Cochlear Implant Mapping Through Telemedicine—A Feasibility Study

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Objective: Access to postoperative aural rehabilitation limits cochlear implant (CI) penetration to the candidate population. The purpose of this study was to evaluate the effectiveness of remote CI programming and aural rehabilitation via telehealth.

Study Design and Setting: Retrospective study of one cochlear implant center.

Patients and Intervention: Patients undergoing cochlear implantation from 2015 to 2018 undergoing remote programming as part of routine audiologic follow up.

Main Outcome Measures: AzBio scores, impedances, comfort and threshold levels, and responses to the International Outcome Inventory for Hearing Aids questionnaire modified for CIs (IOI-CI).

Results: A total of 22 CIs in 20 patients were included during the study period. Threshold, comfort, and impedance levels were readily obtained via telehealth and were not significantly different between telehealth and live sessions. AzBio scores and warble tone pure tone averages were also similar and acceptable in both session modalities. Based on IOI-CI scores, patients were very satisfied with their hearing outcomes.

Conclusions: Using telemedicine, reliable measurements were readily obtained and hearing outcomes after remote programming were comparable to those expected after in-person programming sessions. Patients were overall satisfied with their remote programming sessions. Telehealth is a cost-effective and safe way to deliver post-CI audiologic care, particularly to patients with limited mobility or those in remote locations.

Key Words: Cochlear implant—Remote cochlear implant mapping—Remote cochlear implant programming—Remote healthcare delivery—Remote medical care—Teleaudiology—Telecommunication—Telehealth—Telemapping—Telemedicine—Teleprogramming.

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Cochlear implant (CI) utilization rates in the United States are low, with only 5.6% of the adult candidate population estimated to receive implants (1). Elsewhere in the developed world, adult utilization rates are similar or lower (2). Multiple factors lead to low utilization rates in the United States including lack of awareness and of adequate referral networks. Moreover, a significant personal burden related to travel expenditures and missed work may be incurred by the potential patient due to the intensive aural rehabilitation process that is required. For patients that live in rural or remote areas, access can be limited by the distance of the nearest CI center. The lack of access to cochlear implant services in rural locations creates a significant healthcare disparity and rural residence has been implicated as a cause for delayed implantation in eligible adult and pediatric CI candidates (3–5). Telehealth has been proposed as a way to improve access to care in rural areas and address this disparity (6).

Telehealth is the use of telecommunication to provide healthcare from a distance and is increasingly used in audiology practice for numerous applications. Audiometry, hearing aid counseling, programming, and fittings have all been successfully provided via teleaudiology services (7,8). For cochlear implantation specifically, teleaudiology has the potential to extend the reach of implant centers into remote areas of their healthcare catchment. However, before teleaudiology can be widely applied, it must be proven to be feasible and equivalent to traditional in-person services, the current standard of care. Small pilot studies have demonstrated remote cochlear implant programming is feasible, but larger studies are needed to show that mapping via telemedicine is non-inferior to traditional in-person programming (9,10).

In the present study, CI recipients were evaluated in both in-person audiology encounters and subsequent remote teleaudiology encounters. Standard technical measurements including impedances, threshold levels,

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and comfort levels were obtained and patient performance was assessed based on speech testing with AzBio sentence lists and warble tone averages. Patient satisfaction with the process was also evaluated. This study serves as a proof-of-concept and preliminary evaluation of non-inferiority for teleaudiologic services for CI patients.

MATERIALS AND METHODS

Study Design

A retrospective review of our institution's audiology database was performed to identify adult subjects who underwent teleaudiology services at the Connecticut Veterans Affairs (VA) Healthcare System (West Haven, CT) from 2016 to 2019. This study was formally submitted to the IRB for approval and granted an IRB exemption under #48 CFR 16.104(d) (4). Every subject underwent initial activation and at least the first mapping session in person at his centralized implantation center. After the implementation of a pilot teleaudiology practice that included CI mapping services, subjects were given the option of teleaudiology follow-up at remote locations for ongoing aural rehabilitation. As a matter of routine surveillance, cochlear implant patients underwent regular speech perception testing with AzBio sentence lists. Other data points that were routinely collected at in-person and teleaudiology mapping sessions were threshold levels, comfort levels, and impedances. In addition to collecting audiology data, chart review was performed to collect demographic data including laterality of implantation, age, sex, and hearing loss etiology.

Patients were also contacted after their telehealth sessions to complete an International Outcome Inventory for Hearing Aids questionnaire modified for CIs (IOI-CI) (11,12). The IOI-CI is a seven-question survey with five answer choices each, scored from 1 to 5, evaluating satisfaction, improvement in hearing, and degree of use for cochlear implants. An average patient with severe hearing loss scores a total of 25.5, and a score greater than this is typically considered successful (13).

Teleaudiology

Teleaudiology mapping sessions were conducted using Clinical Video TeleHealth video-conferencing software (United States Department of Veterans Affairs, Washington, DC). At the remote location (another VA system location), the patient was aided by a local trained audiologist who did not have specialized skills in cochlear implant aural rehabilitation. The facilitator at the remote location had programming pods for Advanced Bionics, Cochlear, and Med-El devices. The primary audiologist used Skype screen-sharing (Skype Technologies, Palo Alto, CA) on a standard desktop computer to access the CI software on the remote computer and conduct the mapping session. Although it was never ultimately necessary, the patient and facilitator were instructed to remove the patient's processor in the case of any discomfort, or if connection was lost. All patients at the VA are given two CI processors, so in this event, they were instructed to switch to their other processor if the connection was unable to be restored. AzBio sentence lists were also available at the remote location to conduct speech perception testing.

During a typical teleaudiology session, after the remote audiologist took control of the session, impedances, maximal comfort levels, and threshold levels were checked for each implant electrode. Next, a subjective live voice evaluation was performed and minor volume control or programming modifications were conducted to patient comfort. At this point, the session with any modifications was saved, after which AzBio sentence list and warble tone sound field testing were conducted. Impedances were reported in kilo-ohms (kΩ), while comfort and threshold levels were reported in manufacturer-specific units for each of three CI manufacturers. Results of warble tone testing were reported as hearing levels in decibels (dB HL), using an average of threshold levels at 500 Hz, 1, 2, 3, and 4 kHz. The patient then was asked to repeat an AzBio list of 20 sentences and results were reported as a percentage of correct words. For patients who underwent multiple in-person or teleaudiology sessions, data from the first telehealth session and the last preceding in-person session were captured.

Data Analysis

Statistical analysis was performed using SPSS statistical software for Windows, version 20 (IBM, Armonk, NY). Average AzBio scores, impedances and comfort, and threshold levels between live and telehealth encounters were compared using two-tailed Student's *t* tests. Comfort and threshold levels were analyzed separately for each manufacturer due to the use of incompatible manufacturer-specific units.

RESULTS

A total of 22 cochlear implants were performed in 20 patients during the study period. Average age was 77.1 years and all patients were men. Causes of hearing loss included noise exposure or presbycusis (15 patients, 75%), sudden sensorineural hearing loss, and Menière's disease. Six patients received implants by Advanced Bionics (CA), 10 by Cochlear (Sydney, Australia), and six by Med-El (Innsbruck, Austria). Median times from cochlear implantation to live and tele-health encounters of interest at our site, respectively, were 587 and 735 days, as many of these patient had their cochlear implantation performed and managed elsewhere before presentation.

Impedances, threshold and comfort levels, warble tone averages, and AzBio scores were readily obtained for patients via telehealth. There were no significant differences in impedances between in-person and telemedicine encounters (average in-person to telemedicine impedance difference $0.4 \pm 1.5\,k\Omega$). Threshold and comfort levels were comparable between in-person and telehealth encounters (Table 1).

AzBio scores were available for 21 implants in live sessions and 19 implants in telehealth sessions. Average AzBio scores were 62% for live sessions and 71% for telehealth sessions ($p > 0.05$). Warble tone testing was performed for 16 implants in live sessions and 15 implants in telehealth sessions. Warble tone average hearing levels were 29 dB for live sessions and 30 dB for telehealth sessions ($p > 0.05$). Average IOI-CI score was 27.99.

DISCUSSION

As telehealth has expanded worldwide, its role has also evolved from the fundamental application of increasing access to care to improving convenience and reducing costs (14). On average, patients in the United States

TABLE 1. *Comparison of impedance, threshold and comfort levels, warble tone averages, and AzBio testing between in-person and telehealth sessions*

Characteristic		In-Person Average	Telehealth Average	*p* Value
Impedances (kΩ)		6.88	6.87	>0.05
Threshold levels (manufacturer-specific units)	Advanced Bionics	37	39	>0.05
	Cochlear	124	125	>0.05
	Med-El	4.5	4.7	>0.05
Comfort levels (manufacturer-specific units)	Advanced Bionics	246	253	>0.05
	Cochlear	169	170	>0.05
	Med-El	24.9	25.9	>0.05
Warble tones (dB HL)		29.4	30.6	>0.05
AzBio scores (%)		61.7	70.2	>0.05

spend 123 minutes for a 20 minutes appointment with a healthcare professional, including travel and wait time (15). This figure is likely longer for patients with limited mobility or who live in remote areas. Therefore, telehealth addresses a gross inefficiency in the delivery of healthcare for certain conditions which may not require an in-person consultation.

Cochlear implant programming is well-suited to telehealth. Conventional programming methods typically use a desktop computer and manufacturer-specific software, and remote programming differs only in its use of the internet (16). Therefore, one can expect comparable outcomes provided certain criteria are met. First, all patient information transmitted online must be encrypted and must be sent to and from secure servers. Second, patient safety must be prioritized; safeguards must be in place to allow termination of stimulation and reversal of any changes if the connection is severed for any reason, and an audio-video link between provider and patient must be in place to ensure issues such as facial stimulation can be detected. Finally, patients must have the possibility for physical access to a provider in the event a problem is discovered requiring in-person intervention. Limited past reports of telehealth cochlear implant programming have suggested that these criteria are achievable (9,10,16).

In our current model, programming sessions were conducted between two Veterans Affairs institutions over a secured and encrypted virtual private network. In the future, these sessions could potentially be conducted between medical systems with incompatible records, or even between audiologists and patients at home. For these applications, software would need to be designed to ensure adequate security. Furthermore, patient safety is paramount in implementation of any telehealth endeavor and this was reflected in our study design. We employed an audio-video link and allowed for immediate reversal of any unwanted changes by removing the patient's processor and replacing it with their backup processor. As an additional safeguard, a second audiologist was present in person with each patient undergoing remote programming, although intervention on their part was never needed. For two patients, the tele-audiology connection was lost during intervention without harm to the patient, and the remote audiologist was able to immediately reconnect and continue the session. In our data, CI metrics including impedances, comfort and threshold levels, AzBio scores, and warble tone averages were conserved between telehealth and in-person encounters, indicating equivalence in measurement. AzBio scores and warble tone averages were slightly better in the telehealth group, although not to a statistically significant degree; this may be due to the fact that telehealth encounters were performed later after implantation, and patients had undergone more programming sessions and become more acclimated to their implants. Furthermore, results of IOI-CI testing indicated that our protocol was subjectively successful, although this reflects the combination of in-person and telehealth encounters.

Reimbursement for telemedicine services has historically been an impediment to their adoption in the United States. Currently, 31 states and the District of Columbia require private insurance carriers to reimburse for telehealth visits at commensurate rates to in-person visits (17), and two additional states require reimbursement for telemedicine visits for a predefined list of health services (18). Medicaid provides coverage for telemedicine in all 50 states, although only 11 states provide comprehensive coverage for all telemedicine services. However, Medicare is the most restrictive payer, only providing reimbursement for telemedicine in a predefined list of underserved geographic regions. Unfortunately, the elderly population (primarily serviced by Medicare) is the fastest growing cochlear implant recipient population (19) and all patients in the present work were 65 years of age or older. This leads to a significant gap in the coverage of CI telehealth services. While the Veterans Affairs system does not rely on third-party insurance carriers, reimbursement remains a difficult obstacle to the implementation of CI telemedicine services in other treatment settings.

In addition to providing access to care, improving convenience, and potentially reducing cost for CI patients in developed countries, remote programming of cochlear implants has significant implications for humanitarian missions in the developing world. Congenital hearing loss is more common in the developing world due to higher prevalence of infectious etiologies and unreliable prenatal care, and the overall rate of hearing loss in developing countries is increasing (20). Furthermore, support systems for the deaf are underdeveloped or absent in these settings, leading to a significantly compromised ability to function in society (20). A survey of the William House Cochlear Implant Study Group revealed overwhelming support for CI humanitarian programs in developing countries. However, 83% of respondents cited lacking audiology and rehabilitative resources as the greatest barrier to successful implementation (21). A robust telemedicine system would allow remote programming of CIs with very limited ground presence which could render such humanitarian projects feasible for visiting surgeons. However, as with any surgical humanitarian project, local providers would require training in identifying and managing postoperative complications.

To our knowledge, we report the largest cohort of CIs programmed via telehealth to date. This study serves as a proof-of-concept and feasibility study for the viability of this program. However, several limitations of this study should be addressed. This was a retrospective study and not all audiologic data were obtained for every patient during both in-person or telehealth audiology encounters, and the effects of missing data are unclear. All patients underwent initial device activation in person, and although this process could also be amenable to remote programming, this is not proven in the current work. Finally, we compared patients' telehealth programming sessions to their own previous in-person programming sessions, which is a suboptimal control group. While patients were overall satisfied with their telemedicine experiences and their hearing correlates were reassuring, a matched controlled cohort study would be better suited to determine non-inferiority of this technique.

CONCLUSIONS

A cohort of 20 patients with 22 cochlear implants who underwent remote programming via telemedicine is presented. Reliable measurements were readily obtained and hearing outcomes were comparable to those expected for in-person programming sessions. Patients were overall satisfied with their remote programming sessions based on IOI-CI scores. Telehealth is a cost-effective and safe way to deliver post-CI audiologic care, particularly to patients with limited mobility or those in remote locations.

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