
Converting Patients from Conventional Strategies to HiResolution™ Sound Processing

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HiResolution™ Sound (HiRes™) is intended to represent an advance in capturing, composing, detailing, and delivering sound for hearing via a cochlear implant. This paper reports initial experiences in switching patients from conventional strategies to HiRes™ sound processing, and is intended to answer the most frequently asked questions on this topic. Companion papers, “New Methodology for Fitting Cochlear Implants” and “Tips for Fitting HiResolution™ Sound (HiRes™) in SoundWave™” contain information on the methodology used to program HiRes™ and fitting tips.

Background

Initial experience with HiRes™ was obtained in an IDE clinical trial with postlingually deafened adults. During the clinical trial, the CII Bionic Ear™ was first programmed with conventional strategies and patients were evaluated after one and three months of use. Patients then switched to HiRes™ and were again evaluated after one and three months of use (four and six months of device use). Following approval of HiRes™, additional patients, both adults and children, were switched over to HiRes™ during field trials to evaluate the new SoundWave™ software platform and fitting methodology. Most of these patients used conventional programming for longer periods of time than did the patients in the IDE clinical trial.

Comparison of Adult Patient Performance with Conventional Strategies and HiResolution™ Sound Processing

Speech perception testing was conducted during the IDE clinical trial to compare performance between conventional strategies and HiRes™ sound processing. Fifty-one patients with severe-to-profound postlingual hearing loss were fit initially with conventional processing for the first three months, after which they were crossed over to HiRes™ for three months. Word recognition (CNC words), easy sentence recognition (CID Sentences), and difficult sentence recognition (HINT Sentences) in quiet and in

noise (+10 dB signal-to-noise ratio) were evaluated with conventional strategies and HiRes™ sound processing after one and three months of use. For a subset of 30 patients, consonant recognition in noise (Iowa Consonant test, +10 dB signal-to-noise ratio) was assessed after three days of HiRes™ use and compared to their three-month performance with conventional processing.

Consonant recognition data *obtained after only three days of HiRes™ use compared with three months of conventional strategies* (Figure 1) showed an *immediate improvement with HiRes™*.

Comparison of three-month performance with conventional strategies with one-and three-month performance with HiRes™ *revealed a significant improvement in performance with HiRes™* on all speech perception tests. The largest improvement with HiRes™ occurred on HINT sentences in noise (Figure 2), especially for the patients with relatively low scores with conventional processing.

Although the study design does not allow determination of whether HiRes™ is solely responsible for this significant improvement, the immediate increase in consonant recognition in noise test after only three days of use (Figure 1), as well as the results of the poorest performers (Figure 3) indicate that HiRes™ sound contributed to the observed improvement. For those poor performers, there was no improvement in performance between one and three months conventional-processing use. After switching



Figure 1. Individual Iowa consonant identification scores in noise (+10 dB SNR) after three months using conventional strategies and 1-3 days using HiRes™ sound processing (rank ordered by three-month conventional-strategy results).



Figure 2. Individual scores on HINT sentences in noise (+10 dB SNR) after three months of conventional strategy use and three months of HiRes™ use. Scores are rank ordered by the three-month conventional-strategy results).

to HiRes™, there was a dramatic improvement (mean change = 25%) on this relatively difficult task after using HiRes™ for only one month, with a smaller improvement after two additional months of experience.

Adult Patient Preference for Conventional Strategies and HiResolution™ Sound Processing

In the IDE clinical trial, questionnaires assessed each patient's preference for their conventional strategy or HiRes™ sound processing after three months of experience with each. Patients rated the strength of preference on a scale from 1 (weak preference) to 10 (strong preference). Patients also were asked to indicate whether their preferred strategy helped them in a variety of listening conditions (e.g., speech is clearer in a small group of people, music sounds better).

Fifty patients completed the questionnaire and 45 of them (90%) preferred HiRes™ to conventional sound processing. The mean preference rating for the patients who preferred HiRes™ was 8.5 (range 4-10) compared with a mean rating of 5.3 for the patients who preferred conventional strategies (range 1-8). Patients who preferred HiRes™ reported improved benefits in a wide range of everyday listening situations (Figure 4). Even the highest performing patients, many of whom reached the test ceiling with conventional strategies, reported substantial improvements with HiRes™ (Figure 5). At the 12-month follow-up visit, three of the five patients who initially preferred conventional strategies stated a preference for HiRes™. Thus, 96% (48/50) of the patients preferred HiRes™ sound processing to conventional strategies. The two patients who preferred conventional strategies at the 12-month visit subsequently changed to HiRes™, although one patient uses a HiRes™ program with a reduced stimulation rate and fewer channels which emulates some aspects of CIS. All of these patients continue to use HiRes™.

In the field trial of SoundWave™, 85% of the patients (35/41) preferred HiRes™. Six patients (4 CIS and 2 MPS users) preferred their conventional strategies.

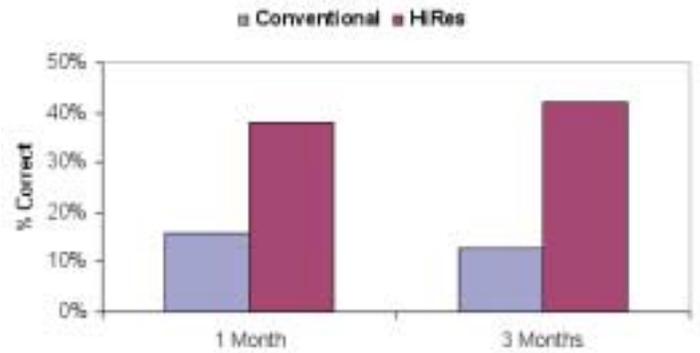


Figure 3. Mean scores of the 19 poorest performing patients (<30% on HINT in noise with conventional processing) after one and three months of conventional sound processing and HiRes™ use.

Effect of Type of Conventional Strategy and Duration of Use on HiResolution™ Sound Processing

Statistical analyses of the data from the 51 subjects in the IDE study revealed that the conventional strategy used by the patient had no significant effect on speech perception performance with HiRes™. That is, HiRes™ performance was comparable among patients who formerly used SAS, CIS, or MPS.

Data collected from a subset of 14 patients in the SoundWave™ field trials showed *no obvious trend in the amount of time that patients required to adapt to HiRes™ as a function of conventional strategy used* (SAS, MPS, or CIS). For these patients, who had used either SAS, CIS or MPS for a *period over 3 months*, the average time reported to adjust to HiRes™ ranged from several days to slightly more than one week. Moreover, there was *no obvious association between adjustment time and duration of conventional strategy use* in these patients.

Experience with Children

In the field trial of SoundWave™, 19 children were switched from conventional strategies to HiRes™. One child was returned to MPS after several months of HiRes™ use.

To examine the impact of HiRes™ on children's performance, parents were asked to complete a questionnaire regarding their child's progress with HiRes™ over the first two weeks after programming in HiRes™. After only 2 weeks of HiRes™ use, parents reported:

- 60% (9/15) showed improved performance with HiResolution™ Sound
- 27% (4/15) showed comparable performance with HiResolution™ Sound
- 13% (2/15) showed poorer performance but were continuing to improve.

Clinicians reported the following performance data on 6 pediatric subjects after one month of HiRes™ use:

- Of the fourteen children in the SoundWave™ trial:
 - 13/14 continue to use HiResolution™ Sound
 - 1/14 returned to conventional strategy after the four week trial

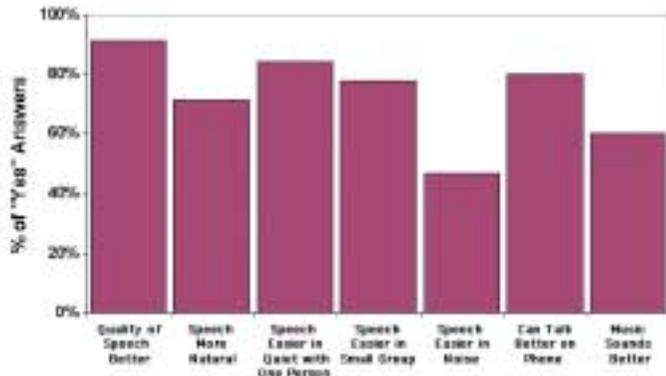


Figure 4. Comparison of benefit in a variety of listening situations for the 45 patients who preferred HiRes™ after three months of use.

Initial Programming of HiResolution™ Sound in SoundWave™

SoundWave™ offers a choice between HiRes-P (Paired) and HiRes-S (Sequential) strategies for adults and older children who can subjectively report their sound processing preference. HiRes-P implements the unique capabilities of the CII Bionic Ear™ to deliver simultaneous paired stimulation while HiRes-S utilizes sequential stimulation. Both HiRes-P and HiRes-S offer the fastest stimulation rates available in today's cochlear implant technology. For young children, it is recommended that HiRes-P be used and that HiRes-S be used if progress is not satisfactory with HiRes-P. Eighteen of the 19 children in the field trial of SoundWave™ were programmed with HiRes-P.

The following information was obtained from the IDE clinical trial and the SoundWave™ field trials. For 91 subjects who evaluated HiRes-P and HiRes-S, the following preference information was reported:

- HiRes-P was preferred by 58% (53/91) patients
- HiRes-S was preferred by 42% (38/91) patients

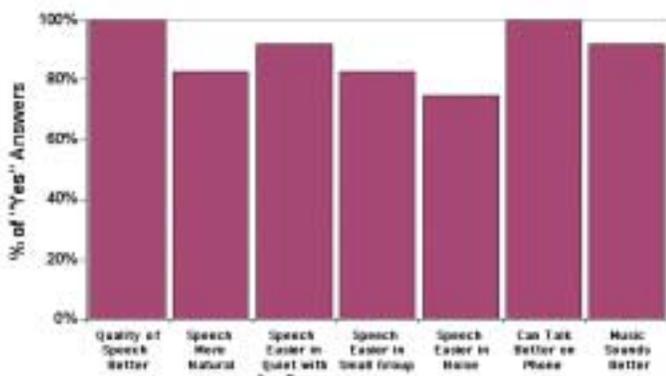


Figure 5. Comparison of benefit in a variety of listening situations for the 12 patients with the highest CNC scores (> 70%) after three months of HiRes™ use. These patients preferred HiRes™ sound processing.

Pediatric Performance Comparison for Baseline Conventional vs 1 Month HiResolution Use (N=6)

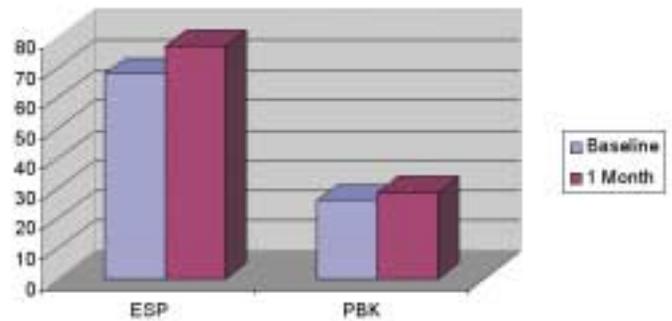


Figure 6. Comparison of children's performance on the ESP and PB-K with conventional strategies and after one month of HiRes™ use.

For the 91 subjects, the breakdown of preference based on conventional strategy use was reported as:

- SAS (36/91):
 - HiRes-P was preferred by 53% (19/36) patients
 - HiRes-S was preferred by 47% (17/36) patients
- MPS (24/91):
 - HiRes-P was preferred by 88% (21/24) patients
 - HiRes-S was preferred by 12% (3/24) patients
- CIS (31/91):
 - HiRes-P was preferred by 42% (13/31) patients
 - HiRes-S was preferred by 58% (18/31) patients

From these data, there appears to be a slight preference for the HiRes-P for subjects crossing over from MPS and SAS. That is, subjects who had previously used a fully or partially simultaneous strategy prefer HiResolution™ Sound with some simultaneous stimulation. On the other hand, subjects who had used the non-simultaneous CIS tend to prefer the sequential HiRes-S.

Performance testing on 25 subjects revealed no significant difference in performance between the two strategies on the Iowa Consonant Test.

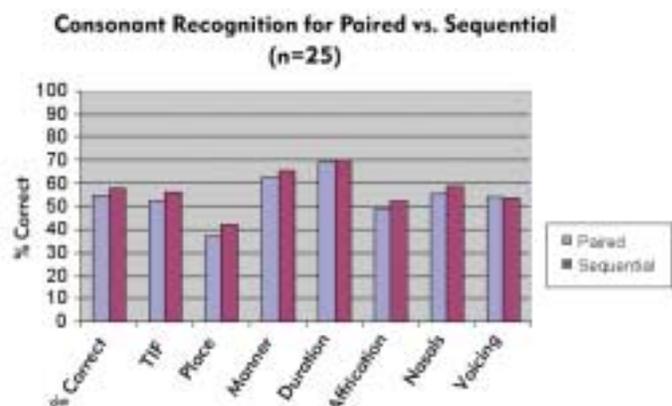


Figure 7. Performance comparison on the Iowa Consonant Test in noise for patients programmed with HiRes-P or HiRes-S.

SUMMARY

Taken together, the results obtained in the IDE clinical trial and SoundWave™ field trials indicate that most patients successfully cross over to HiResolution™ Sound and prefer to use it over conventional strategies. Adult patients adapted to HiRes™ within a few days to slightly more than a week. There was no obvious relationship between the amount of time to adapt to HiRes™ and the type of conventional strategy used (SAS, CIS, MPS), or its duration of use prior to crossover. Clinician observation indicated that some patients who were good performers with their preferred conventional strategy experienced the greatest difficulty initially with HiRes™. Typically these subjects had postlingual and short-term deafness. However, once these patients adapted to HiRes™, they also reported the greatest benefits with HiRes™ in the most challenging listening situations, such as music and noisy environments. Other patients who required more time to adjust to HiRes™ were those who typically did not adapt well to any changes in their programs. Experience also suggests that patients who can report preferences should be programmed with both HiRes-S and HiRes-P, and that young children should be programmed first with HiRes-P. While every patient is unique and new insights may unfold as more patients are crossed over to HiResolution™, the information in this paper may be useful to clinicians as they begin to switch patients from conventional strategies to HiResolution™ sound processing.

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