New Methodology for Fitting Cochlear Implants

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NEW METHODOLOGY FOR FITTING COCHLEAR IMPLANTS

Sound coding strategies for cochlear implants have evolved over the past 30 years with advances in research and technology. Processing schemes have transitioned from the delivery of a diffuse, broad signal in single channel devices to the transmission of detailed sound information to multi-channel devices. This evolution has involved the addition of more channels and more parameter options for adjustment during programming, often adding to the complexity and duration of a programming session. Therefore, most clinician-patient contact time is spent programming and tweaking the processing parameters. Significantly less time is spent counseling or on rehabilitation due to reimbursement constraints (Garber et al., 2002) despite their positive impact on patient outcomes (Sherbourne et al., 2002; Gordon et al., 2000; Bray et al., 1997).

Recently, the U.S. Food and Drug Administration approved the latest advancement in cochlear implant processing, HiResolution™ Sound (HiRes™). HiRes™ processing strategies represent an advanced method of capturing, composing, detailing and delivering sound for hearing via a cochlear implant. This advancement in sound technology necessitated parallel advancements in the fitting paradigm that are respectful of the patient programming needs as well as the reimbursement of clinician's time.

The new software platform used to fit HiResolution™ Sound, SoundWave™ Professional Suite, introduces a new fitting methodology that includes innovative features for psychophysics and automated parameter management. The software is designed to simplify the fitting process and reduce fitting time while simultaneously optimizing patient outcomes.

This paper will explore the new fitting methodology introduced in the SoundWave™ software for programming HiRes™. The new methodology will be compared with the traditional methodology for fitting previous generation processing strategies. In order to assess the clinical viability and clinician acceptance of the new fitting methodology, a field trial was conducted at several centers in North America. This paper will also review the clinician feedback on the new fitting procedure.

NEW APPROACHES TO FITTING HiRESOLUTION™ SOUND WITH SOUNDWAVE™ SOFTWARE

New Approach to Psychophysics: "Speech Bursts™"

The cornerstone of traditional programming is the setting of loudness levels, threshold (T) and most comfortable level (M), for each electrical channel. However, for many patients it is difficult to make loudness judgments in response to electrical stimulation. The process is therefore often time consuming and fatiguing for the patient. Interpolation functions were introduced with the Clarion Cochlear Implant for estimation of loudness levels on unmeasured channels based on the measured T and M level of as few as one channel (Zimmerman-Phillips and Murad, 1999). Interpolation derives from the relative uniformity of loudness levels across channels noted with monopolar, pulsatile stimulation (Osberger and Fisher, 1999). This feature minimized patient fatigue requiring fewer perceptual loudness judgments and saved valuable clinical programming time.

However, the loudness levels set during single-channel psychophysics—measured or interpolated—often do not correspond to the stimulation levels perceived as comfortably loud for dynamic real-time sound input. Studies have shown that the loudness of electrical stimuli with the same average (rms) levels can have very different loudness percepts depending upon temporal fluctuations in the signals (Zhang and Zeng, 1997). These temporal fluctuations are typical of everyday dynamic stimuli like speech and environmental sounds. Moreover, loudness perception is influenced significantly by other variables including pulse amplitude, phase duration, pulse rate, the number of electrodes stimulated simultaneously, the electrode coupling mode, and electrode geometry (e.g., McKay et al., 2001; McKay and McDermott, 1999; Chatterjee et al., 2000; Chatterjee, 1999; Pfingst et al., 1996).

Up until now, most of those parameters have not been taken into account when setting loudness levels for cochlear implants. Traditionally, in order to make the process simple, loudness mapping has been based upon each patient's perception of the loudness of pulse trains presented at slow rates to each electrode separately. This mapping process did not fully represent the stimulation that occurs during live sound processing, when signals with temporal and spectral variability are delivered to the electrode contacts. The discrepancy manifested itself when patients required different loudness levels for single-channel stimulation than for their conventional processing strategies during everyday listening.

Therefore, a new feature was implemented in the Soundwave™ software to better represent dynamic real-time input during the psychophysical fitting process. That new feature, termed "Speech Bursts", is intended to allow clinicians to set loudness levels quickly and accurately using the Soundwave™ software.

Speech Bursts™ are created when a complex stimulus (white noise) is delivered to the processing system and transmitted through the same filters, amplitude detectors and averaging algorithm utilized for incoming acoustic sound. Therefore, the spectral and temporal characteristics of the stimuli used in psychophysical assessment are more representative of real-time stimulation captured during normal device operation. Speech Burst™ stimulation rate is equivalent to that of real-time stimulation with the applied processing scheme (HiRes™) as opposed to slower, constant rate stimuli previously used for psychophysical assessment. With Speech Bursts™, 3-4 channels are fit simultaneously, providing more accurate and reliable estimates of loudness levels for real-time inputs. Figure 1 shows in-house performance evaluations for programs created with single channel psychophysics compared with programs developed with Speech Burst™. Equivalent performance was noted between the two program types, indicating that Speech Bursts™ are appropriate for setting loudness levels in a manner that does not compromise performance.

The ability to set levels for multiple channels concurrently will become more critical as the number of potential real or synthetic channels increases with future advances and choices in sound processing technology. Furthermore, because channels are set at the same time, the number of required loudness judgments is reduced, limiting patient fatigue and reducing programming time. This allows more reimbursed clinician time for counseling and rehabilitation.

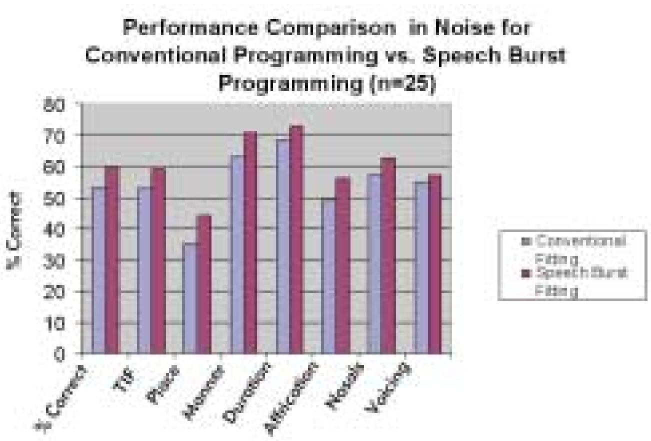


Figure 1: Performance with single channel conventional fitting vs. Speech Burst™ Fitting

New Approach for Setting Threshold Levels: "Auto T"

Setting T levels on each channel is often a difficult aspect of programming from a patient's perspective. Reporting T levels accurately may be even more challenging for patients with tinnitus. Traditionally, T levels are measured in response to single channel pulse trains resulting in the same discrepancies in spectral, temporal and rate characteristics between real-time stimulation and single channel stimulation previously described.

T levels are also not utilized in all processing strategies as, for example, in Simultaneous Analog Stimulation (SAS)(Kessler, 1999). The value of measuring T levels may therefore be questioned for certain types of strategies. In-house testing of HiRes™ programs with T levels and without T (t=1 CU for all channels) showed equivalent performance (Figure 2). While this finding cannot be generalized to all cochlear implant users, it does suggest that there is limited value in making precise, single channel measures of threshold with HiRes™ sound processing. This may be explained by stochastic neural response that is induced by the fast stimulation rates used in HiRes™.

Audibility of sound via electrical stimulation follows a complex relationship involving the system acoustic capture range, sensitivity setting, dynamic acoustic compression (AGC), compression into the patient's electrical dynamic range (Input Dynamic Range [IDR]), and the modulation of stimulation (McDermott et al., 2002; Stone and Moore 2001). Research has also investigated the effect of various stimulation parameter settings on electrical thresholds (Pfingst and Morris, 1993; Chatterjee, 1999) and models have been proposed for the prediction of thresholds for electrical stimulation (Shannon, 1989).

SoundWave™ offers an estimation of threshold level across channels. T levels are automatically set to M/10 based on the average dynamic range (20 dB) of CII Bionic Ear™ users programmed with HiResolution™ Sound. The automatic setting can be adjusted as needed globally or for individual channels in real-time stimulation if necessary. At the initial fitting, only M level judgments are required. M level is often easier for patients to report in response to electrical stimulation and is typically not complicated by

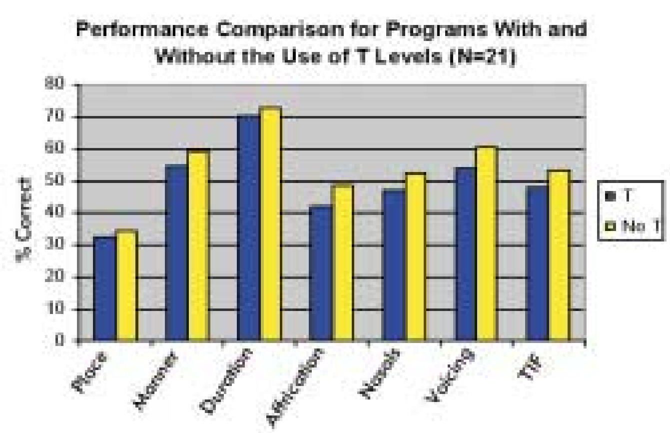


Figure 2: Performance with HiRes™ programs with and without measured T levels

tinnitus. In addition, Speech Bursts™ and Auto T reduce the number of loudness judgments required, saving time and limiting patient fatigue. For example, a HiRes™ program can currently have up to 16 channels. If traditional programming paradigms were used for psychophysics, 32 loudness judgments would be required. With Speech Bursts™ and Auto T, the number of loudness judgments for this same number of channels is typically reduced to between 4 and 7.

New Approach to Parameter Setting: Automatic Pulse Width and Rate Adjustment

Research has validated the usefulness of narrower pulse widths for temporal or spatial pitch perception for cochlear implant users (Aronson et al., 1994; Barretto and Pfingst, 1992). High rates of stimulation may enhance the neural representation of temporal detail and expand electrical dynamic range (Rubinstein et al., 1999). Further, studies have suggested that clinicians can optimize the implant listener's performance by jointly varying pulse rate and pulse width (Loizou et al., 2000). However, with conventional programming methods, clinicians start each patient at a fixed pulse width (and subsequent rate) that is adjusted only when needed to obtain sufficient loudness growth. Any change in pulse width requires re-measurement of channel loudness levels. Therefore adjustments in pulse width are restricted to large increments of 75 µs/phase. Although narrower pulse widths have potential advantages, clinically, adjusting pulse width in tiny increments and then re-measuring loudness on each channel is not feasible. Therefore, tailoring programming to obtain the optimal pulse width and rate for each implant user has not been clinically possible with traditional fitting methods.

HiResolution™ Sound has the capability of providing a broad range of pulse widths (10.8 µs-229 µs) and a wide range of rates (up to 83,000 pps). Given this vast parameter space, using conventional programming paradigms to try various combinations of rate and pulse width in an attempt to optimize performance is not clinically viable. Further, at the time of the initial device fitting, most patients are not sufficiently familiar with electrical stimulation to discern such performance benefits. Most patients participating in the clinical trial of HiRes™ Sound preferred and performed best with programs having the narrowest possible pulse width and highest possible stimulation rate. Based on this result, SoundWave™ implements an Automatic Pulse Width (APW) algorithm for the automatic adjustment of pulse width and rate during programming. Each fitting starts with the narrowest pulse width (10.8 µs) that is automatically adjusted in very narrow increment step sizes of less than 1us (0.89 µs) as needed. Each individual patient fitting is thus optimized to maintain the narrowest pulse width and fastest rate possible. The clinician has the ability to lower the rate and reduce the number of channels if needed. The APW algorithm adjusts the parameters based on each patient's unique stimulation levels required to achieve adequate loudness growth (in response to speech bursts as well as live speech input) and also accounts for system compliance.

Compliance refers to the ability of the internal device to deliver a specified amount of current. With conventional programming, the clinician is not alerted when current level exceeds the system's maximum voltage capability (or, more specifically, the system's ability to deliver the amount of current being requested through programming). If the clinician continues to program current levels beyond the compliance limit, the patient may achieve additional loudness growth only from the introduction of distortion. With SoundWave™, the APW algorithm monitors compliance to limit distortion. The APW algorithm automatically makes all the calculations for each change in pulse width required.

New Approach to Clinical Units (CU): Constant Charge

Traditionally, commercial cochlear implant fitting systems have measured loudness levels in arbitrary 'clinical units' that reflect current amplitude. However, loudness growth is related to both pulse amplitude and pulse duration. This relationship may be expressed as (pulse amplitude * pulse width) with the product referred to as charge. In SoundWave™, clinical units represent constant charge (amplitude*pulsewidth*k, an arbitrary scaling constant) on a scale of 0-6000 CU. Automatic adjustments in pulse width also result in automatic adjustments in pulse amplitude in order to maintain constant charge. Therefore, in contrast to traditional programming paradigms, changes in pulse width do not require re-measurement of loudness levels. While the relationship of equal charge-equal loudness is not perfectly linear for all parameter conditions with other strategies (Zeng et al., 1998), constant charge has allowed for manipulations of pulse duration with little or no needed CU level adjustments with HiRes™ (Overstreet et al., 2003). The ability to make seamless adjustments in pulse width by maintaining constant charge enables the automatic optimization of pulse width and rate in the clinic setting without requiring the patient to make multiple loudness judgments.

New Strategies for HiResolution™ Sound Delivery: HiRes-P and HiRes-S

SoundWave™ currently offers two strategies for delivering HiResolution™ Sound technology. HiRes-P activates the CII Bionic Ear™ system's unique capability to stimulate two channels simultaneously (paired) while HiRes-S stimulates each channel sequentially. Both allow for the fastest stimulation delivery rates currently available in cochlear implant technology (up to 5800 Hz per channel or 83,000 total pulse per second (pps) with HiRes-P and 2900 Hz or 46,400 pps with HiRes-S). The APW will maintain the narrowest pulse width and fastest rate possible within each strategy option.

New Approach to RF Management

Power Estimator (PoEM) is an advanced approach for managing the RF power transparently in the SoundWave™ software, eliminating the need for the clinician to optimize RF at the end of each fitting. With PoEM, each time a patient is locked to the system, a table is automatically generated that specifies the needed RF for a given stimulation level. The table is referred to during device operation (every 1 ms) before a stimulus is sent to the implant to adjust RF based on the dynamic input of various listening environments. PoEM improves lock stability across listening environments, accounts for changes in patient skin flap thickness that naturally occur over time, and operates across various hardware configurations (that is, when you change cables, headpieces or processors). Therefore, a program created on a PSP can be downloaded directly to a BTE with the RF level automatically adjusted to accommodate the change in hardware.

CLINICIAN FEEDBACK ON SOUNDWAVE™ FITTING METHODOLOGY

As part of the new fitting methods field trial, 27 clinicians completed questionnaires specifically related to the methodology. Sixty seven questionnaires were received that provided feedback on a total of 74 fittings (some clinicians completed one questionnaire for multiple fittings in one day). Clinicians were asked to what degree they agree or disagree with the following statements:

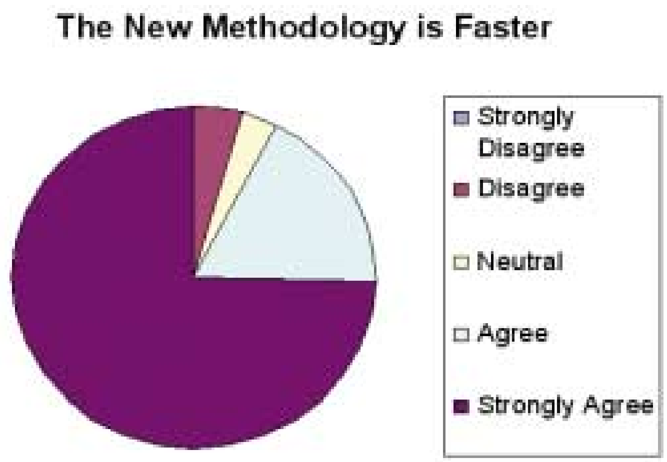
1. Is the new methodology faster than traditional methodology?
2. Is the new methodology easier for the patient than traditional methodology?
3. Overall, is the new methodology an improvement over traditional methodology?

When asked what they liked best about the fitting methodology, 73% of the responses listed the speed of the fitting process. Clinicians reported an average fitting time of 31 minutes (range from 5-90 minutes).

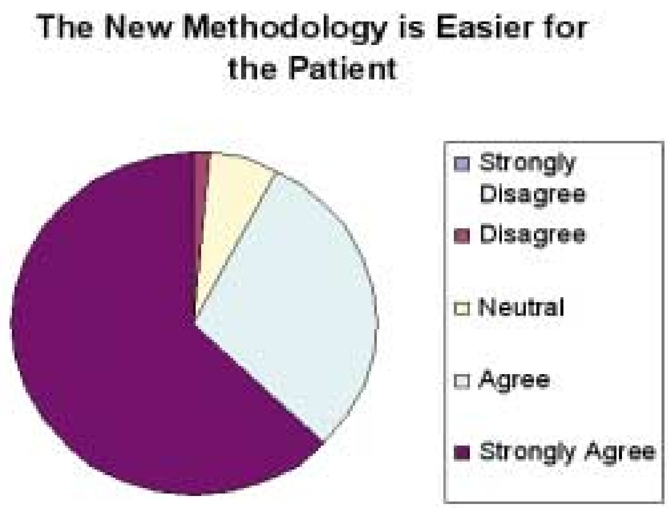
Field trials of SoundWave™ have revealed overwhelmingly positive acceptance of the new fitting methodology. Clinician feedback on features that were confusing or disliked was incorporated into the release version of software you see today. However, clinicians require time to gain experience, comfort and familiarity with any new software fitting platform.

When using multi-band Speech Bursts™ stimulation, many clinicians questioned how to troubleshoot single channel issues. SoundWave™ provides clinicians the ability to isolate single channel problems, such as facial nerve stimulation or somatic response, via single channel toneburst stimulation.

Clinicians also asked how to balance channels as SoundWave™ does not have a "balance" button on the screen. Balancing in SoundWave™ is accomplished by toggling between channels grouped for Speech Bursts™, or by stimulating individual channels with tonebursts.



93% Strongly Agreed or Agreed with the statement



93% Strongly Agreed or Agreed with the statement

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Finally, clinicians inquired about programming conventional strategies in SoundWave™. While the new fitting methodology may be applicable to conventional strategies, at the present time, SoundWave™ does not offer analog stimulation required for SAS. However, SoundWave™ does permit the clinician to emulate general features of a CIS or MPS strategy type by reducing the number of channels and using wider pulse widths and slower rates.

SUMMARY

SoundWave™ introduces a new fitting methodology designed to revolutionize the patient fitting process. SoundWave™ implements innovative features (Speech Bursts™, Auto T) and automated management of compliance, pulse width and RF that allow the *same programs to be used on ear level and body worn processors*. It produces quick and accurate measures that simplify the fitting process and reduces patient fitting time while simultaneously optimizing patient programs.

The new procedures optimize programs at the first device fitting when implant recipients often have the greatest difficulty reporting 'best" fit information in response to electrical stimulation. Despite the automation of several parameters, SoundWave™ provides the flexibility to make single channel adjustments for patients that need it and for clinicians who prefer to use it. Further, SoundWave™ is easy to use for fine-tuning at a time when the patient has more experience with electrical stimulation and can more accurately report on perception and performance.

HiResolution™ Sound represents an advanced method for the capturing, composing, detailing and delivering sound for hearing with a cochlear implant. SoundWave™ embodies the unprecedented, parallel advancements in fitting methodology used to program this technology.

REFERENCES

Aronson L, Rosenhouse J, Podoshin L, Rosenhouse G, Zanutto SB. (1994) Pitch perception in patients with a multi-channel cochlear implant using various pulses width. Med Prog Technol 20:43-51.

Barretto RL, Pfingst BE. (1992) Electrical stimulation of the auditory nerve: effects of pulse width on frequency discrimination. Hear Res 62(2):245-249.

Bray MA, Neault MW, Kenna M. (1997) Cochlear implantation in children. Nurs Clin North Am 32(1):97-107

Chatterjee M. (1999) Effects of stimulation mode on threshold and loudness growth in multi-electrode cochlear implants. J Acoust Soc Am 105(2):850-860.

Chatterjee M, Fu QJ, Shannon RV. (2000) Effects of phase duration and electrode separation on loudness growth in cochlear implant listeners. J Acoust Soc Am 107(3):1637-1644.

Garber S, Ridgely MS, Bradley M, Chin KW. (2002) Payment under public and private insurance and access to cochlear implants. Arch Otolaryngol Head Neck Surg 128(10): 1145-1152.

Gordon KA, Daya H, Harrison RV, Papsin BC. (2000) Factors contributing to limited open-set speech perception in children who use a cochlear implant. Int J Pediatr Otorhinolaryngol 56(2):101-111.

Kessler DK. (1999) The CLARION® Multi-Strategy™ Cochlear Implant. Ann Otol Rhinol Laryngol 108 Suppl 177:8-16.

Loizou PC, Poroy O, Dorman M. (2000) The effect of parametric variations of cochlear implant processors on speech understanding. J Acoust Soc Am 108(2):790-802.

McDermott HJ, Henshall KR, McKay CM. (2002) Benefits of syllabic input compression for users of cochlear implants. J Am Acad Audiol 13:14-24.

McKay C, Remine M, McDermott H. (2001) Loudness summation for pulsatile electrical stimulation of the cochlea: effects of rate, electrode separation, level, and mode of stimulation. J Acoust Soc Am 110(3):1514-1524.

McKay CM, McDermott HJ. (1999) The perceptual effects of current pulse duration in electrical stimulation of the auditory nerve. J Acoust Soc Am 106(2):998-1009.

Osberger MJ, Fisher L. (1999) SAS-CIS preference study in postlingually deafened adults implanted with the CLARION cochlear implant. Ann Otol Rhinol Laryngol 108 Suppl 177:74-79.

Overstreet E, Litvak L, Lee J, Faltys M. Relationship between ECAP and HiResolution program settings in patients using the CLARION CII Bionic Ear. Presentation at the Association for Research in Otolaryngology, Daytona Beach, FL, February 22-27, 2003.

Pfingst BE, Morris DJ. (1993) Stimulus features affecting psychophysical detection thresholds for electrical stimulation of the cochlea II: frequency and interpulse interval. J Acoust Soc Am 94(3):1287-94.

Pfingst BE, Holloway LA, Razzaque SA. (1996) Effects of pulse separation on detection thresholds for electrical stimulation of human cochlea. Hear Res 98(1-2):77-92.

Rubinstein JT, Wilson BS, Finley CC, Abbas PJ. (1999) Pseudospontaneous activity: stochastic independence of auditory nerve fibers with electrical stimulation. Hear Res 127 (1-2):108-118.

Shannon RV. (1989) A model of threshold for pulsatile electrical stimulation of cochlear implants. Hear Res 40(3):197-204.

Sherbourne K, White L, Fortnuni H. (2002) Intensive rehabilitation programmes for deafened men and women: an evaluation study. Int J Audiol 41(3):195-201.

Stone MA, Moore BCJ. Electroacoustic and AGC considerations in the design of a cochlear implant front-end. Presentation at the Conference on Implantable Auditory Prostheses, Pacific Grove, CA, August 2001.

Zeng FG, Galvin JJ, Zhang C. (1998) Encoding loudness by electric stimulation of the auditory nerve. NeuroReport 9:1845-1848.

Zhang C, Zeng FG. (1997) Loudness of dynamic stimuli in acoustic and electric hearing. J Acoust Soc Am 102(5):2925-34.

Zimmerman-Phillips S, Murad C. (1999) Programming features of the CLARION Multi-Strategy Cochlear Implant. Ann Otol Rhinol Laryngol 108 Suppl 177:17-21.

June 2003