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1 **5-Year Hearing Outcomes in Bilateral Simultaneously Cochlear Implanted**

2 **Adult Patients**

3

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27 **ABSTRACT**

28 **Objective:** To report the speech performance and sound localization in adult patients 5 years
29 after bilateral simultaneous cochlear implantation, and to evaluate the change in speech scores
30 between 1 and 5 years.

31 **Design:** In this prospective multicenter study, 26 patients were evaluated at 5 years after
32 implantation using long straight electrode arrays (MED-EL Combi 40+, Standard Electrode
33 array, 31 mm). Speech perception was measured using disyllabic words in quiet and noise,
34 with the speech coming from the front, and a cocktail-party background noise coming from
35 five loudspeakers. Speech localization measurements were performed in noise under the same
36 test conditions. These results were compared to those obtained at 1 year reported in a previous
37 study.

38 **Results:** At 5 years postimplantation, an improvement in speech performance scores
39 compared to 1 year after implantation was found for the poorer ear both in quiet and in noise
40 ($+12.1 \pm 2.6\%$, $p < 0.001$). The lower the speech score of the poorer ear at 1 year, the greater
41 the improvement at 5 years, both in quiet ($r = -0.62$) and at a signal-to-noise ratio (SNR) of
42 $+15$ dB ($r = -0.58$). The sound localization on the horizontal plane in noise provided by
43 bilateral implantation was better than the unilateral one and remained stable after the results
44 observed at 1 year.

45 **Conclusion:** In adult patients simultaneously and bilaterally implanted, the poorest speech
46 scores improved between 1 year and 5 years postimplantation. These findings are an
47 additional element to recommend bilateral implantation in adult patients. The use of both
48 cochlear implants and speech training sessions for patients with poor performance should
49 continue in the period after 1 year postimplantation since the speech scores would improve

50 over time.

51 **Key words:** bilateral implantation, long-term results, speech perception, localization, cochlear

52 implant

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INTRODUCTION

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Bilateral cochlear implantation is now universally accepted for rehabilitating hearing in severe to profound bilateral deafened adults when possible. The efficacy of simultaneous or sequential bilateral cochlear implantation in adults has been demonstrated in relatively large study groups [Müller et al., 2002; Ricketts et al., 2006; Litovsky et al., 2006, Buss et al., 2008, Dunn et al., 2008, Mosnier et al., 2009]. There are two substantial benefits of binaural hearing: better discrimination in noisy environments, and better spatial sound localization. In bilateral cochlear implanted patients, the physical “head shadow effect” is stronger than the two other central mechanisms, the “squelch effect” and “binaural summation” [Litovsky et al., 2006]. The ability to localize the sound source derives primarily from acoustic information arising from differences in arrival time and in level of stimuli at the two ears; multiple studies have demonstrated that bilateral implantation provides a marked improvement in sound localization in quiet and noise compared to unilateral implantation [Tyler et al., 2007; Grantham et al., 2007; Mosnier et al., 2009; Litovsky et al., 2009; Kerber and Seeber, 2012]. Furthermore, bilateral implantation clearly improved the performance when two separate speech and noise sources were used [Litovsky et al., 2006], or when speech perception was evaluated in complex and realistic environments using multiple noise sources [Ricketts et al., 2006; Dunn et al., 2008; Mosnier et al., 2009]. In quiet, the advantage of the bilateral condition in comparison with the better of the two unilateral conditions has been found at a very early stage (1-month post-activation) [Litovsky et al., 2006; Buss et al., 2008]; this bilateral benefit continued to improve during the first 12 months [Litovsky et al., 2006; Buss et al., 2008; Mosnier et al., 2009].

Despite this clear benefit of bilateral implantation, substantial inter- but also intra-individual

78 variability in speech perception scores exists among bilaterally cochlear implanted recipients
79 [Litovsky et al., 2006, Mosnier et al., 2009]. Indeed, in a prospective multicenter study, poor
80 performance of one or both ears was reported at 1 year postimplantation in two-thirds of
81 simultaneously implanted patients despite a short duration of hearing deprivation, and a
82 similar history of deafness between the two ears [Mosnier et al., 2009]. In unilaterally
83 cochlear implanted patients, some studies report a stability of long-term hearing outcome after
84 a learning phase in the first 6 months [Lenarz et al., 2012]. However, two studies assessing
85 the effect of bilateral hearing rehabilitation on long-term performance in adult patients
86 simultaneously implanted, report an improvement in the mean speech perception scores in
87 quiet, and of the squelch effect after 1 year [Eapen et al., 2009; Chang et al., 2010].

88

89 The objective of this study was to report the speech performance in quiet and in noise, and
90 sound localization in noise, of adult patients 5 years after simultaneous and bilateral cochlear
91 implantation, and to analyze the change in speech performance between 1 year and 5 years
92 postimplantation.

93

94

MATERIALS AND METHODS

95 Selection criteria and subjects

96 Subjects enrolled in this study were adult patients with a postlingual bilateral profound or
97 total hearing loss. Inclusion criteria have already been described in detail in a previous study
98 [Mosnier et al., 2009]. Of the 27 adult patients initially enrolled in six tertiary referral centers,
99 one patient in pregnancy did not complete the tests at the 5-year follow-up interval, therefore
100 a total of 26 patients were included in the present data analysis. Their demographic data are
101 reported in Table 1.

102 All patients underwent bilateral implantation in a simultaneous surgical procedure with the
103 same device (MED-EL Combi 40+, Standard Electrode Array, 31 mm length; Innsbruck,
104 Austria). Cochlear implants were simultaneously activated using the same speech coding
105 strategy, CIS (Continuous Interleaved Sampling), in both ears, although each ear underwent
106 independent mapping. The speech coding strategy and the sound processors remained the
107 same for all patients for the 5-year follow-up. All of the patients signed a written informed
108 consent, and the study was approved by the local ethics committee (Saint-Louis, Paris, N°
109 61D0/22/A).

110

111 **Speech perception measures**

112 Speech perception tests have been performed before implantation, and 3, 6, 12 months, and 5
113 years after activation. The study design and the results of the mean speech perception during
114 the first year of follow-up have been reported in a previous study by Mosnier et al. [2009].
115 Measurements were performed in a soundproofed room using five loudspeakers (Monacor
116 MKS-40, frequency response: 80–18000 Hz) positioned at intervals of 45 degrees in the
117 frontal hemi-field, ranging from –90 degrees to +90 degrees. Test materials consisted of 10
118 disyllabic words (50 lists of Fournier words) recorded in quiet and in noise (one different list
119 for each condition). The randomization of test lists presented to each patient was carried out
120 independently at each test site. Responses were scored as the percentage of words correctly
121 identified. Speech was always presented at 70 dB SPL from a loudspeaker placed at 0
122 degrees. The tests in noise were administered at a signal-to-noise ratio (SNR) of +15 dB, +10
123 dB and +5 dB; tests at 0 dB were also performed only at 5-year follow-up. The speech stimuli
124 went from the front, and a cocktail-party background noise from the five loudspeakers,
125 including the central one that presented the speech target.

126 **Sound localization**

127 For sound localization measurements in noise, the test stimuli (disyllabic words) were
128 presented in a random sequence from each of the five loudspeakers (LS1 to LS5, 45 degree
129 intervals in the frontal hemi-field, ranging from -90-degrees to +90-degrees) for a total of
130 three times, at an intensity level varying from 60 to 80 dB SPL. The competing sound
131 material was a cocktail-party background noise coming from the five loudspeakers. In order
132 to test only the localization, without interference from the hearing performance, the SNR was
133 adapted for each subject and each listening condition (monaural right, monaural left, and
134 binaural condition), in order to obtain a 50% correct speech recognition score for disyllabic
135 words coming from the front loudspeaker. After each stimulus presentation, subjects reported
136 the loudspeaker number corresponding to the perceived sound location. For each loudspeaker,
137 the number of correct responses was noted, and results were expressed as the mean percentage
138 of correct responses per loudspeaker.

139

140 **Statistical analysis**

141 *Evolution of speech performance between 1 and 5 years*

142 The better ear was defined as the ear with the better speech score in quiet. In the case of
143 equality of speech scores between the two ears in quiet, the score of the better ear in noise at a
144 SNR of +15 dB was considered. Speech performance score was modeled using a linear mixed
145 model with three fixed effects (1. Time: 1 year or 5 years after implantation; 2. Ear: Better,
146 Poorer or Bilateral; 3. Noise: Quiet, SNR +15 dB, SNR +10 dB or SNR +5 dB) and one
147 random effect (random intercept for each patient). To select the most parsimonious model
148 including only relevant effects of interest, a first model was fitted with the three fixed effects
149 and including all the possible second and third order interaction terms between the fixed

150 effects. Then, a backward selection procedure was applied in order to remove interaction
151 terms that did not contribute to explain speech performance score. The final selected model
152 was the one with the lowest Bayesian Information Criterion (BIC) value. Based on the final
153 model estimates, post-hoc two-by-two comparisons were performed using relevant contrasts
154 with p-values adjusted for multiple comparisons according to the Holm-Bonferroni step down
155 procedure [Holm, 1979].

156 *Correlations between the evolution of speech performance scores and speech performance*
157 *score at 1 year*

158 Spearman correlation coefficients (r) were estimated between the difference in speech
159 performance score from 1 year to 5 years after implantation and the corresponding speech
160 performance score at 1 year after implantation. These analyses of correlations were only
161 performed for conditions where an evolution over time was found to be significant according
162 to the previous analyses. The estimated correlation coefficients were tested against the null
163 hypothesis of an absence of correlation with an a priori Type I Error level fixed at 5%.

164 *Evolution of sound localization between 1 year and 5 years after implantation*

165 The number of correct responses (as a percentage) was modeled using a linear mixed model
166 with three fixed effects (1. Time: 1 year or 5 years after implantation; 2. Ear: Unilateral right,
167 Unilateral left or Bilateral condition; 3. Loudspeaker: LS1 to LS5) and one random effect
168 (random intercept for each patient). Model selection and post-hoc two-by-two comparisons
169 were performed according to the aforementioned procedure used for the evolution of speech
170 performance.

171 All statistical analyses were conducted using R 3.2.3 [R Core Team, 2015].

172

173

RESULTS

174 **Hearing performance after 5 years of bilateral cochlear implantation**

175 Figure 1 shows the mean values of speech performance score observed in each studied
176 condition at 1 and 5 years postimplantation.

177 The most parsimonious linear mixed model that was retained for analyses included a
178 significant interaction term between time and ear effect (global $p < 0.001$) as well as a
179 significant noise effect (global $p < 0.001$) (Table 2). After post-hoc two-by-two comparisons
180 with adjustment of p-values for multiple comparisons, the difference in speech performance
181 scores between 1 and 5 years after implantation was found to be significant in each possible
182 pair of comparisons for noise effect, regardless of time and ear (Table 2).

183 The improvement in speech performance scores between 1 and 5 years after implantation was
184 found to be significant in the subgroup of the poorer ear ($+12.1 \pm 2.6\%$, $p < 0.001$), regardless
185 of the noise. The evolution of speech perception score between 1 and 5 years was not found to
186 be statistically significant in other subgroups of ears (bilateral or better) (Table 2).

187 At 1 year after implantation, the difference in speech performance scores was found to be
188 significant in each possible pair of comparisons for ear effect, regardless of noise (Bilateral –
189 Better: $+8.5 \pm 2.7\%$, $p = 0.01$; Better – Poorer: $+16.9 \pm 2.7$, $p < 0.001$, Table 1). These
190 differences in speech performance scores between ear conditions were not found to be
191 statistically significant at 5 years after implantation (Table 2). The most difficult noisy
192 condition, SNR 0 dB, was only tested at 5 years, therefore it was not considered in the mixed
193 model analysis. The speech perception scores in this condition of noise were: $12 \pm 3.1\%$, $18 \pm$
194 4.3% and $30 \pm 4.6\%$ for the poorer, better and bilateral conditions, respectively (Figure 1).

195

196 **Correlations between the evolution of speech performance scores and speech**
197 **performance score at 1 year**

198 Table 3 shows the estimated correlations between the evolution of speech performance score
199 at 1 and 5 years after cochlear implantation and the corresponding speech performance score
200 at 1 year for each noise condition. The correlations were only calculated for the poorer ear (as
201 it was the only ear for which the evolution between 1 and 5 years after cochlear implantation
202 was found to be significant). For Quiet and SNR +15 dB, a significant negative correlation
203 was found (Quiet: $r = -0.62$, $p = 0.001$; SNR +15 dB: $r = -0.58$, $p = 0.002$) (Figure 2).
204 Overall, the poorer ears with the lower speech perception seemed more likely to have
205 improved over time (with a greater improvement associated with a lower score at 1 year),
206 while poorer ears with the highest scores at 1 year seemed more likely to have been stable or
207 to have decreased over time.

208

209 **Evolution of sound localization between 1 year and 5 years postimplantation**

210 Figure 3 shows the mean values of sound localization score observed for each loudspeaker.
211 The most parsimonious linear mixed model that was retained for analyses included only the
212 main fixed effects (no interaction terms). The loudspeaker and ear effects were significant
213 (global $p < 0.001$ for both effects). The analyses did not highlight a change in sound
214 localization performance over time (Table 4). After the post-hoc two-by-two comparisons
215 with adjustment of p-values for multiple comparisons, the improvement in sound localization
216 was found to be significant between the bilateral condition and the unilateral right or
217 unilateral left condition, regardless of time and ear (Bilateral – Right: $+31.8\% \pm 2.6\%$, $p <$
218 0.001 ; Bilateral – Left: $+29.9\% \pm 2.6\%$; $p < 0.001$). No difference was found between the two
219 sides (Table 3). A difference in sound localization was found to be significant between the
220 most peripheral loudspeakers and the central ones, on the left side (LS1 – LS4: $+13.9\% \pm$

221 3.4%, $p < 0.001$; LS1 – LS3: $+13.0\% \pm 3.4\%$, $p < 0.001$; LS1 – LS2: $+17.1\% \pm 3.4\%$, $p <$
222 0.001), as well as on the right side (LS5 – LS2: $+10.9\% \pm 3.4\%$, $p = 0.009$) (Table 3).

223

224

DISCUSSION

225 In this study, 5 years after simultaneous bilateral implantation, the speech performance of the
226 poorer ear improved in comparison to 1 year postimplantation. In a study prospectively
227 analyzing nine adult patients simultaneously and bilaterally implanted (MED-EL Combi 40+)
228 with poor speech perception scores at 1 year postimplantation (unilateral scores $< 50\%$ for
229 Consonant-Nucleus-Consonant (CNC) words in quiet), Eapen et al. [2009] reported a gradual
230 improvement in the unilateral and bilateral scores over a 4-year follow-up period, and a
231 growth of the squelch effect, whereas the benefit from head shadow and summation effects
232 remained stable. Chang et al. [2010] also observed better speech performance in the bilateral
233 condition for CNC words in quiet at 4 years postimplantation, compared to 1-year
234 performance, in a group of 17 adults simultaneously implanted. Our results corroborate these
235 two studies, but the missing speech perception assessment between the 1-year and 5-year
236 measurement intervals did not allow us to evaluate whether the poorest speech perception
237 scores improved gradually or not over the 4-year follow-up period. The improvement in the
238 poorer ear observed in the present study is possibly related to an enhanced cortical
239 representation of the voice when using bilateral cochlear implants. A positron emission
240 tomography study reported that in adult patients bilaterally and simultaneously implanted for
241 3 years, the bilateral auditory stimulation in quiet improved brain processing of voice stimuli
242 in the right temporal region compared to monaural stimulation, and activated the right fronto-
243 parietal cortical network implicated in attention [Coez et al., 2014]. The improvement of the
244 poorer ear after 1-year follow-up that was observed in the present study has not been reported

245 in patients unilaterally implanted, even in studies with long-term follow-up [Lenarz et al.,
246 2012; Holden et al., 2013]. A link between the score improvement and a more frequent
247 follow-up cannot be ruled out. Indeed, patients having poor performance had a more intense
248 training in terms of frequency of cochlear implant fittings, and of speech training sessions,
249 compared to patients who rapidly obtain good performance, that were consequently less prone
250 to continue the speech rehabilitation exercises. Another aspect that has not been analyzed in
251 the present study was the time of daily use of the cochlear implants. These parameters have
252 not been studied in our study group, and have to be analyzed in a future report.

253 In the present study, the advantage of the bilateral condition over the better unilateral ear in
254 speech perception scores that was present at 1 year was not found 5 years after implantation.
255 Nevertheless, the most difficult condition in noise, i.e., SNR 0, was only tested at 5 years and
256 was not considered in the evolution of the scores and in mixed model analysis. It appears from
257 the results (see Figure 1) that the difference between bilateral and better ear at SNR 0 ($+11 \pm$
258 3.6%) was higher than the other significant differences between bilateral and better ear
259 observed at 1 year both in quiet and in noise. This might indicate that bilateral cochlear
260 implantation could still provide benefit in complex and difficult noisy environments 5 years
261 after implantation compared to unilateral implantation.

262 The sound localization on the horizontal plane provided by the bilateral implant was better
263 than the unilateral one and remained stable after the results observed at 1 year. This result is
264 consistent with several studies evaluating sound localization in quiet, reporting that a major
265 improvement occurred in the first 6 months after cochlear implantation [Basura et al., 2009;
266 Chang et al., 2010]. It appears from the results, as expected, that the localization of the sound
267 source is easier in the most peripheral loudspeakers where the interaural time and level
268 differences are higher, than in the more central loudspeakers regardless of the factor time.

269 In conclusion, this study demonstrates that bilateral auditory stimulation improves the poorest
270 performance after 1 year representing an additional reason to recommend bilateral
271 implantation. The patients with poor performance at 1 year should be encouraged to follow
272 speech training sessions in the period after 1 year postimplantation, and to use both cochlear
273 implants daily because the speech scores would improve further over time. Further
274 investigations are needed to explore the long-term effect of brain processing after reactivation
275 of the bilateral auditory pathways.

276

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282 The authors report no conflicts of interest.

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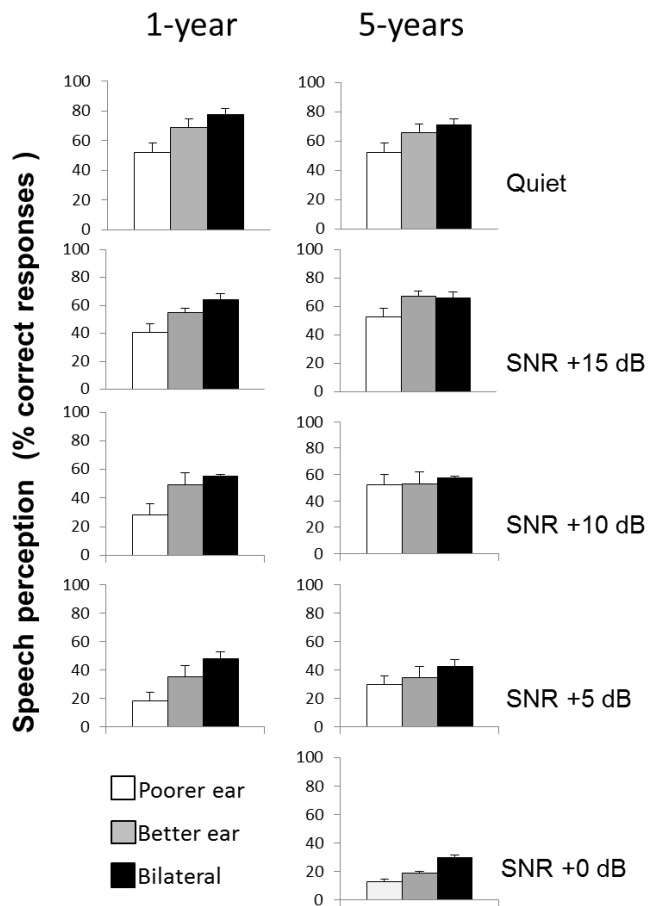
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331

332 **FIGURES**



333

334 Figure 1: Speech perception scores (disyllabic words, 70 dB SPL) in the whole study group
 335 (n=26) at 1 and 5 years after simultaneous bilateral implantation. Results are expressed as
 336 means \pm SEM.

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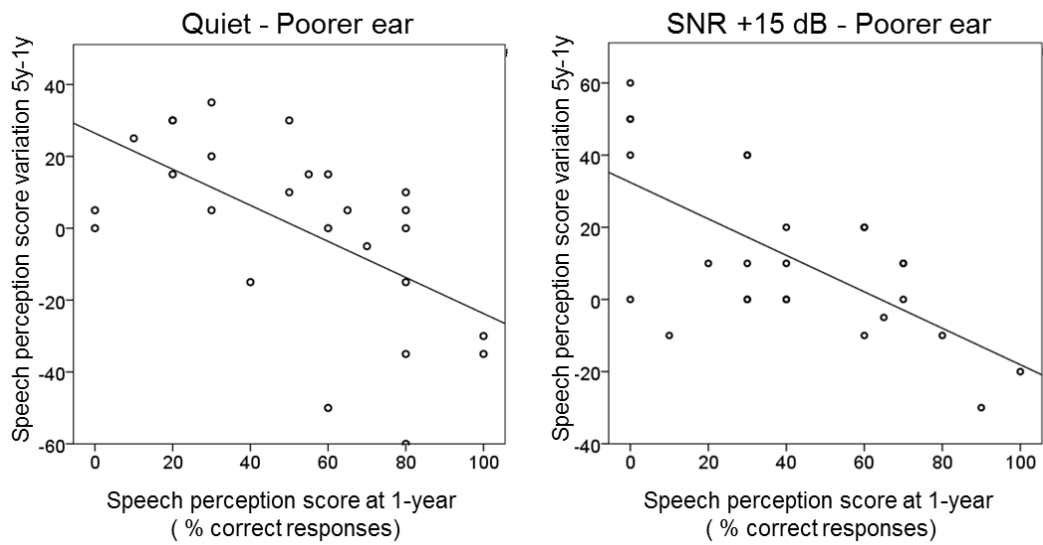
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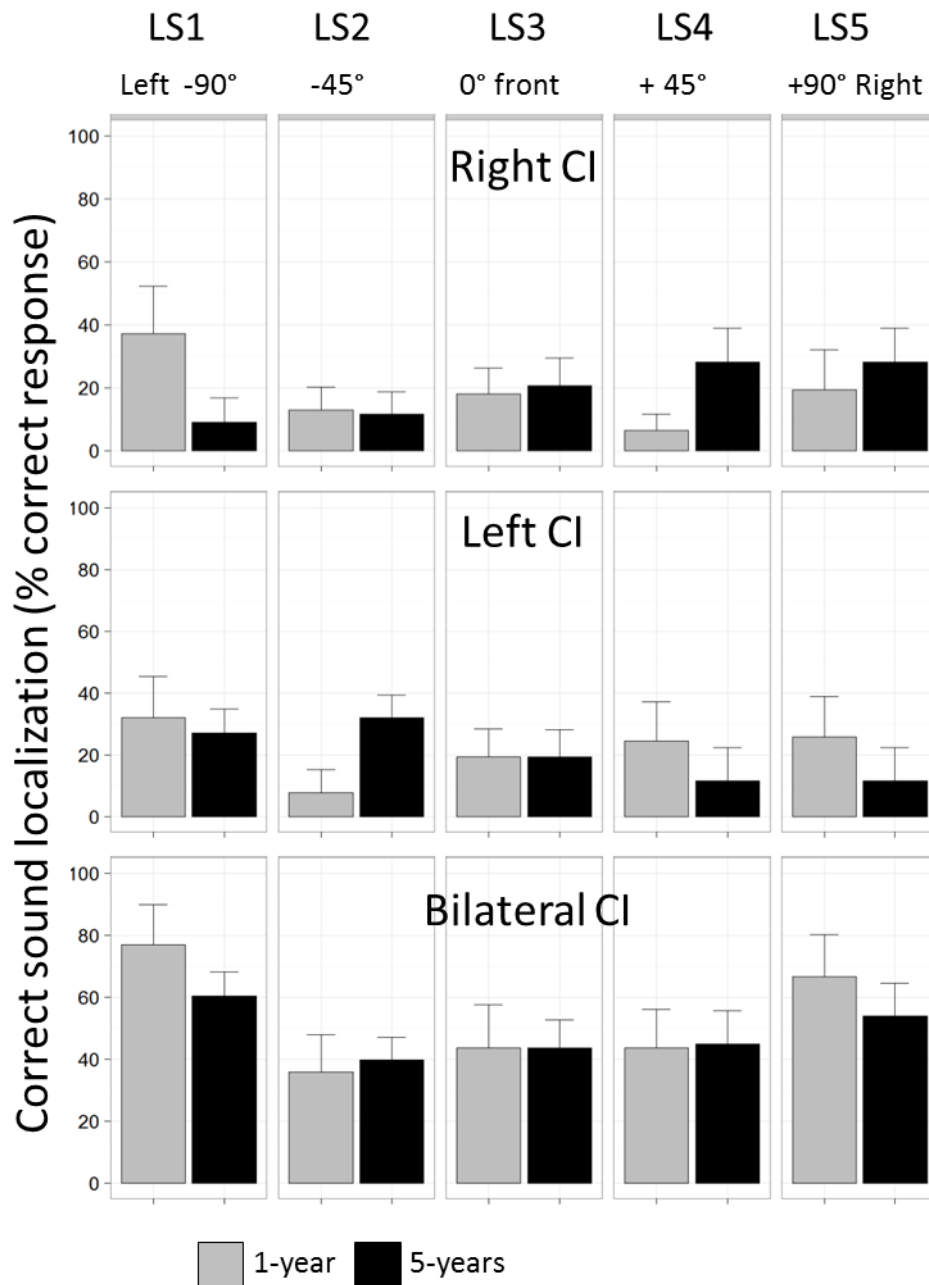
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345 Figure 2: Scatterplots showing the correlation between the scores of the poorer ear at 1 year
346 and the evolution of the scores over time. Correlation between speech perception score at 1
347 year and its variation at 5 years in Quiet ($r = -0.62$) and at SNR +15 dB ($r = -0.58$). The lower
348 the speech perception score at 1 year, the greater the improvement found at 5 years.



349

350 Figure 3: Sound localization in noise in bilateral and unilateral conditions at 1 year and 5
 351 years after simultaneous bilateral implantation (26 patients). The mean correct localization of
 352 the speech stimuli was improved with bilateral implantation compared to either unilateral
 353 right or unilateral left implantation alone for each loudspeaker ($p < 0.001$) at both 1 and 5
 354 years postimplantation. The results were stable between 1 and 5 years postimplantation.

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