



A Strategy for Bone Conduction Device Adoption: Study of Non-Usage Challenges, Skin-Deep Insights and Patient Satisfaction

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BACKGROUND: This study aimed to evaluate patient satisfaction and usage patterns of bone conduction devices (BCDs) for hearing rehabilitation, focusing on both users and non-users. Specific objectives included assessing reasons for non-use, exploring patient perceptions of BCD efficacy, and examining complications associated with BCD implantation.

METHODS: A monocentric investigation was conducted at the Department of Ear, Nose, and Throat Diseases, Head and Neck Surgery at General Hospital Sint-Jan, Bruges. Patients who underwent BCD implantation between 2009 and 2020 were included. A questionnaire based on the International Outcome Inventory for Hearing Aids (IOI-HA) was administered to assess patient satisfaction. Additional questions were added to explore reasons for non-use and interest in alternative devices. Data analysis included descriptive statistics and chi-square tests to compare outcomes between groups.

RESULTS: Among 76 respondents, the majority expressed high satisfaction with their BCDs, reporting significant improvements in daily life and quality of hearing. The non-user rate was 8.9%, primarily attributed to perceived lack of benefit or skin problems. Complications requiring explantation were rare (3.4%). Single-sided deafness (SSD) and non-SSD patients exhibited similar satisfaction levels, but SSD patients reported higher non-use due to insufficient hearing benefits. Patients expressed interest (29.6%) in more advanced BCDs.

CONCLUSION: This study highlights the overall positive impact of BCDs on patient satisfaction and quality of life. Personalized care, informed decision-making, and rigorous preoperative evaluation are crucial in achieving favorable outcomes. Technological advancements offer promising opportunities for further enhancing BCD efficacy, underscoring the importance of ongoing research and innovation in hearing rehabilitation.

KEYWORDS: Bone conduction, hearing aids, hearing loss, patient satisfaction

INTRODUCTION

Hearing loss is a globally increasing health condition. Patients with untreated hearing loss are more likely to suffer from depression or anxiety and are also less likely to participate in social activities compared to patients who utilize customized hearing aids. The appropriate form of hearing rehabilitation is associated with significant enhancements in social, psychological, emotional, and physical aspects of life.¹ In certain conditions, a conventional hearing aid is not feasible. The use of bone conduction devices (BCD) is indicated in cases of conductive hearing loss or mixed hearing loss if no conventional hearing aid or middle ear surgery is indicated. Examples include aural atresia, where it is the only alternative when there are no surgical options for reconstruction or middle ear implants. It is also indicated for conductive hearing loss when a conventional hearing aid leads to recurrent otitis externa or when a conventional hearing aid is not strong enough (e.g., air-bone gap of more than 30 dB). Further indications are for unilateral deafness, both congenital and acquired (e.g., caused by vestibular schwannoma, Meniere's disease, or sudden sensorineural hearing loss). Also in mixed hearing loss, powerful BCDs can be used in addition to active middle ear implants.²-4

A BCD requires surgery in which either percutaneous or transcutaneous procedures are performed to place a sound processor is placed on an abutment or a magnet on a titanium implant for a BCD type connect and BCD type attract. This allows sound

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to be transmitted through bone conduction. The value of comprehensive preoperative evaluation of the patients prior to proceeding with the actual surgical procedure involving the implantation of the titanium implant and the use of an audio processor has already been described.^{5,6} A comprehensive clinical investigation of the patient and his wishes is required to minimize the number of non-users in the long term. The routine practice is a trial of a BCD on a headband for 2 weeks in the home and/or work environment to mimic the effect of an "implanted" BCD. It has already been demonstrated that the initial enthusiastic experience with the headband at the consultation can change over longer periods of use in the home environment as it mimics day-to-day situations to which the patient is habituated.⁵ Commonly cited motivations for not undergoing surgery are insufficient effect or uncomfortable effects when used in everyday situations, such as feedback or whistling. Other reasons are the cost and anxiety about surgery.5 Additionally, several research studies have been conducted on patient satisfaction after BCD implantation. These studies always utilized validated questionnaires that examined the quality of hearing in daily life, as well as side effects experienced by patients.7,8

The main purpose of this study was to evaluate the satisfaction of patients with their BCD and the improvement of hearing according to the patient, with a specific focus on patients who did not use their BCD device after surgery, referred to as non-users. It also examined the reasons why patients did not use their device. Another objective was to pay specific attention to implantation problems, infections, skin problems, pain issues, and the need for abutment replacement after surgery. In addition, it checked the trial period and the reasons why they would not proceed to surgery, referred to as non-adopters. Furthermore, the study aimed to address the differences between patients with single-sided deafness (SSD) and patients without single-sided deafness (non-SSD).

METHODS

Patient Selection

This study is a monocentric investigation conducted at the Department of Ear, Nose, and Throat Diseases, Head and Neck Surgery at General Hospital Sint-Jan, Bruges. We examined all records of patients eligible for a BCD from 2009 to 2020 at our center. The questionnaire was conducted to patients who underwent surgery between 2009 and 2020 by the senior surgeon and was sent in 2020, regardless of how long patients had their BCD or when the surgery took place. The study received approval from the ethics committee of our hospital (EC approval BUN: 80492027000006 Int. Nr. 2796 at

MAIN POINTS

- Patient satisfaction and usage: high satisfaction levels with 8.9% classified as non-users. Positive trial periods were crucial in predicting satisfaction post-surgery.
- Comparison between SSD and non-SSD cases: SSD and non-SSD patients showed no significant difference in trial success rates, but their hearing profiles varied significantly.
- Reasons for non-use: non-use reasons varied, with SSD patients citing insufficient benefit and non-SSD patients reporting skin problems, despite similar overall rates of non-use.

institution General Hospital Sint-Jan, Bruges). Prior to participation, patients were provided with an informed consent form as part of the data processing procedure.

A total of 316 trials with a BCD on a soft band were conducted between 2009 and 2020. These trials involved the use of a BCD on a headband to simulate the performance and wearability of a BCD. A trial was considered negative if the patient did not experience a noticeable improvement in hearing or if they perceived too many side effects, leading to hesitation regarding surgical implantation. A positive trial was considered if the patient did have an improvement in daily life and would proceed to surgery. Out of the 316 trials, 212 were classified as negative, while 104 were positive (Figure 1). Common reasons cited in the negative trials included insufficient improvement in hearing, fear of surgery, and aesthetic concerns.

Among the 104 positive trials, a passive BCD implant was successfully placed in 89 patients, and 15 patients were still using the BCD on Softband® at the time of the study. These mainly consisted of young children awaiting the appropriate age for implantation. A questionnaire was sent to all patients who underwent surgery, resulting in a sample size of 89 patients. Of these 89 patients, 8 were excluded because they had deceased in the meantime, along with 4 who lacked proper contact information. Additionally, 1

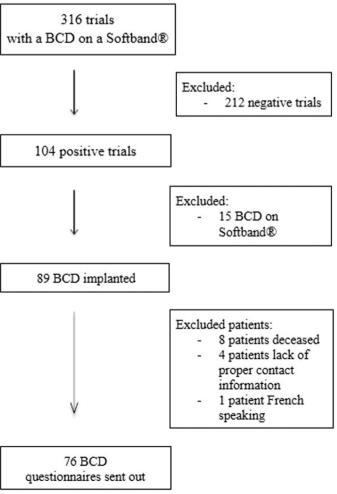


Figure 1. Inclusion and exclusion criteria of the patients.

patient who primarily spoke French was unable to complete the standardized questionnaire in Dutch. A total of 76 questionnaires were sent out.

Methodology

Patients who had undergone implant surgery were administered the Dutch version of the International Outcome Inventory for Hearing Aids (IOI-HA), a validated questionnaire comprising 7 questions. This tool, detailed in the references, gauges patient satisfaction regarding their hearing aid usage. It evaluates both the impact on quality of life and the effectiveness of the hearing aid for individuals. Additionally, non-using patients were asked about the reasons behind their dissatisfaction or non-usage of the device. A suggestion was made to explore their interest in a new, more potent device that could potentially enhance their hearing quality and speech perception in noisy environments. This involved the addition of 3 questions with corresponding answer options:

- The first question added was "If you barely wear your hearing aid, what is your main reason for doing so?" with response options: no improvement in hearing, little improvement in hearing, pain symptoms, inflammation and infection of the skin/skin problems, or not applicable.
- The second added question was, "If you do not wear your hearing aid, what is your main reason for doing so?" For this question the patient was given the same response options as listed earlier in the first added question.
- The last added question: "If you do not/barely wear your hearing aid much, would you be interested in a new, more performant system?" Here, the answer options were yes, no, or not applicable.

These questions sought to understand why patients no longer wore their devices. The study also examined the average trial period before patients decided whether their experience was positive or negative. We also investigated the number of patients undergoing explantation and the reasons behind such decisions.

To facilitate a comparison and assess potential differences in the outcomes of responses between SSD and non-SSD patients, they were classified into these aforementioned groups. The answers on the questionnaires were then compared between both groups. The ultimate goal was to determine whether there were more non-users in a particular group and to understand the specific reasons for this occurrence. Within the groups, an additional examination was conducted to assess the difference in the number of positive trials. Furthermore, an analysis was performed on various characteristics of hearing loss, including average hearing loss, average contralateral threshold, and average air-bone gap. Average hearing loss is the mean degree of hearing impairment, calculated by averaging individual hearing losses typically measured in decibels (dB) and was obtained by using the average from the air conduction thresholds at 500, 1000, and 2000 Hz on a continuous scale.

The study design allowed for the identification of patients who did not use their BCD, commonly referred to as non-users. Additionally, the study aimed to determine the reasons why these patients did not utilize their BCD after surgery. Descriptive statistics were employed for the statistical analysis of the data. A Chi-square test was used to test the independence of 2 categorical variables. A *t*-statistic is used

to determine whether the observed difference in means between 2 groups was statistically significant.

RESULTS

Overall Outcomes

All included patients (n = 89) had varying causes of impaired hearing that made them eligible for a BCD. Common reasons included syndromic conditions, congenital hearing loss, infectious diseases like chronic otitis media, otitis externa obliterans, or mumps. Other frequently occurring reasons were persistent otorrhea that prevented the use of conventional hearing aids, cholesteatoma, and schwannoma. The mean age at the time of implantation was 53.5 years, and the average trial period lasted 24 days. Among the patients, there were 43 males and 46 females. The study also examined the reasons for dissatisfaction with the trial among the patients. Common factors cited included cost, sound quality, insufficient gain, fear of surgery, and concerns related to aesthetics, with some patients finding the processor too conspicuous.

A total of 76 questionnaires were sent out to the patients. The youngest patient was 6 years old at the time of surgery and when the questionnaire was sent. If it was too difficult to answer the questionnaire, parental help was sought. The rest of the minors at implantation (6, with the 6-year-old included 7) were 14 years or older at the time of completing the questionnaire and thereby considered by us to be sufficiently capable of completing the questionnaires deftly. 56 patients responded, resulting in a response rate of 73.7%. Responses obtained from the questionnaire can be seen in Figure 2, showing the answers to the IOI-HA questionnaire. The questions were numbered from 1 to 7, and the responses were categorized from response 1 (R=1) to response 5 (R=5). The questionnaire's English version can be accessed through the provided reference.

The initial question explored the usage of BCDs, specifically inquiring about the average number of hours patients had used their device in the past 2 weeks. The majority of patients responded that they wore their device for more than 8 hours a day. The responses were classified according to the IOI-HA questionnaire, and in our study, the cut-off for non-use was defined as not wearing the device at all. Within this non-use group, 8.9% unequivocally stated that they would not use their device again. If we were to loosen the definition of non-use to less than 1 hour per day, then only 10 patients were categorized as non-users using this criterion, accounting for 17.9%. The second question examined how much the device had provided assistance. In this regard, we observed that the majority of patients indicated that their BCD had helped them very significantly. 8.9% of patients stated that their device had not provided any assistance at all. Furthermore, in question 3, patients were asked about the ongoing challenges they still face in their daily lives regarding their hearing, even with their BCD. In this context, the majority is divided into 2 groups, with patients indicating either "moderate" difficulty or no difficulty. In question 4, respondents were asked whether a BCD is considered worthwhile. In this context, it was observed that the majority of patients find their BCD "quite a lot" or "very much" worthwhile. In question 5, patients were asked whether they encountered difficulties with their hearing during daily activities. In this context, the majority of patients indicated that they experience "slight" difficulties. There was also an inquiry into what patients think about how

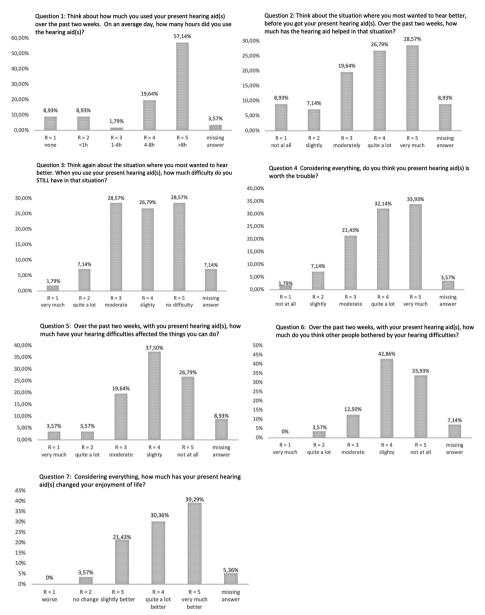


Figure 2. Presentation of the responses to the 7 questions of the validated IOI-HA questionnaire. The questions were numbered from 1 to 7, and the responses were categorized from response 1 (R = 1) to response 5 (R = 5). The questionnaire's English version can be accessed through the provided reference (9).

their surroundings perceive their hearing difficulties. In this regard, the majority indicated that they believe their surroundings are only mildly affected by their hearing loss. In the final question, the focus shifted to changes in life satisfaction due to their BCD. The majority indicated that life satisfaction has significantly improved since using their device (Figure 2).

Three additional questions were added to the standard questionnaire (Figure 3). The majority responded that these questions (questions 8 and 9) were not relevant to them. The other most commonly given reasons were primarily issues with the skin around the abutment and the perception that their device did not significantly improve their hearing. Skin problems were consistently addressed in accordance with guidelines, involving wound care and medical treatment. In some patients, these measures proved insufficient, necessitating surgical intervention and/or removal of the implant. Within the

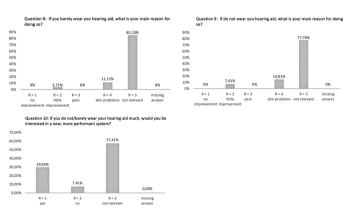


Figure 3. Presentation of the responses to the 3 added questions as cited in the text before. The questions were numbered from 8 to 10 and the responses were categorized from response 1 (R=1) to response 5 (R=5).

entire population of implanted patients, the implant was removed in 3 cases due to recurring and challenging-to-treat skin infections. Surgical intervention with abutment replacement was performed in 2 of these patients, but persistent skin issues led to the decision to proceed with explantation. In the remaining cases, skin issues were successfully treated, resulting in the resolution of symptoms and no explantation.

Furthermore, patients were asked whether they would consider changing their device if a stronger or more performance-oriented model were available on the market (question 10). Again, the majority responded that this was not relevant to them, with 29.6% expressing interest in the question.

Single-Sided Deafness vs Non-Single-Sided Deafness Outcomes

In the study, a total of 316 patients were divided into 2 groups: SSD (142 patients) and non-SSD (174 patients). The success rates of the trial were 23.9% for SSD patients and 31.6% for non-SSD patients, as shown in Table 1. A chi-square test was conducted to compare the success rates between the 2 groups. The null hypothesis (H0) stated that there is no difference in success rates between the SSD and non-SSD groups. The calculated chi-square statistics for both groups were found to be less than the critical value (chi-square for the SSD group = 1.87, chi-square for the non-SSD group = 1.31, critical value = 3.84). As a result, the null hypothesis cannot be rejected, leading to the conclusion that there is no significant difference in success rates between the SSD and non-SSD groups.

When looking at the included patients (n=89), it was observed that the SSD group comprised 34 patients, while the non-SSD group consisted of 55 patients. Among the SSD patients who were dissatisfied with the trial and decided not to undergo surgery, the most common reason was a lack of perceived benefit from the BCD. In this group, the average hearing loss was 100 dB, with an average contralateral threshold of 34 dB. The average age at the time of implantation for this group was 54 years. In the non-SSD group, the average hearing loss was 77 dB, with an average air-bone gap (ABG) of 43 dB. Approximately 78% of these patients had an average ABG exceeding 30 dB. The average contralateral threshold in this group was 57 dB, and the average age at the time of implantation for this group was 53 years (Table 2). The t-statistic for the difference in average hearing loss was calculated to be 2.31, which is greater than the critical value of 1.99 for a t-distribution with 87 degrees of freedom at a significance level of .05. Therefore, we reject the null hypothesis and conclude that there is a significant difference in average hearing between the SSD and non-SSD groups.

Table 1. Representation of the Number of All Trials (n = 316) Within the SSD (n = 142) and Non-SSD Group (n = 174)

Type of hearing loss	SSD	44.94 (n = 142)	Negative trial	76.06% (n=108)
			Positive trial	23.94% (n=34)
	Non-SSD	55.06% (n=174)	Negative trial	68.39% (n = 119)
			Positive trial	31.61% (n=55)

Table 2. Demographic Data for All Included Patients (n = 89)

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Type of hearing	SSD (n = 34)	- Average hearing loss	100 dB
loss		- Average contralateral threshold	34 dB
		- Average age of implantation	54
	Non-SSD (n = 55)	- Average hearing loss	77 dB
		- Average ABG	43 dB
		- Average contralateral threshold	57 dB
		- Average age of implantation	53

Among the completed questionnaires, 42 of the 56 could be classified into SSD and non-SSD groups (the remaining 14 patients were completely anonymous, so they could not be classified into the SSD or non-SSD group). Among these 42 patients, there were 24 in the non-SSD group and 18 in the SSD group.

The majority of patients in both groups reported wearing their device for more than 8 hours per day, as asked in question 1. However, there were 7 patients who did not wear their device or wore it sparingly, with a higher proportion in the SSD group (5 patients or 27.8%) compared to the non-SSD group (2 patients or 8.3%). Assessing the perceived benefits of the device, the majority of patients in both groups considered it to be significantly helpful, as stated in question 7. Specifically, 12 non-SSD patients (50%) and 5 SSD patients (27.78%) reported a substantial improvement in their enjoyment of life. The most common reason reported for non-use in the non-SSD group was skin problems and inflammation, affecting 5 patients, whereas in the SSD group, the main reason was insufficient hearing benefit from the device, reported by 2 patients (added question 8) (Figure 4). Upon analysis, it was found that there was no significant difference in the reasons for non-use or device usage in these 2 groups.

DISCUSSION

This research study was designed to assess patient subjective satisfaction with a BCD and specifically to explore the reasons behind non-use or limited use of the device. The findings indicate that the majority of patients expressed high satisfaction with their BCD, and the number of non-users was relatively low (8.9%).

The importance of the trial period in predicting postoperative satisfaction has been previously established. Positive trial outcomes have been shown to be a significant factor in predicting success and satisfaction after implantation.^{11,12} In our study, the average length of the trial period for patients was 24 days, which is longer than in other studies that often cited 1-2 weeks.⁵ Additionally, it is noteworthy that in our center, patients had the opportunity to easily switch between different types of BCDs during their trial period, and they were informed about and able to test the CROS (contralateral routing of signals) or BICROS (bilateral contralateral routing of signals) hearing aids (this aspect was not further elaborated upon). This was done to ensure an optimal trial experience and enable patients to make a well-informed decision regarding surgery. To substantiate these findings and underscore the importance of a positive trial, conducting a randomized control trial (RCT) with a comparison of outcomes between a trial and non-trial group could be beneficial.

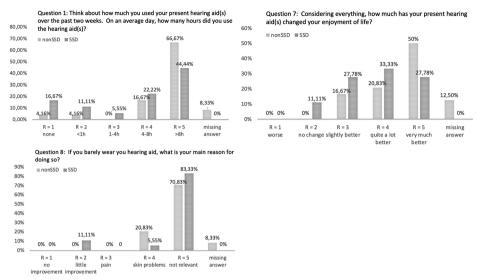


Figure 4. Presentation of the responses to questions 1, 7 and 8 of the validated IOI-HA questionnaire for the non-SSD group and the SSD group.

We observed that, following a positive trial and subsequent successful surgery, most patients express high satisfaction with their BCD. This conclusion is based on the responses gathered from their questionnaires. The study focused solely on the patients' subjective opinions and did not delve into objective improvements, such as gains in audiometry. Only a minority reported not wearing their device or using it infrequently (8.9%). It is essential to consider that the decision to proceed with a BCD implantation remains highly individual, and the patient's personal factors should always be taken into account, as emphasized by R. Powell et al13 Overall, this study reinforces the significance of patient satisfaction, duration of trial periods, and personalized patient care in achieving positive outcomes with BCD implants. It was also indicated that BCD implants have a positive effect on hearing, particularly in the high frequencies compared to the Softband.⁶ Individual factors play a crucial role in the success of a BCD, as stated before. For instance, in the case of SSD patients, hearing loss in the contralateral ear, particularly in the high frequencies, has been identified as a relevant predictive factor for the success of the trial.12

As stated by Van den Heyning et al, 10 there are many studies available with lots of data about the evaluation of benefits, but each with its own methodology, making it very difficult to draw general conclusions from them. They established a protocol for treatment options and outcomes in SSD and asymmetric hearing loss (AHL). This looked at (i) speech in noise testing, (ii) localization testing, (iii) questionnaires to collect quality of life measures and the frequency of device use, and (iv) tinnitus reduction. This study focused solely on the patients' subjective opinions and did not delve into objective improvements, such as gains in audiometry.

There are many studies, each reporting data and results in its own distinct way, making it difficult to compare or draw conclusions among them. As pointed out by Katiri *et al*,¹⁴ there is a significant amount of inconsistency in the field. In the CROSSSD study, consensus was reached on 3 core outcome domains to assess in all clinical trials of interventions for SSD: spatial orientation, group conversations in noisy social situations, and impact on social situations. However, device usage was also identified as a crucial metric in research.

A limitation is that previous studies did not provide a clear definition of non-use, encompassing both patients who did not wear their devices at all and those who wore them for only a limited time during the day. In this study, we defined non-use as the complete lack of device usage, resulting in a non-user rate of 8.9%, compared to the reported use of less than 1 hour per day and a non-user rate of 17.9%. In a previous study by Pennings *et al*, and a non-user rate of 0% was reported, where patients with SSD underwent a 2-week trial, with 32% experiencing a negative trial, and 18% of patients with a positive trial opting not to undergo surgery, while 25 out of 50 had a positive trial and proceeded with surgery. Andersen *et al* onducted a trial with 59 patients with SSD following translabyrinthine resection of acoustic neurinoma, and a quarter of them had a positive trial with a duration of 1 hour. Martin T.P. *et al* of reported a non-user rate of 13%.

Even when considering conventional hearing aids, a clear definition of non-use is lacking. Dillon $et\ al^{17}$ conducted a study to provide a robust representation of the proportion of adults who did not use their conventional hearing aids. The study estimated that approximately 20% of adults did not wear their hearing aids, 30% wore them occasionally, and the remaining 50% of the population wore them most of the time. Lupsakko $et\ al^{18}$ reported similar outcomes, with 25% of hearing aid owners considered non-users and 55% wearing their devices continuously among individuals aged 75 years and older.

Commonly reported side effects associated with percutaneous devices include skin overgrowth, implant loss, and wound infections, characterized by symptoms such as erythema, tenderness, granulation tissue, and crusting. On the other hand, transcutaneous devices may result in pressure complaints and numbness. The Holgers classification and Kruyt's IPS classification are commonly used to describe postoperative complications. ^{19,20} In our study, we observed that persistent skin infections leading to explantation were relatively rare, affecting only a small proportion of our population (3 out of 89 patients). Comparing these findings with other studies, it becomes evident that most implants have a favorable survival rate regardless of the surgical technique employed or the specific implant used.²¹

By incorporating question 10 into our questionnaire, we sought to gauge the interest in a performance-oriented device. A new transcutaneous device recently introduced to the market has demonstrated notable advancements in improving hearing, particularly in the high frequencies. This represents a significant improvement compared to earlier transcutaneous systems, which were limited in their performance at high frequencies due to power loss caused by skin and tissue attenuation. Studies have already indicated that this new system not only enhances the quality and loudness of hearing but also improves speech comprehension.^{22,23} Additionally, this new system offers the advantage of using a smaller magnet, resulting in reduced impact on magnetic resonance imaging (reducing the "halo" effect). However, it should be noted that there are some drawbacks associated with this new system, such as the more frequent requirement for general anesthesia during implantation and the larger incision size compared to percutaneous devices.²²⁻²⁴ In this regard, it was observed that 29.6% of the patients expressed interest in a more powerful system.

Overall, this research study contributes to the understanding of patient satisfaction, usage, and challenges associated with BCDs, emphasizing the importance of personalized patient care, proper preoperative screening, and ongoing evaluation of device performance to ensure optimal outcomes and patient quality of life.

CONCLUSION

The study explored patient satisfaction and reasons for non-use of BCDs post-implantation, focusing on SSD versus non-SSD cases. It revealed that 8.9% of patients were classified as non-users, while 17.9% wore their BCD for less than 1 hour daily. Among 89 patients, SSD and non-SSD groups showed no significant difference in success rates during the trial. However, a significant discrepancy in average hearing loss was observed (t-statistic=2.31, P < .05), indicating distinct hearing profiles between groups. Reasons for non-use varied, with SSD patients citing insufficient benefit and non-SSD patients reporting skin problems. Despite differences in hearing profiles, reasons for non-use did not significantly differ between SSD and non-SSD groups. Comprehensive information during trial periods is crucial for informed decision-making. Standardized definitions for non-use in BCD studies are needed.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author, B.L.The data are not publicly available due to restrictions on patient data and the ethics committee of our hospital.

Ethics Committee Approval: This study was approved by the Ethics Committee of General Hospital Sint-Jan, Bruges (EC approval BUN: 80492027000006 Int. Nr. 2796 at General Hospital Sint-Jan, Bruges).

Informed Consent: Informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

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Literature Search – J.V.d.K.; Writing Manuscript – J.V.d.K.; Critical Review – B.L., N.V. All authors reviewed the results and approved the final version of the manuscript.

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