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Gain and Maximum Output of Two Electromagnetic Middle Ear Implants: Are Real Ear Measurements Helpful?

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Abstract

We compared the output of two electronic middle ear implants: the Otologics MET™ device and the Vibrant Soundbridge™ device. Both devices were programmed in the linear amplification mode. Aided minus unaided sound pressure levels recorded in the ear canal (objective gain) were compared to unaided minus aided soundfield thresholds (functional gain) in 13 patients with severe sensorineural hearing loss. In addition, input/output characteristics were studied with the help of ear canal measurements. Objective gain was consistently lower than functional gain, with wide variation between patients and frequencies. Using input/output data measured in the ear canal in combination with functional gain data, the mean maximum output of the two devices was estimated, expressed in dB SPL. In comparison to NAL-R target values, (functional) gain was adequate; however, the maximum output was low, especially for the Vibrant Soundbridge device.

Key Words: Amplification, functional gain, implantable hearing aid, maximum output, Otologics MET™, probe-tube microphone, Vibrant Soundbridge™

Abbreviations: FG = functional gain; MEI = middle ear implant; REAR = real ear aided response; REUR = real ear unaided response; VSB = Vibrant Soundbridge™

Sumario

Comparamos la salida de dos implantes electrónicos de oído medio: el dispositivo MET™ de Otologics y el dispositivo Vibrant Soundbridge™. Ambos dispositivos fueron programados en el modo de amplificación lineal. Los niveles presión sonora con amplificación y sin ella, registrado en el conducto auditivo (ganancia objetiva) se compararon con umbrales con amplificación y sin amplificación obtenidos en campo libre (ganancia funcional), en 13 pacientes con hipoacusias sensorineurales severas. Además, se estudiaron las características de entrada/salida con la ayuda de mediciones en el conducto auditivo. La ganancia objetiva fue consistentemente más baja que la ganancia funcional, con grandes variaciones entre pacientes y frecuencias. Utilizando los datos de entrada/salida medidos en el conducto auditivo, en combinación con los datos de la ganancia funcional, se estimó la salida máxima promedio de los dos dispositivos, expresada en dB SPL. En comparación con los valores meta para el NAL-R, la ganancia (funcional) fue adecuada; sin embargo, la salida máxima fue baja, especialmente para el dispositivo Vibrant Soundbridge.

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Palabras Clave: Amplificación, ganancia funcional, auxiliar auditivo implantable, salida máxima, Otologics MET™, micrófono de tubo de sonda, Vibrant Soundbridge™

Abreviaturas: FG = ganancia funcional; MEI = implante de oído medio; REAR = respuesta amplificado de oído real; REUR = respuesta no amplificada de oído real; VSB = Vibrant Soundbridge™

In recent years, several different types of implantable hearing aid or electronic middle ear implant (MEI) have been introduced (Miller and Sammeth, 2002). In 1996 the Vibrant Soundbridge™ or VSB became available for clinical evaluation (Dietz et al, 1997), and more recently the Otologics MET™ has been introduced (Kasic and Frederickson, 2001). Typically, an MEI consists of a transducer that is fixed to the ossicular chain and is driven by an externally worn audioprocessor.

To evaluate the amplification of such devices, several different measurements have been applied. Mostly, functional gain measurements were used (e.g., Fraysse et al, 2001; Luetje et al, 2002; Winter et al, 2002). It should be noted that functional gain measurements are not the first option to study the amplification of MEIs because of nonlinear amplification. In case of nonlinear amplification, functional gain only estimates the (relatively high) gain for soft sounds. Input-dependent gain has also been studied (Snik and Cremers 1999, 2001).

Unfortunately, these behavioral measures cannot be supplemented by technical measurements, because calibration devices or "artificial ears" have not yet been developed for MEIs. Brazil et al (1999) and Winter et al (2002) suggested that the sound pressure levels produced in the ear canal might form an objective measure of MEI performance, for sound vibrations initiating from the middle ear transducer will reach the ear canal in reverse direction.

At present, little is known about the reverse transmission of sounds through the middle ear. In guinea pigs, it was found that the reverse transfer function was fairly independent of frequency; the reverse gain was found to be about -30 dB (Magnan et al, 1999). Thus, reverse transmission is less effective than forward transmission. In human temporal bones, the best reverse gain was found to be -20 dB in the region 1 to 1.5 kHz (Offergeld et al, 1997). Unfavorable reverse transfer properties of the middle ear will affect the assessment of MEI performance by measurements of sound pressure levels in the ear canal.

In the past, audioprocessors of MEIs (e.g., the VSB) made use of nonlinear amplification and advanced noise reduction algorithms that could not be turned off. This complicated proper output measurements. With the present audioprocessors, type 404 for the VSB and the Button™ for the Otologics device, this is no longer the case. These processors can be programmed in linear amplification mode, and special noise reduction and speech enhancement options can be switched off.

The aim was to study the gain and maximum output of the two mentioned MEIs. We decided to use a straightforward evaluation with the devices set in linear amplification mode. Gain was determined behaviorally with soundfield threshold measurements. In addition, gain and maximum output were determined with the help of real ear measurements; therefore, sound pressure levels were measured in the ear canal in aided and unaided situations with a tube-probe microphone.

The outcomes of the study are used to discuss candidacy for these devices.

MATERIAL AND METHODS

Audiometry

Pure-tone audiometry and tympanometry were performed according to standard procedures using standard equipment.

Functional gain, that is, the difference between unaided and aided soundfield thresholds, was determined with warble tones from 250 Hz to 8 kHz with a modulation frequency of 5%. A loudspeaker, placed 1 m in front of the patient, presented the warble tones. The soundfield set-up was calibrated according to Morgan et al (1979).

All measurements were obtained in a sound-treated double-walled room.

Ear Canal Sound Level Measurement

Sound pressure levels in the ear canal were measured with the Aurical REM system (Madsen, Denmark), which was developed to obtain real ear measurements from patients using air-conduction devices. In the present application, the subtraction procedure was followed (Tecca, 1995; Revit, 2000): first, in the soundfield, a well-calibrated frequency sweep was produced (warble tones, with a frequency sweep from 250 Hz to 8 kHz at 60 dB SPL) with the audioprocessor switched off. The sound pressure level was recorded in the ear canal with a probe-tube microphone (part of the Aurical REM system). In this way, the so-called REUR, or the real ear unaided response, was obtained (Revit, 2000). Second, the same measurement was carried out with the audioprocessor switched on. In this way, the REAR, or real ear aided response, was determined. Third, the difference between the two recordings as a function of frequency was calculated. For air-conduction hearing aids, this difference is the effective gain of the hearing aid, called the insertion gain. In principle, the insertion gain equals the (behavioral) functional gain in users of air-conduction hearing aids (Tecca, 1995).

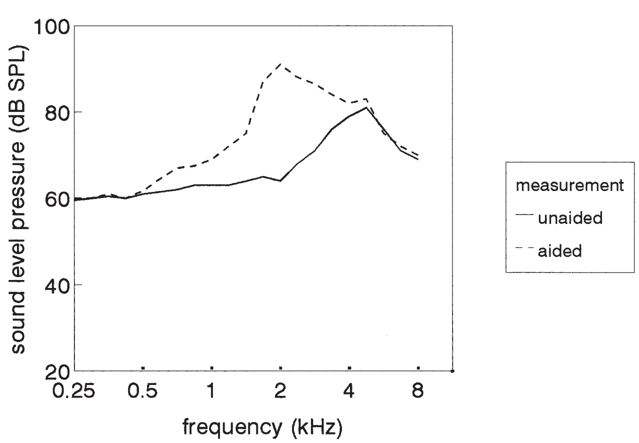


Figure 1. Typical example of aided and unaided sound pressure levels measured in the open ear canal as a function of frequency (patient V6). The frequency sweep used was presented at a level of 60 dB SPL.

Using this setup, we investigated whether this objective gain obtained with the MEI and behavioral gain were comparable. Figure 1 gives a typical example of sound pressure levels measured in the open ear canal in the unaided and aided conditions. Measurements were repeated with frequency sweeps of 50, 70, and 80 dB SPL. The opening of the probe-tube microphone was placed approximately 3 mm from the tympanic membrane using otoscopy.

Similar measurements were taken while the ear canal was occluded with an EARlink foam tip (designed for use with 3A insert earphones; Aearo Company, Indianapolis, USA). These circumstances were intended to exclude direct sounds as much as possible. After insertion of the foam tip, the probe tube was gently pushed through the opening of the plug until it touched the tympanic membrane. Then it was withdrawn approximately 3 mm. The rest of the measurement procedure was analogue to that used on the nonoccluded ear; REUR and REAR curves were obtained once more but with an occluded ear canal.

Input-output curves were constructed from the open ear canal measurements as obtained at the input levels of 50 to 80 dB SPL by plotting the read output levels versus input level at a certain frequency. Typically, the highest output was found between 1 kHz and 3 kHz (see Figure 1). As saturation of the device might be frequency dependent (it will occur most readily in the frequency range with the highest output), the decision was made to construct the input-output curves for 1, 2, and 3 kHz. These curves were used to determine for the three frequencies the input level at which the output leveled off (became independent of the input level). The highest (best) value of the three values was used for further analysis.

Patients and Device Fittings

Thirteen selected MEI users participated in the study; five patients were using the Otologics MET device, while eight patients were using the VSB. Only patients with normal middle ear impedance (type A

Table 1. Some Patient Characteristics and Outcomes

Patient	age (yr.)	m/f	threshold at: 0.5 (dB HL)	1	2	4 kHz	mean FG (dB)	input level at max. output (dB SPL)	ref. NAL (dB)
V1	55	f	70	70	70	80	27	60	-4
V2	55	m	70	65	65	75	33	65	5
V3	65	f	55	60	70	80	38	60	9
V4	51	f	80	70	60	75	27	70	-3
V5	49	f	45	45	75	95	27	65	3
V6	55	f	50	60	60	85	41	65	11
V7	39	m	70	75	75	80	40	60	7
V8	64	f	60	65	65	70	26	65	1
O1	54	f	60	65	100	100	33	70	-2
O2	20	f	70	75	75	75	35	75	4
O3	56	f	60	60	80	80	24	70	-7
O4	37	m	60	75	100	95	43	70	10
O5	42	f	70	65	70	90	35	73	2

Note: Mean FG: average functional gain at 0.5, 1, 2, and 4 kHz (except for subject O1, see text); ref. NAL: functional gain minus NAL target gain, averaged at 0.5, 1, 2, and 4 kHz (except for subject O1); V = Vibrant Soundbridge; O = Otologics MET.

tympanogram) were included. Further, the three-months postsurgery thresholds had to be the same as the presurgery thresholds within measurement error (viz. within 10 dB for individual frequencies and within 5 dB for the average value at 0.5, 1, 2, and 4 kHz). At last, only patients were included with severe sensorineural hearing loss (average hearing thresholds at 0.5, 1, 2, and 4 kHz was 65 dB HL or higher). The age of the patients ranged from 20 to 65 years (see Table 1).

Prior to implantation, all the Nijmegen patients fulfilled the following selection criteria: chronic external otitis that was therapy resistant, symmetrical sensorineural hearing loss with hearing thresholds of between 30 and 70 dB HL at 500 Hz up to between 45 and 80 dB HL at 2 kHz for the VSB (Fraysse et al, 2001). The inclusion criteria for the Otologics MET were comparable with those for the VSB, except that the upper application thresholds were about 10 to 15 dB higher (Kasic and Frederickson, 2001).

The VSB users had been using their device for more than a year. Before the measurements took place, all the audioprocessors were set in linear amplification mode, and when active, noise reduction and speech enhancement functions were switched off. Further, the peak-clipping option was chosen as output limiter, and the output was set at maximum (thus unlimited).

The Otologics MET patients were first-time users. Measurements were obtained at the second or third follow-up session, at least four months after device fitting. The Otologics audioprocessors (Otologics LLC, Boulder, USA) were also programmed in the linear mode. Output adjustment was set at maximum (thus unlimited).

The change from nonlinear to linear amplification was evaluated with the patients. Most patients accepted the change right away without any further fine-tuning. Complaints about the maximum output were not encountered. Minor adjustments concerning the frequency response were made in 2 of the 13 patients, and the overall gain level was adjusted in 4 patients. To assess whether the audioprocessors were fitted adequately, the measured functional gain was compared to target values obtained with the NAL-R method (Byrne et al, 1990). The NAL-R method prescribes desired gain based on (unaided) hearing thresholds. It was developed for linear amplification and has been validated in several research studies (e.g., Byrne et al, 1990; Van den Heuvel et al, 1997; Humes et al, 2000).

RESULTS

Figure 2 shows the mean functional gain (FG) as a function of frequency for the VSB users and Otologics MET users, separately. Vertical lines indicate the range. The figure suggests that the Otologics MET is somewhat louder in the mid and low frequencies while the VSB is somewhat louder for the highest frequencies.

Individual mean FG values, at 0.5, 1, 2, and 4 kHz, varied between 24 and 43 dB (see Table 1). The mean FG of subject O1 was obtained by averaging the 0.5, 1, and 2 kHz data because her unaided threshold at 4 kHz was not measurable (above 100 dB HL).

To study the FG in relation to the degree of hearing loss or, in other words, to study the adequacy of the fitting, NAL-R prescribed FG values were subtracted from the measured FG values. Figure 3 shows the mean result. Table 1, column 10, shows the individual differences between prescribed and measured FG, averaged at 0.5, 1, 2, and 4 kHz. The figure shows that the prescribed minus measured FG values were close to 0 (within 7 dB) with a spread of approximately +/-15 dB. These values are in agreement with values reported in the literature concerning conventional hearing aid fittings (Van den Heuvel et al, 1997).

Figure 4 shows a typical example of the FG and the change in sound pressure level (aided minus unaided) measured in the open

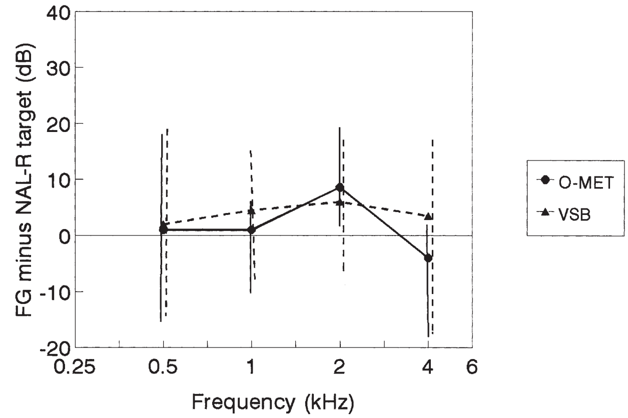


Figure 3. Mean difference (with range) between the functional gain (FG) minus the NAL-R calculated FG as a function of frequency. The full vertical lines indicate the range of the Otologics MET data and the broken vertical lines that of the VSB data.

ear canal. The latter "gain" is further referred to as the open ear canal gain. The figure shows that the open ear canal gain was considerably smaller than the FG. Subtracting the open ear canal gain from the FG resulted in a third curve: the difference trace; Figure 5 shows the individual difference traces of all 13 patients. The difference traces lie above the x-axis, which means that the open ear canal gain was systematically lower than the FG.

Figures 1 and 4 indicate that the sound pressure levels in the ear canal at the low and high frequencies were dominated by direct sound, not the sounds that did originate from the MEI. This suggests that the measurements on the occluded ear canals might be

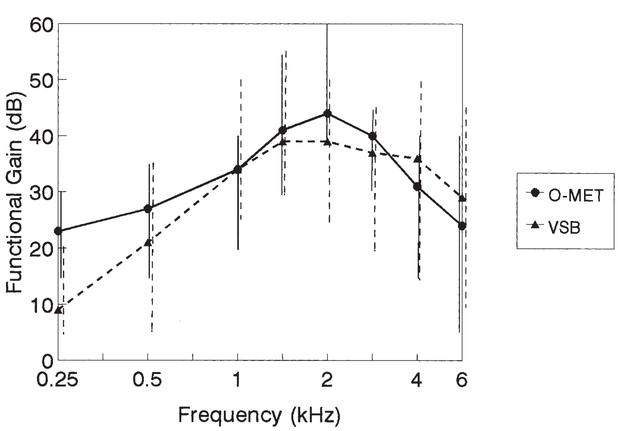


Figure 2. Mean functional gain (and range) as a function of frequency of the VSB users and Otologics MET users. The full vertical lines indicate the range of the Otologics MET data and the broken vertical lines that of the VSB data.

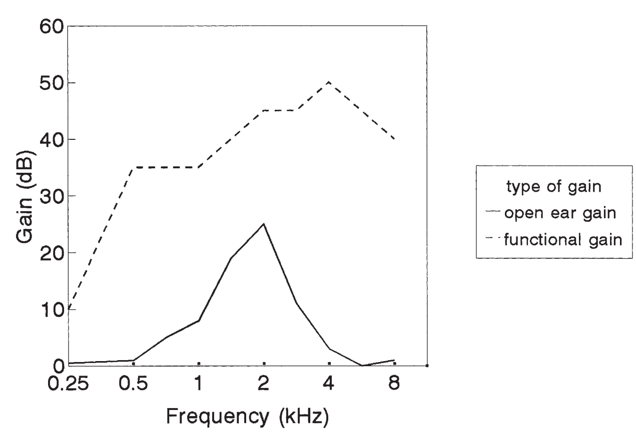


Figure 4. Functional gain (FG) and open ear canal gain as a function of frequency obtained in patient V6.

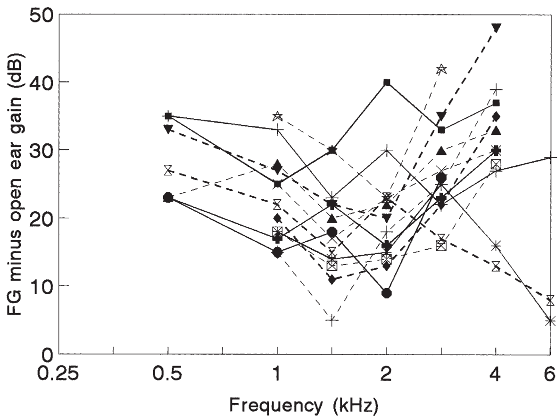


Figure 5. Individual functional gain (FG) minus the gain measured in the open ear canal as a function of frequency. Broken lines connect the data points of VSB users; the full line connects those of the Otologics MET users.

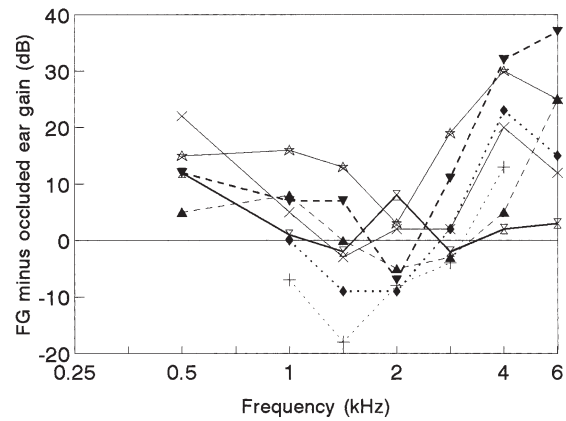


Figure 6. Individual functional gain (FG) minus the gain measured in the occluded ear canal as a function of frequency (VSB users only).

more informative. Figure 6 shows equivalent data to those in Figure 5, however, obtained while the ear canal was occluded. These measurements were only obtained on the 8 VSB users. Occlusion of the ear canal introduces a new variable, namely the individual acoustics of the occluded ear canal. Figure 7 shows the ear canal gain obtained with the ear occluded minus that obtained with the ear canal open. This figure shows that occlusion of the ear canal led to systematically higher ear canal gain, which varied widely between patients, especially above 1 kHz.

Next, from open ear canal measurements with frequency sweeps at different intensity levels (50 to 80 dB SPL), input-output curves were constructed. Figure 8 shows typical

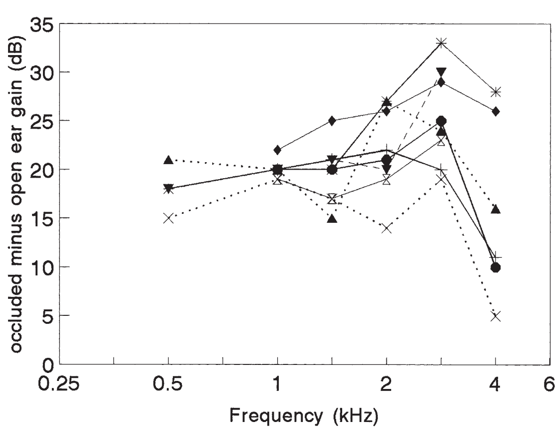
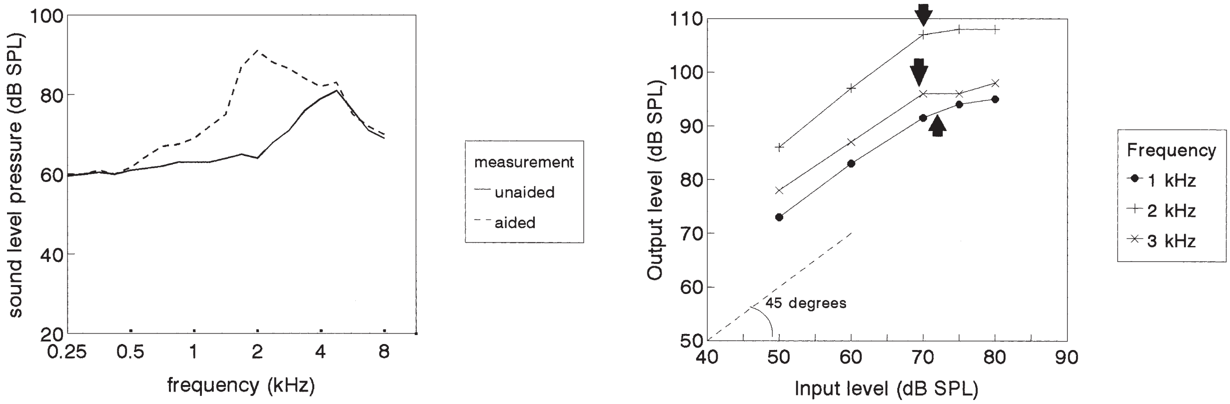


Figure 7. Difference in gain measured in the open and occluded ear canal (VSB users only).

examples of such curves at the frequencies 1, 2, and 3 kHz. Linear growth is present as long as the slope of curve is 45°. This is found up to a certain input level, indicated by an arrow. For higher input levels, the output levels off. The input level at which the output levels off is determined from such graphs. For further analysis, the highest (best) value of the 3 input levels was used, which is 60 dB for subject V8 (Figure 8a) and between 70 and 75 dB for subject O5 (Figure 8b). Table 1 presents these input levels of all the patients (column 9).

DISCUSSION

Gain and maximum output of MEIs were studied in 13 patients with their devices programmed in the linear amplification mode and while output limiting options were deactivated. Before discussing the gain and maximal output, the first question that needs to be addressed is whether the fittings of the audioprocessors were adequate. As a reference, NAL-R targets were used. Validation studies have shown that NAL-R targets indeed are valid; however, significant interindividual differences have been found. Our comparison between FG and NAL-R target values showed an overall result and interindividual differences that were in line with those reported in literature for conventional hearing aids (Byrne et al, 1990; Van den Heuvel et al, 1997; Humes et al, 2000). Therefore, it is concluded that according to one of



a b

Figure 8. Typical examples of input-output curves constructed from the open ear recordings of patient V8 (Figure 8a) and O5 (Figure 8b) at 1, 2, and 3 kHz. The arrows indicate the input level at which output started to level off.

today's standards, the fitting of the audioprocessors was acceptable.

Examining Figure 5, which shows the individual FG minus the gain measured in the open ear canal, considerable variability between patients is seen. Broadly speaking, the difference traces were situated between 15 to 35 dB, which indicates that the open ear canal gain was systematically lower than the gain perceived by the patient. This is in agreement with the results of studies on the (relatively inefficient) reverse transfer functions of the middle ear (see beginning of article).

To minimize the effect of direct sounds, it was decided to repeat the ear canal measurements on occluded ear canals. Figure 7 shows the differences between open and occluded ear canal gain in the VSB users. Considerable interindividual variability was found, which can be ascribed to individual acoustic properties of the occluded ear. Thus the variation in individual ear acoustics has a negative influence on the clinical value of gain measurements obtained from occluded ear canals. Further, Figure 7 shows that occlusion of the ear canal leads to an increase in sound pressure levels of about 20 dB. Winter et al (2002) performed their measurements solely with occluded ear canals. They reported a good match between FG and the gain measured in the occluded ear canal. Present results suggests that this is a coincidence; the 20 dB increase in sound pressure levels owing to the occlusion of the ear canal cancels at least in part the 15 to 35 dB negative gain of reverse sound transmission through the middle ear. In principle, gain derived from ear canal measurements seems not to be an accurate estimate for the gain perceived by MEI users.

Assuming that the reverse transfer function of the middle ear behaves linearly, (open) ear canal measurements might be useful for the evaluation of relative characteristics, such as input-output behavior. From ear canal recordings at different input levels, the input level at which the output reached a plateau was determined. Table 1 shows that VSB output leveled off at input levels of 60 to 70 dB SPL, whereas with the Otologics MET device this occurred at input levels of between 70 and 75 dB SPL. The higher the input level at which output levels off, the better, as long as loudness discomfort is avoided. If this input level is too low, speech sounds are distorted. According to Dillon and Storey (1998), the input level at which the output levels off should be clearly above the loudest parts of normal speech, preferably between 70 and 80 dB SPL. This criterion was met in the Otologics users.

The maximum output in dB SPL can be estimated from these input levels by adding the FG. It should be remembered that these input levels were determined in the frequency interval 1 to 3 kHz. Therefore, we decided to add the mean FG at 1, 1.5, 2, and 3 kHz to the input level at which the output leveled off. In this way, the maximum output was estimated, expressed in dB SPL; for the VSB, it ranged from 92 to 112 dB SPL (mean: 102

dB SPL), whereas for the Otologics MET the range was 103 to 120 dB SPL (mean: 111 dB SPL). Most of the individual values were below the target values for maximum output (targets: 110–120 dB SPL for hearing loss of between 65 and 80 dB HL; Dillon and Storey, 1998). This concerns the data of seven of the eight VSB users and one of the five Otologics MET users.

At last, a remark has to be made on FG measurements. After implantation, hearing deterioration might be present owing to either surgical changes or the presence of the transducer in the middle ear. A postsurgery air-bone gap might result in an equivalent improvement of the FG because it affects directly the unaided thresholds. However, such an improvement has no significance for the patient and should be considered as a treatment artifact. To minimize this effect, we only included patients with unchanged hearing after surgery (within the measurement error) and normal middle ear impedance.

In summary, the amplification of these two types of MEI could not be derived readily from the measurement of sound pressure levels in the ear canal. Behavioral tests remain the first choice to obtain data on gain. However, input-output behavior can be studied with ear canal measurements.

Our results indicated that the maximum output of the VSB was somewhat low in the present patient population, suggesting that their hearing loss was too severe. This observation underlines a conclusion drawn in a previous paper on the VSB programmed in nonlinear mode (Snik and Cremers, 2001), namely that the upper threshold level for application seems to be too high, in the order of 10 to 15 dB. Results in (just) five patients using the Otologics MET device were better in this respect.

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