

# Experiences with novel bone anchored implants

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I have no financial disclosures that would be a potential conflict of interest with this presentation.



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# OUTLINES

- Terminology
- History
- Background
- Types
- Device/sound processor selection
- Audiological evaluation
  - Indications
  - Preop and postop evaluation
- Surgery
  - The best place for the implant
  - Bone thickness
  - Skin thickness
- Our BAHA magnet results



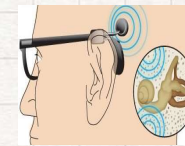
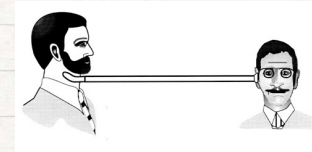
# TERMINOLOGY

- Bone conduction implant (BCI)
- Bone-anchored hearing system (BAHS)
- Bone-anchored hearing aids (BAHA)
- Osseointegrated Bone Conduction Devices



# HISTORY

- The use of bone conduction for sound amplification and hearing augmentation has been first used by Cardano in the **1500s**
- The true breakthroughs in bone conducted amplification happened in Sweden the **1960s** when Brånemark, developed the dental osseointegrated implant.
- And adaptation in the **1970's** by Tjellström with, the use of the implant for bone conducted hearing
- The US Food and Drug Administration (FDA) approved use of the Baha for conductive and mixed hearing loss in **1996** and for single-sided deafness in **2002**.
- In **2009**, Oticon Medical Ponto was born making it the second other bone-anchored hearing system on the market
- The Cochlear BAHA Attract © was approved for use in December, **2013**.

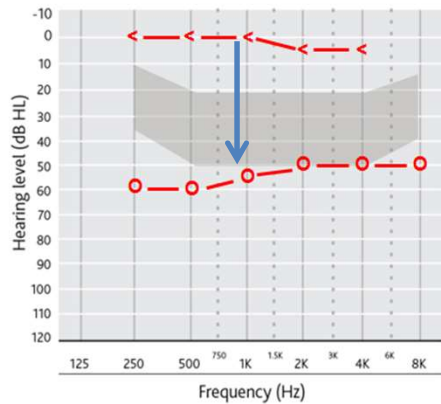




# BACKGROUND

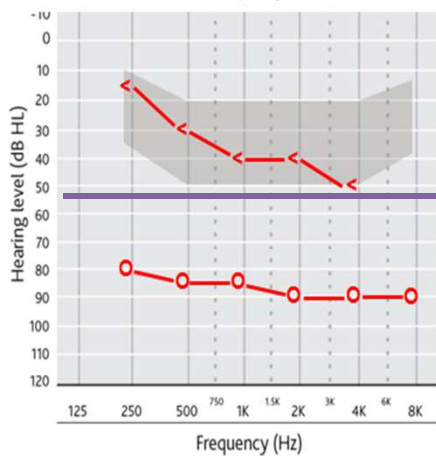
- Sound is transmitted via bone conduction to the cochlea.
- BAHA indications
  - conductive/mix type hearing loss,
  - single-sided deafness
  - difficulty wearing conventional hearing aids
  - due to intolerance or anatomy that makes molding of inserts difficult





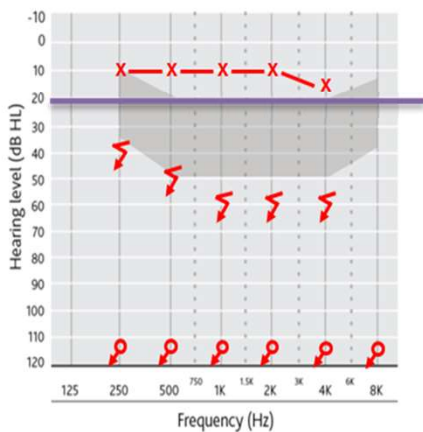
- 1 Conductive Loss
- 2 Mixed Loss
- 3 Single Sided Deafness (SSD)

Air- bone gap of **30dB or greater**



- 1 Conductive Loss
- 2 Mixed Loss
- 3 Single Sided Deafness (SSD)

A pure tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of better than or **equal to 45 dB** (with newer processes up to 60 to 65 dB)



- 1 Conductive Loss
- 2 Mixed Loss
- 3 Single Sided Deafness (SSD)

For patients with single-sided deafness with sensory hearing in the hearing ear **better than 20-dB** average bone conduction thresholds.



# TYPES

WITH PERCUTANEOUS ABUTMENT (CONNECTED)



COCHLEAR BAHA Connected





WITHOUT PERCUTANEOUS ABUTMENT  
(magnet-based)



COCHLEAR BAHA ATTRACT



SOPHONO



COCHLEAR BAHA SUPERPOWER



MEDEL BONEBRIDGE





with abutment

magnet based



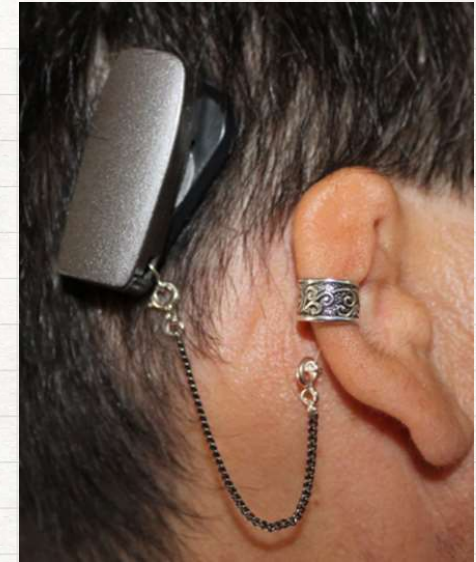
COCHLEAR



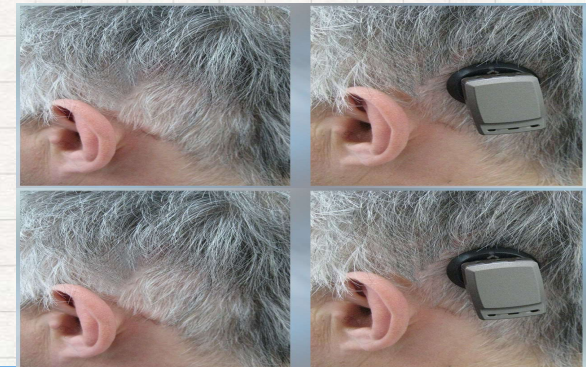
OTICON Ponto



COCHLEAR



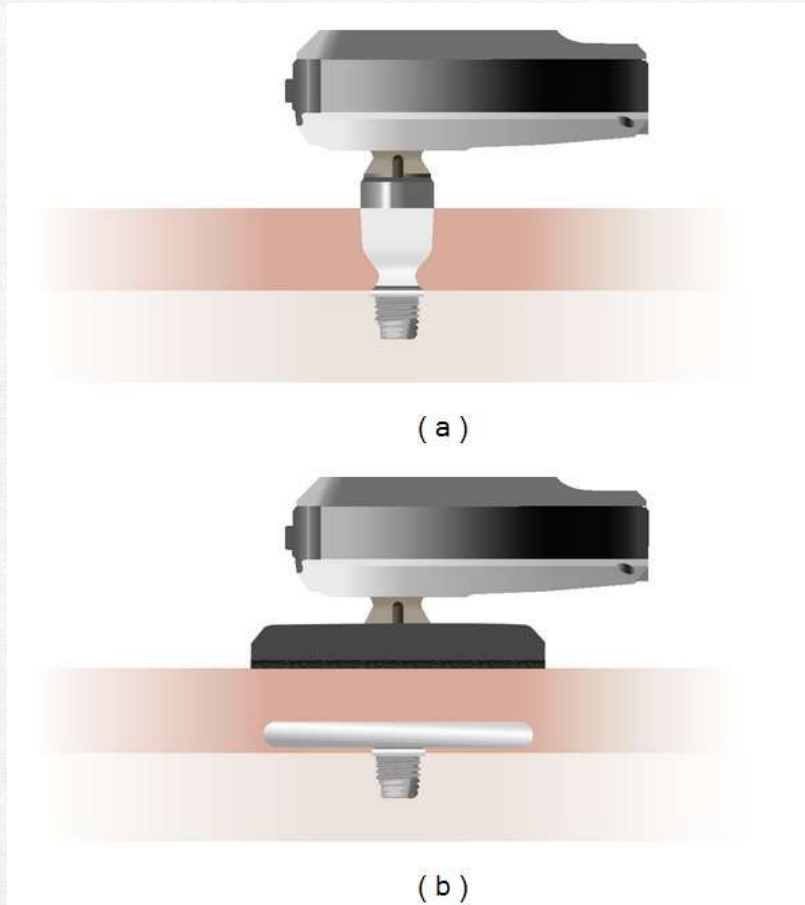
SOPHONO



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# WHICH DEVICE/ SOUND PROCESSOR



- MR is safe up to 3 Tesla
- Skin issues common
- Has more power ( direct connection)
- More stable (for kids)
- Cosmetic concerns

- MR Conditional up to 1.5 Tesla
- Intact skin — less skin issues
- Low complication rate
- High wearing comfort
- Less cosmetic concerns





Device	Bone Scores Attract	Bone Scores Connect	Battery
BAHA 5	35dBHL	45dBHL	312 ( light battery) 3- 5 days
BAHA 5 Power	45dBHL	55dBHL	675 ( heavier battery adds weight) 10 days
Super Power	55dBHL	65dBHL	Rechargeable batteries

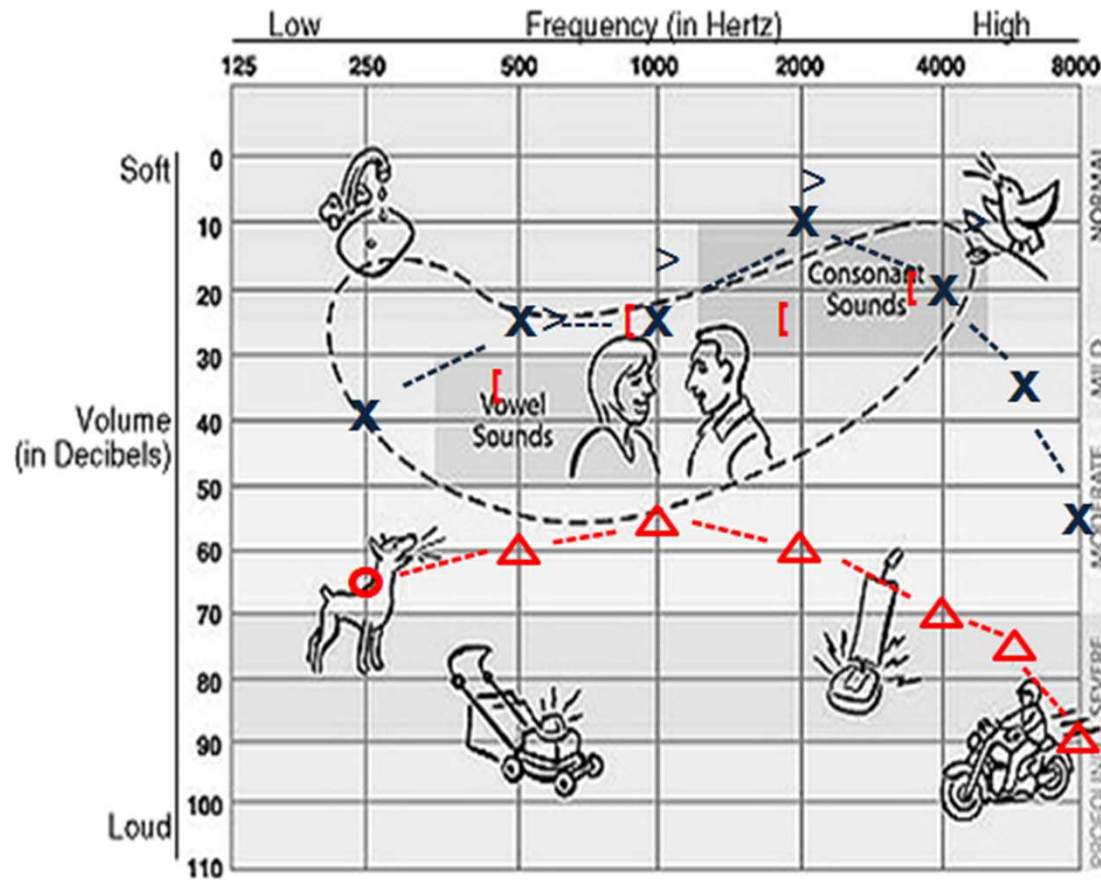
Note-

Fitting at the maximum output of the device will add feedback, distortion.





# Mixed Loss – Magnet BAHA 5



## Pre Implant

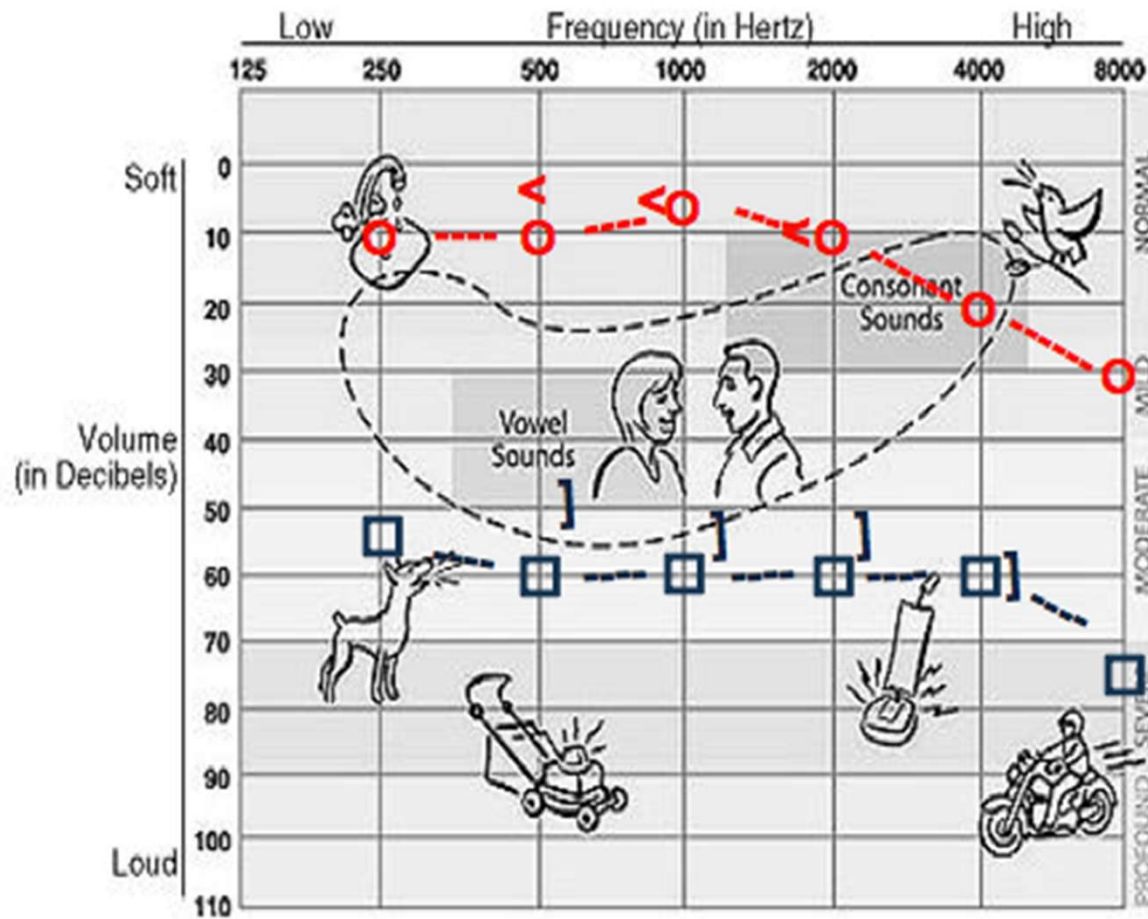
Condition	AzBio
Speech right/multi- talker babble left +5SNR	5% 7 words correct /135 presented
Soft Band BAHA 5 right/ multi- talker babble left +5SNR	92% 139 words correct/ 151 presented
Hard Band BAHA 5 speech right/multi-talker babble left +5SNR	99% 136 words correct – 127 presented.

## Post Implant

AzBio +10 SNR	AzBio +5 SNR
99% words correct /135 presented	92% words correct 139



# SSD



# Pre Implant

Condition	AzBio +10dBSNR	Az Bio 47dBHL/42dBHL +5 dBSNR
Without BAHA	40%	34% List 7
Baha Soft Band	65%	59% List 2
Baha Hard Band	90%	74% List 3

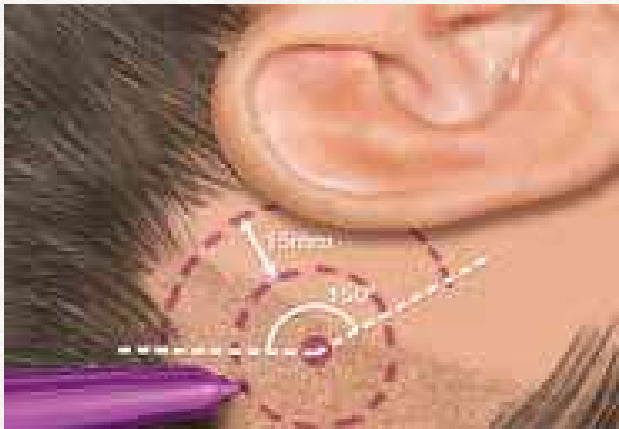
# Post Implant

Condition	AzBio +5dBSNR
BAHA 4	99%





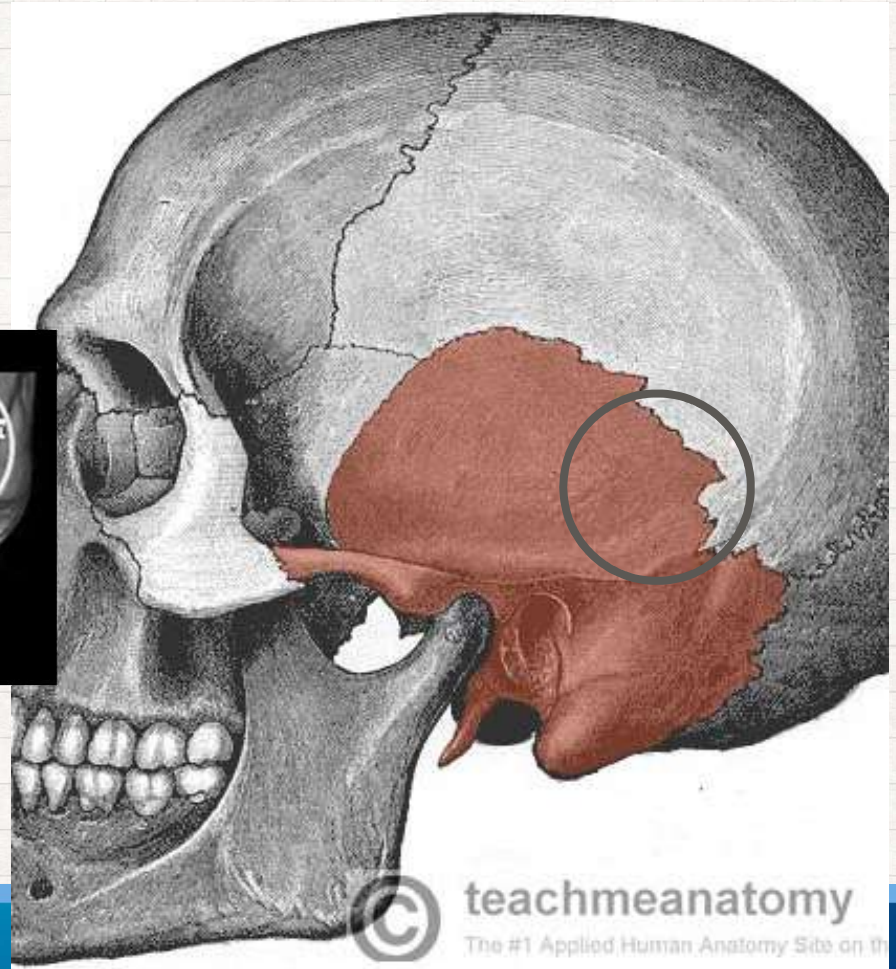
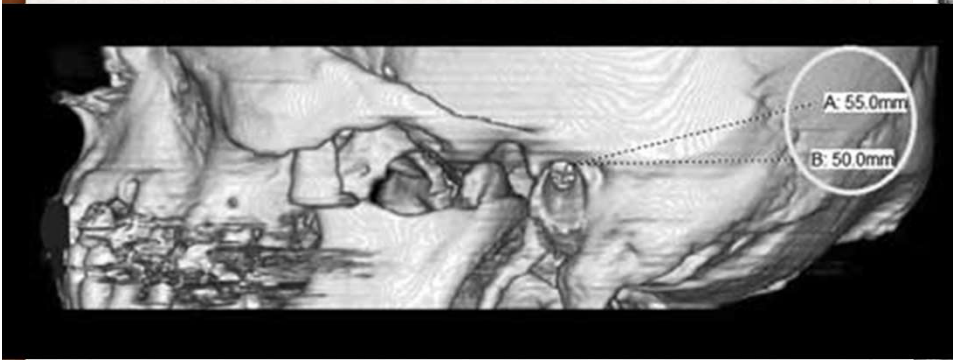
# SURGERY



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# WHERE IS THE BEST PLACE FOR THE IMPLANT?



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The #1 Applied Human Anatomy Site on the

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**WHY is recommend placement of the implant 5-7cm posterior to the ear canal?**

- avoidance of the sigmoid sinus is preferred to minimize the risk of bleeding and epidural hematoma
- avoidance of the mastoid cavity
- accommodation of the external processor
- decrease the feedback for Superpower

**WHY do we want to stay close to ear canal?**

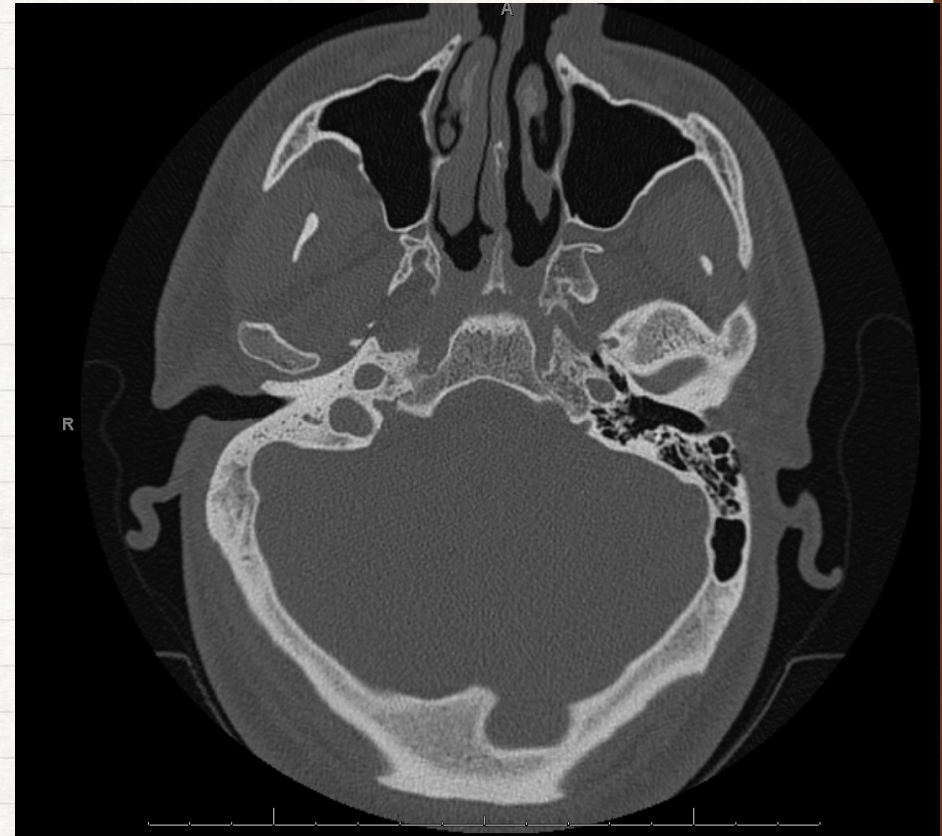
- Hearing is maximized the closer the transducer is to the cochlea.
- More natural position for hearing
- Better orientation



# OUR RECENT RESEARCHES

Table. Demographic and Measurement Data Comparing Diseased to Non-Diseased Ears

	Chronic Ear Disease	No Chronic Ear Disease	p-value
Age, years	49.08 ± 18.54	47.67 ± 16.34	0.72
Measurement 1 (to EAC), mm	33.55 ± 5.19	36.30 ± 3.68	0.00023
Measurement 2 (thickness), mm	6.79 ± 2.06	6.90 ± 2.27	0.76



Baker AR, Fanelli DG, Kanekar S, Isildak H. A Retrospective Review of Temporal Bone Imaging With Respect to Bone-Anchored Hearing Aid Placement. *Otol Neurotol.* 2017 Jan;38(1):86-88.



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We conclude that, based on our imaging study placement of a BAHA implant can be performed closer to the EAC than current guidelines suggest, when taking into account the location of the sigmoid sinus.

In addition, those patients with chronic ear show an even more anterior position of the sigmoid sinus, which would allow for a more proximal placement of the implant.



●● Baha FAST surgery (4mm)



●● Baha two-stage surgery



●● Table 3: Abutment selection

Tissue thickness should be measured prior to injecting local anesthetic.

Tissue thickness (mm)	Abutment length (mm)	Corresponding part number	
		One stage	Two stage
3 or less	6	93329	93333
4-5	8	93330	93334
6-7	10	93331	93335
8-9	12	93332	93336
10 or more*	12	93332	93336

\* With soft tissue reduction.



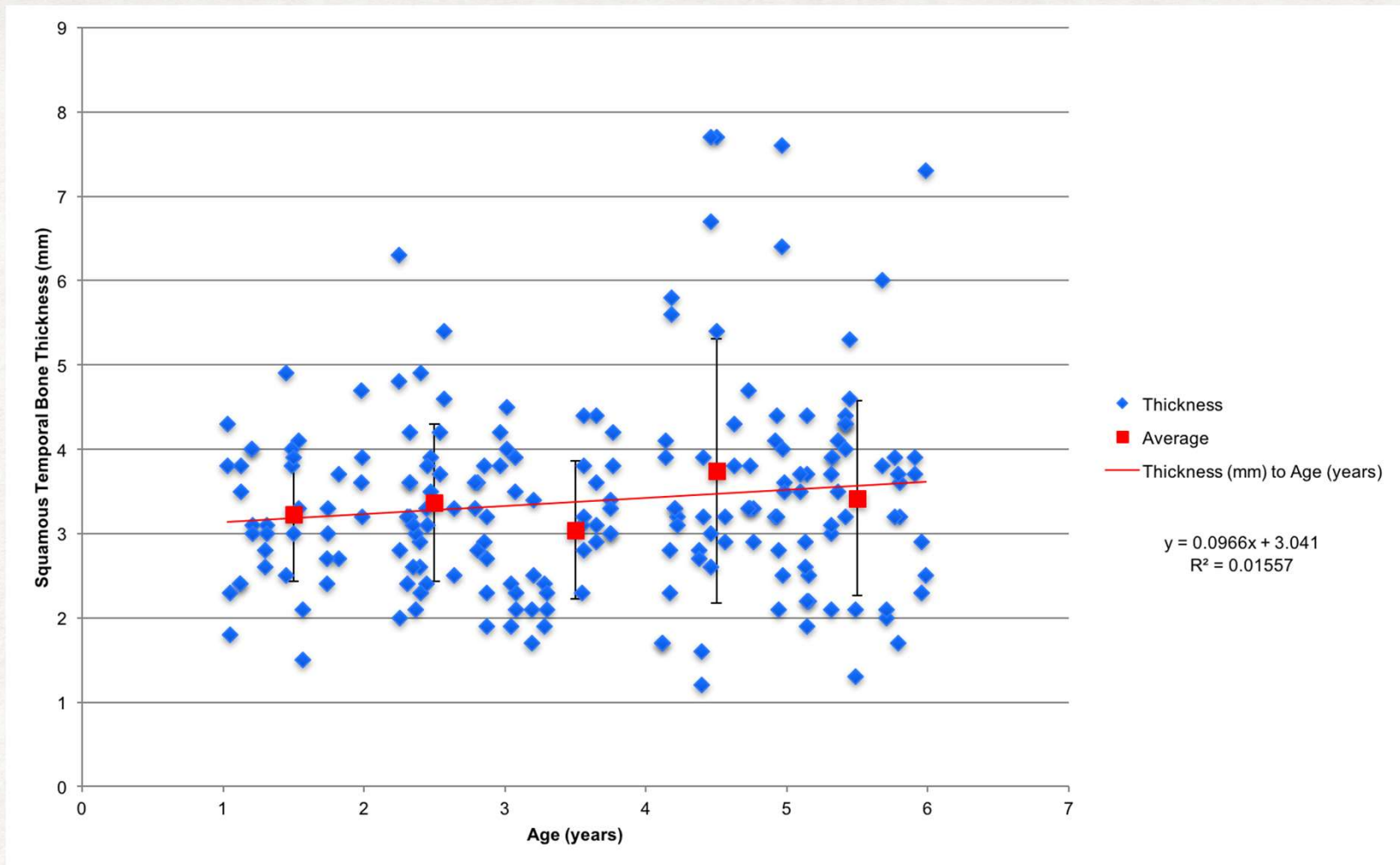


# BONE THICKNESS

- BAHA is particularly useful in congenital conductive hearing loss
- Current FDA guidelines allow for BAHA placement in patients **>5 years of age**
- We sought to obtain objective data regarding temporal bone thickness in the pediatric population to help determine whether implantation in younger populations might be feasible.



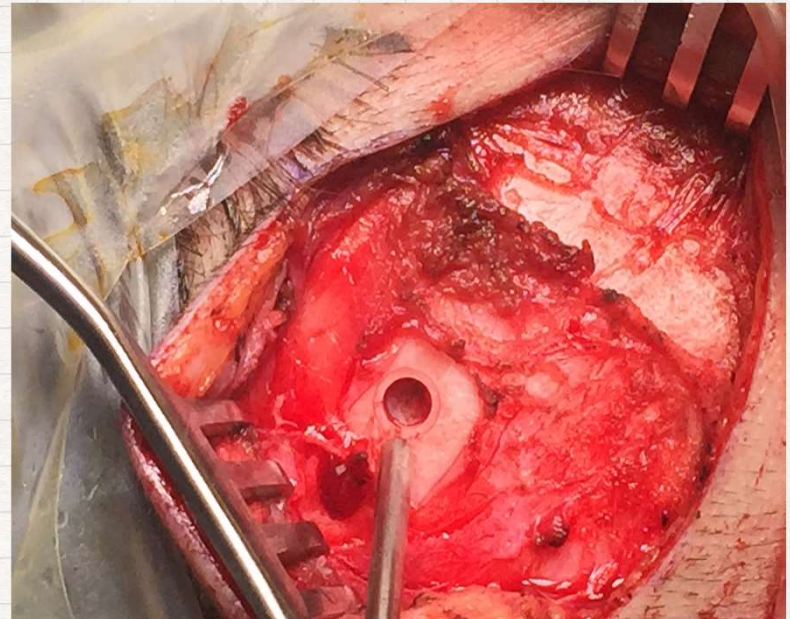




Baker A, Fanelli D, Kanekar S, Isildak H. A Review of Temporal Bone CT Imaging With Respect to Pediatric Bone-anchored Hearing Aid Placement. Otol Neurotol. 2016 Oct;37(9):1366-9



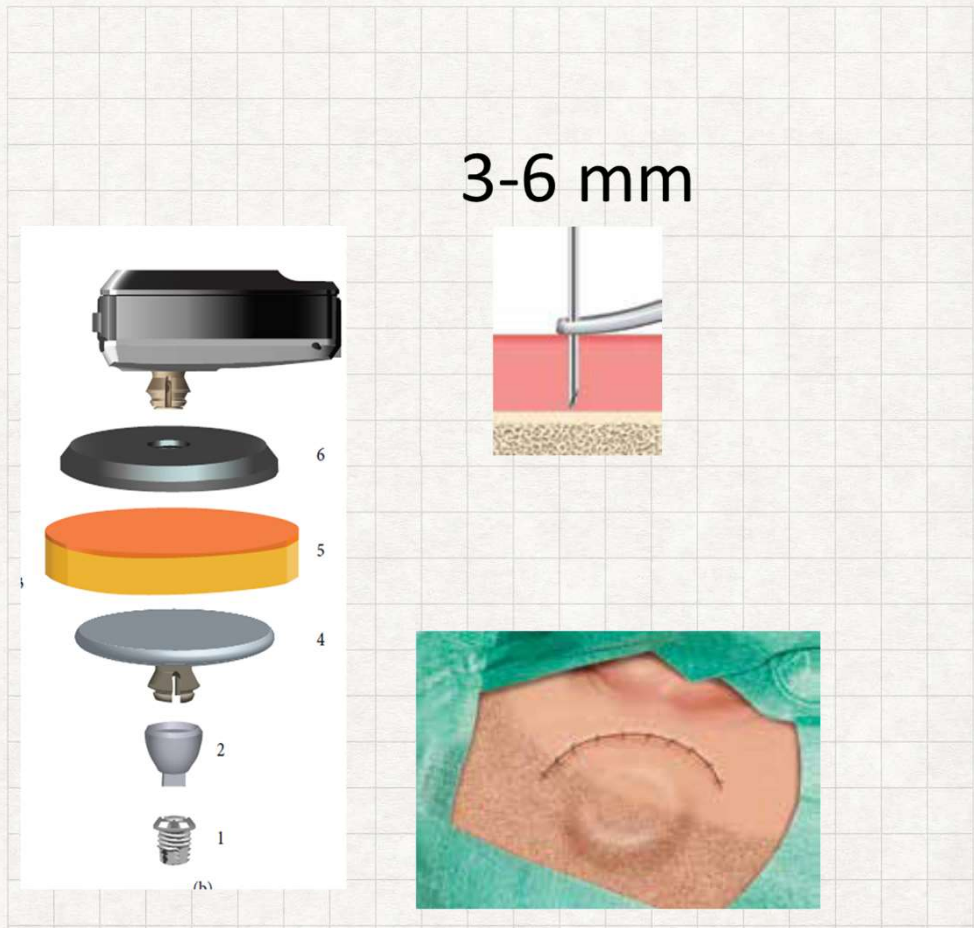
- Our presented data shows that temporal bone thickness is not statistically significantly different when comparing children of 5 years of age to those down to 1 year of age.
- While many of these patients will have dural exposure intraoperatively at the time of implantation, studies have shown that this is of little consequence.
- Bone-anchored hearing aid implantation could be considered for patients younger than 5 years of age.





# SKIN THICKNESS

- Ongoing research





# OUR BAHA MAGNET RESULTS

- A single institution, IRB approved chart review of all patients who underwent BAHA attract implantation between December 2013 and December 2016 was performed.
- Demographics evaluated included age, sex, indication for implantation, surgical time, follow-up time, and patient comorbidities. Patient satisfaction, audiologic outcomes, and complications were also captured.
- We present the largest single institution experience to date with the BAHA magnet system.



### Patient Demographics

Total number of patients	36
Age in years (range)	36.63 (5.98-83.59)
Pediatric patients (<18 years)	15
Adult patients (>18 years)	21
Surgeries performed	37
Follow-up in days (range)	271.8 (71-284)

Five cases were conversion from connected to magnet based implant.

One case was conversion from magnet to connected implant.



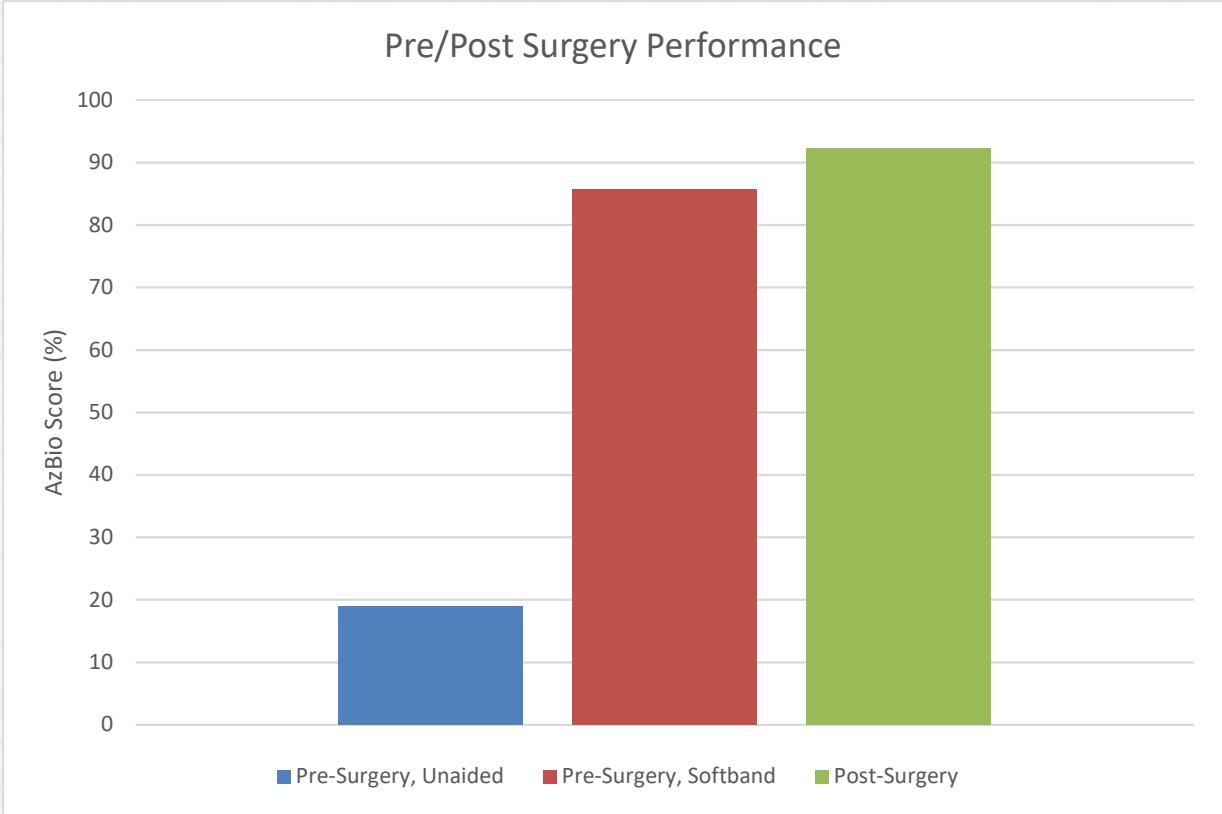
### Use and Complications

Patients using on a regular basis	32/36
Pain at site	3/37
Numbness	2/37
Redness	5/37
Skin break (trauma)	2/37





# AUDIOLOGICAL OUTCOMES



# COMPLICATIONS



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Adjusting magnet strength



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# CONCLUSIONS

- The magnet based BAHA has allowed for patients who were previously unable or unwilling to use the connected device to have hearing rehabilitation.
- Complications in our experience are thankfully rare and easily treated.
- Postoperative issues with skin overlying the transcutaneous magnet implant are uncommon, and frequently addressed by adjusting magnet strength.
- The BAHA power devices are bulkier and have added weight which can be problematic as the patient may require a stronger magnet for retention. The increased magnet strength provides improvement of sound quality and reduces audible feedback; however close monitoring of the magnet site is advised.



- We have found that patients with very thick hair present significant problems with retention and feedback and in one case the patient underwent revision for an abutment.
- Patients with stronger magnets should be periodically checked for skin degradation, and family members are counseled to check the site weekly.
- Devices are now available with adaptive microphone technologies and increased noise management programs. In addition, Bluetooth capabilities significantly enhance the patient's abilities to hear in adverse communication situations.
- BAHA frequency responses provide the greatest gain below 4 kHz, although this response is improving with the addition of power devices





- With the addition of the Super Power devices, we are able to improve the quality of hearing for SSD those patients with hearing levels significantly below the recommended 20dBHL threshold levels.
- We recommend, if applicable, the patient be fitted with amplification for the better ear. Hearing aids and BAHA devices can connect to the advised blue tooth devices, thus providing patients with significant improvements in binaural hearing, and temporal processing, (understanding speech in background noise).
- Our experience with the BAHA magnet shows that the device is successfully used in the both pediatric and adult patients who are candidates for this device.





*THANK YOU!*



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