



**Trends in Bone Conduction:
The New Cochlear™ Baha® SoundArc**

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Feb. 27, 2018

Hear now. And always.



Agenda



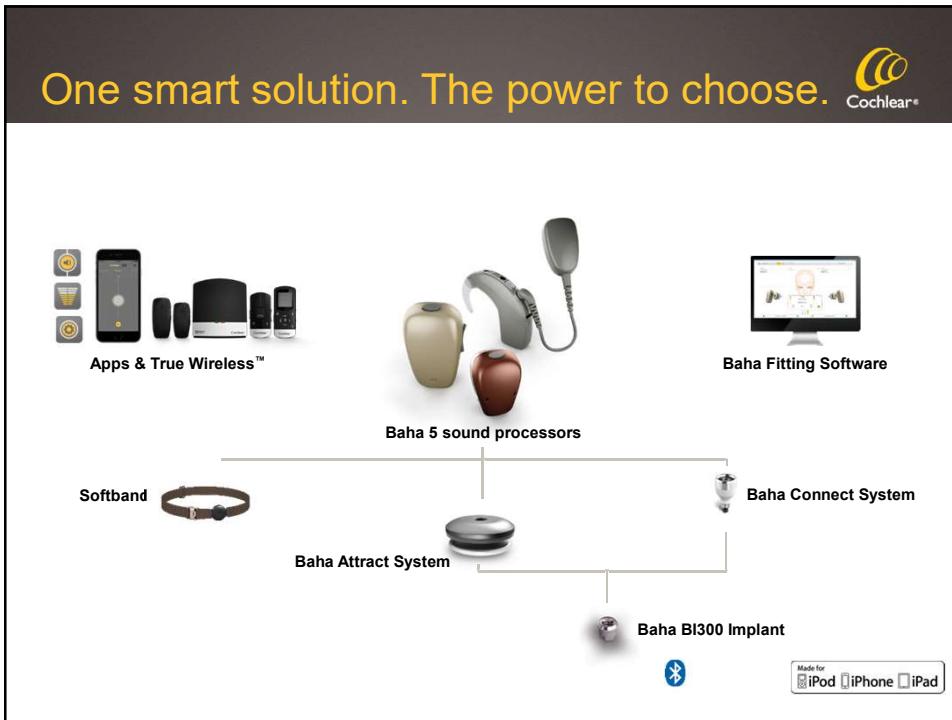
- Treating patients with Baha® Solutions
- Introducing the Baha SoundArc
- Using the Baha SoundArc for better demos
- Baha SoundArc for non-surgical candidates
- Fitting the Baha SoundArc
- Counseling patients
- Q & A

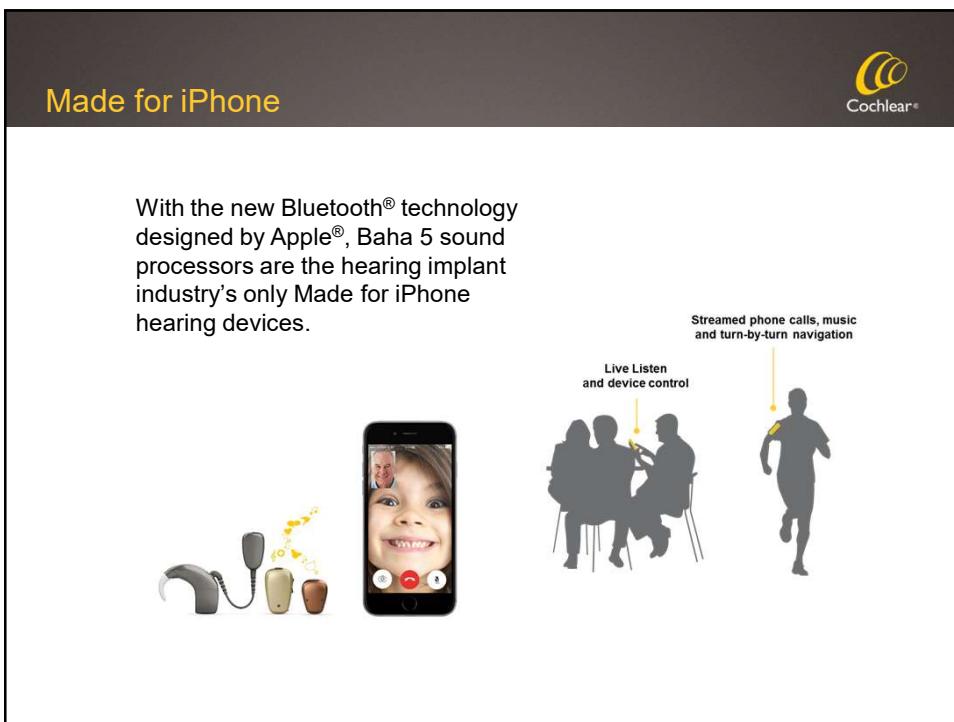
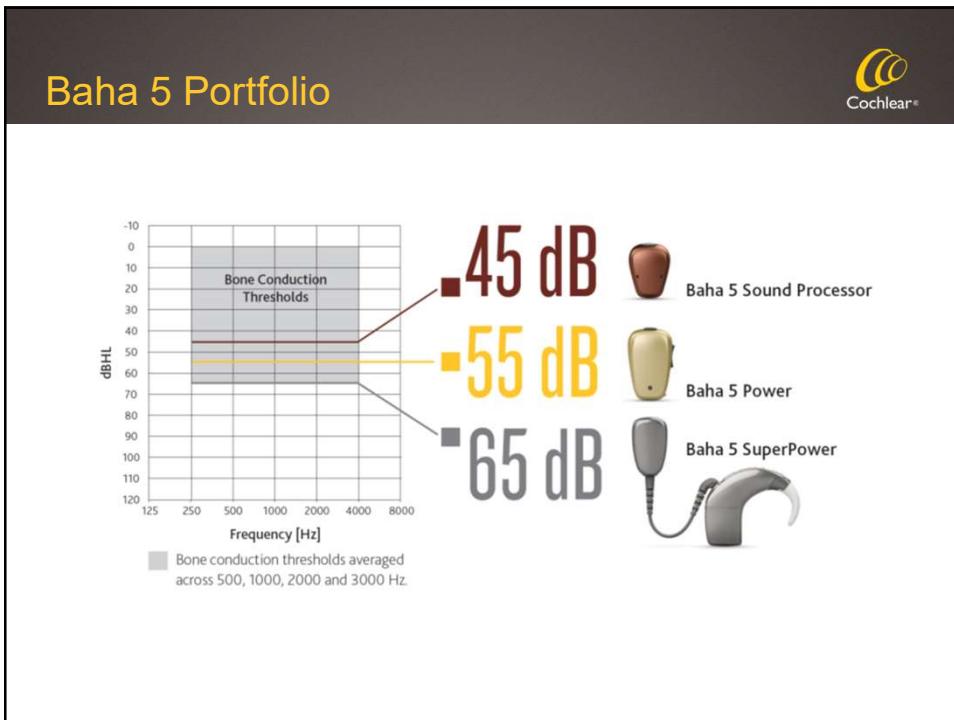


Audiology Online Learning Objectives



- List up to three pediatric-friendly features of the Baha® SoundArc
- Describe both candidacy and indications for the Baha SoundArc
- Explain the daily care and use of the Baha SoundArc to parents/children
- Report on the clinical data related to sound transmission between the Baha® Softband and the Baha SoundArc





True Wireless™ Accessories



Phone Clip

- Stream phone calls directly to the sound processor.
- Answer and adjust the volume just by pushing a button.
- Works with many Bluetooth® enabled devices and MP3 music players.

Mini Mic 2/2+

- Hear better over a distance and in noisy listening situations
- Place near the source of the sound
- Helpful for sounds coming from the side opposite the sound processor.

TV Streamer

- Watch TV without blasting sound all through the house.
- Or constantly ask, "What did they say?"
- The sound processor works like a second, wireless speaker for the TV.



Conductive & Mixed Hearing Loss (CMHL)

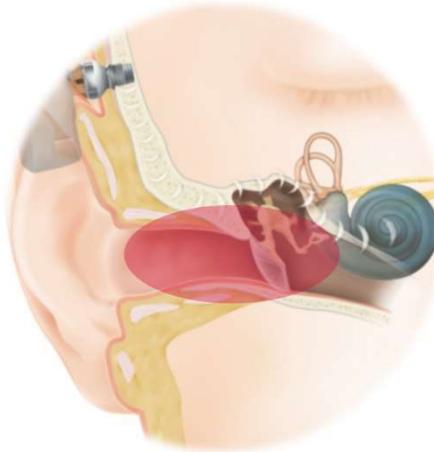
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Conductive & Mixed Hearing Loss (CMHL)



- 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



Treatment Options for CMHL: Middle Ear Surgery



- Common middle ear surgeries include tympanoplasty, ossiculoplasty and stapedectomy
- 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 dB⁶, although that number drops to 64% for revision surgeries⁷

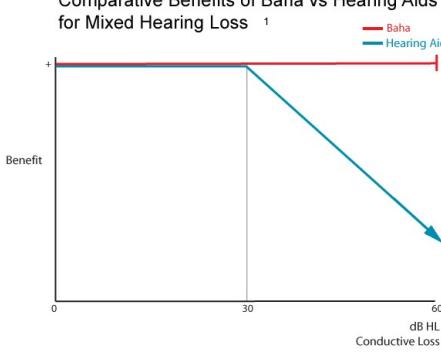
1 - Hall MJ, Schwartzman A, Zhang J, Liu X. Division of Health Care Statistics. National Health Statistics Reports: Ambulatory surgery data from hospitals and ambulatory surgery centers: United States, 2010, Number 102 (February 28, 2011).
 2 - Iniguez-Cuarter R, Alcalid I, Bores-Domenech A, Menendez-Colino L-M, Chalero-Borrego M, Bernat-Sprekelsen M. (2010) Type III tympanoplasty with titanium total ossicular replacement prosthesis: Anatomic and functional results. Otolaryngology & Head and Neck Surgery, 143(3):460-465.
 3 - Cox MD, Trindade A, Russell JS, Domhoff JL. (2017) Long-term hearing results after ossiculoplasty. Otol Neurotol, 38(4):510-515.
 4 - Stanicovic MD. (2005) Audiologic results of surgery for otosclerosis. Short- and long-term follow-up of 100 cases. Otolaryngology & Neurology, 20(7):853-856.
 5 - Gulyas F, Spreng BE, Kammann GB, Dierck RA, Prostakow BP. (2005) Middle ear ossicle reconstruction using interposition. Hearing results and analysis of the middle ear risk index. Otolaryngology & Neurology, 20(5):853-858.
 6 - Vincent R, Sperling NM, Oates J, Jindal M. (2008) Surgical findings and long-term hearing results in 3,050 stapedotomies for primary otosclerosis: a prospective study with the otology-neurology database. Otol Neurotol, 27(8 Suppl 2):S25-47.
 7 - Vincent R, Srovers M, Zingade N, Oates J, Sperling N, Deveze A, Golman W. (2010) Revision Stapedotomy: operative findings and hearing results. A prospective study of 652 cases from the otology-neurology database. Otol Neurotol, 31(8):875-82.

Treatment Options for CMHL: Hearing Aids



Hearing Aid

Comparative Benefits of Baha vs Hearing Aids for Mixed Hearing Loss¹



- The greater the air-bone gap, the more a Baha system will outperform hearing aids²
- Hearing aid prescriptions for conductive and mixed hearing loss require more gain and receive less clinical research than for sensorineural hearing loss³
- Hearing aid fitting can be difficult if there is drainage from the ear, ear pain or a mastoid cavity present after mastoidectomy⁴

1 - Strik AF et al. (2005) Consensus Statement on the Baha System: Where Do We Stand at Present? *Annals of Otol, Rhinol & Laryngol.* 114(12): 105-112
 2 - Mylanas EAM, van der Poog K, Strik M (1998) Intra-individual 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, Donthoffer JL. (2013) Hearing aid tolerance after revision and obliteration of canal wall down mastoidectomy cavities. *Otolaryngology.* 34(4):711-4.

Baha System for CMHL



- ✓ For Baha 5 and Baha 5 Power sound processors, there is nothing worn on the external ear, which is helpful in cases where ear drainage is present¹
- ✓ Baha 5 sound processors do 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 benefit²
- ✓ Use of Baha 5 sound processors are 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 Pediatr 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 - Stærde ISK, Andreassen R, 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.

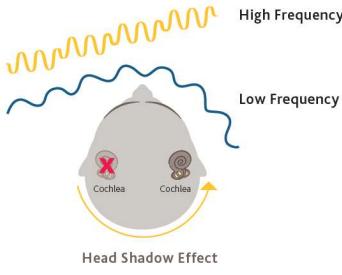


Single-Sided Deafness (SSD)

Hear now. And always.



Two Ears



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

Impact of SSD

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Which problems have you experienced since becoming single sided deaf?

Problem	% of respondents
Difficulties in public areas	5
Difficulties in meetings	2
Discerning direction	6
Difficulties as a pedestrian	56
Cannot be part of a group	54
Social exclusion	55
Lack of "stereo" hearing	79
Work is more difficult	39
Driving difficulties	19
Difficult on telephone	41

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.

Benefits of the Baha System

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- Improved speech understanding in noisy environments¹
- Helps to lift the head shadow effect¹⁻⁴
- Reduces the psychosocial consequences associated with hearing impairment^{1,5-6}
- Long-term patient satisfaction and hearing benefits⁷⁻⁸

1. Hol MKS, Bosman AJ, Snik AFM, Mylanus EAM, Cremers CWRJ. "Bone anchored hearing aids in unilateral inner ear deafness: an evaluation of audiological and patient outcome measurements." *Otol Neurotol* (2005;26): 999-1006.
 2. Lin LM, Bowditch S, Anderson MJ, May B, Cox KM, Zengino 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." *Otolaryngology Head Neck Surg* 2007; 137:172-82.
 3. Puri KK, Kellman C, Ravi T, Patel N, Jindra M, Friedman O, Corcoran D, Jiang D. "Outcome of bone-anchored hearing aids for single-sided deafness: A prospective study." *Acta Oto-Laryngologica*, Early Online 1-5.
 4. Wazni U, Spitzer JB, Ghossain SN, et al. "Transcranial contralateral cochlear stimulation in unilateral deafness." *Otolaryngology Head Neck Surg* 2003;129(3):248-54.
 5. Newman CW, Sandridge DA, Wodzis 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, Rawn 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, Blagini M, Lazzarino Al, Monini S. "Hearing and quality of life in a south European BAHA population." *Acta Oto-Laryngologica*. 2010 130: 1040-1047.

Baha System vs CROS Aids



- ✓ The Baha system is a discreet solution worn on one side, while CROS hearing aids require users to wear devices on both ears
- ✓ Baha 5 sound processors allows wireless streaming to be mixed with environmental mic from the bad side while CROS aids require turning off the bad side in order to stream¹
- ✓ Baha 5 sound processors are the only 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 ear²
- ✓ Studies show that the Baha System provides better speech understanding in noise than CROS hearing aids³⁻⁴

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. *Otolaryngology*, 2003 Jan;24(1):73-78
 4 - Hol MKS, Bosman AJ, Snik AFM, Mylanus EAM, Creemers CWRJ. "Bone anchored hearing aids in unilateral inner ear deafness: an evaluation of audimetric and patient outcome measurements." *Otol Neurotol* (2005;26): 999-1006.



Introducing the
Cochlear™ Baha® SoundArc

Hear now. And always.



Hearing technology has evolved fast

Sound processors now feature state-of-the-art signal processing, Made for iPhone technology and direct-to-device wireless streaming.

These are modern devices for a modern world.

Made for iPod iPhone iPad



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Demo technology has not moved on



Headband Testband

They work well but they are not always:

- Comfortable
- Discreet
- Easy to use



A need for an alternative choice



- The Baha Softband is a good solution for small children
- But for older children there is an opportunity to provide an alternative option



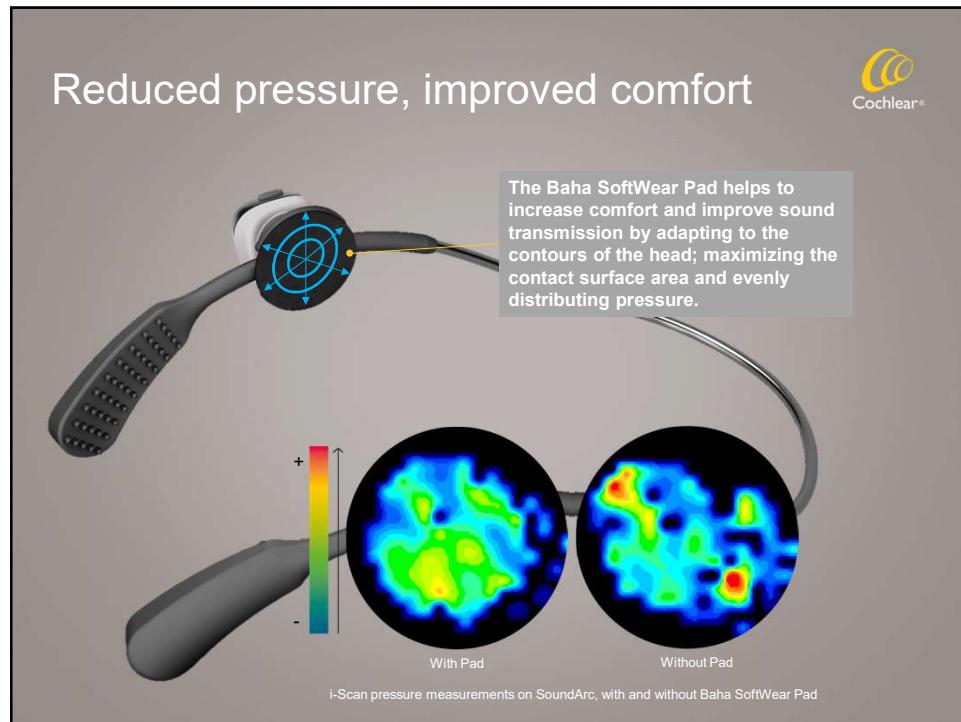
The goal



- Ensure patients feel comfortable and confident in the demo experience
- Help more people discover the potential benefits of bone conduction
- Provide an alternative to the Baha Softband







Stylish, light and discreet



The Baha SoundArc is designed to flow with the contours of the head. Its discreet, unique and modern look is designed to appeal to patients.

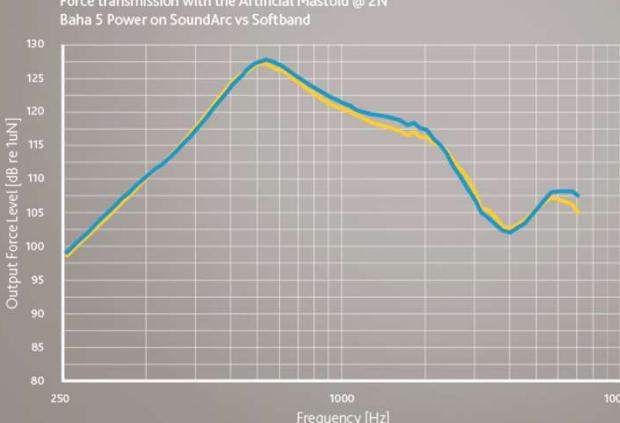



Effective sound transmission



The Baha SoundArc delivers equivalent sound transmission to the Baha Softband¹.

Force transmission with the Artificial Mastoid @ 2N
Baha 5 Power on SoundArc vs Softband



Output Force Level [dB re 1uN]

Frequency [Hz]

Average SoundArc Average Softband



1. Johansson, C. Sound transmission measurements of the Baha SoundArc. Cochlear Bone Anchored Solutions AB, D1122021, 2017.

Excellent patient ratings¹

Scores of at least
4/5
in all demo ratings

- Excellent comfort
- Great sound quality
- Stylish aesthetics
- Strong retention
- Easy to use
- Good speech understanding

At home, 85% of patients were satisfied with their overall SoundArc experience.¹

1. First clinical experiences with Baha SoundArc. Cochlear Bone Anchored Solutions AB, D1247007, 2017.

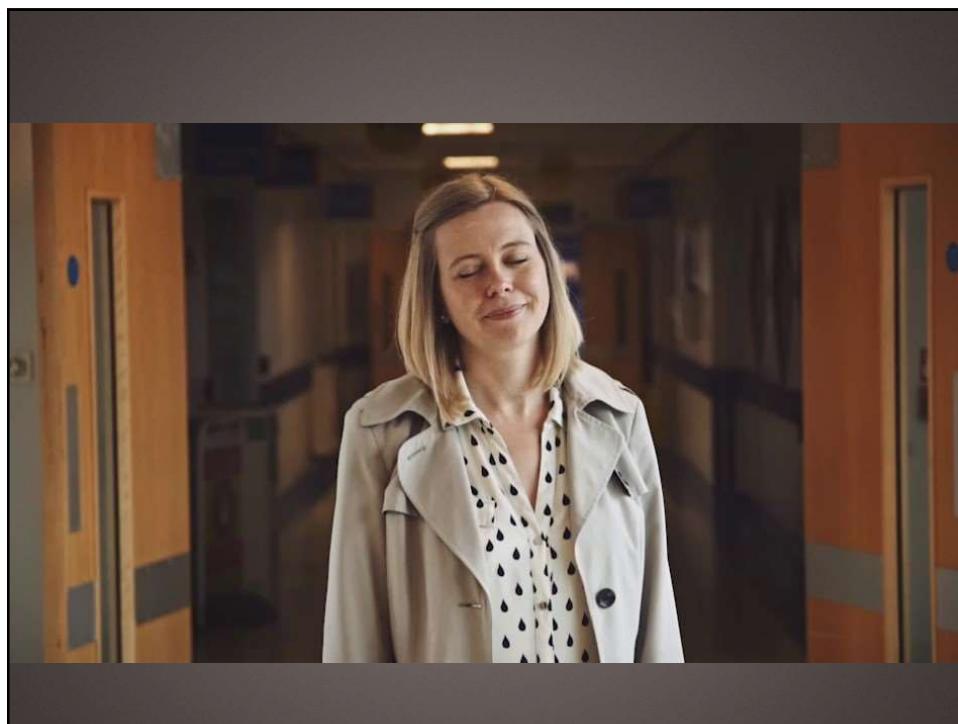
The Baha SoundArc provides:

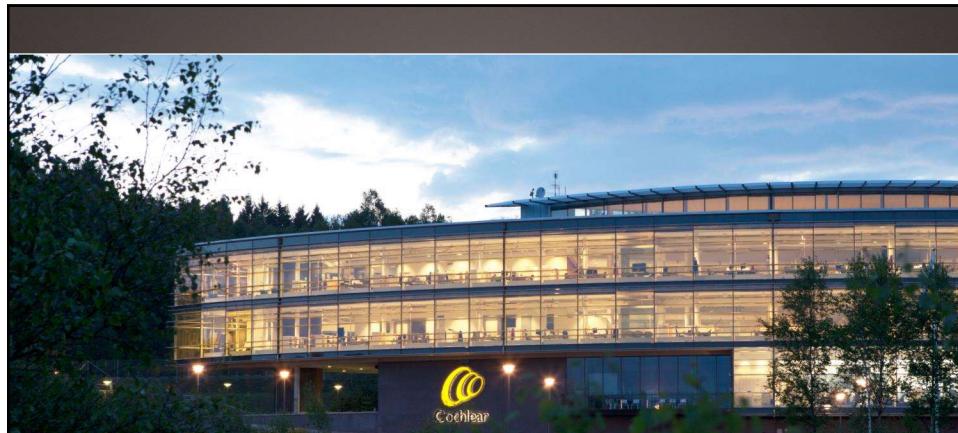
A better demo experience.



A new, cool and exciting option for kids.







The image shows the exterior of a modern, multi-story building with a curved glass facade. The building is illuminated from within, and the Cochlear logo is visible on the side. The sky is blue with some clouds, suggesting dusk or dawn.

Using the SoundArc for Better Demonstrations

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Baha Experiences



Baha Demonstration

- A quick, limited Baha experience
- Processor may be used in “demo” setting and not programmed
- May be completed by surgeon, audiologist, tech, etc.

Baha Evaluation

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

Baha 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

Baha Demonstration



The slide features three images: a close-up of the Baha 5 Power processor, a side view of the Baha 5 system showing the processor and the bone-anchored transducer, and a circular inset showing a hand placing the transducer onto a person's ear.

- Baha 5 Power is recommended for Demonstrations
- Set up “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*)

Baha Evaluations



The slide features a list of benefits of Baha evaluations and a photograph of a healthcare professional adjusting a Baha device on a patient's ear.

- 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):288-64
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.

Baha Trial



• Select the Baha Sound Processor most appropriate for the patient's hearing loss
• Fit the sound processor on a SoundArc (for adults and older children) using Baha Fitting Software
• Instruct the patient on use of the SoundArc and sound processor
• Ask the patient to keep a journal or log of their experiences



Baha Pre-operative Suggestions



- Use the Baha SoundArc for evaluations and trials
 - Clean the SoundArc thoroughly with alcohol wipes and replace the Baha SoftWear Pad between users
- Provide a "take-home" experience whenever possible
- Utilize an evaluation with formal testing when possible to establish benefit
- Fit the processor for an evaluation the same way you would for a fitting (i.e. using Baha Fitting Software)



Baha SoundArc for Non-Surgical Candidates

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Non-surgical Options for Baha

Baha SoundArc
Good performance,
comfortable, stylish and
discreet

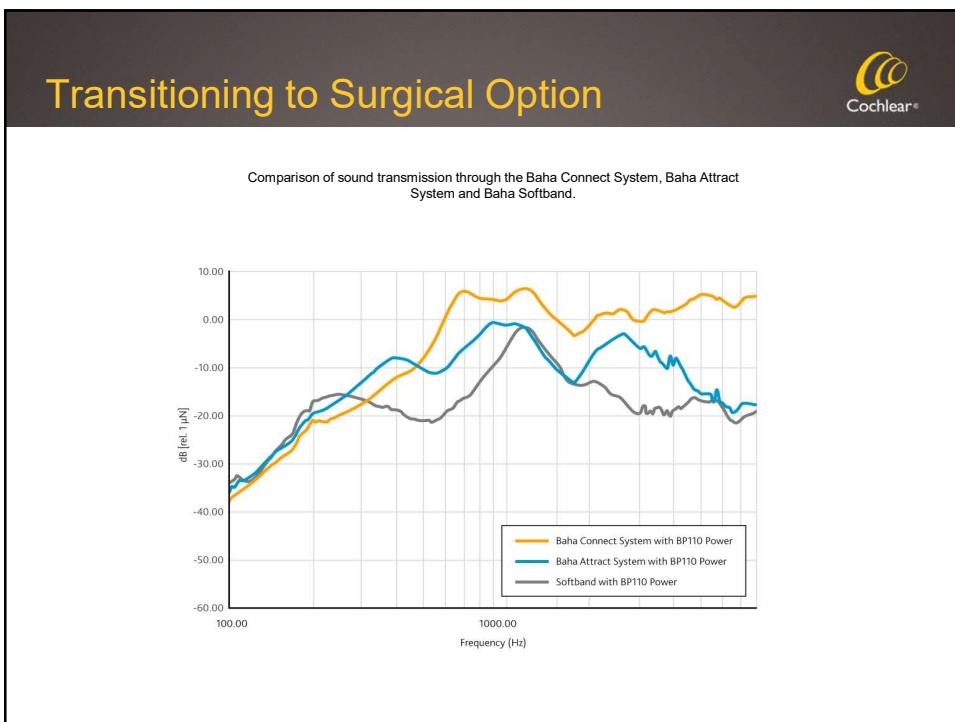
Baha Softband
Good performance,
comfortable, optimal for
young children

Cochlear®

Candidates for a Non-Surgical Option



• Children under the age of 5
• Children over 5 who are not yet surgical candidates
• Medically compromised patient
• Patient preference
• May be a “gateway” to surgery





Baha SoundArc

The Baha SoundArc is available in four sizes: Small, Medium, Large and Extra Large. It is delivered as unilateral and it is possible to create a bilateral version by adding a second Connector Disc.

Available in four sizes: S, M, L, XL

Silicone soft tips with grips for optimal retention

Movable Connector Disc to attach the sound processor.

Bilateral version

Note: The Baha SoftWear Pad should always be used.

Prepare to fit the Baha SoundArc



- The Connector Disc is movable. Slide the Connector Disc on to the soft tip on the left/right side. (Fig 1)
- Attach a Baha SoftWear Pad to the Connector Disc. (Fig 2 step I-III)
- Attach the Baha Sound Processor to the Connector Disc. (Fig 2 step IV)



Fitting the Baha SoundArc



- The SoundArc should be placed just **above the ears and follow the contours of the head**. It should not rest on the **pinna**. Always attach a Baha SoftWear Pad on to the Connector disc(s). The bow should rest against the back of the head.
- The Connector disc is the primary point of contact. Always ensure that the entire area of the **Connector disc sits flush against the skin** on the head above and behind the ear; it should not wobble.
- Ensure the Connector disc is in **direct contact with the skin** under the hair. It may be necessary to move or part the hair.
- The soft tips should rest comfortably and slightly **in front of the ear**.



Fitting the Baha SoundArc (cont.)



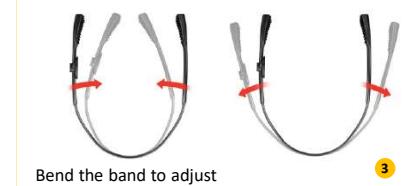
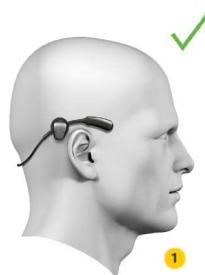
5. Ensure the SoundArc is **optimally fit on patient head prior to programming the sound processor** using Baha Fitting Software.
6. Fit the SoundArc with **any accessory in place**, like glasses, hats or other headworn accessories, so that it can be removed without affecting the position of the SoundArc and/or feedback measures.

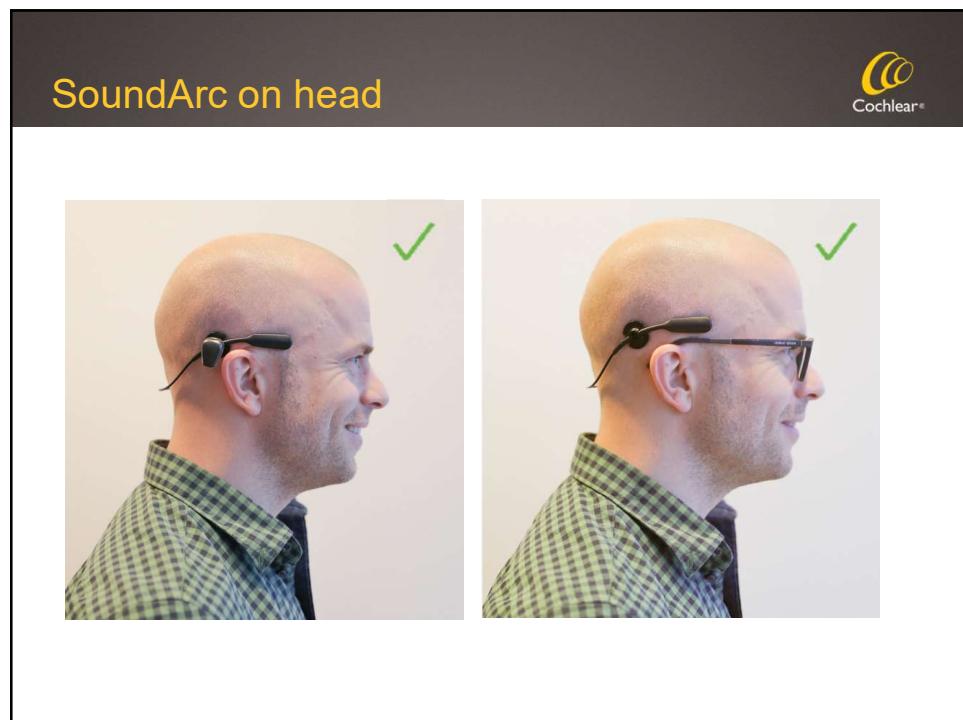
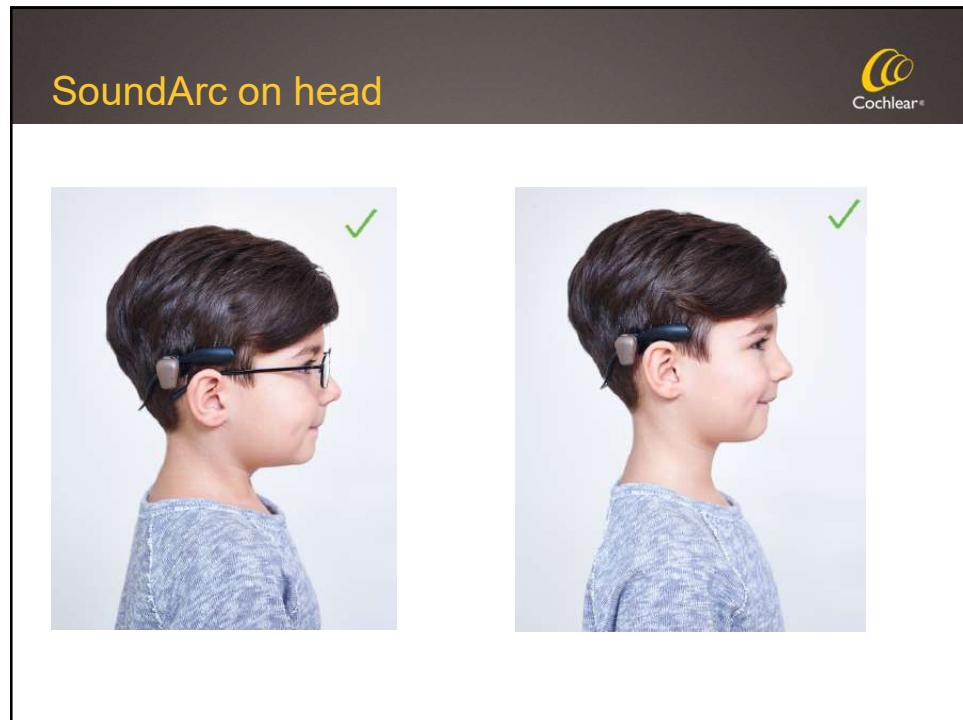


Customize the fit



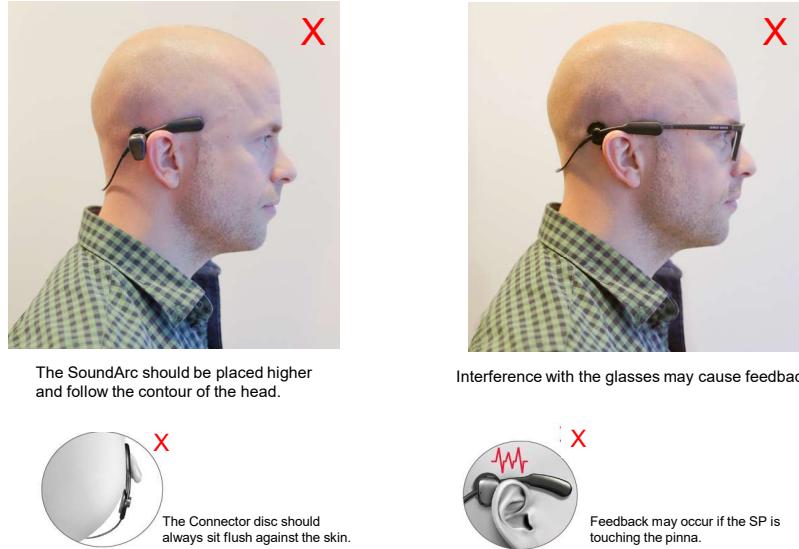
- The Baha SoundArc should sit comfortably and follow the contours of the head. Fig 1
- Ensure the Connector Disc continues to sit firmly against the head.
- If the patient feels discomfort, adjust the Baha SoundArc as shown in Fig 2-3 below.
- If comfort issues persist after adjustment, reduce the pressure by adding a second Connector Disc on the opposite side (See slide: *Assemble a bilateral Baha SoundArc*).





SoundArc on head





The SoundArc should be placed higher and follow the contour of the head.

Interference with the glasses may cause feedback.

The Connector disc should always sit flush against the skin.

Feedback may occur if the SP is touching the pinna.

Assemble a bilateral SoundArc



Bilateral version

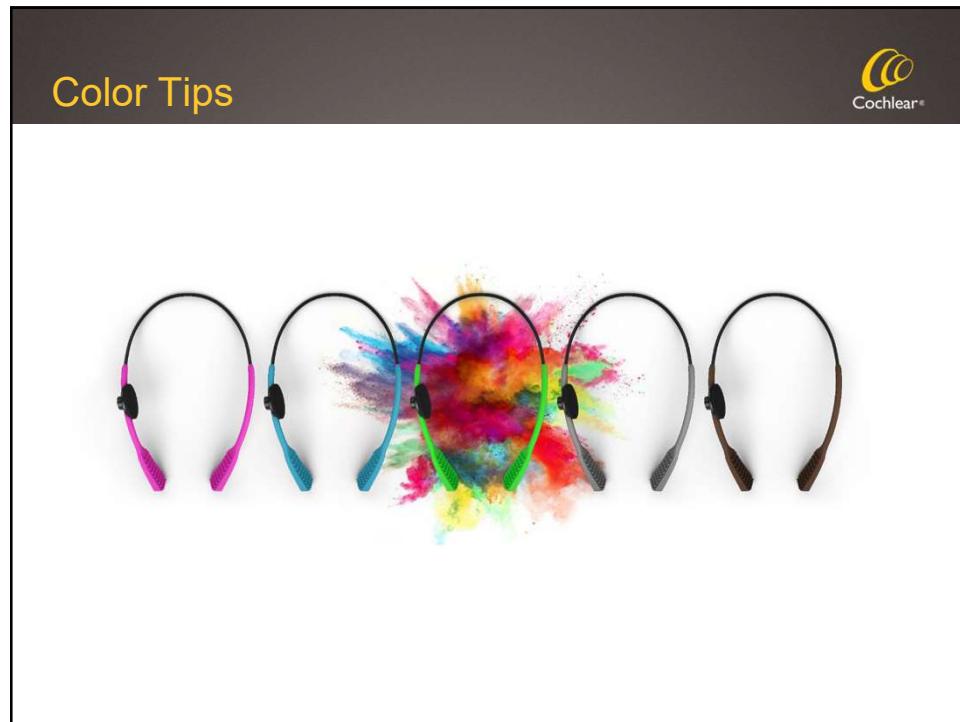
- To assemble a bilateral SoundArc, add a second Connector disc
- It is ordered separately as a spare part.
- Follow the steps as shown below in Fig 1-3.







Slide one of the tips off Add the second Connector disc Slide the tip back on



How to change a color tip

How to change tips

- The best way to change the tips is to roll the tip between your fingers while pulling it off the band. (Fig 1)
- With a new tip in place at the end of the band, repeat the procedure in the opposite direction while rolling and pulling the tip on the band. Ensure the tips have reached the end of the band. (Fig 2-3)
- Slide the Connector disc back on the tip. (Fig 3)

① Slide the tips off
② Insert the color tips
③ Slide the connector disc tip back on

Fitting Tips

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Prior to leaving the clinic

- Have the patient practice taking the Baha SoundArc on and off
- Counsel the patient on proper placement of the Connector disc
- If the patient wears glasses, make sure to try the Baha SoundArc with glasses

*Clean the SoundArc thoroughly with alcohol wipes and replace the Baha SoftWear Pad between users.

Ensuring a comfortable experience

- Instruct the patient on how to adjust and bend the Baha SoundArc for increased comfort
- Use the Baha SoftWear Pad
- Gradually increase wearing time over the first days
- If prolonged redness or soreness occurs, temporarily discontinue use
- Advise the patient to contact you if discomfort persists

Tips to ensure the best experience

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The SoundArc should sit comfortably. Adjustment of the SoundArc may require **firm bending** for comfort, retention or good contact of the Connector disc.

- **If the SoundArc falls backward, is not well retained or there are gaps at back of the head:**
Bend open at point A and inwards at points B. Fit on patient head and check placement of the Connector disc and the location of soft tips.
- The Connector disc **should sit flush against the skin** on the head under the hair, it may be necessary to part the hair to ensure correct placement.
- **If the soft tips sit too far forward:** change to a smaller size.
- **If the soft tips sit too far back:** change to a larger size.



Best practices for professionals

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- Always use the Baha SoftWear Pad.
- Tell the patient to gradually increase wearing time over the first few days.
- Advise the patient to contact you if discomfort persists.
- In a demo situation, clean the SoundArc thoroughly with alcohol wipes and replace the Baha SoftWear Pad between users.

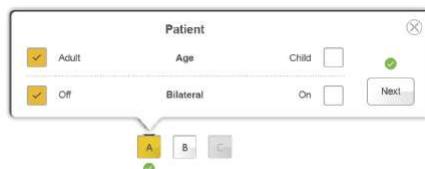



Programming with Baha Fitting Software 5.3

BC select settings BFS 5.3

- Age : Choose Adult or Child setting as applicable. (Fig 1)
- Bilateral: On or Off as applicable. (Fig 1)
- Indication as applicable. (Fig 2)

1



2

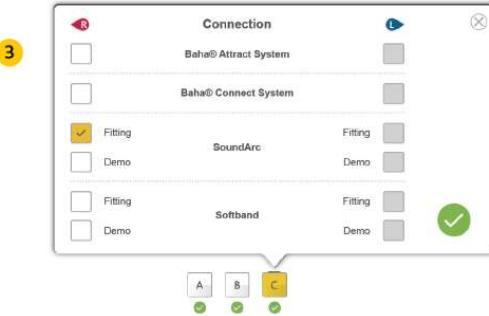


Programming with BFS 5.3 (Cont.)



BC select settings BFS 5.3

- Connection: Choose SoundArc, Fitting. Fig 3
- Run the Feedback Analyser. If feedback issues persist, reduce the gain.
- Proceed with the fitting according to the normal fitting procedure for a Baha sound processor.
- Confirm the sound quality is good for the patient. If not, fine tune.




Counseling Patients

Hear now. And always.



Case #1



• 14 year old girl with bilateral atresia and microtia on the left

• Used Softband successfully when she was younger, but switched to a hearing aid in the right ear only when she was 10 due to cosmetics

• Hearing aid does not provide enough gain and parents feel she does not hear as well with the hearing aid as she did with Softband

• Patient is very reluctant to try anything that will make her look “different”



Review

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Key Takeaways



- The Baha System has several **advantages over other treatment options** for patients with conductive/mixed hearing loss and single-sided deafness
- The new Baha SoundArc can help candidates have a **more comfortable** and confident demonstration experience
- The new Baha SoundArc is an excellent choice for **older children** who must continue to use a non-surgical option
- Counseling for any Baha System should focus on **connecting the patient's goals** to the outcome expected



Questions?



