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AUDITORY IMPLANTS, BONE CONDUCTION AMPLIFICATION

Long-term follow-up of the Bone Conduction Implant

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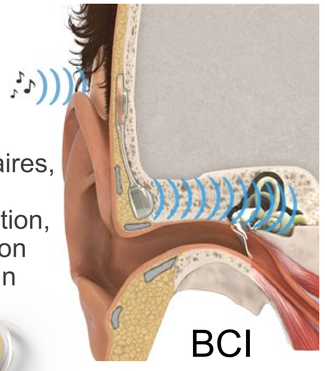
Abstract

The Bone Conduction Implant (BCI) is an active transcutaneous bone conduction device (atBCD) developed in collaboration between Chalmers University of Technology and Sahlgrenska University Hospital, in Gothenburg, Sweden. It has been under clinical investigation since 2012, and the aim of this study is to evaluate the 5-year results of 13 patients.

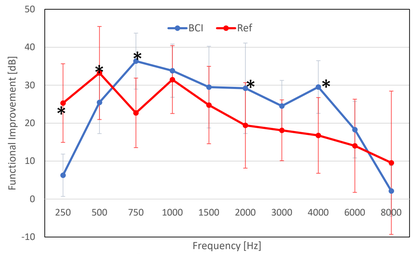
The follow-up has included audiological performance investigations, questionnaires, safety evaluation and objective functionality testing of the device. The results showed statistically significantly improved hearing ability over the unaided situation, and similar or better results compared to a reference device (Ponto Pro Power on softband). The main advantage compared to percutaneous BCDs is that the skin remains intact, which potentially provides fewer skin complications.

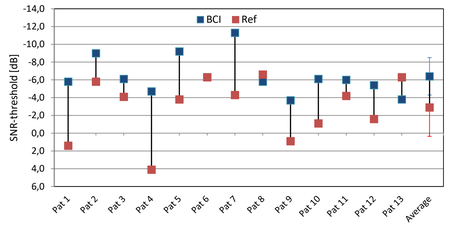
Sentio™ System, from Oticon Medical, is based on the BCI and was CE-marked and FDA approved in July 2024. Please note that the results in this study are based on data from the BCI only, not from Sentio™.

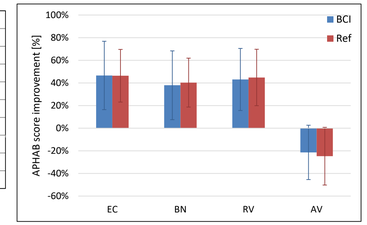


Results

Patients have now (in Sept 2024) had their implant 7.8-11.8 years (accumulated time: 152 years). During this time, no serious adverse events have occurred. One explantation due to implant failure in Jan 2023 – 9.3 years after implantation, replaced by a commercially available atBCD 3 months later.







Average functional improvement: 29.5 dB (PTA_4), average SRT improvement: 24.5 dB, average SRS improvement: 38.1%-units, and average aided SNR-threshold: -6.4 dB.

Patients experience statistically significant subjective benefit using the BCI, shown with APHAB, GBI and IOI-HA.

All results show similar or better performance with the BCI compared to the reference device.

Objectives

The aim is to evaluate the 5-year results of 13 patients, regarding audiological performance, questionnaires, safety, and objective functionality.

Conclusion

The BCI has been shown to be safe and effective for patients with conductive and mild-to-moderate mixed hearing loss.

Methods and Materials

- A total of 16 patients have been implanted with the BCI, 13 in Gothenburg (followed for 5 years) and 3 in Stockholm (followed for 1 year).
- Main inclusion criteria: unilateral or bilateral conductive hearing loss with an air-bone gap of at least 20 dB (PTA over 500, 1000, 2000 and 4000 Hz), and PTA-BC of 30 dB HL or better.
- Audiological measurements: sound field warble tone thresholds, speech recognition threshold (SRT), speech recognition score (SRS) and signal to noise ratio threshold (SNR-threshold).
- Questionnaires: Abbreviated Profile of Hearing Aid Benefit (APHAB), Glasgow Benefit Inventory (GBI) and International Outcome Inventory of Hearing Aids (IOI-HA).
- Reference device: Ponto Pro Power on softband for a period of four weeks prior to the BCI surgery and evaluated with the same protocol.

References

Reinfeldt S, Eeg-Olofsson M, Fredén Jansson KJ, Persson AC, Håkansson B. 2022. Long-term follow-up and review of the Bone Conduction Implant. Hearing Research 421 (2022) 108503.

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