12-1-2013

# Hearing-Aid Safety: A Comparison of Estimated Threshold Shifts for Gains Recommended by Nal-Nl2 and Dsl M[i/O] Prescriptions for Children

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## Citation Information

Ching, Teresa Y. C.; Johnson, Earl E.; Seeto, Mark; and Macrae, John H.. 2013. Hearing-Aid Safety: A Comparison of Estimated Threshold Shifts for Gains Recommended by Nal-Nl2 and Dsl M[i/O] Prescriptions for Children. *International Journal of Audiology*. Vol.52(2). 39-45. https://doi.org/10.3109/14992027.2013.847976 ISSN: 1499-2027

# Hearing-Aid Safety: A Comparison of Estimated Threshold Shifts for Gains Recommended by Nal-Nl2 and Dsl M[i/O] Prescriptions for Children

Published in final edited form as:
*Int J Audiol*. 2013 December ; 52(0 2): . doi:10.3109/14992027.2013.847976.

# Hearing aid safety: a comparison of estimated threshold shifts for gains recommended by NAL-NL2 and DSLm[i/o] prescriptions for children

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## Abstract

**Objective—**To investigate the predicted threshold shift associated with the use of nonlinear hearing-aids set according to the NAL-NL2 or the DSL m[i/o] prescription for children. For medium and high input levels, we asked: 1) for the same audiograms, how do predicted asymptotic threshold shifts (ATS) differ according to the choice of prescription? 2) How does predicted ATS vary with hearing level for gains prescribed by the two prescriptions?

**Design—**A mathematical model consisting of the Modified Power Law combined with equations for predicting temporary threshold shift (Macrae, 1994b) was used to predict ATS.

**STUDY SAMPLE—**The audiograms of 57 children from a previous study and two hypothetical audiogram shapes were used.

**Results—**For the 57 audiograms, DSL m[i/o] gains for high input levels were associated with increased risk, relative to NAL-NL2. The variation of ATS with hearing level suggests that NAL-NL2 gains became unsafe when hearing loss > 90 dB HL. The gains prescribed by DSL m[i/o] became unsafe when hearing loss > 80 dB HL at medium input level, and > 70 dB HL at high input level.

**Conclusion—**There is a risk of damage to hearing for children using nonlinear amplification. Vigilant checking for threshold shift is recommended.

### Keywords

hearing aid safety; threshold shift; hearing aid prescription; children; NAL-NL2; DSLm[i/o]

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**IJA Supplement:** Optimising Rehabilitation Outcomes for Children with mild to profound hearing loss

## Introduction

The implementation of universal newborn hearing screening has made it possible for early detection of hearing loss and fitting of amplification. Audibility of sounds can be greatly improved with amplification, but the use of a hearing aid can also cause further damage to hearing by exposing the ear to high sound levels (Macrae, 1991). To avoid potential damage to hearing involved in hearing-aid use, the American Academy of Audiology (AAA) Clinical Guidelines for Pediatric Amplification (AAA, 2013) have recommended that hearing aids be set according to 'a validated, pediatric-focused prescriptive formula, and account for the real-ear-to-coupler difference'; and that 'temporary threshold shift (TTS) … be monitored if over-amplification is suspected'.

The AAA recommendations were based on a review of literature, which found 9 case series reports or single case studies. The studies revealed that there is a real risk of threshold shift from excessive amplification (Reilly et al, 1981; Heffernan & Simons, 1979), and that the risk is greater for hearing-aid users with more severe hearing loss (Macrae 1994). Use of hearing-aid gains higher than those recommended by the NAL-RP prescription (Byrne & Dillon, 1986; Byrne et al, 1991) or exposure to high input levels (> 65 dB SPL) or both would result in greater amounts of threshold shifts for users whose hearing thresholds exceed 90 dB HL (Macrae, 1994b). A series of papers by Macrae (1991; 1993; 1994; 1995) demonstrated that a mathematical model can be applied to predict the risk of threshold shifts from hearing-aid use as accurately as it can be measured.

For a certain input level, the TTS for hearing-impaired individuals can be predicted by the Modified Power Law (MPL, Humes & Jesteadt, 1991). The MPL is given by:

$$T' = 10\log\left[\left\{\left(10^{T/10}\right)^{P} + \left(10^{TTS_n/10}\right)^{P} - 1\right\}^{1/P}\right] \quad (1)$$

where T' is the TTS-affected threshold of the impaired ear, T is the initial hearing threshold, $TTS_n$ is the temporary threshold shift that would be produced by noise exposure in normal ears, and *p* is 0.2 (Macrae,1994a). The predicted TTS in the impaired ear is the difference, in dB, between the TTS-affected threshold (T') and the initial threshold (T).

On average, any TTS will have reached an asymptotic value (ATS) after 7-8 hours of hearing aid use, even if the noise exposure is fluctuating in level (Mills, 1982). The maximum ATS caused by exposure to an octave band of noise occurs about half an octave above the centre frequency of the band (Mills et al, 1979), and is given by the equation:

$$ATS = 1.7\left[10\log_{10}\left(I_e + I_c\right)/I_c\right], \quad (2)$$

where $I_e$ is intensity of the octave band of noise and $I_c$ is intensity of a critical level. As these critical band levels were determined in the diffuse sound field, Macrae (1994b) noted that estimates of exposure level in hearing-aid use need to be specified at the eardrum by adding the diffuse field to eardrum transfer function (Bentler & Pavlovic, 1992) to the critical levels.

Further, the MPL can be used to determine safety limits for threshold shifts as a function of hearing level (Macrae, 1994b). For the same level of noise exposure, the threshold shift that may occur is greater for ears with normal hearing than for ears with sensorineural impairment (Ward, 1973). For individuals with normal hearing, the safety limit is about 50 dB. The MPL predicts that this safety limit decreases rapidly with increase in hearing loss, and is less than 2 dB for a hearing loss of 100 dB HL. For a mean input level of 61 dB(A)

SPL, Macrae (1994b) showed that using 15 dB more gain than that recommended by the NAL-RP (Byrne & Dillon, 1986; Byrne et al, 1991) procedure at 1kHz is enough to cause TTS of 3 dB for anyone with initial hearing thresholds of 50 dB HL.

The risk of excessive amplification on children using nonlinear hearing aids is not known, given that published safety calculations have all been performed with linear hearing aids. Whereas recommended gains for medium input level and overall maximum power output for linear amplification may be similar to those for non-linear amplification, the gains for high input level differs between the two because nonlinear amplification typically reduces gain with increase in input level (and increases gain with low input level). The AAA clinical guidelines on pediatric amplification (AAA 2013, p. 21-22) makes the assumption that "Exceeding the safety limit is unlikely when hearing aids are fit to independent prescriptive formulae, when nonlinear signal processing is used, and when the user has hearing levels below the severe to profound range (lower gains are necessary)". Verifying these assumptions is important, given that the two independent prescriptive formulae widely used for fitting hearing aids recommend quite different gain-frequency responses for the same audiograms at the same input level (Ching et al.a, this issue). Over-amplification does harm – each increase in hearing loss requires a corresponding increase in gain to restore audibility, which in turn causes an increase in noise exposure and further loss of hearing.

The level of noise exposure in the ear depends on the output of the hearing aid, which is primarily determined by the input sound level, the gains applied and, if saturation of the hearing aid occurs, the real-ear saturated response. Independent fitting methods that have specific prescriptive formulae for children include the National Acoustic Laboratories NAL-NL2 (Dillon et al, 2011) and the Desired Sensation Level multi-stage input/output algorithm or DSL m[i/o] (Scollie et al, 2005). Ching et al (b, this issue) showed that on average, NAL-NL2 prescribed 10 to 15 dB less gain than DSL m[i/o] for frequencies at or below 2 kHz, but similar gains at 4 kHz for the same audiograms. The same applies for low, medium and high input levels; with greater differences in low-frequency gains for sloping than for flat configurations. The gains prescribed for medium and high input levels are especially relevant to calculations of in-ear noise exposure.

This study adds to existing knowledge by calculating the predicted threshold shifts associated with the use of gains for 65 dB and 80 dB input levels as recommended by the NALNL2 and the DSL m[i/o] prescriptions for children. The primary aim was to calculate the ATS associated with using hearing-aid gains recommended by two prescriptive procedures. In order to relate safety calculations to estimates of speech intelligibility and loudness and measured language development (Ching et al. b, this issue), we used audiograms of children who participated in the randomized controlled study on prescription in the Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study (Ching et al. a, this issue). The secondary aim was to examine the variation of predicted ATS with hearing loss, using gains recommended by the two prescriptions for medium and high input levels. The calculations were completed separately for a flat and a sloping audiometric configuration, and compared to safety limits.

## Methods

### Study 1: Predicted threshold shift for 57 audiograms at medium and high input levels

This study uses audiometric data from the better ear of 57 children who participated in the LOCHI study (see Figure 1). For each audiogram, the real-ear-aided gain (REAG) targets were derived using standalone software of the respective prescriptions with either measured or age-appropriate real-ear-to-coupler difference values. The target aided gains were added to an input speech spectrum to yield real-ear-aided response (REAR) values in dB SPL

(sound pressure level at the eardrum). The input spectrum for 65 dB SPL was the international long-term average speech spectra (ILTASS) of Byrne et al (1994), and the input spectrum for 80 dB SPL was that reported in Scollie (2005). These REAR SPL values were converted to intensity by the transform of $10^{(\text{dB SPL}/10)}$ and summed within an octave band for the creation of $I_e$ for the calculation of ATS. The octave band in-ear critical dB SPL levels of Mills et al (1979) were likewise converted to intensity ($I_c$). Frequency-specific ATS values were then referenced in the calculation of T' by applying Equations (1) and (2).

### Study 2: Comparing predicted ATS to safety limits for flat and sloping hearing loss

Two hypothetical audiometric configurations were used (Figure 2). For the flat audiogram, predicted threshold shifts were calculated for hearing levels ranging from 20 dB HL to 110 dB HL in 5 dB steps. For the sloping audiogram, threshold shifts were calculated for low-frequency thresholds (0.25 to 1 kHz) ranging from 0 dB HL to 70 dB HL in 5 dB steps, while keeping the audiogram shape unchanged. For each audiogram shape and each prescription method, REAG targets were derived using standalone software of the two prescriptions, and threshold shifts were calculated at 0.5, 1, 2 and 4 kHz for input levels of 65 and 80 dB SPL as described above. The calculations were performed using Statistica (version 10.0.1011) and R (version 3.0.0), with the additional R package ggplot2 (version 0.9.3.1).

## Results

### Predicted threshold shift for 57 audiograms at medium and high input levels

Figure 3 shows the mean threshold shift calculated for the DSL m[i/o] and NAL-NL2 target gains for 57 audiograms at input levels of 65 dB and 80 dB SPL. An ANOVA with threshold shift as dependent variables, prescription, frequency (0.75, 1.5, 3, 6 kHz) and input level (65 vs 80 dB) as repeated measures was conducted. The main effect of prescription was significant ($F(1,56) = 249.9$, $p < 0.0001$). There was significant main effect of frequency ($F(1,56) = 68.7$, $p < 0.0001$) and input level ($F(1,56) = 1933.8$, $p < 0.0001$). There was significant interaction between prescription and input level ($F(1,56) = 440.5$, $p < 0.0001$). There was also significant interaction between prescription and frequency ($p < 0.0001$), and significant interaction among prescription, frequency and input level ($F(3,168) = 27.4$, $p < 0.0001$).

### Comparing predicted ATS to safety limits for flat and sloping hearing loss

Figures 4 and 5 present the predicted ATS at 0.5, 1, 2 and 4 kHz for gains prescribed by NAL NL2 and DSL m[i/o] for medium (65 dB) and high (80 dB) input levels. Figure 4 shows calculations based on a flat audiometric configuration, and Figure 5 shows calculations based on a sloping audiometric configuration. In each figure, the safety limit curves are shown with predicted ATS, as a function of hearing level.

For flat audiograms, predicted gains prescribed by NAL-NL2 became unsafe when hearing loss exceeds 90 dB HL, for both medium and high input levels. On the other hand, predicted threshold shift became unsafe when hearing loss exceeded 80 dB HL in the low frequencies (0.5 and 1 kHz) and 90 dB HL in the high frequencies (2 and 4 kHz) when gains recommended by DSL m[i/o] for medium input levels were used. For high input levels and gains prescribed by DSL m[i/o], predicted threshold shift became unsafe when hearing loss exceeded 70 dB HL.

For sloping audiograms, predicted ATS associated with the use of gains for medium input levels recommended by both prescriptions remain within safety limits for hearing loss <90 dB HL. The same applies for gains prescribed by NAL-NL2 for high input levels. However,

gains for high input levels prescribed by DSL m[i/o] became unsafe when hearing loss is greater than 70 dB HL.

## Discussion

For the same set of 57 audiograms, the predicted threshold shift for gains recommended by the DSL m[i/o] and NAL-NL2 for medium input level (65 dB) was within 1 dB across frequencies. However, the predicted threshold shift increased at 80 dB input level, and considerably more so for gains prescribed by DSL m[i/o] than by NAL-NL2 (see Figure 2). In line with these findings, the predicted speech intelligibility that allowed for hearing loss desensitization was effectively the same between the two prescriptions for medium and high input levels; but estimated loudness was significantly greater for DSL m[i/o] than for NAL-NL2 (see Ching et al., this issue). It is noteworthy that the choice of prescriptions for the same children was not associated with differences in language development, speech production or functional real-world performance evaluated at 3 years of age (see Ching et al, this issue).

The predicted ATS associated with high input level suggests that there is a real risk of noise-induced hearing loss for young children even when they use nonlinear amplification at the gain levels recommended by the prescriptions. Previous observations on acoustic environments experienced by school-aged children in Canada indicated median sound levels of about 60 to 72 dB Leq(dBA) across different educational settings, with higher levels recorded for the younger age group (Crukley et al, 2011). As 5-year-olds are likely to be in listening situations that are different from those of school-aged children, we monitored the real-world acoustic environments of three 5-year-old children in Australia. We gathered data from a personal dosimeter worn by each child over two days, each for a period of 7 hrs or longer. The dosimeters used were CEL-350 dBadge Personal Sound Exposure meters marketed by Casella-CEL (Bedford, UK), calibrated using a CEL-110 Acoustic Calibrator. These dosimeters sampled A-weighted noise levels over the frequency range of 30 to 12,000 Hz, and calculated equivalent continuous level (Leq) between 65 and 140 dBA in one-minute intervals. The data were downloaded using supplied software with International Standards Organization protocols (ISO 1999 1990). The median Leq was 83.8 dBA (interquartile range: 82.4 to 87. 7). The levels were higher than those reported by Crukley et al (2011), but consistent with that reported by Macrae (1995). As young children are often in listening situations of high sound levels, it is important to examine the degree of hearing loss at which predicted ATS may exceed safety limits.

The systematic variation of predicted threshold shift with hearing level is shown in Figure 4 for a flat audiometric configuration; and in Figure 5 for a sloping audiometric configuration. Figure 4 shows that ATS, and therefore temporary threshold shift, is unlikely to exceed safety limits for children with hearing loss of ≤90 dB HL using hearing-aid gains recommended by NAL-NL2; for medium as well as high input levels. When hearing loss exceeds 60 dB HL, small amounts of ATS can be expected to occur during hearing-aid use, but these amounts are safe for hearing thresholds up to about 90 dB HL. Our findings on medium input levels are consistent with those reported by Macrae (1991; 1994a; 1994b) for linear amplification. This study extended previous data by providing information on predicted threshold shifts associated with high input level for hearing aids that have wide-dynamic-range-compression capabilities. When nonlinear hearing aids are used in an environment with high sound levels (80 dB SPL), ATS becomes unsafe for hearing thresholds greater than 90 dB HL for gains prescribed by NAL-NL2. With provision of audibility for this degree of hearing loss comes with an unavoidable risk of damage to hearing. It appears that the amplification recommended by the NAL-NL2 prescription for

children with profound hearing loss is inherently unsafe and will result in permanent threshold shift.

Figures 4 and 5 also show predicted ATS when gains recommended by DSL m[i/o] are used. For hearing aid-use in medium sound levels, ATS occurs for hearing thresholds greater than about 40 dB HL, and becomes unsafe for hearing loss greater than 80 dB HL at 0.5 and 1 kHz or 90 dB HL at 2 and 4 kHz. For hearing-aid use in high ambient sound levels, ATS exceeds safety limits for hearing thresholds greater than about 70 dB HL. Input levels of 80 dB are sufficient to cause predicted threshold shifts of 5 dB or more for children with hearing loss of 75 dB HL using gains recommended by DSL m[i/o]. Similar conclusions can be drawn for both flat and sloping audiogram configurations.

The present findings suggest that predicted ATS exceeds safety limits at lesser hearing loss when gains prescribed by the DSL m[i/o] rather than NAL-NL2 are used, especially in environments with high sound levels. The occurrence of temporary threshold shift reduces speech reception ability of the individual child, and regular occurrence of threshold shift that exceeds the safety limit is likely to result in permanent threshold shift. With each increase in threshold is an increase in gain and likely increase in noise exposure over the lifetime of hearing aid use by a child diagnosed with hearing loss early in life.

### Clinical Implications

Clinicians need to provide advice about noise-induced hearing loss to parents of young children and older children who use nonlinear amplification. Relevant advice may include the potential effect of using gains higher than those recommended, using amplification in environments with high sound levels, and using hearing protection when the child will be in noisy environments for extended periods of time.

The present calculations of ATS as a function of hearing loss may be used as a guide for alerting clinicians to potential risks; and the AAA recommendation of monitoring temporary threshold shift should be studiously observed if excessive amplification is suspected. Assessments of hearing thresholds of young children need to consider the smaller but growing external ear canal status by using individualized RECD (Bagatto et al, 2005). Typically, temporary threshold shift can be checked by measuring hearing thresholds after about 12 hours without a hearing aid in the test ear and then after 8 hours of hearing-aid use. Gains for high input levels need to be reduced if TTS occurs. For hearing loss exceeding 90 dB HL, predicted ATS will occur irrespective of whether NAL-NL2 or DSL m[i/o] prescription was used, for both medium and high input levels. Coupled with the ineffectiveness of the audible signal for speech intelligibility for this degree of loss (Ching et al, 2011; Ching et al, 2001), the findings suggest that cochlear implantation is likely to be more useful than acoustic amplification.

## Conclusion

In conclusion, the modeling approach adopted for estimating threshold shifts from hearing-aid use indicates that for medium input levels, predicted ATS does not exceed safety limits until hearing loss is greater than 90 dB HL, for both NAL-NL2 and DSL m[i/o] prescribed gains. For high input levels, however, predicted ATS exceeds safety limits when hearing loss is greater than 70 dB HL and gains recommended by DSL m[i/o] are used, and when hearing loss is greater than 90 dB HL when gains recommended by NAL-NL2 are used.

## Acknowledgments

The project described was supported by Award Number R01DC008080 from the National Institute On Deafness And Other Communication Disorders. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute On Deafness And Other Communication Disorders or the National Institutes of Health.

We also acknowledge the financial support of the Commonwealth of Australia through the establishment of the HEARing CRC and the Cooperative Research Centres Program.

This manuscript was supported by a Career Development Award-1 to the second author by the U.S.A. Department of Veterans Affairs Rehabilitation Research and Development Office.

## Abbreviations

| | |
|---|---|
| **AAA** | American Academy of Audiology |
| **ATS** | asymptotic threshold shift |
| **dB HL** | Decibel Hearing Level |
| **dB SPL** | Decibel Sound Pressure Level |
| **DSL m[i/o]** | Desired Sensation Level Multi-stage Input-Output Algorithm |
| **ILTASS** | International Long-Term Average Speech Spectrum |
| **LOCHI** | Longitudinal Outcomes of Children with Hearing Impairment study |
| **NAL** | National Acoustic Laboratories |
| **NAL-RP** | National Acoustic Laboratories' revised for profound hearing loss hearing aid prescription for linear hearing aids |
| **NAL-NL2** | National Acoustic Laboratories' hearing aid prescription for non-linear hearing aids, version 2 |
| **PTS** | Permanent Threshold Shift |
| **RECD** | Real-ear-to-coupler difference |
| **TTS** | Temporary Threshold Shift |

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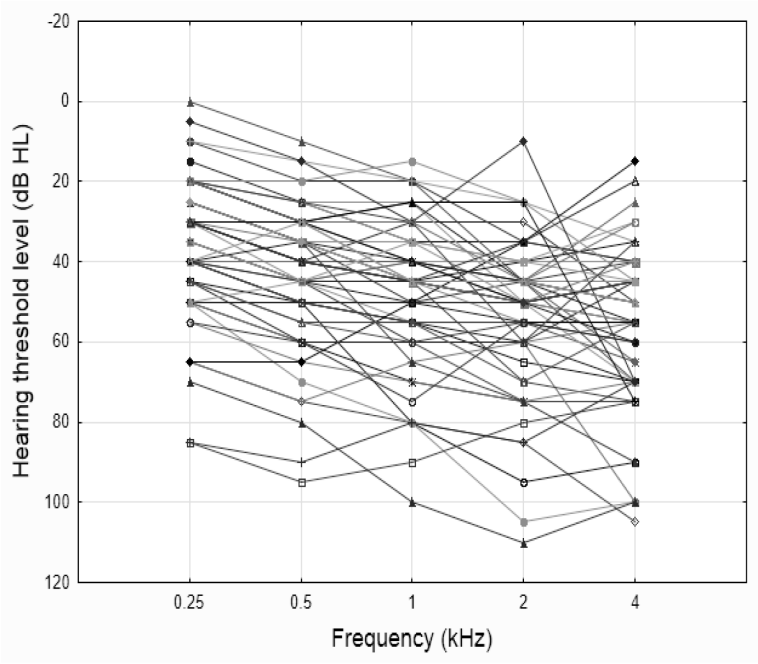


**Figure 1.**
Fifty-seven audiograms of the better ear of children who participated in the longitudinal outcomes of children with hearing impairment (LOCHI) study.

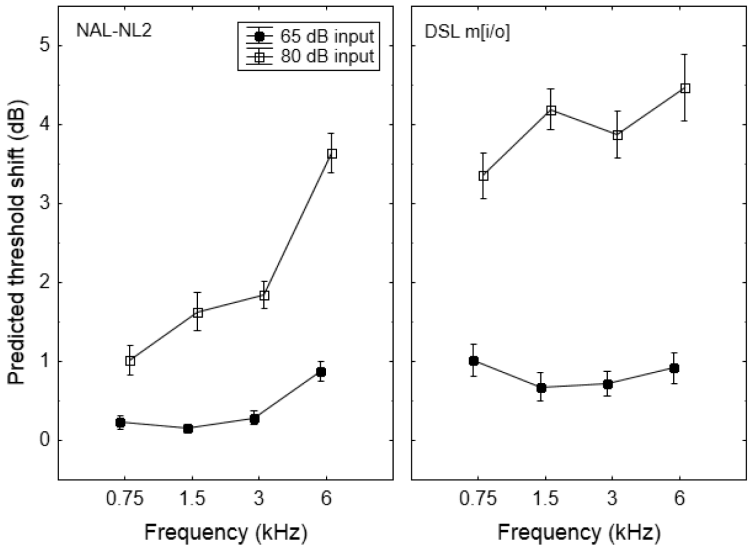


**Figure 2.**

Predicted threshold shift as a function of frequency. The left panel shows calculations based on gains prescribed by NAL-NL2, the right panel shows calculations based on gains prescribed by DSL m[i/o]. Filled symbols depict threshold shifts for 65 dB input, open symbols depict threshold shifts for 80 dB input. Vertical bars indicate 95% confidence intervals.

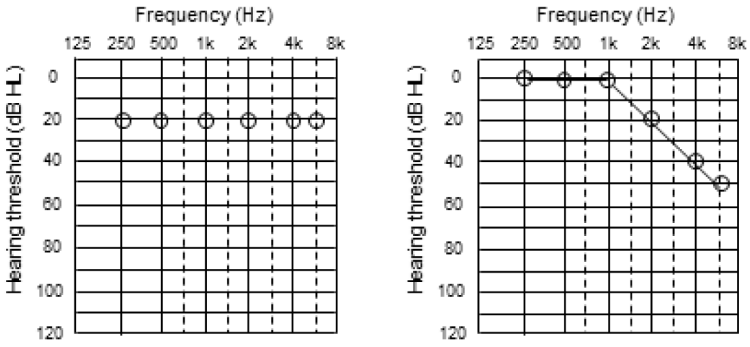


**Figure 3.**
A hypothetical flat (left) and a sloping (right) audiogram configuration used for calculations.

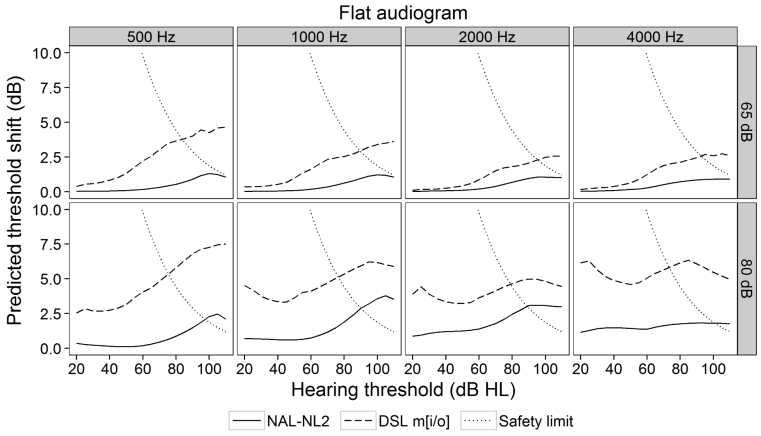


**Figure 4.**

Predicted threshold shift as a function of hearing level for a flat audiogram. The top panels depict findings for 65 dB input, the bottom panels for 80 dB input. Solid curves depict threshold shift associated with gains prescribed by NAL-NL2; broken curves depict threshold shift associated with gains prescribed by DSL m[i/o] (DSL 5.0). Safety limits are represented by dotted lines.

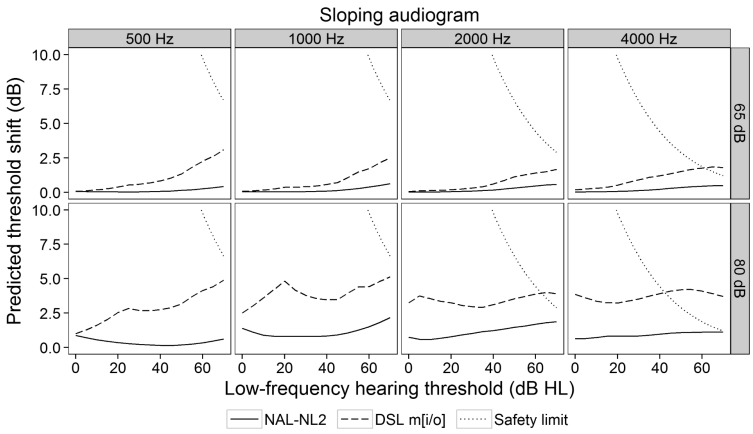


**Figure 5.**

Predicted threshold shift as a function of hearing level for a sloping audiogram. The top panels depict findings for 65 dB input, the bottom panels for 80 dB input. Solid curves depict threshold shift associated with gains prescribed by NAL-NL2; broken curves depict threshold shift associated with gains prescribed by DSL m[i/o] (DSL 5.0). Safety limits are represented by dotted lines.