

# Measurement of Eardrum Vibrations for the optimized Fitting of Vibrant Soundbridge Middle-Ear Implants

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## Introduction

Middle ear implants (MEI) are for the medical rehabilitation of the hearing function in case of sound conduction hearing losses as well as cochlear hearing losses and their combinations. In this case the Floating Mass Transducer (FMT), an electromagnetic device mounted at components of the middle or inner ear, is studied in patients suffering from middle or inner ear hearing loss. It is a special problem to fit them in case of uncooperative or disabled patients.

In (Karkas *et al.*, 2011) the measurement of the reverse transfer function (RTF) of the Vibrant Soundbridge (VSB) middle ear implant (MEI) is already an objective method to evaluate the function of the VSB and can be used to adjust the Connexx value required to reach the optimal VSB gain during fitting sessions for patients with intact ossicular chain and FMT coupled to the long process of the incus. Due to acoustic noise and standing waves in the ear canal at high frequencies it is difficult to establish norm values for optimum adapted middle ear implants. Laser-Doppler-Vibrometry is in comparison a more reliable method to identify the vibrations at a specific place of the eardrum (umbo) to fit a MEI in cooperative and incooperative patients.

## Material and Methods

At first auditory thresholds are determined by the “vibrogram” application (electrical stimulation of the MEI). Based on that values a “first-fit” adjustment of the sound processor is generated in the fitting software Connexx (Version 6.5.5.3480, Symfit Version 7.0). After that the sound-processor is fitted in free field with the aim of an aided threshold at 30 dB(nHL) and the dB<sub>opt</sub> control in the speech audiogram with the result of an “adapted” adjustment with the required amplification in the fitting software.

In addition to that a sound processor adjustment “maximum amplification” for all channels is created with deactivated limiting features like peak clipping (PC) or automatic gain control (AGC). This adjustment was applied only for very short times during Laser Doppler Vibrometry (LDV) measurements for a considerate treatment.

Different calibrated stationary acoustic stimuli (multifrequency stimulus and single tones) with levels 65, 80 and 85 dB are applied directly to the microphone of the sound processor of the implanted ear by a headphone. These sound pressure levels were calibrated by attaching the stimulating circumaural headphone (Sennheiser HDA 280) to an artificial ear.

The eardrum velocities are measured with the Laser Doppler Vibrometry (Polytec Laser Vibrometer CLV-2534) at the umbo with all types of stimuli.

In (Arechvo *et al.*, 2009) the most anterior-inferior region on the bony part of the umbo appeared to be the best zone to measure the tympanic membrane motions. The reproducibility of the LDV measurements was the best at this part of the eardrum area.

The measurements are done using all three different sound-processor adjustments (first fit, adapted, maximum amplification).

Individual eardrum properties like scars, the visibility of the ear-drum and the presence of the light reflex were considered for the analysis by video-otoscopy inspection. The tympanogram compliance was measured for the evaluation of the middle ear status. Additionally the individual middle ear characteristics were included in the evaluations. These are the locations of coupling and the type of FMT (long process coupler LP, clip at the stapes head or round window coupler which has an influence on the tympanogram compliance) as well as the mobility of middle ear bones as given by the surgery report and the pure tone audiogram including the bone conduction.

Based on this information the patients were categorized into groups to gain comparable results because scarred eardrums usually result in lower eardrum displacements for example.

## Analysis of the eardrum velocity amplitudes

All measured values fulfill the criterion to be at least 5 dB above the noise level.

Figure 1 shows the amplitudes of eardrum velocities of a patient with an intact eardrum and therefore the best eardrum features. The amplitudes can be compared for three sound processor adjustments: first fit (ff), adapted (ad) and all channels adjusted to maximum (max) as well as for three different levels of stimulation: 65 dB, 80 dB, and 85 dB (SPL) of a 1 kHz test tone. The dashed curves (LR) design the average of noise levels for the three cases (ff, ad, max).

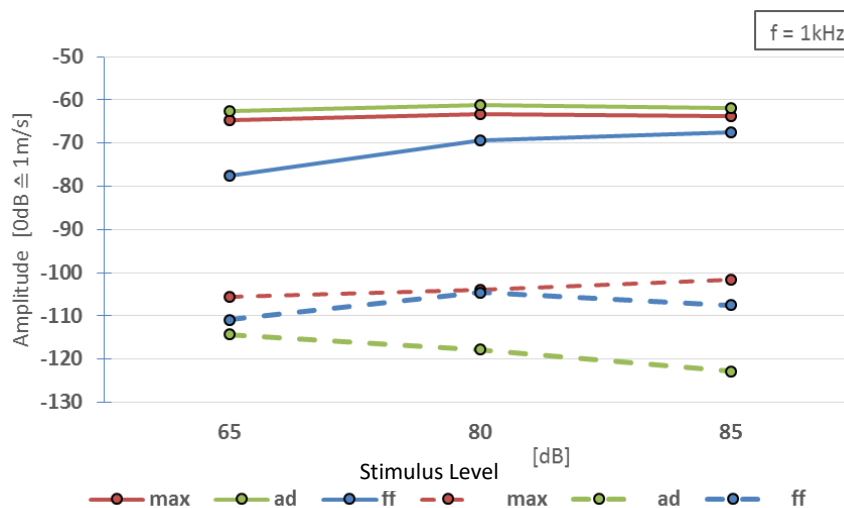


Figure 1: Amplitudes of eardrum velocities of a single reference patient using three different processor adjustments (ff, ad and max)

Figure 2 shows the amplitudes of ear-drum velocities of the same reference patient 1 using the three processor adjustments ff, ad and max but in this case using a multi-frequency stimulus of frequencies used in audiometry (125 Hz, 250 Hz, 500 Hz, 1 kHz, 2 kHz, 4 kHz, 6 kHz and 8 kHz) and a sound pressure level of 85 dB(SPL) in case of the max adjustment where all channels are adjusted to the maximum levels. Furthermore this integrated sound pressure level [85 dB(SPL)] was applied to the patient with a switched off sound processor to exclude eardrum vibrations triggered by bone conduction mechanisms. LR designs the mean values of noise levels for the three different sound processor adjustments.

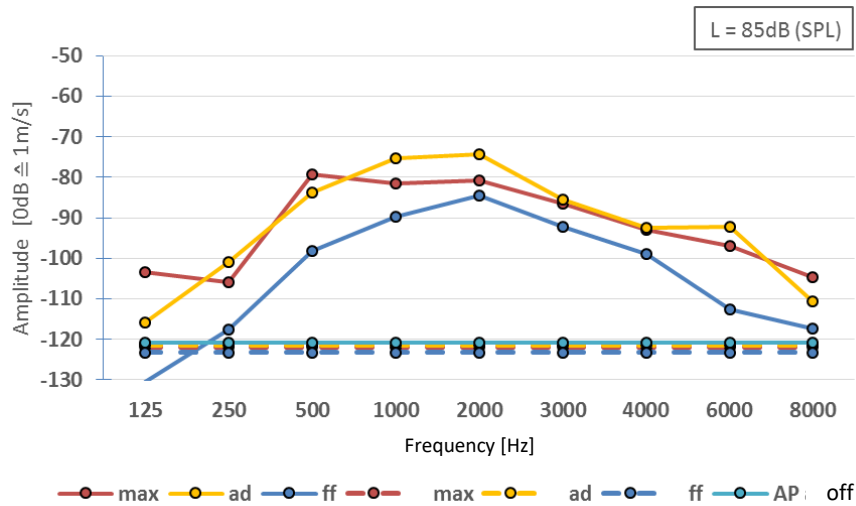


Figure 2: Amplitudes of eardrum velocities of a single reference patient with the processor adjustments (ff, ad and max) and the switched off sound processor.

Figure 3 shows the amplitudes of eardrum velocities of a homogenous group of patients (n = 6) with similar eardrum characteristics (scarred, missing light reflex, similar mechanical compliance) and identical couplings of the FMT at the long process of the incus using an LP coupler.

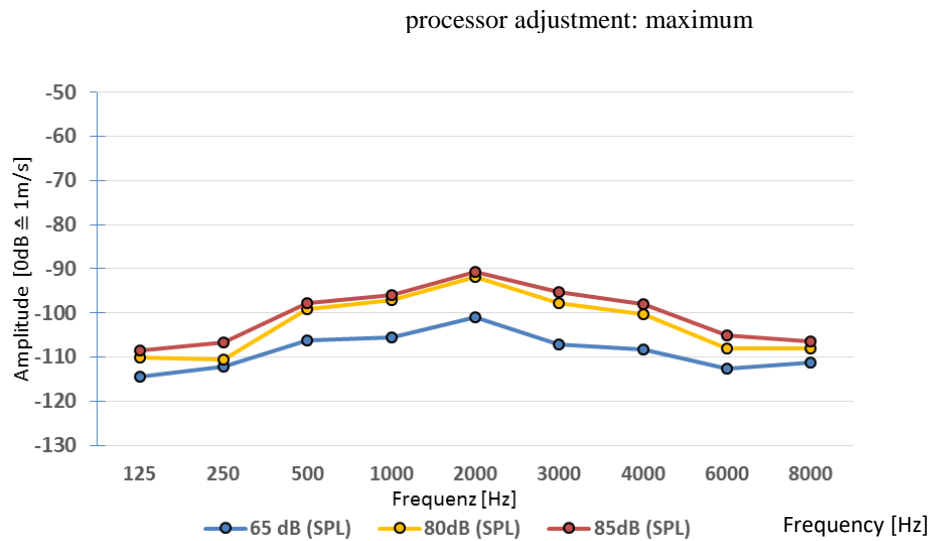


Figure 3: Average amplitudes of eardrum velocities of a group of patients (n = 6) with a sound processor adjustment "max" as a function of three different levels of a multi-frequency stimulus.

Figure 4 shows the amplitudes of eardrum velocities for all evaluable patients (n = 16) with three different sound processor adjustments (ff, ad and max without automatic gain control). The sound processor was set to a stimulus level of 80 dB(SPL).

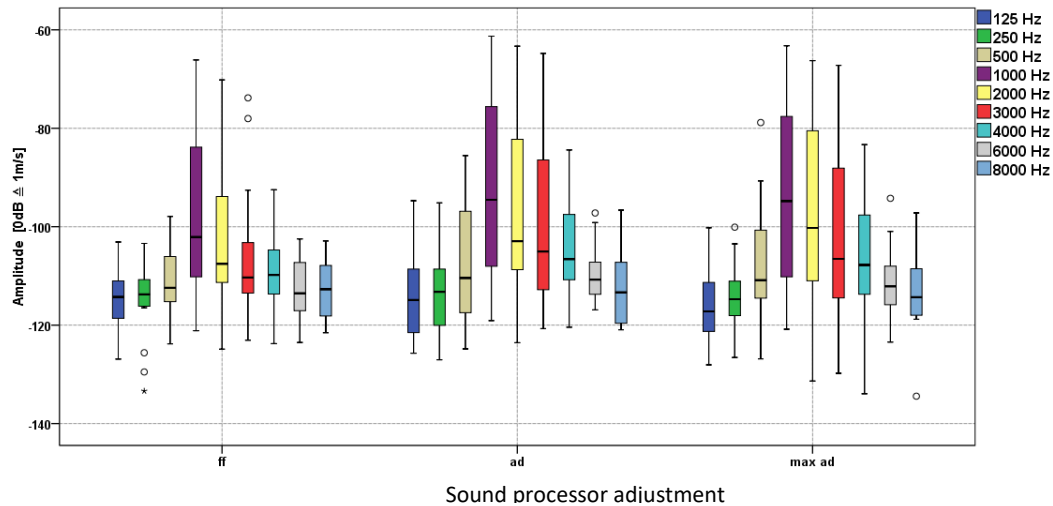


Figure 4: Amplitudes (median, standard deviation (+,-) and maximum values) of eardrum velocities for all evaluable patients (n= 16) using three different sound processor adjustments (ff, ad, max) and a multi-frequency stimulus of 80 dB (SPL) sound pressure level for all used frequencies

The measurement variability depends on the following factors:

1. The unavoidable movement of the patient
2. The accessibility of the eardrum
3. The visibility of the umbo
4. The positioning of the laser point which depends on the manual movement of a tilted mirror by a joy-stick

For low frequencies (125 Hz – 500 Hz) and high frequencies (6000 Hz – 8000 Hz) the standard deviation is considerably higher (up to 15 dB) whereas for middle frequencies (500 Hz - 6000 Hz) the variance is low (2- 4 dB). The intrasubject variability values were stable at the same measuring session and reproducible from month to month.

In (Arechvo *et al.*, 2009) the intersubject variance of LDV characteristics exceeded the intrasubject/inter-test variability. This fact could be seen here as well. Furthermore in (Rosowski *et al.*, 2008) the noise in the LDV's output varies inversely with the strength of the reflected light returning to the velocity decoder, small relative motions between the microscope and the patient can lead to significant variations in reflected light and associate noise.

## Discussion and conclusions

The quality of the measurement results depends on the conditions of the eardrums and the condition of the middle ear. This fact required the classification of patients for a reasonable comparison of measurement results.

There is an expected correlation between the amplification of the stimulus pressure by the sound processor and the increasing eardrum velocities. In some cases there is only a small difference with adjustment adapted (ad) and maximum (max) maybe because these patients were currently at the border of the indication level concerning the pure tone audiogram for a middle ear hearing implant (MEI) and therefore it was not enough gain available for high frequencies.

For frequencies lower than 500 Hz eardrum velocities could only be measured if the components of the multi-frequency stimulus levels were increased substantially according to the lower sensitivity of the hearing organ corresponding to the Hearing Level (HL) sound pressure reference.

No eardrum velocities could be measured with ear bone chain disruptions, stiffening abnormalities in the middle ear, fibre replacement of the malleus / incus complex causing an approximately 50 dB middle ear hearing loss if the 5 dB above noise criteria is supposed as the signal detection rule. Good measurement conditions are especially important in case of damaged eardrums achievable by low background noise levels (quiet environment in a room with noise insulation walls), stable laser-positioning and low patients motion artefacts.

The results show the interrelationship between different processor adjustments or rather stimulation levels and velocities at the umbo of the eardrum.

Using these results we develop characteristic diagrams for different classes of patients with similar eardrum conditions, which represent the mean values of eardrum displacements with different sound processor adjustments being the base for normative data courses. In addition to that this procedure enables the control of the sound processor fitting quality.

The coupling efficacy may be detected by a comparison of bone-conduction and “vibrogram” thresholds in case of cooperative patients. The quality of the coupling was generally worse at low and high frequencies detected by better bone conduction thresholds in comparison to the “vibrogram” thresholds. Concerning the middle frequencies (1-3 kHz) the coupling efficacy was very good determined by partly even better “vibrogram” thresholds than the bone conduction in the pure tone audiogram. Furthermore the transfer characteristics of the used sound-processors “Samba” (type high and low) could have an influence which is a little bit worse for lower frequencies (100-300 Hz).

All in all the Laser Doppler Vibrometry is a more sensitive tool (factor  $10^4$ ) in comparison to the tympanometry (Stasche *et al.*, 1993). Especially for the diagnostics of different types of middle ear diseases as was shown in several former publications.

## Literature

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