Results of the first clinical evaluation of Cochlear™ Baha® 3 Power (BP110 Power) Sound Processor

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This clinical study examined the outcomes of the Cochlear™ Baha® 3 Power (BP110 Power) sound processor when compared to the previous gold standard (the Baha Intenso). A total of 20 patients with mixed hearing loss participated in the study. The results showed that this new, fully programmable high power Baha sound processor provided on average superior speech recognition in noise compared with previous generation of Baha sound processors. Overall, the use of the Baha 3 power (with directional microphone) demonstrated a mean improvement, in noisy listening situations, of 4.8dB (SNR) over the Intenso sound processor. Clinically, this corresponds to an over 50% improvement in speech recognition in noise.

INTRODUCTION

Recently, a number of reports have discussed the benefits in terms of hearing performance received by the latest generation of Baha sound processors. The Baha 3 System sound processors utilise the latest signal processing technology. Amplification is provided through a multiple-channel, non-linear amplification scheme, effectively balancing the requirements for loudness with the limited MPO of bone conduction processors. Amplification targets are prescribed through the only available prescription dedicated to direct bone conduction (Cochlear Baha Prescription), which aims to compensate for the degree of hearing loss and incorporate adaptations specifically for bone conduction. The combination of the latest sound processing technology and specific fitting solutions results in excellent hearing outcomes for patients with conductive, mixed or single-sided sensorineural deafness.

Given the significant development in the Baha 3 Power, it is important that this system be evaluated to determine whether these mechanical and signal processing technologies increase patient benefit. To determine the degree of benefit provided, an evaluation was performed to investigate potential performance improvements of the Baha 3 Power. For comparison, the Baha Intenso was selected as the control device because it represents the current platform for people requiring more power. These could include patients with mixed hearing loss, ones with single-sided sensorineural deafness and a large transcranial attenuation or patients in the demonstration situation where sound is attenuated by the skin.

I. MATERIALS AND METHODS

(a) Subjects

In total, 20 adults with skin penetrating titanium implants for standard attachment of a Baha sound processor participated in this study (Table 1). A total of 21 subjects were enrolled in the study. One subject was withdrawn due to not meeting the inclusion criteria of open-set sentence recognition in noise with Intenso. All subjects had mixed hearing loss, defined as bone conduction thresholds (PTA: 500, 1000, 2000 & 3000Hz), between 15 and 55dBHL with at least a 10dB air/bone gap. The average bone conduction and air conduction thresholds for the participants can be observed in Figure 1. Each subject was selected according to internationally accepted criteria. All participants were experienced Baha sound processor users with at least 12 months prior use.

(b) Instruments

Two sound processors were compared. The Baha Intenso was the control device and the Baha 3 Power was the test processor. It should be noted that the current study took place before the Baha 3 Power was CE marked, which is why manufacturing prototypes PS1 and PS2 were used. Technical verification confirmed that the prototype sound processors...
were equivalent to the commercially available Baha 3 Power.

The Baha 3 Power was designed to have a higher possible full-on gain than the Intenso, no significant differences (p>.05). Figures 2 and 3 illustrate the MPO and comparative performance between subjects 1-10 and 11-20 demonstrated for the study participants demonstrating the mixed hearing loss.

Figure 1: Mean bone conduction and air conduction thresholds for the study participants demonstrating the mixed hearing loss. The shaded area highlights one standard deviation of the mean.

The sound processor prototypes were equivalent in terms of gain, output, fitting prescription, channels, microphones. A sub-analysis comparing the comparative performance between subjects 1-10 and 11-20 demonstrated no significant differences (p>.05). Figures 2 and 3 illustrate the MPO and full-on-gain comparison of the Intenso and Baha 3 Power. The Baha 3 Power was designed to have a higher possible full-on gain than the Intenso, which should be considered in any evaluation of performance. The gain and maximum output were not matched between the sound processors as the purpose of the study was to investigate what expectation of differences in hearing performance may be expected clinically. The control sound processor was fitted as it would be fitted in a clinical situation. The procedures outlined in the Baha Fitting Guide for Professionals were followed. The patients adjusted the sound processor volume control setting to provide a positive initial listening experience. The test sound processor was fitted using the Baha Fitting Software Version 2.9. The Client, Indication and Connection type were configured using the new BC Select step. This enables the audiologist to quickly set up the sound processor and incorporates the latest research data on correction for transcranial attenuation, cross hearing and transmission loss through the skin. This pre-configuration, combined with the measurement of actual thresholds through BC Direct, enables quick sound processor configuration to provide a positive initial listening experience. The patients were not allowed to adjust the volume control setting during the test procedures.

### Procedures

All measurements were conducted in a sound-insulated room meeting ANSI standards for maximum permissible noise levels [ANSI S3.1-1995]. Auditory evoked testing consisting of air and bone conduction testing was performed in accordance with ANSI S3.1 in a sound-insulated test room using a Medison Canara Audiometer. All procedures were randomised between sound processors to control for learning and for procedural effects. For comparison purposes, bone conduction thresholds were obtained at 500, 1000, 2000, 3000, and 4000Hz with narrow-band noise applied via air conduction to the contralateral ear when necessary. Measurement of free-field audibility were collected via loudspeakers placed approximately one metre from the participant. Due to the test sound processor’s active feedback cancellation circuit, measurement of free-field audibility were collected using narrow band noise at 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000Hz.

To evaluate speech recognition in quiet surroundings, monosyllabic phonetically balanced (PB) words were used. It included 12 monosyllabic phonemically balanced (PB) word lists of 10 words with carrier phrases. The test was performed at 50, 65 and 80 dB sound pressure levels (SPL) and test values were expressed in the percent (%) of understood words in a sentence. Scores were recorded as the number of correct words per list. Speech recognition in noisy surroundings was conducted using the Swedish version of the Hearing In Noise Test (HINT).

Speech was presented from the front speaker with noise from the rear speaker. The noise level was kept constant at 65 dB SPL and the level of the speech was adapted to provide a 50% level of understanding. For comparisons, the sound processors’ signal processing was fixed in the omnidirectional mode. To compare speech understanding performance in the omni versus directional microphone mode, the sound processor was fixed in each mode prior to testing. In all measures of speech understanding in noisy surroundings, the noise management system was disabled to ensure equivalence.

Measuring loudness growth was conducted using narrow band noise (1/3 octave) presented with a centre frequency at 500Hz or 3000Hz. The presentation level was randomly varied in 10dB steps between 30dB SPL and 90dB SPL. Participants were asked to respond using a 7-point visual analogue scale ranging between very soft and very loud.

II. RESULTS

(a) Audibility

Free-field audibility readings demonstrated that the Baha 3 Power Sound Processor provided significantly improved (p<.05) audibility from 3000-8000Hz (Figure 4). This is most likely related to two factors. First, the Cochlear Baha Prescription (CBP) specifically increases the amplification in the high frequencies to match the sloping hearing loss. Since the Intenso is fitted without fitting software, it can only increase the overall gain and not specifically match the hearing loss. Second, the Baha 3 Power Sound Processor has been designed to reduce the occurrence of internal feedback, making more gain available before feedback occurs.

(b) Speech recognition in quiet situations

Measures of speech recognition in quiet surroundings (Figure 5) showed small (4%) and no significant difference in speech recognition at 50 dB SPL and 65 dB SPL. It is likely that at 80 dB SPL, there was a ceiling effect since performance was above 97% for both conditions. Importantly, this result demonstrates the benefit of Baha solution as an intervention for people with mixed hearing loss in that it can provide a rate of more than 80% speech recognition at normal conversational levels without visual, grammatical or contextual cues.

(c) Speech recognition in noisy situations

When the Baha 3 Power’s settings were prescribed by the fitting software (and microphone mode fixed to omnidirectional), it performed 2.5 dB better in terms of SNR improvement (Figure 6). To determine statistical significance, an Analysis of Variance (ANOVA) was performed (F[1,19]=26.25, p<.0001) indicating that performance with the Baha 3 Power was significantly better than the Intenso sound processor. Clinically, assuming that each 1 dB improvement in hearing performance equals a 2.7% improvement in overall performance, we can conclude that the Baha 3 Power provides an over 25% improvement in speech understanding recognition in noisy surroundings. Importantly, each subject in the study had better speech recognition scores with the Baha 3 Power than with the Intenso.

Performance studies of the omni and directional microphone modes for the Baha 3 Power indicated a significant benefit (F[19]=.60,.49; p<.0001) of 2.3 dB (Figure 6). Combined, in the most difficult listening situations, this provides an improvement of over 50% in speech recognition.

III. DISCUSSION

The present study clearly demonstrates the improved listening performance that the Baha 3 Power provides for people with mixed hearing loss. The study demonstrates that the latest signal processing provides increased access to high frequency sounds. Importantly, a large clinically significant improvement in speech recognition in noise was also observed. The addition of an automatic directional microphone in the power Baha segment provides a further improvement in speech recognition. Since the P1 function

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Table 1: Demographic details describing the attributes of the 20 participants.

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Figure 2: Maximum output force level measurement comparison of the Baha 3 Sound Processor and the Baha Intenso. The Baha 3 Power has greater force output in the low and high frequencies with increased damping of the peak resonance.

Figure 4: Free-field aided speech (dB SPL) as measured for the control and test sound processor. The air conduction values are also present (proband) an indication of the overall degree of functional gain.

Figure 6: Comparison of speech recognition in noise performance of the Intenso and Baha 3 Power demonstrating a 2.5 dB improvement in signal-to-noise ratio. Comparison of the omni-directional and directional microphone in Baha 3 Power showed a further 2.3 dB advantage in speech understanding in noise. Error bars indicate one standard error. Better performance is indicated by 50% performance in a poorer signal-to-noise ratio.
The addition of fitting software for patients with mixed hearing loss, where it can be hypothesized that there is more slope to the cochlear hearing loss, is invaluables. The gain and MPO were adjusted across the test sound processor’s 12 channels to match the patient’s hearing loss profile. It is interesting that a number of the patients with the control sound processor, despite having on average a large hearing loss, did not use the full volume control setting. It may be hypothesized that this is due to the sloping nature of the hearing loss and the participants setting the preferred volume control setting based on the perceived loudness in their area of best hearing acuity. Therefore, the ability to match the amplification to the hearing loss is invaluables. The audometric results indicated that this enabled increased high-frequency amplification, leading to potentially enhanced communication performance.

IV. CONCLUSIONS

In summary, the Baha 3 Power Sound Processor represents an important addition to the Baha 3 System portfolio. Significant advantages in terms of supra-threshold audibility, speech recognition in soft and moderate levels, and speech recognition in noise were observed when compared with previous generations such as the Baha Intenso. Loudness growth data indicate the effectiveness of prescribing amplification for this population. Furthermore, the directional microphone, available for the first time in a power processor, provides an additional increase in speech intelligibility in noisy surroundings and a reduction in listening effort.

REFERENCES


* The Baha 3 System consists of:

Cochlear Baha B200 Implant (Baha 3 Implant)
Cochlear Baha BA300 Abutment (Baha 3 Abutment)
Cochlear Baha BPT00 Sound Processor (Baha 3 Sound Processor)
Cochlear Baha BPT10 Power Sound Processor (Baha 3 Power Sound Processor)