

## EXPERT WEB SERIES TRANSCRIPT

# Cochlear Implantation in Adults with Unilateral Hearing Loss: Spatial Hearing and Quality of Life

Hi. I'm Margaret Dillon. I am an associate professor and director of cochlear implant clinical research at the University of North Carolina at Chapel Hill. I will be talking to you today about cochlear implantation in adults with unilateral hearing loss, their spatial hearing and quality of life outcomes. Our clinical trial investigative team includes physicians, researchers, speech-language pathologists, and audiologists who have all worked hard to make this project [00:00:30] a success, and have supported our patients and subjects throughout this project.

This clinical trial was supported by a research grant from MED-EL corporation, and cochlear implantation in cases of unilateral hearing loss are not an approved indication in the United States, so we have obtained an investigational device exemption prior to initiation of this clinical trial. I will discuss our clinical trial and cochlear implantation in cases of unilateral hearing loss, as well as review [00:01:00] the study results on speech perception, localization, and quality of life measures, and then discuss the potential variables that may contribute to the performance in our cohort.

With unilateral hearing loss, we know the challenges that these patients experience as compared to normal hearers include poor speech perception and noise, variable ability on localization tasks, and increased report on hearing handicap scales, as well as a report of reduced quality of life. [00:01:30] The current treatment options for patients with unilateral hearing loss include conventional hearing aids, bone conduction devices, as well as the contralateral routing of the signal hearing aids. Unfortunately, these devices are limited for this patient population, because they provide variable ability to use binaural cues for speech perception and noise, and localization abilities have found to be a chance.

We have been investigating cochlear implants as a potential treatment option for patients with unilateral hearing [00:02:00] loss, and the primary question is: Are these patients able to integrate the signal from the cochlear implant with that from their normal-hearing ear, to have improved spatial hearing? Our cohort includes 20 adults with moderate to profound sensorineural hearing loss in the affected ear, and they have a mean duration of unilateral hearing loss of three years, and a mean aided CNC word score of 22%. The contralateral ear has normal to near-normal [00:02:30] hearing from 125 to 8,000 hertz, and this group has a mean age of implantation of 50 years.

For the study, we evaluated patients preoperatively. They then underwent cochlear implantation. Initial activation was conducted two to four weeks after surgery, and then we followed them at one, three, six, and nine, and 12 months after cochlear implantation. Subjects were implanted with the MED-EL concert standard [00:03:00] electrode array. They were fit with an ear-level device to control for microphone effects. They were programmed with the FS4 coding strategy, and our audiology team mapped these subjects by plugging the contralateral

normal-hearing ear and conducting a loudness-balancing technique within the implanted ear, and then between both ears, with the normal-hearing ear unplugged.

Our speech perception tasks included testing in two conditions, first [00:03:30] with the cochlear implant alone, with masking applied to the normal-hearing ear, and this was on a CNC word test presented in quiet, and a second condition was the cochlear implant plus the contralateral ear, so the normal-hearing ear, open, on AzBio sentences in noise, and this was at a signal-to-noise ratio of zero.

First, we have our cochlear implant alone scores, and this was on the CNC word task, so we have percent correct, where a higher value indicates better [00:04:00] performance, and then we have interval, with preop, one month, three month, six month, nine month, and 12 months. At the preoperative interval, they were tested in an unaided condition, so we can see poor performance at the preoperative interval, and then we see this steady growth and speech perception performance between one, three, six, nine, and 12 months, and this follows the typical pattern that we see with conventional cochlear implant recipients. [00:04:30] In the cochlear implant plus normal hearing condition, we tested patients in three spatially separated noise conditions, one with speech from the front and noise to the better-hearing ear, or the normal-hearing ear, one with speech and noise from the front, and one with speech from the front and noise presented to the poor hearing ear, or the cochlear implant side. Again, this is scored on percent correct. In gray, we have performance at the preoperative interval, in [00:05:00] the unaided condition. In blue, we have performance at the one month, green three month, yellow six month, orange nine month, and red 12 months, and we also have, in white, the results from a normal-hearing comparison cohort that was age-matched with our cochlear implant group.

What we can see when noise was presented to the better-hearing ear is a significant improvement by the one month interval, so we saw this early improvement in speech perception performance, [00:05:30] that continued through that 12 month follow-up interval. Performance does not reach that of the normal-hearing group. However, we can see one of our outliers is starting to become close to the performance of the normal-hearing cohort. With speech and noise presented from the front, we can see that our cochlear implant cohort is performing similarly to our normal-hearing cohort at the 12 month interval, and then when we have speech from the front and noise presented to the poor hearing ear, we can see that we've [00:06:00] reached ceiling effects, but what's important to notice in this is: We do not see that performance in the cochlear implant group is reduced with cochlear implant use, and we think that that's showing us that the cochlear implant is not interfering with the normal-hearing ear, that they're able to have noise presented to that cochlear implant side and still demonstrate a benefit.

Next, we have localization. For our localization task, we present a 200-millisecond speech-shaped noise burst, randomly across 11 speakers [00:06:30] at varied intensity levels, and subjects were to indicate the speaker number of the perceived sound source. No feedback was provided during this task. This is reported in RMS error, where a lower value indicates better performance, and again, we have the intervals at the preoperative, one month, three month, six month, nine month, and 12 month intervals, and then we have our normal-hearing comparison cohort.

What we see at the preoperative [00:07:00] interval is that there is a wide variability in patient performance, and by one month, we see a significant improvement in localization abilities. This is continued through that 12 month interval. Again, we see that subjects are not performing at the level of our normal-hearing cohort. However, we do have some subjects that are starting to perform similarly to some of our normal-hearing subjects.

When we look at the one month interval, we see that [00:07:30] there are two subjects that are outliers in this cohort. These subjects were listening to the device for approximately three hours per day by the one month interval. We discussed with them the need to listen to their devices for at least 10 hours a day, and when they returned for the three month interval, they had increased their daily device use, and we can see there is now limited variability throughout our subjects on this task.

Finally, we have the results from our quality of life measures. [00:08:00] These included three questionnaires, the Abbreviated Profile of Hearing Aid Benefit, the Speech, Spatial, and Qualities of Hearing Scale, and the Tinnitus Handicap Inventory. First, we have the results from the Abbreviated Profile of Hearing Aid Benefit. This questionnaire can be scored either with a global result or on individual sub-scales, that include ease of communication, effectiveness in background noise, reverberation, and aversiveness. What we have plotted are [00:08:30] our results from the preoperative interval in white, our one month interval in light gray, and the 12 month interval in dark gray. This is scored on a difficulty percentage, so a lower value indicates better performance. What we can see is that by the one month interval, we are again seeing a significant improvement on this scale, especially for the effectiveness in background noise, which is mirrored by what we were seeing on our spatial hearing task [00:09:00] for speech perception in spatially separated noise.

Next, we have the results from the Speech, Spatial, and Qualities of Hearing Scale. This is scored with perceived ability, where a higher value indicates better performance. It can be scored by the total score or on the speech hearing, spatial hearing, and qualities of hearing sub-scales, and we have the results in white from the preoperative interval, the results in light gray from the one month interval, and dark gray from the 12 month interval. [00:09:30] We can see a significant improvement between the preoperative and the one month interval on each of our sub-scales, and we think that for the speech sub-scale, this is mirroring what we saw for our speech perception task in the sound field, for the spatial hearing sub-scale, what we saw with our localization task, and then for the qualities of hearing scale, we think this is capturing subjects' report of improved listening effort when listening with a cochlear implant, in addition to their report [00:10:00] of the sound quality of the cochlear implant as similar to what they hear from their normal-hearing ear.

Finally, we have the results from the Tinnitus Handicap Inventory. This is scored by tinnitus severity, so a lower value indicates better performance. Our inclusion criteria capped this at patients that had a moderate level of tinnitus severity or less at the preoperative interval, which is indicated by the red line. We can see performance [00:10:30] in gray at the preoperative interval, and then at our follow-up intervals, this is with the cochlear implant on, so we can see that there is a significant change in the level of tinnitus severity with use of the cochlear implant. Now, our subjects do report that when they take the cochlear implant off, that their tinnitus tends to come back. Some of them have reported that the tinnitus has resolved completely, but the majority do

indicate that when they take the processor off at night, that the tinnitus begins to come back, [00:11:00] so we think that the cochlear implant is masking tinnitus in these cases.

So in summary, we have seen that our subjects with unilateral hearing loss have experienced significant improvement on speech perception in the affected ear with the cochlear implant alone, significant improvement on spatial hearing tasks, including speech perception in noise, as well as localization, and are reporting an improvement in quality of life.

So we think there are some potential variables that might be contributing to the performance in our cohort. [00:11:30] The first one is duration of unilateral hearing loss. This group had a short duration on average, of three years, and we know in conventional cochlear implant patients, that duration of hearing loss can contribute to performance, and might be doing the same in this cohort. All subjects had normal hearing in the contralateral ear, and this might be benefiting them by cleaning up the signal from the cochlear implant to help them have that improved performance by the one month interval.

All [00:12:00] subjects were implanted with the standard electrode array, which provides a deep insertion depth. This may allow these patients to take advantage of place coding for a more accurate representation than what might be achieved by an electrode array offering a more shallow insertion depth. All subjects were programmed with the FS4 coding strategy, which provides envelope and fine structure information, and it might be that having that deeper insertion depth and providing fine [00:12:30] structure cues in the apex is contributing to early performance in this group.

Our clinical audiology team used a consistent mapping protocol for all of our subjects, which included behavioral measurement of threshold and comfort levels on all active electrodes. They then conducted loudness-balancing techniques across individual electrodes, and then with the cochlear implant to the normal-hearing ear. Next, our subjects were seen [00:13:00] by our speech-language pathology team, who conducted an oral rehabilitation session. This was completed with direct audio input to the cochlear implant, and we think this required the subjects to again assess the loudness through the cochlear implant so that they could understand the recorded materials.

We think daily device use may be contributing to performance, as we saw the two subjects who were listening on average three hours a day have an improvement in performance when they increase that to 10-plus hours a day. [00:13:30] We also think that listening environment is contributing to the performance outcomes in this group. These were young adults that are in very dynamic environments, and this could be contributing to their performance.

This was also a very motivated group. These were subjects who were looking for an alternative treatment option. They had tried approved treatment options for unilateral hearing loss, and were very dissatisfied and looking for something that could potentially provide them with a better option. And then finally, realistic expectations. [00:14:00] We counseled these subjects preoperatively that we didn't know what would happen with the cochlear implant, and whether it would provide them with the sound quality that would improve their speech perception in

noise and their localization, and these subjects still decided to proceed with undergoing cochlear implantation, so we think that them having realistic expectations prior to undergoing cochlear implantation may have also contributed to their use of the device postoperatively and their [00:14:30] willingness to work hard to see improvements with their cochlear implant. Thank you very much for your attention.