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NIDCD/VA Hearing Aid Clinical Trial and Follow-Up: Coupler and Real-Ear Measurement

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Abstract

A total of 190 individuals participated in a clinical visit during the Cooperative Studies Program (CSP) 418-A Long Term Follow-Up Study. Of this cohort, 158 participants were considered current hearing aid users, and 32 were non–hearing aid users. Of the current hearing aid users, 81 were still using their original 418 study devices, and 77 had acquired new hearing aids. Coupler and real ear measurements were completed on all available hearing aids. Results showed that study aids had remained relatively stable over the six years between CSP 418 and CSP 418-A. On average, these hearing aid wearers preferred use gain settings that were 6–9 dB less than current NAL-RP insertion gain targets. Mean real ear insertion gain (REIG) was comparable to the mean real ear insertion gain of the same participants in the original study, and users did not tend to increase gain as hearing decreased. Real ear saturation responses (RESR) remained unchanged. Loudness discomfort levels (LDL) obtained during 418-A were significantly lower than LDLs obtained on those same participants at both the initial and final visits in the previous study.

Key Words: 2 cm^3 coupler, insertion gain, loudness discomfort, real ear measurements

Abbreviations: 2 cm^3 = 2-cc coupler; CL = compression limiting; CSP = Cooperative Studies Program; FV = final visit; HFA FOG = high frequency average full on gain; HFA OSPL-90 = high frequency average output saturation sound pressure level at 90 dB; IV = initial visit; LDL = loudness discomfort level; NAL-RP = National Acoustics Laboratory response for profound hearing losses; PC = peak clipper; RECD = real ear to coupler difference; REIG = real ear insertion gain; RESR = real ear saturation response; WDRC = wide dynamic range compression

Sumario

Un total de 190 individuos participaron de la visita clínica durante el Estudio de Seguimiento a Largo Plazo 418-A del Programa de Estudios Cooperativos (CSP). De esta cohorte, 158 participantes se consideraron usuarios actuales de auxiliares auditivos (AA), y 32 se consideraron no usuarios de AA. De los usuarios actuales de AA, 81 aún utilizaban sus dispositivos 418 del estudio, y 77 había adquiridos nuevos AA. Se completaron mediciones de acoplador

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y de oído real para todos los AA disponibles. Los resultados mostraron que los AA del estudio había permanecido relativamente estables en los seis años entre el CSP 418 y el CSP 418-A. En promedio, estos usuarios de AA prefirieron el uso de ajustes de ganancia que estaban 6-9 dB por debajo de las metas actuales de ganancia de inserción del NAL-RP. La ganancia media de inserción de oído real (REIG) fue comparable con la ganancia media de inserción de oído real de los mismos participantes en el estudio original, y los sujetos no tendieron a incrementar la ganancia conforme la audición se deterioró. Las respuestas de saturación de oído real (RESR) se mantuvieron sin cambio. Los niveles de incomodidad a la intensidad subjetiva (LDL) obtenidos durante el 419-A fueron significativamente más bajos que los LDL obtenidos en los mismos participantes, tanto en la visita inicial como final del estudio previo.

Palabras Clave: Acoplador de 2 cm^3, ganancia de inserción, incomodidad a la intensidad subjetiva, mediciones de oído real

Abreviaturas: 2 cm^3 = acoplador de 2 cc; CL = límite de compresión; CSP = Programa de Estudios Cooperativos; FV = visita final; HFA FOG = ganancia completa promedio en altas frecuencias; HFA OSPL-90 = Nivel de presión sonora de saturación promedio de salida en altas frecuencias a 90 dB; IV = visita inicial; LDL = nivel de incomodidad de la intensidad subjetiva; NAL-RP = respuesta a pérdidas auditivas profundas del Laboratorio Nacional de Acústica; RECD = diferencia del acoplador de oído real; REIC = ganancia de inserción de oído real; RESR = respuesta de saturación de oído real; WDRC = compresión de rango dinámico amplio

Larson et al (2000) reported the results of a clinical trial that investigated the efficacy of hearing aids as a treatment for sensorineural hearing loss. The trial was a collaborative effort between the National Institute on Deafness and Other Communication Disorders (NIDCD) and the Department of Veterans Affairs (DVA). Entitled "The NIDCD/VA Hearing Aid Clinical Trial" (also "Cooperative Studies Program [CSP] 418"), the trial employed a double-blind, three-treatment crossover design to measure the benefits of three hearing aid circuits that were available at the time of the study, and was conducted across eight VA (Veterans Affairs) audiology laboratories in the United States. The circuits investigated in CSP 418 consisted of a peak- clipper (PC) and two compression circuits, one providing wide dynamic range compression (WDRC) and the other a compression limiter (CL). Participants (360) wore each of these circuits for a three-month period. One of the major challenges of the 418 study was to make sure that the study hearing aids met ANSI S3.22 1987 specifications and remained stable for the entire nine-month duration of the study to insure that electroacoustic variability did not influence or obscure the interpretation of the outcome measures across the three treatments. The results of all coupler and real ear measurements performed on these study aids clearly demonstrated that the experimental devices remained stable over the study period and that outcome measures were not influenced by variability of hearing aid performance (Bratt et al, 2002).

In December 2000, the planning began for a follow-up study, entitled "Long Term Follow-Up of Patients in the NIDCD/VA Hearing Aid Clinical Trial," or "Cooperative Studies Program (CSP) 418-A." As that process unfolded, the study's planning committee determined it would be important to evaluate the present status and stability of these same study devices over the intervening years since the original study. It was also of interest to obtain coupler and real ear measurements on any newly issued or purchased hearing aids of the participants in the study, and to compare those with the original study aids. This report presents the coupler and real ear electroacoustic data that were obtained on the original study devices still being worn, as well as the data obtained from the new aids that were either issued or purchased since the end of CSP 418.

There were a total of 210 participants in 418-A: 13 were interviewed by phone survey, 7 participated in home visits, and 190 completed clinic visits. This particular report will concentrate solely on results obtained from the 190 clinic visits, where electroacoustic coupler and real ear measurements could be obtained. Based upon the study intake questionnaire, of this cohort of 190 participants, 158 (83%) were considered to be current hearing aid users, defined in this study as those participants who had worn their hearing aids at least once at any time within the past month. Thirty-two, or 17% of that cohort, were considered to be non–hearing aid users, defined here as those who no longer had hearing aids, those whose aids were grossly malfunctioning and who had no plans to have them repaired, or those who had usable hearing aids but did not wear them at all. Ten of the 32 participants considered nonusers still had functional study hearing aids that were available for measurement.

Of the 158 current hearing aid users in 418-A, 81 (51%) were still using either one or both of their original 418 study hearing aids, which were then six years old. Of those study aids still being worn, 78% were still set to the circuit that was preferred and programmed into the device at the end of CSP 418, while the remaining 22% had requested a change of circuitry at some point during the intervening six years. The remaining 69 current hearing aid users (44%) had either been provided with new VA-issued hearing aids as eligible veterans or had privately purchased new hearing aids at some time during the six-year period between the end of 418 and the beginning of 418-A. It was unknown if the remaining eight current wearers (5%) had new aids or their old study aids. Of those new hearing aids, 86% were in-the-ear (ITE) aids.

PROCEDURES

From each hearing aid that was available for measurement, whether it was a new aid or a study device, the following electro- acoustic data were obtained: 2 cm^3 coupler measurements, real ear saturation response (RESR) measurements, and real ear insertion gain (REIG) measurements. In addition, loudness discomfort measurements (LDLs) were also reestablished on the clinic visitors for comparison to their originally obtained LDLs.

Coupler measurements were performed per ANSI S3.22 (1996) and in accordance with the 418 study protocol. RESR measurements were also completed in accordance with the 418 study protocol, with one exception. In 418-A, target RESRs were not recalculated, and the target RESRs from the original 418 were used in the analyses. This decision was felt to be appropriate primarily because the measured RESRs in 418 were consistently below target in all cases (Bratt et al, 2002).

Real ear insertion gain (REIG) measurements were completed for each participant who had a functional hearing aid(s). However, the protocol used to measure REIGs in 418-A was slightly different from the protocol used during the 418 study. In 418-A, each participant's target real ear insertion gain (REIG) was calculated using the NAL-RP formula (Byrne and Dillon, 1986; Byrne et al, 1991) based on current hearing loss. Probe microphone software available during 418-A measurements did not allow selection of the NAL-R formula, which was used in 418. Therefore, the NAL-RP formula was used in 418-A. The differences in these two formulae should not have significantly influenced the findings, given the hearing loss characteristics of this study population. In addition, during 418-A, prior to measuring insertion gain, each participant was allowed to set his or her hearing aid(s) to the preferred use gain setting via a standardized study protocol. Per this protocol, the participant was seated facing a calibrated center loudspeaker in the sound booth. A practice passage from the Connected Speech Test (CST; Cox and Alexander, 1987) was presented at 62 dB SPL from a speaker 1.4 m from the participant, at 0° azimuth. The participant was instructed to listen to this passage and adjust his or her hearing aid(s) to a comfortable loudness level. Once set, the aid(s) were removed without changing volume, and the volume setting was marked. This volume setting was then used for all following real ear probe microphone measurements and will be referred to here as "use gain." In the present study, volume control was not set to match insertion gain to a specified target as was done in the original study. Instead, insertion gain measures were obtained at use gain, and the difference between this gain and the newly formulated NAL-RP targets was compared.

For a complete review of the protocols used in 418, see Bratt et al (2002). For the remainder of this report, the study devices still being used, and the ten functional

Table 1. Means and Standard Deviations of HFA OSPL-90 and HFA FOG of Study Aids Measured in 418-A Compared to the Same Study Aids Measured at Final Visit (FV) of 418 (dB SPL)

Variable	n	Mean	SD
HFA OSPL-90 418-A	157	99.6	7.5
HFA OSPL-90 FV 418	162	98.6	5.5
HFA FOG 418-A	157	23.3	7.8
HFA FOG FV 418	162	24.9	6.6

Note: No significant differences ($p < .05$) in FOG or OSPL-90 for 418 FV vs. 418-A.

study aids that were currently not being worn but were available for measurement, will be referred to as "study aids," while the newly issued or purchased aids will be referred to as "new aids."

RESULTS AND DISCUSSION

2 cm^3 Coupler Measurements

Two cm^3 coupler measurements per ANSI S3.22 (1996) were obtained on all study aids still being worn (137 aids). These results were compared to the results of the coupler measurements obtained on these same study hearing aids made during the final visit (FV) of CSP-418. The continued stability of the study devices was demonstrated by examining some of these data. Table 1 provides the means and standard deviations for both HFA OSPL-90 values and HFA FOG values for the study aids in 418-A compared to the mean HFA OSPL-90 and HFA FOG values obtained on these same study aids during the FV of 418. The difference in n values results from five missing data points on these measures in the present study. These findings showed that there was very little change in output or gain over the six-year period between the two studies. A paired t-test indicated no significant difference between the measurements and demonstrated the stability of the aids over time, at least on these particular parameters.

Sixty-nine (44%) of the 158 clinic participants had acquired new hearing aids (either new VA-issued hearing aids or newly purchased hearing aids), during the period between the two studies. Typically, but not always, these new hearing aids were digital. Coupler measurements of these newly acquired hearing aids were also completed. The majority of the digital hearing aids in this study did not contain noise suppression circuitry that might have precluded valid 2 cm^3 coupler measurements, and ANSI measures were not performed on those few hearing aids that did have such circuitry. Table 2 shows the mean HFA OSPL-90 and HFA FOG values of these aids. On average, these values were slightly higher than those of the original study hearing aids.

Real Ear Insertion Gain Measurements

Real ear insertion gain (REIG) measurements were obtained from all current hearing aid users, for both study aids and new aids, as well as on the ten participants who were considered nonusers but still had functional study aids available to them. As noted earlier, each participant's target real ear insertion gain (REIG) was calculated using the NAL-RP formula (Byrne and Dillon, 1986; Byrne et al, 1991) based on current hearing loss. REIGs were then obtained for each hearing aid at the individual's "use gain" setting, obtained per the protocol noted previously. Recall that, whereas in the original 418 study, hearing aids were adjusted to match prescribed NAL-R targets, in 418-A each wearer's REIG

Table 2. Mean ANSI Measurements of Study versus New Hearing Aids in 418-A

ANSI measure	n	Study hearing aids	n	New hearing aids
HFA OSPL-90 (dB SPL)	157	99.6	134	103.2
HFA FOG (dB SPL)	157	23.3	134	25.3

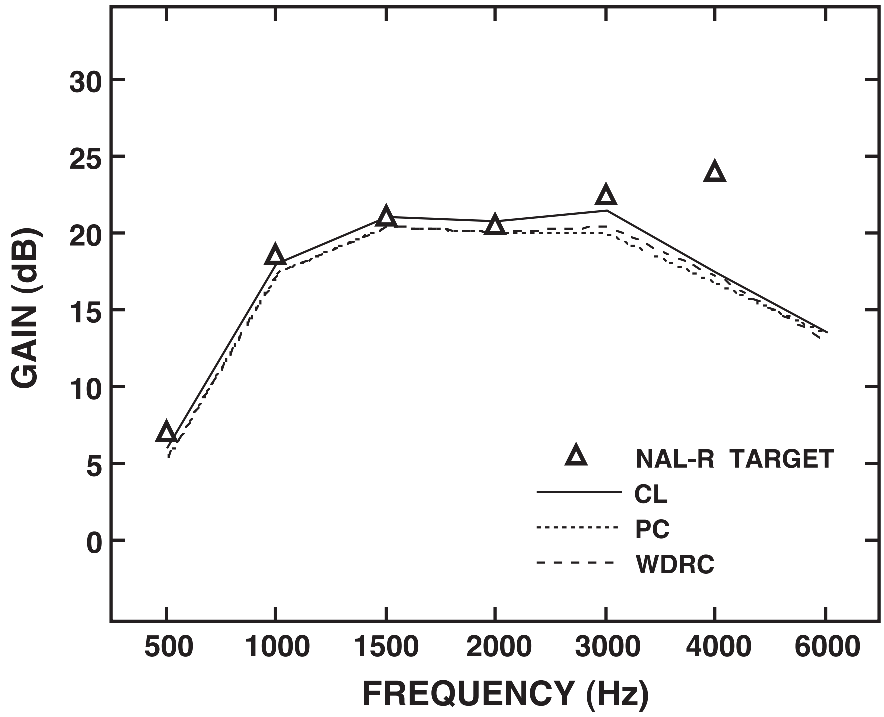

Figure 1. Mean NAL-R targets for all 418 subjects versus mean obtained REIG by circuit type (Bratt et al, 2002).

was measured at the obtained use gain setting, with no attempt to match a prescribed target. The difference between mean REIG obtained at use gain and the newly formulated NAL-RP target mean was then compared.

Figure 1 is taken from Bratt et al (2002) and provides the mean NAL-R targets and REIGs obtained on all participants for each circuit type during the original 418 study. As reported in the original study, all three circuit types were able to achieve a good match to NAL-R target through 3.0 kHz, with the expected undershoot at 4.0 kHz that has been repeatedly documented in the hearing aid literature (e.g., Bratt and Sammeth, 1991). Figure 2 shows the mean preferred use gains of all presently worn hearing aids (study aids and new aids) in 418-A compared to the presently formulated mean prescribed NAL-RP insertion gain targets based on current hearing loss. It should be noted that since the overall hearing of the participants worsened somewhat over the intervening years (Bratt et al, in this issue), the mean NAL-RP target REIGs also increased somewhat. Recall, too, that the REIGs shown here are not the result of an attempted match to specific insertion gain targets but instead indicate the wearer's actual preferred use gain.

As can be seen in Figure 2, the 418-A participants were, on average, setting their hearing aids at use gain that was lower than currently prescribed NAL-RP insertion gain targets. The mean measured insertion gain at use setting was, on average, set 6–7 dB less than current targets in the lower frequencies and shows considerably greater variance from target in the higher frequencies. Similarly, a study by Humes et al (2000) demonstrated that a group of 55 adult hearing aid wearers consistently set the use gain of their hearing aids from 6–9 dB below prescribed NAL-R targets.

Of even greater interest is the comparison between the present mean use gain of all the study aids still available in 418-A and the mean prescribed REIG of these study aids in the original trial. Figure 3 demonstrates that the mean preferred use gain, or "as worn" gain, of all aids in 418-A and the mean insertion gain of those same hearing aids programmed to match target during 418 were similar and differed by only a few dB at any frequency. Although "use gain" was not a question that was addressed in the original study and thus could not be compared to the 418-A "use gain" result obtained here, these REIG data suggest that participants in this study continued to set use gains at levels quite comparable to the levels that were prescribed and programmed in the original trial, despite changes in hearing or hearing aids. Pearson

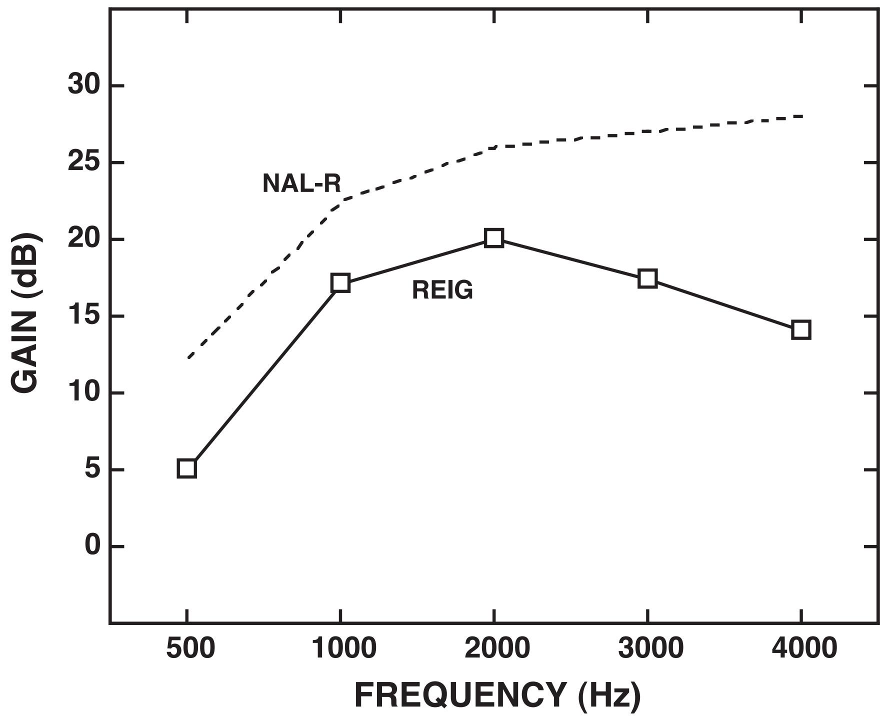

Figure 2. Mean preferred use gains of all presently worn hearing aids (study and new aids) in 418-A versus presently formulated mean prescribed NAL-RP insertion gain targets based on current hearing loss (n = 148).

correlation coefficients were done to determine if changes in individual REIG values correlated with changes in pure tones at .5 Hz, 1.0 Hz, 1.5 Hz, 2.0 Hz, 2.5 Hz, 3.0 Hz, and 4.0 kHz. These measurements showed only two very weak correlations (500 and 1000 Hz for right ear) with no other meaningful correlations at other frequencies ($p < .05$). These results suggested there was little or no correlation between decrease in hearing and setting of use gain.

A possible reason for this might be that

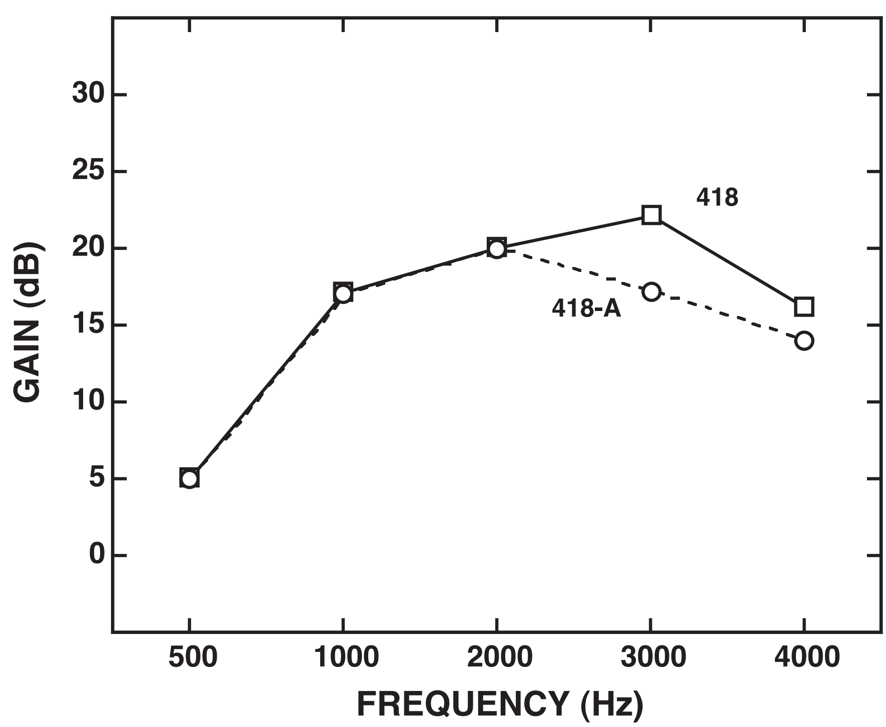

Figure 3. Mean preferred use gain of all hearing aids in 418-A versus REIGs programmed to match NAL-R target for those same hearing aids (i.e., 418-A subgroup) during 418.

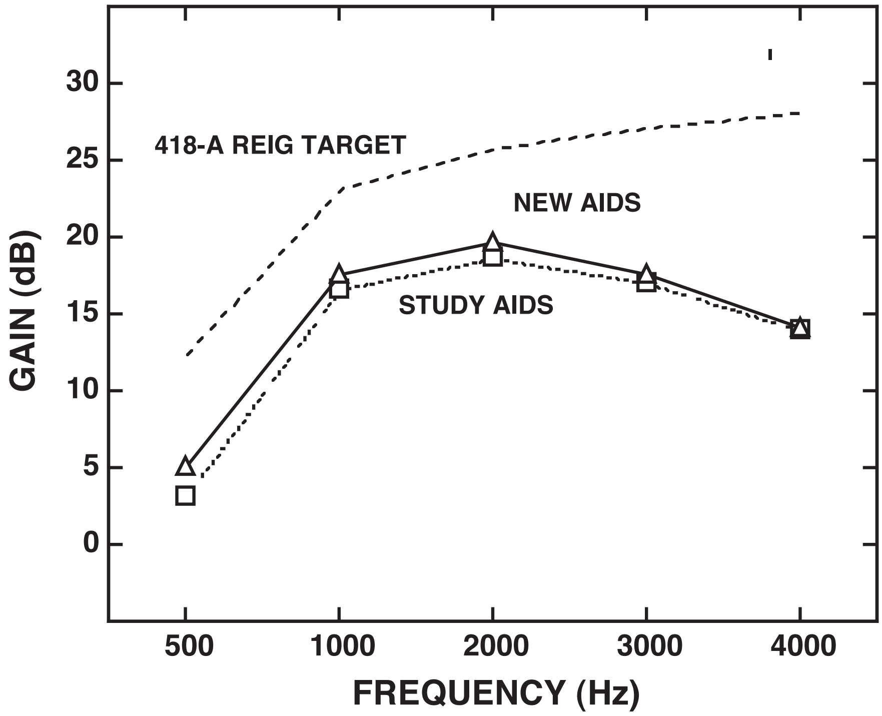

Figure 4. Mean REIGs: Current users of study hearing aids (n = 86) versus new hearing aids (n = 71), versus 418-A target.

during 418 the volume of the original study devices was preprogrammed to a volume setting that provided a good match to target, and this was the initial default setting when the hearing aids were activated by the remote control. It is possible that many of the participants still using their study aids have learned to prefer that default volume setting and have no wish to change it, even though they were allowed to do so for this study. However, when the use gain of the original aids with remote controls was compared to the use gain of the new aids, most of which have volume control wheels and not remote controls, the use gain levels were similar, as shown in Figure 4. When broken down between study aids and new aids, there was little difference in preferred use gain between the study aids and new aids, and both sets of mean data were well below present mean insertion gain targets. This suggests that in addition to or instead of the convenience of the default setting of the remote control, listeners are perhaps influenced by an internal standard for comfortable listening that is not altered by small changes in hearing sensitivity and may reflect a preference for less gain than is prescribed (Humes et al, 2002).

Real Ear Saturation Response (RESR)

Real Ear Saturation Responses (RESRs) were also measured in the follow-up study, according to the original 418 protocol (Bratt et al, 2002). However, as noted earlier, in 418-A, target RESRs were not recalculated, and those from the original 418 were used in the following analyses. Figure 5 shows the mean target RESRs from 418 along with the mean measured RESRs of the three circuit types from the original 418 with regard to Bratt et al, 2002. It can be seen that all measured RESRs in 418 were below the target, with the PC circuit providing the highest RESR of the three circuits studied. According to Bratt et al (2002), this slight increase in output with the peak-clipper circuit compared to the two compression circuits occurred due to the manufacturers software programming, whereby the compression circuits were designed to yield lower output levels to prevent peak-clipping saturation. Depicted in Figure 6 are the measured RESRs obtained in 418-A compared to the original RESR target. It can be seen that the mean measured RESRs from both the study hearing aids and the new hearing aids are similar, and all RESRs continued to fall well below the target RESRs that were prescribed

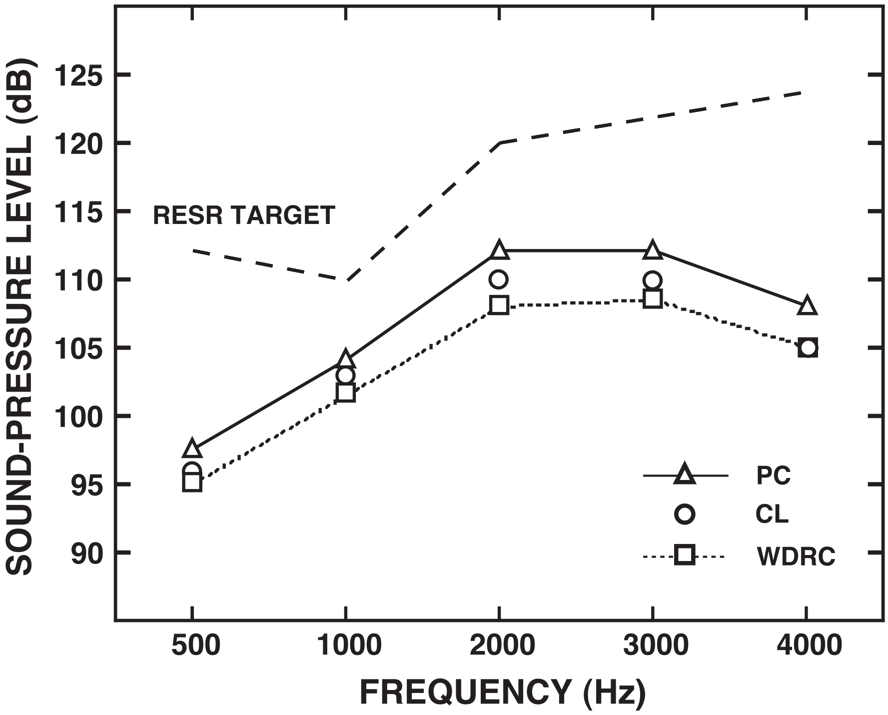

Figure 5. Mean RESR in 418 by circuit type versus RESR target (Bratt et al, 2000).

at 418. In addition, the RESR measures obtained in both 418 and 418-A were very similar. It should be added that there were no reports of loudness discomfort when these measurements were made.

Loudness Discomfort Level (LDL)

Loudness Discomfort Levels (LDLs) were once again measured using the protocol that was prescribed for the original 418, specifically the technique described by

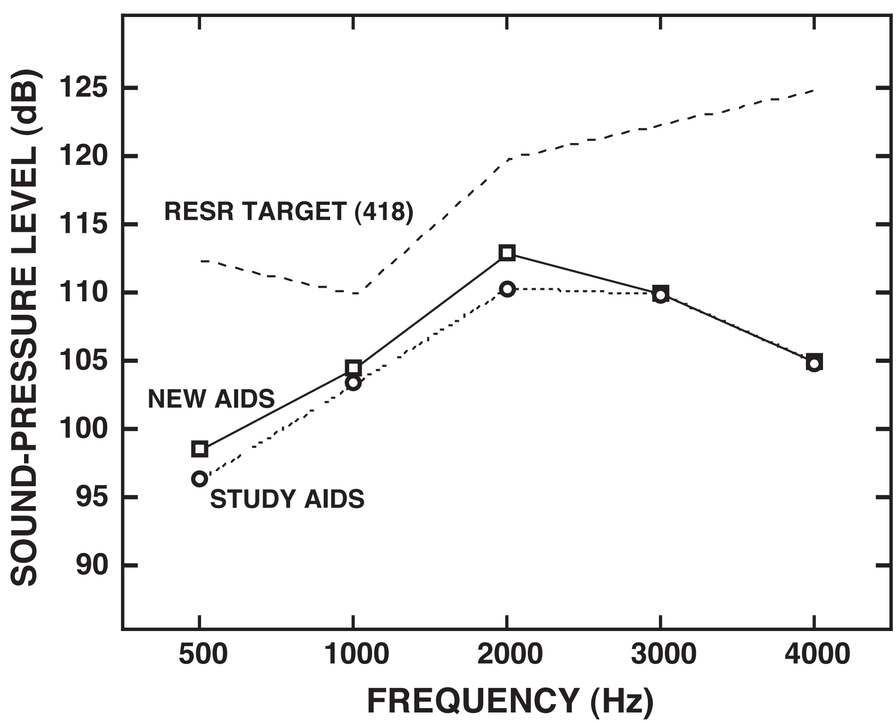

Figure 6. Measured RESRs from 418-A hearing aids (study and new aids) versus original 418 RESR target.

Table 3. LDL Values Obtained during 418 Initial versus Final Visit (dB HL) (Bratt et al, 2002)

Frequency (kHz)	n	.5	1	2	3	4
418 initial visit	330	99.4	99.7	100.9	101.5	104.8
418 final visit	330	101.5*	101.0*	103.4*	106.2*	107.1*

*Significantly different re: 418 initial visit, p < .05.

Table 4. LDL Values Obtained during the Final Visit of 418 versus LDL Values Obtained during 418-A (dB HL)

Frequency (kHz)	N	.5	1	2	3	4
418 final visit	186	102.1	101.6	104.3	107.0	107.9
418-A	186	97.4*	96.3*	96.4*	98.7*	101.8*

*Significantly different re: 418 final visit, p < .001.

Hawkins et al (1987). As shown in Table 3, there was a significant mean increase in LDL values obtained from the initial visit (IV) to the final visit (FV) during 418 (Bratt et al, 2002). This appears to be consistent with many other reports of LDLs increasing with repeated testing, due to a presumed learning or practice effect (Sammeth et al, 1989, Byrne and Dirks, 1996). Table 4 shows the difference in LDLs obtained during the present 418-A study and those obtained from the same individuals at the final visit (FV) of 418, after participants had practiced the protocol a total of six times. These two sets of mean LDL values were separated by a span of at least six years. A paired t-test indicated that the LDLs of 418-A were significantly lower than the LDLs obtained at the FV of 418 after subjects had practiced this task a number of times. These findings suggested that perhaps the learning or practice effect often noted in the literature with this particular measurement may be a more short-term effect and may not last over the six-year span studied here.

Even more interesting is the fact that when the LDLs obtained during 418-A were compared with the LDLs obtained from the same participants at IV of 418 before any practice or learning effect could have taken place, the 418-A values are also significantly lower, as shown in Table 5. This could argue against the notion of acclimatization with respect to tolerance to loud sounds, as most of these individuals had been hearing aid users for six years and were thus frequently exposed to loud sounds. It should be noted, however, that the current 418-A values are more similar to the 418 IV values, and this could suggest a practice effect that is short-lived. Finally, although these sets of values do show statistical significance, they may not be clinically meaningful (Sherlock and Formby, 2005), especially in light of the fact that the standard procedure for this measurement is usually a 5 dB step size, as was used in this study, and the LDL changes noted here are mainly on the order of 1–5 dB.

SUMMARY

The main findings of this 418-A report were:

1. The original study hearing aids evaluated in 418-A have remained stable over the six-year period between the two studies. Measured ANSI characteristics (HFA OSPL-90 and HFA FOG) of the study hearing aids evaluated in 418-A were not statistically different from the original study hearing aids issued five to six years previously.
2. Hearing aid wearers in this follow-up

Table 5. LDL Values Obtained during Initial Visit of 418 vs. LDLs Obtained during 418-A (dB HL)

Frequency (kHz)	N	.5	1	2	3	4
418 initial visit	186	100.3	100.8	102.1	104.4	106.1
418-A	186	97.4*	96.3*	96.4*	98.7*	101.8*

*Significantly different re: 418 initial visit, p < .001.

study, on average, preferred use gain values that were below their presently prescribed NAL-RP targets. Furthermore, present use gains were very close to the gain values originally prescribed, despite decreases in hearing and changes in hearing aid technology. The decreased hearing observed in this study did not lead to increased use gain in 418-A. There does not seem to be a direct relationship between decrease in hearing and increase in use gain in this population.
3. Mean RESRs of the hearing aids measured in the present study were similar to the mean RESRs for the same hearing aids obtained in the original study and were consistently well below target RESRs.
4. LDLs measured for the participants enrolled in 418-A were significantly lower than LDLs measured for those same individuals at both the beginning and at the end of the original 418 study but were more similar to the initial than final 418 LDL measures.

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