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Path to Ponto: Modern Surgery and Counseling Techniques

Recorded March 29, 2023

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- Great, Melissa, thank you so much and welcome everyone to the Path to Ponto: Modern Surgery and Counseling Techniques presentation. We are thrilled to see such a good turnout today, and we are glad to have you joining us. I have the honor of introducing you to two extraordinary men who are pioneering the bone-anchored hearing space. Dr. Coelho currently serves as the director of otologic and neurologic skill-based surgery at Virginia Commonwealth University. He also serves as a professor educating the next generation of Neuro-otologists. Dr. Coelho has a passion for implantable hearing devices and works diligently to provide exceptional care to both pediatric and adult patients. Daniel Lee is the audiology clinical support and business manager for Canada with Oticon Medical.

He specializes in supporting patients and Audiologists as they navigate through the candidacy process for bone-anchored hearing systems. We're so glad to have them presenting today. Before I hand it over to your presenters for today, please allow me to move through today's agenda. As with many clinics, the Audiologist is oftentimes the first person to initiate the counseling around bone-anchored hearing systems. Therefore, today's talk will begin with some modern counseling techniques and information that you can use to support your conversations with candidates as they prepare for their discussion with their surgeon. We will then move towards some Ponto-specific counseling tools. And finally, Dr. Coelho will discuss minimally invasive procedures including his personal experiences using these procedures and how he counsels patients in his own practice.

He also has some excellent pictures of a full surgery to share with us today. So if that's something that makes you a little bit uncomfortable, just beware that you'll be seeing some great photos today. They're very appropriate and they're not too gory, so don't be too worried. By the end of today's course, it is our hope that you'll be able to determine which sound processor will be the most appropriate choice for your patient, while also helping them to understand how a minimally invasive procedure can benefit

them. And we also hope that you'll have a better understanding of why you would choose a percutaneous implant over a transcutaneous device. And we do have some financial disclosures before we get started today.

Daniel Lee is a paid employee of Oticon Medical and Dr. Coelho has received minimal financial incentive for supporting Oticon Medical research and for his participation in today's presentation. There are no non-financial disclosures. So without further ado, please allow me to introduce you to Daniel Lee as he presents on modern counseling techniques in the Ponto system. Go ahead, Daniel.

- Great, thank you Alicia. So today I get the honor of starting things off by walking through some of the counseling strategies that we as clinicians can use when it comes to introducing patients to the bone-anchored hearing systems. So here, if you're attending the webinar today, it probably means that you've worked with or intend to work with bone conduction hearing aids in your practice. We know that with bone conduction hearing aids, they present a very promising solution for the appropriate candidates as an alternative traditional hearing aids or reconstructive surgeries. The dilemma that we have, that we're at odds with here is that, despite their great outcomes, we do have a high dropout rate for bone conduction devices, even when we have the appropriate candidates in front of us.

So in order to look at this issue, a study was conducted by the Ear Foundation in the UK and it helped to provide some insights which we've used to guide today's conversation on the counseling process. When we look at the higher dropout rates, the main concerns that were commonly involved things around surgery, concerns around surgery, cosmetics, and overall low perception of benefits. What was found was that all patients said that they would reconsider if they had access to some of these factors that we've listed out on the slide here. So that includes more discussion, more written information, more contact with other participants and recipients, and most importantly,

a trial period. So when we look at that and we look at what was reported from patients that did proceed with surgery, this is how we know that preoperative counseling, the preoperative counseling piece is so important and it's what we want to focus on today.

The goal really is to help more patients make an informed choice and proceed with bone-anchored hearing systems. So starting with the basics here, a quick overview of the air conduction hearing can really help to support your discussions with patients. Sometimes something short and sweet can make a huge difference. So what I have here is just a video from the National Institute of Health that does an excellent job of explaining the normal hearing pathway. You can use this presentation during counseling sessions and when you do that, it can provide patients with tangible information and can often shorten appointment times. Alternatively, these video links can be shared with the patients afterwards, can be emailed to them and they can watch them at home or share them with family.

So I'll just play you a quick ten second snippet of this just so you have an idea of what we're looking at here. Okay, I'll stop it there. So I think you get the idea. The idea is to have something really accessible, something simple, something that is really easily understood by patients, and it's great to have these sort resources around and I'm sure that a number of you already have different ways of counseling the hearing pathway. But again, it's a great way to start the conversation here. In particular, you may likely need to help patients differentiate their hearing loss from your typical presbycusis or noise-induced hearing loss. So oftentimes when it comes to bone-anchored candidates, we'll be focusing on middle ear mechanisms as it relates to your patients' particular pathology.

For bone-anchored hearing candidates, it's also worthwhile to explore the type of hearing loss and their history of hearing loss, even if they've had it for a long time. And this is not only to build on the rapport with your patient and demonstrate your own

competency, but it also allows your patient to describe to you their understanding of their hearing loss. And it's helpful in identifying opportunities for additional education or gaps in understanding. So for example, if you do have bone-anchored candidates that come to you because of history of failed middle ear surgeries, for example, you take this knowledge and you may adjust your counseling to help patient understand the difference between what a bone-anchored implant is versus a more invasive middle ear reconstructive surgery, which they may have had in the past or a number of times in the past.

So you can use that information to really adjust how you wanna approach your patient. When we look at the key findings in the previous questionnaire that we talked about in the Ear Foundation, it suggests that there is a particular emphasis on the need to convey information in a plain and easy to understand language, as well as incorporating the use of visual aids to help clients with potentially lower literacy skills. In that sense, we offer a wide repertoire of printed materials that can be used throughout the counseling process, including one of my personal favorites, a comprehensive counseling binder that we have imaged here that walks through different stages of the counseling process. And you can also order different printed materials that can be provided to patients for them to take home and read on their own time and reflect on.

These become more useful as we begin to introduce the concept of a bone-anchored hearing system, how it works and what devices are involved in addition to how they may differ from traditional amplification offers that options that they may have been offered in the past. So with device education, I think we can appreciate that most new patients may have a limited understanding on how hearing works, let alone maybe how a bone-anchored hearing system functions. With the whole internet at their fingertips, it can be really easy for patients to mistake a bone-anchored hearing system for something for other implants like a cochlear implant for example. Or some patients

may have the misunderstanding that this is another fix all if their current hearing aid isn't working out.

Identifying and understanding who might be a good candidate can be straightforward for experienced clinicians, but it's worthwhile to explain and share why a device like a Ponto may be a better fit for a patient than a traditional hearing aid or a transcutaneous device or even a cochlear implant if that's the case. Again, if they are the appropriate candidate. So when we look at how a bone-anchored hearing system works, we have a lot of different ways of modeling that or explaining that. So for for us in the way to explain it to patients, a bone-anchored hearing aid is very different from a regular hearing aid. So here we can review the different parts of a bone-anchored hearing system, which is essentially a non-conventional form of application used to treat hearing loss through bone conduction.

Bone conduction hearing aid can be surgical or non-surgically implanted. A bone-anchored hearing device is recommended to patients typically who are unable to use a standard aid because it isn't appropriate. At the heart of it all, bone conduction hearing aid operates in a similar pathway illustrated here where sounds are converted to vibrations, which are then transmitted to the cochlea in the inner years. Helping patients to understand the different parts of a Ponto system helps you to use some shared language when you're engaging in discussions as well. So every Ponto system has these three core components and it's good to explain and show your patients what we're looking at here. So starting from the right there you'll see that three components are comprised of the titanium implant on the far right here.

We have the external abutment in the middle, and then you also have the sound processor on the left. Percutaneous bone hearing systems like the Ponto take advantage of a natural process called osseointegration. So essentially the skull bone itself begins to grow onto the embedded implant, creating a strong physical connection

between them and it establishes a direct route for sound transmission. This picture here is a close up of the osseointegration of bone into the titanium implant. As you can see, the bone fibers are starting to grow into the implant itself. A common question that's asked is how stable are these implants and whether or not patients should worry about knocking the implant loose. It would help to understand this part of the process because when we look at the unique surface design of the Ponto implant, our studies have shown that the areas of the bone bonding to the ajax implant is in fact stronger than the bone itself.

So when we look at the performance of the Ponto system over the last 10 years, the overall implant survival rate is over 98%. This is also a good opportunity to address some of the cosmetic aspects of the abutment and it's a good opportunity to introduce some information about the dimension of these different components involved. So for example, when we talk about what's implanted in the skull, the implant itself is this portion right here and you can see that it's often only up to about four millimeters in length. When we look at the single stage implants shown in a lot of literature, it's shown with the abutment piece here. The length of the abutment itself depends on how thick the soft tissue layer is above the skull.

The abutment itself is not fused with the skull and can in fact be changed out in simple clinical procedures if a longer or shorter length is required down the road. Moreover, when we look at the cosmetic piece of bone-anchored devices, only the top portion of the abutment here is above the skin, which often leaves a lower profile than what many patients initially imagined when they see pictures of the implant and the apartment together in literature. Now at the point where you feel like you've provided a fairly full picture and description of what a bone conduction system is like and how it may benefit your patient, it's time to ask if they would like to experience for themselves.

So from the data that we talked about at the beginning, one of the most critical pieces to helping a patient move from the counseling process to an actual implantation is the opportunity to pursue a trial. And it's one of the most important factors that we can assist with. So when we look at the importance of a trial period, some of the things that we pull out or that we conclude is it's patients are more likely to proceed when they've done a trial. Patients often feel report to be more confident with controls, so they're more used to the device and using the device. They overall had less concerns about having the device and wearing the device and they had more importantly, more realistic expectations.

So this is where we talked a little bit more about the benefits that they experienced themselves as opposed to what we tell them. And this is probably unsurprising if you do work with hearing aids, demos are not necessarily something new in the hearing aid space. But if we stop for a moment, it really is wonderful thought that patients have the opportunity to experience, you know, to a certain degree how an implant will improve their function without actually having to go through the surgery first. So this is not something we necessarily see when you do laser eye surgery or hip surgery for example. So it's really great that we take advantage of this ability here to demo a bone-anchored device.

Oftentimes the length and type of trial periods can be adjusted to the client in the clinical setting that you're using and that you're in. So some of that depends on the different trial options that you opt to go with. So many of you may already know about the soft band here. So that's probably our most common option when it comes to demoing or trialing a Ponto device. And it tends to be more comfortable if you are sending patients out with a device to trial this at home. So if you're doing a week, a two week trial with the Ponto device, this tends to be the most comfortable option for new users. We also have the headband and test band options as well.

These typically are, can be used for in-clinic demos, but at the same time we do have patients that may prefer the headband to the soft band just because they may be a little bit more discreet. Some patients prefer the tension of these headbands or test bands, so they can be used accordingly as well. When we look at this test rod option here, again, depending on the center and how many resources you have, sometimes clinics will do a really quick trial with the test rod on the patient just for a few minutes just for the patient to experience the demo and then understand whether or not they would like to proceed with the longer demo at that point.

With any of these choices, if you choose to do an in-clinic demo, you can always combine that with other strategies that sound field testing or if you want to take your patients out of the clinic into the hallway for more real world experiences. Those are all great options when it comes to trialing the Ponto. Now in combination with the demo period, it's important to have some sort of outcome measure when you're doing that and a lot of you may already have a standard outcome measure tool that you use for hearing aids, which you can easily apply to Ponto as well. Some of the tools that we can offer include the Ponto Trial Companion app. So what this is is it's essentially a diary that a patient has access to on their phone, and they're able to log and make notes of different situations while they are conducting their trial with the Ponto device.

At the end of the different ratings, they can compile those ratings and email a report to you as their clinician so you have an idea of what they've been experiencing. Other options, as I mentioned previously, include sound field testing, aided/unaided sound field testing to really demonstrate the benefits of the device and document this as well for further referral. When it comes to patient resources, we mentioned earlier too that individuals often find that being able to reach out to other users, other individuals that have been implanted or are using Ponto system is an invaluable experience. In that regards, we do have something called Oticon Medical Friends. So this is a nice network to introduce patients to where they can join and connect with other Ponto

users that may help with the peer interaction and to help answer any questions that patients may have for them as well.

We also have access to different clinical materials. So for clinicians that are just beginning to work with Ponto or bone-anchored devices, it's really important to have a good grasp on candidacy and fitting guides. So we have these guides here which are fairly detailed in that you have access to as well, both on the candidacy cast side and the fitted side of things. So switching gears here, once you've arrived to the point where your patient is ready to pursue a trial with bone-anchored device, this is the prime opportunity to introduce them to the newest technology in the bone-anchored space, which is our Ponto 5 family. So from here we're gonna dive into more of the Ponto 5 family, which I'm really proud of because of the way it's taken the audiology world by storm.

So let's start with our standard level processor, which is the Ponto 5 MINI and true to its name, it currently holds the title of one of the smallest button level processors on the market. Highlighted here are some of the innovative features that come with the Ponto 5 family afforded by the industry changing Velox S platform and the group commitment to brain hearing technology. Because of its size, the Ponto 5 MINI really helps to address patients that may have concerns over the size or discreetness of their processor. When looking at candidacy for the Ponto 5 MNI, we are looking at bone conduction thresholds of up to 45 dB HL. And when we're looking at this, we're taking the average of bone conduction thresholds at 500, 1,000, 2,000 and 3,000 hertz.

Do keep in mind that this 45 dB fitting range is meant to be, is meant for implanted patients. If you're looking to trial with a soft band, then the patient should at least have a normal looking bone line, otherwise you may want to look at a superpower device to provide a better idea of what the audibility will be like post implantation. And with that being said, we do have a completely new Ponto 5 SuperPower, which was recently

released last year. The Ponto 5 SuperPower is the strongest abutment level one processor on the market and provides patients with the most odd ability and and greatest dynamic range. With the Ponto 5 SuperPower, it was redesigned to be more robust and reliable while maintaining a sleek and modern design.

So some of the list of features that you see here include non-size specific design, so you're able to program right left independently, you're able to have access to LED indicator lights. You also have an additional program volume and mute button right at the user's fingertip. As you would expect, Ponto 5 SuperPower does have a higher rate fitting range of up to 65 dB. And when you're looking at these average bone conduction thresholds, we're using the same frequencies that we used earlier. So we talked a little bit about the hardware for the Ponto 5 SuperPower. Let's talk a little bit about the improvements in gain. So when we look at the Ponto 5 SuperPower, it is proven to provide more gain compared to the Ponto 3 SuperPower.

So the graph here only shows how the Ponto 5 SuperPower strongly help outperforms the Ponto 3 SuperPower. Especially when we look at the 2,000 to 10,000 frequency region. As we all know, more access to high frequency allow for better speech intelligibility. The improved feedback management via OpenSound Optimizer also allows us to access more usable gain in the fitting software that is traditionally being restricted due to feedback limits. Moreover, the additional gain that we're able to access is gonna be more stable and less susceptible to artifact that you might experience when approaching feedback limits traditionally because of this phenomenally fast processing of the OpenSound Optimizer feature feature, In addition to providing more audibility through better access to gain, the Ponto 5 family has improved signal processing technologies through the combination of OpenSound Navigator and OpenSound Optimizer.

So how does OpenSound Navigator and OpenSound Optimizer work together? This is a simple illustration here that really helps show what each of these features do. So in the orange, we were comparing a device using OpenSound Navigator versus a competitor device that is not. On the right here, you can see that in a noisy environment here, OpenSound Navigator is helping to reduce the noise and preserve speech and that is in this orange signal here. At this point in the middle here, we start to introduce a sudden dynamic feedback risk here. So we're putting bone to the ear and right there, the easiest way to see the difference with OpenSound Optimizer in effect here is right at the four second mark.

Here you can see with the gray signal with the non OpenSound Optimizer device that the speech signal has been suppressed in certain areas. So there's gain reduction applied. Whereas with OpenSound Optimizer active, it's preserved that speech in this area here. In both cases, feedback is controlled, but with the advantage of OpenSound Optimizer, this is done without reducing the gain that we expect from this signal. And that's where we get an additional 6 dB of additional stable gain for the Ponto 5 MINI and then additional 5 dB stable gain for the Ponto 5 SuperPower. Together, they allow more access to sound into wider range of scenarios. So once you've had a successful trial and have confirmed the benefits of the Ponto with the patient, how do we move on to counseling about the need for surgery?

And while there are many, many different topics of discussion when it comes to counseling on bone-anchor hearing systems, questions related to the implantation process are often the most common. This is keeping with the theme of today's presentation because we really wanted to put more focus on the implantation process and explore potentially what other considerations you may want to look at when you're discussing this option with your patients in helping them in that decision making process. So one of the more common questions that might come up post trial is really, do I even need to go through the implant if I'm functioning fine with a soft band or the

headband? And you may hear this a little bit more from patients that are potentially more adverse to surgical options.

So from here as audiologists, we can focus on more the audiological advantages of implantation. So just here displayed here, we can see that when we use a soft band system, extra gain is required to overcome the attenuation from skin and soft tissue. When we have to direct access to the bone, we don't have to pass through the skin, and we get a better representation of the signal and better clarity. In particular, when you look at these mid to high frequencies, we can see an improvement that almost equates to about a 20 dB improvement in sound transmission when we use a direct sound transmission system versus a bone-anchored device on a soft band. Another way to look at this visually to help with clients is with this illustration here.

So essentially you can see there's more power with direct sound transmission and there's more stimulation of the cochlea that's allowed through which transfers to better patient performance essentially. Not discussed here, but well established as well. Other benefits of direct bone transmission includes improvements in aided thresholds and speech perception testing, better sound quality and performance, increased learning speed and enhanced working memory. Of course we talked about the the high frequency emphasis as well just in the last slide there. So these are all points that you can bring up with patients to really support that move to implantation. Moving on, other factors to consider may be related to, again, the actual size of the implant. As we discussed earlier, there are many, many different types of implanted bone conduction devices, but in this case, when this question of size comes up and when patients need to consider what's being implanted in their skull, this slide here gives you a reference for what the relative implant footprint is for the different devices available on the market.

So when we look at the surgical footprint for the percutaneous Ponto implants here, the implant footprint is actually considerably smaller than a lot of its non-percutaneous counterparts. Moreover, as we discuss the Ponto system further, it's important that we address artifacts seen on MRIs that can be caused by implantable devices. We know how important MRIs are in making diagnostic decisions and the amount of artifact on an MRI is something critical to consider if your patient has an involved medical history that may require imaging of the head. So when we look at the size of the artifact, this can be the difference between diagnosing something like an acoustic neuro or monitoring an acoustic neuro or missing one.

So this is one of the reasons why we've made sure that the Ponto is small. In fact, when we look at a comparison of the Ponto implant with other implants, it yields the least prominent artifact on an MRI compared to all the other options on the market. And so you can see here the Ponto being this flashing circle just right in the middle there and it comes in the smallest, a 1.5 centimeter shadow there. So in summary, we do believe that the Ponto system is a future-proof system for the reasons we discussed. It's a small system in its own right, it's non-restrictive because it can be easily removed and it's always been a universal system because it's always been compatible with other available percutaneous sound processors.

And in our opinion, it is really the competent choice for your patients. So at this point in time, I'm gonna go ahead and pass the presentation onto Dr. Coelho. And again, just a disclaimer for those of you who who may find be a little bit more squeamish, we do have some really great surgical photos coming up, but just be aware that they're coming up. All right, off to you, Dr. Coelho.

- They're not that bad. They're not that bad. Hi everybody, good afternoon or good morning, depending on where you are in the world or when you're watching this. Thank you Dan for teeing that up. So your patient has kind of already gone through all this

process and they're thinking about it and they wanna know what's about the surgery and a lot has changed over the course of the past, you know, well lots of change over the course of the last five years or so, but a lot has really changed over the course of the last 20. Remember, these bone conducting implants have been here at least in the US for over 20 years, but their adoption has only really been increasing over maybe the past five to 10 years.

I've done tons of these hundreds and hundreds and hundreds and even my surgical technique and practice have changed a bit over the years. And I will say that generally these are pretty satisfied patients for the right patient, for the right reasons. These are very satisfied patients. Very happy, they're pretty good bang for the buck in terms of the amount of work that the patient and we have to put in towards how much they enjoy it and how much it could be a game changer for them. One other additional benefit that I should mention is that a lot of these patients already have alternative but suboptimal hearing options that they're using. Be they hearing aids, you know, in the ear, behind the ear, you know, any different ones.

And for a lot of people special with chronic ear issues, freeing up that ear canal is pretty nice to not being able to have something inside that ear canal. Not to mention that, you know, with glasses and masks and everything, it gets to be a lot of things on the Oracle. So to have an off the ear option is pretty great for people. So it's a real boom for me and my patients. And there's some people, and I like to think I'm a decent surgeon, but there's some patients who just can't get them to where they need to go. Certainly with the conductive and the mixed hearing losses, this with this severe sensory neuro hearing loss and with single side of deafness, then we find these to be patients are pretty satisfied.

We offer them all options. But lemme talk a little bit about surgical counseling and the techniques and where we go from here. So as I mentioned, a fair amount has changed

over the course of the past 20 years. This used to be kind of the, I don't know, it wasn't something that we as surgeons we really looked forward to. They were kind of ugly surgeries and they were, they kind of violated all the principles of surgery, of tissue respect. One of the primary and overarching themes in surgery is respect for the soft tissue. The more you mess with it, the more you hack it up, the more it's gonna look terrible, the worse it's gonna heal. So you have to be gentle.

But when you had these kind of small implants in the early days 20 years ago and 15 years ago of these implants, there was a lot of skin thinning, a lot of skin grafts. So eventually, first it was a one stage, two stage where you'd put in the implant and then you'd come back sometimes three to six months later. It's a very long process for patients. They didn't wanna have to wait that long to start hearing. Most of the time, with the exception of maybe real small kids we're doing one stage, which means the implant and the abutment are being put in all the same exact time. But even still, when you're doing that all in one stage, there are skin grafts and there were that you have to make, you know, I can show you pictures, I think I've got some, and when it goes wrong, it goes pretty horribly wrong.

Even when it went right, it still wasn't great. So surgeons didn't like doing these procedures. Patients loved the sound outcomes, but they didn't love the problems that they had afterwards. And cosmetically, it wasn't great. So eventually they kind of made it to other different types of techniques and some of us in the field kind of saying, well, we can go more minimally invasive and just do a linear incision without having to do a big skin flap and kind of thin out the skin. And then we got to the point maybe about five or 10 years ago, where we said, well, what if you don't touch the skin at all? We just be very gentle, just put in a screw and essentially, which is essentially what it is.

And the reason that was able to do that, still don't have control of the slides. I don't think. oh wait, lemme go back one more. Oh, well, the reason we're able to do that is

because it turns out that the abutments can be made into different lengths. It used to be thought that if you had to have a very short abutment, which means the implant's about four millimeters long and the abutments were maybe about six millimeters long. So if your skin was more than 10 millimeters thick, which it is for a lot of people, then the abutment wasn't gonna peak through the skin. So you had to thin down the skin to make it so that the abutment would be prominent.

And the thought was it wouldn't be stable if you had a longer abutment. Well, some bright person said, well, let's try with longer abutments and let's make them and see how they do. And it turns out an eight millimeter button works fine, it's stable. So was a 10, so was a 12, so was a 14. I mean, you can't put a flagpole on it. People aren't gonna want that. But if you have people with thicker amount of skin, you don't have to do soft tissue reduction, then it becomes much quicker, much easier, and much less fraught with post-operative problems. So let's go to the next slide. I can't seem to advance here. Okay, so I had a nifty picture here of Pinocchio's Facebook.

You could check it on online, but I'm not allowed to use it for copyright reasons I guess. But there's a really cute picture on the internet of Pinocchio's Facebook pictures, and it's got, you know, him with it. You can't quite see the whole nose. So don't trust if every, you know, everybody will show your their surgical options and their surgical outcomes. And if everything looks completely perfect and normal all the time, then, then, you know, they're probably not telling the truth. And to get back to where I was before, these were tedious operations. You had to take out skin grafts, you had to thin it out. It was necrosis and suboptimal positioning. Anybody who's seen these from 10 years ago knows that these were not great.

And they really didn't do a service to the the field because patients who again would say, well, I like the way it sounds, but I don't love the way it looks and the way it feels. And there'd be numbness and there'd be discomfort and it would be kind of nasty. And

that's again, even when it's not acting up. So, sorry. I still can't advance the slides. So the, thank you. I don't know what's happening, but if you can just keep advancing it for me, that'd be great. So the, you know, an objective scale, the audiologic people were happy with that. Skin reactivity was not so great and the cosmetic outcomes were not so great. But subjectively patients loved it.

Their hearing related quality of life was great, but subjectively again, they didn't love their cosmetics. Next slide, please. So, oh good, here we go. So how did we overcome that? Well, we came up with longer abutments, right? Longer abutments, all can be placed at the same time. Again, it's just like putting a screw into drywall. As long as your screw is long enough, then you're okay. And Oticon Medical really were the pioneers in developing this. Prior to this I used just a punch, which is a skin dermatology punch. I'll show you what that is. But the folks at Oticon Medical took it one step further and made a little cannula to even protect the skin from the drill and from the other things.

Please remember though, that the size of the incision that we're making is tiny. These things are small. These are about four millimeters big, four millimeters deep in about four to five millimeters wide. That's super, super duper, duper tiny. That's less than like a quarter of an inch. So let's go through a little bit and talk about how having longer buttons really made the difference for us. Next slide, please. So this is our main operative tool. It is a literally a 75 cents dermatology biopsy punch. This is five because it's a five, it's five millimeters wide and basically just a bore of stainless steel metal that's sharp at the tip. And you basically just use it. Okay, next slide please.

So this is a patient with a mixed hearing loss. You could see she has a large medias on the right side. This is, she had a prior canal wall down multiple temps, ossicular chain reconstruction were unsuccessful. Next slide. There's lots of different ways to prep out these days. These are old slides, I apologize, but these days I do not shave nearly that

much hair. I'll shave maybe the size of my pinky nail and that's it. Next slide. The, you know, they'll tell you you wanna put the device far enough away from the oracle so that the actual processor doesn't bump into the oracle. You don't want to have that. Some people want it lower, some people want it higher.

The skin is definitely thinner higher. But some people wanna wear hats and some people don't want it that high. I actually prefer it a little higher rather than a little lower. When you put it a little lower, not only is the skin thickness a little higher, a little greater, but the muscles of the neck attached to the skull at this point, and the skull actually curves away a bit. So if you're sitting on a couch and you're like this and it's up over here, it's not so bad, but it's over here and there are pillows on your couch, you'll get a little more feedback. So my personal preference is to put it a little bit higher.

I haven't found any patients that mine, except for patients who wear hats. So actually have patients say to them, bring your hat with you on the day. Bring your favorite hat with you on the day of surgery. And in the pre-operative area, I'll measure it out and I'll say, okay, how about here? Does this work for you? And then that's great. Next slide, please. So we measure that. We just make a little mark with the marking pen to show where it's gonna be, that our permanent marker. And then go ahead. Then you numb up the patient. Most of these are done under local anesthesia. You can see this person is, you can't see, but it's just a oxygen tubing.

Technically, you really could do this in the office. Insurance tends not to cover it in the office, but it's pretty minimally invasive. I did one yesterday and the guy had zero anesthesia, just the local anesthesia. And this is Marcaine, it lasts for about seven to eight hours. So, but they're feeling fine. And by the time they go home, the pain starts wearing off in the mid-afternoon, take a few Tylenol, a few Motrin, and that's it. I won't get into the nitty gritty unless there's, I don't think this is primarily a surgical audience,

but there are some subtle pearls and tips that I can give for your surgeon if you're interested in about how to kind of avoid some problems here and there.

But you'll notice here I'm putting the Novocaine kind of around the area, but not actual in the actual area that I'm gonna do it, that numbs up the field, but it doesn't kind of distort the tissue directly where the implant's gonna go. Next slide please. So you'll, the kind of darker blue area is the area that I numb up and the lighter blue area is not as instilled with the numbing medicine. Okay, next please. Then we clean it up. You can use iodine, you can do soap. This is, you know, just basically some sterile sterile prep. Next please. And then we put on, I don't even use this anymore, this is probably overkill, but the fortunately the scalp is an exceedingly healthy part of the body.

Have you've ever gotten a cut of your scalp? You know, it bleeds a lot. What bleeding is good. If you have a lot of blood supply, that means it's a healthy area, means it's very unlikely to get infected and very unlikely for the skin to break down, provided you don't mess with the skin too much. So this is a little antibiotic sticker that I use to kind of keep the dressing in place. Next slide. And this is what it looks like. Then you put the rest of the drapes on and I drape up and over the patient. So the patient is fully able to breathe and wide open. It's like a tent and their side of the tent is wide open to the anesthesiologist.

They can have a conversation with the patient if their other ear hearing ear is pretty good, they can talk to me while I talk to them. Not a very long conversation. The whole thing takes about five minutes from this point forward. So this, you know, the draping and the prepping takes about two minutes, three minutes and then from here on, and it's about five minutes. So next slide. So this is where we're gonna make our little hole. Next slide. And here's our five millimeter. Goes to show you five centimeters up top, inches on the back. So here's one inch, you know, one inch is whited out, but it's about

half a centimeter. So next please. And then you basically just punch right through the skin and go right to the skull.

If you've ever felt yourself right over here, you'll feel that's hard. That's because there's not a lot of skin between here and the bone. Just a couple millimeters. Next slide please. And then you take off whatever remaining periosteum. Periosteum is the lining of the skull, but your skull is thick. You're definitely not gonna go through it with this instrument or any of the instruments. Next slide. Kind of clean it up a little bit. This picture, it's hard to tell, but that whiteness that you're looking at, right in the center of the hole, that's skull. Skull is white and there's a little bit of pink kind of soft tissue there, but that's all you need. Next slide.

There are a couple different ways to do it. Some people will use, and these comes with a guide drill. But you basically then do just like you're putting a screw into concrete or you're putting a screw into wall. You do a little socket, basically you do a first, a guide drill. So that's what the guide drill is. Go ahead, next. And that only goes in about three to four millimeters. You can see a little hole in the center of the bone there. Next one. And to give you an idea how small it is, you can see how my finger is, you know, compared to the size of the hole. Now here I'm coming in with the drill.

This is done on a very low RPMs, but with a high torque. And it's a self-tapping. It's a self-tapping complex. What you're looking at here is the white is the part that grabs onto the implant and the abutment, but here's the implant. It's the part that goes into the skull. And here's the abutment that goes into the implant, but through the skin. And that's the part that the processor couples onto. Dan had showed you in the beginning that there's really three parts to the processor, the abutment and the implant. But at surgery time, the implant and the abutment go in as one unit. And that's what you're looking at right now. So next slide, please.

And there it is. I had a video at some point, but it literally takes about 15 seconds of watching. It goes slowly and you watch it and it self taps and the drill, it's a special kind of a drill where it feels the tension, it feels the resistance. And when it hits a certain resistance, it stops. It won't over screw it, it won't cause the threads to, I forgot what it's called. When you strip, you know, won't strip anything. And it goes in and it stops. And you can then feel by hand to make sure that it's nice and tight. Next. So this is pretty much immediately at the end of the surgery. Now you'll notice that the implant is only about four, maybe four millimeters wide.

But the hole that we made was five millimeters wide. So you'll notice that there's a little gap just between the implant. There's a little hair going over it. Cause a little gap over there. That's okay, that's gonna close up. But notice that there's no incisions, there's no stitches, there's no skin graft, there's no nothing. Everything I just did from the time I used the punch until that took about five minutes to do. Now, I will say that for patients with single-sided deafness or significant biosensor hearing loss, it's not too weird or bothersome for them. For those people who've got normal bone conduction, but have a significant conductive hearing loss, this can be loud. The drill can be quite loud.

So you have to warn the patient if they're not sedated. Some people want to be sedated. You don't have to be. Some people, if they're not sedated, you gotta say, hey listen, I'm gonna warn you when the drill hits your skull, it's gonna be loud. And most people are totally fine with that. Some people, if you think they're gonna be a little squirrely and they're not gonna be happy with it, then we just give 'em some sedation just like in a colonoscopy and they're kind of out for the whole surgery. But absolutely no need for a breathing tube or anything like that. Now sometimes I will do the surgery in conjunction with another procedure where we're closing off the ear or we're taking out an acoustic neuroma or something like that.

We'll do all everything and the patient happens to be under general anesthesia just because of the other procedure, then fine, that's great. Then there's no issues at all. Next please. So this is a little dressing, I don't know, pictures are coming out a little funny, but this is a little dressing that I use sometimes it's a little sponge foam dressing. Next one. We punch a hole in the center and pop it on top. Next slide. That keeps the skin from swelling. And then we use a little cap. The cap now is kind of see through and clear, but that's pretty much it. And then I tell the patients that they need to keep this on for about five days.

It's probably overkill, but five days. The issue is if this is the implant and this is the skin, you don't want the skin to swell, everything's gonna swell. Just like if you, you know, hit your thumb in a car door, it's gonna swell a little bit. So after even a little surgery like this, the skin is gonna swell a little bit. We don't want the skin to come up and over the implant. Now you can measure the skin thickness prior to doing this. So you know exactly how long. Although it tends to correlate with patient size and weight or BMI to be more exact. It's not a perfect correlation. So I always measure the skin thickness prior to opening the implant that I wanna use.

Sometimes it's deceptively thin, sometimes it's deceptively thick. And you thought, oh gosh, this guy's gonna need a nine millimeter abutment. But turns out, oh wow, actually he needs a 14 millimeter abutment because the skin is much, much thicker than you think. But the dressing stays on for five days. Antibiotics don't make a difference. patients don't need to be on antibiotics. Don't know what that was. Patients don't need to be on antibiotics. And then at five days they just lift it off at home. If they're don't want to, you can see 'em in the office, you can take it off yourself, and they can shower after two days. That little area has closed off by about 48 hours. And you can shower, you can shampoo, and there's just kind of pat the dressing dry.

Next please. This is a year later where it just looks pretty good. The hair is grown up around. Next one. And I've got hundreds of these. Sometimes there's a little redness around it. You have to remember, even though this is made out of, you know, surgical grade titanium, which is pretty much the least reactive, most bio inert material out there is still a foreign body that's going through the skin. It's like having a piercing, you know, it could be titanium or platinum or anything like that. It will require some degree of care. Many people, I would say even most people following this type of procedure don't need any care. In fact, the less the better, the more you leave it alone, the better.

But there are some people who will say, eh, it flares up from time to time, in which case we give them some steroids. Usually not antibiotics, but just steroids. Things calm down a little bit and then it passes. Then hopefully it's months or years before the next time it flares up. Next please. Here's another one. Next please. And this is a woman who'd been radiated. Here's another one. So, you know, yeah, that past one was a one that a woman had been radiated. You could see she's got very sparse hair. But even still it's not a contraindication. Next please. Okay, so why choose minimally invasive procedure? Well, I know why I choose it. I choose it because it's super easy for me.

It just takes a few minutes. Patients are super happy. You don't need to take up a lot of OR time. You don't need general anesthesia. And the results speak for themselves. Patients afterwards are pretty happy. They're like, that was a whole lot of nothing. You know, I've had, I've been to the dentist that had things that were much less. They're a very minor degree of skin reactions. I can show you the data if you want, but with the old techniques, skin reactivity was extremely high. And it was a great white whale of otology and patients who, for doctors who did this is that patients who had to come back a fair amount of time to kind of deal with all these issues.

Now it's relatively small and even the patients who do have issues from time to time, be it low grade tenderness or a little bit of tugging, you know, when they turn or

anything like that. Number one is that all tends to resolve within about six months. Number two, even those patients, you ask them, well, do you want me to remove it? And they're like, oh no, I like this, I like the sound. It's worth it. The benefits outweigh the downsides. Are there people who occasionally will ask it to be removed? Occasionally. And I'd say between those patients, maybe I've had five or so over my whole career of hundred and hundred and hundreds of these.

It's either for just kind of discomfort, maybe we hit a little cutaneous nerve on the way in. It's impossible to know where those are. Or for patients who maybe their trial was not, you know, as helpful for them as we would've hoped it would've been. So it's kind of split between reasons for physical reasons or for people who said, it's not really. But for us in our clinic, it's probably a good 98%, you know, five year utilization rate. And I think that's it. I'm know if I have a next slide or if we're back to you, Dan. So it costs less. Well that's kind of intuitive because there's less time in the operating room. There have been studies that show, at least our institution, that to run an operating room, even if you're not doing anything, just having it open is \$70 a minute.

So every minute that you're in there, unless you're, you know, and the hospital will get paid the same whether you're in there for an hour or you're in there for 10 minutes. Of course patients love it because it's just quick. It's in and out. You don't even have to go to the main hospital. I do mind an ambulatory surgery center. So it's lower surgical costs, lower follow-up costs, less out-of-pocket expenses for the patient because they're not spending all this money on antibiotics and driving to come see you and doing all this other stuff. It really is kind of a set it and forget it type situation. So scarring is pretty minimal. There really is no place for it to scar.

The trick is to make sure that you have enough clearance between the skin and the Ponto. For Pontos, the Pontos will clamp over the abutment. So you need to have a good two millimeters of clearance. It doesn't clamp into it, it clamps over it. So you

have to have a little bit more clearance than you might for for another type of device. Yeah. And everything else that just kind of things I already said that basically if you don't mess with the skin, if you respect the skin, the skin will respect you. And the proof, again, is in the pudding. The patients are are pretty happy with it. Is everything perfect all the time? No, you know, by no means is it perfect all the time, but for me it's a tool that's in our toolbox. One of many tools that we have that has probably almost more than any other tool in my toolbox is ends up with happy patients for relatively little amount of effort on our behalf.

- [Alicia] Great. Thank you both so much. That was all excellent information. We do have a couple of questions. Let's start with Dan, actually, if you don't mind.

- We're both Dan.

- [Alicia] Well Oh, you're well, that's right. Dr. Coelho and Dan. So Daniel Lee, what processor do you recommend trialing on a patient? Do you prefer to trial with the SuperPower or the MINI and why?

- For sure. I have always, if you're looking at a purely audiological perspective, I've always recommend trialing with the Ponto 5 SuperPower primarily because when we're doing, like we mentioned earlier, if you're doing a soft band trial and you have to overcome that additional attenuation that you get from the skin and the soft tissue. When you're using the SuperPower, it gives you more of a dynamic range. It gives you more gain in general. It gives you a better force output from the device, which gives you a better dynamic range so that when a patient is trialing it, they have a better sense of what the device might provide for them post implantation. Right? So really the way you kind of frame it is to let them know that, you know, right now we're gonna trial the SuperPower device.

You'll have the option if they're a candidate for a Ponto 5 MINI, you have the option to switch post implantation, but this one will give you the best idea of what things sound like, right? And really focusing on those types of outcomes is really important when you're counseling about the the trial period. Because sometimes they can be misled. Like if by things like how the soft band feels or how the headband feels. That's not necessarily the focus of the trial. The focus is to see if we're benefiting in the ways that they want to benefit in, right? So long-winded answers. How's that, Alicia?

- [Alicia] That's great. Thank you. And Dr. Coelho, how do you go about measuring the length for the abutment when you're deciding which abutment length would be most appropriate for the patient?

- Yeah, so fortunately Oticon Medical makes it really easy and it makes it even surgeon proof. So they have a little ruler that you make. So what I do, so what you do is you measure the skin thickness by putting a needle in again, either before or you make sure not to put any anesthetic, you know, Novocaine or anything like that in until you've measured the skin thickness and you put a needle in the skin's thickness. And then I'll clamp it with a like a needle driver. And then I take it out and then I measure. Some people will do it with a little marker. They'll put a little marker and then you measure, and if it says six millimeters or seven millimeters of skin thickness, you know, that you have to have.

And this little ruler that Oticon Medical provides makes it really easy. They've got a, on the left side, they show how long it is on the right side, they said this is how long the abutment you should pick. So I call it surgeon proof. So, you can't overthink it or under think it. It says right there exactly how long you want. But generally you want two to three millimeters of clearance above. So the skin thickness is six millimeters, you want a nine millimeter abutment. If it's, you know, seven, then you could probably get by

with nine, but now you wanna start thinking about maybe 12. So you always wanna stay about three ahead at least. It's better to go too long than too short.

- [Alicia] Great. That's very helpful. Another question that we have is, is there anything in particular, Dr. Coelho that you would like to have from your audiologist as you're deciding to move forward with your patient? So whether it's audiologic information or any information that the audiologist might gather from the patient during the counseling session? What is it that you really-

- Yeah, I mean, there are a few things. So I work obviously, you know, very closely with our audiologists and we're constantly talking to each other and talking about these patients. You know, we wanna know what the indication is, we wanna know, we wanna make sure we're on the same page in terms of what does the patient want, right? If it's a single sided deafness patient, and they're getting it because they want sound localization, you know, you have to have a kind of a talk with the patient that that's not necessarily gonna happen. You know, head shadow and things like that. And even though patients will think that their sound localization might be better. Yu know, it's not.

I think that if there's one kind of little pearl that I had to, I mean there's a lot in the communication between an audiologist and the surgeon about. Most of it has to do with what the patient's looking for. And that's particularly true in the asymmetric or the single side of deafness patients. There's more there. The conductive hearing loss patients and the mixed hearing loss patients who've got normal bone line on the other side, they're pretty much uniformly happy. Those are easy, those are the patients who love it. The ones that are a little trickier can be the single sided definite patients. And you have to ask 'em about what do they want? For some of them they say, listen, it's just background noise.

I'm fine, you know, I'm fine everything, but when I'm in background noise, it's really hard for me. And some patients will say I love it, and some patients occasionally won't. We have kind of a protocol using the BKB. I think it's, or the Quicken we use the Quicken. It's not a perfect way of doing it. But sometimes if patients don't do so great in background noise. These are the things I'm gonna wanna know to help counsel the patients. The best part about all of it is, number one is that many insurances cover it. And probably the second best part is what I tell patients is, listen, this is not open heart surgery. This is a six minute putting in a screw.

I'd love to say it's more complicated than that, but dental implant is way more complicated than that. And this is a dental implant, it's just going over here. Worst kind of scenario is you give it six months, it's not what you thought it was. All right, we just remove it. We just take a screwdriver and remove it right in the office. You know, I feel like it doesn't do anybody any good to try and talk this up and say this is some sort of amazingly techno. I mean it is, but it doesn't do anybody any great to say this is some sort of amazing, complicated technology. I find it better if I just tell patients like, well listen, this is just a screw.

I'm just putting in a screw. It's not more complicated than that. And if patients are kind of reassured that it's not a complicated process, then I think they'll be happy. That was way too long of an answer for what the question was. But I would say that to take it back one step at that communication between the audiologist surgeon is super important to make sure that everybody, all three of you are all on the same page about what the patient wants. 'Cause that's when you're gonna run into trouble. If you can't deliver what the patient thinks that they're gonna get, if expectations are and reality don't line up.

- [Alicia] It's an excellent answer. Thank you for the detail. And we have just one more question and we are going just a tiny bit over our time here, but do both of you have

time to answer one more question, Dr. Coelho? Great. So the last question is, have you ever had to remove a Ponto device to move forward with a cochlear implant? And if so, how did that affect your outcomes with the implant?

- Sure, yes. I have had to do that several times for a variety of reasons, but mostly just because sometimes people's hearing poops out, you know, I mean, there's not much you can do about that for whatever reason. It's not because they didn't or never got benefit from their, you know, from their bone conducting device. You know, there are some tricks. The nice thing is about with cochlear implants is that you can kind of put them anywhere. You can angle them anywhere. If, if the person wanted their Ponto up here, then you tend to put the cochlear implant a little lower. If the person had their Ponto down here, then you could put the cochlear implant a a little higher.

You can work around it. It's very rare and frankly would be, I would like to avoid it as much as possible to remove the abutment and close it up. There are sterility issues there that I prefer not to deal with. So I'd like to try and keep the pockets completely, completely separate. I have, I can think of two or three patients that I've seen within the past, maybe not so long ago, the past three months, that actually have both, that have a cochlear implant and an abutment. And they actually will wear one or the other at any given time. Or they'll have one on one side, one the other. But I have a few patients who have 'em both on the same time and I'm like, time for me to remove that abutment.

And they're like, actually no, I kind of use it from time to time, which is interesting because not all patients who get cochlear implant are completely deaf either. Right? So, and we can preserve hearing and again, sorry, overly long question, but yes, and it's absolutely possible you don't burn any bridges by putting in one of those.

- [Alicia] That is fascinating. I can't say that I've seen someone using both at the same time and-

- It's weird.

- [Alicia] Yeah. It's like another version of hybrid.

- Right. Well, whatever floats your boat. That's fine.

- Yeah. All right, well I think that's everything that we have here. Thank you both so much for your time today. And thank you everyone for attending. Excellent. Take care everyone, and thank you.

- Thanks guys.

- Thank you.