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WILEY
Clinical Experience of Vibroplasty With Direct Coupling to the Oval Window Without Use of a Coupler

Sang Hyun Kwak, MD; Young Min Moon, MD; Gi-Sung Nam, MD; Seong Hoon Bae, MD; Sung Huhn Kim, MD, PhD; Jinsei Jung, MD, PhD; Jae Young Choi, MD, PhD

Objectives/Hypothesis: To investigate the efficacy of direct implantation of a Vibrant Soundbridge (VSB) implant in the oval window (OW) without the use of an OW coupler in patients with severe mixed hearing loss.

Study Design: Retrospective chart review.

Methods: A total of 62 patients underwent VSB implantation between July 2016 and December 2018 at Severance Hospital in Seoul, South Korea. Among them, eight patients (nine ears) with moderate-to-severe mixed hearing loss were implanted with a VSB directly in the OW. A floating mass transducer (FMT) was attached to the stapes footplate and covered with tragal cartilage. The outcomes were evaluated using pure-tone audiogram and speech audiogram preoperatively and postoperatively. Word recognition score (WRS; % correct) were measured at the most comfortable loudness (MCL) level to evaluate speech perception.

Results: All cases posed difficulty with round window vibroplasty during surgery, and eventually, an FMT was appropriately placed in the OW without a coupler. Preoperative and postoperative bone conduction thresholds were not different. VSB-aided threshold improved in terms of functional and effective gains. Interestingly, four cases showed improved air conduction thresholds without the use of a VSB. In addition, MCL level with a VSB was significantly lower than that with a hearing aid, and VSB-aided WRS improved over time.

Conclusions: Direct implantation of a VSB in the OW without the use of a coupler showed favorable hearing outcomes, and the OW vibroplasty was safe. Direct OW vibroplasty without a coupler is a reliable procedure and can be a good option for hearing rehabilitation in patients with severe mixed hearing loss.

Key Words: Vibrant Soundbridge, oval window coupler, hearing rehabilitation, severe mixed hearing loss.

Level of Evidence: 4

INTRODUCTION

Patients with chronic otitis media with mixed hearing loss face difficulties in hearing rehabilitation. Ossiculoplasty is often of little benefit due to both anatomical and audiological limitations.1 Gains with conventional hearing aids (HAs) are also usually insufficient, and the fitting of HAs can be difficult, particularly for those undergoing canal wall down mastoidectomy due to a large cavity.2 Recently, active middle ear implants, such as the Vibrant Soundbridge (VSB), have emerged as good options for hearing rehabilitation in patients with moderate-to-severe mixed hearing loss after chronic ear surgery, as the device can stimulate the inner ear while passing the problematic middle ear structure.3,4

Various methods for coupling a floating mass transducer (FMT) and the middle ear structure during middle ear implant surgery using a VSB have been introduced. The original technique for mixed hearing loss is round window coupling introduced by Colletti et al., which can offer sufficient gains in most cases with mixed hearing loss.3 A round window coupler makes this approach easier, as it can avoid having to remove the round window niche. However, this approach is not always available due to anatomical variations, such as high jugular bulb and scar tissue around the round window.5,6 In addition, Schraven et al. reported the highest revision rates among coupling methods for round window vibroplasty.7 Stimulation through the oval window (OW) by coupling the FMT with stapes head or footplate can be another option for patients with mixed hearing loss.7–10 Although OW coupling using specially designed couplers showed comparable results in patients with mixed hearing loss in several studies, this approach still has problems in the perspective of surgical anatomy. In patients who have undergone canal wall down mastoidectomy, the middle ear cavity around the OW tends to be too shallow for the combination of a VSB and coupler, and supporting
cartilage. In addition, there is a high chance of developing adhesive drum, because most patients who need this procedure have poor eustachian tube function. Therefore, the long-term anatomical stability of coupling to the OW could be problematic.

We have attempted direct coupling of the FMT onto the stapes footplate without a coupler in patients with mixed hearing loss after chronic ear surgery. Short-term anatomical and audiological outcomes are discussed in this article.

MATERIALS AND METHODS

Cases

A total of 62 patients underwent VSB implantation surgery between July 2016 and December 2018 at the Department of Otorhinolaryngology at Severance Hospital of Yonsei University Health System, a tertiary hospital in Seoul, South Korea. Among them, eight patients (nine ears, total nine cases) who underwent implantation of an FM without a coupler in the OW were included in this study. The study was approved by the local ethics committee of Yonsei University (2018–1561).

Surgical Procedure

Surgery was performed under general anesthesia. In a patient with automastoidectomy who had not previously undergone surgery, complete sacuerization of the infected air cell was performed, and the malleus, incus, and suprastructures of the stapes were avoided. Notably, the stapes footplate was mobile without fixation (Fig. 1A). Footplate mobility was confirmed using a round window reflex test, which was performed by touching the footplate with a fine pick instrument. The FMT was placed on the stapes footplate without an additional coupler (Fig. 1B). Tympanic cartilage was harvested and placed between the tympanic membrane and FMT (Fig. 1C). The receiver/stimulator and conductor link were tightly embedded into the cortical bone using clean bone dust and cartilage fragments to avoid extrusion of the device to the external auditory canal. Figure 1D shows a schematic diagram of vibroplasty procedure with direct coupling to the OW without the use of couplers.

Audiologic Assessment

All patients underwent audiologic assessment, including pure-tone audiometry (PTA) and speech audiometry, before surgery as well as 1 and 3 months after surgery. VSB was first fitted at 1 month after surgery. All audiologic assessments were performed by an experienced audiologist in a single calibrated and sound-proofed double-walled audiometric chamber. PTA in an unaided condition was also performed with headphones. PTA in aided conditions, including with an HA and VSB, was performed with soundfields with two loudspeakers placed 1 m directly at an angle of 45° and at the level of the patient’s head. Additionally, the unaided condition was also measured under free-field tests. During the free-field test, the contralateral ear was blocked and muffled, and masking was done with headphones covering only the contralateral ear when needed. The PTA included air conduction (AC) and bone conduction (BC) thresholds ranging from 250 Hz to 4,000 Hz. An average of the four frequencies (500, 1,000, 2,000, and 4,000 Hz) presented in the pure-tone audiometry (PTAt) was calculated and defined as the mean value. Functional hearing gain was defined as the difference between free-fields unaided and aided thresholds. Effective hearing gain was defined as the difference between BC threshold and aided threshold.

A word recognition test was performed to acquire maximal speech intelligibility represented by word recognition score (WRS; % correct) measured at the most comfortable loudness (MCL) level using 50 monosyllabic Korean words that are typically heard during everyday life, phonetically balanced, and taken from a validated and standardized resource (Hahn’s list). Measurement of word recognition tests under a preoperative unaided condition was performed in the same audiomteric chamber with headphones. The word recognition test of aided conditions was performed with sound fields positioned the same as in the PTA test condition. MCL level was defined as the level at which the patient best heard and understood unemotional Korean speech, regardless of intelligibility. WRS was measured at MCL level to assess postoperative speech outcomes. We had a limitation in that we compared preoperative unaided WRS with postoperative VSB-aided WRS with different transducers. However, it was able to partially compare preoperative HA-aided WRS with postoperative VSB-aided WRS via loud speaker in four cases. The association of PTA and WRS with VSB implantation is shown in Supporting Figure 1.

TABLE I.

Case Characteristics

<table>
<thead>
<tr>
<th>Cases</th>
<th>Sex</th>
<th>Age, yr</th>
<th>Previous Ear Surgery Site</th>
<th>Preoperative PTA, dB HL</th>
<th>Preoperative WRS at MCL Level, %</th>
<th>Surgery Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>58</td>
<td>CWDM (Lt)</td>
<td>90/50</td>
<td>70</td>
<td>Rt</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>62</td>
<td>CWDM (Rt)</td>
<td>103/53</td>
<td>36</td>
<td>Rt</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>59</td>
<td>CWUM (Lt)</td>
<td>6/0</td>
<td>28</td>
<td>Lt</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>71</td>
<td>CWDM (Lt)</td>
<td>55/55</td>
<td>4</td>
<td>Lt</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>67</td>
<td>CWDM (Lt)</td>
<td>61/46</td>
<td>0</td>
<td>Lt</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>58</td>
<td>CWDM (Lt)</td>
<td>90/50</td>
<td>70</td>
<td>Lt</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>82</td>
<td>CWUM (Lt)</td>
<td>50/41</td>
<td>58</td>
<td>Lt</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>69</td>
<td>CWUM (Lt)</td>
<td>94/49</td>
<td>80</td>
<td>Lt</td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>55</td>
<td>CWDM (Rt)</td>
<td>93/60</td>
<td>64</td>
<td>Rt</td>
</tr>
</tbody>
</table>

Cases 1 and 6 are the same patient.

AC = air conduction; BC = bone conduction; CWDM = canal wall down mastoidectomy; CWUM = canal wall up mastoidectomy; F = female; Lt = left; MCL = most comfortable listening; M = male; PTA = four-frequency pure-tone audiometry (dB HL; 0.5, 1, 2, and 4 kHz); Rt = right; WRS = word recognition score.
Statistical analysis was performed using SPSS software for Windows (version 22; IBM, Armonk, NY) and GraphPad Prism (version 5; GraphPad Software, La Jolla, CA). Audiologic outcomes at each frequency in the PTA were compared among groups of preoperative unaided AC and BC, and VSB-aided conditions were analyzed with two-way repeated measures analysis of variance (ANOVA). Bonferroni correction was applied to the post hoc analysis of between- and within-group comparisons. The results of speech audiometry were analyzed using repeated measures one-way ANOVA. Differences between the mean values of groups were considered statistically significant at $P < .05$.

## RESULTS

### Case Characteristics

Table I shows demographic characteristics of the included cases. Cases 1 and 6 are the same patient but different ears. The patients enrolled in the study were

<table>
<thead>
<tr>
<th>Patient</th>
<th>Site</th>
<th>Drum</th>
<th>Mastoid and Middle Ear Cavity</th>
<th>Reason for OW Coupling</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rt</td>
<td>Granulation</td>
<td>Automastoidectomy status, posterior EAC wall destructed status, missing ossicles</td>
<td>Narrow round window niche</td>
</tr>
<tr>
<td></td>
<td>Lt</td>
<td>Perforated</td>
<td>Recurred cholesteatoma, missing ossicles</td>
<td>Narrow round window niche.</td>
</tr>
<tr>
<td>2</td>
<td>Rt</td>
<td>Perforated</td>
<td>Recurred with cholesteatoma, missing ossicles</td>
<td>Narrow round window membrane</td>
</tr>
<tr>
<td>3</td>
<td>Lt.</td>
<td>Intact drum</td>
<td>Granulation tissues on mastoid cavity, missing ossicles</td>
<td>Very narrow round window niche</td>
</tr>
<tr>
<td>4</td>
<td>Lt</td>
<td>Adhesive</td>
<td>Granulation tissues in mastoid cavity, missing ossicles</td>
<td>Unstable fitting at round window</td>
</tr>
<tr>
<td>5</td>
<td>Lt</td>
<td>Adhesive</td>
<td>Granulation tissues in mastoid cavity, missing ossicles</td>
<td>Narrow round window membrane</td>
</tr>
<tr>
<td>6</td>
<td>Lt</td>
<td>Retracted drum</td>
<td>Stapes head erosion, I-S joint separated</td>
<td>Unstable fixation at round window due to ossification of round window membrane</td>
</tr>
<tr>
<td>7</td>
<td>Lt</td>
<td>Perforated and retracted</td>
<td>Stapes head erosion</td>
<td>Narrow round window niche</td>
</tr>
<tr>
<td>8</td>
<td>Rt</td>
<td>Perforated</td>
<td>Missing ossicles</td>
<td>High jugular bulb</td>
</tr>
</tbody>
</table>

EAC = external auditory canal; I-S = incudostapedial; Lt = left; OW = oval window; Rt = right.
aged between 58 and 82 years and comprised seven female patients and one male patient. Eight cases had previously undergone tympanomastoidectomy due to chronic otitis media. Five cases underwent canal down mastoidectomy, and three cases underwent canal up mastoidectomy, respectively. The one patient affected bilaterally showed automastoidectomy in the right side (case 1) on temporal bone computed tomography (CT). All cases

| TABLE III. Audiologic Outcomes After Vibrant Soundbridge Implantation in Nine Cases. |
|----------------------------------------|----------|----------|----------|----------|----------|
| Frequency | 0.5 kHz | 1 kHz | 2 kHz | 4 kHz | PTA4 |
| Preoperative AC | 85.5 ± 4.6 | 89.4 ± 5.1 | 82.7 ± 5.7 | 102.2 ± 6.5 | 90.0 ± 8.5 |
| Postoperative AC | 80.5 ± 5.9 | 90.0 ± 5.3 | 94.4 ± 4.8 | 103.8 ± 4.7 | 92.2 ± 9.6 |
| Preoperative BC | 45.0 ± 3.7 | 47.7 ± 4.6 | 51.1 ± 4.8 | 55.5 ± 3.6 | 49.8 ± 4.5 |
| Postoperative BC | 46.1 ± 4.2 | 47.2 ± 6.1 | 53.8 ± 5.3 | 58.8 ± 3.9 | 51.5 ± 5.9 |
| FF unaided | 77.7 ± 17.8 | 89.4 ± 21.5 | 92.7 ± 16.7 | 105.5 ± 13.7 | 91.3 ± 11.4 |
| FF VSB-aided | 50.5 ± 10.7 | 39.4 ± 7.6 | 41.6 ± 12.9 | 67.7 ± 12.5 | 49.9 ± 12.8 |
| VSB-aided FG | 27.2 ± 11.7 | 50.1 ± 18.7 | 51.1 ± 21 | 37.7 ± 12.7 | 44.0 ± 10.6 |
| VSB-aided EG | −1.1 ± 10.5 | 9.4 ± 14.4 | 11.1 ± 18.3 | −6.1 ± 14.3 | 3.3 ± 11.7 |

AC = air conduction; BC = bone conduction; EG = effective gain, defined as the difference between BC threshold and aided threshold; FF = free-field thresholds of postoperative 1 month; FG = functional hearing gain of postoperative 1 month (defined as the difference between free-field unaided thresholds and aided AC thresholds); OW = oval window; PTA4 = four-frequency pure-tone audiometry (dB HL; 0.5, 1, 2, and 4 kHz); VSB = Vibrant Soundbridge.

Fig. 2. Audiological comparisons in patients with vibroplasty with direct coupling to the OW. (A) Mean preoperative and postoperative pure-tone audiograms, and postoperative aided with VSB groups (n = 9). There was no significant difference between the pre- and postoperative BC pure-tone audiograms. No differences were observed between the preoperative air-bone gap and postoperative air-bone gap, regardless of surgery. (B) Comparison of free-field thresholds between unaided and VSB-aided conditions at 1 month after surgery. (C) Functional hearing gain compared with stapes coupler vibroplasty group. (D) Effective gain showed improvement at 1 and 2 kHz. AC = air conduction; BC = bone conduction; OW = oval window; Post-OP = postoperative; Pre-OP = preoperative air conduction; VSB = Vibrant Soundbridge.
underwent temporal bone CT before surgery to evaluate middle ear status, and three ossicles were not visible on CT scans. Only one case had normal hearing on the contralateral side of the ear, whereas most of the cases had moderate to severe degrees of mixed hearing loss on the contralateral ear (Table I). AC PTA4 and BC PTA4 of the contralateral ear was 66.2 ± 9.4 dB HL and 42.5 ± 3.8, respectively (Supporting Fig. 2). All cases had been fitted for HAs at least 3 months before surgery; however, no one had experienced satisfied hearing improvement with HAs.

**Surgical Finding**

Surgical findings and reasons for the selection of OW vibroplasty are shown in Table II. Five and three cases had a medical history of open cavity mastoidectomy and canal up mastoidectomy, respectively; one case showed automastoidectomy status due to chronic otitis media. All of the cases showed eroded ossicles, such as missing suprastructures of the stapes. The majority of cases showed a narrow round window niche or membrane, and one case showed typical high jugular bulb. Therefore, round window vibroplasty was not able to be conducted.

Accordingly, we performed a revised mastoidectomy. The mobility of the footplate was confirmed by round window reflex, and all patients showed intact mobility.

**Changes in Hearing Threshold After Surgery**

The preoperative and postoperative pure-tone audiograms are shown in Figure 2A. BC thresholds did not change after implant surgery. Although the overall postoperative AC PTA4 (92.2 ± 9.5 dB HL) did not change after surgery, few patients had a improvement in AC threshold after VSB. Interestingly, AC thresholds were improved without VSB application, mostly at low frequencies in four cases (Supporting Fig. 3). The postoperative BC thresholds were comparable to the preoperative BC values. The mean air-bone gap thresholds seemed to be lower after surgery at low frequencies, although no statistically significant differences were observed.

**VSB-Aided Hearing Threshold**

All audiologic outcomes after surgery are shown in Table III. The VSB-aided PTA4 at 1 month after surgery was 49.9 ± 12.8 dB HL. The VSB-aided auditory

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Fig. 3. Speech intelligibility in a patient with vibroplasty with direct coupling to the oval window. (A, B) Mean preoperative (Pre-OP) and postoperative word recognition score (WRS) at the most comfortable listening (MCL) level (A) and MCL level (B) over time. Preoperative unaided speech test was performed with headphones, whereas postoperative aided conditions were performed with a loud speaker. Bars represent 0.95 confidence intervals and + indicates mean values (*P < .05, ***P < .001). (C, D) WRS at MCL level in Vibrant Soundbridge (VSB)-aided condition was compared with that in preoperative hearing aid (HA)-aided condition (C). MCL level with preoperative HA-aided condition was better than that with VSB-aided conditions in four cases.
threshold was better than the preoperative BC hearing thresholds at 1,000 and 2,000 Hz, although the difference was not statistically significant (Fig. 2A). All nine cases showed a mean functional gain of 44.0 ± 10.6 dB HL (Table III, Fig. 2B). The functional gain with direct OW coupling (41.5 ± 9.8 dB HL) was comparable to that with stapes coupling (37 ± 7.7 dB HL from our previous published data) (Fig. 2C). The effective gain was notable at 1,000 Hz and 2,000 Hz (Fig. 2D). In the comparison of VSB and HA within four cases, the VSB-aided threshold was better than the HA-aided threshold (Supporting Fig. 4).

### Speech Understanding Following VSB

Following VSB implantation, there was a tendency that WRS at MCL was improved, though it was not statistically significant (Fig. 3A). The patients with VSB showed significantly better recognition of words and higher the WRS at the MCL level at 3 months (65.5 ± 27.8%) than 1 month (57.7 ± 25.4%) after surgery ($P < .05$). The preoperative MCL level was 99.3 ± 9.2 dB and changed to 60.9 ± 9.4 dB at 1 month and 58.2 ± 3.8 dB at 3 months after surgery. MCL level was significantly lower after implantation ($P < .001$) (Fig. 3B).

In the comparison of VSB and HA within four cases, the WRS at the MCL level improved in three cases (Fig. 3C), and the VSB-aided MCL level was lower than HA-aided MCL level in all cases (Fig. 3D).

### DISCUSSION

Direct coupling of the FMT to the OW in VSB implantation can be one option in mixed hearing-loss patients. We showed the improvement of hearing outcomes such as effective gain at 1,000 and 2,000 Hz. All cases had a long history of chronic otitis media, which resulted in mixed hearing loss. Combined surgery of canal wall down mastoidectomy and direct coupling of the VSB implantation to the OW can be a good treatment for infection control and hearing loss, simultaneously.

Our previous data showed that the coupling FMT on stapes using a coupler has similar benefits to round window (RW) vibroplasty. If the suprastructures of the stapes are missing, OW vibroplasty with an OW coupler has shown promising hearing outcomes. Busch et al. reported favorable outcomes for OW vibroplasty with an OW coupler. Zehlicke et al. found that direct coupling of the FMT to an OW using the fascia and cartilage should be used as a linkage between the footplate and FMT. Our surgical method is characterized by placement of the FMT of the middle ear implant in direct contact with the stapes footplate without the use of other materials. Our audiologic outcomes of direct coupling the FMT onto the footplate were similar to those of vibroplasty using a stapes coupler (data previously published) (Fig. 2C). Moreover, our data on functional outcomes appeared to be more promising than previously published data, especially at 1,000 and 2,000 Hz. In the literature, Busch et al. showed effective gains with various coupling methods, including the OW coupler, and our data of effective gain were comparable at 1,000 and 2,000 Hz.

OW vibroplasty offers additional benefits above RW vibroplasty in the audiological point. The connection between drum and footplate improves AC hearing similar to ossiculoplasty. Four out of nine cases had a better postoperative unaided AC threshold, compared to preoperative AC PTA (Fig. 3). As their pre- and postoperative BC thresholds were not changed from surgery, suggesting the absence of inner ear damage during surgery, VSB is safe to reconnect a drum and footplate.

WRS at the MCL level is not significantly changed after hearing aid fitting. However, we previously reported improvement in WRS at the MCL level in downsloping sensorineural hearing loss patients with VSB, compared to conventional HAs. We suspect that sufficient functional gains at high frequencies to understand consonant sounds may improve WRS at the MCL level. Moreover, the consistent auditory stimulation of hearing loss frequencies may result in the stimulation of the auditory cortex, and central adaptation may improve speech intelligibility. In terms of speech intelligibility, we failed to show the statistically significant improvement in WRS at the MCL level after direct coupling of a VSB to the OW (Fig. 3B). However, we observed that long-term fitting of VSBs progressively increased WRS at the MCL level.

In addition, we previously described MCL level improvement with VSB in sensorineural hearing loss. Lowering the MCL level is important to helping facilitate communication with others and to reducing conversation handicaps. Our data indicated significant improvement in MCL level after direct coupling to the OW. Improvements of 1 and 2 kHz have been found in previous reports to be significantly correlated with lowering the MCL level, which was also correlated with our current data.

Direct coupling of the FMT on to the footplate has an anatomical advantage, compared to OW vibroplasty using a coupler. Because the middle ear space is too shallow for a canal wall down technique, there is not enough space for the assembly of coupler/FMT/supporting cartilage, which leads to the instability of the FMT. Parra et al. showed the depth of OW niche was 1.7 ± 0.2 mm in 101 ears. The FMT is 2.3 mm in length and the usual size of the OW coupler is 2.5 mm, which means to conduct appropriate OW vibroplasty need more than 4.8 mm space in the middle ear is needed. Because direct coupling needs much less space, FMT is more stable than a technique using a coupler. In addition, shallow space may lead to an unventilated condition after the surgery. Schwab et al. also indicated that an unventilated condition eventually leads to extensive granulation of the middle ear.

One anatomical issue that should be solved for the direct coupling of the FMT onto the footplate is that the size of the OW is sometimes not enough for fitting an FMT. According to temporal bone dissection studies by Mancheno et al., OW width enabled direct fit in the footplate in only 55% of temporal bones. Although we can obtain more space for the FMT by drilling the facial nerve canal or promontory area, we agree that FMTs are still too large for direct coupling onto the OW in some cases. Another concern regarding direct stimulation to a stapes footplate is the mobility thereof. Therefore, confirming...
the mobility of the stapes footplate by checking the round window reflex is mandatory during OW vibroplasty.

CONCLUSION

Direct coupling of an FMT onto the stapes footplate without a coupler is a reliable procedure, and is a good option for hearing rehabilitation in mixed hearing loss patients who have undergone canal wall down mastoidectomy and pose difficulties in RW vibroplasty.

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