Clinical Application of Middle Ear Implants

Presenter: Elizabeth M. Adams, PhD, CCC-A

Thank you for joining today's webinar clinical application of active middle ear implants. It's my pleasure to introduce our presenter, Dr. Elizabeth Adams. Dr. Adams has more than 20 years of service in the field of audiology with over 18 of those educating future audiologists in the academic setting. Her areas of expertise include amplification systems, both traditional and implantable, and the assessment and management of vestibular system disorders. Dr. Adams recognizes the importance of understanding the theory and history of clinical concepts in order to positively impact the learner's ability to apply evidence based practices and provide exceptional patient care.

Dr. Adams, welcome and the floor is yours. Thank you. Thank you Christy for that fantastic introduction. Yes. Hi everyone.

I want to thank you all for being here with us today on the session. Joining today's session where we're going to talk about clinical applic of active middle ear implants. As Christy said, my areas of expertise really are amplification systems, beginning with of course traditional hearing aids, selection, fitting and verification, but also those implantable devices like cochlear implants, auditory brain stem implants, of course, middle ear implants, bone anchored hearing solutions. And so we get the opportunity to talk about active middle ear implants today. I also have a real strong interest in vestibular assessment and management of vestibular disorders.

So I'm really pleased to be able to be here to talk about active middle ear implants. And, and we're really differentiating active middle ear implants from a passive implant like a prosthesis. So we're talking about devices that are sensing sound from the environment, picking up sound from the environment, and actually delivering them to our patient. So let's get into disclosures. These are my disclosures.

The big thing that I want to say about this presentation is it's not sponsored by any specific manufacturer and so we're going to talk about some devices and this content hasn't been sponsored in any way by those manufacturers. These are the limitations and risks associated with this presentation which are happy to review on your own. So what are we going to cover at the end of our presentation? What I'd really like for you to do is to really understand candidacy for for active middle ear implants. So including consideration of hearing threshold level, middle ear status, previous amplification use, we'll talk about that a good bit.

And the otologic health of our patient. So identifying candidacy. We'll also talk through the different technologies that can be used in middle ear implant technology. So we'll talk through piezoelectric technology, electromagnetic and electromechanical we'll talk through some specific devices that employ each one of these types of technology. And then we'll also talk about some limitations and benefits with this technology and in the use and help of patients with hearing loss.

So our agenda will have a brief introduction. We'll talk through candidacy, general function and purpose. We'll talk about those active middle ear implant technologies and materials like the paz, so electric, electromechanical and electromagnetic. We'll talk about the benefits and limitations. And then I'll provide a summary for you at the end of our time together.

You'll have the questions that you'll answer to assess your knowledge. And those get at these core items that we'll talk about today, including the candidacy. We'll talk through typical input to the device and output. So what, what is the device taken and then what is the device delivered to our patient? Just like we talk about with all of our amplification devices.

What's the input? What's the output? We will talk about one completely implantable, commercially available active middle ear implant. And then we'll talk about the two, well, the three different types of transducers. And those will be two of your questions that you'll answer.

So as we're going through the presentation, you'll see quiz hints. And so look for those little hints as we go through the presentation. So if you just sort of quick think about the name active middle ear implant technology, we tend to think middle ear and middle ear implant. And so maybe we're talking about those patients who have a conductive loss or a mixed loss. And right now, middle ear implant technology is only FDA approved for those patients who have moderate to severe sensorineural hearing loss.

So there has been some research out there to support the fact that that there may be benefit to using active middle ear implant technology with those patients who have conductive or mixed losses. But right now, the only FDA approval that we have for middle ear implant technology, active middle ear implant technology specifically, is related to managing those patients with moderate to severe sensorineural hearing loss. We'll talk about that a little bit more as we go through. Interestingly though, you know, FDA approval really only means that whatever the device or pharmacologic intervention is, it only doesn't hurt the patient. It's not necessarily that it provides benefits.

So we'll be a little bit cautious about that. But that is the way our patients and technologies get reimbursed. So anyway, our candidates right now with FDA approval are moderate to severe sensorineural hearing loss. So active Middle ear implant technology, what it essentially does is create mechanical motion that drives the ossicular chain or drives the cochlear fluid. So we're talking about delivering actual motion, mechanical motion or movement to the ossicular chain.

And there are, we'll talk through some partially implantable devices and we'll talk through one fully implantable devices. So the technology itself is delivering to our patient not an acoustic signal like we're used to talking about with traditional hearing aids, not an electrical signal like we would see with a cochlear implant or auditory brainstem implant, but instead is delivering an amplified mechanical motion or movement to the ossicular chain. So who are our candidates? FDA approval for active middle ear implant technology is adult patients who are over the age of 18 years of age. Again, our FDA approval for this technology is going to be our patients who have moderate to severe sensorineural hearing loss.

You may see in the international community that active middle ear implants are being used with a broader patient population, maybe even those patients with conductive or mixed losses. And there have been some researchers who have documented some benefit for using active middle ear implants with those patients who have conductive components. But currently that's not what we have FDA approval for with our devices, speech understanding. So we would expect our speech understanding to be be better than 40 to 60%, and that's going to be device specific. But we're talking about those patients who have a good amount of residual hearing and have pretty strong speech understanding abilities in an unamplified context.

Amplification use or previous amplification use is a really important aspect to consider when you're thinking about your patient for, for an active middle ear implant or your patient is talking to you about an active middle ear implant. So we would expect and strongly recommend that those patients that are considering active middle ear implants would have a history of consistent use of appropriately fit amplification. So not just that they've tried hearing aids for a couple of weeks, not that they've used their hearing aids on what some people consider an as needed basis, but more of they have amplification that's been appropriately fit, verified real ear measures. We know for sure that we're providing the right amount of gain and amplification and that that amplification is used consistently for about three months. Those patients who have gone through that experience of using consistent appropriately fit amplification but still have difficulty with the amplification, let's say they are still having difficulty with the occlusion effect.

Despite our best Efforts with different ear mold styles or coupling styles or venting options, they're still having trouble with the occlusion effect. Or those patients who are still having trouble with feedback, even though we've again adjusted coupling, you know, to the ear. We've tried different venting, we've tried different ear molds, we've tried different feedback algorithms, we've even maybe gone towards reducing gain in certain frequencies to try and get rid of feedback, although we want to be really careful with that. But those patients who have difficulty with feedback in that way, that we can't address patients who have difficulty with comfort, no matter what we've done with the coupling, and even those patients who are reporting a lot of difficulty with distortion once we get to higher gain instruments, those would be the patients that we would really think about for active middle ear implant technology. Interestingly, our patient should have normal middle ear anatomy and physiology.

So normal anatomy of the middle ear, a normally functioning tympanic membrane, normally functioning eustachian tube, ossicular chain should be intact and should be functioning normally as well. So those are our candidates that we're going to consider. Our evaluation of course is going to be pure tone, air and bone. We'll conduct speech reception thresholds and discrimination testing and quiet noise, which will help us validate our patients reported difficulties and help us get an understanding of what some of their difficulties are, help validate their concerns. We'll also assess the status of the middle ear function through tympanometry and do our stapedial reflex threshold testing to help us determine a suspected site of lesion.

I think it's really important too that we include in our assessment, especially for our patients that that might want to talk about active middle ear implant technology, a self assessment measure. I really like the COSI and the afab. Both of these are available in your questionnaire module of noa. Both work really well as the software based models. The cozy, if you're not familiar with it, is pretty quick and easy to use.

Your patient's going to identify the listening difficulties or situations that are difficult and are priority. So they can list off certain things just off the top of their head and then they'll have the opportunity to go back and actually prioritize those. So if they're telling you that talking with their communication partner is important and talking on the phone is important and that they're having difficulty with those two things, they could go back then and put those in sort of rank order with the cosi. So on the front end it allows you to Identify what are some difficulties the patient's having and then let's set some realistic expectations. After they've been fit with the device, you can go back and check to see that progress is being made, that you're seeing some positive change in that.

The COSI can be a little bit intimidating for some patients because it starts off as basically a blank page. But if you're able to help guide them, you can get a lot of good information. The A.F.A.B. of course, is another good one and really nice when you have the software based version since some of the questions are scored in reverse order. But the AFAB provides specific items and has the patient rate their ability on that, that score with a Likert scale.

So including things like aversion to loud sounds, difficulty in quiet, difficulty in background noise, difficulty in reverberation, and again, that can be given pre fitting and then afterwards to document progress.

We really do want our patient to have amplification. A history of consistent use of amplification that's been fit appropriately. Three months is really a great timeline. And again, that they're using their amplification on a full time basis, not just I use it when I need it because we know what that means, but again, appropriately. I think the best way to document that is through real ear measures instead of just asking the patient how it sounds.

So that's our candidacy evaluation. Contraindications would be patients who don't have normal middle ear status. So those patients who have recurrent otitis media, currently FDA approval would not be for those patients who have otosclerosis or ossicular chain discontinuity. But we would expect middle ear status to be normal for our active middle ear implant patients. Additionally, those patients who have experienced a complete mastoidectomy would not be candidates.

And of course our sweet kiddos under the age of 18 are not considered candidates for active middle ear implants.

So how does it work? They're, they're not magic. They, they, they don't work like magic, like Amazon where you press the button and two days later you get a package. Active middle ear implants are going to take the acoustic energy from the environment and transduce it into mechanical motion that oscillates and it oscillates proportional to the original acoustic signal. So that energy, the energy that comes from the environment is going to be transmitted to a mobile structure within the middle ear space.

That structure that's been implanted in the middle air space is going to cause movement of the ossicular chain or a prosthesis and we'll kind of talk through that a little bit more. So thinking about the typical input to a. An active middle ear implant input. Active middle ear implant. Typically that input is going to be acoustic.

We'll talk about an exception, of course, but typically that's going to be acoustic. The output of what's actually delivered to our patient is not acoustic like that traditional hearing aid. Instead, it's going to be a mechanical energy, a mechanical motion that's actually driving the ossicular chain, driving the middle ear system to deliver that signal to our patient. So there are three different transducer types or technology types that we can use to achieve middle ear implant technology. Active middle ear implant technology.

So we'll talk through the piezoelectric material, the use of an electromagnetic device, and then taking that device one step further with electromechanical. So the thing to just be aware of on these images is that they're not to scale, obviously. So I have an image of a piezoelectric crystal here on the left and an electromechanical example here on the right. Those are obviously not to scale, but we'll talk through why that's relevant to have these images here. So let's first talk about piezoelectric crystals.

Piezoelectric materials are materials that when you apply electric current to this organic material, the material itself will change shape and it will expand or contract based on the direction of electrical current that's applied. So where are we going to get electrical current from? Well, recalling that microphones, hearing aid microphones, and microphones of any sort act as our first transducer in the system. So those microphones are going to take the acoustic energy of the environment and change that energy into an electrical signal. So transducing acoustic into electric, of course, our system then is going to take that electric signal and amplify it to be appropriate for our patient.

The way piezoelectric crystals work is as we apply that electrical current, that's going to create expansion and contraction of the actual material, which creates mechanical motion.

So there are a couple of different organic materials that, that have piezoelectric properties. But the material that you're going to see in active middle ear implants is lead, titanium, zirconate. And so that is the specific organic material that's used in piezoelectric active middle ear implants. So the way this technology works is we have that electric signal that has come from, let's say from the microphone that has converted acoustic to electric. That electric signal is then applied to the piezoelectric material.

And that material is going to contract or expand based on the direction of the current. So positive current is going to create an expansion and negative current is going to create a contraction. That movement of the material itself creates mechanical motion. And so I have here an example of a bimorph piezoelectric material. And so in this case, we have actually two pieces of piezoelectric crystal that are fused together with opposite polarity.

And so when you provide the current to this piece of material, one piece of material is going to expand while the other one contracts. And so that creates this bending. And then when you apply the current with the opposite polarity, it creates a flexion. So we end up with this material that actually bends and flexes proportionally to the original acoustic signal. So thinking about those peaks and troughs that are in that original acoustic signal, those are represented as the electric current is delivered to this piezoelectric material.

So literally have this mechanical motion that's created as the electric current is applied.

So the one active middle ear implant that's current fda, currently FDA approved for use in the US is the Envoy Esteem. You, you may have heard of it, you may have had patients ask you about it. Not only is it the only FDA approved device in the US it's also the only fully implantable device. And so a couple of images that just sort of show how this device is implanted and the function. You have the processor itself, which is going to be implanted underneath the skin in a similar location that a cochlear implant would, would be implanted.

And then from that processor you have two leads. One of those leads connects to the head of the malleus. The other one of those leads connects to the head of the stapes. And one thing I want you to notice here is that part of the surgical process related to this device is the fact that part of the incus is removed. So we talked about how intact ossicular chain is required, but through this surgical process, the ossicular chain is, is disarticulated.

And so we have part of the incus that's actually removed.

So a couple of videos that the company provides on their website, you've got the signal in, in the case of the Esteem, because the entire device is implanted, you have the signal that's going to enter the ear canal like a typical acoustic signal would. We're going to have movement of the tympanic membrane.

So the tympanic membrane is going to vibrate just like normal. And that of course is going to move the malleus. Now, attached to the malleus is this sensor.

And so you can see the sensor here on this image in the right. So we have that sensor that's attached that when the tympanic membrane vibrates and the malleus vibrates, that's going to move this little rod here. That movement is going to transduce the mechanical motion of the TM movement, the vibration of the malleus moving into an electrical signal. So we have right here in the very beginning, this acoustic signal that comes in. TM vibrates, malleus vibrates and then we have this signal that's sent from the sensor up to the processor, which is labeled number two here.

At that point, that electrical signal would be modified and amplified to be appropriate for our user. And then from there it's going to be sent down this other lead to the driver. And so what you can see on this driver, this number three here, this bottom piece here, is our piece of piezoelectric material. It's a bimorph. And so that's how this, applying this electrical current to this piece of, well, two pieces of piezoelectric material that when you apply that electrical current, they're actually going to bend and flex and push the stay piece in and out of the oval wind window just one more time looking at that video.

So the envoy is again one of the only, well, it is the only commercially available and FDA approved devices.

So if patients have heard anything about it, it's probably very, very appealing because there's not any, there's not any external hardware completely implantable. There were a couple of radio hosts that were doing a promotion of this technology. So if you haven't heard, if you haven't had patients ask about it, I'm sure they will soon. So that's our piezoelectric material again. We're creating that mechanical motion through applying electrical current.

The second transducer that is available for active middle ear implant technology is our electromagnetic. And so we'll talk through electromagnetic.

Electromagnetic. Middle ear implant technology is going to use induction. So think about telecoil. Think about using the telecoil with the phone or in an induction loop setting or a lasso setting. It's the same technology, just applying it in a little bit of a different way.

So with induction technology, we're going to have a coil of wire. And when that electrical energy is applied to that coil of wire, that's going to create an electrode magnetic field. It's that electromagnetic field that then drives a magnet to create mechanical motion. So again, we've got mechanical motion that's being created and delivered to our patient. But in this case it's because we've applied electrical current to a coil of wire.

So electromagnetic active middle ear implants use really have two main components, a biocompatible magnet as well as an induction coil. And so in this image you've got the magnet that is affixed to the incus directly and then you have this deeply seated ear level device that includes an induction coil. And that's what you see here, that's kind of this gold copper color is the induction coil itself. So you have to have both pieces in an electromagnetic active middle ear implant, both the magnet and the induction coil. The magnet is typically affixed to the ossicular chain.

In this case, you can see this would be a pretty non invasive surgical procedure. The physician would lift the tympanic membrane to place this small magnet and then suture up the tm. So pretty easy, easy for us, right, because we're not going through it. But non invasive in terms of surgical procedures, minimally invasive, I should say. And then we have that induction coil that's very close to that.

Those two things have to be the, the induction coil and the magnet have to be very close together. The further they get apart, the lower the signal is going to be once it actually reaches the patient. So, so you can see and, and I've got another pict in a minute, but you can see how deeply seated that ear level device is. And you would need that, that deep seated device to be there. So how does this technology actually work?

We have this acoustic signal again that's going to be converted to an electric signal by the microphone. So the first transduction of the signal from acoustic to electric is going to happen at the microphone. And then that electrical is going to be amplified, modified to be appropriate for our user. That electrical current then is going to be delivered to an induction coil. That induction coil is going to create a fluctuating electromagnetic field.

And that electromagnetic field is going to fluctuate proportionally to the original acoustic signal. So a more intense signal is going to create a bigger fluctuation, a softer signal will create smaller, and that fluctuation or oscillation is going to match the frequency of the original acoustic signal. So we have this fluctuating electromagnetic field that is created at the level of the coil. That fluctuating electromagnetic field is going to attract and repel the magnet that's been implanted. And so that movement of the magnet is the, the magnet itself is going to oscillate, again, proportional to the original acoustic signal.

So thinking about your peaks and troughs in the original acoustic signal, that is going to correspond to your pushing and pulling, if you will, of the magnet that is affixed to the ossicular chain. So that movement creates motion, mechanical motion of the ossicular chain. So we've taken this electrical current and created an electromagnetic field, Used that electromagnetic field to actually drive a magnet that's attached to the ossicular chain.

Med El has an active middle ear implant Called the vibrant sound bridge. Unfortunately, it's not currently available for fitting in the US or for surgical intervention in the US So. But we can still talk through it. Maybe eventually we'll get to this point. So the Med El sound bridge, Vibrant sound bridge has an implant that looks a lot like a cochlear implant.

So the implantable device looks very similar to the body of a cochlear implant. The difference is what's on the end of the lead. So instead of having the electrode contacts, like we would see with a cochlear implant or auditory brainstem implant, the sound bridge has what's called a floating mass transducer. And so you've got the image here. Now, if you look closely, you can see that this floating mass transducer Is made up of an induction coil.

And so you can see that the. Those that coil of wire, the copper color coil of wire, that coil of wire is actually surrounding the magnet. So with the vibrant sound bridge, we have the magnet and the induction coil in one casing. And that casing is affixed to the ossicular chain. Typically the Incas, Although there are a couple of different configurations that the surgeon could select.

So there could be. There's one that drives in the round window directly, this one that I'm showing that affixes to the incus. And the surgeon would likely make the choice which adapter to use there. So the sound bridge is not fully implantable. So the patient would use, currently, the SAMBA 2 external speech processor.

This is the same processor that they're using with their cochlear implant recipients. And the Samba 2 would work along with the vibrant sound bridge. So the main components of the vibrant sound bridge, the floating mass transducer, which we looked at quite a bit, the whole package of the implant, of the internal device Is called the vorp, and that stands for vibrating ossicular prosthesis.

So how does it actually work? And this is a better picture of. You can see that internal device here. You can see the floating mass Transducer here. The other thing that I really like about this image is that you can see the antenna of this internal device.

And so when the signal is being sent from the processor across the skin, it's this antenna here that's actually going to receive that signal. So I like that you can see that. So how's this technology work? We're going to have the acoustic sound signal that comes into the microphones of the speech processor. Of course the speech processor, the microphone of that processor is going to convert the acoustic signal into an electric signal, modify it to be appropriate for the patient's needs, and then that signal is going to be sent across the patient patient's skin to the internal device through a radio frequency transmission, the same transmission that we use with cochlear implant technology, auditory brainstem implant technology, where what's being sent across the skin is both data and power, which might be magic, I'm not sure.

So we have this, this data and power that's sent across the skin through a radio frequency transmission received by antenna which you can see here, this copper colored antenna here. From there the signal is sent down the lead to the floating mass transducer. That electrical signal is going to be applied to the coil of wire that's part of this floating mass transducer. On the inside of that floating mass transducer on the inside of the coil of wire is the magnet. So that electromagnetic field that's generated is going to create movement of the magnet itself to drive the ossicular chain.

So from, from coming down this lead and being applied to the coil of wire on the floating mass transducer we have this electromagnetic field creates movement of the magnet which drives the stay piece in and out of the oval window.

Another system that makes use of the electromagnetic technology, a system from ototronics called the Maxim system. This one is not currently available, but I think it's relevant to talk about in case, you know, we get to this point where more and more of these technologies are available. This is a larger image of what I showed you earlier where with this technology we actually do have the induction coil outside the middle ear space. But the magnet that's implanted on the ossicular chain are affixed to the ossicular chain. And I like these images because again, it shows the deep seated need for the ear level device, which looks sort of like a cic, only a little different.

But it does have a microphone on it. And so the signal would come into the ear canal like normal. We know that when we put the Microphone that deeply seated in the patient's ear canal, that the overall sound quality should be more normal and natural. We get to take more advantage of the natural resonance of the pinna and some of the ear canal and so some natural localization. So from a sound, a sound perception position, this placement of the microphone is great.

However, it's a pretty deep seated device and you can really see how closely this induction coil is to the tm. This image really shows how small that little magnet is that's implanted and affixed to the ossicular chain. I like this close up of that magnet with the mechanism that's used to actually affix it to the Incas. And this image shows a different version of this ear level device. But I like that you can see the induction coil here and see the size of the magnet in comparison to the this ear level device.

So this is a custom device and would require a pretty deep impression. So not currently available, but good to know about anyway. This is a US based company which I think is, is good to know about too. So our last technology to talk about with active middle ear implants is the electromechanical technology. So electromechanical, some will lump electromechanical with electromagnetic.

I like to separate it because the electromechanical technology adds one more piece to the technology. So with electromagnetic we just have the induction coil, we have the magnet and that electromagnetic field drives the magnet. With electromechanical we have the addition of an actual driver or armature. And so let's talk through those again. Not to scale these pictures, but I like that I can show you the components of these electromechanical devices.

So with electromechanical active middle ear implants we're going to have a driver, we'll have an induction coil. So you can see here, this induction coil that's in this packaging we're going to have have two magnets that are a part of this central casing. And then we have an armature here that drives this rod. So with electromechanical active middle ear implants, we're using electrical current to drive that mechanical motion and specifically delivering that motion with an artificial incus or some sort of rod or drive.

So electromechanical active middle ear implants use a single casing, an all in one packaging that includes the magnet, the induction coil and some sort of driver or artificial incus or armature, something like that. This type of active middle ear implant really was designed to you get around the problem that we, we saw with particularly the ototronics type of a design where you have this distance between the induction coil and the magnet. So understanding again, that the further away those two things the induction coil and the magnet get from each other, the lower the signal strength is once it reaches the patient. So if we can eliminate that distance, distance, then that helps us preserve the signal strength as it reaches the patient. So in electromechanical active middle ear implants, we have an all in one packaging so that we eliminate that distance between electromagnetic field and magnets.

The transducer itself is going to be affixed to the ossicular chain or the round window. And again, this image, of course, is not scale. So a little bit of a deeper dive into how the electromechanical active middle ear implants work. If we were to take that, that casing and sort of slice it in half so that we could get this internal view, the bits that we would see inside would include the coil, the magnets, a diaphragm, a rod, and the armature. So if we look here, this orange area here is supposed to represent a coil.

So it's as if the coil of wire is going around and around, around this, this internal rod. That coil of wire is our induction coil. And so as our signal comes into the system, our acoustic signal is converted to an electric signal and that electric signal is applied to this coil of wire. That coil of wire again, is going to generate an electromagnetic field. That electromagnetic field, of course, is going to oscillate.

It's going to oscillate proportional, proportional to our original acoustic signal. And that oscillation is going to drive the magnets that are a part of this system. So in this case, in this case of electromechanical active middle ear implants, we have two magnets that sit on either side of an armature. And so when those two magnets are moved with the electromagnetic field, that's going to drive the armature up and down and ultimately drive the rod that's going to create the mechanical motion pushing on the ossicular chain to create a push and pull movement.

So Cochlear, a number of years back, acquired a product that was developed in the US From a company called Otologix. They were a Colorado based company and they were developing a fully implantable active middle ear implant. And, and Cochlear bought the rights to this product and have continued some R and D into getting this product market ready. But it's not available for use in the US but maybe eventually we'll get to that point, this is a really interesting concept. So on your left here you have this carina implant from Cochlear.

So Cochlear took the original otologic projects design and made some modifications. And so this is Cochlear's version. Again, the body of this implant looks very similar to a Cochlear implant or auditory brainstem implant. So you've got actually a magnet in the middle. We'll talk about that in a minute.

It should have an antenna here, which I think if you've seen Cochlear's dummy internal devices, they don't typically have the antenna, which I think is what is going on here. But we don't see the antenna, but it would be there In a live device from this implant body, we have two leads. One lead you'll see goes to this device that's labeled microphone. And so this product, this device is designed to be completely implantable with a microphone that's implanted under this skin. So that microphone again, would convert acoustic signals into electric signals and deliver that electric signal up to the processor here.

That signal would be modified for our patient, amplified to be appropriate for the patient, and then would be delivered to the actual driver, which is this other lead that's here. And so you can see on the driver what they're calling the actuator, there is actually a rod driver that's going to be attached to the malleus.

So super interesting system there is. You know, it's hard to conceptualize how a microphone under the skin might provide a clear signal, which might be why it's still in development. But this image here kind of shows where everything would be implanted. So you'd have this device implanted behind the ear, you know, in the same spot that a cochlear implant or auditory brain stem implant internal device would go. And then you would have that lead with the driver that's connected to the malleus and would actually drive the ossicular chain.

Now, Cochlear has designed this product. And this is, this is a step away from the original, original, original design. Cochlear has designed it so that the patient can add an external speech processor. So that's why you have the magnet in this internal device. Cochlear.

The idea is if the patient's hearing thresholds were to change or if the patient was to go into a more difficult listening environment, an environment with noise, an environment with reverberation, they could add the external process. So a lot of flexibility with this device that the patient could use it in a fully implantable context. And then if needed, they could add their speech processor to it. Another interesting design of the Carina is that. And you can see on this left, on the graphic on the left that it says battery.

So this internal device does have a battery that's in a it that has to be recharged. And so on the right side, I've added an image of what this charger looks like. So our patient would need to spend some time attached to their charger every so often, every day or so, they would sit with this charger, with the magnet, so it attaches with the stays close to the internal device, using the magnet that's implanted there and for about 45 minutes, and that would fully charge their internal device. Limited research on this device has shown some benefit, some improvement in AFAB scores, all four subscales of the afab. So in quiet, in background noise, in reverberation, and with aversion to loud sounds.

So there may be some promise and benefit with this device if we can see it move into our market.

So we've talked through the different types of technologies that can be used. We've talked about different devices that are available. The one commercially available device right now in the US the esteem. But let's talk broadly about the benefits and limitations of this technology. We talked about those patients who may have difficulty with their traditional amplification.

So difficulty with feedback, difficulty with distortion, comfort level, occlusion effect. So we're able to provide gain to those patients who have some difficulty with conventional amplification, traditional amplification through the use of active middle earth implants. And there is the fully implantable option, which is, is, I'm sure, very, very attractive to probably a lot of patients. Limitations, on the other hand, a lot of patients are going to be discouraged by the surgical aspect. In our fully implantable technology certainly is a more invasive surgical procedure than something where just the magnet is being implanted.

So there's a surgical procedure that is going to be discouraging for some patients. Of course, with that come the risks of surgery and then recovery time and all of that. The literature that's out there on active middle ear implants has shown that the expectations with active middle ear implants either meet traditional amplification or maybe are a little bit lower than our expectations or outcomes with traditional amplification. So other technologies we're seeing either meet the expectations that we get with active middle ear implants or exceed. So our traditional hearing aids may actually exceed the outcomes with active middle ear implants.

You know, there is a concern that if the patient goes down the route of an active middle ear implant and they're dissatisfied with the results, certainly we have patients who aren't satisfied with their ample amplification for one reason or another. And obviously in this case it's very difficult to go back to a traditional amplification, especially if you've gone through the surgical procedure where part of the ossicular chain is removed or disarticulated. There is somewhat of a cost to this technology. There's a financial cost, There is of course, a time element to it, the effort on the part of the patient, the other resources that go along with managing healthcare needs and audiometric needs specifically. So there is a bit of a cost to active middle ear implant technology.

And then of course, provider familiarity. You know, I think it will gain, people will gain knowledge and experience over time. But right now there aren't a lot of people who are, who have this familiarity. So once our device has been implanted, what does rehab look like? What does our oral rehab look like?

Typically we are going to have device activation three to four weeks post operatively. We have to give time for the area to heal, the patient to heal, and then we're going to have some frequent follow ups. So just like with our traditional amplification, a week after activation, one month later, potentially at least twice during the year. And then we want to keep up with our patients annually. The esteem, the device from Envoy Medical, the one that's FDA approved, currently has a personal adjustment device.

So the patient actually has excess access to make some adjustments themselves. What I love about Envoy is they have a very audiology focused ear, nose and throat physician focused model. And so when you look at their website, when you look at their materials, the patient has access to make changes to their device themselves. But they also, the company itself really refers patients back to their audiologist for additional help and support.

So just one thing to mention about that, our oral rehab, you know, all of our patients with hearing loss, we would love to have them in an oral rehab program to help focus on speech reception at all the different levels. So at the phoneme level, at the word level, at the sentence level, getting them used to listening to this amplified signal and making use of that signal in the most efficient and effective way. It's great to reevaluate your patient with the COSI and or AFAB that allows you to readdress concerns, maybe make modifications in technology or programming to help address concerns that aren't being met. It can help you again address Realistic expectations. So if your patient is talking about things that you know just aren't a possibility, going back through the Cozy and the AFAB give you the opportunity to readdress those and so lots of counseling with continued difficulties.

Realistic expectations and these. The oral rehab of course can be focused in a group setting which is really helpful for patients to be in a room with other people who are experiencing similar similar situation or in one on one settings.

So where have we been in this hour? What we've talked about are the different types of materials that can be used in active middle ear implant technology. So we've talked about piezoelectric, we talked about electromagnetic and taking that electromagnetic one step further with the electromechanical, we looked at very specific devices that employ each of these different types of middle ear implant technologies. Currently the Esteem is the one device that's fully implantable that it's FDA approved for moderate to severe sensorineural hearing loss in adult patients. And we talked through the Med el sound bridge which is not currently available in the U.S. there are some studies, peer reviewed literature that suggest that outcomes with active middle ear implants are at least as good as outcomes comes with traditional hearing aids.

Certainly patients who have experienced difficulty with traditional hearing aids may be a good candidate for active middle ear implants. And then the limitations really being the surgical intervention, lack of flexibility and then our cost that goes beyond just the financial cost.

So I really appreciate you being here with me today and I am very happy to open the floor for questions.

So I have one question that is would you consider a person with extreme dexterity issues to be a candidate for this device? And I would say absolutely, that would be a great person to consider for an active middle ear implant like the Esteem where everything's implanted and there's not any, there's no cleaning or maintenance, changing batteries, that has to happen. So absolutely a fantastic suggestion to consider patients with dexterity for this, for this technology.

Another question that's in the chat box is the longevity of the devices and concerns about ossicular chain changes eroding of those. And I would say that would be a consideration. Most implantable devices are implanted with the idea that they would be implanted for the lifetime. So I'm not actually sure what the longevity would be.

So I appreciate the question.

Okay, another. Do I have time for one last question? Yes, please. Okay. Okay.

So one last question. Is the difference between. Just a little more information on the difference between the electromechanical and electromagnetic. The technology overall is the same. The real difference with electromechanical and electromagnetic really is the addition of some extra hard hardware with the electromechanical.

So the overall premise of creating the electromagnetic field by delivering the electrical current to a coil of wire and when we do that, we create the electromagnetic field that drives a magnet. The the only difference in those two technologies is the addition of of the driver, the addition of a very specific piece of material that would drive the ossicular chain. And feel like that's an important distinction to make that we're adding hardware to the electromechanical versus a traditional electromagnetic. So thank you all for being here with me today. And I'm going to turn it back over to Kristi.

Thank you very much, Dr. Adams, for sharing your time and expertise with us today. This was a really interesting webinar and really helped me understand these devices devices much, much better. So thank you. I'd also like to thank everyone who participated in today's webinar. Don't forget to look for the exam in your pending courses page.

It should be there in about 15 minutes. And remember that you need to complete that within the next week in order to obtain CEUs for the class. We look forward to getting your feedback on the course evaluations and hope to see you on future courses on audiology online. And this concludes today's course, so have a great rest of your day.