



HiRes with Fidelity 120™ Clinical Results

Clinical Studies Summary

HiRes with Fidelity 120* Overview

In 2003, Advanced Bionics released HiResolution™ Sound (HiRes™), a family of strategies that doubled the number of spectral bands and increased temporal rates tenfold over conventional sound processing strategies. Clinical trial results revealed that adult subjects demonstrated significant improvement on all speech recognition tests with HiRes compared to their performance with conventional strategies (Koch et al, 2004). Moreover, 96% of the subjects expressed a strong preference for HiRes strategies.

The flexibility of the Harmony’s electronics platform (CII Bionic Ear™ and HiRes 90K™ implants) allows for the continued evolution of HiResolution sound. HiRes with the Fidelity 120 option (HiRes 120) is designed to build on the strengths of standard HiRes by creating electrical stimulation patterns that more faithfully represent the frequency spectrum of the acoustic input signal. HiRes 120 first analyzes the incoming sound signal by applying a 256-bin Fast Fourier Transform (FFT). The algorithm then processes the temporal and spectral detail in parallel. Temporal detail is extracted using a Hilbert transform while a navigator determines the energy maximum for each electrode pair. The estimated frequencies of the spectral maxima are used to select an optimal “steered” spectral band for each electrode pair. These “steered” spectral bands are created through simultaneous delivery of current to a pair of adjacent electrodes. Conceptually, the effective locus of stimulation can be steered to locations between the electrodes by varying the proportion of current delivered to each electrode of the pair. HiRes 120 is designed to provide eight

spectral bands for each of the 15 electrode pairs, thereby creating 120 separate spectral bands.

HiRes 120 is intended to allow implant users to take advantage of their residual place-pitch perception capabilities by delivering spectral information in higher resolution compared to conventional processing. The increased spectral resolution, in combination with the fine temporal resolution already implemented in HiRes, may lead to better speech perception in noise and improved music appreciation.

CONTENTS

HiRes With Fidelity 120 Overview.....	1
Clinical Study Design.....	2
Subjects.....	2
Speech Perception Results.....	3
Sound Quality and Music Ratings.....	3
Everyday Listening Benefits.....	4
Preference Ratings.....	4
Summary.....	5
References.....	5

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

Clinical Study Design

A recent clinical study documented the listening benefits of HiRes 120 sound processing in adult Harmony users. Performance with standard HiRes was assessed at the baseline visit and compared with HiRes 120 performance after three months of listening experience. Subsequently, subjects were refit and retested with standard HiRes. Outcome measures include speech perception in quiet and noise, music and sound quality ratings, self-reported benefits, and a preference questionnaire. Speech perception tests were administered at 60 dB SPL.

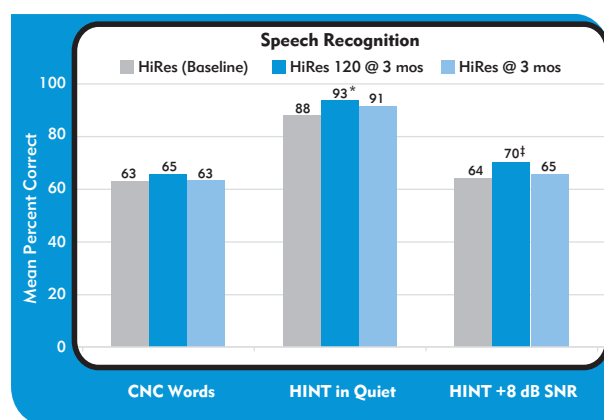


Figure 1. Mean scores for three speech tests at baseline with HiRes, at three months with HiRes 120, and after being refit with HiRes. The “*” indicates a significant difference between the HiRes 120 and baseline HiRes scores ($p < .05$). “†” indicates that the HiRes 120 score was significantly different from baseline and 3-month HiRes scores ($p < .05$).

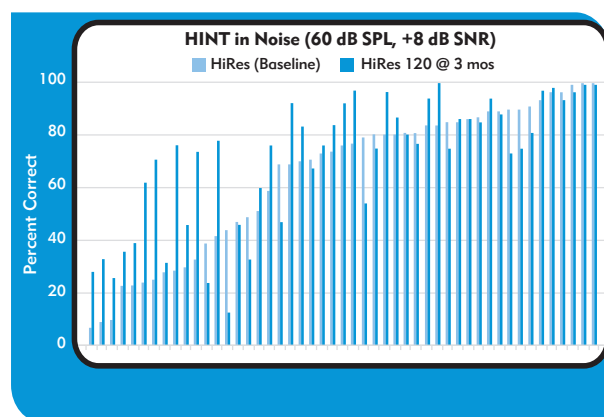


Figure 2. Individual HINT-in-fixed-noise scores at baseline with HiRes and at three months with HiRes 120, rank ordered from lowest to highest HiRes scores.

A unique aspect of the study was use of a direct-connect (DC) system for the speech tests. The system, developed in collaboration with Sigfrid Soli and colleagues at the House Ear Institute (Soli et al, 2005), eliminates the need for a sound booth or speaker array. The direct-connect system uses a family of head-related transfer functions (HRTFs) measured with KEMAR at source locations corresponding to loudspeaker positions appropriate for unilateral or bilateral testing. HRTFs appropriate to the selected source location are applied to the selected signal and presented via direct connection to the auxiliary input of the Auria™ or Harmony™ sound processor at the specified level in dB(A). The HRTFs also incorporate a mapping function that specifies the relationship between electrical inputs provided via direct connection to the sound processors and acoustic inputs received via the T-Mic™. The speech stimulus at a selected location and a noise signal at the same or different specified location can be presented simultaneously at independently specified levels in dB(A) in order to simulate sound field testing.

Subjects

Subjects consisted of 50 adults with postlingual onset of severe-to-profound hearing loss who had previously been implanted with a CII or HiRes 90K device. All subjects used the Harmony BTE processor during the trial. Demographics appear in Table 1.

Table 1. Demographics of study sample

Variable	Mean	Range
Age at implant	54 years	25 to 79 years
Age at Enrollment	56 years	28 to 80 years
Duration of severe-to-profound loss at time of implant	6 years	< 1 year to 29 years
Duration of CI use at time of enrollment	2 years	2 months to 5 years
Duration of HiRes use at time of enrollment	2 years	0 to 4 years

Speech Perception Results

In the clinical study, a battery of speech perception tests was used to compare implant benefit between standard HiRes and HiRes 120. The speech perception tests included CNC words, HINT sentences in quiet, and HINT sentences in noise (using a fixed signal-to-noise ratio of 8 dB). The mean sentence perception scores in quiet and noise were significantly higher for HiRes 120 compared to baseline with HiRes. For sentences in noise, the mean scores for HiRes 120 were significantly higher than scores after subjects were refit with HiRes (Figure 2). As shown in the individual data (Figure 2), subjects who showed the lowest scores at baseline (and therefore had the greatest headroom for improvement on the test measure) appeared to exhibit the greatest gains when using HiRes 120—particularly for the HINT sentences in quiet and noise.

Sound Quality and Music Ratings

In addition to speech testing, study participants rated the clarity of female voices, male voices, child voices, and environmental sounds (from the Iowa Sound Quality Test) (Tyler, 2005) on a proportional scale from 0 (unclear) to 100 (clear). Subjects also rated the pleasantness and distinctness of recorded instrumental music passages on a scale from 0 (extremely unpleasant/indistinct) to 10 (extremely pleasant/distinct). The music samples consisted of a variety of styles including classical, easy listening, and solo instrument passages. Finally, subjects rated their everyday frequency of listening to music (1 = never to 5 = very often) and satisfaction with listening to music (1 = very dissatisfied to 5 = very satisfied).

Subjects listened to and rated sound and music quality with standard HiRes and after using HiRes 120 for three months. For the 50 subjects, clarity of voices and environmental sounds were significantly higher for HiRes 120 compared to baseline with HiRes. Moreover, mean ratings for pleasantness and distinctness of music were higher with HiRes 120 than with standard HiRes (Figure 3). After three months of using HiRes 120, there was an increase in the proportion of adults reporting that

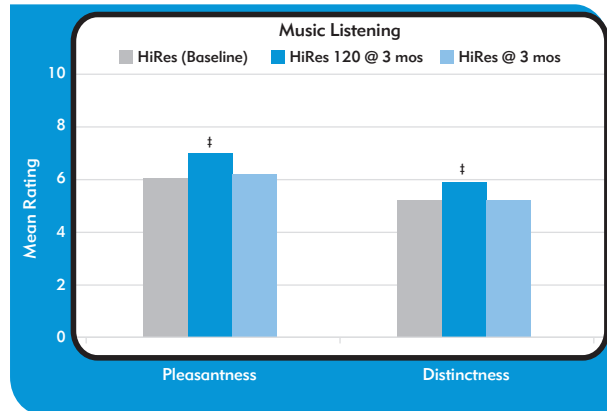


Figure 3. Music pleasantness and distinctness rated on a 0–10 scale. The “†” indicates that the HiRes 120 score was significantly different from baseline and 3-month HiRes scores ($p < .05$).

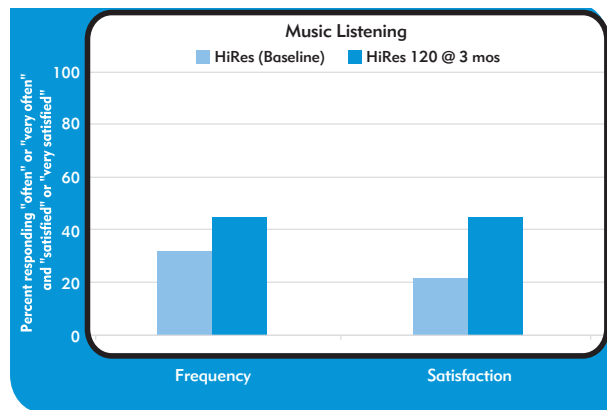


Figure 4. Percent of subjects responding “often” or “very often” and “satisfied” or “very satisfied” when listening to music. The “**” indicates a shift of 15% or greater in the proportion of subjects responding “satisfied” or “very satisfied”.

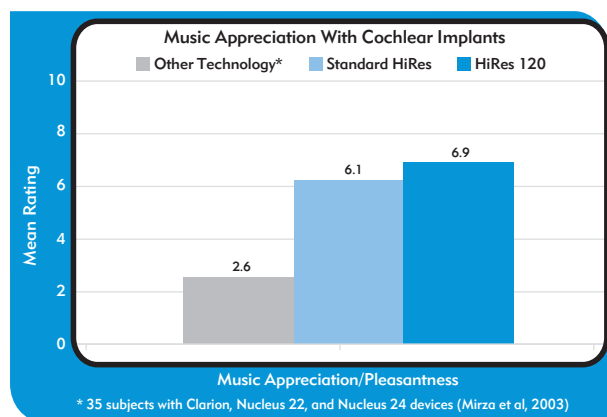


Figure 5. Mean ratings of music appreciation/pleasantness with at least nine months of use with other cochlear implant technologies (from Mirza et al, 2003) compared to at least three months of use with standard HiRes and at the three-month test interval with HiRes 120.

they listen to music “often” or “very often” and there was over a 15% shift in the proportion of subjects, reporting that they are “satisfied” or “very satisfied” when listening to music using HiRes 120 compared to standard HiRes (Figure 4).

These results (particularly ratings of music pleasantness) for subjects using either standard HiRes or HiRes 120 showed markedly higher values compared to ratings reported in an earlier study (Mirza et al, 2003) of music enjoyment with other cochlear implant technologies (Figure 5). It should be noted that the Mirza study asked subjects to rate general music listening enjoyment, whereas the HiRes 120 study asked subjects to rate music pleasantness (and distinctness) after listening to specific musical passages.

Everyday Listening Benefits

Study subjects also rated the sound clarity and ease of listening in everyday situations using a 5-point Likert scale, with 5 being best (clearest or easiest). Ratings were made at baseline with HiRes and after using HiRes 120 for three months.

After three months of HiRes 120 use, a greater proportion of the 50 subjects rated their experience as “clear” or “very clear” for all but one listening situation (at a party). There was over a 15% shift in the proportion of adults reporting “clear” or “very clear” for 3 of 13 situations (Figure 6). Similarly, a greater proportion of subjects rated their experience as “easy” or “very easy” for all but one situation (at home) after using HiRes 120. There was over a 15% shift in the percent of subjects rating their experience as “easy” or “very easy” for 4 of 11 listening situations (Figure 7).

Preference Ratings

Forty-three of 50 subjects (86%) reported a preference for the HiRes 120 over standard HiRes. Subjects also rated strength of preference for the two strategies on a scale from 1 (weak preference) to 10 (strong preference). The mean strength of preference for the 43 subjects who preferred HiRes 120 was 7.9 (range: 1-10). The strength of preference was rated as 8 or higher by 26 of the

43 subjects. Indeed, 16 of the 43 subjects rated their preference as 10 (strong preference). For the seven subjects who preferred standard HiRes, the mean strength of preference was 4.4 (range: 1-9). The strong preference for HiRes 120 suggests that standard objective test batteries are not able to measure quantitatively some of the important qualitative benefits reported by recipients.

Participants also indicated those aspects of sound that were better with their preferred processing mode using the scale: strongly disagree, disagree, neutral, agree, or strongly agree. As seen in Table 2, over three-quarters of the subjects agreed or strongly agreed that HiRes 120 resulted in better

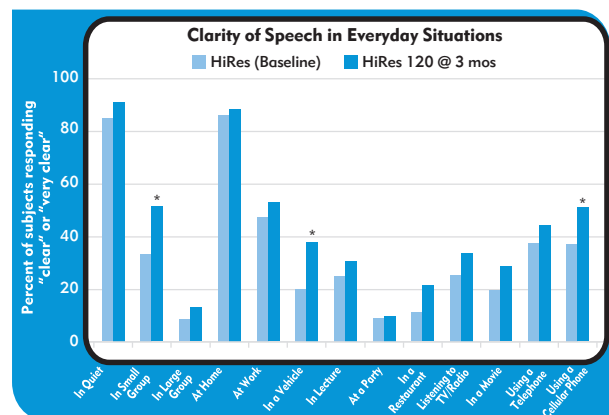


Figure 6. Percent of subjects reporting sounds as “clear” or “very clear” in 13 listening situations at baseline with HiRes and at three months with HiRes 120. The “*” indicates a shift of 15% or greater in the percent of subjects responding “clear” or “very clear”.

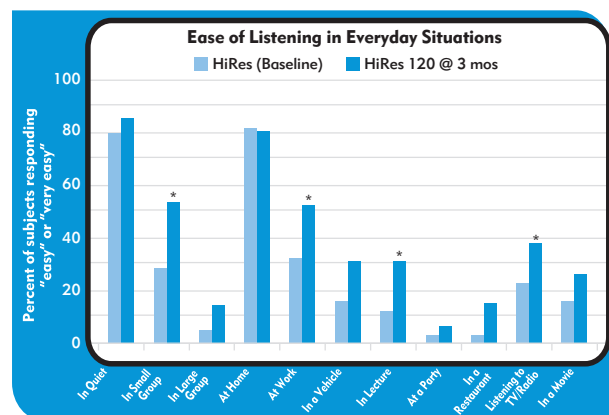


Figure 7. Percent of subjects reporting listening as “easy” or “very easy” in 13 situations at baseline with HiRes and at three months with HiRes 120. The “*” indicates a shift of 15% or greater in the percent of subjects responding “easy” or “very easy”.

overall sound quality and more natural sounding speech, and that environmental sounds were easier to distinguish and sounded more distinct compared with standard HiRes. Table 3 shows that approximately one-half to two-thirds of the subjects who preferred HiRes 120 reported improvement in listening to various aspects of music (agree or strongly disagree).

Table 2. Distribution of Preference Ratings on Speech and Environmental Sounds Items‡

Preference Item	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Quality is better.	2.3%	0%	14.0%	44.2%	39.5%
Speech is more natural.	0%	2.3%	18.6%	46.5%	32.6%
Speech is easier to understand in noise.	2.3%	9.3%	27.9%	27.9%	32.6%
Environmental sounds are easier to distinguish.	0%	0%	18.6%	41.9%	39.5%
Environmental sounds are more distinct.	0%	2.3%	11.6%	51.2%	34.9%

‡ For 43 (of 50) subjects who preferred HiRes 120.

Table 3. Distribution of Preference Ratings on Music Items‡

Preference Item	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Music sounds better.	0%	4.7%	25.6%	37.2%	32.6%
Music sounds more natural.	0%	0%	32.6%	32.6%	32.6%
Music sounds richer.	0%	2.4%	33.3%	31.0%	35.7%
Melody is more enjoyable.	0%	4.7%	27.9%	39.5%	25.6%
Rhythm is more noticeable.	2.4%	2.4%	33.3%	33.3%	28.6%
Singers' voices are more distinguishable from instruments.	0%	2.4%	31.0%	45.2%	23.8%
Singers' voices sound more distinct.	0%	4.7%	39.5%	32.6%	23.3%
Lyrics are recognizable.	0%	11.6%	41.9%	25.6%	20.9%
Individual instruments are distinguishable.	0%	9.3%	34.9%	44.2%	11.6%
Individual instruments sound more distinct.	0%	7.0%	25.6%	51.2%	16.3%

‡ For 43 (of 50) subjects who preferred HiRes 120.

Participating Centers (North America)

Carle Clinic Association, *Urbana, IL*
 House Ear Clinic, *Los Angeles, CA*
 Houston Ear Research Foundation, *Houston, TX*
 Indiana University School of Medicine, *Indianapolis, IN*
 Johns Hopkins University, *Baltimore, MD*
 Mayo Clinic, *Rochester, MN*
 Midwest Ear Institute, *Kansas City, MO*
 New York University Medical Center, *New York, NY*
 Northwestern University, *Evanston, IL*
 Ottawa Hospital (Civic Campus), *Ottawa, Ontario*
 University of Massachusetts, *Amherst, MA*
 University of Texas Southwestern Medical Center, *Dallas, TX*
 Washington University, *St Louis, MO*

Summary

These clinical results indicate that HiRes 120 is a viable sound processing option that may offer additional hearing advantages for some Harmony recipients in a variety of listening environments. The reported benefits extend beyond speech perception and may encompass everyday sounds and music appreciation—outcomes once thought to be beyond expectations for cochlear implant recipients.

References

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