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Technical background of the Vibrogram in-situ measurement for the VIBRANT SOUNDBRIDGE

Hamidreza Mojallal Dr. DI.
Team Leader, Applied Hearing Science, MED-EL, Business Unit Vibrant, 6020 Innsbruck, Austria

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1. Introduction

The Vibrogram in-situ measurement is integrated in the SYMFIT fitting software for the VIBRANT SOUNDBRIDGE (VSB) active middle ear implant. The aim of this white paper is to provide the professional user with some information about the technical background of the Vibrogram and its application in the clinical workflow. This document is divided into a technical and a clinical part.

1.1 Motivation and background

The motivation for the development of the Vibrogram was to create a device-specific hearing threshold measurement based on the principle of in-situ audiometry similar to conventional hearing aids. With conventional hearing aids, in-situ audiometry is defined as the measurement of patient's hearing thresholds with their own hearing aid and earmold in the ear canal. The device related thresholds are used in the fitting software to generate the individual target gain for a given user. The benefits of in-situ measurement are:

- Individual hearing threshold with consideration of device characteristics, acoustic coupling (e. g. sound tube, ear mold and venting effects), insertion depth and individual ear canal shape
- Individual fitting based on individual hearing threshold
- Independent of clinical audiometry in some cases
- Remote care/fitting
- Quick check of hearing fluctuation

2. Technical Part

2.1 Development of the Vibrogram

Early research was reported by Rajan et al [1]. So-called "Vibroplasty threshold measurement" was employed to assess the clinical feasibility of direct measurement by VSB. As a further development, the Vibrogram was introduced in 2012 as an in-situ measurement feature in the SYMFIT6.1 fitting software. The need for implant-specific thresholds is greater for implantable hearing devices as the device-patient interface plays a more critical role than in conventional hearing devices. The reasons for this are the different stimulation pathways, coupling positions and implant-tissue interaction over time. Therefore, additional benefits for the VSB are expected from the use of Vibrogram thresholds and will be discussed in following chapters. Fig. 1 shows the currently most used coupling options for the VSB according to anatomical and audiological criteria.

Figure 1: Different stimulation pathways and coupling positions for the VSB-implantation. From the left: SP-Coupler, LP-Coupler, CliP-Coupler, SH-Coupler, RWS-Coupler

The main part for development of in-situ measurement features is the calibration of the physical output magnitude of the hearing device (in dB SPL) to the clinically relevant hearing thresholds (in equivalent dB HL) perceived by the user. For conventional acoustical hearing aids, it is a straightforward conversion from values in dB SPL to dB HL according to available standardized reference equivalent thresholds (i. e. Reference equivalent threshold sound pressure levels (RETSPLs)) [2]. However, because active middle ear implants (AMEI) have different transmission pathways, this reference is not directly applicable. Next chapter will describe the procedure that was used to identify output-equivalent hearing thresholds for the VSB hearing system.

2.2 Vibrogram for the VSB

The output quantification of AMEIs is based on an ASTM standard and a publication by Rosowski et al. in 2007 [3 & 4]. According to this procedure, the middle ear transfer function (TF) is measured as the stapes footplate vibration velocity as a function of sound pressure in the ear canal (in (mm/s)/P), as shown in Fig. 2. Using this reference, the AMEI's output can be quantified as a quotient of the footplate velocity and the driving voltage of a given transducer (in (mm/s)/V).

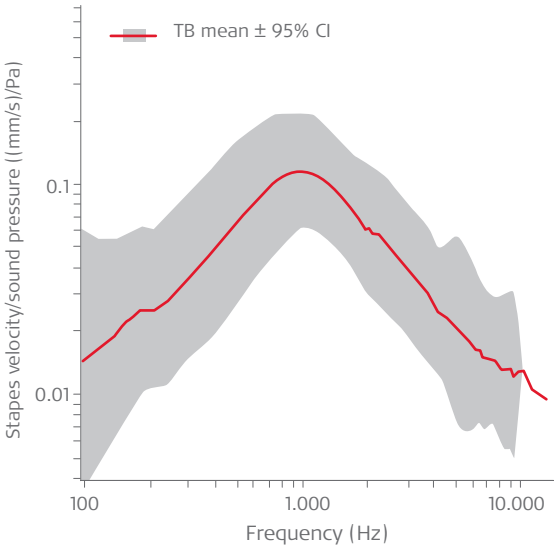


Figure 2: ASTM of middle ear transfer function; TB: Temporal bone [4]

The output quantification of the VSB's floating mass transducer (FMT) is based on temporal bone measurements by Geoffrey Ball and his colleagues in 1990s. In several temporal bone measurements, the vibration of the stapes footplate by electrical excitation of the FMT coupled to the long process of the incus was measured and compared to the middle ear transfer function with constant sound pressure in the ear canal. These measurements showed that the FMT, driven by a current of 1mA, generates nearly the same stapes footplate displacement as approximately 100 dB SPL in the ear canal between 1 and 6 kHz (see Fig. 3 a & b) [5].

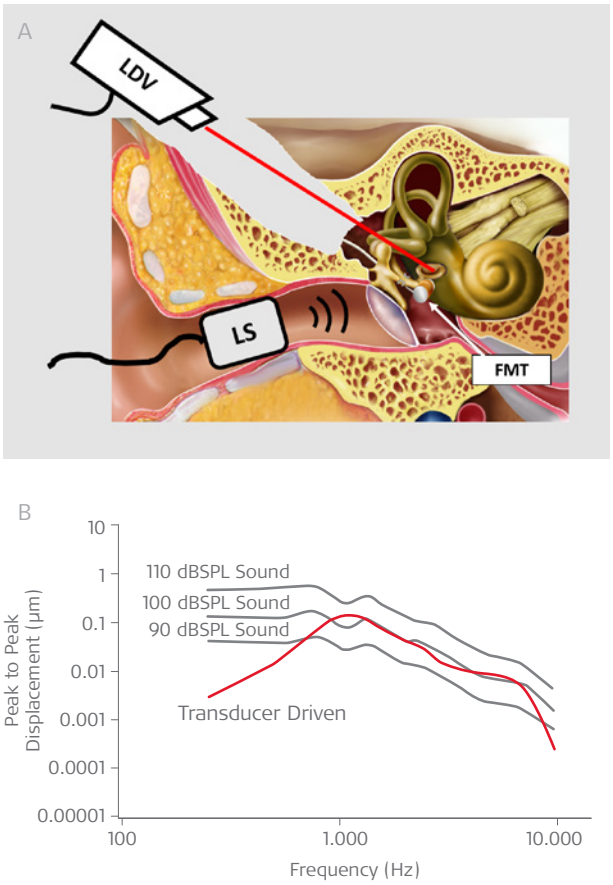


Figure 3: A) Method of output quantification for VSB; LDV: laser doppler vibrometry, LS: loudspeaker. B) Stapes footplate displacement by FMT with 1mA driven current (red line) overlaid on normal middle ear transfer function with defined sound pressure level in the ear canal (gray lines)

If the electrical resistance of the FMT is known, the corresponding driven voltage can be calculated (i. e. according to U=R*I). The average resistance of the FMT is about 70 Ω[1]. Accordingly, a driven voltage of approx. 70 mV_{rms} (-23 dB V) generates the comparable stapes footplate displacement of about 100 dB SPL sound pressure in the ear canal. A driven voltage of 70 mV on the FMT was therefore considered 100 dB SPLeq.

[1] There are negligible differences in internal resistances between different VSB implant generations.

This value was used as the fundamental magnitude for the calculation of output curves and fitting procedures in the software and has been adapted for all frequencies and levels in the Vibrogram. However, as the values were in dB SPL, they needed to be converted into the equivalent dB HL (dB HLeq) magnitudes. For this purpose, the ANSI standard for conversion from dB SPL to dB HL was used[2] [2]. Fig. 4 shows the voltage chart of the current VSB implant (VORP503) for dB SPL and its corresponding Vibrogram levels in equivalent dB HL for two different levels (i. e. 15 and 90 dB SPL and dB HLeq). All levels in between have been defined with a linear characteristic.

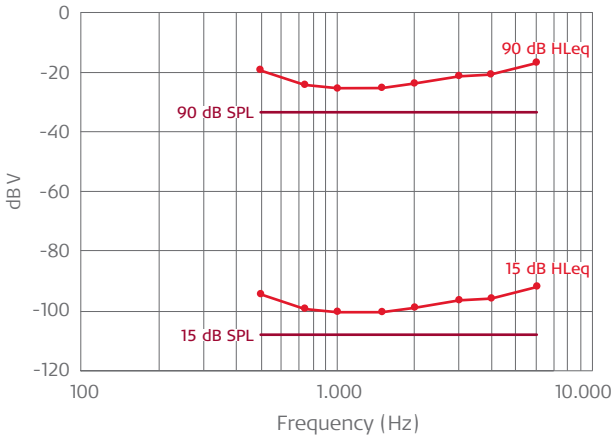


Figure 4: Voltage chart of the VORP503 and Vibrogram for two different levels (in dB SPL and dB HLeq).

According to the calculation mentioned above, the corresponding excitation voltage for 100 dB HLeq at 1 kHz is about -15.5 dB V or about 168 mV_{rms} (i. e. 100 dB SPL: -23 dB V + RETSPL @ 1 kHz: 7.5 dB = -15.5 dB V). As an example, Table 1 shows the calculated excitation voltages for 60 dB HLeq (in both dB V and mV_{rms}) over all Vibrogram frequencies.

Vib. freq. [Hz]	dB HL	dB V	mVrms
250	60	-36	15.85
500	60	-49.5	3.35
750	60	-54	2.00
1000	60	-55.5	1.68
1500	60	-55.5	1.68
2000	60	-54	2.00
3000	60	-51.5	2.66
4000	60	-51	2.82
6000	60	-47	4.47

Table 1: Excitation voltage of VORP503 for 60 dB HLeq.

The same calibration has been used in the software for all types of audio processors (i. e. Lo and Hi). However, since different APs show different output characteristics, for development of the Vibrogram these differences had to be considered. Consequently, all AP variants were calibrated so that the same Vibrogram threshold should be obtained with every variant. When starting a Vibrogram measurement, specific gain settings are applied in the background (see also the next chapter).

2.3 Method

For calibration of the Vibrogram, pre-defined values according to the mentioned calculation above for each sound level and frequency were defined as target values (e. g. Table 1 for 60 dB HLeq). For each AP type, the gain (only in linear fitting) in different frequency bands was adjusted so that the corresponding target value (in dBV ± 3 dB) was recorded at the measuring system. For simulation of the implant, an adapter was used which mimics the internal resistance of the FMT. The electrical output of the simulator was directly connected to the measuring system. The measuring setup is shown in Fig. 5.

[2] Conversion from dB SPL to dB HL for a supra-aural earphone type TDH of an IEC 318 artificial ear.

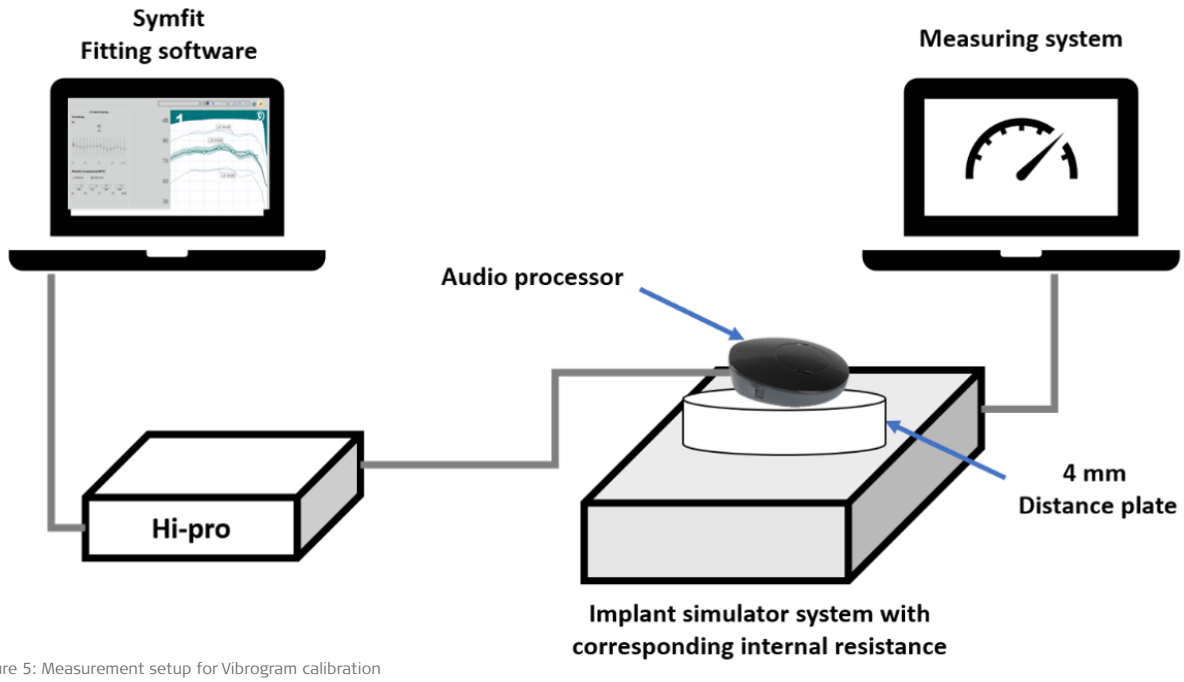


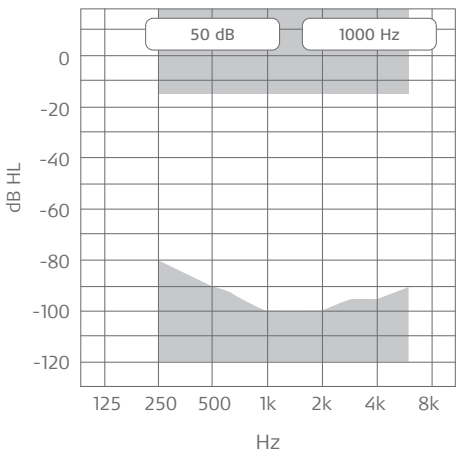
Figure 5: Measurement setup for Vibrogram calibration

3. Clinical part

3.1 Vibrogram threshold measurement

As mentioned before, the same calibration data was used for all AP types. However, as different APs (e. g. high and low) have different noise floor and maximum power output, the measurable Vibrogram levels change consequently. This means that the dynamic range differs between AP types. The consequence is that the mid-level thresholds on the Vibrogram can be easily measured independent from the AP type, but this can affect the threshold measurement in soft and high levels (e. g. with a Hi-AP, thresholds below 35 dB can be masked by device noise floor, or levels louder than 60 dB cannot be measured properly by a Lo-AP due to limited MPO). This fact must be considered during the Vibrogram measurement according to the patient's expected hearing loss and applied AP. The measurable range of SAMBA 2 Lo and Hi-AP, is shown on the Vibrogram screen in the new SYMFIT 8 software as a white background field restricted with shaded areas in the upper and lower parts of the audiogram (Fig. 6).

SAMBA 2 Hi



SAMBA 2 Lo

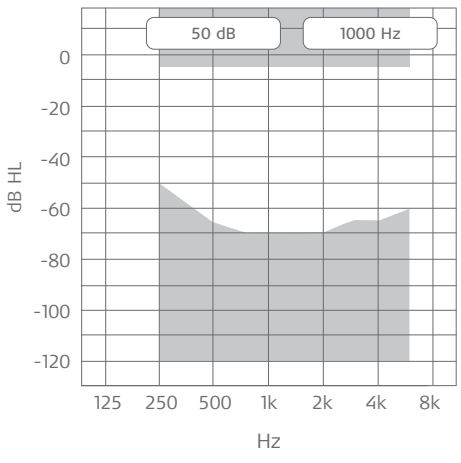


Figure 6: Measurable Vibrogram areas for SAMBA 2 Hi and Lo.

3.2 Benefits of the Vibrogram

Usage of the Vibrogram in the clinical workflow brings several benefits which guarantees a more reliable device fitting and benefit for the patient. These benefits include:

- Facilitation of the clinical workflow
- Individual and implant-specific hearing thresholds (including different pathways and coupler positions)
- Individual fitting based on individual thresholds
- Independent of clinical audiometry in some cases
- Verification of coupling efficacy as a relative measure
- Quick check of hearing fluctuation
- Usage as a tool for supra-threshold measurements (e. g. Loudness scaling, UCL-measurement, dynamic range estimation)
- Device integrity and long-term follow-up

3.3 Limitations and outlook

Despite the benefits of the Vibrogram, this clinical tool still has some limitations or potentials for improvement. First, as shown in Fig. 3, there is a good comparability between the VSB output and the normal middle ear TF between 1 and 6 kHz. This means that for frequencies below 1kHz there is still a discrepancy up to about 20 dB in calibration. This could be one of the main reasons for differences between audiometric and Vibrogram thresholds in clinical findings [6]. It should be considered that the aim of the Vibrogram development was not to replace the clinical measurement. Therefore, direct comparison of audiometric thresholds with Vibrogram thresholds should be done carefully to avoid mistakes regarding estimation of coupling efficiency. However, several clinical data have shown that with some deviation, the Vibrogram can be a useful tool to estimate the coupling efficiency [6, 7, & 8]. In other words, the Vibrogram should not be considered as an absolute measurement to replace the clinical audiometric testing (i. e. AC/BC measurement). Rather, it is a relative testing method to measure the specific level for device fitting regardless of the position of the FMT coupling. Secondly, the calibration is based only on one standard coupling position, namely the incus coupling. Further research is in progress to investigate the influence of different coupling positions and their impact on Vibrogram measurement and consequently on device fitting.

Two limitations of the Vibrogram in former SYMFIT software versions have been improved upon in the new SYMFIT 8 generation. The first is better user friendliness regarding measurement and data entry. The other improvement relates to the direct implementation of the bone conduction audiometric thresholds and Vibrogram thresholds in target gain calculation. This leads to a streamlined and more comfortable first fit, especially for patients with moderate-to-severe mixed hearing loss.

4. References

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