A Multi-Center, Double Blind Clinical Trial Comparing Benefit from Three Commonly Used Hearing Aid Circuits*

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Objective: **Although numerous studies have demonstrated that hearing aids provide significant benefit, carefully controlled, multi-center clinical trials have not been conducted. A multi-center clinical trial was conducted to compare the efficacy of three commonly used hearing aid circuits: peak clipping, compression limiting, and wide dynamic range compression.**

Design: **Patients (N = 360) with bilateral, sensorineural hearing loss were studied using a double blind, three-period, three-treatment crossover design. The patients were fit with each of three programmable hearing aid circuits. Outcome tests were administered in the unaided condition at baseline and then after 3 mo usage of each circuit, the tests were administered in both aided and unaided conditions. The outcome test battery included tests of speech recognition, sound quality and subjective scales of hearing aid benefit, including patients' overall rank-order rating of the three circuits.**

Results: **Each hearing aid circuit improved speech recognition markedly, with greater improvement observed for soft and conversationally loud speech in both quiet and noisy listening conditions. In addition, a significant reduction in the problems encountered in communication was observed. Some tests suggested that the two compression hearing aids provided a better listening experience than the peak clipping hearing aid. In the rank-order ratings, patients preferred the compression limiting hearing aid more frequently than the other two hearing aids.**

Conclusions: **The three hearing aid circuits studied provide significant benefit both in quiet and in noisy listening situations. The two compression hearing aids appear to provide superior benefits compared to the linear circuit, although the differences between the hearing aids were smaller than the differences between unaided and aided conditions.**

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Practitioners and hearing-impaired consumers of the not-too-distant past chose among hearing aids with highly similar electroacoustic characteristics on the basis of style, size and cost. Only about one person of five with hearing impairments in the United States purchased hearing aids (Kochkin, 1992; Ries, 1994) and about 50% of them were less than satisfied with their devices (Kochkin, 1992, 1996). During the past 15 yr, the hearing health care industry has been influenced profoundly by technological evolution. Whereas in the early 1990s, linear hearing aids using Class "A" amplifiers constituted 82% of units sold in the U. S. (Hawkins & Naidoo, 1993), today's practitioners and consumers are confronted with a vast array of choices made possible by a more complete understanding of cochlear processing and the technological capability of implementing complex signal processing algorithms. While anecdotal information abounds, it remains to be documented whether the influences of technology provide superior benefit and improved consumer satisfaction.

During the past few years there has been much interest expressed in the quantification of hearing aid outcome or benefit (c.f. Dillon, Birtles, & Lovegrove, 1999; Humes, 1999; Weinstein, 1997). Indeed, since the early 1990s the Food and Drug Administration and third-party payers such as state and federal agencies and insurance companies have required that manufacturers have evidence that supports claims of benefit

Unfortunately, few carefully controlled, large-scale clinical trials of the benefit provided by hearing aids have been reported. Smaller scale studies

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have been proprietary in nature; have been designed in a manner such that hearing aid characteristics, other than those under examination, were not controlled; and/or were not conducted with appropriate blinding of subjects and examiners.

The need to fill this void in documentation of efficacy remains, both for the more conventional, lower cost technologies and for the newer generation of hearing aids made possible by digital technology. This special issue of *Ear and Hearing* reports details of a large-scale study of benefit (Larson et al., 2000) provided by three conventional hearing aid circuits that command a significant portion of the "market-share." The specific hearing aid circuits studied were representative of conventional, lower-end technologies and are referred to as peak clippers (PC), compression limiters (CL), and a single-channel circuit that employs a signal processing strategy similar to that of some higher performance, multiple channel instruments, the wide dynamic range compressor (WDRC).

Hearing Aid Circuits

As described by Bratt, Rosenfeld, Peek, Kang, Williams, and Larson (this issue), each participant in the clinical trial was fit binaurally with single channel, full-concha, in-the-ear (ITE) hearing aids (Phonak, Inc. model Dyna P2) that could be programmed to function as a PC, CL or a WDRC. The principal differences between the three circuit types can be described in relation to the primary hearing aid fitting goal: to amplify speech so that its frequency spectrum is entirely audible yet below the threshold of loudness discomfort. For linear hearing aids, a fixed-amount of gain is prescribed for the hearing aid user and therefore there is a 1:1 relationship between the change in the input level and the corresponding change in the output level. For more intense sounds, application of a fixed amount of gain to an input signal can potentially exceed the individual's threshold of loudness discomfort so circuit characteristics are selected or adjusted to limit the maximum sound pressure that is delivered to the ears of the wearer. At the point the limit is reached (the limiting threshold), the amplification provided is nonlinear, i.e., there no longer is a 1:1 relationship between the change in level of the input and output sounds.

The traditional, conventional method of output limiting employed in hearing aids electronically removes the positive and/or negative peaks of an alternating current. Referred to as either "hard" or "soft" peak clipping (PC), the circuitry is simple, and therefore inexpensive, and output limiting is effected instantaneously, or nearly so. The primary disadvantage of these methods is that harmonic distortion, and consequently, intermodulation distortion products are created. An alternative method to the PC option, frequently referred to as compression limiting (CL), uses feedback circuitry that detects when the amplitude of an alternating current signal reaches a predetermined level (the threshold of compression) and automatically turns down the amount of amplification (gain) that is provided. Typically, the ratio of input to output sound levels is on the order of ≥8:1, i.e., for a change of 8 dB in the input sound, a 1 dB increase in the output occurs. By this action, the undesirable consequences of the former method are avoided (Krebs, 1972); however, gain reduction is not instantaneous. In order that sudden sounds not exceed discomfort thresholds, the time required by the hearing aid to turn down the gain is typically short (≈10 msec) and is referred to as the "attack time." Once the level of the input signal has dropped to a lower sound pressure, the hearing aid restores its gain to the higher level. This action is also not instantaneous but can be made to be relatively short (50 msec) or long (500 msec) and is referred to as "release time" or "recovery time." Shorter release times are associated with listener's perception of "pumping," i.e., the listener can hear the device going into and out of compression. Longer release times may result in input sounds might not be amplified to levels that are audible. Some devices incorporate circuitry that makes possible release times that approximate the temporal characteristic of the input (c.f. Teder, 1993). Hence, the release time would be shorter for a signal that disappears quickly and longer for a signal that decays more slowly.

The third circuit studied, wide dynamic range compression (WDRC), is a variation of the automatic gain control circuit described above. In theory and in the laboratory, it provides enhanced audibility of speech cues (Braida, Durlach, Lippmann, Hicks, Rabinowitz, & Reed, 1979; Villchur, 1973). In WDRC, the threshold of compression is set to a low level (≈ 50 dB SPL) so that relatively soft speech levels trigger compression. In contrast to the compression limiter, the compression ratio is low, typically on the order of 2:1. The low compression ratio enables a wide range of input sounds to be delivered to a proportionately smaller range of output sounds. In the WDRC studied in this clinical trial, a short release time is employed that is typical of a class of devices sometimes referred to as "syllabic compressors" (Braida et al., 1979). The use of short release times is predicated on the presumption that following brief and more intense low-frequency speech sounds and consequent gain reduction, full gain will

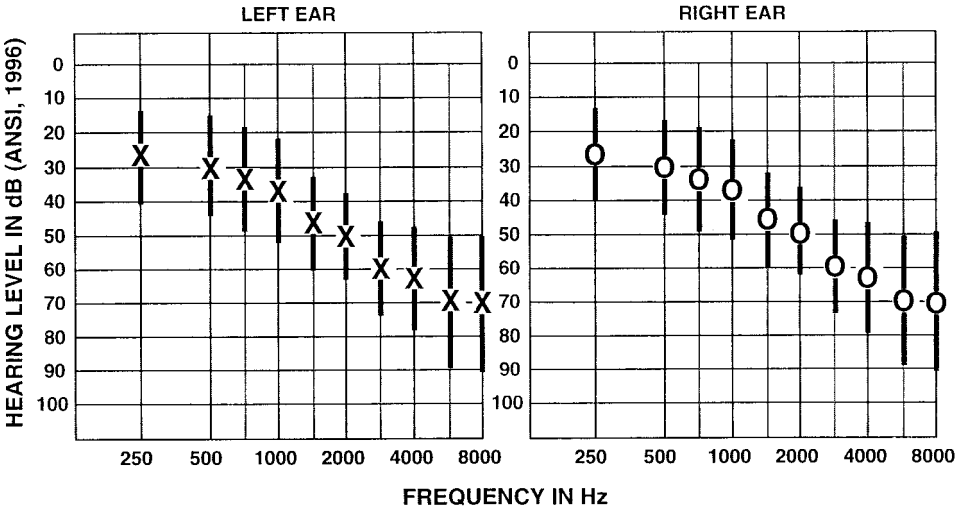

Figure 1. Mean hearing thresholds and standard deviations for the left (left panel) and right ears (right panel) (*N* = 360).

be restored for subsequent weaker, higher-frequency speech sounds.

METHODS

Design of the Clinical Trial

Eight audiology laboratories located within Department of Veterans Affairs Medical Centers participated in the clinical trial. Study personnel were trained in the methodology to perform the procedures used in the study. As described by Larson et al. (2000) and Henderson, Larson, Williams, and Luethke (this issue), the experimental design chosen for the trial was a three-period, three-treatment crossover design. Baseline testing was accomplished using a battery of outcome tests in the unaided condition (no hearing aids). During each of three 90-day trial periods, the subjects were fit binaurally and used one of the hearing aid circuits. At the end of each period, tests were repeated in both the unaided and aided conditions. A double blind protocol was implemented in which neither the audiologist who performed the tests nor the subject could identify the circuit being used. A separate audiologist programmed the device.

Subject Characteristics

The desired sample called for the participation of 360 adults. Of this number, 251 (69.7%) were veterans of military service and 109 (30.3%) were nonveterans. The mean age of the participants was 67.3 yr with a range of 29 to 91. The majority of individuals enrolled in the study were white (78.6%), but a racial distribution approximating that of the population at large was achieved: 12.2% were black, 6.1% were Hispanic, 1.9% were Asian and 1.1% were American Indian. Fifty-seven percent were male and 43% were female. The majority of participants were married (69.2%) and 38.6% had a college degree and 10% had less than a high school education. By self-report, the predominant causes of the subjects' hearing loss were noise exposure and aging.

About one-half (46.7%) had never used a hearing aid; 6% had prior experience with hearing aids but were not using them at the time they were included in the trial; and 48.1% were currently using amplification. The latter group had an average of 9.9 yr (±9.3 yr) of hearing aid experience.

The protocol was approved by the Hines Veterans Affairs (VA) Cooperative Studies Program Coordinating Center's Human Rights Committee and by the Institutional Review Board of each participating VA Medical Center. All subjects provided informed consent. Subjects received $150 as compensation for time and travel expenses and were allowed to keep the hearing aids at the end of the study.

Subjects were required to be fluent speakers of English and have a bilaterally symmetrical sensorineural loss with no evidence of outer ear, middle ear or retrocochlear pathology. The average of audiometric thresholds for the test frequencies 0.5, 1, 2, 3, and 4 kHz could be no better than 25 dB Hearing Level (HL) in either ear, with no threshold from 0.5 to 2 kHz exceeding 70 dB. Figure 1 shows the mean audiometric thresholds (+1/−1 standard deviation) to be characteristic of a moderate, sloping, bilateral loss of hearing sensitivity. For some of the analyses reported in the articles in this issue, the subjects were divided into four groups based on the degree of hearing loss (average of thresholds at 0.5, 1, 2, 3, and 4 kHz) and slope (≤ or >10 dB/octave). The mean data for the subgroups are shown in Figure 2. Group A had hearing ≤40 and a slope ≤10 dB, Group B had hearing ≤40 and a slope >10 dB; Group C had hearing >40 and a slope ≤10 dB; and

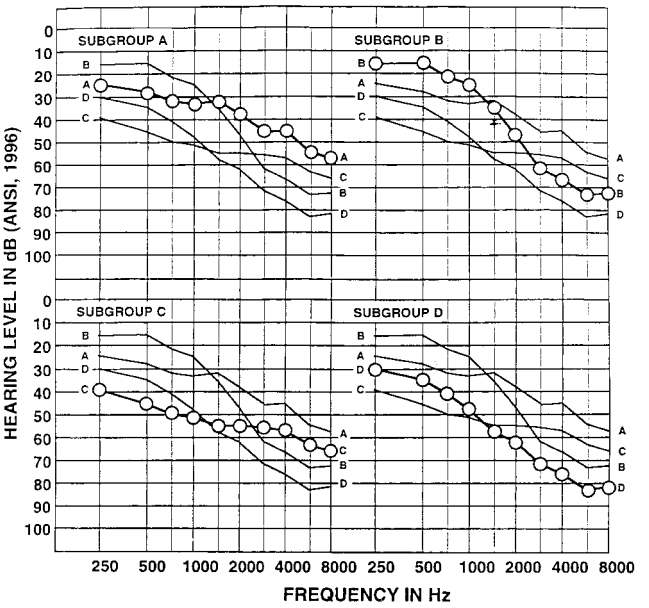

Figure 2. Mean hearing thresholds for hearing loss subgroups: A (*N* = 56), B (*N* = 149), C (*N* = 91), and D (*N* = 62). In each quadrant, the alternate subgroup data are shown for comparison.

Group D had hearing >40 and a slope >10 dB. Bone-conduction audiometry, tympanometry and acoustic reflex measurements were used to rule out conductive hearing loss. Subjects were required to demonstrate a word recognition score, on a recorded version of the CID W-22 test (Wilson, 1993), of at least 28% in each ear with a score difference between ears of no greater than 26%.

Subjects were not included if there was a history of middle ear disease within the past 5 yr, a history of middle ear surgery, or any condition which would suggest a rapidly progressive or fluctuating hearing loss. In addition, subjects were excluded who had a diagnosis of any neuropathic disorder or other mental condition causing dementia or thought disorder which would interfere with behavioral testing; who had a history of unresolved substance abuse; or had literacy or cognitive problems which would affect the subject's ability to perform some of the evaluative tasks or understand the nature of informed consent. Of 360 participants enrolled in the study, 28 did not complete the trial due to illness, relocation of residence, or were lost to follow-up for other reasons. A total of 334 subjects completed the 90-day trial with the peak clipper, 334 with the compression limiter, and 326 with the wide dynamic range compressor. The average reported hearing aid use time for the three circuits did not differ significantly and averaged about 9.8 hr per day with standard deviations of about 4 hr. In addition to patients who were lost to follow-up, sample sizes reported in the series of articles that follow for specific tests and conditions were influenced by the inability of either the subject to perform the task or the occasional inability of the examiner to follow the study's protocol in the conduct of the test.

Experimental Apparatus

All threshold and suprathreshold testing required for the study was carried out within sound-treated audiometric test booths using identical equipment for test presentation and data collection. The experimental system consisted of a personal computer that controlled a three-channel audiometer (Virtual Corp., Model 322) for stimulus delivery, a hearing aid analysis system (Virtual Model 340), and an interface for programming the hearing aid (HI-Pro). Audiometric threshold testing was accomplished using ER-3A earphones. The three-channel audiometer provided a means for delivering test stimuli through one loudspeaker (located at 0° azimuth at 1 meter) and competing, uncorrelated six-talker babble from loudspeakers located at +45 and −45°. One-third octave analyses of the spectra generated by the test systems in the test rooms of the eight sites showed excellent inter-site agreement. A plumb bob was hung from the ceiling at each site to allow the careful alignment of the subject with reference to the horizontal and vertical position of the three loudspeakers. The subject's chair was adjustable vertically and included a specially fabricated headrest in order to control head movement within test sessions.

Strict calibration procedures were followed for both sound field and earphone delivery systems. Ambient noise levels in the test rooms were in conformance with standards for the assessment of hearing sensitivity in sound field (ANSI S3.1–1991) and were assessed weekly. One-third octave analyses of the output of the three loudspeakers were also assessed on a weekly basis. Excellent intra-site stability of the sound fields was observed throughout the duration of the clinical trial. Before each test session, the output of each speaker was carefully calibrated.

Outcome Test Battery

A multi-dimensional battery of outcome tests was employed. These included tests of speech recognition, category ratings of perceived sound quality, and self-assessed subjective ratings of hearing aid benefit. All test conditions and subtests were conducted by study personnel in an order prescribed by a randomization schedule.

Two tests of speech recognition were administered before and after each 3-mo trial period. Details

of the method are described by Shanks, Wilson, Larson, and Williams (this issue). The first was representative of the type of test used routinely in audiologic assessments. In this test, one of four lists of a digitized version of the monosyllabic word-recognition test known as the NU-6 Test (Wilson, 1993) was presented at a sound pressure level of 62 dB SPL. Subjects responded by repeating the word perceived and the examiner judged the response to be correct or incorrect and coded the response into the computer accordingly.

The second test was a sentence test of recognition, the Connected Speech Test. (Cox, Alexander, & Gilmore, 1987; Cox, Alexander, Gilmore, & Pusakulich, 1988). The Connected Speech Test (CST) consists of 46 passages of 8 to10 sentences each. In a single test, two passages were employed resulting in 50 scoreable items, each having a value of 2%. In the test procedure, subjects were provided a "ready" cue via a video monitor. The subject's task was to repeat as much of a sentence as possible and the examiner entered correct and incorrect key word responses into the computer. Following the randomization schedule, the examiner administered the CST (in both unaided and aided conditions) at sound pressure levels of 52 (soft speech), 62 (speech of conversational intensity), and 74 dB (loud speech). The test materials were presented in a background of competing, uncorrelated multi-talker babble (Cox et al., 1987) that was delivered from loudspeakers located to the left and right of center at nominal signal-to-babble (S/B) ratios of 0, +3, and −3 dB. In addition, the CST was administered at 74 dB SPL in a quiet background.

As described in detail by Noffsinger et al. (this issue) and by Larson et al. (2000), a category rating task, called the Quality Rating Test (QRT) was devised and used to study subject's perception of sound quality in three dimensions: loudness, noise interference, and overall liking of the listening experience. Stimuli were presented under the computer's control and the subject responded using a numbered keypad. For each quality dimension, the test was conducted with the speech materials presented at 52, 62, and 74 dB SPL in a quiet background and then in a background of the competing, multi-talker babble with the S/B ratio at +10 dB. The subjects rated the perception of each stimulus on a 10-point scale. The QRT was administered in the unaided and aided conditions before and after each 3-mo trial period.

Haskell, Noffsinger, Larson, Williams, Dobie, and Rogers (this issue) and Larson et al. (2000) describe the methods employed to obtain subjective ratings of performance. Two measures were used to elicit qualitative expressions of hearing aid performance from the subjects. The first was the Profile of Hearing Aid Performance (PHAP) developed by Cox and Gilmore (1990) and the second was the rank ordering of circuits on the basis of preference by subjects completing the trial.

The PHAP quantifies users' experiences with hearing aids and was designed, in part, to assess the effectiveness of different signal processing strategies (Cox & Gilmore, 1990). It quantifies two major aspects of hearing aid performance: speech communication in a variety of daily life situations and reactions to the loudness and quality of environmental sounds. It consists of scores on seven subscales, the scores of which are derived from the responses to a 66-item inventory that is completed by the subject. The inventory was administered to the subjects at the baseline session and then again at the follow-up visits scheduled at 3-mo intervals. At the end of each of the three treatment periods, all subjects completed the inventory in the "unaided" condition and the "aided" condition (i.e., on the basis of their hearing aid experience over the previous 3-mo period).

The second subjective assessment procedure employed in the trial occurred at the final visit after the subject had completed each of the three treatments. Subjects were asked to rank order all three circuits in their order of preference.

Statistical Methods

The sample size of 360 subjects was chosen to permit >95% power to detect a 7.2% difference in the NU-6 test, >95% power to detect a 3.6% difference in the CST, >90% power to detect a 20% difference in the QRT, 90% power to detect a 16.6% difference in the PHAB, and >80% power to detect a small to medium effect size for the patient's overall preference between the three circuits (Larson et al., 2000).

A three-period, three-treatment crossover design was chosen instead of the more traditional randomized, parallel group design because fewer subjects would be required, it permits elimination of between subject variation, and it increased power for other objectives of the trial (e.g., to determine which patient characteristics predict success with the different hearing aid circuits). It was also thought that some of the known disadvantages of the crossover design would not be present in this study: large dropout rate, instability of the patient's condition, and a large carryover effect.

Because of some missing observations, a mixed, repeated measures model was used to compare the three hearing aid circuits for the individual outcome variables. If the overall test was statistically signif-

icant ($p \leq 0.05$), pairwise comparisons were made between the groups using the Bonferonni procedure to adjust the α-level for multiple tests. In addition to patients who did not complete the study, sample sizes reported for specific tests and conditions vary because either the subject was unable to perform the task, or because occasionally, the examiner was unable to follow the study's protocol.

Summary of Results

The articles in this issue by Bratt et al., Henderson et al., Haskell et al., Noffsinger et al., and Shanks et al. present and discuss the results of the clinical trial for the entire sample of 360 subjects (Larson et al., 2000) and for subgroups of hearing aid users. Briefly, however, the data obtained via the multidimensional outcome test battery assembled for this rigorously controlled clinical trial showed that there was significant benefit provided by each of the three hearing aid circuits. Specifically, significant benefit was provided when speech was presented in a quiet background and in noisy background at three speech to babble ratios for low and conversational speech input levels. In addition, each circuit provided a substantial reduction in the frequency of problems associated with listening in their daily lives. The results of this clinical trial provide a clear and unequivocal demonstration that hearing aids provide substantial patient benefit both in quiet and in noisy listening situations. Because the study sample was representative of U.S. adults who are candidates for hearing aids, we believe the study results are generalizable to the U.S. population with sensorineural hearing loss.

The analyses of the data obtained during the clinical trial also showed a few statistically significant but small differences across circuit types for the components of the outcome test battery. Significant differences were observed for the NU-6 test (presented in quiet at conversational levels), the CST test (presented at conversational levels in the 0 dB S/B condition), the loudness rating subtest of the QRT, and the Aversiveness, Distortion and Familiar Talkers scales of the PHAP/PHAB. The preference rankings provided by subjects at the end of the trial favored ($p = 0.001$) the compression limiter (41.6%) followed by the WDRC (29.8%) and the PC (28.6%). In addition the CL was ranked third by the lowest percentage of patients. The results suggest that the compression hearing aids (WDRC and CL) studied were generally superior to the PC circuit, although the differences were small compared to the magnitude of the benefit shared by all three hearing aids. The analyses presented in the articles by Shanks et al., Noffsinger et al., and Haskell et al. suggest, however, that these results do not necessarily apply to subjects with mild, nonsloping losses of hearing sensitivity.

Some speculation on the matter of the lack of, and in some cases small, significant differences across circuit types on some components of the outcome test battery is in order. By design, the frequency-response characteristic was the same for the three hearing aid circuits (Bratt et al., this issue) and for conversational speech inputs the gain provided by the three circuits was not different. The lack of clinically important differences between linear (PC and CL) and the WDRC across conditions might very well herald the importance of spectral audibility to hearing aid benefit. For higher and lower input levels processed through a single channel system, spectral audibility may be of such importance that the theoretical advantages of the WDRC are insignificant, i.e., the combination of low compression threshold, low compression ratio and the short release times have a minimal effect on speech recognition and sound quality. Equally plausible explanations for the lack of clinically important differences among circuits might be that when the hearing aids are well-fit as in this study, the deleterious effects of compression (e.g., alteration of the temporal characteristics of the incoming signal) are, on the average, as degrading as the effects of peak clipping. Finally, recall that the study sample included a wide range of hearing losses. The articles in this issue by Shanks et al., Noffsinger et al., and Haskell et al. explore the performance of subjects with varying degrees of hearing loss on the various components of the outcome test battery.

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