

# NIDCD/VA Hearing Aid Clinical Trial and Follow-Up: Background

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## Abstract

This report provides background regarding the Long Term Follow-Up of Patients in the NIDCD/VA Hearing Aid Clinical Trial study and serves as an introduction to the detailed reports that follow in this issue of *Journal of the American Academy of Audiology*. The authors investigated five- to seven-year benefit/satisfaction in participants from the original NIDCD/VA Hearing Aid Clinical Trial. The new study was designed to investigate current use of the original study hearing aids, to compare changes in selected audiological measures, and to assess possible predictors of long-term hearing aid use. The outcome measures included estimates of speech intelligibility in quiet and noise, self-reported patterns of hearing aid usage, self-reported estimates of activity limitations and quality-of-life issues, estimates of hearing aid satisfaction, and self-reported hearing aid benefit. Overall, the short-term benefits of hearing aid use observed during the original trial were noted to persist in the long term.

**Key Words:** Hearing aids, hearing aid benefit, hearing aid satisfaction, hearing aid use

**Abbreviations:** AHRQ = Agency for Healthcare Research and Quality; CSP = Cooperative Studies Program; CSPCC = Cooperative Studies Program Coordinating Center; DVA = Department of Veterans Affairs; NIDCD = National Institute on Deafness and other Communication Disorders; VA = Veterans Affairs

## Sumario

Este reporte suministra información relacionada con el Seguimiento a Largo Plazo de los Pacientes del Estudio Clínico de Auxiliares Auditivos del NIDCD/VA, y sirve como una introducción de los reportes detallados que siguen a continuación en esta edición del *Journal de la Academia Americana de Audiología*. Los autores investigaron por cinco a siete años la satisfacción/beneficio en los participantes del Estudio Clínico de Auxiliares Auditivos del NIDCD/VA original. El nuevo estudio fue designado para investigar el uso actual de los auxiliares auditivos (AA) originales del estudio, para comparar cambios en las medidas audiológicas seleccionadas, y evaluar posibles elementos de predicción a largo plazo en el uso de AA. Las medidas de resultado incluyeron estimados de la inteligibilidad del lenguaje en silencio y en ruido, patrones auto-reportados de uso del AA, estimaciones auto-reportadas de limitación en la actividad y en asuntos de calidad de vida,

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estimaciones de satisfacción en el uso del AA y auto-reportes de beneficios con el AA. Globalmente, los beneficios a corto plazo del uso de auxiliares auditivos durante el estudio original persistieron en el largo plazo.

**Palabras Clave:** Auxiliares auditivos, beneficio del auxiliar auditivo, satisfacción del auxiliar auditivo, uso del auxiliar auditivo

**Abreviaturas:** AHRQ = Agencia de Investigación y Calidad en Servicios de Salud; CSP = Programa de Estudios Cooperativos; CSPCC = Centro Coordinador del Programa de Estudios Cooperativos; DVA = Departamento de Asuntos de Veteranos; NIDCD = Instituto Nacional de Sordera y otros Trastornos Comunicativos; VA = Asuntos de Veteranos

Between 1996 and 1998, perhaps the largest clinical trial of hearing aid efficacy was conducted in the United States. The trial was initiated in 1993 when the National Institute on Deafness and Other Communication Disorders (NIDCD) of the National Institutes of Health (NIH) assembled an advisory committee to facilitate hearing aid research and to recommend priorities for clinical trials. A planning committee was subsequently formed to (a) refine the research questions broadly conceived by the NIDCD advisory committee, (b) consider and specify outcome measures for use in the clinical trial of hearing aids, and (c) develop and submit a protocol for joint funding by NIDCD and the Department of Veterans Affairs (DVA). This planning committee consisted of invited VA (Veterans Affairs) and non-VA clinicians and investigators, and met in 1993 and 1994. The product of these efforts became a clinical trial entitled the "NIDCD/VA Hearing Aid Clinical Trial" (or "Cooperative Studies Program [CSP] 418") and was chaired by Vernon Larson, with administrative and analytical support provided by the Hines VA Cooperative Studies Program Coordinating Center (CSPCC) in Hines, Illinois. The objective of the trial was to compare the benefits provided to patients with sensorineural hearing loss by three hearing aid circuits in common use at the time of the trial: a linear peak-clipping circuit (PC) and two compression circuits, one providing wide dynamic range compression (WDRC) and the other a compression limiter (CL).

The design of the trial used a double-blind protocol so that neither the participant nor the investigator obtaining out-

come data knew which circuit was under investigation. The three-period, three-treatment crossover design meant that each of the 360 participants in the trial used each circuit for three months and then responded to a set of outcome measures before going on to the next treatment. Each participant in the trial was fit binaurally with analog single channel, programmable, full-concha in-the-ear hearing aids (Dyna P2, Phonak, Stafa, Switzerland) that contained all three circuit options. There were three programs available on the device, each corresponding to one of the three circuits under investigation. The selection capability on the remote control was disabled, resulting in the availability to the listener of just one program at any given time during the treatment period. That program with its corresponding circuit was activated by a study audiologist according to a randomly determined and balanced schedule at the outset of each of the three-month treatment periods. The Dyna P2 permitted constancy as much as possible with regard to the transducers, fit, and frequency response of the instrument while varying the feature under consideration, namely the output circuitry. Also, the single housing of the device supported an effective maintenance of the double-masked feature of the design in that neither the participant nor the investigator obtaining the outcome information could employ visual references relating to the circuit under investigation. The crossover design was used in the trial instead of the more traditional randomized, parallel group design because the crossover design required fewer participants, eliminated between-participant variation, and increased power for other objectives of

the trial (Larson et al, 2000).

The outcome measures of the clinical trial were speech recognition, sound quality, and subjective hearing aid benefit. The three circuits were compared using aided scores and aided minus unaided scores (benefit scores) with repeated measures analysis. Rigorous monitoring of the electroacoustic characteristics of the test circuits was maintained across time and clinical sites, using electroacoustic measurements both in situ and in a hearing aid analyzer. Eight audiology laboratories located within DVA medical centers participated in the trial.

The context, objectives, design, findings, and conclusions of the clinical trial were reported by Larson et al (2000), Bratt et al (2002), Haskell et al (2002), Henderson et al (2002), Larson et al (2002), Noffsinger et al (2002), and Shanks et al (2002). The results of the trial failed to demonstrate a clear superiority of one circuit over the others, consistent with findings of a similar concurrent study (Humes et al, 1999), although the two compression circuits appeared to provide increased benefit on some measures compared to the peak-clipping circuit. Of greater significance, however, was the clear benefit provided by hearing instruments in both the quiet and noise conditions employed in the trial. The clinical trial met the conditions established by the Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Resources (AHRQ, 2002) for the strongest type of evidence (Level 1) that hearing aids, when appropriately fit, are efficacious in the management of sensorineural hearing loss in both the quiet and noise environments where they are frequently used. The CSP 418 findings were limited, however, by the relatively short-term measures of benefit over the nine months of the study and by the fact that the trial did not measure certain domains, such as affect and cognition, that could interact with hearing loss.

The NIDCD convened the "Hearing Aid Trials Working Group" on December 11, 2000, to provide advice about possible future trials. It was recognized at that meeting that a remarkable opportunity existed to investigate the long-term benefits of hearing aid use in the original 418 cohort after several years of experience

with hearing aids, either those provided in the clinical trial or with hearing aids acquired since that trial. A planning committee (Appendix A), convened twice in 2001 by NIDCD and VA, prepared a proposal for a follow-up study entitled "Long Term Follow-Up of Patients in the NIDCD/VA Hearing Aid Clinical Trial" (also known as "CSP 418-A"). A brief telephone survey of the CSP 418 cohort in July and August 2001 at six of the eight original CSP 418 study sites indicated a high probability that at least 200 of the original 360 participants would be available and willing to participate in such a follow-up study. A proposal for funding was submitted to VA and NIDCD in October 2001. It was recognized that the CSP 418 participants composed a unique group of individuals who had experienced the opportunity to utilize hearing aids fit under the stringent conditions created in the original study. It seemed appropriate to revisit these participants to examine hearing aid usage behavior and to determine long-term satisfaction and benefit with their hearing aids.

Following approval and funding of the proposal, an Executive Committee (Appendix B) was appointed to oversee the conduct of the follow-up study. Appendix C lists the members of the study group. As noted in Appendix C, each of the original eight study sites was provided with a participating investigator and a study audiologist.

As in the original clinical trial, the planning committee for the follow-up study selected both control measures and outcome measures for presentation to the study participants. The control measures (Table 1) were designed to identify changes that had occurred within the members of the cohort and within their hearing aids. These included an update of participant demographics and a checklist of life events, otoscopy, measurement of pure-tone thresholds, immittance values, word-recognition ability and loudness discomfort levels, and measurement of hearing aid characteristics both in the cm<sup>3</sup> coupler and in situ using probe microphone measures.

The outcome measures (Table 2) included estimates of speech intelligibility in quiet and in noise, self-reported patterns of hearing aid usage, self-reported estimates of activity limitations and quality-of-life

**Table 1. CSP 418-A Control Measures**

Demographics
Otoscopy
Pure-Tone Audiometrics
Immittance Measures
Word Recognition (CID W-22; Hirsch et al, 1952)
Loudness Discomfort Levels
Hearing Aid Performance (cm <sup>3</sup> and in situ probe microphone)
Checklist of Life Events (Kricos and Erdman, 2002)

issues, estimates of hearing aid satisfaction, and self-reported hearing aid benefit. In some cases, measures were repeated from the original 418 clinical trial; these are designated in Table 2 by asterisks. Other measures were added by the planning committee because a measure might not have been available at the time when the original clinical trial was designed, or because the information provided by that measure was desired. The two new measures, the Hearing Aid Status Questionnaire (HASQ; Boothroyd and Noffsinger, 2001) and the Checklist of Life Events (Kricos and Erdman, 2002), were developed by the authors specifically for this study. The reports that follow in this issue have been organized to provide the results of both the control and outcome measures, with the control results provided first.

Following selection of the control and outcome measures, a kick-off meeting was held in Nashville in September 2002 that included the study chair and national clinical coordinator, the participating investigator and research audiologist from each of the eight VA sites, members of the Executive Committee, and representatives from the CSPCC. A study protocol had been written prior to convening the kick off, and that plan was discussed, modified, and demonstrated so that all individuals involved in the study felt confident in the standardization of procedures across sites.

Participant recruitment for 418-A began in January 2003, and the data collection was complete by the end of the year. During the data collection period, each site was visited by the national clinical coordinator, and sometimes by the study chair, to monitor

**Table 2. CSP 418-A Outcome Measures**

Speech Understanding
*Northwestern University Auditory Test No. 6 (Tillman and Carhart, 1966)
*Connected Speech Test (Cox et al, 1987)
Hearing Aid Usage
Hearing Aid Status Questionnaire (Boothroyd and Noffsinger, 2001)
Quality-of-Life Issues
*Communication Profile for the Hearing Impaired (Demorest and Erdman, 1987)
Life Orientation Test (Scheir and Carver, 1985)
Hearing Aid Satisfaction
Satisfaction with Amplification in Daily Life (Cox and Alexander, 1999)
Hearing Aid Benefit
*Profile of Hearing Aid Benefit (Cox and Rivera, 1992)
Glasgow Profile of Hearing Aid Benefit (Gatehouse, 1999)
International Outcome Inventory for Hearing Aids (Cox et al, 2000)

\*Measure was also used in the original CSP 418 study.

**Table 3. Selected Demographic Characteristics, CSP 418-A versus CSP 418**

	CSP 418-A	CSP 418
Age (years)		
Mean	73.2	67.2
Range	36–96	29–91
Gender (%)		
Female	38.1	43.1
Male	61.9	56.9
Ethnicity (%)		
White	79.4	78.6
Black	12.9	12.2
Hispanic	5.2	6.1
Asian/Pacific Islander	2.1	1.9
American Indian/Alaskan Native	.5	1.1
Educational Level		
College Educated (%)	72	68.3
Veterans (%)	76	70

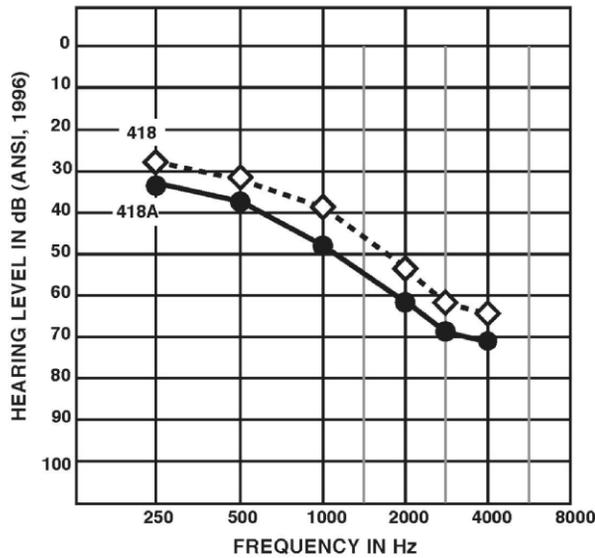
research practices and procedures to help ensure that the study protocol and management of study participants, as specified in the study protocol, were rigorously observed. All study data were routinely forwarded by hard copy to the CSPCC at Hines for analysis and storage. These data and their preliminary analyses were submitted to members of the Executive Committee, the study chair, and participating investigators at the conclusion of the data collection period. A wrap-up meeting, also in Nashville, in February 2004, included, when possible, the same individuals who had been present at the kick off, and the ongoing analyses and reporting schedules were planned.

Of the original 418 cohort, 210 members participated in the follow-up study. Because the maximum amount of information was desired from each participant, home visits by study personnel and phone interviews were permitted when visits to the nearest facility were not possible due to impaired health or travel restrictions. Of the 210 participants in the follow-up study, 190 participants were evaluated in the laboratory, 7 chose home visits, and 13 were surveyed by telephone. The home visits and telephone surveys did not include audiometrics, or speech testing, but did include some subjective measures. This has resulted in uneven sets of data for the control and outcome

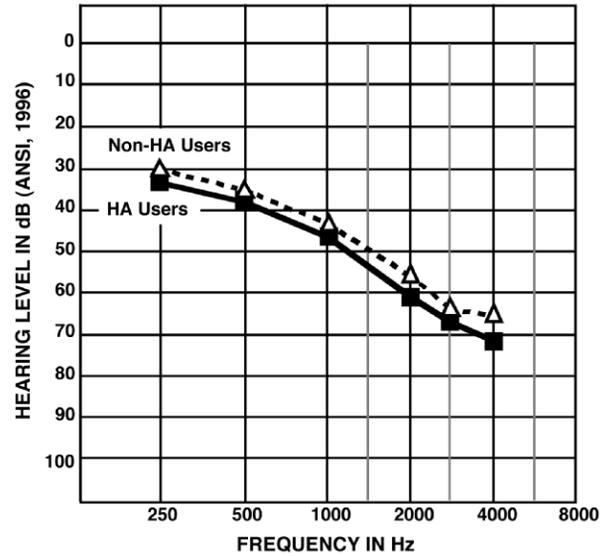
measures, as will become evident in the reports that follow. The authors have carefully defined the populations from which observations were drawn.

Table 3 presents selected demographic data from both the 418 clinical trial and the 418-A follow-up study. At the time of the follow-up study, the average participant age had increased by six years to 73.2 years of age. The age range of the follow-up study remained approximately the same, but the ages themselves had increased to 36–96 years of age. The gender proportions had not changed appreciably and neither had the ethnicity ratios. In the original clinical trial, these two participant characteristics had been carefully monitored to increase the applicability of findings to the general population. Over 75% of the participants in the follow-up study were veterans, and 72% had achieved some level of college education. Approximately 65% of the participating cohort was married, and over 75% of the participants were retired.

Figure 1 presents the audiometric data drawn from participants in the 418-A follow-up study and from these same individuals when enrolled in the original 418 study. Because no significant difference was noted between ears, the data are collapsed across ears, and they show that mean hearing sensitivity had declined in the follow-up participant population by about 5–7 dB



**Figure 1.** Mean pure-tone air-conduction thresholds for participants in CSP 418 and CSP 418-A (n = 185, all frequencies significantly poorer at 418-A, at  $p < .001$  level).



**Figure 2.** Mean pure-tone air-conduction thresholds for hearing aid users and nonusers in CSP 418-A.

across the frequencies measured. From time to time in the reports that follow, a distinction will be made between those participants who continue to wear hearing aids and those who have discontinued use of their hearing aids. The data depicted in Figure 2 indicate that the nonusers had slightly less hearing loss than did the users, but the difference is very small. Finally, Table 4 presents the word-recognition scores in quiet for the participants in the follow-up study, and the same participants when enrolled in the original trial. These data indicate the presence of a 10% decrease in word-recognition scores in the right ear of the follow-up study participants, and a 12% decrease in the left ear of these participants.

The reports that follow present the findings and conclusions of the study group. With few exceptions, there is verification in the discussions that follow that the benefits of hearing aids, observed in the short term in the trial participants, have persisted into the long term. By extension of the original

trial, it follows that the finding of efficacy in the long term, namely that appropriately fit hearing aids provide objective and subjective benefit to listeners with sensorineural hearing impairment, meets the criteria for Level 1 evidence (AHRQ, 2002). Frequently, in the analyses that follow, data are collapsed across populations and conditions; these analyses seemed appropriate to us in the investigation of this interesting cohort that remains from a large clinical trial reported several years ago. It is possible that further analyses of the data may reveal differences between these populations and conditions that may be of interest. It is further noted that, although raw study data are protected by the CSPCC, further analyses of these data are encouraged and may be requested by correspondence with the study chair, Gene Bratt (see contact information on the first page of this article).

**Table 4.** Mean Word-Recognition Scores (CID W-22), CSP 418-A versus CSP 418

	418-A	418
Right Ear (%)	*77	87
Left Ear (%)	*74	86

\* $p < .01$

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### Appendix A. CSP 418-A Planning Committee Members

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Beck, Lucille B., VA Medical Center, Washington, DC  
Boothroyd, Arthur, San Diego, CA  
Dobie, Robert A., Bethesda, MD (now at the  
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Erdman, Sue, Hot Springs, VA  
Gulya, A. Julianna, Bethesda, MD  
Henderson, William, (Hines VA CSPCC, Hines, IL  
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Humes, Larry, Indiana University, Indianapolis, IN  
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### Appendix B. CSP 418-A Executive Committee

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#### Members:

Beck, Lucille B., VA Medical Center, Washington, DC  
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### Appendix C. CSP 418-A Study Group

Chair's Office (Nashville, TN):  
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National Clinical Coordinator: Mia A.L. Rosenfeld

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Study Biostatistician: David Williams  
Project Manager: Tammy Nydam  
Study Programmer: Mazen Abdellatif  
Administrative Officer: Joyce Jimenez

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Co-Principal Investigator: Douglas Noffsinger  
Study Audiologist: Cheryl Byrd

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Participating Investigator: Gail Takahashi  
Study Audiologist: Julie Bridges

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Participating Investigator: Janet E. Shanks  
Study Audiologist: Charlene Mikami

Mountain Home, TN, site:  
Participating Investigator: Richard H. Wilson  
Study Audiologist: Deborah Weakley

Nashville, TN, site:  
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Study Audiologist: Kjersten Branscome

Portland, OR, site:  
Participating Investigator: Gabrielle Saunders  
Study Audiologist: Kathleen Dunckley

Washington, DC, site:  
Participating Investigator: Lucille B. Beck  
Study Audiologist: Sharon Beamer

West Los Angeles, CA, site:  
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Co-Participating Investigator: Douglas Noffsinger  
Study Audiologist: Karen Sugiura