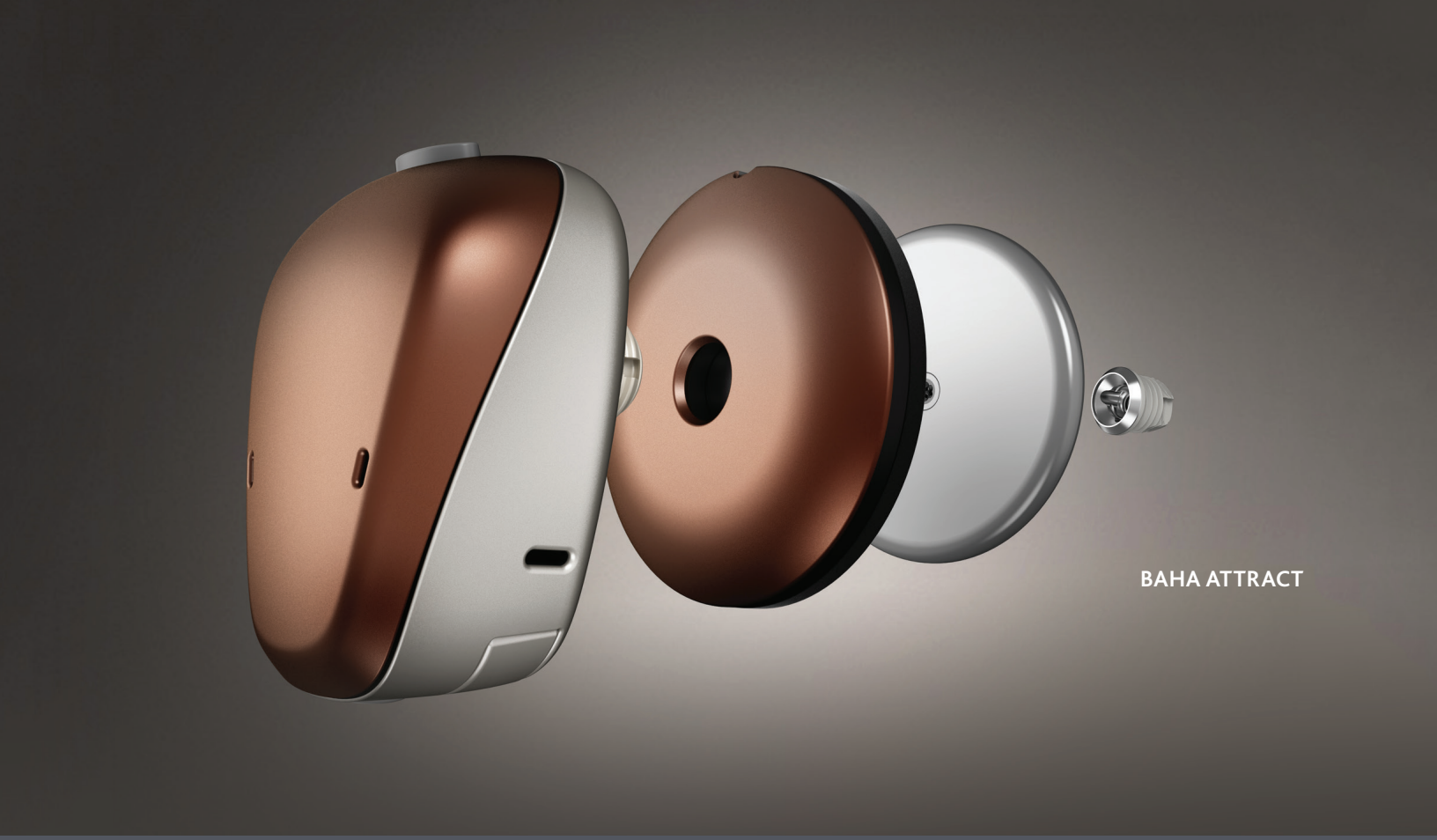
Cochlear™ Baha® 5 System

A Summary of Clinical Evidence

Hear now. And always

Cochlear®



BAHA ATTRACT

ONE IMPLANT TWO SYSTEMS

BAHA CONNECT

Over the years, new bone conduction implant technologies have been developed to address patient needs including hearing performance, aesthetics and reliability.

This review provides a summary of clinical evidence that demonstrates the Cochlear™ Baha® 5 System as an effective surgical treatment option for adult and pediatric* patients with conductive hearing loss, mixed hearing loss and single-sided sensorineural deafness (SSD).

HearYourWay™

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* In the United States and Canada, the placement of a bone-anchored implant is contraindicated in children below the age of 5.

Baha BI300 Implant

The Cochlear BI300 Implant forms the stable foundation of all Baha bone conduction implant systems. Since its launch in 2010, the clinical performance of the BI300 has been reported in over 30 peer-reviewed articles. Compared to previous generation implants, the wider 4.5 mm diameter enhances primary stability while the TiOblast™ surface allows for faster and stronger osseointegration. Together, the design, dimensions and characteristics of the BI300 enable quicker access to sound with reliability proven through long-term clinical application.

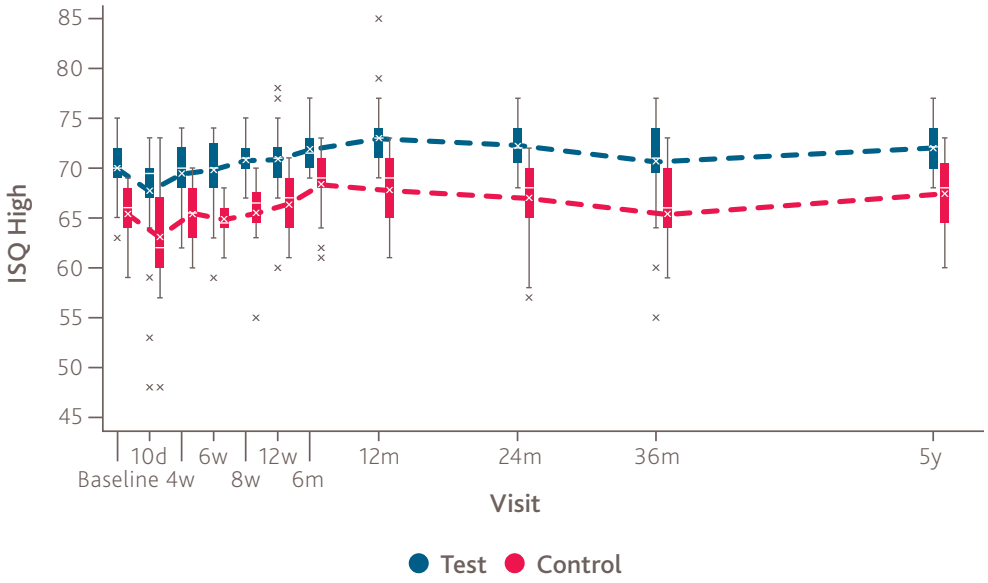
PUBLICATION	IMPLANT SURVIVAL
Baker et al. *Int J Pediatr Otorhinolaryngol. 2015;79(10):1667-1672.*	100%
Briggs et al. *Otol Neurotol. 2015;36(5):834-841.*	100%
Carr et al. *Otol Neurotol. 2015;36(8):1399-1402.*	100%
Carr et al. *Eur Arch Otorhinolaryngol. 2016;273(3):567-571.*	98%
den Besten et al. *Int J Pediatr Otorhinolaryngol. 2015;79(12):2050-2055.*	97%
den Besten et al. *Otol Neurotol. 2016;37(8):1077-1083.*	96%
D'Eredita et al. *Otolaryngol Head Neck Surg. 2012;146(6):979-983.*	100%
Deveze et al. *Eur Arch Otorhinolaryngol. 2015;272(9):2563-2569.*	100%
Felton et al. *Int J Pediatr Otorhinolaryngol. 2014;78(3):513-516.*	100%
Gawecki et al. *Eur Arch Otorhinolaryngol 273(10): 3123-3130.*	100%
Hogsbro et al. *Otol Neurotol. 2015;36(2):e51-57.*	100%
Hogsbro et al. *Otol Neurotol. 2017;38(2):207-211.*	100%
Husseman et al. *J Laryngol Otol. 2013;127 Suppl 2:S33-38.*	100%
Iseri et al. *J Laryngol Otol. 2015;129(1):32-37.*	94%
Iseri et al. *Otol Neurotol. 2015;36(5):849-853.*	100%
Marsella et al. *Acta Otorhinolaryngol Ital. 2015;35(1):29-33.*	100%
Marsella et al. *Otol Neurotol. 2012;33(5):797-803.*	100%
McLarnon et al. *Int J Pediatr Otorhinolaryngol. 2014;78(4):641-644.*	93%
McLarnon et al. *Otol Neurotol. 2012;33(9):1578-1582.*	100%
Mierzwinski et al. *Otol Neurotol. 2015;36(7):1209-1215.*	100%
Nelissen et al. *Eur Arch Otorhinolaryngol. 2016;273(7):1731-1737.*	97%
Nelissen et al. *Otol Neurotol. 2014;35(8):1486-1491.*	96%
Wazen et al. *Am J Otolaryngol. 2015;36(2):195-199.*	100%
Wilkie et al. *Otolaryngol Head Neck Surg. 2014;151(6):1014-1019*	100%
Wilkie et al. *Eur Arch Otorhinolaryngol. 2015;272(6):1371-1376.*	100%

Table summarizing the BI300 Implant survival rates reported in the corresponding publications

Evaluation of Bone Conduction Implant Stability and Soft Tissue Status in Children in Relation to Age, Bone Thickness, and Sound Processor Loading Time.

DEN BESTEN CA, STALFORS J, WIGREN S, BLECHERT JI, FLYNN M, EEG-OLOFSSON M, AGGARWAL R, GREEN K, NELISSEN RC, MYLANUS EA, HOL MK. OTOL NEUROTOL. 2016;37(8):1077-1083.

5-year follow-up of a multicenter, randomized controlled trial (Nelissen et al 2014) comparing implant stability, survival, and soft tissue reactions for BI300 (test) and previous generation (control) implant. The study provides unique long-term results on BI300 reliability with a cumulative survival rate of 95.8% and superiority in terms of mean ISQ (implant stability quotient) values and skin tolerability, both at the single 5-year follow-up visit (n=57) and during the complete follow-up (n=77).



Graph from den Besten et al, 2016, showing long-term implant stability

Long-term stability, survival, and tolerability of a novel osseointegrated implant for bone conduction hearing: 3-year data from a multicenter, randomized, controlled clinical investigation.

NELISSEN RC, STALFORS J, DE WOLF MJ, FLYNN MC, WIGREN S, EEG-OLOFSSON M, GREEN K, ROTHERA MP, MYLANUS EA, HOL MK. OTOL NEUROTOL. 2014;35(8):1486-1491.

Three-year follow-up of 77 adult patients, comparing the Cochlear Baha BI300 Implant (n=52) with previous generation implant (n=25) with regards to stability, implant survival and skin tolerability. The study demonstrates superiority of the BI300 Implant as measured by significantly and consistently higher ISQ (implant stability quotient) values for the new implant and with an implant survival rate of 96.2% the new BI300 implant is concluded to be stable, safe and reliable.

Baha BI300 Implant

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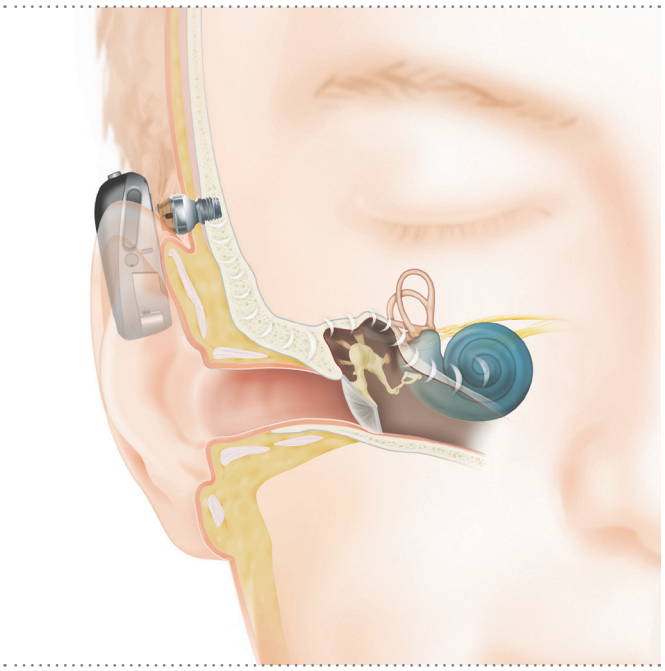
Stable, safe and reliable

Baha Connect System (DermaLock™)

The Cochlear Baha Connect System is a well-proven percutaneous bone conduction implant system allowing direct, single-point sound transmission via a minimally invasive skin-penetrating abutment.

Conventional titanium abutments have been used for 40 years, but despite titanium's well established ability to osseointegrate with bone, it does not integrate with the surrounding tissue. As a result, bone conduction implant surgery generally involved substantial soft tissue reduction to facilitate successful outcomes. Consequently, viable structures of the soft tissue were permanently removed, affecting the healing capacity of the local immune system. The Cochlear Baha BA400 Abutment with DermaLock™ technology features a plasma-sprayed Hydroxyapatite (HA) coating and concave design that promotes soft tissue adherence and stability.



Naturally occurring in bone and teeth; HA has been shown to provide enhanced dermal adhesion, diminishing epidermal downgrowth and pocket formation, thus allowing for preservation of the soft tissue during surgery. This technology helps preserve the hair and skin around the abutment which not only leads to improved aesthetics and reduced numbness, but also dramatically reduces surgery time.

> "... vascularized soft tissue integration not only provides a physical barrier to bacteria but also enables the host's immune defense or systemic antibiotics to reach areas sensitive to bacterial invasion."

Soft tissue integration of hydroxyapatite-coated abutments for bone conduction implants

LARSSON A, ANDERSSON M, WIGREN S, PIVODIC A, FLYNN M, NANNMARK U.CLIN IMPLANT DENT RELAT RES.2015;17 SUPPL 2:E730-735.

Pre-clinical investigation comparing soft tissue adherence and pocket formation with respect to abutment design and coating. Histologic assessment revealed tight dermal adherence and significantly less epidermal downgrowth and pocket formation for the concave, HA-coated DermaLock abutment as compared to the previous generation, uncoated titanium abutment.

Histological Measurements per Abutment Type

MEASUREMENT(σ)	DERMALOCK	TITANIUM ABUTMENT	pVALUE
Pocket depth	0.411 (0.1623)	1.6337 (0.1691)	.0013
Epidermal downgrowth	0.6491 (0.1415)	2.0192 (0.1474)	.0003

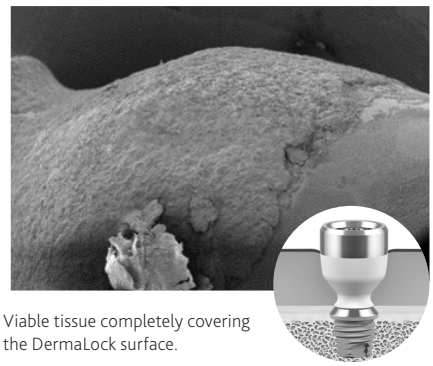
Data derived from Larsson et al 2015, comparing pocket depth and epidermal downgrowth for DermaLock (BA400) and titanium (BA300) abutment including standard deviation. DermaLock shows significantly less pocket formation and epidermal downgrowth than the titanium abutment indicating soft-tissue adherence. Values are in milimetres.

Soft tissue integration for a healthy implant site

Can the Hydroxyapatite-Coated Skin-Penetrating Abutment for Bone Conduction Hearing Implants Integrate with the Surrounding Skin?

VAN HOOF M, WIGREN S, DUIMEL H, SAVELKOUL PH, FLYNN M, STOKROOS RJ. 2015;2:45.

Ex vivo examination of both abutment and surrounding tissue after surgical retrieval of one HA-coated BA400 abutment and one previous generation, un-coated, titanium abutment. A scanning electron microscopy (SEM) analysis showed viable tissue in intimate contact with the HA coating, indicating effective skin integration, and signs of an effective immune system, findings that were absent on the previous generation titanium abutment and the top, un-coated portion of the HA-abutment. The study provides proof-of-principal evidence that the HA-coated DermaLock abutment can integrate with the surrounding skin in vivo.



Viable tissue completely covering the DermaLock surface.

Only skin remnants on the titanium surface (no viable tissue).

Scanning electron micrographs of explanted DermaLock (10 mm BA400 Abutment – soft tissue thickness 7 mm) and titanium abutment (6 mm BA300 Abutment – soft tissue thickness 4 mm) courtesy of Prof. Dr. R.J. Stokroos and Drs. M. Van Hoof.

Baha Connect System (DermaLock)

Surgical and audiological evaluation of the Baha BA400

ISERI M, ORHAN KS, YARIKTAS MH, KARA A, DURGUT M, CEYLAN DS, GULDIKEN Y, KESKIN IG, DEGER K.2015;129(1):32-37.

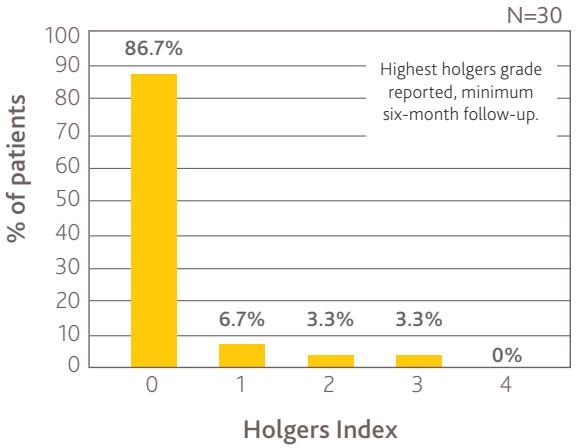
Multicenter case series of 14 adult and 2 pediatric Baha Connect patients implanted with Dermalock (BA400) using soft tissue preservation. During the 12-16 month follow-up, this retrospective review demonstrates that the new HA-coated abutment can be implanted with soft tissue preservation, resulting in less invasive surgery with shorter surgery time (9-34 min), high soft tissue tolerability (95% of observations were Holgers grade 0 -1) and implant stability, improved aesthetics, fewer reports of numbness, and faster healing time compared to conventional implantation with soft tissue reduction.

Osseointegrated hearing implant surgery using a novel hydroxyapatite-coated concave abutment design

WILKIE MD, CHAKRAVARTHY KM, MAMAIS C, TEMPLE RH. 2014;151(6):1014-1019.

Prospective, 6-13 month follow-up of 30 consecutive adult patients implanted with the DermaLock (BA400) abutment using soft tissue preservation. Study shows good clinical and patient-reported outcomes (Overall GBI score of +38) with fast surgery (9-22 min), favorable and rapid post-op wound healing, few soft tissue reactions and a 100% implant survival rate.

Excellent soft tissue outcomes, 93% mild or no soft tissue reactions



Graph showing soft tissue outcomes according to Holgers index. Of the 30 DermaLock patients included in the study (Wilkie et al, 2014), 93% reported none or mild soft tissue reactions (Holgers grade 0-1).

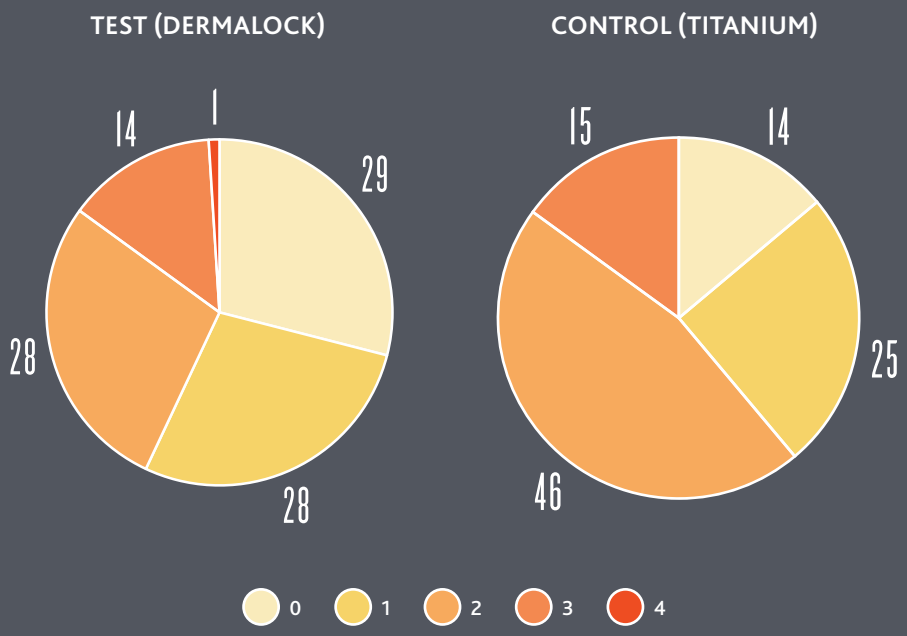
"A new abutment combined with less-invasive surgery improves aesthetics and reduces numbness around the abutment."

In the Pipeline ...

Clinical and Health Economic Evaluation of a New Baha® Abutment, With a Minimally Invasive Surgical Technique. An International Multicenter, Open, Randomized, Comparative, Parallel Group, Investigation.

CLINICALTRIALS.GOV (NCT01796236)

2 year clinical follow-up of 103 adult patients implanted with either the HA-coated DermaLock abutment (BA400, n=52) with tissue preservation or the previous generation, as-machined titanium abutment (BA300, n=51) with tissue reduction, showing significant differences in surgery time, soft tissue reaction and peri-implant numbness in favor of the test (DermaLock) group.



Pie-charts showing the percentage of subjects presenting with 0, 1, 2, 3 or 4 of the four important medical events (Holgers Index > 1, soft tissue thickening/overgrowth, Pain or the presence of numbness) at some point over the first year. Every event is counted only once per subject.

Baha Connect System (DermaLock)

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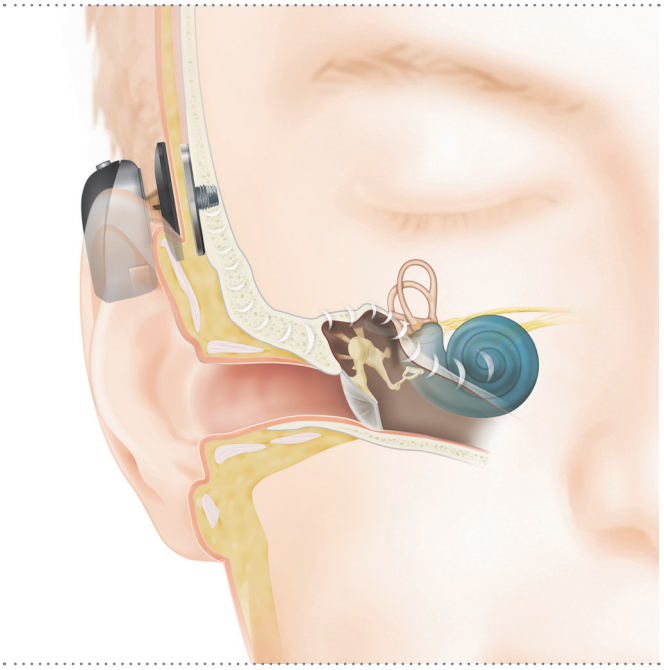
Baha Attract System

The Cochlear Baha Attract System is a transcutaneous bone conduction hearing implant system using magnetic retention to connect the sound processor to the implant, allowing for single-point sound transmission to the cochlea, without the need for a skin-penetrating abutment. The Baha BIM400 Implant Magnet is placed under the skin, providing a more aesthetic alternative to percutaneous systems and eliminating the need for lifelong daily hygienic care. A Baha sound processor attaches to an external SP Magnet that is available in six different strengths for optimal retention. A Baha SoftWear™ Pad on the tissue facing surface of the SP Magnet evenly distributes pressure, thereby enhancing both wearing comfort and sound transmission as well as reducing the risk for pressure-related soft tissue complications.



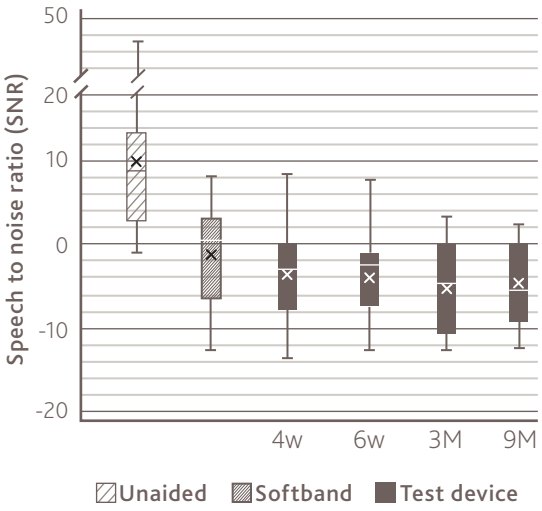
Baha Attract is a good alternative to percutaneous systems especially for patients who value the aesthetic aspect, patients with limited manual dexterity or patients with peri-abutment complications.

"The ease of use of the device may provide significant advantages for patients with disabilities and/or reduced dexterity."

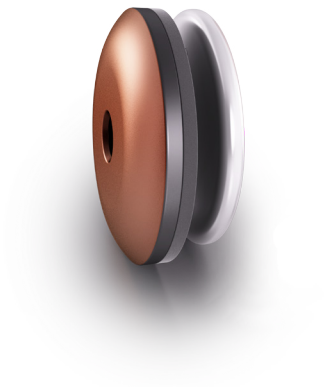
Clinical performance of a new magnetic bone conduction hearing implant system: results from a prospective, multicenter, clinical investigation.

BRIGGS R, VAN HASSELT A, LUNTZ M, GOYCOOLEA M, WIGREN S, WEBER P, SMEDS H, FLYNN M, COWAN R. OTOL NEUROTOL. 2015;36(5):834-841.

Multicenter clinical investigation prospectively evaluating safety and efficacy of the Baha Attract System in 27 adult patients. During the 9 month follow-up the transcutaneous implant system was reported as safe and effective, providing statistically improved hearing performance with minimal soft tissue complications. The majority of patients experienced no or limited pain with overall mean pain scores of 1.19 (SD 0.79; with 1 = no pain, and 10= considerable pain) and the patient-reported average daily use was 7.0 hours per day (SD 3.8 h/d), indicating good wearing comfort.



Graph from Briggs et al 2015[1] showing speech-to-noise ratio (SNR) allowing 50% speech recognition for the unaided situation (preop), Softband (preop), and Baha Attract (4 wk,6 wk, 3 mo, 9 mo). Lower numbers represents better hearing performance.



Excellent hearing performance without skin penetration

Initial UK Experience With a Novel Magnetic Transcutaneous Bone Conduction Device.

CARR SD, MORALEDA J, PROCTER V, WRIGHT K, RAY J. OTOL NEUROTOL. 2015;36(8):1399-1402.

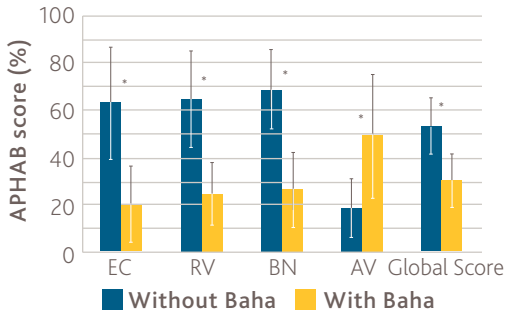
Prospective case series of 10 patients implanted with Baha Attract reporting a high level of satisfaction and a significant decrease in hearing aid disability (GHADP scores 59% to 11%) when compared with the patient's previous hearing aid. In addition, all 10 patients rated sound quality and speech understanding as "good" or "very good" and described the loudness of the system as "ideal."

Baha Attract System

Surgical, functional and audiological evaluation of new Baha® Attract system implantations.

GAWECKI W, STIELER OM, BALCEROWIAK A, KOMAR D, GIBASIEWICZ R, KARLIK M, SZYFTER-HARRIS J, WROBEL M. EUR ARCH OTORHINOLARYNGOL. 2016;273(10):3123-31303

Prospective, 6 month follow-up of 20 adult patients showing good clinical and functional outcomes with the Baha Attract System. The procedure was perceived as easy, safe and effective, providing significant audiological benefit to patients with conductive or mixed hearing loss or single sided sensorineural deafness (SSD).



Graph from Gawecki et al 2016[3] showing the benefits of the Baha Attract System according to APHAB (Abbreviated Profile of Hearing Aid Benefit) questionnaire results; EC ease of communication, RV reverberation, BN background noise, AV aversiveness; (n = 20; *p<0.001).

Transcutaneous Bone-anchored Hearing Aids Versus Percutaneous Ones: Multicenter Comparative Clinical Study

ISERI M, ORHAN KS, TUNCER U,KARA A, DURGUT M, GULDIKEN Y, SURMELIOGLU O. OTOL NEUROTOL. 2015;36(5):849-853.

Prospective Multicenter study comparing the subjective and objective outcomes of 21 Baha Connect (DermaLock) and 16 Baha Attract patients from the age of 5. Significant improvements in hearing thresholds were seen for both systems with mean improvements in PTA4 (0.5-4kHz) of 32.9 dB and 31.0 dB, and Speech Recognition Thresholds (SRT) of 36.7dB and 24.0 dB for the Baha Connect and Baha Attract Systems, respectively. The subjective benefits experienced by the recipient were also significant with total GBI scores of 42.7 for DermaLock and 40.5 for Baha Attract.

Three year experience with the cochlear BAHA attract implant: a systematic review of the literature

DIMITRIADIS PA, FARR MR, ALLAM A, RAY J. BMC EAR NOSE THROAT DISORD. 2016;16:12.

Systematic review of the audiological, clinical and functional outcomes with the Baha Attract System. With a total inclusion of 89 patients and 10 publications, the review reports of significant hearing improvements, low complication rates, and patient-reported satisfaction, especially with regards to the aesthetics of the device.

> "...Attract System has been designed to deliver optimal sound quality while minimizing the risk of soft tissue compression and reaction."

In the Pipeline ...

Audiological and clinical outcomes of a transcutaneous bone conduction hearing implant: 6-month results from a multicenter study.

CLINICALTRIALS.GOV (NCT02022085)

Six-month results from a multicenter clinical follow-up evaluating the audiological and clinical outcomes of 54 adult patients implanted with Baha Attract. The study shows favorable audiological outcomes and health related quality of life with Baha Attract compared to unaided conditions with significant improvements free-field hearing thresholds and speech understanding in quiet and in noise.

Evaluation of Cochlear Baha 5 SuperPower Sound Processor on the Baha Attract System.

CLINICALTRIALS.GOV (NCT02722330)

An international, prospective, multicenter, clinical investigation evaluating objective and subjective hearing, and short term safety with the Baha 5 SuperPower Sound Processor on the Baha Attract System. Results pending.

High patient satisfaction and acceptance ratings

Alternative Surgical Techniques

Vascular mapping of the retroauricular skin - proposal for a posterior superior surgical incision for transcutaneous bone-conduction hearing implants.

PERENYI A, BERE Z, JARABIN J, SZTANO B, KUKLA E, BIKHAZI Z, TISZLAVICZ L, TOTH F, KISS JG, ROVO L.
J OTOLARYNGOL HEAD NECK SURG. 2017;46(1):6.

UK tertiary centre experience of outcomes from osseointegrated transcutaneous magnetic bone conduction hearing system implanted in twenty-five patients using a linear incision technique.

SHARMA S, REDDY-KOLANU G, MARSHALL AH. CLIN OTOLARYNGOL. 2016;[EPUB AHEAD OF PRINT].

First Report: Linear Incision for Placement of a Magnetically Coupled Bone-Anchored Hearing Implant

BARRY JY, REGHUNATHAN S, JACOB A. OTOL NEUROTOL. 2017;38(2):221-224.

Implantation of the Cochlear Baha® 4 Attract system through a linear incision

REDDY-KOLANU G, MARSHALL A. ANN R COLL SURG ENGL. 2016;98(6):437-438.

Baha Attract System

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"... the real benefits of the Baha Attract System will be to avoid maintenance of the percutaneous abutment, reduction but not elimination of skin intolerance and increased aesthetic acceptance"

Transitioning between systems

The Cochlear Baha System is designed to allow continuous sound processor upgrade possibilities due to a shared snap coupling, and importantly, the unique option of transitioning between the two implantable configurations thanks to the common osseointegrating platform - the BI300 Implant.

Transitioning from a percutaneous to a transcutaneous system may be advocated when peri-abutment reactions prevent ideal device usage, something that is especially important during critical stages of language development in children. The option of changing to an abutment may be encouraged when there is a need for improved hearing performance which cannot be met by only upgrading the sound processor e.g. during more significant progressive hearing loss.

Outcomes following conversion of a percutaneous to a transcutaneous bone conduction device in eight children.

CARR SD, BRUCE IA, JONES D, RAY J. CLIN OTOLARYNGOL. 20171

Retrospective review of 8 pediatric patients between the ages of 5-16 years undergoing conversion from a percutaneous system to Baha Attract due to recurrent skin reactions. With a mean improvement in hearing thresholds of 25dB HL, no further complications were observed during the 6-24 month post-operative follow-up.

> "Conversion from a percutaneous bone conduction device to a transcutaneous bone conduction device is a safe and beneficial method of hearing rehabilitation in children with persistent soft tissue complications."

Conversion of traditional osseointegrated bone-anchored hearing aids to the Baha® Attract in four pediatric patients.

CEDARS E, CHAN D, LAO A, HARDIES L, MEYER A, ROSBE K. INT J PEDIATR OTORHINOLARYNGOL. 2016;91:37-42.

Case series describing the clinical experience of conversion from Baha Connect to Baha Attract System in four pediatric patients between 8-13 years old. All four patients had experienced local soft-tissue reactions around the abutment and were counseled for the transcutaneous option. Post-conversion audiology data revealed improved hearing from baseline ranging from 0 to 35dB (depending of frequency) with no post-operative skin infections during the on average near 15 month follow-up. While the aided thresholds were not as good as with an abutment, conversion to the Baha Attract System resulted in more consistent use of the device in all patients and reduced medical costs and inconvenience.

> "Given the known impact of even mild hearing loss on children's learning and development, these relatively minor skin complications can have potentially significant detrimental effects on a child through reducing the ability to have consistent use of the device."

Switching from a percutaneous to a transcutaneous bone anchored hearing system: the utility of the fascia temporalis superficialis pedicled flap in case of skin intolerance.

DEVEZE A, ROSSETTO S, MELLER R, SANJUAN PUCHOL M. EUR ARCH OTORHINOLARYNGOL. 2015;272(9):2563-2569.

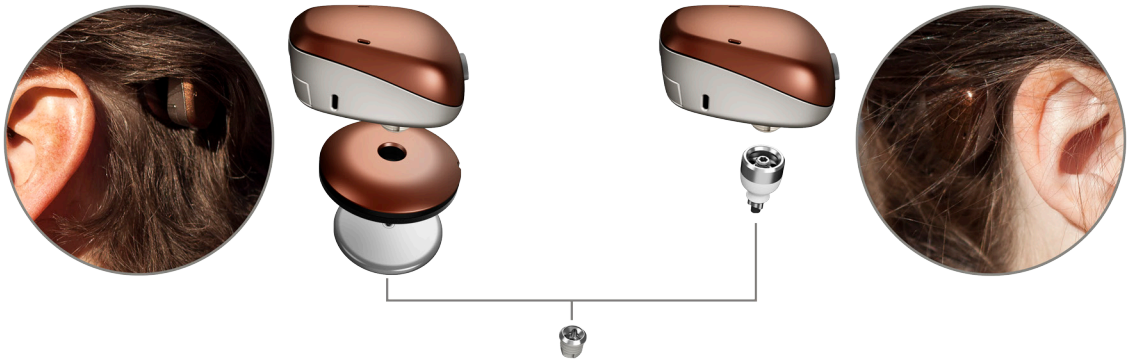
Case report of a successful transition from Baha Connect to Baha Attract following persistent soft tissue complications. The authors describe the use of a fascia temporalis superficialis (FTS) pedicled flap to cover the implant magnet in cases of compromised vascularization e.g. in patients with a history of skin reactions, tissue reduction or skin graft.

Transitioning between systems

UK tertiary center experience of outcomes from osseointegrated transcutaneous magnetic bone conduction hearing system implanted in twenty-five patients using a linear incision technique.

SHARMA S, REDDY-KOLANU G, MARSHALL AH. CLIN OTOLARYNGOL. 2016;[EPUB AHEAD OF PRINT].

Retrospective review of 25 adult and pediatric patients implanted with Baha Attract using an alternative surgical technique involving a linear incision through the center of the Implant Magnet. The study describes a case of successful elective conversion from Baha Attract to Baha Connect. The abutment was mounted on the original BI300 implant using the original linear incision.



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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.

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