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Foundations of Bone Conduction Systems:
Candidacy and Counseling
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- [Rebecca] Welcome to the Candidacy and Counseling for Bone Conduction Solutions course. My name is Rebecca Cale and I'm a clinical technical project manager for Cochlear Americas. At Cochlear, what we like to do, when we're looking at presentations, is we like to always start with our mission. We do this because no matter what we are doing, we wanna make sure we remember what our goal is for that particular day. Today, we are talking about candidacy and counseling. I hope to provide you with a greater understanding of how we can counsel bone conduction candidates, to ultimately treat more people, allowing these individuals to feel more empowered and more connected to others. Our learning objectives for today are for participants to be able to list the candidacy criteria for bone conduction solutions for both single-sided deafness and mixed and conductive hearing.

In addition, we hope to be able to outline considerations for selecting a treatment within the Bone Conduction Portfolio. And we want to have participants be able to identify important points for counseling and candidate and list resources that are available to support bone conduction candidates. The agenda for today is to provide clarity and new information that will help you work with your patients who might be bone conduction candidates. Next, we wanna look at the different options available and how to demo appropriately. And finally, how to choose options for these recipients. To begin, let's look at some common etiologies and explore why bone conduction might be a good choice. We'll start on the left-hand side of the slide.

You'll see we have atresia and microtia listed. Bone conduction is uniquely suited for atresia and microtia. For many of these individuals, a hearing aid may not be an option even after reconstruction surgery. Fitting a bone conduction device can be used in these situations. Bone conduction is also an excellent choice for those with chronic otitis media. Often this hearing is left until last in the treatment pathway. Medical treatment usually comes first. They tend to try to keep the ear dry and subsequent attempts at restoring hearing can be successful, but may also leave the patient with

less than desired outcomes. Use of bone conduction can help make hearing more of a priority early in the treatment process. It doesn't occlude the middle ear, like hearing aids, something that can lead to recurrent infections, and it can create more consistent hearing for patients since the amplification does not need to be adjusted based on the air conduction threshold.

The fitting is only for bone conduction, which usually remains quite stable even as the disease progresses. Otitis externa is another example of an etiology where bone conduction may be beneficial. Again, keeping the ear dry and clear for amplification and providing hearing directly to the cochlea. And finally, otosclerosis. This is another example where a stapedotomy may have been tried and failed. Research tells us that if the hearing was not restored during the first surgery, the chance of restoring hearing with a subsequent attempt are cut in half. Rather than reoccurring attempts at fixing hearing, surgeons can focus on hearing the ear healthy while bone conduction can be used to restore hearing with a very high success rate.

We also know that the number of people struggling with chronic otitis media is staggering. Prevalent surveys uncovered that the global burden of illness for chronic otitis media affects between 65 and 330 million of individuals across the globe. An estimated 200 million of these individuals suffer from significant hearing impairment. This means that chronic otitis media may contribute to more than 50% of the global burden of hearing impairment. It's also important to note the prevalence difference substantially between countries with poor access to healthcare. These countries had a significantly higher prevalence. Although it is a global issue, it is also a North American issue. When we translate the same equation to hearing loss in the United States, we are looking at a number between 800,000 and 1.7 million.

Chronic otitis media causes both conductive and mixed hearing loss since it results in damage to the middle ear space and to the inner ear. It is also important to consider

the sensory neural component of the hearing loss. The condition is complex and the hearing loss can vary depending on many factors, including whether their ear is wet or dry, whether the tympanic membrane is perforated. Whether the ossicular chain is damaged and whether the cochlea is damaged. Moderate hearing loss is typical and is what we often see, but sometimes we may experience a moderately severe hearing loss. Interesting, and as you can see on the slide here, 21% that had middle ear surgery to restore the conductive hearing loss still need some type of amplification.

Reliable hearing is one of the challenges faced by patients with active chronic otitis media. Often with these patients we'll see what we call the cycle of discharge and infection. This term means that the patient will go in to see the ENT, or audiologist. They'll end up wearing hearing aids. The hearing aids will block the air circulating into the ear cavity. They'll then get a middle ear infection with discharge. At that point in time, the patient is unable to wear the hearing aids. So they have to take them out, take a break from the hearing aids until the infection clears up. Once it's clear, they're able to go back to the ENT, an audiologist or audiologist, and they're able to receive approval to wear the hearing aids.

And the cycle starts all over again. We also see this reflected in Cochlear's registration data. We know from our own patient registration that over 60% of our bone conduction patients today suffer from conductive hearing loss or mixed hearing loss from chronic otitis media, which is a larger percentage than any other etiology that we have registered in our Cochlear data. Discussions with ENT surgeries has revealed that standard of care for treatment of chronic otitis media diseases does exist today, but a standard of care for the hearing loss is often not addressed until after the revision surgery and bone conduction may not even be offered as a solution. Many patients suffer for years with variable or unreliable hearing before they are introduced to bone conduction.

So question why is that? One reason is a lack of focus research where there are gaps between comparative treatments and clinical outcomes. A second consideration is the lack of standardization of the definition of hearing loss severity, treatment categorization, and how clinical outcomes are reported. Other healthcare professionals are unaware that bone conduction could be an effective treatment in conjunction with chronic otitis media. So though many professionals are unaware of the potential benefits of bone conduction devices, there are many clinical benefits that we can discuss. To start out with, the ear canal remains open. Having the ear canal open can potentially break the cycle of discharge and infection that we discussed a few slides ago. Number two, the outcomes are very predictable, meaning that we have good evidence that supports consistent and reliable hearing for a long-term solution.

Two main benefits can be seen and can be discussed when looking at the potential patient benefits for our bone conduction system. Number one, hearing performance, even in noisy situations, improves. And number two, the subjective sound quality improves over traditional air conduction devices. So we've just finished discussing why bone conduction is a valuable option. Now let's look and go over who would be a candidate for bone conduction. Later on, we will discuss our indications in more details, but for now it's important to note that there are three different types of hearing loss that can benefit from a bone conduction device. Conductive hearing loss, mixed hearing loss, and single-sided deafness. Let's start with mixed and conductive hearing loss and why we would consider bone conduction for these individuals.

Number one, compared to conventional hearing aids, the research shows that if the air-bone gap exceeds 30 dB, bone conduction outperforms hearing aids. So as the air-bone gap increases, hearing aid performance decreases and Baha performance is not affected. Number two, in the hearing aid world, fitting formulas are based on the assumption of a damaged cochlea. So a sensorineural loss. Therefore, most are based on a 50% compensation rule. That simply means if you have a 50 dB hearing loss, you

would apply 50% of the loss. So 25 dB in this case. However, the Cochlear Bone Baha fitting prescription is unique and specific to bone connection hearing. It's based on a 1/3 gain rule. And we add on a correction factor for the head transfer and also take into account the internal attenuation.

We did that because of the reports that we got when we looked at the loudness growth and patient description and satisfaction. Number three is related to the discussion earlier with the cycle of discharge and infection. We know that hearing aids can be problematic, especially when we are talking about a draining ear. Now let's talk about why we would consider bone conduction devices for SSD patients. With a Baha or Osia system, the outer and middle ear are bypassed and the sound is sent directly to the good ear. This helps with improvement in difficult listening situations, including hearing and background noise, specifically when someone is sitting on their bad side. It also helps to eliminate the head shadow effect, which leads to a reduction in the psychosocial consequences, and ultimately we see long-term patient satisfaction with these devices.

Our Bone Conduction Portfolio is indicated for patients of all ages with conductive hearing loss, mixed hearing loss, up to 65 dB sensory neural hearing loss, depending on the system, and single-sided sensory neural deafness. While we know that children are more likely to have only conductive hearing loss and adults will have some degree of sensory neural hearing loss, on top of the conductive hearing loss, which would give them a mixed hearing loss, it's important to remember to look at the individual needs of each of these patients. Here's a look at the possible treatment pathway for an individual. This pathway begins with the Baha Start option. This is a nonsurgical option. We know not everyone starts with a surgical solution.

This may be because of age of the candidate, or maybe it's because that they are at the appropriate age for an implant, but they are just at the beginning of their journey

and their best choice would be to provide an implantable solution such as an Osia system, after an evaluation, and then demonstration of the Bone Conduction System with the Baha Start. Either children or adults may begin their bone conduction hearing journey with a nonsurgical solution such as the Softband or SoundArc. For example, a baby born with oral atresia may begin with a Softband. When they reach an age where implantation is an option, they may progress to either an Osia or a Baha system, depending on what is most suitable for them.

So the Baha Start option is just that. A start on the bone conduction journey. The same may happen for an older child with an acquired hearing loss. For example, a child with down syndrome who has recurrent ear infections early in life, that cause a conductive hearing loss. Again, Baha Start provides a great first step to hearing with bone conduction and maybe this individual is fit with a Baha 6 Max on a SoundArc. When old enough, they can transition to a surgical solution. Again, the one that makes most sense for the particular individual. In the US, the incidence of sudden sensory neural hearing loss is 27 per 100,000 individuals. That means we could also see a teenager who suddenly wakes up one morning with a profound sensory neural hearing loss.

Imagine an adult with chronic otitis media. They've had surgery to address their infection, but hearing loss still remains. Demonstration with a bone conduction device in clinic is their Baha start. And then we progress to an Osia Baha system, just like the teenager that we talked about earlier. So now that we've talked about the treatment pathway, let's talk about the next steps for choosing the right candidate for Baha Start. Number one, we need to know or look at your professional judgment or choice. Is this the right candidate for a Baha Start? Are they too young or are they not ready for an implant? What are the indications and what is their hearing loss? So potentially, do they have a conductive hearing loss or a mixed hearing loss?

And if they do, does the patient have an air-bone gap that is greater than 30 dB? Is the patient eager for a solution now? Is this particular individual able to use a bone conduction solution? If so, starting them out on the Baha Start journey would be a good option. Now let's look at choosing the right candidate for an Osia device. As a clinician, once again, it's important to use your professional judgment and determine what's the best solution for that particular patient. These should be patients that would prefer an active solution. So that potentially could be because of cosmetics concerns, skin care considerations, or even hygiene considerations. The patient would need to meet the indications by having either an SSD hearing loss, conductive hearing loss, or mixed hearing loss.

If they were looking at conductive or hearing loss or mixed hearing loss, we would wanna look at the air-bone gap once again. And then we would wanna consider if they're willing to go through surgery and any other options that we're looking at or that might be important for this individual patient. In terms of a bone conduction candidate, meaning for the Baha system, we would, once again, start out with your professional judgment or choice. We would want the patient to potentially not be best suited for an active solution. So they would be looking at maybe about concerns about the size of the implant. Maybe they would be preferring a minimalized surgery. So that would move to a good Baha Connect candidate.

Maybe the patient is currently within a 55 dB fitting range, but may soon require more amplification. So they potentially might be moving up to that 65 dB fitting range and need a SuperPower device. We would also wanna look at the conductive hearing loss or the mixed hearing loss. So what does the air-bone gap look like? Is this patient willing to undergo the required surgery? And does this patient require frequent MRIs to look at, depending on what their situation is, in terms of other health concerns? So ultimately what we're doing is we are looking at finding the right solution for the right

patient. There is not one solution or system that's right for everyone. At Cochlear, we provide a portfolio of options So you and your patient can decide what's right for them.

So it's often easy to look at a candidacy through one lens. We can feel like there is one test or one procedure to follow to determine candidacy for bone conduction solution. But often the picture is a bit more complex than that. For example, for any given patient, a bone conduction demonstration may certainly be part of the decision we're deciding whether bone conduction is the right solution for that individual. But there is more to the question than that. We should think about the patient's hearing health history. Maybe this is someone who has been through a lot of attempts at improving hearing. Many of them may have been surgical attempts. How would this color their views on another surgery to help them?

What might we need to explain to them to understand about what a bone conduction solution is before making decision? Maybe this person has also had bad experiences with hearing aids. Possibly we've tried everything we can with hearing aids, but they still never hear well or can wear them for an extended period of time. And so we need to keep that in consideration when we're talking about an individual and the candidacy process. We obviously want to think about this individual's hearing loss. Sometimes, for certain types of hearing loss, for example, those with significant air-bone gaps, bone conduction is really the best treatment solution and will outperform other solutions such as hearing aids. We have to take that into account, regardless of whether or not we can perform a demo.

Another aspect of care that can often be overlooked is goal-setting. So what is this person's goal for treatment? What do they want to be able to do after treatment that they cannot do now? Perhaps we ask them and we find out that the main concern is being able to talk to their grandchildren on the phone. We have to think about the best way to get them there. Maybe it is a direct connect with a made for iPhone device, or

maybe it is a completely different solution to help address their needs. No matter what, the needs and the goals should be at the center of all we do. Finally, there may be other health concerns that help to guide us.

Perhaps hearing reconstruction surgery is no longer an option. Perhaps they will need more surgeries just to keep the ears healthy, which will make wearing hearing aids even more difficult. These kinds of considerations may be just as important as the audiogram or the demo in determining which is the best pathway. Certainly there may be lots more considerations than there are listed on the slide. The point is that a demonstration with a bone conduction device is only one piece of a larger picture for a patient. We are used to working with complex human beings and we need to be sure we don't just look at one aspect, like their audiogram or their demo. We're making decision about what to do next.

Now that we have reviewed the treatment pathway, let's talk about the demonstration process. Here is a list of some key features of a good counseling session. First, do the demo early and counsel the patient while they are wearing the bone conduction device whenever possible. After considering counseling on the optimal wearing options, clarify how surgical option is different than the demo. This will be especially true for Osia patients. And finally, ensure you establish the importance of treating the hearing loss, regardless of the solution chosen. We don't want the recipient to move toward the option of doing nothing or not treating the hearing loss. We know there is a lot of research out there now that discusses the cognitive impacts of untreated hearing loss.

Our goals for demonstrating a bone conduction device is to allow the patient to try the device before they go into surgery. This will assist in your counseling process, and it will also give them a general overview of the outcomes with the device. If possible, you could also do some objective testing in the booth to show them differences in outcomes with and without the device. That being said, as the audiologist, we need to

be aware that the demonstration process isn't really comparing apples to apples. The patient does not have a direct bone conduction device that has been Osia-integrated. Research has shown us that there will be a difference between outcomes when pairing preoperative Softband to post-operative Osia outcomes.

It's important to counsel on these differences. It can't be the only step that we use to determine candidacy. Here we have listed step one for the demo process. In the demo process, you would fit the Baha 6 Max on either a Softband, SoundArc or Test Rod. You have two options. First, you could use the Baha 6 Max sound processor on factory settings. This is what comes out of the box. It's a simpler process, but won't be as accurate of a demo compared to the second option where you go into the software and do a quick demo program based on the recipients hearing loss. Remember, the demo is really for counseling more than assessment. Osia surgical outcomes are much different than the Baha on the Softband.

So it should be used to illustrate bone conduction benefit, but not necessarily tests expected outcomes for the Osia device. With the new fitting software, we now have a much easier way to set up a Baha 6 Max for demonstration purposes. The patient does not need to be present to fit an individualized processor for demo purposes. But as I just stated, there are still two ways to demo device. The out-of-the-box settings can be used, if necessary, but if time permits, we would recommend you use the new fitting flow in the software to set up a demo device for that patient. You'll connect to the sound processor, enter the audiogram and prescribe and save. The processor will be automatically optimized for demonstration whenever the patient arrives.

Here are some tips and tricks that we found helpful in the demonstration process. Fit the patient earlier in the appointment so they can listen to the device while you counsel them. Make sure you choose a demo protocol that fits your center. That means how will you connect to the processor? For example, would that be a Softband, a

SoundArc, or a Test Rod? And how will you actually demo the device? So will you program the device or will you use an out-of-box function? Subjective methods are very helpful to determine potential benefits, as well as provide you with baseline information to use after the patient has had surgery. And number four, the demo should ultimately be a counseling tool to help explain what bone conduction sounds like and what bone conduction really is.

So now let's dive into counseling and device selection process. To help us in our discussion today, I'd like to introduce you to three patients. Krish, Mia and Layla. They are struggling with hearing and we are going to follow them through the bone conduction journey to find out how their clinics handled evaluating them for candidacy, counseling them about their options, and eventually, what decisions were made in regards to their hearing. So here are our patients. Mia is a 26-year-old single-sided deafness after a sudden sensory neural hearing lost five years ago. She's tried steroids, but has had no improvement in her hearing. She's been counseled about the CROS aids, but is uninterested in trying them. Mia works as an insurance specialist for a large company and she is frequently on the phone.

She can hear well on the phone with her good ear, but hates that she can't hear her colleagues or other noise around her when she is on a call. She also feels much less safe walking and running with hearing only in one ear and is she is looking for a solution that will help her with that. Mia's covered by her work's health insurance plan. Now in the middle, we'll see Layla. She's two years old with bilateral conductive hearing loss. She has bilateral atresia and she's on Medicaid. And then on the right-hand side of the screen, you'll see Krish. Krish is a 67-year-old. He is a recently retired school teacher. He has a long history of chronic otitis media with several attempts at surgical reconstruction in both ears.

He's used hearing aids off and on, but struggles with drainage from his ears. So he's going through that cycle of discharge and infection that we talked about earlier. Krish' insurance is Medicare with a supplemental insurance. So before we get started, let's make sure we are all on the same page about what we mean when we talk about bone conduction solutions for hearing loss. So with recent product introductions, it can be a challenge to keep up to date and navigate the candidacy process. But really, the common thread we will talk about is bone conduction, mainly with demonstrating and evaluating how bone conduction will work for individuals, has a wide portfolio of systems that can be used to treat individuals with hearing loss.

These different options are tailored to what's right for the patient in their hearing journey. So this represents the next level of choice for a patient, depending on which system will work best for them in their particular situation. And as we talked about before, this depends on the indications for the patient, their lifestyle needs. It could depend on insurance coverage, their surgical medical needs, et cetera. But deciding which system should actually come after they decide I'm moving forward with a bone conduction solution. So after the system choice, we then choose the particular type of connection. So we'll start off with looking at the Baha Start system, and that's on the left-hand side of your screen. This would be our Softband or SoundArc, which would be paired with our Baha 6 Max sound processor.

Our nonsurgical option that we discussed earlier. Then there is a surgical options with the Osia system that's in the middle of the screen. This option provides a powerful through-the-skin connection. And for patients for whom the Osia system may not be the best choice, but still would benefit from a surgical solution, we also have the Baha system that you can see on the right-hand side of your screen. It uses a percutaneous connection that goes through the skin to connect to the sound processor. Another thing to consider is that patients may not always start in one system choice. There may be a pathway, often from nonsurgical to surgical options, such as our Baha or Osia.

This is definitely true for our pediatrics who may start with a nonsurgical option and move to a surgical option as they get older. But also may be true for adults. This does not mean, of course, that patients will receive a surgical Baha before Osia, but rather that non-surgical might lead to surgical. So now that we've laid out all of our options here, let's look at who we would consider for these different options. In order to do this, we need to look at the key benefits and features of the different systems. Let's start with looking at the Osia system. The Osia system offers a powerful through-the-skin connection that provides excellent hearing, especially in those high frequencies.

It provides with us with high power and really sufficient gain. And it's effectively through a single point of transmission that delivers that gain to the cochlea with full digital sound quality. So high power outcomes is critical in that it provides us with a 55 dB bone conduction fitting range on par with a percutaneous solution using a power sound processor. That high output also allows SSD recipients to be fit with the high frequency gain that would provide them with a clear sound quality. In addition, we also have our wireless accessories and our connectivity. So it has waterproof hearing with the Aqua Plus as well. Here, you'll see the indications for Osia devices. It's important to know that indications is not the same as candidacy.

An indication is the rule or guidelines based on audiometric data. It is included in our package insert as our FDA guidelines for use. The concept of candidacy is different. This is more about the whole patient, including all 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. Candidacy is about the whole person and this is where we would consider those areas discussed earlier, like the results of the demonstration, the hearing health history, the goal-setting and other health concerns. The indications for an Osia device is patients 12 years of age or older that have either single-sided deafness defined as an air conduction pure-tone average at five, one, two and three.

A better hearing ear of 20 dB. Or a conducted or mixed hearing loss with bone conduction at five, one, two, and three, better to or equal to 55 dB. Bilateral candidates should have symmetric bone conduction thresholds, which would be less than 10 dB difference between the ears, on average, at five, one, two and three, or less than 15 dB difference at individual frequencies. So, as we talked about earlier, the Baha Start is the first step for bone conduction devices. For pediatric patient, this may be because they've not reached the age where their implantation is appropriate for them due to bone thickness or bone quality. For adults, it may be 'cause they are in the very early stages where we are just in the demonstration process.

The Baha Start uses the Baha 6 Max processor, which has a 55 dB fitting range. A low production, which is two millimeters shorter when we're coupling that to any of our previous generational devices. It allows for connectivity via the Android or Apple devices and has dust and water protection. To connect this device to the recipient, you would either use the device that is shown on the top right-hand side of your screen. So the SoundArc. Or use the Softband. Typically with babies, we'll see them use the Softband because the connector device can be placed anywhere on the patient's head. Babies, as we know, are often laying down on the floor or potentially in car seats. So the Softband would allow the processor to be placed, not only behind the head, but potentially in the middle of the head to reduce any potential issues with feedback based on the processor touching the floor or maybe the car seat.

With the Baha 6 Max sound processor, the size of it is that of our premium sound processors, but with the output power of a power device. It has a fitting range of up to 55 dB since sensory neural hearing loss. It also allows us to connect the BI300 implant in our DermaLock Abutment, which is clinically proven to integrate with soft tissue. So here's the Baha system indications. You'll see that it states patients are five years of age or older with either a single-sided deafness at air conduction pure-tone average of

five, one, two, or three, The better hearing ear, better than or equal to 20 dB, or a conductive or mixed hearing loss with bone conduction pure-tone average at five, one, two, and three, is equal two or better than 55 dB for the Baha 6 Max sound processor.

Or equal two or better than 65 dB for the Baha 5 SuperPower sound processor. Once again, for bilateral candidates, they should have symmetric bone conduction thresholds. So less than 10 DB difference between the ears, on average, of five, one, two and three, or less than 15 dB difference at individual frequencies. The Baha and Osia system have direct streaming capability for both Apple and Android devices. They also have access to the Smart App, as well as many other wireless accessories, which would include the remote mic or our mini mic system, the phone clip and the TV streamers. So with all the different phone conduction options that are available, how do we decide which to use? The first question is whether or not this patient is a candidate for bone conduction.

If the answer to that is yes, the second step is to make sure to demonstrate the bone conduction early in the process to show the patient what it will be like. In this situation, you would either use the Test Rod or Softband and/or the SoundArc, and you allow them to wear the device during the counseling process. Next, you wanna decide if a nonsurgical option is best. So for example, is this patient under five? If they are, then a nonsurgical option would be best and you would start looking at the BaHa Start system for them. You would then consider an Osia system. If an Osia candidate, then you would wanna look to see if they are indicated, meaning are their bone conduction pure-tone average better than 55 dB?

If it is, if it's worse than 55 dB, then we would consider a SuperPower candidate. So always remember to keep Baha in mind. If Osia doesn't work out due to reimbursement challenges, frequent MRIs, or potentially the indication differences, Baha is still a good consideration for these individuals when we're talking about candidacy. So let's go

back to Mia here. So here's her audiogram. Let's think about which candidacy criteria to look at first. She is obviously SSD. So that's the criteria we should consider. In order to be a candidate for both Osia and Baha, her air conduction thresholds in the good ear should be 20 dB or better. We wanna look at the pure-tone average at five, one, two and three to determine this.

And if you do the math, her pure-tone average is actually 13.75 dB. So she would be considered a good candidate for both Osia and Baha. So a little bit more information about her. She was seen at Big U Medical Center for her Bone Conduction Candidacy Appointment. The audiologist ended up programming a Baha 6 Max sound processor on the SoundArc for her hearing loss for her to wear throughout the visit. So as we discussed earlier, it's helpful to do the demo early on, counsel the patient while they are wearing the bone conduction device whenever possible. So that's great that they went ahead and did that. They then went over her goals, which included hearing better at work, when she was on the phone, and hearing better in noisy situations.

So once again, a good step in the counseling process, making sure we're individualizing that appointment to her and we're addressing her goals, and that if she did move forward with surgery, that those goals would be able to be met with the solution that was chosen for her. Next, they did some testing and sound field, which was noise to the good ear and single to the poor ear. They did an unaided QuickSIN. They got eight dB single-to-noise ratio, which is the moderate sensory neural hearing loss. And then they did a QuickSIN with the Baha 6 Max and a demo, and they got a zero dB single-to-noise ratio, which would be considered normal. So they, in the end, she liked the sound of the bone conduction with a demo and liked that the Osia system because it was transcutaneous.

So she ended up being very interested in the system and wanted to move forward with it. They ended up sending her some brochures and she decided to go on social media

to learn more about the bone conduction device, which is something we commonly see within this world that we live in now with technology at the forefront of everything that we're doing. So it's great that she was able to connect with others and get more information before moving on with next steps. So let's go back to Layla. She's two years old. Remember, she had a bilateral conductive hearing loss with a history of bilateral atresia. She has a bone conduction threshold, a pure-tone average of 8.75 in the right ear and 11.25 in the left ear.

So based on this information, she is a bilateral candidate for a Baha Start solution. So remember she is only two years old. So that's why she's not moving into a surgical solution at this point in time. Also, interestingly, if we look at her bone conduction pure-tone average at five, one, two and three, it needs to be better than 55 dB for the Baha 6 Max sound processor, which it obviously is. And we also look at the differences between the two ears. So she needs to have a symmetric bone conduction threshold, less than 10 dB difference between the ears, on average, at five, one, two and three. And we do see that with her. And there shouldn't be any differences greater than 15 dB on those individual frequencies.

So once again, we do see that with her as well. So here, Layla was seen at University Pediatrics and they wanted to discuss the potential of those different bone conduction options with her parents. And they ended up fitting her with a pre-programmed Baha 6 Max sound processor, and they used the Softband. So like we discussed earlier, making sure that that demo process is appropriate for your clinic. In this particular clinic, they went ahead and did the pre-programmed Baha 6 Max sound processor so it could be ready and used specifically for this individual and her type of hearing loss. Her parents did express concerns with her speech and language development. So they were really looking at some of her goals that needed to be addressed and where her parents wanted to get with amplifying her, their daughter.

And then they also asked about her environment. So she's currently home with her grandma during the day, but parents would like to enroll her in a preschool program when she is three years of age. So that's important to know because she's gonna be in different types of environments. Potentially we could look at discussing some of the monitoring features of the device. So for example, find your processor with the app. Those are all really good options when we're talking about her staying at her grandma's house and being in those preschool settings. So the parents, once again, ended up receiving some brochures from the clinic and they started exploring social media. Layla is covered under her state's Medicaid program.

And her family, they did have some concerns about how long the approval process will take. So what's interesting about that is Cochlear does have a program that address this. So we recognize the importance of providing early access to sound, to promote optimal speech and language development. And therefore, we ended up creating this Lend the Ear Program or Lend an Ear Program. This program allows us to have faster access to sound for children that are 12 years, under 12 years of age. And that really our bone conduction candidates are the right solution for them. So what happens is the clinic will simply request a Baha Start solution that would consist of a Baha 6 Max sound processor and a Softband or SoundArc loaner while waiting on the reimbursement insurance approval process.

So this means that your patient can have access to critical sounds as early as possible to help them hear, learn, and really develop essential communication skills. Cochlear's program is a loan-to-own concept. So where we provide early access to bone conduction equipment with the intent to transfer ownership to the patient after insurance approval has been obtained. Okay, now let's look at Krish' audiogram. So let's look at where he falls in the indications for Osia and Baha. First, we identify that he has a mixed conductive hearing loss in the left ear. So if we consider him a candidate

based on this, we know that he potentially is an Osia candidate or a bone conduction or a Baha Solutions candidate.

He does have better hearing than 55 dB, so he meets the indications for a left implantable device. Krish' was seen at the ABC ENT. His audiologist immediately thought of a bone conduction for him and she fit him with a preset Baha 6 Max on a Softband. So once again, doing that demo process in a fashion that is appropriate for your clinic. And doing that demo process early on in the fitting does help provide a really good demo situation for the patient so they can get used to wearing their device here with the device while they're still sitting there talking to the audiologist. Krish told the audiologist that he most wants to be able to talk to his grandchildren on the phone and communicate better while he and his wife are traveling.

So another great aspect of this demo process is, once again, they talked about the goals that Krish wanted to have while he was progressing through this process. One thing to point out is they did not do any actual formal testing. So that's something nice to consider if you do have time prior to fitting them with the device or going into a surgical option, introducing that component to the counseling process is an excellent solution. So he ended up being sent home with several brochures and also contact information for his local Cochlear volunteer. And he was scheduled to return to the clinic in two weeks to decide on an option. So that's where we stand with those three patients right now.

Let's go back to talking about counseling and then we'll circle back at the end to look at the final results and decide what happens with those patients. So when we talk about counseling, we also start out with what is the purpose of this task? So Cochlear talks about counseling should really be individualized. Looking at the goals of that particular patient. Should also obviously include basic information about what a bone conduction system is and how it is different from other options available to this patient.

Finally, we wanna look at how this option will work with the patient's lifestyle and what accessories they could use. For example, patients with straining ears. So the next step is to make sure candidates understand the differences between the demo and the devices they are considering.

With Baha, it is more predictable, but with Osia, a bone conduction demo is really just an idea of what it would be like. So data shows us that hearing, especially in the high frequencies, is much better with Osia than what it would be with a Softband. So there is a benefit of doing the demo, but is not a direct prediction of how someone will do with the Osia device. One of the key reasons candidates don't move forward with a Baha device or a bone conduction solution, such as an Osia device, is a fear of surgery. We know that bone conduction device surgery is pretty safe and straightforward. In many cases, it is quicker and less complex than other ear surgeries.

So for example, a tympanoplasty. And the recovery is quicker. So we wanna make sure we address this concern head on, especially if the patient mentions it, and also having that conversation with your surgeon on who's gonna discuss this. So is he going to bring it up? And if so, should you also bring it up to make sure the patient is comfortable with the process? Finally, we wanna make sure candidates know what a bone conduction device will do for them. So for example, for individuals with mixed conductive hearing loss, bone conduction systems may provide more benefit than hearing aids when the conductive element is greater than 30 dB. Considerations for treatment of hearing loss for SSD patients include improved speech understanding in noisy environments, especially with the Osia system, which provides, on average, 12 dB more available gain in the high frequencies compared to the percutaneous bone conduction devices.

So Cochlear devices are designed for a lifetime solution, and as a company, we also try to provide a lifetime of support to these patients. So here's an example of how

Cochlear can help with this process. So when we look at the candidate journey, the first step is to have the recipient become aware of their options and then explore possible solutions. Cochlear has an engagement manager assigned to each region to help with this process. The engagement manager's job is to help move this patient through the candidate process. They will connect with patients to help answer different questions. If you do not know who is within your region, please reach out to your local provider and they will be able to give you more information.

Once the patient is fit with the device, they move into the recipient journey. This is where they learn about the device and we try to empower them to feel confident and successful with their bone conduction solution. Cochlear has a recipient solution manager that will help with this process. They will help counsel on pairing of sound processors to wireless accessories, phones, et cetera, et cetera. And even more to make sure that they're comfortable with their device. So Cochlear is committed to recipients and we do strive to provide the most options possible to help treat their hearing loss. Our devices continue to innovate and the design is set up to be backwards compatible whenever possible. And we do have a full portfolio with a broad range of fitting up to that 65 dB to help treat more individuals with this type of hearing loss.

Okay, so to finish up, let's see what happens with our candidacy patients. So let's look at Layla. So Layla was fit with a Baha Start Solution for bilateral Baha 6 Max sound processors. They used a Softband and they went under the Lend an Ear Program. Her parents really liked having access to the Baha Smart app. They were able to control her device. And also, as we discussed earlier, they were able to monitor her device. So they had to find the processor feature, which was a great option for them as well. Her family uses the mini mic when at the park, in the car. And they anticipate Layla will love the direct streaming feature as she gets a bit older.

She is now enrolled in preschool and will start in the next few months when she turns three. So that's a great outcome for Layla and her family. The next patient, Mia, received her Osia system and chose the Aqua Plus accessories since she loves to swim. Mia loves using the direct to iPhone streaming at work, and she can hear much better in that fast-paced office environment. And finally, we have Krish. So after discussions with his clinician and the Cochlear Concierge, he decided to move forward with an Osia system. He also decided to get a mini mic because he travels frequently and he enjoys eating out, which he loves to use the iPhone features that help him connect with his grandchildren.

So all really good outcomes and all different outcomes based on the patient's needs. So you can see that we don't just look at the indications. We need to look at the entire patient, and when we do that, we need to look at their goals and make sure that whatever solution we choose for them addresses these goals. And then we need to go through that demo process. We need to really set up a demo early on in the counseling situation, get them comfortable with the device. Talk to them, any concerns that they may have, and allow them the time to decide what is the best option for them. At that point in time, you would either move forward with the Baha Start process, maybe Lend an Ear program, or you would go through the different surgical options for them based on their individual needs.

So in conclusion, we know that a bone conduction solution can help with the treatment of patients that have a conductive, mixed or SSD hearing loss. Demoing and counseling is a critical component to ensuring your patients receive treatment. No matter which solution is best for them, treating their hearing loss and connecting them with the world is ultimately our goal for these patients. So with that, I want to thank you for taking the time to view the candidacy and counseling presentation. Please reach out to your local Cochlear representative to help answer any additional questions.