AUDITORY CLINICAL RESEARCH
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CLINICAL STUDIES SUMMARY
MARCH 2007

Bilateral Benefit in Adult Users of the HiRes 90K® Bionic Ear System

Background

People with normal hearing, and individuals with impaired hearing who use acoustic amplification, show significant benefit when listening with two ears versus one ear. Binaural benefits in everyday listening situations include better speech understanding in noise, improved localization of sound sources, and improved sound quality and clarity. Because the safety and efficacy of unilateral cochlear implantation is well established, there is a growing trend to provide two devices to patients rather than just one.

Multicenter Study Overview

Advanced Bionics' in-progress, multicenter study is investigating bilateral benefit in a large group of newly implanted postlinguistically deafened adults who receive two HiRes 90K® implants during the same surgery. The study was motivated by recent findings from the University of Iowa that suggest enhanced sound processing may augment the degree of benefit experienced by adults using two implants. The Iowa researchers have reported that bilaterally implanted adults demonstrated significant improvement in speech-in-noise scores with HiResolution sound processing (HiRes®) after only one month of use compared to their scores after long-term experience with CIS (Dunn et al, 2006).

The present study is organized into two phases. In Phase I, a prospective counterbalanced between- and within-subjects design is used to evaluate bilateral listening benefits and to compare sound processing modes (CIS versus HiRes). The study uses a six-month crossover design (three months with each processing mode) with an additional one-month period in which subjects re-evaluate the two processing modes (two weeks with each mode) and indicate a preference. Subjects then are evaluated at one month after using their preferred mode.

Phase II of this study is evaluating the bilateral benefit of the HiRes with Fidelity 120™ (HiRes 120*) sound processing option, an enhanced version of HiRes implemented on the Harmony™ sound processor. Subjects are fit with HiRes 120 and evaluated after three months of use. A multicenter study of unilateral HiRes users who were fit with HiRes 120 demonstrated that HiRes 120 improved benefit appreciably for some recipients in a variety of listening environments, including speech perception in noise, sound quality, and music appreciation (Koch et al, 2007). (In addition to the multicenter bilateral investigation, the University of Iowa is conducting an independent study of the bilateral benefits offered by HiRes 120 with subjects who participated in its study of CIS and standard HiRes.)

Advanced Bionics' multicenter investigation uses a unique direct-connect system for postimplant testing developed by Sigfrid Soli and colleagues at the House Ear Institute. Designed to eliminate the need for a sound booth or a speaker array, the system simulates the sound-field testing by using a family of head-related transfer functions (HRTFs) corresponding to loudspeaker positions appropriate for unilateral or bilateral testing. Left-ear and right-ear HRTFs appropriate to the selected source location are applied to the test signals and presented via direct connection to the auxiliary input of the Harmony or Auria® sound processor at a specified presentation level. (Koch et al, 2006; Soli et al, 2005). Figure 1 shows the simulated loudspeaker locations for localization test.

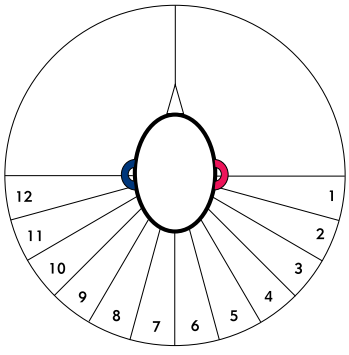

Figure 1. To evaluate localization ability, subjects hear broadband signals that simulate sound originating from 12 loudspeakers located in a horizontal plane spanning 180° from the right ear to the left ear. Subjects indicate the perceived source of the sound by pointing to 1 of 12 speaker positions printed on a response sheet. Localization results indicate each subject's ability to "resolve" the direction from which sound originates.

** In the United States, an optional feature for adults only. See package insert for details.*

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Results to Date

Preliminary data indicate that bilateral implantation is advantageous, consistent with the findings of other investigators. Insufficient data are available at this time to analyze the effect of HiRes versus CIS. Preliminary findings are summarized in Figures 2-4.

Note in Figure 2 that the mean bilateral scores were greater than the unilateral scores for both word and sentence recognition in quiet. The differences between the bilateral scores and the right implant alone results were significant for both tests ($p < .05$).

The mean data in Figure 3 show a 2.8 dB binaural advantage in diffuse noise when comparing bilateral versus best unilateral performance. The binaural advantage is derived by subtracting the bilateral from the better monaural sentence reception threshold, or sSRT (in dB SNR). (A lower sSRT represents better performance.) Typically, normal listeners demonstrate a 1-2 dB binaural advantage. The 5.4 dB head shadow advantage shown here is derived by subtracting the bilateral sSRT from the monaural-ipsilateral sSRT. The head shadow advantage is the effect of using the ear with the better SNR. Finally, the 1.5 dB binaural squelch advantage, which is in addition to the head shadow effect, includes the contribution of the ear receiving the poorer SNR. The binaural squelch advantage is derived by subtracting the bilateral from the monaural-contralateral sSRT.

The mean localization data in Figure 4 indicate that subjects localize at chance levels when using only one implant. Their ability to localize improves greatly when they are using both implants together. Note that even normal-hearing listeners have difficulty resolving sounds from each of the 12 loudspeakers (12-sector accuracy of 45%) although they are very accurate when resolving right from left (2-sector accuracy of 99%).

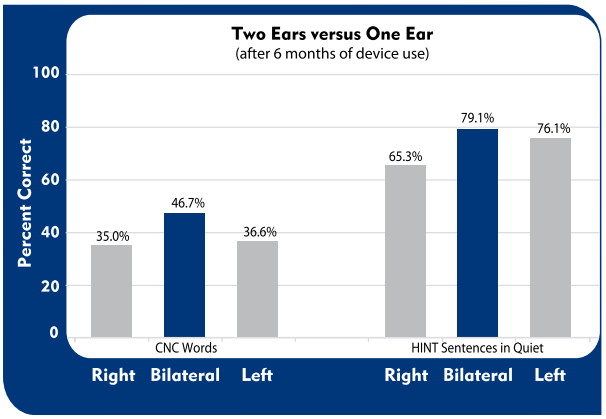

Figure 2. Unilateral and bilateral speech perception in quiet (CNC words and HINT sentences) for 10 subjects who have reached the six-month test interval.

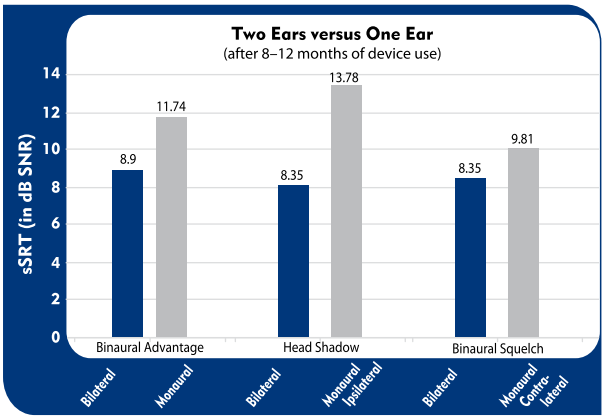

Figure 3. Bilateral advantage, head shadow advantage, and binaural squelch effect when listening to speech in noise for five subjects with 8-12 months of bilateral implant experience.

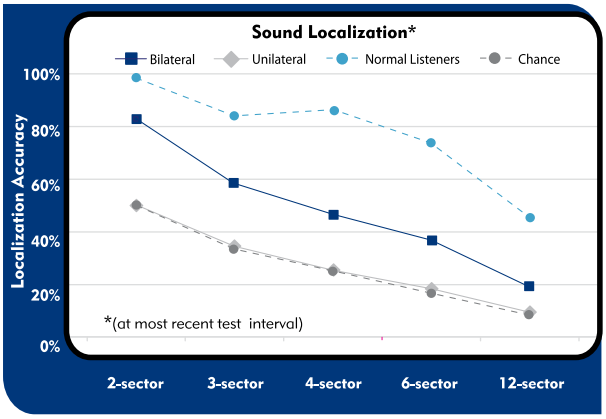

Figure 4. Unilateral and bilateral localization accuracy for 13 subjects. Data reflects patient performance at the most recent test interval for each subject.

References

Dunn C, Dunn C, Tyler R, Witt S, Gantz B. (2006) Effects of converting bilateral cochlear implant subjects to a strategy with increased rate and number of channels. *Ann Otol Rhinol Laryngol* 115:433-438.

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