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When to replace legacy cochlear implants for technological upgrades: Indications and outcomes

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Abstract

Objective: To determine indications, surgical efficacy, and audiologic outcomes of replacing Advanced Bionics Clarion C1.2 internal devices as a means of technology upgrade.

Study Design: Retrospective review, case series

Methods: Ten patients (10 ears) were initially implanted as a child (mean age = 3.87 years) and underwent cochlear implant reimplantation (CIR) with current Advanced Bionics internal device as a young adult (mean duration of implant use = 15.66 years). Demographic data and pre- and post-CIR speech perception scores were collected.

Results: Technology upgrade was the primary (9) or secondary (1) motivation for CIR. No surgical complications were noted and full insertion was obtained in 9 cases. Intraoperative impedance levels and neural response imaging measures were within normal limits for 8 patients. At most recent post-CIR follow up evaluation, all patients (100%) performed within or better than the 95% confidence interval of their pre-CIR word and sentence recognition scores; 55.6%, 50.0%, and 50.0% of patients performed above the 95% confidence interval of their pre-CIR scores for the CNC words, sentences in quiet, and sentences in noise, respectively.

Conclusion: Post-CIR audiologic benefit was stable or improved compared to pre-CIR results in all categories by 3 months after reactivation. Given these results, patients who are unable to use the most current external processors due to incompatibility with a legacy internal device could consider reimplantation to optimize their overall performance with a cochlear implant (CI).

Keywords

cochlear implant; cochlear implant reimplantation; cochlear implant upgrade

INTRODUCTION

Cochlear implantation is the standard of care for individuals with bilateral severe to profound sensorineural hearing loss. Following over forty years of adult cochlear

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implantation and nearly thirty years of pediatric cochlear implantation, our field is facing new questions and challenges in the management of cochlear implant (CI) recipients. For years, professionals have anticipated that cochlear implant reimplantation (CIR) will be necessary for some individuals, particularly those implanted at a young age. Parents are often counseled that their child will likely require CIR at least once in their lifetime should they live to later adulthood.

To our knowledge, outcomes of CIR for the purposes of technology upgrade have not been reported in the medical literature to date. Historically, CIR was not readily considered for individuals with functional internal devices and stable audiometric performance. We suggest CIR may be indicated for the sizeable cohort of CI recipients who are unable to upgrade to the most current external processors due to incompatibility with their aged multi-channel internal device. These patients are unable to take advantage of recent technological advances in sound processing and noise suppression, which may improve their ability to communicate.

Reimplantation is generally considered a low risk procedure for adults and children. Surgical and medical complications are minimal¹ and audiological outcomes are typically stable or improved compared to best pre-CIR performance^{2,3}. The stability of speech recognition abilities is of particular interest, since some patients may continue to demonstrate excellent scores even when CIR is indicated (e.g. in cases of medical complications). Rate of declined performance is typically less than 15% of reimplanted patients^{1,4,5}, with some groups reporting stable or improved audiometric performance in 100% of their CIR patients^{6,7}. It is important to note that patients will require variable time to adapt to their new device and achieve these stable or improved scores⁸. While previous authors acknowledge technological upgrade as a possible reason for CIR, they do not report on any cases in this category^{2,4}.

The aim of this study was to evaluate outcomes of individuals initially implanted with an Advanced Bionics (AB) Clarion C1.2 internal device who underwent CIR with AB HiRes90K Advantage or Ultra HiFocus Mid Scala internal device as a means of technology upgrade.

MATERIALS AND METHODS

This study was completed in compliance with the Institutional Review Board #Pro00064227 at the Medical University of South Carolina.

Patients

Ten patients (seven female, three male) with AB Clarion C1.2 internal devices underwent CIR surgery at our center. All patients were prelingually deafened, bilaterally, and received their first implant in early childhood (mean 3.9 years, SD ± 2.6) with a mean age at CIR of 19.5 years (SD ± 3.1). Patient 2 has a diagnosis of Auditory Neuropathy Spectrum Disorder with bilateral hearing thresholds in the profound hearing loss range. Four of the ten patients use a CI in their contralateral ear and the remaining six do not use a CI or hearing aid in the contralateral ear. Eight of the ten patients communicate orally and two use total communication. Following CIR, all patients were fit with the most recently released external

speech processor (6 with Naida Q70; 4 with Naida Q90). Programming was completed per standard clinical protocols using updated Hi Res Optima S processing strategy and ClearVoice Medium setting. See Table 1 for complete description of patient demographics.

Surgical Detail

All patients included in this study were reimplanted with either an AB HiRes90K Advantage HiFocus Mid Scala or an AB Ultra HiFocus Mid Scala internal device (based on when the reimplantation occurred). Surgical reports were examined to evaluate success of CIR procedure and identify any related complications. Impedance measurements and neural response imaging (NRI) were completed intra-operatively for all patients.

Audiometric Data

Audiometric test data was compiled retrospectively from patient electronic medical records. The best pre-operative scores on recorded word (CNC Word and Phonemes Test⁹) and sentence materials were used to establish baseline pre-CIR performance. Two patients were reimplanted prior to our clinic's use of AzBio Sentence Test¹⁰ for sentence recognition. For these patients, Hearing In Noise Test (HINT)¹¹ in quiet was used for sentence recognition testing. AzBio +10SNR¹⁰ test condition was used for patients scoring >50% on AzBio quiet. Post-CIR scores were measured at regular follow-up intervals of 1, 3, 6, and 12 months following revision surgery. Most current speech recognition scores were used to evaluate post-CIR outcomes. All patients were tested at 3 months post-CIR or later.

Analysis

A statistical comparison of the pre-CIR and post-CIR scores on the CNC Word Test, CNC Phonemes Test, AzBio Sentence Test in Quiet, and AzBio Sentence Test +10 SNR was performed by utilizing a two-tailed paired samples *t*-test. This was chosen for comparison of numerical data that originates from testing of identical subjects under alternating circumstances. Calculations were performed using SPSS version 25 (IBM). A *p*-value 0.05 was used as the measure for statistical significance in all calculations where this was appropriate. Pre- to post-CIR comparisons were also made relative to established 95% confidence intervals for CNC and AzBio testing.^{10,12}

RESULTS

Reason for CIR

Nine of the ten patients examined in this study identified technology upgrade as their primary motivation for CIR (see Table 1). As young adults, all of the patients expressed desire to use a smaller ear level processor with the ability to stream to electronic devices, to sustain moisture and use during water activities, to improve battery life, and to provide potential improvements in speech understanding in quiet and in noise. Subject 2 experienced significant declines in speech perception scores and rising impedances with her C1.2 device, likely consistent with a soft failure, which led to her decision for CIR. However, she reported technology upgrade as her secondary motivation. Poor internal device placement, which caused pain or discomfort when wearing an on-ear processor, was identified as a secondary motivation for CIR for 5 patients. Decrease in speech perception scores was

reported as the secondary motivation for the remaining four patients. Prior to moving forward with CIR recommendations for the patients who reported decrease in speech perception scores, a new clinic loaner processor system was used for testing to rule out problematic external CI equipment function.

Operative Findings

All patients had full insertion of the new electrode, with the exception of Subject 4, (electrode 16 was observed at the opening of the cochleostomy). No surgical complications were noted in any of the CIR procedures. Impedance measurements were within normal limits for all electrodes for all patients. NRI was obtained using a threshold NRI (t-NRI) on all electrodes tested for all patients except electrode 16 for Subject 4 and electrodes 1–3 and 13–16 for Subject 7.

Audiologic Outcomes

Due to some patients experiencing a decrease in speech understanding leading up to CIR, best pre-CIR scores were used to establish each patient's baseline performance. Based on established 95% confidence interval data, post-CIR scores met or exceeded best pre-CIR scores by 3 months after CIR activation (Figure 1). Pre-CIR CNC scores were missing for subject 3 since they were implanted at an outside hospital and previous records were not available. Of the 9 patients with CNC data, 5 (55.6%) showed post-CIR CNC word score improvement greater than the 95% confidence interval. For sentence recognition ability, 5 (50%) had post-CIR improvement in quiet and 3 (50%) in noise (+10SNR) above the 95% confidence interval. Table 2 displays the mean changes in CNC word, CNC phoneme, HINT/AzBio quiet, and AzBio +10SNR pre and post-CIR. As a group, there were statistically significant improvements in the CNC word, CNC phoneme, and sentence recognition ability. Individual patient data are displayed in Figure 2.

DISCUSSION

The literature is rich with investigations of the incidence of and reasons for CIR in adult and pediatric populations. Previous authors acknowledge technological upgrade as a possible reason for CIR, but do not report on any cases in this category^{2,4}. Overall reported incidence rates for CIR fall between 3–13%, with slightly higher rates among children than adults (5–13%)^{2–5, 7,13–15}. CIR may be motivated by a number of factors, including hard device failure (patient performance declines secondary to malfunction of the internal device), soft failure (patient performance declines in the absence of identifiable device malfunction), trauma (e.g. blow to the head), or medical complications (e.g. infection, migration of the internal device)^{1–3,7,13}. From a group of 60 patients undergoing CIR, Donatelli Lassig et al.¹ describe 10 patients who reported technology upgrade as a primary reason for undergoing revision surgery. Four patients were upgraded from a single channel to a multichannel internal device and three patients were reimplanted due to limitations in programming due to facial nerve stimulation. Marlowe et al.⁵ report on 62 cases of CIR, 2 who underwent CIR for single-channel device upgrade. Significant improvements in post-CIR speech perception performance were reported in 87% of total cases, however the authors did not specifically address the scores of the 2 cases of technology upgrade.

Advances in speech processing strategies and microphone technology are accessible in current external speech processors for CI recipients with Med-El and Cochlear devices and do not require the need for CIR. However, patients with AB Clarion C1.2 internal devices are unable to take advantage of these technological advances without CIR. Use of improved external processor technology has proven to enhance speech understanding for Med-El and Cochlear recipients^{16–20}. Wolfe and colleagues reported speech perception results of 35 unilateral cochlear implant users who were upgraded to the Cochlear Nucleus 5 sound processor from the Cochlear Freedom processor¹⁹. Testing was completed in quiet and in noise with both processors and results revealed a 6 to 6.8dB improvement in speech reception threshold (SRT) for users of the Nucleus 5 processor with a noise setting that incorporates beam former technology. Honeder et al.²⁰ evaluated speech perception in noise abilities of 18 adults with the Med-El Sonnet processor using an omnidirectional microphone and a fixed beamformer. The use of directional microphones with beamformer technology significantly improved SRT by 4.3 to 6.1dB over use of omnidirectional microphones. Previous authors have estimated 1dB improvement in SRT may equate to 7% to 9% improvement in speech understanding in noise²¹.

Newer edition AB CI behind the ear (BTE) sound processors (Naida Q70 and Naida Q90) offer various versions of high resolution (HiRes) processing strategy and incorporate improved multi-microphone technology such as ClearVoice and UltraZoom to deliver enhanced signal processing for their users. Previous studies have shown a change in CI processing strategy alone can lead to improved speech perception scores^{22–24}. Buechner and colleagues²² reported on 45 adult AB CI users who used one of three processing strategies: continuous interleaved sampler (CIS), simultaneous analogue stimulation (SAS), or multiple pulsatile stimulation (MPS), for a minimum of 3 months and then changed to a HiRes strategy. An average improvement of 11–17% was noted across the various speech perception test materials when subjects were tested with the HiRes strategy. Compared to the standard processing mode, HiRes mode was selected as the preferred strategy by 96% of their patients. Firszt et al.²⁴ compared HiRes with a more recent AB processing strategy, HiRes120, and found small but statistically significant improvements in speech recognition with HiRes120 compared to HiRes for words in quiet and sentences in noise. All patients in our cohort used CIS, SAS, or MPS processing strategy pre-CIR and HiRes Optima S post-CIR. HiRes Optima S is the same processing strategy as HiRes 120, with the only difference being improvements in battery life. The change in processing strategy from pre-CIR to post-CIR may account for the increased speech perception scores noted in our study. Should AB release a new speech processor compatible with the C1.2 internal device, users will continue to be limited by the processing strategies available to them (CIS, MPS, SAS). While the older edition AB Harmony BTE sound processor allows for use of HiRes and ClearVoice with all internal devices released after the C1.2, these features are not available when the Harmony is programmed for C1.2 internal devices due to lack of current steering with their eight available channels.

Further improvements in speech intelligibility and signal-to-noise ratio (SNR) can be obtained when using multi-microphone noise reduction strategies instead of a single microphone. As mentioned above, previous studies have proven the effectiveness of using beamformer technology to improve speech perception in noise^{25–28}. A recent study by

Mosnier and colleagues²⁹ stated the use of UltraZoom provided a significant improvement of 3.6 dB SRT for 21 subjects who were able to complete testing in difficult noise conditions. AB Naida Q70 and Naida Q90 processors allow for use of UltraZoom, an adaptive multi-channel dual-microphone acoustic signal-processing beamformer that focuses on speech input originating from the front of the listener while attenuating sounds coming from the sides and the rear of the listener. However, UltraZoom is not available in older generations of AB CI processors..

The improved signal processing and technological capabilities of another feature of newer AB processors, ClearVoice, enhance speech recognition particularly in background noise^{30–32} as compared to previous generations of AB processors. ClearVoice is a signal processing noise reduction algorithm created by AB to improve the SNR and enhance speech understanding in noise by attenuating spectral channels where noise is detected^{33–34}. ClearVoice may also serve to decrease listening effort and increase noise tolerance³⁵. Buechner et al.³⁰ found a significant mean improvement of 20% for intelligibility in noise with ClearVoice Medium when using individually set speech-to-noise ratios (within the 0–6 dB range) in a sentence test with the level of stationary speech-shaped noise set at 55 dB. Kam and colleagues³¹ evaluated 12 experienced Advanced Bionics CI users for speech intelligibility in noise and found a small, yet significant improvement of 5.5% for the ClearVoice Medium setting. Another study performed by Wolfe et al.³² compared speech perception in noise scores with and without the use of ClearVoice and findings revealed significant improvement in speech recognition in noise with use of ClearVoice. All patients in our study were activated post-CIR with the noise reduction algorithm ClearVoice Medium and the beam former technology UltraZoom, both of which likely contributed to the increase in speech in noise scores post-CIR. ClearVoice and UltraZoom are exclusively accessible with HiRes speech processing strategies, which the C1.2 internal device is incapable of using. CIR is the only option currently available for C1.2 users to take advantage of noise reduction algorithms and beam former technology. Noise is present in almost all listening situations, and use of updated processing strategies and improved microphone technology can aid in better speech understanding and overall improved communication for CI users. Even patients with excellent speech perception abilities can benefit from these improvements, particularly in adverse listening environments.

A limitation of this study is the lack of use of a formal questionnaire to assess patient preference and satisfaction post-CIR. However, all patients self reported greater satisfaction with speech understanding, speech clarity, and overall communication post-CIR. They also reported improved quality of life with the Naida processor, with the advantage to hear when participating in water activities, longer battery life and ability to use disposable batteries with the Naida processor, and satisfaction with streaming to electronic devices with better clarity during cell telephone calls. Family members of each subject stated they could more easily communicate with the CI user post-CIR than pre-CIR in quiet and in noise conditions.

CIR should be considered for patients who cannot take advantage of new external cochlear implant technology due to limitations of their internal device. Overall, patients considered for CIR must be healthy enough to undergo surgery and require extensive counseling regarding realistic expectations and the need of adaptation period following CIR. Even

though surgical and medical complications are minimal¹, bony regrowth and altered anatomy from initial CI surgery can be a challenge for CIR cases³⁶. In addition, it is important for surgeons to be aware of the characteristics of the legacy internal device at the time of implantation. Therefore, it is necessary to counsel patients appropriately on all potential risks associated with CIR surgery. Results from our study are positive, yet patients may experience slight frustration when acclimating to the differences in sound processing with a new internal and external device post-CIR. While only one of our patients used computer-based aural rehabilitation in the first month following CIR activation, it will be necessary for some patients to use an aural rehabilitation program in the early stages post-CIR to facilitate best speech understanding outcomes.

CONCLUSION

Cochlear implantation is a safe and reliable surgical intervention for profoundly deaf children. As well, CIR is a safe option for those with legacy multi-channel internal devices who cannot use up-to-date external technology with their existing internal device. Complete electrode insertion is achievable in these cases and speech perception outcomes post-CIR are expected to be stable or improved with time, although exceptions may exist. This study supports the notion that CIR motivated by technology upgrade is a reasonable consideration for CI users to improve overall speech understanding in quiet and in noise.

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Figure 1:

Pre vs. post-cochlear implant reimplantation (CIR) data for CNC words, AzBio quiet and AzBio +10SNR. 95% confidence intervals (CI) are outlined in red for CNC scores and blue for AzBio scores.

Figure 2:
Individual patient data for pre vs. post-cochlear implant reimplantation (CIR).

Demographics of each subject

Table 1:

Subject	Sex	CIR Ear	Etiology of Hearing Loss	Unaided Hearing Thresholds	Opposite Ear CI	Age at First Implant (years)	Pre-CIR AB Processor	Primary Reason for CIR	Secondary Reason for CIR	Post-CIR AB Processor	CIR Processing Strategy	Age at CIR (years)	Intraoperative CIR Neural Response Imaging
1	M	R	congenital	Bilateral profound	X	9.26	PSP	technology upgrade	soft failure	Naida Q70	HiRes Optima S	23.52	obtained on all electrodes
2	F	R	ANSD	Bilateral profound	X	1.77	Harmony	soft failure	technology upgrade	Naida Q70	HiRes Optima S	15.44	obtained on all electrodes
3	F	R	congenital	Bilateral profound	X	0.98	Harmony	technology upgrade	soft failure	Naida Q70	HiRes Optima S	14.84	obtained on all electrodes
4	F	R	CMV	Bilateral profound		4.29	PSP	technology upgrade	poor internal device placement	Naida Q70	HiRes Optima S	19.27	obtained on all electrodes except #16
5	F	R	congenital	Bilateral profound		4.86	PSP	technology upgrade	poor internal device placement	Naida Q70	HiRes Optima S	18.72	obtained on all electrodes
6	M	L	congenital	Bilateral profound	X	2.53	PSP	technology upgrade	poor internal device placement	Naida Q70	HiRes Optima S	18.86	obtained on all electrodes
7	F	R	congenital	Bilateral profound		3.21	Harmony	technology upgrade	soft failure	Naida Q90	HiRes Optima S	21.15	obtained on all electrodes except 1–3 and 13–16
8	M	L	congenital	Bilateral profound		1.44	Harmony	technology upgrade	poor internal device placement	Naida Q90	HiRes Optima S	18.33	obtained on all electrodes
9	F	L	congenital	Bilateral profound		3.46	PSP	technology upgrade	poor internal device placement	Naida Q90	HiRes Optima S	20.31	obtained on all electrodes
10	F	R	congenital	Bilateral profound		6.89	Harmony	technology upgrade	soft failure	Naida Q90	HiRes Optima S	24.82	obtained on all electrodes

CIR, cochlear implant reimplantation

AB, Advanced Bionics

Table 2:

Pre- and post- cochlear implant reimplantation speech recognition scores.

Outcome measure (n)	Mean Pre-CIR (SD)	Mean Post-CIR (SD)	<i>p</i> -value
CNC words (9)	41.1% (± 15.3)	63.5% (± 21.4)	0.03
CNC phonemes (9)	63.0% (± 16.2)	78.96% (± 12.7)	0.03
AzBio quiet/HINT (10)	62.9% (± 15.5)	75.0% (± 15.4)	0.002
AzBio +10 SNR (6)	38.5% (± 20.7)	55.6% (± 22.7)	0.08

CIR, cochlear implant reimplantation

CNC, consonant nucleus consonant

HINT, hearing in noise test

SNR, signal to noise