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Initial Operative Experience and Short Term Hearing Preservation Results with a Mid-Scala Cochlear Implant Electrode Array

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Abstract

OBJECTIVE—To describe our initial operative experience and hearing preservation results with the Advanced Bionics (AB) Mid Scala Electrode (MSE)

STUDY DESIGN—Retrospective review.

SETTING—Tertiary referral center.

PATIENTS—Sixty-three MSE implants in pediatric and adult patients were compared to age- and gender-matched 1j electrode implants from the same manufacturer. All patients were severe to profoundly deaf.

INTERVENTION—Cochlear implantation with either the AB 1j electrode or the AB MSE.

MAIN OUTCOME MEASURES—The MSE and 1j electrode were compared in their angular depth of insertion (aDOI) and pre- to post-operative change in hearing thresholds. Hearing preservation was analyzed as a function of aDOI. Secondary outcome measures included operative time, incidence of abnormal intraoperative impedance and telemetry values, and incidence of postsurgical complications.

RESULTS—Depth of insertion was similar for both electrodes, but was more consistent for the MSE array and more variable for the 1j array. Patients with MSE electrodes had better hearing preservation. Thresholds shifts at four audiometric frequencies ranging from 250 to 2,000 Hz were 10 dB, 7 dB, 2 dB and 6 dB smaller for the MSE electrode than for the 1j ($p < 0.05$). Hearing preservation at low frequencies was worse with deeper insertion, regardless of array. Secondary outcome measures were similar for both electrodes.

CONCLUSIONS—The MSE electrode resulted in more consistent insertion depth and somewhat better hearing preservation than the 1j electrode. Differences in other surgical outcome measures were small or unlikely to have a meaningful effect.

INTRODUCTION

The latest focus in cochlear implant (CI) electrode design has been to manufacture an electrode that protects the delicate structures of the cochlea in order to preserve any residual hearing and take advantage of the recipient's ability to integrate both acoustic and electrical stimulation. With residual acoustic hearing preservation, the simultaneous use of electric and acoustic stimulus can result in significant advantages over the use of a single modality [1–3]. Another important goal when designing electrodes for cochlear implantation is achieving adequate insertion depth to minimize mismatch between the frequency of the input stimulus and the presumed characteristic frequency of the stimulated neurons [4–12]. CI users can adapt to this mismatch, at least to some extent [13–15], but failure to achieve complete adaptation may have a negative effect on speech perception [16, 17].

Advanced Bionics (AB) has developed the HiFocus™ Mid-Scala electrode (MSE) designed to achieve placement in the mid portion of the scala tympani and avoid direct contact with cochlear structures. Other manufacturers have also taken advantage of design features conducive to hearing preservation such as shorter, thinner and softer electrodes [18]. The MSE is somewhat shorter than its predecessor the 1j electrode (18.5 mm vs. 23 mm of intracochlear insertion length) [19], but due to its intended mid-scalar location the target insertion angle, according to the manufacturer's claim, is comparable for both electrodes (420° for the MSE and 400° to 500° for the 1j) [19]. Since the commercial availability of the MSE in May 2013, we present our initial surgical experience in 63 implanted ears in both the adult and pediatric population and compare it to our experience with the older, 1j electrode from the same manufacturer. All ears were severe to profoundly deaf. Our main outcome measures are angular depth of insertion (aDOI) of the electrode array and short term hearing preservation assessed with pure tone audiometry (PTA) in the subset of patients who had pre- and post-operative audiograms of the implanted ear. Secondary outcome measures include operative time, incidence of abnormal intraoperative impedance and telemetry values, and incidence of postsurgical complications.

PATIENT POPULATION AND METHODS

Patient Population

All patients who have been implanted at our center with the AB MSE electrode since June 2013 through the end of June 2014 were included in the study. The retrospective review of the patients' charts was approved by the New York Langone Medical Center Institutional Review Board. We had a total of sixty-three implantations in forty-eight patients. There were 23 adult and 40 pediatric (defined as <18 years of age at time of implantation) patient ears. The population characteristics are summarized in Table 1.

In order to equally compare the insertion depth, hearing preservation, and other surgical characteristics with the AB 1j electrode we selected the best possible age- and gender-

matched patients with even distribution among the age groups and similar numbers of bilateral simultaneous versus unilateral implants. The selection of these patients was blinded with respect to all outcome measures. There were no differences between 1j and MSE users in terms of the surgical approach used or in the administration of perioperative medications such as steroids. All patients received an adult equivalent of 10mg IV Decadron intraoperatively, a standard for cochlear implants in our institution.

Surgical Technique

Standard transmastoid approach through the facial recess was utilized for all subjects, unless otherwise specified (i.e, those patients requiring a radical mastoidectomy due to chronic ear disease or when aberrant anatomy favored a modified approach such as removing ossicles). The cochleostomies were drilled at the anteroinferior position from the round window. With only one exception, where a peri-round window approach was used, all electrodes were inserted through a cochleostomy approach. Either the insertion tool or the manual advance-off-stylet method were utilized for all patients. Four different surgeons implanted patients with the 1j electrode and two different surgeons implanted patients with the MSE electrode. Surgeon 1 performed the majority of these surgeries both for the 1j (N=47) and the MSE electrodes (N=37).

Measurement of Angular Depth of Insertion (aDOI)

All patients had intraoperative radiographs taken at a distance of 40" with head turned obliquely with the implanted side up; for adults the tube current was 60–65 mA at 70–80kV and for infants and pediatric patients it was 16–20 mA at 70–73kV. Angular depth of insertion (aDOI) was measured from the intraoperative radiographs based on earlier described methods [20–22] that have received further validation recently [23]. Differences in aDOI were analyzed using two-way ANOVA, with surgeon and electrode type as the two factors. For surgeon 1, the difference in aDOI for the two electrode types was analyzed using a two-tailed t-test. F-tests were used to determine whether aDOI for the MSE electrode array was more consistent than that for the 1j array.

Measurement of Short Term Hearing Preservation

For both patient populations, unaided postoperative pure tone audiograms were acquired for older children (≥ 3 years of age) and adults. There were 37 ears in patients older than 3 who were implanted with the 1j electrode, and 26 that were implanted with the MSE. In the 1j group, 3-month unaided audiograms were available for 13 of the implanted ears. In the MSE group, 15 implanted ears had 3-month follow-up unaided audiograms. Many of the patients were profoundly deaf pre-implantation, with essentially no hearing to preserve or track over time. For this reason, only 28 (MSE and 1j groups combined) of 63 post-operative audiograms were conducted.

Hearing preservation was assessed only at frequencies where a given patient had pre-operative pure tone thresholds of 100dB HL or better. A two-way ANOVA was used to assess changes in hearing thresholds with electrode type (1j vs. MSE) and frequency (250, 500, 1,000 and 2,000 Hz) as the two factors. To explore the possible relation between aDOI and hearing preservation, Pearson product moment correlations were calculated. Again, this

was done only for those patient/frequency combinations where the preoperative thresholds were 100 dB or lower, and it was done for all frequencies taken together as well as for each individual testing frequency (250, 500, 1,000, and 2,000 Hz). A multiple linear regression was performed to examine the influence of electrode array (encoded as a binary variable), aDOI, and testing frequency, on hearing preservation.

Other Measures

Operative time was calculated through retrospective operative report review for surgeon 1 only, from the recorded “incision start” and “procedure end (close to dressing application)” times which include the surgical procedure time, intraoperative neural response telemetry and impedance measurement and obtaining of intraoperative X-ray, just prior to dressing application. This comparison included 37 of the 47 surgeries performed by surgeon 1 with the 1j electrode and 27 out of 37 with the MSE electrode. We excluded surgeries where additional unrelated procedures were performed (petrosectomy, bronchoscopy, orchiopexy, etc) or where patient’s abnormal anatomy led to significant modification of the standard technique (e.g., addition of fluoroscopy). The surgeon operated either with or without an assistant (resident or fellow); we therefore separated the operative times calculations into two separate groups with respect to assistant involvement. Along the same lines, we report separately the duration of unilateral implantation and simultaneous bilateral implantation. For unilateral implants, differences between the operating times of 1j and MSE electrodes were assessed using two-way analysis of variance (ANOVA), with electrode type (1j vs. MSE) and use of assistant during the procedure as the two factors. For bilateral implants, where all but one case were performed without an assistant, the difference between the operating times of 1j and MSE electrode was analyzed using a two-tailed t-test.

Incidence of abnormal intraoperative impedance and telemetry values, as well as incidence of other otologic disorders, x-ray abnormalities, and postsurgical complications were determined by a review of the patients’ charts for all 63 ears with each electrode type. Differences in frequency of abnormal impedance values were evaluated with a chi-square test.

RESULTS

Angular Depth of Insertion

With all the implants combined across surgeon 1 and surgeon 2 (surgeons 3 and 4 did not implant any MSE electrodes), the average angular depth of insertion for the 1j electrode was $431.7^{\circ} \pm 24.7$ (range 308.7° to 540.0°) and for the MSE electrode it was $389.4^{\circ} \pm 6.2$ (the range was 280.8° to 518.2° , but note that the minimum value was an outlier that corresponded to a patient with a malformed cochlea and incomplete insertion noted at the time of surgery). Our measured insertion depths are close to the range of the manufacturer’s claim (400 – 500° for 1j and 420° for MSE). The differences between the average aDOI due to the difference in surgeons ($p=0.672$) or the difference in electrode types ($p=0.099$) did not reach statistical significance. We also looked at the differences among the aDOIs of the 1j vs the MSE electrode across a single surgeon in order to eliminate any possible variability secondary to technique. For the 1j population ($N=47$), the average aDOI was $412.0^{\circ} \pm 9.3$ and

for the MSE population (N=37) it was $398.4^{\circ} \pm 6.2$. The difference in aDOI between the two electrode types was not statistically significant ($p=0.257$). On the other hand, aDOI was much more consistent for the MSE than for the 1j electrode. The standard deviation of aDOI was almost double for the 1j electrode than for the MSE electrode (64 vs. 34°). This result was highly significant regardless of whether we consider the whole dataset from surgeons 1 and 2 or only surgeon 1 ($p<0.001$ in both cases). Figures 1a and 1b reflect these results.

Short Term Hearing Preservation

Average unaided pure tones for the 1j and MSE populations for each frequency (250Hz, 500Hz, 1000Hz and 2000 Hz) and their change after cochlear implantation are shown in Figure 2. When only those preoperative pure tones thresholds at or below 100dB are considered, the average decrease in thresholds for the 1j population was 23.3dB (N=12), 25.6dB (N=9), 25.0dB (N=7) and 29.2dB (N=6) at frequencies of 250Hz, 500Hz, 1000Hz and 2000Hz, respectively. For the MSE population across the same frequencies, the average decrease in thresholds was 12.9dB (N=14), 18.6dB (N=11), 23.3dB (N=6) and 16.3dB (N=4). The difference attributed to the type of electrode (1j vs MSE) in the amount of hearing loss after implantation was statistically significant ($p<0.05$). Postoperative unaided thresholds less than or equal to 100 dB HL were preserved in 7 out of 12 (58%), 2 out of 9 (22%), 1 out of 6 (17%) and 0 out of 6 (0%) patients implanted with the 1j electrode at frequencies of 250Hz, 500Hz, 1000Hz and 2000Hz, respectively. With the MSE electrode, similar results were obtained in 9 out of 14 (64%), 6 out of 11 (55%), 2 out of 6 (33%) and 3 out of 4 (75%) implanted patients across the same frequencies (Figure 3). The data for 2000 Hz is omitted from the graph due to the small sample size (N=4) of the preoperative population with meaningful hearing in the MSE group.

Change in Hearing Preservation with Increasing aDOI

Figure 4 shows pre- to post-operative changes in threshold (y-axis) as a function of insertion depth (x-axis) and testing frequency, for all patient/frequency combinations where the preoperative thresholds were 100 dB HL or lower. When considering all frequencies together, deeper aDOI were associated with a greater degree of threshold shift ($r=-0.385$, $p=0.001$). The correlation was still statistically significant when considering only thresholds at 250 Hz ($r=-0.467$, $p<0.05$), but not when considering only thresholds at 500 Hz ($r=-0.404$, $p=0.08$), at 1,000 Hz, or at 2,000 Hz. Multiple linear regression showed an effect of aDOI on threshold shift ($p<0.05$). Examination of the data in Figure 4 shows the origin of that relationship: insertions between 340° and 450° resulted in less than 20 dB of threshold shift for 56% of the frequency-patient combinations (27 out of 48) whereas insertions deeper than 450° resulted in threshold shifts of less than 20 dB for less than 5% of the frequency-patients combinations (1 out of 21).

Other Measures

For single sided implants (either unilateral or sequential bilateral), surgeon 1 took an average of 63.3 ± 3.9 minutes to implant a 1j electrode without an assistant, and an average of 79.2 ± 6.0 minutes to implant an MSE electrode also without an assistant. With an assistant, it took an average of 118.0 ± 4.4 minutes for the 1j electrode and 127.4 ± 6.5 minutes for the MSE electrode. The differences in surgical times between electrodes, although small, were

statistically significant ($p<0.05$). For bilateral simultaneous implants, without an assistant, it took surgeon 1 an average of 107.4 ± 4.0 minutes to implant a patient with a 1j electrode on both sides. The same case with an MSE electrode took 139.3 ± 9.6 minutes to complete. The difference in these two values was statistically significant ($p<0.05$).

In the MSE group, 12 ears had various levels of vestibulocochlear dysplasia (19.0%), 2 cochleas had significant ossification at surgery (3.2%) and one patient (1.6%) had chronic otitis media requiring a subtotal petrosectomy at time of implant. For the 1j group, five ears (7.9%) had vestibulocochlear dysplasia, there were no patients with cochlear ossification, and one patient (1.6%) had chronic otitis media also requiring a subtotal petrosectomy at time of implantation.

With respect to immediate post-insertion X-rays, one patient in the MSE group (1.6%) had an electrode tip rollover which was corrected before the patient woke up from surgery. The subsequent electrode was in standard position without rollover or kinks. One patient in each group had incomplete insertion of electrodes (dysplastic cochleas in both cases).

Intraoperative impedances and NRTs were analyzed. Measurements in 61 patients for each group were available. Each implant contains 16 electrode contacts so a total of 976 electrodes were tested in each group. The percentage of electrodes with intraoperative high impedance values was very low for both groups: 1.7% in the MSE population and 0.9% in the 1j population, a difference that was not statistically significant. Out of the 26 electrodes with high intraoperative impedance values only two remained with high impedance the day of initial stimulation. Abnormal intraoperative neural responses (absent on one or more tested electrodes) were seen in 10 implants in the MSE group (16.4%) versus 7 implants in the 1j group (11.5%). Detailed data on how many electrodes in each patient had abnormal response was not available.

Rate of other complications was very low for both electrode types. Two patients in the MSE group had a late-onset (>1 month after surgery) wound infection necessitating explantation of the device, and one patient in the 1j group suffered such complication. Two 1j electrodes subsequently failed, one after 3.3 years and the other after 5.6 years. Up to the end of follow-up, which was less than a year for the MSE patients, there were no reported electrode failures. The surgical characteristics are summarized in Table 2.

DISCUSSION

Angular Depth of Insertion and Hearing Preservation

There were no significant differences in mean aDOI between the 1j and MSE electrodes, either when considering all surgeons or when restricting the comparison to a single surgeon. Although the means were not different, the variability in aDOI was significantly smaller for the MSE electrode than for the 1j electrode. Greater consistency of aDOI may be seen as a desirable characteristic in an electrode array. Among other reasons, it will tend to make frequency matching more predictable when programming the speech processor, which could benefit patient performance. There was a significant effect of aDOI on hearing preservation regardless of surgeon, with deeper insertions resulting in worse hearing preservation.

Previously published data on AB electrodes (I, 1j and Helix) reported that deeper aDOIs correlated with worse speech perception outcomes, likely owing to disruption of fine cochlear architecture [3]. When considering all frequencies together, we similarly found that deeper aDOIs ($>450^\circ$) were associated with a greater degree of threshold shift ($r=-0.385$, $p=0.001$). There was a modest but statistically significant advantage of 7 dB favoring the MSE electrode with respect to the 1j electrode. Given the relation between aDOI and hearing preservation, it is possible that this result is due to the more predictable positioning of the MSE. In fact, Figure 1a shows that only three MSE arrays had insertions deeper than 450° whereas this was the case for 18 1j arrays.

It is important to remember that the populations under study had very little residual hearing to begin with and only 28 ears could be evaluated for pre-operative to post-operative changes in hearing thresholds (15 MSE ears and 13 1j ears). Given these preliminary results it would be of great interest to perform a similar analysis in a larger group of patients with more meaningful amounts of pre-operative hearing. Further, long term hearing preservation outcomes continue to be under investigation, especially as hearing is likely to deteriorate with time. Good hearing preservation at lower frequencies for the MSE electrode was recently demonstrated by Hunter et al [24]. Interestingly, they demonstrate that the average rate of hearing preservation is maintained for a year post-operatively. Whether or not aDOI will affect patient performance in our population is yet to be determined.

Other Measures

There was a small but statistically significant difference in the time it takes to implant patients with the new MSE electrode versus the older 1j electrode (16 minutes for unilateral and 32 minutes for bilateral procedures). This small difference may be related to additional caution when using a new insertion device and electrode array. With additional experience the small difference in total operative time that we observed will likely diminish or disappear, although this trend was not clearly observed for the span of time of this study.

Our initial surgical experience with the MSE electrode shows that it can be implanted in infants, older pediatric and adult patients, patients with history of otologic disease or with presence of vestibulocochlear dysplasia and ossification. Intraoperative radiographs showed one tip “rollover” in an MSE patient, and none in the 1j patients. The difference in abnormal intraoperative impedances was not statistically different between the two electrodes. Further, of the 26 electrodes (1.3% of all electrodes tested) with high intraoperative impedance values only two remained with high impedance the day of initial stimulation. A previous study has shown a 9% rate of intraoperative open circuits in the AB family of electrodes, but did not find a correlation with poorer performance outcomes [25]. Low incidence of abnormal intraoperative NRTs was found for both the 1j and MSE groups. The causes of abnormal NRTs are multifactorial, and can be a result of device or patient-specific factors, preventing any meaningful conclusion from our sample data.

Postoperative complications such as wound infection have been reported in 2–8% of revision implants [26]. In our study, late postoperative wound infection rate necessitating revision was 3.2% for the MSE device and 1.6% for the 1j device. There were two 1j device failures

and no MSE failures, but the follow-up time was of course greater for the 1j electrodes, and thus, no meaningful conclusion regarding the difference in failure rates can be drawn.

In conclusion, our initial surgical experience with the MSE electrode suggests that it results in slightly better hearing preservation than the 1j array while allowing similar insertion angles. In addition, MSE insertion angles are more consistent than 1j insertion angles. Other differences between the two electrodes arrays were typically not significant or, in the case of operative time, statistically significant but not very meaningful in practical terms. Taken together, the present data suggest that appropriate design of intracochlear electrodes may result in enhanced hearing preservation. It is quite possible but remains to be seen whether this effect will have any implications for speech perception outcomes.

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Figure 1.

Figure 1A. Depth of insertion of 1j vs MSE electrode: Two surgeon data

Figure 1B. Depth of insertion of 1j vs MSE electrode: Single surgeon data

Figure 2.
Pre- and post-surgical pure tone averages for both MSE and 1j electrodes

Figure 3. Number of patients with postoperative meaningful hearing at 250, 500 and 1000Hz: 1j vs MSE electrode

Figure 4.

Pre- to post-operative changes in threshold (y-axis) as a function of insertion depth (x-axis) and testing frequency, for all patient/frequency combinations where the preoperative thresholds were ≤ 100 dB HL. Note that insertions between 340° and 450° resulted in less than 20 dB of threshold shift for 56% of the frequency-patient combinations whereas this happened for only 5% of the frequency-patient combinations when insertions were deeper than 450° .

Table 1

Cochlear implant population breakdown by electrode type

Electrode	MSE	1j
Total implants	63	63
Adult	23	29
M:F	10:13	14:15
Average age	48.1	52.8
<35	9	5
35–65	9	15
>65	5	9
Pediatric	40	34
M:F	20:20	13:21
Average age	2.1	2.4
<1	15	10
1–2	11	14
>2	14	10
Unilateral or Sequential Bilateral	33	40
Bilateral Simultaneous	30	23

Table 2

Surgical Characteristics: MSE vs. 1j

Electrode	MSE (N=63)	1j (N=63)
Other otologic disorders		
Vestibulocochlear dysplasia	12	5
Cochlear ossification	2	-
Chronic otitis media	1	1
X-ray abnormality		
Rollover	1	-
Incomplete insertion	1	1
Impedances & NRT N (Ne)		
Open electrodes/high impedances	17/976	9/976
Abnormal NRT responses	10/61	7/61
Postoperative complications		
Wound infection	2	1
Failed device	0	2