BAHA

New indications and long-term patient satisfaction

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BAHA

New indications and long-term patient satisfaction

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op het gebied van de Medische Wetenschappen

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General introduction

Chapter 1

INTRODUCTION

Nowadays the Bone-Anchored Hearing Aid (BAHA) is a well-established form of hearing rehabilitation for conductive hearing loss. In 1987 the BAHA system, which was developed in Gothenburg became commercially available.[1-5] In June 1988 the first BAHA patients were implanted in Nijmegen. Almost two decades of experience and a total of more than 750 patients have been fitted with this semi-implantable hearing aid and resulted in two PhD theses at the Radboud University Nijmegen Medical Centre. The first thesis of this formerly new application was titled: 'The Bone Anchored Hearing Aid, clinical and audiological aspects', by Mylanus.[6] The second Nijmegen thesis by Van der Pouw[7] covered further evidence for an improved rehabilitation in a selected group of hearing impaired patients and was called: 'Bone Anchored Hearing, short and long term results'. Dutt (Queen Elizabeth Medical Centre, Birmingham) defended his BAHA PhD thesis in Nijmegen, which was focused on audiological and quality of life aspects.[8] The present Nijmegen PhD thesis describes the evaluation of new indications for BAHA application, patient outcome measures and long-term results. First, it is of value to discuss some basic concepts of bone conduction and the conventional indication for BAHA application before describing the recent history of new BAHA indications.

Bone conduction physiology

The phenomenon of employing bone conduction to aid patients with conductive hearing impairment has been known since the 17th century. Over the 19th century several ingenious bone conduction hearing devices have been constructed.[9] Understanding the physiology of hearing by bone conduction is challenging and several mechanisms have been proposed by various investigators.[10-13] Von Békésy was the first to show that although the pathways of sound waves to the cochlea by air conduction and by bone conduction differed in certain important aspects, the mode of excitation of the cochlear end organs was identical.

The theories of Tonndorf (1966) have been fundamental for the past decades of research in this field. He stated that the perception of sound by the ear itself through bone conduction stimuli is caused mainly by three phenomena:[12]

(1) Sound energy radiated from vibrating bone into the external ear, subsequently proceeding through the middle ear cleft.
(2) Inertial response of the middle ear ossicles and inner ear fluids, causing movement of the inner ear fluids in the scalae and deflecting of the basilar membrane.
(3) Compression of the inner ear, also causing deflection of the basilar membrane as a result of asymmetry of the fluid components.
In more recent years the physical behaviour of bone conducted sound has been further investigated by Stenfelt, based on investigations of a dry skull and also on patients equipped with osseo-integrated titanium fixtures.[14-16] The skull as a transmission medium can be seen as linear at the frequencies and vibration levels used for normal hearing. Vibrations in the skull seem to be transmitted mainly through the bones of the cranial vault rather than through the base of the skull. See figure 1.

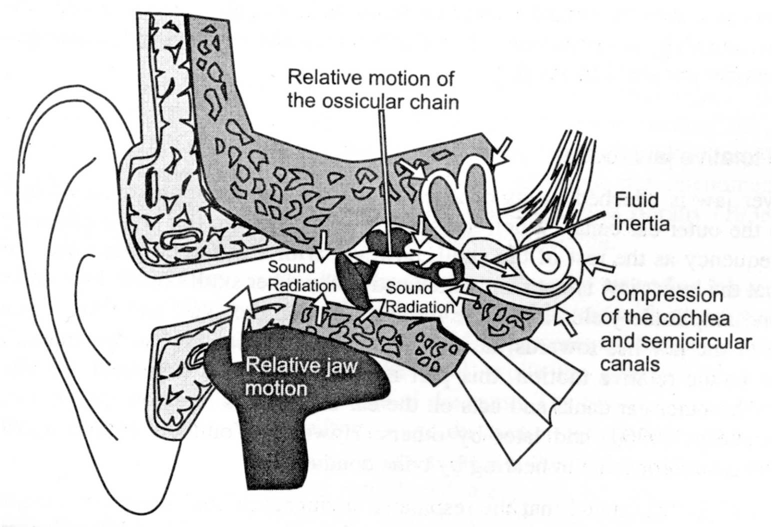

Figure 1. Diagram of sound conduction to the cochlea and anatomy of the ear

Osseo-integration
The original concept of osseo-integration involves a situation in which the surface of implanted material is in direct contact with the living bone tissue without an intermediate connective tissue layer.[17,18] The principle of osseo-integration applied for the concept of direct bone conduction with hearing aids, was introduced by Tjellström et al.[10] The titanium oxide surface is highly biocompatible and osteocytes integrate with this surface to form a stable interface. This results in long-term stability and the capacity to withstand load and stress from various directions.[19,20] An increase in direct bone to metal contact and a larger bone volume between

the screw threads in the inner area were found to be related to longer duration of the implantation.[21,22] Parallel to this finding is the observation of an increase of removal torque of the percutaneous implant with time.[23]

The Bone-Anchored Hearing Aid (BAHA)

The BAHA is a semi-implantable percutaneous bone conduction hearing device secured to the skull by a osseo-integrated titanium fixture as mentioned above. This direct coupling of mechanical vibrations to the skull provides high-quality transmission of sound, while avoiding the drawbacks of the transcutaneous bone conduction devices, such as the static pressure essential for their correct operation by counteracting reactive forces. The pressure of the transducer mounted on a spring or in the sidepiece of spectacles against the temporal bone often results in headaches or skin reactions, while insufficient pressure reduces the gain of the device.

The BAHA sound processor was designed by Håkansson and Carlsson in Gothenburg, Sweden.[1,2,10,24] The BAHA is typically beneficial in patients with bilateral conductive or mixed hearing loss when air-conduction hearing aids cannot be provided successfully (like in hearing impaired persons with a chronic otitis media, an otitis externa or in persons with a congenital aural atresia) and when surgery is not considered to be a feasible option. The higher costs and surgery needed for the application of the BAHA on a percutaneous titanium fixture in the temporal bone, should be outweighed by improved communication capabilities and fewer outpatient clinic visits.

In this respect it seems important to not only evaluate audiological outcomes, but also subjective measurements of outcome. Also, short-term results should be accompanied by long-term follow-up evaluations.

Surgical procedure

The percutaneous titanium implant is attached behind the external ear canal and the exact position should be planned using a template. The percutaneous titanium implant is placed in a way that spectacles of all sizes can be worn easily. In the area around the percutaneous titanium implant subcutaneous tissue is reduced including the hair follicles. Several surgical procedures have been developed in order to achieve this outcome.[25,26] Shortly after the first encouraging results from Gothenburg were reported,[27] an alternative one-stage surgical technique was developed

and refined in Nijmegen.[28,29] In adults this is nowadays thus performed in a single session of surgery and in the vast majority under local anaesthesia with some light sedation. After healing and osseo-integration time of approximately 6 to 8 weeks, the BAHA sound processor can be fitted.
The former Bayonet coupling has been changed to a more convenient Snap coupling in 1998. This type of coupling is in use in Nijmegen since the year 2000. The recently introduced self-tapping fixture is surgeon-friendly and once again an improvement in BAHA surgery.

Historical overview of BAHA types
The first experimental type was the BAHA HC 100, which was updated to a commercially available HC 200 in 1985. This type was updated again in 1992. Since then it was called the HC 300, or the BAHA Classic. With the BAHA Classic, it is possible to virtually “close” the air-bone gap, but any possible sensorineural hearing loss component can only be marginally compensated for as the device provides only 5-10 dB gain in the mid frequencies. This makes the BAHA Classic applicable in patients with conductive or mixed hearing loss with a sensorineural hearing loss component of up to 30-35 dB. Later on in 1998 the BAHA Compact (formerly called the BAHA HC 360) was developed, which is smaller than the BAHA Classic. Due to its size, this type is considered more convenient from an aesthetic point of view. Next to this, a recent study shows that the BAHA Compact is less sensitive to interference with mobile phones.[30] On the other hand, from an audiological point of view, it should be noted that although the gain is comparable to the BAHA Classic, the maximum output is not. Therefore it should only be used in patients with a sensorineural hearing loss component of 30 dB or less.[31] The most powerful device is the BAHA Cordelle, which is connected to a body-worn receiver and became commercially available in 1998.[32] It is the more powerful successor of the BAHA HC 220, which was connected to a conventional body-worn hearing aid. The BAHA Cordelle is best suited for patients with a sensorineural hearing loss component exceeding 35 dB up to approximately 60 dB. In those exceptional patients with severe sensorineural hearing loss, in which the speech intelligibility with the BAHA Cordelle is insufficient, it has been suggested to provide these patients with a cochlear implant.[33] The three types of BAHA devices implemented at present are shown in figure 2.

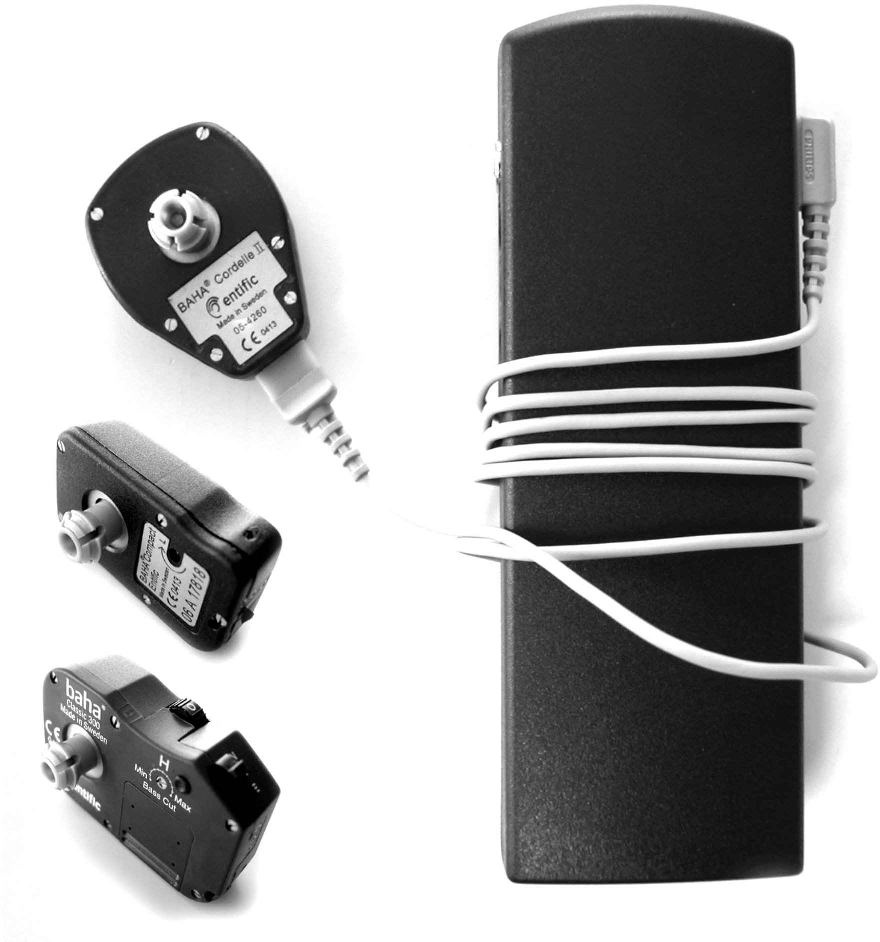

Figure 2. Figure of three sound processors: Cordelle, Compact and Classic. On the right the body-worn receiver of the Cordelle.

Consecutive Food and Drug Administration (FDA) approvals for the BAHA application underline the efficacy of the BAHA. First for the unilateral application in case of bilateral conductive or mixed hearing impairment in adults and later on for the same indication in children. This was followed by the approval for the bilateral BAHA fitting and the use of the BAHA in patients with unilateral inner ear deafness.

NEW INDICATIONS

Unilateral conductive hearing loss

The BAHA provides highly effective rehabilitation in patients with the conventional indication for BAHA application as described earlier.

The majority of these patients, having bilateral conductive hearing impairment, derive sufficient benefit from unilateral BAHA fitting. In view of the successful unilateral application of the BAHA to patients with bilateral hearing impairment, several studies have been performed on extending the indications for BAHA application. For example, in the recent past, bilateral application of the BAHA was studied and proved to restore binaural hearing.[34-36] These studies suggested that transcranial attenuation of vibrations is sufficient enough to enable two different bone conducted inputs to the two cochleae resulting in binaural hearing. A new challenge is set by patients with one ear with impaired hearing and contra lateral an ear with normal hearing. Can the impaired ear, if aided with a BAHA, interact with the other normal hearing ear in such a way that binaural hearing is achieved?

In the past unilateral hearing impairment was considered to have little impact on auditory functioning in daily life. Nowadays, however, professionals are faced with increased demands from patients experiencing limitations in daily life and are more inclined to take note of the detrimental effects of unilateral hearing impairment.[37] Prior to even considering intervention with technical means, it is important to reflect upon the patient's age, occupation, listening demands and motivation for amplification. Mild unilateral conductive hearing impairment of about 40 dB can generally be rehabilitated successfully with a conventional air-conduction hearing aid, provided an air-conduction hearing aid is not contra-indicated as a result of chronic otitis or impossible to fit in case of a severe congenital aural atresia. However, in patients with severe (60 dB) unilateral conductive hearing loss fitting an air-conduction hearing aid may not provide sufficient benefit.[38] In these patients binaural hearing is not possible or at least not effective, as a result of their unilateral conductive hearing loss. However, binaural processing might be restored with a BAHA placed at the side of the impaired ear, assuming that the two cochleae are functioning normally. Chasin and Wade were the first to publish data on the BAHA application in unilateral conductive hearing loss.[39] They showed that patients were able to score 50% correct at a level that was 2.1 dB less intense while wearing the hearing aid. Snik et al. were able to show significant improvements in directional hearing.[40] Other studies also mention that the BAHA is effective in patients with acquired unilateral conductive hearing loss.[40,41]

This PhD thesis further evaluates the results of patients with unilateral conductive hearing loss with the BAHA and focuses on those patients with less convincing audiometric results.

Bilateral conductive hearing loss in very young children

The major congenital aural malformations such as congenital aural atresia are relatively rare.[42] These malformations involve both the tympanic cavity and the ear canal and pinna and can generally be termed as 'congenital aural atresia'. Several classifications have been given.[42-45] It may occur in isolation or in combination with congenital anomalies of the auricle.

The minor congenital aural malformations are limited to the middle ear and involve fixations and defects of the ossicular chain and malformations of the oval and round window regions, with a normal eardrum and ear canal. The incidence of minor congenital anomalies of the middle ear is also very low. Several classifications have been proposed. The early classifications were based on relatively small personal series.[46-48] The more recent Cremers classification[49] was modified and supplemented by Tos in 2000.[50]

The minor congenital malformations may be associated with a series of syndromal diagnoses, like Treacher-Collins syndrome, Branchio-Oto-Renal syndrome and craniosynostoses syndrome.[49,51] Major congenital malformations without auricle malformation, or minor congenital anomalies of the middle ear may even be overlooked in the early years of life. Especially because the occurrence of unilateral congenital aural atresia is far more frequent than bilateral involvement.

In children with bilateral minor or major congenital aural malformations, early hearing rehabilitation is inevitable to provide acquisition of speech and language skills. Rehabilitation in these children, however, has been a problem until recently. Ear canal atresia surgery has to be postponed to at least an age of six years.[52] In case of a severe bilateral involvement a classical surgical repair is not even a realistic option at all, since social hearing can usually not be provided[53]. Therefore, the best option is the fitting of bone conduction hearing aids. Practical problems of these conventional bone conduction hearing aids (the steel headband is inconvenient and may easily shift over the head) sometimes result in delayed hearing aid fitting or usage for only part of the day. It is important to emphasize that the earlier a hearing device is fitted and used continuously, the smaller the impact of the hearing loss on long-term speech and language development.[54] An improvement was given by the early percutaneous titanium BAHA application. However, again there is an age limit for the percutaneous titanium implantation for the application of a BAHA in very young children. One reason is that the essential osseo-integration of the titanium implant might be poor owing to the non-mature structure of a young child's skull.[55,56] Therefore, it is suggested to wait with the placement of titanium implants for the BAHA in children until the age of 3 years or older.[57] The earlier described advantages of the BAHA over the conventional bone conduction hearing aids, still count. Especially, the ability of bilateral application of the BAHA, due to the assembly of the microphone and transducer in the same housing, is an advantage.[58] When a conventional bone conductor is mounted in the sidepiece of spectacle, bilateral application is an option, however, this is not achievable in these very young children. The bilateral BAHA application in children with bilateral conductive hearing loss was first described by Hamann. The youngest age of implantation was 10 years.[59] An important new development for very young children is to wear the BAHA attached to an elastic band by means of the special plastic snap connector disk.[60] This so called BAHA Softband, initiated in the Nijmegen Otorhinolaryngology department, provides a new and well-accepted solution for BAHA application starting from the very first months of life, preferably as soon as possible. The BAHA is attached to an elastic band by means of the special plastic snap connector disk and it also offers the possibility of bilateral BAHA application.

The availability of the BAHA Softband is an enormous step forward in early hearing rehabilitation in this special group of children. Clinical and audiological studies are needed to further evaluate the speech and language development in children with this early (bilateral) BAHA Softband application.

Single sided inner ear deafness

Unilateral inner ear deafness may have different causes, mainly post surgical and particularly from acoustic neuroma surgery. Patients with unilateral inner ear deafness and (almost) normal hearing in the contralateral ear do not experience the advantages of binaural hearing. The impossibility of binaural hearing results in experiencing head shadow effect, the loss of binaural loudness summation and the squelch effect and also the inability of localizing sounds.[61,62]

In the past few decennia, several attempts have been made to help patients with unilateral inner ear deafness.[63] One approach to minimize their communication problems consists of giving advice on preferential seating or counseling the patient to present the ear with normal hearing to the sound signal.

The traditional audiological approach consists of fitting a contralateral routing of sound (CROS) hearing aid. With the conventional CROS, sound is received on the poor ear (PE) with a microphone placed in a behind-the-ear hearing aid. The signal is transmitted by an electrical wire around the neck or by wireless FM transmission to a receiver placed in a behind-the-ear hearing aid at the best ear (BE).[64,65] However, placing an ear mould in the BE and a cord around the neck is often experienced as unpleasant, while the open ear mould only enables transfer of mid and high frequencies from the PE to the BE.[66] This might be the main reason why CROS hearing aids are seldomly used. Alternatively, with a highly powerful air-conduction hearing aid at the PE, amplified sound may be transmitted to the BE by bone conduction through the cranium. This type of fitting is called transcranial or internal CROS.[66]

Another option is the use of conventional bone conductors, mounted on a spring or in the sidepiece of spectacles, pressing against the temporal bone. Due to the limited interaural attenuation of bone-conducted sound, bone conduction hearing aids may be used as transcranial CROS devices. The interaural attenuation amounts to 0-10 dB. The maximum output of conventional bone conductors is, however, rather limited and appears to be strongly frequency dependent.[14,65,67] Besides, the earlier mentioned drawbacks of conventional bone conductors still count. The Audiant, a semi-implantable bone conduction device, which is no longer available, made use of a magnetic coupling for the transcutaneous transfer of vibration energy. Pulec was the first to use the Audiant device as a transcranial CROS bone conduction device, but the results were ambiguous.[68] In all cases maximum volume settings had to be used, which suggested that gain and maximum output power of the device were not sufficient to obtain optimal fittings.

A more recent option is the use of direct coupling of the percutaneous BAHA providing transmission of sound, with appropriate gain and power output for transcranial applications. The design of the BAHA as a bone conduction device is exceptional in the sense that the microphone, amplifier and vibrator are all assembled in the same housing and also sufficient gain can be established. Vaneecloo et al. reported positive results with the BAHA transcranial CROS application (BAHA CROS).[69] It was found that the BAHA CROS was beneficial in specific listening situations, because some of the disadvantages of conventional CROS devices were avoided.[70-74] Ambivalence is reported in literature concerning localization abilities in patients with unilateral profound inner ear hearing loss and the BAHA CROS. Some studies report clearly improved localization abilities,[69,75] while others fail to demonstrate this.[70,74] The patients' opinions on the BAHA CROS are quite favourable, especially in specific listening situations, for example at the dinner table or while driving a car.[70-72,74,75]

In this particular group of patients, arranging a trial for two weeks with a BAHA on a classic steel headband, placed on the mastoid at the deaf ear as part of the preoperative evaluation, may be helpful in ascertaining benefit.

To gain more insight in both the audiological and patient outcome measures, larger groups of patients and long-term follow-up are essential.

PATIENT OUTCOME MEASURES

Subjective outcome measures

Several clinical studies have evaluated surgical and audiometric outcomes with the BAHA and have shown its benefit. Not only in patients with conventional indications, but recently also in new indications, several studies have shown that the benefits of the BAHA extend beyond the boundaries of standard audiological tests.[74-79] Considering the possible risks of the associated surgical procedure (general or local anaesthesia) and in case of some (new) indications a required financial support of the patients themselves, evaluating the effectiveness of the BAHA seems mandatory. One of the important domains of information about the outcomes of medical treatments is the measurement of health-related quality of life.

Formerly, the outcomes of medical treatments have been measured primarily in terms of death, disability or cure. Changes in a patient's health status have been more and more recognized as the primary outcomes of medical interventions. Subsequently, the World Health Organization has extended the definition of health with psychological and social domains. These basic concepts (e.g., psychological, physical and social functioning) are measured by means of health-related quality of life (HRQoL), i.e., health status instruments.[80] There are three types of HRQoL instruments available: generic, disease-specific and domain-specific.

With regard to generic HRQoL instruments, a wide variety of currently available instruments enable comparison of health status across the borders of any specific diseases. Generic instruments, however, may fail to capture those aspects of patients' experience that are of clinical interest in a specific clinical setting. With regard to the change in health status due to hearing impairment, it has been suggested, that generic HRQoL instruments either lack the appropriate sensitivity to assess the gain in HRQoL as a result of an alteration in hearing aids[81,82] or that the change in general health status is too small for them to be detectable.[79]

On the other hand, disease-specific instruments are capable to assess impairment of function, in this context: hearing impairment. Hearing-specific HRQoL instruments do not only assess disability (restriction in daily activity directly as a result of hearing impairment) but also handicap (impact on the individual's social activity directly as a result of the disability). Therefore, disease-specific instruments are more likely to be responsive to change with regard to hearing impairment. A wide variety of instruments is currently available, which leaves the researcher with a confusing array of options. It has been suggested to devise the ideal instrument with a minimal set of core outcome items that would be sufficiently general to apply to many different types of investigations carried out in different countries in the world.[83,84]

The third type of HRQoL instrument, a domain-specific instrument, measures for instance pain or depression.

In addition to these HRQoL instruments, hearing aid related questions may provide additional information. For example, in this thesis, the number of hours of daily BAHA usage and the number of visits to an otorhinolaryngologist due to otorrhea or skin irritations were registered.

Systematic collection of HRQoL data using validated instruments establishes information about the effects of treatment, in order to assist in the evaluation of efficacy of treatment with the BAHA.

In general, the importance of patient outcome measures has become well recognized and a number of recent studies have focused on HRQoL

issues.[74-77,85] In order to obtain clinically meaningful outcome measures, the use of validated and reliable instruments is essential.[86-89]
The ideal instrument is both valid (actually measuring what it purports to be measuring) and reliable. Reliability refers to whether the instrument will produce the same result when administered repeatedly to an individual. Next to this the ideal instrument should be sensitive to change. Responsiveness refers to the extent to which an instrument is able to detect and measure changes in HRQoL after an intervention.
HRQoL instruments can consist of open or closed questions; in a closed question the responder is given a multiple choice of responses to choose from. If the questions are simple and easily understandable the responses may be administered by means of a postal-based instrument. On the other hand, patients who do not respond might be missed and, certain complex instruments are only suitable for interview-based responses.

HRQoL versus audiometric outcome measures
In patients with the conventional indication for BAHA application, research has shown that patients preferred the BAHA to conventional bone conduction hearing aids, as it has better aesthetic appearance, comfort, frequency response and maximum output.[24,90-92] HRQoL and audiometric outcome measures are in agreement in this specific patient group.
In patients with the conventional indication for BAHA, formerly using air-conduction hearing aids, the results are more ambiguous.[78,90,93] In these cases reduction of ear infections and consequently otorrhea was the main reason to prefer the BAHA. HRQoL instruments collect additional information about the outcome of this medical treatment.
In patients with unilateral conductive hearing loss, sound localization and speech recognition in noise with spatially separated speech and noise sources is expected to improve with the BAHA. Fitting a BAHA to patients with unilateral conductive hearing loss seems to have a complementary effect on hearing.[40] In general, sound localization results improved significantly for patients with acquired unilateral conductive hearing loss. The use of a disease-specific HRQoL instrument should underline this benefit.[94]
In patients with unilateral inner ear deafness, with only one functioning cochlea, the use of the interaural time and intensity differences essential for directional hearing is precluded. Thus, in patients with unilateral inner

ear deafness, the application of a conventional CROS or a BAHA CROS device our audiometric measurements did not show that these patients achieved binaural hearing. In order to assess subjective localization abilities a HRQoL instrument on spatial hearing should be beneficial.
An overview of the different instruments used in this thesis is given in table 1.

Table 1. Overview of instruments used in this thesis

Instruments	Chapter	Year of introduction	Name	Type	Administered	Used for
Hearing Handicap and Disability Index (HHDI)	2.1	1996	Van den Brink et al.	Specific	Self-report	Handicap Disability
EuroQol-5D (EQ-5D)	2.1	1990	EuroQol Group	Generic	Self-report	Health status
36-item Short-Form health survey (SF-36)	2.1	1992	Ware & Sherbourne	Generic	Self-report	Health status
Adapted Nijmegen Questionnaire	2.2	This thesis	Hol et al.	Specific	Interview and postal based	Device use and Speech recognition
Chung & Stephens	3.1	1986	Chung & Stephens	Specific	Postal based	Binaural hearing
Speech Spatial and Qualities of hearing Scale (SSQ)	3.2	2004	Gatehouse	Specific	Postal based	Spatial hearing
Abbreviated Profile of Hearing Aid Benefit (APHAB)	4.1- 4.3	1995	Cox & Alexander	Specific	Interview and postal based	Benefit
Glasgow Hearing Aid Benefit Profile (GHABP)	4.3	1999	Gatehouse	Specific	Interview and postal based	Disability, Handicap, Benefit
Intern. Outcome Inventory for Hearing Aids (IOI-HA)	4.3	2002	Cox, Stephens & Kramer	Specific	Interview and postal based	Device use, Satisfaction and Disability
Single Sided Deafness Questionnaire (SSD)	4.3	2003	Wazen	Specific	Interview and postal based	Listening situations

EXTENDED INDICATIONS -NOT IN THIS THESIS-

Mental retardation

Initially patients with a mental retardation were excluded from BAHA treatment, as the percutaneous titanium implant situated behind the ear necessitates daily care. In this group of patients chronic otitis media with effusion is often present combined with narrow ear canals complicating grommet insertion. If, in those patients cholesteatoma gives rise to chronic otitis media, the modified radical ear operation can be applied. Still, conventional air-conduction hearing aids are not always successful as they often sustain chronic otorrhea. After all, a conventional bone conduction hearing aid is the sole option. The complications of these hearing aids mentioned earlier gave rise to searching an alternative. Because recent studies ascertained the stability of the percutaneous implant in clinical trials, the implementation of the BAHA in this special group of patients could be initiated. A report on this topic from the Nijmegen BAHA team is soon to be published.

Otosclerosis

Burell et all proposed to use the BAHA as the third option for patients with otosclerosis.[95] In these patients the first alternative, an air-conduction hearing aid, may fall out of favour as a result of a large air-bone gap, especially when realising the possible better performance with the BAHA and the absence of feedback. The second alternative, surgery, is not an option owing to previous unsuccessful surgery or a second ear with an even more impaired hearing. At present there is few literature about the use of the BAHA as an alternative treatment for patients with otosclerosis.[75,77,95,96]

SCOPE OF THE THESIS

The BAHA has now been in clinical practice since 1987 in many countries outside of Sweden, the country in which the BAHA was first applicated. Several surgical and audiometric studies have shown that the percutaneous coupling of the BAHA to the skull appears safe and stable over time. Furthermore, these studies have consistently shown that in conductive hearing losses the audiological results are superior to those obtained with conventional bone conductors and in many cases, with air-conduction hearing aids.

The success of this specific hearing aid should not be measured with surgical and audiological tests alone, as the importance of patient outcome measures is increasingly recognized. Therefore, the aim of the study described in *chapter 2.1* is to quantify the impact of the BAHA on the health-related quality of life of adults by means of a postal-based prospective questionnaire study and to test the hypothesis that a BAHA improves health-related quality of life because otorrhea and skin irritations decrease. In *chapter 2.2* the long-term follow-up, with a mean duration of nine years, of those patients previously using an air-conduction hearing aid is described with regard to use, care, satisfaction, ear infections and audiometry.

After describing the impact of the BAHA on health-related quality of life and the long-term results of the usage of the BAHA in patients previously using conventional air-conduction hearing aids, the relatively new indication of unilateral conductive hearing loss is described.

In *chapter 3.1* the aimed question “Does the bone-anchored hearing aid have a complementary effect on audiological and subjective outcomes in patients with unilateral conductive hearing loss?” is answered. If we take a closer look at these particular patients, it was seen that variations in outcomes on an individual level were large. The observation that a considerable number of patients already had good binaural performance in the unaided condition, despite the asymmetry in hearing between the two ears (which was between 40 and 65 dB), was the point of departure for the study described in *chapter 3.2*. The aim of this study was to find out which monaural sound cues could explain the fairly good unaided horizontal localization abilities of patients with unilateral conductive hearing loss.

In case of bilateral conductive hearing loss, as a result of congenital binaural atresia, the only early option for hearing rehabilitation in these young children is the fitting of hearing aids (i.e. a bone conduction hearing aid). Surgical correction of the atresia is not an option in most types of atresia[97] and if it is an option the minimum age for reconstructive surgery is typically six years.[98] To fit these young children with a conventional bone conduction hearing aid gives practical objections; the major development in bone conduction hearing, the BAHA, avoids these practical problems. However, the youngest age advocated for percutaneous titanium fixation to the skull is about three years.[55] In *chapter 3.3* results of the BAHA Softband are given, including the speech and language development outcomes in two patients with the first BAHA Softband application worldwide. The BAHA Softband is an alternative for very early hearing rehabilitation in these children.

In the light of unilateral hearing impairment the patients with unilateral inner ear deafness form a separate group and are discussed in *chapter 4*. The BAHA may be used as a transcranial contralateral routing of sound (CROS) device, due to the small interaural attenuation of bone conducted sound. A major drawback of these conventional bone conduction hearing aids is the static pressure essential for correct operation by counteracting reactive forces. The direct mechanical coupling of the BAHA can provide high-quality transmission of sound, sufficient for transcranial applications. In *chapter 4.1* the first experiences of the Nijmegen BAHA group with the BAHA CROS device in a small group of patients are described. To gain greater insight in the experiences and also the opinions of patients with unilateral inner ear deafness the group of patients was extended and is described in *chapter 4.2*. In order to assess the possible effect of enthusiasm bias, these patients participated in a long-term instrument based follow-up study. These results are described in *chapter 4.3.*

A general discussion is presented in *chapter 5.* The data of patients gathered in this PhD thesis with conventional and new indications for the fitting of the BAHA, patient satisfaction and long-term results are integrated and discussed again.

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Quality of life assessment and long-term follow-up

Chapter 2

The bone-anchored hearing aid. Quality of life assessment

Chapter 2.1

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ABSTRACT

Objective: To assess the impact of a bone-anchored hearing aid (BAHA) on the quality of life (QOL) of adults and to test the hypothesis that a BAHA improves QOL because otorrhea and/or skin irritations decrease.

Design: Prospective postal-based questionnaire study using validated health-related QOL instruments, combined with hearing-aid-related questions.

Methods: The study included 56 consecutive adult patients with acquired conductive or mixed hearing loss who were scheduled for BAHA implantation at the University Medical Centre Nijmegen, Nijmegen, the Netherlands. All 56 patients completed the 36-item Short Form health survey 36 (SF-36), the EuroQol-5D (EQ-5D), and the Hearing Handicap and Disability Inventory (HHDI); 36 patients had been using an air-conduction hearing aid (ACHA) and 20 patients a conventional bone-conduction hearing aid (CBHA). Questionnaires were filled out prior to surgery and after 6 months of experience with the BAHA.

Results: In the SF-36 group, there was significant improvement in the scores of the mental health domain (P=.02) When the SF-36 patients were classified according to previous hearing aid, there was no statistically significant change in the scores in any of the domains. In the EQ-5D group and in its ACHA and BCHA subgroups, there were no important differences in the results before and after the patients received their BAHAs. In the HHDI group, the handicap and disability scales showed significant improvement (P<.01) irrespective of the type of previously worn hearing aid.

Conclusions: Overall, generic health-related QOL was not influenced significantly by the use of a BAHA according to SF-36 and EQ-5D. The more disease-specific scales (HHDI) did show improved QOL with a BAHA.

INTRODUCTION

Several clinical studies have evaluated surgical and audiometric outcomes with the bone-anchored hearing aid (BAHA).[1-4] It has been shown that the percutaneous coupling of the BAHA to the skull is safe and stable over time. Furthermore, these studies have consistently shown that the audiological results are superior to those obtained with conventional bone

conductors and, although less convincingly, with air-conduction hearing aids (ACHAs).[1-4]
Because a surgical procedure is involved, and the financial costs are relatively high, it seems more important to evaluate subjective appraisals in studies in which conventional hearing aids were replaced with a BAHA. Most studies[2-8] that reported subjective assessments of patients fitted with a BAHA used questionnaires with items concerning the patient's attitude toward the new hearing aid itself or the patient's performance in various listening situations and conditions. The questionnaires compared the BAHA with conventional hearing aids, and, again, the results favored the use of the BAHA.[5-8]
The importance of patient outcome research is becoming increasingly recognized, and a number of recent studies[9-11] have focused on quality of life (QOL) issues. Instruments used to obtain outcome measurement after hearing aid fitting vary in length and internal structure. Use of an appropriate instrument is essential to obtain valid and clinically meaningful measurement of outcome. Frequently used instruments quantify disability and handicap as well as benefit and health status. In most studies, a significant reduction in hearing disability and handicap was noted, while Dutt et al and other authors[10,11] reported improved QOL.[9] All data collection in these studies can be classified as retrospective, as measurements were only performed after implantation of the BAHA.
The aim of this prospective postal-based questionnaire study was to quantify the impact of hearing rehabilitation with a BAHA on the QOL of adults; 3 different validated instruments were used. The patients answered questions about their QOL with their previous hearing aid (before BAHA) and after 6 months of experience with their new BAHA (after BAHA).
As ACHAs or conventional bone-conduction hearing aids (CBHAs) can be contraindicated because of persistent otorrhea or severe skin irritations caused by the transducer pressing against the skin of the temporal bone, we also tested the hypothesis that a BAHA improves QOL if otorrhea and/or skin irritations decrease. Patients were therefore asked about the prevalence and, if present, the frequency of these hearing-aid-related complaints.

METHODS

Patient groups

Fifty-six consecutive adult patients with acquired conductive or mixed hearing loss and listed for BAHA surgery participated in this prospective questionnaire study. Mean age (and age range) of the patients at implantation and the mean air- and bone-conduction thresholds are listed in Table 1.

Table 1. Characteristics of the patients classified according to previous hearing aid*

Group	No. of patients	Age, years	Sex % male	Hearing loss at 0.5, 1 and 2 kHz, dB HL		Air-bone Gap, dB
				AC	BC	
ACHA	36	47.9 (24-73)	33	63.2 (30-103)	26.8 (9-51)	36.4 (16-60)
CBHA	20	62.0 (42-82)	45	76.5 (40-107)	43.4 (17-63)	36.1 (13-53)
Total	56	52.9 (24-82)	37	68.1 (30-107)	31.8 (9-63)	36.3 (13-60)

Abbreviations: AC, air-conduction; ACHA, air-conduction hearing aid; BC, bone-conduction; CBHA, conventional bone-conduction hearing aid; HL, hearing level.
* Values are expressed as mean (range) unless otherwise indicated.

Most patients (n=51) received a BAHA Classic (Entific Medical Systems, Göteburg, Sweden), while a small proportion (n=5) were fitted with a BAHA Cordelle (a more powerful BAHA with a body-worn amplifier) (Entific Medical Systems) because of their sensorineural hearing loss. Carlsson and Hakansson[12] have shown that, theoretically, it is possible to virtually close the air-bone gap with the BAHA Classic. Also, it is possible to compensate 15 to 20 dB of the sensorineural hearing loss component with the more powerful BAHA Cordelle. As part of the regular evaluation procedure, aided sound-field measurements were performed to see whether these theoretical targets were met. This criterion was fulfilled within 10 dB (at 1, 2 and 4 kHz) in all 56 patients, so the fitting of the BAHAs was considered as adequate.

All patients had been using hearing aids before implantation; 36 of the 56 patients had been using an ACHA, and 20 had been using a CBHA. Table 1 shows that hearing loss was somewhat more profound in the CBHA group than in the ACHA group. The audiometric data listed in Table 1 refer to the ear ipsilateral to the side of implantation, which was always the ear with the best cochlear reserve.

QOL instruments

Generic QOL (or health status) instruments measure basic concepts (eg, psychological, physical and social functioning) that are always relevant to health status. Generic instruments are not disease specific and thus enable comparison of health status across the borders of any specific diseases. For this study, we selected the self-report 36-Item Short Form health survey (SF-36) and the self-report EuroQol-5D (EQ-5D), both of which seem capable of measuring health-related QOL.[13] As a more disease-specific instrument, we selected the Hearing Handicap and Disability Index (HHDI).

Patients were asked to fill out these instruments on 2 occasions: (1) with their previous hearing aid before surgery and (2) after 6 months of experience with the BAHA. The SF-36 was developed in the United States from the Medical Outcome Study General Health Survey Instrument.[14] The SF-36 consists of 36 items with the following domains: physical functioning, role limitations (physical problems), role limitations (emotional problems), vitality, mental health, social functioning, pain and general health perception. The number of response categories per item ranges from 2 to 6; better functioning leads to a higher score on a specific item. The end score is an 8-dimensional profile. The Dutch version used in this study was developed to translate, validate, and normalize the self-report SF-36 in a range of languages and cultural settings.[15] The self-report SF-36 is an internally consistent and valid measure of health status.[14,16-18]

The EQ-5D is a generic health-related QOL instrument which consists of 5 domains: mobility, self-care, usual activities, pain/discomfort and, anxiety/depression.[16] Three response alternatives are available for each domain (1, no problems; 2, some problems; and 3, severe problems). The EQ-5D utility index is obtained by applying predetermined weights to the 5 domains. This EQ-5D utility index ranges from 0 (worse than death) to 1 (perfect health status) and is a societal- based numerical quantification of a patient's health status. The EQ-5D instrument has been developed specifically to generate a generic cardinal index of health, thus giving it considerable potential for use in health care evaluation.[19] Also, patients were asked to rate their own state of health on an EQ-5D visual analogue scale (VAS), made up of a vertical line ranging from 0 (worst imaginable state of health) to 100 (best imaginable state of health). The EQ-5D appears to have good test-retest reliability, is easily self-administered, and has been standardized for use in The Netherlands.[13,20]

Because the SF-36 and the EQ-5D are generic instruments, they need to be supplemented with a disease-specific QOL questionnaire. Therefore, we appended the HHDI (a hearing handicap inventory for the elderly) to establish an inventory for hearing handicap and hearing disability.[21,22] *Hearing handicap* refers to disadvantages imposed by impairment or limitations on an individual's psychological or social functioning. The short version of the HHDI deals with 3 items: emotional response, social withdrawal, and reactions of others.[23] Therefore, these questions represent the nonauditory problems that are caused by hearing impairment or disability and are tailored to investigate the degree of hearing disability. The Dutch equivalent inventory, which has equivalent validity, internal consistency, and reliability, was used in our study.[24]

In the case of missing data, aggregated domains were not computed (at most, this reduced the overall number of patients from 56 to 51). To avoid "enthusiasm bias" or bias that could be caused by possible initial problems with the fitting of the implant, the questionnaires were filled out again after the patients had 6 months of experience with the BAHA.

The patients were asked to answer several hearing-aid-related questions to gain insight into the number of hours of daily BAHA use and the number of visits to an otolaryngologist because of otorrhea or skin irritations. They were also asked about the frequency of episodes of otorrhea and about the prevalence of skin irritations with their conventional hearing aid and with the BAHA.

Analysis

The Wilcoxon test was used to compare the results of the ACHA with those of the CBHA group (data in nonparametric scales) for statistical analyses. Difference scores, which were used to compare presurgery and postfitting results, were analyzed with the *t* test; $P<.05$ was chosen as the level of significance. However, calculating statistical significance is highly dependent on the sample size and does not reflect the clinical relevance of measured differences. Thus, besides difference scores, effect sizes were estimated. Effect sizes are standardized measures and therefore appropriate to assess the magnitude of changes in health-related QOL.[25]

The effect size shows the absolute clinical effect of the difference between the previous hearing aid and the BAHA on a certain question, irrespective of the number of patients. A small effect is given by an effect size of 0.2 to 0.5, a moderate effect by an effect size of 0.5 to 0.8, and a large effect by an effect size of more than 0.8. The effect can be negative or positive.[25] The results were computed using an SPSS software package (Version 10; SPSS Inc, Chicago, Ill). The results of the total study group were used to construct box and whisker plots: the whiskers show the standard error of the mean. To answer the question about the possible influence of the previous hearing aid on outcome measures with the BAHA, we separately analyzed the results for the whole group (irrespective of their previous hearing aid) and for the patients with the 2 different types of previous hearing aids. The likelihood of limitations due to ceiling effects, was low as none of the subscales had a mean score that approached the extremes of the response range in any of the 3 response instruments.

RESULTS

SF-36 scores

In the total group, there was very little difference in any of the domains. Only the scores in the mental health domain improved significantly (P=.02). However, the effect size was small (-0.30). A slight, statistically nonsignificant improvement was seen in the social functioning and pain domains (P=.30), and a very small improvement was seen in the vitality domain. Slight deterioration was seen in the physical functioning, role limitations (physical and emotional problems), and general health perception domains (Figure 1).

Differences in the ACHA group were smaller than those in the CBHA group; there were no statistically significant changes in any of the domains. In the CBHA group, role limitations (emotional) deteriorated after implantation of the BAHA, which means that these patients seem to spending less time on work or daily habits as a result of (increased) emotional problems. However, the change was not significant (P=.19). The scores on the pain domain were also slightly lower (P=.30), which means that patients were experiencing slightly more pain. Effect sizes showed that the clinical effect was small in all SF-36 domains. Table 2 gives an overview of all these changes, classified according to previous hearing aid.

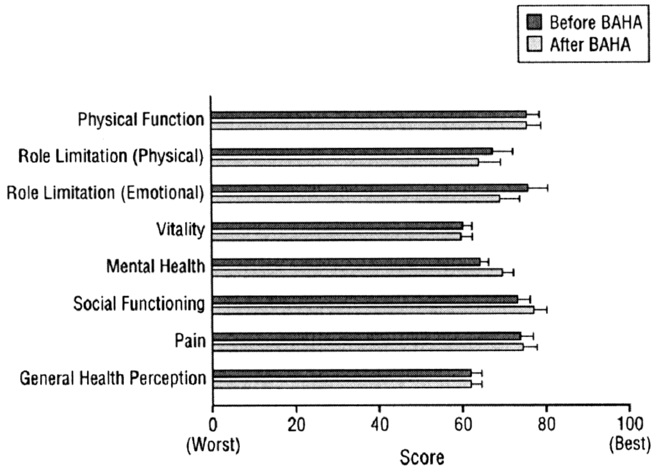

Figure 1. Mean (SEM) scores of the total group of patients on the 8 domains of the 36-Item Short-Form Health Survey before and after implantation of a bone-anchored hearing aid (BAHA).

Table 2. Scores of the total group of patients classified according to previous hearing aid on the 8 domains of the 36-Item Short Form health survey before and after receiving a Bone-Anchored Hearing Aid (BAHA)

	ACHA (n=36)*		CBHA (n=20)*		Mean differences		Effect size	
	Before	After	Before	After	ACHA	CBHA	ACHA	CBHA
Physical functioning	80.3 (21.8)	79.8 (22.4)	69.2 (25.4)	70.8 (24.6)	-0.5	1.4	0.02	-0.06
Role limitations (physical)	71.5 (39.7)	68.9 (40.5)	61.3 (40.1)	57.5 (45.2)	-2.6	-3.8	0.06	0.09
Role limitations (emotional)	76.2 (40.1)	73.2 (38.1)	76.7 (39.1)	63.3 (41.8)	-3.0	-13.4	0.07	0.33
Vitality	60.4 (20.0)	59.9 (19.9)	60.8 (16.6)	61.0 (21.9)	-0.5	0.2	0.02	-0.01
Mental health	62.4 (18.0)	67.9 (21.3)	68.4 (17.6)	74.2 (14.2)	5.5	5.8	-0.28	-0.36
Social functioning	69.8 (28.3)	75.0 (27.8)	80.6 (17.9)	82.2 (18.3)	5.2	1.6	-0.19	-0.09
Pain	74.7 (25.2)	79.2 (25.0)	73.8 (20.0)	67.9 (27.9)	4.5	-5.9	-0.18	0.24
General health	63.2 (21.4)	63.6 (21.2)	61.0 (19.8)	59.5 (20.3)	-0.4	-1.5	-0.18	0.07

Abbreviations: ACHA, air-conduction hearing aid; CBHA, conventional bone-conduction hearing aid. * Values are expressed as mean (SD).

EQ-5D scores

There were no important differences between the presurgery and postfitting results in the EQ-5D group. In the group as a whole, the patients' scores on the mobility, pain/discomfort, and anxiety/depression domains were slightly poorer after implantation of the BAHA. The total group showed a small, non-significant increase in scores on the other domains (Figure 2).

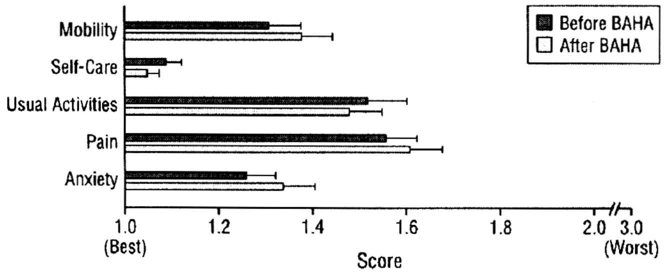

Figure 2. Mean (SEM) scores of the total group of patients on the 5 domains of the EuroQol-5D before and after implantation of a bone-anchored hearing aid (BAHA).

The ACHA group showed slightly increased scores on the mobility and anxiety/depression domains, which means that these patients were slightly less mobile and much more anxious/depressed after implantation. Anxiety/depression increased significantly in this specific group ($P<.01$), but the effect size (-0.30) (eg, the clinical effect of increased anxiety/depression) was small. The slight decrease in the scores on the usual activities and pain/discomfort domains showed that patients were doing somewhat better ($P>.05$). In the CBHA group, there was a small improvement on the self-care, usual activities, and anxiety/depression domains. This means that these patients were less anxious/depressed, although this difference was not statistically significant ($P>.05$). The scores on the mobility and pain/discomfort domains were increased ($P=.26$), which means that the patients were slightly less mobile and experienced more pain/discomfort. The effect size for all of these domains was small (<0.30). Table 3 gives an overview of the changes, classified according to previous hearing aid.

Scores on the EQ-5D VAS did not change statistically significantly after implantation. Before surgery, the total group scored 74 on the EQ-5D VAS compared with a score of 73 six months after implantation. Both of these scores were lower than the general population mean of 82.5.[26]

HHDI scores

Figure 3 shows significant improvement ($P<.01$) not only on the disability scale but also on the handicap scale. These improvements were independent of the previous hearing aid. The effect size (≥ 0.79) showed a large clinical impact. Disability showed a greatly improved clinical effect, especially in the CBHA group (Table 4). Quality of life expressed in terms of disability and handicap due to hearing impairment improved significantly after the patients received a BAHA.

Table 3. Scores of the total group of patients classified according to previous hearing aid on the 5 domains of the EuroQol-5D, the EuroQol-5D utility index, and EuroQol-5D visual analogue scale before and after receiving a Bone-Anchored Hearing Aid (BAHA)

	ACHA*		CBHA*		Differences		Effect size	
	Before	After	Before	After	ACHA	CBHA	ACHA	CBHA
Mobility	1.29 (0.46)	1.31 (0.47)	1.35 (0.49)	1.50 (0.51)	0.02	0.15	-0.04	-0.30
Self-care	1.03 (0.17)	1.03 (0.17)	1.20 (0.41)	1.10 (0.31)	0.00	-0.10	0.0	0.28
Usual activities	1.47 (0.66)	1.44 (0.50)	1.60 (0.68)	1.55 (0.60)	-0.03	-0.05	0.05	0.08
Pain/discomfort	1.49 (0.51)	1.47 (0.51)	1.70 (0.57)	1.85 (0.49)	-0.02	0.15	0.04	-0.28
Anxiety/ depression	1.26 (0.44)	1.42 (0.60)	1.26 (0.45)	1.20 (0.41)	0.16†	-0.06	-0.30	0.13
Utility	0.78 (0.17)	0.77 (0.17)	0.71 (0.23)	0.70 (0.19)	-0.01	-0.01	0.06	0.05
VAS	76.1 (14.1)	73.4 (17.1)	74.0 (16.0)	72.4 (17.4)	-2.7	-1.6	0.17	0.10

Abbreviations: ACHA, air-conduction hearing aid; CBHA, conventional bone-conduction hearing aid. * Values are expressed as mean (SD). †P<.01.

Table 4. Scores of the total group of patients classified according to previous hearing aid on the hearing handicap and disability inventory before and after receiving a Bone-Anchored Hearing Aid (BAHA)

	ACHA*		CBHA*		Differences		Effect size	
	Before	After	Before	After	ACHA	CBHA	ACHA	CBHA
Disability	25.8 (6.5)	20.9 (6.2)	31.0 (6.0)	20.8 (8.2)	-5.0†	-10.2†	0.79	1.42
Handicap	25.0 (5.9)	19.6 (6.7)	27.4 (6.2)	21.8 (8.0)	-5.4†	-5.6†	0.86	0.79

Abbreviations: ACHA, air-conduction hearing aid; CBHA, conventional bone-conduction hearing aid. * Values are expressed as mean (SD). †p<0.01.

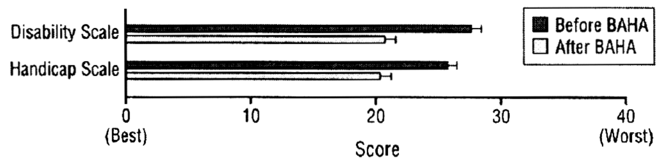

Figure 3. Mean (SEM) scores of the total group of patients on the 2 domains of the Hearing Handicap and Disability Inventory before and after implantation of a bone-anchored hearing aid (BAHA).

Hearing-aid-related questions

In the ACHA group and CBHA groups, 78% and 90% of the patients, respectively, had been using their previous hearing aid for 8 or more hours a day. After implantation, all 56 patients (100%) were using their BAHA for 8 or more hours a day. The patients were also asked about visits to their otolaryngologist for complaints about draining ears over the preceding 6 months. In the total group, the mean number of visits decreased from 10 before implantation to 2.7 after implantation (Table 5).

A substantial proportion of the patients in both groups complained less frequently about problems with otorrhea or skin irritations. This applied to the frequency of otorrhea episodes in 17 patients (47%) in the ACHA group and 5 patients (25%) in the CBHA group. With regard to skin irritations, this applied to 14 patients (39%) in the ACHA group and to 10 patients (50%) in the CBHA group. (Figure 4).

Table 5. Number of otolaryngology visits by patients classified according to previous hearing aid before and after receiving a Bone-Anchored Hearing Aid (BAHA)

Group		No. of patients	No. of visits, mean (SD)	Range
ACHA	Before	32	12.7 (10.5)	0-30
	After	33	3.3 (4.8)	0-25
CBHA	Before	19	5.4 (4.9)	0-20
	After	20	1.5 (2.1)	0-6
Total	Before	51	9.96 (9.5)	0-30
	After	54	2.66 (4.1)	0-25

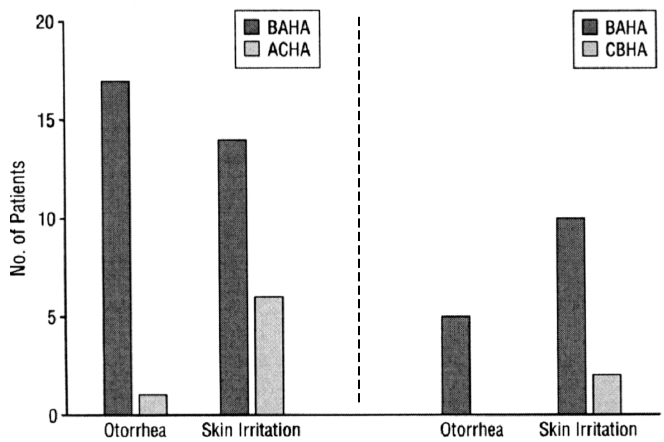

Figure 4. Number of patients who preferred the bone-anchored hearing aid (BAHA) of their previous hearing aid (left, air-conduction hearing aid [ACHA]; right, conventional bone-conduction hearing aid [CBHA]) in regard to otorrhea and skin irritations. The number of patients who experienced no difference is not shown.

COMMENT

Several studies[1-4] have reported patients' opinions on the BAHA, as it is becoming increasingly acknowledged that the benefits of the BAHA extend beyond the boundaries of audiological tests. In general, patient outcome research has consisted of questionnaire studies involving domains dealing with hearing, sound quality, comfort, cosmetic appearance, practical arrangement and utilization time (ie, the amount of time hearing aids are turned on). Either the patients were asked about hearing aid preference or they had to rate a specific hearing aid on a numerical scale. Mostly, questionnaires were administered after the patient had been using the BAHA for a while. Reference data consisted of the patients' opinions about their previous hearing aid. Most studies reported that the patients considered their BAHA to be an improvement with regard to speech recognition, quality of sound, and user comfort.[5-8,27] On a numerical scale, the improvement in speech recognition in quiet and in noise was statistically significant and agreed with the audiological results.[5] Two smaller studies[28,29] reported a statistically significant improvement in questionnaire results with the BAHA compared with the CBHA, a finding that was not reflected by the results on speech discrimination tests. In patients who changed from an ACHA to the BAHA, the reduction of ear infections was a clear improvement in some studies[5,27]. In other studies, the majority of patients reported subjective improvement with the BAHA, irrespective of the type of hearing aid they had previously been using.[6-8]
The studies mentioned above discussed satisfaction with, and/or the performance of, the BAHA in comparison with a previous hearing aid in different situations. However, performance measures cannot adequately characterize the actual impact on a patient's well being. Therefore, questionnaires have been developed to characterize health status and any changes after intervention. Recent articles[9-11] on QOL have made use of the Glasgow Benefit Inventory. This validated, generic, health-related quality of life inventory is a patient-orientated questionnaire that is designed for measuring outcomes after an otorhinolaryngological intervention. These retrospective studies found significant improvement in the patients' QOL after they received a BAHA, an improvement that is comparable to the result obtained with middle ear surgery.[11] However, the Glasgow Benefit Inventory is a measure of patient benefit and not of health status per se.[10]

In our study, the possible gain in health-related QOL was assessed by comparing a baseline measurement taken before surgery to a follow-up measurement taken 6 months after implantation. The SF-36 and the EQ-5D were unable to show that health-related QOL was influenced by the implantation of a BAHA. The scores improved considerably only the mental health domain of the SF-36 health survey, but this effect disappeared when the patients were classified into groups according to their previous hearing aid. On the EQ-5D, the scores on the anxiety/depression domain deteriorated significantly in the ACHA group (P=.01), which means that these patients had become more anxious/depressed after receiving a BAHA. However, the effect size (ie, the clinical effect) was small (-0.30).
It has been suggested that general (age-related) satisfaction with life is independent of satisfaction with hearing.[30] Other more recent studies, however, have found good reason to believe that hearing aids do improve QOL.[9,11,31] It can therefore be hypothesized that the currently available general health status instruments lack the appropriate sensitivity to assess the gain in health-related QOL as a result of an alteration in hearing aids[31,32] or that the change in general health status is too small for them to detect. Considering the significant effect of cochlear implantation on the general health of previously deaf persons[33], it may be argued that just changing from one hearing aid to another (ie, from a conventional hearing aid to a BAHA) does not have a great impact. This theory was possibly reflected by the observation within our study that the EQ-5D VAS did not show a statistically significant change between the presurgery and postfitting measurements.

In contrast, the more disease-specific HHDI reflected that the alteration of hearing aids did have a significantly positive effect, irrespective of the type of previous hearing aid; eg, the patients had to consult their otolaryngologist much less frequently after receiving a BAHA. The ACHA group demonstrated overall improvement with regard to hearing-aid-related questions, especially in regard to the frequency of otorrhea, while the CBHA group also showed overall improvement, particularly in the prevalence of skin irritations. Because all 56 patients reported that they were using their BAHA for 8 or more hours a day, it can be assumed that these effects were directly related to the BAHA.

CONCLUSIONS

According to the outcome measures used in this study, the general health status of the patients did not change significantly after they received a BAHA. However, a hearing-specific QOL instrument showed significant improvement not only in disability but also in handicap ($P<.01$). Furthermore, the hearing-aid-related questions showed that all our patients were using their BAHA for at least 8 hours a day and that the number visits to their otolaryngologist had decreased. These findings are helpful in our preoperative counseling and encourage the continuation of BAHA implementation in patients who meet the selection criteria and have problems with a conventional hearing aid.

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Long-term results of BAHA recipients, previously using air-conduction hearing aids

Chapter 2.2

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ABSTRACT

Objective: To study the long-term results (use, care, satisfaction, ear infections, and audiometry) of the application of a bone-anchored hearing aid (BAHA) to patients with conventional indications who had previously used air-conduction hearing aids.
Design: Follow-up study (mean duration, 9 years).
Setting: Tertiary referral center.
Patients: The study population comprised 27 patients with conductive or mixed hearing loss and who had participated in a previous study (N=34). Seven could not be included anymore as a result of death, Alzheimer disease, or problems related to the implant. Everyone filled out the questionnaire, and 23 patients underwent audiometric evaluation.
Main outcome measures: The patients filled out the adapted Nijmegen questionnaire. Aided free-field thresholds were measured as well as scores for speech in noise and in quiet. Results were compared with those obtained in the initial study.
Results: All 27 patients were still using their BAHA and appreciated it with regard to speech recognition in quiet, sound comfort, and improvements in ear infections.
The audiometric results showed that most patients tested had stable bone-conduction thresholds over the years (after correction for age). Despite the treatment with BAHA, a significant deterioration in the cochlear hearing was observed in the other patients in the ear under study (their best hearing ear).
Conclusions: Positive patient outcome measures emphasized the importance of BAHA application to patients with conventional indications. The audiometric data showed fairly stable cochlear function but not for all patients. This underlines that conservative treatment should be chosen (fitting of bone-conduction devices).

INTRODUCTION

The bone-anchored hearing aid (BAHA) has been applied to patients in Nijmegen, the Netherlands, since 1988, which offers the opportunity to study the long-term results of BAHA users with regard to use, satisfaction, ear infections, and audiometry. Generally, conventional bone-conduction hearing aids are only considered for patients with conductive or mixed hearing loss when air-conduction hearing aids cannot be provided successfully (such as in cases with chronic otitis media, an otitis externa, or congenital aural atresia) and when surgery is not considered to be a better option. Research has shown that patients preferred the BAHA to conventional bone-conduction hearing aids because it has better aesthetic appearance, comfort, frequency response, and maximum output.[1-3] However, several studies that compared the BAHA with the patients' previous conventional air-conduction hearing aid showed somewhat ambiguous results.[1,4-6] In these cases, reduction of ear infections and consequently otorrhea was therefore the main reason to prefer the BAHA. The application of the BAHA to patients using an air-conduction hearing aid is thus less straightforward than to patients with conventional bone-conduction hearing aids.

To provide better candidacy guidelines for potential benefit from the BAHA, Mylanus et al[7] studied 34 patients who had previously been using an air-conduction hearing aid and also had otorrhea before the BAHA was advised. McDermott et al[8] studied 312 patients to test the same hypothesis and made use of the same Nijmegen questionnaire. Although this study involved a larger group of patients, they filled in only the Nijmegen questionnaire retrospectively and did not undergo audiometric evaluation. Both studies concluded that the BAHA is an acceptable alternative for air-conduction hearing aids in patients with chronic ear problems; nevertheless, some patients had better speech scores with the conventional device.[7,8] In the current era of extending the indications for a BAHA, it remains important to emphasize this conventional indication to consider a BAHA.

In light of this, the long-term follow-up of BAHA users previously using air-conduction hearing aids is interesting not only with regard to daily usage but also and perhaps even more with regard to satisfaction (patient outcome measures), ear infections, and audiological performance. The first question asked is "Are all these patients still using their BAHA?" Another important question is "Has patient satisfaction changed over time?" Furthermore, it is assumed that occluding ear molds sustain chronic otorrhea that might have lead in the long-term to cochlear damage. It might be questioned whether the use of a BAHA reduces otorrhea to such an extent that it might lead to stable cochlear function. To find answers to these questions, the patients from the previous evaluation (Mylanus et al[7]) were invited for further follow-up. Audiometric measurements as well as patient outcome measures were collected and compared with those obtained during the initial study by our study group.

METHODS

Patients

The 34 consecutive patients in the Nijmegen BAHA series who participated in the study by Mylanus et al[7] were invited to undergo further follow-up. These patients had bilateral symmetric or asymmetric conductive or mixed hearing loss and chronic ear problems. Eight patients had a second deaf ear. Before the BAHA was fitted, all these patients had been using air-conduction hearing aids. All 34 patients received the BAHA at first monaurally. In the initial study by Mylanus et al[7] 2 patients had already stopped using the BAHA owing to problems with the implant and/or the abutment after 3 months and 2 and a half years of use, respectively. Thus, 32 patients were eligible for extended follow-up. We found that 3 of them had died, another patient had had the abutment removed owing to pain around the implant and had not had a reimplantation, and 1 patient had Alzheimer disease and could not participate. The remaining 27 patients who could be included in our study had an average age of 46 years and 7 months. All 27 patients were invited to participate in the present study. Without exception, they all filled out the questionnaire, and 23 of them took part in the audiometric evaluation. The 4 patients who did not participate in this part of the study were unable to visit our hospital for various reasons (poor physical condition, problems with traveling, or no reason). The duration of follow-up in the total group of participants varied from 6 years and 11 months to 14 years and 2 months, with an average of 9 years and 1 month.

In the group of 23 patients who also participated in the audiological evaluation, the pure-tone average air-conduction thresholds of 0.5, 1, 2 and 4 kHz were found to vary from 33 to 94 dB hearing level (HL) (mean, 61 dB HL). The pure-tone average bone-conduction thresholds at the same frequencies varied from 15 to 54 dB HL, with a mean value of 34 dB HL. The corresponding mean bone-conduction thresholds obtained at the time of implantation was 12 dB better. None of the patients had undergone reconstructive ear surgery. In the meantime, 3 of the 23 patients had received the BAHA binaurally.

All the patients had initially been fitted with a BAHA HC 200, which was changed to an updated (but technically the same) version (HC 300 or BAHA Classic) after 5 years of use (Entific Medical Systems, Göteburg, Sweden). One patient who had previously been fitted with an HC 300 changed to a BAHA Cordelle (Entific Medical Systems).

Questionnaire

The Nijmegen questionnaire was used, that is, the same one as used previously.[7,9] It included 5 questions to compare the BAHA with the previous air-conduction hearing aid. Owing to the extended duration of follow-up, this particular comparison was considered as irrelevant due to recall bias. Thus, the Nijmegen questionnaire was slightly adapted and supplemented by another previously used questionnaire.[9,10] The first part of the adapted questionnaire comprised 7 questions on daily use and care, patient satisfaction and ear infections. In addition, there were 30 questions on speech recognition. These questions were derived from a previous study on hearing aids.[11] Answers could be given on a scale from 1 to 10: score 1 represents the most negative answer (extremely poor) and score 10 the most positive answer (excellent). The 30 questions were divided into 4 different domains to represent speech recognition in quiet (quiet, 5 questions), speech recognition in noise (noise, 9 questions), quality of sound (quality, 11 questions), and whether the BAHA was comfortable to wear (comfort, 5 questions). The adapted questionnaire gives a static representation of a patients' current opinion of the BAHA (see appendix). Answers to corresponding items in this questionnaire and the initial questionnaire were compared (Mylanus et al[7]).

Audiology

Air- and bone-conduction pure-tone thresholds were obtained using standard procedures and equipment and compared with the pre-implantation thresholds. To assess whether cochlear hearing had deteriorated over time, not related to aging, age-appropriate P50 values[12] were subtracted from the measured bone-conduction thresholds (at 0.5, 1, 2, and 4 kHz) and results were averaged per patient. Both the bone-conduction thresholds obtained at time of implantation and those obtained in the present study were corrected in this way for further analysis. Assuming that a change of 5 dB or less can be ascribed to the measurement error, a change greater than 5 dB was considered significant (P=.05).

Aided free-field thresholds (with warble tones) were measured; the set-up was calibrated according to Morgan et al.[13] Furthermore, phoneme scores at 65 dB (SQ) were derived from the measured free-field speech recognition-intensity function (speech audiogram).[14] To quantify speech recognition in noise, the speech in noise (S/N) ratio was determined (Plomp and Mimpen test).[15] The noise was presented at a fixed level of 65 dB, whereas the speech level was adapted such that the speech reception threshold (SRT) was obtained. The S/N ratio is the difference between the noise level and the SRT. A difference of more than 1.7 dB between the 2 S/N ratios can be regarded as significant (P=.05).[10]

All the measurements were carried out in a double-walled sound-treated room. A loudspeaker that was placed 1 meter in front of the patient presented the tone and speech stimuli.

A 2-tailed *t* test was applied to analyze differences in the results between the initial and the present measurements with the BAHA. P<.05 was chosen as the level of significance. The results were computed using the SPSS software package (version 11.0; SPSS Inc, Chicago, Ill).

RESULTS

Questionnaire

All 27 patients filled out the questionnaire. They were still using their BAHA and wearing it for 7 days a week; 24 patients were using their BAHA for more than 8 hours a day, 2 patients for 4 to 8 hours a day, and 1 patient for 2 to 4 hours a day. In the study by Mylanus et al,[7] no questions were asked about daily use of the BAHA.

In the initial study, 9 (27%) of the 33 patients who filled out the Nijmegen questionnaire reported that it was a burden to take care of the skin around the implant. In the present study, 4 (15%) out of the 27 patients described this as a burden.

In the initial study, 32 of the 33 patients stated that the BAHA was better with regard to the occurrence of ear infections. In the present study, 15 (56%) of the 27 patients stated that they had not had ear infections in the past year, whereas the other 12 patients (44%) had ear infections. Two of these patients reported that they always had ear infections, while the

other 10 patients reported an average of 4.3 ear infections in the past year, ranging from 1 to 14 ear infections.
Owing to ear infections, 12 (44%) of the 27 patients had visited the otorhinolaryngologist in the past year. One patient (patient 8) had visited the otorhinolaryngologist for 20 times for this reason and another patient (patient 24), 10 times; the median number of visits was 2 in the past year.
In the initial study, 27 (81%) of the 33 patients had preferred the BAHA, 5 patients had preferred the previous air-conduction hearing aid, and 1 patient had regarded the 2 hearing aids as equal. In the present study, 24 (89%) of the 27 patients preferred the BAHA, 2 patients did not have an opinion, and 1 patient stated that he would like to use the previous air-conduction hearing aid again if possible. The latter patient explained that he preferred the air-conduction hearing aid because of its better sound quality and the capacity for finetuning.
Mean scores for speech recognition in the domains quiet, quality, and comfort were 7.7, 6.5, and 7.6, respectively. These scores were all classified as acceptable. The mean score for the domain noise was classified as poor, with a score of 5.0. An overview of these scores is given in Figure 1.

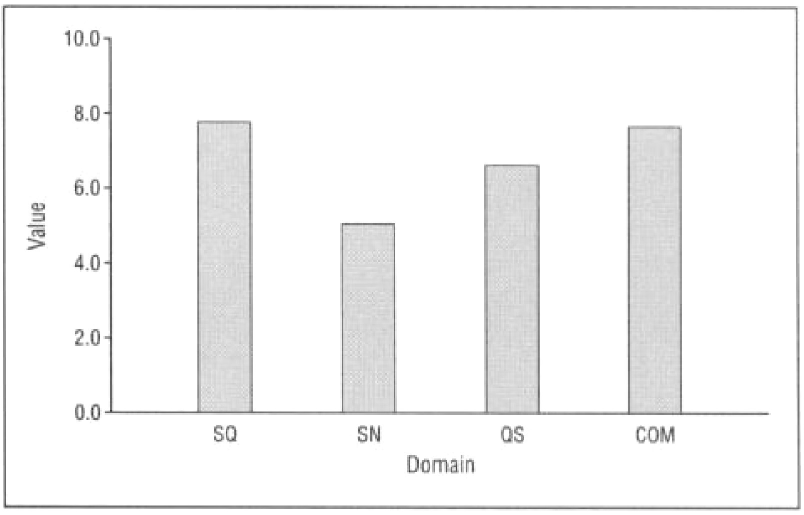

Figure 1. Mean scores on the domains: speech in quiet (SQ), speech in noise (SN), quality of sound (QS), and comfort (COM).

Audiology
In the initial study, all 34 patients participated in the audiological evaluation. In the present study, 23 of the 27 patients participated in the audiological part. More specific comparisons could be made between the

subgroup of 23 patients from the initial study corresponding to 23 patients in the present study.

Mean free-field thresholds obtained with the BAHA in the initial study and the present study are shown in Figure 2. In the initial study, the mean free-field thresholds at the frequencies 0.5, 1, 2, and 4 kHz were 37, 22, 24, and 34 dB, respectively (N=34). The subgroup of patients who participated in both audiometric studies (n=23) initially had about the same mean free-field aided thresholds as the total initial group (shown in Figure 2). At the second audiometric evaluation after a mean duration of follow-up of 9 years and 1 month, at the same frequencies, these mean free-field thresholds were 7 dB poorer.

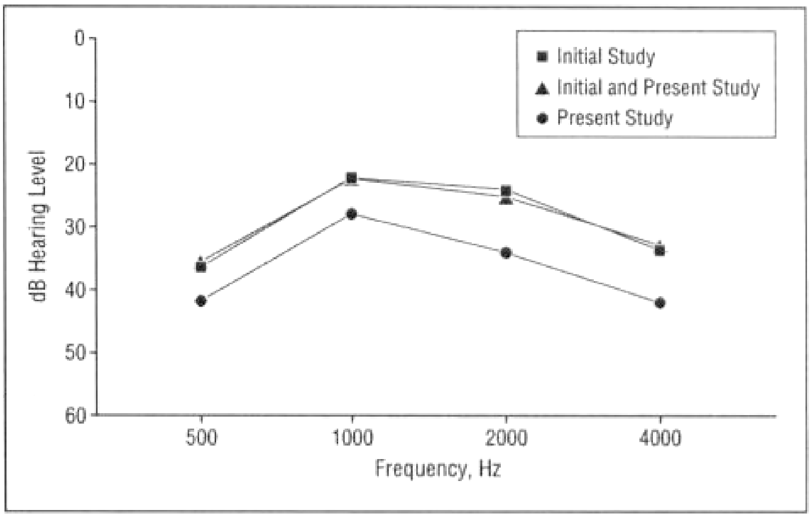

Figure 2. Mean aided thresholds with the bone-anchored hearing aid in the initial (N=34) and present (n=23) studies. Twenty-three of the patients participated in both the initial and present study.

The SQ score of 97% (N=34) in the initial study had decreased significantly to 86% (n=23) in the present study (P<.05). In the initial study, 16 (47%) of the 34 patients obtained an SQ of 100% vs only 2 (9%) of 23 patients in the present study. The SQ varied from 80% to 100% in the initial study (N=34) and from 26% to 100% in the present study (n=23). Using the paired sample test, the SQ in the present study (n=23) was compared with the SQ in the same patients in the initial study. In this subgroup, the mean SQ had decreased from 97% to 86%, which was statistically significant (P<.05).

Only 25 of the 34 patients in the initial study underwent signal-to-noise testing. Of these patients, 21 participated in the present study. This subgroup (n=21) is referred to as the second subgroup. The mean S/N ratio in the second subgroup had deteriorated from -2.0 dB in the initial study to –0.1 dB in the present study, which was statistically significant (*P*=.001). A difference of more than 1.7 dB between the 2 S/N ratios in each individual patient was considered significant (see "Methods" section). Eight patients (38%) showed significant deterioration in S/N ratio, and 1 patient showed significant improvement. Unfortunately, data of 2 patients had to be excluded because of problems with the equipment. The S/N ratio in the other 11 patients (52%) remained stable. Correlation analysis between the changes in the speech scores in quiet and in noise and the changes in mean aided thresholds over time showed poor correlations.

To assess whether cochlear function deteriorated over time, we compared the preimplantation and recent bone-conduction thresholds at the frequencies 0.5, 1, 2, and 4 kHz after correction with P50 values according to International Organization of Standardization norms. Per patient, the average change was calculated; averaged over patients, a mean ± SD deterioration of 5.9 dB ± 8.6 dB was found. Assuming that a change of 5 dB or less can be ascribed to measurement error, 11 of the 23 patients showed a significant deterioration, with a mean ± SD of 13.3 dB ± 4.8 dB (range, 8-23 dB). The remaining 12 patients showed a mean ± SD change of –0.9 dB ± 4.7 dB. A comparisson of these mean values and their standard deviations suggests that there are 2 well-separated subgroups: those with a stable cochlear hearing loss and those with a significant deterioration in cochlear hearing over time.

COMMENT

Over the past decades, the BAHA has proven to be of great value, and the indications for its application have extended widely, which is reflected in BAHA application in patients with unilateral conductive impairment and in BAHA CROS application in patients with unilateral inner ear deafness.[16-19] The pitfall in these new developments is that all the attention has focused on the new challenges encountered and we could lose sight of the long-term evaluation of the more conventional indications. In 1998, Mylanus et al[7] reported that the BAHA proved to be an effective hearing aid for patients with chronic otorrhea who have problems with the fitting of a conventional air-conduction hearing aid. To emphasize the clinical relevance of this conventional indication for the application of the BAHA, we studied the long-term effects of a BAHA in bilaterally hearing-impaired patients who had previously been using air-conduction hearing aids.

All the patients who had participated in the study by Mylanus et al[7] were invited for further follow-up, thus extending the mean duration of follow-up from 2_ to 9 years and 1 month. One outstanding observation was that all the eligible patients were still using their BAHA for 7 days a week. The 9 patients (27%) in the initial study who had trouble taking care of the percutaneous implant diminished to 4 (15%) in the present study, which means that some patients took longer to become acquainted with taking care of the BAHA. Various factors associated with the yearly checkups may have played a role in this slight progress because at these visits the skin around the implant is cleaned, the screw connecting the abutment to the fixture is, if needed, tightened, and additional information is given.

Another striking observation was the satisfaction of the patients with the BAHA, which was reflected in the fact that 24 patients (89%) gave preference to the BAHA. Two patients did not have an opinion on this subject, and only 1 patient stated that he would rather use the previous air-conduction hearing aid because of its sound quality and fine tuning. Nevertheless, this patient still uses his BAHA every day. Allowing a selective usage of the conventional air-conduction hearing aid in listening situations requiring more fine tuning, alternated with BAHA usage in other listening situations, may be a good solution for such a patient.

With regard to the second part of the questionnaire concerning speech recognition, the BAHA was classified as acceptable in the domains quiet, quality, and comfort. The domain noise, however, was classified as poor. This can be explained by the unilateral hearing aid rehabilitation having a bilateral hearing impairment.

The conventional indication for a BAHA implies the existence of chronic middle ear problems and the negative effect of the occlusion of the ear canal by an ear mold on the inflammation process. The number and severity of middle ear and ear canal problems were found to decrease substantially after the conventional air-conduction hearing aid (with its occluding ear mold) had been replaced by a BAHA.[7,8,20,21] In the present study, we only asked about the frequency of ear infections and otorrhea

over the past year. Owing to the risk of recall bias, we did not ask whether the frequency of ear infections and otorrhea was subjectively different from the frequency in the period of air-conduction hearing aid use.
In the previous year, 12 patients (44%) had experienced 1 or more episodes of otorrhea (average, 4.3 episodes). In view of this high prevalence of ear infections, it is concluded that several patients still had (intermittently) chronic middle ear problems. The BAHA might have a positive effect, but it does not prevent middle ear infections in all the patients. Unfortunately, but obviously, there are no objective and prospective data on which to draw conclusions about the frequency of ear infections if these patients had continued to use their conventional air-conduction hearing aid.
Realizing that all the patients had ear infections at the time of BAHA implantation (one of the indications for BAHA application), the present prevalence of 44% means a substantial decrease. Research has shown that chronic otitis media might lead to cochlear damage.[22-25] It has also been shown that the change from a conventional air-conduction hearing aid to a BAHA leads to a decrease in ear infections.[7,8,20] Thus, it might be hypothesized that the use of a BAHA (ie, diminishing ear infections by means of no longer occluding the ear canal) might contribute to preventing further cochlear damage.
In this study, preimplantation and recent age-corrected bone-conduction thresholds were compared with assess changes in cochlear function not related to aging in the ear, ipsilateral to the BAHA. Of the 23 patients, 11 showed a significant deterioration over time in cochlear function. The other patients showed no change; they had stable bone-conduction thresholds over the years, which might (again) be the indirect result of the change from a conventional air-conduction hearing aid to a BAHA. However, at present it can not yet be stated that the change from a conventional air-conduction hearing aid to a BAHA leads to more stable cochlear function, that is, no further increase in the sensorineural hearing loss component.
The free-field evaluations showed that, on average, the aided thresholds deteriorated by 7 dB. This might be ascribed to the deterioration in bone-conduction thresholds (a mean deterioration of 5.9 dB was found with P50 corrections and 12 dB without these corrections). It is expected that increasing the volume setting of the hearing aid can at least partially compensate for any deterioration in cochlear function. However,

apparently, this is not what the patients did. It should be noted that the limited functional gain (the difference between sound field thresholds and bone-conduction thresholds) that can be provided by a standard BAHA might have played a role.[26] Presumably, changing the standard BAHA for a body-worn BAHA (BAHA Cordelle) would have been beneficial for several of the present patients with deterioration in cochlear function.
On average, the SQ and S/N showed deterioration over time, which may have been the result of the deterioration in aided thresholds. However, correlations between the change in speech scores and the change in aided thresholds were poor, indicating that there must be at least 1 other factor. It is assumed that this is a device-related factor (variation in sound quality owing to aging of the device or owing to replaced, updated audio processors).

It can be concluded that the BAHA should be considered more often as a good option in the treatment of patients with chronic otitis media who need amplification or experience problems with their conventional air-conduction hearing aids. Patient outcome measures were very positive after a mean follow-up of 9 years and 1 month. Remarkably, most patients in this study did not show any significant deterioration in cochlear function over time (after corrections for age). Although larger and prospective series are needed to come to firm conclusions, it is plausible that this is a positive indirect effect of BAHA use. The ongoing deterioration of cochlear function in the other patients once more stresses that these patients are still at risk. There may be a strong preference not to use an air-conduction hearing aid with an occluding ear mold because it may evoke ear infections in an ear with an open access to the middle ear; thus, fitting a bone-conduction device like the BAHA, instead of air-conduction hearing aids for these patients may be the better choice.

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Unilateral and bilateral conductive hearing loss

Chapter 3

Does the Bone-Anchored Hearing Aid have a complementary effect on audiological and subjective outcomes in patients with unilateral conductive hearing loss?

Chapter 3.1

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ABSTRACT

Objective: To study the effect of a bone-anchored hearing aid (BAHA) in patients with unilateral conductive hearing loss.
Study design: Prospective evaluation on 18 subjects.
Methods: Aided and unaided binaural hearing was assessed in the sound field using a sound localization test and a speech recognition in noise test with spatially separated sound and noise sources. The patients also filled out a disability-specific questionnaire.
Patients: 13 out of the 18 subjects had normal hearing on one side and acquired conductive hearing loss in the other ear. The remaining 5 patients had a unilateral air-bone gap and mild symmetrical sensorineural hearing loss.
Results: Sound localization with the BAHA improved significantly. Speech recognition in noise with spatially separated speech and noise sources also improved with the BAHA. Fitting a BAHA to patients with unilateral conductive hearing loss had a complementary effect on hearing. Questionnaire results showed that the BAHA was of obvious benefit in daily life.
Conclusions: The BAHA proved to be a beneficial means to optimize binaural hearing in patients with severe (40-60 dB) unilateral conductive hearing loss according to audiometric data and patient outcome measures.

INTRODUCTION

Bone-anchored hearing aids (BAHAs) provide highly effective rehabilitation in patients with bilateral conductive or mixed hearing loss when middle ear surgery or conventional air conduction hearing aids are no longer an option.[1,2] The majority of these patients having bilateral hearing impairment accordingly fulfil the conventional indication for unilateral BAHA fitting and derive benefit from it. In view of the successful unilateral application of the BAHA to patients with bilateral hearing impairment, several studies have been performed on extended indications for BAHA application. For example, in the recent past, bilateral application of the BAHA has proved to be effective, particularly for binaural hearing.[3-5] Another challenge is set by the group of patients with one impaired ear and one ear with normal hearing. With regard to unilateral inner ear deafness, recent studies[6-9] have emphasized the impact of a BAHA as a contralateral routing of signal device to lift the head shadow effect and to improve quality of life. However, directional hearing could not be demonstrated in these patients with only one functioning cochlea.[9] In patients with unilateral conductive hearing loss and normal hearing in the contralateral ear, binaural processing might be restored with a BAHA placed at the side of the impaired ear, assuming that the two cochleae are functioning normally. Nowadays unilateral hearing loss is considered to have a great impact on auditory functioning in daily life and therefore requires intervention. In our society that makes heavy demands on communication, health professionals are facing increasing numbers of patients who experience communicative limitations in daily life. Therefore, health professionals are more inclined to look for solutions required for the detrimental effects of unilateral hearing loss. If, in patients with unilateral conductive hearing loss, binaural hearing cannot be restored by microsurgery and conventional hearing aid fitting is not successful then the option of a bone conduction hearing aid can be considered.[10,11] Mild unilateral conductive hearing impairment of about 40 dB can generally be rehabilitated successfully with a conventional air conduction hearing aid, but this approach does not provide sufficient benefit in patients with maximal conductive hearing loss.[12]

In a previous pilot study, the BAHA effectively improved directional hearing in 6 patients with an acquired unilateral air-bone gap.[11] To gain greater insight into the extent to which patients with unilateral conductive hearing loss can achieve binaural hearing, we extended our group to 18 patients. All these patients had an acquired unilateral air-bone gap, with air conduction thresholds that varied from 40 to 100 dB HL. Thirteen patients had two normal functioning cochleae and 5 patients in this group also had a mild symmetrical sensorineural hearing loss (e.g. presbyacusis). Audiometric evaluations were made and the patients gave their opinions about this special BAHA application in a Dutch version of the disability-specific questionnaire assessing binaural hearing introduced by Chung and Stephens.[13]

Table 1. Patient characteristics; age at the time of implantation is shown in years; months

Patient	Age	Ear	AC (BC) thresholds at different frequencies dB HL				Mean air-bone gap
			0.5 kHz	1 kHz	2 kHz	4 kHz	0.5–4 kHz
1	51;07	normal	15	15	10	5	55
		impaired	80 (15)	60 (0)	70 (15)	70 (30)	
2	38;04	normal	15	20	20	20	63
		impaired	65 (10)	65 (0)	80 (10)	75 (15)	
3	23;09	normal	20	5	0	5	40
		impaired	50 (5)	55 (0)	45 (15)	40 (10)	
4	54;00	normal	20	20	15	25	28
		impaired	45 (20)	45 (20)	45 (25)	65 (25)	
5	36;01	normal	15	10	5	15	55
		impaired	55 (5)	55 (0)	65 (15)	75 (10)	
6	34;08	normal	10	5	5	5	36
		impaired	70 (25)	55 (10)	55 (35)	40 (5)	
7	31;06	normal	10	10	5	15	63
		impaired	65 (0)	75 (0)	60 (15)	65 (0)	
8	44;02	normal	10	15	15	25	34
		impaired	60 (15)	65 (20)	50 (15)	35 (25)	
9	45;08	normal	5	10	10	15	68
		impaired	75 (10)	85 (15)	85 (25)	85 (25)	
10	51;07	normal	10	10	5	20	38
		impaired	50 (5)	50(5)	45 (15)	45 (15)	
11	33;06	normal	5	0	0	0	53
		impaired	65 (10)	70 (10)	65 (20)	65 (15)	
12	66;06	normal	20	10	15	35	41
		impaired	75 (15)	55 (5)	50 (25)	60 (30)	
13	16;02	normal	5	5	5	0	46
		impaired	65 (10)	55 (5)	45 (5)	65 (25)	
14	47;11	normal	30	25	30	40	58
		impaired	85 (20)	85 (25)	90 (50)	95 (50)	
15	53;04	normal	20	25	25	50	59
		impaired	95 (30)	80 (25)	55 (25)	80 (30)	
16	64;04	normal	25	20	30	30	36
		impaired	70 (30)	60 (25)	60 (45)	75 (45)	
17	39;04	normal	15	20	25	75	48
		impaired	65 (30)	80 (25)	85 (35)	95 (65)	
18	52;04	normal	25	10	15	65	51
		impaired	70 (20)	70 (20)	75 (30)	120 (60)	

AC = Air conduction; BC = bone conduction.

Patients 14–18 had mild symmetrical sensorineural hearing loss.

PATIENTS AND METHODS

Patients

The experimental group comprised 18 consecutive patients with (sub)normal hearing in one ear (further referred to as the normal ear) and acquired unilateral conductive hearing loss in the other ear. Implantations were performed in the period between October 1997 and July 2003. Patients had either bilateral normal cochlear function, defined as thresholds of better than 25 dB HL at 500, 1000 and 2000 Hz and better than 30 dB HL at 4000 Hz (patients 1-13), or mild symmetrical sensorineural hearing loss (patients 14-18) (table 1). Causes for the air-bone gap included: chronic otitis media, acquired unilateral atresia, or postcholesteatoma surgery. The mean air-bone gap averaged over the frequencies 500, 1000, 2000 and 4000 Hz was 48 dB. Four patients (No. 1-3 and 14) had also participated in our previous study.[11] Since the beginning of 2003, the BAHA headband has been offered to patients with unilateral conductive hearing loss for a trial period with the BAHA. Thus, patients 11-13 and 17 and 18 participated in the trial with the BAHA headband. During the trial period (until July 2003) there were no negative responses to the headband. Table 1 gives an overview of all the patients in our study group, including their air and bone conduction thresholds in the normal ear and impaired ear.

Audiometry

Pure-tone audiograms were obtained using standard procedures and equipment. Aided thresholds were measured with warble tones in the sound field, as described elsewhere.[11,14] During these measurements the normal ear was blocked with an earplug and earmuff, which led to attenuation of approximately 40 dB [11].

The same soundfield measurement procedure was used as in our previous studies on bilateral BAHA application and on BAHA in patients with unilateral air-bone gap among others. Sound localization was tested in the horizontal plane with a half circle (between _120° and 120°) of loudspeakers at intervals of 30°. The two outermost loudspeakers were included to avoid edge effects.[3] Stimuli consisted of short bursts of 1/3 octave filtered white noise, with either a 500- or 3000-Hz centre frequency. These frequencies were used because directional hearing is mainly based on the detection of interaural phase differences at 500 Hz, whereas at 3000 Hz, it is mainly based on the detection of interaural intensity differences. Stimuli were presented at 65 dB HL. After each burst, the patient was asked to indicate the loudspeaker that had produced the sound. No explicit training or feedback was given. The patients were not permitted to turn their heads during the measurements. Per presentation, the difference in azimuth (i.e. error) was determined between the position of the loudspeaker that had emitted the sound and the position of the loudspeaker indicated by the patient. The mean absolute error (MAE) per measurement condition (500 and 3000 Hz) was the outcome measure. Test-retest measurements have been performed in a previous study.[11] An increment of more than 16° can be considered as a significant change (on a 5% level).

Speech perception was measured with short, everyday Dutch sentences in accordance with the test developed by Plomp and Mimpen.[15] Speech reception thresholds (SRTs) were established using an adaptive tracking procedure. SRTs were measured in a quiet and a noisy listening condition. Speech was always presented by a loudspeaker in front of the patient, while noise was presented by a loudspeaker at either the left or the right of the patient. Therefore only the noise (not the speech) was influenced by head shadow. The noise level was fixed at 65 dB(A), as this is the overall level of normal conversation. The speech-to-noise ratio (S/N ratio) at which sentence recognition is 50% (SRT) is the critical S/N ratio as measured in our study. Each separate condition was measured twice and the results were subsequently averaged. In a previous study, the 95% confidence level for the change in the S/N ratio has been determined as ± 1.6 dB.[16] Therefore, a change in the S/N ratio (thus also the SRT) of 1.7 dB or more was considered to be statistically significant on a 5% level. The tests were carried out in a sound-treated, double-walled room at least 10 weeks after the BAHA had been fitted to give the patient time to adjust to the BAHA.

Patient outcome measures

The patients' opinions about their BAHA were obtained with the Dutch version of a the disability-specific questionnaire introduced by Chung and Stephens.[13] This questionnaire is one of the few that has been developed to gather patients' opinions about monaural versus binaural hearing. In order to avoid enthusiasm bias, the questionnaire was filled out when the patients had at least 6 months of experience with the BAHA. The options for answering were: one hearing aid, two hearing aids or no difference between one or two hearing aids. In the present application, these answers were changed to one BAHA (i.e. binaural), no BAHA (i.e. monaural) or no preference. The patients also answered questions on their (daily) usage of the BAHA and their satisfaction with the BAHA.

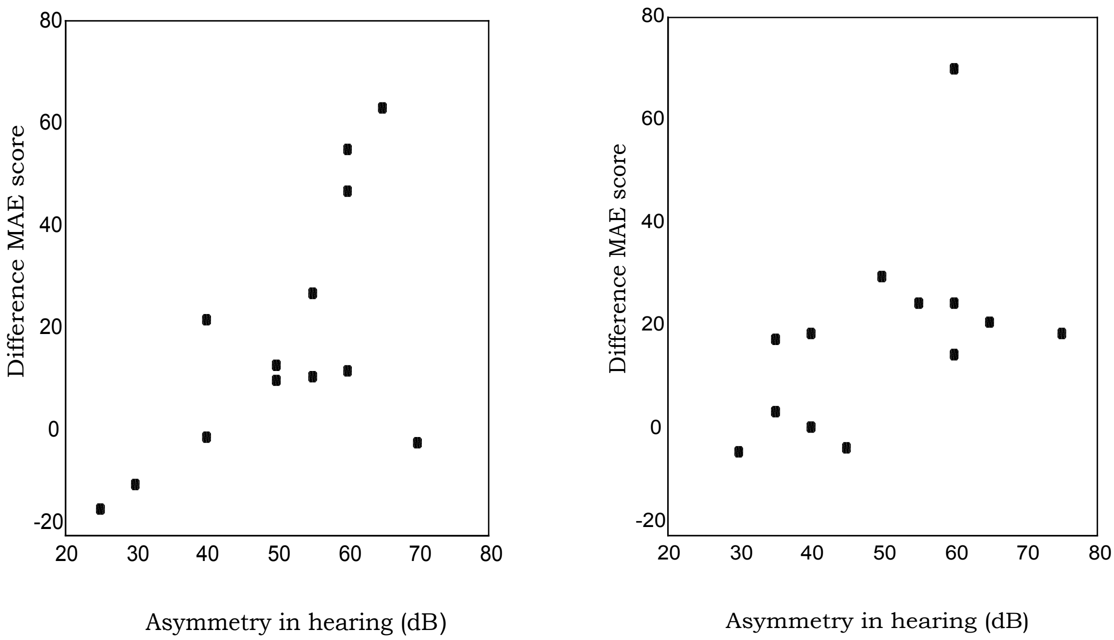

Figure 1a. Sound localization scores of the group with normal bilateral cochlear function (n = 13). Difference in MAE between the unaided and BAHA situation plotted against the asymmetry in hearing thresholds with <u>500-Hz</u> noise bursts. A better MAE score in the BAHA situation is denoted as a positive difference MAE score.

Figure 1b. Sound localization scores of the group with normal bilateral cochlear function (n = 13). Difference in MAE between the unaided and BAHA situation plotted against the asymmetry in hearing thresholds with <u>3000-Hz</u> noise bursts. A better MAE score in the BAHA situation is denoted as a positive difference MAE score.

RESULTS

<u>Patients with normal bilateral cochlear function (patients 1-13)</u>

Sound field measurements

The mean warble tone thresholds with the BAHA (while the normal ear was blocked) at the frequencies of 500, 1000, 2000 and 4000 Hz were 28, 18, 19 and 25 dB HL, respectively.

Sound localization

Figures 1a and b show the results of the unaided and aided sound localization experiments using with the 500-Hz (fig. 1a) and the 3000-Hz (fig. 1b) noise bursts (with the normal ear unblocked). The figures show the relationship between the difference in the unaided and aided MAEs (difference MAE score) and the difference between the air conduction thresholds of the impaired ear and the normal ear obtained at the same frequency (asymmetry in hearing). The difference in air conduction thresholds between the impaired ear and normal ear is considered an effective asymmetry (in hearing) and is comparable with the air-bone gap of the impaired ear in the unaided situation. This variable was chosen, because the largest effect of applying a BAHA was expected to coincide with the largest asymmetry in air conduction thresholds. Figure 1a (500-Hz noise bursts) shows that almost all patients had better MAE scores with the BAHA (i.e. positive difference MAE scores), independent of the preintervention asymmetry in air conduction thresholds. An improvement of 16° or more ($p = 0.05$) however, was seen in 5 of the 13 patients. All the other patients showed changes that were not statistically significant.

Figure 1b (3000-Hz noise bursts) also shows general improvement in MAE scores with the BAHA (i.e. positive difference MAE scores), independent of the preintervention asymmetry in air conduction thresholds (asymmetry in hearing). The best MAE scores are seen in patients with an air-bone gap of 50 dB or more. An improvement of 16° or more ($p = 0.05$) was seen in 7 of the 13 patients. The 2 patients with the poorest MAE scores at 500 Hz also showed the poorest scores in sound localization at 3000 Hz. On average, the patients improved by 18° in MAE score at both the 500- and the 3000-Hz noise bursts with the BAHA.

Speech recognition

Table 2 shows the SRTs in a quiet listening condition and with noise coming from either the side of the normal ear or the impaired ear. A normative study showed that the SRT of subjects with normal hearing in a quiet listening condition is almost 20 dB.[15] This value was not met by any of the patients in the unaided hearing condition, but the application of the BAHA had a significant positive effect in most of the patients. A significant improvement of >1.6 dB was seen in 9 of the 13 patients. A decrease in SRT means an improvement in speech recognition and is thus defined a positive outcome.

In the next listening condition, when speech was presented in front of the patient with noise coming on the side of the normal ear, most of the patients showed improvement in the S/N ratio with the BAHA. Eleven patients had an improvement of > 1.6 dB. On average, the S/N ratio increased by 3.1 dB for this subgroup, which is a significant increase ($p < 0.05$).

Table 2. SRTs in quiet

Patient	SRT results, dB			S/N results, position noise source					
				near normal ear, dB			near impaired ear, dB		
	mon	bin	change	mon	bin	change	mon	bin	change
1	29.1	27.2	1.9	–1.6	–6.7	5.1	–5.6	–7.3	1.7
2	33.7	29.5	4.2	0.6	–5.0	5.6	–9.0	–9.2	0.2
3	26.2	25.6	0.6	–7.6	–9.4	1.8	–9.0	–9.1	0.1
4	39.2	41.2	–2.0	–7.5	–7.4	–0.1	–7.9	–6.5	–1.4
5	35.3	31.6	3.7	–1.3	–1.2	–0.1	–4.9	–2.2	–2.7
6	29.7	27.3	2.4	–0.7	–2.8	2.1	–5.1	–5.7	0.6
7	37.6	35.4	2.2	–1.2	–3.6	2.4	–4.4	–4.4	0.0
8	41.6	38.3	3.3	–1.5	–5.6	4.1	–6.2	–7.6	1.4
9	32.1	27.5	4.6	–3.2	–6.2	3.0	–9.0	–9.0	0.0
10	31.7	32.2	–0.5	1.0	–3.2	4.2	–3.2	–3.5	0.3
11	26.0	22.1	3.9	–1.5	–3.9	2.4	–6.4	–7.3	0.9
12	42.0	37.9	4.1	0.2	–5.0	5.2	–3.2	–3.0	–0.2
13	26.8	26.1	0.7	–0.1	–4.6	4.5	–5.8	–4.6	–1.2
Mean			2.2			3.1			0.0
14	38.1	32.8	5.3	1.2	–2.8	4.0	–1.7	–1.2	–0.5
15	53.8	56.2	–2.4	–0.6	–2.0	1.4	–2.9	–5.6	2.7
16	32.0	30.3	1.7	0.0	–1.3	1.3	0.8	–1.9	2.7
17	41.0	37.1	3.9	–1.0	–1.4	0.4	–6.1	–2.6	–3.5
18	37.1	33.4	3.7	3.0	–0.2	3.2	–1.0	–1.0	0.0
Mean			2.4			2.1			0.0
Total mean			2.3			2.8			0.0

SRT with noise is shown as S/N, with position of noise source. Monaural (mon) for the unaided situation and the situation with the BAHA is termed as binaural (bin). Mon minus bin is denoted as change. Therefore, an improvement in speech recognition is always denoted as a positive outcome. Mean change scores are given for both the separate patient groups and the total group.

Patients with unilateral hearing loss do not usually experience much hindrance when their impaired side is exposed to noise. However, with the BAHA fitted to that side, the amplified noise might be bothersome. If a patient has no trouble understanding speech, in spite of amplified noise, then the score is expected to be around zero. In this last listening condition when speech was presented in front of the patient with noise on the side of the impaired ear, we found fairly wide interindividual variation (table 2). One patient showed significant deterioration of >1.6 dB, whereas 1 patient showed significant improvement of >1.6 dB. On average, the change in S/N ratio from unaided to a BAHA was 0.0 dB, i.e. not significantly different from zero.

Patient outcome measures

The first 2 questions of the disability-specific questionnaire introduced by Chung and Stephens concerned subjective satisfaction with the BAHA.[13] The greater proportion of the patients was satisfied with their BAHA. Nine patients were very satisfied, while 3 patients were satisfied. Only 1 patient (No. 4), with the smallest air-bone gap (table 1), was not satisfied. This patient unexpectedly showed an improvement of his hearing level after BAHA surgery, which will be described in the Discussion section. These improved thresholds are presented in table 1. This patient stopped using his BAHA, since he experienced insufficient benefit of it.

The next 3 questions concerned the (daily) usage of the BAHA. Nine patients were ‘always’ using their BAHA, which meant 7 days a week for at least 8 h a day. Two patients were using the BAHA 7 days a week for 4-8 h a day and 1-4 h a day, respectively. Another patient was using the BAHA 4 days a week for 1-4 h a day. The remaining patient had stopped using the BAHA (No. 4).

The next questions concerned several every day listening situations. Most of the patients gave preference to using the BAHA in these situations. An overview of these 7 questions and answers of the total group of patients is given in table 3. The first 3 questions concerned listening to speech in quiet: all of the patients preferred to use the BAHA. One patient (No. 3) indicated to experience no preference when having a conversation from a distance (over 6 m).

The next 2 questions concerned listening to speech in noise. Three patients found listening to speech in noisy situations easier without the BAHA (No. 4, 5 and 11). One patient found listening while being at a meeting, in church or theatre easier without the BAHA (No. 4).

There was one question on locating sounds. All the patients except for 1 (No. 8, no preference) preferred listening with the BAHA.

The last question concerned comfort: all patients except for 1 (No. 4, nonuser) found listening more comfortable with the BAHA.

Patients with mild symmetrical sensorineural hearing loss (patients 14-18)

Sound field measurements

The mean warble tone thresholds with the BAHA (while the normal ear was blocked) at the frequencies of 500, 1000, 2000 and 4000 Hz were 28, 22, 23 and 45 dB HL, respectively.

Sound localization

Figures 2a and b show the results of the unaided and aided sound localization experiments, using the 500-Hz (fig. 2a) and the 3000-Hz (fig. 2b) noise bursts (with the normal ear unblocked). The figures show the relationship between the difference in the unaided and aided MAEs (difference MAE score) and the difference between the air conduction thresholds of the impaired ear and the normal ear (asymmetry in hearing).

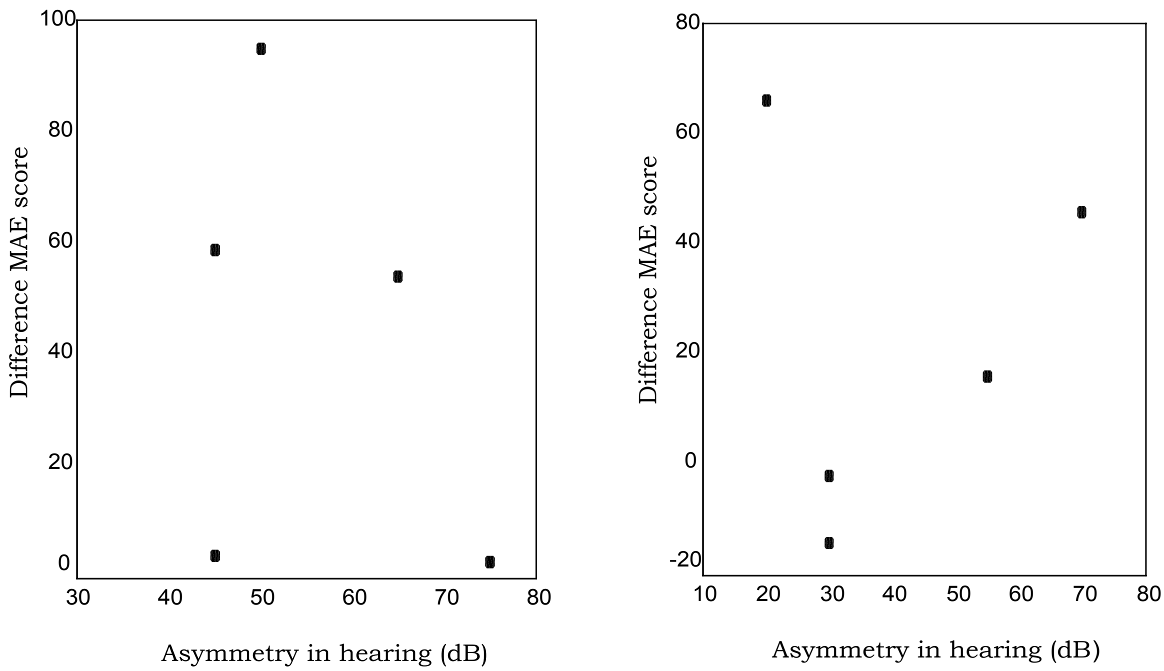

Figure 2a. Sound localization scores of the group with mild symmetrical sensorineural hearing loss (n = 5). Difference in MAE between the unaided and BAHA situation plotted against the asymmetry in hearing thresholds with 500-Hz noise bursts. A better MAE score in the BAHA situation is denoted as a positive difference MAE score.

Figure 2b. Sound localization scores of the group with mild symmetrical sensorineural hearing loss (n = 5). Difference in MAE between the unaided and BAHA situation plotted against the asymmetry in hearing thresholds with 3000-Hz noise bursts. A better MAE score in the BAHA situation is denoted as a positive difference MAE score.

Figure 2a shows that the MAE score of 3 out of the 5 patients improved significantly by more than 16° with the BAHA (i.e. positive difference MAE score). The sound localization measurements of 2 of the 5 patients showed little alteration with or without the BAHA: one had good localization abilities in both situations (low MAE), while the other had a high MAE of around 70°. Figure 2b (3000-Hz noise bursts) shows a significant improvement in the MAE scores of 2 patients with the BAHA. One patient showed non-significant improvement in MAE, while the other 2 patients showed non-significant deterioration in MAE. On average, the patients improved by 43° and 22° in MAE scores with the BAHA at 500- and 3000-Hz noise bursts, respectively.

Speech recognition

Table 2 shows the SRTs in quiet and noisy listening conditions and a decrease in SRT is defined a positive outcome.

Use of the BAHA had a significant effect on speech recognition in quiet in most patients. An improvement of >1.6 dB was seen in 4 out of the 5 patients. One patient (No. 15) showed significant deterioration of 2.4 dB.

In the next listening condition, when speech was presented in front of the patient with noise on the side of the normal hearing ear, 2 out of the 5 patients had significantly improved S/N ratios with the BAHA, the other 3 had a nonsignificant improvement. On average, the S/N ratio increased by 2.1 dB.

In the last listening condition, when speech was presented in front of the patient with noise on the side with the impaired ear, the S/N ratio is expected to be zero within measurement error. Table 2 shows that only 1 patient experienced significantly more difficulty in understanding speech with the BAHA when noise was presented on the impaired side (No. 17). In 2 out of the 5 patients the S/N ratio improved significantly. Two patients did not experience any discomfort or benefit with the BAHA in this specific listening situation. On average, the change in S/N ratio from unaided to a BAHA was 0.0 dB.

Patient outcome measures

The first 2 questions concerned subjective satisfaction with the BAHA. Three of the patients were very satisfied, while 2 patients were satisfied.

Concerning the questions about the (daily) usage of the BAHA, 4 patients were ‘always’ using their BAHA, which meant 7 days a week for at least 12 h a day. One of the 5 patients was using the BAHA 'regularly' (No. 14), which meant 3 days a week for 6 h a day. According to questions presented in table 3, most of the patients gave preference to using the BAHA in several everyday situations. Three of the questions concerned listening to speech in quiet: all of the patients gave preference to the BAHA. Only 1 patient (No. 15) experienced no difference with or without the BAHA when having a conversation from a distance (of over 6 m). Two questions concerned listening to speech in noise: all of the patients gave preference to using the BAHA. There was 1 question on locating sounds. Again, all of the patients answered to prefer the BAHA. The last question concerned comfort: all of the patients found the BAHA comfortable to wear. An overview of the 7 questions and answers of the total group of patients (concerning every day listening situations) is given in table 3.

Table 3. Results of questions 6–12 in the questionnaire

	BAHA	No BAHA	No preference
When you are listening to speech in quiet situations involving 1 or 2 persons, do you find listening easier using:	18	0	0
When you are listening to TV, radio, or compact discs, do you find listening easier using:	18	0	0
When you are listening to a conversation from a distance (over 6 m), do you find listening easier using:	16	0	2[a]
When you are listening to speech in noisy situations, do you find listening easier using:	15	3[b]	0
When you are at a meeting, church or theatre, do you find listening easier using:	17	1[c]	0
When you have to locate sounds, e.g. car horn, do you find listening easier using:	17	0	1[d]
When you are listening, do you find it more comfortable (more relaxed and easier) using:	17	1[c]	0

[a] No. 3 and 15.
[b] No. 4, 5 and 11.
[c] No. 4.
[d] No. 8.

Total group of patients (N=18)

Most patients showed significant improvements in sound localization and/or speech recognition in noise. The average improvements in MAE scores in the total group were 25° and 19° at 500 and 3000 Hz, respectively. The average improvement in SRT in the quiet listening condition was 2.3 dB. When noise was presented on the side with the normal hearing ear, the average improvement in the S/N ratio in the total group was 2.8 dB. With the noise on the side of the impaired ear, the average change in the S/N ratio was 0.0 dB. On an individual level, the results of these tests were condensed into an overall score, described as the summed number of 'positive' outcomes on the 5 tests (sound localization at 500 Hz and at 3000 Hz, speech recognition in quiet, speech recognition with noise on the normal side or on the impaired side). A 'positive' outcome is defined as a significant improvement at the 5% level. Three out of the 18 patients had a positive outcome on all 5 tests; 4 patients had a positive outcome on 4 out of the 5 tests; 3 patients had only 1 positive outcome, while 1 patient had a score of 0 (No. 4). In total, 14 out of the 18 patients had a positive outcome on 2 or more tests.

DISCUSSION

In general, the BAHA produced encouraging results in patients with a unilateral conductive hearing loss. The results of the present study confirm our previous study results.[11] The majority of the patients showed significant improvement on at least 3 of the 5 audiological tests. Most patients gave positive answers to the questionnaire (table 3). However, if we take a closer look at the audiological results on an individual level, we see wide variation. Sound localization abilities in the total group of patients (n=18) showed improvement with the BAHA by an average of 25° and 19° with the 500-Hz and the 3000-Hz noise bursts, respectively. Eight patients showed significant improvement with the 500-Hz noise bursts and 9 patients showed significant improvement with the 3000-Hz noise bursts. However, 2 patients showed deterioration in MAE, 1 of whom was no longer using his BAHA. This patient (No. 4) is described below. Remarkably, these 2 patients already had a low (thus profitable) MAE in the unaided situation. The finding that some patients with unilateral conductive hearing loss are able to localize sounds rather adequately in the unaided situation is an interesting one, but it is not unique.[17] Apparently some patients are able to cope with the asymmetry in hearing thresholds concerning sound localization.

In the majority of patients (72%), SRTs in the quiet listening situation were significantly better with the BAHA. This result can be ascribed to central summation of the speech by two cochleae. This underlines the suggestion that the transcranial attenuation of cranial vibrations is sufficient to enable different inputs to the two cochleae.[16,18] On an individual level, 2 patients showed significant deterioration in SRTs (No 4 and 15).

Speech recognition in noise improved significantly in most patients (72%) with the BAHA when noise was presented on the side of the normal hearing ear. In 3 of the 18 patients (16%), there was little or even no change in SRTs. This situation in which noise was presented to the normal side is normally unfavourable for monaural listening, especially to identify speech in noise. This shows that the use of the BAHA resulted in better listening, i.e. binaural listening (mean improvement of 2.8 dB), as apparently the patients were able to use the aided ear effectively at the shadow side of the head. Given that a change of 1 dB in the S/N ratio equals a change of about 17% in sentence recognition[15], the mean improvement in sentence recognition amounts to 47%, which is considerable.

When noise was presented on the side of the impaired ear, it is possible that the noise amplified by the BAHA would interfere with understanding the speech coming from the front. In most of the patients, there was little or no change in understanding speech when the noise was presented on the impaired side with or without the BAHA (mean change in S/N ratio was 0.0 dB). Two out of the 18 patients experienced a significant negative effect wearing the BAHA in this specific situation (No. 5 and 17). These 2 patients had also poor scores in the other speech in noise situation. Unexpectedly, 3 patients showed a significant improvement in understanding speech when noise was presented to the side of the impaired ear and the BAHA (No. 1, 15 and 16). In a previous study, we showed that release from masking is possible in patients with bilateral conductive hearing loss using bilateral BAHAs. This was concluded from binaural masking level difference tests with low frequency tones, presented via the audio inputs of the BAHA.[3] It might be argued that the improvements in these 3 patients is caused by release from masking, assuming that the normal hearing ear perceives the noise and speech, while by means of the BAHA primarily the noise is heard. An internal comparison of the noise inputs of the two ears might enhance speech perception. Whether these 3 patients had some kind of release from masking, however, is not clear. Especially, no further evidence was found for the fact that only these 3 patients had a beneficial outcome in this measurement. Based on these observations it can be assumed, there is not only a wide intersubject but also a wide intrasubject variation, probably based on a coincidence. This finding underlines the necessity of expanding the number of patients for further additional evaluations (e.g. binaural masking level difference measurements) on a more individual level to draw firmer conclusions.

Patient outcome measurements showed overall satisfaction with the BAHA. The majority of patients were using their BAHA 7 days a week for more than 8 h a day. Almost all the patients gave preference to using their BAHA in quiet listening situations. The majority of the patients (88%) stated to prefer their BAHA when listening to speech in noisy situations. Only 3 of the 18 patients gave preference to listening without the BAHA in noisy situations. One of these patients was No. 4 who stopped using his BAHA. It should be noted that the repeated pre-operative audiometric evaluations of this particular patient showed 65 dB hearing impairment with a sensorineural component of 20 dB. After implantation, this patient proved to be disappointed since he was not experiencing enough benefit of the BAHA. Repeated audiometric measurement showed an improvement of his hearing level. These audiometric data are used in this study and shown in table 1. This case probably illustrates that there is a need for a sufficient large air-bone gap to let the patient have a positive outcome, as binaural interaction is likely present if the ears differ 25 dB or less.[17]

In conclusion, it can be stated that in general patients with an acquired unilateral air-bone gap benefited from using the BAHA. This was not only reflected in the audiological results, but also in the patients' opinions. These results provide encouragement to continue to employ the BAHA to rehabilitate patients with unilateral conductive hearing loss.

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Horizontal directional hearing in subjects with unilateral conductive hearing loss

Chapter 3.2

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ABSTRACT

Objective: To evaluate horizontal directional hearing in patients with unilateral conductive hearing loss.
Study design: Retrospective study.
Methods: Participants comprised eight successive patients with severe to maximal unilateral conductive hearing loss, fitted with a BAHA (bone-anchored hearing aid). Aided and unaided horizontal directional hearing was studied at least one year after BAHA fitting. To explain the good unaided performance of a proportion of the patients, loudness differences due to acoustic head shadow were minimized by varying the stimulation level at random. Measurements were also recorded in low and high reverberant rooms and with the pinna of the normal hearing ear molded with wax. The subjects filled in a special questionnaire.
Setting: Tertiary referral centre.
Results: Several patients had fairly good unaided directional hearing. Eliminating the positive effects of attenuation due to head shadow, changing the room acoustics and wax molding the pinna of the normal ear had no effect. Improvement in horizontal sound localization was found with the hearing aid; the degree depended on the unaided scores. The BAHA improved spatial hearing significantly according to the answers to the questionnaire.
Conclusions: Objective and subjective spatial hearing data were partly conflicting. The mechanism behind the fairly good unaided horizontal localization abilities of several patients could not be explained by the experiments that manipulated monaural sound cues.

INTRODUCTION

Unilateral conductive hearing loss (with a contralateral normal ear) may involve the typical problems associated with unilateral hearing, such as poor sound localization and poor speech recognition in noise.[1] Similar problems occur in subjects with normal hearing when one ear is plugged.[2,3] However, it has been suggested that humans can adapt to unilateral hearing loss in the long-term (at least concerning directional hearing), but published data are not conclusive.[3-5]

In a review of the literature, Colburn concluded that permanent unilateral conductive hearing loss led to impaired binaural hearing in the majority of patients.[5] Near-normal results were only found in a minority of such patients and only on interaural intensity discrimination tasks. Another interesting study in this respect was performed by Wilmington et al.[6] They measured binaural hearing skills in patients with unilateral congenital conductive hearing loss before and after successful reconstructive surgery. They found, on a group level, a significant improvement in localization abilities. However, the patients' scores were still poorer than those of the normal hearing subjects. Remarkably, about one third of their patients already had a fairly good score before surgery. Significant improvements in other binaural listening tasks were also observed after surgery, but the results were poorer than those in controls with normal hearing. The short follow-up period might have played a role. Snik et al. also studied patients with unilateral conductive hearing loss more than one year after successful surgery.[7] The patients underwent a binaural summation test and a binaural fusion test; on average, their results were normal.
From this it can be deduced that in patients with permanent severe unilateral conductive hearing loss in whom reconstructive surgery is not likely to be successful, the application of a hearing device is an option. The question is whether such patients will benefit sufficiently from amplification to enable binaural hearing.

Markides reported that fitting a hearing aid was not beneficial in patients with severe unilateral conductive hearing loss.[4] Since then, a few papers have been published on this issue. Recently, Wazen et al.[8] and Snik et al.[9] have shown the opposite: subjectively, most of their patients with unilateral conductive hearing loss were satisfied or very satisfied with their hearing device. Snik et al. showed that directional hearing improved significantly in most cases. However, in agreement with the above-mentioned studies[2,6] a subgroup of patients already had fairly good directional hearing abilities in the unaided condition.

Recently, there has been new focus on the application of a hearing aid to patients with unilateral conductive hearing loss, because of the success of the BAHA (Bone-Anchored Hearing Aid).[10] In these patients, fitting an air-conduction hearing aid is often contraindicated or not possible owing to the underlying problem, viz. a chronic draining ear or atresia of the ear canal. Then, a bone-conduction device is a good option. The BAHA is the only bone-conduction device that does not need to be fitted by means of a spectacle frame and, most importantly, the microphone is located in the same housing as the amplifier and transducer, i.e. the microphone is on the same side of the head as the impaired ear (in contrast with the conventional bone-conductor behind-the-ear devices). It has been shown that in audiological terms, the BAHA outperforms conventional bone-conductors.[10,11] This is of the utmost importance in patients with unilateral hearing loss so that the aided ear can cooperate effectively with the other ear that has normal hearing.

Lately, Hol et al. have studied the application of the BAHA to such patients.[12] One of their results concerned directional hearing. They reported that after 6 weeks of device use, on a group level, sound localization improved significantly when using the BAHA. However, variations on an individual level were large. One reason was again the observation that a considerable number of their patients already had a significant score in the unaided condition, despite the asymmetry in hearing between the two ears (which was between 40 and 65 dB).

In the case of unilateral conductive hearing loss, both cochleae are stimulated. The cochlea of the normal hearing ear is stimulated by the air- and bone-conduction signals of that ear, while the cochlea of the impaired ear is stimulated by the crossover bone-conduction signal of the normal hearing ear. Moreover, depending on stimulus level, small air- and bone-conduction signals from the impaired ear will reach this cochlea. However, the asymmetry is large, and for the low-intensity stimuli, only signals from the normal hearing ear will reach both cochleae. The proportions of the crossover components are unknown and may be important in localization performance.

When a patient with unilateral conductive hearing loss is wearing a BAHA, the situation is different. The cochlea of the hearing impaired ear will be mainly stimulated by the BAHA-signal (besides the smaller above-mentioned signals), and the cochlea of the normal hearing ear will also receive a large crossover component from the BAHA-signal. Despite the large crossover component, which makes the situation different from the binaural hearing in a normal hearing listener, the patient receives input from both ears and will probably be able to use binaural cues for sound localization. However, it is unknown to what extend the crossover component of the BAHA signal will disturb localization performance. In both unaided and aided situation, the stimulation at each cochlea as a result of bone conduction (head shadow) is unknown.

Assuming that, in the unaided situation, binaural hearing is not possible or at least not effective with such asymmetry, these patients have apparently learned to deal more effectively with monaural sound cues than subjects with normal hearing. Head shadow and other acoustic cues might play a role. Van Wanrooij and Van Opstal showed that although unilaterally deaf patients relied heavily on the head-shadow effect to localize sounds in the horizontal plane, some of these patients extracted azimuth information from their pinna cues.[13]

The aim of the present study was to evaluate the effect of (possibly) minor monaural cues on directional hearing in the patients in the previous studies who had unaided directional hearing scores that were significantly above chance level. Three hypotheses were formulated to explain how these patients might localize sounds:

1. These patients make more effective use of the loudness differences due to acoustic head shadow than normal, also in the case of low-pitched sounds. Measurements have shown that the attenuation owing to head shadow is pronounced at the high frequencies, but not absent at the low frequencies (in the 0.5 to 1 kHz range, it is around 5 to 10 dB, with source directions of 30^0 azimuth or more).[14] To test this hypothesis, directional hearing measurements were recorded while the stimulus levels were varied at random, eliminating loudness as a cue.
2. These patients make use of room acoustics, such as reverberation cues, by comparing the initial direct sound-field and early reflections.[15] The perceived difference between the direct sound and the reflected echo can serve as a cue. To test this hypothesis, measurements were recorded in high and low-reverberant rooms.
3. These patients make more effective use of pinna effects than expected (pinna effects are most pronounced in the high frequency domain and essential for localization in the vertical plane and anterior-posterior plane). To test this hypothesis, measurements were repeated after the pinna of the normal ear had been made ineffective by molding it with wax.

A small monaural cue that we did not investigate is the spectral head shadow effect. However, as far as we know, no indications are ever found that this cue can contribute to sound localization. Moreover, if this small effect could help, it would only be useful in localizing familiar stimuli, and, because of diffraction, for high frequency stimuli.

To assess the benefit experienced by the patients, they filled in a recently developed questionnaire.[16] This questionnaire, called the Speech, Spatial and Qualities of hearing scale (SSQ), focuses specifically on hearing functions that are presumed to be of importance to binaural hearing. Noble and Gatehouse administered the questionnaire to 50 patients with asymmetrical mild to severe hearing loss who did not have any experience with hearing aids.[16] Surprisingly, they found that spatial dysfunction drove the handicap more powerfully than other dysfunctions, such as impaired speech understanding and they suggested that disabled spatial hearing might lead to uncertainty or even anxiety. These findings emphasize the importance of hearing aid fitting to deal with asymmetrical hearing.

SUBJECTS AND METHODS

Subjects

The first 10 successive patients who had participated in the previous study were approached for this investigation.[12] One patient had stopped using the BAHA because of insufficient benefit and one patient refused to participate. The remaining 8 patients had normal hearing in one ear (thresholds of 25 dB HL or better from 0.5 to 8 kHz) and pure conductive hearing loss in the other ear. In all the cases, the cause of the air-bone gap was a chronic draining ear that was resistant to medical therapy. All patients had conductive hearing loss for at least five years. The participants had been using their BAHA regularly for more than one year. All patients were familiar with the localization experiments, as they all participated in the previous study.[12] No specific training was given for the present measurements.

Measurements were repeated on a subgroup of 5 patients who were selected on the basis of good unaided performance on the first directional hearing tests at one or both test frequencies. Table 1 presents some audiometric characteristics of this subgroup and the three non-selected patients.

Table 1. Some audiometric data on the selected and non-selected patients

patient	age	PTA ac NE	PTA ac IE	PTA bc IE	PTA ac IE – PTA ac NE	selected
P1	28	8	48	8	40	yes
P2	47	10	86	19	76	yes
P3	37	6	55	19	49	yes
P4	34	10	66	4	56	yes
P5	53	11	48	10	37	yes
P6	42	24	71	9	47	no
P7	57	11	70	15	59	no
P8	46	16	53	19	37	no

PTA = mean threshold at 0.5, 1, 2 and 4 kHz in dB HL; ac = air-conduction; bc = bone-conduction; NE = normal hearing ear; IE = impaired ear.

For comparison purposes, a reference group was added that comprised 6 subjects with normal hearing in both ears (thresholds of 20 dB HL or better, 0.5 to 8 kHz). Measurements were performed after one ear had been temporarily blocked with an earplug. Attenuation, assessed with sound-field measurements, varied from 30 dB for 125 Hz stimuli to 50 dB to 4 kHz stimuli. Afterwards, the measurements were repeated without the earplug, i.e. in the normal binaural listening condition.

METHODS

Stimuli

Horizontal sound localization of low frequency sounds is mainly based on the detection of interaural time differences (up to about 1.5-2 kHz). In the case of high frequency sounds (above roughly 1.5 kHz), it is based on the detection of interaural level differences. Therefore, the directional hearing experiments were carried out with high (3 kHz) and low frequency (0.5 kHz) narrow-band (1/3 octave) stimuli. Stimuli were generated at levels of 40, 50, 60 and 70 dB SPL. Duration of each stimulus was 1 s.

Setup

Directional hearing was tested in three different rooms (see '*Experiments*') with different acoustics. A crucial point was whether the patient was seated in the direct sound field or in the reverberation field. The critical distance, or the reverberation radius, is the distance at which the reverberant field overcomes the direct field. Table 2 presents the calculated critical distances and the ratio between the actual distance between the patient and the sound source and the critical distance. A ratio of less than 1 meant that reverberation was of minor importance, i.e. the patient was seated in the direct sound field. A ratio of clearly more than 1 meant that the patient was seated in the diffuse reverberation field.

Table 2. Critical distances (or reverberation radii) and the ratio between the real subject-sound source distance and the critical distance, in the low, medium and high reverberant rooms

	critical distance (m)		ratio real/critical distance	
	0.5 kHz	3 kHz	0.5 kHz	3 kHz
low reverberance	1.2	5.3	0.83	0.19
medium reverberance	0.72	0.73	1.8	1.8
high reverberance	0.41	0.31	3.2	4.2

Room 1

Most measurements were recorded in a standard sound-treated double-walled booth (medium reverberance) equipped with 9 loudspeakers at 30^0 intervals, from azimuth -120^0 to $+120^0$. The radius was 1.3 m. The subject was seated in the centre. Per frequency, the stimuli were presented 4 times by each of the 9 loudspeakers in a quasi-random order. All speakers were labeled and subjects had to mention the loudspeaker that they believed the sound had originated from. The subjects were not allowed to move their head. The experimenter could watch the subject through a window to verify that the subject was not moving the head during stimulus presentation.

Room 2

The high reverberance room was created by attaching wooden panels against the walls and ceiling of the sound booth. This caused a large reduction in critical distance (see Table 2), meaning that the number of reflections increased. The measurement method remained unaltered.

Room 3

The low reverberance room was a completely dark, sound-attenuated and echo-free room in which the walls, the ceiling and all large objects were covered with acoustic foam. The critical distance of this room was much larger (see Table 2), meaning that the subject was seated in the direct sound field. In this room stimuli were delivered through a speaker on a two-link robot from 7 different positions from -90^0 to 90^0 at 30^0 intervals. Since the subject had no knowledge about the speaker positions in this room, there were no edge effects, so the two extreme positions (-120^0 and 120^0) could be omitted in these experiments. Each trial started with a central fixation stimulus (a LED) after which the sound stimulus was presented. After presentation of the sound stimulus the subject was supposed to redirect the head toward the apparent sound direction. Head movements were recorded with a magnetic head coil system (for a more detailed description of this system, see Van Wanrooij and Van Opstal[13]). Figure 1 shows an example of recorded head movements (azimuth and elevation) during one trial. Head movements were displayed real time on a monitor, which enabled the experimenter to verify that the subject did not make any head movements during stimulus presentation.

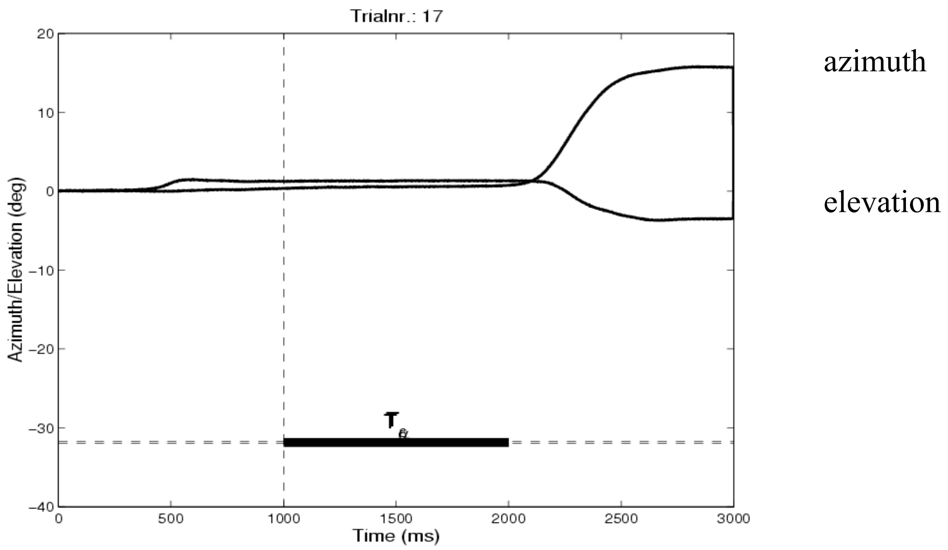

Figure 1. Example of a head-coil output signal (of subject P2). Both the horizontal and vertical head position signals are shown. The thick horizontal line shows when the target was on. Note that no head movements were made during stimulus presentation.

Analysis

In each condition, the angle was noted between the loudspeaker that the subject pointed to and the loudspeaker that had presented the sound. To deal with edge effects, we deleted the identifications of sounds presented by the loudspeakers at $+120^0$ and -120^0. The outcome measure was the mean absolute error in localization (MAE). Perfect localization resulted in an MAE of 0^0, whereas random guessing resulted in an MAE of 80^0. The intra-individual standard deviation of the MAE determined with test-retest measurements was found to be 8^0.[9]

Experiments

To test the three hypotheses several localization experiments were performed. All measurements were carried out in the unaided condition and with the BAHA (unplugged and plugged for the normal hearing controls) and with both 0.5 and 3 kHz stimuli. In none of the experiments, feedback was given.

To start with, the measurements were recorded with a fixed presentation level of 60 dB SPL in room 1. Then, to test the first hypothesis, the measurements were repeated in the same room, but with the presentation level varied between 40 and 70 dB SPL (in 10 dB steps). Instead of presenting each stimulus 4 times by each loudspeaker at a fixed presentation level, the stimuli were presented at 4 different presentation levels by each loudspeaker in a quasi-random order. All 8 patients participated in these measurements.

Remeasurements were carried out on the 5 selected patients on another day. To test the second hypothesis, the measurements with varying presentation level (see above) were repeated room 2 and room 3, with high and low reverberance, respectively (see Table 2).

To test the third hypothesis, the pinna of the normal ear was molded with wax to minimize possible pinna effects. The wax molding changed the pinna shape and thus the spectral cues due to the shapes of the pinna, without occluding the ear canal. Measurements with varying presentation level and the wax-molded pinna were recorded in the low reverberance room.

The subjects with normal hearing only participated in the experiments with constant presentation level of the stimuli.

SSQ

To assess the subjective benefit of the BAHA in daily life, the patients filled in a Dutch version of the SSQ questionnaire.[16] This questionnaire evaluates hearing disability across three domains: speech hearing, spatial hearing and other qualities. As we were primarily interested in spatial hearing, we decided not to use all three categories. Instead, we used spatial hearing and speech hearing that is also closely related to binaural hearing. Each patient received two questionnaires to be filled in at home. The two questionnaires were to be filled in for their hearing situations with and without the BAHA respectively. This enabled us to study subjective benefit in daily life.

RESULTS

Figure 2 shows the individual MAE values of the patients with the 0.5 and 3 kHz stimuli in the aided and unaided conditions. The presentation level was fixed at 60 dB SPL. For reference purposes, the mean data from the controls with normal hearing are also presented in this figure. In the control group, “unaided” meant the situation with one ear blocked, while “aided” referred to the normal binaural listening situation. There was wide spread in the patients’ results. The figure shows that the unaided scores of several patients were clearly better than chance level and clearly below the average level of the controls (which was around chance level). However, this did not apply to all the patients. Considering the aided (binaural) situation, all patients and controls showed scores significantly below chance level. When the aided and unaided situations were compared, not all patients showed significant improvements at both frequencies (i.e. changes in MAE of greater than two standard deviations or 16^0). The degree of improvement in the aided situation depended on the unaided scores, since patients with poorer unaided scores showed more improvement. For both the unaided and the aided situation, subjects performed slightly better in the experiments with high frequency stimuli.

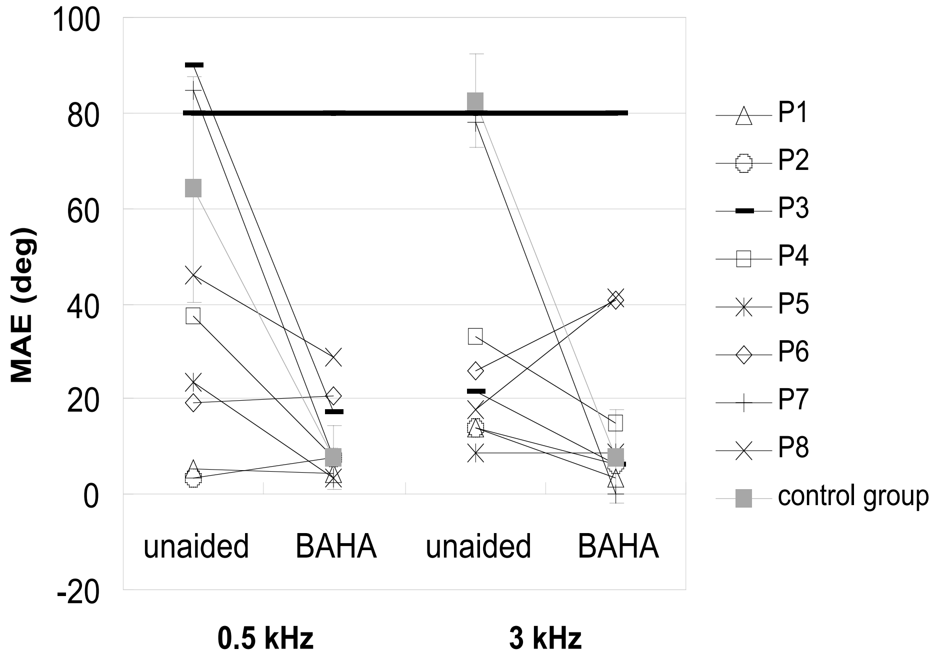

Figure 2. MAE-values of the experiments with stimuli with fixed presentation level. Results for the unaided (monaural) and BAHA (binaural) conditions are shown for both monaural patients and control subjects. MAE-values are shown for 0.5 and 3 kHz stimuli in both unaided and BAHA conditions. The thick horizontal line again depicts chance level. Note that several patients have fairly good unaided scores, while the controls' performance is about chance level (thick horizontal line).

To exclude loudness differences due to acoustic head shadow as a cause for the favorable unaided scores, presentation levels of the stimuli were varied at random. One of the patients (P6) could not participate in these measurements due to time restrictions. Figure 3 shows the results for the 7 remaining patients. Figures 2 and 3 look rather similar. Paired t-tests on the unaided scores obtained with the constant and variable presentation levels showed a minor change in favor of the first condition (0.5 kHz, a mean change of 5.1^0; t=1.95, non significant, and 3 kHz, a mean change of 8.0^0; t=2.58, p=0.04). Several patients showed good unaided scores in the experiments with variable presentation level. All patients showed aided scores far below chance level. Again, patients with poorer unaided scores achieved the largest improvements. Some patients (e.g. P1, P2) were, even with variable presentation level, performing at normal hearing binaural performance level in the unaided situation, so for them, there was no room for improvement in the aided condition.

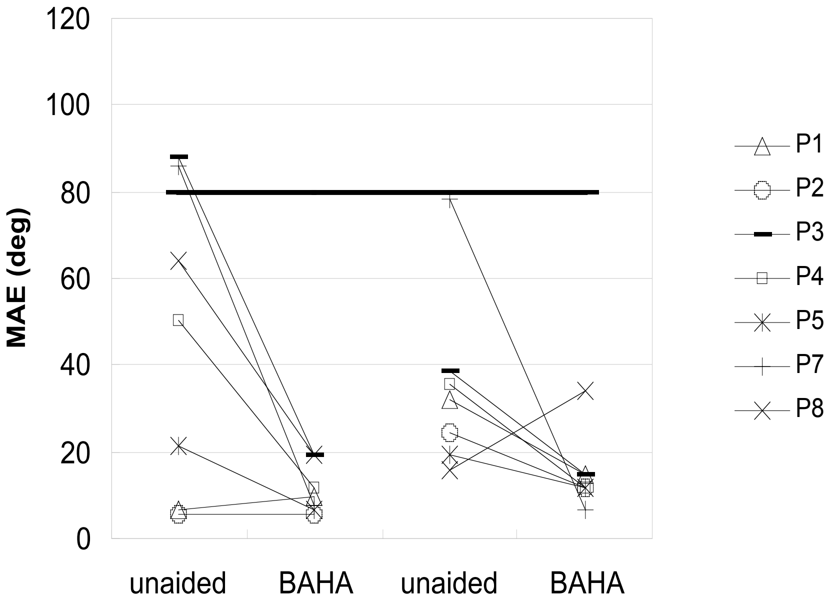

Figure 3. Results for the measurements with variable stimulus presentation levels. MAE-values are shown for 0.5 and 3 kHz stimuli in both unaided and BAHA conditions. The thick horizontal line again depicts chance level. Note that several patients still perform significantly below chance level in the unaided condition.

Figure 4 shows MAE data obtained from one patient (P2) in the rooms with high, medium and low reverberation, including the measurements with the wax-molded pinna in the low-reverberant room. As can be seen, the different experimental conditions did not influence MAE-value markedly. The same holds for the other 4 selected patients; localization performance did not change by different room acoustics or wax molding pinna (data not shown). Paired t-test did not show any significant changes in the unaided and aided conditions between the low vs. high reverberant room or the normal vs. wax-molded pinna. Changing room acoustics and manipulating pinna filtering did not affect the subjects' localization performance.

Next, the MAE of all patients was calculated as a function of the presentation level. For this calculation, the measurements obtained in the low-reverberant room were used. It should be noted that the stimulus level was varied in a quasi-random order, so that each of the 4 presentation levels (40, 50, 60 and 70 dB SPL) was applied once per loudspeaker. Figure 5a shows MAE-values for all 5 selected patients separately as a function of presentation level for the 3 kHz stimuli in the unaided condition. MAE-values tend to decrease with presentation level. To find out more about this dependence, we averaged MAE-values over the 5 patients for both the 0.5 and 3 kHz stimuli. Figure 5b shows the MAE averaged over the 5 patients as a function of the presentation level.

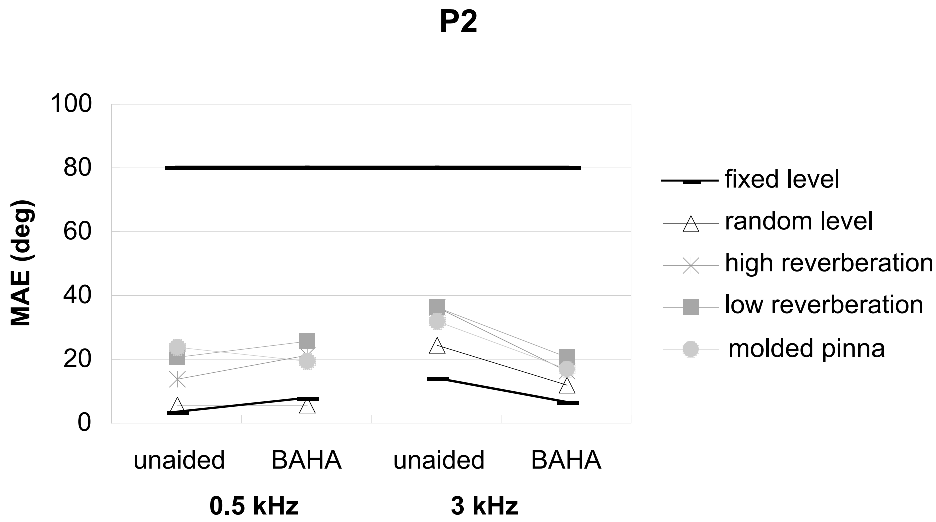

Figure 4. Data from one of the selected patients. MAE-values are shown for all five experimental conditions (see text for details). Note that there is no significant difference in localization performance among the different conditions.

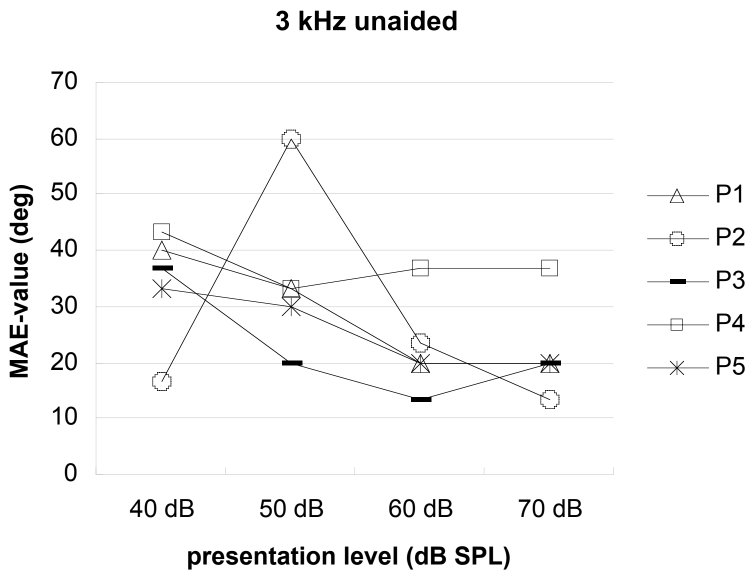

Figure 5a. MAE values of all five selected subjects individually plotted against stimulus presentation level for the 3 kHz stimuli in the unaided condition. Note that MAE-value tends to decrease with stimulus presentation level.

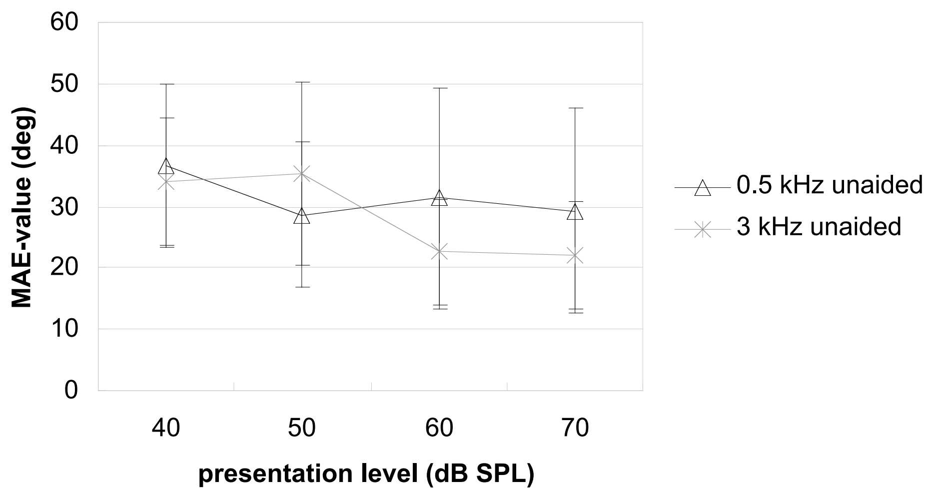

Figure 5b. MAE values of all five selected subjects (means and standard deviations) plotted against stimulus presentation level. Note that the spread of the data is large.

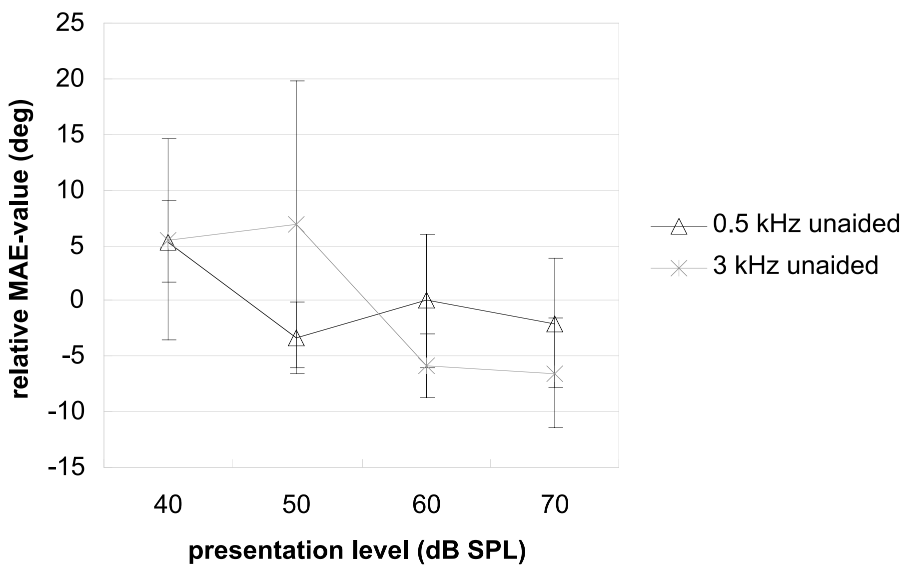

Figure 5c. MAE values are normalized by subtracting each patient's MAE (averaged across presentation levels) and plotted against stimulus presentation level. The best results (lowest relative MAE-values) are systematically obtained with the highest stimulation levels, but the differences are limited.

To deal with differences between patients, the MAE data were normalized by subtracting the MAE (averaged across presentation levels) from the level-specific MAE-values, for each patient separately. Figure 5c shows the resulting normalized MAE values averaged over the 5 patients (standard deviations are also indicated) as a function of presentation level. Dependence was present: the best results were obtained systematically with the highest stimulation levels. However, the differences between the 40 dB SPL and 70 dB SPL values in the unaided situations at 0.5 and 3 kHz were only 7^0 and 12^0, respectively. Moreover, standard deviations were relatively large, despite the normalization over patients. In the aided condition (data not presented in the figure), the differences were 17^0 and 13^0, respectively. Thus, varying the presentation level had a limited effect on the MAE in the unaided situation, while in the aided situation, there was no improvement.

Results of the SSQ questionnaire are shown in table 3. As can be seen, subjects perceived significant benefit with the BAHA on both speech and spatial hearing domains. The unaided scores on the speech domain were in agreement with literature data, while those on the spatial domain were poorer than the scores reported by Noble and Gatehouse.[16]

Table 3. SSQ results, mean value and standard deviation (between brackets) on the domains speech hearing and spatial hearing. Literature data, obtained from 50 patients with an asymmetrical hearing loss, have been added

	domain	unaided	aided
Present study	speech	3.4 (1.2)	7.9 (0.9)
	spatial	3.5 (0.6)	7.1 (1.1)
Noble and Gatehouse, 2004	speech	3.8	n.a.
	spatial	4.8	n.a.

n.a. = not available.

DISCUSSION

In 1977, Markides reported that hearing aid fitting was of little benefit to patients with unilateral conductive hearing loss.[4] Recently, the opposite has been reported by Wazen et al., Snik et al., and Hol et al.[8,9,12] One reason for this discrepancy might be that Markides' patients had insufficient time to adapt to amplification. Research has shown that a “perceptual acclimatization” period may last for several months.[3] The reason why we started fitting hearing aids to patients with unilateral hearing loss was, that they were complaining about directional hearing and listening difficulties in noisy places and asked if we had a solution.

The questionnaire used in the present study (SSQ) and in the previous study[12] clearly showed that many patients might benefit significantly from hearing aid fitting, even though sound localization measurements in the sound field might not be convincing. The speech in noise test in our previous study[12] also revealed obvious benefits.

Control group
Figure 2 shows that when one ear was blocked in the subjects with normal hearing, their scores were near chance level, whereas when they were listening binaurally, their scores were almost perfect. This is in accordance with the literature[2,3] and means at least that the equipment is working properly.

Unaided condition
Comparison of the data in Figures 2 and 3 showed that there is no significant difference between the results of the experiments with fixed and variable stimulus presentation level respectively. Thus varying the stimulus level to minimize the azimuth-dependent attenuation owing to acoustic head shadow did not lead to scores near chance level (unless the patient already had a score at chance level in the condition with a fixed presentation level). Therefore it can be concluded that attenuation due to head shadow did not play a role in the good unaided localization of sounds, which rejects the first hypothesis. The other two hypotheses can also be rejected, because performing measurements in low and high reverberant rooms and wax molding of pinna did not have any significant effect on the MAE values (see figure 4 and the related paired t-test results). Most MAE scores remained far below chance level (unless the score was at chance level in the condition with a fixed stimulus level). Thus, all three hypotheses had to be rejected, which means that the good unaided localization abilities of these patients remain unexplained.

When interpreting the effect of presentation level on the normalized MAE, it should be noted that the number of patients was limited and the spread of the data was large. Figure 5b shows a limited effect of stimulus level in the unaided situation; the best results were obtained with the highest stimulation levels. However, the results at 40 dB SPL were not much poorer, although at this level, we can be sure that the stimulus was below the hearing threshold of the impaired ear in all patients.

Aided condition

Figure 2 shows significant improvements when the BAHA was active. The largest improvements were found in the patients with the poorest unaided scores. Similar trends were found in the other measurement conditions, see Figure 3. Remarkably, MAE-value depended also in the aided condition on presentation level (see figure 5). The poorest results were still found at 40 dB SPL level, which we had not expected since in the aided situation, all stimuli are equally audible.

It remains unclear why some patients have good unaided directional hearing scores, while others have the expected poor scores. Table 1 shows some audiometric data on the patients with good unaided directional hearing at 0.5 and/or 3 kHz (selected: 'yes') and those with poor scores (selected: 'no'). No remarkable differences in the data can be seen between the two groups. As indicated in the Introduction, Wilmington et al.[6] and Slattery and Middlebrooks[2] also reported that a proportion of their patients with unilateral hearing had fairly good directional hearing; thus the present data are not unique. However, in these studies, broadband stimuli were used, while we used narrow-band stimuli in our study. This shows that the broadband spectral shape cues are not essential for the good localization performance of the patients with unilateral hearing impairment.

The present data suggest that our assumption that these patients do not have access to binaural cues might be wrong, at least in a proportion of the patients. Hausler et al. studied directional hearing in subjects with unilateral and bilateral conductive hearing loss.[1] To explain their results, they proposed that there might be some interaction between the input via air conduction and bone conduction. Thus, sound vibrations picked up by the head may be transmitted to the cochleae by bone conduction. In the present patients, it can be argued that owing to the Weber effect[17], this might lead to stimulation of the cochlea in the impaired ear. Additional support for such a hypothesis comes from recent research into patients with one completely deaf ear. Their (unaided) scores were much poorer than those obtained from the present patient group.[18] Moreover, the presentation level-dependence of the MAE-values in the unaided condition suggests that also the impaired ear plays a role in the localization.

Nevertheless, this hypothesis remains speculative and does not explain the differences we observed between patients.

Zurek suggested that, based on the slow sound velocity in bone conduction, there are two ways for unilaterally impaired listeners to localize sounds.[19] First, they can extract (binaural) information from the air conduction signal before the bone conduction signal reaches the cochlea. However, in most of our patients, this was not possible since stimulus levels (of the low-intensity stimuli) were below thresholds. The second possible mechanism for localization is based on the interaction of air- and bone-conducted components in the better ear. Further research is needed to find out whether patients with unilateral conductive hearing loss use this mechanism. We do not expect it to be the major cue, since it does not explain the difference between our patients with unilateral conductive loss and those with unilateral deafness.

Another possibility would be that patients use the spectral cues due to head shadow.[5] But, to our knowledge, no research has ever done on head shadow spectral cues separated from the pinna cues, which we eliminated in the wax-molded condition. Therefore, it is unknown how large the spectral head shadow effect is and whether it would be possible to use it as a cue for sound localization. However, this hypothesis is supported by the fact that on average, subjects performed better in the experiments with the high frequency stimuli, as would be expected if spectral cues were used.

In conclusion, the good unaided performance of some of our patients remains unexplained. The hypotheses we tested can all be rejected: we excluded the use of loudness due to head shadow, the influence of room acoustics and spectral pinna cues. However, there are several other possible mechanisms underlying the localization. Patients can make use of binaural cues based on bone conduction, or they can use monaural cues such as spectral head shadow cues and interference between air and bone conducted components. Further research will be needed to find out which of these cues is really used. For example, experiments can be done using stimuli with different spectral shapes (to complicate the use of spectral head shadow cues) and the use of binaural cues can be investigated by conducting experiments with the better ear masked.

SSQ

Although hearing aid fitting led to limited objective benefit in our experiments in a number of patients owing to good unaided scores, the SSQ data showed that the patients were experiencing significant subjective benefit.

Our results deviated a little from the literature data from Noble and Gatehouse's study.[20] However, the patients in their study had a between-ear difference of on average 35.5 dB (not necessarily one normal hearing ear) which is less than the mean difference in the present study (50.2 dB). Therefore, the poorer scores in our study could be due to the larger asymmetry in hearing loss in our patients.

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The BAHA Softband. A new treatment for young children with bilateral congenital aural atresia

Chapter 3.3

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ABSTRACT

Objective: To evaluate the validity of a bone-anchored hearing aid (BAHA) Softband (fitted unilaterally and bilaterally) in young children with bilateral congenital aural atresia.
Subjects: Two children with severe bilateral congenital conductive hearing loss, who had been fitted with a transcutaneous BAHA Softband at the age of 3 months and 28 months, respectively. The latter child had been fitted with a conventional bone-conduction hearing aid at the age of 3 months; at 28 months, this child had received the BAHA Softband and after 5 months of unilateral application, the BAHA Softband was fitted bilaterally. Follow-up in the two children was 31 and 17 months, respectively.
Methods: Using the artificial mastoid, gain and maximum output were studied in this new transcutaneous application of the BAHA, with the BAHA Classic and the BAHA Compact as sound processor. Results were compared to those obtained with a conventional bone-conduction device (Oticon E 300 P). Aided thresholds and sound lateralization scores were assessed with double visual reinforcement audiometry (VRA). To test the validity of the BAHA Softband, the speech and language development of the children was assessed by means of age-appropriate tests (the preverbal Symbolic play test and the Dutch non-speech test for receptive and expressive language and the Dutch version of the Reynell language test).
Results: The electro-acoustic measurements showed minor differences in gain between the three devices. At a reduced volume setting, the mean input level at which the output levelled off was largely comparable between the BAHA Classic and the conventional device, but somewhat poorer with the BAHA Compact. Both children showed speech and language development that was in accordance with their cognitive development.
Conclusions: The BAHA Softband was a valid intervention in children with congenital bilateral aural atresia who were too young for percutaneous BAHA application.

INTRODUCTION

Ear canal atresia is a relatively rare congenital defect. It may occur in isolation or in combination with congenital anomalies of the auricle. Without auricle malformation, it may even be overlooked in the early years. Unilateral occurrence is far more frequent than bilateral involvement.

The Cremers-Altmann classification, based on the anatomical severity of the congenital anomaly, has proved to be related to the outcome of microsurgery. The severity of the external auditory canal anomalies with or without microtia/anotia, serves as a guide to the classification of Types I, IIA, IIB or III.[1-3] The Altmann classification consisted of a subdivision into three classes, while the Cremers classification split class II into Types IIA and IIB. Type IIA consists of a bony atretic plate at the level of the tympanic membrane and incomplete additional bony atresia, with some skin along the level of the bony ear canal. Type IIB consists of bony ear canal atresia over the full length of the external ear canal. Surgical repair of these anomalies is an option, assuming that the inner ear anatomy and the cochlear function are normal. Classical surgical repair should only be attempted in children who meet specific anatomic criteria and is therefore usually limited to Types I and IIA.[4] The minimum age at which congenital ear canal atresia surgery is advocated, is 6 years. Thus the only option for hearing rehabilitation in these children is the fitting of hearing aids (i.e. bone-conduction hearing aids) during the first 6 years of life, or even longer.

Typically, a bone-conductor comprises a (powerful, thus relatively large) behind-the-ear hearing aid connected to a bone-conduction transducer, held in place by means of a steel band over the head. A major drawback of a conventional bone-conductor is the static pressure essential for correct operation by counteracting reactive forces. The transducer might easily shift over the head, especially in young children. However, many of these children cannot tolerate the steel headband, despite the importance of starting hearing rehabilitation in the first few years of life. The practical problems sometimes result in delayed hearing aid fitting in young children with binaural congenital aural atresia. When hearing aid fitting with the conventional steel band over the head started to be accepted, it was mostly only accepted for part of the day. It is important to emphasize that the earlier a hearing device is fitted and used continuously, the smaller the impact on long-term speech and language development.[5] Next to these practical problems of the conventional bone-conduction device, it functions as a contra-lateral routing of sound (CROS) device, because the vibrator is placed on the mastoid contra-lateral to the side where the behind-the-ear hearing aid is worn. Therefore bilateral application with a steel band over the head is not possible. This means there is a need to find a better solution for non-surgical hearing rehabilitation during the first years of life.

A major development in the field of bone-conductors was the introduction of the bone-anchored hearing aid (BAHA) by Tjellström and co-workers in the 1980s.[6-8] The BAHA employs a titanium implant anchored in the temporal bone to make direct coupling between the vibration transducer and the skull. This is much more efficient than the transcutaneous coupling of conventional bone-conductors, i.e. in the order of 10-15 dB.[8] In contrast to the conventional bone-conduction device, the microphone, amplifier and vibrator are all assembled in one housing (Fig. 1). This enables bilateral application.

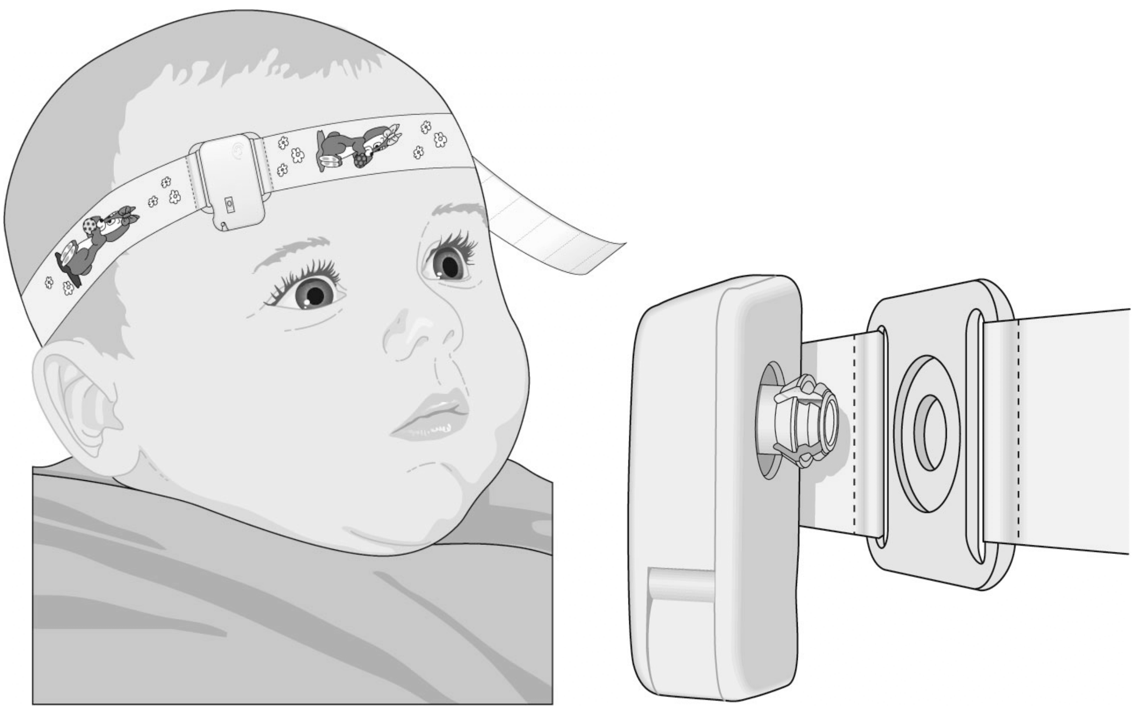

Figure 1. Elastic band around a child's head and a detailed figure of the plastic snap connector as coupling device for a standard BAHA, referred to as the BAHA Softband.

In very young children, the application of a BAHA is disputable. One reason is that the essential osseo-integration of the titanium implant might be poor owing to the non-mature structure of a young child's skull.[9] The youngest age for percutaneous titanium fixation to the skull is about 3 years.[9] Recently, transcutaneous application of the BAHA has been introduced, in which the BAHA is connected to a special plastic disc held in place by a steel spring headband. In this way, the BAHA can be applied without surgery, but the transmission of the bone-conduction vibrations is transcutaneous and thus less efficient. Next to this, the practical problems of a steel spring headband remain to exist.

An even more recent development is to wear the BAHA attached to an elastic band by means of the special plastic snap connector disk. This might be a good temporary solution in children awaiting BAHA implantation. Figure 1 shows this application, called the BAHA Softband. The elastic band seems to be a more acceptable option, because it has a more attractive appearance than a steel headband and it does not shift so easily over the head of a young child.

The present paper reports on the first application of the BAHA Softband to two young children. Two questions were addressed: Does attachment of a BAHA to an elastic band have any additional value over a conventional bone-conduction hearing aid? Is the BAHA Softband a valid treatment in young children?

SUBJECTS AND METHODS

Subjects

Long-term results were obtained with the BAHA Softband from two young children with congenital bilateral aural atresia. Subject 1 was born with binaural atresia in a sibship of three children. At the age of 1 month, hearing loss of 50-60 dBnHL was found, using click ABR testing. At an age of 3 months, a BAHA Softband was fitted with a BAHA Compact. Bilateral application of the BAHA Softband was discussed with the parents, but has not yet been effectuated. Total follow-up was 31 months. Figure 2a shows the audiogram obtained in the sound field. Bone-conduction thresholds were between 5 and 10 dBHL. Recent psychological testing had revealed normal intelligence.

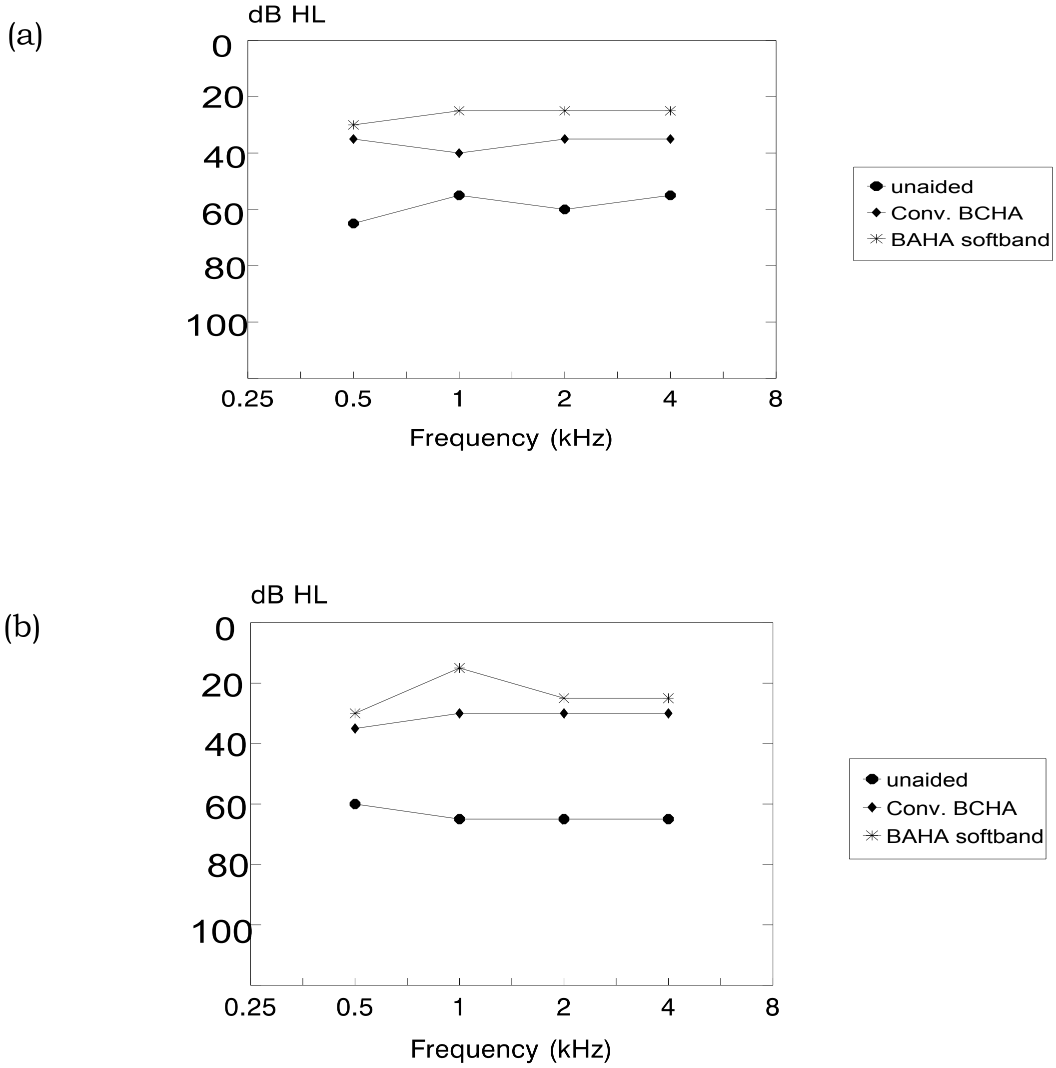

Figure 2. Unaided and aided sound field thresholds in subject one (a) and subject two (b). In both children, the conventional bone conductor device was an Oticon E 300 P. At the time of these evaluations subject one was using a BAHA Compact; subject two was using a BAHA Classic.

Subject 2 was born with several congenital anomalies (a.o. palatoschisis, club feet and binaural atresia) consistent with the De Grouchy syndrome. Mental retardation can also be present in this chromosomal deletion syndrome.[10] At the age of 3 months, click ABR testing revealed hearing loss of 60-65 dBnHL in both ears. Subsequently, a conventional bone-conduction device was fitted (i.e. the Oticon E300-P with a bone-conduction transducer connected to a steel spring; volume setting was 3, tone control was set at wide-band amplification and the output was unlimited).

At the age of 28 months, a BAHA Softband was fitted (with the BAHA Classic), to replace the conventional bone-conduction device. Five months later, bilateral BAHAs were fitted by means of the softband (type: Compact). Follow-up with the first BAHA was 17 months, while follow-up with the bilateral BAHAs was 12 months. Figure 2b shows the sound-field data. Recent psychological testing had revealed mental retardation with an 11 months delay in cognitive development.

Methods

Electro-acoustical evaluation

Two types of BAHA sound processor were used: the BAHA Compact and the BAHA Classic. The BAHA Compact is smaller than the BAHA Classic and its output is somewhat lower.[9] Although the gain and output of BAHAs can be measured with the specially developed "Skull Simulator"[11], this was not appropriate for the present transcutaneous application. Instead, the "Artificial mastoid" was used.[12] Gain and maximum output were determined in a sound-field test setting with the conventional bone-conduction device (the Oticon E 300 P, tone in broad band position, output unlimited), plus the BAHA Classic and the BAHA Compact on headbands. Warble tones of 0.5-4 kHz were applied, presented at 60 dB SPL, as measured near the entrance of the microphone of the devices with a sound level meter (Bruel and Kjaer 2260). In addition, input-output behaviour was studied at the octave frequencies from 0.5 to 4 kHz, with presentation levels that varied between 50 and 80 dB SPL. The bone-conduction devices were connected to the Bruel and Kjaer 4930 Artificial Mastoid, coupled to the Bruel and Kjaer 2260 analyser. The static force with which the bone-conducting devices made contact with the Artificial Mastoid was 2N in all cases. This was the mean value (measured with a spring balance) when the BAHA was fitted to an adult head with a standard steel spring headband.

First, full-on gain was determined. The conventional device was considered as the standard, thus the gain of the two BAHAs was evaluated relative to that of the conventional device. In a second experiment, the volume settings were reduced to a more realistic value, i.e. about 70% of the full scale. This volume setting was slightly adapted so that the mean gain at 0.5, 1 and 2 kHz was exactly the same for the three devices. The resulting volume setting was about volume 3 for the conventional device and volume 2 for the two BAHAs. Again, the measurement with the conventional device was considered to be the standard. Graphs were constructed of the output versus input level measurements to determine where the output levelled off. These evaluations were performed with the full-on gain and the reduced gain (volume 3 for the conventional device and volume 2 for the BAHAs).

Materials

The BAHA Softband was developed by the Entific Company at the request of the Nijmegen BAHA team. It comprises an elastic band with a plastic snap connector as coupling mechanism for a standard BAHA (see Figure 1). Either the BAHA Classic or the BAHA Compact can be used .[9] The snap connector disc is pressed against the skin of the head at a bony location, such as the mastoid or the forehead. As the position of the bone-conduction transducer on the head has limited effect on hearing[13], it can be changed during the course of the day (in case of unilateral fitting).
Instead of an elastic headband, a steel spring headband can be used. The advantage of a steel spring headband is that in principle, there are two pressure points on the head: at the site of the plastic disc with the BAHA and directly opposite on the other side of the head. However, the steel band also causes pressure on top of the head, whereas the elastic band produces pressure around the whole head. The main advantages of the soft band are that it stays in place much better than the BAHA on the steel headband, the pressure of the transducer on the skull can easily be readjusted and the position of the plastic disc on the head can easily be changed.
The BAHAs were used in wide-band amplification mode (“N” position) and the output was unlimited. Hearing thresholds were assessed with a double visual reinforcement audiometry (VRA) set-up, one on either side of the child. This enabled us to measure aided thresholds and sound lateralisation. In the latter case, a children’s song was used (fragment of 4 seconds), presented at 45 dB SPL on the right or left side of the child. For the sound-field threshold measurements, warble tones were used, calibrated according to Stream and Dirks.[14] All the sound-field measurements were carried out in a double walled sound treated room.
To test the validity of the treatment, we assessed the speech and language development of the children. The preverbal Symbolic play test was used to evaluate the conditions for language learning.[15] Further, the NNST[16] was used, which is the Dutch version of the “Non-speech test for receptive and

expressive language", developed by Huer.[17] Norms were available for children in the age range from 12 to 24 months. The NNST assesses language development in a broad sense and can probably better be referred to as development in communication. The evaluations at 24 months and older were performed with (pure) verbal speech and language tests, viz. the Dutch version of the Reynell test[18] (receptive language) and the Schlichting test (expressive language).[19] Scores on all tests were expressed as age equivalents.

RESULTS

Behavioural evaluation

Figure 2a and 2b present the aided thresholds of the two subjects. For comparison purposes, unaided and aided thresholds are presented, obtained with the conventional device. In each child, the conventional device was an Oticon E 300 P with a bone-conduction transducer (volume: 3). Subject 2 was fitted with two BAHAs. Lateralisation was measured using a fragment of a children's song, presented at random on the right or left side, a total of 20 times. At a follow-up of 6 weeks, the score for correct source identification was 70%. At 3 months follow-up, the score was 100% correct.

Electro-acoustical evaluation

The full-on gain obtained with the BAHA Classic and BAHA Compact, relative to that of the conventional device, is presented in Figure 3a. At the low and mid-frequencies, the BAHAs seemed to be somewhat louder than the conventional device. Figure 3b presents the relative gain after adjusting the gain to 70% of its scale and after some additional readjusting to obtain the same mean gain for the three devices. This figure shows that there were only minor differences in the frequency responses between the three devices.

Figure 3c and 3d present the input levels at which the output levelled off as a function of frequency for the three devices and at the two volume settings, viz. maximum volume and the reduced setting. Significant differences were found, with the poorest results for the BAHA Compact. With this device, changing from full-on gain to the reduced gain resulted

in only 2 dB change in the input level at which the output levelled off (compared to 7 dB for the other two devices).
This suggests that at 60-65 dB input at either volume setting, the output of the BAHA Compact was at or close to its maximum. At the reduced volume setting, the mean input levels at which the output levelled off were 64, 76 and 77 dB SPL for the BAHA Compact, the BAHA Classic and the conventional device, respectively.

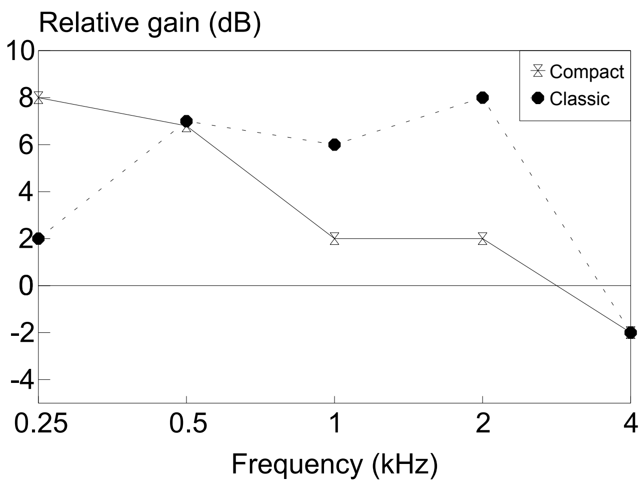

Figure 3a. The full-on gains of the BAHA Classic and Compact are shown relative to the gain of the conventional bone conduction device as function of frequency (kHz).

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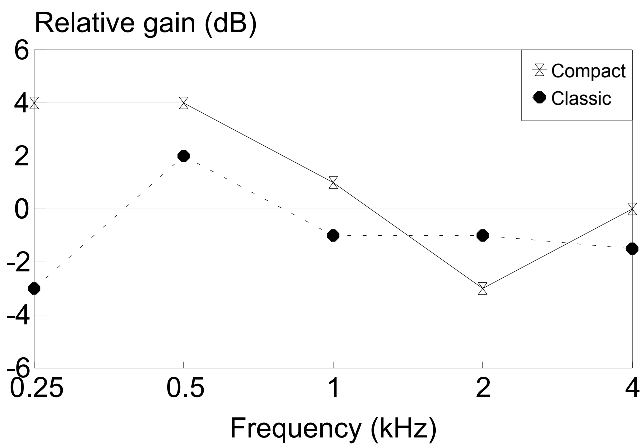

Figure 3b. Relative gains are shown of the BAHA Classic and Compact after adjusting the volume to about 70% of the scale relative to the gain of the conventional bone conduction device.

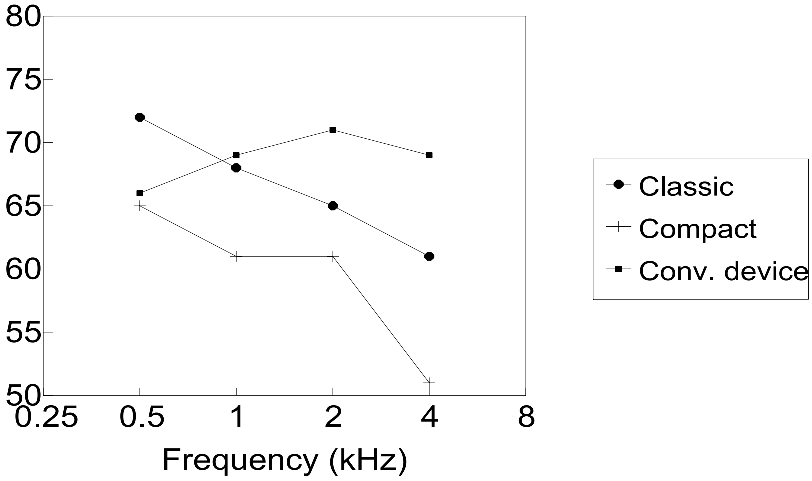

Figure 3c. Input levels (dB SPL) of the three devices at which the output levelled off (saturation level), shown as a function of the frequency (kHz) at maximum volume setting.

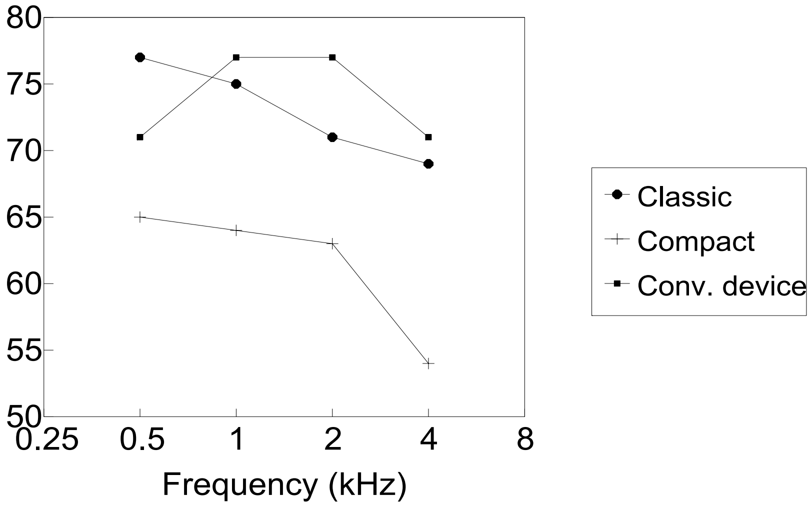

Figure 3d. Input levels (dB SPL) of the three devices at which the output levelled off (saturation level), shown as a function of the frequency (kHz) at reduced volume setting.

Validation

Table 1 presents the data on speech and language development in subject 1, from the age of 15 months up to 34 months. Below the age of 2 years, the NNST was used[16] and steady progress was observed. At 18 months, language development seemed to be age-appropriate. The evaluations at

24 months and later were performed with the Reynell and Schlichting tests (see Methods). Again, age-appropriate scores were found, see Table 1. In subject 2, receptive language development was assessed at the age of 32 months (Reynell test). Language development showed a delay of about 12 months. This was in accordance with the delay in cognitive development. The Symbolic play test to assess preverbal symbolisation, showed a delay of 9 months. Recently, this child has started to imitate speech sounds.

Both children are using the BAHA Softband all day and do not seem to be bothered by the elastic band around their head.

Table 1. Represented are the data on speech and language development in subject 1, from the age of 15 months up to 34 months. At 18 months, language development seemed to be age-appropriate. The evaluations at 24 months and later were performed with the either the Reynell or the Schlichting test. Again, age-appropriate scores were found

Chronological age in months (test)	Receptive language, age-equivalent (months)	Expressive language, age- equivalent (months)
15 (NNST)	13	16
18 (NNST)	20	18
21 (NNST)	23	22
25 (Reynell)	28	
29 (Schlichting)		32
34 (Reynell)	33	

DISCUSSION

In very young children with bilateral congenital aural atresia surgical intervention is not an option and bone-conduction hearing aids have proved to be the only effective treatment. Conventional bone-conduction hearing aids are not popular because there are several major drawbacks. The BAHA is known to be more comfortable to wear and it is highly efficient in audiological terms. The titanium percutaneous implant required for this device is disputable in children before the age of 3 years owing to expected poor osseo-integration.[9] However, early hearing rehabilitation is of prime importance in young children to enable normal speech and language development. To offer them the advantage of bone-conduction hearing without the disadvantages of conventional bone-conduction hearing aids, the BAHA Softband was developed. The application is without surgery. This study was performed on two young

children who had been fitted with a BAHA Softband at an early age. We describe the first experiences over a long-term follow-up period.
In contrast with the fitting of hearing aids to subjects with sensorineural hearing loss, little has been published on fitting bone-conduction devices to children with conductive hearing loss.[20] It has been suggested that aided thresholds of around 20 dBHL should be adequate for subjects with pure conductive hearing loss.[20] Figure 2a and 2b show that in the two children, sound-field aided thresholds were obtained in this range, which indicates acceptable fitting.
First, electro-acoustical measurements showed that the frequency responses were comparable between the two BAHAs and the conventional device (Fig. 3b) after corrections for the average gain. Full-on gain with the BAHAs was somewhat better than with the conventional device (Fig. 3a). The BAHA Classic and the conventional device could process louder sounds properly at levels of up to 70-75 dB SPL (Figs. 3c and 3d). This is found to be adequate.[21] Poorer results were found with the BAHA Compact. This suggests that with the BAHA Softband the BAHA Classic is a better choice than the BAHA Compact. Compared to the conventional device, the BAHA Classic had a little more reserve gain (Fig. 3a). Bilateral fitting might lead to binaural summation (in the order of 3-5 dB) and enable a somewhat lower volume setting, which will have a positive effect on the loudest sounds that can be processed properly. This will enhance the input level at which the output levels off by several dB. Thus, in case of bilateral fitting, the BAHA Compact might be an option. Only the second child had bilateral fitting of the BAHA Compact. In this child, the lateralization scores improved considerably. The source identification score was 100% after 3 months of follow-up. Bilateral fitting was also discussed with the parents of the first child, but they were not yet ready to try it. To determine whether the BAHA Softband is a valid treatment for children with bilateral congenital aural atresia, speech and language development evaluations were of the utmost importance. Subject 1 showed normal speech and language scores, while subject 2 showed a delay that was comparable with its delay in cognitive development.
The first results of two children with binaural congenital aural atresia fitted with the BAHA Softband show encouraging results and urge further investigation of the BAHA Softband in a larger group of children. The BAHA Softband proved to be a valid treatment for these two children at follow-up durations of 31 months and 17 months, respectively.

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Single sided inner ear deafness

Chapter 4

Bone-Anchored Hearing Aids in unilateral inner ear deafness

Chapter 4.1

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ABSTRACT

In nine patients with unilateral deafness and normal hearing in the contralateral ear, measurements of sound localization and speech perception were obtained before intervention, with a conventional contralateral routing of sound (CROS) hearing aid and later with a bone-anchored hearing aid (BAHA) implanted in the deaf ear. Sound localization did not show any differences between the three conditions. Speech perception using short, everyday sentences showed a reduction in the head-shadow effect of 2 dB for both conventional CROS hearing aid and the BAHA in comparison to the unaided condition. Patients' real-life experiences for the three conditions were evaluated using the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire. The results showed a significant benefit with the BAHA in situations involving background noise and reverberation and a reduced aversion to loud sounds in comparison to the unaided and conventional CROS conditions.

INTRODUCTION

Patients with one-sided total deafness and (near-)normal hearing in the contralateral ear often complain of poor directional hearing and the detrimental effects of head shadow when participating in conversations in settings involving ambient noise, especially when the person they are speaking to is situated on the poor hearing side. Head-shadow effects originate from diffraction and absorption of sound energy within the "shadow" region of the head. The effects are most prominent when listening to conversations with one's poorer hearing side, e.g. when driving a car or at dinner parties.
The traditional solution to unilateral inner ear deafness is the conventional contralateral routing of sound (CROS) hearing aid in which a microphone is positioned on the poor hearing side and sound is transmitted to the better ear by a cord around the neck or by wireless FM-transmission.[1,2] Alternatively, a powerful hearing aid may be fitted to the poorer hearing side, allowing the amplified signal to be transferred to the better cochlea by bone-conduction through the cranium[3,4]; this set-up was aptly denoted as transcranial or internal CROS by Valente et al.[5]

Transcranial CROS appears to be feasible, as evidenced by the interaural attenuation for bone-conducted sound of 10-15 dB.[6]

Transcranial CROS stimulation may also be implemented by means of direct bone conduction stimulation on the poorer hearing side. Using the Audiant device[7], which employs transcutaneous transfer of vibration energy, Pulec[8] reported mixed results, which were probably due to the highly limited maximum output power of the device. Vaneecloo et al.[9] reported more positive results with the bone-anchored hearing aid (BAHA) developed by Tjellström et al.[10] As the BAHA employs direct percutaneous coupling of the vibration transducer to a titanium implant anchored in the skull bone it provides high-quality transmission of sound, with sufficient gain and power output for transcranial applications.

This study focuses on experiences of nine patients with unilateral deafness before intervention (unaided condition), when fitted with a conventional CROS hearing aid and after intervention with a BAHA transcranial CROS device. The evaluation involved localization measures, speech perception in noise and a patient questionnaire.

METHODS

We recruited seven patients with unilateral inner ear deafness from our clinic files on acoustic neuroma surgery. All patients showed complete single-sided deafness and near-normal hearing [thresholds better than 20 dB hearing limit (HL) between 500 Hz and 2 kHz] in the contralateral ear. Two patients with long-standing experience with conventional CROS hearing aids were recruited by different routes.

Firstly, all patients were measured in the unaided condition. After a habituation period of 4 weeks, patients were evaluated with the conventional CROS hearing aid. Finally, after 4 weeks of habituation with the BAHA the third evaluation took place. Sound localization was measured with a 9-speaker array at 30° intervals [for details, see Bosman et al.[11]]. Speech perception was measured using short, everyday Dutch sentences.[12] Noise was presented to the front of the listener and speech at ±90° azimuth. The real-life benefits of the conventional and BAHA CROS devices were assessed using the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire.[13]

RESULTS

Sound localization performance appeared to be essentially at the level of chance in all subjects and for all three conditions (data not shown). In Figure 1, speech perception, expressed in terms of the speech reception threshold (SRT), is shown for the three conditions. Note that better performance corresponds to a lower SRT value. Data were collected for speech presented to the normal hearing side (NH) and to the deaf side (Deaf). The difference in SRTs for speech presented to the two sides amounted to ≈ 5 dB for the unaided condition. This difference in SRT was reduced to ≈ 3 dB with either the conventional or BAHA CROS devices. Therefore, the two devices are about equally successful at reducing the effect of head shadow.

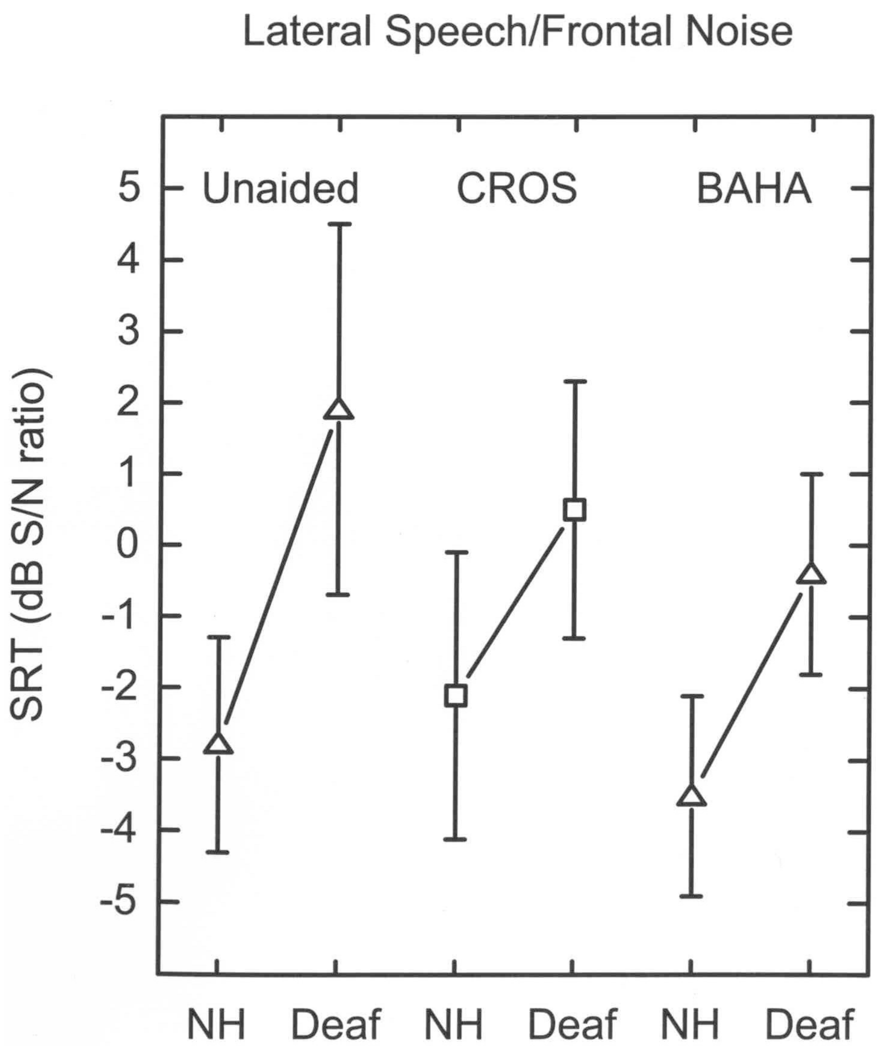

Figure 1. SRTs for the three conditions.

Table 1. APHAB scores (mean values) for the three conditions

Unaided condition				CROS				BAHA CROS			
EC	BN	RV	AV	EC	BN	RV	AV	EC	BN	RV	AV
16.7	67.6	37.7	32.3	12.0	48.0	30.5	33.6	10.9	40.0	20.1	20.9

The results of the APHAB questionnaire are shown in Table I. For each of the three conditions, scores are obtained for four categories: ease of communication (EC); background noise (BN); reverberation (RV); and aversion (AV). No differences were seen for the EC category. In contrast, relatively large differences occurred for the other three categories, with the lowest, most favourable, scores being obtained for the BAHA CROS device.

DISCUSSION

The poor scores achieved for sound localization illustrate the (negative) experiences of single-sided deafness patients in terms of localizing sound in everyday life. The inability to localize sound is a direct consequence of having only one functioning cochlea. Having only one cochlea precludes use of interaural timing and level differences essential for optimal sound localization and speech perception in noise. Thus, using a CROS device (either conventional or transcranial) offers no benefit in this respect.

A major complaint of single-sided deaf patients relates to head shadow. With our set-up, the head-shadow effect was of the order of 5 dB. The effect was reduced by ≈2 dB for both the conventional and BAHA transcranial CROS devices. If the slope of the plot of performance versus intensity is 15%/dB[12], this 2-dB difference is equivalent to an increase in intelligibility of 30% on the poorer hearing side.

The APHAB scores reflected the fact that most patients were satisfied with the BAHA CROS device in everyday life. Eight out of nine patients wore the BAHA for > 8 h per day; the other patient used the BAHA selectively, especially in order to alleviate the effects of head shadow in difficult acoustic situations. This patient did not have any previous experience with a CROS device. In our view, a careful selection procedure, including pre-assessment with a conventional CROS device followed by a trial period with a BAHA fitted on a headband, is a necessity.

In conclusion, a BAHA CROS device may be beneficial in specific listening situations as it avoids some of the disadvantages of the conventional CROS hearing aid, such as impaired perception of direct sound, poor quality of the wearer's own voice and poor quality of sound emanating from the poorer hearing side. Larger scale studies are needed to evaluate the difficulties encountered in real life by the unilaterally deaf and to uncover the common characteristics of patients applying for a BAHA transcranial CROS device.

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Bone-Anchored Hearing Aid in unilateral inner ear deafness: a study of 20 patients

Chapter 4.2

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ABSTRACT

Objective: To evaluate the benefit of a bone-anchored hearing aid (BAHA) contralateral routing of sound (CROS) in 20 patients with unilateral inner ear deafness.

Subjects: 21 patients were recruited; 15 had undergone acoustic neuroma surgery and 6 patients had unilateral profound hearing loss due to other causes; 1 patient was excluded. Only patients with thresholds of better than 25 dB HL (500-2000 Hz) and an air-bone gap of less than 10 dB in the best ear were included.

Methods: Evaluation involved audiometric measurements before intervention, when fitted with a conventional CROS and after implementation and quantification of the patients' subjective benefit with a hearing aid-specific instrument: the Abbreviated Profile of Hearing Aid Benefit (APHAB).

Results: Lateralization scores were not significantly different from chance (50%) in any of the three conditions. Measurements of speech perception in noise showed an increase in the signal to noise ratio (S/N ratio) with the conventional CROS ($p = 0.001$) and with the BAHA CROS compared to the unaided condition when speech was presented at the front with noise on the poor hearing side. On the other hand, a lower S/N ratio was seen with the BAHA CROS ($p = 0.003$) compared to the unaided situation when noise was presented at the front with speech on the poor hearing side. The patient outcome measure (APHAB) showed improvement, particularly with the BAHA CROS.

Conclusions: The poor sound localization results illustrate the inability of patients with unilateral inner ear deafness to localize sounds. The speech-in-noise measurements reflect the benefit of a BAHA CROS in lifting the head shadow while avoiding some of the disadvantages of a conventional CROS. The benefit of the BAHA CROS was most clearly reflected in the patients' opinion measured with the APHAB.

INTRODUCTION

Patients with unilateral inner ear deafness and (almost) normal hearing in the contralateral ear do not experience the advantages of binaural hearing. Binaural hearing eliminates the head shadow effect, yields benefit due to binaural loudness summation and the squelch effect and also enables sound localization. Head shadow effects originate from diffraction and absorption of sound energy within the 'shadow' region of the head.[1,2] An advantage of processing information with two ears over listening with one ear is an increase in loudness, the so-called binaural loudness summation.[3] Binaural release from masking leads to a reduction in deleterious effects of background noise by employing differences in time, intensity and/or phase.[3] Furthermore, listeners with normal hearing may employ interaural time and intensity differences to localize sound in the horizontal plane.

In the past unilateral inner ear deafness was considered to have little impact on auditory functioning in daily life and thus to require little or no intervention. Nowadays, however, professionals are faced with increased demands from patients experiencing limitations in daily life and are more inclined to take note of the detrimental effects of unilateral profound hearing loss. Prior to even considering intervention with technical means, it is important to reflect upon the patient's age, occupation, listening demands and motivation for amplification.

One approach to minimize communication problems in unilateral deafness consists of giving advice on preferential seating or counseling the patient to present the ear with normal hearing to the sound signal. The traditional audiological approach consists of fitting a conventional linear amplified contralateral routing of sound (CROS) hearing aid. With the conventional CROS, sound is received on the poor ear (PE) and is transmitted by a cord around the neck or by wireless FM transmission to the best ear (BE).[4,5] However, placing an ear mould in the BE and a cord around the neck is often experienced as unpleasant, while the open ear mould only transfers mid and high frequencies from the PE to the BE. Due to the limited frequency response with the CROS hearing aid it has been suggested that its success is directly related to the level of hearing loss in the BE.[5] This might be the main reason why CROS hearing aids are not very popular. Alternatively, with a powerful air conduction hearing aid, amplified sound may be transmitted to the best cochlea by bone conduction through the cranium. This type of fitting is called transcranial or internal CROS.[5]

In conventional bone conductors a transducer may be mounted on a spring or in the sidepiece of spectacles and press against the temporal bone. Due to the small interaural attenuation of bone-conducted sound, bone conduction hearing aids may be used as transcranial CROS devices.

Maximum output of conventional bone conductors is, however, rather limited especially in view of an interaural attenuation of 0-10 dB. However, this appears to be strongly frequency dependent and there are large interindividual differences.[6,7] A major drawback of a conventional bone conductor is the static pressure essential for correct operation by counteracting reactive forces. This pressure often results in headaches or skin irritations. Furthermore, variations in static pressure between the transducer and mastoid cause inconsistencies in signal transfer and result in poor sound quality.

In an attempt to improve the coupling between the transducer and skull, the Audiant device was developed.[8] This device makes use of a magnetic coupling for the transcutaneous transfer of vibration energy. Pulec[9] was the first to use the Audiant device as a transcranial CROS bone conduction device, but the results were ambiguous. In all cases maximum volume settings had to be used, which suggested that gain and maximum output power of the device were not sufficient to obtain optimal fittings.[9]

In the 1980s a percutaneous bone-anchored hearing aid (BAHA) was developed by Tjellström and coworkers.[10-12] The BAHA employs direct mechanical coupling of the vibration transducer to a titanium implant anchored in the temporal bone. The direct coupling of the BAHA provides high-quality transmission of sound, with sufficient gain and power output for transcranial applications. Vaneecloo et al.[13] reported positive results with the BAHA transcranial CROS application (BAHA CROS). In particular speech intelligibility in noise and sound localization improved. In addition, a few authors found that the BAHA CROS was beneficial in specific listening situations, because some of the disadvantages of conventional CROS devices were avoided.[14,15] Obviously, the BAHA CROS is not capable of restoring binaural hearing in patients with unilateral profound hearing loss. Nevertheless, these patients' opinions on the BAHA CROS are quite favorable, despite the small differences in measurement results between the aided and unaided conditions.[15] To gain greater insight into the experience and opinions of patients with unilateral inner ear deafness we extended our group of unilateral inner ear deafness patients to 21 individuals.

They underwent audiometric measurements and filled in a form of quantification of patient benefit on a hearing aid specific instrument: the Abbreviated Profile of Hearing Aid Benefit (APHAB) in three conditions:

before intervention (unaided condition), when fitted with a conventional CROS hearing aid and after implementation of the BAHA CROS.[16]

PATIENTS AND METHODS

Patients

We recruited 15 patients from our clinical files on acoustic neuroma surgery. Another 6 patients were included with unilateral profound hearing loss due to other causes (2 with other types of tumor in the cerebello-pontine region, 1 of these was an inflammatory pseudo tumor [17], 2 with congenital unilateral deafness, 1 resulting from stapedotomy surgery and 1 with unilateral Morbus Ménière). Two of these patients had long-term experience with a CROS hearing aid. During the measurements, 1 (satisfied) patient (acoustic neuroma) was excluded from our study because he could not perform all the tests due to reduced mental abilities. Only patients with profound single-sided inner ear deafness and (almost) normal hearing (bone conduction thresholds of better than 25 dB HL between 500 and 2000 Hz and an air-bone gap of less than 10 dB) on the contralateral side were included. An exception was made for patients No. 4, 11, 17 and 20 as they had an air-bone gap of 10 or even 25 dB (No. 11). Three patients were using a BAHA Compact, while the others were using the BAHA Classic. Table 1 presents an overview of sex, age, etiology and duration of unilateral hearing loss at the time of BAHA surgery.

Methods

Preoperatively 27 patients were offered the opportunity to evaluate a BAHA CROS fitted on a headband for 1 or 2 weeks. Six patients responded negatively after this trial and consequently did not participate in our study. Of the remaining 21 patients 1 patient was excluded due to reduced mental abilities.

First, all 20 patients were evaluated in the unaided condition. Following these measurements patients were fitted with a CROS hearing aid and after a habituation period of at least 1 month, they were evaluated with the CROS hearing aid. Six to 8 weeks after BAHA surgery, the BAHA CROS was fitted. This period complies with a recovery period of 6 weeks for osseointegration.[10] The third evaluation was carried out after 4 weeks of habituation with the BAHA CROS.

Table 1. Patient characteristics: age, gender, etiology, duration of unilateral deafness and average preoperative pure tone audiometric measurements ($PTA_{0.5, 1, 2}$) at the frequencies 500, 1000 and 2000 Hz in the BE

Patient	Age years	Gender	Etiology	Duration years/months	$PTA_{0.5, 1, 2}$ dB HL AC	BC
1	52	F	Morbus Ménière	7/11	10	10
2	38	M	Acoustic neuroma	1/12	15	15
3	29	F	Chondrosarcoma os petrosum	3/10	13	10
4	63	M	Acoustic neuroma	1/08	17	7
5	46	F	Acoustic neuroma	6/10	7	7
6	65	M	Acoustic neuroma	2/04	23	18
7	46	F	Acoustic neuroma	1/11	10	10
8	79	M	Congenital	79/03	7	7
9	58	F	Stapedotomy surgery	0/10	10	10
10	62	F	Acoustic neuroma	2/02	8	7
11	46	F	Pseudo tumor	8/08	37	12
12	57	M	Acoustic neuroma	4/05	8	8
13	43	M	Acoustic neuroma	1/11	3	3
14	75	M	Congenital	75/10	17	18
15	45	F	Acoustic neuroma	3/01	25	25
16	33	M	Acoustic neuroma	2/09	7	7
17	70	M	Acoustic neuroma	4/04	33	23
18	56	M	Acoustic neuroma	0/07	2	2
19	51	M	Acoustic neuroma	2/09	20	25
20	64	F	Acoustic neuroma	3/03	20	10

AC = Air conduction; BC = bone conduction.

In all three conditions the audiometric evaluation consisted of sound localization tests and speech perception in noise measurements.

Sound localization testing was carried out with a 9-speaker array at intervals at 30° azimuth. The two outermost loudspeakers were included to avoid edge effects (for details see Bosman et al.[18]). Stimuli consisted of short bursts of one third octave-filtered white noise, with either 500 or 3000 Hz center frequency. These two frequencies were chosen to evaluate the relative contributions of the two factors involved in directional hearing: interaural time and intensity differences. The stimuli were presented at 65 dB HL. After each burst, the subject was asked to identify the loudspeaker that had produced the sound. Answers were scored for correct identification (within 30° of the target loudspeaker) and for correct lateralization (within 90°). These actual scores were compared to chance levels of 11 and 50%, respectively. No explicit training or feedback was given. Speech perception was measured with short, everyday Dutch sentences [19]. Spectrally shaped noise (N) was presented in front (F) of the listener. Speech (S) was presented at +90° (N_FS_R) and -90° (N_FS_L) azimuth and vice versa, i.e. speech in front of the patient and noise at +90° (S_FN_R) and -90° (S_FN_L) azimuth. In the S_FN_F condition, both speech and noise signals were presented in front of the patient. The noise level was fixed at 65 dBA in all the conditions and speech reception thresholds (SRTs) were measured with a 'one up-one down' adaptive tracking procedure.[19] The speech-to-noise ratio (S/N ratio) at which the speech intelligibility is 50% (SRT) is the critical S/N ratio as measured in our study. Each separate condition was measured twice and the results were subsequently averaged.

Patient Outcome Measures

The baseline (unaided) and postintervention (conventional CROS and BAHA CROS) patient outcome measurements were conducted with a Dutch version of the APHAB.[16] Patients were asked to fill in the post-intervention instrument twice: after 1 month of experience with the conventional CROS and after 1 month of experience with the BAHA CROS. The APHAB consists of 24 items assigned to four domains: ease of communication (EC), listening under reverberant conditions (RV), listening in background noise (BN) and aversiveness of sound (AV). Patients with problems have higher scores on specific items.

Analysis

Student's t test was applied to the results of the speech perception measurements and localization tests and to compare means of the different domains of the APHAB. $p < 0.05$ was chosen as the level of significance; $p < 0.025$ in case of a two-tailed t test. The results were computed using the SPSS package (version 10).

RESULTS

Sound Localization

Sound localization data are shown in table 2 for 500- and 3000-Hz noise stimuli. At the 500-Hz stimulus level, localization performance was essentially no different from the chance level in most conditions. Although the correct scores in all three conditions (unaided, conventional CROS and BAHA CROS) were significantly better than the chance level of 11% ($p < 0.005$; 17.4, 15.0 and 15.7%, respectively), these scores were still very poor in comparison with scores obtained from persons with normal hearing.

Table 2. Average sound localization scores for correct identification of the target loudspeaker and for correct lateralization using 500- and 3000-Hz stimuli in the unaided condition, with the conventional CROS (CROS) and the BAHA CROS (BAHA)

Identification	Chance level, %	Frequency Hz	Unaided %	CROS %	BAHA %
Correct	11	500	17.4	15.0	15.7
		3000	18.5	14.8	17.1
Lateralization	50	500	45.1	46.5	44.7
		3000	52.9	46.0	50.4

Chance levels for correct identification and lateralization are shown.

At the 3000-Hz stimulus level, the correct scores in all three conditions (unaided, conventional CROS and BAHA CROS) were again statistically significantly different from the chance level of 11% ($p < 0.002$; 18.5, 14.8 and 17.1%, respectively). Lateralization scores were not significantly different from the chance level of 50% in all three conditions at both 500- and 3000-Hz stimuli levels.

Speech Recognition

Figure 1 shows the mean S/N ratios for the three conditions (unaided, conventional CROS and BAHA CROS). Better performance corresponds with lower S/N ratios; significant changes are indicated. Data were collected while speech was presented in front of the listener and noise was presented to the PE or to the BE; this measurement condition is referred to as lateral noise (fig. 1a, b). Also, data were collected while noise was presented in front of the listener and speech was presented to the PE or to the BE; this measurement is referred to as lateral speech (fig. 1c, d).

When lateral noise was presented to the PE (fig. 1a, b) the S/N ratio in the unaided condition was -1.7 dB. With the BAHA CROS, the S/N ratio increased to -0.9 dB and with the conventional CROS it increased significantly to 0.7 dB ($p = 0.001$). When noise was presented to the BE the S/N ratios of both the conventional CROS (1.2 dB) and the BAHA CROS (1.4 dB) were lower than the S/N ratio of the unaided condition (2.7 dB). Data for lateral speech are shown in figure 1c, d. In the unaided condition, speech presented to the PE produced an S/N ratio of 2.1 dB. The S/N ratio is decreased with the conventional CROS (0.0 dB) and decreased significantly with the BAHA CROS to -0.1 dB ($p = 0.003$). When speech was presented to the BE the S/N ratio of the BAHA CROS (-2.5 dB) remained essentially the same as that in the unaided condition (-2.6 dB); with the conventional CROS, the S/N ratio increased to -1.5 dB.

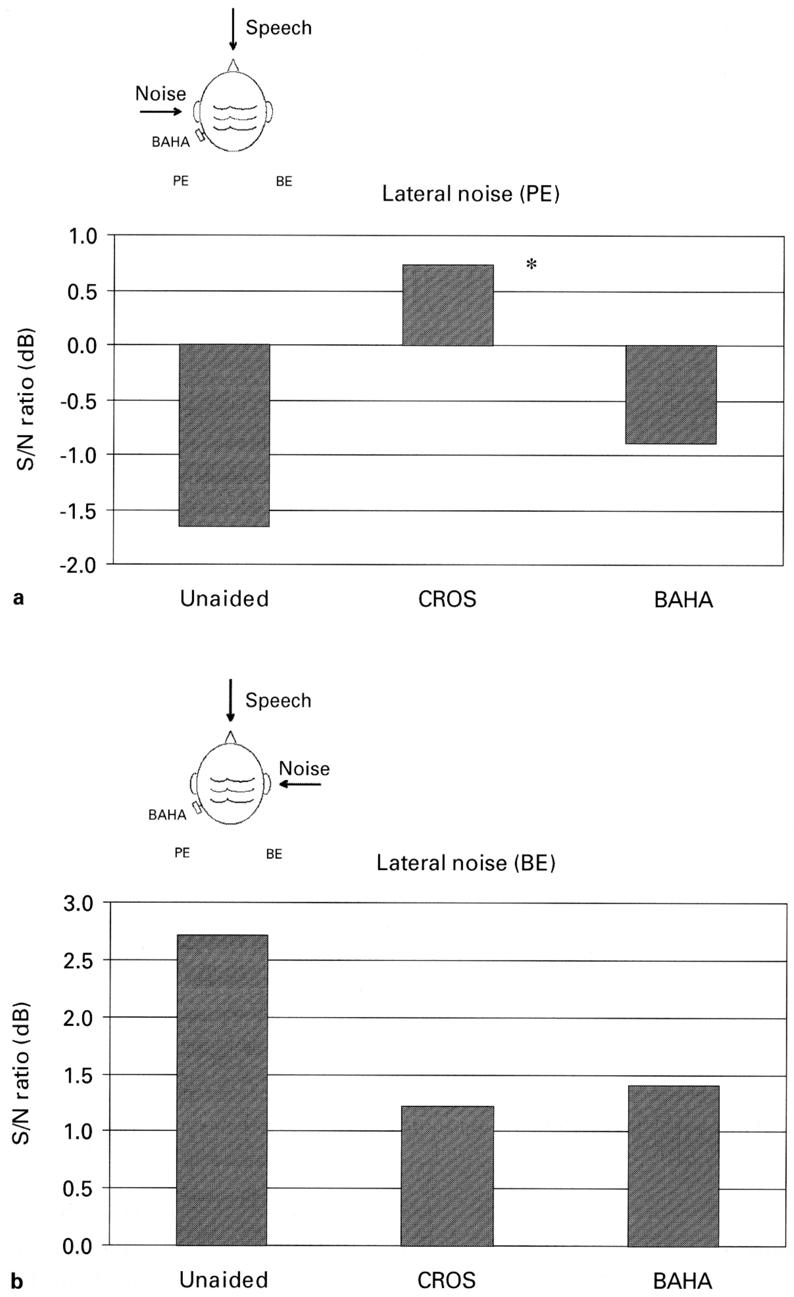
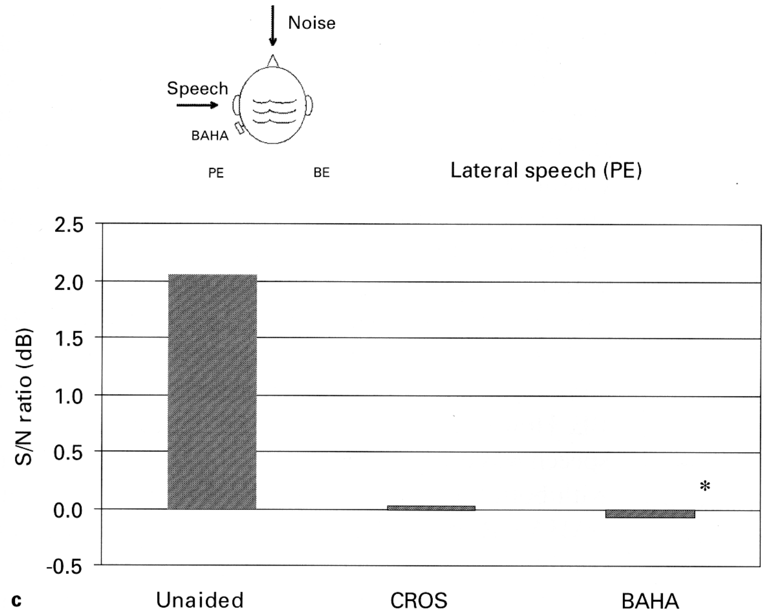


Figure 1. a, b S/N for a speech intelligibility of 50% for everyday Dutch sentences with speech presented at the front, while noise was presented to either the PE or the BE: 'lateral noise' in three conditions: unaided, conventional CROS (CROS) and BAHA CROS (BAHA). * $p < 0.025$, with respect to the unaided situation.



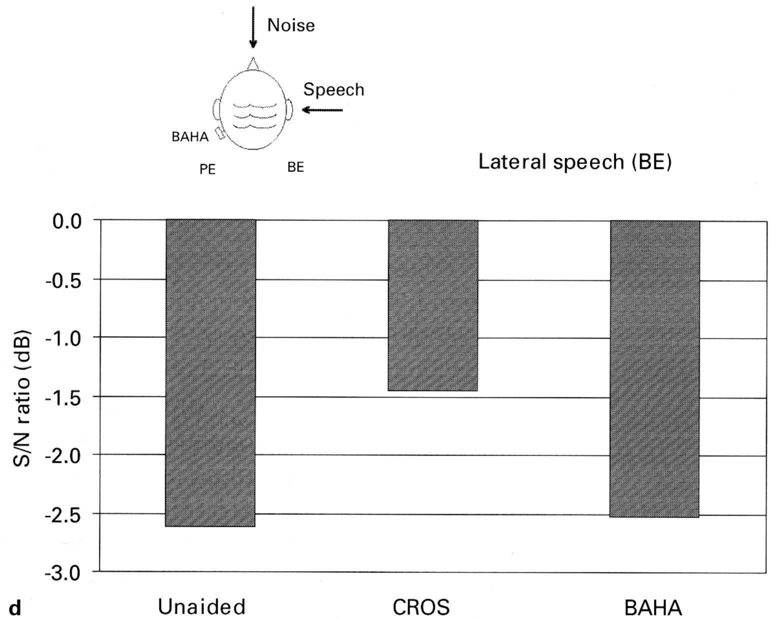


Figure 1. c, d S/N for a speech intelligibility of 50% for everyday Dutch sentences with noise presented at the front, while speech was presented to either the PE or the BE: 'lateral speech' in three conditions: unaided, conventional CROS (CROS) and BAHA CROS (BAHA). * $p < 0.025$, with respect to the unaided situation.

As a reference condition, SRTs were also measured while speech and noise were presented in front of the patient.
The S/N ratio in the unaided condition was -0.7 dB. With the conventional CROS, the S/N ratio was -0.3 dB and with the BAHA CROS -0.2 dB. These measurements were performed in 11 (conventional CROS) and 12 (BAHA CROS) out of the 20 patients.

Patient Outcome Measures
Scores on the four domains of the APHAB are shown in figure 2. Relatively large differences occurred in the communication performance domains: EC, RV and BN. The lowest, i.e. most favorable, results were seen with the BAHA CROS. Differences between baseline and postintervention outcomes were calculated. A negative difference score denoted improved communication. The conventional CROS showed improved scores in the domains EC (-7.6; p = 0.08), BN (-18.4; p = 0.001) and RV (-6.9; p = 0.03).
The BAHA CROS showed greater improvement in each of the domains:
EC (-14.4, p = 0.004), BN (-34.4, p = 0.00) and RV (-18.1, p = 0.00). Compared to the baseline measurement, a significant improvement was found with both the conventional CROS and the BAHA CROS in the domains BN and RV. In the domain EC, a significant improvement was only seen with the BAHA CROS.

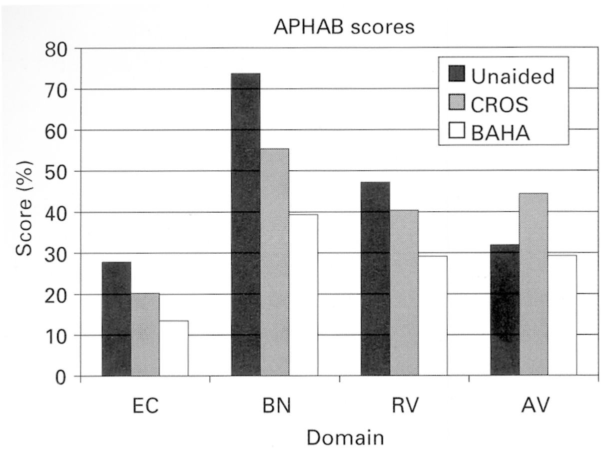


Figure 2. Mean scores of the 20 patients in the domains EC, BN, RV and AV of the APHAB in the three different conditions: unaided, conventional CROS (CROS) and BAHA CROS (BAHA).

In contrast to the above-mentioned data, some deterioration was seen with the conventional CROS (12.4) in the domain AV. However, this deterioration was not statistically significant (p = 0.05). The score in the BAHA CROS condition was equal to that in the unaided condition (-2.7).

DISCUSSION

The poor sound localization scores shown in table 2 clearly illustrate the inability of patients with unilateral inner ear deafness to localize sounds. Although the correct scores in the unaided condition and with the BAHA CROS differed significantly from chance, these scores were vastly different from the mean correct scores obtained by subjects with normal binaural hearing. When the conventional CROS or the BAHA CROS was used, no differences were found in the ability to localize low-frequency stimuli, which are mostly due to interaural time differences, or high-frequency stimuli, which are primarily based on interaural intensity differences.
A second aspect of unilateral inner ear deafness concerns the head shadow effect. The difference between the S/N ratio of the PE and the BE in the unaided condition quantifies the head shadow effect. In the condition with lateral noise (fig. 1a, b), if noise is presented to the BE, the ratios of both the conventional CROS and the BAHA CROS were lower than the S/N ratio in the unaided condition. If noise is presented to the PE, however, the S/N ratio in the unaided condition is lower and therefore more favorable than in the aided conditions. The noise transfer from the PE to the BE can explain this. Although it can be stated that in the condition with lateral noise, presented to the PE, both the hearing aids are inferior to the unaided condition, the BAHA CROS performs better than the conventional CROS. The S/N ratio with the conventional CROS (0.7 dB) was substantially poorer in comparison with the S/N ratios in both the unaided condition (-1.7 dB, p = 0.001) and with the BAHA CROS (-0.9 dB).
In the condition with lateral speech (fig. 1c, d) a fairly similar pattern was seen when speech was presented to the BE. However, figure 1c, d shows most clearly that when speech was presented to the PE, the S/N ratios were better with both the conventional CROS (0.0 dB) and with the BAHA CROS (-0.1 dB; p = 0.003) than in the unaided condition (2.1 dB). The effects of the conventional CROS were probably caused by the ear mould

in the BE that partially blocked direct sound and limited the transfer of low-frequency sound from the PE. The performance-intensity function slope of 15%/dB[19] means that the 2.2-dB difference in the S/N ratio with the BAHA CROS was equivalent to an increase in speech intelligibility of 33%. Overall, these results reflect the benefit of a BAHA CROS in lifting the head shadow effect. This is particularly advantageous in specific listening situations, for example at the dinner table or while driving a car, because some of the disadvantages of a conventional CROS are avoided, such as poor quality of sound emanating from the poorer ear and impaired perception of direct sound as a result of partial occlusion of the BE canal.

The results of Vaneecloo et al.[13] showing clearly improved lateralization and speech perception scores with BAHA are quite different from our findings. A serious difference between the two studies is located in the inclusion of different patients. They included also patients with a mixed hearing loss at the better hearing side and patients with some profitable hearing at the poorer hearing side. In this study unless otherwise stated strict patient criteria were met: profound inner ear deafness on one side (in the majority of cases due to acoustic neuroma surgery) and (almost) normal hearing (thresholds at or better than 25 dB HL) on the contralateral side with a negligible air-bone gap (<10 dB). Second, differences in the experimental setup may partially account for the different findings.

The advantages of the BAHA CROS were most clearly represented in the patients' opinions reported on the APHAB. Although the assessment of hearing aid benefit has not been free of debate, the APHAB has gained popularity as a convenient and clinically practical tool for measuring hearing aid benefit.[16,20] In our study the APHAB showed improvement in the domains EC, BN and RV with both the conventional CROS and the BAHA CROS (fig. 2). The greatest improvement on the APHAB was seen with the BAHA CROS in the BN domain. The improvement was not only significant with the BAHA CROS, but also with the conventional CROS as compared to the unaided condition. Although the changes in the EC domain were small and only significant with the BAHA CROS, they seemed more pronounced than in our previous study.[15] The scores in the AV domain were also more pronounced, and a trend can be seen that the conventional CROS scores were poorer than the scores in the unaided condition and those with the BAHA CROS. The increased aversiveness of sound in some patients with the conventional CROS may be due to the over-amplification of loud sounds, which resulted in sound levels that exceeded the loudness discomfort levels.

The results of the 2 congenitally deaf patients were not significantly different from the average score, despite their long-term experience with unilateral hearing.[21] Also, the results of the 3 patients with an air-bone gap of 10 dB and the patient with an air-bone gap of 25 dB, i.e. beyond our original inclusion criteria, did not differ statistically significantly from the mean scores of the whole group, which suggests that our inclusion criteria may be broadened somewhat.

In conclusion, if a patient has only one functioning cochlea this precludes the use of the interaural time and intensity differences essential for directional hearing. Thus, in patients with unilateral inner ear deafness, the application of a conventional CROS or a BAHA CROS device cannot achieve binaural hearing. The term ‘monaural pseudo-stereophonic hearing’ introduced by Vaneecloo et al.[13] is in our opinion thus not appropriate, as it implies a better performance than a CROS device merits in patients with unilateral inner ear deafness. However, the results of our study did show a certain amount of improvement in favor of the BAHA CROS in the SRT and localization measurements. The APHAB scores for the BAHA CROS were again the most favorable, especially in situations with background noise. In our opinion, the main value of either device can be found in an alleviation of the head shadow effect.

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Bone-Anchored Hearing Aid in unilateral inner ear deafness: an evaluation of audiometric and patient outcome measurements

Chapter 4.3

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ABSTRACT

Objective: To evaluate the benefit of a bone-anchored hearing aid contralateral routing of sound hearing aid (BAHA CROS hearing aid) in 29 patients with unilateral inner ear deafness.
Study design: Prospective clinical follow-up study.
Setting: Tertiary referral centre.
Patients: Thirty patients were recruited. There were 19 patients with a history of acoustic neuroma surgery and 11 patients with unilateral inner ear deafness due to other causes; 1 patient was excluded. The first 21 patients had also participated in a previous evaluation.
Intervention: Audiometric measurements were taken before intervention, when fitted with a conventional CROS, and after BAHA implementation. Patients' subjective benefit was quantified with four different hearing aid-specific instruments: the Abbreviated Profile of Hearing Aid Benefit, the Glasgow Hearing Aid Benefit Profile, the International Outcome Inventory for Hearing Aids, and the Single Sided Deafness (SSD) questionnaire.
Main outcome measures: The same instruments were used at a mean long-term follow-up of 1 year after BAHA implantation.
Results: Sound localization in an audiological test setting was no different from chance level. The main effect of the BAHA CROS that was found was the "lift the head shadow effect" in the speech-in-noise measurements. All instruments also showed positive results in favor of the BAHA CROS at long-term follow-up.
Conclusions: The poor sound-localization results in an audiological test setting illustrated the inability of patients with unilateral inner ear deafness to localize sounds. The speech-in-noise measurements demonstrated the efficacy of a BAHA CROS to lift the head shadow. Patients were still satisfied at 1-year follow-up according to the four instruments.

INTRODUCTION

Several studies have shown that the bone-anchored hearing aid (BAHA) is a highly effective hearing aid in patients with aural atresia, chronic otitis media or externa.[1-4] The BAHA has proved to be extremely well tolerated by patients, and the audiological results are superior to those obtained with conventional bone-conduction hearing aids and air-conduction

hearing aids in patients with a substantial air-bone gap.[2,5,6] More recently, the indications for a BAHA have been extended to include, among others, single sided deafness (SSD).[7-11] The present study evaluated the benefit of the bone-anchored hearing aid contralateral routing of sound hearing aid (BAHA CROS hearing aid) in patients with unilateral inner ear deafness.
Recent literature has shown a tendency to combine audiometric outcomes with patient outcome measures, emphasizing the importance of patient outcome research.[8,11-13] To gain insight into patient benefit and the influence of the BAHA on quality of life, hearing aid-specific instruments are preferred, as scores on generic health-related quality-of-life instruments do not appear to be significantly influenced when a BAHA is fitted after a patient has been using of a conventional hearing aid.[13]
In the present study, since a variety of instruments are available, patients' opinions were evaluated by means of four different patient outcome measures: the Abbreviated Profile of Hearing Aid Benefit (APHAB), which evaluates hearing aid benefit in three different communication domains and one listening comfort domain[14]; the Glasgow Hearing Aid Benefit Profile (GHABP), which evaluates hearing disability, handicap, hearing aid use and benefit, residual disability, and patient satisfaction with their hearing aids[15]; the international outcome inventory for hearing aids (IOI-HA), which is used internationally to assess benefit of hearing aid fitting[16]; and the Single Sided Deafness (SSD) questionnaire, which can detect improvements in quality of life in patients with unilateral inner ear deafness and a BAHA.[8]
Patients were asked to fill out the four instruments at different intervals: in the unaided condition before intervention, with the conventional CROS, with the BAHA CROS (at 6-wk follow-up), and at 1-year follow-up. Thus, it was possible to assess patient benefit in these four different conditions and to compare the outcomes of the instruments.

PATIENTS AND METHODS

Patients

Preoperatively, 39 patients were offered the opportunity to evaluate a BAHA CROS hearing aid fitted on a headband for 1 or 2 weeks. Nine patients responded negatively to this trial, declined BAHA surgery, and consequently did not participate in our study. BAHA surgery took place between January 2001 and May 2003. Thirty patients participated in the present study, 19 of whom were recruited from our clinical files on acoustic neuroma surgery. The other 11 patients had unilateral inner ear deafness due to other causes: 2 patients had other types of tumor in the cerebellopontine region, 1 patient had an inflammatory pseudotumour[17], 3 patients had congenital unilateral deafness, 2 had deafness after stapedotomy surgery, 1 patient had unilateral Morbus Ménière, 1 had deafness after trauma, 1 had deafness after cholesteatoma surgery and 1 had unilateral sensorineural hearing loss *e causa ignota*. Two of these patients had previous long-term experience with a conventional CROS hearing aid. During the evaluations, one (satisfied) patient (acoustic neuroma) was excluded from our study because he could not fill out all the instruments as a result of reduced mental abilities. The first 21 patients in the study group had participated in a previous study to obtain audiometric and APHAB data.[11] Hearing on the contralateral side was (nearly) normal in most cases (i.e. bone-conduction thresholds were greater than 25 dB HL between 500 and 2000 Hz and the air-bone gap was less than 10 dB). Patients 4, 17, and 20 had an air-bone gap of 10 dB, and patients 11 and 29 had an air-bone gap of 25 dB. Patient 27 had bone-conduction thresholds of 10, 45, and 45 dB HL at the frequencies 500, 1000, and 2000 Hz, respectively. Five patients were using a BAHA Compact, and the others were using a BAHA Classic. Table I presents an overview of age, gender and origin and duration of unilateral inner ear deafness at the time of BAHA surgery.

Methods

All 29 patients were evaluated in three different conditions (unaided, with conventional CROS, and with BAHA CROS) to obtain audiometric and patient outcome data. A fourth evaluation was carried out after one year of BAHA CROS use, by means of postal-based questionnaires alone. In all three conditions (unaided, with conventional CROS and with BAHA CROS) the audiometric evaluation consisted of sound localization measurements and speech perception in noise.

First, patients were evaluated in the unaided condition. Second, they were fitted with a conventional CROS hearing aid and evaluated with this hearing aid after a habituation period of at least 1 month. Third, the patients underwent BAHA surgery and the BAHA CROS was fitted 6 to 8 weeks later. This period complies with a recovery period of 6 weeks for osseointegration.[18]

Evaluation was carried out after again 4 to 6 weeks of habituation with the BAHA CROS.

Table 1. Patient characteristics: age, gender, cause or origin, duration of unilateral inner ear deafness, and average pre-operative pure tone audiometric measurements ($PTA_{0.5,\ 1,\ 2}$) at the frequencies 500, 1000 and 2000 Hz in the contralateral ear

Patient No.	Age (yr)	Gender	Cause/Origin	Duration (yr, mo)	$PTA_{0.5,\ 1,\ 2}$ (dB HL)	
					AC	BC
1	52	F	Morbus Ménière	7;11	10	10
2	38	M	Acoustic neuroma	1;12	15	15
3	29	F	Chondrosarcoma os petrosum	3;10	13	10
4	63	M	Acoustic neuroma	1;08	17	7
5	46	F	Acoustic neuroma	6;10	7	7
6	65	M	Acoustic neuroma	2;04	23	18
7	46	F	Acoustic neuroma	1;11	10	10
8	79	M	Congenital	79;03	7	7
9	58	F	Stapedotomy surgery	0;10	10	10
10	62	F	Acoustic neuroma	2;02	8	7
11	46	F	Pseudo tumour	8;08	37	12
12	57	M	Acoustic neuroma	4;05	8	8
13	43	M	Acoustic neuroma	1;11	3	3
14	75	M	Congenital	75;10	17	18
15	45	F	Acoustic neuroma	3;01	25	25
16	33	M	Acoustic neuroma	2;09	7	7
17	70	M	Acoustic neuroma	4;04	33	23
18	56	M	Acoustic neuroma	0;07	2	2
19	51	M	Acoustic neuroma	2;09	20	25
20	64	F	Acoustic neuroma	3;03	20	10
21	59	M	Acoustic neuroma	4;08	22	22
22	56	M	Acoustic neuroma	9;0	8	8
23	49	M	Acoustic neuroma	4;10	12	12
24	72	F	Acoustic neuroma	5;04	27	23
25	54	M	Trauma	5;04	5	5
26	48	F	Sensorineural deafness eci	0;11	20	20
27	59	F	Acoustic neuroma	3;11	38	33
28	42	F	Congenital	42;06	10	3
29	64	F	Cholesteatoma surgery	48;0	38	15

AC=air conduction; BC=bone conduction

In short, sound localization testing was carried out with a nine-speaker array at intervals of 30 degrees azimuth.[10,11] The two outermost loudspeakers were included to avoid edge effects. Horizontal sound localization of low-frequency sounds is mainly based on the detection of interaural time differences. In the case of high-frequency sounds, it is based on the detection of interaural level differences. Therefore, the directional hearing measurements were carried out with low-frequency

(500 Hz) and high-frequency (3000 Hz) narrow-band (one-third octave) noise stimuli of 65 dB sound pressure level (SPL) and duration of 1 second. Answers were scored for correct identification (i.e., identical to the target loudspeaker) and for correct lateralization (within 90 degrees). These scores were compared to chance levels of 11% and 50%, respectively.

Speech perception was measured with short, everyday sentences.[19] Spectrally shaped noise was presented in front of the listener, while speech was presented at + 90 degrees azimuth and – 90 degrees azimuth and vice versa. In the $S_F N_F$ (speech and noise in front of the listener) condition, the speech and noise signals were presented in front of the patient. The noise level was fixed at 65 dBA (A-weighted) in all the conditions and speech reception thresholds were measured with an adaptive tracking procedure.[19] The speech-to-noise ratio (S/N ratio) at which speech intelligibility is 50% was the critical S/N ratio used in our study. Each of the conditions was measured twice, and the average of the results was obtained. The audiometric results of the first 20 patients have been described earlier.[11]

Patient outcome measurements

Baseline (unaided) and post-intervention (conventional CROS and BAHA CROS) patient outcome data were obtained with the Dutch versions of the APHAB, GHABP, and IOI-HA and the SSD questionnaire. The APHAB and the GHABP were filled out in four different conditions (unaided, with the conventional CROS, and with the BAHA CROS at 6 wk and at 1 yr of follow-up). The IOI-HA and the SSD questionnaire were administered in two different conditions (with the BAHA CROS at 6 wk and at 1 yr of follow-up). An independent observer completed the instruments in the first three conditions; the 1-yr follow-up evaluation of the BAHA CROS was postal-based. In the case of missing data, domains were computed with a reduced overall number of patients (at most, the overall number of patients was reduced from 30 to 23).

The APHAB consists of 24 items assigned to four domains: ease of communication (EC), listening under reverberant conditions (RV), listening in background noise (BN) and aversiveness of sound (AV). Patients with certain problems show higher scores on specific domains.[14]

The GHABP evaluates initial hearing disability, handicap, hearing aid use and benefit, residual disability, and patient satisfaction with their hearing aids.[15] This questionnaire consists of two parts. The first part covers four predetermined environments, and in the second part, the patients can choose four additional situations in which they experience hearing difficulties. The four predetermined situations were 1) listening to the television with one other person without background noise, 2) having a conversation with one other person without background noise, 3) having a conversation in a busy street or shop, and 4) having a conversation with several people in a group.

Scoring of the GHABP instrument was carried out by means of the GHABP Information Package.[15] Average scores were calculated for each situation, and values were scaled to lie between 0 and 100. Initial disability, handicap, and residual disability received a score of 100 in the event of the greatest disability/handicap and 0 in the case of no disability/handicap. The domains use, benefit, and satisfaction were scored the other way around.

The IOI-HA was developed for research purposes to facilitate the comparison of data. This instrument can also be applied to make clinical evaluations of hearing aid fitting outcomes.[20] These seven items are use (hours per day), benefit, residual activity limitations, satisfaction, impact on others, and quality of life. Responses were coded from 1 to 5, with a higher score representing a better outcome. We added one additional question: 'Would you recommend the BAHA implantation to someone else with the same hearing loss?' This question could be answered with "yes", "no", or "do not know".

The SSD questionnaire consists of 12 items on use, satisfaction, estimation of hearing aid benefit in different listening situations in comparison with the situation a without hearing aid, aesthetics, and handling of the BAHA. All the items can be answered on a four-point or three-point scale; the questions on satisfaction and aesthetics can be answered on a discrete visual analogue scale (VAS). A score of 10 indicated "very satisfied", and a score of 1, "very dissatisfied".

Analysis

Student's *t* test was applied to the results of the speech perception measurements and localization tests, as well as to compare mean values in the different domains of the APHAB and GHABP. A *p* value of less than 0.05 was chosen as the level of significance, with a *p* value of less than

0.025 in the case of a two-tailed *t* test. The results were computed using the SPSS software package, version 11 (SPSS, Inc., Chicago, IL, U.S.A.).

RESULTS

The mean duration of follow-up was 1 year, 4 months (range, 11 mo-2 yr, 1 mo). Three patients did not respond to the follow-up postal-based questionnaire for different reasons (poor physical health, non-BAHA use because of skin reduction operation, no reason given).

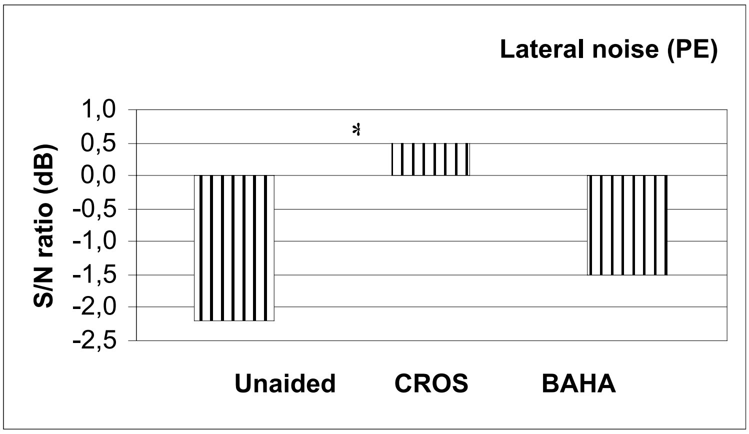
Audiometric measurements

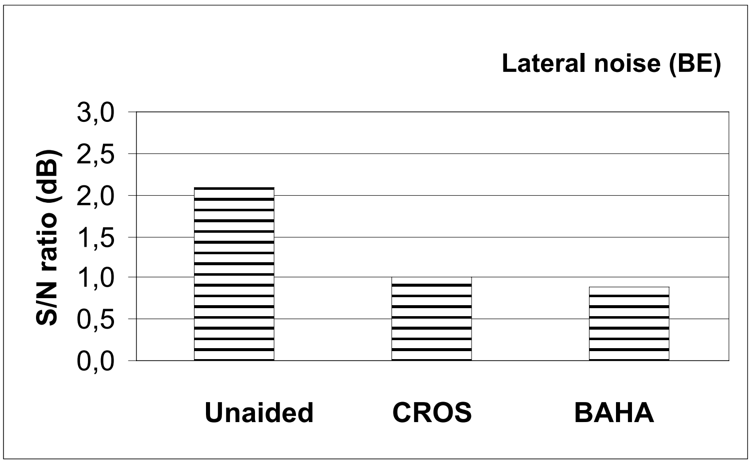
Sound localization

Sound localization data are shown in Table II for 500- and 3000-Hz noise stimuli. With the 500-Hz stimuli, localization performance was essentially the same as chance level in most conditions. These audiometric data were in agreement with previous measurements from 20 patients. The three congenitally deaf patients also had mean correct and lateralization scores that were not statistically significantly different from chance level. The patient with the best correct and lateralization scores was one of these congenitally deaf patients.

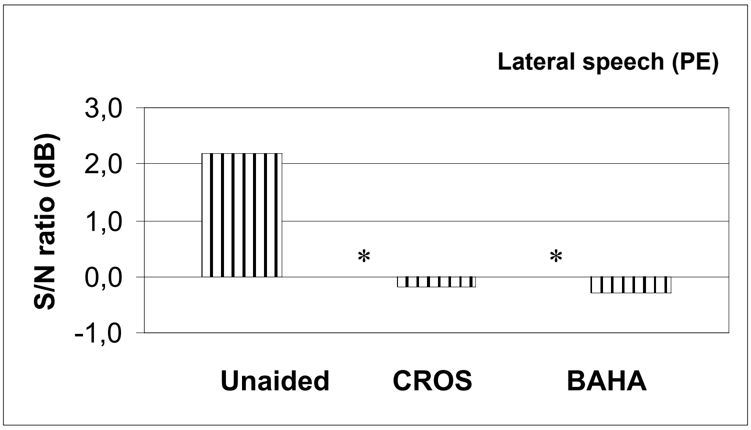
Speech perception

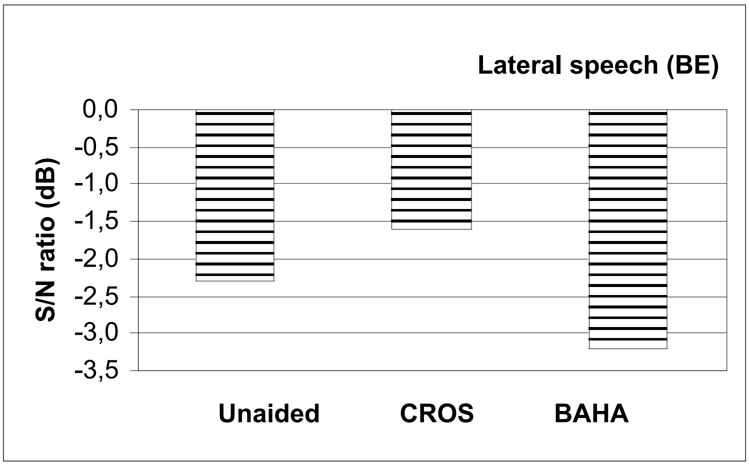
Figure 1 shows the mean S/N ratios for the three conditions (unaided, conventional CROS, and BAHA CROS). Better performance corresponds with lower S/N ratios. An asterisk indicates significant changes. Data were collected while speech was presented in front of the listener, and noise was presented on the side of the poor ear (PE) or best ear (BE); this measurement condition is referred to as lateral noise (Figs. 1, *A* and *B*). Also, data were collected while noise was presented in front of the listener and speech was presented on the side of the PE or BE; this measurement condition is referred to as lateral speech (Figs. 1, *C* and *D*). These audiometric data were in agreement with previous measurements from 20 patients.





Figures 1 (*A* and *B*). S/N ratio for speech intelligibility of 50% for everyday Dutch sentences with speech presented in front, while noise was presented on either (*A*) the poor ear (PE) or (*B*) the best ear (BE): lateral noise in the three conditions (unaided, conventional CROS [CROS] and BAHA CROS [BAHA] (* indicates $p < 0.025$, compared with the unaided situation).





Figures 1 (*C* and *D)*. S/N ratio for speech intelligibility of 50% for everyday Dutch sentences with noise presented in front, while speech was presented on either (*C*) the poor ear (PE) or (*D*) the best ear (BE): lateral speech in the three conditions (unaided, conventional CROS [CROS] and BAHA CROS [BAHA]. (* indicates $p < 0.025$, compared with the unaided situation).

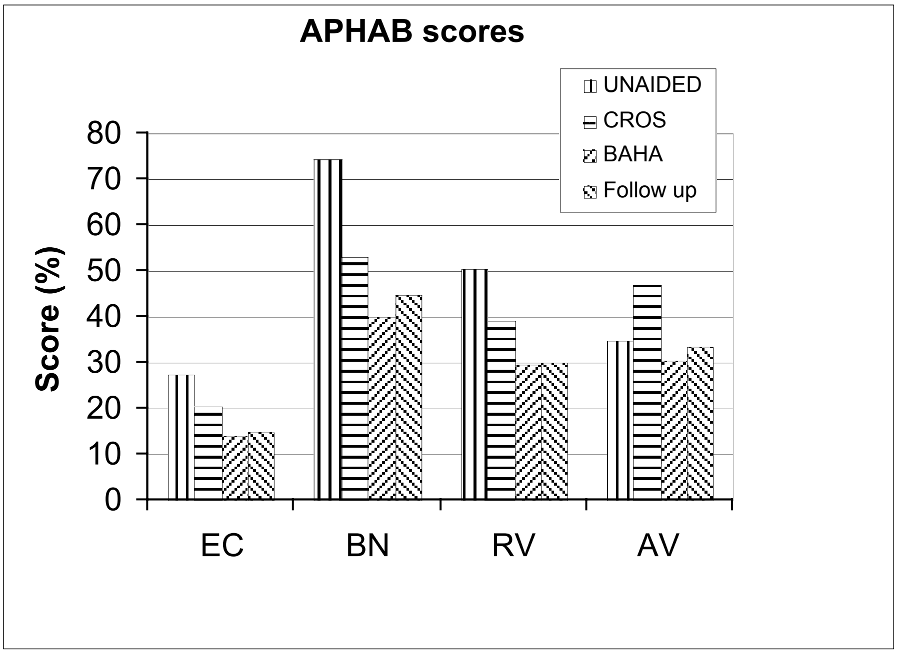


Figure 2. Mean scores of the 29 patients in the domains Ease of Communication (EC), Background Noise (BN), ReVerberation (RV), and AVersiveness of sound (AV) on the APHAB in the four different conditions: Unaided, conventional CROS (CROS), BAHA CROS at 6 weeks (BAHA) and BAHA CROS at 1-year follow-up (Follow-up).

Patient outcome measurements

APHAB

Scores on the four domains of the APHAB are shown in figure 2. Relatively large differences occurred in the communication performance domains: Ease of Communication (EC), Reverberation (RV), and Background Noise (BN). The lowest (i.e., most favorable) results were seen with the BAHA CROS. Differences between the baseline and postintervention outcomes were calculated. A negative difference score denoted improved communication. The conventional CROS showed improved scores in the domains EC (_7.2; p = 0.03), BN (_21.1; p = 0.00), and RV (_9.6; p = 0.001). The BAHA CROS showed greater improvement in each of the following domains: EC (_13.1; p = 0.001), BN (_33.1; p = 0.00), and RV (_19.1; p = 0.00). In the domain Aversiveness of Sound (AV), statistically significant deterioration was seen with the conventional CROS (12.7; p = 0.02). The score with the BAHA CROS was better than the score in the unaided condition, but the difference (_3.7; p = 0.52) was not statistically significant.

After a mean follow-up of 1 year, the scores of 26 patients in each of the domains EC (13.6; p = 0.65), BN (44.9; p = 0.13), RV (29.4; p = 0.81), and

AV (33.3; p = 0.88) showed statistically nonsignificant deterioration compared to the BAHA CROS results obtained after 6 weeks of BAHA CROS use. The domains EC, BN, and RV remained statistically significantly better than in the unaided situation.

GHABP

Initial disability scores in the unaided condition ranged from 20 to 100%, with a mean initial disability score of 54.4%. Unaided handicap scores ranged from 0 to 100%, with a mean unaided handicap score of 40.2% (Fig. 3, *A*).

Figure 3, *B*) shows utility, benefit, residual disability, and satisfaction with the conventional CROS and with the BAHA CROS at 6 weeks of follow-up and at 1 year of follow-up.

Mean day-to-day use was 65% with the conventional CROS, 88% with the BAHA CROS at 6 weeks of follow-up, and 78% at 1 year of follow-up. Mean benefit was 39% with the conventional CROS, 52% with the BAHA CROS at 6 weeks of follow-up, and 49% with the BAHA CROS at 1 year of follow-up. Mean residual disability was 42% with the conventional CROS, 32% with the BAHA CROS at 6 weeks of follow-up, and 37% with the BAHA CROS at 1 year of follow-up. Mean satisfaction was 32% with the conventional CROS, 51% with the BAHA CROS at 6 weeks of follow-up, and 44% with the BAHA CROS at 1 year of follow-up.

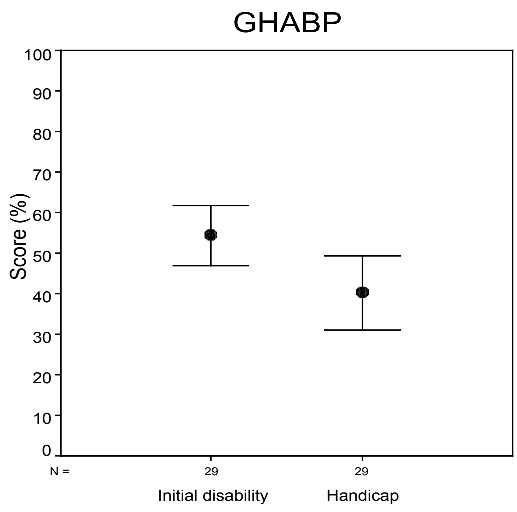


Figure 3*A*. Mean GHABP scores and 95% confidence intervals on the domains Initial Disability and Handicap in all 29 patients.

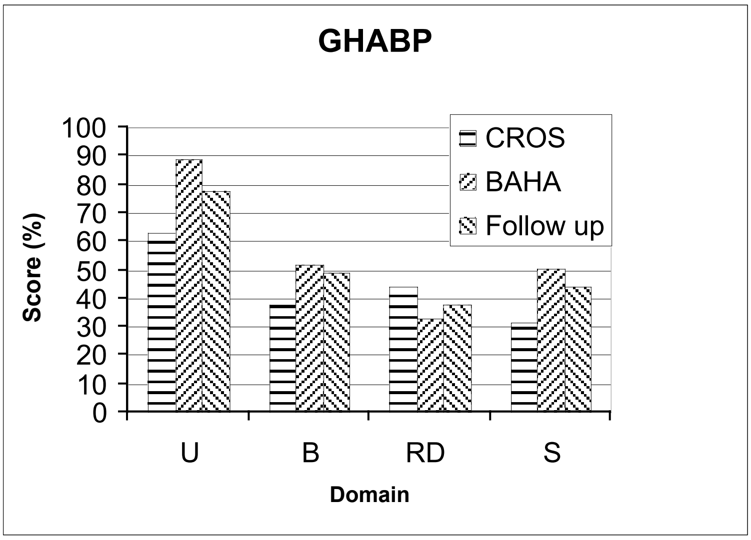


Figure 3*B*. Mean values of the 29 patients on the domains Utility (U), Benefit (B), Residual Disability (RD) and Satisfaction (S) on the GHABP in the different conditions: conventional CROS (CROS), and BAHA CROS at 6 weeks (BAHA), and BAHA CROS at 1-year follow-up (Follow-up).

IOI-HA

The frequency distributions of the responses to this seven-item instrument are shown in Figure 4. The seven items are use, benefit, residual activity limitations, satisfaction, residual participation restrictions, impact on others, and quality of life. Responses were given on a five-point scale; a higher score represents a better outcome. Figure 4 shows the responses of 23 patients in the BAHA CROS condition. Mean scores at 6 weeks on the seven items were 4.6, 3.5, 3.9, 4.0, 4.2, 4.5, and 4.1, respectively. The responses of 26 patients at 1 year follow-up are also shown (Fig. 4). Mean scores on the seven items were 4.2, 3.4, 3.5, 3.7, 4.0, 4.4, and 4.0, respectively. The mean differences in six of the seven items between the BAHA CROS at 6 weeks of follow-up and at 1 year of follow-up were not statistically significant in the same 23 patients. Only item 4 (satisfaction) was significantly poorer at 1 year of follow-up ($p = 0.017$). Median scores only changed on items 2 (4 to 3) and 5 (5 to 4). Twenty-three of 26 patients answered “yes” to the additional item, which indicated that at 1 year of follow-up, they would recommend the BAHA to someone else with the same hearing loss.

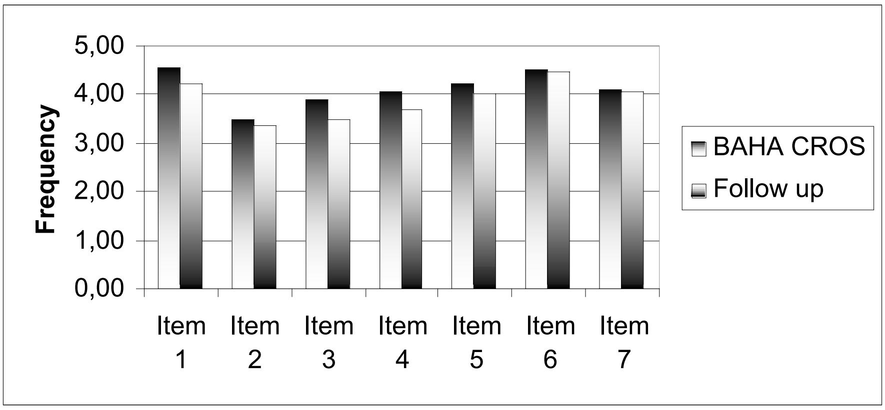


Figure 4. Frequency distributions of the IOI-HA items: with BAHA CROS at 6 weeks and at 1-year follow-up. Higher scores represent better outcomes.

SSD questionnaire

Twenty-four patients filled out the SSD questionnaire for the BAHA CROS situation. The answers showed that 19 patients were using the BAHA every day of the week, for more than 8 hours a day. Quality of life had improved with their BAHA in 21 patients. The mean visual analogue scale (VAS) score on Item 4 (satisfaction with the BAHA) was 7.6. The mean score on Item 7 (aesthetics of the BAHA) was 7.3. The other five items concerned the value of the BAHA in different listening situations in comparison with the unaided situation. In quiet, 17 patients stated that the BAHA was better than the unaided situation, whereas the other 7 patients did not experience any difference. The same distribution of answers was seen in the next three items regarding speaking to a person in a group, listening to music, and watching television, in which 20 patients stated the situation was better with the BAHA. The answers to the last of these four items, regarding the value of the BAHA when sitting at the dining table with someone speaking on the deaf side are worth noting. In this particular situation, 22 patients stated that the BAHA was better, whereas two patients experienced deterioration. The next item asked whether the patients experience found it easier to localize sounds with the BAHA; six patients stated “yes”, five patients stated “no”, seven patients stated both “yes” and “no”, and six patients stated “no difference”. Handling of the BAHA was considered “easy” by 12 patients and “very easy” by 10 patients. At 1-year follow-up, the answers to all the items were essentially the same. All patients were still using the BAHA every day, 14 patients for more than 8 hours a day and 5 patients (who had first been using the BAHA for more than 8 hours a day) for 4 to 8 hours a day. Two more patients answered "yes" to the item regarding ease of localizing sounds at 1 year of follow-up. The mean localization scores of these eight patients did not differ statistically significantly from the total mean localization scores (see Sound Localization in Results section).

Table 2. Average sound localization scores for correct identification of target loudspeaker and for correct lateralization using 500- and 3000-Hz stimuli in the unaided condition, with the conventional CROS (CROS) and BAHA CROS (BAHA) contralateral routing of sound and bone-anchored hearing aid contralateral routing of sound

Identification	Chance level (%)	Frequency (Hz)	Unaided (%)	CROS (%)	BAHA (%)
Correct	11	500	19.1	16.8	16.5
		3000	18.1	14.6	17.4
Lateralization	50	500	45.1	45.1	46.2
		3000	50.3	42.4	52.6

Abbreviations: CROS, conventional contralateral routing of sound; BAHA, bone-anchored hearing aid contralateral routing of sound

DISCUSSION

In patients with unilateral inner ear deafness, the presence of only one functioning cochlea precludes the use of interaural time and intensity differences essential for directional hearing.

The poor sound localization scores (Table 2) clearly illustrate the inability of patients with unilateral inner ear deafness to localize sounds. Although the scores for correct identification in the unaided condition and with the BAHA CROS differed significantly from chance, these scores were vastly different from the mean scores for correct identification obtained by subjects with normal binaural hearing. The results of the present 29 patients agreed with those of our previous study of 20 patients.[11]

The head shadow effect is illustrated in Figure 1 as the difference between the S/N ratio of the PE and the BE in the unaided condition. In the condition with lateral noise (Fig. 1, *A* and *B*), when noise was presented on the side of the BE, both the conventional CROS and the BAHA CROS resulted in lower S/N ratios than in the unaided condition. However, when noise was presented on the side of the PE, the S/N ratio in the unaided condition was lower and therefore more favorable than in the aided conditions. Thus, it can be argued that in the condition with lateral noise on the side of the PE, both hearing aids were inferior to the unaided condition. This negative-side issue also occurred in our previous study[11] and can be explained by the transfer of noise from the PE to the BE by the CROS devices. This effect can be avoided by using the devices selectively in these situations. Nevertheless, the BAHA CROS performed better than the conventional CROS because the S/N ratio with the conventional CROS was substantially poorer than the S/N ratios in the unaided condition and with the BAHA CROS.

In the condition with lateral speech (Fig. 1, *C* and *D*), a fairly similar pattern was seen when speech was presented on the side of the BE. The S/N ratio with the BAHA CROS was better than in the unaided situation; with the conventional CROS, the S/N ratio deteriorated. However, when speech was presented on the side of the PE, the S/N ratios were better with the conventional CROS and with BAHA CROS than in the unaided condition (Fig. 1, *C* and *D*). The smaller effects of the conventional CROS were probably due to the open ear mold in the BE that partially blocked direct sound and limited the transfer of low-frequency sound from the PE to the BE.[21]

The performance-intensity function slope of 15% per decibel[19] means that the 2.2-dB difference in S/N ratio with the BAHA CROS was equivalent to an increase in speech intelligibility of 33%. Overall, these results reflected the efficacy of the BAHA CROS to lift the head shadow effect. This was particularly advantageous in specific listening situations e.g., at the dinner table or while driving a car. With the BAHA CROS, some of the disadvantages of a conventional CROS were avoided, such as poor quality of sound emanating from the PE and impaired perception of direct sound as a result of partial occlusion of the ear canal on the BE side.

The results of the five patients with an air-bone gap of 10 dB and the patients with an air-bone gap of 25 dB (i.e. beyond our original inclusion criteria) were no different from the mean scores of the entire group. This underlines the suggestion in our previous study that our inclusion criteria can be broadened.[11]

Patients' answers to the four different instruments clearly revealed the advantages of the BAHA CROS. Although debate continues regarding the best assessment method for hearing aid benefit, the APHAB has gained popularity as a convenient and clinically practical tool for measuring hearing aid benefit.[14,22] In our study, the APHAB showed improvement in the domains EC, BN, and RV with both the conventional CROS and the BAHA CROS (Fig. 2). The greatest improvement on the APHAB was seen with the BAHA CROS in the BN domain. Improvement was significant with the BAHA CROS and with the conventional CROS compared with the unaided condition. After a mean follow-up of 1 year, the scores on the domains of the APHAB did not differ significantly from the scores with the BAHA CROS. Although these changes were small (the largest change was 4.7 on the domain BN) and nonsignificant, they suggest that the patients were a little less enthusiastic than they had been 1 year earlier before when they had just received the BAHA. The better results with the BAHA CROS at 6 weeks of follow-up may have been partly biased by enthusiasm. This relatively small bias, which indicates that the patients had realistic expectations, may be due to the trial with a BAHA headband before surgery. Also, the patients who gave a negative response to the headband trial were excluded. The scores on the AV domain showed a trend toward the conventional CROS scores being poorer than the scores in the unaided condition and those with the BAHA CROS at 1 year of follow-up also. The increased aversion to sound with the conventional CROS in some patients may have been due to the over-amplification of loud sounds resulting in sound levels that exceeded their comfort levels. This effect was not seen with the BAHA CROS because its maximum output is fairly limited.[23,24]

The GHABP was the only instrument used in this study that included both initial measures (initial disability, handicap) and outcome measures (utility, benefit, residual disability, and satisfaction). This instrument can measure the importance of a hearing aid in specific situations. In 2002, the GHABP was used to evaluate the BAHA.[25] Difference scores were measured by comparing the patients' previous conventional air-conduction or bone-conduction hearing aid with the BAHA. Initial disability and handicap levels were considerable, with median scores of 75% and 82%, respectively.[25] In our study on patients with unilateral inner ear deafness, initial disability was substantially smaller (56%) and residual disability reduced even more. Derived benefit with the BAHA CROS showed improvement at 6 weeks of follow-up and at 1 year of follow-up, whereas with the conventional CROS, less derived benefit was shown. The scores on the domains utility, benefit, and satisfaction were highest with the BAHA CROS at 6 weeks of follow-up (i.e. higher than with the conventional CROS), but they had decreased slightly at 1 year follow-up. This may reflect the same enthusiasm bias as measured with the APHAB.

The norms of the IOI-HA are based on adults fitted bilaterally with in-the-ear hearing aids.[20] Separate norms exist to distinguish mild or moderate subjective hearing problems (unaided) from “moderately severe or severe” problems.[20] Because the GHABP handicap score was considerably lower than the score obtained from BAHA patients with a conventional indication, one can argue that patients with unilateral inner ear deafness belong to the group with initially mild or moderate hearing problems. All the mean item scores were significantly different (in a positive direction) from the normative mean, except for Item 2 (BAHA CROS) and Items 2 and 3 at 1 year follow-up. Thus, in patients with unilateral inner ear deafness, the BAHA resulted in statistically nonsignificantly more benefit (Item 2) and less residual activity limitation (Item 3).

The SSD questionnaire was used and described for the first time by Wazen et al. in 2003.[8] Our patients gave the same positive answers with regard to use and satisfaction, not only in the BAHA CROS situation at 6 weeks of follow-up but also at 1 year of follow-up. Answers to the question about sound localization benefit were of special interest. Both in the BAHA CROS situation at 6 weeks and at 1 year of follow-up, the majority of patients stated that they did not experience any difference in the ability to localize sounds with or without the BAHA. However, at 1 year of follow-up, eight patients stated, quite unexpectedly, that they were experiencing benefit in localizing sounds with the BAHA. This judgement was probably based on the impression that sounds can be localized by differences in sound quality between the PE and BE.

In view of the sound localization results presented in this study, this is a subjective experience rather than the true benefit of restoring *stereo hearing* as stated in another study.[26] Their evidence is limited because it simply concerns questionnaire outcomes in three patients with deafness following acoustic neuroma surgery.

However, patients with congenital unilateral hearing loss may, indeed, learn to rely on the head shadow effect and in this way cope better with familiar acoustic environments.[27] In the current study, the average localization results of the three patients with congenital deafness were no different from those of the total group of patients with unilateral inner ear deafness. However, the patient with the best localization results was one

of these three congenitally deaf patients. Further evaluation of patients with congenital unilateral inner ear deafness is desirable.
The SSD questionnaire clearly showed that the patients appreciated having the head shadow effect lifted so that they could hear sounds more clearly in their PE. This was particularly valuable in situations such as driving a car, sitting at the dinner table or at a meeting with the speaker on the PE side.
Judgment on the BAHA as a transcranial CROS device by the four different instruments was overwhelmingly positive and universal. Although each instrument had its own merits, several domains overlapped and even several items showed overlap. All four instruments detected improvements compared with the unaided situation. Improvement was most clearly visible with the BAHA CROS at 6 weeks of follow-up, and there was only slight regression at 1 year follow-up. The BAHA CROS was superior to the conventional CROS according to all four instruments. Therefore, in our opinion, fewer instruments can be administered to the patients to obtain data in the different situations.

CONCLUSION

Patients with only one functioning cochlea lack the cues essential for directional hearing, namely, interaural time and intensity differences. Thus, according to our measurements, in patients with unilateral inner ear deafness the application of a conventional CROS or a BAHA CROS device cannot restore binaural hearing. The present study showed some improvement in favor of the BAHA CROS in the speech reception threshold measurements. The main value of either of the two devices lies in alleviating the head shadow effect. All four instruments indicated considerable satisfaction. Further evaluation of patients' opinions is advised in patients with unilateral inner ear deafness with the BAHA CROS.

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General discussion

Chapter 5

This thesis describes long-term results and new indications of the bone-anchored hearing aid (BAHA); clinical and audiological results are complemented with data on patient satisfaction.

Chapter 2 presents the impact of BAHA application on the quality of life (QoL) of hearing impaired adults, which is described 6 months after BAHA fitting and at long-term follow-up. In *chapter 2.1* the results of the postal-based questionnaire study using validated health-related quality of life (HRQoL) instruments in combination with hearing-aid related questions are described. In total 56 consecutive patients with acquired conductive or mixed hearing loss filled out these instruments before surgery and after 6 months of experience with the BAHA in order to assess the possible gain in HRQoL. Prior to implantation, all patients used conventional hearing aids, i.e. either air-conduction hearing aids or bone-conduction hearing aids. Both the 36-item short-form health survey (SF-36) and the EuroQol-5D (EQ-5D) were unable to show that generic HRQoL was influenced by the change from a conventional hearing aid to a BAHA. It can be questioned whether the change is too small to be detectable or the instruments are too generic to detect hearing improvement. In contrast, a disease-specific HRQoL instrument, the hearing handicap and disability index (HHDI) used in this study, did reflect that the BAHA had a significant positive effect. All patients stated that they used the BAHA for 8 hours or more a day. Therefore, it was assumed that the reported reduced frequency of otorrhea and reduced prevalence of skin irritations were directly related to the BAHA usage.
In *chapter 2.2* the long-term results of patients previously using conventional air-conduction hearing aids are described with regard to use, care, ear infections and satisfaction in combination with audiometry. After a mean duration of nine years of follow-up all eligible patients were still using the BAHA for 7 days a week and only few patients experienced some difficulty with taking care of the percutaneous titanium implant. These patients are expected to have a tendency towards an increased frequency of skin reactions around the implant, however, the recently introduced elongated version of the snap-coupling (8.5 mm) could be helpful to overcome skin reactions in these patients. All patients classified speech recognition with the BAHA as acceptable. Speech in noisy situations however was classified as poor, which can be explained as a result of unilateral hearing aid rehabilitation in patients with a bilateral hearing

loss. The conventional indication for a BAHA implies an otological situation being the result of chronic middle ear disease (like a radical or modified radical cavity) and frequently, as a result of this, a negative effect on the inflammation process by occluding the ear canal by an ear mould is inevitable. In the year preceding this evaluation, 44% of the patients experienced one or more episodes of otorrhea, which means several patients, were still -although perhaps intermittently- suffering from chronic middle ear problems. Realizing that the conventional indication for BAHA application generally implies therapy resistant otorrhea, the measured otorrhea prevalence of 44% implies a substantial decrease. Audiometric measurements, i.e. free-field evaluations showed that on average, the aided thresholds deteriorated by 7 dB over a 9-year period. This deterioration can at least partially be attributed to limited functional gain or other device-related factors, resulting in the inability to compensate for the age-related deterioration in cochlear function. In general, this study showed no significant general deterioration in cochlear function over time (after corrections for age) and emphasizes accordingly to use bone-conduction devices like the BAHA in these particular patients, with a positive effect on the occurrence of otitis media.

In *chapter 3* quite a new indication to use the BAHA in patients with a large unilateral conductive hearing loss and a normal hearing in the contralateral ear is described. *Chapter 3.1* deals with the question whether the BAHA has a complementary effect on audiological and subjective outcomes in patients with a unilateral conductive hearing loss. All evaluated patients had a large acquired unilateral conductive hearing loss (40-60 dB) and bilateral normal cochlear function or mild symmetrical sensorineural hearing loss. In general, sound localization testing with both 500 Hz and 3000 Hz noise bursts showed improved localization abilities with the BAHA. Only a few patients did not show improvement in localization scores, as they were already able to localize sounds rather adequately in the unaided situation. Speech recognition in noise measurements showed that all the patients were able to use the aided ear effectively. Overall, the patients were satisfied with the BAHA, both in quiet and in noisy listening situations. The BAHA application in patients with large unilateral conductive hearing loss is a unique and new opportunity to provide these patients with binaural hearing again. It is to be expected that this new BAHA indication will become an important treatment modality in this group of patients.

Chapter 3.2 describes those patients with acquired unilateral conductive hearing loss and unaided directional hearing scores that were significantly above chance level in the first study (described in chapter 3.1) as they were asked to participate again. Three hypotheses were formulated to explain these interesting findings in the unaided situation. First, in order to test if these patients make more effective use of acoustic head shadow effects, directional hearing was measured with stimulus levels varying at random, eliminating loudness as a cue. Second, to test if these patients were able to use differences between direct and the reflected sounds as a cue, measurements were recorded in high and low reverberant rooms. Third, to test if these patients were able to make more effective use of pinna effects, measurements were repeated after the pinna had been made 'ineffective' by molding it with wax. All three hypotheses were rejected and thus, so far the exact mechanism behind the good localization abilities of these patients with unilateral conductive hearing loss in the unaided situation remains unexplained and needs further investigation. In order to be more comprehensive, children with congenital unilateral conductive hearing loss treated with the BAHA should be also be evaluated including a prospective evaluation concerning school performance. The instrument used in this chapter to assess QoL, namely: the speech, spatial and other qualities of hearing scale (SSQ), showed that all patients experienced benefit with the BAHA in both domains assessed in this study: speech and spatial hearing.

Next, in *chapter 3.3* the new transcutaneous application of the BAHA is introduced, meant for very young patients with bilateral congenital conductive hearing loss. This conductive hearing loss is generally due to congenital bilateral aural atresia or congenital anomalies of the ossicular chain. In case surgical intervention is not an option (yet) and in case of complete ear canal atresia conventional air-conduction hearing aids are not an option either, bone-conduction hearing aids are the sole option to provide these very young children with auditory cues necessary for adequate speech and linguistic development. Bilateral application is preferred because of the advantage of processing auditory information with two ears over listening with one ear. Furthermore, the provision of interaural time and intensity differences may enable sound localization in the horizontal plane. However, conventional bone-conduction hearing aids can not be used for bilateral fitting, except for those fitted in spectacles with a solid frame and thus not an option in very young children. A great advantage of the BAHA on the other hand, is that the microphone is situated on the same side of the head as the vibrator which makes it applicable for bilateral fitting. However, the youngest age for percutaneous titanium fixation to the skull is about three years as the essential osseo-integration might be poor owing to the non-mature structure of a very young child's skull. In this chapter the recent development initiated in Nijmegen to wear the BAHA attached to an elastic band by means of the special plastic snap connector disk, the BAHA Softband, is described. The results of the first two children with binaural congenital aural atresia fitted with the BAHA Softband are encouraging. Hearing revalidation in the first months of life by means of the BAHA Softband is accepted and appreciated, and has already become a widely accepted new BAHA application. In the near future this will result in larger groups of children treated with the BAHA Softband, which offers us the opportunity of further evaluation with regard to their speech and linguistic development.

In *chapter 4* the use of the BAHA in patients with unilateral profound sensorineural hearing loss is described. The detrimental effects of unilateral hearing loss are more recognized nowadays. The traditional audiological approach consists of fitting a contralateral routing of sound (CROS) hearing aid. The most recent and promising option is to use the BAHA as a transcranial CROS device (BAHA CROS). *Chapter 4.1* mentions the results of the first nine Nijmegen patients with unilateral profound sensorineural hearing loss fitted with the BAHA CROS. The BAHA CROS appeared to be beneficial in reducing the head shadow effect, resulting in an increase in speech intelligibility of 30% for speech presented at the deaf side of the patient and noise in front. Sound localization measurements, however, confirmed the inability of these patients to localize sounds under the tested circumstances. The fact that these patients have only one functioning cochlea precludes using interaural cues essential for binaural hearing. Nevertheless, ambivalence is reported in literature concerning sound localization abilities of patients with unilateral profound sensorineural hearing loss and the BAHA CROS. To gain greater insight in both audiological and subjective patient outcomes, detailed results of twenty patients are described in *chapter 4.2*. Again, with the experimental set-up used in this study poor sound localization scores were found. The benefit of reducing the head shadow effect was confirmed with speech recognition measurements. The baseline (unaided) and post-intervention (conventional CROS and BAHA CROS) patient outcome measurements were administered by means of the abbreviated profile of hearing aid benefit (APHAB). Overall the BAHA CROS showed better scores than the conventional CROS in all the four domains of the APHAB. The largest improvement was seen with the BAHA CROS in the background noise domain. The smallest improvement with the BAHA CROS was seen with regard to aversiveness of sound. In *chapter 4.3* the long-term results of 29 patients with unilateral profound sensorineural hearing loss are shown. Patient outcome measures were administered at one year follow-up by means of four different instruments: the APHAB, the Glasgow hearing aid benefit profile (GHABP), the international outcome inventory for hearing aids (IOI-HA) and the single sided deafness (SSD) questionnaire. All patients were still using the BAHA with an average use of eight hours a day, seven days a week. The patient outcome data were convincing at one year follow-up, although slightly less convincing than after six weeks of BAHA usage, probably reflecting some enthusiasm bias. The majority of the patients indicated they did not experience any difference in the ability to localize sounds with or without the BAHA. In general, although each of the instruments has its own focus, all four instruments indicated considerable satisfaction. The BAHA was appreciated by these patients with unilateral profound sensorineural hearing loss, much more than to be expected considering the audiological outcomes.

In summary, the effectiveness of BAHA usage in patients with conventional indications is underlined in this thesis by the evaluation of long-term results. Furthermore, this thesis described that the BAHA can be used effectively both in patients with severe unilateral conductive hearing loss and in very young patients with bilateral conductive hearing loss by means of the BAHA Softband to restore binaural hearing, but the BAHA was also helpful in patients with unilateral profound sensorineural hearing loss to provide contralateral routing of sound. As the importance of patient outcome research is more and more recognized, the audiological measurements, as obvious part of the fitting evaluation of the BAHA, were complemented with various patient outcome measurements. Still, additional audiological and patient outcome measurements are needed to explore and investigate new extended indications for BAHA application on behalf of hearing impaired patients.

Summary
Summary in Dutch

Chapter 6

The bone-anchored hearing aid (BAHA) system, developed in Gothenburg, has commercially been available since 1987. Although the method to aid patients suffering from bilateral conductive or mixed hearing loss by means of bone conduction was already known for a long time, there had been hardly any development in the field of bone conduction devices until then. The BAHA however, a semi-implantable percutaneous bone conduction device, is innovative, as it overcomes the drawbacks of conventional bone conduction devices. The BAHA system is typically beneficial in patients with conductive hearing loss when air-conduction hearing aids cannot be used successfully and when reconstructive surgery is not a feasible option. In other words, in patients with either persistent otitis media or externa, or (congenital) aural atresia.
The reported impact of the BAHA system in 56 adult hearing impaired patients, who previously used conventional air- or bone conduction hearing aids, is not reflected in a change in their general health status (measured by the SF-36 and the EQ-5D). However, there is a distinct improvement in disability and handicap as shown by the disease-specific quality of life (QoL) instruments. In addition, the patients reported a decreased frequency of otorrhea and prevalence of skin reactions, resulting in a reduced amount of visits to otorhinolaryngologists. The 27 patients who were studied on average nine years after implantation, are still using the BAHA and are very positive about the results in patient outcome instruments. For this type of patients the fitting of a BAHA system is preferable to conventional air-conduction hearing aids, as the occluding ear mould may continue to cause ear infections, especially in ears with an open access to the middle ear.
Various other studies also showed that the BAHA system is a highly effective treatment for patients with this conventional indication (bilateral conductive or mixed hearing loss). Recent research, including the studies described in this thesis, shows that the indication can be broadened.
For example, quite a new indication is to use the BAHA system in patients with unilateral conductive or sensorineural hearing loss. Prospective evaluation of 18 patients with severe unilateral conductive hearing loss, fitted with a BAHA system, showed encouraging results. Patients are able to use the aided ear effectively and, in general, their localization abilities have improved. The mechanism of several patients with unilateral conductive hearing loss, who have good localization abilities even in the

unaided situation, is even after extensive measurements in our experimental set-up not completely understood yet.
Furthermore, patients with unilateral profound sensorineural hearing loss (or unilateral inner ear deafness) benefit from the BAHA system placed at the shadow side of the head by means of contralateral routing of sound via bone conduction. Speech intelligibility tested in 20 patients improved by 30%, when speech was presented at the deaf side of the patient. However, as expected localization abilities did not improve in our experimental set-up as these patients have only one functioning cochlea. The patient outcome instruments showed encouraging results not only after one month of experience with the BAHA system, but also after long-term follow-up (n=29).
Another new BAHA indication, initiated in Nijmegen, is to use the BAHA Softband in very young children with congenital bilateral aural atresia (bilateral conductive hearing loss). The skulls of such young children are too immature to provide stable fixation of the titanium implant. In the case of the BAHA Softband, the BAHA is attached to an elastic fillet, which offers the possibility of bilateral fitting and has proven to be a practical and acceptable solution for these young hearing impaired children. The BAHA Softband is *the* solution to provide these children, awaiting implantation, with auditory cues as early as possible, as they are essential for optimal speech and linguistic development.

Het “in het bot verankerde hoortoestel”, oftewel “bone-anchored hearing aid” (BAHA), is ontwikkeld in Göteborg en commercieel verkrijgbaar sinds 1987. Hoewel de methode om patiënten met bilateraal geleidings- of gemengd gehoorverlies te revalideren middels beengeleiding al sinds lange tijd bekend is, waren er tot dan toe weinig ontwikkelingen op dit gebied. De BAHA echter, een innovatief semi-implanteerbaar percutaan hoortoestel, overtreft de nadelen van conventionele beengeleidings-hoortoestellen. De BAHA is typisch behulpzaam bij die patiënten bij wie luchtgeleidings-hoortoestellen niet succesvol kunnen worden toegepast (bijvoorbeeld wegens looporen, of congenitale atresiën) en bij wie opereren geen haalbare optie is.
De in dit proefschrift beschreven impact die de BAHA heeft bij 56 slechthorende volwassen patiënten, die voorheen conventionele luchtgeleidings- of beengeleidings-hoortoestellen droegen, komt niet tot uiting in een veranderde algehele gezondheidstoestand (gemeten door middel van de SF-36 en de EQ-5D). Er is echter wel een duidelijke verbetering op het gebied van invaliditeit en handicap blijkens de resultaten van ziektespecifieke vragenlijsten naar kwaliteit-van-leven. Deze patiënten meldden daarnaast een afname in de frequentie van oorontstekingen en in het vóórkomen van huidreacties, resulterend in een verminderd aantal bezoeken aan de KNO-arts.
De 27 patiënten die gemiddeld negen jaar na implantatie bestudeerd zijn, gebruiken allen nog steeds de BAHA en zijn in vragenlijsten zeer positief over het resultaat. Voor deze groep patiënten heeft het aanmeten van een BAHA de voorkeur boven conventionele luchtgeleidings-hoortoestellen, aangezien deze door het afsluitende oorstukje oorontstekingen zouden kunnen blijven geven, met name bij oren met een open toegang tot het middenoor.
Ook in diverse andere studies is aangetoond dat de BAHA effectief is bij patiënten met deze conventionele indicatie (bilaterale geleidings- of gemengde gehoorverliezen). Recent onderzoek, met inbegrip van de studies beschreven in dit proefschrift, toont aan dat de indicatie voor een BAHA uitgebreid kan worden. Zo is een vrij nieuwe indicatie voor de BAHA, de toepassing bij patiënten met een eenzijdig geleidings- of juist een eenzijdig perceptief gehoorverlies. Een prospectieve evaluatie van 18 patiënten met een ernstig eenzijdig geleidingsverlies, die de BAHA aangemeten hebben gekregen, leverde bemoedigende resultaten op. Deze patiënten kunnen het slechthorende oor met behulp van de BAHA effectief gebruiken en over het

algemeen zijn hun mogelijkheden om geluid te lokaliseren verbeterd. Het mechanisme waardoor sommige van deze patiënten in de ongeholpen situatie al goed kunnen richtinghoren, is ook na uitgebreide metingen in onze testsituatie, nog niet helder.
Patiënten met een eenzijdige binnenoordoofheid zijn gebaat bij een BAHA die aan de schaduwzijde (dove zijde) van het hoofd geplaatst wordt, waarbij geluid via beengeleiding naar de andere -goedhorende- zijde van het hoofd geleid wordt. Voor spraak, aangeboden aan de dove zijde van het hoofd van de 20 onderzochte patiënten, verbetert het spraakverstaan met 30%. Echter, aangezien deze patiënten slechts één functionerend slakkenhuis hebben, verbetert in onze testsituatie zoals verwacht hun capaciteit om geluid te lokaliseren niet. De vragenlijsten die door de patiënten zijn ingevuld, laten bemoedigende resultaten zien, niet alleen na een maand BAHA gebruik, maar ook in een vervolgstudie van 29 patiënten een jaar na behandeling.
Een andere nieuwe BAHA-indicatie, geïnitieerd in Nijmegen, is om de BAHA Softband te gebruiken bij zeer jonge kinderen met een bilaterale congenitale ooratresie (bilateraal geleidingsverlies). De schedel van deze jonge kinderen is namelijk nog niet genoeg uitgegroeid om een stabiele fixatie van het titanium implantaat te bewerkstelligen. In het geval van de BAHA Softband wordt de BAHA vastgemaakt aan een elastische band, die de mogelijkheid biedt om de BAHA bilateraal aan te meten. Daarnaast blijkt het een praktische en een voor zeer jonge slechthorende kinderen acceptabele oplossing te zijn. De BAHA Softband is dé oplossing om deze kinderen, in afwachting van implantatie, zo vroeg mogelijk te kunnen voorzien van auditieve signalen, hetgeen essentieel is voor een adequate spraaktaal ontwikkeling.

Glossary
Appendix
Acknowledgements in Dutch
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List of publications

Chapter 7

ABR	Auditory-evoked brainstem responses
AC	Air-conduction
ACHA	Air-conduction hearing aid
APHAB	Abbreviated profile of hearing aid benefit
AV	Aversiveness of sound (domain of APHAB)
BAHA	Bone-anchored hearing aid
BC	Bone-conduction
BCHA	Bone-conduction hearing aid
BE	Best ear
BN	Background noise (domain of APHAB)
CBHA	Conventional bone-conduction hearing aid
CROS	Contralateral routing of sound
dB	Decibel
dBnHL	Decibel relative to normal hearing level
Deg	Degree
EC	Ease of communication (domain of APHAB)
Eci	E causa ignota
EQ-5D	EuroQol-5D
FM	Frequency modulation
GHABP	Glasgow hearing aid benefit profile
HHDI	Hearing handicap and disability inventory
HL	Hearing level
HRQoL	Health-related quality of life
Hz	Herz
IOI-HA	International inventory
LED	Light emitting diode
MAE	Mean absolute error
MPS	Maximum phoneme score
NH	Normal hearing side
NNST	Dutch non-speech test for receptive and expressive language
PE	Poor ear
Pinna	Auricle
PTA	Pure tone average (mean hearing loss at 0.5, 1, 2 and 4 kHz)
QoL	Quality of life
RV	Reverberation (domain of APHAB)
S/N ratio	Speech-to-noise ratio
SF-36	36-item short-form health survey
SPL	Sound pressure level (decibel)
SRT	Speech reception threshold
SSD	Single sided deafness
SSQ	Speech spatial and qualities of hearing scale
VAS	Visual analogue scale
VRA	Visual reinforcement audiometry

ADAPTED NIJMEGEN QUESTIONNAIRE 2003

(1) On average, how many days a week do you use your BAHA?
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7

(2) On average, how many hours a day do you use your BAHA?
☐ > 8 hours ☐ 4 – 8 hours ☐ 2 – 4 hours ☐ < 2 hours ☐ not at all

(3) Do you experience difficulty with cleaning the skin around the abutment?
☐ Yes ☐ Sometimes ☐ No

(4) Did you experience ear infections the last year?
☐ Yes, how many: ☐ No

(5) How many times did you visit the ENT physician for chronic otitis media (otorrhea), with regard to the past year?
.. / year

(6) Would you, if possible, like to use your old (behind the ear) hearing aid again?
☐ Yes ☐ No ☐ No opinion

If yes, explain why:

(7) If you are not wearing the BAHA anymore, please answer the following questions:

(a) Since when did you stop wearing the BAHA?

(b) Please describe your considerations to quit using the BAHA, if there was a direct cause, please describe that:

(8) (Speech recognition in quiet):
When it is quiet can you understand with your BAHA the sound of….

	Very bad — Excellent
One man	1—2—3—4—5—6—7—8—9—10
One woman	1—2—3—4—5—6—7—8—9—10
One child	1—2—3—4—5—6—7—8—9—10
Television	1—2—3—4—5—6—7—8—9—10
Radio	1—2—3—4—5—6—7—8—9—10

(9) (Speech recognition in noise):
Can you understand someone with your BAHA who is speaking…

	Very bad — Excellent
While the radio or television is on?	1—2—3—4—5—6—7—8—9—10
At a party or a meeting?	1—2—3—4—5—6—7—8—9—10
In a crowded hall?	1—2—3—4—5—6—7—8—9—10
In a restaurant?	1—2—3—4—5—6—7—8—9—10
In a street with a lot of traffic?	1—2—3—4—5—6—7—8—9—10
In a busy shop?	1—2—3—4—5—6—7—8—9—10
In a lecture hall?	1—2—3—4—5—6—7—8—9—10
On a bus or train?	1—2—3—4—5—6—7—8—9—10
In a car?	1—2—3—4—5—6—7—8—9—10

(10) (Quality of sound):
What is your opinion on the quality of sound with your BAHA of…

	Very bad — Excellent
The voices of men?	1—2—3—4—5—6—7—8—9—10
The voices of women?	1—2—3—4—5—6—7—8—9—10
The voices of children?	1—2—3—4—5—6—7—8—9—10
Your own voice?	1—2—3—4—5—6—7—8—9—10
Music?	1—2—3—4—5—6—7—8—9—10
A telephone conversation?	1—2—3—4—5—6—7—8—9—10
Cutlery?	1—2—3—4—5—6—7—8—9—10
Drilling?	1—2—3—4—5—6—7—8—9—10
Slamming doors?	1—2—3—4—5—6—7—8—9—10
Passing trains?	1—2—3—4—5—6—7—8—9—10
Other traffic?	1—2—3—4—5—6—7—8—9—10

(11) (Wearing Comfort):

Not at all — Very much

Is your hearing aid comfortable to wear?
1—2—3—4—5—6—7—8—9—10

Is your hearing aid practical in every day use?
1—2—3—4—5—6—7—8—9—10

Are you troubled by rustling noises when moving around?

Very much — Not at all

1—2—3—4—5—6—7—8—9—10

How do you view the hearing aid with regard to feedback?
1—2—3—4—5—6—7—8—9—10

Do you experience troublesome intrinsic noise from your hearing aid?
1—2—3—4—5—6—7—8—9—10

(12) Do you think you are improved in general since you are using the BAHA?
☐ Yes ☐ No ☐ No opinion

If yes, explain why:

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Myrthe K.S. Hol
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