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Hearing-Related Quality of Life in 75 Patients With a Percutaneous Bone Conduction Device

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Objective: To evaluate long-term hearing-related quality of life (HRQoL) and device use in bone conduction (BCD) users. Furthermore, to assess differences between indications and changes in HRQoL over time.

Study design: Prospective questionnaire survey.

Setting: Tertiary referral center.

Patients: Seventy-five patients with a percutaneous BCD.

Main outcome measures: Glasgow Benefit Inventory (GBI) at 3 and 12 months postoperatively, Glasgow Health Status Inventory (GHSI) preoperatively, and 6 and 36 months postoperatively, device use at 6, 12, and 36 months. Changes over time were assessed and outcomes were compared between indications.

Results: After implantation, 97% of all patients reported a positive benefit on the GBI total. The GHSI total had improved with median 15 points (Interquartile range [IQR] 12). At 36 months, median device use was 15 hours/day (IQR 10) and one nonuser was reported. Patients with bilateral hearing loss (BHL) showed greater improvement on the

GHSI total (median 18 vs 14, $p < 0.0001$) and used their devices more frequently (median 16 vs 8 h/day, $p < 0.0001$) than patients with unilateral HL (UHL). Postoperative GHSI and GBI scores were consistent over time, in the entire patient population and for every indication. Between 6 and 36 months, device use was stable over time, except for patients with single-sided deafness (SSD; median -6.4 h/day, $p = 0.009$).

Conclusion: The BCD improves HRQoL in patients with BHL, in patients with unilateral conductive/mixed hearing loss and in patients with SSD. Patients with BHL experienced a greater improvement in hearing status compared to patients with UHL. Although use decreased over time in SSD patients, device use was high for every indication.

Key Words: Bone conduction device—Bone-anchored hearing—Hearing loss—Hearing-related quality of life—Indications—Percutaneous.

Otol Neurotol 43:345–351, 2022.

INTRODUCTION

Clinical and audiological outcomes of the percutaneous bone conduction device (BCD) are proven to be beneficial for patients with conductive/mixed hearing loss (CMHL) or single sided deafness (SSD) who can't be rehabilitated with conventional hearing aids or surgery (1–3). A BCD involves a surgical procedure as well as financial costs related to care and replacement of the

devices (3). In order to justify the use of such an implant system, cost-effectiveness studies have become increasingly important (3–5). Unfortunately, cost-effectiveness evaluations are limited by the lack of usable data on quality of life (QoL) and device usage. Generic health-related QoL questionnaires do not seem specific enough to detect changes in QoL related to the BCD (6). Furthermore, studies on hearing-related QoL (HRQoL) either use retrospectively collected data (7–10), or focus

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Outside the submitted work, the authors report financial support to the authors' institution (Radboudumc) for conducting clinical studies from Oticon Medical AB (Askim, Sweden) and from Cochlear Bone Anchored Solutions AB (Mölnlycke, Sweden).

Supplemental digital content is available in the text.

The authors disclose no conflict of interest.

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DOI: 10.1097/MAO.0000000000003442

on short-term HRQoL in patients with a specific indication (11,12). In these studies, HRQoL is mainly assessed by means of the Glasgow Benefit Inventory (GBI) (13). The GBI is a single-shot questionnaire which is widely used to assess the benefit of different otolaryngology interventions (14), despite the fact that it is subject to recall bias. Status questionnaires, such as the Glasgow Health Status Inventory (GHSI), which are administered pre- and postintervention are therefore considered to be more bias-free (13,15). Unfortunately, the GHSI is not commonly used in BCD patients.

The current study evaluated prospectively collected data regarding GBI, GHSI, and device usage outcomes in patients who underwent BCD implantation. Specifically long-term HRQoL and device use, as well as changes over time, were assessed in a general BCD population and for individual indications.

METHODS

Ethical Considerations

The local ethics committee approved of this study.

Study Design and Patient Population

All data were prospectively collected in two clinical trials which were conducted at our tertiary referral center. In these studies, 80 adults underwent percutaneous BCD implantation between 2012 and 2014 with a Ponto implant® (width 3.75 mm or 4.5 mm, length 4.0 mm, Oticon Medical AB, Askim, Sweden) using either the linear incision technique with soft tissue reduction or soft tissue preservation (16–19). The 6-month HRQoL data collected in these studies have been published (17,18). The 3-year HRQoL data of the 75 patients who completed the follow-up have not been described yet and were analyzed in the current study. The HRQoL data of these 75 patients were combined and the total study population was divided into groups based on type of hearing loss. A distinction based on etiology (acquired vs congenital) was not feasible because of the relatively small number of patients with congenital hearing loss.

First, the population was divided into a group with unilateral hearing loss (UHL) and a group with bilateral hearing loss (BHL). Patients with UHL were further divided into a subgroup with CMHL and a subgroup with SSD. Because not every patient with BHL used two hearing devices postoperatively, a distinction was made between patients who were postoperatively fitted with a unilateral BCD (UL fitted), and patients who were either bilateral or bimodal BCD users (BL fitted). Reasons for unilateral fitting in case of BHL were sufficient hearing with one device (19%), contralateral mild hearing loss (25%), unknown (25%) and contralateral profound sensorineural hearing loss (32%). Additionally, the total patient population was divided into patients with, and patients without a postoperative complication occurring within 12 months postoperatively. Postoperative complications comprised of adverse skin reactions (Holgers ≥ 2), pain, bleeding, need for abutment change, abutment removal, or revision surgery.

Questionnaires and Device Use

Two QoL questionnaires were administered: the GHSI and the GBI (13). Both questionnaires comprise 18 questions scored on a five-point Likert scale and result in a total score and three

subscores (general, social support, and physical health). The general domain (12 questions) evaluates general and psychosocial health status, whereas the social support domain (three questions) focuses on the amount of social support patients receive in relation to their impairment. The physical health score (three questions) assesses medication use and the number of visits to the general practitioner. GHSI scores range between 0 and 100 with a higher score indicating a better QoL. GBI scores range between –100 and +100 and are classified as negative (<0), no benefit (=0), or positive (>0). In this study, the GHSI was used to determine the impact of the patient's hearing impairment on HRQoL in the unaided situation before implantation. In patients using a conventional hearing aid or unilateral BCD before surgery, the GHSI was used to assess the aided situation at baseline. Additionally, the GHSI was applied to assess the aided situation at 6 and 36 months postoperatively. The GBI was used to measure change in health status after BCD implantation at 3 and 12 months postoperatively. The GBI was not assessed at 36 months because it was hypothesized that recall bias would increase with time. In addition to these questionnaires, device use was determined at 6, 12, and 36 months. For patients implanted with a second BCD in the current study, device use was only determined for the second device. In case of bilaterally implanted patients, the mean use of the two devices was assessed.

Outcome Measures

Outcome measures were 12-month GBI scores, change in GHSI scores from baseline to 36 months, and 36-month device use. Additionally, changes in GBI scores from 3 to 12 months, as well as changes in GHSI scores and device use from 6 to 36 months were assessed. These outcomes were determined for the total study population and compared between the UHL and BHL group, the CMHL and SSD subgroup, and the UL and BL fitted subgroup. In the analyses of changes over time, outcomes were only included when data on both assessments were available. The 12-month GBI scores and device use were compared between patients with and patients without a postoperative complication within 12 months postoperatively. Correlation analysis was performed between device use and outcomes on the GHSI and GBI.

Statistical Analysis

Data management and analyses were partly performed by independent biostatisticians (Statistiska Konsultgruppen, Göteborg, Sweden). Nonparametric statistics were used. Outcomes were described as medians with Inter Quartile Range (IQR) and, in order to enable comparison with literature, as means with Standard Deviation (SD). For analyses of changes over time, the Wilcoxon Signed rank test was used for continuous variables and the Sign test for ordered categorical and dichotomous variables. The Mann–Whitney *U* test was used for comparisons between groups. Correlation analyses were performed with the Spearman correlation coefficient. Because of the observational nature of this study, corrections for multiplicity were not performed. Statistical tests were two-tailed and conducted at the 0.05 significance level. Analyses were performed by using SAS® v9.4 (Cary, NC) and SPSS statistics v25.0 (IBM Corp., Armonk, NY).

RESULTS

Baseline characteristics are presented in Table 1. All patients used a Ponto sound processor (Ponto Pro [Power]

TABLE 1. Baseline characteristics and number of completed questionnaires for all patients and per indication group

Variable	All Patients	Unilateral HL	Unilateral HL	Bilateral HL	Bilateral HL
	n = 75	Cond/Mixed n = 22	SSD n = 14	Unilateral Fitted n = 16	Bilateral Fitted n = 23
Gender, n (%)					
Male	33 (44)	11 (50)	4 (29)	2 (13)	16 (70)
Female	42 (56)	11 (50)	10 (71)	14 (88)	7 (30)
Age at implantation, mean (SD)	54 (13)	52 (11)	52 (8)	56 (13)	56 (17)
Ethnicity, n (%)					
Caucasian	74 (99)	21 (96)	14 (100)	16 (100)	23 (100)
Other	1 (1)	1 (5)	0 (0)	0 (0)	(0)
Completed questionnaires, n					
Baseline—GHSI unaided	68 ^a	18	14	15	21
Baseline—GHSI aided	30	4	1	8	17
3 months—GBI	75	22	14	16	23
6 months—GHSI aided	71 ^b	19	14	16	22
12 months—GBI	75	22	14	16	23
36 months—GHSI aided	72 ^c	20	14	15	23

Cond/mixed indicates conductive/mixed hearing loss; GBI, Glasgow Benefit Scale; GHSI, Glasgow Health Status Inventory; HL, hearing loss; SSD, single-sided deafness.

^aTwo patients used their hearing device throughout the entire day and the GHSI unaided could therefore not be assessed. The GHSI unaided was missing in five other patients for unknown reasons.

^bQuestionnaires were missing in four patients for unknown reasons.

^cTwo patients were not able to complete the GHSI aided questionnaire because of sporadic sound processor use and non-use, respectively. In one patient the GHSI aided was missing for an unknown reason.

or Ponto Plus [Power]; Oticon Medical AB, Askim, Sweden). The BL fitted subgroup comprised of 8 bilateral BCD users and 15 bimodal users. Out of the eight bilateral BCD users, five patients received a second BCD in the clinical trial and three patients underwent simultaneous bilateral BCD implantation. One of the bimodal users got implanted with a second BCD after 2.5 years of follow-up.

Outcomes for the Total Study Population

Figure 1 shows the GBI and GHSI outcomes for the total study population. For the specific GBI and GHSI scores for the total study population and per subgroup, see Table, Supplemental Digital Content 1, <http://links.lww.com/MAO/B391>.

GBI Scores

At 12 months postoperatively, 97% of all patients had a positive GBI total score and 3% a negative total score. The GBI general score was positive in 96% and negative in 3%.

The median total and general score at 12 months were 31 (IQR 27) and 42 (IQR 33), respectively. Mean scores were 32 (SD 22) and 44 (SD 26), respectively. The majority of patients had a GBI of 0 on the social support (63%) and physical health (63%) domains with median scores of 0 (IQR 17) on both domains. Mean scores were 10 (SD 21) and 8 (SD 23), respectively. Positive benefit on these domains were observed in 32% and 28%, respectively. All categorized GBI scores were similar at 3 and 12 months postoperatively.

GHSI Scores

At 36 months postoperatively, the aided GHSI total and general scores significantly improved with a median of 15 (IQR 12) and 24 (IQR 7) points, respectively, when compared with the unaided scores at baseline ($p < 0.0001$). The aided 36-months GHSI total and general score also improved significantly when compared with the aided scores at baseline with a median of 4 (IQR 23, $p = 0.04$) and 8 points (IQR 32, $p = 0.009$), respectively. No significant improvements were found for the aided GHSI social support and physical health scores at 36 months compared with the (un)aided scores before implantation. At 6 and 36 months postoperatively, all aided GHSI scores were comparable.

Device Use

At 36 months postoperatively, median device use in hours a day was 15 (IQR 10) in the total study population. In total, 61 patients (81.3%) used their device on a daily basis with a median use of 16 hours a day (IQR 4). The three patients who underwent bilateral simultaneous implantation used both their devices throughout the entire day. Thirteen patients (17.3%) did not use their device every day and one patient (1.3%), a construction worker with unilateral conductive hearing loss, was a nonuser because of practical reasons. The 13 nondaily users were comprised of ten patients with UHL (six with SSD), two with bimodal fitting and one unilateral BCD user with BHL. Median use in this group was 2 days per week. Device use did not change significantly between 6 and 36 months.

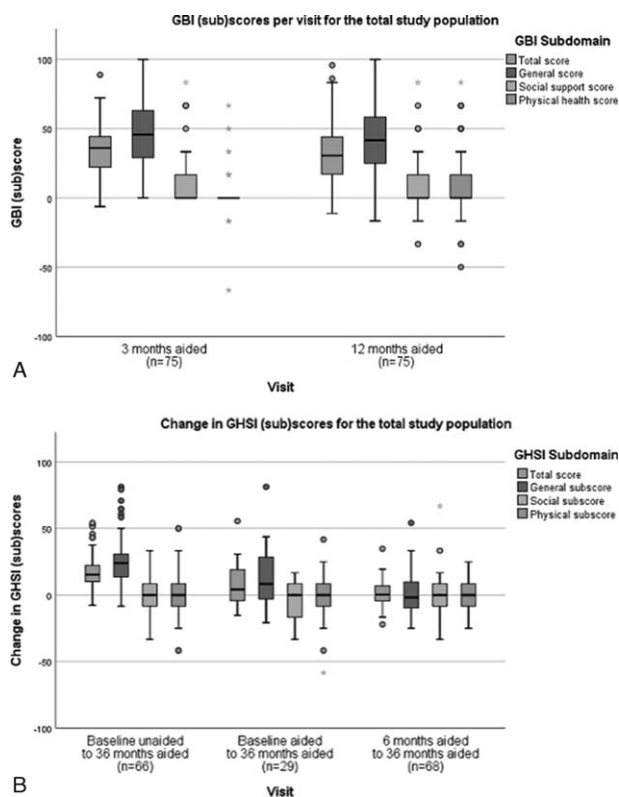


FIG. 1. Boxplot of the GBI (sub)scores *A*, and changes in GHSI (sub)scores *B*, across visits for the total study population. The median is marked by a horizontal line. The boxplots represent the interquartile range, whiskers represent the range with the exception of outliers, the dots represent outliers, and the asterisks represent extreme outliers. GBI indicates Glasgow Benefit Inventory; GHSI, Glasgow Health Status Inventory.

Correlation Analyses

Device use at 36 months was positively correlated with the postoperative change on the GHSI total and general score (change from baseline unaided to 36 months aided). In these cases, weak, but statistically significant, correlations were found ($r=0.31$, $p=0.01$ and $r=0.33$, $p=0.008$, respectively). No correlations were observed between device use and the GHSI social support and physical health scores. The GBI scores at 12 months did not correlate with device use at 12 months (for GBI total $p=0.14$). Postoperative complications did not influence the 12-month GBI scores and device use.

Outcomes Compared Between Indication (Sub)Groups

Figure 2 presents the GBI and GHSI total scores across visits for the different indications. A comparison of baseline GHSI scores between the indication (sub)groups was only performed for the unaided scores, because of the limited number of patients completing the aided GHSI at baseline (Table 1). Figure 3 demonstrates device use per indication group.

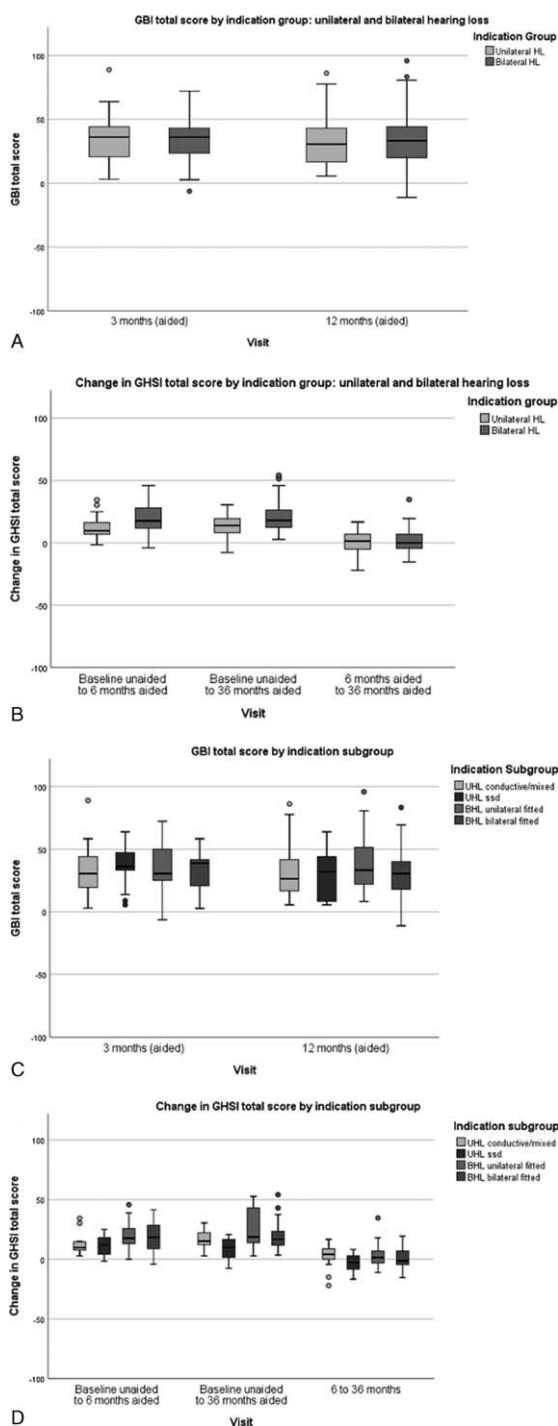


FIG. 2. Boxplots presenting the GBI total score and change in GHSI total score by indication (sub)groups. For patients with unilateral and bilateral hearing loss the GBI total score per visit and the change in GHSI total score are presented in *A* and *B*, respectively. *C* and *D* show the GBI total score per visit and the change in GHSI total score, separately for all four indication subgroups. The median is marked by a horizontal line. The boxplots represent the interquartile range, the whiskers represent the range with the exception of outliers, the dots represent outliers, and the asterisks represent extreme outliers. GBI indicates Glasgow Benefit Inventory; GHSI, Glasgow Health Status Inventory.

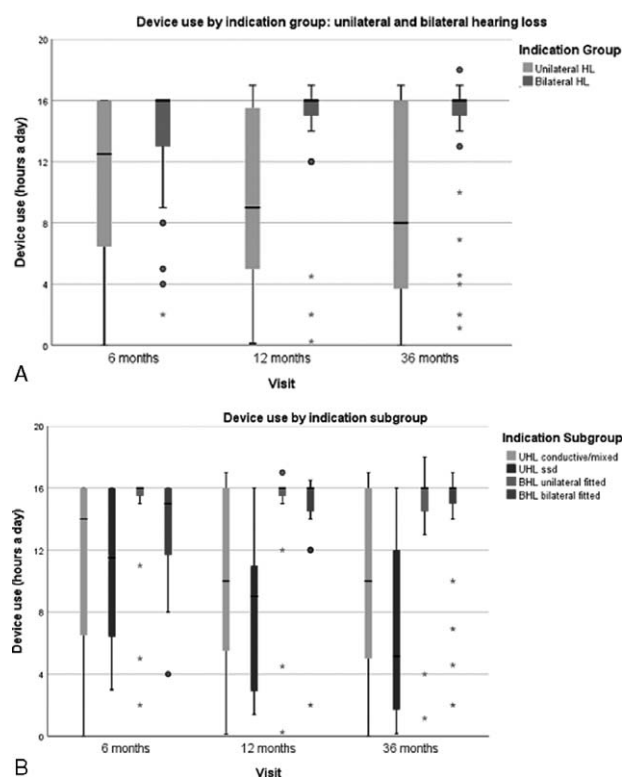


FIG. 3. Boxplots presenting device use in hours a day compared between indication groups *A*, and indication subgroups *B*. The median is marked by a horizontal line. The boxplots represent the interquartile range, the whiskers represent the range with the exception of outliers, the dots represent outliers, and the asterisks represent extreme outliers.

Unilateral Versus Bilateral Hearing Loss

The categorized GBI scores at 3 and 12 months, as well as changes in GBI scores over time, were comparable for patients with UHL and BHL. Before implantation however, patients with UHL had a significantly higher unaided GHSI total score, as well as better general and physical health scores, compared to patients with BHL. The social support score at baseline was however higher for the patients with BHL. The GHSI total and general score at 6 and 36 months had significantly improved for both groups compared with the unaided baseline scores, with a greater improvement for the BHL group. Median change in total score from baseline to 36 months was +14 (IQR 12) in case of UHL and +18 (IQR 13) in case of BHL ($p < 0.0001$). In both groups, the postoperative aided GHSI social support- and physical health score were similar to the unaided scores at baseline.

At all time-points of assessment (6, 12, and 36 months), patients with BHL used their device (either first or second BCD) more often than patients with UHL, with a median difference of 8 hours a day at 36 months ($p < 0.001$). Between 6 and 36 months, device use was consistent in the BHL group, but significantly deteriorated over time in the UHL group with a median difference of 4.5 hours a day ($p = 0.019$).

CMHL Versus SSD

Within the UHL group, the categorized GBI total score, as well as the general and social support scores were comparable between subgroups at 3 and 12 months. The physical health score was significantly lower for the SSD patients. A positive benefit on the physical health domain was reported in nine patients (41%) with CMHL and in only one patient (7%) with SSD ($p = 0.027$). GBI scores were consistent over time except for a slightly increased physical health score in the CMHL subgroup at 12 months.

At baseline, similar unaided GHSI scores were observed for the CMHL and SSD subgroups. At 6 and 36 months, the total and general score had improved in both subgroups, compared with baseline unaided scores. However, at 36 months a greater improvement in these scores was found for patients with CMHL ($p = 0.021$ and $p = 0.026$).

Device use at both 6 and 36 months was comparable between groups. However, in the SSD subgroup, device use decreased over time between 6 and 36 months with a median of 6.4 hours a day ($p = 0.009$). At 36 months, median use in the SSD subgroup was 5.1 hours a day (IQR 11) and 57% used their device on a daily base. For the CMHL subgroup, device use did not change significantly over time ($p = 0.53$).

Unilateral Versus Bilateral Fitting

For patients with bilateral HL, categorized GBI scores and changes in GBI over time were all comparable between the UL- and BL fitted subgroups at both time points. Unaided GHSI scores at baseline were comparable between patients with UL and BL fitting, except for a slightly worse physical health score in the BL fitted subgroup (mean difference -13 , $p = 0.049$). Postoperative GHSI scores at 6 and 36 months had significantly improved for both groups compared to the unaided baseline scores, with a similar improvement in the total and general score. The social support and physical health score remained similar to baseline in both UL and BL fitted patients. In both groups, device use was consistent over time. Similar and high usage rates were observed at 6, 12, and 36 months postoperatively.

DISCUSSION

Key Findings and Interpretation

The current study evaluated hearing-related quality of life (HRQoL) in 75 patients with a percutaneous bone conduction device (BCD), among and across separate indications. After BCD implantation, the majority of patients reported a positive benefit on the Glasgow Benefit Inventory (GBI) total (97%) and general (96%) domain and the Glasgow Health Status Inventory (GHSI) total and general score had significantly improved. In every indication (sub)group, postoperative improvement in HRQoL was observed. Interestingly, postoperative GBI and GHSI scores were consistent over time, in the entire patient population and in every

indication group. During follow-up, high device usage rates were reported among and across individual indications with only one nonuser at 36 months. Except in patients with SSD, device use was stable over time. The current findings underline that BCD implantation results in an improved HRQoL in patients with bilateral conductive/mixed hearing loss (CMHL) and suggest an improved HRQoL in patients with unilateral CMHL and in patients with SSD. The consistency in HRQoL over time, as measured with the GBI and GHSI, might imply that a one-time assessment of the GBI (postoperatively) and GHSI (pre- and postoperatively) is sufficient. In addition, the postoperative time point of questionnaire assessment seems to be of minor importance. We might therefore conclude that GHSI- and GBI outcomes can be compared across studies, independent of time of assessment. On the other hand, the current study only evaluated 12-month GBI and 36-month GHSI outcomes. HRQoL outcomes might change over time in case of even longer follow-ups. Especially since previous studies observed a tendency toward decreasing benefit and device use in patients with SSD, at 3 to 5 years follow-up (20–22). A future study investigating the long-term (>10 years) stability of HRQoL in different indication groups, using modern sound processor technology, would be of interest.

Differences Between Indications

GBI scores were comparable between indication (sub-)groups. This might indicate that the level of benefit achieved with a BCD is independent of indication. More probable explanations include insufficient sensitivity of the GBI, small sample size per group, and heterogeneity in patient characteristics. According to the GHSI outcomes, patients with bilateral hearing loss (BHL) experienced a greater improvement in hearing status after BCD implantation (either first or second BCD) than patients with unilateral hearing loss (UHL). The postoperative change in GHSI total and general scores at 36 months had a weak, but significant positive correlation with device use indicating that satisfied users use their device more frequently. Not surprisingly, patients with BHL used their device more frequently than patients with UHL. These findings are in line with previous studies in which a higher subjective benefit and device usage rate were found for patients with BHL (7,10). In the current study, device use decreased over time in patients with UHL. This decrease can most probably be attributed to the patients with SSD, as use deteriorated with time in this subgroup. This finding suggests, in line with literature, that device use deteriorates over time in SSD patients. Despite the deteriorating use, the majority of SSD patients still seemed to benefit from a BCD, since 57% of them used the BCD on a daily base at 3 years after implantation. Additionally, GHSI scores remained stable over time in this subgroup indicating that these patients still experience benefit from the BCD at 3 years postoperatively. When counseling a patient with SSD applying for a BCD, it is however important to discuss the

variability in usage times among patients and the deterioration in use.

Comparison with Literature

In line with our findings, Meghji et al. found significantly improved GHSI total and general scores after surgery (23). Interestingly, in their study, the physical health score also increased postoperatively.

In the current study, both the categorized GBI and mean GBI scores were reported. According to Hendry et al., categorized GBI scores enable better comparisons between interventions (14). Unfortunately, most studies report mean GBI scores only. Studies evaluating HRQoL in a BCD population with mixed indications reported mean total GBI scores ranging between 31 and 38 (10,24,25). In these studies, the highest mean scores were found on the general domain, followed by the social support and physical health scores. GBI results for our study population were similar, with a mean total score of 32 and the highest mean score being observed in the general domain. Although the mean social support and physical health scores were 10 and 8, respectively, the majority of our patients did not experience a positive benefit in these domains. This finding seems plausible since these domains are related to more generic QoL and do not assess health items which might be influenced by BCD implantation. The number of visits to the ENT-department or number of ear infections are for instance not included in the GBI. In the current study, a positive total GBI benefit was observed in 97%. De Wolf et al., assessed the GBI in older patients with a conventional indication and found a positive benefit in 84% (9). The higher benefit percentage in the current study might be explained by advancements in sound processor technology or lower age. HRQoL studies on cholesteatoma surgery and stapes surgery observed positive benefit on the GBI total in 82% and 85% of the patients respectively (26,27). It must however be noted that in the study on cholesteatoma surgery, ossicular reconstruction was not performed in 12% (27). In general, GBI total benefit scores after BCD implantation appear to be at least comparable to those after reconstructive middle ear surgery. In terms of HRQoL, hearing rehabilitation with a BCD thus seems to be a good alternative to surgical restoration in indicated patients.

Device use in our study population was in line with literature, with a mean use of 11 hours a day for the total study population and 81% daily users. Lekue et al., evaluated a population with mixed indications as well and observed a mean use of 11 hours a day and daily use in 72% of the patients (10).

Strengths and Limitations

This study provides new insights into long-term HRQoL, the consistency of HRQoL over time and differences in HRQoL between indication groups. The use of prospectively collected data and the relatively large sample size are the major strengths of this study. However, dividing the study population into different indication

groups, resulted in small subgroups with heterogenous characteristics. For instance, the UL fitted subgroup comprised patients with bilateral conductive hearing loss, as well as patients with conductive hearing loss on the side of implantation and a contralateral profound sensorineural hearing loss. Furthermore, the BL fitted subgroup consisted of both bilateral and bimodal BCD users. In these patients, device use was only assessed for the BCD that was implanted during the clinical trial. Despite the heterogeneity within subgroups, plausible differences in HRQoL between groups were found in this study.

CONCLUSION

The bone conduction device improves hearing-related quality of life in patients with both unilateral and bilateral conductive/mixed hearing loss (CMHL), and in patients with single-sided deafness. Patients with bilateral hearing loss experienced a greater improvement in hearing status compared to patients with unilateral hearing loss. At 36 months, high device usage rates were observed in every indication group. However, device use decreased over time in patients with single-sided deafness. Outcomes on the GBI and GHSI questionnaire were stable over time across and among separate indications.

Acknowledgments: This study was funded by Oticon Medical AB (Askim, Sweden).

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