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Long-Term Outcomes of a Percutaneous Wide-Diameter Bone-Anchored Hearing Implant: A Clinical Evaluation of More than 800 Implants

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Objective: This study evaluates the clinical outcomes of 807 percutaneous wide-diameter bone-anchored hearing implants (BAHIs) in 701 patients. In addition, it compares patient groups and examines bone conduction device (BCD) usage.
Study design: Retrospective cohort study. Mean follow-up period of 3.8 years.
Setting: Tertiary referral center.
Patients: All patients implanted with a percutaneous wide-diameter BAHI until December 2020 were included. Patients were divided into age groups, "loading-time" groups, and, if applicable, specific subgroups thought to be at risk for complications postsurgery, e.g., intellectual disability and comorbidities.
Main outcome measures: Soft tissue reaction, implant survival, revision surgery, and BCD usage.
Results: In 9.1% of the 5,188 observations of 807 implants, an adverse soft tissue reaction was reported according to the Holgers' scale. Significantly more (*adverse*) soft tissue reactions were observed in children and intellectually disabled (ID) patients ($p < 0.05$). Comorbidity subgroups showed no significant differences in soft tissue reactions. Implant loss percentage, including explantations, was 6.2%. Implant survival was significantly worse in patients with ID (14.1%; $p = 0.021$). Pediatric age, early loading, or comorbidities did not significantly influence implant survival. At least 592 implants (73.4%) were used for bone conduction hearing, of which 65.4% were used daily.
Conclusion: Both children and ID patients are more prone to (*adverse*) soft tissue reactions, ID patients only have a higher risk of implant loss. The rate of implant loss in children seemed to be reduced compared to previous studies and thus more comparable to adults since using wide-diameter implants.
Key Words: BAHA—BAHI—Bone-anchored hearing implant—Bone conduction—Bone-anchored hearing aid—Hearing loss—Implant loss—Soft tissue reactions—Wide-diameter implants.

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INTRODUCTION

The bone-anchored hearing implant (BAHI), introduced in 1977 and in clinical use since the 1980s, rehabilitates patients with hearing loss whose hearing cannot be restored by conventional hearing aids or middle ear surgery (1). A BAHI, consisting of an implant (fixture) and abutment (coupler), is anchored in the temporal bone and transfers sound vibrations, amplified by a coupled sound processor, directly to the cochlea. To achieve firm bone-anchoring of the implant in the mastoid, together with minimum soft tissue-related complications, several implant designs and surgical techniques have been used and evaluated over the past decades (2–5). One of these adaptions was the "wide-diameter implant" (6,7). This implant has a wider diameter of 4.5 mm as opposed to the 3.75 mm of the previous generation implant, resulting in an enlarged bone-to-implant contact area, suggesting higher implant stability and survival (8–10). Previously reported survival rates for wide-diameter implants vary between 93.8 and 100% (9–15) and seem superior to the 74.1% to 100% (10,13,16–19) of previous generation implants. However, these percentages

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cannot be appropriately compared because available studies on wide-diameter implants lack sufficient sample sizes and follow-up time. In addition, prospective comparative studies between the previous generation and wide-diameter implants are currently not feasible due to the standard use of wide-diameter implants in BAHI care.

In 2012, the clinical outcomes of more than 1,000 previous generation implants placed in our center between 1988 and 2007 were evaluated (16,20). Now that the first wide-diameter implant was placed at our center in 2009, we have collected data on the clinical outcomes of more than 800 wide-diameter implants. This article retrospectively evaluates the long-term clinical outcomes of the wide-diameter implant. In addition, it compares patient groups and examines bone conduction device (BCD) usage. Moreover, the outcomes of the current series of implants are juxtaposed with those of the previous generation implant series evaluated by Dun et al. (16).

PATIENTS AND METHODS

All patients implanted with a wide-diameter BAHI in our center until December 2020 were identified and extracted from our BAHI database. For this evaluation, a cohort of 701 patients with 807 implants from Cochlear® or Oticon Medical, who underwent surgery between April 2009 and December 2020, was identified. Two-hundred eighty-eight implants (35.7%) in this study were described in earlier conducted research on implant design and surgical techniques (6,7,21–24).

Patients were again divided into three age groups (Dun et al., 2012) according to their age at implantation, defined as age at the time of (first) surgery: children up to 16 years, adults (17–64 years), and elderly (≥65 years). Patients were also again grouped by loading time, i.e., the time between the implant placement and sound processor loading: loading at 3 to 5 weeks, at 6 to 8 weeks, at 9 to 11 weeks, and at or after 12 weeks.

Mental state and comorbidities thought to be potential risk factors for complications postsurgery were assessed, e.g., intellectual disability (ID) of any severity, diabetes mellitus of any severity, osteoporosis, previous radiotherapy of the skull, skin diseases of the scalp, and chronic use of corticosteroids (16,20,25–28).

Surgical Techniques

As implant designs and techniques for BAHI surgery evolved over the past decade, various implants and surgical procedures were used in this study population. Initially, the Nijmegen linear incision technique with soft tissue reduction (LIT-TR) was used for most surgeries until 2015 (29). In 2016, this technique was replaced by the linear incision technique with soft tissue preservation (LIT-TP)(30,31). As of 2014, a proportion of our patients was operated on using punch-only techniques, such as the Minimally Invasive Ponto Surgery (MIPS) and MONO procedure (one-step drilling), mainly carried out in a research setting (24,32).

Postoperative Care

Aftercare was provided according to our centers' protocol. A healing cap with antibiotic ointment was placed on the abutment directly postsurgery. This cap was removed during the first postoperative visit, after which patients were instructed to apply antibiotic ointment around the abutment twice a day for 2 weeks. In case of sufficient healing, BCD loading was performed at 3 to 5 weeks postsurgery. A subsequent visit was scheduled at 3 months postoperatively, followed by a yearly check-up at the outpatient clinic. Extra visits were planned in case of complaints or complications that could not be handled remotely.

Data Collection

Patients' medical files were reviewed, and relevant information was recorded, which included: age at implantation, gender, mental state and comorbidities, indication for BAHI (re)implantation, surgical notes (e.g., date of surgery, surgeon, type of anesthesia, side of surgery, bilaterality (sleeper) implant and abutment types, implant surface, surgical technique, complications), loading time, sound processor type, antibiotic prescriptions, soft tissue reactions, revision surgery, abutment replacements, implant survival, BCD use, and follow-up period. The number of outpatient visits varied for each patient and implant and depended on the follow-up period and problems that arose. At each visit, the degree of soft tissue reaction was classified using the Holgers' grading system (33). Subsequently, all available IPS scores were collected. This IPS-scale comprising inflammation, pain, and skin height, assigns higher scores to indicate more severe complications, and offers standardized treatment advice (34). BCD use was defined as the last reported usage rates in hours a day and days a week. The follow-up period was defined as the time from implant (fixture) insertion until the last visit to the outpatient clinic or until implant loss occurred.

Statistical Analysis

All data were analyzed using SPSS 25 (SPSS, Inc., Chicago, IL). Mean soft tissue reaction scores were calculated by dividing all observed skin reactions by all observations performed. A more clinically relevant score was calculated by dividing all observed adverse skin reactions (Holgers≥2) by all observations. This second calculation was performed because patients with adverse skin reactions need to be treated, unlike patients with no or mild skin reactions (Holgers≤1). Robust analysis of variance tests were performed to compare the mean (adverse) skin reaction scores and the number of revision surgeries between subgroups. With different sample sizes and assuming unequal variances, pairwise comparisons were performed using a post hoc Games-Howell procedure. Kaplan-Meier curves were used to analyze implant survival. The level of significance for all tests was $p \leq 0.05$.

RESULTS

Baseline Characteristics

Eight hundred and seven percutaneous wide-diameter implants (n = 807) were implanted in 701 patients between

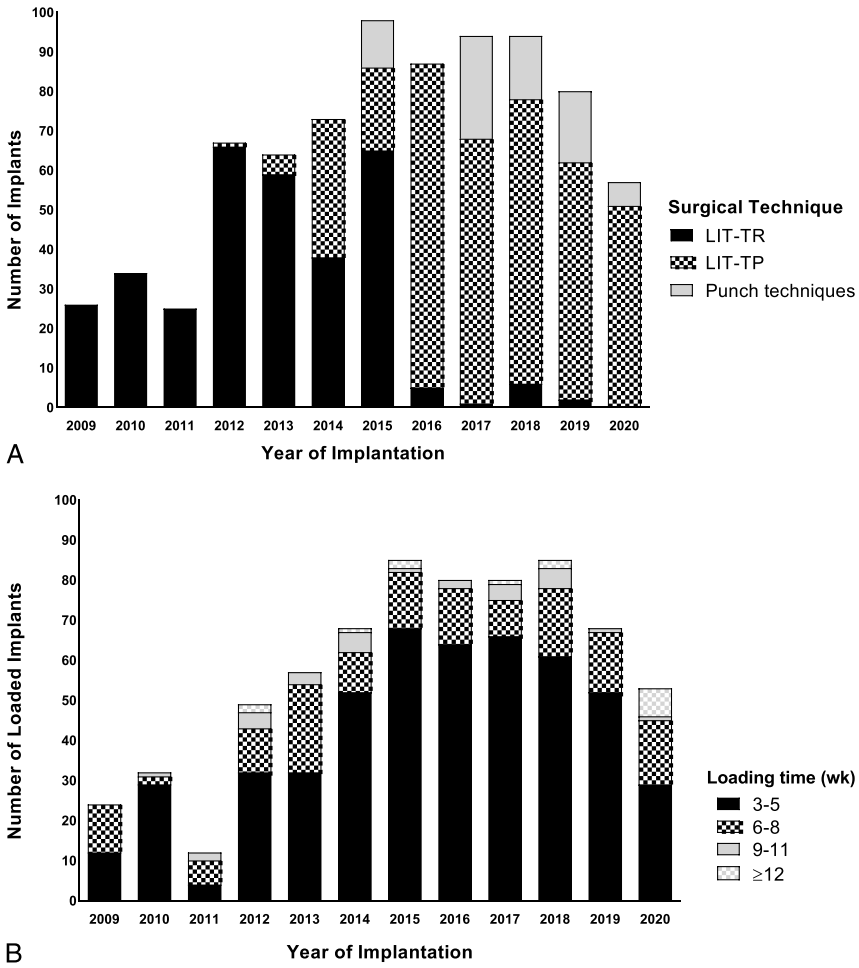

FIG. 1. *A*, Different surgical techniques that have been used in our tertiary center distributed over the year of implantation. *B*, Distribution of the four loading time groups over time (year of implantation). Implantations that have been performed with two-stage surgery are excluded.

April 2009 and December 2020, including 118 children, 410 adults, and 173 elderly. Loading time groups (Fig. 1B) were distributed as follows: loading at 3 to 5 weeks (n = 501), 6 to 8 weeks (n = 148), 9 to 11 weeks (n = 42), and at or after 12 weeks (n = 95). In the latter group, most implants (n = 80) were placed in children, i.e.,two-stage surgery (implantation in two operations, in which the implant is placed during the first operation, and the abutment is attached during the second operation 3 months later). In 21 cases, the loading time could not be obtained from the patient's file due to missing hardcopies.

Mean age at first implantation was 47 years (range, 3–92years; standard deviation [SD], 23 years). The median follow-up period was 3.1 years (mean, 3.8 years; range 0–12 years; SD, 3 years). Forty-nine patients (7.0%) with ID were identified. Baseline characteristics of patient groups based on age and mental state at implantation are presented in Table 1A. An overview of gender, comorbidities and BAHI indications is shown in Table 2.

Bilaterality

One hundred twenty-three patients (17.5%) were implanted bilaterally. Almost two third of them were implanted sequentially (n = 75, 61.0%), and almost a third comprised a child (n = 34, 27.6%). Three children were implanted sequentially,

TABLE 1. *Baseline characteristics of the patient groups as identified by age and intellectual state at the time of BAHI surgery*

	Total	Children[a]	Adults[a]	Elderly[a]	Intellectually Disabled[b]
No. Implants	807	162	453	192	71
No. Patients	701	118	410	173	49
Age, mean (range), yr	47.0 (3–92)	8.1 (3–16)	47.6 (17–64)	72.2 (65–92)	27.5 (3–69)
Follow-up, mean (range), mo	45 (0–143)	43 (0–128)	47 (0–143)	43 (0–142)	50 (0–128)

[a]Age group according to age at implantation: children up to 16 years, adults (17–64 years), and elderly (≥65 years).
[b]No level of disability was described in the patient files, and ID patients of varying severities were included in this group.

TABLE 2. *Indications for BAHI surgery in 701 patients including gender and comorbidities*

Gender	n	%
Female	370	52.8
Male	331	47.2
Comorbidities	n	%
DM	69	9.8
Insulin	17	2.4
Oral medication	44	6.3
Diet/no medication	8	1.1
Skin disease scalp (such as eczema or psoriasis)	30	4.3
Chronic steroid use	19	2.7
Radiation therapy skull	20	2.9
Osteoporosis	6	0.9
Indication	n	%
Acquired conductive/mixed hearing loss	433	61.8
Active CSOM	113	16.1
Status after mastoidectomy	244	34.8
Congenital conductive hearing loss	126	18.0
Atresia/microtia	107	15.3
Single-sided deafness	87	12.4
Combinations/other	55	7.8

[a]DM indicates diabetes mellitus; CSOM, chronic suppurative otitis media; SSD, single-sided deafness.

e.g., because previous bilateral implantation was not yet indicated or after unilateral (instead of bilateral) implantation in a different center abroad. In 58 of the sequentially implanted patients, the primary implant included a previous generation implant; in 15, the second implant included a reimplant.

Of the simultaneously implanted patients (n = 48), i.e., patients with bilateral implantation in one OR session, almost all patients (95.8%) were provided with a wide-diameter implant on both sides. Most of them included children (n = 31, 64.6%).

Reimplantation

Forty-nine patients (7.0%) underwent revision surgery of a failed implant at least once. In total, 92 implants (11.4%) were revised by either reimplantation (n = 82, 10.2%) or by placing an abutment on a sleeper implant. Sleeper implants were initially placed in 95 pediatric patients, and in 10 (10.5%) of them, this had to be used because of loss of the primary implant.

Surgical Technique

In a few sequentially bilateral implanted patients, surgical technique differed per implant site. Therefore, these will be further referred to cases, i.e., inserted implants, instead of patients.

The more common surgical technique for implantation was the LIT-TP, which was used in 394 cases (48.8%). In 327 cases (40.5%), the LIT-TR was used. In 69 cases (8.6%), a variant of the punch technique was used. In 17 cases (2.1%), the surgical procedure was not specified in the surgical record, e.g., because the implant was inserted during extensive ear surgery. Figure 1A presents the techniques that have been used in our center distributed over years of implantation.

Perioperative Complications

Perioperative complications rarely occurred. In 38 cases (4.7%), venous bleeding was mentioned in the surgical report, mostly from an emissary vein. Hemostasis was then easily achieved by electrocoagulation or implant placement. In two cases, both LIT-TR, the incision had to be converted, and in another two, the implant was repositioned. In four cases (0.5%, of which three LIT-TP and one LIT-TR), a dura defect was reported, of which in two cases minimal cerebrospinal fluid leakage was described. In both cases the leakage stopped after implant placement.

Soft Tissue Reactions

During the mean follow-up period of 3.8 years, 5,188 observations were made for the entire group of 807 implants. An overview of soft tissue reaction observations in different subgroups is given in Table 3A. Figure 2 presents the maximum IPS score across visits.

Statistical analysis indicated significant higher mean soft tissue reaction scores in children (mean, 0.48; SD, 0.47) compared with adults (mean, 0.29; SD, 0.36; $p = 0.000$)

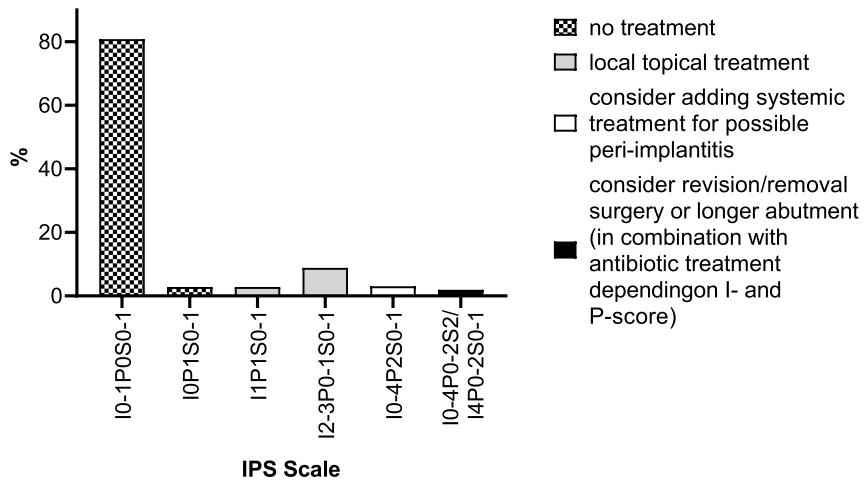

FIG. 2. Maximum IPS score across visits with standardized treatment advice (34).

TABLE 3A. *Distribution of skin reactions (Holgers grading system) over observations as identified by age and intellectual state*

	Total Cohort		Children[a]		Adults[a]		Elderly[a]		Intellectually Disabled[b]	
Holgers Grade	n	%	n	%	n	%	n	%	n	%
0	3947	76.1	684	65.8	2357	77.2	906	82.6	306	63.2
1	767	14.8	206	19.8	443	14.5	118	10.8	99	20.5
2	315	6.1	95	9.1	172	5.6	48	4.4	49	10.1
3	112	2.2	33	3.2	61	2.0	18	1.6	19	3.9
4	47	0.9	21	2.0	19	0.6	7	0.6	11	2.3
Total observations	5188	100.0	1039	100.0	3052	100.0	1097	100.0	484	100.0

[a]Age group according to age at implantation: children up to 16 years, adults (17–64 years), and elderly (≥65 years).
[b]No level of disability was described in the patient files, and ID patients of varying severities were included in this group.

and elderly (mean, 0.23; SD, 0.34; $p = 0.000$). Also, the mean *adverse* soft tissue reaction scores were significantly higher in children (mean, 0.29; SD, 0.43) compared with adults (mean, 0.16; SD, 0.30; $p = 0.005$) and elderly (mean, 0.14; SD, 0.30; $p = 0.002$). There was no statistical difference between adults and elderly in mean (*adverse*) soft tissue reaction scores.

ID patients had significantly higher (*adverse*) soft tissue reaction scores than patients without ID ($p = 0.000$; Tables 3A and 3B). There were no significant differences in mean (*adverse*) soft tissue reaction scores between comorbidity subgroups and patients without the concerned comorbidity.

Implant Survival

In the total study population, 50 implants (6.2%) were lost, i.e., nonelectively extruded or electively explanted, for any reason, with a mean time until loss of 2.9 years (median, 2.2 years; SD, 2.8 years).

In children, 13 implants were lost (8.0%), with a mean time until loss of 1.7 years (median, 1.2 years; SD, 2.0 years), a mean age of 8.5 years at implantation and a mean age of 10.2 years at the moment of loss. In Figure 3, the Kaplan-Meier survival curves for implants are plotted according to the three age categories groups (i.e., children, adults, and elderly). A comparison of implant survival between groups indicated no significant difference in survival between age groups ($p = 0.444$; $p = 0.913$ when ID patients are excluded). Of the 71 implants in ID patients, 10 implants were lost. Implant survival analyses revealed a statistically lower implant survival in ID than patients without ID ($p = 0.021$; Fig. 3). There were no significant differences in implant survival between comorbidity subgroups and patients without the concerned comorbidity. When comparing different surgical techniques, four implant losses (n = 4/25, 16.0%) occurred in the first MIPS trial group and a percentage of 0.0% to 6.7% in the other groups.

Of the 50 lost implants, 39 were primarily placed (n = 39/715, 5.5%), and 10 were reimplanted (n = 10/82, 12.2%). One of 10(10%) "awakened" sleeper implants was lost (a 4 mm implant in a 10-year-oldinsulin-dependent diabetes patient). These losses resulted in a significantly lower implant survival of reimplants, with and without "awakened" sleepers ($p = 0.000$), than primarily placed implants.

Regarding reasons for implant loss, 38 implants (4.7%) were nonelectively extruded (i.e., fallen out), and 12 (1.5%) were electively explanted. Table 4 shows the number of implant losses, including specific causes in loading time groups and period after implantation.

Soft Tissue Revision Surgery

In 39 of 807 implants (4.8%), soft tissue revision surgery of the implant site was performed at least once. Overall, soft tissue revision surgery was performed 43 times (5.3%). An abutment change was also required in 18 (18/43, 41.9%) soft tissue revision procedures. No significant differences in the need for soft tissue revision surgery were observed between age groups (children: n = 15/162, 9.3%; adults: n = 21/453, 4.6%; elderly: n = 7/192, 4.3%). This outcome did not change after excluding ID patients. In children, significantly fewer soft tissue revisions were performed after LIT-TP versus LIT-TR (2.0 vs. 21.0%, $p = 0.003$). No significant correlations in the need for soft tissue revision surgery were observed in the comorbidity groups.

TABLE 3B. *Distribution of most adverse skin reaction (Holgers grading system) over implant cases as identified by age and intellectual state*

	Total Cohort		Children[a]		Adults[a]		Elderly[a]		Intellectually Disabled[b]	
Holgers Grade	n	%	n	%	n	%	n	%	n	%
0	322	40.1	47	29.0	179	39.8	96	50.5	24	33.8
1	214	26.7	46	28.4	124	27.6	44	23.2	10	14.1
2	154	19.2	35	21.6	86	19.1	33	17.4	18	25.4
3	75	9.4	17	10.5	45	10.0	13	6.8	11	15.5
4	37	4.6	17	10.5	16	3.6	4	2.1	8	11.3
Total observed implants	802	100.0	162	100.0	450	100.0	190	100.0	71	100.0

[a]Age group according to age at implantation: children up to 16 years, adults (17–64 years), and elderly (≥65 years).
[b]No level of disability was described in the patient files, and ID patients of varying severities were included in this group.

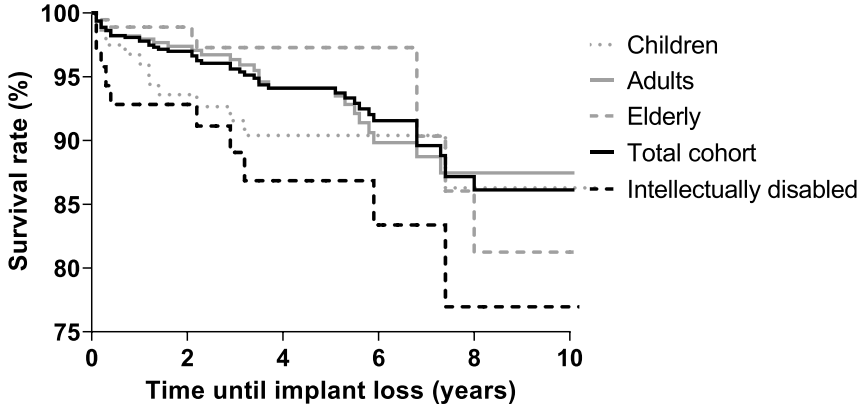

FIG. 3. Implant survival analyses for the total cohort, different age groups, and patients with intellectual disability. * Age group according to age at implantation: children up to 16 years, adults (17–64 years), and elderly (≥65 years). ** No level of disability was described in the patient files, and ID patients of varying severities were included in this group.

Abutment Replacement

In 80 of 807 implants (9.9%), abutment replacement was performed at least once. Overall, abutment replacement with or without tissue reduction was performed 85 times (10.5%). Mostly (n = 47), the length of the initially placed abutment was 6 mm. A new abutment was placed because of soft tissue problems (n = 63) and/or need for a longer abutment (n = 61), need for a shorter abutment (n = 14), or abutment loss (n = 12). Abutment replacement was performed more often after the LIT-TR (n = 49) than after the LIT-TP (n = 31), and significantly more often in children (n = 41/162, 25.3%) than adults (n = 35/453, 7.7%, $p = 0.000$) and elderly (n = 9/192, 4.7%, $p = 0.000$). The difference between adults and the elderly was not significant.

Abutment Loss and Removal

A total of 75 (9.3%) abutments were nonelectively lost or electively removed (on an outpatient basis), with a mean time until loss of 3.1 years (median, 2.4 years; SD, 2.4 years). Abutment loss occurred more often after the LIT-TR (n = 39,) than after the LIT-TP (n = 27). Twenty-three abutments were lost in children, 37 were lost in adults, and 15 were lost in the elderly. Of the 71 implants in ID patients, 10 abutments (14.1%) were lost or removed, and removal or loss because of chronic or recurrent skin problems was the most frequent reason (n = 6).

Elective removal because of nonuse (n = 35) was the most frequent type of abutment loss in all age groups. The second most common cause in adults and the elderly was elective removal because of pain (n = 10). In children, a spontaneous nonelective loss was the second most common cause (n = 10). Other types of loss included trauma or removal because of chronic or recurrent skin problems.

Bone Conduction Device Usage

In total, 592 implants (73.4%; children 74.7%; adults 72.6%; elderly 74.0%; ID patients 67.6%) were used, of which at least 388 daily and 370 the entire day (≥12 hours). Mean BCD usage was 6.8 (SD ± 0.8) days a week and 15.0 (SD ± 3.1) hours daily. Eighty-three implants (10.3%) were used selectively, 126 (15.6%) were not used at all, and for 89 implants (11.0%), BCD usage was unknown. Reasons for selective or nonuse varied widely, e.g., inconvenience of wearing a BCD or of the (mechanical) sound, chronic pain or recurrent skin problems around the abutment, no need for a BCD anymore, or usage of other hearing aids.

TABLE 4. *Implant loss per loading time group (cases with unknown loading times were excluded)*

	Loading Time (Wk)			
	3–5	6–8	9–11	≥12
No. cases **(% of total cases)**	501 **(62.1)**	148 **(18.3)**	42 **(5.2)**	95 **(11.8)**
No. nonelective implant extrusions				
Within 1 yr	9 (5 × S, 2 × SP, 1 × I, 1 × T)	0	3 (2 × S, 1 × U)	1 (U)
1–2 yr	2 (1 × S, 1 × SP)	0	0	1 (SP)
After 2 yr	9 (5 × SP, 3 × T, 1 × U)	4 (1 × S, 3 × T)	4 (2 × S, 2 × T)	2 (1 × S, 1 × SP)
No. elective implant removals				
Within 1 yr	3 (P)	0	0	0
1–2 yr	0	1 (P)	0	0
After 2 yr	3 (P)	2 (1 × P, 1 × I)	1 (P)	1 (P)
Total no. lost implants **(% of implants in loading time group)**	26 **(5.2)**	7 **(4.7)**	8 **(19.0)**	5 **(5.3)**

The bold text indicates the percentage of cases from, or within, a loading time group.
Causes of nonelective implant extrusions: I indicates infection; S, spontaneous loss; SP, spontaneous loss after a period of pain; T, trauma; U, unknown.
Causes of elective implant removals: I indicates infection; P, pain.

DISCUSSION

Principal Findings

With more than 800 implants examined, the present study is the most extensive wide-diameter BAHI-study with the longest follow-up time reported. Overall, of 5,188 observations collected for the 807 implants with a mean follow-up period of 3.8 years, soft tissue around the abutment demonstrated no adverse reaction in 90.9% of the observations. Children and ID patients were most susceptible to *adverse* soft tissue reactions. Of 807 implants, 6.2% were lost, and 4.7% without elective removals. Significantly more implants were lost in ID patients (14.1%). Comorbidities or loading times did not influence implant survival significantly. Furthermore, children showed similar implant survival compared with adults and the elderly.

Comparison with Other Studies

Dun (16) and den Besten (20) et al. retrospectively analyzed a consecutive series of more than 1,000 and 669, respectively, previous generation implants, emphasizing adverse events and potential risk factors. After that, Calon et al. (14) analyzed implant survival for BAHI surgery, including risk factors, for 550 implants, of which 180 were wide-diameter implants. The main foci of the current study were soft tissue reactions, soft tissue revision surgeries, and implant survival. In most of our observations (90.9%), no adverse soft tissue reactions were present (Table 3A). These results are consistent with other studies reporting 71.9% to 99.9% of BAHI implants result in no adverse soft tissue reactions (12,16,17,20). The difference in adverse soft-tissue reaction between the earlier assessed >1,000 implants and the current study (4.6% vs. 8.1%) is possibly due to shorter mean follow-up (4.6 vs. 3.8 years) and the higher proportion of implantations in children (12.8 vs. 20.1%) and ID patients (4.1 vs. 8.8%) in the current study. However, although more soft tissue problems occurred in children, they did not significantly increase soft tissue revision surgery rates (9.3%). Interestingly, revision surgeries in children were significantly more frequently needed after the LIT-TR than after the LIT-TP. The overall revision surgery rate of 5.3% for soft tissue problems was slightly lower than the 7.8% to 7.0% reported by Dun (16) (87% LIT-TR) and den Besten et al. (20), but far lower than other literature (≤44.4%) (17,19). The availability of longer (>6 mm) abutments after introducing the presumably more stable wide-diameter implant can explain this decreased rate. In the event of recurrent skin problems, a longer abutment can easily be placed on an outpatient basis instead of performing a skin reduction in the operating room.

A 6.2% implant loss was observed in the overall group, consistent with previous literature on wide-diameter implants, including recent long-term findings of 58 wide-diameter implants (1.7–10%) (9,12,13,15,21). This also accounts for the implant loss of 8.0% noted for children in this evaluation. It cannot be overlooked that this percentage is far lower than implant loss in children reported in the literature on previous generation implants (17%, including the 15.2% from Dun et al.) (35). This means that since the use of wide-diameter implants in our center implant survival in children is no longer significantly worse than in adults (8.0% vs. 6.2%, $p = 0.444$), meaning pediatric age no longer seems to be a risk factor for implant loss. A total of 133 sleeper implants were placed, predominantly in children (n = 132). Only 10 sleepers (7.5%) were used after failure of the primary implant. This minimal usage rate, coupled with the reduced implant loss in children, prompts reflection for future sleeper placement, particularly at this time when efforts are being made to reduce health care expenses.

Another group known to have lower implant survival was the first MIPS trial group, with an implant loss rate of 16%. This high rate was found to result from insufficient cooling during drilling, as previously described by Caspers et al. (24) All other implant techniques had similar implant survival rates (0.0–6.7%), as described in our previous BAHI literature (32,36). Lastly, a remarkably high loss rate was found for reimplantations, including used sleeper implants, which was significantly higher than for primary implants. It will be a challenge to identify the common risk factor for loss in this group because of the small numbers, and therefore further and more in-depth research is needed.

Another issue that requires further investigation is the rate of nonuse of implants (15.6%). Such an evaluation will be very extensive, involving the subdivision of nonuse into different patient groups (e.g., based on age, BAHI indications, and severity of hearing loss) and comparisons with other types of hearing aids, such as conventional and CROS hearing aids, and is therefore too extensive for this article. We would therefore like to explore this topic further in a future article.

Limitations

The current study has several strengths. First of all, the size and duration of follow-up of the analyzed patient group are unique and allowed us to identify variable subgroups and compare outcomes of BAHI surgery, implant types, and usage across different patient groups. Moreover, as all patients implanted with a wide-diameter implant until 2020 were included in this study, any selection bias could not have occurred. Clinical outcomes were comparable to what was seen in previous reports.

The study used a retrospective design to gather information and identify potential risk factors in such a large group. This design has some inherent limitations. Nevertheless, this design relies on proper clinical documentation and an appropriate follow-up. The follow-up protocol in our center follows strict guidelines and documentation; postoperative visits are scheduled for 1 week, 3 weeks, and then annually. At all visits, a Holgers and—since its introduction in 2017 (34)—an IPS score and BCD use are recorded, ensuring appropriate follow-up.

CONCLUSION

This paper presents the clinical outcomes of wide-diameter BAHI surgery in more than 800 implants, with a maximum follow-up of almost 12 years. The linear incision technique with tissue preservation (LIT-TP) was mainly

used in the most recent 5 years of this follow-up period and demonstrated excellent outcomes. Complications following percutaneous BAHI surgery are rare (5.3%), mild, and easy to treat. In 90.9% of cases, there were no adverse soft tissue reactions. Children and ID patients are still most susceptible to *adverse* soft tissue reactions (14.3% vs. 7.0% of the adults/elderly without ID). An overall lower implant loss of 6.2% was found when carefully compared with the 8.3% in the earlier assessment of >1,000 previous generation small diameter implants, with ID patients as most prone. Interestingly, pediatric age no longer seems to be a risk factor for implant loss. Children show comparable outcomes to adults, resulting in improved implant survival rates since the introduction of the wide-diameter implant.

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