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Bone-anchored hearing aids are effective and associated with a high degree of satisfaction

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ABSTRACT

INTRODUCTION: The objective of this study was to evaluate patients' satisfaction with bone-anchored hearing aids (BAHA).

METHODS: This study was retrospective and based on a postal questionnaire. The study sample consisted of patients undergoing surgery at Odense University Hospital in the 1992-2013-period. The questionnaire was a combination of Satisfaction with Amplification in Daily Life questions from the Hearing Aid Research Lab at the University of Memphis and questions used in a previous Danish study. We also used data from each patient's medical records. All information was collected in a database.

RESULTS: The response rate was 80% and the user percentage 88. The majority of the patients used their BAHA seven days a week and most of the day. 88% reported that it was in their best interest that they had received a BAHA. 80% of the respondents were able to communicate better using their BAHA in one-on-one conversations.

CONCLUSION: BAHA is helpful in one-on-one conversations in quiet surroundings. Sound quality in group situations seems to be the main problem associated with BAHA. However, this study showed that BAHA is an effective hearing aid that is associated with a high degree of satisfaction. **FUNDING:** not relevant.

TRIAL REGISTRATION: not relevant.

A bone-anchored hearing aid (BAHA) is an implantable osseointegrated device designed to stimulate the cochlea by bone conduction. The BAHA is connected directly to an osseo-integrated titanium fixture in the temporal bone, and the transducer (BAHA) transforms sound to vibrations that pass through the fixture to the bone and into the cochlea [1]. BAHA was originally designed to treat conductive hearings losses due to chronic otitis refractory to treatment with conventional hearing aids and to treat malformations of the middle or outer ear [2]. A recent indication for BAHA includes single-sided sensorineural deafness [3]. BAHAs have been used since 1977 with some modification of the surgical techniques since then [4].

Previous studies have demonstrated a low percentage of non-users among BAHA patients as well as a significantly improved quality of life overall [3, 5]. Odense University Hospital (OUH) has 21 years of experience

with BAHA and an evaluation of patient satisfaction with BAHA was considered necessary.

The objective of this study was to evaluate the patients' satisfaction and to study complications by analysing questionnaires completed by patients who had been fitted with a BAHA at OUH and by studying their medical records.

METHODS

Questionnaire

The present study was a retrospective follow-up study that was implemented as a postal questionnaire. The patients were identified through a computer programme called FPAS, in which the patients' identification number and procedure code are linked. The questionnaire used was a combination of the Satisfaction with Amplification in Daily Life (SADL), questions from the Hearing Aid Research Lab at the University of Memphis [6] and guestions developed by Rasmussen et al [3]. The SADL scale was designed to evaluate satisfaction with conventional hearing aids. A Danish translation of the SADL questionnaire was used. The SADL has been translated into Danish and translated back by a native English speaker who had no a priori expertise with SADL to validate the Danish translation. The English and Danish wordings are given in a thesis by Vestergaard [7].

Our questionnaire consisted of 27 questions. Two questions included a visual analogue scale and the line was equivalent to 100 possible points, three yes/no questions, three questions concerning duration of use (hours/day, days/week and years), three questions were specified for those who did not use their BAHA or had had the implant removed, one question in which the patient categorised their hearing loss, one question was related to the patient's ability to hear conversations in different settings. A total of 14 questions from the SADL questionnaire were used with the letters A through G in which A was equivalent to "not at all", B "a little", C "somewhat", D "medium", E "considerably", F "greatly" and G was "tremendously". Question 14 from the original SADL questionnaire was not included as it relates to the price of the BAHA which is provided free of cost for Danish patients. The instructions for manual scoring of the SADL are available for a more detailed description [6].

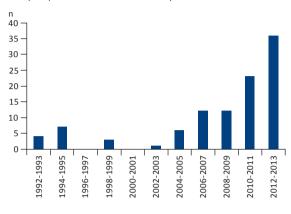
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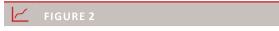
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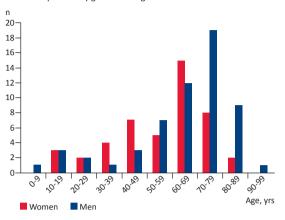
FIGURE 1

Patients undergoing bone-anchored hearing aids surgery at Odense University Hospital from 3 June 1992 to 31 May 2013.





Number of patients by gender and age.



A letter that described the purpose of the study was posted together with the questionnaire. After three months, the first round of phone call was made to non-responders. A voicemail message was left if no one answered the initial phone call. If the patients did not have a voicemail, two more calls were made shortly after the first call. Three months later, a second round of phone calls was made, and the same procedure was followed for those who did not respond the phone call. All information was collected in a Microsoft Access database.

Patient group

Patients treated with a BAHA at OUH from 3 June 1992 to 31 May 2013 were identified through the method described above. A total of 130 patients underwent BAHA surgery at OUH during the period, see **Figure 1**. In all, 104 of 130 patients responded. The remaining 26 patients did not participate for the following reasons: deceased (n = 14), did not have a valid address (n = 3), did not want to participate (n = 1), immigrated to another country (n = 1), and did not respond (n = 7). These numbers yield an 80% response rate.

The group of responders consisted of 46 women and 58 men. Patient ages ranged 6-93 years (mean: 60 years, median: 68 years), see **Figure 2**. Seven patients were under 18 years of age. A total of seven patients were mentally retarded; two of these reported that they had received help filling out the questionnaire from either a family member or an assistant. The follow-up period ranged 2-254 months with a mean of 61 months and a median of 36 months.

Trial registration: not relevant.

RESULTS

In Table 1, the respondent's severity of hearing loss is

listed for the better and the poorer ear, respectively. The majority had a mixed conductive/sensorineural hearing loss in both ears. We could not find information in the records of five responders, and 28 responders had incomplete hearing tests. Two patients had bilateral BAHAs and 43 patients had their BAHA on the left side and 58 on the right side. In one case, the side was unknown.

During the period of investigation, seven different surgical methods were used. 87% of the operations were performed using three different methods. These methods only differ with regard to the handling of the skin around the transplant. The impact of using various surgical methods has not been further analysed.

Thirteen of the responders (13%) did not use their BAHA, and these patients were not included in the assessment of satisfaction, implant use and complication. Five responders lost their implant after a median of 12 months, four had it replaced and one decided to stop using BAHA, see **Table 2**.

Nine patients had their implant surgically removed; two due to complications, four due to dissatisfaction, one did not need BAHA any longer after middle ear surgery, and an additional two had their BAHA removed for unknown reasons. Three responders still had the implant, but were not using it due to lack of satisfaction with the sound.

A total of 91 out of 104 responders were still using their BAHA, which means that the user percentage was 88.

The most frequent complication was infection. A total of 32 (31%) of the responders had experienced problems with minor infections after their surgery, but only one had the implant removed because of this. Another frequent problem was minor bleeding and pain around the implant, but neither had resulted in the removal of

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TABLE

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	Poore	r ear						
Better ear	mild loss	moderate loss	moderate- severe loss	severe loss	profound loss	deaf	unknown loss	total
Normal hearing	1	3	1	0	7	1	1	14
Slight loss	0	1	4	2	3	0	2	12
Mild loss	1	5	2	6	2	0	1	17
Moderate loss	0	4	6	8	5	0	0	23
Moderate-severe loss	0	0	9	9	3	0	0	21
Severe loss	0	0	0	4	5	1	0	10
Profound loss	0	0	0	0	1	1	0	2
Unknown loss	0	0	0	0	0	0	5	5
Total	2	13	22	29	26	3	9	104

Type of hearing loss categorised by pure-tone average in dB hearing level^a. The values are n.

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a) Normal hearing: < 15 dB, slight loss: 16-25 dB, mild loss: 26-40 dB, moderate loss: 41-55 dB, moderate-servere loss: 56-70 dB, severe loss: 71-90 dB, profound loss: > 90 dB, deaf: no response.

any implants. Three patients (3%) had granulations treated with silver nitrate, and six patients (6%) underwent revision surgery because of infection and skin necrosis. Skin overgrowth caused the removal of one BAHA.

Time spent using bone-anchored hearing aids

In all, 76 out of 91 respondents (84%) used their BAHA seven days a week, 71 respondents (78%) used their BAHA more than eight hours per day.

Satisfaction

The vast majority replied that it was in their best interest to get a BAHA; 80 out of 91 (88%). Most patients also found that BAHA was worth the trouble; 76 out of 91 (84%). Use of the BAHA reportedly helped most patients so that they became more able to understand the people they spoke to most of the time; 57 out of 91 (63%). Sixteen out of 91 (18%) reported that the use of the BAHA had reduced the number of times they had to ask people to repeat themselves.

Sixteen out of 91 (18%) of the respondents said "tremendously" or "greatly" when they were asked if they were frustrated from disturbing sounds. A total of 25 out of 91 (28%) were bothered by whistling in high loudness and 11 out of 58 (19%) found that the BAHA was helpful when using their phone with no amplifier or loudspeaker. A total of 14 out of 91 (15%) said that they felt that people were noticing their hearing loss when they were using their BAHA; however, 44 out of 91 (48%) were content with the appearance of the BAHA. Five out of 91 (5%) thought that wearing a BAHA made them seem less capable to other people.

In all, 73 out of 91 (80%) stated that they understood "always well or usually well" when communicating one-on-one in guiet surroundings, while 30 out of 91



Responders with implant losses.

Age at surgery, yrs	Time until loss, months	Cause of loss	Replaced
10	2	Unknown	Yes
46	7	Loss of integration	No
49	23	Unknown	Yes
64	12	Loss of integration	Yes
68	23	Unknown	Yes

(33%) stated the same in one-on-one communication in noisy surroundings. A total of 23 out of 91 (25%) stated the same when taking part in a group conversation.

DISCUSSION

The response rate was 80%, which gives strength to the results of our study. The majority of the respondents used their BAHA seven days a week and most of the day. The user percentage was 88, which is comparable to the percentage reported by Wallberg et al, who reported a 90 user percentage [8].

Complications such as infections and bleeding did occur frequently. To our knowledge, approximately a third of the patients had experienced infections although only one respondent had his implant removed due to infection. All patients who had been receiving antibiotic ointment were registered as having had an infection. A total of 13 patients (12%) received systemic antibiotics. The frequency of complications was high (56%); however, they were not severe. It seems that close follow-up after surgery and treatment of the complications lead to a high degree of satisfaction, as 88% reported that it was in their best interest to get a BAHA and 84% reported that it was worth the trouble.

Skin-penetrating abutment visible behind the ear. A titanium fixture has been surgically embedded 4 mm into the skull and the abutment is connected to this fixture. A sound processor will be placed on the abutment and vibrations will be transmitted to the skull and inner ear, facilitating hearing. Source: photo by Christian Emil Faber with

the patient's authoriza-



In all, seven different surgical approaches have been used during the period of investigation. However, the majority of the surgical interventions were limited to three different approaches. The impact of different surgical approaches on patient satisfaction and complications may be an area for further investigation.

This study was retrospective and based on a postal questionnaire. This type of study contains a risk of recall bias. A total of seven respondents were mentally retarded, but only two reported that they had received help filling out the questionnaire. We do suspect that more than two respondents had received help answering the questionnaire. This may influence the results as the responses may reflect the opinion of relatives or assistants. Another potential source of bias is that people who are satisfied with the aid may be more likely to return the questionnaire than those who are dissatisfied [5]. On the other hand, those who are dissatisfied may have an interest in describing their problems.

Additional information was sought in the patient records. However, hearing tests and information on the type of BAHA were lacking in some of the older patient records. In future studies, information should be collected prospectively to avoid missing data.

Cosmetic appearance does not seem to be a serious problem as 44 out of 91 (48%) were "greatly" or "tremendously" content with the appearance of their BAHA. Although some respondents commented that the BAHA is "bulky", "too big in appearance", "wished BAHA was smaller" and "have problems with wearing beanie". Lekue et al support these findings as 16% reported that the excessive size was the least pleasing factor related to BAHA [2]. Badran et al reported that the placement of the abutment seemed to cause problems for patients

wishing to wear hats [5]. For the majority of patients, however, better hearing outweighed the negative effects of the appearance. Saroul et al reported that 75% found that their BAHA was discrete [9]. Rasmussen et al reported that five respondents noted the size of BAHA as a negative issue, whereas ten respondents reported that the best thing about BAHA was that it was a small aid and well-concealed [3].

A total of 5% of the responders lost their implant. Tjellström & Stalfors found an implant loss percentage of 9.8 in their study, and a worst-case scenario calculation demonstrated an implant loss of 13% [10].

Whistling in high loudness was bothering for 25 out of 91 (28%). An article by Lekue et al supports this finding as 18% reported noise or whistling from the device as the least pleasing thing concerning the BAHA [2]. Rasmussen et al reported that wind noise was a significant problem for most respondents, and 70% considered disturbing sounds annoying or very annoying [3].

We observed a severe drop in satisfaction from one-on-one conversation to group conversation, similar to Rasmussen et al [3]. This is a well-known problem with BAHA, as well as with other hearing aids. Only two respondents had single side deafness and we therefore have no evidence for single-side deafness and the use of BAHA.

CONCLUSION

BAHA was very helpful in one-on-one conversation in quiet surroundings. However, communication in group situations was a problem for BAHA users. This is similar to the experiences reported by many other hearing aid users. Wind noise was a significant problem for many respondents. The frequency of complications was high and this constitutes an area for improvement and further investigation. However, this study demonstrates that BAHA is an effective hearing aid with a high rate of satisfaction for most patients with relevant types of hearing loss.

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