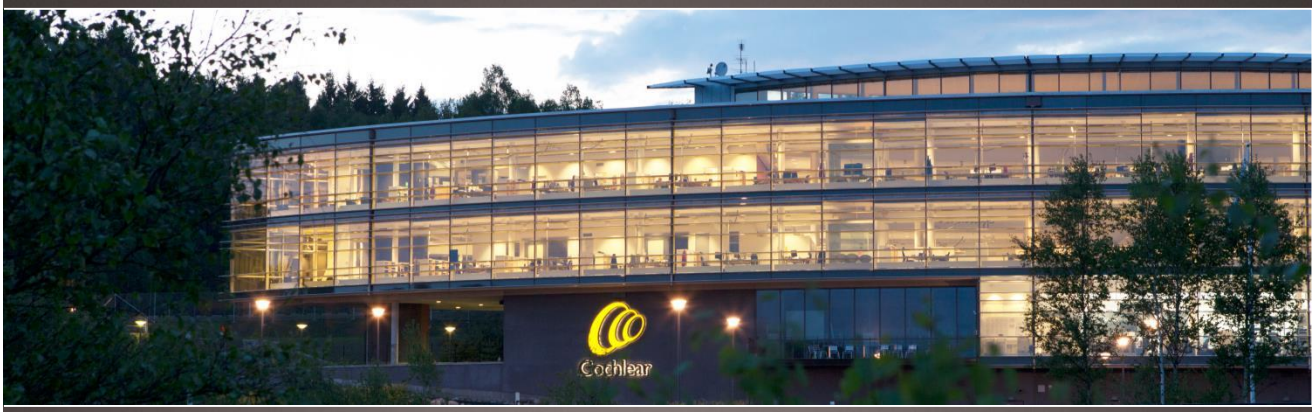


Foundations of Baha® Technology: Candidacy

Mary Beth O'Sullivan, MS, CCC-A
Professional Education Manager

Hear now. And always

Cochlear®

Learner Outcomes

Cochlear®

After completion of this seminar, the learner will be able to:

- List the candidacy criteria for Baha® systems for both Single-Sided Deafness (SSD) and mixed and conductive hearing loss
- List three ways clinicians can demonstrate Baha systems to their patients
- Identify important points for counseling a candidate and list resources that are available to support Baha candidates

Our mission

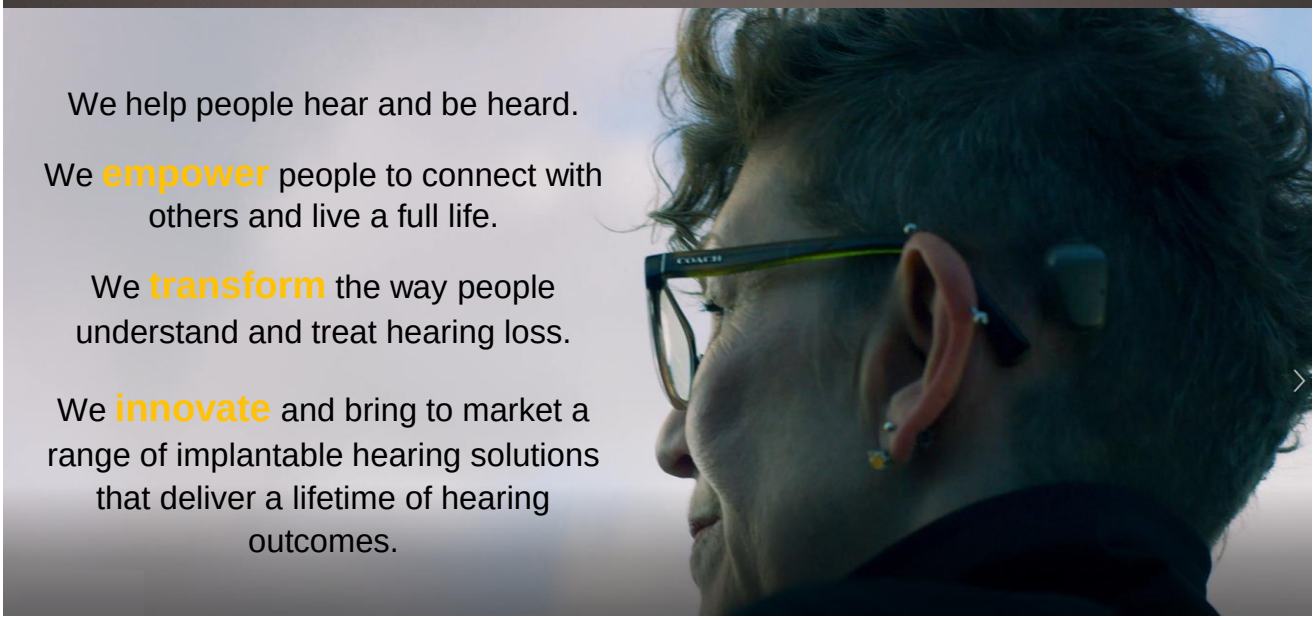
Cochlear®

We help people hear and be heard.

We **empower** people to connect with others and live a full life.

We **transform** the way people understand and treat hearing loss.

We **innovate** and bring to market a range of implantable hearing solutions that deliver a lifetime of hearing outcomes.



Indications for Baha® Technology

Hear now. And always

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Osseointegration

- The process by which living bone tissue bonds with titanium
- Makes direct bone conduction possible
- Provides the basis of long-term predictability and success of the Baha system

Why Baha Technology?

Direct Bone Conduction:

Works independently of ear canal and middle ear

Direct transmission gives clear and natural sound

Pre-operative testing is possible

High wearing comfort

Safe and straightforward surgery

Predictable outcome

Baha System Candidacy

Conductive & Mixed Hearing Loss (CMHL)

Candidacy is based on bone conduction thresholds

Bone Conduction PTA equal to or better than 65 dB at 0.5, 1, 2 & 3 kHz

Bilateral fitting requires symmetric bone conduction thresholds

Less than 10 dB on average (0.5, 1, 2 & 3) or less than 15 dB at individual frequencies

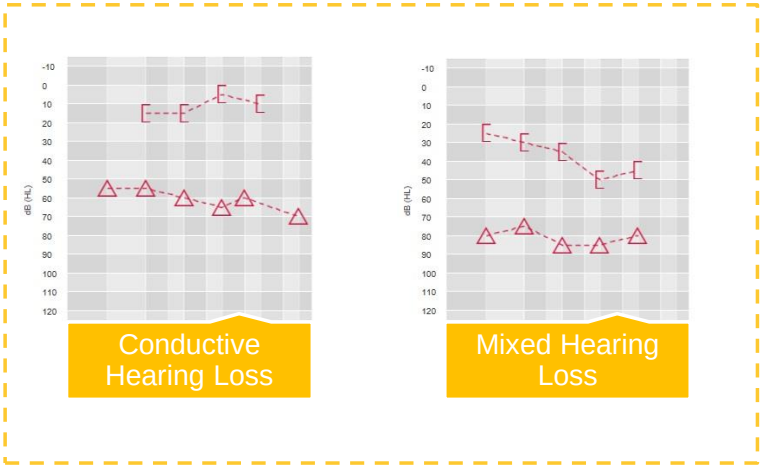
Single-Sided Deafness (SSD)

Profound SNHL in one ear and Normal hearing in the good ear

Defined as Air Conduction PTA equal to or better than 20 dB at 0.5, 1, 2 & 3 kHz

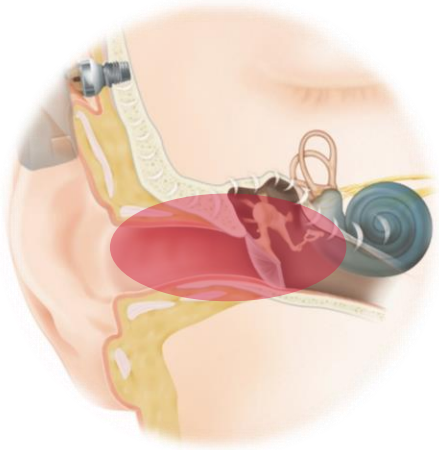
Surgery can be considered for children 5 years of age or older

Baha System Candidacy



Baha System Candidacy: CMHL

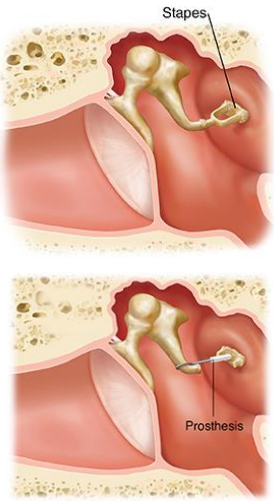
- Direct bone conduction bypasses the outer and middle ear
- Baha solutions treat conductive & mixed hearing loss
  - Atresia
  - Chronic middle ear disease
  - Cholesteatoma
  - Congenital abnormalities
- Baha devices do not have to overcome conductive component, only amplify for any sensorineural component



Baha System Candidacy: CMHL

Treatment option: Middle ear surgery

- Over 300,000 ear surgeries are performed each year in the US (excluding myringotomy and tubes)[1]
- For Tympanoplasty and Ossiculoplasty, 60-70% of patients will have “successful” hearing restoration (air-bone gap of 20 dB or less)[2-5]
- Stapedectomy is more successful with over 90% of patients achieving closure of the air-bone gap to within 10 dB[6], although that number drops to 64% for revision surgeries[7]



1 – Hall MJ, Schwartzman A, Zhang J, Liu X, Division of Health Care Statistics. National Health Statistics Reports: Ambulatory surgery data from hospitals and ambulatory surgery centers: United States, 2010, Number 102 (February 28, 2017)
2 - Iniguez-Cuadra R, Alobid I, Bores-Domenech A, Menendez-Colino L-M, Cballero-Borrego M, Bernal-Sprekelsen M. (2010) Type III tympanoplasty with titanium total ossicular replacement prosthesis: Anatomic and functional results. Otology & Neurotology, 31(3): 409-414.
3 - Cox MD, Trinidade A, Russell JS, Dornhoffer JL. (2017) Long-term hearing results after ossiculoplasty. Otol Neurotol, 38(4):510-515.
4 - Stankovic MD (2008) Audiologic results of surgery for cholesteatoma: Short- and Long-term follow-up of influential factors. Otology & Neurotology, 29(7):933-940.
5 - O'Reilly RC, Cass SP, Hirsch BE, Kameret DB, Bernat RA, Poznanovic SP. (2005) Ossiculoplasty using incus interposition: Hearing results and analysis of the middle ear risk index. Otology & Neurotology, 26(5):853-858.
6 - Vincent R, Sperling NM, Oates J, Jindal M. (2006) Surgical findings and long-term hearing results in 3,050 stapedotomies for primary otosclerosis: a prospective study with the otology-neurotology database. Otl Neurotol, 27(8 Suppl 2):S25-47.
7 - Vincent R, Srovers M, Zingade N, Oates J, Sperling N, Deveze A, Grolman W. (2010) Revision Stapedotomy: operative findings and hearing results. A prospective study of 652 cases from the otology-neurotology database. Otol Neurotol, 31(6):875-82.

Baha System Candidacy: CMHL

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Treatment option: Aural atresia reconstruction

- Degree of hearing restoration is dependent on severity of atresia[1]
- Majority of pediatric patients who have reconstruction will still require some form of amplification after surgery[2]
- About 75% of patients who did not receive a good hearing benefit will also not benefit from a revision[1]

*Images from www.microtia.us.com, December 2017

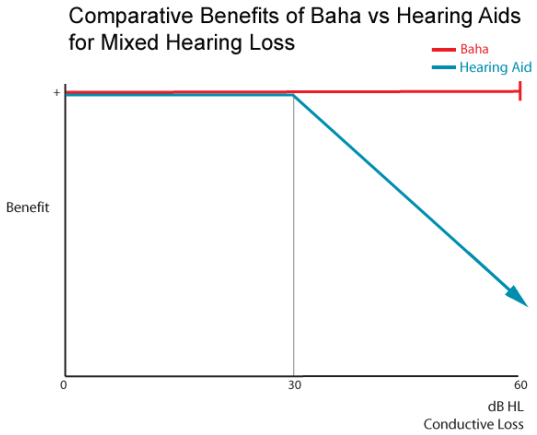
1- Chang SO, Choi BY, Hur DG. (2006) Analysis of the long-term hearing results after the surgical repair of aural atresia. Laryngoscope, 116(10):1835-1841.
2 - Evans AK, Kazahaya K. (2007) Canal atresia: Surgery or implantable hearing devices? The expert's question is revisited. International Journal of Pediatric Otorhinolaryngology. 71(3):367-374.

Baha System Candidacy: CMHL

Cochlear®

Treatment option: Hearing aid

- The greater the air-bone gap, the more a Baha system will outperform hearing aids[1,2]
- Hearing aid prescriptions for conductive and mixed hearing loss require more gain and receive less clinical research than for sensorineural hearing loss[3]
- Hearing aid fitting can be difficult if there is drainage from the ear, ear pain or a mastoid cavity present after mastoidectomy[4]



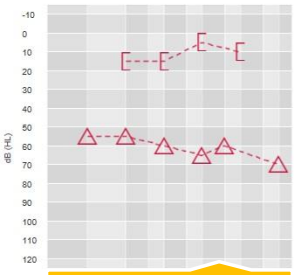
1 - Snik AF et al. (2005) Consensus Statements on the BAHA System: Where Do We Stand at Present? Annals of ORL 114(12S). 195:1-12
2 – Mylanus EAM, van der Pouq K, Snik M (1998) Intraindividual comparison of the bone-anchored hearing aid and air-conduction hearing aids. Arch Otolaryngol Head Neck Surg, 124(3):271-276
3 - Johnson EE. (2013) Prescriptive amplification recommendations for hearing losses with a conductive component and their impact on the required maximum power output: An update with accompanying clinical explanation. J Am Acad Audiol, 24(6):452-60.
4 - Gluth MB, Friedman AB, Atcherson SR, Dornhoffer JL. (2013) Hearing aid tolerance after revision and obliteration of canal wall down mastoidectomy cavities. Otology & Neurotology, 34(4):711-4.

Baha System Candidacy: CMHL

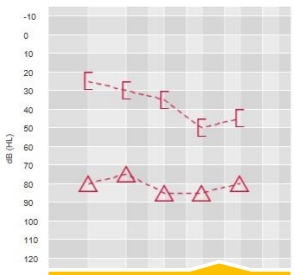
- Nothing worn on the external ear, which is helpful in cases where ear drainage is present[1]
- Baha does not need to be re-adjusted if the air conduction thresholds fluctuate because gain is only required for the bone conduction thresholds
- Pre-operative testing can be used to predict post-operative benefit[2]
- Use of Baha is associated with high user satisfaction and good long-term benefit[3,4]

1 - Bouhabel S, Arcand P, Saliba I. (2012) Congenital aural atresia: bone-anchored hearing aid vs. external auditory canal reconstruction. Int J Pediat Otorhinolaryngol. 76(2):272-7.
2 - Monini S, Filippi C, Atturo F, Biagini M, Lazzarino AI, Barbara M. (2015) Individualised headband simulation test for predicting outcome after percutaneous bone conduction implantation. Acta Otorhinolaryngol Ital. 35(4):258-64
3 - Gardell ISK, Andresen K, Faber CE, Wanscher JH. (2015) Bone-anchored hearing aids are effective and associated with a high degree of satisfaction. Danish Medical Journal, 62(7):A5108
4 - Rasmussen J, Olsen S, Nielsen LH. (2012) Evaluation of long-term patient satisfaction and experience with the Baha bone conduction implant. Int J Audiol. 51(3):194-9.

Baha System Candidacy



Conductive Hearing Loss



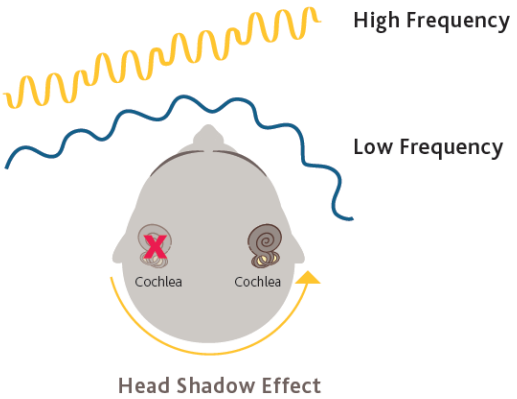
Mixed Hearing Loss

Single-Sided Deafness (SSD)

Baha System Candidacy: SSD

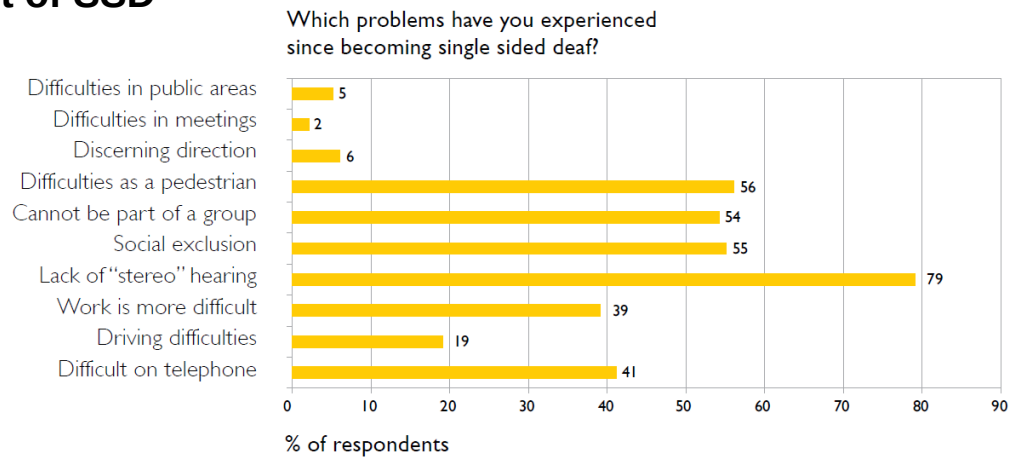
Two ears:

1. Help overcome the head shadow effect
2. Help understanding of speech in background noise
3. Help in the location of sound



Baha System Candidacy: SSD

Impact of SSD



1. Survey contained in "Hear the other side" — A report on single-sided deafness. More information can be found at www.singlesideddeafness.com: A report by the advisory board for single sided deafness. Available from Cochlear — article E80414A.

Baha System Candidacy: SSD

Cochlear®

Treatment options: SSD

- Patient remains untreated*
- CROS hearing aids
- Steroids (sudden hearing loss)
- Medical intervention – surgery
- Bone conduction devices (e.g., Baha)

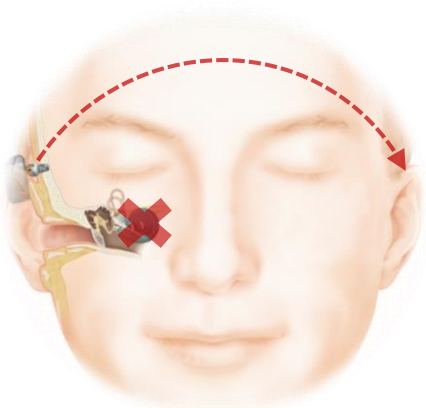
**Patient or physician choice*

Baha System Candidacy: SSD

Cochlear®

Treatment option: Bone conduction

- Improved speech understanding in noisy environments[1]
- Helps to lift the head shadow effect[1-4]
- Reduces the psychosocial consequences associated with hearing impairment[1,5-6]
- Long-term patient satisfaction and hearing benefits[7-8]



1. Hol MKS, Bosman AJ, Snik AFM, Mylanus EAM, Cremers CWRJ. "Bone anchored hearing aids in unilateral inner ear deafness: an evaluation of audiometric and patient outcome measurements." Otol Neurotol (2005:26): 999-1006.
2. Lin LM, Bowditch S, Anderson MJ, May B, Cox KM, Niparko K. Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone-anchored hearing and contralateral routing of signal amplification. Otology and Neurology 2006;27(2):172-82.
3. Pai I, Kelleher C, Nunn T, Pathak N, Jindal M, Fitzgerald O'Connor A, Jiang D. Outcome of bone-anchored hearing aids for single-sided deafness: A prospective study. Acta Oto-Laryngologica, Early Online 1-5.
4. Wazen JJ, Spitzer JB, Ghossaini SN, et al. Transcranial contralateral cochlear stimulation in unilateral deafness. Otolaryngology Head Neck Surg 2003;129(3):248-54.
5. Newman CW, Sandridge DA, Wodzisz LM. "Longitudinal benefit from and satisfaction with the Baha System for patients with acquired unilateral sensorineural hearing loss. Otol Neurotol 2008; 29: 1123-1131.
6. Schroder SA, Ravn T, Bonding P. BAHA in single sided deafness: patient compliance and subjective benefit. Otol Neurotol. 2010; 31: 404-408.
7. Kompis M, Wilhem W, Caversaccio. Long term benefit of bone anchored hearing systems in single sided deafness. Acta Oto-Laryngologica. 2017; 13:398-402.
8. Maurizio B, Biagini M, Lazzarino AI, Monini S, Hearing and quality of life in a south European BAHA population. Acta Oto-Laryngologica. 2010 130: 1040-1047.

Baha System Candidacy: SSD

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Treatment options: CROS vs Baha

- The Baha system is a discreet solution worn on one side, while CROS hearing aids require users to wear devices on both ears
- Baha allows wireless streaming to be mixed with environmental mic from the bad side while CROS aids may require turning off the bad side in order to stream[1]
- Baha 5 sound processors are the first Made for iPhone solutions for individuals with SSD
- The Baha System bypasses outer and middle ear and sends clearer, more crisp sound directly to the inner ear[2]
- Studies show that the Baha System provides better speech understanding in noise than CROS hearing aids[3-4]

1 – Phonak CROS II wireless compatibility, downloaded from: https://www.phonakpro.com/us/en/support/product-support/hearing-aids/cros-ii/compatibility-cros-ii.html December, 2017
2 - Gustafsson J. BCDrive performance vs. conventional bone conduction transducer. Cochlear Bone Anchored Solutions AB, 629908, 2015
3 - Niparko JK, Cox KM, Lustig LR. Comparison of the bone-anchored hearing aid implantable hearing device with contralateral routing of offside signal amplification in the rehabilitation of unilateral deafness. Otology & Neurotology, 2003 Jan;24(1):73-78
4 - Hol MKS, Bosman AJ, Snik AFM, Mylanus EAM, Cremers CWRJ. "Bone anchored hearing aids in unilateral inner ear deafness: an evaluation of audiometric and patient outcome measurements." Otol Neurotol (2005:26): 999-1006.

Determining Candidacy for Bone Conduction Solutions

Hear now. And always

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Determine Candidacy

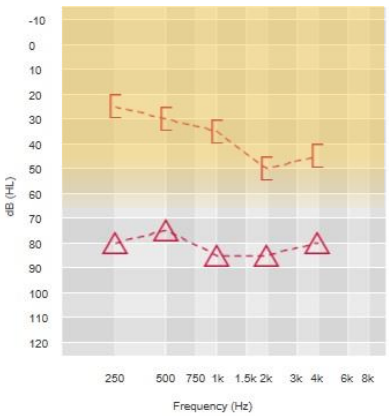
Bone Conduction Thresholds → Demonstration & Testing → Device Selection → Counseling

Determine Candidacy

Bone Conduction Thresholds → Demonstration & Testing → Device Selection → Counseling

MCHL: Compare the patient's bone conduction thresholds to the fitting range of the Baha system

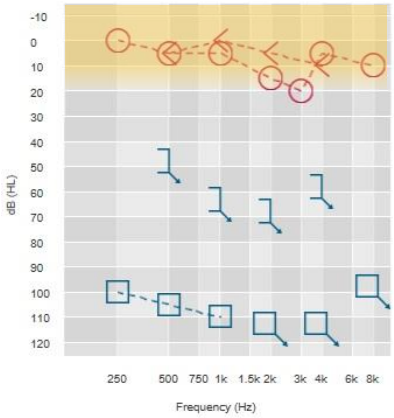
TIP: With borderline decisions; may compare BC direct thresholds from Baha Fitting Software to the fitting range



Determine Candidacy

Bone Conduction Thresholds | Demonstration & Testing | Device Selection | Counseling

SSD: Compare the air conduction thresholds in the good ear to the Baha indications



Determine Candidacy

Bone Conduction Thresholds | Demonstration & Testing | Device Selection | Counseling

Demonstration

- A quick, limited experience
- Processor may be used in “demo” setting
- May be completed by surgeon, audiologist, tech, etc.

Evaluation

- Audiological evaluation of benefit
- Processor is fit using software
- Speech perception testing is completed
- Performed by the Audiologist

Trial

- Candidate is given the Baha system to try for a period of time
- May take place in the clinic or in the patient’s home
- Processor is fit using software

Determine Candidacy

Bone Conduction Thresholds | **Demonstration & Testing** | Device Selection | Counseling

Demonstration

Suggested "Demo" settings in the sound processor:

- Program 1: Conductive Hearing Loss *(10 dB BC thresholds)*
- Program 2: Mixed Hearing Loss *(Program 1 plus 5 clicks overall gain)*
- Program 3: SSD *(Program 2 minus 5 clicks gain in low frequency band)*

TIP: Baha 5 Power is recommended for demonstrations

Determine Candidacy

Bone Conduction Thresholds | **Demonstration & Testing** | Device Selection | Counseling

Evaluation

TIP: Test the patient with and without the Baha to determine potential benefit

- Establish benefit before surgery[1,2]
- Can provide the patient with realistic expectations of surgery
- Can help identify the best surgical candidates
- Can assist in choice of processor

1 – Monini S, Filippi C, Atturo F, Biagini M, Lazzarino AI, Barbara M. (2015) Individualised headband simulation test for predicting outcome after percutaneous bone conduction implantation. Acta Otorhinolaryngol Ital. 35(4):258-64
2 – Snapp HA, Fabry DA, Telischi FF, Arheart KL, Angeli SI. (2010) A clinical protocol for predicting outcomes with an implantable prosthetic device (Baha) in patients with single-sided deafness. J Am Acad Audiol, 21(10):654-62.

Determine Candidacy

Bone Conduction Thresholds | **Demonstration & Testing** | Device Selection | Counseling

Evaluation

1. Fit the SoundArc™ or Softband to the patient's head with a demo processor
2. Use Baha Fitting Software to program the sound processor
3. Perform objective testing in the soundbooth to determine benefit

Determine Candidacy

Bone Conduction Thresholds | **Demonstration & Testing** | Device Selection | Counseling

Evaluation

TIP: Choose speech perception tests that will demonstrate benefit (e.g., single words or speech in noise)

MCHL: Functional Listening Evaluation

Test two situations to help determine individual benefit

1. Unaided Condition: to establish the SNR or speech perception ability without treatment
2. Aided Condition (Baha): to establish SNR or speech perception ability with the Baha System.

Pre-operative testing is predictive of benefit after surgery[1]

1 - Monini S, Filippi C, Atturo F, Biagini M, Lazzarino AI, Barbara M. (2015) Individualised headband simulation test for predicting outcome after percutaneous bone conduction implantation. Acta Otorhinolaryngol Ital. 35(4):258-64

Determine Candidacy

Bone Conduction Thresholds | **Demonstration & Testing** | Device Selection | Counseling

Evaluation

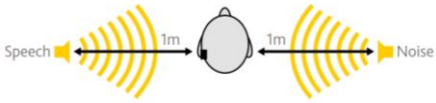


Image A. Set-up of hearing in noise test for SSD candidates.

TIP: QuickSIN, HINT or AzBio may all be used as hearing in noise tests

SSD: Hearing in Noise Testing

Noise should come from the speaker facing the hearing ear while speech comes from the speaker nearest the deaf ear

Test two situations to help determine individual benefit:

1. Unaided Condition: to establish the SNR or speech perception ability without treatment
2. Aided Condition (Baha): to establish SNR or speech perception ability with the Baha System.

Difference in the SNR between the two situations has been shown to be a good predictor of individual benefit[1]

1. Snapp HA, Fabry DA, Telischi FF, Arheart KL, Angeli SI. A clinical protocol for predicting outcomes with an implantable prosthetic device (BAHA) in patients with single-side-deafness. J AM Acad Audiol. 2010 Nov-Dec (10): 654-62.

Determine Candidacy

Bone Conduction Thresholds | **Demonstration & Testing** | Device Selection | Counseling

Trial

TIP: A trial is excellent in cases where candidacy may be unclear or "borderline"

- Select a demo Sound Processor most appropriate for the patient's hearing loss
- Fit the sound processor on a SoundArc or Softband using Baha Fitting Software
- Instruct the patient on use of the device
- Ask the patient to keep a journal or log of their experiences

Determine Candidacy

Bone Conduction Thresholds | Demonstration & Testing | **Device Selection** | Counseling

Baha Attract
Cosmetically appealing
Low risk of soft tissue reaction[1]
MRI safe (up to 1.5 Tesla)

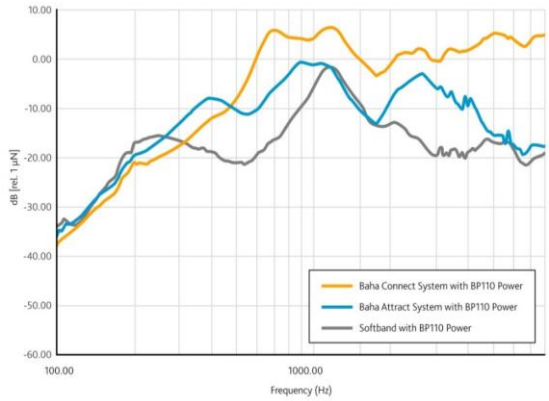
Baha Connect
Maximum hearing performance[2]
No soft tissue reduction
MRI safe

1 Briggs et al (2015) Clinical Performance of a New Magnetic Bone Conduction Solution: Results From a Prospective, Multicenter, Clinical Investigation, Otology & Neurotology, 36:834-841.
2 Iseri et al (2015) Transcutaneous Bone-anchored Hearing Aid versus Percutaneous Ones: Multicenter Comparative Clinical Study. Otology & Neurotology, 36:849-853.

Determine Candidacy

Bone Conduction Thresholds | Demonstration & Testing | **Device Selection** | Counseling

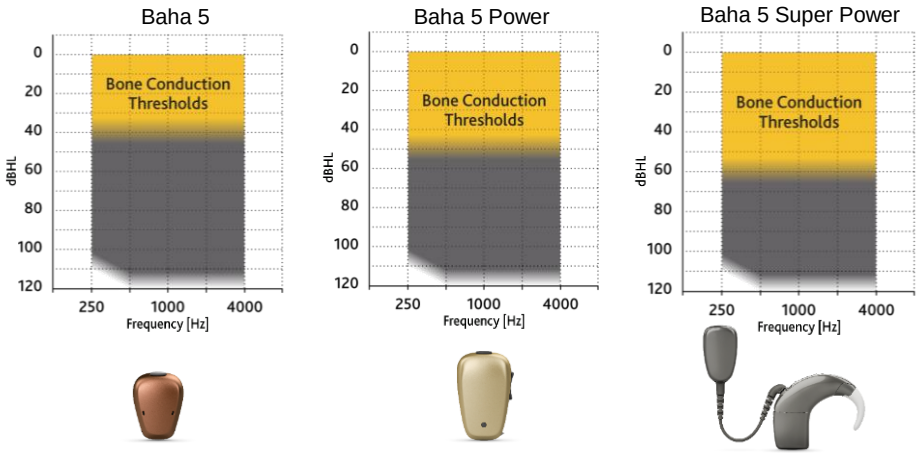
Comparison of sound transmission through the Baha Connect System, Baha Attract System and Baha Softband.



TIP: Performing BC Direct thresholds with a Softband or SoundArc can be a good predictor of the BC Direct thresholds that will be seen with a Baha Attract

Determine Candidacy

Bone Conduction Thresholds | Demonstration & Testing | **Device Selection** | Counseling



TIP: If bone conduction thresholds fall in the lower 10% of the fitting range, consider the more powerful device

Determine Candidacy

Bone Conduction Thresholds | Demonstration & Testing | **Device Selection** | Counseling

All Baha System orders come with one **FREE** wireless device

MiniMic 2 or MiniMic 2+
- Portable, wireless microphone that transmits speech directly to sound processor
- Excellent for students, active adults, those with iPhones®

Phone Clip
- Hands-free connection between processor and smartphone
- Excellent for active adults, those with Android™ phones

TV Streamer
- Hands-free connection between processor and television
- Excellent for less active adults or those who don't need a MiniMic or Phone Clip

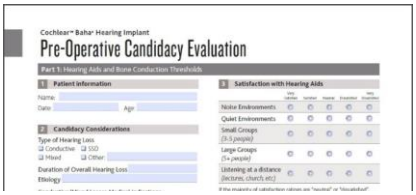
TIP: Consider the candidate's daily needs and challenging listening environments

Determine Candidacy

Bone Conduction Thresholds | Demonstration & Testing | Device Selection | **Counseling**

Determine goals for treatment:

- AAA recommends[1] the use of formal hearing handicap inventories such as:
  - Abbreviated Profile of Hearing Aid Benefit (APHAB)
  - Client-Oriented Scale of Improvement (COSI)
- Can also use informal counseling discussion or Cochlear's Candidacy Worksheet


Cochlear™ Baha® Hearing Implant

Pre-Operative Candidacy Evaluation

Part 1: Hearing Aids and Bone Conduction Thresholds

1 Patient Information

Name:

Date: Age:

2 Candidacy Considerations

Type of Hearing Loss

☐ Conductive ☐ SSD

☐ Mixed ☐ Other:

Duration of Overall Hearing Loss

Etiology

3 Satisfaction with Hearing Aids

	Very Dissatisfied	Dissatisfied	Neutral	Satisfied	Very Satisfied
Noise Environments					
Quiet Environments					
Small Groups (3-5 people)					
Large Groups (5+ people)					
Listening at a distance (lectures, church, etc.)					

1. American Academy of Audiology Clinical Practice Guidelines: Evidence-Based Best Practice Guideline for Adult Patients with Severe-Profound Unilateral Sensorineural Hearing Loss. 5/6/2015

Determine Candidacy

Bone Conduction Thresholds | Demonstration & Testing | Device Selection | **Counseling**

Advantages of Baha System:

- Can be worn off the ear
- High level of user satisfaction[1,2]
- Costs may be covered by insurance
- Choice between magnetic solution (Attract) and direct connection (Connect) and can transition between them if necessary
- Access to Cochlear True Wireless™ technology

1 - Gardell ISK, Andresen K, Faber CE, Wanscher JH. (2015) Bone-anchored hearing aids are effective and associated with a high degree of satisfaction. Danish Medical Journal, 62(7):A5108
2 - Rasmussen J, Olsen S, Nielsen LH. (2012) Evaluation of long-term patient satisfaction and experience with the Baha bone conduction implant. Int J Audiol. 51(3):194-9.

Determine Candidacy

Bone Conduction Thresholds → Demonstration & Testing → Device Selection → **Counseling**

Connect with a Cochlear Concierge

Speak to a team of experts and audiologists, who include cochlear and Baha implant users, here to support and guide your patients through their hearing journey

- Discover the benefits of an implantable hearing solution
- Learn about the experiences of others using Cochlear™ Nucleus® Implant, Cochlear Nucleus Hybrid™ or Baha® Systems
- Get answers to their questions

Email:
Concierge@Cochlear.com

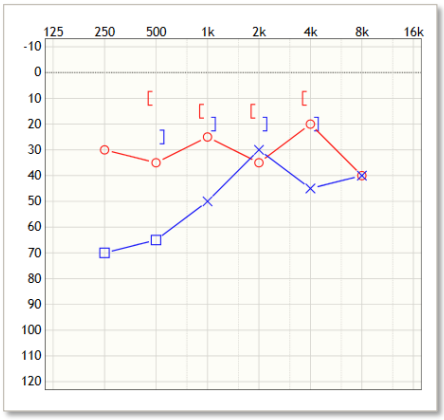
Call:
1(800)216-0228

Case Studies

Hear now. And always

Case Study #1: Roy

- 52 year old man with a history of cholesteatoma in both ears
- History of surgeries
  - RE: 2 surgeries, most recent 1 year ago (ossicular reconstruction)
  - LE: 4 surgeries, most recent 2 years ago (tympanoplasty)
  - No upcoming surgery is planned at this time
- Has an ITE hearing aid for the left ear; often does not wear due to excessive drainage from the ear and he is also not sure it helps him
- Middle school teacher; concerned he may have to retire early since he is so tired by the end of the day due to hearing

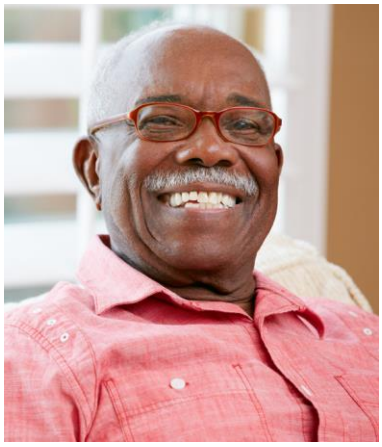


		Word Recognition	
Ear	SRT	Score	Level (masked)
Right	35 dB	100%	75 dB
Left	40 dB	96%	80 dB

Case Study #1: Roy (Cont.)

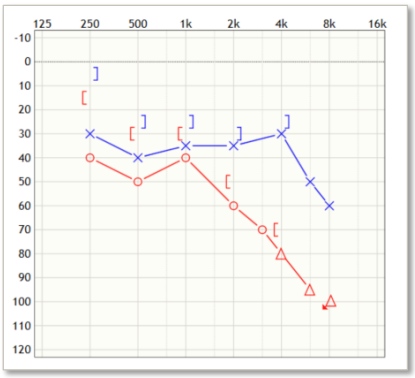
<u>Polling questions for the group</u>:

- Do you feel a Baha demonstration would be appropriate for Roy?
- Would you consider the left ear first? Or the right?
- Would you test Roy in quiet? Or in noise?
- Do you think Roy will be a candidate for Baha technology?



Case Study #2: Kira

- 36 year old woman with a history of hearing loss since childhood and chronic middle ear disease
- History of tympanoplasty in both ears; no further surgeries are planned and she no longer has drainage from her ears
- Currently using ITE hearing aids in both ears that are about 6 years old – reports feeling like she can't get enough volume on the right side



		Word Recognition	
Ear	SRT	Score	Level
Right	50 dB	76%	80 dB
Left	35 dB	92%	65 dB

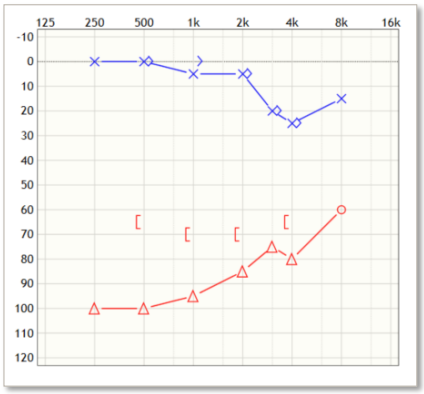
Case Study #2: Kira (cont.)

Polling questions for the group:

- Would you recommend a Baha demonstration for Kira?
- Do you think Kira might benefit from a trial with new hearing aids?

Case Study #3: Max

- 37 year old man with a long history of hearing loss in the right ear
- Surgery in the right ear as a child (he is unsure of the details) but has not had any middle ear problems in either ear since childhood
- Has tried CROS aid in the past but did not like wearing something in his good ear
- Feels he is struggling more over the past few years and his wife agrees
- Works as a software engineer and spends time on the phone with global colleagues; reports he struggles to understand people with accents on the phone



		Word Recognition	
Ear	SRT	Score	Level
Right	85 dB	12%	115 dB
Left	15 dB	100%	55 dB

Case Study #3: Max (Cont.)

<u>Polling questions for the group</u>:

- Would you recommend a Baha demonstration for Max?
- Let's assume Max has the demo and scores the following:
  - Quick SIN Unaided = +9 dB SNR loss
  - Quick SIN with Baha = +3 dB SNR loss
- Would you recommend Max proceed with Baha surgery?

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