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OTOLOGY

Predisposing factors for adverse skin reactions with percutaneous bone anchored hearing devices implanted with skin reduction techniques

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Abstract We present an analysis of adverse events after implantation of bone anchored hearing device in our patient population with focus on individual risk factors for peri-implant skin reactions. The investigation involved a chart review of adult Baha patients ($n = 179$) with 203 Bahas implanted with skin reduction techniques between 1993 and 2009, a questionnaire ($n = 97$) and a free clinical examination ($n = 47$). Skin reactions were graded by severity from 0 (no skin reaction) to 4 (implant loss resulting from infection) according to Holgers. We analyzed the skin reaction rate (SRR) defined as the number of skin reactions per year and the worst Holgers grade (WHG), which indicates the grade of the worst skin reaction per implant. We defined 20 parameters including the demographic characteristics, surgery details, subjective benefits, handling and individual factors. The most frequent adverse events (85 %) were skin reactions. The average SRR was 0.426 per Baha year. Six parameters showed an association with the SRR or the WHG. The clinically most relevant factors are an elevated Body Mass Index (BMI, $p = 0.02$) and darker skin type ($p = 0.03$). The SRR increased with the distance between the tragus and the implant ($p = 0.02$). Regarding the identified risk factors, the SRR might be reduced by selecting a location for the implant near the pinna and by specific counseling regarding post-operative care for patients with darker skin type or an elevated Body Mass Index (BMI). Few of the factors analyzed were found to influence the SRR and WHG. Since most adverse skin reactions could be treated easily with local therapy, our results suggest that in adult patients, individual risk factors for skin reactions are not a contraindication for Baha implantation. Thus, patients can be selected purely on audiological criteria.

Keywords Implants · Otology · Skin reactions · Risk factors

Introduction

Bone anchored hearing devices are an established treatment for conductive, mixed and unilateral sensorineural hearing loss [1–7]. The reported failure rate is 0.6–12 % [8–13].

The key points for successful implantation are stable osseo-integration and a reaction-free skin-implant interface. These requirements are achieved with minimal traumatic surgery and meticulous reduction of the soft tissue surrounding the implant. The resulting thin, hairless skin, which is firmly attached to the periosteum with minimal mobility and maximal stability, mimics the biological condition found at the interface between the skin and finger nails [14]. Successful implantation was also reported when using a linear incision and longer and/or

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coated abutments without soft tissue reduction [15]. The loss of the barrier function caused by a percutaneous implant could cause a peri-implant skin reaction. Skin problems are the most frequent adverse events after Baha implantation [9, 16–19]. This factor might influence the long-term success of Baha implants.

In this study, we analyzed the complications of our adult Baha population. Our approach focused on the clinical observation and resulting skin reactions, which we report in terms of skin reaction rate (SRR) per implant year and worst Holgers grade (WHG) per implant. SRR and WHG may be important for counseling the patients about infectious risks of a percutaneous implant. Our work was devised to determine the patient group at risk for increased peri-implant skin morbidity.

Materials and methods

Subjects

We screened the records of the patients who underwent Baha implantation at our institutions between 1993 and 2009. We included all patients aged 16 or older at the beginning of the study, with a minimal follow-up time of three months. All patients considered had the same conical shaped abutment. Only the length varied, i.e., short 5.5 mm; long 8.5 mm. A short abutment was always used in the first implantation. If needed due to skin overgrowth, the initial 5.5 mm abutment was exchanged to 8.5 mm. The patients with abutments of the latest percutaneous generations from Cochlear or Oticon Medical with other shapes or hydroxyapatite coating were omitted because of the relatively low numbers implanted at the time of the data acquisition. The study was approved by the local ethics committee.

We included 179 patients, of which 24 had bilateral implants (203 implants, 107 right, 96 left). The mean age at implantation was 47.4 years (SD 19.7; range 5–83), and the mean age at the analysis was 53.4 (SD 18.8 years; range 16.0–88.6). The mean follow-up time was 6 years (SD 4 years; range 3 months to 16 years). The patients suffered from pure conductive hearing loss, combined hearing loss or single sided deafness [20]. After surgery and initial processor fitting the patients were instructed to contact the outpatient clinic whenever they experience technical or medical problems with the Baha.

Study design

We classified the severity of the adverse skin reactions using the Holgers grading system [12], where 0 is no irritation, 1 is slight redness (local therapy), 2 is red and slightly moist tissue (local therapy and extra control), 3 is reddish and moist with sometimes granulation tissue (revision surgery), and 4 is implant loss due to infection. Skin reactions needing surgical intervention (Holgers 3 and 4) are referred to as high grade skin reactions.

For the statistical analysis, we defined the SRR as the number of adverse skin reactions per year of implant use and the WHG as the worst grade of skin reaction observed for each implant.

The study design and parameters that we investigated are shown in Fig. 1. The data were acquired from patient records ($n = 179$), additional questionnaires ($n = 97$) and clinical examinations ($n = 47$).

As different data sources might induce a bias, we compared whether our main variables SRR and WHG differed between the three hospital sources. We applied the Kruksal–Wallis Test and Dunn's Multiple Comparison Test because of non-Gaussian data distribution and did not find significant differences.

Chart review

From the patient records we collected demographic data, surgical details and adverse events (particularly SRR and WHG) (cf. Fig. 1 for details).

Regarding surgery, the following skin flap techniques were used: a circular island flap, a superiorly based u-shaped flap and a split thickness skin flap achieved with a dermatome. The set of two-stage surgical procedure cases includes the patients who were implanted at the beginning of our Baha program or patients who received the Baha during a middle ear revision surgery as a fallback solution. The data comprised patients with the first generation of implants, which have a bayonet coupling mechanism, as well as the patients with the current snap coupling mechanism and the patients in whom the bayonet coupling abutment was replaced by a snap coupling abutment.

Questionnaire

The questionnaire in German or French was sent to all patients included in the chart review. The response rate was 54 % (97/179). The questionnaire contained items concerning the benefit from the implant, the handling, and patient-related factors (Fig. 1). The subjective hearing benefit and the overall satisfaction were assessed with a Visual Analog Scale (VAS) from 1 (very bad) to 10 (very good).

For the self-evaluation of the skin type (type I: very fair hair/skin and blue/green eyes, type VI: black hair/skin, dark eyes), we used the standardized portrait photographs of the Swiss Cancer League and the hand photographs of the Cancer Research United Kingdom (with permission).

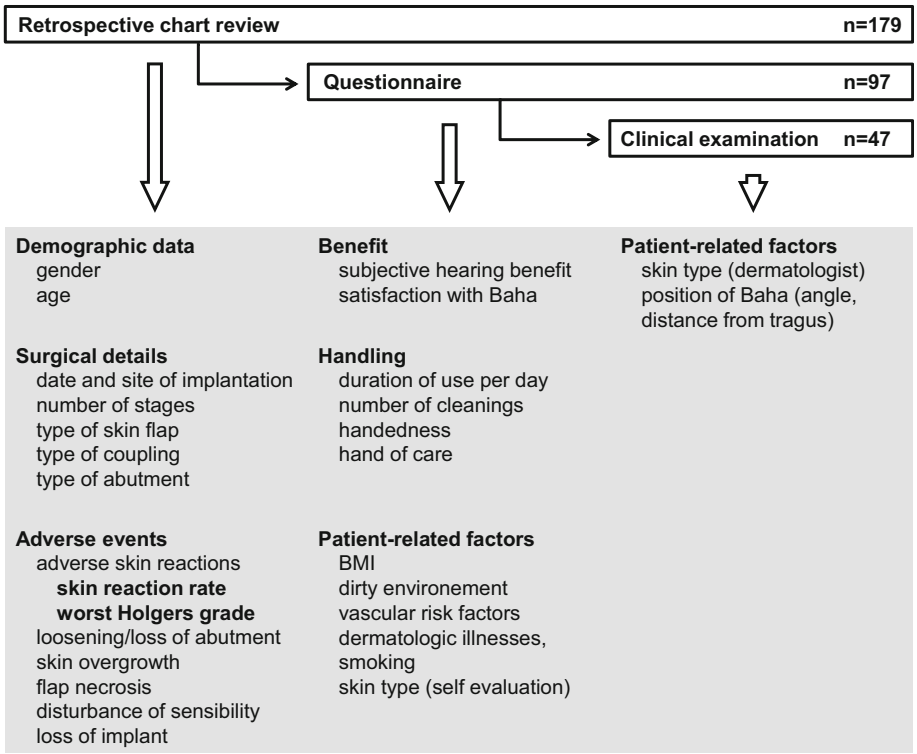

Fig. 1 Study design and parameters analyzed. Main outcome factors used in the statistical analysis

Individual risk factors for skin reactions with low prevalence were not used for further analysis (e.g., immunosuppression, chemotherapy, radiotherapy, allergies, psoriasis, acne).

Clinical examination

A clinical examination was offered to all included in the chart review. The response rate was 24 % (47/197), of which all responded to the questionnaire. The skin type, skin diseases and the localization of the implant were recorded.

Data analysis

For the data analysis we first classified the parameters between patient related factors (e.g., gender age, skin type, as skin type or body mass index) and implant related factors (e.g., abutment type, surgical technique). For implant related parameters we analyzed the entire data set including left and right implants in bilateral cases. For patient related parameters we used only one ear for the analysis. In the bilateral patients, we randomly selected only one implant for bilateral implanted patients because we found no significant differences between the left and right implants for skin reactions.

Statistical analysis of SRR: SRR are ordinal, but not Gaussian distributed data. For two parameters we used the Wilcoxon/Kruskal–Wallis test e.g. handedness (left/right) or negative binominal regression.

Statistical analysis of the WHG was mainly based on the Chi Square test and its derivatives. WHG is categorical data with can be sorted by severity. Cochran Armitage was used to test linear raise for the WHG against categorical data with two parameters, such as Smoking (yes/no). Mantel-Haenszel Chi Square test was used in case of categorical data with more than two parameters, which can be sorted (e.g. skin type I/II/III/IV/V/VI).

We used SAS Version 9.2, (SAS Institute, Inc., Cary, NC, USA) statistical software. We did not apply a Bonferroni correction because the explorative statistics included more than 20 parameters. We regarded the p values between 0.01 and 0.05 as trends.

Results

A descriptive analysis of the recorded adverse events is listed in Table 1. Because 84 % of the adverse events were adverse skin reactions ($N = 402$), we focused on these complications in the following sections. We found sole skin overgrowth in two patients, which consequently were not graded Holgers 3 (Table 1). During follow up consultation by our institution's acoustician specialized in Baha fitting, the abutment screw is routinely controlled with a torque wrench. This explains, why the second most

Table 1 Type and frequency of adverse events after Baha implantation

Adverse events	*n*	Percent (%)	Average rate (per year) Mean ± SD	Max. rate (per year)
Skin overgrowth[a]	2	0.4	0.0009 ± 0.009	0.104
Flap necrosis	2	0.4	0.0005 ± 0.007	0.102
Loosening of abutment	60	12.7	0.008 ± 0.021	0.124
Loss of implant[b]	1	0.2	0.0008 ± 0.011	0.154
Disturbance of sensibility	7	1.5	Persistent[c]	Persistent[c]
Adverse skin reactions[d]	401	84.8	0.426 ± 0.576	3.90
Total	473	100		

[a] Pure skin overgrowth without any secretion or granulation tissue

[b] Not due to infection

[c] Calculation of rate not meaningful

[d] According to Holgers

frequent adverse event in our series was loosening of the abutments ($n = 60$), which was reported in 40 patients. Table 2 shows the statistical analyses of adverse skin reactions.

Adverse skin reactions

Within the analysis period, 30.5 % of the patients did not experience any skin reactions. The average skin reaction rate (SRR) was 0.426 (SD 0.576; range 0–3.899), based on 401 documented adverse skin reactions in 124 patients in 1220 Baha years. The grades of the skin reactions and the proportions of the early and late skin reactions are depicted in Fig. 2.

The WHG was Holgers grade 0 in 59 implants (29.2 %), grade 1 in 9 implants (4.4 %), grade 2 in 97 implants (47.7 %) and grade 3 in 38 implants (18.7 %). No grade 4 skin reactions occurred during the analysis period.

Benefit

The subjective hearing benefit from the Baha and the overall satisfaction with Baha were both 7.5 ($n = 97$; SD 2.4) on the VAS.

Patient-related factors

Questions regarding patient related factors were answered in 95 of 97 questionnaires. The proportions of underweight (BMI < 18.5), normal weight (BMI 18.8–25.0), overweight (BMI 25–30) and obesity (BMI > 30) were 2, 45, 40 and 13 %, respectively. More than two-thirds of the patients stated they were exposed to environmental pollution (68/95). The vascular risk factors, subsuming diabetes type 2 ($n = 4$) and/or arterial hypertension ($n = 30$), were present in 35 % (33/95) of the patients. Approximately one-fourth of the Baha patients (26/95) reported a skin pathology, including acne ($n = 3$), psoriasis ($n = 5$) and allergic diseases ($n = 18$). Approximately, one-fifth of the patients (18/95) were smokers.

The distribution of the skin types according to the self-evaluation in the questionnaire ($n = 97$) was as follows: type I, 3 %; type II, 41 %; type III, 44 %; type IV, 11 %; type V, 1 %; and type VI, 0 %.

Clinical examination ($n = 47$) showed, that the mean distance of the Baha implant from the tragus was 60.6 mm (SD 10.8 mm; range 20–79 mm). The mean angle between the line from the implant to the tragus and the horizontal plane passing through the canthus and the tragus was 44.4 degrees (SD 11°; range 0°–69°).

Statistical analysis

The statistical analysis of the two main factors (the SRR and WHG) is shown in Table 2.

The use of a dermatome for the elevation of the skin flap correlated to a lower SRR when all the grades ($p = 0.0191$) were included. The type of Baha coupling significantly correlated to the SRR for all the grades ($p < 0.0001$) and to high-grade skin reactions ($p = 0.0021$). There were significantly more skin reactions recorded in patients with the newer snap coupling. The patients who needed a change from a shorter abutment (5.5 mm) to a longer abutment (68.5 mm) had a significantly elevated SRR and WHG for all the grades as well as for high-grade skin reactions.

Satisfaction with the Baha and the hearing benefit did not significantly alter the SRR or WHG; however, we found a positive correlation between the hearing benefit and satisfaction with the Baha ($r = 0.897$, SD = 0.051). The duration of daily Baha use, the number of cleanings and the hand used to clean the implant site (hand of care) did not significantly alter the SRR or WHG.

Table 2 Statistical analysis of correlation between multiple potential influencing factors for skin reactions after Baha implantation and skin reaction rate (SRR) or worst Holgers grade (WHG)

Grouping variable	Source	*n* (*n1*/*n2*)	Skin reaction rate (SRR)			Worst Holgers grade (WHG)		
			All grades (1–4)	High grades (3–4)	Statistical test	5 groups (0/1/2/3/4)	3 groups (0/1 + 2/3 + 4)	Statistical test
Gender (m/f)	db	179 (86/93)	0.9847	0.0653	b	0.6045	0.3248	e
Age at implantation	db	179	0.7057	0.7277	b	NA	NA	NA
Age at study	db	179	0.6298	0.3303	b	NA	NA	NA
Nr. of stages (one/two)	db	162 (139/23)	0.0667	0.0603	b	0.1319	0.0515	e
Type of skin flap (dermatome/other)	db	157 (35/122)	0.0191	0.7449	b	0.0536	0.1058	e
Type of skin flap (dermatome/pedicled flap/island flap)	db	157 (35/10/112)	NA	NA	NA	0.4568	0.3627	c
Type of coupling (B or B->S/S)	db	140 (39/101)	<0.0001	0.0021	b	0.4775	0.9245	e
Type of abutment (short/change)	db	159 (146/13)	0.0002	<0.0001	b	0.0002 (0.3319)	<0.0001 (0.3311)	e (f)
Satisfaction with Baha	q	97	0.3659	0.4344	b	NA	NA	NA
Hearing benefit	q	97	0.8135	0.5104	b	NA	NA	NA
Daily use (h)	q	97	0.9305	0.6307	b	NA	NA	NA
Number of cleanings (daily/every 2 days/1–2×/week/1–3/month/less)	q	96 (27/18/31/10/10)	0.9697	0.5415	b	0.7045	0.4579	d
Handedness (right/left)	q	96 (89/7)	0.212	0.8822	a	0.0807	0.915	f
Hand of care (right/left/third person)	q	96 (54/19/23)	0.0535	0.6847	b	0.2256	0.595	c
BMI (continuous)	q	95	0.436	0.0188	b	NA	NA	NA
BMI (under/normal/over/obesity)	q	95 (2/43/38/12)	NA	NA	NA	0.0321	0.0142	d
Dirty environment (no/yes)	q	95 (68/27)	0.6368	0.5296	b	0.2494	0.399	e
Vascular risk factors (no/yes)	q	95 (62/33)	0.1418	0.8933	b	0.335	0.6319	e
Smoking (no/yes)	q	95 (49/46)	0.6872	0.7602	b	0.3334	0.5114	e
Skin type (I/II/III/IV/V/VI)	q	97 (3/40/42/11/1/0)	0.155	0.0301	b	0.2136	0.1674	d
Angle (Tragus-Baha/FHP)	ce	55	0.4713	0.7577	b	NA	NA	NA
Distance from tragus (cm)	ce	55	0.0232	0.0421	b	NA	NA	NA

m male, *f* female, *B* bayonet coupling (first implant generation), *S* snap coupling (state of the art today), *NA* non applicable, *n* total number, *n1*/*n2* distribution per group, *db* database, *q* questionnaire, *ce* clinical examination, *FHP* Frankfurt horizontal plane

Statistical tests: (a) Wilcoxon/Kruskal–Wallis, (b) Neg. binominal, (c) Chi square, (d) Mantel–Haenszel, (e) Cochrane-Armitage, (f) Spearman correlation coefficient

Regarding the position of the Baha, the statistical analysis showed a positive correlation between the distance from the tragus and the SRR ($p = 0.02$), which indicated that more skin reactions were correlated with increasing distance between the implantation site and the outer ear canal. The other parameters that we analyzed did not show a significant effect on the SRR or WHG.

A higher BMI was significantly correlated with a higher SRR for the high-grade skin reactions ($p = 0.0188$) (Fig. 3) and with the WHG ($p = 0.0321$ when comparing all the grades and $p = 0.0142$ when comparing the low vs the high grade skin reactions).

Darker skin types were significantly correlated to an elevated SRR for the high-grade skin reactions ($p = 0.03$) (Fig. 4). Skin pathologies did not significantly alter the SRR or WHG.

The SRR decreased to 0.39 (95 % confidence interval 0.28–0.49) with an increased number of Baha usage years (Fig. 5).

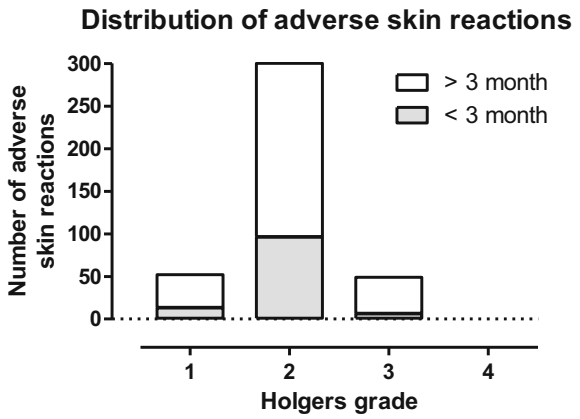

Fig. 2 Distribution of the different grades of skin reactions in the first 3 months after implantation (early *light grey*) and after three months of implantation (late *white*)

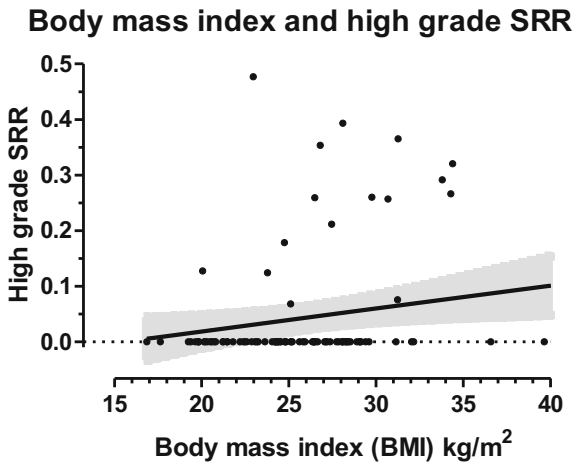

Fig. 3 The correlation of the body mass index (BMI) and the frequency of high-grade skin reactions in Baha ($n = 95$). Higher BMI is associated with higher SRR for high-grade skin reactions. ($p = 0.018$)

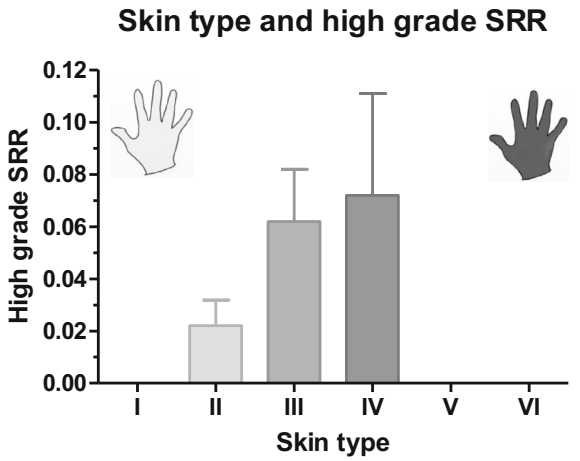

Fig. 4 High grade SRR in different pigmentations of the skin ($n = 97$)

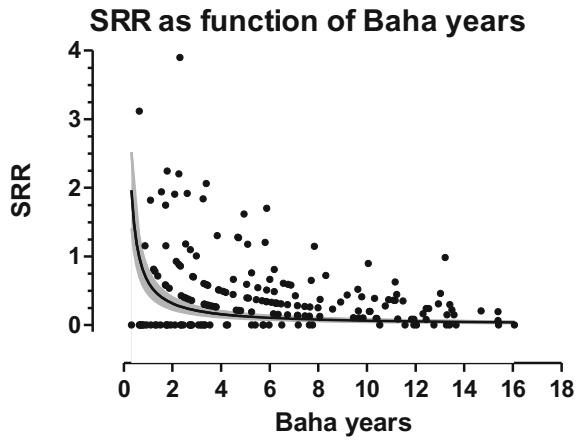

Fig. 5 SRR for each implant as function of the number of years after Baha implantation ($n = 203$)

Discussion

Most of the parameters investigated did not show a significant relation to the SRR or WHG after Baha implantation. However, a darker skin type is associated with a higher SRR for high-grade skin reactions (grade 3 and 4) ($p = 0.03$). It is probable that reactions in dark skin are detected later. Early signs of inflammation, such as redness might be overlooked, and local treatment (disinfection, application of antibiotic ointment) delayed. The reaction propensity of the skin or genetic factors might play a role. A higher keloid formation in black and yellow skin than in white skin has been reported [21].

Another of our findings was the correlation of an elevated body mass index (BMI) with a significantly higher rate of high-grade adverse skin reactions (Fig. 5). Our results are consistent with those of Berenholz [22], who reported BMI to be a risk factor for skin overgrowth. Explanations of the association between the BMI and peri-implant skin reactions should address local, as well as systemic, factors. Local factors include excessive subcutaneous tissue, resulting in a meticulous and complete soft tissue reduction at the implant site being more challenging and causing more tension at the borders of the skin flap. Systemic factors might include differences in the sebaceous and sweat glands and blood supply as well as immunological and hormonal factors that impair wound healing, such as asymptomatic hyperglycemia, hyperinsulinism and hypercortisolism.

We found the SRR to be significantly higher with increasing distance to the tragus. A possible explanation for the elevated SRR could be difficulties in handling and care because of the more posterior position of the implant. Faber et al. [23], in a similar study, found no increase in the SRR with an increased distance to the pinna. Therefore, conclusive explanations can not be reported. Eeg-Olofsson

showed experimentally that bone conduction devices are more efficient if there are shorter distances to the external auditory canal [24]. Based on medical and audiological evidence, the implant should be placed as close as possible to the pinna.

Regarding the surgery-related factors, we confirmed a positive effect from the use of the dermatome for the skin flap ($p = 0.0191$) compared to that of the hand-made flaps, emphasizing the importance of a very thin, uniform hairless flap. The current surgical trend in Baha implantation is a linear incision and less reduction of the subcutaneous tissue [25]. The skin reaction rate was significantly higher in our patients who had a longer abutment because the reason for a change to a longer abutment is predominantly recurrent skin reactions. This finding raises the question of the general use of longer abutments [26], which might be particularly reasonable for patients with an elevated BMI who showed higher SRR. However, only five persons with long abutments returned the questionnaire and, therefore, statistical testing of this hypothesis was not possible in this study.

The patients with implants using the older bayonet nut coupling showed a lower SRR than those with a snap abutment. To our knowledge, the implant material or geometrical design of the skin interface, as well as the surgery, was not different for the two couplings and thus, should not influence the SRR. However, our 39 patients implanted with the older bayonet coupling all have a longer observation time than those with the snap abutment, leading to a generally lower SRR (Fig. 5). Another explanation could be that manipulations, such as exchanges from bayonet to snap abutments provoke a temporary skin reaction, contributing to a higher SRR in the snap abutment group.

Other individual factors that we investigated did not show a correlation with the frequency (SRR) and/or the severity (WHG) of the skin reactions. In contrast to earlier reports, we did not find a correlation between the SRR and age, gender, smoking and vascular risk factors (diabetes and hypertension) [8, 27–30]. There were no associations with the hand that was used for cleaning (left/right/third person) and the exposure of the implant site to dirt and/or dust. These findings indicate that there is no limitation for the use of Baha in different environments regarding skin reactions.

Statistically the number of cleanings does not influence SRR and WHG. Therefore, each patient can determine his/her own cleaning procedure and frequency, rather than adhering to a strict uniform protocol. The overall satisfaction and the duration of Baha use were high and uncorrelated with the SRR and WHG, indicating that adverse skin reactions do not influence the quality of life or the use of the implant.

Our set of parameters was selected based on our knowledge of uncoated Baha devices. Based on a literature review regarding skin reactions with the new implant geometries and coating, we did not find additional risk factors to be studied [27]. But literature data on newer implants also indicate that the number of adverse skin reactions could be reduced further; however, the observation time is shorter and/or the number of implants is lower [27, 31, 32].

Our patients were instructed to present at the outpatient clinic whenever they experience technical or medical problems with the Baha. In other retrospective studies with fixed follow-up schemes the skin reaction score defined as number of skin reactions divided by the number of observations were reported [10, 33]. Individual follow-up potentially result in less observations which would increase the skin reaction score. Therefore, the skin reaction score is not applicable in our study. We decided to calculate the SRR, an indicator for the frequency of the complications known from percutaneous catheters [34]. The advantage of the SRR is that it can be calculated for retrospective studies with fixed and individual follow up schemes.

Conclusion

Most of the analyzed factors did not show a correlation with the frequency and the grade of adverse skin reactions. We suggest that in adult patients, there is no contraindication for Baha because of individual risk factors of skin reactions and that patients can be selected purely on the audiological criteria.

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Compliance with ethical standards

Conflict of interest None.

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