[MUSIC PLAYING]

BARRY HIRSCH: This is an exciting topic that we have about devices that can significantly help people's hearing. And they're varied, and I want to go through some of the specifics and generalities also. What these devices are, what the indications are, what they look like. And what questions you may want to ask of who is going to really be a candidate. I have no financial disclosures. There are some people who contributed pictures and photos. I'd like to thank them as listed on the slide along with the companies that are mentioned below.

So we're going to be talking about implantable devices. These are things that are placed either in the middle ear, or behind the skin or underneath the skin, not things that are in the external canals. So we're not talking about, let's say, hearing aids or a Lyric hearing aid. We're going to break this down into three topics. The first is going to be middle ear implants, then talk about bone-anchored hearing devices, and then finish with cochlear implants.

I'd like to recognize the contributors to Dr. Myers and Snyderman's*Operative Otolaryngology,* that's going to be coming out this year. Much of the information is provided by the authors that I cited. And this information regarding these devices is also covered in this textbook in a more comprehensive fashion.

So let's talk about implantable middle ear hearing devices. Who's a candidate for that? Well, they're not approved in kids, so it has to be done in an adult. You've got to have moderate to severe sensorineural hearing loss. And the middle ear anatomy and function must be normal. So there cannot be any pathology or previous conductive components for these particular devices. People should have failed using hearing aids for either comfort reasons or quality, acoustic feedback, or canal irritation or the sense of occlusion. So they are not happy with how the cochlear-- how their hearing aids are functioning for them.

There are three companies that have FDA approval in our country. This is the Esteem implant, the Vibrant Soundbridge, and the Maxum. We're going to talk about that. You may have heard something about what's called the Earlens hearing aid. It's a device that's attached to the tympanic membrane by contact. This is not an implantable device, and it's of a separate subject.

So this Esteem hearing implant, this is the only fully implantable device that's around. It works off of piezoelectric sensors and transducers, so there is no external microphone. Its power source is a lithium battery like a pacemaker, that's also implanted underneath the skin. And the sound processor, which is part of that device, has automatic gain control and programmable compression circuits. So this is what the device looks like. On the left is the processor, the battery itself, and wires that come in and out of the device, having a sensor and a driver. The sensor is attached to the stapes-- to the incus, and the driver is attached to the stapes.

So how does this work? There is a connection between the sensor that's on the incus itself, but the incus has to be disarticulated from the stapes. So what happens is sound vibration comes into the extremal canal, vibrates the tympanic membrane, sets the malleus and incus into vibration, which is picked up by the sensor. The information's travelled back to the processor. And then a signal is sent down to the driver which drives the stapes in a more exaggerated fashion than just sound waves alone can do. But the ossicular chain is disarticulate.

This is showing a picture from Jack Shohet. This is showing the sensor positioned on the incus on the left picks up the signal, and then it's delivered through a wide facial recess to the driver positioned on the stapes capitulum. So some features about this, you need to have some real hearing loss between 40 to 90 decibels. Word recognition scores have to be greater than 40%. This is a technology labored device that has a steep learning curve. So this is not something you just do out of the bag. It requires going into courses and then being proctored initially.

You need a well-developed mastoid and normal tympanic membrane in middle ear. And, as I mentioned, it requires permanent disarticulation of the IS joint. So that commits you to a maximum conductive hearing loss. So if the device is not working, you have to go back and fix the ossicular chain. Because of the wide size of the facial recess that's needed, the chorda tympani nerve often has to be sacrificed. So taste is sacrificed. Because of the metal and magnetic properties inside the sensors, you cannot have an MRI in the future. During the placement of the device a field engineer has to be present for doing intraoperative testing to make sure that the devices are hooked up properly.

And once completed, the device is actually hooked up at eight weeks. There's a battery inside that lasts approximately five years, that would have to be changed. And this could done under local anesthesia. But the FDA clinical trials show that it brought the speech reception thresholds down to 29 decibels and word recognition scores actually increased up to 69%.

JONAS: So Barry, let me just ask you, this looks to me to be a really fancy way to amplify. But as you point out it requires a pretty technically challenging insertion. Is this covered by insurance?

BARRY HIRSCH: No, this is not. This one and a device that we are going to be mentioning, these are not covered by insurance. Although they're implantable hearing devices like you'd think a cochlear implant is. This is not approved to get reimbursement from insurance companies.

JONAS: So this is an alternative amplifying system, alternative to a hearing aid, and sounds pretty expensive.

BARRY HIRSCH: Yes, and we'll talk about the price if you want in just a few minutes.

So the Vibrant Soundbridge is another one. This was the first semi-implantable, so that means there is an outside device component to this. This has initially gotten approved by the FDA by Symphonix, and now it's run by MED-EL. Again this is only in adults. Moderate to severe sensorineural hearing loss has to be present, no conductive loss. Word recognition scores have to be greater than 50%. Everything has to be normal within terms of the tympanic membrane in middle ear. And ideally, it's a prior hearing aid user who is unhappy with how they're performing.

This gives you a pictorial understanding of what the hearing pattern is for the appropriate candidates. And again, word recognition scores is greater than 50%. So this VORP, this vibrating ossicular prosthesis is shown in the main square. The device is inserted underneath the skin. And the conductor link is carried down through mastoidectomy and through a facial recess, the part called FMT or floating mass transducer that's clipped onto the incus. And the power, this is done where the electromagnetic device, the floating mass transducer excessively vibrates the stapes in a sense more than sound energy could.

And the device is powered by a processor, which is known as the Amade audio processor, which is not like a behind-the-ear hearing aid, but as a separate disk. This is done through the facial recess. We're seeing right facial recess here looking at the round window. And just to the left is the incus stapes. And the device is placed underneath the skin, the wire passed through the mastoid and facial recess. And then this is then clipped onto the incus. And it's very important to have that canister, the floating mass transducer oriented in a perpendicular manner, so it doesn't give distortion of sound vibration.

This outside processor is also activated at eight weeks. There's interesting studies that are being done with the Vibrant Soundbridge. Initially, that's only approved by the FDA for sensorineural hearing loss. Applying this to the round window may actually help conductive and mixed hearing loss. And these trials are ongoing in Europe. So the floating mass transducer sits perpendicular to the round window and is encapsulated by fascia.

This potentially could be used in people who have problems with failed PORPs and TORPs. They keep on extruding, and if you're able to cover up the promontory and put this device in the round window, it may be a means of helping conductive or mixed hearing loss as well. But again to emphasize this is investigational.

The third that I want to mention is the Maxum hearing implant. This also is a semi-implantable electromagnet. There is a part in the external canal called the integrated processor and coil, the IPC. And this sends electromagnetic energy to the middle ear to a device that's attached to the incus and stapes. That device is attached by laser heat as well as a neurologic cement, ionomer cement. This is the place through, this is showing the left ear with a tempanomeatal flap raise, showing that the device is being primped onto the incus stapes.

There is a cement showing, it's fusing it to the incus. And this round light reflex that's coming off the operating microscope is called the full moon light reflex. This indicates optimal positioning of the device, and that it's probably oriented in a perpendicular manner to what you're seeing. So the outside device has the electromagnet-- that sends electromagnetic signal across into tympanic membrane that brings this device to its vibration on the stapes and incus.

JONAS: So these three devices have in common that they require a reasonably normal middle ear. They're for people who can't wear or don't want to wear a hearing aid. But it requires surgical implantation, and none of them are covered by insurance.

BARRY HIRSCH: Correct, I mean there's the rare situation that some policies may, but in general you have to consider this is going to be an out-of-pocket expense. And again, this is doing one ear and a lot of people would like to have things done on two ears.

JONAS: So I want to remind the audience that you're invited to email us questions, if you have one. I'll pick it up on the email here, and we'll try to discuss it as we go on.

BARRY HIRSCH: So let's move on to bone-anchored hearing implants. Now this is different again because the previous ones that we mentioned did not carry indications for conductive hearing loss or mixed hearing loss, where a bone-anchored hearing devices are certainly geared towards that. As opposed to even a cochlear implant, they don't go for conductive or mixed hearing losses. And certainly, this could be done for single-sided deafness.

There are three companies that provide devices. One by Cochlear Corporation is called the BAHA. There are two versions that it has. One comes through the skin which is a percutaneous attachment. And the other goes across the skin which is transcutaneous. The Ponto device by Sophono is a percutaneous, the device comes through the skin. And the third Alpha 2 by Sophono is Medtronic's. And that's a transcutaneous, meaning that's done with magnetic attraction.

So the three types of hearing patterns that we can see are on the left. Conductive hearing loss, where the bone line is normal. In the middle we see a mixed hearing loss, where there's bone line deterioration as well as the conductive hearing loss. And then the third is that single-sided deafness, where one ear is anacoustic and the other ear can have up to about 20 decibel loss.

For those that have to come through the skin or percutaneous devices there's a sequence of surgical steps that are followed, that are similar both for the BAHA and the Ponto. First you'd like to know the thickness of the skin. And this is measured by taking a needle and hemostat and just literally grasping the hemostat at the skin level and on a ruler measuring the distance of the skin. And this should be done prior to the skin being infiltrated with local anesthesia.

And we'll go through this going from left to right. The skin incision is made, we want to have the anticipated place of the device about 10 millimeters posterior to the skin incision, so that skin is retracted, periosteum is elevated. And then using a guide drill, showing up in the upper right hand corner, the guide drill is drilled initially to have a 3 millimeter. And then as the cap is taken off, it creates a four millimeter depth for the guide drill. If that's the sufficient distance, then a widening burr-- which is shown in the middle in the right side-- showing that four millimeter widening burr opens the bony channel in which the implant is placed. We see in the lower left picking up the implant, this is called the fixture. And when it has the attached abutment that's as a single piece that can be picked up and placed in as one unit as shown in the lower middle screen.

There the device is placed in, the skin is brought back over the device. And where you see it protruding, then the skin biopsy punch makes a five millimeter hole over the device, and it's poked through. The skin is closed. And then the device, as we say, is chosen based on the length of the skin. And these are showing the different devices that we can have from BAHA and from Pronto. Based on the skin thickness will tell you what device to choose.

A healing cap is placed on top of the device and underneath that either Xeroform or a foam pad is placed to evenly distribute some pressure. That's left on for seven to 10 days, usually put a Glasscock dressing on overnight. But this device, this packing comes off about seven to 10 days after. If it looks like there's still residual edema, it can be put on for another week. But this is then taken off and a wound is allowed three months in which to heal.

If there is a bone line loss, sensorineural hearing loss up to 45 dB, from the two companies that we see here BAHA has the BAHA 5 and Ponto the three, those devices can be used with a conductive hearing loss on top of a bone line of 45 dB. And as we go up 10 dB, the name of the processor and the strength increases to the BAHA 5P and the Ponto 3 Power. And then the final one, even up to 65 decibels of bone line loss in addition to having a conductive loss, these more powerful, bone conducting devices adequately provide that kind of stimulation.

So we've been talking on the right of what's called the BAHA Connect, and that's where it comes through the skin or percutaneous. There is the BAHA Attract which is transcutaneous, and again the attachment is done by magnetic attraction. This, unfortunately, does not provide the same degree of bone stimulation that the Connect does. So you can only have up to a 30 decibel conductive bone line loss for a magnetic attraction. And the stepwise thing here is that a template's used, you need to have at least a 15 millimeter arc of planned incision away from where the magnet's going to be inserted.

As we go across the semi-circular canals-- semi-circular skin, flap is elevated. The magnet device template is placed there. A guide burr is used to create the hole, you create a widening burr that sets up for us to place the fixture screw which is shown in K in the lower left. With that fixture screw in place then the magnetic component, the magnetic disk can be attached. That is simply screwed into the fixture. The orientation is important, because the outside device really depends on that orientation of that magnet. It's important when you close up the skin that that dead space be closed, and the reason is is that you just don't want seroma forming there.

Again we'll put on a Glasscock type dressing for one to two days depending on the edema. This is allowed to heal. And then after 30 days this device can be hooked up, because there's no real significant torque like there is on the Connect type device. And here we're seeing the processor magnet and the skin incision that's nicely healed. Despite this having a magnet, this is still safe to have a MRI scan.

The Alpha 2 system, again there's no percutaneous attachment. This is abutment-free, nothing's coming through the skin. There is the outside magnet that attaches to the underneath titanium implants that have magnets within them. And this also is indicated for a conductive hearing loss, mixed hearing loss, and single-sided deafness. The bone conduction has to be a little bit better than with the other device, has to be better than 45 decibels. And this is what the device looks like. The outside device is shown on the left. And the two sides of the device that's implanted, that has magnets within a titanium case, are shown on the right.

And this is done by elevating a skin incision with the idea where the prosthesis is-- the device is going to be placed. Two wells are created that have to be approximately two millimeters deep with an intervening bridge. And then using screws, this device is attached to the skull, the skin is closed. And again, healing takes approximately one month. And then since there is no penetrating abutments, there's no real torque on the device, this is considered single stage surgery. And after a month the device could be-- the processor could be fitted.

JONAS: So Barry, we do have a couple of questions from our audience. I guess, the first one is these implantable devices are still not covered by insurance?

BARRY HIRSCH: No, these are all covered by insurance.

JONAS: So this can be covered.

BARRY HIRSCH: Yes, so the implantable middle ear devices, where the middle ear is normal and you're doing it just for sensorineural hearing loss, no coverage. These devices, which can occur for mixed hearing loss, conductive hearing loss, that says these people cannot use a hearing aid at all, because they are having trouble or wound issues, then insurance will pick this up. There can be--

JONAS: I--

BARRY HIRSCH: I'm sorry.

JONAS: I'm sorry, go ahead.

BARRY HIRSCH: There can be exclusions based on the patient's insurance policies. They can actually exclude certain types of devices, but for the most part this is picked up by insurance.

JONAS: And you've been on the FDA panels and looked at some of these, how do you choose between the BAHA and the Ponto or the Alpha 2?

BARRY HIRSCH: One gets approved and the other can dovetail and get approved in a quicker manner, because they're a similar product. They offer slightly different attachments and how it attaches to the abutment. And the processor can be of a different strength. But once one's approved, then the others can come. And then what's it based on? Some of the fine points of the software that-- or some of the hardware that's attached, the cosmetic look of it. So there are things that a patient may be attracted to rather than the doctor or the audiologist saying this is the device you need.

JONAS: And this looks technically challenging, how long does the surgery take?

BARRY HIRSCH: This can be anywhere from 30 to 60 minutes. This is relatively quick for this kind of procedure. Whereas the other procedures, the-- especially that Esteem can take 3 and 1/2 to four hours.

JONAS: So the Esteem is the one where you disarticulate the incodostapedial joint, and then you actually have to put a sensor on both the incus and stapes. That takes three or four hours.

BARRY HIRSCH: Time-intensive and technically very challenging.

JONAS: OK, thank you.

BARRY HIRSCH: And just to finish up with the Alpha 2, this is what the outside processor looks, the magnets underneath that. And this is how we attach. And it seems to evenly distribute over the skin and not cause any compressions or skin break down.

We'd like to now go into the next session on cochlear implants. And there are three companies that are currently available in the United States. This is the Nucleus, Cochlear Corporation one in the upper left, Advanced Bionics in the middle in the bottom, and MED-EL SYNCHRONY system shown in the upper right. They are all similar, but they're all different. How are they similar? Well, you need to have bilateral moderate to profound hearing loss.

Your pure tone average has to be greater than 70 decibels. They have to have shown limited benefit from hearing aids. In fact, hearing is tested with the hearing aids in place. And with them in place, people have to score less than 50% when given certain sentences such as HINT or AzBios. Those are types of sentences that can be delivered while the patient's wearing the hearing aid. And if they don't understand the word clarity, and it comes under 50%, they're considered a cochlear implant candidate.

It's slightly different for Medicare. Medicare has more stringent criteria. Medicare ask that the criteria be under 40% instead of 50%. So here's showing a typical criteria for a cochlear implant patient. We're showing here in the yellow that patients have to-- can have upwards of a 40 decibel loss. And then if they get into the higher frequencies about 2,300 Hertz and above, it should be severe to profound loss.

We mentioned that sentence score responses can be no better than 50% in the ears to be implanted and no better than 60% in the best aided condition on the other ear. And again sentence understanding for Medicare patients is more stringent.

I'm going to just briefly mention about pediatric implant candidacy. Kids can be implanted down to 12 months of age. They need to have a profound loss which is shown in the blue bar on the lower right. Whereas once you get to age two and above, you can then be in the severe to profound loss. The other devices like the Hybrid, that we'll be talking about, are not approved for children or pediatric use yet.

So let's talk about these different devices. This is the one from Advanced Bionics. The Naida is their current processor, it's a behind-the-ear processor. They have a high-res 90k advantage implant. That's usually a high focus implant that's again placed into the scala tympani. And they have a Neptune device, a Neptune processor which is watertight, able to swim with this and have not only the head piece but the processor itself able to be going under water.

MED-EL's system is called the SYNCHRONY. The SYNCHRONY refers to a device that's placed underneath the skin with the electrode into the inner ear. And they have two-- actually three different kinds of processors. There's a processor in the lower left called the RONDO which is just an off-the-ear disk. The SONNET itself is your conventional cochlear implant. And then that on the right you can see the hearing aid mold portion, they were recently approved to have both a hearing aid and a cochlear implant in the same device.

Cochlear Corporation has a nice, thin profile device, and they have two processors, and actually three as well now. The N6 Electric Acoustic shows both a hearing aid and a cochlear implant. That on the right is the N6 Electric, which means it's only working with the electrode, the cochlear implant itself. And they also have a device that's called the Kanso, which is an off-the-ear device that we'll show you in just a moment. Each of the companies has a different design in their electrodes. And there are certain numbers that are designated for each of their electrodes.

In general, Cochlear Corporation has 22 electrodes, MED-EL has 12 pair, and Advanced Bionics has 16. And it's really based on their software that designates how these different electrodes should be stimulated. So we can't say that having 22 electrodes is better than 12 or better than 16. It all depends on how their software is hooked up to program that.

The receiver thickness has come under change over the past few years, which is wonderful because it makes it easier to implant these and have less wound problems. So the receiver thickness now goes up to 4.5 millimeters and down to 3.9. So as you can imagine what that looks like, in fact, having a slight recessed body of-- placing a bone recession into the temporal bone even lowers that profile even more. So this makes it a little easier to insert and hopefully not have wound problems.

I mentioned the off-the-ear processor, so this is the cochlear implant from MED-EL. Their device is called the RONDO. So specifically you're not seeing that behind-the-ear what looks like a hearing aid with a wire attached to the headpiece. This has sufficient bony attraction, [INAUDIBLE] magnetic attraction that doesn't have the concern about getting it knocked off.

JONAS: So do patients have to shave their hair to keep this on?

BARRY HIRSCH: No, no, if someone has very thick hair, it may be an issue, but usually the hair can be brushed to the side. And having just a thin layer of hair and a magnetic attraction is sufficient. And if not, the magnets can be made stronger.

JONAS: And in terms of day-to-day care, can they take the magnet off and get into the shower and that sort of thing?

BARRY HIRSCH: It's expected, so people do not sleep with this. They'll take it off. They go in the shower-- because this certainly would be like a hearing aid, you don't want that kind of wetness to occur to that.

And this is the off-the-ear processor we see from MED-EL called the RONDO. And now Cochlear has one called the Kanso, which looks very similar and functions in the same manner. And again, you can see these people have relatively thick hair, and there's not a problem with the magnetic attraction.

How about that water compatibility that we've mentioned? Advanced Bionics has a separate device called the Neptune, which can be hooked up to the headpiece. And that's attached either to the bathing suit or an arm band. Cochlear has an Aqua+ device. And MED-EL's device is a water-resistance and splash-resistant type of device and not immersible like these other two. And this is what this Advanced Bionics one looks like from showing that Neptune device. And the device can be hooked onto their swim goggles, their bathing suit or an arm band. So that's remarkable.

And Cochlear has something similar with a waterproof casing that can be placed around the existing device. And this is a waterproof coil that's attached and again provides that security of not getting moisture in there and letting usually a child swim in water and still hear.

Now this has been interesting, the MR compatibility has changed over time. Originally, it was said that if you have a cochlear implant, you have a magnet under underneath the skin, you cannot have MRI unless that magnet's removed. It still is the case with Advanced Bionics, but there have been some advances with cochlear implant and especially Cochlear Corporation and especially MED-EL. Their SYNCHRONY device has a unique magnetic design that we'll just over in a sec.

But what happens when you try getting a magnetic scan and with somebody who has a cochlear implant? So we're showing here on the right is someone with the magnet not in place. So it's taken out, but there is still enough metal within the device and titanium that it creates that kind of artifact that you're seeing in that right temporal lobe. What happens when the magnet's in place, the artifact gets quite enormous. And that is supposed to measure 11 to 12 centimeters. And that will just destroy any hopeful information you want to get, if it's especially affecting the left temporal bone.

It can be done safely now. But again, if you're doing head imaging, you're not going to get what you need. MED-EL, as I mentioned, has a unique design where that magnetic-- magnet is placed inside their casing and it's able to rotate. So when it hits the field of the MRI scan, it rotates in the orientation where it's not being pulled or not being misoriented. And you worry also about the magnetization, but with this kind of configuration MED-EL's device can handle MRI scan up to three Tesla. So certainly at the 1.5 Tesla, that we're used to seeing, it's a safe device.

And this is showing the MED-EL device without the magnet on the right. And then with the magnet, again, it will still mess up your image-- the information that you want to get from your scan.

I want to switch to meningitis prevention vaccination program. This was highlighted in 2002, when there was an outbreak of meningitis likely related to a position or related to one of the implants. And there was a higher incidence of meningitis in kids and also adults. And the CDC got together and figured out that there should be a protocol for trying to prevent this kind of problem and provided guidelines on which some meningitis prophylaxis especially for pneumococcus meningitis were proposed.

So the organizations within the FDA are mentioned here. The Center for Disease Control and the Advisory Committee on Immunization Practices were all behind and providing these guidelines. And specifically now since 2012 they recommend that pneumococcus conjugate vaccine, which is called Prevnar 13, it previously was Prevnar 7. Prevnar 13 should be given followed by the PNEUMOVAX vaccine, which is the pneumococcal polysaccharide vaccine PPSV23. And the timing of this varies a lot with the patient's age and their vaccination history.

So in general for adults you'd like to have the Prevnar vaccination done initially first, in two months then followed by the PNEUMOVAX vaccine. The pediatric has a very specific protocol based on the child's age and has to follow with a series of injections, vaccinations rather than the single ones that adults receive.

So let's look at this kind of hearing pattern. What would we do with this kind of good low frequency hearing and then mid-frequencies start to drop off a bit, and the high frequencies are terrible, and word recognition scores are 12%? In days until recently this certainly would not be a good candidate for a conventional hearing aid, because they certainly won't have good results with their word recognition scores. And their low frequencies, having less than 40 decibels of hearing would not let them be a candidate for a conventional cochlear implant.

So these people were really between a rock and a hard place. And even the implantable middle ear devices, that we started talking about initially, this word recognition score is too far gone to allow one of those devices to be implanted. So the low frequencies now are deemed to be pretty important and be able to provide some meaningful hearing, especially in background noise. So people who have low frequency hearing, can maintain that, they may do better in a noisy environment. And also it's thought that they do better when trying to listen to music as much of the tonality of music as provided in those low frequencies. So if those low frequencies can be protected, then certainly they may be able to get the benefit of the low frequencies for sound localization, and quality hearing, and the high frequencies for getting speech.

So comes along the hybrid system. And this hybrid system is remarkable in that you're able to place this cochlear implant with the hybrid electrode in people with essentially normal hearing in the low frequencies, then up above 2000 Hertz they can have a hearing loss of 75 decibels or greater. So that's the pattern in which they have to fit. So they have a very steep sloping hearing loss like I showed in that last slide. They-- that person can now get a cochlear implant, which would significantly help.

JONAS: So the low frequencies come from the apex.

BARRY HIRSCH: Correct.

JONAS: So is the strategy here to just put a shorter electrode in and leave the apex alone?

BARRY HIRSCH: Exactly, so you do not want to try traumatizing or having too long of an electrode going down to that-- going up to the apex. So if it's a shorter electrode, you're hoping that you're atraumatically not upsetting the cochlea and you're still preserving the low frequency. Despite doing that, it still happens. But that's the strategy, and it does work. And different electrodes are still being designed in order to make that happen.

JONAS: So you mention having trouble, I mean these implants, what's your experience? Do, for instance, people have complications with infections? Do surgeons have complications with the facial nerve? Are these pretty unusual?

BARRY HIRSCH: That's a great set of questions, and all are varied. So let's take the facial nerve. Facial nerve paralysis in the cochlear implant, it's got to be the rarest exception. It just shouldn't happen. You're doing it with facial nerve monitoring. Typically, you have imaging beforehand that shows the course of the facial nerve. So you should be cued up for that. That's a very serious complication that shouldn't happen.

Infections are rare. If you start seeing it early, you can treat it with oral or intravenous antibiotics. Again, that's rare. Complications like wound breakdown, yes that can occur down the road. And that can happen with people with frail skin, possibly smokers. So that can be a real difficult problem, especially if they start getting breakthrough of the device.

JONAS: And how long does a cochlear implant last?

BARRY HIRSCH: Ideally, a lifetime. So it's hoped that the device, that's placed in there, is going to be forward compatible to any modifications that are done to the external devices. So these devices are not normally taken out and replaced. They're only taken out if there's a true failure of the device.

JONAS: And then the external device houses the battery. So that can be swapped or changed.

BARRY HIRSCH: Correct, there are--

JONAS: Will they last a few years?

BARRY HIRSCH: The batteries last on the order of days. And they are like replaceable hearing aid batteries.

JONAS: Oh, OK.

BARRY HIRSCH: So this is like a conventional hearing aid.

JONAS: So you have to change them every week.

BARRY HIRSCH: Yeah, you have to. You can get rechargeable ones, which can last most of the day but have to be recharged or disposable batteries, which last a few days. And they also have to be changed. So the external sources are typical batteries similar to a hearing aid.

JONAS: So why don't they use those five year batteries they use in the middle ear devices?

BARRY HIRSCH: Well, those are implanted underneath the skin.

JONAS: They are.

BARRY HIRSCH: There is a lot more hardware involved. We take up valuable space. So I think, the external part-- if everything could be totally implantable, that's been a real challenge of cochlear implants. How do you get a microphone implanted underneath the skin other than the way the Esteem people did? So that's a real challenge. And if you can't get the microphone under the skin and something's still on the outside, then go with the safety of the outside battery sources.

So I mentioned the hybrid system, we're seeing that in the purple. And then down below we have the yellow, which is the conventional cochlear implant. And we do see that there's overlap. So people who fall in that area could potentially be candidate for one or the other. And there's decision making that goes between the audiologist, the surgeon, and the patient on which one to use. So again, here is your traditional cochlear implant from 40dB on. This is done by sentence recognition, less than 50%.

Here is the hybrid candidacy, and this is even more stringent type of test. This is done by word recognition, not sentence. This is between 10 and 60% of recognizing words, and that's certainly a harder task to do. Then the other ear can be a little bit better. But you can see that it's interesting that you can put a cochlear implant in somebody with essentially normal hearing up to the mid-frequencies, and then that's the drop off.

JONAS: So one of our viewers has asked a question. And that is that what if you lose that apical hearing, the low frequency hearing, will this short electrode be capable of giving you good results or do you have to replace it?

BARRY HIRSCH: That's a great question. So in the study that was done by the FDA seeking to approve this device, there were failures, people who lost the low frequency hearing. And a few of those people, because they were afforded anything that needed to be done, went on to have that device explanted and a new, longer device implanted. So that covered. However, the people who also lost hearing, those who lost hearing of the low frequencies and kept the device, they still did as well as people with conventional cochlear implants. Especially, when they were using contralateral hearing aid.

So the hybrid device picking up the high frequencies and a contralateral hearing aid, just regular sound amplification, they did better than they did in the pre-op condition. So I still think, even if you're not covering those low frequencies, the implant can still do well for you for electrically stimulating the high frequencies.

JONAS: So you and I talked about this earlier. But bilateral cochlear implantation, is this being done commonly in adults?

BARRY HIRSCH: It's being done, but I'd say it's not being done commonly. Kids, almost uniformly. Many patients who get a cochlear implant say, I'm doing great. I'm happy with my implant on one side, hearing aid on the other. They don't go for the second one. It really doesn't make things twice as good. But it certainly does help in difficult hearing situations, where there's a lot of background noise. Or it helps better with sound localization, it will do better with that as well.

So here what we're seeing is again two different curves, one that would look like the hybrid type of candidacy in orange and the green for the very typical severe to profound loss. And we could see where these two curves are quite different and how a hybrid implant would certainly help that person with the orange hearing loss. Now MED-EL has come out with their electric acoustic stimulating system, electric acoustic system. Their criteria are still the same showing that you can put their device, which means an implant that's not traumatic inserting this in. And then an outside device that also has not only the electric component but as well as the hearing aid.

But what determines whether someone's going to preserve hearing? There are a lot of concerns and issues that were thought about. What do we do to make sure that if we can get somebody's hearing to be preserved, what's the most important criteria? I think in the end, it's probably going to be the surgical technique. But we're just going to quickly go over some of these other issues such as patient selection, the electrode design, and then both intra- and operative adjuncts.

If you have somebody who has got progressive hearing loss, it doesn't make sense to anticipate that they're going to be able to maintain low frequency if their hearing is dropping out rapidly. The other thing that was shown was that in the study for the hybrid device elderly men seem to have a worse prognosis in terms of being able to preserve their hearing. So you get somebody in their 80s and they weren't as likely as to have successful frequency hearing preservation. So that's just something take into account.

Interoperatively, we like using intravenous steroids at the time of the procedure. There's some question whether they should be applied topically to go to the middle ear or even possibly impregnated into the electrode in a new electrode design. Should they have steroids within its structure? Should a lubricant such as Healon be used, so there's no friction and then use that to seal around window? I think it's pretty universal that everyone does use antibiotics, but should they be continued? And that is somewhat controversial.

Using steroids post-operatively is as advocated as one sort of protocol. And also some people think, all right, you give them steroids after the surgery for a couple of days. They come back in about a month to have the device activated, perhaps, they should have steroids on board also to try and prevent any electrical stimulation for causing trauma to the inner ear.

The main thing I think comes down to the surgical technique. The I think you want to think about as you're entering the scala tympani, you want to avoid blood and any kind of bone dust that may go into that area. You want to avoid suctioning perilymph, because that suction can certainly damage the basilar membrane or hair cells that are remaining. And it's been shown that that under slow speed of insertion, you don't want to just rapidly place this in. Because as you're placing in this electrode, you are displacing some other fluid as it comes out. So it should be a slow advancement as the electrode's inserted.

There's discussion about whether this should be done through a cochleostomy or round window opening. There is two different approaches in how to get into the scala tympani. This is showing a right ear. This is the right facial recess. And what we see is the round window in the slightly oval area. And then the cochleostomy where that hole can be drilled, and that's shown in the circle. That's usually done with about a one millimeter diamond burr, whereas the round window, if that's exposed, you can use a fine knife to open the round window or peel that back and get in there without excessive drilling.

So the proponents of the round window opening as opposed to the cochleostomy say, well, you can flip this window back. You are less likely to get bone dust or blood into the scala tympani. You may even get additional stimulation at the basal turn, because you're entering the inner ear, you're entering that basal turn right where it begins. And if you're not drilling on the otic capsule, perhaps, it's less drilling, drill noise or drill trauma that's going to the inner ear.

So let me present a little bit of the hybrid studies that brought this device to this country. This was initially done in Europe. And the Hybrid L24 was a device that was placed in 66 patients in the European study. They did this with a round window insertion. And the thing to notice is that where it says 26% after a year had greater than 30 decibels hearing loss. So that says about a quarter of the people, despite what you were doing, lost those low frequency sounds. But despite that they still felt that the hybrid use-- that it improved their speech understanding in quieter noise compared to their status when they had just the hearing aid.

How about when the study was brought to the United States? There were 50 patients. And I can't tell you why with the study, but it was done through cochleostomy approach instead of a round window approach. And what happened over time-- and we'll see this in the next slide-- is that 44% of them ended up losing hearing. So it's a greater amount of people lost hearing in those low frequencies. And some of those people, six of those 22 went on to have the full length electrodes placed, as I mentioned where the device was taken out and they had the ability, and it was afforded to them to have a full device inserted.

So as we see six months hearing was preserved in 66% and then at one year it dropped down. So 44% of people lost low frequency hearing, and that means greater than a 30-- at least a 30 decibel loss. More often it meant a near-total loss and where the low frequencies could not be stimulated. But despite this, especially when the hybrid was used with a contralateral hearing aid-- that means in a combined situation-- they excelled in function prior-- compared to what they did prior to the device. So even though they were only stimulating electrically in the high frequencies, they still functioned higher than they did pre-operatively.

So what does this device look like, the hybrid? This is a very narrow device. You can see that the tip of this is a quarter millimeter in diameter. And then in terms of the radius of the devices as it comes back to the proximal end, that's a 0.4 millimeters. That's the diameter of that device where you can see it says six and seven. So this is a very delicate device. And when it's put in, it's meant to go in the anti-modiolar area. So as you see in the bottom area, this is going against the anti-modiolar wall and it does not extend fully towards the apical end as some of the other devices do.

So who-- what's the indication for the hybrid device? You can have low frequency hearing loss up to 60dB loss, it can be from normal up to a 60dB loss. And then these frequencies from 125 Hertz or 1,500 Hertz, as I say, it can be in this normal range. You need to have greater than 75 decibels at two, three, and four. So there's a lot of math as you look at this. And it really it ends up being looking at the gestalt of the curve and finding their results on special testing to see whether they're a cochlear implant candidate, a conventional cochlear implant candidate, or a hybrid candidate.

Medicare will not approve a hybrid device under these criteria. However, if the candidate can meet the criteria of a conventional hearing aid, yet still have some of these criteria, if they meet the conventional criteria, a hybrid device can then be placed. So that means that they have about that overlap where there's about 40 decibels of loss and they still have a lot of high frequency loss. But their word recognition as tested by sentence recognition as opposed to words here, if it's tested by sentences and they meet the criteria coming under 40%, then they can get a hybrid device.

JONAS: So the strategy then, Barry, would be that if you wear a contralateral hearing aid, people with a hybrid device sometimes have better understanding, is it?

BARRY HIRSCH: Exactly, they'll do better in that combined situation even if they lost the low frequencies.

So what's come out of late, this is just about four, five months ago. Again, this is from Cochlear Corporation. This is an even finer device that has a narrow diameter and has an insertion technique brings this to hug the cochlea. So this is modiolar hugging. It's called the Slim Cochlear Implant 532. This is a device that requires a two-handed technique for insertion, has a sheath that goes into the basal turn. And then the electrode is advanced off that sheath. But as you can see in the X-ray in the lower right, a conventional straight electrode is shown on the right. And the slim device-- which is narrower and can extend even further and hug the cochlea, hug the modiolus-- is thought to possibly be the next step in being able to preserve hearing and provide a good device.

So why should this hold promise? Well, right now it's a thin, slim device. It seems to be less traumatic than some of the fatter devices we used in the past. It does achieve the deeper insertion that did the hybrid device. And by having the electrodes so close to the modiolus that the power consumption, the battery power drain on this is slightly less. Because the amount of current that's needed is less than a device that's in the anti-modiolar position.

So here we are at the end. Here I'm going to show you this what could look like a typical audiogram. We have both ears shown. And unfortunately, it doesn't show well, but the word recognition score on the right is 50% and the word recognition score on the left is 54%. So when you have someone like this, you say, wow, can we put a regular conventional hearing aid on them? You could, but they're not going to do that well with the 50% word understanding. Could you put an implantable hearing device, a middle ear device? Some of those devices require that you have better than 60% word understand, so they're excluded from this.

But could you do a cochlear implant device? Absolutely. So you could do a cochlear implant, especially some of these newer devices, where the criteria are not necessarily the word recognition as shown on this. But the word recognition is tested by the CNC words. What does that mean? That means that you can give a different set of testing criteria, have them make that criteria eligible for the CN-- for the hybrid device by using words-- word testing that is much more difficult than sentence testing.

So we're seeing this evolution that I think, we may see hearing aids try their limits. But the next step actually may be a cochlear implant.

JONAS: So we see the surgical differences between obviously a hearing aid and a cochlear implant. But how does a cochlear implant do better than a hearing aid? It's just more amplification?

BARRY HIRSCH: No, it gives a much better signal. Because if you're missing the outer hair cells or inner hair cells in the cochlea, you just can't stimulate them with a hearing aid.

JONAS: So it's the distribution of these electrodes throughout the cochlea that is stimulating the individual nerves and actually getting better recognition.

BARRY HIRSCH: It's actually stimulating the cochlear nerve itself, the true cochlear nerve and not the hair cells.

JONAS: Right.

BARRY HIRSCH: So it bypasses the organ of Corti so to speak, which the hearing aids are dependent on. And these directly stimulate those single fibers coming from the cochlear nerve.

JONAS: You've told us about a lot of fancy technology. Some of it just came out at the end of the year. Are we expecting more changes and challenges in the next year or two?

BARRY HIRSCH: Always, always, smaller and better. This is what they're going for. At first, I had angst about why are they changing things so much. But this is really moving in the right direction, where you can put an implant into somebody with better and better hearing. And hopefully expect safe and reliable outcomes where that device is going to work better than a conventional hearing aid.

JONAS: Very interesting. So I'll solicit our audience one more time for any last second questions and then I'll break for a brief commercial. We are making available our prior webinars as listed here on the slide. They come with CME, if you'd like. They are free online. And you just have to log in and you can look at these webinars each of which is just about an hour. So with that I'd like to think you, our audience, for your interest tonight and being with us. Thank you Dr. Hirsch for your expertise in this very enlightening presentation.

BARRY HIRSCH: Well, Jonas, thank you for having me. It was really a pleasure to be here.