

Pediatric evaluation of the ClearVoice™ speech enhancement algorithm in everyday life

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Abstract

ClearVoice™ enables Advanced Bionics cochlear implant users to improve their speech understanding in difficult listening environments, without compromising performance in quiet situations. The aim of the study was to evaluate the benefits of ClearVoice in children.

Children between six and fourteen years of age randomly tested two modalities of ClearVoice for one month each. The baseline program, HiRes 120™, and both ClearVoice programs were evaluated with a sentence test in quiet and noise. Parents and teachers completed a questionnaire related to everyday noisy situations.

The switchover to ClearVoice was uneventful for both modalities. Adjustments to thresholds and comfort levels were required. Seven out of the nine children preferred a ClearVoice program. No impact of ClearVoice on performance in quiet was observed and both modalities of ClearVoice improved speech understanding in noise compared to the baseline program, significantly with ClearVoice high. Positive outcomes were obtained from the questionnaires and discussions with parents and children.

This study showed that children benefited from using ClearVoice in their daily life. There was a clear trend towards improved speech understanding in noise with ClearVoice, without affecting performance in quiet; therefore ClearVoice can be used by children all day, without having to change programs.

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Introduction

Children receiving a cochlear implant at an early age are now likely to achieve performance levels approaching that of their normally hearing peers.^{1,2} Many of these children, implanted at an early stage, attend mainstream schools and performance is excellent in quiet, but still remains challenging in noisy environments.^{3,4} The use of frequency-modulated (FM) systems, especially in schools, can significantly improve hearing in background noise.⁵ Other technologies offered by the manufacturers of cochlear implants, such as multi-microphone directionality and signal processing noise reduction algorithms, also appear effective in improving speech understanding in noisy situations for adults and children.^{6,7}

In December 2006 Advanced Bionics (Advanced Bionics AG, Stäfa, Switzerland), launched its latest sound coding strategy HiRes 120™, which implements virtual channels by current steering between two adjacent physical electrodes. Several studies have shown the benefits of this strategy over HiRes™, both singularly and in combination with the Harmony™ sound processor, in both adults and children.^{8,9} The use of HiRes 120 at first fitting has now become part of the standard clinical routine in numerous centres both in adults as well as in children (Noël-Petroff *et al.* 2009, personal communication at the 9th European Symposium on Paediatric Cochlear Implantation).⁸ ClearVoice™ is a recent proprietary algorithm from Advanced Bionics, based on the HiRes 120 strategy, and has been designed to improve speech understanding in difficult listening environments by reducing the stationary noise and emphasizing the dynamic channels containing more speech. The algorithm acts on the signal after it has been through the band pass filters, and is based on the assumption that the speech envelope is modulated and the noise envelope is unmodulated. From the analyses of the modulation frequency and modulation depth, the signal-to-noise ratio (SNR) is estimated in each frequency band separately and bands with low modulation depths and thus low SNRs are attenuated. There are three levels of attenuation available: low (-6dB), medium (-12dB) and high (-18dB). ClearVoice can currently be used with the Harmony and Neptune™ sound processors.

Preliminary studies showed very promising results for improving hearing performance in noise with ClearVoice in adults.¹⁰⁻¹³ Limited research, however, is available on the use of ClearVoice in the implanted paediatric population.

A preliminary study of 24 children, conducted at the Children's Hospital of Eastern Ontario in Ottawa (Canada), showed that most of the children studied obtained benefit from ClearVoice in their daily lives (Schramm *et al.* 2011, personal communication at 13th Symposium on Cochlear Implants in Children). The mean age of the children in the study was 11.17 years (SD=3.19) at the time of the testing, ranging from 6 to 17 years old. With ClearVoice activated, a mean improvement of 19% in sentence scores for hearing in noise over the baseline HiRes 120 program was observed. However, it was still necessary to collect more information on the benefit received from ClearVoice in children and to define appropriate paediatric recommendations for the fitting of ClearVoice parameters. The aim of this study

was to collect similar pilot data on the benefit of ClearVoice in the paediatric population that was slightly younger than in the previous study group.

Materials and Methods

Nine subjects were recruited to the study in two phases: a first group of six older subjects aged 8.4 to 13.4 years old (RDP01 to RDP06), with the ability to provide reliable feedback; after positive feedback from this first group, a second group of three younger subjects aged 6.6 years to 8 years (RDP07 to RDP09) was subsequently recruited. All participants were unilaterally implanted with Advanced Bionics CI1™ or HiRes 90K™ cochlear implants and used a Harmony speech processor. They had been using their cochlear implant for an average of 6 years (SD=2.4) with a minimum of 1.8 years and using the HiRes 120 strategy for an average of 3.2 years (SD=0.9) with a minimum of 1.8 years. They were all required to be able to provide feedback on their hearing perception and had no additional disability. Overall, children were aged between 6.6 years old and 13.4 years old with an average of 9.7 years old (SD=2.4) at the time of the study. Speech perception performance was graded according to the categories of auditory performance (CAP)¹⁴ and scores ranged from 5 for five of nine subjects, which corresponds to the ability to *understand common phrases without lip-reading* to 7 for four of nine subjects, which corresponds to the ability to *use of telephone with known speaker*. Subject demographics are shown in Table 1.

This study was approved by the appropriate local ethics committee and the national competent authority. Before participating a signed consent form for each participant was obtained.

Procedures

Subjects were evaluated using the CAP, speech perception testing in quiet and noise, a pure tone audiogram and the APCEI profile.¹⁵ The APCEI profile enables the overall capability of a child to be assessed. It is possible to see at a glance if the child: A = Accepts and wears his/her hearing device, P = Has good auditory perception, C = Can identify sounds or well known words or more, E = Tries to use oral language by means of isolated words or structured sentences, I = Is intelligible or not when s/he speaks. Each area is assigned a score between 0 and 5.

A listening questionnaire was also administered to parents and

teachers at the end of each session. The questionnaire took some of the questions and the scoring system used in the Listening Situations Questionnaire, developed by the MRC Institute of Hearing Research (United Kingdom),¹⁶ to collect information on hearing performance in daily life in various noisy situations. This modified version was then translated into French. The questionnaire was divided in two parts: one dedicated to the parents, with nine questions and one to the teachers, with three questions. Each question was illustrated by a picture of a noisy situation and constructed as follows *Did your child encounter difficulties to...* with five possible answers (Figure 1).

Parents and teachers were asked to complete the questionnaire at the end of each session; baseline for the HiRes 120 program and after one month of experience with each of the ClearVoice programs.

The study required three visits to the centre. During the first visit subjects were evaluated with their baseline HiRes 120 program. Subjects were then randomised into two groups; one group was fitted with ClearVoice medium and the other ClearVoice high. Subjects were then switched-over to one modality of ClearVoice, defined by the group they belonged to, with the Advanced Bionics SoundWave 2.0 software. The fitting parameters were kept the same as those of the baseline program HiRes 120, except for the most comfortable levels (M-levels) and the threshold levels (T-levels), which were adjusted according to the feedback of the child. This program was immediately assessed with speech testing in quiet and in noise, providing a measure of the ClearVoice acute condition. The first ClearVoice program was then used for one month by the child in their daily life.

Example of question:

"Did your child encounter difficulties to understand your instructions when out of doors?"



Figure 1. Example from the questionnaire provided to parents.

Table 1. Description of the population.

Subject ID	Gender	Age at time of testing (years)	Age at implantation (years)	Duration of CI use (years)	Duration of HiRes 120 use (years)	CAP
RDP01	Female	11.3	3.3	8.0	4.2	7
RDP02	Male	8.4	2.2	6.2	3.8	5
RDP03	Female	10.4	4.1	6.3	3.8	7
RDP04	Male	12.4	5.6	6.8	4.2	7
RDP05	Female	13.4	4.0	9.4	3.0	5
RDP06	Male	9.2	1.2	7.9	3.2	7
RDP07	Female	7.3	3.0	4.3	2.6	5
RDP08	Male	6.6	3.2	3.3	2.3	5
RDP09	Female	8.0	6.1	1.8	1.8	5
Mean (SD)	4/9 male	9.7 (2.4)	3.6 (1.5)	6 (2.4)	3.2 (0.9)	5.9 (1.1)

CI, cochlear implant; CAP, categories of auditory performance; SD, standard deviation.

At the second session, children were first tested with the ClearVoice program they had been using for the previous month with the test battery outlined in Table 2. This provided a measure for the ClearVoice chronic condition. Subjects were then fitted with the second modality of ClearVoice, as defined by their group. The program was fitted and assessed in the acute phase as described for the first session. The second ClearVoice program was then used for one month by the child.

At the last session, subjects underwent the same test battery as at the previous sessions with the second ClearVoice chronic program. Subjects then chose which program they wanted to keep on their processor.

Speech testing

Speech perception in quiet and noise was assessed using the sentences taken from the Hearing In Noise Test (HINT) in Canadian French.¹⁷ Five lists of twenty sentences were available at the centre. In order to adapt the test to children, these were then split into two lists of ten sentences each, providing a total of ten lists. The lists were then randomly presented across the three sessions and across children, at a level of 65 dB SPL. Speech was presented from one loud speaker located one meter in front of the child, for speech in noise, continuous speech shaped noise (GN Otometrics) was presented from two loudspeakers located at $\pm 135^\circ$ behind the subject. A score with the usual HiRes 120 program was obtained in quiet, and then the SNR was adjusted until a score of approximately 50% of the score in quiet was obtained. This fixed SNR was then used for all subsequent tests in noise with the ClearVoice programs. Signals were presented via an audiometer calibrated for use in the free field. In order to limit the learning effect of the speech test material, a list of words was presented to children before the sentence lists.

Statistical analysis

Analyses were performed with the Statistica 9.0 software (Statsoft Inc., Tulsa, Oklahoma, United States). The threshold of statistical significance was set at $P=0.05$. Statistical analysis to compare speech tests results (in quiet and noise) across and within sessions and the questionnaire outcomes with the three programs was performed using a non-parametric Friedman ANOVA when comparing more than two samples, and a Wilcoxon matched pairs test when only two samples were compared. When significance was reached when performing a Friedman ANOVA, post hoc testing using the average ranks was conducted in order to define which sample was significantly different from the other.

Results

Speech testing

Speech testing was conducted in all children. However, some difficulties were encountered with the speech testing. The concept of a sentence test was new for all the children potentially leading to a learning effect across sessions and within the same session. Some sessions were very long for some children and therefore a fatigue effect also became a factor. These difficulties were mainly observed in younger children and therefore, only speech tests results from the older group are presented (excluding one subject who had very poor results even with the baseline program), leading to a panel of five subjects.

Speech perception results in quiet across sessions are shown in Figure 2. The scores in quiet obtained with the HiRes 120 program ranged from 50% to 100% with a mean score of 76.4% (SD=18.5). The mean scores obtained with ClearVoice (medium and high modalities combined) ranged from 70.3% to 80.2% across the sessions. The Friedman ANOVA did not show a significant difference over time [$\chi^2(3)=1.320$, $P=0.724$] or between ClearVoice and HiRes 120 [$\chi^2(4)=2.080$, $P=0.721$]. The mean scores obtained with ClearVoice medium and ClearVoice high, after one month of use (in the chronic phase) were not significantly different (Wilcoxon matched pairs tests,

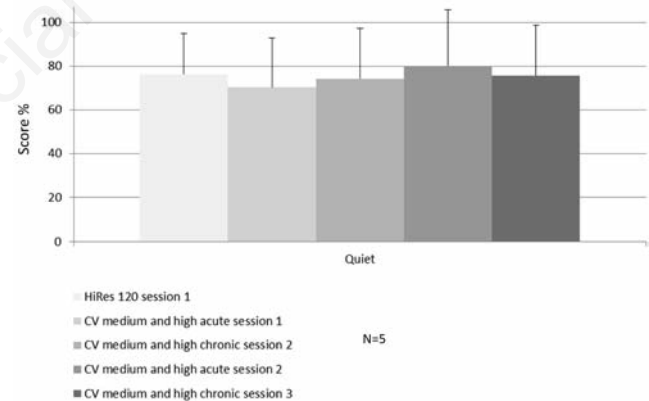


Figure 2. Speech test results in quiet with HiRes 120 and ClearVoice (medium and high modalities combined) across sessions.

Table 2. Testing protocol for each of the three sessions.

Session	Tests conducted	Condition
First	Audiogram, CAP, ACPEI, Questionnaire on HiRes 120	HiRes120
	Sentence test in noise and quiet	ClearVoice acute (medium or high)
Second	Audiogram, CAP, ACPEI Sentence test in noise and quiet Questionnaire on ClearVoice	ClearVoice chronic (medium or high)
	Sentence test in noise and quiet	ClearVoice acute (medium or high)
Third	Audiogram, CAP, ACPEI Sentence test in noise and quiet Questionnaire on ClearVoice	ClearVoice chronic (medium or high)

CAP, categories of auditory performance.

$Z=0.135$, $P=0.892$) with a mean score of 74.5% (SD=22.1) with ClearVoice medium and a mean score of 75.6% (SD=23.6) with ClearVoice high (Figure 3).

For speech in noise testing the mean SNR value defined for these children was 4 dB (SD=2.8) ranging from 1 to 7 dB. Figure 3 shows the scores in noise with the baseline HiRes 120 program, obtained in session 1, the mean score obtained with ClearVoice (acute phase, medium and high modalities combined), also obtained in session 1, and the mean scores for ClearVoice medium and ClearVoice high across sessions. Values for HiRes 120 ranged from 21.6% to 50% with a mean score of 35.2% (SD=10.3) and for ClearVoice (acute) ranged from 11.9% to 57.1% with a mean score of 34.06% (SD=17.2). There was no significant difference between mean scores for ClearVoice (acute) and the baseline program in noise for session 1 (Wilcoxon matched pairs tests, $Z=0.674$, $P=0.500$). The mean score, combined across chronic sessions, obtained with the medium modality of ClearVoice, was 58.3% (SD=19.6) ranging from 27% to 78.8% and with the high modality, 68.9% (SD=22) ranging from 32.4% to 89.5%. The Friedman ANOVA showed a significant difference between the HiRes 120, ClearVoice medium and ClearVoice high programs tested in noise [$\chi^2(2)=8.400$, $P=0.015$]. *Post hoc* testing showed that ClearVoice high was significantly better than the baseline HiRes 120 score and showed no statistically significant difference between medium or high modalities of ClearVoice.

The CAP score remained the same over the study period.

ClearVoice fitting

The switch-over to ClearVoice was uneventful for both modalities. For the majority of children, the T- and M-levels had to be increased for ClearVoice medium and ClearVoice high programs at the initial fitting (Table 3). For one subject, the M-levels were decreased at the initial fitting of ClearVoice medium and increased for ClearVoice high.

These levels were readjusted in most cases at the last fitting session. Three subjects kept ClearVoice medium and HiRes 120 programs, two subjects kept HiRes 120, ClearVoice medium and ClearVoice high programs, three kept only ClearVoice high and one kept ClearVoice medium and ClearVoice high programs. The increase in T- and M-levels was calculated by dividing the change in clinical units by the original value of the parameter, the mean value of the minimum and maximum percentage change is reported. The global increase of the M-levels at the final test session compared to the initial program HiRes 120 was 6.6% (SD=5.1) for the six subjects who kept the medium modality and 8.7% (SD=4.8) for the six subjects who kept the high modality. T-levels increased for three children out of the six who kept the medium modality by 57.9% (SD=27.9) and for five out of the six subjects who kept the high modality by 86.5% (SD=80.8) (Table 4).

Each area of the APCEI was rated at a minimum of 3 for all the children. The profile did not evolve through the duration of the study except for one *P* area, related to perception. For subject RDP05 to subject RDP09, the rating of the *P* area decreased from 4 with the HiRes 120 program to 3 for either one or both of the two ClearVoice programs. When comparing the free field audiograms between HiRes 120 programs and ClearVoice medium and high programs, there was a mean change in free field thresholds of less than +10dB (range +15.8 to -7.5), with a median change in threshold value of 10dB, averaged across all frequencies and subjects.

Program preference

Children were asked to define their preferred program at the last session. In some cases the preference was not clear, so several programs were uploaded onto the processor so that children were able to compare programs further in real life situations. Figure 4 shows a large majority of children (seven out of nine) preferred a ClearVoice program, with a similar spread between the high modality and the medi-

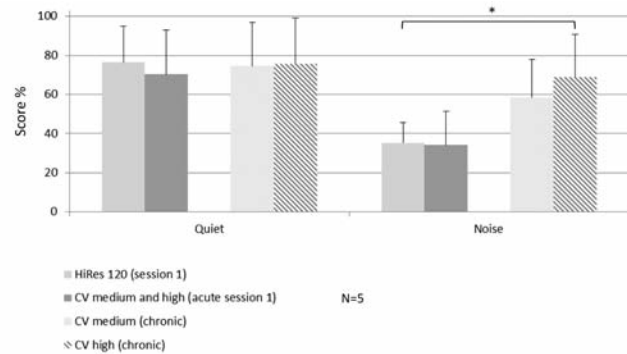


Figure 3. Speech test results in quiet and noise comparing HiRes 120 and ClearVoice in acute session (medium and high modalities combined) and comparing the two modalities of ClearVoice in chronic phase.

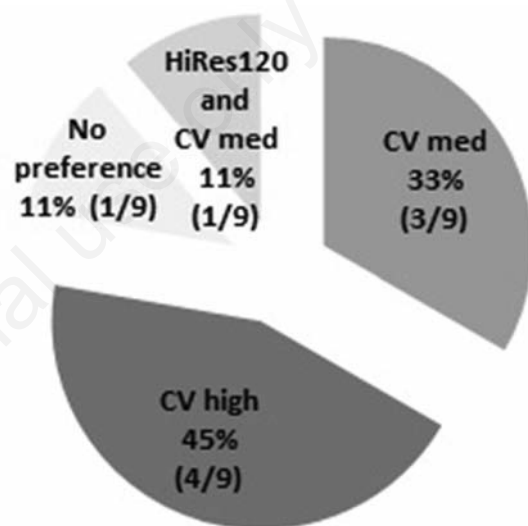


Figure 4. Program preference: the majority of children preferred one of the ClearVoice programs.

Table 3. Number of subjects with M-levels and T-levels increased at the initial fitting of each modality of ClearVoice, medium and high.

Levels	ClearVoice medium	ClearVoice high
Comfortable (M-levels)	6/9 subjects	8/9 subjects
Thresholds (T-levels)	5/9 subjects	6/9 subjects

Table 4. Percentage increase in the M-levels and T-levels for the ClearVoice programs fitted at the last session compared to the initial program HiRes 120.

Levels	ClearVoice medium	ClearVoice high
Comfortable (M-levels) (%); SD (subjects with levels increased/ total subjects fitted with the modality)	6.6; 5.1 (6/6)	8.7; 4.8 (6/6)
Thresholds (T-levels) (%); SD (subjects with levels increased/ total subjects fitted with the modality)	57.9; 27.9 (3/6)	86.5; 80.8 (5/6)

SD, standard deviation.

um modality of ClearVoice. Among the two remaining children, one preferred both HiRes 120 and ClearVoice (medium) programs and the other had no preference between the three programs.

Questionnaire results

Parents' questionnaire part

Questionnaires were completed for all children and for the three programs by parents. Figure 5 shows the scores for individual subjects for the three programs and the mean score for all subjects. A lower score indicates a better result.

In general, parents rated the ClearVoice programs as being more beneficial for their children than the baseline HiRes 120 program, but the Friedman ANOVA did not show a significant difference between any of the programs [$\chi^2(2)=2.667, P=0.263$]. This trend towards a preference for ClearVoice was not observed for the younger children (RDP07, RDP08 and RDP09). When looking at questionnaire scores for the older children only, the Friedman ANOVA did show a significant difference between the programs [$\chi^2(2)=8.333, P=0.015$]. Post hoc testing showed a significant difference between ClearVoice high and the HiRes 120 baseline and no significant difference between ClearVoice medium and ClearVoice high.

Teachers' questionnaire part

Seven out of nine questionnaires were collected from the teachers. Among these results, there was no clear improvement reported with the ClearVoice programs.

Additional comments

Based on questionnaires and discussions with parents and children, feedback was very positive and in favour of ClearVoice.

In the younger group of children, there was no particular comment by parents and all children accepted ClearVoice. Two children mentioned that there was too much noise, one in a restaurant (ClearVoice high) and the other at the cinema (ClearVoice medium). One child reported that ClearVoice high was better for watching television.

In the older group of children, some parents spontaneously reported a remarkable improvement for conversations in a car or on the phone, as well as for watching television. A mother also reported that her child was less tired with one of the ClearVoice programs. One child was more satisfied at school with ClearVoice than with his baseline program.

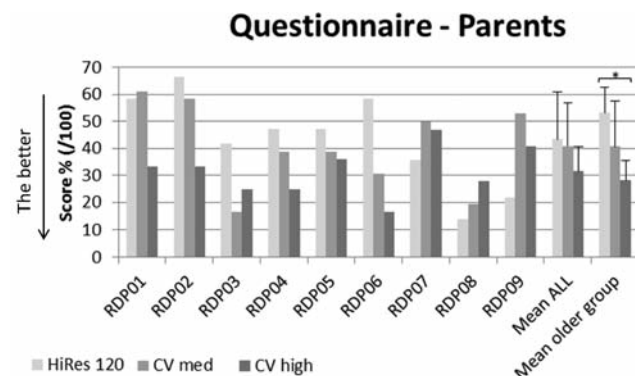


Figure 5. Parents' questionnaire mean scores for HiRes 120 program and both modalities of ClearVoice plotted as a level of difficulties encountered by the child.

Discussion

Although conducted on a small pilot group of children, this study showed significant benefits for the use of ClearVoice in noise. These results are in keeping with outcomes collected in the adult population.¹⁰⁻¹³

In the first session, where Hires 120 was compared to ClearVoice (acute) in the same session, results were equivalent, despite no time being available for acclimatisation and the fact that ClearVoice testing was at the end of a long test session. After one month of use, although only significant for ClearVoice high, there was a trend for improved speech understanding in noise when using the two modalities of ClearVoice, medium and high, compared to the baseline program, HiRes 120 and there was no corresponding improvement in scores in quiet. Although a part of this improvement is due to an improvement in the children's ability to perform the testing, another part of it was due to the addition of the ClearVoice strategy. Significant improvements in speech perception in noise with ClearVoice were also observed in a larger study by Schramm *et al.* (personal communication at 13th Symposium on Cochlear Implants in Children, 2011) conducted in 24 children of similar age.

There was no statistically significant difference in speech perception in noise scores between ClearVoice medium and high and subjective preference also showed a similar split between the medium and high modalities.

Despite the limitations related to the objective testing, subjective feedback from children and parents was very positive towards ClearVoice use. Seven out of nine children from this study preferred a ClearVoice program at the final fitting session. Questionnaires completed by parents in our study showed that children in the older group obtained benefit from using ClearVoice in daily situations, compared to their baseline program, HiRes 120. This benefit was statistically significant with ClearVoice high. However, this tendency differed between age groups with parents from the younger group of children (RDP007, RDP008, and RDP009) rating the baseline program as being more beneficial for their child than the ClearVoice programs. The scores for the baseline program in this younger group were significantly better than the baseline scores for the older group. In both groups, parents completed the questionnaire about the HiRes 120 strategy during the first visit and it may be that, as the study progressed, they became more aware of the situations to attend to. This may have resulted in parents identifying more situations where their child did not hear well, that they had previously not been aware of. This, coupled with the shorter period of implant use of the younger three children, when parents may still be very positive towards their child's performance compared to the parents of the older children, could also account for the difference between the groups.

Additional comments, especially from the older group of children, provided during discussion with parents and children about their experience with ClearVoice during the past months, confirmed the benefits reported. This strong preference in favour of ClearVoice was also shown in the Schramm *et al.* study (personal communication at 13th Symposium on Cochlear Implants in Children, 2011) where, among 19 responses from parents and/or children, the majority reported that ClearVoice was used most of the time following the initial fitting.

Comments collected from teachers reported no clear change when using ClearVoice programs in the classroom. Some of the children were using an FM system at school which is already a great help to cochlear implant users as shown by Wolfe *et al.*⁵ making further benefit difficult to measure. In another study by Gault *et al.*,¹⁸ a benefit when using ClearVoice together with an FM system was observed. However, in this study speech tests were conducted in different levels of noise whereas in our study, only subjective feedback from external observers (e.g.

teachers) was collected, which put the teacher as an additional factor. Only three questions were part of this questionnaire and it seems that these questions were not sensitive enough to evaluate the benefit of ClearVoice in a classroom.

Both modalities of ClearVoice were immediately accepted at the initial fitting by all the children. ClearVoice is based on the HiRes 120 strategy and is optional within the windows program software and once selected can be easily fitted with either a low, medium or high setting. However, this study confirms that the adjustment of the most comfortable and thresholds levels is required when fitting ClearVoice. Previous clinical experience shows that a slight increase of the M-levels can further improve performance with ClearVoice in adults; the fitting recommendation was to increase the M-levels by approximately 5% for the medium modality of ClearVoice and by approximately 10% for the high modality (Brendel *et al.* 2012, personal communication at the 12th International Conference on Cochlear Implants and Other Implantable Auditory Technologies). The optimisation strategy for ClearVoice fitting in children described by Schramm *et al.* (personal communication at 13th Symposium on Cochlear Implants in Children, 2011) is to fit ClearVoice medium with a global rise in M-levels of 5% to 10%. Even though the sample of children remains small, we obtained the same range of values for the adjustment of M-levels in our study. However, it was difficult for some children to evaluate these parameters, especially in a fitting room which is usually a quiet place. It is recommended to obtain feedback from the child in a noisy setting when possible and to adjust levels accordingly. The T-levels increased between the baseline program and the last fitting of ClearVoice, for six out of nine children. The percentage of increased T-level values appear high in our study, but we need to remember that initially, these levels were already set at very low levels, so a change of few current units results in a much higher percentage change than an increase of the same value in M-levels. There was also some variation in the thresholds obtained in free field testing, with some individual results improving when program levels were changed and some worsening. Thus, it remains difficult to draw conclusions from these observations or to provide recommendations. Some clinics fit T-levels individually and others follow the default setting, which corresponds to 10% of the M-levels. In this study, the increase of the T-levels was essentially performed intuitively based on clinician experience. Schramm *et al.* (personal communication at 13th Symposium on Cochlear Implants in Children, 2011) recommended raising the T-levels to make the ambient noise audible, and further investigation focused on this parameter is clearly required. It is recommended to pay particular attention to the correct adjustment of T- and M-levels when fitting ClearVoice and optimising these parameters further could lead to even greater improvements in performance.

In summary, results from this pilot data show an improvement for ClearVoice over HiRes 120 for listening in noise, significantly with ClearVoice high and no deterioration of performance in quiet with ClearVoice. All children accepted both modalities of ClearVoice and there was no significant difference between medium and high settings. The majority of children preferred a ClearVoice program at the end of the study (seven out of nine children). Comments from parents and children were also positive, especially for older children for whom questionnaire results showed a benefit from the use of ClearVoice, with a statistically significant difference when using ClearVoice high. Adjustments to M- and T-levels were needed for most subjects. Particular attention must be paid to this aspect. Further data is needed to confirm the fitting recommendations, especially for T-levels.

As performance remains the same in quiet situations and a benefit was observed for listening in noise, ClearVoice can be recommended for use by children all day, without having to change program depending on the encountered situation.

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