
C1 Harmony Upgrades: The St Thomas' Paediatric Experience and Clinical Lessons Learned

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Introduction

The first two generations of Advanced Bionics cochlear implants (1.0 and 1.2), commonly referred to as the C1, were distributed between 1991 and 2001: with approximately 8,000 devices implanted worldwide. Upgrades are necessary because after at least 20 years since the first 1.0 processor was designed, the original components are no longer available to manufacture or properly maintain these processors. The latest Harmony™ processor which drives the CII and HiRes90K implant generations can now be used with the C1 implant.

It was intended that the C1 Harmony processor would support not only the original strategy types, Simultaneous Analogue Stimulation (SAS), Continuous Interleaved Sampler (CIS) and Multiple Pulsatile Stimulation (MPS), but that the original programme parameters would remain available. This was intended to minimise acclimatisation time to a new sound quality for a recipient. It was anticipated that the C1 Harmony may provide (i) for some children a change from bodyworn to behind-the-ear (BTE) processor, (ii) use of the T-Mic for access to directional sound input, (iii) access to improved front-end processing with the potential for a larger Input Dynamic Range (IDR), (iv) the change from a bodyworn FM system to a wireless FM system using the i-connect earhook and (v) an improved battery life.

For clinicians administering the upgrade for the C1 children, the SoundWave 2.0 Professional Suite fitting software should be used. Since the SoundWave 2.0 programming software was not available at this early stage, the Bionic Ear

Programming Software .NET version (BEPSNet) was used. This paper describes the upgrade experience at the St Thomas' Paediatric Auditory Implant Programme, covers the full clinical deployment and describes clinical lessons learned during the process.

Method

C1 Harmony upgrades were performed in a group of 24 paediatric C1 users. The children ranged in age from 11.8 to 16.4 years with a mean of 14.1 years at the time of upgrade. At implantation the children ranged in age from 2.0 to 7.0 years, mean 3.6 years. Use of the original processor ranged from 8.9 to 11.6 years, mean 10.6 years. The large majority, 17, used the SAS strategy, while 5 used the Pulsatile CIS strategy and 2 the partly simultaneous MPS strategy.

The upgrade involved replicating each user's original programme parameters (strategy type, active electrodes, stimulation rate, T and M levels, IDR and channel gains) in the C1 Harmony processor. After the user's parameters had been downloaded to the new C1 Harmony processor, an evaluation was made to ensure that the volume was comfortable and sound quality acceptable. As it was uncertain whether the conversion tables used in BEPSNet would provide a loud auditory perception, M-levels were deliberately lowered by 40-50 clinical units (CU) before the speech processor was switched to live mode. Once in live mode the M-levels were increased globally to reach, either a comfortable auditory perception, or a level which matched the original programme settings.

The radio frequency (RF) value was set to the required value to maintain communication between implant and processor. RF was evaluated with the processor active, but not connected to the Clinician's Programming Interface (CPI), to ensure consistent lock when the processor was powered by the battery alone. Of note, all children required the maximum RF level (15) for lock to be obtained with their original processor.

Since we report a clinical procedure, rather than a formal prospective clinical study, procedures were not rigorously applied to all of the children. Rather, the most appropriate procedures required to manage each individual child were adopted. During the initial processor upgrade, soundfield aided level testing was conducted, both for the original sound processor and then for the C1 Harmony. Additionally, speech perception testing, either in quiet or in competing noise was measured for the original processor and the C1 Harmony. The BKB sentence test was used pre-upgrade and at one month post upgrade and presented at 70 dBA in quiet. If appropriate, the BKB test was administered using pink noise with a signal-to-noise ratio (SNR) of +10 dB. Where a ceiling effect was noted the SNR was decreased to +5dB or 0dB. Additionally soundfield aided measures were obtained at a one month post upgrade appointment.

Results

All 24 children were successfully upgraded to the C1 Harmony processor. In 20 cases the original programme parameters were maintained, allowing the use of the original strategy and stimulation rate previously used. In the remaining 4 cases, the original strategy was maintained, however the M-levels needed adjustment. The SAS users tended to get used to the new processor immediately; typically acclimatizing before the end of the fitting session. Some CIS users took longer, finding the initial sound quality quite strange, although speech was still understood.

With the C1 Harmony, sounds were reported to be clearer and fuller. Reports of hearing better in school or in noisy places were also noted. For the 16 users for whom complete results were available, group mean soundfield aided (0.5kHz, 1kHz, 2kHz, 4kHz) results were equivalent before and immediately after upgrade, 31.0 and 31.6 dBHL respectively: with a small, non-significant ($p=0.8$) improvement to 29.4 dBHL at the one month follow up appointment (Figure 1).

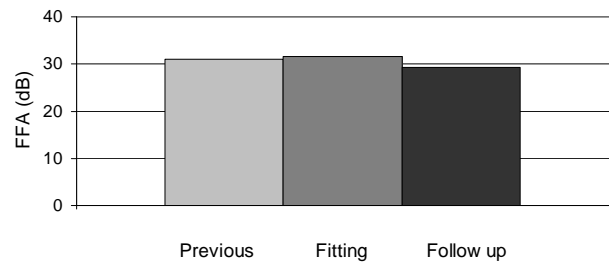


Figure 1: Group mean soundfield aided levels (0.5, 1.0, 2.0 and 4.0 kHz) for the previous processor, the C1 Harmony immediately following upgrade and the C1 Harmony processor at a one-month follow up appointment

Speech perception results were available for 15 of the 24 children before and after upgrade: 13 measured in quiet, 8 in noise, with 6 children having measures for both quiet and noise. Individual results in quiet showed that only 2 of the 11 scores were lower with the C1 Harmony: one child dropping by 1% the other child by 3%. In noise two scores were also lower for the C1 Harmony, one by 5%, the other by 7%. Group mean scores in quiet were 72.1% and 76.6% correct for the previous and C1 Harmony processors respectively. In noise the group mean scores were 60.0% and 66.8 % correct for the previous and C1 Harmony processors respectively (Figure 2). Student t tests showed no significant statistical difference in noise ($p=0.07$), but a significant improvement in quiet ($p=0.02$). A sign test considering all of the speech perception data showed the C1 Harmony to be significantly better at the $p=0.05$ level.

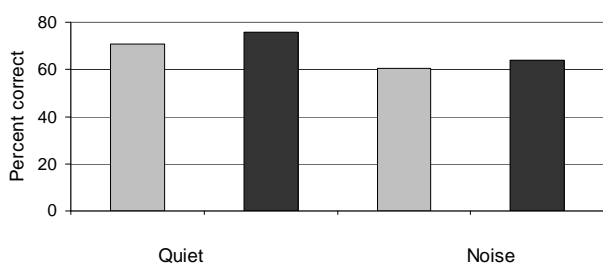


Figure 2: Group mean scores in quiet and in noise for the BKB sentence test for the previously used processor before upgrade (lighter bars) and the C1 Harmony processor after upgrade (darker bars).

The RF level was found to be reduced for the majority of children when using the C1 Harmony, which therefore, improved the battery life. Mean battery life improvement was 2.3 hours across the group: 1.6 hours for SAS and 3.4 hours for CIS. The total battery life, before and after upgrade, was 3.6 and 5.9 hours respectively (Figure 3).

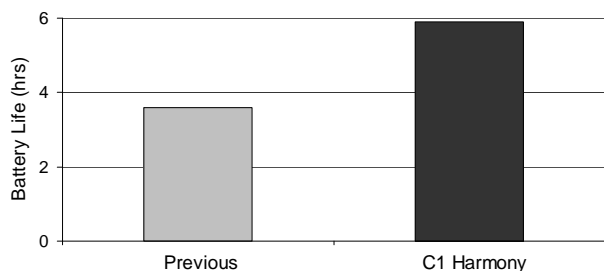


Figure 3: Group mean battery life for the previously used BTE and C1 Harmony processors

Discussion

Upgrades were on the whole successfully conducted. All children were maintained in their original strategies with generally the same programme parameters being used. Attempts to use the improved front end processing of the C1 Harmony were made through increasing the IDR beyond the value used in the previous processor. This was only accepted by 1 child and may be, at least in part, due to the C1 implant being less capable than the more recent CII and HiRes90k implants in terms of digital word length.

The improvement seen in speech perception in quiet could be a result of the updated technology of the C1 Harmony processor. A lack of statistically significant improvement in noise may be explained by only eight of the children being judged suitable for testing in the presence of competing noise, hence limiting the number of test results available. Combining speech perception data between the fitting and follow up sessions is believed to be valid since it will if anything bias against C1 Harmony due to a lack of familiarity where testing was conducted very soon after receiving the new processor.

It is recognised that through this being more of an audit of clinical practice than a formal study, results are not being presented for all children. The reasons for exclusion were that four of the children were autistic and one child was a non-user (of her previous processor yet is now regularly using the C1 Harmony processor). Additionally, four children were not suitable for testing with the BKB sentence material. However, with the large majority (79%) of possible results represented, these scores do form a reasonable picture of C1 Harmony impact.

A clinically significant improvement in battery life should allow a group mean use of around two rechargeable batteries per day rather than three, or four, with the previous BTE processor. This change should also extend the use of each battery since a given number of recharge cycles will now extend over a longer time period.

The BEPSNet software used during these upgrades was not user friendly and has subsequently been replaced by the SoundWave 2.0 fitting software. This change should simplify manipulation of programme parameters in future fitting sessions, making it easier to properly explore the fitting space available to each child and be more time efficient, as all data had to be entered manually into BEPSNet software.

During this process valuable clinical lessons were obtained.

Clinical advice to other clinicians:

- Counsel children, especially younger children, for the upgrade as they have never had an upgrade before.
- Do not change the MAP to improve the sound quality at the initial fitting.
- Don't assume the conversion of M-levels will be correct but change the M levels if sound is uncomfortably loud or too soft.
- Before stimulation, decrease M-levels globally (by at least 40-50 CU).
- Assess the position of the implant package in relation to the processor. If the package is too close to the processor and causes intermittency, then change from the Auria headpiece to the Platinum headpiece (PHP). This was a problem for 5 children and was resolved for 4 by changing to a PHP. One child had to wear the processor on the contralateral ear with a longer lead to the PHP.
- The above issue also caused problems once wireless FM systems were trialled, as the FM receiver was in contact with the headpiece and caused radio frequency interference between the two devices. The use of the FM system was discontinued if the child was not willing to wear the processor on the contralateral ear.
- Assess the required RF level with the processor not connected to the CPI.

In general the following are improvements for children using the C1 Harmony:

- The use of a BTE processor instead of a bodyworn processor
- Lighter and more comfortable
- Better processor retention
- Increased battery life
- Different wearing options available
 - Off the ear power option (OEPO)
 - i-Connect earhook for use with the wireless FM system

Conclusion

All users have adapted to and prefer the new C1 Harmony processor and were therefore successfully upgraded. Speech perception in quiet was significantly improved. Results in noise were not significantly different. Battery life improvement was clinically significantly improved. The C1 Harmony processor now allows this group to continue using their implants with access to improved technology.

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For further information about this work or the auditory implant team, please contact the first author at: anzel.britz@gstt.nhs.uk or look on the website www.gstt.nhs.uk/auditoryimplants