Five Years of Outcomes and Innovation with the Osia System: A Literature Review

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Introduction

Hearing loss negatively impacts quality of life and accounts for over $981 billion in global economic costs[1]. Conductive and mixed hearing losses, affecting approximately 200 million people worldwide, significantly hinder communication and social interactions[2]. The Osia System, utilizing advanced Piezo Power™ Technology, offers a solution by bypassing outer and middle ear issues, effectively managing moderate to severe-profound hearing losses with a sensorineural component up to 55 dB[3]. This review focuses on the Osia System's adoption and real-world performance. Using the Double Diamond design thinking model[4], we will explore its development and highlight the crucial role of collaboration between healthcare professionals and patients in advancing hearing care.

Objectives

This study aims to comprehensively review the journey of the Osia System since its 2019 launch. Through an exploration of real-world usage and patient outcomes, we seek to highlight the outcomes, innovations, and contributions to improving patient care by the Osia system. The Double Diamond framework[4] will be used to guide the study of the Osia System, employing divergent and convergent phases to explore, define, develop, and refine solutions. This method ensured a thorough understanding of user needs and iterative improvements for optimized outcomes.

Methods and materials

The study will follow a scoping review framework: defining the research question, selecting studies, charting data, and summarizing findings[5]. Systematic literature searches will be conducted across electronic health databases. Grey literature and relevant websites will also be explored to retrieve related data. Searches will be limited to articles and other information published from 2019 to 2024.

Initial results

A brief history of the Osia system and the journey of its development
The Osia System received FDA approval in December 2019[6], initially for patients aged 12 and older in the United States. In April 2024, the approval was expanded to include children aged 5 and older[7]. Additionally, the Osia System has been granted CE certification[8], which confirms that the device meets essential EU health and safety requirements and permits its sale within the European market[8].

The Osia System - development over time and innovative use
Since its launch, the Osia System has been appreciated by patients and professionals for its good sound quality and excellent amplification of high frequency sound[9,10]. The Osia System has also continuously advanced through the development of new product versions, such as the Osia 2(I) sound processor[11] and the OSI300 implant[12], which includes a coil magnet compatible with 3T MRI. Equally significant are the innovations from surgeons using the system, including new surgical techniques[13,14] improved methods for transitioning from legacy devices to the Osia System[15], implantation under local anesthesia[16] and securing the implant in a tight periosteal pocket instead of anchoring it to the BI300 implant (off label use)[17]. These innovations illustrate the important co-development of a new system between the manufacturer and health care professionals.

Conclusion

In conclusion, the Osia System, an advanced bone-conductive hearing device, has made notable progress through collaborative innovation. The Osia System has become the most used bone conduction system globally in the short space of five years, which has been facilitated through the collaborative innovation between the health care professionals and the manufacturer. Significant updates include the Osia 2(I) sound processor and the OSI300 implant. These innovations, coupled with the exploration of alternative surgical techniques, underscore a commitment to refining the system and improving patient care.

References

1. McDaid D, Park AL, Chadha S. Estimating the global costs of hearing loss. International Journal of Audiology. 2021 Mar 1;60(3):162–70.
2. World Health Organization. Chronic suppurative otitis media : burden of illness and management options [Internet]. 2004. Available from: https://iris.who.int/handle/10665/42941
3. Cochlear Limited. Clinical evidence on the Osia® System [Internet]. [cited 2024 Sep 9]. Available from: https://mss-p-007-delivery.sitecorecontenthub.cloud/api/public/content/78a8dd1f153b4231b6fa899b2fd92c27?v=c2bc1090
4. Kochanowska M, Gagliardi WR, With Reference To Jonathan Ball. The Double Diamond Model: In Pursuit of Simplicity and Flexibility. In: Raposo D, Neves J, Silva J, editors. Perspectives on Design II [Internet]. Cham: Springer International Publishing; 2022 [cited 2024 May 8]. p. 19–32. (Springer Series in Design and Innovation; vol. 16). Available from: https://link.springer.com/10.1007/978-3-030-79879-6_2
5. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. International Journal of Social Research Methodology. 2005 Feb;8(1):19–32.
6. Goldstein MR, Bourn S, Jacob A. Early Osia® 2 bone conduction hearing implant experience: Nationwide controlled-market release data and single-center outcomes. American Journal of Otolaryngology. 2021 Jan;42(1):102818.
7. Cochlear Limited. Cochlear receives FDA clearance to lower the age for the Osia System to 5-years-old [Internet]. Available from: https://www.cochlear.com/us/en/corporate/media-center/media-releases/2024/osia-lowered-indications
8. Cochlear Limited. CochlearTM Osia®Important information for Osia implant recipients [Internet]. [cited 2024 Sep 11]. Available from: https://assets.cochlear.com/api/public/content/2272179f9224407da8678e142d5893b7?v=c67b8fd5
9. Cowan R, Lewis AT, Hallberg C, Tong MCF, Birman CS, Ng IHY, et al. Clinical performance, safety, and patient-reported outcomes of an active osseointegrated bone-conduction hearing implant system at 24-month follow-up. Eur Arch Otorhinolaryngol. 2024 Feb;281(2):683–91.
10. Nevoux J, Boulet M, Pronost N, Papon JF, Alexandru M. Performance of an active transcutaneous bone conduction implant, the Osia system, in high frequencies and hearing in noise in users converted from a Baha attract system: a prospective study. Eur Arch Otorhinolaryngol. 2023 Oct;280(10):4691–6.
11. Cochlear Limited. Osia® Sound Processor [Internet]. Available from: https://www.cochlear.com/us/en/professionals/products-and-candidacy/osia/osia-processor
12. Cochlear Limited. CochlearTM Osia®OSI300 Implant Technical Brief – Reliability [Internet]. Available from: https://assets.cochlear.com/api/public/content/Cochlear-Osia-OSI300-Implant-Technical-Brief-Reliability
13. Alnoury MK, Daniel SJ. Minimally Invasive OSIA Bone Conduction Hearing Implant MOSIA in Children: How I do it? The Laryngoscope. 2024 Apr;134(4):1901–6.
14. Deep NL, Johnson BJ, Kay- Rivest E, Carlson ML, Friedmann DR, Driscoll CLW, et al. Modifications to Implanting the OSIA ® 2 Bone Conduction Hearing Implant: How I Do it. The Laryngoscope. 2022 Sep;132(9):1850–4.
15. Szabo L, Nagy R, Posta B, Kiss JG, Rovo L, Bere Z. BAHA Attract to Osia conversion patients: comparison of the two systems and long-term outcomes. J Laryngol Otol. 2023 Jul;137(7):757–62.
16. Posta B, Rovó L, Bere Z. How I do it: implantation of Osia® 2 system under local anesthesia. Eur Arch Otorhinolaryngol [Internet]. 2024 Sep 6 [cited 2024 Sep 11]; Available from: https://link.springer.com/10.1007/s00405-024-08921-5
17. Bere Z, Nagy R, Posta B, Perenyi A, Fyrlund H, Jarabin J, et al. Minimally invasive subperiosteal pocket technique for Osia 2 system- implantation without fixation. Eur Arch Otorhinolaryngol [Internet]. 2024 Aug 24 [cited 2024 Sep 2]; Available from: https://link.springer.com/10.1007/s00405-024-08915-3