

# Tinnitus and quality of life after round window vibroplasty

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## Abstract

**Objective:** To measure the Quality of Life outcomes and impact on tinnitus perception in a group of patients after Round Window Vibroplasty (RW-VSB) for mixed or conductive hearing loss. Study design: A single-subject, repeated measures design was employed. All VSB fittings were based on hearing thresholds results and were not set to mask tinnitus. **Methods:** Ten Round Window-Vibroplasty patients were assessed with the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Tinnitus Reaction Questionnaire (TRQ). **Results:** Subjects reported less hearing difficulties in 3 of 4 APHAB subscales. Tinnitus perception was decreased in all subjects with tinnitus pre-operatively. **Conclusion:** Round window vibroplasty in our cohort of patients with mixed or conductive hearing improved quality of life outcomes. There was significant improvement on APHAB scores and a significant decrease in tinnitus perception in subjects experiencing tinnitus prior to implantation.

**Keywords:** hearing loss, ossicular prosthesis, tinnitus.

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## INTRODUCTION

The Floating Mass Transducer, (MedEL, Innsbruck Austria) was initially coupled to the Incus to treat patients who were unable to wear a conventional hearing aids or who were dissatisfied with their hearing aid/s because of issues such as poor sound quality, feedback and/or occlusion effect. Vibrations of the Floating Mass Transducer (FMT) results in movement and sound transmission to the cochlea via the ossicular chain. Incoming sounds are transmitted to the FMT via an externally worn sound processor. After the initial round window vibroplasty by Colletti et al.<sup>1</sup>, various types of FMT coupling modalities have been developed, termed as vibroplasty. In round window vibroplasty, the FMT is placed onto the round window membrane in patients with a conductive or mixed hearing loss who cannot wear conventional hearing aids. By bypassing the pathologic outer and/or middle ear, vibrational sound energy is transmitted directly to the cochlea to compensate for the conductive and/or sensorineural component of the hearing loss.

The improvement in speech perception and access to sound with RW-vibroplasty has been demonstrated in many studies<sup>1-5</sup>. The only study to date that has examined quality of life improvement with VSB use for those with conductive or mixed hearing loss is Baumgartner et al.<sup>3</sup>.

It is estimated that approximately 33% of people experience tinnitus<sup>6</sup> and that 10-20% of this sub-set of people, experience debilitating/crippling tinnitus<sup>7</sup>. It is estimated that 70-85% of the hearing impaired population experience some variety of tinnitus<sup>8</sup> and that prevalence rates are higher with increased hearing loss<sup>9</sup>. For people affected by conductive hearing loss, 35% have been found to have tinnitus<sup>10</sup>. Tinnitus varies in disturbance level from non-bothersome to a disabling condition.

The aims of this study were to measure the QOL outcomes in a group of patients after RW-vibroplasty for a mixed and conductive hearing loss using the APHAB and the Tinnitus Reaction Questionnaire (TRQ). To date, there is no study of VSB outcomes which have examined the benefits of device use on tinnitus perception.

## METHODS

After IRB approval patients were prospectively enrolled into the study. The audiological inclusion criteria were as follows: (1) Sensorineural hearing thresholds better than 45 dBHL at 500 Hz, 50 dBHL at 1000 Hz and 65 dBHL at 2000 and 4000 Hz, (2) scores of 50% or above on a monosyllabic word test at a comfortable listening level in the ear undergoing implantation, and (3) a stable hearing loss. In addition, all patients had trialed an optimized hearing aid in the ear chosen for implantation.

### Audiological testing

Each subject served as his or own control in a single test protocol comparing the effects of the VSB to results attained in the unaided and in the conventionally aided hearing conditions.

Results were obtained for all patients, including those who could not tolerate consistent use of a hearing aid. If a subject had a bilateral hearing loss, then both ears were fitted pre-operatively with conventional hearing aids. Aids were fitted or adjusted to best meet targets according to the NAL-NL1 prescription<sup>11</sup> taking into account the conductive component. Speech testing was conducted using pre-recorded speech material and presented in a sound booth. The sound booth, audiometer and free-field speakers were calibrated to the relevant ANSI standard.

### Speech recognition in quiet

Monosyllabic word test at 65dB SPL was conducted in the following conditions: (1) implanted ear unaided, (2) implanted ear aided with the conventional hearing aid used pre-operatively and (3) implanted ear wearing the VSB. In all three conditions, the contralateral ear was effectively masked.

### Speech in noise testing

The Australian adaptive BKB sentence test version was used in four speaker multi talk babble setup. The patient sat at an equidistance of 1m from two speakers, placed at 0° azimuth and either 90° or 270° azimuth. The target sentences were consistently presented at 0 azimuth at 65dB SPL. The four speaker multi talk babble was varied in 1dB steps until the subject achieved a score ranging between 48-52% (or as close as possible). The resulting signal-to-noise ratio was recorded for all three listening conditions i.e. S0N0, S0N90, S0N270. Percentage scores were then obtained post-operatively while employing the pre-operative signal-to-noise ratio, so that the percentage change in pre- and post-operative performance could be compared<sup>12,13</sup>.

### Quality of life and tinnitus disturbance measures

These were administered pre-operatively and at 1, 3, 6 and 12 months post-operatively.

1. The APHAB- Version A<sup>14</sup>, is a standardised 24 item self-assessment inventory in which the subject reports the degree of difficulty they have with communication and perception of environmental sounds. The questionnaire's outcomes are divided into four subscales: ease of communication (EC), background noise (BN), reverberation (RV); and aversiveness (AV). The subscales EC, BN and RV are used to look at speech understanding in everyday situations. The AV scale looks at negative reactions to environmental sounds.

2. The TRQ<sup>15</sup> was used to assess the degree of disturbance that the tinnitus experienced by the subjects has impacted on their well being, emotions, and lifestyle. The TRQ was also completed before and after surgery in order to compare the post-operative outcomes. With the TRQ a maximum score of 104 and a minimum score of 0 can be reached.

All post-operative testing was conducted at 1, 3, 6 and 12 months, with the most recent results being the post-operative score. The latter was compared to the pre-operative results.

## Data analysis

### **Quality of life measured by the APHAB**

The data distribution of the APHAB Global scale and its four subscales of the individual subjects are shown in graphs. The subjective benefit was measured using the APHAB at different test intervals after implantation and compared to the pre-operative acoustic hearing condition. To detect differences between the pre-operative test results and the most recent post-operative testing, the non-parametric Wilcoxon signed-rank test was applied. The Kolmogorov-Smirnov test was used before to check the data distribution.

To determine also the clinical relevance, a benefit score of the APHAB was assessed, according to the method of Cox & Alexander<sup>14</sup>. The benefit score was calculated by subtracting the aided average (most recent post-operative score) from the unaided average (e.g. pre-operative score). If the difference in benefit scores on the 3 subscales EC, RV, and BN were at least 10% (difference in mean) greater for the respective test

strategy, it can be concluded from the clinical perspective that this difference reflects a true benefit with a 95% probability.

### **Tinnitus disturbance results**

To detect differences between the pre-operative test results and the most recent post-operative testing, the non-parametric Wilcoxon signed-rank test was applied. The Kolmogorov-Smirnov test was used before to check the data distribution.

## RESULTS

A total of 10 patients (7 females and 3 males) were included in the study. Average age of subjects at surgery was 55.45 (SD: +/- 15.84, range of 25.97 - 78.55) years. The average age of the male subjects was 49.7 years and for the female subjects 57.9 years. Four subjects had a pure conductive hearing loss whereas 6 had a mixed hearing loss in the ear considered for implantation. Subjects could not derive benefit from conventional hearing aids because of chronic otitis externa (1, 5-10), blind sac closure (2), pain associated with hearing aid mould use (3), and severe to profound mixed hearing loss (4). Nine subjects had the round window placement in modified radical cavities and one subject (4) was implanted using the facial recess approach. Fascia or perichondrium was used to stabilise the implant in the round window niche and the cable was fixed into a groove in the mastoid with bone pate and soft tissue flaps for cavity obliteration and coverage of the conductor link. See Table 1 for details.

**Table 1.** Subjects' pathology, surgical and audiological characteristics.

Subj No.	Age (yrs)	Pathology	Surgeries (no.) Pre- VSB	VSB Surgical Technique	VSB Experience (mths)	VSB experience post-revision (mths)	Bone Conduction	Air Conduction	4 FAHL (dBHL)
1	51	CSOM	2	RW in MRC	25		18	58	
2	59	CSOM	4	RW in MRC	22		10	41	
3	38	*	CSOM	3	RW in MRC	8	17	9	58
4	66	Otoscl	1	Facial Rec	24		38	101	
5	25	*	CSOM	2	RW in MRC	12	11	23	70
6	60	+	CSOM	1	RW in MRC	4		21	68
7	55		CSOM	4	RW in MRC	14		29	68
8	46	CSOM & Otoscl	4	RW in MRC	9		20	51	
9	72	*	CSOM	2	RW in MRC	0	12	21	78
10	78	\$	CSOM	3	RW in MRC	1	12	40	91

VSB Surgical Technique Employed; 1: Facial recess approach to round window (Facial Rec); 2: Round Window placement in modified radical cavities (RW in MRC); Age (years); Experience with VSB (months); Experience with VSB post revision surgery; Four Frequency Average (4FAHL) of Implanted Ear; Bone and Air Conduction. CSOM (Chronic Suppurative Otitis Media). Otoscl (Otosclerosis) \* required revision surgery with successful outcomes; + required device explantation; \$ intermittent device functioning pre- and post-revision surgery.

The mean hearing loss in the implanted ear using the four frequency average of air conduction thresholds was 68.25 dB (SD: +/- 18.12 dB). The average bone conduction thresholds were 22.75 dB (SD: +/- 10.26) in the implanted ear.

Three of the 10 patients (subjects 3, 5 and 10) in this study required revision surgery either because of FMT displacement or device failure in one subject (subject number 10). In all cases the progressive loss of hearing related to the FMT migration occurred between 3 and 6 months after surgery. Following revision surgery, subjects 3 and 5 had success with the device, whereas subject 10 experienced intermittent sound with the VSB.

Initial testing indicated excellent results for Subject 6. While the skin over the receiver coil was thin, it was intact and there were no indications of infection. After a period of four months, she experienced a severe flare of her rheumatoid arthritis, for which she was prescribed a high dosage of steroids. This led to wound break down over the already thin skin on the receiver coil which resulted in infection in the surrounding area. Treatment (including use of a hyperbaric chamber) was unsuccessful and the implant required explantation.

Subject 1 reported a "static like" noise when he was in close proximity to the telecommunication centre at his work and when walking through department store security doors.

There was no significant deterioration ( $P < 0.05$ ) in the four frequency averaged bone conduction results at 500, 1000, 2000 and 4000 Hz pre-operatively compared to post-operatively pre- versus post-operative bone conduction results. Overall subjects with successful outcomes with the VSB, attained aided thresholds in the free field (where the contralateral ear was masked) of 40 dBHL or better from 500 to 4000 Hz.

Speech Perception in Quiet showed that there is a significant difference ( $P < 0.05$ ) between unaided speech test results and being aided either with a hearing aid or VSB. There was no significant difference ( $P = 0.979$ ) between speech test results when aided with a hearing aid or the VSB. Averaged scores varied from 25.5%, to 91% to 93% in the unaided, conventionally aided with hearing aid and VSB aided conditions respectively. Speech Perception in Noise results indicate a trend for subjects to have better scores when using their VSB compared to their conventional hearing aid in the following listening conditions: (1) Speech and Noise from in front, (2) Speech present in front (noise to implanted ear), and (3) Speech present in front (noise to contralateral ear).

In Table 1, individual mean APHAB percentage scores for the Global score and for the EC, RV, BN, and AV subscales are shown for the pre-operative testing and for

the most recent post-operative testing. The improvement between the pre-operative test condition and the most recent post-operative test condition for the Global score and for the subscales was statistically significant and showed a tendency to statistical significance, respectively (Global score:  $P = 0.043$ ; EC:  $P = 0.018$ ; RV:  $P = 0.043$ ; BN:  $P = 0.063$ ). However, no significant improvement was reached for the AV subscale ( $P = 0.310$ ).

Using the method of Cox & Alexander<sup>14</sup> to evaluate the clinical relevance of the device, the mean differences in benefit scores on the 3 subscales EC, RV and BN between pre-operative testing and the most recent post-operative test results were higher than 10% (30%, 25%, and 22%, respectively) and thus reflected with 95% probability a true benefit of the VSB. The AV subscale was not significant from a clinical perspective according to the method of Cox & Alexander.

For the four subjects (subjects 3, 4, 5, 6) experiencing tinnitus pre-surgery, all experienced a decrease in their perceived tinnitus levels. Subjects 3, 4 and 5 demonstrated clinically significant tinnitus level pre-operatively with scores above 17. A score of 17 is taken as the lowest score for the tinnitus to be considered clinically significant. No subjects had an increase in their tinnitus disturbance (Table 2).

The overall decrease in perceived tinnitus between the pre-operative test condition and the most recent post-operative test condition was statistically significant (Wilcoxon signed-rank test:  $P = 0.018$ ).

## DISCUSSION

Baumgartner et al.<sup>3</sup> compared pre- vs. post-operative results using the APHAB and found that for the 12 subjects who underwent RW-vibroplasty, there was on average a statistically significant improvement on the EC, RV and BN subscales. There was no significant change in the average AV subscale. Significant improvements were also reported on the Hearing Device Satisfaction Scale with a mean improvement from 43% pre-operatively to 74% post-operatively.

Our results are in line with the previous report and indicate that for the majority of subjects, the VSB provided improvements in QOL outcomes. Significant improvements were evidenced for the EC, BN and RV subscales of the APHAB. Particular similarity to Baumgartner's study was observed in the Aversiveness subscale (see table 2). Scores on the aversiveness sub-scale did not increase but decreased slightly. It is expected that with greater access to sound, the tolerance to louder sounds either decreases or remains unchanged. Baumgartner et al.<sup>3</sup> found that aversiveness scores remain unchanged however postulate that this is because of ceiling effects as pre-operatively subjects did not report any problems with sound tolerance.

**Table 2.** Comparison of APHAB scores attained from this study compared to results from the Baumgartner et al., 2010 study.

SubScale	Ease of Communication		Background Noise		Reverberation		Aversiveness	
% Score Pre-Op	66 #	42 *	73 #	52 *	72 #	53 *	30 #	31 *
% Score Post-Op	28 #	14 *	40 #	34 *	40 #	31 *	35 #	26 *
% Change	-38 #	-28 *	-33 #	-18 *	-32 #	-22 *	+5 #	-5 *

# Baumgartner et al., 2010 results; \* This Study's results.

In this study, there were no reported post-operative symptoms such as fullness, taste disturbance or vertigo as found in other studies<sup>16,17</sup>. One subject experienced interference when in close proximity to a telecommunications centre at his workplace and when traveling through security doors. No other study has reported this occurrence. This client may have been particularly sensitive to small changes in FMT positioning causing by changes in external electromagnetic fields.

Three of the 10 patients in this study required revision surgery either because of FMT migration or device failure in one subject (10). Baumgartner et al.<sup>3</sup> also reports migration of the FMT in the round window application of the VSB in one of the twelve subjects. This migration was rectified by device re-positioning. However, results from the Vienna study extended to 3 months post-surgery, whereas in the current study, results extended to 25 months post-surgery. All the subjects requiring revision surgery had undergone at least two mastoid surgeries prior to the VSB surgery and had an underlying Eustachian tube dysfunction. According to Dumon et al.<sup>4</sup> the middle ear function can help gauge the potential of FMT migration, subsequently as a result, we know to routinely reinforce the fascial packing of the FMT with cartilage in middle ears with poor Eustachian tube function in order to eliminate future migration. This so far has been effective and has avoided the need for further revision in our cohort.

Current research indicates that use of amplification devices such as hearing aids can help diminish tinnitus disturbance<sup>18</sup>. Therefore, it was hypothesized that use of the VSB could diminish tinnitus disturbance because of increased amplification of external noise. With less effort required to hear, it was expected there would also be less associated stress which could assist in tinnitus perception.

Scores on the TRQ improved for all 3 subjects experiencing clinically significant tinnitus (scoring 17 + on the TRQ). This positive benefit is a new observation in vibroplasty. The proposed mechanism for this tinnitus reduction is the increase in the level and frequency range of background sounds received by the cochlea<sup>19</sup>. Hearing aids improve understanding of speech and thereby decrease the "strain to hear" phenomenon and decrease the attention given to the hearing problems and tinnitus<sup>19</sup>.

Stimulation via hearing aids and the VSB could be effective in tinnitus reduction because of functional changes occurring in parts of the auditory system due to a decrease in auditory stimulation. It is believed that auditory deprivation induces cortical reorganization<sup>20</sup> and a dysfunctional process of adaptation might be involved in tinnitus generation<sup>21</sup>. Amplification devices can stimulate cerebral plasticity and partly re-establish the proper functioning of auditory nerve pathways limiting one of the likely causes of tinnitus<sup>18</sup>.

Subject 4 had a pre-operative tinnitus score of 87 which decreased to 68 post-operatively. This subject had the greatest air conduction loss present of all the subjects presenting with tinnitus and a history of otosclerosis. Hearing loss and otosclerosis have been found to be a risk factor for tinnitus incidence<sup>9</sup>. Folmer & Caroli<sup>22</sup> found significant tinnitus reduction in a group of 50 subjects who used hearing aids for their tinnitus, after they had used their aids for an average of 18 months. However, this does not hold true for Subject number 4 who had used the device for 24 months.

For future patients undergoing VSB surgery for their mixed or conductive hearing loss, it is recommended that they undergo tinnitus counseling prior to surgery. While no subjects in this study or any other known study have undergone RW-vibroplasty for debilitating tinnitus, it would be worthwhile to give people some understanding about the possible impact on their tinnitus as soon as possible. This subset of the hearing impaired population is unable to wear conventional hearing aids which may give them some tinnitus relief through acoustic stimulation. They are also not good candidates for tinnitus treatments such as the Neuromonics program<sup>23</sup> because of the severity of their hearing loss.

In this study, 66% (2 of the 3) of the subjects reporting tinnitus pre-operatively had a reduction of their tinnitus perception after VSB implantation. In comparison, Surr et al.<sup>24</sup> found that approximately 50% of new hearing aid users reported relief from tinnitus. It could be construed that the VSB-RW application is more effective in tinnitus reduction than conventional aids however the small sample size of this study limits any possible general conclusions. Holgers & Håkansson<sup>10</sup> found that the use of a Baha (Bone anchored hearing aid) for people with conductive hearing losses was useful in reducing tinnitus. This may be related to the absence

of occlusion effect, which is also achieved with VSB. Occluding hearing devices can in some tinnitus sufferers, in particular, in people with good low frequency hearing increase the perception of tinnitus<sup>25,26</sup>.

## CONCLUSION

Round window vibroplasty can improve quality of life in various dimensions in patients with mixed or conductive hearing loss who are not suitable for conventional hearing aids. In addition it can provide significant benefits in tinnitus control. These properties together with the established benefits in hearing performance offer these challenging patients an effective hearing rehabilitation.

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