Evaluation of Remote Check: A Clinical Tool for Asynchronous Monitoring and Triage of Cochlear Implant Recipients

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Background: A new Remote Check App permits remote self-testing of hearing function for Nucleus cochlear implant (CI) recipients and enables asynchronous review by their clinician to support patient-management decisions.

Objectives: To evaluate the Remote Check App for: (1) ease of use; (2) overall acceptance of the test battery by CI recipient or their carer in the home setting; (3) test–retest reliability of audiological threshold and speech recognition measures via wireless streaming; and (4) to compare outcomes from patient-driven measures with conventional clinician-driven measurements of aided-hearing function.

Design: Single-site, prospective, repeated-measures cohort study with 32 experienced CI users (28 adults and 4 children).

Methods: Participants completed self-testing using the Remote Check app at home and in the clinic. Measures include audiological, objective and subjective tests. Self-administered speech recognition in noise, via the digit triplets test (DTT) and aided thresholds, via the aided threshold test (ATT) were reassessed in free-field and by clinicians following conventional clinical protocols. Results of ATT and DTT were compared across test conditions. Completion time and perceived ease of self-driven assessments were documented. Insights from subsequent real-world experience with Remote Check are summarized and compared to the study findings.

Results: Remote Check was rated as easy to use by the majority (87%) of subjects. Mean group test–retest score differences for self-administered testing within the clinic versus at-home environments were non-significant ($p > 0.05$): 1.4 dB (SD = 1.97) for ATT and 1.6 dB (SD = 1.54) for DTT. Mean group test–retest score difference for patient-driven DTT in streamed versus the free-field condition was 1.8 dB (SD = 2.02). Self-administered, streamed, ATT via Remote Check, resulted in significantly lower thresholds compared to clinician-driven warble-tone thresholds in the free-field by 6.7 dB (SD = 6.8) ($p < 0.001$). ATT thresholds via Remote Check were not significantly different from predicted thresholds based on the Threshold Sound Pressure Level of the sound processor.

Conclusion: Remote Check is the first CI telehealth assessment tool that uses wireless streaming to enable comprehensive, easy and reliable self-testing of hearing function by the CI recipient or their carer, in the comfort of their home. Asynchronous access to test results can assist clinicians in monitoring and triaging individuals for appropriate patient-management based on their needs. Use of remote monitoring may also help to reduce the burden of unnecessary clinic visits on clinic resources, patient travel time and associated costs. Remote Check is an important step toward addressing the current growing need for asynchronous audiological telepractice to support long-term care of CI recipients.

INTRODUCTION

Hearing loss is one of the main contributors to the global burden of disease (GBD 2021). Cochlear implants (CIs) can help to significantly improve hearing function for speech understanding and the quality of life for those with significant sensorineural hearing loss (Buchman et al. 2020). To ensure that CI recipients continue to maintain stable outcomes, follow-up clinical appointments are typically conducted frequently in the first year after surgery and then every 6 months or annually (American Academy of Audiology 2019). Cochlear implantation service is provided for the CI recipient by specialized centers lifelong. In healthcare treatments that require visits to a specialist, patient compliance to recommended follow-up visits to specialists may reduce as the distance between the patient and their clinic increases (Chan et al. 2006). Research has also identified that CI recipients may be lost to follow up due to difficulties in traveling to their CI clinic (Rooth et al. 2017). There is a shortage of audiological professionals around the world (Kamenov et al. 2021), and the COVID-19 pandemic has further amplified the difficulties experienced by CI recipients accessing CI services (Ayas et al. 2020). Currently, audiology services are concentrated in densely populated areas and teleaudiology can serve as a great way to provide access to patients living at a distance from the treatment center (Coco et al. 2018).

The most common CI teleaudiology services provided are synchronous services (Buckman & Fitzharris 2020) where the clinician conducts a care session remotely with a recipient by means of video/audio call in real time. Although synchronous services help in overcoming the barriers of distance for the recipient, the overall amount of time spent by the clinicians for each appointment is the same as an in-clinic appointment if not more. It also requires specialized programming hardware to be available at the remote site and relies heavily on uninterrupted internet connectivity to enable video conferencing and control of the remote computer. As a result, many synchronous teleaudiology services are conducted at a satellite clinic situated closer to the patient but seldom at the patient's home (Krumm 2016).

Asynchronous services, where the recipient completes certain tasks or tests by themselves at their convenience and then sends the results to their clinician for off-line analysis, are preferable (Krumm & Syms 2011) as such practices can help to overcome the barrier of distance while enabling some time saving for the clinician. The first step in a CI aftercare session is the determination of the presence, nature and extent of any issues faced by the recipient, typically by means of an interview. The use of a questionnaire is one of the easiest asynchronous methods of teleaudiology and it has been found to be useful

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to identify and to triage recipients who might need a clinic appointment (Howe & Mawman 2015). A self-reported questionnaire has the additional benefit of minimizing any potential acquiescence bias by patients as completing a questionnaire on their own does not have the social pressure implicit in a clinician-led interview (Graham et al. 2007).

Several questionnaires like Speech Spatial and Qualities of Hearing scale (SSQ) (Noble et al. 2013) are available to help identify challenges through self-reporting. As the self-perception of hearing handicap increases, there is an increase in help-seeking behaviors, uptake/use of hearing aids and satisfaction of treatment benefits (Vestergaard Knudsen et al. 2010). Conversely, low levels of self-perception of hearing handicap result in low levels of help-seeking behavior (Palmer et al. 2009).

However, reliance on a questionnaire alone might miss identification of some people with hearing difficulties if they are not able to recognize or acknowledge their hearing handicap. It is common for people with mild decrease in hearing sensitivity to not recognize their resulting hearing handicap (Weinstein & Ventry 1983). This is especially true if the decrease in hearing sensitivity has developed gradually over time due to the well-known phenomenon of creeping normality. For some long-term CI recipients, changes in their aided-hearing performance with their CI might occur gradually and might not easily be recognized or acknowledged. Objective tests can help in identifying issues that are not self-reported in a questionnaire.

Aided threshold assessment is one of the most widely used objective performance measurements with CI recipients (Vaerenberg et al. 2014) and has been shown to be useful to identify MAP-related issues (Govaerts et al. 2006). While used routinely, aided threshold targets vary widely across clinics ranging from 20 to 40 dB HL (Vaerenberg et al. 2014). Thus, rather than comparison to a target, the comparison of each recipient's latest aided thresholds with their previous thresholds is preferable for the identification of hearing acuity issues. Aided threshold tests (ATTs) are well suited for asynchronous teleaudiology purposes as they can be easily and reliably self-administered (Bright & Pallawela 2016).

Speech perception tests are often used to complement ATTs, to objectively assess hearing function for CI recipients and can further help to determine any issues or changes. When presented at a fixed loudness level, speech perception test outcomes for an individual may display a floor effect if the test is too difficult or a ceiling effect if the test is too easy and thus not have the desired sensitivity to detect changes in hearing function overtime. An alternative to fixed-level speech tests is an adaptive speech perception test, where either the stimulus or a competing background noise is adaptively altered to determine the speech reception threshold (SRT) for 50% correct. By continuously assessing at the most sensitive region of the performance intensity function, floor and ceiling effects are reduced or removed (Nilsson et al. 1994). While fixed-level tests like AzBio sentences (Spahr et al. 2012) and CNC words (Peterson & Lehiste 1962) are used by most CI clinics in the United States, inconsistency in the presentation level and the signal-to-noise ratio (SNR) used across clinics makes it difficult to collate or compare reported outcomes (Prentiss et al. 2020). As a result, establishing reliable, universal guidelines to indicate when a change in an individual's hearing performance requires further intervention or not is hindered/difficult. Consistent use of adaptive test methods may be a step toward overcoming some of these issues.

Speech tests are not always performed at CI clinics (Vaerenberg et al. 2014) possibly due to limited time and or access to calibrated facilities amongst other reasons. Alternatively, speech perception tests may also be performed outside the clinic, for example, in the patient's home. Testing at home requires tests that can be easily self-administered. Two such speech perception tests currently available for self-administration are the digit triplet test (DTT) (Smits et al. 2004) and the matrix test (Hagerman 1982; Ozimek et al. 2010). For the first-time use of an individual, a learning effect is observed with both tests, however, only one practice list is required to overcome the learning effect with DTT (Smits et al. 2013), while two lists are required for the matrix test (Kollmeier et al. 2015). DTT is a quick and easy test that is well suited for implementation on a smartphone, is suitable for adults and children, for people with high and low speech perception ability. Researchers have reported the English version of the DTT can be used with both native language and nonnative speakers, requiring only limited linguistic skills (Smits et al. 2013; Potgieter et al. 2018). Outcomes on DTT have been shown to correlate well with the outcome on conventional speech perception tests in English and in Dutch (Kaandorp et al. 2015; Cullington & Aidi 2017). In a recent study (Schönborn et al. 2020), digits in noise were used for self-assessed hearing screening, resulting in an increased rate of help-seeking behavior for hearing impaired people with poorer speech perception scores and older age compared to better performers and younger age.

There is much intersubject variation in speech perception test results for CI recipients which has been attributed to various influencing factors such as etiology, duration of deafness, and implant experience (Blamey et al. 2013). Therefore, comparing a recipient's latest score with their previous scores is better suited to provide clinical insight to the individual's hearing progress over time, and help to identify issues that require intervention (Wolfe & Schafer 2015).

Repeated intrasubject measures for both speech and aided threshold measures permit a complementary view to hearing status and evolution over time. Specifically when comparing outcomes over two intervals, for example, most recent to previous or baseline measures, the test–retest difference needs to be as small as possible to be confident that any change in the result is a "true" performance change rather than a test-measurement error (Hyde 2000).

Additional objective testing that may provide complementary information on the CI recipient's hearing status may include: impedance telemetry, photographs of the implant site and daily device usage data. Patricoski et al. (2003) showed that photographs are useful for identification of medical issues related to the ear. Datalogging is useful for examining device usage and detecting potentially unreported behavioral issues (Easwar et al. 2018). The use of datalogs to monitor longer term trends of device use may also help in minimizing nonuse (Archbold et al. 2009; Wiseman & Warner-Czyz 2018).

Comprehensive asynchronous monitoring has not been available for routine clinical use in audiology to date. A test battery designed for remote monitoring for CI recipients was developed which includes an ATT, the DTT, a questionnaire that includes the SSQ, impedance telemetry, datalogs and

implant site photos (Maruthurkkara et al. 2021). Foundational research, a proof of concept study, involving assessment of included components, showed that the overall outcome of the test battery matched that of the clinician's in-clinic assessment in 99% (92/93) of recipients. Furthermore, the test battery was able to identify 94% of the issues identified by the clinician (Maruthurkkara et al. 2021). The framework of the test battery was subsequently adapted with suggested changes for improvement and implemented via a smartphone app to permit self-administration by CI recipients at their convenience and in their home environment. Previous reports of DTT or aided audiogram self-testing involved the routing of audio signals via cables or presented via loudspeakers (Bright & Pallawela 2016; Cullington & Aidi 2017). Remote check is the first tool which uses wireless streaming via Bluetooth for self-testing of DTT and ATT.

The goal of this study was to investigate first, the ease of use and second, the overall acceptance of the digital application of the test battery via the Remote Check App for self-testing by the CI recipient or their carer for at home use. Third, the study also aimed to evaluate the test–retest reliability of audiological measures, the ATT and DTT, newly innovated for implementation via wireless streaming through the sound processor. Finally, the audiological outcomes via patient-driven self-testing performed remotely were compared to clinician-driven conventional methods in the free-field.

MATERIALS AND METHODS

Study Design

This study used a single-center, prospective, repeated-measures, cohort study design. The ease of using Remote Check for self-administration in the clinic and during take-home was evaluated for the first-time in this trial. Test–retest reliability of patient-driven ATT and DTT outcomes via Remote Check was assessed via repeated-measures within the baseline in-clinic session. Outcomes for ATT and DTT measures in streamed and free-field test conditions performed in the clinic at baseline were compared. DTT was self-administered in both conditions; ATT was self-administered via wireless streaming and a clinician-driven aided audiogram was conducted in the free-field. The study received ethics approval at a single site in Sydney (X17-0133 & HREC/17/RPAH/196).

Research Participants

Nucleus CI recipients living in Sydney who had provided consent to be contacted by Cochlear were invited via email. Thirty-three research participants were enrolled in the study. One participant withdrew due to lack of time to complete the study. Data were available for 32 participants (53 implanted ears): 28 adults and 4 children. Table 1 provides demographic details of the participants. The inclusion criteria were: adults ≥18 years or children ≥4 years, implanted with either a Nucleus CI24RE series or a CI500 series CI in one or both ears, at least 3-month experience with a CI, and the ability to complete closed-set speech perception tests of numbers, 0 to 9, in English as judged by the investigator. Thirty recipients owned a smartphone and used it regularly to make calls, send text messages, browse the internet or take photos. Of the remaining two recipients, one only used it for emergencies, and one did not own a smartphone.

TABLE 1. Demographic details of participants.

	Adults	Children
Number of recipients	28	4
Gender		
Male	16	2
Female	12	2
Mode of hearing		
Unilateral	11	—
Bilateral	17	4
Cause of deafness		
Congenital	8	4
Progressive	17	—
Sudden	3	—
Age at test (yrs)	66.5 (29–86)	9 (7–12)
Age at onset of hearing loss (implanted ear) (yrs)	27.5 (0–60)	0
Duration of hearing loss (before CI) (yrs)	28.6 (0–68)	1.5 (0–5)
Experience with CI (yrs)	9.5 (1–25)	8.25 (4–11)

Remote Check Description

Remote Check is part of the Nucleus Smart App and consists of a set of tests designed to be completed by a CI recipient on their own or by their parent/carer at home. A Remote Check is scheduled by the clinician via the *myCochlear.com* Professional (mCP) web-based portal. On the scheduled day, the CI recipient receives an alert that Remote Check is now available on their smartphone and they are asked to complete all tasks included. The Remote Check test battery includes the following activities: three implant site photos, DTT, ATT, questionnaire, automated impedance test, and collection of usage data and sound processor diagnostics. The results of the tests along with the results of the baseline check are transmitted via the cloud and are displayed on the mCP for the clinician to review. Using their clinical judgment, the clinician determines patient-management actions to be taken including the option of an in-clinic follow-up appointment if needed. Figure 1 shows the flow diagram of the Remote check process and sample screenshots of Remote Check.

Implant Site Photographs • The recipient is asked to obtain photographs of their implant site at two different angles as well as the surgical scar behind the ear. Usability trials during the developmental stages of the Remote Check app revealed that when recipients took photographs of the implant site on their own, the photographs were unfocussed or of an incorrect position as they not able to see what they were photographing. Recipients are instructed to ask someone else to take the photographs so that clear representative images can be obtained. The app provides inbuilt instruction and example photographs for guidance and permits photographs to be retaken as needed. The photographs are reviewed by the clinician along with responses to the questionnaire including relevant questions on skin health to detect the presence of skin inflammation, irritation, or other skin flap complications.

Questionnaire • The questionnaire evaluated in the proof of concept study (Maruthurkkara et al. 2021) was revised to refine wording and add additional questions based on the findings from that study. An adult and a parent version of the questionnaire, with 30 and 38 questions, respectively, are available for completion by the recipient or their carer/parent as age appropriate. The questionnaires include questions to investigate and identify issues related to: training needs, medical status, fitting
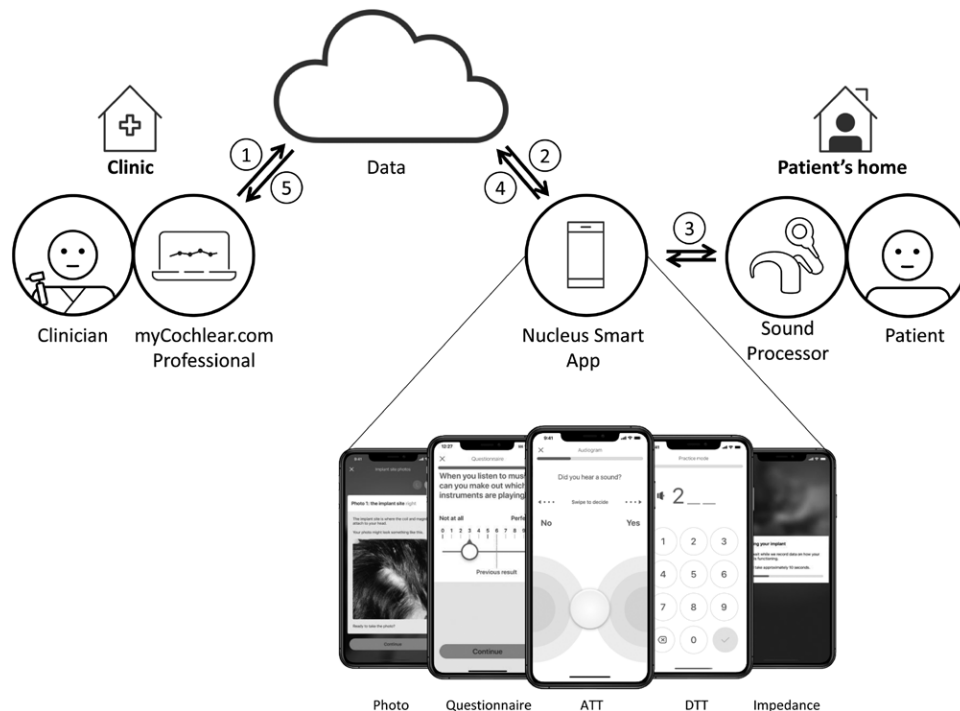
Fig. 1. Diagram of Remote Check. (1) Clinician schedules Remote Check; (2) check available at scheduled time; (3) recipient complete Remote Check; (4) results uploaded; and (5) clinician reviews results on mCP.

parameters, device components, and sound quality. The SSQ rating scores are suitable for tracking hearing performance and have been shown to stabilize by 12-month postimplant (Zhang et al. 2015). The adult questionnaire contains 12-questions from the SSQ12 questionnaire (Noble et al. 2013). The parent questionnaire contains 23 questions from the SSQ for Parents (Galvin & Noble 2013). While answering the SSQ questions, using a rating scale from 1 to 10, the responders are provided their baseline rating to aid in responding. In addition, there are questions aimed at identifying any changes in exposure to listening environments in the adult questionnaire. Remaining questions included in the questionnaire are primarily multiple choice, with an option to provide additional information as appropriate where issues are reported. The responses to the questionnaire are reviewed by the clinician to determine current hearing status and any issues requiring further address including an in-clinic visit. The clinician evaluates the SSQ questions by comparing the latest response with the baseline score. Typically for CI recipients, a difference in SSQ ratings between test intervals of >1 is considered clinically important (Wyss et al. 2020).

Aided Threshold Test • The ATT in the Remote Check app requires the recipient to detect a series of pure-tones streamed directly from the smartphone, giving an aided audiogram across the speech frequencies. Clinicians can use this information to determine if there are any issues with hearing soft sounds. The test begins with instructions for the recipient where they are asked to take the test in a quiet environment and remove their contralateral hearing aid if applicable. For bilateral recipients, each ear is tested separately while the contralateral ear sound processor is muted automatically by the app. A practice mode is included at the start which uses animations to train the recipient on how to respond. When the recipient presses the button on the screen, they then respond to the screen prompt "Did you hear a

sound?" by swiping the button to the right or left of the screen to answer "yes" or "no". Test frequencies and order are as follows: 1000, 2000, 3000, 4000, 6000, 500, 250 Hz, and a repeat at 1000 Hz. For bilateral recipients the test begins in the right ear and then proceeds to the left ear. The latest aided thresholds along with the baseline thresholds for comparison can be viewed as an audiogram on the mCP.

The ATT algorithm was designed to improve the reliability, accuracy, and precision of the results by the inclusion of the six features described below:

1. Patient-controlled presentation: It has been reported that for clinician-driven audiometry patients often wait to be very sure that a tone is actually heard before responding, leading to elevated thresholds and false-negative responses (ASHA 2005). With Remote Check, the ATT stimulus presentations are initiated by the patient directly, which increases certainty regarding timing and presence of sound and thereby likely to reduce false-negative responses and leading to a more accurate response. Furthermore, the increased confidence in knowing when the stimulus is presented and thus heard has the potential to lower auditory thresholds in comparison to clinician-driven auditory threshold measurements. This can be especially helpful to patients who also experience a level of tinnitus.

2. Multiple presentations: In clinician-driven audiometry, only one stimulus presentation is delivered at each intensity level. With the ATT algorithm, the CI recipient can repeatedly press the button to hear multiple sound presentations before providing a response. This increases the chance of the CI recipient responding at the softest level they can hear, thus leading to more accurate and reliable response (e.g., fewer false-negative responses)

and ultimately resulting in lower auditory thresholds than assessed by the clinician in the free-field. Similar to the previous feature this too has the potential to reduce frustration and enhances responsiveness in patients experiencing tinnitus.

3. Nonstimulus trials: In clinician-driven audiometry, false-positive responses can occur where the patient responds when no stimulus is given (ASHA 2005). The patient-controlled nature of ATT, as explained in (1) and (2), while reducing the probability of false-negatives could, however, lead to false positives, mainly through confirmation bias. The ATT algorithm contains a feature to minimize false-positive responses by including "nonstimulus trials," where no sound is presented when the patient presses the stimulus button. The probability of the "nonstimulus trials" starts at 33% but is adapted based on the reliability of a patient's previous responses. When a false-positive response is given for a nonstimulus trial, the recipient receives an app message reminding them that sometimes there is no sound and they should select "no" in those instances. Testing at a specific frequency is deemed as unreliable if there are three false-positive responses for nonstimulus trials. For a default MAP in nucleus sound processors, no electrical stimulation is delivered for signals below 10 dB HL as it is below the Threshold Sound Pressure level (TSPL) at all frequencies (Wolfe & Schafer 2015). Responses below 10 dB HL are considered as false positive and are deemed as unreliable. Testing at a specific frequency is also deemed unreliable if the maximum number of trials (30 trials) is reached without the patient response converging to a threshold. If this occurs the app will move to the next test-frequency. The test-result at any one frequency is deemed as "no-response" if there are three "no-responses" at the maximum test level (62 dB HL). Any frequencies with unreliable thresholds or no-response will be re-attempted once again at the end of the ATT. If an unreliable or no-response is obtained in two runs at a given frequency, then the audiogram shown to the clinician displays "unreliable response" for that frequency.

4. Smaller step-size: The ATT algorithm begins at a presentation level of 40 dB HL and uses a staircase with adaptive step-size procedure to arrive at the threshold for each frequency (Levitt 1971; H. Dillion, personal communication, May 2, 2016). At the beginning of the test, a step-size of 8 dB is used, and the step-size is progressively decreased to a minimum step-size of 1 dB as the stimulus approaches the threshold. Smaller step-size allows for greater precision and results in thresholds closer to the real thresholds (greater accuracy). With clinician-driven audiometry, step-sizes of 5 dB or 10 dB are typically used which can result in higher thresholds and a response further away from the patient's true threshold than if a smaller step-size is used.

5. Standard error: In clinician-driven audiometry, the threshold is recorded as the lowest intensity level where there is a response after two ascending runs. Near threshold for a given frequency, the ATT algorithm continues to present stimuli until the standard error between the levels at which the patient responds negatively and the level

at which the patient responds positively is ≤1 dB. This is done to improve the reliability of the threshold. The algorithm assumes that the "true threshold" is between the lowest level at which the patient responds and the highest level at which the patient does not respond, thus it uses an average of those points to determine the true threshold. Since clinician-driven audiometry records the actual level where response was present, clinician-driven audiometry will always result in a poorer threshold in a consistently responding patient.

6. Repetition of 1000 Hz: The ATT algorithm confirms the overall reliability of the patient responses by repeating the test for the 1000-Hz frequency at the end of the test run for each ear. This effectively provides a within session test–retest reliability check and provides confidence that the patient reliability has not been affected by issues like tiredness, boredom, or even a change in response strategy over the duration of the testing. This increases confidence in the reliability of the results.

The above-mentioned features of ATT that were designed to improve the reliability, precision and accuracy of the test also increases the likelihood of better thresholds with ATT compared to clinician-driven audiometry.

Impedance Check • The impedance check identifies any new open or short circuit electrodes since the last check. Automated impedance telemetry is run using common ground (CG) and both monopolar modes (MP1 and MP2) of stimulation across all active electrodes in the recipient's MAP. Any identified issues with the active electrodes are highlighted on the mCP dashboard. The impedance telemetry values for CG mode is displayed for all intracochlear electrodes.

Digit Triplet Test • DTT determines a recipient's SRT, which is the SNR where 50% of digits are correctly identified. This helps the clinician to determine if there are any issues understanding speech in noise. Randomly generated digit triplets using combinations of the digits 1 to 9 (excluding 7 and 0) are presented in noise via direct streaming to the patient. The intensity of digits was adjusted to provide equal intelligibility. Digit 7 was excluded as it is a bisyllable and digit 0 (spoken as the letter "O") was omitted as equal intelligibility with other digits could not be achieved. The recipient is asked to enter the three-numbers heard by selecting them on the phone screen. A nonmodulated noise designed to mask digits, modeled after the long-term average spectrum of digits, is used. The noise is played for at least 2 seconds before the stimulus is played. No carrier phrase is played before the stimulus to reduce the overall test-time, instead a visual cue on the screen is presented to alert the recipient that the signal is being presented. A practice mode is used to reduce the learning effect and to train the recipient on the test response method. During the practice mode, after the recipient has responded without any cues to a triplet, it is played again with visual feedback showing the correct digits. Visual feedback is provided on correct and incorrect responses. In the practice mode, four triplets are played in quiet (+16 dB SNR) followed by four triplets with progressively lower SNR. The speech and noise levels are varied to produce different SNRs; however, their combined level is always 65 dB SPL. The practice mode also serves as a screening test and the test is terminated if correct responses for all digits are not obtained at least once in the practice mode. The test mode begins at −6 dB SNR and after the first reversal, two blocks of eight triplets separated

by an intermission are presented. The SNR is adjusted by ±2 dB based on the recipient's responses. The average SNR of the 16-triplets is recorded as the SRT. The test is deemed unreliable if the standard deviation of the SNR across both blocks is >3 dB. If the results are unreliable, the test is repeated once. The DTT SRT score as well as the change in scores from the previous (baseline) check are displayed on the mCP. If the test is deemed unreliable in two runs, then "Participant's responses unreliable" is reported.

Usage Data • Usage data captured from the sound processor helps the clinician to determine any device usage or other device-related issues. The sound processor stores the usage data related to time-on-air, coil off, program/accessory/volume/sensitivity/ForwardFocus use, and exposure to different environments. Nucleus Smart App captures a snapshot of the usage data hourly when the smartphone is within range of the processors. The average of the usage data is displayed in mCP using a series of doughnut charts as used in Custom Sound software. In addition, the detailed view per day from the previous Remote Check is displayed for time-on-air, scenes, ForwardFocus algorithm use and accessory usage. The usage data are also used to display any issues with the microphone or processor based on the diagnostic tests within the sound processor.

Calibration of Signals • In Nucleus sound processors, the audio input from streamed audio via Bluetooth is mapped to the T and C levels using the same amplitude growth function and automatic gain control, as used for the signals collected by the microphone. The ATT and DTT require signal calibrations to ensure that the signal presented to the sound processor is at the correct level. Calibration for ATT was performed at design time by determining the appropriate multiplication factor for each of the digital test tones to provide the appropriate sound-booth equivalent dB HL presentation level. For DTT, the calibration signal streamed to the sound processor via Bluetooth was similarly scaled by a global adjustment to ensure equivalence. This calibration was verified by ensuring that the signals streamed to the sound processor via Bluetooth matched the expected output from the processor when the same signal was presented via loudspeakers in an anechoic test box. Since no mechanical transducers are involved and since Bluetooth transmits a digital signal directly from the smartphone to the processor, which is then transmitted to the implant, there is no need for subsequent calibration.

During the ATT and DTT tests, the CI recipient is instructed to use their preferred MAP and the sound processor is put in a Hearing Test mode which disables the Bluetooth volume control and ensures that the microphone input is muted. In this mode all input processing like Adaptive Dynamic Range Optimization, Auto Sensitivity, SNR-Noise reduction are turned-off and the accessory mixing ratio is set to 100% streaming only. As the microphones are turned-off, wind noise reduction and microphone directionality effects in SCAN and ForwardFocus are also temporarily disabled.

Study Procedures

Once the written informed consent was obtained, all participants were provided with a separate iPhone with the Remote Check app installed for the duration of the trial. Participants were asked to complete all activities in the Remote Check at the clinic, which included ATT and DTT. Additionally, repeated measures of DTT (DTT-R) and ATT (ATT-R) in the streamed condition, self-administered DTT in free-field (DTT-FF) and the clinician-driven aided audiogram test under free-field condition (clinician-audiogram) were completed. The participant's preferred MAP was used across all test conditions. The order of the audiological tests was randomized and balanced across conditions and across participants to control for order effects.

Free-field tests were carried out in sound-treated rooms where the ambient noise level was lower than the hearing threshold for humans as per ANSI standard S3.1 (2018) and complied with the maximum permissible noise levels stipulated by ISO 8253-2:2009 standard. The signal and noise were presented from the front loudspeaker (0° azimuth) for all free-field tests. During the free-field tests, recipients used a program where all input processing features were turned-off and the sensitivity was set to the default setting of 12 to ensure settings in free-field and streamed conditions were the same.

The loudspeakers were located at head-height for a seated participant. Sound field calibration of the Average Sound Level (Leq) was performed prior to each test session using a sound level meter using a dB A-weighting (dBA), slow-time weighting. The sound-room equipment was calibrated such that the reference signal is accurate at ear level of a participant seated on the chair. The participants were seated in an immovable chair to maintain the distance between the participant and the loudspeaker.

The clinician-audiogram was measured by audiologists using the modified Hughson Westlake procedure (Carhart & Jerger 1959), for the same frequencies measured by ATT, with a calibrated Aurical Aud audiometer (Natus Medical Incorporated, Denmark). The audiologists were blinded to any ATT results obtained previously from Remote Check. The absolute difference between ATT-R minus ATT, ATT-H minus ATT and clinician-audiogram minus ATT were computed. The Mean absolute difference across all frequencies was calculated by taking the mean of the absolute difference between the thresholds. The mean value of the difference provides an indication of systematic threshold differences for the conditions.

In Nucleus sound processors, the TSPL determines the minimum intensity input level that results in electrical stimulation at the T level for each electrode (see Wolfe & Schafer 2015 for details). The frequency specific TSPL values in dB HL for a default MAP are 250 Hz-21.8, 500 Hz-19.8, 1000 Hz-16.6, 2000 Hz-15.4, 3000 Hz-17.4, 4000 Hz-16.1, and 6000 Hz-15.7 dB HL. For a MAP where T levels have been set at an audible level, it would be expected that the recipient would hear the sounds presented at TSPL (predicted thresholds) for each frequency. In this study, the mean thresholds from ATT were compared to the predicted thresholds.

For DTT-FF, the output from the smartphone was routed through a free-field speaker and the recipient was asked to complete DTT. The difference between DTT scores across all conditions were computed.

The time taken to complete the Remote check and individual tests were calculated from the log files with detailed time stamps stored in the app during the test. Impedance telemetry and collection of Sound processor datalogs was performed using Custom Sound 5.1 software to compare against the corresponding measurements extracted from the Remote Check app.

Recipient Feedback • Two weeks following the in-clinic session, participants were then asked to complete the entire Remote Check in their home environment which included one-run of ATT

(ATT-H) and DTT (DTT-H). Feedback was gathered via a recipient feedback questionnaire with several questions about Remote Check (app) relating to ease of use, convenience over an in-clinic visit, rating on their confidence that they will be cared for while using Remote Check, and the likelihood they would use it again. An example question stated: *"Overall, how easy or difficult was it for you/your child to use the Remote Check app to complete the Remote Check?"* and the participants responded using a five-point Likert scale (very easy = 5 to very difficult = 1).

The responses for easy and very easy were combined and similarly the responses for difficult and very difficult were combined. A one-way chi-square test was used to analyze if the number of responses for easy/very easy was significantly different from difficult/very difficult.

The recipient feedback questionnaire also queried information related to: the number and duration of CI appointments attended in the last year; the distance traveled to their clinic; travel time; and costs incurred, including fuel, parking, and time-off work. Recipients were asked to estimate the percentage of clinic visits that could have been skipped if Remote Check had been available.

To calculate the net promoter score (NPS) (Kinney 2005), participants were asked the question *"Based on your experience of Remote Check, how likely are you to recommend it to another CI recipient or caregiver?"*. The response rating scale was a visual analog scale of 0 to 100, where 0 = not likely at all and 100 = extremely likely. The NPS was calculated by subtracting the number of recipients considered detractors (i.e., providing a rating < 70) from the number of promoters (i.e., providing a rating ≥ 80 or above). Repeated subjective ratings of hearing ability via the SSQ12 included in Remote Check app, were completed by adult recipients during two test sessions with a 2-week intertest interval and compared for test–retest reliability.

Real-world Recipient Feedback Survey • Since completion of this study and following regulatory approval, Remote Check has been used in a limited number of countries for clinical use. Early experiences were evaluated at 10 clinics in the United Kingdom, New Zealand, and Australia (between December 2018 and June 2020). Clinicians prescribed Remote Check for CI recipients using a Nucleus 7 sound processor with a CI24RE series or newer implant. Clinicians determined follow-up care needs for each patient based on the review of the Remote Check results performed in the patient's home. CI recipient feedback on real-world use of Remote Check was subsequently obtained via a voluntary market research survey from CI recipients. Formal consent was obtained from the participants in accordance with EphMRA code of conduct requirements (EphMRA 2019). Since Remote Check was used postregulatory approval, the survey did not require ethics approval. The survey questions used were aligned to the recipient feedback questionnaire used in the current clinical study to query ease of use, perception of time taken for completion, likelihood to use Remote Check in the future and the likelihood to recommend Remote Check to other CI recipients to calculate an NPS.

RESULTS

Recipient Feedback

Eighty-seven percent of participants rated the Remote Check App as easy or very easy to use. Completing ATT, DTT, and the questionnaire was rated as easy or very easy by 84%, 81%, and 84% of participants, respectively. The majority of participants rated completing ATT, DTT, and the questionnaire as easy or very easy ($p < .001$). Fifty percent of recipients rated taking implant site photographs as easy or very easy. The majority of participants (89%) were satisfied or very satisfied with Remote Check ($p < .001$).

Half of the participants had attended at least two appointments with their clinicians in the last year (median = 2; range 0 to 10 appointments). The average duration of in-clinic appointments was 62.5 minutes (range 20 minutes to 2 hours) with ¾ of appointments taking at least 60 minutes. On average, participants traveled 19.4 km (SD = 11.87, range 2 to 50) for a single appointment with an average commute time of 46.4 minutes (range 10 minutes to 4 hours). Forty-four percent of the participants took on an average 5.7 hours (range 1–12), time-off work or school to attend clinic appointments. The average time spent by recipients for a clinic visit including duration of session and the travel time was 1 hour 45 minutes (range 50 minutes to 5 hours). Estimated out of pocket expenses incurred were on average AU\$8.2 (range 0–35) including fuel and parking. One participant reported that they incurred a loss of wages of AU\$350 per clinic appointment attended.

The majority of participants (82%) agreed to the statement "Remote Check is more convenient than receiving in-clinic monitoring" ($p < .001$). Half of the participants felt that between 25% and 100% of their clinic visits in the last 24 months could have been skipped if Remote Check had been available. Significantly more participants (88%) agreed with the statement *"I would feel confident that I am still being cared for by my clinician while using the Remote Check service"* ($p < .001$). Significantly greater number of participants (77%) said that they were likely to want to use Remote Check in the future ($p = 0.01$). For the NPS question, 21 participants (66%) were promoters of Remote Check, with a rating of ≥80; four (13%) were passives, with a rating between 70 and 80 and (22%) were detractors, rating <70. The NPS (promoters minus detractors) for the study cohort was 44%.

Time Taken

ATT was completed on average in 8.2 minutes (range 5.3–22.4) per ear compared to 3.7 minutes (range 2.3–7.9) for the clinician-audiogram. The duration of ATT had a weak yet statistically significant negative correlation (r = −0.36, $p = 0.02$) to the overall rating for ease of use of Remote Check. Patient-driven DTT was completed on average in 3.9 minutes (range 1.6–5.7) per ear. There was a trend for participants with poorer DTT scores to take longer to complete the test; however, there was no statistically significant correlation. The average time to complete Remote Check at baseline for all participants was 38 minutes (range 20 minutes to 1 hour 5 minutes). The time taken to complete an entire Remote Check was on average 32 minutes (range 20 minutes to 1 hour 5 minutes) for unilateral recipients and 41 minutes (range 27 minutes to 1 hour 5 minutes) for bilateral recipients.

Test–Retest Reliability

Individual results for DTT measured via Remote Check are shown for 32 participants (52 ears) in Figure 2. For one bilateral CI adult subject, an unreliable response was obtained for one ear due to inability to complete the practice test. The mean absolute test–retest difference for repeated self-administered streamed tests for ATT (|ATT-R minus ATT|) and DTT (|DTT-R minus
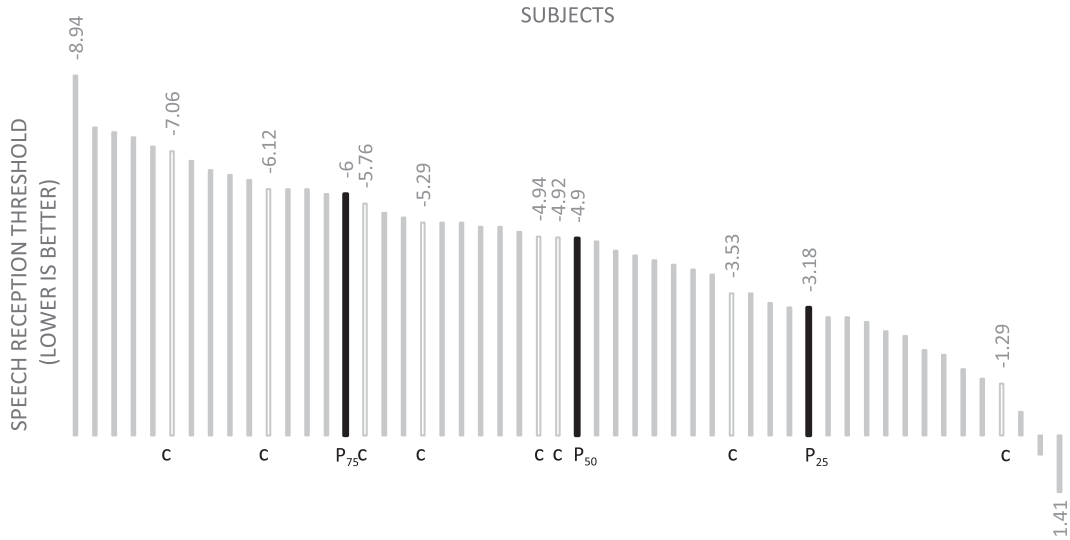
DTT INDIVIDUAL SCORES

Fig. 2. Individual speech reception thresholds with digit triplet test for 32 participants (52 ears) via Remote Check. The scores for children (C), minimum, maximum, 25th (P_{25}), 50th (P_{50}), and 75th (P_{75}) percentile points are highlighted.

DTT|) completed within the same test session in the clinic, was 0.9 dB (SD =1.30) and 1.49 dB (SD = 1.25), respectively.

Group mean aided thresholds per frequency under each test condition are shown in Figure 3. The mean absolute test–retest difference between self-administered tests in the clinic versus at home 2 weeks later was 1.4 dB (SD =1.97) for ATT (|ATT-H minus ATT|) and 1.62 (SD = 1.54) for DTT (|DTT-H minus DTT|). The one tail 95% critical difference was 2.55 dB for ATT and 3.1 dB for DTT.

Free-field Versus Streaming Tests

There was a significant correlation (r = 0.6, $p < 0.001$) between the streamed DTT scores obtained via Remote Check compared to scores obtained in the free-field (DTT-FF). The group mean difference between DTT and DTT-FF (DTT-FF minus DTT) was −1.8 dB (p < 0.001).

The group mean ATT thresholds for all frequencies combined obtained with the Remote Check were significantly better than clinician-audiogram thresholds in the free-field with a mean difference of 6.72 dB (SD = 6.8). There was no significant difference between the streamed thresholds and the predicted thresholds ($p = 0.83$) for Nucleus 7 sound processor. The vast majority 97% of the streamed and predicted thresholds were within 10 dB. The absolute mean difference between the streamed and predicted thresholds was 2.25 (SD = 3.0) dB. Figure 3 shows the per frequency group mean aided thresholds for all three conditions.
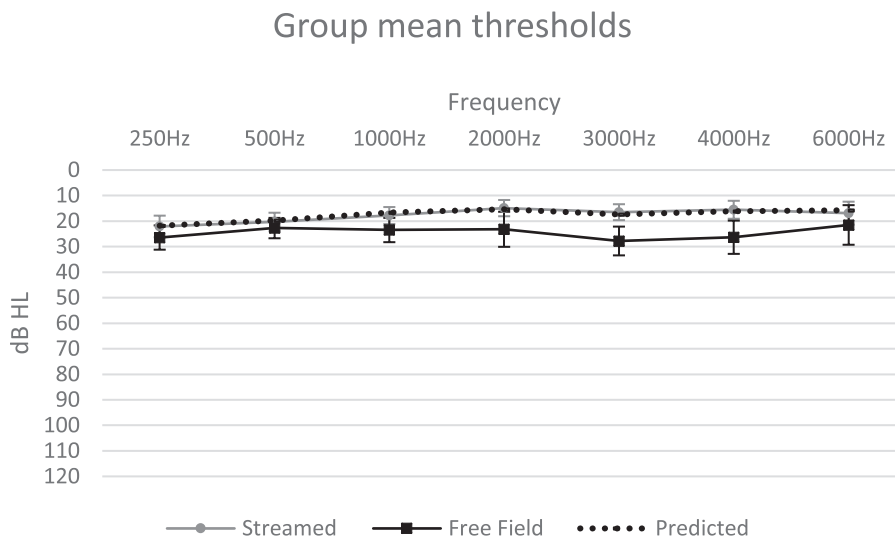
Group mean thresholds

Fig. 3. Grouped mean aided thresholds with self-tested aided threshold test, clinician-driven audiometry compared to the predicted thresholds based on threshold sound pressure level of the sound processor.

Adults Versus Children

The average aided thresholds for children and adults were 16.9 and 17.9 dB, respectively. The average DTT SRT for children and adults was −4.9 and −4.4 dB, respectively. Statistical comparisons of data between age groups were not possible due to the small sample size (4 subjects) of children. Figure 2 shows the individual SRT scores for children and adults.

Impedance Test and Questionnaire

No new electrode faults were detected with the impedance check in Custom Sound software or by Remote Check for all participants. The CG impedance test results with Custom Sound was significantly correlated with Remote Check measurements completed in the clinic ($r = 0.99$; $p < 0.001$) and at home after 2 weeks ($r = 0.98$; $p < 0.001$).

In the follow-up Remote Check, 99% of collective responses for the SSQ12 questions from 28 adults showed either no clinical difference (within ±1 point) or an improved rating (>1) relative to the baseline ratings obtained in clinic. Two adults gave responses that were clinically lower at the follow-up self-assessment in the home environment compared to the baseline rating obtained 2-weeks earlier in the clinic.

Real-world Recipient Feedback Survey

Invitation to complete a survey was sent to CI recipients from 10 clinics where Remote check was used for routine management of CI recipients. The survey was sent to 141 CI recipients who had completed a baseline check with Remote Check and who had provided consent to be contacted for further survey. Forty-seven percent (66/141) responded. Eighty percent of recipients using Remote Check in the real-world found it easy to use. While actual time to complete was not recorded 82% reported that the perceived time taken to complete the Remote Check was as expected or faster (average 28 minutes, range 10–120 minutes). The majority of responders, 89% were likely to use Remote Check again. Based on the likelihood of recommending Remote Check to other CI recipients, an NPS of 44% was obtained for the surveyed cohort.

DISCUSSION

The barriers of access to healthcare due to distance from the clinic are not unique to the field of cochlear implantation. As one example, in the field of cardiac implantable electronic devices (CIEDs), remote monitoring has helped to overcome such barriers. The data on the health of the implant obtained by active automated monitoring are transmitted via the internet to the clinician. In the field of CIED, remote monitoring systems have helped in the earlier identification of issues, improving the outcomes of patient care with excellent patient satisfaction and acceptance due to the reduced need to travel to the clinic and have provided significant benefits to the healthcare system. Remote monitoring has become the standard of care for patients with CIED (Cheung & Deyell 2018).

Ideally, in order for a remote monitoring solution, involving self-administered tests, to be successful, the following criteria should be met: (1) the tests need to be easy to complete at home with minimal guidance; (2) the idea of completing the tests at home needs to be acceptable for the users; and (3) the tests results need to be reliable and valid. Our study aimed at evaluating these three aspects for Remote Check for CI recipients.

Ease of Use

In the clinical study, a significantly higher proportion of participants found the Remote Check App easy to use. All tasks except taking the implant site photographs were rated as easy or very easy by the majority of participants. Some participants reported they found it difficult to find someone else to take the implant site photographs. Self-administered tests allow the participants to complete the test at their own pace and earlier studies (Corona et al. 2020) have shown that self-tests could take longer to complete compared to a clinician-driven test. In this study, the finding that the self-administered ATT took significantly longer than the clinician-audiogram is therefore not surprising. As the duration of ATT had a negative correlation with the rating for ease of use of Remote Check, and was stated as a reason why a small number of recipients would not recommend Remote Check to others, it may be beneficial if efforts are made to reduce the duration of ATT. In any case, given the average time taken to complete the full Remote Check test battery was observed to be 38 minutes, compared to the reported average of 1 hour 45 minutes involved in traveling and completing an in-clinic appointment, Remote Check has the potential to save time for recipients and the clinic overall. A significant majority of participants (82%) felt that Remote Check is more convenient than receiving in-clinic monitoring. In comparison, feedback obtained on Remote Check from the real-world experience surveyed cohort showed similar trends in responses as observed for our study cohort, in terms of time for completion, likelihood to use it again and the NPS.

Acceptability for Recipients

High levels of patient satisfaction have been previously reported for synchronous CI teleaudiology services (Krumm 2016). The increased patient satisfaction and the possibility of greater patient compliance for visits has been an important motivating factor for clinicians to offer synchronous teleaudiology services, despite the increased technical challenges that comes along with it. As Remote Check is an asynchronous solution that puts responsibility on the recipients for the completion of the tasks, it may be preferable for clinicians as it could save time and effort for them. This study showed that although there was a greater task load on recipients, most CI recipients reported they were likely to use Remote Check in the future. Half of the participants felt some or all the clinic visits in the past 12 months would not have been required if Remote Check had already been available. Importantly, as Remote Check actively involves the clinician in care, study participants reported they would feel confident with the level of care provided by their clinician while using Remote Check.

Reliability

It is important that the test–retest differences for the tests are as small as possible so that any change seen in outcomes for DTT or ATT can be more confidently attributed to a true change in the recipient's ability to detect and understand speech at conversational and softer levels. Our observed test–retest difference for ATT within the same session was on average 0.9 dB which is comparatively lower than the inter clinician differences

of 4.1 dB reported by Margolis et al. (2010) for standard clinician-driven audiometry. The study outcomes provide Critical Differences (CDs) for both ATT and DTT calculated based on the observed test–retest differences. We propose that for clinical application, if the difference between the previous and the current results for ATT or DTT is greater than the derived CD of 2.55 and 3.1 dB, respectively, the observed changes are likely indicative of a change in the individual's performance and not attributed to test–retest variance. In any case, the best practice is to consider the results of the whole Remote Check test battery to decide if the recipient needs further intervention.

A difference of −1.8 dB was observed between the streamed and free-field DTT self-test results for our study cohort. All conceivable confounding variables that could affect the streamed versus free-field comparisons were controlled when feasible in this study. A within subject comparison design was used to control patient related variables. The same sound processor, MAP, and identical input processing were used under both conditions to control sound processor related variables. Daily calibration check of the test equipment was performed to control any calibration errors. All testing was completed in a sound-treated room that complied with international standards for ambient noise levels. However, there may be reflection effects in the free field that alter the sound compared to the streamed audio signal. Participants were seated on an immovable chair and were asked to face the speaker during testing to control any level differences in the sound reaching the subject's sound processor. However, it is well documented that subtle changes in the way participants position themselves in the chair might lead to level differences due to head-related transfer functions (HRTF) (Gelfand 2016). To assess the extent to which HRTF might affect the results, test–retest measurements were done on a Head and Torso Simulator, Type 4128C; Brüel & Kjaer, Denmark (HATS). The calibration noise was played via the loudspeaker and the output from the sound processor placed on the HATS positioned on the chair was measured on two separate days. An average difference of 2.2 dB was observed between the measurements on the HATS on consecutive days where the only difference was a slight difference in the position of the HATS. A level difference of up to 3.2 dB was observed in the high frequencies. The only possible explanation for the differences seen between the streamed and free-field DTT results is that, participants were possibly able to utilize the level differences due to HRTF or reflection effects to their advantage to obtain a better result in the free field.

As noted above there is greater interclinician variability for standard clinician-driven audiometry compared to ATT and such variability may be the source of the large variability seen in the aided threshold norms set by different CI clinics worldwide (Vaerenberg et al. 2014). ATT incorporates several features designed to reduce the variability between tests and increase the accuracy of measured thresholds including being a self-initiated test, ability to present repeated stimulus presentations before giving a response, use of nonstimulus trials, use of 1 dB step-size adjustments near threshold, and the use of a standard error rule. Thresholds measured via streaming for ATT were on average 6.7 dB lower than measured with a clinician-driven audiogram. This significant difference is unlikely to be accounted for by the noise floor of the sound-treated room, as the sound room used for the in-clinic testing (FF) meets the ISO and ANSI standards (ISO 8253-2:2009 and ANSI S3.1-2018).

Therefore, these differences can be attributed to the previously mentioned design features of ATT.

As participants in the study had at least one year of CI experience, stable MAPs and no complaints about sound quality, they are typically expected to be able to hear soft sounds at TSPL. When the predicted aided thresholds based on TSPL were compared to the streamed ATT thresholds, there was no significant difference. Aided thresholds that are close to TSPL of the sound processor have not been reported in literature. Our results indicate that ATT may lead to a more accurate aided threshold measurements compared to standard audiometric procedures.

For 99% of the cohort, ratings for hearing ability via the SSQ12 (included in the questionnaire) completed at home, were within ±1 point or better compared to the responses provided 2 weeks earlier in the clinic at baseline. These results were anticipated considering the short intertest interval and are consistent with clinically acceptable test–retest variations reported by other authors (Singh & Pichora-Fuller 2010). The impedance telemetry tests obtained with Remote Check and Custom Sound in this study had the same outcome.

Consistency in repeated test measures over a short interval was observed for ATT, DTT, SSQ, and impedance measurements suggesting that these test results can be used with confidence. Clinically, no observed change in the test results between assessment intervals indicates stable hearing function, while a change greater than the test specific CD might indicate the need for further clinical intervention.

For the English DTT version used in this study, the bisyllabic digits seven and zero were omitted as their psychometric curves were very different from the remaining monosyllabic digits. However, in other languages with low number of monosyllabic digits, like in Finnish, bisyllabic digits may need to be retained. In such cases equal intelligibility across items may be achieved by normalizing the stimulus in noise.

Clinical Implications

The use of a test battery comprising of independent tests that allows the cross check of results has been one of the enduring principles in audiology (Hall 2016). The Remote Check test battery, administered with a collection of apps and software, was previously shown to successfully detect 94% of the issues detected by the clinician in a proof of concept study (Maruthurkkara et al. 2021). The current study showed that the Remote Check digital application is easy to use, acceptable for recipients and provides reliable results for repeated assessments. Remote Check can be a valuable addition to the CI care model for effectively triaging patients based on their needs while presenting the potential for saving time and costs for both the clinic and their recipients.

For clinicians, Remote Check offers real-world insights to supplement clinical decision-making that could help in tailoring the care for their recipients or to prioritize those who need more support. There are several possible clinical use cases for Remote Check, and four popular ones are outlined here. First, for acute support during the early stage after initial activation to monitor the performance, sound quality issues, training needs, device usage and device issues. This will enable clinicians to prioritize the areas to focus during the next scheduled visit. Second, for determining if the recipient has reached stable performance levels at 3 to 6 months after initial activation or not, based on the number and type of issues identified by Remote Check. This will

enable the clinic to decide if the recipient is ready to be transitioned to either a reduced frequency of clinic visits or to annual checks. Third, for routine monitoring of recipients anticipated to have stable results after the first year with CI. This will enable the clinic to determine if changes do occur, to decide if the recipient needs to visit the clinic for their annual in-clinic appointment. Finally, since the clinician can choose to prescribe only a limited subset of tests within the test battery, Remote Check may also be used to support remote troubleshooting at any stage of the CI recipient's journey to gather additional information remotely as needed. For example to check implant integrity using impedance measurements if an impact to the implant site is reported, or to look at implant site photos if issues are reported related to the skin flap, or to look at the datalogs if concerns are raised regarding the device or device usage. The complete Remote Check test battery may not be suitable for some recipients. For example, very young children who may not be capable of completing ATT or DTT, or for adults who do not have support to take implant site photographs or who are unable to complete the self-tests for DTT or ATT. In such cases, the clinician can customize Remote Check by excluding the tests that are not appropriate for that recipient.

For CI recipients, Remote Check offers a quick and easy option to receive care conveniently at home. The heightened awareness of any issues identified can increase their motivation for help-seeking. For CI recipients capable of self-management of their device, this could help with increasing their confidence leading to reduced dependency on their clinic for support. For those less confident with self-management, having their clinician involved with reviewing remotely assessed data and determining intervention required could also provide reassurance about their progress.

Remote Check supports a flexible and blended care pathway of service delivery for those patients with legitimate reasons for not physically attending in-clinic follow-up appointments, so that they can still obtain the same level of quality care required and are not relegated by default as *"lost to follow-up."*

CONCLUSION

Remote Check is the first CI telehealth assessment tool that uses wireless streaming to enable comprehensive, easy and reliable self-testing of hearing function by the CI recipient or their carer, in the comfort of their home. Asynchronous access to test results can assist clinicians in monitoring and triaging individuals for appropriate patient-management based on their needs. Use of remote monitoring may also help to reduce the burden of unnecessary clinic visits on clinic resources, patient travel time, and associated costs. Remote Check is an important step toward addressing the current growing need for asynchronous audiological telepractice to support long-term care of CI recipients.

ACKNOWLEDGMENTS

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