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Upgrade to Nucleus® 6 in Previous Generation Cochlear™ Sound Processor Recipients

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Abstract

Background: The Nucleus® 6 sound processor is now compatible with the Nucleus® 22 (CI22M)—Cochlear's first generation cochlear implant. The Nucleus 6 offers three new signal processing algorithms that purportedly facilitate improved hearing in background noise.

Purpose: These studies were designed to evaluate listening performance and user satisfaction with the Nucleus 6 sound processor.

Research Design: The research design was a prospective, single-participant, repeated measures design

Study Sample: A group of 80 participants implanted with various Nucleus internal implant devices (CI22M, CI24M, Freedom® CI24RE, CI422, and CI512) were recruited from a total of six North American sites.

Data Collection and Analysis: Participants had their external sound processor upgraded to the Nucleus 6 sound processor. Final speech perception testing in noise and subjective questionnaires were completed after four or 12 weeks of take-home use with the Nucleus 6.

Results: Speech perception testing in noise showed significant improvement and participants reported increased satisfaction with the Nucleus 6.

Conclusion: These studies demonstrated the benefit of the new algorithms in the Nucleus 6 over previous generations of sound processors.

Key Words: cochlear implant, Nucleus 5, Nucleus 6, N22, sound processor, upgrade

Abbreviations: ADRO® = adaptive dynamic range optimization; AGC = automatic gain control; ANOVA = analysis of variance; ASC = automatic sensitivity control; CI = cochlear implant; CNC = consonant-nucleus-consonant; DUQ = device use questionnaire; FDA = Food and Drug Administration; GT = gain function threshold; N22 = Nucleus® 22; N5 = Nucleus® 5; N6 = Nucleus® 6; SD = standard deviation; SNR = signal-to-noise ratio; SNR-NR = signal-to-noise ratio–based noise reduction; SRT = speech reception threshold; SSQ-C = speech, spatial, and qualities of hearing scale – comparative; SWN = speech weighted noise; WNR = wind noise reduction; WSP = wearable speech processor

INTRODUCTION

In 1982, the first commercial multichannel cochlear implant (CI) was trialed on a human participant, starting a trajectory of hearing implant innovation worldwide (Clark, 2015). The United States Food and Drug Administration (FDA) approved Cochlear Limited's Cochlear™ Nucleus® 22 Cochlear Implant System for use in adults with postlinguistic profound sensorineural hearing loss in 1985. Five years later, the FDA

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approved this system for implantation in candidates with profound sensorineural hearing loss aged two years and older, making it the first multichannel CI approved for children in the United States. By 1995, over 10,000 individuals worldwide were using the Nucleus 22 (N22) Cochlear Implant System. As technological advances accelerated, research studies showed significant outcomes in electric hearing, and cochlear implantation candidacy expanded to serve a broader population (Patrick et al, 2006). Profoundly deaf children as young as 12 mo of age and individuals who could "detect" but not consistently "understand" speech using hearing aids became recipients. Over the years, sound processors were designed to be smaller and technologically smarter.

A CI system consists of an external processor that collects sound from the environment and an internal receiver/stimulator that sends commands to the intracochlear electrode array to electrically stimulate the hearing nerve. The external sound processor analyzes and codes acoustic signals, and uses a proprietary digital code to communicate transcutaneously with the internal device. Since the introduction of the N22 system, several enhancements in internal devices and sound processors have been made, with each new model offering access to updated sound-coding strategies and enhanced processing features. As receiver/stimulators evolve, older models are retired for more refined designs that meet specific surgical and audiological needs. Initiative is taken to modify new sound processors to be compatible with previous generations of internal devices, so that individuals who received earlier CI systems can upgrade to the newest technology without another surgery (Skinner et al, 1994; Dodd et al, 2005; Berger et al, 2006; Patrick et al, 2006; Beiter and Nel, 2015). After the CI22M (N22) internal implant device, Cochlear released the Nucleus® CI24M, the Nucleus® CI24R, the Nucleus® Freedom® (CI24RE), the Nucleus® CI500, the Nucleus® CI422, and more recently, the Nucleus® Hybrid™ L24 in 2014 and the Nucleus® CI532 in 2016.

The sound processor used by the earliest implant recipients was the Wearable Speech Processor (WSP), which proved to be of significant benefit to supplement speechreading but produced average scores of 12.4% in quiet without visual cues (Hirshorn et al, 1986) on Central Institute for the Deaf Everyday Speech Sentences (Silverman and Hirsh, 1955). In 1989, the mini speech processor replaced the WSP and included an input processing feature designed to reduce background noise, automatic sensitivity control (ASC), and the new Multipeak coding strategy which provided more amplitude and spectral information than older formant extraction strategies. Skinner et al (1991) showed this second generation body-worn processor significantly increased speech understanding on word (average of 16% higher) and Bamford–Kowal–Bench sentence tests (Bench et al, 1979) (average of 19% higher) in quiet and noise (average of 23% higher at 20 dB Signal-to-Noise Ratio [SNR], average of 30% higher at 15 dB SNR, and average of 28% higher at 10 dB SNR). In addition, all participants reported everyday communication was easier with the mini speech processor compared with the WSP (Skinner et al, 1991). In 1994, the Spectra processor was released in conjunction with the new coding strategy Spectral Peak which used a 20-channel filter bank to analyze sounds and stimulate the channels with the greatest amplitudes, yielding average scores of 77.5% in quiet and 61.5% at +10 dB SNR (Skinner et al, 1994) for City University of New York Sentences (Boothroyd et al, 1988).

Newer models of sound processors then became smaller, holding multiple programs, offering more sophisticated signal processing, and generating better speech understanding scores (Patrick et al, 2006; Krueger et al, 2008). In 2000, the ESPrit™ 22 became the first ear-level processor made specifically to be compatible with N22 implants (Dodd et al, 2005). A few years later, Whisper™ input signal processing was incorporated into the ESPrit™ 3G, and it provided listeners better access to soft and distant sounds (Nucleus ESPrit 3G Whisper Setting, N95I75FISSI, CLTD, 2002; Berger et al, 2006).

In 2005, the Freedom® sound processor was released and adaptive microphone directionality (Beam®) and adaptive dynamic range optimization (ADRO®) were added to ASC and Whisper on the first SmartSound® digital processing platform (Patrick et al, 2006). The Freedom's two-microphone design with the Beam preprocessing algorithm yielded a significant benefit for speech understanding in noise: an average of 10–41 percentage points for phonemes in single words as well as an average speech reception threshold (SRT) improvement of 5–16 dB depending upon the noise type used (Spriet et al, 2007). The SRT represents the sound level of the speech signal where 50% of the test sentences are correctly recognized; it was measured using an adaptive procedure. This processor became available to N22 recipients in 2008, and the addition of these new Smartound features resulted in significantly improved scores for consonant-nucleus-consonant (CNC) words (Peterson and Lehiste, 1962). After 10 weeks of take-home experience, participants were tested with the Freedom and their existing processor. For each condition, two lists of CNC words were presented at a soft level of 50 dB SPL RMS and at 60 dB SPL RMS conversational level in quiet. When listening with the Freedom processor, participants experienced a statistically significant improvement ($p < 0.001$) at a soft (average 17.4 percentage point improvement with a mean = 45%) and a conversational level (average 7.2 percentage point improvement with a mean = 53.7%) compared with their existing sound processor (Spectra, ESPrit 22, or ESPrit 3G for N22) (Nucleus Freedom Hearing Performance with Nucleus 22 Recipients, N32746F ISSI, CLTD, 2007).

In 2009, Cochlear launched the Nucleus® 5 (N5) sound processor with two precisely calibrated omnidirectional microphones, and SmartSound 2 which used fixed microphone directionality (zoom) and an improved Beam algorithm. On the AzBio Sentence Test (As CIs became more sophisticated, hearing performance improved to a point where maximum scores were often reached on current standardized tests, making it difficult to measure the relative benefit. Gifford et al (2008) demonstrated the agreement between monosyllable word scores in quiet and AzBio Sentence Test scores in noise. They suggested that the industry moves toward implementation of this more difficult speech test for increased accuracy in performance assessment, rather than continuing to use the Hearing in Noise Test (Nilsson et al, 1994), typically administered in quiet. The AzBio Sentence Test is now a common component of CI test batteries.) in noise (Spahr et al, 2012), both algorithms showed significant benefit over standard microphone directionality with average performance scores of 36.1% for zoom and 46.9% for Beam, versus 18% for standard directionality when presented at 65 dBA and +5 dB SNR (Runge et al, 2016). Soon after, Cochlear developed the Cochlear™ Nucleus® 6 (N6) sound processor with new algorithms that target the persistent challenge of listening in background noise.

N6

This processor was launched in 2013 and was made available to N22 recipients in 2015. It is slimmer, lighter, and smaller than previous generations, and offers more program options, data logging, and advanced sound processing on a digital signal processor chip that provides the platform for an array of new technologies. The N6 processor combines multiple signal processing algorithms through SmartSound iQ technology and is also capable of streaming wirelessly to assistive listening devices, contributing to increased performance in the presence of background noise (Wolfe et al, 2016; Duke et al, 2016). The SmartSound iQ sound management algorithms are discussed below and include SCAN, Signal-to-Noise Ratio–Based Noise Reduction (SNR-NR), and Wind Noise Reduction (WNR); three new algorithms designed specifically to improve hearing in a variety of difficult environments.

SCAN

SCAN is the CI industry's first automatic scene classifier (Mauger et al, 2014). As the acoustic dynamics in a busy room change and shift, SCAN technology automatically adjusts the focus of the processor's two omnidirectional microphones to prioritize speech and limit the interference of background noise. The classifier chooses from six different scene descriptions (speech in noise, speech, noise, wind, quiet, and music) and modifies the microphone response patterns. The selected microphone response, combined with automatically adapting algorithms (such as ASC, ADRO, and SNR-NR) is designed to improve hearing in a variety of difficult listening conditions. For example, in the speech scene, the standard microphone directionality is active, and ADRO keeps sounds comfortable for the listener. In the speech in noise scene, the adaptive microphone directionality (Beam) guides the focus to the target speech, whereas ASC works to make soft speech sounds audible. In the noise scene, fixed directionality (zoom) is primary and SNR-NR reduces the interference of background noise. Algorithms such as ADRO, ASC, SNR-NR, and WNR are always available in a program provided they have been turned on by the clinician; however, they are activated only when the specific sound conditions for each algorithm are met. Wolfe et al (2015) and Mauger et al (2014) describe performance with SCAN; Figure 1 illustrates the order in which SCAN takes information from the signal path to determine the most appropriate scene.

SNR-NR

In a noisy environment, auditory cues such as pitch, timing, and loudness can be used to separate a desired speech signal from unwanted background noise. The best ways to select and represent these cues in hearing devices have been studied and developed into a few commonly used noise reduction algorithms including single-channel noise reduction, spectral-subtraction, and statistical model-based methods. In the N6, SmartSound iQ applies an approach that was optimized specifically for use with a CI, based on subjective preference and performance data obtained in previous research (Mauger et al, 2012a). SNR-NR analyzes each frequency channel to determine its individual SNR. Channels with the better SNRs are selected for transmission and channels with poorer SNRs are attenuated, providing a reduction of steady-state background noise, no matter the direction from which it comes (Mauger et al, 2012b; 2014). Attenuation levels of a channel are determined by a CI-specific gain function which is more aggressive than typical hearing aid noise reduction criteria and is better suited for electric hearing. Mauger et al (2012a) showed that a SNR psychoacoustically based gain function threshold (GT) of 5 dB resulted in the best speech perception in 20-talker babble noise and results were significantly better than those obtained with a 0 dB GT. Results in continuous Speech Weighted Noise (SWN) indicated that a GT between −5 and 5 dB gave the best results. Results with the 5 dB GT produced a 1% nonsignificant increase over the 0 dB GT results. As the sound environment changes, SNR-NR continually analyzes the noise level and updates the gain (e.g., attenuates the gain it applies for each frequency channel with a poor SNR) to reduce the impact of background noise. The channels with positive SNRs usually contain the speech signal and these

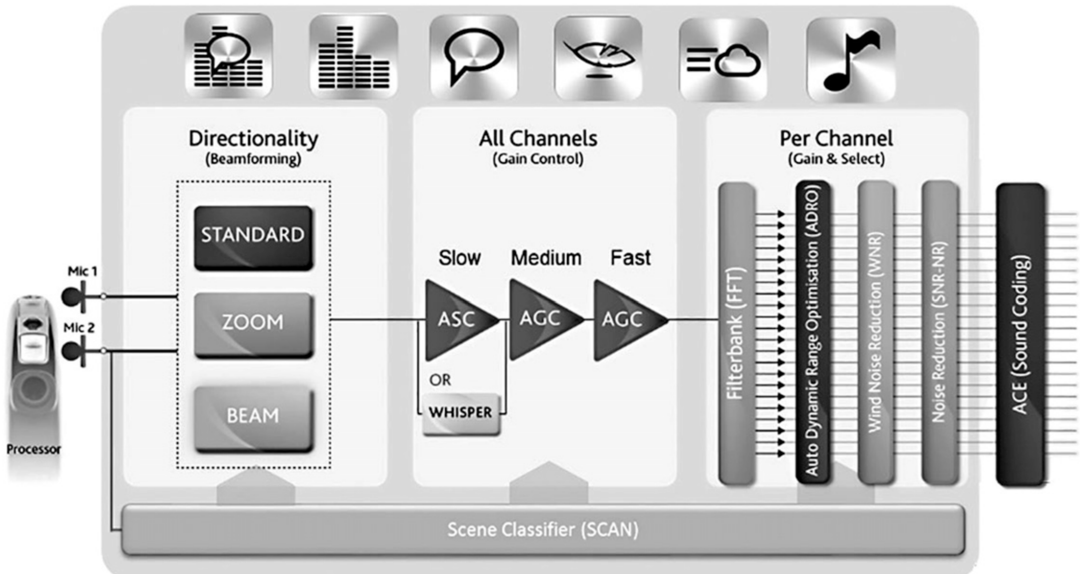

Figure 1. N6 sound processing flow. Image courtesy of Cochlear Americas.

channels are preserved so that speech is clearer and easier to understand (Mauger et al, 2014).

WNR

An additional default N6 feature is WNR—an algorithm that detects wind and uses a twofold process to keep the listener comfortable during outdoor activities. When wind is present, turbulent airflow moves across the processor's microphone ports, negatively affecting the pressure responses of the microphone diaphragm and reducing the ability to hear other sounds (Chung et al, 2010). Although some hearing aids already use advanced algorithms to ease the effects of wind, the N6 is the first CI sound processor to implement a feature specifically designed to preserve the audibility of speech in windy situations. Both the front and rear omnidirectional microphones on the processor work together to detect wind noise and WNR activates in SCAN and non-SCAN programs. The algorithm changes the microphones to a more omnidirectional response pattern and applies multichannel low-level compression to reduce the gain in low-frequency channels where wind interference is most severe (Mauger et al, 2014). Information in the mid- and high-frequency channels remains largely intact to preserve incoming speech signals while wind noise is suppressed. This may allow for easier, more comfortable listening while engaging in leisure activities.

Appropriate feature activation and effective wind noise suppression were demonstrated by White (2013) in a group of 38 CI recipients listening in simulated wind noise. The wind noise was generated with commercially available fans placed in front and behind a test manikin, blowing air at a fixed rate between 7.0 and 7.5 mph. The manikin wore an N6 sound processor and sat directly in the airflow, whereas an 11-cm coil cable connected the processor to the head of the participant who sat off to the side. AzBio sentences were presented at 60 dBA and speech perception was measured with and without the use of WNR. Although not designed to "increase" speech perception, test results (statistical test of noninferiority) showed that enabling WNR did not negatively impact mean speech perception scores.

Study Purpose

The purpose of the studies reported below was to evaluate performance, usability, and satisfaction in recipients upgrading to the N6 processor who used various internal CI models (CI22M [N22], CI24M, CI24RE, CI422, CI512). Three separate U.S. clinical studies were organized. One study, conducted at four CI clinics, evaluated participants upgrading from the N5 processor to the N6 (N = 40). A second study, conducted at three clinics, assessed individuals with CI22M (N22) and CI24M implants upgrading from the Freedom processor (N = 25). The third study, conducted at Cochlear America's Denver Laboratory evaluated N22 recipients upgrading from a Freedom or ESPrit 3G processor (N = 15). A specific aim of these studies was to examine the enhanced signal processing features of the N6 with existing Nucleus CI recipients. Some data in this paper were included in Gilden et al (2015). Because these studies used different protocols and procedures, they are reported separately.

PARTICIPANTS AND MATERIALS

Participants

Eighty unilateral CI recipients, mean age of 43.4 yr (range 13–93 yr), were recruited from multiple clinics across the United States to participate in three studies. In Study 1, 40 participants upgraded from the N5 and used CI24RE, CI422, or CI512 implants. In Study 2, 25 participants upgraded from the Freedom processor and used CI22M (N22) and CI24M implants. In Study 3, the remaining 15 participants upgraded from the Freedom or ESPrit 3G processors and used CI22M (N22) implants. Table 1 summarizes the models of implants and sound processors used in each study. Participants had experienced a number of previous sound processor upgrades and were heterogeneous in terms of duration of CI experience, age at implantation, duration of hearing loss, and postoperative speech perception ability. There was no minimum performance requirement to be considered for study inclusion. In these three studies, speech perception was tested using each participant's current processor with their preferred program and the N6 incorporating the new processing algorithms (SCAN, SNR-NR, WNR). In addition to speech perception testing, subjective questionnaires were administered to gauge preference and acceptance.

Materials

In each study, all participants were tested in quiet using CNC words at 60 dBA, and in noise at 60 dBA at +5 dB SNR (Study 1) or 65 dBA at +10 dB SNR (Studies 2 and 3) using the AzBio Sentence Test with speech from the front and noise at 90° or 270° azimuth on the side of the CI. These studies were designed and executed independently of one another, hence there are some methodological differences which will be noted throughout.

Subjective data were gathered using the Speech, Spatial, and Qualities of Hearing Scale – Comparative version (SSQ-C) (Gatehouse and Noble, 2004) to examine participant preference between their sound processor and the N6. Participants were not blinded to the sound processor(s) they used during the take-home use period; they were simply asked to compare the two processors and the clinician did not provide any additional information. The rating scale on the SSQ-C ranges from −5 (performance much worse) to +5 (performance much better). The questionnaire is divided into three subscales that explore hearing ability in different environments, such as in noisy groups or when listening from a distance, and also ask the participant to describe sound characteristics like clarity and naturalness.

A Device Use Questionnaire (DUQ) was administered to evaluate comfort, ease of listening, and satisfaction using the N6 processor. Participants used a five-point rating scale to indicate their opinion of appearance, functionality, and performance of the N6 compared with their processor. The metric included questions regarding which processor they preferred in a variety of listening situations, their overall satisfaction with the processor in different environments, and whether they would recommend the N6 to someone else.

STUDY METHODS AND RESULTS

Statistical Analysis

Mean differences observed in these studies were tested using paired t-tests with an alpha level of $p \leq 0.05$. In the event that the assumption of normality was not met (i.e., Shapiro–Wilk test of normality, $p \leq 0.05$), a Wilcoxon Signed Rank test was planned but not necessary for the analyses described.

Table 1. Models of Internal Implants and Sound Processors Used in Each of the Three Studies

	Study 1 (N = 40)	
Number of Participants	External Sound Processor	Internal Implant
26	N5	CI24RE
4	N5	CI422
10	N5	CI512
	Study 2 (N = 25)	
Number of Participants	External Sound Processor	Internal Implant
24	Freedom	CI22M (N22)
1	Freedom	CI24M
	Study 3 (N = 15)	
Number of Participants	External Sound Processor	Internal Implant
14	Freedom	CI22M (N22)
1	ESPrit 3G	CI22M (N22)

Study 1: Multicenter N5 Upgrade (N = 40)

There were two visits in this study, with Visit 2 occurring four weeks after Visit 1. During Visit 1, participants were tested with their own processor, upgraded to the N6, and tested immediately in quiet and noise. At Visit 2, participants were tested in noise with the N6 and completed the two questionnaires. During these two visits testing was conducted in the unilateral condition, and Visit 2 served as the endpoint for the study. Table 2 summarizes the evaluation protocol.

Results

CNC Words at 60 dBA in Quiet

Testing with ASC+ADRO in the N5 processor yielded a mean score of 71.0% (standard deviation [SD] 12.85) and default settings in the N6 yielded a mean score of 70.4% (SD 13.65), showing no significant difference in scores ($p = 0.483$) and establishing equivalency between processors in quiet for CNC words.

AzBio Sentences at 60 dBA and +5 dB SNR (3 Participants Tested at 0 dB SNR to Prevent Ceiling Effects)

Use of the new algorithms resulted in a significant benefit when listening in noise ($p < 0.0001$). At Visit 1, the mean score increased significantly from 21.2% (SD 16.8) using ASC+ADRO in the N5 processor to 53.1% (SD 22.5) when using SCAN in the N6 processor. At Visit 2, the mean score with SCAN was 56.4% (SD 23.0), which was not significantly different from the score at Visit 1 ($p = 0.293$). A binomial comparison (Thornton and Raffin, 1978) showed that 35/40 (88%) articipants performed significantly better, 4/40 (10%) demonstrated similar performance, and one participant (2%) showed a significant decrement in performance using the N6 processor compared with their N5.

Additional Testing

To understand the individual contribution of each of the algorithms, testing was conducted by adding in one algorithm at a time and comparing speech perception scores. At Visit 2, the N6 ASC+ADRO alone condition yielded a mean AzBio score of 18.9% (SD 21.7), and the addition of SNR-NR significantly increased the mean score to 24.2% (SD 19.6) ($p = 0.002$). For the SNR-NR testing, the WNR feature was manually disabled in the software, and speech perception in noise testing showed that this did not cause a decrement in scores. The mean score improved significantly to 56.4% using ASC+ADRO+SNR-NR+WNR+SCAN, showing microphone directionality to be the primary contributor to improved performance with the N6.

SSQ-C

After four weeks of take-home use, participants completed the SSQ-C rating the N6 against their current processor on a scale from −5 (much worse) to +5 (much better). On the Speech Hearing subscale (average rating of 1.44), 90% (36/40) of participants reported that the N6 performed better than their previous sound processor, 7.5% (3/40) reported no difference between the two processors, and 2.5% (1/40) reported a negative rating. For Spatial Hearing (average rating of 0.94), 80% (32/40) of participants rated the N6 processor as better, 12.5% (5/40) reported no difference, and 7.5% (3/40) reported it as worse. On the Qualities of Hearing subscale (average rating of 1.36), 95% (38/40) of participants indicated that the N6 was superior, and 5% (2/40) reported no difference.

N6 DUQ

Regarding listening ability with the N6 processor, 93% (37/40) of N5 users reported that it matched or exceeded their expectations, and 95% (38/40) reported that the sound quality of the N6 matched or exceeded their expectations.

Table 2. Study 1 Evaluation Protocol: Participants were Tested in SWN for AzBio Sentences.

Study 1	Visit 1	Visit 2 (4 weeks)
CNC words at 60 dBA in quiet	N5 default (ASC+ADRO)	
	N6 (ASC+ADRO)	
	N5 default (ASC+ADRO)	
	N6 (ASC+ADRO)	
AzBio at	N6 (ASC+ADRO+SNR-NR)	N6 (ASC+ADRO+SNR-NR)
60 dBA and +5 dB SNR	N6 (ASC+ADRO+SNR-NR+WNR)	N6 (ASC+ADRO+SNR-NR+WNR)
	N6 (ASC+ADRO+SNR-NR+WNR+SCAN)	N6 (ASC+ADRO+SNR-NR+WNR+SCAN)
Subjective questionnaires		N6 DUQ
		SSQ-C

Note: Three participants were tested at 0 dB SNR to prevent ceiling effects.

Study 2: Multicenter N22/Nucleus 24 Freedom Upgrade (N = 25)

There were two visits in this study with Visit 2 occurring 12 weeks after Visit 1. During Visit 1, participants were tested in quiet and in noise with their Freedom processor using their preferred Everyday Program. The possible configurations were ASC, ADRO, and Whisper enabled either alone, or in a variety of combinations or no input processing. After testing, participants were upgraded to the N6 processor. At Visit 2, participants were tested with he N6 in quiet and noise using the default setting (SCAN+ASC+ADRO+SNR-NR+WNR) and completed the questionnaires. Table 3 summarizes the evaluation protocol.

Results

CNC Words at 60 dBA in Quiet

Testing with preferred settings in the Freedom processor yielded a mean score of 69.3% (SD 17.5) at Visit 1. At Visit 2, using the default settings in the N6 processor, a mean score of 73.0% (SD 14.7) was obtained, which is statistically significant ($p = 0.027$) but may not be clinically meaningful.

AzBio Sentences at 65 dBA and +10 dB SNR (12 Participants Tested at +5 dB SNR to Prevent Ceiling Effects)

The mean score with the participants' Freedom processor was 34.4% (SD 14.0) at Visit 1. At Visit 2 the mean score increased significantly to 59.6% (SD 23.3) ($p < 0.001$) with the N6, a mean percentage point improvement of 25.2% (SD 26.0). A binomial comparison showed that 23/25 (92%) participants performed equal to or significantly better with the N6 compared with their Freedom. Sixteen of 25 participants (64%) performed significantly better, 7/25 (28%) demonstrated similar performance, and 2/25 (8%) showed a significant decrement in performance.

SSQ-C

After 12 weeks of take-home use, participants completed the SSQ-C, comparing their Freedom to the N6 processor. On the Speech Hearing subscale (average rating of 2.1), 92% (23/25) of participants reported that the N6 performed better than their Freedom and 8% (2/25) reported a negative rating. On the Spatial Hearing subscale (average rating of 1.24), 88% (22/25) rated the N6 processor as better, 4% (1/25) reported no difference, and 8% (2/25) reported it as worse. On the Qualities of Hearing subscale (average rating of 2.13), 100% (25/25) indicated that the N6 was superior.

N6 DUQ

Comparing overall hearing ability with the N6 to their Freedom, 24/25 participants (96%) indicated that their hearing ability was either much better or somewhat better with the N6, and one participant (4%) rated it as "about the same." When asked about hearing in background noise, 23/25 (92%) indicated their hearing was better with N6, 1/25 (4%) indicated their hearing was about the same, and 1/25 (4%) indicated that hearing in background noise was not applicable.

Study 3: Denver Laboratory N22 Freedom/ESPrit 3G Upgrade (N = 15)

There were three visits in this study with Visit 2 occurring four weeks after Visit 1, and Visit 3 occurring 12 weeks after Visit 1. During Visit 1 participants were tested in quiet and noise using their own processor and preferred program. The possible configurations were ASC, ADRO, and Whisper enabled either alone, or in a variety of combinations. One participant did not use input processing. After testing, participants were upgraded to the N6 processor. At Visit 2, participants were tested with the N6 in quiet and noise using the default setting (SCAN+ASC+ADRO+SNR-NR+WNR), and they were also introduced to the wireless accessories. Five participants were unable to return to the laboratory to complete Visit 2. As this was not the study endpoint, results from Visit 2 are provided only as supplementary data. At Visit 3, all 15 participants were tested in quiet and noise with the N6 and completed the questionnaires. Visit 3 served as the endpoint for this study. Table 4 summarizes the evaluation protocol.

Table 3. Study 2 Evaluation Protocol: Participants were Tested in Multitalker Babble for AzBio Sentences

Study 2	Visit 1	Visit 2 (12 weeks)
CNC words at 60 dBA in quiet	Freedom preferred program	N6 (ASC+ADRO+SNR-NR+WNR+SCAN)
AzBio at 65 dBA and +10 dB SNR	Freedom preferred program	N6 (ASC+ADRO+SNR-NR+WNR+SCAN)
Subjective questionnaires		N6 DUQ
		SSQ-C

Note: Twelve participants were tested at +5 dB SNR to prevent ceiling effects. Visit 2 served as primary endpoint for this study.

Table 4. Study 3 Evaluation Protocol: Participants were Tested in Multitalker Babble for AzBio Sentences

Study 3	Visit 1	Visit 2 (4 weeks)	Visit 3 (12 weeks)
CNC words at 60 dBA in quiet	Freedom/ESPrit 3G preferred program	N6 (ASC+ADRO+SNR-NR+WNR+SCAN)	N6 (ASC+ADRO+SNR-NR+WNR+SCAN)
AzBio at 65 dBA and +10 dB SNR	Freedom/ESPrit 3G preferred program	N6 (ASC+ADRO+SNR-NR+WNR+SCAN)	N6 (ASC+ADRO+SNR-NR+WNR+SCAN)
Subjective questionnaires			N6 DUQ SSQ-C

Note: Visit 3 served as primary endpoint for this study.

Results

CNC Words at 60 dBA in Quiet

Testing with preferred settings in the Freedom/ESPrit 3G processor yielded a mean score of 66.6% (SD 24.9) at Visit 1, and default settings in the N6 yielded a mean score of 70.3% (SD 24.2) at Visit 3, showing no significant difference in scores ($p = 0.202$), and establishing equivalency between processors in quiet for CNC words.

AzBio Sentences at 65 dBA and +10 dB SNR

Mean scores with the participants' own processor were 31.3% (SD 29.7) at Visit 1, and significantly increased to 62.3% (SD 29.4) ($p = 0.002$) with N6 at Visit 3, a mean percent point change of 31.0% (SD 30.6) for this group of 15 participants. Note that data were gathered at Visit 2 for the 10 participants who were able to return to the laboratory and showed an increase in group mean score from 19.4% (SD 13.35) with the participants' own processor to 48.9% (SD 26.35) with the N6. No statistics were run because five participants were unavailable, and this was not the endpoint of the study. A binomial comparison of all 15 participants at the Visit 3 endpoint showed that 14/15 (93%) performed equal to or significantly better with the N6 compared with their processor. Ten of the 15 participants (67%) performed significantly better, 4/15 (26%) demonstrated similar performance, and one participant (7%) showed a significant decrement.

SSQ-C

After 12 weeks of take-home use, participants completed the SSQ-C comparing their processor with the N6. On the Speech Hearing subscale (average rating of 1.76), 93% (14/15) of participants reported that the N6 performed better than their processor, and 7% (1/15) reported a negative rating. For Spatial Hearing (average rating of 1.04), 73% (11/15) of participants rated the N6 as better, 13% (2/15) reported no difference, and 13% (2/15) reported it as worse. On the Qualities of Hearing subscale (average rating of 1.76), 87% (13/15) of participants indicated that the N6 was superior, and 13% (2/15) reported no difference.

N6 DUQ

Comparing overall hearing ability with the N6 against their processor, 100% of participants indicated that their hearing ability was either much better or somewhat better with the N6. When asked about hearing in background noise, 12/15 (80%) indicated their hearing was better, 2/15 (13%) indicated their hearing was about the same, and 1/15 (7%) indicated their hearing was somewhat worse.

DISCUSSION

Results from these studies align with outcomes from earlier N6 upgrade studies that show improved speech perception in background noise when using the N6 (Mauger et al, 2014; De Ceulaer et al, 2015; Wolfe et al, 2015; Plasmans et al, 2016). Mauger et al (2014) compared speech perception in quiet, in SWN and in four-talker babble. Both noise types were assessed in two different spatial configurations, colocated (with the signal and noise at 0°), and spatially separated (signal at 0° and noise at 90°, 180°, and 270°) using the N5 and N6 processors in 21 experienced adult participants. In the noise evaluations, participants listened using their preferred N5 noise program and the N6 programmed in the following configurations: no input processing, standard microphone directionality, fixed directionality (zoom), adaptive directionality (Beam), and SCAN. When participants were tested in SWN with speech and noise colocated, a repeated measures one-way analysis of variance (ANOVA) found a significant effect of program type. Post hoc comparisons indicated a significant improvement for N6 SCAN compared with all other programs. No additional significant differences were seen. By contrast, a repeated measures one-way ANOVA revealed no significant differences between programs for speech understanding in colocated four-talker babble.

When participants were tested in spatially separated speech and SWN noise, a repeated measures one-way ANOVA indicated a significant effect of program type.

Post hoc comparisons found significant differences between N6 SCAN, Beam, and zoom programs compared with N5 Preferred and N6 None and Standard programs. Also a significant difference, in favor of N6, between N5 Preferred and N6 None and Standard programs was seen. There were no significant differences between the N6 zoom, Beam, and SCAN programs or between the N6 None and Standard programs. When participants were evaluated in spatially separated speech and four-talker babble, a repeated measures one-way ANOVA found a significant effect of program type. Post hoc comparisons indicated significant differences for N6 SCAN, Beam, and zoom programs compared with the N5 Preferred program and N6 None and Standard programs. Also a significant difference, in favor of N6, between the N5 Preferred and N6 None and Standard programs was seen. No significant differences were seen between N6 zoom, Beam, and SCAN programs or between N6 None and Standard programs. In summary, for all noise conditions tested, mean results indicated N6 SCAN provided equivalent or improved speech understanding compared with the other programs evaluated, including the N5 Preferred program.

Results of the three upgrade studies reported here are consistent with data from Mauger et al. This is important because SCAN automatically chooses the best microphone directionality and activates other algorithms based on the listening environment. It is well known that many implant recipients are reluctant to manually change programs when listening in demanding, noisy environments.

Wolfe et al (2015) evaluated 93 N5 recipients (Freedom CI24RE, CI422, and CI512 CI systems were included). Participants were tested with the N5 and N6 processors immediately after being fit with the N6. Analysis of AzBio Sentences in noise indicated that mean scores with the N5 default program (ASC+ADRO) and N6 with ASC+ADRO were not statistically different. However, both conditions produced poorer mean performance ($p < 0.05$) than the other two N6 conditions (ASC+ADRO+SNR-NR and the N6 default [SCAN+ASC+ADRO+SNR-NR]). SCAN produced significantly better mean speech understanding than the N6 condition with only ASC+ADRO+SNR-NR. Analysis of individual N5 and N6 performance using the binomial distribution showed that compared with the N5 condition, the largest proportions of participants had higher performance using N6 with SNR-NR activated (56% of participants), especially with SNR-NR activated with SCAN (88% of participants). Results of the three upgrade studies reported here agree with Wolfe et al. Mean scores with SCAN were significantly higher compared with participants' preferred program on their processor. Furthermore, binomial comparisons found that most of the participants performed significantly better with SCAN compared with their preferred program on their processor, regardless of sound processor model.

De Ceulaer et al (2015) studied 30 adult N5 recipients who were upgraded to the N6. Participants participated in five clinic visits over a 34-week period. The study used an ABBA design where Condition A was N5 and Condition B was N6. The main objective of the study was to evaluate performance of the N6 SCAN program with SNR-NR compared with the N5 SmartSound Noise program. Adaptive speech-in-noise testing revealed a mean significant improvement when using SCAN compared with N5 (SRT improvement of 1.2 dB, $p = 0.023$). Subjective data indicated that most of the recipients preferred SCAN for listening in quiet and noise. Although the three upgrade studies reported here did not use adaptive speech-in-noise testing, results with fixed level speech-in-noise testing revealed significantly better results with SCAN compared with the participants' preferred noise program on their processor. In addition, most of the participants reported improved hearing on the Speech Hearing subscale of the SSQ-C with the N6 compared with their processor.

Plasmans et al (2016) assessed 25 experienced pediatric N5 recipients to determine any benefit of the noise reduction and SCAN algorithms in the N6 processor compared with N5. The children were six years of age or older, had at least two years of implant experience, were unilateral or bilateral recipients, and had a minimum score of 10% on a test of open set words in quiet. The children participated in three test sessions, each separated by about two weeks. During the first session, each child's speech perception was measured using their N5 processor programmed with their preferred program. Then, they were fit with the N6 using settings equivalent to their N5 program. The children wore the N6 for approximately two weeks and then speech perception was retested. Next, the children were given the default

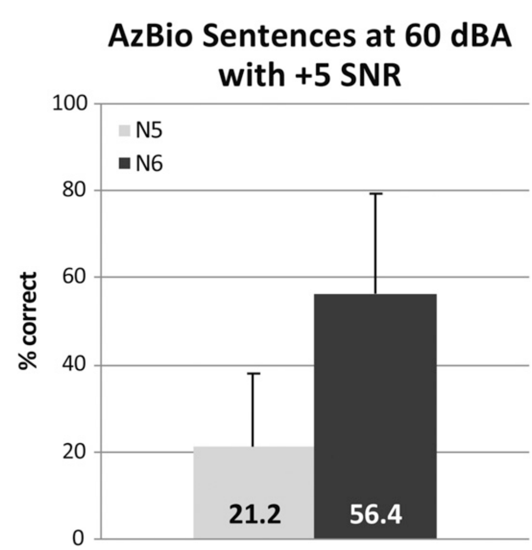

Figure 2. Study 1: Group mean scores of AzBio sentences presented at 60 dBA in SWN and +5 dB SNR with the N5 (21.2%, SD 16.8) and the N6 (56.4%, SD 23.0). N = 40 participants (CI24RE, CI422, and CI512 recipients).

N6 SCAN program and they wore this for about two weeks until the final evaluation. Speech perception was evaluated using monosyllabic words in noise (Belgian speakers) and sentences in noise (English speakers). As expected, paired *t*-tests found no significant difference between the N5 preferred program and the N6 programmed with these same settings for either the Belgian or English speakers. However, paired *t*-tests indicated a significant 16.7 percentage point improvement in group mean scores for the N6 SCAN (50.0%) compared with the N5 preferred program (33.3%) (t = 9, $p < 0.01$) for the Belgian recipients. There was a significant 9.41 percentage point mean improvement in sentence scores for the N6 SCAN condition (71.0%) compared with the N5 preferred program (61.6%) ($t = 16, p < 0.05$) for the English speakers. These results support the use of SCAN and noise reduction algorithms in N6 for children. In addition, these algorithms did not impact these children's listening ability in quiet.

In the current studies, the new algorithms resulted in a significant benefit when listening in noise with mean scores increasing from 21.2% with the N5 to 56.4% with the N6 (Figure 2) and from 33.3% with the Freedom/ESPrit 3G to 60.6% with the N6 (Figure 3).

A binomial comparison showed that 39/40 N5 participants (98%) and 37/40 Freedom/ESPrit 3G participants (93%) performed equal to or better with the N6 compared with their sound processor on AzBio Sentences in noise (Figures 4 and 5).

Subjective data gathered in the N5 and Freedom/ESPrit 3G studies described here showed that the participants could perceive and appreciate the benefits of the N6 sound processing algorithms. Objective testing also demonstrated these benefits. Overall, participants indicated they were satisfied with their hearing ability when using the new sound processor, particularly in difficult listening situations as reflected on the SSQ-C and DUQ. On the DUQ, when comparing the N6 to the participant's own processor, 73/80 total participants preferred the N6 sound processor, and 79/80 participants reported they would be likely to recommend the N6 processor to someone else. On each of the three subscales of the SSQ-C, most of the participants in the three studies reported the N6 processor to be superior: 73/80 participants (91%) on the Speech Hearing subscale, 65/80 (81%) on the Spatial Hearing subscale, and 76/80 (95%) on the Qualities of Hearing subscale. Interestingly, the Freedom/ESPrit 3G users reported increased levels of satisfaction in specific listening situations such as hearing at a café, on the phone, and in background noise versus the cohort of N5 users. This may be due to their transition

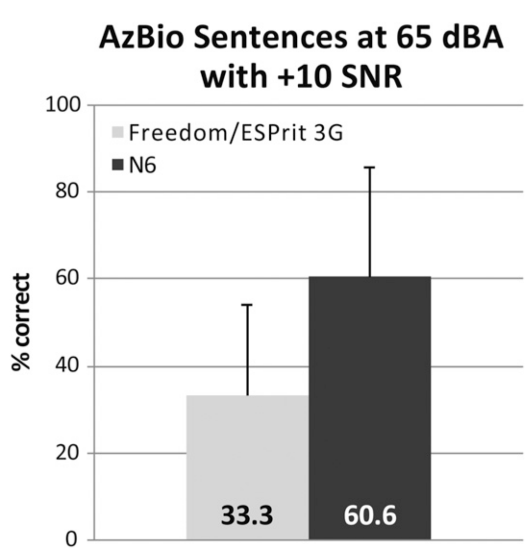

Figure 3. Combined Study 2 and Study 3: Group mean scores of AzBio sentences presented at 65 dBA in ten talker babble and +10 dB SNR with the Freedom/ESPrit 3G (33.3%, SD 21.0) and the N6 (60.6%, SD 25.4). N = 40 participants (CI22M and CI24M recipients).

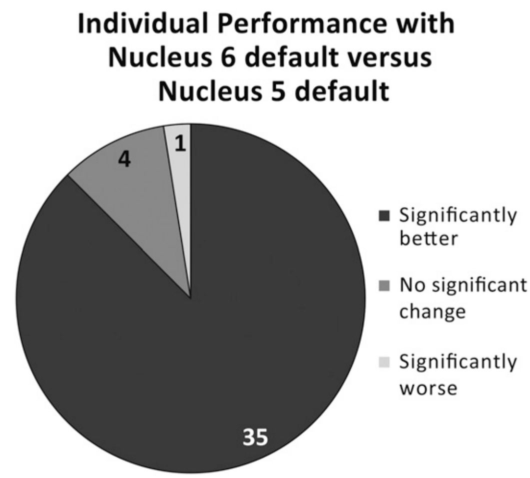

Figure 4. Study 1: Binomial comparison of N6 vs. N5 scores on AzBio sentences in noise. N = 40 N5 users.

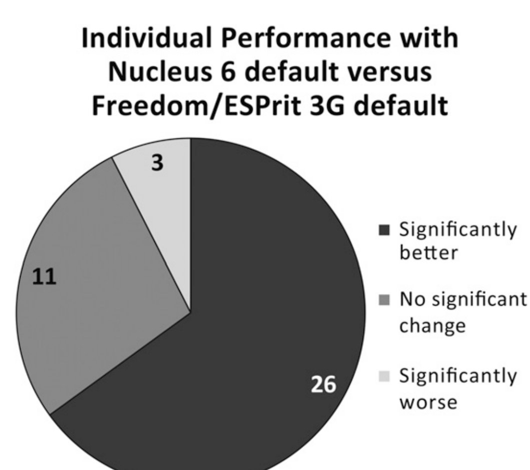

Figure 5. Combined Study 2 and Study 3: Binomial comparison of N6 vs. Freedom/ESPrit 3G scores on AzBio sentences in noise. N = 40 Freedom/ESPrit 3G users.

from third and fourth generation technology to the sixth generation technology, in contrast to the N5 users who had manual access to environmentally optimized microphone directionality before release of the N6.

CONCLUSION

The N6 offers signal processing algorithms designed to improve hearing in noisy settings. In the current studies over 90% of participants reported it to be better in everyday listening situations than previous sound processors. SCAN, SNR-NR, and WNR algorithms have been shown in these and other studies to be advantageous in noisy environments, providing significantly better speech understanding in difficult listening situations. These features are available to all Nucleus implant recipients, including the earliest N22 recipients, via a sound processor upgrade. Regardless of internal device and year of implantation, recipients of all ages in these studies were satisfied with the new processor, and almost 90% (71/80) demonstrated improved speech understanding in noise. Objective data and recipient satisfaction agree with outcomes from the existing body of literature and support the clinical benefits shown with the N6.

SCAN, SNR-NR, and WNR are currently FDA approved in the United States for use by CI recipients age 6 yr and older who can complete speech perception testing in quiet and in noise, and who can report a preference for program settings.

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