Bone Conduction Devices

Implant survival and evaluation of bilateral application in children and young adults

Catharina A.J. Dun

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Bone Conduction Devices

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Contents

List of abbreviations

AC	Air conduction
ACHA	Air conduction hearing aid
Acq	Acquired
AUC	Area under the curve
Baha	Bone anchored hearing aid
BC	Bone conduction
BCD	Bone conducton device
BCI	Bone conduction implant system
CBCT	Cone beam computed tomography
CHL	Conductive hearing loss
COM	Chronic otitis media
Cong	Congenital
CROS	Contralateral routing of signal
CT	Computed tomography
DM	Diabetes Mellitus
ENT	Ear, nose and throat
GCBI	Glasgow Children’s Benefit Inventory
HL	Hearing loss
ILD	Interaural level differences
ISQ	Implant stability quotient
ISQ High	Highest ISQ value obtained from perpendicular RFA measurements
ISQ Low	Lowest ISQ value obtained from perpendicular RFA measurements
ITD	Interaural time differences
LDT	Intelligibility level difference test
MAA	Minimum audible angle
MHL	Mixed hearing loss
PS65	65 dB sound pressure level
RFA	Resonance freqency analysis
S/N ratio	Speech-to-noise ratio
SPL	Sound pressure level
SRT	Speech reception thresholds
SSD	Single-sided deafness
SSQ	Speech Spatial and Qualities of Hearing Scale
UCHL	Unilateral conductive hearing loss

CHAPTER 1

INTRODUCTION

1.1

GENERAL INTRODUCTION

I Hearing physiology

Air conduction hearing

The ear consists of three parts: the outer ear, the middle ear and the inner ear (Figure 1). Auditory stimulation commonly occurs by airborne sound transmission (*air conduction, AC*) through the external ear canal (part of the outer ear), where it induces mechanical vibrations in the eardrum that are transmitted via the middle ear ossicles to the inner ear. The transmission is caused by the vibrating third ossicle, called the stapes, which induces a longitudinal fluid wave that travels from the oval window to the (highly mobile) round window. As the fluid moves, in the upper and lower scala (scala vestibuli and scala tympani, respectively), it produces a travelling wave of the basilar membrane, from the basal part toward the apical end of the cochlea. The amplitude of the travelling wave will have a peak at a certain distance from the base, where the distance is related to the frequency of the sound. For low-frequency signals, the vibration of the basilar membrane is at its maximum at the apical part of the cochlea, and high-frequency signals give maximal vibration in the basal part of the cochlea. At the location where the basilar membrane is stimulated (highest amplitude), the sensory hair cells in the organ of Corti are excited causing action potentials that are transmitted to the brain via the auditory nerve (Figure 2).

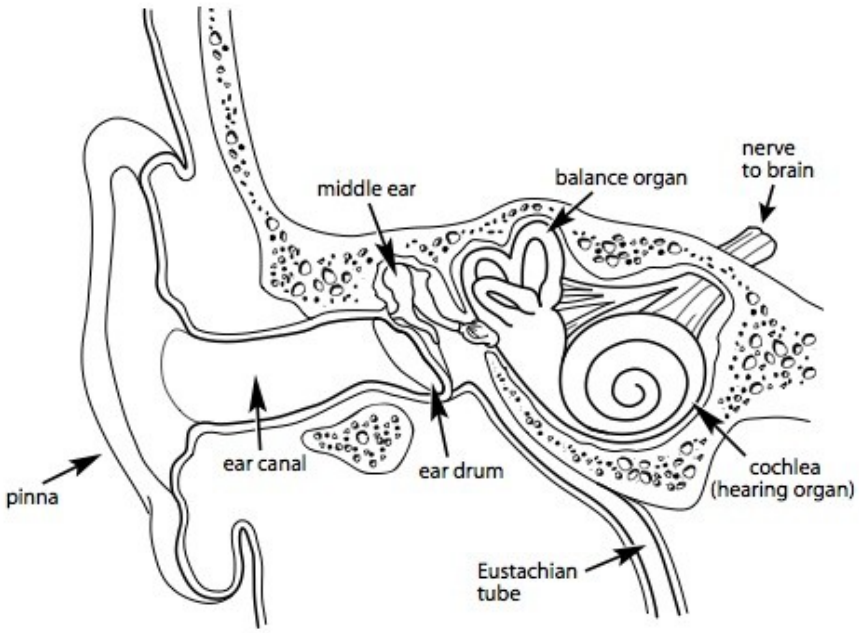

Figure 1. *Schematic impression of a cross section of the ear*. The outer ear consists of the pinna, the cartilageous and bony part of the external ear canal. The middle ear includes three ossicles. The inner ear consists of the cochlea and the balance organ (vestibulum).

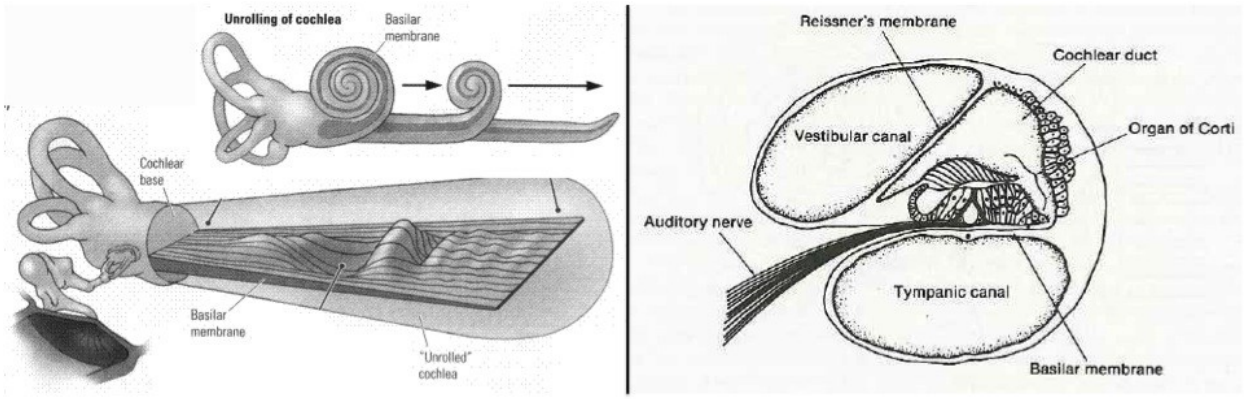

Figure 2. *Schematic impressions of the unrolled cochlea (left) and the rolled up cochlea in cross section (right).* Three compartments can be identified; the scala vestibuli (vestibular canal) and scala tympani (tympanic canal). In between is the cochlear duct, separated from the vestibular canal by the hyper mobile Reissner's membrane. Between the cochlear duct and the tympanic membrane lies the basilar membrane with the sensory organ, organ of Corti. At the location where the basilar membrane is stimulated (highest amplitude), the sensory hair cells in the organ of Corti are excited causing action potentials that are directed to the brain via the auditory nerve.

Bone conduction hearing

Another mode of stimulation that can cause a traveling wave of the basilar membrane is when sound energy is transmitted through the skull bone to the inner ear (*bone conduction, BC).* The BC sound, present as mechanical vibrations of the skull, leads to vibrations of the cochlear shell, which in turn produces fluid motions in the cochlea. These longitudinal fluid waves stimulate the basilar membrane in a similar manner as air-conducted sound.[1,2] To date, it is not entirely understood how skull vibrations produce the longitudinal fluid waves in the cochlea. It has been shown that multiple mechanisms are involved. In 1966 Tonndorf investigated mechanisms contributing to BC sound perception in cats and described seven possible mechanisms.[3,4] Stenfelt and Goode found four of these components to be of significance for BC hearing in the normal and the impaired ear.[5] The relative importance of these contributors differs as a function of sound frequency.

Contributing factors to bone conduction hearing

1. Sound radiated in the ear canal.

   When the skull is excited with BC sound, the ear canal deforms due to the vibrations of the skull, and an airborne sound is produced in the ear canal, further transmitted via the air conduction pathway. With an open ear canal, the sound radiated into the ear canal is not considered to significantly contribute to

the total BC sound perception since it is approximately 10 dB below the other contributing factors. However, when the ear canal is occluded, the sound radiated in the ear canal dominates the BC hearing at low frequencies (400 to 1200 Hz).

2. Middle ear ossicle inertia.
   Middle ear ossicle inertia is believed to influence the BC sensitivity in the mid-frequencies around and above the resonant frequencies of the ossicles between 1.5 and 3.1 kHz. The middle ear ossicles are suspended in the middle ear space by ligaments, the eardrum and tendons. From a mechanical viewpoint, these structures act as springs, holding the ossicles in place. When the skull bone surrounding the middle ear cavity vibrates due to BC excitation, the ossicles vibrate in phase with the skull at low frequencies and do not produce any relative motion. At higher frequencies, the inertial force of the ossicular mass overcomes the spring's stiffness and a relative motion between the ossicles and the surrounding bone occurs. This causes a relative motion of the stapes footplate in the oval window, producing fluid displacement within the cochlea and a sound sensation.
3. Inertia of the cochlear fluids.
   The inertia of the cochlear fluids is considered to be the most dominant contributor to bone conduction, which dominates overall below 4 kHz but may be less important at higher frequencies. The fluids in the cochlea are subject to inertial forces when bone surrounding the cochlea vibrates. The fluids are considered incompressible, but have the possibility to move because of the compliances of the oval and the round windows. The result of these forces is a pressure gradient across the basilar membrane that forms the traveling wave.
4. Compression of the cochlear walls.
   The vibrating bone causes compression and expansion of the cochlear walls. Because the cochlea is unsymmetrical regarding the volume of the fluid compartments (the scalae), compression causes pressure changes that excite the basilar membrane. This mechanism influences the BC hearing primarily at frequencies above 4 kHz.

Another component that is believed to have the potency to contribute to BC hearing is pressure transmission from the cerebrospinal fluid to the inner ear. However, this contribution is probably not significant for hearing by BC in a normal ear.

II Hearing loss

Sensorineural hearing loss

The most common type of hearing impairment is sensorineural hearing loss, mainly based on a dysfunction of the sensory organ in the cochlea. Hearing can usually be rehabilitated by means of a hearing aid, such as a behind the ear device or an in the ear device.

Conductive hearing loss

Other types of hearing loss are conductive hearing loss (CHL) and mixed (both a conductive and sensorineural component) hearing loss (MHL). CHL is mostly caused by a dysfunctional middle ear but sometimes by an occluded external ear canal, as in congenital bony ear canal atresia. In such cases sound perception is limited by an inefficient sound transmission to the cochlea.

Rehabilitation options for conductive hearing loss

There are several options for hearing rehabilitation in patients with CHL and MHL. They may be eligible for reconstructive microsurgery, although the risks of surgery are sometimes prohibitive. For instance, surgery is contraindicated when the patient is too young, or when resolution of the conductive loss is unlikely. In such cases, an air conduction hearing aid (ACHA) may be appropriate as long as the air-bone gap is not too large. However, some patients cannot use ACHAs. The ear canal occluding ear molds that are usually needed for an ACHA are not suitable for patients with therapy resistant otitis. An alternative for these patients is a bone conduction device (BCD); a device that transforms acoustic signals into vibrations of the skull. In a BCD, the sound is transmitted to the cochlea through the skull bone, bypassing the outer and middle ear. In patients with congenital bony malformations of the external ear canal (with or without (partial) malformations of the auricle), the ear mold of an ACHA cannot be fitted properly in the external ear canal and/or the auricle cannot support the ACHA case. Consequently, a BCD is considered to be the only option for these patients.

III Bone conduction devices

Historic review – conventional bone conduction devices

The recognition of hearing via BC is old and (mechanical) BC hearing aids were first applied in the 17th century.[6] Various instruments were developed which in

general made use of sound transmission through the teeth or the mastoid portion of the temporal bone, to the ear. The development of the carbon microphone in the early 20th century allowed the construction of the first electric bone conduction vibrator to be placed on the mastoid. This so-called conventional BCD comprised a transcutaneous coupling of a vibrating transducer and the head, held in place by a steel headband. This BCD consisted of two parts, a microphone with amplifier, and a separate vibrating transducer. The microphone with amplifier could be worn at body or ear level and was connected to the vibrating transducer via a wire. The separate positioning of the microphone and the vibrating transducer resulted in unnatural listening conditions. Sound localization was severely diminished because the side on which sound was received by the microphone differed from the side on which sound was perceived by the patient. This problem was effectively overcome with the development of bone conduction sound processors where microphone, amplifier and vibrating transducer were combined in one housing.

In 1954, a combined BCD was introduced mounted in the arms of a spectacle frame. These BC spectacles were the most widely used BCD from the 1960s to the 1990s. The use of these BC spectacles has declined following the development of the more effective percutaneous BCD systems, although they have not disappeared altogether.

Drawbacks of conventional bone conduction devices

Through the years drawbacks were reported with conventional transcutaneous BCD systems. Firstly, BC spectacles proved unsuitable for children. As young children do not have a bony nasal bridge, eyeglasses easily slide off, resulting in a loss of contact between the spectacle arm and bone conductor, and the temporal bone. Secondly, and this applies to both conventional systems (BC spectacles and steel headband), the vibrating transducer is positioned against the mastoid of the temporal bone with (considerable) static pressure to ensure correct functioning. To provide enough gain, sufficient, constant pressure is especially needed in patients with MHL with a large sensorineural component. Variations in pressure are detrimental to speech recognition. However, the constant pressure of the transducer against the temporal bone often results in local pain, headaches, skin irritation or even open wounds, while insufficient pressure reduces the gain of the device. Also, part of the BC sound is lost in the skin layers between the vibrating transducer and the skull bone, especially at frequencies above approximately 2 kHz.[7] In addition, some patients complain about the esthetics of the devices.

Percutaneous bone conduction devices

Confronted by the above-mentioned drawbacks of conventional BCDs, the idea arose to couple the transducer directly to the skull. This was after Brånemark discovered the concept of osseointegration of a titanium implant in the bone.[8] It was found that sound was conducted well to the inner ear when a bone vibrator was coupled to the percutaneous titanium implant. In 1977, the first three patients were fitted with implants for percutaneous BCDs.[9] This percutaneous BCD comprises an externally worn sound processor coupled to the skull by a percutaneous osseointegrated titanium implant with abutment (Figure 3).

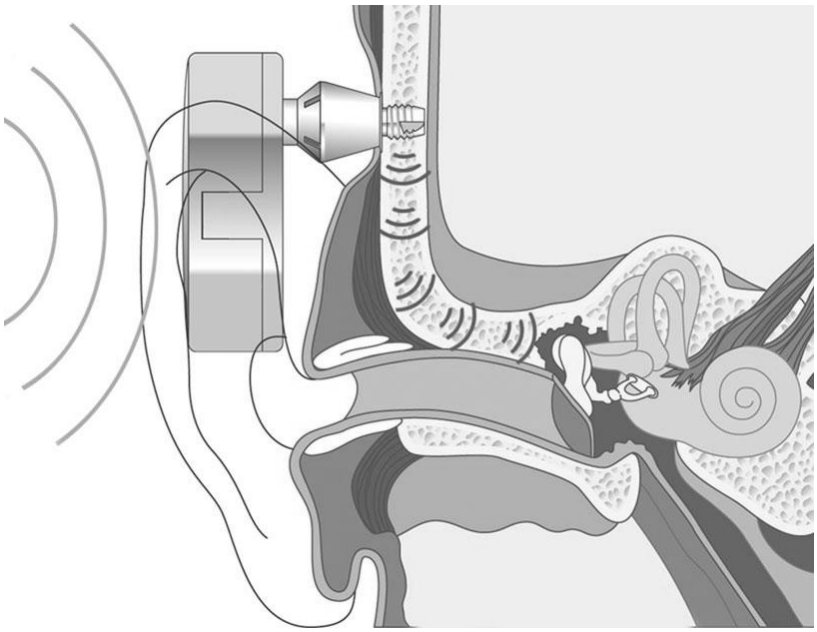

Figure 3 Schematic impression of bone conduction with a percutaneous bone conduction device. An externally worn sound processor is coupled to the skull by an osseointegrated titanium implant with abutment. Sound is conducted through the skull to the cochlea.

BCD sound processors

Since its introduction, several BCD sound processors have been developed. The first commercially available device was the Baha® HC 200, released in 1987. Since then, updates have been made to address more specific hearing needs. The updates also took esthetic aspects into consideration, minimized the size of the processor and introduced different colors. BCD processors on the market today are Cochlear Baha® BP100 and BP110™, Cochlear Baha® Intenso™, Cochlear Baha® Cordelle II™ (*Chapter 1.2* of this thesis[10]) and the Oticon Medical Ponto™, Oticon Ponto Pro™ and the Ponto Pro Power™.[11]

IV (Extended) Indications for BCD

Initially, the target group for a percutaneous BCD consisted of patients with bilateral acquired or congenital CHL or MHL who could not be fitted with an ACHA and in whom a conventional BCD had proved to be inadequate or impossible to fit. Over the years the inclusion criteria were gradually adjusted and redefined. The extended indications for percutaneous BCDs that are recognized nowadays are: unilateral CHL, single-sided inner ear deafness, children from the age of three and patients with moderate mental retardation. These indications are presented in short in *Chapter 1.2* of this thesis.[10] The indication 'bilateral BCD fitting' for patients with bilateral CHL will be discussed in more detail here.

Bilateral percutaneous BCDs for bilateral conductive hearing loss

For years, conventional transcutaneous BCDs were fitted monaurally, with the sound amplified on one side, in patients with bilateral CHL who relied on BC hearing for hearing rehabilitation. This was the only way, because in the conventional transcutaneous BCD, the microphone with amplifier was worn on one side of the head and the vibrating transducer on the other. Later, following the development of all-in-one sound processors, transcutaneous BCDs could be applied bilaterally in hearing BC spectacles. However, with the commercial introduction of the percutaneous BCD in 1987, monaural fitting once again became the practice. Furthermore, there was skepticism about the possible surplus value of a second BCD. The first report on bilateral fitting of percutaneous BCDs was in 1991.[12] At present, bilateral fitting of BCDs is practiced; however, the reported series are small and research into the audiological benefit is sparse (Table 1). People with bilateral hearing loss are still most commonly fitted with a unilateral BCD.

Audiological matters about bilateral BCD fitting

The implementation of the bilateral application of BCDs was aimed at providing binaural hearing for patients with bilateral CHL. Sounds are picked up by microphones in two spatially different positions and the resulting vibrations from each amplifier are applied on each side of the head. However, binaural hearing with BC stimulation can be disputed.

Binaural hearing relies on a comparison of the signals reaching the two ears. With air conduction hearing, a sound from a source is transmitted to both ears, each with a different transmission path. The difference in distance between the source and the ears, together with the interaction between the head and the pinna,

produce differences in amplitude (interaural time difference) and phase (interaural level difference) of the sound reaching the two ears. These (slightly) different stimulations of the cochlea are compared at the brain level and provide the interaural cues that we need for binaural hearing, such as localization of the sound source. Besides (a) sound localization, other well documented advantages of binaural hearing are: (b) Improved hearing sensitivity and speech recognition owing to bilateral summation as inputs received by the two cochleae are added together. (c) Improved speech recognition in noisy situations when speech and noise sources are spatially separated.

The reason for which a beneficial effect of bilateral BCD over monaural BCD fitting was questioned is the recognition that BC stimulation at one place is transmitted to both the ipsilateral and the contralateral cochlea. This so-called cross hearing is possible because the transcranial attenuation of BC sound vibrations in the skull bone is limited. It has been established that this transcranial attenuation is in the order of only 5 to 15 dB.[5,13] Interaural time and level differences can both be negatively affected by the BC transcranial transmission reducing the information separation between the cochleae.[14]

Despite the limited transcranial attenuation of BC stimulated sounds, adequate directional hearing results with bone conductor transducers were found in studies on subjects with normal hearing, temporarily provided with transcutaneous BCDs.[15] An audiological benefit has also been reported for bilateral BCD compared to unilateral BCD in limited series of adult patients with bilateral CHL, using BCD (Table 1).[12,16-20] Compared with monaural application, a second BCD in adults was in general found to improve speech reception in quiet, as well as sound localization abilities and speech recognition in noise. Whether or not these results rely on real binaural processing is not yet entirely understood. Two studies used the binaural masking level difference test to suggest that bilateral BCDs give binaural hearing, and found positive results.[18,20] It is expected that results obtained with bilateral BCDs might depend on the type of hearing loss, the age at onset of the hearing loss and previously used hearing devices.

Patient opinion about bilateral BCD fitting

The first applications of bilateral percutaneous BCDs were mainly based on the positive experience (patient opinion) with bilateral amplification using BC spectacles. Subsequent bilateral BCD fittings were performed in adult patients who had applied for a second BCD based on information from previous bilateral BCD fittings.[16,18,19] It was reported that these patients experienced improved speech recognition in quiet, preferred the bilateral application and used both BCD

devices all day. Also, an improvement in the quality of life was perceived after the second BCD was activated.

Bilateral BCD fitting in children

Based on patient opinions and audiological outcomes with bilateral BCDs in adults, bilateral BCDs have gradually been applied to a limited series of children. As with the application of bilateral BCDs in adults, a cautious and careful attitude was again adopted. Over a period of approximately ten years, two trends were recognized in bilateral BCD application in children. Firstly, the age at which bilateral BCDs were applied was reduced towards 4 years. Secondly, while initially a second BCD was applied after a child had sufficient experience with one BCD, in later years the fitting of two BCDs was increasingly performed simultaneously.[21] While research in children populations is sparse, the combination of personally experienced (by patients) and observed (by ENT physicians and audiologists) benefits was the main motive for the development of these trends. Some of these experiences and observations were reported in literature together with audiological outcomes and showed variable outcomes. Two studies together included 16 children with bilateral BCDs but did not specify the outcomes for these children.[22,23] Audiological measures have been performed in a total of 18 young patients in two studies (n=3 and n=15, respectively) and indicated benefits for bilateral BCDs, although non-benefit was also found (Table 1).[24,25]. In a questionnaire study on 21 children it was found that bilateral BCDs were highly appreciated.[21] However, 16 of 21 children reported that both or sometimes one BCDs were switched off in specific listening situations (e.g. noise or listening to people sitting on one side).

The aforementioned results were obtained in groups of patients with variable indications for bilateral BCDs. It is thought to be especially important for children with bilateral congenital hearing loss to fit suitable bilateral hearing devices early in life in order to benefit from the sensitive period for binaural hearing development. Bilateral transcutaneous BCDs can be fitted with a softband in early life.[26,27] From the age of four the application of bilateral percutaneous BCDs can be considered.[28]

Table 1. Studies on audiological outcomes for unilateral percutaneous BCDs versus bilateral percutaneous BCDs in patients with bilateral conductive hearing loss fitted with bilateral percutaneous BCDs.

Study	Year	N	Mean age at time of tests (range)	General outcomes of audiologic measures		
				Hearing thresholds	Speech recognition in noise	Sound localization
Hamann et al.[12] Paris, France	1991	12	N.A. (5-45)	SRTs in quiet improved with 4 dB with bilateral BCDs vs. unilateral BCD	N.P.	N.P.
Bosman et al. [16-18] Nijmegen, The Netherlands	1998-2001	25	44.3 (12-74)	SRTs in quiet better with bilateral BCDs vs. unilateral BCD (p<0.001)	*Better results with bilateral BCDs in speech recognition when noise was presented from baffle side. Poorer results with bilateral BCDs in speech recognition when noise was presented from the shadow side	Better than chance with bilateral BCDs (p<0.001) Not better than chance with unilateral BCDs
Dutt et al.[19] Birmingham, United Kingdom	2002	11	42.3 (22-54)	Speech in quiet scores were 100% in all participants with right, left and bilateral BCDs		N.P.
Priwin et al.[20] Stockholm, Sweden	2004	12	51.7 (27-68)	Sound-field average tone thresholds improved with bilateral BCDs vs. unilateral BCDs Speech recognition in quiet better with bilateral BCDs vs. unilateral BCDs (p=0.001)		Sound localization abilities improved with bilateral BCDs
Priwin et al.[24] Stockholm, Sweden	2007	3	11.7 (6-17)	No extra gain was found in sound field thresholds with bilateral BCDs vs. unilateral BCDs	A trend was noted towards better performance with bilateral BCDs vs. unilateral BCDs	A trend was noted towards improved sound localization ability with bilateral BCDs vs. unilateral BCDs.

Dun et al.[25] Nijmegen, The Netherlands	2011	15	14.8 (8-26)	N.P.	Improvement in SRTs when sound and noise sources were separated, indicating effective use of incoming stimuli from both BCD sides	Minimum Audible Angle was far better with bilateral BCD than with unilateral BCDs. Correct localization abilities were poor.

* These results apply to three studies. SRT: speech reception thresholds. N.A.: not available. N.P.: not performed. Baffle side: the side with the BCD in the unilateral condition. Shadow side: the side opposite to the BCD in the unilateral condition

V Audiological outcomes of percutaneous BCDs

Percutaneous v.s. transcutaneous

The gain of percutaneous BCDs compared to conventional transcutaneous BCDs is in the order of 5 to 15 dB higher at frequencies above 1 kHz because no sound is lost in hair, skin and muscle tissue.[4] Compared to conventional bone conduction devices, the percutaneous BCD is preferred in terms of both audiological and subjective benefit.[29-36]

Beyond a practical solution; the audiological victory of percutaneous BCDs

Initially, conventional BCDs were mainly applied to solve practical problems in patients. Most patients preferred ACHAs to conventional BCDs, which were considered audiologically inferior and were less known to the public. Conventional BCDs were mainly used when there was no other option for hearing rehabilitation. However, this changed following the development of percutaneous BCDs. For patients with a severe air-bone gap a percutaneous BCD can be a more appealing option than an ACHA.[37] Initially an air-bone gap that exceeded 25 to 30 dB was found to be better rehabilitated with a percutaneous BCD than an ACHA. It was suggested that better performance with a BCD was related to feedback of the ACHA; when there is a large air-bone gap, the ACHA must first compensate for the air-bone gap. This implies high gain and therefore high susceptibility to feedback. The performance of a percutaneous BCD is not affected by the width of the air-bone gap, as this gap is surpassed. In later years, due to developments in ACHAs, the air-bone gap at which BCDs performed better than ACHAs shifted towards 30-35 dB.[38] Recent developments in BCD design again reduced this air-bone gap threshold in the direction of 25-30 dB.[39]

VI Clinical outcomes of percutaneous BCD

The drawbacks caused by the constant skin pressure that accompanies conventional transcutaneous systems are avoided using a percutaneous BCD. However, the percutaneous coupling also involves some drawbacks. To start with, surgery is needed for the application of the titanium implant. Furthermore, complications may occur with both soft and bone tissue. In addition, some patients request the removal of the implant. These drawbacks are discussed here.

Soft tissue complications — skin reactions

After placing the implant the short-term complications mainly concern inadequate wound healing and skin flap necrosis. Skin flap necrosis (partial or total necrosis) occurs in 0-10% of implants and is mainly related to implants placed using the previous free skin graft technique or the flap/dermatome technique.[40-43] With the linear incision technique, which uses no skin graft or flap, the occurrence of skin necrosis can be considered negligible.[43,44] The percutaneous implant with abutment effects permanent skin and soft tissue penetration. Long-term complications mainly comprise soft tissue reactions and hypertrophic skin overgrowing the abutment. These are the most common long-term complications in BCD surgery.[43-51] The occurrence of soft tissue reaction was recognized already in the first reports on BCD.[9,52] Based on these, a classification was developed in 1988 by Holgers et al.,[52] describing different degrees of soft tissue reactions; the so-called Holgers classification (Table 2). To date, this classification is the only one available and it is frequently used to record the clinical findings in the follow-up of BCD patients. A soft tissue reaction of Holgers grade 2 or higher is considered an adverse reaction in need of treatment. However, the transition from one grade to another is gradual and interpretation of a skin reaction will be prone to interobserver (physician) variation. This is an important factor that should be taken into account when interpreting results obtained from this classification.

Table 2. The Holgers grading scale for the classification of skin reactions around skin penetrating titanium implants.

Holgers grading	Description
Grade 0	No reaction
Grade 1	Reddish discoloration of the skin around the implant
Grade 2	Red and moist surface of the skin around the implant
Grade 3	Formation of granulation tissue around the implant
Grade 4	Extensive soft tissue reaction that requires implant removal or leads to implant loss

Soft tissue complications — hypertrophic skin

Currently there is no grading scale for hypertrophic skin, other than indicating whether the skin is level with or above the abutment top (covering the abutment) and that the BCD sound processor cannot be used adequately. Several interventions can be considered to solve hypertrophic skin problems. Conservative treatment consists of an antibiotic and anti-inflammatory ointment in addition to local hygiene. When conservative management fails, corticosteroid injections, soft-tissue revision surgery or the use of a longer abutment may be necessary.[53-56] Significant skin overgrowth that required revision surgery was reported in 6.7% of the dermatome placed implants and in 6% of implants placed using the linear incision technique.[41,43]

Bone-related complications — implant loss

A bone-related complication involves the failed integration of the titanium implant within the bone tissue. This leads to implant loss that may occur shortly after placement due to inadequate primary stability (defined as baseline stability obtained at the time of implant placement) resulting from inappropriate surgical technique or poor bone quality. Loss may also occur within weeks after implantation due to poor secondary stability (defined as stability obtained over time as a result of the osseointegration process). Trauma can result in loss of osseointegration. Spontaneous losses of implants are reported in implants that were previously used without complications. No clear explanation for this has been offered so far. However, it has been suggested that this might be caused by altered bone remodeling properties of the implant surrounding bone in, for instance, patients with diabetes mellitus or irradiated patients.[57,58] These implants show initial good clinical stability but are at higher risk of being lost. Reported rates of overall implant loss vary greatly between different BCD clinics. In adults incidences of 3.5% to 17.4% have been described.[9,41,43,59-63] In children, the rate of implant loss varies from 5.3% to 26%.[64-70] Increased risk of implant loss was also identified in mentally retarded patients, irradiated patients and patients with diabetes mellitus.[58,71,72]

Requested removal of the titanium implant

A small number of patients elect to have the implant removed because of chronic pain at the implant site.[73,74] It is not clear what causes the pain and relieves the pain after removal of the implant, but damage to nervous tissue during surgery or by the implant may be involved. Other reasons for elective implant removal include decreased BCD benefit because of progressive severe hearing loss of the

sensorineural component so that even the strongest BCD sound processor (Baha® Cordelle) is not of sufficient power[75], or even successful conventional middle-ear surgery that eliminated the CHL. The percentage of electively removed implants in a follow-up cohort of 1,132 implants was found to be 1.6%.[71]

VII Osseointegration and implant stability

Osseointegration

The principle of titanium implant osseointegration used in the BCD system was first applied in 1969 with the introduction of oral implants to anchor dental prostheses.[8] Brånemark coined the term osseointegration to describe a direct bone-to-implant interface observed in experimental and clinical investigations.[76] A titanium oxide surface was found to be highly biocompatible and osteocytes integrated with this titanium surface to form a stable interface. In 1981, Albrektsson et al. published a clarification of the term osseointegration after they recognized that the term was even used when there was an evident layer of fibrous tissue between bone and implant.[77] They defined osseointegration as a direct, on the light microscopic level, structural and functional connection between ordered, living bone and the surface of a load-carrying implant. This results in long-term implant stability and the capacity to withstand load and stress from various directions. Parameters considered to be of importance in the outcome of an implantation procedure are material biocompatibility, implant design and surface, the status of the implant bed, the surgical technique, and the loading conditions.[78,79]

Clinical approaches to determine BCD implant osseointegration

Several techniques have been suggested for the determination of osseointegration and implant stability. The reason for which clinicians would like to have objective measures for implant stability is that stability is a prerequisite for the long-term clinical success of osseointegrated implants.

Previously used methods

In 1987, Albrektsson and Jacobsson emphasized that osseointegration is a concept defined at the histological level that could, therefore, only be verified by histological examination.[78] They described how different clinical approaches have also been tried to clinically demonstrate the extent of osseointegration. Finding a mobile implant during the performance of a clinical mobility test was regarded as

the definite evidence of a nonintegrated implant; however, the lack of clinical mobility could not be taken as conclusive evidence of osseointegration. In 1981, Albrektsson developed a clinical approach that might, in theory, be of use to indicate the extent of osseointegration. The idea consisted of using a metal instrument to tap the implant and analyze the transmitted sound. However, at the time no typical 'sound diagram' was available for osseointegrated implants in contrast to implants anchored in fibrous tissue. Plain radiographs were used post-operatively to monitor marginal bone resorption and changes at the implant-bone interface, but findings were difficult to interpret because the optimal resolution capacity of a plain radiograph is unsatisfactory. Computed tomography (CT) has proven to be a reliable method for evaluating bony anatomy, but artifacts produced by metal implants in the radiation field renders CTs of limited value when evaluating temporal bone implants postoperatively.[80]

Currently used methods

The use of resonance frequency analysis (RFA) as a method to measure implant stability was first described by Meredith et al. in 1996.[81] Resonance frequency measurements were undertaken by measuring the response of a small transducer attached to an implant fixture or abutment. It was observed that there was a significant increase in resonance frequency related to the increase in stiffness of an implant in the surrounding tissues. RFA is nowadays a frequently used tool to monitor stability changes over time and to decide when to load an implant in the dental implant field.[82,83] So far, the use of RFA in craniofacial implants is only used to monitor stability changes per implant over time because there are no known reference resonance frequencies for these implants to indicate proper osseo-integration or adequate implant stability.[84,85]

Cone beam computed tomography (CBCT) is used in the dental field for pre- and postoperative assessment of intraoral implants and its use was recently investigated in the evaluation of temporal bone osseointegrated implants.[86] It was found that CBCT provided information about bone resorption around the implant in the follow-up. It has been suggested that this information may be of use in the decision to disconnect implants that are judged to present a risk of future failure and to plan for future implant surgery should failure occur. The radiation dose is low compared to standard computed tomography scans. Just as CBCT is used on a daily base in the dental implant field, CBCT is expected to become the technique to longitudinally examine the fate of osseointegrated implants placed in the temporal bone, and to examine implants exposed to trauma or infection.

VIII Recent developments

Focus on implant design and implant surface

One point of interest is the enhancement of stability and osseointegration of the titanium implant to improve survival rates. Dentistry shares this goal and has modified oral titanium implants in a manner that might have improved osseointegration. Based on technological knowledge from the dental field, the implant originating from the Brånemark implant used since 1977 and essentially kept unchanged was modified in 2010, resulting in the Cochlear Baha® BI300 titanium implant.[85] Compared to previous generation implants, this implant has a wider diameter, small-sized threads at the implant neck, and a moderately rough TiOblast surface on the intraosseous portion of the implant. These modifications were suggested to enhance osseointegration which might be of special use in patients with comprised bone quality.[87,88] Moreover, the shape of the abutment has been changed from a conical design to a rounded, apically converging design. It has been suggested that this rounded design has a positive effect on the stabilization of the peri-implant soft tissue, which is thought to be a key parameter for good soft tissue health.[89] The first short-term results with the Baha® BI300 implant in an ongoing multicenter investigation suggest enhanced implant stability.[85] This enhanced stability might provide the opportunity for forward loading of the implant with the sound processor.

Developments in transcutaneous and intra oral BCD systems

Because of the soft tissue complications that might occur as a result of the permanent skin penetration by the percutaneous BCD system, another point of interest is the development of bone conduction devices that avoid the need for permanent skin penetration. In this light, various (semi-implantable) transcutaneous systems have been developed or are under development.

Previous transcutaneous BCD systems

In 1981 already, Hough (Oklahoma City, USA) introduced a semi-implantable transcutaneous BCD system, the Xomed Audiant.[90] A magnet was placed in the mastoid to osseointegrate, and the transcutaneous coupling with intact skin and soft tissue was realized using an external sound transducer that held the other magnet. Performed tests found that the system worked well and showed good performances at threshold levels. However, in practice its amplification was found to be far too low, due to the skin between the magnets.[91] The Audiant system is no longer on the market.

The application of a percutaneous BCD implant for children under the age of four years (who are in the need of hearing rehabilitation by a BCD) was recognized as undesirable because of limited thickness of the temporal bone.[92,93] However, for young children with bilateral CHL, early hearing rehabilitation is of prime importance to enable normal speech and language development. Initially a conventional BCD on a steel spring was used for these children. However, in the face of the drawbacks of such devices (e.g. skin irritation due to the constant pressure or variable gain due to variable pressure), a softband was developed.[26,27] Using the softband, a sound processor with a microphone and amplifier in one housing is coupled to the elastic headband and applied in the traditional transcutaneous way. It was found that the softband could be comfortably fastened around the head while maintaining sufficient output, and that it is better appreciated than the steal head band.[94] Though this transcutaneous application has the disadvantage of sound damping by the skin, the softband provides an adequate hearing rehabilitation until the child can be fitted with a percutaneous BCD. Besides, a bilateral sound processor fitting is possible with the softband.

Upcoming transcutaneous BCD systems

Otomag

Most recently, Siegert (Recklinghausen, Germany) developed a new partially implantable BCD, using magnetic coupling (Otomag).[95] In this system, a magnetic circle is constructed, to reduce the magnetic perturbations and thereby the pressure on the in-between skin of the externally worn vibrator. The user himself can change the strength of the magnets. This system requires one surgical session for implantation of the magnet. This can be considered an advantage over the percutaneous BCD system, especially in younger children, as many centres still prefer to place the implant and abutment of the percutaneous BCD system in two surgical sessions under general anaesthesia; a first session for the insertion of the implant, and a second session for the placement of the percutaneous abutment. Furthermore, adverse events related to the percutaneous implant are avoided. However, a disadvantage of this system is that sound vibrations still are to be transmitted through the skin layers, which results in a lower gain of approximately 15 dB compared to a percutaneous BCD.[96] Besides, the skin in the contact area could be under constant pressure which might cause some wearing comfort problems.

Bone Conduction Implant System

In 2008, Håkansson et al. reported on a transcutaneous BCD system with an implanted transducer, the Bone Conduction Implant (BCI) System.[97,98] The generic feature of this system is that the skin is kept intact, and that the sound signal is transmitted transcutaneously by a magnetic induction system from an externally worn audio-processor to the fully implanted bone-conduction transducer. Hence, it is the electromagnetic signal that is transmitted trans-cutaneously and not the vibrations as in other transcutaneous systems. The implanted bone-conduction transducer, in the mastoid region, produces vibrations that are induced directly to the skull bone as in percutaneous BCDs and no gain is lost due to attenuation of vibrations through the soft tissue. At the time of writing of this thesis, the BCI System has not yet been applied in a living patient. It is expected that the BCI System will be of significant added value to existing BC hearing aids.

The Soundbite System

The idea of attaching a vibrating transducer to the teeth for long-term hearing rehabilitation has been suggested by several research groups over the years. The advantage with a solution of this kind is that it is noninvasive. Sonitus Medical Inc, USA, has developed the SoundBite system. This system consists of a microphone that is located in the ear canal, and a (removable) vibrating transducer that is applied to the back teeth. Currently the device is only available for single-sided deafness. No safety issues have been identified so far.[99,100]

Scope of this thesis

In Nijmegen, the first three BCDs were fitted in June 1988.[101] This was the starting point of almost 25 years of clinical and audiological experience and over 1,440 titanium implants for BCDs were fitted up until 2011. Previous research resulted in five PhD theses in Nijmegen. The PhD theses are listed below.

1995 EAM Mylanus. The Bone Anchored hearing aid, clinical and audiological aspects.

1998 CTM van der Pouw. Bone anchored hearing, short and long term results.

2005 MKS Hol. BAHA - New indications and long-term patient satisfaction.

2008 SJW Kunst. BAHA, evaluation of extended indications such as mental retardation and unilateral hearing impairment.

2011 MJF de Wolf. Bone anchored hearing aid; Clinical outcomes of the linear incision technique and benefit assessment.

In addition, two PhD theses from the Birmingham BAHA team were defended in Nijmegen (2002, SN Dutt, The Birmingham bone anchored hearing aid programme, some audiological and quality of life outcomes. 2008; A-L McDermott, The benefit and success of BAHA (bone anchored hearing aids)).

The present thesis is the sixth PhD thesis on bone conduction devices originating in Nijmegen. Other PhD theses on the topic of BCD from Nijmegen and Birmingham are on the way to being presented.

Overall objective

The overall objective of this thesis is to assess the long-term application of BCDs in Nijmegen in terms of complications, newly designed implants, bilateral fitting in children, and to support pre- and postoperative BCD consultation with this information.

General Introduction

Chapter 1.1 provides an overview of the developments in BCD application in Nijmegen together with developments that have been reported in literature by other BCD centers.

Chapter 1.2 reviews general BCD aspects such as bone conduction physiology, indications and the development of different generations of BCD sound processors.

Clinical outcomes of BCD surgeries performed from 1988 to 2007

Chapter 2.1 presents the results of over 1,000 BCD implantations. Outcome measures are skin reactions and implant survival. Comparisons are made of outcomes for different patient groups. In addition, the effect on skin reactions and implant loss of loading time in different periods from initial implantation (from 3 to 5, 6 to 8, 9 to 11, and over 12 weeks) is investigated. This provides wide relevant new data on implant survival of the standard type titanium BCD implants (with a turned Brånemark type surface) with the sound processor after much shorter loading times (3-5 weeks).

Chapter 2.2 assesses the use of an 8.5 mm abutment as a treatment option for soft tissue problems of the implant surrounding skin to provide an alternative treatment option for soft tissue revision surgery.

Evaluation of a new implant design

Chapter 3 evaluates the difference in implant stability between implants with a new design and previous generation implants. Also, the aim of the study is to substantiate whether loading the sound processor at 6 weeks after surgery affects the stability of the implant.

Bilateral BCDs in children and young adults

Chapter 4.1 evaluates the subjective benefit of bilateral BCDs in day-to-day life of children, adolescents and young adults.

Chapter 4.2 studies the audiological performances of young bilateral BCD users.

In *Chapter 5* the general discussion is presented**.**

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AN OVERVIEW OF DIFFERENT SYSTEMS: "THE BONE-ANCHORED HEARING AID"

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Abstract

In the past 30 years, a large amount of clinical and audiological research on bone conduction hearing devices has been performed. In this review, we give a brief history of the developments in indications, surgical techniques and sound processors with respect to implantable bone conduction devices like the bone anchored hearing aid or Baha. Starting with the use of Baha in patients with bilateral conductive or mixed hearing loss, the indications for such devices have been extended to patients with unilateral hearing loss (HL), children and moderate mentally retarded patients. Bilateral fitting has been shown to be beneficial in restoring binaural hearing in patients with bilateral acquired or congenital conductive HL. In addition, the surgical techniques used to implant the titanium fixture for Baha application have been modified and further developed to reach two main goals: (a) optimal osseointegration, and (b) preparation of the implant site to minimize the occurrence of soft tissue reactions. Currently, the most used techniques are the pedicled skin flap, dermatome and linear incision techniques. Several generations of the Baha® sound processor have been developed by Cochlear™ to provide sufficient amplification in different hearing situations. Improvements in sound quality, aesthetics and handling have been major points of interest. The Baha sound processors most often used today are the Baha Divino, the Baha Intenso and the Baha Cordelle. Recently, the more flexible Baha BP100 sound processor was launched.

Introduction

In 1984, the bone-anchored hearing aid (Baha), which was developed by Håkansson, Tjellström and coworkers in Gothenburg, Sweden, became commercially available.[1] Currently, the Baha is a well-established device for hearing rehabilitation for conductive hearing loss (HL), and over 250 papers have been published worldwide on this hearing device. In June 1988, the first three Nijmegen patients were fitted with a Baha device[2], setting off more than 20 years of clinical and audiological research and resulting in more than 50 publications in various Baha-related fields. In this review, we give an overview of current knowledge about the Baha in general, with special attention given to research performed over the past several years in our clinic.

Physiology of bone conduction

The physiological concept behind the bone conduction (BC) pathway is still not entirely understood. Tonndorf (1966) described, from studies primarily in cats, several modes stimulating the basilar membrane during BC excitation.[3] The significance of the different modes depends on the frequency. For humans at hearing frequencies the most important way in which the basilar membrane is stimulated seems to be the effect of fluid inertia within the cochlear.[4,5] In short, BC sound is made up of vibrations transmitted through the skull to the cochlea. This then causes the fluids in the cochlea to vibrate as well. As these fluids are incompressible in principle, they will vibrate as a whole and in phase with the bone. However, the cochlea has two mobile windows, the oval and round window. Therefore, inertia of the inner ear fluids will result in longitudinal fluid waves traveling from one window to the other, which causes the basilar membrane to vibrate.

Von Békésy showed that the basilar membrane responds equally to both air-conducted (AC) and BC sound.[6] Distinguish between AC and BC stimulation at the basilar membrane level is not possible. However, the BC route towards the basilar membrane is energywise less efficient than the air conduction route. Therefore, BC hearing aids are primarily used for HL where air conduction hearing aids are contraindicated.

Description of the Baha system.

The Baha® is a semi-implantable percutaneous BC hearing device coupled to the skull by an osseointegrated titanium fixture (Figure 1). The titanium fixture used is a standard Brånemark type of implant with an as-machined surface, developed by

Cochlear™ Bone Anchored Solutions, Gothenburg, Sweden. Recently, as there have been substantial developments of titanium fixtures for the dental industry, a new Baha® BI300 implant has been designed to improve stability and to enhance osseointegration. The new Baha® BI300 implant features a wider diameter (4.5 mm compared to 3.75 mm for the standard implant), small sized threads at the implant neck, and a moderately rough TiOblast™ surface on the intraosseous portion of the implant.

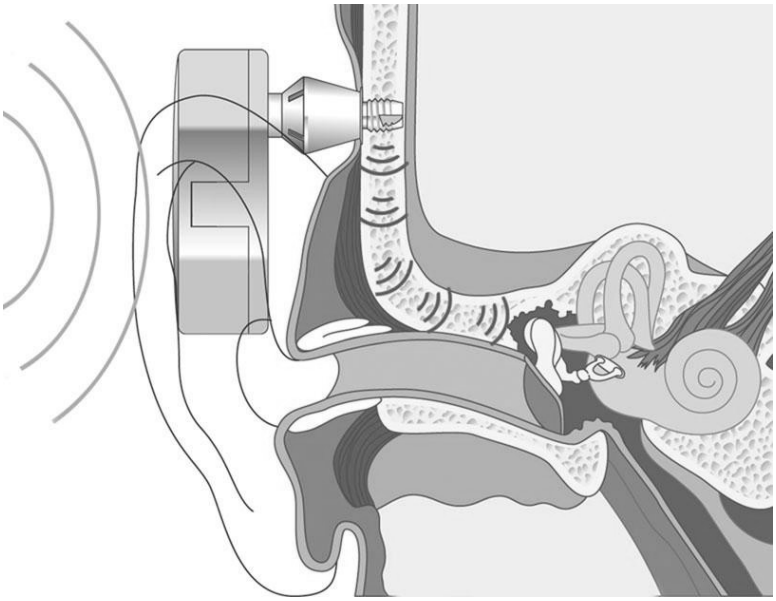

Figure 1. Illustration of the Baha as a semi-implantable percutaneous BC hearing device coupled to the skull by an osseointegrated titanium fixture.

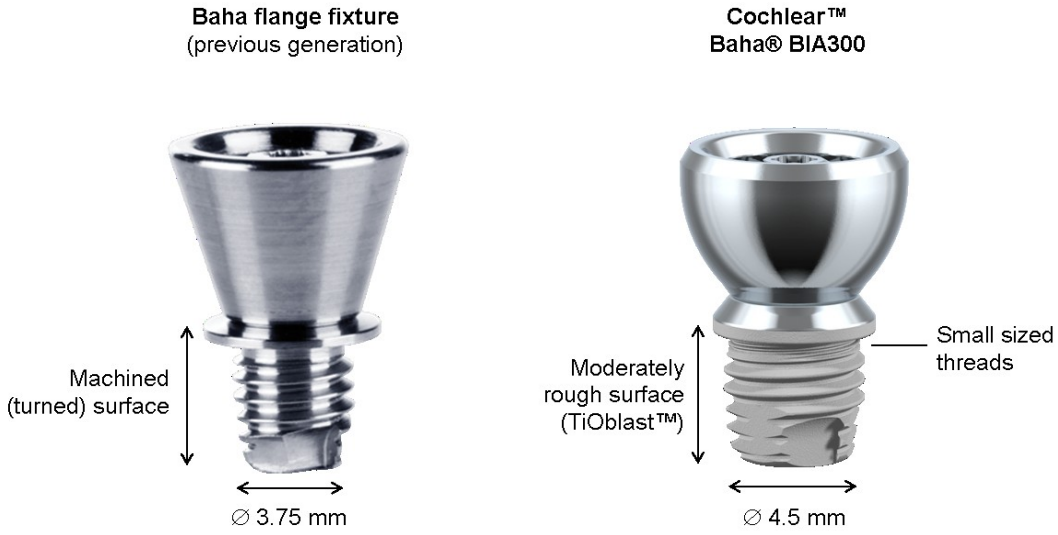

Figure 2. Illustration of the standard titanium implant (left) and the new BI300 titanium implant (right).

Figure 2 illustrates the standard titanium implant and the new BI300 implant (Figure 2). A skin-penetrating abutment is attached to the implant to facilitate coupling of the Baha sound processor. Compared to the standard abutment, the BI300 abutment is a concave shaped abutment. The direct coupling for the mechanical vibrations to the skull provides effective sound transmission of around 5-15 dB higher than the transcutaneous coupling of conventional BC devices.[7]
Because the Baha sound processor is coupled directly to the skull without interference from intermediate tissue, some drawbacks of conventional transcutaneous bone conduction devices are avoided. These drawbacks include pressure of the transducer mounted on a spring or in the sidepiece of spectacles against the temporal skin, which can result in headaches or skin reactions and insufficient pressure, which reduces the gain of the device. Furthermore, when the classical bone conductor is used with a headband, mostly, the positioning of the microphone and vibrational transducer are contralaterally on the skull, resulting in unnatural listening conditions. The same drawbacks apply to conventional BC devices with the amplifier worn on the body. On the other hand, the disadvantages of percutaneous implants include loss of osseointegration and skin reactions around the implant.

Indications

Bilateral mixed or conductive hearing loss (acquired/congenital)

The Baha system is typically beneficial in patients with bilateral mixed or conductive HL who cannot be fitted with conventional acoustic hearing aids (behind the ear or in the ear), including those with chronic otitis and those with congenital aural atresia.[8-10] In patients for whom reconstructive surgery is no longer considered a feasible option and for whom a conventional BC hearing aid has proven to be inadequate, the Baha has been shown to be of great benefit.[11-16]
Whereas most bilateral hearing-impaired patients with sensorineural HL, using acoustic hearing aids prefer binaural amplification over monaural amplification, binaural use of the Baha in bilaterally impaired patients is not yet widely applied.
There are several well-documented advantages of binaural hearing: (a) hearing sensitivity and speech recognition are improved due to bilateral summation when inputs received by the two cochleae are added together[17,18], (b) speech recognition is improved in noisy situations with spatially separated speech and noise sources[19], and (c) directional hearing will be enabled in the horizontal plane. It has been reported that bilateral Baha use in adults has both significant subjective and objective benefits.[14-20]

Unilateral Conductive Hearing Loss

Unilateral conductive HL (UCHL) in patients with a contralateral normal hearing ear may involve the typical problems associated with unilateral hearing (i.e., poor sound localization abilities and poor speech recognition performance in noise). Agterberg et al.[21] reported on sound localization in patients with acquired UCHL fitted with a BC device on their impaired side. Using varied several stimulus characteristics, they demonstrated that BCD users with acquired UCHL were able to localize sounds on the basis of restored binaural hearing.However, some UCHL patients show fairly good directional hearing abilities in an unaided monaural condition.[22,23]

Single-sided deafness

In patients with unilateral sensorineural deafness, a Baha positioned near the deaf ear works as a transcranial CROS (contralateral routing of signal). Sounds received by the Baha system are transmitted to the functional contralateral cochlea via BC. In principle, this will not result in stereophonic hearing, but the negative effects of acoustic head shadow (poor understanding of a person who is talking on the deaf side of the patient) might be decreased.[24,25] Before implantation, a trial should be arranged with a Baha device on a steel headband placed on the mastoid of the deaf ear.[26] The degree of success depends on the motivation of the patient and the listening demands imposed by their lifestyle and working environment. In literature, it is reported that 25-30% of the patients apply for implantation of the Baha system after trial on a headband.[24,27]

Baha use in children

In part, Baha application in children addresses different issues than in adults. Children are known to have more immature and thinner bone. When implanted, they have a higher risk of soft tissue overgrowth, and, compared to adults, more implants are lost within the first year after implantation.[28] Furthermore, cleaning problems have been reported, especially among adolescents.[29,30] A considerable number of the children scheduled for implantation have major congenital (syndromal) malformations of the ear, sometimes combined with skull deformities, making surgery more challenging.[31-34] For Baha surgery in children, there are additional considerations and precautions, including (a) at what age is implantation possible, (b what should be the minimal thickness of the skullbone, (c) what is the best implant position, (d) is there a need to place a second sleeping fixture, and (e) what can be done to prevent postsurgery soft tissue reactions. It is of the utmost importance that children with bilateral conductive hearing loss be

rehabilitated at the earliest age possible as early and consistent stimulation is critical for optimal development of speech and language.[35]

For children who are too young to be fitted with a Baha percutaneously, and to overcome the risks associated with Baha surgery in specific syndromal cases, a conventional transcutaneous bone conductor can be used or the more recently introduced Baha® Softband (Cochlear Bone-Anchored Solutions, Gothenburg, Sweden). This Baha Softband comprises the Baha sound processor connected to a soft elastic headband. Aided sound field thresholds with the Baha Softband are almost equivalent to those obtained with a transcutaneous conventional bone conduction hearing aid.[36] Speech and language development are greatly facilitated by the early use of bone conductors like the Baha Softband[37], and currently, the Baha Softband is generally accepted as the treatment for children under 3 years of age.

Lieu[38] and Lieu et al.[39] found that several children with unilateral HL demonstrate increased rates of school year failure and that they needed additional educational assistance. The Paediatric Workgroup on Hearing Aid Amplification[40] summarized the literature and stated that in children with unilateral conductive or sensorineural HL, amplification should be considered on a case-by-case basis, centered on the child's audiometric data, development, and communication needs.

Baha use in patients with moderate mental retardation

Initially, potential Baha patients with mental retardation were excluded from treatment due to doubts concerning care for the percutaneous implant and surrounding skin. Recently, however, patients with moderate mental retardation and conductive or mixed HL have received Baha treatment. Use of the Baha in this specific patient group has been shown to be beneficial, improving both listening and learning capabilities.[41-43] Following these results, use of the Baha has also been extended as a valuable treatment option for this special patient group.

Baha surgery

Goals of surgery

Independent of the surgical technique used, there are two major goals of Baha surgery: placement of an implant capable of optimal osseointegration and preparation of an implant site that minimizes the occurrence of future soft tissue reactions surrounding the implant. For adequate osseointegration, trauma to the surrounding bone should be minimized. The actual placement (drilling and placing) of the implant is mostly done using the technique reported by Tjellström.[44]

Subcutaneous tissue reduction is carried out to reduce soft tissue movement and the subsequent development of scar tissue and infection around the implant. In addition, hair follicles surrounding the implant should be removed to avoid skin irritation and accumulation of debris. If all of these precautions are taken into consideration and therapy-resistant skin reactions still occur, recent studies have shown that changing to a larger 8.5-mm abutment can be beneficial.[45-47] A recent study by Faber et al.[48] showed that implant location was not correlated with the frequency and severity of skin reactions around the abutment in 248 randomly selected Baha patients.

Handling soft tissue (surgical techniques)

The surgical techniques used to handle soft tissue vary among surgeons. Initially, a free retroauricular skin graft was used, which later became a local pedicled skin flap predominantly.[33,49,50] To standardize the surgical flap technique, a special dermatome was developed to create a hair free, thin, skin flap.[49,51]An alternative surgical technique, using a linear incision, has been developed at the Radboud University Nijmegen Medical Center.[52-54] Both the dermatome technique and linear incision technique provide safe alternatives in Baha surgery and are recommended in the Baha® Surgery Guide (Cochlear).[55]

Loading time

Another point of interest in previous studies has been osseointegration of the titanium implant. Osseointegration of the implant is key to the success of the Baha implant before loading the implant with the Baha sound device. In 2005, Snik et al. [26] published a consensus report by experts in the field recommending a loading time of between 4 and 6 weeks in adults and at least 3 months in children under 10 years of age. In accordance with this report, the current protocol for Baha surgery (Cochlear) includes 6 weeks of unloaded healing to allow for sufficient osseointegration and stability of the implant in adults.[55] In children with bone thickness of 3-4 mm, two-stage surgery is recommended and the Baha sound processor can be attached as soon as wound healing has occurred after the second stage. Longer healing time before loading should still be used in adults being irradiated on the skull bone, in adults with bony disorders and when soft bone is observed during initial fixture implantation.

Development of different generations of the Baha sound processors

Since the introduction, several Baha sound processors have been developed. The first commercially available device was the HC 200, released in 1987. Since this

release, updates have been made to approach more specific hearing needs. Also the aesthetical aspects were taken into consideration in these updates, the size of the processor was minimized and different colours were made available. Nowadays there are four types of Baha sound processors (Cochlear) commercially available: the Baha® Divino, the Baha® BP100, the Baha® Intenso and the Baha® Cordelle (Figure *3*).

Figure 3. Available Baha sound processors (left to right): Baha Divino, new Baha BP100, Baha Intenso and Baha Cordelle with bodyworn receiver (not actual sizes).

The Divino, Intenso and the BP100 are behind-the-ear devices containing microphone, amplifier and vibration transducer in one casing. The Baha Cordelle consists of a separate ear level vibration transducer connected to a body-worn microphone and amplifier. In 1993, this Baha Cordelle was designed out from preceding processors as the HC Superbass, as an even more powerful successor.[56] The Baha Divino was launched in 2005. In contrast to its predecessor, the Baha Compact, this device features a digital sound processor and a directional microphone. Sound-field thresholds and speech tests in quiet did not reveal any statistically significant advantage (or disadvantage) of the Baha Divino when compared to the Baha Compact.[57] However, speech understanding in noise presented at the rear was reported to be better with the Baha Divino, an effect assigned to the directional microphone noise-reduction system. The Baha Intenso, launched in 2007, bridges the gap between the Baha Divino and the Baha Cordelle. Of the ear-level Baha's (i.e. Cordelle not included), the Baha Intenso provides the most gain and the highest maximum output.

To determine the fitting range of three most used types of bone-anchored hearing aid devices, speech recognition data on three groups of Baha users were obtained from the Nijmegen database. Figure 4 presents the (monaural) individual aided phoneme scores in quiet at 65 dB SPL (sound pressure level; PS65) from 90 Baha Compact (predecessor Divino) users, 23 Baha Intenso users and 25 Baha Cordelle users (Figure 4).

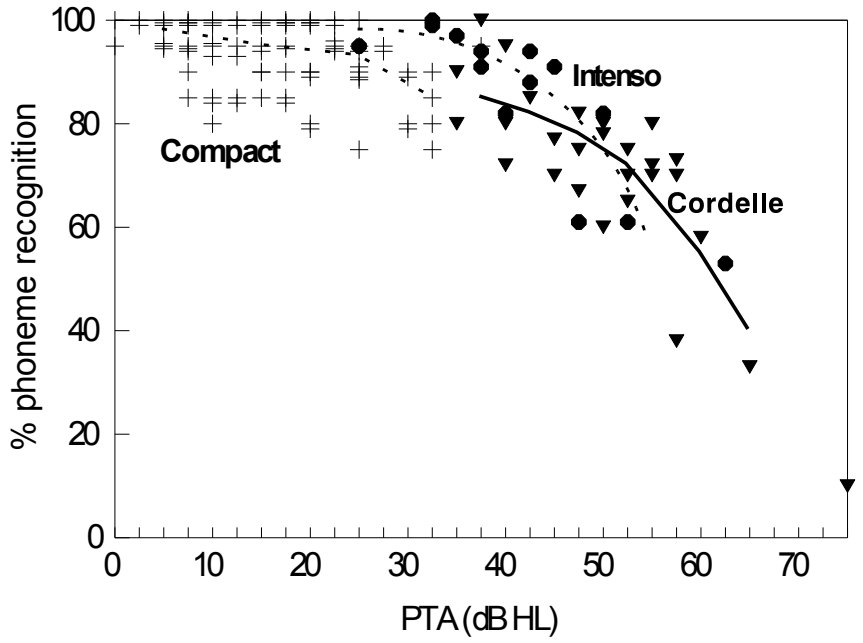

Figure 4. (Monaural) individual aided phoneme scores in quiet at 65 dB SPL (PS65) from three groups of Baha users presented as function of their mean sensorineural hearing loss. The three lines are best-fitted nonlinear regression lines.

All patients had conductive HL or mixed HL, with a sensorineural HL component of up to 70 dB HL. PS65 was presented as function of the mean sensorineural HL component. Nonlinear regression curves of the second order were fitted through the individual data and are also presented. Using these lines, it was concluded that for a sensorineural HL component exceeding approximately 25 dB, scores were better with the stronger Baha Intenso than with the Compact. At this threshold, the PS65 line of the Baha Compact was 10% lower (arbitrary choice) than that of the Baha Intenso and the discrepancy continued to increase with increasing sensorineural HL component. Therefore, assuming that the speech tests in quiet of the Baha Compact and its successor Baha Divino are equally effective, it can be established that the Baha Divino is a good choice for patients with a mild sensorineural HL component of up to 25 dB HL.

In a similar way, the upper limit of application for the Baha Intenso was set at 50 dB HL. At this threshold, the PS65 with a Baha Cordelle was likely to be at least 10% higher than with the Baha Intenso. The Baha Intenso is a good choice for patients with an average sensorineural HL component of between 30 and 50 dB HL (Figure 4).[58]

Bosman et al.[59] assesed the upper levels fitting range of the Baha Cordelle in patients with severe to profound mixed HL. To reach a 50% score at 65 dB, the upper limit of the fitting range as expressed in BC thresholds was set to 50, 55, 65, 60 dB HL at 500, 1,000, 2,000 and 4,000 Hz, respectively. If the gain is insufficient for a particular patient, the next amplification option is the application of a cochlear implant. From a more recent study by Verhaegen et al.[60] it was concluded that a CI takes preference over a Baha device in patients with mixed HL when the mean sensorineural HL component is 65-70 dB or higher or when the PS65 with the Baha Cordelle is less than about 40%.

With the aid of information on the gain-frequency characteristics of Baha, as measured in patients, the straightforward application limits can be shaped into frequencies. The gain-frequency relations have been described in a group of patients using the Baha Intenso and Baha Cordelle.[58,59] Using these frequency-gain data as input and the National Acoustics Laboratory-Non-Linear (NAL-N-L) rule backwards, frequency-specific hearing thresholds can be obtained instead of a mean hearing threshold. The NAL-N-L rule is a well-validated prescription method that prescribes desired gain based on hearing thresholds.[61,62] Figure 5 shows the final result for change from Compact to Intenso and from Intenso to Cordelle (Figure 5). The figure can be used to choose the best Baha option for Baha candidates. The Baha Compact is not available anymore and application data can be used for its successors, the Baha Divino and the Baha BP100.

Towards the end of 2009, a new Baha sound processor was launched, the Baha BP100. The BP100 is considered to be applicable in individuals with bone-conduction thresholds up to 35 dB. This device makes use of full digital processing. With this device, sound is analyzed across 12 channels. It has several automatic systems that operate on the incoming sound signal such as adaptive amplification and automatic noise reduction. Another special feature is that hearing thresholds can be measured directly by stimulation by pure tones generated by the BP100 sound processor such that the gain can be adapted individually and frequency specific.[63] A first clinical evaluation showed that compared with the Baha Divino, speech understanding in noise was on average 2.6 dB better with the Baha BP100.[64] In this evaluation the sound quality of the BP100, assessed by a patient's questionnaire, was reported to be better

compared to the Divino. Company-independent effectivity studies of the Baha BP100 have not yet been published and should be awaited for.

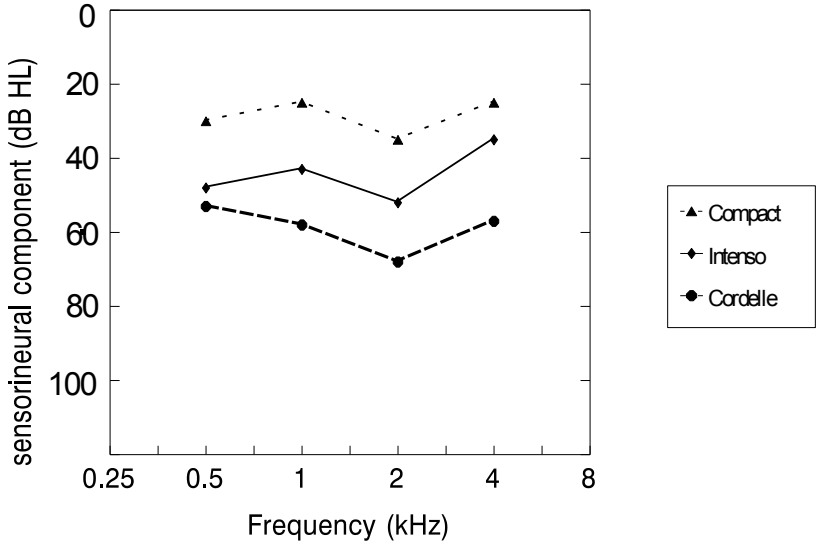

Figure 5. Audiological application range for three types of Baha devices. The Baha Divino and the also the Baha BP100 are expected to have application ranges comparable to their predecessor the Baha Compact.

Recently, alternative implantable BC devices produced by other companies entered the field. Oticon Medical received clearance from the US Food & Drug Administration to market their percutaneous Ponto® system.In 2010, the Sophono, Inc and Otomag, GmbH companies have teamed together to pioneer the development a non-percutaneous implantable BC device, called the Otomag Alpha®.[65]

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CHAPTER 2

CLINICAL OUTCOMES OF BCD SURGERY

2.1

ASSESSMENT OF MORE THAN 1000 IMPLANTED PERCUTANEOUS BONE CONDUCTION DEVICES: SKIN REACTIONS AND IMPLANT SURVIVAL

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Abstract

Objective: This study assesses soft tissue reactions and implant stability of 1132 percutaneous titanium implants (970 patients) for bone conduction devices (BCD). In addition, it examines BCD usage and comparisons between different patient groups.

Patients: The surveyed cohort was divided into 3 different age groups (children, adults, and the elderly). In addition, 4 groups with variable loading times (i.e., the time between placement of the implant and loading the BCD sound processor) were identified as well as a subgroup of patients with mental retardation.

Main Outcome Measures*:* Soft tissue reactions around the percutaneous implants as classified by the Holgers grading system, implant failure and revision surgery rates.

Results: In 95.5% of the 7415 observations of 1132 implants, there were no adverse soft tissue reactions. Implant loss was 8.3%. Significantly more soft tissue reactions and implant failures were observed in children compared to adults and the elderly ($p < 0.05$). Implant survival was lower in patients with mental retardation compared withpatients without mental retardation ($p = 0.001$). The loading time did not influence the occurrence of soft tissue reactions and implant survival rates.

Conclusions: Children and patients with mental retardation are the most vulnerable to soft tissue reactions and implant losses. Additional and more frequent care needs to be given during outpatient consultations. Because loading as early as 3 to 5 weeks did not negatively affect skin reactions or implant survival, full BCD installation can occur earlier without risk.

Introduction

Since the introduction of percutaneous bone conduction devices (BCDs) by Tjellström et al.[1] in 1977, the surgical procedure for the implantation of the titanium implant and abutment has been adjusted several times. Several surgical modifications have subsequently been reported.[2-13] In general, the aim of the modifications is to provide a hairless skin area around the abutment site and provide a maximum reduction of subcutaneous tissue. Both of these factors are intended to achieve a solid and close attachment of the skin to the bone tissue. Better attachment reduces movement of the skin around the implant and debris entrapment.[14] The most frequent complication of a percutaneous implant is a soft tissue reaction around the titanium skin-penetrating coupling.[14] While mild skin reactions can be successfully treated with hygienic care and the use of medical ointment, severe skin reactions can present more serious outcomes, such as skin overgrowth, implant extrusion, and chronic wound infections.[4,8,9,12]

There are several other relevant post-BCD surgery complications, including permanent hypertrophic skin around the percutaneous abutment, implant loss, and persistent pain.[15,16] Surgical outcomes for a variety of patient groups have been reported. However, comparisons of the outcomes between patient groups have always been difficult because the surgical techniques and method of registering complications vary among BCD centers. Depending on the BCD center and the follow-up duration, the rates of implant loss in adults have varied from 3.5% to 17.4%.[1,4,7,8,17-20] In children, the rate of implant loss varied from 5.3% to 26%.[21-27] It is possible that taking good care of the skin surrounding the abutment might be more difficult for children and patients with mental retardation, resulting in higher complication rates. Sheehan and Hans described early soft tissue problems in 47% of adult BCD patients with Down syndrome; however, implant failure rates were not a significant problem.[28] These differences make a comparison of clinical outcomes between different subgroups relevant.

Good implant osseointegration is the key to success of the BCD system, especially before implant loading with the BCD sound device. During the years, the loading time of the implant has been reduced. In 2005, Snik et al. published an expert consensus statement on this topic that was prepared the previous year.[29] In this statement, a loading time of between 4 and 6 weeks was advised for adults, and a loading time of at least 3 months was advised for children10 years or younger. Later, in 2007, Wazen et al. reported on 26 cases with an average loading time between 5 and 9 weeks in adults (average of 6.5 wk).[30] After examining the clinical data in conjunction with laboratory research data, the authors indicated that it would be safe to reduce

loading times from 3 months to 6 weeks in adults but also concluded that additional research based on a larger patient group was needed to confirm their recommendations. On the basis ofclinical experience, a 6-weeks loading time is now generally well accepted and practiced.[19] However, in Nijmegen, before completion of the study of Wazen et al., a loading time between 6 and 8 weeks was already common and in practice for years in healthy adults. However, detailed reports on these clinical outcomes in a larger series comparing variable loading times and the incidence of complications and implant failure rates are still not available.
In Nijmegen, the first BCD surgery was performed in June 1988, and by the end of 2007, more than 1000 BCDs had been implanted. A consistent follow-up of these patients was performed with the systematic recording of main clinical features using a standardized checklist. This procedure resulted in a large amount of data and clinical experience. The current study presents the clinical outcomes of a series of more than 1000 implants. The size of the series allows us also to identify variable groups and compare the outcomes of BCD surgery and usage across different patient groups. Knowledge of these outcomes might be helpful in preoperative and postoperative consultation because the outcome data include data gathered during a 20-year period.

Patients and Methods

The patient cohort consisted of 970 patients who received 1132 titanium BCD implants between September 1, 1988, and December 31, 2007. Initially, the original Tjellström skin graft technique was used. A hairless skin graft was typically derived from the retro-auricular fold. In 1995, the application of a free skin graft had been abandoned because that type of graft proved to be more prone to necrosis. A simplified technique was developed step-by-step at Nijmegen. The end result of the simplification was a simple longitudinal (linear) incision. The technique facilitates a wider subcutaneous tissue reduction while avoiding the need for a thinned skin flap.[18,19,31] The clinical reports on the outcomes of the Nijmegen linear incision technique have been previously described and included the following patient groups: (i) a 3-year follow-up cohort study between January 1997 and December 1999[19], (ii) BCD implantation between 1994 and 2007 in children 16 years and younger[32], (iii) BCD implantation between 1995 and 2007 in adults aged 60 years or older[33], and (iv) BCD implantation in a random sample of patients[34]. The data from these clinical studies formed the basis of the current study. However, over 400 cases have been added, and the total cohort was redivided into subgroups. The patients were divided

into groups according to patient age at implantation (children, adults and the elderly). Four groups with variable loading times were identified as well as a subgroup of patients with mental retardation. The details of how the groups were classified and the group sizes are listed in more detail in the following sections.

Age at implantation

The age at implantation was defined as the patient age at the time of the 1-stage surgery or the first stage in case of a 2-stage surgery. Three different age groups were defined: children up to 16 years (n = 145), adults of 16 to 64 (n = 793), and the elderly older than 65 years(n = 194).

Mental state

Forty-six (n = 46) implants in 38 patients with mental retardation were identified. No level of retardation was ascribed in the patient files, and mentally retarded patients of varying severities were included in this group.

Loading time

Loading time was defined as the time between placement of the implant and loading the implant with the BCD sound processor. In recent years, a trend toward reduced loading time was observable in the series. The loading time varied from 3 to more than 12 weeks. Therefore, the cohort was divided into 4 groups: loading at 3 through 5 weeks (n = 88), loading at 6 through 8 weeks (n = 567), loading at 9 through 11 weeks (n = 203) and loading at or after 12 weeks (n = 228). In 46 cases, loading time could not be obtained from the patient's file.

Data Collection

In general, 2 return visits were needed between the implantation and the fitting of the BCD sound processor, to evaluate the healing process. In the initial years of BCD surgery, after the fitting of the BCD sound processor, patients needed a checkup at least every 4 months. In later years, this checkup interval was prolonged to 6 months, and once every year is the current standard. Patients were responsible for scheduling these outpatient clinic checkups. When problems arose, the physician was able to set up extra visits, and patients were free to ask for extra visits. Using this follow-up policy, the number of outpatient visits varied for each implant and depended on the year of implantation, follow-up time, and the problems that occurred.

At each visit, the degree of soft tissue reaction and the related medical response were classified using the Holgers grading system.[14] A standardized checklist was used for data entry into the medical files at the outpatient clinic.
The patient medical files were reviewed, and indications for BCD fitting, surgical notes, BCD use, revision surgery and implant loss were recorded. For every follow-up visit in the patients file, details regarding skin reactions, skin overgrowth, and pain were noted.

Statistical Analysis
All data were analyzed using SPSS16.0 (SPSS, Inc., Chicago, IL, USA).. The mean skin reaction scores were calculated by dividing the sum of observed skin reactions by the total number of observations performed. A more clinically relevant mean skin reaction score was calculated by dividing the sum of observed *adverse* skin reactions (Holgers≥2) by the total number of observations. This second calculation was performed because patients with adverse skin reactions needed to be treated in contrast to patients with no or mild skin reactions (Holgers≤1). The comparisons of mean (*adverse*) skin reaction scores and the number of revision surgeries between subgroups were performed using a robust analysis of variance test. With different sample sizes and assuming unequal variances, pairwise comparisons were performed using a post-hoc Games-Howell procedure. A Kaplan-Meier curve was used to analyze implant survival. Comparisons between the survival curves of different groups were made using a log-rank test. The level of significance for all tests was $p \leq 0.05$.

Results

Baseline characteristics
Titanium implants (n = 1132) for BCD use were implanted in 970 patients between September 1988 and December 2007. Forty-eight percent (48%) of the patients were men, and 52% were women. The mean age at implantation was 47 years (range, 3-86 yr; standard deviations [SD], 20 yr). A total of 879 (91%) patients were fitted with a BCD on 1 side, and 91 (9%) patients were bilaterally fitted. The median follow-up period was 3.6 years (mean, 4.6 yr; range, 0-22 yr; SD, 4 yr). An overview of the indications for a BCD fitting is presented in Table 1. The baseline characteristics of the patients groups formed by age and mental state at time of implantation are presented in Table 2.

Table 1. Indications for BCD titanium implants in 970 patients

Indication	N (%)
Acquired conductive/mixed hearing loss	756 (77.9)
Congenital conductive hearing loss	117 (12.1)
Single-sided deafness	97 (10.0)
Total	970 (100)

Table 2. Baseline characteristics of patient groups as identified by age and mental state at the time of titanium fixture implantation.

	Children	Adults	Elderly	Mental retardation
No. implants	145	793	194	46
No.patients	105	692	173	38
Age, mean (range), yr	9.5 (3-16)	46.6 (17-65)	72.9 (66-87)	37.7 (3-78)
Follow-up, mean (range), mo	41 (0-262)	61 (0-257)	43 (0-156)	41 (0-219)

Surgical technique

In 108 of the cases, a skin grafting technique was used to manage the soft tissue during the implantation. Most of the skin grafts were taken from the retroauricular fold (n = 87). In 1024 of the cases, various incision techniques that did not make use of a skin graft were performed. The most common incision technique was the Nijmegen linear incision technique (986 cases, 87%).

Skin reactions

During the mean follow-up period of 4.6 years, 7415 observations were made for the total group of 1132 implants. An overview of the skin reaction observations in the different subgroups is given in Table 3. Statistical analysis indicated statistically significant higher mean skin reaction scores in children (mean. 0.31; SD, 0.58) compared with both adults (mean, 0.19; SD 0.30; p = 0.032) and to elderly patients (mean, 0.15; SD, 0.35; p = 0.011). In addition, the mean *adverse* skin reactions scores (Holgers≥2) were significantly higher in children (mean, 0.14; SD, 0.4) compared with adults (mean, 0.05; SD, 0.16; p = 0.042) but not compared with elderly patients (mean, 0.05; SD, 0.20). There was no statistical difference between adults and elderly patients in either the mean skin reaction scores or the mean *adverse* skin reaction scores.

Table 3. Distribution of skin reactions (Holgers grading system) over observations

	Total cohort		Children		Adults		Elderly		Mental retardation	
Holgers grade	n	%	n	%	n	%	n	%	n	%
0	6,329	85.4	535	81.2	4,799	85.0	995	89.9	213	76.9
1	746	10.1	73	11.1	604	10.7	69	6.2	42	15.2
2	253	3.4	33	5.0	186	3.3	34	3.1	13	4.7
3	73	1.0	11	1.7	53	0.9	9	0.8	7	2.5
4	14	0.2	7	1.1	7	0.1	0	0.0	2	0.7
Total observations	7,415	100	659	100	5,649	100	1,107	100	277	100

Table 4. Distribution of skin reactions (Holgers grading system) over observations per loading time group

	Loading time (wk)							
	3-5		6-8		9-11		≥ 12	
Holgers grade	n	%	n	%	n	%	n	%
0	710	84.1	2,691	85.8	1,196	85.4	1,556	85.4
1	103	12.2	309	9.8	135	9.6	171	9.4
2	25	3.0	106	3.4	51	3.6	66	3.6
3	5	0.6	24	0.8	20	1.4	22	1.2
4	1	0.1	5	0.2	0	0.0	8	0.4
Total observations	844	100	3,135	100	1,402	100	1,823	100

Patients with mental retardation had significantly higher skin reaction scores than patients without mental retardation (p = 0.33; Table 3). However, the mean *adverse* skin reaction scores did not differ between these groups.

In Table 4, the skin reaction observations as a function of loading time are presented. Both the mean skin reaction scores and the mean *adverse* skin reaction scores were comparable among the 4 groups ($p > 0.05$).

Implant loss

A total of 94 (8.3%) implants were lost or electively removed, with a mean time until loss of 3.2 years (median, 2.5; SD, 3.4 yr). Most implants were lost in the first 12 months after implantation (n = 53/94 total lost or electively removed implants, 56%; Figure 1). Elective removal (e.g., because of pain or no BCD benefit) of implants occurred only in the first 12 months after implantation.

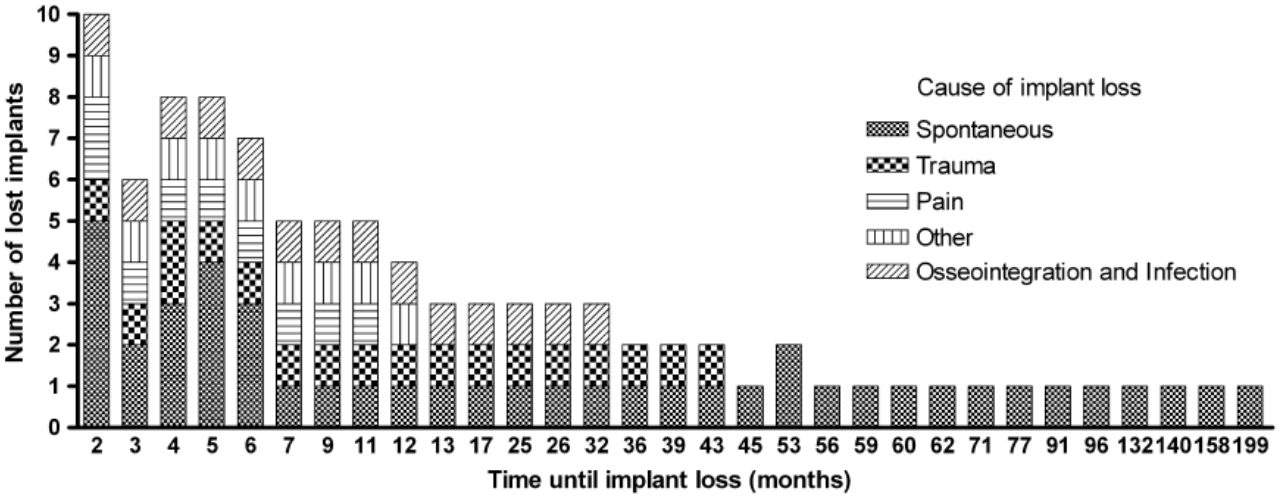

Figure 1. Time until implant loss and reason of loss. Spontaneous indicates no known cause of loss; Trauma, loss caused by trauma; Pain, implants that have been electively removed because of chronic pain; Other, implants removed at the patients' requests because there was no BCD benefit after deterioration of cochlear function, for aesthetic reasons or for re-implantation of implants to achieve a more optimal placement.

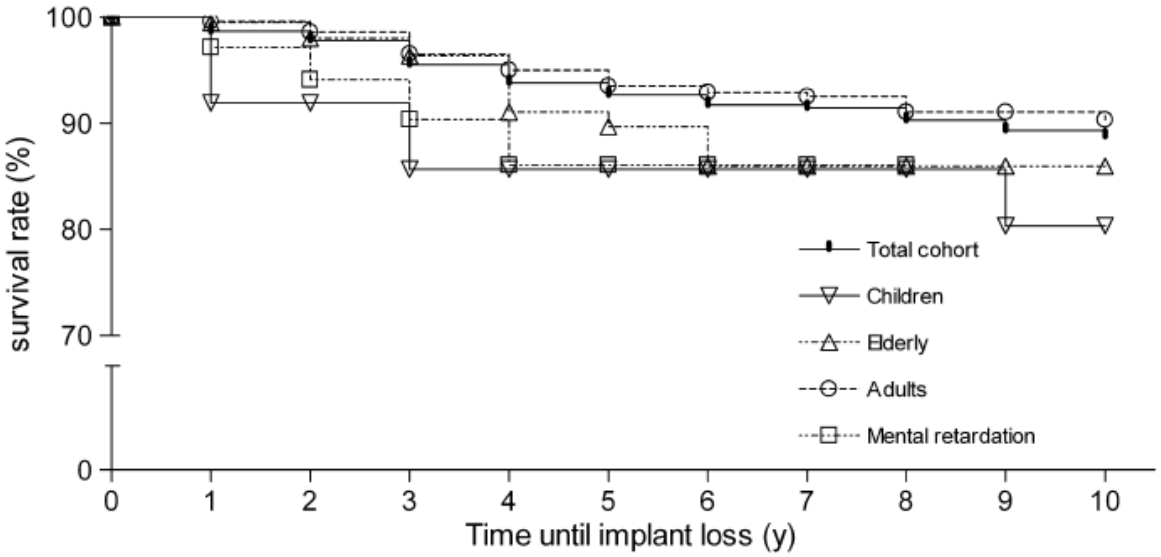

Figure 2. Implant survival analyses for the total cohort, different age groups, and patients with mental retardation.

Twenty-two implants (15.2%) were lost in children, with a mean age of 11 years. In the adult group, 58 implants (7.3%) were lost, and 14 implants (7%) were lost in the elderly group. Spontaneous loss was the most frequent type of implant loss in all age groups. In children and the elderly, the second most common cause of loss was trauma. In the adult group, infection and lack of osseointegration were the second most common cause. In Figure 2, the Kaplan-Meier survival curves for the implants

are plotted according to the three age categories groups (i.e., children, adults and the elderly). A comparison of implant survival between groups indicates that there was a significant difference in survival between age groups (p = 0.000). A pairwise analysis revealed that this statistical difference consisted of a significantly lower survival in children compared with adults (p = 0.000) and the elderly (p = 0.020). The survival curves between adults and the elderly showed no differences.

Of the 46 implants in patients with mental retardation, 8 implants (17.4%) were lost during follow up, and spontaneous loss was the most frequent reason (n = 5). Implant survival analyses revealed a statistically lower implant survival in mentally retarded patients compared to non-mentally retarded patients (p = 0.001).

Table 5 shows the number of implant losses in the 4 loading time groups within a given time period after implantation. A comparison of implant survival curves between the 4 different loading time groups indicated no significant difference (p = 0.550).

Table 5. Implant loss per loading time group

	Loading time (wk)			
	3-5	6-8	9-11	≥ 12
No.cases (% of total cases)	88 (7.8)	567 (50.1)	203 (17.9)	228 (20.1)
No.nonelective implant extrusions				
Within 1 jr	0	12 (2xI, 3xT, 7xS)	3 (S)	14 (2xI, 3xT, 9xS)
1-2 yr	1 (5)	1 (T)	0	2 (1xI, 1xT)
After 2 yr	5 (2x1, 3xS)	20 (4xI, 6xT, 10xS)	8 (2xI, 4xS, 2xT)	5 (1xI, 2xT, 2xS)
No.elective implant extrusions				
Within 1 jr	0	1 (P)	1 (R)	1 (P)
1-2 yr	0	3 (2xP, 1xB)	2 (P)	0
After 2 yr	1 (P)	4 (1xP, 2xR, 1xE)	1 (B)	3 (1xP, 2xB)
Total no. extruded implants (% of implants in group)	7 (8.0)	41 (7.2)	15 (7.4)	25 (11.0)

Causes of nonelective implant extrusions: I indicates infection; S, spontaneous loss; T, trauma
Causes of elective implant extrusions: B indicates no BCD benefit: E, esthetics; P, pain; R, reimplantation of implant to a more optimal position.

Revision surgery

In 68 (6.6%) out of 1032 implants, revision surgery of the implant site was performed at least once. Overall, soft tissue revision surgery was performed 89 (7.8%) times. Other indications for revision surgery included the fitting of a new (or 8.5-mm) abutment (n = 12) and exploration of implant site (in cases of pain and problematic wound healing) (n = 7). Soft tissue revision surgery was performed relatively more often in children (n = 16/145, 11%) than in adult patients (n = 69/793, 8.7%) and elderly patients (n= 4/194, 2%). Statistical analyses indicated that soft tissue revision surgery was performed in significantly fewer cases in elderly patients than in adult cases (p = 0.001) and child cases (p = 0.016). The difference between children and adults was not significant. In patients with mental retardation, soft tissue revision surgery was needed 3 times (n= 3/46, 6.5%), but this was not statistically different when compared with the total cohort.

Discussion

Overall, of the 7415 observations collected for the 1132 implants with a mean follow-up time of 4.6 years, the soft tissue around the abutment demonstrated no adverse reaction in 95.5% of implants. Children were more prone to adverse skin reactions. Of the 1132 implanted and loaded implants, 8.3% were lost. Significantly lower implant survival rates were noted for children and patients with mental retardation. The time between placement of the implant and loading the BCD sound processor did not influence implant survival. Revision surgery rates were lowest in elderly patients and comparable rates were found between the other subgroups.

Since the introduction of the bone-anchored hearing aid technique, several BCD teams have reported on BCD surgery outcomes. Over time, the implantation techniques have been refined and shared among BCD surgeons leading to a reduction in complication rates and surgical time. The Nijmegen bone-anchored hearing aid program joined in these developments and has been implanting patients for more than 20 years. After using several skin grafting techniques, the Nijmegen linear incision technique was developed. In 1999 and 2008, the Nijmegen BCD team reported it to be superior and therefore the preferred technique.[18,19] In our center, it has been the most commonly used technique (87%) in the last 15 years. Van de Berg et al.[16] recently compared the complication rates of four surgical techniques and found that the use of 2 broad pedicled, local skin envelopes (linear incision technique) was associated with significantly fewer major complications compared to skin grafting techniques (full-thickness, split-skin and dermal grafts).

In addition to comparing the outcomes of surgical techniques, the outcomes in various BCD populations are of interest because they can be helpful during pre- and post-operative consultations with different patient groups. Hobson et al.[15] reported details of 602 bone-anchored hearing aid implantation procedures. However, none of the larger series in literature reported internal comparisons between the outcomes of various groups of patients. The present study is the largest BCD population study reported to date, with more than 1000 implants examined. The size of the population allowed us to identify variable subgroups and to compare the outcomes of BCD surgery and BCD usage across different patient groups.

The main foci of this article were soft tissue reactions (as graded according to Holgers grading system), implant loss, and revision surgeries. Using a standardized checklist in the patient chart, this information was made available during every outpatient clinical observation of the BCD implant site, which was of great value in enabling a retrospective evaluation of these data. In the majority of observations (95.5%), no adverse skin reactions were present (Table 3). This result is consistent with other studies reporting that 97.6% and 97.9% of BCD implants result in no adverse skin reactions (Holgers 0 and 1).[8,10] More adverse skin reactions were observed in the tissue surrounding implants in children. This result is consistent with the hypothesis that this group of patients has greater difficulty cleaning the abutment site. Additionally, developmental growth of the skull might interfere with an immobile implant site. Reyes et al. [8] also found the highest frequency of skin reactions in a young age group (<20 ys). However, although more soft tissue problems occurred in children, they did not lead to increased soft tissue revision surgery rates (11%). Most of the time, the use of a medical ointment and specific cleaning advice can solve soft tissue problems. The overall revision surgery rate of 6.6% for skin and soft tissue problems was comparable with the rate reported by Hobson et al. (6.2%).[15]

An implant loss rate of 8.3% was noted for the total cohort. The rate is centered in the range of implant loss percentages reported in literature. In the literature, both comparable and lower survival rates are described for children when compared to the failure rates for adults. The Nijmegen BCD group reported earlier on outcomes regarding implant loss in children[32], in older adults[33] and in a 3-year cohort[19]. However, no statistical comparisons of the survival curves were made. An internal analysis in this large study indicated statistically significantly lower survival rates in children compared to adults and the elderly (Figure 2). Children are more prone to trauma at the implant site through activities such as playing or practicing sports. Hypothetically, osseointegration is sub-optimal or is perhaps more easily disturbed in pediatric patients. An assessment of implant stability, for example, using non-invasive resonance frequency analyses, in a pediatric population would be useful in

testing these hypotheses. In patients with mental retardation, implant survival was significantly lower than in patients without mental retardation (Figure 2). No evidence was found that older patients (>65 years of age) had higher implant failure rates compared to younger patients as has been described previously by Drinias et al.[35]
The time that an implant was left unloaded to allow for optimal osseointegration decreased from 12 weeks to an average of 6 weeks over our 20-year BCD program. Strikingly, in the earliest loading group (3-5 weeks), none of the 88 implants were lost in the first year following loading (Table 5). These results imply that implant osseointegration is already sufficient as early as 3 weeks after implantation for the loading of the BCD sound processor.

Conclusion

This paper presents the clinical outcomes of percutaneous BCD installation in a series of more than 1000 implants, with a maximum follow-up time of 20 years. The simplified linear incision technique was mainly used in the preceding 15 years and demonstrated good outcomes. The results of the study indicate that major complications following BCD surgery are rare. In 95.5% of cases, there were no adverse soft tissue reactions. Children appeared to be most vulnerable to adverse soft tissue reactions. An overall implant failure rate of 8.3% was found and can be mentioned during preoperative consultation about implant loss. Children and mentally retarded patients were most vulnerable to implant loss. These results are relevant for outpatient consultation involving children and mentally retarded patients because they indicate that extra and more frequent care needs to be given to support the regular cleansing of skin surrounding the abutment. In addition, the effective treatment of skin reactions is needed to prevent severe complications such as implant loss. However, the major benefits of hearing rehabilitation gained by BCD application in these 2 vulnerable groups justify the relatively mild complications of BCD surgery. The loading of the BCD sound processor 3 to 5 weeks after placement of the implant in healthy adults was not followed by any implant loss within 12 months. These outcomes are supportive of a reduction in the currently used standard loading time of around 6 weeks. The simplified linear incision technique enables quick wound healing and supports the possibility of earlier BCD application.[16,36] In adults with expected sufficient bone quality, loading can safely be performed at 6 weeks and even be reduced to 3 weeks after an initial 1-stage surgery. A resonance frequency analysis (RFA) of implant stability in the near future would be helpful in further investigating these findings.

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2.2

FITTING OF AN 8.5-MILLIMETER ABUTMENT FOR BONE CONDUCTION DEVICES: INDICATIONS AND POSTINTERVENTION COURSE

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Abstract

Objectives**:** We present indications and clinical outcomes of fitting an 8.5-mm abutment for bone conduction devices.

Methods: In 39 cases with a follow-up time of more than 12 months after fitting of an 8.5-mm abutment, the preintervention and postintervention courses were retrospectively evaluated. The outcome measures were indications for fitting and complications during the preintervention and postintervention courses (local skin reaction, skin level, revision surgery, and implant loss).

Results: Soft tissue overgrowth was the most frequent reason (31 of 39 cases) for fitting the 8.5-mm abutment. Severe skin reactions decreased by 7.9% after fitting, and the number of fixtures that remained free of any skin reaction increased by 32.2%. In 7 cases, soft tissue overgrowth required revision surgery before placement of the 8.5-mm abutment; further surgical intervention was needed only once. In 1 case, the 8.5-mm abutment was removed because of recurring soft tissue problems. No spontaneous abutment or implant loss occurred.

Conclusions: This retrospective evaluation showed that fitting an 8.5-mm abutment is an easy step in managing soft tissue problems and preventing revision surgery. Also, it is of value in patients with a thick scalp that interferes with bone conduction device coupling. In these cases, we advise placing the 8.5-mm abutment during primary surgery.

Introduction

One of the main concerns regarding percutaneous implants for application of a bone conduction device (BCD) is the skin reaction associated with titanium skin-penetrating coupling.[1] The skin reactions are usually treated successfully by regular cleansing in combination with application of antibiotic and anti-inflammatory ointment and/or corticosteroid injections. However, a small percentage of patients with skin reactions will develop problems such as wound infection, soft tissue growth around or over the abutment, or loss of the implant. Recurring soft tissue problems can lead to increased outpatient visits and discomfort associated with BCD use.

Significant soft tissue overgrowth is typically treated by revision surgery in a clinical setting with the patient under local anesthesia. In the literature, the incidence of tissue revision surgery for soft tissue overgrowth after fixture implantation with the Nijmegen simplified linear incision technique varies from 4.6% to 12.7%.[2-4] For some patients, soft tissue problems recur despite revision surgery.

Since 2003, an 8.5-mm abutment has been available. This abutment facilitates a longer distance from the surrounding skin to the coupling site compared to the standard (5.5-mm) abutment. This abutment can be of value in some cases of recurrent soft tissue problems, skin overgrowth and for anatomic reasons such as a thick scalp (Figure 1).

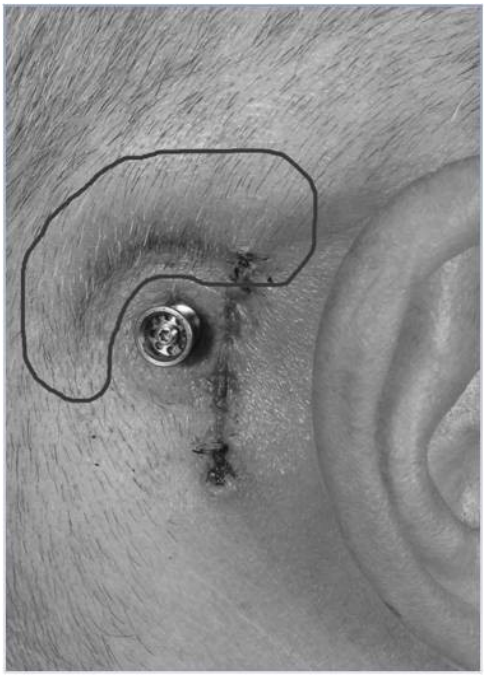

Figure 1. Four weeks after implantation of bone conduction device (BCD). Outlined area illustrates thick part of scalp. Skin thickness caninterfere with BCD coupling, causing resonance of sound from BCD.

To date, 61 abutments of the 8.5-mm size have been fitted in our center, typically during postoperative follow-up for troublesome cases. This study presents the clinical outcomes seen after fitting of the 8.5-mm abutment. The value of this approach in BCD implant site management is stressed. Replacing the 5.5-mm abutment with an elongated 8.5-mm abutment is shown to be valuable in preventing revision surgery.

Patients and Methods

From 1988 to August 2009, 1,140 titanium fixtures for application of BCDs were implanted in our center. The 8.5-mm abutment was introduced in 2003, and 61 abutments of this size were fitted between September 2003 and October 2009 in 58 patients. The medical records of all 58 patients who were fitted with 8.5-mm abutments were retrospectively reviewed. To investigate the postintervention course, we included only cases with a follow-up time of at least 12 months in our analysis. Follow-up time was calculated as time between fitting of the 8.5-mm abutment and last reported clinical visit.

The preintervention and postintervention courses were evaluated with regard to revision surgery, BCD use, and implant loss. For patients with primary soft tissue problems around the abutment site, the preintervention and postintervention courses were evaluated with regard to local skin reactions according to Holgers classification[1] and the level of the skin surrounding the implants. Severe skin reactions were classified as Holgers grade 2 or higher. High skin around the implant was defined as skin in level with the top of the abutment or above the level of the abutment. Low skin around the implant was present if the skin level was lower than the abutment top (ie, normal skin status). All data were entered into the medical files at the outpatient clinic at each visit by means of a standardized stamp.

A standardized protocol was used for assessment after titanium fixture implantation. The patients were followed up at 10 days, 6 to 8 weeks, and 12 months after fixture implantation. When problems arose, the physician was able to set up extra visits, and patients were free to ask for extra visits. In contrast to the post-implantation protocol, there were no fixed visits after fitting of the 8.5-mm abutment. The patients were advised to visit our clinic on a yearly basis for evaluation of the implant site, and they had to schedule these visits themselves. Extra visits could be scheduled when problems arose.

Statistical Analysis

Data were analyzed with SPSS 16.0. A nonparametric test for paired samples (Wilcoxon signed rank test) was used to compare the skin reactions and high skin level observations before and after fitting the 8.5-mm abutment. The number of observed skin reactions and high skin levels were corrected for the total number of observations performed in a specific follow-up period (prefitting and postfitting periods). The level of significance was less than or equal to 0.05.

Results

Baseline Characteristics

Of the 61 cases of 8.5-mm abutments fitted, 39 abutments (38 patients) with a follow-up time of at least 12 months after fitting were included in our analysis (Figure 2). Eight of these 39 cases needed to be recruited to the clinic for evaluation, because no follow-up visit had been performed after fitting the 8.5-mm abutment. In 3 of the 61 cases, use of the 8.5-mm abutment was stopped before the determined follow-up time of 12 months. In the first case, even with the 8.5-mm abutment the BCD device touched the scalp when coupled to the implant and the total implant was replaced. In the second case, BCD use was eventually stopped in a patient with Down syndrome because of persistent soft tissue problems. The third case concerned a male patient with a thick scalp who afterward had aesthetic objections to the protruding abutment. Four patients could not be traced and were classified as lost to follow-up.

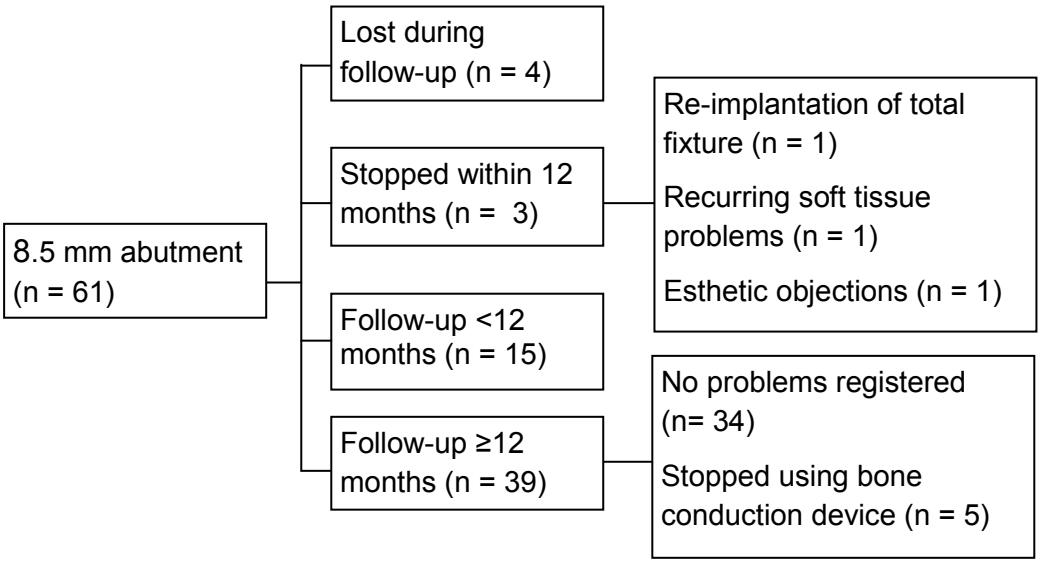

Figure 2. Number of 8.5-mm abutments placed and the follow-up results.

In the follow-up group, there were 25 male and 13 female patients; 1 female patient was fitted with bilateral 8.5-mm abutments. The median age at implantation of a BCD fixture was 36 years (range, 3 to 69 years; SD, 22 years). In 36 cases (92%), the linear incision technique was used in titanium fixture implantation surgery.[5,6] In 2 cases, a U-shaped skin flap was used. In 1 case, a free retroauricular skin graft was used. Skin flap and skin grafting techniques were used until 1994; nowadays, the linear incision technique is the only technique used in our clinic. The median time between implantation of the fixture with a 5.5-mm abutment and fitting of the 8.5-mm abutment was 48 months (range, 0 to 246 months; SD, 42 months).

Table 1[7] shows indications for fitting an 8.5-mm abutment. The most frequent was soft tissue overgrowth (n = 31; 79.5%). In 6 of these 31 patients, excessive soft tissue had been previously removed by surgery, but had recurred. In 7 cases, an 8.5-mm abutment was indicated because of a thick scalp. In 3 of these 7 cases, the 8.5-mm abutment was placed during primary fixture implantation. In 1 case, the indication was not specified in the patient file.

Table 1: Indications for fitting of 8.5-mm abutment.

	Cohort Followed Up		Monksfield et al[7]
Indication	No.	%	%
Soft tissue problems	31	79.5	92
Thick scalp, 8.5-mm abutment fitted during fixture implantation	3	7.7	8
Thick scalp, 8.5-mm abutment fitted at later stage	3	10.3	
Not specified	1	2.5	
Total	39	100	100

Revision Surgery, BCD Use, and Implant Loss.

None of the 6 patients who required surgical removal of excessive soft tissue before fitting the 8.5-mm abutment required surgical intervention afterward. One patient, without a history of skin-reducing surgery, had hypertrophic skin and appositional bone removed 3 years after fitting the 8.5-mm abutment. Five patients stopped using their BCD because it was not longer providing benefit. No spontaneous, traumatic, or infectious implant losses occurred.

Skin Reaction and Skin Level Observations.

In 31 cases in which the 8.5-mm abutment was indicated because of soft tissue problems, 286 evaluations of the implant site were performed before fitting of the 8.5-mm abutment. The mean observation time between primary BCD fixture surgery and fitting of the 8.5-mm abutment was 58 months (range, 6 to 155; SD, 42 months). After fitting of the 8.5-mm abutment, a total of 111 evaluations were performed over a follow-up period of 38 months (range, 12-68 months; SD, 20 months).

Table 2. Distribution of skin reaction types in 31 cases in which abutment fitting was indicated because of soft tissue problems.

	Before fitting		After fitting		
Holgers Grade[1*]	No.	%	No.	%	*P*
0	220	76.9	83	74.8	} 0.028
1	47	16.4	26	23.4	
2	18	6.3	2	1	} 0.016
3	1	0.4	0	0	
4	0	0	0	0	
Total No. of observations	286	100	111	100	

[*] 0 - no irritation; 1 - slight redness; 2 - red and moist tissue; 3 - granulation tissue; 4 - infection leading to removal of abutment.

Table 2[1] shows the distribution of observed skin reactions over the evaluations performed before and after fitting the 8.5-mm abutment. Most observations showed mild skin reactions or no reaction at all, designated as Holgers grades 1 and 0, respectively. Taken together, for Holgers grade 1 and 0 skin reactions, there was a significant increase of 4.9% after fitting the 8.5-mm abutment compared to the prefitting period ($p = 0.028$). The occurrence of severe skin reactions (Holgers grade 2 or higher) decreased by 7.9% after fitting an 8.5-mm abutment; this decrease was statistically significant ($p = 0.016$). Also, statistically more fixtures remained free of any skin reaction after fitting of an 8.5-mm abutment: 54.8% after fitting versus 22.6% before fitting ($p = 0.005$).

In each observation performed, the level of the skin surrounding the abutment was classified as low or high. In 29% percent of all observations before fitting the 8.5-mm abutment, a high skin level was noted. This percentage decreased to 9% after fitting the 8.5-mm abutment (Table 3); this was a statistically significant decrease ($p < 0.001$). In the pre-fitting period, none of the implants remained free of any high skin

observation. After fitting of the 8.5-mm abutment, the number of implants without any high skin observation increased to 23 (74.2%; $p < 0.001$).

Table 3. Distribution of observed skin levels in 31 cases in which abutment fitting was indicated because of soft tissue problems.

	Before fitting		After fitting		
	No.	%	No.	%	*P*
Low skin level	204	71	101	91	<0.001
High skin level	82	29	10	9	
Total No. of observations	286	100	111	100	

Discussion

This study retrospectively evaluated use of the 8.5-mm abutment among patients treated at our center. The outcomes were described according to observations performed following a standardized method (Holgers classification and skin level) before and after intervention. Monksfield et al.[7] evaluated 81 cases in which the 8.5-mm abutment was used. They provided preintervention data and the extent of surgical soft tissue reduction as the only outcome. Doshi et al.[8] reported on 16 children who had an 8.5-mm abutment fitted. They described 1 complication of spontaneous implant extrusion 2 years after fitting an 8.5-mm abutment. However, no other outcome variables were provided. Although the declines in the number of revision surgeries performed and fixture losses described by Monksfield et al.[7] and Doshi et al.[8] are important outcomes, in our opinion the incidence of skin reactions also indicates whether the intervention is successful or not. This is because these skin reactions can lead to discomfort and more frequent visits to the clinic, thus influencing the patient's well-being and cost of care. To the best of our knowledge, no data on skin reaction or skin level observations in patients fitted with 8.5-mm abutments are available in the literature. The current study describes the situations before and after fitting of an 8.5-mm abutment with regard to revision surgery, implant loss, skin reactions, and skin level.

The variable number of observations per implant after intervention with the 8.5-mm abutment can be seen as a shortcoming of this retrospective evaluation. This variability might be due to the fact that there previously was no standard protocol describing the number of control visits needed after this intervention. Patients had to

schedule control visits themselves; therefore, follow-up was patient-dependent. In 12 of 61 cases, the clinic was not contacted for evaluation within 12 months after fitting the 8.5-mm abutment. Eight of these 12 patients were recruited to the clinic, but did not experience major problems. A decline in the number of visits or the lack of any visits after fitting the 8.5-mm abutment seems to indicate that the patient experienced fewer problems. However, no objective observations between visits were able to verify this hypothesis. Another shortcoming can be the different physicians observing the patients over time. In our clinic a standardized stamp was used to facilitate the collection of a defined set of information (skin reaction, skin level, etc) at each visit. Still, interpretation of the skin level and soft tissue reactions may have been subject to interphysician variation.

One patient out of 61 cases stopped using the BCD and had the abutment removed because of persistent soft tissue problems, before the 12-month follow-up. This was a patient with Down syndrome. In patients with Down syndrome, soft tissue problems are relatively frequent (49%), as described by Sheehan and Hans.[9] This may be due to manual manipulation and problems cleaning the implant site in this subgroup of patients.

Skin reactions were evaluated in 31 cases fitted with the 8.5-mm abutment because of soft tissue problems. There were only small changes throughout all preintervention and postintervention observations in the distribution of skin reactions. However, the rate of severe skin reactions (Holgers grade 2 or higher) significantly declined after the 8.5-mm abutment was fitted, from 9.7% to 1.8%; observations of Holgers grade 0 and 1 skin reactions significantly increased. This finding indicates a shift towards less-severe skin reactions after fitting the 8.5-mm abutment. Compared to the literature, the frequencies of severe skin reactions after fitting are low. De Wolf et al.[3,4] found severe skin reactions in 6.5% of the members of a cohort study group and 4% of a group comprising older adults. Another statistically significant shift was observed in looking at the number of implants that remained free of any adverse skin reaction, from 22.6% in the prefitting period to 54.8% in the postfitting period. It appears inconsistent that for 22.6% of implants no observations of adverse skin reactions were made, and eventually the 8.5-mm abutment was fitted. However, these 7 implants were only associated with high skin problems, and no skin reactions according to the Holgers classification were present. Finally, for the number of implants free of any skin reaction, the postfitting situation for all 31 implants is comparable with reports in the literature (values between 49% and 67%).[3] After fitting of the 8.5-mm abutment, the prevalence of skin problems per implant seems to

decrease to a level comparable with the prevalence of skin problems in the general BCD population.
Before fitting of the 8.5-mm abutment, a high skin level was observed in 29% of all observations. This percentage decreased significantly, to 9%, after fitting. In addition, significantly more implants remained free of any high skin after fitting. These results can be interpreted in different ways. As the abutment length increases, the level of the skin in relation to the abutment necessarily decreases. This could explain the observation of a lower skin level shortly after fitting the 8.5-mm abutment. However, when taking the minimal follow-up time of 1 year into account, the lower skin levels observed suggest a decreased tendency of the skin to grow towards or over the abutment top with time.

In the 38 patients (39 abutments) who complied with follow-up, soft-tissue revision surgery was performed seven times (18%) before intervention with the 8.5-mm abutment. Because the evaluated cohort consisted predominantly of patients with implant-related skin problems, it is not surprising that the revision surgery rate is high compared to that of other studies evaluating the linear incision technique (5% to 12.7%).[2-4,10] In 1 case, revision surgery was performed 2 times. In the retrospective study by Monksfield et al.[7], revision surgery was performed before fitting the 8.5-mm abutment in 40 of 81 of cases (49.4%). In this study, multiple revision surgeries were performed in 15 cases (2 times in 11 cases, 3 times in 2 cases, and 4 times in 2 cases). It should be noted that Monksfield et al.[7] used a skin graft technique during primary fixture implantation surgery. Compared to the case series reported by Monksfield et al.[7], our center seems to be more cautious in performing revision surgery in managing soft tissue problems. It also appears that we use the 8.5-mm abutment at an earlier stage in soft tissue management. In the cohort of 39 cases that were followed up, further surgical intervention was needed only once for skin overgrowth, 3 years after fitting the 8.5-mm abutment.

This retrospective evaluation showed that the 8.5-mm abutment is of value in cases with a thick scalp that interferes with BCD coupling. In these cases, we advise to place the 8.5-mm abutment during primary surgery, secondarily after failure of skin revision surgery, or even before performing surgical revision. The first step in management of soft tissue problems is the application of a topical ointment (antimicrobial and anti-inflammatory ointment). In some cases, despite adequate application of the ointment, soft tissue problems recur and result in hypertrophic skin growth around the abutment site. As a next step, administering corticosteroid injections can be considered. However, several doses might be needed, so it may be

a less suitable option for certain patients. In those cases, even before attempting surgical revision of the hypertrophic skin surrounding the abutment, the 8.5-mm abutment is an easy way to reduce soft tissue problems. Replacing the 5.5-mm abutment with an elongated 8.5-mm abutment is shown to be valuable in preventing revision surgery.

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CHAPTER 3

EVALUATION OF A NEW IMPLANT DESIGN; IMPLANT STABILITY AND IMPLANT SURVIVAL

STABILITY, SURVIVAL, AND TOLERABILITY OF A NOVEL BAHA IMPLANT SYSTEM: SIX-MONTH DATA FROM A MULTICENTER CLINICAL INVESTIGATION

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Abstract

Objective: Determination of the difference in implant stability between a novel Baha implant system (test) and the previousgeneration implant system (control).

Methods: In an open, randomized, prospective multicenter clinical investigation, 77 adult patients with Baha implants were included. Test and control implants were randomly assigned in proportions of 2:1. Implant stability quotient (ISQ) values were recorded using resonance frequency analysis at the time of implantation and at 10 days, at 4, 6, 8, and 12 weeks, and at 6 months after surgery. Skin reactions were evaluated according to the Holgers classification. Sound processor fitting was performed from 6 weeks after implantation.

Results: Significantly higher mean ISQ values, measured between 0 and 6 months, were obtained for test compared to control implants (70.4 versus 65.4, $p > 0.0001$). Statistically significant differences were obtained for the study population as a whole and for the subgroup of patients loaded at 6 ± 1 weeks after implant surgery (63.6% of patients). Up to 12 weeks, Holgers rates were comparable, whereas at 6 months, more skin reactions (Grades 1 and 2) were observed in the control implant group. No reduction in mean ISQ values was observed after implant loading.

Conclusion: The test implant showed higher mean ISQ values at the time of placement and over time. The level of osseointegration reached with the implants in adults as early as 6 weeks after implantation was sufficient to support the sound processor. The test implant system is expected to provide additional benefits related to the improvement of the degree of osseointegration, especially for patients with thin or compromised bone.

Introduction

Osseointegrated bone conduction hearing systems (e.g., Baha) have been used clinically for more than 30 years, and worldwide, more than 75,000 patients have benefited from the system. In 1977, Tjellström et al.[1] reported the fitting of their first patient with a bone-anchored hearing device using a Brånemark implant. It was the first time the Brånemark implant was used outside the oral cavity. Since then, long-term follow-up studies have shown clinical results with an overall long-term implant survival rate of greater than 90%.[2,3] Higher failure rates have been reported to occur in irradiated patients[4,5] and in children.[6-8] Developments in implant design to realize faster and stronger osseointegration may be the key in improving outcomes for all patient groups.

It has been considered that sufficient osseointegration before loading the implant with the sound processor is critical to the success of the Baha system.[1,9]. On the basis of this assumption, to allow for sufficient osseointegration and stability of the implant, 12 weeks has been the recommended time to sound processor fitting for Baha FAST (1-stage) procedure in adult patients. However, as demonstrated in the field of dental implantology, where early and immediate loading is a clinical reality[10-12], implants may be successfully loaded before osseointegration is complete as long as good stability without micromovements can be maintained.[13,14] Similarly, the use of reduced loading times with Baha implants has been reported. In 2005, Snik et al.[15] published a consensus report recommending a loading time of between 4 and 6 weeks in adult patients. In 2007, Wazen et al.[16] reported good outcomes in 26 adult cases with a mean loading time of 6.5 weeks, and at the Radboud University Medical Centre Nijmegen (The Netherlands), loading between 6 and 8 weeks has been common practice for a number of years in healthy adults.[3]

Recently, a new Baha implant was designed by Cochlear Bone Anchored Solutions AB (Mölnlycke, Sweden) based on technological knowledge and developments from implant dentistry. Dental studies show that certain geometrical modifications, such as a wider implant diameter, improve the primary implant stability - that is, baseline stability obtained at the time of implant placement.[17-20] It has also been shown that faster and stronger secondary stability - that is, stability obtained over time as a result of the osseointegration process - can be achieved with implants with roughened surfaces compared to implants with the traditional as-machined surface.[21-25]. Furthermore, it has been found that retention elements at the implant neck result in optimized load distribution in the marginal bone.[26] Hence, the new Cochlear Baha BI300 implant has been designed with a wider diameter, small-sized threads at the implant neck, and the moderately rough TiOblast (Astra Tech, Mölndal, Sweden)

surface on the intraosseous portion of the implant (Figure 1). TiOblast is a titanium dioxide-blasted surface modification that has been in clinical use on dental implants for 2 decades with excellent clinical results.[27,28] The new Baha implant design has been validated in a preclinical investigation using a rabbit tibia model. Histologic evaluation showed more bone-implant contacts at the test implant (new design) compared to the previous generation implant, suggesting enhanced osseointegration of the former.[29] Biomechanical findings using the same model showed higher removal torque values for the test implants at all evaluation time points, suggesting a stronger integration/fixation in the surrounding bone.[30]

On the basis of the preclinical findings, it was anticipated that the new implant would provide higher stability and enhanced osseointegration also in the human temporal bone than the previous-generation Baha implant. Also, the authors considered it to be safe to reduce the loading time from the current recommendation of 12 weeks to 6 weeks in adult patient with good bone quality. Hence, to clinically validate the performance of the Cochlear Baha BI300 Series implant design, an open, randomized, prospective, controlled, multicenter clinical investigation was undertaken. The main objectives of the study were to evaluate the difference in implant stability between the new and the previous-generation implants and to substantiate that loading the Baha sound processor at 6 weeks after surgery does not affect the stability of the implant. To this end, resonance frequency analysis (RFA) was chosen as the tool for obtaining objective measures of implant stability. In the dental literature, RFA is a frequently used tool for monitoring of stability changes over time[10,3]) and has also been suggested as a tool for deciding when to load an implant.[32] Resonance frequency analysis has also been successfully used for extraoral craniofacial implants.[33]

The investigation will run for a total of 3 years. The present article reports the results from the first 6 months of follow-up and focuses on implant stability and stability changes during this important period of osseointegration. Results from evaluation of skin reactions are also presented.

Materials and methods

An open, randomized, prospective, controlled, multicenter clinical investigation was undertaken at 4 investigational sites: Radboud University Medical Centre Nijmegen (Nijmegen, The Netherlands), Salford Royal Hospital (Salford, U.K.), Sahlgrenska University Hospital (Göteborg, Sweden), and Manchester Royal Infirmary (Manchester, U.K.). The investigation was performed in accordance with Good Clinical Practice (International Conference on Harmonisation - Good Clinical Practice) and was approved by the local ethics committees and competent authorities.

Implants

The test product was the Cochlear Baha BI300 titanium implant (diameter, 4.5 mm; length, 4 mm) and 6-mm abutment for the Baha system developed by Cochlear Bone Anchored Solutions AB (Figure 1). The comparator (control implant) was the previous-generation as-machined Baha flange fixture (diameter, 3.75 mm; length, 4 mm) and 5.5-mm abutment (Cochlear Bone Anchored Solutions AB). The abutment of the test implant has a rounded, apically converging design, whereas the control abutment is conical. The abutment screw of the test abutments incorporates external threads at the screw head to make it possible to connect a SmartPeg (Osstell, Göteborg, Sweden) for stability measurements. To also enable stability measurements on the control implant, the abutment screw head was modified accordingly.

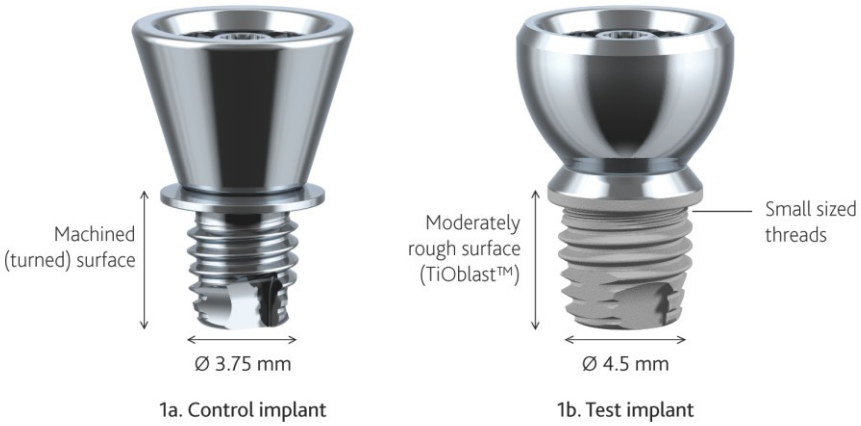

Figure 1.Control (left) and test (right) implants with abutments.

Procedures

Patients were allocated to either of the 2 implant systems at random in proportions of 2:1 (test-control). This randomization was blinded to patients and investigators until time of surgery. To be included in the study, the patient had to be at least 18 years,

have a bone thickness at the implant site of at least 4 mm, and no disease or treatment known to compromise the bone quality at the implant site.

Both test and control implants were premounted with the abutment and were placed according to the FAST (1-stage) surgical procedure recommended by Cochlear, including a skinthinning step. The surgical technique used for soft tissue management was not determined by the investigation protocol and varied between sites but was limited to either the linear incision technique[34] or a flap technique.[35,36]

Follow-up examinations were performed at 10 days, at 4, 6, 8, and 12 weeks, and at 6 months after the implantation procedure. The sound processor was installed from 6 weeks after surgery.

Implant stability was measured using RFA (Osstell Mentor; Osstell, Göteborg, Sweden). The RFA instrument is used to activate a SmartPeg, which is screwed onto the implant or abutment; in the present study, all measurements were performed at the abutment level. The technique is contactless and totally noninvasive, and patients experience no sensation from the measurement, which takes 1 to 2 seconds. The RFA measurement renders implant stability quotient (ISQ) values from 1 to 100 (the higher the number, the higher the stability) displayed by the instrument. The highest (ISQ High) and lowest (ISQ Low) value obtained from perpendicular measurements were recorded. These values correspond to the directions with the highest and lowest stability, which are generally perpendicular to each other.

The status of the soft tissue was monitored throughout the study and classified according to the scale proposed by Holgers et al.[37]

Table 1. Subjects enrolled by site

Site	Test implant (n = 52), n (%)	Control implant (n = 25), n (%)
Nijmegen, The Netherlands	28 (53.8)	14 (56.0)
Salford, U.K.	12 (23.1)	6 (24.0)
Göteborg, Sweden	9 (17.3)	4 (16.0)
Manchester, U.K.	3 (5.8)	1 (4.0

Statistics

Statistical analyses were performed by an independent statistician. For comparisons between test and control implant groups, Mann-Whitney U test was used for all continuous variables, Mantel-Haenszel X2 test for all ordered categorical variables, and Fisher exact test for dichotomous variables. Loss of implants was analyzed by

survival analysis. Loading time was analyzed by using Mann-Whitney U test and presented as a cumulative distribution curve.

A weighted average of ISQ during the period of baseline to 6 months was obtained by mean area under the curve (AUC) calculations using the trapezoid rule. The mean AUC was calculated for the time the implant was in function. For implants lost to follow-up, last-observation-carried-forward was used in the mean AUC calculations. The statistical analyses were performed on the entire study population as well as the subgroup of patients with loading time of 6 ± 1 weeks. A significance level of 95% was adopted.

Results

Patients

Seventy-seven (n = 77) adult patients eligible for the Baha system were consecutively included in the study. The distribution of patients per site is shown in Table 1. Surgery was performed between April 23 and December 18, 2009. Of all patients, 52 patients received the test implant and 25 patients received the control implant. Demographics and baseline characteristics per treatment group are summarized in Table 2. There was no statistically significant difference between groups in baseline characteristics. The indication for Baha included conductive or mixed hearing loss and single-sided sensorineural deafness.

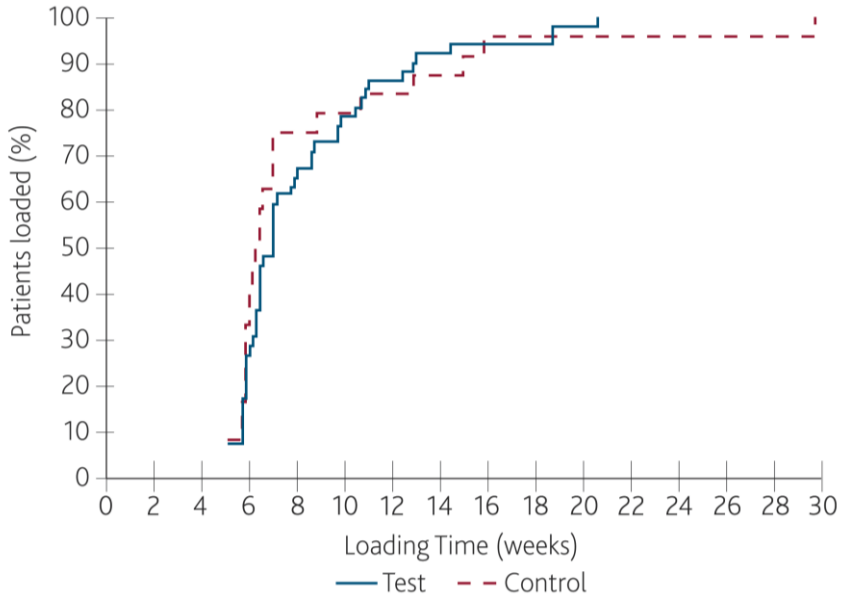

Figure 2. Distribution of loading times for the test (blue line) and control (red line) implant groups.

All patients were analyzed in the group they were randomized into, and all patients received postoperative Baha care as per routine procedures at the hospitals. Adverse events were defined as any undesirable clinical occurrence in a patient whether it was considered device related or not; these were equally divided between both groups.

Loading Time

The distribution of loading times is shown in Figure 2. The mean loading time was 8.26 and 8.48 weeks for the test and control implants, respectively.

Of all patients, 49 patients (63.6%, 31 test and 18 control) received the sound processor 6 $\pm$ 1 weeks after implantation. The remaining patients received the sound processor after 7 weeks or later. Loading outside the 6-week visit window was due to logistical reasons at the hospital (n = 25) or incomplete skin healing (n = 2). One patient (control implant) was withdrawn from the study 10 days after surgery owing to incorrect inclusion because less than 4-mm bone thickness at the implant site was detected at the time of implantation. All other patients were followed up for the complete 6-month study period.

Table 2. Demographics and baseline characteristics

Variable	Test (n = 52)	Control (n = 25)	*P*
Sex, n (%)			
Male	23 (44.2)	15 (60.0)	
female	29 (55.8)	10 (40.0)	0.2925
Age, mean (SD), yr	55.5 (13.8)	61.7 (13.5)	0.0701
Smoking at baseline, n (%)			
No	46 (88.5)	22 (88.0)	
Yes	6 (11.5)	3 (12.0)	1.0000
Indication for Baha, n (%)			
Conductive	14 (26.9)	7 (28.0)	
Mixed	20 (38.5)	13 (52.0)	
SSD	17 (32.7)	4 (16.0)	
Other	1 (1.9)	1 (4.0)	0.4110

SSD indicates single sided deafness

Implant Stability

Mean AUC calculations for ISQ values during the period of 0 to 6 months showed higher values for test compared with control implants. The difference was statistically significant ($p < 0.0001$) for both ISQ High and ISQ Low values. Calculations based on the whole study population (irrespective of loading time) gave similar results as when only patients with loading time of 6 $\pm$ 1 weeks were accounted for. Results from mean AUC calculations are presented in Table 3.

Table 3. Results of mean AUC for ISQ values between baseline and 6 months.

Variable	Test, mean (SD)	Control mean (SD)	*P*
ISQ High, all patients	70.4 (2.1)	65.4 (4.8)	<0.0001
ISQ High, patients loaded at 6 $\pm$ 1 wk	69.9 (2.0)	65.9 (2.7)	<0.0001
ISQ Low, all patients	68.3 (2.6)	62.7 (5.3)	<0.0001
ISQ Low, patients loaded at 6 $\pm$ 1 wk	67.7 (2.7)	63.1 (4.0)	<0.0001

The results presented at continuation refer to the ISQ High values. Mean ISQ Low values per time point were generally 2 to 3 ISQ units lower than the ISQ High values, but comparisons between treatment groups were in line with results obtained for statistical comparisons for ISQ High.

Analysis of ISQ values per visit showed significantly higher ISQ values for test implants at all time points throughout the 6-month follow-up period. Graphical representations of ISQ values over time show comparable outcomes for patients with loading time of 6 $\pm$ 1 weeks (Figure 3A) compared with all patients in the study (Figure 3B).

Assessment of the change in ISQ during the early healing period after baseline showed a statistically significant decrease in stability from baseline to the next follow-up visit 10 days later for both implant types. The initial change in stability between the 2 initial visits was -1.69 ($p = 0.0232$) and -2.44 ($p = 0.0104$) ISQ units for the test and control implants, respectively (all patients included in the calculation). Investigation of the difference between measured and interpolated ISQ values during early healing (interpolation between baseline and 6 weeks of follow-up) revealed a tendency to a larger dip for control compared with test implants ($p = 0.0795$).

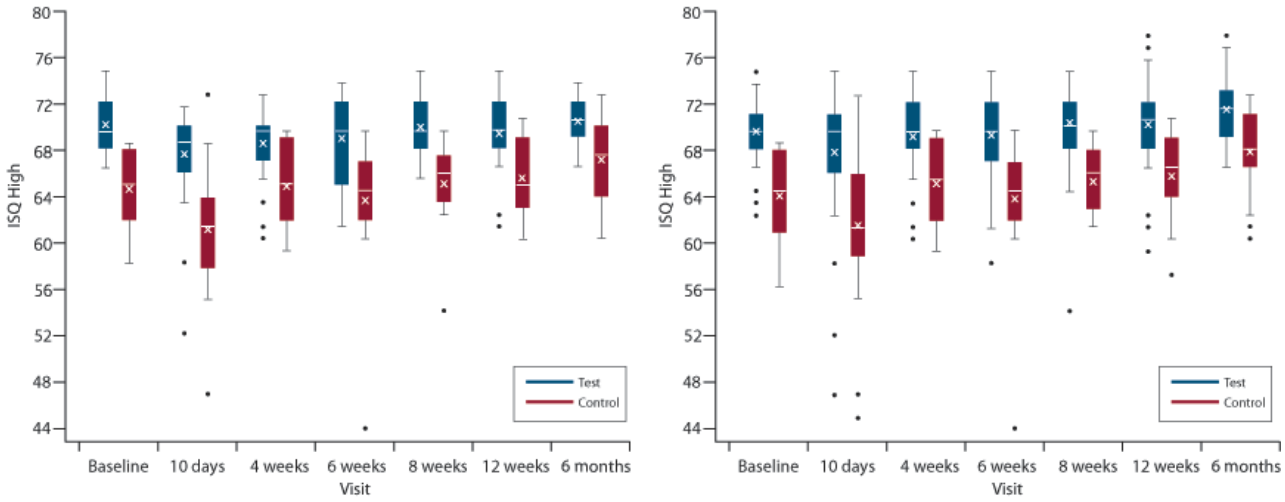

Figure 3. Implant stability quotient by visit for the test (blue line) and control (red line) implant group as represented by line plots of mean ISQ and 95% confidence interval of mean: (A) patients loaded at 6 ± 1 weeks; (B) all patients.

The initial dip was followed by gradually increasing ISQ values for both test and control implants. A comparison of ISQ values recorded at baseline (implant insertion) for the test implants with ISQ values recorded after 6 months for the control implant shows that the test implant provides an initial stability that is higher than the level of stability reached after 6 months of osseointegration for the control implant for all patients and for patients loaded at 6 ± 1 weeks ($p < 0.05$).

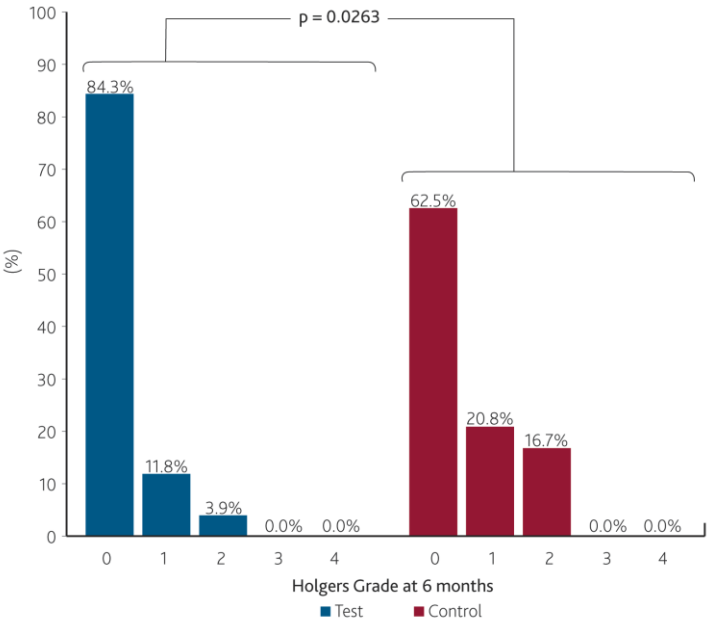

Figure 4. Soft tissue status as measured by Holgers' index at the 6-month follow-up visit, presented as percentage of patients in the test and control implant groups. A comparison between the groups shows statistically significantly improved soft tissue outcomes with the test abutment/implant ($p = 0.0263$). Holgers Grade 0 signifies normal skin; Holgers Grade 1, slight redness; and Holgers Grade 2, red and slightly moist tissue.

Evaluation of stability changes as a result of implant loading showed no reduction in ISQ values after sound processor fitting for both the test and control implants, for all patients, and for patients loaded at 6 ± 1 weeks.

Implant Survival

One implant failure was reported (test implant), giving a cumulative survival rate of 98.1% after 6 months for the test implant and 100% for the control implant. There was no implant loss in the group of patients loaded within the 6-week visit window. The implant loss occurred in a 67.9-year-old man at the time of initial fitting of the sound processor 8 weeks after implant surgery. The patient was under medication for myocardial infarction and Type 2 diabetes mellitus.

Soft Tissue Reactions

Most observations of soft tissue status showed no irritation (Holgers Grade 0) or slight redness (Holgers Grade 1). Red and slightly moist tissue (Holgers Grade 2) was observed incidentally, and no reports of local reactions corresponding to Holgers Grade 3 or higher were reported (Table 4). Up to 12 weeks, rates were comparable for both test and control implants. However, at the 6-month follow-up visit, local reactions (Holgers Grades 1 and 2) were observed significantly more often for control implants ($p = 0.0263$) (Figure 4).

Discussion

The new Cochlear Baha BI300 implant was designed specifically to enhance the implant stability at the time of implantation and over time. For this purpose, it combines a wider implant diameter, small-sized threads, and a moderately rough implant surface. Six-month RFA data gathered in the present multicenter investigation confirms results obtained from earlier preclinical studies[29,30], namely, that the new (test) implant is more stable than the previous-generation (control) implant. Significantly higher ISQ values were recorded for the new implant at all time points from baseline implantation to 6 months of follow-up.

Table 4. Local reactions by visit.

	10 d		4 wk		6 wk		8 wk		12 wk		6 mo	
Holgers grade	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control	Test	Control
0 No Irritation, %	82.7	68.0	60.9	70.8	70.2	77.3	68.8	81.8	74.5	90.5	84.3	62.5
1 Slight redness, %	17.3	28.0	34.8	16.7	25.5	13.6	31.3	9.1	23.4	4.8	11.8	20.8
2 Red and slightly moist tissue, %	0	4.0	4.3	12.5	4.3	9.1	0	9.1	2.1	4.8	3.9	16.7
3 Reddish and moist, %	0	0	0	0	0	0	0	0	0	0	0	0
4 Infection requiring removal of abutment or implant, %	0	0	0	0	0	0	0	0	0	0	0	0
p	0.1105		1.0000		1.0000		0.8126		0.4303		0.0263	

The higher ISQ values obtained at the time of implantation may be ascribed to the wider implant diameter.[18] A statistically significant reduction in stability during the first 10 days after implant insertion was observed for both implant types. The level of stability recorded at baseline was regained already after 4 weeks for both implant types. The initial temporary dip in stability has been reported previously for dental implants[38,39] and has been associated with biologic changes during early bone healing, including bone relaxation after compression and bone resorption, which is a part of the natural bone remodeling process triggered by the trauma to the bone. As bone healing proceeds, bone formation and maturation dominates the bone remodeling, and increasing stability may be expected.[40] In the present investigation, the initial decrease in ISQ values was slightly less pronounced for the test implant, which may be a result of enhanced osseointegration of the TiOblast surface compared with the as-machined surface of the control implant. Improvement of the secondary stability during the early healing phase as a result of implant surface modifications has been reported in the dental literature.[18,19,22] Almost all commercially available dental implants incorporate a topographically modified surface, which, together with good primary stability, has been identified as a prerequisite for successful use of early loading protocols.[20] Successful use of surface-modified implants in cases with suboptimal bone has also been reported.[41-43]

In the present investigation, the Baha sound processor was connected to the abutment from 6 weeks after implantation. No deterioration in implant stability was observed after loading neither for the entire study population nor for the 63.6% of patients loaded at 6 $\pm$ 1 weeks. This result suggests that, for both test and control implants, the level of osseointegration reached as early as 6 weeks after implantation is adequate to support the Baha sound processor in healthy adults with good bone quality. Given the comparable ISQ values reached at 4 and 6 weeks from baseline, sound processor application 4 weeks after implant insertion can be expected to be successful. Moreover, given the overall higher stability of the test implant throughout the early osseointegration period, it is anticipated that an even earlier application of the sound processor may be a safe treatment alternative that merits further investigation.

The survival rates obtained for the test (98.1%) and control (100%) implants compare positively with survival rates reported in the literature.[2,3,34,36] In the single patient in this study who lost the implant, the ISQ values measured at baseline and at 10 days and 4 weeks were not significantly different compared with group data. Unfortunately, ISQ recordings from the follow-up visit preceding implant failure were not collected. It is, however, interesting to note that the single implant

failure occurred in a patient with Type 2 diabetes mellitus using both insulin and oral medication. The effect of diabetes and levels of glycemic control in Baha implant therapy are unknown and should be an area of further study.

From the literature, it is known that Baha surgery is generally safe, and Baha-related complications mainly concern mild to moderate skin reactions around the abutment site.[2,3,9,34,44] The classification of skin reactions using Holgers index showed during the first 3 months overall similar scores for the 2 implant types, whereas at 6 months, significantly less skin reactions were reported for the test implant. The improved soft tissue outcomes at 6 months suggest that the rounded shape of the test abutment may have a positive effect on the stabilization of the peri-implant soft tissue, which is thought to be a key parameter for good soft tissue health.

Conclusion

The new Cochlear Baha implant design provides higher stability as measured by RFA at the time of implant insertion and during 6 months of follow-up compared with the previous-generation Baha implant. No decrease in ISQ values was observed after implant loading, suggesting that the implants can be safely loaded 6 weeks after implant insertion in healthy adult patients.

Although the present investigation was limited to adult patients with good bone quality, it is anticipated that the enhanced stability achieved with the new implant design may improve treatment outcomes in patients with compromised bone.

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CHAPTER 4

BILATERAL BCD APPLICATION IN CHILDREN AND YOUNG ADULTS

4.1

BILATERAL BONE-ANCHORED HEARING AID APPLICATION IN CHILDREN: THE NIJMEGEN EXPERIENCE FROM 1996 TO 2008

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Abstract

Objective: This study presents clinical data and quality of life questionnaire outcomes in children and young adults with bilateral Bone-Anhored Hearing Aids (Bahas)

Study Design: Retrospective review.

Setting: Tertiary care referral center.

Patients: Eligible study subjects comprised 27 patients with bilateral conductive hearing loss fitted with bilateral Bahas in childhood or as young adults at the Radboud University Nijmegen Medical Centre between June 1996 and October 2008.

Methods: Questionnaires comprised the “Daily use of bilateral Bahas” questionnaire, the Glasgow Children’s Benefit Inventory and the Speech Spatial and Qualities of Hearing scale modified for children.

Results: A total of 23 children were selected to fill out the postal questionnaires; 21 (91%) of them responded. In 90%, both BAHAs were being used 7 days a week. One child was using 1 Baha but not the other, and one child was only using both BAHAs at school. Nine children reported that they switched off both BAHAs when the background became too noisy. Bilateral BAHAs provided better hearing quality according to 70%. The Glasgow Children’s Benefit Inventory demonstrated subjective overall benefit of +38 (n = 20). The spatial domain of the Speech, Spatial and Qualities of hearing Scale showed a trend towards better spatial hearing with decreasing age at bilateral application.

Conclusion: Bilateral percutaneous BAHAs can be applied simultaneously from the age of 4 years, after a successful trial period with the BAHA Softband or other equivalent hearing aids. Bilateral BAHAs showed clear benefit in the vast majority. Outcomes of bilateral audiological testing are needed in the near future.

Introduction

In 1981, Tjellström reported on osseointegrated titanium implants in the temporal bone for the application of a bone-conduction hearing aid.[1] This led to the development of the Bone-Anchored Hearing Aid (BAHA), which has become a well-established form of auditory compensation in patients with severe conductive or mixed hearing loss. Initially, mainly adults were fitted with a BAHA. Since 1992, a number of reports have been published on BAHA treatment in children.[2,3] Surgical and audiologic evaluations of children showed that the system forms an effective auditory compensation device in children. In most of the studies, the BAHA had been applied monaurally. Fairly recently, it has been reported that bilateral BAHA application in adults was of subjective and objective benefit, the latter particularly as a means to achieve binaural hearing.[4-10]

Contrary to bilateral Baha application in adults, only very small incidental series of children have been described with bilateral BAHAs. These studies aimed either to obtain audiometric data from a total of 6 patients (speech recognition and the localization of sound)[6,8,11] or to evaluate quality of life aspects and benefit related to bilateral BAHA treatment in 9 patients.[12] It was concluded that adding a second BAHA had beneficial effects on speech perception, localization of sound and quality of life.

In 1998, the Nijmegen BAHA group reported on bilateral BAHA fitting in adults for the first time. Between 1994 and 2006, 27 children aged 16 years or younger received their first BAHA, while their second BAHA was placed between 1996 and 2008. This report presents clinical data and quality of life questionnaire outcomes obtained from this series of children with bilateral BAHAs from Nijmegen.

Patients and Methods

Patients

Evaluations were performed on 27 patients (14 boys and 13 girls) fitted with bilateral Bahas in childhood or adolescence at the Radboud University Nijmegen Medical Centre between June 1996 and October 2008. This group comprised all patients who had been fitted with bilateral BAHAs before the age of 16 years and all patients who had been fitted with 1 BAHA before the age of 16 years and received their second BAHA later on. All patients in this group are further referred to as children for comprehensive reasons. The evaluations included the cause of the hearing loss, BAHA indication, pure-tone thresholds, previous hearing aid

experience and subjective opinions about the BAHA. Audiogram data collected before BAHA fitting were used to evaluate the pure-tone thresholds. Mean age of this group at the time of evaluation was 14.7 years (range 5.9 – 28.7 years).

Methods

A total of 23 out of the 27 eligible children were selected to fill out the postal questionnaires. As we were particularly interested in the opinions of each child without the influence of their parents/carers, the children were asked to fill in the questionnaires themselves. If they really required help, it was made clear to their parents/carers that their child's opinion should form the leading answers to the questions. Four children had to be excluded for the following reasons: 2 children had severe mental retardation (no. 10 with Down's syndrome and no. 7 with Treacher Collins syndrome) and we assumed that they would be unable to understand the questionnaires. Another child (no. 11), living in the Caribbean, had lost one of the implants 2 months after fitting and it had not yet been replaced. One other fairly young child was excluded because her parents did not want her take part at that time. She was the first child worldwide to have used the BAHA Softband and had already participated in several other studies at our center. Detailed data have been published about the outcome of her bilateral BAHA application.[13]

Instruments

Three postal-based questionnaires were used in this study: the 'Daily use of bilateral BAHAs' questionnaire, the Glasgow Children's Benefit Inventory (GCBI) and the second section of the Speech, Spatial and Qualities of Hearing Scale (SSQ) modified for children.

Appendix A presents the first "Daily use of bilateral BAHAs" questionnaire. Questions 1, 3, 4, 5 and 14 were derived from Chung and Stephens.[14] The other questions enquired about (daily) use of the BAHA system.

Day to day health-related quality of life after an otorhinolaryngologic intervention (surgery or therapy) was measured using the Glasgow Children's Benefit Inventory (GCBI).[15] This validated questionnaire comprised 24 questions that covered 4 domains: emotional benefit, physical health, improvements in learning ability and vitality. Each question can be answered on a 5-point Likert scale ranging from a large change from the worst to a large change for the better. A summary score was calculated from the individual question scores. This score was then divided by the number of questions (24 questions) and multiplied by 50

to produce a score of between -100 (maximum deterioration) and +100 (maximum improvement).

To measure binaural functioning and to indentify the advantages, the Speech, Spatial and Qualities of hearing scale (SSQ) was developed by Gatehouse and Noble.[16] The SSQ was modified for children by Karyn Galvin (The Bionic Ear Intitute, Australia) and translated into Dutch by Liesbeth Royackers (Labo Exp. ORL., Belgium). It was used in a previous study by Kunst et al.[17] This questionnaire evaluates hearing abilities across 3 domains: speech perception, spatial hearing and other qualities. In the present study, we only used the spatial hearing section of the questionnaire, because we were primarily interested in spatial hearing abilities with bilateral BAHAs. The spatial hearing section of the SSQ comprises 13 items that address three different components of spatial hearing (direction, distance and movement). Each item is scored using a ruler (equivalent to a visual analogue scale) score marked from 0 to 10, where 0 always represents minimal ability, whereas 10 represents complete ability. Besides the ruler, one of 3 answer options could be selected if the situation was not applicable: “I wouldn’t be able to hear the sound”, “I don’t know”, “does not apply to me”. Whereas the GCBI monitors changes over time, the SSQ and the “Daily use of bilateral BAHAs” questionnaire assess the present status.

Analysis

The analyses were carried out using the Mann-Whitney *U* test in SPSS version 16 (SPSS, Inc., Chicago, USA). A *p* value of less than 0.05 was chosen as the level of significance in a 2-tailed test.

Results

Patient characteristics

All the 27 children had bilateral conductive or mixed hearing loss because of either bilateral congenital ear canal atresia (cong) (n=18) or acquired ear diseases (acq) (n=9). One child had congenital ear canal atresia on one side and a congenital ossicular chain anomaly on the other. Six children had a congenital syndrome; Treacher Collins (TC) was the most frequent (n=3). In the 3 children with TC and in the child with the Oculo-Auriculo-Vertebral syndrome, the hearing loss was of congenital origin. Congenital ear canal atresia was defined according to the Altmann-Cremers classification.[18] Acquired ear diseases were chronic otitis media (COM) without cholesteatoma (n=4), bilateral cholesteatoma (n=1), and

combined problems of COM on one side and cholesteatoma on the other (n=2). Pure–tone average air-conduction thresholds at 0.5, 1, 2, and 4 kHz at the time of BAHA fitting varied from 41 to 81 dB hearing level (HL) (mean, 61 dB HL) in the left ear and from 35 to 96 dB HL (mean, 59 dB HL) in the right ear. Pure-tone average bone-conduction thresholds at the same frequencies varied from 0 to 32 dB HL (mean, 12 dB HL) in the left ear and from 0 to 31 dB HL (mean, 10 dB HL) in the right ear. An overview of the patient characteristics is presented in Table 1.
Two children with congenital ear anomalies (nos. 4 and 6) had undergone reconstructive ear surgery before BAHA fitting. In patient no. 4, the congenital ossicular chain anomaly in the left ear had been corrected by stapedotomy, but the stapes prosthesis was lost, and revision surgery was contraindicated because of the high risk of inner ear damage. Patient 6 underwent unilateral correction of the ear canal atresias. However, owing to problems of otorrhea after surgery and no improvement in the pure-tone average air-conduction threshold, the atresia was reconstructed at the time of BAHA implantation.

All the children had been using various types of hearing aid before BAHA fitting. Table 2 presents the previous hearing device and data on the timing of BAHA fitting. In the group of 9 children with acquired hearing loss (acq), the first hearing aid had mostly comprised a conventional air-conduction hearing device (n=7); 2 patients had been fitted with a conventional bone-conduction hearing aid. Age at first hearing aid fitting ranged from 34 to 87 months (mean, 64 mo).
In the group of 18 children with congenital hearing loss (cong), the previous device had mostly comprised a conventional bone-conduction hearing aid (n=11). In 4 cases, a BAHA had been attached to a steel or soft headband. The remaining 3 of children had been fitted with a conventional air-conduction hearing aid. Age at first hearing aid fitting ranged from 0 to 62 months (mean, 16 mo) in the congenital hearing loss group. Nine children had been fitted before the age of 6 months, 3 children had been fitted before the age of 12 months and 6 children had been fitted after the age of 12 months. Patients 9, 12, 20, 24, and 25 had been fitted with a hearing aid at an older age of between 19 and 62 months. All these children had congenital ear canal atresia type IIA, with normal shaped auricles. In 4 of these 5 children, the ear canal atresia had been diagnosed either after a delay in language development or during a transtympanic drainage procedure. Patient 4 had unilateral ear canal atresia and at the age of 5 years, it had become clear that there was 50 dB hearing loss in what was earlier thought to be the ear with ‘normal hearing’. Stapedotomy was performed on the basis of this finding but, as previously mentioned, was unsuccessful.

Table 1. Characteristics of 27 patients fitted with bilateral bone anchored hearing aids

					PTA 0.5, 1, 2 and 4 (dB)			
					Left		Right	
No.	Sex	Type of hearing loss	Cause of hearing loss	Syndrome	AC	BC	AC	BC
1	Male	Cong	Atresia Type III		73	16	56	16
2	Female	Cong	Atresia Type III		66	14	69	9
3	Female	Acq	Cholesteatoma		45	9	46	3
4	Female	Cong	AD Atresia Type IIB AS Cong ossicular chain anomaly		58	16	54	8
5	Male	Acq	AD COM AS Cholesteatoma		71	21	66	26
6	Male	Cong	Atresia Type IIB		60	9	59	9
7	Female	Cong	Atresia Type	Treacher Collins	81	23	96	25
8	Female	Acq	COM	Leonard	70	26	69	24
9	Female	Cong	Atresia Type IIA		61	10	71	5
10	Male	Acq	COM	Down	79	15	71	15
11	Male	Cong	Atresia TypeIII		79	11	75	14
12	Male	Cong	Atresia Type III	Treacher Collins	68	8	69	8
13	Male	Cong	Atresia Type III		66	5	58	8
14	Female	Cong	Atresia Type III	Treacher Collins	66	8	59	8
15	Male	Acq	AD COM AS Cholesteatoma		55	4	55	4
16	Male	Acq	COM		51	25	41	23
17	Male	Cong	Atresia Type IIA		55	6	61	6
18	Female	Acq	COM		56	11	55	6
19	Male	Cong	Atresia Type IIB		64	0	49	0
20	Male	Cong	Atresia Type IIA		45	5	44	5
21	Female	Cong	Atresia Type IIB		59	6	59	3
22	Female	Acq	COM		44	6	35	5
23	Female	Cong	Atresia Type IIB		46	10	56	3
24	Female	Cong	Atresia Type IIA		41	3	43	4
25	Male	Cong	Atresia Type IIA		63	NA	63	NA
26	Female	Acq	COM		66	33	70	31
27	Male	Cong	Atresia Type IIB	OAVS	51	6	56	1

AC indicates air conduction; Acq, acquired hearing loss; AD, right ear; AS, left ear; BC, bone conduction; COM, chronic otitis media; Cong, congenital hearing loss; NA, not available; OAVS, Oculo Auriculo Vertebral Spectrum; PTA, pure-tone average thresholds at the frequencies 0.5, 1, 2 and 4 kHz AC and BC; TC, Treacher Collins.

Table 2. Previous hearing device and timing of bilateral bone-anchored hearing aid fitting

No.	Year of birth	Type of first hearing aid	Age (yr;mo) at time of first HA fitting	Age (yr;mo) at time of binaural hearing	Age (yr;mo) at first BAHA percutaneous screw fitting	Age (yr;mo) at second Baha percutaneous screw fitting	Time (mo) between first and second percutaneous screw fitting	Time (mo) between first HA and second percutaneous screw fitting
Congenital								
1	1980	CBHA	1;0	24;3	16;2	24;1	95	276
2	1981	CBHA	0;4	14;8	12;5	14;6	24	169
4	1984	ACHA	5;0	11;8	14;3	18;3	47	159
6	1986	CBHA	0;1	12;4	9;0	11;7	30	137
7	1990	CBHA	0;9	11;8	9;5	11;2	20	125
9	1993	ACHA	1;10	1;10	5;10	8;4	30	78
11	1994	CBHA	0;6	-	14;4	14;4	0	166
12	1995	CBHA	0;3	7;6	7;3	7;3	0	84
13	1996	CBHA	0;6	12;7	12;4	12;4	0	142
14	1996	CBHA	0;4	2;8	5;3	6;8	17	75
17	1998	BCHA	1;7	6;8	6;4	6;4	0	60
19	1999	BCHA	0;2	7;1	6;10	6;10	0	80
20	2000	BAHA Soft	5;2	6;3	5;7	5;7	0	4
21	2000	BCHA	0;9	2;7	6;7	6;7	0	70
23	2001	BAHA Soft	0;3	1;11	3;7	3;7	0	39
24	2001	BAHA Steel	2;11	5;5	5;2	5;2	0	26
25	2002	ACHA	2;0	2;0	3;7	3;7	0	19
27	2003	BAHA Soft	0;2	5;7	5;3	5;3	0	60
Acquired								
3	1983	ACHA	6;0	0;0	14;7	18;8	49	152
5	1986	ACHA	6;4	0;0	15;4	20;10	65	173
8	1991	ACHA	4;7	0;0	15;10	15;10	0	134
10	1993	ACHA	6;0	0;0	10;10	13;1	27	85
15	1996	ACHA	7;3	0;0	10;5	11;1	7	45
16	1997	ACHA	5;5	0;0	10;7	10;7	0	61
18	1999	BCHA	4;2	0;0	7;3	7;3	0	37
22	2000	BCHA	5;4	0;0	8;0	8;0	0	32
26	2003	ACHA	2;10	0;0	5;1	5;1	0	26

Age at time of binaural hearing (with bilateral ACHA of bilateral BAHAs). ACHA indicates air-conduction hearing aid; BAHA, bone-anchored hearing aid; BCHA, bone-conduction hearing aid; HA, hearing aid.

In the 18 children with congenital hearing loss, binaural hearing had been achieved at the age of between 1 year 10 months and 12 years 1 month either with 2 conventional (air conduction or bone conduction) hearing aids or with two BAHAs on a steel headband, a softband or on percutaneous screws. Categorization into 2 age groups revealed that 8 children had received access to binaural hearing before or at the age of 5 years and 10 children after the age of 5 years.

The interval between the first conventional hearing aid fitting and bilateral percutaneous screw implantation ranged from 4 to 276 months (mean, 64 mo). Mean age in the total group at the time of the first percutaneous screw implantation was 110 months (range, 43-194 mo). In 11 children (4 acq, 7 cong) the contralateral percutaneous screw was implanted 7 to 95 months (mean, 37 mo) after the first. A total of 16 out of the 27 children underwent bilateral implantation in one surgical setting (5 acq, 11 cong). The first child received simultaneous bilateral implants in 2003 (no. 12). Figure 1 illustrates that, in recent years, more bilateral implantations have been performed simultaneously. Mean interval between implantation of a percutaneous screw and BAHA fitting was 4 months (range 1 - 23 mo) (n=26). Different types of BAHA were applied bilaterally: the BAHA Divino in 12 children, the BAHA Compact in 14 children, and the BAHA Intenso in 1 child. In our study group, 1 child (no. 11) lost one of the implants, so bilateral BAHA fitting could not yet be realized.

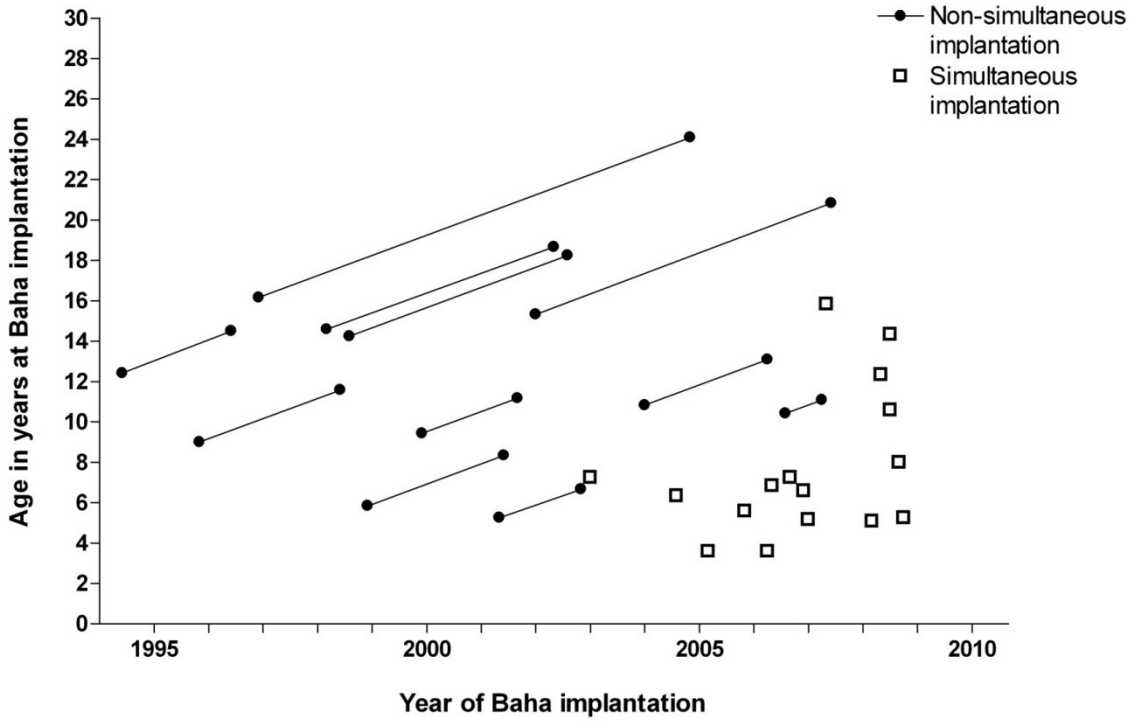

Figure 1. Age of 27 children at first and second BAHA fitting

Questionnaires

A total of 21 (11 boys and 10 girls) of the 23 children responded to the questionnaires (response rate, 91%). The nonresponders were contacted; both are known to be using both BAHAs on a daily basis. Age at the time of questionnaire completion in the responder group was 15 years 4 months (Standard Ddeviation [SD], 87 mo). Congenital hearing loss was the reason for bilateral BAHA fitting in 14 children and acquired hearing loss in 7 children. Twelve children (4 acq, 8 cong) received bilateral implants in 1 sitting, whereas 9 children (3 acq, 6 cong) underwent nonsimultaneous implantation. One child (no. 5) reported that he was using only one of his 2 BAHAs, because he could not get used to the sound of the 2 together. He was using 1 BAHA on alternating sides. Since our recent contact with him, he has successfully restarted using the 2 BAHAs simultaneously. However, as this child had been using both BAHAs for only a few weeks, his data were excluded from the further questionnaire evaluation. The final evaluation therefore encompassed 20 children.

The "Daily use of bilateral BAHAs" questionnaire

All the responders (n=20) were satisfied to very satisfied with their bilateral BAHAs. The majority reported that the BAHAs are worth the effort or very much worth the effort (95%). The BAHAs were being used 7 days a week by 90% (n=18) of the children. One child only used the BAHAs at school, 5 days a week, for 4 to 8 hours a day. Another child only used the BAHAs 6 days a week, for 8 to 12 hours a day.

Sixteen children reported specific situations in which both BAHAs were taken off or switched off. Mostly, these situations were "noise" or a "noisy background" (n=9). The types of BAHA being used by these 9 children were the BAHA Compact (n=3) and the BAHA Divino (n=6). In addition, switching off both BAHAs was related to BAHA device restrictions: taking a shower, swimming or rough physical activity. Situations in which specifically 1 BAHA was used were also reported by 10 of these 16 children: twice because of "noise" and three times because of infected skin around the abutment. Other separate situations were: listening to people sitting on one side, making a telephone call, resting on one side of the head, during the night to hear the baby cry, and being on holiday.

Differences in hearing qualities when only 1 BAHA could be used were reported by 14 children (70%), whereas 3 children did not experience any difference, and 3 children could not or did not answer this question. In 3 cases, the difference in hearing qualities was explained as having trouble defining the direction the sound was coming from, whereas in 11 children, the explanation was a combination of

having trouble defining the direction of the sound and having trouble with understanding people against a noisy background.

Differences in sound qualities between using 1 BAHA or 2 BAHAs were reported by 14 children (Questions 12 and 13). In 12 cases, this comprised one step of deterioration on the 5-point scale, for example, from very good sound with 2 BAHAs, to good sound with 1 BAHA. One child reported 2 steps of deterioration and 1 child reported 3 steps of deterioration. Contrastingly, 1 child reported 1 step of improvement and gave a written explanation for his answer: he noted that his BAHAs did not seem to be adjusted properly.

In answer to the question about recommending bilateral BAHAs to a peer, 18 of the 20 children said that they would, whereas 2 children said "don't know" although they were very satisfied with their BAHAs and their parents would pay for the BAHAs themselves if the intervention was not covered by health insurance. A total of 13 of the 20 parents/carers would be willing to pay for the BAHAs if that was necessary.

The Glasgow Children's Benefit Inventory

The GCBI demonstrated subjective overall benefit of +38 (SD 18.2) (n=20). Viewed per domain, learning showed the most positive change, with a mean score of +56 (SD 25.4). The emotion, physical and vitality domains scored +45 (SD 24.4), +17 (SD12.5) and +32 (SD 18.1), respectively. None of the children reported deterioration. There were no significant differences in the GCBI results between acquired hearing loss and congenital hearing loss or between non-simultaneous implantation and simultaneous implantation. The results are shown in figure 2 and table 3.

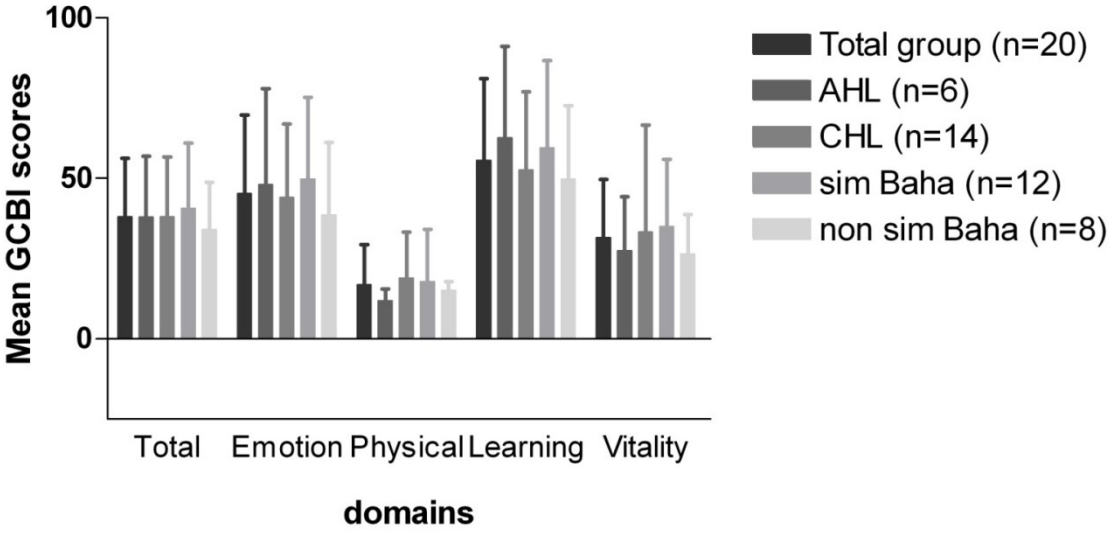

Figure 2. Total GCBI scores and scores per domain in the total group and subgroups

Table 3. Total Glasgow Children's Benefit Inventory scores and scores per domain

	Patients	Total	Emotion	Physical	Learning	Vitality
Present study	15 children, congenital and acquired bilateral conductive hearing loss, bilateral BAHA fitting	+38	+45	+17	+56	+32
Kunst et al, 2008[17]	10 children, congenital unilateral conductive hearing loss, unilateral BAHA fitting	+34	+31	+29	+60	+12
McDermott et al., 2009[12]	84 children, hearing loss NS, unilateral BAHA fitting	+52	+50	+30	+65	+40
Kunst et al., 2007[24]	22 adults and children with mental retardation, hearing loss NS, Unilateral BAHA fitting	+30	+25	+30	+33	+20

Present study and literature data from earlier GCBI studies. Scores per domain could range from -100 (maximum deterioration) to + 100 (maximum benefit). BAHA indicates bone-anchored hearing aid: NS, not specified

The Speech, Spatial and Qualities of hearing scale

All the children (n=20) filled out the SSQ questionnaire. However, 5 of them had experienced difficulties understanding the situations described in the items and had frequently chosen the 'don't know' or 'I wouldn't hear the sound' answer option. Their age ranged from 6 to 13 years. In the case of 'I wouldn't hear the sound' or 'don't know', no score was given on the ruler, so it was not possible to compute a mean score in these children. Therefore, their results were excluded from the further SSQ evaluation.

The mean SSQ score in the remaining group (n=15) was 5.8 (SD 1.7) on a scale from 0 to 10. The results are presented in table 4. To investigate whether the qualities of spatial hearing were related to the cause of the hearing loss, or to the age at which the children had been fitted bilaterally, we compared the mean SSQ scores between these subgroups. The children with acquired hearing loss (n=2) had a mean score of 7.0 (SD 1.09), whereas the children with congenital hearing loss (n=13) had a mean score of 5.6 (SD 1.71). This difference was not statistically significant. The subgroup of children who had been fitted bilaterally before the age of 5 years (n=7) and the subgroup fitted after the age of 5 years (n=8) had mean scores of 6.4 (SD 0.99) and 5.2 (SD, 2.00), respectively. This difference was not statistically significant.

Table 4. Speech, spatial and qualities of hearing scale results, mean values, and standard deviations on the spatial domain of the questionnaire

	Patients	Unaided	Aided
Present study	15 children, congenital and acquired bilateral conductive hearing loss, bilateral BAHA fitting	NA	5.8 (1.7)
Kunst et al., 2008[17]	10 children, congenital unilateral conductive hearing loss, unilateral BAHA fitting	NA	5.6 (2.5)
Kunst et al., 2008[17]	6 adults, congenital unilateral conductive hearing loss, unilateral BAHA fitting	4.5 (2.4)	6.8 (1.2)
Noble and Gatehouse, 2004[25]	50 adults, asymmetrical hearing loss NS, no hearing aid fitting	4.8	NA

Present study and literature data from earlier studies on children and adults with acquired unilateral conductive hearing loss either unaided of aided with a unilateral BAHA. BAHA indicates bone-anchored hearing aid; NA, not available; NS, not specified

Discussion

This study presents clinical data and quality of life questionnaire outcomes in children with bilateral BAHAs. Only incidental reports have appeared in the literature on limited groups of children with bilateral BAHAs. Our study group comprised 27 children, of whom 18 had congenital hearing loss and 9 had acquired conductive hearing loss. Age ranged from 6 to 28 years at the time of evaluation.

In children with bilateral hearing loss, it is recommended that interventions to enable hearing should start within the first few months of life.[19,20]. In 2003, Yoshinaga-Itano[20] reported that the results of language tests were significantly better at the age of 3 to 4 years in children who had received hearing aids before the age of 6 months than in children who had been fitted later in life. In our study group, only 9 out of the 18 children with bilateral ear canal atresia had been provided with any type of hearing device before the age of 6 months. Three out of the 18 children had been provided with a hearing aid after the age of 6 months, but before the age of 12 months. This can be explained by awareness of ear canal atresias in combination with visible deformities of the auricles (atresia types IIB and III), which were present in all these 12 children. The remaining 6 children had been fitted with their first hearing aid later on at an age of between 19 and 62 months; 5 of them had bilateral atresia type IIA, that is with normal auricles. Up to 2002, the Ewing test was used to screen the hearing of children at an age of between 9 and 13 months. Since 2006, a national hearing screening program for newborns has been in operation in the Netherlands. This program can detect newborns with hearing loss (REF OAE Screening). Nowadays, this program can

identify congenital hearing loss at the age of 2 weeks in children with normal auricles and they can be referred for treatment at a very young age. This means that treatment to enable optimal hearing and communication can be provided to all hearing impaired children at a very young age.

A closer look at our children with bilateral aural atresia showed wide variation in the age at which they gained access to bilateral hearing with 2 hearing aids, namely from 1 year 10 months to 12 years 1 month. Age at access to bilateral hearing is of importance because hearing with 2 ears has several advantages compared with hearing with only 1 ear. Besides the amplification of sounds through stimulation of both ears, the arrival of sounds at both cochleae makes it possible to locate sounds and to understand speech in noise (so-called binaural hearing tasks). It has often been argued that the bilateral application of any bone-conduction device may not be effective because the intracranial attenuation of cranium vibrations is so small that even 1 bone-conduction device will stimulate both cochleae. Nevertheless, several studies in adults fitted with BAHAs showed improvement in binaural hearing tasks.[7,8]

Little is known about whether binaural hearing abilities are acquired early in childhood or whether they take longer to develop. Northern and Downs[21] described that the ability to locate sound sources is an age-related maturation process in children with normal hearing from birth to 24 months of age. Van Deun et al.[22] studied binaural tasks in young children of between 4 and 6 years of age with normal hearing. They found that, on several localization tasks, the performance of the 5-year-old children did not differ significantly from that of the adults. However, the 4-year-old children differed significantly from the adults. They concluded that these age effects might be related not only to nonauditory factors (i.e., comprehension and attention) but also to the maturation of binaural hearing skills. This is of interest because if binaural hearing abilities do indeed take some years to mature, it might be beneficial to fit bilateral hearing aids to children with congenital hearing loss early in life, at least before the age of 4 years.

Our retrospective evaluation on 27 children showed a clear trend toward bilateral BAHA implantation at a younger age in recent years. This applied to children with acquired hearing loss and to those with congenital hearing loss. Bilateral percutaneous BAHA implantation is sometimes started even before the age of 4 years, depending on the timing of referral and the child's development in combination with the parents' opinion. Early bilateral hearing aid application is possible nowadays with the BAHA Softband.

Audiometric data and outcomes of quality of life studies have shown the benefit of bilateral BAHA application in adults.[4-7;9;10;23] In the literature, very little is known about the subjective benefit of bilateral BAHAs in children. To evaluate the children's opinions and to measure the benefit of their bilateral BAHA application, three questionnaires were used in our study.

The "Daily use of bilateral Bahas" questionnaire showed clearly that the bilateral BAHAs were mostly being used 7 days a week, for more than 12 hours a day. All the children were satisfied to very satisfied with their BAHAs; they reported that the BAHAs are worth the effort and most of them would recommend bilateral BAHAs to a peer. Noise or noisy backgrounds were the most frequently reported situations in which the children switched off both their BAHAs. Sounds of above 60 to 70 dB might be distorted, owing to the limited maximum output of the bone-conduction device. Noise or noisy backgrounds formed the reason to switch off 1 BAHA in 2 cases. Comparable results were reported by Priwin et al.[23], who found that adults fitted with bilateral BAHAs sometimes turned off one of the BAHAs in situations with a dominant noise source. They concluded that, depending on the position and character of the noise source, patients could benefit from using 1 instead of 2 BAHAs.

Mean overall benefit on the Glasgow Children's Benefit Inventory (GCBI) questionnaire was +38, with the most prominent benefit in the subdomains emotion and learning. This is in accordance with earlier GCBI questionnaire studies that evaluated the benefit of unilateral BAHA fitting in patients with unilateral or bilateral hearing loss.[17,24] McDermott et al.,[12] found higher mean benefit scores on all the domains in children with bilateral hearing impairment and unilateral BAHA fitting. More than 60% of these Birmingham patients had a syndromic diagnosis, which gives an indication of their multiple impairments that are under care at that children's hospital. Such circumstances might have induced enthusiasm bias (orel communication McDermott, June 2008), which would explain the higher appreciation scores. Nevertheless, the most benefit in that study was also found on the subdomains emotion and learning, which both are domains of great importance in the developing child.

In assessing directional hearing abilities with the spatial part of the SSQ questionnaire in all children fitted with bilateral BAHAs in Nijmegen, certain limitations were encountered. First, the children varied widely by age, hearing aid experience and cognitive abilities, illustrated by the fact that 5 of 20 children had difficulties in understanding the situations described and had to be excluded for further SSQ evaluation. Second, because of the retrospective design of this study, no comparison could be made between spatial hearing before and after bilateral

BAHA fitting. In addition, in the literature no reference SSQ data (e.g., bilateral fitted BAHAs or unilateral fitted BAHA in case of bilateral hearing loss) were available to put our scores in perspective with. Nevertheless, when placed in context with the only 2 available studies on BAHA and SSQ in the literature, the subjective spatial hearing score (5.8 [SD, 1.7]) found in our study with 2 BAHAs (i.e., bilateral hearing) seemed to be somewhat better than in adults with unilateral hearing loss in an unaided condition (i.e., unilateral hearing) (scores, 4.5 [SD 2.4] and 4.8 [SD, not available], respectively).[17,25] Compared to a score of 6.8 (SD, 1.2) in adults with unilateral congenital conductive hearing loss aided with 1 BAHA (i.e., bilateral hearing), the score in the present study was lower. The spatial part of the SSQ questionnaire modified for children was earlier used by Kunst et al.[17] In this study, 10 children with unilateral congenital hearing loss fitted with unilateral BAHA (i.e., bilateral hearing) were evaluated. The score in the spatial domain was 5.6 (SD, 2.5), which was almost similar to the score in the present study group. Despite the mentioned limitations and the lack of statistical analysis, the SSQ data in our study indicate that spatial hearing with bilateral BAHAs is experienced and somewhat better compared with patients with unilateral conductive hearing loss in an unaided situation.

In our general questionnaire, 70% of the children reported difficulties with identifying the direction of sound and understanding people against a noisy background when using only 1 BAHA. We also observed that the SSQ outcomes on the spatial hearing domain were somewhat higher in the children who had received bilateral hearing aids before the age of 5 years than in those who were older at the time of bilateral hearing aid application. Although the difference was not statistically significant, the results were in line with the earlier suggestion that bilateral hearing aid application is of value to the maturation process of binaural hearing and spatial orientation. It might be interesting to focus future audiologic research on the mechanisms of early deprivation of bilateral hearing affecting spatial hearing and speech understanding in silent and standardized noisy situations in later years. Comparing audiologic data between children with bilateral congenital conductive hearing loss fitted with either unilateral BAHA or bilateral BAHAs might provide valuable data on how binaural hearing can be restored. Making this comparison, outcomes of bilateral hearing tests in normal hearing children must be taken into account.

The heterogeneous composition of this group was a direct cause of the previously shown step-by-step extended application of bilateral BAHAs from adolescents to even 4-year-old children. Nevertheless, this study showed clinical evidence that early bilateral BAHA application is appreciated in children who fulfilled the criteria

for BAHA treatment. From this point future additional audiologic research in combination with presubjective and postsubjective evaluation is therefore needed to provide more evidence towards the benefits of early bilateral BAHA application.

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Appendix A

The "Daily use of bilateral BAHAs" questionnaire

1. Are you satisfied with your BAHAs?
    a. very satisfied
    b. satisfied
    c. dissatisfied
    d. very dissatisfied

2. Do you think your BAHAs are worth the effort?
    a. no, not worth the effort
    b. somewhat worth the effort
    c. moderately worth the effort
    d. worth the effort
    e. very much worth the effort

3. Do you wear the two BAHAs:
    a. all the time
    b. most of the time
    c. often (at some time everyday)
    d. never

4. On average, how many hours a day do you use your two BAHAs?
    a. 0
    b. less than 1
    c. 1–4
    d. 4–8
    e. 8–12
    f. more than 12

5. On average, how many days a week do you use your two BAHAs?
    a. 0
    b. 1
    c. 2
    d. 3
    e. 4
    f. 5
    g. 6
    h. 7

6. Are there reasons or are there situations in which you take off or switch off **both your BAHAs**?
    a. yes
    b. no

7. If yes, please describe such reasons or situations:

    ……...

8. Are there reasons or are there situations in which you take off or switch off **one**

BAHA?
a. yes
b. no

9. If yes, please describe such reasons or situations:

……

10. Do noises sound different when one of your BAHAs is not working?
    a. yes
    b. no
    c. don't know

11. If yes, does this mean that you have:
    a. trouble understanding other people against a noisy background
    b. trouble identifying the direction of sound.
    c. both
    d. other, namely…….

12. How would you rate the sound quality of your BAHAs?
    a. very good
    b. good
    c. moderate
    d. poor
    e. very poor

13. Although you have two BAHAs, how do you rate the sound quality when you are only using one of them?
    a. very good
    b. good
    c. moderate
    d. poor
    e. very poor

14. Would you recommend two BAHAs to another child with the same sort of hearing problems as yours?
    a. yes
    b. no
    c. don't know

15. Would you (parent/carer) be prepared to pay the 6000 euro's yourself to have your child fitted with two BAHAs?
    a. yes
    b. no
    c. don't know

4.2

IMPROVED HEARING ABILITY IN CHILDREN AND YOUNG ADULTS FITTED WITH BILATERAL BONE CONDUCTION DEVICES

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Abstract

Objectives: The aim of the study was to investigate the audiological benefit of bilateral percutaneous bone conduction device (BCD) fitting in children and young adults with regard to speech perception in noise and directional hearing.

Design: Three audiological tests were performed in a case series of 15 subjects fitted with bilateral BCDs during childhood or adolescence.

Results: After separation of speech and noise sources in the speech intelligibility level difference test, an improvement in speech understanding was found with bilateral BCDs. This improvement was comparable to that found in normal hearing adults. Left-right discrimination task scores in the minimum audible angle test with broadband noise stimuli were found to be far better with bilateral BCDs compared to unilateral fitting. Poor results were found in the sound localization test with 500 Hz and 3000 Hz stimuli. Possibly, localization is impaired when based on only interaural timing differences or only interaural level differences.

Conclusions: The data demonstrate the audiological benefit of bilateral BCD fitting in children and young adults with bilateral conductive hearing loss.

Introduction

Hearing with two ears has several advantages compared to monaural hearing: (1) improved hearing sensitivity and speech recognition owing to bilateral summation as inputs received by the two cochleae are added together; (2) improved speech recognition in noisy situations when speech and noise sources are spatially separated; and (3) improved directional hearing.

For patients with significant bilateral conductive hearing loss, a percutaneous bone conduction device (BCD) is an established option for hearing rehabilitation. (Snik et al. 2005). Bilateral application of BCDs was implemented with the aim of restoring hearing abilities at least to the extent that patients can experience the aforementioned advantages of hearing with two ears. The application of bilateral BCDs has been reported to be of subjective and audiological benefit in adult patients (Snik et al. 1998; van der Pouw et al. 1998; Bosman et al. 2001; Dutt et al. 2002; Priwin et al. 2004; Stenfelt 2005).

In Nijmegen, the bilateral application of BCDs in children was started gradually (Dun et al. 2010). These children have severe bilateral conductive hearing loss due to bilateral congenital major or minor ear anomalies (congenital conductive hearing loss) with or without microtia/anotia. Additionally, children with severe bilateral conductive hearing loss due to resistant chronic inflammation (acquired conductive hearing loss) in whom conventional air conduction hearing aids are not the best option are eligible for the bilateral application of BCDs (Snik et al. 2005). For children who are too young for the application of BCD implants (under the age of 4 years), BCD sound processors can be fitted bilaterally on the Baha® Softband (Verhagen et al. 2008). In contrast to adults, there have been only limited series in children concerning audiological outcomes after bilateral BCD application (Hamman et al. 1991; Priwin et al. 2007). Recently, McDermott et al. (2009) and Dun et al. (2010) showed high compliance and satisfaction after bilateral BCD treatment in children by evaluating quality of life aspects. Priwin et al. (2007) demonstrated that the advantage of bilateral BCD fitting was less pronounced in children than in adults. Conversely, Hamman et al. (1991) reported good results.

This paper presents the outcomes of audiological evaluations. The aim of the present study is to examine the advantages of bilateral BCD fitting in children and young adults who were fitted with bilateral BCDs in childhood. To do so, speech recognition in noise was studied using the intelligibility level difference test (LDT). The LDT quantifies the benefit that a listener has from bilateral input of sounds when speech and noise sources are separated. Directional hearing abilities were

studied using the minimum audible angle (MAA) test. The MAA test is a convenient and reliable option to test directional hearing in the horizontal plane in young participants (Litovsky et al. 2006; Sparreboom et al. 2011). To gain insight into the auditory cues that are used for sound localization with bilateral BCDs, a sound localization test was performed.

Materials and methods

Subjects

Audiological tests were performed on 15 subjects (eight males and seven females) fitted with bilateral BCDs in childhood or adolescence at the Radboud University Nijmegen Medical Centre, The Netherlands. They received their BCDs between June 1996 and October 2009. The group comprised 15 subjects from a total of 29 eligible subjects who had been fitted with bilateral BCDs before the age of 16 (n=13) or who had been fitted with one BCD before the age of 16 and received their second BCD later (n=2) at a maximum age of 20 years. In six subjects, bilateral BCDs were applied at different times (mean age at first fitting was 9.6 y; mean age at second fitting was 12.3 y). In nine subjects, bilateral BCDs were applied during one surgery (mean age: 7.9 y). Of the 29 subjects, 10 did not have the opportunity to visit the clinic in the test period, and four subjects with mental retardation were not included because they were presumed not to have been able to perform the tests adequately. Table 1 gives an overview of the final 15 subjects included in the tests, their audiometric characteristics and the type of BCDs used. One of these 15 subjects (no. 4) completed only one (MAA test) out of three tests for personal reasons. Subjects used their own BCD sound processors with the volume set at the typical daily level. All BCD devices make use of linear amplification. The Baha Divino has a microphone that can be switched manually between omnidirectional and directional. The Baha Divino users were tested while the device was in the omnidirectional mode. The Ponto Pro used by subject no. 4 has an adaptive directional microphone that is normally set in the omnidirectional mode but switches automatically to the directional mode in noisy environments. Because subject no. 4 only completed the MAA test, which was performed in a quiet environment, it can be assumed that the Ponto Pro was set in the omnidirectional mode during this test. All tests were carried out in a sound-treated double-walled room.

Speech intelligibility level differences test

The LDT is the difference between the speech reception thresholds (SRT) firstly when speech (S) is presented from the front and noise (N) is presented from the side at a 90° azimuth (S_0N_{90}) and secondly when both speech and noise are presented from the front (S_0N_0) (Figure 1). If a benefit is achieved from the head-shadow effect, the perceived separation of speech and noise sources in S_0N_{90} should lead to an improvement in the SRT. This benefit is estimated using the LDT test (HearCom 2009).

Table 1. Characteristics of 15 subjects with bilateral BCDs

Subject number	Gender	Age (y) at 1st - 2nd BCD fitting	Age (y) at time of tests	Experience with bilateral BCDs (y)	Etiology	Sound processor	PTA (0.5, 1 and 2 kHz)				
							AD		AS		BCDs
							AC	BC	AC	BC	PTA
1	f	8-8	8	1	acquired	Baha Divino	48	12	47	13	21
2	f	11-11	12	1	acquired	Baha Divino	27	8	57	12	NA
3	m	10-10	12	2	acquired	Baha Divino	33	20	45	30	NA
4	m	10-11	14	3	acquired	Ponto Pro	73	5	70	5	21
5	m	15-20	24	3	acquired	Baha Divino	68	20	105	17	24
6	f	6-6	10	3	cong atresia II[B]	Baha Divino	60	13	65	13	20
7	f	5-5	10	3	cong atresia II[A]	Baha Compact-Baha Divino	43	5	42	5	7
8	m	6-6	11	4	cong atresia II[B]	Baha Divino	50	5	65	5	28
9	m	6-6	12	5	cong atresia II[A]	Baha Divino	65	3	65	3	22
10	m	12-12	14	2	cong atresia III	Baha Divino	60	10	70	5	28
11	f	5-6	14	7	cong atresia III	Baha Divino	70	13	70	15	28
12	m	7-7	15	7	cong atresia III	Baha Divino	72	10	68	10	21
13	f	5-8	17	9	cong atresia II[A]	Baha Divino-Baha Compact	70	13	75	13	27
14	m	9-11	23	11	cong atresia III	Baha Divino	62	8	62	8	22
15	f	14-18	26	8	cong atresia II[B]	Baha Divino	60	15	60	15	23
Mean			14.8	4.6			57	11	64	11	22
SD			5.4	3.1			14	5	15	7	6

Age is the age in years at time of the tests. F, female; M, male; Etiology, Cong is congenital atresia classified according to Cremers et al. (1988); Sound processor: if one is listed, it was used for both sides; if two are listed, the first is for the left BCD and the second is for the right; AC, air conduction; BC, bone conduction; PTA, pure tone average of 0.5, 1 and 2 kHz. BCDs PTA, PTA derived from the free field test with two BCDs; NA, not available

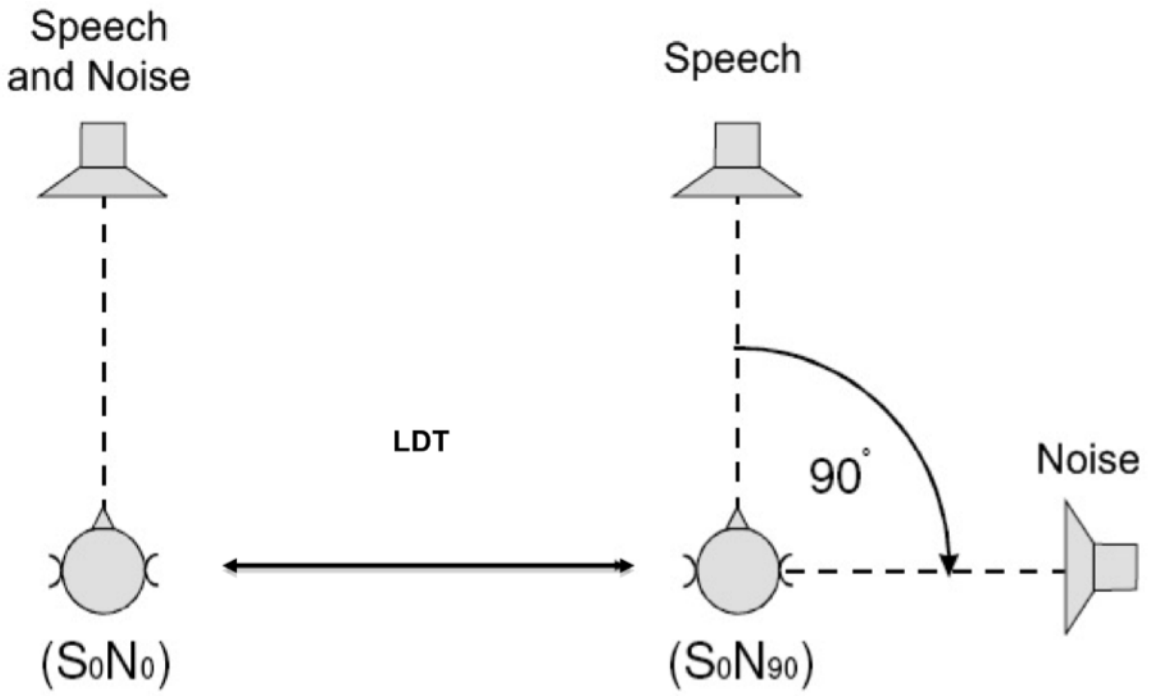

Figure 1. Test setup for the intelligibility level difference test (LDT).

Short, everyday Dutch sentences were used as the speech material (Plomp and Mimpen 1979). SRTs, the presentation level at which 50% of sentences were identified correctly, were established using an adaptive tracking procedure. SRTs were obtained only with bilateral BCDs in two test conditions, S_0N_0 and S_0N_{90}.
For each condition, the SRT was measured twice and the results were averaged. The noise used was steady state noise with the same frequency spectrum as the long-term spectrum of the sentences. The noise level was fixed at 65 dB in all of the measurements. The SRT minus 65 dB (the noise level) is the speech-to-noise (S/N) ratio. Better performance corresponds to a more negative S/N ratio. The LDT was the difference in dB between the S/N ratio in the S_0N_0 condition and the S/N ratio in the S_0N_{90} condition. If a benefit is achieved from the separation of speech and noise sources, a positive LDT is found.
The results were compared with the LDT scores from 10 adults with normal hearing obtained previously (van der Pouw et al. 1998). The LDT was reported to be 3.2 dB (SD 1.3). From those data, the 95% confidence interval (CI) was defined as twice the standard deviation, resulting in a CI of 0.6 to 5.8 dB.

The Minimum Audible Angle

The MAA is a psychoacoustical test that is used to study sound directional hearing abilities. The MAA measures the smallest detectable change in the position of a

sound source in the horizontal plane in the frontal field. The MAA was tested in three conditions:
(1) Unilateral BCD on the left side.
(2) Unilateral BCD on the right side.
(3) Bilateral BCDs.

A broadband noise (500 Hz – 20 kHz, 500 ms) was used. The noise stimuli had randomly selected sound levels in the 40 - 70 dB SPL range in 10 dB steps. By varying the sound level, the use of loudness as an azimuth cue was minimized. Two loudspeakers were positioned in an arc with a radius of 1 m with the subject seated in the middle. The subjects were asked to point to the speaker that they thought was the source of the stimulus. First, a practice run was presented. The actual test started with the two loudspeakers positioned left and right of the subject at an angle of 90°. Four stimuli were presented randomly at the two loudspeaker positions. When all four stimuli were correctly identified at –90° or +90° azimuth, both loudspeakers were repositioned at -60° and +60°. The subsequent positions evaluated whether four stimuli were correctly identified were -/+30°, -/+15°, -/+10° and -/+5°. If the subject failed to correctly identify all four stimuli, another four stimuli were presented at the same loudspeaker condition. If the subject correctly identified these four stimuli, the loudspeakers were positioned at the subsequent smaller angle. The MAA score was defined as the preceding angle at which four stimuli in a row were correctly identified. The worst score that could be obtained was 90°. Scores of 90° through 60° were considered to be poor. Better performance corresponds to a lower MAA value, with a best score in this test setup of 5° because placing the sound sources closer together was impeded by the size of the loudspeakers. No feedback was given during the measurements.

Sound localization test

An additional measure of sound localization abilities in the horizontal plane was applied using five fixed loudspeakers (Kunst et al. 2008). The aim of this test was to gain more insight into the auditory cues that are used for sound localization with bilateral BCDs. Hence, this test was performed in the bilateral BCD condition only. To do so, one-second bursts of narrow band noises (1/3 octave) centered around 500 Hz and 3000 Hz were used. These frequencies were selected because directional hearing at 500 Hz is mainly based on the detection of interaural time differences (ITDs), while at 3000 Hz, it is mainly based on the detection of interaural level differences (ILDs) (Kunst et al. 2008).

The loudspeakers were placed in a circle (between -90° and 90°) at intervals of 45°. The radius of the circle was 1.2 m with the subject's head at the center of the circle. The presentation level was fixed at 65 dB SPL and 23 stimuli were randomly presented from any of the five loudspeakers. After each stimulus, the participant was asked to identify the loudspeaker that had produced the sound. Subjects were not permitted to turn their head during stimulus presentation. No training or feedback was given. The outcome measure was correct localization of stimuli. The chance level was 20%. When the score was modeled as a binomial variable, the 95% confidence level was 48%. Therefore, if the score exceeded this percentage, directional hearing was considered to be adequate.

Table 2. Results of the speech intelligibility level differences test

Subject number	S/N ratio (dB) S_0N_0 condition	S/N ratio (dB) S_0N_{90} condition	LDT (dB)
1	-2.55	-7,70	5.15[a]
2	-2.70	-3.95	1.25[a]
3	-0.60	-2.40	1.80[a]
5	-3.80	-2.10	-1.70
6	-3.30	-3.55	0.25
7	-3.67	-4.30	0.63[a]
8	-3.70	-9.00	5.30[a]
9	-3.15	-9.00	5.85
10	-2.45	-5.20	2.75[a]
11	-5.35	-7.30	1.95[a]
12	-2.60	-6.70	4.10[a]
13	-5.20	-5.70	0.50
14	-6.00	-11.10	5.10[a]
15	-6.70	-8.20	1.50[a]
Mean	-3.70	-6.16	2.46
SD	1.63	2.71	2.30
SEM	0.44	0.72	0.62

S/N ratio, speech to noise ratio; S_0N_0, test condition with speech and noise presented from the front; S_0N_{90}, test condition with speech presented from the front and noise presented at 90° azimuth. LDT, intelligibility level difference. [a] The results are within the 95% confidence interval. Subject no. 4 did not participate in this test.

Results

Speech intelligibility level differences test

Fourteen subjects participated in this test. LDT results are presented in table 2. In the S_0N_0 situation, a mean S/N ratio of -3.70 dB (SD 1.63) was found. A 90° shift of the noise source (S_0N_{90}) resulted in a more negative S/N ratio (mean -6.16, SD 2.71), which represents an improvement in SRT, as was expected.

The mean LDT was 2.46 dB (SD 2.30). In 10 of 14 subjects, the LDT was within the 95% CI (0.6-5.8 dB) obtained from adult data. In two subjects (nos. 6 and 13), there was a non-significant improvement. In one subject (no. 5), the SRTs deteriorated after separation of the sound and noise sources. One subject (no. 9) scored better than the 95% CI.

Minimum Audible Angle

Table 3 lists the MAA results of the 15 subjects. In all subjects, the position of a sound source that could be reliably discriminated was smallest in the bilateral BCD condition (MAA score between 5° and 30°). In the unilateral BCD condition, most of the subjects were not able to discriminate the sound source adequately (scores of 90° and 60°). They perceived the stimuli at the side of the BCD. Subjects 1, 3, 6, 7, and 10 scored better than 60° in one of the unilateral conditions. Nevertheless, compared to scores from the unilateral conditions, four of these five subjects (nos. 1, 3, 6 and 10) performed better with bilateral BCDs. Two subjects demonstrated a MAA of 15° in the unilateral condition. Compared to the best score in the unilateral condition, only subject 7 did not improve in the bilateral condition.

Sound localization test

The sound localization test was performed in 14 subjects. Localization of 500 Hz stimuli was significantly better than the chance level in only five of 14 subjects.

Four of 14 subjects localized 3000 Hz stimuli significantly better than the chance level. Three of them were part of the five subjects that localized 500 Hz stimuli better than the chance level.

Discussion

The present study examined hearing abilities in children and young adults with bilateral conductive hearing loss who were fitted with bilateral BCDs. The results

demonstrate that the sound input from either BCD is effectively used and that directional hearing, as measured with the MAA test, is much better with bilateral BCDs compared to unilateral BCD.

Table 3. Minimum Audible Angle test results

	MAA (degrees)		
Subject number	Unilateral BCD (fitted left)	Unilateral BCD (fitted right)	Bilateral BCDs
1	90	15	10
2	NA	90	10
3	20	30	10
4	90	90	30
5	90	90	5
6	60	30	10
7	90	15	30
8	90	90	30
9	90	90	5
10	90	30	5
11	90	90	10
12	90	90	5
13	90	90	5
14	90	60	10
15	90	90	5

MAA, minimum audible angle; BCD, bone conduction device; NA, not available. A MAA score of 90° corresponds with the inability to correctly localize left and right stimuli. A better score corresponds with lower degrees, with 5° being the minimum value.

In the LDT experiment, an improvement in SRTs was found in most subjects when the sound and noise sources were separated. The LDT score was comparable with the LDT found in normal hearing adults. This implies that, with bilateral BCDs, the head shadow was effectively used and the auditory system effectively processed the incoming stimuli from both sides.

In the present study, left-right discrimination task scores in the MAA test were found to be far better with bilateral BCDs compared to unilateral fitting. With bilateral BCDs, the MAA score was 10° or 5° in most subjects. Three subjects had a score of 30° in the bilateral setting, which was still far better than scores obtained in the unilateral setting. MAA thresholds in normal-hearing children reach 1° to 2°, at which point they are not significantly different from adult MAAs (Litovsky 1997). In the present study, however, the minimum value did not exceed 5° because the loudspeakers could not be put closer together. Most subjects were not able to identify the sound source when only using one BCD. This is in accordance with results found by Priwin et al. (2004) who showed that patients

fitted monaurally with a BCD lateralize sound to the side of the implant, regardless of where the sound source is situated. However, two subjects demonstrated a MAA of 15° in the unilateral condition. Because varying the sound level minimized the possibility to use loudness as an azimuth cue, it is suggested that this performance in the unilateral condition is based on the detection of differences in the pitch of the sound, caused by the frequency specific attenuation of the sound (the head-shadow effect). This suggestion is supported by the observation that some subjects can learn rather quickly to use the ambiguous head-shadow effect cue to localize when the sound level is fixed at one intensity (van Wanrooij and van Opstal 2004), and by the observation that both subjects demonstrated a MAA of 15° during the second unilateral BCD measurement.

The overall localization results from the sound localization test that was performed to gain insight into auditory cues for sound localization were poor. The evident advantage of bilateral BCDs that was found in the MAA test was not apparent in this test. Correct localization abilities for 500 Hz and 3000 Hz stimuli were significantly better than chance in five and four out of 14 participants, respectively. Priwin et al. (2007) found localization scores better than those expected by chance in all three of the children with bilateral BCDs that were tested. It can be speculated that in the subjects with bilateral BCDs, a combination of auditory cues for sound localization is used and that localization is impaired when only ITDs or ILDs are available. The broadband noise used in the MAA test provided a combination of cues, which apparently could be effectively used; however, the poor ITD and ILD results are not in accordance with adult studies where sound localization abilities were found to be significantly better than chance in the majority of subjects with bilateral BCDs (Bosman et al. 2001; Priwin et al. 2004). No clear explanation can be given for the somewhat disappointing localization results in the sound localization test found in the present study. Kunst et al. (2008) used the sound localization test in 10 children with unilateral conductive hearing loss fitted with a BCD and found poor results as well. Although van Deun et al. (2009) reported that the sound localization can be tested adequately in children the present test setup might not be suitable for young subjects.

The subjects in the present study vary concerning the etiology of hearing loss, unaided and aided pure tone averages, age at onset of hearing loss, and age at which bilateral hearing rehabilitation was established. The influence of these differences (e.g., etiology of hearing loss or the age at which rehabilitation was started) could not be explored further due to a small sample. It remains unclear whether early bilateral application has an advantage over sequential bilateral implantation later in life. It might be that there is a certain critical period in which

binaural hearing develops. This calls for further, prospective research in larger patient groups.

While this study showed that bilateral BCD fitting is beneficial, the tests that were performed and the study setup did not reveal which binaural cues are available in bilateral BCD fitted children. Whether based on real binaural hearing or not, the clinical value of bilateral BCDs is obvious and can be translated to real life situations. For example, in young children who are not yet familiar with traffic situations, directional hearing is especially important. Being able to identify a speaker is of great value within group conversations and speech understanding in noise is important in a classroom setting. Besides these advantages, hearing is still possible when one of the devices cannot be used (for a transient period of time). This is of value because children are vulnerable to skin reactions and implant loss, which can limit the use of BCD (de Wolf et al. 2008).

In summary, the beneficial effect of bilateral BCDs over a unilateral BCD in children and young adults has been shown according to quality of life instruments in the past (Dun et al. 2010). The current study indicates that also audiological, by means of the LDT and the MAA test, most of the children and young adults clearly take advantage of bilateral BCDs.

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CHAPTER 5

DISCUSSION

Discussion

With 35 years of clinical experience percutaneous bone conduction devices (BCDs) have become a well-established and generally safe treatment option for patients with conductive hearing loss (CHL) or mixed hearing loss (MHL). Indications have been extended, surgical techniques modified, and several generations of sound processors developed. Nevertheless, research is still ongoing to further improve the outcomes of hearing rehabilitation with BCD. This thesis addresses several aspects of BCD application in terms of complications, newly designed implants, and bilateral BCD fitting in children. This information aims to support pre- and postoperative BCD consultation.

Chapter 2 presents the assessment of clinical outcomes of BCD implants. In *chapter 2.1* the outcomes of 1,132 BCD implants that were fitted in Nijmegen between 1988 and 2007 are reviewed retrospectively with data of the postoperative course collected from the patients' medical records. Out of a total of 7,415 observations performed on the 1,132 implants, 95.5% showed no soft tissue problems around the abutment and overall implant loss was 8.3%. Consistent with results from other studies, children appeared to be most vulnerable to adverse soft tissue reactions. Little is known about causal factors. Cleaning of the abutment site might be suboptimal. It has been suggested that more frequent care needs to be given to support the regular cleansing of the skin around the abutment. Changes in abutment design might effect a more optimal abutment-skin contact and thereby lower the risk of skin reactions.[1] A new transcutaneous system will avoid the need for permanent skin penetration and is therefore expected to be a promising development in the near future especially in this patient group.[2] However, a disadvantage of this system is that sound vibrations are to be transmitted through the skin and subcutaneous layers, which results in a lower gain of approximately 15 dB compared to a BCD.[2] For children with congenital conductive hearing loss, in which a perceptive hearing loss component is not uncommon, a loss of gain of 15 dB is significant. In the upcoming bone conduction implant system (BCI), with an externally worn processor and a fully implanted bone conduction transducer, no gain is lost through the skin, which seems to make it an even more promising technique.[3] More implants were lost in the pediatric population as well as in mentally retarded patients, mainly spontaneously or due to trauma. It can be questioned whether osseointegration is suboptimal or is perhaps more easily disturbed in pediatric patients. An assessment of implant stability in a pediatric population, for example using non-

invasive resonance frequency analyses, would be useful in testing this thought. For mentally retarded patients it is not clear what causes the higher implant loss rate. Suboptimal caretaking of the abutment site may play a role. However, the reported incidence of adverse skin reactions was not found to be higher in this group. A higher risk for small traumas to the implant site in mentally retarded patients could have gone unnoted or underreported.

Another aspect addressed in *chapter 2.1* is the presentation of outcomes of implants based on the time at which they were loaded with the BCD sound processor. Loading times varying between 3 and even more than 12 weeks were identified. Eighty-eight implants were loaded at 3 to 5 weeks from implantation, which was much earlier than the generally advised loading time of 6 weeks. However, the incidences of implant loss and adverse reactions in this group were not different from implants that were left unloaded for a longer period of time. These results imply that implant osseointegration might be sufficient for the loading of the BCD sound processor as early as 3 weeks after implantation.

Chapter 2.2 evaluates the use of an 8.5-mm abutment as an intervention for the management of therapy-resistant skin reactions with imminent soft tissue overgrowth around the skin-penetrating abutment, or for patients with a thick scalp that interfered with sound processor coupling. Out of a total of 61 8.5-mm abutments placed from 2003 to 2009 in Nijmegen, 39 had a follow-up of more than 12 months and were evaluated retrospectively for their pre- and post-intervention course. Fitting was most frequently performed because of recurrent skin problems with imminent soft tissue overgrowth. The condition of the skin around the abutment was classified according to the Holgers grading system. Adverse skin reactions (Holgers ≥ 2) significantly declined after changing from the standard 5.5-mm abutment to the 8.5-mm abutment. The level of the skin relative to the abutment top was registered as well and classified as ‘high skin’ or ‘low skin’. The observation ‘high skin’ significantly decreased after the 8.5-mm abutment was fitted. It was recognized that the classification ‘high skin’ and ‘low skin’ was suboptimal in providing adequate information. Therefore a new classification for skin level is under construction at the moment. Revision surgery for therapy-resistant skin problems was only required in one patient, compared to seven times in the pre-fitting period. In this one patient revision surgery was performed three years after fitting the 8.5-mm abutment. For patients with a thick scalp, the 8.5-mm abutment was found to be useful during primary surgery, or to replace the 5.5-mm abutment in a later phase. The 8.5-mm abutment was applied

during primary surgery in only three cases, but it is expected that placement of the 8.5-mm abutment during primary surgery in cases with a thick scalp (that is presumed to interfere with sound processor coupling) will be of value in preventing revision surgery. However, at present there is no technique available to define the precise thickness of the skin during implantation surgery which therefore depends on the interpretation of the surgeon. It might be beneficial to perform standardized measurements of skin thickness during implantation surgery so as to determine the abutment size that can best be used. Even a 12-mm abutment, which is currently available for research purposes only[4], might be appropriate in some patients with a thick scalp, or as a next step in managing persistent problems despite the use of an 8.5-mm or 9-mm abutment. The 12-mm abutment might also be applicable if upcoming surgical techniques without soft tissue reduction are used.[4]

In chapter 3 a newly designed implant, the Baha BI300 implant with abutment, is assessed in terms of survival and implant stability. The Baha BI300 implant series has been developed to realize faster and stronger osseointegration, which is suggested to be the key in improving implant survival. This might be of special value in patients with compromised bone quality like children, irradiated patients, and patients with diabetes mellitus.

Chapter 3 reports on implant stability quotient (ISQ) values measured by resonance frequency analysis (RFA), and outcomes on implant survival. Six-month data gathered in a multicenter investigation revealed that significantly higher mean ISQ values were recorded for the 52 Baha BI300 implants than for the 25 previous generation implants, which suggests that the Baha BI300 is more stable. The short-term survival rate of the two implants was comparable. For implants loaded 6 weeks after implantation (Baha BI300 implant and previous generation implant), no deterioration in implant stability was observed. This result indicates that, for both implants types, the level of osseointegration reached as early as 6 weeks after implantation is adequate to support the sound processor in healthy adults with good bone quality. In this light, the clinical relevance of the difference in ISQ values that was found between the two implant types can be questioned, mainly because no reference data for extra-oral implants in the temporal bone are available at present. Nevertheless, RFA is a frequently used and functional tool for monitoring stability changes over time within one implant in the dental implantology field. By monitoring stability changes, a statistically significant reduction in stability during the first 10 days after implant insertion was

observed for both implant types. This initial temporary dip is most likely part of the natural bone remodeling process triggered by the trauma to the bone. The initial decrease in ISQ values was slightly less pronounced for the Baha BI300 implant compared to the previous generation implant, which may be a result of enhanced osseointegration. Based on the higher ISQ values found in the Baha BI300 implant, it is expected that the true value of the new design will become clear in patients with comprised bone quality. Cone beam computed tomography (CBCT) is a promising technique that will make it possible to image the level of osseointegration during implant follow-up.[5]

Chapter 4 evaluates the outcomes of bilateral BCD fitting in children and young adults. A beneficial effect of bilateral BCD over monaural BCD fitting has been questioned, because it was recognized that BC stimulation in one place is transmitted to both the ipsilateral and the contralateral cochlea. This cross-stimulation might negatively affect interaural cues, which are normally needed for binaural hearing abilities such as sound localization and speech recognition in noise. However, in adult patients the application of bilateral BCDs has been reported to be of subjective and audiological benefit. Still, adults and young patients with bilateral conductive hearing loss are most commonly fitted with one BCD. In literature, incidental reports have appeared on limited series of children with bilateral BCDs. In Nijmegen, the bilateral application of BCDs in children began in 1996.

Chapter 4.1 presents the clinical data and outcome of quality of life questionnaires for 27 children and young adults with bilateral CHL who were fitted with bilateral BCDs in our center; 18 had congenital bilateral CHL, and 9 had acquired bilateral CHL. At the time of evaluation, the age of the patients ranged from 6 to 28 years. The evaluation showed a clear trend toward simultaneous bilateral BCD implantation at a younger age in recent years. All patients who responded to the questionnaire and were included for further evaluation (n = 20) were satisfied with their BCDs, and the BCDs were used 7 days a week by 90% of patients. Also, measured with the Glasgow Children's Benefit Inventory (GCBI) all patients reported a general improvement in their health status due to the received BCDs. The reported benefit was in accordance with other GCBI studies that evaluated the change in health status after unilateral BCD fitting in patients with unilateral or bilateral CHL. The benefit was most prominent in the subdomains emotion and learning, which are both of utmost importance in the developing child. A noisy environment caused 9 of the 20 (45%) patients to sometimes take off or switch off

both BCDs. Two of them reported that this situation was also a reason to switch off one or both BCDs. Three other patients (14%) reported switching off especially one BCD in specific listening situations (noisy environment, making a telephone call or listening to people sitting on one side). On the other hand, patients reported difficulties understanding people against a noisy background with one BCD compared to bilateral BCDs. This is in accordance with results from audiological tests performed in adult patients with bilateral BCDs.[6-10] These tests found that, compared to the situation of noise presented to the non-BCD side in the unilateral BCD condition, fitting of a second BCD on this non-BCD side resulted in a decline in speech recognition. However, when noise was presented on the side with the BCD in the unilateral condition, the addition of a second BCD resulted in an improvement in speech recognition.

Another aspect evaluated in *Chapter 4.1* is the subjective directional hearing ability with bilateral BCDs. In a general questionnaire, 70% percent of patients reported difficulties identifying the direction of sound with only one BCD. The spatial part of the Speech, Spatial and Qualities of Hearing (SSQ) questionnaire was used to measure self-reported spatial hearing ability. No pre-intervention data or reference data on SSQ scores with bilateral BCDs were available to put the obtained scores in perspective. However, compared to adult patients with unilateral CHL without a hearing aid, children with bilateral BCDs seemed to report a somewhat better score. Children with unilateral CHL who were fitted with one BCD that effected bilateral amplification scored comparably to children with bilateral BCDs in the spatial domain of the SSQ. The results indicate that young patients with bilateral BCDs experience spatial hearing.

Chapter 4.2 describes the results of three audiological tests performed on 15 children and young adults (with a mean age of 15 years) who were fitted with bilateral BCDs in childhood or adolescence. The tests focused on two audiological aspects that were found to be of advantage in normal hearing adults when hearing with two ears is compared to monaural hearing: improved speech recognition in noisy situations when speech and noise sources are spatially separated, and improved directional hearing. The speech intelligibility level differences test was used to examine the benefit to a listener of a bilateral input of sounds when speech and noise sources are separated. Most patients showed an improvement in speech reception thresholds after separation of speech and noise sources, which implies that these patients effectively used the head-shadow effect and the incoming stimuli from both BCD sides. Left-right discrimination tasks were tested

in the Minimum Audible Angle (MAA) test using a broadband noise, and were found to be far better with bilateral BCDs compared to unilateral fitting. Most patients were not able to identify the sound source when using only one BCD. To gain insight into the auditory interaural cues (e.g. interaural time differences, and interaural level differences) that are used for sound localization with bilateral BCDs, a sound localization test was performed using narrow band noises of 500 Hz and 3000 Hz. The evident advantage of bilateral BCDs that was found in the MAA test was not apparent in this test. Although no clear explanation can be given for the poor results, it can be speculated that subjects with bilateral BCDs use a combination of auditory cues for sound localization and that localization is impaired when only interaural time differences or interaural level differences are available. The broadband noise used in the MAA test provided a combination of cues, which could apparently be used effectively. While bilateral BCD fitting was shown to be beneficial, the tests that were performed and the study setup did not reveal whether real binaural cues are available in children fitted with bilateral BCDs. However, the clinical value of bilateral BCDs was obvious and the found improved hearing ability is of importance in real life situations of young children, such as traffic and a classroom setting. Furthermore, prospective research in larger patient groups will be of value to explore the influence on the audiological benefit of bilateral BCDs of variables such as the etiology of hearing loss, the age at onset of hearing loss, and the age at which bilateral hearing rehabilitation was established.

In summary, this thesis evaluates the long term results of 1,132 BCD implants that were placed in Nijmegen. The incidence of skin reactions was low, and implant loss was found to be 8.3%. Children and mentally retarded patients are more at risk of implant loss. Furthermore, the use of the 8.5-mm abutment was found to be a valuable intervention for the management of therapy-resistant skin reactions with imminent soft tissue overgrowth, or in patients with a thick scalp. Other transcutaneous BCHAs are being developed to supply an alternative for a percutaneous BCD. In these systems it is important to reduce the loss of gain through intact skin. In this light, the development of the BCI system seems very promising.

A clinical assessment of a newly designed implant suggested higher stability compared to previous generation implants. The use of implants with a wider implant diameter and modified implant surface might be of special value in patients with compromised bone quality. Measurements of implant stability were

performed using RFA. Further research should focus on the suitability of the implementation of RFA in the follow-up of implants in the outpatient clinic. Possibly, this results in reference RFA values indicating sufficient implant stability for sound processor loading. Also, the application of CBCT for implant follow-up is promising and merits further research.

This thesis also showed the subjective and objective appreciation of bilateral BCD fitting in children and young adults. However, outcomes varied among the examined subjects and more research is needed to reveal the influence of different patient characteristics on the outcomes of bilateral BCD fitting in children.

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CHAPTER 6

SUMMARY / SAMENVATTING

Summary

A percutaneous bone conduction device (BCD) is used for hearing rehabilitation in patients with conductive hearing loss (CHL) or single-sided inner ear deafness when air-conduction hearing aids cannot be used successfully and when reconstructive surgery is not (yet) a feasible option. These patients typically have persistent otitis media or externa, or (congenital) major or minor anomalies of the ear.

Since the commercial introduction of percutaneous BCDs (e.g. Baha) in 1987, more than 75,000 patients worldwide have benefited from the system. However, although BCDs are well accepted in audiological and subjective terms, a drawback of the system is that surgery is needed for implantation and that the skin-penetrating abutment creates a permanent skin defect. Besides, the implant can be lost. For many years, this has been a reason to evaluate the outcomes of BCD surgery. This thesis describes the follow-up of 1,132 percutaneous implants for BCD placed in Nijmegen. It was found that only a minor part (4.6%) of patients suffered from adverse skin reactions of the skin surrounding the skin-penetrating abutment. The occurrence of skin reactions was higher in children (7,8%). The overall implant loss was 8.3%, which is comparable with other BCD reports in the literature. Children and mentally retarded patients experienced implant loss more often (15,2% and 17,4%, respectively). These results indicate that more frequent care needs to be given to children and patients with mental retardation in the outpatient consultation. However, the major benefits of hearing rehabilitation gained by BCD application in these two vulnerable groups are thought to justify the still relatively mild complications of BCD surgery. Another aspect that was evaluated in the BCD population was the period of time between implantation and the loading of the implant with the sound processor. Eighty-eight implants were loaded earlier than the conventional 6 weeks, but showed comparable outcomes with regard to implant loss and skin reactions as implants that were loaded after 6 weeks.

Some patients experienced recurring problems of the soft tissue surrounding the abutment which, despite therapy, resulted in skin hypertrophy. In these cases of skin hypertrophy, sound processor coupling is problematic or impossible. The use of an 8.5-mm abutment instead of the standard 5.5-mm abutment, as an intervention for the management of therapy-resistant skin reactions with imminent soft tissue overgrowth, was studied and found to effectively reduce the further

development of skin problems and the need for revision surgery. In addition, for patients with a thick scalp that interfered with sound processor coupling, the 8.5-mm abutment was found to be of value instantly during primary surgery, or as a replacement of the 5.5-mm abutment in a later phase.

Efforts are being made to improve the outcome of BCD implantology. Special focus lies on the reduction of implant loss and especially the improvement of outcomes for patients with compromised bone quality such as children, patients with diabetes mellitus and irradiated patients. In this light a new implant has been developed that, compared with the previous generation implant, has a wider diameter, small-sized and more numerous threads at the implant neck, and a moderately rough TiOblast surface. Implant stability was measured using resonance frequency analyses (RFA) in 52 adult patients with the new Baha BI300 implant and in 25 adult patients with the previous generation implant. RFA provided higher implant stability quotient values for the Baha BI300 implant at all follow-up visits carried out over a follow-up period of 6 months. Based on the higher implant stability quotient values found for the Baha BI300 implant, it is expected that the true value of the new design will become clear in patients with comprised bone quality. For patients with uncompromised bone quality, the Baha BI300 might be of value to reduce implant loading time.

It is recognized that hearing with two ears has several advantages compared to monaural hearing. Various studies reported that in adult patients with bilateral CHL, the bilateral application of BCDs was of subjective and audiological benefit compared to monaural BCD fitting. In this thesis the application of bilateral BCDs in children and young adults with bilateral CHL was evaluated with regard to patient benefit and audiological outcomes. Bilateral BCDs were highly appreciated by the 21 young participants who filled out the questionnaires. Audiological measurements were performed in 15 eligible young participants and it was found that bilateral BCDs lead to improved hearing ability in the majority of participants, compared to unilateral BCD application. This improved hearing ability is important in developing children. There may be a certain critical period in which binaural hearing develops and bilateral BCD fitting during this period could provide the required auditory stimulation.

Samenvatting

Een percutaan botverankerd hoortoestel, oftewel ‘percutaneous bone conduction device’ (BCD) wordt gebruikt voor hoorrevalidatie bij patiënten met conductief gehoorverlies of eenzijdige doofheid bij wie een luchtgeleidingshoortoestel niet succesvol toepasbaar is en een operatie (nog) geen haalbare optie vormt. Deze patiënten hebben bijvoorbeeld last van recidiverende oorontstekingen of een meer of minder ernstige aangeboren oorafwijking.

Sinds de commerciële introductie van percutane BCD’s (destijds ‘Baha’ genoemd) in 1987 hebben wereldwijd meer dan 75.000 patiënten een percutane BCD aangepast gekregen. Hoewel BCD’s subjectief en audiologisch gezien goed geaccepteerd worden, kleeft er aan het systeem het nadeel dat voor de plaatsing een operatieve ingreep nodig is en dat het tussenstuk van het implantaat permanent door de huid steekt. Daarnaast bestaat er een risico dat het implantaat uitvalt. Om deze redenen zijn de uitkomsten van plaatsing en gebruik van BCD’s al lange tijd onderwerp van evaluatie. In dit proefschrift wordt de follow-up beschreven van 1.132, in Nijmegen geplaatste, BCD implantaten, waaruit blijkt dat slechts een klein deel (4,6%) van de patiënten problemen ondervond van hinderlijke huidreacties rondom het implantaat. Kinderen hadden echter vaker last van deze huidreacties (7,8%). In 8,3% van de gevallen werd het implantaat verloren, hetgeen vergelijkbaar is met andere gerapporteerde BCD studies. Kinderen en patiënten met een verstandelijke beperking verliezen vaker hun implantaat, te weten in respectievelijk 15,2% en 17,4% van de gevallen. De resultaten wijzen erop dat er frequentere poliklinische controles plaats zouden moeten vinden bij kinderen en verstandelijk beperkte patiënten met een BCD. Desalniettemin, het enorme profijt dat hoorrevalidatie met een BCD bij deze twee kwetsbare patiëntengroepen biedt, weegt op tegen het vóórkomen van relatief milde complicaties. Een ander aspect dat in onze BCD populatie is geëvalueerd betreft de tijd tussen de implantatie en het belasten van het implantaat met de geluidsprocessor. Achtentachtig implantaten die eerder belast werden dan de op dat moment gebruikelijke termijn van zes weken, lieten ten aanzien van huidreacties en implantaatverlies uitkomsten zien die vergelijkbaar zijn met die van implantaten die wel na zes weken belast werden.

Sommige patiënten ondervinden terugkerende problemen van de huid rondom het implantaat, hetgeen, ondanks behandeling, kan resulteren in overgroei van de huid. Wanneer de huid (gedeeltelijk) over het tussenstuk heen is gegroeid, wordt

de koppeling van de geluidsprocessor bemoeilijkt of zelfs onmogelijk. Het 8,5-mm tussenstuk, dat het standaard 5,5-mm tussenstuk vervangt, werd als interventie toegepast bij patiënten die kampten met huidproblemen en dreigende huidovergroei. Evaluatie van deze interventie liet zien dat dit een goede oplossing bood om verdere huidproblemen te voorkomen en de noodzaak tot verder operatief ingrijpen te reduceren. Bovendien bleek het gebruik van het 8,5-mm tussenstuk niet alleen al direct van waarde te zijn tijdens implantatie van de BCD bij patiënten met een dikke hoofdhuid die een goede koppeling van de geluidsprocessor in de weg zou staan, maar ook in een later stadium, als vervanging van het 5,5-mm tussenstuk bij patiënten bij wie de relatief dikke hoofdhuid de koppeling van de geluidsprocessor bemoeilijkte.

Er zijn ontwikkelingen gaande om de resultaten van BCD implantologie te verbeteren. Speciale aandacht wordt geschonken aan het reduceren van implantaatverlies en het verbeteren van de resultaten voor patiënten met een matige botkwaliteit, zoals kinderen, diabetici en bestraalde patiënten. In dit licht werd onlangs een nieuw implantaat ontworpen dat, vergeleken met het implantaat van de vorige generatie, voorzien is van een grotere diameter, fijnere en meer schroefdraden in de implantaatnek en een wat ruwer TiOblast oppervlak. De implantaatstabiliteit werd gemeten middels Resonantie Frequentie Analyse (RFA) bij 52 gezonde volwassenen met het nieuwe Baha BI300-implantaat en bij 25 gezonde volwassenen met het implantaat van de vorige generatie. Na een follow-up van zes maanden lieten de RFA-metingen van het Baha BI300-implantaat op alle tijdstippen een hogere implantaat-stabiliteitquotiënt zien. Gezien deze resultaten is de verwachting dat dit nieuwe implantaat van veel waarde zal zijn bij patiënten met een verminderde botkwaliteit. Voor patiënten met een goede botkwaliteit kan het Baha BI300-implantaat van waarde zijn om de tijd tussen implantatie en belasting van het implantaat te verkorten.

Het is algemeen erkend dat horen met twee oren verschillende voordelen heeft ten opzichte van horen met één oor. Verschillende studies hebben beschreven dat bij volwassen patiënten met bilateraal conductief gehoorverlies, een bilaterale BCD aanpassing zowel subjectief als objectief profijt opleverde vergeleken met één BCD. In dit proefschrift worden de subjectieve en audiologische uitkomsten beschreven van een groep kinderen en jongvolwassenen met bilateraal conductief gehoorverlies die gebruik maken van een bilaterale BCD. De 21 jonge deelnemers die de vragenlijsten invulden lieten weten de bilaterale BCD aanpassing sterk te waarderen. Audiologische metingen werden verricht bij 15,

daarvoor geschikte, jonge deelnemers. Deze metingen lieten zien dat vergeleken met een enkelzijdige BCD aanpassing, de bilaterale BCD de hoormogelijkheden van het merendeel van de deelnemers verbeterde. Gesuggereerd wordt dat een dergelijke verbetering belangrijk is voor een zich ontwikkelend kind. Het zou kunnen zijn dat er een bepaalde kritieke periode bestaat waarin de ontwikkeling van binauraal gehoor plaatsvindt en dat een aanpassing met een bilaterale BCD in deze periode de benodigde auditieve stimulatie daarvoor biedt.

Dankwoord

Dit werk zou niet tot stand zijn gekomen zonder de hulp van vele betrokken mensen.

Allereerst wil ik alle patiënten bedanken die hebben meegewerkt aan de verschillende onderzoeken. Treinreizen van twee uur, het invullen van vragenlijsten en vele bezoeken aan de polikliniek bleken allemaal geen probleem door jullie enthousiasme. Speciaal wil ik de kinderen en jongeren bedanken die hun ervaring met de dubbelzijde BCD-aanpassing met ons wilden delen en bereid waren langs te komen voor de hoortesten.

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Beste dr. Hol, 'ha Myrthe'. Zo luidde meestal de aanhef van de enorme bulk aan mailtjes die ik je heb gestuurd. Jouw snelle en altijd duidelijke reacties zijn

onmiskenbaar verbonden aan wat ik nu heb bereikt. Je vaardigheid om aan tijdslijnen vast te houden en mij telkens opnieuw enthousiast te maken is echt fantastisch. Ik ben je hier ontzettend dankbaar voor! Als professional wist je me door het promotieproces te sturen, als Myrthe was je er op het persoonlijke vlak. ‘Linksom of rechtsom, het komt altijd goed’, is jouw motto. En zie het resultaat!

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na een lange treinreis. Bedankt voor jullie huisgenootschap! P.s., zou ik Willem hier nog moeten bedanken?

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Rani, habibi. Niets kan evenaren wat wij samen zijn, jij bent het mooiste wat mij overkomen is. Ons prachtige wonder Noor is de ultieme bekroning hierop.

Curriculum Vitae

Jacolien (Catharina A.J.) Dun werd op 26 november 1982 geboren in Veendam. Kort na haar geboorte overleed haar vader. Ze groeide op met haar moeder en twee oudere broers. Na het behalen van haar VWO-diploma startte zij met de studie Biologie aan de Rijksuniversiteit Groningen. Toen zij met een propedeuse Biologie op zak nogmaals werd uitgeloot voor de studie Geneeskunde, heeft zij een half jaar in Ghana als vrijwilligster op een basisschool gewerkt. Aan de studie Geneeskunde kon ze het jaar daarop beginnen. Deze studie werd begin 2009 afgesloten met een keuzecoschap op de afdeling Keel-, Neus- en Oorheelkunde in het UMC St. Radboud te Nijmegen en halverwege ditzelfde jaar behaalde zij het artsexamen. Direct daarna startte zij, onder leiding van prof. dr. C.W.R.J. Cremers, als arts-onderzoeker een promotietraject dat heeft geleid tot het tot stand komen van dit proefschrift. Per 1 maart 2012 is zij in opleiding tot KNO-arts in het UMC Groningen met prof. dr. B.F.A.M. van der Laan als opleider. In september 2009 trouwde Jacolien met Ben Rani Saleem. Op 11 februari 2011 werd hun dochter Noor geboren.

List of Publications

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Submitted

9 Dun CAJ, Agterberg MJ, Cremers CWRJ, Hol MKS, Snik AFM. Improved hearing ability in children and young adults fitted with bilateral bone conduction devices.