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Response Changes during Insertion of a Cochlear Implant using Extracochlear Electrocochleography

Christopher K. Giardina^{1,2}, Tatyana E. Khan¹, Stephen H. Pulver¹, Oliver F. Adunka³, Craig A. Buchman⁴, Kevin D. Brown¹, Harold C. Pillsbury¹, and Douglas C. Fitzpatrick^{1,2}

¹Department of Otolaryngology/Head and Neck Surgery, University of North Carolina at Chapel Hill, NC

²Department of Biomedical Engineering, University of North Carolina at Chapel Hill and North Carolina State University

³Department of Otolaryngology–Head and Neck Surgery, The Ohio State University, Columbus, Ohio

⁴Department of Otolaryngology, Washington University School of Medicine in St. Louis, MO

Abstract

Objectives—Electrocochleography (ECoChG) is increasingly being utilized as an intraoperative monitor of cochlear function during cochlear implantation (CI). Intracochlear recordings from the advancing electrode can be obtained through the device by on-board capabilities. However, such recordings may not be ideal as a monitor because the recording electrode moves in relation to the neural and hair cell generators producing the responses. The purposes of this study were to compare two extracochlear recording locations in terms of signal strength and feasibility as intraoperative monitoring sites, and to characterize changes in cochlear physiology during CI insertion.

Design—In 83 human subjects, responses to 90 dB nHL tone bursts were recorded both at the round window (RW) and then at an extracochlear position – either adjacent to the stapes or on the promontory just superior to the RW. Recording from the fixed, extracochlear position continued during insertion of the CI in 63 cases.

Results—Prior to CI insertion, responses to low-frequency tones at the RW were roughly 6 dB larger than when recording at either extracochlear site, but the two extracochlear sites did not differ from one another. During CI insertion, response losses from the promontory or adjacent to the stapes stayed within 5 dB in ~61% (38/63) of cases, presumably indicating atraumatic

Corresponding Author: Christopher K. Giardina, 101 Mason Farm Rd, Glaxo Bldg 142, Chapel Hill, NC 27599, USA, Phone: (919)-966-3254, Fax: (919)-966-7941, christopher_giardina@med.unc.edu.

Conflicts of Interest:

CG, TF, SP, KB, and HP declare that their involvement in research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest. CB is a consultant for Advanced Bionics and Cochlear Corporation, and OA is a consultant for MED-EL and Advanced Bionics. OA and CB have equity stakes in Advanced Cochlear Diagnostics.

Author Contributions:

CG, TK, SP and DF designed experiments. Data collection occurred with surgeons OA, CB, KB, and HP at UNC-Chapel Hill. CG and DF wrote the paper and all authors contributed significantly to analysis and revisions leading to its final form.

insertions. Among responses which dropped more than 5 dB at any time during CI insertion, 12 subjects showed no response recovery while in 13 the drop was followed by partial or complete response recovery by the end of CI insertion. In cases with recovery the drop in response occurred relatively early (<15 mm insertion) compared to those where there was no recovery. Changes in response phase during the insertion occurred in some cases; these may indicate a change in the distributions of generators contributing to the response.

Conclusions—Monitoring the ECochG during CI insertion from an extracochlear site reveals insertions that are potentially atraumatic, show interaction with cochlear structures followed by response recovery, or show interactions such that response losses persist to the end of recording.

Keywords

Electrocochleography; Intraoperative Monitoring; Hearing Preservation; Cochlear Implant

Introduction

Intra-insertion trauma during cochlear implantation (CI) is an important factor leading to poor speech and hearing outcomes (Finley, Holden et al. 2008, Adunka, Pillsbury et al. 2009, O'Connell, Hunter et al. 2016). A new approach using electrocochleography (ECochG) to monitor responses to auditory stimuli during insertion is under development in laboratories and is currently being implemented by implant manufacturers (Adunka, Giardina et al. 2015, Dalbert, Sim et al. 2015, Campbell, Kaicer et al. 2016, Dalbert, Huber et al. 2016, Harris, Riggs et al. 2016, Bester, Campbell et al. 2017). The monitoring can be performed by recording from the electrode tip as it advances (Calloway, Fitzpatrick et al. 2014, Campbell, Kaicer et al. 2015, Acharya, Tavora-Vieira et al. 2016, Harris, Riggs et al. 2017, Harris, Riggs et al. 2017) or from a stable extracochlear location during the insertion (Mandala, Colletti et al. 2012, Radeloff, Shehata-Dieler et al. 2012, Dalbert, Sim et al. 2014). Both the intracochlear and extracochlear recording locations have strengths and weaknesses, and, ultimately, could be used in combination. Here, we evaluate different recording locations for the *extracochlear* placement, and describe the types of recordings, or 'insertion tracks' obtained during CI insertion.

Translocation of the CI from scala tympani into scala vestibuli during insertion is a major cause of basilar membrane trauma that has been correlated with poor speech perception outcomes (Skinner, Holden et al. 2007, Finley, Holden et al. 2008, Holden, Finley et al. 2013, O'Connell, Hunter et al. 2016) and loss of hearing thresholds in hearing preservation cases (Schuman, Noble et al. 2010, Noble, Labadie et al. 2011, Wana, Noble et al. 2014, Wana, Noble et al. 2015). In addition, despite implementing the techniques of 'soft' surgeries including selection of flexible, lateral wall electrodes, insertion through the round window (RW) to avoid drilling into the cochlea, protection from bone dust, and employing intraoperative and postoperative corticosteroids to minimize acute endocochlear inflammation (Skarzynski, Lorens et al. 2007, Adunka, Pillsbury et al. 2009, Von Ilberg, Baumann et al. 2011), only half the patients in hearing preservation surgeries have complete or nearly complete preservation (<10 dB loss) of thresholds across speech frequencies (Adunka, Pillsbury et al. 2009, Von Ilberg, Baumann et al. 2011, Skarzynski, Van de Heyning et al. 2013). These patients and others achieve maximal benefit if array insertion

preserves both cochlear anatomy and auditory function, potentially in the electric-only hearing condition as well (Dalbert, Huber et al. 2016). Thus, there is a need for methods to monitor ongoing trauma to determine if it can be detected and avoided during surgery.

The use of ECoChG to monitor physiological responses to sound during array insertion began in animal studies (Adunka, Mlot et al. 2010, Choudhury, Adunka et al. 2011, Demason, Choudhury et al. 2012) and is now being pursued in several clinics and by the implant manufacturers (Campbell, Kaicer et al. 2015, Acharya, Tavora-Vieira et al. 2016, Harris, Riggs et al. 2017). Stimulation with tones produce reliable, often large responses in >95% of CI subjects, including both adults and children (Choudhury, Fitzpatrick et al. 2012, Fitzpatrick, Campbell et al. 2014, McClellan, Formeister et al. 2014, Dalbert, Sim et al. 2015, Formeister, McClellan et al. 2015). Most subjects show sensitivity to frequencies of 1000 Hz and lower, with responses to 250 and 500 being largest on average. Response to higher frequencies of 2000 and 4000 Hz are seen in a minority of cases, except in children identified as ANSD where responses to high frequencies are typical (Fitzpatrick, Campbell et al. 2014, Riggs, Roche et al. 2017). A property of cochlear responses to low frequencies is that, because of the base-to-apex direction of the travelling wave, regions basal to the CF region of the tone also contribute to the net response if the intensity is sufficient. For these reasons an intense, low frequency tone has become the stimulus of choice for characterizing cochlear response due to CI insertion (Calloway, Fitzpatrick et al. 2014, Adunka, Giardina et al. 2015, Campbell, Kacier et al. 2015, Dalbert, Pfiffner et al. 2015, Dalbert, Sim et al. 2015, Harris, Riggs et al. 2016, Harris, Riggs et al. 2017).

The recording capability currently being implemented by the implant companies is to record through the device, using the most apical contact as the recording electrode and using the on-board amplifiers to collect data during acoustic stimulation and transmit this data through the coil and magnet for analysis. A major benefit of responses from an intracochlear electrode is that the responses are larger on average than extracochlear responses (Calloway, Fitzpatrick et al. 2014). However, recordings from the array can fluctuate independently of any change of output from the hair cell and neural response generators, due to the changing position of the recording electrode relative to the generators (Demason, Choudhury et al. 2012). Thus, the advantage of monitoring from a fixed, extracochlear location is that response fluctuations can only be due to changes in the cochlear generators, at the cost of a somewhat smaller signal.

To date, only two reports have evaluated extracochlear ECoChG during CI insertion, and both utilize measurements of response threshold – which requires recordings of low signal to noise ratio and only evoke responses from restricted parts of the cochlea – limiting the ability to obtain timely and useful measurements (Mandala, Colletti et al. 2012, Radeloff, Shehata-Dieler et al. 2012). To improve the technique of recording from a fixed, extracochlear location as the foundation for an intraoperative monitor of cochlear trauma, our first goal was to determine if different locations vary substantially in signal to noise characteristics. A second goal was to describe response ‘tracks’, or changes to suprathreshold tone bursts during insertion, for subjects receiving CIs.

Materials and Methods

Subjects

Eighty-three subjects undergoing CI surgery were enrolled in this study. Inclusion criteria allowed patients of any age, gender, hearing loss etiology, or residual hearing status (as determined by pure tone average, PTA, thresholds) to be included. Patients were excluded if they were undergoing revision surgery or were not fluent in English, requiring an interpreter. Future reports will consider audiometric outcomes but the broad inclusion criteria here were chosen to maximize the number of subjects for extracochlear signal analysis. Cochlear malformations were seen in only 4/83 subjects (2 Mondini and 2 EVA) but these subjects were still included to gain better perspective on the feasibility of intraoperative monitoring in all subjects. All research activity was performed with the approval of the institution's Institutional Review Board (UNC IRB Protocol No. 05-2616). Informed consent was obtained for subjects older than 18 years of age, parental permission was obtained for subjects under the age of 18, and assent was also acquired from subjects between 7 and 18 years of age.

ECochG at the Round Window

Four surgeons performed all cochlear implantations. After anesthesia was induced, a foam earphone insert was placed in the ipsilateral ear canal for sound delivery and surface electrodes were placed on the contralateral mastoid and forehead for recording. A standard transmastoid facial recess approach was then utilized to expose the middle ear antrum and facial recess (Figure 1A) and identify the RW, stapes, and promontory (Figure 1B). Just before CI implantation, a monopolar electrode (Neurosign Surgical Inc. Part 3602-00, Carmarthenshire, UK) was placed in the RW niche. This served as the noninverting input while the surface electrodes at the contralateral mastoid and glabella served as the inverting input and the common, respectively. A Bio-logic Navigator Pro (Natus Medical Inc., San Carlos, CA) was used to record evoked responses to alternating polarity tone bursts (250 Hz, 500 Hz, 750 Hz, 1 kHz, 2 kHz, 4 kHz) at 90 dB HL (87 – 107 dB SPL) delivered by Etymotic ER-3b speakers to the foam insert in the ipsilateral auditory canal. The AEP system we utilized does not have in-ear microphone recording capability, but stimulation levels were calibrated from nHL to peakSPL using a ¼ inch microphone and measuring amplifier (Bruel & Kjaer, Naerum, Denmark). Depending on signal strength and noise level, 50 to 500 repetitions per phase were collected at each stimulus frequency but the exact number of averages was at the discretion of the operator to minimize data collection time within the context of the surgery. Formal signal to noise analysis was performed post-operatively and is described in the ECochG Signal Analysis section of the paper.

ECochG at Extracochlear Locations before CI Insertion

Once the RW recordings were complete, a separate extracochlear electrode was placed at one of two sites between the RW and stapes footplate (S or P in Fig. 1B). Site S was adjacent to and just inferior to the stapes footplate (Fig. 1B, "S"). Site P was anterosuperior to the RW on the promontory (Fig. 1B, "P"), which coincides with the location marked "2" on a promontory diagram identifying cochleostomy sites (Fig. 1B in (Iseli, Adunka et al. 2014)). The decision regarding which recording site to use for a given subject was based

primarily on surgeon preference, but all surgeons had experience with both recording locations.

The recording electrode for the stapes location was an insulated copper wire with a silver tip which is herein referred to as the “stapes electrode”. This electrode was threaded through the attic, its tip placed on the promontory just inferior to the stapes footplate, and its shaft held in place at the anterosuperior angle of the mastoidectomy cavity with bone wax (Fig. 1C). The electrode had a slight bend to avoid the ossicles and allow the tip to sit perpendicular to the bony surface of the cochlea. The wire was flexible enough that surgeons could easily bend it to better accommodate patient-specific anatomy, yet was also rigid enough to hold its form. Using braided wire improved the ability to put in flexible bends with a spring-like property. This strength was paramount for stability because the fixation of bone wax added a downward force to the wire which translated to holding it onto the bone.

The recording electrode used for the promontory location (“promontory electrode”) was a copper electrode with a silver ball on the end held by a custom clamp which mounted to retractors already in the surgical field (Fig. 1D). Multiple degrees of freedom allowed the mount to first be manipulated and locked in position. Next the recording probe was placed through an aperture on the distal end of the mount before entering the superior portion of the facial recess and seated onto the promontory. To reduce surface impedance, a small piece of saline-soaked gelfoam was placed between the electrode tip and the promontory.

The responses at either the stapes or promontory positions were compared to responses at the RW within each subject in order to assess any change in response magnitude or quality when moving to either extracochlear site.

Extracochlear ECochG during CI Insertion

With either extracochlear electrode in place, ECochG was performed to a single low frequency tone burst before, during and after insertion of the CI. The choice of stimulus frequency was either 250 Hz or 500 Hz at 90 dB HL, depending on which RW response was greater. Sequential responses to the tone bursts were assessed throughout CI insertion, each response coupled to an associated CI insertion depth, determined by the number of contacts inserted as reported by the surgeons during data acquisition. For example: “2 contacts inserted” with a MED-EL Standard array would be a 5.4 mm insertion depth (2.2 mm per contact + 1 mm inactive array housing apical to the tip contact), “12 contacts inserted” with this array would be 27.4 mm (26.4 mm active array + 1 mm apical housing) and a “fully inserted” array would be 31.5 mm. Because insertion speed is not perfectly smooth, it is also important to note that the amount of time between subsequent recordings is not equally spaced – that recording tracks are shown as a function of insertion depth and not of insertion time.

ECochG Signal Analysis

Responses were analyzed using custom MatLab routines (MathWorks, Natick, MA) and focused on the magnitude of the ongoing portion (windowed from 7 ms to 23 ms for 250 Hz or 7 ms to 21 ms for 500 Hz stimuli) to avoid the onset and offset characteristics of the CAP. The metric for response magnitude to a given stimulus was the sum of spectral peaks at the

stimulus frequency and its higher harmonics. A spectral peak in the FFT was considered significant when its magnitude was more than three standard deviations (SD) greater than noise, where the noise level and SD were computed from 3 frequency bins on either side of the frequency of interest. The reason for summing the spectral peaks instead of measuring the root-mean square (RMS) value is to give particular significance to harmonic distortions in the magnitude calculation. This additional weighting is justified because the CM and ANN can combine at different phases, such that interference can reduce the fundamental magnitude but increase harmonic distortions (Forgues, Koehn et al. 2014).

At the RW, individual responses to several stimulus frequencies (250 Hz, 500 Hz, 750 Hz, 1 kHz, 2 kHz, 4 kHz) at 90 dB nHL were summed into the ECoChG Total Response “TR” as described elsewhere (Fitzpatrick, Campbell et al. 2014, Formeister, McClellan et al. 2015). In short, the response to each stimulus frequency (in uV) was summed to a total response (in uV) before finally being converted to log-scale relative to a 1 uV response. Thus the TR is represented in dB and represents a metric for residual cochlear health before CI insertion. Extracochlear responses during CI insertion were also converted to logarithmic scale (dB relative to 1 uV) and subsequent measures throughout CI insertion were assessed at this scale. Comparison of the initial response (before CI insertion) to the final response (after full CI insertion) was calculated as the overall response shift, a metric of possible trauma used by our group and others (Dalbert, Sim et al. 2014, Adunka, Giardina et al. 2015, Dalbert, Sim et al. 2015, Dalbert, Huber et al. 2016).

Results

In 83 subjects, responses to acoustic tones were collected at the RW and then at an extracochlear site either adjacent to the stapes (n=29) or on the promontory (n=54). The design was to obtain responses at the RW in order to measure the residual physiology in each subject, move to a fixed extracochlear recording location to compare responses to those at the RW, and then continue extracochlear recording throughout CI insertion. Round window recordings were obtained in all 83 subjects. In nine cases, responses at the extracochlear site did not achieve responses above the noise floor (3/29 at stapes, 6/54 at promontory), despite successful recordings at the RW. Among these 74 remaining cases, most attempts to monitor extracochlear responses throughout CI insertion were successful (n=63/74, 85%) while in a minority of cases (n=11/74, 15%) the recording electrode did not maintain constant contact during the insertion (4/26 at stapes, 7/48 at promontory). Of these final 63 successful cases with response tracks, 22 were recorded from the stapes location and 41 from the promontory. Demographic information and devices used in these subjects are described in Table I.

Responses at the Round Window

The TR was used as a basic metric for overall residual physiology (Fig. 2). Compared to our overall population database of 290 subjects (blue), the TRs of the 83 subjects in this study (red) had a larger initial RW responses (12.3 ± 10.4 dB vs. 5.29 ± 15.2 dB re 1 μ V), and the difference was significant, t-test, $t=4.7$, $df=161$, $p<0.001$). Thus, our sample is representative of the general population of CI subjects with a slight bias towards larger initial responses.

The white bars indicate the nine cases where no responses were obtained at the extracochlear location, despite a measurable RW response. These cases were not limited to low TRs, so it was not simply that the slightly smaller responses typical of the extracochlear location compared to the RW (see below) were below threshold.

Comparison of Extracochlear Recording Locations to RW

Two extracochlear recording sites were used to test whether location was a primary feature for success of the recordings, or if multiple locations could provide similar recording quality. Often, the morphology of the response waveforms (left panels in A-D) and peaks of the FFTs (right panels) were similar between the RW and the extracochlear site (e.g., Fig. 3A). The response from the fixed electrode was usually smaller than the RW (e.g., Fig. 3B), but in some cases the extracochlear response could be significantly larger than from the RW (e.g., Fig. 3C). The phase could either be similar (Fig. 3A and B) or different from the round window (Fig. 3C). In D, we show the case with the smallest signal recorded - this case had an amplitude in the FFT of 100 nV, which was still well above the minimum level for significance, typically about 20 nV for 500 repetitions.

There were a broad range of response magnitude changes when moving from the RW to either extracochlear site across subjects (Fig. 3E). Most changes were within 10 dB (dotted lines, $n=49$, or 66%) but changes could also include decreases greater than 10 dB ($n=23$, or 31%) as well as increases greater than 10 dB ($n=2$, or 3%). Within-subject changes in response magnitude showed significant drops when moving from the RW to the stapes (paired Wilcoxon Signed Rank test, $z=2.80$, $p=0.005$) and the RW to the promontory location (paired Wilcoxon Signed Rank test, $z=4.23$, $p<0.001$), but these drops were not different from one another (Wilcoxon rank-sum test, $z=-0.51$, $p=0.61$). Overall, the median response near the stapes and promontory were 6.8 dB and 6.3 dB smaller than the RW, respectively (Fig. 3F). The median surface impedance at the RW was also slightly lower than at the stapes or the promontory (RW 7.0 kOhm IQR 1-10 kOhm, Stapes 8.0 kOhm IQR 4.25-14.5 kOhm, Promontory 12 kOhm, IQR 5-18 kOhm). However, there was no correlation between change in impedance and change in response magnitude (compared to the RW) for either extracochlear site ($r=0.04$, $p>0.7$). A correlation would have been expected if surface impedance were the sole or main contributor to response magnitude.

A possible explanation for the large response increases sometimes seen could be the presence of perilymph if the RW was inadvertently breached, causing conduction between the extracochlear electrode and the intracochlear environment where responses are known to be of greater magnitude (Calloway, Fitzpatrick et al. 2014, Dalbert, Pfiffner et al. 2015). To explore this, in a subset of subjects extracochlear responses were captured before and after surgically opening the RW ($n=34$). In these subjects the median change in response magnitude was just 0.7 dB higher than the response at the RW obtained prior to opening (Fig. 3F, red). This result indicates that perilymph is unlikely to be present at the extracochlear location very often, but can't be ruled out in individual cases. It is more likely that the change in recording site is biasing the recorded response towards a different set of generators than those at the RW. The change in phase for the case in Fig. 3C suggests that in

this case of a large increase the sources of generators have indeed shifted with the change in location.

Changes in Response During Insertion

During CI insertion, three overall patterns of response changes were identified. In some subjects, the responses were stable throughout the insertion (e.g., Fig. 4A). In others, the response was lower at the end of the insertion (e.g., Fig. 4B). Finally, in some subjects there was a magnitude drop mid-insertion which recovered by the end of insertion (Fig. 4C).

To estimate the size of response loss that might be considered significant, and to assess the ‘test/retest’ reliability of extracochlear recording during the insertion, we plotted a cumulative distribution function of the changes from one recording to the next for all recording pairs among the subjects (Fig. 5). Fifty-six percent of all response changes were 2 dB or less, 83% of changes were within 5 dB (Fig. 5, dashed line), and response shifts greater than 10 dB were seen in fewer than 3% of recording pairs. From these data, we deduced that response changes greater than 5 dB likely reflect physiological change rather than measurement variability.

Using this cutoff, each subject’s response change throughout CI insertion was classified into one of three groups (Fig. 6). The left column in this figure shows the raw response tracks for individual subjects, and the right column shows the changes in response relative to their starting levels (by subtracting the initial response in dB). In the “No Change” group (Fig. 6A), magnitude losses were within 5 dB throughout all stages of the insertion ($n=38$, or 60.1%). In the second “Permanent Change” group, a response drop beyond 5 dB occurred monotonically with no recovery by the end of CI insertion (Fig. 6B, $n=12$, or 19.1%). For subjects in the last, “Reversible Change” group, responses at some point dropped by more than 5 dB and then at least partially recovered by the end of insertion (Fig. 6C, $n=13$, or 20.6%). Note that in this final group the overall response change from beginning to end could be more than 5 dB ($n=8$) or less than 5 dB ($n=5$) depending on the extent of response recovery. In one case, the response dropped nearly 25 dB and fully recovered by the end of CI insertion (Fig. 6C, arrow). Both recording locations were equally represented in each group, with 14 stapes and 24 promontory location subjects in the “No Change” group, 4 stapes and 9 promontory locations in the “Reversible Change” group, and 4 stapes and 8 promontory locations in the “Permanent Change” group. As such, group assignment was not significantly biased by recording location.

In the permanent change group there were no response drops beyond 5 dB until the CI had reached an insertion depth of at least 15 mm (Fig. 6B). Conversely, in the reversible change group (Fig. 6C), responses which dropped within the first 15 mm were all at least partially reversible by the end of insertion. This difference is shown in a histogram of the insertion depth where the response first dropped by 5 dB (Fig. 7). There was a significant difference between the permanent and reversible change groups (Wilcoxon rank-sum test, $U=147$, $p<1e-3$), demonstrating that response drops early on in the insertion were more likely to be reversible whereas response losses at deeper depths were more likely to be permanent.

Summary distributions and statistical comparisons among the three groups are shown in Table II. The pre-insertion RW response and the initial extracochlear responses were not significantly different among the three groups, which demonstrates that group classification was not influenced by pre-insertion responses. The final response was used to calculate the overall shift, which was significantly different between groups, an expected finding because this was the main criteria for separating tracks into groups. The largest shift at any insertion depth was not different between the permanent change and reversible change groups. Additionally, age ranges of subjects in the three groups were similar (1-87 years for “no change” group, 2-78 years for “permanent change” group and 1-76 years for “reversible change” group), and did not differ significantly from one another (1-way ANOVA of age by group, $df=2$, $F= 2.15$, $p = 0.12$).

In addition to response magnitude shifts with deeper insertions, changes in the phase of the ongoing response could also occur. To illustrate one of these cases, the responses are shown from the start of insertion (Fig. 8A, top row) to final CI position (Fig. 8A, bottom row). At each step, the condensation waveform (left column) and average cycle of the ongoing response (right column) are depicted. Between an insertion depth of 8 electrodes and 12 electrodes, the phase of the ongoing signal completely inverted (Fig. 8A, arrow). In this case the morphology of the CAP also changed from a single negative deflection to a larger, biphasic peak, but this was rare (4 subjects). Across all 63 subjects, shifts in the phase of the average cycle formed a continuum from small to large, with most cases showing a small phase shift and a minority of cases with large phase shifts (Fig. 8B). The median phase shift was 0 degrees with interquartile phase changes (box) between -31 and $+43$ degrees, and 99% limits shown (whiskers) with the 6 outliers beyond this range.

Discussion

Preservation of cochlear integrity is important for maximizing speech outcomes with a CI (Finley, Holden et al. 2008, Wanna, Noble et al. 2014, O’Connell, Hunter et al. 2016). The current study compared approaches to extracochlear ECoG and characterized response changes during insertion, as a foundation for an intraoperative monitor of trauma. Responses at two extracochlear recording sites were slightly smaller than those at the RW, but were functionally comparable with each other in terms of signal strength and quality. Thus, the choice for the actual site of extracochlear electrode placement is not critical and can be obtained from multiple sites that are surgically accessible. Throughout CI insertion, most implantations (~60%) showed no significant response change at any stage, with a minority (32%) showing an overall response loss greater than 5 dB, that may (or may not, see below) be due to trauma. Some responses (~21%), declined in magnitude during the insertion but then recovered, particularly when these drops occurred within the first 15 mm of insertion. These temporary fluctuations indicate that using tone-evoked responses to distinguish between an atraumatic adjustment in micromechanics and gross anatomic trauma will likely necessitate more robust analysis than a magnitude change.

Comparison of Responses at Extracochlear Recording Locations

In designing an ECochG system for assessing intraoperative changes in cochlear physiology, a preliminary factor to be addressed was the effect of different extracochlear recording sites on the measured response quality. Moving from the RW to adjacent the stapes or from the RW to the promontory resulted in a median decrease in response magnitude of -6.8 and -6.3 dB, respectively (Fig. 3E). Our initial hypothesis was that responses at any extracochlear location would be lower in magnitude than at the RW, due to higher surface impedance on the cochlear bone versus the membranous RW niche, and more bone resistance between the intracochlear generators and the recording site. Active electrode surface impedances (as measured by the BioLogic), particularly once a saline-soaked piece of gelfoam was placed between the recording probe and the cochlear surface, were only about 7 kOhm higher on average than those at the RW, and we did not see any evidence that larger impedance differences produced large response differences (data not shown). Thus any significant drops in response magnitude, would more likely be from the bone rather than the surface impedance. However, there were also response increases present in some cases at either extracochlear site (Fig. 3). We have previously suggested that ECochG increases seen before and after implantation, when the recording electrode was removed from the RW and then replaced as close as possible to the original site, may have been due to contact with perilymph in the post-implant recordings (Adunka, Giardina et al. 2015), i.e., the electrode was essentially recording in an intracochlear environment where responses are known to be larger (Calloway, Fitzpatrick et al. 2014). However, this explanation cannot apply to the current results where care was taken to ensure the preliminary extracochlear recordings were made prior to opening the RW. An alternative hypothesis for why responses at the RW can differ so greatly from those at extracochlear sites is that the contributions of hair cell and neural populations differ when recording at the various extracochlear locations. Hair cell and neural potentials to the same frequency can interact constructively or destructively, with the presence of a CAP and prominent ANN distortions in the ongoing response as indicators of robust neural activity (Fontenot, Giardina et al. 2017, Riggs, Roche et al. 2017). This may also explain the shift in both phase and distortions when moving from the RW to the extracochlear site in Figure 3C which was independent of RW patency. These results imply the change in response when moving from the RW to an extracochlear site most likely involve a change in the specific population of recorded generators. And despite the overall lower median response magnitude at the various extracochlear sites from the round window, the main point for this study is that recordings from different extracochlear sites were well above the noise floor and functionally equivalent to one another. This finding should allow use of this technique at whichever extracochlear recording site is most surgically convenient, and to be applicable to most CI subjects.

The Extracochlear Electrode Type

Although the two sites were functionally suitable for fixed ECochG, placing the associated recording electrodes through the attic or facial recess warranted very different recording probes and surgical techniques. Specifically, these approaches differed in ease of placement, stability throughout CI insertion, and level of surgical obstruction in view or movement. When placing the flexible stapes electrode, the recording tip was threaded through the attic, maneuvering between the ossicles, and seated on a site inferior to the stapes footplate (Fig.

1C). A major advantage of this approach was that entering the antrum left the facial recess unobstructed during CI insertion. This recording site has also been utilized by Dalbert et al. (Dalbert, Sim et al. 2014, Dalbert, Huber et al. 2016), but they use a needle electrode and the sharp tip was seen as a drawback at our institution. Because of this, we opted for a flexible braided wire that was anchored to the mastoidectomy cavity with bone wax. While usually successful (n=22/25), this approach could be unreliable if the electrode tip lost contact from the surface or if the wax holding the shaft in place dislodged from the bone. These led to an open recording circuit which could not be corrected while the array was being inserted. Conversely, the fixed promontory electrode clamps to retractors, is manipulated independently along multiple degrees of freedom, and small fasteners keep the electrode locked stationary throughout all subsequent steps (Fig. 1D). Placement of this electrode took longer than the stapes electrode but the mount ensured the electrode didn't spontaneously dislodge from the surface. A major limitation of entering the facial recess so close to the RW, however, was that it intruded upon the surgical view and was so close to the RW that in some cases (n=8/49) it could be bumped by insertion forceps. Even small displacements in recording location during insertion (viewed visibly through the surgical microscope) caused immediately visible shifts in the size and quality of the evoked responses which were clearly not due to changes in intracochlear mechanics or trauma.

Changes in Response during Insertion

Most responses were stable throughout CI insertion (~60%), but the transient response drops in 13 subjects (21%) has important implications for the use of the technology. Most important is that intermittent response losses may be the result of changes in cochlear physiology that do not lead to 'trauma,' or permanent damage to cochlear structures. ECoChG magnitude shift is of particular interest because some groups have noted response drops greater than 2.5 dB to be significant with regard to hearing preservation, and ECoChG changes of 25 dB were predictive of complete hearing loss (Dalbert, Sim et al. 2015).

The largest temporary response loss in our study was ~24 dB, which nearly returned to baseline (Fig. 6C, arrow). As such, a drop in response does not necessarily indicate permanent trauma. A similar result was seen in previous studies using gerbils, which demonstrated abrupt drops and recovery of responses could occur differentially across frequency as flexible electrodes were inserted into the cochlea (Demason, Choudhury et al. 2012). In that study, the response drops followed by recovery were interpreted as fixation of the basilar membrane due to electrode contact early in the insertion followed by the shaft losing contact with the membrane as the tip advanced around the end of the basal turn. That every response drop in the current study which occurred within the first 15 mm had at least some recovery (Fig. 7) suggests a similar mechanism as seen in gerbils, i.e., that early contact with the basilar membrane can resolve with further insertion. Exceeding this 15 mm threshold can result in more permanent losses, which may be most important in cases where hearing preservation is desired. Histological trauma to the cochlea is significantly greater when the array extends beyond the first turn (Adunka, Unkelbach et al. 2004, Adunka and Kiefer 2006) and for lateral wall arrays the first turn can be completed at roughly 20 mm of insertion (Franke-Triege, Jolly et al. 2014). In subjects receiving lateral wall arrays, 20 mm arrays had higher hearing preservation rates and more stable hearing preservation over time

than subjects receiving longer, 28 mm arrays (Suhling, Majdani et al. 2016). The upper limit of insertion depth in the current study suggests that most changes during the traverse of the first turn are indicative of cochlear mechanical effects but not of lasting anatomic trauma, and that an electrode emerging from the first turn of the cochlea may be at the highest risk of injuring the cochlea.

Atraumatic interactions between the array and the basilar membrane could also change the relative proportions of CM and ANN as the array is inserted, destructively or constructively interfering with each other, which could potentially cause magnitude fluctuations in the absence of trauma (Fontenot, Giardina et al. 2017). The transient response drops may also occur without any direct interaction between the array and the basilar membrane. One such scenario could be explained by models of basilar membrane stiffening or ST:SV pressure ratio changes during CI insertion – which can negatively (or positively) affect response magnitude in the absence of cochlear trauma (Kiefer, Bohnke et al. 2006). These latter two explanations may shed light on why 7 subjects in this study (11%) had ECochG gains greater than 2.5 dB as a result of CI insertion, three of which grew more than 5 dB, paralleling results by Dalbert et al. who found that in 6 of 19 subjects (30%) increases in response occurred in at least one stimulation frequency as a result of CI insertion (Dalbert, Sim et al. 2015).

Comparison with intracochlear recordings

Attempts to characterize trauma with intraoperative ECochG vary by approach – the largest distinction being whether the acoustic responses are measured from a location outside the cochlea or from within the cochlea, through the implant itself. Implant manufacturers are primarily testing intracochlear recording from the most apical contact as it advances (Adunka, Giardina et al. 2015, Dalbert, Sim et al. 2015, Acharya, Tavora-Vieira et al. 2016, Campbell, Kaicer et al. 2016, Dalbert, Huber et al. 2016, Harris, Riggs et al. 2016, Bester, Campbell et al. 2017). This technique has the advantage of increased signal-to-noise ratio, but the disadvantage that the movement of the electrode will change its relationship to the generators, so a stable response that can be used to detect trauma is not available. Extracochlear responses are smaller on average but do provide the stable recording site. A paradigm previously suggested (Dalbert, Sim et al. 2015) would be to use a mixed approach, in which trauma at the time of surgery is characterized with an extracochlear recording, while electrode placement relative to generators could be optimized with intracochlear recordings, which could also be used to monitor further trauma/fibrosis over time.

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Figure 1.

Surgical anatomy and extracochlear recordings sites. (A) Mastoidectomy cavity reveals the attic (a), incus buttress (ib), and facial recess (fr). (B) Recording sites for extracochlear recordings are adjacent the stapes (S) and on the promontory (P) just superior and anterior to the round window (RW). (C) Stapes electrode threads through the attic and under the incus buttress and is held in place with a piece of bone wax (bw). (D) Promontory electrode extends from a custom rigid electrode mount (arrows) which is fixed to the retractors.

Figure 2.

Distribution of Total Response (ECochG-TR, see methods) from round Window electrocochleography just prior to insertion. The distribution of TRs across subjects in this study (red) was significantly higher than the magnitude of all subjects in our database (blue). Noise at the extracochlear recording site precluding inclusion was more likely in subjects with smaller RW responses (beige) but there was no consistent cutoff.

Figure 3.

Magnitude of Extracochlear Responses compared to Round Window responses. Recordings at the RW could be of similar morphology to those at the extracochlear site (A), smaller than extracochlear responses (B), or larger than the extracochlear site (C). The smallest response measured was just above the noise floor (D). Across all subjects, extracochlear magnitudes were typically smaller than those at the RW but changes included increases as well as decreases (E). Moving to an extracochlear site was roughly 7 dB smaller than those at the

RW but did not differ between stapes and promontory locations. Additionally, these changes in response were not explained by opening the RW (red).

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Figure 4.

Examples of response waveforms obtained during CI insertion. Three patterns emerged were seen (A) steady responses throughout the insertion, (B) a drop in response which persisted to the end of insertion, and (C) responses which dropped mid-insertion but recovered at deeper insertion depths.

Figure 5.

Incremental response drops from one recording to the next, cumulative across all subjects and depths. This plot was used to judge test/retest reliability and estimate when a response was rare enough that it was likely not due to simple variability in measurement. The dotted line at 5 dB is on the knee of the distribution and encompasses 83% of all increments, so a criterion of 5 dB was used to indicate a significant change response.

Figure 6.

Phenotypes of response changes across all subjects. (A) In the majority of subjects, response magnitude changed by < 5 dB throughout insertion depth, and were in the “No Change” group. (B) In 12 subjects, the response magnitude dropped below 5 dB and did not recover, and were assigned to the “Permanent Change” group. (C) In the “Reversible Change” group, 13 subjects showed a response change below 5 dB which at least partially recovered by the end of insertion. The case at the arrow dropped by more than 5 dB at 12 mm insertion and by a total of 25 dB overall, but was nearly fully recovered by the end of insertion.

Figure 7.

Insertion depth when response dropped by 5 dB. In the Reversible Change group, initial response drops usually occurred within the first 15 mm. In the Permanent Change group, primary response drops occurred at deeper insertion depths. *The difference in the distributions was significant (t-test, $t=4.7$, $df=161$, $p<0.001$).

Figure 8.

Inversion of response phase throughout CI insertion. (A) Left column represents waveform response while the right column represents the average cycle of the ongoing segment throughout 5 stages of CI insertion. An inversion of phase (arrow) during the latter stage occurred despite no change in response magnitude. (B) Phase change across all subjects. The majority of phase changes were small, with a median change of 0 degrees, but there was complete distribution across the full range.

Table I

Demographics of subjects in the study with extracochlear recordings throughout CI insertion. Subjects included those of various ages, SNHL etiologies, devices, and residual hearing status.

Characteristic	Count	% Total (Approx.)
<u>Sex</u>		
Female	32	51%
Male	31	49%
<u>Age at Implantation</u>		
0-5 yr old	9	14%
5-18 yr old	9	14%
18-80 yr old	40	64%
80-90 yr old	5	8%
<u>SNHL Etiology</u>		
ANSD	2	3%
Arachnoid Cyst	1	2%
Barotrauma	1	2%
CLDN14 mutation	1	2%
Syndromic	5	8%
Connexin 26 mutation	1	2%
EVA	2	3%
Meniere's	5	8%
Meningitis	1	2%
Mondini Malformation	2	3%
Noise-Induced HL	5	8%
Ototoxicity (Aminoglycoside)	1	2%
Sudden SNHL	7	11%
Unknown	29	46%
<u>Implanted Side</u>		
Left	36	57%
Right	27	43%
<u>Device</u>		
Advanced Bionics MidScala	1	2%
Cochlear 512	5	8%
Cochlear 522	3	5%
MED-EL Flex 24	9	14%
MED-EL Flex 28	17	27%
MED-EL Standard	28	44%
<u>Extracochlear Recording Site</u>		
Stapes Location	22	35%
Promontory Location	41	65%

Electrocochleography characteristics throughout CI insertion for the three groups. Round window responses did not differ between groups, nor did the initial extracochlear magnitudes. The final response, overall shift, and largest response shift differed between groups.

Table II

	Round Window ECochG-TR (dB re 1 μ V)	Extracochlear Probe		
		Initial Response (dB re 1 μ V)	Final Response (dB re 1 μ V)	Largest Shift (dB re 1 μ V)
No Change Group (n = 38)	11.7 $\pm$ 11.4	-5.2 $\pm$ 8.2	-5.7 $\pm$ 8.1	-0.5 $\pm$ 2.9
Permanent Change Group (n = 12)	13.5 $\pm$ 9.6	-2.4 $\pm$ 8.2	-14.8 $\pm$ 7.3	-12.4 $\pm$ 5.8
Reversible Change Group (n = 13)	10.7 $\pm$ 8.5	-2.7 $\pm$ 8.5	-10.7 $\pm$ 9.1	-8.0 $\pm$ 4.9
ANOVA F	0.21	0.79	6.22	46.23
Probability > F	0.808	0.458	0.003	< 1 E-12
				< 1 E-13