




Article

Medical Safety and Device Reliability of Active Transcutaneous Middle Ear and Bone Conducting Implants: A Long-Term Multi-Centre Observational Study

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Abstract: Active bone-conducting hearing devices (aBCHD; e.g., MEDEL Bonebridge[®] (BB)) and active middle ear implants (aMEI; e.g., MEDEL Vibrant Soundbridge[®] (VSB)) use radio frequency transmission to send information from an external microphone and sound processor to an internally implanted transducer. These devices potentially have an advantage over devices with percutaneous links because the skin is closed over the implantable components, which should reduce the risk of skin problems and infection. On the other hand, surgical procedures are more complex, with a greater risk of damage due to surgery. The objectives of this research were to quantify the reliability and long-term survival of MEDEL VSB and BB devices, determine the adverse and serious adverse device-related complications, and consider associated causes. A multi-center observational retrospective and prospective study was conducted at eleven auditory implant centers in the United Kingdom. Data was collected using a surgical questionnaire and audiological reports. Data were obtained from patient notes or from prospective cases that had a minimum follow-up of one year post-implant. Consecutive patient records were reviewed. Datasets from 109 BB and 163 VSB were reviewed. Of these, 205 were retrospective case note reviews, and 67 were prospective cases. The mean follow-up was 4 and 6 years, respectively, for BB and VSB. Kaplan–Meier Survival analyses indicated that the BB survival was 97% and 93.3% at 1 and 5 years, respectively, and the VSB was 92.1% and 87% at the same time points. This is a large cohort study for the field and has indicated that BB and VSB are safe interventions. Care should be taken to monitor magnet strength in the first few months. For the majority of device-related effects, there was no apparent association with etiology. However, an interesting pattern emerged for individuals who exhibited an inflammatory response, e.g., adhesions or device extrusion, and those with a history of chronic suppurative otitis media. This should be considered in future work and is not surprising given that many VSB recipients have a complicated hearing history, often associated with otitis media.

Keywords: bone conducting devices; middle ear implant; surgical approach

1. Introduction

Implantable hearing devices that directly stimulate middle ear structures (active middle ear implants; aMEI) or that provide direct bone conduction to transmit sound to the inner ear (active bone conducting hearing devices; aBCHD) are now routinely used within the United Kingdom and many countries around the world. These devices are used by individuals with hearing loss who cannot use conventional acoustic hearing aids for anatomical and/or medical reasons.

Historically, BCHDs have had two parts: an external sound processor and a surgically implanted connector fixed in the bone behind the ear. The connector (abutment) protrudes through the skin and attaches to the external sound processor, which contains a microphone and hearing aid circuitry. These impart stimulation to the cochlea via bone conduction through the skull, bypassing the outer and middle ears.

aMEIs are different from middle ear prostheses, which functionally replace damaged or absent anatomical structures without providing any driven component. MEIs provide mechanical energy to move the middle ear structures via an attached transducer. This transducer is controlled and driven by an externally worn component containing a microphone, signal processing chip, battery, and transmitter. Good coupling of the transducer to the remaining ossicular elements or the round window is key to providing good outcomes, and issues with coupling can lead to variability in results [1].

In the last two decades, there has been an increase in the use of active devices where the vibrating transducer is powered by and activated by radiofrequency (RF) coupling across intact skin. A surface induction coil surrounds a magnet and is retained by magnetic transcutaneous attraction to a matching subcutaneous coil. These magnets align the coils and maximize RF transmission efficiency. In contrast, devices with a passive percutaneous osseointegrated component are directly connected to a vibrating external processor [2]. The two most commonly used active transcutaneous devices of this type are produced by MED-EL (www.medel.com, accessed on 25 June 2023). The MED-EL devices are an aMEI, the Vibrant Soundbridge (VSB; CE Mark 1997; FDA approval 2000), and an aBCHD, the Bonebridge (BB; CE Mark 2012; FDA clearance 2018). Without any physical connection through a permanent opening in the skin, these devices potentially reduce the opportunity for traumatic, infection-related, inflammatory, or other medical complications. However, the implantation is more complex than for percutaneous devices, which may result in greater surgical risk. Souza et al. [3] in a systematic review of the safety of BCHDs compared the original percutaneous to the transcutaneous approach and found that fewer complications occurred with the transcutaneous approach, and the number of major events was significantly lower for active transcutaneous devices such as the BB.

The BB is indicated for individuals with conductive or mixed losses, and the VSB for individuals with mild to severe sensori-neural losses, mixed losses, or conductive losses who cannot benefit from hearing aids.

Tysome and colleagues [4] conducted a systematic review of the impact on hearing of aMEIs compared with conventional hearing aids. They concluded that many patients could benefit from aMEIs but that high-quality, long-term studies were not available at that time.

The Medical Device Regulation (https://ec.europa.eu/health/md_sector/overview_en, accessed on 25 June 2023) states that follow-up for the lifetime of the device is necessary, which, together with the findings from Tysome et al. [4], provided the motivation for this research on the long-term follow-up of VSB and BB patients. To carry out a comparative review with sufficient cases for the VSB and BB, a multi-site study was conducted to overcome the relatively small number of implantations at individual sites. This study

represents the largest published dataset on these devices, allowing for a fuller exploration of medical outcomes.

This research provides evidence requested in the consensus statements for BCHDs and aMEIs on the consequences of surgery, risks, complications, and device performance (reliability) over time [5]. It is also important for developing evidence-based guidelines (e.g., National Institute of Health and Care Excellence (NICE)) in the UK for clinicians, patients considering treatment, and healthcare agencies funding services. In the UK, the VSB and BB are provided tariff-free to the patient, but costs are still met by the publicly funded National Health Service (NHS). Therefore, good fiscal practice is essential. A low incidence of problems is both clinically and financially important; for these reasons, understanding device reliability and complication rates is necessary.

Device reliability in this context is defined as the probability that the VSB or BB devices will perform the required hearing function without failure over a 5-year period. A survival analysis based on the time from implantation to a serious adverse device-related effect (SAE) was conducted to determine this reliability. Criteria for reliability are related to device failure, explantation, or medical or surgical intervention requiring an overnight hospital stay. Where possible, BB devices were followed up beyond 6 years and VSB devices beyond 15 years. We also explored and reported other device-related adverse effects (AE) with respect to rate, type, and cause observed during the data collection period, but these were not included in the survival analysis.

2. Materials and Methods

The study was developed through a series of focus groups to iteratively build and optimize the protocol and the surgical and medical questionnaires. The focus groups were comprised of surgical and audiological representatives from the contributing clinical sites. The full study design and development of this research protocol were reported by Vickers et al. [6].

A questionnaire was developed to collect surgical and medical complications from intraoperative reports through post-implant follow-ups. The questionnaire was modified to be appropriate for each device (VSB and BB) to reflect the potential complications of the surgical approaches, the different device characteristics, and an opportunity for an open response.

The following demographic data were collected: pre-surgical hearing thresholds, type of hearing category (conductive, sensori-neural, or mixed (both conductive and sensori-neural)), age at implant, age at the event, etiology, sex, and whether single-sided deafness (SSD; BB only)

The device type was noted for each individual, and in addition, for the VSB, the coupling for the vibrating element was recorded (oval window, round window, incus short process, incus long process, and stapes).

Ethics Approval

Multi-site NHS ethical approval (15YH 0229) with National Institute of Health Research (NIHR) portfolio adoption and site-specific information (SSI) approvals were obtained.

Participants

There were two participant groups, they were:

- (1) Prospective participants—Newly implanted patients using a VSB or BB and implanted before 31 December 2019 with 12 months follow-up until 31 December 2020.
- (2) Retrospective participants—Patients implanted with a VSB or BB prior to the start of the study. Data were collected from patient records until 31 December 2020.

Events were categorized as SAE if the patient was explanted or reimplanted or needed a return to the hospital to resolve a problem that required an inpatient stay of longer than 24 h. AEs are events that result in a physical effect. The analysis considers the rate and type of events recorded.

Assessments and monitoring were conducted during routine hospital appointments. These included pre-implant assessment, intra-operative, post-operative medical or sur-

gical review (usually within 2 weeks of operation), device activation (usually 1 month post-operative), 1- or 3-month post-switch-on, 9 or 12 months post-switch-on, and annually thereafter. Data were collected at all these assessment points, and complications were captured.

3. Results

The number of events and long-term device survival are reported here. There were 272 complete datasets. A further 20 datasets had extensive missing data, excluding them from analysis. These unused datasets occurred in cases where follow-up data was not recorded due to patients not attending appointments or changing clinics. There were 109 BB cases (73 retrospective and 36 prospective) and 163 VSB cases (132 retrospective and 31 prospective).

For the BB cases, one patient was implanted bilaterally; there were 39 SSD cases implanted unilaterally; and the rest were unilateral implants in people with bilateral mixed or conductive hearing losses. The average age at implant was 46 years (10–74 years; 2 under 18 years), and there were 63 females and 46 males. For the BB the mean four-frequency average (4FA; 0.5, 1, 2, 4 kHz) air conduction thresholds for those with sensori-neural or mixed losses and SSD was 106 dBHL in the deaf ear and for mixed or conductive bilateral deafness was 64 dBHL (mean air-bone gap of 44 dBHL).

For the VSB cases, 21 patients were implanted bilaterally; there were 71 with sensori-neural, 78 with mixed, 13 with conductive losses, and in 1 case, the information on type of hearing loss was missing. The average age at implant was 55 years (5–84 years; 3 under 18 years), and there were 91 females and 72 males. For the VSB, the mean four-frequency average (4FA; 0.5, 1, 2, 4 kHz) for those with sensori-neural losses was 79 dBHL, and for mixed or conductive losses, it was 84 dBHL (mean air-bone gap of 31 dBHL).

For the BB, there were a total of 18 events (16.5%), of which 6 (5.5%) were SAEs. Two SAEs required reimplantation or transplantation, two required flap thinning surgery to improve the stability of the external components, and two needed intravenous antibiotics. The mean follow-up period per BB device was 4.0 years. For the VSB there were 42 (26%) events in total of which 19 (11.5%) were SAEs. Fifteen required reimplantation or transplantation; three required re-positioning of the transducer; and one needed intravenous antibiotics. The mean follow-up period per VSB device was 6.0 years. Figure 1 shows the distribution of events for the different devices.

For both devices, magnet events were recorded when causing pain or pain with an adverse skin response. There were 7 cases for the BB and 2 for the VSB.

The details of the breakdown of event categories together with the etiology for the BB and VSB are shown in Tables 1 and 2, respectively.

Table 1. Device-related events for BB. CSOM = Chronic suppurative otitis media; SSD = Single-sided deafness.

Event Specifics	Number of Cases	Comment	Etiology
Minor pain	2	Flap thickness issue, unresolved	Unknown, labyrinthitis
Pain	6	Magnet too strong, resolved by changing strength	CSOM, otitis externa, ototoxicity (gentamicin), Unknown (SSD)
Facial nerve insult	1	All spontaneously recovered	Otosclerosis
Wound infection	1	Antibiotics	Stenosis
haemorrhage	2	Resolved intraoperatively	CSOM, Unknown
Wound infection	2	Intravenous antibiotics	Otitis Externa, Unknown
Major pain	2	Flap thinned in surgery	2 × CSOM
Major pain	1	Explantation	Unknown
Device failure	1	Reimplantation	Stenosis

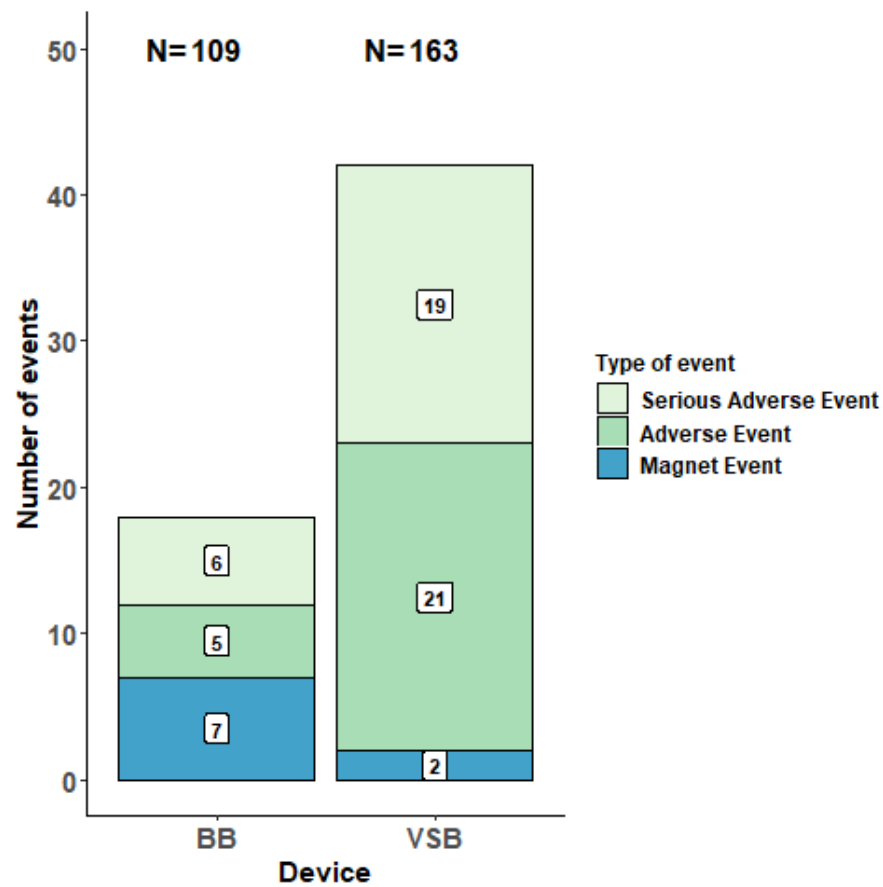


Figure 1. Number of events in three categories for the Bonebridge (BB) and the Soundbridge (VSB) devices. N indicates the total number of participants in that group.

Table 2. Device-related events for VSB cases. CSOM = Chronic suppurative otitis media; OW = Oval window; FMT = Floating mass transducer.

Event Specifics	Number of Cases	Comment	Etiology
Magnet event	2	Magnet strength reduced due to pain	CSOM; Unknown
Pain	2	One resolved with antibiotics; one mild ongoing	Otitis externa; hereditary progressive
Facial nerve insult	5	All spontaneously recovered	2 × CSOM; progressive; 2 × unknown
Wound infection	4	All resolved with antibiotics	Noise-induced; trauma; cholesteatoma; otosclerosis
Tinnitus	1	Unresolved mild	Unknown
Dural tear	4	All repaired intraoperatively	2 × CSOM; otosclerosis; unknown
Chorda sacrifice	4	Intraoperative event—no resolution	CSOM; Meatal stenosis; bilateral menieres; otitis externa
Ear canal damage	1	Occurred during surgery	Otitis externa
Adhesions/tissue growth	7	One surgical removal; Six reimplanted	5 × CSOM; progressive; unknown
FMT migration	2	Remobilisation and repositioned	2 × CSOM
Cholesteatoma	1	Repositioned on OW	CSOM
Device extrusion	1	Reimplanted	CSOM
Device failure	2	Reimplanted	otosclerosis; unknown
Wound infection	2	One explanted; One intravenous antibiotics	2 × CSOM
Ossicular damage	4	One explanted and three reimplanted	Inflammation and eczema; Alstrom’s syndrome; two unknown

When comparing the timepoint at which different events occur, the BB (Figure 2) shows a bimodal distribution, with a peak during and immediately after surgery and another peak at 2–3 years post-device activation. For the VSB (Figure 3) the majority of events take place during and immediately after surgery with small numbers of events scattered across the years.

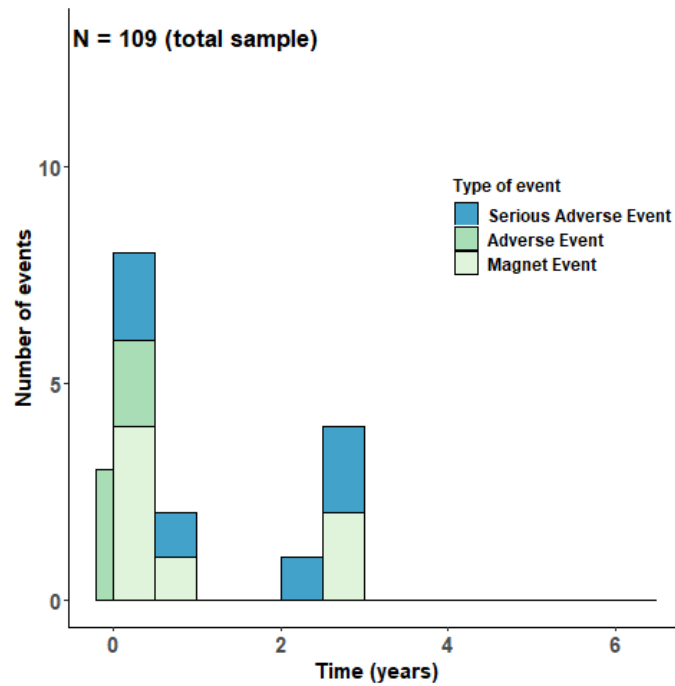


Figure 2. Showing the timepoint post-implant when events occurred for Bonebridge (BB) devices. Intraoperative issues are shown in the bar to the left of the ‘0’ time point.

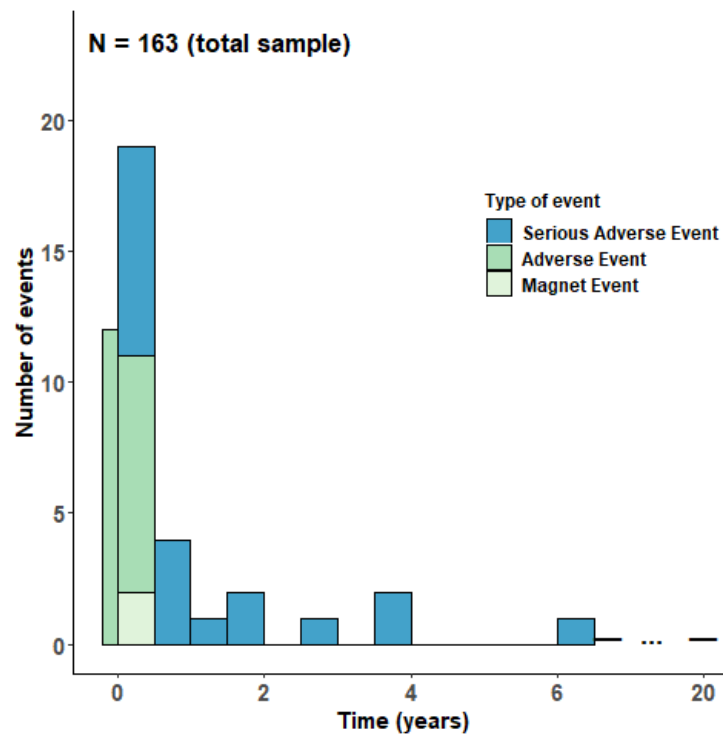


Figure 3. Showing the timepoint post-implant when events occurred for Soundbridge (VSB) devices. Intraoperative issues are shown in the bar to the left of the ‘0’ time point.

The etiology is listed in the tables above. A range of middle and inner ear pathologies and their consequences are evident throughout the data for both BB and VSB. There would appear to be some association between VSB cases with a history of chronic suppurative otitis media (CSOM) and an inflammatory response to the implantation of the device. This is observed in cases of adhesions, tissue growth, device extrusion, and serious wound infections.

Figures 2 and 3 show the distribution of events over time.

Most adverse intraoperative events were resolved during surgery, except for irreversible cases of chorda tympani sacrifice that occurred for the VSB.

The largest number of events for both devices occurred in the first month following device activation. Most events are resolved readily without recurrence.

For the VSB, the number of serious events that required explantation steadily dropped until approximately 3–4 years, with the majority occurring within the first 12 months. A different pattern was observed for BB; again, there were more serious events occurring in the first year, and this did reduce, but there was another peak at around 4 years, suggesting a more prolonged risk for SAEs.

One of the most frequently reported events for the BB was that the use of too strong a magnet results in pain or discomfort, particularly after the first few weeks when swelling of the skin flap has reduced. This accounts for seven of the 17 reported events. For the VSB, the most frequent issue was the development of adhesions (unnatural attachment of tissue due to damage or inflammation). Most of these cases prevented the device from functioning properly and resulted in explantation. These were reported, following surgical exploration, as the main cause of reduced device performance.

Kaplan–Meier survival analyses (time to SAE) were conducted based on the SAE numbers for the entire follow-up period for each device and the estimated cumulative survival scores at 1 and 5 years were calculated. The Kaplan–Meier plots are shown in Figures 4 and 5 for BB and VSB respectively. The cumulative survival rate for BB was 97.0% and 93.3% at 1 year and 5 years, respectively. The cumulative survival rate for the VSB was 92.1% and 87.0% for 1 year and 5 years, respectively.

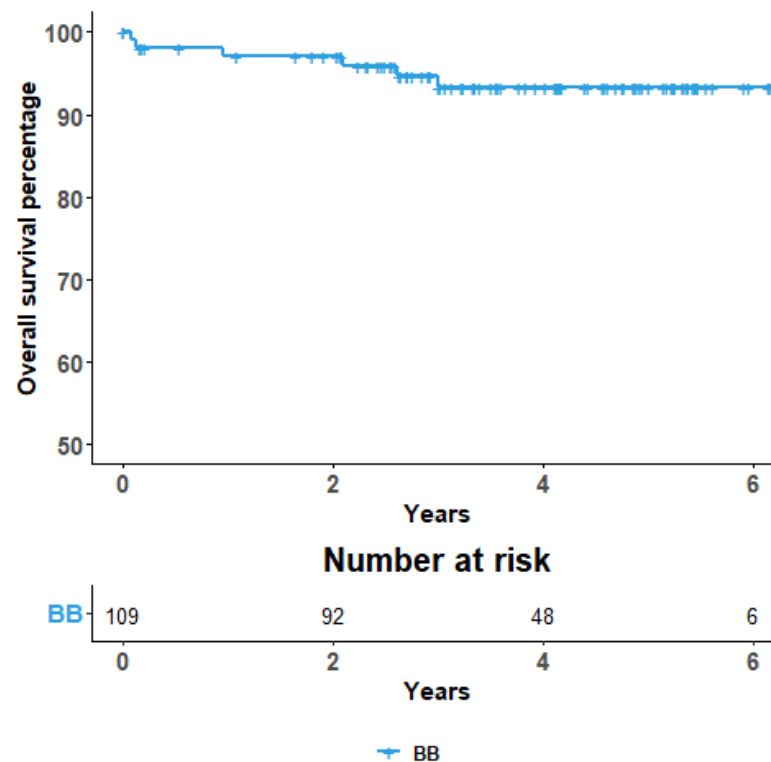


Figure 4. Survival plot for the Bonebridge (BB) device. The number of cases with data at the recorded timepoints is shown below the figure.

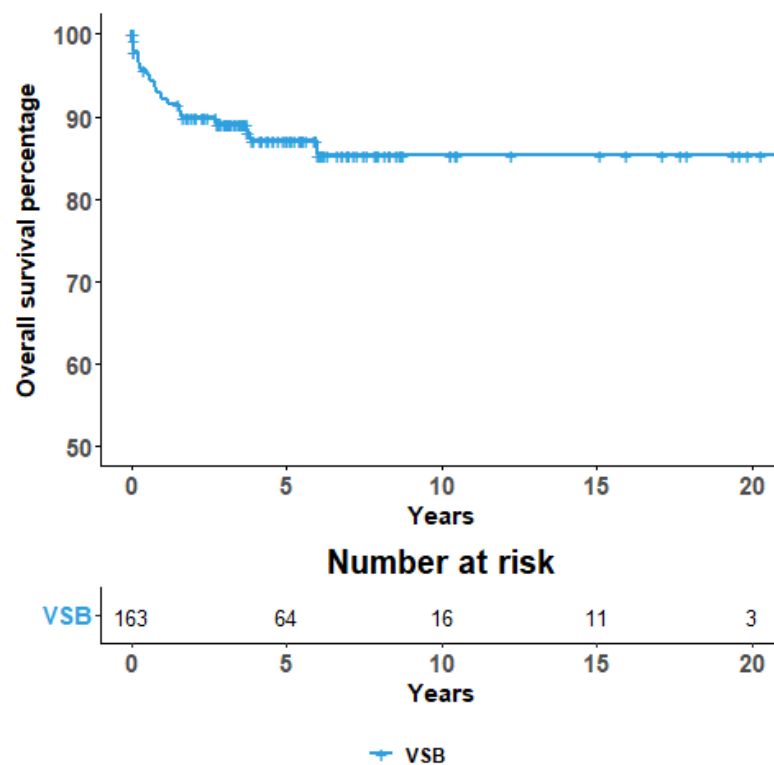


Figure 5. Survival plot for the Soundbridge (VSB) device. The number of cases with data at the recorded timepoints is shown below the figure.

4. Discussion

This research reports the reliability and surgical and medical complication rates for the BB and VSB devices from eleven United Kingdom hearing implant centers. A survival analysis was conducted based on surgical and medical questionnaires and records. From these data, we mapped out complications arising, their associated time course, and frequency of occurrence, and have associated these with patient etiologies.

The BB had a high survival rate of 93.3% at the 5-year post-implant measurement point. This finding is in line with Fan et al. [7], who followed patients with either BAHA, Ponto, or BB devices and reported a 95.7% survival rate (1 out of 23 explanted) for BB. The mean follow-up in Fan et al.'s study was 36 months, compared to 48 months in this study. Our case series is four times as large with a similar survival rate. The two cases of explantation in our series were due to one case of pain and one case of device failure due to wire breakage. In Fan et al. [7], the single explantation case was due to infection at the wound site. There wasn't a clear pattern of causes that led to device failure; however, the number of device failure cases was too small to observe any patterns. There were three cases of wound infection in our series, but they did not require explantation. One was resolved with oral antibiotics, and two required intravenous antibiotics. Although not requiring explantation, the latter two did necessitate an overnight hospital stay. Magele et al. [8] in a systematic review looked at outcomes for BB patients by conducting a meta-analysis of the findings from 49 papers of cohort or case-control studies. The individual articles reported results for between 2 and 38 cases, with a total of 286 ears being evaluated. The average follow-up was 11.7 months (standard deviation ± 4.5). They reported a lower explantation rate, with a survival rate of 98.3%, but this was over a significantly shorter time scale than reviewed in our data. They reported a 7.7% minor event rate; for similar events, our equivalent number is eleven cases, a 10% rate, or a similar incidence.

In our dataset, there were three BB cases where the skin flap was too thick. One case was unresolved, and two cases required additional surgery to reduce the flap thickness.

These problems can be reduced if a skin flap gauge is used during the surgery to identify a skin flap that needs to be thinned [9].

For the BB in our dataset, there were twelve events that did not require a return to the surgical theater. Seven cases required magnet strength reduction due to pain following the use of a higher magnet strength at the initial fitting to ensure a secure fit, but after some time this strength was too high. Initial post-operative swelling at the first fitting of the sound processor required a stronger magnet than was later necessary as swelling reduced. This resulted in unwanted pressure and pain. Another explanation is that although there may not have been a change over time in the wound region, the clinician and patient opted for a slightly stronger magnet than necessary to be confident of good retention. Nevertheless, the findings have highlighted the need to be mindful when setting the magnet strength for the BB and that clinicians should monitor this closely over time. The remaining minor events showed no pattern of occurrence.

The survival rate for the VSB was 87.0% at the 5-year post-implant follow-up, lower than for the BB (93.3%). The lower rate for the VSB may reflect the more complex surgical procedure and the patient characteristics of those receiving a VSB, who tended to have a more complicated hearing health history. Many patients had previously experienced unsuccessful attempts at using other hearing devices.

Brkic et al. [10], in a longitudinal study of 118 VSB devices with an average follow-up of 6.7 years (range 0.7 months–17.9 years), reported a 77% survival rate at the end of the observation period, lower than our reported value. Their device failure rate was 3.4%, and our device failure rate was 1% (two devices).

The largest group of SAEs in our VSB dataset resulted in additional surgery or device explantation related to infection or an inflammatory response. These were adhesions (seven cases), ossicular damage (four cases), cholesteatoma (one case), device extrusion (one case), and wound infection (two cases). There were four other cases of wound infection, but these resolved readily with treatment with antibiotics. Eight of the SAE cases relating to infection or inflammatory response had a history of chronic ear infections. Adhesions are an inflammatory response and result in tissue growth in non-typical locations. This could be related to the etiological characteristics of the group, which has a high rate of individuals with a history of CSOM. It is generally accepted that eustachian tube dysfunction can lead to middle ear pathologies such as retraction pockets, recurrent otitis media, serous otitis media, or cholesteatoma [11]. These can lead to histopathological inflammatory changes that may result in adhesions. This could support the idea of a greater likelihood of inflammatory responses in individuals with CSOM. This is speculative due to the low number of these cases in our series, which is too low for meaningful statistical analysis but of value for exploration in future observational studies. A history of CSOM indicates the importance of careful monitoring of ear health and device function postoperatively.

Schwab et al. [12] included the VSB in a systematic review of AEs associated with BCHDs and aMEIs. They reported the main issues for the VSB to be explantation, device failure, repositioning of the floating mass transducer (FMT), fullness in the ear, dizziness, and pain. We did not find cases reporting fullness or dizziness. Our AEs included two cases requiring FMT repositioning, one case of mild tinnitus, and four cases of minor pain, two resolved by reducing magnet strength, one resolved with antibiotics, and one unresolved.

For the VSB, many of the events were minor or resolved spontaneously, such as a facial nerve insult. Due to the surgical approach for the VSB being more complex than for the BB, there were more events occurring intraoperatively. There were five cases of facial nerve insult that resolved spontaneously, four cases of dural tear, and one case of ear canal damage that was repaired intraoperatively. There were four cases of irreversible chorda sacrifice and four cases of ossicular damage that resulted in explantation or led to hearing levels reducing beyond the criteria for the device.

For most of these surgical events, there were no apparent associated etiological factors that could have predicted them. However, of the five cases of facial nerve injury, three were for individuals with congenital deafness. Conditions suggesting congenital abnormalities

may show an abnormal course of the facial nerve. In this situation, a patient considering VSB should be advised of the possible additional risk of temporary facial nerve insult during the initial consultation.

Future analyses will explore audiometric outcomes, speech perception, device satisfaction, and quality of life. These analyses will provide the evidence required to support realistic expectations of device outcomes in line with the recommendations of the consensus statement [4].

5. Conclusions

This multi-center data collection enabled us to compare findings across a large patient cohort in the United Kingdom over a significant time period. This enabled us to understand device reliability, the occurrence of complications, and factors that might affect events for the BB and VSB. This is the largest compiled dataset on these devices.

Patient safety and device integrity are essential requirements for lifetime implantation. While advances in surgical practice and device manufacture that occur over time may improve outcomes, they cannot always counteract person-specific complications. These may occur, for example, due to low resistance to infection and inflammatory responses to implantation.

We observed high survival rates for BB and VSB devices, with the majority of procedure-related or device-related issues occurring intraoperatively or in the first-month post-implantation and person-specific complications occurring over a longer time frame. The person-specific complications were most apparent for the VSB and are understandable given the complex patient group that cannot use conventional hearing aids.

Both medical, audiological, and administrative support are necessary for good patient and device management. Postoperative advice to patients, particularly during the early period of activation of the device, should emphasize wound care and the importance of monitoring contact pressure from the headpiece magnet. This should be adjusted to maintain good adhesion and transmission while avoiding pain and discomfort. Staff and patients should be aware that over time, alterations in magnet strength should be expected. Factors such as postoperative oedema, skin flap thickness, and hair thickness will vary, and magnets may need to be changed accordingly.

Empowering the patient to maintain the good function of their device by giving training on self-monitoring of the device can promote both best use and prompt and appropriate requests for clinical support, thus helping to avoid gradual deterioration of performance.

Given appropriate support infrastructure from the implanting service, these devices offer a safe and effective treatment for a range of hearing impairments with a low incidence of technical and surgical complications. However, the importance of planning and resourcing for long-term care and the proper counseling of candidates cannot be overemphasized. VSB and BB are safe and effective devices that meet the needs of a group of patients not easily met by conventional hearing aids.

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Informed Consent Statement: Informed consent was obtained for all participants in the prospective arm of the study. For those in the retrospective arm each research and development board at each clinical site determined if patients should be contacted for consent of data in medical notes and where appropriate this was sought prior to data collection.

Data Availability Statement: The datasets generated during and/or analyzed during the current study are available from the corresponding author. Fully anonymized individual participant data will be made available with a data dictionary. No identifiable data will be included.

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Conflicts of Interest: The authors declare no conflict of interest.

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