Speech Recognition Outcomes After Cochlear Reimplantation Surgery

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Abstract

This study compares speech recognition outcomes before and after cochlear reimplantation surgery, in relation to clinical factors known before and at time of surgery. Between 2006 and 2015, 2,055 adult cochlear implant surgeries were conducted at this center, of which 87 were reimplantation surgeries (4.2%). Speech recognition scores (SRS) assessed before and after reimplantation were available for 54 adults. Overall, SRS measured after reimplantation were similar to the best SRS obtained by the patient and greater than the last SRS measured before surgery. Additional complications were noted in the clinical files of all patients for which reimplantation was considered unsuccessful (16%).

Keywords

cochlear implants, revision surgery, CI512, outcomes, reimplantation

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Introduction

The prevalence rate for cochlear implant (CI) surgery is steadily increasing due to greater awareness and acceptance of CIs as a standard treatment for severe to profound sensorineural hearing loss, developments in technology, and expanded candidacy criteria (Clark, Clark, & Furness, 2013). This, in conjunction with recipients having devices for longer periods of time, will mean that the incidence of revision or reimplantation surgery is likely to increase (Wang, Wang, Psarros, & da Cruz, 2014). Therefore, it is important to know not only if revision surgeries can be performed safely but also what functional outcomes are realistic to expect postsurgery. This information will support clinicians' decision making when considering reimplantation

The majority of revision CI surgery publications have focused on surgical factors, providing details on device failures (hard or soft) and the surgical outcomes of revision surgery (e.g., number of electrodes inserted; Battmer, Linz, & Lenarz, 2009; Lassig, Zwolan, & Telian, 2005; Wang et al., 2014). Both Masterson et al. (2012) and Wang et al. (2014) provide a summary of some of these articles. Overall, static revision rates for pediatric and adult groups vary from 7.6% to 8.2% (Masterson et al., 2012; Wang et al., 2014). A more

sophisticated analysis of revision surgery rates by Wang et al. (2014), taking into account the duration of implantation, found a linear relationship between initial duration of implantation and revision surgery at 1% point per year of implantation. This implies that after 30 years of implantation about 30% of CIs would need to be revised.

In contrast to the surgically oriented reports, there is a paucity of studies that examine functional outcomes of reimplantation surgery. In a recent study by Manrique-Huarte, Huarte, & Manrique (2016), of 962 pediatric and adult patients implanted over a 23-year period, 38 patients required reimplantation (28 children, 10 adults). The authors report that aided pure-tone hearing thresholds improved in 44% of the reimplanted patients, with 11% showing no change in their thresholds. Sixty-

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four percent of the patients showed an improvement between 20% and 35% points in their disyllabic word recognition score after reimplantation, with a further 9% showing no change in their speech recognition scores (SRS) from before to after reimplantation.

A more detailed analysis of revision outcomes by Rivas, Marlowe, Chinnici, Niparko, and Francis (2008) found that 5% of 825 adults implanted at Johns Hopkins between 1990 and 2006 required reimplantation over this 16-year period, with four of these patients having multiple reimplantation surgeries. The majority of reimplantation surgeries occurred in the first 6 years (M = 4.1 years) after the initial surgery. Audiological outcomes were evaluated by comparing patients' SRS at three time-points: (a) the best score obtained with the first device, (b) the score obtained just before reimplantation, and (c) the score obtained 6 to 24 months after reimplantation. A criterion of 15% points or greater difference was considered a change in scores. Of the 34 patients with available data, scores after reimplantation were better in 65% of cases, the same in 32%, and worse in 3%, when compared with the score obtained just prior to reimplantation (Rivas et al., 2008). When compared with the best score obtained with the first implant, 31% of patients exceeded this score with their new device, 56% obtained the same level of performance, and 14% did not reattain their original best score.

Mahtani et al. (2014) reported 32 reimplantation surgeries (for 30 patients) from 649 adult surgeries between 1988 and 2012 at their clinic. The mean age of these patients at their first implant was 46 years, and 50 years at their reimplant, with a mean duration between implantation surgeries of 5 years (range 2 months–20 years). The best Bamford-Kowal-Bench (BKB) sentence scores (in quiet and noise) obtained with the first implant were compared with their best scores up to 9 months after reimplantation, with a change of 10% or greater being considered significant. It should be noted that only 16 out of 25 patients were tested in noise; presumably mainly the high performing patients. For the 25 adults with available scores in the quiet condition, 56% had no change in scores after reimplantation, 36% had improved scores, and 8% had poorer scores (Mahtani et al., 2014). For the 16 recipients tested in noise, half demonstrated no significant difference after reimplantation, a quarter obtained significantly better scores, and the other quarter obtained significantly worse scores. There was no relationship between the SRS and either the age at reimplantation or the time interval between the two implantation surgeries (Mahtani et al., 2014). In contrast to Rivas et al. (2008) reporting poorer outcomes for patients reimplanted over the age of 70 years, 3 of the 4 patients implanted over 70 years in Mahtani et al.'s (2014) study showed an improvement with their new device.

To specifically look at the effect of age on revision outcomes, Dillon et al. (2015) compared speech recognition outcomes in 29 adults, 14 of whom were younger than 65 years at the time of the revision surgery. The two age-groups had a similar mean length of CI experience prior to reimplantation (younger group: M = 4.9 years, older group: M = 4.4 years) and best SRS before revision surgery (consonant-nucleus-consonant (CNC) words; younger group: M = 44% points correct; older group: M = 36% points correct). There was also no significant difference between groups in their CNC word scores at either 3 or 6 months after surgery, along with no significant relationship between age and the amount of change in scores before and 6 months after revision surgery, indicating that age was not a factor in determining speech recognition outcomes after revision surgery (Dillon et al., 2015).

Overall, despite the varying methodologies, published results from a number of centers worldwide demonstrate that reimplantation can not only be safely performed when clinically indicated but also additionally that in these cases, speech recognition performance is generally maintained, if not improved, with the new implant. Only a very low percentage of patients require a subsequent second reimplantation or experience a decrement in audiological performance after surgery. However, reporting of outcomes is ambiguous. It is not clear whether SRS before reimplantation were obtained just prior to this event, or whether this was the best score the patient had attained with their original implant. In addition, current studies have focused on the surgical indications for reimplantation and the age of the recipient, without giving consideration to factors that arise during, or after the reimplantation surgery, which might affect outcomes.

One other recent factor of relevance is the recall of the Nucleus CI500 series, manufactured by Cochlear Ltd. On September 11, 2011, Cochlear Ltd. recalled all nonimplanted Nucleus CI512 devices manufactured after January 1, 2011, which was later reported to be due to a loss of hermeticity resulting in the malfunction of the diodes, causing the implant to fail. Cochlear Ltd. provided updates of the CI512 failure rates only until August 2012; that update reported a global failure rate of 4.2% for the CI512 devices implanted in adults and children, with mean time to failure postimplantation of 9.3 months (Cochlear Ltd, 2012; Roberts, 2012). This update also stated that most of the failed devices were manufactured in the first quarter of 2011. The majority of current publications on cochlear reimplantation have excluded CI512 device failures, with only one article found providing independent clinical data as to their failure rates (Hildrew & Molony, 2013). Accordingly, of these 411 implant surgeries conducted over a 7-year period, 122 were from the Nucleus CI500 series and

289 from the Nucleus Freedom series (Hildrew & Molony, 2013). The authors report an overall failure rate of 9.8% for the CI512 implants over this period. Looking specifically at the change in failure rate that occurred with device manufactured before and after the recall period of January 1, 2011, the authors note that the failure rates of the CI512 implants increased from 2.4% to 25%.

The aim of this study was to investigate the speech recognition outcomes after reimplantation surgery for adults implanted at the largest CI center in Australia, taking into account factors known before and at time of surgery that may impact on the outcomes. In addition, the failure rates related to the Nucleus CI512 recall were specifically examined. It is anticipated that this information will be beneficial for further advising clinicians and patients in predicting outcomes of revision surgery.

Methods

Ethical approval for this study was obtained from the Westmead Hospital Scientific Advisory Committee and Human Research Ethics Committee, and all procedures were conducted in accordance with this approval (HREC Ref: (3479) AU RED LNR/12/WMEAD/68).

Participants

This retrospective study included all adult patients who were reimplanted between January 2006 and June 2015 at the SCIC Cochlear Implant Program, an RIDBC service, and a partner within the Australian Hearing Hub. Within this period, the center conducted 2,055 adult CI surgeries (Cochlear 92.4%, MED-EL 7.4%, Advanced Bionics 0.2%), with 351 CI512 devices (implanted between November 2009 and September 2011). Of these 2,055 surgeries, there were 87 reimplantation surgeries (4.2%), with SRS assessed before and after reimplantation being available for 57 surgeries (54 adults; three adults had two revision surgeries each). The reasons for missing SRS included a short interval (less than 3 months) before reimplantation, medical conditions taking priority over speech recognition testing, and patients living in remote regions. Accordingly, the clinical files of 31 females and 23 males with SRS measured before and after reimplantation were included in the analyses. All reimplantation surgeries were conducted in the same ear as the initial implant.

The mean age of initial implantation for the 54 patients was 55.3 years (*SD*: 19.2 years; range: 8.5–85.8 years), and 62.1 years (*SD*: 18.3 years; range: 18.3–91.4 years) at reimplantation. As such, the average duration of CI experience before reimplantation was 6.7 years (*SD*: 6.9 years; range: 0.5–6.5 years). Table 1 displays the CI models explanted and reimplanted. Implantation of the

Table 1. Models of Cochlear Implants (CIs) Explanted and Reimplanted.

| Model | Cochlear implants explanted (n) |
|------------|-----------------------------------|
| N22 or N24 | 26 |
| Freedom | 12 |
| CI512 | 14 |
| CI422 | I |
| Hybrid | 4 |
| | Cochlear implants reimplanted (n) |
| Freedom | 39 |
| CI512 | 14 |
| CI422 | 3 |
| Sonata | 1 |

initial device was conducted between 1982 and 2012 (*Mdn*: 2006). At the time of reimplantation, 36 patients were unilateral CI users, and 21 were bilateral users. For CI512 recipients, the initial implantation occurred between 2009 and 2011.

Procedures

A review of patients' clinical files, which included clinical progress notes, documented clinical communications, and surgical reports, was conducted to identify the circumstances that led to reimplantation, as well as other events that occurred during or after reimplantation surgery that could have affected the SRS. For example, cognitive or central processing issues were noted when neurological degeneration or memory decline was identified around the time of reimplantation (e.g., a head trauma can lead to both cognitive limitations and device failure, with the cognitive limitations potentially remaining after reimplantation).

The City University of New York sentence test was the most common test used to measure speech recognition performance by the clinic. These sentences were spoken by a female, native speaker of Australian English, with clinical test protocols involving presenting the recorded materials from a single loudspeaker at 0° azimuth, at 65 dB sound pressure level. The best and last SRS measured with the previous device were collected and compared with the SRS measured after reimplantation. When only one SRS had been measured before reimplantation, this SRS were considered as both the last and the best SRS. This occurred for 22 out of the 57 surgeries. When multiple SRS measures after reimplantation were available, the highest SRS were chosen. When a plateau in SRS was evident, the data point chosen was the earliest of the plateau. For 10 of the 57 surgeries, only the SRS measured with live voice before and after surgery were available. These cases were also included with the rationale that the clinic used

Table 2. Initial Reason for Reimplantation.

| Reason for reimplantation | Duration previous CI use (years) | Successful outcome (n) | Acceptable outcome (n) | Unsuccessful outcome (n) | Total (N) |
|---------------------------|-------------------------------------|------------------------|------------------------|--------------------------|-----------|
| Hard device failures | | | | | |
| All CI models | 8.3 | 22 | 3 | 3 | 28 |
| (CI512 only) | (2.2) | (9) | (3) | | (12) |
| Device migration | 3.2 | 9 | _ | 2 | 11 |
| Nonauditory sensations | 5.2 | 3 | _ | 1 | 4 |
| Otological condition | 5.2 | 2 | _ | 1 | 3 |
| Loss of LF (short array) | 2.6 | 4 | _ | _ | 4 |
| Patients' request | 7.1 | 2 | I | _ | 3 |
| Damage from impact | 12.3 | 2 | _ | 2 | 4 |
| Total | | 44 | 4 | 9 | 57 |
| % | | 77.2% | 7% | 15.8% | |

Note. CI = cochlear implant; LF = low frequency.

live-voice testing with lower performing patients, and excluding the scores from lower performing patients would potentially have biased the results. For bilateral recipients, the SRS reported are those of the ear to be or that was reimplanted (i.e., not the bilateral CI condition). Choosing the best or the highest SRS from multiple measurements may have caused an overestimation of the participants' performance, but this was chosen to reflect a better approximation of the optimal SRS participants could achieve with their CI.

Data Analysis

Descriptive statistics were calculated, and a repeated-measures analysis of covariance was conducted to compare SRS before and after reimplantation. Statistical significance was set at p < .05, and corrections for multiple comparisons were conducted using Bonferroni adjustments.

Participants were then classified into three groups based on their improvement in SRS after reimplantation. This classification was based on a criterion of 10% or greater change in SRS, which the authors determined to be a "clinically significant change" that also considers the test–retest variability in SRS (cf. Mahtani et al., 2014; Thornton & Raffin, 1978). The authors acknowledge that other articles have taken a more conservative approach, for example, adopting a 20% change as the level for clinical significance (e.g., UK Cochlear Implant Group, 2004).

Results

As presented in Table 2, the majority of reimplantation surgeries resulted from device failure or migration. Hard device failures led to 49.1% of the reimplantation

surgeries. Of these, 42.9% were a failure of the Nucleus CI512 device. Less common reasons for reimplantation included nonauditory sensations (e.g., reports of facial nerve stimulation [FNS] or pain), otological conditions (e.g., infections and cholesteatomas), and patients' requests (i.e., when the recipient had requested for reimplantation for reasons such as severe tinnitus).

With respect to the CI512 failures, of the 351 devices implanted by the clinic between 2009 and 2011, 12 (3.4%) were explanted due to a device failure, consistent with the hermeticity issues that led to the recall of this device. The other two CI512 revision surgeries in this study were explanted for different reasons—one being an otological condition and the other being device migration subsequent to the magnet being removed for a magnetic resonance imaging scan that the patient required.

The mean SRS for the 57 participants at the three time-points relevant for this study were as follows: best score before reimplantation = 75.8% (SD: 31.5% points), of which 4 participants (7%) had no measurable SRS (i.e., 0%); last score before reimplantation = 46.4%(SD: 41.3% points), of which 19 participants (35%) had measurable SRS; and score after reimplantation = 80.1% (SD: 30.7% points), of which 3 participants (5%) had no measurable score (Figure 1). The best SRS measured before reimplantation were obtained on average 4.8 years after activation of the initial device (SD: 6.7 years; range: 0.2–23.5 years). However, it must be noted that this figure is largely influenced by patients who received their previous CI before 2006, when testing and reporting in the electronic database at this clinic were not fully standardized or consistent. As such, for 39% of the patients in this study, no SRS were available for their first 3 years of CI use. For those patients who had data available in their first year of CI use, the best SRS before reimplantation were measured on average

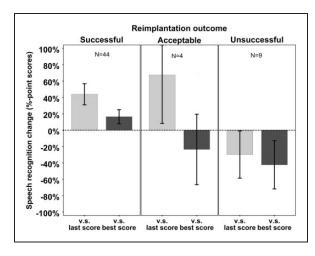


Figure 1. Best and last sentence recognition score before reimplantation and score postreimplantation surgery. Error bars represent the 95% confidence interval had no measurable score.

9.8 months after activation of the previous device (*SD*: 7.8 mo). The best SRS obtained after activation of the new device were measured on average 7.6 months later (*SD*: 6.8 mo).

A repeated-measures analysis of covariance was conducted to compare the last score measured before reimplantation with the score measured after reimplantation. The best score obtained before reimplantation was used as a covariate to control whether the individuals' best score before implantation affected the change measured after reimplantation. There was a statistically significant effect of time of test on the SRS, F(1, 55) = 7.48, p = .008, where scores increased after reimplantation (mean difference = 33.6%, 95% CI: [20.5%, 46.7%] points). There was no significant interaction between time of test and the best score measured before reimplantation, F(1, 55) = 0.71, p = .40, suggesting that the significant improvement in SRS after reimplantation was not dependent on the best SRS. Post hoc pairwise comparisons suggested that there was no significant difference between the SRS obtained after reimplantation and the best SRS obtained before reimplantation (mean difference = 4.4%, 95% CI: [-7.8%, 16.6%] points).

Patients were subsequently classified into three groups after comparing their SRS before and after reimplantation, based on a criterion of 10% or greater difference between the SRS being compared (Figure 2). Those with a successful outcome classification were patients whose SRS after reimplantation were similar to, or better than, their best SRS before reimplantation (i.e., they reached their prior best level of performance). Those classified as having an acceptable outcome were patients whose SRS after reimplantation were better than their last SRS measured before reimplantation but did not regain their best SRS with the previous device.

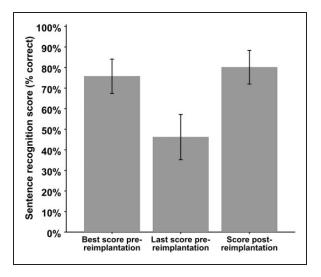


Figure 2. Speech recognition %-point score change before and after reimplantation, categorized in successful, acceptable, and unsuccessful outcome. Error bars represent the 95% confidence interval between the SRS being compared.

Finally, those patients who did not improve from their last-measured SRS prior to reimplantation were classified as having an *unsuccessful outcome*. As presented in Table 2, there were 44 cases with a successful outcome (77.2%), of which 29 used a unilateral CI and 15 used bilateral CIs. Four cases (7%) had an acceptable outcome (3 unilateral, 1 bilateral), and nine cases (15.8%) were classified as having an unsuccessful outcome (4 unilateral, 5 bilateral).

Table 3 reports on any additional issues or events that could have potentially impacted on the SRS outcome. Irrespective of the reason for reimplantation, the majority of patients (77.2%) obtained a successful outcome after reimplantation. Of these 44 surgeries, all but one had no additional complications or issues to consider. However, of the nine patients with unsuccessful outcomes, all had additional issues such as complications during surgery or an incomplete insertion of the new electrode array, cognitive or central processing issues (e.g., dementia), or nonauditory sensations (e.g., FNS affecting the programming of the speech processor). One patient had an otological condition (staphylococcus infection) that persisted despite having the device explanted (without reimplantation at that surgery), and 5 months of treatment before being reimplanted. Of the 12 CI512 failures, nine (75%) patients obtained a successful outcome, but three (23%) did not regain their best SRS before reimplantation.

Of the nine patients in the unsuccessful outcome group, three discontinued their speech processor use in the ear that was reimplanted. The SRS for these three patients decreased from a best performance score $\geq 70\%$ to $\leq 3\%$ points postimplantation. One of these patients

Table 3. Additional Issues.

| | Successful outcome (n) | Acceptable outcome (n) | Unsuccessful outcome (n) | Total |
|---|------------------------|------------------------|--------------------------|---------|
| All CI models (CI512 only) | 43 (9) | 3 (3) | 0 (0) | 46 (12) |
| Complicated surgery or incomplete insertion | I | 0 | 4 | 5 |
| Cognitive or central processing issue | 0 | 1 | 2 | 3 |
| Nonauditory sensations ^a | 0 | 0 | 2 | 2 |
| Otological condition remained | 0 | 0 | 1 | 1 |
| Total | 44 | 4 | 9 | 57 |
| % | 77.2% | 7.0% | 15.8% | |

^aFacial nerve stimulation and pain.

became a nonuser after not being able to perceive any sound with the reimplanted device and subsequently opted to use a hearing aid in their contralateral ear, in conjunction with lipreading. The second patient discontinued use of their reimplanted CI due to poor outcomes and a self-perceived lack of benefit from the CI in that ear. However, this patient was bilaterally implanted and continued to use the CI in the other ear. The third discontinued use of the implant and then received an implant in the contralateral ear. The other six patients continued to use their device, remaining in the same listening configuration as they had at the time of their reimplantation.

Of the 54 patients in the study sample, three (5.5%; 2 bilateral, 1 unilateral) underwent multiple revision surgeries. One of the bilateral recipients was reimplanted in one ear due to an otological condition, and at a later date their contralateral implant failed requiring reimplantation in that ear. The second bilateral recipient was reimplanted in one ear after their CI failed following a head impact, and requested to have their contralateral ear reimplanted at a later date with a newer model because of the difficulties they were having in background noise. That is, both of these bilateral recipients required both of their implants to be replaced in separate operations, for different reasons. The third patient initially had a hybrid implant, and that ear was reimplanted when they lost their low-frequency hearing; however, this second device was later replaced due to device migration.

Discussion

In this center, 4.2% of 2,055 surgeries conducted in adults between 2006 and 2015 were reimplantation surgeries. Statistical analysis suggested that after reimplantation, speech recognition outcomes improved from the last-measured SRS to a SRS similar to the best measured before reimplantation. Specifically, for the majority (84%), speech recognition outcomes were better than the last score measured with the previous device.

These results are comparable to reports from other centers (Mahtani et al., 2014; Manrique-Huarte et al., 2016; Masterson et al., 2012; Rivas et al., 2008). Of note, the most favorable speech recognition outcomes were for patients reimplanted due to hard device failures (Table 2), a finding similar to Rivas et al. (2008). In the nine cases where the outcomes after reimplantation did not reach the level of performance registered before reimplantation, additional events were noted in the clinical files as compromising outcomes. Intraoperative complications such as an incomplete insertion of the electrode array or intrusive nonauditory side effects in the postoperative period were recorded in four cases.

Various surgical complications arising during cochlear reimplantation were identified as the most common reason for poor outcomes. Incomplete insertions usually occur in 7% to 18% of cases (Côté, Ferron, Bergeron, & Bussières, 2007; Lassig et al., 2005; Shin, Park, Lee, Kim, & Choi, 2013) most likely due to cochlear duct obstructions as a result of fibrosis or ossification that occurs following the first implantation (Alexiades et al., 2001; Côté et al., 2007; Miyamoto, Svirsky, Myres, Kirk, & Schulte, 1997). This may lead to a reduced number of channels being available for stimulation and more limited mapping options, which may affect perceptual outcomes. Occasionally, the inability to explant the previously implanted electrode array presents a surgical challenge.

Two patients were affected by clinically significant and persistent FNS. For one patient, FNS was also the primary reason for reimplantation. Wang et al. (2014) identified cases of cochlear ossification, malformation, or otosclerosis as being overrepresented etiologies associated with nonauditory side effects, in particular FNS. Rayner, King, Djalilian, Smith, and Levine (2003) estimated the incidence of FNS to be between 2% and 15% in CI users. Although FNS may be minimized through adjustments in CI programming (i.e., deactivation of electrodes, change in pulse width, intracochlear modes of stimulation; Polak, Ulubil, Hodges, & Balkany,

2006), in extreme cases, reimplantation may be the only option for management. Our experience with array selection suggests that reimplantation with perimodiolar arrays minimizes the further occurrence of clinically problematic FNS. This electrode preference is supported by the findings of other researchers (Battmer et al., 2006; Seyyedi, Herrmann, Eddington, & Nadol, 2013).

Of the remaining three *unsuccessful* cases, two were reimplantation surgeries resulting from damage to the CI following a head trauma. Both of these cases were confounded by cognitive or central processing issues. In one case, the patient was diagnosed with dementia around the same time as the fall, which resulted in the head trauma. In the other case, the patient was involved in a car accident and experienced ongoing memory difficulties after the accident. Both patients discontinued the use of their reimplanted device; however, one of the two patients was a bilateral recipient and continued to use their contralateral CI. The other became a nonuser.

Although device failure resulting from impact or head trauma is frequently discussed in the pediatric literature, it is also a factor that requires consideration for adults and particularly older adults. With an aging population, and the ever increasing number of older adults with CIs, this issue will become increasingly prevalent. With ageing, the risk of falls increases, with gerontology literature reporting the rate of self-reported falls in older adults in the United States to be 15.9% (Stevens, Mack, Paulozzi, & Ballesteros, 2008). Traumatic brain injury leads to 8% of fall-related hospitalizations (Thomas, Stevens, Sarmiento, & Wald, 2008), and as much as it can result in impairment of cognitive and executive functions (Goldstein & Levin, 1995, 2001), it may also be possible that an undiagnosed, preexisting cognitive impairment was the cause of a traumatic brain injury (Thompson, McCormick, & Kagan, 2006).

Also important to note is that rate of falls is exacerbated by the presence of a hearing loss; Lin and Ferrucci (2012) report that in the elderly, there is a threefoldincreased risk of falls in those with a hearing loss. Specifically, Lin and Ferrucci (2012) report on data collected from the national health and nutrition examination survey conducted in the United States from 2001 to 2004 where respondents were audiologically assessed for hearing loss, and provided self-reported information on their history of falls. Among 2,017 participants, aged 40 to 69 years, 14.3% had a hearing loss greater than 25 dB HL. Of these adults with a hearing loss, 4.9% reported falling in the preceding 12 months. In an unadjusted stepwise logistic regression, hearing loss was significantly associated with the odds of reported history of falls. For every 10 dB HL increase in hearing loss, there was a 1.4-fold increase in the odds of that individual reporting a fall in the preceding 12 months. Further, the addition of other potentially confounding factors such as demographic considerations, risk of cardiovascular disease, and vestibular issues did not greatly change the odds ratio (range 1.4–1.6 with the other factors included in the model).

Reimplantation of hybrid users formed another subgroup in this study. This occurred for four of the eight hybrid devices implanted at this center between 2006 and 2015. The mean duration of experience with the hybrid implant for these four patients was 2.6 years. One patient lost their low-frequency acoustic hearing soon after implantation and never obtained satisfactory benefits with the short array. It is unclear from the files whether there were any other factors, in addition to the loss of lowfrequency residual hearing, that contributed to this poor performance. The three other patients initially obtained satisfactory SRS with their hybrid device (i.e., $\geq 90\%$), but their performance later deteriorated as their low-frequency residual hearing thresholds began to decline. All four cases achieved speech recognition outcomes ≥ 89% after reimplantation with a standard electrode array. Our findings are in agreement with the studies in this field, which have reported residual hearing loss occurring from 4 to 30 months after initial implantation, with reimplantation using a full length electrode array resulting in successful outcomes (Carlson, Archibald, Driscoll, & Beatty, 2012; Fitzgerald et al., 2008).

One point of differentiation of this study was the inclusion of patients who were reimplanted due to the recall of the Nucleus CI512 in 2011. In the current study, there were 351 CI512 devices implanted by the clinic between 2009 and 2011, of which 12 (3.42%) were explanted due to hard device failure consistent with the hermeticity issues identified by Cochlear Ltd. This was in line with the global failure rate reported by Cochlear Ltd. of 4.2% in August 2012. Of the 12 CI512 failure reimplantation surgeries, 75% reached their previous best score with their reimplanted device, and 25% achieved an equivalent level of speech recognition performance as their last score before reimplantation. These findings, in conjunction with the outcomes from other hard device failures in this study, suggest that in the absence of confounding factors, either central (i.e., cognitive decline) or peripheral (i.e., cochlear ossification), reimplantation can be performed safely and results in positive audiological outcomes.

In the only other published clinical study found reporting failure rates of the CI512 device, Hildrew and Molony (2013) reported their failure rate to be 25%, which is substantially greater than the 4% failure rate reported by Cochlear Ltd. (Roberts, 2012). The current authors propose that a reason for this discrepancy may be that while Hildrew and Molony (2013) reported their failure rate as a percentage of devices manufactured after January 1, 2011, the Cochlear Ltd. rate referred to all "registered Nucleus CI500 devices globally"; that is,

all the CI500 devices registered since its release in 2009, rather than the devices manufactured from 2011 onwards. It would be reasonable to expect that a large proportion of the registered devices would have been manufactured prior to 2011. According to the Cochlear Ltd.'s (2011) Nucleus® Reliability Report from August 2011, the last report available prior to the recall, there were 25,225 registered CI512 devices globally (13,118 in adults and 12,107 in children). No performance outcomes were reported by Hildrew and Molony (2013) for the reimplanted patients.

Conclusions

Overall, reimplantation surgery is feasible and safe when previously functioning devices fail to sustain adequate audiological outcomes or intrusive nonauditory side effects occur. Reimplantation surgery resulted in equivalent or better performance in the majority (85%) of patients in this study. In patients whose results were poorer after reimplantation, additional confounding issues could be identified in all cases. Because of the small number of patients in each group, it is not possible to conclude whether a specific reason for reimplantation resulted in an unsuccessful outcome more often than another. Only three patients discontinued use of their reimplanted CI, which constituted 5.55% of the population reimplanted in this study. Cases of hard device failure occurring in the absence of any other adverse factors were particularly suitable for reimplantation with 91% achieving a successful or acceptable outcome, and all patients reimplanted due to failure of a CI512 device reattained or exceeded their performance with their previous device. The findings of this study are valuable for counselling patients requiring reimplantation surgery, to help adjust their expectations to realistic outcomes. This information is also useful when working with patients who do not reattain their previous level of performance.

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