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Paediatric Sentio™ transcutaneous bone-conduction hearing implant: early experience

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Abstract

Objective. Sentio™ is novel transcutaneous implantable conductive hearing device. Evidence in paediatric populations, particularly syndromic children, remains limited. We report our local experience in paediatric patients, including syndromic cases.

Methods. A prospective case series of patients implanted between March 2025 and February 2026 was reviewed. Data collected included demographics, underlying pathology, subjective outcomes (Children's Home Inventory for Listening Difficulties), objective outcomes (Bamford–Kowal–Bench) and surgical outcomes.

Results. Four patients (median age, 13.7 years; range, 11–15.5 years) were implanted, with one bilateral case. There was subjective and objective audiological improvement except for one patient, probably caused by poor concentration. Surgical learning points include the use of a longer fixation band to compensate for shallower drilling, careful implant positioning in microtia patients to facilitate future reconstruction and the use of image-guided navigation to avoid previous craniofacial surgery drill holes.

Conclusion. Sentio™ demonstrated favourable audiological and surgical outcomes in paediatric patients, including those with syndromes.

Main Article

Dickson Dewantoro takes responsibility for the integrity of the content of the paper

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Introduction

The Sentio™ System by Oticon Medical™, first established in 2024, is a type of active transcutaneous conductive implantable hearing device. This device, along with other transcutaneous conductionhearing devices is indicated in patients with conductive or mixed hearing loss and single-sided deafness, or in patients with conditions that can be aggravated by the use of ear mould, such as recurrent otitis externa and microtia and canal atresia.hearing devices is indicated in patients with conductive or mixed hearing loss and single-sided deafness, or in patients with conditions that can be aggravated by the use of ear mould, such as recurrent otitis externa and microtia and canal atresia.[1] Sentio™ uses features such as the OpenSound Optimizer™ that allow for detection and prevention of audible feedback, which allows for stable sound throughout the day. It also uses OpenSound Navigator™, which allows for improved sound quality and understanding in a 360-degree radius. This is a feature that is unique to Sentio™ and is not present in other implantable bone-conduction hearing devices.[2] Additionally, unlike middle-ear implants, Sentio™ does not routinely require computed tomography scanning prior to implantation or mastoidectomy for access.[3]

The Sentio™ implant is magnetic resonance imaging (MRI) conditional at 1.5 T, but still leads to an MRI shadow, which reduces the ability to image the area of the head surrounding the implant. The current literature on the use of Sentio™ is limited, particularly in paediatric patients and those with syndromic conditions. To date, only one prospective multicentre study has evaluated Sentio™ in an adult population.[2] This prospective study included 51 adult patients with hearing loss who met the Sentio™ eligibility criteria. Improvements were observed in sound-field thresholds, speech-in-noise performance, and quality-of-life measures following intervention. The findings support both the clinical effectiveness of Sentio™ and the safety of its implantation in the adult population.

Currently, there is an ongoing active study titled 'Pediatric Expansion Study of the SENTIO System', sponsored by Oticon Medical™, that looks at the safety and performance data in the use of the Sentio™ system in children younger than 12 years of age, because the system is currently licensed to be used in those 12 years and older. No preliminary results have been shown from this study.[4]

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Alder Hey Children's Hospital, Liverpool, UK, serves a diverse paediatric population with a high volume of cleft and syndromic patients, and is one of four nationally designated craniofacial surgery centres in the UK. The paediatric otolaryngology department has been implanting Sentio™ devices since March 2025. This study presents the first series of outcomes and key learning points from the implantation of the Sentio™ device in children, with a particular focus on its application in a paediatric syndromic population.

Materials and methods

Study design and setting

This was a prospective series of four case reports of all children who underwent implantation with the Sentio™ transcutaneous bone-conduction hearing device at Alder Hey Children's Hospital from March 2025 to present, following the introduction of the system to the department.

Patient selection

All children who met the manufacturer's candidacy criteria for the Sentio™ bone-conduction hearing system and underwent Sentio™) implantation during the study period were included.

Data collection

Demographic information, underlying pathology, surgical learning points and audiological data were collected at times when patients were listed for implantation, immediately following implantation, during activation of device and subsequent follow ups. Speech perception was assessed using the Bamford–Kowal–Bench sentence test, a validated measure of paediatric speech perception that assesses sentence recognition in noise (speech:noise ratio), with unaided and aided scores recorded pre- and post-operatively. This tests how much a child with hearing loss can actually hear compared with lip-reading and is suitable for patients who are familiar with the language used in the sentences used in the test and who are at least 5 years of age.[5]

Patient-reported hearing outcomes were assessed using the Children's Home Inventory for Listening Difficulties questionnaire, a validated children and caregiver-reported measure of functional listening ability in everyday environments, with pre- and post-operative scores collected where available. The Children's Home Inventory for Listening Difficulties questionnaire score is measured out of eight and provides a subjective assessment of how well a child with hearing loss can hear in eight different situations, which include listening in quite environment without facing the speakers, listening from a distance in a quite environment, hearing movie without captions, understanding other children speaking, hearing in noisy environment, and hearing an alarm.[6]

Surgical details, including laterality, technical considerations, intra-operative findings and complications, were documented.

Outcome measures

Primary outcomes were changes in speech discrimination and patient-reported hearing benefit. Secondary outcomes included surgical feasibility, technical considerations during implantation and complications.

Ethical considerations

No ethical approval was required for this study, but it was registered with the Clinical Governance and Audit Department with Audit Number 7610.

Results

Patient characteristics

Four children underwent Sentio™ implantation during the study period, with a median age of 13.7 years (range, 11 years to 15 years, 6 months). Three procedures were unilateral (all right-sided) and one was bilateral. Three patients had conductive hearing loss (two unilateral and one bilateral), and one had single-sided severe-profound sensorineural hearing loss (SNHL). Patient demographics can be found in Table 1.

All operations were performed by the same surgical team within a tertiary paediatric ENT service following the introduction of the Sentio™ system to the department.

Patient 1

Patient 1 was 15 years old with right conductive hearing loss of 63 dB HL caused by microtia with canal atresia. Patient 1's Bamford–Kowal–Bench post-operative aided performance with the Sentio™ device showed stability at 60:50 (+10 dB speech:noise ratio) (98 per cent) and modest improvement at both 60:55 (+5 dB speech:noise ratio) (from 90 per cent to 94 per cent) and 60:60 (0 dB speech:noise ratio) (from 72 per cent to 80 per cent) compared with the pre-operative soft-band trial. No Children's Home Inventory for Listening Difficulties test has been performed yet as the patient is still awaiting further follow up.

The presence of microtia and canal atresia affected the type of incision made relative to where the implant was placed to aid future reconstruction options and the reconstructive surgeon joined intra-operatively to aid with planning for positioning the implant. In this case, a more posteriorly based implantation allowed enough space and soft tissue for future reconstruction. Patient 1 also wore glasses, so it was important to take this into account when determining positioning and incision placement to ensure comfort and prevent any potential difficulties from wearing glasses.

Patient 2

Patient 2 was 12 years old with right-sided SNHL of 97 dB HL (bone-conduction threshold) and an air-conduction threshold of 10 dB in the better hearing ear. The underlying cause of hearing loss in patient 2 was post-lingual progressive SNHL caused by an enlarged vestibular aqueduct.

Whilst patient 2 showed improvement at 60:50 (+10 dB speech:noise ratio) (from 70 per cent to 90 per cent), there was reduction in post-operative Bamford–Kowal–Bench at both 60:55 (+5 dB speech:noise ratio) (from 80 per cent to 50 per cent) and 60:60 (0 dB speech:noise ratio) (from 40 per cent to 30 per cent). This was also associated with a reduction in the Children's Home Inventory for Listening Difficulties score from 6.7 out of 8 pre-operatively to 5.7 out of 8 post-operatively. These reductions were noted by the audiology team as being probably caused by issues with adequate concentration. Repeat testing will be performed during future follow up.

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Table 1. Patient demographics, hearing characteristics and pre-operative amplification

Patient	Age at surgery	Side implanted	Hearing loss type	Unaided PTA (dB HL), indicated ear*	Underlying pathology	Pre-operative non-surgical bone-conduction device
1	15 years, 6 months	Right	Conductive	63	Microtia with canal atresia	ADHEAR, BC, PONTO MINI 5
2	12 years, 3 months	Right	SNHL (single-sided deafness)	97	Post-lingual progressive SNHL (enlarged vestibular aqueduct)	PONTO MINI 5, BAHA 5/6 MAX, CROS
3	14 years, 11 months	Bilateral	Conductive	58 (right ear), 68 (left ear)	Sweeney–Cox syndrome with bilateral canal stenosis and craniosynostosis	BAHA 6 MAX (bilateral)
4	11 years	Right	Conductive	58	Previously operated ear (canaloplasty and myringoplasty)	ADHEAR

*PTA (Pure Tone Audiogram) represents the air-conduction threshold in the cases of conductive hearing loss and the bone-conduction threshold in the case of sensorineural hearing loss. In the cases of unilateral hearing loss, the contralateral ear air-conduction threshold is always better than 20 dB. SNHL = sensorineural hearing loss; dB HL = decibels hearing level.

Patient 3

Patient 3 was 14 years old with bilateral conductive hearing loss of 58 dB HL in the right ear and 68 dB HL in the left ear caused by Sweeney–Cox syndrome with bilateral canal stenosis and craniosynostosis.

During Bamford–Kowal–Bench testing, patient 3 demonstrated improved speech discrimination with performance at 60:60 (0 dB speech:noise ratio) increasing from 30 per cent pre-operatively to 50 per cent post-operatively and at 60:50 (+10 dB speech:noise ratio) improved from 70 per cent to 80 per cent, but a slight reduction at 60:55 (+5 dB speech:noise ratio) from 70 per cent pre-operatively and 60 per cent post-operatively.

There are several surgical learning points that can be taken from patient 3's case. Firstly, in the presence of abnormal skull shape caused by craniofacial conditions, consideration must be given to avoiding dissection around sites where previous craniofacial surgery has been performed because these sites can have exposed dura from previous drilling, increasing the risk of cerebrospinal fluid leak. Secondly, Oticon™ suggests the depth of the pocket to house the implant to be 3 mm.[7] However, in the case of patient 3, shallower drilling was required, hence the utilisation of the longer fixation band of 45 mm compared with the 39 mm allowed for satisfactory retention of the device to the cranium. Thirdly, image-guided navigation (Medtronic Stealthstation™) was used in patient 3, who underwent bilateral implantation in the context of Sweeney–Cox syndrome, to not only assist with accurate symmetrical implant positioning, but also to avoid previous drilling sites from previous craniofacial surgery with potential exposed dura.

Patient 4

Patient 4 was 11 years old with right conductive hearing loss of 58 dB HL caused by previous ear surgery (canaloplasty and myringoplasty) not amenable for ossiculoplasty. Post-operative Bamford–Kowal–Bench testing was not completed at the time of writing up of this study, but the patient reported audiological outcomes in the form of Children's Home Inventory for Listening Difficulties testing showing improvement in the score from 6.1 out of 8 pre-operatively to 7.7 out of 8 post-operatively.

Discussion

All Sentio™ implantations were completed successfully without intra- or post-operative complications. Our early experience highlighted several technical considerations relevant to paediatric implantation, particularly relating to skull thickness, available implantable surface area and prior or anticipated otological reconstruction.

Audiological outcomes showed overall improvement in both objective (Bamford–Kowal–Bench) and subjective (Children's Home Inventory for Listening Difficulties) assessment. Patient 2 had a reduction in their Children's Home Inventory for Listening Difficulties score, but this may be explained by the time of the day and the patient's lack of focus during the day of testing.

Adequate bone exposure of cortical bone was a consistent requirement across cases to ensure secure band fixation. In younger patients with thinner calvarial bone, insufficient drilling depth necessitated the use of a longer fixation band compared with the shorter band needed to achieve stable implant seating. However, the use of a longer fixation band means that greater cranial exposure is required to allow for adequate placement of the titanium screws. Where anatomical space was limited, modification of band orientation was required to optimise implant position while maintaining fixation security.

In patients with congenital ear anomalies, implant positioning required careful pre-operative planning. In the case of microtia with canal atresia, the implant was deliberately positioned more posteriorly to preserve future options for auricular reconstruction, necessitating co-ordination with the reconstructive surgical team. In the patient with craniofacial abnormality associated with Sweeney–Cox syndrome, an image-guided navigation system was used to accurately identify a safe and optimal implant site, given the altered cranial anatomy and restricted available bone surface. The image-guided navigation system was also helpful in allowing for accurate symmetrical implant positioning.

Limitations

This study has several important limitations. Firstly, it represents a small, single-centre case series with a limited number of patients, reflecting both the rarity of eligible cases and the recent introduction of the Sentio™ system to paediatric practice. As such, the findings may not be generalisable and should be interpreted as preliminary. Secondly, the prospective follow-up nature of data collection resulted in incomplete audiological and patient-reported outcome data, limiting the ability to draw robust conclusions regarding functional hearing benefit. In particular, speech discrimination testing and caregiver-reported outcome measures

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were not available for all patients at the time of reporting. Third, follow-up duration was short, precluding assessment of longer-term audiological outcomes, device retention and complication rates.

- Sentio™ is known to be a safe implantable conductive hearing device licensed for those aged 12 years and older, but the literature on its use in paediatric patients is limited
- This study showed that Sentio™ is a safe device to be utilised in paediatric patients with syndromes, with its use leading to overall improvement in both subjective and objective hearing outcomes
- Consideration of the implant's location through a multidisciplinary approach involving a reconstructive surgical team is crucial for potential future reconstruction in microtia patients
- Shallower drilling to compensate for children's thinner calvarium can be compensated for by using a longer fixation band and bilateral implant placement is feasible under one general anaesthetic
- A navigation system can be used to help with avoidance of previous calvarium drilling from craniofacial surgery and for symmetrical bilateral implant placement

Conclusion

The Sentio™ system appears to be a safe and effective option for transcutaneous bone-conduction hearing implantation in paediatric patients. Our early experience with Sentio™ implantation has been uncomplicated, including in children with craniofacial disorders and congenital ear anomalies. Larger multicentre prospective studies, with longer duration of follow up, are required to better define the clinical utility and long-term outcomes of this novel intervention in this population.

Competing interests. None declared

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