Clinical White Paper

Improving listening in noise with ForwardFocus technology in Nucleus® Sound Processors

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Overview

This white paper describes first results with the Cochlear™ Nucleus® 8 Sound Processor in an early clinical study.

Introduction

The Nucleus 8 Sound Processor is the world's smallest and lightest behind-the-ear cochlear implant (CI) sound processor.[1] Designed to take comfort to the next level, it's 15% smaller and 13% lighter than its predecessor.[#]

Figure 1: Nucleus 8 Sound Processor

The Nucleus 8 Sound Processor features smart hearing technology, including SmartSound® iQ 2 and SCAN 2 functionality.[2] This latest hearing technology more accurately senses changes in listening environments and automatically adjusts settings to provide clearer sound so that CI recipients can hear their best.[3-5]

The Nucleus 8 Sound Processor offers a range of hearing technologies including dual omni directional microphones, signal processing and noise reduction algorithms. ForwardFocus, exclusive to Cochlear devices, is a noise reduction algorithm that works in conjunction with microphone directionality to reduce distracting background noise behind and to the sides of the listener. [±]

ForwardFocus applies a second "layer" of noise reduction, adding further benefit than microphone directionality alone in maximising a recipient's hearing in noisy situations. For the first time, the Nucleus 8 Sound Processor now gives recipients the option to choose between automatically or manually controlling ForwardFocus, providing an even greater, more personalised listening experience.[6]

Connectivity with the Nucleus 8 Sound Processor also reaches a new level, being the first CI sound processor ready for next generation Bluetooth® LE Audio technology.[7,¥] Additionally, it provides direct streaming capabilities with compatible Apple, Android™ and Cochlear True Wireless™ devices and bimodal streaming with compatible ReSound hearing aids. The Nucleus 8 Sound Processor also supports Cochlear's Connected Care solutions. Using the Nucleus® Smart App on a compatible smartphone, a recipient's progress and hearing outcomes can be conveniently monitored remotely.[6,8]

Noise reduction technology

The world is a noisy place. It can be especially challenging for people with hearing loss to focus on and hear speech clearly in many day-to-day environments.[9] Cochlear's sound processors include many smart technologies which take advantage of dual microphones to make hearing easier and more comfortable, especially in background noise. This allows recipients to experience those important hearing moments.

Directional processing options available with the Nucleus 8 Sound Processor include:

i. Standard: a microphone directionality pattern that captures sound broadly, from all-around.

ii. Zoom: a fixed directional technology that attenuates sounds from behind the listener. The point of maximum attenuation is located at ± 120 degrees azimuth to either side and rear of the listener.[10]

iii. Beam: an adaptive directional technology that attenuates the most dominate noise source in a dynamic noise environment. It steers the maximum attenuation towards the loudest noise source occurring behind the listener.[10]

iv. ForwardFocus: an advanced noise reduction algorithm that works in conjunction with microphone directionality to reduce distracting background noise behind and to the sides of the listener.[11]

Advances in ForwardFocus

When first introduced in the Nucleus® 7 Sound Processor, ForwardFocus was used in combination with zoom.[11] It was implemented as a clinician-enabled setting with user-controlled access via the Nucleus® Smart App.

Following further in-house clinical research, ForwardFocus has been further enhanced with user-controlled ForwardFocus now combined with Beam.[12] When speech in noise is detected, Beam directionality steers the maximum attenuation towards the loudest noise source while ForwardFocus provides further reduction of all noise sources behind and to the side of the listener.

User-controlled ForwardFocus via Nucleus® Smart App

New automated ForwardFocus program SCAN 2 FF

Figure 2: ForwardFocus options with the Nucleus 8 Sound Processor

In addition, ForwardFocus is also now provided as an automatic option controlled directly by the SCAN 2 scene classifier.[2] By creating an automated ForwardFocus program (SCAN 2 FF), the appropriate microphone directionality is enabled by SCAN 2, and ForwardFocus applied in various strengths based on the classification of the sound environment (Table 1).

The added flexibility in how ForwardFocus can be used, gives clinicians and their CI recipients more options to help optimise their hearing performance in daily noisy environments (Figure 2).

Table 1: ForwardFocus options available with the Nucleus 8 Sound Processor

Sound class	SCAN 2	User-controlled ForwardFocus ForwardFocus + Beam (adaptive directionality)	Automated ForwardFocus ForwardFocus + Beam (adaptive directionality SCAN 2 FF)
Quiet, Speech, Music	✓ Standard	✓ Adaptive (Beam) maximum ForwardFocus noise reduction	✓ Standard + minimum ForwardFocus noise reduction
Noise	✓ Fixed (zoom)		✓ Fixed (zoom) + maximum ForwardFocus noise reduction
Speech in noise	✓ Adaptive (Beam)		✓ Adaptive (Beam) + maximum ForwardFocus noise reduction

Clinical Study

Study Objectives

The primary aim of this preliminary, in-house, acute clinical study, was to assess and compare speech recognition in noise for adult CI recipients with user-controlled ForwardFocus in the Nucleus 8 Sound Processor (*test-version*) compared with ForwardFocus in the Nucleus 7 Sound Processor.[12]

Study Design

This was a pre-market, within-subject, repeated-measures clinical investigation. A group of adult CI recipients using a Nucleus cochlear implant system for a minimum of 3 months, were invited to take part. To qualify for enrollment, > 30% correct scores for sentences in 4-talker babble noise at +15 dB SNR in S0N0 using a unilateral CI-alone was required. Speech recognition in noise was evaluated over two test sessions in the sound-booth using ForwardFocus in both Nucleus 8 and Nucleus 7 Sound Processors. There was no take home experience with the Nucleus 8 Sound Processor. Study participants were not informed which program or sound processor was in use during testing. Test order effects were limited through counterbalancing.

Ethics approval was obtained prior to the start of the study. All participants formally consented to their voluntary participation. The investigation was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and aligned with regional and national regulations as applicable.

Statistics

The study design was based on a sample of 17 participants required for adequate statistical power to compare outcomes between the two sound processors. Twenty participants were enrolled to account for any unforeseen withdrawals. Based on clinical consensus the clinically important difference for speech reception thresholds (SRT) for speech in noise was $\geq$ 1 dB signal to noise ratio (SNR). Sound processor effects on outcomes were compared using a paired t-test and an Analysis of Variance (ANOVA). The ANOVA model accounted for the sequence and period effects when the sound processor effect was compared.

Speech Testing

Speech recognition in adaptive 4- talker babble noise was assessed with different loudspeaker configurations, using the test measures and sound processor settings described in Table 2. Two lists of AuSTIN sentences were presented at 65 dBSPL per test condition.[13] Results were averaged across both lists per participant with each sound processor using ForwardFocus.[12] The group mean speech reception threshold, per sound processor per test condition, is reported as the average signal-to-noise ratio required to correctly recognize fifty percent of keywords (dB $SNR_{50\%}$).

Participants were assessed in the unilateral, aided listening condition with the contralateral ear (non-test ear) blocked with an ear plug. Participants who had two implanted ears were tested using their preferred ear. The first implanted ear was used as the test-ear where no ear preference was reported.

Table 2: Study conditions with user-controlled ForwardFocus

Test	Conditions	Speaker location	Speech test	Speech level	Noise type
Speech in Noise	Nucleus 7 and Nucleus 8 Sound Processors with ForwardFocus	S0N0 (co-located speech and noise) S0N90/270 (noise at the CI ear and speech from the front)	Australian Speech Test In Noise (AuSTIN) (Dawson et al., 2013)	65 dB SPL	4 talker babble

Participants

Participants included seven men and 13 women, aged 18 years or older, with at least 3 months experience with a Cochlear™ Nucleus® 6, Kanso, Kanso 2 or Nucleus 7 Sound Processor and a Cochlear™ Nucleus® CI600 series, CI500 series or Freedom® series cochlear implant type. All participants had a sensorineural hearing loss, with a progressive loss for 85% (17/20) and a congenital hearing loss in the remaining three cases. The average age at the time of the study evaluation was 65 years, ranging between 33 and 91 years. Additional demographics are shown in Table 3.

Table 3. Participant demographics

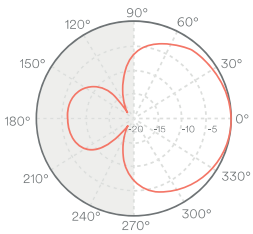
		Test ear	Contra-lateral ear
Age at onset of loss	*mean (years) (median)*	21.2 (19.0)	21.9 (18.5)
	range	0.0 – 60.0	0.0 – 60.0
Time since CI surgery	*mean (median)*	9.7 (10.0)	12.6 (13.4)
	range	0.5 -16.7	1.9 - 20.8
Cause of hearing loss	*proportion of cohort*	Unknown 60%	Unknown 55%
		Genetic 30%	Genetic 30%
		Other 10%	Other 15%

Sound processor programming

All participants were provided with a Nucleus 7 and Nucleus 8 Sound Processor for sound booth assessments. Using Custom Sound® Pro fitting software, prior to assessing speech recognition in the sound booth, sound processors were configured as closely as possible to their preferred MAP as used in their own sound processor. As a final step, ForwardFocus was enabled as a user-controlled option before the MAPs were saved to each sound processor.

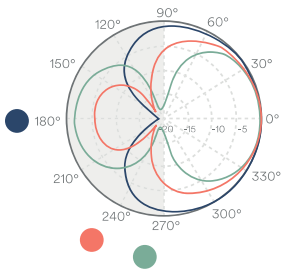
A schematic of how ForwardFocus works in conjunction with directional processing using zoom and Beam, is shown in Figure 3.

Nucleus 7 Sound Processor
ForwardFocus with zoom Fixed Directionality



Note: Shading depicts areas of sound attenuation from behind the listener with ForwardFocus. The red line represents zoom polar plot.

Nucleus 8 Sound Processor
ForwardFocus with Beam® Adaptive Directionality



Note: Shading depicts areas of attenuation from behind the listener with ForwardFocus. The coloured dots represent the noise sources. The corresponding coloured polar plots represent the Beam response.

Figure 3. Schematic polar plots of directional technology and respective null points used in combination with ForwardFocus attenuation of multiple noise sources located in the rear hemi-field.

Results

All 20 participants completed speech recognition in noise assessments. The primary outcome for speech recognition in spatially separated speech in noise (S0N90/270), showed statistically superior group results when using the Nucleus 8 Sound Processor with ForwardFocus compared to the Nucleus 7 Sound Processor with ForwardFocus (t-test and ANOVA, $p<0.001$). The group mean dB $SNR_{50\%}$ with the Nucleus 8 Sound Processor was 11.3 dB (SD 4.22, median -11.5 dB) and with the Nucleus 7 Sound Processor was -6.1 dB (SD 3.42, median -5.7 dB) as shown in Figure 5. This resulted in a significant group mean difference of -5.2 dB (95% CI: -6.16, -4.29 dB).

In co-located speech in noise (S0N0), group mean dB $SNR_{50\%}$ was 3.6 dB (SD 1.8, median 3.6 dB) with the Nucleus 8 Sound Processor and 3.4 dB (SD 2.08, median 3.2 dB) with the Nucleus 7 Sound Processor. As anticipated, there was no statistically significant difference between group mean results with each sound processor in S0N0, 0.18 dB (95% CI: -0.43, 0.79), (t test and ANOVA, p=0.55).

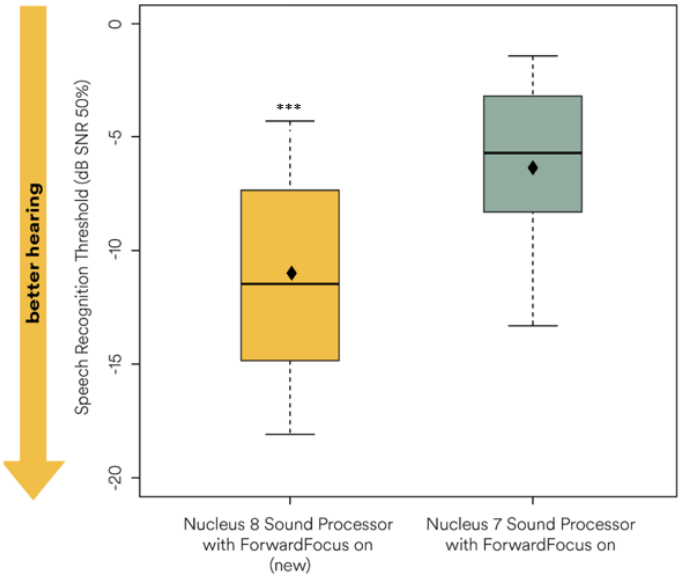


Figure 4: Whisker boxplots showing the distribution of speech recognition thresholds in dB $SNR_{50\%}$ in spatially separated speech in noise (S0N90/270) for each sound processor condition. Lower dB $SNR_{50\%}$ values (Y-axis) indicate better hearing outcomes. Boxplot limits indicate group performance 25th and 75th percentiles and solid horizontal line indicates the median score, 50th percentile. Whiskers with dashed lines indicate minimum and maximum scores. * indicates significantly better performance (p<0.001). ♦ = group mean values.**

Summary

These early study results confirm advantages of the improved implementation of ForwardFocus technology in the Nucleus 8 Sound Processor when listening to speech from in front with competing background noise from the side (i.e. in spatially separated noise). In this condition, a significant improvement in the speech recognition threshold of -5.2 dB $SNR_{50\%}$ was shown with ForwardFocus enabled in the Nucleus 8 Sound Processor compared to using ForwardFocus in the Nucleus 7 Sound Processor.

Study results are inherently influenced by the specific study design, test conditions, test materials and cohort characteristics involved. These findings are indicative only of anticipated results for recipients with similar characteristics contemplating an upgrade to the Nucleus 8 Sound Processor. To determine the benefits of new sound processing technologies for individual recipients, clinicians are encouraged to perform acute in-booth tests, in combination with a take home trial where needed. This may help the individual recipient experience the benefits of personalised settings in their real-world listening environment.

Further investigation of the potential benefits of ForwardFocus in the Nucleus 8 Sound Processor (commercial version) in various in-booth test conditions, including take home experience, for a complementary pool of experienced CI recipients, is underway. As the evidence builds and is reported, the information will help to further support evidence-based choices in patient management aimed at improving hearing ability in their daily life.

Study results confirm that the Nucleus 8 Sound Processor with ForwardFocus enabled, can provide significant hearing benefit for experienced CI recipients when listening to speech in front with competing background noise from the side.

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Compared to previous generation scan.

± ForwardFocus is a clinician enabled, user-controlled feature. It's recommended for children over the age of 12.

¥ As Bluetooth LE Audio compatible devices become available, a sound processor firmware update will be required to use certain features.

Disclaimers: The results from the field evaluation reported here are influenced by the survey design, clinics, clinicians', and recipients involved. Application and suitability of the Nucleus 8 Sound Processor with ForwardFocus in the broader cochlear implant population may vary according to local clinical protocols and individual recipient characteristics. ForwardFocus is not approved for use with paediatrics in all markets. Increasing focus on sounds in front means decreased focus on sounds coming from behind. This may not be suitable to meet the needs for all patients.