Outcomes of Patients Implanted with the Bonebridge Bone Conduction Device

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Introduction

The Bonebridge by Med-El is a new transcutaneous bone conduction implant (TCBCI) for patients with certain conductive or mixed hearing losses. An implantable bone conductor is placed completely under the skin while the external speech processor is attached through a magnetic coil. Unlike older bone conduction implants that have been on the market for a longer period of time, the Bonebridge does not require an abutment that penetrates the skin, which mitigates the risk of the patient developing adverse skin reactions to it. The goal of this systematic review is to look at the studies that detail the outcomes of patients implanted with the Bonebridge, and whether or not it may perform better than older, more established bone conduction devices.

Question

PICO Element	
Patient	Adults and children with conductive or mixed hearing loss
Intervention	Implantation and fitting of the Bonebridge
Comparison	Pre-operative unaided audiological results
Outcome	Functional gain, speech perception, and quality of life

What are the outcomes of adult and pediatric patients with conductive or mixed hearing loss implanted with the Bonebridge relative to their pre-operative, unaided audiological results?

Search Terms

Since this systematic review is only concerned with the Bonebridge by Med-El, 'Bonebridge' was the only keyword used. Transcutaneous bone conduction implant (or any combination thereof) was not used because that would include other devices that are not of interest for this review.

Inclusion / Exclusion Criteria

The following inclusion criteria was used when retrieving studies for the systematic review:

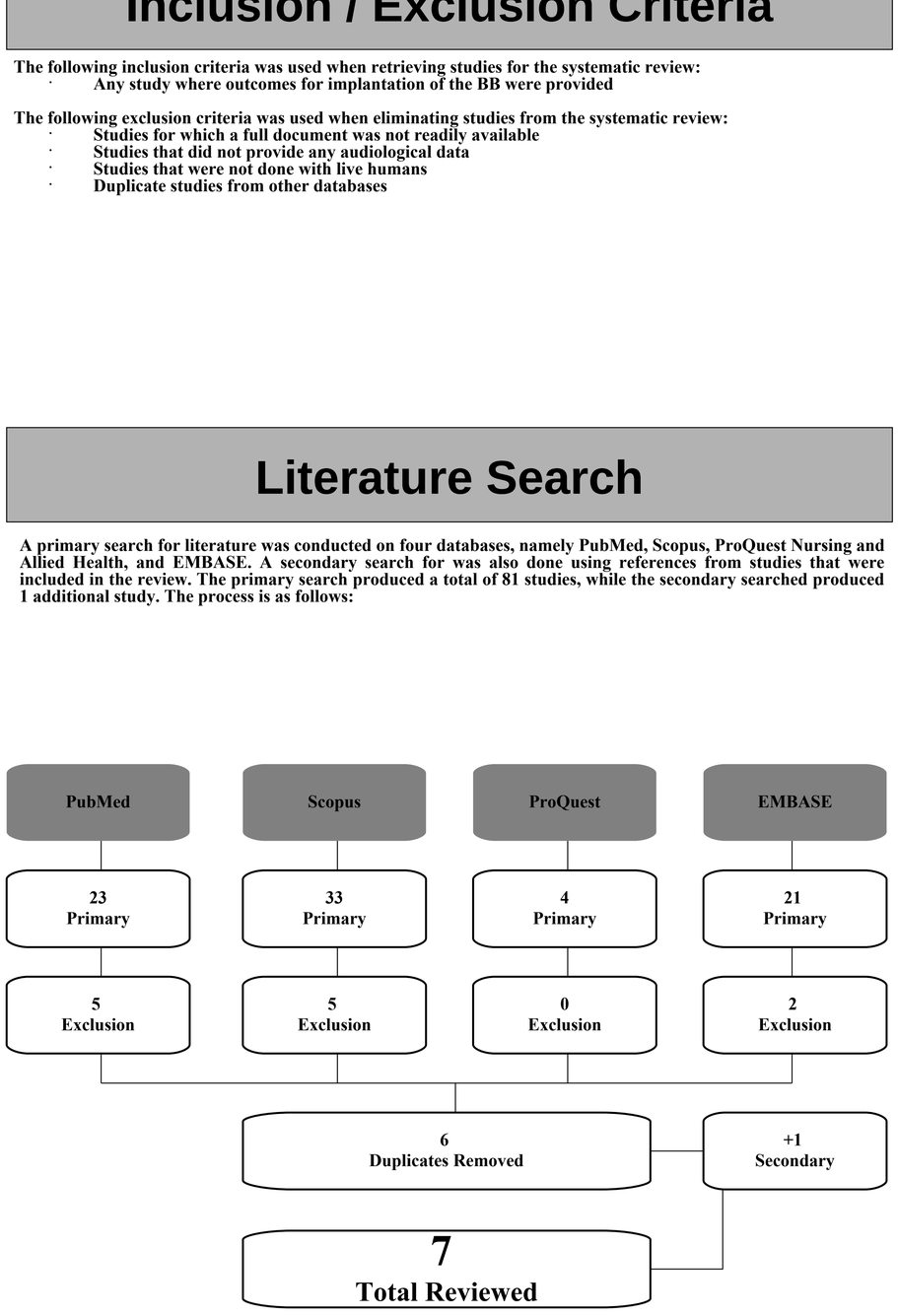
- Any study where outcomes for implantation of the BB were provided

The following exclusion criteria was used when eliminating studies from the systematic review:

- Studies for which a full document was not readily available
- Studies that did not provide any audiological data
- Studies that were not done with live humans
- Duplicate studies from other databases

Literature Search

A primary search for literature was conducted on four databases, namely PubMed, Scopus, ProQuest Nursing and Allied Health, and EMBASE. A secondary search for was also done using references from studies that were included in the review. The primary search produced a total of 81 studies, while the secondary searched produced 1 additional study. The process is as follows:



Results

The literature search produced 7 published studies, and a data extraction tool was used to obtain key information from the studies. Information included the type of study, the types of hearing loss patients suffered from and their etiologies, assessment tools that were used, audiological and subjective (if provided) results prior to and after implantation of the Bonebridge, and the central findings of the study. Each study had their quality appraised using the Crowe Critical Appraisal Tool (CCAT) v1.4, and the raw score (max of 40) was converted to a percentage. The data extracted and quality appraisals for all 7 studies are presented in the table below:

Study Purpose	Sample size, HL type & etiology	Outcome Measure	Results	Conclusion	CCAT Score
To obtain surgical and audiological data from one of the first groups of patients to be implanted with the BB	n = 4 all CHL 2x cholesteatoma 2x COM	AC & BC audiometry SRT	Avg. FG : 35.5 dB HL Avg. SRT change: -35 dB HL No change in unaided AC & BC thresholds	Compared to PCBCIs, the BB has fewer complications with regards to surgery and management. Its functional outcomes are also similar, if not better than well-established PCBCI's.	75%
To review functional results and quality of life of one of the first groups of patients to be implanted with the BB (retrospective chart review)	n = 6 2x CHL, 4x MHL 5x radical cavity 1x atresia	AC & BC audiometry SD (Freiburg @ 65 dB SPL) QOL (Glasgow Benefit Inventory)	Avg. FG: 33.6 dB HL Avg SD improvement: +63.3% in quiet +45.8% in noise Avg. QOL benefit: +32.4 No change in unaided AC & BC thresholds	Audiological and QOL results are satisfying and comparable to other more established solutions. The BB also provides benefits in terms of wound care and cosmetics.	80%
To evaluate functional outcomes of adults and children implanted with the BB	n = 11 (8 adults, 3 children) 4x CHL, 7x MHL 3x malformation (all children) 7x COM 1x SSD	AC & BC audiometry SD (Freiburg for adults, Mainzer for children; both at 65 dB SPL) SRT in noise (German Oldenburg)	Avg. FG: 33.4 dB HL Avg. SD improvement: +56% compared to unaided +21.5% compared to HA Avg. SRT in noise improvement: -1.0 to -7.4 SNR (depending on direction of noise source) No change in unaided AC & BC thresholds	The BB is a safe solution for patients with a CHL or MHL and provides benefits to speech perception, hearing in noise, and sound localization. These results are also seen in children. Results produced from this study are similar to those found in other ones.	80%
To investigate the safety and efficacy of the BB over a 3 month period	n = 12 7x CHL, 5x MHL 3x atresia 4x cholesteatoma 2x COM 1x otosclerosis 1x glomus tumour 1x chr. mastoiditis	AC & BC audiometry SD (Freiburg @ 65 dB SPL) SRT (German Oldenburg) Subjective satisfaction (Hearing Device Satisfaction Scale)	Avg. FG: approx. 24.2 dB HL Avg. SD improvement: +78.7% Avg. SRT improvement: -25.3 dB HL No change in unaided AC & BC thresholds	The BB provides good aided benefit for speech perception and subjective satisfaction. It is a safe alternative treatment for patients with MHL and CHL.	75%
To evaluate functional hearing gain and speech understanding with the BB, including those whose thresholds are higher than the criteria set out by the manufacturer (retrospective chart review)	n = 24 12x CHL, 9x MHL, 3x SSD 12x atresia 2x tympanosclerosis 1x otosclerosis 4x radical cavity 2x tympanoplasty 3x SNHL	AC & BC audiometry SD (Freiburg @ 65 & 80 dB SPL)	Avg. FG: (all groups): 28.8 dB HL Avg. FG (atresia): 32.5 dB HL Avg. FG (MHL): 24.7 dB HL Avg. FG (SSD): 27.2 dB HL Avg. SD improvement: +4.6% @ 65 dB SPL +44.5% @ 80 dB SPL	Patients with atresia obtained the highest FG with the BB, while those with SSD had reduced FG at the lower frequencies. Patients whose BC thresholds exceeded the 45 dB HL threshold criteria had poor tolerance of the implant to the point where some of them had to have it explanted.	80%
To evaluate surgical and audiological results of children implanted with the BB (prior to FDA approval)	n = 3 2x CHL, 1x SSD 1x atresia 1x cholesteatoma 1x congenital SSD	AC & BC audiometry SD (Freiburg @ 65 dB SPL) SRT (Freiburg Numbers @ 65 dB SPL) SRT in noise (German Oldenburg; only done for the SSD patient)	Avg. FG (CHL patients): 33 dB HL Avg. SD improvement: +47.5% Avg. SRT improvement: -24.5 dB HL SRT in noise improvement (SSD patient): -2.5 to -5.5 SNR (depending in direction of noise source) No change in unaided AC & BC thresholds	Off-label (at time of writing) use of the BB in children is feasible, and provides less complications compared to other bone implants that are currently approved for pediatric populations. The BB also provides good ability to hear in noise provided that the noise is not originating from the implanted side, as the implant readily transfers noise to the cochlea in the good ear.	62.5%
To describe the audiological results of patients who underwent implantation of the BB.	n = 5 4x CHL, 1x SSD 4x COM 1x AN removal	AC & BC audiometry SD (Castilian Spanish Hearing in Noise Test @ 65 dB SPL in quiet) SD in noise (Castilian Spanish Hearing in Noise Test @ 65 dB SPL, 10 SNR; only done for the SSD patient)	Avg. FG: 35.6 dB HL Avg. SD improvement: +20% SD in noise improvement (SSD patient): +15%	The BB is a safe solution that produces similar results to PCBIs. It is suitable for patients with SSD in order to overcome the head-shadow effect, and also provides improvements for hearing speech in noise for them.	72.5%

Legend: BB (Bonebridge), CHL (conductive hearing loss), COM (chronic otitis media), AC (air conduction), BC (bone conduction), SRT (speech reception threshold), FG (functional gain), HL (hearing level), PCBI (percutaneous bone conduction implant), MHL (mixed hearing loss), SD (speech discrimination), QOL (quality of life), SSD (single-sided deafness), SPL (sound pressure level), HA (hearing aid), SNR (signal-to-noise ratio), FDA (United States Food and Drug Administration), AN (acoustic neuroma)

Conclusion

The Bonebridge is a viable alternative treatment for patients with conductive or mixed hearing loss, provided their BC thresholds do not exceed the manufacturer's recommendations. There is little evidence of the Bonebridge causing any damage to the patient's hearing, as demonstrated by the lack of any reported significant changes in AC or BC thresholds post-implantation. In terms of performance, the Bonebridge is able to produce similar, if not better outcomes compared to other bone implants that have been on the market for a longer period of time. Since it is implanted completely under the skin, there is a much lower risk for adverse skin reactions and further injury. Many of these studies were done in the past 2 years, therefore further studies on the long-term outcomes of the Bonebridge are warranted.

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