Direct comparison of mastoidal and retrosigmoidal placement of a transcutaneous bone conduction device after canal wall down tympanoplasty

1 | INTRODUCTION

Cholesteatoma and chronic otitis media are common and regularly treated in surgical otology centres. Repeated surgeries are often required in order to eliminate residual disease and reconstruct functional hearing. Frequently, the posterior wall of the auditory canal has to be resected resulting in a canal wall down (CWD) technique with variable hearing outcome. Subsequently, strategies such as incus interposition and alloplastic middle ear prostheses are regularly used for air conduction restoration. However, results are often unsatisfactory due to recurrence of disease, prosthesis extrusion or insufficient air conduction capability of the utilised materials. Even with the support of conventional hearing aids, hearing rehabilitation may be limited resulting in a reduction of quality of life. For these patients, bone anchored active implants might be a viable option to restore hearing if bone conduction hearing values are no higher than 45 dB in the affected ear. Percutaneous bone anchored hearing aids (BAHA) and transcutaneous bone conduction implants (BCI) offer surgeons the possibility to improve functional hearing. While the BAHA has been in clinical use for decades, the BCI has only recently been added to the surgeon’s repertoire. The BCI consists of an implantable electromagnetic floating mass transducer (BC-FMT), which is fixated to the bony structures of the skull with two self-tapping screws. To ensure stability and safety, the BC-FMT can be supported by screw fixation lifts, which enable the BC-FMT to be fitted snugly and securely into a previously drilled boney excavation. The BC-FMT has a height of 8.7 mm and a diameter of 15.8 mm. These measures imply that the surgeon would need enough space within the boney surgical field to secure the BC-FMT. In selected cases, the BCI may also be placed retrosigmoidally (Figure 1). To date, the majority of implants have been implanted into the mastoid (Figure 2).

To the best of our knowledge, no studies have directly compared the hearing outcomes of both of these placement options in cases of canal wall down tympanoplasties at the time of performing this study. It is not yet clear whether the decreased amount of boney mastoid, which implies less bone to conduct the vibratory stimulation of the BC-FMT towards the inner ear, impacts the post-operative outcome. Therefore, the aim of this study was to (a) compare the audiological benefit, as well as to (b) evaluate surgical
outcome between the different surgical approaches after canal wall down surgery.

2 | MATERIALS AND METHODS

2.1 | Ethical considerations

Due to the retrospective nature, an anonymous analyses, the authors had no ethical concerns in performing this study. All patients were intensively counselled and gave informed consent before treatment. The study had no influence on patient treatment or follow-up. The study was submitted to the local review board for approval.

2.2 | Patients and surgical indication

We performed a retrospective chart review of a total of 20 cases, which had been treated with a BCI at the Vienna General Hospital and the Rudolfstiftung Hospital Vienna (teaching hospitals of the Medical University of Vienna) between 2016 and 2017. All patients had a history of multiple surgeries and presented after canal wall down tympanoplasties, where conventional middle ear reconstruction had been unsuccessful, insufficient or impossible. All patients had undergone a preoperative computed tomography of the temporal bone to assist in surgical site selection and preoperative planning. One patient was bilaterally an ears measured separately.

2.3 | Treatment groups

Cases were divided into two groups: In Group A (n = 9) the bone conduction implant had been placed retrosigmoidally (Figure 1), because of the insufficient presence of mastoid bone to anchor BC-FMT of the implant. In Group B (n = 11, 10 patients) sufficient bone substrate had been available to place and stably fixate the BC-FMT in the mastoid (Figure 2).

2.4 | Surgery

In general anaesthesia, a retroauricular approach was used in all cases. In cases with extensive mastoid defects due to previous surgeries, the BC-FMT was placed retrosigmoidally with dural exposition (Group A), in a stable location separated from the previous surgical field. BC-FMT fixation was performed with two self-tapping screws and fixation lifts were used where applicable. In cases where sufficient bony substrate for BC-FMT fixation was present, the BC-FMT was placed in the mastoid region (Group B) and fixated with standard implant screws. In all surgeries, the same sound processor (Amadé®, MED-EL) and the same implant (Bonebridge®, MED-EL) had been used.

2.5 | Audiological testing

Preoperative air and bone conduction values were measured. All patients were within the 45 dB bone conduction cut off value. Aided and unaided sound-field warble-tone thresholds were measured. The contralateral ear was plugged with earplugs and covered with earmuffs (Peltor Optime III; 3M, St. Paul, MN) when necessary. Sound masking of the contralateral ear was performed with a minimum of 50 dB, where applicable.

2.6 | Statistical analyses

The difference between the preoperative bone conduction value and the postoperative aided free field measurement is considered as the primary endpoint, the difference between the unaided and aided free field readings as secondary outcome of interest. To account for the fact that full independence of the observations cannot be assumed, as one patient is included with two observations (ie. ears), the permutation test was used for comparisons of the primary and secondary endpoints between treatment groups (A vs B). Furthermore, bootstrap percentile confidence intervals were calculated for the mean differences (group A minus group B). Both resampling methods are based on 10 000 replications. Two-sided P-values <0.05 were considered as indicating statistical significance.

3 | RESULTS

3.1 | Patient demographics

Both group A (3 male, 6 female) and group B (6 male, 3 female) had an average age of 40 (±18) years.

3.2 | Hearing outcome

Free field unaided and preoperative bone conduction values are shown in Figure 3 for both groups.

Keypoints

- After extensive cholesteatoma surgery, a transcutaneous bone conduction implant is a valuable hearing rehabilitation tool in patients where conventional middle ear reconstruction is ineffective or impossible.
- Both retrosigmoidal and mastoidal implantation achieve good postoperative hearing results, with the possibility of retrosigmoidal superiority.
- Postoperative free field values resembled preoperative bone conduction results, implying optimal air-bone gap closure.
- No adverse effects were reported.
- The greater distance between the inner ear and the retrosigmoidal location of implantation does not significantly alter functional hearing improvement, when compared with mastoidal implantation of a bone conduction implant.
There were no statistically significant differences in postoperative hearing outcome between groups A and B, comparing the postoperative aided free field measurements to the preoperative bone conduction values. (all $P$-values $>0.05$). Bootstrap median differences and confidence intervals for the differences (A minus B) are shown in Figure 4. The assumption of the similarity of mastoid placement and retrosigmoidal BC_FMT placement could not be rejected while hinting at the possibility that retrosigmoidal implantation might yield a slightly better hearing outcome.

There was a strong increase in free field hearing outcome across the whole patient collective. The difference between aided and unaided free field readings for the PTA is estimated by a mean improvement of $-28$ dB for Group A and a mean improvement of $-16$ dB for Group B (Figure 5). The bootstrap median difference (A minus B) was $-12.5$ (95% CI $-28.6$; $6.8$), the difference is not statistically significant ($P > 0.05$).

### 3.3 Adverse effects

There were no adverse effects reported in either group.

### 4 DISCUSSION

To the best of our knowledge, this is the first study directly comparing the audiological and surgical outcome between mastoidal and retrosigmoidal placement of a transcutaneous BCI in patients who had undergone previous canal wall down surgery. Aided free field, and therefore clinically highly relevant, hearing values improved significantly in both groups after implantation. In our patient collective, there were no serious adverse effects. It is notable that no significant difference in intra- and postoperative bleeding could be found. Also, neither group showed a spike in postoperative infections or wound dehiscence. This would indicate that acute surgical complications should be extremely rare for both implant locations. Seeing that the transcutaneous BCI has no protruding screws through the overlying skin, it stands to reason that the risk of postoperative infection should lower than percutaneous alternatives. Additionally, the BCI does not communicate with the affected middle ear directly, which further reduces the risk of inflammation of the device and the surrounding soft tissue or skin.

The hearing outcome results were comparable to the sparsely available data found elsewhere in literature. A recently published study showed dura compression, which may occur during retrosigmoidal placement, may even have a positive effect on hearing outcome. In our patient collective, all be it in a small sample size, we could identify a possibility that soft tissue compression, which regularly becomes necessary in the retrosigmoidal approach, may potentially benefit hearing outcome (Figure 4). The confidence intervals and bootstrap charts of our data can exclude the mastoid placement of achieving superior hearing results even in a patient collective. Seeing that the data hints at the possibility of improved

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**FIGURE 3** Preoperative bone conduction and free field measures, showing the similarity between the groups

**FIGURE 4** Bootstrap median differences and confidence intervals for the differences (A minus B). The assumption of the similarity of mastoid placement and retrosigmoidal BC_FMT placement could not be rejected, while hinting at the possibility that retrosigmoidal implantation might yield a slightly better hearing outcome

**FIGURE 5** Pure Tone Average (PTA) improvement for pre- and postoperative free field measurements
hearing outcomes in the retrosigmoidal group, prospective studies with larger patient collectives are needed to show this trend conclusively. It seems unlikely that the mere absence of the posterior bony canal wall alone would be responsible for this trend. It is our suspicion that the combination of reduced bone quantity and soft tissue stimulation may be responsible for our observations.

Preoperative planning is vitally important. In chronically inflamed ears, such as in our collective, the placement in the mastoid is often difficult. It has been reported that only 60% of cholesteatoma patients actually have enough room in the previously operated mastoid to allow implantation. This makes radiological planning essential, where the surgeon might gage the possible implant sites preoperatively in advance.9 With the rapid improvement of technology, preoperative planning may soon include 3-dimensional simulations such as 3D printing of the temporal bone reconstruction, to simulate surgical conditions.10,11 When utilising conventional hearing aids in cases such as those researched in this study, it is often quite difficult to eliminate the air conduction deficit totally. In our patient collective, all patients approached preoperative bone conduction values, implying optimal air-bone-gap (ABG) closure, without reporting any discomfort. In comparison, total ABG closure is highly unlikely in total ossicular reconstruction with replacement prostheses.

5 | CONCLUSION

Both evaluated groups had a similar audiological benefit, with a subtle trend towards superior outcome in the retrosigmoidal group, all be it with no statistical significance in our limited sample size. Furthermore, no adverse surgical and medical complications occurred in our study collective, who had undergone prior canal down surgery. Therefore, present data suggest that the surgeon may choose a retrosigmoidal implant placement in patients with a history of prior canal wall down surgery, without sacrificing hearing outcome or safety.

DISCLOSURES

No disclosures.

CONFLICT OF INTEREST

None.

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