Boston Scientific Corporation

For more than 25 years, Boston Scientific’s mission has been to advance the practice of less-invasive medicine by providing a broad and deep portfolio of innovative products, technologies, and services across a wide range of medical specialities. As the world’s largest medical device company dedicated to less-invasive medicine, Boston Scientific believes that each innovative product is the outcome of strong research and development, intelligent acquisition, close collaboration with clinicians, outstanding operational and quality processes, and a powerful global distribution channel.

Advanced Bionics Corporation

Founded in 1993 and acquired by Boston Scientific in 2004, Advanced Bionics is a global leader in implantable, high-technology neurostimulation devices for the treatment of deafness, chronic pain, and other debilitating conditions. Advanced Bionics is dedicated to improving the quality of life for hearing impaired individuals through the application of advanced technology and the delivery of high-quality products and services. As the only American cochlear implant manufacturer, Advanced Bionics is committed to offering lifetime services and support for our recipients.
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In 2005, Advanced Bionics published the inaugural issue of the Auditory Research Bulletin, a compendium of worldwide collaborative studies with its HiResolution® Bionic Ear technology. This interim edition of the Auditory Research Bulletin highlights some of the research efforts that have been underway in 2006. It is not intended to be an exhaustive review of all studies—rather a focus on key areas of contemporary research interest such as novel sound processing strategies, music perception, and bilateral implantation.

Scientists and clinicians at more than 100 sites around the globe have been engaged in research with the HiResolution system during the past year. We are indebted to the many investigators who have strived so diligently to advance the field of cochlear implantation. A list of participating investigators and centers can be found at the end of this publication. A comprehensive Auditory Research Bulletin will be published again in 2007.

Advanced Bionics also is pleased to acknowledge special research efforts within the company during 2006. First, Dr. Leonid Litvak, principal scientist at Advanced Bionics, received the prestigious John Abele award from Boston Scientific Corporation—an award named for the co-founder of Boston Scientific recognizing excellence in scientific innovation. The award was given to Dr. Litvak for his work in developing the current steering technology now implemented in HiRes Fidelity 120™ sound processing. Second, Advanced Bionics thanks the worldwide members of its Research and Development and Clinical Research teams for their support of external study centers and for their assistance in the preparation of this bulletin, listed at the end of this publication.

The studies summarized herein reflect Advanced Bionics’ ongoing commitment to our “partners in science” — the clinical researchers and clinicians around the globe who are improving outcomes and helping all cochlear implant patients achieve their maximum hearing potential.

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Electrode Development and Evaluation

Precurved electrodes have been used with cochlear implants since 1991 when Advanced Bionics initiated a clinical trial with its first generation device. Since that time, Advanced Bionics has continued to develop the precurved electrode concept with its current family of HiFocus® electrodes. In the first HiFocus design, the size of the electrode contacts was increased and the contact orientation modified to provide more focused stimulation of the spiral ganglion cells compared to the radial bipolar (spiral) electrode used with the first generation CLARION® device. All subsequent HiFocus electrodes feature 16 contacts intended to focus stimulation toward the neural elements.

The HiFocus Helix® is a highly precurved version of the original HiFocus electrode that is designed for close perimodiolar placement. The insertion technique for the HiFocus Helix electrode is intended to minimize the likelihood of damage to the basilar membrane or lateral wall of the cochlea. Moreover, the thinner version of the HiFocus Helix electrode (“slim Helix”) is designed to require a smaller cochleostomy (1.0 mm) and to minimize damage to cochlear structures.

Human temporal bone studies play an important role in the evaluation of new electrode designs. Several groups of investigators have examined the effect of HiFocus Helix and prototype slim Helix insertions on cochlear structures using a variety of techniques. For example, the microdissection approach of Wright and Roland (Texas, USA) (2005a-b) confirms that both the Helix (Figure 1) and slim Helix designs can be inserted with little trauma to the cochlea. Similarly, using fluoroscopy and microscopy together, Roland (New York, USA) (2005) has shown minimal cochlear damage after insertion of the prototype slim Helix design (Figure 2).

In Germany, Aschendorff and colleagues have used a new radiological technique called “rotational CT” scanning that provides rapid, high-resolution images of the cochlea. Rotational-CT generates updated images within seconds, allowing surgeons to view cochlear implant electrodes in situ, both in temporal bones and in clinical patients. In combination with other radiological data, it is possible to determine electrode array location with respect to cochlear anatomy, thereby allowing highly accurate determination of electrode placement and integrity within scala tympani. Their data demonstrate that the slim Helix produces minimal trauma to the cochlea, as shown in Figure 3.
Also under study is a slim version of the HiFocus 1j—a prototype design having approximately half of the cross-sectional area of the HiFocus array. Lenarz (Germany) (2006) has evaluated the design by inserting it into five fresh frozen human temporal bones. All five insertions were made without incident via the round window, and full insertions were achieved. Following fixation, histological analysis was carried out using a technique whereby thin sections were ground away and the revealed surfaces were polished and photographed. All arrays remained entirely in the scala tympani with no obvious damage to cochlear structures. These early findings suggest that this prototype electrode design is atraumatic and may support electroacoustic stimulation in future applications.

Ramos (Spain) (2004) has explored the effect of cochleostomy location on insertion-related cochlear trauma. He implanted Contour™, Contour Advance™, and Helix electrodes via cochleostomies located either anterior and superior to the promontory, anterior to the round window, or anterior-inferior to the round window. High-resolution CT and microdissection showed that no damage occurred when the insertion was done through the anterior-inferior position for any electrode type.

Fitzgerald O'Connor (United Kingdom) (2006) also has explored the impact of the cochleostomy on electrode positioning and cochlear trauma. Traditionally, the insertion tube for the HiFocus electrode array has been inserted approximately four millimeters into the cochleostomy. Because the electrode contacts lie in a lateral position, some neural elements in the basal turn may not be stimulated sufficiently. In this study, six consecutive electrode insertions were made through the round window—the electrode tip being expelled a few millimeters before being guided though a slit in the round window membrane. The study goals were to obtain a more medial electrode location and to reduce cochlear trauma. NRI responses were used to compare the efficacy of the round window approach to a series of six consecutive, traditional cochleostomy insertions. Improved...
intraoperative NRI responses were found for the round window series, with basal NRI responses being obtained for 100% of the electrodes compared to 50% for the traditional approach. The quality of NRI responses was considerably better for the round window group, indicating that this surgical approach may be advantageous. Speech perception and sound quality outcomes will be followed to determine whether advantages of the round window approach are reflected in everyday patient benefit.

Because temporal bone studies are essential for developing and testing new electrode designs, Zarowski (Belgium) (2006) has developed a new technique to image temporal bones with sub-10 micrometer resolution. His Micro-CT technique provides near histological quality images without risk of artifacts introduced during analysis. Moreover, the imaging technique, which takes about one week, is substantially faster than histological analysis. A series of human temporal bones have been imaged and are being analyzed for the dimensions of the scalae at various points. Maximum and minimum dimensions will be extracted and stored in a database to form a repertoire of highly detailed information on the cochlea. In addition to aiding the development of new electrode designs, the images can be used for surgical training because this high resolution technique allows even small structures to be imaged, as seen in Figure 4.

Additionally, the effect of electrode placement on patient outcomes is being explored by Finley (USA) (2006) and collaborators. Using a combination of methods—CT scans and computer models to determine electrode contact location, NRI to estimate neural survival, demographic data, and speech perception scores—these investigators are attempting to determine how the implant system can be programmed more effectively based upon individual peripheral physio-anatomic factors.

References


Figure 4. A Micro-CT cross section through a human temporal bone, showing the detailed anatomical structures visible with nearly histological resolution.
Harmony and Connectivity

The new Harmony™ behind-the-ear (BTE) speech processor is designed to provide the same reliability and user-friendly features as the award-winning Auria® processor. Harmony’s new features include:

- 16-bit, CD-quality front-end signal processing
- Greater power efficiency and longer battery life
- Built-in T-Coil
- Built-in status LED

As with Auria, earhook options for Harmony include the standard T-Mic®, iConnect, and Direct Connect—enabling users to adapt Harmony to a variety of assistive accessories and listening environments. Harmony implements standard HiRes® sound processing and HiRes with the Fidelity 120™ option*. With its easy-to-use controls and low-profile headpiece, Harmony is designed for comfortable, real-world listening.

Harmony Studies

A recent study reported by Séguin and colleagues (Canada) (2006) found that the CD-quality, front-end signal processing and new external controls offered by Harmony resulted in improved sound quality and satisfaction in adult CII Bionic Ear® and HiRes 90K® users. In particular, significant improvements (p < 0.05) were noted in the clarity of environmental sounds (Figure 1) and the clarity of speech on a mobile phone. A majority of users rated speech as more natural and easier to understand, environmental sounds more distinct, and music as sounding better. In addition, PowerCel™ operating times were longer with Harmony compared to the Auria, as shown in Figure 2. Average operating time increased with Harmony from 7 to 14 hours for the PowerCel Slim and from 15 to 24 hours for the PowerCel Plus.

After one week of Harmony use, 86% of subjects (19 of 22) preferred Harmony to their own processors. Using a five-point Likert scale (strongly disagree, disagree, neutral, agree, or strongly agree), subjects indicated various aspects of sound that were better with their preferred processor. For subjects who

* In the United States, an optional feature for adults only. See package insert for details.
preferred Harmony, the percentages of subjects who “agree” or “strongly agree” with various questionnaire statements are listed in Table 1. Notably, there are few, if any, other published reports that describe improvements in listening benefits resulting solely from changing the sound processor.

Notably, there are few, if any, other published reports that describe improvements in listening benefits resulting solely from changing the sound processor.

Table 1. Distribution of preference responses for subjects preferring Harmony

<table>
<thead>
<tr>
<th>Preference Statement</th>
<th>Percent Responding “Agree” or “Strongly Agree”</th>
</tr>
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<tbody>
<tr>
<td>Quality of sound is better.</td>
<td>79%</td>
</tr>
<tr>
<td>Speech is more natural.</td>
<td>63%</td>
</tr>
<tr>
<td>Environmental sounds are more distinct.</td>
<td>63%</td>
</tr>
<tr>
<td>Environmental sounds are easier to distinguish.</td>
<td>63%</td>
</tr>
<tr>
<td>Speech is easier to understand.</td>
<td>53%</td>
</tr>
<tr>
<td>Various aspects of music sound better.</td>
<td>50-67%</td>
</tr>
</tbody>
</table>

† n = 19

Demonstrating the benefits from the Harmony processor in children, a study by Crozat-Téissier and colleagues at Hôpital Robert Debré (France) (2006) showed that Harmony could be fit without reprogramming and that children accepted the new processor readily. Moreover, speech understanding was stable. Indeed, families reported an increase in sound perception abilities. Parents expressed appreciation for the status-LED feature and the increased battery life of the Harmony compared to the Auria.

T-Mic Studies

In addition to the aforementioned Harmony studies, several studies are exploring the benefits of the connectivity options for the Harmony and Auria processors—options designed to accommodate a variety of listening environments. For example, the T-Mic is the unique, in-the-ear microphone that is standard for adult use. It is designed to improve listening in noisy environments and to provide cable-free access to cellular telephones, consumer audio electronics, and assistive listening technology.

A recent study conducted by Soli (USA) and colleagues at the General Hospital of People’s Liberation Army in Beijing (China) (2006) compared speech understanding in noise between the T-Mic, the Auria BTE microphone, and the Platinum Headpiece (PHP) microphone in native speakers of Mandarin Chinese. An earlier study in English-speaking adults showed that the position of a cochlear implant microphone can affect speech intelligibility (Soli et al, 2005). Head–related transfer functions (HRTFs) were measured for the ear canal and for sound processed through the PHP microphone as well as for the BTE microphone and the T-Mic. Sentence reception thresholds (sSRTs) in noise were evaluated in 14 normal-hearing Mandarin-speaking listeners in free field as well as under headphones—the latter in which sound direction and microphone position were simulated using HRTFs. Using the Mandarin HINT-adaptive test, sSRTs for speech coming from the front were measured in the presence of noise originating from the front and from the right side. The T-Mic, which is positioned very near the entrance to the ear canal, produced the largest head shadow advantage, as shown in Figure 3. This advantage decreased by 5 dB or
more at high frequencies for the BTE and PHP microphones. This decrease in head shadow advantage reduced noise-side thresholds by about 2 dB in Mandarin compared to 4 dB in English. The binaural directional advantage was decreased by 1 dB in Mandarin compared to 2-3 dB in English. These findings indicate that the T-Mic can facilitate improved speech understanding in noise, especially when speech and noise are spatially separated.

In contrast to using HRTF simulations, Madell and colleagues (USA) currently are studying the benefits of the T-Mic in real-world listening conditions. They are comparing speech perception in noise between the standard BTE microphone and the T-Mic in a group of adults. In addition, they are evaluating everyday listening benefits using a questionnaire.

**iConnect Studies**

Another earhook option offered by Harmony and Auria—the iConnect—provides cable-free access to the Phonak MicroLink® MLx®S (Figure 4), which is one of the most common miniaturized FM receivers used in schools worldwide. With a separate power source, the iConnect is designed to provide reliable FM reception without compromising regular power consumption. Several studies have shown that the iConnect/FM option is beneficial to both adults and children.

For example, a study by Wolfe and colleagues (USA) (2006) assessed both the effects of mixing ratio and gain setting on speech perception in adults and children using the iConnect/FM option compared to using the implant alone. A within-subjects design compared speech recognition performance with the FM transmitter turned off (CI alone) and FM transmitter turned on (implant plus FM system) in the following conditions: speech presented at soft (50 dB SPL) and conversational (65 dB SPL) levels as well as speech presented in background noise (+10 dB SNR). Adults were tested with 30/70 and 50/50 mixing ratios and gain settings of +10 dB and +16 dB. Children were tested with only a 50/50 gain setting because it is generally accepted that young children should be able to monitor their voices. Pediatric testing also was completed with gain settings of +10 dB and +16 dB.

In the Wolfe et al study, the mean results for adults showed the largest improvement on sentence recognition in noise with the FM compared with the implant alone (Figure 5). Performance was essentially the same for the two mixing ratios for speech recognition in quiet and slightly higher in noise with the 30/70 mixing ratio. Although mean results were similar for +10 and +16 dB gain settings (30/70 ratio), the individual results showed that some adults performed better with a +16 dB gain setting. In contrast, all children demonstrated higher speech recognition in noise with the iConnect/FM system.
recognition scores with a +16 dB gain setting. Unlike the adults, the children also showed relatively large improvements in quiet (soft and conversational levels) with the FM compared with the implant-alone condition.

At the Medizinische Hochschule Hannover in Germany, Frohne-Büchner and her co-workers (2006) conducted a study of the iConnect with FM system in adults. Subjects listened to speech in quiet and in noise with and without the FM system. Three mixing ratios were tested: auxiliary (aux) only (signal only from FM), 50/50, and 30/70. As summarized in Figure 6, using the aux-only ratio, speech-in-noise scores were equivalent to speech-in-quiet results. The 30/70 ratio provided the next highest benefit in noise although the 50/50 ratio also provided some advantage. Interestingly, 9 of the 10 adult users preferred the aux-only setting when listening to speech in noise.

Similarly, Rafter and colleagues (2006) have conducted a study with the iConnect in school-aged children at St. Thomas’ Hospital in the United Kingdom. They tested the same mixing ratios as did Frohne-Büchner and colleagues. In noise, speech understanding was improved when using the iConnect/FM system over the implant alone (Figure 7). Scores were equivalent for the aux-only and 30/70 test conditions, but poorer for the 50/50 condition. Questionnaire data indicated that the children found the system easy to use and comfortable. No changes were required in the programs except for adjusting the mixing ratio. These researchers recommended setting the system to a 30/70 ratio to maximize hearing with the FM system while still allowing some acoustic signals through the BTE microphone, enabling children to monitor their own voices and receive some environmental sound information.

At the Royal National Throat, Nose & Ear Hospital (United Kingdom), Brinson (2005) showed the importance of verifying the functionality of the iConnect/FM system for children in a classroom setting to ensure better performance in background noise at different distances and in poor acoustic environments. Her study evaluated the iConnect/FM system in quiet and in noise (at a 90- or 270-degree azimuth) with various adjustments in the
Mixing ratio. The results indicated that a special program should be created for FM use only—with a 30/70 mixing ratio typically yielding the best results. This recommendation requires teachers to switch between programs. Therefore, teachers should be trained on appropriate device settings, and they should routinely complete short questionnaires to verify each child’s optimal performance with FM systems in classroom settings. Certainly, a balance must be struck between not compromising the incidental learning that is gained from “overhearing” via the speech processor microphone and optimizing speech perception in noise with the iConnect/FM system.

Several planned studies with Harmony’s pediatric accessories will be initiated during the coming year.

## Participating Centers and Clinics Worldwide

Beth Israel-New York Eye and Ear Cochlear Implant Center, New York, USA  
Carle Clinic, Illinois, USA  
General Hospital of Chinese People’s Liberation Army, Beijing, People’s Republic of China  
Guy’s and St. Thomas’ NHS Foundation Trust, London, United Kingdom  
Hôpital Robert Debré, Paris, France  
House Clinic & House Ear Institute, California, USA  
Houston Ear Research Foundation, Texas, USA  
Indiana University, Indiana, USA  
Integris Health, Oklahoma, USA  
Johns Hopkins University, Maryland, USA  
Mayo Clinic Rochester, Minnesota, USA  
Medizinische Hochschule Hannover, Hannover, Germany  
Midwest Ear Institute, Missouri, USA  
New York University, New York, USA  
Ottawa Hospital (Civic Campus), Ontario, Canada  
Royal National Throat, Nose & Ear Hospital, London, United Kingdom  
University of California—San Francisco, California, USA  
University of Massachusetts, Massachusetts, USA  
University of Minnesota, Minnesota, USA  
University of Texas Southwestern Medical Center, Texas, USA  
Washington University, Missouri, USA

## References


Early research suggested that additional “virtual” spectral channels (or pitches) could be created by stimulating two electrodes at the same time (Townshend et al, 1987; Wilson et al, 1994). That is, these studies showed that the perception of pitch could be varied systematically by adjusting the proportion of current delivered simultaneously to two electrodes. The additional pitches were intermediate to the pitches heard when either electrode was stimulated alone.

The HiResolution® Bionic Ear system has the capability of creating additional spectral bands using current steering. Conceptually, through simultaneous delivery of current to pairs of adjacent electrodes, the locus of stimulation can be “steered” to sites between the contacts by varying the proportion of current delivered to each electrode of the pair, represented schematically in Figure 1. Current steering is made possible because each electrode has a separate power source. Thus, in theory, many intermediate regions of stimulation may be created with fine control over the proportion and amplitude of current delivered to each electrode.

Recent studies have explored the number of pitch perceptions that can be heard by adult HiRes 90K® and CII Bionic Ear® users when active current steering is implemented. In these psychophysical experiments, subjects were asked to loudness balance and pitch rank three electrode pairs—a basal pair, a mid-array pair, and an apical pair. They then identified the electrode with the higher pitch while current was varied proportionally (“steered”) between electrodes.

Data from 57 ears in North America indicated that the number of pitch percepts averaged 5.4 for the basal pair, 8.7 for the mid-array pair, and 7.2 for the apical pair. Assuming the number of pitches that could be heard for these three electrode pairs represented the entire array, the estimated total potential number of pitch percepts ranged from 8 to 466, with an average of 93, as shown in Figure 2 (Koch et al,
in press; Firszt et al, submitted). A similar study in Europe (Eklof et al, 2006) showed comparable results. In a population of 103 ears, the total potential number of pitch percepts ranged from 3 to 233, with an average of 42. A similar study of current steering is underway at the Soree Clinic in South Korea.

Another mechanism for evoking pitches that are intermediate to those evoked by stimulating discrete physical electrodes uses passive, non-simultaneous stimulation (McDermott and McKay, 1994). In this approach, when a frequency of a single tone is changed continuously, the intermediate pitch percept may vary continuously because of the “skirts” that have been designed into the analysis filters for each channel, thereby causing stimulation on adjacent electrodes to overlap in time.

Because entirely different mechanisms are involved in passive and active current steering, Vampoucke and colleagues (Belgium) (2006) have compared simultaneous and non-simultaneous stimulation in 10 patients with the HiRes 90K device. In these psychophysical experiments, the pitch percepts created either through active simultaneous stimulation or passive sequential stimulation showed two very different loudness profiles. The actively current-steered pitches showed consistent loudness percepts across all experimental conditions, whereas the passively, non-simultaneously generated pitch percepts varied greatly in loudness depending upon the proportion of current delivered to each electrode of a pair. The greatest problem with the passive approach was that current had to be raised well above most comfortable loudness levels in order to create...
mid-electrode percepts (see Figure 3). Thus, using non-simultaneous stimulation to generate additional pitches would require correcting for loudness variations in every possible combination of current, thereby making this technique difficult to implement in a wearable sound coding strategy. Active simultaneous current steering, however, requires no loudness adjustments and has been implemented successfully in HiRes sound processing with the Fidelity 120 algorithm.

Modeling data support the concept that “steered” stimulation is similar to stimulation of single hard-wired contacts. Briaire and colleagues (the Netherlands) have modeled neural response patterns for both current-steered stimulation and single-contact stimulation. The resulting electric field gradients and patterns of neural excitation are similar between the two methods of stimulation (Briaire et al, 2006).

These data suggest that it is feasible to create peaks of excitation that move along the cochlea, thereby stimulating different populations of neurons. Together the modeling and psychophysical results indicate that additional spectral information can be introduced by stimulating sites between the physical electrode contacts through the use of active current steering.

References


HiResolution Sound Processing

In 2003, Advanced Bionics released HiResolution® Sound (HiRes®), a strategy that implemented more channels, higher rates of stimulation, and greater representation of temporal fine structure than previous generation sound processing. Numerous studies around the world revealed improved performance in adults and children with HiRes compared to previous-generation sound processing. (See the Auditory Research Bulletin, 2005.) Some of these studies are continuing to evaluate HiRes benefit over time. Bosco and colleagues (Italy) have followed children using HiRes for three years. Their results continue to support their earlier findings that children using HiRes experience greater benefit than children using previous generation sound processing (Bosco et al, 2005 a-b). In addition, Rivas and his team (Colombia) are conducting a study using a battery of speech perception and production measures. In their study, children are randomized to CIS/MPS or HiRes and followed for two years.

A new study has been initiated by Bevilacqua and colleagues (Brazil) to examine the acquisition of auditory and vocal milestones in young children who use HiRes from the time of initial stimulation. Performance will be monitored using the IT-MAIS and the PRISE, a new tool developed to evaluate the development of spoken language in young children (Kishon-Rabin et al, 2005). Both the IT-MAIS and PRISE were translated into Portuguese for use in the study.

HiRes with Fidelity 120*

In 2006, Advanced Bionics introduced HiRes sound processing with the Fidelity 120™ option (HiRes 120). The goal of the HiRes 120 feature is to build on the strengths of standard HiRes processing by improving representation of the stimulus spectrum in the electrical stimulation pattern.

In standard HiRes, the incoming sound is filtered into 16 spectral bands. The energy of each band is extracted, and its envelope modulates a high-rate pulse train that is delivered to a single corresponding electrode.

In HiRes 120 processing, the input signal is analyzed in greater spectral detail than with standard HiRes to achieve a maximum of 120 spectral bands. HiRes 120 first analyzes the incoming sound signal using a 256-bin Fast Fourier Transform (FFT). Next, a detailed analysis of temporal and spectral information is processed in parallel. The temporal detail is extracted using a Hilbert transform while a navigator locates the spectral maximum for each electrode pair across the 120 spectral bands. The estimated frequency of the spectral maximum is used to compute the rate of the pulse train and to continuously select the optimal location for delivering stimulation, as diagrammed in Figure 1.

For HiRes 120, the spectral bands are delivered to locations along the electrode array by precisely varying the proportion of current delivered simultaneously to adjacent electrodes in each electrode pair through the implementation of active current steering. (Psychophysical studies show that intermediate pitch percepts can be generated through current steering, as discussed in the section Current Steering: Psychophysics and Modeling.) For each electrode pair, there are eight spectral bands. When all 16 electrodes are enabled, 120 total spectral bands are created—that is, 15 electrode pairs times 8 spectral bands.

![Figure 1. For HiRes 120, temporal information is extracted with Hilbert processing (A) while a navigator locates the spectral maximum to determine the corresponding spectral band for stimulation (B).](image-url)

* In the United States, an optional feature for adults only. See package insert for details.
Initial Studies with HiRes 120

A multicenter study was initiated in North America to investigate the potential benefits of HiRes 120. This investigation was conducted in previously implanted adults because the architecture of the CII Bionic Ear® and HiRes 90K® implants can provide new sound processing options through software upgrades. Because subjects who participated in the study had reached a stable level of performance with standard HiRes processing, the specific benefits of HiRes 120 could be evaluated without the effect of learning that would have occurred in newly implanted patients. A wide range of outcome measures was used to capture the benefits that might be derived from increased spectral resolution, such as greater music appreciation and improved sound quality. Consistent with a growing trend among clinicians, questionnaires also were included to assess benefits in everyday listening situations—outcomes not tapped by traditional tests of speech recognition.

Baseline performance was assessed with HiRes processing and compared with HiRes 120 after one and three months of use. Subjects then were refit with a HiRes program and tested again. Some subjects showed improved speech recognition in noise with HiRes 120 processing, as seen in Figure 2. Note that almost half of the subjects showed near ceiling effects (> 80%) even with standard HiRes processing.

Some of the most striking findings were obtained with the questionnaires. The Listening Benefits Questionnaire assessed the clarity of sound and ease of listening in a variety of everyday situations. Subjects rated clarity on a scale from 1 (extremely unclear) to 5 (extremely clear) for 13 situations. After three months of HiRes 120 use, a greater proportion of subjects rated their experience as “clear” or “extremely clear” for all but one situation (at home). There was over a 15% shift in the proportion of adults reporting “clear” or “extremely clear” in the following situations:

- In quiet
- In a small group
- In a vehicle
- Listening to TV/radio
- In a movie
- Using a telephone
- Using a cell phone

Subjects also rated their ease of listening in 11 situations on a scale from 1 (very difficult) to 5 (very easy). After three months of HiRes 120 use, a greater proportion of subjects rated their experience as “easy” or “very easy” for all situations (Figure 3). A 15% shift in the percent of subjects rating their experience as “easy” or “very easy” was seen for the following situations:

- In a small group
- At work
- In a lecture
- In a restaurant
- In a movie

![Figure 2. Individual baseline HiRes and 3-month HiRes 120 HINT-in-noise scores for 26 subjects. Score pairs are rank-ordered by baseline HiRes results.](image)

![Figure 3. Percentage of subjects responding “easy” or “very easy” for 11 listening situations at baseline with HiRes and at three months with HiRes 120.](image)
These data indicate that subjects had to exert less energy during challenging communication situations when using HiRes 120 compared to standard HiRes processing.

Also, the test battery included instrumental music samples that the subjects rated for pleasantness and distinctness. Figure 4 shows that both the pleasantness and distinctness ratings were higher for HiRes 120 than for standard HiRes. Subjects also reported a higher frequency of listening to music and satisfaction in listening to music with HiRes 120 compared to HiRes sound processing.
Preference data indicated that:

- 20 out of 26 subjects (77%) preferred HiRes 120 over standard HiRes processing.
- The mean strength of preference for the 20 subjects who preferred HiRes 120 was 8.3 (1 = weak preference, 10 = strong preference).
- The strength of preference was rated as 8 or higher by 14 of the 20 subjects; 11 of them rated their preference as 10 (strong preference).

Subjects indicated various aspects of sound that were better with their preferred strategy, using a five-point Likert scale (strongly disagree, disagree, neutral, agree, or strongly agree). For subjects who preferred HiRes 120, the percentages of subjects who “agree” or “strongly agree” with various questionnaire statements are listed in Table 1.

Similar to the data from the North American study, results from Brendel and colleagues in Germany (2006) are showing overall improved performance with HiRes 120. Adults with at least two years of experience using standard HiRes processing were fit with HiRes 120 for one month. After one month, they showed significant improvement in sentence-in-noise scores (Figure 5). Subjectively, these subjects reported improved clarity, naturalness, and overall quality of sound. They also reported a reduction in the interference from noise in everyday situations.

Shown in Figure 6 is the preference distribution for the Harmony™ sound processor with HiRes 120 for 17 subjects in the Brendel et al study. Slightly more than half of the subjects preferred HiRes 120 implemented with the Harmony sound processor. Of the remaining subjects, 29% preferred the Harmony to their original processors. (See the Harmony and Connectivity section of this bulletin for benefits of the Harmony processor).

Table 1. Distribution of preference responses for subjects preferring HiRes 120

<table>
<thead>
<tr>
<th>Preference Statement</th>
<th>Percent Responding “Agree” or “Strongly Agree”</th>
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<tbody>
<tr>
<td>Environmental sounds are more distinct.</td>
<td>90%</td>
</tr>
<tr>
<td>Quality of sound is better.</td>
<td>85%</td>
</tr>
<tr>
<td>Environmental sounds are easier to distinguish.</td>
<td>90%</td>
</tr>
<tr>
<td>Speech is more natural.</td>
<td>85%</td>
</tr>
<tr>
<td>Speech is easier to understand in noise.</td>
<td>65%</td>
</tr>
<tr>
<td>Music sounds richer and more natural.</td>
<td>65%</td>
</tr>
<tr>
<td>Melody of music is more enjoyable.</td>
<td>70%</td>
</tr>
<tr>
<td>Rhythm of music is more noticeable.</td>
<td>80%</td>
</tr>
<tr>
<td>Individual instruments are easier to distinguish.</td>
<td>70%</td>
</tr>
<tr>
<td>Singers’ voices are easier to distinguish from instruments.</td>
<td>65%</td>
</tr>
<tr>
<td>Singers’ voices are more distinct.</td>
<td>55%</td>
</tr>
</tbody>
</table>

‡ n = 20

Figure 5. Mean speech perception scores for eight German adults comparing standard HiRes with subjects’ own processors versus one-month trials for standard HiRes and HiRes 120 with the Harmony sound processor. Performance was similar with standard HiRes on the subjects’ own processors and the Harmony. HiRes 120 results showed improved word recognition and sentence recognition in single-talker noise compared to standard HiRes—both tests representing difficult listening situations.
**Multicenter Studies in Europe**

Currently, several adult multicenter studies are in progress in Germany, Italy, the Netherlands, Sweden, and the United Kingdom.

In three protocols, adult users of standard HiRes processing are evaluated with their own processor and then fit with HiRes 120. Subjects are re-evaluated at different times depending upon the protocol.

Another study uses a six-month crossover design (where each strategy is used for three months) to compare outcomes with standard HiRes and HiRes 120 for newly implanted adults.

**Tonal Language Studies with HiRes 120**

A fundamental characteristic of tonal languages such as Mandarin Chinese, Thai, and Vietnamese is that tonal patterns in a syllable convey lexical meaning. The potential benefit of HiRes 120 for improving tone-language perception will be studied in children who are native speakers of Mandarin by Xu (USA) and collaborators at the Tongren Hospital in Beijing, China. In this study, performance will be compared between standard HiRes and HiRes 120 for words that differ in tonal contrast. The hypothesis is that HiRes 120 represents the pitch information and fine structure necessary for distinguishing the tonal contrasts required for understanding words in Mandarin Chinese. This information has not been preserved adequately in conventional sound processing algorithms previous to HiRes and HiRes 120.

Additionally, evaluation of HiRes 120 in pediatric Mandarin speakers will be undertaken during the coming year at the National Cheng Kung University Hospital and Cheng Hsin Rehabilitation Medical Center in Taiwan. Also in the coming year, a study in Cantonese-speaking patients will begin at the Chinese University of Hong Kong.

**Summary**

In summary, the clinical results in adults indicate that HiRes Fidelity 120 is a viable sound processing option that may improve benefit appreciably for some CII and HiRes 90K recipients in a variety of listening environments. The reported benefits can extend beyond speech perception and encompass everyday sounds as well as music appreciation.

The findings summarized here indicate the need to develop new assessment tools that can quantify the benefits of music and everyday listening in adults as well as children—benefits not tapped by traditional measures of speech recognition.
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.

**Studies in Adults**

Several ongoing studies of adults are exploring the benefits of using two Bionic Ears. In the United States, adults who have received bilateral implants during the same surgery are participating in a prospective, counterbalanced between- and within-subjects study. The study is evaluating bilateral benefits and the effect of sound processing mode on bilateral listening. The first part of the study is a six-month crossover design with an additional one-month period in which subjects evaluate and indicate a preference for either CIS or standard HiRes processing. Subjects then use their preferred processing mode for one month and return for re-evaluation. At the end of the eight-month test session, subjects are fit with the HiRes with Fidelity 120™ option (HiRes 120) and wear it for three months. Results to date indicate that subjects experience greater speech perception benefit (Figure 1) and improved localization abilities (Figure 2) when using two implants compared to using either implant alone. Early trends indicate that HiRes sound processing provides greater bilateral benefit than CIS. To date, no subjects have reached the HiRes 120 phase of the protocol.

Another ongoing bilateral study at the University of Iowa (USA) is examining whether HiRes 120 will provide enhanced bilateral benefit to adults who were implanted simultaneously with two CII implants. The same subjects also have participated in a comparison of CIS and standard HiRes processing. Both the HiRes Sequential and Paired strategies resulted in dramatic improvements in speech perception in noise, and listeners were able to tolerate a more difficult signal-to-noise ratio with HiRes than with a conventional CIS strategy (Dunn et al, 2006). Moreover, the increases in scores were much greater
for these bilateral subjects than for unilateral implant users who were converted from conventional sound processing to HiRes (Koch et al, 2004).

Tyler and colleagues will extend their investigation of HiRes by examining the contributions of increased number of electrodes versus faster rate of stimulation in their bilateral subjects. In another study, the bilateral benefits of HiRes 120 will be evaluated.

Studies in Children

The bilateral benefits demonstrated in adults using HiRes sound processing indicate that bilateral implantation should be advantageous to children as well. A recent 2005 report from Bébéar and colleagues from Hôpital Pellegrin in Bordeaux (France) on the performance of bilaterally implanted children indicates strongly that this approach should become the intervention of choice in the future. They also reported that acceptance of a second device may be more difficult with sequential implantation compared to simultaneous bilateral implantation, recommending therefore that it is essential to have a psychologist as part of the cochlear implant counseling and rehabilitation team for children.

In addition to direct clinical evidence, there are other compelling reasons for considering two implants for very young children. First, even though studies have shown improved language acquisition in children with one implant relative to their preimplant performance with hearing aids (for example, Robbins et al, 1999; Svirsky et al, 2004), implanted children still lag behind their normal-hearing peers in the mastery of complex language structures that are requisites for academic success (Spencer et al, 2003). Normal-hearing children acquire much of their language through incidental learning rather than through didactic instruction. That is, language is learned during everyday social communication and by “overhearing” the language of others. If young deaf children receive bilateral implants, the rate of incidental language learning is likely to be accelerated because they will be able to understand speech better in everyday situations and to localize to the most relevant speech signals in their surroundings. Second, providing sound input to both ears in a young deaf child assures that sound is processed on both sides of the brain. Thus, conceptually, the right and left auditory cortices can develop in a more normal sequence. In contrast, if a child is implanted on only one side, the parts of the brain that would have been stimulated by the non-implanted ear will not develop, and eventually plasticity will be greatly diminished.

Based upon these considerations, a variety of studies of bilateral implants in children are just underway. At four centers in the United Kingdom, Summerfield and colleagues are beginning a prospective study that will compare benefits between children ages 18-36 months who are implanted with either one or two implants. Benefit will be documented using measures of spatial hearing, language development, and overall health status. The study will follow the children over three years in order to compare benefits and costs between unilateral and bilateral implantation.

Another multicenter study in Europe will follow spatial awareness, speech acquisition, and binaural processing in young children implanted simultaneously with two devices. One of the unique aspects of the study is use of a bilateral version of the Auditory Speech Sound Evaluation (A$E®) developed by Govaerts and colleagues in Antwerp (Belgium) (2006). The A$E uses isolated speech sounds to assess detection, discrimination, and identification, and is suited for young preverbal children. The A$E is designed to be language-independent and to provide auditory perception information while minimizing cognitive bias. The bilateral version of the A$E will evaluate the perception of speech presented in spatially separated noise.

A multicenter study in the United States will be tracking bilateral cochlear implant outcomes in a cohort of 50 children, ages 12 to 36 months at time of surgery, who receive two implants in the same operation or in two different surgeries with the initial fitting of the devices separated by no more than six months. Acquisition of auditory milestones and speech recognition skills (which underpin the development of spoken language) will be assessed on a battery of outcome measures typically used to
quantify implant benefits. Baseline data obtained with hearing aids prior to surgery will be compared to post-implant benefit with two devices after 3, 6, 12, 18, and 24 months of device use. The study also will identify variables that may predict the degree of implant benefit (such as age at implant, preimplant hearing thresholds, communication mode, family socioeconomic status, postimplant aided thresholds, and simultaneous initial fitting of both devices versus sequential fitting separated by up to six months).

Also in the United States, Buchman at the University of North Carolina, Niparko at Johns Hopkins University, and their colleagues are assessing bilateral benefit in very young children who receive two devices at the same time. Performance will be examined on measures that assess acquisition of preverbal communication skills, speech recognition, speech production, and language skills. In addition, health-related quality of life and functional benefit will be assessed using survey instruments. The performance of the children implanted with two devices will be compared to unilaterally implanted deaf children as well as to children with normal hearing who are participating in a multicenter study—Childhood Deafness after Cochlear Implantation (Eisenberg et al, 2006).

Firszt and her team at Washington University (USA) are beginning a study comparing unilateral and bilateral benefit in children implanted with HiRes 90K devices between 12 and 36 months of age. Each bilateral subject will be age-matched with a unilateral subject. Speech recognition and language will be assessed at three-month intervals, and reaction time and attention measures will be administered at 18, 21, and 24 months post-activation. Children will be followed for approximately three years after implantation to document the advantages of bilateral implantation and to determine (and develop) appropriate pediatric measures of binaural hearing.

In South America, several adults and children now are enrolled in a study of bilateral implants conducted by Rodriguez and Munevar (Colombia). This study is assessing bilateral HiRes 90K benefit in subjects implanted with two devices simultaneously. Adults and children are evaluated after implantation using age-appropriate speech materials. Tests include vowel and consonant discrimination, closed-set word identification (numbers, colors, animals, days of the week, and items of clothing), sentence recognition in quiet and noise, Ling sounds, the Early Speech Perception (ESP) test, and tests of speechreading ability. A Spanish version of the HINT test is used in conjunction with the direct-connect system developed by Soli and colleagues (USA) (2005).

Novak and his colleagues at Carle Clinic (USA) are continuing to follow the progress of identical twins implanted bilaterally with HiRes 90K devices before their first birthdays. After 12 months of implant use, both children show receptive language skills commensurate with normal-hearing children of the same chronological age. Expressive language skills are slightly behind those of normal-hearing age peers.

**Bimodal Study**

Binaural benefit also may be experienced by individuals using a cochlear implant in one ear and a hearing aid in the other ear. A preliminary study by Luntz and co-workers (Israel) (2006) has explored ways in which the frequency processing of the HiRes 90K can be aligned with the residual hearing of the contralateral ear. The first results were acceptable to the subject in a clinic setting, however, they need to be verified in everyday listening situations. Currently, additional subjects are being evaluated in this study.

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**References**


Bilateral Implantation & Bimodal Hearing 25

Participating Centers and Clinics Worldwide
Beth Israel-New York Eye and Ear Cochlear Implant Center, New York, USA
Birmingham Children’s Hospital, Birmingham, United Kingdom
Brnai Zion Medical Centre, Haifa, Israel
Boys Town National Research Hospital, Nebraska, USA
California Ear Institute & Let Them Hear Foundation, California, USA
Carle Clinic, Illinois, USA
Children’s Healthcare of Atlanta, Georgia, USA
Children’s Hospital of Alabama, Alabama, USA
Children’s Hospital of Eastern Ontario, Ontario, Canada
Dallas Otolaryngology, Texas, USA
Emmeline Centre for Hearing Implants, Cambridge, United Kingdom
Hacettepe University, Ankara, Turkey
Hôpital Pellegrin, Bordeaux, Bordeaux, France
Hospital San Ignacio, Bogotá, Colombia
House Clinic & House Ear Institute, California, USA
Indiana University, Indiana, USA
Johns Hopkins University, Maryland, USA
Kilmarnock Cochlear Implant Programme, Kilmarnock, United Kingdom
Manchester Royal Infirmary, Manchester, United Kingdom
Massachusetts Eye and Ear Infirmary, Massachusetts, USA
Medical College of Wisconsin, Wisconsin, USA
Medical University of South Carolina, South Carolina, USA
Midwest Ear Institute, Missouri, USA
New York University, New York, USA
Nottingham Pediatric Cochlear Implant Programme, Nottingham, United Kingdom
Phoenix Children’s Hospital, Arizona, USA
South of England Cochlear Implant Centre, Southampton, United Kingdom
Spectrum Health, Michigan, USA
St. Louis Children’s Hospital, Missouri, USA
Tampa Bay Hearing and Balance Center, Florida, USA
The Children’s Memorial Hospital, Illinois, USA
The Eargroup, Antwerp, Belgium
University of California—Los Angeles, California, USA
University of California—San Francisco, California, USA
University of Iowa, Iowa, USA
University of Massachusetts, Massachusetts, USA
University of Miami, Florida, USA
University of Minnesota, Minnesota, USA
University of North Carolina, North Carolina, USA
University of Rome La Sapienza, Rome, Italy
University of York, York, United Kingdom
Vanderbilt University, Tennessee, USA
Washington University, Missouri, USA
Music Research

Music plays important psychological and social roles in everyday life. However, despite its importance to quality of life, music listening has received far less attention than speech perception in cochlear implant research. Moreover, while performance on standard speech perception tests has improved with advancements in sound processing, studies of music perception and appreciation typically have shown poor results in implant recipients.

With the introduction of HiRes® sound processing and the Fidelity 120™ feature (HiRes 120), CII Bionic Ear® and HiRes 90K® recipients now have access to greater temporal and spectral resolution. While speech can be understood in the presence of severe degradation of spectral and temporal cues, music recognition and appreciation are compromised by even mild degradation (Shannon, 2005). Thus, the unrivaled signal processing of HiRes and HiRes 120 offers present and future Bionic Ear users the potential for improved music appreciation and overall sound quality.

Studies in Adults

Several studies are underway to evaluate and optimize music listening in adult HiRes 90K recipients. The North American multicenter study of standard HiRes and HiRes 120 included instrumental music samples that subjects rated for pleasantness and distinctness. (See the HiResolution Sound Processing section of this bulletin.) Both the pleasantness and distinctness ratings were higher for HiRes 120 than for standard HiRes processing. Subjects also reported a higher frequency of listening to music and greater satisfaction in listening to music with HiRes 120 compared to standard HiRes. In other experiments, subjects listened to instrumental music passages and identified whether they heard a solo instrument, a small ensemble, or a large ensemble. Figure 1 shows the percentage of responses that were correct for this task. The trend observed is that this ability improves, especially after using HiRes 120 for three months. Notably, this more objective ability regresses after subjects are refit with standard HiRes.

In another aspect of this study, the instrument identification task, subjects were asked whether they could discern and name any individual instruments. Figure 2 shows the percentage of all responses for which two or more instruments were identified correctly. This task, which requires spectral resolution, proved especially difficult and yet showed a trend for improvement with the HiRes 120.

Given these positive results, additional music studies with HiRes 120 are planned for the coming year.
Specifically, the music perception test battery developed by Rubinstein and colleagues (USA) will be used to evaluate HiRes 120 music benefits in greater detail. This test battery includes measures of pitch perception, melody recognition, and timbre recognition (Kang et al, 2006). Studies will be initiated in North America, Europe, and Asia.

Recently, Fraysse and colleagues (France) (2006) have reported on initial results of a within-subjects, six-month crossover study in adult HiRes 90K recipients in which the effect of cochlear frequency alignment on music perception is evaluated. In their study, pitch and timbre thresholds are compared between the default filterbank and a filterbank using a Greenwood-like model to derive the filter cutoff frequencies according to each subject’s individual electrode placement inside the cochlea, which is evaluated using a postoperative x-ray. Early data indicate that pitch perception may be improved using the frequency-aligned (FA) program and that timbre dimensions related to frequency spectrum show a trend towards improvement with the FA program. The testing software was developed by Pressnitzer and Bestel (2005) at the L’Ecole Normale Supérieure in Paris.

Studies in Children

Music ability development in implanted children has become an important area of research as technology has advanced. Rocca (United Kingdom) (2006) has evaluated strategies used by music educators to help children with cochlear implants access their innate musicality. Moreover, she has looked at ways of assessing the musical development and achievements of implanted children. By analyzing DVD clips of children improvising, composing, and performing, Rocca has shown qualitative differences in musical expression. She has concluded that students perceive music as an entity and experience it highly personally. Consequently, she has called

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**Participating Centers and Clinics Worldwide**

- Carle Clinic, Illinois, USA
- Dokuz Eylul University, Izmir, Turkey
- Hacettepe University, Ankara, Turkey
- Hadassah Medical Organization, Jerusalem, Israel
- Hôpital Avicenne, Bobigny, France
- Hôpital Beaujon, Clichy, France
- Hôpital Gui de Chauliac, Montpellier, France
- Hôpital Pellegrin, Bordeaux, France
- Hôpital Purpan, Toulouse, France
- House Clinic & House Ear Institute, California, USA
- Houston Ear Research Foundation, Texas, USA
- Indiana University, Indiana, USA
- Johns Hopkins University, Maryland, USA
- L’Ecole Normale Supérieure, Paris, France
- Mary Hare School, Berkshire, United Kingdom
- Mayo Clinic Rochester, Minnesota, USA
- Midwest Ear Institute, Missouri, USA
- New York University, New York, USA
- Northwestern University, Illinois, USA
- Osman Gazi University, Eskisehir, Turkey
- Ottawa Hospital (Civic Campus), Ontario, Canada
- SB Bozyaka Hospital, Izmir, Turkey
- University of London, London, United Kingdom
- University of Massachusetts, Massachusetts, USA
- University of Texas Southwestern Medical Center, Texas, USA
- Washington University, Missouri, USA
for a qualitative assessment of musical perception and described how the improvisatory techniques of music therapy combined with the structured methodologies of music education can help define such a qualitative approach. Based upon this work, Rocca developed the Music Time DVD to provide parents and teachers with examples of how to incorporate these ideas into everyday music listening practice.

Concurrently, a questionnaire has been created with input from Rocca and Graham Welch (United Kingdom) that maps the stages of music development in children. The questionnaire is divided into key assessment areas that include General Information, Sound Awareness and General Reaction, Exposure to Music, Melody and Dynamics Changes, Rhythmic Changes, and Emotional Aspects. Within each assessment area, the components are arranged hierarchically. The response format is the same as the format used in the IT-MAIS and MAIS. The questionnaire is being validated as part of a multicenter European study in which normative data from normal-hearing children and implanted children will be obtained.

In Turkey, Yuçel and colleagues (2005) have developed a home-based music training program for children founded on the hypothesis that improvement in pitch discrimination may result in improvements in speech perception. Using a color-coded electric keyboard, parents help children learn to discriminate notes and to listen to easy nursery rhymes. Early results show that children ages 3–8 years can learn these tasks and that speech perception may be accelerated in children who receive music training compared to children who do not receive training.

Also in Turkey, Incesulu (2006) is using video analysis to observe the stages of musical behavior development in children who have been implanted with the HiRes 90K and in children with normal hearing (Figure 3). Using a profile developed according to the key stages in musical development (general musical behavior, pitch perception, and rhythm perception), these researchers will assess whether such musical abilities develop at different rates between the two groups.

Figure 3. Five-year-old girl participating in musical activities as a part of the video analysis study by Incesulu and colleagues.

References


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Objective Measures

In addition to programming the HiResolution® Bionic Ear System, the SoundWave™ Professional Suite software offers tools for testing the implanted electrode array and for objectively assessing the function of the hearing nerve. Neural Response Imaging (NRI) measures the response of the hearing nerve to electrical stimulation. Single-channel NRI recordings can be made with SoundWave, whereas research software has been designed to measure banded NRI responses in which multiple electrodes are stimulated simultaneously. SoundWave’s unique Speech Burst stimuli can be used to elicit electrical stapedius reflexes, the thresholds of which relate closely to everyday most comfortable listening levels (M levels). Studies are ongoing worldwide to investigate the relationships among single-channel and banded NRI responses, M levels, and electrical stapedius reflex thresholds. The intent of these studies is to define how such objective tools can be used (1) to assess the integrity of the electrode array and (2) to program the HiResolution Bionic Ear system in individuals who have difficulty making behavioral judgments of loudness.

NRI and Electrical Stapedius Reflex Thresholds (ESRTs)

A multicenter study in Europe was conducted to develop guidelines for fitting the HiResolution system using NRI and ESRT measurements. NRI measurements were made using stimulating/recording electrode pairs 3/1, 7/5, 11/9, 15/13 in 114 subjects (36 adults, 78 children) from 14 European study sites. tNRI and 1st NRI were evaluated intraoperatively, at initial fitting, and after 3, 6, and 12 months of implant use. ESRT recordings were made intraoperatively using Speech Burst stimuli and (when possible) single-channel stimulation. Wearable programs were made using Speech Bursts and automatic threshold levels (T levels) set to 10% of most comfortable levels (M levels).

Single-channel ESRTs could be measured in 66% of subjects, which is consistent with the success rate reported in the literature. In contrast, Speech Burst ESRTs could be obtained in 85% of the cases—higher than the success rate reported for single-channel ESRT measurements. NRI responses were measurable intraoperatively in 84% of the subjects, whereas postoperatively the success rate increased to 98%. For the 82 subjects who underwent any type of NRI testing, at least one neural response was obtained, thereby yielding a success rate of 100%.

Figure 1 shows the intraoperative objective measures (tNRI and ESRT) and the M levels at three postoperative test intervals as a function of location on the electrode array in 28 pediatric subjects for whom all measurements were available. The M levels increased from initial fitting to six months, and the M levels at six months were significantly higher (by 52 CU) than the initial M levels. By six months, the M levels were stable across the electrode array. On average, the six-month M levels fell consistently between the intraoperative tNRI and the intraoperative ESRT across the electrode array. A significant correlation was observed between intraoperative Speech Burst ESRTs and six-month M levels. However, the correlation coefficient was quite low ($r = 0.31$, $p < 0.01$).

![Figure 1. Mean intraoperative tNRIs and eSRTs, and M levels at initial fitting, three months, and six months as a function of location along the electrode array in 28 pediatric subjects. Note that for stimulating/recording electrodes 15/13, responses were obtained in only 24 of the 28 subjects.](image-url)
In the United States, a multicenter study is nearing completion that compares single-channel NRI responses and ESRTs, *Speech Burst* ESRTs, and M levels in adults. Preliminary analyses show that ESRTs elicited by *Speech Bursts* most closely approximate behavioral M levels and that tNRIs always fall below M levels. Poissant (USA) is analyzing these data in more detail to determine the influence of demographics on the results and to develop clinical guidelines for using the objective tests to set program levels. In South Korea, researchers at the Samsung Medical Center will be investigating the application of ESRTs and electrically evoked steady-state auditory responses in cochlear implant recipients.

Pursuing another line of study, Cooper and Craddock (2006) measured spread of excitation using both the NRT and NRI measurement tools. With a forward-masking masker-probe paradigm, they used the reduction in response amplitude with masker-probe separation as a measure of spread of excitation. These researchers speculated that this method provides a measure of the overlapping regions of neural excitation for the masker and probe. They found no relationship between spread of excitation and pitch ranking ability or between spread of excitation and duration of deafness. However, they did find a weak but significant relationship between spread of excitation and open-set speech recognition.

**Banded NRI**

Banded NRI is a procedure in which neural responses are elicited by stimulating three or four consecutive electrodes at the same time with an overall rate that approximates *Speech Burst* stimulation. Shapiro (USA) (2006) has compared banded and single-channel NRI responses and psychophysical M levels in 34 adults. He reported that banded tNRIs are robust and easily measured, can be acquired 30% faster than single-channel responses, and are more reliable and less variable than single-channel tNRIs. Moreover, banded tNRIs always fall below behavioral M levels and therefore can be used as a guide for setting program levels without the risk of over-stimulation (Figure 2). Shapiro also is evaluating application of banded NRI in the operating room to verify electrode function and to provide initial programming information.
Similar studies have been conducted in South Korea by Park and colleagues (2005) and in Turkey by Akin and colleagues (2006). Both studies obtained results similar to those of Shapiro et al. In addition, Akin et al found that in a group of eight adults and nine children a reasonable correlation between banded tNRIs and M levels after three months of implant use. This correlation remains to be verified in a larger group of subjects but holds promise for using banded NRI as a programming aid.

Wolfe and his group at Integris Health in Oklahoma (USA) are conducting a parametric study of neural and psychophysical responses to single-channel and banded NRI stimulation. They also will be evaluating temporal integration (neural refractory characteristics) associated with both modes of stimulation.

### Electrically Evoked Brainstem and Central Auditory Responses

Guiraud and colleagues (France) (in press) have investigated the effect of brainstem pathology on electrical auditory brainstem responses by comparing EABR latencies and deafness characteristics. EABRs for eight adult HiRes 90K users were compared to the literature on normal-hearing adults. The latencies of wave III and V were longer when a high-frequency stimulus was used compared to a low-frequency stimulus in normal-hearing listeners. Guiraud believes that this latency difference reflects the longer nerve fibers and lower fiber density at the base of the cochlea compared to the apex. Interestingly, the interpeak interval IIIe-Ve remained the same along the electrode array. EABRs from the
implanted subjects showed a range of patterns. For example, some subjects showed no latency difference between stimulation of the apex and the base, indicating damage in both regions. This pattern was particularly evident in subjects with congenital deafness. Subjects with duration of deafness greater than seven years had wave III and wave V latencies longer than normal-hearing subjects, indicating poor neural survival in this group. These EABR data support the idea that higher M levels are found in regions with poorer neural survival.

Guiraud’s group also has followed the development of cortical reorganization over time in order to determine whether the auditory cortex is tonotopically organized in long-term cochlear implant users (HiRes 90K recipients). They found that tonotopic organization could be demonstrated in cochlear implant users and that it was similar to the tonotopic patterns observed in normal-hearing subjects. These researchers are looking further to determine if a relationship exists between frequency perception and tonotopic organization based upon their preliminary data.

**Smart NRI**

If NRI is to be useful clinically in guiding the setting of program levels in individuals who cannot provide adequate behavioral feedback, then the neural responses must be easily identifiable by all clinicians, regardless of experience levels. However, the inherent overlap of a large stimulus artifact with the much smaller neural response makes the accurate determination of neural response thresholds a task requiring considerable skill and experience. Consequently, the current use of objective measures simply may replace a difficult behavioral observation with a difficult subjective analysis of objective measurements, thereby negating their potential advantages. To facilitate objective measures as a clinical tool, Litvak and colleagues (USA) (2005) have developed Smart NRI™, a rigorous, statistically based method for determining the stimulation level at which a neural response is present in a set of NRI responses. An analysis of over 1,000 NRI measurements has verified a model that accurately represents residual artifact. From this model, a metric has been determined that is sensitive enough to identify 99.7% of neural responses classified by experienced clinicians, yet rejects the vast majority of non-responses—yielding a highly acceptable (clinically) total error rate of 2.5%. (See Figure 3.) Thus, the system can remove subjectivity from interpretation of NRI measurements—thereby providing a method for quick and straightforward identification of valid NRI measures that closely relate to psychophysical M levels.

**References**

Clinical Assessment Tools

As cochlear implant technology advances, new test materials and procedures may be helpful for evaluating the benefits experienced by recipients and for making clinical testing more efficient. New procedures for assessing music perception and appreciation are detailed in the HiResolution® Sound Processing and Music Research sections of this bulletin. Other innovative methods for evaluating speech perception also are under development.

Typically, speech perception testing involves presenting very controlled materials at a single, fixed presentation level. Using these materials, performance of cochlear implant users often is extremely high and uncorrelated with self-assessment of speech perception abilities. That is, conventional speech tests do not represent everyday listening situations where speech levels vary and listening environments are challenging.

Advanced Bionics, in collaboration with Quentin Summerfield (United Kingdom), has developed the ABC Sentences Test to better represent the difficult situations encountered in everyday life (Boyle et al, 2005). The test consists of 25 lists of 30 sentences—each with multiple talkers, varying presentation levels, and varying rates of delivery. The procedures have been evaluated in cochlear implant patients by Terry Nunn at St. Thomas’ Hospital (United Kingdom) (Boyle et al, 2006) who has tested the effect of AGC on sentence recognition. In standard test situations, the implant user can adjust the settings on the processor to hear speech optimally. However, when the signal level varies, as it does in the ABC Sentences Test, the front-end of the sound processor is challenged. Nunn's initial study results suggest that the ABC Sentences Test is sensitive enough to be able to tease out differences between different AGC settings, as shown in Figure 1.

Despite the ceiling effect that occurs for many speech tests, a need still exists to have some easier materials for monitoring progress in implant users who find many tests too difficult. Tests such as the CUNY sentences presented audiovisually can be used for this purpose. Wanda Alesky (United Kingdom) (2006) has collaborated with Advanced Bionics to update the CUNY sentence test. She has changed the video laser disc format to a DVD format, with computer-controlled stimulus delivery and response recording. The updated test will be evaluated in clinics across the United Kingdom over the next year.

In addition to speech tests, questionnaires have become useful for evaluating cochlear implant benefit in everyday situations. Questionnaires can highlight areas of improvement or degradation that are not observed in standard clinical speech tests. In Europe, a new Everyday Listening Questionnaire was developed by Advanced Bionics and tested at ten centers. Many everyday benefits and situations were assessed including telephone use, work environments, social settings, and music enjoyment. Listening in different environments was evaluated in terms of ease and pleasantness. In addition, the questionnaire evaluated which accessories provided optimized listening experiences (Krüger et al, 2006).

Figure 1. Individual and mean scores on the ABC Sentences test obtained for five subjects using two different AGC settings.
To date 73 adults have completed the Everyday Listening Questionnaire. The mean age of the subjects was 51 years, and the mean use of the implant was 15 hours per day. Subjects reported using their cochlear implants in all of the different listening situations represented on the questionnaire. The majority of subjects used the phone, went to the cinema, visited the theater, and listened to music. The average self-assessment of speech understanding in quiet was 4.4 out of 5, falling to 2.2 out of 5 in the presence of noise. In addition, 93 percent of the subjects reported frequently listening to music for enjoyment. Most could follow familiar melodies, recognize a familiar vocal or instrumental track, and identify musical instrument categories. Also, 92 percent of the subjects used the telephone for an average of 5-10 times per week.

The most commonly used accessory was the T-Mic®, which generally achieved the highest ratings in difficult listening situations. The T-Mic was reported to be particularly useful for music perception and in challenging work environments, as shown in Figure 2.

As more questionnaire materials like the Everyday Listening Questionnaire and the FLAQ are developed and used clinically, it would be useful to have one place to store all the questionnaires electronically as well as to collate the results and facilitate data analysis. The ABQuest™ software was developed to address these needs and is currently under field testing to determine its clinical utility.

Another tool that is being used in clinical field studies is a direct-connect system. This software and hardware system, which is implemented on a PC, was developed by Advanced Bionics in collaboration with Sigfrid Soli and colleagues at the House Ear Institute in California (USA). The system is designed to eliminate the need for a sound booth or a speaker array, thereby allowing speech recognition and localization tests to be administered quickly and easily. The direct-connect system is based upon a family of head-related transfer functions (HRTFs) measured with KEMAR (Knowles Electronics Mannequin for Acoustic Research) at source locations corresponding to loudspeaker positions appropriate for unilateral or bilateral testing. Left-ear and right-ear HRTFs appropriate to the selected source location and T-Mic characteristics are applied to the selected signal and presented via direct connection to the auxiliary input of an Auria® or Harmony™ sound processor at a specified level. The system controls stimulus delivery as well as recording and scoring subject responses.
Recently, Soli and colleagues in Korea (2006) have verified a direct-connect Korean version of the Hearing in Noise Test (HINT) that was developed to facilitate comparative cross-language studies of functional hearing. The relationships between the rules used to measure HINT thresholds in Korean, the signal-to-noise ratios at threshold, and percent intelligibility at each threshold were similar to those for English. The performance-intensity functions for both languages were almost identical for normal-hearing subjects. When Korean and American HiRes 90K users were compared directly using the normative anchor points for each language, performance of both groups was similar.

Similarly, direct connect studies have been conducted in Japan and China. (See also the Harmony and Connectivity section of this bulletin.) During the coming year, a Cantonese version of the HINT will be evaluated at the Chinese University of Hong Kong.

References
HiRes® and HiRes with Fidelity 120™ sound processing enable only a fraction of the capability and flexibility of the CII Bionic Ear®/HiRes 90K® electronics platform. Thus, individuals implanted since 2001 have access to current and future sound processing options as technology advances.

A variety of sound processing algorithms are under study or in development with the CII and HiRes 90K systems. Several investigators are experimenting with the modulation carrier parameters (pulse shapes and multipolar patterns) to improve aspects of the electrical–neural interface—such as channel selectivity, temporal responses, or neural efficiency. For example, Macherey from Catholic University of Leuven (Belgium) is exploring the use of delayed pseudomonophasic pulses to reduce power consumption. Mens and the group at Radboud University Nijmegen (the Netherlands) are investigating the use of quadrapolod electrode coupling for improving channel selectivity and speech perception. Frijns (the Netherlands) and Litvak (USA) are exploring channel selectivity using triphasic stimulation.

Other investigators are evaluating innovative sound processing algorithms to improve information transfer to the auditory nerve. As examples, Rubinstein at the University of Washington (USA) is investigating the use of neural conditioning to promote stochasticity in the auditory nerve and to increase dynamic range. Van Dijk and colleagues at the Groningen University Medical Center (the Netherlands) are using a phase-locking speech coding strategy intended to convey better acoustic fine-structure and potentially improve pitch perception. Nogueira at the University of Hannover (Germany) has developed a sinusoidal extraction algorithm that may provide increased spectral resolution through current steering without a degradation in temporal processing. Morse at Aston University and Stocks at Warwick University (United Kingdom) are looking at using subthreshold multiplicative noise to enhance information transmission.

Other groups are exploring the flexibility inherent in the CII/HiRes 90K system for optimizing listening benefit. Firszt and her group at Washington University in Missouri (USA) are varying minimum and maximum stimulation levels (with respect to behavioral thresholds and loudness growth), frequency boundary settings, stimulation rate and pulse duration, and input dynamic range to optimize fitting parameters for each subject. The procedures will be applied to users of both one and two implants in an effort to generate guidelines for optimizing unilateral and bilateral fittings.

The flexibility of the CII/HiRes 90K system also allows investigation of various aspects of auditory function using software developed specifically for research. As an example, psychophysical spectral resolution capabilities have been evaluated by Saoji and colleagues in Arizona and California (USA) (2005) using Spectral Modulation Transfer Functions (SMTFs) to measure the ability of cochlear implant listeners to identify different spectral patterns. The results strongly correlate with vowel and consonant recognition scores (Figures 1A and 1B). Thus, SMTFs may be useful for evaluating the efficacy of new sound processing strategies aimed at improving spectral resolution and speech perception. SMTFs also offer a nonlinguistic method to measure spectral resolution across non-native speakers of English using cochlear implants. Research software is also being used by Franck and Eisen (USA) to assess pitch discrimination. Using a current steering paradigm, stimuli are presented either alone or paired with a noise stimulus across four electrodes on the array.

Advanced research software is under development to provide investigators with a flexible and easy-to-use platform for a wide range of studies. Such study areas and modules include:

**Psychoacoustic Test System (PACTS)**
- Framework for conducting psychophysical experiments
- Acoustic or direct electrical output
- Adaptive threshold procedures, ranking, balancing
- Closed-set identification

**Streaming Software**
- For acute sound processing prototyping
- For psychophysical testing with long-duration and complex electrical stimuli
- PC-to-implant communication via a high speed USB-based CPI
Objective Measures Toolbox

- Smart NRI™ measurements
- Artifact reduction options
- Spread-of-excitation algorithm
- Cochlear mapping function
- Refractory recovery measurements

Questionnaires (ABQuest™ software)

- Customized patient and clinician questionnaires
- Database
- Export capability

Microcomputer Tomography

- High-precision (9 mm) imaging
- Electrode design evaluation
- Database of human cochleae

Many of these research tools were used in studies summarized in this publication. Some of the research interfaces also were used during the early development of HiResolution® sound processing.

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