The following full text is a publisher's version.

For additional information about this publication click this link.
http://hdl.handle.net/2066/85866

Please be advised that this information was generated on 2019-01-07 and may be subject to change.
BONE ANCHORED HEARING AID

CLINICAL OUTCOMES OF THE LINEAR INCISION TECHNIQUE AND BENEFIT ASSESSMENT

Maarten JF de Wolf
BONE ANCHORED HEARING AID

CLINICAL OUTCOMES OF THE LINEAR INCISION TECHNIQUE AND BENEFIT ASSESSMENT
Bone anchored hearing aid
Clinical outcomes of the linear incision technique and benefit assessment
Thesis Radboud University Nijmegen Medical Centre
ISBN / EAN 978-90-9026047-1
© 2011 Maarten J.F. de Wolf

All rights reserved. No part of this publication may be reproduced in any form or by any means, electronically, mechanically, by print or otherwise without written permission of the copyright owner

Financial support for the publication of this thesis was provided by Cochlear Bone Anchored Solutions, Atze Spoorfonds, Oticon Medical, Nationale Hoorstichting/Sponsor Bingo Loterij, Carl Zeiss, Vereniging voor Keel, Neus en Oorheelkunde en Heelkunde van het Hoofd-Hals gebied, Alk-Abelló, GlaxoSmithKline, Specsavers, Stallergenes, Atos Medical B.V., Entermed, Pentax, Bernafon Nederland, Laservision Instruments B.V., Schoonenberg hoorcomfort, Electro Medical Instruments B.V., Beter Horen, Entercare.

2. de Wolf MJF, Hol MKS, Huygen PLM, Mylanus EAM, Cremers CWRJ. Clinical outcome of the simplified surgical technique for BAHA Implantation. Otol Neurotol 2008;29:1100-1108
BONE ANCHORED HEARING AID
CLINICAL OUTCOMES OF THE LINEAR INCISION TECHNIQUE
AND BENEFIT ASSESSMENT

Een wetenschappelijke proeve
op het gebied van de Medische Wetenschappen

PROEFSCHIFT

Ter verkrijging van de graad van doctor
aan de Radboud Universiteit Nijmegen,
op gezag van rector magnificus prof. mr. S.C.J.J. Kortmann,
volgens besluit van het college van decanen
In het openbaar te verdedigen op
dinsdag 12 april 2011 om 15.30 uur precies

door

Maarten Johannes Frederik de Wolf
Geboren op 30 augustus 1979
te Haarlem
Promotores:
Prof. dr. C.W.R.J. Cremers
Prof. dr. ir. A.F.M. Snik

Copromotores:
Dr. M.K.S. Hol
Dr. E.A.M. Mylanus

Manuscriptcommissie:
Prof. dr. M.A.W. Merkx (voorzitter)
Prof. dr. R. de Groot
Prof. dr. D.W. Proops, BDS, FRCS (University of Aston and Queen Elisabeth Hospital, Birmingham, UK)
Aan mijn ouders
Chapter 1  General Introduction

Chapter 2  BAHA surgery using the linear incision technique

2.1  Clinical outcome of the simplified surgical technique for BAHA implantation

2.2  Nijmegen results with application of a bone-anchored hearing aid in children: simplified surgical technique

2.3  Bone-anchored hearing aid surgery in older adults: implant loss and skin reactions

2.4  Bone-anchored hearing aid implant location in relation to skin reactions

Chapter 3  Patient outcome measures

3.1  Age-related use and benefit of the bone-anchored hearing aid compact.

3.2  Benefit and quality of life after Bone Anchored Hearing Aid fitting in children with unilateral or bilateral hearing impairment

3.3  Benefit and quality of life in older Bone Anchored Hearing Aid users

Chapter 4  Discussion

Chapter 5  Summary / Samenvatting

Dankwoord

Curriculum Vitae

List of publications
GENERAL INTRODUCTION
INTRODUCTION

The most common type of hearing impairment is sensorineural hearing loss. Its etiology lies mainly in a dysfunction of the cochlea. Hearing can usually be rehabilitated by means of a hearing aid behind the ear or in the ear canal.

A less common type of hearing impairment is conductive hearing loss. This is mostly caused by a dysfunctional middle ear but sometimes by an occluded external ear canal, as in congenital aural atresia. Sound is no longer transmitted to the cochlea efficiently, resulting in an overall damping of the sound. Patients with a pure or mixed conductive hearing loss have several options for rehabilitation. They may be eligible for reconstructive surgery; if not, an air conduction hearing aid may be appropriate. In some cases these patients cannot use air conduction hearing aids because of congenital malformations of the outer and middle ear or recurrent otitis, mostly due to the occluding earmolds. An option for these patients is a bone conduction hearing aid. Briefly, a bone conduction device transmits sound as vibrations through the skull directly to the cochlea, bypassing the outer and middle ear (Figure 1). The Bone anchored hearing aid (BAHA) comprises an externally worn

Figure 1: Schematic artist’s impression of bone conduction with a Bone anchored hearing aid. 1) BAHA sound processor; 2) Abutment; 3) Implant; 4) stapes fixed on the oval window; 5) round window; 6) Basilar membrane; 7) The cochlea comprises three fluid components: the scala vestibuli and scala tympani containing perilymph and the scala media containing endolymph; 8) longitudinal fluid wave.
audio processor fastened to the skull by a surgically inserted percutaneous coupling. This coupling consists of a skin-penetrating abutment connected to an implanted fixture by means of an inner screw (Figure 1). Since it allows better speech understanding than conventional bone conductor devices, the BAHA is now the gold standard for these patients.1

In Nijmegen the first three patients were fitted with a BAHA in June 1988. This was the starting point of more than 20 years of clinical and audiological research resulting in over 50 publications on various BAHA related fields and up to now four PhD theses. In addition two PhD theses from the Birmingham BAHA team have been defended in Nijmegen. The Nijmegen 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

2002 SN Dutt
   The Birmingham Bone Anchored Hearing Aid Programme, Some audiological and quality of life outcomes

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

2008 A-L McDermott
   The benefit and success of BAHA (bone anchored hearing aids)

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

The present thesis is the fifth BAHA PhD thesis originated in Nijmegen. It presents a clinical evaluation of the linear incision technique that was developed in Nijmegen and refined there over the past 15 years. The studies have focused on the pediatric population as well as the (older) adult population.

Before describing the key features of BAHA surgery and patient outcome measures, some background information is provided on bone conduction physiology and osseointegration. The key features comprise a historical overview of the surgical techniques, clinical outcomes in adults, children and older-adults. Finally, the patient outcome measures are introduced.
**Bone Conduction Physiology**

The principle of auditory perception is that sensory cells are effectively stimulated when an acoustic signal is presented. These sensory cells, or inner hair cells, directly activate the (auditory) nerve fibers. As part of the basilar membrane, the hair cells detect deflections of this membrane. Movement of the basilar membrane, which is caused by sound stimulation, can be achieved in two ways: via the air conduction pathway and via the bone conduction pathway.

![Figure 2: Schematic artist's impression of three phenomena describing bone conduction physiology: 1) Sound energy radiation concept; 2) Bone conduction concept. 3) Bone compression concept.](image)

In the **air conduction pathway**, the acoustic signal travels through the external ear canal and is transformed into vibrations by the eardrum. These vibrations are transmitted to the cochlea via the middle ear ossicles. The third ossicle, called the stapes, is connected to the scala tympani by the oval window (Figure 1). The vibrating stapes induces a longitudinal fluid wave, traveling from the oval window to the (highly mobile) round window. As the fluid moves, in respectively the upper and lower scala (scala vestibuli and scala tympani), it produces a 'traveling wave' of the basilar membrane, with a frequency specific pattern (Figure 1). It is this basilar movement that stimulates the sensory hair cells.
As yet, the bone conduction pathway is not entirely understood. Bone conduction hearing is a result of vibration of the skull bone, e.g. by a vibrator placed behind the ear. The skull transmits such vibrations with relatively high efficiency. Vibrations of the bony cochlear shell cause the fluids in the cochlea to vibrate. This fluid is incompressible, so in principle it should vibrate in phase with the bone. But in effect the cochlea has two mobile windows; the oval and round window. The inertia of the inner-ear fluids will result in longitudinal fluid waves from one window to the other, causing the basilar membrane to vibrate, as in air conduction transmission (Figure 1). Furthermore there are several other mechanisms (described by Tonndorf 1966) that contribute to the stimulation of the cochlea, these are described below.

First, the cochlear fluids are governed by inertia as explained above (Figure 1).

Second, when a vibration is transmitted to the skull, energy is radiated into the external ear canal by its vibrating bony and cartilaginous walls. This acoustic signal is processed via the air conduction pathway (Figure 2).

Third, owing to the inertia of the middle ear ossicles the vibrating skull bone results in penduling ossicles. This effect occurs at its own characteristic frequency (in humans approximately 2 kHz) and, subsequently, the inner ear is stimulated in the normal way (Figure 2).

Fourth, the walls of the cochlea become compressed. When the bone surrounding the inner-ear fluid compartments vibrates, the fluid compartments themselves will be compressed. These compartments have different volumes; the scala vestibuli is relatively large compared to the scala tympani because of the fluid connection between the scala vestibuli and the vestibule. Thus, in the presence of mobile cochlear windows, the compression will lead to displacement of fluid and the basilar membrane. As the upper scala (scala vestibuli, connected to the vestibule), is much larger than the scala tympani (Figure 2).

Fifth, the cranium is connected to the cochlea at several points. Any vibrations in the cerebrospinal fluid caused by skull vibrations can reach the cochlea through these connections. They can then induce an additional longitudinal fluid wave there. However, this will only occur if the cochlear windows are mobile.

Bone conduction hearing works but is far less effective than air conduction. It produces the same type of stimulation as air conduction.
When a pure tone is transmitted via bone conduction it can be cancelled by simultaneously presenting a tone with the same frequency via air conduction of the same perceived magnitude (in dB HL).

HISTORICAL OVERVIEW OF THE OSSEO-INTEGRATION CONCEPT

The term osseointegration means “direct contact between living bone and an implant surface” and was coincidentally discovered by Per-Ingvar Brånemark. In 1950 this biologist discovered that the titanium inspection chambers he used to observe red blood cells in the bone marrow of rats were fixed to the bone and could not be removed. It was not until the early 1960s that he conducted further research on this phenomenon. It led to the introduction of osseointegrated titanium implants for dental prostheses in 1965. The osseointegration concept was studied extensively by the biomaterials group at the Department of Biomaterials and Handicap Research, within the Institute (BHI) of Surgical Sciences, Gothenburg University, Sweden. They found that the clinical success of osseointegrated titanium implants in dentistry depends on several factors.

1. Commercially pure titanium is the best material to use.
2. A screw shaped implant results in the largest bone-to-metal surface without fibrous tissue.
3. The screw surface blasted for 75 micro meter is the most stable.
4. Bone condition must be optimal, e.g. no irradiation or infection present.
5. Bone is heat-sensitive, so during surgery the temperature should not rise over 47°C for more than one minute.
6. Direct loading does not stimulate the osseointegration process.

Professor Hallén of Sahlgrenska University Hospital in Sweden was the first to attach a bone conduction transducer to a patient’s dental implant. Thereby, the first step had been taken toward hearing rehabilitation through this system. In 1977 Tjellström fitted the first patients using the Brånemark implant to apply a BAHA. This was the first time a titanium implant was used outside the oral cavity.
HISTORICAL OVERVIEW OF BAHA SURGERY

In essence BAHA surgery has two major goals: placement of an implant capable of optimal osseointegration and preparation of an implant site that minimizes the occurrence of soft tissue reactions surrounding the implant in the future. To enable optimal osseointegration, the bone should be traumatized as little as possible. The temperature of the bone during drilling should not rise over 47°C for more than one minute. Therefore, the surgeon must only use sharp drills. Moreover, the drill speed should be low, between 1500 and 3000 rounds per minute. The placement of the implant itself should be done at a rotation speed of between 8 and 15 rpm. During the entire drilling procedure cooling is necessary by means of saline irrigation. To minimize the occurrence of post operative soft tissue reactions around the part of the implant that penetrates the skin (abutment), tissue movement should be restricted. Subcutaneous tissue reduction is done to prevent soft tissue movement and the subsequent development of scar tissue and infection around the implant. Also hair follicles in an area of approximately 1 to 3 cm surrounding the implant should be removed to avoid accumulation of debris and skin irritation. The aim is to provide a thin hairless skin site that can attach itself firmly to the deeper bony layer.

Figure 3: Schematic illustration of fixture placement.
Gothenburg

The initial BAHA surgical technique was developed in Gothenburg, Sweden and was described by Tjellström in 1981. At that time 14 patients were implanted in two surgical sessions at an interval of three to four months. In the first session a retroauricular incision was made, just below the linea temporalis, incising the periosteum as well. A burr hole of approximately 4 to 6 mm deep was prepared and was subsequently threaded with a titanium tap. Next, the implant was placed, the periosteal flap was tightly sutured around the implant and the skin flap was sutured separately. In the second surgical session a hole was punctured in the skin and the subcutaneous tissue above the implant, after which an abutment was screwed onto it. In the early days of BAHA surgery, soft tissue reduction was not performed. It was noted that a few patients with a thick subcutaneous layer and a skin with sebaceous glands experienced skin irritations. One remedy could be to locally excise the skin and cover it with a thin graft from the arm. Alternatively, the surgeon could trim a thick subcutaneous flap over the implant site. These solutions would later become major issues in BAHA surgery.

In a second report in 1983 looking back on their five years of experience, Gothenburg BAHA team described two modifications to the surgical

Figure 4: schematic overview of the surgical technique based on a free split thickness skin graft used in the early days of BAHA surgery.
technique. Since then, surgeons have used a spiral drill to widen the hole and a counter-sink to level the bone surface with the purpose of obtaining optimal contact with the flange of the implant. Figure 3 is a schematic illustration of the implant placement is presented in. The second modification was that, during the second stage of the procedure, the soft tissue is reduced such that the skin slopes nicely down towards the implant area. If the skin is free of hair follicles, the local skin flap is thinned out as much as possible. But if the implant is situated in a region with hair follicles a pedicled or free skin graft is used to establish a hair free zone of at least 7 mm around the implant. Figure 4 gives an impression of the procedure. A plastic healing cap is placed on the implant to keep an ointment-soaked gauze dressing in place for a period of 7 to 10 days. After removal the patient is asked to clean the area daily and apply a mild antibiotic ointment like Terra-Cortril® for two weeks.

In 1989, a new one stage surgical technique was developed in Sweden. In maxillofacial surgery, the interval between placement and loading of the implant is three to six months. This much time is needed for osseointegration that is sufficient to withstand the forces of chewing. Regarding BAHA placement, however, the forces impinging on the implant are much weaker. Therefore the modification to one-stage surgery could be adopted and it has since become the gold standard in adults. In one-stage surgery, soft tissue handling is performed directly after the implant is placed. The major clinical benefit of this technique is that it reduces healing time to between six and ten weeks after placement. This is much shorter than the three to six months initially required between the first- and second- stage surgery plus the four weeks it took for the soft tissue to heal after the second stage.

To improve the outcome, over the years, the skin flap technique was used as an alternative to avoid a free skin transplant from the retro auricular fold. It was also used when there are hair follicles at the implant site. The anterior based skin flap was made thin with a blade to remove the hair follicles. However, some say that this technique is time consuming. Moreover, they say there is a risk of developing partial necrosis of the skin flaps and a potential to develop adverse skin reactions when hair follicles are still present. To avoid this complication, the technique was standardized by developing of a dermatome, which was introduced in 2001 (Figure 8B).
This device renders a split skin flap 25 mm in width with a thickness of 0.6 mm. The base of the flap is placed at the anterior end. However, the direction of the flap is not of vital importance. The hair follicles bearing soft tissue is removed underneath the flap and the surrounding tissue, thereby providing a gentle sloping of the skin. The periosteum is partly removed in an area of approximately 5 to 7 mm around the implant. The flap is sutured down on the thicker layer of periosteum.\(^\text{25}\)

In 2003 the newly designed self-tapping implant was implemented in Sweden (Figure 5a and 5b). Facilitating the BAHA implantation procedure, tapping was no longer necessary before insertion. Also the introduction of a pre-mounted bone implant to the BAHA coupling made BAHA surgery easier.\(^\text{23}\) More recent developments concentrate on coated surfaces for the implant and newly designed angulated abutments.
Nijmegen

In Nijmegen BAHA surgery started in June 1988, initially the Gothenburg technique was used.\textsuperscript{21,26,27} Early studies reported on clinical outcome of the first 36 patients (38 implants) who had been fitted with a BAHA using the two-stage technique.\textsuperscript{21,26}

Shortly after the first encouraging clinical results of the one-stage surgical technique from Gothenburg,\textsuperscript{20} an alternative one-stage surgical technique was developed in 1991.\textsuperscript{28} This technique comprises the same drilling and placement procedure as described above.\textsuperscript{6} However, the technique takes a different approach to soft tissue handling (Figure 6):

1. The incision is longitudinal instead of semi-circular, allowing the surgeon to reduce the subcutaneous tissue around the implant site more extensively over an area of 2 cm around the incision.
2. The periosteum is removed over an area of approximately 1 to 2 cm around the intended implant site providing the opportunity for a deeper soft tissue reduction than the Gothenburg technique.
Initially, following the skin incision and implantation, a free skin graft (without hair follicles) is transposed from the retroauricular fold, then thinned and sutured over the implant. The skin graft then makes direct contact with the bone tissue. Finally, the graft is punctured over the implant so that the abutment can be placed. The healing cap placement interval is now shortened to six or seven days. Further treatment consists of applying an antibiotic ointment daily or every other day.

Due to the increased risk of skin necrosis using a free retroauricular graft another adaptation was made. It resulted in the currently used linear incision technique. In 1999 van der Pouw et al. reported the first short-term clinical results of a more simplified one-stage surgical technique. (Figure 7) The new method implied a pure longitudinal incision. A free skin graft was no longer applied. This new technique is described extensively in Chapter 2.1. Recently a surgical guide was provided for the linear incision technique. (Cochlear BAS, Gothenburg, Sweden).29,30

**Birmingham**

In 1996 Proops et al. reported the results of BAHA surgery at their clinic.31 For their first 60 patients they also employed the two stage technique.6 Unlike their colleagues in Gothenburg20 and Nijmegen28, the Birmingham BAHA team used the Rothera method, another one-stage surgical technique for soft tissue reduction (Figure 8A).31,32

The Rothera method consists of a free local split skin graft. The graft is harvested from a flat mounted heap (injected with local anesthetic fluid) by means of a silver’s dermatome or a number 10 surgical blade. The periosteum remains in place while, the surrounding soft tissue is undermined. After implant placement, the split skin graft is replaced and punctured allowing the abutment to be fitted.32

Another surgical technique used in Birmingham consists of a thinned pedicle flap (Figure 8C).31 It was developed in the same period as the one-stage Nijmegen linear incision technique. This revised skin flap technique was used in several other clinics.33 The skin flap is inferiorly based because there is less need for undermining inferiorly. The rationale is that gravity would help and the tissues located superiorly could be made thinner (personal communication, Mr Proops).
Other clinics

In Glasgow in 1990, Browning described a Z-plasty technique to transpose a retroauricular hairless skin flap directly into the ear by baring the implant site. This flap was thinned to about 2 mm.34 (Figure 8D)

In Staffordshire in 2000, a modification of Tjellström’s free skin graft technique was introduced. Besides using a retroauricular transplanted skin graft or an inferiorly based skin flap, they used four radial incisions at the implant site to further reduce the soft tissue surrounding the site under direct visual control. The periosteum was reduced as well.35 This technique can be considered in special cases, notably when there is an unusual amount of subcutaneous tissue at the implant site (Figure 8E).

In Herts in 2006, Persaud et al. introduced another technique involving four local skin flaps created by cruciate incisions. In this technique, the hair follicles are removed from the flaps and the soft tissue is removed underneath the flaps and from the surrounding area. The periosteum is also removed.36 (Figure 8F)

In 2009 àWengen, speaking at the Second International Symposium on Bone Conduction Hearing – Craniofacial Osseointegration, which was held in June 2009 in Gothenburg, Sweden, presented his modified dermatome technique. It was combined with a linear incision and trapezoid extensions. The aim of this technique is to provide even wider exposure with smaller skin flaps, thereby reducing the risk of necrosis.

In 2009 Hultcrantz (Stockholm) and Soo (Hong Kong)37 also addressed the Second International Symposium on Bone Conduction Hearing – Craniofacial Osseointegration. There, they presented preliminary clinical results of a modification of the linear incision technique for patients with little or no subcutaneous tissue. In that their modification did not include any subcutaneous tissue reduction. Diabetic patients and patients with too much subcutaneous tissue at the implant site were excluded from this prospective trial. Furthermore a special high abutment of 8.5 mm was used instead of the regular 5.5-mm abutment.

The three surgical techniques that are most commonly used nowadays are the dermatome technique, the pedicled skin flap technique and the linear incision technique.30,38
Introduction

Figure 8: Author's impression of, A: Rhotera technique (1996); B: Dermatome technique (2001); C: Proops technique (1996) (personal communication); D: Z-plasty (1994); E: Radial incision technique (2001); F: Cruciate incision technique (2006).
Clinical outcome measures

Introduction

The clinical outcome measurements of BAHA surgery can be divided roughly into two categories: bony tissue complications and soft tissue complications. These complications may, to some extent, be related to the surgical technique that had been used.

The bony tissue complication is failure of osseointegration, leading to subsequent implant loss. Apart from loss owing to poor osseointegration, extrusion may occur as a result of trauma or infection. Implants may have to be removed because of chronic pain at the implant site. No explanation for spontaneous loss has been offered so far. However, Hwaaja et al. found that in two cases (a spontaneous loss and a surgically removed implant) keratinocytes may play a role in this process. It is thought that keratinocytes block the titanium osseointegration through migration to the implant site. Yet other causes of implant removal unrelated to BAHA surgery are possible: no more benefit because of progressive hearing loss; or successful middle-ear surgery. The latter would eliminate conductive hearing loss, for example in children with a congenital ossicular chain malformation who were initially too young for reconstructive surgery.

Regarding soft tissue, the short-term complications mainly concern inadequate wound healing and skin flap necrosis. Long-term complications mainly comprise skin reactions and hypertrophic skin overgrowing the abutment. Skin reactions around the abutment can be classified by a grading scale developed by Holgers et al (Table 1).

Table 1. The Holgers grading scale for the classification of skin reactions around skin penetrating titanium implants.

<table>
<thead>
<tr>
<th>Holgers grading</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No reaction</td>
</tr>
<tr>
<td>Grade 1</td>
<td>Reddish discoloration of the skin around the implant</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Red and moist surface of the skin around the implant</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Formation of granulation tissue around the implant</td>
</tr>
<tr>
<td>Grade 4</td>
<td>Extensive soft tissue reaction that requires implant removal or leads to implant loss</td>
</tr>
</tbody>
</table>
A skin reaction of Holgers grade 2 or higher is considered a severe reaction in need of treatment.\textsuperscript{3,45} It is suggested that all BAHA implant check-ups should be done with the help of this classification. The Nijmegen BAHA team uses a prefabricated stamp as shown in figure 9. The process of inflammation around the BAHA implant is not fully understood yet. However, the amount of biomarkers containing fluid might be related to a higher Holgers classification. There are also signs of increased soft and bony tissue turnover at inflamed BAHA implant sites.\textsuperscript{46} For hypertrophic skin, there is no grading scale other than indicating that the BAHA processor cannot be used adequately. Interventions like tissue reduction, corticosteroid injections,\textsuperscript{47} or the placement of a higher (8.5-mm) abutment than normal can be considered as ways to solve soft tissue problems.\textsuperscript{48} A predictor for developing hypertrophic skin and major skin reactions is a BMI > 30 Kg/CM\textsuperscript{2} in male BAHA users. In females such a relation has not been found. In these cases a 8.5-mm abutment placement is advised at initial surgery.\textsuperscript{49}

To present a more comprehensive overview of clinical outcomes per surgical technique the identified manuscripts are divided into ‘initial reports’ and ‘currently most used techniques’.

**Initial reports**

The early clinical results of BAHA surgery are from the Gothenburg group. They mainly comprised the pedicled or free skin graft technique (Table 2).\textsuperscript{3-8} A detailed overview per study of these clinical results is given in chapter 2.2 on page 67.
Chapter 1

The current experience

Dermatome technique

The dermatome technique has been evaluated by several clinics (2007 to 2008).\textsuperscript{24,25,42,50-52} Short term complications arise in 0.7% to 1.3% of the cases and consist of flap necrosis in the first six weeks after surgery.\textsuperscript{25,42} Long-term follow-up (mean follow-up of three years) reveals an incidence of 3.3% of skin reactions classified as Holgers grade 2 or higher.\textsuperscript{24} Skin overgrowth was seen in 7.4% of dermatome placed implants (follow-up, zero to four years).\textsuperscript{42}

Skin flap technique

Reports in the literature on the skin flap technique alone are sporadic. One study, by Tjellström and Granström in 2006, shows an incidence of 9.2% necrosis at six weeks post surgery.\textsuperscript{25} In the long term (mean follow-up three years), there was an incidence of 1.6% of Holgers grade 2 or higher skin reactions.\textsuperscript{24}

When most other clinics report their clinical results, they have already mixed the series with outcomes of subsequent interventions. The results would then include the initial use of a skin flap or graft and later surgery using the dermatome technique. To relate the complications to the exact technique used is therefore not possible.\textsuperscript{50,52}

Linear incision technique

The first clinical results of the linear incision Technique were reported in Table 2. Concise overview of the initial reports (1983 to 2000) on the pedicled or free skin graft technique.

<table>
<thead>
<tr>
<th></th>
<th>Short-term follow-up (2.4 to 4.4 years)\textsuperscript{3-8}</th>
<th>Long-term follow-up (6.3 years)\textsuperscript{1}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall implant loss</td>
<td>1.5 to 10.7%</td>
<td>17.4%</td>
</tr>
<tr>
<td>Failed osseointegration</td>
<td>0 to 5%</td>
<td>6%</td>
</tr>
<tr>
<td>Infection</td>
<td>0.4 to 1.5%</td>
<td>0%</td>
</tr>
<tr>
<td>Other (i.e. trauma, removal, chronic pain)</td>
<td>5 to 8%</td>
<td>11.4%</td>
</tr>
<tr>
<td>≥ Holgers grade 2</td>
<td>1.7 to 4%</td>
<td>2.8%</td>
</tr>
<tr>
<td>Graft necrosis (partial / total)</td>
<td>-</td>
<td>9.8% / 0.6%</td>
</tr>
</tbody>
</table>
1994 and concern the free skin graft.53 Two implants were lost (3%). Holgers skin reactions of grade 2 or higher were seen in nine of the 65 patients (14%). The results on the linear incision technique for one-stage surgery show that two implants were lost (6%). Skin reactions of Holgers grade 2 or higher were seen in seven patients (21%).28 There were no significant differences in the occurrence of skin reactions between the implants placed by means of one-stage surgery with a skin graft, two-stage surgery with a skin graft, or one-stage surgery without the use of a skin graft.54

One of the main objectives of this PhD thesis is to compile the long-term clinical results of the one-stage linear incision technique without the use of a skin graft.55-57

**Implant location**

In choosing a location for the implant fixture the surgeon is guided by the distance between the pinna and the eventual position of the audio processor, which must be able to vibrate freely. Some clinics use Computed Tomography (CT) to ascertain adequate bone thickness. This can be particularly useful for BAHA placement in patients with congenital skull deformities.58 Other clinics determine the ideal implant position by means of CT (revealing the thickness of the bone) and determine the patient's best subjective hearing with the test head band.59 A distance of 25 mm from the external acoustic canal (EAC) would be the most ideal place from an audiological perspective.60 However, this is not practical because of the size and position of the auricle. Therefore placement as close to the meatus as possible is advised, taking into account the clinical considerations mentioned above. This usually amounts to approximately 55 mm from the EAC.

Most clinical outcome measures found in the literature concern implant loss and skin reaction around the implant. However, there are only a few reports on predictors of the occurrence of such reactions, i.e. hypertrophic skin and infections. To the best of our knowledge there has not been any study relating implant position to skin reaction.54

Another objective of this PhD thesis is to evaluate implant location in relation to skin thickness and to incidence and degree of adverse skin reactions.
BAHA surgery in children

Introduction

BAHA is applied in children to address different issues than in adults. The younger population is known to have more immature and thinner bone, more appositional temporal bone overgrowth during their growth period, more risk of soft tissue overgrowth and trauma, as well as cleaning problems in the adolescence.61-65 A considerable proportion of the children fitted with a BAHA have congenital (syndromal) malformations of the ear, sometimes combined with skull deformities, which make surgery more challenging.65-68 When weighing BAHA surgery in children, due consideration should be given to the following;

1. Age at implantation
2. Bone thickness
3. Implant position
4. Spare implant and inter-distance
5. Soft tissue reactions

So far, no consensus report has appeared on the ideal age for BAHA implantation. In the USA, stipulations of the FDA approval restrict the application of BAHA to persons aged of five years or older. On the one hand, it is of the utmost importance that children should be rehabilitated at the earliest age possible.69 On the other hand, the age at which sufficient thickness of the bone is reached is four to seven years.66 In the early days of BAHA surgery in children, the age of implantation was lowered to between 1.5 and 2.5 years through bone augmentation techniques (see below) and a prolonged inter surgical staging.65,66,70,71 The general advice was to implant these children at the age of two to four years.65,72 For children too young for implantation, the conventional solution has to be used, namely a transcutaneous coupling of the bone vibrator to the skull. One recent development in this field is a BAHA with the audio processor mounted on a softband, which was introduced in 2001. These children are now being fitted with a BAHA at the age of three months. The BAHA can be applied bilaterally on the softband.73,74 Thereby, it is possible to avoid early titanium implantation, for which the best timing (mostly at age four or five) can be awaited.55,72 The decision ‘when to implant a child’ was initially based on the thickness of the skull. With the application of the transcutaneous bone conductor, the decision can now be based on estimates of normal language development, which is tested regularly to monitor the child’s progress.69,74
As noted above, the thickness of the cortical bone in children is a critical consideration.\textsuperscript{67} Even in ten-year-olds the thickness of the bone might necessitate the use of 3-mm implants. In 50\% to 100\% of the paediatric population, a 3-mm implant is used.\textsuperscript{64,67,75,76} Some reports state that 3-mm implants might increase the risk of osseointegration failure.\textsuperscript{7,22,76} Yet while other studies did not find such a correlation.\textsuperscript{62} Bone thickness of 2.5 mm is considered to require placement of a 3-mm implant without additional procedures.\textsuperscript{66} However, such incomplete inserted implants (when the thickness of the bone is less than 2.5 mm) might lead to implant loss.\textsuperscript{67} Bone augmentation technique with the use of e-PTFE membranes or PGA/PLA or a collagen test membrane (OV4, OV6, Gore & Associates AB WL, Molndal Sweden) might solve this problem.\textsuperscript{61,64,75,77,78} Also a mixture of bone dust and tissue-glue can be used to fill the gap between the implant flange and the cortical bone. However, in most older children, bone of sufficient thickness can be found on the linea temporalis.\textsuperscript{79} In approximately 27\% to 55\% of the cases, the dura or sigmoid sinus was exposed due to insufficient bone thickness.\textsuperscript{62,64,67,75,76,80} Usually, the exposed dura is closed naturally with compact bone.\textsuperscript{64} If a sigmoid bleeding occurs during surgery it can be stopped by implanting the fixture.\textsuperscript{64} Nowadays, BAHA surgery in children is still performed as a two-stage procedure.\textsuperscript{65} In recent years, the one-stage technique has been used, though only in children older than ten years having, a bone thickness of at least 4 mm.\textsuperscript{70,76,81} Lately, some reports have been published on regular one-stage BAHA surgery in children younger than four years, although only in small series.\textsuperscript{76,82} The overall consensus is nonetheless that BAHA two stage surgery should still be the gold standard for children under ten years.\textsuperscript{72}

Another consideration is the appropriate position of the implant, particularly in a child with a congenital ear malformation. For children with an anotia or microtia combined with a congenital ear canal atresia the implant should be placed approximately 6.5 to 7 cm posterior to the presumed location of the ear canal. Positioning it there would facilitate reconstructive surgery if necessary.\textsuperscript{83} In a normal anatomical formation of the child’s skull the implant should be placed at least 5.5 cm posterior to the bony ear canal in order to assure a good position of the BAHA in the future.\textsuperscript{64} The temporal bone grows in an appositional manner, whereby the implant remains in its original position.\textsuperscript{66} As the skull contour is primarily used to determine the position of the implant, conventional radiographs or CT are generally not required for a preoperative assessment of the child. Besides, CT often requires sedation or general anesthesia, which
Chapter 1

exposes these children to extra risk.72 Therefore it is not generally recommended to use CT for implant positioning. Patients with syndromic features might be an exception, as has been reported for Dubowitz syndrome.84

The development of a young child is dependent on exposure to speech and language, which requires hearing.69 When an implant is lost, it takes a new BAHA implant three to six months to fully osseointegrate. To reduce the period of ‘non-usage of the BAHA’, a spare implant can be placed during the initial implantation procedure.62,67,75,81,85 An abutment can then be placed directly after allocation of the sleeper implant. This new abutment can be loaded after a one- to two-week healing period of the surgical wound. In exceptional cases, the sleeper implant cannot be used any more due to tilting of the screw or bony overgrowth caused by oppositional bone growth.67 However, particularly in the developing child, the potential benefit of early loading of the replacement implant outweighs the risk of a useless sleeper. A sleeper implant can be placed on the contralateral side in children with bilateral conductive hearing loss in whom a bilateral BAHA might be considered an option in the future.86 This is done because the ipsilateral sleeper implant is not used very often. Placing the implant on the contralateral side facilitates bilateral BAHA's in the future. Yet little is known of the long-term fate of the unloaded sleeper implant. There is one case report about a sleeper implant that remained unloaded for 20 years. The implant was well integrated and covered with 1 mm bone without signs of resorption.87 This suggests that sleeper implants can still be used after lying dormant for a considerable length of time.

Another major concern regarding BAHA in children is the possibility of soft tissue reactions around the implant.55,62,68,85,88 The paediatric population relies on carers for proper hygiene around the implant. But children might not be willing to let their carers clean the skin around the implant site. Also the tendency for hypertrophic skin to occur, particularly in children, puts them more at greater risk of soft tissue problems. Traditionally this problem was solved by surgery with soft tissue reduction. However several recent studies propose injections with corticosteroids as a treatment option for hypertrophic skin (though not in children).89,90 Another option is to use a longer abutment (8.5 mm instead of 5.5 mm).48 The short-term results in children, (one implant extrusion [out of 16 cases] over a follow-up period ranging from six months to six years) are promising, particularly in a selected paediatric population. The long-term outcomes still have to be fully evaluated.91
Clinical results

In 1992 the first study on implants in children was published by the Gothenburg group.92 Since then several other clinics have published their results.62,64,67,68,70,75,76,81,85,92 The pedicled skin flap or graft technique is still the one most commonly used technique in children. The overall implant loss ranged from 5.3% to 26%. Implant loss due to lack of osseointegration or infection ranged from 2.5% to 13.2%. Most losses occur in the first year of follow-up.62,93 Interestingly, children are more at risk of losing the implant. The incidence of skin reactions of Holgers grade 2 or higher per observation ranged from 1% to 9.4%. The incidence of tissue revision surgery ranged from 6.3% to 27%.

A breakdown of these data is presented in Chapter 2.2 page 71. This study describes the use of the linear incision technique and expands on long-term clinical evaluation in children.

BAHA surgery in older adults

In the literature little is found on the outcome of BAHA surgery in older adults as a separate group. This specific population might be more at risk of losing an implant because of increased bone resorption, osteoporosis, unfavorable loading, adverse skin reactions, or inability to clean the skin around the implant.93 Drinias et al.93 evaluated 131 osseointegrated implants, 67 of which were BAHA implants, the rest being implants used for attaching auricular epithesis. They found that advanced age was significantly correlated with a higher implant loss. Blood flow in the bone at the end of the drilled hole as measured by laser Doppler flowmetry was significantly less in the older adult. The authors suggest that the decreased blood flow might be a risk factor for implant loss.

A specific study to evaluate BAHA fitting in the older adult is presented in Chapter 2.3.
PATIENT OUTCOME MEASURES

Introduction

An important outcome of medical treatment, apart from the clinical and audiological outcome measures, is subjective benefit, which reflects the patients’ own view of their health status. The World Health Organization has extended the definition of health to embrace the psychological and social domains. These issues can be measured with generic and disease-specific validated questionnaires. While generic instruments enable comparisons of health status, they often fail to capture aspects that are important to a specific clinical setting, such as hearing impairment. Thus, they might lack the sensitivity to assess the benefit in a patient’s sense of well-being after treatment. In other words, the changes are too small to be detected by these instruments. In contrast, disease-specific instruments assess impairment of function, in this case hearing impairment and communication. These questionnaires measure not only disability, but also handicap and are therefore more responsive to changes in hearing status.

To be acceptable, a questionnaire designed to evaluate a change in hearing status should cover several aspects:

1. Questions on the patients’ opinion about his or her general state of health and related quality-of-life questions.
2. The benefit of specific hearing interventions on the general quality of a patient’s day-to-day life.
3. The effect of the initial and remaining hearing impairment on the individual’s functioning in daily life and on one’s sense of being handicapped.

To acquire reliable data, one’s experience with improved hearing (a new hearing device) should not be too long, minimizing recall bias. To that end, prospective studies should be preferred to retrospective studies. However, on the other hand, patients must have sufficient experience to give an adequate response. Since feelings of gratitude or enthusiasm should not affect the outcome, it is advisable to use a long evaluation period minimizing the enthusiasm bias. To the best of our knowledge, no single questionnaire meets all the criteria mentioned above. Therefore, in this PhD thesis, several well-known validated questionnaires have been used in parallel.
Introduction

BAHA patient outcome

History

In one of the first studies to be carried out on subjective BAHA evaluation, published in 1989, the patients were asked not only about audiometric improvements, but also for their opinion on benefit they had derived from the device. In the mid nineties, the Nijmegen group

Table 3. Overview of questionnaires used in this thesis.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Full name</th>
<th>Type</th>
<th>Number of Items</th>
<th>Number of Domains</th>
<th>Scale Range</th>
<th>Used For</th>
<th>Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>APHAB</td>
<td>Abbreviated Profile of Hearing Aid Benefit</td>
<td>Disease Specific</td>
<td>24</td>
<td>4</td>
<td>Ease of communication, background noise, reverberation and evasiveness of sound</td>
<td>1-99</td>
<td>Snapshot of the situation Benefit</td>
</tr>
<tr>
<td>GBI</td>
<td>Glasgow Benefit Inventory</td>
<td>Disease Specific</td>
<td>18</td>
<td>3</td>
<td>General, social, physical health</td>
<td>-100/+100</td>
<td>Benefit</td>
</tr>
<tr>
<td>GCBI</td>
<td>Glasgow Children's Benefit Inventory</td>
<td>Disease Specific</td>
<td>24</td>
<td>5</td>
<td>General, emotional, physical health, learning, vitality</td>
<td>-100/+100</td>
<td>Benefit</td>
</tr>
<tr>
<td>HHIE-S</td>
<td>Hearing Handicap Inventory for the Elderly [screening version]</td>
<td>Disease Specific</td>
<td>20</td>
<td>2</td>
<td>Emotional consequences and social/situational effects</td>
<td>0-40</td>
<td>Handicap</td>
</tr>
<tr>
<td>HUI3</td>
<td>Health Utility Index (Mark 3)</td>
<td>Generic</td>
<td>15</td>
<td>8</td>
<td>Vision, hearing, speech, ambulation, dexterity, emotions, cognition, pain</td>
<td>-0.36/1.00</td>
<td>Snapshot of health status</td>
</tr>
<tr>
<td>IOI-HA</td>
<td>International Outcome Inventory for Hearing Aids</td>
<td>Disease Specific</td>
<td>7</td>
<td>7</td>
<td>Daily use, benefit, residual activity limitations, satisfaction, residual participation restrictions, impact on others and quality of life</td>
<td>0-5</td>
<td>Device use, satisfaction and disability</td>
</tr>
<tr>
<td>NCIQ</td>
<td>Nijmegen Cochlear Implant Questionnaire</td>
<td>Disease Specific</td>
<td>60</td>
<td>6</td>
<td>Basic sound perception, advanced sound perception, speech production, self-esteem, activity limitations and social interactions</td>
<td>0-100</td>
<td>Snapshot of the situation Benefit</td>
</tr>
</tbody>
</table>
evaluated the BAHA compared to conventional bone conduction and air conduction hearing aids.\textsuperscript{98-101} Amongst other tools they constructed and used their own instrument, called the Nijmegen questionnaire. A more recent, widely used validated questionnaire is the Glasgow Benefit Inventory (GBI), which was first administered used in 2001 and is now widely used.\textsuperscript{102} Several other validated questionnaires have been used in various specific and general BAHA populations.\textsuperscript{62,80,96,103-116} Table 3 gives an overview of the questionnaires covered in this PhD thesis.

Several subsets of questionnaires are used depending on the research questions. All of these questionnaires have been previously applied in BAHA research. The GBI is a common choice for quality-of-life assessment and has been used in the general adult BAHA population.\textsuperscript{102,105,106,112,113,117} The Glasgow Children’s Benefit Inventory (GCBI) is suitable for children and adults with a mental disability.\textsuperscript{62,109,110,118,119} The Abbreviated Profile of Hearing Aid Benefit (APHAB) is frequently chosen for patients with Single Sided Deafness (SSD), for whom the BAHA serves as a trans-cranial CROS device.\textsuperscript{104,116,120-123}

\textbf{Literature results}

In the literature three questionnaires have been deployed to assess subjective benefit: the Glasgow Benefit Inventory (GBI) for adults; the Glasgow Children’s Benefit Inventory (GCBI) on quality of life; and the Abbreviated Profile of Hearing Aid Benefit (APHAB) on the level of disability.

Table 4 presents the mean GBI scores in series of adult BAHA patients with bilateral conductive or mixed hearing loss\textsuperscript{102,124} and those with unilateral sensorineural hearing loss as well as those using a BAHA as a CROS device (contralateral routing of sound).\textsuperscript{120} For bilateral BAHA users the additional BAHA does add some benefit although not statistically significant.\textsuperscript{125}

In children, the GCBI, has been used to evaluate the benefit of the BAHA. The GCBI was also used previously to evaluate children with unilateral hearing loss as well as mentally retarded patients from the Nijmegen BAHA center (Table 4).\textsuperscript{118,126}

The subjective benefit was also assessed by means of the APHAB. This questionnaire was administered twice: once to obtain a ‘snapshot’ of the current situation with the BAHA and the second time to investigate the unaided situation. In the BAHA literature the APHAB is mostly applied.
to evaluate unilateral sensorineural hearing deafness (SSD) (Table 4).\textsuperscript{104,116,120-123}

Another instrument is the simple overall questionnaire to measure the outcomes of hearing aid fitting is the International Outcome Inventory for Hearing Aids (IOI-HA). It deals with aspects such as use of the hearing device, satisfaction, and disability.\textsuperscript{127,128} The IOI-HA has been applied to evaluate BAHA benefit in patients with unilateral sensorineural hearing loss, after six weeks and after one year of BAHA use\textsuperscript{123} (Table 4).

To the best of our knowledge, there has not been any hearing handicap study (HHIE-s) on BAHA use. A similar questionnaire, the Hearing Handicap and Disability Index (HHDI), has been administered to patients with symmetric perceptive hearing loss who regularly use a unilateral air conduction hearing aid.\textsuperscript{129}

On a generic level, the HUI3 would serve to assess a general state of health (generic health-related quality of life questionnaire). The HUI-3 is a multi-attribute preference-based instrument to measure general health-related quality of life.\textsuperscript{80,130,131}

\begin{table}[h]
\centering
\begin{tabular}{|l|c|c|c|}
\hline
 & Conventional BAHA users & Bilateral BAHA user (range) & Unilateral BAHA user & BAHA CROS user \\
\hline
GBI & 103 & 125 & 123 & \\
Total & 31 - 33 & 38 (33 - 34) & 17 - 20 & \\
General & 37 - 42 & 50 (43 - 57) & 25 - 28 & \\
Social & 23 - 24 & 14 (8 - 21) & 26 - 31 & \\
Physical & 11 - 14 & 18 (11 - 25) & 12 - 13 & \\
\hline
GCBI & 127 & 127 & \\
Total & 51 & 34 & \\
Emotional & 53 & 31 & \\
Physical & 38 & 29 & \\
Learning & 64 & 60 & \\
Vitality & 51 & 12 & \\
\hline
APHAB & 103, 117, 121, 124 & \\
Ease of communication & 5.8 - 16.2 & \\
Reverberant rooms & 15.8 - 26.4 & \\
Background noise & 15.7 - 33.1 & \\
Aversiveness to sound & 11.4 - 9 & \\
\hline
IOI-HA & 6 wks (1 year)\textsuperscript{24} & \\
Use & 4.6 (4.2) & \\
Benefit & 3.5 (3.4) & \\
Residual activity limitation & 3.9 (3.5) & \\
Satisfaction & 4.0 (3.7) & \\
Residual participation restriction & 4.2 (4.0) & \\
Impact on others & 4.5 (4.4) & \\
Quality of life & 4.1 (4.0) & \\
\hline
\end{tabular}
\caption{Overview of questionnaire outcome in BAHA literature.}
\end{table}
The Nijmegen Cochlear Implant Questionnaire (NCIQ)\textsuperscript{132} can provide a snapshot of the current situation regarding BAHA use.\textsuperscript{132,133,134} This questionnaire is a disease-specific ‘disability and handicap’ instrument initially designed for patients with cochlear implants. It is known to be sensitive to hearing-related quality-of-life issues in patients with cochlear implants and can elucidate the current situation regarding hearing aid use. It consists of 60 items in six subdomains: Basic Sound Perception (BSP), Advanced Sound Perception (ASP), Speech Production (SP), Self-Esteem (SE), Activity Limitations (AL) and Social Interactions (SI). The former three subdomains are disability-specific, while the latter three are handicap-specific.

To the best of our knowledge there has not been any study applying the NCIQ to evaluate patients using a BAHA. However, it has been used for patients with other auditory implants and conventional hearing aids.

In the study reported in chapter 3.1, patients with conductive or mixed hearing loss were asked to evaluate the BAHA by means of the International Outcome Inventory - Hearing Aid (IOI-HA). Of particular interest were their responses on age-related use and patient satisfaction.

The next Chapter (3.2) evaluates, a distinct group of BAHA users: children with unilateral conductive hearing loss or bilateral conductive hearing loss. The Glasgow Children’s Benefit Inventory (GCBI), the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Health Utility Index Mark 3 (HUI-3) were used to assess disease specific benefit and general quality of life.

Chapter 3.3 deals with benefit and quality of life issues for the older adult BAHA population. That study evaluated 134 older adult BAHA users by administering four questionnaires: the Glasgow Benefit Inventory (GBI); Abbreviated Profile of Hearing Aid Benefit (APHAB); Nijmegen Cochlear Implant Questionnaire (NCIQ); and the Hearing Handicap Inventory for the Elderly screening version (HHIE-S).
SCOPE OF THIS THESIS

The overall objective of this thesis is to collate clinical data on a specific surgical implantation technique for the Bone anchored hearing aid (BAHA) and present it alongside data on patients’ opinions on the benefit and quality of life they derive from using a bone anchored hearing aid (BAHA). The thesis comprises four chapters.

The first chapter (or introduction) gives an overview of the different types of surgery to place the implant. It covers the application of BAHA and the benefit-related topics found in the BAHA literature.

Chapter 2 deals with BAHA surgery performed with the linear incision technique. In Section 2.1 the linear incision technique is described extensively and the long-term clinical results of a consecutive series of BAHA users are presented. Section 2.2 deals with a specific and challenging group of BAHA users, namely children. It presents the clinical results of the linear incision technique. In Section 2.3 the linear incision technique is evaluated for older adults. The emphasis of this section is on wound healing and complications. In Section 2.4 the relation between implant position, soft tissue reaction, and skin thickness is studied in adult BAHA patients.

Chapter 3 comprises three studies on patient related audiologic benefit outcomes. In Section 3.1 the overall benefit of BAHA users is studied in relation to the patients’ age. Section 3.2 evaluate the benefit of BAHA in the day-to-day lives of children with unilateral conductive hearing loss, as well as the benefit to those with bilateral conductive or mixed hearing loss, using validated questionnaires. Chapter 3.3 evaluates subjective benefit and quality of life in older adult BAHA users with mixed hearing loss.

Chapter 4 presents a general discussion. A summary of this PhD thesis in English and Dutch, is provided in Chapter 5.
REFERENCES


Introduction


47. Ghossaini SN, Spitzer JB. Local steroid injections in the management of skin growth over the abutment in BAHA patients. *Otolaryngol Head Neck Surg* 2009;141:530-532.


49. Berenholz LP, Burkey JM, Lippy WH. High body mass index as a risk factor for skin overgrowth with the bone-anchored hearing aid. *Otol Neurotol* 2010;31:430-432.


Introduction


Chapter 1


Chapter 1


121. Hol MKS, Kunst SJW, Snik AFM. Cremers CWRJ. Pilot study on the effectiveness of the conventional CROS, the transcranial CROS and the BAHA transcranial CROS in adults with unilateral inner ear deafness. Eur Arch Otorhinolaryngol 2010;267:889-896.


44


BAHA SURGERY USING THE LINEAR INCISION TECHNIQUE
CLINICAL OUTCOME OF THE SIMPLIFIED SURGICAL TECHNIQUE FOR BAHA IMPLANTATION

M.J.F. de Wolf
M.K.S. Hol
P.L.M. Huygen
E.A.M. Mylanus
C.W.R.J. Cremers
ABSTRACT

Objective: To evaluate the clinical outcome of a simplified surgical technique for BAHA implantation, in terms of implant failure and its causes.

Design: Retrospective analysis.

Methods: Analysis of a consecutive cohort of 142 patients (150 loaded implants) fitted with the BAHA implant between January 1, 1997, and December 31, 1999. The simplified surgical Nijmegen technique comprises a longitudinal post auricular incision, extensive subcutaneous tissue reduction, and removal of the periosteum. Clinical outcomes were the rate of implant failures, its causes for this, and skin reactions around the percutaneous implants classified according to Holgers. Clinical results were compared with other BAHA series.

Results: Mean follow-up was 5.6 ± 2.7 years (range, 0-10.5 yr). Holgers grade 2 or more severe skin reactions were seen in 6.5% of the 1,038 follow-up visits. Extrusion of the implants occurred as a result of failed osseointegration (N = 3), trauma (N = 5), infection (N = 1), and (other) medical reasons (N = 5 explanations). Total extrusion rate was 9.3%. Only 3% (1 and 3) were due to failed osseointegration or infection around the percutaneous implant.

Conclusion: The modified Nijmegen surgical technique is a simple straightforward surgical procedure without the use of a pedicled skin flap. Surgery takes approximately 20 minutes. Meticulous performance of the procedure is considered important to achieve optimal results in the long-term. Particularly the soft tissue reduction has to be done with great care. In terms of the low rates of implant failure and adverse tissue reactions, the Nijmegen surgical technique proved to be a good alternative to other techniques.
INTRODUCTION

In 1977, a percutaneous titanium implant was introduced in a clinical experimental setting to support a skin-penetrating bone conduction hearing aid (BAHA) (Entific Medical systems AB, Goteborg, Sweden). The surgical implantation technique has gradually been simplified. The original 2-stage surgical procedure was reduced to a 1-stage procedure in 1989 and has remained the surgical standard in adults since then. In the early 90s, a simplified surgical technique was developed step by step in Nijmegen. Ultimately, only a longitudinal incision remained, instead of the previous (semi) circular incision, to facilitate wider subcutaneous tissue reduction and to avoid the need for a thinned free skin flap. A thinned free-skin graft was avoided, and the sometimes-associated skin necrosis of the free-skin graft disappeared. Furthermore, the periosteum was removed widely. The duration of surgery dropped to 20 minutes, and only 2 postoperative check-ups were needed. Finally, routine follow-up visits were limited to once a year.

One of the main concerns regarding the percutaneous implant is the skin reaction around the titanium skin-penetrating coupling. Regular cleaning usually prevents skin reactions, and in case of skin reactions, the use of a medical ointment usually treats these reactions successfully. However, skin reactions can have a more serious outcome such as skin overgrowth, skin necrosis, implant extrusion, and more severe wound infections. Also, an intracerebral abscess has been reported as a complication of an abutment change.

The aim of this study was to evaluate long-term clinical data regarding the simplified Nijmegen surgical BAHA implantation technique. Attention is given to the frequency and degree of tissue reaction around the implantation site, extrusion rate, and management of these complications. The surgical procedure is described and illustrated. The clinical results are presented and compared with previously reported results in literature.

PATIENTS AND METHODS

The patient's cohort consisted of 142 patients who were fitted a titanium BAHA implant between January 1, 1997, and January 1, 2000.
Figure 1A-F: Presentation of the surgical technique applied to implant the BAHA implant. A: Implantation location. B: Exposure of the periosteum. C: Drilling procedure and placement of the fixture under saline irrigation. D: Area of subcutis reduction. E: Subcutis reduction procedure. F: Healing cap and position of the yankauer.
Simplified surgical technique for BAHA implantation

technique was used. Two surgeons, C.W.R.J. C. and E.A.M. M., performed the same surgical technique; their combined results are included in this study.

Surgical Intervention of the Nijmegen Surgical BAHA Procedure

The surgical procedure in adults is generally performed in day care. The ideal site of implantation is located mostly approximately 50 to 55 mm posterosuperiorly to the ear canal on the mastoid, leaving enough space posterior to the auricle for the BAHA transducer. A longitudinal incision of approximately 30 mm is made (Figure 1A). After sharp dissection of the subcutaneous tissue, the periosteum is exposed and mobilized (Figure 1B). Next step is the drilling procedure described by Tjellström and Granström. Sufficient cooling is achieved by saline irrigation. The implant is placed, and the implant is control-tightened manually (Figure 1C).

Subsequently, subcutaneous tissue is reduced extensively over an area of approximately 2 cm around the incision. The skin is stretched between 2 hooks; the fingertip of the surgeon is placed on top of the stretched skin, providing the best control to thin the skin maximally, first by excision and, additionally, by scraping away the remaining subcutaneous tissue guided by palpation (Figure 1, D and E). Additionally, the remaining periosteum is removed. The wound is closed with at least 4 sutures. The caudal end of the longitudinal incision is left open for drainage (Figure 1F). During the entire procedure, suction is done by a Yankauer (Tyco Healthcare, Tullamore, Ireland) positioning itself at this location. During closure of the wound, the Yankauer provides a vacuum, avoiding blood retention. The implant is relocated, the skin at this area is punctured with a pouch, and the abutment is placed. In case the implant is in line with the skin incision, puncturing of the skin is not needed. Gauze soaked in antibiotic ointment (Terra-Cortril®) (Pfizer BV, Capelle a/d IJssel, The Netherlands) is wrapped around the abutment after the healing cap is snapped on. Finally, a pressure head dressing is applied around the head for at least 3 hours, preferably 24 hours (Figure 1G). Removal of the Terra-Cortril gauze and healing cap is done in the outpatient clinic at the first visit after 1 week. Further treatment consists of the application of anti-inflammatory ointment (Terra-Cortril®) around the percutaneous implant once a day, for 2 weeks. Preoperative oral antibiotics were not used.
In these series, a total of 15 children were operated in a 2-stage surgical procedure. First, through a longitudinal incision as previously described, 2 implants are placed with a cover screw, and the skin is closed in 2 layers. One implant will be loaded; the other will remain subcutaneous as a "sleeper." Three months later, the second stage is performed on one of the implants as previously described. Only loaded implants were included in the study.

<table>
<thead>
<tr>
<th>Indication titanium implant</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquired conductive / mixed hearing loss</td>
<td>120 (80)</td>
</tr>
<tr>
<td>Congenital conductive hearing loss</td>
<td>27 (18)</td>
</tr>
<tr>
<td>Unilateral inner ear deafness</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Total</td>
<td>150 (100)</td>
</tr>
</tbody>
</table>
Follow-Up

In adults, the BAHA transducer was fitted after a recovery period of 6 to 8 weeks to provide sufficient osseointegration. In this period, 2 return visits were needed. The patients initially had to check up at least once every 4 months. Later, the check-up interval was prolonged to 6 months, and nowadays, once every year is the standard. Patients had to make an outpatient clinic appointment for these yearly check-ups themselves.

Evaluation of the tissue reaction around the abutment was done according to the classification by Holgers et al.8 This was done using a prefabricated table on a stamp in the medical records. Inspection of the temporal bone and the abutment stability on the implant was done manually with the use of specific instruments. These evaluations were done during every outpatient clinic follow-up visit.

Statistics

To determine the extrusion rate, only the loaded implants are noted. When an implant loss occurred within the observed years, the replacement implant was considerate a new implant. Comparisons of categorical variables were made using $\chi^2$ tests or Fisher's exact test. Time-to-event analyses were conducted using the log-rank test and Kaplan-Meier curves. SPSS version 14 (SPSS, Inc., Chicago, IL, USA) and Prism graph pad 5 (GraphPad Software, La Jolla, CA, USA) were used. The level of significance applied was $P = 0.05$. 

![Figure 3: Type of implant loss according to survival time (in months).](image)
RESULTS

One hundred fifty implants were implanted in 142 patients in 1997, 1998, and 1999. Fifty-six patients were men, and 86 were women. The mean age at implantation was 56 years (standard deviation, ± 20 yr). The age distribution is presented in figure 2. One hundred thirty patients were fitted a BAHA on 1 side; 14 patients were fitted a BAHA on 2 sides (bilateral fitting), 6 of which were fitted a second BAHA in the same 3 years. Eight patients received a second implant for bilateral BAHA application in more recent years; these second BAHA implants were excluded from this study.

Table 1 gives an overview of the indications for fitting patients with a BAHA. The most common reasons for fitting a patient with a BAHA in those years were chronically infected ears and minor or major congenital anomalies of the ear.

In 133 cases (88.7%), the 1-staged surgical technique was used. The mean age of these patients was 51 ± 16 years (range, 15-82 yr). In 15 cases (10%), a 2-stage surgical technique was used. This group consisted
Table 2: Life table for BAHA implant in the studies by, Tjellström and Håkansson and the current study.

<table>
<thead>
<tr>
<th>Follow-up period (years)</th>
<th>Current study</th>
<th>Tjellström and Håkansson</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No.</td>
<td>Implant loss</td>
</tr>
<tr>
<td>0-1 y</td>
<td>150</td>
<td>1</td>
</tr>
<tr>
<td>1-2 y</td>
<td>140</td>
<td>0</td>
</tr>
<tr>
<td>2-3 y</td>
<td>134</td>
<td>0</td>
</tr>
<tr>
<td>3-4 y</td>
<td>124</td>
<td>3</td>
</tr>
<tr>
<td>4-5 y</td>
<td>117</td>
<td>2</td>
</tr>
<tr>
<td>5-6 y</td>
<td>110</td>
<td>1</td>
</tr>
<tr>
<td>6-7 y</td>
<td>80</td>
<td>0</td>
</tr>
<tr>
<td>7-8 y</td>
<td>64</td>
<td>0</td>
</tr>
<tr>
<td>8-9 y</td>
<td>39</td>
<td>3</td>
</tr>
<tr>
<td>9-10 y</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>10-11 y</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

mainly of children. One adult (49 years old) was operated in 2 stages because of mental retardation. The mean age of the children in this group at implantation was 9.6 years (range, 4 to 14 yr). One patient only underwent a second-stage procedure in this clinic because the first stage was done elsewhere. In 1 other case, a second-stage procedure was done on a previously implanted sleeping implant.

All 150 implants except 2 were 4-mm implants. A mean of 72 months (range, 0-125 months) of follow-up for each titanium implant and a mean of 6.9 ± 4.5 observations per implant were found.

Figure 3 shows the causes of implant loss (N = 14 [9.3%]). Implant loss was spontaneous in 2% (N = 3), whereas 1 implant was lost due to a Type 4 skin reaction (0.7%). Trauma caused implant loss in 5 patients (3.3%). All lost implants were 4-mm implants. Duration until implant loss ranged from 5 to 55 months (Figure 3): average duration until implant loss was 27 months. One spontaneous loss occurred in a 4-year-old child after 7 months of use. The others occurred in elderly persons aged 62 and 79 years after 55 and 43 months of use, respectively. No explanation was found for the implant loss. A Type 4 skin reaction caused the implant loss in a 12-year-old child after 16 months of use. Survival is shown in Table 2, whereas Figure 4 presents a survival curve.
Table 3: Clinical data on skin reactions (according to Holgers) and revision surgery.

<table>
<thead>
<tr>
<th>Types of skin reactions</th>
<th>Distribution</th>
<th>Most severe skin reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%) Per observation</td>
<td>N (%) Per implant</td>
</tr>
<tr>
<td>0 = no irritation</td>
<td>866 (83.4)</td>
<td>74 (49.3)</td>
</tr>
<tr>
<td>1 = slight redness</td>
<td>105 (10.1)</td>
<td>36 (24.0)</td>
</tr>
<tr>
<td>2 = red and moist tissue</td>
<td>53 (5.1)</td>
<td>27 (18.0)</td>
</tr>
<tr>
<td>3 = granulation tissue</td>
<td>11 (1.0)</td>
<td>10 (6.7)</td>
</tr>
<tr>
<td>4 = infection leading to removal of abutment</td>
<td>3 (0.4)</td>
<td>3 (2.0)</td>
</tr>
<tr>
<td>Total</td>
<td>1038 (100.0)</td>
<td>150 (100.0)</td>
</tr>
</tbody>
</table>

Number of adverse skin reactions

<table>
<thead>
<tr>
<th>Number of adverse skin reactions</th>
<th>N (%) Per observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>74 (49.3)</td>
</tr>
<tr>
<td>1</td>
<td>36 (24.0)</td>
</tr>
<tr>
<td>2</td>
<td>24 (16.0)</td>
</tr>
<tr>
<td>3</td>
<td>3 (2.0)</td>
</tr>
<tr>
<td>4</td>
<td>3 (2.0)</td>
</tr>
<tr>
<td>5</td>
<td>5 (3.3)</td>
</tr>
<tr>
<td>7</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>8</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>9</td>
<td>2 (1.3)</td>
</tr>
<tr>
<td>10</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>Total</td>
<td>150 (100.0)</td>
</tr>
</tbody>
</table>

Revision surgery

<table>
<thead>
<tr>
<th>Revision surgery</th>
<th>N (%) Per observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subcutis reduction</td>
<td>10 (43.5)</td>
</tr>
<tr>
<td>Reduction skin-overgrowth</td>
<td>9 (39.1)</td>
</tr>
<tr>
<td>Second stage</td>
<td>4 (17.4)</td>
</tr>
<tr>
<td>Total</td>
<td>23 (100.0)</td>
</tr>
</tbody>
</table>
A total of 1,038 observations of the skin around the abutment were recorded during the follow-up period of 10,765 months. No abnormalities were found in 866 observations (83.4%). An overview is given in Table 3.

Adverse skin reactions were observed in 172 cases; 61% was Type 1 skin reactions, 30.8% was Type 2, 6.5% was Type 3, and only 1.8% was Type 4 skin reaction.

Table 3 shows the adverse skin reactions. There were no episodes of skin reaction in 74 patients (49%), whereas 76 patients (51%) showed some sort of skin reaction. The most severe tissue reaction in each patient is presented in Table 3. Type 4 skin reactions were observed only 3 times. This (Type 4 reaction) led to failure of 1 implant and to temporary removal of 2 abutments to allow the skin to heal.

Holgers grade 2 skin reactions or higher occurred at some point during follow-up in a total of 40 implants (27%). In 8 of these implants, the patients were younger than 16 years. This accounted for 50% of the children in this study (N = 16). In the older patients (N = 134), only 32 implants had a Holgers grade 2 skin reaction or higher (24%). The difference between the age groups was significant (P = 0.03).

In the first 60 months of implant use, Holgers grades 2 to 4 skin reactions arose in the interval mostly from 11 to 21 months (median, 16 months; 95% confidence interval), whereas Holgers grade 1 reactions mostly arose between 20 and 58 months (median, 39 months; 95% confidence interval). After 60 months of use, there were no longer any differences in occurrence between the groups.

Tissue revision surgery took place 23 times in 20 patients (15%): 8 times because of skin overgrowth, 10 times because of thick tissue around the abutment, and 4 times as part of second-stage surgery after spontaneous loss or trauma to the abutment (Table 3).

In these 20 patients, second revision surgery was needed in 3 cases: 2 patients needed a second operation to reduce the subcutaneous tissue, and 1 patient needed surgery after spontaneous abutment loss and a second episode of tissue overgrowth around the new abutment, both needed revision surgery. Average interval until the first tissue reduction operation (N = 16) was 39 months (range, 5-86 months). Holgers grade 2 skin reaction or higher was present in 3 cases at the time of revision surgery, whereas 9 implants had shown Holgers grade 2 skin reactions or higher at some time during the period before tissue revision surgery. Thus,
9 of the 40 implants that had a Holgers grade 2 skin reaction or higher also needed tissue revision surgery. This was a significant difference compared with the 7 implants in the group with the Holgers grade of lower than 2 (N = 110) (P = 0.003). There was no significant difference in the need for tissue revision surgery between adults and children.

When thick skin was persistent or recurrent, an 8.5-mm abutment placement can be a useful solution besides revision surgery. This was done in 6 cases, and all were successful.

**DISCUSSION**

Since Tjellström et al.\(^1\) first introduced the BAHA system in 1977, it has undergone adaption at several clinics worldwide. Over the years, the surgical procedure has been adjusted. Several BAHA teams have reported their modifications to the technique.\(^5,10,14-21\) In essence, there are 2 major goals: osseointegration and the prevention of soft tissue reactions. Subcutaneous tissue reduction prevents soft tissue movement and subsequently reduces the development of scar tissue and infection. The aim is to provide a thin hairless skin site that can attach itself to the deeper bony layer.

Overall, the surgical techniques used by several experienced surgeons vary in their methods of soft tissue reduction. The issues are whether the periosteum should be removed and whether a skin graft can be avoided. Initially, a free retroauricular skin graft was used,\(^10,19\) which later mostly became a local skin flap.\(^16,19\) In more recent years, several surgeons have made modifications to the surgical procedure: some started to use a dermatome to create the skin flap,\(^10,18\) others used cruciate incisions in a circle\(^15\) or a circular incision with 4 radial incisions into the surrounding tissue.\(^17\)

In Nijmegen, Mylanus and Cremers\(^6\) initially used a linear incision and a retroauricular split-thickness skin graft. The main difference was the longitudinal incision instead of a round or U-shaped one. The intention was to facilitate more extensive subcutaneous tissue reduction and removal of the periosteum while keeping tissue trauma to a minimum. Since then, a few additional modifications have been made to discontinue the use of a free-skin graft.
<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Location</th>
<th>N**</th>
<th>Mean follow-up in years ± SD (min–max)</th>
<th>Type of surgery</th>
<th>Skin reactions</th>
<th>Complications</th>
<th>Implant loss</th>
<th>% T&amp;R loss</th>
<th>N (No. loaded implant)</th>
<th>% Loss (tot. implants)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BAHA implants N ≥ 100</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current study</td>
<td>2008</td>
<td>Nijmegen</td>
<td>142</td>
<td>5.6 (0 – 10.5)</td>
<td>Linear incision</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>House and Kurtz</td>
<td>2007</td>
<td>California</td>
<td>149</td>
<td>NA (0 – 4)</td>
<td>Split-thickness flap / dermatome</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tjellström, et al.</td>
<td>2007</td>
<td>Göteborg</td>
<td>138</td>
<td>1.9 (0.4 – 3.4)</td>
<td>Dermatome</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tjellström and Granström</td>
<td>2006</td>
<td>Göteborg</td>
<td>76</td>
<td>0.1 (0 – 0.1)</td>
<td>Skin flap</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reyes et al.</td>
<td>2000</td>
<td>Göteborg</td>
<td>149</td>
<td>6.7*** (0 – 8)</td>
<td>Skin graft</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Van der Pouw et al.</td>
<td>1999</td>
<td>Nijmegen</td>
<td>155</td>
<td>0.7 – 7</td>
<td>Skin graft (N= 131) / linear inc. (N= 32)</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poops et al.</td>
<td>1996</td>
<td>Birmingham</td>
<td>188</td>
<td>NA (0 – 9)</td>
<td>Skin graft</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tjellström and Håkansson</td>
<td>1995</td>
<td>Göteborg</td>
<td>149</td>
<td>2.7*** (0 – 5)</td>
<td>Skin graft</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tjellström and Grandström</td>
<td>1994</td>
<td>Göteborg</td>
<td>100</td>
<td>8 – 16</td>
<td>Skin graft</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tjellström et al.</td>
<td>1989</td>
<td>Göteborg</td>
<td>230</td>
<td>4.4 (0 to 11)</td>
<td>Skin graft</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BAHA implants N &lt; 100</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shirazi et al.</td>
<td>2006</td>
<td>Maywood</td>
<td>58</td>
<td>NA (1 – 3)</td>
<td>Superficial based skin flap</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persaud et al.</td>
<td>2005</td>
<td>Herts</td>
<td>21</td>
<td>NA</td>
<td>4 thin local skin flaps</td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lekakis et al.</td>
<td>2005</td>
<td>Kent</td>
<td>11</td>
<td>0.8 – 3.3</td>
<td>Full thickness skin flap</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gillett et al.</td>
<td>2006</td>
<td>Ashfort</td>
<td>63</td>
<td>2 – 9</td>
<td>Skin graft</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Snyder et al.</td>
<td>2003</td>
<td>Omaha</td>
<td>15</td>
<td>NA</td>
<td>Full thickness skin graft</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mylanus &amp; Cremers</td>
<td>1994</td>
<td>Nijmegen</td>
<td>33</td>
<td>0.8 – 2.1</td>
<td>Linear incision + graft</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Holgers et al.</td>
<td>1988</td>
<td>Göteborg</td>
<td>60</td>
<td>0.3 – 8</td>
<td>Skin graft</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tjellström et al.</td>
<td>1995</td>
<td>Göteborg</td>
<td>214</td>
<td>0 – 5</td>
<td>Skin graft</td>
<td>Grade ≥ 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NA = No data available * Number / patient ** Number of included patients *** personal communication O = Osseointegration I = Infection T = Trauma R = Other causes for loss or removal # = same population**
This modified Nijmegen surgical technique has several advantages. First, a 2.5 to 3-cm longitudinal incision causes only minimal disturbance of the skin at the graft site. Second, soft tissue can be reduced extensively (over an area of approximately 6 by 4 cm \([18.9\, \text{cm}^2]\)) because of the wide scope of the scalpel and because of the removal of the periosteum. Third, it is no longer necessary to preserve the periosteum to facilitate graft perfusion. Fourth, absence of a pedicled or free-skin graft completely avoids necrosis. According to the literature, the periosteum was traditionally left in situ to maintain an adequate blood supply to the skin graft.\(^{11,19,22,23}\) With the Nijmegen surgical technique, the small longitudinal incision causes only minimal tissue damage and does not disrupt the adequate blood supply in the outer layers of the skin; therefore, the periosteum can be removed. No skin necrosis occurred in the population evaluated in this study. Fifth, in experienced hands, the surgical procedure takes an average of 20 minutes. Sixth, the children in another Nijmegen\(^{24}\) study attended an average of only 1.8 ± 0.8 check-ups in the first 4 months after implantation, which indicated quick and uneventful recovery.

In the literature, we focused on larger studies (\(N \geq 100\)) with a relatively long follow-up period. In these studies, overall implant loss was 5.5 to 17.4%. In this study, we found 9.3% implant loss, which is in line with the literature.\(^{9,16,20,25}\)

In evaluating BAHA surgical procedures, however, implant loss due to osseointegration and infection are considered to be directly related to the surgical procedure and are therefore presented separately. Loss due to failed osseointegration ranged from 0.4 to 7%, and loss due to infection ranged from 0.4 to 2.7% (Table 4).\(^{5,9-11,14,16,20,26}\) Implant loss rates due to failed osseointegration and infection in this study on a total of 150 implants were 2% and 0.7%, respectively. These rates were comparable with earlier Nijmegen BAHA team reports. Of 163 implants, van der Pouw et al.\(^{25}\) lost 1 implant (0.6%) because of failed osseointegration and 3 (1.8%) because of infection. With respect to failure due to infection, the outcome of this Nijmegen study was comparable with the literature.

Overall loss due to failed osseointegration was relatively rare. Nevertheless, implant loss was significantly higher in Birmingham (14 [7%] of the 188; \(P = 0.024\))\(^{16}\) and in Gothenburg (9 [6%] of the 149; \(P = 0.05\))\(^{9}\) than in this Nijmegen series (3 [2%] of the 150). This might suggest that the long-term results of osseointegration with the Nijmegen surgical
Simplified surgical technique for BAHA implantation

In the literature, adverse skin reactions have been described several times by means of the Holgers classification. The literature states a 3.7 to 8% incidence of adverse skin reactions when all adverse skin reactions (Holgers grades 1-4) are taken into consideration.\(^4,5,9,25\) In the literature, however, mostly, Holgers grade 2 or higher was used to indicate potentially dangerous skin infections. Rates ranged between 1.7% and 2.8% in the large studies (N = 142-155, Table 4).\(^5,9,25\) Many studies reported the percentage of adverse skin reactions according to the total number of observed skin reactions.

With respect to all adverse skin reactions (Holgers grades 1-4), our results show more frequent (16.6%) adverse skin reaction. The major part (10.1% of the total) consists, however, of a Grade 1 (slight redness) reaction.

In the present study, 6.5% of the skin reactions were Holgers grade 2 or higher, which was almost twice as those in the literature. Comparison of the percentage adverse skin reactions in earlier and more recent periods of this study (and possibly other studies) is incorrect from a methodological point of view. The systematic and tight outpatient clinic follow-up was, over time, abandoned as a result of the good outcome in
the Nijmegen series. Over time, the follow-up interval increased from 4 to 12 months. Next to this, patients had to make an appointment themselves, and there was a tendency for patients to visit the outpatient clinic only when problems occurred. This might imply that we saw relatively more adverse skin reactions. Therefore, the overall number of routine check-ups may not be such a reliable and precise measurement as was presumed earlier. A good alternative might be to present the data in terms of the highest number of potentially dangerous (Holgers grade ≥ 2) adverse skin reaction per implant. In this study, 40 (26.7%) of the 150 implants had a Holgers grade 2 skin reaction or higher at least once during follow-up. This was comparable with our 1994 results (21%), although that population was smaller (N = 33) and follow-up was short (0.8-2.1 yr).7 The surgical procedure used at that time involved a linear incision with a free-skin graft, which indicates that the new surgical technique is equally as good with regard to the occurrence of skin reactions.

Tissue complications that require revision surgery also reflect the outcome of implantation techniques. In the literature, only a few BAHA teams reported these complications,11,12,14,16,27,28 Their incidences ranged from 3 to 17%. The techniques used were dermatome,11 a superiorly based skin flap,12 local skin graft,27 and retroauricular skin graft.16,25 In the present study, 18 overgrown implants needed revision surgery in 16 patients (10.7%). This was comparable with House and Kutz11 and Gillett et al.27 The presence of an adverse skin reaction before most of the tissue revision surgeries might indicate that these potentially dangerous skin reactions play a role in the development of thick skin and skin overgrow around the abutment, as reported previously by van der Pouw et al.25 It is also possible that removal of the periosteum facilitates the formation of scar tissue. A helpful solution seems to be the replacement of the 5.5-mm abutment with an 8.5-mm one.

In conclusion, the Nijmegen surgical technique to implant BAHA implants in the cortical bone produced very favourable results. Meticulous performance of the procedure is considerably important to achieve optimal results in the long term. Particularly, the soft tissue reduction has to be done with great care. In terms of the low rates of implant failure and adverse tissue reactions, the Nijmegen surgical technique proved to be a good alternative to other techniques. It has several advantages: it is relatively simple, avoids skin necrosis and requires little time.
REFERENCES


Chapter 2.1


NIJMEGEN RESULTS WITH APPLICATION OF A BONE-ANCHORED HEARING AID IN CHILDREN: SIMPLIFIED SURGICAL TECHNIQUE

M.J.F. de Wolf
M.K.S. Hol
P.L.M. Huygen
E.A.M. Mylanus
C.W.R.J. Cremers

ABSTRACT

Objectives: A retrospective analysis was performed to evaluate the clinical outcome of percutaneous bone-anchored hearing aid (BAHA) application in children with the outcome measures of implant loss and skin reactions.

Methods: An analysis was done of 93 of the 101 children 16 years of age or younger who underwent the simplified Nijmegen surgical technique between January 1994 and July 2007.

Results: Twenty-one of 129 implants (16.3%) were lost or removed. In 12 cases, osseointegration failed. The majority of the implant losses (86%) occurred within 1 year after surgery. No differences were found between 3 age groups or between implant lengths (seven 3-mm implants versus fourteen 4-mm implants). The BAHA implants were less stable in children than in adults. In 8 cases, Holgers grade 4 skin reactions were noted at an average (±SD) of 5.5 ± 4.7 months after surgery, ie, significantly sooner than the milder reactions (P = 0.001). In 28 cases (22%), skin reactions of Holgers grades 2 to 4 were observed. Revision surgery to reduce subcutaneous scar tissue was necessary in 22 implants (17%).

Conclusions: Implant loss was more frequent in children than in adults. The age of the child and the length of the implant did not appear to influence implant stability. Children should undergo frequent checkups at the outpatient clinic.
INTRODUCTION

After initial development in Gothenburg,1 the bone-anchored hearing aid (BAHA) became commercially available in 1987. Over the years, indications for BAHA application have been extended from bilateral (mainly conductive) hearing impairment to unilateral congenital or acquired conductive hearing impairment.2-4 Binaural application has proved to be worthwhile in patients with bilateral hearing impairment.5-7 In selected patients with acquired unilateral inner ear deafness, the BAHA may provide benefit as a CROS (contralateral routing of sound) device.8 Patients with mild developmental retardation are no longer excluded from BAHA application and are known to benefit from it.3,4

The minimum age for BAHA implantation has not been settled. The appropriate age is now considered to be 3 to 4 years, related to the presence of sufficient thickness of the cortical bone.9 The introduction of the BAHA softband in 2001 provided the opportunity to postpone the time of actual implantation from 2 to 4 years to 4 or 5 years of age. In the United States, the minimum age is 5 years. The BAHA softband was developed to enable children with substantial bilateral congenital conductive hearing loss to hear at a very early age. This application, with a BAHA fitted on an elastic headband, is more patient-friendly than the bone conductors on a steel band over the head. This system provides children with access to auditory stimuli before the age of 3 years, which improves the development of speech and language skills.10

In this study, a consecutive series of 101 children of younger than 16 years underwent clinical evaluation after BAHA application. The focus was on the outcome of a specific surgical technique in 93 cases that did not involve the use of a skin transplant or local skin flap.

Patients and methods

The BAHA was first implemented in this series in June 1988. Since then, 101 children received a BAHA. (Figure 1).

In 1994, a new surgical technique became available in Nijmegen that did not involve the use of a skin graft. This study was performed on the 93 children 16 years of age or younger, in Nijmegen, who between January
1994 and July 2007 underwent this new technique. Patient 1 through 6, 33 and 71 were excluded, because the surgical technique had included a free skin graft. These 8 patients were evaluated separately.

In children of up to the age of 10 years, the Nijmegen BAHA surgical procedure was generally performed in 2 stages, as was the initial BAHA procedure in adults in the early days of BAHA surgery. Children more than 10 years old mostly had a 2-stage procedure. In more recent years, a 1-stage procedure has usually been performed. The decision for applying the 1-stage technique in children over 10 years was based on bone thickness (more than 4 mm) and the surgeons' experience. The Nijmegen procedure involved a straight longitudinal posterosuperior incision behind the auricle and no use of a free skin graft, as described by Van der Pouw et al., Mylanus and Cremers and De Wolf et al. (Figure 2).

In the majority of children, 2 titanium implants were implanted: 1 to be loaded with a BAHA and the other as a “sleeper,” so that an osseointegrated implant would be available if the loaded implant was lost. Surgery was performed by two experienced surgeons.

A retrospective review was made of the medical records of all 93 children who underwent BAHA application in Nijmegen by the modified surgical technique to evaluate the outcomes and complications. The following data were recorded for use in the analysis: age at surgery, gender, type of malformation or syndrome if present, and indication for

Figure 1: Cumulative number of children operated in Nijmegen by year
Figure 2: Presentation of the soft tissue handling in the Nijmegen surgical technique. A: Linear retroauricular incision. B: Exposure of implant site with local removal of periosteum. C: Areas of subcutis reduction in numeric order. D: removal of subcutis. E: healing cap with pressure dressing. (Figures B to E are reprinted with permission of Cambridge University Press.) Some additional lines and numbers (1-6) have been added to C-E.

BAHA application. Surgical analysis data comprised the type of surgery, number of implants implanted, length of the implants, presence of dural exposure, and time interval between the first and second stages of the procedure.

Skin reactions following the new surgical technique were classified according to Holgers et al. A grade 2 or higher reaction was interpreted as an adverse skin reaction. Implant failure was also noted.
Chapter 2.2

All Patients (age < 16 years) who Underwent Operation in Nijmegen

| n = 10 |

Patients included in this study 219 implants (linear incision technique) (n = 93)

- 75 unilateral implants 81%
- 18 bilateral implants 19%

129 loaded implants

- 73 unilateral
- 18 bilateral
- 18 replanted

3-mm implants (n = 31/129) 24%

4-mm implants (n = 98/129) 74%

7/31 implant loss 22% of total loss

14/98 implant loss 14% of total loss

Figure 3: Number of loaded implants and sleepers

If an implant was lost, the sleeper was considered a new implant when the patient was younger than 16 years. In this way, only loaded implants were included in the study.

Initially, the patients were followed up every 4 months. Later, the follow-up protocol was changed to 6 months and finally to 12 months. The follow-up examination included checking the levels of osseointegration and abutment stability by means of a Unigrip torque driver (Entifíc Medical systems AB, Goteborg, Sweden, Maximum applicable force of

Figure 4: Age distribution at time of implantation in 129 implants.
Table 1: Specific syndromic diagnosis in 25 of 93 children.

<table>
<thead>
<tr>
<th>Syndromic Diagnosis</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Down syndrome</td>
<td>7</td>
<td>28</td>
</tr>
<tr>
<td>Goldenhar syndrome or hemifacial microsomia</td>
<td>6</td>
<td>24</td>
</tr>
<tr>
<td>Treacher Collins syndrome</td>
<td>6</td>
<td>24</td>
</tr>
<tr>
<td>Grouchy syndrome (del.18q)</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Turner syndrome</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Ectodermal dysmorphia</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Branchio-Oculo-Facial syndrome</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>100</td>
</tr>
</tbody>
</table>

25 Newton centimeters) or the surgeons’ experience of the maximum applicable force. The skin reaction according to the Holgers classification was noted.16

Statistical analyses

Comparisons of categorical variables were made with chi-square tests or Fisher’s exact test. Time-to-event analyses were conducted using the log-rank test (Mantel-Cox) and Kaplan-Meier curves. SPSS version 14 was used. The level of significance applied was $P = 0.05$.

Table 2: BAHA indication in 93 children.

<table>
<thead>
<tr>
<th>BAHA indication</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquired hearing loss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic otitis media</td>
<td>22</td>
<td>24</td>
</tr>
<tr>
<td>Total</td>
<td>22</td>
<td>24</td>
</tr>
<tr>
<td>Congenital malformation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congenital ear canal atesia</td>
<td>47</td>
<td>51</td>
</tr>
<tr>
<td>Treacher Collins syndrome</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Goldenhar syndrome or hemifacial microsomia</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Grouchy syndrome (del. 18q)</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Branchio-Oculo-Facial syndrome</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
<td>65</td>
</tr>
<tr>
<td>Combination of csom and syndromic features</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Down syndrome</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Turner syndrome</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Ectodermal dysmorphia</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>93</td>
<td>100</td>
</tr>
</tbody>
</table>
Chapter 2.2

Results

The separate group of 8 out of the 101 patients whose surgery had involved a skin graft was followed-up for a mean duration of 78 months (range, 2 to 229 months). Syndromic features were present in 5 of these 8 children; in 3 cases these represented the Treacher Collins syndrome. Only 3 implants were lost or removed in 3 children: 1 was lost because of infection, 1 was lost because of trauma, and 1 had to be removed because of mechanical damage to the inner thread of the implant. In 1 child, tissue revision surgery was performed. Holgers grade 2 or greater skin reaction occurred in 4 children.

The new technique without skin grafting was applied to 93 patients (47 boys and 46 girls). A total of 210 implants were implanted, and 129 were loaded. The characteristics of this population sample are presented in figure 3.

The mean (±SD) age at surgery was 9.0 ± 3.8 years (range, 3 to 16 years; Figure 4). In 71 of the 129 loaded implants, the mean interval between implantation and loading was 18.7 ± 7.2 weeks. These data were missing in the remaining patients. Twenty-Five of 129 (19%) of the implants were implanted in patients with syndromic features; Down syndrome had the highest prevalence (N = 7; Table 1). The indications for BAHA application are shown in table 2. Table 3 lists the types of incision and surgical methods. In 1 child, auricular prostheses were implanted at the same time, by means of a question mark-like incision.

Table 3: Operative technique used in 129 implants.

<table>
<thead>
<tr>
<th>BAHA surgery</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical method</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two-stage</td>
<td>91</td>
<td>71</td>
</tr>
<tr>
<td>One-stage</td>
<td>21</td>
<td>16</td>
</tr>
<tr>
<td>Additional 2nd stage on “sleeper” after loss 1st implant</td>
<td>17</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>129</td>
<td>100</td>
</tr>
<tr>
<td>Incision used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Linear incision</td>
<td>113</td>
<td>87</td>
</tr>
<tr>
<td>Converted incision; square, horseshoe, question mark</td>
<td>16</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>129</td>
<td>100</td>
</tr>
</tbody>
</table>
In the group of 129 implants, 31 implants (24%) had a length of 3 mm and 98 (76%) had a length of 4 mm. In 69 cases (52%) the drilled hole ended in bone, whereas in 52 cases (43%) the dura was exposed. A sinus was visible in 6 patients (5%). These data were missing in only 9 cases. There was no significant difference in implant loss due to failed osseointegration or infection between the drill holes that ended in bone and those in which dural or sinus exposure occurred. Neither was there any significant difference found in implant length and implant loss. In 92 implants, primary surgery consisted of 2 stages. On average, the interval between the first and second stages of the procedure in these 92 implants was 18.47 weeks (range, 8 to 151 weeks). In only 9 cases was the

![Figure 5: Causes of implant loss according to interval since implantation.](image)

Table 4: Abutments and implants lost or removed.

<table>
<thead>
<tr>
<th>CAUSE</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ABUTMENT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin reaction grade 4</td>
<td>3</td>
<td>42.9</td>
</tr>
<tr>
<td>Removed due to deterioration of cochlear function</td>
<td>3</td>
<td>42.9</td>
</tr>
<tr>
<td>Spontaneous loss</td>
<td>1</td>
<td>14.2</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>100.0</td>
</tr>
<tr>
<td><strong>Implant</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No osseointegration</td>
<td>12</td>
<td>56.2</td>
</tr>
<tr>
<td>Skin reaction grade 4</td>
<td>5</td>
<td>23.8</td>
</tr>
<tr>
<td>Trauma</td>
<td>3</td>
<td>14.2</td>
</tr>
<tr>
<td>Removed because of skin overgrowth</td>
<td>1</td>
<td>4.8</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>100.0</td>
</tr>
</tbody>
</table>
interval between first and second stage shorter than 12 weeks (consensus statement\textsuperscript{16}), and not shorter than 8 weeks in any cases. The 16 lost implants in this group all had an interstage interval of more than 12 weeks. The loading time was on average 23.85 weeks (range, 11 to 152 weeks). On 9 occasions, the loading interval was shorter than the 14 weeks prescribed in the consensus statement\textsuperscript{16} but it was never shorter than 8 weeks. The 16 lost implants in patients 1, 2, 9, 14, 16, 19, 47, 51, 52, 57, 59, 64, 70, 79, 80 and 85 were all loaded after at least 14 weeks.

The total duration of follow-up time was 3,869 months (average, 30 months; range, 0 to 159 months). A total of 457 follow-up examinations were made, with an average of 3.5 ± 3.1 per implant. On average, 1.8 ± 0.8 follow-up visits occurred in the first 4 months after surgery.

In 17 of the 93 children, 21 implants (16.3\%) were lost or removed by the surgeon (Table 4 and Figure 5). A Holgers grade 4 skin reaction was correlated with implant loss in 5 patients an average of about 3.8 ± 3 months after surgery, and spontaneous loss due to failed osseointegration occurred in 12 patients after an average of 10 months (range, 0 to 50 months). In 10 of the 12 cases of failed osseointegrated (83\%), spontaneous loss occurred in the first 8 months after surgery (Figure 5). One patient experienced spontaneous loss after 39 months of use, for no observable reason. In another patient, the implant was surgically removed after 50 months, because the implant had become loose and tilted due to bone apposition. In 1 child, the implant was removed and reimplanted after 98 months of use because of skin overgrowth. Figure 6 gives an overview of the causes of implant loss according to age at

![Figure 6: Cause of implant loss in three groups at the time of surgery.](image-url)
surgery in 3 age groups. No differences in the total number of implants lost or in spontaneous implant loss were found between the 3 age groups.

All implants lost because of failed osseointegration (spontaneous loss), trauma, and infection (skin reaction Holgers grade 4) are presented in a life table in table 5\textsuperscript{17} and in a Kaplan Meier survival curve in figure 7.\textsuperscript{17}

Table 5: Life table for BAHA implants.

<table>
<thead>
<tr>
<th>Follow-up period (y)</th>
<th>Current study</th>
<th>Tjellström and Häkansson\textsuperscript{17}</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No.</td>
<td>%</td>
</tr>
<tr>
<td>0-1</td>
<td>129</td>
<td>100</td>
</tr>
<tr>
<td>1-2</td>
<td>67</td>
<td>52</td>
</tr>
<tr>
<td>2-3</td>
<td>49</td>
<td>38</td>
</tr>
<tr>
<td>3-4</td>
<td>44</td>
<td>34</td>
</tr>
<tr>
<td>4-5</td>
<td>37</td>
<td>29</td>
</tr>
<tr>
<td>5-6</td>
<td>29</td>
<td>22</td>
</tr>
<tr>
<td>6-7</td>
<td>19</td>
<td>15</td>
</tr>
<tr>
<td>7-8</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td>8-9</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>9-10</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>10-11</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>11-12</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>12-13</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Figure 7: Kaplan Meier survival curves for 149 adults by Tjellström and Häkansson\textsuperscript{17} (follow-up 0 to 5 years) and the current study (follow-up 0 to 13 years.) (N = 129). Events were implant loss due to failed osseointegration, infection or trauma. Confidence interval 95%.
The lost implants comprised seven 3-mm implants and fourteen 4-mm implants (differences not statistically significant).

In the group who underwent implantation in 2 stages (109 implants: 92 with primary 2-stage surgery and 17 with reimplantation on a “sleeper implant”) the mean follow-up was 27 months (range, 0 to 129). A total of 18 implants (16.7%) were lost in this group. In the remaining group (21 implants), the first and second stages of the procedure were performed simultaneously. The main age in this group was 14 ± 2.4 years. During a mean follow-up of 48 months (range, 1 to 159 months), 3 out of 21 implants were lost (14.3%): 2 spontaneously and 1 because of trauma.

Skin reactions were grouped according to the classification of Holgers et al. No adverse skin reactions were observed in 355 of 457 observations (77.7%; Figure 8). About 55.8% of the implants remained free of any tissue reaction, and 78.3% had grade 0 to 1 skin reactions (Table 6). In the follow-up period of 36 ± 46 months, the skin reaction was a solitary event.

### Table 6: Most severe skin reaction per implant (Holgers classification)

<table>
<thead>
<tr>
<th>Skin Reaction Grade</th>
<th>No.</th>
<th>%</th>
<th>Mean (±SD) Interval (mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>72</td>
<td>55.8</td>
<td>32 ± 34</td>
</tr>
<tr>
<td>1</td>
<td>29</td>
<td>22.5</td>
<td>33 ± 32</td>
</tr>
<tr>
<td>2</td>
<td>14</td>
<td>10.9</td>
<td>41 ± 52</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
<td>6.2</td>
<td>5.5 ± 4.8</td>
</tr>
<tr>
<td>Total</td>
<td>129</td>
<td>100.0</td>
<td></td>
</tr>
</tbody>
</table>

### Table 7: Number of adverse skin reactions per implant

<table>
<thead>
<tr>
<th>Number of Adverse Skin Reactions</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>39</td>
<td>68.4</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>10.5</td>
</tr>
<tr>
<td>3</td>
<td>6</td>
<td>10.5</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>1.8</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>5.3</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>1.8</td>
</tr>
<tr>
<td>9</td>
<td>1</td>
<td>1.8</td>
</tr>
<tr>
<td>Total</td>
<td>57</td>
<td>100.0</td>
</tr>
</tbody>
</table>
in 68.4% of the affected implants. The maximum number of skin reactions per implant was 9, and the mean was 1.8 ± 1.5 (Table 7). On average, the first adverse skin reaction (Holgers grade ≥ 2) was noted after 27 months (range, 1 to 117 months). The severe type of skin reaction (Holgers grade 2 to 4) occurred within 2 years after surgery in 21 of the 28 cases (Figure 9). In the group with Holgers grade 1, only 11 of the 28 (29%) skin reactions arose within 24 months. No significant differences in adverse skin reactions (Holgers grade ≥ 2) were found between the 3 age groups shown in figure 6.

In this study, 25 implants were implanted in children with syndromic features. No significant differences in outcome (ie, skin reaction and implant loss) were noted between these children and those without syndromic features. In the patients whose medical condition included bone malformation of the skull, 15 implants were implanted. No differences were found between them and patients without skull malformations in the occurrence of skin reactions or implant loss. In 10 other patients, there was some degree of developmental delay. There were no differences between them and patients without developmental delays in the occurrence of skin reactions or implant loss.

Twenty-two implants (of 129; 17%) in 19 patients needed revision surgery. Tissue revision was performed in 13 patients and in 2 of them a second revision was performed. In 1 of these patients the implant eventually underwent reimplantation. In 5 patients the second-stage surgical procedure was performed on the sleeper because of loss of the first
abutment. In 1 of these patients tissue revision was also required. Appositional bone growth in one patient also led to revision surgery.

**DISCUSSION**

The first results of the BAHA application in children were presented in 1992. Since then, several larger studies have been published. One of the main concerns with BAHA application is implant loss due to failed osseointegration, trauma, or infection around the percutaneous implant. Children run a higher risk than adults. Table 8 gives an overview of the literature.

In the present study, 21 implants (16.3%) were lost, 12 (9.2% of the 129 implants) of them due to failed osseointegration. It was remarkable that the first 10 were lost within 8 months after surgery. Our rates of implant loss with respect to failed osseointegration and infection were comparable with those reported in the Birmingham and the London series (Table 8). Trauma to the BAHA and its implant is one of the unpredictable risks related to BAHA use. Playing football was the cause of 2 out of the 3 implant losses in 1 of the 2 children who had trauma-related losses. McDermott reported considerable implant loss in children, particularly in children younger than 5 years (16 of the 55). In our study however, no significant difference was found in implant loss between the 3 different age groups.

A large proportion (18 of the 21) was lost within the first year after surgery, but spontaneous loss also occurred after 3 and 4 years of use. One implant was lost for no apparent reason, and the other was lost because of appositional bone growth that tilted the implant so that osseointegration failed.

In the literature, implant failure rates in children range from 5.3% to 30%. There is considerable variation in the number of implants studied per publication. In comparison with the implant loss rates in children with only a BAHA in the larger series (Table 8), the outcomes in this new study are good and similar to the results of the Birmingham series. These 2 series both had abandoned the free skin graft technique and left the original skin in place without the use of a dermatome (Entific Medical systems AB, Goteborg, Sweden). This finding confirms that good results
can be expected with the surgical technique evaluated in this study. The incidence of implant loss caused by infection was higher in the Birmingham series, and might have been related to the younger age of the patients or to preservation of the periosteum. Evaluations on new and large series are needed to determine which surgical technique should take precedence.

In 1995, Tjellström and Håkansson\textsuperscript{17} reported implant loss in 149 consecutive BAHA patients in a life table presentation. (Figure 7, Table 5). Compared to our data on children there was a significant difference in the rates of implant loss ($P < 0.0001$). This once again indicates that implant loss is more likely to occur in children, especially in the early period after implantation.

In the literature, the incidence of tissue revision surgery incidence is 6.3\% to 26.7\% (Table 8). Most studies, however, are relatively small. Of the 182 observed Birmingham BAHA loaded implants, 14 implants needed tissue revision surgery (7.7\%).\textsuperscript{23} In our series 14 of the 129 implants (10.9\%) needed tissue revision surgery at least once. These rates are comparable. The incidence rates of tissue revision surgery in the general population in the literature vary from 3.2\% to 7.4\%, indicating that children are more at risk for soft tissue problems that require revision surgery,\textsuperscript{12,30,31} particularly very young children, as reported by McDermott.\textsuperscript{24}

The average thickness of the cortical bone at the age of 4 years was found to be 2.5 mm (range, 1 to 4 mm), which is considered to be the minimum thickness needed to implant a 3-mm implant.\textsuperscript{21,32} Several studies suggested that implant loss was related to the use of 3-mm implants,\textsuperscript{23} whereas others did not find any relation between implant loss and the length of the implant.\textsuperscript{22,28} In the current study, 76\% of the implants were 4 mm long, and 24\% were 3 mm long (Figure 3). Analysis showed that 67\% of the lost implants were 4 mm. No significant difference in implant loss was found between the 3-mm and 4-mm implants. This study did not confirm the higher rate of implant loss with 3-mm implants, and is in line with that of Lloyd et al.\textsuperscript{22} Therefore, in our view, it does not matter which length of implant is used in young children.

At some centers, the 1-stage adult BAHA surgical procedure was performed in children who had a bone thickness of more than 4
In our series, 21 children with a mean age of 14.4 ± 2.4 years had implantation with a 1-stage procedure. The rate of implant loss in this group was 3 out of 21 (14%), compared to 18 out of 109 (17%) in the 2-stage group. The difference was not statistically significant. A 1-stage procedure may prove to be adequate in children of 10 years of age and older who have a skull thickness of over 4 mm. None of the larger studies have shown that 1-stage surgery involves additional risks in this age group. Therefore, new follow-up studies are needed to test this hypothesis.

In very young children who are candidates for BAHA application, it is crucial to their speech and language development that they have access to auditory stimuli as early as possible, but sometimes implantation cannot be carried out because the cortical layer of their temporal bone is too thin. To solve this problem, the BAHA softband was developed by the former Cochlear Company (i.e. Entific) at request of the Nijmegen BAHA team in 2001. The device comprises the BAHA sound processor connected to a soft elastic headband. It has been accepted as a good alternative to BAHA implant implantation in very young children. Even bilateral application has proved possible and worthwhile. The BAHA softband is considered to be a safe and non-invasive treatment to facilitate speech recognition in children who are too young to be fitted with a percutaneous titanium implant. The aided sound field thresholds with the BAHA softband (20 dB) are almost equal to those obtained with a transcutaneous conventional bone conduction hearing aid (27 dB). Speech and language development are strongly facilitated by the use of the BAHA-softband. Nowadays the BAHA softband is generally accepted as a treatment of first choice in children younger than 3 years. Another development in BAHA application in children is the initiative of the Birmingham BAHA team to implant a spare implant (“sleeper”) during the initial procedure, so that if the loaded implant is lost, BAHA use can be continued rapidly, because an osseointegrated implant is already in place. In later reports there was doubt about the usefulness of a “sleeper” in children with a cortical bone thickness of 4 mm or more. The implant failure rates in the 3 Nijmegen age groups (3 to 5, 6 to 10 and 11 to 16 years) were equal. In our series, most of the children were also implanted with a “sleeper”. The placement of a spare implant is still regarded to be a good and patient-friendly measure in view of the increased risk of implant loss in children.
Table 8: Overview of follow-up duration, age at surgery, skin reactions, tissue revision surgery and implant loss in the literature.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Location</th>
<th>N.pts.</th>
<th>follow-up (y) Mean±SD</th>
<th>Age (y) Mean±SD</th>
<th>Skin reactions</th>
<th>Holgers classification maximum</th>
<th>Number / all observations</th>
<th>revision tissue surgery per patient in %</th>
<th>Implant loss</th>
<th>% O&amp;I loss</th>
<th>% T&amp;R loss</th>
<th>% T&amp;R loss of loaded fixt.</th>
<th>N (No. of loaded fixt.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wolf MJF de, et al.</td>
<td>Current study</td>
<td>Nijmegen</td>
<td>93</td>
<td>2.2 ± 3 (0 - 13.5)</td>
<td>9.3 ± 3.6 (3 - 16)</td>
<td>Grade 2</td>
<td>43 / 457 = 9.4%</td>
<td></td>
<td>14 / 129 = 10.9</td>
<td>12</td>
<td>5</td>
<td>13.2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>McDermott, AL et al.</td>
<td>2008</td>
<td>Birmingham</td>
<td>182</td>
<td>NA (4 - 13)</td>
<td>6.8 (2.0 - 15.1)</td>
<td>Grade 3</td>
<td>34 / 182 = 19%*</td>
<td></td>
<td>14 / 182 = 7.7*</td>
<td>8</td>
<td>19</td>
<td>12.6</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>McDermott, AL et al.</td>
<td>2008</td>
<td>Birmingham</td>
<td>39</td>
<td>NA NA</td>
<td>3.3 (2.0 - 4.9)</td>
<td>Grade 3</td>
<td>17 / 39 = 44%*</td>
<td></td>
<td>8 / 55 = 14.5</td>
<td>11</td>
<td>0</td>
<td>20</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Davids, T et al.</td>
<td>2007</td>
<td>Toronto</td>
<td>40</td>
<td>4.5 ± 3.4 (3.6 - 17.2)</td>
<td>9.6 ± 3.5 (4 - 17)</td>
<td>Grade 2</td>
<td>23 / 71 = 31.9%*</td>
<td></td>
<td>8 / 55 = 8.9*</td>
<td>6</td>
<td>3</td>
<td>10.6</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Lloyd, S et al.</td>
<td>2007</td>
<td>London</td>
<td>71</td>
<td>1.5 (0.1 - 4.4)</td>
<td>5.8 (2.4 - 14.9)</td>
<td>NA</td>
<td>17 / 71 = 24%*</td>
<td></td>
<td>8 / 55 = 14.5</td>
<td>7</td>
<td>2</td>
<td>10.6</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Yellon, R.F, et al.</td>
<td>2007</td>
<td>Pittsburgh</td>
<td>13</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>4 / 15 = 26.7</td>
<td></td>
<td>7 / 44 = 23.7</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>9.1</td>
</tr>
<tr>
<td>Priwin, C et al.</td>
<td>2005</td>
<td>Gothenburg / Stockholm</td>
<td>41</td>
<td>0 (0 - 21)</td>
<td>8.4 ± 4.6 (1.5 - 16)</td>
<td>Grade 2</td>
<td>13 / 539 = 2.4%</td>
<td></td>
<td>7 / 44 = 23.7</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>9.1</td>
</tr>
<tr>
<td>Tietze, L et al.</td>
<td>2001</td>
<td>Toronto</td>
<td>19</td>
<td>0 (0 - 2)</td>
<td>12.2 ± 4.8 (4 - 18)</td>
<td>Grade 1</td>
<td>12 / 74 = 16%</td>
<td></td>
<td>2 / 19 = 10.5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>5.3</td>
</tr>
<tr>
<td>Zeitoun, H et al.</td>
<td>2001</td>
<td>Birmingham</td>
<td>51</td>
<td>3.2 ± 1.6 (0.5 - 7)</td>
<td>7.6 ± 3.2 (2 - 10)</td>
<td>Grade 2</td>
<td>8 / 214 = 3.8%</td>
<td>NA</td>
<td>5 / 32 = 15.6</td>
<td>3</td>
<td>3</td>
<td>11.7</td>
<td>5</td>
<td>11.7</td>
</tr>
<tr>
<td>Granström, G et al.</td>
<td>1997</td>
<td>Gothenburg</td>
<td>37</td>
<td>8 ± 4.2 (1 - 13)</td>
<td>8.7 (2 - 15)</td>
<td>Grade 2</td>
<td>12 / 248 = 4.8</td>
<td>NA</td>
<td>3 / 37 = 8.1</td>
<td>3</td>
<td>0</td>
<td>8.1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Papsin, BC et al.</td>
<td>1997</td>
<td>Toronto</td>
<td>32</td>
<td>0.1 - 4.5</td>
<td>8.9 ± 3.6 (4.1 - 16.9)</td>
<td>Grade 1</td>
<td>26 / 32 = 82%*</td>
<td></td>
<td>8 / 37 = 21.6</td>
<td>3</td>
<td>0</td>
<td>8.1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Jacobsson, M et al.</td>
<td>1992</td>
<td>Gothenburg</td>
<td>16</td>
<td>3.3 (0.1 - 144)</td>
<td>9.3 ± 4.6 (3 - 16)</td>
<td>Grade 2</td>
<td>1 / 108 = 1%</td>
<td></td>
<td>1 / 16 = 6.3</td>
<td>1</td>
<td>0</td>
<td>6.3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

NA = No data available; O = Osseointegration; I = Infection; T = Trauma; R = Other causes for loss or removal

* Number / patient
Chapter 2.2

It also reduces the number of hospital admissions and enables early continuation of BAHA use.

Although many studies reported skin reactions around the abutment and classified them according to Holgers et al., it is difficult to compare these data for several reasons. In many cases, adverse skin reactions were expressed as a percentage of the total number of observed skin reactions. A Holgers grade of at least 2 was used to indicate a potentially dangerous skin infection. The incidence reported in a number of studies varied from 1% to 4.8%. Five out of these 6 studies were performed in Gothenburg. In the present study, 9.4% of the skin reactions were Holgers grade 2 or higher, which was almost twice as many as previously reported in the literature. This difference might have been caused by the increased postoperative check-up interval at our clinic. On the basis of positive experience during 19 years of BAHA application, for instance, the follow-up interval at our hospital has gradually changed from 4 to 12 months. Skin reactions are usually only noted during routine checkups, so events that occur at home without a doctor’s supervision are not recorded. Besides this, in our clinic the present policy is for patients to make a follow-up appointment themselves or to visit us when problems occur. So, naturally, relatively more adverse skin reactions per check-up are observed. Thus, the presentation of adverse skin reactions per total number of routine check-ups may not reflect reliable and precise presentation of the data.

An alternative, and probably better, way to present the data might be to note the total number of potentially dangerous (Holgers grade of 2 or higher) adverse skin reactions observed per implant. In our series, 22% of the implants had a grade 2 (or higher) skin reaction at some time during follow-up. As a comparison, McDermott reported skin reactions of Holgers grade 3 or more in 17% of their children in 2008. When the latter classification was applied to our series of children, 15% had a grade 3 or higher skin reaction at some time during follow-up. Lloyd et al. found a grade 2 (or more) skin reaction in 37% of their children at some point during follow-up. In our study, this rate was 22%. It can therefore be concluded that our data on skin reactions seem to be comparable with those reported in the recent literature.

Figure 9 presents detailed information about the interval between surgery and the onset of Holgers type 2 to 4 adverse skin reactions. This information emphasizes the need for regular checkups at the outpatient
BAHA surgery in children

Nowadays the BAHA system is not only available at university medical centers, but also at 1 in 3 general hospitals in the Netherlands. Although we encourage yearly check-up visits at our outpatient clinic in Nijmegen, a small group of patients prefer to attend follow-up at their regional hospital. Skin care around the implant site is now gradually becoming the patient’s own responsibility. Obviously, it can be questioned whether children (and/or caretakers) should be held fully responsible for their own skin care. Moreover, children run a higher risk of implant loss. Therefore, we propose that routine follow-up twice a year for at least 5 years would be reasonable in children. More frequent follow-up might be indicated after a patient has had a skin reaction of Holgers grade 2 or higher.

The surgical procedure used in a large proportion of the children in the Nijmegen series has been described by de Wolf et al.\textsuperscript{14} and is presented in figure 2. In the descriptions of the surgical technique, most authors\textsuperscript{18,20,22,23,25,26} have referred to Tjellström et al.,\textsuperscript{1,17,36,37} who first introduced the use of a free post-auricular skin graft. Later, Tjellström changed his technique to the use of a U-flap and, most recently, a specially designed dermatome to produce a thinned pedicle skin flap. Overall, various techniques are used by experienced surgeons to reduce the amount of soft tissue. The Birmingham BAHA team adapted their technique avoiding using a skin transplant. They preferred the thinned pedicle flap, such as described by Proops.\textsuperscript{31}

The Nijmegen surgical technique can be used in children and adults. It has several advantages, such as minimal tissue disturbance, extensive soft tissue reduction, the avoidance of necrosis, a 20-minute procedure, and an average of only 1.8 ± 0.8 postoperative checkups.

In conclusion, our series of children had a higher incidence of implant loss than adults, in accordance with the literature. Implant loss in children occurred after a shorter period of BAHA use. The stability of the implant did not appear to be influenced by the age of the child or the length of the implant. It is important that children undergo frequent checkups, because potentially dangerous skin reactions arose at least once in one quarter of the implants.
REFERENCES


Bone-anchored hearing aid surgery in older adults: implant loss and skin reactions

M.J.F. de Wolf
M.K.S. Hol
C.W.R.J. Cremers
E.A.M. Mylanus
ABSTRACT

Objective: We evaluated the clinical outcome measures of implant loss and skin reactions in older-adult users of percutaneous bone-anchored hearing aids (BAHAs).

Methods: We performed a retrospective analysis on 224 older-adults (at least 60 years of age) who underwent implantation of 248 implants with the simplified Nijmegen surgical technique between January 1995 and May 2007.

Results: During a mean follow-up of 39 months (range, 0 to 144 months), 16 out of the 248 implants were lost (6.5%). The causes were failed osseointegration in 9 cases, trauma in 6 cases, and implant loss in irradiated bone 1 case. There were no losses due to infection. Implant loss was not significantly correlated with age. In 40 implants (16.9%), severe skin reactions of Holgers grade 2 or more were observed. Skin revision surgery was performed around six implants (2.4%). None of the patients had an 8.5-mm abutment to overcome severe skin reactions.

Conclusion: The outcome of BAHA surgery in older-adults was favourable. The rate of implant loss was comparable with that in the overall population of BAHA recipients. There were low risks of severe skin reactions or developing thick skin around the implant.
INTRODUCTION

About 30 years ago, the bone-anchored hearing aid (BAHA, Cochlear Bone Anchored Solutions AB in Göteborg, Sweden) was developed. It comprises a bone conduction hearing aid connected to a percutaneous titanium implant in the temporal bone.1,2 The BAHA was first applied to patients with significant bilateral conductive or mixed hearing loss in whom conventional solutions had failed.1,3,4 As a result of its success, the indications have been extended. Children have been included, as well as patients with moderate mental retardation.5-9 Other indications for BAHA treatment are unilateral inner ear deafness (BAHA-cros [contra lateral routing of sound])10 and unilateral acquired and congenital conductive hearing impairment.11-14 The BAHA-softband was first introduced in 2001 as a transcutaneous device for infants and toddlers who were candidates for BAHA implantation.15

Over the years, the surgical technique used to implant the percutaneous implant and handle the soft tissue has been simplified. In adults and children (of older than 10 years); the two-stage technique has been reduced to one stage. The application of a free skin graft has been abandoned. Nowadays, a pedicled thinned skin flap is used, or a simple longitudinal incision with maximal subcutaneous and periosteal tissue reduction.4,16-19 In general the aim is to achieve a thin hairless skin site (fixed to the bone) around the percutaneous titanium implant to minimize skin reactions.

Depending on the BAHA implant centre and the duration of follow-up, the rates of implant loss varied from 3.5 to 17.4% in adults4,11,16,19-24 and from 5.3% to 30% in children.6,7,25-33 The cause of the wide variation in outcomes is still not well understood. Children are more vulnerable to implant loss and differences have been found between age groups.26,29 Skin care around the BAHA implant is a difficult issue in children, because it is not always possible for them to perform skin care adequately. The same might also apply to the older-adult population due to various age-related problems, such as visual impairment, decreased mobility of the fingers or hands, lack of assistance.

In the literature, data on older-adult BAHA users are scarce.34 Therefore, to investigate whether this group of BAHA users might be at more risk of implant loss and adverse skin reactions, we retrospectively analyzed the
Clinical outcomes in older-adult patients who received implants by the Nijmegen linear incision technique.

Patients and Methods

Patients

The study cohort comprised 224 consecutive patients 60 years of age or older (111 men and 116 women) who had undergone implantation of a BAHA in Nijmegen between January 1, 1995, and May 1, 2007. The mean (±SD) age at implantation was 65 ± 6.5 years (range 60 to 87 years).

Surgical technique

Older-adult BAHA users were included in this retrospective study if they had undergone implantation by the simplified Nijmegen one-stage linear incision technique. This surgical technique consisted of a longitudinal incision of approximately 3 cm, 50 to 55 mm posterosuperiorly to the ear canal. After removal of the periosteum, the titanium implant was placed according to the one-stage technique described by Tjellström et al.21 Subcutaneous tissue was reduced extensively over an area of approximately 2 cm around the incision. After wound closure, a pressure dressing provided hemostasis.19 This linear incision surgical technique has been described by Mylanus et al.35, Van der Pouw et al.23 and De Wolf et al.19 Over the years, three surgeons have been involved in the technique. Their combined results are presented below.

Case analysis

Data were obtained from the medical files of the 224 older-adult BAHA users on age, gender, indication for a BAHA, type of implant (3 or 4 mm), type of ending of the drilled hole, possible (post) operative complications, implant failure, time of failure, skin reactions (Holgers grade),36,37 and the duration of follow-up. The Holgers classification comprises five grades: 0) no irritation, 1) slight redness, 2) red and moist tissue, 3) granulation tissue, 4) infection leading to removal of the abutment. A grade 2 or higher reaction was interpreted as an adverse skin reaction. In the literature, several reasons were mentioned for implant failure, such as failed osseointegration, infection, trauma, non-
Table 1: Postoperative wound healing complications.

<table>
<thead>
<tr>
<th>Postoperative complications</th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>234</td>
<td>94.4</td>
</tr>
<tr>
<td>Minor wound dehiscence</td>
<td>10</td>
<td>4.0</td>
</tr>
<tr>
<td>Moderate wound dehiscence</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td>Small skin lesion</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Haematoma</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Total</td>
<td>248</td>
<td>100.0</td>
</tr>
</tbody>
</table>

use because of progressive sensorineural hearing loss, and improved hearing after conventional ear surgery.\textsuperscript{1,16,19,20,22,38,39} Pain rarely was given as the reason to remove the implant.\textsuperscript{40,41} Clinical outcomes were divided into 5-year subgroups according to the age of the patient at implantation.

Statistics

Comparisons of categorical variables were made using chi-square tests or Fisher’s exact test. Time-to-event analyses were conducted using the log-rank test and Beslow test and Kaplan Meier curves. SPSS version 16 (SPSS, Inc., Chicago, Illinois) and Prism Graph Pad 5 (GraphPad Software, La Jolla, California) were used. The level of significance was 0.05.

RESULTS

Between January 1, 1995 and May 1, 2007, 224 older-adult patients had received 248 implants. In 12 patients, BAHAs had been placed bilaterally (N = 25). In 1 case, one of the bilateral BAHA implants had been placed by means of a skin graft technique; therefore, this implant was excluded from the analysis.

Chronic otitis media, ie, the conventional indication, was the cause of the hearing impairment in 202 patients (90.2%). Unilateral sensorineural hearing impairment was the indication in 21 patients (9.0%). A BAHA had been placed to achieve directional hearing in one patient (0.4%) with congenital unilateral conductive hearing impairment and in another patient (0.4%) with unilateral acquired conductive hearing impairment due to trauma.
During surgery, the drilled hole had ended in bone in 198 cases (80%), in the dura in 22 cases (9%) and in a sigmoid sinus in 18 cases (7%). Only 10 observations were missing (4%). All the implants were 4 mm except for 1.

Mean follow-up of each titanium implant was 39 months (range, 0 to 144 months), with a mean of 4.8 ± 3.6 observations per implant.

Table 1 shows the postoperative wound healing complications. Minor wound dehiscence was the most common complication. It took an average of 6.4 weeks (range 2 to 10 weeks) of treatment to clear up. Moderate wound dehiscence occurred in two patients and had taken considerably longer to treat (35 and 19 weeks, respectively). The small skin lesion had healed within 3 weeks.

Figure 1 shows the causes of implant loss (N = 16, 6.5%) and the durations until implant loss. Failed osseointegration was the major cause in 9 of the 16 patients. Trauma was the cause in 6 cases. One patient lost two implants because of trauma. Another patient lost an implant because of failed osseointegration after 45 months of use and lost the replacement because of trauma after 32 months. After this loss, she received a second replacement. A patient who had been treated with local radiotherapy to intra-cerebellar metastases from large cell lung carcinoma lost one implant. Although 1 Holgers grade 4 skin reaction occurred, no implants were lost due to infection in this group of older-adult BAHA users. None of the patients with lost implants had perioperative complications. Figure 2 shows a Kaplan Meier survival curve of all the lost implants. The-time-to event analysis did not show any significant correlations between implant loss and age.
The abutment had been removed in only 2 cases: one after 20 months of use because of chronic pain and the other after 4 months for psychological reasons following a period of neuralgic pain. Two other abutments were lost because of trauma, and another one became loose and was lost in association with Holgers grade 4 skin reaction. The implants themselves were not lost, however.

During the total investigation period of 9669 months, 1180 observations had been made. In the majority of observations (1046; 88.6%) no abnormalities were found (Table 2). To achieve a more clinically oriented presentation of the data, we noted the grade of the worst skin reaction per implant during follow-up. In 167 of the 248 implants (67.3%), no adverse skin reactions were observed. In 40 implants (16.9%), Holgers

<table>
<thead>
<tr>
<th>Holgers grade</th>
<th>Distribution</th>
<th>Most severe skin reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%) Per observation</td>
<td>N (%) Per Implant</td>
</tr>
<tr>
<td>0 = no irritation</td>
<td>1046 (88.6)</td>
<td>167 (67.3)</td>
</tr>
<tr>
<td>1 = slight redness</td>
<td>83 (7.0)</td>
<td>41 (16.5)</td>
</tr>
<tr>
<td>2 = red and moist tissue</td>
<td>37 (3.1)</td>
<td>27 (10.9)</td>
</tr>
<tr>
<td>3 = granulation tissue</td>
<td>13 (1.1)</td>
<td>12 (4.8)</td>
</tr>
<tr>
<td>4 = infection leading to removal of abutment</td>
<td>1 (0.01)</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>Total</td>
<td>1180 (100.0)</td>
<td>248 (100.0)</td>
</tr>
</tbody>
</table>
Table 3: Number of adverse skin reactions (per implant).

<table>
<thead>
<tr>
<th>Implants</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>167</td>
<td>67.3</td>
</tr>
<tr>
<td>1</td>
<td>58</td>
<td>23.4</td>
</tr>
<tr>
<td>2</td>
<td>11</td>
<td>4.4</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>2.0</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>1.2</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>10</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Total</td>
<td>248</td>
<td>100.0</td>
</tr>
</tbody>
</table>

grade 2 or higher was observed. More details are presented in table 2 and 3. There were no significant differences between the age groups in the occurrence of the worst skin reactions (Table 4 and 5).

Revision surgery of the skin surrounding the implant was performed for 6 implants (2.4%) in 5 patients (Table 6). In one of these patients, revision surgery was performed twice. The 3 lost abutments were replaced by means of second stage surgery. In this older-adult population, no 8.5-mm abutments were used in the initial surgical procedure, or later to overcome severe skin reactions.

**DISCUSSION**

BAHA implant loss can be the result of failed osseointegration, infection around the percutaneous implant, surgical removal because of severe pain at the implant site or trauma. Children are the most vulnerable to failed osseointegration and trauma. In children 5 to 10

Table 4: Skin reactions per observation (Holgers grade) per age group.

<table>
<thead>
<tr>
<th>Age (y)</th>
<th>Total no. of observations</th>
<th>Skin reaction Holgers grade</th>
<th>Severe skin reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>60 - 64</td>
<td>398 (33.7)</td>
<td>342 (85.9)</td>
<td>36 (9.0)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>342 (85.9)</td>
<td>36 (9.0)</td>
</tr>
<tr>
<td>65 - 69</td>
<td>321 (27.2)</td>
<td>294 (91.6)</td>
<td>17 (5.3)</td>
</tr>
<tr>
<td>70 - 74</td>
<td>236 (20.0)</td>
<td>209 (86.6)</td>
<td>16 (6.8)</td>
</tr>
<tr>
<td>75 - 79</td>
<td>148 (12.5)</td>
<td>141 (95.1)</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>80 - 84</td>
<td>70 (5.9)</td>
<td>53 (75.7)</td>
<td>12 (17.1)</td>
</tr>
<tr>
<td>85 - 89</td>
<td>7 (0.6)</td>
<td>7 (100)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>1180 (100.0)</td>
<td>1046 (88.6)</td>
<td>83 (7.0)</td>
</tr>
</tbody>
</table>
years of age, the rate of implant loss was 40%. To the best of our knowledge, no clinical data are available specially on older-adult BAHA users. Drinias et al. reported on a series of 131 implants that included 29 implants in older adults (60+ years); 25 out of these 29 implants were BAHA implants, and 4 were auricular prosthesis implants. During a total follow-up of 3 to 17 years, implant loss was 20% (6 of 29). This incidence was greater than that reported in the literature on the general BAHA population.

To gain greater insight into BAHA use in older-adults, we analyzed the outcome of 224 older-adult patients who had received 248 implants with the Nijmegen linear incision technique. Special attention was paid to the risk of losing an implant and adverse skin reactions that might have resulted from difficulties with cleaning the skin around the implant.

The most common reasons for implant loss in this population were failed osseointegration and trauma. Infection around the implant and the medical reasons reported in the literature were not among the causes of

### Table 5: Worst skin reaction per implant (Holgers grade) per age group.

<table>
<thead>
<tr>
<th>Age (yr)</th>
<th>N (%)</th>
<th>N (%)</th>
<th>N (%)</th>
<th>N (%)</th>
<th>N (%)</th>
<th>N (%)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 - 64</td>
<td>76 (30.6)</td>
<td>45 (59.2)</td>
<td>15 (19.7)</td>
<td>12 (15.8)</td>
<td>3 (3.9)</td>
<td>1 (1.3)</td>
<td>16 (21)</td>
</tr>
<tr>
<td>65 - 69</td>
<td>61 (24.6)</td>
<td>42 (68.9)</td>
<td>12 (19.7)</td>
<td>4 (6.6)</td>
<td>3 (4.9)</td>
<td>0 (0)</td>
<td>7 (11.5)</td>
</tr>
<tr>
<td>70 - 74</td>
<td>56 (22.8)</td>
<td>38 (67.9)</td>
<td>10 (17.9)</td>
<td>5 (8.9)</td>
<td>3 (5.4)</td>
<td>0 (0)</td>
<td>8 (14.3)</td>
</tr>
<tr>
<td>75 - 79</td>
<td>35 (14.1)</td>
<td>29 (82.9)</td>
<td>1 (2.9)</td>
<td>4 (11.4)</td>
<td>1 (2.9)</td>
<td>0 (0)</td>
<td>5 (14.3)</td>
</tr>
<tr>
<td>80 - 84</td>
<td>17 (5.7)</td>
<td>10 (58.8)</td>
<td>3 (17.6)</td>
<td>2 (11.8)</td>
<td>2 (11.8)</td>
<td>0 (0)</td>
<td>4 (23.5)</td>
</tr>
<tr>
<td>85 - 89</td>
<td>3 (1.2)</td>
<td>3 (100)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Total</td>
<td>248 (100)</td>
<td>167 (67.3)</td>
<td>41 (16.5)</td>
<td>27 (10.9)</td>
<td>12 (4.8)</td>
<td>1 (0.4)</td>
<td>40 (16.9)</td>
</tr>
</tbody>
</table>

### Table 6: Implant loss and complications per age group.

<table>
<thead>
<tr>
<th>Age (yr)</th>
<th>N (%)</th>
<th>N (%)</th>
<th>N (%)</th>
<th>N (%)</th>
<th>N (%)</th>
<th>N (%)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 - 64</td>
<td>76 (30.6)</td>
<td>7 (9.2)</td>
<td>5 (6.6)</td>
<td>2 (2.6)</td>
<td>4 - 55</td>
<td>1 (1.3)</td>
<td>1 (1.3)</td>
</tr>
<tr>
<td>65 - 69</td>
<td>61 (24.6)</td>
<td>4 (6.6)</td>
<td>1 (1.6)</td>
<td>3 (4.9)</td>
<td>2 - 47</td>
<td>6 (9.8)</td>
<td>4 (6.6)</td>
</tr>
<tr>
<td>70 - 74</td>
<td>56 (22.8)</td>
<td>2 (3.6)</td>
<td>1 (1.8)</td>
<td>1 (1.8)</td>
<td>3 - 129</td>
<td>4 (7.2)</td>
<td>1 (1.8)</td>
</tr>
<tr>
<td>75 - 79</td>
<td>35 (14.1)</td>
<td>1 (2.9)</td>
<td>1 (2.9)</td>
<td>0 (0)</td>
<td>43</td>
<td>1 (2.9)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>80 - 84</td>
<td>17 (5.7)</td>
<td>2 (11.8)</td>
<td>2 (11.8)</td>
<td>0 (0)</td>
<td>70 - 76</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>85 - 89</td>
<td>3 (1.2)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>8.7 (0-21)</td>
</tr>
<tr>
<td>Total</td>
<td>248 (100)</td>
<td>16 (6.5)</td>
<td>10 (3.6)</td>
<td>6 (2.4)</td>
<td>12 (4.8)</td>
<td>6 (2.4)</td>
<td></td>
</tr>
</tbody>
</table>
implant loss.

The rate of implant loss in this study was 6.5% (10 out of the 248 implants). Time-to-event analysis did not reveal any significant correlation between the outcome and age.

In a previous study by the first author, the rate of implant loss was 9.3% (14 out of the 150) in a consecutive series of 150 implants placed between January 1, 1996 and December 31, 1999. All ages were represented in the population (56 ± 20 years [SD]), and the mean follow-up was 30 months (range, 0 to 159 months). In the current population, the mean follow-up was 39 months (range, 0 to 144 months), which indicates that the rate of implant loss was comparable with earlier studies and not disproportionally high in older adults as was previously mentioned by Drinias et al.

Figure 2 shows the present clinical data on implant loss due to failed osseointegration and trauma in the form of a Kaplan-Meier survival curve and includes previously published data from our clinic on implant loss (failed osseointegration, trauma and infection) in the consecutive series of 150 implants and a pediatric series of 129 implants. There was no significant difference in the occurrence of implant loss between the current study and the consecutive series of adults and children (P > 0.09). However, a significant difference in implant loss was found between the pediatric series (N = 129) and the older adults in the current study (N = 248; P < 0.001). This finding once again confirms that children are at more risk of implant loss.

In the literature, the overall rates of implant loss in the general population ranged from 3.4% to 17.5%; 0.4% to 13.6% of losses were due to failed osseointegration. These populations contained adults and children (age range 2 to 89 years). Mean follow-ups ranged from 1.9 to 6.7 years.

In the current study, total rate of implant loss was 6.5% (16 out of the 248); 3.6% of losses (10 out of the 248) were due to failed osseointegration. The mean follow-up was 3.3 years. These outcomes are consistent with those reported in the literature. More research is needed to further determine the risk factors for BAHA implant loss in the older adults.

Skin reactions around the implant are another major factor in the clinical outcome of BAHA surgery. In general, the rate of skin reactions around the percutaneous implant might be influenced by the surgical soft tissue
BAHA surgery in older-adults

technique applied. At our clinic, these outcomes were also negatively influenced by extended intervals between the outpatient check-ups, which were due to the tendency of the patients to postpone their visits until they experienced problems around the implant.

In this study, 167 of the 248 implants (67.3%) remained free from any skin reaction. During the 1,180 observations, 51 (4.3%) implants had Holgers type 2 to 4 skin reactions (Table 2).

A significant difference in the incidence of severe skin reactions was seen between the current study and the earlier Nijmegen BAHA studies on the consecutive series of patients in which the incidence of severe skin reactions was 6.5% (67 out of the 1,038 observations) in the adults and 9.4% (43 out of the 457 observations) in the children (P = 0.003 and P < 0.001). In the current study, the incidence of the highest grade skin reaction per implant was 16.9% (40 of the 248), whereas in the consecutive series, the incidence was as high as 26.7% (40 of the 150). The significant difference in severe skin reactions between the current study and the consecutive series (P = 0.01) indicates that older-adults had less-severe skin reactions around the implant and fewer events of severe skin reactions than the overall population studied at our clinic.

However, in the literature, incidence rates of severe skin reactions per observation (Holgers grade 2 to 4) ranged from 1.7% to 6.5% in studies on over 100 cases. Thus, the older adults in our study had comparable results.

Interestingly, tissue revision surgery was only performed around 6 implants in 5 patients in the current population, ie, 2.4% of all the implants. This is a large difference compared to the previous Nijmegen publication on BAHA surgery in which tissue revision surgery was performed on 19 cases in the consecutive population of 150 implants (12.6%; P < 0.001).

In the literature, the incidence of tissue revision surgery ranged from 3.2% to 12.6% in the overall BAHA population. The incidence of revised surgical reduction of subcutaneous tissue was particularly high in the two more-recent studies on the skin flap technique: 14 of the 177 (7.4%) and 11 of the 149 (7.9%), respectively. These differences were significant (P = 0.04). Thus the older adults in this study were at less at risk of developing hypertrophic skin that required revision surgery around the implants. This finding can be explained by the normal ageing processes in the dermis: irreversible degeneration of tissue. None of our population had a higher 8.5-mm abutment, although its application
might have reduced the number of surgical revisions even further. More research on this specific topic is needed to draw reliable conclusions.

Besides long-term tissue complications, short-term complications also occurred. With the use of the simplified linear incision technique, however, local skin necrosis did not occur in this population. Nevertheless, there were 12 cases of minor or moderate wound dehiscence around the implant (4.8%). Diabetes mellitus was present in two of these patients. It can be speculated that an important cause of wound dehiscence in specific populations is removal of the stitches at a relatively too early stage. In general, stitches are removed within 7 days, probably too early in the older-adult population with other general health problems.

These short-term complications of minor or moderate wound dehiscence around the implant were not observed in the other Nijmegen studies on the linear incision technique. In that technique, the exact location of the implant related to the incision line is determined during surgery. It can be placed in the incision line or just beside it. In the latter case, the incision line is sutured and a small hole is punctured for the abutment at the implant site. It is possible that the occurrence of wound dehiscence was influenced by the location of the implant in relation with the incision in some of the older-adult patients with wound healing issues, such as those associated with diabetes mellitus. However, this hypothesis could not be tested retrospectively from the patient files. No additional surgery was needed in these patients.

In the literature, very few data are available on postoperative wound healing problems besides skin necrosis. Incidences ranged from 1% to 10.5% with the skin flap technique and reach 3% with the dermatome. It should be emphasized that one of the advantages of the linear incision technique is the prevention of skin flap necrosis. However, special attention must be paid to the wound healing process in older-adult BAHA patients.

In conclusion, BAHA surgery in older-adults had a favourable outcome. The rate of implant loss was similar to that in the overall BAHA population. The incidence of severe skin reactions was very low. There was less risk of developing hypertrophic skin around the implant, but a slightly increased tendency towards postoperative wound healing problems occurred.
REFERENCES


42. McDermott, A. L. The Benefit and Success of BAHA (Bone Anchored Hearing Aids). 2008. Nijmegen, the Netherlands, Radboud University Nijmegen. (Thesis)


Bone-anchored hearing aid implant location in relation to skin reactions

H.T. Faber*
M.J.F. de Wolf*
Y.W.J. de Rooy
M.K.S. Hol
C.W.R.J. Cremers
E.A.M. Mylanus

*Both authors contributed equally to this study
ABSTRACT

Objective To evaluate the effect of implant location and skin thickness on the frequency and degree of adverse skin reactions around the abutment.

Design Retrospective multivariate analysis of implant position related to skin thickness and clinical variables.

Setting Tertiary referral center.

Patients Random sample of 248 patients with bone-anchored hearing aids.

Interventions Bone-anchored hearing aid implant placement by means of the linear incision technique.

Mean Outcome Measures Type and number of skin reactions and implant loss.

Results The mean (SD) distance from the external auditory ear canal to implant was 48.8 (8.0) mm (range, 29-84 mm). The mean skin thickness was 5.5 (1.9) mm. Severe skin reactions (Holgers grade, 2-4) were seen in 46 of the 248 patients (18.5%). Implant loss occurred in 4 patients (1.6%). Three implants were lost owing to failed osseointegration (1.3%), and another implant was removed because of deterioration of cochlear function (0.9%). No implant was lost as a result of infection.

Conclusion Implant location and skin thickness were not correlated with implant loss or the frequency or degree of adverse skin reactions around the abutment.
INTRODUCTION

Brånenmark et al.\(^1\) first described the principle of osseointegrated implantation in the dental region. On the basis of osseointegration between bone and titanium, a new hearing device was introduced, the bone-anchored hearing aid (BAHA).\(^2\) Tjellström et al.\(^3\) initiated the first clinical application of a BAHA device coupled to a skin-penetrating, bone-anchored titanium implant (anchored to the temporal bone of the skull). The implant in the skull enables sound vibrations to be transmitted to the cochlea via bone conduction. Since 1987, the BAHA system has been successfully introduced in many countries. In the Netherlands, the BAHA program was established at the University Medical Center in Nijmegen in 1988. In patients with conductive or mixed hearing loss, the BAHA has been a well-established treatment for over 25 years.\(^4-5\)

One of the main concerns in BAHA surgery is to achieve a stable implant with a zone of reaction-free skin around the percutaneous abutment. It has been reported that movement of the tissue around the percutaneous implant is a risk factor for skin reactions.\(^6\) Surgical thinning of the skin around the abutment reduces the chance of epithelial debris or crusts being trapped between the abutment and the skin and acting as foreign bodies.

Regular cleaning is the most effective way to prevent skin reactions. If skin reactions occur, they can usually be treated successfully with a medicated ointment. Skin reactions should be avoided because they can have a more serious outcome, such as skin overgrowth, implant extrusion, and severe wound infection.\(^7-9\) The probability of losing an implant as a result of adverse skin reactions is fairly low. However, if left untreated, a skin reaction may eventually lead to implant loss or withdrawal.\(^10\) Also, preexisting skin impairment, such as dermatoses, thick skin, previous radiotherapy, and poor hygiene, can impair the clinical outcome.\(^6,11-12\) Other factors that might influence the long-term results are soft-tissue reduction during BAHA surgery and the implant location on the skull, which might also influence soft tissue in the long term. We evaluated the effect of the implant location and skin thickness on the frequency and degree of adverse skin reactions around the abutment.
METHODS

Patients

Patients who were scheduled for their regular (yearly) follow-up visit to the BAHA outpatient clinic were invited to participate in the study. Inclusion criteria were: age older than 17 years, implant using the Nijmegen linear incision technique, unilateral application, and at least 1 year of BAHA use. Patients with syndromic features and skull deformities were excluded. The patients were informed about the study, including the skin thickness measurement using a needle and the lateral skull radiograph. A random sample of 248 patients agreed to participate in the study. They had undergone implantation during the period of January 1, 1992, through December 31, 2006.

BAHA surgery

All the patients had received their BAHA using the Nijmegen linear incision technique. In general, the Nijmegen linear incision technique consists of a longitudinal incision approximately 3 cm long, 50 to 55 mm posterosuperiorly to the ear canal. After removal of the periosteum, the titanium implant was placed according to the 1-stage technique described by Tjellström and Granström. Subcutaneous tissue was reduced extensively over an area of approximately 2 cm around the incision. After wound closure, a pressure dressing provided hemostasis. The handling of the soft tissue is described by de Wolf et al. and was not modified during the study period.

Skin thickness measurements

Skin thickness at the implant site was estimated by using a needle to penetrate the skin up to the bone on the contralateral side at the matching position (relative distance of the implant from the ipsilateral rim and pinna). The procedure was performed by 2 otolaryngologists (E.A.M.M. and M.K.S.H.). Measurements were recorded as the number of millimeters the needle penetrated the skin during the regular checkups.
**Implant position**

A standardized digital lateral conventional radiograph of the whole skull (Siemens, Erlangen, Germany), taken of the ipsilateral side of the implant, was used to determine the position of the implant on the skull. The side of the implant was always positioned nearest to the x-ray detector to avoid differences in the magnification factor. The distance from the upper center of the external auditory ear canal to the implant was measured using the ruler function in a radiological program, with the Frankfurter horizontal plane (FHP) as a baseline (adopted at the 1884 Craniometrical Conference in Frankfurt am Main, Germany, cited in 1958 by Moorrees and Kean\(^{15}\)). It consists of a straight line between the most superior point on the upper margin of the external auditory ear canal and the most central point on the upper margin of the external auditory ear canal (EAE C) to implant along the FHP; and Y, the distance from the upper centre of the EAE C to implant vertically perpendicular to the FHP.

![Figure 1: Frankfurt Horizontal Plane (FHP) coordinates of the implant (x- and y-coordinates) used to measure the distance from the upper centre of the external auditory ear canal to the implant (l) X indicates distance from the upper centre of the external auditory ear canal (EAE C) to implant along the FHP; and Y, the distance from the upper centre of the EAE C to implant vertically perpendicular to the FHP.](image)
inferolateral point in the orbital cavity (Figure 1). The position of the implant was recorded as x- and y-coordinates (horizontal and vertical, respectively) using the FHP as the x-axis.

Case analysis

Data were retrieved from the medical records. These include age, sex, indication for a BAHA, surgical method, type of implant (3 or 4 mm), type of abutment (5.5 or 8.5 mm), type of tissue at the end of the drilled hole, implant loss, duration until loss, skin reactions (according to the classification published by Holgers et al.,\textsuperscript{16} hereinafter Holgers classification), time of implantation, and duration of follow-up.

Follow-up

The tissue reactions around the abutment were evaluated according to the Holgers classification: 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; and grade 4, extensive soft-tissue reaction that requires implant removal or leads to implant loss.\textsuperscript{16} The state of the skin around the implant was also observed. Thick skin around the implant was noted when it was level with the top of most of the abutment. At each follow-up visit, the implant stability was checked manually with a torque wrench. All these data were entered into the medical files by means of a standardized stamp. Initially, the patients attended the checkups at least once every 4 months. Later, the interval was prolonged to 6 months, and currently, once a year is the standard interval.

Statistical analysis

Comparisons of categorical variables were made using multivariate correlation tests, 1-way analysis of variance, and independent sample t tests. Time-to-event analyses were conducted using Kaplan-Meier curves. The analyses controlled for age at surgery, sex, duration of follow-up, and tissue type at the end of the hole drilled for the abutment. SPSS software (version 16; SPSS Inc, Chicago, Illinois) and Prism Graph Pad 5
(GraphPad Software, La Jolla, California) were used to perform statistical analysis. The level of significance was set at $P = 0.05$.

RESULTS

Description of population

Our population comprised 100 men and 148 women with a unilateral percutaneous titanium implant. The mean (SD) age at implantation was 52.5 (14.7) years. Figure 2 shows the age distribution. Implants had been placed on the left side ($N = 128$) and on the right side ($N = 120$). Indications for BAHA fitting were bilateral acquired conductive or mixed hearing loss ($N = 209$ patients [86.7%]), congenital conductive hearing loss ($N = 8$ [3.8%]), and unilateral inner ear deafness ($N = 31$ [12.5%]). The latter group comprised 30 cases of acoustic neurinoma and 1 case of intracranial rhabdomyoma. The etiology of the hearing loss in 1 patient (0.4%) was trauma. A total of 12 patients were classified as having mental retardation.

A 1-stage surgical procedure had been used to place 247 implants (99.6%). In 1 patient, the second stage (abutment placement and tissue reduction) was performed separately.

![Figure 2: Age at time of surgery per implant (N = 248 patients) and number of implants.](image)
During surgery, the drilled hole had ended in bone in 213 cases (85.9%), at the dura mater in 21 cases (8.5%), and in the sinus in 8 cases (3.2%). Only 6 observations were missing (2.4%). All of the implants were 4 mm except for 1. In 2 cases, the length of the implant was not noted in the medical records. All the abutments were 5.5 mm except for 1. This patient did not report any adverse skin reactions or thick skin. The mean duration of follow-up was 67.7 (39.4) months (range, 12 to 215 months) with a mean of 7.4 (4.9) observations per implant.

**Implant location measurements on the lateral radiographs**

The mean (SD) distance from the upper center of the external auditory ear canal to the implant was 48.8 (8.0) mm (range, 29.0 to 84.0 mm), the mean distance of the x-component was 44.8 (8.5) mm (range, 22.0 to 82.0 mm), and the mean distance of the y-component was 18.6 (10.6) mm (range, −13.0 to 48.0 mm). Figure 3 shows a lateral representation of the scatter of implant positions.

In patients with congenital atresia (N = 8), the mean distance of the y-component was 21.3 mm. Compared with the mean distance of the y-
component in the other patients (18.5 mm) this was not a notable difference. Their x-component was 46.3 mm compared with the other patients, which was not clinically significant. The mean distance between the upper center of the external auditory ear canal and implant was 51.5 mm. This difference (0.3 mm) was not clinically significant compared with those of the other patients. The measurements in the patients with congenital atresia did not notably affect the distances in the total group of patients. In the patients who had undergone translabyrinthine schwannoma surgery, the x-component of the implant location did not differ from that in the patients who underwent "regular" BAHA surgery.

**Implant loss**

A total of 4 of the 244 implants (1.6%) were lost: 3 owing to failed osseointegration (1.3%) and 1 that was removed owing to deterioration of cochlear function (0.9%). No implants were lost as a result of infection. Statistical analysis did not show any relationship between implant loss and the distance from the upper center of the ear canal to the implant, the mean distance of the x-component, and the y-component.

**Skin reactions**

Skin reactions were observed in 130 patients (52.4%); in 84 patients the most severe skin reaction was Holgers grade 1 (33.9%), in 32 patients this was Holgers grade 2 (12.9%), in 12 patients this was grade 3 (4.8%), and only 2 patients had a grade 4 skin reaction (0.8%). In this group, 46 patients (18.5%) had a skin reaction that required treatment (classified as Holgers grade 2 to 4). This type of reaction occurred only once in 33 of

<table>
<thead>
<tr>
<th>Skin reactions</th>
<th>Distribution Per observation</th>
<th>Most severe skin reaction Per implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 = no irritation</td>
<td>1505 (64.7)</td>
<td>118 (47.6)</td>
</tr>
<tr>
<td>1 = slight redness</td>
<td>206 (11.4)</td>
<td>84 (33.9)</td>
</tr>
<tr>
<td>2 = red and moist tissue</td>
<td>52 (2.9)</td>
<td>32 (12.9)</td>
</tr>
<tr>
<td>3 = granulation tissue</td>
<td>12 (0.7)</td>
<td>12 (4.8)</td>
</tr>
<tr>
<td>4 = infection leading to removal of abutment</td>
<td>2 (0.1)</td>
<td>2 (0.8)</td>
</tr>
<tr>
<td>Total</td>
<td>1777 (100.0)</td>
<td>248 (100.0)</td>
</tr>
</tbody>
</table>
Table 2: Frequency of Skin Reaction and Most Severe Skin Reaction Around the Implant.

<table>
<thead>
<tr>
<th>Frequency of skin reactions follow-up</th>
<th>Total number (% of adverse skin reactions per implant)</th>
<th>Total number (% of Holgers 2-4 skin reactions per implant)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>118 (44.5)</td>
<td>202 (81.5)</td>
</tr>
<tr>
<td>1</td>
<td>68 (27.2)</td>
<td>33 (13.3)</td>
</tr>
<tr>
<td>2</td>
<td>27 (13.1)</td>
<td>9 (3.6)</td>
</tr>
<tr>
<td>3</td>
<td>15 (5.9)</td>
<td>2 (0.8)</td>
</tr>
<tr>
<td>4</td>
<td>7 (3.1)</td>
<td>2 (0.8)</td>
</tr>
<tr>
<td>5</td>
<td>7 (2.8)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>2 (1)</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>4 (1.7)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>248 (100.0)</td>
<td>248 (100.0)</td>
</tr>
</tbody>
</table>

The 46 patients (71.7%) (Table 1 and Table 2).

The mean intervals in months between implantation and the skin reactions were 42.5 months for grade 1, 37.8 months grade 2, 37.8 months for grade 3, and 76.5 months for grade 4 (Table 3). The mean interval until the first skin reaction, irrespective of the grade, was 24.3 months (range, 0-129 months).

The distance from the upper center of the external auditory ear canal to the implant was not correlated with Holgers grade 1 to 4 skin reactions or the total number of skin reactions. Furthermore, there was no correlation between skin reactions or implant loss and the x- and y-components of the distance from the upper center of the ear canal to the implant.

**Skin thickness, measurements observations and revision surgery**

In 204 patients (82.3%), skin thickness was measured on the side contralateral to the percutaneous implant. Skin thickness varied from 2.0 to 11.0 mm, with a mean (SD) thickness of 5.5 (1.9) mm. Analyses did not
show any statistically significant correlations between skin thickness and implant loss ($P = 0.58$), or skin reactions of Holgers grades 1 and 2 ($P = 0.48$ and 0.65, respectively; there were too few cases of Holgers skin reactions of grades 3 and 4 for statistical comparison), or with the total number of skin reactions ($P = 0.39$). There was no significant correlation between skin thickness and the vertical component ($y$) ($P = 0.57$). However, skin thickness was significantly correlated with the horizontal component ($x$) (0.2 mm; $P < 0.002$) and the mean distance from the implant to the ear canal (0.2 mm; $P < 0.001$).

Next to the measurements of the thickness of the skin at the contralateral side to the implant, the state of the skin level around the abutment was recorded during follow-up in 192 patients. Thick skin, that is, skin reaching to the top of the 5.5-mm abutment, had been noted in 81 patients (42.2%), with a mean rate of 2.4 observations (range, 1 to 12 observations). Only 40 patients (16.1%) had 1 single observation of thick skin. The latter once-only events accounted for 49.4% of all the observations of thick skin. The mean (SD) interval until the first observation of thick skin was 47.0 (33.6) months. In most of the cases, the thick skin was treated successfully with antibacterial and steroid ointment or watchful waiting.

Tissue reduction surgery was performed on 23 implants (9.4%) at a mean period of 34 months after implantation (range, 4 to 119 months) when thick skin persisted. One patient required 1 subsequent tissue reduction surgery.

**DISCUSSION**

We evaluated the effect of the implant location and skin thickness on the frequency and severity of skin reactions around the abutment. To evaluate this correlation, the position of the implant (the mean distance from external auditory ear canal to the implant) was measured (48.3 mm). This corresponds with the ideal site according to the Nijmegen BAHA surgical procedure because it leaves enough space to accommodate the BAHA transducer behind the auricle. No correlation could be found between implant location and the frequency and severity of skin reactions in this study.

To our knowledge, no previous studies have investigated a possible correlation between implant location and skin reactions. Eeg-Olofsson et
al., however, described the position of the implant in relation to the external auditory ear canal. Their study was set up to determine the extent to which bone dampened sound transmission to the cochlea. They found that moving the vibrating stimulus closer to the cochlea increased the velocity at the cochlear promontory. Combined with the results of our study, the ideal implant site in terms of optimal sound transmission and low incidence of skin reactions would be as close to the cochlea as possible.

It should be noted that skull dimensions can vary among individuals. Skull dimensions also change with advancing age (e.g., progressive decrease in the height of the neurocranium). Patil and Mody described significant differences in 10 cephalometric dimensions between men and women. In the current study, we adjusted the statistical analyses for sex and age to address the differences in skull dimensions.

In BAHA surgery, special attention must be given to the handling of the soft tissue in order to obtain thin hairless skin with optimal reduction of mobility. The soft-tissue reduction technique used results in a gentle slope of the soft tissue in an area of approximately 15 to 20 cm² around the percutaneous implant, depending on the length of the incision. At the basis of the abutment, postoperatively the skin thickness varies from approximately 1 to 1.5 mm. Unfortunately, because skin thickness measurements at the implant location were not performed in a structural manner, a prospective analysis was not possible.

Implant loss is one of the major clinical outcome measures in BAHA surgery. In our study, the total implant loss was 1.6% (4 of the 248 implants). Recent studies by the Nijmegen BAHA team reported a 9.3% implant loss (14 of 150 implants) in a consecutive series of 142 patients who had undergone BAHA surgery and in 6.5% (14 of 248 implants) in 224 elderly patients who had undergone BAHA surgery. In the literature, implant loss caused by failed osseointegration ranged from 0.4% to 7%, whereas loss caused by infection ranged from 0.4% to 2.7%. The mean (SD) duration of follow-up in the current study was 78.4 (48.3) months (range, 12 to 220 months) compared with a range of 6 to 141 months in the literature. Rates of implant loss in these Nijmegen series are substantially lower than those described in literature.

An explanation for the differences in implant loss might lie partly in the exclusion of children from this study. Compared with the adult skull, the infant skull is less thick and has fewer minerals content and more water.
content. This is believed to be one of the causes of the higher risk of failed osseointegration in the younger population. In the study by Proops, implant loss occurred in 19 of 188 patients (10.1%); 10 of these 19 (52.6%) occurred in children. In the Nijmegen consecutive series of children, implant loss in children also accounted for a relatively large part of the percentage. Overall implant loss in the Nijmegen series was 16.3% (21 of 129).

Another major clinical outcome measure in the follow-up after BAHA surgery is skin reactions. Our data showed that 46 of the 248 patients (18.5%) had a severe skin reaction (Holgers grade, 2 to 4) at least once during follow-up. In this group of patients, 33 (71.7%) had a severe skin reaction only once. The rates of severe skin reactions in the current study conform with those in the literature (3.4% to 39.6%). These data are also in line with those of previous studies performed within the BAHA program at the University Medical Centre. de Wolf et al. found an incidence of 26.7% (40 of 150) in a consecutive series of patients with BAHA implants.

Besides implant location, another potentially relevant variable is skin thickness. Measurements found in this study varied from 2.0 to 11.0 mm, with a mean (SD) thickness of 5.5 (1.9) mm. No correlations were found between skin thickness and implant loss, Holgers grade 1 to 4 skin reactions, the y-component, or the total number of skin reactions. Measurements of the skin thickness were taken on the side contralateral to the implant. Skin thickness was significantly positively correlated with the x-component and the distance between the implant and the ear canal (0.22 mm, P < 0.002; and 0.24 mm, P < 0.001, respectively). Thus, the greater the distance between the implant and the ear canal, the thicker the skin. The procedure used for skin thickness measurements was based on the assumption that the skin is of equal thickness on both sides.

In conclusion, no correlations were found between the distance from the superior part of the external auditory ear canal to the implant nor between the horizontal and vertical positions of the implant and the type and number of skin reactions. Skin thickness measured on the contralateral side was not correlated with the type and number of skin reactions. Comparatively, implant loss was not correlated with the distance from the superior part of the upper center of the external auditory ear canal to the implant, the position of the implant, or skin thickness.
REFERENCES


PATIENT OUTCOME MEASURES
AGE-RELATED USE AND BENEFIT OF THE BONE-ANCHORED HEARING AID COMPACT

M.J.F. de Wolf
J.M. Leijendeckers
E.A.M. Mylanus
M.K.S. Hol
C.W.R.J. Cremers
A.F.M. Snik

Abstract

Objective: To study age-related patient satisfaction with the bone-anchored hearing aid (BAHA) compact.

Methods: A retrospective postal questionnaire, the International Outcome Inventory for Hearing Aids (IOI-HA), was sent to 211 BAHA Compact users. Questionnaire responses from 135 BAHA users were analyzed related to age, sex, years of BAHA experience, and the hearing thresholds (pure-tone average) at the aided side. Age ranged from 18 to 77 years.

Results: The IOI-HA showed that the BAHA Compact was greatly appreciated by almost all of the users: most patients stated that they were using the device for most of the day; it helped them to hear better and it reduced the number of situations in which hearing impairment was problematical. The cumulative score on the questionnaire was negatively influenced by age (\(\rho = -0.191\), \(P = 0.05\)). Furthermore, increase in sensorineural hearing loss (SNHL) component was associated with decrease in total IOI-HA scores (Spearman \(\rho = -0.193\), \(P < 0.05\)). A significant correlation was found between age and the SNHL component (Spearman \(\rho = 0.525\), \(P < 0.001\)).

There were no significant differences in the levels of difficulty with placing the BAHA on the implant or with handling the BAHA between the age groups. Cleaning the skin around the implant causes the most difficulties in the youngest age group (\(p < 0.02\)).

Conclusion: The BAHA Compact enhances participation in various domains of communication. Differences in patients' satisfaction seemed to be correlated with the SNHL component rather than age.
INTRODUCTION

The bone-anchored hearing aid (BAHA) was introduced in 1977 by Tjellström et al. Since then, it has been applied widely at many other clinics all over the world. The BAHA system can be used to treat patients with conductive or mixed hearing loss who are unable to use a conventional hearing aid, for example, because of otitis media or aural atresia. During the years, the indication for BAHA application has expanded, including bilateral application, application in patients with unilateral congenital or acquired conductive hearing impairment, or as a Contralateral Routing of Sound (CROS) device. In recent years, quality of life (QOL), benefit, and satisfaction aspects after BAHA placement have received increased attention. To the best of our knowledge, there are no previous studies on age-related BAHA use and patient’s satisfaction. In the present study, opinions were gathered in retrospect using the International Outcome Inventory for Hearing Aids (IOI-HA). The Dutch version of the IOI-HA was evaluated by Kramer et al. Since its development, the IOI-HA has been used in several studies on the use of hearing aids, particularly in older adults. It has also been used in BAHA studies on unilateral or bilateral conductive hearing loss. The present study analyzed the audiological and questionnaire data from a group of experienced BAHA Compact users with conductive or mixed hearing loss. The BAHA Compact was the most frequently applied BAHA at our clinic between 2000 and 2007. Indications comprised conductive hearing loss or mixed hearing loss with a sensorineural component up to 35 dB. Furthermore, all patients fulfilled the indication criteria as listed in the consensus statements at the time of implantation, for example, for these patients; the BAHA was the only alternative owing to either aural atresia or chronic otitis media. Larger sensorineural hearing loss (SNHL) components require the more powerful BAHA Intenso or Cordelle. However, because this group was fairly limited in size and mainly comprised older patients, the Cordele users were excluded from the current comparison. To provide insight into age-related patient satisfaction and benefit, the respondents were divided into 3 age groups: 1) aged 18 to 40 years, 2) 41 to 60 years, and 3) older than 60 years.
Table 1: patient data per age category.

<table>
<thead>
<tr>
<th>Age Categories (years)</th>
<th>18-40</th>
<th>41-60</th>
<th>&gt;60</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaires sent</td>
<td>49</td>
<td>87</td>
<td>55</td>
<td>211</td>
</tr>
<tr>
<td>Questionnaires received</td>
<td>29</td>
<td>64</td>
<td>42</td>
<td>135</td>
</tr>
<tr>
<td>Response rate</td>
<td>58%</td>
<td>73%</td>
<td>77%</td>
<td>73%</td>
</tr>
<tr>
<td>Mean Age</td>
<td>30</td>
<td>51</td>
<td>67</td>
<td>52</td>
</tr>
<tr>
<td>Years of Baha experience (SD)</td>
<td>4.5 (1.6)</td>
<td>4.3 (1.8)</td>
<td>4.6 (1.8)</td>
<td>4.4 (1.7)</td>
</tr>
<tr>
<td>Indication for Baha</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bilateral cond. / mixed loss</td>
<td>18</td>
<td>49</td>
<td>33</td>
<td>100</td>
</tr>
<tr>
<td>Unilateral cond. / mixed loss</td>
<td>5</td>
<td>10</td>
<td>8</td>
<td>23</td>
</tr>
<tr>
<td>Unilateral cond. / mixed loss other ear deaf</td>
<td>6</td>
<td>5</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>PTA (0.5, 1, 2, 4) (SD)</td>
<td>15 (9)</td>
<td>21 (11)</td>
<td>28 (9)</td>
<td>22 (11)</td>
</tr>
<tr>
<td>PTA (1, 2, 4) (SD)</td>
<td>16 (10)</td>
<td>23 (12)</td>
<td>31 (11)</td>
<td>24 (13)</td>
</tr>
<tr>
<td>Air bone Gap (SD)</td>
<td>45 (11)</td>
<td>37 (13)</td>
<td>32 (12)</td>
<td>37 (13)</td>
</tr>
</tbody>
</table>

PATIENTS AND METHODS

Patients

The IOI-HA was sent to 211 consecutive BAHA Compact users who were older than 18 years and had conductive or mixed hearing loss. Questionnaires were returned by 135 patients. It was possible to contact 30 (55%) of 55 non-responders. They all stated that they were still using the BAHA. To provide insight into age-related patient satisfaction and benefit, the respondents were divided into 3 age groups: 1) aged 18 to 40 years, 2) 41 to 60 years, and 3) older than 60 years. Mean age was 52 years (range, 18 to 77 yr). An overview of questionnaire responses and patients’ hearing thresholds is presented in Table 1.

Methods

Patients were asked to fill in the IOI-HA, an internationally applied questionnaire designed to evaluate the effectiveness of hearing aid treatment. The IOI-HA is a brief questionnaire that consists of 7 questions on use (Use), benefit (BEN), residual limitation in activity (RAL), satisfaction (SAT), residual participation restriction (RPR), impact on others (loth), and QOL related to, in this case, the BAHA Compact (Appendix 1). To answer
each of these questions, the patient selected 1 of the 5 possible responses that roughly covered the whole range from "no benefit" to "very much benefit." The validated Dutch version of the IOI-HA was used.\textsuperscript{17,22}

The questionnaire outcomes were related to age, sex, and the pure-tone average bone-conduction (PTA\textsubscript{bc}). The focus was on age because bone-conduction thresholds deteriorate with increasing age, which may compromise the potential (subjective) benefit of the BAHA Compact. Some extra questions concerning everyday use of the BAHA were added to the IOI-HA as well as questions concerning potential difficulties with placing the device on the implant, handling the device, and cleaning the skin around the implant (response format: everyday use and difficulties placing [yes, no]; handling the device [yes, sometimes, no]). The IOI-HA results are compared with those in the literature on other types of hearing aids.

\textbf{Statistics}

Comparisons of categorical variables (the IOI-HA domains and the extra questions on "everyday use," "placement," "operation," and "cleaning") were made using Fisher’s exact test. Correlations between the IOI-HA outcome and demographic factors were evaluated using Spearman [rho]. SPSS version 16 (SPSS, Inc., Chicago, IL, USA) was used.

\textbf{RESULTS}

The means and standard deviations (SDs) on each of the 7 domain scores of the IOI-HA are presented in table 2. Missing data are also

\begin{table}[h]
\centering
\begin{tabular}{lccc}
\hline
 & Responses & No responses & Mean & SD \\
\hline
1 USE & 135 & 0 & 4.59 & 0.9 \\
2 BEN & 130 & 5 & 4.17 & 1.0 \\
3 RAL & 129 & 6 & 3.95 & 0.9 \\
4 SAT & 135 & 0 & 4.31 & 0.9 \\
5 RPR & 130 & 5 & 4.01 & 0.9 \\
6 loth & 132 & 3 & 4.40 & 0.7 \\
7 QOL & 130 & 5 & 4.37 & 0.9 \\
\hline
\end{tabular}
\caption{Descriptive statistics for each of the seven domains of the IOI-HA in the total study group (N = 135).}
\end{table}
presented; ranging from 3 (2.2%) to 6 (4.4%). Figure 1 presents mean data per domain and age group and the results of each of the 7 questions separately. "USE" shows that approximately 80% of the patients in the 2 younger subgroups were using their BAHA for more than 8 h/d. In the patient group older than 60 years, approximately 70% were using the BAHA for more than 8 h/d. "BEN" shows that 96.4% of the patients in the youngest subgroup experienced at least moderate benefit with the BAHA in the situations where they most wanted to hear better; 89.2% of them even indicated "quite a lot" or "very much benefit." In the 41- to 60-year-old age group, these outcomes were 91.9 and 82.3%; in the patient group older than 60 years, these outcomes were 87.5 and 67.5%.

In response to "RAL," concerning "difficulty understanding speech despite the use of the BAHA," less than 8% of the patients were still experiencing significant problems, whereas most had only moderate problems or no difficulties. Interestingly, the patients who responded with "very much difficulty understanding speech" were 60 years or older (3 patients). Within this group, there were 2 patients who responded "quite a lot of difficulty." Moreover, 6 (9%) of the 64 patients from the middle-aged group responded with "quite a lot of difficulty."

"SAT" represents patient satisfaction with their BAHA. Nearly all of the patients considered the BAHA to be worth the trouble. Only 1.6% reported that the BAHA was not worth the trouble (all in the 41- to 60-yr-old age group). The patients in the group older than 60 years seemed to be more conservative in their reports regarding satisfaction: 45.2% indicated the "very much worthwhile" domain compared with 54.7 and 72.4% scored by the other groups.

More than 70% of the patients indicated that their BAHA did not restrict their participation in activities (RPR), or that it only restricted them slightly. Only 2.6% of the patients in the group older than 60 years felt very much restricted in the things they could do because of the BAHA.

Although more than 90% of the patients in the 2 youngest age groups stated that other people were only slightly or not at all bothered with the patient’s hearing problems (loth), 20% of the patients in the group older than 60 years indicated bother at a moderate or above average level. This suggests that the older BAHA users are more inclined to think that others are bothered by their hearing limitations.
Figure 1: Patients’ responses to each of the IOI-HA questions. USE: Most patients use the Baha for more than 8 h/d. BEN: Approximately 90% of the Baha users report at least moderate benefit, there was a tendency that the 2 youngest age groups report more benefit. RAL: most patients reported only moderate to no residual limitations in activity. SAT: the patients from the group older than 60 years seemed to be more conservative in their reports regarding satisfaction. RPR: most patients report slightly or no restrictions in participation in activities. However, the older adults report the most restrictions. Ioth: the older Baha users are more inclined to think that others are bothered by their hearing limitations. QoL: although most reported greater enjoyment of life owing to the Baha, the patients from the group older than 60 year were least inclined to indicate the last domain ‘very much better’.
Responses to the QOL question show that, although most reported greater enjoyment of life because of the BAHA, the patients in the group older than 60 years were least inclined to indicate the domain "very much better." Almost 44% of the patients in the group older than 60 years reported "very much better" QOL with the BAHA compared with almost 60 and 55% in the 2 younger age groups.

In response to the extra questions, more than 95% of the patients in each age group reported that they did not have any difficulty placing the BAHA on the implant. Nor did they have any problems with handling the BAHA (not shown). Interestingly, only 41% of the youngest age group reported that they did not have problems cleaning the skin around the implant compared with 66 and 63% in the other 2 age groups (Figure 2). Thus, cleaning the skin around the implant caused the most difficulties in the youngest age group (P < 0.02). However, there were no significant differences between the 3 age groups in the level of difficulty with placing the BAHA on the implant or with handling the BAHA. A separate analysis of the oldest patients in this study (age > 70 yr, N = 8) revealed that only 1 of them reported problems with placing the BAHA on the implant, none reported problems with handling the BAHA, and only 3 reported that they sometimes had problems cleaning the skin around the implant.

To identify correlations between the demographic factors (patients' age and SNHL component) and the questionnaire responses, Spearman [rho] correlation coefficients were calculated. Correlations at the P < 0.05 level were considered significant.
The cumulative IOI-HA score was significantly negatively influenced by age (\(\rho = -0.191, P < 0.05\)). A larger SNHL component was associated not only with a poorer score on domain 6 (ioth, \(\rho = -0.212\)) but also with the total IOI-HA score (Spearman \(\rho = -0.193, P = 0.026\)). The significant correlation between age and the average SNHL component that was found (Spearman \(\rho = 0.525, P < 0.001\)) suggests that it is not age per se that is related with IOI-HA but rather the (age-related) SNHL component.

**DISCUSSION**

The IOI-HA questionnaire was developed as a brief useful tool to compare the outcomes of hearing aid fitting. It can also be used to evaluate individual performance with a hearing aid.\(^{17,23}\) The approach of this study was to use it to compare different subgroups with the same hearing aid, for example, age-related benefit. In the IOI-HA, hearing aid users were asked to evaluate the previous 2 weeks of their hearing aid use, that is, to provide very recent retrospective data. Thus, the IOI-HA can be considered to represent a “snapshot” of the situation. Because of this setup, the recall bias was assumed to be negligible.

The overall response rate, defined as the ratio between the number of questionnaires received and sent, was 71\%, which is favorable compared with the literature.\(^{17,18,23-25}\) Furthermore, a large proportion of the non-responders could be contacted. Their reasons for not answering the questionnaire were diverse, but they all stated that they were using the BAHA on a daily basis and were satisfied with it. This indicates that our results are a good estimate of the outcome in the whole group. Table 1 shows that the response rate in the 18- to 40-year-old age group was lower than the response rate in the 2 other age groups. Nevertheless, the 18- to 40-year-old age group is large enough to be considered of value.

The IOI-HA outcome in this study showed that almost all users appreciated their BAHA Compact: they were using it for most of the day; it was clearly helping them to improve their hearing; it reduced the number of situations in which hearing loss was problematic; it was considered to be worth the trouble; limitations due to hearing loss were no longer present or had diminished; and it was having a positive impact on the enjoyment in life for most of the patients.
Subdivision into age groups provided more insight into the responses to in the IOI-HA domains. Some differences in patients' benefit were found between the age groups, but in most cases, they were not substantial. The patients in the age group from 18 to 40 years were experiencing more benefit than those in the age group older than 60 years. Differences between the 18- to 40-year-olds and the 41- to 60-year-olds were less pronounced. Another interesting finding was that there was no general effect of age on ease of handling the BAHA. Thus, patients of all ages were capable of handling and placing the BAHA. Interestingly, the youngest age group reported more difficulty with cleaning the skin around the implant. This supports the assumption that older BAHA users are at least comparably capable of using and taking care of the implant and the BAHA.

There seemed to be a link among the level of appreciation of the BAHA, the degree of SNHL, and age. Although the BAHA provides access to sound, threshold deterioration with age will result in poorer speech recognition. Thus, (sensorineural) hearing loss, rather than age, is probably the major cue. It should be mentioned that these correlations, although significant, were relatively weak.

The IOI-HA has also been used to evaluate hearing devices. However, most of these studies comprised patients with pure SNHL, fitted with conventional air-conduction hearing aids. The patients' types and severity of hearing impairment differed largely; therefore, no valid comparison could be made.

In conclusion, the BAHA Compact enhances participation in various domains of communication in patients with conductive or mixed hearing loss with an SNHL component between 0 and 44 dB. Differences in patients' satisfaction seemed to be correlated with the SNHL component rather than age.

Acknowledgment

The authors thank Carine Hendriks for collecting the data.
REFERENCES


APPENDIX 1

USE: “Think about how much you used your BAHA over the past two weeks. On an average day, how many hours did you use the BAHA?”

☐ Not at all  ☐ <1 h/day  ☐ 1-4 h/d  ☐ 4 - 8 h/d  ☐ >8 h/d

BEN: “Think about the situation where you most wanted to hear better, before you got your BAHA. Over the past two weeks, how much has the BAHA helped in those situations?”

☐ Not at all  ☐ Slightly  ☐ Moderately  ☐ Quite a lot  ☐ Very much

RAL: “Think again about the situation where you most wanted to hear better. When you use your BAHA, how much difficulty do you STILL have in that situation?”

☐ Very much  ☐ Quite a lot  ☐ Moderately  ☐ Slightly  ☐ Not at all

SAT: “Considering everything, do you think your BAHA is worth the trouble?”

☐ Not at all  ☐ Slightly  ☐ Moderately  ☐ Quite a lot  ☐ Very much

RPR: “Over the past two weeks, with your BAHA, how much have your hearing difficulties affected the things you can do?”

☐ Not at all  ☐ Slightly  ☐ Moderately  ☐ Quite a lot  ☐ Very much

Loth: “Over the past two weeks, with your BAHA, how much do you think other people were bothered by your hearing difficulties?”

☐ Not at all  ☐ Slightly  ☐ Moderately  ☐ Quite a lot  ☐ Very much

QOL: “Considering everything, how much has your BAHA changed your enjoyment in life?”

☐ Worse  ☐ No change  ☐ Slightly better  ☐ Quite a lot  ☐ Very much better
BENEFIT AND QUALITY OF LIFE AFTER BONE ANCHORED HEARING AID FITTING IN CHILDREN WITH UNILATERAL OR BILATERAL HEARING IMPAIRMENT

M.J.F. de Wolf
M.K.S. Hol
E.A.M. Mylanus
A.F.M. Snik
C.W.R.J. Cremers
ABSTRACT

Purpose: To evaluate the benefits of a bone anchored hearing aid (BAHA) in the daily lives of hearing impaired children.

Design: Retrospective questionnaire study

Setting: Nijmegen Medical Centre, Nijmegen, the Netherlands.

Patients: Thirty-eight BAHA users with a minimum age of 4 years at BAHA fitting and 1 to 4 Years of use, divided into groups with bilateral conductive or mixed hearing loss and either normal cognition or mental disability and a group with unilateral conductive hearing loss.

Methods: Scores on the Glasgow Children’s Benefit Inventory, Abbreviated Profile of Hearing Aid Benefit, and Health Utility Index Mark 3.

Results: The Glasgow Children’s Benefit Inventory showed a subjective overall benefit of +32, +16 and +26 in the 3 groups (on a scale from -100 to 100). The Abbreviated Profile of Hearing Aid Benefit also showed an overall mean benefit in the groups. On an individual level, a clinically significant benefit was reported by more children in the group with bilateral hearing loss and normal cognition (7 patients [70%]) than in the unilateral hearing loss group (4 patients [27%]). Overall mean health utility scores and disability index scores on the Health Utility Index Mark 3 were comparable among the 3 groups.

Conclusions: Overall, BAHA fitting can be considered effective and beneficial in children with bilateral or unilateral hearing loss.
INTRODUCTION

Since its introduction over 30 years ago, the bone anchored hearing aid (BAHA) has become an established treatment option for auditory rehabilitation in patients with chronic conductive or mixed hearing loss.\(^1\)–\(^3\) When the BAHA was first introduced, it was mainly fitted in adults.\(^4\) In 1992, Jacobsson et al.\(^5\) reported the use of the BAHA in children. This was followed by reports from other BAHA teams describing their clinical findings on the surgical and audiological aspects of BAHA fitting in children.\(^5\)–\(^16\) Gradually, the BAHA has been recognized as first-line therapy in children with bilateral conductive hearing loss (BHL) who are still too young to undergo microsurgery of the middle ear.\(^3\)\(^,\)\(^17\) Infants with hearing impairments can be fitted with the BAHA softband during their very early years of life.\(^18\)\(^,\)\(^19\) This facilitates hearing earlier in life, particularly in the bilaterally impaired. For unilaterally impaired children, this benefit is disputed. In children with congenital unilateral conductive hearing loss (UHL), the BAHA provides a valuable way of creating binaural hearing.\(^3\)\(^,\)\(^17\)\(^,\)\(^20\)\(^,\)\(^21\) For these subgroups, however, the audiological outcome varies.

In addition to doing a clinical evaluation, some research groups have used non-validated questionnaires to gain insight into patient satisfaction regarding their day-to-day use of the BAHA.\(^22\)–\(^24\) In such studies, quality of life questionnaires (QOL) are typically used as supplements to other research. More recently, the QOL and treatment benefits have been addressed by means of validated questionnaires in adults\(^25\) and children.\(^11\)\(^,\)\(^21\)\(^,\)\(^26\)–\(^29\) In the pediatric population, these QOL studies have examined different causes and pathological processes of disorders. For example, studies have been conducted among children with diverse types of unilateral hearing impairment, both acquired and congenital\(^21\)\(^,\)\(^26\)\(^,\)\(^28\); bilateral acquired or congenital conductive hearing impairment\(^21\); and Down syndrome.\(^27\)\(^,\)\(^30\)\(^,\)\(^31\) In 2008, McDermott et al.\(^29\) evaluated QOL in a cross-sectional study of children with unilateral or bilateral conductive hearing loss using the Glasgow Children’s Benefit Inventory (GCBI). They concluded that the BAHA significantly enhanced the general well-being of the children. It is essential, though, to obtain and analyze QOL data on the effects of the BAHA fitting for each type of hearing loss, particularly for unilaterally impaired children, in whom it is not yet clear how to predict treatment success. To the best of our
knowledge, only one study (Priwin et al.\textsuperscript{21}) has evaluated the subjective benefits and QOL in separate groups of children with BHL or UHL.

The ideal tool for evaluating the subjective effects of hearing aid fitting in day-to-day life should assess several aspects. First, it should assess the effect of the impairment on an individual’s auditory functioning in daily life and the benefit the person experiences with regard to his or her disability when using the hearing aid. Second, the tool should accurately evaluate the hearing aid’s contribution to the general quality of a patients’ day-to-day life. Third, the patient’s opinion about his or her general state of health (ie, QOL) should also be assessed.

To obtain reliable data in retrospective evaluations, recall bias should be minimized. To do so, the interval between the evaluation and the device fitting should not be too long. In contrast, it is important that the patient have had sufficient experience with the hearing device to give adequate responses and to minimize bias caused by initial enthusiasm. Recall bias and questionnaire completion can be managed by having the parents and the child fill out the questionnaires together.

To our knowledge, none of the questionnaires that were recently made available address the disability, handicap, benefit, and quality of life simultaneously. Moreover, no study on BAHA use in children has addressed these items simultaneously. To address this lack of data, 3 well-known, validated questionnaires were used in this study.

The aim of this study was to evaluate the effect of the BAHA on the day-to-day lives of children with UHL and BHL by means of validated questionnaires.

**Patients and Methods**

*Patients*

A total of 38 out of 134 children fitted with a BAHA in Nijmegen, the Netherlands, were included in this study. The inclusion criteria were a minimum age of 4 years at BAHA fitting and 1 to 4 years of BAHA use. Parents were asked to fill out the questionnaires with their child to emphasize the opinion of the child.
To adequately evaluate the questionnaire results, the population was divided into two groups, those with BHL and those with UHL.

Within the BHL group, subgroups of children with normal cognition (BHL-NC) and children with mental disability (BHL-MD) were defined because mental disability might influence patient outcomes. In the UHL group, all

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>BHL-NC (N = 10)</th>
<th>BHL-MD (N = 6)</th>
<th>UHL (N = 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you still using your Baha?</td>
<td>Yes</td>
<td>10 (100)</td>
<td>6 (100)</td>
<td>15 (100)</td>
</tr>
<tr>
<td></td>
<td>Not anymore</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Over the past 2 wk, how many hours a day did you use your Baha on average?</td>
<td>Not worn</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>&lt; 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>1-4</td>
<td>0</td>
<td>1 (17)</td>
<td>2 (13)</td>
</tr>
<tr>
<td></td>
<td>4-8</td>
<td>1 (10)</td>
<td>1 (17)</td>
<td>5 (40)</td>
</tr>
<tr>
<td></td>
<td>&gt; 8</td>
<td>9 (90)</td>
<td>4 (67)</td>
<td>7 (47)</td>
</tr>
<tr>
<td>Do you consider your Baha to be worth the effort?</td>
<td>No</td>
<td>0</td>
<td>1 (17)</td>
<td>1 (7)</td>
</tr>
<tr>
<td></td>
<td>A little</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderately</td>
<td>2 (20)</td>
<td>1 (17)</td>
<td>4 (27)</td>
</tr>
<tr>
<td></td>
<td>Much</td>
<td>2 (20)</td>
<td>3 (50)</td>
<td>4 (27)</td>
</tr>
<tr>
<td></td>
<td>Very much</td>
<td>6 (60)</td>
<td>1 (17)</td>
<td>6 (40)</td>
</tr>
<tr>
<td>Do you find it difficult to place your Baha?</td>
<td>Yes</td>
<td>0</td>
<td>1 (17)</td>
<td>1 (7)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>10 (100)</td>
<td>5 (83)</td>
<td>15 (100)</td>
</tr>
<tr>
<td>Can you handle your Baha well?</td>
<td>Yes</td>
<td>10 (100)</td>
<td>4 (67)</td>
<td>14 (93)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>0</td>
<td>1 (17)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Are you familiar with the extra options on your Baha (for example, the audio connection)?</td>
<td>Yes</td>
<td>2 (20)</td>
<td>2 (33)</td>
<td>4 (27)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>8 (80)</td>
<td>4 (67)</td>
<td>11 (73%)</td>
</tr>
<tr>
<td>Do you find it difficult to clean the skin around the implant?</td>
<td>Yes</td>
<td>0</td>
<td>1 (17)</td>
<td>2 (13)</td>
</tr>
<tr>
<td></td>
<td>Sometimes</td>
<td>2 (20)</td>
<td>2 (33)</td>
<td>5 (40)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>7 (70)</td>
<td>3 (50)</td>
<td>7 (47)</td>
</tr>
<tr>
<td>What do you think about the quality of sound from your Baha?</td>
<td>Very good</td>
<td>2 (20)</td>
<td>1 (17)</td>
<td>2 (13)</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>6 (60)</td>
<td>2 (33)</td>
<td>9 (60)</td>
</tr>
<tr>
<td></td>
<td>Reasonable</td>
<td>2 (20)</td>
<td>3 (50)</td>
<td>3 (20)</td>
</tr>
<tr>
<td></td>
<td>Bad</td>
<td>0</td>
<td>0</td>
<td>1 (7)</td>
</tr>
<tr>
<td></td>
<td>Very bad</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Would you recommend the Baha to a friend with the same type of deafness?</td>
<td>Yes</td>
<td>9 (90)</td>
<td>4 (67)</td>
<td>10 (67)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>1 (10)</td>
<td>2 (33)</td>
<td>5 (33)</td>
</tr>
<tr>
<td>Would you (parent / caregiver), be prepared to pay (3000 euros) yourself, to have your child fitted with a Baha?</td>
<td>Yes</td>
<td>7 (70)</td>
<td>3 (50)</td>
<td>11 (73%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>2 (20)</td>
<td>3 (50)</td>
<td>4 (27)</td>
</tr>
</tbody>
</table>
children had normal cognition and a congenital origin of their unilateral hearing loss. Audiological data were also obtained.

**Methods**

This retrospective questionnaire study used the following four tools: 1) a “daily device use” questionnaire (a nonvalidated questionnaire designed for this study to evaluate the BAHA in daily situations [Table 1]), 2) GCBI, 3) the Abbreviated Profile of Hearing Aid Benefit (APHAB) and 4) the Health Utility Index Mark 3 (HUI-3).

The GCBI retrospectively measures the health-related quality of a child’s day-to-day life after an otorhinolaryngologic intervention, such as BAHA fitting. It is, therefore, considered to be a disease-specific QOL instrument. The questionnaire is comprised of 24 questions that are divided into four domains: emotion, physical health, learning, and vitality. The GCBI outcome is quantified with a score between -100 to 0, which reflects a diminished QOL, and a score between 0 to +100, which reflects an improved QOL.

The APHAB assesses auditory functioning in daily life and is a hearing disability-specific questionnaire. A reduction in hearing disability achieved by fitting a hearing aid (in this case, a BAHA) is measured by 24 questions subdivided into four subscales: ease of communication (EC), reverberation (RV), background noise (BN), and aversiveness of sound (AV). The APHAB has a scoring scale from 1 to 99, with a higher score indicating more frequent problems. The APHAB was completed twice by the study participants, with the first questionnaire based on the current situation and the second one based on the previous situation without the BAHA. To define clinical significance on an individual level for each subdomain, a difference of at least 22 points was considered to be statistically significant. An overall difference in the scores of more than 10 points for a given subdomain (i.e., EC, RV and BN) was also considered to be statistically significant. Data collected by Cox from a normative group of young controls with normal hearing were used for comparison.

The HUI-3, a generic, multi-attribute preference-based instrument used to measure general health-related QOL. This is one of the few general QOL questionnaires that is able to capture changes in quality of life as a result of hearing aid fitting. The HUI-3 consists of the following eight
subdomains: vision, hearing, speech, ambulation, dexterity, emotion, cognition and pain. In the HUI-3, there are two types of score: the single-attribute utility and the multi-attribute utility. The single-attribute utility score varies from 0 (highest degree of impairment or disability) to 1.00 (no impairment). The multi-attribute utility score varies from -0.36 (most disabled) to 1.00 (perfect health), whereas 0 corresponds to death.\textsuperscript{35,40-42}

In this study, the HUI-3 was used to provide a “snapshot” of the current health status of the subgroups. In addition, the HUI-3 can also be used to assess a handicap index.\textsuperscript{43} This index has the following four categories: no disability (1.00), mild disability (0.89 to 0.99), moderate disability (0.70 to 0.88) and severe disability (< 0.70).

**Statistical analysis**

The unpaired, 2-tailed t-test and the Krusskal-Wallis test were used to compare the mean values on the different domains of the GCBI to determine a difference between the benefits experienced by the BHL-NC group and the BHL-MD group. A P value of less than 0.05 was chosen as the level of significance, which corresponded to $P = 0.025$ for the 2-tailed t-test. Correlations between demographic factors and the questionnaires and interquestionnaire correlations were tested with Spearman rho. SPSS version 16 (SPSS, Inc., Chicago, Illinois, USA) and Prism

<table>
<thead>
<tr>
<th>Table 2: Descriptive Population data.</th>
<th>BHL-NC (N = 10)</th>
<th>BHL-MD (N = 6)</th>
<th>UHL (N = 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital origin of hearing loss, No. (%)</td>
<td>8 (80)</td>
<td>2 (33)</td>
<td>15 (100)</td>
</tr>
<tr>
<td>Age at implantation, mean (range), y</td>
<td>7 (5-13)</td>
<td>11 (4-16)</td>
<td>7 (4-12)</td>
</tr>
<tr>
<td>Age at questionnaire, mean (range), y</td>
<td>10 (6-15)</td>
<td>12 (6-17)</td>
<td>9 (5-16)</td>
</tr>
<tr>
<td>Bilateral BAHA users, No. (%)</td>
<td>5 (50)</td>
<td>3 (50)</td>
<td>NA</td>
</tr>
<tr>
<td>Conventional bone conductor use before BAHA, No. (%)</td>
<td>5 (50)</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>PTA\textsubscript{ac} mean (SD), dB HL</td>
<td>4 (8)</td>
<td>23 (9)</td>
<td>10 (10)</td>
</tr>
<tr>
<td>PTA\textsubscript{bc} mean (SD), dB HL</td>
<td>49 (11)</td>
<td>61 (15)</td>
<td>56 (17)</td>
</tr>
<tr>
<td>Air-bone gap, mean (SD), dB HL</td>
<td>45 (15)</td>
<td>34 (13)</td>
<td>46 (14)</td>
</tr>
<tr>
<td>Type of mental disability, No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Down syndrome</td>
<td>NA</td>
<td>3 (50)</td>
<td>NA</td>
</tr>
<tr>
<td>Grouchy syndrome</td>
<td>NA</td>
<td>1 (17)</td>
<td>NA</td>
</tr>
<tr>
<td>Unknown</td>
<td>NA</td>
<td>2 (33)</td>
<td>NA</td>
</tr>
</tbody>
</table>

Abbreviations; BAHA, bone-anchored hearing aid; ac, air conduction; bc, bone conduction; BHL, bilateral conductive hearing loss; HL, hearing level; MD, mental disability; NA, not applicable; NC, normal cognition; PTA, pure-tone average; UHL, unilateral conductive hearing loss.
Graph Pad 5 (GraphPad Software, La Jolla, California, USA) were used for analysis.

RESULTS

Patients

The response rate to the questionnaires was 82% (31 of 38 children). Non-responders (N = 7) were contacted by phone. Reasons for non-participation were diverse. Mean age at implantation was 7 years (range 4-15 years). Age at the time of the questionnaire was 10 years (6-17 years). Eighteen patients (58%) were male and 13 (42%) were female. Descriptions of the subgroups (BHL-NC, BHL-MD and UHL groups) are given in table 2.

The bilateral hearing loss (BHL) group

A total of 16 children responded to the questionnaire: 10 in the BHL-NC group and 6 in the BHL-MD group.
Benefit and quality of life in children with a BAHA

The "daily device use" questionnaire

In the BHL-NC group, 9 children (90%) were using the BAHA for more than 8 hours a day (Figure 1). Most children in this group (8 [80%]) reported that the BAHA was worth the effort (Figure 2). There were no reports of problems with placement or handling of the BAHA, and only 2 of 9 children (22%) experienced occasional problems with cleaning around the implant (Figure 3). See table 1 for more details. In the BHL-MD group (N = 6), the answers were more varied (Table 1).
The Glasgow Children’s Benefit Inventory (GCBI)

An overview of the GCBI scores is given in Table 3 and Figure 4. In the BHL-NC group, 8 children reported benefits from using the BAHA. However, 2 children (20%) were having problems in at least one of the subdomains. The BHL-MD group had lower overall scores on the GCBI. Three children had negative scores on the GCBI.

Although the overall mean scores of the BHL-MD group were lower than those of the BHL-NC group, there were no significant differences between these groups for any of the subdomain scores.

<table>
<thead>
<tr>
<th>Questionnaire subdomain scores (mean, SD)</th>
<th>BHL-NC</th>
<th>BHL-MD</th>
<th>UHL</th>
</tr>
</thead>
<tbody>
<tr>
<td>GCBI Total</td>
<td>32 (25)</td>
<td>16 (34)</td>
<td>26 (22)</td>
</tr>
<tr>
<td>Emotion</td>
<td>40 (32)</td>
<td>20 (36)</td>
<td>27 (30)</td>
</tr>
<tr>
<td>Physical</td>
<td>11 (16)</td>
<td>1 (38)</td>
<td>16 (19)</td>
</tr>
<tr>
<td>Learning</td>
<td>47 (33)</td>
<td>29 (40)</td>
<td>40 (28)</td>
</tr>
<tr>
<td>Vitality</td>
<td>31 (20)</td>
<td>10 (32)</td>
<td>19 (17)</td>
</tr>
<tr>
<td>APHAB Ease of Communication, unaided</td>
<td>50 (17)</td>
<td>NA</td>
<td>30 (16)</td>
</tr>
<tr>
<td>Reverberation, unaided</td>
<td>63 (23)</td>
<td>NA</td>
<td>53 (13)</td>
</tr>
<tr>
<td>Background Noise, unaided</td>
<td>73 (24)</td>
<td>NA</td>
<td>53 (22)</td>
</tr>
<tr>
<td>Aversiveness to Sound, unaided</td>
<td>22 (24)</td>
<td>NA</td>
<td>26 (20)</td>
</tr>
<tr>
<td>Ease of Communication, aided</td>
<td>18 (22)</td>
<td>NA</td>
<td>20 (16)</td>
</tr>
<tr>
<td>Reverberation, aided</td>
<td>29 (9)</td>
<td>NA</td>
<td>33 (14)</td>
</tr>
<tr>
<td>Background Noise, aided</td>
<td>35 (20)</td>
<td>NA</td>
<td>26 (15)</td>
</tr>
<tr>
<td>Aversiveness to Sound, aided</td>
<td>40 (27)</td>
<td>NA</td>
<td>37 (26)</td>
</tr>
<tr>
<td>Ease of Communication, benefit</td>
<td>38 (21)</td>
<td>NA</td>
<td>14 (15)</td>
</tr>
<tr>
<td>Reverberation, benefit</td>
<td>34 (21)</td>
<td>NA</td>
<td>21 (18)</td>
</tr>
<tr>
<td>Background Noise, benefit</td>
<td>38 (26)</td>
<td>NA</td>
<td>27 (24)</td>
</tr>
<tr>
<td>Aversiveness to Sound, benefit</td>
<td>-19 (30)</td>
<td>NA</td>
<td>-10 (18)</td>
</tr>
<tr>
<td>HUI-3 Vision</td>
<td>1.00 (0.00)</td>
<td>0.82 (0.4)</td>
<td>1.00 (0.01)</td>
</tr>
<tr>
<td>Hearing</td>
<td>0.80 (0.10)</td>
<td>0.69 (0.20)</td>
<td>0.85 (0.11)</td>
</tr>
<tr>
<td>Speech</td>
<td>0.91 (0.12)</td>
<td>0.54 (0.14)</td>
<td>0.90 (0.12)</td>
</tr>
<tr>
<td>Ambulation</td>
<td>1.00 (0.00)</td>
<td>0.86 (0.11)</td>
<td>1.00 (0.0)</td>
</tr>
<tr>
<td>Dexterity</td>
<td>1.00 (0.0)</td>
<td>0.61 (0.45)</td>
<td>1.00 (0.0)</td>
</tr>
<tr>
<td>Emotion</td>
<td>1.00 (0.03)</td>
<td>1.00 (0.04)</td>
<td>1.00 (0.02)</td>
</tr>
<tr>
<td>Cognition</td>
<td>0.97 (0.06)</td>
<td>0.71 (0.23)</td>
<td>0.92 (0.11)</td>
</tr>
<tr>
<td>Pain</td>
<td>1.00 (0.07)</td>
<td>0.96 (0.09)</td>
<td>1.00 (0.00)</td>
</tr>
<tr>
<td>Multiattribute Utility</td>
<td>0.83 (0.14)</td>
<td>0.26 (0.25)</td>
<td>0.82 (0.12)</td>
</tr>
</tbody>
</table>

Abbreviations: APHAB, Abbreviated Profile of Hearing Aid Benefit; BHL, bilateral conductive hearing loss; GCBI, Glasgow Children’s Benefit Inventory; HUI-3, Health Utilities Index Mark 3; MD, mental disability; NA, not applicable; NC, normal cognition; UHL, unilateral conductive Hearing Loss.
The Abbreviated Profile of Hearing Aid Benefit (APHAB)

To determine the amount of benefit derived from using the BAHA, the patients were asked to fill out the APHAB retrospectively, thereby taking their situation before BAHA fitting into account. A dotted line at the 10-point level and the norm scores are shown in figure 5. The mean group scores on subdomains EC, RV and BN were all above the 10-point level. Individual data, however, showed that 7 patients (70%) experienced a significant overall clinical benefit. None of the patients reported a clinically significant deterioration in their hearing when using the BAHA. Four of these 7 patients had not been using a hearing aid previously, and 3 of them had used a conventional bone conductor. No differences were seen between these two groups.

Only 3 of 6 caregivers for the children in the BHL-MD group responded to the APHAB questionnaire. One of them remarked that the questions were too difficult for the child to answer. Therefore, all the APHAB data from this group were excluded.

Health Utility Index mark 3 (HUI-3)

The scores on each of the 8 subdomains are presented in table 3. In the BHL-NC group, the mean (SD) scores ranged from 0.80 (0.10) to 1.00 (0.00). The overall mean utility score was 0.83 (0.14). The disability scale categorized patients as having no disability (N = 1; [10%]), mild disability...
(N = 2; [20%]), moderate disability (N = 6 [60%]), or severe disability (N = 1 [10%]).

In the BHL-MD group, the mean scores were considerably lower. Ranging from 0.54 (0.14) to 1.00 (0.04), with a mean utility of 0.26 (0.25). The lower scores were mostly due to comorbid conditions and lower scores for dexterity, speech and cognition. In this group, all children were classified as having severe disability on the disability scale.

Figure 5: Mean (SD) benefit scores on the Abbreviated Profile of Hearing Aid Benefit (APHAB) subdomains ease of communication (EC), reverberation (RV), background noise (BN), and aversiveness of sound (AV). BHL indicates bilateral hearing loss; NC, normal cognition; and UHL, unilateral hearing loss. There was significant benefit for the majority of the children in the BHL-NC group (scores above the 10-point line). In the UHL group, there was a significant benefit seen for BN on a subdomain-specific level (the majority of the scores are above the 22-point line).
Findings across questionnaires

Within the BHL-NC group, there were no differences in the GCBI, APHAB and HUI-3 scores between the following groups: the unilateral BAHA users and the bilateral BAHA users; BAHA users with congenital causes and those with acquired causes; and those who previously used conventional hearing aids and those who did not. A negative correlation was found between the age at BAHA fitting and the scores on the GCBI, which indicated that the younger the child was at the time of BAHA fitting, the greater the benefit that could be experienced (rho = -0.68, P=0.02).

There were no interquestionnaire correlations between the domains or subdomains of the questionnaires used. However, a trend was seen between the learning subdomain of the GCBI and the BN subdomain of the APHAB (rho = 0.6, P = 0.06).

The Unilateral Hearing Loss (UHL) group

"Daily device use” questionnaire responses

In the UHL group (N = 15), 7 children (47%) were using their BAHA devices for more than 8 hours a day, and 6 children (40%) were using them for 4 to 8 hours a day (Figure 1, Table 1). The BAHA was considered to be either worth the effort or very much worth the effort by 10 (67%) of the patients surveyed (Figure 2, Table 1).

GCBI Responses

An overview of the GCBI scores is given in table 3 and figure 4. The results were comparable with those found in the BHL-NC group, although 3 children (20%) reported problems in at least one of the subdomains.

The Abbreviated Profile of Hearing Aid Benefit (APHAB

Only 4 children (27%) experienced a significant overall benefit (scores of 10+ for each subdomain) from using the BAHA, according to the results of the APHAB. Significant deterioration did not occur. A significant benefit was seen in 4 children (27%) for subdomain EC, 7 children (47%)
for subdomain RV and 8 children (53%) for subdomain BN. The age at the BAHA fitting was negatively correlated with the subdomain BN (rho -0.54, P=0.02), which indicates that patients experience a greater benefit when the BAHA is fitted at an early age. None of the other subdomains showed significant correlations with age.

Health Utility Index mark 3 (HUI-3)
The mean (SD) scores on the HUI-3 subdomains ranged from 0.85 (0.11) to 1.00 (0.0). The overall mean utility score was 0.82 (0.12). The disability scale categorized patients as having no disability (N = 2 [13%]), mild disability (N = 3 [20%]), moderate disability (N = 8 [53%]) or severe disability (N = 2 [13%]).

Findings across Questionnaires
The learning GCBI subdomain showed a statistically significant correlation with the APHAB benefit of BN (rho = 0.53, P = 0.04). The unaided APHAB RV subdomain score was positively correlated with the GCBI overall subdomain (rho = 0.71, P = 0.003), the emotion subdomain (rho = 0.66, P = 0.008), the learning subdomain (rho = 0.54, P = 0.04) and the “vitality” subdomain (rho = 0.53, P = 0.04). This suggests that patients, especially those experiencing problems hearing in large rooms (e.g., lecture halls, theatres or classrooms) because of reverberation, might experience some benefit from use of the BAHA.

DISCUSSION
This study aimed to evaluate the effect of BAHA fitting on the day-to-day lives of children with either unilateral or bilateral conductive hearing loss. Different questionnaires were used to measure different outcomes.

The response rate in our study was 82%, which is comparable with response rates reported in the literature (73% to 87%).11,22,29,44 This high level of participation was mostly due to an active recruitment method that consisted of multiple reminder letters and telephone calls. To avoid enthusiasm bias as much as possible, we included children who had been using their BAHA for at least one year. To complete the
retrospective questionnaires, parents and children had to recall their situation before the BAHA was fitted, which was as long as four years ago. This may have posed a limitation for the study; however, the choice of four years as the upper limit for duration of the BAHA allowed for a study population (large enough) to sufficiently evaluate the level of benefit. The parents were asked to answer the questions based on the child’s opinion as much as possible. All parents stated that they could sufficiently recall their child’s situation before the BAHA was fitted. Therefore, the answers were considered to be reliable. The minimum age for inclusion in the study was four years, the age at which Dutch children go to nursery school, where their abilities are tested more completely than at younger ages.

In this study population, there were 6 children with mental disabilities. The literature shows that patients with disabilities do indeed derive benefit from the BAHA.\(^27,30\) However, to evaluate this specific patient group, their findings need to be analyzed separately. Three of the 6 parents were unable to respond to the APHAB on behalf of their child. As a result, the APHAB was determined to be too difficult to use in this population and the data from the APHAB was excluded for this group.

It was not possible to draw any firm conclusions regarding comparisons of the BHL-NC and the BHL-MD groups because the number of participants was too small. Nevertheless, some of the children in the BHL-MD group derived more benefit from the BAHA than the previous device, whereas others did not. The very low scores on the HUI-3 could be explained by co-morbidities related to mental disability and/or physical handicap. Overall, the study population was relatively small and, therefore, more research on this specific BAHA population is needed to draw more firm conclusions.

**The BHL group**

The BAHA is considered to be the best option for children with bilateral conductive hearing loss (our BHL-NC group) (consensus statements, Snik et al.\(^3\)). In general, these children derive a great benefit from the BAHA in everyday situations. Our findings support those of other publications on the use of the BAHA in pediatric populations.\(^11,22,29\)

Overall, the GCBI revealed a general benefit of BAHA use in the BHL-NC group. There was a particularly large benefit on the learning subdomain,
which underscores the impact of the BAHA on hearing impaired children’s education. High scores were also seen for the emotion subdomain, which is an encouraging finding for a child’s development.

We found that a younger age at the time of BAHA fitting correlated with higher scores on the GCBI, which emphasizes the need for early hearing aid fitting in children with bilateral hearing loss.

Figure 6 shows the scores from all children who participated (N = 31) compared to findings reported in the recently published literature. In a retrospective study, McDermott et al. evaluated data from 84 children who had been fitted with a BAHA during a period of 15 years. The GCBI scores for all subdomains reported in their study were significantly higher than the scores reported herein (P < 0.01). One explanation for this discrepancy may be the differences in the study populations. In our study, about 19% of study participants had syndromic features compared with 48% in the population studied by McDermott et al. Their approach to these patients, who require additional treatment for their particular comorbidities, involved an integrated program of evaluation and rehabilitation. It is possible that this program created additional subjective treatment benefit for these patients, which was reflected in the scores of the GCBI.

Figure 6: Mean (SD) Glasgow Children’s Benefit inventory (GCBI) scores for each subdomain for the current study’s total population (N = 31) compared to the total population evaluated by McDermott et al. (N = 84). The scores for the current study population are significantly lower for all subdomains (P < 0.01).
Benefit and quality of life in children with a BAHA

Mean scores on the APHAB showed a significant treatment benefit in the majority of children in the BHL-NC group (Figure 5, Table 3). The scores on the subdomains EC, RV and BN all fell around the 80th percentile line for normal hearing subjects, which indicates that 80% of the normative group with normal hearing experienced fewer problems in these listening conditions than the current population (Figure 7). These findings emphasize that, although the BAHA provides benefit in the majority of cases, there is still residual disability compared to normal hearing children.

In the BHL-NC group, the HUI-3 results also support the fact that there is still a residual disability when the BAHA is used. In the current study, the overall mean multi-attribute utility score on the HUI-3 was 0.83 (0.14), which correlates with a moderate disability score. Table 3 shows that a large part of the deviation from perfect health in preference scores can be attributed to the hearing and speech domains, which is not surprising because speech relies heavily on auditory input. The HUI-3 score in the BHL-NC group indicated comparable a general QOL compared with previous reports in the literature.

The results found in children with BHL show an interquestionnaire trend between the benefit of the BAHA in listening conditions with background noise and the beneficial effect of the BAHA on learning capabilities (rho = 0.6, P = 0.06). Thus, the beneficial effects of BAHA use, especially in
noisy environments, may also explain its positive effect on learning in these children.

**UHL group**

According to the consensus statements, the BAHA is also an important treatment option for children with UHL. However, it is still unclear what the predictor for success is in this group. Kunst et al. studied 10 children and 10 adults with UHL. The BAHA had a beneficial effect on speech recognition in a noisy environment in a setup with spatially separated speech and noise sources, although this result could be attributed to effectively lifting the acoustical head shadow.

Priwin et al. did not find any benefit from the BAHA during directional hearing tests in a group of 6 children with congenital UHL. In some cases, directional hearing even deteriorated when the BAHA was used.

Overall, there is no clear evidence to date that a BAHA is beneficial to all children with UHL. To gain more insight into the mechanisms of how patients derive benefit from the BAHA in this patient group, we evaluated the subjective measurements of the BAHA in 15 children with congenital UHL. On the daily device use questionnaire, the UHL group reported that the BAHA was worth the effort in general. However, they did not seem to be using the BAHA all day, and they were not overly impressed by the sound quality. Furthermore, only 67% of the children with UHL would recommend the BAHA to peers compared with 90% in the BHL group. Some of the patients with UHL responded that they used the BAHA only in the classroom, which has also been reported in other studies. The BAHA has proved to be particularly beneficial in speech recognition tests in the setting of noise in patients with UHL. Therefore, the BAHA might be particularly beneficial in the school environment for these children, which is the most important time of the day.

In this study, children with UHL and a BAHA showed a similar benefit, as measured by the GCBI, as the children with BHL and a BAHA. However, 3 of 15 children with UHL had a negative score on 1 of the subdomains. These disappointing results emphasize the importance of performing a trial with a headband to predict which children will benefit most from a BAHA in different listening conditions, including both at home and in school. Previously, Kunst at al. used the GCBI to study 10 children with
Benefit and quality of life in children with a BAHA

Figure 8: Mean (SD) Glasgow Children’s Benefit Inventory (GCBI) scores for each subdomain for the current study’s unilateral hearing loss group (N = 15) compared with the children with unilateral conductive hearing loss (N = 10) in a study by Kunst et al.26 Both studies showed comparable results.

UHL recruited from this clinic. The scores for the subdomains were comparable to those from our study (Figure 8).

On the basis of the fact that the study subjects scored highest on the learning subdomain, it can be concluded that, in children with a unilateral air-bone gap, the BAHA is particularly beneficial in educational settings.

Only 4 patients in the UHL group (27%) derived a significant benefit overall from the BAHA, according to the APHAB assessment made with the criteria defined by Cox.36 Their poor results could be attributed to a low score of 27% on the EC subdomain compared to 47% and 53% on the RV and BN subdomains. These findings indicate that the BAHA does not lead to a significant benefit in all domains assessed by the APHAB in children with UHL. Hypothetically, patients with a congenital, unilateral air-bone gap use their normal contralateral ear to compensate for their impaired ear, which would undermine the benefit of the BAHA. The relatively positive results seen in the subdomains RV and BN might be due to the synergistic effect of binaural hearing and lifting the head shadow, respectively.

The results of the APHAB reiterate that it is of the utmost importance for children with UHL to undergo a trial period with the BAHA on a headband or softband to establish whether or not the BAHA will provide optimal treatment.
The HUI-3 and disability scores in the UHL group were comparable with the scores in the BHL-NC group. For this population, therefore, the BAHA has a beneficial effect, although a residual moderate disability remains. It is difficult to assess the benefit of a BAHA in this population; therefore, a preoperative screening for disability conducted in reverberated rooms using the APHAB might be a valuable way to assess potential additional benefits.

CONCLUSION

This study further supports the finding that the BAHA is beneficial for children with BHL. Children with normal cognition and those with mental disability gave positive subjective reports about the BAHA. Subjective evaluations by the children with UHL were more varied than those by the children with BHL. In children with UHL, the decision to use a BAHA should be made on an individual basis with the aid of a trial period of at least two weeks, which allows the child to use the BAHA in a variety of settings, particularly in a school environment. Overall, the BAHA was particularly beneficial for a child’s learning, which may be largely due to its beneficial effects in noisy surroundings.
REFERENCES


BENEFIT AND QUALITY OF LIFE IN OLDER BONE-ANCHORED HEARING AID USERS

M.J.F. de Wolf
M-L.C. Shival
M.K.S. Hol
E.A.M. Mylanus
C.W.R.J. Cremers
A.F.M. Snik
ABSTRACT

Objective: Benefit and quality-of-life analysis in the older adult bone-anchored hearing aid (BAHA) users.

Study Design: Retrospective evaluation.

Methods: Four questionnaires (Glasgow Benefit Inventory [GBI], Abbreviated Profile of Hearing Aid Benefit [APHAB], Nijmegen Cochlear Implant Questionnaire [NCIQ], and the Hearing Handicap Inventory for the Elderly screening version [HHIE-S]) were used.

Results: The response rate was 80%, mean age was 75 years (range, 62 to 93 yr), and mean pure-tone average at frequencies of 500, 1,000, 2,000, and 4,000 Hz for bone conduction was 42 to 13 dBHL. More than 80% of the patients were using their BAHA for more than 8 hours a day. To obtain a snapshot of current BAHA use, the NCIQ, HHIE-S, and the APHAB were used. The NCIQ showed good disability and handicap results (score range, 49 to 64). The HHIE-S showed that 60% of the patients had a mild to moderate handicap. The APHAB aided scores ranged from 39 to 58%. Mean benefit scores of the Glasgow Benefit Inventory were positive in 112 of the 134 patients (84%). The APHAB showed clinically significantly more benefit with the BAHA than with the previous aided or unaided situation. A trend could be seen, the higher the pure tone average at frequencies of 500, 1,000, 2,000, and 4,000 Hz for bone conduction, the smaller the mean benefit scores on the questionnaires.

Conclusion: Bone-anchored hearing aid users aged 60 years or older were able to place and handle the device very adequately and clean the skin around the implant. Most patients reported comparable or increased general benefit and good quality of life with the BAHA.
INTRODUCTION

In 1965, Bränemark et al.\textsuperscript{1} began using osseointegrated titanium implants to fit dental prostheses. This led to the development and fitting of the first bone-anchored hearing aids (BAHAs) by Tjellström et al.\textsuperscript{2} in Göteborg, Sweden, in 1977. In the spring of 1982, the first 10 patients were fitted with a BAHA.\textsuperscript{3} The BAHA is mostly used by patients with conductive or mixed hearing loss who are unable to wear a conventional air conduction hearing aid (ACHA) mostly due to chronic otitis. For these patients, the BAHA is usually the only remaining option.

In June 1988, the first patients were implanted with a BAHA in Nijmegen, the Netherlands. Two decades later, 1,076 patients have been fitted with a BAHA in Nijmegen. Most of these patients were adults with the previously mentioned "conventional" indication. However, within these 1,076 (28\%) patients, 297 were 60 years or older, and 168 were considered suited for inclusion in this study. The sensorineural hearing loss component is known to increase with age. In general, sensorineural hearing loss affects 25 to 40\% of the population 65 years or older. The prevalence increases dramatically with age: 40 to 60\% in the 75+ age group and more than 80\% in the 85+ age group.\textsuperscript{4} It is possible that BAHA users who originally had pure bilateral conductive hearing loss will experience more problems as the sensorineural component becomes more prominent with aging. Thus, the BAHA might become less suitable for these persons over the years.

Important outcomes of medical treatment nowadays are subjective benefit and the patient's own view of their health status. These issues can be measured with 3 types of validated instrument: generic, disease-specific, and domain-specific. Generic instruments enable comparisons of health status but often fail to capture aspects that are important to a specific clinical setting such as hearing impairment. Thus, they seem to lack sensitivity to assess the gain in quality of life after changes in treatment\textsuperscript{5,6}, or change is too small for them to detect.\textsuperscript{7} In contrast, disease-specific instruments can assess impairment of function, in this case, hearing impairment. They not only assess disability but also give an indication of handicap and are therefore more likely to be responsive to changes in hearing impairment. The third category of instruments is domain-specific, which means that they can measure, for example, pain and depression.
A recent study by Bagai et al.\(^4\) on older adults with hearing impairment has shown that the patients who were not using their conventional hearing aid were more likely to report sadness and depression, worry and anxiety, paranoia, decreased social activity, emotional turmoil, and insecurity than those who were using their hearing aid. The same problems might arise in patients of all ages if their hearing aid does not work properly or is not suited to the type of hearing loss. Hearing impairment has commonly been associated with functional disability and emotional, social, and behavioral problems.\(^8\) Disabilities can be very severe even when audiologic testing shows that the hearing loss is relatively mild. For older adults, a BAHA can be suitable provided that the cochlear function is adequate. However, their cochlear function is likely to deteriorate with aging, which would cause additional hearing problems. It is possible that precisely these older patients, with mixed hearing loss, will derive benefit and improvements in quality of life from BAHA fitting.

The purpose of this study was to evaluate subjective benefit and quality of life in older adult BAHA users with mixed hearing loss.

**MATERIALS AND METHODS**

**Patients**

All consecutive patients 60 years or older were identified who had been fitted with a BAHA for the conventional indication between April 1990 and April 2007. After exclusion of the patients who had died, questionnaires were sent to the 168 suitable candidates who had bilateral conductive or mixed hearing loss and had used the BAHA for at least 1 year. A response rate of 80% (N = 134) was achieved after several reminders. Reasons for nonparticipation (N = 34) were 18 patients had moved and could not be contacted, 8 were not interested in the study, 2 had dementia, and 6 patients had stopped using their BAHA (3 due to chronic pain at the implant site, 1 because of implant loss due to trauma, 1 had deteriorating health, and 1 had not experienced sufficient benefit).
Table 1: Descriptive Population data.

<table>
<thead>
<tr>
<th>Descriptive Population data (N = 134)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 75 years (range 62-93 years)</td>
</tr>
<tr>
<td>men 56 (42%)</td>
</tr>
<tr>
<td>women 78 (58%)</td>
</tr>
<tr>
<td><strong>PTA\textsubscript{bc}</strong> 42 ± 13 dB HL</td>
</tr>
<tr>
<td>Bilateral BAHAs 11 (8%)</td>
</tr>
</tbody>
</table>

**Indication**

- Bilateral mixed hearing loss 98 (73%)
- Mixed hearing loss in one ear, other ear deaf 36 (27%)

**Mean duration of BAHA use**

- < 1 year of use 11 (8%)
- < 5 years of use 67 (50%)

**Previous HA**

<table>
<thead>
<tr>
<th>no BAHA (N = 13, 10%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>age 67 ± 6 years</td>
</tr>
<tr>
<td><strong>PTA\textsubscript{bc}</strong> 38 ± 16 dB HL</td>
</tr>
<tr>
<td>air bone gap 33 ± 12 dB HL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ACHA (N = 81, 60%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>age 68 ± 6 years</td>
</tr>
<tr>
<td><strong>PTA\textsubscript{bc}</strong> 36 ± 11 dB HL</td>
</tr>
<tr>
<td>air bone gap 32 ± 12 dB HL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BCHA (N = 40, 30%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>age 69 ± 6 years</td>
</tr>
<tr>
<td><strong>PTA\textsubscript{bc}</strong> 45 ± 15 dB HL</td>
</tr>
<tr>
<td>air bone gap 35 ± 13 dB</td>
</tr>
</tbody>
</table>

**Methods**

The patients were sent 5 different questionnaires. One concerned “daily use” and satisfaction with the BAHA. Satisfaction was defined as a positive response to 2 of 3 of the following aspects: recommendation to a peer, being prepared to pay for the BAHA yourself, or choosing the BAHA again (Table 1). The other 4 questionnaires comprised widely accepted and validated instruments.

Three of the questionnaires (Abbreviated Profile of Hearing Aid Benefit [APHAB], the Hearing Handicap Inventory for the Elderly-Screening version [HHIE-S]\textsuperscript{9,10}, and the Nijmegen Cochlear Implant Questionnaire [NCIQ]\textsuperscript{11}) were used to obtain a “snapshot” of the current situation regarding BAHA use.\textsuperscript{12,13} Two questionnaires were used to assess subjective benefit: the Glasgow Benefit Inventory (GBI) and the APHAB.
Chapter 3.3

The APHAB, developed by Cox and Alexander\textsuperscript{12}, is a disease-specific "disability" questionnaire with 24 items scored in four 6-item subscales. Three of the subscales address speech understanding in various everyday environments: ease of communication (EC, under relatively favorable conditions), listening under reverberant conditions (RV, communication in reverberant rooms such as halls or churches), and listening in background noise (BN, in settings with high background noise levels). The fourth subscale measures the negative reactions to environmental sounds: aversiveness of sounds. Responses can be given on a 7-point scale.

The HHIE-S, developed by Lichtenstein et al.\textsuperscript{9} and Ventry and Weinstein\textsuperscript{10}, is a "handicap"-specific screening tool for elderly subjects with hearing loss. It consists of 10 items and 2 domains: emotional consequences and social/situational effects, with 3 response categories: "yes" (4 points), "sometimes" (2 points), and "no" (0 point). Scores can range between 0 (no handicap) and 40 (maximum handicap). The HHIE-S was adapted for use in the BAHA-aided situation. A score of 0 to 8 points meant a probability of 13\% that the hearing impairment was forming a handicap (no handicap). With a score of 10 to 24, there was a 50\% probability of mild to moderate handicap, and with a score of 26 to 40, there was a probability of 84\% of severe handicap.\textsuperscript{10,14}

To assess more detailed information on hearing related disability a third questionnaire was added. The NCIQ, developed by Hinderink et al.\textsuperscript{11}, is a disease-specific "disability and handicap" questionnaire initially designed for patients with cochlear implants (CIs). This questionnaire is known to be relatively sensitive to hearing-related quality-of-life issues in patients with CIs. It consists of 60 items on 3 domains: physical, psychologic, and social. These can be subdivided into 6 subdomains: basic sound perception (BSP), advanced sound perception (ASP), speech production, self-esteem, activity limitations (AL), and social interactions. The former 3 subdomains are disability-specific, whereas the latter three are handicap-specific. The response format is a 5-point Likert scale and a "not applicable" option. Scores can range between 0 and 100 (optimal). For use in the present BAHA population, the NCIQ was adjusted by excluding 3 of the questions on speech production and 1 question in the social interactions domain because they refer specifically to the use of signs, shouting, and communication with deaf persons in CI users. The resulting questionnaire was expected to be sensitive in BAHA patients,
but this was the first time that it has been applied to a BAHA in this population.

The 2 questionnaires used to assess subjective benefit were the GBI and the APHAB. The GBI is a retrospective generic quality-of-life questionnaire developed by Robinson et al.\textsuperscript{15} to measure outcomes after otorhinolaryngologic procedures. It is sensitive to changes in "health status" that result from an intervention, and it enables comparisons between different interventions. Three domains are covered by 18 items, 12 related to general improvement, 3 to social improvement, and 3 to physical improvement. Responses can be given on a 5-point Likert scale. Scores range from -100 (maximum lack of benefit), to 0 (no benefit), to +100 (maximum benefit).

The APHAB can also be used to assess benefit if pre-intervention and post-intervention data are available. Differences in benefit score on each of the EC, RV, or BN subdomains of more than 10 points are considered to be clinically significant with a chance occurrence of only 4\%.\textsuperscript{13} On a subdomain-specific level, a difference of 22 points is considered to be clinically significant.\textsuperscript{13}

Demographic characteristics of the patients (age; years of BAHA use; previous type of hearing aid [none/air conduction/bone conduction]; and the most recent measured pure-tone average at frequencies of 500, 1,000, 2,000 and 4,000 Hz for bone conduction [PTA\textsubscript{bc}] and air-bone gap) were used to analyze statistical correlations. Inter-questionnaire correlations were also calculated.

\textbf{Statistics}

The statistical analyses were performed using the SPSS 16.0 system (SPSS, Inc., Chicago, IL, USA). Spearman [rho] was used to correlate the variables to the outcomes of the questionnaires. Only statistically significant correlations of 0.4 or more were regarded to be clinically significant. Linear regression analyses were used to perform inter-questionnaire analyses.

\textbf{RESULTS}

This population comprised 134 BAHA users 60 years or older. Descriptive data are presented in table 1. The interval in years between the most recent audiologic test and the questionnaires taken was 2.3 ± 1.9 years.
Table 2: The “daily use” questionnaire.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you still using the BAHA?</td>
<td>Yes</td>
<td>131 (98%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>How many hours per day have you been using the BAHA on a regular basis over the past two weeks?</td>
<td>Not worn the BAHA</td>
<td>2 (2%)</td>
</tr>
<tr>
<td></td>
<td>Less than one hour a day</td>
<td>1 (1%)</td>
</tr>
<tr>
<td></td>
<td>1-4 hours a day</td>
<td>14 (10%)</td>
</tr>
<tr>
<td></td>
<td>4-8 hours a day</td>
<td>8 (6%)</td>
</tr>
<tr>
<td></td>
<td>More than 8 hours a day</td>
<td>109 (81%)</td>
</tr>
<tr>
<td>In general, is your current BAHA worth the effort?</td>
<td>No</td>
<td>2 (2%)</td>
</tr>
<tr>
<td></td>
<td>A little</td>
<td>4 (3%)</td>
</tr>
<tr>
<td></td>
<td>Moderately</td>
<td>22 (16%)</td>
</tr>
<tr>
<td></td>
<td>Much</td>
<td>26 (19%)</td>
</tr>
<tr>
<td></td>
<td>Very much</td>
<td>78 (59%)</td>
</tr>
<tr>
<td>Do you have difficulties placing the BAHA?</td>
<td>Yes</td>
<td>13 (10%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>120 (90%)</td>
</tr>
<tr>
<td>Can you handle the BAHA controls well?</td>
<td>Yes</td>
<td>126 (94%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>8 (6%)</td>
</tr>
<tr>
<td>Are you familiar with the extra application options?</td>
<td>Yes</td>
<td>46 (34%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>83 (62%)</td>
</tr>
<tr>
<td>Do you have difficulties cleaning skin around the implant site?</td>
<td>Yes</td>
<td>12 (9%)</td>
</tr>
<tr>
<td></td>
<td>Sometimes</td>
<td>25 (19%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>96 (72%)</td>
</tr>
<tr>
<td>How do you judge the sound of the BAHA?</td>
<td>Very good</td>
<td>16 (12%)</td>
</tr>
<tr>
<td></td>
<td>Good</td>
<td>61 (46%)</td>
</tr>
<tr>
<td></td>
<td>Reasonable</td>
<td>47 (35%)</td>
</tr>
<tr>
<td></td>
<td>Bad</td>
<td>8 (6%)</td>
</tr>
<tr>
<td></td>
<td>Very bad</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Would you recommend the BAHA to a friend with the same hearing loss as yours?</td>
<td>Yes</td>
<td>121 (90%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>12 (9%)</td>
</tr>
<tr>
<td>If you had to pay for the BAHA (3000 euro) yourself, would you still have it fitted?</td>
<td>Yes</td>
<td>95 (71%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>35 (26%)</td>
</tr>
<tr>
<td>Would you, based on your experience with the BAHA, choose the BAHA again?</td>
<td>Yes</td>
<td>123 (92%)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>8 (6%)</td>
</tr>
</tbody>
</table>

Daily Use

Responses to the questionnaires (Table 2) showed that 131 of the 134 patients (98%) were currently using their BAHAs; 81% were using their BAHAs for more than 8 hours a day. Reasons for no longer using the BAHA were problems with skin disease (psoriasis), unexplained dysfunction of the hearing aid, and illness of the spouse. These 3 patients had stopped using their BAHA less than 14 months before the study after
Benefit and quality of life in older BAHA users

Figure 1: Mean NCIQ results in the conventional BAHA group (n=134) subdivided into Basic Sound Perception (BSP), Advanced Sound Perception (ASP), Speech Production (SP), Self-Esteem (SE), Activity Limitations (AL), and Social Interactions (SI). And a comparison with the literature.

4, 7, and 11 years of use, respectively. Their responses were included in the analysis.

The general questionnaire showed that the BAHA had been fairly well accepted. Most of the patients did not have any difficulties with putting their BAHAs on (90%), cleaning the skin around the implant (72%), or handling the BAHA (94%). Satisfaction with the BAHA (81%) was reflected

Figure 2: Mean scores in the aided condition (N = 134) plotted against a norm group with linear air conduction hearing aids Cox.13 On the subdomains EC, RV and BN, the mean BAHA scores fell on the 80th percentile, thus 80% of the norm group had fewer problems.
in the responses to recommend the BAHA to a peer (90%), willingness to pay for the BAHA (71%), and choosing the BAHA again (92%). An overview of the data is given in table 2.

Current Status of BAHA Use

The NCIQ, APHAB, and HHIE-S provided a "snapshot" of current BAHA use in terms of disability and handicap. Higher scores on the NCIQ mean better outcomes. Lower outcomes in the APHAB and HHIE-S reflect milder handicap.

The disability-specific scores on the BAHA-aided subdomains of the APHAB are presented in table 3. Figure 2 shows the mean scores in the aided and unaided conditions plotted against those of a norm group of older ACHA users studied by Cox (gray lines).13

Interestingly, the HHIE-S showed higher levels of handicap in the social/situational setting than in the emotional setting (111 of the 134; 83%) for most patients; 14 patients (10%) had comparable levels of handicap in the 2 settings, and only 9 patients (7%) had more severe emotional than situational handicap. This handicap scale showed that in the BAHA-aided condition, 23 patients had "no handicap" (17%), 80 patients had mild to moderate handicap (60%), and 31 patients (23%) had severe handicap.

The following demographic variables were used in the analyses: age at administration of the questionnaires, duration of BAHA use in years, PTA_{abc}, and air-bone gap. Spearman [rho] showed that there were no clinically
significant correlations (all correlations were ≤ 0.4) between these variables and the outcomes of the questionnaires. However, trends were seen between the sensorineural hearing loss component and the subdomains BSP and ASP of the NCIQ (r = -0.36 and -0.37, respectively; P < 0.000). This indicates that sound perception benefit in the BAHA-aided condition might depend on the sensorineural hearing loss component. A trend in PTA_{bc} was also seen on the HHIE-S (r = 0.34, P < 0.000), which might indicate that the level of handicap depends on the sensorineural hearing loss component (Figure 3).

Benefit in the BAHA-Aided Condition

On the GBI, the higher the score, the greater the benefit. A total of 112 of the 134 (84%) patients had a positive mean GBI score. These outcomes are shown in table 3 and figure 4.

On the APHAB, patients were asked to fill in the questionnaire retrospectively and according to the current situation with the BAHA. In this population, 45 of the 134 patients (34%) reported significant overall benefit with the BAHA compared with their previous situation. Deterioration was reported by 2 patients (2%), whereas 87 patients (64%) had not experienced any significant difference.

The data were also divided into subgroups according to the previous aided or unaided situation (no HA, ACHA, or BCHA). Benefit scores for these subgroups are presented in table 3. In the ACHA and BCHA
Table 4: Linear regression results of the NCIQ subdomains BSP, ASP, and SP explaining the total score on the HHIE-S.

<table>
<thead>
<tr>
<th>Step</th>
<th>B</th>
<th>SE B</th>
<th>Beta</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Constant)</td>
<td>38.63</td>
<td>2.45</td>
<td>15.77</td>
</tr>
<tr>
<td>Advanced sound perception</td>
<td>-0.25</td>
<td>0.05</td>
<td>-.58</td>
</tr>
<tr>
<td>Basic sound perception</td>
<td>-0.01</td>
<td>0.05</td>
<td>-.03</td>
</tr>
<tr>
<td>Speech production</td>
<td>-0.08</td>
<td>0.04</td>
<td>-.18</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Constant)</td>
<td>38.67</td>
<td>2.43</td>
<td>15.91</td>
</tr>
<tr>
<td>Advanced sound perception</td>
<td>-0.26</td>
<td>0.04</td>
<td>-.60</td>
</tr>
<tr>
<td>Speech production</td>
<td>-0.09</td>
<td>0.04</td>
<td>-.18</td>
</tr>
</tbody>
</table>

Note R² = 0.51 for step 1; Δ R² = 0.00 for step 2

...groups, 2 patients experienced clinically significant deterioration after changing from an ACHA (1%) or a BCHA (3%) to the BAHA.

Inter-questionnaire Correlations

In response to the "snapshot" questionnaires on the current aided condition, the subdomains EC and BN in the APHAB showed clinically significant correlations with all the subdomains of the NCIQ (r = 0.44 to 0.64; P < 0.00). The subdomain RV in the APHAB showed correlations with BSP, ASP, and AL in the NCIQ (r = 0.44 to 0.47; P < 0.00). The total handicap score on the HHIE-S correlated with the aided scores on the

Table 5: Linear regression results of the EC, RV, and BN subscales of the APHAB explaining the variance in the HHIE-S scores.

<table>
<thead>
<tr>
<th>Step</th>
<th>B</th>
<th>SE B</th>
<th>Beta</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Constant)</td>
<td>1.226</td>
<td>2.108</td>
<td>0.582</td>
</tr>
<tr>
<td>Ease of communication aided</td>
<td>0.088</td>
<td>0.037</td>
<td>-0.203</td>
</tr>
<tr>
<td>Background noise aided</td>
<td>-0.168</td>
<td>0.036</td>
<td>-0.417</td>
</tr>
<tr>
<td>Reverberation aided</td>
<td>-0.065</td>
<td>0.040</td>
<td>-0.130</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Constant)</td>
<td>3.291</td>
<td>1.687</td>
<td>1.951</td>
</tr>
<tr>
<td>Advanced sound perception</td>
<td>-0.101</td>
<td>0.036</td>
<td>-0.234</td>
</tr>
<tr>
<td>Speech production</td>
<td>-0.188</td>
<td>0.034</td>
<td>-0.468</td>
</tr>
</tbody>
</table>

Note R² = 0.42 for step 1; Δ R² = -0.012 for step 2
Benefit and quality of life in older BAHA users

APHAB (EC, BN, RV; r = 0.47 to 0.59; P < 0.00) and all the subdomains in the NCIQ (r = -0.5 to -0.77; P > 0.00). Linear regression showed that the subdomains BSP, ASP, and speech production of the NCIQ, representing disability, explained 51% of the total score on the HHIE-S (Table 4). The APHAB-aided subscales EC, RV, and BN explained 42% of the variance in the HHIE-S scores (Table 5).

Inter-questionnaire correlations between the “Benefit” questionnaires were clinically significant for the total and general scores on the GBI and the subdomain scores EC, RV, and BN on the APHAB (r = 0.40 to 0.52; P < 0.00).

DISCUSSION

Nowadays, the BAHA, developed in 1977, is accepted worldwide. It is regarded as the gold standard for patients with chronic otitis or middle ear malformations who cannot be treated with a conventional air-conduction hearing aid. This study concentrated on the benefit and a "snapshot" evaluation of the effect of the BAHA in older adults by measuring certain quality-of-life aspects (remaining disability, remaining handicap, benefit, and satisfaction) using different questionnaires.

To gain insight into the satisfaction of this population, several items were addressed in the first general questionnaire. Satisfaction was defined as a positive response to 2 of 3 of the following: recommendation to a peer, paying for the BAHA yourself, or choosing the BAHA again. This revealed that 95 patients (71%) were satisfied.

The questionnaire data also showed that 131 patients (98%) were still using their BAHA, and that 109 of them (81%) were using it for more than 8 hours a day. Most of the patients did not have any difficulties handling the BAHA (N = 126; 94%) or cleaning the skin around the implant (N = 96; 72%). Only a very small percentage of the patients (N = 2; 1.5%) felt that the BAHA was not worth the effort or that the sound quality was poor (N = 9; 7%). Overall, these results indicated that the BAHA was functioning well in the daily lives of these older adults. The NCIQ, APHAB, and HHIE-S were used to make the “snapshot” evaluation.

The disability scores on the APHAB showed the best results on the EC subscale. Patients only experienced problems 38% of the time (Figure 2). This indicates that the BAHA enables good performance in what is
Chapter 3.3

qualified as the most important situation: communication with others. In reverberant conditions and situations with background noise, the patients reported less favorable results in terms of problems in 58% and 57% of the cases, respectively. An explanation for these poor results may be that 92% of this population was fitted with only 1 BAHA. Listening with bilateral BAHAs might be of specific value in these conditions.

The aided scores reported in the APHAB were comparable with those in a norm group described by Cox and Alexander\(^{12}\) and Cox\(^{13}\) (Figure 2). Their norm group consisted of mostly elderly conventional hearing aid users with mild-to-moderate sloping or flat bilateral hearing loss who had been using their device for at least 1 year for 4 or more hours a day. When the mean scores from the BAHA population fell on the 50th percentile line, this means that the 2 populations were experiencing comparable hearing problems. However, in this BAHA population, the mean scores on the subdomains EC, RV, and BN fell on the 80th percentile, which indicated that 80% of the norm group was experiencing fewer problems. An explanation for the poorer scores on the subdomains RV and BN might be that in our BAHA population, only 11 of the 134 patients (8%) were fitted bilaterally compared with 42% in the population studied by Cox and Alexander.

The HHIE-S gives an indication of the subjective severity of their handicap. Our results showed that in the BAHA-aided condition, almost 80% only had a mild level of residual handicap. A trend was seen (Figure 3) that with increasing sensorineural hearing loss, the severity of the handicap also increased. However, in some cases, there was not always a linear relation between the severity of the hearing loss and the subjective handicap (Figure 3). In the literature, HHIE-S scores (13 points) from patients with a unilateral air-conduction hearing aid (N = 98) were comparable with the scores from our population.\(^8\)

In this BAHA population, the NCIQ scores ranged from 49 to 65 points, which means that the patients were able to function or hear on a "regular" to "usual" basis in different situations. This can be considered as a good outcome in these patients (Figure 1). Although the NCIQ was not designed for BAHA patients, and no other studies have used it for this purpose, the results of this first application showed that the NCIQ can also be used to obtain data from a BAHA population. Its various subdomains gave more specific indications in which direction the problem or benefit lay with the BAHA. The NCIQ results can be
Table 6: NCIQ comparison between cochlear implant and BAHA.

<table>
<thead>
<tr>
<th>NCIQ</th>
<th>Current study (N = 134, mean age 75 ± 6)</th>
<th>Hinderink et al. 11 (N = 45, mean age 50 ± 16)</th>
<th>Damen et al. 16 (N = 37 mean age 55 ± 16)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2009 BAHA+</td>
<td>2000 CI+</td>
<td>2004 CI+</td>
</tr>
<tr>
<td>BSP</td>
<td>49 ± 24</td>
<td>64 ± 24 **</td>
<td>61 ± 25*</td>
</tr>
<tr>
<td>ASP</td>
<td>58 ± 22</td>
<td>54 ± 20</td>
<td>54 ± 20</td>
</tr>
<tr>
<td>SP</td>
<td>65 ± 10</td>
<td>82 ± 18**</td>
<td>83 ± 18**</td>
</tr>
<tr>
<td>SE</td>
<td>59 ± 15</td>
<td>67 ± 16**</td>
<td>67 ± 19**</td>
</tr>
<tr>
<td>AL</td>
<td>59 ± 20</td>
<td>73 ± 16**</td>
<td>74 ± 20**</td>
</tr>
<tr>
<td>SI</td>
<td>64 ± 19</td>
<td>71.9 ± 14.5*</td>
<td>64 ± 15</td>
</tr>
</tbody>
</table>

Means and standard deviations of the different subdomains of the NCIQ. Significant changes between BAHA and cochlear implant are indicated with an asterisk (Unpaired t-test) *p<0.05; **p<0.01.

Compared with the CI outcomes obtained 1 year after the intervention in the earlier studies by Hinderink et al. 11 and Damen et al. 16 Data are presented in Table 6 and Figure 1. This questionnaire is known to be relatively sensitive to changes in hearing-related quality-of-life issues in patients with CIs. 11 Although CIs and BAHAs work on different principles, the NCIQ questions address general hearing-related issues. Therefore, it can be argued that it is also suitable for BAHA users. The poorer outcomes in the BAHA users might be explained by differences in lifestyles (coping strategies) between the 2 patient groups. The explanation for this is that it was expected that the postintervention scores in the CI patients would be poorer (going from total deafness to moderate/severe hearing impairment) than in the patients who changed their previous non-optimal hearing device for a BAHA (going from moderate hearing impairment to moderate/mild hearing impairment). Apparently, CI users can cope more easily with remaining disability than BAHA users. Subjective perceptions of disability levels play a role. To obtain NCIQ reference values for BAHA patients, it is recommended to use this questionnaire in other populations of BAHA users.

Patient characteristics such as PTAbc and the air-bone gap did not show any clinically significant correlation with the "snapshot" outcome of these questionnaires. In the case of the air-bone gap, this was not a surprise because the BAHA bypasses the air-bone gap. 17 However, the sensorineural hearing loss component showed a negative trend on the subdomains BSP and ASP on the NCIQ (r = -0.36 and -0.37; P < 0.000). This indicates that poor sound perception with the BAHA might be due to a
large sensorineural hearing loss component and illustrates the limitations of BAHA fitting in patients with more severe sensorineural hearing loss.

In general, retrospective benefit assessments, for example, using the GBI or APHAB, give rise to difficulties. One of the major drawbacks is that patients sometimes have to recall how their situation was several years ago.

In the present population, most patients had been using their BAHA for a long period of time. Recollection of the problems experienced before the BAHA was fitted may have weakened over time and caused recall bias, thus changing the results. To obtain the best results and thereby avoid recall bias, a group should have been chosen whose maximum duration of use was 1 year. In our study, this would have applied to a group of 11 patients (8%). The data were reanalyzed twice, once with only the patients with a follow-up of 1 year and once with the group with a follow-up of up to 5 years. This analysis showed only minor differences in overall benefit scores between these 2 subgroups and the total population. The mean scores on the GBI and APHAB in the 1-year group, the 5-year group, and the total population were 18 ± 16, 23 ± 21, and 23 ± 22 (GBI) and 12 ± 25, 19 ± 23, and 17 ± 23 (APHAB), respectively. The most accurate way to evaluate health-related quality of life and subjective benefit is to administer the questionnaires before BAHA fitting and to repeat these measurements after certain intervals, which will avoid recall bias. However, such an assessment procedure had not been followed.

The GBI was used to examine the subjective benefit of BAHA use. In this population of older adults, it produced positive results on all the

---

Figure 5: GBI comparison with the literature. Mean results on the general, social and physical subdomains.
subdomains, which indicates that the patients were experiencing benefit from their BAHAs. In the literature, 3 studies evaluated the subjective benefit of BAHA use by means of the GBI.\textsuperscript{18-20} Figure 5 presents the results. The subjective benefit outcomes in the subgroups “mastoid disease” and “otitis media” have been combined to facilitate adequate comparison. The current data were the poorest. Reasons might be the relatively long follow-up in our study (although recall bias is unlikely because duration of follow-up has little effect on the GBI score) or enthusiasm bias in the other studies owing to persisting feelings of gratitude during the relatively short follow-up. In our population of older adults, the sensorineural hearing loss might have been more profound and therefore possibly weakened the benefit that can be provided by a BAHA.

The APHAB was also used to assess the subjective effect of the BAHA in the present older population. It was chosen to compare the BAHA to the previous hearing aid (no HA, ACHA, BCHA). In the "no HA" subgroup, 54% of the patients reported significant overall benefit. In the other 2 subgroups (ACHA or BCHA), these percentages were 32 and 30%, respectively. These data showed that in approximately one third of our older adult patients, the BAHA was providing greater audiologic benefit than their previous situation, and it had also brought relief from the chronic otitis (ACHA) or pressure pains (BCHA).

Inter-questionnaire analysis of the "snapshot" questionnaires showed clinically significant correlations between the EC and BN subdomains in the APHAB and all the subdomains in the NCIQ. In addition, subdomain RV in the APHAB was correlated with subdomains BSP, ASP, and AL in the NCIQ. This indicates that these 2 questionnaires assess comparable disability issues. The significant correlations can be regarded as validation of the study setup. Correlations were found between the total handicap score in the HHIE-S, the aided scores on the APHAB (disability), and all the subdomains in the NCIQ. This suggests that any remaining subjective handicap was closely associated with the subjective level of disability.

In conclusion, our older BAHA users were able to place and handle the device very adequately and clean the skin around the implant. They also reported good quality of life when using the BAHA. Most were experiencing comparable or increased general benefit from the BAHA despite their age-related hearing deterioration.
REFERENCES


GENERAL DISCUSSION
DISCUSSION

CLINICAL OUTCOME MEASURES

This thesis addresses two aspects of BAHA surgery and BAHA use. First, clinical outcomes such as implant loss and skin reactions around the implant are discussed in view of a specific surgical technique focusing on children, adults and older adult user groups (Chapter 2). Second, the amount of benefit and the quality of life gained from the BAHA device was are evaluated in these groups.

An overview of the literature on BAHA puts its development into perspective. Initially, a free retroauricular skin graft was used with subcutis reduction to create hairless skin at the implant site. The mobility of the free skin graft was reduced through an extensive reduction of the subcutaneous tissue. However, the use of a free skin graft was gradually abandoned as it enhanced the risk of skin necrosis and donor site morbidity. A manually performed pedicled skin flap gradually replaced it. In order to simplify this technique, a dermatome was used to produce an appropriate skin flap. The skin flap technique, with or without the use of a dermatome, has since been used extensively in BAHA implant surgery. Parallel to this development, the Nijmegen BAHA team devised the linear incision technique, which is now used by an increasing number of implant teams.

Chapter 2.1 describes the linear incision technique and a retrospective evaluation of a consecutive series of Nijmegen BAHA patients. This study shows that the linear incision offers an acceptable alternative to other techniques with respect to implant loss and adverse tissue reactions. The linear incision technique has several advantages. It causes minimal disturbance of the cutis. Disruption of the blood supply to the cutis is in principle less severe than when performing a free skin graft or a dissection of the skin with a dermatome. Therefore, extensive reduction of subcutaneous tissue and periosteum may have a less detrimental effect on vascularisation. Moreover, it does not disrupt the blood supply to the outer layers of the skin. Thus, there is little risk of necrosis. The periosteum can then be excised safely and subcutaneous soft tissue can be reduced sufficiently. This procedure takes on average 20 minutes in skilled hands. In very recent literature, others have evaluated the linear incision technique as well. Mudry compared the skin flap and the linear incision techniques with respect to the short-term skin healing process. In the linear incision group, he found less need for revision surgery and less frequent unforeseen post-operative control visits. This study demonstrated statistically lower risks of skin problems with the linear incision
Chapter 4

Van de Berg et al. compared the free auricular skin graft, a pedicled skin flap, the dermatome technique, and the linear incision technique. They found that the linear incision technique was associated with significantly fewer major complications than the pedicled skin flap and the dermatome technique in a follow-up period of approximately two years. They recommended the linear incision technique for BAHA surgery. This PhD thesis shows that the long-term clinical outcomes of the linear incision technique are comparable to those reported by Reyes et al. in the only study known to have a comparably long follow-up period. Supported by recent literature it is advocated that the linear incision technique should be considered for BAHA implantation.

Recently, questions have been raised about the need for any soft tissue reduction at all. Preliminary reports on abandoning soft tissue reduction show promising results in selected patients with little pre-existing subcutis. The omission of soft tissue reduction would result in a shorter surgical procedure and fewer wound healing problems, while it could lessen complaints such as prolonged hyperesthesia. It should be taken into consideration that the initial decision to perform subcutis reduction was based on a limited number of patients. In that light, it would be worthwhile to evaluate its necessity, starting by studying patients with little pre-existent subcutaneous tissue. Factors such as skin condition, skin type, and length of the implant would then have to be evaluated.

In Chapter 2.2 the linear incision technique is evaluated for the paediatric population. In general BAHA surgery and usage in children addresses different issues than in adults. This is due to the fact that children may have more immature and thinner bone, appositional temporal bone overgrowth, more risk of soft tissue overgrowth, congenital (syndromal) malformations of the pinna, and cleaning problems, for instance. The present study concurs with the consensus that children are more at risk of implant loss and adverse skin reactions. Rates of implant loss due to failed osseointegration and infection were found to be comparable to those reported in the Birmingham and the London series, irrespective of which surgical technique was used. Short implant length (3 mm compared to 4 mm) and young age are said to be risk factors for implant loss in children. This study, however, demonstrates that with the linear incision technique, there is no significant relation between implant loss and age or implant length. A noteworthy finding is that most implants were lost within eight months after surgery, suggesting that incomplete osseointegration might be involved. Intra-operative stability measurements (resonance frequency analysis) might play a role in optimizing the conditions for osseointegration, especially in children. When an implant is lost, the interval between its loss and its
replacement should preferably be brief. To that end the placement of a sleeper ‘implant’ during the implant surgery has been advocated. Serious skin reactions occurred in at least one-quarter of the implanted children. Clearly, it is important to counsel the parents and to see children in the outpatient clinic more frequently than adults. One option for children with hypertrophic skin might be the use of a longer (8.5-mm) abutment.

Overall, this PhD thesis shows that 31 out of the 93 (33%) children required revision surgery (e.g. a new implant or new abutment placed on a sleeper, tissue revision). For children, it seems to be even more important than for adults to explore ways of improving the implant-to-bone and implant-to-skin interface. One way forward might be to develop new percutaneous implant designs and material.

If one is in doubt as to whether or not a child’s bone is suitable for a percutaneous implant, alternative treatments are available. These include the application of a conventional transcutaneous bone conduction device (such as the BAHA softband). However, research has shown that, for audiological reasons, percutaneous coupling is to be preferred over transcutaneous intervention, even in young children, at least starting at an age of 4 to 5 years. An alternative invasive treatment might be found among the recently introduced semi-implantable transcutaneous bone conduction devices, one being the Otomag device introduced by Siegert. Furthermore, on an experimental basis, semi-implantable middle-ear implants have been applied to children with aural atresia. These alternative treatments call for extensive evaluation. The first Nijmegen experience with a child using an Otomag device showed results comparable to those found with a BAHA.

In Chapter 2.3 the Nijmegen linear incision technique is evaluated for in older adults. Special attention is drawn to the risk of losing an implant and of adverse skin reactions that might have come from possible difficulties in cleaning the skin around the implant, as a result of their young age. The most common reasons for implant loss in this population were failed osseointegration and trauma; the loss was not related to infection around the implant site. The incidence of implant loss was comparable to that seen in the general population (Chapter 2.1). Notably, severe skin reactions occurred significantly less often among older adults than in the general population and tissue revision surgery was needed significantly less often. Thus the older adults in this study were less at risk of developing hypertrophic skin around the implants. The normal aging processes in the dermis, whereby the degeneration of tissue is irreversible, might explain this finding. Although skin necrosis was not encountered, minor or moderate wound dehiscence did occur. It can be speculated that the removal of the stitches
within seven days might be too early in the older adult population. This complication was not observed in the general population. The location of the abutment penetrating the skin in or just beside the incision line might be a factor in developing wound dehiscence. However, this hypothesis was not tested.

Chapter 2.4 describes the effect of the implant location and skin thickness on the frequency and severity of skin reactions around the abutment among patients in whom the linear incision technique was used. No correlations were found between the distance from the superior part of the bony external auditory ear canal to the implant nor between the horizontal and vertical positions of the implant on the one hand and the type and number of skin reactions and implant loss on the other. This means that from a medical point of view the surgeon’s choice of implant location is not critical. However, other factors might be of importance. For instance, audiological factors (most sensitive direction of the microphone) could affect the device. So could the distance between the implant and pinna, as the surgeon seeks to avoid touching the pinna with the transducer. In case of anotia or microtia of the pinna, the distance to a foreseen reconstructed auricle should be acceptable. A rigid adherence to the rule of 55 mm from the ear canal may therefore be not necessary. In patients with a thick scalp or thick soft tissues, the surgeon may customize the location to the patient, keeping the clinical factors mentioned above in mind. The rate of implant loss reported in this chapter is even lower than that described in the literature and in the preceding chapters. Nevertheless, the incidence of severe skin reactions found in this study is in line with that reported in previous studies.

**PATIENT OUTCOME MEASURES**

The second part of this thesis deals with another important outcome of this treatment, namely subjective benefit or the patients’ own view of changes in their quality of life. In recent years, the patients’ opinion has become more central to treatment evaluation and may be said to be a valuable supplement to the audiological outcomes.

In Chapter 3.1, the IOI-HA questionnaire is used to evaluate the outcomes of BAHAR-related benefit for adult subgroups of various ages. The IOI-HA showed that almost all users appreciated their BAHAR device. The age-related sensorineural hearing loss component was probably the main factor in the decreasing appreciation with increasing age. Patients in all age brackets were capable of handling and placing the BAHAR. Interestingly, the youngest age group reported more difficulty with cleaning the skin around
the implant. This supports the assumption that older BAHA users are more capable of using and taking care of the implant and the BAHA than younger, adult users. The standard BAHA is beneficial in the various domains to patients who have conductive or mixed hearing loss with a moderate sensorineural hearing loss component of up to 40 dB.

Chapter 3.2 evaluates the effect of BAHA fitting on the daily performance of children with either unilateral or bilateral conductive hearing loss. Several questionnaires were used. In general, the children with bilateral conductive hearing loss derived significant benefit from the BAHA in everyday situations. However, a residual disability was seen compared to normal hearing children. Our findings are in agreement with those in other pediatric BAHA publications. Moreover, the GCBI, which measures the change in health-related quality of life with respect to the pre-implant situation, revealed a general benefit of BAHA use in this group, particularly on the 'learning' subdomain. This underscores the impact of the BAHA on education. The APHAB questionnaire, assessing auditory functioning in daily life, showed some benefit in listening conditions with background noise. This may explain the positive effect on learning in these children. Younger age at the time of BAHA fitting was correlated with higher scores on the GCBI, which emphasizes the need for early BAHA fitting in children with bilateral hearing loss. This PhD thesis supports the consensus that children with bilateral conductive hearing loss derive great benefit from the BAHA.

Children with unilateral conductive hearing loss reported that the BAHA was worth the effort in general. However, they did not seem to be using the BAHA all day. Some responded that they only used the BAHA in the classroom; behavior that has also been reported in other studies. As in the bilaterally hearing impaired children, the subjects scored highest on the 'learning' subdomain. It can be concluded that for these children, the BAHA might be specifically beneficial in school. This study also shows that not all children with unilateral conductive hearing loss had positive scores. It goes on to emphasize the importance of performing a substantial trial of several weeks with a head band to assess whether a child will benefit from a BAHA, including the use at home and at school. It should be realized that it is difficult to assess the benefit from a trial with a BAHA on a headband. The use of structured questionnaires like the APHAB might be of value. Only a few children derived significant overall benefit from the BAHA, according to the disability-specific APHAB questionnaire. The relatively positive results of the BAHA for these children were found for the subdomains 'reverberated rooms' and 'background noise'. This might be due to a lifting of the head shadow by the Baha. Especially the child with congenital unilateral conductive hearing loss might benefit from (semi) implantable-middle ear
implants in the very near future. When a BAHA is applied, the contralateral ear is stimulated as well, owing to the inevitable cross stimulation. In contrast, middle-ear implants stimulate only the implanted ear.

Chapter 3.3 concentrates on the beneficial effect of the BAHA in older adults (60+) by measuring certain quality-of-life aspects (remaining disability, remaining handicap, benefit, and satisfaction) by means of questionnaires. Almost all patients were using their BAHA on a daily basis, and most of the patients did not have any difficulty handling the BAHA or cleaning the skin around the implant. Overall, these results indicated that the BAHA was functioning effectively. The subjects experienced some benefit, particularly regarding ease of communication. This indicates that the BAHA enables good performance in communication with others. In reverberant conditions and situations with background noise, however, the patients reported less favorable results. One explanation may be that the majority had been fitted with only one BAHA. Secondly, all of these patients had a significant sensorineural hearing loss component. Listening with bilateral BAHAs might be of specific value under these conditions and should therefore be considered. Almost 80% of the subjects had a mild level of residual handicap (HHIE-S questionnaire). A trend was obvious: with increasing sensorineural hearing loss, the severity of the remaining handicap also increased. When the sensorineural hearing loss component was severe, the benefit was limited, illustrating the limitations of BAHA for such patients.

In summary, this thesis shows that the linear incision technique has the longest follow-up evaluation and shows, in the first years good clinical outcome. It is a safe, simplified surgical procedure. Children are more at risk of implant loss and skin reactions, irrespective of which surgical technique is used. The placement of a ‘sleeper’ implant is advised and more research is needed into the predicting factors for implant loss in children. In addition, research should focus on the process of osseointegration, especially in children. In the older adult, special attention should be given to the process of wound healing.

Assessment quality of life and benefit reveals that the BAHA is well appreciated and effective. It has been shown that the patients’ satisfaction is affected by the sensorineural hearing loss component rather than by age. This thesis also shows that the BAHA is beneficial to children with bilateral conductive hearing loss. Subjective evaluations of children with unilateral conductive hearing loss showed variable results. In these children, the decision to use a BAHA should be made on an individual basis. Overall, the BAHA was rated as particularly beneficial in educational settings, which may be largely due to the reported benefit of speech recognition in noisy surroundings.
REFERENCES

1. Mudry A. Bone-anchored hearing aids (BAHA): skin healing process for skin flap technique versus linear incision technique in the first three months after the implantation. Rev Laryngol Otol Rhinol (Bord) 2009;130:281-284.


SUMMARY / SAMENVATTING
DANKWOORD
CURRICULUM VITAE
LIST OF PUBLICATIONS
The bone-anchored hearing aid (BAHA) is the gold standard for hearing rehabilitation among patients with significant bilateral conductive hearing loss, mixed hearing loss, unilateral conductive hearing loss, or single-sided deafness. The BAHA system comprises an implant that is surgically placed in the temporal bone; a skin-penetrating abutment is affixed to the implant and an audio processor is coupled to this abutment. Today, there are three generally commonly accepted surgical procedures for mounting this device: the dermatome technique, the pedicled flap technique, and the linear incision technique. This thesis includes an evaluation of the long-term clinical outcomes of the latter, which was developed in Nijmegen.

In Chapter 2.1 a consecutive series of 150 implants in 142 patients was evaluated. The results, in terms of implant failure and adverse tissue reactions, were comparable with those published in the literature. Therefore, it was concluded that the linear incision technique can be considered a good alternative to the other techniques.

BAHA application in children addresses different issues than in adults. The younger population is known to have more immature and thinner bone and more risk of tissue overgrowth, while skin cleaning problems tend to occur in adolescence. In Chapter 2.2 the linear incision technique was evaluated for children (93, 129 implants) operated on by this technique until July 2007. This study shows that their implant loss was more frequent than in the adults. Implant loss occurs mainly in the first year after surgery, suggesting an incomplete osseointegration. The age of the child and the type of implant did not correlate with implant loss. Children are probably in need to undergo frequent check-ups at the outpatient clinic. More research is needed on osseointegration in children.

In Chapter 2.3, the outcomes for 224 older adult BAHA users, with 248 BAHA devices implanted by the linear incision technique were evaluated. This study showed that the rate of implant loss was similar to that in the overall BAHA population and the incidence of severe skin reactions was relatively low. There was less risk of developing hypertrophic skin around the implant, but a slightly increased tendency towards postoperative wound healing problems was observed. Therefore it is advised to pay extra attention to the skin during the postoperative checkups.

In Chapter 2.4, the effect of implant location and skin thickness on the frequency and degree of adverse skin reactions around the abutment was evaluated in a random sample of 248 BAHA users. This study showed that implant location and skin thickness had no relation to the frequency and severity of skin reactions around the percutaneous abutment.
In recent years, patient opinion has become more central in treatment evaluation. Particularly the patients' opinion on their experienced benefit and quality of life are now considered an important aspect of treatment outcome. This thesis presents three patient opinion studies evaluating the BAHA using several validated questionnaires in distinct populations.

In Chapter 3.1, 135 experienced users of the standard BAHA Compact who have conductive or mixed hearing loss with a sensory neural hearing loss (SNHL) component between 0 and 44 dB were asked to evaluate the BAHA by means of the International Outcome Inventory-Hearing Aid (IOI-HA). Of particular interest were the questions of age-related use and satisfaction. It was shown that the BAHA Compact enhances participation in various domains of communication. Differences in the patients' satisfaction seemed to be correlated with their SNHL component rather than with their age.

In the next chapter (3.2), the evaluation focused on 31 children with unilateral conductive hearing loss or bilateral conductive hearing loss. The Glasgow Children's Benefit Inventory (GCBI), the Abbreviated Profile of Hearing Aid Benefit (APHAB), and the Health Utility Index Mark 3 (HUI3) were used to assess disease-specific benefit and general quality of life. This study shows that the BAHA is beneficial to children with bilateral conductive hearing loss. The results of the evaluations of children with unilateral conductive hearing loss were less straightforward. The decision to use a BAHA in these children should be made on an individual basis after a longer trial period, allowing the child to try out the BAHA in a variety of settings. In this subgroup, the BAHA was particularly beneficial to a child's schooling, which may be largely due to its beneficial effects in noisy surroundings.

Chapter 3.3 deals with benefits and quality of life for the older adult BAHA population. One hundred and thirty-four older adult BAHA users were evaluated by means of four questionnaires (Glasgow Benefit Inventory (GBI), Abbreviated Profile of Hearing Aid Benefit (APHAB), Nijmegen Cochlear Implant Questionnaire (NCIQ), and the Hearing Handicap Inventory for the Elderly - screening version (HHIE-S)). On the average, they were able to place and handle the device adequately and clean the skin around the implant effectively. Most patients reported a comparable or increased general benefit and a good quality of life with the BAHA.

In conclusion, this PhD thesis shows that the linear incision technique is a good alternative to other BAHA implantation techniques. Nowadays, the linear incision technique is widely applied and recognized as an established treatment. In agreement with previous studies, the present data show high patient compliance, satisfaction, and a general sense of well being among the BAHA users.
Het bot verankerd hoortoestel (BAHA) is de gouden standaard voor de revalidatie van patiënten met een significant bilateraal conductief gehoorverlies, gemengd gehoorverlies, eenzijdig conductief gehoorverlies en enkelzijdige doofheid. Het BAHA-systeem bestaat uit een implantaat dat operatief wordt geplaatst in het temporale bot met daarop een abutment waarop de BAHA processor geplaatst kan worden. De drie chirurgische technieken, die hier het meest voor gebruikt worden zijn de dermatoom techniek, de gesteelde flap-techniek en de lineaire incisie techniek. De laatste techniek is door Nijmegen ontwikkeld. Dit proefschrift evalueert onder andere de klinische lange termijn resultaten van deze techniek. In hoofdstuk 2.1 werd een opeenvolgende reeks van 150 implantaten (142 patiënten) geëvalueerd. De resultaten, incidentie van uitval van het implantaat en ongunstige weefselreacties, zijn vergelijkbaar met de literatuur. Om die reden kan de lineaire incisie techniek een goed alternatief zijn voor de andere technieken.

BAHA toepassing bij kinderen betreft een andere problematiek dan bij volwassenen. Van jongere kinderen is bekend dat zij minder volgroeid en dunner bot hebben en dat er meer risico op weefsel overgroei is. In de adolescentie kan juist het schoonmaken van de huid rondom het implantaat een probleem zijn.

In hoofdstuk 2.2 werd de lineaire incisie techniek geëvalueerd voor 93 kinderen (129 implantaten) geïmplanteerd met deze techniek. Deze studie toont aan dat implanataavertenties vaker voorkomt bij kinderen dan bij volwassenen. Het verlies van een implantaat treedt voornamelijk op in het eerste jaar na implantatie. Mogelijk is incomplete osseointegratie (ingroei in het bot) hier de oorzaak van. De leeftijd van het kind en de lengte van het implantaat lijken de stabilité van het implantaat niet te beïnvloeden. Een vervolgstudie die zich specifiek richt op de osseointegratie bij kinderen is nodig om dit verder te onderzoeken.

In hoofdstuk 2.3 werden 224 oudere BAHA gebruikers (248 BAHA implantaten) geëvalueerd. Alle implantaten werden geplaatst met de lineaire incisie techniek. Deze studie toonde aan dat het percentage verloren implantaten bij ouderen gelijk is aan dat bij de gemiddelde BAHA populatie. De incidentie van ernstige huidreacties was laag. Bovendien was er minder risico op het ontwikkelen van hypertrofische huid rond het implantaat. Wel werd er een licht verhoogde neiging tot postoperatieve wondgenezingproblemen waargenomen. Derhalve werd geadviseerd hier extra aandacht aan te blijven besteden in de postoperatieve periode.
In hoofdstuk 2.4 werd het effect van de implantaatlocatie en dikte van de huid op de frequentie en de mate van huidirritatie rond het percutane abutment geëvalueerd in een aselecte steekproef van 248 BAHA gebruikers. Deze studie toonde aan dat de locatie van het implantaat en de dikte van de huid geen relatie hadden met de frequentie en ernst van huidreacties rond het percutane abutment.

In de afgelopen jaren, is de mening van de patiënt steeds meer centraal komen te staan in de evaluatie van behandelingen. Met name de mening van de patiënt over het ervaren nut en de kwaliteit van leven worden tegenwoordig gezien als een belangrijk onderdeel. Dit proefschrift beschrijft de meningen van drie patiëntengroepen ter evaluatie van de BAHA, met behulp van verschillende gevalideerde vragenlijsten.

In hoofdstuk 3.1, werden 135 ervaren BAHA Compact gebruikers, met een geleidings- of gemengd gehoorverlies gevraagd om de BAHA te evalueren door middel van het International Outcome Inventory for hearing aids (IOI-HA). Met name het leeftijd gerelateerde gebruik en de tevredenheid van de patiënt werden geëvalueerd. Deze studie toonde aan dat de BAHA Compact de participatie in diverse domeinen van de communicatie versterkt. Verschillen in patiënttevredenheid lijken eerder te zijn gecorreleerd met de grootte van de perceptieve component in het gehoorverlies dan met de leeftijd.

In het volgende hoofdstuk (3.2), werden 31 kinderen met een unilateraal en bilateraal geleidingsgehoorverlies gevraagd hun BAHA te evalueren. De Glasgow Children's Benefit Inventory (GCBI), Abbreviated Profile of Hearing Aid Benefit (APHAB) en de Health Utility Index Mark 3 (HUI-3) werden gebruikt om het profijt met betrekking tot gehoorverlies en de algemene kwaliteit van leven te beoordelen. Deze studie toont aan dat met name kinderen met een bilateraal geleidingsverlies profiteren van de BAHA. Het profijt van de BAHA bij kinderen met een unilateraal geleidingsverlies liep meer uiteen. Bij deze kinderen zal het besluit om al dan niet de BAHA toe te passen op individuele basis genomen moeten worden. Het dragen van een BAHA op een testhoofdband gedurende een langere proefperiode kan hierbij behulpzaam zijn. Zodoende kunnen verschillende situaties getest worden. Over het algemeen was de BAHA bijzonder gunstig voor de schoolgang van een kind. Dit is grotendeels te danken aan de gunstige effecten in een rumoerige omgeving.

Hoofdstuk 3.3 gaat over het profijt van de BAHA en de ervaren kwaliteit van leven van 134 oudere BAHA gebruikers. Zij beoordeelden hun BAHA door middel van vier vragenlijsten; de Glasgow Benefit Inventory (GBI),

198
Abbreviated Profile of Hearing Aid Benefit (APHAB), Nijmegen Cochlear Implant Questionnaire (NCIQ) en de Hearing Handicap Inventory for the Elderly screening version (HHIE-S). Gemiddeld genomen waren ze goed in staat de BAHA te plaatsen, te hanteren en de huid rond het implantaat te onderhouden. De meeste patiënten vermelden een vergelijkbaar of hoger algemeen profijt en een goede kwaliteit van leven met de BAHA te ervaren.

Concluderend laat dit proefschrift zien dat de lineaire incisie techniek een goed alternatief is voor andere BAHA implantatietechnieken. Inmiddels wordt deze techniek derhalve op grote schaal toegepast. Uit dit proefschrift blijkt, in overeenstemming met eerdere studies, dat er een hoge therapietrouw, tevredenheid en een algemeen gevoel van welzijn bij BAHA gebruikers bestaat.
Onderzoek doen is gelukkig niet bepaald een solitair traject, zeker niet als je in de gelukkige positie bent om in een reeds rijdende trein je steentje bij te dragen. Vele mensen hebben een rol gespeeld in dit 5e BAHAc promotietraject en de totstandkoming van dit proefschrift. Enkelen wil ik hier met name noemen.

Beste Professor Cremers, al vele jaren voor aanvang van dit promotietraject was “dokter Cremers”, en “de KNO in Nijmegen” een begrip in Huize de Wolf. Toen had ik niet kunnen weten dat er een prettige, efficiënte en vruchtbare samenwerking zou volgen. Graag wil ik u bedanken voor uw tomeloze inzet en grenzeloze mogelijkheid om over alle facetten van het “onderzoeken” te praten. Wonderlijk hoe beschikbaar u ondanks uw drukke programma heeft kunnen zijn. Met name wil ik refereren aan de laatste KNO vergadering. Toen bleek dat er geen otoloog aanwezig kon zijn om mijn voordracht bij te wonen, hebt u uw agenda aangepast en bent u speciaal op en neer gereden. Met u kan men wel een boekje schrijven!!

Professor Snik, beste Ad, voor audiologische problemen, maar vooral ook ‘kwaliteit van leven’ vraagstukken kon ik geregeld en ongelimiteerd bij je terecht. Je integere en gedreven werkwijze waarbij de mens achter de onderzoeker niet ongemoeid wordt gelaten maakt grote indruk. Bedankt voor de prettige samenwerking.

Dokter Hol, beste Myrthe, jij bent de verbindende factor geweest door het gehele project heen. Je hebt alle stukken in rap tempo kunnen voorzien van de nodige en zeer nuttige correcties en suggesties. Zo hebben we regelmatig tot laat bij jou aan de eettafel stukken besproken onder het genot van een bruin biertje. Ik ben onder de indruk van hoe je je werk en privé kunt combineren. Dat maakt dat ik zowel op otologie gebied als daarbuiten veel van je hoop te leren.

Dokter Mylanus, beste Emmanuel, overleggen met jou heeft altijd een bepaalde flair; vaak haastig lopend kom je aan, druk als altijd. Toch ben je ook altijd in staat enthousiasme voor onderzoek over te brengen, scherpe kritische opmerkingen te maken en de sociale kant van het leven te benadrukken om vervolgens weer door te rennen naar de volgende afspraak. Ik wil je bedanken dat ook jij je hebt willen verbinden aan dit proefschrift.

Geachte leden van de manuscriptcommissie, bedankt voor de vlotte beoordeling van dit proefschrift.
Beste Patrick Huygen, bedankt voor je inzet bij hoofdstukken 2,1 en 2,2 met name betrekking hebbend op het statistische gedeelte.

Beste Hubert, je hebt een grote bijdrage geleverd aan hoofdstuk 2,4 in dit boek, bedankt. Onlangs ben je aangenomen voor de opleiding tot KNO-arts en is de basis gelegd voor jouw BAHA promotietraject. Ik kijk uit naar een prettige samenwerking en het slaan van enkele balletjes.

Beste Joop Leijendeckers, jij hebt het fundament gelegd voor hoofdstuk 3,1. Onze samenwerking verliep altijd buitengewoon prettig, bedankt voor al je input.

Beste My-linh Shival, bedankt voor jouw aandeel in een nauwgezette analyse van kwaliteit van leven van de oudere BAHA gebruiker, bedankt voor je inzet voor hoofdstuk 3,2.

Beste Jacolien Dun, als “opvolgende” BAHA promovendus ben je met overgave begonnen met het opzetten van je eigen projecten. Daarnaast heb je mij veel werk uit handen genomen tijdens de bekende laatste loodjes. Dit en vele andere goede eigenschappen maken je een fijne collega om mee te werken. Onze KNO-collega’s in Groningen zullen blij met je zijn. Bedankt voor je betrokkenheid op vele vlakken.

BAHA patiënten, zonder jullie zou dit proefschrift natuurlijk niet mogelijk zijn geweest. Bedankt voor het invullen van de vragenlijsten, met soms zo’n 150 vragen is dat niet gering. Toch was het niet ongebruikelijk om een formulier terug te krijgen vol met op- en aanmerkingen. Het is zeer motiverend om te zien hoe gedreven en betrokken mensen kunnen zijn.

Beste medewerkers van het Volwassen Audiologisch Centrum en met name Mieki en Teja. Elke keer dat ik het VAC oploop heerst er een prettige en gemoedelijke sfeer. Nooit is het een probleem om de nieuwste weetjes over de BAHA uit te wisselen. Jullie zijn een voortreffelijke vraagbaak geweest, bedankt.

Beste Carine Hendriks, verscholen achter de kamerplanten gaat iets waardevols schuil. De BAHA-database die jij beheert vormt het uitgangspunt voor het merendeel van de BAHA onderzoeken in dit proefschrift. Bedankt voor de prettige samenwerking.

Beste Niels van Druten, bedankt voor je betrokkenheid bij dit proefschrift en je bereidheid daar waar je kon ondersteuning te bieden. Veel succes met je verdere carrière in Londen.
Dankwoord

Beste secretaresses, verpleging, balie- en archiefmedewerkers, bedankt voor de prettige werksfeer op de poli, het Kinder Audiologisch Centrum, het Volwassen Audiologisch Centrum, de OK, de afdeling en de poli.

Beste Judith Abma-Hill, bedankt voor je inzet met betrekking tot de correcties van mijn Engels gestuntel. Je geregisseerde stukken geven het fenomeen puzzelen een geheel nieuwe dimensie. Toch gingen de verbeteringen veelal verder dan alleen de typo’s, bedankt voor je nauwgezetheid.

Beste Diny Helsper, bedankt voor je kwaliteitscontrole in de laatste fase van het tot stand komen van dit proefschrift.

Beste Thomas en Rinaldo, als techneuten van het aangrenzend Mond-Kaak- en Aangezicht chirurgisch specialisme zijn jullie veel bezig met 3D beeldvorming. Mede door jullie inzet en meedenken is er een mooie kaft om dit boekje gekomen, bedankt.

Voor het merendeel van de medische promoties geldt dat dit in het kader van een opleidingstraject verricht wordt. Ik ben de staf van de KNO in het Radboud, met name Professor Marres, dankbaar dat er in de opleiding ruimte is voor wetenschappelijke ontwikkeling.


Misschien wel het belangrijkste in een werkend leven is een goede werksfeer en leuke collega’s. Dat dit geregeld resulteert in een borrel in ‘Anneke’, maakt het helemaal af. Beste KNO-assistenten, Amici, collegae, jullie zijn een fijne club.

Beste Sylvia, ik vind het heel bijzonder dat jij als ‘oud BAHA promovendus’ nu mij als paranimf wil bijstaan tijdens mijn verdediging.

Disputet; Heeren van het goede leven, weer een boekje dat op de plank in “de grot” bijgezet kan worden. Broeders, bedankt voor alle interesse.

Club; eindelijk is het dan zo ver, het boekje is er. Inhoudelijk hebben jullie niet veel bijgedragen aan deze promotie, maar jullie waren een welkome onderbreking in het westen van het land.
Lieve Pien; jij hebt het overgrote deel van dit promotieproject van dichtbij meegemaakt en je hebt me altijd onvoorwaardelijk gesteund. Je vermogen om zaken net in een ander daglicht te stellen zijn vele keren een eyeopener geweest. De tijd met jou samen is me nog steeds zeer dierbaar.

Lieve Loes, dat we allebei arts zijn is niet het enige wat we qua werk gemeen hebben. Ook jij combineert je opleiding met een promotie-traject. Ik heb bewondering voor je geduld, rust, toewijding en betrokkenheid in de dingen die je doet. Dit zal je later als huisarts nog goed van pas komen.

Lieve Adriaan, feitelijk sta jij aan de basis van dit boekje en mijn verdere opleiding tot KNO-arts. Zonder jou was ik hier nu niet geweest. Ik ben ontzettend trots dat jij ondanks je gehoorverlies zo’n fijn en uiterst sociaal persoon bent geworden. Je rol als paranimf en bereidheid te poseren voor de kaft van mijn proefschrift geven mijn promotie een extra persoonlijke dimensie.

Lieve Ouders, Lieve papa, samen met jou heb ik de eerste stappen in de wondere wereld van de wetenschap gezet. Je hebt me enthousiast gekregen voor het doen van onderzoek. Daardoor had ik een vliegende start in Nijmegen. Lieve Mam, jij weet als geen ander wat ‘lezen’ voor een plek bij mij heeft ingenomen. Je hebt me letterlijk door meters boeken heen geholpen. Door al jouw inzet in mijn kinderjaren weet ik nu dat je Bommel-ding beter kunt lezen als Bom-melding. Ik ben je heel erg dankbaar dat jij mijn doorzettingsvermogen dusdanig hebt weten te stimuleren dat ik nu in de medische voetsporen van pappa kan treden. Lieve pap, mam, Ik ben jullie ongelofelijk dankbaar voor al jullie steun die heeft geleid tot waar ik nu sta en wie ik nu ben.

Joanneke, lieverd, het begin van ons leven samen staat gemarked door onze promoties. Ik vind het zeer bijzonder dat wij zij aan zij naar deze afronding hebben kunnen werken. Ik kijk uit naar een enerverend en gelukkig rest van ons leven.
Maarten de Wolf was born in Haarlem on August 30th, 1979. In 1999 he finished his pre university education at het Wessel Gansfort College at Groningen. In anticipation of admittance to the faculty of Medical sciences, he studied Mechanical Engineering at the faculty of Engineering Technology of the University of Twente. He passed the propaedeutic exam with good result. In 2001 he was admitted to study Medicine at the faculty of Medical Sciences of the University of Groningen. After successfully finishing his internships at the Medisch Spectrum Twente at Enschede, he started his scientific training as a junior researcher at the department of Otorhinolaryngology of the Radboud University Medical Center at Nijmegen, the Netherlands. After his graduation in May 2008, he was appointed a research project on the Bone Anchored Hearing Aid to finish his thesis under the devoted supervision of professor C.W.R.J. Cremers. In August 2009 he started his residency at the same department. He expects to complete his education as a ENT surgeon in July 2014. Maarten lives together with Joanneke Plooij, who will defend her thesis on the 13th of April 2011.

2. de Wolf MJF, Hol MKS, Huygen PLM, Mylanus EAM, Cremers CWRJ. Clinical outcome of the simplified surgical technique for BAHA implantation. Otol Neurotol 2008;29:1100-1108


5. de Wolf MJF, Leijendeckers JM, Mylanus EAM, Hol MKS, Snik AFM, Cremers CWRJ. Age-related use and benefit of the bone-anchored hearing aid compact. Otol Neurotol. 2009 Sep;30(6):787-92


