Bone Anchored Surgery for Audiologists

Recorded June 16, 2020

Presenter: Corey Brackmann, AuD

AudiologyOnline.com Course #34974

Partner: OticonMedical

- [Corey] Hi there everybody, this is Corey Brackmann. Glad to see couple of names that I recognize. Welcome to today's seminar on Oticon Medical Ponto Bone Anchored System. I've been providing research expert for bone anchored surgeries for almost, maybe 17 years, I'm an audiologist. Today I'll be taking you through the journey of how bone anchored surgeries have developed. You start from about an hour to an hour and a half surgery and now it just happens in minutes. So we're gonna look at that quick and easy procedure that has become today. If you have any questions go ahead and type them in and I will do my best to answer them. The learning objectives you should know by the end of this course are. You should be able to explain the benefits of the MIPS procedure when compared to earlier approaches. You'll be able to describe the benefits of the Oticon Medical abutment shape and style. You'll be able to describe some differences between adult and pediatric surgeries. You'll also be able to describe considerations that contribute to device feedback, and how to solve them.

Today we'll talk through bone anchored surgeries in general, I will emphasize development within Oticon Medical since their launch, we just had our launch of 10 years we've had our anniversary. The surgical procedure and the devices have improved immensely over the past 10 years. So let me go back to where osseointegration first started, some of this may be obvious, some of it may be quite new for you. But this is a picture of Professor Branemark and he is the father of osseointegration. He was the first to recognize that osseointegrated properties, titanium and he actually coined the word osseointegration osseo meaning bone and integro meaning new. It was 1965, when Dr. Branemark place the first titanium implant into a patient's mouth, making the first dental implant. The Branemark implant system is still sold today from a company called Nobel Biocare. This is actually I took this right off the web. This is a picture of the Branemark implants that are sold by Nobel Biocare and you'll see in that top jaw there, that you'll see throughout this presentation that our implants look very very similar to those implants that are in the mouth. So, what is osseointegration? Osseointegration is a process where living bone tissue bonds with

titanium, and this is what makes bone conduction possible. So here is an actual picture of osseointegration and you'll see the bone and the titanium are actually growing together. So the implant is not only accepted, but it becomes an actual part of the bone they come just one piece. If osseointegration works the way that it's supposed to, which typically it does, it is something that is there for the lifetime of the patient if you think of dental implants, there are something that are there for the life of a patient they're not something that comes out unless something has gone wrong. So this is a picture of Dr.Tjellstrom, Dr.Tjellstrom is an ENT in Sweden, and he created the first Baha surgery. The Dr.Branemark and Dr.Tjellstrom they worked at Chalmers Institute of Technology in Sweden. Dr. Branemark was trying to discover an acoustic way to evaluate the degree of osseointegration in the temporal bone.

Dr.Tjellstrom, Dr.Branemark worked together. Dr.Tjellstrom placed it was actually Oticon bone vibrator onto the implant in the patient's mouth, and they could hear a tone, very very well. So Bo Hakkeson, that's another name here. Bo Hakkeson was actually working on this thesis and he was conducting research trying to measure how much sound was reaching the cochlea through the mastoid and they still work together, I like to say poof. The first permanent device for bone anchored hearing was developed. And in 1977, the first bone anchored surgery was performed. This is an actual device that Bo Hakkenson created it's very primitive but that is the bone anchored device, of course they've come very far, since this time. But this is an actual picture of the first bone anchored device. So as I mentioned this temporal bone implant started back with Nobel Biocare, which is manufacturer the dental implant system. There are three distinguished contributors to the field of bone anchored devices that I'd like to mention. One you just heard me mentioned Bo Hakkeson, and we have Patrick WesterKull and Lar Jinton. I'm very proud to say that these three gentlemen have collaborated all in the past, or they still do with the Oticon Medical. So we actually have a very long history in the bone anchored space. So Nobel Biocare spun off the portion of their business and opened their own bone anchored and cranial patient division

called Entific Medical Systems. Scientific Medical was the first bone anchored company in the US, and that's where I started my career from being an audiologist in the clinic. And then I started with and Entific Medical Systems. Don't try to guess my age here. Sorry, Entific was acquired by Cochlear Limited in 2005, and that was right as Medicare approved the bone anchored surgeries. This is when bone anchored surgeries really took off. So in 2004, Patrick had left Entific to develop his own system, he founded a Swedish device research company that he called Otorix. And this project that formed the original foundation of Otrix was sold to Oticon in 2006. And that is when the first patient was implanted, first Ponto patient was implanted. 2007 the first device with improved coupling, which is the attachment to the abutment on the device, which used on the Ponto device. We'll revisit the coupling system in a minute. So as you can see the Ponto sound processors were four years in development before they even came to the market. So, this is very important to review.

So what do we call bone anchored surgeries or devices, do we say BAHS, do we say bone anchored hearing appliance, do we say Ponto, do we say Baha. This is very very important, and a lot because of insurance. You look at the old research on bone anchored devices. Even if you google that the old research is all on bone anchored hearing aid. So Baha was broken up into bone anchored hearing aids. Well, if you think about what Medicare does not cover Medicare does not cover hearing aids or glasses. So, when I would say when we, when I was part of a Entific Medical Systems, it was a real big fight to try to get insurance to cover bone anchored surgeries because said bone anchored hearing aid. Once you put in hearing aid is denied. So in 2005, when Medicare approved insurance coverage for the osseointegrated devices, Baha had to become a trademarked name for Cochlear's device. So when you say Baha people use it like saying Kleenex but when we say Baha we are actually talking about Cochlear device. Something that I do wanna point out that if you're ever trying to get a patient or helping a patient. She falls more on the surgery schedulers in the doctor's office. If they have already bone anchored hearing aid, and it gets submitted to insurance, they get a

denial almost right away because it says hearing aid. So when I talk to offices, I have to really try to train them to say osseointegrated bone anchored device, actually that's what insurance calls it and not hearing aids. And I tell patients try not to call and ask if you have insurance cover this because once they hear the word hearing aid insurance companies are gonna deny you. So it wasn't until fall 2009 that patients, the Ponto received FDA clearance and Oticon Medical was launched in the USA. And that's when I first started with Oticon Medical. Might wonder where the word Ponto came from, Ponto is a Italian word for bridge, so they thought it was nice cause they're bridging the air bone gaps, that's where the word Ponto comes from. And you sometimes see it calling Ponto or Pinto sometimes when I go into surgeries and I see on the board that it's a Oticon Medical Pinto Surgery. Let's go back to the clearances. So it was the Ponto system was cleared in 2009. And that was just a Ponto system that similarly bone down to 45 dB that was our first device.

And then in 2011, we launched the Ponto Power and that was able to stimulate bone down to 55 dB. Remember for these devices, we're just looking at bone conduction thresholds, we don't really care so much about air cause we're just stimulating the bone conduction threshold. And we'll I pointed out later, but we do have now our superpower device, that is able to stimulate bone down to 65 dB. So, I wanna talk about a little bit with the FDA clearance. The Ponto implant and the processor system are FDA cleared and be used among a range of bone anchored products in lines, I'm actually gonna read this. This says the Ponto Pro but it's all of them, the Ponto Pro sound processor is intended to be connected to the Oticon Medical bone anchored implant system, or to the Baha trademarked abutment snap coupling from Cochlear. In addition, Oticon Medical abutments can be used for connection of the Baha sound processes with snap coupling from Cochlear. So you can see that the FDA says that, any device can fit onto any processor. Okay, so let's take a look at the snap coupling. The weak spot that was on the original bone anchored devices, was when the device was put on. We've tried to train people to put a device on their abutment at an angle

but people would put it straight on the left. So what would break there was a stem that stuck out of the original processors, and it would compress an airspace that was inside the device and the transducer would break. So, the coupling system again Patrick is the one who developed this spring loaded. So when you put it on the abutment, the abutment, the coupling I'm sorry actually widens, and then it goes on to the head of the abutment and it kind of graphs on. Okay so that has been very reliable that coupling. Let's go to the next slide. So, with Oticon coupling design, we eliminated the potential problem of damaging the transducer, when the patient is putting the processor on. They put it on directly and not on the angle the coupling system will protect the transistor by butting up against the body of the sound processor, instead of the medical change sorry mechanical transducer. So if you ever seen a Ponto device if you hit that coupling or that attachment there, just butts up to the device and there is no aerospace inside. So we have a very reliable device, we do not have a huge track record for our devices breaking.

And actually, just on a side note, if something does ever break with our processors, they can be sent in and we send out a brand new not refurbished, in place of the processor that was sent in for repair. So, back to the implants and abutments. So our coupling system, it spreads out on springs and then it grasps the lips. So on the left under Oticon Medical Ponto System you can see the lip there. So we need that lip for the Ponto processor to snap on. Well the Baha implant system they change their design of their abutment in 2010 so they took away the lip. So, at that time, what happened to our processors could no longer fit onto the Cochlear abutment. So people were doing at the beginning, just because the Ponto was new and people wanted to try it. They were unscrewing the abutment from the implant on the Cochlear side, and they're putting on the Ponto abutment. Well, the way that these connect is actually called a hex lap, there's a hexagon shape on the implant, and a hexagon shape on the abutment which is the top part, and that the hex lock the two hexagon shapes they fall together, and they lock together. So, that's actually how dental implants are connected

as well. So, it was sometime after 2010 that Cochlear changed their connection, so you can no longer put an Oticon Medical abutment onto the Cochlear implants. Or osseoscrew or osseo Cochlear implant. So let's just make sure we know the different parts of the system. If they keep saying abutment or implant you need to understand this. There's a processor on the outside, I'm going from left to right. And then there's a little screw, we've got an abutment, and then we've got a titanium implant. So the abutment and the implant are actually one piece, they can of course come apart, that's only change sizes of abutment et cetera. So they're just held together by the screw okay we do the hex lock and then we screw it together. So I'm gonna refer to the titanium implant as the implant, and the abutment is actually the percutaneous part that's the part that sticks through the skin, where we hook the device on. So, let's take a look at the development of the abutments. This was the top ones were from Nobel Biocare, and actually Entific when I first started there.

The first abutments, you can see there's like a circle, actually right here, there was sharp edges on the top of the abutment and that would cause a lot of skin problems. So, when Entific came out we had the abutment it was changed to this shape here, so we took off the sharp edges. Now this abutment or this top part right here, when it was Entific it was very short, it was 5.5 millimeters. Okay, so we'll explain why that matters in a little bit. We were bought by Cochlear that was the first implants they used. Then in 2010 you could see they took away the flange and it wasn't until 2012 where they changed the way that this connected. So Oticon Medical in 2009, we made the abutment a little bit longer. We first came out, we only had a six millimeter, it was just a little bit longer than the other ones. But 2009, we made it longer, and you can see here, where the arrow is. See that lip right here, we actually moved that lip up on our abutments. So the reason that we increased the length of the shaft on the abutment so it's a smoother surface and the shoulder extended at a higher level, and having a shoulder there with aim to vent skin movement and support the skin from above. So we're trying to hold down the skin because the problem that you'll see as I go on with

this presentation that the, sometimes the skin could grow over the abutment. So the thought was that, if we have that shoulder there, it will help hold down this skin. You can just see from left to right with the Ponto abutments that in 2012, there was a little bit of a different shape of the implant itself, and I'll go into that in a second. So before we move on to the evolution of the surgical procedure. Let's take a look at the Ponto FDA clearances and improvements in the past 10 years. So some of these when I mentioned MIPS or things like that, we will go back and revisit those words later to understand what they are. So in 2006 before we were able to come to the US market. We had our implant the diameter was 3.75, and there was just a device called the Ponto implant. But when we launched in 2009, we have the Ponto Pro, if you do a, if any of you dispense Oticon hearing aid it may sound familiar that we are on the RISE platform back there. We're very lucky as a company, we're under William Demant, there's a lot of companies under William Demant.

But we are a sister company to Oticon and we're very fortunate because, Oticon does a lot of research on the different circuits and then they translated later time into the bone anchored devices. So we know, by the time that we get these circuits in the bone anchored devices, they've really been proven that they all work very well. To the Ponto Pro in 2009 was on the RISE platform, and then I told you in 2011, we launched the Ponto Pro Power that went down to 55 dB boom. 2012, we made a wider implant, and we made a 12 millimeter abutment. In December, 2013, we came out with the Ponto Plus and the Ponto Plus Power. 2015 came out with the even longer abutment. 2015 again, which is something we still use now is the MIPS that we have talked about. MIPS stands for minimally invasive Ponto surgery. In 2016, we changed the implant and call it BHX implant, we'll revisit that as well. And in 2016, we came out with the Ponto 3 devices that were on the Inium Sense platform. And then our latest device which has been fantastic for us, is the Ponto 4. And I'm not gonna go into all the circuitry of the devices and the fittings that's for another course that will be offered on audiology online. But the Ponto 4 is on the Velox S platform, the same as the open

hearing aids from Oticon. Is everybody with me I know you can't talk, but if you have any questions go ahead and type them in for me. Okay, so let's move on to the surgical approach. Now I'm gonna walk you through how the surgical approach has changed so much over the 10 years. So, in the past 10 years, as I mentioned earlier, the surgery, used to be a very long and bloody surgery, and it changes something quick and it's very non invasive. So if you look at the left of the screen, we had all these little different surgical components here. This is not even all of them, this right here is called a dermatome. This is called a healing cap, a guide drill countersinks we'll talk about all this. But the reason why I still Ponto, almost every surgery I can is because when the hospital needs to order. It's a different lens, could be three millimeters four millimeters and a doctor doesn't know what they're gonna use until they actually start drilling. So they would have to, the as the householder they have to order all these different components and the hospital gets like one box that has this guide drill, the box with a three millimeter another box with the four millimeter in it.

So there's all these different boxes and then you heard me mentioned the different size, abutments so they could get like 15 little boxes and bone anchored surgery is not something that happens every single day, so the nurses are looking all these boxes, they have no idea what to open and get very confused. So they would say get 15 boxes and of course I would be there, to tell them what they have to open. There's more than my job is just telling them what's open but that is something that I do. So then if we look here on the right, this is new MIPS surgery, everything comes in one box. So it's not as intimidating to the OR or when they receive a box of Ponto products they don't have, they go from 15 boxes to maybe four of them come in there, so it's a lot easier for the OR to use. Okay, let's get to the, Okay, this is I'm gonna take you through a one stage, and explain what that means, the original surgical procedure that was for adults. So the placement of the abutment is always into the temporal bone, we take that white thing that little white thing right here, we call it dummy. And that dummy is just so the surgeon can mark where they wanna put the device. Now we always

measure 50-55 millimeters from the opening of the ear canal. And the reason that is, so if the device is too close to the ear, they can get feedback with the device. They also have to take into consideration, if a patient wears glasses, where the temples of their glasses are. Sometimes people are bikers or they work with instructions that wear a hats. So, people always bring those things into the OR, so then we can make sure that the dummy is place where it's not going to get in the way of worrying the things that people need in their everyday life. Those are all considerations. So they mark where the, they want the abutment to be. So we really don't use the dermatome anymore but when there was first an old wooden stage surgery. This dermatome was 24 millimeters wide, and it created a flap, I don't mean some gruesome but the only hair compared to it's like a cheese slicer, it would just displace the skin, that's actually a real picture here. And it would make a flap that was 0.6 millimeters thick. So I say thick but it was very very thin, okay and it didn't matter which way they use the dermatome but they were creating this flap. So with the flap, during the procedure, they had to keep them moist and doctors would use their blade and they would have to try to take off all the hair follicles on the flap. They wanted to make it as clean as possible so that when it was put down, there was no loose hair follicles or anything that went into the surgical site that can cause an infection.

So, may not sound like a big deal but it actually was very time consuming to remove those hair follicles. Then the, they had to remove this is subcutaneous tissue right here. To the right, they are here they are thinning the flap so before they move to hair follicles they had to thin this flap right here. And when they took out the tissue right here where the arrow is to the right, they had to take out 60 millimeters of tissue that's 30 millimeters on each side that is really long. Now remember I said when the abutments, originally they were 5.5 millimeters, and when Ponto came out they were six which isn't that much of a difference. But if you didn't take out enough tissue around the spot, the tissue would grow back, and it would grow over the implant. And we said, it is not a fungus but we said it was like a fungus because no matter how much you would take

out what happens in time, that tissue would grow back. I've been doing this so long there's kids who have this procedure and as they get older and their heads get bigger, that tissue grows back. And we're lucky nowadays it's much easier to fix that, before when that happened, there weren't longer abutments, and they had to go back in and revise so the tissue didn't grow over the abutment. This picture here, they actually need to scrape away. It's called the periosteum it's the layer over the bone because we want the implant to lay directly on the bone for the integration. So I don't know if any of you have seen patients that got their bone into devices, a long time ago, but they have this kind of indent in their head and that's because of all the tissue that had to be taken out, I think actually there's a better. So let me go back. So right over here, I can see here, that there's a instead of little dotted lines. So he tried to make the tissue so it didn't look like a big step into the head they tried to make it like a smooth transition from a lot of tissue down to the skull. And when they were taking out the tissue, and so vascular there there was so much blood and it just took a really really long time. This is what made the, this whole part these first few slides that could take 45 minutes for a doctor to prep the skull before they put the implant in there. So, the first thing they start with, this right here is called a guide drill. This is irrigation going in there, we need to keep the bone cool during the procedure, if the bone heats up during the procedure can affect the osseointegration. So this is called a guide drill hear, and the surgeon is drilling down this little mark right here, this is only three millimeters, and then we've got this spacer right here. So they would go down three millimeters, then they would take an instrument, from the tray and they poke and there's still more bonus what they looking for or are they hitting durop. Typically, eight years maybe 10 years old and older, have at least four millimeters of bone. The younger patient is the less thick bone they will have. So here I have taken off the spacer and now they are going, another four millimeter, another millimeter right here. Of course, the deeper you can go the better because then there's more place for the integration to connect on to the implant. So, one millimeter may not seem like a lot but it's actually very significant. So then the next component they had to grab was a three millimeter. I chose a drill the first guide drill,

can be three millimeters if that's all they can go then they have to use three millimeter countersink if they can go four millimeters so they go four millimeter countersink. And what this is doing is actually, it's making the top layer of bone so it's even so the implant goes in straight it's actually widening the hole. And then we put this right here, is called an abutment inserter, that's one of the surgical instruments that comes in the bone anchored tray,. But we actually cannot touch the implant itself, titanium is considered a scavenger metal can pick up a lot of debris. A lot of stuff from be attracted to it, so if something touches the titanium will affect the chemical properties of the titanium and will affect the integration. Whenever we go in surgery, adding to the amount of boxes sometimes doctors will want to have an extra implant because if the implant is dropped, they can't reuse it. I'm always there also another part of my job is to tell the scrub nurse, hey when you open up that ampule that the implants is in this here, don't dump it out. So it's may seem minor but if we dump it into the glove it's gonna change the chemical properties and it's not going to work. So, I see my role is very important telling you what to do.

So anyway, we use this abutment inserter, we opened the ampule, and all the drilling that has been done up to now it's been done with a high speed of the drill. So they pick up the implant using the abutment inserter when we place it into the skull we change speed to a very slow speed and the implant is really a screw so we actually screwing the implant into the bone. So then, when surgeries first started we put that skin flap back over the implant is white thing kind of where my hair is right here. It's called a biopsy punch it was four millimeters at the time, they'll punch over the implant making a hole. And then the implant would go through that hole and then that brown thing we're looking at on the right is called a healing cap. The certain put on some kind of dressing, usually something called zero form which has some antibiotics in there, it's a pressure dressing. and that cap would keep it, will keep pressure on the site where the implant went. So look right here, let's see it's sloping down there, so that's what they were trying to create by taking all that tissue. So this is actually a very nice picture

of the picture, going through with the skin reduction. It may be a little bit hard to tell but right here you can see the skin is a little thicker here, but they've had to take out all the skin around here and you can see all the skin. You can see here that this is the dermatome right here, and this actually looks really good. Patients would lose about a quarter size of hair around the abutment, you don't wanna hair going through the abutment, making it harder for an attachment. So that's where they had to remove the hair follicles. So people would get like quarter sized box bolts. So these are actually really nice pictures, they didn't always look this nice. If you go and look at pictures, if you put up a Baha pictures cause everything was called Baha back then. They don't always look this nice, these are actually very nice pictures. But you can see there's the using my own Right here you can see the bald spot here, you can see the bald spot here. But these are actually really nice pictures of what the procedure look like. So there were some post op complications.

Sometimes there could be implant loss there still can now, there is a higher implant loss for children a lot has to do with the bone quality. Like I said, children have thinner bone, so if an abutment is sticking out and there's not even four millimeters of bone, the implant could be hitting it can come out, I think it's not in there too deep. The implant loss is less than adults. There could be inflammation infection around the abutment, it could be just due to poor hygiene. You know, maybe some people I cover Hawaii and a lot of times assume it there, you would see a bigger infection right there. Sometimes skin would overgrowth, if you look at this picture right here. This skin has totally grown over the abutment. I was actually giving a talk to the Acoustic Neuroma Association one time and this man stood up was telling everyone how easy his surgery was. And so excited he was gonna go in and get his device fit soon. And I did not have the heart to tell him that I couldn't see his abutment, this is what it looked like. The skin had grown over, remember, that was before we had these longer abutments people could get numbness and pain when you're taking out all that skin. You can affect the area make it numb, people would have pain and it's funny, sometimes the pain wasn't

even actually around the abutment, it is weird, it would be in other places of the head. But I have been in the clinic where someone's trying to fit a device and the patient can't even feel where their abutment is, because of the numbness. And then also there could be heat loads or scar tissue. So all these complications, yes, there are some complications, but not like there were way back, at this time we don't see this anymore. Let me talk a little bit about the implants. So the top picture is our original implant. I was telling you in 2012 right here, you can see from here to here, that the diameter changed from 3.75 millimeters to 4.5 millimeters wide. Now, going through that original surgery, you think, hey, why didn't they just put a longer abutments on these implants? But they couldn't really do that because the longer abutment would make the implant not stable. So they had to make the implant wider in order to make it more stable. So we made it from 3.7 millimeters to 4.0 millimeters wide. We call this our OptiFit geometry. By increasing the diameter and the shape, you can see here, in 2012, it's more like a V-shape, we increase the amount of bone to implant conduct. So as the implant gets screwed in, it's actually there's more bone conduct to the implant. And that made that in turn provided initial stability.

So the more stable the implant was, you were able to put longer abutments on these implants. Also, let me point out from here, you see these threads here, we also added a lot more threads here. So the integration happens throughout these threads, so you could see that there's more places for the bone to go in there, so that also added to the stability of the implant. So we're gonna talk about what we mean by tissue preservation in the next section, but OptiFit implants, they were designed for this tissue preservation surgery. You can see here that our abutments are very smooth, we changed it from having this hourglass shape over here because these pockets they felt that bacteria could go into these pockets and could lead to more of an infection. So we're gonna see in the next section how the surgery became a lot quicker and that complication rate went down. In 2016, we changed the surface of our implants and introduced the first laser-ablated titanium surface. Unique bio helix laser ablation can

be found, right here we can see that picture. But in the grooves of the OptiGrip geometry of our implant. The bio helix increase the strength of the bone to implant interface by more than 150%. Bone binding they actually found that it's actually stronger than bone itself, I've questioned what they meant when they first said that. And when they did removal tests, which actually was in a rabbit bone, they could not remove the implants, the implant would actually break. So it actually becomes bonded with the bone. So we've always had a very high implants survival rate, but with the laser-ablated, we've increased our survival rate to 90%. We also found with the laser ablation in there, the test showed that our implants became stable very quick. So we were shown to have the implant stability happen faster than some other implants but I do have to say that, you know, over time, they're all very stable.

Titanium works really well for the integration. So let's take a look at our abutments. When he first came out, I told you there was this six millimeter abutment here. Then when we made a little wider we went to a nine millimeter abutment. Then in 2012 went to 12 millimeter abutment, remember I'm talking about just this part here, the part that is percutaneous. Then 2015, we came up a 14 millimeter abutment. So Ponto abutment families on the OptiFit implants. And we use those depending on the patient's in the surgery and we'll get into that in a second. Most patients choose majority of patients choose a nine millimeter abutment and we actually for pediatrics, not a lot of people use six millimeter because the patients tend to grow and then they need a longer abutment anyway. So you'll see if you ever see a patient come in and they have an abutment and you wanna know if it's a, a Cochlear abutment or if it's a an Oticon Medical abutment, you'll see green connections srew that makes the Ponto abutment very easy to identify. And we know that it has this hexagon interface meaning that it connects with the hexagon. So if any of your patients have been fit before, somewhere in 2010, or before they can wear a Ponto product, if they've been implanted later and they have a Baha device on they most likely would not be able to use ours. And I would also say ask them when their original surgery was, remember

2010 is about the cutoff when those patients can wear our device. So also this greens screw means it's ISQ compatible, and the ISQ is implant stability quotient. And that's how it was there's actually an instrument that exists can get and I should say it's not really used so much in the US because kind of expensive and it's not really necessary. But they can put a machine and they could take the typical machine and put it on that screw. And there's numbers that come up on this machine and scale from one to 100. And the number correlates to how stable the implant is. So on a side note, the reason why people they wanna, we have three months, the FDA says there's three months from the time of the surgery to the time of the fitting of the device, everyone wants to load they say or fit the device quicker. So I'm only allowed to tell people because the FDA says three months we know that people do not necessarily wait three months, but there's actually a study that's going now, where physicians are putting in the implant in a week later they are fitting the device. So eventually we'll see, if maybe we can change the FDA requirements of three months and make it a little bit shorter. But they can use this ISQ and since there is not as long as a healing period, which we're gonna see in a second to see if we are able to load or fit the device before the three months. Okay, I'm gonna take you to the linear incision.

So first one to the one stage. one stage surgery, where we use the dermatome and then came to linear incision in the linear incision, we no longer use the dermatome. Remember, when the linear incision came out, we first had the nine millimeter abutments. We didn't quite have the 12 and 14 that came later, so the linear incision we used for tissue preservation surgery. Again, here they're marking 50, 55 millimeters from the opening of the canal. This dotted line here is the incision. So they would make the incision they would open up the skin here they're scraping that little piece that's where the implant is gonna go, they're taking away the periosteum there. Then we're doing the guy jaw again, we actually changed our countersinks a little bit, it's just widening the hole, you can really see here on the top before see that little reiterate there, before that was a lot bigger. So we're trying to keep as much bone as possible

for the integration to occur. So the more bone there's actually threads on the bottom side of our implants at the bone grow into the threads at the implant. And then here they are just putting the implant in, there closing up the incision, and some people would put the abutment on the side of the incision. Or if we look for the green arrow is some people would put it through the incision, six of one half dozen of another. They could choose whatever they wanted to do. The only thing I will say that on this linear incision, sometimes when the abutment comes through the incision, it's funny, it's like the body knows that there is a foreign body that titanium is very well accepted by the body, you could actually see where the skin or the body is trying to get rid of that implant. And you could see just a little bit around here, how the tissue would kind of become a little puppy there, because it's like it's trying to push the implant out. Sometimes you need a little bit of revision to take that down, but not as much as before. The thought with this is, the less that you mess with the tissue or you mess with the whole surgical site, the less problems there's going to be and actually we'll see how that is, it is very true. So when the linear incision first started, we only had a nine millimeter abutment, why?

Because the tissue preservation is because they didn't have to take out the 30 millimeters of tissue on each side because now remember, it went from 5.5 or six millimeters on the abutment to nine. So unless someone had a ton of tissue, they had to take out a little but not as much as they had to be before. So they don't have that big indent in their head like they used to. This is actually a picture you can see right here, this little line, that's what the linear incision was, but she doesn't have a big bald spot necessarily. And there's no indent in the head like there was before. Okay, so it's minimal soft tissue reduction. I'm gonna move into pediatric surgery. Pediatric surgery week. Here is set for a two-stage surgery which I'll tell you what the days are when someone sees on a radiated bone. The first stage you put the fixture in, the fixture meaning the implant, we don't put an abutment to stick out. The second part is surgery, which is three to six months later depending on the quality of bone, we put the

implant on. So, we have to consider with pediatric considerations and I should say, the only patients that are take a 50% chance that it may, that the implant may integrate or radiate to patients. So we put a sleeper sometimes in a radiated patient as well. These patients have thin or soft bone, so sometimes you don't even have three millimeters of bone. So what surgeon will do is leave what we say the implant is proud, it's kind of sticking out of the bone. And they can create additional bone by using bone chips and putting it underneath the plant or the part of the implant that sticks out and we'll actually make an extra layer of the bone. So as I said, because the thin, the bone so thin, the risk of trauma to the implant is much greater in children. And also we've got to think about that kids, their motor skills aren't necessarily as as good as adults and they can be a little bit clumsy. And so the implant could come a little bit easier. So a two-stage surgery, just real quick, we pick up the implant. Here we can see the other piece look like a flower picking up the implant but this piece of metal right here. We're putting the implant in and then here we're putting something called a cover screw on.

The reason why I put a cover screw is so the bone does not grow into the implant and later on, there's a little bit of hole, there's a hole there so we can put the abutment onto the implant, I showed you which is held together by a screw. So then when they close up the surgical site, there's nothing sticking out. So then three to six months later, we can feel where that implant was put in cause that cover screws sticks up a little bit and these kids used to have thin skin and we go ahead and we put the abutment on depending on what size they need. What's really nice we have come out with I showed you before there was that big brown thing this is a soft healing cap we use now and that soft healing cap, once the abutment is put on even coming right out the OR, they can put that healing cap on and a piece you can actually wear the device with that healing cap so you don't have to wait another two weeks for site to heal after the second stage is performed. So I'm gonna take you through the MIPS procedure. I see I've got to speed up just a little bit. This is what we use now I cover three states and I've got to say 99% of my patients, my surgeon use the MIPS procedure. This slide

says over 50% of all BAHS surgery done with MIPS I'm gonna say it's probably even more now. The numbness is almost non existent, nowadays, the soft tissue outcomes are excellent, and it looks much nicer than it ever did. So what I'm gonna do, is I'm gonna walk you through the surgical video here. And I'm gonna share this video is actually longer than the actual procedure is. Which is kind of funny because this is four minutes long. Hey, the minimally invasive Ponto surgery. So first the doctor is measuring, he's not using a ruler if I were there and make a measure 50-55 millimeters from the opening of the ear canal and he's just shaving a little piece. Some people don't even shave that much. How do we know what size abutment, they stick a needle in, they clamp it, we have this nifty ruler. One side says how thick is the skin, the other side says what abutment length corresponds to that, we need two millimeters more because we need that lift to stick out, so our device will go on to the abutment. He's putting in some inside of a cane just to numb it and stop some of the bleeding.

That means a biopsy punch, it's a five millimeter biopsy punch, we go all the way down to the periosteum that bottom layer there, and he's scraping away the periosteum. He's taking out that little piece of tissue scraping away the periosteum there so the implant goes directly on the bone. And then we're gonna start the drilling. So this is called the cannula that comes in the surgical kit that the over orders. The reason why we have a see these drill bits are a lot bigger now. So we're making the skin retract from the drill bit, it's not touching the drill bit so it's not going to become inflamed or it's not gonna get chewed up in that drill bit. Putting the irrigation in went three millimeters. Now they're checking hey I'm drilling a bone and they're still bone so we're taking that stuff off and boom, we're at four millimeters there okay. So they're going another millimeter, we're using a lot of irrigation, can't start drilling it's another thing I tell them they got to irrigate. So now he's going down an extra millimeter, four millimeters, usually even a little quicker than this. Next is going to use the widening drill is gonna put on. So this is just making the hole a little wider so you have four millimeters this is a four millimeter widening drill bit. Gutter irrigation widening the hole.

All this is happening at a fast speed, now we're gonna put the implant in a pick up the implant that's a suction we don't even have that suction in the US but they're just making sure that there's nothing in the hole that the implant is gonna go in. You can see here that it up as messed up, I went backwards. Sorry, I try to go for more forward sorry, guys. Okay, start there. So he's putting in the implant. The change to low speed we have to, we know we go four and a half turns for four millimeters. Until we know it's in three and a half turns if it's a three millimeter implant. And there's our soft healing cap that we put on and he's going to put on the dressing. I think in this video he uses zero form then only needs to stay on for about a week.

Okay, I'm gonna go back into the lobby that is the entire surgery. So it actually takes longer to get the patient in or in prep than it does to actually do the procedure. So we did a retrospective study within our company, that looked at and that looked up over the past 10 years. systematic review of the outcomes over the past 10 years and surgical results were evaluated from 27 publications. And they looked at over 1100 patients with mixed hearing loss, single-sided deafness, conductive loss. And then looked at adverse skin reactions, which is considered a Holgers score greater or equal to two. And that was evaluated across the patients up to five years. Very quickly, this is the Holgers score that doctor use. And we look at Holgers score scale of zero new irritation, and it gets really bad at Holgers score of four when an implant comes out. Okay, so it's a reading skill of the irritation. So results from a systematic 10 year review indicated that 95% of all follow up visits, there was no need for skin related aftercare so that's a big difference from before. It's a beautiful surgery patient don't lose their hair, they don't have the indent in their head. It's very quick surgery because you know what size of abutment they need, before we even start the surgery. So the Ponto system today, we offer two devices right now. Ponto 4 which is the world's smallest, it's down here on the bottom. It's the smallest device it's on the market today. It's on the open platform the Velox S. Now we have the Superpower, but it can actually can't over amplify these patients with a bone anchored devices, you can actually use it on

any of your patients it has the highest output of any patient, or we call them max force level so there's no distortion in the sounds can come in there before they reach the output of the device. The Ponto 3 Superpower uses a streamer the Ponto 4 does not. Both have the widest frequency range on the market. Now this is really important for 38% wider than any of the other devices. And of course we know that this is so important because especially with children or with anyone for the clarity of speech, we all know that we need this high frequency for the clarity of speech. So we know that the wider frequencies is very important. So let me summarize, 98% of patients in electro spectrum studies they report improved quality of life after their Ponto surgery. 95% of the patients there's no skin-related treatment.

The Ponto 3 and Ponto 4 really great sound processor. And we know that the Ponto system that it's a quick procedure, a safe and simple procedure and it's a lifetime of change, for a lifetime of improvement for the patient. I know we have five minutes I needed to hurry a little bit at the end. But I just want to let me actually, because I know it's a question that you have our devices throughout the history of 10 years we've never had back problems, but something I wanna mention that if there is feedback problems can easily be solved. If you've seen our Genie Medical Software, it's just like the Genie software or very similar. You can be spent Oticon hearing aids or have no trouble with the Ponto devices. So any feedback can be solved using Genie medical software, where you've got to remember we have different lengths of abutments. And sometimes the skin just grow to the top of the abutment. And that's something that can easily be changed even in the office, just unscrew the abutment and then put a new one on. So I'm gonna leave you with this last video. I really wanna thank you for joining me today and I hope that you found the information useful or at least interesting. You're more than welcome to contact me or you can call Oticon Medical and put this on and I really wanna thank you guys all for being here today, I hope that this was good for you.

- [Narrator] Over 10 years ago, the first users switched on their Ponto sound processors and opened up a world of sound. Today, more than 200,000 users around the world rely on bone anchored hearing solutions, and there are many benefits. The procedure can be done in minutes and changes users lives forever.

- That's been the difference, that's really I'm me again, and after nine years of not being me, I'm me again you know.

- [Narrator] Since its launch, the Ponto system has developed immensely, through advanced technologies, groundbreaking research, and insights gained from close relationships with users and clinics. In just a decade, the bone anchored procedure has changed and soft tissue reduction and large incisions are a thing of the past. Now, it's about tissue preservation with a minimally invasive procedure.

- It was 10 minutes and there is no pain, I just felt a couple of vibrations here and there but no, it was a rather smooth surgery.

- [Narrator] Sound remains at the heart of all development. And as part of a world leading hearing healthcare group, we use the most advanced technologies to meet users daily hearing needs. That's why Ponto users can benefit from the very same state-of-the-art technologies as users of conventional hearing aids and get a hearing solution optimized for their needs.

- The first time I heard through my Ponto it was amazing compared to what I was used to, it was analog versus digital now, so the clarity of sound was amazing.

- And then I couldn't really hear and everyone properly like the teachers and stuff This one has really made a change and when I go and sit at the back it will, it really makes a difference.

- The Ponto is just so much more. It's just more if the sound, the clarity of the sound, the way it tunes in the variation of sounds, and the naturalness if you can say.

- [Narrator] The Ponto system offers people at all stages of life a simple, safe procedure with proven results.

- I would highly recommend it, it's made a huge impact on my life. And for me that the biggest fear was the actual surgery and the thought of having the fitting, but it's fine. I don't know it's there. Once it's it's healed cause you don't need to do anything different.

- [Narrator] Over 10 years ago, the first users switched on their Pontos and opened up a world of sound. All commitment to providing innovative products and solutions that enhance the life of bone anchored users continues.

- We are really positive about the future because the technique when hearing devices and problems like this, they evolve so fast, so we have to trust that it's only gonna be better for Sam.

- Oticon Medical is so much more than just a company that has hearing aids. They care about their patients, they want to make sure that their product is where it needs to be and what to do to improve it.

- Don't waste another day of poor hearing, don't waste another day of not hearing your children clearly another day of not being yourself. Discover what hearing can be like again.

- [Narrator] Be part of the journey choose sound, choose Ponto.