

This unedited transcript of a continued webinar is provided in order to facilitate communication accessibility for the viewer and may not be a totally verbatim record of the proceedings. This transcript may contain errors. Copying or distributing this transcript without the express written consent of continued is strictly prohibited. For any questions, please contact customerservice@continued.com

Optimize Patient Outcomes Through
Combinations of Acoustic and Electric Stimulation
Recorded February 9, 2023

Presenter: Cheryl Lechtenberg, MS, FAAA; Laura Lassen, AuD;
Mary Beth O'Sullivan, MS, CCC-A

- Welcome to today's course from Cochlear, presented by so many wonderful people today. Mary Beth O'Sullivan, Cheryl Lechtenberg, and Laura Lassen from Cochlear Americas. It has been said that innovation is seeing what everybody has seen and thinking what nobody has thought. This month on AudiologyOnline, we're celebrating innovation in the hearing industry in our third industry innovation summit. Thank you for joining and we hope to see you in other classes. We would like to thank our title sponsor, Care Credit, and all of the companies who are participating in this year's classes. It is my pleasure now to turn the microphone over to Mary Beth.

- Thank you guys so much for joining us today, and thank you so much for that introduction, Melissa. My name's Laura Lassen, I'm an audiologist and I'm senior manager of market expansion here at Cochlear. And in my role, my team and I really look at how we can bring access and awareness to professionals and help them understand what implantable solutions can look like. So we're so glad to have you here for our presentation today on optimizing the patient outcomes through combinations of acoustic and electrical stimulation. So I'd also like to introduce my co-presenters today. So Cheryl?

- Yeah, hello everyone. I'm Cheryl Lechtenberg, and I am an audiologist and I've been practicing in the South Florida area for about 30 years and I joined Cochlear a little over a year and a half ago as the area market expansion manager for Florida. And my primary role is to increase awareness about the current candidacy for cochlear implants and bone conduction. And I'm very happy to be providing that information today during this presentation.

- Mary?

- And I'm Mary Beth O'Sullivan. I'm the senior manager of clinical marketing strategy, and that means I help put together the conferences that hopefully you'll all be attending

and make sure we have courses like this available as the need comes up. So thank you very much for joining us today.

- All right, let's kick things off, Cheryl.

- We will have questions at the end, and please, as Melissa said, type them in and if we don't have time to get to your questions, we will reach out to you to make sure everything is answered or reach out to us, I'll provide the information at the end. I hope we are able to demystify candidacy for you today and the referral guidelines and point you to resources when questions come up in the future. Collectively, our goal is always to get the right treatment at the right time to the right patient. And we want to experience optimal hearing in both ears with the most appropriate technology. Sometimes that means two hearing aids, sometimes that means two implants, and there's a lot of both and options along that continuum.

So that's what we're gonna talk about today. Two studies that were published in 2022 demonstrated very low awareness of when and how to identify hearing loss across the primary care professionals and patients. So you can see in the bottom, only 9% of patients could correctly identify a normal or average amount of hearing. And so you can imagine that it's hard for them to know when it's time to start treating their hearing loss or seeing a professional. The average wait time was six years for people before they were treated with hearing loss. And a third of people with hearing loss globally have never seen a hearing loss professional. So we have a lot of room to grow, getting the right people to the right place at the right time.

For people that qualify for cochlear implants, less than in 20 adults who could benefit have actually received that technology. When we talk about indications versus candidacy, sometimes these two terms are tossed about interchangeably, but they're actually pretty different. And here's how we're gonna use these terms today. An

indication is the rule or the guideline based on audiometric and speech perception data. It's included in our labeling as our FDA guidelines for use, but the concept of candidacy is different and it looks more at the whole patient. So all of the additional factors that may be equally, if not more important than simply following an indication for a device, it's more than just the audiogram or just the speech score.

And that's where the clinical professionals can do all of the evaluation and take everything into account and help determine candidacy for the patient. Ongoing research indicates that patient satisfaction and outcomes improve when individualized treatment for hearing loss includes a plan for optimizing the acoustic and electric technology when appropriate. And so of course the goal today is to introduce all of the treatment options, best practice guidelines and current research outcomes in cases where patients may experience both acoustic and electric stimulation. A one hour course may not answer all of your questions, but we hope that you'll leave with key practical information to integrate into your clinical practice. There are many resources available for deeper dives and we will point those out throughout our course today.

But there are handouts attached to the course that we're in, this AudiologyOnline course, which includes other AudiologyOnline courses. So we have a whole menu of of resources on our partner page where you can go and find a lot of really rich information. We also have a cochlear professional newsletter, so I encourage you to subscribe, because that's where we have articles about things like Medicare Expansion and the latest in technology and current research. So that's a great resource. And of course we are coming to conferences, so there will be an a deeper discussion about candidacy and thought leadership and where that's headed and where that's come from, presented by Dr. Doug Slaten at AAA. And of course we always have a presence at ACI.

So please look for us at conferences and reach out if there are resources you're looking for that you're not easily able to find. We wanted to put a definition slide up to make sure we all know what we're talking about today. Again, sometimes terminology can be tossed around and used in different ways. And so today bilateral means both sides. Binaural is specific to ears, so both ears. Bimodal means a hearing implant on one ear and a hearing aid on the other. And looks like I forgot to include EAS, the electric acoustic, we will talk about that today. And that is in the same ear, so electric and acoustic in the same ear, as opposed to bimodal.

Unilateral hearing loss is a general term for one ear having normal hearing and the other ear having hearing loss. It's an undesignated amount of loss, whereas single-sided deafness, one ear has hearing levels in the normal range and then the other ear is severe to profound. So it's a subset of unilateral hearing loss. So if you hear that used interchangeably today, we're gonna try to keep it pretty specific. When I became an audiologist in the nineties, I certainly never anticipated that innovations in medical technology would take us to places it is today. So the amount of telehealth options and remote care and what people can do on their phones is just so exciting and I really have feel privileged to have been able to participate and I'm excited about all of the possibilities to come. So I will hand it off to Cheryl.

- [Cheryl] Yes, thank you Mary Beth. So in this portion of the presentation, I'm gonna review the evolution of candidacy indications and when to refer a patient for a cochlear implant evaluation based off traditional audiometric results. But first off, I wanna review the history of Cochlear's innovation. Cochlear has been providing implants for over 40 years and has definitely been a clear leader in innovation and outcomes. And you can see we've made many advancements over the years in our electrodes, our cochlear implants and our sound processors. Along with improvements, innovation, the products have gotten smaller and better outcomes. Next I wanna review the evolution of cochlear implant indications. So as you can see here, the first indication was

approved in 1985, and that was for adults only who basically were deaf and had zero understanding ability.

Then in 1990 they added children down to the age of two and still they had to have essentially no speech understanding. And then in 1998, fortunately for the kiddos, the age went down to 18 months. And then as far as benefit from amplification, it set stated that they should get limited benefit, but there were no specific speech scores at that point. And then the hearing loss went from profound to include severe to profound. And then in 2000, we'll see again that the age for kids dropped down to 12 months of age. And now we have a little bit more information on results expected with amplification. And the guideline was if the ear to be implanted was 50% or less, or the best aided binaural condition was 60% or less.

And now the hearing degree has expanded to moderate to profound levels. And then again, another expansion for the kids in 2020, down to nine months of age. However, I wanna step back in time 'cause this was another significant indication that occurred in 2013, where the hybrid implant system became available, which is a combination of acoustic and electrical stimulation. And Mary Beth will speak to that more later in the presentation. And lastly, I wanna highlight that in 2022 we received approval for the treatment of unilateral hearing loss and single-sided deafness for adults and children five years and older with their CNC word scores less or equal to 5%, via a cochlear implant system. So now let's look at what the actual FDA indications are.

So the FDA that states that for adults to be implanted with a nucleus cochlear implant, they should have a moderate profound sensorineural hearing loss bilaterally. So you can see in the low frequencies the hearing loss can range from moderate to profound, but from the mid to highs it should be equal to or greater than 90 dB. And limited benefit, again, as I mentioned in the ear to be implanted it should be be equal to or less than 50%. And then in the best ADA condition on recorded sentence measures, it

should be equal to or less than 60%. Now what I wanna point out is the FDA requirements are based off of recorded sentence testing and this is an important evaluation process in the cochlear implant evaluation.

However, in routine automatic evaluations, most clinicians do not perform recorded sentence measures. So that is a bit of a mismatch between what we do and in not knowing when to refer because what we do routinely doesn't match what they do in a CI evaluation. So it can cause some confusion yet to know when to refer and then to make things even a little more complicated, Medicare's criteria did didn't match the FDA criteria. They required that the best aided condition be 40% or less. But I'm happy to tell you there's been some exciting news effective last December 26th, Medicare increased the coverage, they took it from 40% up to 60% or less. So this was a huge accomplishment. And I wanna point out if you had any patients evaluated before September 26th last year, it will be worthwhile to have them reevaluated with this expanded criteria because they may qualify and get the proper treatment that they could benefit from at this point.

Now, this change took years of research, evidence research, and a lot of this information was spearheaded by Dr. Terry Zwolan and Craig Buckman, and we can provide you that reference if you'd like more information. So we went over all the indications, but that is a lot of information to remember. So I wanna break it down to practical terms to know when you're in your clinic and you're performing your routine automatic evaluation, what's a guideline that you can use to appropriately refer patients? So this research project was done by Terry Zwolan, who was previously at University of Michigan, and she actually looked at 661 patient charts to see if there was a pattern based on pure tone averages and speech understanding scores that could accurately identify and appropriately refer patients for CI evaluations.

And she found 96% of the time if their PTA in their better ear was equal to or greater than 60 db, they could qualify for cochlear implant. And she found the same thing for speech understanding if their discrimination was 60% or less, 96% of the time they would qualify for a cochlear implant. So if there's one takeaway from today's presentation that we want you to remember is the 60/60 guideline is a very evidence accurate referral tool to use. Also, I wanna talk about the revolution of bone conduction and I'm just gonna highlight a couple of the key improvements. So what I wanna point out is, since 1995 with the bone conduction devices, there had to be an abutment in order for the processor to be attached.

And as you see along the timeline, those abutments have gotten smaller, more durable and more reliable. But you know, patients weren't really a fan of having you to use the abutment, but that was the only option available. But then fortunately in 2014, cochlear introduced the Baha Attract, which is the first bone conduction system to have a magnet and not require the use of abutment. So that was a huge step forward in bone conduction technology. And then in 2019, we took it to the next level and we introduced the Cochlear Osia system, which is the first active system to use electro piezo technology, and again, doesn't require the abutment and it's magnetically connected and can provide up to 55 dB fitting range.

And we'll talk more about that later in the presentation. So now let's take a look at the indications for bone conduction devices for mixed and conductive hearing losses versus single-sided deafness. So as I mentioned, for bone conductions, the indication is that their thresholds must be equal to or greater than 55 db. And then for single-sided deafness, the good ear, the bone conduction, excuse me, the air conduction PPA must be equal to or greater than 20%. And the impaired ear, the degree of hearing loss must be 80 dB or greater. So you see the Osia 2 and the Baja 6 can accommodate a 55 dB fitting range. And we just want to make sure you're aware that if you need bone conduction device to fit a 65 dB hearing loss, we still have our

Baja 5 superpower device available. So now that we've reviewed the guidelines and a candidacy, I wanna turn it over to Laura for the next part of the presentation.

- [Laura] Great, thank you so much Cheryl. It's always, you know, it's so interesting to look at, you know, how candidacy has evolved over the years and the technology and we all know that's just gonna continue to change. And Mary Beth, you know, kind of defined it here at the beginning of presentation, but I'm gonna talk more about bimodal stimulation and what that means. So again, when we say bimodal, we're looking at electrical stimulation in one ear with the cochlear implant and then still providing acoustic information through that hearing aid on the other side. And so what do we know about bimodal benefits is that, again, this works for a lot of patients and actually about 70% of CI users are bimodal in set up, and it provides a lot of benefits.

So if we wanna go to that next slide. So what are some of the bimodal benefits that we see? You know, and when we look at so many of our studies and research projects, obviously we really focus on that speech perception and speech understanding. So we know that patients get improved benefit there in both quiet and in noise. But again, with the multitude of research studies that have been done on bimodal, seeing again these other areas where patients have improvement. So obviously maintaining that acoustic information helps with their sound localization, their overall sound quality. And again, I think when we look at these last three really thinking about how do these patients function in their real life and finding that they can perform better in real life environments, they get that quality of life.

And sometimes I think, again, when we think about music and implants, that they can't enjoy it and that's not the case. You know, we see with bimodal patients that their perception of music is improved with that as well. So again, we know that bimodal is a great setup for patients. And so what does some of the speech understanding kind of look like? So we wanted to go through this study to kind of look at, okay, how did

these patients perform bilaterally with their hearing aids? And then in that bimodal situation, so the graphs on the left, this was kind of looking at our Nucleus 7 sound processor and a compatible Resound hearing aid for the bimodal, and then the bilateral hearing aids, again, these were appropriately fit, matched to real measurements.

So they were tested with those and then this testing was done six months postoperatively for these patients. So you can see again, when we talk CI evaluation, they're using that minimum speech test battery. So looking at CNC words and these AzBio sentence testing. So you can see for both those situations for bilateral hearing aids, 29% for words, and 32% on sentence testing and just significant improvement in that bimodal, almost 40 percentage points better in the bimodal situation for words. And again, you know, over 20% better for sentence testing. So these patients, you know, and I always think about what does that mean with how they're functioning in life? Those are such dramatic changes for how that patient can actually perform and what they can do every single day with those kinds of test results.

So again, bimodal an amazing setup. And one of the things that I think was interesting if you, you wanna go back on this study as well is that they looked at having these patients and these recipients rate themselves in terms of satisfaction. So rating themselves with the two hearing aids versus the bimodal. And you can see again overall rating themselves at 9% with two hearing aids to 95%. So again, I think when you think about that patient's life, you know what that really means for what they can do every single day. So one of the questions though, again, we know bimodal can be beneficial, but what can patients really expect? So they also kind of in this next study looked at, let's look at that hearing loss in the aided ear and compare it.

So let's look at how did they do with their best fit hearing aids, then just looking at six months with the CI and then that bimodal situation. So again, looking at the different degrees of hearing loss. So on the left that moderate severe pure tone average, severe,

severe to profound and then profound. So you can see in the three left conditions for moderate severe hearing loss to severe to profound, that bimodal condition giving them nine to 10% improvement for words in quiet. So again, being able to explain to these patients that yes, you know, wearing that hearing aid, you're gonna have, you know, extra benefit. What is interesting though, if you look at that last condition where again, profound hearing loss, only getting a 2% improvement in the bimodal setup versus just their CI.

So we know the CI is really the component that's driving that understanding and that huge improvement versus their bilateral hearing aids and the hearing aid not adding too much. And so this very many times can be a situation where bilateral implants, you know, what could we do to maximize this patient's binaural hearing? So that very many times might be that situation where we're starting to introduce bilateral implants to a patient since again, they're not receiving as much benefit there. But obviously there's a lot that comes into, you know, making that determination for a patient. But again, you know, we see that as the hearing loss progresses in that other ear. So one of the things when it comes to bimodal is that obviously this brings a lot of questions, you know, for those of you that maybe work primarily with hearing aid patients, you know, how do I manage this patient?

What am I supposed to do with this person? And what do they say about how to set the hearing aid? And that's where in 2022, a group of wonderful professionals in the hearing aid and CI space made a publication around what are the guidelines for best practices in managing patients with bimodal hearing configuration. So this is an absolutely, you know, great resource to now have to really understand what can you do in clinic to help these patients? Because that's one of the things that we know, obviously patients that have a cochlear implant may stay within that CI center for their hearing aid as well, but for some that might be a long distance. So they may wanna

stay with their local professional who they've worked with their hearing aid for many, many years.

So again, that might be you that's listening today. And so it's important to understand, you know, what do you need to know on that? So this is a great resource for that. And again this is where they really address some of the questions with advancements in hearing aid technology, you know, things like frequency lowering and you know, synchronization of automatic gain control between a CI and hearing aid and really spell out that the evidence, not necessarily being there to support utilizing those types of things. So how you need to set up the hearing aid and the CI to maximize for those patients. So, and when we talk about, you know, Cochlear's options that are available and then we have such wonderful technology sharing with Resound, this is where we have such a range of bimodal solutions on the market.

And so going back to 2013 with our N6 sound processor and being able to offer these patients that bimodal streaming with accessories. And so now, bimodal in general just refers to any acoustic hearing aid, but that's where again, our partnership with Resound, we can really, you know, hopefully maximize for some of these patients being able to take advantage of particularly that streaming that made for iPhone compatibility and things like that. And the great part is is that obviously as Cochlear's technology advances, we most recently launched our N8 sound processor, Resound recently launched their Omnia Hearing Aid. Again, continuing to provide that compatibility. So for those of you again who maybe you primarily work with hearing aid patients, obviously things are always changing on the technology front.

We really encourage you, you know, if you are working with a patient where maybe they're gonna be looking at an implant or they're in that process now, we have some amazing resource guides online as well as Resound has it on their website where you can look at that compatibility. So if you're talking about potentially an instrument for the

other ear, you know, you can really see what would be that best option for those patients. So I always think it's helpful when we have a case study, right? 'Cause I think this is what puts it into practice for what you guys do every single day. And so wanted to kind of look at this audiogram and you know, how do we think about it?

Because again, we may look at this and obviously we see that asymmetry between the right and the left ear, right? You know, absolutely they've got that kind of severe to profound hearing loss. Very poor word rec. This is where, you know, I think it's interesting you look at the left ear and say well their word rec's at 96%, yeah they've got that moderate to severe hearing loss. I don't know like what, what am I supposed to do? And this is where to what Cheryl referenced before on that 60/60 guideline is so helpful I think in just being able to look at this and say, you know, what am I supposed to do? What should I say to this patient?

So again, it defines, you know, 60 db or greater pure tone average in the better hearing ear. So in this case that left ear has a pure tone average of 65. So based on that we would say yes, you know, this patient should be referred for evaluation. So obviously this patient was, and again they were also reporting struggles not being able to do well on the phone, asking for repetition and things like that, but they were referred for that CI evaluation. And one thing again with you know, our standard audiogram and we look at word recognition versus what's done in a CI evaluation, this is where again the CI evaluation really looks to do speech testing, speech perception testing to put different demands on the auditory system.

So again, when they're going for that evaluation, they're gonna look at aided testing for these patients for both ears and then binaurally. And again, this is what really gives us the information to see if they are a candidate for a CI. So again, the 60/60, I think this is a great case example of a patient that should be referred. And so let's look at how this patient's doing and how they did during their testing. So preoperatively again, the CI

evaluation looks at those AzBio, sentence testing, aided, and CNC words. So you can see in the right ear obviously doing very poor in both conditions, just 9% for words and 27% for the sentences, the left ear performing a little bit better obviously, but still very different from what we saw for those word recognition scores, right?

So again, a little bit more challenging for that patient and then binaurally seeing that they actually do poorer with information in both those ears. So based on that 60% this patient would be a candidate. And with that right ear being poorer in this situation, this is one where again looking to implant that right ear to give that patient kind of the best from a binaural situation. So the patient was implanted in the right ear and then the graph on the bottom or the chart there, outlines how does this patient doing three months postoperatively? So you can see the huge improvement in that right ear, the left ear obviously again with the hearing aid, same results as what they had before.

And then you can see that dramatic improvement in the binaural condition. So again, thinking of that patient as a whole, I think it's amazing to see likely what they would be able to do in their life on a day-to-day situation. And you know, for what Cheryl and I do every day, you know, we obviously work with professionals who maybe don't necessarily work with cochlear implants but obviously have patients who could benefit. So a lot of the information I shared earlier about improvements that patients can see their satisfaction, that's great information to be sharing with your patients if you are recommending that they go for further evaluation. You know, we know that patients can have a lot of hesitations, so some by sometimes showing them that, really showing them how again this can improve and really help their quality of life can really help that patient move forward and be interested in taking the next step. So that's a little bit on bimodal and so now I'm gonna pass it back to Cheryl and she is gonna talk about unilateral hearing loss and single-sided deafness.

- [Cheryl] Yes, thanks Laura. So in this section I'm going to be reviewing the evaluation and treatment options for unilateral hearing loss and single-sided deafness. But first off I wanted to provide a differentiation between, you know, what is classified as unilateral hearing loss and what's classified as single-sided deafness. Because these terms a lot of times get used interchangeably. So to go over that, you'll see on the left side of the screen a technically unilateral hearing loss is in the affected ear. It can be any degree of hearing loss, there's no specific degree, and of course in the normal ear, it's gonna be 30 degree or 30 dB or better. And then when we look at single-sided deafness, the affected ear, the degree of hearing loss in the affected ear has to be 80 dB or greater.

And in the contralateral ear it is also 30 dB or better. So I just wanted to let you know that the difference is that single-sided deafness is really a subset of unilateral hearing loss, but there is definitely different degrees of hearing loss associated with unilateral hearing losses versus single-sided deafness. So when we think about treating an adult for a unilateral hearing loss or single-sided deafness, we have to recognize that the treatment pathway can be quite different than what would be performed on a candidate for traditional cochlear implant. And a lot of that has to do with a single-sided deafness, usually due to the medical e etiology, which becomes more of a concern. We don't know if it was from meningitis, you know, we wanna try to, in our history in the examination determine to the best of the ability what is the etiology?

And then also when we do the examination, we're dealing with a normal ear and an impaired ear. So that makes the evaluation kind of complex. So we need to be able to isolate the I imperative. So sometimes during examination it's required to put an ear plug in and put a high level of background noise in there, masking noise in there, the isolate the ear so we can get an accurate audiological profile on that patient. And then once that's been accomplished it's deemed that it's time for imaging. So usually the next step is to have an MRI because we really need to check the health of the auditory nerve. We wanna make sure that the auditory nerve is healthy, that it doesn't have any

deformity or aplasia, because if it does, then treatment for SSD may not , the best option may not be a cochlear implant, right?

Because the cochlea isn't healthy. So if those situations arise, then the better option may be to go with a bone conduction device for the treatment of single-sided deafness. So let's look at the different options available to treat SSD. So it can actually range from doing nothing at all, right? Because they still have a essentially normal hearing ear and a lot of times people can compensate. So that's the first option. And then usually what will happen at some point they'll try a cross or bi-cross and you know that can be beneficial but remember that's just routing the signal over to the better ear. So they're gonna lose a lot of the binaural benefits when you're doing a cross or bi-cross.

And then the other treatment paths are to go with a bone conduction device or a cochlear implant. So there's several different options and I wanna take a look on the next slide at a study that would've done to help us identify which treatment option would be the best pathway for these patients. So as I mentioned in 2022 we got approval for the treatment of SSD with our cochlear implant. So in anticipation of that approval, we actually had a thought leadership meeting at our headquarters and we brought in 24 people that are experts in treating single CTO deafness, which included surgeons, audiologists and hearing scientists. And we wanted to get their input and come up to a treatment plan for actually determining how to evaluate them, what's the best way to program for them and what protocol should we use for treating them just in general.

So in this study what they did is they wanted to look at the different treatment options and determine which ones are gonna provide the best auditory benefit, and the areas that they looked at for auditory benefit included, overcoming the head shadow effect, improving sound lateralization, improving localization abilities, having the ability of

binaural summation and binaural squelch. So I think it's pretty obvious if we look at the no treatment option, that there are a bunch of Xs, no check marks because they're not actually addressing any of the issues. And then when we look at the the cross systems and the bone conduction systems, we have a couple check marks, but as I mentioned before, when we choose these options it's going to route the signal to the better ear.

So we're not gonna get improved localization, we're not gonna get the benefit of binaural summation and binaural squelch, which can be very advantageous in complex listening situations. So as you can see here, if that cochlear nerve is healthy, the clear choice is to go with a cochlear implant so they can get all of these auditory benefits. Now let's look at the indications when to treat single-sided deafness with a cochlear implant versus a bone conduction. They're somewhat similar. So we first look at the cochlear implant in the poorer ear, their thresholds have to be 80 dB or worse, and then in the better ear they have to be 30 or greater. Same thing for bone conduction, 80 dB in the affected ear, and in the better year they have to be 20 or greater.

And that's applies to individuals that are five years and older, whether it goes with a cochlear or bone conduction. But it's all gonna be depending on that medical evaluation as to which one's going to be the most appropriate option. And then another factor that comes in is actually insurance coverage. So bone conduction devices for the treatment of SSD have been around for several years and been approved. So insurances are typically covering those and since the treatment of SSD for cochlear implants has been more recent, some insurances are covering it, some are still waiting for more evidence. So that is something to really have your patients check out with their insurance company. So not only does the medical evaluation become important in determining which option, so does health coverage is another consideration.

So next I mentioned that in 2019 we introduced the Osia, and that was the first bone conduction system to use piezoelectric technology. And there's several advantages to this technology. It's really more of a vibrational technology. So there aren't actual moving parts with like gaps between the mechanics which could, you know, after wear and tear of years have some mechanical issues. So it's a very stable, reliable product. And then also it doesn't require the abutment as I mentioned before, because the processor can magnetically connect to it. And also additional benefits of the Osia are that it can actually increase the gain in the high frequencies by 12 dB compared to a bone conduction device, and the frequency range goes out to 6,000 hertz.

So when the implant audiologist is choosing a bone anchor device versus the Osia or a bone conduction device, it's important to note that the Osia can give 12 dB more high frequency, again, expanded frequency range, which is going to really enhance the patient's outcomes, particularly in noisy, complex environments. 'Cause we know we're most of the speech intelligibility comes from is those high frequencies. So that's a huge advantage of the Osia system. And again, I think the case studies, you know, really are impactful as Laura mentioned before. So let's take a look at this first case study and then we'll look at one where the decision was to choose a cochlear device versus a bone conduction device, based on their history and their medical etiologies.

So this is a woman who was at age 47, she had a sudden sensorineural hearing loss and she had a tinnitus associated with it. Her medical evaluation was unremarkable, and they felt overall the most likely etiology was a virus that had occurred and then also they did the MRI and they were able to verify that the cochlea was in good health. So they decided that the cochlear implant would be a good option. But before they decided to proceed, they wanted to go ahead and have her try a hearing aid in that left year just to see if she could potentially get some benefit. They knew it was probably not too likely, but you know, you always wanna try acoustic amplification and then see how they do.

'Cause sometimes we're surprised, right? But in this case she did not do well with the hearing aid. So she waited about six months after the onset of her single-sided deafness, and she decided to move forward with the cochlear implant. So you can see here on the left side, her preoperative evaluation scores show for the left ear on the AzBio, only 12% understanding and for the CNC words, 9% understanding. So really struggling that left ear, which is not surprised when you look at the degree of the hearing impairment shown below on the audiogram. And now let's look at her postoperative evaluation at three months later. And you can see there that her aided went from 12% to 76% on the AzBio sentences.

And then on the CNC words, it went from 9% to 58%. I mean that increase in hearing capabilities is just life-changing, because now she's getting binaural information, she's getting binaural squelch, binaural summation, it's gonna improve her ability to localize, she's gonna have better sound perception and just really perform so much better in complex listening environments. So as you can see there, this was a very successful end result for this patient. Okay, let's look at the next case study. So this is actually a teenager, but he was diagnosed with unilateral hearing loss at age two. And as you can see from the audiogram, it was in the left ear and it was profound sensory neural in nature. At that time the parents decided since he had the normal hearing ear not to proceed with any type of treatment acoustic or implant wise.

And overall he did quite well when he was younger academically and the speech development he did well. But once he got into high school, where the academic levels became more challenging, he was in more social situations with complex listening areas, he started to struggle more and more. So they decided to go ahead and try a hearing aid. He was age 13 at that at that point, and not surprising with that degree of loss, it wasn't successful. So they waited another year until he was 14 and they decided at this point to go with the Osia because his hearing loss had been greater

than a duration of 10 years. And research shows if the duration is longer than 10 years, a bone conduction may provide better results than a cochlear implant.

So now on the next slide, let's look how he's done with that bone conduction device. So you can see on the left side we did some institute measurements through our software to see how he was hearing through that bone conduction device. And in the lower left hand corner you'll see that his thresholds are back within the normal area. And then on the graph on the right side, the soft, average and loud fall within the predicted speech range. And that was verified by his post-operative measures. So he said school is much more manageable. He's not feeling fatigued like he used, like he did before he was implanted, feeling much better in noise. His grades have gotten better and overall he's just performing better in life. And a lot of that again is because the Osia was chosen, and as I mentioned, on average it provides 12 dB more high frequency gain and it has an expanded bandwidth out to 6,000 hertz. So definitely a good choice for this situation. So I'm going to now switch back over to Mary Beth.

- [Mary Beth] Okay, well I hope that you all have a list going of patients that you are thinking of as you're hearing about all these points we're covering because it's always fun to be able to take this information and integrate it into your clinical practice. And for my case studies, I'm gonna have you, I'm gonna try to make this as interactive as possible in a webinar of this format and have you kind of create your own adventure and work with a patient that you are thinking of. So we'll look at all the variables, but try to come up with some, some names of people that you know in your practice while we're talking about this next section.

So again, electric and acoustic EAS is the same ear. And what does that look like? So in cases where a patient has addable residual hearing postoperatively, studies do show benefits of taking advantage of that acoustic potential. So the acoustic component can maximize that low frequency resolution and the electric component restores high

frequency sensitivity, and across the array. With improvements in electro design and surgical technique, there's actually a growing opportunity to help patients by adding that acoustic component. When programming a cochlear sound processor in hybrid mode, which is our, the EAS component, we have the acoustic and electric overlap, and in the acoustic component that goes down to 90 db and then the electric frequency cutoff is calculated at 70 dB and it's helpful to have a redundancy in that stimulation information for an enriched hearing experience.

And so this is the the real techy part of it, but that looks different when we program. So I'll get to the programming slides in just a moment. The fitting range for hybrid mode is roughly that yellow shaded area. And the models nucleus six, seven, and eight, are all compatible with an acoustic component. So for cochlear, you just snap that receiver on, much the same way you would with a hearing aid. And in the software you tick a box that says the processor will now function in hybrid mode. So all of these processors come with that capability, should there be an opportunity to enable it. On our website, all of the manuals are available for each of these models in all of the indications.

And so again, here's the resource, please go check out that website and if you are looking for something that you can't find, reach out to us. We definitely want to get you all of the resources you can. So here we're getting to the the case study that you're gonna do while you listen to me talk. So who do you have in mind? Think of a person that might have some acoustic capability after they receive a cochlear implant. When we're considering this, we're looking at postoperative thresholds in the implanted ear that are 70 dBHL or better through 500 hertz. So the audiogram that you see on the page, here on the screen, is a postoperative audiogram. There's no audiogram entered in the left ear.

So this leaves a little bit of flexibility for you to think about who this patient is in your practice. What are some of the etiologies that you can think of that might result in a postoperative audiogram that looks like this, where a patient would be a cochlear implant candidate? If you think about the 60/60 referral discussion, the audiogram's not the only factor. So something that would cause the speech perception score to qualify this person for a cochlear implant, sometimes the left ear is dead and the right ear is not optimally functioning. So the cochlear implant is the better solution. What about Meniere's disease? Maybe they have bilateral Meniere's disease, but they've just got one implant. Other possibilities are meningitis, noise-induced hearing loss, sudden hearing loss and trauma.

And all of those situations could lead to somebody qualifying for an implant in a situation where it might surprise you if you just looked at the audiogram. So we have a patient, the audiogram has been entered into the software system and these are the screens that will come up for programming. So on the left side, this is what it looks like when you're doing the acoustic component. So you would have ticked the box, as I mentioned, that indicates this is a hybrid mode enabled and the frequency allocation is automatically defaulted based on the audiogram you have entered. But there's room over on that, on the right side of the left screenshot you can see there's the ability for the audiologist to manually make adjustments as needed.

On the right side of the screen you can see a screenshot that looks more like a pretty typical cochlear implant programming screen for Cochlear. And in this case you can see all of the electrodes are active, but again, the frequency allocation table has been automatically prescribed based on the audiogram that was entered. And that is adjustable. And so if there's a point where you decide not to utilize the acoustic component, you would just return to full electric mode and get the full frequency table re-enabled. So while you're thinking about this patient, the point of the whole exercise today, our full hour with you has been to think about that other ear. So now in one ear

we have electric and acoustic stimulation, depending on the etiology, we wanna see what's going on in the left ear.

Is that a hearing aid? Is it a cochlear implant? Are they hearing normally? And you're not gonna put any intervention on that side. What does the whole patient look like? And while you're thinking about that and all of the ways that this patient could receive technology intervention, you may also be thinking about all of the apps and all of the accessories and all of the things that go with it. And so I'd like to talk a little bit about the support provided by Cochlear. It's really such an exciting time with telehealth capability and we have a lot of services available to empower the patient to order a repaired device at 11:00 PM on a Saturday, because if they have a cochlear device, they can go to the online store and get that started.

We have apps where they can adjust a lot of things that they wouldn't have been able to many years ago. And they can also do remote programming or not remote programming, remote checking with their clinician. So what does this, how do we enable this? One really powerful resource is our recipient solution manager team. And the patient can sign up for a session, either one-on-one or in a small group and it's device specific to some degree, and there's a rehab session and they can choose what they need to know more about at that time and have a cochlear professional work with them to explain how to use their accessories, when to use something like the mini mic, when to use, how to set up their phone, how to pair it.

And all of that is done outside of the clinic in their home where they are using their own, they're in their own living room. They can say like, I have trouble in this situation. So it's not a troubleshooting session, but it is a very comfortable, their partner can be there, there can be family members and we've gotten very, very high satisfaction ratings from these sessions. So it's a wonderful way to support patients. We also have remote check and remote assist. So these are a little bit different. Remote check

enables the patient to asynchronously check in. So there's a few different components of that, a sound check. And they can take a picture of the site under the coil to make sure that's healthy, and the clinician can then check all of that information and determine if the patient needs to be seen in person.

So it's a little bit of a screener. If somebody calls, they might be able to say, oh, I see it's just your coil. And then that saves the patient a trip to the clinic. Remote assist is live and that is where it is a little bit more. There's more involved, there's more help to the patient. And the clinician is right there and it's live video. So this has come a really long way. The clinicians that have adopted this technology have reported really outstanding success. And I encourage you to go to our AudiologyOnline courses from the fall where we have had some clinicians report out on how they're rolling it out in their clinics. It's always really helpful to hear from our colleagues how that is actually working in real life.

So we did also, you may know we launched the Nucleus 8 sound processor and so I have a really entertaining introduction to that processor next in case you have not been privy to it. So that gets us to the end of our hour today. If you have questions that aren't answered today, here's a way to contact us directly. There's a phone number and the email address. And Melissa, are there questions in the chat that we need to address?

- [Melissa] At this time we don't.

- I'm sorry I'm not able to hear you Melissa, but I think, I think you said that there's no question. So I did wanna point out that the resource paper about The SSD study is in our attachments. There's a resource about our reimbursement team and the support that they can provide. And especially during a product launch, people are thinking about patients and their upgrades and questions about that. So please reach out, use

those resources and then contact us if there's more that you need. Thank you very much for attending today and I hope that this really brought you some tools you can take back and use immediately.