Cochlear™

Nucleus® Freedom™ Hearing Performance with Nucleus® 22 Recipients

ABSTRACT

The Freedom™ sound processor is available for use with the first generation Nucleus® 22 (N22) cochlear implant. Thirty-one recipients with an N22 implant were tested using the Freedom for N22 processor compared to their existing N22 processor. Significant improvements in speech perception were observed for soft and conversational level speech in quiet. The Freedom for N22 provided equivalent performance for speech perception in noise. Many of the recipients preferred to use a MAP with a SmartSound™ technology for listening in noisy and quiet situations.

Overall, recipients expressed a high level of satisfaction for the sound performance and usability of the Freedom processor. They remarked that they could hear more with this processor and liked the flexibility of the Freedom in terms of additional battery options and being able to use the processor with confidence around water. This processor upgrade also allowed recipients who could only use a Spectra bodyworn processor previously, to upgrade to an ear level processor for the very first time.

INTRODUCTION

Cochlear's latest sound processor, the Nucleus® Freedom™ is now available for recipients using the first generation implant, Nucleus® 22 (N22). The Freedom sound processor is used globally by over 25,000 recipients with Cochlear's second, third and fourth generation implants.

Fulfilling a promise of lifetime commitment, the Freedom for N22 provides SmartSound™ for a variety of listening environments, more choices in wearing configurations, battery options and accessories, moisture resistance and improved wearing comfort. The Freedom for N22 is the same sound processor used for the Nucleus® 24 (N24) and Freedom implants. The coil is different due to the transmission frequency.

A number of clinical studies have reported on the hearing performance outcomes and benefits for recipients using the Freedom processor with N24 and Freedom implants(1, 2). This paper presents the outcomes of a clinical study with 31 N22 implant recipients who used the Freedom processor. Additionally, this paper provides an overview of the technology in the Freedom processor and refers to some of the advantages and benefits reported in the literature.

THE CLINICAL VALIDATION STUDY

This study was conducted at Cochlear Limited in Sydney and Melbourne and Cochlear Americas in Denver. Ten recipients were recruited from Melbourne Cochlear Implant Centre in Melbourne, 15 recipients from Sydney Cochlear Implant Centre in Sydney and six recipients from Rocky Mountain Cochlear Implant centre, Denver Ear Associates and Southern Colorado Ear Nose and Throat Denver.

The main aims of the study were to:

1. Evaluate the Convert and Upgrade options available in Custom Sound™ 2.0 for existing N22 MAPs;
2. Compare speech perception performance with the Freedom and existing N22 processors (ESPrit™ 3G for N22, ESPrit™22 and Spectra);
3. Evaluate the benefit of SmartSound technologies with the Freedom processor for N22 recipients; and
4. Compare the usability of the Freedom with the existing processors.

The difference between Upgrade and Convert on the Freedom for N22 is the frequency allocation table. Where possible, Convert will copy the frequency allocation boundaries from the N22 processor onto the Freedom processor. Upgrade will use the Freedom default frequency allocation table for the number of channels in use. Both the Convert and Upgrade options:

- copy the T and C levels from the N22 processor MAP;
- apply a 40 dB IIDR (as this has shown to have additional benefits for hearing performance(3));
- increase the maxima to 8 (where a maxima less than 8 was previously used);
- copy Autosensitivity™ input processing if this was applied on the N22 processor; and
- adopt the Freedom default settings for volume and sensitivity levels.

PARTICIPANTS

The 31 participants were long term users of the N22 cochlear implant. Eighteen were ESPrit 3G for N22 users, eight were ESPrit22 users and five were Spectra users. No Mini Speech Processor (MSP) users were recruited for the study as none could be located at the trial sites. The mean age of the participants was 51 years (range 17-81 years). A summary of the age groups and associated processor information is presented in Figure 1.

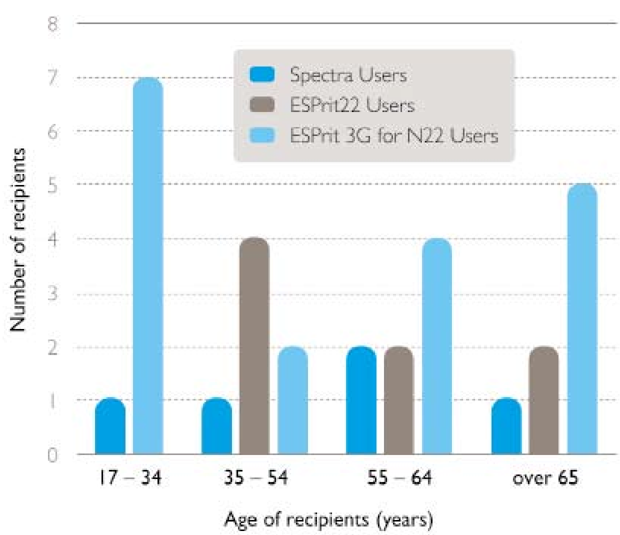

Figure 1: Histogram of recipient age by N22 processor type, N = 31.

PROCEDURES

The protocol was as follows:

1. The MAP on the recipient's existing processor was reviewed and optimized if not done in the last six months. The recipient had at least one week of use after the MAP was optimized.
2. Recipients logged battery life for at least one week and completed a usability questionnaire on their existing processor.
3. The fitting consisted of both an Upgrade and Convert MAP for all recipients.
4. Recipients had four weeks of take-home experience with the Convert and Upgrade MAPs and were encouraged to use both programs.
5. After four weeks, recipients chose their preferred MAP to continue with in the study. The Upgrade option was provided when recipients indicated no clear preference. Four MAPs were randomly assigned to the four programming locations in the Freedom processor to evaluate the use of SmartSound:
   - No input processing (none);
   - ADRO®;
   - Whisper™ + ADRO; and
   - Autosensitivity (ASC).
6. After seven and 10 weeks of experience, speech perception was evaluated with the recipient's preferred MAP(s) on the Freedom and existing processor in quiet and in noise:
   - CNC words at a soft level (50 dB SPL RMS) in quiet (2 lists);
   - CNC words at conversational level (60 dB SPL RMS) in quiet (2 lists); and
   - CUNY sentences at 65 dB SPL RMS in noise (3 lists with competing 8-speaker babble background noise. The signal-to-noise ratio (SNR) was determined for each individual to avoid ceiling and floor effects).
7. Recipients logged battery life with the Freedom throughout the study using suitable battery options as indicated in Custom Sound software. Types used included the Freedom BTE Controller (with three Zinc-air batteries) and the Freedom BTE rechargeable battery (Lithium Ion BTE battery) and the Freedom Mini BTE Controller (with two Zinc-air batteries).
8. Recipients completed questionnaires on usability and general satisfaction with their existing and the Freedom processor during weeks four and 10 of the study.

RESULTS AND DISCUSSION

1) Freedom for N22 Processor: Convert/Upgrade MAP Preference

There was no difference in preference between the Convert and Upgrade MAPs. Forty-eight percent of recipients (15/31) indicated a preference for the Upgrade MAP and 52% (16/31) preferred the Convert MAP. Preference for an Upgrade or Convert MAP was not related to:

- age;
- N22 processor type;
- frequency allocation table used;
- number of maxima (total stimulation rate increase); or
- number of active channels.

Recipients were asked to indicate how strong their preference was for an Upgrade or Convert MAP. Approximately half (44%) of those who indicated a preference for the Upgrade MAP specified a moderate or strong preference, and 67% of those who picked the Convert MAP showed a moderate or strong preference.

2) Speech perception results: Comparing the Freedom and existing N22 processor

The results in Figure 2 show the mean speech perception for the N22 and Freedom processor at week 10. Deviations from the protocol resulted in not all recipients completing testing in quiet and noise. Scores were analyzed using a One Way Repeated Measures ANOVA. Recipients used their preferred MAP(s) in quiet and in noise (i.e. some recipients used MAPs with SmartSound technologies). Some of these recipients also used ASC on their existing processor in the noise and quiet testing and a small number of the ESPrit 3G recipients used Whisper for testing in quiet.

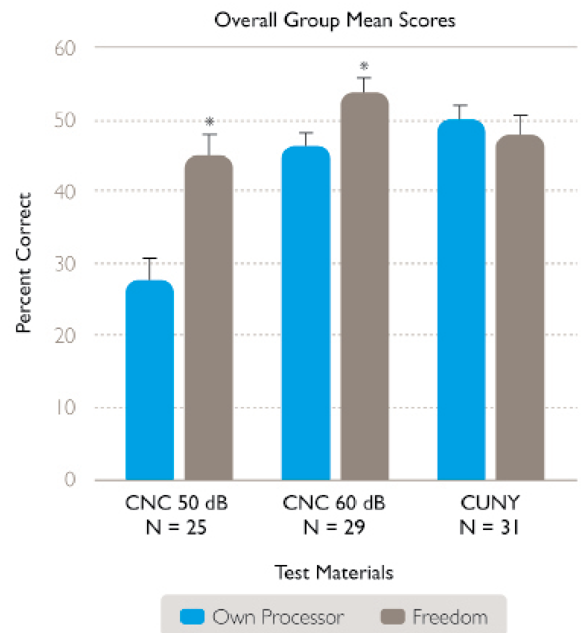

Figure 2: Overall group mean scores for speech perception testing using own and Freedom for N22 processor. Error bars show the standard error.

Performance in Quiet

Results showed a statistically significant improvement in speech perception with the Freedom when listening to CNC words at a soft level in quiet ($p<0.001$) and CNC words at a conversational speech level in quiet ($p<0.001$). Specifically, when listening to soft speech, there was an average 17.4% improvement for recipients using the Freedom (mean = 45%) over their existing N22 processor (mean = 27.6%). Listening to conversational level speech resulted in an average 7.2% improvement with the Freedom (mean = 53.7%) over their own N22 processor (mean = 46.5%).

Performance in Noise

There was no statistical difference for scores on the CUNY sentences test demonstrating that the Freedom (48.6%) is equivalent to the recipient's own processor (50%) in noise.

3) Use of SmartSound

SmartSound Preference in Quiet

Recipients were asked to select their preferred MAP in quiet and in noise from a choice of a standard MAP (no input processing), ADRO, ASC and Whisper + ADRO. Recipients were blind to which MAP was in each programming location on their Freedom processor.

At 10 weeks, just over half of the subjects preferred the use of SmartSound (55%). Among those who preferred a SmartSound technology, an equivalent percentage chose ADRO (22.5%) and Whisper + ADRO options (22.5%), and 10% of recipients preferred to use ASC.

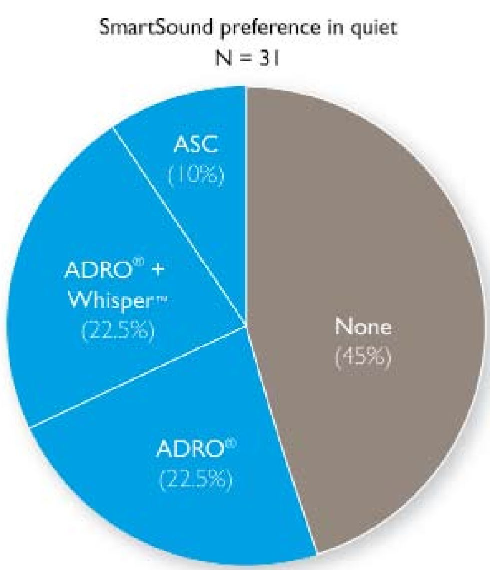

Figure 3: Descriptive statistics showed 55% of the participants (17/31) opted for a SmartSound technology for use in quiet situations with the Freedom for N22. Note: not all of the SmartSound technologies were used in this study.

The increase in Instantaneous Input Dynamic Range (IIDR) as well as an increase in microphone sensitivity on the Freedom, may account for the 45% of recipients choosing not to use input processing in quiet. This result is comparable to other Freedom studies[1, 2]. Due to being long-term users of their existing processors, this group of recipients may show an increase in the uptake of SmartSound technologies over time as they become more familiar with the Freedom processor.

SmartSound Preference in Noise

Overall, 77% of recipients preferred to use a SmartSound technology for listening in noise. Sixty-one percent of recipients preferred to use ASC and 16% of recipients indicated a preference for ADRO in noise. No recipients indicated a preference for the Whisper + ADRO option in noise which is an expected result as the use of Whisper is not recommended in noisy environments[4].

The high preference for ASC could be related to how the technology monitors the noise level of the incoming signal and automatically modifies the sensitivity (or gain) of the microphone so that the noise level is kept at a comfortable level for speech understanding. ADRO automatically analyzes the frequency channels of the incoming signal, reducing the gain of channels that may be potentially uncomfortable and increasing the gain on channels that may be potentially inaudible. The result of using ADRO is comfortable and audible sound, which may explain why 10% of recipients chose this SmartSound technology. The remaining 23% of recipients who preferred not to use a SmartSound option in noise may prefer a sound closer to their own N22 processor.

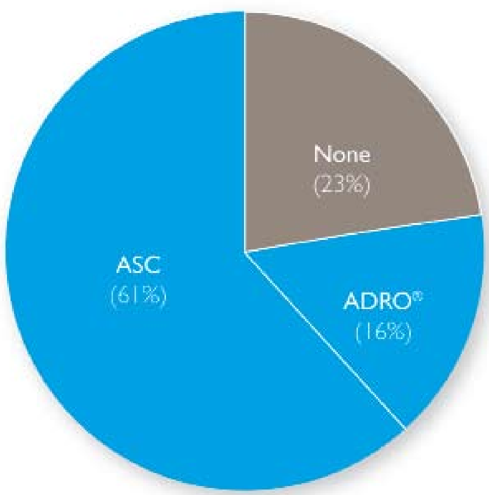

Figure 4: 77% of recipients (24/31) opted for a SmartSound technology in Noise. Note: not all of the SmartSound technologies were used in this study.

In general, the quiet and noise preference data suggests that recipients do discern differences among the SmartSound technologies and recipients' subjective comments support this. Individuals may prefer different SmartSound options for various listening scenarios to optimize speech percpetion and music enjoyment.

4) Evaluation of overall satisfaction with the Freedom sound processor

Recipients completed questionnaires on the use of the Freedom processor after four weeks of use. Twenty-four recipients completed this questionnaire during week four. A second questionnaire was administered at week 10, of which 12 were returned.

Results of the first questionnaire indicated that 83% of the participating recipients were satisfied or very satisfied with the Freedom sound processor. This level of satisfaction refers to:

- the sound quality of the processor;
- features of the Freedom processor such as different battery options; and
- usability.

A small percentage of recipients indicated they were neither satisfied nor dissatisfied (4%) or somewhat dissatisfied (13%). These participants reported some difficulty adjusting to the sound and usability differences with the Freedom processor. The participants recorded improved satisfaction levels when completing the second usability questionnaire at the 10 week study visit, indicating further adjustment to the sound quality and usability of the Freedom after a longer period of use. Some recipients reported shorter battery life in comparison to their existing N22 processor, but liked that they had the option of the Freedom BTE rechargeable battery.

Information on Battery Life

Some recipients in this study experienced a reduction in battery life with the Freedom processor. The Freedom processor uses digital signal processing which has increased power requirements over the N22 analogue processors. Furthermore, the additional features with the Freedom technology such as the LCD will also use more battery power.

The recipients in this study had an average battery life of 34 hours with the Freedom BTE Controller (i.e. using three Zinc-air batteries). The average battery life of the Freedom BTE rechargeable battery was 14.3 hours. The average battery life of the Mini BTE Controller (using two Zinc-air batteries) was 25.6 hours. During the trial, seven recipients used the Mini Controller. Note: a small proportion of N22 recipients will not be suitable for using Zinc-air batteries due to the higher power requirements of the N22 implant coupled with high stimulation level requirements of some N22 recipients.

Subjective Comments

It is difficult to capture listeners' perceptions of many real-world environments by means of quantitative data collection, such as speech testing and questionnaires alone. For this reason, in addition to the performance and preference data presented, participants were given questionnaires to write comments about their listening experiences during the trial. Several themes emerged when analyzing the anecdotal comments from the questionnaire. These comments correlate well with the speech perception and SmartSound preference data.

The first theme was general acceptance of the sound quality delivered by the Freedom processor. Although most recipients in this study took approximately four weeks to acclimatize to the sound and use of the Freedom, some recipients needed a longer period to adjust. Most recipients reported that they could hear more sound than with their previous processor (which was advantageous but took some time to get used to for some recipients). This could be explained by the wider IIDR available in the Freedom processor and an increase in microphone sensitivity, resulting in improved speech perception at low input levels.

The second theme reflected by the recipients was the advantages in having access to all of the new features available through the Freedom, providing flexibility. Recipients in the study commented on the availability of more battery options including the Freedom BTE rechargeable battery which helps to reduce cost of ownership. Recipients also commented on the comfort of the Freedom processor with some of the recipients, i.e. Spectra users, being able to wear a BTE processor for the first time. Recipients reported being able to use the Freedom around water with confidence. Recipients also liked having access to features like the LCD, telecoil and battery tones. Finally, access to different SmartSound technologies within the four programs in the Freedom, along with the ability to adjust volume and sensitivity, was rated as a benefit in terms of increased performance and comfort in different listening situations.

CONCLUSION

The results in this study show that the Freedom sound processor is equivalent or better than the recipient's own sound processor for different listening situations. In both quiet and in noise, the majority of participants prefer the use of SmartSound. SmartSound technology provides more options and automates some of the manual functions that recipients have performed in the past. Most participants were satisfied with the overall performance of the Freedom processor. Some recipients reported reduced battery life with the Freedom processor compared to their own processor. This reduction is mostly due to additional processing capabilities and features of the Freedom.

Recipients report that they liked the additional flexibility in terms of increased battery configurations and being able to wear the processor around water. Recipients also remarked they heard more sound with the Freedom than with their existing N22 processor. As a result of this, counselling may be needed on the impact of the wider IIDR and the availability of increased microphone sensitivity. It is anticipated that some N22 recipients who have used their existing processor for many years, may need a longer duration to adjust to the sound of the Freedom as the technology and parameters used in the Freedom are quite different to what they have experienced with N22 processors.

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