

Efficacy of Auditory Implants for Patients With Conductive and Mixed Hearing Loss Depends on Implant Center

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Introduction: Although from a technological point of view, progress is impressive, most implantable hearing devices for conductive or mixed hearing loss have a limited capacity. These devices all bypass the impaired middle ear; therefore, the desired amplification (gain) should be based on the cochlear hearing loss (component) only. The aim of the study is to review the literature with regard to accomplished gain with current implantable devices.

Method: Thirty-one articles could be included. Aided thresholds were compared with prescribed values, based on cochlear hearing loss (bone-conduction thresholds), according to the well-validated NAL rule.

Results: For the majority of the studies, NAL targets were not met. Variation in accomplished gain between implant teams was unacceptably large, largely independent of the type of device that was used. NAL targets were best met at 2 kHz, with worse results at the other frequencies.

Conclusion: Large variations in reported results were found, which primarily depended on implant center. Based on the analyses, a pragmatic fitting procedure is proposed which should minimize the differences between implant centres.

Key Words: Aided thresholds—Baha—Codacs—Fitting rule—Gain—Ponto—Vibrant Soundbridge.
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The number of publications on the efficacy of middle ear implants and bone-conduction implants for patients with conductive and mixed hearing loss is increasing steadily. The studied devices concern: percutaneously coupled bone-conduction devices like the Baha device (Cochlear BAS, Gothenburg, Sweden) and Ponto device (Oticon Medical, Askim, Sweden), the more recently introduced transcutaneously coupled Sophono device (Medtronic, Boulder, CO) and Baha Attract device (Cochlear BAS, Gothenburg, Sweden), as well as the active transcutaneous Bonebridge device with an implanted actuator (Med-El, Innsbruck, Austria). Furthermore, middle ear implants have also been applied successfully in patients with conductive and mixed hearing loss; Colletti et al. (1) published the first report on coupling the actuator of the Vibrant Soundbridge

(VSB; Med-El, Innsbruck, Austria) to one of the cochlear windows. More recently, the Codacs device was introduced (Cochlear, Mechelen, Belgium). That device has been developed for patients with advanced otosclerosis; its implanted actuator is connected to a conventional stapes prosthesis that directly drives the perilymph in the cochlea (2).

The primary efficacy outcome of most studies is the gain of the device. Often, the so-called “functional gain” is reported, which, by definition, is the difference between aided and unaided sound-field thresholds. The “functional gain” has been defined for (linear) hearing devices, applied in sensorineural hearing loss (3). Owing to the definition of “functional gain,” the status of the malfunctioning middle ear in mixed or conductive hearing loss, as expressed by the air-bone gap, does directly affect the “functional gain” value. The larger the air-bone gap is, the higher the “functional gain” of any device that bypasses the middle ear can be. Therefore, to evaluate efficacy in conductive and mixed hearing loss, “functional gain” should not be used; the “effective gain” is the preferred gain measure, defined as the cochlear (bone-conduction) thresholds minus the aided thresholds (1,4–6).

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A major advantage of the “effective gain” is that validated fitting rules, developed for sensorineural hearing loss, can be applied to prescribe the “effective gain” (e.g., the NAL (National Acoustic Laboratories) rule or DSL (Desired Sensation Level) rule (3)). In the present study, the “effective gain” is used as the primary efficacy measure. (Note that the bone-conduction thresholds should be properly masked when applying a middle ear implant, while unmasked when a bone-conduction device is used. In the latter case the stimulation is not ear specific owing to the low attenuation of bone-conduction vibrations in the skull bone (7,8)).

Using data from published manuscripts, the “effective gain” is calculated and evaluated in relation to NAL prescribed gain values. This enabled the development of a dedicated pragmatic fitting procedure.

METHOD

To find relevant publications, it was decided to use publications from systematic reviews; this concerned the reviews by Colquitt et al. (9), Verhaert et al. (10), Ernst et al. (11), Dimitriades et al. (12), and Sprinzl and Wolf-Mangele (13). These systematic reviews dealt with the application of implantable devices in patients with conductive or mixed hearing loss. Only those selected publications were considered that presented frequency-specific audiometric data. Duplicates were removed as well as studies with five patients or less, studies published before 2006 and unpublished presentations. Air-conduction and bone-conduction thresholds were collected as well as aided sound-field thresholds, to enable the calculation of the “effective gain.” More detailed information is presented in the Appendix (see Supplemental Digital Content 1, <http://links.lww.com/MAO/A753>).

Table 1 reviews the numbers of included publications and the total number of included patients per device type. A subdivision in publications was made according to the mean cochlear hearing loss thus the mean bone-conduction threshold (PTAbc, the average at 0.5, 1, 2, and 4 kHz); see Table 1, columns 2–4.

Next, the calculated “effective gain” values were compared with gain values prescribed by the NAL-RP fitting rule (addition RP stands for Revised, Profound) (3). That rule has been developed for linear devices (the choice of the NAL-RP rule is further addressed in the Discussion section). According to the NAL-RP rule,

desired gain at a frequency of 1 kHz and above is approx. 0.45 times the cochlear hearing loss (± 2 dB). At 0.5 kHz the prescribed gain is significantly lower (3). Note that the desired aided thresholds equal the cochlear thresholds minus the NAL gain (0.45 times the cochlear thresholds), so, the desired aided thresholds equal 0.55 times the cochlear thresholds.

RESULTS

Figure 1 presents frequency-specific ratios for each reviewed study, obtained by dividing the mean “effective gain” by the mean cochlear hearing loss (2,14–24). This ratio was calculated for 0.5, 1, 2, and 4 kHz, separately. Full lines in Figure 1 present mean data for patients with mixed hearing loss with a mean cochlear hearing loss exceeding 35 dB HL (Table 1, column 4), presented per device type (powerful Baha/Ponto processors, VSB, and Codacs device). Mean data (across studies) per device type are presented; to calculate the mean, group size of each study was taken into account. Figure 1 shows an obvious effect of the type of device used. Only at 2 kHz, the calculated gain ratios are relatively close to the NAL target value of 0.45 (see the Method section).

The dashed lines in the figure show similar data obtained from studies in patients with mean cochlear hearing loss between 25 dB HL and 35 dB HL. This concerned patients using VSB or medium power Baha/Ponto devices (Table 1, column 3). If the calculated ratio is negative, it means that, on the average, for that frequency, the air-bone gap is not “closed.” Again, best results are found at 2 kHz, with a clear roll-off toward the higher and lower frequencies. A similar trend is found for predominant conductive hearing loss (cochlear thresholds below 25 dB HL; Table 1, column 2); these data are not displayed as all those ratios are negative and off scale (below -0.3).

According to the NAL-RP rule, the ratios shown in Figure 1 should be 0.45, except for 0.5 kHz (see the Methods section); the 0.5 kHz data will not be further considered.

Figure 2A presents the “effective gain” obtained at 2 kHz of all the reviewed studies, thus at the frequency with the best gain ratio (2,5,6,14–41). The mean gain is presented as a function of the mean cochlear hearing loss, for each individual study. This figure shows that the “effective gain” at 2 kHz is rather close to the NAL

TABLE 1. Per device type, the number of included studies and included patients. Columns 2 to 4 present a subdivision according to the degree (severity) of the mean cochlear hearing loss (PTAbc): predominant conductive loss (PTAbc < 25 dB HL), mixed hearing loss (PTAbc > 35 dB HL), and the in between group

Device	Number of Studies; Patients	PTAbc<25 dB HL	25<PTAbc≤35 dB HL	PTAbc>35 dB HL
VSB	12; 205	2; 17	4; 63	6; 125
Baha/Ponto	11; 230	3; 42	4; 118	3; 70
Baha Attract	0	0	0	0
Bonebridge	5; 43	5; 43	0	0
Codacs	3; 43	0	0	3; 43

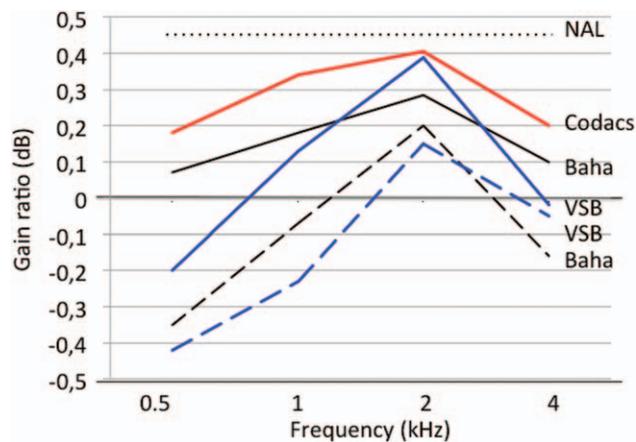


FIG. 1. The ratio (mean “effective gain” divided by the mean cochlear hearing threshold) as a function of frequency. The full lines refer to the averaged data of respectively the Codacs (2,23,24), Baha (14,15,22) and VSB devices (16–21; see labels) obtained from studies in patients with a mean cochlear hearing loss exceeding 35 dB HL. The dashed lines present similar data for studies in patients with a cochlear hearing loss between 25 and 35 dB HL. The NAL target line is also presented as a dotted line, labelled NAL.

target (indicated by the dashed line with a slope of 0.45), however, only for studies with a cochlear hearing loss greater than 35 dB HL. For a cochlear hearing loss below 25 dB HL, most studies showed a negative “effective

gain.” Figure 2B shows the related aided thresholds as a function of cochlear loss at 2 kHz. The full line presents the NAL prescribed aided thresholds. For cochlear hearing loss below 35 dB HL, the aided thresholds seem to be

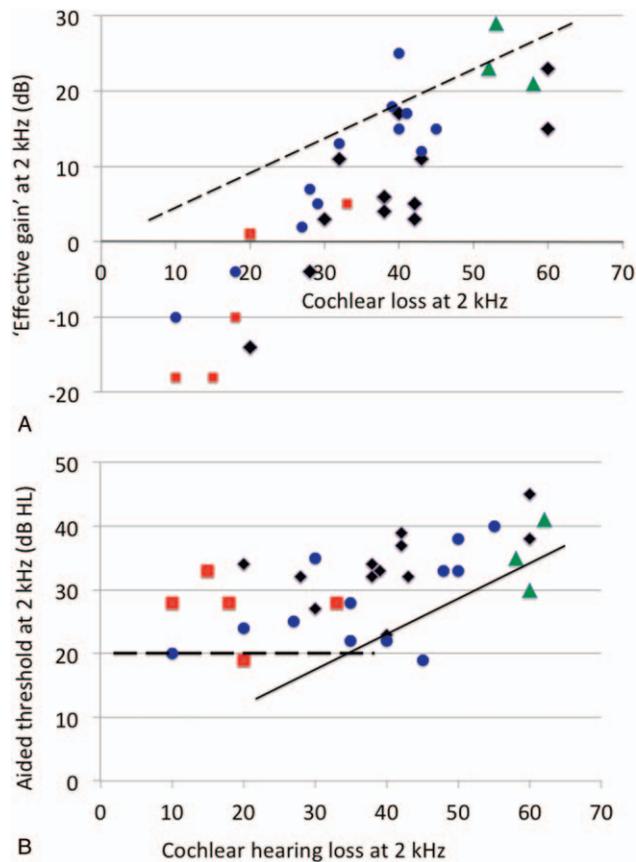


FIG. 2. The “effective gain” (A) and the aided thresholds (B) at 2 kHz as a function of the cochlear hearing loss. Data from each individual study are presented. The triangles refer to the Codacs studies (2,23,24), the squares to Bonebridge studies (34–38), the dots to VSB studies (16–21,27–33) and the diamonds to Baha/Ponto studies (5,6,14,15, 22,25,26,36,39–41). The lines in the figures present NAL target values.

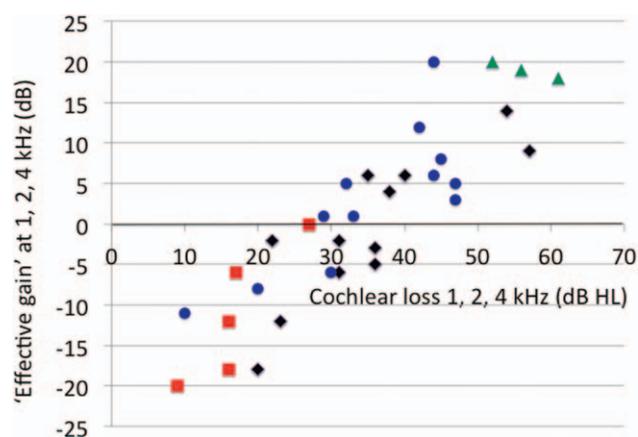


FIG. 3. The “effective gain” at 1, 2, and 4 kHz averaged as a function of the cochlear hearing loss averaged across the same frequencies. The triangles refer to the Codacs studies (2,23,24), the squares to Bonebridge studies (34–38), the dots to VSB studies (16–21,27–33) and the diamonds to Baha/Ponto studies (5,6,14,15, 22,25,26, 36,39–41).

independent of the hearing loss. Figure 3 shows the “effective gain” averaged over the frequencies 1, 2, and 4 kHz; data points are approximately 5 dB worse than those presented in Figure 2A. Inspection of the figures suggests that spread between studies (clinics) is more dominant than the spread between the types of devices.

DISCUSSION

The use of the “effective gain” instead of “functional gain” enables a proper comparison between devices as well as a comparison with the well-known prescription rules. Figure 1 shows that the calculated ratios are clearly below NAL targets. The figure suggests “under-amplification,” which, although seldom discussed, might have been applied to minimize feedback. Another reason might be the limited maximum output (MPO) of most implantable devices (7,42). To deal with a limited MPO and, consequently, a limited “aided dynamic range of hearing,” patients might choose a relatively low gain setting (7). As discussed elsewhere (8), patients using percutaneous bone conductors might prefer limited gain in the low frequencies owing to the “own voice” issue that is common to patients using bone-conduction amplification. The Codacs device is the only device with a high MPO that is not limiting (42), explaining the relatively high, favorable gain ratios.

From Figure 1, it is also concluded that the frequency response of the devices is not optimal, with roll-off in the high and low frequencies. Especially for studies in patients with cochlear hearing loss below 35 dB HL, this phenomenon is prominent. In most of these studies, significant “air-bone gaps” were still present after treatment, in the order of 10 to 20 dB; see Figure 3, where the negative “effective gain” reflects the “remaining air-bone gap.”

Figure 2A and, even more clearly, Figure 3 illustrate that large variations exist, up to 15 to 20 dB, between studies (thus implant centers). This indicates that a well-defined fitting procedure is needed. Figure 2B suggests

that the aided thresholds for cochlear loss above 35 dB HL are reasonably close to NAL targets (full line) while the aided thresholds below 35 dB HL vary between 20 and 35 dB HL, independent of the cochlear hearing loss. It has been argued before that in case of conductive hearing loss, the first 20 dB can be missed (3). The dashed line represents that suggestion; now, 40% of the data points lay within 5 dB from the two target lines, viz. the dashed line up to 35 dB HL and the solid line above 35 dB HL. These data further suggest that the other 60% of the clinics used a more conservative approach. Figure 3 shows the combined data obtained at 1, 2, and 4 kHz; with the same criterion (data points should not be more than 5 dB above the target lines), 33% of the data met this criterion.

So, as a pragmatic approach, it is suggested that the aided threshold at 2 kHz should be 20 dB HL whenever the cochlear threshold is 35 dB HL or less, and 0.55 times the cochlear threshold when the cochlear thresholds exceed 35 dB HL. Although it will be harder to accomplish, there is no obvious reason not to use these target values for 1 and 4 kHz as well. These target values are summarized in Table 2.

For validation purposes, the target aided word scores were calculated, using the method described by Mueller and Killion (43). For this calculation, the assumption was that the cochlear hearing loss was sloping (10 dB per octave). The target word scores are presented in Table 2, as a function of the mean cochlear hearing loss. For a less sloping hearing loss, target word scores are (somewhat) higher.

The Use of the NAL-RP Rule

The NAL-RP rule was used, assuming linear amplification because nonlinear amplification (compression) is not the first choice in (predominant) conductive hearing loss. Compression, to deal with the inherently restricted “dynamic range of hearing” in sensorineural hearing loss (3), has also been used to deal with the restricted “dynamic range of hearing” caused by using a device

TABLE 2. Table 2a presents the desired (target) aided threshold as a function of the cochlear hearing loss for each of the frequencies: 1, 2, and 4 kHz; Table 2b presents the expected (target) word score at 65 dB SPL as a function of the mean cochlear hearing loss

Table 2a							
Cochlear loss (dB HL)	5	15	25	35	45	55	65
Target aided threshold at 1, 2, 4 kHz (dB HL)	20	20	20	20	25	30	36
Table 2b							
Mean cochlear loss (dB HL)	5	15	25	35	45	55	65
Target word score (% correct)	>95	>95	>95	>95	85	75	65

with a low MPO (e.g., (13)). Using compression instead of linear amplification suggests that instead of the NAL-RP rule, the NAL prescription rule for nonlinear amplification should have been used (the NAL-NL rule; the addition NL stands for nonlinear) (3). While the prescribed gain at conversational levels is comparable with either rule, the prescribed gain for low-level sounds is higher and thus the target aided-thresholds are lower when using NAL-NL. Therefore, choosing the NAL-RP is a conservative approach.

Recently, Hodgetts et al. (8) presented a more sophisticated prescription method, specially developed for fitting percutaneous bone-conduction devices. Their prescription takes into account the MPO of the individual percutaneous device being fitted and adjusts the frequency response and compression characteristics according to the dynamic range of the patient with the cochlear thresholds as the lower end of the dynamic range and the device MPO as the high end.

In summary, the use of “effective gain” instead of “functional gain” enabled a direct comparison between types of devices and clinics as well as comparison with a well-validated fitting rule. Target values for the “effective gain” might optimize device fittings in general and minimize the large differences in outcomes between clinics. Desired (target) aided thresholds and desired word recognition scores are presented (Table 2).

When choosing an amplification option for a patient, device efficacy should play an important role but is not the only factor. Other issues, not considered here, should be taken into account like surgical issues, costs, stability, as well as personal factors.

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