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OTOLOGY

Stapes surgery leads to significant improvement in quality of life, independently from the surgical method: evaluation of stapes surgery using different prostheses and different quality of life measurements

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Abstract

Objectives To compare quality-of-life (QoL) measurements with audiological results after stapes surgery with two different prostheses.

Methods This is a retrospective longitudinal study. All patients required stapes surgery for otosclerosis and ossicular chain reconstruction with either a titanium band prothesis (TBP) or receiving a nitinol head prosthesis (NHP). Intervention was between January 2011 and March 2017 patients received stapes-surgery with either TBP ($n = 95$) or NHP ($n = 50$). Audiological measurements at three different time points (preoperatively, early follow up < 3 months, late follow-up > 3 months) were compared and two different QoL-inventories, the Glasgow-Benefit-Inventory (GBI) and the Stapes-Plasty-Outcome-Test-25 (SPOT-25) were investigated postoperatively. The main outcome measures were Pure tone average (PTA) at 0.5, 1, 2, 3 kHz at early and late follow up after stapes surgery were compared and correlated with the subjective benefit on the QoL inventories. The perforation method and the type of surgery were analyzed as potentially influencing factors.

Results All patients showed a significantly reduced air bone gap (ABG 0.5, 1, 2, 3) at the two follow-up visits (visit 2: mean: 13.6 dB, SD 7.7; visit 3: mean: 12.7 dB SD 8.1) compared to preoperative measurements (mean: 28.9 dB, SD 9.9) and subjectively benefitted from stapes surgery (mean GBI score: 21.55; SD 20.60, mean SPOT-25 score: 28.03; SD 18.53). The outcome of the two questionnaires correlated with each other. Neither the hearing-outcome nor the subjective benefit was significantly influenced by the prosthesis, the perforation method or the type of anesthesia.

Conclusions Both prostheses were safe and led to comparable hearing results as well as to subjective benefits in the Health-related-Quality-of-Life (HrQoL). A combination of the two questionnaires is recommendable for postoperative quality control.

Keywords Stapedotomy · Stapes surgery · GBI · SPOT-25

Introduction

Otosclerosis is defined as a bony transformation, caused by alternating phases of bone resorption and formation leading to a fixation of the stapes footplate. Up to four in 1000 individuals in the Caucasian population is affected [1]. The consequence is a conductive hearing loss eventually accompanied by tinnitus. The disease peaks between the age of 15 and 45 and women are affected more frequently than men with a ratio of 2:1. In 70–80% of the cases both ears are affected [2].

The treatment options are hearing aids or surgery. During surgery, the stapes suprastructure is removed and the oval window is opened, either by perforation with a perforator or a laser. The stapes footplate is removed either partially (stapedotomy) or in total (stapedectomy) and a prosthesis is inserted into the oval window. Then, the oval window is sealed with soft tissue.

Stapedotomy and stapedectomy are considered successful, if an ABG < 10 dB or an average air conduction of less than 30 dB is achieved [3, 4]. The hearing outcome depends

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on multiple factors, for example on a tight fixation of the prosthesis to the malleus handle [5] but also on minimal manipulation forces during surgery [6, 7]. With the aim to avoid trauma to the inner ear while still achieving a sufficient sound transmission via the ossicular chain, the right balance between least necessary manipulation and ideal fixation of the prosthesis is a challenge in both the surgical technique and the prothesis design. Several surgical techniques and a vast variety of prostheses have been introduced to the field addressing this challenge. To reduce intraoperative forces, shape-memory prostheses have been developed [8]. Even though the material is considered safe, disadvantages due to strangulation of the incus or heat-induced mucoperiost-damage are being discussed [9, 10]. Prostheses with a nitinol head using spring characteristics instead of heat induced memory effects have been introduced with the hypothesis of using the material properties of nitinol without disadvantages of heat effects.

Hearing impairment not only leads to a poorer Quality of life (QoL) but was also found to have an influence on the development of dementia and cognitive dysfunction [11]. Since otosclerosis may be a progressive disease but not deleterious, treatment focuses mainly on the improvement of hearing and the related QoL. It has been shown, that the postoperative reduction of the ABG is not the only factor influencing the patient's subjective benefit from surgery and that focusing on the audiological outcome alone may overestimate the surgical success [12-14]. For this reason, nowadays measurements to reflect the patient's perception of their health status have gained importance and became an important indicator of the therapeutic success [15, 16]. Usually, standardized questionnaires investigating everyday-life-situations, difficulties in communication or social contacts and co-symptoms such as tinnitus are used to assess the impairment due to hearing handicap [17, 18]. The Glasgow Benefit Inventory (GBI) has become a reliable tool to monitor the outcome of surgical interventions in Otorhinolaryngology [19]. Lately the Stapes-Plasty-Outcome-Test-25 (SPOT-25) inventory has been developed as a procedure-specific questionnaire for stapes surgery [16]. It is designed to evaluate the outcome of stapes-surgery by pre- and post-surgical measurement. A correlation to the hearing outcome was proved.

Following the recommendations of current reviews [20], it was the aim of this study to evaluate QoL-measurements in daily practice and to compare the long-term hearing results in otosclerosis patients with different prostheses and correlate the audiological results to the patient's subjective benefit from the surgery. Titanium band protheses (TBP) and nitinol head prostheses (NHP) were used and correlated to two different questionnaires for the assessment of QoL (GBI and SPOT-25). With the aim to achieve procedure-specific results the SPOT-25 was used. Both questionnaires were correlated with each other to investigate whether the SPOT-25 can be used as an outcome-measurement in hearing research. In addition, we evaluated whether the perforation-method of the footplate (CO_2-laser-assisted perforation versus perforator) or the type of anesthesia (general versus local anesthesia) affected the hearing-outcome or the subjective benefit from the surgery. This is the first study addressing this subject in a large cohort.

Methods

Patient selection

In this longitudinal study, 151 patients receiving stapesplasty as a primary intervention between 2011 and 2017 were assessed for eligibility. Six patients had to be excluded due to missing postoperative data, leaving 145 patients for further analysis. One group ($n=50$) received a NHP(NitTiFlex, Heinz Kurz GmbH, Dusslingen, Germany) the second group ($n=95$) received a TBP (K-Piston, Heinz Kurz GmbH, Dusslingen, Germany).

Data were recruited from a tertiary hospital, a university medical center. Cognitive disabled patients not able to undergo follow-up audiometry were excluded. The local ethics committee (Registration number: A2017-0022) approved the study. All study participants gave informed consent.

The underlying surgery-indication was determined by conductive or combined hearing loss with negative Rinne's tuning fork test at 512 Hz (c^2) and 1024 Hz (c^3) and normal otoscopic findings.

Surgical procedure

Stapedotomy was performed under local or general anesthesia, depending on the patient's preference. The tympanomeatal flap was lifted by an endaural approach. The incustapedial joint, the stapes tendon and the crura were cut and the stapes-suprastructure was removed. Either a pulsed CO_2-Laser (Lumenis, Sharplan 30C, Yokneam, Israel) or a Fisch-perforator (Storz, Tuttlingen, Germany) was used to perforate the footplate. Either a TBP or a NHP prosthesis was placed into the oval window and the perforation was sealed with fascia.

Questionnaires

The GBI and the SPOT-25 were used to evaluate the postoperative QoL. The GBI is a well-studied and validated outcome instrument that was proved to be maximally sensitive to otosurgical interventions [16, 19]. Responses to the GBI are based on a five-point Likert-scale. Scores range on a

benefit-scale from − 100 (maximal negative effect) to 0 (no effect) to + 100 (maximal positive effect).

The SPOT-25 also refers to a 5-point Likert-scale with subscales concerning hearing function, tinnitus, psychological aspects and social impairment. High scores correlate with a poorer quality of life. A minimal score of 0 (best result), a maximum score of 100 (worst result) can be achieved. It was designed to be used as a follow-up monitoring. In this study, it was used retrospectively only to find out whether there is a statistically significant correlation to the GBI-scores and to prove a possible use as a procedure-specific-outcome-measurement.

Audiological measurements

All measurements were performed with calibrated instruments in a sound-proofed room (DIN EN ISO 8253). Operators were blinded with respect to the type of prosthesis. Measurements included standard pure-tone audiometry (air conduction: 0.25–8 kHz; bone conduction: 0.5–6 kHz), performed with a clinical audiometer (AT1000, Auritec, Hamburg, Germany), performed by audiologically experienced personnel in 5 dB steps.

Air-bone gaps (ABG) were calculated as the difference between the pure tone averages of the air conduction thresholds, measured at 0.5, 1, 2 and 4 kHz (ABG4) and at 0.5, 1, 2, and 3 kHz (ABG3) and the respective average bone conduction thresholds.

Audiometric results directly preoperatively (visit 1) and postoperatively during early (visit 2) and late follow-up (visit 3) were collected.

Statistical analysis

All statistical tests were selected before data collection. Statistical analyses were performed using Prism (version 7, GraphPad Software, La Jolla, CA, USA). The significance level was set to $p < 0.05$.

The assumption of normality in the ABG distributions was tested graphically as well as with the D'Agostino-Pearson normality test. No Gaussian distribution could be found.

The individual ABGs and the bone-conduction threshold at the three different visits were compared with the Friedmann test and the Analysis of Variance (ANOVA) using the within-subject factor "visit" (three levels) and the Wilcoxon test.

Mann–Whitney test was used to compare the prostheses, the perforation methods and the type of anesthesia.

Spearman-test was used to find correlations between the groups. The Kruskal–Wallis test was applied to find differences between the QoL-scores between the subgroups of the audiological outcome.

Results

Audiological data

145 patients, 44 males (30%) and 101 females (70%) with a mean age of 49 years (SD 11.7) with 75 left and 70 right ears were analyzed. 50 patients (34.4%) received a NHP and 95 a TBP (65.6%). Questionnaire-data from 71 patients (49%) for the SPOT-25 and from 72 for the GBI (49.7%) was available. 71 matching pairs of patients resulted that had completed both, the GBI and the SPOT-25. Audiological data at early follow-up were available from 143 patients (98.6%) ($n = 94$ TBP, $n = 49$ NHP) and from 78 patients (53.8%) ($n = 49$ TBP, $n = 29$ NHP) at late follow up (Fig. 1).

The mean bone conduction thresholds remained stable after surgery (mean preoperative BC threshold 26.65 dB, SD 13.99; mean postoperative BC threshold 25.91, SD 13.64; $p = 0.10$). The individual BC shifts of the two different prostheses are shown in Fig. 2a. The mean follow-up period was 5 weeks (SD 3 weeks) at early and 18 months (SD 18 months) at late follow-up.

According to recommendations in hearing reporting standard and to the Committee on Hearing Equilibrium guidelines [21], only the ABG3 is considered relevant for evaluating the results of treating conductive hearing loss. Furthermore, only the ABG3 is referred to as ABG.

All patients showed a significant reduced ABG at both follow up visits (visit 2: mean: 13.6 dB, SD 7.7; visit 3:

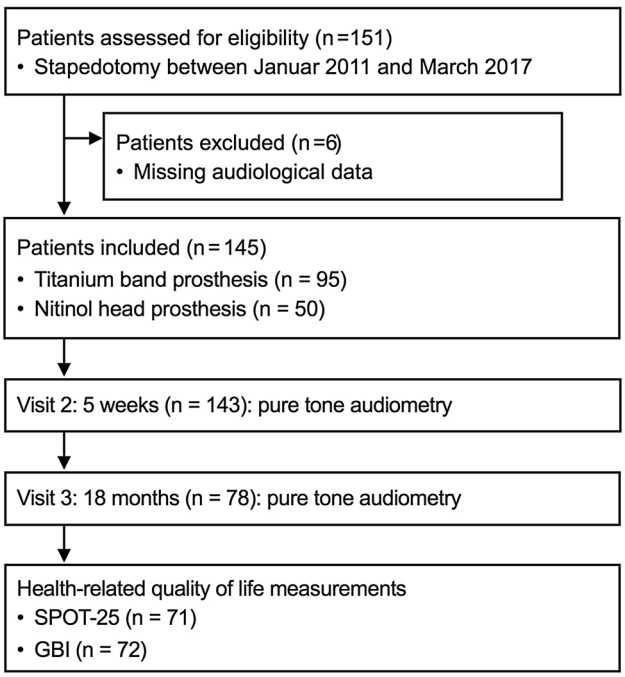

Fig. 1 Study flowchart

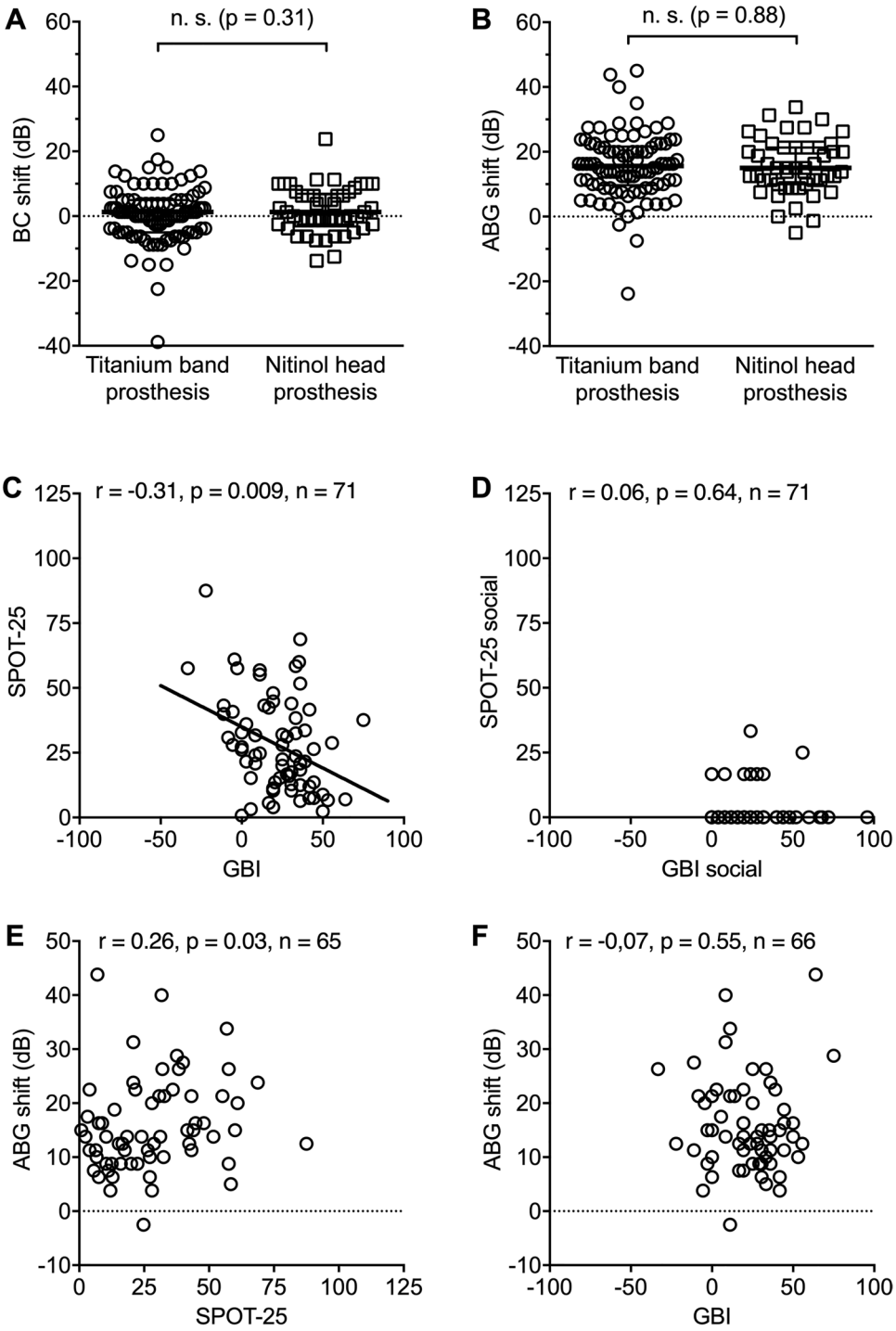

Fig. 2 ABG and score data of the prostheses and the questionnaires. **a** Scatter-plot showing the BC threshold shifts after stapes surgery. No significant differences between the two prostheses between visit 1 and visit 2 were observed ($p=0.31$). Bold line indicates mean, error bars indicate standard deviation. Negative values in BC shifts correspond to an elevation of BC threshold, i.e. a hearing deterioration. **b** Scatter-plot of the ABG-shift between visit 1 and visit 2. No significant difference between the two procedures could be found ($p=0.88$). Positive values in ABC shifts correspond to an reduction of the ABG; *r* Pearson's correlation coefficient; **c**: scatter-plot of the questionnaire-score-results showing a negative correlation between the overall score of the GBI and the SPOT-25 questionnaires ($p=0.009$) $n=71$ data-pairs were analyzed; *r* Pearson's correlation coefficient; **d**: scatter-plot of the social subscores of the SPOT-25 and the GBI showing no correlation ($p=0.55$); $n=71$ data-pairs were analyzed; *r* Pearson's correlation coefficient; **e**: scatter-plot of the showing a significant correlation between the ABG-shift and the postoperative SPOT-25-score ($p=0.03$); $n=65$ data-pairs were analyzed; *r* Pearson's correlation coefficient; **f**: Scatter-plot of showing no correlation between the ABG-shift and the GBI ($p=0.55$); $n=66$ data-pairs were analyzed

mean: 12.7 dB SD 8.1) compared to preoperative measurements (mean: 28.8 dB, SD 9.9) and remained stable at visit 3 (Fig. 3a). The mean postoperative air conduction threshold was 39.5 dB; SD 17.2 at visit 2 and 39.5 dB; SD 18.2 at visit 3. 76 pairs with matching data from all three visits were available for Friedman-test and showed statistically significant changes between all visits. No difference was found between the procedure types (Fig. 2b).

Quality of life

The mean GBI score was 21.55; SD 20.6 (TBP 19.75; SD 24.07, NHP: 23.36; SD 16.58), the mean SPOT-25 score was 28.03; SD 18.53 (TBP 32.15; SD 19.79, NHP: 24.02; SD 16.51). Both questionnaire scores show an average subjective benefit from the surgery. No statistically relevant differences between the prostheses were found.

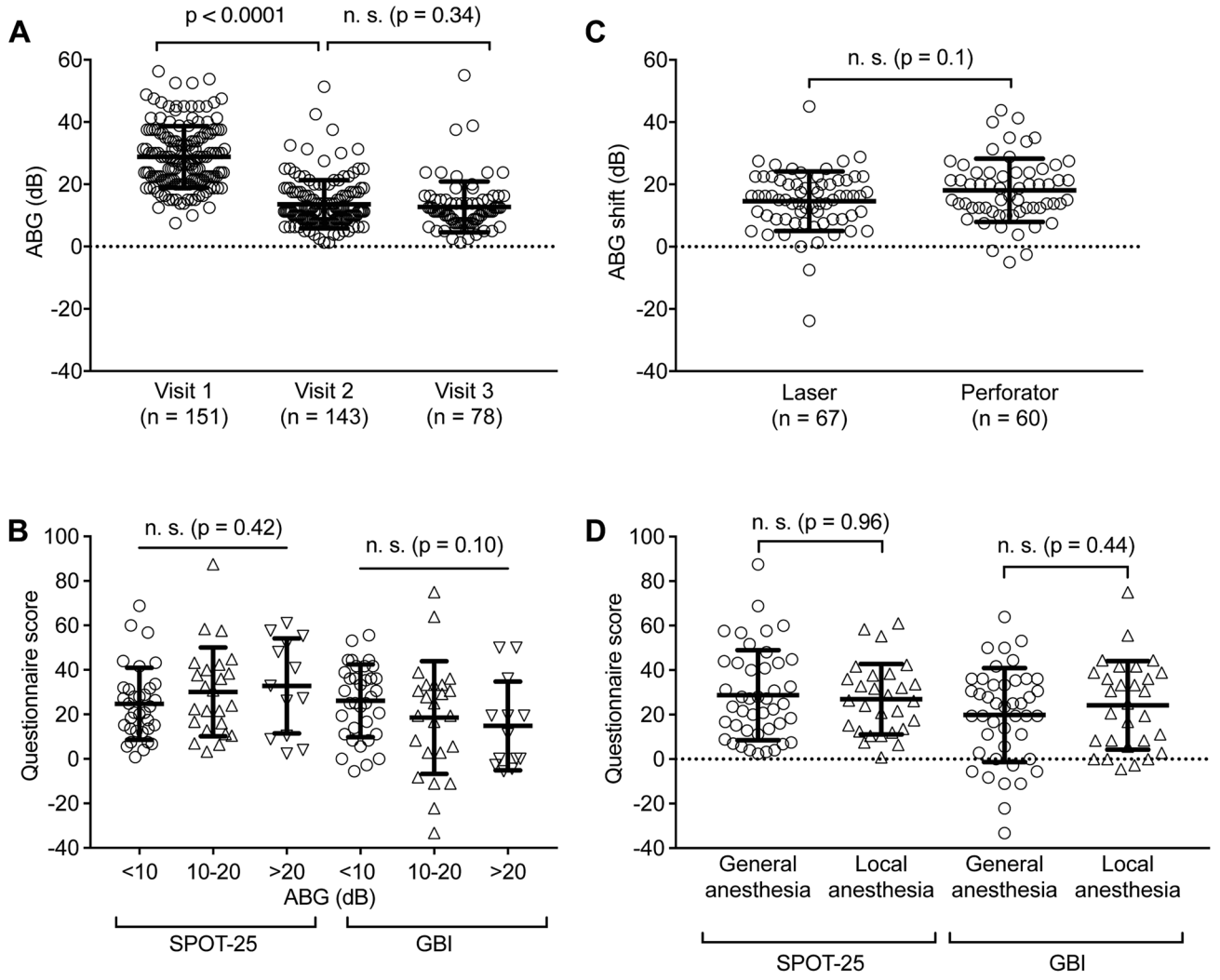

Fig. 3 **a** Scatter-plot showing the individual ABG at the 3 different visits showing a significant improvement between visit 1 and visit 2 ($p < 0.0001$) and stable results between visit 2 and visit 3 ($p = 0.34$); **b**: scatter-plot showing the individual questionnaire scores regarding the subgroups of postoperative ABG (ABG ≤ 10 dB; ABG 10–20 dB; ABG ≥ 20 dB). No significant differences were found among the subgroups for both the SPOT-25 and the GBI; **c**: scatter-plot showing the individual ABG divided into two groups regarding the perforation method ($C0_2$-Laser versus Perforator); no significant difference between the audiological outcome between the groups was observed ($p = 0.1$); **d**: scatter-plots comparing the individual questionnaire scores of the SPOT-25 and the GBI regarding the type of anesthesia (general anesthesia versus local anesthesia); no significant difference between the scores for either group was observed (GBI: $p = 0.44$; SPOT-25: $p = 0.96$)

Overall scores of the two questionnaires showed a significant negative correlation with each other ($r = -0.31$, $p = 0.009$, $n = 71$; Fig. 2c). The subscales of social impairment did not significantly correlate between the questionnaires ($r = 0.06$, $p = 0.64$, $n = 71$; Fig. 2d). A significant correlation between the SPOT-25 and the ABG shift could be found but not for the GBI regarding the complete cohort (Fig. 2e, f). The air conduction threshold did not correlate with the SPOT-25. Regarding only the subgroups of the different prostheses, no difference between the prostheses was found. An additional analysis was performed dividing the audiological outcome in three groups (ABG ≤ 10 dB; ABG 10–20 dB; ABG ≥ 20 dB) according to the recommendations of reporting the hearing outcome for conductive hearing loss [22]. No significant difference of the questionnaire scores among these subgroups was found (Fig. 3b).

In 127 cases, data about the perforation method was available. In 67 cases, the footplate was perforated with the CO2-Laser, in 60 cases with a perforator. Statistical analysis showed no significant influence of the perforation method neither on the audiological outcome (Fig. 3c) nor on the QoL. In $n = 59$ cases, surgery was performed in local anesthesia, in $n = 86$ cases under general anesthesia. No

significant correlation between the type of anesthesia and the two questionnaire scores was found (Fig. 3d).

Discussion

This study analyses the functional and subjective beneficial outcome of stapedotomy with two different kinds of prostheses. In total 145 patients either receiving TBP or NHP were evaluated at two different postoperative visits and with two different quality of life inventories.

Since the only indication for stapes surgery is an improvement of hearing, a focus on the ABG-closure is of main importance for the evaluation of the surgical benefit. Recently published studies have reported various mean improvements with different postoperative ABG, including 10.7 dB (SD 8.4; $n=37$) [23], 2 dB (SD 6 dB, $n=995$) [24], 12.03 dB (SD 10.26 dB; $n=276$) [25], 9 dB (SD 5.5 dB; $n=1688$) [26].

In the present study population, the ABG was improved from a mean of 28.8 dB preoperatively (SD 9.9; $n=151$) to a mean level of 13.6 dB at visit 2 (SD 7.7 dB; $n=143$) and of 12.7 dB at visit 3 (SD 8.1 dB; $n=78$) which is a significant improvement of hearing. Differences to the studies mentioned above can be explained by the small number of patients at late follow up and the heterogeneity of the outcome as shown by the standard deviation.

The development of new prostheses aims to further facilitate and secure the procedure to reduce the patient's risk. Long-term results can be influenced by the biocompatibility of the material, wound healing and the negative impact to the vascularisation of the ossicular chain, particularly the long incus process. Further age, gender, preoperative ABG, the affected side, bilaterality, the perforation method for the footplate, prosthesis diameter and the consistence of the footplate are regarded as influencing parameters [24, 27]. In the present study-population, no difference between the prosthesis-types was found. Neither did the perforation method have an impact (Fig. 2a) on the audiological outcome. Any kind of local reaction to either of the prostheses could not be observed.

Nonetheless, all of the procedures led to a significant improvement of the ABG at short term follow up that continued to improve significantly over a long term follow up period. However, an ABG < 10 dB could be achieved in only 48 patients (34%). 51 patients (36%) achieved an air-conduction threshold below 30 dB. These results do not fit the recommendations for successful surgery where an ABG < 10 dB and a PTA of air-conduction less then 30 dB has to be achieved [3, 4]. It has to be considered, that the mean preoperative bone conduction threshold was already 26.6 dB in this cohort. Many patients with an additional sensorineural hearing loss (combined hearing loss) want to obtain a reduction of the ABG to achieve a higher profit from their conventional hearing aids after surgery. In those cases, the subjective benefit may diverge from the audiological outcome and is not taken into account when only audiological data is used to prove the success of surgery.

Due to the diverse selection of prostheses and the frequent development, the choice of the correct prosthesis can be challenging and depends on multiple preconditions [28]. Especially the crimping of the prosthesis head around the incus is discussed with regard to long term stability. The positive effect of a tight fastening of the prosthesis for better sound transmission [5] has to be weighed against the risk of necrosis to the long incus process [29-31]. Our data confirm the safety and effectiveness of both, NHP and TBP. Both show no statistical difference concerning the audiological outcome, long time stability and the patient's satisfaction.

In the literature, the GBI is rarely used for the investigation of hearing outcome in German-speaking countries. In 2013, it was used in a 34 patient-cohort and showed a post-interventional success [32]. A currently published review recommended the frequent use of this questionnaire to strengthen the knowledge about the currently available QoL measurements and to gain comparable data [20]. The same authors used it in a 37 patient cohort in combination with the SPOT-25, also confirming a correlation to the SPOT-25 but not to the audiological results [23]. However, the current study is the first one describing a high number of participants that is also taking into account other influencing factors such as the type of anesthesia or the perforation method. A limitation of the present study may be that the QoL measures were only applied at the latest follow-up. Yet, this study was designed as a retrospective study also following the aim of investigating, whether a retrospective use of these measurements can be helpful for the categorization of already existing data. The SPOT-25 as a procedure-specific questionnaire was added to the GBI as a well-studied outcome measurement. We aimed to evaluate whether the addition of the both leads to additional information on the procedure specific influences on the patient's quality of life.

A significant correlation between the two questionnaires was observed in the current investigation, confirming the results that the SPOT-25 can be helpful as a disease-specific questionnaire in the retrospective use, as well as in prospective follow-ups, especially when combined with the GBI. The GBI alone did not correlate with the ABG shift or the air conduction threshold confirming, that not only the hearing outcome is of importance to the patient in the procedure of stapes surgery. Since the large majority of patients had subjectively benefitted from surgery as shown by the GBI, we assume, that even small changes in hearing improvement lead to significant improvements in QoL and that psychosocial aspects after surgery are underestimated with focusing

on audiological results only. The questionnaires should be used frequently to obtain reliable outcome controls.

Conclusion

Both prostheses showed stable results with a significant hearing improvement above all visits, assuming that both prostheses are safe. The average of the patients had subjectively benefitted from the surgery and the procedure was appropriate for a significant improvement of the ABG.

Neither the audiological outcome nor the subjective benefit from the surgery were significantly influenced by the prosthesis, the type of anesthesia or the perforation method.

In the present cohort, only the QoL scores of the SPOT-25 but not of the GBI questionnaire correlated with the ABG shift leading to the assumption that a combination of a procedure specific measurement to an outcome measurement is useful. A correlation between the results of the two different questionnaires was observed.

It can be suggested, that a combined use of both questionnaires is beneficial for future assessment of a successful surgical outcome to supplement the statement of audiological results.

Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

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