Cochlear™ Baha® System

Bilateral Benefits of the Baha System

A Summary of Clinical Evidence

Hear now. And always

Cochlear®

Bill — bilateral Baha Connect user

Getting the best outcomes for your patients.

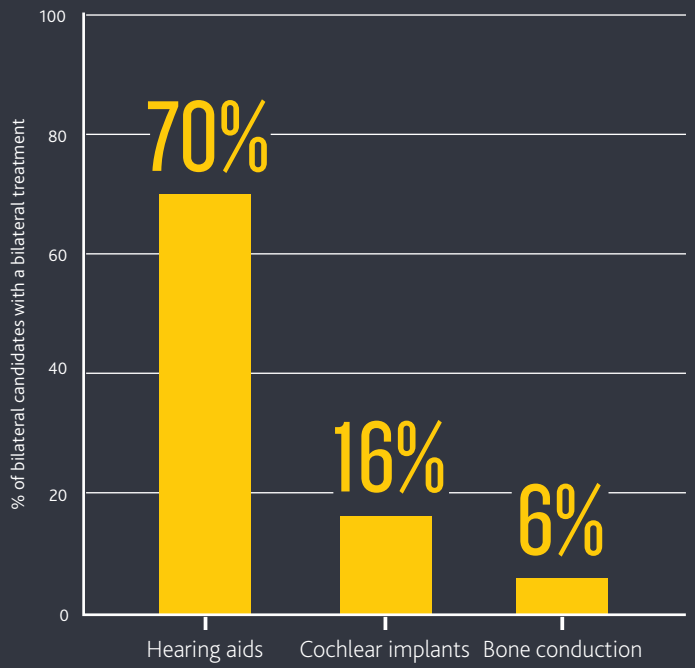
"Two ears are better than one" seems like an obvious statement. And for decades, treating people with bilateral hearing loss with two hearing aids has been the standard of care. The benefits are well established and providing just one hearing aid seems counterintuitive to most.

But what about bone conduction? Do people with bilateral conductive and mixed hearing loss not also benefit from bilateral stimulation? Available clinical evidence suggests that a two ear approach leads to:

- Better audibility through a binaural summation effect[1-3]
- Improved hearing in noise[1-3]
- Enhanced ability to localize sound[4-6]
- Increased quality of life[7, 8]

The intention of this summary is to help clinicians make the best evidence-based treatment decisions for their patients.

Bilateral penetration in ten developed markets[9]



"Bilateral cochlear implants are no longer a big deal. I think the same will happen with bone conduction."

Surgeon, US / Extract from Cochlear bilateral market survey, 2018

Binaural hearing.

Hearing sounds from all around is important in providing a complete soundscape. It is beneficial in all situations, including discussions and meetings at work, in school and at home. A bilateral fitting provides a summation effect leading to improved dynamic range and better hearing in quiet.[1, 2] Additionally, in patients with symmetrical bone conduction thresholds, it has been proven to result in binaural processing in both adults and children leading to improved hearing in noise.[1, 3, 6, 8]

Up to

3.1 dB

improved SNR when going from a unilateral to bilateral fitting[2]

Up to

5.4 dB

summation effect when going from a unilateral to a bilateral fitting[2]

Scientific highlights

Binaural hearing ability with bilateral bone conduction stimulation in subjects with normal hearing: implications for bone conduction aids.[1]

Study:
Comparison of binaural benefits between air conduction (AC) and bone conduction (BC) stimulation in 27 normal hearing subjects.

Outcome:
In all tests used, results with bilateral BC illustrated an ability to extract binaural cues. The level of benefit was overall better with AC stimulation, however, binaural hearing is present in patients using bilateral bone conduction.

Conclusion:
According to the current study there is a clear and significant binaural benefit with bilateral BC stimulation.

Binaural processing is present when stimulation is bilaterally applied by bone conduction.[1]

Bilateral [bone conduction implants] for bilateral permanent conductive hearing loss: a systematic review.[2]

Study:
Systematic review of 11 published studies with a total of 168 subjects included, 146 of whom had bilateral fitting.

Outcome:
Improved hearing sensitivity in quiet, improved speech perception in quiet, improved speech perception in noise in most listening conditions, improved localization/lateralization, improvement in patient perception of quality of life and sound quality. Some patients experienced a deterioration of understanding speech in noise with bilateral [bone conduction] due to loss of the head-shadow advantage for noise to the shadow ear.

Conclusion:
Based on the evidence reviewed in this study, the authors would recommend considering bilateral fitting to all patients with a reasonable symmetrical bilateral hearing loss otherwise indicated for a bone conduction solution.

Bilateral fitting of [bone conduction implants and unilateral fitting of SSD patients]: acoustical aspects.[3]

Study:
Technical evaluation of benefits in a bilateral bone conduction fitting by acoustical measurements. The technical findings were validated against published clinical results. A similar protocol was also applied for evaluating the benefits of a unilateral fitting of SSD patients.

Outcome:
Provided the patient has a symmetrical cochlear sensitivity both clinical measurements reported in the literature, and the technical acoustic analysis performed in this study, show that the patient benefits from bilateral fitting.

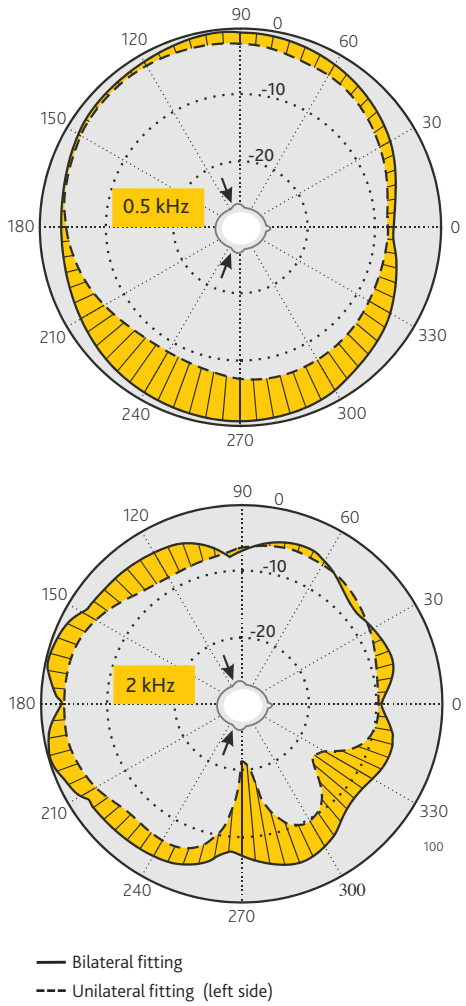
Conclusion:
Bilateral fitting will provide greater stimulation level, better directional hearing and space perception and overall better speech perception in noise.

Difference in speech reception threshold in quiet

Study	N	Mean Improvement in SRT with Bilateral vs Unilateral fitting
Bosman et al[4]	25	4.0 dB (P<.001)
Hamann et al[10]	23	4.0 dB
Priwin et al[18]	12	5.4 dB (P=.001)

Abbreviations: SRT, speech reception threshold; dB, decibels.

Improvement in hearing sensitivity with bilateral fitting relative to unilateral fitting.

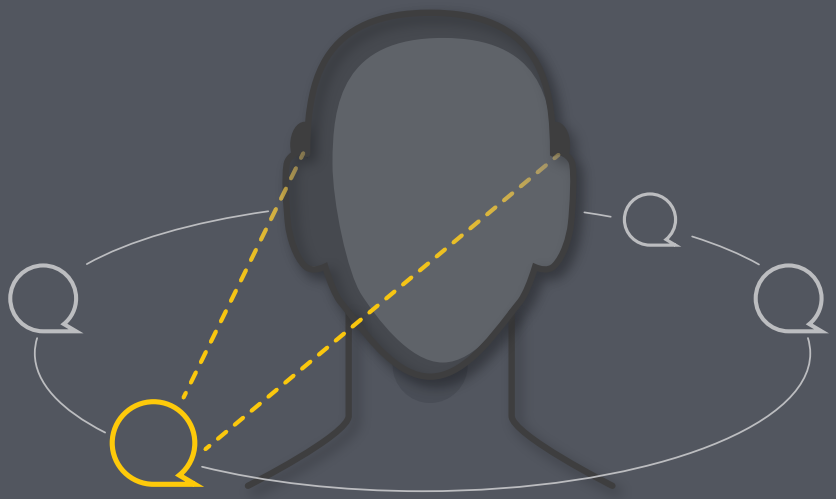


The radial lines between the solid and dashed lines indicate the improvement due to the use of bilateral fitting.

NOTE: Additional references on bilateral hearing with bone conduction[11-34]

Localization.

One of the highest-ranking needs among people with hearing loss, and people with monaural aiding, is to localize sound.[35] Several studies demonstrate clear benefits in terms of localization when comparing a unilateral bone conduction fitting to a bilateral fitting.[4-6]



Bilateral patients are able to localize sound at 2 kHz

9 out of 10

times, while unilateral patients are close to chance level.[4]

Scientific highlights

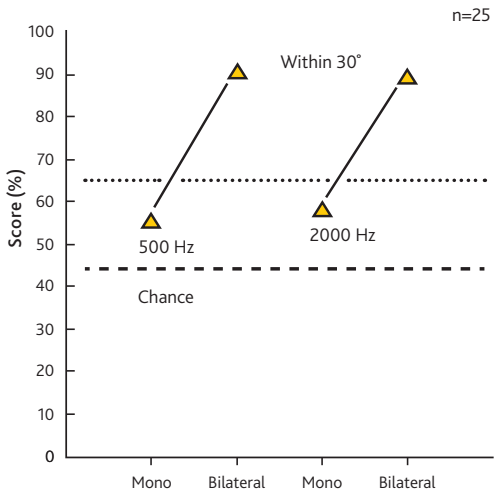
Audiometric evaluation of bilaterally fitted [bone conduction implants].[4]

Study:
Retrospective evaluation of 25 patients with bilateral fittings and at least three months experience using the Baha System. Measurements on localization of sounds were made according to three criteria: correct answers only, responses correct within 30° and lateralization.

Outcome:
Results revealed that in a unilateral fitting most sounds were identified as coming from the fitted side and the score did not exceed chance level. Significant improvements were found with bilateral fittings over unilateral fittings, both for 500 Hz and 2 kHz stimuli.

Conclusion:
With bilateral fitting the percentage of correct localization increased significantly and patients could localize the sound source within 30° in 90% of the attempts showing a great improvement.

Localization of sound, bilateral vs unilateral



Mono = Unilateral fitting
Bilateral = Bilateral fitting

Conductive hearing loss and bone conduction devices: Restored binaural hearing?[5]

Study:
Chapter on bilateral fitting in Karger book on implantable bone conduction [implants]. Three studies from the Radboud University Medical Centre on patients with bilateral, acquired unilateral and congenital unilateral conductive hearing were used as reference.

Outcome:
Results revealed that patients with bilateral conductive hearing loss had the biggest benefit with a 40° improvement in localization accuracy, going from chance level to being able to localize sounds within 25°. Patients with acquired unilateral hearing loss increased their localization accuracy by 34° and those with congenital unilateral hearing loss by 4° (all measured at 500 Hz).

Conclusion:
Patients with bilateral conductive hearing loss have a larger audiological benefit going from a unilateral to a bilateral fitting than patients with a unilateral hearing loss. Both summation and localization accuracy are greatly improved.

Mean absolute error (SD) in degrees in the different groups

	500 Hz NB		3,000 Hz NB	
Group	Unilateral	Bilateral	Unilateral	Bilateral
Bilateral HL	66 (14)	26 (8)*	56 (13)	25 (8)*

*$p < 0.025$, two-sided t test. NB = Narrow-band noise.

Bilateral bone conduction devices (BCD): Improved hearing ability in children with bilateral conductive hearing loss.[6]

Study:
Retrospective evaluation of 10 children using the Minimal Audible Angle test (MAA). Two loudspeakers were positioned with varying distance between them 1 meter in front of the subject resulting in 6 different angles between speakers.

Outcome:
The average angle where subjects could identify sounds correctly in a unilateral fitting was 68° and in a bilateral fitting 13° demonstrating a significant improvement in localization.

Conclusion:
The present results in children with bilateral severe conductive hearing loss demonstrate a clear beneficial effect of bilateral BCD implantation, even while both cochleae are poorly acoustically separated due to cross-stimulation. Bilateral fitting improved performance in all 10 children.

Spatial resolution, results of the MAA test

	Minimal audible angle		
Subject number	Bilateral BCDs	Unilateral BCD Right	Unilateral BCD Left
1	10°	15°	90°
2	10°	90°	NA
3	10°	30°	30°
4	10°	30°	60°
5	30°	15°	90°
6	30°	90°	90°
7	5°	90°	90°
8	5°	30°	90°
9	10°	90°	90°
10	5°	90°	90°

An MAA score 90° corresponds with the inability to correctly localize left and right stimuli. A better score corresponds with lower degrees, with 5° being best possible score. BCD, bone conduction device; MAA, minimum audible angle; NA, not available.

NOTE: Additional references on bilateral hearing with bone conduction[11-34]

Patient satisfaction.

Studies examining patient satisfaction in bilateral bone conduction fittings show a patient satisfaction score that is significantly higher than many other otological interventions.[7,8] Interestingly, patients graded their second Baha System as more successful than the first in a study on 11 patients with sequential bilateral fittings.[7]

9 out of 10

patients report increased quality of life when fitted bilaterally[7]

Scientific highlights

Bilateral bone [conduction implant]: impact on quality of life measured with the Glasgow Benefit Inventory.[7]

Study:
Retrospective postal survey using the Glasgow Benefit Inventory (GBI) on 93 adult patients with a response rate of 76%.

Outcome:
Overall the benefit score for bilateral fitting was +38 which is higher than what studies on unilateral fittings have reported. Positive QoL scores were reported across all domains and 92% of patients reported improvements.

Conclusion:
In short, if one meets the criteria for bilateral implantation, one Baha [System] is good, but bilateral Baha [Systems] are probably better.

Benefits scores of bilateral versus unilateral bone conduction implants

	Bilateral BC	Unilateral BC		
Overall GBI score	**+38 (33–44)**	**+31 (22–41)**	**+33 (25–42)**	**+32 (10–55)**
Number in study	93	60	94	59
Total response	71	51	69	41
Response rate	76%	85%	73%	69%
	Ho et al.7	*Arunachalam et al.31*	*McLarnon et al.32*	*Gillett et al.33*

The GBI score for Gillett et al was calculated from the box and whisker plot in their article. Values in parentheses are 95% confidence interval.

Bilateral [bone conduction implant] application in children: The Nijmegen experience from 1996 to 2008.[8]

Study:
Retrospective study on 27 children fitted between June 1996 and October 2008. Patient satisfaction was followed up using the Glasgow Children Benefit Inventory (GCBI) and the Speech, Spatial and Qualities of Hearing scale (SSQ).

Outcome:
The GCBI showed a subjective benefit of +38. Interestingly, the SSQ showed a trend toward better spatial hearing with decreasing age at bilateral fitting.

Conclusion:
The study revealed a clear trend towards bilateral fitting at an earlier age towards the end of the follow-up period. At the end of the follow-up period the surgeries were performed simultaneously as the benefit of bilateral fitting became more obvious.

This study showed clinical evidence that early bilateral fitting is appreciated in children.[8]

NOTE: Additional references on bilateral hearing with bone conduction[11-34]

Josh's story.

At the age of six, Josh was diagnosed with congenital cholesteatoma. He received his first set of hearing aids, but they did not work well for him. Later, his doctors found there was a risk of repeat infections if he wore hearing aids, so at the age of nine he was implanted with his first Baha System. Two years later Josh received his second Baha System. This is his story told by his mom.

Tell us, how did hearing loss affect Josh's life?

I noticed him struggling to interact with other people in school, in classes. He couldn't hear that well, so he wouldn't pay attention, or he would hear something in the back of the room and he was just really distracted. He wasn't doing well in school. Some things he couldn't do that other kids could do – like wear headphones. It was hard to see, something just pulled him back from things.

How did Josh experience his first Baha System?

The first year with his first Baha [System], he just showed so much improvement with his social life. He's always been very social, but just interacting with kids was a lot better. School was a lot better. He was able to hear the teacher. [He] just learned a lot better with that. He's able to listen to music, which was his number one thing. He's loved music, and he was finally able to listen to [his own] music. ... Just interacting and communicating became so much better for him.

So, what made you consider a second Baha System?

I would say after the first one, it was still uneven. And even though he loved it and it helped a lot, it was just offset because it was only one. So since Joshua has hearing loss in both ears, a few months after he got his first Baha [System], the audiologist said he qualified for a second one. Getting a second Baha [System] meant that he was able to hear on both sides. I just wanted to give him the best opportunity to hear whatever he could.

What was the change like when getting the second Baha System?

After getting the second Baha [System], he heard a lot better because it was just balanced out. He didn't have one ear that heard better, he had both. So, it helped him out with communicating, with talking on the phone, listening to music. He was able to hear all around versus just on one side of the classroom. I would have to make sure I was talking to one side of him, now [he hears on] both.

And school?

I think he started doing better in school because he was able to hear the teacher a lot better. And he became more confident in raising his hand, asking questions. Because before, when he didn't have any Baha [Systems], or any hearing aids, he would be scared to ask questions, because he's like, 'Maybe the teacher went over that already but I didn't hear it.' And he didn't want to be that kid in the class, who didn't hear it.

What would you say to someone that's in the situation you were in some years ago?

The benefit just definitely outweighs the fears. It's a whole new world that they just walk into once they get the Baha [Systems]. He's able to do so much, anything that a regular kid can do and can hear. It improves [his] confidence. And he's able to communicate a lot better... He's able to interact with kids his age better. And with school, and there's a lot of different [improvements] that you'll see.

> "When he got the second Baha System, it was incredible. It wasn't just one ear that he heard better out of, it was both that were just leveled out perfectly for him."

Hear now. And always

As the global leader in implantable hearing solutions, Cochlear is dedicated to bringing the gift of sound to people with moderate to profound hearing loss. We have helped over 450,000 people of all ages live full and active lives by reconnecting them with family, friends and community.

We aim to give our recipients the best lifelong hearing experience and access to innovative future technologies. For our professional partners, we offer the industry's largest clinical, research and support networks.

That's why more people choose Cochlear than any other hearing implant company.

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Not everyone with hearing loss is a candidate for a Baha. All surgical procedures include an element of risk, and it is impossible to guarantee success. For complete information regarding the risks and benefits of a Baha procedure, please refer to the Instructions for use for the Baha Implant available at www.Cochlear.com/US/BahaIndications.

Views expressed are those of the individual. Consult your hearing health provider to determine if you are a candidate for Cochlear technology. Outcomes and results may vary.

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