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# Long-term Outcome of Round Window Vibrant SoundBridge Implantation in Extensive Ossicular Chain Defects

**Liliana Colletti, PhD[1], Marco Mandalà, MD[1], and Vittorio Colletti, MD[1]**

*No sponsorships or competing interests have been disclosed for this article.*

## Abstract

*Objective.* To evaluate retrospectively the long-term safety and efficacy of the first 50 patients, all suffering from severe ossicular chain defects and with moderate to severe mixed hearing loss, who received the Vibrant SoundBridge with the floating mass transducer located on the round window membrane. To evaluate differences in outcome versus etiology and age of the patient population.

*Study Design.* Case series with planned data collection.

*Setting.* Tertiary referral medical center.

*Subjects and Methods.* Patients eligible for implantation of the floating mass transducer on the round window membrane ranged in age from 2 months to 74 years with a moderate to severe conductive or mixed hearing loss from different etiologies. For each adult patient, preoperative versus postoperative bone and air conduction thresholds, air-bone gaps, and speech understanding scores were evaluated at 24-month follow-up. At 60-month follow-up, data were available from 33 patients. Preoperative and postoperative free-field auditory brainstem responses were studied in infants and children. Intraoperative and short- and long-term postoperative complications are presented.

*Results.* There were significant improvements in speech perception and pure-tone audiometry in adults and auditory brainstem response thresholds in infants immediately after surgery and at follow-up examinations (12 to 71 months). No significant complications or device extrusions were observed in the present series.

*Conclusions.* Infants, children, and adults with moderate to severe conductive or mixed hearing loss obtained substantial benefit from implantation of the floating mass transducer on the round window membrane regardless of the etiology of hearing loss and previous surgery.

## Keywords

active middle ear implant, conductive mixed hearing loss, bone conduction, hearing aid, ossiculoplasty, chronic otitis media, radical or modified radical cavities, congenital aural atresia, tympanosclerosis

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The difficulties faced in surgical restoration/rehabilitation of hearing in patients with extensive and complex disorders of the outer and middle ear[1-3] and the fact that mechanical vibration via the round window membrane (RWM) and oval window are equally effective for cochlear stimulation prompted Colletti et al[4] to suggest the use of the RWM as the fitting location for an active middle ear prosthesis.

This new approach triggered the development of several innovative solutions benefiting from new fully or partially implanted active middle ear implants, and different actuators fitted on the residual ossicular chain provided promising short-term outcomes.[5-10] All of these innovations become good alternative treatment options for patients, often disappointed by the current surgical and aural rehabilitation procedures, when supported by long-term safety, stability, and efficacy studies. Long-term complications and device extrusion rates were also investigated at the last follow-up.

The present study retrospectively evaluated the short- and long-term outcome (safety and efficacy) of RWM implantation on the first 50 patients of different ages and etiologies, all suffering from severe ossicular chain defects, with moderate to severe mixed hearing loss. The prerogative of the RWM implantation is to bypass the complex abnormalities of the middle ear of these patients and locate the floating mass transducer (FMT) of the MED-EL Vibrant SoundBridge (VSB) on the very last point of entry to the inner ear. All patients were operated on by a single surgeon and with the same standardized surgical protocol. The specific

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aims of this investigation were to clarify whether differences in outcome are indeed observable versus etiology and age.

## Methods

The cohort was recruited between January 2005 and January 2012 at a tertiary referral hospital (Otolaryngology Department, University of Verona, Italy).

The criteria for inclusion in the study were (1) extensive ossicular chain defects leading to moderate to severe mixed hearing loss; (2) chronic otitis media (COM) canal-wall-up (CWU) or canal-wall-down (CWD) procedures, all with previously unsuccessful functional surgery or radical or modified radical cavities (RCs) or severe congenital aural atresia (CAA); and (3) no benefit from and/or no acceptance when fitted with conventional air conduction (AC) and bone conduction (BC) hearing aids or bone-anchored hearing aids.

### *Outcome Measures*

Preoperative and postoperative measurements at 0.5, 1, 2, and 4 kHz at 24- and 60-month follow-up included (1) BC and AC thresholds; (2) air-bone gap (ABG) between BC and AC thresholds; (3) percentage of bisyllabic words correctly repeated at 65 dB HL in the Italian language; (4) VSB-aided AC (VSB-AC) thresholds; (5) VSB-aided ABG (VSB-ABG), as the difference between BC and VSB-AC thresholds, used to quantify the gain provided by the FMT on the RWM; (6) percentage of patients with postoperative VSB-ABG $< 0$ dB HL (overclosure), VSB-ABG between 0 and 5 dB HL (closure within 5 dB HL), VSB-ABG between 0 and 10 dB HL (closure within 10 dB HL), and VSB-ABG greater than 30 dB HL (underclosure); (7) preoperative and postoperative free-field auditory brainstem responses (ABRs) in infants and children younger than 5 years; and (8) intraoperative and postoperative complications and FMT displacement or extrusion rate.

The University of Verona Ethics Committees approved the study, and all patients gave their informed consent.

### *Device and Surgery*

All patients had the FMT VSB (manufactured by MED-EL Hearing Technology, Innsbruck, Austria) fitted. Device characteristics, surgical principles, and device activation have been described previously.[4,5,8,10] Patients were operated on using the same surgical protocol by the senior author (V.C.).

The optimal fitting position of the FMT on the RWM was supported in most patients by intraoperative electrocochleography (ECoG).

The surgical approach was individually selected according to the specific anatomical situation (CWU, CWD, RC, and CAA) and analysis of previous surgical treatments and clinical and radiological examinations. For all patients, fitting of the FMT onto the RWM strictly adhered to the following steps (**Figure 1**):

1. Removal of any secondary RWM, of the bony lip obscuring full view of the RWM, and of the bony floor impeding precise seating of the FMT inside the RW niche with a perpendicular and full contact of the FMT with the RWM.
2. Elimination of any potential bony contacts of the FMT by interposing pieces of fascia between the FMT and the RWM and all around the FMT.
3. Ensuring stability of the RWM/FMT coupling by inserting the FMT approximately 1 mm inside the RW niche and placing a disk of cartilage on the opposite side of the FMT.
4. Visual validation of the RWM/FMT coupling, by touching the stapes or footplate and verifying the inward and outward movement of the FMT.
5. Objective ECoG validation of the RWM/FMT coupling with compound action potentials (CAPs) evoked by clicks and tone-burst stimuli at frequencies of 0.5 to 2 kHz. For details, see Colletti et al.[10]

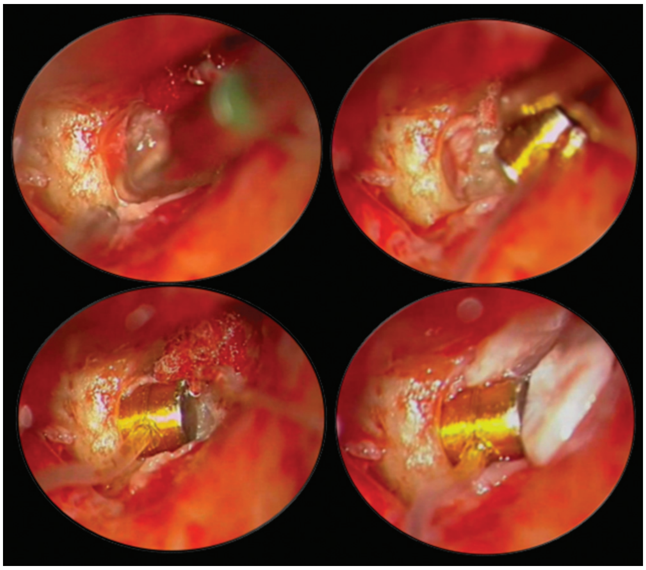

**Figure 1.** Correct coupling of the floating mass transducer to the round window membrane is performed step by step.

### *Statistical Analysis*

Statistical comparisons between preoperative and postoperative outcome measurements at 24- and 60-month follow-up were conducted by paired Student *t* test or Wilcoxon–Mann–Whitney test as appropriate (significance: $P < .05$). Comparison of outcomes among the 3 subgroups was conducted by analysis of variance (ANOVA) test with Tukey post hoc test (significance: $P < .05$).

## Results

Fifty patients (21 males and 29 females), ranging in age from 2 months to 74 years, were treated with RWM-FMT implantation. The patients included 26 COM adults (15 with CWU and 11 with CWD procedures, all with previously unsuccessful functional surgery), 9 adults with RCs, and 15 patients with severe CAA (10 children, ranging in age from 2 months to 16 years, and 5 adults).

**Table 1.** Distribution of patients among the 3 groups at the different follow-up times.

| | Adults | | | Children | |
|---|---|---|---|---|---|
| Follow-up, mo | COM | RC | CAA | CAA | Total |
| 12 | 26<br>15 CWU<br>11CWD | 9 | 5 | 10 | 50 |
| 24 | 26<br>15 CWU<br>11CWD | 9 | 5 | 4 | 44 |
| 36 | 25<br>15 CWU<br>11CWD | 8 | 4 | 3 | 40 |
| 48 | 24<br>15 CWU<br>11CWD | 8 | 4 | 2 | 38 |
| 60 | 22<br>15 CWU<br>11CWD | 7 | 4 | 1 | 34 |

Abbreviations: CAA, severe congenital aural atresia; COM, chronic otitis media; CWD, canal-wall-down; CWU, canal-wall-up; RC, radical or modified radical cavities.

**Table 2.** Demographic data for the 3 groups of subjects.

| | Adults | | | Children |
|---|---|---|---|---|
| | COM | RC | CAA | CAA |
| Number of subjects | 26 | 9 | 5 | 10 |
| Age, y | 51.2 ± 16.1 | 59.2 ± 10.6 | 26.8 ± 3.4 | 5.7 ± 5.5 |
| Sex, M/F | 10/16 | 6/3 | 3/2 | 7/3 |

Abbreviations: CAA, severe congenital aural atresia; COM, chronic otitis media; RC, radical or modified radical cavities.

Four patients were excluded from further follow-ups, 2 with device replacement for VSB failure and 2 with a misdiagnosed severe hearing loss, explanted and fitted with a cochlear implant. Patients after reimplantation were excluded from the study because replacement surgery could introduce a bias and because they did not reach the 12-month follow-up.

Half of the patients had undergone previous multiple surgical procedures with unsuccessful results.

**Table 1** reports the distribution of patients among the 3 groups at the different follow-up times.

## *Outcomes in Adults and Older Children*

Demographic data for the 3 groups of subjects are presented in **Table 2**. Significant differences were observed among the 3 different pathology groups, with the CAA patients presenting the youngest mean age ($P < .05$).

The mean follow-up time of the study was 53.3 ± 24.2 months (range, 12-71 months). At the last follow-up, all patients were daily users of their implants.

The means and standard deviations of the hearing thresholds observed for all RWM-FMT patients preoperatively and at 24- and 60-month follow-up times are reported in **Table 3**. The final VSB-AC thresholds compared with preoperative AC and BC thresholds are reported in **Figure 2**. The final mean magnitude of hearing improvement was from 34 ± 12.1 dB HL to 64 ± 13.4 dB HL at 0.5 and 2 kHz, respectively.

The differences between the preoperative and postoperative mean BC thresholds ($P = .3$), unaided mean AC thresholds ($P = .3$), mean postoperative VSB-AC thresholds ($P = .5$), and mean preoperative ABG ($P = .9$) at 24- and 60-month follow-up times were not statistically significant. The differences between the mean preoperative AC and postoperative VSB-AC thresholds were highly significant, both at the 24- ($P = .0008$) and 60-month follow-up times ($P = .0007$). The mean VSB-ABG was −9.4 ± 4.1 dB at 24 months and −9.7 ± 6.2 dB at 60 months. No significant difference was observed for VSB-ABG at the 2 follow-up times ($P = .8$ and $P = .7$, respectively).

## *Outcomes in Younger Children*

No significant differences were observed between the preoperative and postoperative mean ABR BC thresholds at both

**Table 3.** Means and standard deviations of the hearing thresholds observed for all RW-FMT implantation patients at 24- and 60-month follow-up.

| | BC | AC | VSB-AC | ABG | VSB-ABG |
|---|---|---|---|---|---|
| Preoperative | 37.5 ± 11.5 | 79.1 ± 10 | — | 41.6 ± 9.2 | — |
| 24-month follow-up | 39.9 ± 14.6 | 82.1 ± 11.9 | 30.5 ± 9.8 | 42.2 ± 11.6 | –9.4 ± 4.1 |
| 60-month follow-up | 41.6 ± 13.1 | 82.7 ± 9.7 | 31.9 ± 8.8 | 41.1 ± 10.3 | –9.7 ± 6.2 |
| Statistical analysis | $P$ = .3[a] | $P$ = .3[a] | $P$ = .5[b] | $P$ = .9[a] | $P$ = .8[b] |
| | AC vs VSB-AC (24-month follow-up), $P$ = .0008[b] | | | | |
| | AC vs VSB-AC (60-month follow-up), $P$ = .0007[b] | | | | |

Abbreviations: ABG, air-bone gap between BC and AC thresholds; AC, air conduction threshold; BC, bone conduction threshold; FMT, floating mass transducer; RW, round window; VSB-ABG, air-bone gap between BC and Vibrant Soundbridge–aided AC thresholds; VSB-AC, Vibrant Soundbridge–aided air conduction threshold.
[a]Anova test.
[b]*t* test.

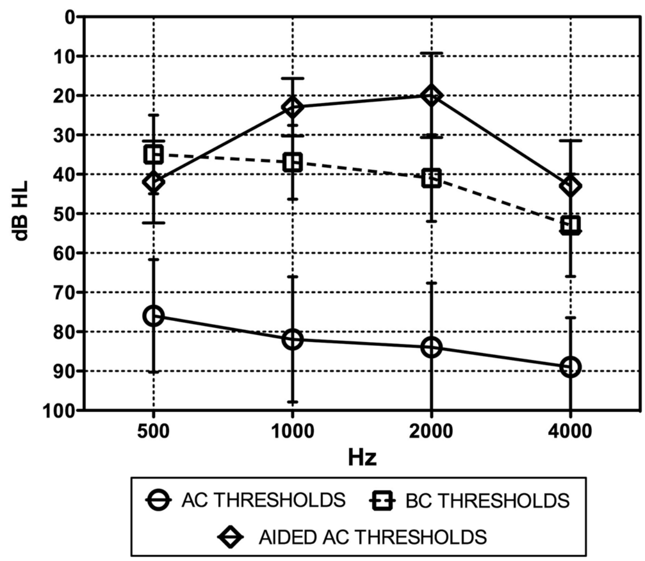


**Figure 2.** Preoperative bone conduction thresholds and preoperative unaided and postoperative aided VSB air conduction thresholds at 0.5, 1, 2, and 4 kHz evaluated at 60-month follow-up.

follow-ups ($P > .05$). The postoperative ABR VSB-AC thresholds in children younger than 5 years (5 subjects) showed a mean value of 28 ± 8.4 dB HL at the last follow-up. The difference between preoperative AC and postoperative VSB-AC thresholds was highly statistically significant ($P < .0001$; **Table 4**).

### Overclosure and Closure of the ABG

**Table 5** details the number and percentage of patients with VSB-ABG overclosure and closure at 5 and 10 dB HL values at the different follow-ups considered together and among the different subgroups.

### Speech Understanding

Speech understanding of bisyllabic words at 65 dB HL shifted from preoperative values of 8.5% ± 5.6% to postoperative values of 75.7% ± 17.4% and 72.4% ± 15.6% at 24- and 60-month follow-up, respectively (**Figure 3**). The difference between preoperative and postoperative values was significant for both follow-up times ($P < .0001$).

### RWM-FMT Implantation Outcomes versus Pathology

All 3 groups (COM, RC, and CAA) showed a consistent hearing improvement. Significant differences in postoperative BC and unaided AC thresholds across the etiology groups could be observed only when comparing the COM and RC groups against the CAA patients who showed better results ($P < .05$; ANOVA test with Tukey post hoc test). The VSB-AC threshold and postoperative VSB-ABG were not significant among the groups ($P > .05$), despite the fact that the CAA subjects always performed better.

An ANOVA test on the differences among the 3 groups showed a statistically significant difference in speech understanding at 24 months ($P$ = .02), with the COM and RCs subjects improving up to 73.8% ± 17.4% and 68.9% ± 11.7%, respectively, whereas the CAA patients improved up to 91% ± 15.2%, but there was no further significant improvement at 60-month follow-up in the 3 subgroups ($P > .05$).

## Discussion

Fully or partially implanted active middle ear implants, with the actuator fitted on the residual ossicular chain or on the RWM, have demonstrated very promising outcomes,[4-10] and the number of new studies is growing rapidly.[11-17]

The purpose of the present study was to verify whether RWM-FMT implantation is a safe and effective option for patients suffering from severe ossicular chain defects and with moderate to severe mixed hearing loss, considering that most of these patients had previously been submitted unsuccessfully to standard middle ear surgical procedures to restore their hearing at ages spanning from childhood to elderliness.

Furthermore, considering that, with the RWM approach, the normal mechanical function of the middle ear and the complex function of the Eustachian tube and middle ear mucosa are bypassed and the mechanical energy is delivered directly to

**Table 4.** Free-field ABR outcomes in infants and younger children with congenital aural atresia at the last follow-up.

| Infants and younger children (n = 5) | BC | AC | VSB-AC |
|---|---|---|---|
| Preoperative | 32 ± 8.4 | 78 ± 10.9 | — |
| Postoperative (12 mo) | 36 ± 8.9 | 84 ± 13.6 | 28 ± 8.4 |
| Wilcoxon-Mann-Whitney test | *P* = .5 | *P* = .5 | AC vs VSB-AC: *P* < .0001 |

Abbreviations: ABR, auditory brainstem response; AC, air conduction threshold; BC, bone conduction threshold; VSB-AC, Vibrant Soundbridge–aided air conduction threshold.

**Table 5.** Patients with ABG overclosure and closure at 5 and 10 dB HL at the 60-month follow-up.

| | | Total, n (%) | COM, n (%) | RC, n (%) | CAA, n (%) |
|---|---|---|---|---|---|
| n | | 34 | 22 | 7 | 5 |
| Overclosure (<0 dB HL) | | 20 (58) | 13 (59) | 4 (57) | 3 (60) |
| Closure | 0 ≤ X ≤ 5 dB HL | 9 (26) | 6 (27) | 2 (28) | 1 (20) |
| | 0 ≤ X ≤ 10 dB HL | 14 (42) | 9 (41) | 3 (43) | 2 (40) |

Abbreviations: ABG, air-bone gap; CAA, severe congenital aural atresia; COM, chronic otitis media; HL, hearing loss; RC, radical or modified radical cavities.

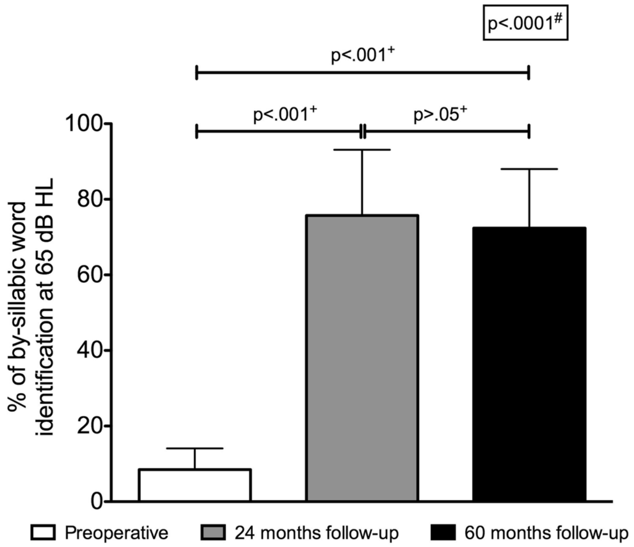


**Figure 3.** Results of speech understanding of bisyllabic words at 65 dB HL preoperatively and at 24- and 60-month follow-up. #Analysis of variance test. +Tukey post hoc test.

the inner ear via the RWM by the FMT, we wanted to verify if the outcomes from the different population etiologies differ substantially from one group to another.

Indeed, we could demonstrate that the RWM approach allows compensation of both the conductive and the sensorineural component of hearing loss, regardless of the etiology of the severe cochlear or ossicular chain abnormalities and of age.

Finally, the long-term high level of therapeutic efficiency of RWM-FMT implantation compared with traditional ossiculoplasty[5] provides clear evidence that coupling of energy from the FMT to the RWM is highly and consistently efficient in delivering mechanical energy directly to the inner ear.

## *Long-term Effects on Hearing*

There was no intraoperative (ECoG[10]) or medium- or long-term evidence of damage to both components of hearing for this series of subjects. Improvements in audibility produced by the RWM-FMT VSB procedure were reflected in all of the test procedures. In detail, the range of preoperative ABG versus postoperative VSB-ABG values offered the possibility to quantify the different degrees of coupling and extrapolate from these the possible reasons for such differences. At the 24-month follow-up, a VSB-ABG overclosure of less than 0 dB (59% of patients) and a closure of less than 10 dB (32%) suggested an optimal to good RWM/FMT coupling, while a closure of more than 30 dB HL, observed in 9% of the total population, strongly implied an incorrect coupling, an undiagnosed coexisting severe footplate fixation, or a device failure.

The auditory effect of the additional amplification provided by the FMT located on the RWM and related to the degree of the sensorineural component was reflected in the VSB-ABG and in the gain values, which reached the remarkable mean value of −9.7 dB at the 60-month follow-up. The present study confirmed previous findings[4] that the highest gains are obtained at 1 and 2 kHz, at which a significant overclosure of the VSB-ABG was observed[18] (**Figure 2**). These outcomes were subsequently reported by other investigators.[9] The ‘‘underclosure’’ for frequencies less than 1 kHz is due to the frequency roll-off of the FMT below 1.0 kHz and not to a mismatch in the respective diameters of the FMT and the RWM and niche, which would be present systematically at all frequencies.

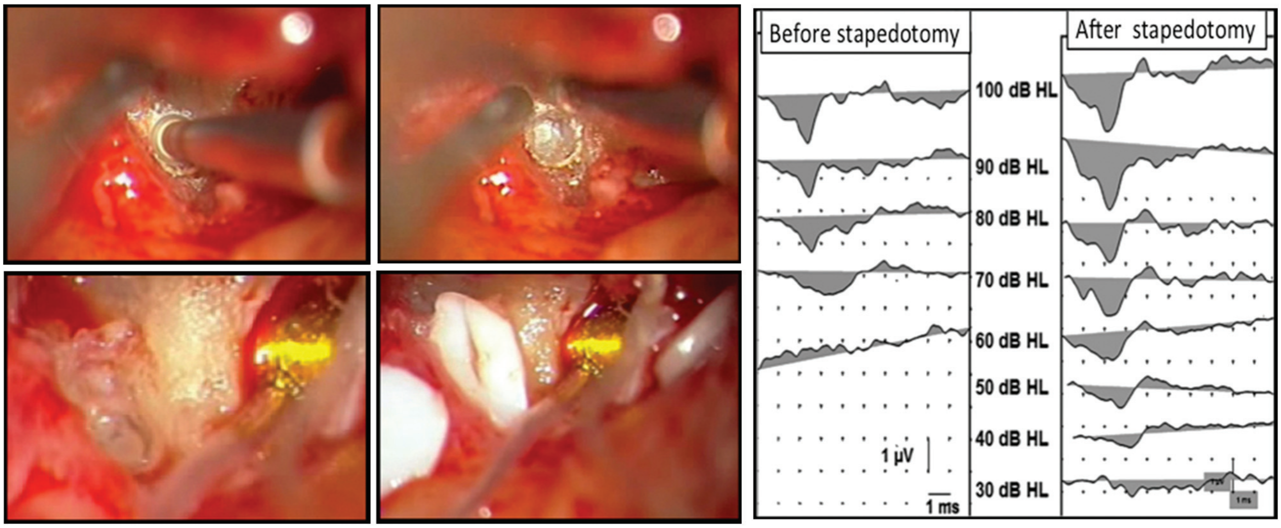


**Figure 4.** Oval window drill-out 0.2 to 0.5 mm fenestration to improve Vibrant SoundBridge electrocochleography (ECoG) responses in oval window ossification. ECoG monitoring was performed before and after stapedotomy.

Despite the limitation of the FMT in its ability to close the ABG at frequencies less than 1 kHz, a large number of patients exhibited a substantial improvement in speech intelligibility. The number of patients able to achieve 100% speech intelligibility dramatically increased from 2 preoperatively to 43 postoperatively.

Significant differences in terms of VSB-AC threshold were not observed among the 3 groups; however, in speech perception, the CAA patients outperformed the other 2 groups, probably due to younger mean age and lower BC thresholds.

## Variability in Outcomes

The variability in outcomes with the RWM-FMT procedure[6,9,12] may be significantly reduced with intraoperative ECoG.[10] The surgeon can monitor his or her surgery and modify it accordingly if the outcomes are not as expected.[10,19] The ECoG measurements have provided a new insight into the mechanisms governing the mechanical stimulation of the cochlea and the conditions that can adversely affect outcomes. The critical effect of a fixed footplate on the input impedance at the RWM, because of coexisting otosclerosis or tympanosclerosis (**Figure 4**), was reflected in high-threshold and low-amplitude values of CAPs. These CAP values immediately shifted to significantly lower-threshold and higher-amplitude CAP values after performing a limited platinotomy, clearly indicating an improved transfer of vibratory energy from the FMT to the cochlear fluids.

## Stability

Migration of the FMT may represent a very long-term complication associated with this procedure; however, in the present study, no subjects showed any significant gradual or sudden deterioration of aided hearing threshold resulting from FMT migration from its location. An indication of the remarkable stability of RWM placement was observed in a patient with RC fitted with the RWM-FMT when, during removal of debris from her ear canal, the FMT cable was accidently exposed but the patient did not complain of any change in hearing.[10]

## Safety

In patients with previous surgery for CWU, CWD, RCs, or CAA, the surgeon has to consider the preliminary surgical steps for RWM-FMT implantation specific to the individual candidate patient. Despite the fact that no subjects have shown severe anatomic contraindications to RWM-FMT implantation, in CAA patients, the variable anatomy and landmarks could challenge the identification of inner ear structures and the facial nerve (**Figure 5**). In cases in which the facial nerve overhangs or conceals the RW niche, the RWM-FMT procedure may be contraindicated, especially if a facial nerve transposition or a subfacial approach is not feasible.

## Complications

In the present series of patients, no intraoperative or postoperative complications such as extrusion or dislocation of the VSB were observed. Four patients experienced mild dizziness on the first postoperative day, which resolved without intervention. At 60-month follow-up, all patients were daily users of their implants.

At the follow-up of 24 months, a VSB-ABG of more than 30 dB HL was observed in 4 patients (2 COM, 1 RC, and 1 adult CAA patient) operated on during the first 2 years with no ECoG assistance and in none of the 34 tested at 60 months. Two had a device failure and were successfully reimplanted. They experienced device benefit with the initial device but in 1 patient, performance declined progressively over 1 year and in the other patient over 2 years following device fitting. Revision surgery with ECoG

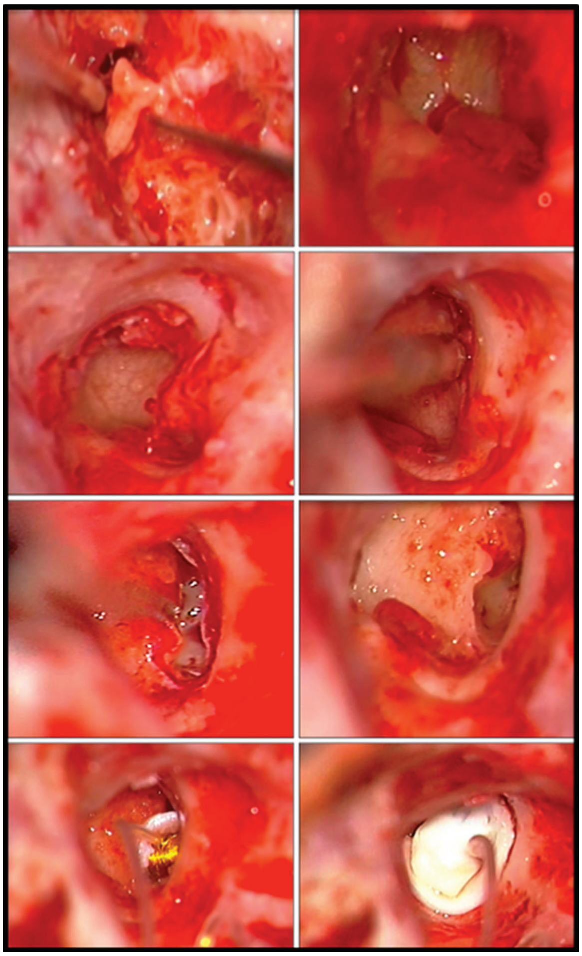

**Figure 5.** Vibrant SoundBridge implantation in a patient with congenital aural atresia in whom the variable anatomy and landmarks could challenge the identification of inner ear structures and facial nerve.

confirmed the device failure, and observation of the RW area indicated that the FMT was in correct anatomical contact with the RWM. Device replacement was uneventful, and the good CAPs anticipated the good hearing benefit observed on the days immediately after surgery. The 2 other patients were recognized to have a misdiagnosed severe hearing loss. These 2 were also explanted and fitted with a cochlear implant 1 and 2 years after RWM-FMT implantation.

## Conclusions

To the best of our knowledge, this study on the RWM-FMT procedure analyzes the largest series of patients with histories of COM, CAA, and RCs and has the longest follow-up in terms of safety, stability, and efficiency. Typically, most of these patients have had repeated middle ear surgery with no substantial hearing benefit and were reluctant or unsuitable candidates for aural rehabilitative procedures. The long-term high-level therapeutic efficiency of RWM-FMT implantation compared with traditional ossiculoplasty[5] is probably the result of the highly efficient coupling of energy from the FMT to the RWM. Considering that many patients with severe damage to the middle ear chain often undergo multiple surgical procedures to improve their middle ear function, often without adequate hearing improvement, one might decide to use RWM approach as a first-line treatment in these cases, thereby avoiding repeat surgery and sparing patients time lost from work.

Comparison of long-term outcomes with other active middle ear implants using non–RWM-FMT procedures is currently impossible because of the unavailability of sufficient personal and literature data.

## Author Contributions

**Liliana Colletti**, conception and design of the study, acquisition of data, drafting the article, revision, final approval; **Marco Mandalà**, conception and design of the study, acquisition of data, analysis and interpretation of data, drafting the article, revision, final approval; **Vittorio Colletti**, conception and design of the study, acquisition of data, analysis and interpretation of data, drafting the article, revision, final approval.

## Disclosures

**Competing interests:** None.

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