Comparing Cochlear's Osia 2 to other Bone Anchored Hearing Devices, presented in partnership with the University of Pittsburgh

Presenter: Melanie Lutz, AuD

- [Instructor] Hello and welcome to the classroom everyone. We'd like to welcome Dr. Melanie Lutz. Dr. Lutz is a Clinical Audiologist at the UPMC Children's Hospital of Pittsburgh. This course is coordinated in partnership with the University of Pittsburgh and we'd like to thank all the coordinators. At this time I'd like to hand the mic over to you, Dr. Lutz. It's my pleasure to welcome Dr. Melanie Lutz. Today, this presentation is in partnership with the University of Pittsburgh. Dr. Lutz is a clinical audiologist at the UPMC Children's Hospital in Pittsburgh, and we'd like to welcome her on the mic. Thank you so much Dr. Lutz for being with us today.

- Thank you. Good afternoon. Thank you everyone who's joining me today for this talk and thank you to AudiologyOnline for having us perform this talk. So again, my presentation is titled Comparing Cochlear's Osia 2 to Other Bone Anchored Hearing Devices, and this is presented in partnership with the University of Pittsburgh. So here are my disclosures. Our learning outcomes for today are threefold. One, to identify characteristics of a bone anchored hearing device candidate, two, to describe the offerings of the Cochlear Osia device, and three, to compare the Cochlear Osia to other bone anchored hearing device options. So let's begin. Here we see two audiograms. On the right, a conductive hearing loss where the air conduction thresholds are elevated above normal and the bone conduction thresholds are normal.

On the left we see a mixed hearing loss where both air and bone conduction thresholds are elevated, but there is also an air-bone gap present. When a patient is identified as having a conductive or mixed hearing loss, their treatment plan and follow up will likely differ from that of an individual with a plain sensorineural hearing loss. This patient population can be challenging and complex and the management can differ from one another even in seemingly similar situations or cases, like in a case of two fairly identical audiograms. Depending on your clinical setting, you may not have these patients walking through your door frequently, or this might be a common occurrence

in your clinic. Either way, the management of a patient with conductive or mixed hearing loss can be a bit intimidating or at least might require some forethought compared to a typical normal hearing or sensorineural hearing loss.

My hope for today is that we can simplify the management of these patients and leave you feeling more confident in your ability to help support this population of patients by identifying the options available to them and understanding the difference between those options. There are benefits and drawbacks to all the devices I will discuss today, and having a good understanding of these differences and benefits can help with the device selection. For patients with a conductive or mixed hearing loss who end up being candidates for amplification, we will discuss what types of amplification might be most appropriate for them and how to best program and verify those options to meet the patient's needs. We will identify many of the current bone anchored hearing device options and how those can be coupled or worn, and how they differ from one another.

Then finally, we will discuss the Cochlear Osia system and describe how this device compares to other amplification options for patients with a conductive or a mixed hearing loss. Throughout the case we will also review a few case studies featuring patients that I have worked with in our clinic. Again, I am primarily a pediatric audiologist at the Children's Hospital of Pittsburgh and one of my responsibilities there is to serve as the audiology liaison to our ENT congenital ear clinic. This is a specialty clinic that manages the care for most of our patients that end up utilizing or at least being candidates for a bone conduction hearing device. Our ability to collaborate with ENT in the management of these often complex patients has been extremely valuable and productive for our patients and our clinic team.

It can help us to ensure that the patient receives timely coordinated care and that they are fit with amplification as soon as possible, which as we know is extremely important especially in the pediatric population. Once a conductive or mixed hearing loss has

been identified, the patient should be medically evaluated, ideally by an ENT. Many of these conductive components are able to be resolved or they may resolve on their own without medical management. As a pediatric audiologist, I frequently diagnose a transient conductive hearing loss in the presence of abnormal outer or middle ear function. Later these will often resolve following the placement of tympanostomy tubes or a similar management strategy. These patients with otitis media with effusion and accompanying conductive hearing loss are very common in my practice, but most of them end up resolving on their own even without medical management.

But not every conductive or mixed hearing loss as we know can be resolved so easily. There are many etiologies that present with a conductive or a mixed hearing loss. In some of these cases, surgery is attempted, but it may not improve hearing. For example, something that I often see is patients who undergo ossicular chain reconstructive surgery and often or sometimes this surgery can fail or not be as successful as hoped, which can lead to the same hearing thresholds that were obtained preoperatively or in some cases a worse or decreased postoperative audiogram. A young patient with a structural anomaly such as microtia or atresia, may be a candidate for a reconstructive surgery when they are a bit older, but it may not yet be an option for that patient due to their size and their continued expected growth of their skull.

And that typically leaves that patient with a conductive or mixed hearing loss for the interim until they're able to receive that surgery. There are a variety of factors that can impact the decision of whether or not to surgically intervene when it comes to a conductive or mixed hearing loss. The pathology of the hearing loss will obviously play a major role in this decision as will the degree of the hearing loss and/or the size of the air-bone gap. The age of the patient will be another important factor and any comorbidities that would impact their surgical candidacy or put them at greater risk for surgical complications. Another factor for the audiologist and the medical team to

consider is the status of hearing in the contralateral ear if the ear in question to possibly undergo surgery is a normal hearing ear.

So we may or may not decide to perform surgery on one ear if there's also a risk of worsened hearing over time in the contralateral ear. When the conductive component for a patient persists despite medical management, the audiologist and medical team should then begin to consider amplification options for the patient. Our discussion today is focusing primarily on bone conduction devices, but it is important to note that some patients with a conductive or a mixed hearing loss can and certainly will benefit from an air conduction hearing aid and this could include any style of hearing aid. However, most commonly these patients will be fit with a behind-the-ear hearing aid with an occluding ear mold as that is typically the amount of power that they'll need for their hearing loss.

A bone conduction device works similarly to an air conduction device until the final transduction stage, at which point that output transducer is the bone conduction receiver. A bone conduction device, as we probably all know, takes electrical energy and converts it into mechanical energy. Not every patient with a conductive or a mixed hearing loss will be a candidate for a traditional air conduction hearing aid. There are a few things that we can consider when we're determining the candidacy for a patient and whether they should be fit with an air conduction device or a bone conduction device. First, what is the etiology of their hearing loss? If the patient does not have a complete external ear canal, or sorry, external ear, or a complete opening to their ear canal, we cannot easily fit them with a traditional air conduction device.

It won't stay on their ear as easily. Even in atretic ear canal can make it difficult to fit an air conduction device. Like I mentioned earlier, some of these patients will undergo several otologic surgeries prior to pursuing amplification and in some cases this can lead to an external auditory canal that cannot be properly occluded because it is large

or maybe because it has a smaller opening with a larger cavity past that. So it's hard for us to take an ear mold impression and get a properly fitting ear mold for them. Patients with these surgical ears or those who perhaps have chronic otitis media might experience frequent ear drainage and an air conduction hearing aid on that patient would likely frequently be occluded with that drainage, and it may also negatively impact their ear health as well as serving effectively as an earplug instead of a hearing aid whenever it is occluded with drainage.

For these patients we also need to consider the severity of the hearing loss when determining air conduction versus bone conduction devices, as well as the severity or size of the air-bone gap. For patients with a conductive or mixed hearing loss, we have to overcome that air-bone gap with whatever amplification option that we select. This can be difficult with a air conduction hearing aid as we need a lot of power to overcome that air-bone gap and that's not always feasible with an air conduction hearing aid. As the size of the air-bone gap increases, the performance with an air conduction hearing aid will decrease. Performance with a bone conduction device is not impacted in this way.

A bone anchored hearing device does not have to overcome that air-bone gap. It may still need to amplify for a sensorineural component if present in a mixed hearing loss, but it might just have to, in a purely conductive loss, simply bypass the outer middle ear to stimulate the cochlea. For patients who might be a good candidate for both air conduction and bone conduction device, it might ultimately come down to patient preference. Some patients may not be interested in a surgical procedure understandably, but they might not also be interested in a bone conduction device that needs to be consistently worn on the head via a headband or similar method. They instead might prefer the look or a feel of an on the ear hearing aid.

If the patient and provider are both not sure of which option to select, it might be beneficial to have the patient trial one of the two devices and then utilize a qualitative measure like the abbreviated profile of hearing aid benefit or a related survey to see how they perform. It can be difficult for patients and families to understand how a bone conduction device works when they have never used one and when they don't have a background knowledge of bone conduction hearing. I find it very useful in our clinic to keep a demo bone conduction device in our office for this purpose. For example, if I'm working with a younger child who is a candidate for a bone conduction device, I will provide the parents with the demo device and have them place it on a listening check abutment that is included typically with these devices so that they can press that against their forehead and experience how the bone conduction device sounds to them.

Sometimes that's much easier than trying to explain it or looking at pictures, things like that. It's also advised to have older patients trial the device in the office prior to ordering or dispensing their device so that they can have the experience and knowledge of how it's going to sound, and so that they can appropriately set their expectations for how they might benefit from the device. Once an amplification option is selected, we need to ensure that the device is appropriately programmed. When programming and verifying an air conduction hearing aid for a conductive or mixed hearing loss, you must enter both the air and bone conduction thresholds into the programming software and the Verifit. If the bone conduction values are not entered, the prescriptive formula and targets will differ and they will not be set to provide enough power to overcome the air-bone gap.

This will leave the patient being under fit. When you do not enter the bone conduction values, the thresholds, the most comfortable levels and the upper comfort levels, will all be, or when you, sorry. When you do enter the bone conduction levels, all of those values will be elevated the same amount and this increase represents the amount of

attenuation of the middle ear, which is our air-bone gap. So when we do enter those bone conduction values, the targets are able to be set so that we can overcome that air-bone gap. If you're like me and you work with AuD students or if you just want to see this for yourself, I like to use the Verifit and create an example where I plug a flat 60 dB hearing loss in for both ears and use a dual view so I can see the left and right ear targets together, but I will only enter the bone conduction values for one of the ears, and for the other ear I won't enter it.

In this way I get to side by side see how these targets differ and how much it matters. A bone conduction device is, again, bypassing the outer and middle ear, so therefore the device does not have to overcome that air-bone gap and it simply needs to amplify for any sensorineural component that may be present. If there is no sensorineural component, the bone conduction device just needs to bypass the outer and middle ear. A good rule for determining bone conduction device candidacy is that a patient with an air-bone gap of about 30-35 dB HL or greater will perform better typically with a bone conduction device compared to an air conduction device. So, usually I implement that 30-35 dB rule for these patients.

Once you have determined that your patient is a candidate for a bone anchored hearing device, there are a new set of options for you and the patient to consider. Within the bone anchored hearing device options, there are both surgical and non-surgical choices, as well as choices for a transcutaneous delivery of sound or a percutaneous delivery of sound, and we will define these later on in the presentation. Let's review some of the key points that we have discussed so far. A patient may be a good candidate for a bone anchored hearing device if their etiology prevents an adequate fit of an air conduction device or if the air-bone gap is too great for the air conduction hearing aid to overcome.

Additional considerations in this decision include the inability to occlude the ear canal for adequate amplification ear drainage that might impede the function of a hearing aid, severe stenosis of the ear canal, and even severe allergies to ear mold material which we have seen as well. A patient with microtia and/or atresia, or a severe stenosis of the air canal, would prevent them from using an air conduction hearing aid. A patient with chronic otitis media may need to keep their ear canal open and aerated and they may also experience frequent drainage which would lead, again, to the recommendation of a bone anchored hearing device rather than an air conduction device. An additional group of patients we may consider here are those who have undergone a radical mastoidectomy and that may lead them postoperatively with a mastoid cavity that either makes it difficult to occlude the ear canal or prevents us from fitting traditional amplification appropriately to meet their needs.

I also want to mention the use of bone anchored hearing devices for single-sided deafness. A bone conduction device for SSD patients functions as a transcranial routing of the signal, so the sound arriving at the processor on the poor-earing ear will then travel across the skull to the cochlea of the normal-hearing ear. This can improve the head shadow effect which is a benefit, but the device in this situation will not provide the patient with true binaural hearing and it will not likely improve localization. Additionally, when we compare its use to an option like a CROS hearing aid for these patients, a bone conduction device would be larger and less aesthetically pleasing. Bone anchored hearing devices for single-sided deafness are included in the FDA criteria for many of the devices that I will talk about today.

But in my experience, and in the experience of other clinicians in my clinic, patients do not typically end up preferring these devices for their single-sided deafness and they often become non-users or opt to switch to another method. However, I do present all of these options to my patients with single-sided deafness. Following this presentation, I would be interested to hear if your clinic utilizes bone conduction devices for

single-sided deafness and if you find that patients are enjoying that device. So now we'll take a minute to look at a case study from my caseload. So this is a nine-year-old with a bilateral conductive hearing loss and recurring otitis media with effusion. They have had many cholesteatoma in both ears and have been surgically treated multiple times to reduce this cholesteatoma.

Following these surgeries, the patient has continued to have this ongoing chronic conductive hearing loss. The conductive hearing loss has fluctuated for this patient depending on their middle ear status, but on average the patient presents with a moderate conductive hearing loss in both ears. Initially this patient was fit with a traditional behind-the-ear hearing aid in both ears, coupled to silicone ear molds. But frequent drainage following surgeries and an increasing air-bone gap led us to make the switch from air conduction to a bone conduction device. At that point, the patient had been wearing an air conduction hearing aid for a few years and was very comfortable with that device so making that transition was a bit difficult for them.

However, once we did fit them with the bone conduction device and even when we trialed it in the office, they were very happy with the sound quality and how loud it did sound to them. So they were very happy and it felt good for them to not have anything in their ears. That was some of their initial reports. So on the left you'll see this patient's unaided audiogram, that moderate, mild to moderate, conductive hearing loss in both ears and we see that air-bone gap there about 30 dB or more. On the right we see the patient's aided audiogram. And AB here is standing for a bilateral aided condition. So here the patient was wearing, in this case, two BAHA 6 Max processors on a SoundArc and they got really great responses here as you can see and now we're able to keep those ear canals open for the patient.

This was a non-surgical option so perhaps in the future this patient can undergo another surgery that could improve their air conduction thresholds and in that case we

can simply not wear the BAHA and SoundArc anymore. But until then they have this option for them to give them access to sound and to help them with their communication and education. So when we are thinking about bone anchored hearing devices, there are both surgical and non-surgical options of our bone anchored hearing devices. The surgical, or implanted devices, can generally be divided into a transcutaneous option and a percutaneous option, and we will discuss those later in more detail. Our non-implanted options requiring no surgery to use include a bone conduction processor that is worn in a variety of ways.

The most traditional, but a bit less popular now compared to other options, is a basic headband with a abutment for the processor. So this would look and feel similar to how a bone vibrator is placed on a patient when we perform bone conduction testing. A soft band, or soft headband, is a popular option especially for infants and children and the soft band itself is available with Cochlear BAHA devices. With this device, the bone conduction processor is connected to an abutment that is placed on a soft elastic headband that will go all the way around the patient's head and is adjusted to fit snug against their head. Generally I recommend that the soft band should be fit snug but should allow for a finger to be slipped under the device to ensure that it's not too tight that it will be causing harm, which is especially important to check for our very young patients.

The soft band comes in a variety of colors and it can be made for both a unilateral or a bilateral device use, so either one or two bone conduction devices can be placed on the soft band. Cochlear Americas also offers the SoundArc system, which I mentioned in our case study earlier. This is similar to a headband but it fits around the lower back part of the head with two kind of grippy pressure points that hold the SoundArc to the head near the ears, almost like the reverse of how you wear glasses, and this is where you would place the abutment near the ear for the BAHA processor to snap into. The

SoundArc is a more aesthetically pleasing option in many cases as it can be kind of hid behind hair and it comes in several colors as well as multiple sizes.

They have extra small through extra large. Another option is the ADHEAR from MED-EL and this is a bit different option. The ADHEAR is also a non-implanted option that uses an adhesive adapter, which is essentially a soft pad that has adhesive on one side and a plastic processor connector on the other side. So this sticky part of this device is placed behind the ear on that hairless area behind your ear, kind of on your mastoid there. Once that sticker, that adhesive component is placed, it is water resistant, and the company reports that it can stay on most patients for three to seven days without having to replace it. The ADHEAR processor can then be snapped on and off of that abutment fairly easily as needed.

In our clinic with the pediatric patients that we work with, all patients who are to be fit with a bone conduction device will always begin with a non-surgical option and this can help to ensure, one, that they will benefit from the bone conduction device that is going to be surgically implanted, and it can give us the chance to make sure the patient likes this bone conduction stimulation and that it works well with who they are. Additionally, many insurance companies will also require a trial of some period of time with a non-surgical device prior to surgery. Typically in very young patients, this initial trial will begin with the Cochlear BAHA on a soft band as we in our clinic have found it to be the most appropriate option and easiest to use for very young children.

A non-implanted bone anchored hearing device will require a consistent amount of pressure of that bone conduction processor against the mastoid region or the head, against the skull. And this is done in a number of ways that we just talked about. Maybe a headband, the soft band, the SoundArc or the ADHEAR adhesive component, for example. For some patients, as you can imagine, this required pressure can create some discomfort, it can lead to indentations in the skin, and some patients do report

headaches when they utilize these different forms of retention. Again, with that consistent pressure that's needed, even though we're using all that pressure, the non-implanted transducer is still limited in its output capabilities and we see this output limitation especially in the high frequency output for these devices.

There is this high frequency roll off in the output limitations of non-surgical bone conduction processors and that is a drawback for this option when we compare it to surgical options. A non-implanted bone anchored hearing device does not have FDA criteria for candidacy and is generally easy to have approved for patients with a conductive or mixed hearing loss or for those with single-sided deafness. However, the cost of these devices has been fairly high and the reimbursement rate, at least in the past, has been relatively low. While I won't be able to go into detail on billing during today's talk, I would like to mention that new billing codes have gone into effect as of January 1st of this year, and if your clinic works with these bone conduction devices, these osteo-integrated devices, I urge you to investigate these new codes and implement them as you are able.

When we program a non-implanted bone anchored hearing device, our options are relatively straightforward as there are not many parameters that can be adjusted when we compare how we program a traditional air conduction hearing aid for example. So, consider a Cochlear BAHA 6 Max processor and the programming of that device in my opinion and many others opinions that I've talked to is relatively quick and straightforward. There is an option to perform in situ testing via the BC Direct function of that programming software but this is not required and if for example I'm fitting a very young infant or child and I may not be able to perform that task, that's okay, it's not required, but I will need to enter my air and bone conduction values and enter how the device is being coupled to the patient's head.

We will also need to complete a feedback test while the patient is wearing the device and this may make changes to the output of the device in order to attempt to prevent feedback, which is a common problem that we'll discuss. Verification of bone conduction devices is possible if you have the Verifit Skull Simulator or a similar component. Because there is no acoustic output of a bone anchored hearing device, we need this special component or attachment to serve as an artificial mastoid. The Skull Simulator will match the impedance of the skull and then an accelerometer will measure the vibrations. This device can fit in the Verifit hood and when using it you can conduct speech map verification as you would with a traditional air conduction hearing aid.

Unfortunately, that is an additional component that does not readily come with the Verifit as far as I'm aware and it may not be feasible for your clinic to go ahead and purchase or acquire this device. I do not have access to this equipment in my clinic, so instead I primarily rely on validation measures, like aided behavioral testing, and qualitative measures, like patient and parental surveys, and that helps me determine the validation of that device for the patient. The available surgical options for bone anchored hearing devices can be grouped into two major categories. We mentioned these topics before, the percutaneous and transcutaneous. Both types rely on osseointegration and that osseointegration is when human tissue or bone will bind or bond with a material that's non-human, typically a metal, and most commonly titanium, as titanium has the the best efficacy with osseointegration for implants.

And this osseointegration allows for that direct bone conduction stimulation. A percutaneous option includes an abutment device that protrudes through the bone and skin. Above the skin there will be an abutment for the bone conduction processor to connect to or snap into. The vibrations are then transmitted directly to the patient's skull. The general candidacy for a percutaneous device includes a patient five years or older with conductive hearing loss or single-sided deafness, or a mixed hearing loss

where the bone conduction thresholds are 65 dB HL or better. So just looking at that, we can see that these type of devices, this style of device, percutaneous device, can provide a lot of power. They're overcoming such a big air-bone gap.

A transcutaneous device is an option that includes an implant that is fixed to the skull, so it also requires some form of osseointegration, and that implant is coupled to a magnetic plate. There is nothing protruding from the skin or through the skin. Instead the processor, the external processor, will attach to the skin via a magnet almost similar to how you see a cochlear implant magnet attaching to the skin. Vibrations are then sent through the skin to the processor to the internal component. The general candidacy for a transcutaneous device includes a patient five years or older with conductive hearing loss, single-sided deafness, or a mixed hearing loss with bone conduction thresholds 45 dB HL or better. So we see that this has a different amount of output available compared to our percutaneous device and we'll talk about that more.

The FDA recommends that implanted devices in these cases are only for those ages five and older, and this is because we need to wait for the maturation of the mastoid and we need to wait for the skull thickness to increase and be at least 2.5 millimeters. So very young children who do not have a fully developed mastoid or have too thin of skull thickness, if we try to implant them with these devices, it might negatively impact the implant's ability to osseointegrate. The programming of these devices are, again, fairly straightforward depending on the company and the software that you're using or that you're working with. There are many features available in the programming software that are similar to an air conduction hearing aid, including Bluetooth connectivity.

For a cochlear device, directionality options are available with their dual microphone for some of the processors that they have, but this is only implemented when the patient is

wearing the processor with a surgical abutment because that is when we know that the processors will always be in the same spot and we can use directionality a bit better. So if you indicate that your patient is wearing their processor on a soft band, it will automatically disable those directionality features. If the patient is a binaural user of the BAHA Connect, they will need to make sure that the correct processors are on the correct side to be able to benefit from those directionality features. For some patients you may need to consider whether the individual should be fit unilaterally with a bone anchored hearing device or if they should be wearing two binaural processors.

For example, I recently saw a patient with a binaural atresia and the family wanted to know if they could go with two devices or if just one would suffice. They had an understanding of how bone conduction hearing worked and they brought up that if she had one bone conduction device it would technically be vibrating the whole skull. Theoretically. So one should suffice. However, there is a lot of research that supports the use of binaural thinning if the bone conduction scores for each cochlea are relatively similar. A binaural thinning can improve the patient's interaural cues which can help with complex listening tasks like hearing a noise or a localization. A percutaneous option allows for the transmission of signal directly to the skull and this can allow for more power or gain to be delivered to the individual and that can result in better aided benefit, better aided thresholds.

An example of a percutaneous option is Cochlear's BAHA Connect device and the Oticon Medical Ponto device. Another benefit to these, this style of devices, is the retention. So once the processor is snapped into the abutment, it is very secure and in place and this is great for our patients who are very active. When we compare this to a non-surgical option that needs to be firmly held against the skin with a headband or something similar, this might be a more comfortable option compared to that. Additionally, our percutaneous devices, such as the Cochlear BAHA Connect, can allow for MRI up to 3 Tesla with a relatively low shadow. A transcutaneous device

includes options like the Cochlear Attract, the MED-EL BoneBridge and the Cochlear Osia.

However, we will discuss later how this differs from a traditional transcutaneous device. These devices are FDA approved for use within about four weeks of surgery, which is less time that's needed for healing the percutaneous option. Aesthetically a transcutaneous device is pretty ideal because once the processor is taken off, there is little to no visual evidence that the individual has any type of implant. There's no abutment coming out of the skin like there is for a percutaneous device. There is also less risk of complication around the device site or incision site for infection. That leads us to some of the limitations of these devices. Let's start with our percutaneous devices. So following the surgery to place that percutaneous implant, a waiting period of three to six months occurs prior to the dispense or activation of the processor and this is because that osseointegration that we rely on to have this device work so well takes time.

We need that living bone to firmly integrate with the implant before we can utilize the processor. After the implant is fully integrated and the wound is healed, the user must be mindful of the site where the abutment is and take regular care of it to prevent infection or skin overgrowth. During those initial three to six months of healing period, daily cleaning of the site is needed and very close attention is needed for that site. The patient might at some point during that time require antibiotic cream or steroid cream and they might be in and out of the ENT office to check on the status of the device. Skin overgrowth is a common problem for a percutaneous device and for some of these patients who are experiencing this, they can have placed a longer abutment that sticks further out of the skin, which can help prevent skin from completely overgrowing the abutment.

A lapse in this care or a lapse in proper hygiene near the device can have negative implications, including the formation of granulation tissue, and that can lead to the requirements of additional surgery or it can just prevent them from being able to use their bone conduction device. There is also a risk with these percutaneous devices associated with head trauma. So for example, if there is a hit to the head at or near the site of the abutment, it could compromise the device function. Transcutaneous devices need to deliver their signal through the skin and we know that there is an attenuation of about 10-15 dB that occurs anytime oscillations are delivered across skin. This attenuation is often worse at the high frequencies, which is why we mention and we'll talk more about that high frequency roll-off that we usually see with a non-surgical option or a transcutaneous option.

So therefore because of that attenuation, a traditional transcutaneous device may not provide enough power for a patient whose bone conduction scores are in the mild to moderate range. It might be more appropriate in some cases for those with a conductive hearing loss that is in the moderate or mild range to pursue a different option if we don't think that we're going to be able to deliver enough power. Although the processor does not need to be pressed against the skin in these transcutaneous options with something like a headband, the magnet that's needed to adhere it to the skin can create discomfort in itself. It can create pressure on the skin. If the magnet strength is an inappropriate strength, like too strong, it could damage that skin and cause some skin breakdown, which would require us to stop using the device until that skin heals over and then we can change out the battery strength.

Additionally, if we are not using a strong enough battery or magnet for a transcutaneous device, we may have frequent problems with retention. Users with a traditional transcutaneous device are also not approved for an MRI with greater than 1.5 Tesla because of the magnet that's within the internal component. So now we're going to move on to discuss the Cochlear Osia device. This is a fairly new device. I say

fairly new but it has been out for several years and we're already on the Osia 2I processor and the 300 series other implant, but the Osia device is rather unique and it's a great option for us to discuss for at least some of this patient population. Again, Cochlear recently released the new Osia OSI300 implant and the Osia 2I sound processor and we will highlight some of the new features that those encompass later today as well.

So the Osia is a transcutaneous device. It is an active transcutaneous device but it differs in several key ways from the transcutaneous devices that we've already discussed. With the Cochlear Osia, the transducer is under the skin instead of being within the external processor. Additionally, unlike other transcutaneous systems that utilize electromagnetic technology, the Osia uses piezoelectricity. And the use of piezoelectricity enables increased power output and better high frequency delivery with less chance of feedback. The external processor itself is very slim and light, it's only 9.4 grams, and like other transcutaneous devices, it attaches and connects to the internal component with magnetic attraction. When the patient is wearing the external processor, it typically sits above and behind the pinna and the two dual microphones are ideally positioned above the pinna.

And I should say that it is nice for this device to be light because we often will then need a less strong strength of the magnets on the skin, which can be helpful for the patient's comfort. So what is it about the Osia, and specifically the new OSI300 implant, that makes it potentially a better option for my patients with a conductive or mixed hearing loss? Let's first talk a bit more about the transducer. Previous devices have used electromagnetic technology like we mentioned, rather than this piezoelectric electricity. With piezoelectricity a current is applied to the piezo material which leads to the material bending back and forth and there are two small tungsten weights that are at the end of the piezo material.

And when that piezo material is moved or activated, those little weights that are positioned there will move as well as a result and produce vibrations, and then those vibrations are sent through the implant. Piezoelectricity is more energy efficient, especially at its ability to convert mechanical energy into electrical energy and that reduces the power requirements of the device. Piezoelectric materials can also be compacted into a smaller size compared to other transcutaneous devices that require an electromagnetic system. Because of this, the implant for the Osia can be very thin as we see here, and the surgery requires very little bone removal when it is placed onto the bone. The entire implant itself features a monolithic design, meaning it is all one piece, and the parts of the implant aren't at risk of moving away from each other following the surgery.

But the biggest benefit to highlight in reviewing the Cochlear Osia, in my opinion as a clinician, are the outcome capabilities. Cochlear states that this device has a fitting range that encompasses bone conduction thresholds up to 55 dB HL. So for comparison, the transcutaneous system of the MED-EL BoneBridge, which is a comparable device, has a fitting range of 45 dB HL. This opens up a really nice, sleek transcutaneous device option for patients who may have only been a candidate for percutaneous devices in the past. In addition to this increased fitting range capability, the Osia has improved high frequency response, which is something that has been consistently lacking in products for our bone conduction device users. The Osia has been shown to provide users with up to 12 dB more gain, which is huge for these patients and it's exciting for me to see as a clinician.

Osia also has Bluetooth connectivity, direct to iPhone capability, and it's compatible with all of Cochlear's wireless technology. So things like the remote microphone and the TV streamer can be used. There's also a dedicated app for the Osia, that's the Osia Smart App. One of the best ways to compare Cochlear Osia technology to other devices is to talk more about the comparison between electromagnetic technology and

piezoelectricity. Again, electromagnetic technology, which is currently used in in systems like the Cochlear BAHA tract, the Oticon Medical Ponto, and the Medtronic Sophano Alpha may require higher power consumption and therefore have increased battery usage. The cochlear Osia use of that piezoelectricity improves the battery life and Cochlear states that the patient should expect the battery to last about two to four days, which as we all know can probably vary based on how much they're streaming.

The frequency response of these devices is also, of a device that uses electromagnetic technology, is constrained by the output capabilities of the electromagnetic system, which is not the case in a piezoelectric system and this enables the Cochlear Osia to have a greater bandwidth. Electromagnetic systems also include, within the system itself, magnets that can become demagnetized or damaged if the patient needs to undergo an MRI, which is something to consider for some patients. Meanwhile, the Cochlear Osia system is MRI compatible up to 3.0 Tesla. Another key advantage of the Osia system is the reduced risk of feedback and this is very big for a lot of my patients. In other bone conduction devices, feedback occurs when the amplified sound reenters the microphone and creates that unpleasant noise and we know this can be bothersome to the patient and surrounding family, anyone with them.

The piezo technology used in the Osia device allows for a more controlled transmission of energy and sound without that risk of feedback that we see in a more traditional system. And the way that the implant itself is designed also contributes to reducing that feedback. There's a fixed distance between the microphone and the actuator, which can help prevent sound from reentering the system in a way that would cause feedback. And another thing to note here is that the surgery for the Osia is deemed to be relatively straightforward. It requires, again, not very much bone to be drilled out and it is relatively quick. While the specifics of Cochlear's signal processing remain proprietary information, we do know that the programming software utilizes the SmartSound iQ, which we'll review a bit in the next slide.

In our clinic, and in my experience, I have found the Osia to be easy to fit and to use. The programming software which was recently updated to Osia 2.1 fitting software is streamlined. It's not very different from the software used to program Cochlear's other bone conduction devices. During the initial fit of the Osia device it is helpful to use like, a checklist that they provide on their website of what needs to be done, as there are few things that need to be done in the initial fitting that don't need to be done at following connections, and this includes the digital link calibration which you'll be prompted to complete. And this step usually, again, only occurs during the first fitting.

The purpose of this step is to calibrate the external processor to the implant and that can provide us one, with a baseline for gain, and it can also give us estimates for what magnet strength would be most appropriate for the patient based on the distance between the coils through the skin. So essentially what this is doing, and what the patient will experience, is a period of a pure tone sweep and they will hear this so it might be wise to let them know that they will be hearing that, and it can be stopped if they are uncomfortable. BC Direct is also available in the processing programming of the Osia device. The recent update to the software includes an enhancement that I'm excited about and this is the data logging information.

So previously data logging information for Cochlear's BAHA devices didn't give us too much information about how long they were really wearing the device. THey gave us like, one big number, but now we'll be able to see a daily average wear time for these patients. Many of the patients that I have fit with an Osia device had previously worn a non-surgical bone conduction device and I have found in my initial fittings that even after the in situ testing, the patient feels that once the device is turned on it's very loud and I often need to or I'm asked to reduce gain for at least the first few weeks of their device use. I would suspect that this is due to the difference in sound transmission

between a non-surgical option and this direct transcutaneous stimulation of the Osia device.

But I'd be interested to hear if anyone else has experienced similar feedback from their patients. So again, here is an example of the SmartSound iQ signal processing. I'm going to jump ahead a little bit more quickly here, but this processing is somewhat similar to what is used for their cochlear implants. It does use a scene classifier that is consistently listening to the environment and making changes to the signal processing as needed. The current indications for the Osia system in the US are as follows. The system is for patients 12 years or older and the Osia can be used for patients with single-sided deafness as defined as air conduction pure tone averages equal to or better than 20 dB at those listed frequencies in the contralateral normal hearing ear.

And then it's approved for a conductive or mixed hearing loss with bone conduction pure tone average equal to 55 dB or better at those tested frequencies. When we look to compare the Osia to other comparable relatable devices, we often compare it to the MED-EL BoneBridge, and this device is similar. It is a transcutaneous device that uses an internal coil that receives electromagnetic signals from the external sound processor, which is called the Samba. The fitting range for the BoneBridge is up to 45 dB HL for bone conduction thresholds, which when we compare that to the Osia, they have a fitting range of 55 dB HL. So we see a benefit there with the Osia. Additionally, that BoneBridge has the negative factors of the limitations of the electromagnetic devices like we mentioned before.

So we'll now go through two quick case studies. I might just go over one as we're running out of time, but here we see a 15-year-old patient with left microtia and atresia who previously wore a BAHA 5 on a soft band. They were hesitant to pursue surgical options but the patient ultimately became a teenager and didn't want to wear a BAHA on a soft band. They didn't like the feeling of the SoundArc. So we decided to pursue a

unilateral Osia implant for this patient. And here we see the comparable aided thresholds for the BAHA 5 on a soft band and then when we tested this patient with the Cochlear Osia postoperatively. And we see those improved thresholds, especially in the high frequency region when we tested the patient with the Osia device.

And then I'm just gonna skip ahead here a little bit. So here's a case with a 7-year-old who previously wore a BAHA 6 Max for a unilateral conductive hearing loss. And again here we see the aided threshold when the patient had the BAHA 6 on a soft band and when they had the Cochlear Osia. So to summarize today, the management of these patients with conductive or mixed hearing loss can be very different from one another and it can be different from a sensorineural hearing loss. It's important for us as clinicians to understand the options available to these patients to help them better select what will be most appropriate for their care. And the Cochlear Osia, we talked about the main benefits, which include less feedback, more gain, and its compatibility with the MRI.

Okay, thank you very much for attending.

- [Instructor] Thank you so much Dr. Lutz. We'll go ahead and open up the floor for any questions or comments that you all might have. We have a question here. What types of tests do you do for your verification?

- Sorry. For a patient that has a bone conduction device who I might not be able to use a verification measure like the Verifit, the component that we were talking about, we typically will use, depending on the patient's age, aided thresholds and speech recognition. We'll sometimes do listening in noise, a speech and noise test if possible. It depends on the patient's age. I also try to always include some qualitative measures to see how they're benefiting with the device, whether it be in school or at their job. So more often we're doing a validation.

- [Instructor] Thank you Dr. Lutz. We have a couple comments here from a couple participants and they're just saying great presentation and thank you. It was very informative. I agree. We'll take one last question here from Anne. Anne says, what a great talk. When you start discussing the transition from non-surgical to surgical solutions with families, do you find benefit in discussing surgical options earlier?

- Hmm. Thank you, Anne. That's a great question and this is one of the reasons that it's so nice that our clinic works closely with that specialty ENT congenital ear clinic because we work together so that I can have a better idea of when that patient might be eligible for surgery based on their medical history, etiology, things like that. But I do find it helpful, even when the patient is beginning their journey with a bone conduction device, to present to them that a surgical option might be available to them later in life, even if it isn't available now. And that's something that our ENTs in that specialty clinic will also do so that we're all on the same page, in that if we want to pursue a surgery for that device later on, we can and we're prepared to do so.

- [Instructor] Thank you, Anne, for your question. We'll go ahead and close the classroom. I'd like to thank Dr. Lutz and also the University of Pittsburgh for coordinating this course. We appreciate your attendance today, and we hope you have a wonderful day. Thank you.