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Short title: 5-Year Outcomes in Simultaneous Bilateral CIs

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ABSTRACT

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

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

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

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

over time.

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

INTRODUCTION

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

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

MATERIALS AND METHODS

Selection criteria and subjects

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

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

Speech perception measures

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

Sound localization

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

Statistical analysis

Evolution of speech performance between 1 and 5 years

The better ear was defined as the ear with the better speech score in quiet. In the case of equality of speech scores between the two ears in quiet, the score of the better ear in noise at a SNR of +15 dB was considered. Speech performance score was modeled using a linear mixed model with three fixed effects (1. Time: 1 year or 5 years after implantation; 2. Ear: Better, Poorer or Bilateral; 3. Noise: Quiet, SNR +15 dB, SNR +10 dB or SNR +5 dB) and one random effect (random intercept for each patient). To select the most parsimonious model including only relevant effects of interest, a first model was fitted with the three fixed effects and including all the possible second and third order interaction terms between the fixed effects. Then, a backward selection procedure was applied in order to remove interaction terms that did not contribute to explain speech performance score. The final selected model was the one with the lowest Bayesian Information Criterion (BIC) value. Based on the final model estimates, post-hoc two-by-two comparisons were performed using relevant contrasts with p-values adjusted for multiple comparisons according to the Holm-Bonferroni step down procedure [Holm, 1979].

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

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

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

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

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

RESULTS

Hearing performance after 5 years of bilateral cochlear implantation

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

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

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

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

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

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

Evolution of sound localization between 1 year and 5 years postimplantation

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

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

DISCUSSION

In this study, 5 years after simultaneous bilateral implantation, the speech performance of the poorer ear improved in comparison to 1 year postimplantation. In a study prospectively analyzing nine adult patients simultaneously and bilaterally implanted (MED-EL Combi 40+) with poor speech perception scores at 1 year postimplantation (unilateral scores < 50% for Consonant-Nucleus-Consonant (CNC) words in quiet), Eapen et al. [2009] reported a gradual improvement in the unilateral and bilateral scores over a 4-year follow-up period, and a growth of the squelch effect, whereas the benefit from head shadow and summation effects remained stable. Chang et al. [2010] also observed better speech performance in the bilateral condition for CNC words in quiet at 4 years postimplantation, compared to 1-year performance, in a group of 17 adults simultaneously implanted. Our results corroborate these two studies, but the missing speech perception assessment between the 1-year and 5-year measurement intervals did not allow us to evaluate whether the poorest speech perception scores improved gradually or not over the 4-year follow-up period. The improvement in the poorer ear observed in the present study is possibly related to an enhanced cortical representation of the voice when using bilateral cochlear implants. A positron emission tomography study reported that in adult patients bilaterally and simultaneously implanted for 3 years, the bilateral auditory stimulation in quiet improved brain processing of voice stimuli in the right temporal region compared to monaural stimulation, and activated the right fronto-parietal cortical network implicated in attention [Coez et al., 2014]. The improvement of the poorer ear after 1-year follow-up that was observed in the present study has not been reported in patients unilaterally implanted, even in studies with long-term follow-up [Lenarz et al., 2012; Holden et al., 2013]. A link between the score improvement and a more frequent follow-up cannot be ruled out. Indeed, patients having poor performance had a more intense training in terms of frequency of cochlear implant fittings, and of speech training sessions, compared to patients who rapidly obtain good performance, that were consequently less prone to continue the speech rehabilitation exercises. Another aspect that has not been analyzed in the present study was the time of daily use of the cochlear implants. These parameters have not been studied in our study group, and have to be analyzed in a future report.

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

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

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

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The authors report no conflicts of interest.

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FIGURES

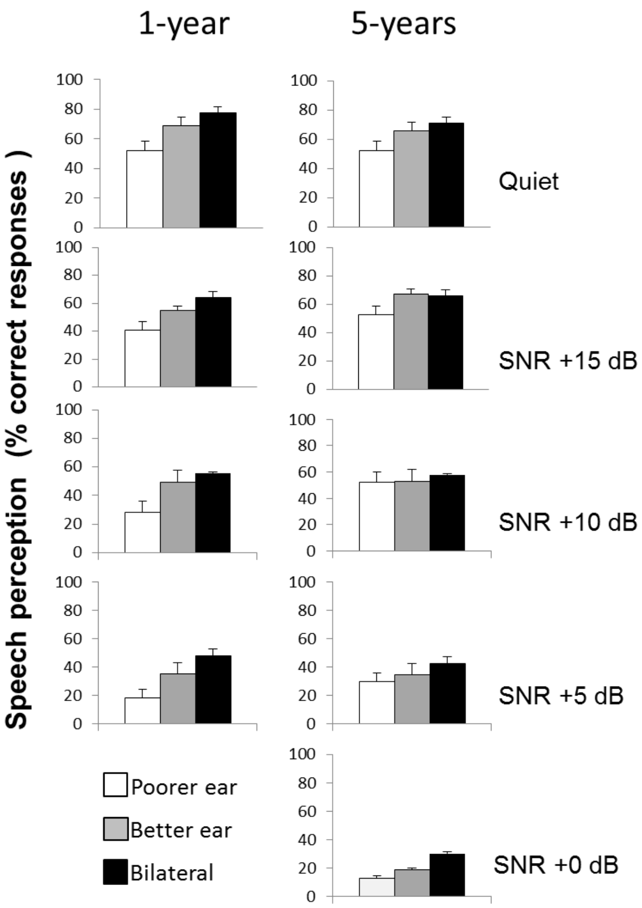

Figure 1: Speech perception scores (disyllabic words, 70 dB SPL) in the whole study group (n=26) at 1 and 5 years after simultaneous bilateral implantation. Results are expressed as means ± SEM.

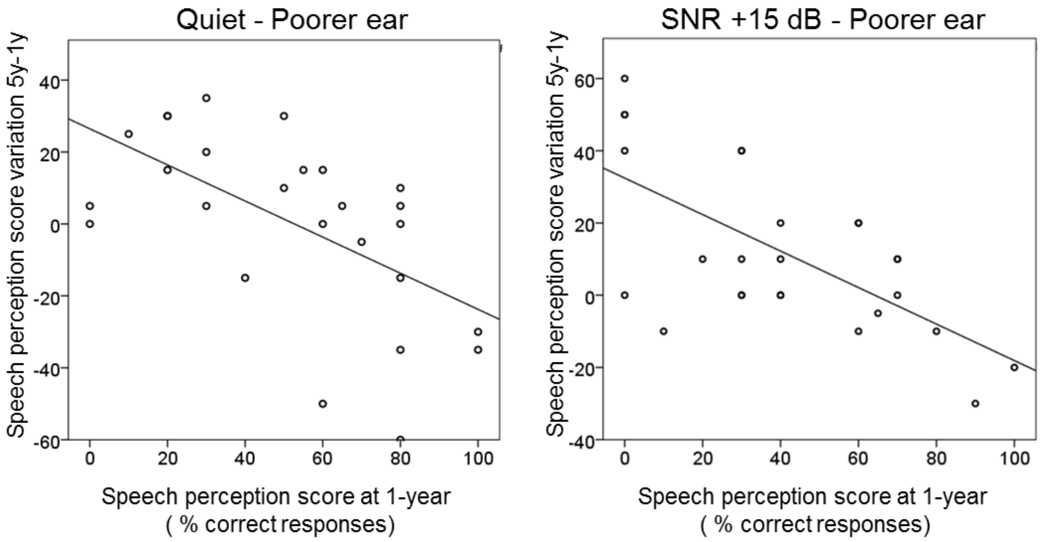

Figure 2: Scatterplots showing the correlation between the scores of the poorer ear at 1 year and the evolution of the scores over time. Correlation between speech perception score at 1 year and its variation at 5 years in Quiet (r = –0.62) and at SNR +15 dB (r = –0.58). The lower the speech perception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

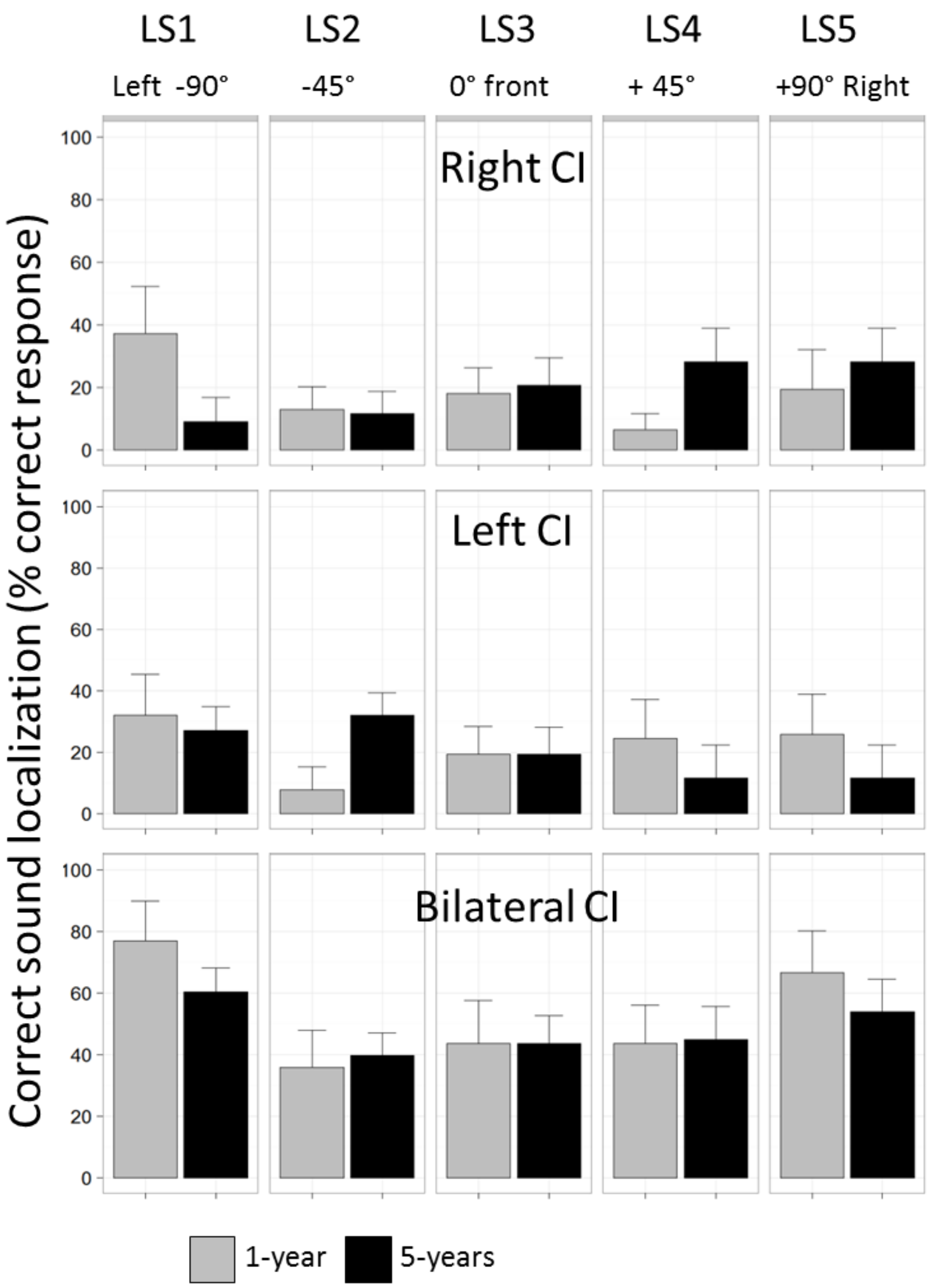

Figure 3: Sound localization in noise in bilateral and unilateral conditions at 1 year and 5 years after simultaneous bilateral implantation (26 patients). The mean correct localization of the speech stimuli was improved with bilateral implantation compared to either unilateral right or unilateral left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