The new Cochlear™ Baha® 4 system. How innovations in a bone conduction system lead to better outcomes for your patient.

Niels van Druten
General Manager
Cochlear Benelux
Cochlear™ Baha® 4 Systems

More possibilities for a lifetime of better hearing

Baha 4 Sound Processor
Smarter hearing – wireless freedom

Baha 4 Attract System
Invisible link to better hearing

Baha 4 Connect System with DermaLock
Proven hearing performance with soft tissue preservation

Baha BI300 Implant
Strong foundation
Cochlear™ Baha® BIA400 DermaLock Implant and Abutment

Proven hearing performance with soft tissue preservation
It’s all in the surface

DermaLock™

TiOblast™
Cochlear™ Baha® 4 Connect System

Cochlear™ Baha® BIA400 Series implants

- Wider diameter designed for increased primary stability.
- 3 mm implant with conical shaped TiOblast™ surface technology for stronger and faster osseointegration.
- 4.5 mm small sized threads at the implant neck for optimal load distribution at the marginal bone level where peak stresses occur.
- Tight connection between implant and abutment to reduce soft tissue reactions.

TiOblast™ surface technology for stronger and faster osseointegration.

Wider diameter designed for increased primary stability.
BI300 Stability: 36 month data from multicentre randomised clinical study

2010
The Cochlear™ Baha® 3 System set new standards for implant stability and loading time.

2012
Cochlear™ Baha® DermaLock™ Abutment (BA400) is specifically designed and approved for soft tissue preservation.
Background – Soft tissue reduction

• Early research on percutaneous devices suggest that lack of adherence between the implant and surrounding tissue results in epidermal downgrowth and ultimately failure by epidermal encapsulation\(^1\)\(^-\)\(^2\).

• Based on clinical experience from Dr Tjellström, surgical thinning of the soft tissues has been advocated since the early days of Baha.

• Soft tissue reduction effectively improves soft tissue stability, ensuring acceptable soft tissue complications rates and high survival rates with Baha implants.

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Background – Soft tissue reduction

With surgical removal of supraperiosteal tissues, soft tissue complications are kept at an acceptable level ...

**BUT**

... the aesthetic outcome is compromised

... the soft tissue is disturbed

... numbness is not uncommon

... adds complexity to surgery
Design goals – Abutment for no soft tissue reduction

- Develop an abutment that makes it possible to preserve the soft tissues in order to:
  - Minimise soft tissue disturbance
  - Streamline surgical procedure
  - Improve the aesthetic outcome

- The abutment shall provide good stability of the soft tissues with minimal epidermal downgrowth and pocket formation.

- The rate of adverse soft tissue reactions should be similar or better than for traditional Baha surgery with soft tissue reduction.
Machined titanium
- an inert biomaterial

While an inert surface is adequate for certain medical device applications, other situations require that "the material should specifically react with the tissues rather than being ignored by them".\(^3\)

Hydroxyapatite
- enhanced biological response

Ability to bind to living tissues thanks to specific adsorption of important cell-binding proteins\(^4\).

Research hypothesis – Soft tissue integration

With hydroxyapatite it is possible to achieve **adherence** between abutment and surrounding soft tissue

⇒ which leads to **limited epidermal migration**

⇒ which leads to **limited pocket formation**

⇒ which results in **good peripheral defence**

⇒ and **good long-term outcomes**
Deep epidermal pocket

Significant epidermal downgrowth

Courtesy of Ulf Nannmark & Anna Larsson.
Hydroxyapatite-coated abutment

Non/limited epidermal downgrowth and pocklet formation

Close dermal adherence

Courtesy of Ulf Nannmark & Anna Larsson.
Hydroxyapatite-coated abutment

DermaLock - 80% reduction in pocket depth

The pre clinical study concludes that the hydroxyapatite coated abutment can be used to stabilise soft tissue when performing surgery with soft tissue preservation.¹

Pre-clinical study – Soft tissue integration

Pocket depth

- **Control**: 1.6 mm
- **Test**: 0.4 mm

Mixed model analysis was used for statistical comparisons. The statistical analysis was performed by an independent bio-statistician.

DermaLock - Good clinical outcomes

- More than 2,000 patients worldwide successfully treated
- Clinical experiences reported by several teams at Osseo in Newcastle:
  - Study on 190 subjects in the US reported Holgers 0-1 in 94% of patients
  
  - Good outcomes were reported using straight incision offset to implant site as well as alternative incisions including punch only techniques

- Good cosmetic results, shorter surgery times, faster healing, less post-operative problems and less clinic visits reported from several studies

4. Wróbel M, Gawęcki, Borucki L, Pastusiak T, Szyfter W. Clinical evaluation of a new concept of the percutaneous bone conduction system with respect to surgical technique and design of the abutment. Poster presentation at Osseo 2013, Newcastle, UK.
Smarter hearing –
wireless freedom

Cochlear™ Baha® 4 Sound Processor
Ardium™ — our new, intelligent DSP platform

- New chip: three times faster, and with eight times more on-board memory
- PureSound iQ signal processing
- 2.4 GHz wireless connectivity
IMPROVED HEARING PERFORMANCE
Baha PureSound™ iQ - Superior sound quality

- Scene Classifier
- Natural Sound Resolution
- Active Balanced Directionality
- Noise Manager II
- Data logging
- Outdoor program with WindShield
- Dual Track Feedback Manager
# Patient Information

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Improved Speech Recognition in Quiet

(N=11)

>30% Improvement in Speech Recognition in Noise

Sound Quality Preference

BETTER FEEDBACK PERFORMANCE
Dual Track Feedback Manager

The Dual Track Feedback Manager uses two separate phase cancellation tracks to increase the available individual stable gain with reduced artefacts and improved overall feedback performance.
3dB Increased Feedback Margin

Artefacts to pure tones

Test setup:
- 500, 1000, 1500 and 6000 Hz pure tone presented at 50 dB HL
- Output from sound processor measured on mannequin head in sound room
- All automatic systems in the devices activated (directionality, noise reduction and feedback manager)

WIRELESS BENEFITS
True wireless – no strings attached

- **Easy to use**
  Discreet and easy to use accessories without the burden of a neck-worn device.

- **Robust connections**
  Clear and secure audio directly to the sound processor through Cochlear 2.4 GHz technology.

- **Clean, crisp sound**
  Outstanding sound quality with minimal latency for lip sync.
Overcoming Noise and Distance with Wireless Accessories

On average, up to 7dB SNR improvement in noise over a directional microphone solution for adults wearers of Baha

Summary

• The Baha 4 Sound Processor gives the patient access to our most advanced signal processing benefits and a truly wireless connection

• Utilising the classifier and new DSP platform provides improved speech understanding in challenging listening situations (e.g. Noise)

• Dual Track feedback management system increases available gain while reducing the impact of annoying artefacts

• Wireless accessories increase usability in addition to reducing the impact of distance and noise
Cochlear™ Baha® 4 Attract System

Invisible link to better hearing
Cochlear™ Baha® 4 Attract System

Sets new standards for transcutaneous solutions

No skin penetration

A leap in hearing performance*

Wearing comfort and reliable retention

Straightforward surgical procedure

*compared to a conventional transcutaneous system
Cochlear™ Baha® 4 Attract System

Invisible link to better hearing

Strong foundation with the BI300 Implant.

The BIM400 Implant Magnet for an invisible link to better hearing.

SP Magnets with the unique Baha SoftWear™ Pad ** for comfort and reliable retention.

Advanced sound processor portfolio.
Pre-clinical comparison to Softband and Percutaneous Baha

International Multi-center Investigation

Investigational site:  

Bnai Zion Hospital  
(Haifa, Israel)

HEARing Cooperative Research  
Centre (Melbourne, Australia)

Chinese University of Hong Kong (Hong Kong, China)

Clínica Las Condes (Santiago, Chile)

Principal investigator:  

Prof. Michal Luntz

Prof. Robert Cowan

Prof. Andrew Van Hasselt

Prof. Marcos Goycoolea
Excellent hearing performance

- Significantly improved **speech recognition in noise** compared to the unaided situation and compared to the sound processor on a Softband.

Design for optimal wearing comfort

Rigid sound processor magnet  
Uneven load distribution¹ with a rigid sound processor plate can cause soft tissue discomfort and complications.

Baha Attract System with Baha SoftWear™ Pad  
Optimal load distribution¹ with unique Baha SoftWear™ Pad enables better wearing comfort and less risk of skin irritations.

Wearing comfort

- All patients are successful wearers of the device after 3 months
- The patients used the device on average **7 hours per day** (SD 3 h/day, range 3-14 h/day)
- Overall good pain scores
- Post-operative numbness reduces over time

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N=27

• The Baha 4 Sound Processor gives the patient access to our most advanced signal processing benefits and a truly wireless connection

• The DermaLock technology facilitates soft tissue preservation and several studies show good clinical outcomes

• The Baha 4 Systems provides more possibilities to connect patients to hearing as well as a migration path for the future, all based on the same proven implant

• The Baha Attract System will provide a transcutaneous solution providing a leap in hearing performance
Vacature: CI Clinical Technical Specialist Nederland
Careers.cochlear.com