Cochlear Reimplantation With Same Device: Surgical and Audiologic Results

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Objectives/Hypothesis: To study to what extent it is possible to achieve identical insertion depths and to maintain the same performance after cochlear reimplantation.

Study Design: Outcome research on a retrospective case series in a tertiary university referral center.

Methods: Data were collected for 12 adults and three children who underwent reimplantation during the last 3 years with a new HiRes90K device with HiFocus 1J electrode owing to failure of the feed-through seal. Multislice computed tomography scans were used to compare positions of the original and newly placed electrode arrays. The speech-perception scores on a consonant-vowel-consonant word test before and after reimplantation were compared.

Results: All reimplantations were successfully performed by two experienced cochlear implantation surgeons, and no complications were observed. Postoperative imaging showed that the average displacement of the new implant was only 0.59 mm. Reactivation of the implant gave immediate open set speech understanding in all patients, and speech perception rapidly returned to the previous level obtained with the original implant within weeks; it was even significantly better at the 3-month follow-up. No relation was found between changes in performance and the amount of displacement of the electrode array.

Conclusions: After cochlear reimplantation with the same device, electrode-array position can be accurately replicated and speech perception can be regained or even improved within weeks.

Key Words: Cochlear implant, reimplantation, electrode array displacement, speech perception, performance, radiologic imaging.

Level of Evidence: 4.

INTRODUCTION

Cochlear implantation has proved to be an excellent therapy for patients with severe to profound sensorineural hearing loss. It restores the ability to hear sound and to understand speech to various degrees. From the beginning of cochlear implantation, many studies have focused on improvements with regard to surgical technique, implant design, and rehabilitation programs to further improve speech-perception scores. Still, in certain situations revisions or reimplantations of the implanted device are inevitable. Several circumstances can lead to revision surgery, or even reimplantation, such as optimizing insertion of electrode array, secondary inflammation after implantation, or the patient’s wish to receive an upgraded implant model. The most documented reason for reimplantation is, however, internal device failure. Although internal device reliability has improved over the years, reimplantation due to device failure is performed repeatedly in many centers. With the growing numbers of cochlear implantation procedures, the revision and reimplantation rate is growing proportionally. Therefore, reviewing and reporting the surgical and audiologic results for this group of patients has become more important.

Although reimplantation is an undesirable consequence of cochlear implantation, many studies have shown good post-reimplantation results in terms of speech-perception scores. In those studies, the scores were equal to or better than the speech-perception scores before reimplantation. Only a few studies have reported patients who did not achieve the same perception scores after reimplantation. However, in most, if not all, published studies, the period between first implantation, occurrence of the defect, and subsequent reimplantation was fairly long. For that reason, in most cases, a newer type of implant or another brand had
become available and was implanted instead of the device that was initially used.\textsuperscript{1,7} As a result, the newer device was an upgraded version of the former device and was coupled with improved software to drive the new implant. Hence, those changes in design, brand, or software could be the explanation of the same, or even better, speech-perception scores. Consequently, the confounding variable of a different type of implant weakens the comparison between speech-perception outcomes from the first implantation and the reimplantation.

In this study, we investigated the effect of reimplantation on speech-perception scores while using the same implant type. Our study group showed a confirmed feed-through seal defect in the device\textsuperscript{11} within a relatively short period (9–53 months) after first implantation. Because the defect was manifested within a short time frame, the previously used implant type was still the newest available version and was used again at reimplantation. As a result of this defect, generally known as Vendor B defect, patients had sudden and intermittent complaints of a higher volume of sound, a change in their perception of sound, or failure of the implant–radio frequency (RF) link. Although a device problem could be readily identified, the particular reason behind the problem could not be identified through in vivo tests performed by an audiologist. Still, the Vendor B defect could always be confirmed following explantation and return to the manufacturer. Even though this defect was a very unfortunate outcome for the patients, it did give our center the exceptional chance of evaluating surgical and audiologic results after reimplantation in patients with the same type of device within a very short time frame. To our knowledge, research from this unique situation has not been reported before.

In the case of reimplantation in patients with good speech-perception scores, we felt that a minimal change in electrode position should be pursued to minimize the risk of deterioration in performance; it is known that a 3-mm displacement in the cochlea would lead to a tonotopic change of 1 octave.\textsuperscript{12} We believe that hearing with the new implant will be more familiar to the patient if the electrode array is placed at the same location in the cochlea because sound levels and pitch sensations are comparable to the previous situation. This should minimize the rehabilitation and adaptation period with the new implant. Therefore, we used the same type of implant and the same type of electrode array for reimplantation. Pursuing minimal displacement from the original electrode contact locations, we investigated changes in speech-perception scores and adaptation time with the new implant. We analyzed to what extent it is possible to position the new array at exactly the same place in the cochlea as the original electrode array. Time between detection of implant failure and reimplantation was evaluated as another performance indicator.

MATERIALS AND METHODS

Patients

In the population of 410 patients who underwent a cochlear implantation between 2000 and 2009 with a CII or HiRes90k at the Leiden University Medical Center, 12 adults and three children with a HiRes90K implant and a HiFocus 1J electrode (Advanced Bionics, Sylmar, CA) underwent a reimplantation with the same device and in the same ear without complications (Table I). One adult patient with a Gemini implant (bifurcated electrode array for ossified cochleae) also underwent reimplantation, but those results were not analyzed in this study. These 15 patients all had the specific feed-through seal defect, known as Vendor B defect, which was confirmed by intensive testing by the manufacturer, Advanced Bionics, after explantation. All 15 patients underwent their first cochlear implantation procedure at our institution between 2003 and 2006. The 12 adult patients were postlingually deafened. The mean duration of deafness until the first implantation was 22 years (range, 5–43 years). At first implantation, the mean age of the adult patients was 49 years (range, 22–73 years). The children were 3, 4, and 6 years old at first implantation.

All arrays were fully inserted, which was confirmed with the postoperative computed tomography (CT) scan that was obtained immediately after surgery in children and 1 day after surgery in adults. This imaging technique was chosen, because it provides high-resolution images of the temporal bone on which anatomic landmarks, such as the pyramidal process and round window niche, can be directly visualized. The ability to make multiplanar reconstructions within any desired plane after the scan procedure makes this technique independent of patient positioning and ensures accurate measurements of insertion depth even in serial scans.\textsuperscript{13} The fact that a volume scan contains information on the height of the cochlea CT potentially also provides information on the scalar localization of an electrode contact. However, because we believe that radiation exposure should be as limited as possible, we are currently conducting a study to investigate the value of low-dose CT and cone-beam CT to minimize radiation exposure in future postoperative imaging.

The mean period between initial implantation and detection of the device failure was 2.2 years (range, 0.8–4.4 years). Reimplantation was realized within 16 days on average (range, 3–30 days) after detection of the failure, with the exclusion of one child whose parents needed more time to consider reimplantation (87 days).

Reimplantation

After detection of a problem with the internal device, all efforts were made to reimplant within the shortest time. The surgery was performed by two experienced cochlear implantation surgeons to ensure a fastidious and fluent change of arrays. The performance of this delicate procedure by two surgeons facilitates careful removal of the old array and positioning of the new array within a very short time frame. After skin incision and elevation of the skin flap, the array was approached and cut as close as possible near the posterior tympanotomy. This enabled coarse manipulation of the implant body, without tension on the intracochlear array and the risk of either inadvertent electrode removal or trauma to the cochlea. Then, after the pocket had been opened, the implant body was removed and the lead withdrawn from the mastoid through a tunnel.\textsuperscript{14} Next, the area around the cochleostomy was prepared in advance of the array change. If necessary, an incision was made into the fibrous sheath that had formed around the old electrode array. With the new array ready in the insertion tool (tip already slightly protruding), the old array was removed and the new one inserted carefully without disruption of the fibrous sheath. After the old array was removed, it was used for biofilm research,\textsuperscript{15} while the body and the attached lead were sent back to the manufacturer for cause-of-failure testing.
### TABLE I.
Demographic Information for the Subjects Who Underwent Reimplantation.

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Cause of Deafness</th>
<th>Duration of Deafness (yr)</th>
<th>Age at First Implantation (yr)</th>
<th>Ear side</th>
<th>Degree of Insertion Angle for First Implant*</th>
<th>Recent Phoneme Score Before Defect† (%)</th>
<th>Time Between First Implantation and Defect (mo)</th>
<th>Time Between Defect and Reimplantation (d)</th>
<th>Degree of Insertion Angle for Second Implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult 1</td>
<td>Unknown</td>
<td>7</td>
<td>64</td>
<td>Right</td>
<td>500</td>
<td>87.5</td>
<td>9</td>
<td>7</td>
<td>498</td>
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<tr>
<td>Adult 2</td>
<td>Unknown</td>
<td>24</td>
<td>54</td>
<td>Right</td>
<td>491</td>
<td>84.5</td>
<td>14</td>
<td>17</td>
<td>515</td>
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<tr>
<td>Adult 3</td>
<td>Sudden deafness</td>
<td>43</td>
<td>73</td>
<td>Right</td>
<td>479</td>
<td>72.5</td>
<td>41</td>
<td>24</td>
<td>481</td>
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<td>Virus</td>
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<td>50</td>
<td>Left</td>
<td>418</td>
<td>83.0</td>
<td>13</td>
<td>3</td>
<td>418</td>
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<tr>
<td>Adult 5</td>
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<td>35</td>
<td>Left</td>
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<td>88.0</td>
<td>10</td>
<td>21</td>
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<tr>
<td>Adult 6</td>
<td>Unknown Progressive</td>
<td>15</td>
<td>22</td>
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<td>513</td>
<td>80.0</td>
<td>19</td>
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<td>22</td>
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<td>423</td>
<td>90.0</td>
<td>19</td>
<td>26</td>
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<tr>
<td>Adult 8§</td>
<td>Iatrogenic antibiotics</td>
<td>36</td>
<td>45</td>
<td>Left</td>
<td>449</td>
<td>24.5</td>
<td>42</td>
<td>8</td>
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<tr>
<td>Adult 9</td>
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<td>36</td>
<td>Right</td>
<td>461</td>
<td>82.5</td>
<td>35</td>
<td>17</td>
<td>388</td>
</tr>
<tr>
<td>Adult 10</td>
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<td>41</td>
<td>Left</td>
<td>485</td>
<td>93.5</td>
<td>36</td>
<td>13</td>
<td>466</td>
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<tr>
<td>Adult 11</td>
<td>Hereditary progressive</td>
<td>24</td>
<td>50</td>
<td>Right</td>
<td>414</td>
<td>74.0</td>
<td>53</td>
<td>18</td>
<td>530</td>
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<tr>
<td>Adult 12</td>
<td>Hereditary progressive</td>
<td>7</td>
<td>50</td>
<td>Left</td>
<td>599§</td>
<td>74.5</td>
<td>33</td>
<td>12</td>
<td>594</td>
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<tr>
<td>Child 1</td>
<td>Hereditary congenital</td>
<td>3</td>
<td>3</td>
<td>Left</td>
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<td>31</td>
<td>11</td>
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<tr>
<td>Child 2</td>
<td>Meningitis</td>
<td>6</td>
<td>6</td>
<td>Left</td>
<td>507</td>
<td>–</td>
<td>32</td>
<td>11</td>
<td>516</td>
</tr>
<tr>
<td>Child 3</td>
<td>Iatrogenic antibiotics</td>
<td>3</td>
<td>4</td>
<td>Right</td>
<td>511</td>
<td>–</td>
<td>13</td>
<td>87§</td>
<td>557</td>
</tr>
</tbody>
</table>

*Most recent computed tomography scan before reimplantation.
†Average phoneme scores (consonant-vowel-consonant monosyllabic words) at 65 and 75 dB sound pressure level in quiet.
‡The period of 30 days was due to a request by the patient himself for private reasons.
§Patient stated he was postlingually deafened, although his speech production and phoneme scores are more in line with prelingual deafness.
¶Parents needed more time to consider reimplantation owing to dysfunctional social circumstances.
Positioning of New Array

To place the new array in exactly the same location as the old array, the position of the old array was evaluated in situ on the CT scan that was obtained after the first implantation. Close attention was paid to the position of the “jog” of the array in relation to the pyramidal process and the rim of the round window niche (Fig. 1). Using this relation, we pursued the identical position during surgery.

Evaluation of Position After Reimplantation

To evaluate the position of the newly placed electrode array, a postoperative CT scan was also obtained after reimplantation. From these scans, multiplanar reconstructions were produced, consisting of consecutive slices through the cochlea along the center of the modiolus and parallel to the basal turn of the cochlea. Using an in-house–designed postprocessing program (Matlab; Mathworks, Novi, MI), the electrode contact positions and their insertion angles were determined in a three-dimensional coordinate system that fulfills the requirements set by an international consensus working group (Fig. 2A and 2B). These data were used to calculate the exact linear displacement of each electrode contact with respect to the previous position at the first implantation. Although the position of the whole electrode array was evaluated, special attention was paid to the position of electrode contact 16, the most basal electrode. During placement, the surgeon was able to see the most basal electrode contact almost until full insertion was reached. The position of this particular electrode contact is most strongly correlated with the surgical variability and is therefore most important in evaluating and influencing electrode-array position perioperatively and defining its potential dislocation postoperatively.

Rehabilitation and Evaluation After First Implantation

In general, hookup is carried out within 4 to 6 weeks after implantation. The standard rehabilitation program starts with 30 intensive hearing rehabilitation sessions with a specialized speech therapist during a period of 4 weeks. The rehabilitation program comprises 10 levels, starting with sound detection and ending with telephone training and speech perception in noise. During these training sessions, special attention is paid to speech details, such as consonant identification. After this intensive program, frequency of the training sessions is decreased and tailored to each patient's individual needs.

From the moment of hookup, progression of speech perception is tested at set intervals. Speech perception is measured using consonant-vowel-consonant monosyllabic words through the standard Dutch speech audiometric test. All tests are conducted in free field conditions in quiet (65 and 75 dB sound pressure level) and in speech-shaped noise. By using this standardized follow-up program, progress of each patient was carefully examined and documented.

Rehabilitation and Evaluation After Reimplantation

Because the shorter surgical time without much soft-tissue damage or bone work resulted in a faster healing process, hookup was carried out within 2 to 3 weeks of surgery. From the moment of hookup, patients received a less-intensive rehabilitation program (approximately 15 sessions). Speech-training sessions were given daily during the first 2 weeks, reiterating crucial steps from the standard rehabilitation program. After these 2 weeks, additional training sessions were optional and the exercises were adapted to the individual needs of the patient.

In the 12 adults, speech perception was monitored intensively in the first weeks after reimplantation to determine whether (and when) patients recovered to the performance level they had before implant failure. Speech perception was...
therefore measured only 1 hour after hookup and after 1 week, 2 weeks, and 3 months. After these 3 months of intensive measurement, speech-perception measurements again fell in line with the standard follow-up scheme in our center. Because of the differences in measures and time scales used to evaluate the children’s performance, their speech-perception data were not included in the analysis.

**Failure Rates**

After the feed-through (Vendor B) defect had been recognized in several cochlear implants, every implant recipient with a feed through by Vendor B was identified and carefully followed because the failure risk was substantially higher than for the non–Vendor B devices. The total failure rate, which is the sum of all failures divided by the total number of patients who underwent implantation at our center, was measured. For this analysis, adults and children were included, as well as every failing device, regardless of device manufacturer. In particular, the Vendor B failure rate, which is the number of failing Vendor B implants divided by the total number of Vendor B implants, was measured.

**Statistical Analysis**

The most recent speech-perception scores with the first functional implant were compared with the scores that were measured at specified times after reimplantation by using a paired t test and the nonparametric Wilcoxon signed rank test.

The audiologic outcomes were related to the surgical outcomes to determine whether a correlation existed between changes in performance and the amount of electrode-array displacement. For this analysis, the Spearman rank correlation test was applied.

**RESULTS**

**Surgical Outcomes**

Each reimplantation was carried out following the procedure described previously. For each reimplantation, full insertions were achieved and no complications were observed. In Figure 3, the displacement of electrode contact 16 between the original and reimplanted electrode arrays is shown. The average displacement was 0.59 mm (approximately 0.5 contact distance), which means a deeper insertion after reimplantation. All but two patients had a displacement of electrode contact 16 between –2 and 2 mm after reimplantation. One patient (patient no. 12 in Fig. 4) showed a displacement of 5.33 mm. For this patient, there were two CT scans available for the first electrode array. The first CT scan was...
obtained 1 day after surgery, and the second CT scan was obtained several weeks before reimplantation to evaluate the sound-quality complaints of the patient. An obvious difference (6.3 mm) in position of the array between the two CT scans was observed, with deeper insertion immediately after implantation. Based on this observation, we attempted to restore the first position instead of the most recent position.

Audiologic Outcomes

In Figure 4, the speech-perception scores per adult patient at the different evaluation intervals are shown: 1 hour, 1 week, 2 weeks, and 3 months. The scores of these four measurements were compared to the speech-perception score obtained most recently before the device failed. The black line indicates the speech perception before reimplantation. All but one patient (patient no. 3 in Fig. 4) reported, at the time of the hookup of the new implant, that the sound was very similar to the sound quality obtained with the previous implant. All patients, with the exception of the low-performing patient (no. 8), were able to communicate without lip-reading with their new implant within minutes.

In Figure 5, the mean speech-perception scores for all 12 adult patients are shown for each test interval. Both a paired t test and the Wilcoxon signed rank test showed a significant difference \((P = .002)\) between the mean level before reimplantation and that found 1 hour after hookup of the reimplanted device. The average decline was 11%. However, 3 months after reimplantation there was a significant improvement of 4% on average \((P = .014)\) relative to the scores before reimplantation.

Correlation Between Surgical Outcomes and Audiologic Outcomes

The audiologic outcomes were compared with the surgical outcomes to determine whether a correlation existed between changes in performance and the amount of electrode-array displacement. The results for 1 hour and 3 months after hookup are shown as scatterplots in Figure 6. No significant correlations were found for any of the four measurement intervals.

Device Failure Rates

Between 2000 and 2009, 16 of 410 patients who underwent implantation at our center underwent reimplantation, all due to failures of Vendor B devices: the 12 adult patients already discussed, three children, and an adult patient with a Gemini implant. Therefore, the total device failure rate in this cohort is 3.9%, with a failure rate of 4.5% in adults and 2.5% in children.

In Figure 7, a Kaplan-Meier plot shows the survival function of the Vendor B devices from the moment of implantation. A total of 60 patients were identified as having a Vendor B feed-through seal. One of those patients had undergone bilateral implantation and received two Vendor B devices; thus, the Vendor B failure rate was 26%. The remaining patients with Vendor B devices are being closely followed, and any of their complaints will be thoroughly investigated.

DISCUSSION

In a group of 15 patients who underwent reimplantation with the same type of implant, the surgical and audiologic outcomes were evaluated. Failure rates within the center’s cochlear implant population, as well as within the Vendor B population, were calculated. Analyzing positions of the electrode array showed displacements of between −2 and 2 mm for virtually all of the patients. This demonstrates that it is possible to perform a reimplantation and to replicate the original electrode-array position very accurately. For the 12 adult patients, the changes in speech-perception scores and adaptation time with the new implant were analyzed. The speech-perception scores indicated an initial drop in performance directly after hookup, although all patients except one were able to communicate through sound only within minutes after hookup. Within 2 weeks, most patients had adapted to the new implant and had regained their original performance level, and after 3 months most patients had even a slightly better speech perception than with their old implant.
The revision rate of reimplantation at our center is comparable to that at other centers. In the literature, revision rates of 3.7% to 9.3% have been reported.3,4,7,8 However, the Vendor B failure rate of 26% is considerably higher, despite the relatively short follow-up period (5.8 years on average). Although the failure rate seemed to have stabilized after 50 months (Fig. 7), just before submission of this report, another child underwent reimplantation as a result of the Vendor B failure after an implant use of 5.5 years, although this child was not included in this study. Therefore, all patients with Vendor B implants have now been identified and will be tested intensively if they present with sound-quality complaints that could indicate a device failure.

In this series, the revision rate of 2.5% among children (mean follow-up, 5.9 years) is low compared to other reported rates. Rates between 5.6% and 15.4% among children have been reported.3–5,8,23 Many articles report higher rates of reimplantation in children than in adults as a result of defects due to trauma and breakage of the implant casing.3 In this study, only three children from the total population underwent reimplantation, all owing to the Vendor B failure. However, because of the variability in performance and no technical test option, the detection of a Vendor B failure in children is difficult. Therefore, we continue to be especially careful in monitoring and following the children with a Vendor B feed through.

When patients first started to present with complaints of sound-perception changes, the feed-through seal defect had not yet been uncovered. To analyze the complaints, in some cases an extra CT scan was obtained to check for intracochlear changes and changes in array position. When these scans were analyzed, some were indeed found to show different electrode-array positions as compared with the first postoperative scan (0.5–6.3 mm). However, when the complaints intensified and could not be corrected with fitting procedures, the circumstances surpassed beyond what could be expected from and ascribed to shift of electrode-array position. Based on these observations, it was concluded that the complaints were the result of a device failure, and reimplantation followed. In all cases, Vendor B failure was subsequently confirmed by the manufacturer following explantation. Further research was started to investigate these array-position changes, and findings will be reported in the near future. Nevertheless, when there was a change of array position detected through the second CT scans, the array position was carefully evaluated, and in almost all cases the latest position of the array was pursued during reimplantation.

Although other centers report complications like intraoperative cerebral spinal fluid leakage, epidural hematoma, and postoperative flap breakdowns with implant extrusion,5,8,23 no such complications were observed in our population. To change the array quickly to prevent contamination or collapse of the fibrous sheath (as previously stated by Henson et al.9), all reimplantations were executed by two experienced surgeons. Although we realize operating with two surgeons is a large investment and may not be possible to arrange in all centers, our series of reimplantations indicates that this precaution helps to prevent the reported adverse effects.

We hypothesized that the bigger the displacement, the harder the adaptation to the new tones would be for the patient, but in this study no correlation was found between the change in speech perception and displacement of the array. This finding was also described by Henson et al.9 The fact that no correlation between displacement and speech perception was demonstrated indicates that array position within the small variations (<2 mm) in this series does not affect perception and thus adaptation to a new implant; the effect of larger displacements remains unknown. Therefore, we decided to carry on with our exact positioning procedure in future reimplantations to maintain very small displacements.

Interestingly, the mean speech-perception score of the adult patients with the Vendor B failure before reimplantation was comparable to the mean scores at 6 months and 2 years, 74.5% and 75.0%, respectively, for the total group of adult patients implanted between 2000 and 2009 with a HiRes90K HiFocus 1J implant without a Vendor B feed through (P > .4). This means that the patients with the Vendor B device showed no signs of dysfunction or lower performance before the failure of the implant became apparent. This falsifies the hypothesis that the increase in performance after reimplantation was due to lower speech-perception scores before detection of the failure. Furthermore, the mean perception score at 3 months after reimplantation compared to the scores of the total group of implanted adults at 6 months, 1 year, and 2 years was 4% higher, although this difference was not significant.

However, the improvement in speech perception could be ascribed to the training sessions during the
first 2 weeks after hookup, as in these sessions all the crucial steps of the standard rehabilitation program were repeated. It is interesting to note that reimplantation with limited displacement of the arrays and extra training sessions in all patients led to an improved speech perception.

CONCLUSION

This study confirms that not only can the electrode-array position be accurately restored in virtually all reimplantation cases, but also the speech-perception performance rapidly returns to at least the level that was obtained with the original implant.

In addition, we conclude that small displacements, like were seen in this series, will not negatively affect speech perception; the effect of larger displacements cannot be predicted from these data. The setup with two experienced surgeons may facilitate this accurate positioning and thereby help to avoid adverse effects. The concomitant short rehabilitation and rapid adaptation to the new implant may justify the additional cost and effort of involving two surgeons.

BIBLIOGRAPHY