# **Expert opinion on Candidacy for Bone Conduction** Hearing Implants: Osia System and Baha Connect System

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# Introduction

Bone conduction hearing implants (BCHI) are a widely used solution for patients with conductive hearing loss (CHL), mixed hearing loss (MHL), or single-sided deafness (SSD)<sup>1</sup>. This expert review<sup>2</sup> explores candidacy criteria for selecting between active transcutaneous bone-conduction hearing devices (Osia® System) and passive percutaneous bone-conduction hearing devices (Baha® Connect System) with the aim to assist surgeons in their decision-making process, especially in scenarios where the Osia System may not be feasible for all patients due to limitations like capped healthcare budgets.

# **Objectives**

This expert opinion offers clinical guidance as it presents indications for the use and advantages BCHI implants for different patients, which is not generally known. Suggestions presented in this expert opinion reflect the outcomes from discussions amongst experienced otology surgeons on candidacy for two direct-drive bone conduction systems: a percutaneous solution, the Baha Connect System, and an active transcutaneous solution, the Osia System.

# Methods and materials

Eight otology surgeons experienced in the implantation of the Baha Connect System and the Osia System from seven different countries in Europe participated in two online surveys and two virtual sessions between May 2022 to February 2023 to share insights and experiences.

# Results

The key results from the online surveys and virtual discussions between the expert surgeons where thematically categorized into eight themes:

- 1. Indications for a bone conduction solution i.e., general and audiological indications such as the dynamic range of the device and to consider potential progressive hearing loss,
- 2. Selecting which solution to choose for the individual patient (Figure 1),
- 3. Skin condition, risk of infections, esthetic and hygienic aspects e.g., if patients are prone to skin infections or if there is a risk of implant loss,
- 4. Future MRI scans. For patients requiring repeated MRIs in the head and neck area.
- 5. History of ear surgeries and previous hearing devices e.g., patients that undergo cholesteatoma canal wall down surgery and after that cannot use conventional hearing aids and those with a history of failure with percutaneous solutions,
- 6. Type of anesthesia and surgery e.g., Baha Connect can be implanted using minimal surgery and local anesthesia. In selected cases Osia implantation can be performed under local anesthesia with sedation,
- 7. Patient preference and benefit e.g., patient preferences regarding what is most important for them for example, aesthetics, ease of use, hygiene aspects etc., and
- 8. Patient age, bone thickness, and anatomical conditions i.e., indication for the Osia in the United States is children ≥5 years and a body weight of  $\geq$ 7 kg. In Europe children need to have a specific bone thickness.

# Conclusion

The expert panel emphasised aligning clinical indications with patient preferences for optimal outcomes when choosing between the Osia System and Baha Connect System. They recommended the Baha Connect System for patients requiring minimally invasive surgery or frequent MRI scans, and those with specific hearing loss profiles. Conversely, they advocated the Osia System as the primary choice for patients needing optimal hearing acuity, those with skin issues, and children aged 5 years and older weighing  $\geq$ 7 kg.



# **Factors in the decision-making process**

General indications and guidelines						
Skin condition	Immunosuppression	Future MRI scans	History of ear surgeries / previous devices	Type of anesthesia and surgery	Patient preference	Patient age, bone thickness and anatomy

### Patient groups more suitable for a specific **BCHI** solution

- Pediatric patients wanting a lifetime and wearing
- Patients preferring the Osia® System
- Patients who want to swim or work in humid environments
- want to care for an abutment
- infections
- have failed
- Patients with learning disabilities or with limited dexterity

for the Osia System and the Baha Connect System

#### Baha<sup>®</sup> System candidacy considerations

- Patients requiring minimally invasive short surgery
- Patients who cannot undergo general anesthesia
- Patients needing ipsilateral MRI of the head to monitor cholesteatoma regrowth or follow-up after removal of vestibular schwannoma
- Patients needing regular MRI of the head due to neurological diseases
- Patients with bone conduction threshold over 50 dB
- hearing level

# References

- 1. Ellsperman SE, Nairn EM, Stucken EZ. Review of Bone Conduction Hearing Devices. Audiology Research. 2021 May 18;11(2):207-19.
- 2. Arndt S, Cantore I, Smeds H, Goldberg-Bockhorn E, Lok W, Marco J, Röösli C, Gawęcki W. Expert opinion on candidacy for bone conduction hearing implants Osia System and Baha Connect System. Otolaryngol Pol (in press).

- **Osia<sup>®</sup> System candidacy** considerations
  - solution ensuring high quality hearing

  - Patients who are unable to or do not
  - Patients with soft bone
  - Patients with a higher risk of skin
  - Patients in whom percutaneous solutions

Figure 1: Schematic representation of candidacy considerations