One-year follow up of auditory performance in post-lingually deafened adults implanted with the Neurelec Digisonic® SP/Saphyr® Neo cochlear implant system

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Abstract

This study aimed to quantify outcomes in a group of patients who were implanted with an Oticon Medical Neurelec (Vallauris, France) cochlear implant system, the Digisonic® SP/Saphyr® Neo. Ten participants took part in this preliminary study. Their speech perception capacities were evaluated at 3, 6, and 12-months after cochlear implant activation and compared to pre-implantation scores and to scores observed with former versions of the sound processor. Compared to former versions of the sound processor, patients using the Saphyr® Neo processor obtained better speech perception scores for sentences in silence at each tests session (3 months: 79%, 6 months: 82% and 12 months: 94%) compared to Digisonic® users (respectively: 58%, 69% and 75%) and Convex sound processor users (resp. 39%, 59% and 51%). These observations confirm that the technological improvements made in the Saphyr® Neo sound processor coupled with the Digisonic® implant, provided quantifiable benefits in speech perception in Quiet compared to former versions of the processor Convex and Digisonic® SP.

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Introduction

Cochlear implants (CI) currently constitute the most successful machine-brain interface and an ever-improving treatment of choice for patients with severe-to-profound hearing loss.[1] With nowadays more than 300,000 implanted patients worldwide, CIs provide remarkable changes to many patients with congenital or acquired deafness. Thanks to CI, deaf children can develop oral communication skills, improve their intellectual abilities and access higher education no differently than normal-hearing children.[2] Post-lingual deafened adults can maintain or recover communication abilities, with positive effects on their social interactions, quality of life and beyond.[3,4] Continuous advances in sound-processing technologies and surgical methodologies today warrant for high-levels of efficiency and reliability, and have progressively enlarged the spectrum of CI indications.[5,6] For already implanted patients, improvements in technology can regularly be available through updates of the external part of the CI system, the sound processor. Sound processor upgrades naturally aim to improve auditory capacities and thus the quality of communications and sound experience of users. However, this claim must be supported by objective measures quantifying these improvements. The goal of the present mono-centric follow-up study was to measure the evolution of auditory and speech perception outcomes in patients who were implanted with a new generation of CI, comprising new sound processors: the Digisonic® SP/Saphyr® Neo system (Oticon Medical Neurelec, Vallauris, France), in order to evaluate objective benefits of the change in sound-processor generation. We therefore monitored auditory performance as evaluated by free-field warble tone thresholds before and one year after cochlear implantation and speech intelligibility in quiet and in silence, before and at three stages during the first year of CI usage, thereby monitoring the patients' habituation phase.

Materials and Methods

Patients

Ten adults (6 F/4 M) who became deaf post-lingually took part in this observational study that was conducted at the center for cochlear implantation in Lyons, France, at the Edouard Herriot Hospital. General characteristics of the tested population are provided in Table 1. The selected patients represent a heterogeneous population in terms of age at cochlear implantation [N=10; M=55.9; standard deviation (SD)=11.06; Min=34 y; Max=70 y], deafness duration (N=7; M=3.57; SD=3.10; Min=1 y; Max=10 y), or etiology of hearing loss (Table 1). This allows observations to be relatively independent of any particular population characteristics and reflecting the post-lingual cochlear implanted patients' population in general. Patients were implanted with a 20 electrodes array, inserted electrodes were on average (M=19.3 electrodes (el); SD=1.16); activated electrodes were on average (M=17.8 el; SD=2.69; Min=12 el; Max=20 el).

The study was conducted in agreement with the declaration of Helsinki and in conformity with clinical best-practices, the ICH referential and the ISO Norm 14155:2011. All procedures implicated are routinely performed during post-implantation follow-up appointments. Before taking part into this survey, all patients were informed of the technical and practical details of the experiment and signed a written informed consent form.

The Digisonic® SP cochlear implant and Saphyr® Neo processor

The Digisonic® SP is a transcutaneous multielectrode cochlear implant using the main peak interleaved sampling (MPIS) coding strategy.[7] The implanted part is composed of a receiver/stimulator (RS) positioned at the surface of the temporal bone thanks to a reliable fixation system employing specifically designed self-tapping screws,[8] and a multielectrode array of 25 mm of length, surgically positioned into the *scala tympani* of the cochlea, containing 20 individual electrodes.

The Saphyr® Neo sound processor is the latest release of the CI sound processor from the manufacturer Oticon Medical Neurelec, which was introduced in 2013. Main improvements compared to the previous versions of the SP included Crystalis XDP™ a new signal processing strategy based on a post-spectral decomposition output compression scheme optimizing the perception of speech sounds through a dedicated treatment of soft sounds and VoiceTrack™ an adaptive digital multi-channel noise reduction system.

Auditory and speech outcomes assessments

Perceptual thresholds were measured using free-field warble-tone audiometry, 1 month before (BCI) and 12 months after cochlear implantation (M12). Thresholds were acquired for target-frequencies 0.5, 1, 2 and 4 kHz. Tests were conducted in a soundproof booth and thresholds, expressed in dB HL were determined with the implant in function at M12. For patients routinely wearing a hearing aid on the contralateral ear, thresholds were determined without this supplementary aid.

Speech perception was evaluated via free-field vocal audiometry, 1 month BCI and during 3 routine follow-up appointments at 3, 6 and 12 months of implant usage (M3, M6 and M12). Speech perception scores were acquired under three different experimental conditions. In the first condition, intelligibility performance, expressed as a percent of words correctly reported, was assessed using single presentations of 10 dissyllabic words from the Fournier lists, presented at 65 dB SPL in a quiet background (Words Quiet). The second condition used the same material but words were presented against a background made of speech-shaped noise (Words Noise), presented at a +10 dB signal-to-noise ratio (SNR). Condition 3 was run in quiet but using sentences (Sentences Quiet).[9]

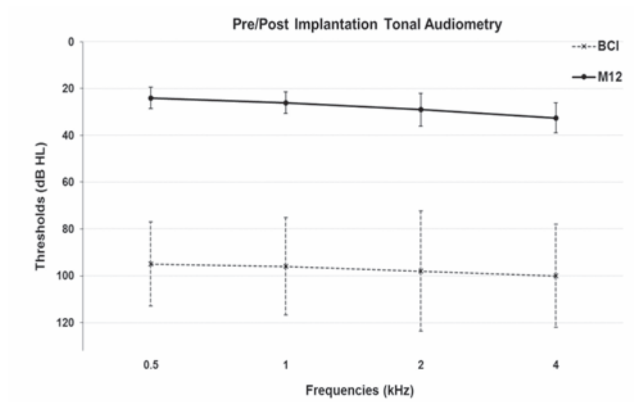

Figure 1. Average free-field warble-tone thresholds measured at 0.5, 1, 2 and 4 kHz, before cochlear implantation (BCI, dashed line) and after one-year cochlear implantation with the Digisonic® SP/Saphyr® System (M12, black line). Error bars represent standard deviation of mean.

Table 1. Summary of patients' details: gender distribution, age at cochlear implantation (M=55.9 year; standard deviation=11.06), right- and left-ear hearing loss status, deafness duration when known and number of inserted and activated electrodes.

Id	Gender	Born	Age at CI (y)	Right ear	Left ear	Deafness duration (y)	Etiology	Inserted electrodes	Activated electrodes
1	M	1959	53	Severe	Profound	Unknown	Unknown	20	20
2	M	1959	53	Cophotic	Severe	5	Otospongiosis	18	12
3	F	1955	57	Profound	Profound	3	Accident	20	20
4	F	1943	69	Cophotic	Profound	1	Unknown	20	18
6	F	1947	66	Cophotic	Cophotic	Unknown	Genetic	20	19
5	F	1963	50	Cophotic	Profound	2	Unknown	20	15
7	F	1953	60	Severe	Severe	2	Unknown	17	16
8	M	1979	34	Profound	Profound	10	Malformation	20	20
9	F	1966	47	Profound	Profound	2	Evolutive	18	18
10	M	1943	70	Profound	Profound	Unknown	Sudden	20	20

CI, cochlear implantation.

Results

Tonal audiometry

Results from the tonal audiometry measure are shown in Figure 1. Before cochlear implantation, patients had average warble-tone thresholds of 95.0 (SD=18.0); 96.0 (SD=20.8) and 98.0 (SD=25.7) and 100.0 (SD=22.0) dB HL, respectively at 0.5, 1, 2 and 4 kHz, well in the range of cochlear implantation indication. One year after cochlear implantation, measured thresholds had improved to 24.0 (SD=4.6); 26.0 (SD=4.6); 29.0 (SD=7.0) and 32.5 (SD=6.4) dB HL, respectively at the same frequencies, leading to statistically significant improvements (all paired *t*-tests $t(9)>2.26$, $P<0.05$) at each tested frequency. CI decreased auditory thresholds on average by 71.0, 70.0, 69.0 and 67.5 dB HL at 0.5, 1, 2 and 4 kHz in the present group of patients.

Cochlear implantation with the Digisonic® SP/Saphyr® Neo system led in the tested group to an average improvement of free-field warble-tone thresholds of 69.38 dB HL over the 0.5 to 4 kHz range after one year of usage.

Vocal audiometry

Results from the vocal audiometry measures are shown in Figure 2 and detailed in Table 2. For sentences played in a quiet environment, the scores observed before cochlear implantation were 9.1% correct responses (SD=19.2) due to 2 participants scoring 44.0% and 47.0% correct responses, all other participants scoring 0% correct responses. Three months after CI (3M) the scores rose to an average of 78.4% (SD=25.0), and continued improving after 6 months of CI usage (M=81.6%, SD=25.8) to reach 94.4% correct identification (SD=7.8) after 1 year of use. A one-way repeated-measures analysis of variance (ANOVA), considering intelligibility scores as dependent variable and testing factor test session (4: BCI, 3M, 6M, 12M), revealed a significant main effect of this factor ($F(3, 27)=48.73$, $P<0.05$) confirming the difference between intelligibility scores measured on the different test sessions. Resolving this main effect with a *post hoc* least significant difference (LSD) test ($\alpha=0.05$) first revealed that intelligibility scores were higher for all post-implantation sessions compared to BCI (all P values <0.05) and that scores significantly increased between session 3M and session 12M ($P<0.05$).

For the perception of isolated words, all intelligibility scores before CI were equal to 0%, no patient successfully reporting a single word, either in quiet or in noise. Three months after cochlear implantation, the scores rose to 68.0% (SD=19.9) in quiet and 35.0% (SD=24.2) in speech-derived noise at +10 dB SNR. In quiet, the scores then appeared to remain stationary after 6 months (M=62.0%, SD=21.5), to rise up to 78.0% (SD=12.3) after 1 year of use. In noise, scores raised across the three sessions, to reach 43.3% (SD=22.9) and 52.0% (SD=19.3) after one year of CI use. A repeated-measures ANOVA considering intelligibility scores as dependent variable and testing factors: test session (3: 3M, 6M, 12M) and backgrounds (2: Quiet, Noise) revealed significant main effects of these two factors, scores raising across test-sessions ($F(2, 16)=6.62$, $P<0.05$) and intelligibility being always lower in noise than in quiet ($F(1, 8)=35.58$, $P<0.05$). The interaction remained non-significant suggesting that the increase in scores was present for both words presented in quiet and in noisy background. A *post hoc* LSD test ($\alpha=0.05$) resolving the main effect of Test Session showed that scores were significantly larger at M12 compared to both M3 ($P=0.003$) and M6 ($P=0.01$), revealing a significant improvement of the intelligibility of single words both in silence and noise over the test-period.

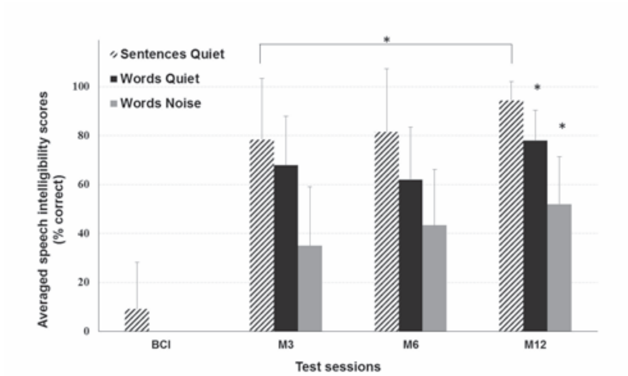

Figure 2. Evolution over the three test sessions (BCI, M3, M6 and M12) of averaged speech intelligibility scores expressed in percent correct, for sentences in quiet (hashed), words in quiet (black) and words in +10 dB SNR speech-shaped noise (grey). Error bars represent the standard deviation of measures. (*) Significant differences: for sentences in quiet scores raised from M3 to M12 and for single words in silence and in noise, scores were significantly larger at M12.

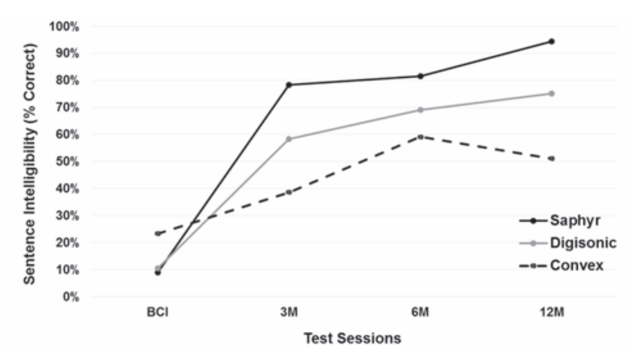

Figure 3. Evolution of sentence in quiet intelligibility scores over three successive generation of speech processors, comparative data from Lazard *et al.*[9] Convex (released 1999, black dashed line), Digisonic® (released 2004, grey plain line), and Saphyr® (released 2014, black plain line).

Table 2. Number of data-points, mean (% correct responses) and standard deviation on intelligibility measures for sentences and words in quiet, and words in –10 dB SNR speech-shaped noise.

Test session	BCI			3M			6M			12M		
Background	Quiet		Noise	Quiet		Noise	Quiet		Noise	Quiet		Noise
Material	Sentences		Words	Sentences		Words	Sentences		Words	Sentences		Words
No. responses	10	10	10	10	10	10	10	10	9	10	10	10
Mean (%)	9.10	0.00	0.00	78.40	68.00	35.00	81.60	62.00	43.33	94.40	78.00	52.00
SD	19.20	0.00	0.00	24.96	19.89	24.15	25.77	21.50	22.91	7.76	12.29	19.32

BCI, before cochlear implantation. M3, M6, M12, three test sessions; SD, standard deviation.

Discussion

The aim of the present study was to quantify the improvements on auditory abilities caused by cochlear implantation with the Digisonic® SP/Saphyr® SP CI system (Oticon Medical Neurelec) in a group of 10 post-lingually implanted adults. Auditory abilities were evaluated by warble-tone threshold measures and vocal audiometry over the first year of CI use. Results showed that thresholds were improved from an average of 97.3 dB HL to 27.9 dB HL one year after implantation, yielding an average 69.38 dB HL improvement over the 0.5 to 4 kHz frequency range. These improvements in auditory thresholds were accompanied by improvement in speech perception, both for sentences, reaching 94.4% intelligibility after one year, demonstrating successful recovery of oral communication abilities in post-lingually deafened adults. Isolated word identification scores reached in quiet and in noise at the end of the one-year follow-up period.

In order to test the improvement of quality between the Saphyr® SP users and former generation of speech processors from the same brand, we compared the current scores with those published by Lazard and colleagues who compared speech perception skills for post-lingually deaf patients implanted with two less recent Oticon Medical Neurelec sound processors: the Digisonic® Convex and the Digisonic® SP.[9] Indeed, the study by Lazard *et al*. was conducted within the same center for cochlear implantation in Lyon, France at the Edouard Herriot Hospital and in comparable testing conditions, but only in Quiet.

Results show that intelligibility scores for isolated words in quiet increased on average from 43.0% after 1 year use in the Convex generation (launched in 1999) to 67.8% in Digisonic® SP devices (released in 2004), to 78.0% with the Saphyr® SP device (launched 2014), current study. Single word intelligibility could thus be improved by 21.3% from the first to the second generation and again by 8.3% with the last generation, confirming technological improvements over time transferred to intelligibility score increases. Over the same period, scores for sentence intelligibility (Figure 3)[9] raised from 51.1% to 75.2% to 94.4%, leading to average generation improvements of +17.9% for the first step and +17.3% from the second to the third generation of speech processors, thereby providing quantified evidence of the translation of technological improvements into speech intelligibility benefits for CI users. The difference between device generations is already present after three months, suggesting rapid benefits of newer devices. Moreover, resolving the linear regression for sentence comprehension in quiet from the comparative dataset and comparing it to the data points obtained from the current study we obtained the slope values: 0.10 for the Convex intelligibility dataset, 0.20 for the Digisonic® dataset and 0.26 for the current Saphyr® SP observations. This suggests that the improvement of absolute performance with device generation is also accompanied by a modification of the speed of adaptation/habituation to the signal processing scheme, more recent devices leading to faster improvements.

Conclusions

This study aiming at quantifying auditory abilities and speech perception in post-lingual deaf adults who received a CI showed that the technological advances made in the Saphyr® Neo sound processor coupled with the Digisonic® SP implant, provided measurable increases in speech perception for words and sentences in Quiet compared to former versions of the speech processor Convex and Digisonic® SP.

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