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Evaluating the effectiveness and reliability of the Vibrant Soundbridge and Bonebridge auditory implants in clinical practice: Study design and methods for a multi-centre longitudinal observational study

Deborah Vickers[a,*], Angela Canas[a], Aneeka Degun[a,b], John Briggs[a,f,j], Mina Bingham[c], Joseph Toner[c], Huw Cooper[d], Sarah Rogers[d], Stacey Cooper[d,i], Richard Irving[d], Patrick Spielman[e], Samantha Batty[e], Stephen Jones[e], Abi Asher[f], Mark Chung[b,f], Neil Donnelly[f], Anna Skibinska[g], Robert Gardner[g], Chris Raine[g], Rachel Andrew[h], Kevin Green[h], Hashmat Ghulam[i], Terry Nunn[i], Dan Jiang[i], Severin Fürhapter[k], Michael Urban[k], Kate Hanvey[l], Sarah Flynn[m], David Lovegrove[n], Shakeel Saeed[a,b]

[a] Faculty of Brain Sciences, University College London, UK
[b] Royal National Throat, Nose and Ear Hospital, University College London Hospital NHS Foundation Trust, UK
[c] Auditory Implant Centre, Belfast HSC Trust, UK
[d] Midlands Hearing Implant Programme, Queen Elizabeth Hospital, Birmingham, UK
[e] Department of Otolaryngology, Ninewells Hospital NHS Tayside, Dundee, UK
[f] Emmeline Centre for Hearing Implants, Cambridge University Hospitals NHS Foundation Trust, UK
[g] Yorkshire Auditory Implant Service, Bradford Teaching Hospital NHS Foundation Trust, UK
[h] Audiology (Hearing and Balance) Centre, Central Manchester University Hospital NHS Foundation Trust, UK
[i] Hearing Implant Centre, Guy's and St Thomas' NHS Foundation Trust, London, UK
[j] MED-EL UK Ltd, UK
[k] MED-EL Electromedizinische Geraete, GmbH, Innsbruck, Austria
[l] Birmingham Children's Hospital NHS Foundation Trust, UK
[m] University Hospital Southampton NHS Foundation Trust, UK
[n] Lothian University Hospitals NHS Trust, Edinburgh, UK

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ABSTRACT

Background: The Vibrant Soundbridge middle ear implant and the Bonebridge bone conducting hearing device are hearing implants that use radio frequency transmission to send information from the sound processor to the internal transducer. This reduces the risk of skin problems and infection but requires a more involved surgical procedure than competitor skin penetrating devices. It is not known whether more complex surgery will lead to additional complications. There is little information available on the reliability of these systems and adverse medical or surgical events. The primary research question is to determine the reliability and complication rate for the Vibrant Soundbridge and Bonebridge. The secondary research question explores changes in quality of life following implantation of the devices. The tertiary research question looks at effectiveness via changes in auditory performance.

Method: The study was designed based on a combination of a literature search, two clinician focus groups and expert review.

A multi-centre longitudinal observational study was designed. There are three study groups, two will have been implanted prior to the start of the study and one group, the prospective group, will be implanted after initiation of the study. Outcomes are surgical questionnaires, measures of quality of life, user satisfaction and speech perception tests in quiet and in noise.

Conclusion: This is the first multi-centre study to look at these interventions and includes follow up over time to understand effectiveness, reliability, quality of life and complications.

* Corresponding author. University College London Division of Psychology and Language Sciences, 2 Wakefield Street, London, WC1N 1PF, UK.
E-mail address: d.vickers@ucl.ac.uk (D. Vickers).

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1. Introduction

Implantable hearing devices that directly stimulate middle ear structures (middle ear implants; MEI) or provide direct bone conduction to transmit sound to the inner ear (bone conducting hearing devices; BCHD) are becoming routinely used within the United Kingdom National Health Services (NHS). These devices are used by hearing impaired individuals who cannot use conventional acoustic hearing aids.

A traditional BCHD has two parts: an external sound processor and a surgically implanted connector fixed in the bone behind the ear. The connector projects through the skin and attaches to the processor which contains a microphone and hearing aid circuitry producing vibration to the skull and in turn the cochlea bypassing the outer and middle ear.

In the last two decades, there has been an increase in the use of devices where the implantable component which is activated via radio frequency from an external sound processor rather than by a mechanical link directly through the skin. Such devices have been produced by MED-EL (www.medel.com). The MED-EL devices are a MEI the Vibrant Soundbridge (VSB; CE Mark 1997 & FDA approval 2000) and a BCHD the Bonebridge (BB; CE Mark 2012 & FDA approval in process).

In the VSB and BB sound is picked up by the microphone of the external sound processor held over the receiver of the internal component by magnetism without skin penetration. The processor transmits electrical signals through the skin activating the moving components of the device, either driving a middle ear structure (VSB) or producing vibrations in the skull (BB), transmitting to the cochlea via bone conduction.

Without physical connection through a permanent opening in the skin, these devices potentially reduce opportunity for traumatic, infective or other medical complications. However, the implantation is more complex than for implantable percutaneous BCHDs, which may in turn lead to other opportunities for surgical complications.

A systematic review was conducted [17] of the impact on hearing of MEIs compared with conventional hearing aids. They concluded that some patients gain benefit from MEIs, but high-quality, long-term studies were not available, providing motivation for this research.

Comparison data are available for other BCHDs. It was reported that 4.5% of one clinics 602 BCHD caseload required device removal [16]; 2% due to pain, 1.2% due to infection, and the remaining due to a variety of other reasons. To conduct a comparative review of outcome with sufficient cases for the VSB and BB a multi-site study is required to overcome the relatively small number of implantations at individual sites.

This research is important for clinicians and commissioners developing services, patients considering treatment and the National Institute of Health and Care Excellence (NICE) who develop NHS guidelines for the UK. NICE produced guidelines on Auditory Brainstem Implants in 2005 [12], Cochlear Implants in 2009 [13] and have released guidance on Hearing Loss (adult presentation) in 2017. Ultimately, they may produce guidelines for all implantable auditory devices and will require high quality data to be able to develop evidence-based guidance.

The primary research question for this trial looks at the reliability and medical complication rate of the VSB and BB, the secondary research question explores changes in quality of life and the tertiary research question looks at the change in auditory performance.

2. Methods

The study design was developed through two focus group meetings involving representatives from eleven auditory implant centres in the UK, together with representatives from MED-EL and the chief investigators from University College London (UCL). The discussions were facilitated by the chief investigators from UCL.

Prior to the first focus group a draft study protocol was developed based upon a literature search to identify the most important outcomes used in the field. These outcomes fell under the following themes: medical complications, functional outcomes and quality of life. These themes were then used to inform the research questions. In the first focus group the themes were discussed with respect to how the data could be collected as part of clinical routine. The amended protocol was then prepared and the second focus group was conducted to refine the details.

The focus groups discussed the patient pathways, relevant audiological practice, functional outcome measures and the recording of medical procedures and complications used routinely in clinical practice. Through a process of discussion and consensus the assessment, fitting and patient management protocols were developed. All study sites agreed to follow the same protocols to enable quality data collation.

To be able to collect the information on the surgical and medical complications a questionnaire was developed for each implant (VSB and BB) because the tools were not available for this purpose. The development of this is explained in Saeed et al. [15].

2.1. Ethics approval

Multi-site NHS ethical approval (15YH 0229) with National Institute Health Research (NIHR) portfolio adoption and site specific information (SSI) approvals are in place at the participating study sites.

2.2. Study design

The developed study design is a multi-centre longitudinal observational study.

There are three main data collection groups:

1) Prospective participants (assessed and implanted following study initiation)
2) Retrospective follow up participants (assessed and implanted prior to study initiation but enlisted for follow up assessments according to study protocols)
3) Retrospective participants (existing patient data obtained via notes review)

The former two groups involve the attendance by the patients at clinic to undergo the perceptual assessment test battery.

The analysis will look at rate of device survival and medical complication over time, as well as changes in auditory performance and quality of life.

It was decided that assessments will be conducted at standard appointment times and all audiological tests and patient questionnaires would be standardized and in addition, wherever possible questionnaires would be self-administered.

2.3. Data collection

It was concluded that audiological measures and the speech tests will be administered by the audiologists or speech and language therapists who will also complete the case report forms for the study. The surgical questionnaires will be completed either by the surgeon or audiologist based on the notes. Quality of life and device satisfaction questionnaires will be self-completed by the patients.

2.4. Demographic information

The following demographic information will be the minimum data set for the study to be able to account for any confounds in the analysis. When the data for each individual are reported on the Case Report Form a code will be used to pseudo-anonymise the data collection:

- Gender
- Age at implantation
- Onset of hearing loss (calculated from when they thought their hearing loss was at the level they experienced prior to implantation)
- Home language and which is the first language for the individual
- Aetiology of Deafness
- Additional Difficulties
- Any other factors that may affect outcomes
- Device in left ear (make and model)
- Device in right ear (make and model)
- Listening configuration during testing (e.g. individuals may use a hearing aid or cochlear implant in the other ear)

2.5. Participant numbers

The power analysis was conducted for the prospective group only. The primary outcome for this arm of the study was the Health Utilities Index questionnaire (HUI23) which is a combination of two versions, which is a validated stand-alone questionnaire [6]. The power calculation indicated that there should be 24 participants in each group based on a medium effect size (0.57). Therefore in total across the ten study sites there should be 72 participants in total because there are three sub-groups for analysis, these are: Soundbridge for individuals with conductive or mixed losses, Soundbridge for individuals with sensori-neural losses and Bonebridge for conductive losses.

For the two retrospective groups all data that is available will be collated.

2.6. Audiology and speech measures

A **standard pure-tone audiogram** will be recorded pre-implantation for octave frequencies from 250 to 8000 Hz and bone-conduction thresholds will be measured from 500 to 4000 Hz.

A **soundfield audiogram** using either warble tones or narrow-band noises will be conducted to determine the thresholds across the frequency range (from 250 to 4000 Hz in octave steps) post-implantation and in aided conditions pre- and post-implantation.

Sentence perception in quiet will be assessed with the Bamford Kowal Bench (BKB [1]; sentence test presented at 50 dBA and 40 dBA, spoken by a male talker, presented from a speaker 1 m in front of the listener. The minimum dataset will be to only present the stimuli at 40 dBA. The percent key words understood correctly in the sentence will be recorded.

In addition **sentence perception in noise** will be conducted using BKB sentences. This would either be with fixed level noise presentation with the noise presented at a level to avoid ceiling and floor effects or alternatively with an adaptive version of the BKB sentence test in noise in which the test adjusts the signal-to-noise ratio to determine the level where 50% of speech is perceived. The minimum test configuration is for speech and noise to be presented from the same speaker 1 m in front of the listener.

To assess spatial speech perception with bilateral hearing impairment, there will be three conditions, the first condition will involve speech and noise being presented from the same speaker, the second condition will involve the speech being presented from the speaker in front and the noise will be presented from a speaker at 90° on the left. The third condition will involve the noise being presented from 90° on the right. The difference between scores with speech and noise presented from the same speaker minus the scores for each side at 90° is the spatial release from masking.

In the cases of single-sided deafness the configuration will be that speech is presented through a speaker on one side and the noise on the opposite side and repeated in the reverse configuration to determine the benefit obtained for speech in noise from the hearing device.

Word perception in quiet will be assessed with the Arthur Boothroyd (AB [3]; monosyllabic word test (one syllable real words). The test comprises of 13 lists of 10 words of which three lists will be presented in each condition (i.e. 30 words). Each word list is equivalent, eight of the words in each group assess consonant contrasts and two assess vowel contrasts. A recording of a spoken word is presented and the participant repeats what they hear. Stimuli will be produced by a male talker, from a loudspeaker 1 m in front of the listener at 50 dBA and 40 dBA with the minimum dataset being 30 words presented at 50 dBA.

The self-completion of the **Health Utilities Questionnaire (**HUI23**)** will be used. It is a standardized multi-attribute questionnaire looking at health status and provides a single summary score of the health-related quality of life. This questionnaire can only be used with the prospective group because it specifically relates to health status in the last four weeks.

The retrospective assessment group will use the validated **Glasgow Benefit Inventory** (GBI [14]; which is a patient-reported questionnaire evaluating the change in quality of life following an intervention. For this questionnaire the comparison is made between before and after receiving the intervention so the time aspect is not as critical as for the HUI23.

In addition, to evaluate spatial hearing, centres can use the **Speech, Spatial, Qualities Questionnaire** [8]. This is a standardized questionnaire which is used to assess spatial speech perception in the real-world.

Finally, the **Hearing Device Satisfaction Scale** will be used to capture any device specific information relating to usage and satisfaction. This questionnaire was developed by the implant company Symphonix.

2.7. Participant inclusion criteria

2.7.1. Prospective data collection

Newly implanted adults and children over the age of 5 years using a VSB or BB from the date at which the hospital obtained Site Specific Information approval. Each participant will be consented and followed for a minimum of 6 months and data from all participants will be recorded until July 31st, 2018. There will be three main demographic groups based on configuration of hearing loss type and device. These are: 1) VSB users with conductive or mixed hearing losses (both conductive and sensorineural), 2) VSB used with sensori-neural losses & 3) BB with conductive or mixed hearing impairments.

2.7.2. Retrospective follow up

Adults and children implanted with a VSB or BB prior to the start of the study who still attend clinic for follow up appointments will be recruited into this group. All retrospective data will be collated and the surgical questionnaires completed. At the point where the patient visits the clinic for a routine clinical appointment they would be consented for the study and the standard assessment test battery would be conducted, including questionnaires but the HUI would be replaced with a GBI.

2.7.3. Retrospective data collection

Adults and children implanted with a VSB or BB prior to the start of the study who no longer visit clinic for follow-up would be recruited into this group. Surgical questionnaires and a record of any assessment scores will be recorded.

2.8. Data collection points

2.8.1. Prospective group

There will be a minimum of 6 months data collection for each individual. Data will be collected at the following time points as a minimum data set:

Pre-implant where assessments and self-completion questionnaires will be completed.

Surgery in which the intra-operative surgical questionnaire will be completed.

Initial fitting where patient specific set up, adjustment of device, results of performance assessments and self-completion questionnaires will be recorded.

1–3 months post-fitting where assessments and self-completion questionnaires completed.

6–9 months post-fitting where assessments and self-completion questionnaires completed.

The assessments and questionnaires will be completed at each follow-up appointment afterwards until study close.

At the initial fitting and the appointments afterwards the surgical questionnaire will be updated to capture any medical/surgical/device issues that happen over time.

2.9. Retrospective follow up group

For this group at the point when they attend clinic the assessments and self-completion questionnaires will be completed and the surgical questionnaires will be filled in to capture any details of problems that occurred over the entire time period that the individual had their device. Over this time period any results of audiological or speech perception tests will also be recorded.

2.10. Retrospective group

There will be no assessment points for this group. Patient notes will be reviewed and the surgical questionnaire completed relating to the entire time period that the individuals have their. In addition any audiological and speech perception results will be recorded.

3. Discussion and conclusion

The final protocol will be followed by all study sites producing the first multi-centre evaluation of surgical and performance outcomes in VSB and BB users. These findings will be compared to similar studies for other BCHDs to determine how the devices compare on reliability and complications [10]; [5,9]. A survival analysis will be conducted based on surgical questionnaires to map out potential complications that may arise, the associated time course and frequency of occurrence. Other measures to be compared to the literature will be patient satisfaction, benefit and quality of life [4,7,18], soundfield hearing thresholds [2,4,11] and speech perception [2,4,11]. Changes in surgical practice that have occurred over time will be considered in the review to determine the impact that these may have had on performance.

Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.conctc.2018.03.007.

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