PEDIATRIC MORPHOMETRIC ANALYSIS AND HEARING REHABILITATION WITH NOVEL TRANSCUTANEUS BONE ANCHORED IMPLANT SYSTEMS

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1. INTRODUCTION

Bone conduction implants (BCI) have been used widespread since their discovery and have provided ideal solution for patients with conductive hearing loss (CHL) mixed hearing loss (MHL) or single sided sensorineural deafness (SSD). Their main advantage is that the system creates hearing sensation through an alternative route: the information transmits as vibration through a titanium implant fixed to the temporal bone and reaches the cochlea through the so-called bone conduction route. Therefore BCIs are ideal in those cases, where reconstructive surgery or conventional hearing aids failed to work; for example in congenital or acquired external ear canal, middle ear or complex craniofacial malformation, as well as in chronic otitis media, when recurrent discharge limits proper fitting of the hearing aid.

The first Baha implants were direct percutaneous implants, where direct processor-implant connection provided good signal transmission and therefore good hearing experience. In case of Baha® Connect system the vibration from the speech processor passes through the abutment which is fixed to a titanium implant (BI300) - drilled in the skull bone. Since the connection between the sound processor (SP) and the BI300 is direct through the abutment, the damping effect of the adjacent soft tissue is less pronounced, which has a significant impact especially on high frequencies. Based on the bone and soft tissue thickness, different abutment sizes (DermaLock 6-8-10-12 mm) and implant sizes (3-4 mm BI300 titanium implant) are currently available on the market. However, their disadvantage is that the penetrating abutment directly connects the skin surface and the bone. Although manufacturers developed tissue-friendly abutment coatings like hidroxy-apatite that prohibits formation of a soft tissue pocket and bacterial biofilm around the abutment, soft tissue infection due to improper cleaning, tissue hypertrophy and direct trauma can be an issue, especially in children. Moreover, aesthetic outcome of penetrating BCI system is also unfavorable

The transcutaneous systems solved many of these problems. They were designed to minimize the occurrence of soft tissue complications by eliminating skin penetrating titanium abutment and improve cosmetic outcome. In case of passive transcutaneous implants, like CochlearTM Baha® Attract, the abutment function is replaced by a magnetic disk which is placed under the skin and attached to the implant, thus a magnet-to-magnet connection keeps the SP in place. The SP is retained via attraction to the internal magnet, and vibrates in response to sound, while vibratory force passes through the skin, indirectly to the BI300 implant that is fixed to the temporal bone (Fig.1). The indisputable advantage of Baha® Attract is the safety and the more

favorable aesthetic outcome, however, the attenuation of the soft tissue adversely affects signal transmission, which is more significant in frequencies 2000 Hz and above.

To maximize the previously mentioned advantages of percutaneous and passive transcutaneous devices, new active transcutaneous implants have been designed recently. The Cochlear™ Osia® 2 system is an innovative active, transcutaneous, osseointegrated steady-state implant system that uses digital piezoelectric stimulation. The piezoelectric transducer is fixed to the skull via the BI300 titanium implant, similar to Baha® Connect or Baha® Attract system, but signal is transferred between implant and SP via a digital radiofrequency link. Compared to Baha® systems, the Osia® system grants high-power output and improved high frequency gain for optimizing speech perception and it provides significantly higher functional gain at higher frequencies (5–7 kHz). Since it is transcutaneous, the possibility of trauma and soft tissue complications is lower compared to percutaneous BCIs, and aesthetically more feasible, similarly to Baha® Attract.

Considering the audiological and safety benefits of active transcutaneous systems, early application of these devices in the pediatric population would be advantageous. However, date of surgery, type of implanted system, applied surgical techniques, and complication management in young children is always a major concern. Therefore, stable, safe, high-power implants and straightforward surgery adapted to younger patient population is necessary. At present, implantation of different Baha® systems is approved above the age of 5 or a skull bone thickness greater than 3 millimetres. Under 5 years/3 mm bone thickness, Baha SP can be applied with Softband or SoundArc. In contrast, Osia® implant in the United States is approved for patients aged 12 years and above, whereas in Europe it is independent of age, the only criteria that the body weight has to be at least 7 kg. Since children are smaller and have morphological differences, e.g. thinner soft tissue and bone structure compared to adults.

Choosing the ideal implant size-fit for the child bone thickness helps to reduce intraoperative complications, such as exposition of the dura, injury of the sigmoid sinus and consequent bleeding, or entering the mastoid cavity. Also, soft tissue thickness has to be considered. Below 3 mm, the possibility of soft tissue complication such as necrosis or permanent pain to magnet compression is increased while thick soft tissue prohibits proper signal transmission. Therefore, knowledge of age-dependent anatomy is essential. Since cranial CT scan is not recommended prior Baha® Attract or Osia® implantation, to know how to do the implantation surgery safely, a morphometrical/clinical study of the implant area is required.

2. OBJECTIVES

Since Baha® and Osia® surgeries require minimal bone work, they can be safe solutions in pediatric hearing rehabilitation. However, a number of studies focused on surgical safety of Baha® and Osia® systems, only few of them involved bone and soft tissue thicknesses. Inadequate BI300 implant size and malposition can lead to dural exposure or excessive bleeding, while too thin or too thick soft tissue hinder uninterrupted SP usage. Since preoperative CT imaging is not necessary in case of these implants and especially cranial CT should be avoided in children, studies that focus on pediatric morphometry of the implant region are essential. The aim of our two studies was to perform a morphometric investigation to analyse different aspects of the temporal region and develop a safe surgical protocol for Baha® Attract and Osia® implantation in children without preoperative cranial CT. Based on our findings, the results of the first pediatric Attract® and Osia® implantations are presented in the thesis.

2.1 Baha® Attract study

Our aim was to demonstrate Baha® Attract application in childhood:

- Perform morphometric analysis of the thickness of the skull bone and soft tissue at the recommended implant site based on CT scans among 1 to 8 year-old patients.

2.2 Osia® study

The aim of our Osia® study was to perform a morphometric investigation among 5–12-year-old children to develop a safe surgical protocol for implantation of the Osia® 2 system. Main quests for our investigation are the following:

- Measure the bone thickness to recommend optimal size BI300 for children.
- Measure the soft tissue thickness in different levels, whether tissue thickness is adequate to provide magnet compression or transducer vibration and ensure proper signal transmission between the SP and the coil.
- Assess the risk of complications (exposing the dura, injury of the sigmoid sinus and consequent bleeding, or entering the mastoid cavity) and the method that helps avoid them.
- Based on the previous considerations, define the optimal position for BI300 with regards to the dimensions of the implant (i.e. coil and transducer, and sound processor).

3. MATERIALS AND METHODS

Ethical approval for both studies was obtained from the Institutional Review Board (Human Investigation Review Board, University of Szeged, Albert Szent-Györgyi Clinical Centre.

3.1 Baha® Attract study

Cranial CT scans (a minimum of 0.625 mm slice thickness) of 72 children (both male and female) aged 1 to 8 years were investigated in the database of University of Szeged, Albert Szent-Györgyi Medical School. Each age group consisted of 9 patients, whose cranial CT was necessary due to: 1) polytrauma/whole body CT (with no trauma in the region of interests) (n=23), 2) prior to ear surgery/cochlear implantation (n=35), 3) preoperative cranial CT for neurosurgery patients or cranial CT for patients with particular neurological disorder (n=14). None of the patients had severe craniofacial malformation, however, unilateral ear canal atresia patients were also included in the study.

CT scans were analysed with GE PACS (General Electric Picture Archive and Communication System, GE Healthcare, Chicago) radiology software. Based on manufacturer's guideline, the position of the BI300 was determined: since the titanium implant should be 50-70 mm from the ear canal, and the superior edge of the processor should be in line with the top of the pinna, reference points were dedicated as the opening of the external ear canal (EEC) and the inferior margin of the orbit, which are almost in line with the superior margin of the pinna. Once possible implant position was localised, three additional sample points were determined, and average bone and soft tissue thickness was calculated in a multi-planar view in each age group (Fig. 4).

During 2013 to 2017 overall 35 Baha® Attract implantations were performed at our clinic, out of which 8 were juvenile. The mean age of the patients was 13.2 ± 3.2 years (ranging from 7 to 17 years), 6 males and 2 females.

The surgeries of Baha® Attract were performed under genereal anesthesia. Instead of the officially recommended 8-9 cm long "C-shaped" retro-supraauricular incision, 3-4 cm "modified posterosuperior incision" was used. This technique was developed in our Clinic. Surgeries were performed with 3 mm implants. Patients were discharged for homeon the first postoperative day, and surgical follow-up was minimum 6 months. SPs were fitted four 4 weeks after surgery.

3.2 Osia® study

High resolution cranial CT scans with a minimum of 0.625 mm slice thickness (0.4 mm in a proportion of cases) of 40 children between the ages of 5 and 12 years were collected from our clinical database and systematically analysed. Scans from individuals with any form of head trauma including temporal region or severe complex craniofacial malformations were excluded. Different attributions of the retroauricular/temporoparietal region were measured in four specific age groups (5–6 years; 7–8 years; 9–10 years, and 11–12 years). The number of patients in each group was 10, and both male and female candidates were selected.

All output of CT data were converted into Digital Imaging and Communications in Medicine (DICOM) files, and exported to RadiAnt DICOM viewer 2020.2 (Medixant, Poznań, Poland). Based on the recommended position and dimensions of the implant soft tissue and bone thickness was determined.

Since structure of the Osia implant is more complex compared to Baha® Attract, to achieve a reproducible measuring method, fix points were assigned: lower margin of the orbita, zygomatic arch and the EEC midline. Implant parameters were marked on the reference lines defined by the fix points. Bone and soft tissue thicknesses were calculated in a multi-planar view along the aforementioned reference lines. Three additional sample points were taken and average skin and bone thickness was determined in each session. With this method, soft tissue thickness was assessed in the level of the SP and in the level of the transducer, while bone thickness was calculated in the level of transducer/possible position of BI300 implant, i.e., EEC midline. Besides the recommended BI300 position, bone thickness was also measured superior to the EEC midline to collect information of bone structure and to determine whether alternative placement of the titanium implant would be feasible. For safety purposes, sigmoid sinus distance from the posterior wall of the EEC, and bone thickness above the sinus was also measured. Both the left and right temporal areas of each patient were analysed. For further planning, representative samples were printed in 3D to validate our technique of measurement.

Two pediatric Osia implantations were performed in collaboration with Prof. Gabor Katona and Dr. Zsuzsanna Csakanyi (Ear Nose Throat Department, Heim Pal National Pediatric Institute, Budapest, Hungary) in 2021 September. Both patients presented with unilateral grade 4 anotia (patient „A” 7 year old male, right side anotia, patient „B” 6 year old male, left side anotia) and

CHL- normal bone conduction (BC) and 50dB air conduction (AC) along the frequencies. Operations were performed under general anaesthesia. BI300 implant position was determined based on manufacturers guideline and 3 mm BI300 implant was fixed to the temporal bone. (Fig. 7) After wound closure, cranial CT was performed with Siemens Cios Spin® Mobile C arm. Patients were emitted on the first postoperative day. SP was fitted after 4 week.

3.3 Surgical questionaire and inicial audiological results

A short surgical questionnaire was administered to all patients who underwent Baha Attract implantation and Osia implantation. The questionnaire was designed to capture the following data: type of anaesthesia, surgical time, soft tissue reduction, intraoperative complications, healing problems, aesthetic outcome, pain, and numbness. Questionnaire data were collected following each implantation surgery and questions related to patient reported data (i.e. healing problems, aesthetic outcome, pain, and numbness) were repeated at first fitting (4 weeks after surgery). Patients scored the questions about pain and numbness from 1 to 5 with the help of a visual analogue scale.

Since children were investigated in the studies, only unaided and aided pure tone audiometry (PTA) was performed; unaided AC thresholds with supra-aural headphone (125-8000 Hz) and BC thresholds over the mastoid process were measured at 250, 500, 1000, 2000, and 4000 Hz and the measurement repeated in free field with SP after the first fitting. In case of unilateral CHL and MHL cases normal functioning ear was masked during unaided threshold measurements.

3.4 Statistics

Statistically analysis (ANOVA) was performed with SYSTAT 13 Software (Inpixon Inc., Version 13. Palo Alto, United States). Results are presented as mean ± SD.

4. RESULTS

4.1 Results of Baha® Attract morphometric study

4.1.1 Bone thickness

Average bone thickness was 3.39 ± 1.05 mm in the recommended position of the BI300 implant. In the eldest group (8 years old), the average thickness measured 3.7 ± 0.1 mm which was significantly thicker (ANOVA, Dunn's Test, $p < 0.001$) than in the youngest age groups: group of 1 (2.8 ± 0.7 mm) and 2 (2.8 ± 0.2 mm) year-old subjects.

4.1.2 Soft-tissue thickness

Soft tissue thickness also increases gradually with age. In the localisation of the implant, average soft tissue thickness is 3.3 ± 0.4 mm and significant difference (ANOVA, Mann–Whitney Rank Sum Test, $p < 0.001$) was found between the eldest and the two youngest groups, i.e. 3.7 ± 0.2 mm in the age group of 8-year-old subjects, 2.9 ± 0.3 mm in the age group of 1-year-old and 2.9 ± 0.9 mm in the age group of 2-year-old subjects.

4.2 Results of Osia® morphometric study

4.2.1 Soft-tissue thickness

Average soft tissue thickness in the level of the SP in the entire population was 3.7 ± 0.6 mm, which was significantly lower compared to the level of the transducer 6.3 ± 2.2 mm (ANOVA, Mann–Whitney Rank Sum Test, $p < 0.001$). No difference between the left and right side was found. In the different age groups, no significant difference was found in the level of SP, however, in the level of transducer, soft tissue thickness slightly reduced with age.

4.2.2 Bone thickness

Average bone thickness was 4.8 ± 1.6 mm in the recommended position of the BI300 implant (EEC midline) and 4.5 ± 1.2 mm at the level of the mastoid tegmen. However, at this level, the cortical bone was found to be compact in each age group, in contrast to the recommended position, where underlying mastoid cavity was found in 57% of cases. Significant differences (ANOVA, Mann–Whitney Rank Sum Test, $p < 0.001$) were found in bone thickness between the youngest and eldest age groups, where average bone thickness was 3.5 ± 1.1 mm in those 5-6 years and 4.7 ± 0.3 mm in 11-12 years in the recommended position.

4.2.3 Sigmoid sinus

Average distance of the anterior wall of the sigmoid sinus and posterior wall of the EEC was 1.3 ± 0.2 cm and no significant difference (ANOVA, Mann-Whitney Rank Sum Test, p <0,001) was found among age groups. In contrast, the distance between the bone surface and the bony sigmoid sinus wall increased with age and this was statistically significant ($p = 0.006$). However, these data suggest not only compact cortical bone, but perisinusoidal cells spreading above the sigmoid sinus in 55% of cases (20% in 5-6 year-old, 40% in 7-8 year-old, 70% in 9-10 year-old and 90% in 11-12 year-old subjects).

4.3 Surgical results

4.3.1 Baha® Attract

Surgeries were performed under general anaesthesia (in 2 subjects on the right side and 6 subjects on the left side). Based on the morphometrical study, BI300 implants was applied and the internal magnets were inserted in one stage. The average time of the surgical procedures was 30 minutes. Soft tissue reduction or cortical bone thinning were not necessary in either case. Intraoperative bleeding was insignificant and could be managed with a bipolar cautery. In the case of a 7-year-old patient, the dura mater was visualized, therefore the implant was partially inserted, in order to avoid direct contact of the dura. The intra- and postoperative period was uneventful in all cases. Neither complications, nor wound healing issues were observed.

4.3.2 Osia®

Two male patient with unilateral anotia was selected (patient „A” 7 year old male, right side anotia, patient „B” 6 year old male, left side anotia). Surgeries were performed under general anaesthesia. Similarly to Baha® Attract surgeries, instead of retroauicular incision, the implantations was performed from a posterior approach, i.e. incision line was in the posterior region of the temporal area, behind the future position of the transducer. No soft tissue reduction was necessary at the level of the coil. Based on the morphometric study, 3 mm BI300 implant was applied. Neither the dura mater, nor the sigmoid sinus, nor the mastoid air cells were be detected after the the bed for the BI300 was completely drilled. Average surgical time was 35±5 minutes. To evaluate pain and numbness, visual analog scale (VAS) was used. Pain was tolerable in the postoperative period and ceased with the time. The patients reported a localised numbness in the temporal area after surgery but this sensation also reduced with the time**.**

4.4 Audiological results

4.4.1 Baha® Attract audiological results

The audiological results were evaluated separately due to the different audiological indications for surgery. Group I (n = 6) including patients with single (n = 3) or bilateral (n = 3) CHL or MHL. In the free-field audiometry of unilateral hearing loss the healthy contralateral ears were masked with earplugs or earmuffs. In uni- and bilateral CHL and MHL group, improvement in speech frequencies reached 51.6 ± 11.2 dB HL.

Group II consisted of patients with SSD (n = 2). In those cases, the objective assessment of the true hearing improvement by surgery is difficult, because only contralateral cochlea function (i.e. cross-hearing) can be investigated. Therefore, in aided free field tests, the contralateral BC is not masked, and aided PTA threshold represents cross-hearing. In such cases, subjective feedback of the patient is more likely to represent the success of the implant surgery, because the implantation restores only the possibility of bilateral perception, deteriorated by the shadowing effect of the head.

4.4.2 Osia® audiological results

Preoperative audiogram showed CHL in both cases with normal BC and increased AC thresholds with approximately 70 dB ABG. Aided thresholds showed significant 20-30 dB improvement along the test frequencies.

5. DISCUSSION

Early implantation of a proper implantable hearing aid in childhood can support effective hearing rehabilitation. Moreover, implantable hearing devices can be effective in those cases, where conventional hearing aids would fail: patients with craniofacial malformation, ear canal atresia, or chronic otitis media with recurrent discharge can overwhelmingly benefit from a BCI. However, it is important to note, that surgery in pediatric cases can be difficult due to the altered anatomy and dimensions of the juvenile skull. The “implant team” has to consider the type and severity of the hearing loss, as well as the morphological property of the implant area during planning, and chose the safest option that ideally matches the patients’ needs with regards to their hearing loss. Previously, percutaneous Baha® Connect systems provided excellent audiological performance especially on high frequencies, and overall resonance transmission was better than passive transcutaneous Attract due to direct transmission through the abutment. However, especially in childhood, percutaneous solutions are not ideal;

considering age-specific features such as higher water and lower mineral content in the bones, osseointegration is uncertain in young patients. This significantly increases the chances of implant loss, which has been confirmed by several studies. Roman et al. estimate the incidence of implant loss in the pediatric population to be 40%. For children between the ages of five and ten, this value is only 8%. This value is around 1% in the adult population. Amonoo-Kuofi also reported relatively high, 50% complication rate, even ~13% implant loss in children with Connect system. Kraai et al found a serious complication in 44% of all cases, and traumatic implant loss which required abutment removal in three cases (n = 31, mean age 8.2 years, 23 months – 16.8 years). Beside osseointegration problems that lead to implant instability, soft tissue hypertrophy and peri-implant skin infection also prohibit the proper use of the hearing aid. Considering these disadvantages of percutaneous Baha® Connect, decisions have shifted to transcutaneous solutions in the last decade. Since transcutaneous implants (i.e. passive Baha® Attract and active Osia® 2) remain hidden under the temporal tissue flap, possibility of trauma or soft tissue problems are significantly lower. However, it does not mean that transcutaneous BCI surgery does not require caution. To reduce intraoperative complications such as dura or sigmoid sinus exposure, accurate positioning of BI300 implant and choosing the ideal size of implant size are crucial. Although preoperative cranial CT for surgical planning, especially in young children, is controversial due to unnecessary irradiation and anaesthesia.

Implantation of BI300 does not generally require preoperative CT, and in the clinical practice, number of CT prior to Baha® surgery is low. In addition, overall number of cranial CT scans in early childhood is limited, and studies that could aid the prediction of the ideal implant size in children and determine the position of BI300 are scarce. However, “blind implantation”, even when Attract® and Osia® surgery requires minimal bone work can lead to intraoperative complications. The aim of our studies was to analyse several cranial CT scans of children to map the retroauricular area in different age groups to help planning Baha® Attract and Osia® surgery; therefore, bone thickness, soft tissue thickness, and position of sigmoid sinus were determined.

Although, especially in childhood, most common indications of BCIs are external ear canal/middle ear malformations and chronic otitis media, patients from non-otological cases were also selected to create an average population in both studies, similarly to other researcher groups. The idea behind our patient selection (i.e., otological and non-otological cases together) was, that previous study of pediatric uni- and bilateral ear canal atresia patients indicated that

neither age nor diagnosis of atresia reliably predict a lower chance of identification of adequate bone thickness at typical implant sites, and no significant difference in bone thickness was found on the affected site compared to the non-affected side. Moreover, SSD patients do not necessarily have any anatomical abnormality. In addition, hidden anatomical variations, different degree of mastoid air cell opacification, variation in mastoid pneumatisation resembles ventilation disorder also occurred in patient with no previous history of known ear problem, as we also perceived during the analysis.

Soft tissue thickness

Appropriate soft tissue thickness is more critical in case of Baha® Attract. Since it is a passive transcutaneous system, vibration is transmitted from the SP to the implanted magnet interface trough the soft tissue. However, different magnet types with different magnet strength (M1 to M5, 1-lowest strength and 5- highest strength) can be used, direct compression, resonance and consequent heating cause erythema, discomfort, numbness or pain, which adversely affect the use of the system. These problems are relatively frequent, even if Baha SoftWear Pad is used, which is evenly spreading pressure and maximising the contact surface to improve comfort and performance. Moreover, studies show that flap thickness below 3 mm may adversely affect the risk of soft tissue complication due to pressure, vibration and heat. Additionally, skin flap, covering the magnet becomes thinner due to compression with the time and increase the risk of tissue necrosis. In contrast, too thick skin flap (≥6 mm tissue thickness) requires soft tissue reduction, otherwise the possibility that the SP accidentally falls off will be high. In case of Osia®, to ensure a stable link between SP and coil, soft tissue thickness should be under 9 mm at the level of the SP, similarly to Attract. Soft tissue thickness of 3-6 mm is considered to be ideal. In contrast with the passive Baha® Attract, magnet strength in the Osia® system is only necessary to hold the SP in place, the vibration is generated in the implanted transducer, so magnet force, vibration and consequent heating does not occur; therefore, the skin complications caused by strong magnet compression are reduced.

Predicted position of the Osia SP almost similar to the position of Attract magnet and SP. Both studies showed that average soft tissue at the magnet level was significantly below 6 mm in each age group, therefore soft tissue reduction could be avoided in children. It has also been proven, that soft tissue thickness slowly increases with the age at this level, and average tissue thickness at 5 years, which is the minimum age for implantation, is above 3 mm. Moreover, clear data correlation was seen in our two BCI studies, since average tissue thickness and progression in thickness with the age was the same in the two different study populations. At

the level of Osia® transducer, thicker tissue can reduce sound transmission with passive devices and lead to increased loads placed on the transducer to compensate for losses. Reduced tissue thickness in the older group may be due to the increasing size of the whole temporal area.

Bone thickness

Size and shape of the mastoid process develops continuously with age. However, most studies focus on the volume and shape of the mastoid cavity, which is important when large portions of the implant or the transducer have to be recessed. In a previous study of Rahne et al., many child mastoids were analysed to predict the probability of fitting Bonebridge in different age groups and to find the most ideal transducer shape. Nowadays, implantation softwares are also accessible to help preoperative planning of more robust implants (i.e. Bonebridge). These 3D methods provide full detail of temporal bone density and volumetry. Schilde et al. also highlighted that interindividual variation of temporal bone shape underlines the necessity of radiological preoperative planning in these cases. An indisputable advantage of Baha® systems and the new Osia® system is that implantation needs minimal bone work.

The recommended placement of Baha® Attract based on the guidelines is the retroauricular space, at the upper level of the pinna, 5-6 cm from the external ear canal. In contrast, ideal position of the Osia® system is determined by the size of the transducer, which needs space behind the pinna and limits the position of the magnet and coil, as well as the SP. To accommodate differing bone thickness, different size (3 and 4 mm) BI300 titanium implants can be chosen.

In our study, bone thickness was measured at different levels of the retroauricular space. Both studies showed, that 3 mm BI300 is safe even in young children around the age of 5; and a 4 mm implant can be used in children aged 11–12 in the recommended position. The question often arises, when the implantation is safe in younger patients. For example, in the Central European market, the only requirement for Osia® is body weight of at least 7 kg, which refers to a normally developing 6-12 month old child, corresponding to the WHO Child Growth Standards. Although, children under 5 years were not examined in our Osia® study, our Attract study indicates, that bone thickness remains below 3 mm close to the tegmen region. In the level of ear canal midline, which is the recommended level of Osia® implant, further investigation is necessary. Therefore, a 3 mm implant is presumably too long for children below the age of 5 years, and dural exposition can be an issue. It is important to note, that a study of Vyskocil indicated, that dura or sinus compression with Bonebridge did not increase the

possibility of postoperative complications, however, we believe, it is better to avoid direct contact with these anatomical landmarks wherever it is possible. Moreover, thin soft tissue can be an issue for very young patients since the thickness of the magnet in case of the Attract and size and thickness of Osia® transducer is bigger than magnet and housing of cochlear implants.

The possibility of entering the mastoid cavity in Osia® surgery increases with age due to the development of the air cells. Osseointegration in these cases is also questionable, however, as the Osia® system is transcutaneous, the possibility of tangential shear force, which can displace the system, is low compared to the percutaneous Baha® Connect. Alternatively, positioning of the BI300 closer to the tegmen, where bone is more likely compact is advised. This can also be a good solution in cases, where the mastoid has previously been operated on, or where the possibility of future mastoidectomy is high. In case of Attract, recommended position of BI300 is outside of the mastoid cavity region.

Sigmoid sinus

For safety purposes, knowing the position of the sigmoid sinus is also important during Osia® surgery. At the level of the recommended EEC midline the distance between the posterior wall of EEC and the anterior bony wall of the sigmoid sinus was relatively constant. However, the space between the sigmoid wall and the bone surface significantly increased, mainly due to developing mastoid cells. It is important to note that all our measurements were performed on a healthy population, without any severe malformations. In the study of Granström et al., possible dura and sigmoid sinus contact was found with 3 and 4 mm Branemark type (Nobel Biocare) implants in 26 and 11% of all 129 insertion cases, respectively. However, the age group was between 1 and 15 years, and a large number of patients had severe craniofacial malformations, which may influence mastoid cell formation and bone thickness. Average bone thickness measured in 26 cases was also lower than in our study (2.5 ± 0.8 mm); however, the mean age of our study population was higher. Considering these findings, a 3 mm implant is the safest option for use in children.

Baha® Attract and Osia surgeries

Our Department was always in the forefront of the Hungarian surgical hearing rehabilitation program and contributed to the development of Baha surgeries. Based on a former morphometrical study of the temporal area, a modified surgical approach was presented for Baha® Attract surgery. This minimal invasive, “posterosuperior incision” technique significantly shortens surgical time since it reduces the possibility of vessel injury and

contributes to lower postoperative complication such as numbness due to minimalised surgical approach. In the presented patient series, Baha® Attract surgical time was shorter compared to what is found in the literature (mean 47-57 min) and no severe postoperative complication was observed in the 6-month follow-up period. In case of Osia® surgery, similar approach was applied, but with a longer incision to ensure enough wide space for the implant fixation. Except mild protrusion of the skin at the level of the transducer, no other aesthetical problem or wound healing complication was observed during the surgical follow-up. In terms of BI300, 3 mm implants were used in all the cases based on the two studies. Neither dural exposure nor sigmoid sinus injury nor any other kind of bleeding was experienced during the surgery.

Audiological results

Compared to unaided thresholds, aided PTAs showed significant improvement when using either BCI. Functional gain in our study was comparable with the results of other groups that tested Attract and Osia systems. However direct comparison of audiological performances between the two systems was not investigated. On one hand, Baha® Attract study was performed from 2013-2017, and patients were fitted with older series of Baha SPs. On the other hand, the limited number of patients in the different groups did not allow correct statistical analysis.

6. LIMITATION OF THE STUDIES

The limitation of our studies is the small sample size due to limited number of pediatric cranial CT scans; therefore, creation of much younger age groups or subgroups with different abnormalities within the age groups would be challenging.

7. CONCLUSIONS

Both studies provide a basis of guidance Baha® Attract and Osia® system implantation in the pediatric population. Based on our results, 3 mm BI300 implants are likely to be the uniformly good choice in pediatric cases. A slight superior positioning of the Osia® implant may prevent breaching the mastoid air cells. Under the age of 5 implantation requires great care, since bone thickness values tend to be under 3 mm, and the thin soft tissue may lead to postoperative complications. Considering these findings, preoperative CT is not necessary for Baha® Attract or Osia® implantation in non-complicated cases, above the age of 5. However, surgery of patients with complex craniofacial malformation might need more precise preoperative planning with CT.