligibility in noise was measured using the Dutch sentence test developed by Plomp & Mimpen [1979]. After determining the speech reception threshold in quiet (SRT-Q), which is defined as the level at which 50% of the test sentences was reproduced correctly, the SN ratio was measured at a noise level of 20 dB above the SRT-Q level using an up-down technique with 2 dB steps in order to obtain a reliable estimate for the critical SN ratio. All sounds were presented through a loudspeaker at a distance of 1 meter from the patient (free-field condition). Measurements were performed with and without hearing aids in the ear. Improvement of the signal-to-noise ratio (SN ratio) was defined as the difference between the aided and the unaided SN ratio.
- real-ear insertion response. Real-ear responses were recorded in 1/24 octave bands within a frequency range of 125 Hz to 8 kHz (144 steps) using a clinical measuring system (PortaRem-2000, RD Rastronics Division, Denmark or Unity, Siemens, Germany). Final analysis was carried out at four octave bands (500, 1k, 2k and 4kHz). Slope of the response (in dB/octave) was defined as half of the difference of the average gain at 1k and 500 Hz and at 2k and 4k so that more positive slope-values corresponded to a steeper frequency response (more amplification at higher frequencies). Similar to this, audiogram slopes were calculated from the pure-tone thresholds at the same four frequencies so that high-frequency hearing losses corresponded to higher slope-values.

Statistical analysis

Percentages for subgroups were tested by means of the Chi-square or Fisher's exact test. Means were tested with the t-test or ANOVA. Non-parametric testing

was performed when data were not normally distributed. We used Wilcoxon's test for paired comparisons, the Mann-Whitney U-test for unpaired comparisons and the Kruskall-Wallis test for comparison between more than two groups. Multivariate regression techniques were used for analysis of differences in outcome between subgroups with different fitting procedures. In case of a binary outcome measure, logistic regression analysis was used, while otherwise linear regression techniques were applied. All data were analyzed using SPSS software release 12.0.1 (SPSS Inc.). The following grouping variables were distinguished:

- Fitting procedure: prescriptive vs. comparative
- Three strata of maximum speech intelligibility: 50-74%; 75-89%; 90-100%
- Experienced vs. first-time hearing-aid users
- Unilateral vs. bilateral fittings
- Fittings with BTE vs. ITE hearing aids

Results

POPULATION

We were able to include 254 hearing impaired patients in a 3-year period: 92 men (36%) and 162 women. Age ranged from 29 to 95 years with a mean age of 71 years (SD 13.5 years). Mean pure tone audiogram thresholds were 57.5 dB HL and ranged from 30.6 to 102.5 dB HL. Speech reception threshold (SRT) ranged from 11.4 to 94.6 dB with a mean of 53.2 dB. Detailed data are shown in table 3-1. The results of all participating centers were comparable.

Table 3-1: *General features of the study population and numbers for the three strata.*

	h.a. user		h.a. fitting		type of h.a.		sex	
stratum	**inexp.**	**exp.**	**unilat.**	**bilat.**	**BTE**	**ITE**	**male**	**female**
50-74%	7	27	10	24	33	1	20	14
75-89%	37	42	12	67	71	8	57	22
90-100%	71	70	36	105	112	25	86	55
total	**115**	**139**	**58**	**196**	**216**	**34**	**163**	**91**

SPEECH IN QUIET

Due to missing data (profound losses; limited amplification at testing) in three of the 184 successful hearing aid fittings, we were able to calculate results for 181 clients. On the whole, speech intelligibility after hearing aid fitting improved to the same extent for both fitting procedures with 6%.
Because maximum possible improvement of the aided speech intelligibility score was determined by the unaided performance, largest improvements were found in the lower stratum: 21% (median), while for the middle and upper stratum 11% and 3% improvement was found. Data are shown in figure 3-1. We found no significant differences between the two fitting procedures. As can be read from figure 3-2, improvements were equal for inexperienced and experienced hearing-aid users in all strata.

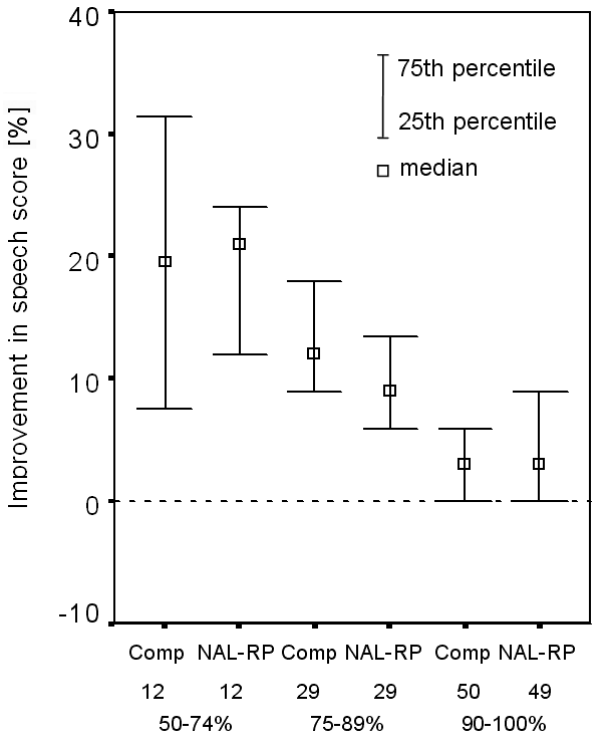


Figure 3-1: *Improvement of speech score in quiet for the number of comparative ("Comp") and prescriptive ("NAL-RP") fitting procedures for each stratum of maximum speech intelligibility score.*

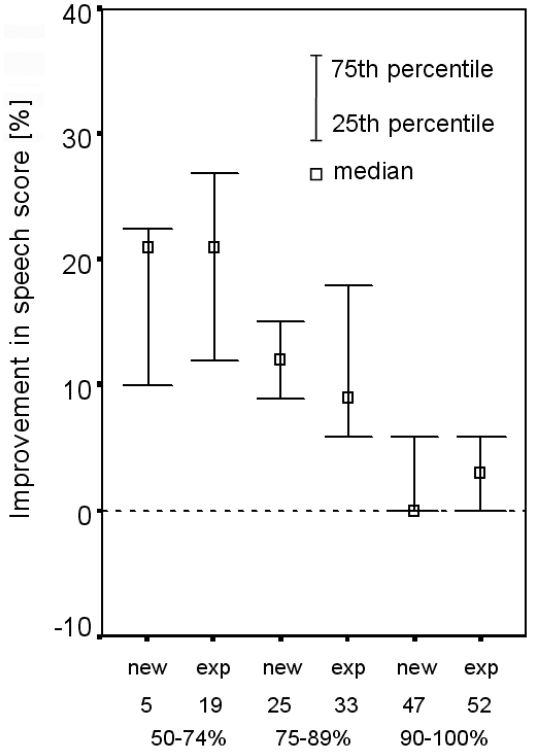


Figure 3-2: *Improvement of speech scores in quiet for the number of first-time ("new") and experienced ("exp") hearing aid users for each stratum of maximum speech intelligibility score.*

Analysis on subgroups (inexperienced and experienced hearing-aid users, unilateral and bilateral fittings, ITE and BTE-fittings) did not show any significant difference between the prescriptive and comparative fitting procedures, except for ITE-fittings, where a significantly larger median improvement in speech intelligibility was found for the prescriptive fitting procedure: 9% compared to 0% for the comparative method. Despite of the small number of ITE fittings, this improvement was significant (p=0.002; t-test).
We concluded that improvement of the intelligibility score of speech in quiet was the same for both fitting procedures and was proportional to the degree of hearing loss characterized by unaided intelligibility of speech in quiet.

SPEECH IN NOISE

Changes in SN ratio were calculated for 132 subjects, which is substantially less than the 181 subjects for which we were able to calculate the improvement of the

speech scores in quiet. This was due to the fact that speech-in-noise measurements were obtained at a level of 20 dB above the speech reception threshold (SRT). In a number of cases our equipment was not able to deliver the required stimulation level for unaided scores (maximum output level: 100 dB SPL). When combining all comparative fittings (three strata), no improvement in SN ratio after hearing aid fitting was found in this group. However, in the prescriptive group, a median improvement of 0.80 dB was found. Although this improvement seemed to be small, it was significantly better when compared the outcome to the comparative fitting group (p=0.002).
The median SN ratios for the two fitting procedures in all three strata are depicted in figure 3-3. Median improvement turned out to be in favour of the prescriptive procedures in all three strata, although statistical significance could only be proven in the middle stratum (p=0.03).

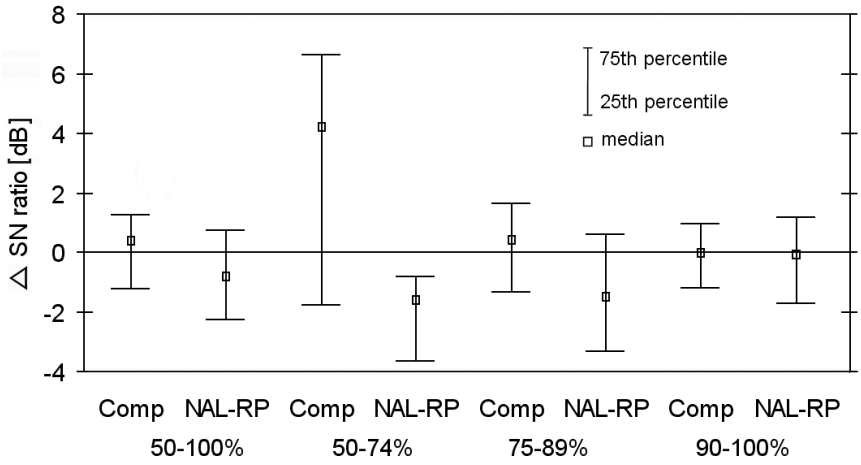


Figure 3-3: *Improvement of the SN ratio after fitting according to the comparative fitting procedure ("Comp") and the prescriptive procedure ("NAL-RP") for the complete population (two left bars) and for each stratum of maximum speech intelligibility score. Note that more negative SN ratios point to better performance.*

No significant differences were present in the lower stratum due to the small number of subjects and in the upper stratum due to the small effect in spite of its relatively large group size. The difference was significant in the middle stratum only (p=0.03) and was in favour of the prescriptive procedure.
No significant differences in improvement of SN ratios were found in the distinguished subgroups. Data are shown in figure 3-4.

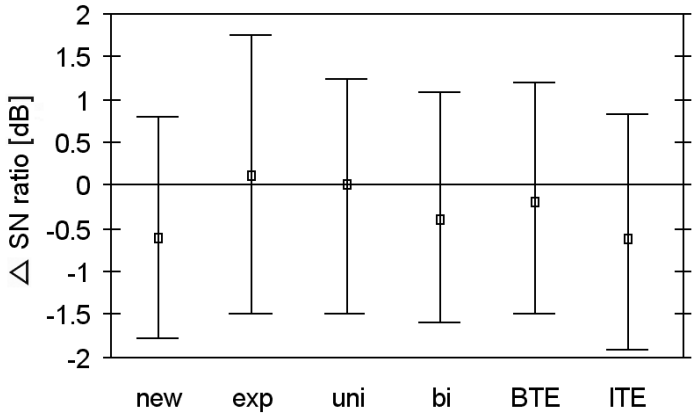


Figure 3-4: *Improvement of the SN ratio broken down for some population characteristics. Note that more negative SN ratios point to better performance after hearing aid fitting. Abbreviations: "new" = first hearing aid users, "exp"=experienced hearing aid users, "uni"= unilateral fitting, "bi"=bilateral fitting, "BTE"=fitted with behind-the-ear hearing aid(s), "ITE"=fitted with in-the-ear hearing aid(s).*

REAL-EAR INSERTION RESPONSE

We found a comparable slope of the real-ear insertion gain measured after fitting according to either procedure. This was also the case for each of the three strata separately (ANOVA; $p>0.1$). No differences in slope were found in each of the other subgroups studied. A comparable and significant correlation between the slope of the audiogram and real-ear insertion gain was found in the prescriptive and comparative fitting subgroups (Pearson correlation 0.309; $p<0.001$). A scatter plot is depicted in figure 3-5. This was also found in all three strata separately.
We concluded that both fitting procedures are comparable with respect to the slope of the frequency response prescribed for a population of different sloping and varying degrees of hearing losses.
Further investigation was carried out in order to correlate real-ear insertion responses to speech in noise data. This was done in order to search for any relationship between the improvement of the SN ratio and the amount of high frequency amplification provided. Here, it must be realized that the insertion gains were measured for each fitted ear separately, while SN ratios were obtained in bilateral conditions.
A significant correlation between the improvement of the SN ratio and the insertion gain slope was not clearly evident (Pearson correlation -0.180; $p=0.05$). We only found a significant correlation between the improvement of the SN ratio and the slope of the audiogram (Pearson correlation -0.278; $p<0.001$). A scatter plot is given in figure 3-6.

We therefore concluded that patients with high frequency hearing losses (steeply sloping audiograms) tended to benefit most from high-frequency amplification in general, regardless of type of fitting procedure investigated in this study.

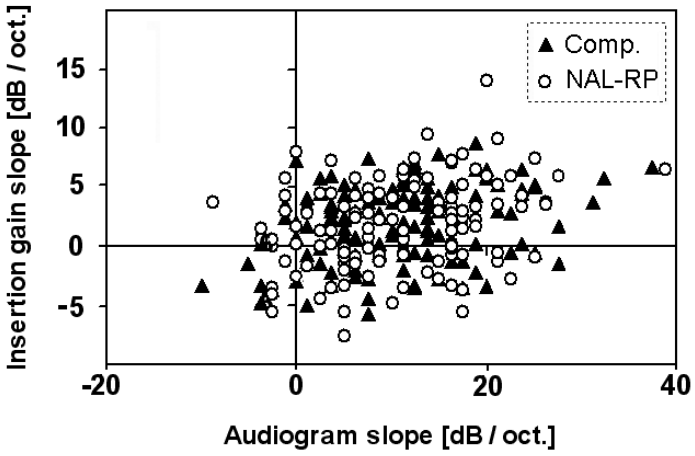


Figure 3-5: *Scatter plot of insertion gain slope versus audiogram slope. NAL-RP: n=126, comparative: n=131.*

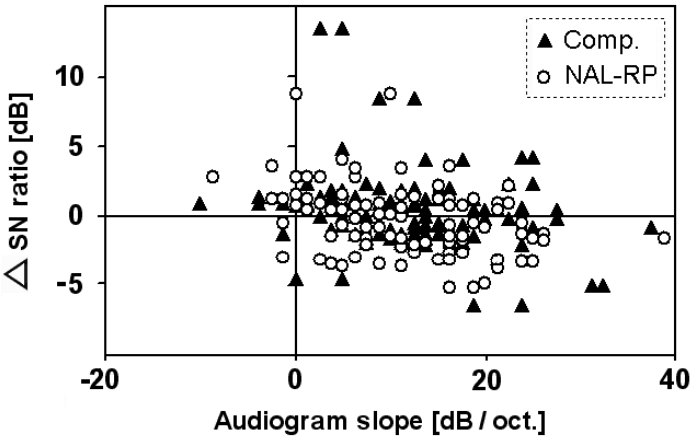


Figure 3-6: *Scatter plot of improvement of SN ratio versus audiogram slope. NAL-RP fitted patients: n=102, comparative: n=105. Note that improvement is represented by negative SN ratios.*

Discussion

Comparative evaluations of hearing aid fitting procedures according to a double blind randomized clinical trial are scarce in the literature.
We see that the aim of better speech scores has not been realized to a larger extent in the population fitted according to the comparative procedure than in those fitted according to the NAL-RP formula. Although the starting-points and goals were formulated differently, the outcome appeared to be very similar. It might be surprising that although the comparative procedure aimed to optimize speech intelligibility, the NAL-RP even in a few cases resulted in even slightly better speech scores.
One can argue that the outcome of NAL-RP fittings in a normal clinical setting will be somewhat different from ours, because we may have implemented the way of fitting according to this formula too strictly. Calculated target gains were controlled by measurements of the real-ear insertion gains. Coupler responses that we have measured in order to facilitate computerized selection of hearing aids were obtained from straightforward analogue electrical circuits with linear amplification. Compression was used as little as possible in order to avoid any unpredictable effect of nonlinear amplification. In normal clinical practice some leeway will be given to complaints of patients about too much high-frequency amplification. This may have influenced the outcome of the comparative fitting procedure more than the NAL-RP group. However, we found no clear differences in real ear measurements and must conclude that this aspect would be insignificant.
Regarding the recent and current developments in hearing aid technology, it will be clear that the formula that we have used will not be applicable for the current range of commercially available hearing aids, provided with digital and/or programmable nonlinear circuitry. These hearing aids involve many more features than were considered in this study.
We have deliberately chosen not to implement hearing aids with digital circuits and/or WDRC compression algorithms for a couple of reasons valid at the time of the study:

- The extra value of digital hearing aids had not been proven or was not evident and probably not present in the digital hearing aids at the time.
- Various ways of signal processing (like WDRC) were used in digital hearing aids, which would influence the acoustic response of the aid in a complex and inscrutable way, making a comparison between hearing aids far more complicated if not impossible. Moreover, we had no insight into the detailed working of digital hearing aids and their fitting software.

- Generic fitting procedures for digital / WDRC hearing aids were and are in a state of development.
- The answer to the research question would most probably not be different when hearing aids provided with more sophisticated circuitry were used as the effects would affect both fitting procedures to a similar extent.

We included only 254 patients in the study while the power calculation resulted in a required number of 480 patients. There were some reasons for this. We particularly had an insufficient number of patients in the lower two strata. One reason had to do with the presence of significant co-morbidity in the subgroup of patients with a speech intelligibility between 50 and 75%, which resulted in a higher exclusion rate than anticipated. Another reason was the growing request for digital and/or programmable hearing aids from the potential participants. Extending the inclusion period was not considered a practical option as we expected the second reason to become more relevant and outspoken, particularly in the group of poorly performing users. We therefore had to accept smaller numbers of users participating in the study especially in the lower strata. One has to realize that, where differences between the groups were studied, the significance could not always be proven due to relatively small numbers.

Improvement of speech intelligibility in quiet did not show significant differences between the two fitting procedures. This is in accordance with the results of van Buuren et al [1995] who demonstrated that even the intelligibility of speech in noise in mild to moderate hearing losses appears not to be very critical for the hearing aid gain provided over a wide range of spectra. It was remarkable that although the evaluation of speech intelligibility served as a major criterion during hearing aid selection and fine-tuning in the comparative fitting procedure, no better results in terms of this outcome-measure were achieved. A reason for this may be the limited number of test items, being 33 consonants and vowels for each list of 11 CVC-words. This means that performance differences between hearing aids for individuals can only be significant for differences of more than about 10%. This is relatively large in view of the total possible improvement.

The improvement of the SN ratio measured with the Dutch sentence test after hearing aid fitting is in accordance with the data from Verschuure & van Benthem [1992] and from van den Heuvel et al [1997] who found a small positive effect of a hearing aid on intelligibility of speech in noise. In our study, this improvement was only found in the NAL-RP subgroup. We were not able to point to a clear reason for this finding. Analysis of (unilateral) real-ear insertion gains did anyhow not reveal significant differences in insertion gain-slope between hearing aid fittings according to the NAL-RP formula and the comparative procedure. It has often been suggested that amplification with high-frequency emphasis should result in better

speech intelligibility in noise in spite of poorer sound quality, but we can not support this assumption from our results.
From our analysis of insertion gains in relation with audiogram-slope and improvement of S/N-ratios, it appeared that patients with high frequency hearing losses (steeply sloping audiograms) tended to benefit most from high-frequency amplification with respect to improvement of the SN ratio. This is in accordance with the finding from Lee et al [1993]. From their analysis on a group of patients with high-frequency hearing loss it appeared that speech in noise tests were the most sensitive indication of improved speech recognition after hearing aid fitting.

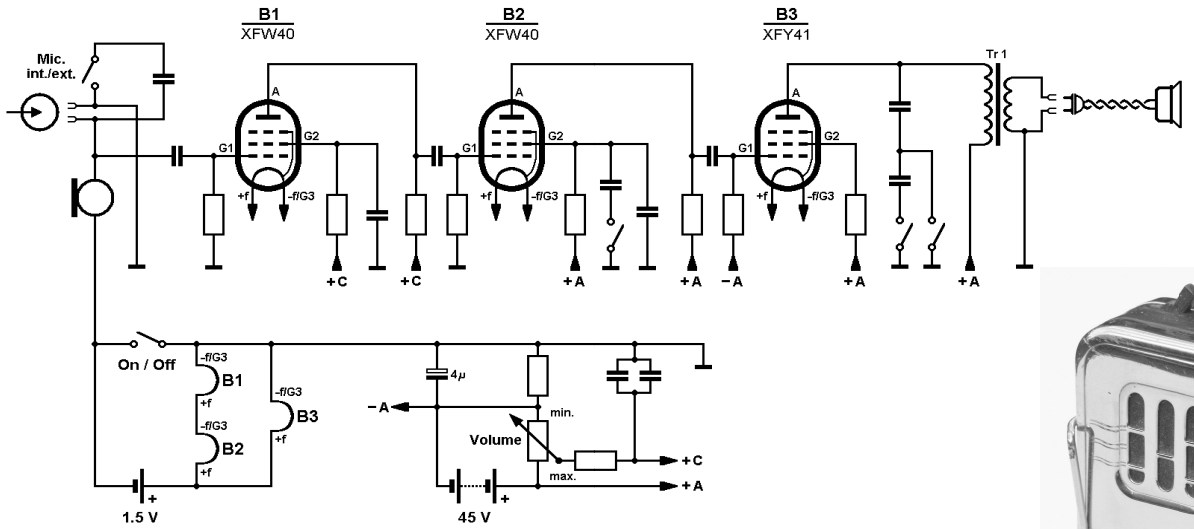
Conclusions

Our data were obtained from experienced and first-time hearing-aid users with a variety of predominantly sensorineural hearing losses. Analogue hearing aids with linear amplification were prescribed. The conclusions listed below are therefore to apply to comparable populations and hearing aids:

1. Improvement of speech intelligibility in quiet was comparable after hearing aid fitting according to both the comparative and the prescriptive procedure studied.
2. Hearing aid fitting according to the strictly implemented NAL-RP formula resulted in a small improvement of the speech-to-noise ratio. No improvement was found after fitting according to the comparative procedure. The difference in the extent of improvement between the two fitting procedures was significant.
3. Comparable real-ear insertion responses for the range of hearing losses included in the study were found for both fitting procedures. No significant differences in slope of the insertion response were found between hearing aid fittings according to the NAL-RP formula and the comparative fitting procedure.
4. Patients with high frequency hearing losses (steeply sloping audiograms) tended to benefit most from high-frequency amplification.

Acknowledgements

This study has been conducted with financial support by the Dutch CVZ (College voor Zorgverzekeringen). The authors would like to thank all the hearing impaired patients that have participated in this study.



AUDIUM ELECTRO-ACOUSTISCHE IND. N.V.
Singel 160, Amsterdam-C. – Telefoon 42733

Figure 4-0: Audium model 600. Body-worn hearing aid with three miniature electron tubes (made by Hivac) and built-in microphone. This example dates from around 1950. Dimensions 9.2x5.7x2.1 cm. Two batteries are needed for operation: 45 Volt for the plate voltage and a 1.5 Volt cell for heating of the filaments. Circuit diagram reconstructed by the author. Hearing aid from the author's collection. Photograph by the author.

Chapter 4

Self-reported disability and handicap after hearing aid fitting and benefit of hearing aids: comparison of hearing aid fittings, degree of hearing loss, experience with hearing aids and uni- and bilateral fittings

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Eur Arch Otorhinolaryngol. 2009;266(6):907-917

Abstract

Self-reported outcome on hearing disability and handicap as well as overall health-related quality of life were measured after hearing aid fitting in a large-scale clinical population. Fitting was performed according to two different procedures in a double blind study design. We used a comparative procedure based on optimizing speech intelligibility scores and a strictly implemented fitting formula (NAL-RP). Hearing disability and handicap were assessed with the Hearing Handicap and Disability Inventory (HHDI) and benefit of hearing aids with the Abbreviated Profile of Hearing Aid Benefit (APHAB). Effects on health-related quality of life and depression were assessed with the EuroQol-5D (EQ-5D) questionnaire and the Geriatric Depression Scale (GDS).

We found that hearing aid fitting according to either procedure had a significantly positive effect on disability and handicap associated with hearing loss. This effect lasted during several months. Only the effect on disability persisted after one year follow-up. Self-reported benefit from hearing aids was comparable for both fitting procedures. Unaided hearing disability was more pronounced in groups of participants with greater hearing loss, while the benefit of hearing aids was independent from the degree of hearing impairment. First-time hearing aid users reported greater benefit from their hearing aids. The added value from a bilateral hearing aid fitting was not significant. Overall health-related quality of life and incidence of depression did not alter after hearing aid fitting.

Introduction

Hearing impairment has a negative effect on the health-related quality of life in elderly persons, due to communication difficulties [Dalton et al, 2003]. Effects on social, emotional, communicative and cognitive functioning can be partly compensated with hearing aids [Mulrow et al, 1990]. Although the whole process of auditory rehabilitation focuses on many more aspects such as the learning of communication strategies and adaptation to the acoustical environment, hearing aid fitting is one of the first essential steps.

The consequences of hearing impairment can be investigated in the domains of disability and handicap according to the conceptual framework proposed by the WHO in 1980 [WHO, 1980]. Since 2001, the WHO has replaced these terms by ‘activity limitation’ and ‘participation restriction’ in their International Classification of Functioning, Disability and Health [WHO, 2001].

From the literature, little is known about the extent to which hearing aid fitting procedures succeed in alleviating the consequences of activity limitation and

restriction of participation, suffered by a hearing-impaired individual or by a group of hearing-impaired subjects fitted with hearing aids. Reports from comparisons of different types of fitting procedures in large-scale clinical populations are scarce. We compared a comparative hearing aid selection and fitting approach with a strictly implemented prescriptive method in a double blind randomized clinical trial [Meister, 2005]. A comparative procedure principally approximates the primary criterion (e.g. speech intelligibility, sound quality) chosen as close as possible. This offers direct clinical evaluation with the hearing aid in place. However, a comparative way of fitting could be expected to be more time-consuming and to be dependent on the knowledge and experience of the hearing aid fitter. A prescriptive method is based on a fitting formula that usually has been distracted from physical data and clinical research. A fitting formula can easily be automated and offers a quick and reproducible method for the initial hearing aid selection. While the number of prescriptive formulae is gradually increasing, and the comparative fitting approach seems to steadily loose popularity, little is known about the effects of these types of fitting procedures on self-reported hearing disability and handicap and on overall health-related quality of life.

We performed this study to answer the following questions:

- Does a group of hearing-impaired patients report differences in hearing-specific and in general health-related quality of life after hearing aid fitting according to a comparative or a prescriptive fitting procedure?
- Which characteristics of hearing impaired populations are related to changes in self-reported hearing-specific and general health-related quality of life after hearing aid fitting?
- Are changes in self-reported hearing-specific and general health-related quality of life preserved during one-year follow-up?
- To what extent are hearing-specific and general health-related quality of life measures able to assess the effects of rehabilitation with hearing aids?

Material and methods

POPULATION

All patients included in this study visited the department of Clinical and Experimental Audiology in the Academic Medical Center in Amsterdam or the Audiology Department of the Erasmus Medical Center in Rotterdam, the Netherlands because of hearing-impairment over a period of at least three years. The main criterion for auditory rehabilitation with hearing aids was an average pure-tone audiometric threshold of more than 35 dB at the better ear (insurance

company criterion for partly reimbursing hearing aid expenses in the Netherlands). We included purely sensorineural hearing losses and mixed losses with a dominant sensorineural component. First-time candidates as well as experienced hearing aid users were included after having obtained informed consent.
Exclusion criteria were:

- A maximum speech score in quiet of less than 50 percent on the better ear
- A retrocochlear hearing loss
- Meniere's disease (active phase)
- (Severe) tinnitus
- Significant co-morbidity
- Not being capable of answering the questionnaires or not being able to understand and speak the Dutch language to a sufficient amount.

The possibility of withdrawal from participation at any moment during the study was guaranteed.

STUDY DESIGN

A double-blind randomized study design was followed that has been described in detail previously [Metselaar et al, 2008]. Stratification was performed according to maximum (unaided) speech intelligibility at the better ear. Three strata of speech intelligibility were distinguished (50-74%, 75-89%, 90-100%).
The aim of the comparative approach was to improve speech perception as much as possible, at least to the maximum speech intelligibility found in the (unaided) speech audiogram. For each fitting, a number of possibly suitable hearing aids was selected by the hearing aid fitter. This selection was based on both the hearing thresholds of the patient and the experience of the fitter. Free-field speech intelligibility in quiet was compared with each of the selected hearing aids in situ and served as the primary selection criterion. A second criterion was used, based on sound quality judgements by the patient. This procedure has been described in detail by Verschuure [1994].
The prescriptive procedure applied was based on the NAL-RP formula [Byrne & Dillon, 1986; Byrne & Cotton, 1988] with the modification for profound hearing losses [Byrne et al, 1990]. The formula has been designed to prescribe linear amplification for mild to profound sensorineural hearing losses. Strict implementation of the prescriptive method was made possible by use of a computerized selection and fitting program that was written exclusively for this study.
Once included in the study, each participant was initially fitted according to the comparative as well as the prescriptive procedure in an arbitrary sequence. This

was done by different hearing-aid fitters who were not informed about each others results, except for the type of hearing aid prescribed (behind-the-ear (BTE) or in-the-ear (ITE) hearing aid) and the ear(s) to be fitted. Unilateral as well as bilateral fittings were performed. These choices were determined by the first hearing-aid fitter and were kept the same for both prescriptions.
We have chosen to fit hearing aids that were adjusted to provide linear amplification. This was prescribed as much as possible in order to provide us with a set of precisely predictable output characteristics, enabling accurate fitting according to the NAL-RP formula. Moreover, it facilitated random swapping within the range of possibly suitable hearing aids, allowing a uniform comparison and selection. No digital and WDRC-compression hearing aids were used as clear fitting procedures were lacking at the time of inclusion of the participants in our study.
Both selection procedures resulted in a prescription for a specific brand and model of a hearing aid with an exact specification of the settings (gain, tone settings, and maximum output) as well as the type of earmould. One out of these two prescriptions was randomly given to the patient. Hearing aids were actually provided by the hearing-aid acoustician one to two weeks after randomisation. This period was required to get the hearing aids delivered from the manufacturer and the ear mould produced. Hearing aids fitted according to the prescriptive procedure were adjusted as closely as possible to the calculated target, which was confirmed by insertion gain measurements. Hearing aids provided in the other group were adjusted according to the settings who were finally found during the initial evaluation process.
Each patient was given the hearing aid(s) on trial during a 12-week period of acclimatization and experience. In case of a comparative fitting, hearing aids were examined once halfway this period and further adjusted if necessary. Aided speech intelligibility was used as the main criterion. Just for keeping the fitting procedure hidden / blinded to all clients, the prescriptive fitting group also visited the Audiological Center. This ‘dummy’ visit was used for the completion of some of the questionnaires (table 4-1).
At the end of his or her 12-week evaluation-period, the study protocol of each patient was closed. The result of the fitting was assessed to be successful or not. This was done by an independent audiologist (not the investigator) who measured aided speech intelligibility in quiet and in noise. In case of a satisfactory result, the opinion of the patient was asked for. When the patient was also satisfied with the result, the hearing aid fitting was finalized. Analysis of the data in this study has been performed on data derived from successfully fitted patients only. When the patient was not satisfied after fitting according to the prescriptive method, he was

offered a fitting according to the comparative procedure that was being regarded as the golden standard. Dissatisfaction with the comparative procedure could occur in case of a request for re-fitting with a specific kind of digital or WDRC-hearing aid or for example with an ITE instead of an initially chosen BTE-hearing aid. From this phase on, the blinding was ended.

Table 4-1: *Moments of completion of all questionnaires used in the study.*

moment of completion:	questionnaire:
t=0 'randomisation'	HHDI
	GDS
	EQ-5D
t=2 weeks	APHAB (baseline profile)
t=6 weeks	APHAB
t=12 weeks	HHDI
	EQ-5D
	GDS
t=6 months	APHAB
t=12 months	HHDI
	GDS
	EQ-5D

QUESTIONNAIRES

To assess the effects of hearing aid fitting on the experienced hearing disability and handicap and on the general and psychological well-being of hearing-impaired subjects, a number of validated hearing-specific and overall health-related measures was chosen.

1. *Hearing Handicap and Disability Inventory (HHDI).* This questionnaire measures the consequences of hearing impairment in the domains of disability and handicap, according to the conceptual framework proposed by the WHO [1980]. Disability is measured by subscale 'Performance', while three handicap subscales are used: 'Emotional response', 'Social withdrawal', and 'Reactions of others'. The latter subscale consists of the subscales 'Positive' and 'Negative reactions of others'. All items were scored in four response

categories (range 1 to 4). Higher scores represent more disability or handicap [van den Brink et al, 1996].

2. *Abbreviated Profile of Hearing Aid Benefit (APHAB).* This self-report questionnaire quantifies disability associated with hearing loss in a number of acoustically different daily life situations [Cox & Alexander, 1995]. Benefit of hearing aids was computed by subtracting the results of performance with the hearing aid during fitting (6 weeks) and after 6 months follow-up from performance without the hearing aid (or with the previous hearing aid for experienced users) that was measured two weeks after randomization. The items are clustered in four subscales: 'Ease of Communication' (EC), 'Background Noise' (BN), 'Reverberation' (RV) and 'Aversiveness of sounds' (AV). The Dutch translation of the original text was cross-translated into the English language to verify the quality of the translation. Some of the listening situations had been adapted to the Dutch environment. All items were scored on a visual analogue scale. Higher scores are indicating more problems. As an addition to the APHAB, also the frequency of occurrence, importance of understanding speech, and proportion of time the hearing aid was used were investigated for each listening situation, as proposed by Gatehouse [1996]. This information determines to what extent the hearing aid contributes to subjective auditory functioning of the client and served as a weighing factor for each question.
3. The *Geriatric Depression Scale (GDS)* is a self-rating screening scale for depression in the elderly population [Yesavage, 1983]. This scale has been validated for subjects over 55 years of age. We used the short version of the GDS [Sheikh & Yesavage, 1986]. This scale contains 15 propositions that can be answered with "yes" or "no". Depression was diagnosed when more than 5 out of 15 items were scored positive.
4. The *EuroQol-5-Dimensions instrument (EQ-5D)* is a generic self-report questionnaire consisting of two parts [EuroQol Group, 1990]. The first part records self-reported problems on each of five different dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is divided into three levels of severity corresponding to no problem, some problem, and extreme problem. Applying a weighing system [van Hout & McDonnel, 1992] outcome of this part can be presented as a single health index ($EQ\text{-}5D_{index}$). The second part records self-assessed rating of general health on a visual analogue scale ($EQ\text{-}5D_{vas}$). This scale ranges from 0 to 100, representing worst to best imaginable health condition respectively.

All questionnaires were self-administered and were completed at three different moments during the fitting process. Help was being offered when necessary in

order to avoid unanswered questions as much as possible. The moments of completion of the questionnaires differed and are given in table 4-1. However, the timing scheme was equal for both fitting procedures.
Because of the fairly large amount of questionnaires used in this study, we divided the moments of completion among the several visits necessary for hearing-aid fitting and evaluation. As a result of this, the first APHAB was completed 2 weeks after randomisation. Because the actual hearing aids were not really fitted to the clients before that time, we regarded this moment as 'baseline' as well. Although some patients had to be encouraged somewhat, most of them did not really object to the workload caused by completion of the questionnaires.

Results

POPULATION

In total, 254 hearing-impaired patients (163 men, 91 women) were included in the study. Age ranged from 29 to 95 years with an average age of 71 years and SD of 13.5 years. Average pure-tone audiogram thresholds (averaged over 1, 2 and 4 kHz) were 57.5 dB HL ranging from 30.6 to 102.5 dB HL. Speech reception threshold (SRT) varied from 11.4 to 94.6 dB with a mean of 53.2 dB. Thirty-four patients were included in the lower stratum, 79 and 141 were included in the middle and upper stratum respectively. We included 113 (44.5%) first-time hearing aid users, 196 (77.2%) were fitted bilaterally. After randomisation, 119 (46.9%) patients were fitted according to the comparative procedure. About half of the participants (50.8%) were recruited in Amsterdam. In 184 patients (72.4%), hearing aid fitting was regarded successful according to the aforementioned criteria.

HEARING HANDICAP AND DISABILITY INVENTORY (HHDI)

Comparable scores on all HHDI-subscales were found before hearing aid fitting in the comparative and prescriptive subgroups (figure 4-1). Significant improvements (that means: corresponding to lower scores) were measured in both subgroups directly after fitting in the disability-subscale 'performance' and in two of the three handicap-subscales 'emotional response' and 'withdrawal' ($p<0.001$; Wilcoxon). In the subscales 'performance' and 'emotional response' this effect was preserved during the one-year follow-up period, while it disappeared in the subscale 'withdrawal'.
At the end of the fitting procedure (12 weeks), a significantly larger improvement on handicap-subscale 'withdrawal' was found for the prescriptive subgroup. This difference disappeared at one-year follow-up. One year after fitting, differences

between improvement were found to be significant in subscales 'performance' and 'negative reactions of others' ($p<0.05$; M-W U-test) in favour of comparative procedure.

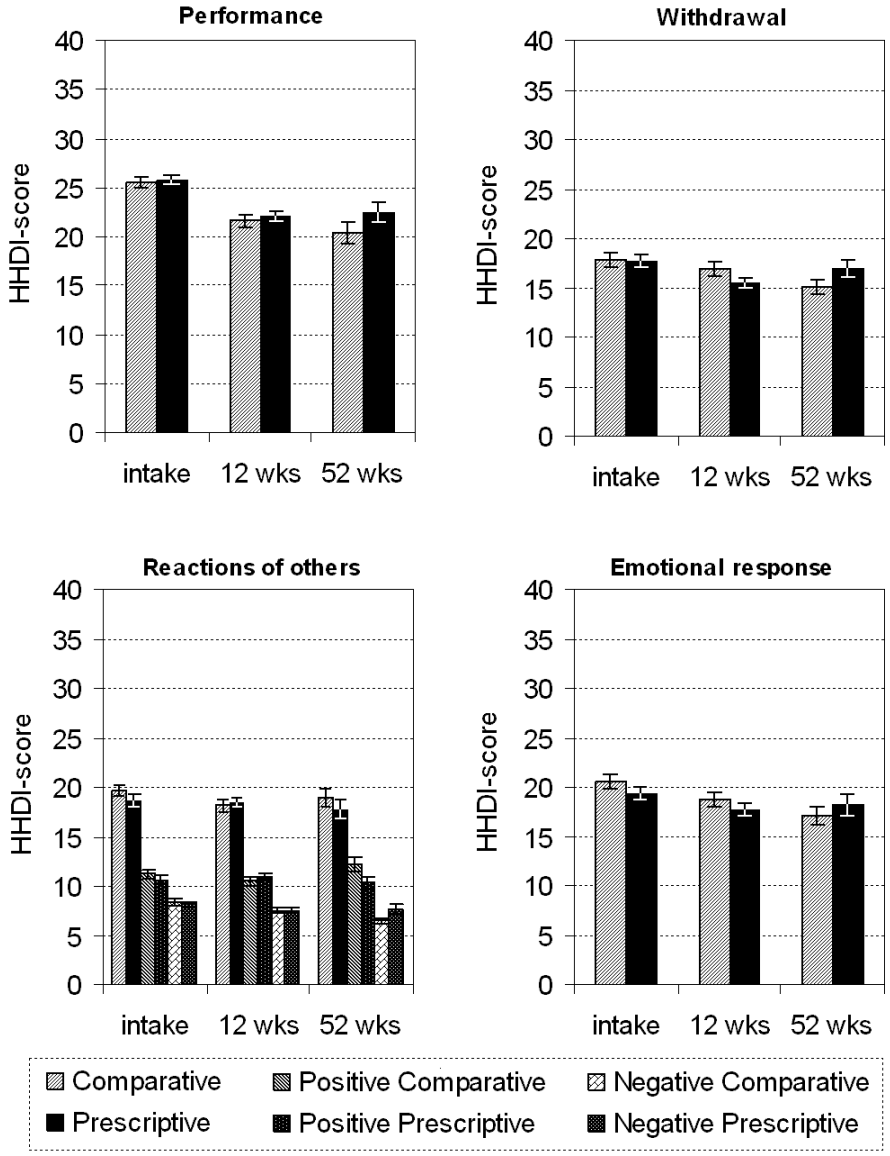

Figure 4-1: *Scores on all four HHDI-subscales and standard errors at the three moments of completion of the questionnaire in the study for comparative and prescriptive fittings. Reactions of others have been characterized as either positive or negative (lower left panel). Lower scores represent better results.*

Next, we analyzed the HHDI-scores for the three strata of maximum unaided speech discrimination (see figure 4-2). We found significant differences ($p<0.005$) only in disability subscale 'performance' for the lower two strata (50-74% and 75-89%) compared to the highest stratum (90-100%) These differences were present before and after hearing aid fitting and at one year follow-up and were better in the highest stratum (figure 4-2: left panel). Hearing disability was not different between the lowest two strata.

Within the three strata of maximum unaided speech discrimination, no significant differences between the two fitting procedures were measured in any of the HHDI-subscales, except for the lowest stratum in subscale 'emotional response' directly after fitting (12 weeks) where a significant difference was measured in favour of the prescriptive procedure ($p<0.05$ M-W U-test).

Clients that had not been wearing hearing aids before scored significantly better only on handicap subscale 'withdrawal' compared to experienced users ($p<0.05$) at all three moments of completion of the questionnaire (figure 4-2: right panel). Scores on all other subscales were not significantly different for first-time and experienced hearing aid users.

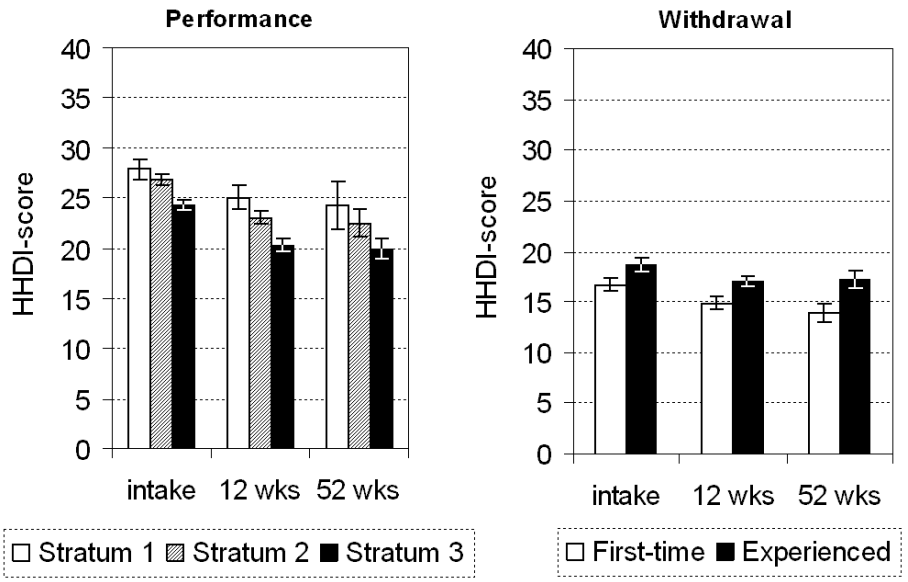

Figure 4-2: *Average scores on the HHDI-questionnaire for the three moments of completion on subscale "Performance" broken down after stratum of unaided speech intelligibility (left panel) and "Withdrawal" for inexperienced and experienced hearing aid users (right panel). Error bars show ± 1SE.*

We found no differences between the two fitting procedures amongst first-time and experienced hearing aid users on any of the HHDI-subscales, except for subscale 'performance' at 52 weeks. In this subscale first-time hearing aid users scored significantly better when fitted according to the comparative procedure ($p<0.005$). No differences in any of the HHDI-subscales were measured between the two fitting procedures in the subgroups with unilateral and bilateral hearing aid fittings.

ABBREVIATED PROFILE OF HEARING AID BENEFIT (APHAB)

Significant benefit ($p<0.005$; Wilcoxon) in all subscales was measured during hearing aid fitting (6 weeks), except in subscale aversiveness ($p>0.05$; Wilcoxon), see figure 4-3. Benefit was preserved after 26 weeks follow-up except for the subscale aversiveness where again no difference was measured.
No significant differences in benefit measured at 6 and 26 weeks were found between the two fitting procedures in any subscale.
No significant differences in benefit between the three strata of maximum unaided speech recognition were found in any subscale on any moment of completion of this inventory.

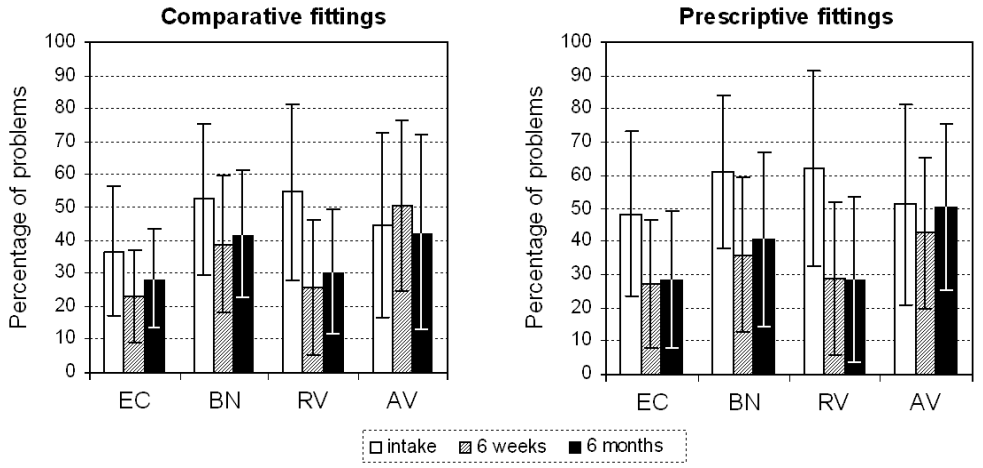

Figure 4-3: *Average APHAB-scores for the three moments of completion (before fitting, during fitting and at 6 months follow-up). Error bars show ± 1SD. Scores are shown for each APHAB subscale. See text at page 63 for abbreviations of subscales.*

Also, no differences in benefit between both fitting procedures were found in each of the three strata of maximum unaided speech discrimination.

First-time hearing aid users reported significantly more benefit at 6 weeks and 26 weeks compared to experienced users in subscales 'EC', 'BN' and 'RV'. In subscale 'AV' the benefit was negative: first-time users reported more problems compared to experienced users. Results are given in table 4-2.

Table 4-2: *Average benefit and standard deviations on all APHAB-subscales during (at 6 weeks) and after (at 26 weeks) hearing aid fitting for first-time and experienced hearing aid users. Benefit is indicated by positive numbers.*
[¥] significant (p<0.005; M-W U-test) compared to experienced hearing aid users.
[‡] significant (p≤0.05; M-W U-test) compared to experienced hearing aid users.

APHAB-subscale	First-time		Experienced	
	6 weeks	26 weeks	6 weeks	26 weeks
EC	+27.2[¥] ± 26.1	+25.8[‡] ± 29.9	+11.3 ± 25.7	+15.8 ± 23.6
BN	+33.2[¥] ± 28.1	+27.8[‡] ± 27.9	+10.9 ± 26.7	+13.4 ± 24.7
RV	+45.8[¥] ± 31.3	+42.9[‡] ± 32.7	+15.4 ± 26.9	+20.0 ± 27.0
AV	-12.7[¥] ± 29.1	-8.4[‡] ± 37.8	+9.4 ± 27.0	+6.6 ± 21.9

Table 4-3: *Average benefit and standard deviations on all APHAB-subscales after hearing aid fitting (relative to the pre-fitting results) during fitting (at 6 weeks) and after long-term follow-up (at 26 weeks). Benefit is indicated by positive numbers.*
[‡] significant differences (p<0.05; M-W U-test) compared to unilateral fittings.

APHAB-subscale	Unilateral		Bilateral	
	6 weeks	26 weeks	6 weeks	26 weeks
EC	+14.2 ± 22.9	+20.3 ± 21.3	+19.5 ± 28.1	+19.7 ± 2 7.5
BN	+10.9 ± 25.2	+14.3 ± 26.0	+23.7[‡] ± 30.0	+19.7 ± 27.0
RV	+22.8 ±26.8	+24.9 ± 33.2	+32.2 ± 34.1	+29.6 ± 31 .3
AV	-0.8 ± 25.7	-13.6 ± 26.0	-0.4 ± 31.1	+2.3 ± 30.6

However, we found no differences in benefit in any of the APHAB-subscales for experienced and inexperienced users between both fitting procedures.
In the group with bilateral fittings, significantly (p<0.05; M-W U-test) more benefit was reported only in acoustical circumstances with background noise (subscale 'BN') during hearing aid fitting (6 weeks). This difference was not found after 6 months follow-up. No differences were measured in the other subscales, neither

during fitting nor after follow-up. No differences were measured between the two fitting procedures for subgroups with unilateral and bilateral hearing aid fittings. Results are given in table 4-3.

GERIATRIC DEPRESSION SCALE (GDS)

The short (15-item) version of the GDS was completed at the baseline-time (t=0), at the end of the hearing-aid fitting (12 weeks later), and one year after fitting. At baseline, 8.8% of the study-population of over 55 years of age met the criteria of depression according to the GDS (average score 2.05; sd 2.44), which seems to be somewhat lower than compared to a random American population [Gurland, 1976]. No clear correlations were found between GDS-score and age (Pearson correlation -0.036; $p>0.5$) and between GDS-score and degree of hearing loss as represented by maximum unaided speech intelligibility (Pearson correlation 0.025; $p>0.5$). Average GDS-scores and percentages of depression remained stable directly after and one year after hearing aid fitting (1.57; 6.2% and 2.32; 8.3% respectively). No differences were found between the comparative and prescriptive subgroups (figure 4-4: left panel). No significant differences were found between the three strata of maximum unaided speech discrimination. Experienced hearing aid users reported significantly higher GDS-scores ($p<0.05$) compared to first-time users only after one year follow-up (figure 4-4: right panel).

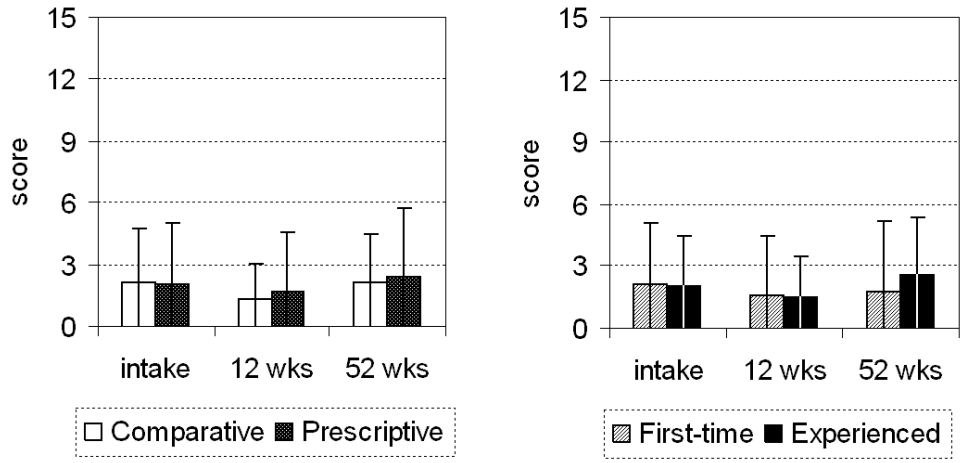

Figure 4-4: *Average GDS-scores during the three moments of completion (before and directly after hearing-aid fitting and after 1 year follow-up). Error bars show ± 1SD. Difference between first-time users and experienced users is significant after 52 weeks (right panel).*

We concluded that prevalence of depression according to the GDS in our population was relatively low and remained unchanged after fitting with hearing aids according to either procedure during a one-year follow-up period.

EUROQOL-5D (EQ-5D)

At baseline, EQ-$5D_{index}$ was 88.1. Correlation with age was significant (Pearson –0.16; $p<0.05$). No correlation with degree of hearing loss was found (Pearson 0.03; $p>0.5$). Directly after fitting and after one year follow-up EQ-$5D_{index}$ was 88.6 and 87.6 respectively. These numbers were not significantly different from baseline-situation ($p>0.05$; paired t-test). No differences between both fitting-procedures were present (figure 4-5: left panel).
The rating of general health on a visual-analogue scale (VAS) was initially 77.4 (SD=14.8) for the whole study population. Again, correlation with age was significant (Pearson –0.16; $p<0.05$). No correlation with degree of hearing loss was found (Pearson -0.02; $p>0.5$). Directly after fitting, the VAS-score was not significantly different from baseline (76.3, $p=0.7$; paired t-test). However, one year after fitting it was rated significantly lower (75.6; $p<0.05$; paired t-test). Results were similar for both fitting procedures (figure 4-5: right panel).

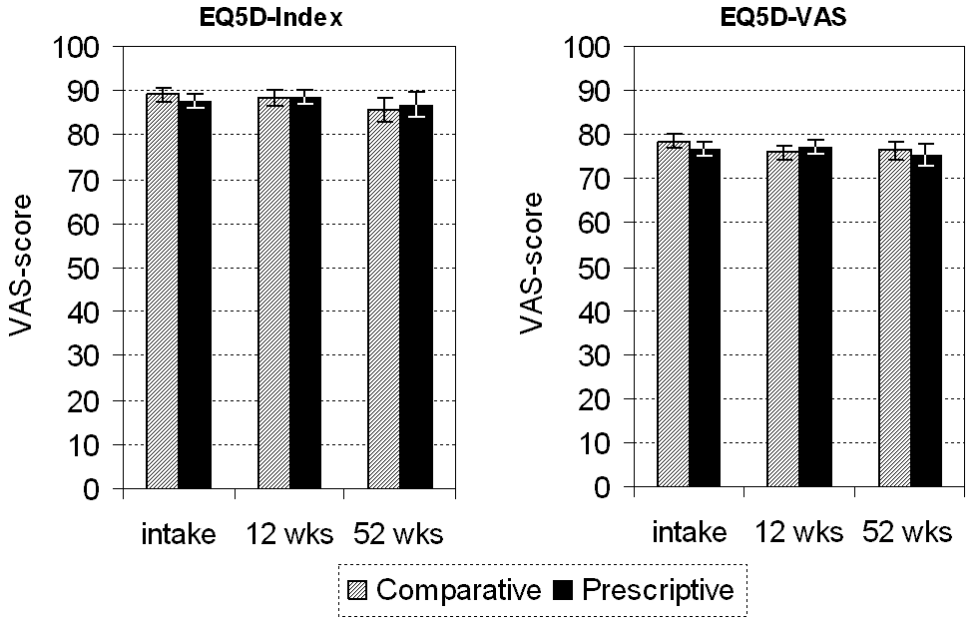

Figure 4-5: *Scores on EuroQol health index and VAS at the three moments of completion for the complete population. Error bars represent standard errors.*

No significant differences were found between first-time and experienced hearing aid users and between the three strata of maximum unaided speech discrimination. We concluded that hearing aid fitting did not alter self-reported general health according to the EuroQol-5D. A decrease in self-reported VAS-rating of general health over a one-year follow-up period was observed in our study population. This was not related to the type of fitting procedure.

Discussion

This study is one of the few relatively large clinical studies to evaluate a comparative and a prescriptive fitting procedure in a randomized setting. We have chosen a linear fitting formula (NAL-RP) to fit hearing aids with linear amplification as much as possible in order to be able to predict the hearing aid output most accurately.

We realize that, as a consequence of these choices, the results of the present study may not be extrapolated to modern digital nonlinear hearing aids. On the other hand, we would not have been able to perform such a comparison of selection and fitting procedures with the currently available modern hearing aids. Summarizing the results of the present study, we found no consistent differences in self-reported hearing disability and handicap in favour of either fitting procedure. The supposed differences between the fitting procedures could therefore not clearly be established. A strictly implemented (computer-aided) prescriptive fitting procedure provides an equal amount of hearing aid benefit and reduction of hearing disability and handicap to a comparative (adaptive) procedure, in which the hearing aid can be fine-tuned according to the clients' suggestions after initial fitting. This finding has also been reported in a pilot study that investigated the effects of additional fine-tuning after hearing aid fitting on self-reported benefit [Cunningham, 2001]. The authors found no significant differences between a group of first-time hearing aid users that was able to adjust their aids after initial fitting and a group that was withheld from additional fine-tuning. It seems that the wearing of hearing aids itself is primarily responsible for the benefit, rather than the specific procedure used to fit them.

We found that self-reported hearing disability according to the HHDI was dependent on the degree of hearing loss that has been classified in one of the three strata of maximum unaided speech intelligibility at the better ear. Disability was significantly more pronounced in the lower two strata compared to the highest stratum. Surprisingly, this difference was preserved directly after hearing aid fitting and even after one-year follow-up. Apparently, fitting with hearing aids did not wipe out the influence of the degree of the hearing loss on disability. This finding was in

accordance with our data on the self-reported benefit of hearing aids (measured with the APHAB). We found that the extent of self-reported benefit of hearing aid fitting was not dependent on the degree of hearing loss and thus was comparable in the three strata. This finding was also reported in a study by Meister et al [2005]. They evaluated the hearing aid fittings of a large number of all different kinds of hearing impaired listeners using a fairly extended inventory. One of their findings was that a more severely impaired hearing loss caused greater problems with hearing aids. In a study after the outcome of hearing aid fitting, Stark & Hickson [2004] also found a relationship between self-reported hearing disability and degree of hearing impairment. They measured disability with the Hearing Handicap Inventory for the Elderly (HHIE) [Ventry & Weinstein, 1982] before and after hearing aid fitting and found a significantly greater reduction in HHIE-scores for participants with a three-frequency average (3-FA) hearing loss of greater than 35 dB, when compared to the reduction measured for those with a 3-FA hearing loss of less than 25 dB. Although the study by Stark & Hickson also reports a dependence of hearing disability and hearing loss, their findings are clearly different from ours. These contradictory results might be explained by the fact that we did not include participants with a 3-FA hearing loss of less than 35 dB in our study. All of our participants met the criteria of the more severely hearing impaired group in the above-mentioned study.

We found a rather limited self-reported surplus value of bilateral hearing aid fittings compared to unilateral fittings. A temporarily positive effect for acoustical circumstances with background noise (APHAB subscale ‘BN’) was found during hearing aid fitting that disappeared after follow-up of several months. No differences were found in the subscales ‘Reverberation’ and ‘Aversiveness’. These data are in accordance with the literature. Noble & Gatehouse [2006] used the Speech, Spatial and Qualities of Hearing Scale (SSQ) for a study on self-reported hearing benefit for people fitted unilaterally and bilaterally. They found no benefit in various self-rated contexts of listening against relatively stationary competing noise. Benefit of two hearing aids over one was only reported in more challenging speech hearing contexts

Finally, we found no effect of hearing aid fitting on the quality of life measured with the generic EuroQol-5D (EQ-5D) questionnaire. This finding is in accordance with the study by Joore et al [2003] who used the EQ-5D to measure the impact of hearing aid fitting in a population of 80 inexperienced hearing aid users. According to their results, the generic quality of life of hearing impaired people did not change directly after fitting with hearing aids. On the contrary, it declines with age, as we found after one year both the EQ-5D index and the VAS to be lower than at the start of the study. The difference of the latter parameter was even significant. It is

likely that the decrease can be explained by the progression of age during follow-up, as we found significant correlations with age for both the EQ-5D index and VAS.
We measured no significant changes on self-reported depression in elderly patients after hearing aid fitting in this study. The association between hearing impairment and depression that was assessed with the GDS has been investigated in a population of 472 elderly individuals of which 106 were identified as hearing-impaired [Mulrow et al, 1990]. Although the authors found no significant relationship between depression and hearing loss, a relatively small but significant improvement in depression scores was measured after hearing aid fitting. Apparently, the generic questionnaires used in this study were not sensitive enough to detect changes in general health-related quality of life after hearing aid fitting.

Conclusions

In this double blind randomized clinical trial we have focused on self-reported outcome of hearing aid fitting according to a comparative fitting procedure and a prescriptive method using a strictly implemented fitting formula (NAL-RP).
Our data were obtained from a large group of both experienced and first-time hearing-aid users with a varying degree of sensorineural hearing impairment. Hearing aids with linear amplification and analogue circuitry were prescribed. The conclusions listed below are thus primarily and possibly only relevant to this population, fitted with the kind of hearing aids that have been used in the study.

1. Hearing aid fitting in general had a significantly positive effect on self-reported disability and handicap associated with hearing loss. This effect was measured after fitting according to either procedure investigated in this study. The effect on disability was preserved during a follow-up period of one year. Effects on handicap were less consistently durable.
2. We found no consistent difference in self-reported hearing disability and handicap between fitting according to a comparative procedure and a strictly implemented prescriptive method using a linear fitting formula.
3. Self-reported hearing disability was more pronounced in the lower two strata of maximum unaided speech discrimination compared to the highest stratum both before and directly after fitting and also after one year follow-up.
4. Hearing aid benefit was not dependent on the degree of hearing loss that was defined after maximum unaided speech discrimination at the better ear.
5. First-time hearing aid users reported significantly less withdrawal (HHDI) than experienced users before fitting, directly after fitting and after one-year follow-

up. They also experience a larger degree of hearing aid benefit compared to experienced users.

6. A bilateral hearing aid fitting only temporarily results in more self-reported hearing aid benefit in situations with background noise (APHAB).
7. No significant effects of hearing-aid fitting were measured on self-reported overall health-related quality of life (EQ-5D) and depression (GDS).

Acknowledgments

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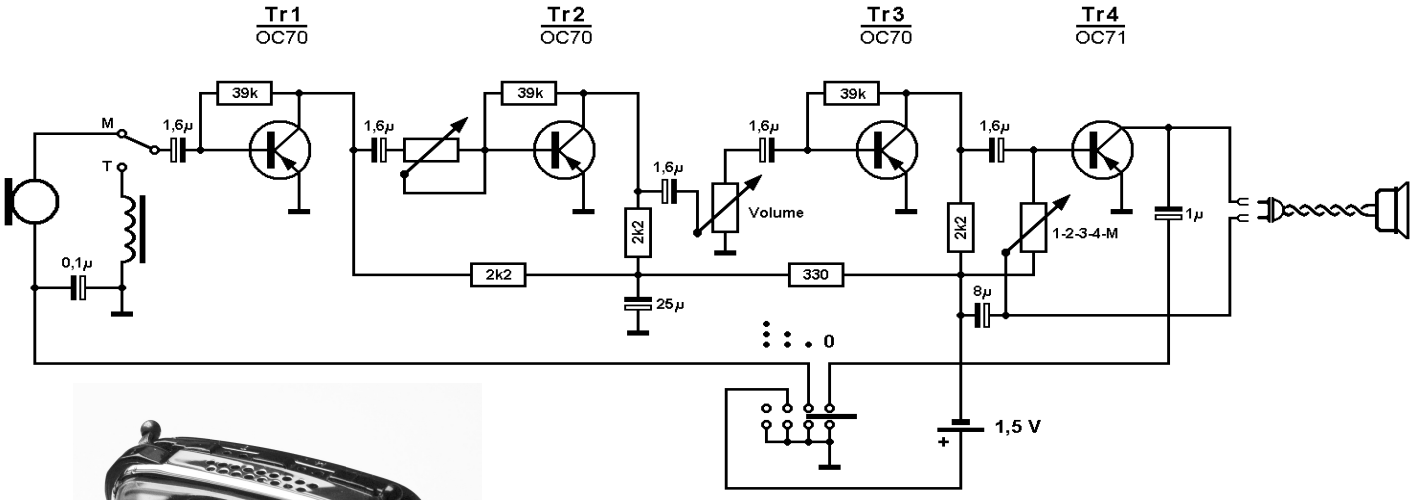

PHILIPS
MADE IN HOLLAND

Figure 5-0: KL 5500: the first all-transistor hearing aid by Philips was brought to the market in 1955. Body-worn aid with built-in microphone. Dimensions 6.8x6.4x1.9 cm. The circuit uses 4 germanium transistors (OC70 and OC71). A single 1.5 Volt battery is needed for operation. Circuit diagram reconstructed by the author (resistor values in Ohms, capacitor values in Farad). Hearing aid from the author's collection. Photograph by the author.

Chapter 5

Real-ear measurements of hearing aid gain related to speech in noise measurements in a large-scale clinical hearing-impaired population

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Submitted

Abstract

In this study we analyzed the effects of amplification through hearing aid fitting on speech perception in noise. These effects have been studied for two different fitting procedures and are interpreted in terms of the real-ear insertion gain values (REIG) measured after fitting.
Hearing aids were fitted to hearing impaired participants using a strictly prescriptive procedure (based on the NAL-RP formula) and a comparative fitting procedure in which the free-field speech intelligibility in quiet served as the primary selection criterion. In this study we included hearing aids with linear circuitry only in order to avoid unpredictable amplification effects due to poorly specified compression algorithms and/or the effects of new noise-reduction algorithms. We were primarily interested in the effects of amplification as a function of frequency.
We found close similarities between the measured insertion gain at 500, 1000 and 2000 Hz and the NAL-target insertion gain. At 4 kHz the amount of real-ear insertion gain was considerably lower than prescribed by NAL. This difference was equal in both fitting groups.
For the complete study population we found hardly any significant differences between the signal to noise ratios (SN ratio) measured under unaided and aided conditions. However, the SN ratio showed clinically relevant improvements and deteriorations in limited numbers of participants. The slope of the audiogram and to a lesser extent the slope of the real-ear insertion gain was positively correlated to the degree of improvement in the SN ratio after hearing aid fitting. Negative correlations were found for the audiometric thresholds at 500 and 1000 Hz and the average at 500, 1000 and 2000 Hz.
We concluded that participants who tend to benefit most from the fitting of a hearing aid in noisy situations have sloping audiograms and relatively good thresholds at 500 and 1000 Hz. The overall gain delivered by the hearing aid seems to be of less importance.

Introduction

Speech intelligibility can be regarded as one of the most relevant outcomes of a hearing aid fitting. This is especially true for speech intelligibility in noisy environments as these are most common in everyday life. However, many hearing-aid users experience little or no added value of their hearing aid(s) in these situations. Nowadays a number of techniques have been developed and applied in modern hearing aids, ranging from active detection and suppression of competing noise to the use of directional microphone-arrays. These techniques may influence

the ability to understand speech in noisy environments but are not included in this study, because the focus of this study is on the effects of (frequency-dependent) amplification. Fitting hearing aids bilaterally can offer additional benefit to the intelligibility of speech in noise [Boymans et al, 2008] and this will be taken into account.

Many authors have investigated the effects of providing high-frequency amplification on the recognition of speech in quiet [Ching et al, 1998; Hogan & Turner, 1998] and in noise [Turner & Henry, 2002; Plyler & Fleck, 2006; Amos & Humes, 2007; Horwitz et al, 2008] and found somewhat contradictory results. Ching et al found that for listeners with severe hearing losses speech recognition scores in quiet at low sensation levels were better than predicted by the Speech Intelligibility Index (SII), while the speech recognition scores in quiet at high sensation levels were worse than predicted by the SII. They suggested that it might be counterproductive to amplify high frequencies to high sensation levels for listeners with a severe hearing loss in this frequency range. Possible reasons they identified for this effect are distortion, reduced frequency and temporal resolution and downward spread of masking [Ching et al, 1998]. Hogan and Turner concluded that listeners with a high-frequency hearing loss above 55 dB HL did experience less benefit from additional high-frequency amplification [Hogan & Turner, 1998]. Amos and Humes found that for elderly hearing-impaired listeners the ability to understand speech in noise (and in quiet) was not influenced by the addition of high-frequency speech information. Furthermore, the degree of high frequency hearing loss in these listeners was negatively correlated to the speech-intelligibility performance [Amos & Humes, 2007].

Turner and Henry found that amplification resulted in an increase in speech recognition score when high-frequency speech information was provided to hearing-impaired listeners, even if the overall gain was small. The authors explain their results by a less audible speech signal that they used in their experiments compared to the studies mentioned above. They therefore created more headroom for improvement [Turner & Henry, 2002]. These findings are in agreement with the study from Plyler & Fleck [2006] who suggested from their data that high-frequency amplification significantly improved speech recognition in noise for hearing impaired listeners with a more or less pronounced degree of high-frequency hearing loss. Horwitz et al [2008] found in one of their experiments with hearing impaired participants and speech shaped noise that maximum speech recognition was achieved when the speech signal was offered with the widest bandwidth.

All of the above mentioned studies have been carried out with normal hearing persons and/or limited numbers of hearing-impaired listeners using filtered speech. In the present study we used a considerably larger clinical population of hearing

impaired participants that were referred to the participating audiological centers for hearing aid fitting. Fitting of hearing aids was performed either according to a strictly prescriptive fitting [NAL-RP] formula or according to a comparative approach that aimed at reaching the optimum for maximum speech intelligibility in quiet and listening comfort. These parameters were assessed for a number of possibly suitable hearing aids. We analyzed the effect of hearing aids on the perception of speech in noise measured under monaural conditions after fitting and tried to interpret these data in relation to the real-ear insertion gain. We tried to address the following questions:

1. To what extent differs the amount of amplification prescribed by both fitting procedures?
2. What is the effect of hearing aids on speech intelligibility in noise?
3. Which variables taken from the audiogram and the insertion gain can be distinguished that are clinically relevant to predict the improvement (or deterioration) in the speech intelligibility in noise?

Material and methods

POPULATION

Data from 211 ears of 118 patients were used. They were potential hearing aid candidates who were referred for hearing aid fitting and participated in a study to evaluate two different hearing aid fitting procedures [Metselaar, 2008]. Age ranged from 29 to 95 years with a median of 69 years (p10=41; p90=81.1 years). Fifty-seven patients (48.3%) were recruited in Amsterdam; the others were included in Rotterdam. Speech recognition threshold (SRT) measured from the (unaided) speech audiogram in the better ear ranged from 11.4 to 81.8 dB with a mean of 49.9 dB. Ninety-three patients were fitted bilaterally (78.8%), resulting in 211 ears to be fitted. Mean pure tone audiogram air conduction thresholds (0.5, 1, 2, 4, kHz) for all fitted ears were 56.1 dB HL and ranged from 21.3 to 110.0 dB HL. Data for each of the three strata are given in table 5-1.

The main inclusion criterion for hearing aid fitting was an average pure-tone audiometric threshold of more than 35 dB at the better ear (insurance company criterion for partly reimbursing hearing aid expenses in the Netherlands). We included purely sensorineural hearing losses and mixed losses with a dominant sensorineural component. First-time candidates as well as experienced hearing aid users were included.

Exclusion criteria were:
- maximum speech score in quiet of less than 50 percent on the better ear
- any suspicion of a retrocochlear cause of hearing loss
- Meniere's disease (active phase)
- (severe) tinnitus
- significant co-morbidity

All participants gave informed consent according to the declaration of Helsinki and the Medical Ethics Committee of the participating hospitals approved the study. Stratification was performed according to the maximum (unaided) speech intelligibility at the better ear. This was done to obtain a more balanced distribution of different degrees of hearing impairment. Three strata of speech intelligibility were distinguished: a lower stratum containing speech scores of 50 to 74%, a middle stratum with scores between 75 and 89% and a high stratum with speech scores at and beyond 90%.

Table 5-1: *General features of the study population and numbers for the three strata.*

	sex		h.a. fitting		type of h.a.		h.a. user	
stratum	**female**	**male**	**unilateral**	**bilateral**	**BTE**	**ITE**	**1st time**	**exp.d**
50-74%	2	5	1	6	6	1	3	4
75-89%	7	28	4	31	31	4	18	17
90-100%	35	41	20	56	61	13	35	41

STUDY DESIGN

Standard pure-tone audiometry was performed with the Madsen OB-822 clinical audiometer and TDH-39 earphones. Speech audiometry was performed with the same equipment for each ear separately. Lists of 11 phonetically balanced CVC-words [Smoorenburg, 1993; Bosman, 1989] were offered at 10 dB intervals. Each consonant or vowel added 3 percent to the total score.
Hearing aid fittings were carried out according to a comparative and to a prescriptive fitting procedure. Both procedures are being described in more detail in the next paragraphs. These were carried out by different persons who were not aware of each others fitting results.
Each selection procedure resulted in a prescription for a specific brand and model of a hearing aid with an exact specification of the settings (gain, tone settings, and maximum output) as well as the type of earmould. The prescription according to

one of both fitting procedures was randomly chosen and was blinded to both the participants and to the researchers. Hearing aids were actually provided by the hearing-aid acoustician who also produced the earmould.
Participants were given their hearing aid(s) on trial during a 12-week period for acclimatization and experience. In case of a comparative fitting, hearing aids were examined once halfway this period and further adjusted if necessary.
At the end of the 12-week evaluation-period, aided speech intelligibility in noise was measured for each participant and real-ear insertion gains were obtained for each ear fitted in the study. These measurements are being explained in detail in the next paragraphs. After that, the blinding was ended.

COMPARATIVE FITTING PROCEDURE

The aim of the comparative approach was to improve speech perception as much as possible, at least to the maximum speech intelligibility found in the (unaided) speech audiogram. During the fitting session a number of possibly suitable hearing aids were tried to find the best fitting. This selection was based on both the hearing thresholds of the participant and the experience of the fitter. Free-field speech intelligibility in quiet was compared with each of the selected hearing aids in situ and served as the primary selection criterion. A secondary criterion was based on sound quality judgments by the participant. The hearing aid that was deemed most appropriate was chosen. This procedure has been described in detail by Verschuure [Verschuure, 1994]. After a six-week period of initial acclimatization to the sound and the wearing of the hearing aid, adjustments of hearing aid settings were performed if necessary in order to further optimize speech intelligibility and listening comfort.

PRESCRIPTIVE FITTING PROCEDURE

Prescriptive hearing aid fittings were strictly carried out according to the NAL formula [Byrne & Cotton, 1988; Byrne & Dillon 1986] with the modification (-RP) for profound hearing losses [Byrne et al, 1990]. Corrections for an air-bone gap were performed by adding 25% of the difference between the air and bone conduction thresholds to the gain at each specified frequency [Lybarger, 1963]. NAL-RP 2 cc coupler gain was calculated from the pure tone audiogram thresholds for a maximum of 9 frequencies between 250 Hz and 6 kHz. To predict the required amount of gain for each individual the NAL-target response was corrected for the real-ear unaided response (REUR). We used the method proposed by Müller (1989) who considered the KEMAR-REUR as average. The differences between

the patients' open ear response and the KEMAR REUR were added to the NAL-RP target response.
Hearing aid selections were performed by means of a computer program that has been exclusively designed for this study. Coupler responses of all hearing aids available in our departments had been measured in advance for a number of combinations of the available tone-controls settings. Measurements were carried out in the test chamber of a PortaRem-2000 system (RD Rastronics Division, Denmark) with a 2 cc coupler in accordance with the IEC 118-7 standard [IEC 118-7, 1983] which was commonly used at the time of the study. All the responses were stored in the database of the program. For a number of acoustically different earmoulds, correction responses were stored in the database of the selection program [Dillon, 1985]. The actual selection process consisted of a comparison of the NAL-RP target response corrected for the patients' open ear response with all coupler responses of the available hearing aids in the database, calculated for different types of earmoulds. The hearing aid and earmould that delivered a response most similar to the prescribed NAL-RP target were selected. After these had been delivered to the patient, the aid was adjusted as close as possible to the NAL-RP target real-ear insertion response. This was confirmed by real-ear measurements. Patients were encouraged to wear the hearing aid(s) during the 12-week period for acclimatization and experience.

REAL-EAR MEASUREMENTS

Real-ear responses were recorded in 1/24 octave bands within a frequency range of 125 Hz to 8 kHz (144 steps) using a clinical measuring system (PortaRem-2000, RD Rastronics Division, Denmark or Unity, Siemens, Germany). Data were converted to four octave bands (500, 1k, 2k and 4 kHz) upon which the analysis was carried out. Slope of the response (in dB/octave) was defined as half of the difference of the average gain at 1k and 500 Hz and at 2k and 4k so that more positive slope-values corresponded to a steeper frequency response (more amplification at higher frequencies). Similar to this, audiogram slopes were calculated from the pure-tone thresholds at the same four frequencies so that higher slope-values corresponded to more pronounced high-frequency hearing losses.

SPEECH INTELLIGIBILITY MEASUREMENTS

Speech intelligibility in noise was measured using the Dutch sentence test developed by Plomp & Mimpen [Plomp & Mimpen, 1979]. After determining the

speech recognition threshold in quiet (SRT-Q), which is defined as the level at which 50% of the test sentences was reproduced correctly, the SN ratio was measured at a noise level of (if possible) 20 and 30 dB above the SRT-Q level using an up-down technique with 2 dB steps in order to obtain a reliable estimate for the SN ratio at threshold. All sounds were presented through a loudspeaker at a distance of 1 meter from the patient (sound-field condition) in a sound booth. When the SN ratio measurements at two noise levels (+20 and +30 dB) were available, the average value was calculated. When, due to limitations of the testing equipment, only the 20 dB level had been measured, this value was used. Measurements were performed with and without hearing aids in the ear. Improvement in the signal-to-noise ratio (SN ratio) was defined as the difference between the aided and the unaided SN ratio so that a positive difference represents an improvement.

Statistical analysis

All data were analyzed using SPSS software, release 16.0.1 (SPSS Inc.). Differences between group averages were tested with the paired t-test or independent samples t-test. When distribution functions of the data showed clear deviations from normality, non-parametric testing was performed. We used Wilcoxon's test for paired comparisons and the Mann-Whitney U-test for unpaired comparisons.
As differences between the two fitting procedures with respect to speech intelligibility in noise and real-ear insertion responses appeared to be small and clinically irrelevant [Metselaar et al, 2008], the data from all patients were used for the analysis.

Results

POPULATION

In total, 254 hearing impaired patients (163 men, 91 women) were included. Data from 211 ears of 118 patients were used. The rather small inclusion rate was mainly due to missing data that occur during SN ratio testing. These were inevitable because measurements that had to be carried out at levels of 20 dB above the SRT-Q tended to be either unpleasant to the patients or unable to perform due to limitations of the equipment.

REAL-EAR MEASUREMENTS: ACTUAL GAIN VS NAL-RP TARGET

For all ears included in the study, irrespective of fitting procedure, calculated NAL-RP target insertion gain has been compared to the actual REIG measured at the end of the fitting procedure. Results for the complete study population are depicted in figure 5-1for each of the three strata of maximum speech intelligibility score at the better ear. In all three strata, differences between measured and calculated insertion gains at 0.5 and 1 kHz were minor and nonsignificant ($p>0.1$; paired t-test). Differences at 2 kHz were significant in the middle and highest stratum. In these cases the NAL-RP target prescribed more gain than was measured at the end of fitting ($p<0.01$; paired t-test). At 4 kHz, differences were even more significant and were present in all of the three strata ($p<0.001$; paired t-test). Next, we searched for differences between the two fitting procedures. Because the differences in the three strata separately were nonsignificant $p>0.1$; t-test), the ears of all strata were combined. Results are given in figure 5-2. The distribution of the differences between the measured and NAL-target insertion gain (black and white bars) was similar for both fitting procedures. Furthermore, the figures show that the distribution of differences was statistically normal. The mean of the differences was statistically not different from zero at 500 Hz, 1 kHz and 2 kHz (-1.2; SD=7.1, -0.1; SD=7.9, -1.9; SD=6.8 respectively). However, the mean difference was significantly negative at 4 kHz (-9.1; SD=9.2), indicating that less actual gain was measured than was prescribed by the NAL-RP formula.

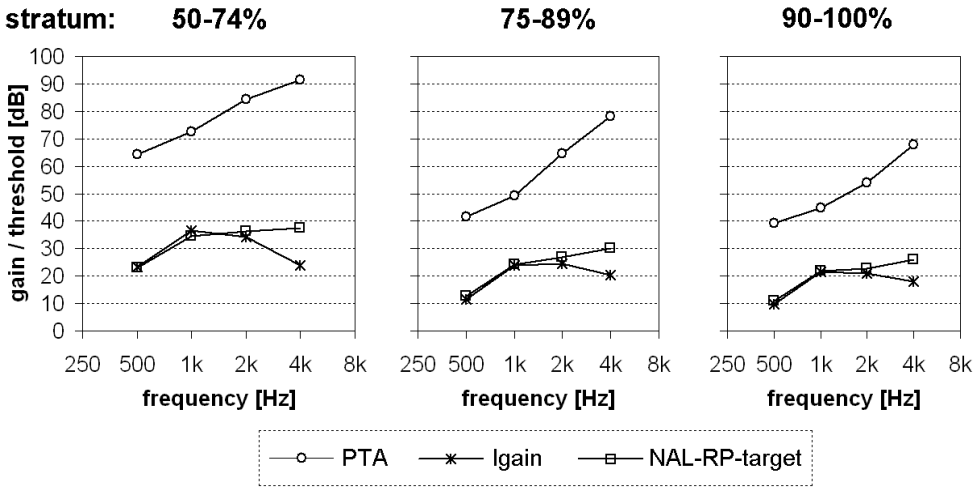

Figure 5-1: *Average actual real-ear insertion gain, calculated NAL-RP target insertion gain and average PTA air conduction thresholds for each of the three strata of maximum speech intelligibility score in the (unaided) speech audiogram. The three panels show the data for all three strata.*

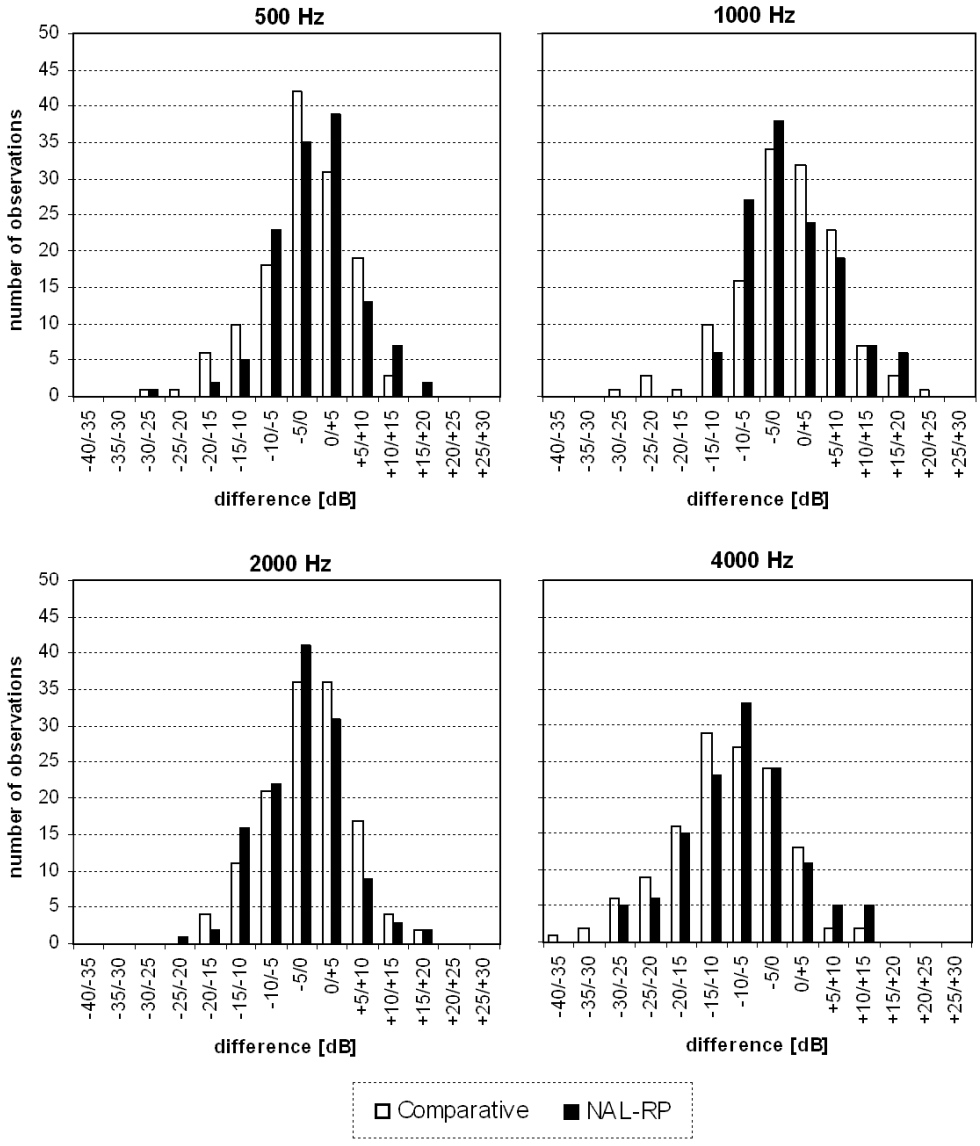

Figure 5-2: *Distribution of differences between actual real-ear insertion gain and NAL-RP target insertion gain for all ears in the population at four frequencies. White bars represent the results from fittings according to the comparative fitting procedures (n=131 ears) and black bars represent the ears fitted according to the NAL-RP formula (n=127 ears). Negative values indicate less actual gain than prescribed by NAL-RP.*

REAL-EAR MEASUREMENTS: ACTUAL GAIN VS AUDIOGRAM THRESHOLDS

The relation between the amount of insertion gain measured after fitting at each of the four frequencies between 500 and 4000 Hz has been investigated for all ears that have been fitted in the study. Distinctions were made for fitting procedure and for degree of hearing loss (stratum of maximum speech intelligibility). Results are depicted in figure 5-3. The amount of insertion gain varied roughly between one quarter and one half of the threshold, depending on the frequency. This comes close to the one-third gain and half gain fitting rules. Although differences between fitting procedures were small, significantly more gain at 500 and 4000 Hz was measured after fitting to the NAL-RP procedure ($p<0.05$; t-test). In the lowest stratum, significantly more gain was measured at 500 Hz than compared to the other strata ($p \leq 0.01$; t-test).

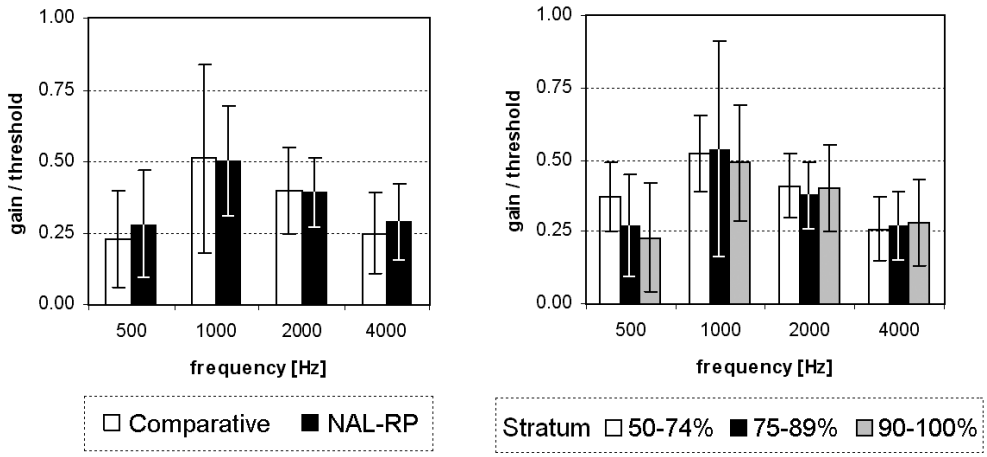

Figure 5-3: *REIG in relation to audiogram threshold at the 4 frequencies. Results are given for fitting procedure (left) and degree of hearing loss (right). Error bars show 1 SD.*

IMPROVEMENT OF SN RATIO

Improvement of the signal to noise ratio after hearing aid fitting was defined simply as the difference between the aided and unaided SN ratio ($SN_{unaided} - SN_{aided}$). Because these two measurements had been carried out in the sound field we had to make sure that:

- both had been measured under either monaural or binaural conditions.
- In case of monaural conditions, the same ear (left or right) had been responsible for the result of the unaided an aided measurement.

These conditions were realized by applying the following rules:

- Unaided measurements were regarded as monaural when the difference between the average hearing threshold levels at 1, 2 and 4 kHz was more than 10 dB. In these cases, the better ear was assumed to be responsible for the result of the unaided SN ratio.
- The aided SN ratio was regarded as monaural when only the better ear was fitted with a hearing aid.
- When the other ear was fitted instead, the unaided (better) ear could also have contributed to the result of the aided measurement. Such cases were therefore excluded from further analysis.
- When unaided and aided measurements had been carried out under monaural and binaural conditions respectively (or vice versa), the case was excluded from further analysis.

When the difference between the average threshold from the left and the right ear was not more than 10 dB, we derived the NAL-RP target gain from the average threshold of both ears on each frequency. Otherwise it was calculated from the thresholds of the better ear.

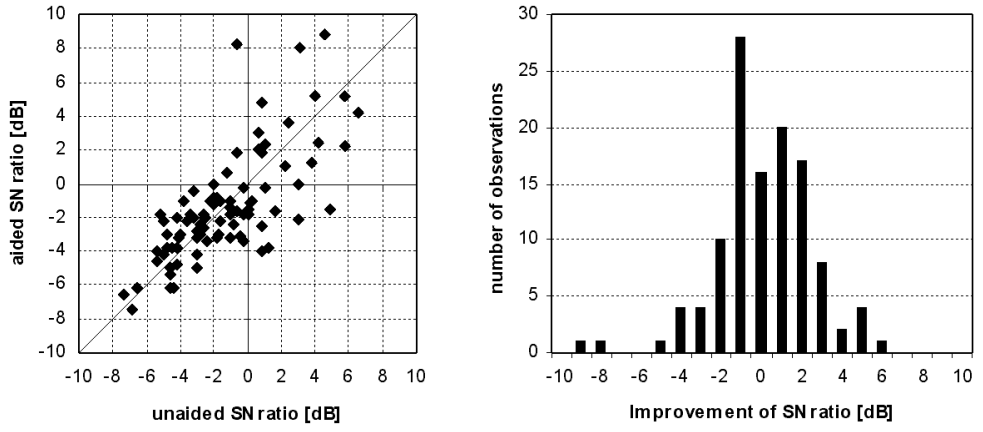

Figure 5-4: *Left panel: SN ratio with hearing aid plotted against SN ratio without hearing aid aid (n=88). Right panel: distribution of the improvement in the SN ratio after hearing aid fitting ($SN_{unaided} – SN_{aided}$). Positive values on the x-axis represent improvement, while negative values represent deterioration of the SN ratio with the hearing aid(s) compared to the situation without.*

In our population SN ratios had been measured under either monaural or binaural conditions for 15 and 73 participants respectively. Aided and unaided SN ratios had been measured under different conditions in 30 participants. Their data were therefore excluded from the analysis.
The improvement in the SN ratios of the 88 included listeners ranged from -8.8 to +6.4 dB with a mean of +0.07 (SD 2.34). As positive values stand for an improvement in the SN ratio, we concluded that over the complete study population suitable for analysis, the SN ratio did slightly improve after hearing aid fitting. Data from the aided and unaided SN ratios are given in the right panel of figure 5-4 and the improvement after fitting is depicted in the left panel of the same figure.
We were curious whether the degree of improvement in the SN ratio after hearing aid fitting was dependent on the REIG or on the audiogram. We therefore defined a number of variables from the REIG and the audiogram to describe the shape and the degree of the hearing loss and the hearing aid gain characteristic. These variables are listed in the tables 5-2, 5-3 and 5-4. As explained above we measured the improvement in the SN ratio under either monaural or binaural conditions. For participants who had been measured under binaural conditions, the parameters were derived from the average audiogram thresholds and insertion gains of both ears.
We felt that different statistical methods could give us more insight in the structure of the data. The following statistical methods were used to explore our data:

- calculation of bivariate correlations
- factor analysis (principal component analysis)
- multiple regression analysis

Each of these will be explained in separate paragraphs below.

BIVARIATE CORRELATIONS

We calculated the correlations between the improvement in the SN ratio and all of the separate variables that were explored with factor analysis and multiple regression analysis. Pearson correlation coefficients for each of them are given in table 5-2. We found significant correlations at the 1% level between the improvement in the SN ratio and a number of audiogram-related variables of which the threshold at 500 Hz and the audiometric slope showed the highest correlations. Also the slope of the insertion gain and the insertion gain at 1 kHz were found to correlate significantly with the improvement in the SN ratio after fitting, although their correlations were less significant. This is demonstrated by scatterplots for the two most significant audiogram-variables and the most significant insertion gain-variable that are depicted in figures 5-5.

Table 5-2: *Pearson correlation coefficients between improvement in SN ratio after fitting and a number of audiogram- and insertion gain-related variables. Correlation coefficients significant at the 1% level are shown in bold. Variables are sorted by Pearson's correlation coefficient (descending) and significance.*

variable	Pearson	significance
audiogram threshold at 0.5 kHz	**-0.439**	**0.000**
audiogram slope	**0.394**	**0.000**
audiogram threshold at 1 kHz	**-0.358**	**0.001**
average audiogram threshold at 0.5-1-2 kHz	**-0.327**	**0.002**
insertion gain slope	**0.313**	**0.004**
insertion gain at 1 kHz	**-0.286**	**0.008**
insertion gain at 0.5 kHz	-0.240	0.028
average insertion gain at 0.5-1-2- kHz	-0.229	0.036
average insertion gain at 1-2-4 kHz	-0.155	0.158
average audiogram threshold at 1-2-4 kHz	-0.128	0.247
insertion gain at 2 kHz	-0.075	0.496
audiogram threshold at 4 kHz	0.052	0.641
average insertion gain at 2 and 4 kHz	-0.041	0.709
average audiogram threshold at 2 and 4 kHz	0.024	0.826
audiogram threshold at 2 kHz	-0.014	0.899
insertion gain at 4 kHz	0.005	0.964

We concluded from this statistical method that the improvement in the SN ratio is mainly related to some audiogram-related variables, being especially the slope (positive correlation) and the threshold at 500 Hz (negative correlation). The amount of insertion gain delivered by the hearing aid is apparently of less importance as long as the REIG complies with some one-third to half gain rule.

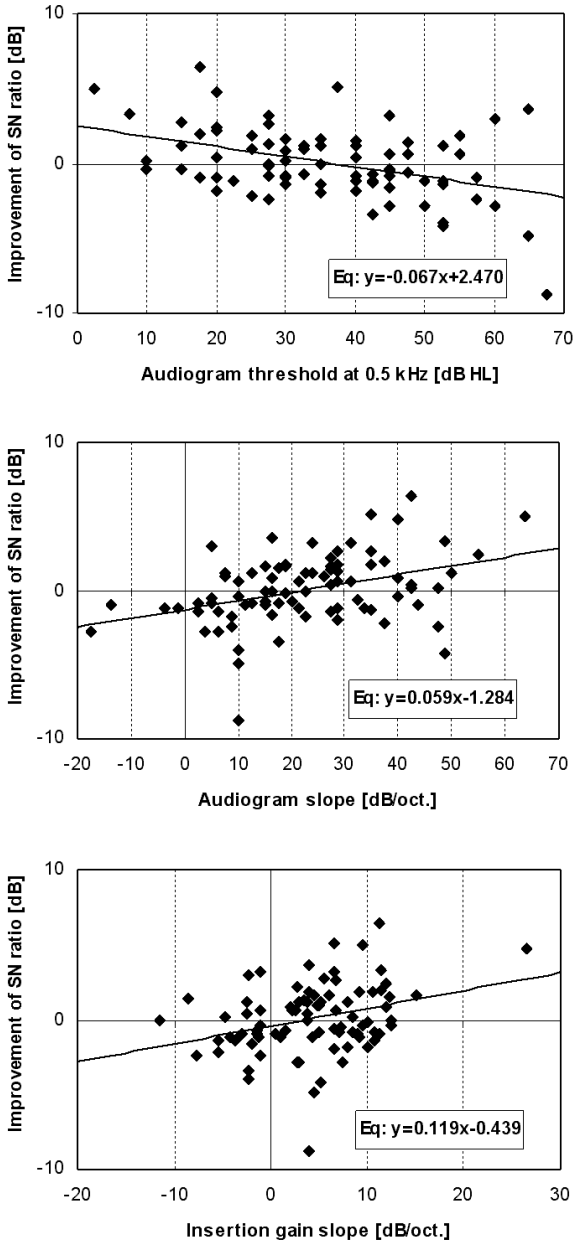

Figure 5-5: *Scatterplots showing the relation between the improvement of the SN ratio ($SN_{unaided} - SN_{aided}$) and threshold at 0.5 kHz (upper panel); audiogram slope (middle panel), and slope of the insertion gain (lower panel). In all three figures the regression line and equation are given.*

FACTOR ANALYSIS

A number of audiogram and REIG related variables that we have distinguished were likely to show a certain extent of dependency. We performed factor analysis (principal component analysis) in order to reduce the number of variables and to search for a limited number of components that were able to explain a sufficient amount of variance.

Table 5-3: *Results of factor analysis (principal component analysis) after varimax rotation for the same variables as mentioned in table 2. These 4 components together explained 89.6% of the variance. Only values of variables having significance of >0.4 are given.*

variable		component			
		1	**2**	**3**	**4**
	% of variance	56.3	16.0	10.8	6.5
	improvement of SN ratio			*-0.610*	
audiogram	threshold at 0.5 kHz			0.795	
	threshold at 1 kHz		0.425	0.746	
	threshold at 2 kHz		0.831		
	threshold at 4 kHz		0.866		
	Slope		0.507	-0.829	
	average threshold at 0.5-1-2 kHz	0.448	0.600	0.647	
	average threshold at 1-2-4 kHz		0.901		
	average threshold at 0.5-1-2-4 kHz	0.404	0.799	0.422	
insertion gain	gain at 0.5 kHz	0.736			0.430
	gain at 1 kHz	0.753			0.459
	gain at 2 kHz	0.807			
	gain at 4 kHz	0.835			
	Slope				-0.942
	average gain at 0.5-1-2 kHz	0.859			
	average gain at 1-2-4 kHz	0.935			
	average gain at 0.5-1-2-4 kHz	0.928			

Table 5-3 shows the results after varimax rotation for four components that together explain 89.6% of the variance. The first component mainly contains the insertion gain related parameters while only audiogram related parameters are found in the second component. This goes for the third component as well which is of particular interest because the improvement in the SN ratio is also found in this component. The difference with the second component is that the third component seems to be more specifically related to the slope of the audiogram. The variables that loaded most on the third factor were the slope and the thresholds at the lower frequencies. These can be expected to be dependent variables that are obviously negatively correlated.
From factor analysis it can be concluded that the improvement in the SN ratio is mostly dependent on the audiogram slope.

MULTIPLE REGRESSION ANALYSIS

Instead of searching for underlying communal parameters, like we did with factor analysis, the combined correlation between a number of variables and the improvement in the SN ratio can be investigated with multiple regression analysis. We investigated the relation of all the above-mentioned independent variables on the improvement in the SN ratio as a dependent variable. Results are given in table 5-4. The model is highly significant (p=0.004) although the explained variance is quite low (R^2=25.2%). What can be seen from the table is that the regression coefficients, both unstandardized and standardized, of most of the variables are quite low (maximum values approximately 0.1 and 0.5 respectively). The variables with the highest standardized coefficient (beta) are the slope of the audiogram and the average threshold at the four frequencies (negative coefficient). Of these two audiogram-related variables the slope yielded the highest level of significance (p=0.036).
We have also tried a stepwise procedure to enter some of the most significant variables. Only three variables were entered in the model when the significance level of the F value was chosen less than 0.2. These were the audiogram threshold at 500 Hz, the audiogram slope and the insertion gain slope. The models are shown in table 5-5.

Table 5-4: *Results of multiple regression analysis. The variables are identical to those mentioned in the two previous tables. It turned out that some variables were excluded from the analysis. These values are consequently not shown in the table. The multiple correlation R=0.502, the explained variance R^2=25.2%. The model is significant (p=0.004).*

variable		coefficients			
		B	**std. error**	**Beta**	**sig.**
	constant	1.231	1.271	0	0.336
audiogram	threshold at 0.5 kHz				
	threshold at 1 kHz	0.040	0.055	0.250	0.463
	threshold at 2 kHz	0.008	0.040	0.048	0.841
	threshold at 4 kHz				
	slope	0.072	0.034	0.481	0.036
	average threshold at 0.5-1-2 kHz				
	average threshold at 1-2-4 kHz				
	average threshold at 0.5-1-2-4 kHz	-0.104	0.069	-0.499	0.136
insertion gain	gain at 0.5 kHz	0.098	0.090	0.302	0.280
	gain at 1 kHz				
	gain at 2 kHz				
	gain at 4 kHz	-0.012	0.080	-0.038	0.877
	slope	0.096	0.071	0.254	0.180
	average gain at 0.5-1-2 kHz				
	average gain at 1-2-4 kHz				
	average gain at 0.5-1-2-4 kHz	-0.047	0.129	-0.135	0.717

Table 5-5: *Results of multiple regression analysis after a stepwise entry of variables. The significance level of the F value was chosen less than 0.2. Three models are proposed with different numbers of variables entered. Excluded variables are not shown in the models. The multiple correlation R is 0.439 (model 1), 0.469 (model 2) and 0,487 (model 3). The explained variance R^2 is 19.3% (model 1), 22.0% (model 2) and 23.7% (model 3). All three models are significant (p=0.000).*

model	variable	coefficients			
		B	**std. error**	**Beta**	**sig.**
1	constant	2.607	0.618	0	0.000
	threshold at 0.5 kHz	-0.071	0.016	-0.439	0.000
2	constant	1.199	1.044	0	0.254
	threshold at 0.5 kHz	-0.051	0.020	-0.317	0.012
	audiogram slope	0.031	0.018	0.204	0.100
3	constant	0.725	1.096	0	0.510
	threshold at 0.5 kHz	-0.043	0.020	-0.267	0.040
	audiogram slope	0.028	0.018	0.189	0.127
	insertion gain slope	0.055	0.041	0.145	0.180

IMPROVEMENT OF SN RATIO AND DIFFERENCE TO NAL-RP TARGET

It is interesting to investigate the differences between the unaided and aided SN ratio that are clinically relevant, that means outside the 95% confidence interval. Verschuure & van Benthem [1992] found a standard deviation of about 1.5 dB for the same speech material resulting in a 95% confidence interval of 3.0 dB. It can be seen from our figures that this is somewhat smaller than we have measured in our population. We counted 11 participants with an improvement of more than 3.0 dB and 9 participants with deterioration (negative improvement) of more than 3.0 dB. The remaining 98 participants fell within the assumed 95% confidence interval and thus showed no clinically relevant change of SN ratio after hearing aid fitting. The average audiogram of these three groups of participants is given in figure 5-6 (left panel) together with the average insertion gain (middle) and the difference between the insertion gain and the average NAL-RP target gain (right panel). Although the difference between the average actual gain and the average NAL-RP target gain at 1 kHz seems to be higher for the group that deteriorated after fitting

compared to the two other groups, the differences between the three groups of improvement in the SN ratio were not significant (M-W U-test; p>0.1). Pearson correlations between the improvement in the SN ratio and the deviation from the prescribed NAL-RP target were also calculated. There were no significant correlations at any of the four frequencies (p>0.2).

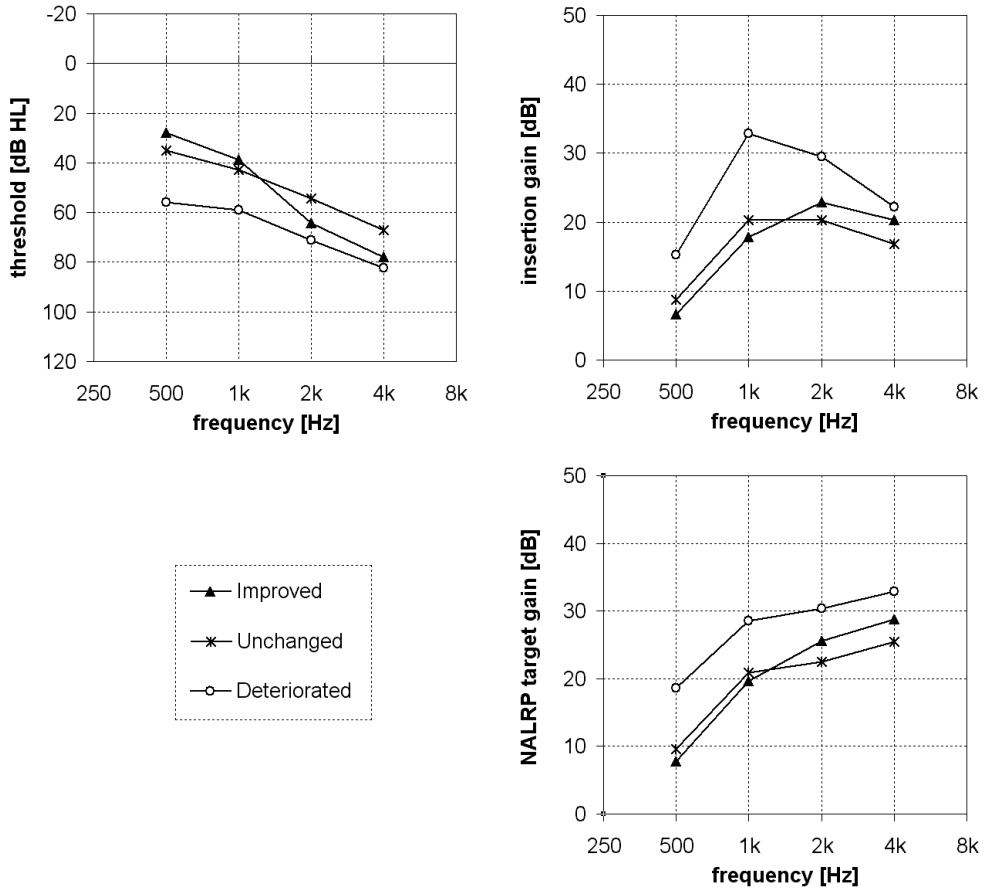

Figure 5-6: *Average audiogram air conduction thresholds (upper left panel), insertion gain (upper right panel) and NAL-RP target gain (lower panel). Three groups of change in SN ratio are depicted: a group of participants (n=9) that showed clinically significant improvement after fitting (triangles), a group (n=5) that did significantly deteriorate (open circles) and a group (n=70) that showed no significant change after hearing aid fitting (asterisks).*

Discussion

One of the most frequently reported problems with hearing aids is the limited intelligibility of speech in noisy situations. The use of speech tests in hearing aid fitting has been debated by several authors [Turner & Henry, 2002; Plyler & Fleck, 2006; Amos & Humes, 2007; Horwitz et al, 2008]. The distribution of the differences between the aided and unaided SN ratio in our population was very similar to the results described by Verschuure & van Benthem [1992], indicating that the test material developed by Plomp & Mimpen [1979] can be used as an accurate evaluation tool in a clinical population with a large variety of hearing losses.

The hearing aids that were fitted according to the prescriptive formula were selected by means of a computer program that was written exclusively for this purpose. On theoretical grounds the program selected a combination of a specific hearing aid and a specific earmould that delivered a response most similar to the calculated target. However, in most cases it turned out that a certain number of responses were found that matched closely to the target. These 'second best' responses corresponded with different hearing aids and sometimes different types of earmoulds too. This gave us the possibility to choose the best suitable hearing aid based on different criteria like hearing aid size and battery type which was especially convenient when participants were fitted bilaterally. No matter how, the selection program prescribed the exact type of hearing aid and tone settings including the specifications of the earmould.

The participants in our study who were randomized to the prescriptive fitting procedure, received hearing aids and earmoulds that were selected by means of the computer program and were adjusted to match the NAL-RP target by means of real-ear measurements. Despite this strictly implemented prescriptive procedure and repeated verification of the REIGs that we used, relatively large differences between the target gain and the actual insertion gain were encountered after fitting, especially at the higher frequencies. This can easily be ascribed to the fact that the hearing aids that we used during the time of inclusion were unable to produce the required amount of high frequency amplification. This imperfection was probably mainly due to the acoustical limitations of the hearing aid's receivers. It is questionable whether the participants would have accepted the prescribed amount of gain in the higher frequencies or that they would have requested for a less shrill sound. Although the participants that were fitted according to the comparative procedure were allowed to do so, the amount of prescribed high-frequency gain turned out to be not significantly different between the two fitting procedures. As a

consequence, we have not been able to establish a direct effect on the SN ratio of high-frequency amplification, prescribed by one of the two fitting procedures. When the prescribed amount of high frequency gain by the NAL-RP formula would be beneficial on the SN ratio after fitting, one could suppose that the slight improvement that we found in our population can be ascribed to a lack of high frequency amplification. If that were true, then a relationship between the deviation from the NAL-RP target especially at the higher frequencies and the extent of improvement in the SN ratio after fitting could be expected. However, we could not establish such a relationship.

The question then arises which factor determines the improvement in the SN ratio after fitting. The NAL-RP target is directly derived from the pure-tone audiogram thresholds. Although less strictly related, the amount of gain prescribed by the comparative fitting procedure should in some way be dependent on the audiogram as well. The REIG that we measured after hearing aid fitting according to either fitting procedure should be related to the amount of gain that was prescribed during fitting. Consequently it is possible that the extent of improvement in the SN ratio depends on the audiogram thresholds and the amount of REIG that was measured after fitting.

We therefore searched for any relationship between audiogram and REIG characteristics and the improvement in the SN ratio, being either positive or negative. When high-frequency amplification would be beneficial on the SN ratio, one or more REIG-related variables should in some way be correlated. Because of the relatively large amount of variables that we distinguished, we have used different statistical procedures to explore our data.

We started with the calculation of bivariate correlations for the set of audiogram- and REIG-related variables that we defined. Although single correlation coefficients may suggest a simplified relationship between the two variables studied, they give a clear look on the influence that each of the separate variables has on the SN ratio and the importance of each variable with respect to the others. Some audiogram-related variables showed the highest correlation coefficients that were significant. Because the audiogram slope and the audiogram thresholds at the lower two frequencies were mutually correlated, this suggested that the shape of the audiogram has the highest effect on the improvement in the SN ratio after fitting.

Because the number of variables that we defined was somewhat abundant while some were likely to be dependent, we used factor analysis to search for underlying components. It turned out that after varimax rotation all the REIG-related variables with the exception of the slope on one hand and almost all audiogram-related variables on the other hand were clustered in the first two components. Four

components were found that explained almost 90% of the variance. The improvement in the SN ratio was found in a different component that also contained the slope of the audiogram and the two low-frequency thresholds. This was again an indication that the improvement in the SN ratio could be more related to the shape of the audiogram than to the overall amount of gain (and thus to the levels delivered to the eardrum).
The third statistical method that we used was multiple regression analysis to look for a combination of independent variables that could act upon the improvement in the SN ratio as a dependent variable. The variable that was most significant of all variables that were included in the model was the slope of the audiogram. Moreover, this variable had the highest standardized coefficient (Beta) but one. This was the third indication that the audiogram slope had more influence on the improvement in the SN ratio than the variables representing overall insertion gain.
Our outcomes are contradictory to the results of some of the studies that were mentioned in the introduction. This may have to do with differences between studies with respect to differences of the population and the degree hearing loss, the types of speech test and outcome measure that were used, and whether the additional effect of high frequency speech information was achieved by filtering the speech samples or by adjusting the hearing aid gain. It should be noted that our data come from a large-scale clinical hearing-impaired population and that our speech measurements were carried out with an individualized amount of overall hearing aid gain.
The clinical implications of our study are in accordance with those from the study by Amos & Humes [2007] who advised to restrict the provision of gain when acoustical feedback can not be established due to high-frequency amplification.

Conclusions

The difference between the measured and the calculated NAL-RP insertion gain was in our study not dependent on the type of fitting procedure (NAL-RP formula or comparative).
Differences between the measured and the NAL-RP target insertion gain were minor and not significant at 500 and 1000 Hz for the complete study population. At 2 kHz the difference was significant in the middle and highest stratum in favour of the NAL-RP target. At 4 kHz, the NAL-RP formula prescribed significantly more gain than was realized for the complete study population.
For a large-scale clinical population of hearing impaired participants, the SN ratio was not changed by the fitting of hearing aids. However there were individual exceptions.

The effect of hearing aids on the SN ratio was mainly related to some audiogram-related parameters, of which the air conduction threshold at 500 Hz (negative correlation) and the slope of the audiogram (positive correlation) were most significant. It was not significantly related to the hearing thresholds at 2000 and 4000 Hz.
The effect of hearing aids on the SN ratio was less strongly correlated to the REIG-related variables. The amount of insertion gain at 2000 and 4000 Hz did not correlate significantly to the improvement in the ability to understand speech in noise with hearing aids.

Acknowledgments

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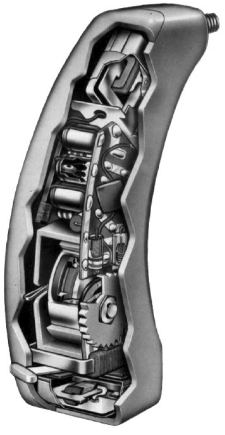

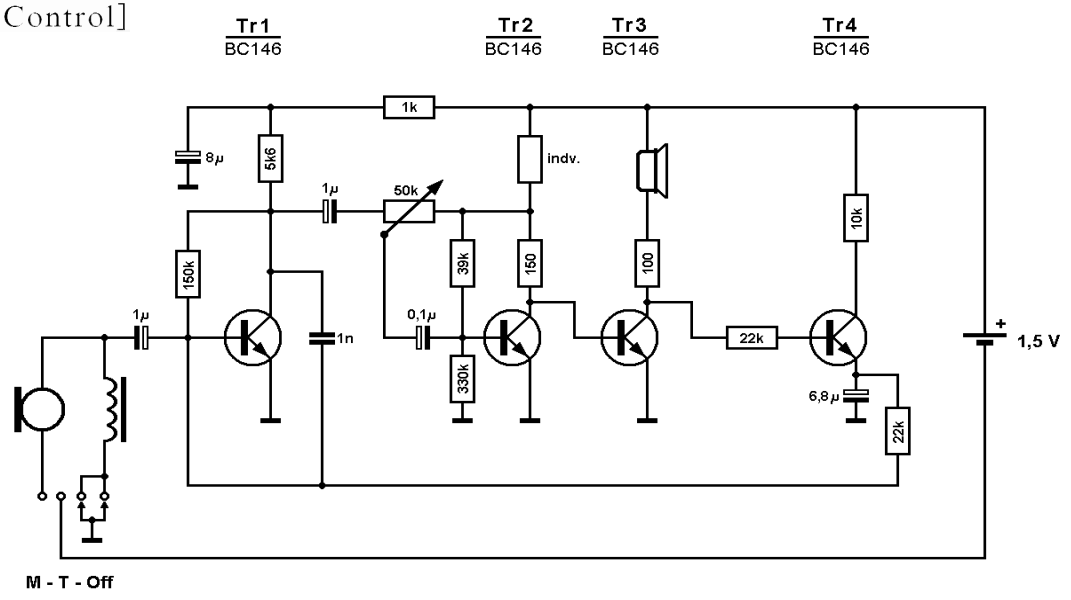

Figure 6-0: The 601 AVC “Minarette” was one of the first behind-the-ear hearing aids made by Widex. It was brought to the market in 1960. The circuit uses 4 silicium transistors, has a telecoil and an automatic volume control (AVC). A button cell is needed for operation. Circuit diagram and drawings were kindly provided by Widex (resistor values in Ohms, capacitor values in Farad.

Chapter 6

General discussion

General discussion

There is no doubt from our study and those of many others that hearing aids are generally effective in the rehabilitation of hearing loss. The amplification of sound, either brought about in an acoustic or electronic manner, is the most obvious way to deliver sound energy to the cochlea at supra-threshold levels. Much research has been done to assess the amount of amplification that would bring the optimal support to the residual hearing and at the same time be pleasant to the hearing impaired person. As a result a considerable number of hearing aid fitting procedures have been developed according to different philosophies, resulting in various procedures for the selection and fitting of hearing aids. The validity of many of these procedures has usually been investigated for a limited number of hearing impaired persons and usually with respect to only a small set of criteria. The relevant quality measures of a hearing aid fitting can include coupler measurements, aided thresholds, speech intelligibility scores in quiet and in noise, sound quality, wearing comfort, experienced benefit of hearing aids and hearing-specific and overall health-related quality of life. Another interesting aspect is the efficiency of a hearing aid fitting procedure. This deals with the amount of effort and costs required achieving a satisfying result and it is closely related to cost-effectiveness, today an important aspect in the evaluation of medical treatment modalities.

This thesis describes the results of a clinical study done to compare the quality and efficiency of two hearing aid fitting procedures based on completely different starting points. One was a linear prescriptive formula based on pure-tone audiogram thresholds, while the other was an interactive procedure in which a small number of selected hearing aids were compared by fitting them on a specific hearing-impaired person. We used the new NAL-formula [Byrne & Dillon, 1986] with the modification for profound hearing losses [Byrne et al, 1990] as a prescriptive procedure (NAL-RP). The advantage of a linear procedure was that linear hearing aids could be used for fitting. Since the amount of amplification of these aids is not dependent from the level of the input signal, the acoustic behaviour was much more predictable. This enabled us to strictly implement the NAL-RP procedure. The Dutch comparative procedure [Verschuure, 1994] was the comparative method. We will comment on some aspects concerning the comparison of hearing aid fitting procedures. We also argue the choices that we have made for the objective and subjective outcome measures. Finally, the analysis of costs is presented after which the conclusions can be drawn and suggestions for further research are given.

Objective outcome measures

SUCCESS RATE

We defined the end result of a successful hearing aid selection and fitting procedure as both patient and hearing aid fitter are satisfied with the prescribed hearing aid(s). When one of both was not content with the result, the fitting process started all over or was terminated. We compared the success rate of two fitting procedures in our study. The Dutch fitting procedure was regarded as the golden standard. This implied that a NAL-RP fitting that was unsuccessful was followed by a fitting according to the Dutch comparative procedure. However, when the NAL-RP fitting was successful from an audiological perspective, but the patient requested another hearing aid, we also regarded the initial fitting successful. The reason was that at the time of the study the first digital hearing aids entered the market and some patients specifically requested for these kinds of hearing aids. In these cases the reason for an “unsuccessful” fitting was mostly driven by advertisement campaigns and not by a technical deficiency.
We found a success rate of 85% in the comparative fitting procedure while the prescriptive procedure according to the NAL-RP formula was successful in 71% of cases. Comparable results have been claimed for other fitting procedures.
Although the difference between the success rates of both fitting procedures was significant (t-test; $p<0.01$) the relevance is at least doubtful. In our study we performed both the prescriptive procedure and the comparative fitting procedure before randomization. Therefore every patient was actually been fitted twice and had probably received more information and counselling than usual. It seems obvious that counselling will be positively correlated to the success of a hearing aid fitting. A single fitting according to a strict and highly standardized fitting formula (like NAL-RP) in a procedure that leaves little room for counselling and leeway in case of complaints will probably lead to a lower success rate.

SPEECH IN QUIET

In the literature search we found that the improvement of the intelligibility of speech in quiet and in noise was used as an outcome measure in nearly half of the publications. These were also a primary outcome measure of our study. We measured a clear and positive effect of hearing aids on the improvement of speech intelligibility in quiet after hearing aid fitting according to either procedure.
Speech scores in quiet can not exceed 100%. Therefore the room for improvement is also dependent on the initial score without hearing aids. We distinguished three strata of participants according to maximum unaided score in the speech

audiogram. It is to be expected that for both fitting procedures the largest degree of improvement of speech intelligibility in quiet was measured in the lowest stratum and that little improvement was found in the highest stratum.
One could wonder whether patients in the highest stratum would be suitable hearing aid candidates at all. However, although these patients already had unaided speech scores of almost 100% they fulfilled the criterion for (partial) reimbursement of hearing aids in the Netherlands. This is dependent on the average pure-tone audiometric thresholds at 1, 2 and 4 kHz which has to be at least 35 dB HL at the best ear.
We were particularly interested in differences of improvement between the two fitting procedures. The comparative fitting procedure aimed to optimize speech intelligibility. The prescriptive procedure (NAL-RP) was purely based on pure-tone thresholds. Despite these different starting points we were not able to prove any difference of the improvement of speech intelligibility in quiet between the two fitting procedures. This may be explained by the limited number of test items, being 33 consonants and vowels for each list of 11 CVC-words. As a consequence, performance differences between hearing aids for individuals can only be significant for differences of more than about 10%. This is relatively large in view of the total possible improvement that was limited by the maximum speech score of 100%.

SPEECH IN NOISE

The use of standardized tests for speech intelligibility helps to generate reproducible test results. However, it also implies some uncertainty about the extrapolation of hearing aid benefit to everyday life circumstances with a variable amount of background noise and reverberation. The effects of these factors has been investigated by Cox & Alexander [1991]who tested the intelligibility of speech in three listening conditions: (1) a favourable one with a low level of background noise and reverberation and with visual cues available, (2) a situation with relatively low background noise but reduced availability of speech cues due to reverberation and (3) a situation with a high level of background noise and available visual cues. They found that the improvement of the intelligibility score with hearing aids was highest in the favourable test condition and poorest in the situation with background noise.
After his study of the literature on the effects of sensorineural hearing impairment on speech intelligibility, Plomp argued for the use of tests that were carried out under highly standardized experimental conditions. He developed a reliable test for the measurement of the speech reception threshold (SRT) using short everyday

Dutch sentences in free-field conditions [Plomp & Mimpen, 1979]. The Dutch sentence test is an accurate evaluation tool that has been validated in clinical populations with a large variety of hearing losses. The standard deviation of the signal-to-noise (SN) ratio with this test ranges from about 1 dB in a normal-hearing reference group to 1.5 dB in a clinical population of hearing impaired patients [Verschuure & van Benthem, 1992].
The amplification of sound above hearing thresholds obviously leads to better understanding of speech in quiet. This threshold-effect may also produce better understanding of speech in noisy situations as long as the signal to noise ratio is sufficiently advantageous to the hearing impaired listener. However, this is unfortunately not the case in many acoustical circumstances. The problem with most of the patients with a sensorineural hearing loss is that they suffer from a deterioration of monosyllable discrimination and an increase in the necessary signal-to-noise threshold [Carhart & Tillmann, 1970]. Welzl-Müller & Sattler [1984] found that even with a hearing aid, the necessary signal-to-noise threshold of hearing impaired patients was considerably higher than that of normally hearing persons. Furthermore, for all patient measured in their study there was no significant difference between the signal-to-noise threshold with and without hearing aids. With his model of the SRT of hearing-impaired listeners, Plomp argued that on average a hearing aid does only provide intelligibility at noise levels below 50 to 60 dB SPL. His model predicted no added value of hearing aids for higher noise levels [Plomp, 1986] and thus explains why many hearing aid users experience little or no added value of their hearing aids in the understanding of speech in noisy situations. We found that in our study population the SN ratio did only slightly improve after hearing aid fitting. Comparison between the two fitting procedures showed a small but significantly positive effect only in the middle stratum after a NAL-RP fitting compared to a fitting according to the comparative procedure, after which no improvement was found. This difference could possibly be explained by differences between the real-ear insertion gains measured after fitting according to both procedures. These will be explored in the next section.

REAL-EAR MEASUREMENTS

Some correlation between the improvement of speech scores in quiet and in noise after hearing aid fitting and the amount of amplification that is delivered by the hearing aid(s) might be presumed. Hearing aid gain is usually expressed as the output of a hearing aid in an acoustical coupler with respect to a stimulus of a certain level. The problem with this so-called “coupler gain” is that it does in practice not always correspond with the amount of gain that is actually being

delivered at the eardrum of the individual patient. This is due to the acoustical characteristics of the earmould that is used and to anatomical variations in ear canal geometry and eardrum immittance. The coupling of the earmould and ear canal also plays a role [Mason & Popelka, 1986]. We therefore measured the real-ear insertion gain after every hearing aid fitting. Gains were converted to average gain at the centre frequencies of the four octave bands. Pure-tone audiometry (PTA) was carried out in all participants before fitting. From the audiogram thresholds at 500 Hz, 1, 2 and 4 kHz and the insertion gains at the same four centre frequencies we calculated some variables which we deemed relevant like the slope and the average threshold/gain at two or more centre frequencies. Because all participants were randomly assigned to one of both fitting procedures, the variables derived from the audiogram were equal in both groups. Any significant difference of speech intelligibility between both fitting procedures was therefore likely to be explained by differences of one or more insertion gain variables (e.g. slope, average gain).

However, analysis of real-ear insertion gains did not reveal significant differences in any of the above-mentioned variables between hearing aid fittings according to the NAL-RP formula and the comparative fitting procedure.

We also calculated the NAL-RP target insertion gains from the audiogram thresholds and compared these to the actual REIG measured after fitting to either procedure. We found that for both fitting procedures significantly less insertion gain at 4 kHz was measured than was prescribed by the NAL-RP formula ($p<0.001$; paired t-test). The distribution of the differences between the measured real-ear gain and NAL-target insertion gain was similar for both fitting procedures. It was striking that in spite of the completely different approach for both fitting procedures the insertion gains were comparable. Even with a strict implementation of a fitting formula (NAL-RP) we were apparently not able to achieve the prescribed amount of high frequency gain. However, we do not have an explanation for the larger degree of improvement of the SN ratio after the prescriptive fitting procedure in the middle stratum. This is possibly due to the reduction of the real-ear gain to octave bands at 4 centre frequencies (500 Hz, 1, 2 and 4 kHz), which eliminated the possibility to detect differences for smaller frequency bands that could still be clinically relevant.

The statistical analysis showed that the effect of hearing aids on the SN ratio was mainly related to some audiogram-related variables. The air conduction threshold at 500 Hz (negative correlation) and the slope of the audiogram (positive correlation) were the most significant. The analysis further showed that the effect of hearing aids on the SN ratio was less correlated to the REIG-related variables than to the audiogram related variables. The amount of insertion gain at 2 and 4 kHz did

not correlate significantly to the improvement of the ability to understand speech in noise with hearing aids. This is in accordance with the finding from a study that was done in a group of patients with high-frequency hearing loss [Lee et al, 1993]. It was found in this study that speech in noise tests were the most sensitive indicators of improved speech recognition after hearing aid fitting. Amos and Humes found that for elderly hearing-impaired listeners the ability to understand speech in noise (and in quiet) was not influenced by the addition of high-frequency speech information [Amos & Humes, 2007].
However, some other studies that have investigated the effects of high-frequency amplification on the recognition of speech in noise found different results [Turner & Henry, 2002; Plyler & Fleck, 2006; Horwitz et al, 2008]. They showed that high-frequency amplification improved speech recognition in noise for hearing impaired listeners with a varying degree of high-frequency hearing loss. The difference between our results and those mentioned here may be explained by the characteristics of the study populations. The above-mentioned studies have been carried out with limited numbers of hearing-impaired listeners and/or normal hearing persons using filtered speech. It seems plausible that in our population consisting of hearing-impaired participants with varying degrees of sensorineural hearing impairment, a considerable percentage suffered from a reduced frequency-resolving power. Because spectral filtering is essential for separating one sound from another, the discrimination of speech in noise will for these patients not improve by the amplification of the competing signals with hearing aids.

Subjective outcome measures

The comparison of the quality and efficiency of hearing aid fitting procedures in a clinical population encompasses more than the effects in the physical domain only. The extent to which hearing aids are beneficial in various acoustical environments and successful in alleviating the consequences of hearing loss should also be analyzed. This can be expressed in several domains that will be mentioned below. Many questionnaires are available to measure the benefit of hearing aids in different acoustical circumstances. We have chosen for the abbreviated profile of hearing aid benefit (APHAB) which is a widely used and validated 24-item self-assessment inventory to investigate disability associated with hearing loss with and without hearing aids in four acoustically relevant subscales. We found significant benefit of hearing aids ($p<0.005$; Wilcoxon) in all of the APHAB-subscales. However, there were no differences between the improvement for the comparative procedure and the prescriptive fitting procedure. We also found that the benefit of hearing aids was not dependent on the degree of hearing loss.

The consequences of hearing impairment are concerned to social, emotional, communicative and cognitive functioning. They can also be assessed in the domains of disability and handicap. These terms that were formerly used in the WHO-conceptual framework (1980) have been replaced by ‘activity limitation’ and ‘participation restriction’ in the International Classification of Functioning Disability and Health (ICF) in 2001. At the time of the study we did not have a questionnaire at our disposal that was designed and validated according to this new concept. We therefore had to use a questionnaire that was compatible with the former WHO-terms. There were some more demands that a suitable questionnaire had to fulfil. It should have been validated for the use of a clinical population and should preferably be available in the native language of the study population. Finally, for practical reasons the number of items should be limited.
The questionnaire that we found to completely satisfy our demands was the Hearing Handicap and Disability inventory (HHDI). This 40-item self-report questionnaire measures the consequences of hearing impairment in the domains of disability and handicap. It had been validated on a clinical population and was originally written in Dutch and in English.
We found that self-reported hearing disability according to the HHDI was dependent on the degree of hearing loss characterized by the maximum unaided speech intelligibility at the better ear. Disability was significantly more pronounced in the lower two strata than in the highest stratum. However, fitting with hearing aids did not level out this difference. This might seem to be contradictionary, but does probably correspond with the equal amount of benefit that was perceived from hearing aids irrespective of the degree of hearing loss. The relationship between self-reported hearing disability and degree of hearing impairment was demonstrated in a study that investigated hearing disability after fitting with the Hearing Handicap Inventory for the Elderly (HHIE) which is a similar questionnaire [Stark & Hickson, 2004]. The authors found a significantly greater reduction in HHIE-scores for participants with an average hearing loss of more than 35 dB then those with a hearing loss of less than 25 dB. The contradiction with our results might be due to the fact that we did not include participants with an average hearing loss of less than 35 dB in our study. It seems plausible that the effects of hearing aids on disability and handicap are level-dependent up to a certain degree of hearing loss.
For economic evaluation the effects of hearing aid fitting must be expressed in terms of a change in overall health-related quality of life (HRQoL). The concept of HRQoL covers several domains of which physical, psychological and social functioning are the most relevant. Various inventories have been developed for this purpose. We have chosen the EuroQol-5-dimensions instrument (EQ-5D) because

it is a short (5+1 items) generic self-report questionnaire to measure and value HRQoL. Moreover, the EQ-5D has been successfully used in an older population before [van Roijen et al, 1996]. However, we found no effect of hearing aid fitting on generic HRQoL as measured with the EQ-5D in our population. The usefulness of the EQ-5D to evaluate the effect of hearing aids on generic HRQoL has been debated by a number of authors. They found that although hearing aids improve hearing, no significant improvements are shown on generic measures of HRQoL [Bess, 2000]. Barton et al. recommended the use of more than one generic measure of HRQoL because different questionnaires measure different concepts while no single HRQoL questionnaire has been identified as optimal [Barton et al, 2003]. They suggested the Health Utilities Index Mark III (HUI3) to be one of these. The HUI3 has 8 dimensions of which hearing is one [Feeny et al, 1995]. This might explain why the HUI3 estimates the overall-HRQoL of a hearing-impaired person lower than the EQ-5D, which instead focuses more on performance [Joore et al, 2003].

We investigated the incidence of mental depression as an item of general HRQoL because we thought this of relevance in a clinical population of mainly elderly hearing impaired people. When hearing loss would be a causative factor for depression, it might be reversed by the rehabilitation with hearing aids. We used the short version of the General Depression Scale (GDS) that has been validated for people over 55 years of age. This matched our study population that had an average age of 71 years (SD 13.5 years). We found that the prevalence of depression according to the GDS was comparable to a series of Dutch elderly patients [Kok et al, 1995] but remained unchanged after fitting with hearing aids. We neither found differences between the two hearing aid fitting procedures during one year follow-up.

The effects of hearing impairment on quality of life has been evaluated in a population of elderly individuals [Mulrow et al, 1990] of which a considerable number had a hearing loss. The authors used a battery of disease-specific and generic measures. They found that hearing loss was associated with significant emotional, social and communication dysfunction. A significant relationship between mental depression and hearing loss could not be established. However, a relatively small but significant improvement in depression scores was measured after hearing aid fitting. The authors concluded that adverse effects were best detected with disease-specific rather than generic functional status measures. Nachtegaal et al [2009] investigated the association between the degree of hearing loss and psychosocial functioning. Self-reported psychosocial health was assessed with a set of questionnaires. Hearing loss was defined as a reduced signal-to-noise ratio and expressed as psychosocial functioning in the domains of distress,

somatization, depression and loneliness. The authors found that hearing loss was associated with higher distress, somatization, depression and loneliness.
We agree with the authors from the above-mentioned studies that, although depression seems to be associated with hearing loss, a generic inventory like the GDS was insufficiently sensitive to observe changes in the incidence of mental depression after hearing aid fitting. This also goes for the use of the other generic inventories that we have used to measure effects of hearing aids on overall-HRQoL.

Costs

The system of health care finance in the Netherlands has no direct relation to real costs. It consists of a complex system of instructions on tariffs and declarations, but the rates do not represent the relation to scarcity of manpower, resources and capital. In fact, this relation is reflected by cost prices. Therefore, real cost prices have to be calculated of health care facilities that are relevant for this study. This required an accurate stock-taking of investments in five categories: manpower, equipment, means and materials, overhead and accommodation. A distinction has to be made between direct and indirect costs and subsequently between medical and non-medical costs. Direct costs can be medical, for example a visit to the audiologist or otolaryngologist, and non-medical. These latter costs are made by the patient and his/her companion of which the main categories are travelling and time expenses. Indirect costs are related to loss of productivity due to hearing impairment.
In this study different procedures for hearing aid fitting have been compared. Because these procedures do not represent completely different treatment modalities, it is not likely that the indirect costs would differ between both fitting procedures. Therefore they were left out of consideration.
After having charted all direct medical and non-medical costs for the comparative and prescriptive hearing aid fitting procedures, we arrived at the following conclusions:

1. The direct medical costs of a NAL-RP fitting were slightly but not significantly lower than that of the Dutch comparative approach. It took indeed less time to complete a NAL-RP fitting. This advantage was partly nullified due to a higher average number of visits necessary for the verification of the fitting according to the formula. Moreover, when the NAL-RP fitting was not successful, a number of additional visits were necessary to complete the fitting procedure according to the comparative approach. Therefore, the average costs of the hearing aids that were fitted with both procedures were almost equal.

2. The costs of the prescribed hearing aids and the costs of the visits to the general practitioner, to the otolaryngologist and to the hearing aid dispenser were comparable for the both fitting procedures.

We concluded that the NAL-RP based fitting procedure was not significantly cheaper than the Dutch comparative approach, neither was it more expensive (Polder et al, 2000). This indicates that the degree of standardization can be increased to the same amount of costs.

The reason that the NAL-RP procedure was not cheaper had to do with the way in which this fitting procedure was implemented in our study. We adjusted the hearing aid(s) according to the NAL-RP formula 2 weeks after the first visit in which the prescription was generated. This second visit can in practice be skipped when the adjustment is done during the delivery of the aid and earmould by the hearing aid dispenser. Further savings can be carried through. Due to a high degree of standardization, the actual fitting according to a formula can also be performed by the hearing aid dispenser. According to the results of our study this could be done in more than 70% of the cases. Referral to an audiological centre would be indicated in the other 30% of the cases in which no satisfactorily result is achieved. We have searched for characteristics of patients that would predict the success of a hearing aid fitting according to one of both procedures. Unfortunately, we were not able to assign patients to a hearing aid dispenser or to an audiological centre beforehand.

Conclusions and recommendations

We investigated the quality and efficiency of two different procedures for hearing aid fitting: a comparative approach that was commonly used in the Netherlands and one according to a linear fitting formula (NAL-RP). The study was done in a large-scale clinical population of hearing-impaired patients in a double-blind randomized design. Quality was defined in terms of improvement of speech intelligibility in quiet and in noise, self-reported benefit of hearing aids in different acoustic situations and improvement of hearing-specific health-related quality of life (APHAB) and generic quality of life measures (EQ-5D and GDS). From this study we concluded the following:

- The two hearing aid fitting approaches deliver the same quality.
- All hearing aid users and first-time users in particular experience a relevant degree of benefit of hearing aids and an improvement of hearing-specific HRQoL.
- General HRQoL and mental depression did not alter after hearing aid fitting. The EQ-5D and the GDS are insensitive to measure the effect of hearing aids.

- In-the-ear hearing aids and behind-the-ear hearing aids deliver an equal amount of improvement of speech intelligibility and sound quality.
- The total costs of a hearing aid fitting according to a comparative procedure and a prescriptive formula are in the same range.
- Hearing aid fitting according to a prescriptive formula offers the advantage of standardization. However, attention must be paid to those fittings that are not successful.
- Rearrangements of procedures for fitting and dispense of hearing aids can lead to shifts and probably to further savings of costs.

As expected, our study did not clear up all questions and therefore leaves space for the following recommendations for future research:

- It would be of great value to be able to define cases that are unsuitable for a prescriptive fitting approach. Further research is required to identify characteristics to make this distinction.
- We have chosen a linear fitting formula to fit hearing aids with linear amplification. The results of our study can not be extrapolated to nonlinear hearing aids with digital circuitry that have been developed after we closed the inclusion of our study. Therefore the use of nonlinear fitting algorithms and the surplus value of modern digital hearing aids with applications like noise reduction, feedback cancellation and loudness compression would be an area of future study.
- It is advisable to use different measures to investigate the effect of hearing aids on generic HRQoL. The HUI3 should at least be included.

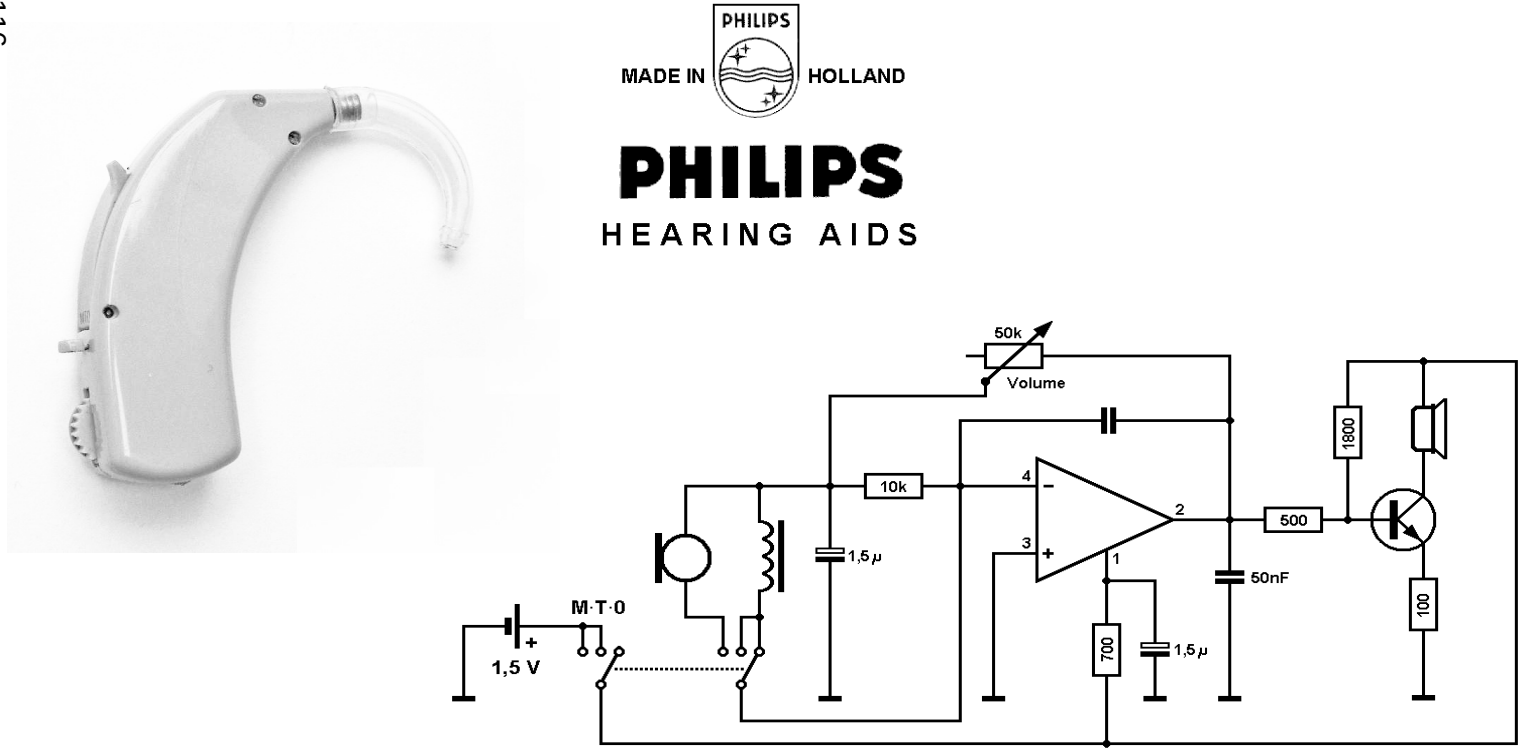

Figure 7-0: Philips HP8220. This is a high-power BTE hearing dating from 1968 with a telecoil. The relatively small housing (dimensions 42x14x10.5 mm) has been realized by using a miniature differential amplifier and one silicium transistor. The microphone is located at the bottom of the aid to prevent acoustic feedback. Circuit diagram reconstructed by the author (resistor values in Ohms, capacitor values in Farad). Hearing aid from the author's collection. Photograph by the author.

Chapter 7

Summary / Samenvatting

Summary

Since the invention of the electronic hearing aid a wide variety of procedures has been developed to fit a hearing aid to the hearing loss of the user. This thesis describes the results of a study that has been done to compare the quality and the efficiency of two different fitting procedures. One of the procedures was widely used in the Netherlands and followed an interactive and comparative approach. The other was the well-known NAL-RP formula to calculate the desired amount of hearing aid gain from the pure-tone audiogram thresholds. Advantage of a comparative procedure can be the direct testing of the objective (e.g. speech intelligibility) with the hearing aid in situ. Furthermore, demonstrating the hearing aid sound is part of the process of counselling. A drawback is the relatively large amount of effort and time that is necessary for fitting while the quality of the fitting depends on the level of competence of the hearing aid fitter. These latter aspects can be advantages of a fitting formula, for this offers an objective and controllable result that depends to a much smaller extent on the quality of the fitter. Moreover, it can at least partly be automated and (therefore) requires relatively little time. Drawbacks of a prescriptive rule are that not every patient will fit in a formula and that the correlation between the calculated target and the actual performance with a hearing aid will be different for many patients.
Our study was designed as a double-blind randomized trial and was performed in a large-scale clinical population of hearing impaired patients who were potential candidates for the wearing of hearing aids. All hearing aids used in the study had analogue electrical circuits and were adjusted to linear amplification. No digital circuits and/or WDRC compression algorithms were used as clear fitting procedures for these hearing aids and amplification-mode were emerging at the time of the study and would make it impossible to apply the strict design of the project.
Double-blind randomized comparisons of hearing aid fitting procedures in large-scale clinical populations have until now hardly been reported in the literature. This might have to do with a number of practical difficulties that we also have encountered when designing and performing our study. **Chapter 2** gives a review of a number of studies that compared the outcome of two or more hearing aid fitting procedures. We found 15 studies that met our criteria for inclusion. Of these studies we have looked at some characteristics that we found important for a good comparison. These were study design, whether the data were collected blinded or not, and the outcome measures that were chosen. It appeared that all but one study have been done according to a crossover setup. One study was done according to a parallel design. In most of the studies that were reviewed the

number of participants was relatively small. The size of the population necessary for detecting clinical relevant differences was argued in only one publication. Stratification that can be necessary to obtain sufficient numbers of certain hearing-impaired patients has not been carried out. Many different outcome measures have been used. These were physical (e.g. target gains or real-ear insertion gains), psychophysical (speech intelligibility in quiet and in noise) and questionnaires to evaluate the benefit of hearing aids and to report changes in hearing-specific and generic health-related quality of life.

Chapter 3 reports about the primary outcome measures of our comparative study on hearing aid fitting according to the Dutch comparative procedure and according to the NAL-RP formula. These were improvement of speech intelligibility in quiet and in noise and real-ear insertion responses. Speech intelligibility in quiet was measured in a free-field condition with the recorded NVA lists that each contained 11 CVC-words. Speech intelligibility in noise was measured with the Dutch sentence test. Real-ear responses were obtained at the end of every fitting that was completed in the study. Some subgroups of the study population were distinguished with respect to degree of hearing loss, previous experience with hearing aids, unilateral and bilateral fittings and the type of hearing aid (behind-the-ear or in-the-ear) prescribed. We found equal improvement of speech intelligibility in quiet for both fitting procedures, while the NAL-RP formula achieved somewhat better SN ratios. Real-ear insertion responses were comparable after fitting according to both procedures.

The secondary outcome of our study is given in **chapter 4**. This consisted of self-reported hearing disability and handicap and overall health-related quality of life (HRQoL). The benefit of hearing aids in all kinds of acoustical circumstances was assessed with the abbreviated profile of hearing aid benefit (APHAB). The effect on hearing-specific HRQoL was assessed with the hearing handicap and disability inventory (HHDI). General HRQoL was measured with the Euroqol-5-dimensions questionnaire (EQ-5D) and depression as a part of overall HRQoL was investigated with the short version of the geriatric depression scale (GDS). We found that hearing aid fitting according to both fitting procedures had a significantly positive effect on disability and handicap associated with hearing loss (HHDI). The effect lasted for several months. Only the effect on disability persisted after 1-year follow-up. Self-reported benefit from hearing aids (APHAB) was comparable for both procedures. Unaided hearing disability was associated with the degree of hearing loss, but the benefit of hearing aids was independent from the degree of hearing impairment. First-time hearing aid users reported greater benefit from their hearing aids. The surplus value from a bilateral fitting was not significant. Overall

HRQoL (EQ-5D) and the incidence of depression (GDS) did not alter after hearing aid fitting.
The effects of amplification through hearing aid fitting on speech perception in noise are further analyzed in **chapter 5**. We found close similarities between the measured real-ear insertion gain at 500, 1000 and 2000 Hz and the NAL-target insertion gain. At 4 kHz the amount of insertion gain was considerably lower than prescribed by NAL. This difference was equal in both fitting groups. For the complete study population we found a slight improvement of the signal to noise ratio (SN ratio) measured under aided conditions. However, the SN ratio showed clinically relevant improvements and deteriorations in a limited number of participants. The slope of the audiogram and to a lesser extent the slope of the real-ear insertion gain was positively correlated to the degree of improvement of the SN ratio after hearing aid fitting. Negative correlations were found for the audiometric thresholds at 500 and 1000 Hz and the average at 500, 1000 and 2000 Hz. We concluded that participants who tend to benefit most from the fitting of a hearing aid in noisy situations have sloping audiograms and relatively good thresholds at 500 and 1000 Hz. The overall gain delivered by the hearing aid seems to be of less importance.
The investigation of costs that was part of the study revealed that the fitting procedure according to the NAL-RP formula was not cheaper than the Dutch comparative approach. Given the equal results of both fitting procedures on the primary and secondary outcome measures and the advantage of the NAL-RP formula with respect to the degree of standardization, this implies that hearing aid fitting according to such a fitting formula offers a higher degree of standardization to the same amount of costs. The implementation of such procedure in practice can possibly be done with further savings. The fitting itself can be performed by the hearing aid dispenser. According to the results of our study this could be done with satisfactorily results in more than 70% of the cases. In the other 30% further fine-tuning is necessary. Unfortunately, we were not able to identify patients who are dissatisfied with the NAL-RP procedure beforehand. The fine-tuning procedure requires a high degree of training and should be reserved for expertise centers like audiological centers.
It seems likely that the conclusions drawn from this study can at least partly be applied to modern fitting formulas and modern (digital) hearing aids with compression algorithms. However, future research to the extrapolation of our results to the current hearing aid technology would be recommended.

Samenvatting

Sinds de uitvinding van het elektronische hoortoestel is een groot aantal methoden ontwikkeld om hoortoestellen aan te meten aan het gehoorverlies van de gebruiker. Dit proefschrift beschrijft de resultaten van een onderzoek dat werd verricht om twee soorten aanmeetmethoden van hoortoestellen met elkaar te vergelijken. De ene methode was een interactieve vergelijkende procedure die lange tijd in Nederland in gebruik is geweest. De andere was een rekenkundige methode die gebruik maakt van de bekende NAL-RP formule om de benodigde versterking van het hoortoestel te berekenen uit de drempels van het toonaudiogram. Als voordeel van de vergelijkende methode kan worden gezien dat het doel (bijvoorbeeld het optimaliseren van spraakverstaan) direct met het hoortoestel in het oor gemeten kan worden. Bovendien kan het laten horen van een hoortoestel nuttig zijn om de patiënt te adviseren en te begeleiden in zijn keuze. Het nadeel van een dergelijke methode is dat het vergelijken van diverse hoortoestellen nogal tijdrovend kan zijn terwijl de kwaliteit van de aanmeting wordt bepaald door de kundigheid en ervaring van degene die het toestel aanmeet. Dit zijn juist de aspecten die in het voordeel kunnen werken van een rekenkundige aanmeetmethode. Een dergelijke methode levert een meer constante kwaliteit die minder afhangt van de persoon die het toestel aanmeet. Een ander voordeel van de rekenkundige methode kan zijn dat deze tot op zekere hoogte geautomatiseerd kan verlopen en (mede daardoor) weinig tijd in beslag neemt. Het bezwaar van een rekenkundige methode is dat niet elke slechthorende precies in een standaard berekening zal passen waardoor de voorgeschreven versterking bij verschillende personen zal kunnen leiden tot een ander resultaat van het voorgeschreven hoortoestel.
Ons onderzoek is ontworpen als een dubbelblind gerandomiseerde trial en werd uitgevoerd op een relatief grootschalige klinische populatie van 254 slechthorenden die zich bij een audiologisch centrum hadden aangemeld voor een aanmeting met (een) hoortoestel(len). De hoortoestellen die in het kader van het onderzoek werden voorgeschreven waren analoog en werden zoveel mogelijk ingesteld volgens een lineaire versterkingskarakteristiek. Er werden geen digitale toestellen gebruikt en er werd geen compressie voorgeschreven omdat een heldere aanpasmethode voor deze toestellen ten tijde van de onderzoeksperiode niet voorhanden was. Anders zou het voorspelbare aanmeetresultaat van de gebruikte rekenregel verloren kunnen gaan.
Dubbelblind uitgevoerde onderzoeken naar aanmeetmethoden van hoortoestellen op grote populaties patiënten zijn in de literatuur nauwelijks te vinden. Dit heeft waarschijnlijk te maken met de diverse praktische problemen, waar wij bij de opzet

en de uitvoering van ons onderzoek ook tegenaan gelopen zijn. **Hoofdstuk 2** geeft een overzicht van een aantal onderzoeken waarin 2 of meer aanmeetmethoden van hoortoestellen met elkaar zijn vergeleken. Wij vonden 15 studies die aan onze criteria voldeden. Hiervan werd een aantal voor ons belangrijke kenmerken nagegaan, zoals studieopzet, het al dan niet geblindeerd verkrijgen van de onderzoeksgegevens en de verschillende uitkomstmaten die zijn gebruikt. Op één na bleken alle onderzoeken te zijn opgezet volgens een kruislingse methode. Eén onderzoek was verricht volgens een parallelle opzet. De meeste onderzoeken waren verricht met relatief kleine aantallen personen. De grootte van de onderzoekspopulatie die nodig was om klinisch relevante conclusies te kunnen trekken werd slechts in één onderzoek beargumenteerd. Stratificatie, bedoeld om voldoende personen met een bepaalde eigenschap in het onderzoek te kunnen betrekken, werd in geen van de bekeken onderzoeken uitgevoerd. Diverse uitkomstmaten werden gebruikt. Deze konden worden onderverdeeld in zuiver fysisch (bijvoorbeeld doelversterking of insertion gain), psychofysisch (zoals spraakverstaansmetingen in stilte en ruis) en vragenlijsten om het effect van hoortoestellen te kunnen evalueren en veranderingen in gehoorspecifieke en algemene kwaliteit van leven te meten.
In **hoofdstuk 3** wordt verslag gedaan van de primaire uitkomstmaten die in ons vergelijkende onderzoek naar aanmeten van hoortoestellen volgens de Nederlandse vergelijkende methode en de NAL-formule werden gebruikt. Dit waren de verbetering van spraakverstaan in stilte en in ruis en de insertion gain responsies die met de toestellen werden gemeten. Spraakverstaan in stilte werd gemeten met de NVA-woordlijsten in het vrije veld. Spraakverstaan in ruis werd gemeten met de Plomptest. Aan het eind van elke aanmeting werd ter controle van elk toestel de insertion gain gemeten. Binnen de onderzoekspopulatie werden diverse subgroepen apart bestudeerd, zoals ernst van het gehoorverlies, ervaren en onervaren toesteldragers, enkelzijdige of dubbelzijdige aanmetingen en het soort hoortoestel (achter het oor of in het oor) dat werd voorgeschreven. Wij vonden vergelijkbare verbeteringen van spraakverstaan in stilte voor beide aanmeetmethoden. Met de NAL-RP formule werd gemiddeld een iets betere spraak-in-ruis verhouding bereikt. De insertion gains waren na beide aanmeetmethoden vergelijkbaar.
Hoofdstuk 4 doet verslag van de secundaire uitkomstmaten van ons onderzoek. Deze bestonden uit vragenlijsten die door de patiënten zelf werden ingevuld en waarmee gehoorgerelateerde invaliditeit en handicap en algemene kwaliteit van leven werden gemeten. Het nut van hoortoestellen in diverse akoestische omstandigheden werden gemeten met een daartoe ontworpen vragenlijst (APHAB). Het effect op gehoorgerelateerde kwaliteit van leven werd gemeten met

de Groninger vragenlijst voor hoorrevalidatie (GVH). Algemene kwaliteit van leven werd gemeten met de EuroQol en het vóórkomen van depressie als onderdeel hiervan werd gemeten met de verkorte versie van de geriatrische depressieschaal (GDS). Wij vonden dat hoortoestellen aangemeten volgens de beide onderzochte methoden een significant positief effect hadden op gehoorgerelateerde invaliditeit en handicap (GVH). Dit effect hield enkele maanden aan. Alleen het effect op gehoorgerelateerde invaliditeit werd na 1 jaar nog gemeten. Het nut van hoortoestellen (APHAB) was in beide onderzoeksgroepen vergelijkbaar. Gehoorgerelateerde invaliditeit was voor personen zonder hoortoestel gerelateerd aan de ernst van het gehoorverlies, terwijl het nut van hoortoestellen hiervan niet afhankelijk bleek. Onervaren hoortoesteldragers rapporteerden meer nut van hun toestellen. De meerwaarde van een tweezijdige aanmeting was niet significant. De algemene kwaliteit van leven (EuroQol) en het vóórkomen van depressie (GDS) veranderde na het aanmeten van hoortoestellen niet.
De effecten van hoortoestellen op het spraakverstaan in ruis werd verder onderzocht in **hoofdstuk 5**. Wij vonden duidelijke overeenkomsten tussen de gemeten insertion gain bij 500, 1000 en 2000 Hz en de doel-insertion gain die door de NAL-RP formule was voorgeschreven. Bij 4 kHz werd echter aanzienlijk minder versterking gemeten dan was voorgeschreven. Dit verschil werd na aanmeting volgens beide methoden gevonden. In de totale onderzoekspopulatie vonden wij een geringe verbetering van de spraak-in-ruis verhouding met hoortoestel. Echter, bij diverse personen werden evidente verbeteringen en verslechteringen gemeten. De helling van het audiogram en in mindere mate de helling van de insertion gain bleek een positieve correlatie te hebben met de mate van verbetering van de spraak-in-ruis verhouding na hoortoestelaanmeting. Een negatieve correlatie werd gevonden voor de hoordrempels bij 500 en 1000 Hz en het gemiddelde bij 500, 1000 en 2000 Hz. Wij concludeerden dat bij personen met steil aflopende audiogrammen en relatief goede hoordrempels bij 500 en 1000 Hz de spraak-in-ruisverhouding na hoortoestelaanmeting het meest verbeterde. Daarbij leek de totale versterking van het hoortoestel minder belangrijk te zijn.
Uit de kostenstudie die bij het onderzoek werd verricht bleek dat de rekenkundige methode niet goedkoper was dan de Nederlandse vergelijkende methode. Gegeven de gelijkwaardige resultaten van beide aanmeetmethoden met betrekking tot de geformuleerde primaire en secundaire uitkomstmaten en het voordeel van de rekenkundige methode met betrekking tot mate van standaardisatie betekent dit dat de rekenkundige methode in feite een hogere standaardisatiegraad biedt tegen dezelfde kosten. De rekenkundige methode zou in de praktijk nog wat kostenbesparender kunnen worden geïmplementeerd, bijvoorbeeld door de aanmeting door de audicien te laten verrichten. Dit zou volgens ons onderzoek in

ongeveer 70% van de gevallen zonder problemen kunnen. In de overige 30% is verdere afstemming noodzakelijk om tot een bevredigend resultaat te komen. Helaas geeft ons onderzoek geen uitsluitsel over wie tot deze categorie zal behoren. De procedure na een mislukte aanmeting volgens een rekenkundige methode dient in een expertisecentrum plaats te vinden, zoals een audiologisch centrum. Het lijkt erop dat de resultaten van ons onderzoek ook zullen gelden voor moderne aanpasregels en moderne (digitale) hoortoestellen met niet-lineaire compressie-algoritmen. Echter, verder onderzoek naar de extrapolatie van onze resultaten naar de huidige stand van de techniek van hoortoestellen zou wenselijk zijn.

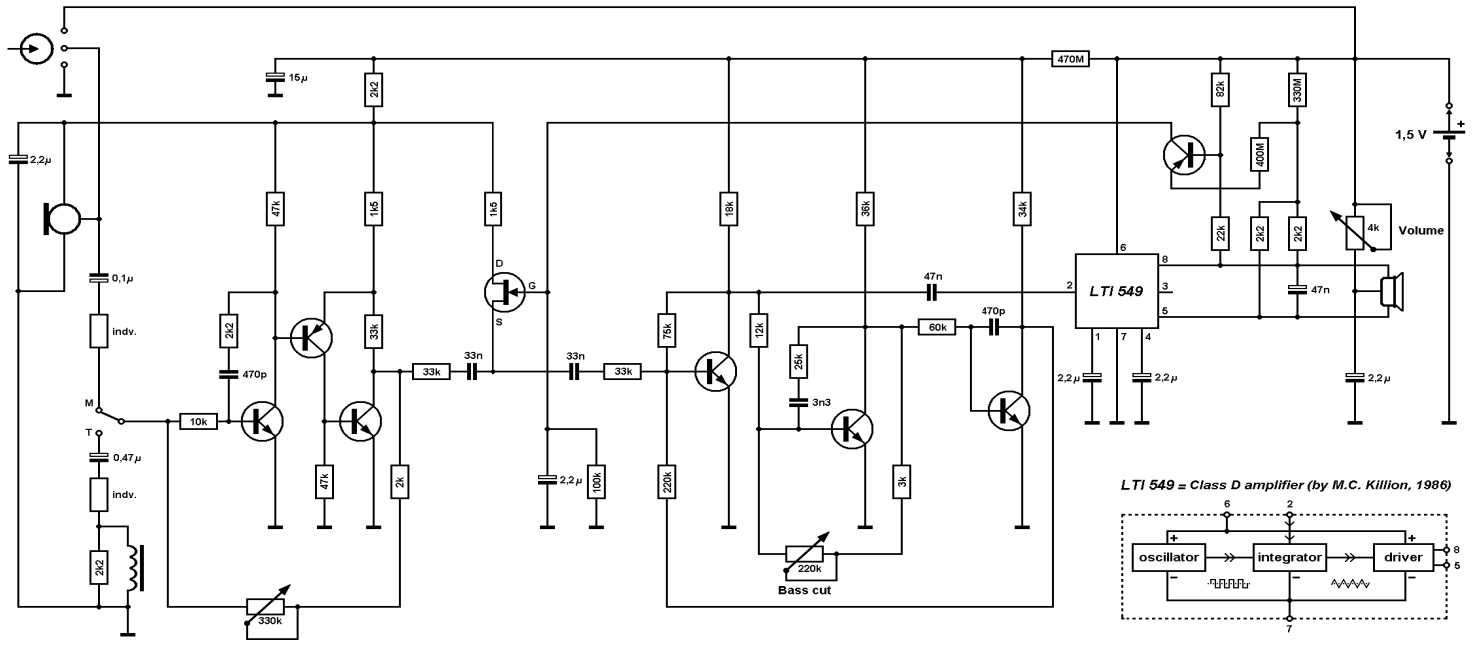

Figure 8-0: Widex ES-8. This is a hearing aid from the nineties with a class D amplifier, that was patented by M.C. Killion in 1986. This type of amplifier combines both the advantages of low distortion of sound and low power consumption. Electric diagram was kindly provided by Widex.

Chapter 8

Hearing aid fitting according to the NAL-RP procedure

The NAL-RP formula

Hearing aid fitting with the NAL-formula was performed according to the procedure that was developed by the Australian National Acoustic Laboratories (“NAL”). We used the updated (NAL-Revised, addition “R”) procedure [Byrne & Dillon, 1986]. To achieve the best reproducible fitting result in our study, we performed fittings according to the prescriptive formula according to a strict procedure. The following steps were taken:
The target gain was calculated at nine frequencies between 125 Hz and 6 kHz using the NAL- formula. The variables to be entered in the formula were the air conduction thresholds from the pure-tone audiogram. To correct for an air-bone gap, 25% of the difference between the air and bone conduction thresholds was added to the target gain at each specified frequency [Lybarger, 1963].
The “X” factor in the equation equates the “3-Frequency Average Hearing Threshold Level” (3FA-HTL) at the frequencies of 500 Hz, 1 kHz and 2 kHz. It corresponds with the degree of the hearing loss. When the air-conduction threshold at 2 kHz was 95 dB or more, a series of correction factors was added to the target gain values. As a result, the slope of the target curve is diminished.
The basic formula is as follows:

$$G_f = X + 0{,}31 * A_f + 0{,}25 * ABG_f$$

with

$$X = 0{,}05 * (A_{500} + A_{1000} + A_{2000}) \qquad (3FA\text{-}HTL \leq 60\ dB)$$

$$X = 0{,}05 * (A_{500} + A_{1000} + A_{2000}) + (0{,}2 * ((A_{500} + A_{1000} + A_{2000}) - 180)/3) \qquad (3FA\text{-}HTL > 60\ dB)$$

$$ABG_f = A_f - B_f$$

where

G_f = the target gain at a certain frequency (f)
A_f = the air conduction threshold (from PTA) at a certain frequency (f)
ABG = the air-bone gap at a specified frequency (f)
B_f = the bone conduction threshold (from PTA) at a specified frequency (f)

and

3FA-HTL = the average threshold at 500 Hz, 1 kHz and 2 kHz

A hearing loss with an air-conduction threshold at 2 kHz of 95 dB or more is regarded as a profound hearing loss (NAL-R addition “P”). In this case a set of frequency-dependent correction factors “C” is added to the target [Byrne et al,

1990, see table 8-1] to prescribe relatively more low-frequency gain and less high-frequency gain. As a result, the slope of the target curve is made shallower.

Table 8-1: *When the HTL at 2000Hz is 95 dB or greater, add the appropriate correction figures "C" [dB] from the following table [Hodgson & Dillon].*

A_{2000} [Hz]	250	500	750	1000	1500	2000	3000	4000	6000
95 dB	+4	+3	+1	0	-1	-2	-2	-2	-2
100 dB	+6	+4	+2	0	-2	-3	-3	-3	-3
105 dB	+8	+5	+2	0	-3	-5	-5	-5	-5
110 dB	+11	+7	+3	0	-3	-6	-6	-6	-6
115 dB	+13	+8	+4	0	-4	-8	-8	-8	-8
120 dB	+15	+9	+4	0	-5	-9	-9	-9	-9

With this basic formula the required real-ear gain and the 2cc coupler gain (according to IEC 126) can be calculated by adding the appropriate gain at each frequency. However, because the coupler gain is determined by the acoustical characteristics of the type of hearing aid (BTE, ITE or body worn), different gain values "T" must be added to the target gain depending on the type of hearing aid that is prescribed. These are given in table 8-2.

Table 8-2: *The gain values "T" [dB] that must be added to the NAL-RP formula depending on the type of hearing aid prescribed to calculate 2cc coupler gain.*

frequency [Hz]	250	500	750	1000	1500	2000	3000	4000	6000
BTE	-14	-6	-3	+1	-2	0	+7	+3	-3
ITE	-16	-6	-2	+1	-1	-1	0	-2	-11
body worn	-15	-13	-7	-2	+7	+10	+11	-2	--

The complete formula is then as follows:

$$G_f = X + 0{,}31 * A_f + 0{,}25 * ABG_f + C_f + T_f$$

With this formula we were able to calculate the 2cc coupler target gain at nine frequencies for each type of hearing aid. The formula prescribes the target gain

that is expected to correspond to average used gain. It is recommended that this gain is provided for a volume control setting about 15 dB below maximum. In practice, this will correspond with a level of 2/3 to 3/4 of maximum.
For a hearing loss with near to normal thresholds at 250 and 500 Hz, the formula will prescribe a negative gain. In this case, the NAL-gain is set to zero.

Hearing aid selection

With the above-mentioned procedure we were able to calculate the required 2cc-target response from the pure-tone audiogram for the intended type of hearing aid. However, the final result of the fitting will be modified due to influences on the frequency response by the normal variations in ear canal geometry and eardrum immittance of the hearing aid candidate. For a more precise fitting result, these influences have to be included in the target response. We therefore measured the real-ear unaided gain (REUG) of every ear to be fitted. The difference between the individual REUG and the standard open ear response of a manikin (KEMAR, table 8-3) that has been incorporated in the NAL-formula, has to be added to the NAL-target gain. In formula:

$$G_f = X + 0{,}31 * A_f + 0{,}25 * ABG_f + C_f + T_f + (REUG_f - KEMAR_f)$$

Table 8-3: *Open ear gain of the KEMAR manikin ("Knowles Electronic Manikin for Acoustic Research") that has to be distracted from the patients' REUG to individualize the amount of gain prescribed by the NAL-RP formula [Shaw, 1974].*

frequency [Hz]	250	500	750	1000	1500	2000	3000	4000	6000
gain [dB]	0	2	3	3	5	12	16	13	6

One has to realize that the NAL-target response that is calculated for BTE and body worn hearing aids with the above-mentioned correction factor T has been defined for a 2 mm straight and unvented tubing (type 6B0). When a hearing aid is fitted with a different earmould with respect to tubing and venting, additional corrections have to be made. These figures are given in the tables 8-4 and 8-5 and must be added to the target gain. Correction factors for tubing and venting can simply be added together.

Table 8-4: *Correction figures [dB] for venting compared to an unvented earmould [Sachs & Burkhard, 1972; Dillon, 1991].*

frequency [Hz]	250	500	750	1000	1500	2000	3000	4000	6000
Libby, 3 mm.	-1	-2	-2	-2	+1	0	+6	+8	+2
Libby, 4 mm.	-1	-2	-3	-3	0	-2	+6	+10	+6

Table 8-5: *Correction figures [dB] for two types of ear horns compared to a 2 mm constant diameter tubing, type 6B0 [Dillon, 1985].*

frequency [Hz]	250	500	750	1000	1500	2000	3000	4000	6000
1 mm venting	-1	0	0	0	0	0	0	+1	+1
2 mm venting	-7	-1	0	0	0	+1	+1	+1	+2
open	-26	-20	-14	-12	-8	0	+2	0	0

We used the following principles for the application of venting:

3FA-HTL < 20 dB: open earmould
3FA-HTL between 20 and 35 dB: 2 mm venting
3FA-HTL between 35 and 50 dB: 1 mm venting
3FA-HTL > 50 dB: unvented earmould

The hearing aids were selected with a computer program that was exclusively written for our study. It had a database at its disposal in which for every hearing aid that was available in our assortment a number of 2cc coupler responses were stored. These responses had been measured for a combination of different tone settings. The 2cc coupler was standardized in the 2nd revision of the IEC publication 126 (1973). All measurements were carried out on a PortaRem-2000 clinical measurement system (RD Rastronics Division, Denmark). The position of the hearing aid in the test chamber is depicted in figure 8-1. The BTE hearing aids were attached to an HA-2 coupler. The ITE hearing aids were attached to an HA-1 coupler. This is shown in figure 8-2.

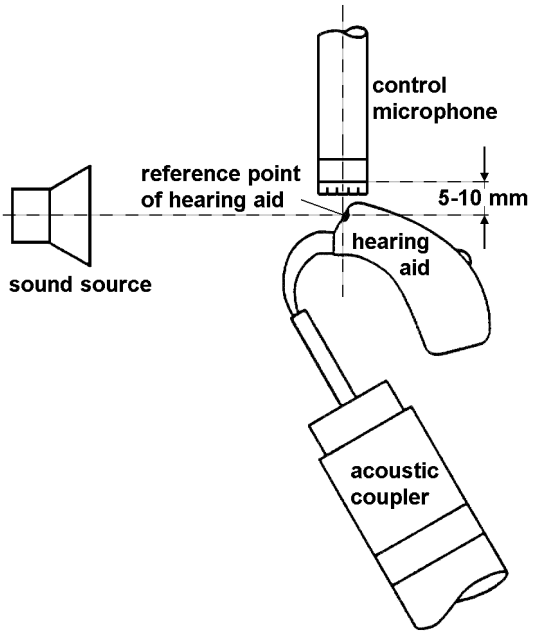

Figure 8-1: *Procedure for measurements on BTE hearing aids. The aid is attached to an HA-2 2cc coupler. The measurement is carried out in an anechoic test chamber (drawing by Rastronics).*

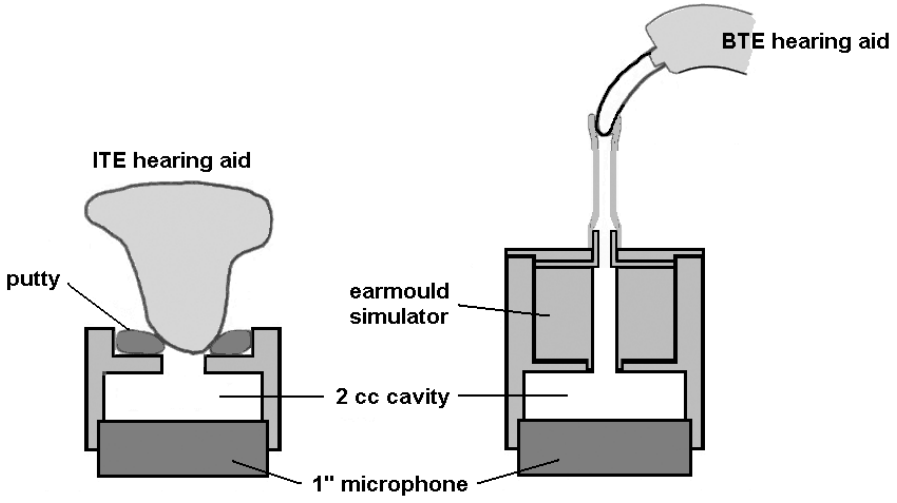

Figure 8-2: *Two types of hearing aids attached to a 2cc-coupler. Left: ITE hearing aid attached to an HA-1 coupler. Right: BTE hearing aid attached to an HA-2 coupler (drawing by the author).*

The procedure that we used to obtain the coupler responses of all hearing aids was largely in accordance with the IEC-standard 118-7, 1st edition (1983) which was the common standard at the time of the study. However, some deviations from this standard were made.

1. It appeared that when the hearing aid characteristics that were measured according to the standard (that is with the gain control set to reference test gain); the volume-wheel in most hearing aids was set at almost maximum level. Therefore, we have chosen to set the gain control to “user level”. This level was defined as the position of the volume-wheel at which hearing aid gain at 1638 Hz was 15 dB below full-on gain (input level of 60 dB SPL). This corresponded to a setting of the volume-wheel of about ¾ of maximum.
2. Although the standard prescribes the use of sweep tones as input signal, we have chosen for speech-weighted (SW) noise. The reason was that the spectrum of SW-noise corresponds better to that of everyday environmental sounds. This could be of importance for the following reasons:
    - Nonlinear hearing aids with input-dependent compression circuits behave more in accordance with normal hearing aid use.
    - Intermodulation distortion will be absent when pure tones (sweep tones) are used, but can occur during normal use of hearing aids.

We tried to acquire linear input/output conditions by switching off compression circuits and peak clipping as much as possible. With the tone controls set to combinations of minimum and maximum several responses were measured for each hearing aid.

The above-described procedure for the measurement of hearing aid coupler responses was not applicable for some ITE-hearing aids that were delivered as prefabricated modules with given (fixed) specifications. Of these hearing aids, we only had one module for measurement purposes while the responses of all the available modules were given in the data sheet. In these cases, the coupler response of the available module was measured. The printed response of the corresponding module from the data sheet was entered into the computer using a pen tablet. By comparing these two responses, we compensated for procedural differences between our measurement and the printed response. Next, the printed responses of the other modules were entered into the computer in the same way. According to this method, we were able to calculate the coupler responses of all modules of a certain ITE-hearing aid and to store them in our database.

During the hearing aid selection process the NAL-RP-calculated target response of the specified type of hearing aid and earmould was compared to all the coupler responses in the database. This was done by a computer that was provided with our specially developed software application.

The two responses were compared with respect to the similarity of shape and the distance. This was done at seven frequencies ranging from 500 to 4000 Hz. The two frequencies outside these limits (250 and 6000 Hz) were thought to be of minor significance for the intelligibility of the speech signal. The similarity of shape was defined as the standard deviation of the seven differences [dB]. The value of this so called “shape parameter” was not influenced by the distance between both responses. The distance was characterized by the so called “distance parameter” that was defined as the average difference [dB] between the two responses over the seven frequencies, taking into account that this difference could be either positive or negative. The distance parameter is therefore insensitive to deviations of shape. Within a certain range the value of the distance parameter can be changed by turning the volume wheel of a hearing aid.
The outcome of a computer-aided hearing aid selection procedure consisted of a list of 50 most similar hearing aid responses to the target. Each response on the list belonged to a combination of a particular hearing aid adjusted to a specified setting and type of earmould. The responses were sorted with respect to shape parameter in such an order that those with the lowest values (highest similarity with the target) were presented at the top provided that the distance parameter was within a certain range. Consequently, the hearing aids that were responsible for these responses were found most suitable for fitting.
In practice it frequently turned out that more than one response was almost similar to the target. When this was the case, the choice for a particular hearing aid was based on other grounds. The most important further hearing aid characteristics that were used were price and size. For bilateral hearing aid fittings, we tried to prescribe hearing aids that were similar in as much as possible respects (brand, model, size, battery etc.).

Hearing aid fitting

The computerized hearing aid selection procedure that we used for the NAL-RP prescriptions in our study was based on the assumption that the hearing aid of which the coupler response was most similar to the NAL-RP target was able to deliver best the desired NAL-insertion gain. To calculate the NAL-insertion gain the same basic NAL-RP formula can be used as mentioned above but with a different set of gain values “T” to compensate for the mean difference between coupler gain and real-ear gain at each frequency. These are given in table 8-6.

Table 8-6: *Gain values "T" [dB] that must be added to the NAL-RP formula to calculate the target insertion gain.*

frequency [Hz]	**250**	**500**	**750**	**1000**	**1500**	**2000**	**3000**	**4000**	**6000**
gain	-17	-8	-3	+1	+1	-1	-2	-2	-2

After the selected hearing aid was delivered to the patient by the hearing aid dispenser, it was adjusted as close as possible to the calculated NAL-RP insertion response. The real-ear insertion gain was measured with the prescribed hearing aid and earmould in the ear and compared with the NAL-RP target insertion gain. Measurements were done in a sound proof booth with the PortaRem-2000 clinical measurement system. The gain control of the hearing aid was set to "user gain" or to ¾ of maximum. Speech-weighted noise at a level of 60 dB SPL was used as the stimulus. The calculated and measured insertion gains were depicted on the screen of the measurement system simultaneously to assess the similarity. Deviations from the target were as much as possible corrected by adjustment of the available tone settings on the hearing aid.

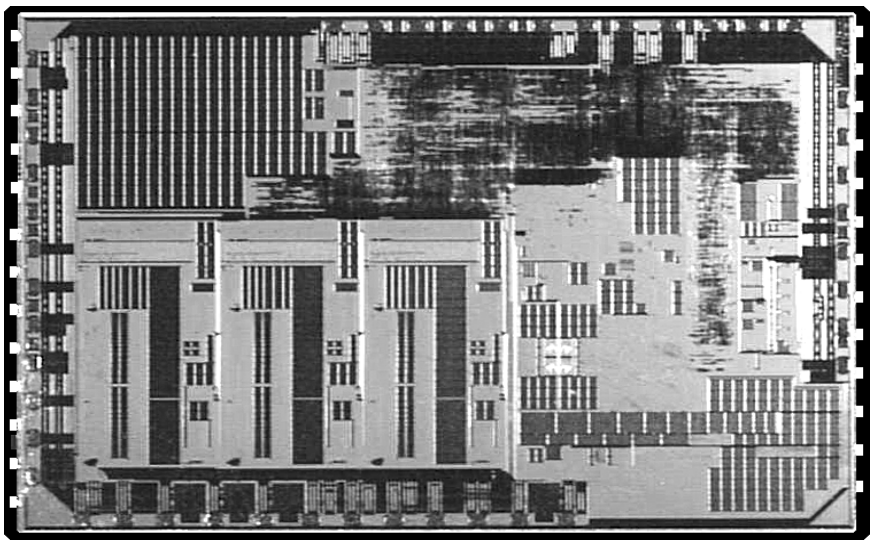

Figure 9-0: The Oticon Dual is a modern small (26x11x7 mm) digital hearing aid. The receiver is located in the ear canal. The digital integrated circuit (right figure) is called RISE. It enables sound reproduction up to 10 kHz and has the ability to let the hearing aids share information about the acoustic environment. This should lead to better loudness restoration. Pictures were kindly provided by Oticon.

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Abbreviations

3-FA	three-frequency average
APHAB	abbreviated profile of hearing aid benefit
ANOVA	analysis of variance
ANSI	American national standards institute
BTE	behind-the-ear hearing aid
CVC	consonant-vowel-consonant
dB	decibel
DSL	desired sensation level (a hearing aid fitting procedure)
EQ-5D	euroqol-5 dimensions questionnaire
FIG6	figure 6 (refers to a hearing aid fitting procedure)
GDS	geriatric depression scale
HA	hearing aid
HHDI	hearing handicap and disability inventory
HL	hearing level
HUI3	health utilities index Mark 3
Hz	hertz (cycles per second)
IEC	international electrotechnical commission
ITE	in-the-ear hearing aid
KEMAR	Knowles electronic manikin for acoustic research
LGOB	loudness growth in octave bands (a hearing aid fitting procedure)
M-W U-test	Mann-Whitney U-test
NAL	national acoustic laboratories
NAL-RP	national acoustic laboratories' revised fitting formula for profound hearing losses
NVA	Nederlandse vereniging voor audiologie
POGO	prescription of gain/output (a hearing aid fitting procedure)
RECD	real ear to coupler difference
REAG	real-ear aided gain
REIG	real-ear insertion gain
REUG	real-ear unaided gain
SD	standard deviation
SN ratio	signal-to-noise ratio
SPL	sound pressure level
SRT	speech reception threshold
VAS	visual analogue scale
WDRC	wide dynamic range compression
WHO	world health organization

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dat is niet bitter en niet zoet,
maar wel een beetje jammer.

[Herman Pieter de Boer – Het lot van de Rotterdammer]

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