Cochlear Implants and Single-Sided Deafness: Protocol and Case Studies from Baylor College of Medicine

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- [Barb] Hello, and welcome to the webinar, and thank you for joining us today. My name is Barb Foster, clinical education manager for MED-EL Corporation. Today, we'll be talking about cochlear implants and single-sided deafness. I'll review the foundational principles of the MED-EL Cochlear Implant System, a unique approval for this new indication and available resources. Then Dr. Michaela Stapp from Baylor College of Medicine, will review her clinical experience fitting the SSD population, including some case studies. From the beginning, MED-EL's core design philosophies have always centered around our mimicking the natural hearing system. Let's take a look at a video of our flex electrode insertion reaching into the apical region of the cochlea. Foundational to our philosophies are our long electrode arrays designed to cover the entire cochlea, stimulating the cochlea and the way it's naturally designed and gentle free-fitting electrode arrays to preserve delicate cochlear structures. We refer to these three core concepts as triformance. Triformance is comprised of key philosophies that define everything we do to mimic the hearing system in the most natural way. Flexible, free-fitting electrode arrays designed to preserve cochlear structures and support electric acoustic stimulation in patients with low frequency hearing.

Long electrode arrays to reduce spectral mismatch and provide earlier benefits in speech perception after implantation, and finally find structure processing using rate matched stimulation to improve perception of low pitch sounds, including voices and music appreciation. Not only have triformance concepts been at the forefront of our minds from the beginning, but MED-EL has a long history of innovation in the cochlear implant industry, including the first bilaterally implanted patient, the first BTE audio processor, the first single unit audio processor, the first fully MRI safe cochlear implant, the synchrony, and most recently, the first and only FDA approved cochlear implant for patients who are single-sided deaf, or that have asymmetric hearing loss. For many, many years, persons experiencing SSD or AHL have struggled to hear in a myriad of situations. However, traditional solutions like bone conduction hearing aids and CROS or BiCROS hearing aid systems have been unsatisfactory solutions. Not only have they

struggled with hearing in noise and localizing sounds, which are well known, unilateral hearing challenges, SSD, AHL also impacts quality of life from social interactions to stress and fatigue. Let's look at a video where Simon explains how living with SSD affected his life.

- And the other thing that was really difficult was I'm very social, and I started feeling very withdrawn in groups, like going to dinner with friends, I'm a professional, so I meet and greet people, You know, CalCPA organization has, you know, events, and I didn't feel comfortable 'cause I could never hear the person over here, the person over here, a little bit over here, the only person I could really talk to is the person on this side. So I started tuning out, I started not going to events. I started not, I would sit at dinners and I'd be sorta like this, you know, and my fiance, my wife now was worried 'cause like it's not like you. So that's, I'd say what was worrying me.

- [Barb] MED-EL's 2019 approval for cochlear implants in the SSD and asymmetric hearing loss population can offer patients like Simon, the opportunity to have access to true binaural hearing. The FDA approval indications are for patients five years of age and older with a profound sensory neural hearing loss in the ear to be implanted. The profound loss is defined here as a pure tone average of 90 dB or greater using a four-frequency pure tone average at 500, 1000, 2000 and 4,000 hertz. Additionally, the ear to be implanted should have a word score of less than 5% on CNC words or developmentally appropriate list for children. The FDA approval defines SSD and AHL as follows. A patient has single-sided deafness if there is normal hearing to a mild sensory neural hearing loss in the contralateral ear defined as a pure tone average of less than or equal to 30 dB at five, one, two and 4,000 hertz. A patient has asymmetric hearing loss if they have mild to moderately severe sensory neural hearing loss in the contralateral ear defined as a pure tone average between 31 to 55 dB at 500, one, two and 4,000 hertz. To gain this unique indication approval, submitted data came from several clinics who gathered information, including the university of North Carolina, House Ear Institute, Antwerp university Hospital in Belgium and The University of

Western Australia in Perth. Not only did the data show improvements in many areas, including the naturalness of sound quality post implantation, patients reported improvements in the following quality of life measures. Improved speech perceptions in noise, increased sense of spatial awareness, reduction in fatigue from listening effort and a greater participation in social and work activities. We showed Simon describing situations in which he was struggling with SSD. Now that he's been implanted, he describes how he's hearing better in social situations, and he's motivated to go to dinner with people again. Another SSD cochlear implant recipient describes how much he enjoys music and feels immersed again now that he's hearing with two ears instead of one. These are moving testimonies that really demonstrate how impactful this technology can be in patient's lives. Traditional cochlear implant candidates have had thresholds in the severe to profound sensory neural hearing loss range for adults and profound in the pediatric population.

For the electric acoustics stimulation or the EAs system, adults can be considered implant candidates if they have stable thresholds in this defined area. And now with approval of MED-EL cochlear implants for a single-sided deafness and asymmetric sensorineural hearing loss, candidates can have thresholds in the non-implanted ear up to 55 dB with a profound loss in the ear to be implanted. So when we put it all together, MED-EL offers a cochlear implant solution for a wide range of hearing losses that span the audiogram. For additional resources on any of our hearing implant technologies, you can reach us online, including our professionals blog at blog.medel.pro. Please note that this blog is international, therefore not all products or indications are available in every region. A few months ago, our manager of regulated research, Dr. Allison Racey and Dr. Meg Dillon from UNC recorded a webinar on audiology online detailing the data submitted in efforts to gain FDA approval. So I encourage you to seek that out as well. Some of the resources mentioned today are listed here along with the FDA approval letter and summary of safety and effectiveness data. Now I'd like to turn it over to Dr. Michaela Stapp to share her clinical experiences with this population.

- [Michaela] All right, well, thank you so much to Barbara for the introduction. I am very happy to be here today, and I'm honored to have the opportunity to share some insights into our experiences with clinical care of cochlear implant candidates and recipients with SSD at Baylor College of Medicine. As Barbara stated, this is a new advancement in the continuing growth of CI candidacy, and I'm extremely excited to be a part of this era of advancement. So here's a quick agenda of what I'm going to be going over today. I'm gonna give you a little intro into our CI program and the members of our team. Some challenges that patients with asymmetric hearing loss or SSD face on a daily basis. The way that we developed our SSD evaluation protocol, an overview of what our protocol looks like, and then some considerations for mapping aural rehab and counseling these patients, and then I will also go over a couple of case studies of patients that we've had in our program.

So first and foremost, I really need to start by acknowledging our hardworking adults CI team at Baylor College of medicine. These individuals truly put their heart into everything that they do, and we are all constantly striving to improve patient care. We've got a really great team here and I'm extremely proud of the program we're continuing to build. We've got a smaller team than some programs, but I think one of the benefits of having a team our size is our regular collaboration and ability to easily develop and implement new protocols like the one I'm gonna go over with you today. So let's start by outlining some of the challenges that our patients with SSD or asymmetric hearing loss face on a daily basis. As audiologists, we all know that two of the largest challenges these patients face are understanding speech in noisy environments and also localizing where sounds are coming from. So today I'm going to go into some of the physiologic explanations as to why these environments are particularly challenging, but I also really want to highlight the decrease in quality of life that is seen in these populations. Many patients with SSD or asymmetric hearing loss report increased listening fatigue, social withdrawal, anxiety, a lot of those same qualities that Barbara just listed for you. Additionally, we see a really high rate of

extremely bothersome tinnitus in our sudden hearing loss populations, which oftentimes have SSD. As an audiologist and a healthcare provider, improving quality of life is really at the heart of what we do, so I think it's important to highlight that these SSD patients are experiencing more than just difficulty hearing. We're gonna discuss quality of life throughout today's discussion, but we're first going to start by discussing some of the binaural processing phenomena that are especially important for understanding in noisy environments and localizing the sound source. So the head shadow effect occurs when speech and noise are spatially separated. It creates an acoustic shadow resulting in an improved SNR in one ear and allows the listener to selectively attend to the ear with the better SNR. The head shadow effect is a physiologic effect that does not require any central auditory processing, but it does require two ears. Interaural time difference and level differences are also physiologic effects that do not require any central auditory processing.

The interaural time difference refers to the difference in time of arrival of a sound at one ear compared to the other, while the interaural level difference refers to the difference in sound intensity at one ear compared to the other. And both of these are a direct result of the head shadow effect. These cues are both extremely important for localizing the sound source. Unlike the head shadow effect, the ITDs and the ILDs, binaural squelch and binaural summation do require central auditory processing. So binaural squelch also occurs when speech and noise are spatially separated, and each ear is receiving different acoustic inputs, and it's shown to reduce SNR by about two to three dB. Binaural summation occurs when both ears are presented with a similar signal and is shown to result in a doubling of perceptual loudness up to three dB. So all of these phenomena have a significant effect on our understanding in noisy environments, and individuals with SSD are unable to take advantage of all of these binaural cues and processing. Unfortunately, our traditional treatment options, including CROS or BiCROS and BAHA route the sound to the better hearing ear and do not restore binaural hearing. With traditional treatment options, the patient with SSD is still missing out on benefits of head shadow, ITD, ILDs, binaural summation and

binaural squelch. Using direct electrical stimulation, a cochlear implant is the only way to truly stimulate the poor ear and potentially restore benefits of binaural hearing. So following the FDA approval of cochlear implants for single-sided deafness and asymmetric hearing loss, the CI team here at Baylor decided that we needed a more formal way to evaluate these patients. We had previously been evaluating SSD patients for off-label and for implantation using our standard CI evaluation protocol, but we found that we were missing some key elements that are really unique to SSD patients. So our team got together to brainstorm and create a comprehensive evaluation protocol. I really wanna emphasize what a team effort this new protocol was, and commend my team for working so hard to create this, and also being flexible to modify some details as we began implementing the protocol. There were some details of this protocol that were critical to fulfill FDA criteria, including the CNC word scores. When our protocol was initially created, we only specified aided CNC words, however, we've since modified the protocol to include unaided CNC words, because our traditional audiologic evaluations are using NU-6 words, we wanted to have a more direct comparison of unaided versus aided performance, especially when considering some of the data that Ted McCracken and the team at NUSC have found that show a poor correlation between unaided and aided word recognition.

Additionally, we felt that some elements of our standard CI protocol, including AzBio sentence in noise were critical for evaluation in a slightly more real world environment. We also felt that one of the most critical items to include were quality of life questionnaires. So we routinely administer questionnaires in our traditional CI evaluations, but we recognized that many of the challenges experienced by SSD or asymmetric hearing loss patients can not be evaluated by traditional sound field testing alone. We identified a key desired element in our protocol that included assessment with traditional SSD treatment options, including CROS and BAHA. This element is unique to our SSD evaluation protocol. So we felt that including the evaluation with traditional options was crucial because we don't routinely require an extended trial period with a CROS prior to implantation. We also referenced the Buss et al article out

of UNC Chapel Hill, which as Barbara mentioned, was one of the primary pieces of research that was used to obtain FDA approval. And we use this article for a lot of our discussion. Obviously some of the measures that were used in this study were conducted in a research environment, and we're not able to replicate those measures precisely in our clinical setting, so we used really all of these critical and desired elements to create a modified protocol that's unique to our clinical setting. So our SSD evaluation protocol is really an extended version of our traditional CI protocol. As you'll find out our SSD evaluation appointment is really extensive, and therefore we schedule it for two hours. So I like to warn patients ahead of time that this evaluation may be exhausting and frustrating. We begin the evaluation by administering the quality of life questionnaires, so that includes the Nijmegen Cochlear Implant Questionnaire, the Speech, Spatial and Qualities or SSQ12 questionnaire and the Tinnitus Handicap Inventory. We feel that these questionnaires cover a broad range of hearing loss related concerns, and we feel they do a great job assessing multiple aspects related to the patient's quality of life.

Once the questionnaires have been completed, then we start the aided evaluation, which includes several listening conditions that we'll go over in depth in the next couple of slides. The patient typically sees the otologist on the same day to discuss surgical considerations, but because of the potential cognitive burden and stress created by the evaluation, we choose to schedule our counseling and device selection appointments on a different day. Additionally, we're also very lucky to have a licensed professional counselor on our team, so she can provide some pre-implant counseling and referral for additional services as needed. So I'm now gonna go into a little bit more detail regarding the specifics of our aided evaluation protocol. The goals of our aided evaluation are threefold. So one, we want to evaluate the patient's performance in a variety of simulated listening environments. We also want to demonstrate the traditional SSD treatment technology, and I think most importantly, we want to provide an opportunity for in-depth counseling. As with any medical intervention, a cochlear implant may not be the most suitable option for every patient with asymmetric hearing

loss or single-sided deafness. So when we developed our protocol, we wanted to ensure that the questionnaires we administer and the testing we perform give us insight into multiple aspects of the patient's hearing loss and open the door for important counseling conversations. For some patients, this may translate into realistic expectations with a CROS system, and for others, it may be the starting point of their cochlear implant journey. So to assist in explaining our protocol, I've created some very basic visual tools. I've been explaining this protocol to a few of our medical residents, and I found that it can be a little bit wordy and confusing sometimes, so I realized that the images here look a little bit rudimentary, but I found that when it comes to explaining our setup, the simpler the better, so bear with me. In these images, we're going to assume that the patient's poor ear is the right ear, so the ear here with the x on it.

We begin the evaluation with the patient seated at zero degrees azimuth, which should look familiar for anyone completing traditional CI candidacy evaluations. In this condition, we're testing both aided and unaided CNC words. So aided CNC words are completed through the speaker with the better ear masked and unaided CNC words are completed under insert earphones, again, with the better ear masked. Additionally, we complete AzBio sentence in the best aided condition at the end of the evaluation, and this is solely for counseling purposes. So for some individuals who might not meet criteria, this opens up another avenue for those important counseling conversations. So in the next condition, we physically turn the patient so that the speakers are at 90 and negative 90 degrees azimuth. So in this position, we're using AzBio sentence presented at a zero dB SNR. As we recall, the patient's right ear has the hearing loss. So in this condition, the speech is being presented toward the ear with hearing loss here, and the noise is being presented toward the better hearing ear here. We complete one list of AzBio sentence with each of the following treatment options, traditional amplification, CROS, or BiCROS, and the BAHA on a test band. Now, while the patient remain seated, we're going to switch the presentation of speech and noise. So now, the speech is being presented toward the better hearing ear while the noise is

being presented towards the poor hearing ear. Again, we're going to use AzBio sentence at zero dB SNR with each of the treatment options. And just to give you a little note, we did decide to use zero dB SNR because as the speech and noise are spatially separated, even five dB SNR would have been too easy for most of these patients. So is everybody exhausted yet? I sometimes feel tired just explaining that protocol. And as I stated earlier, the CNC word score is really all that specified for the FDA criteria. So you may be wondering why we've decided to put our patients through all this testing, and in truth, we do not enjoy torturing our patients. We truly feel that this is a comprehensive evaluation protocol that provides an opportunity to adequately counsel these patients. I can also tell you in complete honesty that I've never had a patient leave my office disappointed after this evaluation. Whether they choose to proceed with a cochlear implant or any other treatment option, they're all extremely thankful that someone's taking their concerns seriously and truly trying to provide the best solution for them as an individual.

So after all that comprehensive testing, let's say we've determined that the patient is a cochlear implant candidate. So I often get questions, how do you counsel this patient? How is it different from a traditional CI candidate? Just as with any hearing aid or cochlear implant patient, counseling on realistic expectations is critical for patient's success. For patients with SSD in particular, it's extremely important that they understand that our goal with the cochlear implant is not to restore normal hearing. Our goal is to restore audibility. And this is an important distinction to make as the cochlear implant will not sound like their normal hearing ear, and the patient really should not go into this journey with that expectation. So remember that these patients do have a normal hearing ear to compare to. So you wanna make it very clear that the CI will not sound the same, and we are not restoring that normal hearing. Along those lines, you'll also wanna emphasize that aural rehabilitation is critical for successful outcomes with the CI. Again, these patients have that normal hearing ear, so their brain's natural tendency will be to rely on that ear. I'll discuss some rehab considerations for these patients a little later, but they should absolutely be aware going into this journey, that

rehab is critical. Another expectation that you do wanna temper is in relation to tinnitus suppression. So for some of these patients, their primary goal with the cochlear implant is to reduce the severity of their tinnitus. Although the majority of recipients do report a decrease in tinnitus severity, I find that it's important to inform the patient that there are no guarantees. And also, as you may have noticed in Barbara's slides earlier, the SSD criteria does specify duration of deafness as less than 10 years as one of the criteria. So you do want to factor in that for patients with SSD, duration of deafness is a really important factor to consider. Another important factor to consider when counseling patients with SSD is the distinction between FDA approval and insurance approval. As we are all well too familiar with, each insurance plan has its own criteria for cochlear implantation, and just because someone meets the FDA criteria, does not mean that insurance will be willing to pay for it. So this is something in our adult clinic that we especially have to think of when discussing these options with Medicare patients.

Okay, so now we're gonna jump into some mapping considerations for patients with SSD who have received their cochlear implant. So just with traditional CI recipients, there are both behavioral and objective measures to use when programming MCL levels. So you may use a loudness scale similar to this one shown here and have the patient scale their perception of the volume, or you may use objective measures like ECAP and ESRT. Additionally, you might ask the patient to balance the loudness between their cochlear implant and their normal hearing ear. One question that seems to come up frequently is should you plug the better ear while mapping? And in all honesty, you may hear different answers to this question from each person you ask. Personally, I do choose to plug the better ear while performing loudness scaling, but I prefer to program patients using objective measures, and I'm gonna go into significant amount of detail about those objective measures here in just a minute. So when it comes to objective measures for cochlear implant programming, we're typically referring to either electrically evoked compound action potentials, ECAPs or electrically evoked stapedial reflex thresholds, ESRT. There are some important distinctions

between these measurements. So the ECAP measure verifies the output of the cochlear implant, but it's pretty poorly correlated to MCL levels while the ESRT measure has been a reliable measure to correlate levels to upper stimulation levels. There is a plethora of data out there, so I would encourage you if you haven't looked into it to look into that. It's really not a widely used measurement despite all of that evidence. And I think many of those reasons are because people think that it is overwhelming or time consuming and difficult to get set up. But just like anything you do, it gets a little easier every time you do it. So I'm going to give quite a bit of information about ESRT. For anybody who knows me, they know that I love ESRT. So today I'm hoping I can convince you that it's not as scary as it sounds, and the benefit that it will provide your patient is more than worth it in the end. So what is ESRT? It's really a contraction of the stapedius muscle. That's a time-locked response to an electrical stimulus.

So ESRT is a bilateral response, which means that you elicit the response on the ipsilateral and contralateral ears, and can measure the response on either ear. So with somebody whose middle ear function may have been affected by a cochlear implant, you still are able to read that measurement in the contralateral ear. In order to complete this measurement though, you do need completely normal middle ear function. If your patient has abnormal middle ear function, the measurement will be absent. And, you know, I do also wanna note that ESRT unfortunately cannot be elicited on all patients with normal middle ear function. Some studies have estimated that approximately 63 to 80% of cochlear implant recipients have ESRT responses using a standard 226 hertz probe tone. But Jace Wolfe has published some really excellent work for optimization of ESRT measurements, which suggest that using a 678 hertz probe tone may be more appropriate. And that is actually what we use in our clinic to elicit responses for all of our patients. So this slide is a little bit worried, and I definitely won't bore you with the details of the acoustic reflex arc, as I'm sure you're all very familiar with it already. But the diagrams here are just trying to show you that the ESRT response is elicited in the exact same way that the acoustic reflex is. So on most CI

recipients, the response is a little bit easier to read on the contralateral ear, so that's why you'll see most setups shown like this one here, but you can also measure it on the ipsilateral ear as well. So to debunk the myth that ESRT setup is too difficult, I've decided to give you all a little glimpse into my personal setup. So a special thanks here to a couple of our other CI audiologists who are acting as both a model and a photographer for this one. So as you can see here, I've got the tympstar on a mobile cart that I bring in for ESRT measurements during my CI mapping appointments. Please send your prayers that might tympstar never breaks. So our clinical setup here also has an audioflex in each room that allows us to use dual screen computer monitors, but I've found that my responses are much easier to read on the tympstar, so that is why I hope that it never breaks, and I bring it into my office every day. So I control the CI programming software with one hand, here is my right hand while I control the admittance bridge with the other.

So this may sound a little bit overwhelming, but when you are familiar with the programming software and the admittance bridge you can easily control both pieces of equipment. Once you get proficient at the equipment setup and reading ESRT measurements, you'll really easily be able to record the responses across the entire electrode array. So to get started, I place the admittance probe on the contralateral ear and run a tymp you'll then switch the admittance bridge to the reflex decay function so that you have that extended stimulus recording window. So you'll start the stimulus recording and then present the stimulus through the cochlear implant. And you'll be able to measure a time-locked response on the admittance bridge. A little note for these SSD patients, make sure that if you are measuring a response on the contralateral ear, you turn your probe stimulus down so that you don't elicit the reflex decay response from the normal hearing ear. Okay, so we're going to look at a video of an ESRT response that I measured in the clinic. So as you can see here, the response is clearly present and time-locked with three pulses of the electrical stimulation. As with a traditional acoustic reflex, you should see growth with the increased intensity, which is what we see here toward the end of the recording window. I do want to make

a little note here and disclose that I am by no means a pediatric CI audiologist. So everything that I've told you here is more than relevant for adult recipients, but I do realize that there are some additional considerations when it comes to keeping a child still and quiet while you're running this measurement, but for most adult patients, they're typically compliant enough to sit still for the five to 10 minutes while you do this measurement. So overall, the setup and measurements of ESRT are really pretty easy once you start doing them regularly. As far as map parameters go, I am typically leaving these maps set at default. So as with a traditional CI activation, I completely disable volume control and create progressive maps at that activation. I typically elect to have the patients set the map using loudness scaling at activation and perform ESRT at their one week follow up visit. So we're next going to discuss some considerations for aural rehabilitation.

As I mentioned earlier, the rehab is critical for successful outcomes for patients with SSD who receive a CI. So the exercises we recommend are really the same as traditional CI recipients, such as iAngelSounds, online resources from manufacturers, audio books, podcasts. The main difference here is the mode of rehabilitation. So because these patients have a normal hearing ear, it's critical you to use that direct streaming into the CI for the rehab exercises. We also highly encourage in-person AR therapy with an AVT just as we do with our traditional CI recipients, and we're very lucky to have those crew at the University of Houston that do all of our in-person AR therapy. Another note I'd like to mention relates to the psychology of getting a patient to really buy into this rehab process. So I've found that some SSD patients may have a harder time buying into the importance of AR therapy because their normal hearing ear is enough to get by with. So these patients do require some additional counseling and more of a required and not recommended approach. My goal with SSD patients is to have them make progress as quickly as possible so that they're more motivated to continue full time use. The last thing I want is for a patient to go through this surgery and end up not using the device because they don't find it beneficial, which history has shown us is more common in these SSD patients. So if we can get these patients to

buy into the rehab process, we're likely to see larger improvements faster and better outcomes in the long run. So now we're gonna jump into a couple of case studies that we've had in our clinic. So this first case study we have is a male in his mid 50s. He had a sudden hearing loss in January 2019, he received multiple transtympanic steroid injections and courses of oral steroids with no benefit. When he first came into our office, he had been using a CROS system for about six months and he was extremely dissatisfied with the lack of benefit that he received. So this patient is a commercial airline pilot, and he was really worried about his ability to hear the co-captain on his left side. He is in a little bit more difficult listening environment as obviously those airplane cockpits are probably not a quiet environment to be in. But what this patient was most concerned about was the really bothersome tinnitus that he had been experiencing since the sudden hearing loss.

And he even reported that he had started taking sleeping medications due to the severity of tinnitus and difficulty falling asleep at night. So you can see here, his audiogram, he's got normal hearing in the right ear and a moderate to profound hearing loss in the left ear. His unaided word recognition was 0%. So we did the CI candidacy evaluation and he scored 6% CNC words. Just as a little side note, we've been doing a lot of these SSD evaluations and we see 6% very frequently. That 5% criteria is really tough to hit when you're using that 50-word CNC list. So it can be a little bit frustrating, but obviously we've gotten patients approved even when they have hit 1% too high. The other thing that I really wanna point out about this CI evaluation was his score on the Tinnitus Handicap Inventory. So he scored a 66, which put him in a severe handicap range. And I think this really demonstrates the importance of evaluating quality of life as the severity of his tinnitus is not addressed by sound field testing or any traditional evaluation techniques. So our CI team meets to discuss every SSD patient and ensure that we all agree that they're a good candidate and the cochlear implant is the most appropriate solution. So some key points from the discussion on this case were obviously the significant distress that the patient supported surrounding the severity of his tinnitus and its impact on his quality of life.

The patient is also a very highly motivated man. And I underlined very here because he's really just one of those patients that everyone in the office knows due to his persistence. Based on his motivation and persistence, I had full confidence that he would follow through with any recommended AR therapy and follow any instructions that I gave him to be a successful user. So as a team, we decided that he would be a good candidate and we elected to proceed with surgery. He was subsequently implanted with the MED-EL SYNCHRONY FLEXSOFT in December 2019. I do want to point out that this patient is still technically considered off-label as he did not meet that FDA criteria for either CNC word score at 6% or PTA at 81.25 dB. His insurance company actually approved the surgery based on the tinnitus severity, which again, emphasizes the need for that assessment of quality of life. So we've got a couple of screenshots here. This patient was programmed via loudness scaling at his activation. So I created progressive maps and the loudness, the loudest map, excuse me, from his activation is shown here on the left.

At his one week activation, post activation appointment, I completed ESRT, which is shown here on the right. So as I stated earlier, this patient is very highly motivated, and he was actually allowing himself to be slightly overstimulated based on his motivation. So we had a very lengthy conversation regarding appropriate stimulation levels and allowing his brain to really do the hard work. I've noticed that some highly motivated patients may allow themselves to become overstimulated, and this is both true with SSD and traditional CI recipients because they really think that if they push themselves to success, that they'll be more successful. So it's really our job to explain to them why louder does not always mean better. And in this case, that was something we definitely had to work on with him. So the patient returned for his one month post activation appointment and was very excited to jump right into the sound booth because he felt like he had made significant improvements since activation. So as you can see, his CNC word score improved from six to 42%, which he was very pleased with, and I however was much more excited about that reduction on the Tinnitus Handicap Inventory. So the patient went from a severe handicap with a score of 66 at his pre-

evaluation to a slight handicap at one month post activation. And this patient also reported that he stopped taking sleeping medications, thanks to the significant reduction in tinnitus, and he was extremely excited to be putting less medication into his body. When this patient returned for his three-month post activation appointment, we saw continued improvement in that CNC word score. Additionally, I put the patient back in the zero dB SNR condition with the speech toward his poor now cochlear implant ear. His scores improved from 37 to 81%, and the patient actually anecdotally reported that this condition felt easy, which was a big surprise to me. So some considerations and key takeaways from this case, the patient is again, very highly motivated. He spends at least one hour a day completing aural rehab through that direct streaming, and honestly, if every patient I had was as highly motivated as this man would be, this man is, my job would be a lot easier. He's followed all the recommendations that I give him.

And like I said, he's completing at least an hour a day of aural rehab using direct streaming. He also had a really short duration of deafness of only about a year, which has definitely been beneficial for him. And the last key takeaway for me was that the ESRT measurement for him was critical because the patient was so highly motivated that he would have been overstimulated using those behavioral measurements. I think that's contrary to what most people see with ESRT measurements. And I'm gonna show you a case study here of another patient who's the complete opposite and why ESRT measurements were so critical for her. So our second case study is a 50-year old female who also had a sudden sensory neural hearing loss. Hers was in her right ear approximately five years ago. Unlike our previous case, she had not been utilizing a CROS or any form of amplification, but just like our previous case, she reported very bothersome tinnitus and significantly decreased quality of life. So at this patient's evaluation, you can see that she scored 0% CNC words and clearly fit that criteria based on both CNC and that audiogram shown on the previous slide. So our case discussion for her was pretty straightforward. She met all of the FDA criteria and she also expressed significant distress with her tinnitus and her quality of life. So as a

team, we decided she was a good candidate and she was also implanted with the SYNCHRONY FLEXSOFT in December 2019. So here we have this patient's maps from her behaviorally set map at activation and her ESRT map at one month post activation. So you can see that this is pretty different from the results that we saw from our previous case study, as these ESRT results are significantly higher than her behavioral responses. So without ESRT, this patient would have been understimulated. After ESRT, the patient also reported a significant improvement in loudness balance between her normal hearing ear. So here we can see the patient's progression of CNC words from 0% up to 42% at her three-month post activation appointment. So some considerations and key takeaways here, this patient had a longer duration of deafness and poor performance preoperatively than the first case. Although her progress has been steady, it has been a little bit slower than the first case, and I think it's a longer duration of deafness and severity of hearing loss preoperatively are definitely factors that should be considered for that. As with the previous case, ESRT was critical for programming.

However, unlike the previous case, like I said, this patient was significantly understimulated with her behavioral measures. So both of these cases together, I think represent the large range of results that you're gonna see when working with these SSD patients and the importance of those objective measures to ensure appropriate programming. So I've got to wrap up today's discussion with a few key points that I've learned while working with these population, and the evidence shows us is true. Overall, I think it's important to remember that patients with SSD are unique population who faced really unique challenges. As probably any audiologist would agree, these population have always been the most difficult for us to treat because they do have such unique challenges. And because of those unique challenges, I think it's important to consider how our evaluation procedures may need to be adapted. So this includes speech perception, testing, but also includes those quality of life measures, which have shown to be critical in some of these cases, and for some people, the reason that they actually get the treatment that they need. As audiologists, we need to be aware of

these unique challenges and adapt our counseling techniques accordingly to set realistic expectations. And last but certainly not least, I hope I'm not beating a dead horse here today, but the evidence has clearly shown that the benefits of ESRT and objective mapping techniques are more than beneficial for these patients, and both of our case studies as you can see, they work critical for appropriate stimulation. So I'd like to thank everyone for their time and attention. If anyone has any questions or concerns, please don't hesitate to contact me, I am always available for any questions, comments, anything further.

- [Barb] Thank you so much for your attention today, and especially thank you to Dr. Michaela Stapp from Baylor College of Medicine for sharing her clinical experiences with a single-sided deafness population. And I am a big fan of using objective measures to corroborate appropriately set loudness levels for any cochlear implant patient, so I really appreciate that as well. We look forward to hearing from you if you have any questions regarding cochlear implants in the single-sided deaf or asymmetric hearing loss population, including any reimbursement questions that you may have, we have specialists ready to assist you. Please contact us at medel.com or eight, eight, eight, MED-EL CI.