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ANATOMICAL, FUNCTIONAL, AND QUALITY-OF-LIFE RESULTS FOR MASTOID AND EPITYMPANIC OBLITERATION WITH BIOACTIVE GLASS S53P4: A PROSPECTIVE CLINICAL STUDY

Short title: Mastoid and epitympanic obliteration with bioactive glass

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ABSTRACT

Objective: To analyze the anatomical, functional and quality-of-life results when using bioactive glass in mastoid and epitympanic obliteration.

Design: Prospective clinical study.

Setting: Tertiary referral center.

Participants: Forty-one cases (39 patients) operated between May 2013 and January 2015.

Main outcome measures: Anatomical results were evaluated by otomicroscopy 1 year after surgery and using imaging to detect residual disease. Functional results were studied by post-operative hearing gain. Quality of life was assessed with the Glasgow Benefit Inventory questionnaire and the success of surgery by a surgery-specific questionnaire.

Results: At 1 year, all patients presented a well-healed external auditory canal, with an intact tympanic membrane. In cases with cholesteatoma (n=23), no recurrent retraction pockets or residual disease were observed on imaging studies. The overall air-bone gap closure was 7.7 ± 1.84 dB (mean $\pm$ standard error of the mean, $p < 0.001$, paired t -test). No significant differences were found on hearing results when comparing primary vs revision surgery, canal-wall-up vs canal-wall-down obliterations, type of tympanoplasty, and presence of cholesteatoma (multi-factor ANOVA).

The Glasgow Benefit Inventory improved with an average score of 28 and the success of surgery questionnaire showed a significant improvement in ear discharge and a moderate improvement in hearing and equilibrium.

Conclusions: The use of bioactive glass for mastoid and epitympanic obliteration in canal-wall-down or canal-wall-up tympanoplasties is an effective procedure in both primary and

revision surgery. The anatomical and functional results appear to be well correlated with patient experience and to the improvement in quality of life.

INTRODUCTION

Mastoid and epitympanic obliteration has been proposed for the rehabilitation of a canal-wall-down mastoidectomy to avoid cavity-related drawbacks. Otorrhea, difficulty in fitting a hearing aid when needed, and vertigo or imbalance due to thermal stimulation of the posterior labyrinth are often undesirable outcomes of a canal-wall-down mastoidectomy¹⁻³. Obliteration has also been performed in canal-wall-up mastoidectomy, though less frequently, to reduce the recurrence and residual rate of cholesteatoma in adults and children^{4,5} and to facilitate middle ear aeration⁶ after a closed technique with insufficient post-operative middle ear aeration. In both canal-wall-down and canal-wall-up mastoidectomies, obliteration of the paratympanic spaces reduces the mucosal surface thus slowing gas absorption and pressure changes responsible for recurrence, and improving long-term surgical outcome⁶.

Many materials have been used for obliteration, either autologous (cartilage, bone paté, bone chips, fat, muscular flaps) or biocompatible (bone substitutes, titanium, silicon blocks, hydroxyapatite cement). The bioactive glass S53P4 (BG) is a bone-substitute, silica-based biomaterial composed of a mixture of oxides (53% SiO₂, 23% Na₂O, 20% CaO, and 4% P₂O₅). It is osteoconductive and osteopductive⁷, and has the unique property of being antibacterial to many aerobic, anaerobic and multiresistent bacteria⁸. The inhibition of bacterial growth is probably due to the release of ions at the first stage of implantation that causes elevation of pH and osmotic pressure. BG granules have been used as bone graft substitute in various clinical applications⁹. Beside these interesting properties, which have established the material as a first-line choice when using biocompatible materials in oblitative surgeries, only three reports¹⁰⁻¹² have been published concerning ear surgery, and only one was a prospective study. The safety of the granules of BG with regard to inner ear and skin tolerance has already been published¹³.

The aim of this prospective study was to analyze the anatomical, functional, radiological and quality-of-life results of mastoid and epitympanic obliteration using the BG in primary and revision canal-wall-down and canal-wall-up mastoidectomies.

MATERIALS AND METHODS

Ethical considerations

This study was authorized by the ethical institutional board, and all patients gave their written consent for the use of their personal clinical data. The BG used in this clinical trial was produced by BonAlive[®] Biomaterials Ltd (Turku, Finland) and was approved for clinical use in Europe in 2004 and in the United States in 2007.

Study design

This prospective, observational uncontrolled study was carried out between May 2013 and January 2015 in a tertiary referral center. Inclusion criteria were all the canal-wall-down (primary or revision) surgeries (Fig. 1A) performed in this period with obliteration using granules of BG and canal-wall-up mastoidectomies requiring obliteration for the stabilization of an attic reconstruction after a large atticotomy (Fig. 1B).

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The surgical technique has been described previously¹³. Briefly, in both canal-wall-up and canal-wall-down mastoidectomies, obliteration of the paratympanic spaces, using granules of BG of 0.5–0.8 mm in diameter, followed:

- Removal of the lesions (cholesteatoma and/or inflammatory mucosa);
- Extensive drilling of the cavities until healthy bone was reached with removal of all visible pathologic mucosa;
- Reconstruction of the middle ear (tympanic drum + ossiculoplasty when needed).

All of the BG granules in contact with the skin of the external auditory canal were carefully covered by cartilage and fibrous tissue. The type of tympanoplasty was classified as: Type I (myringoplasty with no ossicular chain reconstruction), type II (partial ossicular replacement

prosthesis used on an intact stapes), type III (total ossicular replacement prosthesis used on an intact footplate), and type IV (platinectomy with fibrous tissue interposition and placement of a total ossicular replacement prosthesis). Titanium prosthesis (Aerial Kurz[®], Tübingen, Germany) of adapted length was used when needed. Intraoperative intravenous antibioprophylaxis with amoxicillin/clavulanate was performed in all patients after having performed intraoperative bacteriological tests on otorrhea, cholesteatoma matrix (if present), mastoid skin (in case of revision canal-wall-down procedure) and middle ear/mastoid mucosa. Oral treatment with amoxicillin/clavulanate was continued until it was adapted to the results of the intraoperative bacteriological test; if there were no pathogenic bacteria, antibiotherapy was stopped. If some pathogenic bacteria were found, the oral antibiotherapy was adapted to the antibiogram and delivered for 14 days following recommendations for chronic otitis¹⁹ and cochlear implant surgeries²⁸ with mastoid obliteration. Ear drops of ofloxacin were administered to all patients for 1 month. Perioperative complications were noted, as well as the presence of cholesteatoma.

Anatomical results were evaluated with otomicroscopy 3 months and 1 year after surgery: the presence of a well-healed external auditory canal with no visible granules of BG and an intact tympanic membrane was considered to indicate a successful procedure. In the case of cholesteatoma, a computed tomography (CT) scan and non-echo-planar diffusion-weighted magnetic resonance imaging (MRI)¹⁴ were also performed 1 year after surgery to detect residual disease in the middle ear and/or in the filled spaces.

Functional results were evaluated using the air-bone gap (ABG) closure, defined as the difference between pre-operative and post-operative ABG. The ABG was calculated as recommended by the committee on hearing and equilibrium using pure-tone audiometry (mean of 500, 1000, 2000, 4000 Hz) in both air-conduction and bone-conduction conditions.

Quality of life was evaluated 1 year after surgery through two questionnaires: the Glasgow Benefit Inventory (GBI)¹⁵, and a surgery-specific questionnaire¹⁶. The GBI measures the changes in health status produced by surgery and it was divided into three subgroups (general, social support and physical health) and the results were reported from –100 to +100 for each subgroup and for the global score with zero being no change as a result of the intervention, –100 maximal deterioration and +100 being maximum quality-of-life improvement.

The surgery-specific questionnaire encompassed four questions:

- 1) Compared with before your ear surgery, how is your ear drainage?
- 2) Compared with before your ear surgery, how is your ear hearing?
- 3) Compared with before your ear surgery, how is your equilibrium?
- 4) Would you recommend this surgery to a family member?

The possible answers for the first three questions were noted using a Likert scale ranging from 1 to 5 (1 = dramatically worse; 2 = somewhat worse; 3 = not changed; 4 = somewhat improved; 5 = dramatically improved). For the last question, possible answers were: 1 = would discourage; 2 = unlikely to recommend; 3 = indifferent; 4 = likely to recommend; 5 = highly recommended.

Statistical analysis

Data were presented as mean $\pm$ standard error of the mean (SEM). Comparison between pre- and post-operative results was done with a paired *t*-test. A multi-factor ANOVA was used to analyze the influence of different tympanoplasty subgroups (type I, II, III and IV), the presence or not of a cholesteatoma, and primary vs revision surgery on ABG closure. Differences in quality of life (GBI scores) between primary and revision surgery were analyzed using the Mann–Whitney *U*-test.

For all comparisons, $p < 0.05$ was considered to indicate a statistically significant difference.

All statistical analyses were performed using IBM SPSS for Windows (v 22.0, SPSS Inc., Chicago, Illinois, USA).

RESULTS

Participants

Forty-one cases (39 patients, two operated bilaterally) were included (Table 1): there were 22 males and 17 females. The mean age was 46 ± 2.5 years (range 16–79 years). There were 25 right side and 16 left side cases. Thirty-six cases (88%) were revision surgeries; the median number of previous surgeries was 2 (range 1–5). Of these 36 revision cases, 26 cases (72%) had already been operated with a canal-wall-down mastoidectomy, whereas 10 (28%) were previously operated with an intact canal wall technique.

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Intraoperative findings

Revision cases (n=36) underwent revision canal-wall-down mastoidectomy in 26 cases (72%), a canal-wall-down mastoidectomy in six cases (17%), and a canal-wall-up mastoidectomy in four cases (11%).

Primary cases (n=5) were operated on with an open technique in three cases (60%) and with a closed technique in two cases (40%). Overall, an open technique was obliterated in 35 cases (85%), whereas a closed technique in six cases (15%). Tympanoplasty type I was performed in five cases (12%), type II in 19 cases (46%), type III in 14 cases (34%), and type IV in 3 cases three cases (8%). Cholesteatoma was found in 23 cases (56%).

Perioperative complications occurred in seven cases (17%). There were six cases (15%) where an opening of the inner ear occurred during surgery: two cases of a pre-operative identified fistula of the lateral semicircular canal, three cases of a fractured/absent stapes footplate who underwent type IV tympanoplasty, and one case of round window membrane opening during dissection of the cholesteatoma invading the sinus tympani and

hypotympanum. In one case (2%), cerebrospinal fluid (CSF) leakage occurred during dissection of the skin over a tegmen tympani defect.

Anatomical results

Three months after surgery, 34 cases (83%) presented a well-healed external auditory canal with an intact tympanic drum (Fig.2); two cases (5%) presented a narrow but functional external auditory canal with an intact tympanic drum. Four ears (10%) presented various degrees of lateralization of the tympanic drum. Only one patient (2%) presented uncovered granules in the external auditory canal and underwent revision surgery 5 months after the first surgery, under local anesthesia, to cover the granules with cartilage. At 1 year, he had a well-healed external auditory canal and tympanic drum.

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At 1 year after surgery, these results were unchanged. No cases of recurrent cholesteatoma and/or retraction pocket were observed. In the post-operative CT (Fig. 3) and MRI studies (n=23), no residual disease was found at 1 year after surgery.

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Functional results

Pre-operative hearing status for each patient is detailed in Table 1. The pre-operative air-conduction and bone-conduction pure-tone averages were 59 ± 3.2 dB and 32 ± 2.7 dB respectively. Patients with opening of the membrane of the round window experienced immediate total ipsilateral hearing loss. Post-operative pure-tone averages (n=40, deaf patient excluded) were 47 ± 3.6 dB and 27 ± 2.8 dB for air and bone conduction, respectively. There

was no statistically significant difference between pre- and post-operative bone conduction threshold (paired *t*-test). The mean ABG closure was 7.7 ± 1.84 dB and the difference was statistically significant ($p < 0.001$, paired *t*-test). Detailed functional results following type of tympanoplasty, primary vs revision surgery, canal-wall-up vs canal-wall-down, and presence vs absence of cholesteatoma are shown in Table 2. No statistically significant differences were found in the ABG closure when comparing the different types of tympanoplasty, primary vs revision surgery, canal-wall-up vs canal-wall-down procedures, and the presence vs absence of cholesteatoma (NS, multi-factor ANOVA).

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Questionnaires

The overall quality of life improved after epitympanic or mastoid obliteration. The overall GBI score was 28 ± 3.6 (range -22 to 78); three patients had a negative score indicating a worsening of the quality of life. No statistically significant differences were found when comparing primary vs revision surgeries (Mann–Whitney *U*-test) (Table 4). Detailed results for each question are shown in Table 3.

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Regarding the surgery-specific questionnaire, the median values of the responses were 5, 4, 4, and 5 for discharge, hearing, equilibrium, and recommendation, respectively, showing a significant improvement in the discharge of the ear felt by the patient. There was also a moderate improvement in hearing and equilibrium and almost all patients highly recommended such an operation. Detailed results are shown in Table 5.

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DISCUSSION

The goals of cholesteatoma surgery are the complete eradication of the disease, preventing a recurrence, and maintaining or restoring hearing. A canal-wall-down procedure is often the results of multiple operations to achieve these objectives, exposing the patient to cavity-related problems.

Mastoid obliteration is used to reduce the recurrence and the residual rate in primary cholesteatoma surgery using both canal-wall-up^{4,5} and canal-wall-down procedures¹⁷⁻¹⁹.

Moreover, obliteration of an unstable mastoid cavity leads to significantly better results for discharge^{1,20,21}, hearing rehabilitation²² and imbalance³ than a revision canal-wall-down procedure²³.

Since 1911²⁴, many materials, either autologous or biocompatible, have been used for obliteration. The disadvantages of using autologous materials are donor-site morbidity and the risk of resorption over time²⁵. Using biocompatible materials, the most feared complication is infection and its subsequent extrusion. This is why the antibacterial activity of BG granules to the most frequent bacteria involved in chronic otitis seemed very attractive to us.

Synopsis of key findings

This study shows that the obliteration of both canal-wall-up and canal-wall-down procedures in primary or revision surgery is an effective technique and the initial results showed no adverse effects.

Regarding anatomical results, no infection of the implanted material has been reported with the necessity for removal of the BG granules. An intact external auditory canal with a well healed tympanic membrane was achieved in most of our patients. Various degrees of lateralization of the tympanic membrane can be expected, especially in multi-operated ears. A narrow external auditory canal was found in 2 cases; this was probably the result of the

bulging of the postero-superior wall of the external auditory canal that is sometimes observed one month after surgery; in such a case an insertion of an expandable sponge packing with eardrops containing corticosteroids for two weeks can help in achieving an appropriate conformation of the external auditory canal.

No recurrence was seen within the study follow-up period (with a maximum follow-up of three years) or residual disease in post-operative imaging studies.

Regarding functional results, an overall improvement in hearing was achieved, even though not spectacular. Considering that most of our cases were revision surgeries, our results are in line with the reported literature^{18,19,25}, and the reconstructed external auditory canal allowed changes in external ear resonance²⁶ and facilitated the use of hearing aids²².

For quality of life, an overall significant improvement was observed in all procedures. The results of the GBI questionnaires are similar to those obtained in other studies^{16,27} with a significant improvement in quality of life and this improvement is similar when considering primary and revision cases. Results for the surgery-specific questionnaire showed a marked improvement in the discharge of the ear, and mild or no improvement in hearing and balance, thus permitting a good correlation between objective and subjective results.

Comparison with other studies

Only three studies have been published which use BG in ear surgery, but none simultaneously report anatomical, functional and quality-of-life results.

In 2010, Stoor et al.¹⁰ retrospectively analyzed seven cases of obliteration of discharging cavities reporting good skin tolerance and no infection of the implanted material. In 2012¹², the same department retrospectively analyzed 25 cases (including the seven cases previously published with longer follow-up) treated over a 15-year period; 92% of patients has a dry

smaller cavity after the operation but no statistical analysis was performed with regard to hearing. Finally, the only prospective study was performed by Silvola¹¹ who reported on 14 patients treated with BG granules between 2007 and 2011 using different surgical techniques; he achieved a dry ear in all patients.

Strengths of the study

To our knowledge, this is the first prospective study on a large cohort of patients treated for mastoid and epitympanic obliteration in a short time with the same surgical technique.

Analyzing both objective and subjective data allows a better comprehension and evaluation of the results, both anatomically and functionally. The quality of life and success of surgery questionnaires are essential when reporting results in chronic ear surgery.

Study limitations

The short 1-year follow-up is the main limitation of the study, especially when considering recurrence/residual results, but this is inevitable when performing a prospective study in a tertiary referral center. For patients with longer follow-up, anatomical results remain stable, but 5-year follow-up is necessary to evaluate the long-term results of the obliteration.

Moreover, the results of questionnaires could be overrated due to patient complacency.

Clinical applicability of the study

Despite its limitations, this study demonstrates that BG is an effective material for mastoid and epitympanic obliteration with no infection in the present series and with anatomical and functional results that are well correlated with the improvement in quality of life.

Conflicts of interest: none declared.

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Fig. 1. An example of a right canal-wall-down (A) and left canal-wall-up (B) mastoidectomy obliterated with granules of bioactive glass (black star). In the canal-wall-down mastoidectomy (A), cartilage (white star) is used to cover the granules in the new external auditory canal filled with resorbable mesh (white arrow). In the canal-wall-up mastoidectomy (B), granules are used to stabilize the attic reconstruction after a large atticotomy (black arrow) after reconstruction of the middle ear with a titanium total ossicular replacement prosthesis (white arrow).

Fig. 2. An example of 1-year otoscopy of a right canal-wall-down (A) and left canal-wall-up (B) mastoidectomy obliterated with granules of bioactive glass. In the canal-wall-down mastoidectomy (A), black dotted lines indicate the reconstruction of the postero-superior canal wall and the black star the cartilage used for the reinforcement of the tympanic drum. In the canal-wall-up mastoidectomy (B), the black arrow indicates the cartilage used to reconstruct a large atticotomy (dotted lines); mastoid and epitympanic obliteration is performed in these cases for the stabilization of the attic reconstruction.

Fig. 3. High resolution CT scan in axial (A) and coronal (B) plane performed one year after surgery showing the complete obliteration of the paratympanic spaces and a well-aerated middle ear with partial ossicular replacement prosthesis in place.

Table 1. Patient demographics, pre-operative physical examination and hearing status, post-operative anatomical and functional results

Patient	Pre-operative				Surgery				One-year results				
	No. of previous surgeries	Open cavity	BC Threshold (dB)	ABG (dB)	Type of surgery	Tympanoplasty type	Cholesteatoma	Complications	Otoscopy	BC Threshold (dB)	ABG (dB)	ABG closure	Global GBI score
1	3	Yes	18.75	27.5	Revision CWD	1	No	No	Well healed	27,5	22.5	5	30.55
2	1	No	18.75	20	CWD	2	Yes	No	Well healed	7,5	17.5	2.5	66.66
3	3	Yes	20	32.5	Revision CWD	1	No	No	Well healed	45	22.5	10	58.33
4	0	No	25	20	CWD	2	Yes	No	Well healed	8,75	22.5	-2.5	33.33
5	2	No	48.75	42.5	CWU	3	Yes	No	Well healed	46,25	23.75	18.75	19.44
6	0	No	22.5	32.5	CWD	3	Yes	No	Well healed	13,75	38.75	-6.25	22.22
7	3	Yes	37.5	31.25	Revision CWD	2	Yes	No	Well healed	45	6.25	25	77.77
8	3	Yes	61.25	21.25	Revision CWD	4	No	Platinectomy	Well healed	38,75	36.25	-15	61.11
9	3	Yes	53.75	16.25	Revision CWD	2	No	No	TD lateralization	52,5	20	-3.75	33.33
10	2	Yes	20	35	Revision CWD	2	Yes	No	Well healed	11,25	18.75	16.25	58.33
11	3	Yes	37.5	27.5	Revision CWD	4	No	Platinectomy	Well healed	28,75	21.25	6.25	19.44
12	3	Yes	30	25	Revision CWD	3	Yes	LSC fistula	Well healed	18,75	23.75	1.25	16.66
13	4	Yes	52.5	30	Revision CWD	4	No	Platinectomy	Well healed	23,75	12.5	17.5	55.55
14	0	No	15	3.75	CWU	2	Yes	No	Well healed	15	6.25	-2.5	25
15	1	Yes	23.75	26.25	Revision CWD	1	No	No	Well healed	6,25	13.75	12.5	2.77
16	1	Yes	22.5	21.25	Revision CWD	2	No	No	Well healed	15	3.75	17.5	47.22
17	5	Yes	16.25	36.25	Revision CWD	2	No	No	Well healed	16,25	23.75	12.5	2.77
18	3	Yes	18.75	26.25	Revision CWD	3	Yes	No	Well healed	8,75	11.25	15	44.44
19	1	No	45	25	CWU	2	Yes	No	Well healed	32,5	20	5	5.55
20	2	Yes	30	15	Revision CWD	3	Yes	No	Well healed	20	10	5	41.66
21	3	No	33.75	13.75	CWU	2	Yes	No	Well healed	13,75	26.25	-12.5	16.66
22	3	Yes	38.75	20	Revision CWD	3	No	No	Narrow EAC	42,5	21.25	-1.25	16.66
23	4	No	15	42.5	CWU	2	Yes	Opening of the RW membrane	Well healed		Anacusis		-19.4
24	2	Yes	11.25	51.25	Revision CWD	2	Yes	No	Well healed	26,25	37.5	13.75	22.22
25	3	Yes	30	43.75	Revision CWD	3	No	No	Narrow EAC	30	20	23.75	27.77
26	3	Yes	16.25	37.5	Revision CWD	3	No	No	TD lateralization	27,5	25	12.5	25
27	2	Yes	21.25	23.75	Revision CWD	3	No	No	Well healed	15	18.75	5	0
28	1	No	8.75	22.5	CWD	2	Yes	No	Well healed	6,25	12.5	10	33.33

29	3	Yes	21.25	41.25	Revision CWD	1	Yes	No	Well healed	17,5	11.25	30	-2.77
30	1	Yes	7.5	16.25	Revision CWD	3	No	No	Well healed	12,5	6.25	10	41.66
31	2	No	27.5	31.25	CWD	3	Yes	No	Well healed	26,25	17.5	13.75	44.44
32	2	No	35	20	CWD	2	Yes	No	Well healed	26,25	10	10	36.11
33	3	Yes	36.25	15	Revision CWD	1	Yes	No	Well healed	35	23.75	-8.75	22.2
34	1	No	62.5	38.75	CWD	3	Yes	LSC fistula	Well healed	57,5	30	8.75	50
35	1	Yes	55	35	Revision CWD	2	No	No	Well healed	38,75	26.25	8.75	2.77
36	1	Yes	58.75	35	Revision CWD	2	No	No	TD lateralization	52,5	16.25	18.75	33.33
37	0	No	31.25	43.75	CWD	2	Yes	No	TD lateralization	31,25	41.25	2.5	25
38	0	No	13.75	12.5	CWU	2	Yes	No	Well healed	5	16.25	-3.75	8.33
39	2	Yes	25	13.75	Revision CWD	3	No	CSF leak	Well healed	27,5	15	-1.25	8.33
40	3	No	87.5	22.5	CWD	2	Yes	No	Well healed	92,5	32.5	-10	50
41	2	Yes	51.25	28.75	Revision CWD	3	No	Uncovered granules at 3 months: revision surgery	Well healed	57,5	23.75	5	-22.2

BC, bone conduction; ABG, air–bone gap; CWU, canal-wall-up; CWD, canal-wall-down; LCS, lateral semicircular canal; RW, round window;

CSF, cerebrospinal fluid; TD, tympanic drum; EAC, external auditory canal; GBI, Glasgow Benefit Inventory.

Table 2. Detailed functional results according to the type of surgery (n=40, deaf patient excluded)

Type of surgery	Pre-operative ABG	Post-operative ABG	ABG closure	N	Multi-factor ANOVA
Primary	22.5±7	25±7	-2.5±5	5	F=2.61, p=0.11
Revision	28±2	19±1	9±2	35	
CWU	20±7	18.5±3	1.5±5	6	F=0.51 p=0.47
CWD	28±2	20±1	8±2	34	
Type1	28±4	19±3	10±6	5	F=1.11, p=0.36
Type2	26±3	20±2	6±2	18	
Type 3	28±3	20±2	8±2	14	
Type 4	27±3	24±7	3±10	3	
Cholesteatoma yes	26±3	21±2	5±2	22	F=0.2 p=0.81
Cholesteatoma no	27±2	19±2	8±2	18	

Data are expressed in dB as mean ± SEM. CWU, canal-wall-up; CWD, canal-wall-down;

ABG=air-bone gap.

Table 3. Glasgow Benefit Inventory (GBI) summary of results

Question	Median	Interquartile range	Number of respondents per answer				
			5	4	3	2	1
1. Effect on life	4	2	17	7	16	1	0
2. Overall effect on life	4	1	20	12	7	2	0
3. Optimism about the future	4	1	5	23	12	1	0
4. Embarrassment	4	1	5	16	18	2	0
5. Self-confidence	3	1	3	16	19	3	0
6. Dealing with company	3	1	6	13	19	3	0
7. Support from friend	3	1	4	8	28	1	0
8. Visit to GP	4	1	4	17	18	2	0
9. Job opportunities	3	1	4	9	25	3	0
10. Self-consciousness	3	0	1	8	28	4	0
11. People who care	3	0	0	4	33	2	2
12. Frequency of illness	3	1	5	13	19	3	1
13. Frequency of medication	4	1	9	14	16	2	0
14. Self-opinion	4	0	8	26	6	1	0
15. Family support	3	1	4	12	24	1	0
16. Inconvenience	4	2	11	17	10	3	0
17. Social activities	3	1	3	11	23	4	0
18. Social situations	3	1	2	11	24	4	0

GP, general practitioner.

Table 4. Glasgow Benefit Inventory (GBI) subscale results by type of surgery

	Entire cohort (n=41)	Primary surgery (n=5)	Revision surgery (n=36)	Mann–Whitney <i>U</i> -test
Overall	28	23	28	NS
General	31	27	32	NS
Physical	29	13	31	NS
Social	13	17	12	NS

Data are presented as mean values.

Table 5. Results of success of surgery questionnaire

Question	Median	Interquartile range	Number of respondents per answer				
			5	4	3	2	1
Improved drainage	5	0	34	2	4	1	0
Improved hearing	4	2	14	12	7	6	2
Improved equilibrium	4	1	9	13	17	2	0
Recommendation	5	1	27	12	2	0	0

Possible answers for the first three questions were 1 = dramatically worse; 2 = somewhat worse; 3 = not changed; 4 = somewhat improved; 5 = dramatically improved. For the last question, possible answers were: 1 = would discourage; 2 = unlikely to recommend; 3 = indifferent; 4 = likely to recommend; 5 = highly recommended.