Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic exploration report number:	**TER308**
Topic:	Active transcutaneous bone conduction hearing implants for complex hearing conditions
Summary of findings:	Active transcutaneous bone conduction implants (atBCI) may serve as a solution for those with complex hearing conditions where conventional hearing aids are ineffective of unsuitable, such as moderate to severe conductive (CHL), mixed hearing loss (MHL), as well as those affected by single-sided deafness (SSD). We identified four systematic reviews, one randomised controlled trial and ten observational studies evaluating the effectiveness of atBCIs. Systematic reviews compared atBCI with unaided, bone-anchored hearing aids (BAHA) or pre-operative atBCI. Based on the audiological outcomes, atBCI provided higher patient satisfaction, low complication rates, and high functional gain. The authors conclude that atBCI is a safe and effective treatment for patients suffering from hearing loss when conventional hearing aids are not an option. However, most of the evidence included in the systematic reviews and identified by our searches were observational, such as cohort studies and case studies. Furthermore, studies were often comparing pre-operative, unaided versus post-operative atBCI. One randomised controlled trial was identified that evaluated the surgery, and the short-term benefits of the new active bone conduction hearing implant called the Osia in comparison to BAHA. Ten observational studies were identified, two comparative studies (Bravo-torres et al. 2018, Scotta et al. 2020) and eight single arm studies that analysed the effectiveness of atBCI. The type of hearing conditions among study populations and comparators varied, with some studies comparing atBCI to BAHA, or comparing different types of atBCI. In summary, seven out of ten observational studies concluded that the atBCI demonstrated improved hearing thresholds and speech recognition.

Introduction and aims

Health Technology Wales researchers searched for evidence on the clinical and cost effectiveness of active transcutaneous bone conduction hearing implants for complex hearing conditions.

Evidence overview

Systematic reviews

We identified four systematic reviews on the effectiveness of atBCI (Bezdjian et al. 2017, Magele et al. 2019, Sprinzl & Wolf-Magele 2016, Zernotti & Sarasty 2015). These reviews varied in their aim and/or objective and therefore also differed in their inclusion criteria (i.e., different hearing conditions, different comparisons or no comparison with other hearing devices, and different outcomes). Most of the evidence identified by the systematic reviews appear to be lower levels of evidence such as case studies and cohorts. From the abstracts of these papers, the chosen comparators were often unclear or that studies lack comparative evidence.

The most recent review, Magele et al. (2019) aimed to critically assess the safety efficacy and subjective benefit after atBCI (39 studies, 487 participants). All outcomes summarised in the review reflected beneficial audiological performance (A mean weighted benefit in word recognition score at 65dB (decibels) of 52.1% was found with the atBCI for all subject groups, and high patient satisfaction (subjective device satisfaction ranged from 49 to 100% with a mean of 98%. The SSQ (Speech, Spatial and Qualities of Hearing) questionnaire was applied in two studies with 8 participants. The minor complication rate reported for atBCI recipients was considerably low with one minor event in 9.9 person-years.

Bezdjian et al. (2017) presented outcomes of atBCI. From a total of 125 articles, 8 studies with 86 patients using 99 implants were selected. The present systematic review revealed a pure tone average (PTA) auditory gain of 31.10 (±8.29) dB in 86 patients and a mean SRT gain of 33.56 (±5.64) dB. In their review, only three patients (3.5%) had serious adverse events from the implantation of the device.

Sprinzl and Wolf-Magele (2016) compared the clinical effectiveness of the atBCI when compared to no hearing aids in adults and children. A total of 29 studies, 17 published and 12 presentations, were identified. The highest quality evidence was from three single-arm trials. In those assessing the safety of implantation, 6 of 117 patients experienced a minor adverse event with superficial revision surgery being required in one case. Speech perception in quiet was measured in five studies using Freiburger disyllabic words presented at 65 dB SPL and was found to significantly improve from <25% to scores ranging on average from 77% to 93% with atBCIs. Four studies also established the 50% speech reception threshold and measured a mean improvement of between 19 to 36 dB after receiving atBCI.

Zernotti and Sarasty (2015) compared atBCI to percutaneous BAHA. They selected only five publications to include in this systematic review. The review analyses 20 patients that received atBCI with different approaches and pathologies. The study concluded that the atBCI is a solution for patients with conductive/mixed hearing loss and SSD with different surgical approaches, depending on their anatomy. The study concluded that the atBCI shows low complications rate, improved functional gain and speech discrimination.

Primary Studies

We identified 11 primary studies which included one randomised controlled trial (Gawecki et al. 2020) and 10 observational studies.

Gawecki et al., (2020) compared the short-term benefits of atBCI (Osia) to BAHA (8 participants). It was observed that pure tone audiometry and speech audiometry in free field improved significantly after the implantation of atBCI (mean gain in pure tone audiometry for the Osia group 42.8 dB SPL and for the BAHA group 38.8 dB SPL). However, atBCI had longer mean surgery time (119 versus 51 minutes).

Observational studies

Ten observational studies were identified that assess the clinical effectiveness of atBCI for complex hearing conditions (Bravo-Torres et al. 2018, Hundertpfund et al. 2020, Lee et al. 2021, Oh et al. 2019, Salcher et al. 2017, Scotta et al. 2020, Seiwerth et al. 2021, Sprinzl et al. 2021, Volgger et al. 2021, Zernotti et al. 2019). Most studies (n =8) compared the effectiveness of atBCI with un-aided or no comparator. One study compared atBCI with bone conduction hearing implants (BCHA) (Bravo-Torres et al. 2018) and one study compared atBCI with BAHA (Scotta et al. 2020).

In summary, seven out of ten observational studies concluded that the atBCI demonstrated improved hearing thresholds (Bravo-Torres 2018, Lee et al. 2021, Salcher et al. 2017, Scotta et al. 2020, Seiwerth et al. 2021, Sprinzl et al. 2021, Volgger et al. 2021, Zernotti et al. 2019) and speech recognition (Bravo-Torres 2018, Hundertpfund et al. 2020, Oh et al. 2019, Salcher et al. 2017, Scotta et al. 2020, Seiwerth et al. 2021, Volgger et al. 2021, Zernotti et al. 2019) when compared to the alternative or standard care in their studies. Improved functional gain was also concluded in six studies (Lee et al. 2021, Oh et al. 2019, Scotta et al. 2020, Seiwerth et al. 2021, Volgger et al. 2021, Zernotti et al. 2019) along with improved patient satisfaction (Hundertpfund et al. 2020, Oh et al. 2019, Salcher et al. 2017, Scotta et al. 2020, Sprinzl et al. 2021, Volgger et al. 2021). Two studies concluded improved surgical handling with the atBCI (Sprinzl et al. 2021, Zernotti et al. 2019) and only one study explicitly reported major surgical complications Seiwerth et al. 2021 (4 out of 32 participants). Two studies report improved quality of life with atBCI (Hundertpfund et al. 2020, Oh et al. 2019). Finally, five studies reported manageable minor adverse events due to the level of surgical procedure needed for the atBCI (Hundertpfund et al 2020, Oh et al. 2019, Scotta et al. 2020, Zernotti et al. 2019, Bravo-Torres 2018). Bravo-Torres (2018) reported a small number of broken processors because of faults (n = 4) and skin irritation (n = 2).

Scotta et al. (2020) reported that surgical times were significantly longer for the atBCI (Bonebridge group) than the BAHA group (90 versus 42 minutes). There were no device failures reported in either group.

Economic evidence

One study conducted a longitudinal economic analysis of Bonebridge BCI 601 versus pBAHD over a five-year follow-up period (Amin et al. 2020). The mean total cost per patient of the Bonebridge device (atBCI) was significantly higher than percutaneous bone-anchored hearing devices at one-year post-implantation (£8,512 versus £5,590, $p < 0.001$); however, by five-years post-implantation this difference was no longer statistically significant (£12,453 versus £12,575, $p > 0.05$). The overall cost convergence was mainly accounted for by the increased long-term complications, revision surgery rates and higher cost of the percutaneous bone-anchored hearing device external processor compared to Bonebridge.

Ongoing research

There are two ongoing systematic reviews related to our inclusion criteria:

Active versus Passive Transcutaneous Bone Conduction Hearing Implants: Systematic Review of Outcomes and Complications in Adult Patients, registered with PROSPERO in April 2020 and due for completion December 2019 (Forner & Shoman 2020)

Active versus Passive Transcutaneous Bone Conduction Hearing Implants: Systematic Review of Outcomes and Complications in Paediatric Patients, registered with PROSPERO in July 2020 and due for completion in April 2021 (Forner et al. 2020).

The estimated completion date for both reviews has passed, we did not identify any published versions in our exploratory searches. For these studies, the atBCI is compared directly with passive transcutaneous bone conduction hearing implants. Main outcomes for both reviews include audiological outcomes (pure tone audiogram gains, speech reception and threshold gains).

Areas of uncertainty

The objective, comparator and study population varied across both primary and secondary sources, and consideration would be needed as to what comparators would be appropriate to include if this topic was to proceed to fuller appraisal.

The current proposed population (complex hearing loss) is a broad condition area that would require refining for appraisal.

Primary evidence in systematic reviews is often limited to mainly observational studies.

Literature search results

Health Technology Assessments and Guidance
Hearing loss in adults: assessment and management - NICE guideline [NG98] Published: 21 June 2018 Available at: https://www.nice.org.uk/guidance/ng98 Hearing loss in adults (Quality Standard [QS185]: Published 10th July 2019) Quality Statement 5: Provision of hearing aids Available at: https://www.nice.org.uk/guidance/qs185
Evidence reviews and economic evaluations
Bezdjian A, Bruijnzeel H, Daniel SJ, et al. (2017). Preliminary audiologic and peri-operative outcomes of the SophonoTM transcutaneous bone conduction device: A systematic review. International Journal of Pediatric Otorhinolaryngology. 101: 196-203. doi: 10.1016/j.ijporl.2017.08.014. Available at: http://www.epistemonikos.org/documents/2039b99b40c2ba5d6aabf329df71a765667d8913 Magele A, Schoerg P, Stanek B, et al. (2019). Active transcutaneous bone conduction hearing implants: Systematic review and meta-analysis. PloS one. 14(9): e0221484. doi: 10.1371/journal.pone.0221484. Available at: http://www.epistemonikos.org/documents/a9e99c64b95da142c80453845f087c7561b2e742 Zernotti ME, Sarasty AB. (2015). Active Bone Conduction Prosthesis: Bonebridge(TM). International archives of otorhinolaryngology. 19(4): 343-8. doi: 10.1055/s-0035-1564329. Available at: http://www.epistemonikos.org/documents/ffa459afb64ed6b9fd44cebf2991537677247a63 Sprinzl GM, Wolf-Magele A. (2016). The Bonebridge Bone Conduction Hearing Implant: Indication criteria, surgery and a systematic review of the literature. Clinical otolaryngology : official journal of ENT-UK ; official journal of Netherlands Society for Oto-Rhino-Laryngology & Cervico-Facial Surgery. 41(2): 131-43. doi: 10.1111/coa.12484. Available at: http://www.epistemonikos.org/documents/d6c33fa88ca8a33a0a414a126853ed7c0290e72c
Individual studies
Bravo-Torres S, Der-Mussa C, Fuentes-Lopez E. (2018). Active transcutaneous bone conduction implant: audiological results in paediatric patients with bilateral microtia associated with external auditory canal atresia. International journal of audiology. 57(1): 53-60. doi: http://dx.doi.org/10.1080/14992027.2017.1370137 Hundertpfund J, Meyer JE, Ovari A. (2020). Patient-reported long-term benefit with an active transcutaneous bone-conduction device. PloS one. 15(11 November): e0241247. doi: http://dx.doi.org/10.1371/journal.pone.0241247 Lee H-J, Kahinga AA, Moon IS. (2021). Clinical effect of an active transcutaneous bone-conduction implant on tinnitus in patients with ipsilateral sensorineural hearing loss. Auris Nasus Larynx. 48(3): 394-9. doi: http://dx.doi.org/10.1016/j.anl.2020.09.009 Oh S-J, Goh E-K, Choi S-W, et al. (2019). Audiologic, surgical and subjective outcomes of active transcutaneous bone conduction implant system (Bonebridge). International journal of audiology. 58(12): 956-63. doi: http://dx.doi.org/10.1080/14992027.2019.1657242 Scotta G, Dimitriadis PA, Wright K, et al. (2020). Surgical and functional outcomes of two types of transcutaneous bone conduction implants. Journal of Laryngology and Otology. 134(12): 1065-8. doi: http://dx.doi.org/10.1017/S0022215120002339

Seiwerth I, Frohlich L, Gotze G, et al. (2021). Clinical and functional results after implantation of the bonebridge, a semi-implantable, active transcutaneous bone conduction device, in children and adults. European Archives of Oto-Rhino-Laryngology. doi: http://dx.doi.org/10.1007/s00405-021-06626-7

Sprinzl GM, Schoerg P, Ploder M, et al. (2021). Surgical Experience and Early Audiological Outcomes With New Active Transcutaneous Bone Conduction Implant. Otology & neurotology : official publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology. doi: http://dx.doi.org/10.1097/MAO.0000000000003230

Volgger V, Schiesler IT, Muller J, et al. (2021). Audiological results and subjective benefit of an active transcutaneous bone-conduction device in patients with congenital aural atresia. European archives of oto-rhino-laryngology : official journal of the European Federation of Oto-Rhino-Laryngological Societies (EUFOS) : affiliated with the German Society for Oto-Rhino-Laryngology - Head and Neck Surgery. doi: http://dx.doi.org/10.1007/s00405-021-06938-8

Salcher R, Zimmermann D, Giere T, et al. (2017). Audiological Results in SSD With an Active Transcutaneous Bone Conduction Implant at a Retrosigmoidal Position. Otology & Neurotology. 38(5). Available at: https://journals.lww.com/otology-neurotology/Fulltext/2017/06000/Audiological_Results_in_SSD_With_an_Active.4.aspx

Zernotti ME, Chiaraviglio MM, Mauricio SB, et al. (2019). Audiological outcomes in patients with congenital aural atresia implanted with transcutaneous active bone conduction hearing implant. International Journal of Pediatric Otorhinolaryngology. 119: 54-8. doi: https://doi.org/10.1016/j.ijporl.2019.01.016

Gawecki W, Gibasiewicz R, Marszal J, et al. (2020). The evaluation of a surgery and the short-term benefits of a new active bone conduction hearing implant - the Osia®. Brazilian journal of otorhinolaryngology. doi: 10.1016/j.bjorl.2020.05.021. Available: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02140382/full

Ongoing research

Forner D, Shoman N. (2020). Active versus Passive Transcutaneous Bone Conduction Hearing Implants: Systematic Review of Outcomes and Complications in Adult Patients. Available at: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=150856

Forner D, Shoman N, Hong P, et al. (2020). Active versus Passive Transcutaneous Bone Conduction Hearing Implants: Systematic Review of Outcomes and Complications in Pediatric Patients. Available at: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=187121

Evidence submitted by topic proposer

Amin N, Soulby AJ, Borsetto D, et al. (2021). Longitudinal economic analysis of Bonebridge 601 versus percutaneous bone-anchored hearing devices over a 5-year follow-up period. Clinical Otolaryngology. 46(1): 263-72. doi: https://doi.org/10.1111/coa.13659

Date of search:	**August 2021**
Concepts used:	“Active transcutaneous bone conduction hearing implants” and “complex hearing conditions”