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Counseling Patients through the Ponto Trial Journey:
Benefits of Direct Sound Transmission
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- [Carissa] Hello, everyone, welcome. My name is Carissa Moeggenberg, and I am an audiologist and a training manager for Oticon Medical. It is my pleasure to be here with all of you today, to talk about Counseling Patients through the Ponto Trial Journey: the Benefits of Direct Sound Transmission. I hope that wherever you're coming from it's a beautiful day. I live in Michigan and the snow has finally melted. The sun is out and I hear the birds chirping so it is one of those nice spring days here in Michigan. A little bit about my background, I've been an audiologist for a little over 28 years, worked primarily in the field of cochlear implants. I began my career at the University of Michigan Hospitals where I was a member of the cochlear implant team for 11 years.

I transitioned to advanced bionics and was in charge of training and education for the company for many years, and then recently joined Oticon Medical a little over a year ago. So again, it's my pleasure to be here with all of you today, and the goal for this presentation is probably not to provide you with a lot of new information, especially for those of you who are experienced bone conduction, have used bone conduction devices often and have fit patients over the years, but really to give you just some additional things to consider as you're working with patients and counseling them through this whole process of trying a bone conduction device. So our learner objectives for today are that the participants following completion of this course would be able to describe the benefits of direct sound transmission, that you'll be able to list the steps involved in the trial process of a Ponto System, and that you will be able to illustrate effective counseling tips to use during the patient journey process.

So that's really the learner objectives for today's course. The agenda that I have put into place is just to do a review of bone conduction hearing. I know that you all know that, but just as a review so we're all on the same page. Discuss the Ponto System. Talk about the trial process and as you work with either adults or pediatrics through this process. Discuss specifically the benefits of direct sound transmission and why it's really important to counsel patients during the trial process about these benefits.

Discuss when and how to transition from a trial device to the abutment and the implant. And then finally, to support the benefits of direct sound transmission, we have some very nice clinical evidence that we'll share with you.

So we'll start with bone conduction hearing and the Ponto System. I know that you all know this, but just as a review, the components of a bone-anchored hearing system or a bone conduction hearing system consist of the following. We have our sound processor, the coupling, the abutment, which comes in various lengths, the screw at the center, which is designed that you can utilize the screw to remove it and change the abutment should you need to, and then the actual implant itself, which is embedded into the bone. Bone-anchored hearing systems take advantage of a natural process called osseointegration. And so when a small, or three or four millimeter implant, titanium implant which you see here, is placed into the skull bone, the bone itself actually begins to grow onto the implant, creating a strong, physical connection between them.

And this is because the bone cells naturally want to integrate to the implant in the surrounding bone, and as a result, they establish this direct route for sound transmission. This is a nice close-up of osseointegration as that process begins. Onto the bone into that titanium implant, as you can see, the bone fibers are actually growing onto the implant itself. So this is under a microscope, it is heavily magnified, but just so you get the feel of what this connection looks like. And I think as you work with patients, that it's really important to describe to them what this process is and how it occurs naturally, and the importance of it for providing that stability that you need for the implant.

Now, for direct bone conduction to work, as we all know sounds are converted. So they're picked up by our sound processor here, converted to a vibration, which are transmitted directly to both inner ears, as you see here, and this is just a really nice

animated visual that I also think is very helpful to use with patients as you're counseling them on what that is because a lot of times they may have heard of what a hearing aid is or how hearing aids work, but we're actually doing a different way of sound transmission, and I think sometimes it's difficult for patients to fully understand what that is. The Ponto System today consists of our Ponto 4 sound processor.

Hopefully you guys are familiar with it. It is the smallest sound processor presently on the market and it has advanced sound processing incorporated into it. We also have the Ponto 3 SuperPower, which is the most powerful abutment level sound processor presently available on the market. Now, both of these sound processors share the basic foundation built on brain hearing, which is really a philosophy that kind of guides everything that we do at Oticon Medical. When we think of research and development, we always look to, is it something that's going to support brain hearing, meaning that is it going to help the patient better understand, have better access to sound with less listening effort? So our Ponto System today really does offer the widest frequency bandwidth in the market, it has a durable design and coupling so no matter which sound processor you choose, you have that wide frequency bandwidth, a durable design and coupling, and both sound processors incorporate Oticon Inc.

sound processing and feedback management. So one of the nice things is if you're familiar with Oticon products and fit hearing aids, this is a continuation of those sound processing features, and the feedback in the software is also a very natural flow from hearing aid fittings into bone conduction fittings as the user interface is very similar to what Oticon uses. So let's take a minute and talk a little bit about the trial process. Patients considering a bone-anchor solution for their hearing loss have many options. And as clinicians, as we begin this process of discussing patient choices, there are many factors that patients often consider including the style of sound processor, the surgical features, the wearing comfort, the cosmetic appeal, but I think oftentimes

candidates often overlook or undervalue those intangible benefits of better hearing, of providing that rich sound quality without distortion or feedback.

That's so important for them to hear well in everyday environments. So the trial process is very different for adults versus children, and I just listed them out separately here so that you see for an adult, it typically is an acute simulation completed just in one appointment. Typically, the clinician has demo product available that they can fit acutely at the appointment on a test band and do some verification measures in a sound booth using a test protocol. They can also administer a subjective questionnaire to the patient. It helps with counseling to do this type of acute simulation. We don't see very often where adults actually take that Ponto device outside the clinic and wear it for a period of time.

Now, some of you may offer that and I think that that's great, it just gives them more time with the device and more time to experience that overall sound quality and see the benefits of it, but most of the time it's done really acutely in the office. Now for children, that's different because for children it's really meant to be a non-surgical process that's done over a matter of years until the child meets that minimum age requirement. It's typically done with a soft band fitting. There is obviously, the parents are counseled, all of that, the parents usually have a report measure that they're given, some sort of a skills checklist that the clinician can kind of monitor, get a baseline of where the child is before they're fit with a Ponto device and then after.

Typically, they do some baseline testing and then they're usually seen back quite often for follow-up testing and monitoring with their device until they're at that age when the surgeon and the audiologists feel comfortable to move forward to that surgical option. Some of the clinical tools and resources that we encourage you to have available for a patient first fitting or a patient trial, is the actual processor itself to have some sort of a way to verify whether that's through a skull simulator or a test protocol, that the device

is fit appropriately, and also the test protocol provides a nice way to compare devices or to look at unaided versus aided benefit with the bone conduction device.

We do encourage the use of a subjective questionnaire or some sort of parent report measure. For adults again, we recommend the test band, and for kids, you're gonna start off with that soft band. We do have a Ponto counseling kit that you are welcome to use, and it goes through all of the different color options and accessories that are available to the patient. We do have the Ponto Care app, which we just launched, which is a nice, easy downloadable app that they can download to their smart phone, and there is a trial companion component where the user can actually rate their experience using the device. And then certainly, it's important to provide them with brochures so that after they leave the appointment, they can refer back to the information that you discussed that day.

So why is this non-surgical process important? Well, first of all, it really provides your patients that opportunity to hear with the device, kind of the nice way to try it before they commit to that device. It's nice that you can do this with a bone conduction device because with a cochlear implant, you aren't able to do this so this is a very nice opportunity to have them hear with the device. It also provides you the opportunity to verify benefit, to make sure that this is the solution that's going to give them the most optimal hearing. It allows you to compare different hearing solutions. You know, maybe this is a patient who has utilized a cross system for years and they want to try a bone conduction system, or you're comparing two different styles of processors, or even two different manufacturers.

This trial process allows you to do that, especially with adults. It allows you to assess the patient's first subjective impressions. You know, what do you initially think of the sound quality? You know, are you able to hear better? Is it clearer? Can you understand in a noisy environment? How does it sound in the clinical setting? If you

have them walk outside and experience sound outside the clinic, does it sound differently? So those objective questionnaires are really important to give you that feedback initially and allows you to counsel the patient better, and it allows you to make adjustments to the sound processor fitting if needed. Again, it assists with counseling, it helps you with that counseling process, and it does provide best practice.

So let's look a little bit at direct sound transmission. So when we think about counseling patients, there are more options than ever before for patients considering a bone conduction device. There are a variety of solutions out there and available from all of the manufacturers. The benefits and limitations, however, in the different solutions for the individual patient should include the following questions: You know, does the solution provide enough amplification and output to meet their hearing loss and if their hearing loss should change? Is it comfortable enough to wear for a full day? Cosmetically, does the patient have any concerns? And as you look at the various solutions, you need to take a minute to think about all the different solutions out there and that cosmetic appeal to the patient.

And then, what are the benefits available beyond better hearing? And when I talk about beyond better hearing, you know, because the sound they can hear the sound and it initially sounds better, that's great, but how do they do in everyday life? How do they do at the end of the day after wearing the device all day long? You know, we have evidence to show that the importance of providing a solution that supports brain hearing, that supports less listening effort, that the patient doesn't have to work as hard to hear a sound is really important, and it's hard to explain that to a patient. And so as a professional, we must ensure that patients have all of the information in order to make an informed decision before any surgical intervention occurs.

And so that's really our goal. And so if we think about direct sound transmission versus skin transmission systems, bone-anchored hearing devices can be placed in these two broad categories, right? So there's either a skin transmission solution where the vibrating unit is placed on top of the skin and the sound vibrations have to pass through the skin and are typically attenuated before they reach the bone, before they reach the bone, and then on into that inner ear, versus direct sound transmission, where the sound goes directly to the bone and vibrates the skull, and then down to the inner ear. Direct sound transmission solutions are typically percutaneous or active transcutaneous solutions, that we'll talk about those next, but just so we all have an understanding of what the two different types of bone conduction devices out there are, there are skin transmission solutions and there are direct sound transmission solutions.

So obviously when we're doing our trial process with a patient, we are likely utilizing a skin transmission solution, so we're vibrating through the skin on a soft band or a test band, and these are non-surgical solutions. And so for a child, they may utilize a soft band solution until the age of five or older when the surgeon and audiologist is ready to do the implant, so you may fit them before 12 months and they may utilize that for the next five years. We also have those direct sound transmission solutions and these consist of the percutaneous solution, such as the Ponto device with its abutment and implant where the device is implanted directly into the bone, and we also have an active transcutaneous solution which is the transducer, is actually in the implant itself, so it vibrates inside and you have a magnetic solution on the outside.

And then we also, back to our skin transmission, we have that passive transcutaneous solution, which is an implanted magnet and it's still going through skin to vibrate the skull and the inner ear. And so for our focus today, we're gonna focus on direct sound transmission via a percutaneous solution and a skin transmission solution with a non-surgical option as a soft band. So what are the benefits of direct sound

transmission? Well, there's lots of data out there to show that because of a skin transmission solution, sounds are attenuated and that they can be attenuated by as much as 20 DB. So a direct sound transmission solution can oftentimes provide an extra 10 to 20 DB of output in that mid to high frequency range.

The mid to high frequency range contains really all that important information that's important for speech understanding. And so another way of looking it, and this is a really nice visual that I have seen that we have available in a counseling card that you can use with your patients to kind of talk about the difference or as they're considering to transition to that surgical option, of what really the benefits are of direct sound transmission. And you can see here, that with a direct sound transmission solution, because there's not that attenuation through the skin, you are better able to provide them more frequency information and more access to those higher frequency consonants that are so critical for the understanding of communication, especially in challenging listening environments.

Another way of looking at it is actually, as you know, this shows a skin transmission solution and this shows you the direct sound transmission. It just shows you that you're offering more frequencies to the recipient, that they're more robust, it's more of a direct route of sound, it's likely clearer. And so for your patients, really the benefits and what we've seen from the research is that hearing thresholds obtained are approximately five to 20 DB lower or better between the frequencies of 600 Hertz out to 6,000 Hertz. We also see that speech reception thresholds are four to seven DB lower than conventional devices. And so it means for your patients, access to more sounds and access to softer sounds. So it's a clearer, more natural sound with fewer distortions and less feedback, and so really, as you're working with your patients and trying to counsel them on the importance of continuing through that trial process to the implant, these are definitely things that need to be discussed and should be discussed with your patients, and I think oftentimes that whole, I don't wanna go through a

surgical procedure or I don't like the cosmetic appeal, I think if you can talk to the benefits and really what they'll get by transitioning to that direct sound transmission is so important for the recipient.

So let's look at some other important considerations that I think that patients often think about as they're going through this process and that a lot of audiologists talk to or talk with the patients. The first one is wearing comfort. And so I think as, and this is just a study that was done by Briggs and then by Dutt et al in 2014 and 2015, and this is just when the magnetic solution first came out with the Baha Attract that looked at the difference in actual wearing comfort between the Ponto device on an abutment versus a magnetic solution, and one of the things that they found was that with the Ponto device, that there was really minimal physical sensation of the device, that the device really does stay attached to the abutment to mean that coupling is very strong so that children and adults can be very active and not have to worry about the device falling off.

Also, there's nothing to prevent the user from wearing it all waking hours, and what we've heard from patients is oftentimes they forget it's on. We've had several children who actually forget that they're wearing a device throughout the day, and they'll fall asleep with it and the parents are often going in to remove the device after they've fallen asleep, just because of how comfortable it is to wear. And in fact, in this study, they found that 90% of the users wear the device for eight hours or more versus that magnetic solution, they found only 22% of the users wore the device for eight hours or more. And that a lot of times there was a higher risk of retention issues because of that magnetic attraction, that oftentimes, if the child or the adult were very active, the device would fall off.

And then there's some considerations of just the skin thickness and having to remove some of that thickness with a magnetic or an Attract solution so that you get that

retention that you need after surgery. The other considerations are cosmetic considerations, and I think oftentimes patients will ask, well, if this is an implant, how much hair is going to be shaved? How big is the incision? How much time will it need to heal? And so one of the nice things about the Ponto System, especially with the MIPS procedure, which we'll talk about in a few minutes is that there really is no incision made to date. And this is an older picture that shows a smaller incision, but with the MIPS procedure there's no incision, there's no sutures.

The device is implanted in place, and that's the end of story. With a magnetic solution or even an active transcutaneous solution, you are gonna have a larger incision just of the size of the device that you're implanting. And so again, looking at comparisons between our MIPS procedure and the Attract is that we have designed our procedure to be as minimally invasive as possible, so that the patient experiences less numbness and pain, and that's really important. And so you can see here the difference between the two, and what we've seen, even in comparing the MIPS procedure to a linear incision, is that after nine days, they're experiencing some numbness with that linear incision. At three weeks they're still experiencing numbness, and even at 12 weeks, they're still reporting some numbness versus with the MIPS procedure, at nine days there's some numbness reported, that would be pretty standard, but by three to 12 weeks, they're essentially reporting no numbness, which I think is really important.

The other really important thing is that this is preserving the tissue, there's no need to thin the tissue with the MIPS procedure and the average surgical time is about seven minutes versus 45 minutes with a magnetic solution. And again, we're seeing fewer and fewer post-surgical complications with a percutaneous device, and I think that there's this very big misconception out there with surgeons, that there are a lot of complications with a percutaneous solution, however, we're not seeing that. We're actually seeing fewer complications and we have some data that I'll show you that

points to that, whereas with a passive transcutaneous system such as an Attract, they are seeing some complications with that type of device in general.

So I think whenever you're doing a surgical solution you're going to have some complications, but the importance is how severe these complications are, how few they are, and really with a percutaneous device such as the MIPS procedure, we're seeing very little complications and I'll show you some data. MRI considerations also is a factor for patients to consider as they're going through this decision process of which solution to choose. And MRI is a widely standard procedure and the likelihood that a patient will need that within their lifetime is probably pretty high, and you can see here, the different types of MRIs that are done, whether it's on the spine or the brain, head and neck, upper extremities, lower, the majority of MRI scans are done on the brain and spine, and because of where they're being focused or what the area that they want to look at, that has to be a consideration when considering your options of bone conduction solutions.

And we know with the Ponto System, that one, it is MRI conditional up to three Tesla and it's going to produce a very small artifact in comparison to what we see with a magnetic solution. And that's been reported in the literature is that it's 1.5 MRI conditional, and that you're gonna get a larger artifact just because of the size of the device, the implant itself underneath the skin, and the fact that it is using a magnet. So that has to be a consideration as well. So who are the candidates if sound matters? So if we think about when we're counseling patients and counseling adults, it's really important that for pediatrics and adults with a conductive and mixed or single-sided deafness, that really the direct sound transmission solution is going to provide the best option and the best and the most optimal hearing for the patient.

So let's talk a little bit about the transitioning to that implant. So when I mentioned the MIPS procedure and that stands for a minimally invasive Ponto surgery, and this is

something that is exclusive to Oticon Medical, and in fact, 80% of all Ponto operations in the United States are done with MIPS, and really what that means for your patients is it minimizes postoperative complications because there's less tissue disturbance, the patients report less numbness or irritation, there are no sutures because there's no incision so there's no scarring, we're seeing better cosmetic outcomes. It takes seven minutes on average versus a much longer surgery, which you sometimes see with other types of solutions, and it's really tailor made. So we have designed these components to allow for a minimal and safe procedure, and our long-term goal is really to further reduce the need for any type of post-surgical treatment or complication.

So a little up close and personal look at our Ponto implant. It is the BHX implant and it is a very unique design in that it is the first ever laser-ablated titanium surface. And what that means is it just has this nice etching or if you will, kind of ablation there, that allows for the bone to actually adhere quicker and faster, and provides more stability for the patients. So this is our Ponto BHX implant. And then our abutments are really nice because they have this unique design for tissue preservation. So our abutments are available in four lengths, six, nine, 12, and 14, and they fit naturally within that circular incision that's used with that MIPS technique, and you'll see that the surface is very smooth and straight for a gentle interface with the soft tissue.

So what that means is there's no pockets or anything created that where bacteria or anything can occur. So that's really important 'cause it helps with reducing those post-surgical complications of a possibility of an infection. So the MIPS procedure is extremely simple. There are actually six steps and I've highlighted them here. You're gonna prepare the site, you're going to do a punching and inserting with a cannula so there's a biopsy punch. You're gonna do the initial drilling with a cannular guide drill. Then, there's a widening drill. You'll do the implant installation and then attach the healing cap and dressing. So in these six steps, it really is that simple to do and done

very quickly, either in an operating room, a surgical suite, it can be done under local anesthetic, so there are options.

If you'd like to learn more about the MIPS procedure we have other courses available on Audiology Online that speak to this, but just so you understand the procedure is minimally invasive for your patients. So I think as you're counseling patients through this process, it's really important just to highlight how minimal it is and how little aftercare is needed. So on that note, it's always important to talk about safe outcomes for your patients and I think that one of the things that we've done to design our system to make it as safe as possible so that the technology that we've designed and the procedure of the MIPS kind of go hand in hand. So we have these more stable implants that we've developed with longer abutments in a variety of lengths to accommodate different skin thicknesses, and using these less invasive techniques really supports better patient benefit and safer outcomes, and even at times, earlier activations can be possible because of how quickly the implant stabilizes in the bone.

And so some of the studies that we have looked at that really support safe outcomes are we've done some quality of life studies, and this is a paper that was published in 2020 that looked at five studies evaluating 176 patients with either a conductive, mixed, or single-sided deafness, and they administered the Glasgow benefit inventory, which is a health-related quality of life questionnaire. And the results indicated that 98% of our users reported an improvement in their quality of life after a Ponto surgery. And so that's a really strong statement to say that patients are really seeing a significant improvement in their overall quality of life with the Ponto System. And not only that, but when we looked at this data and we compared it to other types of implants and surgeries that are done such as a cochlear implant or other types of middle ear implants, we actually found that the improvement was larger than what we see with middle ear implants, and almost as large as what we see for cochlear implants.

And so the mean score for a middle ear reconstructive surgery was 17, and for a cochlear implant was 38, and the Ponto surgery had a mean score of 33. And so I think that that's a really important finding is that we're seeing that with the MIPS procedure and the results that we're seeing with our advanced sound processing, that patients are seeing a significant improvement in their quality of life, and it's comparable to what they see with a cochlear implant. Now from a surgical perspective, what we see is out of the 27 studies and more than 1,100 patients that were peer reviewed, and this is unbiased data, that we revealed that in 90% of the follow up visits there was no treatment required for any skin related issues with our Ponto percutaneous device.

And this also is really important and yet another element to counsel patients on. And then another big concern regarding the recommendation of a percutaneous device is always the implant survival. How long will it survive? And what we also saw in a systematic literature review that included traumatic losses, that we reported an overall 98% survival rate, which again, just shows you that this implant is designed very well, it's very stable, and we have this huge survival rate that we see based on unbiased peer reviewed literature over 10 years time. So with regard to safe outcomes, we've talked about the improvement in quality of life, though the fact that we're not seeing a huge issue with aftercare needs with regard to skin irritations or treatments and that the implant is strong and sturdy, and we have a very good survival rate.

One of the things that we wanted to give patients was the ability to monitor their device, to empower our patients to monitor their device over time. And I think it's particularly important that we created this app, the Ponto Care app and specifically, the aftercare section of it, so that patients could, especially if they weren't able to get into their provider because of the pandemic or because of things that have occurred this past year, that they could take a picture of their site shortly after surgery and then have it available as a baseline and monitor that over time to make sure that there's nothing

changing about the site, that the site is still healthy, everything looks good, but if there are any changes, that they're able to monitor it themselves and send this information into their health care provider.

And so that's some of the uniqueness of the Ponto Care app. And so if you're not using it with your patients, I would really encourage you to start counseling your patients to download this app during the trial process and then after they get the implants. And again, there's those two sections. So you can see here that there's a trial section that really allows them to rate their experience as they're trialing the sound processor on a test band or a soft band, and then after they receive the device, there's a whole section after they get the implant. There's a whole section that allows them to follow their aftercare. It discusses how to live with the device, how to clean the device, all of that is located in there.

There's no login required, the information that is obtained within the app is only on the patient's phone, it's never sent on further so it actually adheres to the highest privacy standards. It's developed with all age groups in mind and it's free for everyone. And so really the benefits to the patient is it provides them that guidance and engagement during the trial process and then it gives them the opportunity afterwards, after they've had the implant to self-monitor their implant site, as well as their hearing. There's a diary in there and they can monitor the different sounds that they're hearing and what they think of those sounds, and it helps the professional by providing a better way for them to engage with their patients, it can assist them with patient management and counseling, and so as they're coming in for their post-trial visits, they have a structured approach because they have this information at hand that they can talk to their patient with.

So again, if you haven't taken a look at the Ponto Care app, I encourage you to take a moment to download it and review the benefits that you find and discuss it with your

patients. And so the last part of the section is to really look at the clinical evidence that's out there that supports direct sound transmission for your patients. And so I'm gonna show you three separate studies. And so I think the first thing to think about is that the choice of a system and a sound processor will impact the user's everyday life in fundamental ways. And so the choice of which system you do will affect how fast a child will learn and it will have an impact on the ability of the recipient to remember information.

And the choice of sound processor will impact the level of effort needed to understand speech. And so these are some critical studies that I'm gonna show you that support these two statements. And so, as we've talked about in the beginning of this presentation is that we use brain hearing as our guiding star, and we strive to develop products that make it easy as possible for the brain to make sense of sound. And so with the Ponto System, we want to have more cognitive resources available so that they can be used for understanding, remembering, and enjoying life. And so the first study that I'll show you is one that really is done on children and it looked at the effects of children using the Ponto device on a soft band versus an abutment, and the investigator was Andrea Pittman.

And what she found is that children learned faster by having that direct sound transmission solution that we see with an abutment and an implant. And so I have a very short video clip of her describing her study and the results that she found.

- If we can give children a clearer, more comprehensive signal, they can learn much faster. Our most recent study was with the Ponto, which is a bone-anchored hearing system, and we configured it into different configurations. One was where it was attached in a skin drive configuration, so the child wore it on a soft band, and then in a direct drive, sort of a direct sound transmission configuration where they wore it on their own implanted abutment. We tested each of them with four different tasks and

what we find to be the most interesting task is our word learning task. And in this task, we ask children to associate a word they've not heard before, it's a word we make up, with a nonsense image.

So they have to learn several of these at the same time through a process of trial and error, but they're given reinforcement for each correct response. When we analyzed the results, we found that when the device on the soft band was activated, the children needed many, many more trials to learn the six words that we had them learn. It was about 166 trials, but when they were using the direct drive device, they only needed 60. So that's more than two-and-a-half times faster learning. The data suggests that they will do quite a bit better with the direct drive device because they're getting that clearer, more comprehensive signal. The results are helpful to clinicians because they can give this sort of information to parents who are trying to decide whether having the abutment surgery is going to be worthwhile for their child, and our data suggests that it would be.

- [Carissa] And so just to summarize that this study was really one of the first of its kind that looked at the difference between the direct sound transmission on a child using both as a comparison to that skin solution. And again, what we saw was that children learn those new words two-and-a-half times faster using the direct sound transmission, and I think that as you're working with parents, this is information that's really critical because if we think of children as they're developing speech and language, how important it is for them to have access to that sound information. It's really critical. And so this second study is done with adults and it's set up in a very similar format, and this is a colleague Thomas Lunner, and he will actually describe how the study was done, but again, he used 16 adult participants and they had either a conductive or mixed hearing loss, again, he fit them with the Ponto on a soft band, and then their own direct drive, and he did a memory recall task.

And he'll describe that where they heard seven sentences and they had to remember the last word of each sentence. And so let's take a look at this video.

- The sound quality of the device is very important. It's important for the brain because if you have a high quality sound presented to the brain, you remember more. So in this study, we wanted to compare direct sound transmission with skin drive and we used the same Ponto device. The idea was that if you're getting distortions with the skin drive solution, then you probably have to devote more working memory just to the processing to get the sounds. Then you will have less memory resources. In that situation, they had to do this word test. As you listen to daily life sentences, then you have to repeat the last word in the sentence, not just to repeat, you have to remember it too.

The results were that with the skin drive solution they remember 46% of the words but in the direct sound transmission solution, they remember 52% of the words. So the relative improvement with the direct sound transmission was 13% and there was a significant difference. So actually, you remember more with direct sound transmission.

- [Carissa] So again, this just highlights the summary of the data that he found, which was a 13% relative improvement in recall performance with direct sound transmission. So what that means is that there are fewer resources needed to process that signal and more resources can be used for remembering. And I think that's really critical for adults and a consideration that needs to be shared with them as they're going through this process of deciding on which device or which solution to choose. And our last study looks at some really unique clinical evidence on less listening effort. And this is using a task called pupil dilation or pupillometry, on where it's actually measuring how hard the user is working to listen to that sound.

And so the investigator is an employee of Oticon Medical, her name is Federica Bianchi, and she looked at 21 adults with, again, a mixed or conductive hearing loss. And the conditions that she used, she used three different types of sound processors and she wants to really evaluate how important is the amount of output that a sound processor provides to the patient's overall understanding of sound? And so let's look and see how this study was done.

- We know that all bone-anchored hearing systems, they have a maximum force output they can transmit. When the input sound level plus the amplification reaches this maximum output, the sound gets distorted.

- Listening to speech with a device that has a higher maximum force output can reduce the listening effort. In other words, the allocation of mental resources that are required in order to process speech can be reduced when listening to a less distorted speech signal.

- [Federica] In this study, we wanted to see how much extra effort it is to for the brain to process such a distorted sound.

- [Dorothea] The participants performed a speech and noise test. Their task was to listen to speech and noise, retain for three seconds, and repeat back afterwards. With an eye tracking camera, we then recorded their pupil dilation as an indicator of their listening effort.

- We used the Ponto Pro, which has a low maximum output, then we use the Ponto 3, which has a higher maximum output, and then the Ponto 3 SuperPower, which has a very high maximum output. This pitch level was individually adjusted to reach the maximum output of the Ponto Pro, but not the maximum output of the Ponto 3 SuperPower. This means that we were comparing listening effort with a device where

speech would be distorted and a device where the sound would not be distorted. The results showed that there was a significantly lower effort when using the Ponto 3 and the Ponto 3 SuperPower as compared to the Ponto Pro as indicated by overall pupil size. In particular, there was a significant reduction in pupil dilation by 38% with the Ponto 3 as compared to the Ponto Pro, and by 50% with the Ponto 3 SuperPower, as compared to the Ponto Pro.

By using the Ponto 3 SuperPower, which has a higher maximum force output, we can reproduce a larger variety of input sound levels more naturally, and the brain requires significantly less effort to process the sounds. So we need less resources every day to process and understand speech.

- [Carissa] Again, I think that this also is one of those key studies that looks at using an objective measure, such as pupillometry to see what type of listening effort is exerted to understand speech, and in this situation, by having that extra amount of power needed, especially for a mixed conductive hearing loss, the Ponto 3 SuperPower as they indicated, is the most powerful sound processor on the market. This is also a really important distinction when counseling patients through this process. And then finally, I have a pediatric case study and then this is just one case study that was done that I'm gonna show you, but before I do that, I just wanna talk about the overall importance of providing early amplification.

And if we think about children and the age at which we fit children, and how important and how predictive it is for speech perception, speech production, and spoken language skills, you know some of the data is two to three of every 1,000 children in the United States are born with a detectable hearing loss in either one or both ears. A child who has a unilateral hearing loss is typically not identified until they're five or six years old. By the first grade, roughly 5% of children have a noticeable speech disorder. So this is important also if you think about children, 22 to 35%, there's a 22 to 35%

rate of failing one grade in school due to a unilateral hearing loss. So again, if we think about kids, not only with a mixed or conductive hearing loss, but these kids with a single-sided deafness or a unilateral hearing loss, it's really important to consider providing amplification at a very early age, especially as that auditory system is developing.

And so this is a case study that was done in 2008 that looked at the importance of a timely transition to that direct sound. And so what you see here, and I'll just point it out again, one child, he was fit at a few months old on a soft band and we saw a really nice increase in the child's receptive language abilities after that initial fitting on a soft band. So you can see that here. And then what we saw, that he started to plateau as he got older. And we sometimes see that with children with hearing loss, is as they get used to this transmission of sound through a skin drive solution, through a skin solution, he started to plateau a little bit.

And then at the age of four, he was implanted with a Ponto device, a Ponto implant, and what we saw is this acceleration of his receptive language. And so that's really exciting to see and really helpful for parents to understand that it's not just enough to fit them with that soft band solution, but when the time is right that there is enough evidence out there to show that there is a really strong correlation and advantage with a direct sound transmission solution. So it's important to use this information as you're counseling patients. So just for a summary for pediatric is children need to wear hearing solution which has high maximum audibility, especially in those higher frequencies in order to facilitate word learning.

The solution that we provide to them, we talked about wearing comfort and the importance that it's worn all day to develop language and communication skills, especially in school and during social activities, and you want a device that's not easily lost. We know that when it's on that abutment that it's on there very well. It's not gonna

fall off, especially as children are very active, lead very active and busy lives. Prior to surgery, soft band really is the only choice and that's normal. We wanna fit them as soon as possible on that soft band device, but when the audiologist and surgeon feel it's ready to transition, that we transition to that direct drive solution because it does provide the best access to those high-frequencies.

So hopefully this clinical evidence provided you some additional information to help as you counsel patients through this transition from a soft band or a test band as is the case within adults, to that direct sound transmission solution by getting the implant. So we're seeing that children learn faster, that adults remember more, and that we're seeing less listening effort used by having a device that provides the most power for their hearing loss. And so to summarize, the Ponto System uses direct sound transmission and allows for the most efficient transmission of speech and sounds via that skull bone directly to the cochlea, without that skin dampening. With the most abutment level sound processor available on the market, we can provide access to a larger range of everyday sounds with less distortion, which is really important when we think about less listening effort in promoting overall brain hearing.

So some of the takeaways of today's session is direct sound transmission delivers the optimum sound quality so it really is the gold standard of care. It increases sound quality, it leads to a reduction in listening effort, and this is especially important for our pediatric population, especially as they're developing language. It's critical. There's a wide array of considerations to take into account that patients may be aware of, and I think there are a lot of misconceptions out there that they may hold as they come into your clinic or as they're having these conversations, and it's important to understand what they're hearing and what their concerns are, but also to counsel them on really what the long-term benefits are of a direct sound solution.

So we want patients to make an informed decision whichever device they choose, and we believe that this can only be done with providing them with the correct information. So hopefully today's discussion gave you enough information that if you're not presently counseling on some of these items, that you start counseling. If you'd like additional resources, or maybe some of the counseling cards that I talked about, please reach out to your clinical specialists. I know they'd be more than happy to provide you with this information so that you have everything that you need when you're counseling patients towards this transition from a skin solution to a direct sound transmission solution. So on that note, I am at the top of the hour and I don't see any questions, so you guys are free to go ahead and have a wonderful rest of your day.

Also in your handout are all the references and studies that I spoke to so you have those available if you'd like to go back and take a deeper look at them.