

CLINICAL-RADIOLOGICAL EXAMINATIONS FOR OPTIMIZATION OF SURGERY AND RESULTS OF IMPLANTABLE HEARING AIDS

PhD Thesis

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PUBLICATIONS RELATED TO THE THESIS:

- I. **Adam Perenyi**; Zsafia Bere; Janos Jarabin; Balazs Sztano; Edit Kukla; Ziad Bikhazi; Laszlo Tiszlavicz; Ferenc Toth; Jozsef Geza Kiss; Laszlo Rovo.
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Impact factor: **1.485**
- II. Rovo L, Bere Zs, **Perenyi A**
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- III. Posta B, Jarabin JA, **Perényi Á**, Bere Z, Neagos A, Tóth F, Kiss JG, Rovó L.
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Impact factor: **0.322**
- IV. **Perényi Á**, Jóri J, Csanády M, Rovó L.
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Impact factor: **0.322**
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- VII. **Perényi Á**, Bella Z, Baráth Z, Magyar P, Nagy K, Rovó L.
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I. INTRODUCTION

Hearing loss is one of the leading causes of disability worldwide. Approximately 15% of the world's population has hearing loss to some degree and over 5% out of them, ca. 360 million people, suffer from hearing loss higher than 40 dB on the better hearing ear in adults and 30 dB in children. Ear surgery has been undergoing a revolutionary change, i.e. a growing proportion of the surgical procedures are undertaken to rehabilitate hearing with or without implantable hearing aids while the number of surgeries of the chronic ear has had a tendency to decrease. The numbers of implantations including bone-anchored hearing aids (BAHA) and cochlear implants (CI) in prelingual and postlingual subjects has been increasing worldwide lately.

The implants differ in type and dimensions, and the anatomical dimensions of the pediatric and adult population are also variable. The efficacy and design of modern implants meet the need of the increasing number of surgeries in young children: the possibility of safe and minimally invasive surgical techniques.

Several studies regarding hearing rehabilitation have been conducted at the Department of Otorhinolaryngology, Head and Neck Surgery, University of Szeged in cooperation with other centers and implant manufacturers. Being a member of the workgroup of implantable hearing aids, from the beginning of my training I have been deeply involved in the full range of implant procedures, i.e. patient selection, preoperative examinations, surgical procedure, and postoperative follow-up.

I am focusing my thesis on specific aspects of modern (a) BAHA and (b) CI surgery: (i) the optimal preoperative diagnostic tool and the optimal surgical approach for passive transcutaneous BAHA, (ii) the most relevant similarities and differences in anatomy between the pediatric and the adult population for BAHA and CI surgery and (iii) the surgical benefits of the technological advancements in CI design.

I.1. Bone-anchored hearing aids – with focus on passive transcutaneous implants

The newly developed transcutaneous magnet-connection bone conduction systems have gained increasing popularity. The surgery is straightforward, fast, and can be performed either in local or general anesthesia. An obvious advantage of the transcutaneous systems compared to the percutaneous ones is that the skin over the implant is left intact; thus, patients are more likely to accept the cosmetic results and adverse events (e.g. tissue overgrowth, peri-implant skin necrosis, numbness, or extrusion of the device) can be prevented effectively.

Potential drawbacks include the two magnets that put static and dynamic pressure on the skin that lies in-between, and the significantly larger surgical exposure in contrast to that used for the percutaneous implants.

Major injuries to the macrocirculation are strictly connected with compromised microcirculation, which results in compromised vitality of the skin flap, pain, numbness, and discomfort wearing the device. Injury of the neurovascular system leads to damaged perfusion of the given skin area. Skin erythema, discomfort, pain and hematoma have been reported.

I.2. Anatomical aspects of CI surgeries in infants and toddlers

Early and successful audiological rehabilitation of infants and toddlers is of the utmost importance, because untreated severe hearing loss would impede their speech abilities. If cochlear implantation is performed in time, the toddlers have a high chance of reaching equivalent levels of speech performance to their normal hearing peers without much delay in their speech development.

The mastoid cavity is still immature, and the sigmoid sinus and the facial nerve run quite superficially. During posterior tympanotomy, an access to the cochlea is made for the stimulating electrode through the facial recess, i.e. in the triangle that is defined by the short process of the incus, the mastoid segment of the facial nerve, and the chorda tympani.

Due to the proximity of important anatomical structures, this surgical step carries the risk of injury of the facial nerve and chorda tympani. Infants and toddlers have a smaller head circumference than adults so it could be logically thought that the facial recess and the tympanic cavity are smaller, which could be associated with an increased risk of neural damage compared to adulthood.

I.3. Placement and securing of the processor to the skull

The classical surgical technique for cochlear implantation required a large access, which was not a major problem whilst the majority of the implantations were performed on adult subjects. Today, however, a large number of surgeries are performed in infants and toddlers. The earlier types of CIs were thick in order to provide good impact resistance, and for this reason a bony well to sink the implant into the skull was necessary. Creation of a bony well required a long, up to 10 to 15 cm incision and wide access that considerably compromised stability of the soft tissues, and fixation of the implant package to the bone was necessary.

One important aspect of the design of the device is size. Decreasing size, especially thickness, facilitates minimally invasive surgical techniques as thin implants can be implanted

into a subperiosteal pocket without a bony well. The newest Profile devices from Cochlear Ltd. (Sydney, Australia) have an almost 50% decrease in thickness compared to Nucleus® Freedom devices. This provides the basis to examine the practical value of such changes and allows us to assess the first experiences with the device from the user's perspective.

I.4. Characteristics of two different modiolus hugging CI electrodes

There are currently different trends in CI electrode design. Several authors suggest that quality of sound and speech perception is primarily influenced by the properties of the electrode arrays, the gentle insertion of the electrode array into the scala tympani and the good programming of the speech processor. Some authors experienced better results in quality of sound and speech perception with electrode arrays that are in close proximity to the modiolus, while others found better results with coverage of the cochlea with long arrays.

Although debated whether the straight or the pre-curved electrode arrays provide better hearing results, the importance of the relationship of the stimulating electrodes to the modiolus is underlined by an experience, i.e. quality of sound perception and speech discrimination proved to be better if the electrodes were closer to the modiolus, if precurved arrays are used. Our team experienced that the CI532 implant (mounted with Slim modiolar, SM array) was capable of eliciting neural responses with less current than the CI512 implants (mounted with Contour Advance®, CA array) in a large number of subjects.

I.5. Important aspects of imaging in CI and BAHA

Accurate diagnosis and preoperative planning in temporal bone surgery is strongly supported by imaging with enhanced visualization. Computed tomography (CT) is often used to examine structures within bony frameworks.

CT examinations provide more detailed information and possibilities of multiplanar reformations and 3D reconstructions that are often helpful in doubtful cases. Given the hazards of ionizing radiation, repetitive imaging studies exponentially increase the risk of damages to radiosensitive tissues, thus low-dose protocols and new modalities should be used. Magnetic resonance imaging (MRI) after implantable hearing aid surgeries is limited due to artefacts and safety limitations by the magnet and other metallic components. Current guidelines for BAHA implants suggest a minimal bone thickness of 3 mm at the implant site. CT allows accurate assessment of bone thickness. Postoperative follow-up is usually not required unless a head trauma caused issues with the implant and surrounding tissues.

II. OBJECTIVES

1. to potentially decrease the surgical time and complication rate for magnet connection transcutaneous bone-conduction implants by (1) determining the preferable surgical incision, (2) finding the best suitable imaging method to determine the individual vascular and neural anatomy of the soft tissues of the retroauricular temporal-parietal region in a large number of subjects (50 in total) and (3) determining whether individual preoperative imaging is desirable.
2. to characterize the major anatomical differences that should be considered during Baha and CI surgeries between pediatric and adult candidates and to determine whether these differences alone make CI surgery more hazardous in comparison with adults and therefore delayed implant surgery is acceptable
3. to assess the practical advantages of the low-profile CI generation with regards to the modification of the surgical technique and any changes in comparison with the earlier CI generations
4. to characterize the position of two types of perimodiolar electrode arrays of the same generation of CIs that form the basis of promising preliminary electrophysiological results to suggest that the slim perimodiolar electrode array has the potential to elicit similar neural responses as the thicker perimodiolar electrode array
5. to determine the role of cone-beam CT (CBCT) in CI and BAHA surgeries

III. MATERIALS AND METHODS

III.1. Vascular mapping of the retroauricular skin

Implanted subjects received the Cochlear™ Baha® 4 Attract System for this study, which is a transcutaneous bone-conduction hearing device reimbursed by the Hungarian social security system.

The vascular pattern and blood flow of the temporal-parietal soft tissue was examined in 50 subjects. The examinations were performed with cadaver dissection (13 subjects), magnetic resonance angiography (12 subjects), and in vivo Doppler ultrasound (25 subjects).

General exclusion criteria from the study were a history of a previous ear surgery and considerable stenosis of the carotid arteries. The parietal temporal region of 25 healthy adult subjects was examined with color Doppler ultrasound (20 subjects) and with preoperative portable handheld Doppler (5 subjects).

Statistical analysis was done with the above described template in the cadaver, MRA, and Doppler ultrasound evaluations, whereas a case-by-case analysis was performed for the handheld Doppler assessments

III.2. Anatomical measurements for CI

High resolution computed tomography scans, as part of the routine examination of cochlear implantation, were enrolled. The scans of the youngest 10 children and 10 randomly chosen adults were postprocessed and analyzed with 3D Slicer 4.5 Software with respect to the most relevant dimensions of the internal electronic package, including the stimulating electrode of the cochlear implant, by measuring the squama of the temporal bone, the mastoid cavity and the facial recess.

III.3. Evaluation of a low-profile CI generation

The surgeries were performed using the Cochlear™ Nucleus® Profile implants (CI512 and CI522). The profile thickness of the implant was decreased compared with the earlier model, the Nucleus® Freedom, from 6.9 mm to 3.9 mm.

The surgical experiences with the thin implant types were collected and compared in a retrospective multi-center study on the basis of the first 73 thin implants and 59 recipients. The surgeons gave feedback about the changes in their surgical technique with the thin, low-profile implant family compared with the earlier, thicker types. Five leading cochlear implant centers in Central and Eastern Europe were enrolled:

III.4. Measurement of the proximity of perimodiolar CI electrode arrays to the modiolus

The first 54 subject that were implanted with Cochlear Nucleus CI532 and the first 54 subjects that were implanted with Cochlear Nucleus CI512 were enrolled.

As part of the routine clinical protocol, digital radiography of the skull (Stenvers projection) was performed on the day after surgery to determine the position of the implant. The relationship between the electrode array and the modiolus was described and the maximum diameter of the loop was measured in the basal turn of the cochlea. These diameters of electrode

loops were compared in the two patient groups. The statistical evaluation was performed with Student's t

Two months after implantation, the energy consumption of the two implants with different perimodular electrode arrays was estimated after the device was programmed with the Cochlear™ Custom Sound® Suite 4.4 software by using the same speech processor (Cochlear™ Nucleus® CP910).

III.5. Evaluation of CBCT in medical imaging of CI and BAHA

A thorough workup of the literature was made to find the role of CBCT in CI and BAHA surgery. Personal imaging experiences are also added.

IV. RESULTS

IV.1. The vascular map of the retroauricular skin

The results demonstrate the location and arterial pattern in the temporal parietal region. The relatively large arteries, i.e. the posterior auricular artery and a postauricular branch of the superficial temporal artery, are likely to be found in the strip close behind the auricle. Via the occipital access, the occipital artery was found. In contrast, the area between the above arteries, i.e. the posterior superior parietal region, is relatively poor in arteries. The blood flow is directed from the center (external carotid artery) to the periphery.

The prevalence of arteries that were detected with cadaver dissection correlate well with those obtained via MRA of the twelve living subjects. The results were consistent with those of our cadaver study. The Doppler study could precisely confirm the results of the cadaver and MRA studies.

The sum of arterial lengths proved to be highest in the retroauricular sectors because the posterior auricular and the occipital arteries enter the retroauricular temporal region there. Also these sectors contain the large arteries and, therefore, they have to be considered as they are situated in the high surgical “danger zone”. The upper and posterior sectors are less dangerous because of the low-sum total length and small diameter of the arteries. The analysis of the total lengths of prevalence of arteries in the upper posterior sectors is significantly lower than in the retroauricular and inferior sectors.

IV.2. Dimensions of the human temporal bone relevant to CI

The mean distance between the incus short process and the mastoid tegmen (D1) was 5.0 ± 1.5 mm in adults, while 6.5 ± 1.9 mm in children ($P = 0.014$), which is significantly higher in children. The mean distance between the mastoid planum and the facial nerve (D2) was 13.2 ± 1.9 mm in children, while 24.3 ± 3.5 mm in adults ($P = <0.001$), thus significantly higher in adults. The mean distance of the mastoid tegmen and mastoid tip (D3) was 17.8 ± 2.4 mm in children, while 35.9 ± 5.6 mm in adults ($P = <0.001$), thus significantly higher in adults. The mean distance between the facial nerve and the tympanic annulus (D4) was 5.2 ± 0.7 mm in adults and 5.4 ± 0.7 mm in children. The mean distance between the round window and the tympanic annulus (D5) was 6.7 ± 0.6 mm in adults and 6.9 ± 0.8 mm in children. The mean distance between the round window and the facial nerve (D6) was 5.2 ± 0.1 mm in adults and 6.6 ± 0.7 mm in children. There was no significant difference between D4 and D6 distances between adults and children.

IV.3. Experience with a low-profile cochlear implant generation

The average length of the surgical incision measured was less than 5 cm in 2 centers and between 5 and 7 cm in 3 centers. When compared with the earlier type of implant, the incision was found to be considerably shorter (3 out of 5 centers; 60%), slightly shorter (1 out of 5 centers; 20%), and unchanged (1 out of 5 centers; 20%).

A bony well was created only in few cases in 2 centers and in all cases in 3 centers. If a bony well was created, it was performed by removing the outer cortical bone only in three centers. The bony well was deeper than the outer cortical bone, but less deep than the implant thickness in one center and the bony well was as deep as the implant thickness in one center. When compared with the earlier type of implant, the bony well was reported to be considerably shallower in 4 centers and slightly shallower in 1 center.

None of the centers fixated the implant to the bone. Periosteum and temporalis muscle was always used for fixation in 2 out of 5 centers. No intraoperative or early postoperative complication was reported by any of the centers. Minimal displacement of implant electronics was registered in one center, without the need for a revision surgery. This center reported to have drilled a bony well as deep as the implant thickness and used the periosteum for fixation.

The surgical time for unilateral surgery from incision until wound closure was reported to be less than 50 minutes in 2 centers, 50 to 70 minutes in 1 center and 90 to 110 minutes in 2 centers. The shorter times were seen in those centers in which a bony well was not drilled. When compared with the earlier types of implants, the surgical time was shorter in all 5 centers.

The operating surgeons found the implantation procedure for the recent type of implant considerably easier in 2 centers, moderately easier in 1 center and slightly easier in 2 centers. They also found the implantation considerably safer in 2 centers, moderately safer in 1 center and slightly safer in 2 centers. The surgeons all agreed that the thin nature of the new implant did not necessitate a classical bony well.

IV.4. Proximity of perimodiolar CI electrode arrays to the modiolus

The mean of the largest turns of the arrays within the cochlea was 4.2 ± 0.5 mm in the CI532 group and 4.9 ± 1.1 mm in the CI512 group (t-probe: $p=0.00136$). Sequential bilateral implantation was performed in one of our patients: a CI512 was implanted to the right ear and a CI532 into the left ear one and half years apart. The electrode arrays were found to be in perimodiolar position on both sides, and the SM electrode array had shorter loop diameter within the cochlea.

The "Auto power" level was significantly lower in the CI532 group ($44.81 \pm 5.05\%$) than in the CI512 group ($50.85 \pm 8.35\%$) ($p < 0.05$). With higher "maxima" values (7.50 ± 0.87 vs. 6.56 ± 1.02), the estimated "lifetime" of the battery is longer for the thinner perimodiolar electrode line.

IV.5. The characteristic features of CBCT in comparison with MSCT

Given the hazards of ionizing radiation, repetitive imaging studies exponentially increase the risk of damages to radiosensitive tissues (genetic disorders, malignancies of radiosensitive tissues, e.g. eye lens, thyroids, salivary glands, bone marrow and the skin). The eye lens is one of the most sensitive human tissues. According to the statement of the International Commission on Radiological Protection in 1990, a single 0.5 to 2.0 Sv and a total of 5.0 Sv fractional radiation doses contribute to development of cataract and loss of vision. A recent retrospective study in a large population suggests that the risk of developing cataract of the eye lens was significantly risen after 4 cranial CT scans.

The algorithm of the CBCT makes isotropic voxels that can be as small as 0.075 mm, depending on the scanning presets. This is significantly smaller than the voxel size (0.4 mm) of a high resolution multislice CT (MSCT).

The scanning of the paranasal sinuses with isotropic voxels involved an effective dose of 0.17 mSv with CBCT and 0,87 mSV with MSCT, an approximately 80% decrease in favor of CBCT. The effective radiation dose of CBCT of the head with a field of view of 16 cm was reported to be 0.1 to 0.35 mSv, depending on the requirements of the imaging protocol (e.g.

optimized to bone or soft tissues). In contrast, the effective dose of an unenhanced head MSCT scan scored significantly higher at 1 to 2 mSv.

CBCT can be integrated into the preoperative assessment flow in cochlear implantation, as the bony structures (e.g. cochlear turns, developmental status and air volume of the mastoid process and size of the bony labyrinth) can be well assessed.

The position of the CI stimulating electrode (e.g. insertion depth, proximity to the modiolus, tip fold-over, scala tympani and scala vestibuli) can be assessed. Mobile C-arm CBCT machines enable intraoperative imaging in the surgical theater.

V. DISCUSSION

V.1. The posterior superior surgical incision for BAHA – A successful modification

To our knowledge, our study is the first in the literature with the aim to reveal the vascular pattern of the retroauricular temporal parietal area to optimize the position of the surgical incision. Our study suggests that, apart from individual variations, the average tendency is that the larger arterial branches are close to the auricle, whereas the superior posterior area of the temporal parietal region contains small arteries only.

An optimal incision preserves good vascular capacities, i.e. the proximal (outflow) sections. Ideally, the incision is short and placed where the arteries and nerves have split already into their smaller branches. The original official suggestion by the manufacturer CochlearTM is a 7.5 cm curved incision behind the auricle and 15 mm apart from the rim of the internal magnet plate. A 7.5 cm long incision crosses three sectors with two major arteries. Our results suggest that this causes considerable injuries on both macrovascular and, consequently, microvascular levels. If a similar incision is made in the posterior superior area, the risk to traverse a major artery is limited.

Our results clearly reveal that it is not possible to conduct such surgeries without transecting at least one major artery with the given 7.5 mm incision, which underlines the necessity to make the incision as short as possible. In our experience, proper exposure can be achieved from a 2.5 to 4 cm curved incision in the upper posterior area by undermining and mobilizing the skin and soft tissues from the periosteum, not only over the implant but also distal to the incision line. The skin can be retracted enough, and there is enough space, to complete each step of the implantation.

Our cadaver dissection and imaging studies confirmed that the vascular anatomy is stable in most of the cases, i.e. the posterior superior area is less vascularized than the anterior area. This makes not only the expensive (MRA) but also the easy-to-access and cost-effective preoperative imaging studies (Doppler) unnecessary and thus improves time efficiency. Those patients in which the vascular architecture has already been stressed from previous ear surgery (e.g. mastoidectomy, radical middle ear surgery) are challenging because the previous exposures have deteriorated the blood supply and further incisions diminish it even more. In our opinion, preoperative Doppler examination performed with a simple portable handheld instrument is sufficient even after previous ear surgeries.

On 19 February 2018, the manufacturer released our modified surgical technique that was based on the results of our study on the blood supply of the retroauricular skin: “How I do it? Alternative surgical technique for Cochlear Baha Attract” Authors: Laszlo Rovo MD, PhD, Zsofia Bere MD, PhD, and Adam Perenyi MD. The reason why our technique is considered superior to the original recommendation is listed below: This surgical technique results in the preservation of large vessels and nerve fibers, and a scar-free retroauricular area. In comparison to the recommended surgical technique, it provided a shorter surgery time, less pain and numbness around the surgery site, and negated the need for bone polishing. Additionally, this technique facilitates future reconstructive surgery if the patient has accompanying congenital ear malformations. Importantly, no significant differences were found in audiological outcomes when using this technique as compared to the manufacturer's recommended technique.

V.2. Dimensions in the temporal bone relevant to CI

The skull and soft tissues are significantly thinner in children than in adults. The cranial-caudal dimensions of the mastoid antrum can be characterized by the distance between the short process of the incus and mastoid tegmen. The lateral dimensions (depth) of the mastoid cavity is characterized by the distance of the mastoid planum and the mastoidal section of the facial nerve, and the cranial-caudal dimensions are characterized by the distance of the mastoid tegmen and mastoid apex. The ratio between the antrum and the mastoid cells was 0,14 in adults and 0,37 in children.

Our results are consistent with the data in the literature from cadaver and imaging studies, i.e. the skull grows after birth, but the dimensions of the inner ear and the facial recess are constant after birth.

V.3. Advantages of a low-profile cochlear implant

Universal newborn hearing screening enables early detection of hearing loss, well under the age of 1 year. Binaural hearing not only helps to localize the source of sound but also improves speech perception, especially in noisy environment. Therefore, optimum outcomes can be achieved in these infants by providing them with bilateral cochlear implants.

Although several factors are in favor of simultaneous bilateral implantation, this procedure is associated with longer surgical time and increased load, especially in infants and toddlers. For this reason, an important goal of implant surgery is to use faster and minimally invasive surgical techniques. The classical technique of cochlear implantation requires the drilling of a bony bed and fixation of the device to the skull and is associated with several risk factors, predominantly in infants and toddlers. The bone and soft tissues are very thin in these age groups and this makes subjects more prone to complications. The biggest advantage of thin implants is that they can be implanted into a shallow bony well or even without a bony well and often without the need for fixation.

The results of the multi-center questionnaire show that the surgical techniques made possible by the thin implants had several benefits compared to the older devices, which were clinically relevant:

- 1) The surgical incision used was shorter, which is associated with less blood loss, as the bleeding stops sooner and wound closure is faster.
- 2) No bony well was necessary, or if used it could be made shallow. This reduces the risk of complications and time can be saved.
- 3) No other fixation of the implant to the skull other than the subperiosteal tight pocket has to be used. This ensures enough stability of the implanted device and time can be saved.
- 4) The rate of displacement (1 out of 73 cases) was comparable to other techniques. Note: The only displacement was observed at the site in which the standard technique is to make a bony well as deep as the implant thickness. A deep well requires a large view and the tissues of the subperiosteal pocket will be weakened.
- 5) The above-mentioned factors made the implantation procedure simpler, reduced surgical time and decreased the load of postoperative care and duration of hospital stay. This is a considerable advantage, especially in simultaneous bilateral implantations in infants and toddlers.

V.4. Better modiolus hugging properties of the Slim Modiolar electrode array

The results of hearing (re)habilitation are influenced by the individualized choice of the device and the electrode. The importance of locating the perimodiolar electrodes as close as possible to the modiolus is highlighted, i.e. the quality of sound perception and speech perception depends primarily not on the length of the electrode array and the depth of insertion, but on the position of the electrode array relative to the modiolus.

Compared to the thicker CA electrode array, the SM array is less traumatic and occupies a considerably smaller volume from the liquid space of the scala tympani and is also predominantly under the bony part of the basal membrane, which less compromises the hydrodynamic function of the cochlea. This is an important issue for preservation of usable residual hearing.

The difference between patient groups implanted with different electrodes could be clearly detected in direct digital radiography due to the standardized protocol, with a high number of cases involved. We found a significant difference in the intracochlear loop diameter and energy consumption of the two types of perimodiolar electrode arrays, the thinner electrode array being more beneficial.

V.5. The role of CBCT in the imaging of CI and BAHA

The current, most widely used, and routine imaging protocol involves MSCT and MRI before cochlear implantation and radiography after cochlear implantation. CBCT provides comparable information with less effective dose in the preoperative assessments. The Stenvers projection allows detection of the complications which require removal and repositioning of the electrode array, e.g. due to electrode tip fold-over with relatively high sensitivity.

A disadvantage to be taken into account is the summative nature of radiography that does not allow discrimination of the intracochlear structures (scala tympani, scala vestibuli). If quality control requires such discrimination, high resolution computed tomography is recommended. Given the hazards of ionizing radiation, repetitive imaging studies, that involve radiation, exponentially increase the risk of damages to radiosensitive tissues. The eye lens is one of the most sensitive human tissues. For this reason, the use of alternatives to the high-dose MSCT with comparable image quality is strongly supported. With appropriate indication and imaging technique, CBCT is equal to or better than MSCT in preoperative and postoperative needs in temporal bone surgery including cochlear implantation.

VI. CONCLUSION AND NEW RESULTS

VI.1. Bone-anchored hearing aids, focusing on passive transcutaneous implants

Our study clearly confirms the coherent advantages of the short posterior superior incision when transcutaneous bone-conduction hearing devices are implanted, based on the surgical anatomical vascular relationships. The undeniable similarities of the anatomical vascular relationships among the individual subjects put the necessity of preoperative imaging (not only the expensive MRA but also the cost-effective ultrasound) into question. Our opinion is that, with regards to the vascular network, preoperative imaging is recommended in those cases, only in which the retroauricular area was subject to previous surgical stress. In those cases, portable handheld Doppler examination is reliable, quick, and cost effective. In any case, the surgeon should aspire to make the shortest possible incision.

VI.2. Dimensions of the human temporal bone relevant to CI

As demonstrated by our workgroup, bone and soft tissue thickness of the skull of children is significantly lower than in adults. The maximum size of posterior tympanotomy and the position of the round window are similar in children and adults. The very thin skull and soft tissue especially around 1 year of age underline the need for the thinner cochlear implants too.

The surgical technique of cochlear implantation is not necessarily associated with higher risk due to the anatomical peculiarities of the low-age group. On the contrary, easier visualization of the round window and the need for less bone work in the immature temporal bone enable a less traumatic procedure in infants and toddlers. From our study we conclude that the anatomical characteristics of the age group around 1 year, i.e. the anatomical dimensions that are relevant for cochlear implantation in the temporal bone, do not complicate the surgical procedure and a delay in the timing of this hearing rehabilitation surgery is not acceptable.

VI.3. The advantages of a low-profile cochlear implant generation

Thin implants are advantageous because they fit to the shape of the skull and cause only slight protrusion of the soft tissues, even without a bony well. The smaller incision (exploration) is associated with less blood loss and a drop in surgical time. Our study underlines that the new thin implants are associated with real benefits, in that they allow us to further develop and simplify the surgical technique for cochlear implantation. One should note that if the surgical incision is larger than necessary and the integrity of the soft tissues is not preserved, the pocket for the implant will necessarily be weakened. In such cases, in order to prevent implant

displacement, the implant should be fixated to the bone (with bony well and/or sutures). In our opinion, the development of cochlear implant design should be directed towards a decrease in thickness and adaption to the shape of skull.

VI.4. Better modiolus-hugging properties of the Slim Modiolar electrode array

Our measurement data indicate that the thin perimodiolar electrode takes a significantly closer position to the modiolus than the thick perimodiolar electrode, which explains our observation from preliminary electrophysiological studies: the same stimulus can be obtained with a lower current with the thin perimodiolar electrode compared to the thick perimodiolar electrode.

VI.5. The role of CBCT in the imaging of CI and BAHA surgery

CBCT provides high-resolution imaging and reformations in any optional plane and in space with considerably lower effective radiation dose than MSCT. CBCT with appropriate indications proved to be an excellent diagnostic tool in otorhinolaryngological imaging. It can be effectively applied in the preoperative, perioperative and postoperative assessments for CI and BAHA surgeries. We recommend to integrate CBCT into the diagnostic flow as the low-radiation alternative of MSCT, especially in those cases which possibly necessitate repetitive imaging with ionizing radiation.