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Patient Preferences in Sound Processor Loading Time After BAHI Surgery

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Objective: Sound processor loading times after bone-anchored hearing implant (BAHI) surgery have gradually decreased over time. This study assessed patient preferences in loading time.
Study Design: Prospective patient questionnaire study.
Setting: Tertiary referral center.
Patients: Patients indicated for BAHI surgery received two questionnaires preoperatively: the validated Glasgow Health Status Inventory (GHSI) and a nonvalidated questionnaire that assessed patient preference for loading time and the rationale behind it. This preference questionnaire was also provided immediately, 7 days and 3 weeks (moment of sound processor loading at our center) postoperatively.
Main Outcome Measures: The preoperative and postoperative preferred loading time and the postoperative changes in preference were determined. Correlations between preference and patient-specific variables were assessed.
Results: Sixty patients were included. Preoperatively, 70% preferred loading within 1 week after surgery. Of all patients, 43% preferred loading on the day of surgery, mainly motivated by the fast hearing rehabilitation and practical considerations. These preferences were not correlated with the total GHSI score or duration of hearing loss. Directly postoperatively, no change in preference was observed. However, 7 days and 3 weeks after surgery, significantly more patients preferred loading at a later moment. At 7 days and at 3 weeks, 50 and 40% preferred loading within 1 week, and 12.5 and 7.5% preferred loading on the day of surgery, respectively.
Conclusion: The preference for the timing of sound processor loading varied among patients and differed pre- and postoperatively. Despite the postoperative decline in patients preferring earlier loading, approximately half of all patients preferred sound processor loading within 1 week after BAHI surgery.
Key Words: Bone-anchored hearing aid—Bone-anchored hearing implant—BAHS—bone conduction device—hearing loss—loading time—patient-centered care—sound processor.

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Percutaneous osseointegrated titanium bone-anchored hearing implants (BAHIs) have been in clinical use since the 1980s. These systems provide an important hearing rehabilitation option for specific patients with conductive or mixed hearing loss and single-sided deafness (1–3). There are two stages of implant stability in the temporal bone: primary and secondary stability. Primary stability is defined as the mechanical fixation of the implant in bone directly postoperatively. Secondary or biological stability is achieved through the process of osseointegration. This latter stage involves a dynamic process of bone regeneration and bone remodeling at the bone-implant interface integrating the implant into the remodeled bone (4). Factors that may influence osseointegration include implant surface characteristics and patient factors, e.g., bone quality and wound healing (5). Within the first few weeks after implantation, the transition from mechanical stability to biological stability occurs, which may involve a period of reduced stability (6). Therefore, in the original protocols, implant surgery consisted of two stages allowing a 3- to 6-month osseointegration time before connecting the percutaneous abutment to the implant (7). As

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a consequence, patients had to wait at least 3 months after initial surgery before they could wear their hearing device. After the introduction of a one-stage surgical approach in adults, it became feasible to decrease sound processor loading times (8). During a consensus meeting in 2005, a loading time of 4 to 6 weeks after implantation was advised for adults (1). A large retrospective review in 2012 showed that loading the bone conduction device (BCD) on the BAHI 3 to 5 weeks postoperatively in healthy adults resulted in similar rates of adverse skin reactions and implant survival compared with longer loading periods (9). Additionally, since the introduction of the wider-diameter implants (Ø 4.5 mm compared with 3.75 mm), loading times of 3 weeks were found to be safe (10,11). This wider implant diameter design was developed to increase the implant–bone contact area and, therefore, to improve the initial stability and increase the surface area for osseointegration. Recently, even shorter times until loading have been reported to be sufficient (12,13).

All currently published studies assessing optimal loading time have merely focused on objective clinical endpoints, such as implant loss, the implant stability quotient (ISQ), and skin complications. However, in light of patient-centered care (14), we think it is of utmost importance to investigate patients' preferences and perspectives regarding optimal loading time after BAHI surgery, especially since loading after 1 week has been proposed (12).

METHODS

This single-center, prospective, questionnaire study determined patient preferences for sound processor loading times after BAHI surgery and evaluated the rationale behind it. The current study also assessed whether patient preferences differed pre- and postoperatively and whether this could be explained by postoperative complaints or other variables.

Patients aged more than or equal to 18 years with normal bone quality and those indicated for percutaneous BAHI surgery with a Ponto Wide implant (Oticon Medical AB, Askim, Sweden) or a Cochlear BI300 implant (Cochlear Bone Anchored Solutions AB, Mölnlycke, Sweden) were included. Patients were excluded according to the standard exclusion criteria used in clinical trials conducted at our center, namely: 1) reimplantation surgery, 2) a medical history of disease and/or treatment compromising bone quality at the implant site, e.g., radiation therapy or osteoporosis, 3) mental disability or a medical history of psychiatric disease, and 4) inability to participate in the follow-up (15–19). The included patients were randomly divided into four groups: groups A, B, C, and D. Group A consisted of 30 patients, and groups B, C, and D consisted of 10 patients each. All groups received two questionnaires before surgery. Postoperatively, three questionnaires were administered. Group A received these postoperative questionnaires at three previously defined time points: directly after surgery, 7 days after surgery and on the day of sound processor loading (approximately 3 weeks). Groups B, C, and D received these postoperative questionnaires at only one out of three postoperative time points: group B received the questionnaires directly postoperatively; group C received the questionnaires 7 days postoperatively; and group D received the questionnaires on the day of sound processor loading. This study setup was chosen to detect and, if needed, account for practice bias in the repeatedly sampled group (group A). Practice bias could be induced by assessing the same questionnaires at multiple time points.

All study participants were treated according to our standard clinical care, including sound processor loading approximately 3 weeks after surgery.

To determine baseline values, all included patients (test and control) received two questionnaires before surgery: the validated Glasgow Health Status Inventory (GHSI) (20) and a specific questionnaire inquiring about loading time preferences. The GHSI measures the impact of patient hearing impairment on hearing-related quality of life (HRQoL), resulting in a total score and three subscores (general, social support, and physical health). All scores range between 0 and 100, with a higher score indicating a better HRQoL. The outcomes of the GHSI were used as a measure to determine whether patient preferences in loading timing were influenced by the severity of their hearing impairment. The loading time preference questionnaire is a nonvalidated set of questions in which patients select their preferred moment for sound processor loading. They can choose from six options, ranging from the day of surgery to more than 3 weeks after surgery. Patients are also asked to specify a reason for selecting this specific moment. The postoperative questionnaires consisted of the loading time preference questionnaire and two visual analogue scales (VAS), which assessed subjective well-being and the severity of complaints after surgery; higher grades on these VAS scales indicate a better well-being and a higher complaint-severity level, respectively. In addition to the questionnaires, demographic data and patient-related characteristics were collected.

Statistical Analysis

Descriptive data were presented as frequencies (%), means (standard deviations [SDs]) and, in cases where data were not normally distributed, medians with interquartile ranges (IQRs). Between-group comparisons were performed using the χ^2 test for nominal variables and the Kruskal-Wallis test for continuous and ordinal variables. For the correlation analysis, the Spearman correlation coefficient was used in the case of continuous and ordinal variables, and the Pearson correlation coefficient was used in the case of normally distributed dichotomous variables. For nonnormally distributed dichotomous variables, the Mann–Whitney U test was performed to detect a difference in preference between the two values of the variable. Changes in the preferred loading time were assessed using the Wilcoxon signed-rank test. With the independent t test (normally distributed continuous data), Mann–Whitney U test (not normally distributed continuous data) and Fisher's exact test (categorical binary data), clinical variables were compared between patients who changed their preferred loading time postoperatively and patients who did not.

All statistical analyses were conducted using SPSS statistics v. 25.0 (IBM Corp., Armonk, NY). A confidence interval (CI) of 95% was used, and a p-value < 0.05 was considered statistically significant.

Ethical Considerations

This study was approved by the local ethical committee and conducted according to the guidelines established in the Declaration of Helsinki (Washington 2002, ISO 14155) and Good Clinical Practice (International Conference on Harmonization Good Clinical Practice). Upon inclusion, informed consent was obtained from all participants.

TABLE 1. *Clinical parameters of all 60 patients*

Clinical Parameter	Frequency (%)
Gender	
Male	24 (40.0)
Female	36 (60.0)
Age at surgery, mean (SD)	57 (15.0)
Ethnicity	
Caucasian	57 (95.0)
African	1 (1.7)
Asian	2 (3.3)
Smoking	
No	33 (55.0)
Yes	13 (21.7)
Unknown	14 (23.3)
Duration of hearing loss in years, median (IQR)	24 (9–48)
Glasgow Health Status Inventory, mean (SD)	
Total score	54.3 (9.1)
General score	49.2 (11.1)
Social score	83.6 (1.6)
Physical score	44.9 (22.9)
Previous BAHI experience	
Yes[a]	7 (11.6)
Indication	
Acquired conductive hearing loss	45 (75.0)
Congenital conductive hearing loss	2 (3.3)
Single-sided deafness	12 (20.0)
Perceptive hearing loss[b]	1 (1.7)
Surgical technique	
Linear incision technique	36 (60.0)
Minimally invasive Ponto surgery	24 (40.0)
Anesthetic technique	
Local anesthesia	50 (83.3)
General and local anesthesia	10 (16.7)
Perioperative complications	
None	47 (78.3)
Drilling into vein	4 (6.7)
Exposed dura	9 (15.0)

[a]These patients either underwent reimplantation or received a second BAHI.
[b]Conventional hearing aids were contraindicated in this patient.

RESULTS

A total of 60 patients were included in this study and implanted with a percutaneous wide-diameter BAHI. Table 1 presents the clinical and surgical characteristics of these patients. No major perioperative complications occurred. The demographic characteristics, preoperative duration of hearing loss, GHSI scores, and surgical indications did not differ between groups. The median VAS score for well-being directly postoperatively was 10 (IQR 8–10). At 7 days after surgery and on the day of loading, the median VAS score for well-being was 9 (IQR 8–10). The median VAS score for the severity of complaints was 0 at all postoperative time points with an IQR of 0 to 0 directly postoperatively, 0 to 4.5 7 days after surgery, and 0 to 2 on the day of loading.

Between-group comparisons showed a significantly lower VAS score for well-being on the day of loading for group D compared with group A. Since all other outcome measures were comparable between groups at any time point, further data analyses were performed on the compiled data of all patients.

Preferences in Loading Time

Table 2 shows the patient preferences in loading time per assessment time point. Preoperatively, the majority of patients (70%) preferred sound processor loading within 1 week after surgery. Out of all patients, 43% preferred loading on the day of surgery, mainly motivated by the fast hearing rehabilitation and practical considerations (implantation and sound processor loading in one visit instead of two). Patients who did not prefer immediate loading stated that they needed time to heal and/or get accustomed to the implant.

A weak, positive, monotonic correlation between preoperative preference in loading time and the GHSI general subscore was observed (r_s 0.27, $n = 60$, $p < 0.037$). However, no significant correlations were found between any of the other GHSI (sub)scores and preoperative preferences. Furthermore, the preoperative preference did not correlate with other clinical variables, such as age, preoperative duration of hearing loss, or indications. Additionally, no difference in preferred loading time was observed between men and women or between patients with and without BAHI experience.

At the three postoperative time points, the preference for loading on the day of surgery ranged from 7.5 to 35%. Additionally, 22 to 40% of the patients preferred loading 3 weeks after surgery. For each time point, correlations between preference in loading time and patient-specific

TABLE 2. *Preferences in loading time at the four different time points at which the loading time preference questionnaire was administered*

Time Point of Questionnaire	Before Surgery,	Directly After Surgery,	7 Days After Surgery,	± 3 Weeks After Surgery,
Preference	n (%)	n (%)	n (%)	n (%)
0 days	26 (43.3)	14 (35.0)	5 (12.5)	3 (7.5)
1–5 days	6 (10.0)	6 (15.0)	8 (20.0)	7 (17.5)
1 week	10 (16.7)	7 (17.5)	7 (17.5)	6 (15.0)
2 weeks	2 (3.3)	3 (7.5)	6 (15.0)	5 (12.5)
3 weeks	13 (21.7)	10 (25.0)	9 (22.5)	16 (40.0)
>3 weeks	3 (5.0)	0 (0.0)	5 (12.5)	3 (7.5)
Total	60 (100)	40 (100)	40 (100)	40 (100)

variables such as demographic data, surgical technique, perioperative complications, and postoperative VAS scores were assessed. A weak, positive, monotonic correlation was observed between age and the preference for loading directly postoperatively (r_s 0.39, n = 40, $p = 0.038$). This indicates that younger patients prefer loading at an earlier moment. A weak, positive, monotonic correlation was also found between the grade for severity complaints and preference at 7 days after surgery (r_s 0.32, n = 40, $p < 0.045$). Additionally, at 7 days after surgery and on the day of loading, women preferred loading at a significantly later time point compared with men ($U = 259$, $p = 0.014$ and $U = 273$, $p = 0.047$). No correlations were found between postoperatively preferred loading times and ethnicity, preoperative duration of hearing loss, or indications. Postoperative preferences were not significantly different for patients with BAHI experience, compared with patients without experience. Additionally, similar postoperative preferences were found for patients with and patients without a perioperative complication, as well as for patients who underwent surgery using minimally invasive Ponto surgery and patients who were implanted using the linear incision technique with soft tissue preservation.

Postoperative Change in Preferred Loading Time

Figure 1 shows the preferred loading times at the preoperative time point and the three postoperative time points. As illustrated in this figure, comparable preferences for the time of loading were observed preoperatively and directly after surgery. However, at 7 days and on the day of loading, the preferred loading time increased significantly compared with the preoperatively preferred loading time ($Z = -2.76$, $p = 0.006$; $Z = -3.55$, $p < 0.001$, respectively); at these postoperative time points, only 50 and 40% of the patients preferred loading within 1 week, respectively. Specifically, the number of patients with a preference for loading on the day of surgery declined.

When assessing postoperative changes in the entire population, 50% of the patients did not change their preference, 40% had a preference for loading at a later time point, and 10% had a preference for loading at an earlier time point. Out of the 26 patients with a preoperative preference for loading on the day of surgery, 15 (58%) changed their preference to loading at a later time point postoperatively. Patients changing their preference to loading at an earlier time point, all had a preoperative preference for loading 3 weeks after surgery.

None of the patients changed their preference for loading on the day of surgery. The patients who preferred loading at a later time point postoperatively stated that more time was needed to recover from surgery, to obtain complete wound healing, or to get accustomed to the implant than was expected beforehand. The VAS score for well-being 7 days after surgery was significantly lower in these patients ($U = 94$, $p = 0.027$) compared with patients who did not change their preference postoperatively. A nonsignificantly lower VAS score for well-being ($U = 113$, $p = 0.069$) and a nonsignificantly higher VAS score ($U = 116$, $p = 0.063$) for the severity of complaints were also observed in this group on the day of loading. In contrast, a few patients preferred loading at an earlier moment because the surgery itself had less impact and because wound healing occurred faster than expected preoperatively.

DISCUSSION

At our center, sound processor loading after BAHI surgery is usually performed approximately 3 weeks after surgery. Currently, earlier loading times have been

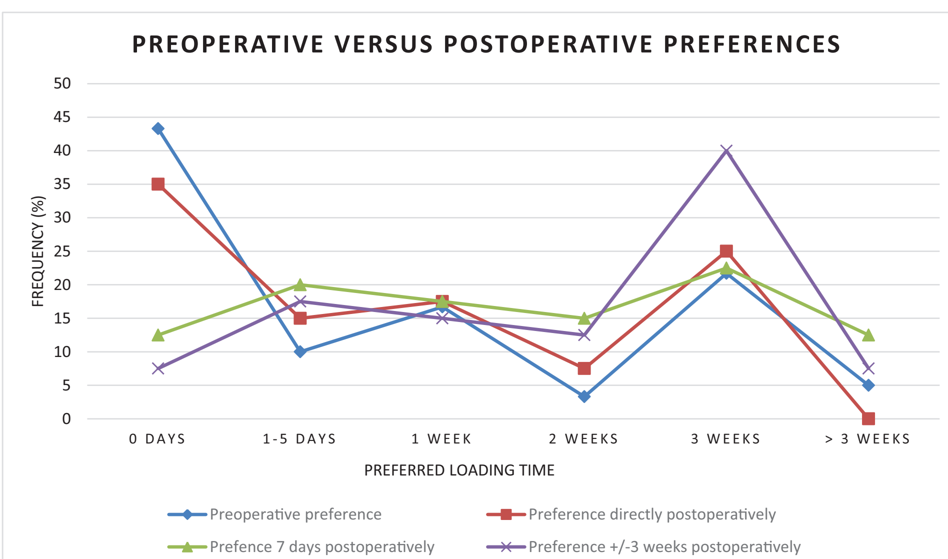

FIG. 1. Preferred loading time at the preoperative (rhombus) and three postoperative time points. The square represents preference directly postoperatively, the triangle preference at 7 days after surgery, and the cross preference on the day of loading.

proposed (12,13). Since little is known about the effects of patient perspective on the timing of loading, this study aimed to evaluate patient preference regarding the moment of sound processor loading after BAHI surgery. When asked preoperatively and directly postoperatively, the majority of patients preferred loading within 1 week after surgery. Loading on the day of surgery was preferred by one-third in almost half of all patients. However, at the other postoperative time points (7 days and the loading moment at approximately 3 weeks), these numbers declined, and significantly more patients preferred sound processor loading at a later point in time compared with their preoperative preferences.

Strength and Limitations

To the best of our knowledge, this is the first study to evaluate the effects of patient perspective on the timing of sound processor loading. The major strengths of this questionnaire survey were its prospective nature and relatively large sample size. Furthermore, correlations between patient-specific variables and preferred loading time were determined to detect possible confounders for loading time preferences. However, a few limitations of this study can also be addressed. Upon inclusion, patients were informed about the aim of the study. Study participants were also aware that sound processor loading was usually performed around 3 weeks in our institution. This might have resulted in a response bias. Furthermore, other variables such as travel distance to the hospital or use of a contralateral hearing aid might also have influenced the preference of our patients and were not assessed. To detect potential practice bias, questionnaires were distributed at multiple postoperative time points in group A and at only one postoperative time point in groups B, C, and D. Unfortunately, this setup resulted in some disadvantages in terms of the comparisons over multiple time points. Since both paired and unpaired data were present at each postoperative time point, comparisons of the preferences in loading times could only be conducted for each postoperative time point individually. Finally, nonvalidated questionnaires were used, and the generalizability of this study is arguable since all patients underwent surgery in one tertiary referral center in one country.

Interpretation of the Findings

The number of patients preferring an earlier moment for sound processor loading than the current clinical practice at our institution was initially very high but did decline 7 days and approximately 3 weeks after surgery. These patients reported preferring a later moment in time because they needed more time to heal and/or become accustomed to the implant. A significantly lower VAS score for well-being and a nonsignificantly higher VAS score for severity of complaints was also observed in this group. Since the preference directly postoperatively did not differ from the preoperative preference, it might be suggested that most patients were well aware of the impact of the BAHI surgery itself but underestimated the postoperative period. The observed change in loading time preference could, however, also have been caused by response bias. It seems that (some) patients were inclined to choose the same time point for loading as the time point at which they received the questionnaire. When the questionnaire was, for instance, assessed 7 days postoperatively, a higher number of patients preferred loading within 1 week after surgery. When the questionnaire was assessed on the day of loading, an increase in preference for loading at (more than) 3 weeks was observed. Another possible explanation for the changing preferences is confounding clinical variables. To account for such variables, several patient-specific variables were assessed. One of these variables was previous experience with a BAHI. Interestingly, no differences in preference were observed between patients with and without BAHI experience. In the correlation analysis, only weak correlations, which were not consistent over the different time points, were found. For example, the GHSI general subscore correlated with preoperative preference, whereas age correlated with preference directly postoperatively. Additionally, while the severity of complaints was correlated with the preference 7 days after surgery, it was not correlated with the preference directly after surgery or at approximately 3 weeks after surgery. Because of these inconsistencies, it is difficult to interpret these outcomes and to determine which variables truly contribute to the variability in preference for loading time. With caution, it could be hypothesized that patients with a lower general GHSI subscore have a higher disease burden and therefore prefer earlier loading preoperatively. Postoperatively, other clinical variables, such as well-being and severity of complaints (or other non-assessed clinical characteristics), were more important in the preference for a certain point in time. Since the impact of these variables on loading time preference cannot be estimated preoperatively, it is unfortunately not feasible to include these variables in a standardized loading time scheme.

Implication of These Findings

Despite the limitations of this study and the postoperative decline in preference for earlier loading, a relevant number of patients preferred sound processor loading at an earlier moment than currently advocated: loading within the first week after surgery was preferred by 40 and 50% of the patients when asked 7 days and approximately 3 weeks postoperatively, respectively. On the other hand, sound processor loading at (more than) 3 weeks (the current practice) was preferred by a substantial number of patients as well (35–47.5%). Thus, based on our findings, the preference for the time of sound processor loading varies among patients and differs pre- and postoperatively. Unfortunately, no clear explanation for this variability was found in this study. Currently, the focus on patient-centered health care is increasing, and we think it is important to provide care that is in accordance with patient preferences. However, it should also be feasible to deliver this care, in terms of safety, logistics, and finance. Bearing this in mind, one possible way to cater to our patients' preferences and to improve efficacy could be loading the sound processor 1 week after surgery. Loading can then be combined with the regular postoperative follow-up visit, resulting in fewer visits. The study conducted by Hogsbro et al. (12) demonstrated that loading at 1 week is also feasible regarding safety. In this study of 25 patients, no implant losses or decreased ISQ values were observed after sound processor loading at 1 week postoperatively. We should, however, take into account that only adult patients with normal bone quality were included in this study and that sound processor loading was only performed in cases of sufficient soft tissue healing. The same was applied for the study conducted by Hogsbro et al. (13), in which loading was performed 2 weeks after surgery. Therefore, it remains questionable whether loading within 1 or 2 weeks would be safe in the entire adult patient population. In addition, based on the findings in the current study, not all patients prefer earlier loading. Another option for sound processor loading would be to conduct loading when sufficient stability (based on ISQ values) and wound healing have been reached, as proposed by McLarnon et al. (21) and Mierzwinski et al. (22). However, such a protocol might induce logistic challenges and uncertainty for the patients. Moreover, the correlation between ISQ and osseointegration is still debatable, and no lower limit ISQ value at which loading is safe has been determined (13,15).

CONCLUSION

Despite the postoperative decline in patients preferring earlier loading than currently advocated, approximately half of all patients preferred sound processor loading within 1 week after bone-anchored hearing implant surgery. To both cater to our patients' preferences and improve hospital efficacy, sound processor loading 1 week (instead of 3 weeks) after surgery might be implemented. However, when determining the time of sound processor loading, in addition to individual patient preferences, logistics, and clinical characteristics should always be taken into account.

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