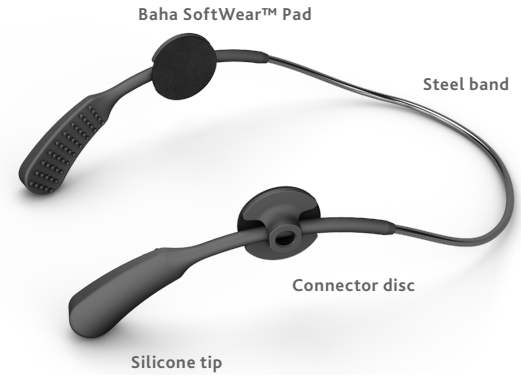
Design concept, technical verification and patient testing of the new Cochlear™ Baha® SoundArc

Before the first implantable Cochlear™ Baha® System was launched, one of the only solutions available to those that could not benefit from air conduction hearing aids was bone conductors fitted to steel headbands or glasses. Although it is commonly agreed that a pre-operative trial is important to provide candidates with realistic expectations,[1-3] similar devices are still being used for patients testing bone conduction as part of the counselling process for an implantable solution. In 2002, the Baha Softband was developed by Cochlear as a solution for children that were too young, or not ready for an implantable solution. This device has sometimes been used as a demo solution, providing a more comfortable alternative to headbands or testbands. However, the aesthetics of the Softband do not appeal to everyone. Indeed, previous research has shown that the most common reason to reject the proposal of an implantable bone conduction solution is the cosmesis.[4] It could be hypothesized that the use of steel headbands and the Softband as demonstration devices have created additional barriers to the adoption of an implantable solution. Clinicians have also raised concerns that for older children that reject the Softband due to aesthetics there is no alternative solution, which in the worst case may leave them without amplification. This whitepaper summarizes the outcomes from the testing performed on the Cochlear Baha SoundArc to ensure it meets the expectations of users and their hearing care professionals.

Introduction



The Baha SoundArc is designed to sit over the ears and be worn behind-the-head with a Baha sound processor attached to the Connector disc. The SoundArc is made of a steel band with two silicone tips fitted on either side of the head serving the dual purpose of increasing comfort and securing retention. The sound processor, attached to the Connector disc, is positioned over the silicone tip to ensure stability of contact and to isolate vibrations from the band improving the feedback performance. A Baha SoftWear™ Pad is attached on the Connector disc to improve sound transfer efficiency and increase comfort. The SoundArc is delivered in a unilateral configuration and a second Connector disc can be added if a bilateral fitting is desired. As standard, both the band and the silicone tips are black. However, colored tips are available in a Color Kit to allow the patient to customize the look of their SoundArc. When designing the concept's discreet behind-the-head look, efficient sound transfer and wearing comfort were top priorities. Multiple iterations of both design and shape were required before a solution could be delivered that met the requirements for discreetness, efficiency, comfort and retention.

Technical verification

To serve as an effective demo tool or a long term solution, the SoundArc has to provide similar or better performance compared to existing solutions. The SoundArc was therefore compared in technical tests to the Baha Softband, the Headband and the Testband *(Figure 1)*.

When thinking about the performance of non-surgical bone conduction solutions, rely mainly on two factors: sound transfer efficiency and minimizing feedback. To assess sound transfer efficiency, the solutions were mounted on an artificial mastoid using the pressure typically provided by the respective solution (SoundArc 2 N, Softband 2 N, Headband 4 N and Testband 6 N). A Cochlear Baha 5 Power Sound Processor was fitted to each solution and the output force level was measured. The actuator in the sound processor was excited electrically using a stepped sine sweep from 100 to 10,000 Hz. As seen in *Figure 2*, the SoundArc and Softband provide similar sound transfer efficiency and both the Testband and Headband are slightly less efficient above 2,000 Hz.

To assess the feedback properties, the solutions were mounted on an anatomically model which was placed in an acoustic booth.

Three feedback measurements were performed for each solution using the Feedback Analyzer in the Baha Fitting Software 5.2 and the average feedback level for each solution is shown in *Figure 3*. Lines above -40 dB in the graph indicates a high risk for feedback and hence there is less feedback but a greater amount of gain. Similar to the sound transfer efficiency tests, the performance of the SoundArc and Softband were comparable. However, the Headband and Testband performed significantly worse, particularly in the mid frequencies.

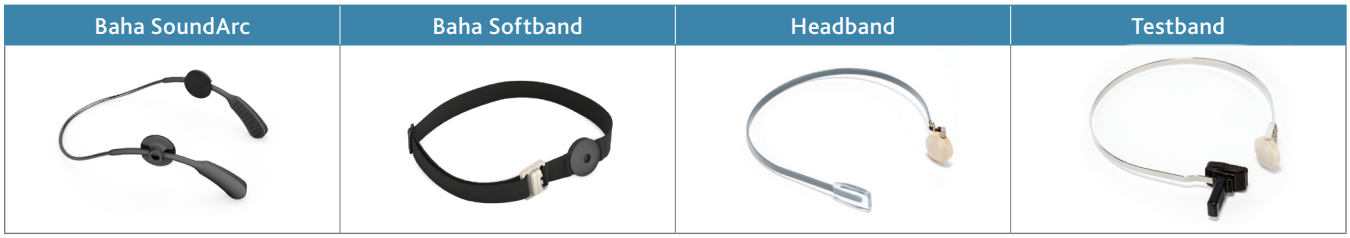


Figure 1. Compared concepts

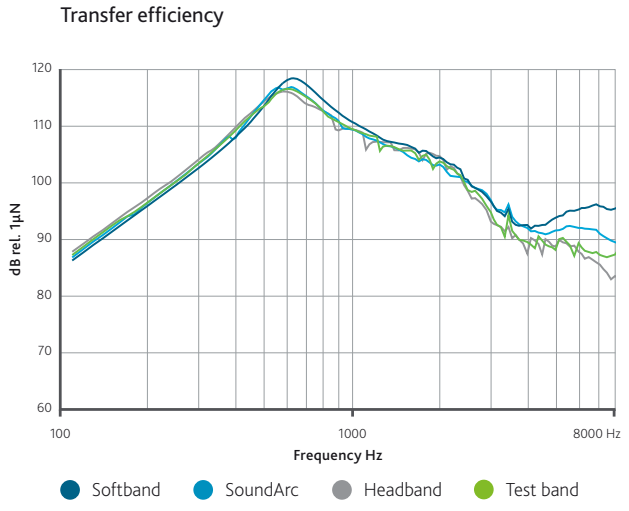


Figure 2. Transfer efficiency of the Baha SoundArc compared to the Baha Softband. Both were mounted on an artificial mastoid.

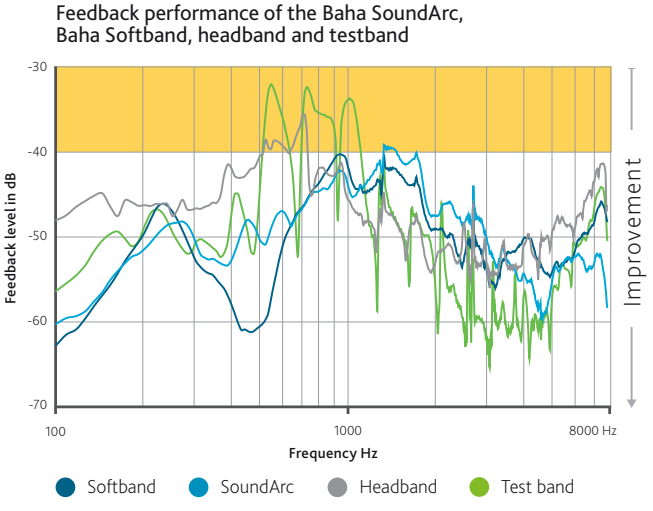


Figure 3. Feedback performance of the Baha SoundArc, Baha Softband, Headband and Testband.

The feedback performance of a bilateral fitting was also measured. This test demonstrates that the vibrations from one side did not cause feedback signals on the other. The SoundArc was fitted bilaterally with two Baha 5 Power Sound Processors, where both the microphones and actuators were directly connected to a control unit to facilitate measurement of open loop feedback on both the stimulated side and the non-stimulated side. As expected, the feedback signal was stronger on the stimulated side, indicating an adequate contralateral dampening of the signal *(Figure 4)*.

In summary, the technical verification of the SoundArc demonstrated equal performance to the Softband and superior performance to the Headband and Testband.

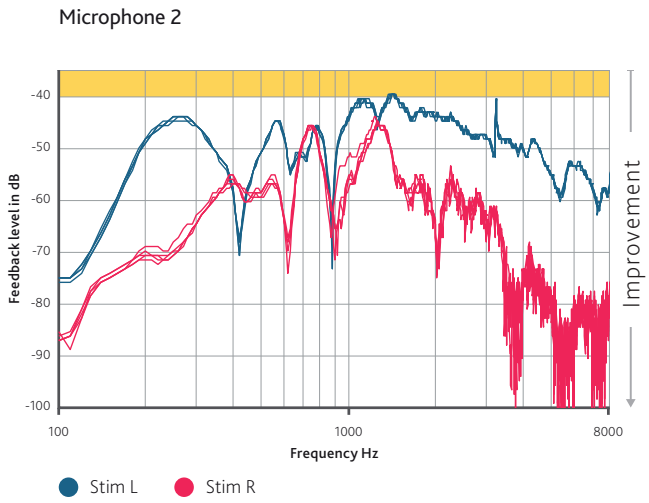


Figure 4. SoundArc fitted with bilateral sound processors. Signal on left side and measurement of open loop feedback on right and left side. Lower values on right side indicate adequate damping of signal on non-stimulated side.

First Experience Program

To gain insights from the market the SoundArc was used by five UK clinics in a First Experience Program (Freeman Hospital, Central Manchester University Hospital, Countess of Chester Hospital, Sheffield Teaching Hospital and Nottingham University Hospital). A total of 41 patients were included: 14 children (below 18 years old) and 27 adults. Ages ranged from 6-85 years with a mean age of 44 years. 34 patients had a conductive-mixed hearing loss and seven patients had single-sided sensorineural deafness (SSD).

Two types of evaluations were performed:

- Demonstration of hearing through bone conduction using the SoundArc in the clinic.
- Home test of the SoundArc where patients used it in everyday situations outside the clinic.

33 patients evaluated the SoundArc in the clinical setting and 25 patients evaluated it during a home trial, 17 patients performed both tests. In the home test patients evaluated the SoundArc or 5-38 days with an average of 13 days.

Cochlear Baha 5 sound processors were used in all cases and the fitting range of the sound processor was adapted to the bone conduction thresholds of the patients *(Table 1)*. The distribution of SoundArc sizes among the patients can be seen in *Table 2*, indicating that the most common sizes were medium and large.

Selected sound processor	
Baha 5	51%
Baha 5 Power	38%
Baha 5 SuperPower	11%

Table 1. Selected sound processors during patient trials

Size of SoundArc	
Small	16%
Medium	45%
Large	32%
Extra large	7%

Table 2. Size of SoundArc used in the trial

Both the clinicians and patients were asked to complete a questionnaire on their subjective experience with the SoundArc. The focus for the clinicians was to understand the ease of use and fitting procedure. When it came to the ease of locating the correct placement of the Connector disc, this was reported as "Easy" in 83% of the fittings. In patients with long and/or thick hair, the fitting was sometimes reported as more challenging. The shape of the SoundArc was adjusted for 58% of the patients with the fitting of the SoundArc averaging 30 minutes. Fitting included programming the sound processor using the Baha Fitting Software.

Patients were asked to rate the hearing experience, wearing comfort and usability of the solution in a demo situation.

Hearing experience – three aspects of the hearing experience were evaluated: perception of loudness, speech understanding, and sound quality. In terms of loudness, 63% of the patients rated it as just right *(Figure 5)*.

The sound quality and speech understanding were rated by the patients both at first fitting and after the home trial. Importantly, the initial positive ratings remained with small adjustments after the home trial, demonstrating the effectiveness of the SoundArc after initial impressions *(Figure 6)*.

Wearing comfort – users were asked to rate the wearing comfort and retention of the SoundArc, with 88% reporting both the comfort and retention were good or very good *(Figure 7)*. During the home trial they were also asked to compare the comfort and retention between the SoundArc and Softband with 68% of the patients reporting SoundArc to be better or much better than the Softband in terms of comfort. In terms of retention, 60% of patients rated SoundArc as equal to other solutions, with the remaining 20% either preferring SoundArc or Softband respectively *(Figure 8)*.

Usability – users were asked about the ease of use and their rating of the aesthetics. Here 82% of the users rated the SoundArc as good or very good both for ease of use and aesthetics *(Figure 9)*. To evaluate the usability after the home trial we asked the patients how confident they had felt using the SoundArc in different situations. Here 57% were confident or very confident using it during activities and sports, 86% when using it at work and 73% at home. Importantly, this may encourage candidates to evaluate a bone conduction solution outside of the clinic in everyday situations, which is important to allow them to correctly judge the benefit during a trial period *(Figure 10)*.

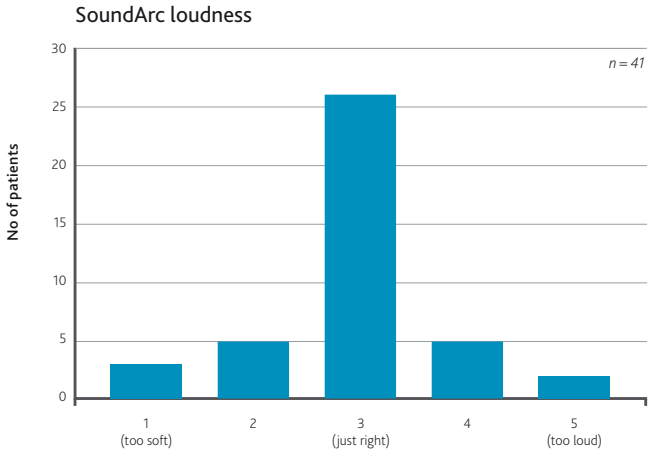


Figure 5. Patient ratings of SoundArc loudness.

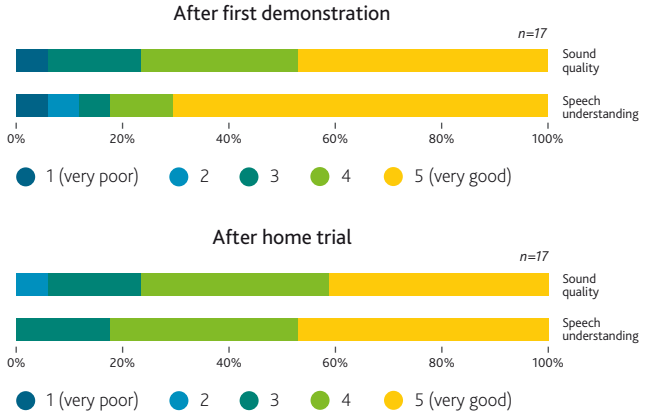


Figure 6. Patient rating of sound quality and speech understanding before and after home trial using the SoundArc.

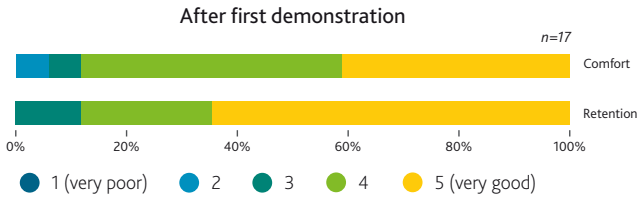


Figure 7. Rating of wearing comfort and retention at demonstration visit.

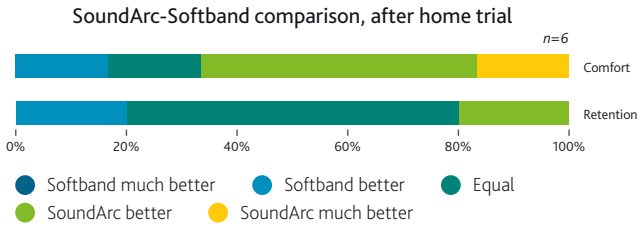


Figure 8. Comparison of wearing comfort and retention between SoundArc and Softband.

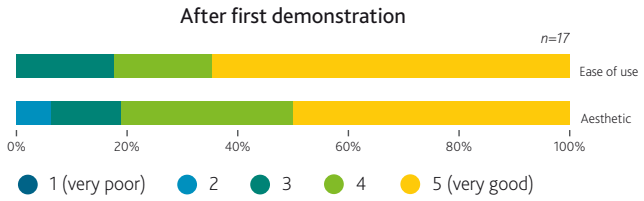


Figure 9. Rating of ease of use and impression of aesthetics before and after home trial.

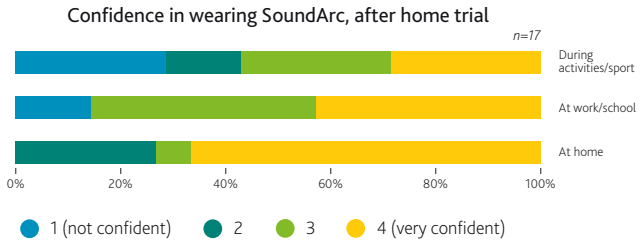


Figure 10. Rating of confidence in wearing the SoundArc in different situations.

Finally, all 24 patients participating in the home trial were asked how they would like to go forward in selecting a solution for their hearing loss. Out of the 16 adult participants, six chose to continue using SoundArc, six opted for an implanted solution, and four declined to use bone conduction (two patients reported they did not get enough amplification, one preferred to continue using their CROS aid, and one did not provide a reason for this preference). Out of the eight children, five chose to continue using the SoundArc, two to get an implanted solution and one of them already had an abutment but wanted to try the SoundArc. These results may indicate that the improved aesthetic and wearing comfort of the SoundArc had a positive impact in allowing candidates to accept a bone conduction solution.

Summary

Substantial technical and research efforts have gone into the development and verification of the SoundArc to ensure it performs well both in the demo situation and during longer term use. The discreet behind-the-head design, combined with the silicone grips for retention and comfort was appreciated by clinicians and patients in the First Experience Program. Whether used as a demo solution for bone conduction hearing or as a longer term solution, the data presented shows that the SoundArc provides a superior solution to the previous Headband and Testband solutions and a good complement to the Softband. We are confident that the SoundArc will provide a beneficial addition to the existing solutions giving candidates the best possible demo experience. This will allow them to evaluate the benefit while feeling confident about aesthetics, which may result in more candidates choosing a bone conduction solution and having more realistic expectations when doing so. Equally important, children that reject the Softband due to aesthetics now have an attractive alternative to the Softband allowing consistent hearing to facilitate speech and language development.

References

1. Desmet J, Bouzegta R, Hofkens A, De Backer A, Lambrechts P, Wouters K, Claes J, De Bodt M, Van de Heyning P. Clinical need for a Baha trial in patients with single-sided sensorineural deafness. Analysis of a Baha database of 196 patients. Eur Arch Otorhinolaryngol. 2012; 269(3):799-805.
2. Pennings RJ, Gulliver M, Morris DP. The importance of an extended preoperative trial of BAHA in unilateral sensorineural hearing loss: a prospective cohort study. Clin Otolaryngol. 2011 Oct;36(5):442-9.
3. Faber HT, Kievit H, de Wolf MJ, Cremers CW, Snik AF, Hol MK.Analysis of factors predicting the success of the bone conduction device headband trial in patients with single-sided deafness.Arch Otolaryngol Head Neck Surg. 2012 Dec 1;138(12):1129-35.
4. Zawawi F, Kabbach G, Lallemand M, Daniel SJ. Bone-anchored hearing aid: why do some patients refuse it? Int J Pediatr Otorhinolaryngol. 2014; 78(2):232-4.

Notes:

www.Cochlear.com/US

Cochlear Americas
13059 East Peakview Avenue
Centennial, CO 80111 USA
Telephone: 1 303 790 9010
Support: 1 800 483 3123

Cochlear Canada Inc.
2500-120 Adelaide Street West
Toronto, ON M5H 1T1 Canada
Support: 1 800 483 3123

BUN655 ISS1 JAN18

Cochlear®