

VIBRANT SOUND BRIDGE- A CLINICAL STUDY

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Introduction

The Vibrant Soundbridge is the first FDA-approved implantable middle ear hearing device to treat sensorineural hearing loss, and has been implanted in thousands of patients worldwide. It is a partially implantable middle ear hearing device initially developed by Geoff Ball (1996). The Vibrant Soundbridge is a semi-implantable hearing aid consisting of two parts: the speech processor worn externally, and the implantable vibrating Ossicular prosthesis. The vibrating ossicular prosthesis is surgically placed subcutaneously in the postauricular area. The Floating Mass Transducer (FMT) is connected to the internal receiver, and is attached to the stapes. The FMT is a unique electromagnetic transducer that consists of a magnet of inertial mass within two electromagnetic coils. When activated, the magnet mass vibrates within the FMT between the two coils; causing the entire unit to vibrate. Titanium strips are attached around the long process of the incus to hold the device in place. The FMT is oriented in the direction of the stapes; so that the device vibrates directly into the inner ear, parallel to the plane of the stapes. The external auditory processor is held in place over the internal receiver by a magnet.

The auditory processor contains a microphone that picks up sound from the environment and converts it into an electric signal. The auditory processor is contained within the external unit, which also contains an induction coil to transmit the electric signal to the internal vibrating ossicular prosthesis. A receiving coil picks up the signal and transmits it to the FMT, causing it to vibrate, which stimulates the cochlea. Placement of the internal device requires an outpatient mastoidectomy similar to cochlear implantation. The facial recess is widely opened to visualize the incudostapedial joint, and to allow the FMT to pass through easily. The FMT is crimped onto the incus after the vibrating ossicular prosthesis is embedded in the cortical bone; in a seat behind the mastoid posterior to the sigmoid sinus. The surgery lasts for about 2 to 2.5 hours. The external processor is attached 6 weeks after

surgery, at which time the device is programmed. Clinical trials for the Vibrant Soundbridge began in 1996, and the device was approved by the FDA in 2000.

Need for the study

Clinical evidence describes that the value of VSB devices as tools for the rehabilitation of sensorineural hearing loss is copious. VSB is an upcoming middle ear implant procedure for patients with moderate to severe sensorineural hearing loss. It has now gained popularity in India and the present study focuses on highlighting the effectiveness of VSB in the clinical population in an Indian scenario.

Aim

The aim of this study is to hypothesize the effectiveness of Vibrant Sound Bridge (VSB) in the rehabilitation of persons with sensorineural hearing loss in Indian population:

- 1) To compare the pre and post operative audiometric threshold.
- 2) To determine the Functional Gain provided by the Vibrant Sound Bridge in different frequencies.

Methodology

The aim of this study is to hypothesize the effectiveness of Vibrant Sound Bridge (VSB) in the rehabilitation of persons with sensorineural hearing loss in Indian population:

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- 2) To determine the Functional Gain provided by the Vibrant Sound Bridge in different frequencies.

Subjects

A total of ten subjects from different parts of India; who met the selection criteria for the middle ear implant (Vibrant Sound Bridge) were chosen to be the potential subjects for the unilateral VSB implant surgery. In general, middle ear implants are best suited for persons diagnosed as having mild to severe sensory neural hearing losses or mixed losses.

Selection Criteria

The patients were selected on the basis of the following criteria:

- 1) No prior history of middle ear dysfunction (OME, Ossicular chain discontinuity, No recurrent ME infections).
- 2) The audiometric Air conduction threshold should not exceed beyond the given intensities in the following frequencies: 500Hz-65dB,1000Hz-75dB,2000Hz-80dB,4000Hz-85dB)
- 3) A minimum of at least 50% of Speech Recognition ability is mandatory.
- 4) There should be no signs or indications of retrocochlear and central auditory disorders.

Instruments Used and the Test Environment

The study was typically carried out in a sound treated room; wherein the pure tone average thresholds of the patients were measured using Elkon EDA 3N3 multi audiometer which was calibrated according to the ANSI standards. A baseline audiogram was taken prior to the surgery and a second audiogram was taken eight weeks post surgery and the differences amongst them were compared. The VSB audio processor404 was programmed on the basis of the post operative audiometric thresholds and the pure tone average threshold were measured in the free field henceforth. The functional gain provided by VSB was thereby measured. The results were then analyzed by means of a detailed statistical analysis (Paired sample t-Test).

Results

A baseline audiogram was carried out in all subjects prior to the implantation surgery. The post surgery audiogram; which was taken eight weeks later was then compared with the baseline audiogram. The results revealed a minor difference in the hearing thresholds i.e. the hearing thresholds seemed to be slightly worse when compared to the pre operative audiogram because of increase in the mass load on the ossicles as a result of the Floating Mass Transducer placement on the long process of incus. A paired sample T-test was carried out to compare the results of pre and post audiogram. The statistical analysis revealed significance differences between pre and post surgery thresholds at all frequencies (250, 500 & 1000 Hz – 7 dB; 2000 Hz- 8 dB; 4000 Hz – 7.5 dB) as tabulated (Table 1 & 2) and explained in Figure 1 shown below. Fisch, Cremers, Lenarz, Weber, Babighian, Uziel et al. (2001) measured pre and post surgery thresholds in patients using Vibrant Sound Bridge. It

was found that the mean threshold changes were less than 5 dB across all frequencies. They concluded that the Vibrant Sound Bridge device can be used safely in the treatment of patients with moderate to severe sensorineural hearing loss.

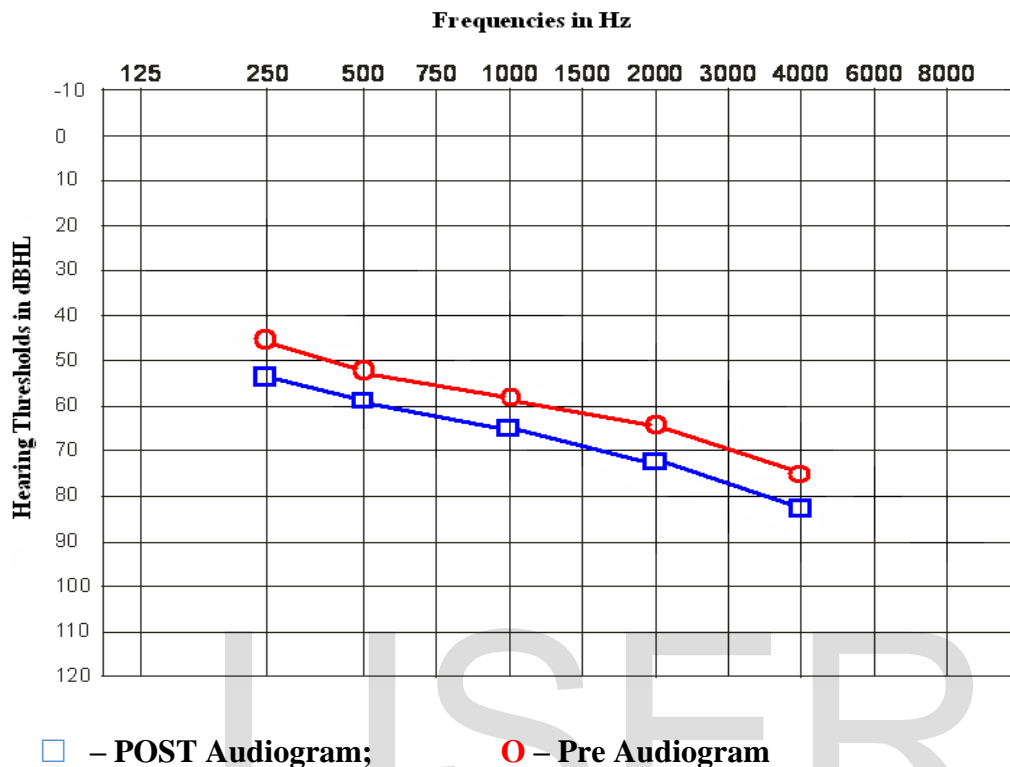


Figure 1: Depicting the pre- and post-operative audiogram

Frequency	Pre-Audiogram	Post-Audiogram
250 Hz	45.50	52.50
500 Hz	51.50	58.50
1000 Hz	57.50	64.50
2000 Hz	64.00	72.00
4000 Hz	75.50	83.00

Table 1: Pre and Post operative audiometric hearing thresholds

Paired Sample t-Test

Condition	Paired difference		T-Value	DF	Sig
	Mean	SD			
Post-Audiogram – Pre-Audiogram (250 Hz)	7.0000	4.2164	5.250	9	*
Post-Audiogram – Pre-Audiogram (500 Hz)	7.0000	3.4960	6.332	9	*
Post-Audiogram – Pre-Audiogram (1000 Hz)	7.0000	4.2164	5.250	9	*
Post-Audiogram – Pre-Audiogram (2000 Hz)	8.0000	4.2164	6.000	9	*
Post-Audiogram – Pre-Audiogram (4000 Hz)	7.5000	3.5355	6.708	9	*

(* - Significant Difference)

Table 2: Paired sample t-Test comparing the pre- and post- operative audiometric hearing thresholds

In order to find out the functional gain of Vibrant Sound Bridge, the audio processor was programmed based on the post operative audiogram. The functional gain of the VSB was measured by comparing the post operative audiogram with aided VSB in free field audiogram. This is evident in the following audiogram (Figure 2) and is further explained in the tabulate given below (Table 3). A statistical analysis was carried out using the Paired Sample T-test to compare the outcomes between post operative and Aided VSB thresholds. Results revealed a significant difference at 1% ($P < 0.01$) level in the Paired sample t-Test as can be seen in Table 4.

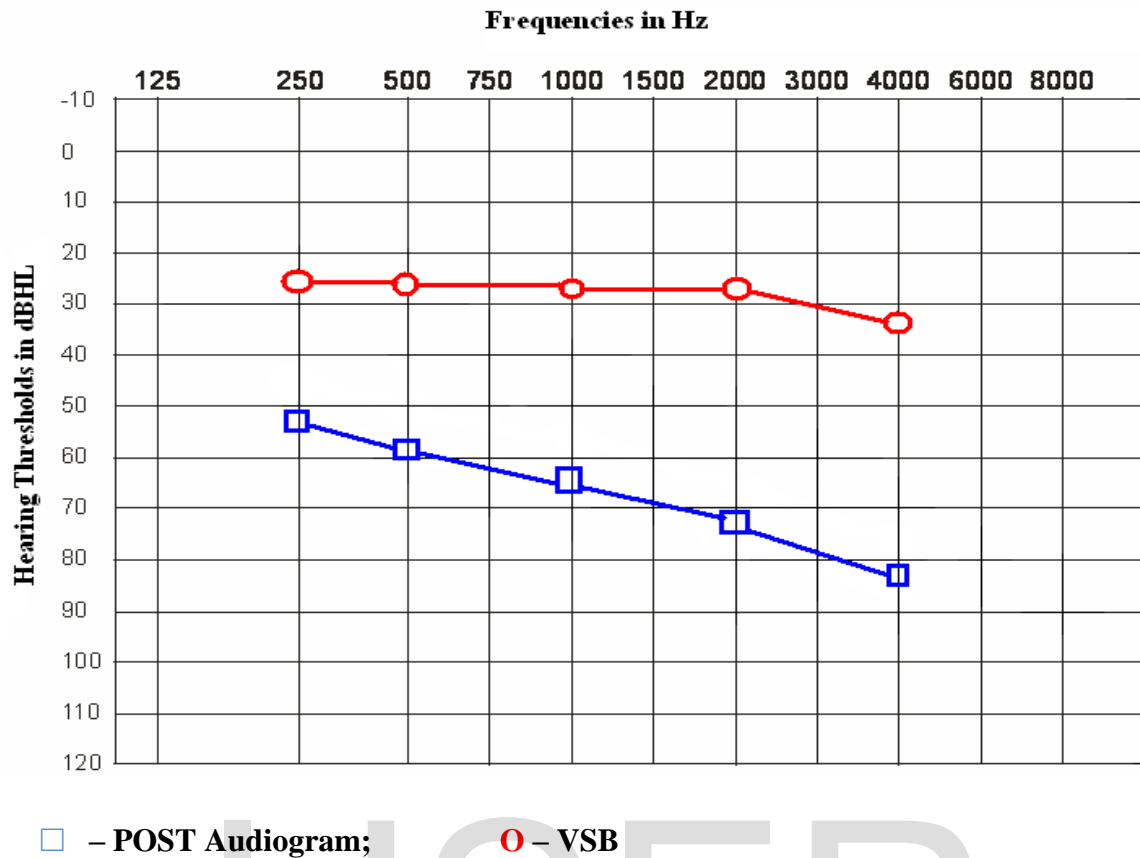


Figure 2: Depict the Vibrant Sound Bridge and Post-operative audiogram

Frequency	Post Audiogram	VSB
250 Hz	52.50	26.00
500 Hz	58.50	26.50
1000 Hz	64.50	27.00
2000 Hz	72.00	27.50
4000 Hz	83.00	33.00

Table 3: Post-operative & Vibrant Sound Bridge audiometric hearing thresholds

Paired Sample t-Test

Functional Gain	Paired difference		T-Value	DF	Sig
	Mean	SD			
Post-Audiogram – VSB (250 Hz)	26.5000	6.6875	11.207	9	*
Post-Audiogram – VSB (500 Hz)	32.0000	4.8305	20.949	9	*
Post-Audiogram – VSB (1000 Hz)	37.5000	11.3652	10.434	9	*
Post-Audiogram – VSB (2000 Hz)	44.5000	8.3166	16.920	9	*
Post-Audiogram – VSB (4000 Hz)	50.0000	8.4984	18.605	9	*

(* - Significant Difference)

Table 4: Paired sample t-Test between Post-operative & Vibrant Sound Bridge audiometric hearing thresholds

Discussion

This study has documented that the new VSB middle ear implant system is a safe and an effective choice for the treatment of moderate to severe sensorineural hearing loss patients. As can be seen in the present study, there seems to be a significant difference in the functional gain across all test frequencies when using the VSB implant. These results happen to correlate well with the findings of Luetje, Brackman, Balkany, Maw, Baker, Kelsall et al. (2002); who in their study found that a majority of patients happened to be satisfied or very satisfied with the VSB system.

The clinical findings of the current study seems to show that there was a slight decrease in the post operative hearing thresholds; owing to the increased mass in the ossicles; i.e. long process of stapes. However, the difference in the thresholds may be statistically significant but clinically insignificant; due to limited sample size. These conclusions seems to be in harmony with the results obtained from a longitudinal study carried out on the post operative hearing thresholds with the VSB system; wherein they found a statistically

significant difference in the hearing thresholds (pre-versus post operative) for frequencies of 0.5 and 4 kHz. (Vincent, Fraysee, Lavieille, Truy, Sterkers & Vaneecloo 2004). Also, the maximum functional gain was measured at high frequencies; which therefore indicates VSB to be a good option for patients with sensorineural hearing loss.

Similarly, research findings done by Sterkers, Boucarra, Labassi, Bebear, Dubreuil, Frachet et al. (2003) describes the VSB system to be an excellent choice of treatment for patients with sensorineural hearing impairment; with a wide range of characteristics.

Hence, in a nutshell, the above studies seem to prove the efficacy of the Vibrant SoundBridge middle ear implant system to achieve improved functional gain in potential candidates having a sloping sensory neural hearing loss; who are either not satisfied or would not benefit from conventional amplification devices. Nonetheless, it is important to keep in mind the fact that the sample size chosen for the given study is not clinically significant and that these results are bound to variations with differing sample size and other parameters.

Summary & Conclusion

The primary objective of the study is to highlight the clinical significance of the VSB in Indian population. This study proves to be an effective tool to carry out further research in the field of middle ear implants in India; as this one of the first study that attempts to emphasize the emergence of direct drive system for sensory neural hearing loss patients in our country. The present study was carried out with a total of ten patients; who were potential candidates for the unilateral VSB implant surgery. These patients were selected on the basis of selection criteria for the middle ear implant. i.e. they should have no prior history of external or middle ear infections, their speech recognition scores should not be worse than 50% and also their hearing loss should neither be retrocochlear nor should be progressive in nature.

A pure tone audiogram was taken pre- and post- operatively to identify any changes in the hearing thresholds of these patients across the frequency ranges. There seemed to be a negligible shift in the thresholds; within 7 dB at all frequencies; as a result of the increased mass in the ossicles due to the placement of the Floating Mass Transducer. Also, a paired sample t-test was done to determine the functional gain using the VSB implant.

Results indicated that there was a significant increase in the functional gain in all the patients using the VSB implant. Therefore, it could be seen that the direct drive systems such

as that of the Vibrant SoundBridge provided significantly larger functional gains; which is especially suitable for patients with sloping sensory neural hearing loss; of mild to severe degree.

In conclusion, it can be said that the Vibrant SoundBridge direct drive middle ear implants are a safe and efficient alternatives for patients with sensory neural components of varying degree.

References:

1. Andreas, A., Christof, S., Claudia, C., Flurin, P. & Martin, K. (2010). Factors Improving the Vibration Transfer of the Floating Mass Transducer at the Round Window. *Otology & Neurotology*, 31(1), 122-128.
2. American National Standards Institute (ANSI). ANSI S3.6-1969 (R1989). *American National Standard Specifications for Audiometers*. New York: ANSI.
3. American Speech Language Hearing Association (1997). Alpiner, J. G & McCarthy, P. A. (2000). *Rehabilitative Audiology Children and Adults* (3rd ed.). Washington: Lippincott Williams & Wilkins.
4. American Speech Language Hearing Association (1998). Alpiner, J. G & McCarthy, P. A. (2000). *Rehabilitative Audiology Children and Adults* (3rd ed.). Washington: Lippincott Williams & Wilkins.
5. Ball, G (2010). The vibrant soundbridge: design and development. *Adv Otorhinolaryngol*, 69, 1-13.
6. Beleites, T., Neudert, M., Beutner, D., Huttenbrink, K. B. & Zahnert, T. (2011). Experience with vibroplasty couplers at the stapes head and footplate. *Otol Neurotol*, 32(9), 1468-1472.
7. Bernardeschi, D., Hoffman, C., Benchaa, T., Labassi, S., Beliaeff, M., Sterkers, O., Grayeli, A. B et al. (2011). Functional results of Vibrant Soundbridge middle ear implants in conductive and mixed hearing losses. *Audiol Otol Neurotol*, 16(6), 381-387.
8. Boheim, K., Nahler, A. & Schlogel, M. (2007). Rehabilitation of high frequency hearing loss: use of an active middle ear implant. *HNO*, 55(9), 690-695.
9. Dazert, S., Shehata- Deiler, W. E., Deiler, R., & Helms, J. (2000). Vibrant Soundbridge middle ear implant for auditory rehabilitation in sensory neural hearing loss. *Laryngorhinootologie*, 79 (8), 459- 64.
10. Eric, T., Benedicte, P., Jean-Francois, V., Samia, L. & Lionel, C. (2008). Vibrant Soundbridge Versus Conventional Hearing Aid in Sensorineural High Frequency Hearing Loss: A Prospective Study. *Otology & Neurotology*, 29 (5), 684-687.

11. Fisch, U., Cremers, C. W., Lenarz, T., Weber, B., Babighian, G. & Uziel, A. S. (2001). Clinical experience with the Vibrant Soundbridge implant device. *Otol Neurotol*, 22(6), 962-972.
12. Fraysse, B., Lavieille, J. P., Schmerber, S., Enee, V., Truy, E., Vincent, C et al. (2001). A multicenter study of the Vibrant Soundbridge middle ear implant: early clinical results and experience. *Otol Neurotol*, 22(6), 952-961.
13. Frenzel, H., Hanke, F., Beltrame, M., Steffen, A., Schönweiler, R. & Wollenberg, B. (2009). Application of the vibrant soundbridge® to unilateral osseous atresia cases. *The Laryngoscope*, 119(1), 67-74.
14. Isabelle, M., Olivier, S., Didier, B., Samia, L., Jean-Pierre, B., Philippe, B et al. (2008). Benefit of the Vibrant Soundbridge Device in Patients Implanted For 5 to 8 Years. *Ear & Hearing*, 29(2), 281-284.
15. Klaus, B., Stefan-Marcel, P., Max, S & Peter, F. (2010). Active Middle Ear Implant Compared With Open-Fit Hearing Aid in Sloping High-Frequency Sensorineural Hearing Loss. *Otology & Neurotology*, 31(3), 424-429.
16. Lenarz, T., Weber, B. P., Issing, P.R., Gnadeberg, D., Ambjornsen, K., Mack, K.F. & Winter, M. (2001). Vibrant SoundBridge System. A new kind hearing prosthesis for patients with sensorineural hearing loss. *Laryngorhinootologie*, 80(7), 370-80.
17. Lenarz, T., Weber, B. P., Mack, K. F., Battmer, R. D. & Gnadeberg, D. (1998). The Vibrant Soundbridge System: a new kind of hearing aid for sensorineural hearing loss: Function and initial clinical experiences. *Laryngorhinootologie*, 77(5), 247-55.
18. Luetje, C. M., Brackman, D., Balkany, T. J., Maw, J., Baker, R. S., Kelsall, D et al. (2002). Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: A prospective controlled multicenter study. *Otolaryngology - Head and Neck Surgery*, 126, (2), 97-107.
19. Luetje, C. M., Brown, S. A. & Cullen, R. D. (2010). Vibrant Soundbridge implantable hearing device: critical review and single-surgeon short- and long-term results. *Ear Nose Throat*, 89(9), 9-14.
20. Sprinzl, G. M., Wolf-Magele, A., Schnabl, J. & Koci, V. (2011). The active middle ear implant for the rehabilitation of sensorineural, mixed and conductive hearing losses. *Laryngorhinootologie*, 90(9), 560-72.
21. Todt, I., Seidl, R. O., Gross, M. & Ernst, A. (2002). Comparison of different vibrant soundbridge audioprocessors with conventional hearing aids. *Otol Neurotol*. 23(5), 669-673.
22. Vincent, C., Fraysee, B., Lavieille, J. P., Truy, E., Sterkers, O. & Vaneecloo, F. M. (2004). A longitudinal study on postoperative hearing thresholds with the Vibrant Soundbridge device. *Eur Arch Otorhinolaryngol*, 261, 493-496.