IMPLANTABLE BONE ANCHORED HEARING AID SOLUTIONS

ASPECTS OF INDIVIDUALIZED INDICATION

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Ph.D. Thesis

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II. **Jarabin János**, Bere Zsófia, Tóth Ferenc, Perényi Ádám, Jóri József, Kiss József Géza, Rovó László
Első tapasztalataink a Baha DermaLock implantátum rendszerrel
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III. **Jarabin János**, Bere Zsófia, Tóth Ferenc, Perényi Ádám, Jóri József, Kiss József Géza, Rovó László
A Baha DermaLock implantátum rendszerrel elért audiológiai eredményeink
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IV. **Jarabin János**, Kiss József Géza, Tóth Ferenc, Jóri József, Rovó László
Alternatív lehetőség a tympanoplasticai módszerekkel nehezen megoldható, dominálóan vezetéses jellegű, szerzett halláscsökkenések kezelésére felnőtt korban - a BAHA Magyarországi indikációjának kibővítése.
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V. **Jarabin János**, Matievics Vera, Tóth Ferenc, Rovó László, Kiss József Géza
A BAHA implantációt megelőző audiometriai és betegelégedettségi tesztek értékelése, és összehasonlítása a hagyományos csontvezetéses hallókészülékekkel elérhető eredményekkel
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VI. Torkos A, Czigner J, **Jarabin J**, Toth F, Szamoskoezi A, Kiss JG, Jori J
Recurrent bacterial meningitis after cochlear implantation in a patient with a newly described labyrinthine malformation
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ABBREVIATIONS

ABG	air-bone gap
BAHA	bone anchored hearing aid
DPOAE	distortion product otoacoustic emission
LDF	laser-Doppler flowmetry
LHT	local hyperaemia test
PTA_4	average pure tone audiogram for four frequencies of 0.5, 1, 2 and 4 kHz
PU	perfusion unit
SNR	signal-to-noise ratio
SP	sound processor
SRT	speech recognition threshold
SSD	single sided deafness
STP	soft tissue preservation
STR	soft tissue reduction
STSG	split-thickness skin flap

CONTENTS

I. INTRODUCTION

I. 1. Hearing through bone conduction and its application in assistive hearing devices – historical review [1]

The great pioneering anatomical and physiological studies by ***Andreas Vesalius*** (1515 – 1564), ***Gabriele Falloipio*** (1523 – 1562), and ***Bartolomeo Eustachi*** (1500 or 1514 – 1574) might be considered the start of the functional diagnosis of hearing disorders, included the phenomenon of bone conduction as well.

During the Renaissance an Italian physician, philosopher and mathematician, ***Girolama Cardano*** **(**1501 – 1576) mentioned his peculiar phenomenon how sound may be perceived by means of a rod or the shaft of a spear held between one's teeth through bone conduction. He noted his observation in *De Subtilitate* (1551). Other authors (Ingrassia, Fabricius, and Plater) mentioned the bone-conduction phenomenon only with theoretical interest.

Hieronymus Capivaccius (died 1589) an Italian physician interpreted the diagnostic value of Cardano's observations, and employed it in the differential diagnosis of the "disorders of the tympanic membrane".

In the coming century an English physician, ***John Bulwer*** (1644 – 1662), who is known for developing a method for communicating with the deaf and dumb, also illustrated in his impressive work, *Philocophus* a remarkable case of a man who is listening to music through bone conduction by his teeth (*Figure 1*).

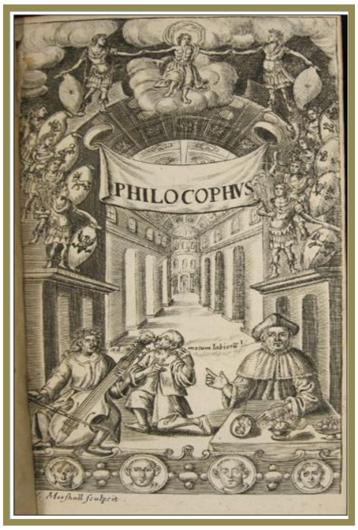


Figure 1. Illustration from the work "Philocophus". A kneeling man who is listening to music by his teeth, through bone conduction.

Falling into oblivion for a time perceiving sounds through the vibration of the skull bones mediated by the teeth was re-unfolded by ***Joannes Jorrison*** in 1757, and subsequently by ***Jean Marie Gaspard Itard*** (1773 – 1838) a French military surgeon, who invented a "teeth-to-teeth" bone conduction stimulator (*Figure 2*).

Figure 2. "Teeth-to-teeth stimulator". A wooden rod shaped into "bone conduction hearing device" acting through "teeth-to-teeth" vibration energy transmission.

His book, the *Traite des Maladies de l'oreille et de L'audition* presented several illustrations of different hearing devices.

In 1920 ***Joseph Prenn*** patented a mechanical bone conductor.

The first electric bone vibrator was invented by ***Augustus G. Pohlmann and Frederick W. Kranz*** in the 1920's, for use in some audiometers and a few table model hearing aids (*Figure 3*) [2].

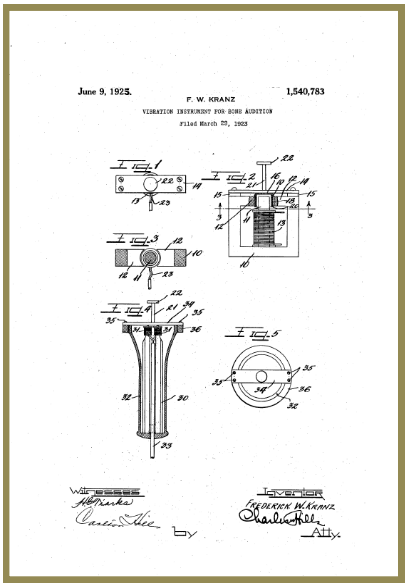


Figure 3. Kranz's patent for "Vibration Instrument for Bone Audition" June 9 of 1925.

In 1929, the Sonotone Company was established by **Hugo Lieber** (born in 1868 in Germany, died 1936), as an outgrowth of Siemens hearing aids. He invented the revolutionary bone conduction receiver in 1932. In 1934 it was advertised as the *Leiber Oscillator.*

An improved bone vibrator was patented by **E. H. Greibach** and Sonotone became the licensor for this in 1934 (*Figure 4*) [3].

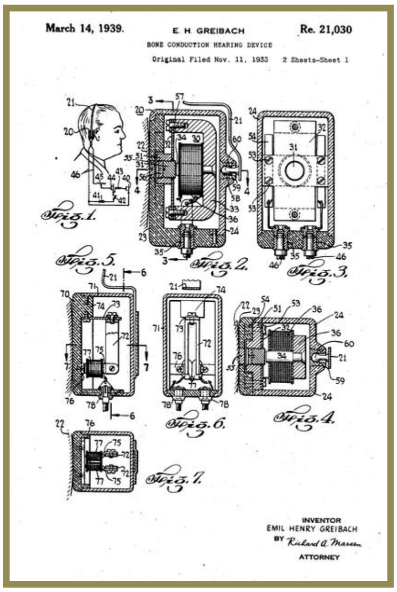


Figure 4. E.H. Greibach's patent for "Bone conduction hearing device" March 14 of 1939.

Hearing aids mounted into eyeglasses were commercialized first in 1954 and until the last decades were the first rehabilitative option in those conductive hearing losses that could not be managed with reconstructive ear surgeries. Nevertheless the frequent problems with this concept (loss of vibration energy in the soft tissues, feed-back phenomenon, uncomfortable wearing, frequent problems with the adaptation to the individual shape of the head, etc) promoted the idea to put the vibrator directly into the temporal bone.

The first system pioneering of this new therapeutic concept, based on the histological observation of direct titanium-to-bone integration (i.e. osseointegration) was introduced in 1977, called Bone Anchored Hearing Aid (*BAHA*).

I.2. The physiology of bone conduction

I.2.1. Fundamental observations on bone conducted sound perception

Perceiving a sound through "bone conduction" is when the vibration energy propagates through the skull bones, cartilages, skin and soft tissues, acting on the basilar membrane of the organ of Corti, generating travelling waves, resulting in the excitation of the sensory hair cells in the cochleae. Although many studies have been carried out since the beginning of the 20th century, the mechanisms of bone conduction are still not fully clarified.

The first question was whether bone conduction stimulates the same cochlear sensory apparatus or acts on a different sensory end organ. Békésy was the first to study the function of the auditory organ experimentally, replacing theoretical considerations by empirical evidence [4]. In his famous cancellation experiment, that air conduction pure tone can be cancelled by bone conduction tone concluded that being the stimulated sensory apparatus identical one. He succeeded in subjective cancellation of an air conducted tone with a bone conducted tone at 400 Hz [5, 6].

Observations gained on the analysis of finite element models of the human middle ear and cochlea confirmed that basilar membrane vibration characteristics are essentially invariant regardless of whether the excitation is via bone conduction, independent of excitation direction, or via air conduction [7-9], as the basilar membrane is effectively driven by the anti-symmetric component of the oval and round window volume velocities resulting in differential slow wave component (i.e. anti-symmetric) of the fluid pressure [10].

The best frequency map indicates the frequency corresponding to the peak basilar membrane vibration as a function of location along the basilar membrane. The best frequency map doesn't change significantly due to differences in the method of cochlear excitation [10].

Distortion product otoacoustic emission (DPOAE) could be elicited by air and one bone conduction tones either. Properties unique to bone conduction, such as simultaneous bilateral stimulation and reduction of stimulus magnitude in the ear canal, may make bone conduction attractive for clinical measurement of DPOAEs [11]. Emissions of similar magnitude are obtained with stimuli that are of similar magnitude at the place of generation, the bone conduction IOgram may be aligned with the one obtained using air conduction [12].

I.2.2. Bone conduction pathways

Experimental researches aimed to identify different ways of vibration energy transmission in the skull bones that inherently involve multiple pathways with different importance. The terminal stimulation of the basilar membrane of the organ of Corti is contributed by the summation of these hardly distinguishable vectors of sound vibrations, travelling through different media (i.e. air, soft-tissue, and bone or fluid).

Narrowing the possible pathways for propagation of bone conduction summarized by Tonndorf in 1966 [13], *Stenfelt and Goode in 2005* described five components declared to be the most significant ones contributing to sound perception through bone conduction in human [14]:

1) Sound pressure in the ear-canal and the occlusion effect – osseo-tympanic stimulation
2) Inertia of the middle-ear ossicles
3) Inertia of cochlear fluids and fluid pressure transmission
4) Alteration (compression and expansion) of the cochlear space
5) Pressure transmission from the cerebrospinal fluid

1) The external ear mechanisms – osseo-tympanic stimulation

Due to the concomitant deformation of the walls of the external auditory canal, bone vibrations transform into airborne radiated sounds that propagate similar to conventional air conduction signals. Low-frequency signals transmitted efficiently through soft tissue conduction, also called non-osseus bone conduction (e.g. skin, cartilage), while high frequency sound vibrations are susceptibly transmitted through the bony walls of the ear-canal [15-17].

If the ear-canal opening is occluded (i.e. “occlusion effect”) this pathway of bone conduction sound transmission could become significant, depending on the physical characteristics of the occluding mass and on its position in the ear-canal (i.e. ear-mould or shell). With the ear canal occluded the level of ear canal sound pressure is 15 to 20 dB higher at frequencies below 1 kHz due to the major contribution of vibrations of the cartilage and the soft tissues in the ear canal. Decreasing the occluded volume, the less important the occlusion effect is that contributes to the effectiveness of insert phone measurements [18]. The occlusion effect can be also reduced or eliminated by a vent in the ear-mould or shell. This additional bore connects the residual ear canal volume with the air outside the ear. The origin of the occlusion effect at the high frequency range is a change in the resonance properties of the ear canal (2.7 to 5.5 kHz, with opened and occluded ear canal respectively) [19, 20], while at the lower frequencies the eliminated high-pass filter effect might explain the occlusion effect [13].

2) The middle ear inertial mechanism

It is dominant around the middle-ear ossicles' resonance frequency (approx. 1-3 kHz), but is still not considered to be significant as the removal of the ossicles has only minimal effect on bone conduction. In the lower frequency range the ossicles vibrate in phase with the skull bones, while at higher frequencies, when the ossicular mass overcomes the stiffness of the suspending ligaments and tendons, they decouple from the phase of the surrounding bone vibrations, resulting in a relative motion between the stapes footplate and the otic capsule [14]. Bárány studied first this effect contributing to bone conduction hearing [21], by manipulating the inertia of the tympanic membrane and the ossicular chain, and by changing the static air pressure in the external auditory canal.

3) Inertia of cochlear fluids and fluid pressure transmission

This factor might be the most significant component of bone conduction in normal and pathological ear as well. Fluid itself regarded as incompressible since the wavelength of the fluid acoustic wave is much larger than the size of the cochlea. The cochlear fluid vibrates in response to the translational vibratory movement of the surrounding bone. When the temporal bone vibrates the secondary fluid displacement is possible due to the existence of the membranes of the oval and round window and the pressure gradient between them that promotes fluid flow between the scala vestibuli and scala tympani, resulting in the travelling waves of the organ of Corti [14]. The oval and round windows are comparatively large in area and short in length, thereby minimizing the impedance of bulk fluid motion between these windows and promoting sound transmission [10].

There are other relatively thin and long normal "windows" between the inner ear fluids and the cranial cavity, contributing to compliant pathways on both sides of the basilar membrane.

The complex compliant structure of “third window”, collectively referred to as a *normal* third-window, includes the:

- cochlear aqueduct (openings: 1. the posterior cranial fossa; 2. the scala tympani of the cochlea adjacent to the round window membrane)
- vestibular aqueduct (openings: 1. the posterior cranial fossa; 2. the medial wall of the bony vestibule)
- as well as micro channels parallel to blood vessels and nerves while entering or leaving the cochlea [22-26].

These smaller diameter and longer channels are functionally closed to sound flow due to their high impedance, therefore considered to have negligible auditory impact in physiological hearing [27].

On the contrary *pathologic* third-windows may direct the air-conducted sound energy away from the cochlea, while improving thresholds for bone-conducted sounds of leaving them unchanged, appearing in a picture of conductive hearing loss on the audiogram.

Anatomical discrete lesions may be classified by their location, possessing variable inertial effects on cochlear fluids:

- semicircular canals (superior, lateral or posterior canal dehiscence),
- bony vestibule (large vestibular aqueduct syndrome, or other inner ear malformations),
- cochlea (carotid-cochlear dehiscence, DNF-3 or X-linked deafness with stapes gusher, Apert-syndrome, etc.).

Developmental disorders of the inner ear according to Jackler et al can be considered as a result of prematurely arrested embryogenesis [28]:

- With an absent or malformed cochlea:
    - Complete labyrinthine aplasia (Michel deformity)
    - Common cavity
    - Cochlear aplasia
    - Cochlear hypoplasia
    - Incomplete partition (Mondini deformity)

- With a normal cochlea:
    - Vestibule-lateral semicircular canal dysplasia
    - Enlarged vestibular aqueduct

Those malformations that are not able to be explained by this system are potentially being the result of an aberrant embryogenesis or the combination of the two possibilities. Such a malformation has been observed and published as a newly described one in the International Journal of Pediatric Otorhinolaryngology co-authored by the author of this present thesis [29].

In Paget disease of the temporal bone the excessive breakdown and formation of bone, followed by disorganized bone remodeling may lead to a diffuse anatomical lesion of the bony labyrinth, resulting in “diffuse” third window effect. Third window lesions should be considered in the differential diagnosis of patients with conductive hearing loss.

Consideration should always be given that conductive hearing loss, defined as an air-bone gap (ABG) on the audiogram may due to disorders of the inner ear as well, with pathologic third windows in the background. Clues to suspect such a lesion include a low-frequency ABG with supranormal thresholds for bone conduction, the presence of acoustic reflexes, vestibular myogenic responses or otoacoustic emissions. Imaging techniques are also essential for detailed differential diagnostics [23].

4) Compression and expansion of the cochlear space

The cochlear fluid spaces would change due to the compression and expansion of the otic capsule secondary to vibrations produced by a bone conduction stimulus. The underlying physical background is the discrepancy in compliance between the round and oval windows (the round window approx. 20 times more compliant), and the volume disequilibrium, where the scala vestibuli contains more fluid (with a volume ratio of 5:3) [13]. The effect of compression might have a role at frequencies above 4 kHz, but may not be a major factor on the lower frequency range.

5) Pressure transmission from the cerebrospinal fluid

Static pressure in the cerebrospinal fluid is transmitted through a narrow fluid channel to the cochlear fluids, primarily through the cochlear aqueduct. However anatomical studies suggest that this channel is occasionally blocked with tissues in healthy ears. Experimental studies confirmed that the affect of intracranial sound pressure changes on bone vibrations measured on the promontory are only negligible [30].

I.2.3. Physical aspects of bone conduction

The frequency-to-place conversion occurs within the cochlea, responding similarly when is fed via air or bone conduction either [6], although central mechanisms believed to be involved in pitch perception. The overall shapes of the basilar membrane velocity magnitude distributions are similar among different excitation cases [7-9].

Different vectors of bone conduction excite the inner ear through the above mentioned pathways [14], characterized by several modes of skull vibrations. Longitudinal/compressional, transversal/shear waves and their combination, as well as bending/flexural waves all can propagate within the skull bones linearly, at least for frequencies between 0.1-10 kHz and up to 77 dBHL [14, 31].

At low frequencies the skull vibrates as a rigid body. Increasing the forced vibration frequency up to around 800 Hz a bi-nodal line pattern appears in opposite phases. At around 1600 Hz the skull starts to vibrate in quadrants. Newer techniques showed complex vibrations, made up of rotational and translational components, without any dominating one [14].

Transcranial attenuation of a bone-conducted sound is defined as the difference in sensitivity between an ipsilaterally transmitted and a contralaterally transmitted sound positioned at identical points at the two sides of the head [32]. In the frequency range of 0.25 to 4 kHz transcranial attenuation is approximately 0 to 15 dB, highly depending on the stimulation position and the frequency. Stenfelt reported 2 to 3 dB lower median transcranial attenuation at the position of an implanted bone conduction hearing aid, compared to that gained from the stimulation in the mastoid region, with large intersubject variability (up to 40dB) [33].

I.3 Epidemiology of hearing impairment

Hearing loss is the leading cause of disability worldwide. Approximately 15 % of the world's population has hearing loss to some degree, and 5.3 % out of them, around 360 million people, has hearing loss greater than 40 dB in the better hearing ear in adults, and 30 dB in children. The current production of hearing aids covers the 10 % of the global need [34-36].

I.4. Implantable bone conduction solutions

Based on the route of the vibration energy transmission, implantable bone-conduction hearing solutions can be divided into three groups, direct drive, skin drive and in the mouth systems [37]. Those that directly vibrate the bone are referred to as direct drive implant systems (i.e. without a skin barrier), whereas those systems that transmit vibration energy to the bone through intact skin are referred as skin drive devices (this includes devices held to the head via soft band devices or eyeglasses and magnet connection implants). Finally, in the mouth systems generate vibrations of the skull bone through placement at the upper back teeth (*Table 1.*).

The scope of this thesis focuses on the clinical and experimental based assessment of the Baha® Connect and Baha® Attract systems.

BONE CONDUCTION DEVICES							
DIRECT-DRIVE				**IN-THE-MOUTH**	**SKIN-DRIVE**		
PERCUTANEOUS BAHA		ACTIVE TRANSCUTANEOUS (IMPLANTED TRANSDUCER)			CONVENTIONAL HEADBAND OR EYEGLASSES	PASSIVE TRANSCUTANEOUS (IMPLANTED MAGNET CONNECTION)	
BAHA® CONNECT	PONTO	BCI	BONEBRIDGE™	SOUNDBITE™		SOPHONO®	**BAHA® ATTRACT**

Table 1. Classification of Bone conduction solutions. The focus of the thesis is marked with red.

I.4.1. Percutaneous direct-drive BAHA (the Baha Connect system)

Since the introduction in 1977, osseointegrated, direct-drive systems have used different kinds of modified percutaneous abutment connections through snap coupling to maintain the connection between the implanted component and the sound processor (SP) [38].

These systems have provided hearing rehabilitation with good clinical outcome for over 150.000 patients in the last forty years with conductive or mixed hearing loss and single-sided sensorineural deafness.

The classic, well-established surgical techniques of implantation, which rely on different skin flap creation and soft tissue reduction (STR), have been successfully used in the last decades [38-40]. The primary aim of the STR was to achieve a stable epidermal covered bone surface around the implant (*Figure 5*).

Figure 5. Intraoperative (A) and postoperative (B) photos: of our first Baha-patient supplied with percutaneous direct-drive Baha Connect system applying the classic surgery with STR from 2009 **[Jarabin et al, 70]**

Later experiences, gained on large series of patients in independent studies have shown a range of incidence from rare to more frequent for variably severe peri-implant skin complications. Short-term complications arise in 0.7–1.3 % of the cases [40, 41]. Long-term follow-up reveals an incidence of 3.3 % of skin reactions classified as Holgers grade 2 or higher, which may often require revision surgeries [42-44]. Long-term follow-up identified an increasing risk of complications over time (*Figure 6*) [45].

Figure 6. Postoperative skin-flap necrosis: Holgers grade 4. complication and its reconstruction with flap rotation (patient from the Baha Connect group, classic surgical technique with dermatome)

The risk of adverse skin reactions has been addressed by new developments that incorporated microsurface technology for the implant component (e.g., titanium-dioxide surface), aimed at reducing the loading time, coupled with advanced redesign of the physical attributes of the abutment (new concave shape), which lowered the tendency for peri-implant pocket formation and adverse skin reactions.

Other studies showed that patients receiving the 8.5 mm abutment during initial implantation are significantly less likely to require in-office procedural intervention or revision surgery postoperatively as compared to those receiving the shorter, 6 mm implant at initial surgery, furthermore applying linear incision with no or minimal soft tissue removal, with the longer (8.5 mm) abutment provided comparable or better complication rates than the previously accepted surgical techniques [46-49]. The percutaneous osseointegrated implantation technique without skin thinning proved to be also beneficial for children [50].

However while titanium is ideal for integrating with bone, it does not bond with soft tissues (skin and the underlying layers). With the application of hydroxyapatite coating on the abutment the overall soft tissue tolerance has improved through the reduced tendency for epidermal down-growth and "pocket formation". Animal experiments have proven the excellent soft tissue adherence to the implant surface and faster wound healing around the abutment, which are key factors in the effectiveness of this therapeutic concept [51].

Due to these characteristics of the abutment during the "FAST surgical" method of implantation the reduction of any soft tissues became unnecessary (*Figure 7*). According to the individual's soft tissue thickness (preoperatively measured) the abutment's length can vary form 6-12 mm.

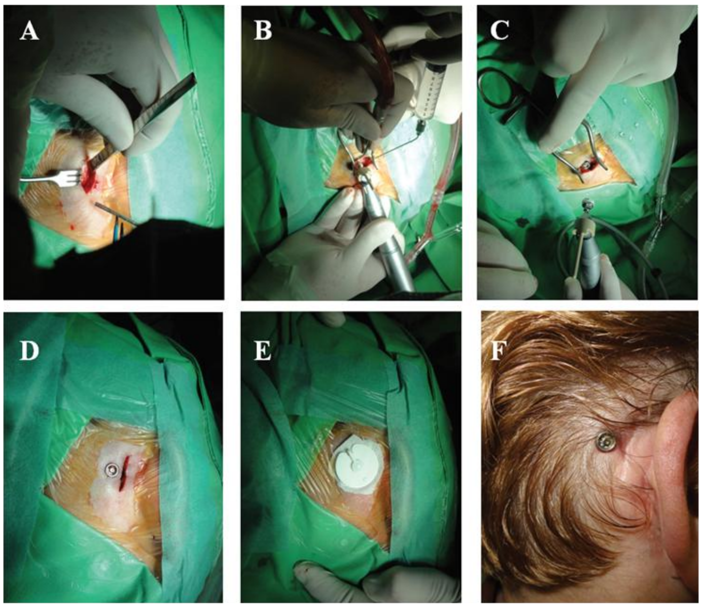


Figure 7. Steps of the "FAST" surgery of the minimal invasive linear incision technique (also known as DermaLock^{TM} surgical procedure). A: soft tissue mobilization following incision; B: drilling of the implant's site; C: implantation; D: perforation of soft tissues and relocation of the mobilized layers; E: healing cap placement; F: following postoreative wound healing. **[Jarabin et al, 72]**

However, this method might have other substantial advantages compared to the classic surgical procedures.

Further explanation may be derived through observations of surgical outcomes for treatment of other diseases, where deteriorated peripheral blood circulation leads to similar skin reactions, such as complications of diabetes mellitus, including ulcerations and infections in the most severe cases. In view of these similarities, it was hypothesized that a major causative factor for the peri-implant skin reactions is diminished vascular capacity, which could be reduced by soft tissue preservation (STP) methods. As such the skin's macro-, and microcirculatory reservoirs are maintained through minimal traumatization of the soft tissues.

Microvascular assessments with Laser-Doppler Flowmetry (LDF) have recently grown in importance in the diagnosis and treatment of hypoxia and ischemia-related tissue disorders, providing valuable information about the management of peripheral vascular disease, or diabetes treatment, or in plastic surgery, the evaluation of flaps, etc [52-55]. These studies conclude that the better blood supply, the better skin conditions. LDF of the peri-implant areas, by assessing the preservation of macro-, and microvascular capacity patterns, thus might give important information about the expectable improvement in soft tissue complications compared to the earlier methods.

Nevertheless, irrespectively the surgical approach or the applied abutment type, the well-known complications associated with the direct-drive, percutaneous abutment connection systems are still related to adverse skin reactions (*Figure 8/ A,B*).

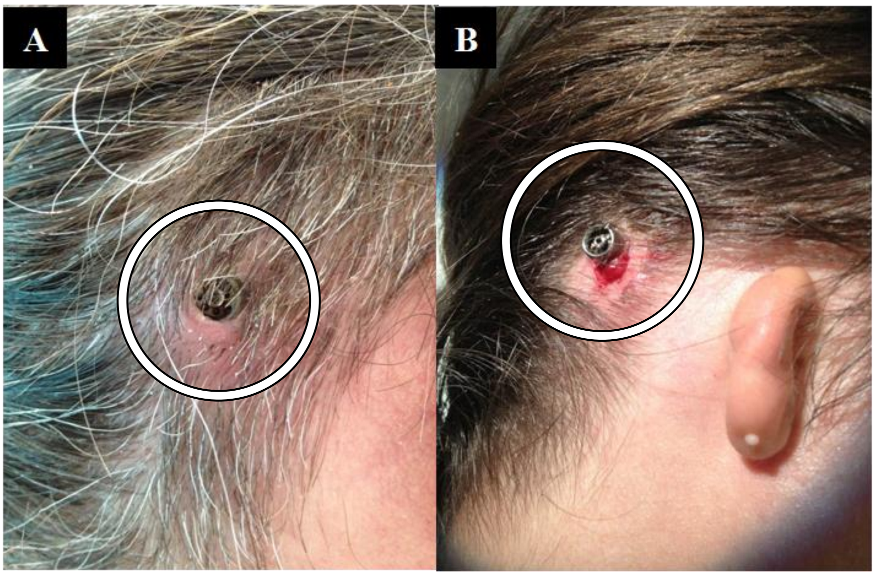


Figure 8. Postoperative complications from the Baha Connect STP group. Both subjects had undergone minimal invasive linear incision technique surgery, without any soft tissue reduction.
A: peri-implant skin overgrowth. **B**: peri-implant granulation.

I.4.2. Transcutaneous skin-drive BAHA (the Baha Attract system)

As change in paradigm, skin drive transcutaneous magnet connection (i.e. without skin-penetrating abutment) implants have the potential to mitigate soft tissue complications and the associated drawbacks.

The first system pioneering this concept was introduced in 1986 (Audiant® Bone Conductor, Xomed-Treace Inc., USA) [56, 57] which has since become obsolete for several reasons. Due to the relatively low output, The Audiant system was limited to application in patients with near normal bone conduction hearing levels and who refused to accept a direct drive abutment connection. Researchers concluded that whenever feasible the preferred treatment choice was conventional air conduction amplification [58, 59].

In recent years the Sophono® system (Medtronic, USA) uses two magnets implanted in the temporal bone and is fixed with five titanium implant screws. As a consequence the distribution of the static force is provided over a relatively large (more than 2.5 cm^2) contact area [60-62].

The current skin drive magnet connection system is the Baha® Attract which is anchored on the same BI300 implant component that has been used for the Baha® direct-drive abutment connection system (*Figure 9*). However, instead of an abutment a magnetic plate (D=27.0 mm) is fixed on the top of the implant under the skin. This plate serves as a single focused and centralized vibration transmission pathway. The connection between the SP through the intact skin is maintained with an outer magnet (D=29.5mm), which is available in variable strengths. To equalize the pressure distribution on the surface of the skin, a special soft pad is applied. The Baha Attract system has been available in the EU and US markets since the end of 2013.

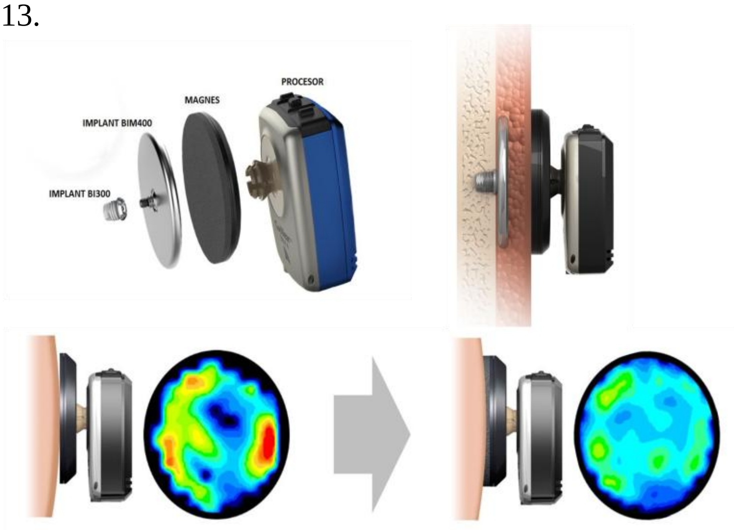


Figure 9. The Baha Attract system. The upper-left side shows the implantable components and the SP, while on the right side their in situ position is presented. The lower part of this figure illustrates how the applied Softpad distributes the pressure over the contacted area of the skin (i.e. w/wo Softpad).

I.4.3. The development of the sound processors

Parallel, the ongoing development of the SPs in use has significantly contributed to the treatment success of the concept of osseointegrated hearing implant solutions. Initial SPs such as the HC 200 [63] and Classic 300 SPs were superseded by the Baha® Compact device, marketed in 2000, which was followed by the first digital sound processor Divino, in 2005, offering much greater fine tuning flexibility. In 2009, the Baha® 3 sound processor (also known as BP 100) was introduced [64]. A series of higher output power systems to meet the needs of individuals requiring more gain includes the Baha Cordelle II, Baha® Intenso, and later the BP 110 [65]. The most up to date, fully digital Baha® 4 SP is now equipped with enhanced noise reduction and wireless features.

A recent study has reported a 10 to 15 dB higher output with the Baha system over that of the Sophono system. Furthermore, outcomes for sound field thresholds, speech recognition thresholds (SRT) and speech comprehension scores at 65 dB were better for Baha Attract users [66].

While reduced incidence of adverse skin reactions can be achieved with the skin drive magnet connection implants, the transmission pathway through the intact skin is anticipated to yield lower output compared to the classic direct drive abutment connection systems. This is due to the attenuating effect of the soft tissues, which are more apparent for the higher frequencies from 1 kHz and above [37].

However, recent studies have shown only small differences in aided speech comprehension scores between the two types of transmission pathways, which may be attributed to adequate fitting of the advanced SPs currently available [67]. As an active collaborator during the controlled market release of the Baha Attract commencing in October 2013, our ENT department introduced the concept of skin drive magnet connection systems into routine clinical practice.

Since then, more than 35 of our patients have supplied with the Baha Attract solution.

I.5. The history of Baha in Hungary

Following by nearly three decades the international introduction in 1977, Baha became a unique rehabilitation approach for conductive hearing loss in children population in Hungary as well. In 2003 Baha was introduced by Professor Gábor Katona as an organized program at the Department of Otorhinolaryngology of the Pál Heim Children's Hospital of

Budapest with the Cochlear Baha devices. The indication field at that time was limited to those special cases of congenital bilateral stenosis and atresia of the external auditory canal in Treacher Collins syndrome, also known as mandibulofacial dysostosis. Experiences gained on 3 years long follow up period were published in the Otorhinolaryngologia Hungarica [68].

The work was followed six years later, in 2009 by the foundation of the Baha Implantation Centre for adults at the Department of Otorhinolaryngology and Head-Neck Surgery of the University of Szeged. Since then the chairman of the Department, Professor László Rovó performed with only a few exceptions (those related to the previous chairman, Professor József Jóri) more than 50 successful surgeries in adults.

The program started with the implementation of the classic surgical method of skin flap creation with dermatome and the application of a permanently penetrating, percutaneous titanium abutment [69, 70]. In 2013 the surgical method was converted into a minimal invasive, linear incision technique integrating a newly designed hydroxyapatite coated abutment [71, 72].

As the well-known complications associated with direct drive systems are still related to adverse peri-implant skin reactions, developments aimed to eliminate the percutaneous abutment connection to a non-penetrating, skin drive magnet connection. The current representative of this method is the Baha Attract (*Figure 10*).

Now Baha implantation is a routinely used integral part of the therapeutic pool of conductive or mixed type hearing loss and of the special indication of single sided deafness in five centers of the country.

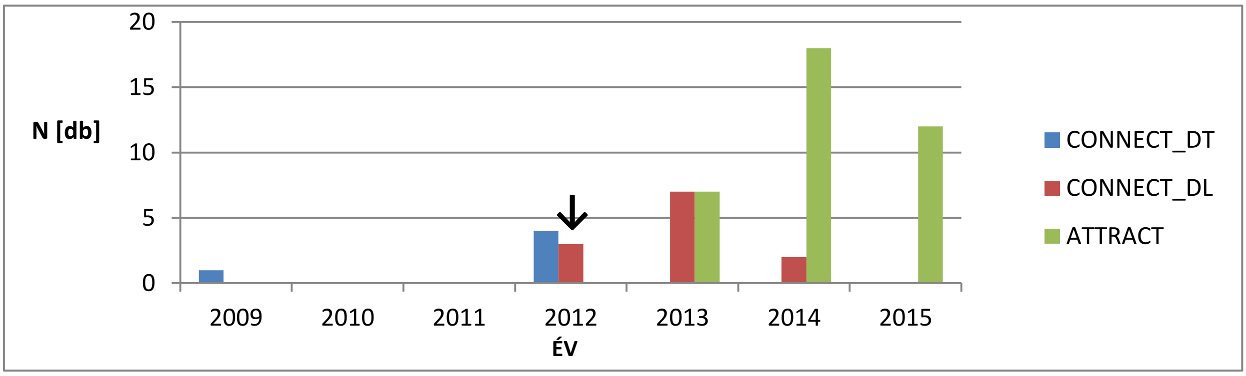


Figure 10. Annual distribution of Baha implantations at the Dpt. of Otorhinolaryngology and Head-Neck Surgery of Szeged from 2009 to 2015 (n=54). CONNECT_DT=Connect *D*erma*T*ome; CONNECT_DL=Connect *D*erma*L*ock; ATTRACT=Attract.
Black Arrow = National Health Insurance acceptance

II. OBJECTIVES

The aims of the thesis were:

1. to compare the rehabilitative efficiency of the conventional bone conduction hearing aids versus the preoperative acute-trial results collated from Baha-softband sound field warble tone and speech reception threshold examinations;

2. to compare patient satisfaction with conventional bone conduction hearing aids and implantable bone anchored hearing aid solutions;

3. to study the impact of hydroxyapatite coating of newly designed osseointegrated fixtures' abutments and the minimally invasive linear incision technique on the postoperative complication rates using precise experimental evaluation of the dynamic microcirculation patterns of the peri-implant soft tissues by Laser-Doppler Flowmetry;

4. to assess the audiological performance of study cohorts of patients recruited based on different surgical approaches and abutment solutions for percutaneuos implants;

5. to compare the audiological and psychophysical benefits of patients using osseointegrated hearing implants with either an abutment connection or magnet connection for the Baha systems;

6. to offer well established, individualized solutions for patients with conductive or mixed type hearing loss or single sided deafness.

III. SUBJECTS AND METHODS

III.1. The comparison of audiological benefits of conventional bone conduction hearing aids versus the preoperative Baha-softband examinations. Patient satisfaction survey.

III.1.1. Patients

Eighteen subjects were recruited into our preoperative prospective case series study. All the subjects met the standard indication criteria for implantation with an osseointegrated hearing implant. Ages ranged from 29 to 85 years, with a mean age of 66.4 years (±16.27SD). The ratio of genders was 1:3, M:F. Seventeen of them have bilateral mixed type hearing loss due to chronic otitis media in their case histories, and one subject had ossicular chain fixation. All subjects were experienced hearing aid users with a minimum duration of 14 years wearing bone conducted spectacles (Viennatone AN90; Viennatone Hörgeräte Gm, Austria).

III.1.2. Examination protocol

All subjects were assessed preoperatively with sound field warble tone measurements and with speech recognition tests in aided conditions with the initially fitted bone conducted spectacles (Viennatone AN 90) and the Baha sound processor fitted onto a Softband as an acute trial, with particular attention on the rehabilitative effects of them in noise.

The noise level was sustained at a constant 65 dBHL the speech level was increased by 1 dBHL steps (i.e. change the signal-to-noise ratio, SNR) up to the minimum intensity at which the subject recognized 50% of the speech material.

Furthermore, aided with the Baha Softband test equipment the influence of changing the localization of the noise source on speech recognition was analyzed while the signal source of speech was constantly held at the front. The effect of different characteristic patterns (i.e. directional or omnidirectional) of the microphone's directionality on speech recognition was investigated as well, to identify the optimal circumstances of operation for the Baha sound processor.

As control we collated speech recognition results at constant 50 and 70 dBHL speech intensity without noise but aided with conventional and implantable solutions either.

Audiological tests were performed with a GSI61 clinical audiometer (Grason-Stadler Company, USA).

Air-conduction hearing thresholds for 0.125 – 8 kHz and bone conduction hearing thresholds at 0.5, 1, 2 and 4 kHz were measured using TDH-50P (Telephonics Company, USA) and B-71 bone vibrator (Radioear Corporation, USA), respectively. The audiometer was calibrated according to International Organization for Standardization standards.

Patient satisfaction survey was performed to compare the rehabilitative efficiency of the conventional bone conduction spectacles versus the implantable bone conduction hearing aid solutions. The questionnaire covered the assistive hearing devices' specific and general functional skills in different situations, and esthetics as well.

III.1.3. Statistics

The Sigmaplot 10.0 and SPSS Statistics 16.0 statistical packages for personal computers were used for the statistical analysis. The results were expressed as mean ± SD. Student's t-test was used to evaluate significance. A level of $p \leq 0.05$ was considered statistically significant.

III.2. Microvascular pattern analysis through Laser-Doppler Flowmetry.

III.2.1. Control and implant patients

Prospective assessments were performed in three groups of subjects. A naive control group (n=7) without implant, as an inter-subject control group, and two subgroups of osseointegrated fixtures, implanted with either STR or STP surgical techniques, assessed bilaterally in implanted and non-implanted contralateral retroauricular areas acting as intra-subject and inter-subject controls. The naive control group was made up of seven patients, 4 women, 3 men, ages ranged from: 29 to 42 years; average: 36.2 years with 13 non-operated retroauricular areas examined, to represent the increasing of blood flux following LHT on healthy subjects. Seventeen consecutive implantees, 8 women, 9 men were recruited. Ages ranged from 18 to 77 years, average 45.8 years. All 17 patients met the standard indication criteria for osseointegrated bone conductor implantation. Skin perfusion related diseases (e.g. diabetes mellitus) were excluded in all cases. All implanted patients had undergone previous ear surgeries for treatment of ear diseased. In the first seven implanted patients (STR group) the classic STR surgery with U-shaped dermatome flap was performed, with BI300 implants. The latter ten patients (STP group) underwent the linear incision surgical procedure with STP according to the official guidelines, using the hydroxyapatite coated BA400 implant. Both implant types were the products of the same manufacturer (Cochlear).

III.2.2. Laser-Doppler Flowmetry

Measurement of microcirculatory variables of skin flaps using LDF alone, or coupled with various provocation tests routinely used has been demonstrated in different wound healing studies to estimate skin microcirculatory function non-invasively.

The method is based on the evaluation of the Doppler shifting of laser light on moving objects: the coherent, monochromatic laser beam penetrates into the tissues and partially scattered on static cells (non-shifted light fraction). Another fraction of photons is reflected back from red blood cells, moving within the microvascular bed, while the frequency of the light is shifted. From the above parameters, red blood cell flux could be calculated, which is linearly correlated with skin blood flow and expressed in perfusion unit (PU). The measuring depth depends on tissue properties, such as density of the capillary beds, or pigmentation, as well as from the wavelength of the laser light. Standard wave length changes between 633 and 810 nm, which are capable of transluminating 1 mm2 9 1–1.5 mm tissue volume. The laser light reaches the tissue via fiber-optic cable which also conducts reflected, frequency shifted light to a photo detector, converts input voltage to PU (1 mV = 10 PU). To evaluate reserve compensatory capacity of the peri-implant skin area, local hyperaemia test (LHT) was applied. Increase of the local temperature as a powerful vasodilator stimulus was used to characterize microvascular dysfunction in patients with diabetes mellitus and systemic sclerosis. The percentage of perfusion changing is suggested and accepted as a representative parameter, than the largely variable absolute PU values.

III.2.3. Examination protocol

All of the measurements were performed between 2 and 4 months following osseointegrated bone conductor implantation, with wound healing completed to create postoperative time-matched study groups. Each patient was assessed on implanted and non-implanted sides of the head acting as intra-subject controls. The study participants were acclimatized for 10 min before the evaluation in a comfortable sitting position. Throughout the entire observation period, the room temperature (20 ± 2 ˚C) and the axillary temperature of the patient (36 ± 0.5 ˚C) were maintained constant. The pulse and blood pressure (HR, BPsys, and BPdias respectively) were measured at the beginning of the procedure. The blood flow in the skin flap was recorded with a Laser-Doppler Flowmetric device (supplied by a 780 nm laser diode; PeriFlux System 5000, Perimed, Järfälla, Sweden) with a sterilized fiber-optic probe (#457, “thermostatic probe”; fiber separation: 0.25 mm, penetration depth ~1 mm). The flow probe was fixed perpendicularly to the skin, in the proximity of the abutment by means of an adhesive strip which restricted the angular movements of the probe. Characteristic flow curves were reproducibly detected in the s = 0.03 s mode, showing that pressure artifacts were avoided. After the required signal quality had been reached, baseline flow value recordings were made during a 10 min long period and then, the skin was warmed up to 44 ˚C for 5 min. Measurements (baseline and with heat provocation) were repeated on the non-implanted contralateral (identical surface area) of the patient, for intrasubject control. Change in tissue perfusion was expressed as percentage of blood flow increase (%). Data were collected and stored on a computer and subsequently analyzed with the computer software supplied together with the LDF device.

III.2.4.Statistics

The Sigmaplot 10.0 and SPSS Statistics 16.0 statistical packages for personal computers were used for the statistical analysis. The results are expressed as mean ± SE. The variances are different, thus the one-way ANOVA for unequal variances (Welch) was used, with multiple comparisons according to Tamhane. A level of $p \leq 0.05$ was considered statistically significant.

III.3. The comparison of audiological and psychophysical benefits gained with either an abutment or magnet connection for different Baha systems.

III.3.1. Patients and study groups

Forty-two consecutive implantees, 25 women and 17 men, were recruited into this prospective case series study. Ages at implant ranged from 11 to 77 years, with a mean age of 46.27 years (±18.37SD). All the subjects met the standard indication criteria for implantation with an osseointegrated hearing implant.

Patients were divided into two major groups based on the applied vibration energy transmission pathway. Users of direct drive, abutment connection, were called the Connect group and users of the skin drive, magnet connection, were called the Attract group. The Connect group was represented by 17 subjects, 9 women and 8 men; with an average age of 48.34 years (±18.37SD). In five patients the classic surgical method of skin-flap creation with dermatome was applied, while in 12 patients the linear incision technique was performed without soft tissue reduction. Twenty-five subjects were in the Attract group, 16 women and 9 men; with an average age of 44.86 years (±18.61SD). All subjects were operated with a modified surgical technique where the orientation and length of the incision line were adapted to the anatomical situation of the individually assessed macro- and microcirculation patterns (based on unpublished data).

The Attract group was divided further into three subgroups based on the audiological indication:

I. bilateral conductive or mixed type hearing loss
(n=13; gender ratio: 6 M, 7 F)

II. unilateral conductive or mixed hearing loss, with contralateral age-related normal hearing
(n=6; gender ratio: 2 M, 4 F)

III. single-sided deafness (SSD)
(n=6; gender ratio: 1 M, 5 F)

III.3.2. Audiological Evaluation

Measurements included preoperative pure tone thresholds and pre- and postoperative sound field warble tone thresholds and speech reception thresholds in aided and unaided listening conditions. All subjects were assessed preoperatively in aided conditions using a SP fitted onto a Baha Softband as an acute trial. During the preoperative sound field measurements (unaided and aided), the contralateral ear was plugged with an ear plug and further masked by a hearing protector headphone (Peltor Optime II., Areo Ltd, UK). All postoperative audiometric tests were carried out with well adapted fitting parameters for the sound processor. Audiological tests were performed with a GSI61 clinical audiometer (Grason-Stadler Company, USA). Air-conduction hearing thresholds for 0.125 – 8 kHz and bone conduction hearing thresholds at 0.5, 1, 2 and 4 kHz were measured using TDH-50P (Telephonics Company, USA) and B-71 bone vibrator (Radioear Corporation, USA), respectively. The audiometer was calibrated according to International Organization for Standardization standards.

III.3.3. Speech processor fitting

The initial programming of the SP for patients wearing the Baha Connect system was carried out using the Cochlear™ Baha® Fitting Software, versions 2.0 and later 4.0. For cases wearing the Baha Attract system, versions 4.0 and later 4.1 of the official software were used. We applied the standard fitting protocols; i.e. feedback analysis (in cases with BP110 and Baha 4 SPs) and direct bone conduction threshold measurements (BC Direct). The automatic algorithms for noise reduction and automatic directionality were switched off. During the tests, the patient's everyday program was used with omnidirectional microphone characteristics and default feedback manager settings. Postoperatively, the initial implant loading occurred during the 3rd to 4th week for the Connect group, and during the 4th to 6th week for the Attract group. Following the initial fitting, two or three fine-tuning sessions were performed.

III.3.4. Statistics

The Sigmaplot 10.0 and SPSS Statistics 16.0 statistical packages for personal computers were used for the statistical analysis. The results were expressed as mean ± SD. Student's t-test was used to evaluate significance. A level of $p \leq 0.05$ was considered statistically significant.

IV. RESULTS

IV.1. The comparison of audiological benefits of conventional bone conduction hearing aids versus the preoperative Baha-softband examinations. Patient satisfaction survey.

Audiometric results collated form sound filed warble tone measurements of patients (n=18) fitted with conventional bone conduction spectacles and Baha Softband test instrument were analyzed. At all measured frequencies (500, 1000, 2000, 4000 Hz) significant improvement could be achieved in warble tone hearing thresholds when fitted with Baha Softband over the conventional bone conduction assisting hearing device (i.e. Viennatone AN90) (*Figure 11/A*).

IV.1.1. Aided speech recognition measurements without noise exposure

Speech recognition was measured at constant levels of speech intensity of 50 and 70 dBHL in aided condition with conventional and implantable solutions either without exposure to noise, where significantly better outcome values were gained with the Baha Softband. Superior results were more apparent at the lower, 50 dBHL intensity of speech level that give significant benefit in the daily interpersonal routine (*Figure 11/B*).

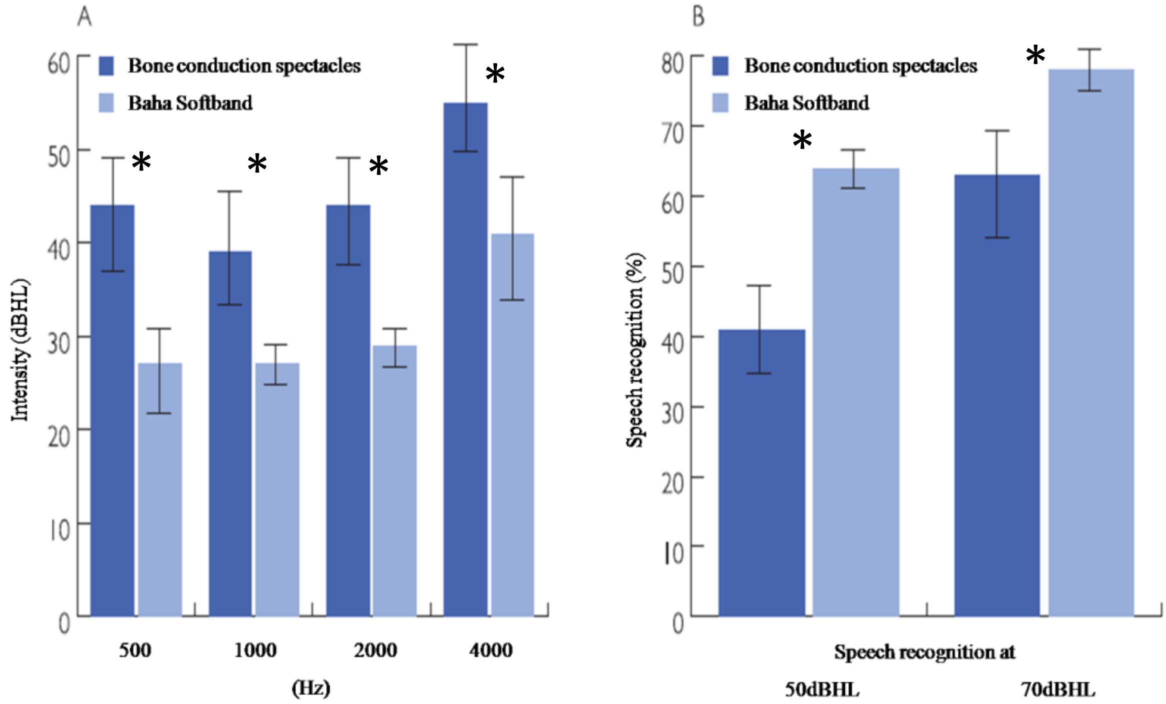


Figure 11. A: Mean warble tone sound field thresholds in aided conditions. **B:** Mean sound field speech recognition at constant levels of speech at 50 and 70 dBHL, without noise. **(n=18); *= p≤0.05** **[Jarabin J et al, 69]**

IV.1.2. Singal-to-noise ratio in variable situations

The effects of different investigative situations on speech recognition were studied in noisy circumstances, where the source of the noise and the directionality of the microphone characteristic were changed. While sustaining the noise level at a constant 65 dBHL the speech level was increased by 1 dB steps up to the minimum intensity at which the subject recognized 50% of the speech material correctly. The source of the speech signal was continuously held at the front speaker, while the noise-source was variably routed to the front or to the back. The SNR expressed in dBHL that characterized the investigated situation was derived from the difference between the speech and the noise intensity (*Figure 12/A, B*).

Significantly better SNR values were achieved when subjects were fitted with the Baha Softband as a consequence of the highly impressive capability to understand speech is noisy environment. By switching the microphone's characteristics form omni-, to directional one the SNR and thus the speech recognition could be enhanced further. In other words, to achieve the same performance the amplification need remains below with the Baha compared to the conventional assistive solutions, which is more comfortable for a hearing aid wearer.

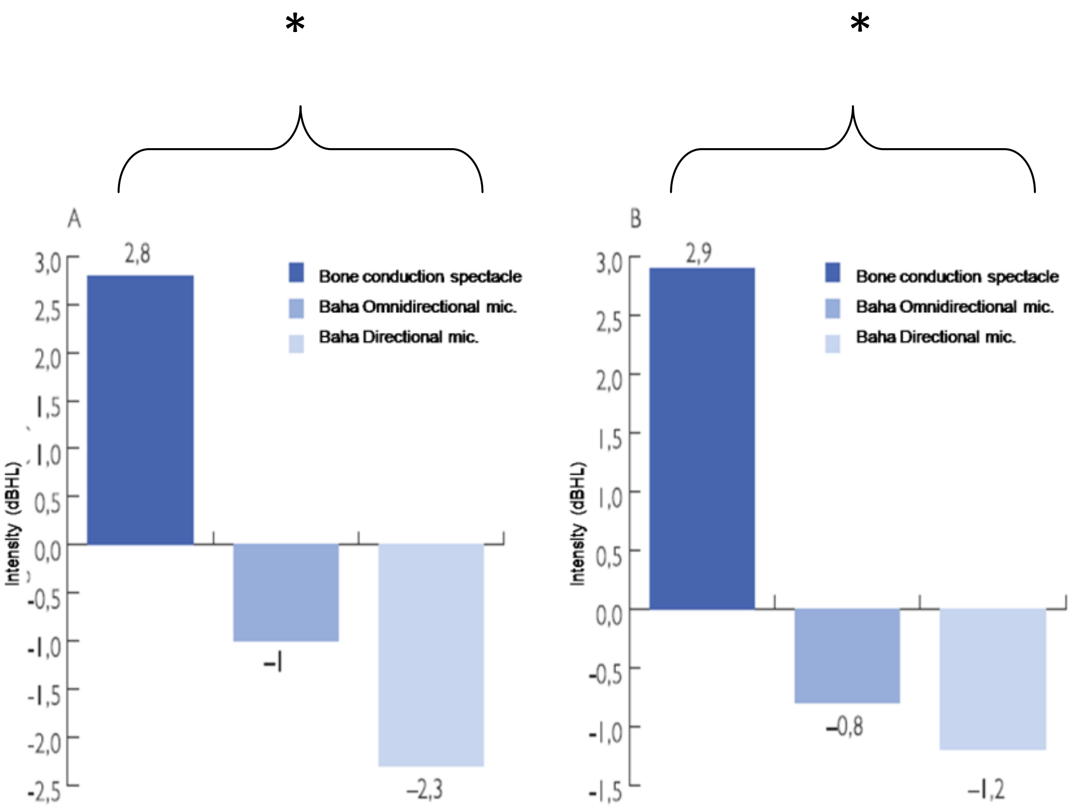


Figure 12. A: Mean SNR with 65dBHL noise level sourced from the <u>back</u> speaker**. B:** Mean SNR with 65dBHL noise level sourced from the <u>front</u> speaker. **(n=18); *= p≤0.05**

[Jarabin J et al, 69]

IV.1.3. Patient satisfaction survey (n=18)

According to the subjects' responses all of them were dissatisfied with the conventional bone conduction spectacles due to the ongoing need for repair and the unfavorable prevailing feedback phenomenon. Furthermore, speech recognition in noisy circumstances was the most challenging for the respondents. Due to the relatively low maximum sensitivity level the system was further limited to application in patients with near normal bone conduction hearing levels. Loudness sensation and sound quality were weaknesses of this rehabilitative concept too.

In contrast reports from the Baha revealed an outstanding capability of speech recognition accompanied with comfortable loudness sensation and sound quality. One should note that during the tests the Baha SP were fitted onto a Softband, thus the postoperative expectations, through the optimization of the vibration energy transmission, could be even superior on these aspects. Balanced opinions were collated only with regard to esthetics (*Table 2*).

	AN90>>Baha	AN90>Baha	AN90=Baha	AN90<Baha	AN90<<Baha
SR in noise	0%	0%	0%	33%	67%
SR in silence	0%	0%	0%	42%	58%
Loudness	0%	0%	0%	25%	75%
Sound quality	0%	0%	8%	17%	75%
Feed back	0%	0%	8%	42%	50%
Esthetics/Size	0%	0%	42%	16%	42%
Overall performance	0%	0%	0%	33%	67%

Table 2. Patient satisfaction survey (n=18).
Legends:
>> **or** **<<**: significantly worse or better
> **or** **<** : slightly worse or better
= : equally skilled
Blue colored columns represent the superiority of the Baha system over the conventional assistive devices.

[Jarabin J et al, 69]

IV.2. Microvascular pattern analysis through Laser-Doppler Flowmetry.

Characteristic flow curves demonstrated consistent significant increases in blood flow from baseline levels to post-heat provocation levels in all three subgroups (*Figure 13*) on average and for all individual patients (*Figures 14, 15*). LDF coupled with local LHT was used to estimate skin microcirculation post-provocation reserve capacity function per patient, which is graphically demonstrated in *Figure 15*.

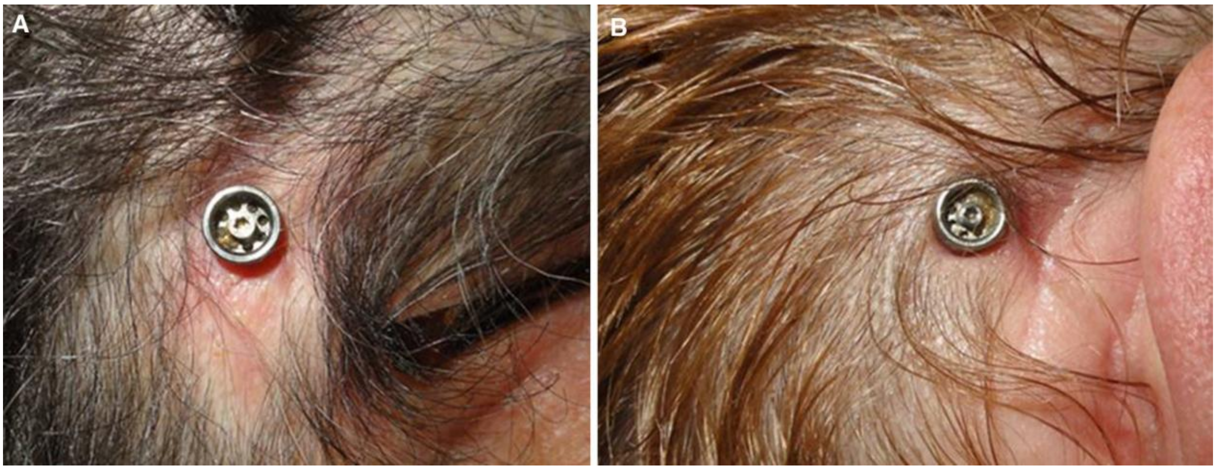


Figure 13. Postoperative photos of two patients representing the different surgical methods. On the left side a 59-year-old male patient (STR) is seen, underwent the classic STR surgery with U-shaped dermatome flap, TiO_2 surface abutment (**A**). On the right side a 44-year-old woman (STP) is seen, underwent the official surgical procedure with STP hydroxyapatite surface abutment (**B**) **[Jarabin J et al, 55]**

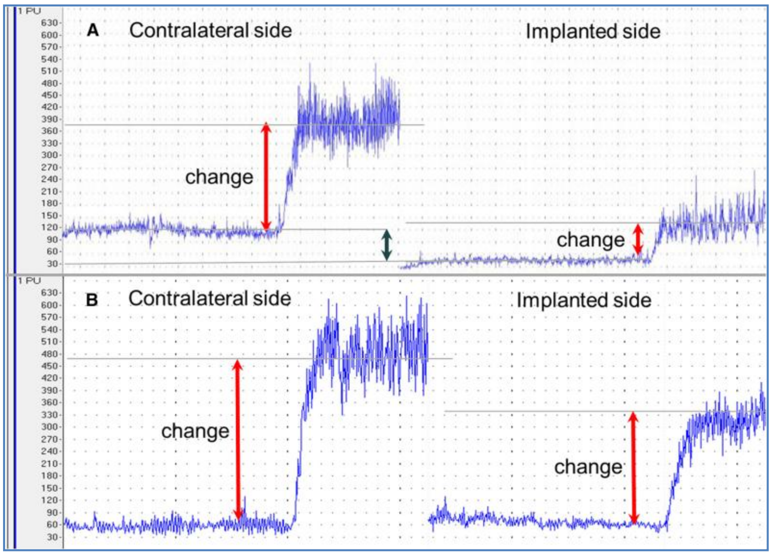
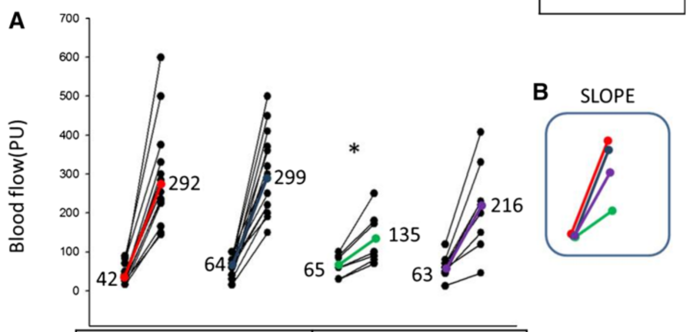


Figure 14. Representative records of two patients with different surgical methods. The curves demonstrate the skin microvascular reserve level differences at baseline and following heat provocation at the surgical area for the two patients with classic STR (A) and the STP (B) technique, for implanted and contralateral sides. Blue double arrow for patient A, indicates a notably reduced baseline microcirculation intra-subject in the implanted ear relative to the contralateral control ear. **[Jarabin J et al, 55]**

It is clearly seen, that in isotherm conditions the baseline blood flow remained stable in all implanted groups (means varied from 63 to 65 PU) (*Figure 15*). *Figure 16* shows, that the control naive patients demonstrated a significant average increase for the group of 13 ears of more than 700% of blood flux in the intact healthy skin area. On average, the contralateral ears for the implanted subgroups of patients, often previously stressed through surgical procedures, demonstrated slightly, but not significantly (p=0.09) lower, blood flux indexes (average 500%) compared to the healthy naive inter-subject control group. The STR side of the implantees, however, showed a significantly lower (average 217%) post-heat provoked blood flux index compared to the naive controls and to the non-implanted contralateral sides of these patient groups (p<0.001). The STP sides of patient subgroup demonstrated a slightly lower, but not significant reduction in the blood flux index increase post-heat provocation (average 316%) compared to the contralateral side control groups (p=0.53). STP sides demonstrated a significantly better blood flow improvement post-heat provocation compared to the STR sides (p=0.02). Looking at individual case values, the lowest pair of PU values (at baseline and post-heat provocation) for the STP side was noted for a young female with Goldenhaar syndrome (Patient 4th of STP group) who had undergone complex reconstructive esthetic surgical procedure, which largely involved the retro-auricular area (*Figure 15*).

	Control		Implant	
	Naive	Contralateral	STR	STP
Baseline	42.2±6.8	64.1±5.6	65.0±10.6	62.8±8.6
Provocation	291.8±37.4	299.4±24.7	134.6±25.4	216.4±32.2
				MEAN±SE



Control		Implant	
Naive	Contralateral	STR	STP
N=13	N=17	N=7	N=10

Figure 15. **Dot-diagram of the individual's skin blood flow changing following LHT** (A). The connected dots represent the pre-and post-heating perfusion units in all subjects. Connection lines show corresponding pairs. The dotted lines represent the average result following LHT in the four ear conditions across the three patient groups. The average group PU gradients shown in figure B clearly demonstrate a significantly reduced reaction for the STR subgroup compared to other groups (asterisk). Table 3 Mean baseline and post-heat provocation blood flow values in the different groups. Data are represented in mean ± SE. There is no significant difference between baseline values in the different groups. P values are detailed in the text. **[Jarabin J et al, 55]**

In our cohort of patients no differences in audiological outcomes have been observed between the two treatment groups, with different osseointegrated fixtures. Similarly no differences were observed in the early postimplant period up to 4 months in the incidence of skin complications between the two treatment groups. One patient had a Holgers Grade 2 skin reaction in the STR group, and one patient had a Holgers Grade 1 skin reaction from the STP group, both cases managed successfully with conservative treatment.

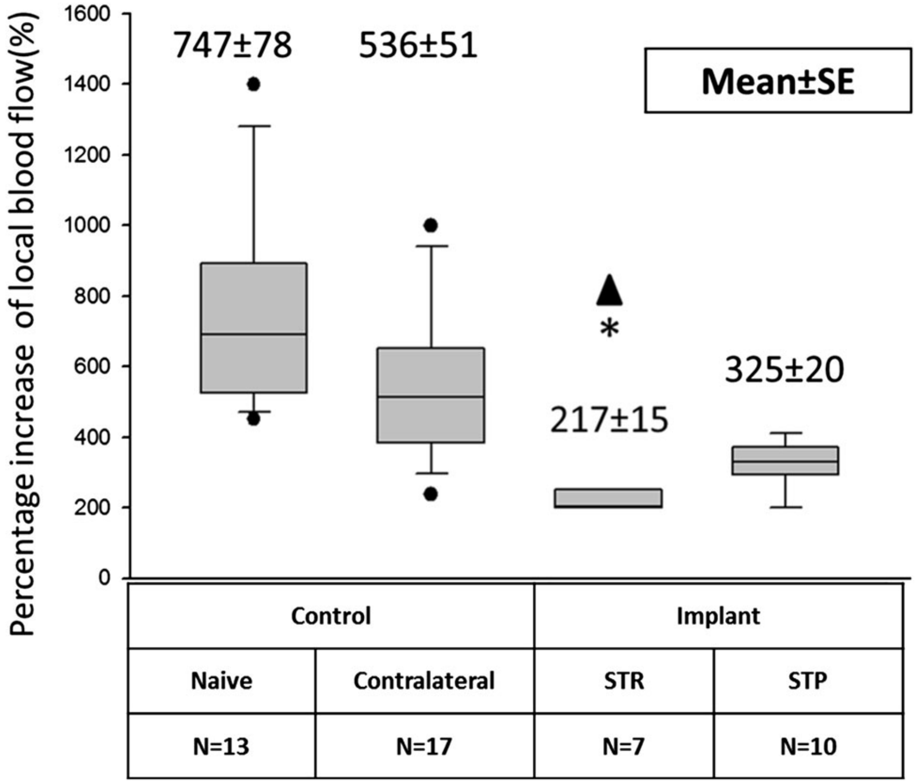
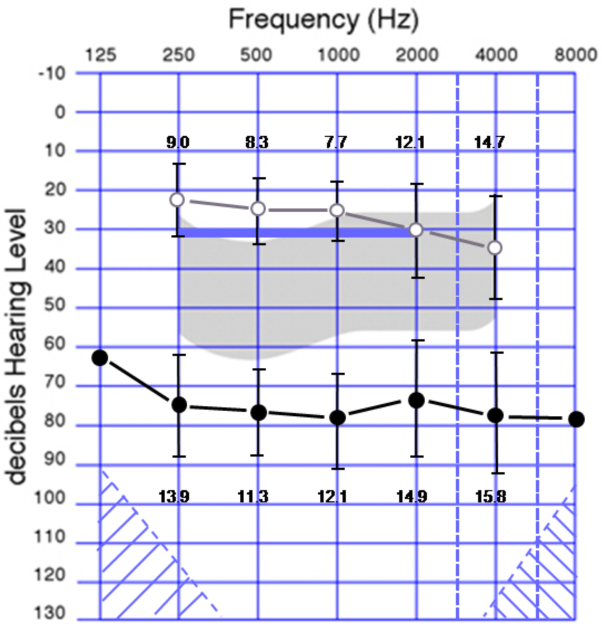


Figure 16. Box diagram of percentage increase of blood flow to local heating test with different surgical methods compared to naive and within subject controls. Peak flow reduction was found in STR and STP on the implant side. Flow reduction is significantly pronounced in STR compared to the contralateral side (asterisk) and STP (triangle). There is no significant difference between percentage flow increase to local heating in between the STP and the contralateral side.
[Jarabin J et al, 55]

IV.3. The comparison of audiological and psychophysical benefits gained with either an abutment or magnet connection for different Baha systems.

IV.3.1. Baha Connect group

As shown in *Figure 17*, the mean preoperative pure tone air conduction hearing threshold (four frequency average for 0.5, 1, 2 and 4 kHz, PTA_4) for the five patients operated with the classic technique was 75.75 dBHL (±14.01) in unaided conditions, while the postoperative warble tone bone-conduction threshold in the sound field was 23.50±9.49 dBHL for the aided condition.



Frequency	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
ABG GAIN	52.1 dB	51.5 dB	53.5 dB	43.8 dB	43.4 dB

Figure 17 Connect group (N=17):
Unaided preoperative average air conduction threshold (black filled dots) vs aided postoperative average sound field threshold with Baha (grey empty dots). Standard deviations (SD) are marked at each frequency, with exact values.

The air bone gap gain (ABG) values were derived from the difference of the preoperative unaided air conduction levels and the postoperative Baha-aided bone conduction levels.

The postoperative mean sound field SRT was 73.00 dBHL (±8.37) in unaided and 25 dBHL (±10.00) in aided conditions. The Student’s t-test showed speech data to be significantly better in aided over unaided conditions (p<0.001), with an average gain of 48 dBHL in the SRT.

The mean preoperative pure tone air conduction hearing threshold (i.e. four frequency average for 0.5, 1, 2 and 4 kHz) for the 12 patients operated with the linear incision technique was 77.40 dBHL (±13.27) in unaided conditions, while the postoperative mean bone conduction threshold in the sound field was 31.15 dBHL (±10.13) in the aided condition.

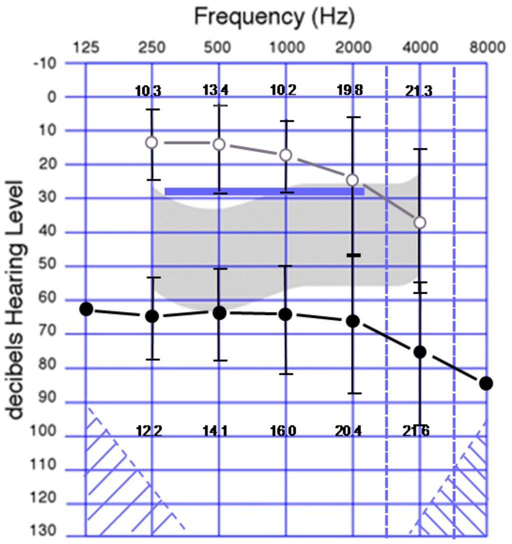
The mean sound field SRT was 76.25 dBHL (±8.82) in unaided and 30.83 dBHL (±9) in aided conditions. The Student's t-test showed speech reception thresholds to be significantly better in aided over unaided conditions (p<0.001), with an average gain of 45.42 dBHL.

Statistically the two subgroups fitted with the Baha Connect system achieved equivalent therapeutic efficiency in terms of sound field warble tone and SRT values either, thus the application of these competing alternatives mainly depends on surgical aspects and not audiological ones.

Hereinafter we analyzed them as one Connect group for comparison to the Attract group.

IV.3.2. Baha Attract group

The audiometric data is presented for individually for the 3 subgroups of the Attract group. *Figure 18* illustrates the results for the Attract subgroup I: bilateral conductive or mixed HL. Their mean preoperative PTA$_4$ was 67.41 dBHL (±18.02SD) in the unaided



Frequency	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
ABG GAIN	50.0 dB	48.9 dB	45.7 dB	40.4 dB	35.8 dB

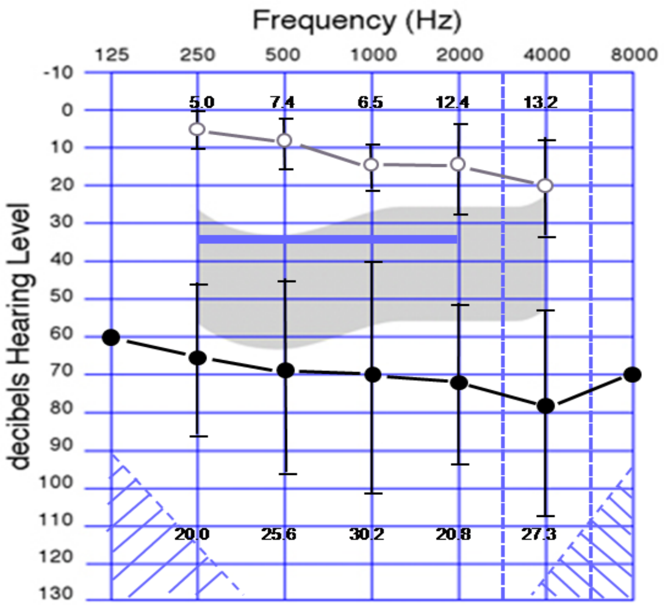
Figure 18 Attract I. subgroup (N=13): Unaided preoperative average air conduction threshold (black filled dots) vs aided postoperative average sound field threshold with Baha (grey empty dots). Standard deviations (SD) are marked at each frequency, with exact values.

The air bone gap gain (ABG) values were derived from the difference of the preoperative unaided air conduction levels and the postoperative Baha-aided bone conduction levels.

condition, while the postoperative mean bone conduction threshold in the sound field was 24.72 dBHL (±16.18) in the aided condition. The mean sound field SRT was 57.31 dBHL (±21.08) in unaided and 23.46 dBHL (±10.68) in aided conditions. The average gain for the SRT was 36.07 dBHL.

Figure 19 shows the results for the Attract subgroup II: unilateral conductive or mixed HL with contralateral age-related normal hearing. The mean preoperative PTA_4 was 71.75 dBHL (±25.99SD) in unaided conditions, while the postoperative mean bone conduction threshold in sound field was 14.25 dBHL (±9.90SD) in aided conditions.

The mean sound field SRT was 16.00 dBHL (±10.84) in unaided and 9 dBHL (±6.52) in aided conditions. The average gain of the SRT was 7 dBHL.



Frequency	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
ABG GAIN	55.0 dB	56.0 dB	54.0 dB	56.0 dB	52.0 dB

Figure 19 Attract II. subgroup (N=6):
Unaided preoperative average air conduction threshold (black filled dots) vs aided postoperative average sound field threshold with Baha (grey empty dots). Standard deviation range and values (SD) are marked at each frequency.

The air bone gap gain (ABG) values were derived from the difference of the preoperative unaided air conduction levels and the postoperative Baha-aided bone conduction levels.

Figure 20 displays the results for the Attract subgroup III: single sided deafness. By definition, there was no response in SSD ears. The mean preoperative PTA_4 for the intact good ear was 5.83 dBHL (±8SD). No air bone gap was indicated in the audiograms. The postoperative mean bone conduction threshold in the sound field was 7.92 dBHL (±6.54) in the aided condition.

The mean sound field SRTs were the same at 10 dBHL in unaided and aided conditions, thus yielding no added gain for the SRT. It is noted that no ear protection was used over the intact ear for the unaided condition.

As there is only one viable cochlea in the SSD subgroup, results in the Baha aided condition compared to a functional anacusis on the same side, could lead to misinterpretation of the overall individual benefit, thus using the intact ear's bone conduction threshold may provide more realistic data.

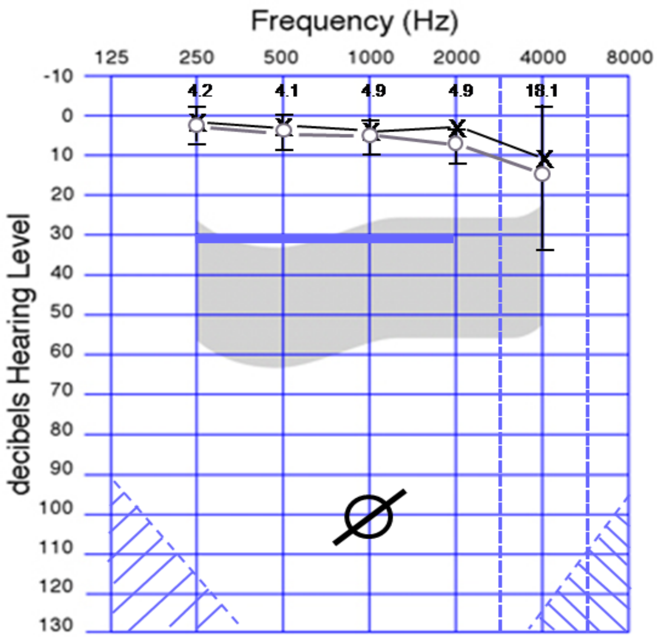


Figure 20 Attract III. subgroup (N=6):
Unaided preoperative average bone conduction threshold (black 'X's) vs aided postoperative average sound field threshold with Baha (grey empty dots).

The Baha-side average air conduction was immeasurable. Standard deviations range and exact values (SD) are marked at each frequency.

The Student's t-test showed SRT to be significantly better in aided over unaided conditions ($p<0.001$) in subgroups I and II, while as expected the difference was insignificant for subgroup III.

IV.3.3. Sound processor fitting: psychophysical findings

The most frequent challenges experienced during postoperative sound processor fitting were experienced by the Connect group. Excessive resonance occurred in a total of 41%: 23.5% (4/17) experienced it as sound reflection from the surface of the skull bone and 17.6% (3/17) experienced it from the surrounding wall surfaces. Problems were alleviated by utilizing the Feedback Analyzer software option (BP110, Baha 4 SPs) or by manipulating the middle to high or high frequency range during fine tuning. The resonance effect resulting in feedback was not reported in the Attract group, although one patient experienced resonance that could be easily eliminated by minimally decreasing the gain in the high frequency range.

An echo effect appeared in 3/17 (18%) cases in the Connect group. In the Attract group only 2/25 patients (8%) presented with this complaint; the issue was resolved for both patients following the first fitting procedure.

Problems in noisy and windy environments were reported in 9/17 (52%) Connect users. In the Attract group, 2/25 (8%) complained of having such difficulties in some background noise.

Specific to the Attract group are considerations of magnet strength (values range from 1, the weakest, to 6, the strongest). One of the 25 cases (4%) required an even stronger magnet than normally provided due to a very active lifestyle. During the first fitting, the average magnet strength was 3.84±0.98SD. Following the complete remodeling of the soft tissue during postoperative wound healing, it was possible to decrease the magnet strength in 14 cases (56%) down to 2.92±0.87SD.

IV.3.4. Comparison of outcomes

Comparing the ABG gain, derived from results in the preoperative unaided and the postoperative aided conditions, for the Connect group versus the Attract subgroup I, no significant difference was observed. Hence the audiological findings for these groups were combined. Figure 5 shows the pre-, and postoperative individual SRT values in the Baha Connect and Attract I groups respectively as well as the achieved gain.

Viewing the speech reception threshold improvements for the Attract subgroup I and the Connect group, significantly higher gains were observed for the Connect group ($p=0.01$). However following exclusion of a single outlier value with higher amplification needs using the BP110 SP in the Connect group, the group performance difference was no longer significant ($p=0.18$) (see *Figures 21 and 22*).

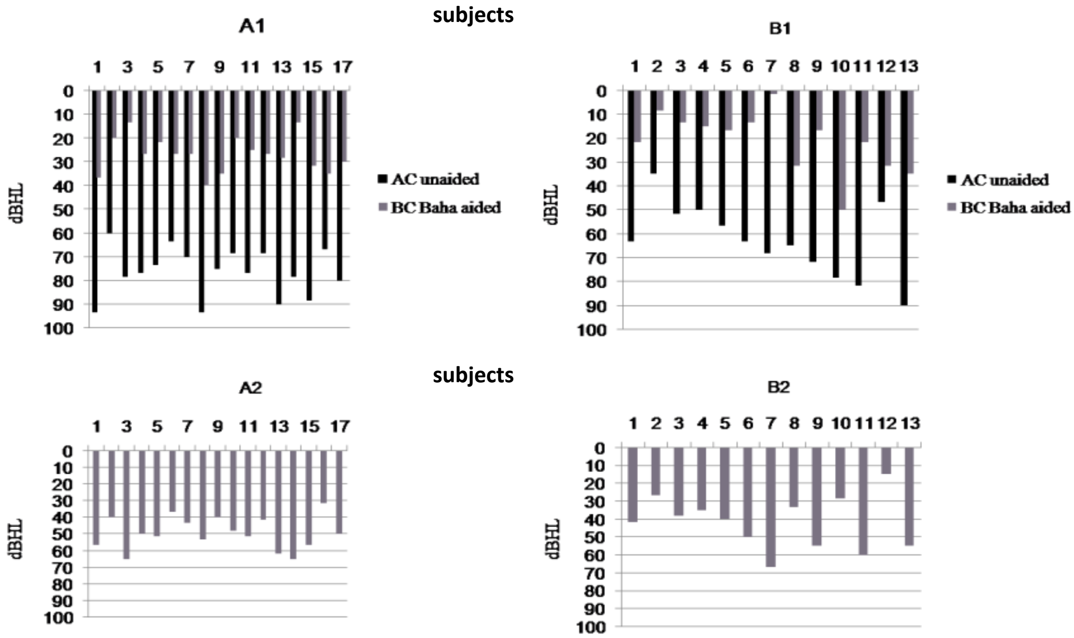


Figure 21 A1 and B1 shows the preoperative and postoperative individual speech reception thresholds (SRT) in the Baha Connect and Baha Attract groups respectively. A2 and B2 graphs present the individually achieved SRT gain values. The difference found to be significant (p=0.01) between the two subject cohorts.

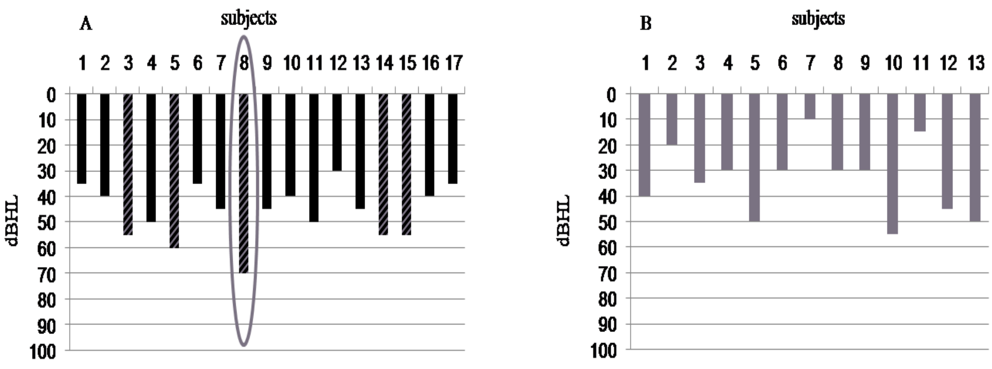


Figure 22. Comparing the individuals' speech reception threshold improvement, achieved in the Attract I. group ('B' columns; n=13) to the unselected Connect group ('A' columns; n=17), where results with both the BP100 (black columns) and the BP110 (black-grey striped columns) SPs were collated; significantly better gain value was presented in the latter one. By excluding only one outlier value (the 8th subject from the Connect group) with high amplification need, the difference found again to be insignificant (p=0.18) between the two subject cohorts.

V. DISCUSSION

Prior to any decision making thorough preoperative audiological tests should be performed to achieve well-grounded indication including an unimpeachable cornerstone in the diagnostic pool, the soft-band test. This non-invasive, easy to perform sound field measurement ensures the implant candidate and the audiologist as well to gain experience on the achievable postoperative rehabilitative effect of the implant fitted with the proper sound processor. One should note that applying the baseline audiogram the psychophysicist can accurately and individually fit the sound processor that is an inevitable need. Our comparative preop-audiological tests clearly proved its significance [69, 73-74].

V.1. Baha Connect system

V.1.1. Consideration of surgical aspects of implantation

Historically, for surgeries employing direct-drive percutaneous osseointegrated implant solutions, the preparation of a skin flap with a dermatome employing soft tissue reduction is the most well-established technique for optimal functional outcome [38-40].

However, the reduction of the inner skin layers, requiring cross section of the nutritive circulation pathways has a deteriorating effect on the physiology of the remaining upper skin layers that are potentially further stressed by the penetrating abutment.

The risk of adverse skin reactions has been addressed by new developments that incorporated microsurface technology for the implant component (e.g., titanium-dioxide surface), aimed at reducing the loading time, coupled with advanced redesign of the physical attributes of the abutment. The new concave shape through achieving a 14% more (2.1 to 2.4 mm) soft tissue contact surface and decreasing the angle between the soft tissues and the abutment’s contour from 73° to 50° lowered the tendency for peri-implant pocket formation and adverse skin reactions.

However while titanium is ideal for integrating with bone, it does not bond with soft tissues (skin and the underlying layers). On the other hand, as the Baha Connect system was such an effective method for vibrational energy transfer between the SP and the implant, a new microsurface technology was developed. The application of an approximately 80 µm thick hydroxyapatie coating ($Ca5(PO4)3(OH)$; ISO 13779-2) on the abutment has superiorly improved the overall soft tissue integration [51], without the need for soft tissue or hair reduction, thus leaving the peri-implant area outstandingly intact. This resulted in a more cosmetically attractive implant site as well.

At the same time our results demonstrate the potential to preserve vascularization through soft tissue preservation over previous surgical techniques with soft tissue reduction.

The integumentary system comprises the skin and the skin-associated structures, the appendages, including sebaceous glands, sweat glands, hair, etc. This organ system forms an effective barrier between the organism and the environment, preventing invasion of pathogens and fending off chemical and physical assaults, as well as the unregulated loss of water and solutes [75]. This multiple skin function highly depends on its vascular system integrity.

Macrovascular supply of the retroauricular region originates from the branches of the external carotid artery (i.e. posterior auricular artery, occipital artery) forming anastomosing nets behind the auricles. The microcirculation of the skin is organized as two plexuses situated parallel with the surface, embedded into the multiple layers of ectodermal tissue. The superficial and the profound layers are interconnected with paired ascending arterioles and descending venules (AV-shunts), representing the thermoregulation component (~85 %). From the upper layer arterial capillaries rise to form the dermal papillary loops, representing the nutritive component (~15 %) [76]. Endosurface layers of microvascular segments (e.g. precapillary arterioles, capillaries, postcapillary venules), which are closely linked, take part in the haemostasis and in the regulation of inflammatory cascades and vascular resistance. This is controlled by exogenous environmental impacts (e.g. temperature, pressure), through the nociceptive system. The afferent neuronal reflex pathways are built up from non-myelinated C-fibers of the skin nerves. The damage made on this sophisticated system obviously diminishes the protective reserve of the skin against environmental (thermal, mechanical, inflammatory) assaults.

Diseases which have influence on blood microcirculation and thus on vascular reserve capacity may cause severe alterations in skin functions [77, 78]. Various reactivity tests, coupled with techniques measuring skin blood flux, are used to non-invasively explore both endothelial and microvascular functioning in humans [79].

LDF alone, or coupled with LHT is routinely used in different wound healing studies [80-83]. LDF demonstrates well the microcirculation of the upper 1–1.5 mm of the skin. However, the absolute blood flow is widely variable in different locations, the change of flux is generally accepted parameter in determining the quality of microcircular function. Accepting that the human body is symmetric, the contralateral identical areas were used to provide a statistically appropriate study, which was strengthened by the results of healthy control retroauricular areas assessed at the same location.

In the history of osseointegrated bone conductor surgeries the split-thickness skin flap (STSF) creation with STR has become a well-established technique [38, 39]. The dermatome creates a STSF 25 mm in width with a thickness of 0.6 mm, which composed of the top layers of skin (the epidermis and part of the dermis), comprising the superficial dermal papillary vascular loops. The graft is initially nourished by a process called plasmatic imbibition, then new blood vessels begin growing from the adjacent soft tissues and the periosteum of the recipient area into the transplanted skin within 36 h in a process called capillary inosculation. This emphasizes the necessity of the intact periosteum beneath the flap.

As our results show, these regeneration processes provide even an appropriate baseline blood flow, but only a reduced vascular reserve, which might be insufficient especially in extreme environmental conditions. Thus the reduction of the inner layers of skin by transecting the nutritive circulation pathways has a deteriorating effect on the physiology of the remaining upper skin layers. This might be in the background of the well-known potential complications, beside the generally suspected peri-implant “pocket formation” [51]. These adverse events generally can be decreased by careful patient selection either in terms of social and medical issues, which on one hand more or less limits the indication field. The increasing incidence of complications over time might influence the patient compliance as well [41, 45]. In contrast the preservation of all the layers of the skin and thus the microcirculation network, as in STP technique, might further decrease the complication rate in short and potentially also in the long term. The vertical skin incision has practically no effect on the horizontally structured microcirculation. Our study unambiguously proves the early acceptable recovery of the microcirculation reserve. Generally the soft tissue regeneration after the STP technique is complete within days, which allows a relative shorter loading time for the speech processor, compared to the STR technique. Our study however, revealed a tendency of a diminished blood flow flux on the implanted sides compared to the normal skin in naive controls and to the contralateral side controls. Moreover, on those surgical sides, which were previously stressed with multiple scarring skin incisions, the values were also well below the normal skin values. These findings may indicate the role of macro circulation and neurovascular regulation in the background of an intact microcirculation, thus the importance of the preservation of the larger blood vessels and the skin nerves. In our patient series we did not find significant difference in complication rates between the different surgical groups.

Consequently the preferable application of the minimally invasive technique employing the newly modified abutment is well-grounded clinically and experimentally either, while kept our focus on the simplicity of the surgical technique or the course of the improved postoperative peri-implant wound-healing, resulting in decreased complication rates.

V.1.2. Consideration of audiological aspects

On the contrary the functional audiological rehabilitative performance was still an area of interest. Our comparative audiometric tests following surgery definitely proved that there is no significant difference in sound field warble tone or either speech recognition thresholds between subgroups operated with the classic surgery with STR or the advanced minimal invasive linear incision technique with STP of the percutaneous direct-drive systems (i.e. Baha Connect group), thus being the decision surgical or audiological based, one should indicate the minimal invasive technique.

Nevertheless, the most common complications associated with direct drive abutment connection systems, even in case of the minimal invasive linear incision technique employing hydroxyapatite coated abutment, are still related to adverse skin reactions immediately around the abutment.

V.2. Baha Attract system

V.2.1. Consideration of surgical aspects of implantation

As a paradigm changing in the transmission pathway of the vibrational energy, skin drive magnet connection systems can mitigate the drawbacks of soft tissue complications associated with direct drive systems (see Chapter I.4.2. on page 13th).

Based on our clinical observations during the postoperative follow-up period of a minimum of six months, only minor irritations occurred in two cases of the Attract group (n=2/25, 8%). A temporary suspension of wearing the SP and the application of a reduced magnet strength relieved the tenderness around the implanted area relatively quickly. In contrast, we have seen three (n=3/17, 18%) skin overgrowths, one peri-implant granulation (n=1/17, 6%), and one (n=1/17, 6%) skin flap necrosis from the 17 subjects with abutment connection systems. Two subjects needed revision surgery, while the other three improved following conservative treatment. The overall complication rate in the Connect group is close to 30%. According to studies carried out on a large series of patients (n=602) by Hobson et al.

the overall complication rate was 23.9%, while the rate of revision surgery was 12.1% for direct drive system users [84].

V.2.2. Consideration of audiological aspects

Our focus during audiological tests was the detection of the potential attenuating effect of the soft tissue layers [37]. Our observations were consistent with studies that showed only small differences between the aided speech reception thresholds observed users of direct drive and skin drive systems, and that the differences may be reduced with optimizing the fitting via advanced SPs [37, 67]. As such osseointegrated hearing solutions are applicable in a substantial number of cases with a mild moderate sensorineural conductive hearing loss component, however only for a minority of cases with a more significant hearing loss where higher amplification needs cannot be met.

In our study, all subjects with the Attract system were supplied with the technically advanced Baha 4 SP.

It should be noted that, during aided postoperative audiometric testing for a given individual with two functioning cochlea, both are simultaneously stimulated. This needs to be taken into consideration when interpreting the results gathered from the Baha Attract subgroups I and II where the non-Baha ear had hearing close to or at normal levels. In these subgroups, regardless of whether the SRTs were significantly changed or not is less relevant than the importance of the subjective positive feedback of the restored hearing from both sides of the head physically. It is important to emphasize during the patient counseling that there may be potential for improved perception of sound quality and sound awareness within the environment rather than just the absolute hearing threshold changes to help mould the appropriate expectations.

The observations suggest that effective fitting of osseointegrated hearing implants plays a major role in the ultimate outcome and user satisfaction. The source of feedback is not solely related to leakage from the transducer back to the system microphone and may relate to origins from a mechanical source, such as skull vibration, soft tissue interference, or other variables that are known to play a part in the feedback pathway for Baha® Sound Processors [85]. The resonance/feedback problems encountered in the study patients could be resolved in most cases following evaluation using the Feedback Analyzer software available in the sound processor (i.e. BP 110 and Baha 4). Additionally, it was possible to manipulate the gains specific for mid to high or high frequency ranges, although the latter methods are known to decrease speech perception.

Although infrequent in our sample, the echo effect, where a person's own voice is first heard through unaided means and then immediately heard (as an echo) through the Baha system, was seen in three Connect and two Attract users. Although it was challenging to resolve the problem, it was possible by decreasing the gain in the mid to low and low frequency ranges. As mentioned earlier, such adjustments may lead to decreased speech understanding. For those affected in the Attract group resolve was reached readily during the first fitting session.

For noisy and windy environments, there are several options available. These environmental factors cause significant complaints for all types of implanted systems, but predominantly affect those who wear older SPs (i.e., BP 100 and BP 110). Fine tuning and the proper choice of the suitable program (such as noise or music) may provide improvements, to some extent, and provide enough support to encourage patients to face these challenges. Through the Baha 4 SP changes in the environment are automatically recognized and effective noise-reduction algorithms are applied. Both of these features improve hearing and speech recognition within noisy and windy conditions.

In our study cohort, all Baha Attract system users were fitted with a Baha 4 SP, and minimal reports of feedback, resonance or echo effect were observed. Briggs et al. presented similar good hearing performance outcomes and additionally wearer comfort and minimal tissue complications [86]. In a recent multicenter study reported by Iseri et al. superior audiological performance outcomes were observed for users of the direct drive abutment connection system, however as it involved more than one center there may have been some inherent heterogeneity in the psychophysical programming approaches used [87]. Although the Attract system provides lower gain above 1 kHz compared to the Connect system, our findings indicate that with an appropriately fitted Baha 4 SP no significant difference in audiological performance was observed.

V. SUMMARY

VI.1.

As an integral part of the preoperative audiological assessments acute trials with carefully programmed SPs fitted onto a Softband are essential and validated diagnostic approaches. Results gained through these tests are in good correlation with the postoperative outcomes with outstanding predictive value for patients and audiologists as well [I].

Based on our audiometric results the rehabilitative efficiency of the direct-drive percutaneous and the skin-drive transcutaneous osseointegrated hearing assisting solutions were significantly superior over the conventional bone conduction hearing aids irrespectively the type of surgery and the employed interface (i.e. abutment or magnet connection) between the implant and the SP [I, II, III, IV,].

VI.2.

Through evaluation of patient satisfaction surveys osseointegrated bone anchored hearing aids are well established parts of the therapeutic pool of conductive and mixed hearing losses or single sided deafness. Reports from the Baha revealed an outstanding capability of speech recognition accompanied with comfortable loudness sensation and sound quality resulting in advanced wearing comfort over achieved with the conventional bone conduction spectacles [II].

VI.3.

Our result shows that following the STR technique, the normal vascular reserve of the skin could not be re-established, that should be considered as a limitation in patient selection, and during patient counseling, because of the need for proper after care. In contrast after the STP technique, more viable regeneration processes were observed in the peripheral implant area, where the normal skin’s vascular capacity levels could be approximately achieved. The potential for both faster wound healing and lower complication rate post implant may support to widen the inclusion criteria for treatment with osseointegrated fixtures and may subsequently lead to greater outcome success including improved quality-of-life [V].

VI.4.

Our postoperative comparative audiometric test results definitely proved that the functional rehabilitative performances gained with the classic surgery with STR and the minimal invasive linear incision technique with STP are statistically indistinguishable, that allows the surgical based preferences to overcome. As STP techniques inherently leave the peri-implant are outstandingly intact, thus decreasing the complication rates even further, such approaches should be indicated against the classic methods with skin-flap creation [III, IV].

VI.5.

Employing the passive transcutaneous skin-drive magnet connection, the postoperative complication rates could be eliminated compared to even when the minimally invasive linear incision technique is used.

Our results demonstrate that the vibrational energy transmission pathways of the direct drive abutment connection and the skin drive magnet connection systems provide significant improvements in hearing and speech recognition thresholds over the unaided condition.

Comparative audiological analysis revealed that only with few exceptions the distortion and the lower sensitivity caused by the presence of the intact barrier of soft tissues could be well compensated for with accurate fitting of the latest technology sound processors. Few patients with high amplification needs, near the upper limit of the fitting range may require direct-drive systems fitted with power SPs.

VI.6.

Wound healing processes are more rapid and the postoperative overall complication rates are significantly reduced or nearly eliminated with the current skin-drive system (i.e Baha Attract) compared to that described in published reports for cases where the classic surgical techniques of direct-drive systems (i.e. Baha Connect) have been used.

The surgical approach is as simple as the minimal invasive linear incision technique, with duration of approximately 30 minutes in topical anaesthesia in experienced hands.

With only a few exceptions of patients with high amplification needs near the upper limit of the fitting range at the high frequency range (above 1 kHz) almost all of our patients could have been superiorly supplied with the Attract system. The inherently presenting lower sensitivity of the skin-drive system in most of our cases could have been successfully compensated by a carefully fitted advanced SP.

As a consequence, our findings suggest possible opportunities to broaden the current inclusion criteria for treatment with osseointegrated skin drive, magnet connection systems. Use of magnet connection systems may lead to greater success for overall outcomes including improved esthetics, quality of life, substantially reduced needs for postoperative care, while preserving the substantial audiological rehabilitative effects of the predecessor systems.

The rehabilitative treatment success highly depends on the thorough preoperative diagnosis. Consideration should always be given that conductive hearing loss, defined as an ABG on the audiogram may due to disorders of the inner ear as well, resulting in pathologic third windows. Clues to suspect such a lesion include a low-frequency ABG with supranormal thresholds for bone conduction, the presence of acoustic reflexes, vestibular myogenic responses or otoacoustic emissions. Imaging techniques are essential for detailed differential diagnostics [I, II, III, IV, V, VI].

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