Adults with Single Sided Deafness

Understanding the Candidacy, Treatment Options, and How to Counsel Your Patients

Hear now. And always

Cochlear®

Learning Goals:

Cochlear®

1. Introduction
   - What is Single Sided Deafness (SSD)
   - Impact of hearing with only one ear
2. Treatment Approach
   - Comparing treatment options
   - Benefits of bone conduction in treatment
3. Identifying Candidates in Clinic
   - Candidate criteria
   - Testing and evaluation
   - Contraindications
4. Clinical Considerations & Counseling
   - Select the right system based on need
   - How to fit a Baha® System for SSD
5. Case Study Examples

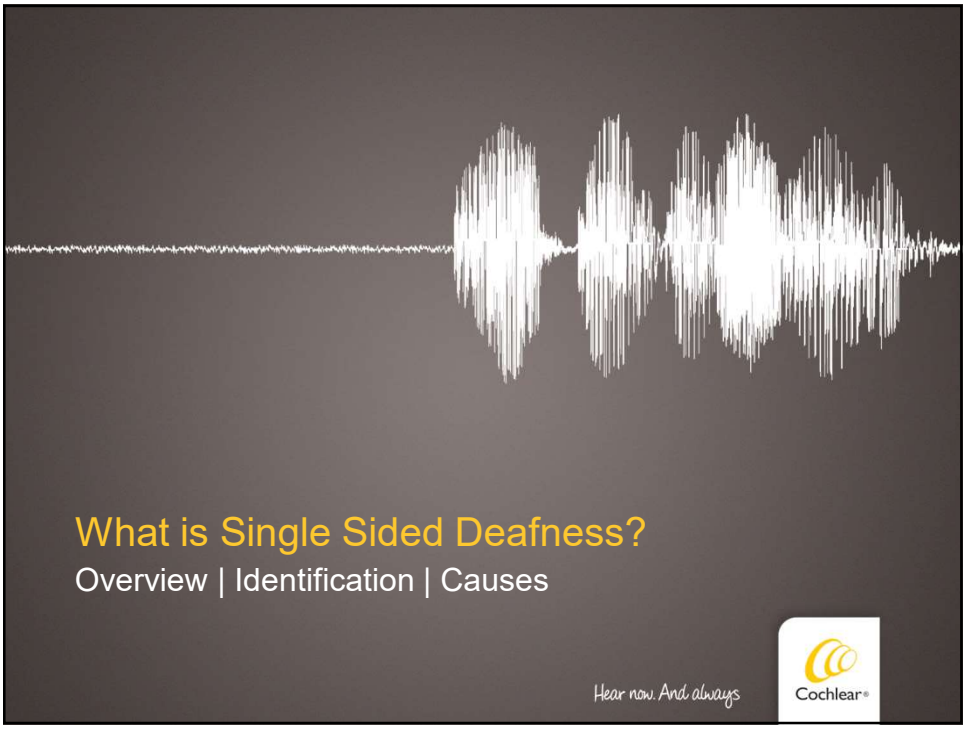
Cochlear's Mission

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.



What is Single Sided Deafness?

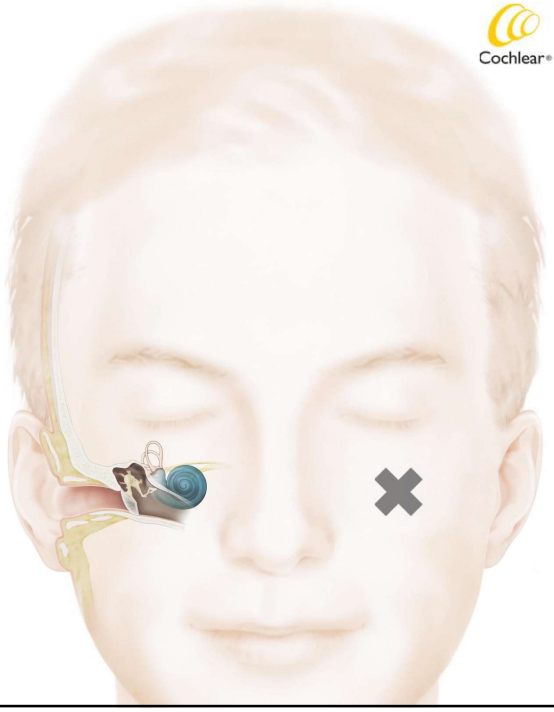
Overview | Identification | Causes

Hear now. And always

SINGLE-SIDED DEAFNESS (SSD)

Having a profound sensorineural hearing loss or a non-functional ear on one side with normal hearing on the other side is known as SSD.

Sounds from the deaf side are not heard and speech understanding in noise is likely more difficult in background noise.



Identifying SSD Candidacy

- **Poor Ear**
  - Non-functional hearing (i.e. un-aidable, profound hearing loss)
- **Good Ear**
  - PTA AC Threshold ≤ 20 dB @ 500Hz, 1kHz, 2kHz and 3kHz

Key Factor: The poor or "bad" ear has not or will not receive benefit when traditional acoustic amplification is applied.

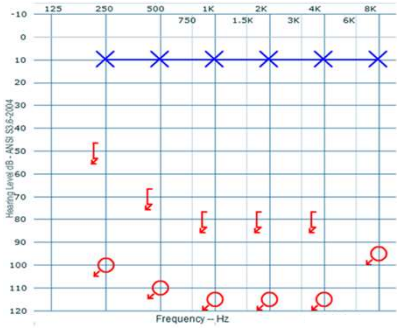


Figure 1

Common Causes of SSD

SSD has a number of etiologies including

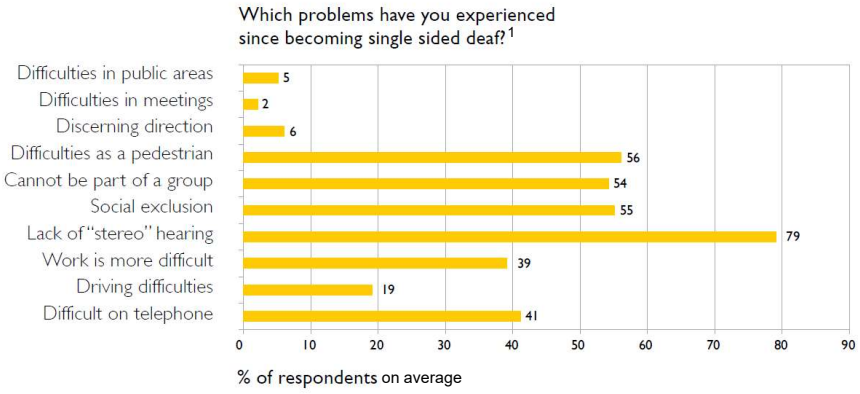
- Sudden idiopathic deafness
- Ototoxic drugs
- Trauma
- Genetic factors
- Surgical intervention such as the removal of an acoustic neuroma
- Viral infections
- Measles
- Meniere's disease

Binaural Hearing vs Monaural Hearing

Speech Perception

Hard to understand speech and sounds, especially in noisy environments

Safety and Social Impact

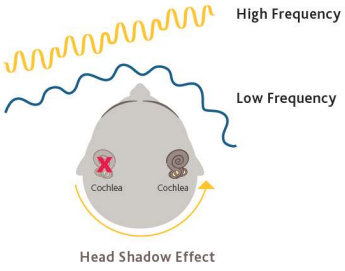


1. Survey contained in "Hear the other side" — A report on single-sided deafness. More information can be found at www.singlesideddeafness.com: A report by the advisory board for single sided deafness. Available from Cochlear — article E80414A.

Localization & Head Shadow Effect

Localization

- Normal localization is based on inter-aural time and level differences.
- When input from one ear is missing, the brain has difficulty telling where the sound originated.



Head Shadow Effect

- Most often effects high frequency sound coming from the poorer hearing side which is attenuated by the head as it travels to the better hearing ear.[1]

1. Van Wanrooij MM, Van Opstal JA. Contribution of head shadow and pinna cues to chronic monaural sound localization. J Neuroscience. 2004 ;24: 4163-4171.

Most Common Treatment Options for SSD

- Patient remains untreated*
- CROS Hearing Aids (HAs)
- Steroids
- Medical intervention - surgery
- Bone Conduction Devices - Baha System

**Patient or physician choice*

How do you decide which treatment option is right for your patient with SSD?

- Simple solution?
- Power delivery to cochlea?
- Cost for patient?
- Cosmetic needs?
- Patient motivation/ expectations?

Comparing Treatment Options for SSD

Sudden SSD Typical Treatment Paths

First Line → Steroids → CROS Hearing Aids

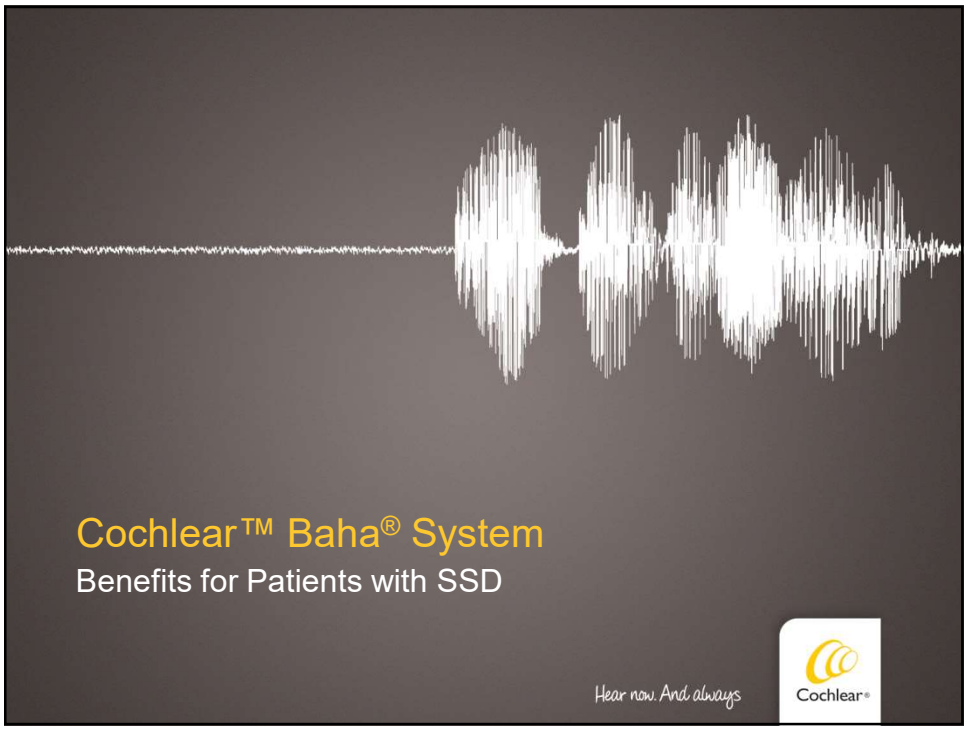
Second Line Bone Conduction

Notable exception includes:

- **Resections including acoustic neuroma,** bone conduction can be used as the primary treatment option.[1]

"In a recent survey of 29 hearing health professionals, **bone conduction** was the **most successful treatment**. Nearly 9 out of 10 times it served as the last or final line of treatment for patients with SSD.*

1. Schroder SA, Ravn T, Bonding P. BAHA in single sided deafness: patient compliance and subjective benefit. Otol Neurotol. 2010; 31: 404-408
*Findings from Market Research Firm, 2/2017-3/2017. Conducted interviews among 29 U.S.-based ENTs and Audiologists who have conducted or fitted more than two bone conduction implants over the past year. Each interviewee brought up to five patient files. Results are based on experience and opinions of the 29 interviewees as well as the combined 135 patient files.



How a Baha® System Works

Baha Attract

1. A sound processor detects sound and transforms it to vibrations.
2. Sound Processor magnet transfers the vibrations from the sound processor through the skin.
3. The Implant magnet received the vibration and transmits it to the implant.
4. The implant transfers sound vibrations to the cochlea.

Baha Connect

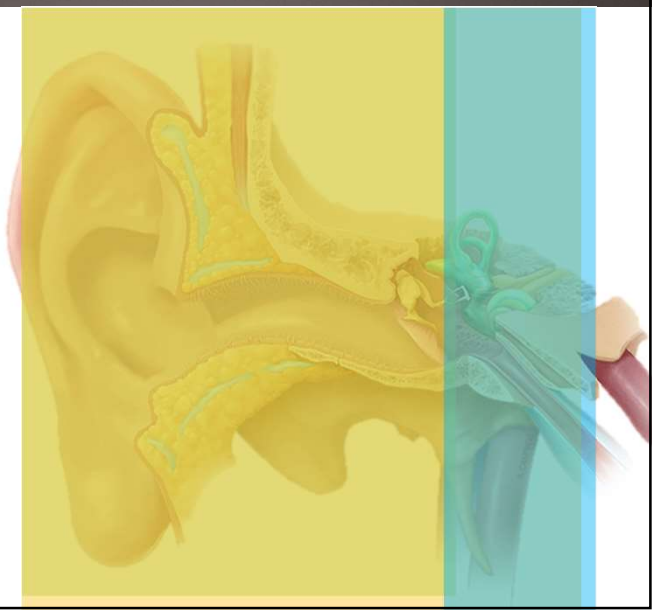
1. A sound processor detects sound and transforms it to vibrations.
2. DermaLock™ Abutment connects the sound processor to the implant.
3. Implant transfers sound vibrations directly to the cochlea.

Cochlear

Baha® System Candidacy Indications

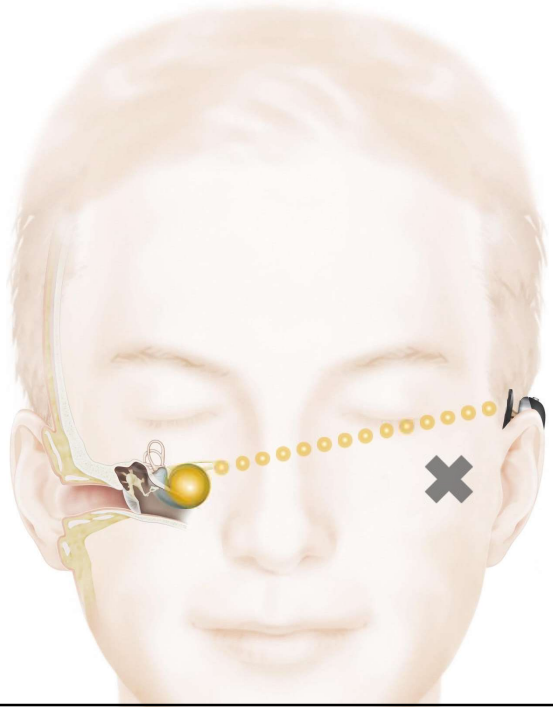
Cochlear

- Conductive loss
- Mixed loss
- Single Sided Deafness



The Baha System for SSD

When using the Baha System in SSD, the signal is routed to the normal hearing ear via bone conduction across the skull, from the deaf side to the healthy cochlea on the hearing side.



Clinically Proven Patient Benefits

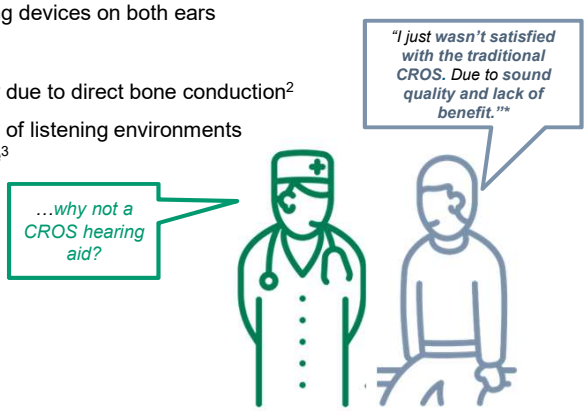
- Improved speech understanding in noisy environments.[1]
- Helps to lift the head shadow effect[1-4]
- Reduces the psychosocial consequences associated with hearing impairment. [1, 5-6]
- Long term patient satisfaction and hearing benefits. [7-8]

1. Hol MK, Bosman AJ, Snik AF, Mylanus EA, Cremers CW. Bone-anchored hearing aids in unilateral inner ear deafness: an evaluation of audiometric and client outcome measurements. Otology & Neurotology 2005 Sep;26(5):999-100.
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. Otolaryngol Head Neck Surg 2003;129(3):248-54.
5. Schroder SA, Ravn T, Bonding P. BAHA in single sided deafness: patient compliance and subjective benefit. Otol Neurotol. 2010; 31: 404-408.
6. 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.
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 vs. CROS Hearing Aids

Benefits of Baha System for SSD

- No hardware in or occlusion of the hearing ear
- No need to wear hearing devices on both ears
- Better hearing in noise[1]
- Improved sound quality due to direct bone conduction[2]
- More useful in a variety of listening environments experienced in daily life[3]

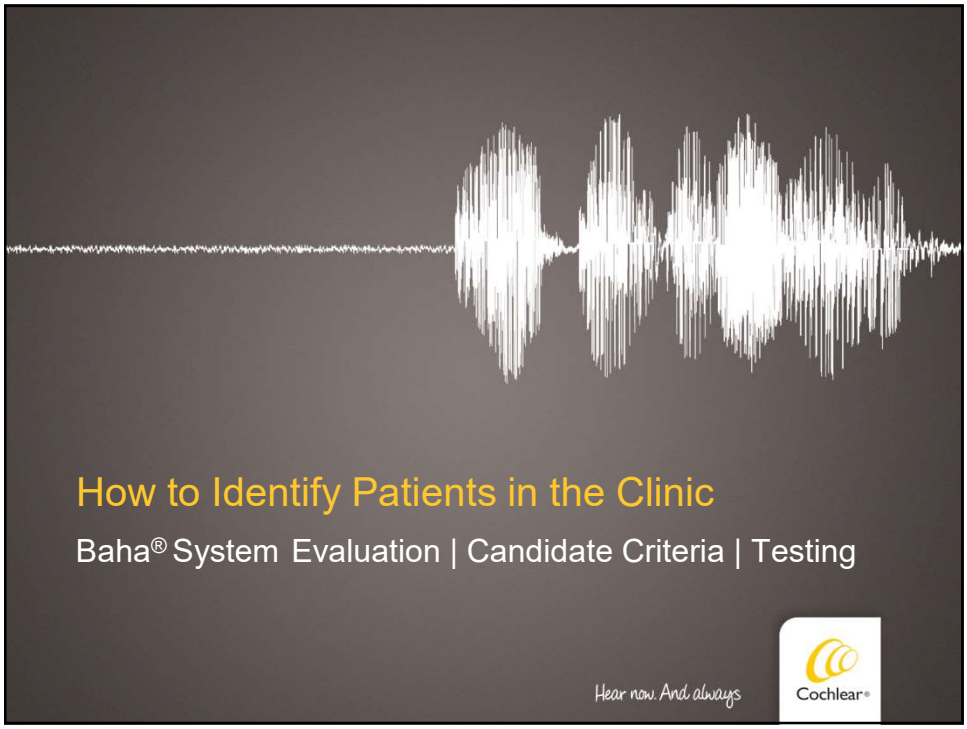


1. Lin LM, Bowditch S, Anderson MJ, May B, Cox KM, Niparko K. Amplification in the rehabilitation of unilateral deafness: speech in noise and directional hearing effects with bone-anchored hearing and contralateral routing of signal amplification. Otology and Neurology 2006;27(2):172-82.
2. Edminston RC , Aggarwal R, Green K M J. Bone conduction implants – a rapidly. The Journal of Laryngology & Otology. 2015; 129:936-940.
3. Niparko JK, Cox K, 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; 24(1):73-78

*Findings from Market Research Firm, 2/2017-3/2017. Conducted interviews among 29 U.S.-based ENTs and Audiologists who have conducted or fitted more than two bone conduction implants over the past year. Each interviewee brought up to five patient files. Results are based on experience and opinions of the 29 interviewees as well as the combined 135 patient files

Other Important Patient Benefits

- No extra hardware or occlusion in the hearing ear
- Demonstration of the Baha System
  - Ability to try before you decide
- Reimbursement
  - Often covered by insurance
- Wearable Technology
  - Customization and control of your hearing with,
    - Made for iPhone®
    - Baha Smart App
    - True Wireless™ Accessories



Baha® System Evaluation for SSD

Step 1: Candidate Criteria

Step 2: Audiometric Testing

Step 3: Benefit Evaluation
- Hearing-in-noise testing
- Softband demonstration
- Subjective assessment

Step 4: Counsel the Candidate
- Fitting considerations
- Surgical consideration
- Which system and sound processor?

Step 5: Refer to an ENT specialist for a consultation or proceed with fit non- surgically

Step 1: Candidate Criteria

Determine patients who can benefit from a bone conduction system

Patient Characteristics

All Ages
- Baha Attract and Connect System *(Surgical Implant)*
  - Indicated for ages 5 and up
  - Contraindicated for below the age of 5 years
- Baha Softband (*Non-surgical)*
  - Indicated for all ages

Common Causes
- Sudden onset hearing loss
- Idiopathic
- Genetic factors
- Surgical intervention, i.e. removal of an acoustic neuroma.

Patients with Certain Existing Conditions

Acoustic neuroma
- May consider treating SSD and AN at the same time

Cannot wear hearing aids

Recently lost hearing
- The more recent the hearing loss, patients are more motivated to seek treatment than those who have lived with hearing loss longer term.[3]

Patient Attitude and History

Willing and able to care for and maintain the implant site

Are comfortable with and open to a surgical option
- Are scheduled for resection or similar surgery and placement of a bone conduction implant can be done concurrently

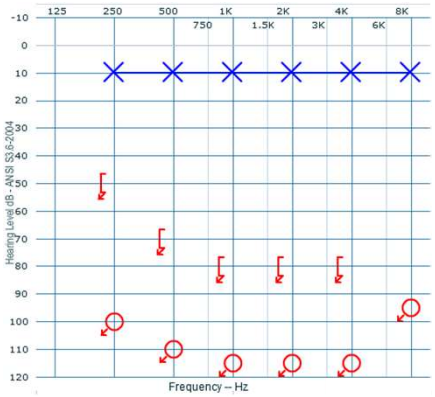
Do not want to wear a device in their good ear

Have a realistic expectation of benefit

Step 2: Audiometric Testing

Includes unmasked and masked bone conduction

- Implant Ear (Poor Ear)
  - Severe to profound SNHL
- Contralateral (Good Ear)
  - Normal hearing
    - PTA AC Threshold ≤ 20 dB @ 500Hz, 1kHz, 2kHz and 3kHz



Note: In cases where there is a more significant hearing loss in the good ear, a bone conduction implant may not be the best solution.

Step 3: Clinical Benefit Evaluation

SSD Test Considerations

Hearing in Noise Testing

- QuickSin, HINT or AZ Bio, are recommended to evaluate the benefit.
- Noise should come from the speaker facing the hearing ear, while speech comes from the speaker nearest the deaf ear.

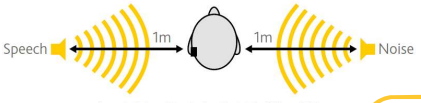


Image A. Set-up of hearing in noise test for SSD candidates.

- Test two situations to help determine individual benefit
  1. Unaided Condition
     - Test to establish the SNR or speech perception ability without treatment
  2. Aided Condition: Baha Softband
     - Test again to establish SNR or speech perception ability with the Baha System.

Patient speech-in-noise measurements can be used as an accurate predictor of the **overall benefits** of a **bone conduction** system for **patients with SSD** prior to implantation.[14]

Difference in the SNR between the two situations has been shown to be a good predictor of individual benefit. The bigger the difference, the more benefit can be expected from the Baha System.

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.

Softband Demonstration

- Demonstrate the processor you intend to fit post surgery
- Cochlear expects demonstration outcomes using the Softband to be similar to Baha Attract outcomes.
- You should expect better sound transmission using Baha Connect due to the percutaneous implant.

Step 4: Counsel the Candidate

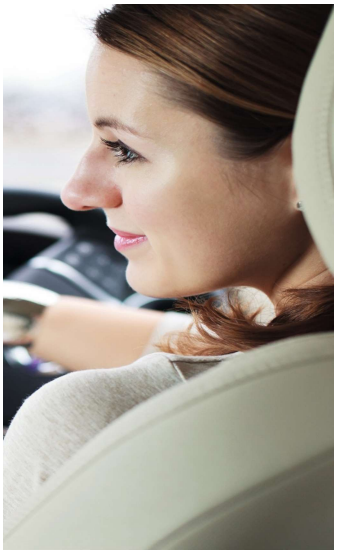
Determine which Baha System and Sound Processor is right for your patient

Fitting Considerations

- Practical points to consider
  - Hearing Expectations
  - Cosmetics
  - Hygiene
  - Dexterity
  - Sporting Activities/Head Gear
  - Radiation/ MRIs

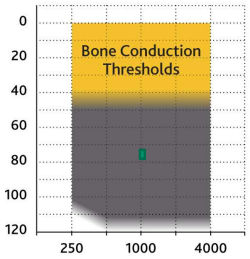
Surgical Considerations

- Discuss surgical expectations
  - Typically a routine outpatient procedure
  - Performed under general anesthesia
  - Established treatment option +40 years
- Review the Guidebook, "*What to Expect at Surgery/Activation*"

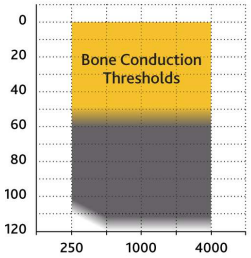


Select the right power level*

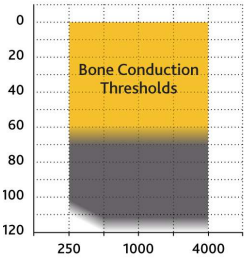
Up to 45 dB SNHL



Up to 55 dB SNHL



Up to 65 dB SNHL



Bone-conduction thresholds averaged across 500, 1000, 2000 and 3000 Hz
Air-conduction thresholds may extend into this area

** Baha System fittings for SSD require normal hearing in the good ear. Power level selection for patients with SSD will be based on the transcranial and soft tissue attenuation needs.*

Determine Which System

The Baha Connect System
Transmits vibrations through a percutaneous abutment, which connects the sound processor to the implant.

- Direct sound transmission for maximum amplification
- High transcranial attenuation
- Indicated for ages 5 and up

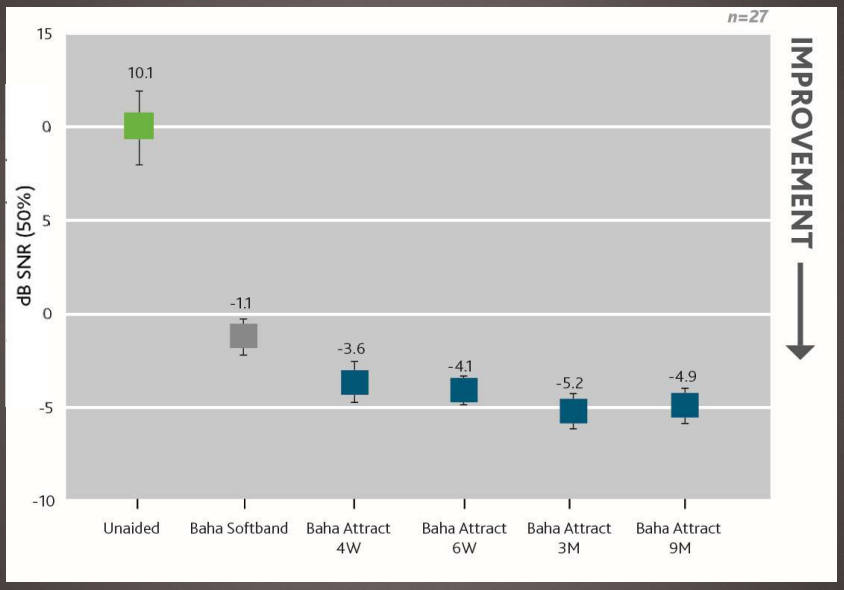
The Baha Attract System
Transmits sound vibrations to the inner ear through a magnetic connection, between the sound processor and the transcutaneous implant under the skin.

- Provides a good aesthetic outcome with no need for daily care.
- Low transcranial attenuation
- Indicated for ages 5 and up

The Baha Softband
Uses a flexible headband to hold the sound processor, which transmit vibrations to the bone through the skin.

- Non- surgical option
- Low transcranial attenuation
- Indicated for children below the age of 5 years or older if recommended

Clinically proven hearing performance[1]



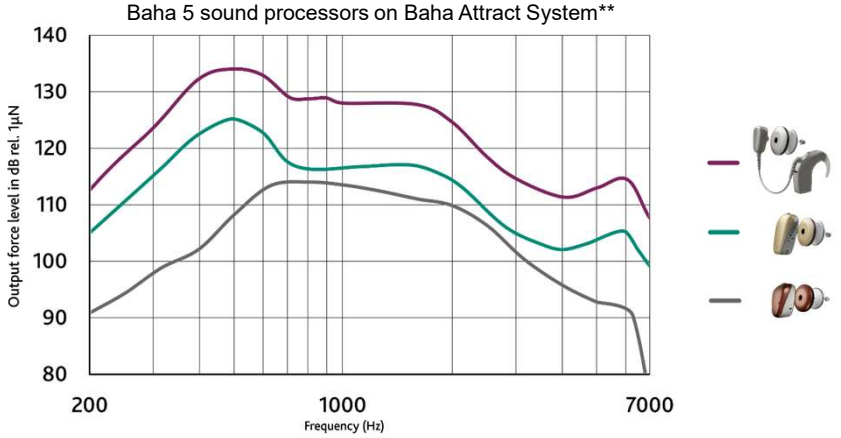
1. Briggs RJ, Van Hasselt A, Luntz M, Goycoolea M, Wigren S, Weber P, Smeds H, Flynn M, Cowan R. Clinical performance of a new magnetic bone conduction hearing implant system: results from a prospective, multi-center, clinical investigation. Otol Neurotol 2015 [Epub ahead of print].

Cochlear™ Baha® Attract System

Cochlear

Baha Attract with more power in the high frequencies*

Baha 5 sound processors on Baha Attract System**

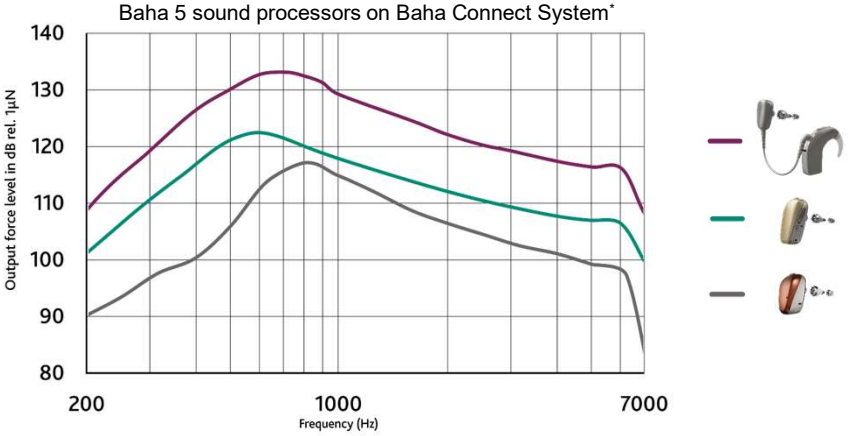


*Baha 5 SuperPower compared with BP110 Power at 6,000 Hz
**OFL90 measured on Artificial Mastoid IEC 60318-6

Cochlear™ Baha® Connect System

The strongest and most complete direct system[1]

Baha 5 sound processors on Baha Connect System*

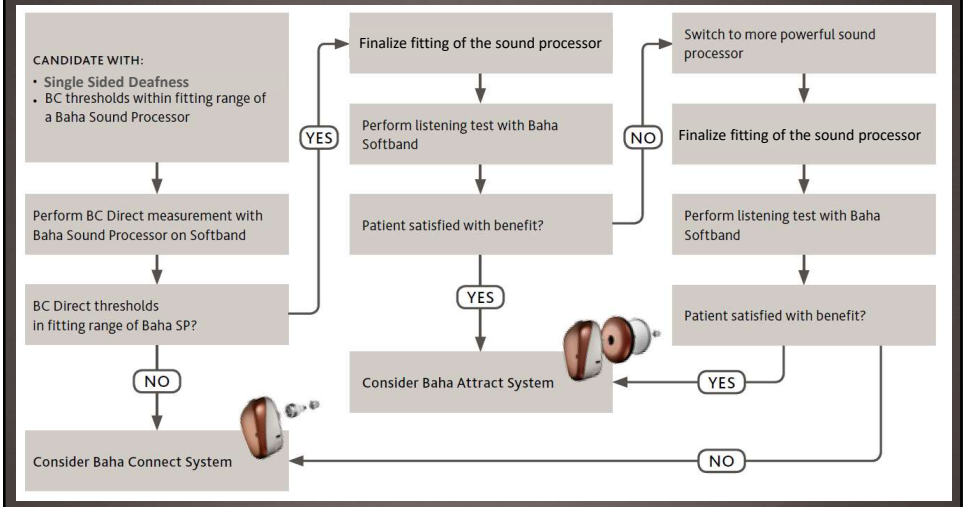


1. Norrman, J. Review of fitting ranges. Cochlear Bone Anchored Solutions AB, D773528, 2015
*OFL90 measured on skull simulator TU1000

SSD Fitting Scenarios

Baha Softband or Baha Attract	Pure SSD on a Connect System
You might need a Power processor to overcome the transcranial attenuation + soft tissue attenuation	Should be managed by Baha 5 but occasionally you will come across high transcranial attenuation and need more power in order for the recipient to perceive benefit.

Overview of Suggested Evaluation Process



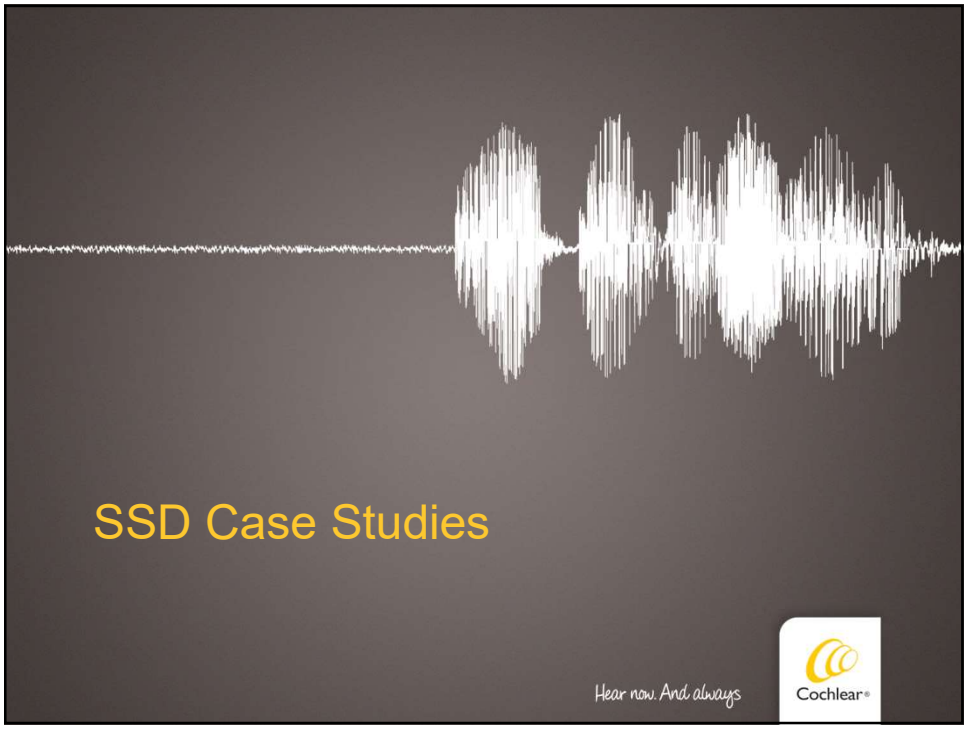
Contraindications to the Implantation of Baha®

1. **Poor bone quality or thickness (eg. Osteoporosis)**
2. **Poor hygiene (if considering Connect)**
3. **Unrealistic expectations (particularly with SSD)**
4. **Medical conditions affecting bone and skin growth**
5. **Age (contraindicated in children below the age of 5)**

Step 5: Refer to an ENT specialist for a consultation or proceed with non-surgical fitting

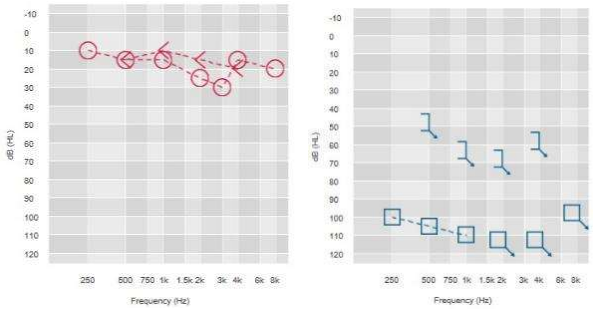
Next Steps:

- If your SSD patient meets candidate criteria outlined in Steps 1-4, your next step is to refer your patient to an ENT specialist for a consultation.
- If your patient does not want to proceed with surgery, but does find value from the demonstration, consider fitting a Baha sound processor non-surgically and reevaluate over time.



CASE 1

Steve



Audiogram thresholds:

L	250	500	750	1000	1500	2000	3000	4000	6000	8000
BC		NR		NR		NR		NR		
AC	100	105		110		NR		NR		NR

R	250	500	750	1000	1500	2000	3000	4000	6000	8000
BC		15		10		15		20		
AC	10	15		15		25	25	15		20

- Steve is a 38 year old man with sudden SSD of unknown etiology 3 years ago
- He sings in a 1940's tribute band and wears suits and horn- rimmed glasses everyday.
- He has been using a CROS aid, but he does not like wearing it with his glasses and he feels that his good ear is plugged, especially when he is trying to follow his bandmates

CASE 1

Steve - outcome

	SNR loss (Quick SIN)*
Unaided (pre-op)	14 dB
Baha on softband (trial)	6 dB
Baha on abutment (post-op)	4 dB

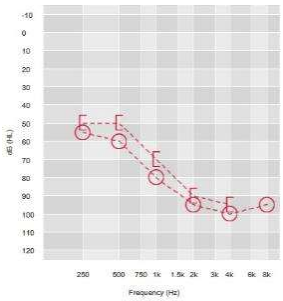
*lower number is better

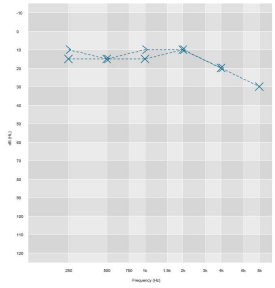
- Following a successful trial in the clinic, Steve elected to move forward with a Baha Connect in the left ear
- He successfully uses his Baha every day and reports it is so comfortable he sometimes forgets he is wearing it

"I love using the Baha to talk on my iPhone – I didn't expect that it would be so clear to use the phone."
-Steve

CASE 2

Lia





- Lia is a 62 year old woman with a congenital hearing loss in the right ear. Recently, she has noticed some loss of hearing in her good ear and she is struggling to communicate at work.
- Lia is a florist who owns her own shop. She is very active and does not plan on retiring any time soon!
- Lia has not tried any previous treatment options for her hearing loss

Audiogram thresholds:

L	WRS	250	500	750	1000	1500	2000	3000	4000	6000	8000
BC		10	15		10		10		20		
AC	96%	10	15		15		10		20		30

R	WRS	250	500	750	1000	1500	2000	3000	4000	6000	8000
BC			15		10		15		20		
AC	0%	10	15		15		25	30	15		20

CASE 2

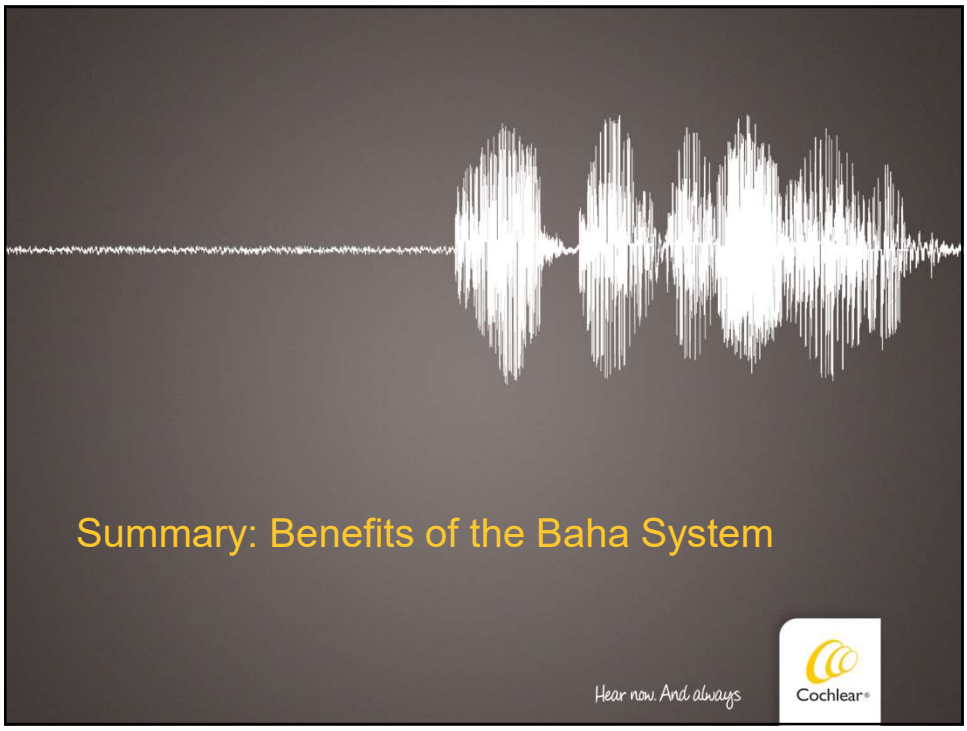
Lia - outcome

	SNR loss (Quick SIN)*
Unaided (pre-op)	12 dB
Baha on softband (trial)	8 dB
Baha on abutment (post-op)	7 dB

*lower number is better

- Lia's clinician discussed treatment options and she opted to trial the Baha first
- She loved the sound of a Baha 5 Power on the softband and elected to proceed with the Baha Connect
- Lia uses her Baha daily and especially likes using the Mini Mic 2+ at work with her colleague

"I barely notice my Baha but my employees at work definitely notice if I don't have it on!"
-Lia



Benefits of the Baha® System for SSD

Cochlear

- Improved sound quality due to direct bone conduction
- May report a sense of directionality due to increased sensation of sound on side with loss
- Improved speech understanding in noisy environments.
- Long term patient satisfaction and hearing benefits
- Try before you decide

Compared to CROS Hearing Aids:

- No need to wear hearing devices on both ears
- No occlusion of the hearing ear

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